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Stent and leaflet stresses of balloon-expandable compared to self-expanding transcatheter aortic valves

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Self-expanding and Balloon-expandable transcatheter aortic valve replacement (TAVR) devices are equally effective in treating intermediate-, high-, and prohibitive-risk patients with severe symptomatic aortic stenosis. However, as TAVR moves to low-risk, younger patients, long-term durability is of paramount importance. Durability depends in part upon valve design, particularly leaflet stresses and TAVR durability is currently unknown. Our objective was to compare leaflet stresses of self-expanding vs balloon-expandable TAVR using finite element analyses.

METHODS AND RESULTS

Commercial self-expanding Medtronic CoreValve Evolut R (26mm) and balloon-expandable Edwards Sapien S3 (26mm) underwent micro-computed tomography scanning. Precise geometries were reconstructed based on radiologic images. Finite element simulations were performed at quasi-static mean blood pressure using ABAQUS software.

Maximum principal stresses were 4.21MPa vs. 2.90MPa on Sapien S3 and CoreValve Evolut R leaflet respectively, while 44.4GPa and 23.2GPa on on Sapien S3 and CoreValve Evolut R stent at mean arterial pressure respectively. Maximum principal stresses were primarily located at the tips of the commissures for Sapien S3, while they were located lower down away from the tips of the Corevalve Evolut R.

CONCLUSIONS

Our study demonstrated that maximum leaflet stresses appeared in commissure locations, though more pronounced at the commissural tips for balloon-expandable devices. Magnitudes of peak leaflet stresses on CoreValve Evolut R was significantly lower than Sapien S3. Our results suggest that leaflet stresses which may impact long-term durability were lower for self-expanding TAVRs. Investigation of changes in these stresses in patient-specific conditions will lead to further insight into relative TAVR durability.

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A single-centre study evaluating real-life usage of Excimer laser-facilitated angioplasty in complex coronary lesions: procedural success and medium to long-term outcomes

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THEME: Coronary Interventions
TOPIC(S): STEMI, Other Coronary Interventions

AIMS

Excimer laser (ELCA) can be a useful adjunctive tool for the treatment of complex coronary lesions, such as calcific stenosis, chronic total occlusions, non-compliant plaques, in-stent restenosis and under-expanded/ recoiled stents. We retrospectively assessed the indications, procedural success and medium to long term safety and efficacy of ELCA in a high volume tertiary cardiac centre.

METHODS AND RESULTS

Data was evaluated from our centre's laser dataset from January 2009 to August 2018. Procedural data was assimilated from British Cardiac Intervention Society database, clinical follow up obtained from electronic hospital database and mortality information from the Welsh Demographic National Statistics database. Primary endpoint was target vessel failure (TVF): combination of cardiac death, target vessel myocardial infarction (TV-MI) and target lesion revascularization/target vessel revascularization (TLR/TVR). Secondary endpoints were technical (successful usage of laser) and procedural success [successful procedure using laser without in-hospital major adverse cardiovascular events (MACE)]. During the study period, a total of 62 patients were treated with ELCA. 0.9 and 1.7 mm-diameter ELCA catheters were used most frequently (33.8%), followed by 1.4 mm-diameter catheter (24.1%). Of 62 patients, 27 (43.5%) were treated for compliance modification, 13 (20.9%) for in-stent restenosis (ISR), 14 (22.5%) for thrombus vaporization, 5 (8.0%) for plaque debulking, 1 (1.6%) for under-expanded stent and 2 (3.2%) for stent recoil. Patients not unexpectedly were comparatively older with an average age of 68 years with a higher than usual prior history of myocardial infarction (43%), revascularisation (66%) and left ventricular systolic dysfunction (61%). 60% had an acute presentation and radial access was used in 80%. Vessels treated included RCA (37%), LAD (35%), SVG (18%), Cx (8%) and intermediate artery (2%). In addition to laser, scoring-balloon was used in 14.5% and rotablation in 9.6%. ELCA was unsuccessful in 7 (11.2%) of the cases. This was mostly (5 out of 7) due to inability to cross the lesion despite laser usage. One developed no-reflow after laser use while another became hypotensive and developed complete heart block and the procedure had to be abandoned. Stents were deployed in 50 (80.6%) cases while 2 (3.2%) had POBA only and 3 (4.8%) had their stents optimized. All stents implanted were Drug-Eluting Stents. 77% of patients had long lesions (>20-mm) treated. Technical success was achieved in 88.8%. Post procedure adverse events included major bleeding in 1 (1.6%) and cardiac death in 2 (3.2%), thus giving an overall procedural success of 82.4%. Target-vessel myocardial infarction (TV-MI) was seen in 3 (4.8%), target lesion revascularization (TLR) in 5 (8.0%), non-target vessel revascularization in 2 (3.2%) and target vessel revascularization (TVR) in 1 (1.6%). No patient had stent thrombosis. Minimum follow-up of patients were 4 months with mean follow-up being 543 days. Primary endpoint of target vessel failure (TVF) was observed in 11.2% of patients after a mean follow-up of 543 days.

CONCLUSIONS

ELCA can be a safe and effective option in a subset of complex coronary disease with satisfactory medium to long-term outcomes.

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Pre-stenting thrombus volume assessed by dual quantitative coronary angiography enhances prediction of microvascular obstruction: a MRI study in patients with STEMI

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Coronary microvascular obstruction is a frequent occurrence after primary percutaneous coronary intervention (PCI), and distal embolization of athero-thrombotic material is a major responsible mechanism. Dual-quantitative coronary angiography has been validated for advanced assessment of intracoronary thrombus volume. We aimed to evaluate the correlation between dual-quantitative coronary angiography thrombus volume and the presence and severity of coronary microvascular obstruction assessed by cardiac magnetic resonance in patients with ST-segment elevation myocadial infarction (STEMI).

METHODS AND RESULTS

Forty-eight patients with STEMI undergoing primary PCI, and receiving cardiac magnetic resonance imaging 4 to 7 days after admission were included. Pre-stenting dual-quantitative coronary angiography thrombus volume was calculated as the difference between edge-detection and video-densitometry area functions along the culprit lesion. Delayed-enhancement coronary microvascular obstruction volume was quantified by using a manual region of interest to trace the areas of low signal within the areas of brightly enhancing infarcted myocardium and expressed in grams (coronary microvascular obstruction mass) and normalized to left ventricular mass (percentage of coronary microvascular obstruction). Angiographic no-reflow was defined as post-PCI TIMI <3 or TIMI 3 with myocardial blush grade 0-1.

Pre-stenting dual-quantitative coronary angiography thrombus volume was significantly greater in patients with coronary microvascular obstruction as compared to those without (5.85 mm3 [2.05–16.71] vs. 1.88 mm3 [1.03–6.92], p=0.009). After dividing the study population in tertiles according to the dual-quantitative coronary angiography thrombus volume, patients in the third tertile showed higher prevalence of coronary microvascular obstruction compared to those in the second and first tertiles (62% vs. 50.0% vs. 25.0%, p=0.035), as well as higher values of coronary microvascular obstruction mass (113.3 gr [0.0 – 203.8] vs. 58.5 gr [0.00 – 144.4] vs. 0.0 gr [0.0 – 60.225], p=0.031) and percentage (2.17% [0.00 - 5.25] vs. 0.46% [0.00 – 3.87] vs. 0.0% [0.0 – 0.32], p=0.087). The best cut-off value of dual-quantitative coronary angiography thrombus volume for predicting the presence of coronary microvascular obstruction was 2.07 mm3 (area under the curve: 0.720). Dual-quantitative coronary angiography thrombus volume’s predictive value for the presence of coronary microvascular obstruction at cardiac magnetic resonance analysis was superior to that of the traditional angiographic definition of no-reflow.

CONCLUSIONS

Pre-stenting dual-quantitative coronary angiography thrombus volume predicts the presence of coronary microvascular obstruction assessed by cardiac magnetic resonance imaging in patients with STEMI undergoing primary PCI. This novel methodology may aid the identification of patients at higher risk of

developing coronary microvascular obstruction and guide adoption of preventive strategies.

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The ORIGA-MI registry: ORal antIcoagulation in fraGile pAtients for a conservative treatment of Myocardial Infarction

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS
The most current guidelines recommend an early invasive strategy in patients with acute coronary syndromes independently from age, frailty and comorbidities. However, in the clinical practice the role of an invasive strategy in frail elderly patients remains controversial. The aim of this study was to assess the impact of an invasive strategy, in nonagerian patients presented in a tertiary center and/or referred to the hub center for a coronary angiography.

METHODS AND RESULTS
The The ORIGA-MI (ORal antIcoagulation in fraGile pAtients for conservative treatment of Myocardial Infarction) registry included unselected nonagenarian patients presenting to a tertiary center with an indication for coronary angiography from January 2010 to January 2019 (up to now). A comprehensive geriatric assessment, including frailty status, was performed during hospitalization. The impact of frailty status and comorbidities on the incidence of cardiac death, reinfarction or new revascularisation at six months was evaluated. From 247 patients included, 192 were analyzed. Among those 83% were frail.
Patients undergoing an early invasive strategy were admitted with an ACS and were younger and less frail and with suspicion of LAD disease ($p<0.001$). The incidence of cardiac events was more common in patients managed conservatively, after adjusting for comorbidities and mean age ([HR] 2.03, 95% confidence interval [CI]: 1.26-6.34, $p=0.06$). Remarkably, this benefit was not present when data were analyzed according to the frail status and severity ($p=0.138$).

CONCLUSIONS
An invasive strategy was independently associated with better outcomes in nonagenarian patients undergoing coronary angiography. Frailty status is a critical determinant of the outcome of elderly patients and should be routinerly evaluated in order to tailor the best personalized therapeutic approach.

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A comparison of the procedural outcomes in buddy-consultants vs. single-consultant in complex PCI

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease, Bifurcation lesion

AIMS
There is no data comparing the procedural outcomes of buddy-consultants versus single consultant in subjects with complex coronary anatomy undergoing percutaneous coronary intervention (PCI). We sought to evaluate the procedural outcomes of the complex coronary intervention in the two groups.

METHODS AND RESULTS
Patients who underwent complex coronary intervention were stratified in 2 catergories; single-consultant (group 1) and buddy-consultants (group 2). Complex PCI was defined as having at least one of the following features: unprotected left main stem lesion, calcified lesions, chronic total occlusion (CTO), patients with severe left ventricular systolic dysfunction undergoing PCI, cardiogenic shock, vein graft PCI, left main stem (LMS) PCI, ostial lesions, ≥2 lesions treated, total stent length >20 mm, minimal stent diameter <3.0 mm and bifurcation as target lesion. We retrospectively analysed the data from the British Cardiovascular Intervention Society database between 2008 and 2017.

Of 15,500 patients, 2911 (18.7%) underwent complex PCI: 2674 were included in group 1 (mean age 66.0±11.3 years; 77.6% male) and 237 in group 2 (mean age 67.2±11.4 years; 81% male). The co-morbidities including diabetes, hypertension, peripheral vascular disease and prior stroke did not differ significantly between the groups. More patients had prior PCI in group 2 (37.1 vs 26.5%; p 0.0008), while prior myocardial infarction (43.6 vs 45.5%; p 0.58) and prior CABG (15.5 vs 15.6%; p 1.0000) were similar between the two groups. Severe LV systolic dysfunction (15.1 vs 8.8%; p 0.0071) and cardiogenic shock (4.1 vs 1.6%; p 0.078) were more common in group 1. Intra-aortic balloon pump was used more often in group 2 (6.7 vs 1.9%; p 0.0001). Transfemoral access was more commonly used in group 2 (47.2 vs 19.6%; p 0.0001) while transradial in group 1 (85.1 vs 79.3%; p 0.0186). The indication for procedure was similar between the group 1 and group 2 – NSTEMI (52.1 vs 49.9%; p 0.498), stable angina (47.8 vs 50.2%; p 0.498). More patients had ≥3 vessels treated in group 1 (11.7 vs 9.7%; p 0.397). Left main stem was treated more frequently in group 2 (21.9 vs 14.6%; p 0.0045) while vein bypass graft was stented more often in group 1 (14.7 vs 6.3%; p 0.0002). Two or more lesions were treated in 57.2% in group 1 compared to 50.6% in group 2 (p 0.055). The number of in-stent restenosis treated did not differ significantly between the two groups (4.1 vs 5.0% p 0.501). Chronic total occlusion was treated more commonly in group 2 (37.9 vs 26.8%; p 0.00004). With regards to the complications, coronary dissection was more common in group 2 (6.3 vs 3.1%; p 0.014), while other complications were similar between group 1 and group 2: coronary perforation (1.0 vs 0.4%; p 0.509), retroperitoneal bleed (0.07 vs 0.8 p 0.035) and emergency CABG (0.03 vs 0,0%; p 1.000). There was no significant difference in mortality between the two groups (0.9 vs 1.6%; p 0.301).

CONCLUSIONS
This study demonstrates that PCI undertaken by buddying consultants can result in similar outcomes to single

consultant operator despite increasing procedural complexity.

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Characteristics, treatment and outcome in transient STEMI vs. STEMI

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

An estimated 4-24% of patients presenting with ST-segment elevation MI (STEMI) subsequently show resolution of ST-segment elevation and relief of symptoms before revascularisation therapy. The mechanisms of spontaneous reperfusion in STEMI are unclear. Given the more favourable outcome of transient STEMI it is important to get insights in differential aspects of patients with either persistent or transient coronary occlusion.

METHODS AND RESULTS

We included 251 patients from two cohorts with either transient STEMI (n = 141) or STEMI (n = 110). Demographics, clinical, angiographic and laboratory data were documented. Cardiac magnetic resonance imaging (MRI) was performed at 2-8 days and clinical follow-up at one year.

Transient STEMI patients had slightly more cardiovascular risk factors compared to STEMI patients, with more frequently peripheral artery disease (8.5% versus 0.0%, p = 0.001), previous percutaneous coronary intervention (PCI) (5.7% versus 3.6%, p < 0.001) and higher cholesterol values (total cholesterol respectively 5.3 ± 1.1 mmol/L versus 4.7 ± 1.1 mmol/L, p < 0.001). Furthermore, at admission transient STEMI patients had higher levels of thrombocytes compared to STEMI (262 ± 69 ? 109/L versus 234 ± 70 ? 109/L, p = 0.02). In the vast majority of patients in the transient STEMI group pre-PCI TIMI flow was 2-3, with only in 2.1% TIMI flow 0-1, which was accompanied by signs of reinfarction. In the STEMI group 60% of the patients had TIMI 0-1 flow (p < 0.001). Also, 40% of STEMI patients had a high thrombus burden, while 41% of transient STEMI patients had no angiographic evidence of thrombus at all (p < 0.001). Left ventricular ejection fraction (LVEF) was more preserved in transient STEMI than STEMI patients (57.8 ± 6.7% vs. 52.5 ± 7.6%, p < 0.001) and median MRI-derived infarct size was 1.4% (IQR, 0.0-3.7%) compared to 8.8% (IQR, 3.9-17.1%; p < 0.001), respectively. Furthermore, microvascular obstruction (MVO) was more frequently present in patients with STEMI than with transient STEMI (34.6 versus 4.2%, p < 0.001, respectively). Mortality at 1-year follow-up was low in both groups (transient STEMI 2.2% versus STEMI 2.8%, p = 0.76).

CONCLUSIONS

Transient STEMI is an acute coronary syndrome distinct from STEMI, resulting in less myocardial injury compared to STEMI.

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FFR after PCI in patient with and without CTO

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Fractional flow reserve (FFR) can be used to detect residual disease burden after percutaneous coronary intervention (PCI). A lower post procedure FFR (< 0.90) has been shown to be associated with an increased risk of adverse clinical events. This study aimed to investigate the post-PCI FFR in patients with chronic total occlusion (CTO) and in patients without CTO.

METHODS AND RESULTS

One thousand consecutive patients prospectively enrolled within the FFR-SEARCH Registry (Fractional Flow Reserve – Stent Evaluated At Rotterdam Cardiology Hospital) were evaluated. Patients with CTO and non-CTO lesions were matched applying 1:2 propensity score matching. Post-PCI FFR values, quantitative coronary angiography analysis and one-year clinical follow-up were reported. A total of 111 patients, 37 CTO patients and 74 non-CTO patients undergoing post-PCI FFR, were evaluated. Clinical characteristics were well balanced between groups. Overall 53.9% of the patients despite a satisfactory angiographic result showed a suboptimal post-PCI FFR ≤ 0.90. In particular post-PCI FFR ≤ 0.90 was observed in the 64.9% of the patient with CTO and in 47.3% of the patient without CTO (p=0.11). In addition FFR ≤ 0.80 was reported in 21.6% and 12.1% of patients in the CTO and non-CTO group respectively (p=0.26). Conversely, angiographic post-PCI percentage diameter stenosis (DS) was overall low (-2.7±12.4 CTO group vs 3.7±15.3 non-CTO group, p=0.03). One year mortality and MACE did not differ significantly between the matched groups.

CONCLUSIONS

The present study suggests a relevant rate of suboptimal post-PCI FFR values in both CTO and non-CTO treated lesions. CTO lesions showed a high rate of final FFR ≤ 0.80 despite satisfactory angiographic results.

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Inter-hospital transfer for primary PCI has worse outcome compared with direct admission to a heart attack centre: an observational study of 25,315 patients with STEMI from the London Heart

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Background and Aims

In patients with ST-segment elevation myocardial infarction (STEMI), mortality is directly related to time to reperfusion with guidelines recommending patients are delivered directly to centres for primary percutaneous coronary intervention (PPCI). The aim of this study was to describe the impact of inter-hospital transfer on reperfusion time and to assess whether or not treatment delays influenced clinical outcomes in comparison with direct admission to a PPCI centre in a large regional network.

METHODS AND RESULTS

Method and results

We undertook an observational cohort study of patients with STEMI treated with PPCI between 2005 and 2015 at the eight PPCI centres in London, UK. Patient details were recorded at the time of the procedure in databases using the British Cardiovascular Intervention Society PCI dataset. The primary end-point was all-cause mortality at a median follow-up of 3.0 years (interquartile range 1.2-4.6 years). Secondary outcomes were in-hospital major adverse cardiac events (MACE). Of 25,315 patients, 17,580 (69.4%) were admitted directly to a PPCI centre and 7,735 (30.6%) were transferred from a non-PPCI centre. Patients in the direct admission group were older and more commonly had left ventricular impairment than the inter-hospital transfer group. Median time from call for help to reperfusion in transferred patients was 52 minutes longer compared to patients admitted directly ($p < 0.001$). However, call to first hospital admission was similar. Kaplan-Meier analysis demonstrated significantly lower mortality rates in patients who were transferred directed to a primary PCI centre compared to patients who were transferred from a non-PPCI centre (17.4% direct vs 18.7% transfer, P=0.047). After regression adjustment, which incorporated the propensity score as a covariate in a proportional hazard model, transfer of patients for PPCI was still a predictor of all-cause mortality, irrespective of whether symptom to balloon time was included (HR 0.80; 95% 0.61-0.96) or not included (HR 0.84; 95% CI 0.65-0.98) in the model. Furthermore, after propensity matching, direct admission for PPCI was still a predictor of all-cause mortality (HR: 0.86 95% CI: 0.68-0.91).

CONCLUSIONS

Conclusions

In this large registry of over 25,000 STEMI patients treated by PPCI survival was better in patients admitted directly to a cardiac centre versus patients transferred for PPCI, most likely due to longer call to balloon times

in patient transferred from other hospitals.

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Impact of frailty status on 30-day mortality in patients with valvular heart disease undergoing percutaneous transcatheter valve interventions

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Transcatheter strategies to treat valvular heart disease (VHD) are an established therapeutic option in elderly patients, not suitable for open heart surgery. The current ESC guidelines recommend the STS score and EuroSCORE II as tools for risk stratification. However, these surgical risk scores have major limitations, as they do not consider important risk factors such as frailty, cognitive and nutritional status.

The aim of this study was to assess the frailty status in patients with severe VHD evaluated for transcatheter treatment strategies and to investigate the impact on mortality.

METHODS AND RESULTS

Our study cohort consisted of 456 consecutive patients (mean age 79±7.9 years, median STS-score 3.15 and median EuroSCORE II 3.65) who were evaluated for percutaneous treatment of severe aortic valve stenosis (n=311), mitral valve regurgitation (n=100), and tricuspid valve regurgitation (n=45) between February and September 2018. The frailty status in these patients was assessed using the Katz Index of Independence in Activities of Daily Living, the Lawton Instrumental Activities of Daily Living Scale (L.A.D.L.), the five times chair rise, and the Score for assessment of frailty phenotype by Fried et al. The Mini Nutritional Assessment - Long Form (MNA) and the Controlling Nutritional Status (CONUT) score were used for the assessment of the nutritional status of the cohort.

Assessment by the Score for frailty phenotype showed that 220 (48.2%) cases were considered frail, 200 (37.3%) cases as prefrail, and only 36 (6.7%) patients considered robust. Regarding the MNA, 212 (46.5%) patients were at normal nutritional status, whereas 207 (45.4%) patients were at risk for malnutrition, and 37 (8.1%) patients were already malnourished.

The overall 30-day mortality rate was 3.1% (n=14). Multivariate analysis showed a significant association of 30-day mortality with baseline serum creatinine (1.2 mg/dl [IQR:0.9 – 1.5 mg/dl] for survivors vs 1.6 mg/dl [IQR: 1.4 – 2.2 mg/dl] for non-survivors, p=0.14), high-sensitive cardiac troponin T (24.3 ng/l [IQR:16.0 – 42.6 ng/l] for survivors vs 55.6 ng/l [IQR: 40.4 – 84.7 ng/l] for non-survivors, p=0.002), and the five chair rise test (p=0.005). Interestingly, there was no significant correlation of nutrition scores and frailty tests with 30-day mortality except for the five chair rise test. Linear regression analysis showed serum creatinine (p=0.04; OR: 1.4, CI: 1.0 – 1.8) and the five chair rise test (p=0.03; OR: 0.7, CI: 0.5 – 1) as independent predictors of the mortality.

CONCLUSIONS

A comprehensive assessment of the clinical patient condition including frailty status is thought to be crucial for risk stratification and the decision making process which treatment option a specific patient should undergo. However, in our study only the five chair rise test was found to be an independent predictor of 30-day mortality in patients with valvular heart disease undergoing percutaneous therapeutic options and seems to be an easy-to-assess test to assess the mortality risk of a specific patient.

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Methodology of activity tracking as novel parameter in the disease monitoring of heart failure in patients undergoing transcatheter valve repair

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THEME: Interventions for Heart Failure
TOPIC(S): Chronic heart failure

AIMS

This study was designed to establish activity tracking as a novel method in the disease monitoring of heart failure (HF) patients. Daily physical activity has been suggested as a beneficial parameter to complement the decision on the type and timing of interventional therapies in valvular HF. However, out-of-hospital activity tracking is currently neither implemented nor standardized in daily clinical practice.

METHODS AND RESULTS

The application of activity tracking devices was prospectively analyzed in a cohort of 102 HF patients (mean age 79 years, 57% female, 94% NYHA ≥ 3) suffering from severe mitral and/or tricuspid regurgitation (baseline: all mitral or tricuspid regurgitation grade 3+ of 4). All patients were scheduled for various transcatheter mitral or tricuspid valve repair treatment strategies between May 2017 and December 2018. All patients were equipped with activity tracking devices (Fitbit, San Francisco, USA) to the wrist for out-of-hospital activity tracking 2 - 4 weeks before the intervention and at follow-up (median follow up 59 days). The majority of patients carried the devices for 7 - 8 days with similar duration of activity tracking at baseline (6.6 ± 2.0 days) and follow-up (7.2 ± 2.0 days, p = 0.16). Additional heart rate monitoring assured the adherence to the devices. The application of a quality control (adherence for ≥ 10 h within a defined activity time between 7 a.m. and 22 p.m.) allowed approval of 94% tracked days for activity analysis. The mean steps per day were referred to as continuous physical activity (CPA) and were defined as the main outcome measure in this study. Median CPA at baseline was 3,288 (1,567 - 4842) steps/d and improved by 26.8% after transcatheter valve repair (p < 0.001). Similarly, intraday activity within the highest and lowest performance days improved by 26.1% and 36.1%, respectively (both p < 0.001). A precise estimation of CPA with a relative standard deviation (SD) < 10% was observed after 7 days in a medium-activity subgroup of patients (CPA: 3,000 - 4,000 steps/d, n = 31). A high-active subgroup of patients (CPA: > 6,000 steps/d, n = 30) showed lower variability of daily activity and CPA was accurately measured after only 4 days with relative SD < 5%. In contrast, low-active patient collectives (CPA: < 2,000 steps/d, n = 18) showed a relative SD of 20% after 10 days, and thus benefit from prolonged activity tracking assessment. Furthermore, the correlation between baseline CPA and classical HF measures was tested. Baseline CPA correlated to the serum level of the natriuretic peptide proBNP, the results of a six-minute walk test and the assessment of Quality of Life as measured by the Minnesota Living With Heart Failure Questionnaire (MLHFQ, all p < 0.001).

CONCLUSIONS

Out-of-hospital activity tracking with assessment of CPA is feasible and easy to acquire in HF patients. CPA seems to be a reliable measure with good correlation to conventional HF monitoring strategies. We suggest that CPA should be introduced in routine disease monitoring of HF.

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Complete revascularisation is associated with improved survival after out-of-hospital cardiac arrest

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Multi-vessel coronary artery disease is common in patients with Out of Hospital Cardiac Arrest (OOHCA) but evidence for revascularisation strategies and effect on long-term outcomes remain unclear. We evaluated the relationship between complete revascularisation and long-term outcomes after OOHCA, including neurological recovery.

METHODS AND RESULTS

619 patients with OOHCA were admitted at our centre between 1st May 2012 and 31st December 2017. 221 were excluded for having a non- cardiac aetiology. 398 patients (median age 64.2 (IQR 21.3, 25.8% females) were included in the final analysis. 71.3% had ventricular fibrillation, 78.9% were witnessed and 77.4% occurred at residence. Mean Follow-up was 293 days (+-468). Patients with incomplete data were excluded from the analysis.

287 patients had early coronary angiography at the admitting clinician's discretion. 22.1% had normal coronary arteries, 42.9% had single vessel disease and 35% had multi-vessel involvement. 19.4% had presence of at least one chronic total occlusion. The single-vessel group were younger than the multi-vessel group (59.4 vs. 66.1 years) but otherwise had similar baseline characteristics. Long- term mortality was higher in the multi-vessel group at follow- up 30.9% vs 50.0% (p=0.0045).

Of the 221 patients that had PCIs, 133 (60.6%) had complete revascularisation (CR) compared with 39.4% with incomplete revascularisation (IR). There was no difference in rates of cardiogenic shock between both groups (CR 61.1% vs. IR 69% p=ns), but patients with complete revascularisation were younger (CR 58.6 vs. IR 68.1 years).

Complete revascularisation was associated with lower mortality at hospital discharge (29.9% vs. 48.3% (p=0.0057), lower mortality at follow- up (30.1% vs 54.0% p< 0.001) and improved survival with good neurological recovery (60.9% vs. 46.5% p 0.0369). Complete revascularisation was an independent predictor of improved survival (OR 0.45 0.29–0.71 p<0.001). There was a trend to a higher increase in left ventricular ejection fraction at 48 hours in the complete revascularisation group compared with those without (5.0% vs. 2.3%) (p=0.07) and a trend to a lower rate of cardiogenic deaths (7.9% vs. 20.9% p=0.10).

There was no significant difference in requirement for renal replacement therapy (CR 20.2% vs. IR 25.6%), GUSTO classified minor to life- threatening bleeding (CR 17.2% and SVD 15.9%) or vascular complications (MVD 3.0 % vs SVD 1 1.1%) between both groups (p=ns).

CONCLUSIONS

Complete revascularisation in a primary coronary aetiology OOHCA group is associated with reduced early and long-term mortality, which may be driven by improvement in LV systolic function and a reduction in cardiogenic deaths. Prospective randomised trials in this population are warranted.

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TAVR and concomitant non-severe mitral stenosis

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Coexisting mitral stenosis (MS) in candidates for transcatheter aortic valve replacement (TAVR) is an increasingly important issue of concern. The objective of this study was to investigate the prevalence and progression of MS among patients undergoing TAVR and the impact of concomitant MS on post-TAVR clinical outcomes.

METHODS AND RESULTS

The study included 272 patients who underwent TAVR successfully in our institute during April 1, 2012 to December 31, 2017. 19(7.0%) patients were identified with concomitant mitral stenosis (mean mitral valve area 1.85±0.30 cm2) according to echocardiographic results, being mild in 89.5% (17 patients), moderate in 10.5% (2 patients) and no severe mitral stenosis. Baseline characteristics were comparable between patients with or without MS. In-hospital all-cause mortality (2.8% vs 0%, p=0.60) and all stroke rate (2.0% vs 0%, p=0.69) were similar between the two groups. At 30 days and 1 year, patients with concomitant non-severe mitral stenosis didn’t show an increased mortality (30 days: 4.0% vs 0%, p=0.50; 1 year: 7.1% vs 5.3%, p=0.61). In addition, the severity of mitral stenosis stayed stable during the follow-up until 1 year after TAVR(in-hospital: 36.8% with no MS,57.9% with mild MS,5,3% with moderate MS; 30 days: 35.3% with no MS: 52.9% with mild MS, 11.8% with moderate MS; 1 year: 41.7% with no MS, 50% with mild MS, 8.3% with moderate MS, p=0.06).

CONCLUSIONS

Approximately one-tenth of patients undergoing TAVR have concomitant mitral stenosis. Non-severe mitral stenosis is not associated with increased risk of death or stoke at short-term and long-term follow-up. The degree of mitral stenosis remains consistent following TAVR.

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Acute coronary collaterals reduce mortality and improve left ventricular function in patients presenting with STEMI

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THEME:
TOPIC(S):

AIMS

The rapid development of acute coronary collaterals at the time of an ST elevation myocardial infarction (STEMI) is observed frequently during primary percutaneous coronary intervention (pPCI). However, previous studies have reported conflicting reports whether the presence of collaterals imparts improved prognosis. We sought to determine the effect of well-formed coronary collaterals on prognosis in patients presenting with STEMI undergoing pPCI.

METHODS AND RESULTS

We reviewed all patients presenting to our tertiary centre for pPCI or rescue PCI (following thrombolysis) in the setting of a STEMI from January 2018 to December 2018. After excluding 24 patients with previous coronary artery bypass grafting or spontaneous coronary artery dissection, 215 patients were included in the analysis. The mean age was 65.35 (± 13.80) with 22.8% females, whilst the mean BMI was 27.67kg/m2 (± 5.03). The left anterior descending (LAD) artery was the most common culprit vessel, accounting for 47.9% of cases, followed by the right coronary artery (32.1%) and the left circumflex artery (20%). 176 patients (81.9%) had poorly developed collaterals, as defined by either Rentrop grade 0 or 1, whilst 39 (18.1%) had well developed collaterals, defined as Rentrop grade 2 or 3.

Patients with well-developed collaterals were younger than those without (61.5 vs 66.2, $p<0.05$) and had a greater time from symptom onset to angiography time, although this was not significant (1449.93 mins vs 745.09 mins, $p=0.17$). All other demographics were well matched between the groups.

The presence of well-developed collaterals were associated with a trend toward reduced in-hospital mortality (2.56% vs 7.39%, $p=0.14$), whilst in patients with thrombolysis in myocardial infarction (TIMI) flow <3 in the culprit vessel, well developed collaterals were associated with lower in-hospital mortality (0% vs 7.33%, $p<0.001$). Well-developed collaterals were also associated with better left ventricular ejection fraction (LVEF) (52.43% vs 45.99%, $p<0.0001$), and were less likely to have LV dysfunction (25.6% vs 52.4%, $p<0.01$). Patient with well-developed collaterals also had a higher initial systolic blood pressure than those with poorer formed collaterals (130.67mmHg vs 120.03mmHg, $p<0.05$). The degree of collateral formation did not affect need for inotropes, incidence of ventricular arrhythmias, intensive care unit admission rates or biochemistry results.

On multivariate analysis, after correcting for age, sex and LVEF, coronary collaterals remained independently predictive of in-hospital mortality ($p<0.05$).

CONCLUSIONS

In patients presenting with STEMI, the presence of well-developed collaterals is associated with improved left ventricular function and independently associated with lower in-hospital mortality. The pathophysiological

mechanism of collateral formation should be further studied to elucidate any potential therapeutic targets.

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The right heart in patients undergoing TAVR: insights from cardiac MRI

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Cardiac magnetic resonance (CMR) provides the gold standard for the assessment of ventricular volumes and mass. However, data on right ventricular systolic dysfunction (RVSD) and its prognostic significance on outcome in patients undergoing transcatheter aortic valve replacement (TAVR) are lacking.

METHODS AND RESULTS

We consecutively enrolled patients with severe aortic stenosis scheduled for TAVR who underwent preprocedural CMR. Kaplan-Meier estimates and multivariate Cox-regression analysis were used to identify factors associated with outcome, including RVSD. A composite of heart failure hospitalization and/or cardiovascular death was selected as primary study endpoint.

145 consecutive patients (80.5±7.6 years; 51.7% female) were prospectively included, 25 (17.2%) of which had RVSD defined as RV ejection fraction (RVEF) <40%. RVSD was significantly associated with male sex, atrial fibrillation, reduced left ventricular (LV) EF (<50%) and RV endsystolic volume on CMR (all p<0.05). Serum NT-proBNP (14065±12042 vs. 3203±4615 ng/ml; p<0.001) and creatinine levels (1.59±0.96 vs. 1.29±1.03 mg/dl; p=0.201) were elevated in patients with RVSD. A total of 27 events occurred during follow-up (29±13 weeks). While LVSD was not significantly associated with outcome (p=0.654), RVSD showed a strong and independent association with event-free survival in the multivariate Cox-regression analysis [hazard ratio 3.836 (95% confidence interval 1.670-8.810); p=0.002], which included all relevant CMR parameters, cardiovascular risk factors and routine biomarkers.

CONCLUSIONS

RVSD rather than LVSD, as determined by CMR, is an important predictor of outcome in patients undergoing TAVR. RV function might thus add useful prognostic information on top of established risk factors.

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Clinical impact of elevated tricuspid valve gradient after transcatheter tricuspid valve repair

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THEME: Interventions for Valvular Disease
TOPIC(S): Tricuspid / Pulmonary valve

AIMS

Transcatheter edge-to-edge tricuspid valve repair (TTVR) is a novel treatment approach in heart failure patients with moderate-to-severe tricuspid regurgitation (TR) at prohibitive surgical risk. The aim of this study was to investigate the mean tricuspid valve gradient (TVG) over time and compare patient characteristics and outcome of patients with a post-procedure TVG of > 3 mmHg vs. ≤ 3 mmHg.

METHODS AND RESULTS

Between March 2016 and October 2018 we treated 145 consecutive patients with moderate-to-severe secondary TR with TTVR. Trans-thoracic echocardiographic assessment of TVG was performed pre-procedurally, pre-discharge, after 1, 6, and 12 month. Patients were treated with TTVR for severe TR alone (70 patients) or in combination with mitral valve repair for concomitant severe mitral regurgitation and severe or moderate-severe TR with significant annulus dilatation (75 patients). One clip was implanted in 17 (11.7%), 2 clips in 83 (57.2%), 3 clips in 40 (27.6%) and 4 clips in 4 patients (2.8%). Reduction of at least 1 degree of TR was achieved in 136 Patients (93.8%). The median baseline TVG of all patients was 1 mmHg [Inter Quarter Range, IQR 1.0 -1.4 mmHg]. The median TVG - measured at post-procedural trans-thoracic echocardiogram predischarge - increased to 2 mmHg [IQR, 1.6 – 3.0 mmHg] and remained constant up to 12 month (2.0 mmHg [IQR 1.0 – 2.0 mmHg). Of these, twenty-five patients showed an elevated TVG > 3 mmHg post-procedurally. Patients with TVG > 3 mmHg were younger (73.1±11.0 vs. 77.5±9.2 years, p=0.038) and presented with lower levels of pro-BNP at baseline (median 2276 ng/l [IQR, 906-5150] vs. 4182 ng/l [2310-8629], p=0.008) compared to patients with TVG ≤ 3mmHg. All other baseline characteristics were balanced, especially the peri-procedural risk estimated with EURO-II-Score (5.4 [3.2-9.7] vs. 5.7 [3.8-9.4], p=0.74). There were no differences in procedural success (TR reduction of ≥ 1 grade in 96% vs. 93.3%, p=0.946) and number of clips implanted (p= 0.697). At one month follow-up there were no differences in NYHA class (NYHA class ≥ 3 in 24% vs. 30.8%, p=0.559), quality of life measured with the Minnesota Living With Heart Failure Questionnaire (MLHFQ3, 32.0±22.9 vs. 31.1±16.3, p=0.833), 6 minute walking distance (255.5±140.6 vs. 250.5±111.7 metre, p=0.872), continuous physical activity (3171 [1389-3950] vs. 3254 [1874-5384] steps/day, p= 0.452) and cardiac output (3.65±1.00 vs. 4.43±2.04 l/min, p=0.192). The clinical endpoints 1-year mortality (HR 1.22; 95% CI [0.46-3.27], plogrank=0.691) and hospitalization for heart failure (HR 0.57; 95% CI [0.2 to 1.65], plogrank=0.304) did not differ between patients with a TVG > 3 mmHg vs. patients with a TVG ≤ 3mmHg.

CONCLUSIONS

TTVR results in a small increase in the tricuspid valve gradient, which remains constant up to one year. A small cohort of patients shows an elevated TVG higher than 3 mmHg after the procedure. This elevation has no impact on the clinical endpoints mortality and hospitalization for heart failure.

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Impact of aortic angulation on the outcome of TAVI with self-expanding devices: comparison between Evolut-R, Portico, and ACURATE neo

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

To investigate the impact of aortic angulation on device success and paravalvular leak (PVL) rates among three new-generation self-expanding trancatheter aortic valve implantation (TAVI) devices.

METHODS AND RESULTS

This retrospective single-center study included 392 patients with symptomatic severe aortic stenosis, who underwent TAVI with Evolut-R, Portico, and Acurate NEO (07/2015 – 12/2018) with available computed tomography (CT) measurements of the aortic angle (AA). AA was calculated from the implantation projection in which the three coronary cusps were aligned, and was defined as the angle between the horizontal plane and the plane of the aortic annulus. Patients were divided in two groups (horizontal and non-horizontal) using as cutoff the 75thpercentile (AA=57°).

Horizontal aorta (AA>57°) was found in 91 (23.2%) of 392 patients. Baseline demographic and clinical characteristics were not significantly different among the two groups. On CT, patients with horizontal aorta showed significantly larger aortic annulus perimeter, area, left ventricular outflow tract, and ascending aorta, as compared to non-horizontal patients (respectively P=0.012, P= 0.005, P= 0.019, P<0.001). Predilatation was performed more frequently in Acurate NEO patients, compared to Portico and Evolut-R. In the horizontal group, Evolut-R patients showed a significantly greater mean implantation depth (6.8±3.8 mm) compared to Acurate NEO patients (4.5±2.7 mm, P=0.026), whereas it was similar to that of Portico patients (6.0±2.4 mm, P=0.45). Rates of ³moderate paravalvular leak (PVL) were higher in the Evolut-R horizontal group (35.4%), compared to the Portico and Acurate NEO horizontal group (respectively 5.0% and 8.7%; P=0.005). Similarly, device success was lower in the Evolut-R horizontal group (66.6%) compared to the Portico (90.0%) and Acurate NEO (87.0%) horizontal group with borderline significance (P=0.048), whereas it was comparable among non-horizontal patients (respectively 90.2%, 86.8%, 88.7%; P=0.78). On ROC analysis including only the Evolut-R population, AA was a significant predictor of ³moderate PVL (AUC 0.68, P=0.002) at a cutoff value of 52°(sensitivity 71%, specificity 60%). On multivariate analysis performed in the horizontal population, implantation depth at the level of left coronary cusp (OR 1.24; P=0.045) was an independent predictor of ³moderate PVL.

CONCLUSIONS

In patients with horizontal aorta (AA >57°), Portico and Acurate NEO showed excellent PVL and device success rates compared to Evolut-R, which was conversely associated with a low implantation. In these patients, implantation depth at the level of left coronary cusp was the strongest predictor of ³moderate PVL.

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Sex-specific PCI strategies in patients with AMI and cardiogenic shock: a substudy of the CULPRIT-SHOCK trial

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

Women are more likely to suffer from a cardiogenic shock (CS) as the most severe complication of an acute myocardial infarction (AMI) and tend to have a higher mortality. Data concerning optimal management among women with CS are lacking. Aim of this study was therefore to better define characteristics of women suffering a CS and to investigate the influence of sex on different coronary revascularisation strategies

METHODS AND RESULTS

In the CULPRIT-SHOCK trial, patients with CS complicating AMI and multivessel coronary artery disease were randomly assigned to one of the following coronary revascularisation strategies: either percutaneous coronary intervention (PCI) of the culprit lesion only or immediate multivessel PCI. Primary end-point was a composite of death from any cause or severe renal failure leading to renal-replacement within 30 days after randomisation. We investigated sex-specific differences in general and according to the revascularisation strategies.

Among all 706 randomised patients 26% were women. After 30 days, the primary end-point occurred in 55% women and 49% men (p=0.20), showing a relative risk of 1.14; 95% CI 0.94 -1.38; p=0.17, women vs. men. Those women were older, more frequent diabetic and had more peripheral artery disease and less frequent smokers and less often family history of coronary artery disease.

Regarding revascularisation strategy the composite end-point occurred in 55.8% women treated with the culprit-only strategy (vs. 42.4% men, p=0.04) and in 54.7% women in the multivessel group (vs. 55.6% men, p=0.99). This resulted in a no-significant difference among both groups (interaction p-value of 0.11).

CONCLUSIONS

In this large randomised trial among patients with multivessel coronary disease and CS complicating AMI, women had similar outcome for mortality and severe renal failure. Sex did not show to influence mortality and renal failure according to the different coronary revascularisation strategies. These data suggest that women and men presenting with CS should be treated equally.

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TAVR Operator Radiation Exposure (TAVORE)

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

There has been a widespread adoption of Transcatheter Aortic Valve Replacement (TAVR) across the globe. However, amount of radiation exposure (RE) to the operators doing TAVR remains unknown. The aim of this study is to measure the amount of RE to primary operator (PO) and secondary operator (SO) performing TAVR procedure

METHODS AND RESULTS

Total radiation expousre to the operators was prospectively collected for all consecutive Transfemoral TAVR cases from 9/25/17- 11/28/18. Operator RE was assessed with a set of two real time radiation detection dosimeters (Raysafe i3 System, Billdal, Sweden) strategically placed on head and thorax for both the PO and SO. The radiation dose was measured in MilliSieverts (mSv). A total of 76 Transfemoral TAVR cases were performed during the study period. The mean age of the patients was 82 years and 58% of the patients were female. Mean BMI of patients was 29.11+ 4.6 kg/m2. The mean total radiation dose to the primary operator (PO) was 119.34+ 95.14 mSv [Head 22.75+22.23 mSv, Thorax 96.59+76.84 mSv] and for the secondary operator (SO) was 54.34+52.13 mSv [Head 20.19+18.82 mSv, Thorax 34.14+35.19 mSv]. Primary operator had higher radiation exposure as compared to secondary operator (p< 0.001) and it was significantly higher for thorax (< 0.001), but not for head exposure (p=0.11). Ad hoc percutaneous coronary intervention (PCI) was significantly associated with increased RE for PO only (p = 0.0031). Factors significantly associated with higher RE for SO only were the use of transesophageal echocardiogram (p= 0.0146) and balloon pre-dilation (p = 0.0351). While obesity (BMI >30 kg/m2) and complications during procedure significantly affected RE in PO (p= 0.0002 and 0.0034 respectively) and SO (p= 0.0093 and 0.0022 respectively), valve type (self-expandable versus balloon expandable) and post-dilation did not have any significant effect on either operators RE.

CONCLUSIONS

The operators performing TAVR are exposed to excessive amount of radiation (approximately 8 times compared to a regular PCI and 17 times compared to a diagnostic angiogram). The major factors associated with excessive amount of RE are obesity and complications during the procedure

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Initial outcomes after multidisciplinary introduction of the MANTA closure device

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

The MANTA vascular closure device is a recently approved, collagen-based device for the closure of large bore femoral access ranging from 10-25F. The device is available in 2 different sizes (18F and 14F) and was introduced at our institution in March 2018. Here, we report outcomes of the first 100 consecutive cardiovascular procedures with MANTA device closure.

METHODS AND RESULTS

Patients underwent TAVI (n=75), endovascular aortic replacement (EVAR, n=20), Impella left ventricular support (n=4) and Mitraclip implantation (n=1). In these 100 patients, a total of 122 MANTA devices were used (22 patients had bilateral large bore access). Immediate hemostasis was achieved in 70%, hemostasis within 1 min in 79%, and within 5 min in 87% of patients. None of the patients received protamine. Major vascular complications related to the MANTA device occurred in 7% of patients (Femoral artery occlusion in 2%, ongoing bleeding in 4%, delayed rupture of a pseudoaneurysm in 1%). Patients were treated with covered stent implantation in 2%, 5% required surgical revision. Patients were discharged after a median of 4 (IQR 2-5.5) days. At 30 days, all-cause mortality rate was 1% and 2% had suffered a stroke.

We identified patterns of device failure, allowing to postulate 3 distinct failure mechanisms. In vessels with a high atheroma burden, elevation of the toggle may lead to occlusion of the artery (1), incomplete apposition of the plug may lead to perivascular (potentially retroperitoneal) bleeding (2), and pseudoaneurysm formation with the risk for delayed rupture (3).

CONCLUSIONS

The MANTA vascular closure device achieved immediate hemostasis in the majority of patients. However, the rate of major vascular complications related to the use of the MANTA was not negligible. If selected for presentation the authors will present and discuss the different mechanisms of device failure and illustrate them with case examples.

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TAVI-related futility: prevalence, predictors and clinical risk model

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Failure of projected therapeutic outcome is called a medical futility. We aimed to elucidate prevalence, predictors and clinical risk model of futility following transcatheter aortic valve implantation (TAVI).

METHODS AND RESULTS

We included consecutive 464 patients undergoing TAVI from April 2010 to December 2017. Futility was defined as death and/or hospitalization for heart failure within one year after TAVI. Average age of 464 patients was 84.4 years, and 69% were female (EuroSCORE2: 6.3%). The rate of device success was 95.7%, and 30-day mortality was 1.1%. Forty-six patients (9.9%) experienced TAVI related futility. Thirty-two of 46 patients (69.6%) had died within one-year after TAVI, and two-thirds were attributed to non-cardiac causes. Among background and procedural factors, previous hospitalization for heart failure (HR 2.20, 95%CI 1.13-4.35), chronic obstructive pulmonary disease (HR 3.39, 95%CI 1.12-8.42), and other valve disease (moderate/severe mitral or tricuspid regurgitation) (HR 2.98, 95%CI 1.32-6.27) were independent predictors of futility. Futility-risk model, assigning one-point to each predictor (zero-point summed=low-risk, one-point=intermediate-risk, and two- or three-points=high-risk group), clearly stratified individual futility risk of three groups (freedom from one-year futility: 96.2% in low-risk, 82.1% in intermediate-risk, and 67.9% in high-risk group). Our futility risk model presented better discrimination than EuroSCORE2 and STS score (c-statistics: 0.73 vs. 0.68 vs. 0.67).

CONCLUSIONS

Therapeutic futility defined as death and/or heart-failure hospitalization within one-year was recognized in 9.9% of patients undergoing TAVI. Previous heart failure hospitalization, chronic obstructive pulmonary disease, and mitral or tricuspid regurgitation were related with futility. Risk model derived from three independent predictors had good performance in predicting risk of TAVI related futility.

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Prognostic impact of a redo transcatheter mitral valve repair in patients with residual or recurrent mitral regurgitation

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair

AIMS

Despite of increasing implementation of redo transcatheter mitral valve repair (TMVR), little is known about its prognostic impact. The aim of this study is to investigate the prognostic impact of a redo TMVR using the MitraClip system (Abott Vascular, Santa Clara, California) for the treatment of residual or recurrent mitral regurgitation (MR).

METHODS AND RESULTS

From January 2011 to September 2018, a total of 35 consecutive patients underwent redo TMVR with the MitraClip system for the treatment of MR ≥2+ after the first TMVR (prior-implanted devices: MitraClip, n=23; Cardioband, n=4; Mitralign, n=4; Carillon, n=3; Neochord, n=1). As a control, patients with MR ≥2+ and treated conservatively (n=188) were identified. Propensity matching and Cox proportional hazards regression models were used to investigate the impact of redo TMVR on clinical prognosis. Primary measure was one-year survival rate of all-cause mortality or unexpected hospitalization due to heart failure. Propensity score (PS) derivation identified atrial fibrillation (odds ratio (OR), 4.37), prior utilization of implantable cardioverter defibrillator or cardiac resynchronization therapy (OR, 5.13), and severity of MR (OR, 10.2) to be associated with undergoing redo TMVR. After 2:1 PS matching, there were no significant differences in baseline characteristics and echocardiographic parameters. One or more clips were implanted in 34 patients (97.1%) and procedural success (MR ≤2+) was achieved in 29 patients (82.9%) in the redo TMVR group, with no periprocedural complication or in-hospital death. One-year events-free survival rate was significantly higher in the redo TMVR group compared to conservatively treated patients (79.7% and 53.1%, Log-rank p=0.02). Cox proportional hazard analysis identified redo TMVR was significantly associated with lower risk of adverse-events (Hazard ratio (HR), 0.32; 95% confidential interval (CI), 0.12-0.85; p=0.023). Similar association was found for all-cause mortality (HR, 0.24; 95% CI, 0.05-1.08; p=0.06) but not statistically-significant.

CONCLUSIONS

Redo TMVR using the MitraClip system for the treatment of residual or recurrent MR after a first TMVR procedure is associated with better one-year outcomes compared to a conservatively treatment approach.

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Risk-adjusted comparison of in-hospital outcomes of transcatheter and surgical AVR

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Transfemoral transcatheter aortic valve replacement (TF-TAVR) is the standard therapy for patients with severe aortic valve stenosis at high operative risk. If the transfemoral access is not possible, a transapical access is an alternative. However, it is known from randomized trials and large registries that outcomes after transapical TAVR (TA-TAVR) are inferior to TF-TAVR. Therefore, we compared in-hospital outcomes of patients undergoing TA-TAVR or SAVR in a nationwide data-set, in order to identify patients' groups, who benefit from SAVR or TA-TAVR.

METHODS AND RESULTS

We identified all 13,151 isolated SAVR and 4,625 TA-TAVR performed in Germany 2014 and 2015 on the basis of ICD- and OPS codes. In order to compare outcomes, we adjusted for risk factors using a covariate adjusted analysis. Patients undergoing TA-TAVR were older (68 vs. 80 years), had more co-morbidities, and accordingly an increased logistic EuroSCORE (LogES 5.3 vs 16.7%). However, stroke, acute kidney injuries, relevant bleedings, and prolonged mechanical ventilation occurred less frequently in patients undergoing TA-TAVR (OR TA-TAVR vs SAVR: stroke 0.66, p=0.017; acute kidney injury 0.72, p=0.002; relevant bleeding: 0.38, p<0.001; prolonged mechanical ventilation >48h: 0.5, p=<0.001). The risk for a new permanent pacemaker was higher after TA-TAVR (OR 2.44, p=<0.001). Without adjustment in-hospital mortality was higher after TA-TAVR (2.0% vs. 5.9%). After covariate adjustment, the difference disappeared (OR TA-TAVR vs. SAVR 1.2, p=0.136). In order to identify subgroups, which may benefit from TA-TAVR or SAVR, we compared mortality in different subgroups after risk adjustment. Patients under 75 years (OR TA-TAVR vs. SAVR: 1.86, p=0.01) and female (OR 1.48, p=0.043) patients had a lower risk for in-hospital mortality after SAVR. In all other groups (age 75-79, 80-84, > 85, log. EuroScore <4, 4-9,>9, NYHA III/IV, previous CABG, COPD, pulmonary hypertension, chronic renal failure, Diabetes) none of both treatment strategies was superior.

CONCLUSIONS

TA-TAVR is with regard to in-hospital mortality not superior to SAVR in clinical practice. Younger patients under 75 years and female patients benefit from SAVR. However, complications such as bleeding, stroke, or prolonged ventilation were less frequently in patients undergoing TA-TAVR.

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Comparison of bedside lung ultrasound and left ventricle end diastolic pressure in patients with STEMI submitted to primary PCI

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Elevated left ventricle end diastolic pressure (LVEDP) is related to diastolic dysfunction, increased retrograde pulmonary capillary pressure and pulmonary congestion. Diastolic dysfunction precedes the onset of systolic dysfunction in acute ischemia, and the prognostic utility of LVEDP in ST-segment elevation myocardial infarction (STEMI) is well known. Bedside lung ultrasound (BLU) is a novel, simple and sensitive method for evaluating pulmonary congestion. The aim of this study is to assess LVEDP and BLU correlation and to evaluate their prognostic ability.

METHODS AND RESULTS

This is a prospective cohort of STEMI patients treated in a tertiary care hospital. BLU was performed by two independent operators blinded to Killip class and performed before primary percutaneous coronary intervention (PCI). Our protocol consisted of eight scanning sites, which were considered positive for congestion in case of three or more B lines/each. LVEDP was blinded to BLU results and performed before primary angioplasty.

We included 42 patients with a mean age of 56 (±12) years and 71% were male. Killip class I, II, III and IV at admission was present in 68%, 17%, 5% and 10% of the patients, respectively. Median LVEDP and BLU positive sites were 15 [12, 22] and 1 [0, 4], and spearman correlation between both was 0.42. In-hospital mortality was 9.5%. BLU and LVEDP C-statistic for in-hospital mortality was 0.88 (p=0.013) and 0.81 (0.047), respectively. For patients with 5 or more positive BLU scanning sites, hazard ratio for in-hospital mortality was 33.0 (2.57-423, p=0.007). For patients with LVEDP higher than 30 mmHg, hazard ratio for in-hospital mortality was 8.0 (0.87-73.5, p=0.66)

CONCLUSIONS

Correlation between LVEDP and BLU was moderate. Both methods are excellent to predict in-hospital mortality, with a greater area under the curve for BLU. In-hospital mortality was 33 times higher in patients with 5 or more positive BLU scanning sites. No cutoff value of LVEDP significantly predicted in-hospital mortality, which may be due to the small number of patients in our preliminary study.

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Vessel injury in relation with strut thickness assessed by OCT (VISTA)

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

The primary objective of the study was to compare the degree of vascular injury caused by a bioresorbable polymer, thick strut (120 µm) DES with that caused by a polymer free, thin-strut (50 µm) DES, evaluated by OCT. The primary end-point was the OCT-based injury score estimated after implantation of the thin strut and thick strut DES. Secondary end-points were tissue prolapse area, apposition and stent expansion.

METHODS AND RESULTS

50 patients with ischemic symptoms or evidence of myocardial ischemia in the presence of >50% de novo stenosis, were randomized. Baseline and post stent OCTs were performed and analysed with QIVUS software (Medis, Leyden, The Netherlands). Baseline OCT included a quantitative analysis of the lesion (minimum lumen area, eccentricity, reference area) and a qualitative evaluation of the plaque composition. Post-stent OCT analysis included quantitative evaluation of vessel injury through the injury score, tissue protrusion, stent expansion and apposition. 80% of the patients were men, there were no differences between groups regarding cardiovascular risk factors, previous cardiac history and clinical presentation. The indication for revascularization was unstable angina in 58% of the cases.

The arteries treated were similar in both groups (p=1). Baseline OCT showed no differences in minimum lumen area (1.46 [1.30-2.08] vs 1.42 [0.89-2.16] mm2, p=0.49), reference vessel area (6.84 [4.96-8.75] vs 5.82 [4.70-7.45] mm2, p=0.25) or % area stenosis (75 [68.95-79.41] vs 75.55 [65.81-79.20] %, p=0.25), for thin and thick strut respectively. Plaque composition (fibrous, lipid, calcified; p=0.45) and eccentricity (p=0.43) were also similar between the groups.

There were no significant differences in procedural characteristics. Same percentage of cases were treated with pre-dilatation (17 vs 21%, p=0.32), with similar size of balloons (2.0 [2.0-2.5] vs 2.5 [2.0-2.5] mm, p=0.12) and pressure (14 [10-14] vs 12 [10-14] atm, p=0.83). Mean stent diameter (3.0 [2.5-3.5] vs 3.0 [3.0-3.5] mm, p=0.66), length (19 [16-24] vs 18 [18-28] mm, p=0.41) and implantation pressure (14 [14-16] vs 14 [12-16] atm, p=0.81) were similar between groups. Post-dilatation was performed in 80% in thin strut and 64% in thick strut group (p=0.35), with similar balloon diameters (3.5 [2.875-4.0] vs 3.25 [3.0-3.5] mm, p=0.72) and pressures (16 [14-20] vs 16 [14-18] atm, p=0.94).

The injury score was numerically higher with the thick strut stent 0.32 (0.10-0.50) vs 0.23 (0.13-0.35), but the difference was not significant (p=0.61). The number of major dissections (>300µm) was not different between groups (p=0.40). The thick strut group had more proximal dissections: 7 (28%) vs 3 (12%), but the difference was not significant (p=0.29). Distal edge dissections were also similar (p=1).

Total prolapsed area was greater with the thin strut stent (2.26 [1.93-3.96] vs 1.83 [1.13-2.60] mm2, p=0.035). No differences were observed regarding post-stent minimal, mean and maximum luminal and stent area. Stent expansion and symmetry index were also similar (84.52% vs 93.63%, p=0.08; and 0.82 vs 0.80, p=0.25). No significant difference was observed in the total malapposition area (1.85 [1.20-3.72] vs 1.47 mm2 [0.33-4.41], in thin and thick strut respectively, p = 0.48).

CONCLUSIONS

There was no difference in the OCT based injury score between a thin strut and a thick strut DES platform. Prolapse area was higher with the thin strut DES reflecting a higher stent embedment in the vessel wall.

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Primary PCI in patients with STEMI and pre-hospital cardiac arrest

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Pre-hospital cardiac arrest (CA) is associated with a poor prognosis with only 10% alive after 30 days. Post-resuscitation care focuses on improving both survival and quality of life after the event. STEMI-patients in general have a good prognosis, however patients with CA and STEMI are infrequently included in the major STEMI-studies. We therefore aimed to describe a resuscitated STEMI-cohort with pre-hospital CA admitted to hospital with return of spontaneous circulation (ROSC) with regards to demographics, angiographic results and survival.

METHODS AND RESULTS

A total of 231 STEMI-patients (23% of an unselected, resuscitated and consecutive CA-cohort, n=1,003) with pre-hospital CA were included in this prospective study during 2007-2011. Patients were admitted for post-resuscitation care including coronary angiography at two tertiary centres in the Capital Region of Denmark.

Patients were 63±12 years (min. 34 years, max 93 years), and 80% (n=184) were male. The majority had shockable primary rhythm (82%, n=190), time to ROSC was 24 minutes (Q2-Q4: 13-39 min), and 17% (n=40) were awake at hospital admission not requiring ventilator therapy nor intensive care unit admission. 57% (n=129) had no previous comorbidity registered. Previous ischemic heart disease was noted in 19% (n=43), and congestive heart failure in 18 (8%) of patients.

Acute angiography was performed in 86% (n=199), and 1 vessel disease (VD) was found in 53% (n=105), 2-VD in 19% (n=38), 3-VD in 20% (n=39), and atheromatosis without significant stenosis in 7% (n=13). Primary PCI was performed successfully in 88% (n=175), and CABG in 6% (n=12). Patients with 1- or 2-VD were compared to patients with 3-VD significantly younger (61±11 vs. 64±10, p=0.04), had more often successful acute PCI performed (92% vs. 77%, p=0.007), less often CABG performed (3% vs. 21%, p<0.005), and were more often found with LVEF <35% (48% vs. 77%, p=0.002), whereas no difference in previous comorbidity, pre-hospital circumstances (bystander CPR, witnessed CA, public CA, primary rhythm nor in time to ROSC) or in number of comatose patients at hospital arrival were found.

A total of 58% of patients (n=135) were discharged alive from hospital. Agood neurological outcome (defined as Cerebral Performance Category 1/2) at hospital discharge was found in 84% of the discharged patients (n=114). All but one of the 40 waking patients at hospital admission survived to hospital discharge (98%). Stratifying by number of VD, survival to hospital discharge was 70% for 1-VD, 71% for 2-VD, and 51% for 3-VD (p<0.001), whereas 11 out of 13 patients (85%) with atheromatosis without significant stenosis were discharged alive from hospital. Hazard ratio for 3-VD vs. 1- or 2-VD with regards to 30-day mortality was 1.73 (95%CI: 1.01-3.00, p=0.04), whereas after adjustment for age a significant difference in mortality was no longer found (HR=1.54 (0.89-2.67, p=0.1).

CONCLUSIONS

STEMI-patients represent one quarter of a consecutive unselected cohort with pre-hospital cardiac arrest

admitted with ROSC. More than half of the patients had no previous comorbidity. Primary PCI was performed successfully in 9 out of 10 patients. All but one of the waking patients at hospital arrival was discharged alive. Survival to hospital discharge was high (70%) in patients with 1- and 2- vessel disease, whereas in patients with 3-vessel disease survival was significantly lower (51%), however after adjustment for age a difference was no longer found.

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Predictors of clinical outcomes after polymer-free amphilimus - and biolimus-eluting stents: the FREE-FUTURE study

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(1) ,

THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Despite impressive improvements in drug eluting stents (DES) technology, diabetic patients still represent one of the main unsolved issue for percutaneous coronary intervention. In this setting, the Cre8 polymer free amphilimus eluting stent (AES) has shown some promising results in both preclinical and clinical studies. However, there is still a low number of studies comparing this new generation DES with other devices, and, importantly, no direct comparison between the Cre8 AES and other polymer free DES are available at this point in time.

METHODS AND RESULTS

In the FREE-FUTURE study, the Biofreedom polymer-free biolimus-eluting stents (BES) and the Cre8 AES were compared after propensity score matching pooling two large-scale multicenter registries including 2,320 real-world patients treated at 22 Italian centers between 2011 and 2016 (RUDI-FREE, N=1,104; ASTUTE, N=1,216). The primary endpoint was target-lesion failure - a composite of cardiac death, target-vessel myocardial infarction (TV-MI), and target lesion revascularization (TLR). In the present sub-analysis, we performed multivariable analyses stratified for DM status in order to assess the presence and the impact of predictors on the primary endpoint.

In non-DM patients, the multivariable analysis identified STEMI as clinical presentation (HR 4.12, 95% CI 1.38-12.28) and shorter DAPT duration (HR 0.36, 95% CI 0.24-0.52) as independent predictors of TLF at 1 year. In DM patients, use of BES (HR 0.23, 95% CI 0.07-0.76), increasing age (HR 1.09, 95% CI 1.02-1.17), STEMI as clinical presentation (HR 3.75, 95% CI 1.09-12.87), LVEF<30% (HR 3.55, 95% CI 1.01-12.39), and shorter DAPT duration (HR 0.38, 95% CI 0.22-0.64) were identified as independent predictors of TLF at 1 year.

CONCLUSIONS

This first direct comparison between two polymer-free DES in real-world all-comer patients shows that in non-DM patients, BioFreedom BES and Cre8 AES have similar efficacy outcome, with STEMI presentation and shorter DAPT duration identified as predictors of TLF at 1 year. Conversely, in DM patients, the use of the Cre8 AES resulted in improved outcomes, and increasing age, STEMI as clinical presentation, LVEF<30%, and shorter DAPT duration were independent predictors of TLF at 1 year.

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Stratified medicine in angina: can we improve health outcomes using an interventional diagnostic procedure?

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Background: Vasospastic angina (VSA) and microvascular angina (MVA) are common causes of ischaemia in patients without obstructive coronary artery disease (INOCA).

Aim: We tested the hypothesis that an interventional diagnostic procedure (IDP) linked to distinct medical therapy improves angina symptoms in patients with INOCA.

METHODS AND RESULTS

Prospective randomized, controlled, blinded clinical trial of stratified medicine versus standard care in patients with angina (NCT03193294). Patients with angina undergoing invasive coronary angiography (standard care) were recruited. Patients without obstructive CAD were immediately randomised 1:1 to the intervention group (stratified medicine) or the control group (standard care, IDP sham procedure). The IDP consisted of pressure-temperature sensitive guidewire-based assessment of coronary flow reserve, microcirculatory resistance, fractional flow reserve, followed by vasoreactivity testing with acetylcholine (ACh). The IDP was used to make a diagnosis of MVA, VSA or non-cardiac chest pain each aligned with distinct management based on ESC guidelines. The primary endpoint was the mean difference in angina severity at 6 months (assessed by the Seattle Angina Questionnaire). A total of 391 patients were enrolled over a 12 month period from Nov 2016. Coronary angiography revealed obstructive disease in 206 (53%), these patients were excluded from further study. One hundred fifty-one (39%) patients without angiographically obstructive CAD were randomized (N=76 intervention group; N=75 blinded control group). The intervention resulted in a mean improvement of 11.7 U in the Seattle Angina Questionnaire summary score at 6 months (95% confidence interval [CI]: 5.0 to 18.4; P=0.001). In addition, the intervention led to improved quality-of-life (EQ-5D index 0.10 U; 95% CI: 0.01 to 0.18; p=0.024) and visual analogue score (14.5 U; 95% CI: 7.8 to 21.3; p < 0.001). There were no differences in major adverse cardiac events at the 6-month follow-up (2.6% controls vs. 2.6% intervention; P=1.00).

CONCLUSIONS

Vasospastic and/or microvascular angina are common, distinct and treatable disorders that may be missed on invasive coronary angiography.

Interventional cardiologists can rule in or rule out these disorders using an IDP in the cardiac catheterisation laboratory.

This approach was safe, routinely feasible and improved angina and quality of life for patients with no obstructive CAD.

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Functional assessment of intermediate lesions of collateral donor artery of coronary CTOs

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease, CTO

AIMS

This study is aimed at evaluating by fractional flow reserve (FFR) the amount of ischemia subtended to the angiographic intermediate stenosis of collateral donor vessel before and after successful percutaneous coronary intervention (PCI) of CTO. Main outcomes were change in FFR values of donor vessels and change in ischemic segments as assessed by CMR before and after PCI of the CTO.

METHODS AND RESULTS

Methods. This is a prospective pilot study. We screened 23 patients with stable angina and CTO with collaterized distal vascular bed, and collateral donor vessel with angiographic intermediate lesion. However, we excluded 9 patients who presented any of the exclusion criteria. Eventually 14 patients patients with stable angina and CTO with collaterized distal vascular bed and collateral donor vessel presenting a single angiographic intermediate lesion (50-70% diameter stenosis by quantitative coronary angiography) were included. In order to indicate recanalization by PCI all patients were referred to cardiac magnetic resonance (CMR) evaluation to assess the presence of myocardial viability. During the procedure, FFR of the donor vessel was performed before the PCI of CTO, and whenever FFR value was ≤0.80, the measure was reassessed after the procedure. A second CMR was performed 1 month after the index PCI.

Results. In the group of patients presenting a FFR value ≤0.80 before PCI (n=7; 50%), FFR measures of the donor artery significantly increased after revascularization of CTO (0.75 [0.73-0.78] vs. 0.83 [0.81-0.84]; p=0.017). Eventually, only 3 patients showed hemodynamically significant values of FFR after CTO recanalization requiring further revascularization. There was a trend towards a reduction of the number of ischemic segments (2.5 (0-4) vs. (0 [0-0.25]; p=0.066) evaluated by CMR before and after PCI of the CTO. No major adverse cardiac events were reported during 2-year follow-up.

CONCLUSIONS

Our data suggest that FFR measurements in intermediate stenoses of collateral donor vessel of a CTO may overestimate the severity of the lesions. Therefore, the strategy of primarily focus on CTO revascularization and thereafter on the assessment the intermediate lesion in a collateral donor vessel may be recommended.

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Increased levels of high sensitive cardiac troponin and coronary plaque morphology in patients with stable coronary artery disease: an OCT study

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Increased levels of high sensitive cardiac troponin T (hs-TnT) are associated to adverse cardiovascular outcome in general population and in patients with stable coronary artery disease (SCAD). The aim of the study was to search by optical coherence tomography (OCT) for coronary athero-thrombosis as possible cause of hs-TnT release.

METHODS AND RESULTS

We assessed by OCT plaque morphology of 73 de novo coronary lesions from 58 patients with stable CAD. Patients were divided in two groups according to the level of hs-TnT on admission: high hs-TnT group (≥0,014 µg/L) and normal hs-TnT group (<0,014 µg/L).

The high hs-TnT group consisted of 22 lesions and the normal hs-TnT level group 51 lesions. No significant difference was found in main clinical data, cardiac function and angiographic features between the groups except for an older mean age in patients with high hs-TnT levels. By OCT, we found signs of coronary instability, like thrombosis, rupture, macrophages infiltrates, microvessels and thin-cap fibroatehroma in both groups, but their prevalence was not different between patients with high and normal hs-TnT levels. Other plaque morphology features like extension of lipid and calcium infiltrations and severity of stenosis in terms of minimal lumen area and percent of area stenosis were also similar

CONCLUSIONS

Increased hs-TnT levels in SCAD patients are not associated with coronary plaque instability features, like athero-thrombosis. Other mechanisms, like microvessel disfunction and/or myocardial abnormalities could explain the increased hs-TnT levels and the worse prognosis in this setting of patients.

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Balloon rupture during aortic valvuloplasty with compliant balloon: predictors and outcomes

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS
Low profile compliant balloons have been developed to reduce vascular complications of balloon aortic valvuloplasty (BAV). The aim of this study was to assess the prevalence and outcomes of balloon aortic rupture with compliant low profile balloon in BAV

METHODS AND RESULTS
Single center, retrospective (2016-2018) study in patients undergoing BAV with compliant balloons, excluding TAVR procedures. Rupture was defined as a sudden release of contrast in the aorta during inflation. Baseline echocardiography and computed tomography (CT) were analyzed. Best cutoff point (ROC curve) for calcium score was assessed. In order to assess rupture, a bench test was performed in an ovale metal ring with smooth edges. Chi2 was used for frequencies and Mann Whitney for quantitative variables. Long term mortality was analyzed with Kaplan Maier (log rank). SPSS Software (IBM) was used. Rupture occurred in 30/90 (33%) of BAVs, more frequently in elderly patients independently of risk factors, surgical risk and frailty scores. Patients experiencing rupture had increased mean gradient [53.5 (44-64) vs 44 (35-49) mmHg, $p<0.05$] and reduced aortic valve area [0.61 (0.46-0.76) vs 0.76 (0.64-0.83) mm2, $p<0.05$) on echo. Aortic valve calcium score on CT was available in 41% of patients, and values >2686 HU (best cutoff) were more frequent in the rupture group (41% vs 10%, $p<0.05$) and more patients in the 3rd tertile of calcium score experienced rupture (75% vs 23% vs 41% for 3rd, 2nd and 1st tertile, respectively, $p<0.05$). Median gradient reductions [30 (20-50) vs 30 (17-39) mmHg] were similar among groups. Contrast CT was available in 77% of patients, with no differences among any measurements of the annulus. No patient with rupture had any complication. No significant difference in mortality was observed at one month (rupture 0% vs 3.5% no rupture), and in long term follow up (median 389 days). In vitro test required more volume and strength to induce balloon rupture than used in BAV.

CONCLUSIONS
Balloon rupture is frequent in BAV using compliant low profile balloons, occurs in more elderly patients independent of clinical condition, frailty and surgical risk. Rupture was more frequent with more calcified aortic stenosis and reduced area. It occurs at the level of calcified leaflets, it does not affect BAV efficacy, and it is not associated with further complications. In vitro test showed that inflation volume and strength are not related to rupture.

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Potential role of transcatheter interventions for severe tricuspid regurgitation patients presenting to a tertiary care setting

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THEME: Interventions for Valvular Disease
TOPIC(S): Tricuspid / Pulmonary valve

AIMS

Patients with severe tricuspid regurgitation (TR) and prohibitive surgical risk are lacking treatment options, but the magnitude of this unmet clinical need and the potential role of transcatheter interventions remain unknown. Thus, we aimed at evaluating the indication for treatment, surgical risk and potential for treatment with percutaneous options in severe TR patients.

METHODS AND RESULTS

We retrospectively evaluated the reports of 11,943 echocardiograms performed at our institution between October 2014 and May 2016 to identify patients with severe TR. These patients were then evaluated as to whether they had a guideline indication for surgical correction of TR, their surgical risk and eligibility for percutaneous treatment.

Of 241 severe TR patients, only 73 (30.3%) had an indication for intervention according to guidelines. These 73 patients had significantly more co-morbidities like coronary artery disease (39.7% vs. 24.4%, p=0.016) and poorer general conditions as indicated by a higher prevalence of liver dysfunction (41.1% vs. 27.4%, p=0.047) and previous cardiac decompensation (71.2% vs. 50.0%, p=0.001). Only 1 (1.4%) of them was found to be at acceptable surgical risk. Of the remaining 72 prohibitive surgical risk patients, 32 (44.4%, i.e. 13.3% of the total cohort) were considered potentially eligible for percutaneous approaches. Patients eligible for percutaneous treatment had less co-morbidities as compared to those ineligible, such as liver dysfunction (21.9% vs. 57.5%, p=0.032), chronic obstructive pulmonary disease (9.4% vs. 40.0%, p=0.006) and previous cardiac decompensation (50.0% vs. 87.5%, p=0.002). If treatment was theoretically indicated in the total cohort, only 2.1% (5) would be of acceptable surgical risk but potentially 54.2% (128) would be eligible for percutaneous treatment.

CONCLUSIONS

Patients identified with severe TR by echocardiography in a tertiary academic center have significant co-morbidities and, irrespective of whether they have a guideline indication for treatment, are not good surgical candidates, but percutaneous transcatheter devices may be feasible in up to half of these patients. This study highlights that patients with severe TR should be identified and referred for evaluation at a much earlier stage.

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Impact of combined plaque structural stress and wall shear stress on coronary plaque progression, regression and changes in composition

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

The focal distribution of atherosclerotic plaques suggests that local biomechanical factors, including wall shear stress (WSS) and plaque structural stress (PSS), may influence plaque development. The aim of this study was investigate whether PSS and WSS biomechanics forces are associated with progression and regression of atherosclerotic plaques. This would allow to better idnetify those plaques that are at risk of aggrressive progression and thus rupture and clinical events.

METHODS AND RESULTS

We studied 40 patients at baseline and over 12 months by virtual-histology intravascular ultrasound and bi-plane coronary angiography. We calculated plaque structural stress (PSS), defined as the mean of the maximum principal stress at the peri-luminal region, and wall shear stress (WSS), defined as the parallel frictional force exerted by blood flow on the endothelial surface, in areas undergoing progression or regression. Changes in plaque area (PA), plaque burden (PB), necrotic core (NC), fibrous tissue (FT), fibrofatty tissue (FF) and dense calcium (DC) were calculated for each co-registered frame. A total of 4029 co-registered frames were generated. In areas with progression, high PSS was associated with larger increases in NC and small increases in FT vs. low PSS (difference in?ΔNC: 0.24±0.06mm2; p<0.0001, difference in ΔFT: -0.15±0.08 mm2; p=0.049). In areas with regression, high PSS was associated with increased NC and decreased FT (difference in ΔNC: 0.15±0.04; p=0.0005, difference in ΔFT: -0.31±0.06mm2; p<0.0001). Low WSS was associated with increased PB vs. high WSS in areas with progression (difference in ΔPB: 3.3±0.4%; p<0.001) with a similar pattern observed in areas with regression (difference in ΔPB: 1.2±0.4%; p=0.004). PSS and WSS were largely independent of each other (R2 =0.002; p=0.001).

CONCLUSIONS

The current study represents the first investigation that a) evaluates the relationship between baseline PSS and WSS and future plaque composition, b) examines the relationship between PSS and WSS and c) evaluates whether the associations observed between PSS and WSS and future plaque growth are independent of the other biomechanical force. We find that baseline PSS is primarily associated with changes in plaque composition irrespective of whether overall change, progression or regression was assessed. Specifically, in areas of progression, high PSS was associated with larger increases in NC and smaller increases in FT, and therefore evolution to a more vulnerable plaque phenotype. Even in areas of regression, high baseline PSS was associated with larger decreases in FT and smaller decreases in NC. In contrast, WSS is largely associated with plaque growth, defined by changes in PB. Thus, low WSS was associated with a greater increase in PB and/or PA in areas that progress, or smaller decreases in areas that regress, than high WSS.

In conclusion, we demonstrate that areas with high PSS undergo compositional changes suggestive of

increased plaque vulnerability. Areas with low WSS demonstrate greater growth in areas of progression and lower plaque loss in areas of regression. These associations with PSS and WSS persist irrespective of the level of the other biomechanical force, suggesting that the interplay between PSS and WSS may have an important role in determining future plaque behaviour.

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FFR in patients with reduced ejection fraction

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Fractional flow-reserve (FFR) has never been investigated in patients with reduced ejection fraction (LVEF) and associated coronary artery disease (CAD). We evaluated the impact of invasive FFR on management strategies of these patients and related clinical outcome.

METHODS AND RESULTS

From 2002 to 2010, all consecutive patients with LVEF≤50% undergoing coronary angiography with ≥1 intermediate coronary stenosis treated based on angiography (Angiography-guided group) or according to FFR (FFR-guided group) were screened for inclusion.

In the FFR-guided group, 433 patients were included and matched through non-parsimonious propensity score with 866 contemporary patients included in the Angiography-guided group.After FFR, the number of stenotic vessels per patient was significantly downgraded within the FFR-guided group (from 2.0 ± 0.84 to 1.4 ± 0.98; p<0.01) and compared with the Angio-guided group (1.4 ± 0.98 vs. 2.02 ± 0.84; p<0.01). This was associated with a significantly lower revascularization rate as compared with the Angio-guided group (52% vs. 61%; p <0.01). In addition, PCI was more frequent in the FFR-guided group (36% vs. 28% of the angio-guided group; p<0.01); while CABG was more frequent in the Angiography-guided group (32% vs. 16% of the FFR-guided group, p<0.01). In patients undergoing CABG treated according to FFR guidance, off-pump (37% vs. 11%; p< 0.01) and minimally invasive surgery (7% vs. 1%; p<0.01) were more frequently performed as compared with patients treated according to angiography guidance, with lower rate of venous grafts per patient (1.02 ± 0.8 vs. 1.28 ± 0.7; p=0.01).

The rate of all-cause death at 5-year follow-up was significantly lower in the FFR-guided group as compared to the Angiography-guided group (22% vs. 34%. HR [95% CI] 0.61 [0.48-0.76]; p<0.01). Similarly, the rate of major adverse cardiovascular and cerebrovascular events (MACCE) was significantly lower in the FFR-guided group (40% vs.47% in the Angiography-guided group. HR [95% CI] 0.78 [0.65-0.93]; p<0.01).

CONCLUSIONS

In patients with reduced LVEF and CAD, an FFR-guided revascularization strategy was associated with lower rates of death and MACCE at 5-year follow-up as compared with an Angiography-guided strategy. This beneficial impact was observed in parallel with less CABG and more patients deferred to PCI or medical therapy.

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High-definition IVUS vs. OCT to assess coronary artery disease and results after stent implantation

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Previous studies demonstrated a systematic overestimation of lumen area (LA) with conventional 20-40 MHz grey-scale intravascular ultrasound (IVUS) compared to optical coherence tomography (OCT). The aim of this prospective study was to correlate findings of the new 60 MHz high-definition IVUS (HD-IVUS) technology with those obtained by OCT before and immediately after coronary intervention.

METHODS AND RESULTS

A total of 29 consecutive patients (29 lesions) prospectively undergoing systematic examination with both HD-IVUS and OCT, before and immediately after stent implantation, were analyzed. Pre-intervention, OCT was superior to HD-IVUS to define plaque rupture (0 vs 4 lesions [14%]; p=0.0382) or the presence of intraluminal thrombus (0 vs 4 lesions [14%]; p=0.0382). Post-intervention, OCT was superior to HD-IVUS to quantify the presence of tissue protrusion (frames with protrusion 1.5±1.4 vs 3.0±2.4; p<0.001), malapposition (percentage of malapposed struts 1.8±1% vs 3.9±2%; p<0.001) and stent-edge dissections (4 [14%] vs 13 [46%]; p=0.0089). There were no significant differences in LA measurements (6.6±3.3 vs 6.6±3.3 mm2; p=0.7333) between both techniques. Notably, HD-IVUS showed an exceptional concordance in the estimation of LA compared to OCT (mean difference between estimations of only 0.05±0.35 mm2; intraclass correlation coefficient [ICC] of 0.944). This excellent concordance was consistent in both pre and post-intervention studies (ICC 0.918 and 0.924, respectively).

CONCLUSIONS

HD-IVUS showed an exceptional concordance with OCT on LA measurements, both before and after coronary intervention. However, before intervention OCT was superior to HD-IVUS to identify the presence of plaque rupture or intraluminal thrombus. Likewise, after intervention OCT was superior to HD-IVUS to identify tissue protrusion, stent-edge dissection and acute stent malapposition.

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Predictors of adverse procedural outcomes during rotational atherectomy

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THEME: Coronary Interventions

TOPIC(S): Other Coronary Interventions

AIMS

Rotational atherectomy (RA) is now more commonly used in contemporary percutaneous coronary interventions (PCI). While the determinants of long-term adverse cardiac events in RA have been well studied, predictors of adverse procedural outcomes are not well established. Our aim is to explore the predictors of adverse procedural outcomes in patients undergoing rotational atherectomy.

METHODS AND RESULTS

Patients who underwent RA between 06/2010 and 02/2018 (n=407) were divided into two groups according to the occurrence of adverse procedural outcomes (a composite of residual stenosis ≥ 30 %, persistent slow flow, dissection requiring additional stenting beyond the primary lesion, perforation, burr entrapment, and in-hospital major adverse cardiac events [MACE]). Patients with a history of coronary artery bypass grafting (n=83) and those who presented with myocardial infarction (n=48) were excluded. Target vessel SYNTAX score was calculated and predictors of adverse procedural outcomes were investigated.

A total of 51 adverse procedural outcomes (residual stenosis ≥ 30 % (n=6), slow flow (n=12), dissection (n=17), perforation (n=6), burr entrapment (n=1) and in-hospital MACE (n=9)) occurred in 38 patients (13.5%). Demographic characteristics were balanced among the study population. More multiple stenting (84.2% vs. 67.5%, p=0.038), longer procedural duration (median[IQR]:132[90-168] vs. 84[63-111] min, p<0.001) and more contrast agent usage (250[200-387] vs. 180[120-255] ml, p=0.035) were observed in patients with adverse procedural outcomes. Anatomical determinants of adverse procedural outcomes included: left anterior descending artery (LAD) as a target vessel (68.4% vs. 49.4%, p=0.036), target vessel tortuosity (52.6% vs. 29.2, p=0.008) and long lesions(>20 mm) (89.5% vs. 72.8%, p=0.027). Other anatomical criteria such as aorto-ostial lesions (15.8% vs. 17.3%, p=1.000), bifurcation lesions (42.1% vs. 36.6%, p=0.589) and chronic total occlusion (18.4% vs. 7.8%, p=0.063) were not significantly different among patients with and without adverse procedural outcomes.

Target vessel SYNTAX score was higher in patients with adverse procedural outcomes (19.5[15-24] vs. 12[9-17], p<0.001). A target vessel SYNTAX score cut-off value of 15 (area under the ROC curve: 0.756, p<0.001) showed 79% sensitivity and 61% specificity for predicting adverse procedural outcomes.

CONCLUSIONS

Adverse procedural outcomes remain relatively common in the setting of RA and are more common in patients with LAD lesions, long lesions, and a tortuous target vessel. Target vessel SYNTAX score is a practical tool that can predict adverse procedural outcomes in the setting of RA.

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Neointima pattern as a prognostic marker for DEB angioplasty treatment in patients with in-stent restenosis: an OCT study

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Stents and scaffolds

AIMS

Optical coherence tomography (OCT) has demonstrated that neointimal tissue patterns are associated with clinical outcomes in patients after drug-coated balloon angioplasty (DCB). However, the changes in neointima patterns after DCB are not well understood. This study aimed to evaluate the serial changes of neointima patterns and their clinical implications in patients who underwent DCB for ISR.

METHODS AND RESULTS

A total of 67 patients with drug-eluting stent (DES) restenosis treated by DCB underwent periprocedural and follow-up OCT. Neointimal tissue was categorized as homogeneous, heterogeneous, layered, or neoatherosclerotic. Homogeneous and layered neointima were defined as favorable neointima patterns, whereas heterogeneous neointima and neoatherosclerotic neointima were unfavorable neointima patterns. Major adverse cardiac events (MACEs), including cardiac death, myocardial infarction (MI), and clinically-driven target lesion revascularization (TLR), were assessed according to the neointima patterns. The median follow-up duration between the two OCTs was 9.77 months (IQR, 9.07–14.57 months). The majority of homogeneous (66.7%, 10/15) and layered neointima (68.2%, 15/22) identified by periprocedural OCT appeared as homogeneous neointima at follow-up OCT; most heterogeneous (70%, 7/10) neointima remained unaltered at follow-up. Over the median clinical follow-up duration from DCB of 57.4 months (IQR, 36.3–66.0 months), both periprocedural and follow-up OCTs showed that patients with unfavorable neointima patterns experienced MACEs more frequently than patients with favorable neointima patterns. Patients that maintained an unfavorable neointima pattern during the follow-up period had lower MACE-free survival than patients with other neointima pattern transitions. Multivariate analysis identified that sustained unfavorable pattern was an independent predictor of future adverse cardiac events.

CONCLUSIONS

Patients with unfavorable neointimal patterns before and after DCB experienced MACEs more frequently than those with favorable patterns. Sustained unfavorable neointima pattern may serve as a prognostic marker in patients treated by DCB for ISR.

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STEMI - When to give the loading dose of the P2Y12 inhibitor?

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS
To characterize the practice of a country in chosen time to LD-P2Y12, before or during/after the catheterization. Identify its independente predictors (IP) and assess their prognostic impact.

METHODS AND RESULTS
Methods: Retrospetive and multicenter study, based on a national register between the dates of 30/10/2010 to 09/19/2017. Inclusion criteria were patients with STEMI submitted to primary angioplasty with LD-P2Y12 carried out. Two groups were established, patients with loading dose before the cardiac catheterization (PRE-LD-P2Y12) and another group with patients with loading dose during or after cardiac catheterization (CAT-LD-P2Y12). Univariate and multivariate analysis of clinical history, data of hospitalization and treatment strategies was perform.

Results: The analysis identified 4123 patients, 2774 (66.3%) with PRE-LD-P2Y12 and 1349 (32.4%) with CAT-LD-P2Y12.
IP of PRE-LD-P2Y12 were: age <45 years (p=0.01; OR 0.54-0,93), left bundle-branch block (LBBB) (p=0.05; OR 0.02-1,00), class KK>1 (p<0.01; 0.38-0.68) and LVEF <50% (p<0.01; 0.25-0.35).
IP of CAT-LD-P2Y12: history of smoking (p<0.01; OR 1.10,51), angina pectoris (p<0.01; OR 2.05-3,15), MI (p<0.01; 1.54-2.49) and dementia (p<0.02; OR 1.17-4,77), anterior STEMI (p<0.01; OR 1.37-1,90), PS of chest pain (p<0.01; 1.36-3.65) and ressurrected cardiac arrest (RCA) (p<0.01; OR 1.50-9,67), heart rate (HR) >100bpm (p<0.01; OR 1.16-1,88), systolic blood pressure (SBP) <90mmHg (p=0.02; 1.16-3.01) and time Symptoms-Ballon (S-B) >120 minutes.
PRE-LD-P2Y12 was a IP of minimal hemoglobin (Hb) <10 g/dL (p=0.03; OR 0,48-0,97), fall of Hb >2 g/dL in patients with class KK=1 (p<0.01; OR 0.32-0,51), re-infarction (p<0.03; 0.05-0.88), HF (p<0.01; 0.39-0.66) and HEMAT (composite endpoint: fall of Hb >2 g/dL, major bleeding and blood transfusion) (p<0.01; OR 0,37-0,58), higher number of complications (shock/atrial fibrillation/mechanical complication/AV block/ventricular) (p<0.01; 0.57-0.93).
The time of administration of DC-P2Y12 was not predictor of intra-hospitalar death, stroke and MACE.

CONCLUSIONS
Conclusions:
In patients with STEMI:

The predictors for PRE-LD-P2Y12 were age <45years, “de novo” LBBB, KK class >1 and LVEF<50%. The predictors for CAT-LD-P2Y12 were history of smoking, angina pectoris, MI and dementia, anterior STEMI, chest pain or RCA as predominant symptoms, HR>100bpm, SBP <90mmHg and time S-B >120min.

PRE-LD-P2Y12 was predictor of hemorrhagic events (Hb <10; fall of Hb<2 g/dL in patients with class KK=1

and HEMATS). It was predictor of re-infarction and other complications after MI too.

Despite the strategy chosen does not affect the mortality and MACE, in this population, the LD-P2Y12 before cat lab has not reduced the number of thrombotic events and significantly increased the number of hemorrhagic complications.

These results contradict the current recommendations, putting into question the indication for administration of LD-P2Y12 early. These results may open doors to a larger randomized study to assess more accurately the impact/benefit prognosis between one and another strategy.

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Long-term clinical and haemodynamic outcomes of TAVI in patients with bicuspid aortic valve

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Transcatheter aortic valve implantation (TAVI) in patients with bicuspid aortic valve (BAV) has been proved to be safe and associated with satisfactory mid-term outcomes comparable to their tricuspid counterparts. However, long-term performance of TAVI in BAV remains unknow and concerning. The purpose of the study was to evaluate the long-term clinical and hemodynamic results of TAVI in this unique and important patient population.

METHODS AND RESULTS

The study population is constituted of consecutive patients who underwent transfemoral TAVI for native severe aortic valve stenosis between April 2012 and February 2018 at the largest TAVI center in mainland China. The clinical outcomes and bioprosthetic valve performance during follow-up were compared according to aortic valve morphology, ie. bicuspid versus tricuspid. Patients in whom aortic valve morphology remained indeterminate on computed tomographic angiography were excluded.

The primary outcomes of interest were all-cause death, and transcatheter valve dysfunction requiring reintervention. Valve hemodynamic parameters as assessed by echocardiography, including mean trans-aortic pressure gradient (PGmean), peak jet velocity (Vmax) and the grade of paravalvular aortic regurgitation (PAR), were also compared between groups.

During the study period, 301 TAVI procedures were performed at our institution. After excluding patients with prior aortic bioprosthesis (n = 4), data of 163 patients with BAV (97 type 0 and 66 type 1) and 134 patients with tricuspid aortic valve, were analysed. BAV patients trended to be younger (73.4 ± 6.1 years vs 74.3 ± 6.4 years, 0.198). At baseline, concomitant moderate or severe aortic regurgitation was less frequent (8.6% vs 41.0%, P < 0.001) and PGmean was higher (65.1 ± 19.9 mmHg vs 60.1 ± 17.3 mmHg, P = 0.023) in BAV patients. The incidence of residual PAR > mild was not significantly different between the two groups immediately after the procedure (8.0% vs 4.5%, P = 0.22). Postprocedural PGmean was significantly higher in BAV patients (15.4 ± 9.3 mmHg vs 12.7 ± 5.2 mmHg, P = 0.002).

During a median follow-up of 35 months [interquartile range (IQR): 23 to 49 months), reintervention was required in 1 (0.6%) of the BAV patients due to transcatheter valve thrombosis and in none of the patients with tricuspid aortic valve, survival rate was similar between the two groups [92.0% vs 90.3%, Log Rank P = 0.586; adjusted HR = 0.87 (0.4 to 1.9), P = 0.72]. A total of 51 patients (32 with BAV and 19 with tricuspid aortic valve) had available follow-up echocardiography performed beyond 3 years (median: 45 months; IQR: 42 to 54 months) after TAVI. Patients with BAV had numerically higher PGmean (14.2 ± 9.8 mmHg vs 10.2 ± 4.6 mmHg, P = 0.059) compared to those with a tricuspid aortic valve, but similar to their measurements immediately after the procedure (14.2 ± 10.0 mmHg vs 16.2 ± 9.8 mmHg, P = 0.273).

CONCLUSIONS

TAVI appears to produce satisfactory and durable long-term outcomes in BAV patients. Longer-term follow-up data up to 10 years are required to justify the expansion of TAVI into this technically challenging group.

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Feasibility and safety of intravascular lithotripsy in severy calcified left main coronary stenoses

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion, Other Coronary Interventions

AIMS

To assess the feasibility and safety of intravascular lithotripsy in treating severe calcified left main stenoses.

METHODS AND RESULTS

Between May and December 2018, thirteen patients with severe calcified left main stenosis were treated with percutaneous intravascular lithotripsy at 4 European centres. Median age was 75 years (IQR 68-80). Overall, patients had a high risk profile: prior MI 62%, CABG 31% previous PCI 39%, peripheral artery disease 46% and chronic kidney disease 39%, and low LVEF (<40%) in 23% of cases. In 8 cases (61%) the clinical presentation was acute coronary syndrome. LVEF: 53% (40-60).

In 12 cases (92%) the LM bifurcation was involved (Medina 1-1-1 in 50% of cases) The unprotected LM was more frequently in 9 cases (69,2%). Mechanical support during PCI was used in 23% of cases. Radial access was performed in 5 cases (38,5%). Lithotripsy was performed during 4 Atm balloon inflation. Whenever required, energy delivery during lithotripsy (median 50 pulses, IQR 40-80) was distributed in shorter balloon inflations to avoid profound ischaemia. Arterial hypotension occurred in 2 cases (15%). There were no arrhythmic or no-reflow events. In 12 patients stenosis severity improved from 75% (IQR67-85%) to 29% (IQR18-64%) before stenting. In these patients the degree of stenosis modification by lithotripsy was, therefore, variable. In one case (in-stent restenosis in calcific LM) no significant modification of the stenosis was noted (post lithotripsy 70%). In cases with good response to lithotripsy (54%) no further predilation was performed before stenting, while in the rest additional predilation was performed, predominantly with non-compliant balloons. The bifurcation was successfully managed with provisional stenting in 9 (75%) cases, two-stent technique in 2 (17%), and 1 (8%) with drug eluting balloon (in-stent restenosis). Intracoronary imaging was used to guide PCI in 69% of cases.

Procedural success rate was 92%. Procedural failure occurred in one case (8%) (in-stent restenosis in calcific LM treated with lithotripsy). Cardiac biomarker rise indicating peri-procedural MI occurred in 2 cases (16%).There were no deaths, re-interventions or cades of subacute stent thrombosis.

CONCLUSIONS

In this first reported series the use of intracoronary lithotripsy to treat heavily calcified left main coronary stenoses was associated with good procedural outcomes. Further research will confirm the potential superiority of this approach to other techniques of plaque modification in the calcific left main stem.

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Functional mitral regurgitation beyond the COAPT: what is the applicability of the randomised study in the real world? What are the outcomes of uneligible patients?

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair

AIMS

Transcatheter treatment of functional mitral regurgitation has recently been under the spotlight. The COAPT trial showed lower rates of hospitalization and mortality in patients treated with the MitraClip device, however inclusion criteria of the study were extremely narrow. This study aims at assessing the applicability of the COAPT study in the real-world as well as the outcomes of patients treated with MitraClip outside the COAPT criteria.

METHODS AND RESULTS

All patients affected by functional mitral regurgitation and treated with transcatheter mitral valve repair with the MitraClip device from 2008 to 2017 at our Institution were retrospectively reviewed. Patients were individually analysed based on inclusion and exclusion criteria of the COAPT study, to judge their eligibility within the study. Only 46/253 patients (18.2%) would have been eligible for randomization. The main variables responsible for exclusion of patients from the trial were: 43% of patients excluded for lack of hospitalization for heart failure in the 12 months prior to MitraClip implant; 23% excluded for LVEF not comprised between 20 and 50%; 5.5% of patients had a left ventricular end systolic diameter larger than 70mm; 5.5% underwent PCI less than 30 days prior to transcatheter mitral valve repair; 8.7% of patients had preoperative systolic pulmonary pressure above 70mmHg; 24% of patients required preoperative inotropic or mechanical support with IABP, 23.1% would have been excluded due to mitral anatomical reasons. Regarding baseline characteristics, age was similar in the two groups (72.2±10.31 vs 69.5±9.01, p =0.078), and NYHA functional class II, III and IV was equivalent between groups (p=0.57). LVEF was lower within the uneligible group (25 [19;33] vs 28.5 [24;38], p=0.031), together with left ventricular end-diastolic volume which was significantly higher (198 [145;249] vs 159 [130;190], p=0.007).Acute mortality and residual moderate and less than moderate mitral regurgitation were similar between the two groups, respectively 2.2% vs 1.9% (p=0.99) in the eligible and uneligible groups, and 91.2% vs 90% (p=0.65). At 1-year, there was no difference in survival between eligible and uneligible patients, 81.58±6.29%, 95% CI [65.21-90.76] vs 87.01±2.71%, [80.60-91.42] (p=0.38), respectively. 1-year moderate and less than moderate mitral regurgitation was documented in 64% of uneligible patients and 69% of eligible patients (p=0.31).

CONCLUSIONS

In this retrospective, single-centre real-world experience, only a minority of patients treated with MitraClip would have been eligible for enrollment in the COAPT. Despite being affected by a more advanced left ventricular disease, good short-term survival was seen in uneligible patients. While the present data are to be considered only hypothesis-generating, they underline the fact that at least some patients outside the COAPT criteria can achieve good short-term outcomes up to 1-year. More data are necessary to confirm these findings and to clarify the selection criteria required to achieve a good outcome in the real-world COAPT-uneligible

patients.

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Resting Pd/Pa and FFR discordance affects the diagnostic performance of quantitative flow ratio with FFR as reference standard: results from an IPD meta-analysis?

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Quantitative flow ratio (QFR) is a novel, clinically feasible method for computation of fractional flow reserve (FFR) based on standard coronary angiography. It is unclear how QFR performs in patients with discordance between FFR and resting distal-to-aortic pressure ratio (Pd/Pa).

METHODS AND RESULTS

PubMed, Scopus and Google scholar were searched until 25. April 2018 for prospective studies with paired assessment of QFR and FFR using the CE-marked QFR application (Medis medical imaging b.v. and Pulse Medical Imaging Technology Co). The main comparison was of the diagnostic performance of QFR with FFR as reference stratified by correspondence between FFR and resting Pd/Pa. Secondary outcome measures included distribution of pressure-bound coronary flow reserve (Pb-CFR) and clinical/procedural characteristics stratified by FFR and resting Pd/Pa correspondence. Diagnostic cut-off was ≤0.80 for FFR, ≤0.80 for QFR and ≤ 0.92 for resting Pd/Pa. Four studies provided patient level data reaching a total of 759 patients and 887 vessels with paired FFR, QFR and resting Pd/Pa: FAVOR II China (n=304); FAVOR II Europe-Japan (n=232); WIFI II (n=163) and FAVOR Pilot (n=60). Median FFR was 0.85 (IQR: 0.77-0.90). Diagnostic accuracy of QFR with FFR as reference was better if FFR corresponded to resting Pd/Pa: accuracy 90% (95%CI: 88-92) vs. 72% (95%CI: 64-80), p<0.001 and sAUC 0.93 (95%CI: 0.90-0.95) vs. 0.73 (95%CI: 0.69-0.77), p<0.001. Resting Pd/Pa and FFR discordance was partly related to the patients' clinical characteristics and the underlying flow as approximated by Pb-CFR.

CONCLUSIONS

The diagnostic performance of QFR with FFR as reference is impaired for lesions with discordant FFR and resting Pd/Pa measurements. Plausible physiological explanations should be explored in prospective studies.

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Comprehensive angiographic assessment of coronary atherosclerosis in oncologic patients presenting ACS: total burden, anatomical complexity and distribution of plaque rupture

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THEME:
TOPIC(S):

AIMS

Differently from other clinical scenarios, oncologic patients have prothrombotic states, vasospasm and vascular injuries that may precipitate acute coronary syndromes (ACS). We aim to provide a description of the atherosclerotic burden and lesion complexity of oncologic patients presenting ACS.

METHODS AND RESULTS

Prospective study that enrolled patients of two tertiary care centers collecting all consecutive cases of ACS in oncologic patients. The number and location of coronary lesions with obstructions greater than 50% were recorded. Each lesion was classified based on Ambrose's, Goldstein complexity, Leaman and SYNTAX scores. From 2012 to 2018 a total of 516 lesions from 100 oncologic patients with ACS were assessed. The mean age was 69.4±7.9 years old, 66% were male, 35% were diabetics, 12% did not have significant coronary artery disease and 71% had multivessel disease. The mean Leaman and SYNTAX Scores were 14.3±11.1 and 19.3±14.7, respectively. About the morphology of the lesion, it was found that 35% were at least Ambrose type II (high complexity). Regarding the distribution of complex lesions (thrombus, ulceration, haziness or impaired flow) in coronary tree, it was found that plaque rupture occurred predominantly in proximal segments.

CONCLUSIONS

Oncologic patients presenting ACS have high atherosclerotic burden and lesions with complex morphology were frequently found, demonstrating that type I myocardial infarction is frequent in these individuals.

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A real-world registry of patients with left main coronary artery stent restenosis: clinical, angiographic characteristics, therapeutic management and medium- long-term follow-up

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THEME: Coronary Interventions
TOPIC(S): STEMI, Left main and multivessel disease

AIMS

The purpose of this study was to evaluate the clinical and angiographic characteristics, management and follow-up of patients with intra-stent restenosis of unprotected left main coronary artery (ISR ULMCA).

METHODS AND RESULTS

A "real-world" registry including all patients with a significant (≥50%) ULMCA restenosis from January 2001-January 2018 was done. Clinical and angiographic characteristics, therapeutic management and clinical follow-up variables were analysed in all patients for assessment of major cardiovascular events (CV death, TLR, TVR, non-fatal AMI and stent thrombosis).

Overall, 41 patients were included during that period, 67±12 years-old, 78% (n=32) male, 80% (n=33) hypertensive, 63% (n=26) diabetics, 76% (n=24) dyslipidemics, 12% (n=5) smokers / 39% (n=16) former smokers, 24.3% CKD. 40% (n=16) presented other lesions besides ISR ULMCA.

The mean time from first treatment to restenosis was 539±467 days (1.47±1.27 years, median 310 [198-1478 days]). Most of them presented with NSTEMI (31.7%, n = 13), followed by unstable angina (24.4%, n = 10) and stable angina (24.4%, n = 10). Access was radial/ulnar in 87.3% (n=35), 6F 75%. The Syntax score I was Low (0-22) 68.42% (n=26), Intermediate (23-32) 26.32% (n=10) and High (>32) 5.26% (n=2).Restenosis was located in the distal main vessel (Bifurcational, LM-LAD or LM-Cx) in 36 patients (87.8%). The most frequent angiographic types was Mehran IC "focal body" (35%, n=14) and Mehran II "intra-stent" (35%, n=14) presenting angiographic calcification in 40% (n=16). The QCA analysis revealed 3.29 ± 0.63 mm of ref diameter vessel, 9.14 ± 4 mm length and 76± 11% of stenosis. Any intracoronary imaging techniques was used in 32.5% (n=13), OCT was used in 22.5% (n=9) and IVUS in 10% (n=4).

The initial planned strategy was DES implantation in 67.5% (n=27), 30% (n=12) drug-coated-balloon (AngiosculptX or DCB) and Surgery in 2.5% (n=5). 100% (n=27) were DES-ISR (2nd Gen).

In the management, predilatation was performed in 76.92% (n=30), with Scoring Balloon in 52.5% (n=21) and postdilatation in 58.54% (n = 24). A provisional strategy was the technique used in the majority of patients (87.18%, n=34) followed by Double Kissing Crush technique in 3 patients (7.69%).The success of the procedure (residual stenosis <30%) was achieved in 95.12% (n=39).

The overall MACE rate at the 3-year follow-up was 31.7% (6 CV deaths, 2 Stent Thrombosis, 5 non fatal AMI, 6 TLR, 2 TVR).

CONCLUSIONS

Our data demonstrate that PCI for ULM is already the preferred choice in the management of ULM intra-stent restenosis however the MACE it remains a problem of the first magnitude in our usual practice. Involvement of distal bifurcation and the presence of diabetes are the principal risk factors for restenosis. A therapeutic

strategy based in the Syntax score its necessary to improve results of ISR ULM outcomes in the future.

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Intravascular lithotripsy for the treatment of in-stent stenosis due to stent underexpansion in severely calcified lesion

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

In-stent stenosis (ISR) has been associated to stent underexpansion due to severe coronary calcifications. Intravascular lithotripsy (IVL) has been recently proposed for the treatment of calcified coronary lesions. It can modify calcified plaques and promise low pressure PTCA and subsequently lower rate of complication. However, its effectiveness in in-stent stenosis due to stent underexpansion in severely calcified lesions is unknown. Aim of this study is to determine the effect of intravascular coronary lithotripsy on in-stent stenosis due to stent underexpansion in severely lesion.

METHODS AND RESULTS

We treated 14 patients with in-stent stenosis due to stent underexpansion after previous stenting in severely calcified lesions with IVL. The investigational Shockwave balloon device was prepared and used according to instruction for use. Primary endpoint was strategy success and safety outcome. Strategy success was defined as complete stent expansion after delivery of 8 x 10 shocks and no evidence of in-hospital MACE after PCI. Safety outcome were procedural complication, defined as coronary dissection, slow or no reflow, new coronary thrombus formation during PCI, abrupt vessel closure and device failure (inability to place the balloon, malfunction, or burst) and in hospital MACE. The overall average of applied Shockwave pulses was 69.0 ± 29.0. Average diameter of calcified stenosis was 87.9 ± 9.4 % at baseline and decreased significantly to 15.7 ± 19.53 % (p-value: 0.01) after PCI. MLD was 0.97 ± 0.6 mm at baseline and significantly increased after Shockwave procedure (2.49 ± 0.7 mm, p-value < 0.01). The strategy success was reached in 12 of 14 patients. In two cases residual in stent diameter stenosis was > 20 %. One patient showed need for target lesion revascularization after 6 months.

CONCLUSIONS

Intracoronary lithotripsy provides an alternative strategy for treatment of in-stent stenosis due to stent underexpansion after previous stenting in severely calcified lesions. However, strategy success was missed in 2 of 14 patients and in one patient non ischemia driven target lesion failure occurred. Larger studies are warranted before the use of the Shockwave lithoplasty can be generally recommended.

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Impact of specific crossing techniques in CTO PCI on recovery of absolute myocardial perfusion

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Different techniques in chronic coronary total occlusion (CTO) percutaneous coronary intervention (PCI) are developed to cross complex lesions. The aim of the present study was to compare recovery of quantitative myocardial blood flow (MBF) and perfusion defect size after the use of different techniques in CTO PCI.

METHODS AND RESULTS

Consecutive patients with [15O]H2O PET perfusion imaging before and three months after successful CTO PCI were included. Change in quantitative hyperemic MBF, coronary flow reserve (CFR) and perfusion defect size were compared between antegrade wire escalation (AWE), retrograde wire escalation (RWE), antegrade dissection and reentry (ADR) and retrograde dissection and reentry (RDR), and further between specific subintimal crossing and wire reentry techniques. 193 patients were included and treated with AWE (N=90), RWE (N=24), ADR (N=35) and RDR (N=44). Significant improvements (all $p<0.01$) in hyperemic MBF (AWE 1.19±0.77, RWE 0.94±0.65, ADR 1.09±0.63, RDR 1.02±0.75 mL/min/g), CFR (AWE 1.34±1.08, RWE 1.14±1.09, ADR 1.31±0.96, RDR 1.24±0.99) and perfusion defect size (AWE 3.17±2.13, RWE 3.00±2.21, ADR 2.74±2.09, RDR 2.93±1.92 segments) were comparable between the four approaches ($p=0.40$, $p=0.84$ and $p=0.77$ respectively). Recovery of hyperemic MBF was less after subintimal crossing with a knuckle compared to the CrossBoss in ADR and RDR ($p=0.02$), and less after wire reentry with subintimal tracking and reentry (STAR) in ADR compared with the Stingray or limited antegrade subintimal tracking (LAST) ($p=0.02$ and $p<0.01$).

CONCLUSIONS

Recovery of hyperemic MBF, CFR and perfusion defect size was significant after CTO PCI and comparable between AWE, RWE, ADR and RDR. Improvement of hyperemic MBF was inferior after using a knuckle compared to other subintimal crossing and wire reentry techniques, although the knuckle was used in more complex CTO lesions.

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Clinical implications and predictors of coronary perforations during CTO PCI: insights from 1066 patients treated in the multicentre Latin American CTO registry

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Our study sought to identify the frequency, predictors and clinical implications of coronary perforation in chronic total occlusion (CTO) percutaneous interventions (PCI).

METHODS AND RESULTS

We reported the data of a prospective multicenter Latin American registry including CTO patients who underwent CTO PCI in 30 centers in the following countries: Brazil, Argentina, Puerto Rico, Chile, Colombia, Ecuador and Mexico. Coronary perforation was defined as evidence of extravasation of dye or blood from the coronary artery during or following the interventional procedure. A stepwise logistic regression was performed to investigate the independent predictors of coronary perforations.

From January to December 2018, 1066 patients underwent CTO PCI in the participating centers. The mean age was 64.2± 10.7 years, 79.8% were male, 35.3% diabetics and 6.7% had heart failure. The most commonly involved CTO vessel was RCA (41.4%), the mean J-CTO score was 2.0±1.3 and the mean CL score was 2.7±1.6. The overall procedural success rate was 81.9%.

Coronary perforations ocurred in 3.3% of cases: Type 1 in 1.8%, Type 2 in 0.9% and Type 3 in 0.6%. In comparison with patients without coronary perforation was observed, those with such complication requiered more often blood transfusion (8.6% vs. 0.7%; p<0.001), experienced more cardiac tamponade (13.4% vs. 0.4%; p<0.001), but not all-cause in-hospital mortality (0 vs. 1.0%; p=1.00; respectively).

At multivariate analysis, the independent predictor of coronary perforation was an activated clotting time (ACT) during PCI > 470 seconds (OR 6.5; 95%CI 2.4 - 17.3; p<0.001), baseline heart failure (OR 4.2; 95%CI 1.2 - 14.6) and J-CTO score > 2 (OR 7.5; 95%CI 1.00 - 59.1).

CONCLUSIONS

Coronary perforation during PCI in Latin America occurred in 3.3% of patients, being related with adverse events but not in-hospital all-cause mortality. Pharmacological managment, high anatomical complexity and heart failure were identified as independent predictors of this complication.

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The impact of 3D quantitative coronary angiography based vessel FFR on heart team decision making: a pilot reclassification study

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease

AIMS

Wire-free vessel fractional flow reserve (FFR) derived from 3D quantitative coronary angiography (vFFR) has a high linear correlation to invasively measured FFR, a high diagnostic accuracy to detect FFR≤0.80 and a low inter-observer variability. The aim of the present study was: i) to evaluate the feasibility of performing 3-vessel-vFFR screening of patients consulted by the Heart Team in whom the treatment decision was based on angiography and ii) to evaluate the impact of vFFR assessment on reclassification of coronary stenosis significance and treatment decision by the Heart Team.

METHODS AND RESULTS

Consecutive patients from 2 different institutions referred for consultation by our Heart Team between 2015 and 2017 were screened for eligibility. Exclusion criteria involved: FFR/iFR lesion severity evaluation prior Heart Team consultation, presentation with ST-segment elevation myocardial infarction (STEMI), significant valve disease, left ventricle ejection fraction <30%, previous coronary artery bypass grafting (CABG), inadequate quality of angiogram precluding vFFR computation in all 3 epicardial coronary arteries (i.e. absence of a minimum of two angiographic projections with views of at least 30 degrees apart, substantial foreshortening or overlap of the vessel, ostial left or right coronary artery disease) and unavailability of baseline aortic root blood pressure. vFFR computation was performed in each coronary artery up to 2.25 mm of diameter as assessed by quantitative coronary angiography. Angiographically visualized lesions were reclassified using a vFFR threshold of ≤0.80.

Of the 495 patients screened for eligibility, 145 patients (435 vessels) (mean age 69.4 ± 10.2, 79.3% were male) were included in the vFFR-based reclassification analysis. The most important reason for screening failure was insufficient quality of coronary angiogram (52.7%). Eighty-five patients (58.6%) presented with stable angina, 15 patients (10.3%) with unstable angina and 45 patients (31.0%) with non-STEMI. Following Heart Team consensus, 43 patients (29.7%) underwent CABG, 91 patients (62.8%) underwent percutaneous coronary intervention (PCI) and conservative treatment was advocated in 11 patients (7.5%).

vFFR screening of each epicardial artery in the coronary tree resulted in lesion significance re-classification in 38/145 patients (26.2%) corresponding to 42/435 vessels (9.7%). Of them, 13 vessels (30.9%) were reclassified as significant while the remaining 29 vessels (69.1%) were re-classified as non-significant by vFFR. Left circumflex (LCX) (18/42 – 42.9%) and left anterior descending (LAD) (17/42 – 40.5%) were more often reclassified as compared to right coronary artery (RCA) lesions (7/42 – 16.6%).

The global ischemic burden as assessed by 3-vessel vFFR was 2.21 ± 0.29 in the overall cohort, with a mean vFFR of 0.76 ± 0.17 for RCA, 0.69 ± 0.15 for LAD and 0.76 ± 0.15 for LCX.

Patients referred for CABG had a higher ischemic burden (2.07 ± 0.26) as compared to patients referred for PCI (2.24 ±0.27) (p = 0.027) or conservative treatment (2.50 ± 0.38) (p = 0.010).

CONCLUSIONS

The use of 3D quantitative coronary angiography based vFFR in all three epicardial coronary arteries is feasible in around 29% of the patients referred for routine Heart Team discussion, a limitation that is mostly based on insufficient angiography quality. Furthermore, three vessel vFFR resulted in reclassification of 26.2% of the patients referred to the Heart Team.

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Comparing the effectiveness of oral and intravenous administration of nicorandil on coronary microcirculation in patients undergoing elective PCI: an open-label, randomised, non-inferiority trial

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

About 50%~75% perioperative myocardial injury is caused by microvascular dysfunction. Nicorandil might protect coronary microcirculation when administered before PCI. However, the best administered way of nicorandil in protecting coronary microcirculation were not well known. This study was designed to find whether single dose of oral nicorandil was not inferior to intravenous nicorandil before PCI with the effect of microcirculatory protection in patients undergoing PCI.

METHODS AND RESULTS

In this prospective, randomised, parallel-group, open-label, non-inferiority multicentre trial, 100 patients from 18 to 80 years old and planned to undergo elective PCI from 5 centres in China were enrolled from Dec 5, 2016 to Feb 1, 2018. The patients were randomised into the control (n=20; blank), oral (n=40; nicorandil 20 mg oral 0.5~1.0 hours before PCI), and IV (n=40; nicorandil 6 mg injected intravenously at the beginning of PCI) groups. The index of microcirculatory resistance (IMR) was detected immediately after PCI, creatine kinase-muscle/brain (CK-MB), high-sensitivity troponin T (hs-TnT) or cardiac troponin T (cTnI) were measured 6h, 12h, 18h, 24h, 48h after PCI, electrocardiograms and echocardiograms before and after PCI were collected. All patients were followed-up for 48h after PCI. The primary endpoint was IMR, the secondary endpoints included: incidence of perioperative myocardial infarction and myocardial injury; changes of CK-MB or troponins; and incidence of adverse events (AEs). Finally, data of 97 patients were analysed as the IMR values of 3 patients were failed in detecting. The average ages of the control group (n=20), oral group (n=39) and IV group (n=38) were 62.65±11.08 years, 60.51±10.04 years and 63.92±8.77 years respectively. There were no significant differences in age, sex, height, weight, diagnosis, comorbidities, blood pressure, heart rate, status and therapy of target vessel among three groups. The IMR of the oral group (15.18±7.83U) and the intravenous group (17.28±11.20U) were similar, and lower than that of the control group (25.94±30.86U), but the difference was not statistically significant (P=0.0570). Although the incidence of perioperative myocardial infarction (20.00% vs. 5.13% vs. 13.16%) and myocardial injury (20.00% vs.12.82% vs. 28.95%) did not differ significantly among the control, oral and IV groups (all P>0.05), but the ratio of troponins after and before PCI in the oral group and the IV group were lower than that in the control group (7.27±17.05 vs. 9.71±15.55 vs. 60.50±158.73, P=0.0301). The incidence of AEs was lowest in the oral group (25.64%), followed by the IV group (31.58%) and the control group (35.00%), but also no statistically significance (P=0.7273); and no serious AEs were noted.

CONCLUSIONS

In this study, single dose nicorandil administered before elective PCI, both oral 20mg and IV 6mg, were safe and were associated with reduced microvascular dysfunction with IMR serving as an index of myocardial

microcirculation, and could reduce the elevated degree of myocardial injury marker after PCI. However, the coronary microcirculatory protective effect of single nicorandil orally administered before PCI didn’t reach the non-inferiority threshold when compared with IV administration. A larger sample was needed for further study.

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Twelve-month outcome of magnesium BRS implantation in ACS

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THEME: Coronary Interventions
TOPIC(S): NSTEMI, Stents and scaffolds

AIMS

Bioresorbable vascular scaffolds (BRS), the newest coronary stent technology, were developed to improve long-term outcomes compared to metallic drug-eluting stents (DES).

METHODS AND RESULTS

The study population consisted of the fifty consecutive patients who underwent PCI with the Magmaris BRS in the settings of ACS and were followed up for 12 months. Patients with ST-segment elevation myocardial infarction were excluded from enrollment. Baseline demographic and angiographic characteristics, as well as 6-month and 12-month, follow up were prospectively analysed.

Patients were enrolled at mean age 62.9±8.4 years. Treated fifty-one de novo lesions were located in LAD (37%), LCX (14%), and RCA (49%), respectively. Angiographic success in the target lesion was 100%. One case of ischemia-driven target vessel revascularization (ID-TLR) was reported during index in-hospital stay, no other events were observed (procedural success of 98%). All patients remained on prescribed DAPT for the whole period of observation (12 months). Six-Month follow up showed none device-oriented endpoints such as cardiac mortality, target vessel myocardial infarction or target vessel revascularization; and none early scaffold thrombosis was reported. Twelve-month follow up revealed one case of scaffold restenosis treated by DES implantation (9 months after index PCI). None other device-oriented endpoints such as cardiac death, target vessel myocardial or scaffold thrombosis were observed. On a voluntary basis, 12-month control angiography and optical coherence tomography (OCT) assessment were performed in 38 patients (76%). OCT confirmed the 100% neointimal coverage of magnesium scaffolds that were already largely degraded and most of the original magnesium alloy has disappeared.

CONCLUSIONS

The implantation of the Magmaris BRS in ACS patient is associated with a procedural safety and promising mid-term and long-term clinical outcomes. A longer follow-up and further evaluation in large prospective randomized controlled trials are needed.

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Hybrid transcatheter and minimally invasive left ventricular reconstruction for treatment of ischaemic cardiomyopathy: early results

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THEME: Interventions for Heart Failure
TOPIC(S): Chronic heart failure

AIMS

Remodelling of the left ventricle (LV) after anterior myocardial infarction can result in a pathological increase in LV volume and reduction in LV ejection fraction (EF). We describe the early results of a novel hybrid transcatheter technique to reconstruct the remodelled LV by plication and exclusion of the scar, and reduction of the excess volume, resulting in decreased wall stress and increased EF.

METHODS AND RESULTS

Methods

Patients who were considered eligible for the procedure presented with symptomatic heart failure (NYHA-class ³ II) and ischemic cardiomyopathy (EF<40%) after anterior myocardial infarction. All patients had a dilated LV with either an a- or dyskinetic scar in the anteroseptal wall and/or apex of ³ 50% transmurality. This novel hybrid transcatheter and minimally technique relies on micro-anchoring technology (Revivent TC™ System, BioVentrix Inc. San Ramon, CA USA). The LV is reconstructed by plication of the fibrous scar. This is achieved by implantation of a series of internal and external micro anchors brought together over a PEEK (poly-ether-ether-ketone) tether to form a longitudinal line of apposition between the LV free wall and the anterior septum. Internal anchors are deployed by transcatheter technique on the right side of the ventricular septum through the right internal jugular vein. Paired external anchors are advanced through a left sided mini-thoracotomy and deployed on the LV epicardium. A specialized Force Gauge is used to bring these “RV-LV” anchors together under measured compression forces. “LV-LV” anchor pairs through the LV apex beyond the distal tip of the RV complete the reconstruction.

Results

Between October 2016 and October 2018 16 patients (14 males, 2 females; mean age 59 ± 14 years) were operated in a single Dutch centre. Procedural success was 94%. On average 2.6 anchor-pairs were used to reconstruct the LV. Comparing echocardiographic data pre- and directly postoperatively, LVEF increased from 33 ± 9% to 43 ± 10% (change +36%, P<0.0001) and LV-volumes decreased: LVESVI 59 ml/m2 ± 21 ml/m2 to 32 ± 16 ml/m2 (change -49%, P<0.0001) and LVEDVI 83 ml/m2 ± 31 ml/m2 to 55 ± 21 ml/m2 (change -43%, P=0.05). One patient underwent a postoperative revision because of RV restriction. After removal of 1 “RV-LV” anchor-pair, the patient made a full recovery. One patient underwent an uncomplicated minimally invasive tricuspid valve replacement because of a lesion to the tricuspid valve during the procedure. Hospital mortality was 0%. Median duration of ICU–stay was 2 days (IQR 1-46 days) and median length of hospital stay was 7 days (IQR 5-57 days).

CONCLUSIONS

Hybrid transcatheter and minimally invasive LV reconstruction is a promising novel treatment option for patients with symptomatic heart failure and ischemic cardiomyopathy after anteroseptal myocardial infarction. Early results demonstrate that the procedure is safe and results in significant improvement in EF and reduction

in LV volumes.

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The interplay between lesions' morphology and the coronary artery stenosis in non-culprit non-ischaemic native coronary lesions of diabetic patients - Data from COMBINE (OCT-FFR) study

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

With the increase of coronary artery stenosis increases the risk of acute coronary events. However, the interplay between lesions' morphology and coronary artery stenosis in non-ischemic lesions of diabetes mellitus (DM) patients was scarlessly reported. This report describes the lesions morphology of non-ischemic native coronary lesions with respect to artery stenosis in DM patients enrolled in the COMBINE trial

METHODS AND RESULTS

COMBINE (OCT-FFR, NCT02989740) study is a multi-center, prospective natural history study which assesses non-culprit lesions to better predict adverse events in diabetes. OCT analysis identifies plaque composition, estimates calcium arc (o), lipid arc (o), and measures thickness of the fibrous cap (μm) covering the lipid core. Moreover, OCT records the presence of typical plaque vulnerability traits like TCFA, PE, PR, heterogenous tissues (a probably healed plaque rupture), and macrophages accumulation (bright spots). A dedicated software estimated the interpolated percentage area stenosis (AS, %) measuring the minimal lumen area and reference vessel area. Then the analyzed lesions were divided into three groups: mild (AS<50%), intermediate (AS 50 to 69%), and severe (AS>70%) lesions. OCT imaged 361 lesions for first 300 patients of COMBINE study. The mild lesions were presented in 63 (17.5%), intermediate in 198 (55%), and severe in 100 (27.5%) lesions. The FFR values were significantly lower [0.89 IQR 0.85-0.94 vs. 0.96 IQR 0.92-0.98), p=0.021] and the prevalence of TCFA was higher [62(21%) vs. 8(11%), p=0.044] in AS>50%. There was just a trend towards an increase of the lipid arc (172±12, 191±7, 201±9, p=0.149) and decrease in cap thickness (161±23, 141±8, 124±10, p=0.152) while lesions progressed from mild to intermediate and severe stenosis. There was no difference in the calcium arc (142±14, 132±9, 166±12, p=0.117), in the prevalence of PR [6(9%), 14(7%), 12(12%), p=0.442] and PE [3(4%), 9 (5%), 8 (8%),p=0.447] between mild, intermediate, and severe lesions respectively. Interestingly, bright spots appeared less frequently in mild lesions [19 (27%), 90 (47%), 58 (58%), p<0.001] and heterogeneous tissue occurred more often in severe lesions [9(13%), 33 (17%), 28 (24%), p=0.028].

CONCLUSIONS

Theses results confirms that the progression of vessel stenosis was associated with plaque rupture and healing, previously documented only in autopsy studies. Furthermore, it presented that plaque vulnerability, local inflammation and ischemia increases with the progression of non-culprit lesions stenosis in diabetic patients. The patients' follow-up will reveal whether any of th identified plaque morphology traits in non-ischemic lesions carries any prognostic value on adverse cardiac events in these high-risk patients.

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DynamX Bioadaptor, an innovative device that adapts to patient's physiologic anatomy to treat coronary artery disease - a quantitative coronary angiography and IVUS imaging review

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Drug Eluting Stents (DES) are the mainstay in coronary artery disease treatment. The DynamX Bioadaptor System is a novel, thin strut bioresorbable polymer coated drug eluting bioadaptor releasing Novolimus, a macrocyclic lactone mTOR inhibitor with anti-proliferative properties. The DynamX Bioadaptor with its uncaging elements is designed to offer the acute performance of a current generation DES with the potential advantage of minimizing compliance mismatch and geometric distortion, providing normal vessel pulsatile motion and supports early adaptive remodeling.

METHODS AND RESULTS

The DynamX Bioadaptor contains a drug dose of 5 µg of Novolimus per mm of bioadaptor length with device availability in multiple diameters (2.5 – 3.5 mm) and lengths (14, 18 and 28 mm). In a non-randomized, mechanistic clinical study, 50 patients were enrolled at 6 sites in Belgium and Italy to assess the safety and performance of the DynamX Bioadaptor. Patients were analyzed for multiple clinical endpoints including: device and procedure success; target lesion failure (TLF), a composite endpoint of cardiac death, target vessel MI, or clinically-indicated target lesion revascularization (CI-TLR), the individual components of TLF, and bioadaptor thrombosis at 1, 6 and 12 months and annually to 3 years.

Mean age at baseline was 65.8 ± 8.9 years, 76% were males, and 26% diabetics. Physician visual assessment showed an average reference vessel diameter of 3.2 ± 0.3, lesion length of 12.8 ± 4.6, a pre-procedure percent diameter stenosis (% DS) of 78.1 ± 9.9, and 50% of lesions were type B1/B2. Pre-dilatation was performed in 98% of patients and post-dilatation in 64% of lesions. The average DynamX deployment pressure was 12.2 atm.

Multimodality imaging endpoint analyses using Quantitative Coronary Angiography (QCA) and Intravascular Ultrasound (IVUS) was performed at either 9 or 12 months. These analyses will include an assessment of minimum lumen diameter, percent diameter stenosis (%DS) and late lumen loss by QCA and mean area changes for the bioadaptor, vessel and lumen and percent neo intimal volume (%NIV). Both methodologies will be interrogated for changes in vessel motility.

Interim analysis results of the mechanistic characteristics at both 9 month and 12-month in a subset of patients specific to the QCA and IVUS imaging endpoints will be presented. To date no device-related clinical events have been reported.

CONCLUSIONS

The DynamX Novolimus Eluting Coronary Bioadaptor System is novel medical device which combines the acute attributes of metallic DES with longer term attributes of normal vessel pulsatile motion and supporting early adaptive remodeling for a more complete revascularization. Multiple case examples with 9 or 12-month follow-up QCA and IVUS imaging data will be presented.

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Outcomes of transcatheter tricuspid valve intervention in patients with pacemaker or defibrillator leads: data from the TriValve registry

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THEME: Interventions for Valvular Disease
TOPIC(S): Tricuspid / Pulmonary valve

AIMS

The interference of a trans-tricuspid cardiac implantable electronic devices-leads (CIED) with the TV function may contribute to the mechanism of TR and poses specific therapeutic challenges during TTVI. Feasibility and efficacy of TTVI in presence of a CIED is unclear.

METHODS AND RESULTS

Data from TriValve Registry on patients undergoing TTVI with different CIED were analyzed. The study population consisted of 470 patients with severe symptomatic TR treated at 21 centres between 2015 and 2018. The association of CIED and outcomes were assessed.

Pre-procedural transvalvular lead was present in 121/470 patients (25.7%) undergoing TTVI. The most frequent location of the CIED was the postero-septal commissure (44%) or the posterior leaflet (18%). An interference of the CIED contributing to TR was described in 44% of the cases. As compared to patients without a transvalvular lead (no-CIED group), patients having a tricuspid lead (CIED group) had similar clinical risk profile (EuroScore II 10.8±10% Vs 10.3±11.5 –p=00.6), but were more symptomatic (NYHA class III-IV in 95.9% vs 92.3% -p=0.04; ascites in 33.6% Vs 21.2% - p=0.008), had higher level of NT-proBNP (7920±1079 pg/ml Vs 4851±446 pg/gl) and more frequently had at least 1 hospitalisation for RV failure (87,8% Vs 69% - p=0.0018). CIED patients had larger LVEDD (54±11.6 Vs 49.3±8.5 mm –p=0.0004) and lower LVEF (43.2±15% Vs 52.4±12% -p<0.0001). No-CIED patients had more severe TR (EROA 0.7±0.6 cm2 Vs 0.58±0.3 cm2, p=0.02; VC 1.3±1.7 cm Vs 1.0±0.7, p=0.03), but significantly better RV function (TAPSE 16.7±5 mm Vs 15.9±4 mm, p=0.04) and higher sPAP (41.6±14.9 mmHg Vs 37.5±15.3 mmHg, p=0.008). The most frequently used TTVI device in CIED group patients was MitraClip (106 patients, 87,6%). Procedural success (defined as device successfully implanted and residual TR ≤2+) was achieved in 80% of no-CIED group and in 78.6% of

CIED-group (p=0.74), with an in-hospital mortality of 2.9% and 3.7%, respectively (p=0.7). At 30 day, residual TR≤2+ was observed in 70.8% of no-CIED group and in 73.69% of CIED-group (p=0.6). Symptomatic improvement was observed in both groups (NYHA class I-II at 30 days 66% Vs 65% - p= 0.3). Actuarial survival at 14 months was 75.7±4.3% in no-CIED group and 68.3±7% in CIED-group (p=0.3). Procedural success was identified as independent predictor of mortality at follow-up.

CONCLUSIONS

Compared to no-CIED patients, TR patients with CIED have worse baseline left ventricular function and more symptomatic right heart failure despite preserved right ventricular function and less severe TR. TTVI is feasible in patients with CIED and acute procedural success and short-term clinical outcomes are comparable to those observed in patients without a trans-tricuspid lead.

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Percutaneous interventional treatment of high-risk and intermediate-to-high risk acute pulmonary embolism: long-term clinical outcome of a single-centre experience

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THEME: Peripheral Interventions
TOPIC(S): Other peripheral interventions

AIMS

Acute pulmonary embolism (PE) is a common disease associated with significant morbidity and mortality and treatment strategies vary widely among patients, according to their clinical presentation and hemodynamic status.

Percutaneous interventional procedures seem to be attractive considering the high prevalence of contraindications to systemic fibrinolysis (SF) among patients presenting with high or intermediate-to-high risk PE.

We sought to retrospectively evaluate patients' outcome who submitted percutaneous interventional treatment because of high or intermediate-to-high risk PE.

METHODS AND RESULTS

Between March 2011 and March 2018, in our Institution, 42 patients affected by high risk or intermediate-to-high risk PE initial diagnosed by computed tomography (CT), submitted urgent percutaneous interventional treatments by means of rheolytic thrombectomy (RT) or ultrasound–assisted thrombolysis (USAT).

26% of patients had absolute contraindication to SF and other patients had significant comorbidities resulting in a potentially high risk of major bleeding in case of SF.

Loco-regional fibrinolytic was administered in all patients, even when treated with RT, by means of tissue-type plasminogen activator at maximum dosage of 40 ml; infusion duration in patients treated with USAT was 12 hours.

All procedures were performed by transfemoral venous access. In RT treated patients, after pulmonary angiography, 8F JR4 guide catheter was used to reach pulmonary arteries and thrombectomy catheter was advanced under fluoroscopy guide till segmental pulmonary branches in wich several thrombectomy runs were performed; in USAT treated patients, pulmonary angiography was never performed and catheters were positioned under fluoroscopy guide in culprit major vessels according to CT performed at hospital admission.

Primary endpoints were considered as efficacy, in terms of technical and procedural success, and safety, in terms of low rates of major bleedings.

Technical and procedural success, defined as the ability to deliver catheters in pulmonary arteries and to significantly reduce thrombus burden improving patients' hemodynamic conditions was obtained in 95,3% of cases.

In-hospital mortality rate was 7% due to refractory cardiogenic shock, all in high risk PE treated by means of RT; only one major bleeding according to BARC classification was experienced due to access site complication because of femoral pseudoaneurysm requiring blood transfusion and percutaneous repair.

In all patients, early improvement in right ventricle systolic function by echocardiographic post-procedural evaluation was documented, regardless of patients' risk status at presentation and interventional strategy

adopted.
At 36 months median follow-up, 4 patients died because of cancer. All survivors were free of symptoms without any residual right ventricle dysfunction or residual pulmonary hypertension at echocardiogram.

CONCLUSIONS

Our seven year experience confirms efficacy and safety of percutaneous interventional treatment in PE, especially when complicated by severe hemodynamic compromise or when SF therapy is contraindicated, even at long term follow-up

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Acute management of patients with spontaneous coronary artery dissection. The DIssezioni Spontanee COronariche (DISCO) Italian registry

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Spontaneous coronary artery dissection (SCAD) is a challenging clinical scenario and represents a non–negligible cause of acute coronary syndrome (ACS) in young women. In–hospital management (conservative versus interventional) and medical therapy at discharge are debated, especially Dual antiplatelet therapy (DAPT) prescription.

METHODS AND RESULTS

DISCO (DIssezioni Spontanee COronariche) is an italian, multicenter registry which includes patients admitted with a diagnosis of SCAD. Baseline, procedural characteristics, in–hospital management and outcomes of SCAD patients were collected. One-hundred seventy SCAD patients from 25 Italian centers were included in the registry. They were mainly female (77.6%) with a mean age of 53 years. STEMI (ST–segment elevation myocardial infarction) was the main admission diagnosis (48.8%), followed by NSTE (non–ST segment elevation)–ACS (44.7%) and stable coronary artery disease (6.5%). Type 4 SCAD(23.6%) was the main finding at coronary angiography. More than half of patients were initially treated with medical therapy (54.4%), while PCI (percutaneous coronary intervention) or CABG (coronary artery bypass graft) were performed in 41.4% and 4.2% of them, respectively. PCI procedural success was reached in 77% of cases. DAPT was prescribed in 63% of patients medically-treated only. In these patients Ticagrelor and Clopidogrel resulted the P2Y12 inhibitors of choice (both administered in half of cases). In–hospital MACE rate was 8.2%. In-hospital all cause death, non-fatal Myocardial infarction, unplanned PCI occurred in 1.2%, 3.5% and 6.5% of patients respectively.

CONCLUSIONS

Medical therapy represented the initial treatment of choice in SCAD patients. A high portion of patients experienced a cardiovascular event during hospitalization. Although ACS was the main admission diagnosis,the optimal DAPT regimen remain controversial in those medically treated.

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Comparison of everolimus- and biolimus-eluting coronary stents with everolimus-eluting BRS (EVERBIO II): a five-year clinical and angiographic follow-up

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Although bioresorbable vascular scaffolds (BVS) are considered inferior to current metallic drug-eluting stents (DES), long-term data are scarce. The aim of the study was to assess the 5-year angiographic and clinical outcome of BVS compared with everolimus-eluting stents with persistent polymer (EES) and biolimus-eluting stents with bioabsorbable polymer (BES) in all-comers undergoing percutaneous coronary interventions.

METHODS AND RESULTS

The EVERBIO II trial (Comparison of Everolimus- and Biolimus-Eluting Stents With Everolimus-Eluting Bioresorbable Vascular Scaffold Stents II) was a single-center, assessor-blinded study of 240 patients randomly assigned in a 1:1:1 ratio to EES, BES, or BVS. The primary endpoint was angiographic late lumen loss (LLL) at 5 years. Secondary endpoints included patient-oriented major acute coronary events (MACE) (death, myocardial infarction [MI], and any revascularization), device-oriented MACE (cardiac death, MI, and target lesion revascularization), and stent thrombosis at 5 years. Clinical follow-up was obtained in 225 patients (95%) and follow-up angiography was performed in 140 patients (59%) at 5 years. In-stent LLL was similar between patients treated with BVS (0.60±0.65 mm) and those treated with EES/BES (0.59±0.40 mm; p =0.25). The clinical outcomes were not statistically different between the groups: the patient-oriented MACE rate was 35% in BVS and 40% in the EES/BES group (p=0.55) and the device-oriented MACE was 25% in BVS 18% (p=0.16) in the EES/BES group. There were no episodes of stent thrombosis observed in any of the groups after two years of follow-up.

CONCLUSIONS

The current data shows no significant differences with regard to clinical and angiographic outcomes at 5 years between BVS and DES.

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Prolonged mechanical unloading: the PROPELLA concept as a novel heart failure treatment option for acute inflammatory cardiomyopathy

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THEME: Interventions for Heart Failure
TOPIC(S): Acute heart failure

AIMS
Mechanical circulatory support is often required to stabilize patients with cardiogenic shock. Extracorporeal life support as most frequently used approach increases left ventricular afterload and causes LV distention. Mechanical cues, involving integrins, are major drivers of cardiac fibroblast activation leading to increased production of extracellular matrix, myocardial fibrosis and LV dysfunction. Unloading via a temporarily percutaneously implanted left ventricle (LV) assist device (Impella-pump) over several weeks is a novel strategy to improve heart failure due to acute cardiomyopathy.

METHODS AND RESULTS
Methods:
The prolonged Impella (PROPELLA) concept was etablished as a new unloading concept for enhancing myocardial recovery in patients with chronic inflammatory cardiomyopathy. In 6 patients LV-IMPELLA 5.0 were implanted via an axillary approach, provides support in awake, mobilized patients for several weeks. Endomyocardial biopsies (EMB) were taken over time for immuno-histological investigations. A new weaning concept (including conductance catheter evaluation and stressechocardiography) was etablished to define the appropriate time point for weaning strategies and for changing or discontinuing unloading in these patients.

Results:
Impella implantation resulted in an significant improvement in LV-EF and a reduction in NT-pro-BNP levels (over 8000 to below 250 pg/ml). During presence of the Impella, cardiac immune cell presence decreased, paralleled by a drop in α1, α5, α6, and α10 integrins EMB mRNA expression by 2.0-, 2.0, 4.0-, and 6.0-fold, respectively, an effect which was abrogated after removal of the pump. Imaging mass spectrometry further revealed a drop in collagen α-2VI and vimentin expression during unloading. Dynamic echocardiography based investigations and short loading periods define appropriate time point for weaning strategy.

CONCLUSIONS
Prolonged unloading with an Impella device implanted via an axillary approach provides support in awake, mobilized patients for several weeks with additional disease modifying effects important for bridge of recovery in patients with fulminant inflammatory cardiomyopathy. The present findings support the link between mechanical loading, cardiac remodeling and underlying inflammatory pathways.

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Validation of quantitative flow reserve and residual quantitative flow reserve to predict FFR post stenting from the Does Optical Coherence Tomography Optimize Results of Stenting study (DOCTORS) population

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THEME:
TOPIC(S):

AIMS

Quantitative flow reserve (QFR) is a computation of fractional flow reserve (FFR) based on angiography without use of a pressure wire. The ability to predict post-PCI FFR using residual QFR after virtual stenting (pre-PCI), and using QFR (post-PCI) remains unknown. We sought to evaluate the correlation and diagnosis accuracy of residual QFR and post-PCI QFR to predict post-PCI FFR.

METHODS AND RESULTS

From the DOCTORS (Does Optical Coherence Tomography Optimize Results of Stenting) study population, we blindly analyzed the following from angiography, and compared them to post-PCI FFR: pre-PCI residual contrast QFR (cQFR) and fixed QFR (fQFR), and post-PCI cQFR and fQFR.

93 post-PCI QFR measurements and 84 residual QFR measurements were compared to post-PCI FFR measurements in 93 patients. Compared to the post-PCI FFR mean value of 0.92 ± 0.05, mean values of residual cQFR, residual fQFR, post-PCI cQFR and post-PCI fQFR were, respectively: 0.94 ± 0.05, 0.93 ± 0.05, 0.93 ± 0.06 and 0.93 ± 0.05 (p values >0.05 for all pairs except for residual cQFR versus FFR (p=0.01)). Pearson correlation coefficients of residual cQFR, residual fQFR, post-PCI cQFR and post-PCI fQFR compared with post-PCI FFR were, respectively: 0.62, (95% CI: 0.46-0.73); 0.61, (95% CI: 0.45-0.73); 0.75, (95% CI: 0.64-0.83) and 0.73, (95% CI: 0.62-0.81). Area under the curves for these indices with a post-PCI FFR cutoff value of 0.92 were, respectively: 0.79, 0.78, 0.85 and 0.84.

CONCLUSIONS

cQFR and fQFR correlated well and had similar diagnostic performance. Pre-PCI QFR analysis with virtual PCI, and post-PCI QFR analysis, correlated well with post-PCI FFR, and had similar diagnostic accuracy. Further studies are needed to prospectively validate a QFR-guided PCI strategy.

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Haemodynamic and clinical impact in adult patients with anomalous aortic origin of the coronary artery evaluated with quantitative flow reserve

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Other Coronary Interventions

AIMS

Anomalous origin of the right coronary artery (ARCA) represents the most frequent form of abnormal coronary origin and may potentially increase the risk for sudden cardiac death. Evaluation of ARCA in adult patients referred for invasive coronary angiograms (ICA) is difficult, and clinical impact is unknown. Quantitative flow reserve (QFR) is an available method able to virtually calculate fractional flow reserve using 3-dimensional quantitative coronary angiography (3D-QCA) based on ICA. We sought, to evaluate the feasibility of QFR analysis in patients with ARCA and its clinical impact.

METHODS AND RESULTS

Using the registry of proximal anomalous connections of coronary arteries (ANOCOR registry), a multicentric observational registry including 472 adult patients with ANOCOR between 2010 and 2013, we retrospectively performed QFR analysis from ICA and evaluated the rate of death, myocardial infarction, unplanned revascularization and hospitalization in cardiology at 5 years.

Among 128 patients with ARCA, 41 (32%) could have QFR analysis with median clinical follow-up of 8.3 years. The mean QFR value was 0.90 ± 0.10, and 3D-QCA analysis showed preserved lumen area despite the elliptical shape of the proximal part of the ARCA which in the worst cases appeared on ICA as a significant narrowing. The event rate was 14.6% (n=6), including three deaths (one due to cancer, one due to stroke, and one cause remains unknown), two unplanned revascularizations, and one hospitalization for heart failure at 5 years. No myocardial infarction was reported.

CONCLUSIONS

QFR analysis of ARCA is feasible and non-significant QFR values are associated with good clinical outcome at 5 years. QFR of ARCA could be the evaluation of choice to help in clinical decision-making during ICA, when applicable.

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Treatment of left main using DES with bioresorbable polymer

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease

AIMS

to assess the performance of a thin-strut sirolimus-eluting stent with bioresorbable polymer in a subgroup of patients with left main coronary artery (LMCA) disease.

METHODS AND RESULTS

e-Ultimaster is a prospective, multicentre registry which enrolled > 37,000 patients treated with Ultimaster DES worldwide. Of the 19482 patients that reached 1-year follow-up, 612 patients were treated in LMCA, among which 284 patients were treated only in LM (LM), while 328 patients were treated in LM plus one or more vessels (LM+MV). Most of the patient characteristics were similar between these two groups, with a mean age of 69.7±10.9 and 68.4±10.3years, body mass index of 27.0±5.3 and 27.3±4.8kg/m2, 73.4% and 69.6% with hypertension, 65.6% and 64.4% with hypercholesterolemia in the LM and LM+MV group respectively ($p>0.05$ for all). 41.4% of patients in LM group and 34.4% in LM+MV group ($p=0.08$) had previous PCI, while 23.4% and 17.1% ($p=0.06$) had history of CABG. Regarding lesion characteristics, 45.6% of patients in the LM group had lesions longer than 25mm, while more than half of the patients (53.7%) in LM+MV group had long lesions ($p=0.05$). Among treated lesions, 33.2% of LM and 29.7% of the LM+MV group had moderate or severely calcified lesions. Regarding the procedure, approximately 67% of the procedures were performed via radial access in both groups, while imaging (OFDI or IVUS) were used in 41.1% of the procedures in LM and 31.2% in LM+MV group. In LM and LM+MV groups, direct stenting was performed in 29.0% and 33.8% ($p=0.14$) of the lesions, while post dilatation was performed in 72.7% and 53.7% ($p<0.01$) of the lesions respectively. The number of Ultimaster stents implanted per patient was 1.4±0.8 in LM only group and 2.2±1.2 in LM+MV group, and the total length of successfully implanted Ultimaster stent was 31.1±21.3mm and 47.6±30.0mm.
At 3-month and 1-year follow-up, 91.9% and 69.5% of treated LM patients were on DAPT, and the majority of patients was angina-free at 1 year (98.3%). At one year, the clinical outcomes in all LMCA patients are the following, any death 7.0% with 4.7% of cardiac cause, target vessel MI 1.1%, target lesions and vessel revascularization 3.3% and 4.4% respectively. The definite and probably stent thrombosis rate is 0.82%, and the composite endpoint of target lesion failure is 8.2% at one year. These rates were comparable in LM and LM+MV group with no statistical difference ($P>0.05$ for all).

CONCLUSIONS

In complex patients treated for LMCA disease, with or without additional treated vessels, the Ultimaster DES showed good clinical outcomes at 1 year. These results indicate that thin strut sirolimus-eluting Ultimaster stent with bioresorbable polymer offers a good option for treating LM patients.

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Ticagrelor monotherapy in patients with impaired renal function treated with PCI is safe in ACS but not in stable coronary artery disease - Insights from the randomised multicentre GLOBAL LEADERS study

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THEME: Coronary Interventions
TOPIC(S): NSTEMI, Stable CAD

AIMS

Impaired renal function has been associated with a higher risk of both ischemic and bleeding adverse events among patients undergoing percutaneous coronary interventions (PCI).

The study aimed to evaluate the safety and efficacy of ticagrelor monotherapy in relation to baseline renal function among patients undergoing PCI.

METHODS AND RESULTS

Coronary artery disease (CAD) patients that underwent PCI in the randomized multicentre open-label Global Leaders study (n = 15991) were stratified based on Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation-derived estimated glomerular filtration rate (eGFR) and on clinical presentation (stable CAD versus acute coronary syndromes [ACS]). Impaired renal function was defined as eGRF < 60 ml/min, according to pre-specified definition.

The experimental strategy consisted of 23-month ticagrelor monotherapy (after one month of ticagrelor and aspirin), whereas the reference strategy comprised 12-month dual antiplatelet treatment followed by 12-month aspirin monotherapy. The primary endpoint was a composite of 2-year all-cause mortality or nonfatal, centrally adjudicated, new Q-wave myocardial infarction (MI). Two-year clinical outcomes including patient-oriented composite endpoint (POCE: all-cause mortality, any stroke, MI or revascularization) and net adverse clinical events (NACE: POCE and bleeding type 3 or 5 according to the Bleeding Academic Research Consortium [BARC]) were reported.

At two years, among patients with impaired renal function (n=2545), experimental vs. reference treatment strategy was associated with lower, but not statistically different, rates of the primary endpoint (7.0% vs. 8.7%, rate ratio [RR] 0.80, 95% confidence interval [CI] 0.60–1.06, p=0.122), all-cause mortality (5.6% vs. 7.4%, hazard ratio [HR] 0.74; 95%CI 0.55-1.01; p=0.057), POCE (18.1% vs. 20.1%, HR 0.89, 95%CI 0.75–1.07, p=0.220), definite or probable stent thrombosis (ST) (0.9% vs. 1.7%, HR 0.57, 95%CI 0.28–1.15, p=0.114) and NACE (20.6% vs. 21.8%, HR 0.94, 95%CI 0.80–1.12, p=0.485). There were no differences in the rate of primary safety outcome of BARC-defined bleeding type 3 or 5 (4.4% vs. 3.4%, HR 1.30, 95%CI 0.87–1.93, p=0.203) in both treatment groups. No significant treatment effect interactions were found between renal function impairment and any of the outcome variables.

Among patients with ACS and impaired renal function, experimental vs. reference treatment was associated

with lower rates of definite and probable ST (1.1% vs. 3.0%, p=0.025) and a numerically lower rate of POCE (20.5% vs. 25.4%, p=0.074), BARC 3 or 5 type bleeding (3.5% vs. 5.0%, p=0.276) and NACE (20.5% vs. 25.4%, p=0.051). On contrary, among stable CAD patients with impaired renal function similar rates of POCE, ST and NACE were found in both treatment groups, while bleedings BARC 3 or 5 type (5.1% vs. 2.10%, p=0.044) occurred more often in the experimental group.

CONCLUSIONS

In this large all-comer population undergoing PCI baseline renal function did not imply differences in the safety and efficacy of the experimental treatment strategy at long-term follow-up. In patients with ACS and impaired renal function ticagrelor monotherapy (after one month dual therapy with aspirin) may be associated with net clinical benefit (given lower rates of both ischemic and bleeding events). In stable CAD patients with impaired renal function ticagrelor monotherapy was associated with a higher risk of bleeding, as compared with twelve-month dual therapy with aspirin.

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Clinical outcome after coronary bifurcation stenting: a systematic review and network meta-analysis of PCI bifurcation techniques comprising 5,572 patients

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

The optimal PCI technique for bifurcation lesions remains a matter of debate. Several RCT have compared different bifurcation PCI techniques. Provisional stenting has been recommended as the default technique for most bifurcation lesions. However, emerging data suggests that double-kissing crush technique can be considered in true left main bifurcation lesions and has been endorsed by the European Sociery of Cardiology Guidelines.

METHODS AND RESULTS

We searched MEDLINE for randomized clinical trials (RCT) comparing PCI bifurcation techniques for coronary bifurcation lesions. Outcomes of interest were major adverse cardiovascular events(MACE) defined as the composite of cardiac death, myocardial infarction (MI) and target vessel or lesion revascularization (TVR/TLR), and the individual components of MACE. Stent thrombosis was also assessed as defined by the ARC. Stratification based on left-main or distal bifurcations was performed. We evaluated the studies' risk of bias in accordance to the Cochrane Handbook for Systematic Reviews of Interventions, and certainty of evidence using the Grading of Recommendations Assessment, Development and Evaluation framework. We estimated summary odds ratios (ORs) using pairwise and network meta-analysis with random effects. We identified 263 studies and of these included 19 RCT including 5572 patients treated with five bifurcation PCI techniques namely provisional stenting, systematic T-stenting, crush, culotte and double-kissing crush. Median follow-up was 12 months (IQR 8 to 36). When all bifurcation lesions were combined, double-kissing crush technique reduced the occurrence of MACE (OR 0.42; CI 0.28 to 0.61) compared to provisional stenting. This difference was driven by a reduction in TVR/TLR (OR 0.39; CI 0.25 to 0.65). No differences were found in cardiac death, MI or stent thrombosis among analyzed PCI techniques. No differences in MACE were observed between provisional stenting, systematic T-stenting, crush. In distal bifurcations (n= 17 studies, 4634 patients), double-kissing crush also showed to reduce MACE (OR 0.48; CI 0.29 to 0.67 vs. Provisional). In left-main bifurcations (n= 3 studies, 938 patients) no differences in MACE were found between PCI techniques.

CONCLUSIONS

In this network meta-analysis, PCI bifurcation techniques were similar with respect to the occurrence of cardiac death, myocardial infarction and stent thrombosis. When all coronary bifurcations were combined, an advantage of double-kissing crush was observed in terms of MACE driven by lower rate of repeated revascularization.

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Etiology-based clinical scenarios predict procedural outcomes in patients undergoing transcatheter tricuspid valve edge-to-edge repair

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THEME: Interventions for Valvular Disease
TOPIC(S): Tricuspid / Pulmonary valve

AIMS

Transcatheter tricuspid valve repair (TTVR) is an emerging technique to treat tricuspid regurgitation (TR) in patients at increased surgical risk. Predictors of adverse events are scarce, and stratification by TR etiologies is lacking.

METHODS AND RESULTS

We report the procedural outcomes of 164 patients undergoing TTVR for TR from a bi-center registry classified into four etiology-based clinical scenarios (CS): lone atrial fibrillation TR (Afib-TR), pulmonary hypertension TR (PHT-TR), concomitant mitral regurgitation TR (MR-TR), and TR in patients on dialysis (Dialysis-TR). TTVR procedural success was defined as a TR reduction by ≥1 grade. Clinical characteristics, procedural outcomes and the co-primary endpoints mortality and a combined endpoint (mortality, re-hospitalization and tricuspid valve re-intervention) at mid-term follow-up at one year were evaluated.

In total, 164 patients were assessed. Fourty-four (27%) patients were categorized as Afib-TR, 30 (18%) as PHT-TR, 74 (45%) as MR-TR, and 11 (7%) as Dialysis-TR. We applied a stepwise categorization approach that classified patients on chronic hemodialysis into Dialysis-TR; patients not undergoing dialysis with MR grade ≥3 into MR-TR; patients not meeting the inclusion into Dialysis-TR or MR-TR with an invasively-determined systolic pulmonary artery pressure >50mmHg into PHT-TR; and the remaining patients into Afib-TR in case a history of atrial fibrillation/flutter existed. Five patients (3.0%) did not meet pre-specified inclusion criteria and were excluded from the analysis. Procedural success was > 80% in all CS and did not differ between groups (p=0.38). The Dialysis-TR CS had the highest STS-scores (14.60 [12.93; 30.03]; p<0.01), largest coaptation gap (6mm [3.61; 7.17]; p=0.03), and rate of NYHA class ≥ 3 (n=11/11 (100%); p<0.01). Patients categorized into the Afib-TR CS had the lowest STS-scores (3.09 [2.99; 4.28]; p<0.01), lowest rate of NYHA class ≥ 3 (n=35/44 (79.5%); p<0.01), and highest functional capacity (6MWT; 316m [264; 341]; p<0.01). Concomitant MR clipping was highest in MR-TR CS (69/74 (93%); p<0.01).

Within the group of patients that had procedural success, CS predicted the combined primary endpoint (Afib-TR CS (n=5/37 (13.5%), PHT-TR CS (n=15/26 (57.7%)), MR-TR CS (n=25/69 (36.2%), and Dialysis-TR CS (n=4/9 (44.4)); p<0.01). One-year mortality was highest in the PHT-TR CS when compared to the other CSs (p=0.03). One-year heart failure hospitalization was highest in the PHT-TR CS (12/26 (46.2%); p=0.02)). The rate of re-intervention was not significantly different among CSs.

CONCLUSIONS

Stratification according to etiology-based clinical scenarios may add value to the risk prediction in the heterogeneous patient population of TR patients currently evaluated for TTVR, overcoming some of the limitations of regression-based risk prediction models and may better guide decision-making in the TTVR patient population.

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One-year VARC-2 defined outcome using a novel self-expanding transcatheter heart valve

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Initial reports on the clinical performance of patients undergoing transcatheter aortic valve implantation (TAVI) with the ACURATE neo (Boston Scientific) are promising, however information regarding one-year outcome is scarce, especially when the composite endpoints proposed by the updated Valve Academic Research Consortium (VARC-2) are considered. We therefore aimed to analyse outcome with the ACURATE neo at one year according to the VARC-2 criteria with emphasis on the composite endpoints “clinical efficacy after 30 days” and “time-related valve safety”.

METHODS AND RESULTS

Between January 2014 and October 2016,151 consecutive patients treated with the ACURATE neo for severe stenosis of the native aortic valve were enrolled. Data was prospectively collected and assessed according to the VARC-2 definitions. Event rates during follow-up were calculated using Kaplan-Meier estimates.

The Mean age was 81.1±5.9 years, 49.7% (75/151) were female with a median logistic EuroScore of 13.8% [8.2-20. 5]. The distribution across the small, medium and large size of the prosthesis was 33.1% (50/151), 36.4% (55/151) and 30.5% (46/151), respectively. In 88.1% (133/151) of patients device success was achieved; 7.9% (12/151) showed residual moderate paravalvular leakage, while procedure related mortality was 0.7% (1/151). Rates of in-hospital complications, i.e life-threatening bleeding, major vascular complications and stroke were 5.3% (8/151), 13.9% (21/151) and 1.3% (2/151), respectively. Permanent pacemaker implantation (PPI) in pacemaker naïve patients (n=137) was required in 10.2% (14/137).

At one year all-cause and cardiac mortality were 3.3% (5/151) and 1.3% (2/151), respectively, while PPI occurred in 14.0% (19/137). The “clinical efficacy after 30 days” was observed in 24.8% (37/151), with symptom worsening in 11.3% (17/151) of cases being the main contributor. “Time-related valve safety” occurred in 22.0% (33/151) with structural valve deterioration as primary cause in 9.3% (14/151) of cases. Patients showed a considerable symptomatic benefit after procedure, with patients reporting a NYHA functional class II or less in 86.7% at 1 year. From baseline to 1 year, symptom improvement of at least one functional class was observed in 70.9% of patients.

CONCLUSIONS

In the current analysis using the self-expanding ACURATE neo, we found a favorable safety profile with low all-cause mortality and high symptomatic benefit at one year. For the first time for this prosthesis, the composite endpoints at one year are reported and reveal low rates of patients experiencing the composite endpoint “clinical efficacy after 30 days” and “time-related valve safety”.

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Is it Safe to MObilise patients Very eARly after transfemoral cardiac catheterisation? SAMOVAR

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS
To investigate the occurrence of haematomas and bleeding in patients mobilised either immediately or 2 hours after transfemoral coronary angiography (CAG) or percutaneous coronary intervention (PCI) and to describe patient comfort in terms of low back and groin pain in relation to mobilisation and bed rest.

METHODS AND RESULTS
The trial was conducted as a controlled non-inferiority trial with patients randomised to immediate mobilisation (IM) or 2 hours bed rest (BR) after transfemoral CAG or PCI and use of the Angio-SealTM closure device. Patients using oral anticoagulation, those with visible groin haematoma at the end of the procedure, procedures requiring 8 French sheaths or the use of glycoprotein IIb/IIIa inhibitors were excluded. Heparin dosing was reversed with protamine sulphate. The primary endpoint was a > 5 cm groin haematoma developed after the procedure, and before discharge, retroperitoneal haematoma, pseudo-aneurysm and transfusion-requiring bleeding. Secondary endpoints were persistent oozing or bleeding from the puncture site requiring manual compression and haematoma measuring 2-5 cm or > 12 cm in diameter. Patient comfort scores were measured.
2027 patients were randomised (IM n=1010; BR n= 1017). The indication for CAG was stable angina in 36.8% and unstable angina/NSTEMI in 31.5% and STEMI in 3.6%. 803 (39.6%) patients underwent PCI. Baseline characteristics were comparable in the two groups, IM versus BR: age 64 [56-71] versus 64 [56-71] years (p=0.71), female sex 30.4% versus 27.4% (p=0.16), BMI 26[24-29] versus 26[24-29] kg/m2 (p=0.66), hypertension 55.4% versus 53.4%, (p=0.38), known renal disease (p=0.95) or indication for the procedure (p=0.18).
The primary outcome measure was recorded in 7(0.7%) patients randomised to IM versus 5(0.5%) of those randomised to BR (odds ratio [OR] 1.41(0.38-5.66); p=0.58). There was no difference in the incidence of 2-5 cm haematoma: 59(5.8%) versus 66(6.5%) (OR 1.13 (0.78-1.62); p=0.52). Persistent oozing requiring additional manual compression was seen in 119 (11.8%) of IM patients versus 92 (9%) of BR patients (OR 1.34 (1.01-1.79); p = 0.04). Only 1 haematoma > 12 cm developed in a patient randomised to BR. After univariate logistic regression, treatment assignment was not a predictor of the development of > 5 cm haematoma (OR 1.41 (0.45-4.77); p=0.56) or 2-5 cm haematoma (OR 1.06 (0.73-1.55); p=0.75). We found no predictors of > 5 cm haematoma and only BMI predicted development of 2-5 cm haematoma (OR 0.95 (0.91-0.99); p=0.04). After multivariate analyses treatment assignment (OR 1.35 (1.00 - 1.82); p= 0.05), a history of hypertension (OR 0.71(0.53.0.95); p=0.02), female sex (OR 0.66(0.46 - 0.93); p=0.02), and indication for the procedure (STEMI or unstable angina/NSTEMI (OR 1.42 (1.05 - 1.91); p= 0.02) were all associated with persistent oozing from the arterial puncture site.Vagal reactions were observed in 3 patients randomised to IM and 1 patient in BR. One pseudo- aneurysm developed in a patient randomised to BR. Patients mobilised immediately reported less pain in the back (p<0.001); there were no significant differences in patient reported groin pain (p=0.95).

CONCLUSIONS

Transradial CAG and PCI is now guideline-recommended. Some patients still require transfemoral approaches. In selected patients, use of Angio-SealTM after transfemoral CAG and/or PCI and protamine to reverse anticoagulation after PCI allows immediate mobilisation with very low rates of complications and improved patient comfort.

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Influences of thickness and circumferential angles of calcification on the capability of fracturing calcification of the cutting balloon: an experimental investigation

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Fracturing calcification before stenting is desired to reduce stent underexpansion. Although lesion modification devices are available, there is little knowledge about influences of thickness and circumferential angles of calcification on the capability of fracturing calcification. We developed calcified stenotic coronary artery models with circumferentially complete calcification (360° calcification model) and with circumferentially 180° calcification (180° calcification model), and investigated capability of fracturing the models using cutting balloon (CB) and non-compliant balloon (NCB).

METHODS AND RESULTS

The 50 % stenotic concentric calcification models with the reference diameter of 3.0 mm were developed. The calcification model with the internal diameter and longitudinal length of 1.5 mm, and 5 mm was prepared. As to the calcification thickness, 400 mm, 450 mm, and 500 mm were prepared by changing the outer diameter. In addition, 360°- and 180°- calcification models were developed. The calcification was fabricated by the mixture of calcium-sulfate-hemihydrate powder, cement powder, and polyurethane resin, and the artery model was fabricated with silicone. We conducted preliminary experiments to determine the mixture ratio using the 360° calcification models. We chose the calcification model with the mechanical strength that the calcification can be fractured when the NCB (NC Emerge, Boston Scientific) with 3.0-mm diameter and 10-mm length is inflated at approximately rated balloon inflation pressure (20 atm). The CB with three metallic blades in every 120° (Wolverine, Boston Scientific) with 3.0-mm diameter and 12-mm length were used.

In the experiment using the 180° calcification models, influences of the CB diameter on capability of fracturing the calcification model were investigated, with a hypothesis that the 2.0-mm diameter CB may have larger capability of fracturing the 180° calcification model because the circumferential distance between two blades is shorter than the internal circumferential length of the calcification and two blades among the three can be theoretically placed inside the calcification.

The 360° calcification models with 400mm thickness was fractured at 18.6 ± 1.2 atm (n=6) using the NCB and fractured at lower inflation pressure of 6.2 ± 1.0 atm (n=6) using the CB ($p < 0.001$). For the 450 mm and 500 mm thick calcification models, the CB could fracture the calcification at 13.0 ± 1.3 atm (n=6), and 19.5 ± 0.8 atm (n=6), respectively, whereas no facture was achieved using the NCB.For the 180° calcification models, no facture was observed regardless of the NCB and the CB when 3.0 mm diameter balloons were used. However, when 2.0 mm diameter balloon was used, the CB could fracture the 400mm-thick calcification at 13.7 ± 0.8 atm (n=6), and the 450mm-thick calcification at 17.3 ± 0.8 atm (n=6), respectively. No fracture was observed when the NC balloon was used. These data indicated that the presence of two blades inside the calcification is prerequisite for fracturing calcification. Our study elucidated that the proper CB diameter exists for fracturing

the 180° calcification.

CONCLUSIONS

It was elucidated that the CB is effective for fracturing completely tubular calcification of thicker calcification with lower inflation pressure as compared with the NCB. Moreover, for the 180° calcification, the proper size selection of the CB is essential for maximizing the capability of fracturing calcification.

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BRS - A tale of 253 scaffolds from a single-centre review

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Bioresorbable scaffolds (BRS) held great promise of overcoming the shortfalls of metallic stents. A high rate of device thrombosis, which has been linked to implantation technique, has resulted in their decline. In our institution we have used a consistent deployment technique for BRS implantation. We aimed to review patients who received BRS to ascertain our rate of stent thrombosis, target lesion revascularisation (TLR), and cardiac death.

METHODS AND RESULTS

A retrospective review of all patients receiving BRS in our institution. Demographic, procedural and follow up data was collated. From the date of first to the last BRS (October 2013-March 2017), 154 patients received 256 BRS. Follow up data was available on 152 patients (98.7%) who received 253 scaffolds (average 1.66 scaffolds/patient). 123 (80.9%) were male. The average age was 58years.

The indication was STEMI 57 patients (37.5%), NSTEMI 46 (30.3%), unstable angina 27 (17.7%), stable angina or silent ischaemia 22 (14.5%). A single operator was responsible for >99% of procedures. Of the 252 scaffolds, 138 were to the LAD, 45 to the left circumflex, 65 to the right coronary artery, one to a ramus intermedius, and 4 to vein grafts. All (100%) lesions were predilated (average predilation balloon:device diameter ratio 0.87:1). The median scaffold diameter used was 3.5 mm with an average stented length of 30.5mm.

122 (48.2%) of scaffolds were deployed with imaging guidance: 95 OCT, 23 IVUS, 4 both IVUS and OCT. 98.4% were post dilated (average post dilation NC balloon:device diameter ratio 1.1:1). The median post dilation pressure was 20 atmospheres. Two patients (1.3%) had inadequate aposition of stent struts on OCT despite high post dilation pressures and had subsequent deployment of metallic drug eluting stents inside the BRS at the index procedure. One patient (0.65%) had a dissection into the LMS (caused by predilation) treated with metallic DES. All patients received dual antiplatelet therapy.

The average follow up was 674 days (range 4-1468). Two cardiac deaths occurred (1.3%). One patient treated with BRS for a NSTEMI died at 4 days post stent implantation. No evidence of stent thrombosis was found at post mortem and death was assumed arrhythmic. A second patient developed progressive heart failure dying at 55 days post procedure. A further patient died due to lung cancer.

One stent thrombosis occurred (0.65%) at 4 days post procedure, in the context of non compliance with dual antiplatelets. Three (1.97%) had unplanned TLR: one was the aforementioned stent thrombosis. The second had angina and severe in-stent restenosis requiring metallic DES at 19months and subsequent coronary artery bypass grafting. The third patient had staged PCI to another vessel one week post the index procedure and was found to have an intramural haematoma at the site of the previous BRS which was stented with a metallic DES.

CONCLUSIONS

Acute scaffold thrombosis rates of up to 2.1% and TLR rates of up to 4% have been reported with BRS use. Our scaffold thrombosis rate was 0.65% (occurring in the context of non compliance with antiplatelet therapy) and total TLR was 1.97% over an average of 674days (1.85years) follow up. Our deployment technique including adequate lesion preparation, intravascular imaging assisted optomisation and 98.4% post dilation rate, to high pressures with adequately sized NC balloons may explain our favourable outcomes in comparison to the published literature.

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Clinical value of sirolimus-coated balloon angioplasty in patients with coronary artery disease: long-term results from real-world NANOLUTE registry

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Over the past decade, drug coated balloons have emerged as a potential new treatment for atherosclerotic lesions. The main advantage of this new technology is anti-proliferative drug which is more homogenously released compared to drug eluting stent. The aim of this registry was to evaluate long term safety and efficacy of MagicTouch – sirolimus coated balloon (Concept Medicals) in patients with Coronary Artery Disease who underwent percutaneous coronary intervention (PCI).

METHODS AND RESULTS

NANOLUTE registry is prospective, multicentre real world registry where patients are treated according to routine clinical practice. The primary endpoint was Major Adverse Cardiac Event (MACE) rate which mainly includes Cardiac Death, Target vessel Myocardial Infarction (TV-MI) and Target vessel/lesion Revascularization (TLR/TVR) at 1 year. 2 years' clinical follow-up was also achieved, and MACE rate was calculated to assess the long-term performance of MagicTouch in overall population.

Total 450 patients were treated for 479 lesions with 534 devices. The main risk factors, hypertension and diabetes mellitus were present in 48.0% and 45.3% patients respectively. 55.6% patients had history of previous PCI. 92% patients underwent SCB alone therapy while 8.0% patients underwent SCB and additional therapy. At 1 year, 100.0% clinical follow-up was achieved, and MACE rate was calculated as 3.8% with higher prevalence of TLR/TVR (3.1%) followed by 0.4% cardiac death and 0.2% TV-MI. 89.1% clinical follow-up was achieved at 2nd year. The MACE rate was found to be 4.5% with 3.5% TLR/TVR, 0.7% cardiac death and 0.2% TV-MI. The prevalence of TLR/TVR were higher compared to cardiac death and TV-MI on long term.

CONCLUSIONS

This registry showed reduced rates of revascularization up to 2 years of clinical follow-up. This supports the fact that treatment of coronary artery disease with MagicTouch SCB was effective and safe in a longer duration.

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Final two-year results of the randomised evaluation of short-term DAPT in patients with ACS treated with new-generation DES (REDUCE) trial

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

To compare 3 vs 12 months dual antiplatelet therapy (DAPT) in Acute Coronary Syndrome (ACS) patients treated with new generation Drug-Eluting Stent (DES).

METHODS AND RESULTS

REDUCE (Clinical Trials.gov: NCT02118870) is a prospective, multicenter, investigator-initiated study designed to randomly assign (1:1), based on a non-inferiority design, 1500 ACS patients after treatment with a new generation DES (COMBO) to 3 or 12 months of DAPT. Clinical follow-up was conducted at 3, 12, and 24 months. Primary endpoint was a composite of all cause mortality, myocardial infarction, definite/probable stent thrombosis (ST), stroke, target-vessel revascularization and bleeding (BARC II, III, V) at 12 months.

A total of 1496 ACS patients were randomly assigned to 3 (n=751) vs. 12 months (n=745) DAPT. No difference was observed in baseline characteristics, except for female gender (p=0.01). No difference in the primary endpoint was observed between 3 and 12 months DAPT (11.6%vs.12.1%,p=0.76). Among the secondary endpoints, no significant difference was observed in overall mortality (3.1%vs.2.2%,p=0.27), cardiac mortality (1.8%vs.1.1%,p=0.28), definite/probable ST (1.6%vs.0.8%,p=0.16), and major bleeding complications (3.3%vs.4.0%,p=0.47).

CONCLUSIONS

The final 2-year results of the REDUCE trial shows that among ACS patients treated with new Generation DES, 3 months DAPT is non-inferior to 12 months DAPT. Until additional larger trials will become available, 1-year DAPT should still be recommended in ACS. However, our results suggest that a 3 months DAPT strategy could be safely considered if required even in an ACS population.

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Ticagrelor pre-treatment compared with treatment during percutaneous procedure in patients with STEMI undergoing primary PCI

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

There is some evidence favouring clopidogrel pretreatment in patients with STEMI undergoing primary PCI (pPCI). Regarding the most recent oral P2Y12 inhibitors, prasugrel has not been studied in this context and a randomized trial with ticagrelor showed disappointing results.

This study aimed to investigate the effect of ticagrelor pretreatment on clinical outcomes in this group of patients.

METHODS AND RESULTS

Retrospective study of 3968 STEMI patients who underwent pPCI and were enrolled in a nationwide multicentre registry between January 2013 and December 2018. Patients with prior exposure to oral antithrombotic drugs (except acetylsalicylic acid), patients not managed with ticagrelor prior or during pPCI, and those with missing data were excluded. A total of 678 patients were included for analysis, 327 (48.2%) received ticagrelor pretreatment (Group 1) and 351 (51.8%) patients were treated with ticagrelor only in the catheterization laboratory (Group 2). The primary endpoint of the study was related to reperfusion outcomes and defined as a composite of pPCI failure (post dilation Thrombolysis in Myocardial Infarction (TIMI) flow grade <3), bailout use of GIIb/IIIa inhibitors or need for aspiration thrombectomy. The secondary safety endpoint was defined as a composite of in-hospital major bleeding according to the registry criteria, need for red blood cell transfusion or haemoglobin drop ≥2g/dL, and the tertiary endpoint was defined as composite of in-hospital all-cause death, stroke or re-infarction. Multivariate analysis was performed to determine the correlates of ticagrelor pretreatment and each of the endpoints. One-year follow up was achieved in 139 patients (42.5%), 38 of Group 1 and 101 of Group 2.

Overall, mean age was 61±12 years and 22.6% patients were female. Crude event rates showed differences between groups regarding the primary endpoint (30.7% versus 12.9%; p=0.001) and the secondary safety endpoint (35.2% versus 11.1%; p=0.001) favouring the use of ticagrelor during pPCI, while the tertiary endpoint did not differ (2.8% versus 3.4%; p=0.637). Differences in the primary composite endpoint (odds ratio [OR]: 0.21; 95% confidence interval [CI]: 0.12-0.36; p=0.001) and the secondary safety endpoint (OR: 0.25; 95%CI: 0.15-0.44; p=0.001) remained after multivariate analysis. At one-year follow up, there was a trend for higher crude rates of the composite of all-cause death, stroke or re-infarction in the group receiving ticagrelor pretreatment (p=0.046).

CONCLUSIONS

In this nationwide and multicentre cohort of STEMI patients undergoing pPCI, ticagrelor treatment given only in the catheterization laboratory was associated with better reperfusion outcomes and safety profile with no differences regarding in-hospital all-cause mortality, stroke or re-infarction. These results show that ticagrelor pretreatment may be harmful, reinforcing the scarce published evidence discouraging its use.

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Transcatheter treatment of secondary tricuspid regurgitation with a novel annuloplasty device: results from the Study of Transcatheter Tricuspid Annular Repair (STTAR)

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(1) ,

THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair, Tricuspid / Pulmonary valve

AIMS

To evaluate the safety and performance of MIA, Minimally Invasive Annuloplasty Device, a novel system for the percutaneous treatment of secondary tricuspid regurgitation (TR). Anchors connected with suture are implanted percutaneously into the tricuspid valve annulus. The anchors and tissue are approximated after deployment to reduce annular dimensions and TR.

METHODS AND RESULTS

METHODS: Eight patients with heart failure symptoms and moderate – severe or severe secondary TR on optimal medical treatment were divided into two groups. In group A surgical tricuspid annuloplasty was performed with MIA concomitant with mitral valve surgery through sternotomy between August and November 2017. In group (B) isolated secondary TR was treated percutaneously in 5 patients with a 12F delivery system from a trans-jugular approach through a 17F steerable sheath. Two of the group B patients had right ventricle pacemaker leads in situ. Safety, defined as periprocedural adverse events such as death, myocardial infarction, stroke, or cardiac tamponade, and feasibility, defined as successful implantation of 5 or more anchors and reduction of TR by at least 1 grade and/or reduction of annular dimensions, were evaluated periprocedurally, before discharge and up to 12 months. Group A is a single center experience. Group B includes patients from 3 European sites.

RESULTS: Device implantation was achieved in all patients in both groups. In group A (n=3) mean patient age was 69 years, 2 were females (66%). Mean EuroSCORE II was 2%. At baseline, 2 patients (66%) were in NYHA functional class III, with a mean left ventricular ejection fraction of 58%. After device deployment and anchor approximation, average 35% and 18% reductions in tricuspid valve area and annular circumference were observed respectively. There were no serious adverse events related to the device implantation either acutely or during follow-up. Acute reductions in valve dimensions and TR were maintained at follow-up: all 3 patients had trace TR post-procedure, at discharge and through 12-month follow-up.

In group B (n=5) mean patient age was 75 years, 2 were males (40%). Mean EuroSCORE II was 6.2%. At baseline, 2 patients (66%) were in NYHA functional class IV, with a mean left ventricular ejection fraction of 65%. After device deployment and anchor approximation an average reduction of 43% in tricuspid valve area and a 1-2+ grade reduction in TR was observed acutely in 4 of 5 patients. No significant change in annular dimensions or TR was achieved in 1 patient due to inaccurate placement of the anchors. There were no serious adverse events related to the implantation of the device in any patient.

CONCLUSIONS

The safety and feasibility of tricuspid valve repair with the MIA, Minimally Invasive Annuloplasty, device has been demonstrated. Further studies are needed to confirm these data in larger cohorts of patients and to investigate whether this technique leads to clinical benefit in patients with secondary TR. Pacemaker leads are not a contraindication for device implantation with this system.

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Balloon vs. self-Expandable valve for the treatment of bicuspid Aortic valve sTenosis: insights from the BEAT international collaborative registry

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

The BEAT (Balloon vs Self-Expandable valve for the treatment of bicuspid Aortic valve sTenosis) multicentre observational registry compared the outcome of consecutive patients who underwent transcatheter aortic valve implantation using Evolut R or Sapien3 valves in bicuspid aortic anatomies at 19 centers between January 2010 and October 2018.

METHODS AND RESULTS

A total of 353 patients [n=242 (77.5%) treated with Sapien 3 valve and n=50 (22.5%) treated with Evolut R] were included in the final analysis. Mean patient age was 77.8 ± 8.3 years and 64% were males; mean STS-M was 4.4±3.3%. VARC-2 device success was similar between Sapien 3 and Evolut R (85.6% vs. 87.2%, p=0.68), with a higher rate of of pre-discharge moderate-severe paravalvular aortic regurgitation (PAR II+) in the Evolut R group (10.8% vs. 0.8%, p=<0.001). Self-expandable valves were more frequently pre- and post-dilated (predilatation: Evolut R=58.7% vs Sapien 3=36.5%, p=<0.001; postdilatation: Evolut R 45.9% vs Sapien 3=14.5%, p=<0.001). In the Sapien 3 group, 4 patients experienced annular rupture whereas this complication did not occur in the Evolut R group. The rate of permanent pacemaker implantation was similar (Sapien 3=16.1% vs Evolut R 16%). At 30-days, mortality, stroke rate and cardiac hospitalization were similar between the 2 groups (all cause death 4.3%, stroke rate 3.3%, cardiac hospitalization 2.2%). A 1-to-1 nearest neighbor propensity score-matching resulted in 77 matched pairs. After propensity score matching, VARC-2 device success was similar between the 2 groups (Sapien 3= 85.7% vs Evolut R 84.4%, p=0.821). Patients treated with Sapien 3 had higher post-procedural gradients (11.5 ± 4.3 mmHg vs 9.7 ± 4.9 mmHg, p= 0.026); however, Evolut R implantion required more frequent postdilation (42.7% vs 14.3%, p=<0.001) and was associated with an higher rate of PAR II+ (10.4% vs 0%, p=<0.001). No differences in 30-day outcomes were found between the matched populations.

CONCLUSIONS

This large international study confirms the feasibility of both Sapien 3 and Evolut R implantation in BAV anatomy; however a higher rate of moderate to severe PAR was observed in the Evolut R group. Further studies are needed to confirm our findings.

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Intravascular lithotripsy for calcified coronary lesions - single-centre experience of a novel device

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Coronary arterial calcification increases procedural complexity in percutaneous coronary intervention (PCI) with a higher risk of major adverse cardiac events. The Disrupt-CAD I study suggested benefit with the use of intravascular lithotripsy (IVL) in selected cases. We present outcomes for IVL-assisted PCI in a broader all comers population

METHODS AND RESULTS

We included all procedures utilizing IVL at our institution. Demographic, procedural and post-procedural outcomes were recorded with comparison between those enrolled in Disrupt-CAD I and Disrupt-CAD II to a clinical population. The indication for IVL use was based on presence of an undilatable lesion, under-expanded stent and severe calcification on angiography or on intravascular imaging.

74 procedures (mean 75.9 years, 70% male) were included (19 study and 55 clinical procedures). The clinical group differed by including patients with acute coronary syndromes (49%), renal replacement therapy (14%), left main stem and multivessel intervention (28%). 11% in total had a previous undilatable lesion. Optical coherence tomography (OCT) was utilised in 53% of cases (see Figure 1). Total procedural success was 91% with 100% facilitation of stent delivery. On OCT, the MLA was similar in both groups (4.3+/-2.6mm2vs 4.2+/-1.4mm2, p=0.83), as was the mean residual area stenosis (19.0% vs 21.9%, p=0.55). There were no cases of IVL related coronary perforation, no reflow or 30-day target lesion failure in both groups.

CONCLUSIONS

IVL is a novel technology enabling modification of severe coronary calcification and provides a safe and feasible alternative to currently available techniques with increasing clinical applicability.

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FFR derived from microcatheters vs. standard pressure wires: a stenosis-level meta-analysis

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Stents and scaffolds

AIMS

To determine the agreement between sensor-tipped microcatheter and pressure wire derived Fractional Flow Reserve.

METHODS AND RESULTS

Studies comparing FFR obtained from microcatheters (FFRMC, Navvus Microcatheter System, ACIST Medical Systems, Minnesota, USA) versus standard pressure wires (FFRPW) were identified and a meta-analysis of numerical and categorical agreement was performed. The relative levels of drift and device failure of microcatheter and pressure wire systems from each study were assessed. Six studies with 440 lesions (413 patients) were included. The mean overall bias between FFRMC and FFRPW was -0.029 (FFRMC lower). Bias and variance were greater for lesions with lower FFRPW ($p < 0.001$). Using a cut-off of 0.80, 18% of lesions were re-classified by FFRMC versus FFRPW (with 15% being false-positives). The difference in reported drift between FFRPW and FFRMC was small. Device failure was more common with microcatheters than pressure wires (7.1% versus 2%).

CONCLUSIONS

FFR derrived from microcatheters systematically overestimates lesion severity, with increased bias in more severe lesions. Using microcathers to measure FFR rather than pressure wires changes revascularisation guidance in approximately 1 out of every 5 cases. Pressure wire drift was similar between systems. Device failure was higher with microcatheters.

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Conventional vascular access site approach vs. fully transwrist approach for CTO PCI: a multicentre analysis

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Chronic total occlusion (CTO) percutaneous coronary intervention (PCI) historically relied on the use of trans-femoral access (TFA), which however has been associated with a non-negligible risk of vascular complications and major bleeding. We evaluated whether a fully trans-wrist access (TWA) is associated with decreased incidence of vascular complications and major bleeding in CTO PCI.

METHODS AND RESULTS

We combined consecutive patient data from five multi-operator CTO programs. We divided patients into two groups depending on vascular access site: subjects treated with at least one TFA were included in the Conventional group, while patients with a fully TWA (single radial/ulnar, double radial/ulnar, radial+ulnar) were added in the fully TWA group. The primary safety endpoint was a composite of vascular complications (local haematoma, pseudoaneurysm, dissection, retroperitoneal haematoma) and major bleeding (causing haemoglobin drop >3 g/dl and/or requiring transfusion, vasopressors, percutaneous or surgical intervention). The primary efficacy endpoint was procedural success, defined as successful deployment of the stent at the target lesion and residual stenosis <30% with antegrade TIMI 3 flow, without in-hospital major cardiovascular events. Multivariable logistic regression analysis was conducted to identify independent predictors of the primary endpoint.

We included 1900 patients (Conventional n=1496, fully TWA n=404). Conventional patients showed higher prevalence of comorbidities and features of occlusion complexity (mean J-CTO score was 2.1±1.2 vs. 1.5±1.1, in Conventional vs. fully TWA, p<0.001).Antegrade guiding catheter size was larger in Conventional patients (7.2±0.7vs. 6.4±0.6, p=0.05), as was the case for the retrograde guiding size (6.6±0.7vs. 6.1±0.4, p<0.001). The retrograde approach (34% vs. 15%, p<0.001) and antegrade dissection/re-entry (14% vs. 11%, p=0.09) were used more frequently in Conventional patients. Procedural success showed no significant difference between Conventional and fully TWA groups (85.7% vs. 83.0%, p=0.17). The primary safety endpoint occurred more frequently in the Conventional group (10.3% vs. 4.5%, p<0.001), which was driven by vascular complications (9.4% vs. 3.7%, p<0.001). However, major bleeding alone did not demonstrate any significant difference (1.6% vs. 1.0%, p=0.36). On multivariate analysis, not using a fully TWA approach (i.e., utilizing a Conventional vascular access strategy) was an independent predictor of the study endpoint (odds ratio 2.56, 95% confidence interval 1.54-4.35, p<0.001), after adjusting for age, sex, diabetes, body mass index, chronic kidney disease, prior coronary artery bypass graft, and J-CTO score.

CONCLUSIONS

Our data suggest that embracing a more minimalistic approach, based on a fully TWA, for CTO PCI might be associated with lower incidence of a composite endpoint of vascular complications and major bleeding, without impacting the performance of the procedure.

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Correlation of FFR values with frequency of vulnerable plaque features in non-significant lesions - Insights from the COMBINE study

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Deferred revascularization based on fractional flow reserve (FFR) is associated with a low future major adverse clinical events however, recent data show that diabetes mellitus (DM) patients might have worse outcomes than non-DM patients in regard to negative FFR lesions. Furthermore, recent studies show that plaque complexity is inversely related to FFR hyperaemic values.

The aim of our study was to determine whether a decreasing FFR value is associated with higher plaque complexity in DM patients in non-significant lesions.

METHODS AND RESULTS

We performed optical coherence tomography (OCT) analysis of the first 300 patients from the COMBINE study (NCT02989740); a multi-centre, prospective natural history study which combines OCT morphologic and FFR hemodynamic assessments of non-culprit lesions to better predict adverse event outcome in DM patients.

From 300 patients, 360 FFR-negative (>0.80) lesions were evaluated. The median FFR value was 0.88 (IQR 0.84-0.92). The patients were divided into two subgroups: Group A (0.80< FFR ≤0.88) and Group B (FFR >0.88), both with optimal medical therapy alone. The clinical risk factors did not differ between the two groups. The mean angiographic diameter stenosis was 52.6±10.3% in both groups (p=0.116).

No significant difference was observed between Group A vs. B regarding the incidence of TCFA: 20.5% vs. 18.3%, respectively (p=0.602). Similarly, the prevalence of angiographic hidden plaque rupture was 8.9% and 8.8% (p=0.967). The prevalence of plaque erosion 4.2% and 7.1% (p=0.239) and thrombotic calcified nodule was 10.0% and 7.1% (p=0.321) in Group A and Group B, respectively. The prevalence of all complicated plaques, such as plaque rupture, erosion and thrombotic calcified nodule was 22.6% vs. 21.2% (p=0.739).

CONCLUSIONS

In DM patients the prevalence of vulnerable plaques (TCFA lesions), as well as complicated lesions, such as plaque rupture, erosion and calcified nodule was high, but did not correlate with FFR hyperaemic values in hemodynamic non-significant lesions.

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Six vs. twelve months of DAPT in myocardial infarction patients undergoing PCI with second-generation DES: a pooled database analysis from SMART-DATE and DAPT STEMI trials

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

Second-generation drug-eluting stents (DES) have significantly reduced the rates of stent thrombosis (ST) in all patients, including myocardial infarction (MI) patients. Current guidelines recommend 6 months of DAPT in stable patients. Whether 6 months of DAPT is also safe in MI patients is debatable.

METHODS AND RESULTS

MI patients who underwent percutaneous coronary intervention (PCI) with durable-polymer second-generation DES from two large randomized trials; SMART-DATE (NCT01701453) and DAPT-STEMI (NCT01459627) were pooled. The primary endpoint (PE) was a composite of all-cause mortality, any MI, stroke and BARC 3-5 bleeding between 6-18 months after index PCI. A total of 2016 patients, 1014 and 1002 in 6 vs. 12 months DAPT or longer, respectively were analyzed. Kaplan-Meier estimates of the PE were 31(3.1%) vs. 29(2.9%), HR 1.06; 95%CI (0.64-1.76), p=0.82. MI occurred in 20(2.0%) vs. 9(0.9%), HR 2.20, 95%CI (1.01-4.85), p=0.05; major bleeding 2(0.2%) vs. 9(0.9%), HR 0.22, 95%CI (0.05-1.02), p=0.05; stroke: 7(0.3%) vs. 5 (0.5%), HR 1.39, 95%CI (0.44-4.38), p=0.57. All-cause mortality occurred in 7(0.7%) vs 10(1.0%) patients, HR 0.69; 95%CI (0.26-1.82), p=0.46.

CONCLUSIONS

In MI patients undergoing PCI with durable-polymer DES, 6 vs. 12 months of DAPT resulted in comparable outcomes in terms of a combined adverse clinical events endpoint. Twelve months DAPT significantly reduced the MI rates, but at the cost of an increase in major bleeding with no benefit neither in cardiac nor all-cause mortality. Therefore, after 6 months, continuation of DAPT, duration should be tailored based on patient specific ischemic and bleeding risks.

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Intravascular imaging for unprotected left main stem PCI: a survival analysis of 11,264 cases from the British Cardiovascular Intervention Society (BCIS) national database

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease

AIMS
Registry data supports the use of intravascular imaging during unprotected left main-stem PCI (uLMS-PCI) to improve patient outcomes. However, relatively few patients have been studied, and the majority of the data is derived from centres outside Europe. Therefore, in an attempt to address these limitations, we used the British Cardiovascular Intervention Society national PCI databaseto explore temporal changes inthe use of intravascular imaging for unprotected left main stem PCI, defined the associates of imaging use, and correlated clinical outcomes including 12-month survival with imaging.

METHODS AND RESULTS
Data were analysed from 11,264 uLMS-PCI procedures performed in England and Wales between 2007 and 2014. Using the BCIS dataset, patients were categorised into imaging use or not during uLMS-PCI. Study definitions were used as in the BCIS database. Multivariate logistic regression was used to identify associates of imaging use. To adjust for missing data, we used multiple imputations with chained equations. Individual logistic regressions were done on the imputed data set for each of the MACE events according to the imaging status to quantify the independent association between imaging and outcomes. In order to adjust for baseline characteristics that might influence outcomes and thus to attempt to quantify the independent effects of access site on outcomes, we ran a 1:1 propensity matching creating 5,056 pairs of subjects with and without imaging. Finally, a multivariate logistic regression to identify the independent predictors of 12-month mortality was performed. Use of imaging increased from 30.2% in 2007 to 50.2% in 2014 ($p<0.001$ for trend). The majority of imaging used was IVUS although OCT increased significantly over the study period (4% on 2014, $p<0.001$). The factors independently associated with increased imaging use were stable presentation (OR 1.20, 95% confidence interval[1.147:1.246)], $p<0.001$), complexity of baseline disease (OR 1.32 [1.23:1.42], $p<0.001$), bifurcation LMS disease (OR 1.22 [1.14:1.30], $p<0.001$), previous PCI (OR 1.32 {1.20:1.44], $p<0.001$), radial access 1.266 (1.217:1.317), and trainee first operator (OR 1.14 [1.09:1.19], $p<0.001$). In unadjusted analysis, immediate coronary complications and clinical outcomes were lower when imaging was used. After adjustment for baseline differences, imaging remained was associated with a lower rate of slow flow and dissection, and associated with lower in-hospital mortality (OR 0.39 [0.296:0.514], $p<0.001$), in-hospital MACE (OR 0.474 [0.377:0.596], $p<0.001$), 30-day mortality (OR 0.542 [0.434:0.677], $p<0.001$) and 12-month mortality (OR 0.663 [0.574:0.766], $p<0.00$) when compared to no imaging use. In logistic regression modelling of death at 12 months in all patients undergoing uLMS-PCI, imaging use was independently associated improved survival.

CONCLUSIONS

Although the uptake of intravascular imaging for unprotected LMS-PCI, only 50% of cases in the most contemporary years utilised this technology. Use of intravascular imaging was associated with fewer acute procedural complications and better short and long-term survival.

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Five-year outcomes with newer-generation ultrathin-strut vs. thin-strut DES in patients undergoing percutaneous coronary revascularisation: a subgroup analysis of the BIOSCIENCE randomised trial

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Newer-generation ultrathin-strut (60-65 μm) drug-eluting stents (DES) were recently associated with lower 1-year target lesion failure (TLF) rates, driven by a reduced risk of myocardial infarction (MI) and stent thrombosis (ST), compared with thicker-strut (81-120 μm) second-generation DES. Long-term clinical outcome data from randomized controlled trials investigating newer-generation ultrathin-strut versus thin-strut DES have not yet been reported.

METHODS AND RESULTS

We performed a subgroup analysis of patients included in the randomized, single-blind, multicenter, non-inferiority BIOSCIENCE trial (NCT01443104). Patients with minimal exclusion criteria undergoing percutaneous coronary intervention (PCI) for stable coronary artery disease or acute coronary syndrome (ACS) were randomly assigned to treatment with biodegradable polymer sirolimus-eluting stents (BP-SES; 60 μm and 80 μm strut thickness for stent diameters ≤3 mm and >3 mm, respectively) or durable polymer everolimus-eluting stents (DP-EES; 81 μm strut thickness). Patients were further divided according to vessel size into small- (stent diameter in any lesion ≤3 mm) and large-vessels (> or = 1 stent with stent diameter >3 mm) subgroups. Accordingly, patients in the small-vessels group were treated with ultrathin-strut (60 μm) BP-SES or thin-strut (81 μm) DP-EES, whereas patients in the large vessels group received thin-strut BP-SES (80 μm) or DP-EES (81 μm). The primary endpoint was TLF, a composite of cardiac death, target vessel MI, and clinically indicated target lesion revascularization (TLR) within 12 months.

Between March 1, 2012 and May 31, 2013, 2’109 out of 2’119 patients randomly assigned to treatment with BP-SES (n=1’056) or DP-EES (n=1’053) were included for analysis. In the small-vessels group (n=1’234; mean age, 66.2 years; male, 73%; diabetes, 24%; ACS, 53%; ST-segment elevation myocardial infarction, 17%), 603 patients were treated with ultrathin-strut BP-SES and 631 patients were treated with thin-strut DP-EES. There were no significant differences in target lesion characteristics among patients receiving ultrathin-strut BP-DES and thin-strut DP-EES in the small-vessels group. At 5 years, TLF had occurred in 124 patients (cumulative incidence, 22.3%) treated with ultrathin-strut BP-SES and 109 patients (18.3%) treated with thin-strut DP-EES (rate ratio [RR] 1.22; 95% confidence interval [CI] 0.94-1.58; p=0.13) in the small-vessels group, and in 72 patients (17.2%) treated with thin-strut BP-SES and 80 patients (19.5%) treated with thin-strut DP-EES (RR 0.87; 95% CI 0.63-1.20; p=0.39) in the large-vessels group (p for interaction=0.11). Cumulative incidences of cardiac death (9.0% vs. 6.7%; RR 1.29; 95% CI 0.85-1.96; p=0.23), target vessel MI (5.9% vs 6.6%; RR 0.92; 95% CI 0.58-1.47; p=0.73), and clinically indicated TLR (13.1% vs 10%; RR 1.34; 95% CI

0.95-1.89; p=0.10) were similar in patients treated with ultrathin-strut BP-SES and thin-strut DP-EES in the small-vessels group. There was no difference between groups in the cumulative incidence of definite ST at 5 years in both small-vessels (1.7% vs. 1.6%; RR 1.08; 95% CI 0.43-2.72; p=0.87) and large-vessels (1.6% vs. 1.8%; RR 0.96; 95% CI 0.33-2.74; p=0.94) groups (p for interaction=0.87).

CONCLUSIONS

At 5 years, newer-generation ultrathin-strut BP-SES did not improve clinical outcomes compared with thin-strut DP-EES in all-comer patients undergoing PCI.

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LAA thrombus and TAVI: prevalence and clinical outcome

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Approximately one third of patients undergoing transcatheter aortic valve implantation (TAVI) are suffering from atrial fibrillation. However, the exact prevalence of left atrial appendage (LAA) thrombus in these patients remains unknown. The risk of intraprocedural embolism and potential therapeutic implications remain unclear. The aim of this study was to assess the prevalence and determine the impact of LAA thrombus or spontaneous echo contrast (SEC) on clinical outcome in patients undergoing TAVI.

METHODS AND RESULTS

A retrospective single-center analysis evaluated 2549 consecutive patients who underwent TAVI between 2008 and 2017. Patients with valve-in-valve procedures, cerebrovascular protection devices or insufficient transoesophageal echocardiographic imaging were excluded (n = 831). From the remaining 1718 patients, 161 patients with a solid LAA thrombus or moderate/severe SEC (group 1) were propensity-score matched to 161 patients without LAA thrombi or only mild/mild to moderate SEC (group 2) according to baseline and procedural variables. The primary outcome was disabling ischemic stroke within 24 hours after TAVI. The secondary outcome was defined as a composite of all-cause mortality, acute kidney injury stage 3 or any stroke at 30 days. Additional outcomes were evaluated in accordance with the VARC-2 definitions.

The prevalence of solid LAA thrombi was 4.4% (13.2% of patients with AF) in the overall TAVI population; moderate/severe SEC was detected in additional 6.0% of patients (17.8% of patients with AF). Propensity-score matching yielded a well-balanced high-risk patient population (median age 82.8 [78.4-85.9] years, STS score 7.1±4.8%, 95% NYHA classes 3-4, CHAD2DS2-VASC-Score 4.1±1.1) without significant differences in baseline or procedural parameters. The primary outcome of early disabling ischemic stroke was 5.6% in group 1 and 2.5% in group 2 (p=0.25). The composite secondary outcome was 20.4% and 14.5%, respectively (p=0.25). There were no significant differences regarding additional VARC-2 defined endpoints between the two groups.

CONCLUSIONS

In a relevant number of patients undergoing TAVI, LAA thrombi or its precursors were detected. Moreover, a numerically higher rate of early strokes in these patients was found in these patients, albeit not reaching a level of statistical significance. Because of the clinical relevance of procedure-associated cerebrovascular events, any measures of prevention, e.g. the use of cerebral embolic protection devices, need to be investigated in these patients.

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Performance of supra-annular, intra-annular and infra-annular transcatheter heart valves in patients with small aortic annulus undergoing TAVI

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Small aortic annulus in patients undergoing surgical valve replacement and transcatheter aortic valve implantation (TAVI) is associated with increased risk for patient-prosthesis mismatch (PPM). Whether specific transcatheter heart valve (THV) designs yield superior hemodynamic performance in these small anatomies remains unclear. Our analysis aimed (i) to determine the incidence of PPM in patients with a small aortic annulus undergoing TAVI and (ii) to compare outcome and hemodynamic performance of different THV in this patient population.

METHODS AND RESULTS

A total of 1,501 consecutive patients treated with TAVI in 2014-2017 were retrospectively evaluated. In 185 of these patients a small aortic annulus was diagnosed were diagnosed, as defined by a MDCT-derived annulus area <400 mm2, and were included in this analysis. TAVI was performed with self-expanding supra- (Evolut R [n = 14]; Acurate neo [n = 58], balloon-expandable and self-expanding intra- (Sapien-3 [n = 64] and Portico [n = 30]), and mechanically-expandable infra-annular THV (Lotus [n = 19]). PPM was defined as indexed effective orifice area <0.85cm2/m2. Hemodynamic performance and early clinical outcomes were assessed.

Overall, the prevalence of small aortic annuli was 12.3%. These patients were 82.2 years (95% CI 78.7-86.1) old, 94.6% female, and at increased surgical risk (STS-PROM 4.7%, 95% CI 3.3-6.6%). Baseline mean aortic annulus area was 370 mm2 (95% CI 345-384) and similar among THV-groups (p=0.53). PPM after TAVI was detected in 24.6% of patients with small annuli. The incidence was higher after balloon-expandable intra-annular (42.8%) or mechanically-expandable infra-annular (23.1%) compared to self-expanding intra- and supra-annular THV implantation (8.4% and 14.6%, p=0.002). Correspondingly, residual mean transvalvular gradients were 11 mmHg (95% CI 9.0-14.0), 13 mmHg (95% CI 7.3-15.0), 7 mmHg (95% CI 5.0-9.6), and 8 mmHg (95% CI 5.0-11.0), respectively (p<0.001). Paravalvular regurgitation >mild was 3.3% and one-year mortality was 7.1% overall without significant differences among treatment groups.

CONCLUSIONS

In a contemporary TAVI population, a substantial number of – predominantly female – patients presented a small aortic annuli. A relevant number of these patients was left with PPM after TAVI. Self-expanding supra- or intra-annular THV may offer superior hemodynamics in these patients at risk.

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Six-month outcomes from the multicentre, prospective study with the novel PASCAL transcatheter valve repair system for patients with mitral regurgitation in the CLASP Study

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair

AIMS

Severe mitral regurgitation may lead to an impaired prognosis if left untreated. Transcatheter treatment options have emerged as an alternative to surgery and an adjunct to medical therapy. We report the six-month results of the PASCAL transcatheter valve repair system in treating patients with mitral regurgitation enrolled in the multicenter, prospective, single arm CLASP study.

METHODS AND RESULTS

The PASCAL implant is comprised of two broad and curved paddles, two clasps capable of independent leaflet capture, and a Nitinol woven spacer which enable optimized leaflet capture, intended to reduce mitral regurgitation while minimizing concentrated stress on the leaflets. Eligible patients had clinically significant MR despite optimal medical therapy and were deemed candidates for transcatheter mitral repair by the local Heart Team. Safety, performance, and clinical outcomes were prospectively assessed at baseline, discharge, 30 days, and 6 months post-procedure. All major adverse events (MAE) were adjudicated by an independent clinical events committee and echocardiographic images were assessed by a core lab. The MAE rate was the primary safety endpoint, defined as the composite of cardiovascular mortality, stroke, MI, new need for renal replacement therapy, severe bleeding, and re-intervention for study device-related complications.

Between June 2017 and September 2018, 62 patients were enrolled at 14 sites worldwide for transcatheter mitral valve reconstruction using the PASCAL system. The mean age was 76.5 years (62.9% male). All patients had MR grade ≥3+, with 59% functional, 34% degenerative, and 7% mixed etiology. The average STS Score for MV repair was 4.4%, EuroSCORE II was 5.2%, and 51.6% of patients were in NYHA Class III/IV. Successful implantation of the PASCAL device was achieved in 95% of patients. At discharge, 95% of patients had MR grade ≤2+ with 81% grade ≤1+. The MAE rate was 4.8%. At 30-day follow-up, paired analyses shows that 98% of patients had MR grade ≤2+ with 81% grade ≤1+ and 88% were in NYHA Class I/II ($p<0.0001$). The 6MWD improved by 38.9 m ($p=0.0015$) and was accompanied by average improvements in KCCQ and EQ5D scores by 14.1 points ($p<0.0001$) and 8.3 points ($p=0.0028$), respectively. The six-month data will be available for presentation.

CONCLUSIONS

In this early device experience, the Edwards PASCAL transcatheter valve repair system showed an acceptable safety profile and performed as intended in treating patients with mitral regurgitation. The PASCAL device resulted in significant MR grade reduction, which was associated with clinically and statistically significant improvements in functional status, exercise capacity, and quality of life. Continued follow-up is warranted to validate these initial promising results.

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TAVI in bicuspid aortic valve type 1: the role of the raphe on procedural outcomes

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Bicuspid aortic valve (BAV) type I, according to Sievert and Schmidtke classification, is characterized by the presence of a raphe. During the last decade, transcatheter aortic valve implantation (TAVI) has been recognized as a safe and effective treatment for aortic valve stenosis. However, BAV disease is still considered as a relative contra-indication for TAVI because of a low devices success and complications. Aim of this work was to evaluate the role of the raphe on procedural outcomes in BAV disease treated with TAVI.

METHODS AND RESULTS

We analysed all consecutive patients underwent TAVI for BAV type I disease at our institution between September 2007 and September 2018. A retrospective analysis of contrast-enhanced multislice computed tomography was done. The Annulus dimensions and the relative raphe length [RRL, (raphe length/annulus diameter derived by area) x100], the calcium score with Agatston and the raphe calcium volume (RCV, using a threshold of 850HU) were evaluated. The population was also stratified into two groups: who received a valve sized and who received a valve undersized, according to the operator preference and experience. The primary endpoint was the moderate to severe paravalvular leak (PVL≥2) and the not complete valve expansion (NVE). The devices success and procedural outcome were also evaluated.

Among a total of 19 BAV type I, 73.7% had a R-L raphe. Mean annulus perimeter was 77±7 mm with a mean annulus diameter derived by area of 24±2 mm. Mean raphe length was 12±3 mm with a mean RRL of 50±10%. The mean Agatston score was 4281±2219 AU and the median of RCV was 100 mm3 (IQR, 40-137 mm3). All but one TAVI were performed with a self-expandable valve. The devices success was of 84,2%, with a 15.8% of moderate to severe PVL. The predilatation was done in 52.6% of the cases and the postilatation in 57.9%. The rate of NVE was 31.6%. No annulus rupture, conversion to surgery, need for second valve or intraprocedural death were observed. There was a significant association between Agatston score with PVL≥2 (p=0.001), as well as a significant correlation between RRL and RCV with PVL≥2 and NVE (r=0.514, p=0.024). Furthermore, raphe length was an independent predictor for PVL at univariate analysis [OR 1.18 (95%IC, 1.01-1.39) p=0.047]. In our experience 11 prosthesis were sized (58%) and 8 (42%) undesized. Compared with undersized group, the incidence of PVL≥2 and NVE was of 77% in sized group when a RRL ≥ 50% was present. All PVL ≥2 occurred in this group when a RRL was ≥50% and RCV was ≥100 mm3.

CONCLUSIONS

Bicuspid aortic valve (BAV) type I is characterized by the presence of a raphe. In our experience, a raphe with a RRL ≥50% and RCV ≥100 mm3 was associated with PVL≥2 and NVE, particularly when a valve sized was implanted. In that subset of patients an undersizing of prosthesis could be suggest.

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First clinical evaluation of the PREVAIL paclitaxel-coated percutaneous transluminal coronary angioplasty balloon catheter: primary outcomes from the PREVAIL trial

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Treatment of stenosed lesions during PCI with a drug-coated balloon (DCB) can be a useful technique in the setting of in-stent restenosis or small vessels. The PREVAIL trial was designed to evaluate the clinical safety and efficacy of the next-generation Prevail Paclitaxel-coated Percutaneous Transluminal Coronary Angioplasty (PTCA) Balloon Catheter in the treatment of coronary de novo small vessel lesions and in-stent restenosis.

METHODS AND RESULTS

PREVAIL is a prospective, multicentre, single-arm study conducted at 10 centres in Europe and Asia-Pacific. Patients enrolled had documented stable or unstable angina and/or clinical evidence of ischemia, with 1 or 2 target lesions of ≤25 mm length, 2-4 mm reference diameter, ≥50% to <100% stenosis and amenable to treatment with DCB. Successful pre-dilatation with balloon angioplasty alone was required to proceed with study treatment by DCB. Clinical follow-up was planned for 30 days, 6 months and 1 year; angiographic follow-up at 6 months will assess in-stent (balloon) and in-segment late lumen loss (LLL), percent diameter stenosis, binary angiographic restenosis rate and minimal lumen diameter. The primary endpoint of the study was in-stent (balloon) LLL at 6 months as measured by coronary quantitative angiography. Secondary endpoints included rates of death, target vessel myocardial infarction, target vessel/lesion failure and target vessel/lesion revascularization. Fifty patients were enrolled in the study from October 2017 to July 2018. Patients' baseline characteristics included mean age of 64.9 ± 9.2 years, 82% male, 34% diabetics, 22% current smokers, 78% with prior PCI and 12% with prior CABG. Fifty-four target lesions were treated with DCB, with 48.1% treated as de novo lesions and 51.9% due to in-stent restenosis. A total of 35.2% of target lesions were in the left anterior descending artery, 33.3% in the left circumflex artery, and 31.5% in the right coronary artery. The 6-month primary endpoint and secondary endpoints will be presented at EuroPCR.

CONCLUSIONS

Clinical and angiographic results at 6 months with the Medtronic Prevail Paclitaxel-coated PTCA Balloon Catheter will be presented for the first time at EuroPCR 2019.

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First comparison of post-procedural bivalirudin infusion at full or low regimen in patients with ACS with or without STEMI: an analysis of the MATRIX trial

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

The value of prolonged bivalirudin infusion after percutaneous coronary intervention (PCI) in acute coronary syndrome (ACS) patients with or without ST-segment elevation remains unclear. The aim is to assess efficacy and safety of a full or low post-PCI bivalirudin regimen in ACS patients with or without ST-segment elevation

METHODS AND RESULTS

The MATRIX program (NCT01433627) assigned bivalirudin to patients without or with a post-PCI infusion at either a full (1.75 mg/kg/h) for up to 4 hours, or reduced (0.25 mg/kg/h) for up to 6 hours, regimen at the operator's discretion. The primary endpoint was the 30-day composite of urgent target-vessel revascularization, definite stent thrombosis, or net adverse clinical events (composite of all-cause death, myocardial infarction, or stroke [MACE] or major bleeding).

Results: Among 3610 patients assigned to bivalirudin, 1799 were randomized to receive and 1811 not to receive a post-PCI bivalirudin infusion. Post-PCI full bivalirudin was administered in 612 (STEMI=399; NSTE-ACS=213) whereas 1068 (STEMI=519; NSTE-ACS=549) patients received the low regimen. The primary outcome did not differ in STEMI or NSTE-ACS patients who received or did not receive post-PCI bivalirudin. However, full as compared to low bivalirudin regimen remained associated with a significant reduction of the primary endpoint after multivariable (rate ratio 0.21, 95% CI 0.12-0.35; p<0.001) or propensity-score (rate ratio 0.16, 95% CI 0.09-0.26; p<0.001) adjustment. Full post-PCI bivalrudin was associated with improved outcomes consistently across ACS types and in comparison with the no post-PCI infusion or heparin groups.

CONCLUSIONS

In ACS patients with or without ST-segment elevation, the primary endpoint did not differ with or without post-PCI bivalirudin infusion but a post-PCI full dose was associated with improved outcomes when compared with no or low-dose post-PCI infusion or heparin..

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Extended validation of novel 3D quantitative coronary angiography based software to calculate vessel FFR: the FAST EXTEND study

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Fractional Flow Reserve (FFR) assessment requires the use of a costly pressure wire in combination with a hyperemic agent, which may contribute to its low adoption in clinical practice. We recently demonstrated that FFR based on 3D-QCA (vessel FFR) as determined using novel software has a high linear correlation to invasively measured FFR, a high diagnostic accuracy to detect FFR≤0.80 along with a low inter-observer variability. The aim of the present study was to find the optimal diagnostic vFFR cut-off in a large series of patients who underwent routine pre procedural FFR.

METHODS AND RESULTS

Observational, single-center cohort study. Three hundred and three patients presenting with stable- or unstable angina or non-ST segment elevation myocardial infarction, referred for coronary angiography with or without percutaneous coronary intervention (PCI) and an indication to perform FFR between Jan 2016 and June 2018 were included. FFR measurements were performed using a pressure wire based system (St. Jude Aeris, Abbott Vasuclar, St Paul, MA). Two orthogonal angiographic projections were acquired to create a 3-D coronary artery reconstruction of the coronary artery using the CAAS workstation software (Version 8.0, Pie Medical Imaging, Maastricht, The Netherlands). vFFR was subsequently calculated using the aortic root pressure by a trained investigator blinded to the invasively measured FFR.

Mean age was 65±11 years and 67% were males. Mean FFR and vFFR were 0.84±0.07 and 0.85±0.07 respectively. A good linear correlation was found between FFR and vFFR ($r = 0.89$; $p < 0.001$). vFFR had a better accuracy in the identification of lesions with an FFR≤0.80 as compared to 3D-QCA, (AUC 0.95; 95% CI [0.93 - 0.98]) vs. (AUC 0.63; 95% CI [0.55 – 0.67]) respectively. vFFR had a sensitivity of 97% and a sensitivity of 74% to identify lesions with an FFR≤0.80. Positive and negative predictive values were 85% and 89% respectively.

CONCLUSIONS

vFFR based on 3D-QCA as determined using novel software has a high linear correlation to invasively measured FFR, a high diagnostic accuracy to detect FFR≤0.80 with a similar cut-off as invasively measured FFR.

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Aorto-ostial coronary CTO. Results and technical implications

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS
Percutaneous coronary intervention (PCI) of aorto-ostial coronary chronic total occlusion (CTO) is a challenging procedure due to lack of antegrade support, proximal cap ambiguity, and unclear vessel course. The aim of this study was to analyse the procedural aspects and outcomes of aorto-ostial CTO PCI

METHODS AND RESULTS
All patients undergoing aorto-ostial CTO PCI at 2 high-volume specialized CTO PCI programs between February 2013 and December 2018 were included. Aorto-ostial CTO location was considered if the proximal cap was within 5 mm of the aortocoronary ostium. Technical success was defined as residual stenosis <30% with TIMI 3 flow in the CTO vessel. Procedural success was defined as technical success plus the absence of in-hospital adverse events (all-cause death, Q-wave myocardial infarction, stroke, recurrent angina requiring target-vessel revascularization with PCI or coronary artery bypass graft, tamponade requiring pericardiocentesis or surgery). Major adverse cardiac events (MACE) on follow-up were defined as a composite of cardiac death, myocardial infarction, and clinical-driven target lesion revascularization. A total of 80 patients were included. Mean age was 63±11 years and 92.5% of patients were male. The most frequent target CTO vessel was the right coronary artery (n=77, 96.2%). Three patients (3.7%) presented an occluded left main and one patient (1.2%) had a CTO of a circumflex artery with an independent ostium. The mean J-CTO score was 2.9±1.0 and 26 (32.5%) were flush ostial CTOs (i.e., total absence of a stump). A retrograde approach was attempted in most of the patients (n=59, 73.7%). Technical success was achieved in 61 (76.2%) patients. Procedural success was observed in 59 (73.7%) patients. The most frequent successful crossing techniques were retrograde techniques: true-to-true in n=12 (19.7%) and reverse controlled antegrade and retrograde tracking in n=25 (41.1%) patients. In flush ostial CTOs, retrograde techniques were the crossing technique in an even higher proportion of cases (n=15, 78.9% vs. n=22, 52.4%, in flush vs. no flush ostial CTO; p<0.01). Reasons for failed recanalisation were: the absence of interventional collaterals in 9/19 patients (47.4%), the presence of an impenetrable cap in 7 (36.8%) and the impossibility to advance the microcatheter through the collaterals after successful wiring in the remaining 3 (15.8%). On multivariable analysis, the only predictor of recanalization failure was the absence of interventional collaterals (OR: 15.49, 95% IC: 3.01-79.85; p=0.001). Regarding in-hospital complications, 5 (6.2%) patients suffered a periprocedural myocardial infarction, 4 (5.0%) subjects presented contrast-induced nephropathy and 3 (3.7%) patients had a target CTO vessel perforation requiring covered stent implantation. No cardiac tamponade was observed. After a median follow-up of 30 months, MACE rate was 11.2%. Two (2.5%) patients died from cardiovascular cause and 7 (8.7%) needed repeat target vessel revascularization.

CONCLUSIONS
Aorto-ostial CTO is a complex anatomic subset. In our series, success rates were lower than those reported in contemporary registries in all-comers with CTOs. As a retrograde approach is usually required to cross the occluded segment, the presence of interventional collaterals seems to be key in the procedure success.

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Right ventricular reverse remodeling occurs early after TTVR for severe tricuspid regurgitation

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THEME: Interventions for Valvular Disease
TOPIC(S): Tricuspid / Pulmonary valve

AIMS

Transcatheter edge-to-edge tricuspid valve repair (TTVR) is a novel treatment approach in heart failure patients with moderate-to-severe tricuspid regurgitation (TR) at prohibitive surgical risk. We have previously shown that TTVR is associated with right ventricular reverse remodelling (RVRR) after 6 months. We investigated whether RVRR occurs early after TTVR and its potential implications for further outcome.

METHODS AND RESULTS

We measured standardized right heart parameters by transthoracic echocardiography (TTE) at baseline (BL) in 65 consecutive patients undergoing TTVR and obtained follow-up TTEs after 1-month and 6-month follow-up (FU).

Patients were treated with percutaneous edge-to-edge repair for severe TR alone (24 patients) or in combination with mitral valve repair for concomitant severe mitral regurgitation and at least moderate TR (41 patients). At BL, patients showed dilated right ventricular (RV) size with mean end-diastolic area (RVEDA) of 27.8±8.6cm2 and RV mid diameter of 41.5±7.3cm2. Tricuspid annulus was enlarged with 46.8±6.4mm. Fifty patients (77%) showed impaired RV systolic function with either a fractional area change (FAC) <35% or tricuspid annular plane excursion (TAPSE) <17mm. Right atrial (RA) end-systolic area was dilated with 38.5±13.3 cm2. Periprocedural TR reduction by at least 1 degree was achieved in 64 Patients (98%, p<0.001). During further clinical FU (mean 362±176 days), 24 patients died, 1 patient underwent heart transplantation and 1 patient was lost to FU.

Echocardiographic follow-up (Echo-FU) was possible in 54 patients (83%) after 1 month and 48 patients (74%) after 6 months. For 44 patients, echo data was available at all three timepoints. TR reduction was stable after 1 month with a TR grade ≤2+ in 48 patients (79%, p<0.001) compared to 3 (6%) before intervention. We could detect RVRR in the majority of patients with 1-month Echo-FU: RVEDA decreased from 27.6±8.5 to 25.0±7.6 cm2 (p<0.001) and RV mid diameter from 41.3±7.2 to 39.1±8.9 mm (p=0.049). The tricuspid annulus decreased from 46.5±6.5 to 41.6±5.5 mm (p<0.001). RV end-systolic area (17.4 to 16.0cm2, p=0.13) and RV longitudinal diameter (71.5 to 69.6mm, p=0.26) did not change. We did not observe a significant change in TAPSE (15.6mm to 15.2 mm, p=0.38) or FAC (s36.9% to 34.5%, p=0.0502). In addition, RA area decreased from 37.6±12.3 to 35.2±10.1 cm2 (p=0.05). After 6 months RVRR persisted compared to 1-month Echo-FU with RVEDA of 24.2±7.5cm2 (Figure A left) and RV mid diameter of 36.9±7.9mm (Figure A right). Although the tricuspid annular diameter increased significantly to 43.7±6.8mm (p<0.001 vs 6-month FU), there was still a significant reduction compared to baseline (p<0.001). The RA area dilated again to baseline levels (37.0±14.8cm2).

We evaluated a possible association of RVRR with clinical outcome and stratified patients into two groups with more or less than median change in RVEDA (< or ≥ 9.1% reduction after 1 month compared to BL). Patients with pronounced RVRR at 1-month Echo-FU had fewer combined clinical endpoints (death, repeat intervention or hospitalization for heart failure; 11 vs 27, p=0.002, Figure B) at FU.

CONCLUSIONS

Our report demonstrates that RVRR occurs already 1 month after TTVR and persists up to 6 months. Presence of RVRR is associated with less clinical endpoints.

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Better outcomes related with rotablation and provisional stenting approach in patients with bifurcation lesion

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion, Other Coronary Interventions

AIMS

Coronary bifurcations lesions are present in up to 20% of PCI. PCI in this setting is complex. In spite of several approaches described SB compromise and need for treat them are common. This increases procedural complexity worsening cardiovascular and angiographic events rates. We report data from patients with BL treated or not with rotational atherectomy (RA) and provisional stenting (RAPS).

METHODS AND RESULTS

population randomized included 64 consecutive patients that underwent RA for 87 BL (RA+) with a control group (RA-) of 64 pt with BL non-treated with RA. We observed better results and outcomes with RA+ than in RA-. This assessment is based on the lower rates of provisional stenting, lower need of balloons and stents per lesion and lower rates of two-stent technique in RA+ vs RA-: 1.4 vs 4.6 (p = 0.002), 1.6 vs 2.3 (p = 0.04) and 0% vs 40.6% (p < 0-001) respectively. In addition, procedural time and fluoroscopy time were lower in RA+. After 3 years of FUP these results correlate with a lower TVF: target vessel failure (composite of: cardiac death, vessel-related MI, TVR) and TBR (target bifurcation restenosis) in RA+ vs RA-: 13.1% vs 24.8% (p = 0.04) and 1.5% vs 7.8% (p = 0.03) respectively.

CONCLUSIONS

Slow-speed RAPS for BL reduces angiographic complexity, increases side-branch patency and improves TVF and TBR outcomes.

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Outcomes in patients with pre-existing atrial fibrillation undergoing TAVI

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Chronic atrial fibrillation is common among patients with aortic stenosis undergoing transcatheter aortic valve implantation (TAVI). There is limited information regarding the impact of atrial fibrillation on outcomes following TAVI. We examined the anticoagulant medication regimen and outcomes in patients with or without a documented history of atrial fibrillation in REPRISE III.

METHODS AND RESULTS

REPRISE III is a randomised, multicentre trial comparing a mechanically-expanded to a self-expanding TAVI valve in patients with severe aortic stenosis at high or extreme risk for surgery. A total of 912 patients were randomised 2:1 (607 mechanically-expanded: 305 self-expanding valve). Enrolled patients were required to have a Society of Thoracic Surgeons risk of mortality score ≥8% or another indicator of high or extreme risk (based on Heart Team assessment); 51% were female.

Chronic atrial fibrillation was present in approximately one-third of REPRISE III patients (n=310); two-thirds did not have diagnosed atrial fibrillation at baseline (n=600; atrial fibrillation status was unknown in 2 patients). In patients with pre-existing atrial fibrillation, 55% (165/310) received an oral anticoagulant at discharge while 45% (135/310) did not. In patients treated with an oral anticoagulant, most received warfarin (77%, n=127/165); 64 patients also received aspirin, 46 clopidogrel, 45 both aspirin and clopidogrel while 10 received the oral anticoagulant alone. Patients with baseline atrial fibrillation who did not receive an oral anticoagulant at discharge were treated with dual antiplatelet therapy (n=95), aspirin alone (n=17), clopidogrel monotherapy (n=11) or neither antiplatelet nor anticoagulant medications (n=12).

Mortality through 2 years was 30% in patients with pre-existing atrial fibrillation and 17% in patients without atrial fibrillation (P<0.01). Stroke occurred in 13% of atrial fibrillation patients compared with 8% of non-atrial fibrillation patients (P=0.01). There was an increase in disabling stroke in patients with atrial fibrillation (9.1% vs 4.4%, P=0.01). Hospitalization for worsening congestive heart failure (NYHA class III or IV) was 22% versus 17%, respectively (P=0.02). The occurrence of life-threatening or major bleeding within 2 years was 20% versus 24% in patients with and without baseline atrial fibrillation (P=0.32); after excluding procedural bleeding, the bleeding rates were 14.6% vs 9.3% (P=0.03). Multivariate adjustment of baseline characteristics and an analysis of patients who developed atrial fibrillation post-procedure will be available at the time of the presentation.

CONCLUSIONS

Almost half of all patients with atrial fibrillation at baseline in REPRISE III were not treated with oral anticoagulation. Mortality, stroke, hospitalization, and post-procedural bleeding were increased in patients with atrial fibrillation.

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Impact of frailty in elderly patients hospitalised for ACS

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(1) ,

THEME: Coronary Interventions
TOPIC(S): NSTEMI

AIMS

Frailty status is difficult to define especially in the elderly. There is no standardised method for assessment of this condition. Frailty has a strong impact on clinical prognosis also in patients with acute coronary syndrome (ACS). The aim of this prospective study was to: 1) establish the prevalence of frailty in elderly (≥75 years) patients hospitalized for ACS scheduled for invasive strategy; 2) evaluate the possible association between frailty and in-hospital complications; 3) estimate short term changes in muscular strength during hospitalization and at 1 month control.

METHODS AND RESULTS

The 5-item FRAIL scale (FS) was administered to all ACS patients ≥75 years on admission. Handgrip strength (HGS) was evaluated on admission, at discharge and 1 month later at clinical follow-up. Assignment of frailty status depends on a combination of FS score and HGS: Frail = FS frail and FS pre-frail with HGS weak; Non-frail= FS robust and FS pre-frail with HGS normal or strong. We enrolled 203 consecutive ACS patients (117 men, 86 women; age 81±6 yrs). On admission 37% were Frail and 63% Non-frail. The Frail group were generally older, female and presented more comorbidities. During hospitalization 8.4% of patients experienced episodes of altered cognitive state (15% Frail and 2% Non-frail); acute kidney injury occurred in 12.8% of cases (23% Frail and 7% Non-frail); bleeding (Bleeding Academic Research Consortium ≥ 2) was diagnosed in 14.3% (17% Frail and 9% Non-frail). At discharge HGS had increased in women (p=0.01) and in men (p=0.04). These findings remained stable at 1 month follow-up.

CONCLUSIONS

Elderly ACS patients are frequently frail and are more subject to in-hospital complications. Recognition of frailty is important for proper care of these patients. The combination of the FS and HGS allows easy definition of frailty status in elderly ACS patients managed for invasive strategy.

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Dabigatran in patients with atrial fibrillation undergoing primary PCI for STEMI - A subanalysis of the randomised RE-DUAL PCI trial

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Patients with ST elevation myocardial infarction (STEMI) undergoing primary PCI have a high thrombotic risk and dual antiplatelet therapy is recommended to reduce stent thrombosis and recurrent ischemic events. In RE-DUAL PCI, dabigatran dual antithrombotic therapy reduced the risk of major or clinically relevant non-major bleeding versus warfarin triple therapy in patients with atrial fibrillation after coronary stenting, with similar efficacy. To explore whether dabigatran and a P2Y12 inhibitor is effective and safe in patients with STEMI, we performed a subgroup analysis.

METHODS AND RESULTS

There were 305 patients with STEMI randomized to dabigatran 150 mg (n=86) or 110 mg (n=113) plus clopidogrel/ticagrelor, or warfarin (n=106), clopidogrel/ ticagrelor and aspirin (for 30 days post bare metal stents (BMS), 90 days for drug eluting stents (DES).

In the combined analysis of both dabigatran doses the primary endpoint (ISTH major or clinically relevant non-major bleeding)was significantly reduced with dabigatran (odds ratio 0.41; 95 % CI 0.21-0. 81) versus warfarin without any difference for the main ischemic endpoint, a composite of thromboembolic events,death or unplanned revascularization(odds ratio 1.12; odds ratio 0.60-2.10). For dabigatran 110mg and 150 mg the corresponding odds ratios for bleeding were 0.39 (95 % CI: 0.20-0.74) and 0.43 (95 % CI: 0.21–0.89) and for ischemic events 1.61 (95 % CI: 0.85-3.08) and 0.56 (95 % CI: 0.20-1.51).

CONCLUSIONS

In this subgroup analysis in the STEMI population of the RE-DUAL PCI trial, consistent to the overall trial results dabigatran compared to warfarin reduced the primary bleeding endpoint without an increase in ischemic or embolic events. Therefore, double therapy with dabigatran and a P2Y12 inhibitor should be preferred over warfarin triple therapy even in the high-risk STEMI population

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Efficacy of alcohol septal ablation for hypertrophic cardiomyopathy with mid-ventricular obstruction

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THEME: Interventions for Valvular Disease
TOPIC(S): Other valvular and structural interventions

AIMS

Several reports have demonstrated the efficacy of alcohol septal ablation (ASA) for hypertrophic cardiomyopathy with left-ventricular outflow tract obstruction, however, that for mid-ventricular obstruction (MVO) remains unknown. We assessed the clinical outcomes of ASA for hypertrophic cardiomyopathy with MVO.

METHODS AND RESULTS

We analyzed consecutive 26 patients with MVO undergoing ASA from March 2008 to December 2018. ASA had been performed under local-anesthesia with contrast transthoracic echocardiography. The procedural endpoint of ASA was the ablation of culprit stenotic lesion. Mean age of 26 patients was 61 ± 20 years, and 18 patients (69%) were female. Although all patients had been receiving optimal medical therapy (β-blocker in 26 patients [100%], calcium channel blockers in eight patients [31%], and class I antiarrhythmic drugs in 24 patients [92%]), they had refractory heart failure symptom or ventricular arrhythmia. In ASA, number of ablated septal branch was 2.4 ± 0.7 branches, and amount of the ethanol used was 3.5 ± 1.3 ml. Mean peak plasma creatinine phosphokinase released was 1,263 ± 732 IU/l. Peak systolic pressure gradients between left-ventricular apex and ascending aorta had decreased from 100 ± 54 mmHg to 56 ± 44 mmHg ($p<0.0001$). Procedural major adverse events had occurred in three patients (12%: two coronary artery injury, and one transient atrioventricular block not necessitating permanent pacemaker implantation). The New York Heart Association functional class had improved from 2.3 ± 0.7 before ASA to 1.3 ± 0.4 at 3-month follow-up ($p<0.0001$). During follow-up of 4.9 ± 2.6 years, there were three deaths (12%; the causes of death were cerebral infarctions in two patients, and breast cancer in one patient), and five re-interventions of ASA (19%). The freedom from all-cause death and all-cause death or re-intervention were 100%/96%, 95%/79%, and 95%/79% at one-, three-, and five-year following ASA.

CONCLUSIONS

ASA had alleviated the New York Heart Association functional class in patients with MVO, and long-term outcome following ASA is relatively favorable. In patients with MVO presenting refractory symptom despite optical medical therapy, ASA should be a good therapeutic option.

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Platelet inhibition affects high-intensity transient signals to cerebral circulation during TAVI

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Transcatheter aortic valve implantation (TAVI) has provided a therapeutic alternative to patients suffering from symptomatic severe aortic stenosis. Despite the established dual antiplatelet treatment, embolic cerebrovascular events remain a major concern peri-operatively and following TAVI. It has been shown that high Residual Platelet Reactivity (RPR) may contribute to platelet aggregation, propagating thrombosis on implanted materials. Therefore, we evaluated whether high RPR may predispose to an increased number of cerebrovascular emboli during the procedure.

METHODS AND RESULTS

Consecutive patients who underwent transfemoral TAVI with the self-expandable Medtronic CoreValve™ Evolut™ R system were prospectively studied. Dual antiplatelet therapy with aspirin and a P2Y12 inhibitor was administered to all patients 24 hours prior to the procedure at loading dose. The number of detected High-Intensity Transient Signals (HITS) was assessed using Rimed Digi-Lite™ Transcranial Doppler (TCD) on both cerebral arteries during the following phases of the procedure; Phase 0: 30 minutes prior to procedure initiation, Phase I: between access site puncture and introduction of the pre-dilation balloon, if needed, Phase II: during valvuloplasty (if applied), prior to valve deployment, Phase III: during the implantation of the mounted prosthesis, until the removal of the delivery system. Platelet inhibition was measured prior to the procedure and expressed in PRU, using the VerifyNow® assay and defined as high RPR if PRU≥208.

Out of 36 total patients (81±7 years, 23 males (64%)), 15 patients (81±9 years, 10 males (66.7%)) had PRU ≥208 (high RPR group), while 21 patients (81±5 years, 13 males (61.9%)) had PRU≤208 (low RPR group). All device implantations were performed without balloon pre-dilation. Among the high RPR group, a statistically significant higher number of HITS was recorded compared to the low RPR group (716±134 vs. 526±139, p<0.001).This was mainly driven by the number of HITS detected during Phase III, compared to the rest procedure stages (235±79 vs. 167±27, p:0.003). A statistically significant correlation of PRU with the total number of HITS was found (r2: 0.27, p: 0.001).

CONCLUSIONS

High RPR after dual antiplatelet loading resulted in a larger burden of embolic HITS during TAVI. It seems that this is more prominent during the stage of valve deployment across the heavily calcified aortic annulus.

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Outcome of PCI with the Xience family everolimus-eluting stents compared with a pooled set of other commonly used modern DES: nationwide data from the Swedish Coronary Angiography and Angioplasty Registry (SCAAR)

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

The Abbott Xience family drug-eluting stents (DES) are among the most commonly used DES worldwide for percutaneous coronary intervention (PCI). The aim of this study was to compare outcome with Xience DES to outcome with other commonly used modern DES in a large, unselected, nationwide, real-world population undergoing PCI.

METHODS AND RESULTS

This observational study was based on the Swedish Coronary Angiography and Angioplasty Registry (SCAAR). 11562 patients treated with Xience DES were compared with a pooled set of 53548 patients treated with other, commonly used modern DES (Biosensors Biofreedom and BioMatrix; Biotronik Orsiro; Boston Scientific Promus family and Synergy; Medtronic Endeavor, Endeavour Resolute, Resolute Integrity and Resolute Onyx; Terumo Ultimaster).

All stents were implanted between January 2007 and December 2017. Mean follow-up time was 4.3 years for patients treated with Xience DES compared with 2.9 years for those treated with other DES. Outcomes were analyzed on individual and stent level. End-points were presented using Kaplan-Meier plots and differences in outcome assessed by log-rank test and Cox Regression. Several additional regression models and a propensity score matched model were used for sensitivity analyses. The groups were similar in age, gender, comorbidities, indication for PCI as well as in PCI-related technical data, at baseline.

The primary outcome, a composite of all-cause death, acute myocardial infarction (AMI) or revascularization with PCI occurred in 3689 patients among the Abbott DES treated (corresponding event rate 9.1% per year) and in 15110 patients treated with other DES (11.9% per year), hazard ratio (HR) 0.928 (95% confidence interval [CI] 0.90-0.96) adjusted HR 0.992(95% CI 0.95-1.03).

All cause-death occurred in 2.9% and 3.5% per year, respectively, HR 0.869 (95% CI 0.82-0.92), adjusted HR 0.958 (95% CI 0.90-1.02). Rates of AMI were 1.7% and 1.8% per year, respectively, HR 1.077 (95% 1.00-1.17), adjusted HR 1.054 (95% CI 0.97-1.15). The rate of PCI revascularization was 5.7% per year for Abbott DES and 7.8% for other DES, HR 0.950 (95%CI 0.91-0.99), adjusted HR 0.999 (95% CI 0.95-1.05). All sensitivity analyses were consistent with the main analysis.

In the stent level analysis, rates of restenosis were 0.7% (n=1073) per year for Xience DES vs 0.7% (n=3481) for other DES, HR 1.079 (95%CI 0.99-1.17), adjusted HR 0.926 (95%CI 0.81-1.06). Rates of definite stent thrombosis were 0.2% (n=347) per year vs 0.2% (n=1170), HR 1.140 (95%CI 0.99-1.32), adjusted HR 1.067 (95%CI 0.82-1.39). All sensitivity analyses including only single stent-treated patients, propensity matched group analyses and subanalyses on small-, medium- and large size stent subgroups were consistent with the

main results showing similar outcome for Xience DES and other DES. Mean follow-up time was 1516 days and 1034 days, respectively, on stent level.

CONCLUSIONS

In this large, unselected, nationwide, real-world study of patients undergoing PCI for all indications we found no difference in the outcome of patients treated with Xience family DES compared with patients treated with a pooled set of other commonly used modern DES. Results were consistent for the primary composite end-point of all-cause mortality, AMI or revascularization with PCI, and for the individual components of the composite endpoint. Rates of restenosis and definite stent thrombosis were low and similar for Xience DES and other modern DES.

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Value of GRACE risk score in risk stratification in ACS patients undergoing PCI in the Global Leaders study

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

Aims: We sought to evaluate the value of GRACE risk score in stratifying acute coronary syndrome patients undergoing percutaneous coronary intervention in the Global Leaders study.

METHODS AND RESULTS

Methods: Global Leaders study was a prospective, multi-center, open-label, all-comers, randomized controlled trial comparing ticagrelor monotherapy after 1 month of dual antiplatelet therapy (DAPT) as experimental therapy with aspirin monotherapy after 12 months of conventional DAPT (reference therapy) in patients who received PCI with biolimus-A9 eluting stent. We assessed the predictive value of GRACE risk score in ACS patients undergoing PCI in the present analysis. Patients were stratified according to GRACE risk score into low (1-108), moderate (109-140), High (141-372) risk group. Clinical outcomes at 2 years after PCI were assessed and compared among risk groups. Interaction between GRACE risk score and antiplatelet regimen were analyzed by the interaction term in Cox model.

Results: GRACE risk score was calculated from 8 clinical parameters at presentation. Among ACS patients, 1664 patients were categorized in low risk group, 2903 patients were in moderate risk group, and 2028 patients were in high risk group. The rate of all-cause mortality, any stroke, patient-oriented composite endpoint (POCE) were highest in the high-risk group at 2 years (All-cause mortality; low risk 1.4%, moderate risk 2.5%, high risk 6.1%, log rank test p value < 0.0001, any stroke; low risk 0.7%, moderate risk 1.0%, high risk 2.0%, log rank test p value 0.001, POCE; low risk 12.4%, moderate risk 11.9%, high risk 16.61%, log rank test p value < 0.0001). The rate of myocardial infarction, all revascularization and definite or probable stent thrombosis were not different among three groups. There was no interaction between GRACE risk score and treatment regimen on clinical outcomes at 2 years.

CONCLUSIONS

Conclusion: GRACE risk score is valuable in identifying ACS patients with highest risk of all-cause mortality, any stroke and POCE at 2 years after PCI. In ACS, ticagrelor monotherapy did not improve the outcomes at 2 years in the three strata of the GRACE risk score.

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Five-year clinical outcomes after edge-to-edge mitral valve repair by MitraClip system: insights from the GRASP-IT registry

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair

AIMS

To investigate 5-year clinical outcomes of a large multicentre real-world population undergoing MitraClip implantation.

METHODS AND RESULTS

The GRASP-IT (Getting Reduction of mitrAl inSufficiency by Percutaneous clip implantation in ITaly) registry retrospectively collected data from 304 consecutive patients with symptomatic moderate-to-severe (30%) or severe (70%) mitral regurgitation (MR) undergoing MitraClip implantation between October 2008 and October 2013 at 4 Italian centres, with no exclusion criteria. Mean age was 72 (10) years and 64% of patients were males. Primary MR was observed in 64 (21%) patients, whereas ischaemic and idiopathic functional MR were detected in 136 (45%) and 104 (34%) subjects respectively. Acute procedural success was achieved in 92% of population. During the follow-up a total of 117 patients died at median of 552 days, 64 out of them due to cardiovascular cause. At a median of 334 days, 85 patients experienced hospitalization due to heart failure (HF). The composite end-point, including all-cause death and HF hospitalization, occurred in 166 patients at a median of 362 days. Survival free from 5-year all-cause death was 54.7% and significantly higher in patients with primary MR (63%) and idiopathic functional MR (64.7%) compared to those with ischaemic functional MR (44.8%) (P= 0.022). The same trend was observed for survival free from 5-year cardiovascular death, which was 70.1% (77.7% in primary MR, 76.7% in idiopathic functional MR and 61.1% in ischaemic functional MR; P= 0.033). Survival free from 5-year HF hospitalization was 60% and numerically higher in patients with primary MR (76.2%) compared to those with ischemic (52.9%) and idiopathic functional MR (58.6%) (P=0.064). Survival free from 5-year composite end-point was 37.2% and significantly lower in patients with functional ischaemic MR (28.3%) compared to idiopathic functional MR (43%) and primary MR (47.7%) (P=0.023). Ischaemic aetiology of MR was associated to an increased adjusted relative risk of 5-year all-cause death or HF hospitalization (HR=1.52 [95% CI: 1.1-2.1]; p=0.012). Among patients with ischaemic functional MR those with advanced New York Heart Association (NYHA) class (IV) and dilated left ventricle (LV end-diastolic diameter [LVEDD] ≥65mm) had even worse prognosis. In the overall population, NYHA class IV and LVEF ≤30% were independent predictors of both all-cause and cardiovascular death at 5 years; and in addition to ischaemic aetiology, acute procedural failure was an independent predictor of 5-year composite end-point. Finally, LVEDD≥65 mm, previous hospitalization due to HF, history of COPD and previous aortic interventions were independent predictors of both HF hospitalization and composite end-point at 5 years.

CONCLUSIONS

Five-year clinical outcomes after Mitraclip had different trends according to MR aetiology. Patients with functional ischaemic MR had significantly worse prognosis compared to those with functional idiopathic and primary MR. Advanced disease (severe symptoms, LV dilation and dysfunction) and acute procedural failure

also affect long-term outcomes.

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The efficacy of novel DEB with citrate ester excipient in PCI of de novo lesions: an all-comer registry study

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THEME: Coronary Interventions
TOPIC(S): NSTEMI, Stable CAD

AIMS

The aim of this single-center all-comers retrospective registry study was to assess the efficacy of a novel drug-coated balloon (DCB) with citrate ester excipient (acetyl tributyl citrate, 2 µg/mm2 paclitaxel, AgentTM, Boston Scientific) in PCI of de novo lesions including large proximal coronary arteries.

METHODS AND RESULTS

A total of 341 PCIs were performed in 489 de novo lesions using Agent DCB, respectively. Outcome endpoints were major adverse cardiac events (MACE) and ischemia-driven target lesion revascularization (TLR). MACE was defined as cardiovascular death, non-fatal myocardial infarction or TLR. The mean follow-up time was 22±12 months. The mean age of the patients was 71±11, 68% were male and 48% had an acute coronary syndrome. In 12% of cases rotational atheroctomy was used. The mean diameter of the DCBs used was 2.7±0.5 mm. At 12 months, the TLR and MACE rates were 6.2±1.3% and 12.1±1.8%, respectively. Bailout stenting was used in 8% of lesions.

CONCLUSIONS

This is the first report of Agent DCB in PCI of de novo coronary artery lesions. The DCB-only strategy using this novel DCB was safe and effective in an all comers population.

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Risk of cardiac and sudden death with and without revascularisation for each target coronary CTO

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Previous analyses highlighted different impact of successful chronic total occlusion (CTO) percutaneous coronary intervention (PCI) on cardiac mortality depending on target CTO vessel. The discrepancies between studies could be explained by different proportion of CTOs in the territory of previous myocardial infarction. The aim of this study is to investigate the impact of successful CTO PCI on clinical outcome depending on target infarct related artery (IRA).

METHODS AND RESULTS

Between 1998 and 2008, 1162 patients who underwent CTO PCI attempt were included in this long-term analysis: 837 patients with successful CTO revascularization (CTO-R) vs. 325 not-revascularized (CTO-NR); 634 with IRA CTO vs. 528 NON-IRA CTO; 360 (31%) CTOs in left anterior descending (LAD) coronary artery, 485 (42%) in right coronary artery (RCA), 311 (27%) in left circumflex coronary artery (LCx). The primary endpoint was the rate of cardiac death during follow-up; the secondary endpoint was the rate ofsudden cardiac-death (SCD) and/or sustainedventricular-arrhythmias (SVAs).

Up to 12-year follow-up(median 6-year), compared to CTO-R patients, those with CTO-NR had significantly higher rate of cardiac death [13% (43/325) vs. 6% (48/837); p<0.001]and SCD/SVAs [7.5% (24/325) vs. 2.5% (20/837); p<0.001]. The risk of cardiac death and SCD/SVAs was mainly driven by the subgroup of patients with infarct-related artery (IRA) CTO on LCx (21% vs. 7% vs. 5%, p<0.001; 13.5% vs. 7% vs. 4%, p=0.003; IRA-CTO LCX vs. IRA-CTO RCA vs. IRA-CTO LAD respectively), and was significantly higher in IRA LCx CTO-NR patients (40.5% vs. 17.5%, p<0.001; 24% vs. 10%, p<0.001; IRA LCx CTO-NR vs. NON-IRA LCX CTO-NR, respectively). At Multivariable Cox hazards regression analysis CTO-NR and LCx remain the strongest independent predictors of higher risk of cardiac death and of SCD/SVAs in the overall population and in IRA CTO patients.

CONCLUSIONS

At long term follow-up, the presence of CTO on LCx was associated with higher cardiac death and SCD/SVAs compared to LAD and RCA, regardless of revascularization. The risk was mainly driven by the presence of an infarct-related artery (IRA CTO) not-revascularized.

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Outcome of TAVI in bicuspid aortic valve stenosis with new-generation devices: comparison between Lotus, Evolut-R, and ACURATE neo

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

To compare procedural outcome of three second-generation trancatheter aortic valve implantation (TAVI) devices in patients with bicuspid aortic valve stenosis.

METHODS AND RESULTS

This retrospective study included 44 patients with bicuspid aortic valve stenosis demonstrated at computed tomography (CT) angiography, who underwent TAVI with Lotus (N=12, 27.3%), Evolut-R (N=18, 40.9%), and Acurate NEO (N=14, 31.8%) at three institutions between 2015 and 2018.

Overall, mean age of the study populations was 76.1 ± 10.8 years; no significant differences in the rates of cardiovascular risk factors were evident among the Lotus, Evolut-R, and Acurate NEO groups. STS score tended to be higher in Evolut-R patients (4.0 ± 2.2) as compared to the Lotus and Acurate NEO ones (2.3 ± 1.6 and 3.6 ± 2.1; P=0.09). Ejection fraction was overall preserved (51.3% ± 14.5%) with elevated mean gradients (52.9 ± 15.7 mmHg). On CT angiography, a semi-horizontal aorta (aortic angle >50°) was a frequent finding in 48% of patients, calcium volume 800 was elevated (711.9 ± 477.9 mm3), and ascending aorta was dilated (mean diameter 38.2 ± 5.7 mm) with no differences among the three groups.

Predilatation was performed more frequently in Acurate NEO patients (100%) as compared to Lotus (83.3%) and Evolut-R (50%; P=0.004); implantation depth at the level of left coronary cusp was greater in the Evolut-R group (7.6 ± 3.4 mm) as compared to Acurate NEO (3.0 ± 3.2 mm) and Lotus group (4.8 ± 2.7 mm; P=0.001) whereas no differences were evident at the level of the non-coronary cusp (P=0.22).

Postoperatively, the rate of moderate paravalvular leak was higher in Evolut-R patients (44.4%) as compared to Lotus (8.3%) and Acurate NEO patients (7.1%; P=0.04).

Conversely, mean gradients were higher in the Lotus group (14.8 ± 7.1 mmHg) with respect to Evolut-R (8.1 ± 4.1 mmHg) and Acurate NEO groups (9.6 ± 2.7 mmHg; P=0.003).

Device success was 68.1% and tended to be higher in Acurate NEO and Lotus patients (respectively 85.7% and 75%) compared to Evolut-R (50%) patients (P=0.08).

CONCLUSIONS

In patients with bicuspid aortic valve stenosis, implantation of Acurate NEO and Lotus was associated with good PVL and device success rates, as compared to Evolut-R, which was conversely associated with a lower implantation at the level of left coronary cusp.

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TAVR using the Hydra self-expanding bioprosthesis- A single-centre experience

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS
This study was aimed to analyse and document the initial experience with transcatheter aortic valve implantations using the Hydra self-expanding aortic bioprosthetic valve in patients with symptomatic, severe aortic stenosis.

METHODS AND RESULTS
Implantation of the Hydra aortic valve was performed in patients with symptomatic, severe calcific aortic stenosis with tricuspid morphology in a tertiary care centre. Hydra has a self-expanding Nitinol stent frame, with a bovine pericardial tissue valve. It has non-flared inflow section of the frame and a supra-annular valve leaflet design. The valve has got 3 tentacles or antenna for better anchorage and larger cells (10mm). The delivery cable is highly flexible and18 F compatible, and the device can be recaptured/ repositioned after around 85%-90% deployed.
In the study cohort, surgical aortic valve replacement was deferred based on heart team assessment of an estimated high and intermediate surgical risk. The valve was implanted in 9 patients with mean Society of Thoracic Surgery score 5.1%, mean age 76.5 years, mean aortic valve area 0.68 cm2, mean aortic pressure gradient 61.33 mmHg. In 7 patients, the procedure was performed under general anaesthesia with online TEE monitoring, while conscious sedation was used in the rest. Surgical femoral arteriotomy was used in 7 patients, whereas the remainder had a percutaneous transfemoral approach. All but one valves were predilated. All valves were post dilated.
Valve deployment was successful in all patients in one attempt. There was one procedural death due to refractory hemodynamic collapse from right ventricular perforation, after a successful valve deployment. There was no coronary occlusion, major bleeding or major vascular complications. One patient developed transient complete AV block which recovered in 4 hours and was managed conservatively. No patient required new permanent pacemaker implantation. At 30-day follow-up, the median aortic valve area and pressure gradient were 1.83 cm2 and 8 mmHg, respectively. The prevalence of more than mild paravalvular leakage and new complete left bundle branch block was 11.1% (1 patient) and 33.3% (3 patients), respectively. None of the patients suffered from stroke or TIA.

CONCLUSIONS
The new Hydra aortic bioprosthetic valve appear safe and useful for transcatheter treatment of severe calcific aortic stenosis with tricuspid valve morphology. The study results showed a good hemodynamic performance and complication rates comparable to those reported for second-generation transcatheter aortic self-expanding bio prostheses.

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Comparison of safety and efficacy of a personalised radial haemostasia protocol using pneumatic vs. mechanical wristbands

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

Current protocols of haemostasia after catheterisation through the radial access disregard both the type of procedure and the type of wristband. The aim of this prospective observational study was to evaluate the efficacy and safety of a personalised protocol of haemostasia, empirically designed in our cathlab, comparing the type of wristband (pneumatic vs. mechanic).

METHODS AND RESULTS

36 patients undergoing cardiac catheterization through radial access were submitted to a personalised protocol of haemostasia with varying compression times: 45 minutes, 2 hours and 4 hours for a diagnostic procedure, a percutaneous coronary intervention (PCI) or any procedure in an anticoagulated patient, respectively, using pneumatic wristbands, vs. 30 minutes, 1 hour and 2 hours, respectively for mechanic wristbands. The type of haemostasia device was left at the operator's discretion. 24 patients (66.66%) were male,
median age 65.6 years. Seven (19.45%) and 29 (80.55%) patients were treated with pneumatic and with mechanic wristbands, respectively. In the group of pneumatic device, 5 patients (71.43%) underwent diagnostic procedure, 1 (14.29%) PCI and 1 (14.29%) were anticoagulated, as compared with 12 (41.38%), 14 (48.28%) and 3 (10.34%) in the group of mechanic device, respectively. After 24 hours of follow up neither haemorragic (external bleeding or haematoma) nor thrombotic episodes (pain, arterial occlusion, loss of pulse) were observed in any of the groups.

CONCLUSIONS

This pilot study suggests that a personalised haemostasia protocol, taking into account the type of wristband and the type of intervention, is safe and effective, thus enabling substantially shorter compression times if a mechanic device is used. These pilot results encourage their confirmation in a larger randomised study.

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Five-year single-centre experience on ultrasound-facilitated thrombolysis and rheolytic thrombectomy in patients with acute pulmonary embolism at high risk or intermediate-high risk

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THEME: Peripheral Interventions
TOPIC(S): Other peripheral interventions

AIMS

Ultrasound-facilitated thrombolysis (UFT) and rheolytic thrombectomy (RT) are two catheter-based treatments providing a high efficacy with a reduced bleeding risk in patients (pts) with acute pulmonary embolism (PE). In this study, we present our five-year single-center experience on in-hospital and long-term outcomes in pts with PE at intermediate-high and high risk (IHR, HR) treated with UFT or RT.

METHODS AND RESULTS

Our study was based on the retrospective analysis of the overall 243 pts (131female, age 61.1 ± 16.1years) with documented PE who underwent UFT (n=202), RT (n=38) or both RT following UFT (n=3) using the dedicated systems. The systematic work-up including multidetector computed tomography (MDCT), Echo, biomarkers and PE severity indexes were performed in all pts, and Qanadli score (QS) was used as the measure of the thrombotic burden in pulmonary arteries (PA).

Results: The IHR and HR were noted in 152 and 29 pts of UFT group, and in 37 and 3 pts of RT group, respectively. Clinical, Echo and MDCT measures and median time delay from symptoms to treatment were comparable between UFT and RT groups ($p>0.05$). Failure in placement of catheters was experienced in one RT attempt, but in none of the UFT procedures. Mean RT activation time was 296.7±94.5 seconds. Tissue-plasminogen activator (t-PA) dosage were 35.7±13.6 mg and treatment duration was 24.1±7.1hours in UFT arm, irrespective of unilateral or bilateral UFT ($p >0.05$) whereas adjuvant t-PA (15.7±4.9 mg) was needed in 11 pts (26.8%) treated with RT. Advance life support including ECMO was requiredin 5 pts. Regardless the risk status, both UFT and RT resulted in significant improvements in tricuspid annular planary systolic excursion (mm), PA pressures (mmHg), QS, right to left ventricle diameter ratio (RV/LV) and right to left atrial diameter ratio (RA/LA) and PA diameters (mm) within days ($p<0.001$ for all). End-point which was described as oxygene saturation % in room air at the time of discharge ≥90, was achieved in 182 (90%) pts in UFT group and 36 (88%) in RT group. Major bleeding, minor bleeding and in-hospital mortality rates were 6.4%, 11.4% and 5.9% in UFT group and 9.7%, 7.3% and 9.7% in RT group, respectively. The RT induced short-term bradicardia or conduction disturbances during system activation, and a gross hemoglobinuria not resulting in acute kidney injury for one or two days in all pts. Age, risk group, t-PA duration and dosage was not associated with bleeding risk after UFT. All-cause mortality rate was 13.4% during median 555 (1-2271) days following UFT, and HR vs IHR related a higher risk (29.6% vs 10.8%, hazard ratio: 2.54;1.09-5.66, $p=0.031$). In RT group, post-discharge mortality was not documented during median follow-up for 839 (1-1127) days.

CONCLUSIONS

Irrespective of the IHR or HR status, both UFT and RT provide seemed to be effective in terms of thrombus resolution and stabilization of hemodynamics and right heart functions in pts with PE at the expense of the

relatively low rates of complications. Age, risk group, t-PA dosage and duration was not associated with bleeding risk after UFT whereas HR vs IHR increases long-term mortality.

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Rotablation in the very elderly multicentre real-world data

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Rotablation is used as an adjunct tool to modify calcified and fibrosed plaque during Percutaneous Coronary Interventions (PCI). Elderly patients undergoing coronary intervention are more likely to have calcified and torturous coronary arteries. However, limited data exists regarding rotablation in very elderly patients (≥80 years). The aims of this retrospective study are to define demographics, procedural characteristics and outcomes in very elderly patients undergoing rotablation compared to those <80 years of age.

METHODS AND RESULTS

We performed retrospective analysis of the PCI database from three United Kingdom high volume PCI Cardiac Centres between 2014 and 2017.

213 patients were included in the study. Mean age was 74.8 years (range 43 to 93 years) and 28.6% (n=61) were female. One third (33.3%, n=71) were ≥80 years.

There was no difference in cardiovascular risk factors between the very elderly and those <80 years of age. In the ≥80 years cohort, more than half presented with Acute Coronary Syndrome (ACS) compared to the younger cohort (53.5% versus 33.8%, p=0.006). Severe angiographic calcification was seen in 47.9% of the ≥80 years cohort compared to 37.3% in the younger cohort (p= not significant [NS]). The Left Anterior Descending Artery and/or the Left Main Stem was the commonest artery rotablated (67.6% very elderly versus 67.6% <80 years, p=NS). Contrast use in the very elderly (median, [range]; 180ml, [122.5-248.8] versus 200ml, [150-250], p=NS) and radiation dose in the very elderly were no different to the younger cohort (median, range; 6667.3, [4834.7-11306.4] versus 7730, [4420.5-11650], p=NS).

In-hospital outcomes (composite of stroke, myocardial infarction, death, patients requiring urgent CABG, vascular damage, coronary perforation, bleeding and renal impairment) were similar in the two patient cohorts (4.2% each, p =NS). The mean hospital stay was longer in the elderly patient cohort (2.8 ± 6 days versus 1.3 ± 1.9, p=0.009). Kaplan-Meier curves demonstrated that mean survival was significantly lower in the older cohort (34.7 months versus 54.9 months, p=0.003).

CONCLUSIONS

We have demonstrated that rotablation can be safely performed in the very elderly patient cohort and their in-hospital outcomes are similar to younger patients. In-hospital stay was significantly longer for patients ≥80 years and the long-term survival was better for younger patients. To the best of our knowledge this is one of the first studies to assess rotablation in the very elderly population.

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Non-respect of SYNTAX score II treatment recommendation of surgery (PCI treated) negatively impacts four-year mortality in patients with left main coronary artery disease

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease

AIMS

The SYNTAX Score II (SSII) was construed to predict 4-year mortality after left main (LM) or multivessel disease revascularization and to facilitate the decision-making process by the heart teams. SSII combines anatomic and clinical data, providing the following treatment recommendations: i) CABG or PCI (equipoise risk); ii) CABG preferred (excessive risk for PCI); iii) PCI preferred (excessive risk for CABG).We sought to investigate the impact of not following the SSII recommendation in patients with left main coronary artery disease (LMCAD) in the EXCEL randomized patients for PCI or CABG.

METHODS AND RESULTS

Methods and Results: Randomized clinical trials assessing revascularization strategies (PCI or CABG) for 3VD or LM do not take into account the SSII recommendation for randomization, allowing a patient that had SSII recommendation for PCI to undergo CABG and vice-versa. Thus, RCTs are the most adequate model for assessing the mortality impact associated with the lack of concordance between SSII recommendation and actual treatment. Treatment recommendations based on SSII calculation using core laboratory assessment of the anatomic SYNTAX score were compared with actual treatments, and the mortality at 4 years was assessed with Kaplan-Meier method.

SSII variables were available in EXCEL in 1807/1905 (95%) patients. When evaluating the patients that received a SSII recommendation to undergo “PCI only”, there was no impact on mortality if they received CABG as the actual treatment. However, if the recommendation was to undergo “CABG only”, the rate of all-cause death was higher in those who received PCI than of those receiving CABG (14.1% vs. 5.3%, HR 2.74, 95% CI 0.87 to 8.61, p=0.07, respectively) at 4 years. If the recommendation was for “PCI or CABG”, there was no difference in mortality at 4 years if the patient received either treatment (9.0% for PCI vs. 7.5% for CABG, HR 1.19, 95% CI 0.81 to 1.75, p=0.37).

CONCLUSIONS

For patients with left main coronary artery disease, non-compliance with the SYNTAX score II recommendation to undergo CABG (i.e. treating the patient with PCI) was associated with a trend towards higher 4-years all-cause mortality. This is an important message to heart team members as for decision making, especially in patients with SSII recommendation for CABG.

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Primary PCI for the STEMI late presenter: nationwide multicentre cohort study

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Current European guideline for patients with ST-segment elevation myocardial infarction (STEMI) recommends a routine primary percutaneous coronary intervention (PCI) as a class IIa in patients presenting late (12-48 hours) after symptom onset. However, evidence for this recommendation is limited (level of evidence is B).

METHODS AND RESULTS

Using the KAMIR-NIH, a nationwide prospective multicenter registry in Republic of Korea, we analyzed the data of 5,970 patients with STEMI from 2011 to 2015. The study subjects were classified into 3 groups according to symptom to admission time (S to A time): early presenter (S to A time <12 h), 5,105 (85.5%); late presenter (12 h ≤ S to A time <48 h), 599 (10.0%); and very late presenters (S to A time ≥48 h), 266 (4.5%). The primary outcome was patient oriented composite outcome (POCO), defined as a composite of all cause death, all myocardial infarction, and any revascularization. In early presenters, primary PCI [door to balloon time (D to B time) ≤90 min] was associated with a lower rate of POCO, compared with delayed PCI (D to B time >90 min) [delayed PCI vs. primary PCI, 24.6% vs. 14.6%, hazard ratio (HR) adjusted by inverse probability weighting (IPW) 1.379, 95% confidence interval (CI) 1.256-1.516, P <0.001]. In contrast, primary PCI was not associated with a better outcome in late presenters as well as very late presenters (late presenters: delayed PCI vs. primary PCI, 22.1% vs. 18.2%, HR adjusted by IPW 1.100, CI 0.850-1.422, P=0.469, very late presenters: delayed PCI vs. primary PCI, 16.9% vs. 18.6%, HR adjusted by IPW 0.734, CI 0.482-1.118, P=0.149). Regarding cardiac death, early presenters showed a better outcome by primary PCI (delayed PCI vs. primary PCI, 14.3% vs. 5.6%, HR adjusted by IPW 1.811, 95% CI 1.571-2.088, P <0.001). However, primary PCI did not show beneficial effects for cardiac death in late presenters and very late presenters (late presenters: delayed PCI vs. primary PCI, 9.8% vs. 9.9%, HR adjusted by IPW 0.781, CI 0.534-1.141, P=0.201, very late presenters: delayed PCI vs. primary PCI, 12.0% vs. 9.3%, HR adjusted by IPW 1.051, CI 0.622-1.778, P=0.852). All cause death, and MACE, a composited of cardiac death, all myocardial infarction, and stroke showed the same trend. Independent predictors for POCO in early presenters were delayed PCI, old age (age >65), female, Killip 3 or 4, high baseline creatinine (serum creatinine ≥1.5), and non-post PCI TIMI flow grade 3. In late presenters, predictors were old age, Killip 3 or 4, and high baseline creatinine. In very late presenters, they were high baseline creatinine, and non-post PCI TIMI flow grade 3.

CONCLUSIONS

Our study does not support the current guideline recommending primary PCI to STEMI late presenters.

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Have outcomes following CABG surgery for left main disease improved over the last decade? A propensity-matched analysis from the EXCEL and SYNTAX randomised trials

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease

AIMS

Coronary artery bypass graft surgery (CABG) has been the preferred approach to treat patients with complex coronary artery disease (CAD) for several decades. However, while results of percutaneous coronary intervention (PCI) have been steadily improving with better devices and techniques, whether surgical outcomes are improving over time is not fully elucidated. We sought to compare the current outcomes of patients undergoing CABG with prior surgical results, in the context of randomized trials including the left main stem.

METHODS AND RESULTS

We performed a propensity-matched analysis of patients randomized to CABG in the SYNTAX (enrollment period 2005 – 2007) and EXCEL (enrollment period 2010 – 2014) trials. All patients had left main (LM) disease with or without multivessel disease. Adjustment was based on 15 clinical and angiographic variables, including core laboratory assessed anatomic SYNTAX score, with a 2:1 ratio for EXCEL and SYNTAX, collectively analyzing 909 subjects (n=580 and n=329 respectively). The primary endpoint of this analysis was major adverse cardiovascular and cerebrovascular events [MACCE - the composite of all-cause death, myocardial infarction (MI), stroke or ischemia-driven revascularization (IDR)] at 3 years. We also assessed MACCE at 30 days, the composite endpoint of MACE at 30 days and 3 years and the non-hierarchical individual components of the primary endpoint at 30 days and at 3 years.

Baseline characteristics, anatomic SYNTAX score, number and types of grafts and duration of hospitalization for the procedures were similar in both groups. CABG procedures in EXCEL compared to SYNTAX were more often off-pump (29.6% vs. 15.4%, p<0.001), more often had intermittent cross-clamping (31.2% vs. 1.3%, p<0.001) and guideline-directed medical therapies were used more frequently in the EXCEL surgical cohort. The primary endpoint occurred in 14.0% and 20.9% (p=0.008) of patients in EXCEL and SYNTAX, respectively. At 30 days MACCE rate did not differ between the EXCEL and SYNTAX patients (3.5% vs. 4.3%, p=0.54), whereas at 3 years it occurred in 14.0% and 20.9% of patients, respectively (relative risk 1.54, 95% confidence interval 1.12 to 2.14, p=0.008). The 3-year composite rate of death, MI or stroke (MACE) was also lower after CABG in EXCEL compared with SYNTAX (9.6% vs. 14.0%, p=0.05). With the exception of MI (4.1% vs. 3.7%), all non-hierarchical events tended to contribute to the improved outcomes: all-cause death (5.5% vs. 8.5%), stroke (2.2% vs. 4.2%), and IDR (7.1% vs. 9.4%) in EXCEL and SYNTAX, respectively.

CONCLUSIONS

The present comparison of surgical outcomes from the older SYNTAX trial and the contemporary EXCEL trial

in patients with LMCAD over a 5-7-year period showed no difference at 30 days outcomes, but improved event-free survival after CABG during 3-year follow-up, consistent with improving results over time with cardiac surgery.

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Mitral annulus dilation predicts significant mitral regurgitation recurrence or rehospitalisations for heart failure after successful MitraClip implantation: preliminary results from Mi-Zu-Br registry

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair

AIMS

The aim of this study was to assess the prognostic impact of preexisting mitral annulus dilation in patients with heart failure and secondary mitral regurgitation undergoing successfull MitraClip implantation.

METHODS AND RESULTS

Between October 2008 and January 2019, a total of 187 patients with significant (moderate to severe), symptomatic, secondary mitral regurgitation treated successfully with MitraClip implantation were enrolled. All patients underwent clinical, bio-chemichal and echocardiographic evaluation before MitraClip implantation. Annular dilation was defined by the presence of antero-posterior or latero-lateral annulus > 35 mm. Patients were divided into two groups according to the presence or absence of mitral annulus dilation. Effectiveness end-point was defined as a composite of mitral regurgitation >=3+ recurrence or re-hospitalizations for heart failure. Patients with annular dilation showed less atrial fibrillation (50.0% vs. 18.2%, p = 0.001) and significantly enlarged left atrial volume (130.3 ± 37.1 vs. 108.1 ± 33.7, p = 0.002), left ventricular end-diastolic diameter (69.3 ± 10.0 vs. 64.5 ± 8.6, p = 0.010) and left ventricular end-diastolic volume (222.9 ± 72.5 vs. 196.6 ± 58.3, p = 0.045). At 2-years median follow-up, effectiveness end-point was significantly different between the two groups (annular dilation 70.8%; no-annular dilation 65.2%; p = 0.027). At univariate analysis, annular dilation and severe left ventricular dysfunction were associated with a worse outcome. At multivariate Cox-regression analysis, mitral annulus dilation was identified as the only independent predictor (HR 1.849, p = 0.047).

CONCLUSIONS

Mitral annulus dilation can be considered as a predictor of adverse mid-term outcome after successful MitraClip implantation for secondary mitral regurgitation and not only as a marker of a more compromised valvular heart failure condition.

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Initial experience with an implantable left-sided pressure sensor for monitoring of patients with heart failure

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THEME: Interventions for Heart Failure
TOPIC(S): Chronic heart failure

AIMS

?Heart failure (HF) is a leading cause of hospital admissions. This unmet clinical need was thus far not successfully met by non-invasive solutions, despite advancements in diagnostic and therapeutic modalities in recent years. Invasive right-sided pressure-guided therapy, on the other hand, has been shown to improve outcomes. The Vectorious Medical Technologies V-LAP™ is a novel battery-less and wireless left-sided pressure monitoring system, directly assessing left-atrial pressure (LAP) in an ambulatory setting. We hereby describe the progress made with the device thus far.

METHODS AND RESULTS

We initially thoroughly characterized the unique needs of patients with chronic HF, including the challenges of reduced compliance, elevated risk of comorbidities- which may also increase the risk of readmission, the physiological advantage of left- versus right-sided pressure measurement, the risk of pressure drift and the personal differences between each patient. We have ultimately developed a device which is able to measure and calculate pressures in the left atrium, learn unique attributes of each patient, compensate for pressure drift, transmit data wirelessly in a user-friendly manner, and detect common comorbidities such as atrial fibrillation and mitral regurgitation. The V-LAP™ wireless sensor is implanted using a trans-septal approach, under angiographic and echocardiographic guidance. The system includes an external unit, which powers the implant remotely and collects data via radio frequency communication upon activation, designed to be operated on a daily basis.

In pre-clinical studies, the device was shown to enable accurate and safe measurement of LAP. We have recently initiated the V-LAP™ left atrial monitoring systEm for patients with Chronic sysTOlic and diastolic congestive heart failuRe first-in-human (VECTOR) study- a prospective, multicenter, single arm, open-label clinical trial to assess the safety, performance and usability of the V-LAP system in patients with heart failure. At time of submission, the device has been successfully implanted in the first enrolled patient in the clinical trial at the CardioVascular Center, in Frankfurt, Germany. During the conference we will be able to describe the first case series and discuss potential developments of the V-LAP™ wireless sensor, as it may play a role in the management of patients with HF in the future.

CONCLUSIONS

The V-LAP™ wireless sensor is an embodiment of needs-based innovation in the world of heart failure, harnessing cutting-edge technology in order to answer the unique needs of the HF population. The clinical trials will demonstrate whether the system enables optimal therapy for these patients, reduces readmissions and detects co-morbidities in a personalized manner.

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Screening for TMVR: derivation and validation of a decision tree algorithm

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair

AIMS

Transcatheter mitral valve replacement (TMVR) provides a novel therapeutic approach for high-risk patients suffering from severe mitral valve regurgitation that are ineligible for surgery or approved interventional therapies. Anatomical proportions are a major limiting factor in screening process leading to a high percentage of patient rejection. The aim of this study was the derivation and validation of a screening algorithm for TMVR based on anatomical patient data.

METHODS AND RESULTS

From 2016-2018 a total of 87 patients with severe mitral valve regurgitation and ineligible for surgery with subpar anatomy for interventional mitral valve repair were screened for dedicated TMVR devices at our institution. Throughout the overall screening process 184 screenings were performed. 31 (16.8%) patients were found eligible for TMVR, whereas 153 (83.2%) screenings resulted in rejection for TMVR due to suboptimal clinical or anatomical conditions. We compared baseline clinical and anatomical parameters of both patients accepted for TMVR (Accepted group; n=31, 35.6%) and patients ultimately rejected for all screened devices (Rejected group; n=56, 64.4%). Subsequently, a decision tree was derived by KNIME Analytics Platform utilizing echocardiography and ECG-gated full cardiac cycle computed tomography (CT) data of an 80% subset of all patients (n=63). Validation was accordingly performed in a 20% subset of patients (n=17). Selection of subsets was accomplished by stratified random sampling. Patients found eligible for devices with low percentage of eligibility (n=7) were excluded from the analysis.

Comparison of Accepted and Rejected group at baseline revealed significantly lower baseline ejection fraction (all results as follow Accepted median vs. Rejected median: 37.0 vs. 55.0%, p<0.0016) and larger left ventricular (LV) dimensions (LVEDD: 58 mm vs. 53 mm, p=0.045; LVEDV: 138.8 ml vs. 115.7 ml, p=0.039) in the Accepted than in the Rejected subgroup. LV size remained significantly dissimilar in CT measured by annulus center-to-apex distance (diastolic: 97.8 mm vs. 89.9 mm, p=0.03; systolic: 91.1 mm vs. 82.8 mm, p=0.011). Furthermore, native left ventricular outflow tract area was larger in the Accepted group (530.8 mm2 vs. 443.1 mm2, p=0.001).

Based on the derivation subset data a five-step decision tree algorithm, resulting in a preliminary recommendation for two distinct devices, or in predicted unsuitability for TMVR, was created. The stepwise decision process comprised CT scan parameters exclusively: diastolic mitral annulus, calcium distribution, systolic and diastolic trigon distance, systolic left ventricular dimension and the aortomitral angulation. The observed overall agreement with the clinical decision was 74.6% in the derivation subset and 73.7% in the validation subset.

CONCLUSIONS

Evaluation of anatomical proportions by CT scan and echocardiography is obligatory for patient selection in the

screening process for TMVR. We derived and validated a decision tree based on a high number of performed screenings for TMVR, enabling fast and reliable decision making in terms of eligibility and choice of device in the preclinical screening process. Extended further experience in the field of TMVR is necessary to approve and expand the use of this algorithm.

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A single-centre experience with DEB angioplasty for treatment of de novo lesion in primary PCI

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

To assess the safety and effficacy of Drug Coated Balloon(DCB) angioplasty for the trreatment of de novo lesions in patients undergoing Primary Percutaneous Coronary Intervention

METHODS AND RESULTS

26 patients (77% Male) who had de novo lesions treated with DCB between January 2015 and January 2017 during Primary PCI were identified and analyzed. Endpoints were Target Lesion Revascularization (TLR) and clinical MACE events at 26 patients (77% male) who had de novo lesions treated with DCB between January 2015 to January 2017 during Primary PCI were identified and analyzed. Endpoints were cTarget Lesion Revascularization (TLR) and clinical MACE events at 9 ± 6 months follow up. The Left Anterior Descending Artery and the Right Coronary Artery were the most common target artery (39%). The majority of patients had traditional risk factors for coronary artery disease (CAD), such as hypertension (81%), Diabetes Mellitus (58%) and Dyslipidemia (19%). The mean vessel diameter treated was 2.6mm ± 0.4mm. 2 patients had non-flow limiting dissection post DCB inflation. In hospital mortality was 7.7% (2 patients) due to cardiogenic shock with multiorgan failure. During follow up period, there were 2 reported deaths (1 case was due to complication stroke).

CONCLUSIONS

DCB angioplasty to de novo lesions in the setting of STEMI appears to be a feasible option. However, further study with a larger cohort of patients is required to ascertain this hypothesis.

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Incidence and outcomes of bioprosthetic valve thrombosis after surgical and TAVR: a meta-analysis

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

The frequency and the clinical consequences of bioprosthetic valve thrombosis (BVT) after surgical and transcatheter aortic valve replacement (SAVR and TAVR) are debatable. We sought to perform a systematic review and a meta-analysis to assess the incidence of and the clinical outcome associated with BVT after SAVR and TAVR.

METHODS AND RESULTS

We searched PubMed, MEDLINE, Cochrane library, Central Register of Controlled Trials, and EMBASE databases up to July, 2018 for studies reporting the incidence and/or outcomes of BVT in patients who underwent bioprosthetic aortic valve replacement (SAVR or TAVR).

Forty-one studies were included (22 SAVR, 17 TAVR, and 2 SAVR+TAVR) comprising 26,375 patients. The estimated weighted incidence of clinical BVT was 0.31% (95% CI: 0.10 – 0.53%) after SAVR and 0.86% (95% CI: 0.52 – 1.21%) after TAVR. The corresponding incidence of subclinical BVT was 5.28% (95% CI: 2.24–8.33%) after SAVR and 4.0% (95% CI: 2.83– 5.17%) after TAVR. BVT was not associated with increased risk of all-cause mortality but was associated with increased risk of stroke/transient ischemic attack in the overall population (relative risk [RR]: 3.08 [95% CI 1.89 – 5.01]). This association was more evident after SAVR (RR= 4.87 [1.71 – 13.88]) than after TAVR (RR= 2.18 [0.84 – 5.69]) and remained significant in sensitivity analyses excluding/including the studies that applied routine multislice computed tomography screening for BVT detection (RR: 5.23 [95% CI: 1.83 – 14.98]) and RR: 2.66 [95% CI: 1.54 – 4.61]; respectively).

CONCLUSIONS

BVT is a significant morbidity after aortic valve replacement, is more often subclinical, and is associated with increased risk of cerebrovascular events especially after SAVR.

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Outcomes after resorption of coronary BRS

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

The safety of everolimus-eluting coronary bioresorbable scaffolds (BVS) has been challenged by the evidence of increased scaffold thrombosis both early and late after implantation. Little is however known on the outcomes after device resorption, which is expected to occur at three to four years after implantation.

METHODS AND RESULTS

Data on 5 years follow-up in 368 consecutive patients (291 males, age 63±12 years, 70 diabetics, 271 acute coronary syndromes, 417 lesions) treated with BVS between May 2012 and January 2014 were collected. The incidence of adverse cardiac events including target lesion failure (TLF), target lesion revascularization (TLR), cardiovascular death, in-scaffold restenosis and thrombosis) was evaluated at 1 year, between 2 and 3 years, and between 4 and 5 years after implantation. Predictors of lesion failure at each time point were investigated.
The Kaplan.-Meier estimates for the annual incidence (±SE) of each endpoint (respectively, year 1, years 2 and 3, years 4 and 5 after implantation) were as follows: TLR: 6.2±13%, 3.0±1.3%, 1.15±0.9%; restenosis: 2.0±0.7%, 2.4±1.1%, 0.6±0.6%; thrombosis: 3.6±1.0%, 1.1±0.8%, 0.4±0.5%; TLF: 7.8±1.4%, 4.2±1.6%, 2.5±1.4%. Independent predictors of TLF between 4-5 years included diabetes (P=0.006, OR=4.9[1.6-14.9] and eGFR (P=0.046, OR=1.0[1.0-1.0].

CONCLUSIONS

Supporting the concept of vascular regeneration, the incidence of events at the level of lesions previously treated with BVS was very low after device resorption. None of the device/lesion parameters that were associated with complications before resorption maintained its predictive power thereafter.

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Agreement between quantitative flow ratio and FFR in assessment of functional significance of intermediate coronary artery stenosis

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

The primary aim of this study was to estimate the agreement between Quantitative Flow Ratio (cQFR), a minimally invasive method to compute FFR value from coronary angiograms in accordance with individual speed of contrast flow within coronary artery (CA), in comparison with FFR, a gold standard method for assessment of functional significance of CA stenosis. The secondary aim was to assess the difference between cQFR and FFR on making a treatment decision.

METHODS AND RESULTS

Sixty-two patients who have undergone coronary angiography revealing intermediate stenosis (lumen stenosis of 35-75%) by visual evaluation and for whom FFR measurements were performed between 1st January 2017 and 31st December 2018 have been prospectively included into our single centre study. Offline cQFR analyses were performed three times: at inclusion and repeated twice with the interval of three days. The level of significance was chosen $p < 0.01$. Excellent inner agreement of three cQFR analyses were found, $r = 0.997$, $p < 0.001$. Averaged cQFR values were compared to FFR values. In total, 69 lessons (49 Left Anterior Descending (LAD), 8 left circumflex (LCX) and 12 Right Coronary Artery (RCA)) were analysed. In the analyses of all lessons, a strong significant correlation coefficient between cQFR and FFR was found, $r = 0.869$, $p < 0.001$. After dividing lessons according to CA, following results have been found: LAD $r = 0.899$, $p < 0.001$; LCX $r = 0.609$, $p = 0.109$ and RCA $r = 0.877$, $p < 0.001$. The analyses of extracted LAD and RCA have shown strong significant correlation coefficients, while LCX did not significantly correlated, probably due to low number of cases in LCX sub-group. The secondary outcome was the agreement of clinical decision-making between cQFR and FFR. In the analyses of all lessons, strong significant correlations between cQFR and FFR have been found, $r = 0.807$, $p < 0.001$. Compared to FFR as a reference, cQFR had a sensitivity of 100%, specificity of 84.2% and accuracy of 94.2%.

CONCLUSIONS

A coronary intervention substantiated by the evaluation of CA stenosis significance is widely recommended. Due to that, cQFR acceptance in everyday clinical practice may improve patients' outcomes by identifying target lessons and avoiding unnecessary coronary interventions and possible following complications. cQFR do not add the risk of complications to ordinary coronary angiography and is easy-to-use method with an excellent correlation with FFR in both CA stenosis functional significance assessment and clinical decision making with a great sensitivity, specificity and accuracy. The greatest agreement was found in LAD and RCA. The study is being continued.

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Patients experience undergoing TAVI in local anaesthesia

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THEME: Interventions for Valvular Disease
TOPIC(S): Other valvular and structural interventions

AIMS

Aim: To explore the patients' experiences and needs when undergoing a TAVI procedure in local anaesthesia, in order to provide the nursing care based on the patient's individual wishes and needs.

METHODS AND RESULTS

Background: Transcatheter Aortic Valve Implantation (TAVI) is a procedure offered to patients with severe aortic stenosis who, due to age and fragility, have a high risk of complications related to open heart surgery. TAVI has been shown to be as effective as surgical replacement of the aortic valve. In 2015 at a large university hospital the procedure was changed from being performed in general anaesthesia to local anaesthesia without any anaesthesia staff present. A literature review did not identify any studies investigating patients' experiences when undergoing a TAVI procedure in local anaesthesia. Methods: Qualitative interviews were conducted with ten patients, the day after the TAVI procedure. The interviews were recorded, transcribed and analysed according to the qualitative inductive content analysis.
Results: Eleven categories emerged from the interviews. The transversal analysis revealed four themes: "The diversity of pain", "That's the way it is", "They have got it under control" and "I want to be involved".

CONCLUSIONS

TAVI treatment in local anaesthesia was experienced as a procedure in which a variety of pain, discomfort and anxiety were expected and accepted by the patients as long as the interdisciplinary team acted professionally. The elderly and often frail patients wish and need to be involved in their own care and treatment

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Comparison between optical frequency domain imaging and IVUS in PCI guidance for biolimus A9 eluting stent implantation (MISTIC-1)

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Intracoronary imaging techniques provide clinically relevant information in navigating successful percutaneous coronary interventions (PCI) and optimal stent implantation. In this study, we sought to compare imaging surrogates and clinical outcomes after drug-eluting stent implantation between intravascular ultrasound (IVUS) and optical frequency domain imaging (OFDI) guidance.

METHODS AND RESULTS

The MISTIC-1 (Multimodality Imaging STudy In Cardiology cohort 1) is a prospective, single-blinded, randomized-controlled, non-inferiority trial comparing imaging and clinical endpoints between OFDI-guided and IVUS-guided PCI using Biolimus A9 eluting Nobori stent (Clinicaltrials.gov identifier: NCT03292081). We enrolled patients with stable coronary artery disease who have symptoms or clinically relevant myocardial ischemia proven by non-invasive or invasive functional testing. Patients were randomly assigned to either OFDI-guided or IVUS-guided PCI. Stent landing zones (i.e. reference sites) were selected in the most normal looking sites with largest lumen and without percentage plaque area >40% in IVUS group while without lepidic plaque of >3 quadrants or suggestive thin-cap fibroatheroma in OFDI group. Stent sizing was based on external elastic lamina (EEL) in IVUS group, while by taking 10% or 0.25mm larger than mean lumen diameter at reference sites in OFDI group. Stent optimization with in-stent minimum lumen area ≥90% of the average lumen area at proximal and distal reference sites was encouraged in both groups. Post-procedural OFDI was investigated regardless of randomization, while the image was blinded to the operators in IVUS-guided PCI arm. Primary efficacy endpoint is in-segment minimum lumen area (MLA) assessed by OFDI at 8 months. Secondary safety endpoint is a composite of cardiovascular mortality, target-vessel myocardial infarction, or target-lesion revascularization. Based on the assumption that mean in-segment MLA at follow-up was 4.5mm2 with a standard deviation of 2.0mm2 in the control (IVUS) group and a non-inferiority limit of 1.2mm2 in OFDI group, sample size was estimated as 48 cases in each group with 5% type I error and 90% statistical power. Since June-2014 and August-2016, we prospectively enrolled 109 patients (mean age 70 years, male 78%) with 126 lesions having stable coronary artery disease in two Japanese cardiovascular centres. Baseline patient and lesion characteristics were well balanced and mean number of stents per lesion was 1.1±0.2. Procedure time was comparable while total contrast volume was significantly higher in OFDI group than in IVUS group (147mL vs. 121mL, respectively). Post-procedure minimum stent area was 6.24mm2 in OFDI group and 6.72mm2 in IVUS group (p=0.20). At 8-month follow-up, in-segment MLA (primary endpoint) was 4.56mm2 in OFDI group and 4.13mm2 in IVUS group (Pnon-inferiority <0.001, Psuperiority=0.23). Incidence of major adverse cardiac events did not differ between the two groups (3.7% in OFDI group and 5.5% in IVUS group, p=0.7). No definite or probable stent thrombosis were documented in both groups.

CONCLUSIONS

OFDI-guided PCI demonstrated comparable results in achieving satisfactory imaging surrogates as well as clinical outcomes after newer generation DES implantation as compared to IVUS-guided PCI.

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Safety and performance of the resorbable magnesium scaffold, Magmaris in a real-world setting - First 800 subjects at 12-month follow-up of the BIOSOLVE-IV registry

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

The aim of this registry is to investigate the clinical performance and long-term safety of the Resorbable Magnesium Scaffold (Magmaris) in a real world setting. Up to 2054 subjects in up to 120 clinical sites in Europe, Asia and Asia-Pacific countries will enrol in this registry. This analysis includes the 6-month and 12-month follow-up data of the first 800 enrolled subjects.

METHODS AND RESULTS

Between September 2016 and April 2018, 800 subjects with 837 de-novo coronary artery lesions were enrolled in this prospective, multi-centre, controlled, global registry. The primary endpoint is Target Lesion Failure (TLF) at 12-month follow-up. Definite or probable scaffold thrombosis is powered for superiority at 12-month as secondary endpoint. Clinical follow-up visits are scheduled at 6, 12, 24, 36, 48 and 60 months. All endpoint related serious adverse events and all procedure/ device-related events were adjudicated by an independent clinical events committee. All endpoint related cases were analyzed by an independent core laboratory, if applicable.

607 men (75.9%) and 193 (24.1%) women were enrolled at 71 sites in 20 different countries. The mean age was 61.3 ± 10.8 years. The mean lesion length and reference vessel diameters were 14.8 ± 4.3 mm and 3.2 ± 0.3 mm, respectively. Based on our preliminary data, 66.3% of the analysed subjects had hypertension, 66.0% hypercholesteremia, and 61.2% smoking history, and 21.3% of the subjects were diabetic. 49.4% of the subjects experienced stable angina, 17.5% unstable angina and 15.3% documented silent ischemia. The percentage of subjects who presented with an AMI was 17.7%. Type B1/B2 lesions percentage was 64.6%.

98.1% (785/800) follow-up compliance at 6-month was achieved. Preliminary data of the first 800 subjects undergoing 6-month clinical follow-up showed a low TLF rate (3.2%) which is comparable to second generation permanent drug eluting stents. Definite or probable scaffold thromboses rate was 0.6%. Excluding cases with early antiplatelet or anticoagulant interruption, the scaffold thrombosis rate was 0.1%. 12-month data will be available upon presentation.

CONCLUSIONS

The Magmaris scaffold showed a very good safety profile up to 6-month with a target vessel myocardial infarction rate of 1.3%, TLF rate of 3.2%, and definite or probable scaffold thrombosis rate of 0.6%.

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Two-year follow-up: "Provisional T" stenting of left main coronary artery in patients with true bifurcation stenosis

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THEME: Coronary Interventions

TOPIC(S): Left main and multivessel disease

AIMS

to evaluate the long-term results of the use of drug-eluting balloon catheters in patients with Left Main (LM) bifurcation stenosis.

METHODS AND RESULTS

Methods: the analysis involved 142 patients with true bifurcations of the Left Main. Randomization in 2 main groups: Group I (n=52) included patients, who received kissing- dilatation with traditional NC balloon catheters and Group II (n=52), who had a kissing-dilatation of the main bifurcation artery with a traditional NC balloon catheters, and a side branch - with drug-eluting balloon catheters. In retrospectively, the third (III) control group (n=38) was formed, where the two-stent technique was performed. All patients from main groups had previously performed «Provisional T» stenting and final «kissing balloons» dilation technique. Coronary angiography and OCT were performed to evaluate the results of all patients. Inclusion criteria: true LM bifurcation stenoses according to QCA and OCT; SYNTAXscore <32. Primary endpoints: incidence of MACE - death, MI, re-interventions. Secondary endpoints: the incidence of restenosis and late stent thrombosis.

Results: after 24 months the total incidence of MACE were 11.5 vs. 3.8% in groups I and II respectively ($p<0.05$). When comparing the results in group II and III, the frequency of MACE was 3.8 vs. 13.2%, respectively ($p<0.05$). Restenosis of the side branch of more than 50% according to QCA was detected in 4 patients (7.7%) from group I and in 1 patients (1.9%) from group II ($p<0.05$). In patients from group I, the average MLA in the side branch after 24 months was 5.58±1.34 and 4.12±1.21 mm2, respectively ($p<0.05$), compared with data after PCI; in the main branch - 6.34±1.56 and 5.88±1.14 mm2, respectively ($p>0.05$). In patients from Group II, the average MLA were, respectively, 5.38±1.24 and 5.12±1.44 mm2 in side branch ($p>0.05$) and 6.68±1.75 and 6.36±1.22 mm2 in main branch ($p>0.05$). When comparing the data of MLA in the side branch in groups I and II, there was a significant difference (4.12±1.21 vs. 5.12±1.44 mm2; $p<0.05$). There were no cases of late thrombosis of the stents.

CONCLUSIONS

the use of dug-eluting balloon catheters for the «Provisional T» stenting in patients with true LM bifurcation stenoses, associated with significantly lower frequency of MACE and side branch restenosis, according to OCT data, compared with patients who used traditional NC balloon catheters for «kissing- dilatation» and two-stent technique strategy.

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Twelve-month safety and performance outcomes of a new self-expanding transcatheter heart valve

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

The Biovalve Transcatheter Heart Valve (THV) is a self-expanding, supra annular nitinol valve, made from porcine pericardial tissue. It is available in two sizes: M (29mm) and S (26mm). The delivery system is compatible with 0.035" guide wires and 18F introducer sheaths. The prosthesis can be re-sheathed once. Twelve month results of safety, effectiveness and hemodynamic performance of the non-randomized, prospective, multi-center BIOVALVE study will be reported.

METHODS AND RESULTS

The study was conducted in 12 centers in Europe (Germany, Belgium, Switzerland and Netherlands). Follow-up visits' evaluations encompass the primary endpoint of early safety at 30 days (according to VARC-2 criteria). Additional safety endpoints, echocardiographic results and functional assessments are investigated at 30 days, 3 month, 6 months and annually up to 5 years.

Echographic results are analyzed by an independent corelab and all adverse events are adjudicated by an independent clinical events committee.

Transfemoral THV implantation was initiated in 68 patients with severe aortic stenosis and high surgical risk. The mean age was 82.4 ±5.3, 62% were female, 70% were in NYHA class III and 57.4% had concomitant coronary artery disease.

Implantation was successfully completed in 64 patients. 7 received a 26mm valve size and 57 patients were implanted with a 29mm valve.

Clinical follow-up was performed for 66 patients at 30 days and 51 patients at 6 months post-procedure.

The primary endpoint was observed in 13 patients (19.1%). One patient died before 30 days of a non-cardiac cause and further 4 patients died between 30 and 180 days (7.8%). Two of them from a cardiac death: one myocardial infarction at day 62 and one heart failure at day 92.

Disabling stroke was observed in one, respective two patients at 30 and 180 days. 9 patients (13.4%) were implanted with a new permanent pacemaker within 30 days. Two patients (3.8%) had moderate or severe paravalvular leakage at 30 days and 4 (9.1%) at 6 months, effective orifice area increased from 0.7±0.2 cm2 at baseline to 1.9±0.4 cm2 at 30 days and remained stable up to 180 days and mean gradients were 6.4 mmHg at 30 days and 6 months. No structural valve deterioration was reported.

At 30 days NYHA class I/II was observed in 78% of patients and this improved to 85% patients at 6 month.

CONCLUSIONS

The self-expanding transcatheter Biovalve showed low early complication rates, improved and stable hemodynamic outcomes up to 6 month and low incidence of major complications in a high surgical risk population.

Final clinical and echocardiographic data up to 12 months follow-up will be available upon presentation.

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Prognostic significance of the Medina classification in bifurcation lesion PCI

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

The Medina classification is the most widespread method to describe bifurcation lesions. Little is known regarding the prognostic significance of the classification following percutaneous coronary intervention (PCI).

METHODS AND RESULTS

The study included 738 consecutive patients from a prospective bifurcation registry. There were 609 patients (82.5%) with “true bifurcation” (TB) lesions (Medina class 1.0.1, 1.1.1, 0.1.1) and 129 (17.5%) in all other categories (“non-true bifurcation”=NTB). We compared rates of death and major adverse cardiac events (MACE: cardiac death, myocardial infarction, or target vessel revascularization). Patients with TB had lower rates of previous bypass surgery (9.4% vs. 12.2%, p=0.03) and hyperlipidemia (75.2% vs. 79.0%, p=0.04). TB lesions were more likely to be calcified (33.8% vs. 28.2%, p=0.03) and ulcerated (8.9% vs. 3.4%, p<0.01). All cause death rates at 3 years were higher for TB PCI (10.1% vs. 4.9%, p=0.002), as were rates of MACE (27.2% vs. 11.6%, p<0.001). After performing regression analysis, TB remained an independent predictor for poor outcomes (OR-3.93 at 12 months, CI 1.45-10.66, p=0.007, OR-3.26 at 3 years, CI 1.47-7.25, p=0.004).

CONCLUSIONS

TB lesions, according to the Medina classification, portend worse prognosis for patients undergoing bifurcation PCI. This may guide prognostication and decision making in treatment.

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Safety and clinical performance of the drug-eluting absorbable metal scaffold in the treatment of subjects with de novo lesions in native coronary arteries at 24-month follow-up- Biosolve-II and Biosolve-III

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Assessment of the safety and clinical performance of the Sirolimus-Eluting Bioabsorbable Magnesium Scaffold (DREAMS 2G) from the combined analysis of Biosolve-II and BIOSOLVE-III studies at 24-month which is 12 months beyond the completion of device absorption.

METHODS AND RESULTS

184 subjects have been enrolled in BIOSOLVE-II and BIOSOLVE-III studies. Clinical follow-ups are scheduled at 1, 6, 12, 24 and 36-months. Angiographic follow-ups are planned at 6-month and voluntarily at 12-month and 36-month in BIOSOLVE-II and one angiographic examination is mandatory at 12-month in BIOSOLVE-III study. Dual antiplatelet therapy is recommended for a minimum of 6 months.
The angiographic results are analyzed by an independent corelab and all clinical events are adjudicated by an independent clinical events committee.

One hundred eighty four patients (117 men and 67 women) with 189 lesions and a mean age of 65.5 ± 10.8 years were enrolled at 18 clinical sites in Europe, Brazil and Singapore. 75% of patients had stable angina at baseline. Hypertension was present in 79.3% of the subjects, 62% of them had hyperlipidemia and 25% were diabetic. None of the study subjects had an acute coronary syndrome. The mean lesion length was 12.6±5.1 mm with a mean reference vessel diameter of 2.70±0.43 mm. None of the lesions was located in the left main. Calcification was little or none in 84% of cases and no complex bifurcations were involved.

At 12-month, 97 angiographic follow-up were available. There was no difference in late lumen loss between the two studies; in the overall population, it was 0.25±0.31 mm in-segment and 0.39±0.34 mm in-scaffold. The target lesion failure (TLF) rate of the combined population was 3.3% at 12 months, including two cardiac deaths (1.1%), one target vessel myocardial infarction (0.6%), and three clinically driven target lesion revascularizations (1.7%).
The clinical 24-month results of BIOSOLVE-II study are available. Target lesion failure occurred in seven patients (5.9%) and included two cardiac death (1.7%), one target-vessel myocardial infarction (0.9%) and four clinically driven target lesion revascularizations (3.4%). No definite or probable scaffold thrombosis was

observed.
The 24 month clinical data of the combined cohort will be available upon presentation.

CONCLUSIONS

The 24-month safety and clinical performance results of DREAMS 2G 1 year beyond the completion of device absorption are encouraging and will be presented for a larger population of subjects enrolled in BIOSOLVE-II and BIOSOLVE-III studies.

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TMVR using dedicated devices: an early series using transapical or transseptal devices

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair

AIMS

Dedicated devices for transcatheter mitral valve replacement (TMVR) hold the promise of meeting an unmet clinical need for patients with severe mitral regurgitation (MR) who are ineligible for surgery. This early series reports acute clinical experience using dedicated devices.

METHODS AND RESULTS

A total of 87 patients were screened for TMVR from 2016-2018. Of these, 24 (27.6%) high-risk patients (15 male, median age 75.5 years, median logEuroSCOREII 5.9%, all NYHA class III/IV) were found eligible considering anatomical and clinical criteria. Transapical TMVR using Neovasc TIARA (n=14), Abbott Tendyne (n=7), HighLife Valve (n=1) or transseptal TMVR using Edwards CardiAQ (n=2) devices were performed for severe symptomatic functional (n=17), degenerative (n=5) or mixed (n=2) MR. Data from compassionate-use cases (n=9) are presented in accordance with Mitral Valve Academic Research Consortium (MVARC) definitions.

In all patients immediate technical success was achieved. Median procedure and fluoroscopy times were 160 (125; 190) and 31.0 (22.3; 46.7) minutes, median amount of contrast agent was 70.0 (31.0; 114.0) ml. Device repositioning was necessary due to intraprocedural left ventricular outflow tract obstruction in one case. Extubation in the hybrid OR immediately following the procedure was successful in 8/9 patients. Median duration of intensive care and overall hospital stay were 1 (1.0; 2.0) and 12 (8.0; 17.0) days. Device and procedural success rates at 30 days were 77.8% and 88.9% respectively, the first due to one case of cardiogenic shock requiring repeated intensive care unit admissions and one case of cardio-pulmonary resuscitation due to ventricular fibrillation, the latter due to one death on day 2. All-cause in-hospital and 30-day mortality was 11.1% (1/9) due to right ventricular perforation of a temporary pacemaker lead with subsequent surgical revision and multi-organ failure on day 2. Transthoracic echocardiography upon discharge revealed adequate valve function with no (n=6) or trace (n=3) residual MR in all patients and peak/mean transvalvular gradient of 8 (4.75; 10.75)/3 (1.75; 4.25) mmHg.

CONCLUSIONS

Excellent hemodynamic results after TMVR using three dedicated devices were demonstrated in this preliminary series of selected patients. Careful patient selection by computed tomography and echocardiographic parameters is key for clinical success.

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The DIRECT II randomised, controlled study: final five-year follow-up

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Stents and scaffolds

AIMS

Reducing vascular access site size via ‘SIender’ PCI in appropriate subsets has been associated with improved procedural outcomes and patient comfort. Direct stenting has been associated with reduced procedure times, radiation exposure, contrast administration and costs compared with conventional stenting with pre-dilatation. The Svelte sirolimus-eluting coronary stent Integrated Delivery System (IDS) is designed to facilitate TRI / ‘Slender’ PCI and direct stenting. The DIRECT II study was undertaken to demonstrate the feasibility of the Svelte IDS in a randomized, controlled setting.

METHODS AND RESULTS

The Svelte IDS utilizes a 81µm thick CoCr stent with bioresorbable amino acid-based (PEA) drug carrier eluting sirolimus mounted on a low-compliant balloon affixed to a 0.014” integrated Asahi wire. The DIRECT I First-In-Man study (n=30) reported 0% clinically-driven MACE through final 5-year follow-up. DIRECT II, a prospective, randomized study to establish non-inferiority of the Svelte IDS compared with the Resolute IntegrityTM DES, was undertaken at 18 clinical sites in Europe. 159 patients with symptomatic ischemic heart disease due to de novo lesions in arteries with RVD 2.5mm – 3.5mm and lesion lengths < 20 mm were enrolled. Clinical and angiographic follow-up was performed at 6 months to assess TVF and LLL as well as multiple secondary endpoints, with fianl clinical follow-up at 5 years. Stent evaluation post-procedure and at 6 months via OCT was also performed in 30 patients. All events and imaging were reviewed and adjudicated by an independent DSMB and core lab.

The transradial approach was used in 67% of interventions; approximately 40% of the invetigators were first-time users of Svelte IDS. At 6 months, in-stent LLL was 0.09 ± 0.31 mm with the Svelte IDS compared to 0.13 ± 0.27 with Resolute Integrity ($p<0.001$ for non-inferiority). OCT revealed good stent coverage (94.2 + 9.0%) and low stent strut malapposition (0.7 + 1.9%) with Svelte IDS. 6-month and 4-year TVF rates were similar between groups (4.6% vs. 7.8%, $p=0.469$ at 6 months; 8.3% vs. 11.8%, $p=0.757$ at 4 years in the Svelte IDS and control arms, respectively). No patients experienced stent thrombosis through 4 years, with MACE reported as 4.5% and 7.8% ($p=0.270$) in the Svelte IDS and control arms, respectively. A subanalysis of top enrolling sites demonstrated reduced procedural times with the Svelte IDS, with 22 minutes (n=23) and 31 minutes (n=26) reported in the Svelte IDS and Resolute Integrity arms, respectively ($p=0.039$). In addition, device times were 4 minutes in the Svelte IDS group vs. 11 minutes in the Resolute Integrity group ($p=.005$). Trends toward reduction in fluroscopy time and contrast use with the Svelte IDS were also observed.

Final 5-year clinical follow-up on all patients will be available March 2019.

CONCLUSIONS

This is the first report of final 5-year clinical outcomes in the DIRECT II study. DIRECT II demonstrated non-inferiority of Svelte IDS to the Resolute Integrity DES with respect to LLL at 6 months. Clincial outcomes remain numerically similar through 4-years. Procedure and device times were reduced with Svelte IDS, wth trends toward reduction in fluoroscopy time and contrast use. Svelte IDS facilitates TRI, 'Slender' PCI and direct stenting, offering the potential to enhance procedural outcomes and patient comfort while reducing the time and cost of PCI.

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Comparison of EuroCTO (CASTLE) and J-CTO scores in predicting success of CTO PCI

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Success prediction scores could help in case selection, planning and risk stratification of chronic total occlusions (CTO) PCI. The novel EuroCTO (CASTLE) scoring system has been recently derived and validated from the large multicentre EuroCTO registry, It is comprised of 6 factors (age> 70 years, previous CABG, blunt proximal cap, severe tortuosity, severe calcification and lesion length > 20 mm, 1 point for each factor with minimal score of 0 and maximal score of 6). We sought to compare the predictive efficiency of the novel EuroCTO score with the more commonly used J-CTO score.

METHODS AND RESULTS

In this analysis, we evaluated all CTO PCIs performed in a tertiary cardiac centre since the onset of a dedicated CTO programme from June 2012 to November 2018. Clinical, angiographic, and procedural characteristics were prospectively collected and the EuroCTO and J-CTO scores were calculated. Overall, 660 CTO PCIs were performed (mean age: 66±11 years, 84% male). The overall technical success for the period assessed was 77%. The mean J-CTO and EuroCTO scores were 1.86 ± 1.2 and 1.74 ± 1.2, respectively. Antegrade wire escalation (AWE), antegrade dissection re-entry (ADR) and retrograde approach (RA) were used in 82%, 14% and 37% of cases, respectively. The successful strategy was AWE ADR or RA in 67%, 11%, 22% of the cases respectively. J-CTO score appeared to overestimate case complexity compared to EuroCTO score (J-CTO >= 3 in 28% vs. EuroCTO >= 4 in 9% of cases, p<0.001). There was a significant decline in success rates with increased case complexity as graded by both scores [J-CTO: 0 (96%), 1 (90%), 2 (76%), >=3 (62%), p<0.001; EuroCTO: 0-1 (88%), 2 (78%), 3 (63%), >=4 (58%), p<0.001]. Receiver-operator characteristic analysis demonstrated comparable discriminatory capacity between the two tests (AUC: 0.698, 95%CI: 0.653-0.742 p<0.001 for J-CTO vs. AUC: 0.676, 95%: CI 0.627-0.725, p<0.001 for EuroCTO; AUC difference: 0.022, p=0.5). However, for more complex procedures (J-CTO >= 3 or EuroCTO >= 4), the predictive capacity of EuroCTO appeared superior compared to J-CTO score (AUC: 0.462, 95%CI: 0.379-0.544, p=0.4 for J-CTO vs. AUC: 0.591, 95%: CI 0.509-0.673, p=0.035 for EuroCTO; AUC difference: 0.129, p=0.03)

CONCLUSIONS

The novel EuroCTO score has a comparable predictive capacity to J-CTO score and appears to more accurately predict successful outcomes for the most complex cases.

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Comparison of long-term outcomes among ACS and non-ACS patients treated with Xience everolimus-eluting stent: a patient-level pooled analysis from four Xience post-approval trials

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THEME: Coronary Interventions
TOPIC(S): NSTEMI, Stents and scaffolds

AIMS

Patients with ACS have been associated with worse short-term and long-term PCI clinical outcomes compared to non-ACS patients. This analysis aims to compare clinical outcomes in ACS vs. non-ACS, in a large pool of patients treated with XIENCE V.

METHODS AND RESULTS

We performed a patient-level pooled analysis of 4 all-comer real world post-approval registries (XIENCE V USA, XIENCE V Japan, XIENCE V China and XIENCE V India) with a total of 10,000 enrolled patients treated with XIENCE and 4-year follow up. ACS designation was site determined. ACS patients, compared to non-ACS, were more likely to be smokers (28.5% vs. 21.7%, p<0.0001), had a higher rate of multi-vessel disease (44.2% vs. 39.1%, p<0.0001) and AMI (38.9% vs. 2.5%, p<0.0001). ACS compared to non-ACS patients were associated with lower rates of restenotic lesions and bifurcations but a higher rate of ostial lesions (16.7% vs. 13.3%, p<0.0001). Adjusted Kaplan-Meier analysis from 0-4 years demonstrated that ACS vs. non-ACS patients were associated with similar rates of all-cause death (ACS 7.4% vs. Non-ACS 7.9%, p=0.16), similar cardiac death (ACS 4.0% vs. Non-ACS 3.5%, p=0.43), but with lower non-cardiac death (ACS 3.7% vs. Non-ACS 4.7%, p=0.007). MI rates were similar between the two groups (ACS 2.5% vs. Non-ACS 2.8%, p=0.96). Ischemic driven TLR rates out to 4 years were lower for ACS patients vs. non-ACS (ACS 5.3% vs. Non-ACS 6.2%, p=0.007). However, ACS patients had higher ST (def/prob) rates (ACS 1.1% vs. Non-ACS 0.7%, p=0.02).

CONCLUSIONS

In this large pooled patient-level analysis, with current generation DES, ACS presentation was not associated with increased mortality (all cause and cardiovascular), or MI, but was associated with higher rates of ST (def/prob).

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A prospective randomised multicentre study to assess the safety and effectiveness of the Orsiro sirolimus-eluting stent in the treatment of subjects with up to two de novo coronary artery lesions - BIOFLOW IV: four-year clinical results

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

The aim of the BIOFLOW-IV study is to compare the safety and effectiveness of the Orsiro Sirolimus Eluting Stent (SES) with Xience Prime/Xience Xpedition Everolimus Eluting Stent (EES) in a prospective multi-centre randomized controlled non-inferiority trial in a mixed population of Caucasian and Japanese subjects.

METHODS AND RESULTS

A total of 575 subjects (age 64.7 ± 9.6 years) were enrolled in the Intention to Treat population at 46 sites in Europe, Israel, Japan and Australia. All subjects were randomly assigned (2:1) to receive Orsiro (n= 385) or Xience (n=190), respectively. The randomization was stratified for diabetes. Hypertension (75.1%) and Hypercholesteremia (69.0%) were the major cardiovascular risk factors in the overall population. 30.6% of the subjects presented with a history of myocardial infarction.

Clinical follow up visits were performed at 1, 6, 12, 24, 36 and 48 months post index procedure. All angiographic index images were analyzed by an independent Corelab. All clinical events were adjudicated by an independent clinical events committee. Statistical analysis was performed for the total study population

Both randomization groups showed comparable baseline results with regards to demographics, medical history and risk factors, and lesion characteristics. The primary endpoint TVF (Universal Definition) rate at 12 months (including a time window of 14 days) was 5.1% in the Orsiro group vs 6.6% in the Xience group. Non-inferiority between the two treatment groups was confirmed with p=0.0003. At 36 months (including a time window of 30 days), the TVF failure estimates were 10.4% (Orsiro) vs 9.7% (Xience) (p= 0.8382) for the overall cohort. Definite or probable stent thrombosis failure estimates were 0.8% in the Orsiro group vs 0.0% in the Xience group (p=0.5544). 48 months results are currently being analyzed and will be presented for the first time during EuroPCR 2019.

CONCLUSIONS

The ultrathin Orsiro SES with biodegradable polymer was non inferior to the Xience EES with durable polymer at 12 months for TVF. There were no statistically significant differences in other clinical endpoints at 12, 24 and 36 months between the two treatment groups in a mixed population of Japanese and Caucasian subjects. Long-term results up to 48 months will be presented for the first time during EuroPCR 2019.

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Impact of right ventricular dysfunction on outcomes after transcatheter edge-to-edge tricuspid valve repair; results from the TRIVALVE registry

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THEME: Interventions for Valvular Disease
TOPIC(S): Tricuspid / Pulmonary valve

AIMS

Right ventricular dysfunction is associated with a worse prognosis among patients undergoing valvular heart surgery. We aimed to assess its impact on the benefit and outcome of transcatheter edge-to-edge tricuspid valve repair (TTVR) among patients presenting severe tricuspid regurgitation (TR).

METHODS AND RESULTS

We compared the outcome of TTVR according to baseline right ventricular function using data from the TRIVALVE Registry that includes patients undergoing edge-to-edge TTVR in 14 centres from Europe and North America. Tricuspid annular plane systolic excursion (TAPSE) was used to assess right ventricular function. Overall, 249 patients with severe TR treated with edge-to-edge TTVR between June 2015 to June 2018, were followed for a mean of 292 ±195 days. Mean TAPSE was 15.8 ±15.3mm with a lowest value of 5mm. Patients were divided according to their quartile of TAPSE into 4 groups: TAPSE <13mm (n=54); TAPSE between 13 and 16mm (n=62); TAPSE between 16 and 19mm (n=61); and TAPSE>19mm (n=65). Patients in the lowest TAPSE quartile were younger (73.8 ±12.5 yrs compared to 77.5 ±7.9 yrs in the second quartile group, 77.5 ±9.1 yrs in the third quartile group and 78.9 ±7.8 yrs, global P = 0.029). They had more frequently a previous admission for RV failure (88.9% vs. 68.9%, 81.7% and 59.7% respectively, P= 0.001) and ascites (37.0% vs. 24.2%, 16.4%, 15.9% respectively, P = 0.025). There was a non-significant trend towards a higher rate of NYHA III-IV grade in the lowest TAPSE quartile (94.4% vs. 96.8, 100%, 90.8% respectively, P=0.07). The EuroSCORE II was significantly higher when compared with the second quartile group (15.0 ±14.9 vs. 9.1 ±6.5 in the second quartile, 12.3 ±12.5 in the third quartile and 8.1 ±10.5 in the highest quartile, P=0.005.
Procedural success rate, defined as a successful implantation of the clip device and a post-procedural TR of grade 2+ or less, was similar in all groups (79.6% in the first quartile group, 80.6% in the second quartile group, 77.0% in the third quartile group, and 76.9% in the fourth quartile group, P=0.95). At final follow up, improvement in NYHA was observed in all groups. NYHA class I-II was found in 66.8% of patients in the lowest TAPSE quartile group, 65.4% of patients in the second quartile group, 65.2% in the third quartile group, and 65.4% in the fourth quartile group (P=0.3). There was no difference in the combined endpoint of survival free from hospital admission at one year (LogRank P value = 0.42; Figure). Similarly, there was no difference in the individual endpoints of survival or absence of heart failure hospital admissions between the four groups (survival: P value = 0.3, absence of HF hospital admission: P value = 0.98).

CONCLUSIONS

Among patients undergoing TTVR for severe TR, contrary to tricuspid surgery where right ventricular

dysfunction is associated with worse outcome, clinical benefit and survival free from hospital admission at one year are not influenced by baseline TAPSE. Accordingly, TTVR is an attractive option among patients with pulmonary right ventricular dysfunction, and patients should not be denied TTVR on the basis of severe ventricular dysfunction.

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12-month clinical results from the dedicated bifurcation cobalt-chromium sirolimus-eluting stent first-in-man registry

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THEME: Coronary Interventions

TOPIC(S): Left main and multivessel disease, Bifurcation lesion

AIMS

The optimal approach to coronary bifurcations treatment by PCI is still a subject of debate and the dedicated bifurcation stents are one of proposed solutions. The aim of this report was to present 12-month clinical results from the new dedicated bifurcation stent – sirolimus-eluting BiOSS® LIM C (Balton, Poland) Registry.

METHODS AND RESULTS

To evaluate the safety and feasibility of the sirolimus-eluting BiOSS LIM C® stent, patients with stable coronary artery disease or non-ST-elevation acute coronary syndrome (NSTE-ACS) were enrolled into this multicenter registry between August 2016 and December 2017. Main exclusion criteria were ST-elevation acute coronary syndrome (STE-ACS), bifurcations with Medina 0,0,1, serum creatinine level ≥ 2.0 mg/dl, inability to take dual antiplatelet therapy (DAPT) for 12 months, bifurcations a priori qualified to the treatment with a two-stent technique as well as the lack of an informed consent. Written, informed consent was obtained from all patients before cardiac catheterization. Institutional Review Board approved the study protocol (No 84/2016)

The BiOSS LIM C® is a dedicated bifurcation balloon expandable stent made of cobalt-chromium (strut thickness 70 μm). The stent releases sirolimus (1.4 μg/mm2) from the surface of a biodegradable coating comprised of a copolymer of lactic and glycolic acids. The degradation of the polymer lasts approximately 8 weeks. The BiOSS LIM C® stent consists of two main separate parts with different diameters: wider proximally, and distally smaller. The proximal part is always shorter than the distal one (avg. 1 mm). The ratio of the proximal part to the distal one varies between 1.15 to 1.3, ensuring physiological compatibility and optimal flow conditions. In the middle zone both parts are connected by two struts (2.0 – 2.4 mm in length after the BiOSS® stent implantation).

Provisional T-stenting was the obligatory strategy of the treatment. The primary endpoint is the cumulative rate of cardiac death, myocardial infarction (MI) and clinically-driven target lesion revascularization (TLR) at 12 months.

A total of 95 patients with lesions in coronary bifurcations were enrolled (mean age 66.8±9.8 years, 17.9% of female). There were 25.2% of patients with NSTE-ACS, 90.5% with hypertension, 33.7% with diabetes, 53.7% had previous MI, and 46.3% and 14.7% underwent prior PCI and CABG, respectively. Worth stressing is the fact that true bifurcations were present in 52.6% (n = 50).

The device success rate was 100%. The side branch was treated with an additional classical DES implantation in 18.9% of cases. The rate of proximal optimization technique was 53.7%, whereas the final kissing balloon inflation was performed in 29 patients (30.5%), reflecting a good result in the side branch after stenting.

The periprocedural MI (MI type 4a) was observed in four cases (4.2%). At 12 months MACE rate was 9.5%, cardiac death – 1.1%, MI – 2.1% and clinically-driven TLR – 6.3%.

CONCLUSIONS

Bifurcation treatment with a single dedicated bifurcation stent (BiOSS LIM C) is feasible and highly successful

(100% implantation rate). Twelve-month clinical results are promising, and long-term observations are pending.

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Angiographic and OCT assessment in follow-up of a new paclitaxel-eluting balloon, with an ultrasonic nanotechnology drop dosage system, for the treatment of in-stent restenosis

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

In-stent restenosis (ISR) treatment remains challenging. Drug-eluting balloons (DEB) have shown to be a valid treatment option in many trials, nonetheless no class-effect should be claimed, so every new DEB has to be evaluated through clinical studies. This study sought to assess the efficacy of a new DEB, the paclitaxel-eluting balloon ESSENTIAL™ (iVascular) in the setting of ISR and cross-comparing results with those reported for other currently available DEB for ISR.

METHODS AND RESULTS

This study is a prospective, multicenter, single-arm study that included consecutive patients undergoing PCI on ISR (Mehran patterns I and II). All patients were treated with the ESSENTIAL™ balloon. This is a paclitaxel-eluting balloon with a concentration of 3 µg/mm2 and a proprietary coating technology (TransferTech™, iVascular) consisting in a nanotechnology drop dosage system that yields a multilayer microcrystalline thin coating for a faster drug absorption rate. A 6-months angiographic and OCT follow up was scheduled. The primary end-point was OCT derived in-segment maximal area stenosis. Secondary endpoints included QCA-derived in-segment late lumen loss (LLL) at 6 months and target lesion failure (TLF) rate at 6, 12 and 24 months, defined as the composite of cardiac death, target-vessel myocardial infarction and target lesion revascularization (TLR). A Core Lab analysis of QCA and OCT data was conducted. A central adjudication of clinical events was attained. A total of 33 consecutive patients fulfilling the study criteria were included with age 58±10 years, 21% females, 67% ISR of drug-eluting stents (DES), Mehran pattern I 42% and Mehran pattern II 58%, lesion length 11.6±5.5 mm and reference vessel diameter 2.7±0.4 mm. In 31 patients the treatment was successfully accomplished with DEB while the other 2 required a new DES implantation. At 6 months 26 patients underwent the scheduled angiographic follow up. Among the remaining 5 patients: 1 non-cardiac death within first month, 1 TLR at 4 months, 1 asymptomatic patient moved to other country and 2 asymptomatic patients refused. The OCT analysis showed an in-segment maximal area stenosis of: mean 51.4 ± 13% and median 53% (IQR 46.4-59.5). In DES-ISR subgroup 52.6 ± 10% and 55.2% (IQR 49.3-58.5). In-segment LLL was 0.25±0.43 mm with only 2 patients showing binary restenosis (> 50%). Incidence of TLF was 10% at 6 months, 13.3% at 12 months and 13.3% at 24 months with all events corresponding to TLR since no cardiac death, myocardial infarction or thrombosis occurred. There were 1 non-cardiac death and 4 revascularizations out of target vessel. Regarding OCT area stenosis these results appear comparable to those published for the IN.PACT Falcon™ (Medtronic) median 47.7% (37.3-60.7), SeQuent Please™ (Braun) mean 50% but lower compared to DIOR ™(Eurocor) median 66.4% (49.9-76.6). With respect to the in-

segment LLL, the findings are in the range of the most evidence supported DEB, SeQuent Please™ (Braun), with mean values at 6 months ranging from 0.1 to 0.4 mm with an standard deviation of ± 0.4 to 0.6 mm.

CONCLUSIONS

In this study, the ESSENTIAL™ DEB showed a good and sustained efficacy in prevention of recurrent ISR (mostly of DES). This new DEB could perform comparably to the most evidence-supported DEB.

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First-in-human experience with patient-specific computer simulation of TAVI in bicuspid aortic valve morphology

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Patient-specific computer simulation of TAVI in bicuspid aortic valve morphology (BAV) has been retrospectively demonstrated to predict the development of both paravalvular regurgitation and conduction disturbance. We wished to evaluate its clinical utility in a prospective patient cohort.

METHODS AND RESULTS

Between June and December 2018, all patients with BAV who were referred for TAVI prospectively underwent patient-specific computer simulation using TAVIguide technology (FEops, Ghent, Belgium). Pre-procedural CT imaging was used to create a patient-specific finite element model of the aortic root. A finite element model of a self-expanding transcatheter heart valve (THV) was positioned within the aortic root model. Finite element analysis was performed to simulate the interaction between the THV and the aortic root. The blood domain was extracted and computation fluid dynamics performed in order to simulate paravalvular regurgitation. The membranous septum was used to identify the location of the left bundle branch. The pressure exerted by the THV on the left bundle branch was recorded in order to simulate conduction disturbance. For each patient, the simulations were repeated multiple times, varying both the simulated THV prosthesis size and the simulated THV implant depth. The output of these multiple computer simulations was then used to determine the optimal treatment strategy for the patient.

A total of 8 patients underwent patient-specific computer simulation. The computer simulations altered the treatment strategy in six patients (75%). In one patient, the computer simulations suggested severe paravalvular regurgitation and the patient was referred for surgical aortic valve replacement. The remaining seven patients underwent TAVI with a self-expanding THV. Following review of the computer simulations, five of these patients had their planned THV prosthesis size and/or implant depth altered, in order to minimise paravalvular regurgitation. In one of these patients, the computer simulations also suggested significant conduction disturbance after TAVI and a permanent pacemaker (PPM) was inserted prior to the TAVI procedure.

Following the TAVI procedure, no patient developed moderate/severe paravalvular regurgitation. The patient in whom a pre-procedure PPM had been inserted became pacing dependent with underlying third-degree atrioventricular block. No other patient required post-procedural insertion of a PPM.

CONCLUSIONS

Patient-specific computer simulation of TAVI in BAV can be used to risk-stratify patients and to alter procedural strategies. The usage of patient-specific computer simulation to guide the THV prosthesis size and implant depth was associated with favourable clinical outcomes.

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Evaluation of the novel, self-expanding CENTERA transcatheter heart valve system at two years

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

The CENTERA™ transcatheter heart valve (THV) is a low-profile (14F eSheath compatible), self-expanding nitinol valve, with a motorized delivery system allowing for repositionability of up to 85% of its deployment. The 2-year effectiveness and safety of the CENTERA THV has been assessed from the CENTERA-EU Trial.

METHODS AND RESULTS

Implantations were completed in 23 centres in Europe, Australia, and New Zealand. Echocardiographic outcomes were adjudicated by a core laboratory to 2 years. Major adverse clinical events were adjudicated by an independent clinical events committee.

Between March 2015 and July 2016, 203 high-risk patients (82.7±5.5 years, 67.5% female, 68.0% NYHA Class III/IV, STS score 6.1±4.2%) with severe, symptomatic aortic stenosis underwent transcatheter aortic valve replacement with the CENTERA THV. Transfemoral access was used in all patients. The primary endpoint of the study was 30-day mortality (1.0%). At 2 years, 157 (77%) patients completed their follow-up visit. Overall mortality was 18.8%, cardiovascular mortality was 11.2%, disabling stroke was 4.1%, cardiac-related rehospitalization was 16.5%, and prosthesis valve endocarditis and thrombosis were 2.9% and 1.6%, respectively. Hemodynamic parameters were stable at 2 years, with a mean aortic valve gradient of 6.7±2.5 mmHg (n=127), a mean effective orifice area of 1.7±0.4 cm² (n=113), and no incidences of severe or moderate paravalvular regurgitation (PVL).

CONCLUSIONS

The CENTERA-EU trial demonstrated mid-term safety and effectiveness of the CENTERA THV, with low mortality, sustained improvements in hemodynamic performances, and no severe or moderate PVL in high-risk patients with symptomatic aortic stenosis.

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Cardiac autonomic nerves stimulation improves haemodynamics and clinical status in advanced heart failure patients

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THEME: Interventions for Heart Failure
TOPIC(S): Acute heart failure

AIMS

Despite therapy advances in the management of heart failure, symptomatic congestion and low cardiac output in acute heart failure is a leading cause of mortality and morbidity. An electrode catheter-based technology is being investigated to transvenously stimulate cardiac autonomic nerves to control left-ventricular contractility and heart rate (HR) in order to improve hemodynamics.

METHODS AND RESULTS

The purpose of this study was to investigate transvenous cardiac autonomic nerve stimulation (CANS) effects on in-hospital hemodynamics and signs and symptoms of congestion. The study was a single-center, observational, clinical investigation of CANS. Twelve (12) subjects with reduced left ventricular ejection fraction (LVEF < 40%), who presented with at least two signs and symptoms of congestion were consented and enrolled. A purpose-built electrical stimulation catheter was placed in the left brachiocephalic vein via left subclavian vein access. A purpose-built neurostimulator was then connected to the catheter and used to deliver CANS therapy bedside for up to 96 hours. Hemodynamic effects and measures of signs and symptoms of congestion were observed over the therapy period.

The majority of the subjects were male (9/12), had a mean age of 62 years, mean body mass index of 29, a mean baseline NT-proBNP of 10,915 pg/mL, a mean baseline LVEF of 24%, a mean baseline pulmonary capillary wedge pressure (PCWP) of 19 mmHg and presented with an average of 3 signs and symptoms of congestion. CANS therapy was provided, at physician discretion, for a mean duration of 59 hours and was well tolerated. There were no device or study related adverse events reported.

During the in-hospital CANS therapy period hemodynamics improved. Average cardiac index increased (1.7 to 2.1 L/min/m2), systemic vascular resistance (SVR) decreased (25 to 20 WU), and PCWP decreased (19 to 14 mmHg) with little change in mean arterial pressure (84 to 82 mmHg) or HR (74 to 75 BPM). Hemodynamic improvements were associated with improved clinical status over the in-hospital CANS therapy period and at 30 day follow-up. Patients were net negative in fluids an average of 1.3 L, edema pitting score improved 2 points, and 6 minute hall walk distance (6MHW) increased 54 meters at discharge. At 30 day follow-up, edema pitting score improved 3 points, 6MHW increased 106 meters and the KCCQ-12 summary score improved 37 points from baseline.

Hemodynamic and clinical improvements occurred in the presence of stable medical management. Patients received at least 80 mg/day of furosemide, had minimal change to existing heart failure medical management, received no new vasoactive therapies, and a majority of the patients (9/12) received no furosemide dose up titration during CANS Therapy.

CONCLUSIONS

Alongside concomitant medical therapy, CANS directly improved hemodynamics and was associated with

improved signs and symptoms of congestion in advanced symptomatic heart failure patients. These improvements, coupled with a positive safety profile, demonstrate that CANS holds promise as a tool to improve in-hospital hemodynamics and relieve congestion.

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Long-term results of the left main coronary artery stenting with the use of different generation DES

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease

AIMS

The aim of our study was to evaluate long-term results of the unprotected left main coronary artery stenting with various types of stents and highlight the risk factors of major adverse cardiovascular events.

METHODS AND RESULTS

The retrospective cohort study included 282 patients with the unprotected left main coronary artery lesion. The observation was 34.6 month. The average age of patients was 62.3 ± 10.4 years. Depending on the used stents, patients were divided into group I (1st generation stents, N = 100), II (2nd generation stents with insoluble polymeric carrier, N = 101) and III (3rd generation stents with a bioresolbable polymeric coating, N = 81). Patients in groups I and II received dual antiplatelet therapy for 12 months; in group III the therapy was 4 months.

The frequency of major adverse cardiovascular events (including cardiovascular death, myocardial infarction, stroke and target lesion repeat revascularization) at 3 years was higher in group I (29%, 9.9% and 4.9%, p<0.0001). In group I, a higher frequency of repeat revascularization (27%, 11.9% and 7.4%, p <0.0001) and a frequency of target lesion repeat revascularization for (8%, 1% and 0%, p = 0.0028) was observed. There was no statistically significant difference in the incidence of stent thrombosis between groups, however the incidence of sirolimus eluting stent thrombosis was higher compared to everolimus eluting stents (10.4% and 0-3.8%, p=0.046). There were no differences in the incidence of thrombosis in groups I and II with standard antiplatelet therapy and III with a reduced duration of this therapy (4.5% and 1.2%, p = 0.663). Hazard ratio (HR) analysis revealed clinical and angiographic predictors of major adverse cardiovascular events. They included age over 75 (HR 1.153, 95% confidence interval (CI) 1.052 – 1.264), the presence of peripheral artery disease (HR 1.129, 95% CI 1.009 – 1.151), creatinine clearance level <60 ml/min (HR 1.931, 95% CI 1.017 – 3.667), p<0.05. The Syntax score higher than 32 (HR 1.428, 95% CI 1.159 – 1.760), the absence of stent high pressure postdilatation (HR 3.062, 95% CI 1.765 – 5.312), the use of two stent strategy (HR 1.207, 95% CI 1.031-1.413) and first generation drug eluting stents (HR 3.770, 95% CI 2.091 – 6.797) were angiographic predictors of major adverse cardiovascular events (p<0.05).

CONCLUSIONS

optimization of the stenting technique and the use of new generation drug eluting stents significantly improved the results of left main coronary artery stenting. The use of second and third generation drug eluting stents is associated with a lower frequency of repeat revascularization and major adverse cardiovascular events. Additional risk factors of major adverse cardiovascular events include age over 75, peripheral artery disease, creatinine clearance level <60 ml/min, the Syntax score higher than 32, the absence of stent high pressure postdilatation and the use of two stent strategy.The use of stents with a bioresolbable polymer coating provides possibility to reduce the duration of dual antiplatelet therapy to 4 months in such group of patients with,

however additional studies are needed.

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Single low-dose apixaban vs. single acenocumarol in patients with atrial fibrillation after TAVI. A propensity score matched analysis

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Study aimed to compare single low dose apixaban (APX) and single acenocumarol (ACC) with regards to the incidence of mortality and adverse events in patients with atrial fibrillation after transcatheter aortic valve implantation (TAVI) with Edwards Heart Valves system.

METHODS AND RESULTS

Observational registry in one center including consecutive patients meeting the following criteria: TAVI procedure with Edwards prosthesis with at least one year follow up, previously known or new onset atrial fibrillation, treatment with APX 2.5 mg BID or ACC both with no antiplatelet therapy associated. A propensity score matching process was done to derive two comparable cohorts. Among the 410 patients treated with TAVI, 103 patients met the criteria, out of these 67 were on ACC and 36 on APX. The propensity score matching yielded two groups of 36 patients each. The main clinical characteristics were comparable: age (81.2±8.3 yrs in ACC vs.82.3±5.3 yrs in APX, p=0.5), females (39% vs. 33%, p=0.8), CHA2DS2-VASc (4.1±1.4 vs.4.2±1.2, p=0.7) and HAS-BLED (2.64±1.05 vs. 2.67±1.1, p=0.9). At one year follow up, death (11% vs. 5.5%, p=0.7) and cardiac death (2.7% vs. 0%, p=0.9) were comparable but numerically higher in ACC group. An equivalent incidence of MACCE (death, myocardial infarction and stroke) was found in both groups (11% vs. 11%, p=1), but a significantly lower incidence of bleeding BARC ≥ 2 was observed in APX group (16.6% vs. 0%, p=0.03). In addition, a trend for less major bleeding BARC ≥ 3 (11% vs. 0%, p=0.12) and a lower NACCE (death, myocardial infarction, stroke and bleeding BARC ≥ 2), 25% vs. 11%, p= 0.2, was observed in APX group as well.

CONCLUSIONS

In this registry, compared to single Acenocumarol, single Apixaban 2.5 mg BID resulted in a similar incidence of MACCE but a significantly lower incidence of actionable bleeding at one year after TAVI.

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Treatment of CTO: experience from a large worldwide registry

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds, CTO

AIMS

To evaluate techniques and outcomes of contemporary treatment of chronic total occlusions (CTO) using a sirolimus-eluting stent with bioresorbable polymer in a large real life registry.

METHODS AND RESULTS

e-ULTIMASTER is a prospective, single-arm, multicentre registry, designed to further validate the safety and efficacy of the Ultimaster DES in unselected patients enrolled worldwide. Of the 19482 patients enrolled so far and reached 1-year follow up, 1028 patients with at least one successfully treated CTO lesion were enrolled in a pre-specified subset.

The mean age of CTO group of patients was 64.2 years, 81.3% were males, 32.8% of patients had diabetes mellitus, 63.7% had hypertension, and 61.1% had hypercholesterolemia. In total 34.4% of patients had previous PCI and 11.8% prior CABG. Among these patients, 23.4% have treatment in more than 1 vessel, and the number of lesion identified and treated per patient was 1.9±1.0 and 1.6±0.9, respectively. The most frequently treated vessel was RCA (50.4%), followed by LAD (44.0%) and Circumflex (28.4%). The number of study stent implanted per patient was 1.9±1.1 with a total stent length of 50.4±31.1mm. Regarding the CTO lesion, approximately 83% were treated using antegrade and 17% retrograde approach. The average radiation dose was 1741mGy (mSv?) and the contrast volume was 236ml. Direct stenting was performed in 22.7% of treated lesions while post dilatation was performed in 51.4% of treated lesions. Microcatheter was used in 23.2% of the procedures and imaging (IVUS or OCT) was used in 13.3% of the patients.

At 1 year 2.3% of patients died, with 1.4% from cardiac causes, 1.1% had suffered a myocardial infarction during follow up and 1.4% underwent target lesion revascularization (TLR). Composite endpoint of target lesion (TLF) and target vessel failure (TVF) were both 3.0% at 1 year. Definite or probable stent thrombosis occurred in 1.0% of the patients at 1 year follow up. In a multivariable analysis, we further explored the possible predictors for 1-year clinical outcome of CTO patients after PCI, and we identified current smoker as predictor of TLR (odds ratio OR: 4.14, p=0.02) and TLF (OR: 2.23, p=0.06) at 1 year follow up.

CONCLUSIONS

CTO patients treated using Ultimaster DES in the e-ULTIMASTER registry showed good clinical outcome at 1 year, with particularly low revascularization and stent thrombosis rate. Risk factors identified in this analysis provided additional insights into successful treatment of this challenging lesion

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Comparison of subclinical leaflet thrombus between TAVI vs. AVR in early acute phases

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Subclinical leaflet thrombosis after Transcatheter Aortic Valve Implantation (TAVI) has recently described called as hypo-attenuated leaflet thickening (HALT) using multi-detector computed tomography (MDCT). This phenomenon is not observed only TAVI but also Surgical Aortic Valve Replacement (SAVR) as well. We sought to evaluate and compare the frequency of HALT and clinical findings between TAVI and SAVR patients.

METHODS AND RESULTS

Methods

From August, 2016 to December, 2018 in our center, consecutive 127 patients with severe aortic stenosis underwent TAVI and examined contrast MDCT at discharge in 80 patients without chronic kidney disease (CKD). Of these, 4 patients were excluded because of poor quality images and valve in valve procedures. Consecutive 76 patients were enrolled in this study as a TAVI group. On the other hand, consecutive 30 patients underwent SAVR and had contrast MDCT as well from January to December, 2018. 2 patients were excluded due to mechanical valve replacement, and 28 patients were enrolled as a SAVR group. We evaluated MDCT findings and compared clinical findings between these two groups. All the patients were treated with anti-coagulation therapy after operation in SAVR patients, and either anti-platelet therapy or anti-coagulation therapy in TAVI group.

Results

There was significant difference in patient age between TAVI and SAVR groups (TAVI 85.3 vs SAVR 74.3 year-old). Echocardiographic parameters regarding aortic valve at discharge were significantly improved in TAVI group (Aortic Valve Area 1.94 vs 1.63 mm2, peak pressure gradient (PG) 20.1 vs 28.5 mmHg, mean PG 10.6 vs 16.1 mmHg, $p<0.001$ each). However, HALT was more frequently seen in TAVI groups than SAVR group (27.6% vs 7.1%, $p=0.032$). There was no difference in valve type between balloon expandable valve versus self expandable valve in TAVI group (26.5% vs 29.6%, $p=0.77$). No case of stroke or embolism was seen in both TAVI and SAVR group during this follow up period. Focusing on HALT or non-HALT, no significant difference in D-dimer, but significantly lower platelet level was observed in HALT positive patients (16.9±8.3 vs 12.5±4 105/μL, $p=0.028$). In patients with anti-coagulant therapy after operation, there was no statistical difference between TAVI and SAVR (12.1% vs 7.1%).

CONCLUSIONS

In our study, HALT was more frequently seen in TAVI patient than SAVR. Anticoagulation therapy may be effective for this phenomenon. Further follow up will be needed to evaluate clinical outcomes.

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FANTOM II trial: safety and performance study of the Fantom sirolimus-eluting bioresorbable coronary scaffold - First report: three-year clinical outcomes

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Stents and scaffolds

AIMS

The primary objective of the FANTOM II study was to evaluate the safety and performance of native coronary artery stenting using the Fantom Sirolimus-Eluting Bioresorbable Coronary Scaffold by assessing the incidence of Major Adverse Cardiac Events (MACE) and Late lumen Loss. The Fantom scaffold is a fully resorbable scaffold, manufactured from TyroCore, which is composed mainly of an iodinated, polycarbonate copolymer of tyrosine analogs. Fantom is completely radiopaque and is comprised of thin struts (125 micron) that facilitate device delivery and precise target lesion treatment.

METHODS AND RESULTS

The FANTOM II study was a prospective, multicenter trial which enrolled 240 patients with single de novo coronary stenosis with reference vessel diameter 2.5 to 3.5 mm diameter and lesion length ≤20 mm. Major adverse cardiac events (MACE) through 36 months follow-up were assessed. Angiographic follow-up was performed in consecutive patient cohorts at 6 months (n=117) and 9 months (n=123). Acute delivery success, acute technical success, acute procedural success and clinical procedural success rates as defined in the clinical protocol were 97.9% (235/240), 95.8% (230/240), 99.1% (228/230) and 99.6% (227/228), respectively. The mean in-stent late lumen loss at 6 months and 9 months were 0.25 ± 0.40 mm and 0.33 ± 0.36 mm respectively, and in-segment binary restenosis occurred in 2.0% and 7.6% of patients respectively. MACE and TLF through 36 months will be complete in March 2019 and will be reported at the EuroPCR Course as well as any late scaffold thrombosis.

CONCLUSIONS

The Fantom sirolimus-eluting bioresorbable coronary scaffold demonstrated favorable safety and effectiveness performance at 3 years of follow-up. Longer-term follow-up through 5 years is ongoing to examine the late outcomes with this novel device.

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Contemporary bifurcation treatment practice: what we can learn from a large global registry

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

To explore the real world bifurcation treatment by analysing data from a large worldwide registry

METHODS AND RESULTS

e-ULTIMASTER is a large, prospective, multicentre registry that enrolled patients treated with thin-strut DES with bioresorbable polymer (Ultimaster). Among 19482 patients who reached 1-year follow up, 2541 patients were treated on at least one bifurcation lesion. Patients had a mean age of 65.9 years, 77.6% were male, 27.7% had diabetes mellitus and 47.3% of the patients presented with ACS. More than half of the bifurcation lesions were true bifurcation according to Medina classification with: 1.1.1 (36.0%), 1.0.1 (8.1%), and 0.1.1 (8.4%). In total 1298 patients (50.3%) were treated in both main and side branches, and among them 584 (22.6%) patients received stenting in both branches. The distribution of two stent techniques was: T-stenting 27.9%, Culotte 14.7%, TAP 13.4%, Crush 12.8%, Kissing stents 8.6%, V-stenting 7.0%. Kissing balloon post-stenting was performed in 36.7% of patients, while POT was used in 31.2% of the patients.

Clinical outcomes at 1 year were: any death 3.1% with 2.0% of cardiac cause, target vessel (TV) MI 1.5%. Clinically driven target lesion revascularisation (TLR) of 2.9% and target vessel revascularisation (TVR) of 4.2% at 1 year, respectively. The composite endpoint of target lesion failure was 5.5% with a stent thrombosis rate of 0.8% at 1 year.

We further performed several propensity matched analyses to adjust for baseline and procedural differences when comparing the one-year outcome in 4 types of subgroups. (1) True bifurcation (n=1255) vs other bifurcation (n=1089): similar outcome (cardiac death, TV-MI, and TLR) at 1 year, except for a trend toward a higher clinically driven TVR in true bifurcation (5.0% vs 3.5%, p=0.077). (2) POT (n=755) vs no POT (n=1620): similar death rate at 1 year, while less TV-MI (0.7% vs 1.9%, p=0.02), fewer TLR (1.6% vs 3.5%, p<0.001), fewer stent thrombosis (ST, 0.11% vs 0.91%, p=0.023), and trend toward lower TVR (3.3% vs 4.9%, p=0.077) in patients treated with POT. (3) Final kissing balloon (n=867) vs no final kissing balloon (n=1508): no significant differences regarding cardiac death, TV-MI, TLR, TVR and ST. (4) One stent (n=1823) vs two stent (n=552) technique: comparable outcomes regarding cardiac death, TLR, TVR and ST, while two stent technique group had more TV related MI (2.3% vs 1.1%, p=0.04).

CONCLUSIONS

Data from this large real-life registry reflect good performance of Ultimaster DES in treating bifurcation lesions. Patients treated with POT had lower TV-MI, revascularization and ST rate comparing with no POT while two stent technique is associated with a higher TV-MI.

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Correlation between stent expansion criteria and post-PCI FFR: insights from the DOCTORS study

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THEME:
TOPIC(S):

AIMS

Although being a major determinant of short and middle term outcome following PCI, the most adequate stent expansion assessment by intra-coronary imaging is not completely established. The current study aimed to analyse in a large cohort of patients the relationship between the recently proposed ILUMIEN-3 device expansion criteria and the final PCI functional result.

METHODS AND RESULTS

This prospective multicenter study included patients treated for NSTE-ACS (<72 h) undergoing PCI of the infarct related artery (IRA). OCT was performed before and after PCI. The functional result of PCI was assessed by the measurement of post PCI fractional flow reserve (FFR). OCT runs were retrospectively reviewed by two operators to assess the quality of stent expansion by DOCTORS criteria and ILUMIEN-3 criteria. The following variables were assessed: plaque presence and composition in proximal and distal landing zones, proximal and distal reference segments luminal areas and diameters, proximal and distal reference segments EEL to EEL diameters, intra stent minimal area in proximal and distal halves of the stent. Optimal stent expansion was defined as follows: minimal stent area x 2/ (proximal reference luminal area+ distal reference luminal area)> 80% (DOCTORS criteria); minimal stent area /reference luminal segment area >95 % in both proximal & distal sections of the stent (ILUMIEN-3 criteria). Acceptable expansion was defined as follows: minimal stent area /reference luminal segment area ranging from 90 to 95% in both proximal & distal sections of the stent (ILUMIEN-3 criteria). Post PCI FFR value >/= 0.90 defined procedural success.

The analysis included n=120 patients (Age:60.8±11.5 years / male gender:71%). The final stent expansion was considered as optimal in 10%, acceptable in 9% and unacceptable in 81% of the cases according to ILUMIEN-3 criteria, although being considered successful in 68% of the cases according to the DOCTORS criteria.

Patients with unacceptable ILUMIEN-3 expansion were more frequently men and had a lower history of dyslipidemia. Patients with unacceptable ILUMIEN-3 expansion had a significantly higher incidence of atheroma in the distal landing zone (96 vs. 73%, p=0.02), a larger proximal reference segment luminal area (8.6±2.7vs. 7.3±2.7mm2, p<0.05) and a larger EEL to EEL proximal reference diameter (4.1±0.5 mmvs. 3.8±0.6mm, p<0.05). However, the minimal intra-stent area was comparable in the two groups (6.1±1.76 vs. 6.7±2.46 mm2 , p=0.12).

The mean final FFR value was 0.93±0.004 in the whole cohort and FFR >/=0.90 was observed in 87% of the patients. However, we did not observe any difference between functional results within groups: FFR values were respectively 0.93±0.05 and 0.93±0.03 (p=0.91) in patients with unacceptable and optimal+ acceptable ILUMIEN-3 expansion criteria. Moreover, FFR values were respectively 0.94±0.04 and 0.93±0.04

(p=0.78) in patients with optimal and non optimal expansion according to DOCTORS criteria.

CONCLUSIONS

In the current analysis, we did not observe any impact of optimal stent expansion according to ILUMIEN-3 OCT criteria on final post-PCI FFR results. These data confirm that post-PCI FFR values are driven by multiple parameters including diffuse atherosclerosis.

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Possible mechanism of chronic late lumen enlargement after DEB treatment for de novo coronary artery disease

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Other Coronary Interventions

AIMS

Some recent reports demonstrated that chronic late lumen enlargement (LLE) phenomena after Drug-coated Balloon (DCB) treatment for de novo coronary artery disease (CAD) has sometimes been observed and it was one of the clinical benefits of non-stent DCB therapy. However, its mechanism remains unclear. The aim of this study was to seek the possible mechanism of LLE after DCB treatment for de novo CAD.

METHODS AND RESULTS

This study was prospective observational study enrolled 38 consecutive lesions (31 patients) treated with DCB after pre-dilatation with scoring balloon, using intravascular ultrasound (IVUS) both at index procedure and 9 months follow-up. By IVUS, the cross section was measured at every 1 mm interval throughout the length of each lesion. Mean (= sum of parameters at 1-mm interval / DCB treatment lesion length) and Delta (Δ) values (= follow up – post-procedure) of each parameter were calculated. LLE was defined that Δmean lumen area was positive value. We calculated Dissection Index which was defined as summation of point as follow, 2; dissection over external elastic membrane (EEM), 1; intra EEM, 0; no dissection in every 1-mm interval, and divided by lesion length.After 9 months, clinically driven restenosis was observed in 2.6%. By the follow up IVUS examination, 28 lesions indicated LLE (LLE group; 73.7%) and the remaining 10 lesions (26.3%) showed no LLE (non-LLE group). The ratio of pre-dilatation balloon to reference distal vessel diameter was significantly larger in LLE group (0.96 ± 0.14 vs. 0.74 ± 0.31; p=0.011). Δvessel mean area of LLE group was significantly larger and Δplaque mean area was significantly smaller than that of non-LLE group [(Δvessel mean area: 0.51mm2(0.18mm2, 1.11mm2) vs. -0.24mm2(-0.63mm2, -0.08mm2); p=0.002, Δplaque mean area: -0.30mm2(-0.73mm2, -0.02mm2) vs. -0.01mm2(-0.33mm2, 0.43mm2); p=0.05, respectively)] which suggests vessel enlargement and suppression of plaque proliferation were more frequently observed in LLE group. Furthermore, Dissection Index were significantly higher in LLE group (0.55±0.35 vs. 0.074±0.15; p<0.001). And, Dissection Index was significantly associated with both lumen and vessel enlargement (R2= 0.483, p<0.001 and R2 = 0.316, p<0.001, respectively).

CONCLUSIONS

This study suggests that LLE after DCB treatment for de novo CAD may be caused by both vessel enlargement and suppression of plaque proliferation. The extent of dissection may be important mechanism of LLE.

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Early feasibility trial of the second-generation Colibri dry, pre-mounted, pre-packaged TAVR valve with six-month outcome

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

The second generation Colibri heart valve is a pre-mounted, pre-packaged, low-profile, ready-for-use dry TAVR valve with conical cusp design mounted in manufacture upon a balloon-expandable delivery system in a manner similar to coronary stent systems and is packaged encapsulated within a delivery sheath for insertion into the body. Though dry at insertion, the pericardial membrane leaflets function immediately on deployment in the body. An early feasibility study of a first five patient group with 6 month follow-up was conducted.

METHODS AND RESULTS

The first-in-human use of the second generation Colibri valve was conducted in an early feasibility study initiated March 2018. Primary endpoints at 30 days included: successful valve implantation, valve performance including gradient, aortic valve area, regurgitation/paravalvular leak, and major adverse cardiac and cerebrovascular events (defined as the composite of device related death, non-Q-wave myocardial infarction, Q-wave myocardial infarction, emergent cardiac surgery, valvular thrombosis, structural valve deterioration, hemorrhagic or ischemic stroke). In an initial group five patients with severe aortic stenosis were enrolled and successfully implanted by transfemoral approach.

In two 27 mm and three 24 mm implants there was successful delivery and deployment of a single device in the proper anatomical location, immediate valve function on deployment and retrieval of the delivery system. By echocardiography at 30 days aortic valve areas were 3.6 and 2.7 cm2 for the 27 mm valves and 2.2, 3.0, and 2.1 cm2 for the 24 mm valves. Doppler velocity indexes were 0.63 and 0.57 for the 27 mm valves and 0.51, 0.64, and 0.50 for the 24 mm valves. Paravalvular leak was absent in two cases and trace in three. There were no major adverse cardiac and cerebrovascular events at 30 days. At 6 months aortic valve areas were 3.8 and 3.0 cm2 for the 27 mm valves and 2.6, 2.7, and 2.1 cm2 for the 24 mm valves. At 6 months Doppler velocity indexes were 0.67 and 0.63 for the 27 mm valves and 0.61, 0.62, and 0.50 for the 24 mm valves. Paravalvular leak was absent in three cases and trace in two.

CONCLUSIONS

In the early feasibility trial of TAVR with the second generation Colibri pre-mounted dry valve technology results at 30 days and 6 months showed robust therapeutic effect, including the appearance of large valve areas and Doppler velocity indexes that compare favorably with those of predicate devices, asserting the effectiveness of the pre-mounted dry TAVR valve construct. This observation must be confirmed in further case experience. Results of 1 year follow-up and further patient groups will be reported.

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Long-term outcomes of culotte or T-stenting for non-left main bifurcation lesions compared between first- and second-generation DES

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

To compare long-term outcomes of two stenting strategies for non-left main bifurcation lesions between patients treated with first-generation DES and those treated with second-generation DES.

METHODS AND RESULTS

We retrospectively identified 483 consecutive patients with non-left main bifurcation lesions treated by either culotte or T stenting with either first- or second-generation DES (first-generation DES: Cypher and Taxus stents; second-generation DES: Xience, Promus Element, and Resolute stents) between 2004 and 2014. The primary clinical outcome measure was target-lesion revascularization. The secondary clinical outcome measures were all-cause death, cardiac death, myocardial infarction, and definite or probable stent thrombosis. Clinical outcomes were assessed by Kaplan-Meier methods and were compared by the log-rank test. The median follow-up duration was 5.6 years (interquartile range, 3.1 to 7.7 years). The most common culprit vessels in bifurcation lesions were the left anterior descending artery and its diagonal branch (61.3%). Nearly all the lesions (92.5%) were true bifurcation lesions. Culotte stenting was performed on 226 patients (first-generation DES, 57; second-generation DES, 169) and T stenting on 257 patients (first-generation DES, 201; second-generation DES, 56). The five-year cumulative incidence of target-lesion revascularization was significantly lower in patients treated with second-generation DES than in those treated with first-generation DES, irrespective of stenting strategy (culotte stenting, 23.7% vs. 8.4%, log-rank p = 0.002; T stenting, 22.4% vs. 5.5%, log-rank p = 0.01), and those of all-cause death, cardiac death, myocardial infarction, and definite or probable stent thrombosis were not significantly different in either stenting strategies or stent generations.

CONCLUSIONS

In the treatment of non-left main bifurcation lesions, the use of second-generation DES may reduce target-lesion revascularization compared with that of first-generation DES in the long term, regardless of stenting strategy.

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Same-day admission facilitated by a nurse-led pathway reduces hospital length of stay for transfemoral TAVI

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

There is a growing interest in reducing the hospital length of stay for patients undergoing TAVI, with particular focus on patients who are suitable for a transfemoral approach under local anaesthesia. Early discharge has been shown to be safe for a select patient population. However same day admission will also influence hospital length of stay and there is little data on the feasibility and safety of this approach. This aims to highlight how same day admission can be implemented safely by sharing local experiences and data before and after a same day admission policy was implemented.

METHODS AND RESULTS

A same day admission programme was commenced in our unit in April 2017, supported by the introduction of a TAVI Specialist Nurse. Patients treated under the same day admission programme (same day group) were compared to a control group who were admitted the day before their procedure (standard care group). Length of stay, baseline and procedural characteristics, and in hospital and 30 day follow-up outcomes were analysed. A total of 77 patients in the standard care group and 102 patients in the same day group were analysed. In the same day group, same day admission was planned in 97 patients (95%) with 6 patients ineligible as they had a travel time of more than 3 hours. 91 (94%) of these patients underwent same day admission. TAVI was performed successfully in 89 of these patients – one patient was cancelled due to an overrunning list and the other due to a chest infection. The incidence of same day cancellation was lower in the same day group (11% vs 2%). The average length of stay in the same day group was lower than that of the control group, There was no difference in mortality, procedural complications or readmission rates.

CONCLUSIONS

Routine same day admission for TAVI can be safely implemented for patients undergoing transfemoral TAVI with the support of a Specialist Nurse. This led to a shorter length of hospital stay with no detrimental effect on procedure outcomes or readmission rate and has the potential to lead to significant cost savings.

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Diagnostic accuracy of a fast computational approach to derive FFR from coronary CT angiography

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

The goal of this study was to evaluate the diagnostic accuracy of a new computational method for identifying hemodynamically significant stenoses in patients with coronary artery disease (CAD) from non-invasive coronary CT angiography (CTA), using fractional flow reserve (FFR) as the reference standard.

METHODS AND RESULTS

Data obtained in patients who underwent both coronary CTA imaging and pressure wire-based FFR assessment were retrospectively analyzed in a core laboratory. The lumen borders of the coronary arterial tree were traced using a semi-automated contour detection algorithm. Resting coronary blood flow was estimated based on the allometric scaling law. Data were subsequently converted into hyperemic flow under the assumption of normal microcirculation. Finally, the quantitative flow ratio (QFR), a novel computational algorithm to derive FFR from imaging data without using a pressure wire, was applied to derive CTA-based QFR (CT-QFR), using the reconstructed coronary tree and the hyperemic flow as boundary conditions.

Comparison of CT-QFR and FFR was performed in 156 vessels from 134 patients. Average FFR was 0.82±0.10 and 41.7% vessels were hemodynamically significant using a threshold of 0.80. CT-QFR AUC for identifying vessels with FFR≤0.80 was 0.92. On a per-vessel basis, CT-QFR yielded diagnostic accuracy, sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood ratio and negative likelihood ratio to be 87.2% [95% CI: 81.9%–92.5%], 87.7% [95% CI: 77.2%-94.5%], 86.8% [95% CI: 78.1%-93.0%], 82.6% [95% CI: 71.6%-90.7%], 90.8% [95% CI: 82.7%-95.9%], 6.65 [95% CI: 3.89-11.35] and 0.14 [95% CI: 0.07-0.27], respectively. CT-QFR in vessels with extensively calcified plaques had numerically lower correlation with FFR compared with in vessels with no or less calcification, despite of statistically nonsignificant (r=0.76 versus r=0.81; p=0.444). Meanwhile, higher variability in repeat analysis of CT-QFR was also observed in the cohort with extensively calcified plaques (0.06 versus 0.04, p=0.013). Compared to CTA alone using diameter stenosis and minimal lumen area, CT-QFR demonstrated improved diagnostic performance (increase of AUC= 0.16; p<0.001 and increase of AUC = 0.20; p<0.001).

CONCLUSIONS

Integration of CT-QFR with coronary CTA imaging improved its diagnostic performance in identifying hemodynamically significant coronary stenosis. The diagnostic performance and reproducibility of CT-QFR were influenced by extensively calcified lesions.

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Effect of combination of non-slip element balloon and DEB for in-stent restenosis lesions (ELEGANT study)

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

In-stent restenosis (ISR) still exists and remains a problematic issue of coronary interventions. Non-slip element balloon (NSE) is a balloon catheter with 3 longitudinal nylon elements which are attached to the balloon. We investigated whether NSE pre-dilatation improves angiographic outcomes, compared to a high pressure pre-dilatation non-compliant balloon for drug coating balloon (DCB) treated ISR lesions with optical coherence tomographic imaging (OCT).

METHODS AND RESULTS

Patients were eligible for the study if one or more in-stent restenosis lesions were treated with DCB. Patients were randomized to NSE pre-dilatation (NSE group) or high pressure non-compliant balloon pre-dilatation (POBA group) in 17 hospitals. The primary endpoint was in-segment late loss at 8 months. One hundred and five patients were allocated to each group. Balloon slippage (7.9% versus 22.9%, P=0.002) and geographical miss (6.9% versus 21.9%, P=0.002) were observed less, and acute gain was significantly larger in the NSE group (1.17+/-0.41 mm versus 1.06+/-0.35mm, P=0.04) compared to the POBA group, but post minimum stent lumen area analyzed by OCT was similar between the 2 groups (3.85+/-1.67 mm2 versus 3.81+/-1.93mm2, P=0.64). At 8 months, lesion length was significantly shorter than the POBA group (5.78+/-3.26 mm versus 6.97+/-4.59mm, P=0.038). Average in-segment late loss was similar between the 2 groups (0.28+/-0.45 mm versus 0.27+/-0.38mm, P=0.75).

CONCLUSIONS

Eight month angiographic outcomes were similar between NSE and non-compliant balloon pre-dilatation in DCB treated ISR lesions. However, NSE pre-dilatation has advantages such as reduction of balloon slippage and geographical miss during the procedure.

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Optimal duration of DAPT according to lesion complexity in patients with ACS: insight from SMART-DATE study

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Limited data regarding the optimal duration of dual antiplatelet therapy (DAPT) according to lesion complexity exist in patients with acute coronary syndrome (ACS) undergoing percutaneous coronary intervention (PCI). We performed post hoc analysis of SMART-DATE trial (NCT01701453), in which compared efficacy and safety of the 6-month versus 12-month or longer DAPT after PCI in patients with ACS.

METHODS AND RESULTS

Complex PCI was defined as having at least 1 of the following characteristics: ≥3 lesions treated, ≥3 stents implanted, unprotected left main lesion, bifurcation lesion, calcified lesion, or total stent length >40mm. The primary efficacy endpoint was a composite of myocardial infarction (MI) or stent thrombosis (ST). The primary safety endpoint was the Bleeding Academic Research Consortium (BARC) type 3 or 5 (major) bleeding. Of enrolled patients, 957 and 1,750 patients underwent PCI for complex and non-complex lesions, respectively. In complex PCI group, the incidence of primary efficacy endpoint was significantly higher in the 6-month DAPT group than the 12-month or longer DAPT group (2.7% vs. 0.8%; hazard ratio (HR), 3.19; 95% confidence interval (CI), 1.20-8.51; p=0.03). The incidence of primary safety endpoint was comparable between the two groups (1.1% vs. 1.1%; HR, 1.07; 95% CI, 0.31-3.71; p=0.91). In non-complex PCI group, the incidences of the primary efficacy and safety endpoints were not different between the two groups (1.7% vs. 1.0%; HR, 1.62; 95% CI, 0.73-3.61; p=0.25 for MI or ST, and 0.1% vs 0.6%; HR, 0.19; 95% CI, 0.02-1.66; p=0.13 for BARC 3 or 5 bleeding, respectively).

CONCLUSIONS

Among patients with ACS undergoing PCI, 12-month or longer DAPT should be mandatory to prevent coronary thrombotic event without increased bleeding risk after complex PCI. On the other hand, 6-month DAPT after non-complex PCI may be considered according to individual basis with balancing the beneficial effects and the bleeding risk.

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Doctor! How long will my coronary artery stent last? Well, that depends! 10-year follow-up in the SORT-OUT II study

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

We sought to identify predictors of stent treatment failure after 10 years follow-up of all-comer patients treated for a variety of coronary artery lesions with first-generation drug-eluting stents in the SORT-OUT II study.

METHODS AND RESULTS

Data were retrieved from the SORT-OUT II database (NCT0038934) that encompasses 2845 non-left main coronary artery lesions in 2072 patients randomized to treatment with one of the two first generation drug-eluting stents. Ten-year follow-up was 99.2% complete and all events were adjudicated by the event committee. Events were censored for death and emigration. The device oriented end-point stent treatment failure was defined as the composite of definite or probable stent thrombosis, target lesion revascularization, angiographic ≥ 70% stenosis left untreated, or cardiac death definitely connected to the initial PCI. Stent treatment failure was found in 16.7% and definite or probable stent thrombosis was found in 6.4% of all treated lesions. Predictors of stent treatment failure were identified by univariate Cox regression analysis among an array of patient demographic, lesion and stent characteristics, and subsequently entered into a multivariate Cox regression model with calculation of hazard ratio (HR) and 95% confidence interval (CI).
Multivariate predictors of stent treatment failure were:

Smaller stent diameter. HR for 3.0 mm stent diameter: 1.24 (CI 0.96-1.61), for 2.75 mm: 1.32 (CI 0.87-2.0), for 2.5 mm: 1.96 (CI 1.49-2.58), and for 2.25 mm: 2.21 (CI 1.52-2.90) compared to stent diameter ≥ 3.5mm
Longer stent length. HR for 20-30 mm stent length: 1.09 (CI 0.86-1.38), for 31-40 mm: 1.37 (CI 1.01-1.86), and for > 40mm: 2.28 (CI 1.74-2.98) compared to stent length < 20 mm
Stent in a bifurcation lesion HR: 1.59 (CI 1.21-2.10)
Any previous revascularization HR: 1.28 (CI 1.02-1.63)
Treatment of a restenotic lesion HR: 2.22 (CI 1.46-3.38)
Diabetes mellitus HR: 1.31 (CI 1.05-1.64)

The impact of smaller stent diameters was observed in all coronary segments. The significance of overlapping stents (HR 1.22 (CI 1.10-1.36)) was eliminated by stent length in the multivariate analysis. There was no interaction between stent type and the predictors of stent treatment failure. Smaller stent diameter, longer stent length, bifurcation and restenotic lesions were also multivariate predictors of definite or probable stent thrombosis.
For lesions treated with stent diameter ≥ 3.5 mm and stent length ≤ 30 mm (or only one stent) in a patient without other risk predictors the risk of stent treatment failure and definite or probable stent thrombosis during 10 years can be estimated from the Cox regression model to be less than 10% and less than 4%, respectively.

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CONCLUSIONS

From a study population with 99.2% complete 10-year clinical follow-up and adjudicated events we identified predictors of stent treatment failure of which stent diameter ≤ 2.5 mm, stent length > 40 mm, and treatment of a restenosis doubled the hazard. First-generation drug-eluting stents have a good long-term patency in large subsets of treated lesions.

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The identification of physiological predominance in serial coronary lesions using pressure-wire pullback: differences between iFR, FFR and hyperemic-iFR

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Cross-talk phenomenon between stenoses in physiological measurement during hyperemia is complex and unavoidable issue to evaluate each stenosis severity in serial lesions. The purpose of this study was to clarify how differently patients could be treated when pressure-wire pullback in hyperemic status is used for decision-making compared with that in resting condition which has little interaction between stenoses.

METHODS AND RESULTS

Eighty-eight vessels (70 patients, mean age 70.3 ± 9.4 years, 80% male) with serial lesions and with pressure-wire pullback performed in all iFR, FFR and hyperemic-iFR were included in this study. Most frequently investigated vessel was left anterior descending artery (59%). Median iFR, FFR and hyperemic-iFR were 0.85 (interquartile range [IQR]: 0.74 to 0.91), 0.73 (IQR: 0.65 to 0.80) and 0.60 (IQR: 0.49 to 0.71), respectively. When judged against iFR-based physiological lesion predominance (i.e. proximal or distal) according to delta pressure gradient along the vessels, lesion predominance changed in 22.7% (20/88) in FFR and in 20.5% (18/88) in hyperemic-iFR, respectively. There was no statistical difference between FFR and hyperemic-iFR for impact on these changes (p = 0.77).

CONCLUSIONS

Misclassification of more significant stenosis in serial lesions under hyperemic status occurred in approximately 20% of the cases either in whole cardiac cycle or in wave-free period. The lesion-specific ischemia identification would be achieved more simply and accurately in resting condition.

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Single-centre experience with Stentys - self-apposing stents - in left main PCI - Safety and efficacy

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease

AIMS

Background: Stentys are Self-Apposing stents that can adapt itself acutely to different diameters along the vessel. There are just few works aiming to the study the safety and efficacy of Stentys at the treatment of left Main (LM) Lesions.

METHODS AND RESULTS

We aimed to study the safety and the efficacy of Stentys on 44 Patients after LM interventions. Our primary endpoint was one of major adverse cardiac and cerebral events
(MACCE), which are defined as cardiac death, myocardial infarction (MI), target lesion revascularization (TLR), and stroke assessed after 6 Months and one year. Our secondary endpoint is Stent thrombosis within a year.

The median age at the entire Cohort was 73±11 years. We have divided the Cohort to two groups: Acute coronary syndrome (ACS) and stable Angina (SA). 32 % (14) of the Patients were presented with ACS as diagnosis [4 (25%) unstable angina, 9 (56,3) NSTEMI, 3 (18.8%) STEMI] and 68 % (30) of the patients were presented with stable angina (SA). The median age was 73 years in the SA group and 76 years in the ACS group. The median SYNTAX score (I) was 23.6 in the SA group and 23.0 in the ACS group.
After 1-year follow-up in the SA and in the ACS group occurred no MACCE. In both groups occurred in the early phase (within 12 hours) cardiac death by Patients with very bad Prognosis under cardiogenic shock and after the use of Imella assist device (once in the ACS group and in two cases in the SA group) and extracorporeal Oxygenation (1 case in the ACS group)

CONCLUSIONS

The use of Stentys DES for the treatment of LM lesions using showed good clinical outcomes at 1-year follow-up in patients with SA and ACS.

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Bicuspid aortic valve stenosis treated with a fully repositionable and retrievable transcatheter heart valve: two-year clinical outcomes from the RESPOND study

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS
To evaluate clinical outcomes through 2 years following transcatheter aortic valve implantation (TAVI) in patients with bicuspid aortic valves treated with the fully repositionable and retrievable Lotus Valve System in the RESPOND post-market registry.

METHODS AND RESULTS
In the prospective, open-label, single-arm RESPOND study, patients with calcific aortic stenosis were treated with the Lotus Valve System in routine clinical practice at 41 sites in Europe, New Zealand, and Latin America. Bicuspid aortic valve anatomy was initially identified by the sites and verified by echocardiography and/or computerized tomography (CT) coronary angiography. The primary endpoint was the rate of all-cause mortality at 30 days and 1 year. Echocardiographic data at discharge and 1 year were adjudicated by a core laboratory. Clinical end points up to 2 years were evaluated using VARC-2 criteria.
Of the 996 patients enrolled in RESPOND, 31 (3.1%) were identified as having bicuspid aortic valves (mean age, 76.4 years; 64.5% male; baseline STS score, 6.0±10.2%). Based on the Sievers' valve classification scheme, 74.2% of patients (23/31) had Type 1 valve anatomy (21 L-R; 2 R-N), Type 0 valves were present in 16.1% (5/31), and Type 2 valves were present in 3.2% (1/31; 1 R-N); 2 patients were unable to be classified due to scan quality. Both the bicuspid and tricuspid cohorts demonstrated high rates of procedural success, with correct positioning of the valve in 100% and 99.8% of cases, respectively. In the bicuspid cohort, there were no cases of migration, embolization, or deployment of a second valve.
There were no significant differences between bicuspid and tricuspid patients in mean aortic valve (AV) gradient at hospital discharge (12.38 ± 4.87 vs 10.76 ± 4.53; P=0.06) and 1 year post procedure (13.33 ± 8.22 vs 10.67 ± 4.91; P=0.17). Likewise, mean effective orifice area (EOA) was similar between the two cohorts at discharge (1.64 ± 0.39 vs 1.81 ± 0.45; P=0.05) and 1 year (1.62 ± 0.44 vs 1.79 ± 0.45; P=0.10).
Paravalvular leak (PVL) was not significantly different between the two cohorts at either discharge (P=0.10) or 1 year (P=0.13). No patients in the bicuspid cohort exhibited moderate or greater PVL following TAVI; mild PVL was present in 13.8% and 15.0% of bicuspid patients at discharge and 1 year, respectively. In the tricuspid cohort, moderate PVL was noted in 0.3% and 0.4% of patients at discharge and 1 year, respectively, while mild PVL was present in 7.5% and 4.7% of patients at these respective time points.
There was no significant difference between bicuspid and tricuspid patients in the rate of all-cause mortality at

30 days (3.2% vs 2.2%; P=0.51), 1 year (9.7% vs 11.7%; P=0.74), or 2 years (16.4% vs 19.7%; P=0.65). Other principal safety outcomes, including cardiovascular mortality, stroke, hospitalization for valve-related symptoms or worsening congestive heart failure, and pacemaker implantation were also not significantly different between the two cohorts at 2 years post procedure.

CONCLUSIONS

Data from the RESPOND registry suggest that TAVI with the Lotus Valve in patients with bicuspid aortic valve anatomy is associated with a high degree of procedural success, improved haemodynamics, and good clinical outcomes through 2 years. Given the limited number of bicuspid patients enrolled in RESPOND, these results should be confirmed in a larger study.

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Comparison of residual added index with residual SYNTAX score in the risk stratification of patients with incomplete coronary percutaneous revascularisation after STEMI

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THEME:
TOPIC(S):

AIMS

Incomplete coronary revascularization after PCI is common, particularly in patients presenting with acute coronary syndromes, and it is associated with a worse prognosis as compared with complete revascularization. The residual syntax score (rSS) has been previously showed to predict ischemic outcomes at 1 year. The Added index, namely the ratio between minimal lumen diameter (MLD) and Duke Jeopardy Score (DJS), showed high accuracy to predict FFR. We aimed this study at investigating the prognostic value of the residual Added Index (rAI) as compared with rSS in patients with STEMI and MVD.

METHODS AND RESULTS

We included 605 patients presenting with STEMI and in whom pPCI was successful. Patients with previous coronary artery bypass grafts (CABG) or presenting with cardiogenic shock were excluded. Both rAI and rSS were retrospectively calculated. All patients were divided in rAI tertiles (first <1.79 [n=94], second from 1.79 to 3.49 [n=93], and third rAI tertile >3.49 [n=97]) and rSS tertiles (first <3.00 [n=83], second from 3.00 to 6.00 [n=107], and third rSS tertile >6.00 [n=94]), patients without residual coronary artery stenosis served as control group (n=321). Primary end points were: 1) major adverse cardiac event (MACE), defined as overall death, myocardial infarction, repeat revascularizations; 2) non-target vessel oriented adverse cardiac event (VOCE), defined as overall death, non-target vessel related myocardial infarction and non-target vessel related urgent or not urgent revascularizations.

Follow-up was obtained in 80% of patients at a median of 24 months (14-36 months). At multivariate analysis, MACE rate was significantly higher in the third tertile of both rAI (30% for the Third Tertile vs. 15% for the Second Tertile vs. 7% for the First Tertile vs. 7% for control patients, adjusted HR: 2.19 [1.53-3.15], $p < 0.001$) and rSS (26% for the Third Tertile vs. 19% for the Second Tertile vs. 5% for the First Tertile vs. 7% for control patients, adjusted HR: 1.92 [1.35-2.75], $p < 0.001$). The rate of VOCE was equally significantly higher in the third tertile of both rAI (24% for the Third Tertile vs. 14% for the Second Tertile vs. 6% for the First Tertile vs. 4% for control patients, adjusted HR: 3.07 [1.91-4.95], $p < 0.001$) and rSS (20% for the Third Tertile vs. 18% for the Second Tertile vs. 3% for the First Tertile vs. 4% for control patients, adjusted HR: 2.77 [1.71-4.49], $p < 0.001$). The predictive accuracy for both rAI and rSS was moderate (respectively, c-statistics for MACE: 0.70 and 0.70, $p<0.001$).

CONCLUSIONS

The residual ADDED index represents a simple tool in the prognostication of patients with residual coronary artery stenosis after primary PCI, allowing prediction of 2-years MACE and VOCE with a moderate accuracy as well as the residual Syntax Score.

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Role of the added index to guide complete percutaneous coronary revascularisation in patients presenting with STEMI and multivessel coronary artery disease

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THEME:
TOPIC(S):

AIMS

Incomplete coronary revascularization is common, particularly in patients presenting with acute coronary syndromes, and it is associated with a worse prognosis as compared with complete revascularization. The Added index, namely the ratio between minimal lumen diameter (MLD) and Duke Jeopardy Score (DJS), showed high accuracy to predict FFR. The aim of the present study was to investigate the role of the Added Index to guide a complete coronary revascularization after percutaneous coronary intervention (PCI) of the culprit lesion in patients presenting with STEMI and multivessel disease.

METHODS AND RESULTS

We included 596 patients presenting with STEMI and in whom pPCI was successful. Patients with previous coronary artery bypass grafts (CABG) or residual chronic total occlusions (CTO)or presenting with cardiogenic shock or died during the index hospitalizations were excluded. Patients were divided into 3 groups: 1) Patients without any residual coronary artery stenosis (Control group); 2) Patients with at least one residual coronary artery stenosis with an ADDED index lower than 2.23 (ADDED Negative group); 3) Patients with at least one residual coronary artery stenosis with an ADDED index equal to or higher than 2.23 (ADDED Positive group). Primary end points were: 1) major adverse cardiac events (MACE), composite of overall death, myocardial infarction, clinically driven revascularizations; 2) non-target vessel oriented adverse cardiac events (VOCE), composite of overall death, non-target vessel related myocardial infarction and non-target vessel related revascularizations.

Patients included in the ADDED Positive group were older with higher prevalence of diabetes mellitus, hypertension and peripheral artery disease as compared with both the Control group and the ADDED Negative group. In addition, the left anterior coronary artery (LAD) represented more often the culprit lesion in both the Control group and ADDED Negative group as compared with the ADDED Positive group. Follow-up was obtained in 86% of patients at a median of 24 months (14-36 months). At multivariate analysis the rate of both MACE and VOCE were significantly higher in the ADDED Positive group as compared with both the ADDED Negative and the Control Groups.

CONCLUSIONS

Deferring treatment of residual coronary artery stenosis with an ADDED index equal to or higher than 2.23 after revascularization of the culprit lesion is associated with a significant higher risk of cardiovascular events.

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One-year outcomes of the TRI-REPAIR study assessing Cardioband tricuspid valve reconstruction system for patients with severe tricuspid regurgitation

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THEME: Interventions for Valvular Disease
TOPIC(S): Tricuspid / Pulmonary valve

AIMS

Severe tricuspid regurgitation (TR) is associated with high morbidity and mortality rates with limited treatment options.

We report the one-year outcomes of the Cardioband™ Tricuspid Valve Reconstruction System in the treatment of severe functional TR in 30 patients enrolled in the TRI-REPAIR study.

METHODS AND RESULTS

Between October 2016 and July 2017, 30 patients were enrolled in this single-arm, multicenter, prospective study. Patients were diagnosed with severe, symptomatic TR in the absence of untreated left-heart disease and deemed inoperable because of unacceptable risk for open-heart surgery by the local heart team. Clinical, functional, and echocardiographic data were prospectively collected before and up to one year post-procedure. An independent core lab assessed all echocardiographic data and an independent clinical event committee adjudicated the safety events.

Mean patient age was 75 years, 73% were females, 23% had ischemic heart disease, and 93% had atrial fibrillation. At baseline, 83% were in NYHA Class III-IV, 63% had edema, and LVEF was 58%. Technical success was 100%. Through one year, one patient had a reintervention and exited the study. Five patients died of which one was device-related. Between baseline and one year (paired analyses), echocardiography showed average reductions of annular septolateral diameter of 16% (44mm vs. 37mm; $p<0.0001$), PISA EROA of 49% (0.73cm2 vs. 0.37cm2, $p=0.0037$), and mean vena contracta of 30% (1.2cm vs. 0.9cm, $p=0.0046$). Clinical assessment showed that at one year 78% of patients were in NYHA Class I-II ($p=0.0003$). Six minute walk distance improved by 42m ($p=0.0525$). Kansas City Cardiomyopathy Questionnaire score improved by 19 points ($p=0.0009$). Edema was absent in 70% of the patients.

CONCLUSIONS

These results show that the Cardioband tricuspid system performs as intended and appears to be safe in patients with symptomatic and severe functional TR. At one year significant reduction of TR through a sustained decrease of annular dimensions, improvements in heart failure symptoms, quality of life, and exercise capacity were observed. Further studies are warranted to validate these initial promising results.

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Clinical relevance of functional angiography for non-culprit stenosis in patients with AMI

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THEME:
TOPIC(S):

AIMS

Angiography-derived computational quantitative flow ratio (QFR) has demonstrated a high diagnostic accuracy in predicting fractional flow reserve (FFR). However, data regarding the reliability of QFR in evaluating functional significance of non-culprit stenosis in patients with acute myocardial infarction (AMI) is scarce. This study sought to evaluate the diagnostic performance of QFR in assessing functional significance of non-culprit vessels in AMI, using QFR assessment of stenoses in stable ischemic heart disease (SIHD) as a reference.

METHODS AND RESULTS

105 non-culprit vessels from 82 AMI patients and 254 vessels from 182 SIHD patients who underwent FFR and QFR measurement were included. In AMI patients, FFR in non-culprit vessels was measured during index procedure. Contrast QFR, derived from computation of 3-dimensional quantitative coronary angiography (3D QCA) and Thrombolysis in Myocardial Infarction frame-counts, was compared with FFR as a reference standard in both non-culprit vessels of AMI and vessels of SIHD. Mean %DS, FFR, and contrast QFR were 61.2±4.1%, 0.78±0.13, and 0.78±0.13 for non-culprit vessel with AMI, and 49.9±19.8%, 0.81±0.12, and 0.82±0.14 for vessel with SIHD, respectively. Contrast QFR strongly correlated with FFR in both non-culprit vessel of AMI (r=0.858, p<0.001) and vessels of SIHD (r=0.857, p<0.001) (p for difference=0.974). Contrast QFR showed high diagnostic accuracy to predict FFR≤0.80 in both non-culprit vessels of AMI (93.3%, 95% CI 86.8-97.3%) and SIHD (89.8%, 95% CI 85.4-93.2%) (p for difference =0.300). Among various anatomic or physiologic indices (%DS, percent area stenosis by 3D QCA, instantaneous wave-free ratio, fixed QFR, and contrast QFR), contrast QFR showed the highest c-index to predict FFR≤0.80 in both non-culprit vessels of AMI (0.967, 95% CI 0.936-0.999) and SIHD (0.946, 95% CI 0.919-0.974) than other indices (p<0.001 in both AMI and SIHD). The changes of FFR and contrast QFR according to increased stenosis severity were similar in both non-culprit of AMI and SIHD (overall comparison p=0.209 and 0.404, respectively).

CONCLUSIONS

Contrast QFR showed excellent correlation and diagnostic accuracy with invasive FFR in evaluating non-culprit stenosis of AMI patient, and diagnostic performance of contrast QFR was not different between non-culprit vessels of AMI and SIHD patients.

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Safety and efficacy of TAVR with continuation of vitamin K antagonist or direct oral anticoagulant

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

A significant proportion of patients undergoing transcatheter aortic valve replacement (TAVR) have an indication for long- term oral anticoagulation. The optimal periprocedural management of such patients is unknown. We investigated, if TAVR with periprocedural continuation of oral anticoagulation is equally safe and efficacious as TAVR with periprocedural interruption of oral anticoagulation.

METHODS AND RESULTS

Consecutive patients on oral anticoagulation therapy with either a vitamin K antagonist or a direct oral anticoagulant who underwent transfemoral TAVR at three European centers between 2015 and 2018 were enrolled. Oral anticoagulation was either stopped 2-4 days prior to TAVR and restarted after TAVR or continued throughout the procedure. Totally, 186 patients underwent TAVR with continuation and 185 patients with interruption of anticoagulation. The rates of major or life threatening bleedings were 19 (10.2%) versus 20 (10.8%) among patients with continuation and with interruption of anticoagulation, respectively (p = 0.867). Major vascular complications occurred in 16 patients with continuation of anticoagulation as compared with 19 patients with interruption (8.6% vs 10.3%, p = 0.857). Ischemic strokes were rare and occurred in 1 (0.55%) vs 6 (3.24%, p = 0.122), respectively. Mortality at 30 day was 4.3% vs 2.2%, respectively (p = 0.380). Kaplan Meier estimates of survival at 1 year were 91% in both groups (log rank p = 0.277)

CONCLUSIONS

Continuation of oral anticoagulation in patients undergoing TAVR was safe and efficacious. Accordingly, there is no need to discontinue anticoagulation before TAVR. This may help to simplify the periprocedural management of such patients.

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Acute and long-term outcomes of patients with impaired left ventricular function undergoing rotational atherectomy

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Rotational atherectomy (RA) historically is contraindicated in patients with impaired left ventricular (LV) function due to inherent cardio-depressive effects. Contemporary RA practice is less aggressive than traditional RA and is no longer withheld from patients with reduced ejection fraction (EF). Our aim is to explore the outcomes of RA in patients with reduced LVEF

METHODS AND RESULTS

In a single-center observational study, patients undergoing RA (n=644) were divided into three groups according to their LVEF (severely-reduced ≤ 35 %, n=82; moderately-reduced 36-54%, n=170; preserved LVEF ≥55%, n=392). Procedural outcomes, in-hospital and 5-year major adverse cardiac events (MACE) were assessed. The rate of angiographic failure was significantly higher in patients with severely reduced LVEF as compared to patients with preserved LVEF (12.2% vs. 3.3%, p=0.003), driven by more residual coronary stenosis ≥ 30% (8.5% vs. 2%, p=0.008) and slow flow (11% vs. 2%, p<0.001). Moreover, severely reduced LVEF was associated with higher rates of in-hospital MACE (9.8% vs. 2.3%, p=0.004), driven by a higher peri-procedural myocardial infarction (MI) rate (6.1% vs. 1.5%, p=0.049), while no difference in the rate of angiographic failure and in-hospital MACE was observed between preserved and moderately reduce LV function. At long-term follow-up we observed a stepwise increase in all-cause death with lower left ventricular function (LVEF ≤ 35 vs. LVEF ≥55%: 42% vs 15%, adjusted HR: 2.57, CI: 1.38-4.79, p=0.003; LVEF 36-54% vs. LVEF ≥55%: 23% vs 15%, adjusted HR: 1.95, CI: 1.15-3.29, p=0.013). On the other hand, at 5 years revascularisation and MI rates were not affected by left ventricular function.

CONCLUSIONS

Compared to patients with preserved LVEF, those with severely reduced LVEF have worse acute outcomes after RA. Whereas, a moderate reduction of LVEF poses no additional acute hazard after RA. After 5 years, the extent of left ventricular dysfunction was associated with a corresponding increase in mortality but did not affect the MI and revascularisation rates

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3D mapping of the X-ray scatter fields in the cardiac cathlab for the occupational safety of Doctors, Nurses and Allied health staff

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

To create a 3D colour map of the x ray scatter fields in the cath lab during cardiac catheterization / PCI.
Enabling safer working practises for medical, nursing and allied staff during procedures. By creating a better understanding of the safest staff positioning and shielding during the various angiographic views .

METHODS AND RESULTS

We used a chest phantom (BMI 25) and a Unfortm radiation detector to measure x-ray scatter energy at six cardinal points around the patient phantom at 3 consistent distances from patient centre (1m, 2m, 3m).
At each of these 18 points we measured the scatter dose at 3 different body heights (50cm (knee), 100cm (gonads) and 160cm (eye height)).
Imaging was done in both fluoroscopy and high energy acquisition in the AP, Lao30/Cra30, Rao30 /Cra30, Lao30/Cau30, and Rao30/Cau30 views. To simulate a scatter cloud in a typical cardiac catheterization.
The resultant 162 data sets created a cohesive X/Y/Z data map enabling a 3D colour representation of the x-ray scatter clouds in the cath lab.
From this easy scatter visualation, it was found that there was a large variance in the direction and amount of x-ray scatter in the various cardiac imaging views..
Important staff safety findings where;

Broadly the AP and caudal views created more scatter to the lower legs than to the gonads or eyes. Whereas the cranial views resulted in a higher gonadal dose than to the legs or eyes

The Rao30/Cra30 views created a larger scatter dose to the left side of the lab. Especially high at the gonadal height at the 135 Deg position, where the contrast and pressurised saline are hanged on the table. Which is a worrying for the circulating scout nurse who is often at this position.

We also found that the Rao30/Cra30 view also creates a high scatter dose at the 90 Deg position (control room door).
A usual position for the circulating scout nurse to sit during during previous procedures.

The Lao30/Cra30 views created a larger scatter dose to the right side of the lab. With concernedly higher eye and gonad dose at the scrub nurse position (225Deg), compared to the Physicians position (270 Deg) .
The Lao30/Cau30 view reversed this finding, with the Physician’s position receiving a higher scatter dose than the scrub nurse position at all three body heights.

Alarmingly the Lao30/Cau30 view also had a high scatter dose at all body hieghts in the direction of our stent cabinet. Again a concern for the circulating scout nurse. Standing here should be avoided during imaging in this view

CONCLUSIONS

Mapping the x-ray scatter clouds in the usual cardiac imaging views as in this experiment, should be mandatory for all cardiac catheter labs. As a safety survey to entail the safest work place behaviour in staff positioning or in finding the need for extra staff shielding . This survey will also help find the safest placement of stock and equipment cabinets and where data entry Pc's shoud be placed.

A future consideration would be to create a software app that could create virtual scatter map data to help in the design phase of new cardiac suites.

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ANGIOLITE trial two-year follow-up. Non inferiority randomised clinical trial comparing the efficacy and safety of Angiolite vs. Xience

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Following on promising pre-clinical and initial LLL data with Angiolite, a cobalt chromium sirolimus-eluting stent (CoCr-SES), we decided to prove its non-inferiority in terms of efficacy and safety vs Xience, a cobalt chromium everolimus-eluting stent (CoCr-EES) considered as the gold standard to be used as control for most randomized clinical trials.

METHODS AND RESULTS

We have conducted a randomized, prospective and multicentric phase IV trial to compare these stents in patients with different clinical indications. A total of 223 patients undergoing revascularization were randomized 1:1 to Xience or Angiolite. A total of 300 lesions were treated, 153 lesions in the Xience arm and 147 lesions in the Angiolite one. Patients with symptoms or signs of ischemic heart disease, de novo lesions ≥ 70% with reference diameters ≥ 2 mm and ≤ 4 mm were included. Patients with totally occluded artery, left main disease, cardiogenic shock, life expectancy less than 1 year, DAPT intolerance, previous restenosis, and in whom all lesions won't be treated with Angiolite or Xience, were excluded. The clinical and angiographic characteristics were well balanced in both groups without significant differences. The acute QCA analysis for acute gain, intra-stent and intra-segment post-stent QCA were mostly equal with no significant differences. At 6 months, the intra-stent QCA analysis showed minimal lumen diameter of 2.54 mm (±0.53) for Xience vs 2.49 mm (±0.47) for Angiolite), and 11.8% stenosis vs 12.3% respectively. Intra-segment 6 months QCA analysis showed lesion diameter of 2.32 mm (±0.53) for Xience vs 2.29 mm (±0.50) for Angiolite, with similar 19.3% stenosis for both groups. The 6 months in-stent late lumen loss was 0.08 mm (±0.38) for Xience vs 0.04 mm (±0.39) for Angiolite (p= 0.002).

At 12 months, the designed primary end point was target lesion failure (TLF) as a composite of cardiovascular death, target vessel-related myocardial infarction (MI) with definite thrombosis or ischemia-driven TLR. TLF occurred in 7 patients (6.7%) for Xience vs 4 patients (4%) for Angiolite (p= 0.387). There was 1 cardiac death in the Xience arm vs 0 in the Angiolite group (p= NS), 2 MIs vs 1 (p= NS), and 4 clinically driven TLR vs 3 (p= NS), respectively.

CONCLUSIONS

The results of this trial demonstrate the non-inferiority of the Angiolite CoCr-SES as compared with Xience CoCr-EES, both from safety and efficacy points of view.
These are the 12 months follow-up results; 24 months follow-up results will be available in April so they can be presented in EuroPCR 2019.

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Clinical impact of residual SYNTAX score after physiology guided state-of-art PCI in three-vessel disease: insight from the SYNTAX II trial

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease

AIMS

The aim of this study was to investigate the clinical impact of residual SYNTAX Score (rSS) after hybrid iFR-FFR guided state-of-art PCI in patients with three vessel disease (3VD).

METHODS AND RESULTS

The SYNTAX-II study was a multicentre, single arm study that investigated the impact of the state-of-art PCI strategy on clinical outcomes in 454 patients with de novo 3VD, without left main disease. All the patients treated with the state-of-art PCI in the SYNTAX II trial were retrospectively screened and analysed for rSS. The rSS was defined as the SYNTAX Score (SS) recalculated after PCI. The state-of-art PCI strategy included: heart team decision-making utilizing the SYNTAX score II, hybrid iFR-FFR decision-making strategy, intravascular ultrasound guided stent implantation, contemporary chronic total occlusion revascularization techniques and guideline-directed medical therapy. The primary endpoint of this substudy was major adverse cardiac and cerebrovascular events (MACCE – a composite of all-cause death, any stroke, myocardial infarction, or revascularization) at 2 years. Patients with rSS were stratified according to angiographically complete revascularization (rSS of 0) and previously proposed rSS cut-off value of 8 (>0 to 8, and >8).

A total of 454 patients were screened and rSS were analysable in 441 patients (97.1%). Before PCI, anatomical SS was 20.3 ± 6.4 which was after PCI reduced to 3.9 ± 4.5 (rSS). Only 67 patients (15.2%) had rSS >8 (mean 12.3 ± 4.1). Two-year MACCE occurred in 58 patients (13.2%). Patients with MACCE had similar rSS to those without MACCE (2.0 (IQR: 0.0 to 6.0) vs. 2.0 (IQR: 0.0 to 5.0), p = 0.313). Kaplan-Meier analysis showed similar 2- year incidence of MACCE with rSS stratifications (rSS of 0 (n=140): 15.0%, >0 to 8 (n=234): 12.0%, >8 (n=67): 13.4%, log-rank p for overall = 0.703).

CONCLUSIONS

After hybrid iFR-FFR guided state-of-art PCI in 3VD, residual SYNTAX Score was very low, suggesting that complete or reasonable incomplete revascularization was achieved in majority of cases. Previously proposed rSS cut-off value of 8 was not associated with a worse clinical outcome.

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Feasibility of same-day discharge following percutaneous coronary angioplasty: experience of Abderrahmen Mami hospital

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THEME: Coronary Interventions

TOPIC(S): Other Coronary Interventions

AIMS

Background:Ambulatory diagnostic coronary angiography is routinely performed on an outpatient basis with no increase in complication rates compared to inpatient coronary angiography.There is currently a tendency to adopt this outpatient approach for percutaneous coronary angioplasty.

Aim of the study:The aim of this prospective study was to report the experience of Ariana Abderrahmene Mami hospital's cardiology department in terms of ambulatory percutaneous coronary intervention (PCI) and assess its feasibility in the Tunisian context and its medium-term results.

METHODS AND RESULTS

Methods: We performed a prospective descriptive and analytical study including 115 patients who underwent ambulatory PCI at cardiology department of AbderrahmenMami Hospital, Ariana between July 2015 and June2017.The occurrence of cardiovascular events was evaluated after 24 h and at 3 months.

Results:A total of 115 patients (mean age 60.7 ± 9.9 years, 72.2% male) with 125 coronary lesions were included in the ambulatory PCI protocol.. The most frequent cardiovascular risk factors were as follows: diabetes (69.9%), hypertension (61.7%), dyslipidemia (50.4%) and smoking (35.7%). The clinical presentations were the following: stable coronary artery disease (76.5 %), acute coronary syndrome (13.4%), unstable angina (5.2%) and silent myocardial ischemia (5.2%). Multi–vessel disease was found in the half of the patients. The treated lesions were type A, B1 (63.5%), type B2 (13%) and C (23.5%). The majority of procedures (97.4%) was performed via 6F radial approah. The procedural success rate was 100%. Three patients (2.6%) were finally hospitalized for one night, including 2 patients for cardiovascular causes (arm hematoma). No other cardiovascular event was noted during the first 24 hours. During the follow-up, 1 case of death was observed following subacute stent thrombosis. At 3 months, survival and survival without cardiovascular events were 99.1% and 97.4%, respectively.

CONCLUSIONS

Conclusions: In our center experience, ambulatory PCI represents an efficient and safe procedure in selected patients, with low rate of complications and good mid-term outcomes.

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Invasive assessment of the human palmar arch collateral function during transradial catheterisation

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Direct invasive hemodynamic assessment of the human palmar arch function has not been attempted so far. The present study aimed to quantitatively measure the pressure-derived function of the palmar collateral circulation during transradial catheterization.

METHODS AND RESULTS

Invasive palmar arch function was obtained via the 0.7mm-diameter Teflon-catheter of the radial artery puncture needle, i.e., after needle removal and before sheath insertion. Palmar arch collateral function was determined using recorded radial artery pressure signals in the non-obstructed vessel (Pnonoccl, mmHg), and during brief manual occlusions of the more proximal radial artery (Poccl, mmHg), and of the radial plus ulnar arteries (P2occl, mmHg). Collateral flow index (CFI), the ratio of mean occlusive divided by mean non-occlusive blood pressure, both subtracted by central venous pressure, was determined for radial artery occlusion (CFIrad) and for radial plus ulnar artery occlusion (CFIrad+uln). Prior to invasive CFI measurements, the modified Allen-Test was carried out in all patients.

Two hundred and fifty patients undergoing transradial access coronary angiography were included in the study. CFIrad was equal to 0.802±0.150 (95% confidence interval, CI, 0.783-0.820). CFIrad+uln was equal to 0.424±0.188. (CI 0.400-0.447). There was an inverse linear relation between CFIrad and time to blush in seconds (s) during the modified Allen test: time to blush = 64 - 63 * CFIrad (r2=0.229, p<0.0001). Two-hundred eleven patients had a normal and thirty-nine patients an abnormal modified Allen test, the latter as defined by a blush time >15s. The group with a normal test had a CFIrad of 0.830±0.111, patients with abnormal modified Allen test had a CFIrad of 0.648±0.224 (p<0.0001). Using the modified Allen test as a reference, a CFIrad threshold of <0.745 detected an abnormal test result with a sensitivity of 0.59 and a specificity of 0.85 (area under the ROC curve =0.748 (p<0.0001).

CONCLUSIONS

Direct invasive hemodynamic assessment of the palmar arch function reveals collateral supply to the briefly occluded in comparison to the patent radial artery of 0.802. During external occlusion of both radial and ulnar artery, the collateral flow index amounts to an unexpectedly high value of 0.424.

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Impact of pre-procedural left ventricle mass index on mortality following TAVI

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

In contrast to previous surgical aortic valve replacement studies, left ventricle (LV) hypertrophy (LVH) had not been clearly associated with mortality following transcatheter aortic valve implantation (TAVI). Our aim was to evaluate this association in a contemporary TAVI cohort.

METHODS AND RESULTS

We performed a retrospective analysis of patients enrolled in the Israeli multicenter TAVI registry between 2012 and 2016, for whom pre-procedural LV mass index (LVMI) was available. Patients were divided into 3 categories according to LVMI: none or mild LVH (NLVH; <109gr/m2 for females and <132gr/m2 for males), moderate LVH (MLVH; 109-121 gr/m2 for females and 132-148 gr/m2 for males), and severe LVH (SLVH; ≥122gr/m2 for females and ≥149gr/m2 for males). The cohort consisted of 1559 patients, 46.5% males, with a mean age of 82.2(±6.8) years and mean LVMI of 121(±29) gr/m2. Rates of NLVH, MLVH and SLVH were 807(52%), 279(18%), and 475(30%) of patients, respectively. During a mean follow-up of 2.9(±1.2) years, 426 patients died. For every increase in 10 units of LVMI the risk for mortality increased by 3% (HR 1.03, 95% CI 1-1.06, p=0.047). Compared to NLVH, MLVH and SLVH were associated with increased risk of all-cause mortality during follow up in both univariable (HR 1.37, 95%CI 1.05-1.78, p=0.019; and HR 1.32, 95%CI 1.07-1.64, p=0.01; respectively) and multivariable (HR 1.39 95%CI 1.07-1.81, p=0.013; HR 1.29 95%CI 1.04-1.61, p=0.022; respectively) models.

CONCLUSIONS

Increased baseline LVMI is associated with long term all-cause mortality in patients with severe aortic stenosis who are referred to TAVI. This parameter should be incorporated into the pre-procedural assessment for mortality.

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Comparison of ticagrelor with clopidogrel on myocardial blood flow measured by N-13 ammonia positron emission tomography in patients with ACS

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

In the Platelet Inhibition and Patient Outcomes (PLATO) study, compared with clopidogrel, ticagrelor has shown impressive cardiovascular benefits for patients with acute coronary syndrome (ACS). There are no available data related to coronary circulation after chronic treatment of ticagrelor in patients with ACS who have altered resting coronary blood flow dynamics due to advanced coronary artery disease. We sought to understand the relationship between maintenance therapy of antiplatelet agents and myocardial blood flow (MBF).

METHODS AND RESULTS

METHODS

This study was designed to assess the relationship between maintenance therapy of antiplatelet agents and myocardial blood flow (MBF) in patients with ACS undergoing percutaneous coronary intervention (PCI) who were treated with ticagrelor or clopidogrel. To assess MBF, we used N-13 ammonia PET imaging. Participants were randomized to receive ticagrelor 90 mg twice daily or clopidogrel 75 mg once daily after at least 6 months. Rest and stress MBF were measured using N-13 ammonia positron emission tomography (PET) among PLEIO patients at 6 month follow-up visit. Myocardial flow reserve was calculated as stress MBF divided by rest MBF.

RESULTS

N-13 ammonia PET imaging were performed in 94 patients. Of the 94 patients, 46 were in the ticagrelor group and 48 in the clopidogrel group. . There was no discontinuation of antiplatelet therapy among the patients for 6 months. Compliance was more than 95% for both groups and concurrent medications were similar. The two groups were well balanced with respect to baseline characteristics.

Resting MBF was similar (0.69±0.20 vs. 0.70±0.21, P=0.89) between the two groups. However, hyperemic MBF and myocardial flow reserve of ticagrelor group were significantly higher compared with clopidogrel (1.75±0.46 vs. 1.52±0.59, P=0.03 and 2.71±0.89 vs. 2.20±0.81, P=0.02, respectively). We analyzed 223 non-culprit vessels of registered patients using the results of physiological measures performed during the 6-month follow-up. Rest MBF (0.77±0.25 vs. 0.78±0.18, P=0.87), hyperemic MBF (1.95±0.55 vs. 1.74±0.66, P=0.80), and myocardial flow reserve (2.60±0.75 vs. 2.32±0.79, P=0.56) were not different between the ticagrelor and the clopidogrel group.

On a per-patient level, myocardial flow reserve was significantly different between the ticagrelor and clopidogrel group. There was no difference in regard to SSS (8.85±8.13 versus 8.39±7.75, p = 0.81), SRS (5.76±7.41 versus 4.28±6.43, p = 0.38), SDS (3.09±3.07 versus 4.14±3.67, P=0.20), infarct size (8.58±12.23

versus 6.03±10.87, P=0.36), ischemia size (4.79±4.59 versus 6.47±6.06, P=0.20), and defect size (12.545±12.707 versus 12.195±13.578, P=0.44) between the two groups.

CONCLUSIONS

We compared the effects of ticagrelor and clopidogrel on MBF over a 6-month follow-up period among patients with ACS treated with PCI. Maintenance treatment of ticagrelor increased hyperemic MBF, and increased myocardial flow reserve compared with clopidogrel. These differences were not observed in non-culprit vessels.

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Invasive pharmacology strategy: local intracoronary eptifibatide and alteplase into culprit vessel in primary PCI in acute STEMI within 12 hours of symptom onset. Dissolving residual thrombus and distal microembolisation

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

This study is to obtain the effects of local intracoronary (IC) single bolus administration of eptifibatide (EPT) and alteplase (ALP) in order to get complete reperfusion of epicardial artery and microvascular level in patients with TIMI 0/1 acute STEMI.

METHODS AND RESULTS

A prospective nonrandomized controlled study, after recanalizing by manual thrombectomy or balloon inflation, we administered local IC bolus of eptifibatide 3.75 mg, followed by ALP 3. 5 mg (dilluted in 10 ml Saline) and after stent deployment, local IC Nitroglycerine (NTG) 200 µg was added. Echocardiographic assessment Pre and Postprocedural. The control group is colleagues' patients with standard Primary Percutaneous Coronary Intervention. TIMI, MBG flow and corrected TIMI Frame Count (cTFC) were graded by two interpreters.

There were 114 patients from October 2016 to September 2018, age 26 - 81 y, Symptom to procedural time was 2.0-12 hours, 105 males, 9 females, 59 anterior and 55 inferior wall infarction. Preprocedural TIMI and MBG 0 were 96 patients, TIMI and MBG 1 were 18 patients. Postprocedural TIMI and MBG 3 were 104 patients, TIMI and MBG 2 were 10 patients, door to wire crossing time-DWCT was 26-250 minutes, LVEF increased 7.44-31.5%. 2 patients with gums bleeding, 2 patient haematuria, hospital mortality was 3/114 (2.63 %). There were 3 patients hospitalized due to Congestive Heart Failure and no mortality during 30 days follow-up. The control group was 114 patients, Preprocedural TIMI and MBG 0 were 99 patients, TIMI and MBG 1 were 15 patients. Postprocedural TIMI and MBG 3 were 58 patients, TIMI and MBG 2 were 52 patients, TIMI and MBG 1 were 4 patients. median-cTFC 23.0. Statistically, there was significant difference in postprocedural TIMI, MBG flow, cTFC between the 2 groups ($p < 0.05$).

CONCLUSIONS

Local intracoronary administration of eptifibatide, alteplase, and nitroglycerine showed a successful dissolved of occlusive thrombus in epicardial artery, improved reperfusion microvascular level and Left Ventricle function in acute STEMI patients.

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Periprocedural myocardial infarction and clinical outcomes after paclitaxel-coated balloon angioplasty

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

The aims of this study were to evaluate the occurrence of PMI and its clinical relation with clinical outcomes after coronary angioplasty using PCB.

METHODS AND RESULTS

We included all consecutive patients who underwent coronary angioplasty using PCB from 1 January 2010 to 31 December 2013. The PCB angioplasty was performed using current conventional techniques: after predilation with a plain balloon, the PCB was inflated for 60s. We evaluated the PMI rate after PCB angioplasty. The PMI definition followed the new PMI definition proposed by the Society for Cardiovascular Angiography and Interventions. The primary endpoint was the incidence of major adverse cardiac events (MACE), a composite of cardiac death, myocardial infarction (MI), and clinical-driven target lesion restenosis (TLR). Total of 96 patients with 103 lesions were treated with PCB, comprising 75 (72.8%) in-stent restenosis (ISR) lesions and 28 (27.2%) de novo lesions (DNLs). Patient mean age was 66.50 ± 10.840 years, 60.2 % were male, 45.1 % had diabetes mellitus (DM) and 3.9 % had end stage renal disease (ESRD). 15.5 % patients had MI before PCB angioplasty. The median total vessel occlusion time and the median total vessel occlusion number (including plain old balloon angioplasty before PCB, PCB, and bailout stenting) were 101.5 seconds and 4 times were respectively. Success rate of PCB angioplasty was 92.2%. PCB angioplasty failures were reported in 8 lesions (3 dissections, 1 under expansion, 1 no reflow in DNL, 2 under expansions, 1 no reflow in ISR lesions). All PCB angioplasty failures were successfully treated with bail out stenting. PMI occurred in 4 lesions and all 4 lesions were ISR. 2 of the 4 PMIs were associated with PCB failure (1 under expansion, 1 no reflow). Side branch compromise occurred in 7 lesions (6.8%). The median follow-up time after PCB angioplasty was 2003 days. Overall survival free from MACEs was 89.2 % at 12 months, and 73.6 % at 48 months, with a total of 7 cardiac deaths, 16 MI, and 21 TLR. At multivariate analysis, MI at PCB angioplasty (hazard ratio [HR] 5.448, 95% confidence interval [CI] 2.386-12.442, P = 0.000), dyslipidemia (hazard ratio [HR] 2.283, 95% confidence interval [CI] 1.075-4.851, P = 0.032), ESRD (hazard ratio [HR] 4.910, 95% confidence interval [CI] 1.384-17.423, P = 0.014), PMI (hazard ratio [HR] 4.068, 95% confidence interval [CI] 1.164-14.214, P = 0.028) were independent predictors of MACEs at long-term follow-up. At multivariate analysis, total vessel occlusion number (hazard ratio [HR] 1.430, 95% confidence interval [CI] 1.137-1.800, P = 0.002) was the independent predictor of PMI.

CONCLUSIONS

Even we included MI patients in our study, the PMI rate (3.88%) after PCB angioplasty was not high. PMI has also been identified as a one of the major predictors of MACE after PCB angioplasty in our study. This study suggests that total vessel occlusion number rather than total vessel occlusion time may be related to PMI after PCB angioplasty. Considering that the SB compromise rate was very low in this study, PMI after PCB angioplasty seems to be related to distal embolization by small thrombi due to multiple dilations of the lesions.

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Comparison of aortic gradient assessment modalities in balloon aortic valvuloplasty; is there a correlation between echocardiograpic and invasively obtained aortic gradients?

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THEME: Interventions for Valvular Disease
TOPIC(S): Other valvular and structural interventions

AIMS

Percutaneous balloon aortic valvuloplasty (BAV) has recently regained popularity with the increasing utilisation of transcatheter aortic valve replacement (TAVR). Currently, aortic gradients are measured both invasively and with echocardiography. The validity of both of these methods for assessing change in gradients has not been previously investigated. We sought to determine if there was any correlation between invasive and echocardiograpic aortic gradients before and following BAV.

METHODS AND RESULTS

We reviewed 119 consecutive patients who received clinically indicated BAV therapy at a single high volume centre between March 2010 and November 2018. The mean age of patients was 82.2+6.9 with 60% being males. Pre and post-operative aortic gradients recorded both invasively and by echocardiography were analysed. Echocardiographic obtained pre-BAV gradients were measured on average 18.4 days prior to BAV, whilst post-BAV gradients were measured on average 1.6 days after BAV. Statistical analysis was obtained using PRISM Version 7.0B (09/16). Assessment of pre-BAV gradients demonstrated a positive correlation between invasively determined peak gradient and echo mean gradient ($p<0.0001$ & $R2=0.59$ [95% CI=0.67-0.84]). Furthermore, there was a positive correlation between invasive mean gradient and echo mean gradient ($p<0.0001$ & $R2=0.52$ [95% CI=0.59-0.81]), as well as invasive peak gradient with echo peak gradient ($p<0.0001$ & $R2=0.60$ [95% CI=0.68-0.84]). Similarly, analysis of post-BAV gradients revealed a positive correlation between invasively determined peak gradient and echo mean gradient ($p<0.0001$ & $R2=0.46$ [95% CI=0.56-0.77]), invasive mean gradient and echo mean gradient ($p<0.0001$ & $R2=0.32$ [95% CI=0.41-0.69]), as well as invasive peak gradient with echo peak gradient $p<0.0001$ & $R2=0.41$ [95% CI=0.51-0.74]).

CONCLUSIONS

The success of BAV is determined by assessing aortic gradients prior to therapy, and comparing with gradients post therapy, with a desire to significantly reduce aortic pressure gradients. Current standard practice suggests the use of both invasive and echocardiographic pressure measurements. This study has successfully determined a positive and statistically significant correlation between aortic gradients obtained both invasively and by echocardiography, before and after BAV. It is reasonable to deduce that assessment of aortic gradients can be obtained by either modality, which may have significant implications for staffing and resources in the catheter laboratory.

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Endovascular recanalisation of common carotid artery total occlusion: two case reports and literature review

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THEME: Interventions for Stroke
TOPIC(S): Carotid stenting

AIMS

Common carotid artery (CCA) total occlusion with concomitant ipsilateral internal carotid artery (ICA) stenosis is rare, with an incidence of less than 5%. The standard treatment is surgery. Prevous studies revealed good mid-term outcomes with hybrid technique for revascularization. However, the safety of endovascular therapy is still controversial considering the possibility of distal embolization. With the use of protection devices, the endovascular approach has shown promise. Herein, we present two cases of CCA total occlusion that received endovascular revascularization.

METHODS AND RESULTS

Case 1

A 71-year-old man with no underlying diseases presented to our neurology outpatient department due to dizziness and left upper extremity weakness for several days. Carotid duplex showed right CCA total occlusion with reversed right ophthalmic artery flow. CT angiography revealed right CCA long total occlusion, and angiography showed isolated common carotid artery occlusion (CCAO). A 6French 90-cm Flexor shuttle sheath (Cook medical, Bloomington, IN, USA) was inserted to the right CCA using a 0.035-inch guidewire (Terumo corporation, Japan) and a 5Fr JR 4 (Boston Scientific, USA) support. The lesion was crossed with a Conquest Pro wire (Asahi INTECC CO, Japan) assisted with Stride microcatheter (Asahi INTECC CO, Japan). Then Fielder Fc wire was then advanced to the ICA, and the CCA lesion was dilated with a 2.0mm/30mm balloon to a maximum of 14 atm. A Filter wire crossed the CCA lesion, and a distal protection device (FilterWire EZ 190cm, Boston Scientific, USA) was deployed in the ICA. Intravascular ultrasound (IVUS) was checked. The CCA lesion was dilated with a 4/20 balloon to a maximum of 8 atm. A 7 Fr. Export aspiration catheter (Terumo, Japan) was used and several pieces of thrombi were retracted. The 9.0mm/50mm and 9.0mm/30mm Wallstents (135cm, Boston Scientific, USA) were deployed in the CCA, folowed by post-dilatation. There was good flow to the ICA and ECA after stenting. His symptoms improved after revascularization. Three months later, angiography showed a patent stent with complete expansion.

Case 2

A 53-year-old man with a history of nasopharyngeal carcinoma post radiotherapy 15 years ago presented with right upper limb weakness and difficulty in raising his hands for several months. In the recent one month, left upper limb weakness and dizziness were also noted. Carotid CT revealed right CCA dissection and left CCA total occlusion. Angiography showed 80% stenosis of the right CCA with a dissection flap. The left CCA was totally occluded, and flow arose from the left subclavian artery. A 9mmx40mm Wallstent (135cm, Boston Scientific, USA) was deployed first in the right CCA. Six months later, he was admitted for left CCA stenting. An 8Fr JR4 was used to engage the CCA. The CCA was then crossed with a Conquest 8/20 wire and predilated, and the filter wire crossed the CCA and was deployed in the ICA. A 7 Fr. Eliminate catheter was used, and some debris was retrieved. IVUS was performed. Three stents were deployed in the CCA. Blood flow in the CCA was subsequently regained. The symptoms of upper extremity weakness and dizziness both improved.

CONCLUSIONS

Common carotid artery total occlusion is rare and with variable etiology. In both cases, we found thrombus and debris within the CCA and successfully treated with endovascular revascularization. From our experience, routine IVUS and thrombosuction for CCA total occlusion in endovascular therapy may be helpful.

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Ultrasound-guided vs. fluoroscopy-guided femoral artery access in transfemoral TAVR using the Medtronic CoreValve system: single-centre experience

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS
We report on a single-center experience with transcatheter aortic valve replacement (TAVR) performed via femoral access site using ultrasound-guided versus fluoroscopy-guided femoral artery access

METHODS AND RESULTS
Between October 2017 and July 2018, 92 consecutive patients underwent TAVR in our department.
All of them with CoreValve implant from the femoral access site were included in the analysis.
The ultrasound-guided femoral artery access and cross-over technique was introduced in order to reduce the rate of access-site complications. Patients were randomly assigned to ultrasound-guided versus fluoroscopy-guided femoral artery access.

The study patients were divided into two subgroups: group A – patients treated with fluoroscopy-guided femoral artery access (n = 46); and group B – patients treated with ultrasound-guided femoral artery access (n = 46). No significant difference between baseline characteristics of the 2 groups was reported. No difference in VARC, hemotransfusion, haemoglobin variation was noted. However mean glomelural filtration rate (GFR) significantly decreased in group A compared to group B – 2.59 vs 0.8 ml/min ($p< 0.0021$). Also, fluoroscopy time significantly decreased from 54.95 to 21.11 ($p<0.0039$) minutes, and procedure time significantly decreased from 98.65 to 76.3 minutes ($p<0.0002$). In-hospital and 30-day mortality was zero in both groups.

CONCLUSIONS
Ultrasound-guided femoral artery access did not reduce the incidence of access site complications in TAVR patients. However, it significantly reduced fluoroscopy time, procedure time, and worsening renal function. Further studies with larger populations are warranted to determine if this approach could potentially reduce morbidity and mortality.

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Contributing mechanism of immune factors and endothelial dysfunction on complication for coronary atherosclerosis

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

To assess coronary arterial lesions by using angiography, its severity of coronary artery disease, involvement of endothelial dysfunction and some immune factor to the pathogenesis of the coronary atherosclerosis.

METHODS AND RESULTS

Methods

All patients who underwent coronary angiography (n=240) a cross-sectional design, Gensini and SYNTAX score evaluated coronary angiographic scoring systems for assessing the severity of coronary atherosclerosis. The 80 patients used case-control study design chose feature criteria from all patients. The main inclusion criteria of the 40 patients with AMI are that the patient should have a ruptured plaque of coronary atherosclerosis, confirmed by clinical symptom, electrocardiography, troponin I and coronary angiography. Also, 40 patients with coronary stable stenosis without plaque rupture were included in the patient of stable CAD. Serum oxidized LDL (oxLDL), anti-oxLDL antibody, MMP-9 titers were determined by ELISA according to the manufacturer's recommended protocol. Additionally, C reactive protein (CRP) was measured by a full automated analyzer.

Peripheral blood (10ml each) was collected from 12 patients (AMI 4, stable CAD 4 and healthy people 4). Endothelial progenitor cell (EPC) is cultured by using an endothelial basal medium (CFU-Hill) with supplements. After 6 days in vitro, Colony forming units of EPCs are determined as absolute numbers of colonies. The endothelial NOS (eNOS) enzyme was identified by enzyme binding reaction.

Results

The average age of the study population was 58.9±11.38 years. Coronary total occlusion, diffuse lesion, bifurcation stenosis significantly more occured in 60-69 age group ($p<0.001$), but severe coronary tortuosity was occured in 70-79 age group ($p=0.002$). Age significantly related to severity of coronary artery disease (Gensini $F=2.26$, $p=0.041$; SYNTAX $F=2.12$, $p=0.046$).

The AMI group had significantly greater oxLDL ($p=0.011$), anti-oxLDL antibody ($p<0.001$), MMP-9 ($p<0.001$), CRP ($p=0.009$) compared stable CAD group. The binary logistic analysis shows that oxLDL (OR=1.011, $p=0.016$), anti-oxLDL antibody (OR=1.127, $p<0.001$), MMP-9 (OR=1.171, $p<0.001$), CRP (OR=1.041, $p=0.003$) may play a role in the pathogenesis of the plaque rupture in coronary atherosclerosis. Severity of coronary atherosclerosis (Gensini score) were significantly positively correlated to serum anti-oxLDL antibody ($r=0.248$, $p<0.05$) and MMP-9 ($r=0.424$, $p<0.001$). Whereas serum MMP-9 ($r=0.424$, $p<0.001$), CRP ($r=0.299$, $p<0.05$) were significant correlated to injury of myocardial infarction.

The stable CAD patient had significantly decrease ($F=17.2$, $p<0.001$) numbers of EPC colonies and eNOS enzyme ($F=6.2$, $p=0.003$) compared with AMI patient and healthy people.

CONCLUSIONS

Serum anti-oxLDL antibody and MMP-9 are significantly powerful involved in the complication of coronary atherosclerosis. Decreasing number of EPC colonies and eNOS enzyme levels are important factor of the

pathogenesis that leads to AMI.

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One-year result of stent graft for carotid artery pseudo-aneurysm in Behcet's disease patients

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THEME: Interventions for Stroke
TOPIC(S): Other stroke interventions

AIMS

The aim of the study is to evaluate the results of stent graft deployment as a definitive treatment for carotid artery pseudo-aneurysm in Behcet's disease patients.

METHODS AND RESULTS

A retrospective study was done where Behcet's patients treated by stent graft exclusion between 2008 and 2017 at Alexandria University Hospitals were included. All study subjects met the international study group criteria for diagnosis of Behcet's disease. None of them had any previous open vascular repair of their aneurysms. All patients were managed by endovascular deployment of stent grafts. At day 2 postoperative all patients had a color duplex ultrasound scan to verify the exclusion of the whole pseudo aneurysm and thrombosis of its lumen. Follow-up period was 1 year, where all cases had CT angiography to detect any further aneurysmal formation or endoleaks and measure regression of the size. All patients were subjected to rheumatological consultation for proper medical control prior to intervention.

Nine patients were included in the study. The mean age (+SD) was 38 (+5.2). Six patients were males and 3 were females. Six cases (67%) had pseudo-aneurysmal dilatation affecting the internal carotid artery while 3 cases (33%) had involvement of the common carotid artery. The mean pseudo-aneurysm size (+SD) was 3.3 cm (+1.2). Technical success was 89%. In 1 case of the common carotid artery pseudo-aneurysms, cannulation of the internal carotid artery was impossible. Therefore, open surgical repair was resorted to. Two patients had access site complications; 1 had a false aneurysm at the site of groin puncture and the other had superficial femoral artery thrombosis. The first patient was followed up with color duplex ultrasound every 3 months and was not operated for his 2.2 cm groin pseudo-aneurysm. The other patient was managed conservatively after refusal of surgical thrombectomy. At day 2 post-operative color duplex ultrasound revealed complete exclusion and thrombosis of the false aneurysm lumen in all cases. After 1 year, CT angiographies revealed a primary patency rate was 88%; only 1 had an occluded stent. This patient was asymptomatic with rich intra-cerebral collaterals. He was kept on anti-platelets and followed up by CT angiography every year. CT angiography also revealed complete thrombosis in the pseudo-aneurysms lumen with a mean regression in size (+SD) of 1.8 (+0.6) cm. One case had a recurrent pseudo-aneurysm at the distal margin of the stent graft. This was a small size dilatation of 1.8 cm and had not caused any signs of refilling of the previously excluded lumen, thus follow up with color duplex ultrasound every 3 months was recommended.

CONCLUSIONS

Endovascular management of carotid pseudo-aneurysm in Behcet's patients, by stent graft exclusion, has a high technical success and mid-term primary patency rates. It clearly avoids the hazardous complications of surgery. We think it should be the preferable first line of treatment.

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Impact of the stent design with smaller cell area on slow flow phenomenon and residual in-stent irregular protrusion in ACS

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Irregular protrusion identified by optical coherence tomography (OCT) immediately following stent implantation has been reported as an independent predictor for device-oriented clinical events, which is more often observed in patients with acute coronary syndrome (ACS). Durable polymer zotarolimus-eluting stent (DP-ZES) has unique feature such as smaller circular cell area than other slotted tube stents. We investigated the effects of the stent with smaller cell design on slow-flow phenomenon (SF) and irregular protrusion in ACS.

METHODS AND RESULTS

We enrolled consecutive ACS patients underwent PCI with DP-ZES or biodegradable polymer everolimus-eluting stent (BP-EES) in this SF study. Of them, we evaluated irregular protrusion (IP), strut malapposition, neointimal hyperplasia thickness (NIH) and uncovered struts for the consecutive patients underwent OCT guided PCI at baseline as OCT sub-study. We followed up to evaluate those findings using OCT at 3 months and 12 months after stent implantation. The occurrence of SF at baseline was evaluated in SF study. We defined final thrombolysis in myocardial infarction (TIMI) flow grade 3 after SF as transient SF and final TIMI flow grade 0-2 as persistent SF.

We assessed 191 ACS patients (91 DP-ZES, 100 BP-EES) in SF study. The occurrence of SF became 20.9 % in DP-ZES and 35.0 % in BP-EES ($p<0.05$), but that of persistent SF became 7.7 % in DP-ZES and 9.0 % in BP-EES ($p=0.80$). We have no significant difference in all-cause mortality, cardiovascular mortality and target lesion revascularization for 12 months in this study. In OCT sub-study, we analyzed 41 lesions (21 DP-ZES, 20 BP-EES) using OCT images. There were no differences between the 2 sub-groups in baseline clinical characteristics. Just after stent implantation, the total IP area and maximum percentage of IP area/stent area in DP-ZES were significantly less than those in BP-EES (6.3±5.0 vs. 12.6±6.5 mm^2; $p<0.01$ and 12.4±6.3 vs. 18.6±7.4 %; $p<0.01$, respectively). At 3-month follow-up, IP had been completely disappeared in both sub-groups, and DP-ZES had significantly higher occurrence of strut malapposition than BP-EES (2.4±2.6 vs. 0.8±1.2 %; $p<0.05$). At 12-month follow-up, DP-ZES had significantly thinner NIH than BP-EES (87.5±38.0 vs. 144±79.9 %; $p<0.01$). On the other hand, there were no differences in the rate of uncovered struts and that of strut malapposition between the 2 sub-groups.

CONCLUSIONS

DP-ZES seemed to reduce transient SF and residual in-stent irregular protrusion just after stent implantation, leading to achieve adequate healing after 12 months. These results suggest that DES with smaller cell design could compress greater amounts of thrombus and plaque component into the space between the stent and arterial wall.

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Comparison of side branch dilation techniques after resorbable magnesium scaffold implantation: a bench study

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Resorbable magnesium scaffolds have demonstrated good safety profile to treat de novo lesions. Nevertheless, bifurcations lesions involving a side branch>2.0mm in diameter were excluded from these studies and such lesions remain technically challenging due to concerns of scaffold deformation or fracture. The purpose of this bench study was to evaluate different side-branch dilation strategies after provisional T stenting strategy with resorbable magnesium scaffolds using silicon bifurcation phantoms.

METHODS AND RESULTS

All procedures were performed under fluoroscopy in the catheterization laboratory on silicon fractal geometry bifurcation phantoms with angles of 60° (n=6) and 30° (n=6) were used. The first step consisted in three different bifurcation strategies and the second step consisted in step by step proximal overexpansion, with optical coherence tomography and micro-computed tomography imaging.

Three different bifurcation strategies were compared: Proximal optimization technique (POT) - side branch dilation - and "re-POT", Kissing Balloon Inflation and Mini Kissing Balloon Inflation strategies. Strut and connectors fractures were evaluated by micro computed-tomography and apposition by optical coherence tomography. Twelve MagmarisTM scaffolds (n=4 in each group) were successfully implanted. There was no difference on struts and connectors fractures among the 3 techniques as no fracture was visualized. Optical coherence tomography demonstrated that mini-kissig balloon inflation sequence significantly decreased global malapposition following side-branch inflation as compared with "re-POT" or kissing balloon inflation strategies (95.3% vs 88.3% of perfectly apposed struts; p<0,0001 and 93.6% ;p = 0.004, respectively for mini-kissig balloon inflation vs. "re-POT" and kissing balloon inflation). After step by step overexpansion of n=6 resorbable magnesium scaffolds with 3.75, 4.0 and 4.5mm non-compliant balloons at 16 atm (ie, +1.5mm from the initial 3.0mm scaffold), no strut or connector fracture could be visualized.

CONCLUSIONS

Provisional MagmarisTM one stent technique on a bifurcation lesion is technically feasible with these 3 different strategies without scaffold fracture. Mini-kissing balloon inflation strategy resulted in better apposition rates as compared to kissing balloon inflation or "re-POT" strategies and should therefore be the technique of choice if resorbable magnesium scaffolds are to be used in provisional T stenting. Nevertheless, MagmarisTM use in bifurcation lesions should not be advised and such experimental results needs to be confirmed by in vivo studies.

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Safety and benefit of glycoprotein IIb/IIIa inhibitors in-out-of-hospital cardiac arrest patients treated with PCI

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

Out of hospital cardiac arrest patients requiring percutaneous coronary angioplasty (PCI) are at higher risk of both stent thrombosis and bleeding. The use of aggressive antiplatelet therapy could lead to a higher risk of bleeding in these patients. Indeed, data on glycoprotein IIb/IIIa inhibitors use in this specific indication is scarce. We therefore sought to evaluate the benefit and safety of glycoprotein IIb/IIIa inhibitors in out of hospital cardiac arrest patients requiring PCI.

METHODS AND RESULTS

Between January 2007 and December 2017, we retrospectively included all consecutive patients treated with PCI for an out of hospital cardiac arrest from cardiac cause. Exclusion criteria included age<18-year-old, and patients that did not have stent implantation. Two groups were therefore defined according to glycoprotein IIb/IIIa inhibitors administration. Clinical, procedural data and in-hospital outcomes were collected and compared between these two groups.

Three hundred and eighty-five patients were included. Glycoprotein IIb/IIIa inhibitors were administrated in 41.3% of cases (159 patients). Patients who received glycoprotein IIb/IIIa inhibitors had less prior PCI (9.4% vs 24.9%, p<0.001), more often an initial shockable rythm (87.3% vs 76.8%, p=0.01), a ST-elevation myocardial infarction on electrocardiogram (83.0% vs 64.6%, p<0.01), a Thrombolysis in Myocardial Infarction (TIMI) 0 or 1 flow before PCI (79.9% vs 58.0%, p<0.0001) and thromboaspiration use (63.9% vs 28.9%, p<0.0001). There were no differences regarding in-hospital stent thrombosis among the two groups (11.9% in the glycoprotein IIb/IIIa inhibitors group vs 7.1% in the non-glycoprotein IIb/IIIa inhibitors group, p=0.10) or in-hospital mortality (48.6% vs 49.3%, p=0.68). Nevertheless, the incidence of any bleeding (33.3% vs. 19.6%; p=0.002), and major bleeding (21.9% vs. 16.8%; p=0.007) was significantly higher in patients receiving glycoprotein IIb/IIIa inhibitors. Indeed, using multivariate analysis, glycoprotein IIb/IIIa inhibitors use was the only predictor of major bleeding (p=0.03).

CONCLUSIONS

In patients treated with PCI for out of hospital cardiac arrest from cardiac cause, the use of glycoprotein IIb/IIIa inhibitors was associated with an increased risk of major bleeding events, without difference on in-hospital stent thrombosis or death. These results suggest that glycoprotein IIb/IIIa inhibitors could be potentially harmfull in this population and further studies are required to insure the safety of glycoprotein IIb/IIIa inhibitors in the very specific population of patient undergoing PCI following a cardiac arrest.

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Percutaneous coronary angioplasty of out-of-hospital cardiac arrest patients: balancing the risk of thrombosis and bleeding with clopidogrel vs. new P2Y12 inhibitors

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

Out-of-hospital cardiac arrest survivors undergoing percutaneous coronary intervention (PCI) are at high thrombotic and bleeding risk. The type of antiplatelet agent that should be used in these patients remains controversial. The study objective was to compare the impact of new P2Y12 receptor inhibitors use on thrombotic and bleeding events as compared to clopidogrel in this specific population.

METHODS AND RESULTS

This is a retrospective, observational study of consecutive patients treated for out-of-hospital cardiac arrest associated to an acute coronary syndrome between January 2007 and December 2017. All consecutive patients who benefit from PCI with stent implantation and treated by dual antiplatelet therapy were included in the present analysis. Baseline characteristics, in-hospital mortality, in-hospital hemorrhagic and thrombotic events were compared between patients who received clopidogrel and those who received new P2Y12 receptor inhibitors such as ticagrelor or prasugrel.

Among the 359 patients included, 197 had received clopidogrel and 162 had received ticagrelor or prasugrel. Patients in the clopidogrel group had longer no-flow duration (4.2 vs 3.1 min, p=0.02), more diseased arteries (2 vs 1.8, p=0.01), more implanted stents (1.6 vs 1.4, p=0.03) but less frequently drug-eluting stent implantation (13.7% vs 69.8%, p<0.0001) and left anterior descending artery as culprit lesion (48.2% vs 62.9%, p=0.005), as compared with the new P2Y12 receptor inhibitors group. There was no statistical difference in the primary composite endpoint (death, stent thrombosis and major bleeding) between the two groups: 57.4% in the clopidogrel group vs 52.5% in the new P2Y12 group; p=0.35. Any bleeding events occurred more frequently in the new P2Y12 receptor inhibitors group group as compared with the clopidogrel group (31.5% vs. 21.8% , p=0.04). Nevertheless, there was no difference on major bleeding, defined by Bleeding Academic Researc Consortium (BARC) 3-5 (25.3% vs 19.3% , p=0.17). Moreover, using multivariate analysis, the treatment associating aspirin and clopidogrel was a predictor of higher mortality (OR=2.52, IC95% [1.15- 5.51], p=0.02).

CONCLUSIONS

In this specific population, new P2Y12 receptor inhibitors use was not associated to a reduced thrombosis rates as compared to clopidogrel but with a higher hemorrhagic risk. Nevertheless, there was no difference of major bleeding among groups and the use of aspirin and clopidogrel was a predictor of higher mortality in multivariate analysis. This study is therefore in favor of new P2Y12 receptor inhibitors use in out-of-hospital cardiac arrest patients treated with PCI. Further randomized studies should be undertaken in this very specific population at higher bleeding and thrombosis risk.

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Comparison of the biodegradable polymer everolimus-eluting stent with contemporary DES: a systematic review and meta-analysis

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Despite similar efficacy and safety profile in pilot studies, bioresorbable polymer-drug eluting stents (DES) could have potential benefit over latest generation durable polymer-DES by facilitating vessel healing, therefore reducing inflammation and neoatherosclerosis leading to enhanced clinical safety. Therefore, we sought to perform a meta-analysis of randomized clinical trials comparing the safety and efficacy of everolimus-eluting bioresorbable polymer-DES to second-generation durable polymer-DES.

METHODS AND RESULTS

We conducted a systematic review and meta-analysis to examine the safety and efficacy of bioresorbable polymer-everolimus eluting stents in patients treated for coronary artery disease. We searched PubMed, Scopus, and the Cochrane Library through February 2018 for randomized clinical trials that included outcome data on bioresorbable polymer-everolimus eluting stents. We identified four eligible studies, which included a total of 4,631 patients. Three studies reported a follow-up of one year and one study of five years. The bioresorbable polymer-everolimus eluting stents group, included 2,315 patients and the durable polymer-DES group included 2,316 patients (1,143 treated with durable polymer-everolimus eluting stents and 1,173 treated with durable polymer-zotarolimus eluting stents). Patient’s characteristics were comparable between the two groups except for higher prevalence of prior myocardial infarctions in the durable polymer-DES group (25.7 vs 22.5%, respectively, p=0.001). Procedural characteristics were comparable among groups except for slightly longer lesions in the bioresorbable polymer-everolimus eluting stents group compared to the durable polymer-DES group (mean 15.1 vs 14.9 mm, p=0.04). No significant differences were observed for cardiac mortality (p=0.72), occurrence of myocardial infarction (p=0.64), any target lesion revascularization (p=0.93), stent thrombosis (p=0.85) or major adverse cardiac events (p=0.43).

CONCLUSIONS

Overall,based on the available data bioresorbable polymer-everolimus eluting stents had similar one-year outcomes compared to contemporary durable polymer-DES. Whether these devices could enhance clinical safety remains to be evaluated at longer follow-up.

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Validating the performance of five risk scores for major adverse cardiac events in patients who achieved complete revascularisation after PCI

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Risk scores, like SYNTAX Score (SS), Clinical SYNTAX Score (CSS), Logistic SYNTAX Score (Core model [LSScore] and Extended model [LSSextended]), ACEF Score (AS) and Modified ACEF Score (MAS), are thought to be predictive for major adverse cardiac events (MACE, including all-cause mortality, myocardial infarction, and all revascularization) in patients underwent PCI. However, few studies tried to validate the performance of these scores in CR patients. We aim to compare the performance of previous risk scores in patients who achieved complete revascularization (CR) after PCI.

METHODS AND RESULTS

All 10724 patients underwent PCI at Fuwai Hospital in 2013 were enrolled. Risk scores were calculated by experienced cardiologists who were blinded to clinical outcomes. Discrimination of risk scores were determined by the area under receiver-operating-characteristic curves (AUC). 50.1% (5375/10724) of patients underwent PCI achieved CR. At a mean follow-up of 2.4 years, the incidence of mortality and MACE was 1.2% and 7.7%, respectively. SS was not predictive for mortality (AUC=0.51, 95% confidence interval [CI]: 0.44-0.59). All scores containing clinical variables, especially MAS (AUC=0.73, 95% CI: 0.66-0.79), could predict mortality. The most accurate score for myocardial infarction was LSSextended (AUC=0.68, 95% CI: 0.61-0.75). Only SS and LSSextended were predictive for revascularization, with marginally significant AUCs (SS: 0.54; LSSextended: 0.55). No score was particularly accurate for predicting MACE, with AUCs ranging from 0.51 (AS) to 0.58 (LSSextended).

CONCLUSIONS

For CR patients, risk scores containing clinical variables may help to predict mortality, however, no risk scores showed helpful discrimination for MACE.

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Impact of post-dilatation following balloon expandable TAVI

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

To investigate the effect of post-dilatation following balloon expandable transcatheter heart valve (THV) implantation on clinical and echocardiographic outcomes.Post-dilatation after THV implantation was associated with larger aortic valve areas in large-scale registries; however, the specific effects of post-dilatation are poorly understood.

METHODS AND RESULTS

From May 2016 to June 2018, a total of 224 consecutive patients underwent transcatheter aortic valve replacement using SAPIEN 3. THV diameter was assessed 1) during, 2) after implantation, 3) during post-dilatation, and 4) after post-dilatation by quantitative fluoroscopy. Acute recoil was observed from during (23.0 ± 2.0mm) to after implantation (22.5 ± 2.0mm, P<0.001) with an absolute recoil of 0.52 ± 0.25mm. Of the 224 patients, 121 patients (54.0%) underwent post-dilatation (same contrast volume: N=101, +1ml: N=17, +2ml: N=3) . After post-dilatation, THV diameter significantly increased from 22.5 ± 2.0mm to 22.9 ± 2.1mm (P<0.001), with smaller absolute recoil (0.39 ± 0.21mm, P<0.001).THV area assessed by multi-detector computed tomography was significantly larger in patients with post-dilatation than in those without post-dilatation (471.4 ± 78.1mm2vs. 447.5 ± 76.3mm2, P=0.02). The effective orifice area (EOA) was significantly larger in patients who underwent post-dilatation compared with those who did not (at discharge 1.70 ± 0.30mm2vs. 1.53 ± 0.31mm2, P<0.001; at 30-day 1.66 ± 0.33mm2vs. 1.45 ± 0.27mm2, P<0.001), before and after adjusting for baseline characteristics. There was a positive correlation between final THV diameter and EOA at discharge (r=0.54, 95% confidence interval 0.44–0.63, P<0.001) and at 30-day follow-up (r=0.56, 95% confidence interval 0.45–0.64, P<0.001).

CONCLUSIONS

Post-dilatation irrespective of the degree of paravalvular aortic leakage after implantation of the latest generation SAPIEN 3 valve was associated with larger THV and less acute recoil, followed by larger EOA at short-term follow-up, even though most patients underwent post-dilatation using the same contrast volume.

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Inter-observer differences in interpretation of coronary pressure-wire pullback data by non-expert cardiologists

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

The physiological pattern of coronary artery disease as determined by pressure-wire pullback (i.e. physiologically focal or physiologically diffuse) is important for decision-making of revascularisation and risk stratification of patients. However, it remains unclear whether inter-observer differences in interpretation of pressure-wire pullback data depends on the expertise of physicians and how this expertise could be developed.

METHODS AND RESULTS

Five-hundred and forty-five iFR pressure-wire pullback traces (510 patients) were classified into predominantly focal (48%) or predominantly diffuse (52%) by consensus opinion of seven expert interventional cardiologists without access to coronary angiogram. Defined expert consensus as the standard reference, we evaluated 10 non-expert physicians' classification performance which was calculated as a percentage by dividing the number of correctly classified cases by the total number of cases. Ten observers were grouped equally by 2 ways: (1) years of experience as interventional cardiologists (middle-level doctors and junior-level doctors) and (2) level of institutions where they belong to (high-volume centres and low-volume centres).

When judged against the expert-defined consensus, the accuracy of non-expert observers in assessing whether a pullback trace was predominantly focal or predominantly diffuse varied between 69.1% and 85.0%. There was no evidence for a moderating effect of years of observer experience; the pooled accuracy of middle-level doctors was 78.8% (95% CI 72.8% to 84.7%) vs. 79.1% (95% CI 75.9% to 82.2%) for junior-level doctors ($p = 0.950$ for the difference). On the other hand, we observed a significant moderating effect of centre volume. Accuracy across non-expert doctors in high-volume centres was 82.7% (95% CI 80.3% to 85.1%) vs. 75.1% (95% CI 71.9% to 78.3%) for low-volume centres ($p = 0.0002$ for the difference).

CONCLUSIONS

First, this study quantified the subjectivity involved in interpretation of coronary pressure-wire pullback trace. Second, this study demonstrated that the expertise for better interpretation could be mainly acquired not by years of personal experience but by sharing experience and knowledge of pressure-wire pullback in clinical practice. Our results encourage the routine performance of coronary pressure-wire pullback as a part of physiological stenosis assessment, in addition to simply measuring intracoronary pressure values.

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Clinical safety and efficacy of low-dose fondaparinux in patients undergoing peripheral endovascular treatment due to critical limb threatening ischaemia

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THEME: Peripheral Interventions
TOPIC(S): Below the knee, AAA

AIMS

We sought the evaluate the safety and efficacy of fondaparinux administrated for a short period of time (2-4 weeks) in addition to dual antiplatelet therapy (DAPT) in patients with CLTI after endovascular procedures.

METHODS AND RESULTS

We performed a nonrandomized, single-centre, retrospective study in patients with CLTI who received endovascular treatment in our institution. Fondaparinux was administrated for 2-4 weeks after the procedures in a dose of 2.5 mg s.c. per day, together with dual antiplatelet therapy at the discretion of the interventional angiologist (fondaparinux arm). Patients who received standard DAPT were retrospectively matched by age, gender, lesion complexity and Rutherford class to patients receiving fondaparinux, and were defined as our control arm. Demographic and angiographic data including the degree of lesion calcification by the Peripheral Arterial Calcium Scoring System (PACSS) were collected at the time of the intervention. Follow-up data, including (i) clinically significant bleeding and (ii) target vessel revascularization or major amputation were assessed after 12 months.

Twenty-four patients (78.7±6.9yrs., 14 (58%) female, 4 TASC B, 10 TASC C and 10 TASC D lesions, total lesion length=210±98mm, PACSS score=2.5±0.8, mean Rutherford class=4.7 ± 0.6) received fondaparinux and DAPT (over a period of 22 ± 9 days, range 7-28 days) versus 24 control patients who received DAPT (78.3±8.4yrs., 14 (58%) female, 4 TASC B, 8 TASC C and 12 TASC D lesions, total lesion length=204±73mm, PACSS score=2.4±0.9, mean Rutherford class=4.6 ± 0.6). During follow-up, 3 patients (13%) of the fondaparinux arm exhibited significant bleeding versus 5 patients (21%) of the control arm (p=ns). In addition, 4 (17%) patients of the fondaparinux arm underwent target vessel revascularization or major amputation versus 6 (25%) patients of the control group (p=ns).

CONCLUSIONS

The addition of fondaparinux to standard DAPT in patients treated endovascularly for critical limb ischemia does not result in major bleedings and is associated with a relatively low rates of re-intervention and amputation. Further prospective, randomised studies are now warranted in order to test the value of fondaparinux in larger patient cohorts with CLTI, treated by endovascular procedures.

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Predicting angina-limited exercise time using invasive coronary physiology

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

To determine the relationship between all commonly-used indices of physiological stenosis severity and angina-limited exercise time in patients with stable angina.

METHODS AND RESULTS

Fractional Flow Reserve (FFR), instantaneous wave-Free Ratio (iFR), hyperemic stenosis resistance (HSR) and coronary flow reserve (CFR) were measured in 23 patients (61 ± 8 years) with single-vessel, stable coronary artery disease. Immediately following physiological assessment, patients maximally exercised on a catheter-table-mounted ergometer until they developed angina (ETangina). Relationships between FFR, iFR, HSR, CFR and ETangina were assessed using linear regression. Twenty-one patients underwent subsequent PCI and repeat maximal supine exercise. This permitted additional assessment of the relationships between the post-PCI increment in exercise time (deltaET) and both baseline FFR, iFR, HSR, CFR and deltaFFR, deltaiFR, deltaHSR, deltaCFR.

Mean stenosis diameter was 74.6%±10.4. Median FFR, iFR, HSR and CFR were 0.54 (0.44-0.72), 0.53 (0.38-0.83), 1.67 (0.84-3.16) and 1.35 (1.11-1.63), respectively. Mean ETangina was 144±77 seconds (4.3±1.2 metabolic equivalents). Anatomical stenosis characteristics were not significant predictors of ETangina ($p>0.05$ for all). Conversely, FFR ($R=0.52$, $p=0.01$), iFR ($R=0.68$, $p<0.001$), HSR ($R=-0.62$, $p<0.01$) and CFR ($R=0.40$, $p<0.05$) all predicted ETangina. Post-PCI, median FFR rose to 0.91 (0.85-0.96), iFR to 0.98 (0.94-0.99), CFR to 2.73 (2.50-3.12) and HSR fell to 0.16 (0.06-0.37, $p<0.0001$ for all). Post-PCI deltaET was predicted by baseline iFR ($R=-0.51$, $p=0.02$) and deltaiFR ($R=0.53$, $p=0.01$) only.

CONCLUSIONS

In stable angina patients, physiological stenosis severity predicted angina-limited exercise time and the observed functional improvement in exercise time following unblinded PCI. Conversely, no relationship was demonstrated between anatomical stenosis severity and angina-limited exercise time.

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The role of mean platelet volume in the prediction of coronary artery disease severity and risk stratification of ACS

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THEME:
TOPIC(S):

AIMS

Aim: Platelets play a crucial role in thrombotic episodes. Mean Platelet Volume (MPV) is the primary indicator of platelet's activation; its measurement is easy and time-effective. We tested the hypothesis that MPV is correlated with SYNTAX score in patients that suffered Acute Coronary Syndrome (ACS).

METHODS AND RESULTS

Methods and Results: 104 patients, who were hospitalized for an ACS, underwent coronary angiography. Syntax score, as an indicator of the severity of coronary artery disease (CAD), was calculated. We tried to investigate the correlation between the first measured MPV, CRP, Creatinine and high sensitivity Troponin with the Syntax score of the patient and the association of MPV and a possible hospitalization Major Advanced Cardiac Event (MACE). The mean age of patients was 64.2(±11.), 79 (76%) were male, and 25 (24%) were female. According to Syntax score, patients were sorted in 4 categories: Control Group-Syntax score 0, Mild CAD-Syntax score 1-22, Moderate CAD-Syntax score 23-32, and Severe CAD-Syntax score ≥33. 4 (3.8%) patients developed a MACE during their hospitalization. MPV was significantly correlated to Syntax score ($p<0.001$) and was found to be an independent predictor factor of MACE (exp(b)=3.315, 95% confidence interval). The cut-off value of MPV was 7.5 with a sensitivity of 98% and a specificity of 30.8%.

CONCLUSIONS

Conclusion: We determined a positive correlation between MPV and Syntax score, transforming this simple test in a possible factor of risk stratification in ACS.

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The relation of obstructive sleep apnea syndrome with ACS

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THEME:
TOPIC(S):

AIMS

Obstructive Sleep Apnea Syndrome (OSA) is a clinical entity that is often under-diagnosed, although it has been associated with many cardiovascular complications. Polysomnography is the method of choice for the diagnosis of obstructive sleep apnea, but it has been shown that the use of appropriately weighted questionnaires is a reliable alternative. The study aimed to investigate the correlation between the possibility of obstructive sleep apnea in a patient who suffered an acute coronary event.

METHODS AND RESULTS

Eighty patients who were hospitalized for an acute coronary event in our hospital clinic were weighted for the likelihood of sleep apnea with the STOP-Bang questionnaire and Berlin questionnaire, and assessed for Epworth sleepiness within thirty days of the onset of the syndrome. Depending on the questionnaire used, 48 (Berlin) and 45 (STOP-Bang) patients were found to be at high risk for OSA, while 32 (Berlin), 35 (STOP-Bang) patients were not at risk of suffering from OSA. Also, 38 patients were likely to suffer from excessive daytime sleepiness and 42, probably, did not run such a risk according to the Epworth scale.

CONCLUSIONS

The high proportion of high-risk patients for OSA among ACS patients is a serious indication of a pathophysiological correlation between the two entities. By using easy-to-use questionnaires, it is possible to timely risk stratification for OSA in patients who suffered an ACS, with a possible effect on the course of their treatment.

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Percutaneous treatment of pulmonary vein stenosis after radiofrequency ablation for atrial fibrillation

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THEME: Peripheral Interventions
TOPIC(S): Other peripheral interventions

AIMS

Iatrogenic pulmonary vein stenosis (PVS) is a rare but deleterious complication of catheter ablation of atrial fibrillation (AF). As this procedure expands, percutaneous solutions for post-ablation PVS should also improve. The aim of our study is to analyse demographics, technical characteristics, follow up and prognosis of patients treated for post-ablation PVS.

METHODS AND RESULTS

Ours is a monocentric retrospective study of 12 patients who have undergone a total of 20 procedures (12 index procedures and 8 restenosis) for 24 pulmonary vein (PV) among 27 stenosed.

In our study group: 1/3 had two procedures of pulmonary vein isolation for AF. The mean age was 51,7 ± 16,1-years-old. Symptom presentation on diagnosis was : dyspnoea for 90%; 35% haemoptysis and chest pain (5%). Computerized tomography angiography, ventilation / perfusion pulmonary scan lead to diagnosis confirmed by angiography associated to hemodynamic study. The average interval from diagnosis to intervention was of 5,65 ± 6,17 months. A total of 24 PV were treated as follow: balloon angioplasty in 63,63% of cases, stenting in 33,33% and only thromboaspiration in 3,04% of cases. Our immediate success rate was 83,33% with a trend towards a better result when the PV was not completely occluded. Antithrombotic and antiplatetlet prescription were guided by patient’s profile and inspired by coronary angioplasty guidelines. Restenosis rate was 36% and occurred in average delay of 5,12 ± 6,42 months. Restenosis rate was 45% in the balloon angioplasty group and 27,27% in the stent group.

CONCLUSIONS

Percutaneous treatment of post-ablation PVS needs further assessment via randomized prospective clinical trials or large registries in order to elaborate adequate recommendations.

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Novel predictors of late lumen enlargement in distal reference segments after successful recanalisation of coronary CTO

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Although successful recanalization of coronary chronic total occlusion (CTO) can induce subsequent positive vascular remodeling in the distal segment, the predictors are not fully understood. The aim of this study was to investigate the extent of and determinants related to luminal gain after successful CTO recanalization.

METHODS AND RESULTS

A total of 134 patients who underwent intravascular ultrasound (IVUS)-guided percutaneous coronary intervention (PCI) for CTO and follow-up angiography were included. Angiographic parameters were assessed qualitatively and quantitatively at baseline and follow-up. Gray-scale IVUS images during the PCI procedure were also analyzed. Lumen diameter at distal reference on the post-PCI angiogram was compared with corresponding lumen diameter at follow-up coronary angiography. At the mean follow-up of 10.0±2.7 months, lumen diameter at distal reference was significantly increased by 15.9% from baseline to follow-up (2.06±0.62 vs. 2.30±0.55, $p<0.001$). Univariable analysis showed that the left anterior descending artery (LAD), no moderate or severe calcification, presence of peri-medial high-echoic band on IVUS, and impairment of final coronary flow and small distal reference diameter at baseline were associated with greater late lumen enlargement. Multivariable analysis showed the LAD, no moderate or severe calcification, and small lumen diameter at distal reference as independent predictors of greater late lumen enlargement.

CONCLUSIONS

The segment distal to recanalized CTO showed significant late lumen enlargement, especially in the case with small distal reference, in the LAD, and without moderate or severe calcification.

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The functional severity assessment of coronary stenosis using coronary CT angiography-based myocardial mass at risk and minimal lumen diameter

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

We investigated whether or not the addition of myocardial mass at risk (MMAR) to quantitative coronary angiography was useful for diagnosing functionally significant coronary stenosis in the daily practice.

METHODS AND RESULTS

We retrospectively enrolled 111 consecutive patients with 149 lesions who underwent clinically indicated coronary computed tomography angiography and subsequent elective coronary angiography with fractional flow reserve (FFR) measurement. MMAR was calculated using a workstation-based software program with ordinary thin slice images acquired for the computed tomography, and the minimal lumen diameter (MLD) and the diameter stenosis were measured with quantitative coronary angiography. The MLD and MMAR were significantly correlated with the FFR, and the MMAR-to-MLD ratio (MMAR/MLD) showed a good correlation. The area under the receiver operating characteristic curve (AUC) of MMAR/MLD for FFR ≤0.8 was 0.746, and the sensitivity, specificity, positive predictive value and negative predictive value were 60%, 83%, 68% and 77%, respectively, at a cut-off value of 29.5 ml/mm. The addition of MMAR/MLD to diameter stenosis thus made it possible to further discriminate lesions with FFR ≤0.8 (AUC = 0.750). For the proximal left coronary artery lesions in particular, MMAR/MLD showed a better correlation with the FFR, andthe AUC of MMAR/MLD for FFR ≤0.8 was 0.919 at a cut-off value of 31.7 ml/mm.

CONCLUSIONS

The index of MMAR/MLD correlated well with the physiological severity of coronary stenosis and showed good accuracy for detecting functional significance. The MMAR/MLD might be a useful parameter to consider when deciding the indication for revascularization.

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Physiologic and clinical assessment of resting physiologic indices: resting full-cycle ratio, diastolic pressure-ratio, and iFR

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Recently, resting pressure-derived indices such as resting full-cycle ratio (RFR) or diastolic pressure-ratio (dPR) have been introduced to assess the functional significance of epicardial coronary stenosis. The current study sought to investigate: 1) agreement of RFR or dPR with other pressure-derived indices (instantaneous wave-free ratio [iFR]) or fractional flow reserve (FFR); 2) sensitivity of RFR or dPR for anatomical or hemodynamic stenosis severity; and 3) prognostic implications of RFR or dPR, compared with iFR

METHODS AND RESULTS

RFR and dPR were calculated from resting pressure tracings by an independent core laboratory in 1,024 vessels (435 patients). The changes in resting physiologic indices according to diameter stenosis (%DS) were compared among iFR, RFR, and dPR. Among 115 patients who underwent 13N-ammonia PET, the changes in those indices according to basal and hyperemic stenosis resistance and absolute hyperemic myocardial blood flow (MBF) were compared. The association between resting physiologic indices and the risk of 2-year vessel-oriented composite outcomes (VOCO, a composite of cardiac death, vessel-related myocardial infarction and vessel-related ischemia-driven revascularization) were analyzed among 864 deferred vessels. Both RFR and dPR showed a significant correlation with iFR (R=0.979, p<0.001 for RFR and R=0.985, p<0.001 for dPR), which was higher than that with FFR (R=0.822, P<0.001 and R=0.819, p<0.001, respectively). RFR and dPR showed a very high agreement with iFR (c-index 0.987 and 0.993). Percent difference of iFR, RFR, and dPR according to the increase in anatomical and hemodynamic severity was almost identical. The diagnostic performance of iFR, RFR, and dPR was not different in prediction of myocardial ischemia defined by both low hyperemic MBF and low coronary flow reserve by 13N-ammonia PET. All resting physiologic indices showed significant association with the risk of 2-year VOCO (iFR per 0.1 increase: HR 0.514 [95% CI 0.370-0.715], p<0.001; RFR per 0.1 increase: HR 0.524 [95% CI 0.378-0.725], p<0.001; dPR per 0.1 increase: HR 0.587 [95% CI 0.436-0.791], p<0.001) in deferred vessels.

CONCLUSIONS

All resting pressure-derived resting physiologic indices (iFR, RFR, and dPR) can be used as invasive tools to guide treatment strategy in patients with coronary artery disease.

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Left atrial volume as a quick indicator for heart failure with preserved ejection fraction

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THEME: Interventions for Heart Failure
TOPIC(S): Chronic heart failure

AIMS

AIM: In approximately 30-50% of the individuals who develop congestive cardiac failure, the systolic function as assessed by left ventricular (LV) ejection fraction is either normal or relatively normal. We have done the study to establish the efficacy of a simple noninvasive assessment, i.e. left atrial (LA) volume to diagnose diastolic dysfunction (Heart failure with preserved ejection fraction).

METHODS AND RESULTS

METHODOLOGY AND RESULTS: 600 patients were included in the study. These patients underwent a screening echocardiography to confirm presence of left ventricular hypertrophy and diastolic dysfunction. Left atrial volume assessment was done in these patients. We found a significant correlation between increased left atrial volume, left ventricular hypertrophy and diastolic dysfunction. 79% patients with evidence of diastolic dysfunction by tissue Doppler had a higher left atrial volume.

CONCLUSIONS

CONCLUSION: Increased left ventricular mass is associated with increasing severity of diastolic dysfunction. Increased left ventricular mass is also associated with increased left atrial volume indexed to body surface area (LAVi). Left atrial volume correlates with the duration of diabetes mellitus. Increasing severity of left ventricular diastolic dysfunction correlates significantly with increased left atrial volume indexed to body surface area.At milder degrees of diastolic dysfunction, left atrial enlargement may not be the best predictor of severity. But with increasing severity of diastolic dysfunction in left ventricular hypertrophy, left atrial volume indexed to body surface area may be a sensitive and easy marker for assessment of severity and thus the long term prognosis in terms of atrial fibrillation, stroke and mortality.

Keywords- Left atrial volume, diastolic dysfunction, hypertrophy, tissue Doppler, echocardiography.

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Diagnostic performance of iFR for evaluation of intermediate left main coronary artery stenoses

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Coronary angiography presents several limitations for the evaluation of left main (LMCA) stenoses, due to multiple reasons: short length, frequent overlapping with side branches, lack of a reference segment, reverse tapering. Fractional flow reserve (FFR) is a useful tool for functional evaluation of LMCA stenoses, but is rarely used. Very recently, an adenosine-free, alternative index has been developed, the instantaneous wave-free ratio (iFR), which could further simplify the measurement. However its performance for evaluation of LMCA stenoses wasn’t explored yet.

METHODS AND RESULTS

FFR was measured under maximal hyperemia (i.v. adenosine infusion at 140 mcg/Kg/min). iFR was measured as the distal-to-proximal pressure ratio, measured during the diastolic wave-free period, as we previously described in the Forecast study.

A total of 87 measurements were performed on angiographically intermediate left main coronary artery stenoses, included at 3 italian centers. The comparison between iFR and FFR showed a significant correlation ($p<0.001$). At ROC analysis, iFR revealed a good diagnostic performance, when compared to FFR (AUC=0.94; $p<0.001$). Applying the currently used iFR cutoff of 0.89 (≤0.89 classified as positive tests) and the FAME-validated FFR cutoff ≤0.80 resulted in diagnostic concordance between iFR and FFR in 80.5% of cases. Nine of the seventeen discordant measurements where FFR-positive but iFR-negative, while the remaining eight where FFR-negative but iFR-positive.

CONCLUSIONS

The present study is the first demonstrating that the evaluation of LMCA stenoses with the iFR is a feasible and promising adenosine-free alternative to classic FFR. If confirmed in larger populations, these findings could be of relevance a real world setting. However, attention should be paid to understand the reason for discordance between the two methods.

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Novel prognostic score for immediate and late success after percutaneous mitral balloon commissurotomy in patients with mitral stenosis

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair

AIMS

Percutaneous mitral balloon commissurotomy (PMBC) remains the preferred treatment for patients with severe symptomatic rheumatic mitral stenosis (MS) and suitable anatomy. The aim of this study was to propose a new score for the prediction of immediate and late success.

METHODS AND RESULTS

This is a single-center retrospective analysis of all 1582 patients with severe mitral stenosis who underwent successful PMBC from august 1987 to june 2010. The composite outcome was cardiovascular death, new PMBC or mitral valve repair surgery. Mean age was 36.8 ± 12.9 years, most female (86.4%), and Wilkins score was between 9-11 (49.1%). In the multivariate analysis, the predictors of immediate success were age (OR: 0.98, 95% CI: 0.96-0.99, p=0.01), left atrium size (OR: 0.96, 95% CI: 0.93-0.99, p=0.01), mean mitral gradient pre procedure (OR: 0.93, 95% CI: 0.89-0.96, p=0.0001), Wilkins-score 9-11 (OR: 0.62, 95% CI: 0.40-0.94, p=0.02) and Wilkins-score ≥ 12 (OR: 0.35, 95% CI: 0.16-0.76, p=0.008). Median follow-up was 8.3 years, with a maximum follow-up of 23 years. For prediction of late events, age (HR: 0.98, 95% CI: 0.97-0.98, p=0.0001), NYHA III-IV (HR: 1.50, 95% CI: 1.18-1.92, p=0.0009), left atrium size (HR: 1.02, 95% CI: 1.02-0.04, p=0.003), Wilkins-score 9-11 (HR: 1.10, 95% CI: 0.87-1.38, p=0.40) and Wilkins-score ≥ 12 (HR: 2.02, 95% CI: 1.30-3.15, p=0.001) were significant.

CONCLUSIONS

In this large population, not only the established Wilkins score, but also clinical and hemodynamic features, seem to be relevant in predicting immediate and late success for patients with rheumatic MS who underwent PMBC.

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Diagnosis of STEMI by artificial intelligence with 12-lead electrocardiograph

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Patient delay is a worldwide unsolved problem in ST-segment elevated myocardial infarction (STEMI). Electrocardiograph (ECG) with accurate auto-warning system may be a solution for this problem. Artificial intellegence has been applied in diagnosis and decision-making in various field of clinical practice. Therefore, our aim is to develop a deep learning-based algorithm for the detection of STEMI from regular 12-lead ECG, which may help to reduce the patient delay time in the future.

METHODS AND RESULTS

Mehtods: A deep convolutional neural network were developed for the detection of STEMI. The algorithm was trained by using data set of 8175 ECGs (449 STEMI ECGs and 7726 control ECGs). All ECGs were evaluated by 3 expert cardiologists and further validated by coronary angiography (CAG). The resultant algorithm underwent an internal evaluation. Then, a real-world comparative test was performed to compare the diagnostic accuracy of the algorithm and 15 medical doctors.

Results: A total 8476 ECGs from 8476 patients (597 STEMI ECGs and 7879 control ECGs) were enrolled in the study. In STEMI group, average age is 73.25±12.48 years, 46.4% were women. In control group, average age is 75.5±18.2 years, 46.6% were women. For detecting STEMI, the algorithm had an area under the receiver operating curve (AUC) of 0.944 (95%CI 0.911-0.978), the sensitivity, specificity and accuracy were 88.8%, 87.5% and 88.1%, respectively in the internal evaluation. In the real-world comparative test, the algorithm had an AUC of 0.95 (95%CI 0.911-0.997), the sensitivity, specificity and accuracy were 94.0%, 94.0% and 94.0%, respectively. While the medical doctors had a sensitivity, specificity and accuracy of 71.73%, 89.33 and 80.53%, respectively.

CONCLUSIONS

An AI-based algorithm for identifying STEMI ECGs has been developed with high sensitivity and specificity, which has better performance than medical doctors. In the future, Combing the algorithm with wearable device has a promising application to reduce the patient delay in terms of STEMI.

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Long-term results of PCI in cardiac allograft vasculopathy in a tertiary hospital

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Cardiac allograft vasculopathy (CAV) affects 50% of cardiac transplants in long-term follow-up. Percutaneous coronary intervention (PCI) is a treatment option, but few studies show great benefit and most of them show high restenosis rates and target lesion revascularization (TLR). The aim of this study is to review our experience using stents in percutaneous coronary interventions in cardiac allograft vasculopathy.

METHODS AND RESULTS

Methods: We studied retrospectively 38 patients with CAV treated with PCI from 2000 to 2017. Surveillance angiography was performed in 85% of stents. Stent restenosis (SR), stent thrombosis (ST), target lesion revascularization (TLR) and patient survival are reported. Results: One-hundred and two stents were placed in 96 lesions: 16 bare-metal stent (BMS), 34 first-generation drug-eluting stent (FDES), 52 second and third generation drug-eluting stent (SDES). Primary success was obtained in 99% of lesions. 6% of stents were placed in left main coronary artery, 43% in left anterior descending coronary artery, 28% in circumflex coronary artery, and 23% in right coronary artery. Pre-PCI stenosis was 75.5 ± 13.2%, average stent length 20.2 ± 7 mm and average stent diameter 2.8 ± 0.5 mm. Mean time from transplantation to PCI was 11.5 ± 5 years. Mean clinical follow up was 5.3± 4.4 years. Mean angiographic follow up was 40 ± 47 months. A total of 27 (31%) stents presented events during follow-up: 27 SR, no ST. 7 occurred in BMS, 9 in FDES, 11 in SDES (p=0.4). There were no difference in rate of SR between BMS and DES (44% vs 39%, p=0.24). We performed 15 (17.2%) TLR. Post-PCI survival was 72.7% at 5 and 50.3% at 10 years, and freedom from lesion SR and/or ST at 1 (96%), 5 (57%) and 10 (47%) years.

CONCLUSIONS

In cardiac transplant recipients, PCI with stent can be performed with high rates of primary success. Our series show a low rate of SR at 1-year-follow-up, similar to coronary disease in non-transplant patients. However, after a very long-term follow-up, the rate of SR is still high.

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Head-to-head comparison of a pulsatile and a continuous flow left ventricular assist device in high-risk PCI setting - iVAC2L vs. Impella 2.5

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease

AIMS

Due to significant progress in interventional techniques, percutaneous coronary intervention (PCI) has become an alternative therapy to coronary bypass surgery in complex stenosis. Several circulatory support devices have been developed to support cardiac output or maintain sufficient circulation in critical situations or complications during PCI. We compared in a prospective trial the hemodynamic and clinical performance of a new trans-femoral pulsatile assist device (iVAC2L) with the most used continuous flow assist device (Impella 2.5) in high-risk PCI patients.

METHODS AND RESULTS

In 30 patients [7 female, age 75±8 years, left ventricular ejection fraction (LVEF) 45±12%] high-risk PCI (complex left main n=20, last remaining vessel n=2, severe three vessel disease and reduced LVEF n=8) was performed under circulatory support with the Impella 2.5 (n=13) or IVAC2L system (n=17). Aortic pressure data and flow measurements were collected before and after device placement as well as immediately after PCI. Blood parameters of hemolysis were collected before and after support.

Correct device placement was achieved in 14 (82%) patients in the iVAC2L-group and in 12 (92%) patients in the Impella-group (p=n.s.). PCI was successful in 29 (97%) patients. Except for contrast agent (276±26ml), no additional fluids were infused. Mean support time was shorter in the Impella-group (130±26 vs. 103±67min, $p<0.05$). There was no early increase in systolic, diastolic and mean aortic blood pressure under full iVAC2L-support, but with prolonged support time these parameters increased significantly and kept their higher level. In contrast, diastolic and mean aortic pressure increased significantly immediately after starting Impella-support, but with increasing support the increase in these hemodynamic parameters was comparable between the two groups after PCI. Continuous flow generated by the Impella device was significantly higher before and after PCI, as compared to the pulsatile flow generated by the iVAC2L device (2.05±0.08l/min vs. 1.25±0.06l/min, $p<0.001$). In five patients (three under iVAC2L-support) critical events during PCI occurred (massive vasospasm, coronary perforation, no flow in LCA, II°-AV-block with hemodynamic significance, pericardial tamponade), but both devices helped to maintain stable hemodynamic conditions with no need for cardiopulmonary resuscitation. After PCI, one severe bleeding in each group (both due to aneurysm of the femoral artery) and one stroke <24h in iVAC2L-group occurred. There was no reference of significant hemolysis in both groups.

CONCLUSIONS

High-risk PCI under circulatory support with either the pulsatile iVAC2L or the continuous flow Impella 2.5 device is feasible and safe. Aortic pressure increases under circulatory support with both devices, but seems to increase earlier under Impella support. Potential differences between the two supporting systems with respect to patients' outcome or hemodynamic parameters need to be evaluated in large multi-center studies.

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A simple score to predict success in PCI CTO for beginners

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

There are several angiographic scores to predict success of CTO PCI but any clinical score has been cheched in this complex group of patients

The objective was analyse if any clinical/ angiographic characteristics are associated to CTO PCI failure

METHODS AND RESULTS

Methods: 676 consecutive patients carrying 712 CTO, treated by PCI in a single center by a single doctor were includded in the analisys We includded from their first CTO PCI. We retrospectively analysed thel population in order to design a new risk score . Several clinical, angiographic and procedural items were registered and analysed. We also calculated several clinical and angiographic scores. Univariate and multivariate analysis were done to compare failure versus succes

RESULTS: On univariate analysis we found that procedural failure was associated to the following:

CLINICAL CHARACTERISTICS : age (65.1±9.5 in failure group vs 62.5±10.6 in succes group, p:0.004), renal insufficiency (17.9% vs 11.9%p:0.047), previous AMI (39.1% vs 36.6%, p:0.037) and previous CABG (16.8% vs 10.7%, p:0.033)

ANGIOGRAPHIC CHARACTERISTICS & PROCEDURAL CHARACTERISTIS: occlusion length(26.6±15.8mm vs 19.4±11.8mm, p<0.001) , calcification on CTO body(<0.001) and CTO prpoximal vessel (p<0.001) , bend >45°(59.7% vs32%,p<0.001), blunt stump (47% vs 66%, p:0.001), the presence of a proximal branch near the occlusion (64.5% vs 50.1%, p:0.001), ostium CTO (13.3% vs 6.8%)p:0.006), CTO in a bifurcation (26% vs14.6%, p<0.001) and JCTO score (2±1 vs 1.22±0.9, p<0.001)

We made a predictor model with the significant clinical characteristics: age previous AMI, previous CABG remained predictors of failure.The angiographic features significantly associated with failure were: length >15mm, vessel calcificatrion >2, bend >45°, blunt stump and proximal branch. In a mixed model made by the significant clinical and angiographic items only morphological features remained significant : length > 22mm ((0.000 OR2.99 (IC95%(1.8-4..8)), Ca++ vessel 1- 2 ((0.000(OR2.9 IC95%(1.9-4.6)), Ca++ vessel >2((0.000(OR8.9(IC95%(4.4-17.9)), bend >45°((0.000(OR3.3(IC95%2.2-5)), blunt stump ((0.006(OR 1.7(IC95%(1.18-2.7)), proximal branch ((0.015 5 OR1.6(IC1.1-2.5)).

With this factors we made a simple score well calibrated and able to correctly predict failure: rang from 0 to 10 points : length < 15 mm: 0 points, 15-22mm 1 point, >22mm 2 points. Ca++ vessel 0: o points, 1-2, 2 points and >2, 4 points. Bend >45° 2 points, proximal branch 1 point, blunt stump 1 point . The possibility of succes with a score of 0 is 95.7% and with the score of 10 is only 33.3%

CONCLUSIONS

Any clinical characteristic even if is statistily associated with failure is strong enough to built a risk score to predict CTO PCI failure. The most powerful factors that contributes to failure were vessel calcification, bend

and length > 22 mm. We propose a simple score to facilitete patient selection for beginers in CTO PCI

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Long-term outcomes of alcohol septal ablation with the same dose of ethanol (3ml) in 150 consecutive hypertrophic cardiomyopathy patients

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THEME: Coronary Interventions

TOPIC(S): Other Coronary Interventions

AIMS

To assess hospital and long-term results of alcohol septal ablation with the same dose of ethanol.

METHODS AND RESULTS

Between 2000 and 2017, 150 patients (78 males, 72 females) with obstructive hypertrophic cardiomyopathy underwent alcohol septal ablation procedures. In all cases we intentionally used the same dose of ethanol (3ml). The median of age was 52 (interquartile range: 41-60) years.

Risk factors were as follows: smoking - 30 (20%), syncopes - 19 (12,7%), arterial hypertension 81 (54%), family history of hypertrophic cardiomyopathy - 11 (7,3%), coronary artery disease - 20 (13,3%). Sustain ventricular tachycardia was observed in 3 patients at baseline.

The median of follow-up was 71 (interquartile range: 36-110) months. Hospital mortality was 0,57% (1/175 hospitalizations). The cause of death - sepsis. Hospital complications were as follows: deep vein thrombosis - 2, femoral pseudoaneurysm - 2, gastrointestinal bleeding - 1, left main dissection - 1 (managed by coronary artery bypass grafting), right coronary artery thrombosis due to ethanol leakage (managed by percutaneus coronary intervention) - 1 . Perioperative high-grade atrioventricular blocks, which required permanent pacemaker implantations - 18 (12%). Permanent pacemaker implantations in the follow-up - 5 (3,3%). Long-term survival rates were as follows 95,1% (95%CI:92,7-97,5), 85,8% (95%CI:83,7%-87,0%) ? 81,7% (95%CI:79,7%-83,7%) at 5-, 10- and 15-years follow-up, respectively. One-sample log-rank test didn’t find significant difference in 15-years survival rates between alcohol septal ablation cohort and age- and sex-matched Russian population.

CONCLUSIONS

Alcohol septal ablation with the same (3 ml) ethanol dose is safe and efficient. Survival rates after alcohol septal ablation are compatible with those in age- and sex-matched general Russian population.

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FFR and iFR for non-culprit stenosis in patients with AMI

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THEME:
TOPIC(S):

AIMS

There has been debate regarding the reliability of FFR or iFR for non-culprit stenosis in the acute stage of AMI. The aim of this study was to compare the changes of fractional flow reserve (FFR) or instantaneous wave-free ratio (iFR) with severity of epicardial coronary stenosis between non-culprit vessel of acute myocardial infarction (AMI) and stable ischemic heart disease (SIHD).

METHODS AND RESULTS

One hundred AMI patients underwent comprehensive physiologic assessment including FFR, iFR, coronary flow reserve (CFR), and index of microcirculatory resistance (IMR) for non-culprit vessel stenosis after primary percutaneous coronary intervention (PCI) for culprit vessel. The changes in FFR and iFR for diameter stenosis (% DS) of non-culprit vessel stenosis were compared with FFR and iFR measured in 203 patients with SIHD. From 40% to 80% stenosis, FFR and iFR measured in non-culprit vessel of AMI patient showed significant decrease with worsening stenosis severity (all p values<0.001). Non-culprit vessel of AMI patients showed lower CFR than SIHD, however, IMR was not different between non-culprit vessel of AMI and SIHD patients. FFR and iFR were not significantly different between non-culprit vessel of AMI and SIHD patients in all % DS groups from 40% to 80% (all p values>0.05). In addition, percent difference of FFR and iFR according to the increase in %DS was also not significantly different between non-culprit vessel of AMI or SIHD. There was no significant interaction between clinical presentation and the changes of FFR and iFR for worsening % DS (Interaction p value = 0.698 and 0.257, respectively).

CONCLUSIONS

Changes in FFR and iFR for the non-culprit stenosis of AMI patients were not significantly different with those in SIHD patients, even in the acute stage of AMI.

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Prospective longitudinal survey on the use of dual and triple antithrombotic therapies in patients with an indication for anticoagulation undergoing PCI: recent changes in practice

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Antithrombotic treatment strategies for patients with both an indication for oral anticoagulation and additional antiplatelet therapy following percutaneous coronary intervention must balance the prevention of stent thrombosis and embolic events with the risk of bleeding. Recent evidence from randomized trials has led to changes in clinical practice. We present the results of a prospective longitudinal survey among German interventional physicians on the implementation of dual and triple antithrombotic therapy in clinical practice.

METHODS AND RESULTS

Interventional cardiologists in Germany were invited to participate in an electronic survey in the years 2015 and 2018. The project was supported by the Working Group on Interventional Cardiology of the German Society of Cardiology. The same 27 questions on the pre-, intra- and postinterventional management in patients with an indication for oral anticoagulation were asked at both timepoints. We focus here on the implementation of dual and triple therapy after implantation of either a drug-eluting (DES) or a bare-metal stent (BMS). 136 physicians answered the 2015 survey, 135 the 2018 one.

The use of triple therapy comprising a vitamin K antagonist, acetylsalicylic acid and a thienopyridine decreased from 50.7% in 2015 to 8.15% in 2018 ($p<0.0001$). Dual therapy (a vitamin K antagonist and a thienopyridine) was implemented by 23.53% in 2015 and 8.15% in 2018 ($p=0.001$). The percentage of clinicians who administered a dual therapy comprising a novel oral anticoagulant (NOAC) and a thienopyridine rose from 5.88% in 2015 to 66.67% in 2018 ($p<0.0001$). In patients who received triple therapy after DES implantation, triple therapy was continued for one month or less by 51 (37.5%) within the first and 90 (66.67%) within the second survey ($p<0.0001$). Use of triple therapy for 1-6 months decreased from 55.9% to 31.9% ($p=0.0001$). Similarly, the use of vitamin K antagonist-based triple therapy in patients with acute coronary syndromes (ACS) decreased from 48.5% to 8.9% ($p<0.0001$). In contrast, use of a NOAC-based triple therapy rose from 22.1% to 41.5% ($p= 0.001$). In ACS patients, use of vitamin K antagonists in dual therapy with clopidogrel decreased from 11.0% to 2.2% ($p= 0.0058$), while that of NOAC and clopidogrel rose from 2.2% to 38.5% ($p<0.0001$). Use of short-term (1 month) administration of triple therapy after DES implantation in ACS increased from 21.3% to 47.0% ($p= 0.0008$).

CONCLUSIONS

The implementation of dual and triple therapy in practice has changed. Although the approaches favoured by physicians are not homogeneous yet, our survey showed a trend towards an increased application of dual therapy on the one and a reduction in both the use and duration of triple therapy on the other hand.

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REABSORBS registry (REgistro ABSORB Sanremo): long-term evaluation of patient selection-predilation-proper sizing-postdilation (4Ps) BRS implant in real-world setting

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Evaluating long-term outcomes of Patient Selection-Predilation-Proper Sizing-Postdilation (4Ps) technique-implanted everolimus-eluted BRS Absorb in a real-world setting.

METHODS AND RESULTS

This registry includes all consecutive patients (pt) treated with BRS in our cath lab between December 2012 and March 2017.

Registered endpoints are: cardiac death (CD), target vessel myocardial infarction (TV-MI), scaffold thrombosis (ScT), target vessel revascularization (TVR), target vessel failure (TVF), ischemia-driven target lesion revascularization (ID-TLR), angiographic success (AS) defined as: successful BRS deployment, residual stenosis (RS) < 30%, final TIMI 3 flow.

220 pt (58.6±9.5 years; male 85.5%; diabetics 15.9%) were enrolled, 253 PCI were performed (90.5% radial) on 321 lesions and 376 BRS were implanted.

166 PCI (65.6%) were performed in STEMI, NSTEMI or UA.

Stenoses were mainly on LAD (168, 52.3%); 210 lesions (65.4%) were Ellis type B2-C; in particular 100 (31.2%) were soft plaques with thrombus and only 16 (5.0%) stenoses were calcific but none severe.

187 pt (85%) were on DAPT with new P2Y12 inhibitors.

Preprocedural QCA showed a 83.7±15.2% diameter and 21.6±11.3 mm lenght stenosis and a 2.89±0.41 mm reference vessel diameter.

Predilation with non-compliant balloon (NCB) at 19.6±3.8 atm was performed in 366 cases (97.3%) with balloon-artery ratio 1:1 in 282 (77%).

After careful sizing BRS was released at 12.9±2.7 atm; BRS length per vessel was 32.7±18 mm; marker-to-marker BRS overlap was present in 84 PCI (22.3%), a DES-BRS overlap in 47 (18.7%). 17 PCI (6.7%) were IVUS or OCT-guided.

Postdilation with NCB at 21.8±4.2 atm was performed in 376 cases (100%), NCB was 0.5 mm oversized in 156 (41.5%).

At QCA no RS was >30%; there were 3 final TIMI flow < 3 (all in STEMI pts) and 1 BRS implant failure, leading to a 98.9% AS.

At a median follow-up (FU) of 1144 days (interquartile range 919-1511) in the overall cohort we had 2 CD (0.9%, both for heart failure), 6 TV-MI (2.7%), 16 TVF (7.3%), 14 TVR (6.4%), 8 ID-TLR (3.6%), 7 restenosis (3.2%), 2 very late definite ScT (0.9%) causing NSTEMI.

One ScT of a 2.5x28 mm BRS occurred at 20 months FU (Reference Vessel Diameter RVD 2.4 mm, final Minimum Lumen Diameter, MLD 2.1 mm), the other ScT of a 2.5x23 mm BRS occurred at 15 months FU (RVD 2.3 mm, final MLD 2.2 mm); DAPT was interrupted respectively 4 months and 1 week before events.

CONCLUSIONS

In our experience, with the limitations of a single-center registry, Absorb 4Ps implant in a population with complex but non-calcified lesions and with a large presence of soft plaques seems to have a good AS and a low rate of events at a median FU of 38 months.

Extra caution should be given when dealing with 2.5 mm diameter BRS implanted in small vessels.

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Vascular effects of dapagliflozine in patients with type 2 diabetes

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THEME: Interventions for Heart Failure
TOPIC(S): Chronic heart failure

AIMS

Large-scale cardiovascular outcome trials with sodium glucose cotransporter-2 (SGLT2) inhibitors showed significant results in preventing cardiovascular outcome. The main mechanisms may control vascular risk factors.

METHODS AND RESULTS

Methods & Results: This was a randomized, single-blind, placebo-controlled, parallel study. Age, sex, and body mass index were matched between groups. All patients were recommended not to change diet and exercise pattern until a study ends. Thirty-five patients with type 2 diabetes in each group were given placebo or dapagliflozine 10 mg, respectively daily for 2 months.

Placebo therapy did not significantly change triglyceridies and triglyceridies/HDL cholesterol ratio. Placebo therapy did not significantly change flow-mediated dilation and high-sensitivity CRP relative to baseline measurements. However, dapagliflozine therapy significantly reduced triglyceridies and triglyceridies/HDL cholesterol ratio relative to baseline measurements (both $P<0.05$ by paired t-test). Also, dapagliflozine therapy significantly improved flow-mediated dilation and reduced high-sensitivity CRP relative to baseline measurements (both $P<0.05$ by paired t-test). Of interest, When compared with placebo, dapagliflozine significantly decreased triglyceridies and triglyceridies/HDL cholesterol ratio (both $P<0.05$ by unpaired t-test). When compared with placebo, dapagliflozine significantly improved flow-mediated dilation and reduced high-sensitivity CRP (both $P<0.05$ by unpaired t-test).

CONCLUSIONS

Conclusions: Dapagliflozine controls vascular risk factors in patients with type 2 diabetes. These effects are one of main mechanisms in preventing cardiovavascular outcome by SGLT2 inhibitors.

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Absolute coronary blood flow measurement and microvascular resistance in Takotsubo cardiomyopathy

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

The pathophysiology of Tako-Tsubo Cardiomyopathy (TTC) is still unclear. There is evidence suggesting the involvement of microvascular dysfunction (MD) in its pathogenesis. We sought to evaluate the feasibility and safety of quantification of coronary absolute blood flow (AF) and myocardial resistance (MR) using a new thermodilution method in the setting of TTC.

METHODS AND RESULTS

Between May 2017 and October 2018, six consecutive patients admitted to Hospital in the two participating centers with an acute TTC were prospectively included in our study.

After coronary angiography, a ventriculogram and an invasive physiological assessment of the microcirculation was systematically obtained in every patient in the left anterior descending artery (LAD) using a pressure-temperature sensor-equipped wire and according to thermodilution principles. The main parameters assessed were: the index of microvascular resistance (IMR), the coronary flow reserve (CFR), the fractional flow reserve (FFR), the AF and the MR.

IMR and CFR were obtained in agreement with previously reported studies administering intravenous adenosine (140 - 160 µg/kg/min) to induce steady-state maximal hyperemia and then three 1-mL injections of room-temperature saline were given.

The technique for AF and MR measurement is precise and not operator-dependent. It requires a continuous infusion of a low amount of saline (10-20 mL/min) through a specific multipurpose infusion catheter positioned selectively in the proximal coronary artery, adenosine is not necessary because intracoronary infusion of saline at room temperature through this catheter induces steady-state maximal hyperemia.

The most common trigger of TCM was physical stress (3/6, 50%).

A typical apical TC ventricular morphology was identified in 4 patients (66%), the rest were atypical ventricular morphologies. The most frequent electrocardiographic change was T-wave inversion in precordial leads, which was present in 4 patients (66%). Fifty percent (3/6) of the patients presented with a Killip class I, two cases presented with a Killip II and one in Killip III.

The average time needed for all physiological measurements was 19±3 min, and there was no complication.

Mean age was 73±7 years and all the patients were females. Coronary angiography revealed no significant epicardial coronary lesions in any patient.

The median (interquartile range) time from symptom onset to the coronary thermodilution measurements was 20 (8-31) hours. Most patients presented a normal or borderline IMR value (normal value ≤22) with a mildly reduced CFR (normal value≥2.5). However, we found that, in our patients, AF and MR were considerably impaired compared to a recently reported study in ischemic patients by Xaplanteris (Mean LAD values in Xaplaneteris study: AF 189 [151-235 mL/min] and MR 390 [347, 466 Wood U]).

The average measurements obtained in our study regarding coronary physiological were: IMR: 17.5±6; FFR 0.9±0.07; CFR 2.3±0.9; AF (mL/min) 158±47; MR (Wood Unit) 515±135.
In two patients the study was repeated two weeks later. An increase of AF (66% in one patient and 7% in the other one) and a reduction of MR (9% and 7% respectively) were found.

CONCLUSIONS

The thermodilution technique using a continuous intracoronary infusion of saline allows feasible measurement of AF and MR. Our results suggest that AF and MR may be impaired in the acute presentation of TTC patients. This technique opens a door to better understand the TTC physiopathology.

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Prognostic implication of modality treatment in CTO patients, the never-ending discussion?

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

There is some information about prognosis implication on success versus failure PCI CTO . There are no randomized studies about prognosis including the 3 mode of treatment in CTO patients . The objective was to analyse if any mode of CTO treatment has a prognostic implication in all commers CTO patients

METHODS AND RESULTS

We included 1252 patients: 631 included in group I, 323 in group II and 297 in group III. The main clinical and angiographic characteristics were: patients managed by medical therapy had a worse clinical profile were older (70±11 years vs 64±10.6 in group II and 65.2±9 in grop III, p<0.001), have a worse renal (1.35±1 creatinine vs, 1.16±0.7 group II and 1.17±0.78 in group III, p=0.001)and left ventricular systolic function (43±14% vs 49±13% in group II and 48±11%,p <0.001), higher Syntax II 47.6±13.6,vs 39.8±12.2 in group II and 43.4±10.8 in group III, p<0.001) and ACEF scores(1.97±0.89, 1.5±0.7 and 1.17±0.78, p=0.001) and more previous (36.2% vs 28.8% and 26.6%, p=0.005) and ongoing AMI(22.7% vs11.8% vs 11%,p<0.001). Patients sent to CAGB had higher Syntax score (29.8±12.3, vs 23.8±12 in group I and 20.8±10.4 in group II, p<0.001), more often a significant left main disease (30% vs11% in group I and 4.6% in group II, p<0.001) and 3 vessel disease (57.9% vs 39.6% in group I and 29.7% in group II, p<0.001).

During the follow up(4.3±2.06 years) 41% of patients under medical therapy received PCI in non CTO vessel , 51.7% of patients of CTO PCI 8.8% of CABG group. 5.7% of CABG patients received CTO PCI

The most important finding is that patients from group I had 3 times higher cardiac death than patients from group II or III (27% vs 9.6 in CTO PCI group and 9.8% in CABG group , p<0.001)

On multivariate analysis independent predictor factors of cardiac death were: Age (10.2HR(IC95% 1.03-10.4)p=0.021), creatinine (1.184 HR(IC95%10.24-1.36)p=0.022), DLP(HR1.7(IC95%1.2-2.5,p=0.003), Syntax 1 (1.016HR(IC95%1.002-1.03,p=0.027) and 2 (1.036HR(IC95%1.01-1.057,p=0.001), and ACEF (1.62HR(IC95%1.03-1.04,p=0.021) scores . Iindependent predictor factors associated to a better survival were CABG(0.42HR(IC95%0.26-0.68, p<0.001) and PCI (0.41HR(IC95%0.21-0.8,p=0.009) compared to medical therapy

CONCLUSIONS

We can reduce cardiac mortality in CTO patients by means of revascularisation CABG or PCI. In CTO patients We have to learn how to choose the better modality of treatment in these patients

A big population and a long term follow up its needed order to show the real benefit of any strategy

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Long-term outcomes after percutaneous revascularisation for left main coronary artery disease with everolimus-eluting stents: a gender-based single-centre perspective

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease

AIMS

Background and Aim. Everolimus-eluting stents (EES) are largely adopted for percutaneous coronary interventions (PCI) of the left main (LM) coronary artery. Long-term follow-up of patients undergoing LM PCI in a real world clinical setting, in particular of women, have been scarcely reported.

METHODS AND RESULTS

Methods. Consecutive patients undergoing LM PCI with EES at a single institution from December 2006 to April 2016 were included. Baseline clinical features, including procedural data, were collected. Main outcome assessed was the occurrence of major adverse cardiovascular events (MACE: a composite of death, myocardial infarction or target lesion revascularization) at follow-up

Results. Overall, 589 patients, of whom 122 (20.8%) women, were included in the present analysis. Women were older, had lower BMI and presented more frequently hypertension compared to men. Main clinical presentation was stable coronary disease; unstable angina was more frequent in women compared to men, whereas STEMI was less frequent,. After 69.7 ± 28.3 months of follow-up, 47 patients overall experienced MACE (1.43 per 100*patients/year). MACE rate was higher in female compared to male patients, with a rate of 2.49 and 1.17 per 100*patients/year, respectively (P=0.015). The difference was driven mainly by higher mortality in women (0.89 vs. 0.15 per 100*patients/years, P=0.002). At multivariable Cox regression, female gender was independently associated with an increased risk of MACE at follow-up (HR 2.21, 95% CI 1.20 – 4.08, P=0.011).

CONCLUSIONS

EES can be safely and effectively adopted for LM PCI. Women, in particular, should be carefully selected and monitored, as they might experience a higher rate of adverse events at follow-up.

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Comparison of the prognostic value of the SYNTAX and Residual SYNTAX scores in NSTE-ACS

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THEME: Coronary Interventions
TOPIC(S): NSTEMI

AIMS

The residual SYNTAX score (RSS) quantitatively assesses angiographic completeness of revascularization after percutaneous coronary intervention (PCI).

The purpose of this study was to determine whether the RSS could predict one-year mortality more than Syntax score in patients with NSTE-ACS.

METHODS AND RESULTS

Patients admitted in our cardiology department between 01 November 2015 and 31 October 2016 for NSTE-ACS and treated by PCI were prospectively evaluated.The Syntax score and the residual syntax score (RSS) were calculated. The RSS was based on the recalculation of the SYNTAX score after PCI.A ROC curves were developed to define the SS and RSS score cutoffs that best predicts one-year mortality.

132 patients were evaluated: mean age was 62 ± 12 years and 66.7 % were male. The one-year mortality was 3.8% .The syntax score and RS score in these patients were significantly higher (27.1± 6.5 vs. 15.8 ± 5.2 ; p =0.005) and (22.4± 7.9 vs. 5.2 ± 6.5 ; p < 10-3) respectively. Syntax score > 22 showed a sensitivity of 80.0 %, specificity of 81.6%. The area under the ROC curve was 0.85 (95% confidence interval of 0.74-0.96).Residual Syntax score > 18 showed a sensitivity of 80.0 %, specificity of 96.4%. The area under the ROC curve was 0.95 (95% confidence interval of 0.88-1.00).

CONCLUSIONS

We believe our results show that RSS more than SYNTAX score is a strong predictor of one-year mortality in patients with NSTEACS and that more extensive revascularization might improve the prognosis of these patients. However, randomized studies are needed to confirm this hypothesis.

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Pre-procedural predictors of the need of multiple clips in percutaneous edge-to-edge mitral valve repair

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair

AIMS

It was our aim to explore the possible predictors for the use of multiple clips.

METHODS AND RESULTS

Methods: We retrospectively analysed 127 patients treated with the MitraClip system between January 2011 and August 2018 in central hospital, Bad Berka, Germany. Group I: included patients treated with a single clip (58 patients; 45,5%) and group II: with more than one clip (69 patients; 54.5%). We examined the predictors of the use of multiple clips. Clinical and echocardiographic 3-months follow up was performed in all study patients.

Results: The differences of patients' demographic characteristics between both groups were not statistically significant except for male gender 48.3% in group I and 68.1% in group II. Left atrial and mitral annuluar size were significantly larger in the group II patients, LA and mitral annulus size (mean±SD) were 47.5±5.3mm vs 50.7±9.2mm (p=0.017) and 32.7±3.3 vs 34.4±4.0mm (p=0.026); respectively. Also, vena contracta was broader in group II 6.6±1mm vs 6±0.9mm in group I, p value 0,001. Severe mitral annulus calcification was observed in 36.2% in group I vs 10.1% group II; p value 0.0001. In the multivariate analysis, vena contracta width corelated positively with the use of multiple clips (B 0.125, p value 0.013) and severe annular calcification correlated inversely with it (B 0.35-, p value 0.002).

CONCLUSIONS

Vena contracta width and severe annular calcification are important factors in preprocedural planning of MitraClip.

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Impact of OCT-guided PCI on clinical outcomes in comparison between patients with and without diabetes mellitus

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Even in the 2nd-generation drug-eluting stent (DES) era, diabetes mellitus (DM) patients have high incidences of restenosis and repeat revascularization after percutaneous coronary intervention (PCI).

The aim of this study was to compare vascular response after stent implantation and major adverse cardiovascular events 2-year after stenting between DM and non-DM patients by using optical coherence tomography (OCT).

METHODS AND RESULTS

We analyzed 584 consecutive lesions treated by OCT-guided PCI using 2nd-generation DES from 2011 to 2014 (DM: n=239, non-DM: n=345). We did OCT-guided PCI using a specific stent optimization strategy to achieve at least acceptable stent expansion (in-stent area stenosis of at most 20%). We evaluated the incidence of postprocedural OCT findings (malapposition area, area stenosis, minimum stent area, stent eccentricity index, in-stent thrombus volume), and compared device-oriented clinical endpoints (DoCE) two years after stenting between DM and non-DM patients.

After optimal lesion preparation using OCT, there were no significant differences between the two groups in the incidence of stent malapposition, proximal and distal edge dissection, in-stent thrombus. Postprocedural quantitative OCT findings were not different between the two group (malapposition area: 0.30 ± 0.69 vs. 0.31 ± 0.56 mm2 (p=0.76), area stenosis: 23.9 ± 10.2 vs. 24.2 ± 10.5 % (p=0.72), minimum stent area: 4.74 ± 1.58 vs. 4.86 ± 1.64 mm2 (p=0.41), stent eccentricity index: 0.84 ± 0.08 vs. 0.84 ± 0.22 (p=0.75), in-stent thrombus volume: 1.03 vs 1.05 mm3 (p=0.96), respectively). The incidence of 2-year DoCE did not differ between the two groups (7.1% in DM group vs. 4.6% in non-DM group; P=0.20).

CONCLUSIONS

OCT-guided PCI using a specific stent optimization strategy was useful and resulted in similar future clinical events between DM and non-DM patients.

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Clinical predictors and angiographic features of ACS caused by systemic embolism

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

To identify the clinical predictors, angiographic characteristics and in-hospital mortality of coronary occlusion caused by systemic embolism.

METHODS AND RESULTS

From 2003 to 2018 we identified 40 patients with definitive main vessel coronary occlusion caused by systemic embolism. A comparison was made with 4989 patients with similar clinical characteristics that presented with acute coronary syndrome of atherosclerotic cause. We excluded intracoronary thrombosis of other aetiology

In the group of systemic embolisms, age <45 years was found more frequently (28% vs 10% in control group, p <0.001) and there were more women (43% vs 22%, p 0.003).
Neoplasia (18% vs 7% p 0.009) and previous valvular surgery (13% vs 0.5%, p <0.001) were more frequent in patients with systemic embolism.
Cases with embolic occlusion had more often atrial fibrillation of any type (40% vs 5%, p <0.001) and were more frequently under treatment with warfarin for any cause (15% vs 3% in the control group, p <0.001).

Regarding clinical presentation STEMI was more frequent in the embolic group (83% vs 67% in the control group, p 0.04).

With regards to angiographic characteristics patients with embolic occlusion had no stenosis in other vessels (number of other vessels with at least 1 severe stenosis was 0 in the embolism group vs 1.33 + 1 in the control arm, p <0.001).
PCI was attempted in 75% of the patients with occlusion of embolic origin while in the atherosclerotic group PCI was performed in 100% of the cases p <0.001).
PCI was successful in 80% of the patients with embolic occlusion vs 99% in control group, p <0.001)

In-hospital mortality was 15% in the embolic group vs 4% in the control group, p <0.001.

A multivariate analysis was performed to determine the independent predictors of systemic embolism: i) age: OR 1,06 (1,03 – 1,08), p <0.001. ii)female sex: OR 2,78 (1,37 – 5,65), p 0.007, iii) neoplasia: OR 3,37 (1.33-8,54), p 0.02. iv) previous valvular surgery: OR 4,28 (1.19-15.5), p 0.04. v) Atrial fibrillation: OR 16.1 (7,23 – 35,9), p <0.001 and vi) chronic warfarin treatment: OR 5,78 (2,46 – 13.55), p <0.001.

CONCLUSIONS

Atrial fibrillation, chronic warfarin treatment, previous valvular surgery and neoplasia are independent predictors of acute coronary syndromes caused by coronary embolism.

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Myocardial perfusion improved three months after CS Reducer implantation: another proof for the efficacy of this novel treatment

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Coronary Sinus Reducer (CS-Reducer) as a novel device for the Treatment of Therapy Refractory Angina.
There a lot of studies proving the efficacy of this Treatment by patients without interventional goal in the coronary angiography and with a positive ischemia test. Almost all of those studies are based on clinical parameters. We aimed to compare the myocardial perfusion index using cardiac MRI in our patient 3 months after the CS-Reducer implantation.

METHODS AND RESULTS

We are reporting a 71 year old male who was admitted to our hospital several times with stable angina symptoms interpreted as CCS III according to the Cardiac Cardiovascular Society classification. A 3-vessel coronary disease is known with several cardiac risk factors (Diabetes mellitus, hypertension, dyslipidemia). He has a chronic kidney disease und he doesn’t give up to smoke. We performed a stress cardiac MRI which showed positive signs of ischemia. A new coronary intervention showed good results after multiple PCIs. We discussed with our patient the possibility of implanting a CS-Reducer, which was accepted from him. After 3 Months the patient was readmitted for a routine control after the implantation. The patient showed a clear improvement in the CCS classification, from CCS III to CCS I. Furthermore we stated a significant improvement in the myocardial perfusion in cardiac MRI.

CONCLUSIONS

Coronary Sinus Reducer should be considered as an alternative for the treatment of refractory angina. The improvement of myocardial perfusion after the implantation explains the recover from symptoms and suggests a good therapy goal.

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Early haemodynamic changes and long-term outcome in patients with severe low-gradient aortic stenosis after TAVR

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

About 40% of patients with severe aortic stenosis (AS) have low gradients. This entity is in focus of investigations to gain a deeper understanding of pathophysiology and to optimize therapy management. The aim of the study was to investigate the hemodynamic changes measured invasively after transcatheter aortic valve replacement (TAVR) in the different subgroups of patients with severe low gradient aortic stenosis (LGAS) and to analyze the effect on long-term outcome.

METHODS AND RESULTS

600 patients with symptomatic LGAS (mean transvalvular gradient <40mmHg, aortic valve area ≤1.0cm2) and full invasive hemodynamic assessment before and after TAVR were included. Patients were divided into three groups: normal-flow low-gradient AS (NFLG-AS; n=296), paradoxical low-flow low-gradient AS (PLFLG-AS; n=153) and classical low-flow low-gradient AS (CLFLG-AS; n=151).

Mean age was 81.0±6.6 years, 50.8% were female and the mean EuroSCORE II was 6.7±5.6%. Acute device success was achieved in 95.8%. PLFLG-AS and CLFLG-AS showed a significant reduction of left ventricular global afterload ($p<0.005$), as well as a significant elevation of SVI, cardiac index, left and right ventricular stroke work index compared to NFLG-AS ($p<0.001$). Otherwise, NFLG-AS was associated with elevation of Zva and a decrease of SVI ($p<0.05$). Overall survival was highest in NFLG-AS, followed by PLFLG-AS and CLFLG-AS (1-year: 80.1/76.5/66.2%, p=0.006; 5-years: 39.2/39.1/27.5%, p=0.001). All subgroups experienced similar symptomatic improvement.

CONCLUSIONS

PLFLG-AS and CLFLG-AS patients showed an early left and right ventricular hemodynamic reverse response directly after TAVR. Otherwise, NFLG-AS had less severe cardiac damage and experienced less reverse changes but the same symptomatic benefit as well as the best survival rate.

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Double vessel AMI showing simultaneous total occlusion of two coronaries: a single-centre case series of 10 patients

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Simultaneous thrombosis of more than one coronary artery is an uncommon angiographic finding in acute ST-segment elevation myocardial infarction (STEMI), and usually leads to cardiogenic shock or even sudden cardiac death. Management of this complicated condition is as good as treating a case of acute Left main were timely revascularization plays a major role.

METHODS AND RESULTS

METHOD: This was an observational prospective study which enrolled all consecutive patients with ECG showing ST Elevation in two arterial territories and angiography confirming thrombotic occlusion of two coronary artery. A total of 10 cases were enrolled in our study during the period of six month (May to October 2018) . Mean age of patients was 56 ± 4. Eight (80%) were Male and two (20%) Female. Among risk factors 8 (80%) were smokers, 6 (60%) Hypertensive, 6 (60%) Diabetic and 4 (40%) with high lipids. ECG showed ST Elevation in precordial leads in all cases, inferior leads in eight cases and lateral lead in two case. Six patient presented in Killip class II, two in class III and two in class IV. Pressure support with Noradrenaline and Dopamine was used in all cases

RESULT:. Left Anterior descending involvement in nine (90%) cases, Right coronary in seven (70%) and Left Circumflex in four (40%). Two patient had VT during PCI which was cardioverted, slow flow was noted in three patient which was managed with nicorandil and GP2B/3A inhibitors. Thrombus aspiration was done in two patients. TIMI III flow was restored in all patients with no in hospital mortality.

CONCLUSIONS

Acute STEMI caused by simultaneous multi-vessel coronary occlusion is as good as Left main equivalent, it needs aggressive immediate revascularization owing to the higher mortality rate and complicated hospitalization course with arrhythmia, heart failure, and cardiogenic shock. Though there are no fixed guidelines for these type of cases as these cases are rare. We do not recommend to reperfuse any particular vessel first rather whichever vessel is easy to open should be attempted first in order to save jeopardized myocardium.

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Impact of OCT in evaluating intraprocedural stent thrombosis

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Intra-procedural stent thrombosis (IPST), excluded from the ARC definitions, is a serious complication of primary PCI in patients with ACS, however is associated with out-of-lab stent thrombosis (ST) and mortality.While previous studies based on angiography reported the incidence as infrequent (<1%), the mechanism and optimal management strategies remain poorly understood. This study was aimed to evaluate the efficacy of OCT for detection of IPST and to summarize our approach for preventing out-of-lab ST.

METHODS AND RESULTS

We analyzed consecutive 91 ACS patients (STEMI:39, NSTEMI:23, UAP:29) treated by OCT-guided coronary stent implantation (DES:48, BMS:43) from April 2013 to December 2018. A loading dose of 200mg of Aspirin and 300 mg of Clopidogrel were administered to patients who were not pretreated with antiplatelet therapy. Definition of IPST was an angiographically confirmed intraluminal filling defect within the stent resulting in total occlusion or delayed anterograde flow that occurred after stenting procedure.

IPST developed in 6 patients (6.6%), including 5 patients with STEMI and 4 patients after BMS implantation. Only one patient with NSTEMI was pretreated with Aspirin. OCT findings immediately after stent deployment revealed platelet-dominant thrombus (mean % thrombus area:32±11%) despite a lack of haziness on coronary angiogram, and no stent malapposition nor inadequate stent expansion was observed. All patients were treated with second Clopidogrel loading, while four out of the six patients were also treated with IABP. Adjunctive balloon dilatation was used in one lesion with TIMI 0 flow, although no additional rescue stent was performed. A final result with thrombus resolution and restoration of TIMI III antegrade flow was successfully achieved in all fivecases. However one STEMI patient with DES implantation developed subacute ST at 12thday. OCT detected platelet-rich thrombus.

CONCLUSIONS

IPST is more common than previously reported, and platelet thrombus may be strongly associated with pathogenesis. Early detection by OCT and systemic management of platelet thrombus are helpful to prevent out-of-lab ST defined by ARC.

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Differential prognostic accuracy of the Seattle heart failure model and MAGGIC score in patients with severe mitral regurgitation with or without right ventricular dysfunction one year after percutaneous mitral valve edge-to-edge repair

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair

AIMS

MitraClip is an established therapy for severe MR in symptomatic patients (pts) under optimal medical therapy (OMT) unsuitable for surgery due to high perioperative risk. Recently, MitraClip has been shown to reduce both the rates for heart failure rehospitalization and mortality. Right ventricular dysfunction (RVD) is an important prognostic marker in these patients. However, the prognostic accuracy of established heart failure risk scores like the Seattle heart failure model (SHFM) and MAGGIC score in pts undergoing MitraClip with or without RVD has not been investigated separately so far.

METHODS AND RESULTS

SHFM and MAGGIC score were calculated retrospectively. RVD was determined as tricuspid annular plane systolic excursion (TAPSE) <= 15mm. Area under receiver operating curves (AUROC) of SHFM and MAGGIC score were performed for an endpoint of all-cause mortality within one year after MitraClip.

Between 2013 and 2017, n=103 pts with MR III (73 ± 11 years, 29% female, LVEF 37 ± 17%,mean LVEDD 62mm ± 10mm, NTproBNP 5220 ± 10869 pg/ml, EuroScore II: 9 ± 7.55%)underwent successful MitraClipimplantation with 2 ±1 clips and a reduction of at least I° MR. MR mechanism was functional in 42 % and degenerative in 58 %. One-year mortality was 28.2%.

In Kaplan-Meier analysis, one-year mortality was significantly higher among patients with RVD (n=57 pts without RVD: 23.2%, n= 46 pts with RVD: 34.8%, log rank p = 0.009). Pts with RVD had significantly lower LVEF (33 ± 17 vs. 42 ± 16%), higher NTproBNP levels (8111 ± 16089 vs 3115 ± 3253pg/ml) and a higher EuroScore II (12 ± 8 vs 7 ± 6, all p < 0.05).

AUROC values for SHFM and MAGGIC score revealed comparable values for SHFM and MAGGIC score (SHFM: 0.704, MAGGIC: 0.692). In separate analysis of pts without RVD, SHFM displayed a higher AUROC value compared to MAGGIC score (SHFM: 0.776; MAGGIC: 0.551). In reverse, the analysis of pts with RVD showed that the MAGGIC score displayed a higher AUROC value of 0.796 indicating good diagnostic accuracy in this subset of pts, compared to the SHFM score (AUROC: 0.623).

CONCLUSIONS

RVD is an important prognostic marker in MR pts undergoing MitraClip. The established heart failure models SHFM and MAGGIC displayed adequate over-all prognostic power also in MitraClipÒpts. However, a differential diagnostic utility for these scores in pts with and without RVD has been demonstrated, indicating higher prognostic power of the MAGGIC score in pts with RVD and a higher over-all sensitivity of SHFM in pts

without RVD. Therefore differential usage of the SHFM and MAGGIC score must be taken into account for adequate prognostification of MitraClipcandidates with and without RVD.

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Impact of transcatheter PFO closure to prevent recurrent decompression illness among professional divers

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THEME: Interventions for Stroke
TOPIC(S): Other stroke interventions

AIMS

Patent foramen ovale (PFO) has been shown to increase the risk of decompression illness (DCI). Data on the clinical impact of PFO closure in professional divers are scarce.
The aim of the present study was to investigate the efficacy of transcatheter PFO closure to prevent recurrence of DCI among divers pursuing intense diving activity after the procedure.

METHODS AND RESULTS

Thirty-nine divers (30 males, 45 ±9 yrs, median number of dives before DCI = 1095) experiencing 48 events were included in this multicenter registry. Nine of them had more than one DCI before PFO closure. The type of DCI was mainly cochleo-vestibular (N=22) and cutaneous (N=17), less frequently cerebral (N=8) or spinal (N=3). The PFO was closed successfully in all patients with zero complications and using several devices : Amplatzer occluder in 22 cases, Occlutech Figulla (N=5), Gore Septal Occluder (N=2), Starflex (N=6), Cardia (N=3) and Premere (N=1). The diving activity was restarted at a median time of 60 days after the procedure with no reduction in the intensity and habits of diving : mean number per yr (105±93 vs 111±102), mean depht (33±9 vs 34±9 m), mean number deeper than 30 m (37±27 vs 42±38), mean duration (59±22 vs 54±11 min) were not statistically different (p=NS for the all the comparisons) before and after PFO closure.
Among patients undergoing successfully PFO closure without residual shunt and with a complete follow-up (142 patient-years, median follow-up 1072 days), there were zero DCI, zero late prosthesis dysfunction, one ischemic stroke, 2 short episodes of atrial fibrillation and one death (due to cancer, no device- or procedure-related). Antiplatelet therapy was stopped at a median time of 182 days after the procedure.
Kaplan-Meier analysis showed an overall survival and event-free survival at 97±2 % and 89±6 %, respectively.

CONCLUSIONS

This study shows that transcatheter PFO closure after DCI is safe and efficient to prevent recurrent DCI among professional divers pursuing their intense diving activity.

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Safety and efficacy of prolonged DAPT in reducing cardiac mortality in patients undergoing complex PCI

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease, Bifurcation lesion

AIMS

The use of DAPT as part of long-term therapy requires consideration of both reduced thrombotic events and increased bleeding risk. In the general population, short DAPT duration (3-12 months) has not shown any difference in death when compared to prolong DAPT (>12 months). However, there is a subtle balance between the benefits and harms of prolonged DAPT that requires taking consideration of patient's clinical factors and complexity of the coronary anatomy.

METHODS AND RESULTS

In the current systematic review, our objective was to compare death, major adverse cardiac events (MACE), and major bleeding in patients on prolonged (≥12 months) or short-course DAPT (3 to 12 months)undergoing complex PCI. Complex coronary stenting was defined as a procedure with at least 1 of the following angiographic characteristics: 3 vessels treated, >3 stents implanted, >3 lesions treated, bifurcation lesions, total stent length >60 mm, left main or proximal LAD, a vein graft stent or chronic total occlusion as target lesion. A thorough computer-based search was performed using 4 major databases. Of the 3453 titles searched, 3 randomized and 2 observational studies met the inclusion criteria comparing short and prolonged DAPT therapy. We applied a random-effects model to acknowledge the variation in study design, treatment duration, and length of follow-up among studies. There was a reduction in cardiac mortality with prolonged DAPT (OR 1.77, 95% CI 1.09 –2.86, P =0.02, I2 = 0%). On sensitivity analysis, the results did not change even after removing the study with the highest weight. MACE was significantly reduced with prolonged DAPT (OR 1.32, 95% CI 1.04 –1.68, P =0.02, I2 = 22%). On the other hand major bleeding was increased with prolonged DAPT (OR 0.57, 95% CI 0.39 –0.83, P =0.004, I2 = 0%). There was no difference in the all-cause mortality (OR 1.16, 95% CI 0.82 –1.63, P =41, I2 = 0%).

CONCLUSIONS

Complex PCI, a predictor of higher MACE, needs special consideration when deciding the duration of DAPT. The benefits of prolonged DAPT in this subgroup will need confirmation in a larger randomized study.

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Below-the-knee arterial in patients who underwent percutaneous transluminal angioplasty; propensity score-matched analysis

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THEME: Peripheral Interventions
TOPIC(S): Below the knee

AIMS

Although percutaneous transluminal angioplasty (PTA) is considered as an effective treatment in patients (pts) with critical limb ischemia (CLI), below-knee (BTK) CLI is particularly challenging. This study sought to compare primary stenting and standard plan old balloon angioplasty (POBA) in BTK artery on 1-year clinical outcomes.

METHODS AND RESULTS

This study consisted of 357 (400 limb, 697 lesion) consecutive lower extremity arterial disease pts with BTK lesion from Sep 2010 to Dec 2016. All the enrolled pts were received primary stenting (111 limbs in 102 pts) or POBA (289 limbs in 255 pts) with PTA. Procedural success, complications and clinical outcomes were compared between the two groups up to 1-year. After PSM analysis, 2 propensity-matched groups (93 pairs in pts, n= 186; 101 pair in limbs, n=122, C-statistic=0.808) were generated, and the baseline clinical characteristics of the two groups were balanced. Procedural success, complication incidences were similar between both groups. Large diameter (2.62 ± 0.43 mm vs. 3.4 ± 0.71 mm, $p<0.01$) and short lesion (185 ± 88 mm vs. 51 ± 27 mm, $p<0.01$) was frequent in stenting group before and even after PSM analysis. Six to 9-month CT or angiographic follow-up, there were similar incidence of binary restenosis, primary, and secondary patency. One-year clinical, there were similar incidence of individual hard endpoints including mortality, myocardial infarction, limb salvage, and any extremity amputations except the target extremity revascularization (TER) were more incidence in primary stenting group (18.9 % vs. 11.1%, $p=0.002$) than POBA group.

CONCLUSIONS

Although the TER was increased with BTK stenting, other major individual clinical outcomes and limb salvage rates were similar between the POBA and stenting for the BTK lesions. Stenting could be a reasonable treatment option in the treatment of BTK lesion depending on clinical and baseline lesion characteristics. It need a randomized, large scale, long-term follow further study.

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Diagnostic agreement of quantitative flow ratio with FFR and iFR

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Quantitative flow ratio (QFR) has a high diagnostic accuracy in assessing functional stenoses relevance, as judged by fractional flow reserve (FFR). However, its diagnostic performance has not been thoroughly evaluated using instantaneous wave-free ratio (iFR) or coronary flow reserve (CFR) as the reference standard. This study sought to evaluate the diagnostic performance of QFR using other reference standards beyond FFR.

METHODS AND RESULTS

We analyzed 182 patients (253 vessels) with SIHD and 82 patients (105 non-culprit vessels) with AMI in whom coronary stenoses were assessed with FFR, iFR and CFR. Contrast QFR analysis of interrogated vessels was performed at blinded fashion by a core laboratory, and its diagnostic performance was evaluated with respect to the other invasive physiological indices. Mean % diameter stenosis, FFR, iFR, CFR and QFR were 53.1±19.0%, 0.80±0.13, 0.88±0.12, 3.14±1.30, and 0.81±0.14, respectively. QFR showed higher correlation (r=0.857 with FFR vs. 0.725 with iFR, p<0.001), diagnostic accuracy (90.8% vs. 81.3%, p<0.001), and discriminant function (area under curve [AUC]=0.953 vs. 0.880, p<0.001) when FFR was used as a reference standard than when iFR was the reference standard. However, when CFR was used as an independent reference standard, FFR, iFR, and QFR showed modest correlation (r= 0.169, 0.323, and 0.147, respectively) and discriminant function (AUC= 0.682, 0.765, and 0.677, respectively). In addition, there were no significant differences in diagnostic accuracy among FFR, iFR, and QFR (65.4%, 70.6%, and 64.9%, all p values in pairwise comparisons>0.05, overall comparison p=0.061).

CONCLUSIONS

QFR has a high correlation and agreement with respect to both FFR and iFR, although better when FFR is used as the comparator. The differences observed between QFR and FFR with respect to iFR may be explained by CFR. As a pressure-gradient index not depending on wire or adenosine, QFR might be a promising tool for improving the adoption rate of physiology-based revascularization in clinical practice.

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Clinical and laboratory characteristics of patients with coronary artery anomalies

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THEME: Coronary Interventions

TOPIC(S): Other Coronary Interventions

AIMS

Coronary artery anomalies are rare congenital abnormalities often found incidentally on conventional coronary angiogram or coronary computed tomography angiography. They may result in various clinical outcomes. The objective of this study was to investigate the prevalence of coronary artery anomalies, the clinical and laboratory characteristics of patients with coronary artery anomalies and the outcomes at 1 year follow up of this patients in a high-volume coronary interventional center in Romania.

METHODS AND RESULTS

To define the study population we reviewed all coronary angiograms performed between 01.01.2014 and 31.12.2014. A total number of 5832 coronary angiograms were analyzed and we identified 31 patients with coronary artery anomalies. We included in the study the patients with anomalies in the origin, course and number of coronary arteries and with coronary fistulas. We excluded from the study population patients with myocardial bridging of coronary artery because they represent another category of patients that can erroneously raise the incidence of coronary artery anomalies.

The prevalence of coronary artery anomalies was 0.53%. 87.4% of patients had origin and distribution anomalies, and 12.9% of patients had a coronary artery fistula. The most common coronary artery anomalies were the anomalous origin of the right coronary artery (48,25%) and the anomalous origin of the left circumflex artery from the initial segment of the right coronary artery. 70% of patients underwent coronary angiogram due to atypical chest pain. Only 9.6% of patients had significant coronary artery disease. Of those patients, 2 were treated by percutaneous coronary intervention and 1 by coronary artery bypass graft. The mortality rate was 0% at 1 year follow up.

CONCLUSIONS

The prevalence of coronary artery anomalies in this study was slightly lower but still similar to that of previous studies. Patterns of coronary artery anomalies in our patient population were similar to those of previous studies. The majority of patients presented with atypical symptoms, and only a minority had coronary artery disease. The mortality rate of 0% at 1 year follow up shows the benign prognosis of most coronary artery anomalies.

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How to develop and maintain cardiovascular education and training in cathlab: a Canadian experience

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

New cutting-edge interventional modalities in the rapidly growing field of interventional cardiology drives staff changes as well. Building top cardiovascular services requires keeping up with the latest advances in technology. To build an excellence ,a high quality and well-motivated staff is essential.This article presents the educational framework and values we are applying in our center to determine long term productivity and profitability.

METHODS AND RESULTS

To climb on the top or stay in the excellence in Cath lab,the presence of more efficient,effective,and highly – motivated team is a necessity. Many times the medical staff feel trapped at their current position, advancement and productivity. Accordingly, an ongoing service training program for new and current employees helps them adjust to rapidly-changing job requirements. Cathlab staff are organization's greatest asset, and the training and education of those assets must be viewed as an investment in workforce and not just an expense. The benefits of training and education in any organization include increased productivity, fewer errors, higher staff moral, lower turnover rates, behavior consistency, decreased need for supervision and customer advocacy. Providing knowledge and expertise to cath lab staff must be a gradual process consisting of a cycle of assessing ,planning,implementing and re-assessing to provide dynamic skills ,required to meet our business goals.

In our center, to set a realistic roadmap, maximize learning, minimize frustration and avoid confusion, we started our training process by performing a survey among nurse -tech employees to determine training objectives, topics of interest and necessity, select training methods and mode, and means of evaluation. Our target group included the new and current staff. Based on the gathered data and the essential topics for cathlab, series of procedural educational kits were prepared in three levels of basic,intermediate and advanced and routine on the job- training programs officially started.The next step was providing the policy and procedures based on the content of these educational kits and standard international guidelines. Furthermore ,our interprofessional orientation of medical team let us confirm a coherent process of enhancing the organization's ability to adopt and use advances in technology .Finally , covering each educational package, would end into re-assessment and could be a base of further surveys to ensure adequate skilfull human resources for expansion into new programs.

CONCLUSIONS

To get the most of the advanced cardiovascular technology , the quality of employees and their development through training and education are major factors. Educational program benefits include saving time, increasing productivity, and improving performance and output. To achieve these aims , the department of interventional cardiology of our center has started a structured service training program including a format of preceptorship for the new employees and a format of ongoing standard on-the -job training for current staff and developing the policies and procedures.This model of interventional cardiovascular education can be considered as a

sample method to develop workforce in cathlab setting.

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Procedural and clinical benefits of selective thrombus aspiration in AMI treated with primary PCI. Insights from the TAPER registry

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

After the results of several randomised studies, routine thrombus aspiration (TA) has been left in the background for not improving the prognosis of patients with STEMI and even supposedly increasing the stroke rate. However, this technique can facilitate primary PCI (pPCI) by improving its results. Aim: to assess the advantages of TA during pPCI, its safety and benefits after 1-year follow-up.

METHODS AND RESULTS

The TAPER registry (efficacy and safety of selective Thrombus Aspiration in Real clinical Practice) retrospectively included 687 patients (76.9% males, 64±12 years) with STEMI treated with pPCI in four high-volume centers of different countries. Clinical and procedural characteristics were analyzed and the presentation of a combined endpoint of cardiovascular death, non-fatal myocardial infarction, stent thrombosis, target lesion revascularization or stroke was evaluated after one-year follow up.

Procedures were performed by 18 interventional cardiologists using TA at their discretion. The culprit lesion was more frequently located at the left anterior descending (LAD) coronary artery (45.6%), followed by the right coronary artery (RCA) (36.9%). 48.1% of patients presented multivessel disease. Initial TIMI flow was 0-1 in 72.7% of cases and TIMI Thrombus grade was ≥3 in 61.6%.

TA was performed in 40% of cases (90% as the initial strategy after crossing the culprit lesion with the coronary guidewire, whereas in 10% as a bailout technique after distal thrombus embolization).

When TA was performed we achieved a significant improvement of TIMI flow [2.4, CI 95% (2.2-2.5); p<0.0001] and a significant reduction of TIMI thrombus grade [2.6, CI 95% (2.4-2.8); p<0.0001]. There were no significant differences between both groups in the occurrence of no-reflow phenomenon (TA: 9.6% vs. no-TA: 7.1%; p=0.24) or distal embolization (TA: 1.6% vs. no-TA: 1.6%; p=0.97). Direct stenting rate was double in the TA group (TA: 71.2% vs. no-TA: 32.9%; p<0.0001) and procedural success rate was high and similar in both groups (TA: 95.2% vs. no-TA: 92.4%; p=0.16)

After 1-year follow-up, there were not significant differences in the combined endpoint rate (TA: 8% vs no-TA: 5.7%; p=0.24) neither in any of individual adverse events: cardiovascular death (TA:5.2% vs no-TA:3.9%, p=0.38), MI (TA:2.4% vs no-TA: 3.4%; p=0.47), ST: (TA: 2.4% vs no-TA: 2.3%, p=0.9), or TLR (TA: 4.4% vs no-TA: 4.8%; p=0.85). The incidence of ischemic cerebrovascular events was similar in both groups (TA: 0.4% vs no-TA: 0.5%; p=0.92). Only one patient was diagnosed of transient ischaemic attack in the TA group that happened >30 days after pPCI. No patient of this group suffered a stroke during follow-up. In the no-TA group, two patients suffered a stroke (one ischemic, 24 hours after pPCI, and one hemorrhagic, 3 months after the procedure in a patient with double antiplatelet treatment and anticoagulation for atrial fibrillation).

CONCLUSIONS

TA is frequently used during pPCI, mainly as an initial strategy. TA has a high technical success rate, leading to a significant reduction of the thrombus burden and an improvement of TIMI flow, facilitating pPCI with a higher rate of direct stenting. TA was not associated with higher rates of ischemic cerebrovascular events neither with any differences in the rate of adverse events at 1-year follow-up.

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Periprocedural myocardial infarction and safety of different loading doses of 2PY12 inhibitor in elective PCI

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Stents and scaffolds

AIMS

Nowadays, the ESC/EACTS Guidelines on Myocardial Revascularization recommend clopidogrel loading dose of 300 or 600 mg added to 150-300 mg of AAS in elective percutaneous coronary interventions (PCI). However, there are few evidence of this recomendation and other P2Y12 inhibitors have not been tested in this patients.

The purpose is to evaluate the effectiveness and safety of different loading doses of clopidogrel and ticagrelor in patients without double antiplatelet therapy and stable coronary disease (SCD) undergoing elective PCI.

METHODS AND RESULTS

Retrospective study of 147 consecutive patients with SCD undergoing elective PCI (67.9 ± 10,9 years, 77,5% male) between March-2014 and May-2017. All patients were been treated with acetylsalicylic acid (AAS) chronically. Loading 2PY12 doses evaluated were clopidogrel 600 mg, clopidogrel 300 mg, clopidogrel 150 mg and ticagrelor 180 mg. We evaluated the occurrence of major adverse cardiovascular events (MACE) defined as cardiovascular death, myocardial infarction (periprocedural myocardial infarction -PMI- and myocardial infarction at follow up), target lesion or vessel revascularization and stents thrombosis. PMI and myocardial injury was defined according to "2012 Third Definition of Myocardial Infarction" criteria. Also, we evaluated major bleeding according to TIMI criteria. The median of follow up was 17 months.

At cath-lab, 125 patients were treated with clopidogrel (16 with clopidogrel 150 mg, 7 with clopidogrel 300 mg, 93 with clopidogrel 600 mg) and 21 with ticagrelor 180 mg before or after PCI . There were no differences between the demographic characteristics, complexity of coronary disease, revascularized vessels or number of stents between the different groups. Ticagrelor group was undergoing PCI by radial approach most frequently (p=0.001) but there were no differences between radial and femoral approach in terms of major bleeding and haemoglobin drop post PCI .

Ticagrelor group had lower post-procedural troponin-I peak significantly (0.7±3.4 vs 0.3±0.7 ng/ml, p=0.02) and lower rate of myocardial injury (27.8% vs 33.1%, p=0.4). Troponin-I peak was lower in ticagrelor group than clopidogrel 600 mg group, and these presented lower values than the 300 mg and 150 mg clopidogrel group (0.7±3.4, 0.8±0,1 and 2±4,3 ng/ml, p=0.1). PMI and MACE rates at follow-up were not difference. There were

no differences between groups in terms of major bleeding and haemoglobin drop post PCI.

CONCLUSIONS

In patients without dual antiplatelet therapy undergoing elective PCI, the use of ticagrelor showed lower postprocedural myocardial injury without more bleeding complications. However, this had no impact on the medium-term follow-up.

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Long-term results and durability of the CoreValve transcatheter aortic bioprosthesis: outcomes beyond five years

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

To determine long-term outcomes of high-risk patients who underwent transcatheter aortic valve implantation (TAVI) with third-generation CoreValve device, according to the 2017 EAPCI/ESC/EACTS definition of valve durability.

METHODS AND RESULTS

Between 2007 and 2013, 278 consecutive patients were enrolled in our prospective single-centre CoreValve registry (mean age 82±6 years, mean Society of Thoracic Surgeons (STS) score 6.4±5.0%); median follow-up of survivors was 6.8 years. The Cox proportional hazards model was used to identify independent predictors of heart failure (HF) rehospitalization and all-cause mortality. Predictors of HF rehospitalization were LVEF, mitral regurgitation and paravalvular leak at last echocardiographic follow-up. Age-adjusted baseline predictors of mortality included creatinine level, severe chronic obstructive pulmonary disease and postprocedural acute kidney injury. The majority of patients were in NYHA class I or II and showed mild/trivial paravalvular leak throughout follow-up. Mean pressure gradients remained stable over time. The overall crude cumulative incidences of structural valve deterioration and bioprosthetic valve failure were 3.6% and 2.5% respectively.

CONCLUSIONS

Although overall mortality was high in this elderly patient cohort, the CoreValve bioprosthesis showed excellent durability at 7-year follow-up.

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Cardiology vs. radiology in performing pre-procedural multi-sliced CT analysis in patients undergoing TAVI

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

To investigate the interrater reliability of cardiologists and radiologists in the analysis of pre-procedural multi-sliced computed tomography scans (MSCT) in patients undergoing transcatheter aortic valve implantation (TAVI).

METHODS AND RESULTS

329 patients from 09/2015-01/2018 with severe, symptomatic aortic stenosis, scheduled for TAVI underwent native and contrast-enhanced, electrocardiogram gated high resolution MSCT (150ms, 128x0.6mm, “SOMATOM Definition AS+”, Siemens Healthcare) for pre-procedural planning. The best diastolic phase was used to reconstruct axial images with a slice thickness of 0.6-1.0mm. The coronary oblique view and the sagittal oblique view were used to define the double oblique transverse view. The radiologists directly analyzed relevant anatomical structures within the reconstruction, whereas the cardiologists transferred the full MSCT images data volume to a dedicated work station, which offers the same views for further evaluation (3Mensio Structural HeartTM, Pie Medical Imaging BV). Analyzed anatomical structures included the dimensions of the annular plane, the sinotubular junction (STJ) and the sinus of Valsalva as well as the distance of the annular plane to the coronary arteries and the left ventricular outflow tract (LVOT) angle and aortic dimensions). Both specialties were blinded and the measurements retrospectively compared using the intraclass correlation coefficient (ICC, Pearson correlation with two-way random/absolute agreement model) to assess the interrater reliability.

The STJ (cardiology/radiology: 27.3mm ± 3.5 vs. 32.7mm ± 3.8, ICC 0.762 [0.70-0.80]) and the dimensions of the aorta ascendens (cardiology/radiology: 31.9mm ± 4.2 vs. 31.3mm ± 3.7, ICC 0.756 [0.69-0.80]) correlated excellently. A fair correlation was found for the distance measurements of the left (cardiology/radiology: 13.4mm ± 2.6 vs. 12.3mm ± 2.9, ICC=0.563 95% CI [0.41-0.67]) and the right coronary artery (cardiology/radiology: 14.6mm ± 3.9 vs. 13.6mm ± 3.5, ICC 0.594 95% CI [0.46-0.68]) to the annular plane and the mean aortic annulus diameter (cardiology/radiology: 22.9mm ± 2.0 vs. 24.7mm ± 3.0, ICC 0.462 95% CI [0.17-0.63]. The LVOT angle correlated poorly (cardiology/radiology: 60.2° ± 6.2 vs. 55.9° ± 15.2, ICC 0.025 95% CI [0.18-0.28]).

CONCLUSIONS

The interrater reliability of both specialties ranges from excellent in the prediction of simple two-dimensional distance measurement to a fair to poor correlation in the assessment of more complex structures like the annular plane which is crucial for sizing and the final determination of valve size.

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Medium-long-term results of using bioabsorbable scaffolds in patients with ACS

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Patients with ACS need the earliest possible revascularization of the coronary arteries, which is the key to successful treatment.

Aims: To evaluate the efficacy and safety, as well as mid-term results of the implantation of BRS in patients with acute coronary syndrome.

METHODS AND RESULTS

The study included 277 patients with acute coronary syndrome, who were divided into two groups. The first group included 143 patients who used the BRS. The second group included 134 patients who were implanted with a DES. These patients underwent emergency or delayed order, at different periods of hospital stay, underwent coronary angiography followed by PCI for a symptom-related artery. The immediate success of the procedure was assessed immediately after stenting, in the form of ST-segment resolution, the absence of anginal pain, stable hemodynamic parameters, then the hospital period and for 6-9-12 months.

Results: Immediate results: implantation success and clinical success are almost comparable to 100% and 99.5%, respectively. Acute stent thrombosis was observed in 2 (1.49%) in the second group. Mortality at the hospital stage was absent in both studied groups. For the observation period, repeated PCI was required in the first group of 4 (2.8%) patients, and in the second group 3 (2.2%). The MACE frequency in the studied groups was 4.3% and 3.7%.

CONCLUSIONS

The implantation of bioabsorbable stents in a small group did not lead to any angiographic and clinical complications at the hospital stage in patients with acute coronary syndrome. For a final assessment of the clinical efficacy of bioabsorbable stents, angiographic as well as OCT monitoring of long-term (36–48 months) results of endovascular treatment of patients is needed. Currently, in the treatment of such patients, longer therapy should be considered dual antiplatelet therapy.

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Results of four-year experience with iFR in invasive assessment of myocardial ischaemia

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Analyse the contribution of iFR in the therapeutic decision-making of patients with moderate and severe angiographic coronary lesions in which the heart team indicated invasive assessment of coronary lesions due the absence of myocardial ischemia evaluation with previous non-invasive diagnostic methods or discrepancies between these methods and the anatomy in coronary angiography.

METHODS AND RESULTS

Methods: We performed iFR in 52 patients, 73% males, with 96 coronary lesions (1.85 lesions/patients) from May 2014 to March 2018. Coronary lesions were classified according the percentage of stenosis by visual estimation in moderate (41-70%) or severe (71-90%).

To perform iFR, Corporation's S5 equipment (San Diego, California-USA) was initially used with the 0.014" Prime Wire Prestige guide wire and, after 2015, the 0.014" Verrata Pressure guide wire. Angioplasty guide catheter was always used during the assessment. iFR ≤ 0.89 was considered positive for myocardial ischemia.

Stenting was the study end-point and regression with elastic net was applied for stent use, the main variable. Independent variables; the age, sex, arterial hypertension, diabetes mellitus, dyslipidaemia, smoking, family history, obesity and previous myocardial infarct were analysed to identify related predictors with stenting. The non-parametric classification tree evaluated possible interactions between the predictors. The Roc curve identify sensitivity and 1-specificity of cut-off point for iFR values, established by the classification tree. We use the R package for statistical calculation, value of $p < 0.05$ was considered statistically significant.

Results: Among 96 lesions, 56 were moderate (58.3%) and 40 severe (41.7%). Regarding the coronaries arteries studied; 54.1% were anterior descending artery (ADA), 11.4% circumflex, 9.3% right coronary artery, 10.4% diagonal and 9.3% marginal. The marginalis artery, posterior ventricular, left and right posterior descendent branches and the left main represented 1,1% each one. The clinical presentation was: 36.5% stable angina, 40.4% acute coronary syndrome, where only the non-culprit lesion was studied, and 23.1% others symptoms in diagnostic investigation due the possibility of coronary disease.

The iFR was positive in 21.4% of moderate and 57.5% of severe lesions. A total of 30 stents were used, representing a very low percentage (31.25% of all studied lesions, 33.3% moderate and 66.6% severe). However, iFR positive that wasn't stenting was represented by two severe lesions in ADA who patients were referred to CABG instead of stenting, one severe lesion in ADA with tandem lesion and iFR negative after stenting the most important lesion and two moderate lesions in patients with aortic stenosis referred to TAVI and posterior lesion assessment.

The vessel in which stents were used, the median iFR=0.92 (0.82-0.94) was observed in moderate lesions and iFR=0.79 (0.61-1.00) in severe lesions. Classification tree demonstrated that iFR ≤ 0,87 was statically

associated with stenting in 37.5% of moderate lesion. For the cut-off point of 0.87 in the iFR the sensitivity = 0.57 and 1-specificity = 0.88. Presence of iFR ≤ 0.87, diabetes mellitus and dyslipidaemia were independent variable predictors of stenting in moderate lesions.

CONCLUSIONS

The iFR contributed to the reclassification of lesions and significantly reduced stenting, especially in moderate lesions, adding value in decision-making approach of both, moderate and severe lesions.

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Characteristics, prognosis and predictors of air embolisation during percutaneous LAA occluder implantation

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THEME:
TOPIC(S):

AIMS

Air embolization is a common complication in the procedure of percutaneous left atrial appendage occluder (LAAO) implantation. In some situations, air embolization still occurs despite careful and meticulous manipulations during the procedure. The risk factors and outcome of air embolization during LAAO implantation have not been addressed before. We sought to address these issues in a single center study.

METHODS AND RESULTS

A total of 76 LAAOs were implanted (41 Amplatz cardiac plug [ACP]/Amulets and 35 Watchmans). Air embolization was noted in 14 of these procedures. The air was detected in the delivery sheath in 8, in aorta in 2, in the left ventricle in 2, and in the right coronary artery in 2 of the procedures. In 8 of the procedures with air in the delivery sheath, the air spread out into the systemic circulation before sucked out in 3 and was sucked out in 5, and all were uneventful without any sequelae. In 4 of the procedures with air in the aorta or left ventricle, the air could be sucked out by a pigtail catheter. In 2 of the procedures with air in the right coronary artery, one was complicated with high ST-elevation in inferior leads of electrocardiogram, marked bradycardia and shock, and after vigorous patent-blood injection into the right coronary artery and brief cardiopulmonary resuscitation, ST-elevation and bradycardia remitted. The other was complicated with bradycardia only and spontaneously remitted. In the multivariable analysis, we found male gender (odds ratio [OR] 13, P=0.030), ACP/Amulet use (OR 5, P=0.092), low left atrial pressure (OR 32, P=0.001) and non-intubated procedure (OR 22, P=0.01) were independent predictors of air embolization.

CONCLUSIONS

In conclusions, in addition to meticulous manipulations during LAAO implantation, air embolization may still occurs, but is predictable, manageable and mostly uneventful.

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Second-generation DES implantation for non-left main trunk bifurcation lesions by two stenting compared with three- and two-link DES

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

The association between stent designs and the outcomes of second-generation DES implantation for non-left main trunk bifurcation lesions by two stenting is not well studied. We aimed to evaluate the outcomes after 3- and 2-link second-generation everolimus-eluting stent (EES) implantation for non-left main trunk bifurcation lesions by two stenting.

METHODS AND RESULTS

Between 2010 and 2017, 261 lesions (257 patients) underwent EES implantation for non-left main trunk bifurcation lesions by culotte or T stenting, of which 208 lesions (206 patients) underwent follow-up within 1 year after the procedure. We defined two stenting as culotte and T stenting. The 208 lesions were classified into two groups by stent design: 3-link EES group (89 lesions, [42.8%]) and 2-link EES group (119 patients, [57.2%]). The 3-link EES group consisted of lesions treated with Xience, and the 2-link EES group consisted of those treated with Promus Element. Multiple lesions in one patient treated by two stenting were counted on a lesion-by-lesion basis for statistical analysis. Bifurcation lesions were defined as lesions in the main branch ranging from the proximal stem to the distal main branch with boundaries defined by the segments 5 mm proximal and distal to the stent and those in the side branch ranging from the bifurcation carina to the distal side branch with boundaries defined by the carina and the segment 5 mm distal to the stent. The outcomes of the 3- and 2-link EES groups were as follows: in-stent restenosis rate, 22.4% (20/89 lesions) vs. 10.9% (13/119 lesions), p = 0.024; bifurcation restenosis rate, 18.0% (16/89 lesions) vs. 6.8% (8/119 lesions), p = 0.012; and target lesion revascularization rate, 4.5% (4/89 lesions) vs. 5.0% (6/119 lesions), p = 1.000.

CONCLUSIONS

After second-generation EES implantation for non-left main trunk bifurcation lesions by two stenting, 2-link EES was superior to 3-link EES in the rates of in-stent restenosis and bifurcation restenosis; however, no significant difference was observed in the target lesion revascularization rate between them. Our data suggest that even between EESs, the difference in stent designs affects angiographic outcomes after two stenting, but does not affect clinical events.

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Left main PCI - Radial vs. femoral access

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease

AIMS

Transradial access (TRA) is often avoided in favor of the Transfemoral access (TFA) during percutaneous coronary interventions (PCI) of the left main (LM) coronary artery, due to technical and safety concerns. However, there is limited evidence supporting the use of one access site over other for LM interventions. The aim of this study is to compare clinical outcomes and procedural characteristics of TRA versus TFA in patients who underwent PCI for LM disease by performing a meta-analysis.

METHODS AND RESULTS

We conducted an electronic database search including PubMed, Web of Science, Google scholar and Cochrane Database of all published data for studies that compared TRA with TFA in patients undergoing PCI of LM disease. Event rates were compared using a Forest plot of odds ratio(OR) using a random-effects model assuming interstudy heterogeneity. A total of 11 studies (n= 16,863; TRA= 7845, TFA= 9018) were included in the final analysis. Clinical and angiographic characteristics were similar between the two groups. TRA compared to TFA was associated with a significant reduction in Access site Bleeding (OR = 0.11, 95% CI = 0.04 - 0.26, I2= 0%, P < 0.0001), Major bleeding (OR = 0.45, 95% CI = 0.28 - 0.72, I2= 0%, P =0.0008) or any bleeding episode (OR = 0.62, 95% CI = 0.47 - 0.82, I2= 0%, P =0.0007). The In-Hospital Mortality (OR = 0.49, 95% CI = 0.31 - 0.79, I2= 11%, P =0.004) was also lower in the TRA group. There was no difference between the two access sites in terms of Procedural success (P= 0.22), Procedure time (P= 0.08), Fluoroscopy time (P= 0.34), Contrast volume (P= 0.11), In- Hospital myocardial Infarction (P= 0.17) and In-Hospital target vessel revascularization (P= 0.05)

CONCLUSIONS

TRA compared to TFA is associated with reduced rates of access site bleeding, major bleeding, any bleeding and in-hospital mortality in patients undergoing PCI of LM disease

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Intraprocedural valve-in-valve deployment for treatment of aortic regurgitation following TAVR: an individualised approach

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Aortic regurgitation (AR) following transcatheter aortic valve implantation (TAVI) is usually due to paravalvular leak, is more common with self-expanding valves and is associated with adverse outcomes. Treatment of AR with a second valve (valve-in-valve) has been reported, however the mechanism of benefit is unclear. We hypothesized that location of the initial valve in relation to the aortic annulus should guide positioning of the second valve.

METHODS AND RESULTS

We assessed the outcomes of valve-in-valve deployment for treatment of AR following implantation of self-expanding valves in a single-center TAVR registry. Location of the initial valves was defined as supra-annular, intra-annular or infra-annular according to the position of the device pericardial skirt relative to the annulus. Positioning of the second valve was selected according to the location of the initial valves. Among 285 TAVR patients who received Corevalve or Evolut-R valves, 11 (3.8%) underwent valve-in-valve deployment due to AR. Position of initial valves was supra-annular in 6 cases (group-1), intra-annular in 3 cases (group-2) and infra-annular in 2 cases (group-3). In group-1, second valves were implanted 9±4 mm lower than the initial valves. In group-2, second valves were implanted 7±4 mm higher than the initial valves. In group-3, second valves were implanted 9±1 mm higher than the initial valves. Valve-in-valve deployment reduced AR grade in all 3 groups.

CONCLUSIONS

Valve-in-valve deployment decreased AR grade during TAVR procedures. We suggest that positioning of the second valve should be guided by the location of the initial valve relative to the aortic annulus.

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Comparison of clinical outcomes between very long stents and overlapping stents for the treatment of diffuse coronary disease in real clinical practice

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

The stent length as well as the stent overlap for the percutaneous treatment of diffuse coronary artery disease (CAD) have been considered predictors of adverse events. However, there are no comparative data on the use of very long stents (VLS) or overlapping stents (OS) in this scenario. Aim: to compare the clinical results of very long stents (≥40mm) or overlapping stents in real clinical practice.

METHODS AND RESULTS

We evaluated 2823 consecutive PCIs and analyzed those performed in difusse CAD in which a single VLS (≥40 mm) or ≥2 OS were implanted. We included 643 lesions in 628 consecutive patients treated with a single VLS (≥40mm) (251 lesions) or ≥2 OS (392 lesions). We analyzed the procedural characteristics and the presentation of the combined endpoint [cardiac death, non-fatal myocardial infarction, need for target lesion revascularization or stent thrombosis] after a follow-up of 20 months.

Total stent length was 54±18 mm and minimum diameter was 2.9±1.2 mm. At the end of follow-up, the rate of adverse events was 8.3% (cardiac death: 4.9%, myocardial infarction: 1.7%, target lesion revascularization: 3.1%, stent thrombosis: 0.7%). There were no significant differences between both groups in the presentation of the combined endpoint (OS: 9.7% vs VLS: 6.2%, p=0.15). Procedures with overlapping stents had more contrast volume (309±115 vs 273±127 ml;p=0.002), longer duration (47±22 vs 39±18 min;p<0.0001) higher fluoroscopy time (20±13 vs 16±9 min;p<0.0001) and higher number of stents to treat the index lesion (2.2±0.5 vs 1;p<0.0001).

CONCLUSIONS

Clinical outcomes with the new designs of very long stents in the percutaneous treatement of diffuse coronary disease are very favorable and similar to those obtained with the stent overlap after a median follow-up of 20 months. The use of very long stents can reduce the number of stents per patient, and may be a factor associated with a lower duration of procedures, fluoroscopy time and contrast volume.

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Long-term clinical outcomes after modified jailed balloon technique for bifurcation lesions

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

Aims) Percutaneous coronary intervention (PCI) for bifurcation lesions is high risk of adverse events. Provisional approach is recommended to treat most of bifurcation lesions. However, it is associated with the risk of side branch (SB) occlusion after main branch (MB) stenting even if guidewire protection. Therefore, strategies are important to avoid SB occlusion. We have already reported safety and efficacy for bifurcation treatment by using “Modified jailed balloon technique (MJBT)”. To investigate long-term efficacy of this MJBT, we report long-term clinical outcomes.

METHODS AND RESULTS

Methods and Results) We have already reported novel bifurcation technique called MJBT. In brief, after crossing guidewires into both branches, a jailed balloon was introduced into SB, while a stent was placed in MB as crossing over side branch. The position of jailed balloon is carefully adjusted as its proximal end is attaching to MB stent. Both stent and jailed balloon were simultaneously inflated with same pressure. After that, the proximal optimization technique, guidewire exchange, kissing balloon inflation and provisional stenting were applied in accordance with the situations.

From February 2015 to December 2017, 500 patients with 532 bifurcation lesions underwent PCI with the use of this MJBT. We investigated long-term clinical outcomes including all cause death, cardiac death, definite stent thrombosis and target lesion revascularization (TLR).

Baseline characteristics showed that mean age was 71.4 +/- 9.9 years old. The patients with acute coronary syndrome were including 83 patients (16.6%). Lesion characteristics showed that unprotected left main disease was included in 99 lesions (18.6%). Transradial interventions were performed in 465 patients (93.0%). All commercial used drug-eluting stents were available in this technique. Procedural success was achieved in all patients. We confirmed the only one patient with side branch loss during procedure (0.02%). The median follow-up period for clinical outcomes was 590 days (interquartile ranges 330 - 892 days). The cumulative incidence of all cause death was 26 patients (5.2%). Cardiac death was 5 patients (1.0%). During follow-up period, TLR was performed in 23 patients (4.6%) with 29 lesions (5.5%). No patient met the definite stent thrombosis during follow-up period.

CONCLUSIONS

Conclusions) This MJBT is safe and effective in the preservation of side branch patency during bifurcation stenting. Moreover, long-term clinical outcomes after MJBT are excellent.

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Analysis of mechanical properties of fossa ovalis in lamb hearts as they relate to transseptal punctures

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair

AIMS

Trans-septal puncture is performed via special needles on fossa ovalis, to provide access to the left side of the heart enabling minimally invasive operations at Mitral valve or the left atrium. Optimization of needles characteristic for trans-septal puncture is of paramount importance to reduce the extent of deformation of the tissues. The main objective of this study is to characterize the mechanical properties of fossa ovalis tissue in lamb hearts. The fossa ovalis tissue samples were subjected to experimental indentation and tensile tests for determining the deformation of tissues.

METHODS AND RESULTS

Lamb hearts (n = 14) were dissected to obtain fossa ovalis tissue samples. These were subjected to indentation and tensile tests to determine the puncture and rupture forces respectively. Indentation tests were performed using two different indenters: conventional Brockenbrough needle (bevel tip) and steel indenter with a hemispherical tip. Tensile tests were performed using Zwick Roell (Z005) tensile machine at 100N load cell. ImageJ analysis was also performed to determine the diameter and shape of fossa ovalis.

Indentation results demonstrated that the hemispherical indenter requires a greater punch force compared to the puncture force with Brockenbrough needle. The mean punch force of hemispherical indenter (15.57N) was nearly 3 times greater than the puncture force of Brockenbrough needle (5.47N). The difference between the two indenters provides an insight about the importance of device geometry on trans-septal procedures. The tensile test results illustrated a typical failure pattern with a toe region, linear region and failure region. The mean rupture force determined was 10.51N. ImageJ analysis confirmed an oval shape of fossa ovalis and diameters measured were in the range 9.0 – 15.3 mm.

CONCLUSIONS

The mechanical characteristics of fossa ovalis in lamb hearts were successfully studied through a series of experimental indentation and tensile tests. We discuss the role of collagen fiber orientation regarding the tissue response to tensile (stretching) and indentation (compressive) forces. This provide an insight about the deformation of fossa ovalis tissue with regard to various mechanical forces.

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Serial analysis of neointimal healing after implantation of BRS in coronary bifurcations using OCT

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds, Bifurcation lesion

AIMS

Heterogeneous neointimal response has been observed after implantation of all generations of stents. Our aim was assessing local hemodynamical factors involved in the neointimal response after implantation of bioresorbable scaffolds (BRS) in bifurcations, including baseline shear stress (SS) and plaque burden

METHODS AND RESULTS

Ten patients with BRS implanted at coronary bifurcations in the BIFSORB pilot study were analysed. Follow-up optical frequency domain imaging (OFDI) was performed at 1-month and 2-years. Coronary lumen and BRS at baseline were delineated and reconstructed by fusion of OFDIand coronary angiography. Baseline plaque burden and SS were quantified using post-procedural OFDIdata and were matched with follow-up OFDI using anatomical landmarks. Strut coverage at 1-month follow-up was correlated with baseline SS at the matched corresponding location, with a region of interest of 0.3-mm length and 0.3-mm arc-width that assembled twice of the strut size. For 24-months follow-up, segmental level analysis was performed for each stented bifurcation. A total of 444 struts (54 jailing struts) were matched between baseline and 1-month follow-up. Time-average SS (TASS) and its gradient was significantly lower after implantation for covered struts than for uncovered struts at 1 month in non-bifurcation segments (TASS: 1.81±1.87 vs. 3.88±3.72 Pa, p<0.001; TASSG: 9.55±9.45 vs. 20.30±19.12 Pa/mm, p<0.001). The trend remained the same for jailing struts, although statistically insignificant (TASS: 10.85±13.12 vs. 13.64±14.48 Pa, p= 0.328; TASSG: 66.71±69.39 vs. 79.87±73.68 Pa/mm, p=0.308). For 2-years follow-up, a total of 66 sub-regions (20 distal, 29 core and 17 proximal) were analysed. Neointimal hyperplasia area (NTA) was negatively correlated with TASS (ρ=-0.389, p=0.037 and ρ=-0.094, p=0.58 for the core and non-core segments) and positively correlated with plaque arc degree (ρ= 0.116, p=0.548 and ρ=0.387, p=0.018 for core and non-core segments). Two new parameters of combined_d= log (TASS/ (PlaqueArc+1)) and combined_m= log (TASS* (PlaqueArc+1)) were generated to explore the interaction between SS and plaque arc burden. The combined_d had a higher correlation with NHA both in core sub-segments and non-core sub-segments with ρ= -0.395 (p=0.015) and -0.412 (p=0.026).

CONCLUSIONS

The hemodynamic microenvironment after BRS implantation may regulate neointimal response in both short and long term. Baseline plaque burden may also be a modulator of modulate neointimal formation. These findings underline the role of integration of plaque information and local hemodynamics on vessel wall healing.

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Impact of renal dysfunction on long-term outcomes and limb salvage in patients with peripheral artery disease

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THEME: Peripheral Interventions
TOPIC(S): Other peripheral interventions

AIMS

The aim of present study was to investigate that renal dysfunction was associated mortality and limb salvage in patients with peripheral arterial disease (PAD).

METHODS AND RESULTS

From January 2011 to March 2016, 290 consecutive patients with PAD undergoing endovascular treatment (EVT) in our hospital were retrospectively examined. According to estimated glomerular filtration rate (eGFR), the patients were divided into 3 groups: 1) 112 patients with preserved renal function (eGFR≥60 ml/min/1.73m2) (PRF group); 2) 103 patients with chronic kidney disease (eGFR<60 ml/min/1.73m2) (CKD group); 3) 75 patients on hemodialysis (HD group). Overall survival and amputation-free survival (AFS) were compared among three groups by the Kaplan-Meier method. During follow up period (mean: 36.4±23.1months), 14 patients (4.8%) underwent major amputation and 84 patients (29.0%) died. Major amputation rate were significantly higher in HD group than CKD group and preserved renal function (PRF) group (12.0%, 2.9% and 1.8%, respectively, P=0.003). Critical limb ischemia (CLI) and repeat revascularization were significantly higher in HD group compared with PRF and CKD groups. Overall survival at 3 years were 91.7% in PRF group, 71.1% in CKD group, and 57.6% in HD group, respectively (P<0.001). Amputation-free survival at 3 years were 89.7%, 72.1%, and 57.1%, respectively (P<0.001). Overall survival and amputation-free survival in HD group were significantly lower than CKD group and preserved renal function group (respectively, P<0.001).

CONCLUSIONS

In patients with PAD, renal dysfunction was associated with significantly higher mortality and major amputation.

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Impact of switch time between CTO crossing strategies

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Coronary chronic total occlusions represent the most challenging lesions in interventional cardiology and typically required the use of multiple recanalization techniques. However, there is still no clear time criterion for changing of initial crossing technique. As a result, some operators can switch to a more complex strategy too early, thereby increasing the risk of complications, and others - too late, leaving little chance for successful CTO crossing.

The purpose of our study was to analyze the effect of switch time between crossing techniques on the procedural success CTO PCI.

METHODS AND RESULTS

Between 2013 and 2017, 99 CTO PCI using both antegrade and retrograde strategies were performed. In all cases crossover from antegrade to retrograde was implemented. Median age was 58.9 ± 7.2 years, 13.1% were women. In most cases CTO target vessel was the right coronary artery the right coronary artery (71.7%), followed by the left anterior descending (18.2%) and circumflex (9.1%) arteries. In one case CTO was located in the Left Main. The complexity of CTO's was classified using J-CTO (Multicenter CTO Registry in Japan) score as easy (8.1%), intermediate (27.3%), difficult (28.3%), and very difficult (36.3%). The mean J-CTO score was 2.1 ± 1.1. To determine the threshold value, time was step-wise categorized (i.e. using cut-offs of 2, 4, 6 mins and so on) and tested in the logistic regression. The threshold value of time to switch crossing technique was 33 min. Of the 66 patients with a time below 33 min, there were 53 cases (80.3%) of procedural success. By contrast, there were 18 (54.5%) cases of success among those with the switch time greater than 33 min. Therefore, the odds of procedural success with earlier switch were 3.4 times higher (95% CI: 1.3 to 8.6). The chances of success reduced by 3% for every 1 min longer the threshold value of time (the OR of 0.97; 95% CI 0.94 to 0.99, p=0.05). Mean procedure time was 62.3 ± 27.7 min. The average switch time between crossing strategies was 28.2 ± 16.9 min. On average, 1.8 ± 1.4 stents per patient was implanted.

CONCLUSIONS

Accurate planning of CTO PCI is crucial. Switch to the retrograde approach should be considered no later than after 33 minutes of the antegrade wire manipulation in order to maintain the maximum chances of final technical success.

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Relationship between diastolic blood pressure at discharge and cardiovascular outcomes after PCI for AMI

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THEME: Coronary Interventions

TOPIC(S): Other Coronary Interventions

AIMS

In hypertensive patients, a U-shaped relationship has been reported between blood pressure and future events. However, there is little information about the significance of blood pressure on the adverse outcomes of patients with coronary artery disease who have been re-vascularized. The study assessed the risk of cardiovascular events according to diastolic blood pressure (DBP) at discharge in patients with acute myocardial infarction (AMI) underwent percutaneous coronary intervention (PCI).

METHODS AND RESULTS

We evaluated 10,926 patients from a nationwide, dedicated registry for AMI. The DBPs at discharge were categorized into 3 discrete groups (<70, 70-80 [reference], and ≥80 mmHg). The primary outcome was a composite of all-cause death, non-fatal myocardial infarction (MI), and re-hospitalisation for heart failure. The hierarchical logistic regression was used to test the association between DBP and primary outcome, with a spline term for DBP to assess nonlinearity. A total of 1,142 (10.5%) experienced a primary outcome during a median follow-up of 12 months. In the unadjusted model, DBP was associated with primary outcome with a U-shaped relationship (unadjusted hazard ratio [HR]: 0.987, 95% confidence interval [CI]: 0.981-0.993, p<0.001, p for nonlinearity=0.045), with a progressive increase in hazards of primary outcome as DBP at discharge decreased below reference. After adjustments, a lower DBP (<70 mmHg) was associated with a higher risk for the primary outcome (adjusted HR: 1.228, 95% CI: 1.078-1.539, p=0.005); and a higher DBP (≥80 mmHg) also tended to be increased risk of the primary outcome (adjusted HR: 1.231, 95% CI: 0.982-1.543, p=0.072). A similar non-linear relationship with a higher risk of events at lower DBP was found for all-cause death and re-hospitalisation for heart failure, but not non-fatal MI

CONCLUSIONS

Compared to a DBP of 70 to <80 mmHg, a lower DBP at discharge was associated with a higher risk of adverse events in patients with AMI underwent PCI, supporting the existence of a U-shaped phenomenon. This finding suggests that caution should be taken in the use of agents that can reduce DBP in patients with AMI even after coronary revascularisation.

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Sheathless radial artery access does not prevent vascular injury in patients undergoing coronary angiography and intervention

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

The aim of the study was to compare the presence of radial artery injury between sheathless and conventional transradial intervention (TRI).

METHODS AND RESULTS

Patients planned for diagnostic coronary angiography were randomized to conventional transradial access (CTRA) or sheathless transradial access (SLTRA). After the procedure, study participants underwent optical coherence tomography of the radial artery. Primary endpoint of the trial was radial artery injury, defined as a composite of intimal tears (IT), medial dissection (MD) and intraluminal thrombus (TR). The occurrence of RAO, radial artery spasm and hand dysfunction were also compared between both treatment groups. Twenty-six patients were randomized to CTRA and 25 patients to SLTRA. There was no difference in composite primary endpoint of radial artery injury (39% vs 56% resp., p = 0.27). There were no differences in other pre-defined clinical endpoints.

CONCLUSIONS

There is no benefit of SLTRA over CTRA in reducing radial artery injury and clinical outcome.

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TAVR in patients with large and extra-large aortic annuli: haemodynamic performance of new-generation balloon and self-expandable aortic valves

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

To analyze short and mid-term performance of new generation balloon- and self-expandable valves in patients with large (area≥575 mm2 or perimeter≥85mm) and extra-large (≥680 mm2 or perimeter>92.4mm) aortic annuli undergoing transcatheter aortic valve replacement (TAVR).

METHODS AND RESULTS

A total of 543 patients with symptomatic aortic stenosis and large aortic annulus that underwent TAVR with Sapien 3 (S3) 29mm (n=408) and Evolut-R (ER) 34mm (n=135) from 12 centers were included. Clinical, anatomic and procedural characteristics were retrospectively reviewed and Valve Academic Research Consortium-2 outcomes were reported. The mean aortic annulus area and perimeter were 622mm2 [600.0-660.0] and 89.9±4.2mm, respectively (subgroup with extra-large annulus area of 692mm2 [681-719]). Global device success was 82.9% with a 30-day mortality rate of 3.1%. There was a higher rate of second valve implantation and valve embolization in ER group (3.7% vs 0.7%; p=0.026 and 2.2% vs 0.2%; p=0.049, respectively). Prosthetic valve gradient >20mmhg (0.8% S3 vs 0.8% ER, p=1.0) and aortic regurgitation (AR) ≥3 (2.1% S3 vs 6.3% ER, p=0.021) were scarce in both groups. Final device success rate was 84.8% for S3 group compared to 77% in ER group (p=0.038). These results remained similar in the extra-large annulus group. While major vascular and bleeding complications favored ER group, permanent pacemaker implantation and paravalvular AR were lower in S3 group. Predictors for paravalvular AR were annulus size and valve type.

CONCLUSIONS

In patients with large and extra-large aortic annuli, TAVR with balloon- and self-expandable valve offer an effective and safe technique with good hemodynamic performance. Some differences in clinical outcomes and hemodynamic performance were observed between these transcatheter heart valves and may guide the decision to treat patients with aortic stenosis and large aortic annulus.

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The impact of ticagrelor monotherapy following one-month DAPT after bifurcation PCI in a largest all-comer trial: Global Leaders trial

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds, Bifurcation lesion

AIMS

The aim of this study was to investigate the impact of ticagrelor monotherapy following one-month dual antiplatelet therapy (DAPT) after bifurcation percutaneous coronary intervention (PCI).

METHODS AND RESULTS

GLOBAL LEADERS was a randomized, superiority, all-comers trial comparing one-month DAPT with ticagrelor and aspirin followed by 23-month ticagrelor monotherapy (experimental treatment) with standard 12-month DAPT followed by 12-month aspirin monotherapy (reference treatment) in patients treated with a biolimus A9-eluting stent. Bifurcation PCI was identified using dedicated e-CRF based on the MADS classification. The primary endpoint was the composite of all-cause death or new Q-wave myocardial infarction (MI) up to two years after randomization.The composite secondary endpointwas target vessel failure (TVF: a composite of all-cause death, myocardial infarction, or target vessel revascularization) at 2 years. Other secondary endpoints included the individual components of TVF, definite or probable stent thrombosis (ST).A total of 15,968 patients were included in this prespecified subgroup analysis. There were 2507 patients (15.7%) who underwent at least one bifurcation PCI, of whom 492 patients (19.6%) were treated with 2-stent technique. The incidence of primary endpoint was similar between bifurcation and non-bifurcation group (4.7% vs 4.0%, p=0.089). The TVF rate in the bifurcation group was higher compared with the non-bifurcation group (10.8% vs 9.2%, p=0.006). Two-stent technique for bifurcation PCI was associated with higher incidencesof primary endpoint andTVF compared with One-stent technique (primary endpoint: 6.9% vs 4.1%, p=0.009, TVF: 16.7% vs 9.4%, p<0.001). The experimental treatment showed a significant benefit on 2-year definite or probable stent thrombosis in patients with bifurcation PCI (HR: 0.46; 95% CI: 0.22-0.97) compared with those without bifurcation PCI (HR: 1.20; 95% CI: 0.85-1.69; p for interaction = 0.022). However, in terms of TVFat 2 years, the experimental treatment did not show a benefit in patients with bifurcation PCI (HR: 0.95; 95% CI: 0.75-1.21) compared with those without bifurcation PCI (HR: 0.90; 95% CI: 0.81-1.01; p for interaction = 0.702).

CONCLUSIONS

PCI for bifurcation lesion with a biolimus A9-eluting stentwas associated with worse clinical outcomes thannon-bifurcation lesion. Ticagrelor monotherapy following one-month DAPT after bifurcation PCI showed a significant benefit on definite or probable stent thrombosis at 2 years compared with aspirin monotherapy following 12-month standard DAPT.

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Edge-to-edge percutaneous mitral repair for functional ischaemic and non-ischaemic mitral regurgitation: a systematic review and meta-analysis

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(1) ,

THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair

AIMS

Recently, randomized controlled trial comparing the use of the Mitraclip device in addition to medical therapy to medical therapy alone in patients with secondary mitral regurgitation (MR) have shown conflicting results. Only few studies have assessed if these differences could be due to the underlying secondary MR etiology; the aim of this study is to investigate the differences after percutaneous edge-to-edge repair in patients with ischemic and non-ischemic secondary MR.

METHODS AND RESULTS

PubMed, EMBASE, Google scholar database and international meeting abstracts were searched for all studies about MitraClip. Studies where results were not delineated between MR aetiology, with <25 patients or with overlapping population were excluded.

The prespecified primary efficacy endpoint was the composite of all cause death and heart failure related hospitalization. Secondary endpoints were the single components of the primary endpoint.

This study is registered with PROSPERO (CRD42018115060).

A total of seven studies investigating the midterm outcome of percutaneous edge-to-edge repair in patients with ischemic versus non-ischemic MR were included in the meta-analysis (n=2,908).

At 2 years, the risk of the prespecified primary endpoint was similar among patients with ischemic and non-ischemic MR (risk ratio (RR) 1.06; 95% CI: 0.91 to 1.23).

Conversely, the rate of all-cause death was significantly higher in patients with ischemic MR compared to patients with non-ischemic MR (RR 1.26; 95% CI: 1.06 to 1.52), while the rate of rehospitalization for heart failure was similar in the two groups (RR 1.21; 95% CI: 0.91 to 1.61).

CONCLUSIONS

This meta-analysis suggests that percutaneous edge-to-edge repair is likely to be more efficacious in terms of mortality in patients with non-ischemic than ischemic MR, despite similar rate of rehospitalization for heart failure.

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Results of PCI with overlapping stents with homogeneous or heterogeneous drug for the treatment of diffuse coronary disease in real clinical practice

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Stents and scaffolds

AIMS

The stent overlap is a common practice to treat diffuse coronary disease (DCD). However, there are insufficient data on the prognostic impact of overlapping multiple platforms with different pharmacological characteristics. Our aim was to compare the results of the stent overlap according to their pharmacological characteristics.

METHODS AND RESULTS

From April 2014 to December 2017, 2823 angioplasties were performed, using OS in 12.1%. We analyzed the 343 lesions treated with OS in 339 consecutive patients (73% males, 68 ± 12 years). Two groups of OS were performed according to whether they had the same pharmacological characteristics [homogeneous: (HO)] or different [heterogeneous: (HE)], comparing the presentation of the combined endpoint [cardiac death, non-fatal myocardial infarction (AMI), need for target lesion revascularization (TLR) or stent thrombosis (ST)] after a median follow-up of 20 months (7-46).

The clinical presentation at cathlab was stable ischemic heart disease in 43.4% of the sample and acute coronary syndromes in the 56.6%. The mean ejection fraction was 49 ± 12%. 41.8% were diabetics. 15% of the lesions were treated with bare metal stents, 62.2% with drug-eluting stents (22.7% everolimus, 41.4 zotarolimus, 30.8% sirolimus, 1.4 biolimus, 2.4% paclitaxel) and 21.5% with a combination of both. Bioresorbable platforms were used in 1.2% of the cases. 32.8% of the lesions were bifurcations and the mean Syntax score was 22.3 ± 13.2. The total length of overlap was 59.6 ± 22 mm and the minimum diameter was 2.8 ± 1.5 mm. The number of OS was 2.2 ± 0.9. The angiographic success rate was 99.1%. There were no significant differences between the two groups in relation to the baseline or procedural characteristics procedures except for a higher rate of bifurcations in the heterogeneous group (HE: 38% vs HO: 28%, p = 0.048), a greater number of overlapping stents (HE: 2.3 ± 0.6 vs HO: 2.1 ± 0.4mm, p = 0.001) and a greater length of overlap (HE: 64.3 ± 25.6 vs. HO: 55.3 ± 16, 7 mm, p <0.0001). At the end of the follow-up, there were no differences between the two groups in the rate of adverse events (HE: 7.1% vs. HO: 11.9%, p = 0.14), cardiac death (HE: 4.5% vs. HO 6.2%, p = 0.5), AMI (HE: 4.5% vs. HO: 2.5%, p = 0.74) or ST (HE: 1.3% vs. HO: 0.6 %; p = 0.5), although there was a trend towards a lower rate of TLR in the group of heterogeneous stents (HE: 2.6% vs. HO: 6.9%, p = 0.07). After adjusting the unevenly distributed variables between both groups, the use of heterogeneous platforms maintained a statistically significant trend as a TLR protective factor [OR = 0.2 IC95% (0.6-1.1), p = 0.06]

CONCLUSIONS

The overlapping of stents of homogeneous or heterogeneous pharmacological characteristics showed very favorable and similar results, although a tendency towards a lower rate of TLR was observed when platforms with different pharmacological characteristics were overlapped.

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Nobori biolimus-eluting stent implantation vs. CABG for unprotected left main coronary artery disease: a comparison of long-term outcomes

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease

AIMS

To evaluate the long-term outcomes of Nobori biolimus-eluting stent (BES) implantation in patients with unprotected left main coronary artery (ULMCA) disease in comparison with those of CABG.

METHODS AND RESULTS

We retrospectively identified 393 patients with ULMCA disease treated by PCI (239 patients, PCI group) or CABG (154 patients, CABG group) between 2011 and 2013. Sixty-eight patients undergoing implantation of DES other than Nobori BES were excluded from the PCI group. Also, 65 patients in the PCI group and 101 patients in the CABG group were excluded for having either previous PCI or CABG, or acute myocardial infarction (MI) within 24 hours from the onset. Remaining 106 patients in the PCI group and 53 patients in the CABG group were compared for the final analysis. We assessed the 6-year cumulative incidences of clinical outcomes such as all-cause death, cardiac death, target vessel revascularization (TVR), major adverse cardiac and cerebrovascular events (MACCE: all-cause death, MI, stroke, and TVR), a composite of death, MI, and stroke, and definite or probable stent thrombosis or graft occlusion. The mean age was 70.6 years, and men accounted for 85%. The median follow-up duration of the survived patients was 5.5 years (interquartile range, 3.9 to 6.4 years). Between the PCI and CABG groups, the CABG group was significantly younger and had significantly more previous cerebrovascular events and three-vessel disease (72.0 ± 9.3 years vs. 67.8 ± 11.5 years, $p = 0.01$; 17% vs. 34%, $p = 0.03$; and 22% vs. 62%, $p < 0.001$), but no significant difference was found in the mean SYNTAX score (30.0 ± 7.5 vs. 32.2 ± 9.7, $p = 0.15$); no significant differences were found in the 6-year cumulative incidences of clinical outcomes (all-cause death: 23.2% vs. 15.9%, $p = 0.24$; cardiac death: 5.4% vs. 0%, $p = 0.11$; TVR: 9.9% vs. 6.6%, $p = 0.43$; MACCE: 40.8% vs. 33.4%, $p=0.18$; and a composite of death, MI, and stroke: 35.3% vs. 31.8%, $p = 0.30$), except for that of definite or probable stent thrombosis or graft occlusion, which was significantly higher in the CABG group (0% vs. 21.2%, $p < 0.001$). Between the PCI and CABG groups stratified by low/intermediate and high SYNTAX scores (<33 and ≥33), no significant difference was found in the 6-year cumulative incidence of a composite of death, MI, and stroke in either low/intermediate or high SYNTAX score stratum (low/intermediate, 30.3% vs. 42.5%, $p = 0.90$; high, 40.9% vs. 16.5%, $p = 0.25$), but the CABG group had a significantly higher 6-year cumulative incidence of definite or probable stent thrombosis or graft occlusion in both low/intermediate and high SYNTAX score strata (low/intermediate, 0% vs. 31.0%, $p = 0.001$; high, 0% vs. 16.0%, $p = 0.009$); the 6-year cumulative rate of TVR did not significantly differ in the low/intermediate SYNTAX score stratum (3.8% vs. 10.2%, $p = 0.28$), but tended to be higher in the PCI group in the high SYNTAX score stratum (16.5% vs. 0%, $p = 0.07$).

CONCLUSIONS

In patients with ULMCA disease, the risk of serious adverse events after PCI with Nobori BES appears to be comparable to that after CABG in the long term, irrespective of SYNTAX score. No definite or probable stent thrombosis occurred after Nobori BES implantation, whereas graft occlusion has gradually increased after

CABG.

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Comparison of two different strategies in PCI: directional coronary atherectomy adjunctive with DEB and DES implantation

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THEME: Coronary Interventions

TOPIC(S): Other Coronary Interventions

AIMS

PCI with DES implantation has some inevitable problems such as side branch occlusion, stent thrombosis and late stent failure. We evaluated efficacy of directional coronary atherectomy (DCA) followed by drug-coated balloon (DCB) compared with DES implantation.

METHODS AND RESULTS

Methods: We analyzed 66 patients treated by DCA-DCB (33 cases, 35 lesions, from April 2016 to December 2018) or DES (33 cases, 34 lesions, from April 2011 to March 2016). Lesions in the DES group were selected retrospectively, if evaluated as possible candidates for DCA on CAG and IVUS. Hemodialysis patients and restenotic lesions were excluded. Quantitative coronary angiography (QCA) data and clinical outcomes were compared.

Results: Both groups were comparable in patient characteristics including UAP and NSTEMI (DCA-DCB group 30%, DES group 24%: p=0.58) and lesion profiles. In QCA analysis, the mean reference diameter of the target vessel, the mean length, and the minimal diameter of the lesion at base line were similar in the two groups (3.21±0.50mm vs 3.08±0.39mmm, 13.2±5.7mm vs 14.2±6.4mmm, and 1.05±0.56mm vs 1.03±0.45mm, respectively). Immediately after the procedure, minimal diameter of the lesion (2.95±0.41mm vs 3.07±0.46mm) and acute gain (1.90±0.59mm vs 2.04±0.44mm) showed no significant difference. Follow-up angiography was completed in 49% and 94% of each group. Although follow-up duration was significantly shorter in the DCA-DCB group (193±42 days vs 310±222 days, p=0.007), late loss (0.16±0.39mm vs 0.32±0.57mm) and MACE rate (6% vs 7%) were similar.

CONCLUSIONS

DCA-DCB strategy may be as effective as DES implantation in selected lesions.

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LAA occlusion using LAmbre device: four-year follow-up

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THEME:

TOPIC(S):

AIMS

Left atrial appendage (LAA) closure procedure currently is a promising alternative to warfarin for ischemic stroke prevention in non-valvular atrial fibrillation patients. This retrospective study demonstrates safety and feasibility of LAA occlusion procedure with LAmbre™ device and reports four-years outcomes after the implantation.

METHODS AND RESULTS

This is a single-centre and non-randomized study. Fifteen consecutive patients underwent LAmbre™ device implantation between November 2012 and December 2013 were retrospectively analysed. All patients underwent cardiac computed tomography and transesophageal echocardiography prior the procedure. The population's mean age was 60.93±10.61 years, having high thrombotic risk with mean CHA2DS2-VASc score 2.33±1.49 and moderate bleeding risk with mean HAS-BLED score 2.67±1.04. Device implantation was successful in 100% patients. No post-procedural adverse events (device leakage, systemic embolization and pericardial effusion) were found during hospitalization. During follow up period (mean 4.13±1.35 years) two patients develop ischemic stroke (2/52 patient years, 0.038 cases per patient year) and two non-cardiovascular deaths occurred (both deaths are due to other illness, not device-related).

CONCLUSIONS

LAA closure with LAmbre™ device is a safe and feasible option for ischemic stroke prevention in non-valvular atrial fibrillation patients.

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Reduction of in-hospital mortality in inpatients with STEMI, after implementation of the inpatient rapid myocardial infarction pathway at a tertiary hospital in Melbourne, Australia

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Unpublished data from a large Victorian Percutaneous Coronary Intervention database suggests a higher in-hospital mortality for patients experiencing ST-Elevation Myocardial Infarction (STEMI), than the self-presenting population. It was recognised that at the study institution, there were unnecessary, lengthy delays in the initiation and transfer of inpatients with suspected STEMI to the Catheter Laboratory resulting in a high mortality rate. In response, we initiated a process of change management to facilitate rapid Catheter Lab activation and transfer for eligible patients.

METHODS AND RESULTS

We reviewed The Cardiac Society of Australia and New Zealand guidelines for the management of Acute Coronary Syndromes and adapted best practice recommendations to facilitate compliance with the Victorian Cardiac Outcomes Registry (VCOR) standard of reperfusion for STEMI within 90 minutes. A consensus process aimed at clarifying key staff roles, responsibilities and procedures related to transfers of patients with suspected Myocardial Infarction (MI) to the Catheter lab was undertaken with key stakeholders. This resulted in the development of the Inpatient Rapid MI Pathway, which was implemented in November 2017.

The pathway was utilised in 20 patients during the first 12 months of implementation; 18 patients required intervention (90%) and 2 had normal coronary angiograms (10%). In the 12 months post implementation: onset of pain-to-balloon time was significantly lower (M=77.8 mins, SD=43.2 mins) compared to pre-implementation (M=161.9 mins, SD=55.2 mi

CONCLUSIONS

The Inpatient Rapid MI Pathway has been effective in streamlining the early identification and treatment of patients with STEMI through clear delineation of roles and processes. Implementation of the pathway has led to a clinically significant reduction of onset of pain to balloon time and in-hospital mortality for inpatients having a STEMI. However, further work is required to ensure vigorous compliance with the pathway in all specialty areas of the hospital and reduce the duration of transfers during out-of-hours times.

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The ability of OCT to predict functional significance of the left main coronary artery stenosis

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease

AIMS

The aim of this study was to assess the safety and diagnostic efficacy of FD-OCT in identifying functional severity of the LM stenosis determined by fractional flow reserve (FFR).

METHODS AND RESULTS

Seventy eight patients with LM lesion (20-70% diameter stenosis angiographically) underwent FFR measurement and FD-OCT imaging of the LM before any intervention. The following parameters were measured by OCT in the LM: reference lumen area (RLA), reference lumen diameter (RLD), minimum lumen area (MLA), minimum lumen diameter (MLD), lumen area stenosis % , diameter stenosis % .

FFR at maximum hyperemia was ≤0,80 in 26/78 (33,3%) patients. Six (7.6%) patients showed ischemic symptoms during OCT image acquisition but none had any major adverse cardiac event. Angiographically ostial LM stenosis (at proximal third of the LM) was present in 23/78 (29.4%) patients. Twenty out of 23 (87%) ostial LM stenoses and all the 55/55 (100%) non-ostial LM stenoses were visualized optimally by OCT, (p=0.001).

FFR values were correlated significantly with OCT derived LM MLA (r=0.48, p<0.01) and LM % lumen area stenosis (r=0.41, p<0.01). Receiver-operating characteristic curve suggested an OCT measured MLA <5,3 mm² (area under the curve:0.93, p<0.01, sensitivity 85% and specificity 93%,) and % lumen area stenosis>55% (area under the curve:0.73, p<0.001, sensitivity 69% and specificity 68%) as the best cut-off values for predicting FFR<0.80 .

CONCLUSIONS

FD-OCT is safe and feasible for the LM imaging even in ostial lesions. MLA <5,3 mm and lumen area stenosis >55% measured by FD-OCT strongly predict the functional severity of a LM stenosis.

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Myocardial infarction due to acute left circumflex occlusion: electrocardiographic parameters, infarct size, reperfusion delay, average hospital stay and cardiovascular mortality

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Left circumflex (LCx) occlusion is underdiagnosed in most of reperfusion studies about myocardial infarction, due to its poor electrocardiographic expressiveness and late diagnosis. This late diagnosis leads to longer reperfusion time and higher infarct size. We tried to compare reperfusion delay, peak of cardiac biomarkers, electrocardiographic abnormalities, hospital stay and survival in acute and subacute myocardial infarction, due to left anterior descending (LAD), left circumflex (LCx) or right coronary artery (RCA) occlusion.

METHODS AND RESULTS

Observational retrospective study including 1634 coronary angiographies in a single university hospital between January 2016 and January 2018. We analyzed baseline characteristics, clinical presentation, delay from emergency unit to invasive cardiology department, peak of biomarkers, electrocardiographic parameters, complications after procedure, average hospital stay, cardiovascular events and short and medium-term mortality.

873 patients (74% male; 66± 13 years) with myocardial infarction were analyzed, of which LAD, LCx and RCA were occluded in 16%, 10% and 17% respectively. 38%, 52%, and 10% of cases with LCx occlusion presented as Non-ST Segment Elevation Myocardial Infarction (NSTEMI), ST Segment Elevation Myocardial Infarction (STEMI) and subacute myocardial infarction respectively. We found no differences in baseline characteristics between groups. No differences on time from symptoms onset to emergency department were detected (p=0.201), but mean time from emergency unit to invasive cardiology department arrival was 292, 1608 and 350 minutes in LDA, LCx and RCA occlusion (p<0,001).

CPK-peak was significant higher in LDA (2703 +/- 2266 IU/l) than in LCx (1555 +/- 1230 IU/l) and RCA occlusion (1720 +/- 1540 IU/l) (p<0.001). Troponin levels were also higher in LDA (53 +/- 35 ng/ml) than in LCx (37 +/- 31 ng/ml) and RCA occlusion (40 +/- 29) (p=0.002).

The most frequent ECG findings in patients with LCx occlusion were “ST depression in V1-V4 leads and ST elevation in inferior and lateral leads” (5%). Isolated ST depression in I,AVL,V4-V6 was the most frequent finding detected in NSTEMI due to LCx occlusion (sensitivity 13%; specificity 91% [97% in subacute myocardial infarction]). Specificity and positive predictive value increases up to almost 100% when a transthoracic echocardiography shows left ventricular inferior, septal and/or posterior wall hypokinesia.

Patients with LDA occlusion presented lower systolic function after AMI (p<0.001) and higher rate of all-cause mortality before discharge (p= 0.028). A higher rate of third degree atrioventricular block was found in RCA occlusions (p<0,001). Average hospital stay was 8.3, 12 and 7.2 respectively (p=0,255) and no differences in all-cause mortality 1 month, 6 months and 1 year after AMI were found (p=0.082; p=0.080 and p=0.155).

CONCLUSIONS

Isolated ST depression in lateral leads seems to be a low sensitive but highly specific electrocardiographic parameter in NSTEMI due to LCx occlusion, especially when ventricular inferior, septal and/or posterior wall hypokinesia is associated. Our study showed higher reperfusion delay in patients with acute LCx occlusion, which didn´t lead to higher infarct size, longer average hospital stay, nor long time all-cause mortality.

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Bioabsorbable magnesium scaffold implantation in ACS: feasibility and mid-term outcomes

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THEME: Coronary Interventions
TOPIC(S): STEMI, Stents and scaffolds

AIMS

ACS might constitute a specifically good target group for BRS implantation due to the pathophysiologic nature of the disease. The purpose of this prospective multicenter study was to evaluate the feasibility and short- and medium-term outcome after implantation of coronary resorbable magnesium scaffold in a de novo culprit native coronary lesion in the setting of ACS.

METHODS AND RESULTS

Primary objective was a device-oriented composite end-point (DOCE) including definite/probable stent thrombosis (ST) and clinically driven target-lesion revascularization (TLR) at 30 days and secundary objectives were DOCE at 6 months and at follow-up.

Exclusion criteria were: Haemodynamic instability, complex lesions (Left main, true bifurcations, severe tortuosity/calcification), culprit lesion not clearly identified, treatment with oral anticoagulants, contraindication to 12-month of dual-antiplatelet therapy, high thrombus burden defined as TIMI thrombus grade (TG) 4-5 (angiographic thrombus with greatest linear dimension >2 vessel diameter). Lesions treated were defined as culprit based on angiographic evidence of intraluminal thrombus, ECG changes and/or regional wall abnormalities in the corresponding perfusion territory and if it was not clearly the patient was excluded. The study was approved by the local ethics committee.

From Jan 2017 to Dec 2018, eighty-three patients were enrolled. Mean age was 55.7±10 years and 76% were males.

Angiographically evident thrombus defined as TG 2-3 was present in 18%, the rest of patients showed a TG 0 (no evidence of angiographic thrombus) or TG 1(angiographic characteristics suggestive but not diagnosis of thrombus).

Technical success was achieved in all cases (100%). Radial approach was performed in 97.5% of procedures (81/83).

Predilatation was performed in 76 (91.6%) lesions, in most cases using a non-compliant balloon (54/76, 71%) with a mean diameter of 3.04±0.4mm and in 3 cases (3.9%) a scoring balloon was used. A total of 93 scaffold were deployed with a mean diameter of 3.3±0.24mm. Postdilatation with a non-compliant balloon was performed in 62 (75%) lesions with a mean diameter of 3.6±0.4mm and at 16.5±3 atm. Stent optimization was guided by intracoronary OCT in 69%(57/83) cases. All the patients were treated with AAS (100%), 71% (59/83) with Ticagrelor, 25% (21/83) with clopidogrel and 3.5% (3/83) with prasugrel. Mean fluoroscopy time was 12±7min, mean contrast volume was 216 ± 78ml.

There were five complications during scaffold implantation: 2 edge dissections which were successfully treated overlapping a new BRS in one case and a new DES in other; 1 catheter-induced ostial dissection successfully treated with a DES implantation and 2 cases of no-reflow successfully solved with usual treatment. Ten patients (12%) required a second overlapped scaffold (80%, 8/10 cases for insufficient scaffold length).

Mean follow-up was 24±10 months. At 4 months follow-up one case (1.2%) of definite ST ocurred a few days after antiplatelet treatment discontinuation. One case of recurrent ischemia was observed a few days after the procedure due to edge-dissection that was successfully treated with a new overlapped DES and one case of scaffold reestenosis was document at 4 months follow-up. Therefore DOCE at 30 days was 1.2% (1/83), at 6 months 5.2% (3/57) and at follow-up 3.6% (3/83).

CONCLUSIONS

Our short- mid-terms results show that resorbable magnesium scaffold are a feasible and promising option in the setting of ACS.

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Assessment of the clopidogrel action with regard to CYP2C19 gene polymorphisms in patients with coronary artery disease after implantation of DES stents

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Aim of the work to assess the impact of CYP2C19 polymorphisms, including those of CYP2C19*1, CYP2C19*2, CYP2C19*3 and CYP2C19*17 on clopidogrel response variability in patients undergoing percutaneous coronary intervention (PCI) following DES implantation.

METHODS AND RESULTS

45 patients undergoing PCI with the following implantation of DES were enrolled in the study. All patients were diagnosed with coronary heart disease and were admitted for elective coronary intervention (aged 46-65 years; mean age 52±11.6; male n=28). Blood samples for platelet function testing were collected before clopidogrel administration (baseline) and at the 36 hours after the loading dose. Platelet aggregation was performed in a two-channel aggregometer and assessed by inhibition of platelet aggregation (IPA). Genotyping of the CYP2C19* polymorphisms was performed using polymerase chain reaction (PCR).

Among 45 patients, 42% of patients had CYP2C19*1, 20 % CYP2C19*2, 9% CYP2C19*3 and 29% CYP2C19*17 genetic polymorphisms. Only 84 % of patients had a response to clopidogerel. Most of the non-responders were subjects with CYP2C19*2 and CYP2C19*3 genotypes. IPA significantly increased in 36 hours after loading dose in CYP2C19*17 genotype with 5 mmol/L and 20 mmoll/L ADP ($P<0.01$), and normal increased in 36 hours after loading dose in CYP2C19*1 genotyping subjects ($P<0.05$) whereas IPA did not changed significantly in subjects with CYP2C19*2 and CYP2C19*3 genotypes with 5 mmol/L and 20 mmoll/L ADP ($P>0.05$).

CONCLUSIONS

Carriers of the CYP2C19*2 and CYP2C19*3 single nucleotide polymorphisms are a predictor of the clopidogrel non-responders whilst CYP2C19*17 polymorphisms are strong responders in our population.

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Features of pressure data and electrocardiogram after intracoronary Nicorandil

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Intravenous Adenosine is a gold standard for obtaining hyperemia during measurement of FFR, furthermore, intracoronary Nicorandil is often used in recent years to reach the equivalent FFR value to Adenosine. However, the effects of Nicorandil during hyperemia on pressure data and electrocardiogram have not been investigated enough.

METHODS AND RESULTS

Forty-one consecutive patients with intermediate stenosis in LAD at coronary angiography were enrolled in this study. FFR was measured with the following three stimuli without moving the wire position in each patient; intravenous Adenosine triphosphate (ATP) 140μg/kg/min, intracoronary Papaverine 8mg and intracoronary Nicorandil 2mg. The pressure and electrocardiogram data of Papaverine and Nicorandil were compared to those of ATP.

Both papaverine and Nicorandil had good correlation with ATP in FFR values, however, the FFR value was significantly higher in Nicorandil compare with ATP. There was no significant difference between Papaverine and ATP in mean distal coronary pressure (Pd) and mean aortic pressure (Pa) at maximum hyperemia, but Nicorandil was significantly higher in Pd (ATP; Pd 68±14, Pa 83±14, Nicorandil; Pd 72±14, P=0.020, Pa 86±14, P=0.089). Ventricular tachyarrhythmia did not occur with all the stimuli, but in Papaverine the QTUc significantly increased compared to ATP, and in contrast, Nicorandil was significantly shorter than ATP in QTUc. (QTUc ATP 0.513±0.085; Papaverine 0.570±0.088, P<0.001, Nicorandil 0.487±0.068, P=0.032)

CONCLUSIONS

The Pd and Pa after intracoronary Nicorandil were slightly higher than ATP, but the FFR value had good correlation. In intracoronary administration of Nicorandil to patients with stable angina, QTUc was not prolonged unlike Papaverine.

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Differences of the predictors for target lesion revascularisation between de-novo and in-stent-restenotic lesions after everolimus-eluting stent implantation

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

In-stent-restenotic lesion (ISR-lesion) was one of the problem after DES implantation even in second generation DES era. The incidence and predictors of target lesion revascularization (TLR) after everolimus-eluting stent (EES) implantation for ISR-lesion were still unclear in Japanese patients. The aims of this study were to clarify the incidence of TLR and evaluate the predictors of TLR in ISR-lesion after EES implantation.

METHODS AND RESULTS

The study subjects were 3152 lesions (2812 patients) which were treated with EES between 2010 and 2016. We investigated clinically-driven TLR within 5 years and assessed the predictors for TLR by multivariate analysis in de-novo lesion (Denovo-lesion) and ISR-lesion, respectively. The patient characteristics were 72.1±9.7years, 73.4% male, 40.6% diabetes mellitus and 67.3% statin-use. The lesion characteristics were 83.8% type B2/C lesion, 30.9% true-bifurcated lesion and 10.5% ISR-lesion (332 lesions, 310 patients). The number of stents per lesion was 1.28±0.57 and mean stent size/ length were 2.95±0.41/ 28.9±18.4mm. IVUS-guided PCI was performed in 96.5% lesion. Mean minimum stent area (MSA) assessed by IVUS was 5.74±2.27mm2. The incidence of TLR in Denovo-lesion was 3.0% (62/2820) and that in ISR-lesion was 11.3% (29/332) during median follow-up period 3.7 (2.1-5.0) years. On multivariate analysis, the independent predictors for TLR in Denovo-lesion were statin-use (HR=0.36, 95%CI:0.21-0.60, p=.0001), stent length > 30mm (HR=1.92, 95%CI:1.12-3.30, p=0.018), true-bifurcated lesion (HR=1.89, 95%CI:1.10-3.22, p=0.020) and diabetes mellitus (HR=1.80, 95%CI:1.08-3.00, p=0.023), and those in ISR-lesion were MSA < 5.4mm2 (HR=2.95, 95%CI:1.28-7.64, p=0.011) and %plaque-area at MSA > 56% (HR=2.83, 95%CI:1.14-8.51, p=0.023) measured by intravascular ultrasound (IVUS).

CONCLUSIONS

In this retrospective study, TLR rate in both Denovo-lesion and ISR-lesion after EES implantation were exceedingly low, and there were differences in the predictors of TLR between Denovo-lesion and ISR-lesion. Moreover, it is obvious that sufficient stent expansion guided with IVUS was important to prevent TLR for ISR-lesion, whereas statin therapy was important for Denovo-lesion after EES implantation

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Percutaneous left appendage closure under conscious sedation. Initial experience in a single institution

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THEME:
TOPIC(S):

AIMS

We sought to investigate the safety and feasibility of percutaneous left appendage closure guided by transesophageal echocardiography under conscious sedation.

METHODS AND RESULTS

We included all consecutive patients with non-valvular atrial fibrillation who underwent percutaneous left appendage closure under conscious sedation in our institution from February 2016 to August 2018. Transseptal puncture was guided by transesophageal echocardiography. Conscious sedation was performed using intravenous Propofol and Meperidine. Hemodynamics and oximetry parameters were carefully monitored. Variables were prospectively recorded.

42 patients were included (mean age 75.1 ± 7.4. Male 59.5 % ± 0.5). They were at both high thrombotic and bleeding risk: Mean CHA2DS2-VASc 4.3 ±1.5, mean HAS-BLED 3.9 ±1.2. Procedural success was accomplished in 100% of the cases. Mean procedure time was 76.2 ± 21.0 minutes and mean fluoroscopic time 12.4 ± 4.6 minutes. Watchmann® device was used in 25 cases (59.5%), mean size 26.5 ± 4.3 mm and Amulet® device was used in 17(41.5%), mean size 25.1 ±2.6 mm. Conscious sedation was performed using Propofol and Meperidine (Mean propofol dose 77.3 mg ± 44.1, mean Meperidine dose 41.9 mg ± 33.2) and no complication related to conscious sedation was observed. No device embolization occurred, and one patient experienced cardiac tamponade successfully treated with pericardiocentesis and autotransfusion. Treatment at discharge was simple anti-platelet treatment in 38 (90.47%) of the cases: 18 (42.82%) Aspirin, 10 (23.8%) clopidogrel and simple anti-platelet plus anticoagulation in 4 (9.53%, 3 novel oral anticoagulant, 1 warfarin) . Transesophageal echocardiography was performed at 45 days after the procedure exhibiting complete left appendage exclusion with no significant leak or thrombus. During a median follow up of 152 days (IQR25/75 104 – 256) one transient ischemic was reported and 3 deaths were reported from causes unrelated to device nor cardiovascular causes.

CONCLUSIONS

In our experience, percutaneous left appendage closure under conscious sedation may be a feasible, reproducible and safe procedure which may have an impact in reducing its complexity.

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EffectivenesS of additional x-ray PRotection dEviceS in reducing Scattered radiation in radial interventiOn: the ESPRESSO randomised trial

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

A number of interventions have been developed to minimize operator-received scatter radiation in the setting of coronary procedures, less is known for radial interventions. We set out to examine the impact of three different radiation protection devices in a real-world situation of radial artery catheterization.

METHODS AND RESULTS

In a double-blind, all-comer randomized trial, consecutive coronary diagnostic and intervention procedures were assigned in a 1:1:1 ratio to a shield-only protection (shield group), shield and overlapping 0.5mm Pb panel curtain (curtain group) or shield, curtain and additional 75x40cm, 0.5mm Pb drape placed across the waist of the patient (drape group).

The primary outcome was the difference in relative exposure of the primary operator among groups. Relative exposure was defined as the ratio between operator's exposure (E in μSv) and patient exposure (dose area product in cGy·cm²).

A total of 710 consecutive coronary procedures were randomized; of these, 533 procedures were conducted using the radial access (N=192 shield group, n=220 curtain group, N=201 drape group). Radial access was associated with a 22% higher exposure for the assistant operator (P=0.01) and an 8% higher exposure for the first operator (P=0.82). There were no differences among groups in patients´ age (P=0.588), body surface area (P=0.183), type of procedure (intervention vs diagnostic, P=0.871), average procedure time (P=0.147). The relative exposure was significantly lower in the drape group for both the first operator (absolute reduction 17% vs shield and 24% vs curtain, P=0.036 by ANOVA) and the assistant (absolute reduction 27% vs shield and 32% vs curtain, P=0.010 by ANOVA). The type of radiation protection used was an independent predictor of relative exposure for operator (P=0.003) and assistant (P=0.001) also after correction for the patient´s body surface area and type of procedure.

CONCLUSIONS

In clinical daily practice, the standard use of shield-attached panel curtains and of an additional drape reduces radiation exposure of both the first and second operator, while the curtain alone is ineffective. This study supports the routine use of this type of additional protection devices in the catheterization laboratory.

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Three-year outcomes of cobalt-chromium everolimus-eluting stent in the very small coronary artery

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

This study is a merged cohort of 2 prospective government mandated registries designed to evaluate the safety and efficacy of 2.25 mm Cobalt-chromium everolimus-eluting stents (CoCr-EES) in routine clinical practice at 30 centers representative of the clinical environment nationwide in Japan.

METHODS AND RESULTS

Consecutive 412 patients (312 Xience Prime SV, 100 Xience Xpedition SV) who underwent PCI using at least one 2.25-mm CoCr-EES with 430 lesions were enrolled and 382 patients were followed up to 3 years (93%). Seventy seven percent of patients were male, and mean age was 69. Coronary risk factors were 18% of smoking, 82% of hypertension, 67% of dyslipidemia, 53% of diabetes, and 3.9% received hemodialysis. PCI was performed for ACS in 25% of the cases. De novo lesion was 94%. Lesion was located in RCA 24%, LAD 34%, LCx 36%, LM 0.2%, HL 5%, arterial graft 0.5% and SVG 0.2%. Mean reference vessel diameter was 2.1 mm and mean lesion length was 17 mm. DAPT was maintained in 76.4% of the patients up to 3 years. Definite or probable stent thrombosis occurred in 3 patients (0.7%). Death, Cardiac death, MI, ischemia-driven TLR rates at 3 years were 6.3%, 0.7%, 1.5%, 5.6%, respectively. Major bleeding complication occurred in 3 patients (2 GI bleeding and 1 cerebral bleeding).

CONCLUSIONS

Three-year clinical outcomes of PCI for very small vessel using 2.25-mm CoCr-EES in the real-world setting appears to be similar to those of core size EES.

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Impact of ostial stenting for left main coronary artery disease without ostial lesion

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease

AIMS

The preferable stenting strategy may different by the location of stenosis in LMCA.
In many cases, the length of left main coronary artery (LMCA) is relatively short.
Ostial stenting can be one of the options for distal LMCA disease.
The aim of this study was to clarify the impact of ostial stenting for LMCA disease without ostial lesion on clinical outcomes.

METHODS AND RESULTS

From January 2012 to December 2017, 122 consecutive patients who had LMCA disease had treated with second generation drug-eluting stents.
In these patients, we excluded ostial lesion cases and acute myocardial infarction cases.
Remaining 76 patients were divided into two groups according to with or without ostial stenting.
Eighteen patients were deployed stents over the LMCA ostium to the lesion site (ostial stenting group), and 58 patients were deployed stents in only lesion site (non-ostial stenting group).
We compared the two year clinical outcomes between ostial stenting group and non-ostial stenting group.
The 2-year cardiac death rate showed no significant difference between two groups (0% vs 1.8%, p=0.57). The cumulative target lesion revascularization rate also showed no significantly difference (7.1% vs 3.9%, p=0.70).
In non-ostial stenting group, 2 patients required TLR. Restenosis was shown in LMCA ostium in both patients.
By contrast one patient in ostial stenting group required TLR because of restenosis in LMCA bifurcation.
Stent thrombosis was not observed in two groups.

CONCLUSIONS

Ostial stenting for LMCA disease without ostial lesion did not affect the incidence of mortality and TLR.

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Prevalence, characteristics and clinical correlates of stent - and scaffold - fractures

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Strut fractures (SF) of metallic stents or bioresorbable vascular scaffolds (BRS) are a possible mechanism for late complications following percutaneous intervention (PCI) including stent or BRS thrombosis and restenosis. However, the frequency, characteristics and clinical implications of this phenomenon remain incompletely understood.

Based on a previously published pathological classification, optical-coherence tomography (OCT) was used to identify and analyze SF in patients with previously implanted stents and BRS.

METHODS AND RESULTS

The multi-center study includes 514 devices (201 metallic stents, 313 BRS) implanted in 406 patients (62±11years of age, 78% males, 26% diabetics) between 2007 and 2017 and imaged with OCT in an elective control setting. In 322 cases, the analysis was performed at implantation; in the remaining 192, at 367[295-408] days after implantation. In 38 devices (32 patients), OCT was triggered by specific clinical reasons (19 thromboses and 19 restenoses). 2D- and 3D-quantitative and qualitative analysis was performed centrally using the Medis (Leiden, Netherlands) software and standardized definitions. Fractures were found in 96 control devices (20.2%, 87 patients). SFs were more frequent in scaffolds than drug eluting stents (26.0% vs 11.4%, P<0.001) and, independently of device type, were more often found in the setting of restenosis or thrombosis than in controls (71% vs 20%, P<0.0001). Fractures were classified in 4 patterns: one single stacked strut (41%); two or more stacked struts (23%); deformation or transection, without gap (27%); in-stent gap (9%). The most common pattern was pattern a single stacked strut in both device types (2.7% of 2nd generation DES and 11.8% of BRS, P=0.001), but complex patterns were common in restenosis and thrombosis (P<0.0001, ischemia vs control). The inter-rater agreement for the diagnosis of fracture was K=0.83.

In multivariable analysis, a calcium arc larger than 180°, implantation in the RCA and BRS implantation, were associated with fractures (all P<0.05). Fractures were associated with a larger stent eccentricity, i.e. a smaller eccentricity index and a larger asymmetry index, with peri-strut low-intensity areas (p=0.001), uncovered (P=0.003) and malapposed struts (p=0.036). In logistic regression analysis, fractures were the strongest correlate of stent/scaffold complications (p=0.01, OR=3.9[1.4-10.9]).

CONCLUSIONS

The incidence of OCT-diagnosed SF was ~20% in the setting of elective controls without restenosis or thrombosis, but it increased by ~3-fold in the setting of device failure. Fractures were more frequent in scaffolds than metallic stents, were associated with evidence of inflammation and device complications, and they showed a strong association with restenosis and thrombosis.

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Angiographic profile and laboratory predictors of coronary slow flow phenomenon

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

This study aimed to analyze clinical presentation, angiographic profile and risk factors associated with coronary slow flow phenomenon (CSFP) with out coronary obstructive lesion in patients who came for coronary angiogram.

METHODS AND RESULTS

Case-control study included patients who underwent coronary angiography and classified into 2 groups: coronary slow flow (case group, n=107) and patients with normal coronary flow (control group, n=100). Coronary flow was measured using corrected thrombolysis in myocardial infarction frame count (CTFC). The slow flow was defined as CTFC beyond 2 standard deviations from normal published range. Various clinical risk factors (age, sex, body mass Index (BMI), diabetes mellitus(DM), hypertension, dyslipidemia, smoking), hematological and biochemical parameters (complete blood picture, platelet count, total and differential leucocyte count, platelet-to lymphocyte ratio (PLR), neutrophil-to-lymphocyte ratio (NLR), lipid profile and Alkaline Phosphatase(ALP)) were assessed. In both groups, clinical information was collected and laboratory parameters were measured and compared.

Patients with CSFP were more likely to be male and active smokers. Total cholesterol, triglyceride, platelet count, and prevalence of significantly higher BMI, DM and ALP were more common in the CSFP group compared to the control group. A Platelet to Lymphocyte Ratio (PLR), Neutrophil to Lymphocyte Ratio (NLR), uric acid and Hs-CRP were high in CSFP group compared to the control group ($P < 0.0001$).The diagnostic value of PLR>150; NLR > 2 albumin level <3.5 g/dl ; uric acid > 6 mg/dl for prediction of CSFP were [sensitivity 83.2%, 90%, 50.1%, 76.8% and [specificity 86.8%, 90.5%, 53.2%, 83.2%] respectively. The multivariate analysis showed that NLR >2 and ALP >68 U/L was the only independent predictor of PSCF.

CONCLUSIONS

CSFP was common in males, smokers, DM patients and it is associated with high PLR, NLR, uric acid and Hs-CRP levels. The independent predictor of CSFP was NLR, High BMI and High serum ALP levels.
These findings provide an impetus for additional studies to confirm the role of other inflammatory markers in CSFP patients and treatment strategies depending on that.

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Impact of moderate to severe chronic kidney disease on outcomes after PCI

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

The aim of this study is to determine the effect of varying degrees of renal insufficiency (moderate to severe) on death and cardiac events after percutaneous coronary intervention (PCI).

METHODS AND RESULTS

This study included 420 patients having moderate to severe chronic kidney disease who underwent percutaneous coronary intervention from March 2014 till May 2018 in our institute .Out 420 patients only 320 patients were followed up . Statistical analysis was performed to determine independent variables associated with mortality and major adverse cardiovascular events (MACE).

The study group divided into two groups : Group I with eGFR >45 – 60 and Group II with eGFR <45 In group I 14 patients (5.9%) and in group II 7 patients (3.2%) had MACE .In group II we observed the association of age

(p = 0.025) and hypertension (p= 0.001) with MACE was statistically significant .

CONCLUSIONS

In severe CKD, older age and hypertensive patients were significantly associated with MACE events

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Changes in index of microcirculatory resistance during PCI in the left anterior descending coronary artery is associated with total length of stents implanted

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Our aim was to investigate the relationship between stent length and changes in coronary microvascular resistance during PCI with stent in stable coronary artery disease.

METHODS AND RESULTS

We measured fractional flow reserve (FFR), index of microcirculatory resistance (IMR) and coronary flow reserve (CFR) before and after stenting in 42 consecutive subjects with stable coronary artery undergoing PCI in the LAD. The relationship between changes in coronary flow indices and total stent length were analyzed with ANOVA and repeated measures. Patients that had very long stent length (38-78 mm) had lower FFR before stenting than patients with long (23-37 mm) and moderate (12-22 mm) stent length (0.59 [±0.16], 0.70 [±0.12], 0.75 [±0.07], p=0.009). FFR improved after stenting and more so in subjects with very long stent length compared to long and moderate stent length (0.27 [s.d±16], 0.15 [s.d ±0.12], 0.12 [s.d±0.07], p for interaction = 0.007). Changes in corrected IMR (IMRcorr) was related to stent length in LAD; IMRcorr increased after stenting in subjects who had very long stent length whereas IMRcorr was lower after stenting in subjects who had long or moderate stent length (4.6 [s.d ± 10.7]), -1.4 [s.d±9,9]) and -4.2 [s.d.±7.8], p for interaction = 0.009). Changes in CFR were not significantly related to stent length.

CONCLUSIONS

PCI with very long total stent length in the LAD of patients with stable coronary artery disease is associated with an acute increase in coronary microvascular resistance possibly influencing post-PCI FFR.

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Comparison between the skin dose mapping given by the DACS DOSITRACE during interventional radiological procedures and clinical tests using Gafchromic films

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

During an Interventional Radiology procedure, the patient's skin-dose can become strong enough that a burn may be produced. In order to avoid the skin deterministic effects to occur, an accurate estimation of the skin-dose mapping is highly needed. The Dose Area Product & fluoroscopic time are the only dosimetric information. These parameters have been shown to be a poor indicator of skin dose.
The aim was to develop a model to: (1) calculate and (2) localize the radiation dose received by patients to integrate it into our 'Dose Archiving and Communication System (DACS)' called "DOSITRACE".

METHODS AND RESULTS

DOSITRACE uses a mathematical model to reconstruct a two-dimensional skin-dose mapping that reflects the magnitude, shape, and localization of irradiation fields on the skin of patients undergoing IR examinations. The reconstruction is based on geometrical and dosimetric information contained within the stored acquisition DICOM files.
The theoretical model was validated by comparison with clinical tests performed on phantoms using the fixed IR machine. Gafchromic films were placed on the phantom's back and so were exposed identically to the skin. After irradiation, a darkening is produced at the film reflecting the field's shape and is proportional to the received dose. Film scanning and analyzation allow us to obtain the accurate received dose value. Note that four experimentations have been performed including 34 field projections simulating simple and very complex acquisition cases.
Comparison between simulated & measured skin dose on phantoms showed a difference less than 15 %. Moreover, the simulation of DOSITRACE produces results with a very good level of geometrical accuracy: simulated & measured fields have the same shape, size, and localization. Very small field displacement were reported for very few ones and are due to machine's uncertainty on the tube angle (measured to be +/- 1 to 2°). Deep analysis will be performed in order to resolve these small dose and geometric inaccuracies.

CONCLUSIONS

This study shows that our software is a reliable tool to warn physicians when a high radiation dose is reached and then deterministic effects can be avoided. Thirty chronic total occlusion procedures will be performed soon during real patient procedures.
Evaluation of the skin-dose mapping according to the intervention time, 3-D patient representation including patient's anatomy, and real-time reconstruction are our planned development.

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FFR vs. angiography-guided CABG: a meta-analysis

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Left main and multivessel disease

AIMS

Clinical benefit of invasive functionally guided revascularization using Fractional Flow Reserve (FFR) has been mostly investigated and proven for percutaneous coronary intervention. However, the role of FFR assessment in guiding coronary artery bypass graft surgery (CABG) is unclear from the available evidence. The aim of this study is to compare the clinical outcomes of FFR-guided CABG to the traditional angiography-guided CABG by performing a meta-analysis.

METHODS AND RESULTS

We conducted an electronic database search including PubMed, Web of Science, Google scholar and Cochrane Database of all published data for studies that compared FFR versus Angiography guided CABG in patients with multivessel coronary artery disease. Event rates were compared using a Forest plot of odds ratio (OR) using a random-effects model assuming interstudy heterogeneity. A total of 3 studies (n= 833; FFR= 261, Angiography= 572) were included in the final analysis. Mean follow up period was 30.15 months. Clinical and angiographic characteristics were similar between the two groups. Pooled analysis revealed that is no difference between FFR guided CABG versus Angiography guided CABG in relation to Overall Mortality (OR = 0.50, 95% CI = 0.24 – 1.08, I2= 0%, P = 0.08), Myocardial Infarction [MI] (OR = 1.10, 95% CI = 0.56 – 2.17, I2= 0%, P = 0.78), Target Vessel Revascularization [TVR] (OR = 1.26, 95% CI = 0.60 – 2.62, I2= 0%, P = 0.54), Major Adverse Cardiovascular Events [MACE] (OR = 0.87, 95% CI = 0.54 – 1.41, I2= 0%, P = 0.57) and Graft occlusion rates (OR = 0.51, 95% CI = 0.08 – 3.23, I2= 80%, P = 0.47)

CONCLUSIONS

FFR guided CABG compared with Angiography guided CABG has no difference in terms of Overall mortality, MI, TVR, MACE and graft occlusion rates

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International experience with the use of Cocoon septal occluder for catheter closure of atrial septal defects. Procedural and follow-up results

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THEME: Interventions for Heart Failure
TOPIC(S): Acute heart failure, Chronic heart failure

AIMS

Transcatheter closure of atrial septal defects (ASDs) is an established treatment modality but no current device provides an ideal solution. The Cocoon septal occluder (CSO) is a new device with certain design features that make it potentially attractive for closure of ASDs.

METHODS AND RESULTS

:The mean ASD diameter was 17 ± 7 mm (range 10-27 mm) and 20 mm ± 8 mm (range 13 – 36 mm) in pediatric and adults patients, respectively. Mean device diameter was 18±6 mm (range 14-28mm) and 24±8 mm (range 16-40 mm) in the pediatric and adult population of the study, respectively. The CSO was permanently implanted in 5222 (patients (99.4%).). Echocardiographic evaluation at one month follow-up revealed complete closure in 5211 patients (99. 6 %). Thrombus formation in one adult patient was only device related procedural complication. During a follow-up period of 6 -74 months no patient developed device related erosions or allergic reactions to nickel or other major complication.

CONCLUSIONS

. Our data indicate that the CSO is a safe and effective device that adds to our armamentarium for catheter closure of secundum atrial septal defect in children and adults.

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Copeptin as a novel cardiac biomarker in the diagnosis of ACS

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THEME: Coronary Interventions
TOPIC(S): NSTEMI

AIMS

1-To measure the level of copeptin in patients with ACS (STEMI,NSTEMI,UA) and patients with atypical chest pain.

2-To compare copeptin to cardiac troponin as a cardiac marker for early pick up patients with AMI and its relation to the duration of chest pain and to correlate the level of serum copeptin to the degree of LVEF in post AMI patients with impaired left ventricle function.

METHODS AND RESULTS

Subjects and Methods

This study enrolled one hundred fifty (150) patients admitted to the emergency department or to the Coronary Care Unit (CCU) in Basra cardiac center diagnosed with ACS in one hundered fourteen (114) patients and thirty six (36) patients with atypical chest pain.

Three ml of venous blood was drown from all patient on admission for measrement of serum level of troponin and copeptin using immunoassay.

The level of cardiac markers (copeptin, troponin) compared among different subgroups of patients with AMI (STEMI and NSTEMI), Unstable Angina and atypical chest pain using Anova test. Moreover correlation between Copeptin level and LVEF were performed using spearman correlation. Statistical analysis were performed using Statistical Package for Social Science (SPSS ver 23)

Results

This is a cross sectional study in which 150 patients aged (58 years ± 13) with (58 % male, 42 % female) admitted with chest pain to emergency department or coronary care unit of Basra cardiac center from January to June 2018. It had been found that there is significant statistical analysis in level of copeptin among different patients groups (AMI, UA, and atypical chest pain, with highest level among AMI group (47.3 ± 16 pmol/L) compared to low level of only 19.5 ± 4.5 pmol/L, 18.9± 4 pmol/L in patient with UA and atypical chest pain respectively. Patients presented earlier to the emergency department (within 3 hours of chest pain) had higher level of copeptin (57.5 ± 15.7 pmol/L) which statistically significantly differ from those after 3 hours in addition copeptin correlated negatively with the duration of chest pain.

In patients with LV systolic dysfunction copeptin level was significantly higher (47 ± 14pmol/L) than those with good LV systolic function (38.4±18 pml/L). additionally it's level was inversely correlated to the degree of ejection fraction in post AMI patients.

Receiver Operating Characteristic (ROC) curve for AMI patients presented early(less than 3 hours) showed better area under the curve (0.830) for copeptin as compared to troponin (0.405) and this is found to be highly

significant statistically(000.1).Area under the curve for combined testing of copeptin and tropinin shows better diagnostic performance than copeptin or troponin alone.

CONCLUSIONS

Conclusions

1. Copeptin level was statistically higher in AMI patients presented early (<3 hours) than those presented later allowing rapid ruleout of AMI, moreover The combined negativity of troponin and copeptin justify the rapid and reliable exclusion of AMI.
2. Copeptin level inversly correlated with the degree of LV function , make it a promising prognostic biomarker in this subset group of patients.
3-Combined testing of troponin and copeptin shows better diagnostic performance than troponin or copeptin alone.
4-Copeptin testing is not useful in the diagnostic work-up of patients with unstable angina.

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Mortality after TAVI by surgical risk score: analysis from the SOURCE 3 study, at three years

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Nowadays, patients at low risk (LR) for surgery (logistic EuroSCORE [logES]<10%) are referred to TAVI because they have comorbidities not included in surgery risk score calculations (e.g., hostile chest [severe radiation damage] and liver disease). We compared outcomes in patients enrolled in the SOURCE 3 (SAPIEN 3 Aortic Bioprosthesis European Outcome) cohort according to risk score, for up to 3 years.

METHODS AND RESULTS

All patients underwent transfemoral TAVI; LR patients (n=475, 40.8% female, age 78.5±7.5) with mean logES of 6.7±2.1% and HR patients (logES≥10%; n=1079, 53.3% female, age 83.2±5.6 years) with mean logES of 22.7±12.6%. At baseline, patients at LR presented with less hypertension (76.8% vs 84.6%, p<0.001), coronary artery disease (42.7% vs 52.9%, p<0.001), CHF (29.1% vs 39.0%, p<0.001), and MI (7.8% vs 12.2%, p=0.010) and CABG (4.6% vs 11.8%, p<0.001) compared with HR patients, but a higher rate of previous chest irradiation (2.5% vs 0.6%, p=0.002) and liver disease (2.5% vs 1.4%, p=0.139). Mortality was adjudicated as cardiovascular (CV) or not by an independent committee. Three-year all-cause mortality (HR: 31.9%, LR: 23.8%; p=0.002) and CV mortality (HR: 20.9%, LR: 12.8%; p<0.001) were higher in the HR group than the LR group.

CONCLUSIONS

In this large real-world European cohort of TAVI, a third of patients were at low surgical risk, but presented with specific comorbidities at baseline, such as previous chest radiation damage and liver disease. Despite this burden, LR patients had a CV mortality 40% lower than HR patients at three years follow up.

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New modified jailed balloon technique is very useful to prevent side branch occlusion after main vessel stenting in coronary bifurcation lesions.

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

Coronary bifurcation lesions are involved in approximately 15% of all PCI. A major complication of bifurcation PCI is side branch (SB) occlusion after main vessel (MV) stenting. SB occlusion may cause peri-procedural myocardial infarction or hemodynamic compromise, even if in small branch. In case two-stenting is not suitable, strategies to reduce the risk of SB occlusion during MV stenting are preferable.

METHODS AND RESULTS

Recently modified jailed balloon technique (MJBT) has gotten known for one of the strategies to reduce SB occlusion during MV stenting. But many of traditional MJBT need POT after stenting because of the stent malapposition in proximal MV. In our institution, we perform improved method in two points. First, we set SB balloon only a little protruded into MV. Second, stent is inflated three times. First two stent inflations are performed simultaneously with those of SB balloon. Then, stent balloon is inflated alone. These ingenuities safely reduce MV stent underexpansion and POT demand. We retrospectively evaluated the utility of our MJBT. Between January 2016 and December 2018, we picked out 311 patients (76.2% male, mean age 70.2 years) with 333 consecutive coronary bifurcation lesions underwent PCI. Among them, MJBT was used in 119 lesions, while MV stenting was performed only with SB wiring or no protection in others. Small SB (<1.5mm) cases were excluded. To investigate the SB occlusion rate according to the predicted risk, we divided all lesions to three ranges on the basis of the RESOLVE Score (JACC Cardiovascular interventions 2015; 8: 39-46, low-risk: 0-2, intermediate-risk: 3-9, high-risk: ≥10) and compared outcome in strategies with (MJBT group) or without (non-JBT group) MJBT at each risk range.SB occlusion was defined as no blood flow or any TIMI flow grade decrease in SB after MV stenting.All patients PCI and clinical data were followed during hospitalization. The majority of the patients had stable angina (73.9% in MJBT group, 60.7% in non-JBT group) and LAD-Diagonal lesions (67.2%, 60.7%). Distal left main (LM) coronary artery disease were contained in 17 patients (14.3%) and 26 patients (12.1%) respectively. Stent diameter (3.0±0.5 mm in MJBT group and 3.0±0.5 mmin non-JBT group, p=0.50) and length (23.9±8.0 mm and 24.4±7.4 mm, p=0.56) were similar. SB balloon diameterand length in MJBT group were 1.84±0.33 mm and 12.8±2.2 mm. All PCI procedures were complete. After MV stenting, no jailed SB balloon was entrapped. SB occlusion occurred in 35 (10.5%) of 333 bifurcation lesions. The SB occlusion rate in MJBT group (3 of 119, 2.5%) was significantly lower than in non-JBT group (32 of 214, 15.0%, p=0.001), whereas the RESOLVE score of MJBT group was higher than that of non-JBT group (9.1±4.8 vs 7.9±4.3, p=0.027). There was no SB occlusion was seen in both groups at low-risk range. At intermediate-risk range, no SB of 51 lesions was occluded after MV stenting in MJBT group, but 14 side branches of 119 lesions (11.8%) were occluded in non-JBT group (p=0.014). At high-risk range, SB occlusion rate in MJBT group (3 lesions, 5.1%) was lower than in non-JBT group (18 lesions, 24.3%, p=0.006).

CONCLUSIONS

Our new MJBT is a safe and easy procedure required little effort and time to prevent SB occlusion after MV stenting. It is useful especially for PCI to the bifurcation lesions predicted the intermediate or high risk of SB occlusion such as severe stenosis at bifurcation core or SB ostium, low MV TIMI flow grade.

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Mortality benefit of angiotensin-converting enzyme inhibitor therapy compared to angiotensin receptor blocker in patients with AMI undergoing contemporary PCI: a nationwide cohort study

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

The renin-angiotensin-aldosterone system plays an important role in the pathophysiology of atherosclerosis. However, there are limited studies comparing outcome data between therapy with angiotensin-converting enzyme inhibitors (ACEI) and angiotensin receptor blockers (ARB) after revascularization. This study sought to compare the clinical outcomes between ACEI and ARB therapy in patients with coronary artery disease (CAD) undergoing contemporary percutaneous coronary intervention (PCI).

METHODS AND RESULTS

Based on the National Health Insurance claims data in South Korea, patients aged 18 years or older who had undergone PCI for the diagnosis of CAD between 2011 and 2015 were enrolled. According to the discharge medications, patients were categorized into ACEI (n=25,542) and ARB (n=24,913) therapy groups. The study participants were also classified either as patients with angina or acute myocardial infarction (AMI). The primary endpoint, defined as a composite of all-cause death, was compared between the two groups using a propensity-score matching analysis. The study population had a median follow-up of 2.2 years (interquartile range, 1.2–3.2). In the propensity-score matched angina group (10,878 pairs), there was no signi?cant difference in the incidence of the primary endpoint between the ACEI and ARB groups (adjusted hazard ratio [aHR] of ACEI, 1.113; 95% confidence interval [CI]: 0.986–1.257; p=0.084). However, in the propensity-score matched AMI group (8,341 pairs), the occurrence of all-cause death was significantly lower in the ACEI group than in the ARB group (aHR, 0.823; 95% CI: 0.715–0.947; p=0.006).

CONCLUSIONS

In this nationwide Korean cohort study, medical therapy with ACEI or ARB led to similar clinical outcomes in patients with angina. However, ACEI therapy showed reduced mortality rates in patients with AMI when compared to that with ARB therapy.

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Clinical impact of low-flow, low-gradient aortic stenosis after TAVI: an insight from long-term follow-up

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Low-flow, low-gradient aortic stenosis with reduced ejection fraction (LEF-LG AS) and paradoxical low-flow low-gradient aortic stenosis (PLF-LG AS) are often recognized in patients with severe aortic stenosis, however, long-term outcomes of these conditions are undetermined. The purpose of this study is to elucidate the long-term prognosis of the LEF-LG AS and PLF-LG AS following transcatheter aortic valve implantation (TAVI).

METHODS AND RESULTS

We retrospectively analyzed consecutive 575 patients undergoing TAVI between October 2013 and August 2018 in Sakakibara Heart Institute. All patients fulfilled the criteria of severe aortic stenosis (aortic valve area < 1.0 cm2). LEF-LG AS (n=33) was defined as mean pressure-gradient < 40 mmHg with ejection fraction < 50%, whereas PLF-LG AS (n=101) was defined as mean pressure-gradient < 40 mmHg with ejection fraction > 50%. High-gradient aortic stenosis (HG AS) (n=441) was defined as mean pressure-gradient > 40 mmHg. Average follow-up period was 757 days. LEF-LG AS had greater incidence of New York Heart Association (NYHA) class3/4 ($p < 0.001$), coronary artery disease ($p < 0.001$), peripheral artery disease (p=0.006), implanted rhythmic device (p=0.035), lower value of serum albumin ($p < 0.001$), and body mass index (p=0.02), compared with the other two groups. Baselines characters of PLF-LG AS were equal to that of HG AS except aortic valve area (p=0.001). As for procedural factors, LEF-LG AS had fewer transfemoral approach than HG AS, but the frequencies of general anesthesia, second-generation valve used and device success were comparable between three groups. In long-term survival, LEF-LG AS was significantly worse than HG AS (one-year: 84.7% vs. 94.8%; two-year: 66.4% vs. 91.0%, p=0.005), whereas PLF-LG AS was equivalent to HG AS (one-year: 91.8% vs. 94.8%; two-year: 87.6% vs. 91.0%, p=0.33). Among baseline and procedural factors, NYHA3/4 (HR 4.54, 95%CI 1.66-12.4), chronic obstructive pulmonary disease (HR 3.93, 95%CI 1.56-9.88), and albumin value (HR 0.44 per 1g/dl, 95%CI 0.20-0.98) were independent predictors of mortality, but LEF-LG (HR 0.93, 95%CI 0.27-3.15) was not.

CONCLUSIONS

The long-term outcome of LEF-LG AS was worse than HG AS, and it should be attributed to much comorbidities of LEF-LG AS. The backgrounds and outcomes of PLF-LG AS were identical to HG AS.

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Incidence, risk factors and outcome of post-operative delirium after TAVR

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

The aim of the present study was to analyze incidence, risk factors, and in-hospital outcomes of postoperative delirium after transcatheter aortic valve replacement (TAVR).

METHODS AND RESULTS

661 consecutive patiens undergoing TAVR were prospectively enrolled from January 2016 to December 2018. Postoperative delirium was assessed regularly during ICU-stay using the CAM-ICU test.

The incidence of delirium was 10.0% (n=66). Patients developing delirium were predominantly male (65.2%; P=0.006), had higher EuroSCORE II (5.4% vs. 3.9%; P=0.041) and were more often considered frail (essential frailty toolset score 2.9 vs. 2.0; P<0.001). In addition, the rate of chronic kidney disease (baseline creatinine 1.55 vs. 1.30 mg/dl; P=0.040) and atrial fibrillation (68.2 vs. 39.8%; P<0.001) was significantly higher. Patients with delirium had undergone TAVR more often under general anesthesia instead of conscious sedation (72.7 vs. 54.1%; P=0.004)

Postoperative delirium was associated with more periprocedural complications including vascular complications (19.7 vs. 9.4; P=0.017), bleeding (12.1 vs. 5.4%; P=0.050); stroke (4.5 vs. 0.7%; P=0.025), respiratory failure requiring ventilation (16.7% vs. 1.8%; P<0.001), acute kidney injury (all stages: 16.6 vs. 5.9%; stage 2 and 3: 6.0% vs. 2.5%; P=0.009), pneumonia (34.8% vs. 7.1%; P<0.001) and antibiotic treatment (45.5 vs. 15.0%; P<0.001). Consequently, patients with delirium had significantly longer ICU- (7.9 vs. 3.2 days P<0.001) and hospital-stay (14.9 vs. 9.0 days; P<0.001), and higher in-hospital mortality (6.1 vs. 2.1%; P=0.017).

Cox proportional hazard analysis identified male sex (hazard ratio (HR) 2.5 (95% confidence interval (CI) 1.4 – 4.4); P=0.002), pneumonia (HR 6.6 (CI 3.5 – 12.4); P<0.001), vascular complication (HR 2.8 (CI 1.2 – 6.1); P=0.014), and general anesthesia (HR 2.3 (CI 1.2 – 4.2); P=0.009) as independent predictors of delirium.

CONCLUSIONS

Postoperative delirium is a frequent finding after TAVR and associated with increased in-hospital mortality. Male sex, pneumonia, vascular complication and general anesthesia are predictors of delirium. The impact of delirium on late mortality has to be elucidated.

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Predictors of long-term mortality and hospital re-admission after TAVR

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Aim of this study was to identify predictors of late mortality and hospital readmission after transcatheter aortic valve replacement (TAVR).

METHODS AND RESULTS

Predictors of late mortality and hospital readmission within one year after TAVR were analyzed in 835 patients undergoing TAVR at a German high volume center between January 2013 and August 2016. Clinical outcomes were evaluated according to the VARC-2 criteria.

Mean age was 81.5±6.2 years, 51% of patients were female and had an intermediate- to high risk for conventional surgery expressed by an EuroSCORE I of 18.6±14.1% and relevant comorbidities including COPD (21.8%), peripheral artery disease (PAD; 26.7%), Diabetes mellitus (32.4%), hypertension (914%), hyperlipidemia (56.0%), pulmonary hypertension (58.7%) and atrial fibrillation (46.8%). 23.0% underwent previous cardiac surgery. Baseline creatinine was 1.35±0.88 mg/dl. Rates of vascular complications were 10.1% (major 3.0%), bleeding 11.1% (life-threatening 2.9%) and stroke 2.3%.

30-day, 1-year and 2-year mortality was 5.3%, 18.0% and 29.3%, respectively. Cox proportional hazard analysis identified male sex (hazard ratio (HR) 1.47 (95% confidence interval (CI) 1.10 – 1.96); P=0.009), baseline creatinine (HR 1.24 (CI 1.12 – 1.38); P<0.001), COPD (HR 1.61 (CI 1.18 – 2.20); P=0.003), atrial fibrillation (HR 1.48 (CI 1.11 – 1.96); P=0.007), insulin-dependent diabetes mellitus (HR 1.46 (CI 1.01 – 2.10); P=0.043), and life-threatening bleeding (HR 4.74 (CI 2.25 – 9.97); P<0.001) as independent predictors of mortality.

1-year hospital readmission rate was 24.1%. Cox proportional hazard analysis identified baseline creatinine (HR 1.24 (CI 1.08 – 1.44); P=0.003), moderate/severe mitral regurgitation (HR 1.91 (CI 1.29 – 2.82); P=0.001), and PAD (HR 1.61 (CI 1.10 – 2.36); P=0.015) as independently associated with hospital readmission.

CONCLUSIONS

Apart from life-threatening bleeding, long-term outcome and hospital readmission after TAVR is mainly determined by baseline comorbidities.

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Prevalence of transthyretin and immunoglobulin light chain cardiac amyloidosis in patients undergoing TAVR

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

A significant number of aortic stenosis (AS) patients suffer from coexisting cardiac amyloidosis (CA). Only transthyretin (TTR) CA has so far been described in AS although immunoglobulin light chain (AL) is the most common CA form. The present study evaluated the prevalence of TTR- and AL-CA in AS patients scheduled for transcatheter aortic valve replacement (TAVR).

METHODS AND RESULTS

200 consecutive patients (80.8±8.1 years; 48.8% female) were screened for CA between October 2017 and December 2018 and were prospectively enrolled. Patients underwent echocardiography with strain analysis, ECG, cardiac magnetic resonance imaging (CMR), 99mTc-DPD bone scintigraphy, and serum and urine free light chain assessment. Myocardial biopsy was performed in AL-CA.

CA was found in 10.6% (n=19) of patients, including TTR-CA (n=17) and two cases of AL-CA. By CMR, extracellular volume (ECV) and native T1 relaxation time did not differ significantly between AS and CA-AS patients (P for both>0.05), and typical patterns of late gadolinium enhancement were only present in 26.8% of CA. In addition, no significant differences were found with respect to relative apical longitudinal strain on echocardiography between patients with and without CA [median, 0.90 (IQR 0.77-1.12) vs. 0.80 (IQR 0.72-0.93); P=0.094]. Furthermore, characteristic ECG features were not different between groups [Sokolow Index: 1.95mV (IQR 1.23-2.49) in CA-AS vs. 2.20mV (IQR 1.60-2.86); P=0.314; voltage/mass ratio: 0.014 mV/g/m2 (0.009-0.019) vs. 0.016 mV/g/m2 (0.012-0.023); P=0.107].

CONCLUSIONS

Comprehensive screening for CA in AS patients scheduled for TAVR revealed 10.6% of patients with concomitant CA. While 90% of CA cases were affected by TTR-CA, 10% were found to suffer from AL-CA. Screening modalities should be regarded as complementary, since characteristic diagnostic features of CA and AS overlap. As AL-CA overall is the most frequent form of CA, its prevalence in younger, intermediate- or low-risk patients scheduled for TAVR or surgery for AS has yet to be defined.

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QRS score: a simple marker to quantify the extent of myocardial scarring in patients with chronic total arterial occlusion

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

The Selvester QRS score is used to quantify myocardial scarring and delayed gadolinium enhanced cardiovascular magnetic resonance imaging (LGE-CMR) is used as the golden standard to explore the correlation between these two methods to provide a simple and feasible method for the treatment of chronic total occlusion (CTO).

METHODS AND RESULTS

The medical records of 134 patients with absolute CTO who underwent coronary angiography at the First Affiliated Hospital of Dalian Medical University from May 1, 2014 to December 30, 2017 were retrospectively reviewed. All patients underwent cardiac magnetic resonance imaging. A total of 62 patients who met the inclusion criteria were included for analysis. Among these patients, 26 had a history of myocardial infarction, while four had twice or more episodes. Six patients had abnormal Q waves with no clinical symptoms. All patients were assigned to one of four groups according to the CTO location (RCA CTO group, LAD CTO group, LCX CTO group, and multi-vessel CTO group). All patients underwent standard 12-lead electrocardiography to determine the Selvester QRS score. The degree of myocardial scarring was determined according to the Selvester QRS score and LGE-CMR. All patients were followed up for at least 12 months. Of the 62 CTO patients, 55 had occlusion of a single vessel and seven had occlusion of multiple vessels, of which 28 (50.9%) were in the RCA CTO group, 14 (25.4%) in the LAD CTO group, 13 (23.6%) in the LCX CTO group, and 7 (11.29%) in the multi-vessel CTO group. The area under the receiver operating characteristic curve for the QRS score was 0.806, with a sensitivity of 94.7% and specificity of 42.1%. Selvester QRS score and LGE-CMR measures of scar size were correlated in the RCA CTO group, LCX CTO group, and multi-vessel CTO group (r = 0.466, 0.593, 0.775, respectively). Major adverse cardiac events occurred in 10 (16%) patients and 2 (3%) patients died during the follow-up period.

CONCLUSIONS

The Selvester QRS score is feasible to detect myocardial scarring in CTO patients and is much easier and cheaper than LGE-CMR.

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Routine histological analysis of debris from cerebral protection device Sentinel during TAVI procedure

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Major ischemic strokes during TAVI are found in 2-3% of patients. However, minor and micro-strokes are very frequent (according to studies using MRI). Our study focused on a micro-analysis of debris captured during TAVI by the Sentinel (Claret Medical, now Boston Scientific) protection device.

METHODS AND RESULTS

Cerebral protection was used in 34 patients with severe aortic stenosis undergoing TAVI implantation over the last two years (self-expanding valve via transfemoral approach in all cases). From those, 26 cerebral protection cases (52 baskets) were sent for histological analysis: 16 baskets (30.7%) contained no m terial; in 22 patients (84.6%), at least one basket was found with captured material; in 14 patients (53.8%) in both baskets. Captured material was found equally in the proximal basket (17, 47.2%) and the distal one (19, 52.8%). The type of tissue found in baskets were as follows: fibrous (69%), calcification (13%), blot clot (8%), cholesterol crystals (5%), valve structure (5%). Maximal diameter of found debris was 3.2 mm (mean 0.98 mm).

CONCLUSIONS

The routine use of Sentinel cerebral protection is an efficient method for the prevention of brain embolization caused by tissue from the aortic wall and aortic valve. Cerebral protection can decrease microembolization - apparently frequent during the TAVI procedure - and decrease brain damage, which contributes to post-procedural delirium and a reduction of mental capacity in patients undergoing TAVI procedure.

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The effect of body mass index on prognosis after TAVI in Japanese population: a clinical impact of underweight

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

The obesity paradox in transcatheter aortic valve implantation (TAVI) has been reported in western population, however, most studies included a small number of underweight patients. We hypothesize the underweight, which are not uncommon in Japanese population, has worse outcome than the others following TAVI.

METHODS AND RESULTS

We retrospectively analyzed consecutive 575 patients who had undergone TAVI from October 2013 to April 2018. The body mass index (BMI) is defined as the weight in kilograms divided by the square of the height in meters. Patients were classified according to their BMI into three groups according to the World Health Organization criteria: underweight (<18.5 kg/m2; n=78 [14%]), normal-weight (18.5-24.9 kg/m2; n=366 [64%]), and overweight (≥ 25 kg/m2; n=131 [23%]). Compared with the other two groups, the underweight group included more female (underweight vs. normal-weight vs. overweight: 85% vs. 67% vs. 73%, p=0.006) and comorbidities, including malnutrition (serum albumin: 3.7±0.5 vs. 3.8±0.4 vs. 3.9 ±0.4 g/dl, p=0.008), anemia (hemoglobin: 11.1±1.3 vs. 11.7±1.4 vs. 12.1±1.6 g/dl) and peripheral artery disease (26% vs. 15% vs. 6.1%, p=0.0004). As for procedural characteristics, there were more non-transfemoral approach (22% vs. 9.0% vs. 7.6%, p=0.002), first generation valves (47% vs. 29% vs. 28%, p=0.007), and lower rate of device success (90% vs. 97% vs. 99%, p=0.0006) in the underweight group. The long-term prognosis of underweight was worst (freedom from all-case mortality at one-year and two-year: 83.5% and 73.5% vs. 94.7% and 90.4% vs. 97.5% and 93.4%, p=0.0096), and multivariate analysis detected underweight as independent predictor of mortality (HR 2.02, 95%CI 1.13-3.62).

CONCLUSIONS

14% of patients undergoing TAVI met the criteria of underweight. The presence of underweight has negative impact on long-term survival after TAVI.

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Device motion indication guidance improves clinical outcomes during implantation of coronary stents

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Geographical miss denotes a sub-optimally deployed coronary stent, associated with a higher incidence of MACE. The hearts` cyclic movement dictates relative axial movement between the coronaries and the pre-deployed devices with potential for their mal-positioning. Applying our previously described device motion indication (DMI) feature (1), we used the simultaneously measured relative coronary segment displacement aiming to optimize stent length and coverage.

METHODS AND RESULTS

Balloon assisted lesion preparation was our default approach. Using the DMI feature of the SyncVision System we objectively obtained device (balloon) movement measurement (DMM) at the different coronary artery segments. The instantaneously available DMM was translated into extra stent length, aiming to neutralize the impact of device displacement on GM. A total of 193 patients underwent PCI with the system support. 218 branch point sites were identified. Applying DMM coupled stent deployment strategy our one-year TLR rate was 2.2% with TVR occurring in 6 patients (2.75%).

CONCLUSIONS

Relative device displacement is a potential contributor to GM. Adopting this simple, yet valuable strategy our clinical endpoints were comparable to the no geographical miss arm in the STLLR study (2).

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Percutaneous transcatheter pulmonary valve implantation in right ventricular outflow tract dysfunction in adult congenital heart disease

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THEME: Interventions for Valvular Disease
TOPIC(S): Tricuspid / Pulmonary valve

AIMS

Transcatheter pulmonary valve replacement (tPVR) is emerging as a viable alternative to surgical replacement in right ventricular outflow tract (RVOT) dysfunction. The Melody® valve has previously demonstrated good clinical outcomes but is limited due to its narrow profile. The Edwards Sapien S3 may offer an alternative with a larger profile for the adult congenital heart disease patient. There is limited data describing the use of the Edwards Sapien S3 in tPVR for RVOT dysfunction.

METHODS AND RESULTS

We conducted a retrospective, observational analysis of all patients who underwent tPVR with the Edwards Sapien S3 for RVOT dysfunction at our institution. Patients were routinely followed-up on day one, 1-, 6-, 12-months with transthoracic echocardiogram.

Four patients underwent TPVI with the Edwards Sapien S3 transcatheter valve between August 2017 and February 2018 with a median age of 40 years (R: 34-46) . Baseline congenital conditions were: repaired Tetralogy of Fallot (n=3) and Rastelli repair of Transposition of the Great Arteries (n=1). Indication for TPVI was severe pulmonary stenosis (n=2), and severe pulmonary regurgitation (n=2). In patients with pulmonary stenosis, mean and peak pressure gradients were 89mmHg and 53mmHg respectively and reduced to 36mmHg and 22mmHg on day one. In patients with pulmonary regurgitation mean baseline pulmonary regurgitation was 4/4 and right ventricular end-diastolic dimension (RVEDD) was 4.5cm, this improved to 0/4 and 3.1cm at follow-up. All patients are alive to date and there were no VARC-2 defined procedural complications. One patient developed ventricular tachycardia intraoperatively, requiring cardioversion.

CONCLUSIONS

Our data demonstrates safety and feasibility of tPVR with Edwards Sapien S3 for RVOT dysfunction in repaired congenital heart disease.

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Primary PCI in STEMI with an ectatic infarct-related artery

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

The aim of the study was to describe procedural characteristics, myocardial perfusion and long-term outcomes in ST elevation myocardial infarction patients with an ectatic infarct-related artery (IRA).

METHODS AND RESULTS

The retrospective analysis included 1270 consecutive STEMI patients treated by primary percutaneous coronary intervention which were categorized according to the coronary anatomy of the infarct related artery in: ectatic group (n=91) and control group (n=1179).

Compared to the control group, patients in the ectatic group experienced lower Thombolysis in myocardial infarction grade 3 flow rate after PCI (64.8% vs 88.2% [ectatic group vs non-ectatic group], p<0.001) and more frequent distal embolization (44.4% vs 11.1, p<0.001). ECG ST resolution was significantly lower in the ectatic group (p<0.001). Paradoxically, the left ventricular ejection fraction values at discharge were significantly higher in the ectatic group (p=0.032) and the infarct size assessed within 6 to 12 months after discharge tended to be smaller (p=0.06). The 30-day mortality rate was not significantly different between two groups (3.3% vs 5.0%, p=0.378) as well as Kaplan–Meier analysis for long-term overall survival in both groups (p=0.8).

CONCLUSIONS

Patients with ectatic infarct related artery were characterized by discrepancies between high angiographic thrombus burden in a larger vessel and impact on left ventricular function which may influence their long term survival.

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Gender differences in platelet reactivity in diabetic patients receiving DAPT

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Increased comorbidities and a perceived high-bleeding risk often prevent the use of dual antiplatelet therapy (DAPT) in female patients. However, more aggressive antithrombotic treatment would certainly offer additional outcome benefits in coronary artery disease, especially among diabetic patients. Aim of the present study was to evaluate the gender differences in high-residual on treatment platelet reactivity (HRPR) among diabetic patients treated with DAPT.

METHODS AND RESULTS

Our population is represented by a consecutive cohort of diabetic patients treated with DAPT (ASA + clopidogrel or ticagrelor or dose-adjusted prasugrel) for an acute coronary syndrome or elective PCI, undergoing platelet reactivity assessment at 30-90 days post-discharge Aggregation was assessed by multiple-electrode aggregometry. HRPR was defined for values above the lower limit of normality (in non-treated patients). In addition, in diabetic patients naïve to antiplatelet therapy, baseline platelet reactivity was assessed by light transmission aggregometry, surface expression of P-selectin and plasma concentration of Thromboxane B2 (TxB2).

We included 472 patients, among them 113 (23.9%) were women. Female gender was associated with more advanced age, lower body size and rate of acute coronary syndromes at presentation (p<0.001). Female gender related with the rate of renal failure (p=0.01), use of diuretics (p=0.03), insulin (p=0.02) and previous myocardial infarction (p=0.03), HDL and LDL cholesterol levels (p<0.001 and p=0.001), and inversely with platelet count (p=0.008) and hemoglobin (p<0.001). Mean platelet reactivity did not differ according to gender. The rate of HAPR was low and not affected by gender (p=0.14, adjusted OR[95%CI]= 0.59[0.27-1.33], p=0.21). HRPR for ADP antagonists was similar in women as compared to men (p=0.91, adjusted OR[95%CI]=1.24[0.25-1.80], p=0.27). Similar results were obtained when considering separately the DAPT strategies with clopidogrel, or new ADP antagonists (ticagrelor or prasugrel), however, the benefits of the new ADP-antagonists on platelet reactivity were lower in women than in men (p interaction=0.01).

Among 50 diabetic patients naïve to antiplatelet therapy, (38% females) we observed no impact of gender on platelet aggregation at light transmission aggregometry, after collagen stimulation (p=0.12), and neither for the increase in surface expression of P-selectin (p= 0.08) or plasma concentration of Thromboxane B2 (p=0.97).

CONCLUSIONS

Among diabetic patients receiving dual antiplatelet therapy for an acute coronary syndrome or elective percutaneous coronary intervention, gender does not affect platelet reactivity or the rate of high-on treatment platelet reactivity. However, a significant interaction was observed with the type of antiplatelet drug, with the benefits of new-ADP antagonists being mitigated in women.

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Clinical outcomes following balloon aortic valvuloplasty

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THEME: Interventions for Valvular Disease
TOPIC(S): Other valvular and structural interventions

AIMS
Balloon aortic valvuloplasty (BAV) remains a treatment option for selected patients with severe aortic stenosis. The most common indications are palliation or as bridging to definitive intervention, either due to clinical instability or uncertainty around potential symptomatic benefit. We examined the clinical outcomes and risk factors associated with mortality in patients undergoing BAV for severe aortic stenosis at a high-volume TAVI centre.

METHODS AND RESULTS
Patient demographics, cardiac catheterisation and echocardiography data were extracted from routinely collected data in all patients undergoing BAV from January 2010 to March 2018 (n=167). Clinical outcomes were obtained from linkage with the Scottish Morbidity Record (SMR01), Information Services Division, Scotland.

Patients undergoing BAV were elderly (median 80, interquartile range [IQR] 73 – 86 years) and half (n=87, 52%) were male. Left ventricular ejection fraction was reduced in 103 (61%) patients and the median aortic valve mean gradient was 41 (IQR 31 – 49) mmHg. BAV was performed as an urgent procedure in 93 patients (56%).

Median follow-up was 11.1 (IQR 3.5 – 27.5) months from the index procedure. All-cause mortality at 30-days was 11% (n=18). All-cause mortality at 12 months was 43% (n=72) with a median time to death of 212 (IQR 54 – 490) days. Cox regression models were constructed for mortality as the primary outcome with age, sex, hypertension, diabetes, ischaemic heart disease, chronic lung disease, chronic kidney disease, ejection fraction and procedure urgency as the independent variables. Ejection fraction was the only variable independently associated with overall mortality (hazard ratio [HR] 1.8, 95% confidence interval [CI] 1.1 – 3.0 for ejection fraction 30-50%; HR 2.0, 95%CI 1.2 – 3.3 for ejection fraction <30%).

Symptomatic status post-BAV was available in 120 patients. Seventy-five (63%) patients reported symptomatic improvement. Multivariable logistic regression analysis did not identify any independent clinical factors associated with symptomatic improvement.

Repeat intervention was performed in 67 (40%) patients. Nine patients underwent BAV, 42 underwent TAVI and 16 underwent high-risk surgical AVR. Compared to patients who underwent no further intervention, mortality at 1 year was lower in patients who underwent TAVI or surgical AVR following the index BAV but not amongst those who underwent repeat BAV (62%, 10%, 19% and 67% respectively, log-rank test p<0.001). The median time to death from repeat intervention in patients undergoing a second BAV was 37 (IQR 26 – 178) days. There were no differences in survival following repeat intervention after stratification by symptomatic improvement.

CONCLUSIONS

Balloon aortic valvuloplasty as a bridge to definitive aortic valve intervention in patients with severe aortic stenosis is a reasonable clinical option in appropriately selected patients. In contrast, isolated BAV relieved symptoms in two-thirds of patients, while repeated BAV did not improve survival compared to no repeat intervention. These findings are observational but may inform clinician-patient discussions regarding the clinical balance of risks and benefits of BAV in this setting.

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Relationship between adenosine A2a receptor polymorphism rs5751876 and FFR during PCI

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THEME: Coronary Interventions

TOPIC(S): Stable CAD, Other Coronary Interventions

AIMS

Fractional flow reserve (FFR) assessed during adenosine-induced maximal hyperaemia has emerged as a useful tool for the guidance of percutaneous coronary interventions (PCI). However, genetic variants of the adenosine receptor A2a (ADORA2A gene), could modulate the hyperemic response and account for the interindividual variability in the effect of adenosine. However, no study has so far evaluated the impact of the single nucleotide polymorphism rs5751876 of ADORA2A on the measurement of FFR in patients undergoing percutaneous coronary intervention, that was therefore the aim of our study.

METHODS AND RESULTS

We included patients undergoing coronary angiography and FFR assessment for intermediate (40 to 70%) coronary lesions. FFR measurement was performed by pressure-recording guidewire (Prime Wire, Volcano), after induction of hyperemia with intracoronary boli of adenosine (from 60 to 1440 µg, with dose doubling at each step). Restriction fragment length polymorphism (RFLP) analysis was performed to assess the presence of rs5751876 C>T polymorphism of ADORA2a receptor.

We included 204 patients undergoing FFR measurement of 231 coronary lesions. A total of 134 of them carried the polymorphism (T allele), of whom 41 (30.6%) in homozygosis (T/T). Main clinical and angiographic features did not differ according to ADORA2A genotype. The rs5751876 C>T polymorphism did not affectmean FFR values (p=0.91), the percentage of positive FFR (p=0.34) and the duration of maximal hyperemia. However, the time to recovery to baseline FFR values was more prolonged among the T-allele carriers as compared to wild-type patients (p=0.04).

CONCLUSIONS

In patients with intermediate coronary stenoses undergoing FFR assessment with adenosine, the polymorphism rs5751876 of ADORA2A does not affect the peak hyperemic response to adenosine and the results of FFR. However, a more prolonged effect of adenosine was observed in T-carriers.

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Clinical experience with a novel large bore vascular closure device

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Transfemoral TAVR is a consistently increasing treatment option. However, vascular complications still remain a significant procedural risk factor and are predominantly attributed to vascular closure device failures. This is the first report on the clinical experience with the new InClosure vascular closure device (VCD) following the CE mark approval.

METHODS AND RESULTS

In 41 patients undergoing transfemoral TAVR, closure of the large bore puncture site was achieved by implantation of the InClosure VCD, an intravascular closure device based on a biodegradable membrane supported by a nitinol frame. A variety of currently available transcatheter heart valves systems and introducer sheaths were used. Time to hemostasis, perioperative bleeding and vascular complications were reported and postoperative Doppler ultrasound studies were evaluated.

5 Acurate neo valves (Lotus S sheath), 10 sapien 3 size 23/26 (14 Fr. eSheath), 6 Sapien 3 size 29 (16 Fr. eSheath), 8 Evolut R 23-29 (14 Fr. Cook), 11 Evolut R 34 / Evolut PRO (16 Fr. CooK) and one Evolut PRO (20 Fr. Cook) transcatheter heart valves were implanted using the specified delivery sheaths. In 40/41TAVR patients, mean age 80.4 + 6,6 years and mean sheath to femoral artery ratio (SFAR) 0.8 (range 0.67-1.02), the InClosure VCD was implanted successfully. Mean time of primary hemostasis was 66 + 102 seconds. Intraoperative angiography confirmed hemaostasis and absence of vessel stenosis at the puncture site in all cases. No VARC-2 defined major bleeding or major vascular complication occured. One VCD failed to anchor at puncture site for puncture-related femoral artery dissection leading to stent-graft implantation. In the remaining 40 patients four minor vascular complications, two pseudoaneurysms and two hematomas were recorded (10%). The two access site haematomas and one case with prolonged time to hemostasis counted for three minor bleeding complications (7.3%) according to VARC-2 criteria. Doppler ultrasound studies before discharge excluded stenosis in all access site vessels.

CONCLUSIONS

The novel InClosure VCD seals large-bore puncture holes up to 24 French promoted by an intravascular biodegradable membrane supported by a nitinol frame. This first single center experiences with the novel InClosure VCD demonstrates a reliable implantation of the VCD. In the study, VCD promoted hemostasis was achieved in 40/41 cases without VARC-2 defined major bleeding or major vascular complications. The VCD is compatible with all commonly used implantation sheaths for the currently available transcatheter heart valve systems. The new and innovative vascular closure device has the potential to reduce the rate of vascular complications in TAVR procedures.

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Mid-to-long-term clinical outcomes of PCI using new-generation DES in coronary artery disease patients with lesions featuring moderate-to-severe calcification: five-year results of CENTURY II randomised controlled trial substudy

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Coronary calcification is an independent predictor of major cardiac adverse outcomes following PCI. Here, we compared the mid-to-long term safety and efficacy of a new-generation bioresorbable polymer sirolimus-eluting stent (BP-SES) to a permanent polymer everolimus-eluting stent (PP-EES), in a subgroup of CENTURY II RCT patients featuring moderate-to-severe calcification.

METHODS AND RESULTS

CENTURY II is a randomised, multicentre study with 1119 enrolled patients (intention-to-treat), of which 248 presented with at least one moderately-to-severely calcified target-lesion. Patients underwent PCI with new-generation DES (137 BP-SES (Ultimaster) or 111 PP-EES (Xience)). The primary endpoint of this study was target lesion failure (TLF) at 9 months in the total study population, defined as a composite of cardiac death, target vessel-related myocardial infarction (TV-MI) and clinically-driven target lesion revascularization (CD-TLR). The source data was 100% monitored and an independent clinical events committee adjudicated all major adverse cardiac events. 9-months and 5-year follow up outcomes of CENTURY II total study population have already been published.

In the present substudy mean patient age was 69 years in both groups. The PP-EES arm featured more male patients 75.9% vs 86.5%; p=0.04, while BP-SES group displayed higher rate of dyslipidaemia 79.4% vs 68.2%; p=0.045 and more previous smokers 54.1% vs 40.7; p=0.04. Remaining baseline patient characteristics were majorly equal. Rate of high-risk ACS -including STEMI and NSTEMI cases- was similar in BP-SES vs PP-EES (15.3% vs 16.2%; p=0.85, respectively). Silent ischemia was more prevalent in PP-EES arm (16.1% vs 29.7%; p=0.01). Both groups had equal rates of multivessel disease patients 50.4% vs 51.4; p=0.88 and similar mean Syntax score 12.7±8.5 vs 12.7±6.8; p=0.62. No difference in access site preference was noted between the compared groups, with radial artery approach being the most often utilized in this study (65%). 25% of all target-lesions were severely calcified, while B2/C type comprised 95.3% vs 97.2%; p=0.44 of all target-lesions in BP-SES vs PP-EES arm, respectively. Number of treated lesions per patient (1.5±0.8 vs 1.4±0.6; p=0.14) and a total implanted stent length per patient (36.1±20.5 vs 36.8±23.1; p=0.95) were equal in BP-SES and PP-EES arms.

At 1- and 5-year follow-up, no significant differences were noted between the BP-SES and PP-EES in any of the major clinical outcomes. The rates of all death were 2.2% vs 3.6%; p=0.50 at 1-year and 10.2% vs 10.8%; p=0.88 at 5-years, respectively. The incidence of cardiac death was 1.5% vs 2.7%; p=0.49 at 1-year and 3.7% vs 5.4%; p=0.51 at 5-years. TV-MI rate was 4.4% vs 4.5%; p=0.96 at 1-year and remained unchanged in both groups up until 5-years. CD-TLR was 5.8% vs 5.4%; p=0.88 at 1-year and 9.5% vs 9.0; p=0.90 at 5-years. Composite endpoint of TLF amounted to 9.5% vs 10.8%; p=0.73 at 1-year and 15.3% vs 16.2%; p=0.85 at 5-years. The rate of stent thrombosis (definite and probable) was 2.2% vs 2.7% p=0.79 at 1-year and 2.9 vs 2.7%; p=0.91 at 5-years.

CONCLUSIONS

This substudy of the CENTURY II RCT demonstrates excelent and comparable mid-to-long term safety and efficacy performance of the two studied new-generation DES, in a complex patient population featuring moderately-to-severely calcified lesions. The reported data, however, is only hypothesis-generating and its confirmation warrants an additional dedicated trial.

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Sex-specific differences in outcomes of TAVI

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Differences in baseline characteristics and anatomy between female and male patients with aortic valve stenosis may influence outcomes after transcatheter aortic valve implantation (TAVI). Female gender has been linked to increased risk of periprocedural adverse events which contrasts with paradoxically more favorable long-term outcomes. We sought to evaluate baseline characteristics and anatomy between female and men and the effect of gender on in-hospital and 1-year survival after TAVI.

METHODS AND RESULTS

Our retrospective monocentric study included 652 consecutive patients (343 women, 52.6%) with severe, symptomatic aortic stenosis who underwent TAVI from January 2010 to July 2017. Women were likely to be older (84 years versus 81 years, $p < 0.0001$) with lower rate of known coronaropathy (38.5% versus 61.8%, $p < 0.0001$), peripheral arteriopathy (6.7% versus 19.4%, $p < 0.0001$), past cardiac surgery (11.1% versus 21.0%, $p = 0.001$) and COPD (8.7% versus 24.9%, $p < 0.0001$). Ilio-femoral severe tortuosity and calcifications attested by computed tomography were more frequent in men group, while ilio-femoral vessel diameter < 7 mm in women group (49.7% versus 30.4%, $p < 0.0001$). The 30-day mortality was not significantly different between women (7.6%) and men (7.4%) group, $p = 0.947$. During the postoperative course, women experienced more frequent hemopericardia (11.4% versus 6.1%, $p = 0.019$) but Valve Academic Research Consortium-2 major vascular complications (18.1% versus 13.3%, $p = 0.093$) and major bleeding composite criteria (Bleeding Academic Research Consortium type 3b, 3c and 5) (17.8% versus 14.9%, $p = 0.319$) didn't significantly differ between the two groups. The primary Valve Academic Research Consortium-2 efficacy composite criteria (mortality, stroke, myocardial infarction, hospitalization for valve-related symptoms or heart failure beyond 30 days) occurred in 97 (28.3%) in women and 82 (26.5%) in men, $p = 0.619$. The incidence of 1-year all-cause mortality was 16.6% (n=57) in women and 23.9% (n=74) in men group, $p = 0.02$. After multivariate analysis, the only independent predictors of 1-year all-cause mortality were acute heart failure at admission (adjusted hazard ratio [HR] 1.75, 95% confidence interval [CI] [1.21 to 2.54], $p = 0.003$), femoral access (adjusted HR 0.67, 95% CI [0.46 to 0.99], $p = 0.044$) and first generation devices (adjusted HR 2.29, 95% CI [1.47 to 3.57], $p < 0.0001$) but not female gender (adjusted HR 0.76, 95% CI [0.53 to 1.11], $p = 0.155$).

CONCLUSIONS

In conclusion, the 1-year all-cause mortality was lower in women after TAVI in this large cohort of patients, with relatively similar in-hospital outcomes. After multivariate adjustment, initial acute heart failure, femoral access and first-generation devices was the independent predictors of 1-year all-cause mortality but not gender.

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Clinical outcomes at two years of the Absorb BRS vs. the Xience metallic DES in patients presenting with ACS vs. stable coronary disease - AIDA trial substudy

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

Patients with acute coronary syndrome (ACS) might represent a specific subgroup, in which bioresorbable scaffold implantation in percutaneous coronary intervention, might lead to better outcomes when compared to conventional treatment. ACS patients (STE-ACS patients in particular) are generally younger, and most often have lesions with softer plaques, a lower plaque burden and less extensive coronary artery disease. In this pre-specified subgroup analysis of the AIDA trial, we evaluated the clinical outcomes of Absorb BVS versus Xience EES treated patients presenting with or without ACS.

METHODS AND RESULTS

This analysis includes the 2-year outcomes of all 1845 patients randomized in the AIDA trial subdivided by clinical presentation, a pre-specified subgroup analysis. We compared patients presenting with ACS with those presenting without ACS (ACS versus no-ACS patients). Patients presenting with ACS were further sub-categorized according to the presence or absence of ST-segment elevation at presentation (STE-ACS versus NSTE-ACS patients). Baseline status by clinical presentation was known in all patients, and 842 (45.6%) patients presented with ACS, 456 (25.2%) with STE-ACS and 377 (20.4%) with NSTE-ACS.The rate of the 2-year primary endpoint of target vessel failure (TVF) was similar after treatment with Absorb BVS or Xience EES in ACS patients (10.2% versus 9.0% respectively; p=0.49) and in no-ACS patients (11.7% versus 10.7% respectively; p=0.67) Definite or probable device thrombosis occurred more frequently with Absorb BVS compared to Xience EES in ACS patients (4.3% versus 1.7% respectively, p=0.03) as well as in no-ACS patients (2.4% versus 0.2% respectively; p=0.002). There were no statistically significant interactions between clinical presentation and randomized device modality for TVF (p=0.80) and for the endpoint of definite or probable device thrombosis (p=0.17).

CONCLUSIONS

In ACS patients within AIDA, we found no difference in rates of target vessel failure between the Absorb BVS and Xience EES groups. Rates of definite or definite/probable device thrombosis were higher in the Absorb BVS group throughout all clinical presentations. No significant interaction between ACS and no-ACS patients and the occurrence of TVF or definite/probable device thrombosis was found between the two treatment arms.

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Clinical implication of quantitative flow ratio computed after DES implantation in best of PCI practice: insight from the SYNTAX II trial

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THEME: Coronary Interventions

TOPIC(S): Stents and scaffolds, Left main and multivessel disease

AIMS

The aim of this study was to investigate the clinical implication of quantitative flow ratio (QFR) computed after percutaneous coronary intervention (PCI) on clinical outcome.

METHODS AND RESULTS

All the vessels treated with state-of-art PCI in the SYNTAX II trial were retrospectively screened and analysed for post-PCI QFR. State-of-art PCI includes: heart team decision-making utilizing the SYNTAX score II, hybrid iFR-FFR decision-making strategy, intravascular ultrasound guided stent implantation, contemporary chronic total occlusion revascularization techniques and guideline-directed medical therapy. The primary endpoint of this substudy was vessel-oriented composite endpoint (VOCE) at 2 years, defined as the composite of vessel-related cardiac death, vessel-related myocardial infarction, and target vessel revascularization. Receiving-operating curves (ROC) was used to calculate the best cut-off value of post-PCI QFR for predicting 2-year VOCE. All the analysable vessels were classified on the basis of this cut-off value.

A total of 968 vessels treated with PCI were screened and post-PCI QFRs were analysable in 79.6% of the vessels (771 vessels). In these 771 analysable vessels, 52 VOCEs (6.7%) were recorded at 2 years follow-up. The mean post-PCI QFR value was 0.914 ± 0.073 and the mean QFR gradient across the stent was 0.018 ± 0.045. The diagnostic performance of post-PCI QFR to predict 2-year VOCE was moderate (area under the curve: 0.702±0.035 [0.633-0.772]) and the best cut-off value of post-PCI QFR for predicting 2-year VOCE was 0.90 (sensitivity 0.652, specificity 0.635). The incidence of 2-year VOCE in the vessels with post-PCI QFR ≤0.90 (n=284) was significantly higher compared to ones with post-PCI >0.90 (n=487) (12.0% vs. 3.7%, HR 3.37 [95%CI: 1.91-5.97], p<0.001). This difference was driven by significantly higher incidence of target vessel revascularization in the vessels with post-PCI QFR ≤0.90 (10.6% vs. 2.9%, HR 3.83 [95%CI: 2.03-7.22]).

CONCLUSIONS

A higher post-PCI QFR value is associated with a better vessel-related clinical outcome in best of PCI practice. This finding should be confirmed in future prospective trials.

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Coronary microvascular dysfunction is common among subjects undergoing elective coronary angiography due to stable coronary artery disease and it is associated with haemoglobin, renal insufficiency, and pro-BNP

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Coronary microvascular dysfunction (CMVD) is associated with adverse cardiovascular outcomes. The frequency of CMVD in consecutive patients undergoing elective coronary angiography due stable of coronary artery disease (CAD) is not known. Our aim was to determine the frequency of CMVD in subjects undergoing coronary angiography due to stable CAD.

METHODS AND RESULTS

We prospectively enrolled 274 consecutive patients of 693 eligible patients scheduled for coronary angiography due to stable coronary artery disease. Selection-bias was minimized by enrolling patients by non-interventional physicians before coronary anatomy was known. Fractional flow reserve (FFR), coronary flow reserve (CFR) and index of microcirculatory resistance (IMR) were measured in the LAD only. Subjects with extensively diseased LAD (n=26), inadequate measurements (n=22), withdrawn consent/violation of protocol (n=6) were excluded from further analysis. The proportion of patients with IMRcorr >25 was 25% (95% CI 19%-31%) in all 220 patients. In patients with FFR>0.75 in the LAD (n=158) the proportion of IMRcorr>25 was 28% (95% CI 26%-36%) and the proportion of impaired coronary flow (IMRcorr>25 or CFR≤2.0) was 40% (95% CI 32%-48%). Among subjects without obstructive CAD (n=86) the proportion of IMRcorr >25 and impaired coronary flow was 27% (95% CI 17%-36%) and 37% (95% CI 27%-48%), respectively. In patients with obstructive CAD in any coronary vessel the proportion of IMRcorr was 24% (95% CI 17%-31%). Haemoglobin (r2=0.087, p<0.001), no obstructive CAD (r2=0.052, p=0.001), pro-BNP (r2=0.021, p=0.035) and creatinine clearance (r2 =0.052, p=0.001; inversely), were independently associated with IMRcorr in multivariate analysis.

CONCLUSIONS

CMVD is common among subjects with stable coronary artery disease with or without obstructive CAD and it is associated with renal insufficiency, pro-BNP, and hemoglobin.

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BRS vs. Xience metallic stents: outcomes in the AIDA trial stratified by SYNTAX score

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Extent of coronary artery disease (CAD) may affect outcomes after percutaneous coronary intervention (PCI). The SYNTAX score (SXscore) is an angiographic scoring system of the coronary anatomy and lesion characteristics, which can be used as a measure of CAD complexity.The SXscore has prognostic value in patients with de novo CAD undergoing PCI, and has been used to compare outcomes after PCI with 1st and 2nd generation drug-eluting stents. In this pre-specified subgroup analysis of the AIDA trial we evaluated the impact of SXscore on clinical outcomes

METHODS AND RESULTS

AIDA was a multicenter trial comparing Absorb BVS with the Xience EES. SX score was assessed using the baseline diagnostic angiograms. Each coronary lesion with diameter stenosis ≥50% in vessels ≥1.5 mm was scored. All lesion scores were combined to provide the overall SXscore. The angiographic SXscore calculations were performed by core laboratory analysts who were blinded for clinical events (Cardialysis B.V., Rotterdam, The Netherlands). . Clinical outcomes were subsequently stratified according to SXscore tertiles: SXlow (SXcore ≤8), SXmid (SXscore >8 and ≤15) and SXhigh (>15). The primary endpoint of this AIDA-trial substudy was target vessel failure (TVF), defined as a composite of cardiac death, target vessel myocardial infarction and target vessel revascularization.

The SXscore was prospectively calculated in 1661 of the 1845 patients (90%) enrolled in the AIDA trial. The predominant reason for not being able to calculate the SXscore was the unavailability of the baseline angiograms with visualization of both coronary arteries. The SXscore ranged from 1 to 57, with a mean±SD of 12.9 ± 8.5 and a median of 11 (Q1-Q3 7 - 17).In this analysis the SXscore tertiles were defined as SXlow (SXcore ≤8) (n=589), SXmid (SXscore >8 and ≤15) (n= 538), and SXhigh (>15) (n=534). Patients in the SXhigh group were older, had a more extensive medical history for previous revascularizations (both PCI and coronary artery bypass grafting), and were more likely to present with a ST-elevation myocardial infarction.

At two-year follow-up the Kaplan-Meier estimates of TVF rate for the overall AIDA study population was 15.5% in the SXhigh tertile, 10.4% in the SXmid tertile and 4.7% in the SXlow tertile (hazard ratio (HR) 3.53 95% CI 2.28-5.45; P<0.001). The event rate of the primary endpoint of TVF was numerically lower in Absorb BVS when compared to Xience EES (3.7% versus 5.6%; HR 0.64; 95% CI 0.29 - 1.40; p=0.257) in the SXlow tertile. Patients treated with Absorb BVS and a SXscore >8 had significantly higher event rates as compared to patients with a SXscore ≤8. The rates of TVF in the Absorb BVS population are 15.5% (SXhigh), 11.4% (SXmid), and 3.7% (SXlow), with a significant difference between the SXlow versus SXmid (HR 3.27; 95% CI 1.61 – 6.68; p=0.001) and SXlow versus SXhigh (HR 4.57; 95% CI 2.29 – 9.10; p<0.001).

CONCLUSIONS

This study demonstrates that implantation of the Absorb BVS in patients with a SXscore ≤8 is associated with numerically lower TVF rates as compared to the Xience drug-eluting stent. The rate of scaffold thrombosis in this SXlow tertile, while still higher for Absorb BVS, is more acceptable than in SXmid and SXhigh score tertiles. Higher SXscore (i.e. >8), both Sxmid and SXhigh, however, appears to be associated with markedly increased risk of device thrombosis, revascularization and myocardial infarction in patients treated with the Absorb BVS.

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Impact of neutrophil-to-lymphocyte ratio on in-hospital mechanical complications in patients with STEMI undergoing primary PCI

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

The neutrophil-to-lymphocyte ratio (NLR) has been proved as a reliable inflammatory marker. A recent study reported that elevated NLR is associated with adverse cardiovascular events in patients with ST-segment elevation myocardial infarction (STEMI). We investigated whether NLR is associated with in-hospital mechanical complications in patients with STEMI who had undergone primary percutaneous coronary intervention (PCI).

METHODS AND RESULTS

A total of 744 patients with STEMI who underwent successful primary PCI from 2009 to 2018 were enrolled in this study. Total and differential leukocyte counts were measured at admission. The NLR was calculated as the ratio of neutrophil count to lymphocyte count. Patients were divided into tertiles according to NLR. The primary end point was in-hospital mechanical complications, including cardiovascular death, sudden cardiac arrest, stent thrombosis, pericardial effusion, pericarditis, post-infarction ventricular septal rupture, free-wall rupture, left ventricular thrombus, and acute mitral regurgitation.

Patients with high NLR group (> 4.90) had higher risk of in-hospital mechanical complications ($p = 0.001$) compared with those in low and intermediate groups (15 % vs 17 % vs 27 %). On multivariable analysis, NLR remained an independent predictor for in-hospital mechanical complications (RR = 1.947, 95% CI = 1.136 - 3.339, $p = 0.015$) with symptom-to balloon time ($p = 0.002$) and left ventricular dysfunction ($p < 0.001$).

CONCLUSIONS

In conclusion, NLR is an independent predictor of in-hospital mechanical complications in STEMI patients undergoing primary PCI. Patients with STEMI with high NLR are at increased risk for in-hospital mechanical complication and should receive more intensive treatment after PCI.

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One-year clinical outcomes of PCI with new-generation DES in patients with prior CABG: comparative analysis of revascularisation of vein grafts vs. native coronary arteries

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

The goal of this study was to assess the current real-world clinical outcomes of PCI procedures with new-generation DES performed in patients with prior coronary artery bypass graft (CABG) requiring revascularisation of either vein grafts or new lesions in native coronary arteries.

METHODS AND RESULTS

eUltimaster is a prospective, multi-centre, world-wide registry, following up on more than 37000 coronary artery disease patients who underwent a PCI treatment using sirolimus-eluting stent with bioresorbable abluminal polymer coating (Ultimaster). The primary endpoint is target lesion failure (TLF) at 1 year follow up. Among 19481 patients who completed 1-year follow-up, we focused on 1115 (5.7%) patients with previous CABG, excluding patients with arterial grafts. We compared clinical outcomes of 214 patients subjected to PCI of vein grafts (CABG-VG) to 901 previous CABG patients on which native coronary artery PCI (CABG-CA) was performed.

CABG-VG patients were older (72±9 vs 69±10; p<0.0001), with higher proportion of octogenarians (19.2% vs 12.9%; p=0.02). Baseline patient characteristics, such as mean BMI, diabetes, hypertension, hypercholesterolemia, family history of heart disease and renal impairment rate were alike. At presentation, acute coronary syndrome (ACS) rate was higher in CABG-VG vs CABG-CA patients (55.6% vs 38.5%; p<0.0001), mainly driven by significantly higher NSTEMI incidence in CABG-VG arm (32.7% vs 21.5%; p=0.001), as STEMI and unstable angina rates were alike. Stable angina and silent ischemia were more frequent in CABG-CA arm (38.3% vs 49.6%; p= 0.003 and 6.1% vs 11.9%; p= 0.01, respectively). Trans-radial artery access was more often used in CABG-CA group (53.3% vs 65.5%; p=0.001).

At 1-year, CABG-VG group had significantly worse major clinical outcomes, with rates of all-cause death 7.5% vs 3.8% (p=0.03), cardiac death 5.6% vs 2.8% (p=0.05), target-vessel related myocardial infarction (TVMI) 4.2% vs 1.2% (p=0.01), clinically-driven (CD) revascularizations 10.8% vs 3.6% (p<0.0001) and CD target-lesion revascularization (CD-TLR) 4.7% vs 2.8% (p=0.19) in CABG-VG and CABG-CA, respectively. TLF-a composite endpoint of cardiac death, TVMI and CD-TLR were also higher in CABG-VG (12.6% vs 5.4%; p<0.0001), similarly to the composite endpoint of cardiac death and MI (10.3% vs 3.8%; p<0.0001) and patient-oriented composite endpoint (POCE) of all death, MI and revascularizations (19.6% vs 8.4%; p<0.0001). The rate of definite and probable ST was similar at 1-year in the two groups (1.9% vs 0.9%; p=0.26), under alike DAPT regiment. The incidence of stable angina at 1-year follow-up was significantly higher in CABG-VG arm (17.1% vs 10.5%; p=0.01).

CONCLUSIONS

Our analysis confirms that in patients with prior CABG, PCI renders worse outcomes in vein grafts than in native coronary arteries, at the same time demonstrating still good safety and efficacy of the new-generation

DES Ultimaster in this challenging setting. Here, specific design features of the Ultimaster DES, including its thin struts and abluminal bioresorbable polymer coating, are the likely drivers of its good performance in per se more vulnerable vein graft milieu.

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Accomplishment of virtual FFR acquisition in real-world invasive procedures: analysis from ILUMIEN-I trial

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Stents and scaffolds

AIMS

Virtual Fractional Flow Reserve (vFFR) is a new method for the functional assessment of coronary ischemia utilizing angiographic images. Previous studies showed good correlation between vFFR and FFR in selected patients, with pre-specified image acquisition requirements, such as static table and at least 30 degrees of difference between projections. However the feasibility of performing vFFR in non-selected patients has not yet been determined. We investigated whether vFFR analysis is feasible in real world procedures that were previously acquired and not primed for specialized analysis.

METHODS AND RESULTS

This is a sub-analysis of the ILUMIEN I study, a large, prospective, observational, non-randomized study of percutaneous coronary intervention (PCI) procedural practice in patients undergoing intra-procedural pre and post-PCI FFR. The patient population was already described in ILUMIEN I main study, that in summary included patients presenting with stable coronary disease, unstable angina and non-ST-elevation myocardial infarction. We utilized vFFR from CAAS Workstation 8.1 (Pie Medical Imaging). From 624 measurements from 312 patients with pre and post-PCI FFR, 219 (35.1%) could be analyzed, including 115 (52.5%) pre-PCI and 104 (47.5%) post-PCI. The main reasons for analysis failure were: only 1 angiographic projection (37.5%), table movement while acquiring angiographic images (25.7%), angiography pixel incompatibility (15%) and absence of 2 orthogonal projections (11.1%), reflecting a low successful application of vFFR in clinical practice without following specific instructions for image acquisition. The cases with angiographic pixel incompatibility might reflect problems during imaging transfer and storage, with a potential loss of important metadata, not being related to the software itself.

CONCLUSIONS

We concluded that vFFR can be analysed in one-third of real-world angiographies without any further action or image acquisition needed. If vFFR is intended to be used in the daily practice, small changes in the procedure should be done, with minimal risk added to the patient. Further prospective studies need to be performed in order to validate vFFR.

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Motorised FFR pullback: accuracy and reproducibility

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Functional assessment of coronary stenosis using fractional flow reserve (FFR) is recommended for decision making regarding myocardial revascularization. The present study aimed at determining the accuracy and reproducibility of motorized FFR pullback in patients with stable coronary artery disease.

METHODS AND RESULTS

Duplicated FFR pullbacks were acquired using a motorized device at a speed of 1 mm/s in intermediate coronary stenosis. In addition, a single FFR value was measured at an anatomical landmark. The agreement between FFR measurements was assessed using the Bland-Altman method and area under the pullback curve (AUPC). Mixed effect model was used to account for the correlation of FFR values within vessels. A total of 37,326 FFR values were obtained in twenty vessels. The mean FFR from the pullbacks was 0.91±0.08 whereas the mean FFR at the distal location was 0.85±0.09. The mean difference between pullbacks was -0.002 (LOA -0.058 to 0.054). The difference in AUPC between the two FFR pullbacks was 2.1±1.6%. At the pre-specified anatomical location, the mean difference between the FFR derived from the pullback data and the measured FFR was 0 (limits of agreement -0.040 to 0.039). The repeatability of the distal FFR measurement was high (mean difference -0.003, limits of agreement -0.046 to 0.041).

CONCLUSIONS

A motorized FFR pullback was accurate to assess the distribution of epicardial resistance in patients with intermediate coronary artery disease. The reproducibility of the FFR pullback was high. Further studies are required to determine the potential usefulness of a hyperemic FFR pullback strategy for decision making and treatment planning.

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Quality evaluation of OCT image acquisition: insights of ILUMIEN-I trial

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THEME: Coronary Interventions

TOPIC(S): Stable CAD, Stents and scaffolds

AIMS

Optical coherence tomography (OCT) provides excellent image resolution but requires blood displacement with contrast injection for image acquisition, as opposed to other intravascular imaging modalities. In addition, there are other small differences that make that process more challenging, such as fixed pullback size and tortuosity of lesions. The aim of this study was to assess the quality of OCT images acquired as part of an international, multicenter study and emphasize the importance of the first step in the use of OCT: image acquisition.

METHODS AND RESULTS

We evaluated 533 pullbacks from the ILUMIEN I study that had OCT performed. The cases were analyzed for completeness and quality of the image, using previously published standardized methods. In addition, we evaluated the causes of suboptimal image acquisition. Left anterior descending 60% (n=322) was the most common imaged vessel, followed by right coronary 18.2% (n=97), and circumflex 17.8% (n=95). The image of the target segment, defined as the lesion or stented segment plus references, was incomplete in 16.5% (n=88) pullbacks, with the most common reason being the pullback starting too proximal 67% (n=59), followed by inappropriate pullback size selection relative to the target length 15.9% (n=14) and pullback starting too distal 10.2% (n=9). Among the cases with incomplete target segment, 65.62% (SD=±30.53) of the target length was analyzable. The quality of image interpretation was affected by residual blood due to inadequate contrast flow 22.30% (n=97) or volume 22.30% (n=97), followed by artifacts in 17.93% (n=78) pullbacks.

CONCLUSIONS

We identified a significant number of cases with suboptimal image acquisition, and its causes, that can be easily fixed with small changes during the procedure. Better education and training on image acquisition will reduce the number of pullbacks necessary to adequately image a vessel, reduce contrast usage and lead to better data quality, ultimately improving patient outcome.

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Flow as a risk marker in high-gradient aortic stenosis patients undergoing TAVI

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Indexed stroke volume (SVi) is an echocardiographic measurement that is used for low gradient aortic stenosis. We studied whether SVi is a high risk marker in high gradient aortic stenosis patients and whether SVi is related to other clinical factors contributing to this risk.

METHODS AND RESULTS

699 consecutive patients who underwent TAVI were screened, and only patients with high gradient aortic stenosis were included. A 35 ml/m2 cut-off for SVi was used to define patients with high versus low flow. The primary endpoint was defined as a combination of cardiovascular death and re-admission to hospital with heart failure at 30 days.

Of the 390 patients with high gradient severe aortic stenosis, 168 (43%) had low flow. They had higher NTproBNP [2578 (1043-5480) vs. 1714 (821-3599) ng/L, P=0.005], and smaller indexed valve area [0.28 (0.23-0.36) vs. 0.35 (0.29-0.42) cm2/m2, P< 0.001]. SVi was lowest in TAVI patients with coronary artery disease and LV impairment 32.0 (24.5-38.7) ml/m2 (P<0.001) and they had worse clinical outcomes (P= 0.039). The primary endpoint was significantly more frequent in low flow compared to high flow patients [8.92% vs. 3.60%, HR 2.54 (95% CI 1.08 to 5.98), P=0.034].

CONCLUSIONS

SVi can further characterise patients with high gradient aortic stenosis and may help to identify those who are at increased risk following TAVI.

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Patient disposition and clinical outcomes among patients referred to a dedicated TAVI clinic

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI, Other valvular and structural interventions

AIMS

Aortic stenosis affects about 3.4% of the population over 75 years of age. In the era of transcatheter aortic valve implantation, percutaneous therapy is the standard of care for inoperable, high and intermediate risk patients. However,it has become apparent that a certain proportion of patients referred for TAVI proceed with a different treatment strategy. There is scarce data describing the final treatment allocation of patients referred to a TAVI clinic and the rationale behind it. We sought to evaluate the disposition of patients assessed at a TAVI centre in contemporary clinical practice.

METHODS AND RESULTS

This prospective, single-centre study was conducted between 1st February 2014 and 31st August 2017. Data was collected on all patients with aortic stenosis referred for TAVI assessment. Baseline demographic, clinical, laboratory, echocardiographic, and procedural data were prospectively recorded. Patients were categorized according to treatment allocation: TAVI, surgical aortic valve (SAVR) or optimal medical therapy (OMT). Clinical characteristics, surgical risk and outcomes were evaluated in all groups.

Total of 245 patients were referred for TAVI assessment during the study period. Patients with moderate aortic stenosis (N=32; 13%) and asymptomatic severe aortic stenosis (N=32; 15%) were excluded. Following Heart Team discussion 132 (73%) patients were allocated to TAVI, 31 (17.1%) to OMT and 18 (9.9%) to SAVR.

Reasons for medical management included patient's preference in 12 cases (38.7%); excessive surgical risk (N=4; 12.9%); severe frailty and immobility (N=5; 16.1%); end-stage pulmonary disease (N=3; 9.7%); severe cognitive impairment (N=2; 6.5%); and end-stage malignancy (N=1; 3.2%). In 4 cases (12.9%), the patients died before completion of their out-patient TAVI work-up.

Majority of clinical characteristics were similar in all groups. Patients managed with SAVR were significantly younger than those in either the OMT or TAVI cohorts ($P < 0.001$). SAVR patients also had the lowest average STS-PROM score.

When compared to TAVI, SAVR was associated with higher procedural (5.6% vs. 0.8%) and 30-day mortality (11.1% vs. 2.3%). Six-month follow-up data was available for all patients in the OMT and SAVR group, and for 129 (97.7%) patients in the TAVI cohort. Median follow up was 14 months in the OMT cohort, 16.5 months in the SAVR group and 12 months for TAVI patients. Six-month all-cause mortality was highest among patients managed medically as compared to SAVR or TAVI (19.4% vs 16.7% vs. 9.3% respectively).

CONCLUSIONS

Almost half of all patients with severe AS referred for TAVI assessment did not receive a transcatheter heart valve, as they were either asymptomatic or had less than severe AS. Of those with truly symptomatic severe AS, majority underwent TAVI, but others were referred for SAVR or were managed medically due to expected futility or patient's choice. Screening for AS and raising patients' awareness may help to reduce the number of patients unlikely to benefit from intervention.

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Predictors of in-hospital mortality in percutaneous treatment of lesions in SVG

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease

AIMS

The angiographic characteristics associated with saphenous vein graft degeneration and the high-risk profile of these patients increase the probability of adverse outcomes during and after percutaneous coronary intervention. This study set out to analyze hospital outcomes of percutaneous coronary intervention performed in saphenous vein grafts, and to investigate predictors of in-hospital mortality in this group.

METHODS AND RESULTS

A retrospective, observational study based on records kept by a national database of cardiovascular Interventions between 2006 and 2016. The following in-hospital clinical outcomes were analyzed: periprocedural acute myocardial infarction, need for urgent coronary artery bypass grafting, and all-cause mortality. A total of 2,361 patients were included. Mean patient age was 67.4 years, 33.4% were diabetic. Clinical presentation with ST-segment elevation myocardial infarction was 9,3%. The prevalence of periprocedural acute myocardial infarction was 0,9% and mortality 0,8%. No patient required urgent coronary artery bypass grafting. Simple logistic regression analysis revealed the following in-hospital mortality predictors: advanced age, ST-segment elevation acute myocardial infarction, Killip class 3/4, long lesions, thrombi-containing lesions, three-vessel disease and periprocedural acute myocardial infarction. According to multiple logistic regression analysis, age (OR 1.07; 95%CI 1.02-1.13; p=0.01), smoking (OR 3.26; 95%CI 1.13-9.39; p=0.03), ST-segment elevation acute myocardial infarction (OR 10.36; 95%CI 3.96-27.07; p<0.01) and periprocedural acute myocardial infarction (OR 86.08; 95%CI 15.81-468.63; p<0.01) were correlated with mortality outcomes.

CONCLUSIONS

Identification of in-hospital mortality predictors may contribute to improve procedural planning for adverse events prevention in patients undergoing percutaneous coronary intervention of saphenous vein grafts.

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Platelet activation and endothelial dysfunction markers and angiographic results in patients with STEMI

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THEME: Coronary Interventions
TOPIC(S): STEMI, Other Coronary Interventions

AIMS

To evaluate the performance of platelet activation, endothelial dysfunction and thrombogenesis markers in patients with ST elevation Myocardial Infarction (STEMI) in coronary and peripheral venous artery samples.

METHODS AND RESULTS

Methods: Multicentric, observational prospective cohort analytical study, preliminary results of Platelet Activation and Thrombogenesis in Cocaine users with STEMI (PATh-CocAMI). Patients with STEMI with less than 12 hours of evolution in whom primary PCI was performed. Those with a history of previous angioplasty, prior revascularization surgery, thrombolysis and the use of oral anticoagulants were excluded. An arterial sample is taken from the coronary artery culprit at the time of pPCI and a peripheral venous sample from antebraquial vein. Levels of Profilin-1 (PFN-1), soluble intracellular adhesion molecule (sICAM) and Thrombin activation time (TAT) were measured. The angiographic microvascular flow was measured according to the corrected TIMI frame count calculation (cTFC).

Results: 39 patients included, men 80%, average age 56.8 ±8.7 years, 50% hypertensive, 32.5% diabetes, 30% dyslipidemia, 52.4% smoking. Mean consultation time 265.8±192.5 minutes, door-to-reperfusion time 129.4±89.9 minutes, 78.9% in Killip I. Culprit arteries: 41% left anterior descending, 45% right coronary. 53.8% lesion in another vessel besides culprit and 8.8% three vessels disease.

Radial access was used in 97.4%, thromboaspiration 74.4%, predilatation 76.9%, post-dilation 25.6%. In 89.7%, a stent was implanted. On average, 1.13±0.65 stent was implanted per patient, total length 24.48±17.1 mm, final TIMI 3 flow was achieved in 87.5%.

Of the 39 patients, 35 coronary samples and 24 venous samples obtained were valid. The coronary and venous levels of PFN-1 were similar 1747.5 ± 1028.3 pg/ml vs 1793.2 ± 1012.7 pg/ml ($r = 0.655$, $p < 0.001$), as well as sICAM levels (306, 7ng/ml coronary vs 330.1 ng/ml venous, $r = 0.711$, $p < 0.001$) and TAT (3.98 ug/L coronary vs 3.95 ug/L venous, $r = 0.89$, $p < 0.001$) . No difference was found in the arterial-venous gradients of the markers (PFN-1: 1573.5 vs 1833.4, sICAM: 135.3 vs 135.4, TAT: 3.98 vs 3.95)

When comparing results of angioplasty according to cTFC> 23, no differences were found in the arterial or venous levels of PFN-1, sICAM and TAT (graphic)

CONCLUSIONS

In these preliminary results, the levels of platelet activation markers (PFN-1), endothelial dysfunction (sICAM) and thrombogenesis (TAT) measured in peripheral venous and coronary culprit blood are comparable. In this STEMI sample, these markers did not correlate with an immediate result of angioplasty measured by cTFC. A greater number of cases and clinical follow-up are necessary to establish definitive conclusions.

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Diagnostic ability of resting full-cycle ratio as newly developed non-hyperemic indices for physiological lesion assessment

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Although fractional flow reserve (FFR) is a gold standard method to evaluate functional lesion severity in the catheterization laboratory, the need of hyperemic condition limits the widespread adoption of FFR. Recently, the resting full-cycle ratio (RFR) which was newly developed resting indices was launched. It is unclear whether RFR as resting condition could assess physiological lesion severity of coronary artery stenosis. The aim of this study was to evaluate the diagnostic ability of RFR compared to FFR in entire range of coronary artery stenosis.

METHODS AND RESULTS

Methods

A total of 53 patients with 70 lesions were enrolled in this study. The RFR was measured after adequately waiting for stable condition, while FFR was measured after intravenous administration of ATP (180mcg/kg/min). Lesions with FFR ≤0.80 were considered functionally significant coronary artery stenosis.

Results

In all lesions, reference diameter, diameter stenosis, lesion length, RFR, and FFR were 3.3±0.8mm, 44±12%, 14.6±7.2mm, 0.90±0.11, and 0.83±0.11, respectively. Functional significance was observed in 24 lesions (34%) of all lesions. The RFR showed a significant correlation with FFR ($y = 0.800x + 0.239$, $R^2 = 0.667$, $p < 0.001$). The Bland-Altman plot demonstrated a good agreement with a mean difference of 0.07 and a standard deviation of 0.06 between RFR and FFR across entire range of coronary artery stenosis. ROC curve analysis showed an excellent accuracy of RFR cut-off of ≤0.90 in predicting FFR ≤0.80 which had 78% sensitivity and 87% specificity (AUC 0.87).

CONCLUSIONS

The RFR as newly resting indices is reliable to the assessment of functional lesion severity. This physiology-based approach may be a possible alternative method for FFR measurements in daily practice.

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FANTOM I: pilot study of the REVA sirolimus-eluting BRS - first report: four-year outcomes

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THEME: Coronary Interventions

TOPIC(S): Stable CAD, Stents and scaffolds

AIMS

The primary objective of the FANTOM I Pilot study was to evaluate the initial safety of a unique bioresorbable scaffold platform in native coronary arteries that includes incorporation a new scaffold material TyroCore, which is composed mainly of an iodinated, polycarbonate copolymer of tyrosine analogs. Fantom is completely radiopaque and is comprised of thin struts (125 micron) that facilitate device delivery and precise target lesion treatment.

METHODS AND RESULTS

The FANTOM I Pilot study is a prospective, multicenter trial which enrolled 7 patients with de novo coronary stenosis with reference vessel diameters between 2.7 to 3.3 mm in diameter and lesion lengths ≤ 14mm. The Primary Endpoint of the study which was MACE through 6 months of follow-up was 0%. Through 4 years of follow-up only a single MACE event occurred in this study, which was a TLR at the 13 month timepoint. All other patients remain event free through 48 months with no report of scaffold thrombosis. Acute technical success, acute procedural success and clinical procedural success rates as defined in the clinical protocol were 100% (7/7) in all cases. Angiographic follow-up was performed at 4 months (n=7) in all patients. The angiographic in-stent percent diameter stenosis at 4 months was 7.6 ± 11.9%, and the in-stent late loss had a median value of 0.22mm. The OCT analysis showed that at 4 months 99% of the struts had been covered by tissue.

CONCLUSIONS

The Fantom I Pilot Study has demonstrated favorable safety and effectiveness performance through 4 years of follow-up. This study was used as a basis to launch the FANTOM II trial in a larger patient population. Longer-term follow-up of all Fantom I patients is ongoing through 5 years and will examine the late outcomes with this novel device.

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Optimal strategy and long-term clinical outcomes of antiplatelet therapy after endovascular revascularisation for lower extremity peripheral artery disease

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal

AIMS

The optimal strategy of antiplatelet therapy in patients with lower extremity peripheral artery disease (PAD) after endovascular revascularization has not been clearly established. This study assessed the long-term clinical outcomes of lower extremity PAD after endovascular revascularization according to antiplatelet therapy strategy.

METHODS AND RESULTS

From March 2008 to February 2013, we analyzed 693 lower extremity PAD patients treated with endovascular revascularization according to strategy of antiplatelet therapy consisting of mono antiplatelet therapy (MAPT) and dual antiplatelet therapy (DAPT) of 1-, 3-, and 6-month maintenance. The primary outcome was major adverse cardiovascular events (MACE; a composite occurrence of all-cause death, myocardial infarction and stroke) and major adverse limb events (MALE; a composite occurrence of repeat revascularization and major amputation) during the 5-year follow-up period. The major safety outcome was defined as severe or life-threatening bleeding. We further performed propensity score adjustment for clinical outcomes. During the 5-year follow-up, ≥ 6-month DAPT strategy showed the lowest MACE and MALE rates rather than other antiplatelet therapy strategies without increasing severe of life-threatening bleeding events. MACE occurred less frequently in the ≥ 6-month DAPT group than the < 6-month DAPT + MAPT group (17.3% vs. 31.3%, hazard ratio [HR]=0.44, 95% confidence interval [CI]=0.30-0.65, p<0.001). MALE also occurred less frequently in the ≥ 6-month DAPT group than the < 6-month DAPT + MAPT group (21.5% vs. 43.7%, HR=0.42, 95% CI=0.30-0.58, p<0.001). There was no significant difference in severe or life-threatening bleedings between the 2 groups (2.3% vs. 3.5%, HR=0.61; 95% CI=0.17-2.18, p=0.447). The trend of long-term clinical outcomes for favoring ≥ 6-month DAPT was consistent even after propensity score matching.

CONCLUSIONS

The risk of MACE and MALE were significantly lower in the ≥ 6-month DAPT group without increasing severe or life-threatening bleeding events. Prolonged DAPT over 6-month may improve long-term clinical outcomes after endovascular revascularization for lower extremity PAD.

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Different response to myocardial ischaemia between culprit and non-culprit vessels

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THEME:
TOPIC(S):

AIMS

There have been studies on the physiological response of coronary vessels due to ischemic injury in acute coronary syndrome (ACS). However, it is not known whether such physiological responses are localized to culprit-vessels or globalized to whole myocardium. The goal of this study was to investigate whether the microvascular dysfunction differ between culprit and non-culprit vessels in ACS patients who underwent percutaneous coronary intervention (PCI).

METHODS AND RESULTS

Methods

We prospectively enrolled 120 patients with ACS who were successfully treated by PCI. Immediately after the PCI and six months later, baseline aortic pressure (Pa) and distal intracoronary pressure (Pd), fractional flow reserve (FFR), coronary flow reserve (CFR), and index of microcirculatory resistance (IMR) of the target vessel were measured. These measures were then performed on non-culprit vessels. Delta FFR was defined as the difference of baseline Pd/Pa and FFR. Such physiological measures were compared between culprit and non-culprit vessels. The association between the IMR and delta FFR was investigated.

Results

In comparison of baseline physiologic data between the two groups, culprit vessel group showed higher IMR, lower CFR and FFR (all $P<0.01$), compared with non-culprit vessel group. Six-month follow-up data showed that IMR was not different between the two groups. However, CFR and FFR (both $P<0.01$) were significantly lower in the culprit-vessel group than the non-culprit vessel group. In an analysis of the changes within each group, 6-month IMR was significantly lower in culprit-vessel group than baseline. However, there were no significant changes in CFR and FFR for non-culprit vessel group during 6 months treatment period, respectively. In culprit-vessel analysis, delta FFR showed a modest correlation with IMR in baseline ($r = -0.25$, $p = 0.006$) and 6-month ($r = -0.30$, $p = 0.002$). Non-culprit-vessel analyses, whereas, showed that delta FFR was not significantly correlated with IMR in baseline ($r = -0.006$, $p = 0.932$) and 6-month ($r = -0.132$, $p = 0.065$).

CONCLUSIONS

The physiological response to ischemic insult might occur locally. There was a negative correlation between IMR and delta FFR in culprit-vessels.

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Two-year outcomes after left main coronary artery PCI in patients presenting with ACS

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease

AIMS

Percutaneous Coronary Intervention (PCI) of left main coronary artery (LMCA) has been a safe and effective revascularization strategy in patients with stable coronary artery disease. We aim to evaluate long-term outcomes after LMCA PCI in patients presenting with ACS.

METHODS AND RESULTS

A total of 6429 consecutive patients with Acute Coronary Syndrome (ACS) who underwent PCI in Fuwai Hospital in 2013 were enrolled in this study. Patients are divided into Left Main (LM) group and non-Left Main (Non-LM) group according to whether the target lesion was located in LMCA. Prognosis impact on 2-year major adverse cardiovascular and cerebrovascular events (MACCE) is analyzed across 2 groups, including occurrence of all-cause death, cardiac death, myocardial infarction, revascularization, in-stent thrombosis, stroke and bleeding. 155 (2.4%) patients have target lesion in LM, while 6274 (97.6%) patients belong to non-LMCA group. Compared with Non-LMCA patients, LMCA patients have higher age, higher proportion of diabetes, in-hospital β-blockers use and clinical presentation of unstable angina, and lower levels of hemoglobin and glomerular filtration rate. LMCA patients also have higher pre-procedural SYNTAX score, higher proportion of tri-vessel disease, staged PCI, intravascular ultrasound and intraaortic balloon pump use. 2-year follow-up reveals that LMCA patients have significantly higher rate of cardiac death (2.6% vs. 0.7%, p=0.034), myocardial infarction (7.1% vs. 1.8%, p<0.001), in-stent thrombosis (4.5% vs. 0.8%, p<0.001) and stroke (7.1% vs. 6.4%, p=0.025) compared with non-LMCA patients. After adjusting for confounding factors by Cox regression analysis and Propensity Score Match (PSM), LMCA remains independently associated with higher 2-year myocardial infarction rate (HR = 10.992, 95% CI: 2.000 – 60.417, p=0.006).

CONCLUSIONS

In patients presenting with ACS, LMCA-targeted PCI is associated with higher risk of 2-year cardiac death, myocardial infarction, in-stent thrombosis and stroke. LMCA-targeted PCI is an independent risk factor for 2-year myocardial infarction.

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Systemic fluid status by bioelectrical impedance spectroscopy predicts outcome in patients undergoing TAVR

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Volume overload and cardiac decompensation are cardinal signs indicating the necessity of intervention in patients with valvular heart disease. Risk stratification of patients scheduled for transcatheter aortic valve replacements (TAVR) largely relies on established risk scores, which fail to incorporate signs of fluid overload. Systemic fluid status can be assessed by bioelectrical impedance spectroscopy (BIS), which is a validated non-invasive tool for treatment monitoring of hemodialysis patients. The prognostic significance of fluid overload as assessed by BIS in TAVR patients is unknown.

METHODS AND RESULTS

Consecutive patients with aortic stenosis scheduled for TAVR underwent systemic fluid status assessment using BIS on the day preceding intervention, and were prospectively followed. Kaplan-Meier estimates and multivariate Cox-regression analysis were used to identify factors associated with outcome, including BIS. A composite of heart failure hospitalization and cardiovascular death was selected as primary study endpoint.

In total, 135 consecutive patients (80.4±7.9 years; 45.1% female) with valid BIS data were included. The study population was stratified according to the 75th percentile of overhydration (OH; +1.8l). No associations between OH and baseline characteristics were found, including age and NYHA functional class ($p>0.05$). However, patients in the topmost OH quartile had higher serum levels of NT-proBNP (9017±9601 ng/ml vs. 3807±5889; $p<0.001$) and creatinine (1.83±1.44 mg/dl vs. 1.22±0.82; $p<0.001$). A total of 35 events occurred during follow-up (27±21 weeks). Patients with an OH of >1.8l were more likely to experience an event (log-rank, $p=0.001$). By multivariate Cox regression, including all relevant cardiovascular risk factors and routine biomarkers, OH >1.8l [hazard ratio 3.341 (95% confidence interval 1.121-9.961); $p=0.030$] showed the strongest association with survival.

CONCLUSIONS

Overhydration by BIS is a strong predictor of outcome and outperformed known risk factors in TAVR patients. Routine use might help to risk stratify patients, guide fluid management, and optimize the time point for intervention.

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Impact of Longitudinal Stent deformation shortening and Elongation during Expansion of 0 to 20 Atmospheric Pressure.

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Longitudinal stent shortening and elongation is often observed in the clinical settings. However, the phenomenon may make it difficult to place the stent in the precise position, especially in bifurcation or ostial lesion. We examined changes in longitudinal stent length.

METHODS AND RESULTS

We examined Synergy with four different sizes; 2.5 x 16 mm, 3.0 x 16 mm, 3.5 x 16 mm, 4.0 x 16 mm (n = 6 per each size). The stents were expanded from 0 atm with increase of every 1 atm up to the maximum pressure of 20 atm underwater and microscopic digital images were obtained for later analysis. The longitudinal stent length was measured from the digital images. The shortening and extension rate were calculated as follows: (length at each pressure – length before expansion) / length before expansion. The longitudinal stent lengths of before expansion of each sizes of stent were as follows: 2.5 mm, 15.9±0.1 mm; 3.0 mm, 16.4±0.1 mm; 3.5 mm, 16.4±0.1 mm; 4.0 mm, 16.5±0.1 mm. The differences between the longitudinal stent lengths of before expansion and standard length were less than 3%. All stents shortened until complete expansion. Complete expansion was observed in 6 atm in 2.5 mm stent and the other sizes of stent completely expanded at 4 or 5 atm. The shortening rates of the stents at the complete expansion were as follows: 2.5 mm, -1.27±0.78%; 3.0 mm, -1.44±0.25%; 3.5 mm, -1.85±0.67%; 4.0 mm, -3.49±1.46%. And then all stents were elongated with pressurization. At the nominal pressure (11 atm), the extension rates were as follows: 2.5 mm, 0.31±0.44%; 3.0 mm, 1.23±0.71%; 3.5 mm, 1.04±0.88%; 4.0 mm, -0.64±1.37%. At the rated burst pressure (16 atm), all stents were elongated. approximately 1.7 to 3.5%. The extension rates of rated burst pressure (16 atm) were as follows: 2.5 mm, 2.30±0.51%; 3.0 mm, 3.46±1.03%; 3.5 mm, 3.29±1.28%; 4.0 mm, 1.69±1.61%.

CONCLUSIONS

The longitudinal length of each size of stent with expansion rate of relative low pressure became shorter than the length of before expansion. By nominal pressure, stent length became closer to the length of before expansion, while all stent elongated by rated burst pressure. Understanding the phenomenon of change in stent length of each commercially available stents may provide additional knowledge for the precise coronary stenting when facing the coronary bifurcation and ostial lesions.

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Clinical outcomes of PCI treatment using new-generation DES in STEMI patients complicated by cardiogenic shock: one-year follow-up evidence from a world-wide e-Ultimaster registry

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS
PCI in AMI patients complicated by cardiogenic shock (CS) remains associated with significant morbidity and in-hospital mortality of 25-30%. In this study we aimed to assess the current PCI clinical outcomes in the high-risk subpopulation of STEMI-CS patients, using the real-world data of e-Ultimaster registry, which follows up on >37000 PCI-treated coronary artery disease patients.

METHODS AND RESULTS
eUltimaster is a prospective, multi-centre, world-wide observational study of Ultimaster DES, a new-generation sirolimus-eluting stent with bioresorbable abluminal polymer coating. The primary endpoint of this study is target lesion failure (TLF) at 1-year follow-up - a composite of cardiac death, target vessel (TV)-related myocardial infarction (MI) and clinically-driven (CD) target lesion revascularization (TLR). All deaths, MI, revascularizations and stent thromboses (ST) were independently adjudicated.
Among 3895 PCI-treated STEMI patients with completed 1-year follow-up, at hospital presentation 55 (1.4%) cases displayed evidence of cardiogenic shock - Killip class IV. Mean age in the STEMI-CS group was 63.7±10.3 years (70.9% male). STEMI patients with no CS (STEMI-other) had lower rate of diabetes (19.2 vs 30.9%; p=0.04), multivessel disease (MVD) (46.4 vs 67.3%; p=0.003), but higher rate of smokers, family history of heart disease and higher mean LVEF (51.4±11.0 vs 43.5±13.0; p=0.001) than STEMI-CS. The other baseline patient characteristics were largely similar.
Pain/door-to-balloon times were alike in the two groups. Pre-PCI hemodynamic support was more frequently used in STEMI-CS (30.9% vs 4.7%; p <0.0001). The use of pre-procedural GPIIb/IIIa inhibitor and thrombolysis, pre-/intra-procedural DAPT and adjunctive cardiac therapy was largely alike in the two groups. In STEMI-CS patients, trans-radial access was utilized less (69.1 vs 83.7%; p=0.01) and thrombus aspiration more often (38.2 vs 25.7%; p=0.04). Mean number of identified diseased vessels/lesions and treated lesions per patient was higher in STEMI-CS group (1.9±0.7 vs 1.6±0.8; 0.03) / (2.3±1.2 vs 1.8±1.1; p=0.002 and 1.5±0.7 vs 1.2±0.5; p=0.02, respectively). Left main and circumflex coronary arteries were more often treated in STEMI_CS group. TIMI flow score pre- and post-procedure was similar. Mean time-to-discharge was delayed in STEMI-CS group (6.8±4.9 vs 5.2±14.4 days; p=0.03).
All cause/cardiac death was higher in STEMI-CS patients, in-hospital (10.9 vs 0.9%; p<0.0001 / 7.3 vs 0.8%; p<0.001, respectively), at 30-days (16.4 vs 1.5%; p<0.0001 / 10.9 vs 1.3%; p<0.001) and at 1-year follow-up (16.4 vs 2.8%; p<0.0001 / 10.9 vs 2.0%; p=0.001). At 1-year, TLF was higher in STEMI-CS (10.9 vs 3.5%; p=0.01), mainly driven by early post-procedural cardiac death within the first month, as TV-MI and CD-TLR rates at 1-year were 0 vs 0.8%; p=0.99 and 0 vs 1.6%; p=0.99, respectively. At 1-year, the rate of definite and probable ST was alike (3.6 vs 1.2%; p=0.15), under similar DAPT regiment. At 1-year, majority of patients were angina-free (93%), with alike rates of stable and unstable angina in the two groups.

CONCLUSIONS

Our analysis confirms the feasibility of an early PCI in STEMI-CS patients and demonstrates a good safety and efficacy of the new-generation DES Ultimaster in this challenging patient setting. When compared to data published in earlier studies, herein reported contemporary real-world PCI outcomes in STEMI-CS patients are more promising, with equal survival rates of 84 % at 30 days and 1 year.

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Three-year clinical outcomes of biodegradable hybrid polymer Orsiro sirolimus-eluting stent and the durable biocompatible polymer Resolute Integrity zotarolimus-eluting stent: a randomised controlled trial

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Recent advances in coronary stents have been focused on thin strut thickness and biodegradable polymers. Previously, the ORIENT (randomized controlled open-label noninferiority trial to compare angiographic outcomes between the Orsiro and the Resolute-Integrity stents) trial showed similar angiographic outcomes between the biodegradable hybrid polymer Orsiro sirolimus-eluting stent (H-SES) and the durable biocompatible polymer Resolute Integrity zotarolimus-eluting stent (R-ZES) at 9 months after stent implantation. In this study, we report 3-year clinical outcomes of the ORIENT trial.

METHODS AND RESULTS

A total of 372 patients were prospectively enrolled and randomly assigned to the H-SES (n=250) and R-ZES (n=122) groups in a 2:1 ratio. The primary study endpoint was target lesion failure, a composite of cardiac death, nonfatal myocardial infarction, and target lesion revascularization. After coronary stent implantation, 98%, 96%, and 93% completed clinical follow-up at 1, 2, and 3 year, respectively. At 3 years, target lesion failure occurred in 4.7% and 7.8% of the H-SES and R-ZES groups, respectively (hazard ratio, 0.58; 95% confidence intervals, 0.24?1.41; P=0.232). Secondary endpoints including cardiac death, myocardial infarction, and target lesion revascularization showed no significant differences between the two groups. Stent thrombosis occurred in 2 patients, all of who were in the R-ZES group (0.0% vs 1.6%, P=0.040 by log-rank test).

CONCLUSIONS

This study confirms and extends the excellent safety and efficacy profiles of both coronary stents. However, we found a tendency toward lower adverse event rates with H-SES compared to R-ZES, although statistically insignificant. In addition, the risk of stent thrombosis was significant lower with H-SES.

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Impact of pulmonary hypertension on outcomes after transcatheter edge-to-edge tricuspid valve repair

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THEME: Interventions for Valvular Disease
TOPIC(S): Tricuspid / Pulmonary valve

AIMS

Pulmonary hypertension is a bad prognosis predictor in patients undergoing valvular heart surgery. We aimed to assess its impact on the benefit and outcome of transcatheter edge-to-edge tricuspid valve repair (TTVR) among patients presenting severe tricuspid regurgitation (TR).

METHODS AND RESULTS

Using data from the TRIVALVE Registry that includes patients undergoing edge-to-edge TTVR in 14 centres from Europe and North America, we assessed the outcome of TTVR according to baseline systolic pulmonary artery pressure (sPAP). 249 patients with severe TR treated with edge-to-edge TTVR between June 2015 to June 2018, were followed for a mean of 292 ±195 days. Mean sPAP was 43.6 ±16.0mmHg (maximum sPAP 117mmHg). Patients were divided according to their quartile of sPAP into 4 groups: sPAP <34mmHg (n=61); sPAP between 34 and 43mmHg (n=57); sPAP between 43 and 51mmHg (n=65); and sPAP>51mmHg (n=61). In the highest sPAP quartile, mean sPAP was 63.9 ±12.0mmHg. There was no difference in baseline characteristics regarding gender, previous hospital admission for RV failure, symptoms, and surgical risk. The only differences were patients age (74.4 ±11.7 yrs in the lowest quartile group, 76.1 ±9.5 yrs in the second quartile group, 80.2 ±6.9 yrs in the third quartile group, and 77.1 ±8.8 yrs in the highest quartile group, global P = 0.006), and the rate of MR grade III-IV (14.4% vs. 38.6%, 41.5%, and 60.6% respectively, P = 0.020).
Procedural success rate, defined as a successful implantation of the clip device and a post-procedural TR of grade 2+ or less, was similar in all groups (65.6% in the first quartile group, 86.0% in the second quartile group, 73.8% in the third quartile group, and 83.6% in the fourth quartile group, P=0.32). At final follow up, improvement in NYHA was observed in all groups. NYHA class I-II was found in 62.2% of patients in the lowest sPAP quartile group, 71.4 % of patients in the second quartile group, 59.2% in the third quartile group, and 70.9% in the fourth quartile group (P=0.4). There was no difference in survival free from hospital admission at one year (LogRank P value = 0.21, Figure), neither in survival at one year (Logrank P value = 0.65), nor in the absence of hospital admission for heart failure at one year (Logrank P value = 0.39) between the four groups.

CONCLUSIONS

Acknowledging the limitations of echocardiographic sPAP assessment in severe TR, the clinical benefit and survival free from hospital admission at one year are not influenced by sPAP in patients undergoing TTVR for severe TR. Accordingly, TTVR is an attractive option among patients with pulmonary hypertension, in whom valvular surgery is at high risk.

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Resheathing of self-expanding bioprosthesis: impact on prosthetic valve durability and clinical outcome after TAVI

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Malpositioning is a cause of potential complications after transcatheter aortic valve implantation (TAVI). New devices were recently developped, enabling to resheath and reposition the prosthesis during the deployment. Data about the safety and the impact on the outcome after this recapture maneuver are scarce.

METHODS AND RESULTS

On 348 consecutive patients undergoing TAVI in our center between January 2008 and December 2018, recapture and repositionning of the device was performed in 11% of cases (group 1, N=39 : 8 Portico and 31 Evolut-R prosthesis). Group 2 included 309 patients successfully implanted without resheathing, using Portico (N=23), Corevalve/Evolut-R (N=110) or Sapien/Sapien XT/Sapien 3 (N=176) devices. There were no difference in baseline characteristics between group 1 and 2 : age 84±6 vs 84±7 yrs, male gender 41 vs 48%, aortic valve area 0,7±0,2 vs 0,6±0,2 cm2, peak gradient 79±18 vs 75±23mmHg and STS score 5,3±2 vs 6,9±6; p=NS for all comparisons.

At the periprocedural period, according to Valve Academic Research Consortium-2 criteria, device success (97 vs 98%), all-cause mortality (zero vs 2,2%), disabling stroke (2,5 vs 1,2%), major bleeding (5,1 vs 1,9%), post-dilatation (18 vs 10%), need for second valve implantation (2,5 vs 1,2%), were similar between groups 1 and 2, respectively. Peak gradient was dramatically reduced at 5±5 mmHg in group 1 vs 5±4 mmHg in group 2, p=0,4. New pace maker was implanted more frequently in group 1 than in group 2 (34 vs 10% ; p=0,01), but was not different as compared with patients of group 2 receiving a self-expanding valve (15% ; p=0.15 vs group 1).

At follow-up (mean duration 822 days, 781 patients-years), the rate of moderate structural valve deterioration according to the new standardized European definition, was similarly low in both groups (2,5 vs 3,5% ; p=NS). Univariate analysis showed that resheathing was not associated with death : HR 1,072 (0,496-2,314) ;p=0,86, nor with structural valve deterioration : HR 1,351 (0,586-2,678), p=0,94.

Kaplan-Meier analysis showed a similar overall survival at 1 year (84±7 vs 77±2%) and at 2 years (67±16 vs 66±3%) between group 1 and 2, respectively (p=0,86).

CONCLUSIONS

The present study suggests that the resheathing maneuver is safe and do not have a negative impact on the prosthetic valve durability nor on the outcome of patients after TAVI, up to mid-term follow-up.

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Incidence and outcomes of bailout stenting following use of DEB

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THEME: Coronary Interventions

TOPIC(S): Stable CAD, Stents and scaffolds

AIMS

The incidence of bailout stenting post-drug coated balloon use (DCB) in the literature has been up-to 21% (in Bello trial) and this variation could be due to the different criteria used to consider bailout stenting. Our eyes are trained to expect stent like result and anything less is considered sub-optimal and this could be one of the reasons for high incidence of bailout stenting. Although immediate results post-DCB may not appear optimal, but we expect the vessel to positively remodel overtime. We have evaluated the incidence and outcomes of patients needing bailout stenting in our centre.

METHODS AND RESULTS

We evaluated all patients who were treated with DCB between January 2016-August 2017. Bailout stenting per lesion were identified and studied for endpoints which included cardiac death, target vessel MI, stent thrombosis, target lesion revascularization (TLR) and target vessel revascularization (TVR).

Between the study period; 468 lesions (in 364 patients) were treated with paclitaxcel DCB (Sequent Please, B Braun, Germany). Bailout stenting was required in 23 lesions (4.9%) and of which 12 (52%) was for flow limiting dissections (type C or more) and the remaining 11 was for recoil (of >50%). Majority of the lesions were in de novo (18; 78%). All bailout stenting was performed with second and third generation limus eluting stents. During a median follow-up of 18.14 months (range; 7 – 33 months), there was no cardiac death and target vessel MI occurred in 1 patient (4.3%). The TLR and TVR were 13% (3-lesions) and the MACE rate (combination of cardiac death, target vessel MI and TVR) was 13%. There were no cases of stent thrombosis as per the ARC definition.

CONCLUSIONS

One of the highlights of our study is very low-rates of bailout stenting. This may be due to our criteria of not stenting type A and B dissections (unless they are flow limiting) and also to accept recoil of up-to 50% post-DCB as we get positive remodelling of vessel with time. The outcome in bailout stenting group is acceptable especially with hard endpoints (cardiac death, target vessel MI and stent thrombosis) although TLR and TVR rates were higher indicating synergistic effect of paclitaxcel and limus may not offer additional benefits. In addition, the use of DCBs is usually in small vessels and hence bailout stenting maybe detrimental as it defeats the purpose, which may explain high rates of TLR and TVR.

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Angiographic restenosis in coronary bifurcations treatment with regular DES and dedicated bifurcation DES. Analysis based on randomised POLBOS I and POLBOS II studies

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

The wide variation in bifurcation anatomy has generated an ongoing search for stents designed specifically for coronary bifurcations. The aim of this study was to compare the recurrence rates and patterns between dedicated bifurcation BiOSS stents (Balton, Poland) and regular drug-eluting stents based on data from two clinical trials POLBOS I and II.

METHODS AND RESULTS

The POLBOS I and POLBOS II were international, multi-center, randomized, open-label, controlled trials. In POLBOS trials dedicated bifurcation BiOSS® stents were compared with DES in patients with stable CAD or NSTE-ACS (POLBOS I: paclitaxel eluting BiOSS® Expert vs DES; POLBOS II: sirolimus eluting BiOSS® LIM vs DES). The inclusion criteria were: stable coronary artery disease (CAD) or non-ST-segment elevation acute coronary syndrome (NSTE-ACS), age ≥ 18 years, de novo coronary bifurcation lesion (including unprotected left main [LM] stem), main vessel (MV) diameter ≥ 2.5 mm, and side branch (SB) diameter ≥ 2.0 mm on visual estimation. The main exclusion criteria were: ST-segment elevation myocardial infarction (STEMI), Medina 0,0,1 bifurcations, baseline serum creatinine level ≥ 177 μmol/L (2.0 mg/dl), inability to undertake dual antiplatelet therapy for 12 months, left ventricular ejection fraction ≤ 30%, and lack of informed consent. (ClinicalTrials.gov Identifier: POLBOS I - NCT02192840, POLBOS II - NCT02198300). Provisional T-stenting was the default strategy. The primary endpoint was the major adverse cardiovascular event (MACE) rate defined as the rate of cardiac death, myocardial infarction (MI) or target lesion revascularization (TLR). Quantitative coronary angiographic (QCA) analysis was performed using the dedicated bifurcation software CAAS 5.11 (Pie Medical Imaging BV, the Netherlands).

445 patients with 222 patients in BiOSS group and 223 patients in DES group were analyzed. In BiOSS group there were 24 cases of angiographic restenosis (10.8%) and in DES group – 17 cases (7.6%) at 12-month follow-up (angiographic control rate at follow-up – 90.3%).The rates of restenosis in BiOSS group in MV, MB and SB were 41.7% (n = 10), 37.5% (n = 9) and 54.2% (n = 13), respectively. Whereas rates of restenosis in DES group in MV, MB and SB were 35.3% (n = 6), 41.2% (n = 7) and 64.7% (n = 11), respectively. The largest LLL value was located 2.43 ± 2.00 mm from the point of bifurcation in the MV and 4.17 ± 3.00 mm in the MB in BiOSS stents. Interestingly the similar profile was observed in the DES group (2.88 ± 1.92 mm and 4.29 ± 2.0 mm, respectively).

In the BiOSS group most frequent Medina classification in restenotic cases was 0.0.1 (25%), whereas in DES – 0.0.1 and 0.1.1 (23.5% each). According to modified Mehran classification restenosis type I was observed in

58.3% and 52.9% in BiOSS and rDES groups, respectively. Whereas the other types were less frequent (type II: 20.8% vs 29.4%; type III: 8.3% vs 11.8%; type IV: 12.5% vs 5.9%). In BiOSS group most commonly restenosis type IA (focal, in MV) was observed (28.6%), whereas in DES - restenosis type IC (focal, in SB) with incidence of 17.7%.
In multivariate regression analysis proximal optimization technique was associated with the lowest chance for restenosis (OR 0.15, 95% CI 0.06 – 0.33), whereas diabetes on insulin was associated with the highest risk of restenosis (OR 4.21, 95% CI 1.48 – 11.44).

CONCLUSIONS
The angiographic restenosis pattern and rate were similar between BiOSS stents and DES in coronary bifurcation lesions.

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Revisiting the use of the provocative acetylcholine test in chest pain patients with non-obstructive coronary arteries: five-year follow-up from the AChPOL registry with the special focus on patients with the history of MINOCA

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

A significant proportion of patients undergoing coronarography due to chest pain has normal or near normal coronary arteries. The aim of this study was to assess the angiographic characteristics, efficacy and safety of provocative test with acetylcholine (ACh) in mid-European patients with non-obstructive coronary arteries and its influence on further treatment. Additionally, we analyzed the 5-year follow-up of this population with a special focus on patients with MINOCA history.

METHODS AND RESULTS

AChPOL Registry is a prospective ongoing single center registry including patients undergoing provocative test with ACh (AChT). From December 2010 to March 2013 we performed AChT in patients referred for further diagnostics with suspicion of variant angina or coronary microcirculation dysfunction based on COVADIS criteria. Acetylcholine was injected in incremental doses of 25, 50 and 75 mg into the right coronary artery and 25, 50 and 100 mg into the left coronary artery. Patients were followed-up for 5 years.

In AChPOL Registry we enrolled 211 patients. The mean age was 60.5±7.8 years, and women stand for 67.8%. The ACh test revealed variant angina in 99 patients (46.9%), and coronary microcirculation dysfunction was seen in another 72 patients (34.1%). In patients with variant angina the spasm was most frequently observed in left anterior descending artery (89.9%) and was most frequently diffuse (61.6%). The most common adverse events were: pause lasting over 4 s (7.6%) and paroxysmal atrial fibrillation (0.9%). The most common Ca-blockers prescribed in case of positive test were diltiazem (67.7%), amlodipine (27.3%) and verapamil (7.1%).

Interestingly, patient with variant angina and coronary microcirculation dysfunction comparing with patients with negative AChT were younger (59 ± 9.6 vs 58.4 ± 8.9 vs 68.1 ± 10.8 years, p = 0.02), there were more females (67.7% vs 83.3% vs 40%, p = 0.03), had more frequently chest pain at rest (7.17% vs 61.1% vs 40%, p = 0.02) and at night (62.6% vs 54.2% vs 22.5%), more frequently had thyroid dysfunction (23.2% vs 26.4% vs 2.5%, p =0.04), were smoking (22.2% vs 15.3% vs 5%, p = 0.04) and had history of prior MI (19.2% vs 31.9% vs 7.5%, p = 0.04), whereas had less frequently positive exertional treadmill test (43.4% vs 51.4% vs 77.5%, p = 0.02), supraventricural premature beats (5.1% vs 5.6% vs 37.5%, p = 0.01), atrial fibrillation (7.1% vs 5.6% vs 40%, p = 0.02) or diabetes type 2 (5.1% vs 5.6% vs 17.5%, p = 0.04).

The median follow-up was 56 months (range 48 – 60). In the microcirculation dysfunction subgroup there was a significant higher rate of recurrent chest pain requiring hospitalization (HR 2.76, 95% CI 1.45–3.52). Interestingly, also patients with the history of MINOCA had higher rates of MI (15.6% vs 4.2%, HR 4,01, 95% CI 1.08–14.86) and recurrent chest pain requiring hospitalization (35.6% vs 10.8%, HR 3,91, 95% CI 1,65–9,29).

CONCLUSIONS

Provocative test with AChis both effective and safe in mid-European population. In 5-year follow-up patients with recognized microcirculation dysfunction and MINOCA history characterized the highest risk of MI or recurrent chest pain requiring hospitalization.

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Delirium after TAVI: incidence, predictors and relation to long-term survival

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Patients undergoing Transcatheter Aortic Valve Implantation (TAVI) are at increased risk of postoperative delirium (POD), which is associated with increased morbidity and mortality. Prospectively collected data on delirium after TAVI are scarce. Aim of this study is to report the incidence of POD after TAVI and to analyze the direct clinical outcome and short- and long-term survival.

METHODS AND RESULTS

POD was assessed prospectively in all consecutive patients treated with TAVI in our center between 2008 and 2017, according to the Diagnostic and Statistical Manual of Mental Disorder (DSM)-IV criteria. TAVI was performed under general anesthesia. Outcome was reported according to the updated VARC2-criteria. Survival status was checked by consulting the Municipal Civil Registries. POD was observed in 16.5% (116/703) of all patients. Stroke and new onset of atrial fibrillation were more often observed in delirious patients (6.9% vs. 1.9%, p=0.007 and 12.1% vs. 5.1%, p=0.005, respectively). Independent preoperative predictors of POD were prior delirium (OR 2.56 [95% CI: 1.52-4.31], p<0.001), aortic valve area (AVA)<0.75 cm2 (OR 2.39 [1.53-3.74], p<0.001), age (1.08 [1.04-1.12], p<0.001) and BMI (0.94 [0.90-0.99], p=0.018). POD was the strongest independent predictor of long-term mortality (HR 1.91 [1.36-2.70], p<0.001) and resulted in impaired 30-day survival (92.2% vs. 97.9%, p=0.001) as well as 5-year survival (53.7% vs. 69.9%, p=0.035).

CONCLUSIONS

One-in-six patients suffered from POD after TAVI. Prior delirium and more calcified aortic valve were the strongest independent predictors of POD. POD was the strongest predictor of long-term mortality and severely impaired both short- and long-term survival.

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Clinical outcomes of haemodialysis patients undergoing PCI with a bioresorbable polymer sirolimus-eluting stent

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Chronic kidney disease (CKD) is a comorbidity that is markedly associated with poor outcomes of PCI patients. Patients undergoing haemodialysis (HD) are at a higher risk of CAD with increased morbidity and mortality rates. We aimed to assess the clinical outcomes in HD patients undergoing PCI with a thin strut sirolimus eluting stent on this high-risk subgroup of patients compared to non-HD CKD patients.

METHODS AND RESULTS

e-Ultimaster registry enrolled over 37,000 all-comer patients in 50 countries worldwide. Patients are treated with sirolimus-eluting Ultimaster, a thin strut cobalt chromium stent, abluminally coated with a bioresorbable polymer. The primary endpoint was target lesion failure (TLF) at 1 year defined as a composite of cardiac death, target vessel related myocardial infarction (TV-MI) and clinically driven target lesion revascularization (CD-TLR). Currently, 1466 (7.5%) patients with renal insufficiency, defined as an estimated glomerular filtration rate (eGFR) of less than 60 ml/min/1.73m², were treated and completed 1-year follow-up. Among these, 167 (11%) were on haemodialysis. We applied weighted propensity score matching for the comparison with non-dialysis renal insufficiency patients. An independent clinical events committee adjudicated all events.

Baseline characteristics were comparable after weighted matching. Average age of the patients was 68.8 years with 68.2 % being male. A mean body mass index of 26.6±4.7 kg/m2 and diabetes mellitus rate of 60.7% was observed. A hypertension rate of 87.5%, hypercholesterolemia 66.2% and acute coronary syndrome 46.6% were prominent risk factors. Pertaining to lesion characteristics, multivessel treatment rate was 24.3% in both groups and 19.3 % of the patients had bifurcation lesions. Ostial lesions rate was 15.3% vs 11.2%; p=0.12 and severe to moderate calcification lesion rate of 34.1% vs 29.7%; p=0.25 in the HD and non-HD groups respectively. As expected, femoral access was used in 50% of the patients in both groups probably due to the presence of haemodialysis permacath. Procedural information showed balloon predilatation rate of 81.3 % vs 73.0; p= 0.02.

The rate of TLF at 1 year was 9.7% vs 6.9%; p=0.19, cardiac death rate 6.65% vs 5.0%; p=0.38, TV-MI rate of 0.8% vs 1.3%; p=0.56 and CD-TLR of 3.1% vs 1.1%; p= 0.04 in the HD and non-HD groups respectively. Rate of stent thrombosis (ST) in HD patients, although numerically higher, did not reach statistical significance as compared to non-HD (1.5% vs 1.0%; p=0.57). At 1 year, 91.5% of HD patients were angina free vs 86.9% in the non-HD group (p=0.14). DAPT rate was 65.2% vs 62.1%; p=0.46 and any bleeding reported rate was 5.9% vs 3.1%; p=0.07 in the HD vs Non-HD group respectively. After adjusting for demographic and procedural differences, HD tended to remain associated with increased risk of TLF among renal insufficiency patients at 1 year (odds ratio1.74, 95% confidence interval 0.98 to 3.09; p=0.06).

CONCLUSIONS

This analysis indicates that despite complex lesions and higher comorbidities, with adequate vessel

preparation, patients undergoing haemodialysis can benefit from PCI treatment of CAD. Clinical outcomes at 1 year particularly the low ST rate indicate the good performance of the Ultimaster stent in this challenging patient population. Follow-up is ongoing and data on a larger number of pateints will be available at the time of presentation.

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TAVI in patients with pre-existing mechanical mitral valve prostheses

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Transcatheter aortic valve implantation (TAVI) has become standard therapy for aortic stenosis patients with intermediate or high operative risk. Treatment of patients with pre-existing mechanical mitral valve replacement (MVR) are challenging due to possible interference between TAVI prosthesis and MVR. In this paper we present our single center experience with this special patient cohort.

METHODS AND RESULTS

From 1960 patients who underwent TAVI at our institution between 2009 and March 2018, 16 patients had pre-existing mechanical MVR. Device success and adverse events were analyzed according to the VARC2 criteria. Patients were followed for at least 12 months.

Mean age of patients was 81.5 ± 4.4 years and they showed an average logistic EuroSCORE of 37.1 ± 13.5 % and STS score of 7.1 ± 3.2 %. Successful valve deployment was achieved in all patients, periinterventional stroke rate was 0% and permanent pacemaker was implanted in 2 patients (12.5%). Two patients experienced major complications with blockage of the MVR disc in one of them and annulus rupture in the other. Hence, 30-day mortality was 12.5 % and 25.0 % at one year.

CONCLUSIONS

TAVI in patients with mechanical MVR is challenging and needs careful preparation and choice of TAVI device. Repositionable and retrievable devices seem to be a safer option.

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Clinical outcomes following TAVI with the Portico valve according to the estimated surgical risk: a sub-study of the Portico I trial

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

To investigate the performance of the Portico transcatheter heart valve at 30 days and one year in patients with severe aortic stenosis whom are deemed high risk for surgery according to their STS-PROM score and other factors outside of the STS score that are known to increase a patient's surgical risk.

METHODS AND RESULTS

Portico I is an ongoing prospective, long-term follow-up study of patients with symptomatic, severe aortic stenosis at high surgical risk as determined by the Heart Team treated with the self-expanding, repositionable Portico™ transcatheter aortic valve (size 23, 25, 27 and 29 mm) via a transfemoral access (11 Fr and 12 Fr expandable sheath compatible). Adverse events (VARC-2 criteria) are adjudicated by an independent Clinical Events Committee and echocardiograms (30 days, 1 year) are evaluated by an independent Core Lab.

A total of 941 patients underwent an implant attempt between April 2013 and September 2017 at 61 sites across 14 countries (Europe, Australia and Canada). STS score and/or other risk factors were available to confirm a patient's high surgical risk according to an objective guideline-based definition in 478 patients. Heart team assessment concluded that additional patients were high risk, but objective criteria was required for inclusion in this sub-analysis. Patients were objectively classified as high risk if they had and STS>8, or >2 frailty indices, or >2 compromised organ systems, or a surgical procedural impediment. Of the 478 included in the sub-study analysis, 161 (33.7%) had an STS score of <4%, 158 (33.1%) had an STS between 4-8% and 159 (33.3%) patients had an STS score >8%. Among those patients with an STS <8%, 265 (83.1%) had >2 frailty indices, 77 (24.1%) had >2 compromised organ systems, and 38 (11.9%) exhibited a surgical procedural impediment. Using STS alone can be misleading for surgical risk classification but may still be a useful tool for predicting TAVR outcomes. The high-risk patients with a STS<4% (L-STS) were further compared against the patients with an STS>4% (I-STS) in this sub-study. The mean STS for each group was 2.7±0.8% and 9.3±5.8%, respectively (p<0.001). Patients in the L-STS group were younger (79.9±6.1 vs. 84±5.8 years, p<0.001) and were more frequently male (41% vs. 29%, p=0.009).

There were no differences between groups in TAVR procedural success (L-STS: 98.1%, I-STS: 98.1%, p=1.0) and periprocedural complications such as disabling stroke, life-threatening bleeding, stage 3 AKI or new pacemaker implant. There were also no differences in valve performance (residual gradient, paravalvular leaks) between groups.

At 1-year follow-up, all cause and cardiovascular mortality were lower in the L-STS group (7.7% vs. 17.1% for all-cause mortality, and 4.5% vs. 10.4% for CV mortality; p=0.04 and p=0.007 respectively). The STS score had no impact on the rates of the remaining clinical events.

CONCLUSIONS

Guidelines and clinical practice acknowledge that the STS score alone is not a good determination of risk, this

sub-study demonstrates that 2/3 of the patients in the Portico I study are high risk due to factors outside of the STS score. The sub-study also shows that the Portico valve can be safely implanted in all high-risk patients regardless of STS score with similar procedural and 30-day outcomes. Lower rates of all-cause and cardiovascular mortality were observed in the L-STS group at one year. A risk model integrating only frailty parameters failed to improve the risk estimation in the L-STS group. Further studies in a pre-specified low risk population are warranted.

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Two-year outcomes following real-world TAVI with a supra-annular self-expanding repositionable valve: results from the multicentre FORWARD study

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

TAVI is an alternative to surgery for patients with severe aortic valve stenosis who are at intermediate or higher risk of early surgical mortality. Extended follow-up data beyond the short term in larger patient populations are of utmost importance. 2- Year outcomes of the FORWARD study will be presented at the time of the meeting.

METHODS AND RESULTS

The Evolut R FORWARD Study is a multicentre, prospective, single-arm, observational post-market study to document safety and performance of the Evolut R system (23 mm, 26 mm or 29 mm valve sizes, Medtronic, Minneapolis, MN, USA) in a routine hospital setting at 53 centres in 20 countries on 4 continents. The Evolut R is a self-expanding, supra-annular porcine pericardial valve within a conformable Nitinol frame that can be partially or fully repositioned during implant to assist with accurate placement. Eligible patients had symptomatic native aortic valve or surgical bioprosthesis stenosis and were considered at high or greater risk of surgical mortality/morbidity based on Heart Team assessment. A Clinical Events Committee adjudicated serious adverse events.

A total of 1040 patients underwent attempted implant of the Evolut R valve. Patients were elderly with a mean age of 81.8±6.2 years, more often women (64.8%), with a mean STS score of 5.5±4.5% and mean EuroSCORE II of 5.7±5.0%. Patients were symptomatic (72.0% had NYHA III/IV symptoms) and 34.2% were considered frail. Additional comorbidities included; pulmonary hypertension in 46.1%, porcelain or severely atherosclerotic aorta in 16.0% and chronic lung disease in 26.3% of patients. At 1 year, the all-cause mortality rate was 8.9%, the cardiovascular mortality rate was 6.9%, the disabling stroke rate was 2.1%, and a pacemaker was implanted in 19.7% of patients. 77.7% had none or trace PVL at 1 year.

CONCLUSIONS

The Evolut R TAV was shown to have a good safety profile through 1 year in routine practice. We plan to present 2-year clinical outcomes at the time of the EuroPCR 2019 meeting.

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Safety and efficacy of polymer-free biolimus A9 eluting stent in patients with and without chronic kidney disease: insights from the RUDI-FREE registry

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(1) ,

THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

In the LEADERS FREE trial, the BioFreedom polymer-free biolimus A9-eluting stent (PF-BES) was superior in terms of safety and efficacy compared to a bare metal stent in patients at high bleeding risk. However, a prespecified subgroup analysis showed a significant heterogeneity of treatment effects with regard to target lesion revascularization according to the presence of chronic kidney disease (CKD). The aim of this study is to assess the clinical performance of the PF-BES in real world patients with and without CKD.

METHODS AND RESULTS

All consecutive patients undergoing percutaneous coronary intervention with the PF-BES at 16 Italian centers were included in a prospective registry. CKD was defined as an estimated glomerular filtration rate (eGFR) according to the Modification of Diet in Renal Disease equation lower than 60 ml/min/1.73 m2. The primary safety endpoint was the composite of cardiovascular death, myocardial infarction (MI), and definite/probable stent thrombosis (ST) at 1 year. The key secondary efficacy endpoint was the target lesion revascularization (TLR) at 1 year.

Between January 2015 and May 2016, 1,104 consecutive patients treated with PF-BES were included. CKD was present in 167 patients (15.1%). Patients with CKD were older and had more comorbidities than those without CKD. Mean eGFR in patients with CKD was 41+19 ml/min/1.73 m2.

At one year, the rate of the primary safety endpoint was significantly higher in CKD patients with than no-CKD (10.7 vs. 2.8%, p<0.001). Rates of cardiac death (10.7 vs. 2.8%, p<0.001) and MI (4.8 vs.1.2%, p=0.004) were significantly higher in CKD patients than no-CKD patients, while the rate of definite/probable ST was numerically but not significantly higher in CKD than no-CKD patients (2.4 vs. 0.9%, p=0.096). Conversely the key secondary efficacy endpoint TLR showed no differences between patients with and without CKD (2.4 vs. 1.2%, p=0.184).

CONCLUSIONS

CKD is associated with an increased ischemic risk among patients undergoing PCI. However, the efficacy of BioFreedom PF-BES appears not to be affected by the presence of CKD.

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Site vs. core laboratory variability in CT angiography-derived SYNTAX scores in the SYNTAX III trial

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Left main and multivessel disease

AIMS

To investigate the variability between site and core laboratory (CL) calculation of the anatomical SYNTAX Score (ASS) based on coronary computed tomography angiography (CTA) alone and functional SS (FSS) based on coronary CTA and FFRCT in the SYNTAX III trial.

METHODS AND RESULTS

The SYNTAX III trial was a multicenter, international study that included patients with three-vessel coronary artery disease (n=223). FSS was computed by subtracting non-flow limiting stenosis (FFRCT >0.80) from CTA-derived ASS. SS was combined with clinical information to generate the SYNTAX Score II (SS II) that provides treatment recommendations. Agreement in SS and treatment recommendations based on SS II between site versus CL was assessed using intraclass correlation coefficient (ICC) and Cohen's kappa, respectively.

The mean ASS based on coronary CTA alone was 33.4±12.7 by site and 37.1±13.4 by CL ($p<0.001$). The mean FSS based on coronary CTA and FFRCT was 30.5±13.0 by site and 33.3±13.6 by CL ($p<0.001$). The ICC was 0.49 (95% confidence interval (CI) [0.37, 0.59]) in the ASS and 0.62 (95% CI [0.52, 0.70]) in the FSS. The Cohen's kappa comparing treatment recommendation between site and CL was 0.68 (95% CI [0.58, 0.78]) based on the ASS and 0.71 (95% CI [0.60, 0.82]) based on the FSS

CONCLUSIONS

The mean anatomical SS derived from coronary CTA alone and functional SS based on coronary CTA and FFRCT were higher in CL than in sites. However, substantial agreement in treatment recommendation by SS II between sites and CL was demonstrated.

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Recovery of absolute flow and resistance in CTO coronary arteries after PCI

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

This study aimed to investigate the physiology of absolute blood flow and microvascular resistance after percutaneous coronary intervention (PCI) of chronic total occlusion (CTO).

METHODS AND RESULTS

In this pilot study 8 patients scheduled for elective PCI of a right coronary artery CTO were selected. Before performing PCI of the CTO, absolute flow and resistance were measured in the donor vessel, using the novel thermodilution method with a multifunctional monorail infusion catheter, whereafter PCI of the CTO vessel was performed. After successful PCI, absolute flow and microvascular resistance was measured in the just opened CTO vessel and again in the donor vessel. All measurements were repeated after 6 weeks to re-evaluate absolute blood flow and resistance in the CTO territory and the donor artery. Complete measurements were obtained in all patients.

These comprehensive measurements showed a significant increase in blood flow in the CTO vessel over the course of time in all patients. Flow in the CTO artery increased from 161 ± 36 ml/min immediately after opening to 248 ± 73 ml/min at six week follow-up (p=0.012). In corollary absolute resistance in the myocardial territory perfused by the CTO artery, decreased from 448 ± 114 WU to 359 ± 130 WU.

CONCLUSIONS

This study demonstrates that absolute blood flow and microvascular resistance can be measured invasively ad-hoc after PCI of a CTO and recovers to normal within several weeks.

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Three-year mortality in men and women after TAVI using the SAPIEN 3 transcatheter aortic valve, via the transfemoral route

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Previous TAVI investigations demonstrated better survival in women compared to men. We studied 3-year post-TAVI survival and its predictors by sex, in a real-world cohort that underwent transfemoral TAVI using SAPIEN 3.Previous TAVI investigations demonstrated better survival in women compared to men. We studied 3-year post-TAVI survival and its predictors by sex, in a real-world cohort that underwent transfemoral TAVI using SAPIEN 3.

METHODS AND RESULTS

Methods & results: SOURCE 3 (SAPIEN 3 Aortic Bioprosthesis European Outcome) is a post-approval, multicenter, observational registry. Patients (N=1694, 834 women and 860 men, age 81.7±6.7 years) with severe aortic stenosis and high risk for surgery (logistic EuroSCORE 17.8%, 5.3% EuroSCORE II), who underwent transfemoral TAVI between 2014 and 2015 were analyzed for survival by sex. Predictors of overall mortality were identified using a Cox multivariate proportional hazard model. At 3 years, women had significantly lower all-cause mortality than men (32.1 v 26.2; p=0.003). No difference was observed for cardiac mortality between sexes (19.4 vs 16.9; p=0.21). After matching for age, height, weight, NYHA functional class, renal dysfunction and tricuspid regurgitation, no differences were found in mortality between sexes.

CONCLUSIONS

In this large, real-world cohort, cardiovascular mortality was similar between sexes at 3 years post TAVI. While overall women had a lower all-cause mortality than men, this difference between sexes was not evident after matching for confounding factors. No difference was observed for cardiac mortality between sexes.

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Six-year clinical outcomes of NOBORI biolimus-eluting stent vs. XIENCE everolimus-eluting stent in diabetic patients

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Diabetes mellitus remains a significant predictor of adverse clinical outcomes even in the newer-generation drug-eluting stent (DES) era. However, long-term clinical outcomes of various DES in diabetic patients have not yet been fully evaluated. We sought to compare long-term clinical outcomes between NOBORI biodegradable polymer biolimus-eluting stent (BP-BES) and XIENCE durable polymer everolimus-eluting stent (DP-EES) in diabetic patients.

METHODS AND RESULTS

From February 2010 to August 2012, 2481 patients were treated only with NOBORI biodegradable polymer biolimus-eluting stent(BP-BES n=1339) or XIENCE durable polymer everolimus-eluting stent(DP-EES n=1142). Of these, 1075 diabetic patients (BP-BES, n=576; DP-EES, n=499) were retrospectively enrolled in this study. We followed them for 6 years.

The average age of the two groups was 70.1 and 69.3 years old. Diabetes mellitus control was similar. HbA1c was 7.6% and 7.3% respectively. 70.5% and 67.5% of patients were treated by oral antidiabetics. 18.6% and 21.2% of patients were treated by insulin. 10.6% and 9.2% of patients recieved hemodialysis.

Cumulative 6-year incidence of targeted lesion revascularization(TLR) and Clinically-driven TLR were also comparable between BP-BES and DP-EES groups (18.6% vs. 19.6%, p=0.66 and 15.8% vs. 15.9%, p=077, respectively). Cumulative incidence of definite stent hrombosis was very low and similar between the 2 groups (0.87% vs. 1.20%, p=0.59). Acute miocardial infarction was also not significantly different between both groups (2.95% vs. 2.61%, p=0.73).

There is some study limitation. This study was an observational, retrospective, single-center study.In this study, there were some difference in patient characteristics and lesion and procedural characteristics between BP-BES and DP-EES groups

CONCLUSIONS

At 6 years, both NOBORI biodegradable polymer biolimus-eluting stent (BP-BES) and XIENCE durable polymer everolimus-eluting stent (DP-EES) showed similar clinical outcomes in diabetic patients. So we can use both stents safely for diabetic patients.

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Treatment of extremely small de novo vessel coronary artery disease with DEB - a single-centre experience

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Stents and scaffolds

AIMS

To compare the outcomes of Paclitaxel-Drug-eluting Balloon (DEB) angioplasty in patients with ≤2.25mm and >2.25mm de novo small vessel coronary artery lesions.

METHODS AND RESULTS

All patients underwent de novo coronary artery lesions angioplasty with DEB between January 2012 and December 2017 were included in the analysis. Patient baseline characteristics, angiographic data, post-procedural and 12-months follow-up outcomes, including cardiac death, myocardial infarction and major adverse coronary event (MACE) were compared.

A total of 1070 patients with 1171 de novo small coronary artery lesions were included in the study. Mean age was 59±10 years with a predominance of males (n= 901, 84%). Majority were hypertensive (n=791, 74%) and diabetes mellitus accounted for 620 (58%) of cases. Fourteen percent presented with acute coronary syndrome (ACS), 5% had STEMI, 5% had NSTEMI and 4% unstable angina. Diffuse vessel disease were present in 575 cases (49%). Majority of the stenotic lesions were in the left coronary artery; left anterior descending artery, n=445, (38%) and left circumflex artery, n=379 (32%). Three hundred and fifteen (27%) lesions were in the right coronary artery and 22 were in the bypass grafts (2%). Majority of the lesions were type B2 and C lesions (n=719, 61%). Pre-dilatation of the lesions were performed in majority of cases (n=1159, 99%) with a pressure of 11±5 atmospheres. The mean DEB diameter and dilatation pressure were 2.5±0.4 mm and 8±4 atmospheres, respectively. The mean inflation time was 60±17 seconds. Flow-limiting lesions post DEB that were bailed out with stents were 21 (1.8%). Eight hundred and nineteen (77%) patients received both Aspirin and Clopidogrel on discharge. Clinical follow-up were available in 1047 (98%) patients. There were no complications of acute or subacute vessel thrombosis following treatment. Out of 1171 lesions, 432 (37%) cases treated with DEB had a diameter of ≤2.25mm. Dissection in vessels ≤2.25mm and >2.25mm were in 24 (5.6%) and 49 (6.6%) cases respectively (p=0.463). Flow limiting dissection was not significant in vessels ≤2.25 mm as compared to vessels >2.25 mm (p=0.693), which occurred in 9 (2.1%) and 13 (1.8%) cases respectively. At follow-up, major adverse cardiac events (MACE) in vessels ≤2.25 mm and >2.25mm were 6 (1.5%) and 15 (2.3%), respectively (p=0.382). Cardiac deaths were 3 (0.8%) in vessels ≤2.25mm and 2 (0.3%) in vessels >2.25mm (p=0.372). TLR in vessels ≤2.25 mm were 2 (0.5%) and 12 (1.8%) in vessels >2.25mm (p=0.07).

CONCLUSIONS

Our experience demonstrates that using DEB in the treatment of extremely small de novo vessels in coronary artery disease was favourable and safe with a low MACE rate at mid-term follow-up and offers an alternative treatment to stenting in de novo small vessel coronary artery disease.

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Transapical chordal mitral valve repair - What the involved team should know about it

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair

AIMS

This presentation will inform the audience about this primarily surgical approach which is always done in collaboration with the cardiological department. This transapical concept is also of interest for the cardiological community, especially taking into consideration that there is also the possibility of combining the transapical chordal mitral valve repair with other procedures which are already approved or in development and that there are other similar transfemoral, transseptal approaches in development.

METHODS AND RESULTS

The medical background and the corresponding indications and contraindications to the transapical chordal mitral valve repair are content of this presentation. Furthermore the necessary materials, the technical equipment, the emergency backups, the patient preparation and the surgical procedure itself are discussed.

CONCLUSIONS

This kind of mitral valve repair seems to be a safe and alternative treatment option for patients affected by degenerative mitral valve regurgitation.
For surgical teams that are used to perform cardiac surgery via minithoracotomy regularly it´s not a major problem to deal with this method safely and experienced in a short period of time.

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Distal radial approach for coronary angiography and PCI in patients with low body mass index

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Other Coronary Interventions

AIMS

Aims: We aimed to evaluate the feasibility and safety of the distal radial approach (DRA) as a default route for coronary angiography (CAG) and PCI in patients with a weak constitution.

METHODS AND RESULTS

Methods and results: The study population consisted of patients undergoing CAG or PCI with the DRA between July 2018 and December 2018. After excluding patients with nonpalpable distal radial artery or suspected ulnar artery occlusion by Allen's test and those being considered unsuitable by the investigators, 510 patients were divided into two groups on the basis of body mass index (BMI): patients with BMI <20 kg/m2 (low BMI group, n = 54) and the other patients (non-low BMI group, n = 456). The procedural success rates and complications were compared between the two groups. The mean age was 70.9 years, men represented 80.2%, and the mean BMI was 24.2 kg/m2. Of the 510 patients, 392 patients (77%) underwent CAG, with a procedural success rate of 81% (317/392 patients), and 118 patients (23%) underwent PCI, with a procedural success rate of 89% (105/118 patients). The overall use rate of the right DRA was 80%. The sizes of introducer sheaths used for CAG were 4 Fr in 229 patients (58%), 5 Fr in 159 (41%), and 6 Fr in 4 (1%); those used for PCI were 5 Fr in 52 (44%) and 6 Fr in 66 (56%). Double antiplatelet therapy was administered in 270 patients (53%), single antiplatelet therapy in 128 (25%), both double antiplatelet and anticoagulant therapies in 15 patients (3%), both single antiplatelet and anticoagulant therapies in 46 (9%), anticoagulant therapy alone in 10 (2%), and no pharmacotherapy in 41 (8%). The mean hemostasis time was 180 ± 47.7 minutes (178 ± 45.8 minutes for CAG and 183 ± 53.5 minutes for PCI). No major bleeding, defined as BARC bleeding type 2, 3, or 5, occurred, but minor hematoma occurred in 33 patients (6.5%). One patient developed peripheral neuropathy and is still treated at the time of writing. The low BMI group was older and had more women. Between the low and non-low BMI groups, no significant differences were observed in the procedural success rate (83.3% vs. 82.9%, p = 0.9) and the incidence rate of minor hematoma (9.1% vs. 5.7%, p = 0.36).

CONCLUSIONS

Conclusions: The DRA for CAG and PCI are feasible and safe, irrespective of BMI.

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Clinical impact of geographical variations between Japanese and non-Japanese patients treated with Ultimaster bioresorbable polymer sirolimus-eluting stent: observations from the e-ULTIMASTER registry

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Geographical and clinical practice variations remain influencing factors on clinical outcomes of PCI patients. We sought to assess the differences in baseline clinical characteristics between the Japan and non-Japan cohorts as well as 1-year clinical outcomes in the e-ULTIMASTER registry.

METHODS AND RESULTS

The e-ULTIMASTER registry is a large, prospective, single-arm, multi-centre registry that is designed to further validate the safety and efficacy of the Ultimaster drug-eluting stent (DES) (Terumo, Japan) in unselected patients enrolled worldwide. Currently, 19,482 patients (Japan cohort, n=721; non-Japan cohort, n=18761) enrolled in the e-ULTIMASTER registry have completed 1-year follow-up. Compared to the non-Japan group, the Japan group had high-risk features such as advanced age, diabetes mellitus, renal failure, and prior percutaneous coronary intervention (70.1±9.9 vs. 64.4±11.1 years; 44.1% vs. 27.6%; 22.2% vs. 7.0%; 42.0% vs. 24.9%; p <0.001, respectively). The Japan group included predominantly patients with stable coronary artery disease (64.8%), whereas 57.1% of the non-Japan group presented with acute coronary syndrome. The Japan group had considerably greater lesion complexity such as bifurcation lesion, chronic total occlusion, left main coronary artery lesion, and long lesion requiring total stent length >25-mm (23.2% vs. 12.8%; 7.6 % vs 5.2 %; 8.2% vs. 3.0%; 59.5% vs. 42.8%; p <0.01, respectively). Several differences in procedural characteristics between both groups were also observed, while intravascular ultrasound was much more frequently used in the Japan group than the non-Japan group (81.4% vs. 2.4%, p <0.001). At 1-year, clinically driven target lesion revascularization rate was significantly higher in the Japan group than in the non-Japan (4.9% vs. 2.1%, p <0.001), although the rates of cardiac death and stent thrombosis were comparable between both groups (1.7% vs. 1.3%, p = 0.40 and 0.42% vs. 0.66%, p = 0.63, respectively).

CONCLUSIONS

Several significant differences in baseline clinical features between the Japan and non-Japan cohorts were observed in the e-ULTIMASTER registry, being associated with the differences in health-care policies and standard of PCI procedures among countries. Despite these differences, both Japan and non-Japan cohorts yielded acceptable 1-year clinical outcomes.

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Comparison of mid-term healing response after DES implantation between IVUS-guided and optical frequency domain imaging-guided PCI

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Although response of vessel healing after drug-eluting stent (DES) implantation has been extensively investigated, it is still unknown whether imaging guidance (intravascular ultrasound [IVUS] vs. optical frequency domain imaging [OFDI]) during the PCI procedure could give an impact on healing response after DES implantation. We thus sought to assess the neointimal healing score at 8 months in a randomized population with direct comparison of IVUS-guided vs. OFDI-guided PCI.

METHODS AND RESULTS

This is a sub-study of the MISTIC-1 (Multimodality Imaging STudy In Cardiology cohort 1) which is a prospective, single-blineded, randomized-controlled, non-inferiority trial comparing imaging and clinical endpoints between OFDI-guided and IVUS-guided PCI using Biolimus A9 eluting Nobori stent (Clinicaltrials.gov identifier: NCT03292081). We enrolled the patients with stable coronary artery disease who have symptoms or clinically relevant myocardial ischemia proven by non-invasive or invasive functional testing. Patients were randomly assigned to either IVUS-guided or OFDI-guided PCI. Stent landing zones (i.e. reference sites) were selected in the most normal looking sites with largest lumen and without percentage plaque area >40% in IVUS group while without lepidic plaque of >3 quadrants or suggestive thin-cap fibroatheroma in OFDI group. Stent sizing was based on external elastic lamina (EEL) in IVUS group, while by taking 10% or 0.25mm larger than mean lumen diameter at reference sites in OFDI group. Stent optimization with in-stent minimum lumen area ≥90% of the average lumen area at proximal and distal reference sites was encouraged in both groups. Post-procedural OFDI was investigated regardless of randomization, while the image was blinded to the operators in IVUS-guided PCI arm. The neointimal healing score was calculated per lesion based on the following stent-related characteristics; (1) intraluminal defect (ILD) assigned a weight of “4”, (2) both malapposed and uncovered struts (MU) assigned a weight of “3”, (3) uncovered struts alone (U) assigned a weight of “2”, or (4) malapposed struts alone (M) assigned a weight of “1”. Neointimal healing score was calculated as (%ILD*4)+(%MU*3)+(%U*2)+(%M*1). Since June-2014 and August-2016, we prospectively enrolled 109 patients (mean age 70 years, male 78%) with 126 lesions in two Japanese cardiovascular centres. Baseline patient and lesion characteristics were well balanced and mean number of stents per lesion was 1.1±0.2. Procedure time was comparable while total contrast volume was significantly higher in OFDI group than in IVUS group (147mL vs. 121mL, respectively). OFDI follow-up was performed for 58/64 lesions (90.6%) in IVUS group and in 54/62 lesions (87.1%) in OFDI group. At 8-month follow-up, neointimal healing score was comparable (0.43 [95% CI, 0.00-3.30] in IVUS group vs. 0.16 [0.00-3.14] in OFDI group, p=0.43), and 43.1% in IVUS group and 50.0% in OFDI group demonstrated perfect healing response indicated as neointimal healing score of 0. Stent thrombosis was not observed in both groups during the follow-up.

CONCLUSIONS

This study demonstrated comparably excellent healing responses at 8 months after Biolimus A9 eluting Nobori stent implantation between IVUS-guided and OFDI-guided PCI. Our data may support the mid-term safety of PCI under the guidance of intracoronary optical imaging techniques.

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Is inappropriate dose reduction of direct oral anticoagulants according to the standard criteria really inappropriate when used with antiplatelet agents?

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Atrial fibrillation (AF) patients undergoing percutaneous coronary intervention (PCI) with metallic stent implantation are increasing all over the world because of the overlapped risk factors of coronary artery disease and AF. Whether the standard criteria for dose reduction of direct oral anticoagulant (DOAC) can be applicable when used with antiplatelet agents still remains to be investigated.

METHODS AND RESULTS

We conducted a single-center prospective observational registry of AF patients with DOACs: the DIRECT registry (UMIN000033283). In the overall cohort of 2216 patients, 477 patients treated with both DOACs and antiplatelets were assessed (mean follow-up: 412±374 days). Patients were divided into 2 groups according to the prescription dose of DOAC: Appropriate dose group (N=382) and inappropriate dose reduction group (N=95) according to the standard criteria provided by the pharmaceutical company. Appropriate dose group included patients with regular dose and reduced dose based on the standard criteria. Inappropriate dose reduction group included patients with reduced dose despite that regular dose was recommended by the criteria. Any bleeding (defined as a composite of major bleeding according to the ISTH criteria and clinically relevant bleeding) and major bleeding were co-primary safety endpoints. Primary efficacy endpoint was stroke. Clinical endpoints were compared between both groups (Kaplan-Meier analysis, Log-rank test). Patient background including hypertension, diabetes mellitus, dyslipidemia, CHADS2 score, and ORBIT score were well balanced. Kaplan-Meier estimated 2-year any bleeding rate was numerically lower in the inappropriate dose reduction group than in the appropriate dose group (28.7 % vs. 22.1 %, p=0.071), although it did not reach a statistical significance. The major bleeding rate was similar between both groups (5.0 % vs. 4.2%, p=0.816). Kaplan-Meier estimated 2-year stroke rate was not significantly different between the groups (1.0% vs. 1.1%, p=0.560).

CONCLUSIONS

The present Asian real-world data suggested that, when AF patients treated with DOACs use add-on antiplatelet agents, inappropriate dose reduction according to the criteria provided by the pharmaceutical company could be more appropriate than regular dose. Further prospective investigations should be conducted.

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Two-year efficacy and safety of the ABSORB BRS implanted in small vs. large coronary arteries: a subgroup analysis of the German-Austrian ABSORB RegIstRy (GABI-R)

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

The ABSORB bioresorbable vascular scaffold raised safety concerns due to higher rates of scaffold thrombosis (ST). Smaller scaffold diameter (SD) was an infrequently quoted predictor of major adverse cardiac events (MACE). Therefore, we evaluated the impact of SD on 2 year outcome in the all-comer real life GABI-R cohort.

METHODS AND RESULTS

We compared patients with implanted large SD ≥3 mm (LSD) vs. small SD ≤2.5 mm (SSD). 1341 patients with LSD compared to 444 patients with SSD more often presented with ST-Elevation myocardial infarction (35.8% vs. 20.6%, p<0.0001) and single-vessel disease (50.6% vs. 36,5% p<0.0001). After 24 months follow-up, there was no difference in regard of MACE (9.66% vs. 12.31%, p=0.14) or definite/probable ST (2.47% vs. 2.82%, p=0.71). Despite no difference in target lesion revascularisations (TLR) (5.81% vs. 7.71%, p=0.18), there was a higher need for target vessel revascularisation (TVF) in the SSD-group (11.57% vs. 7.51%, p<0.05).

CONCLUSIONS

Compared to larger SD, ≤2.5 mm SD demonstrated comparable safety in regard to MACE and ST as well as efficacy in regard to TLR. Differences in TVF rates are explained by the higher cardiovascular risk burden in the SSD-group. Resorbable scaffold technology should not be restricted to large vessel diameters.

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Assessment of dynamic load acting on transcatheter aortic valve at valve closure: biomechanical insights into an influence of paravalvular leak on durability

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Although moderate to severe paravalvular leak (PVL) after transcatheter aortic valve replacement (TAVR) is associated with adverse outcomes and increased mortality, there are no data about the influence of presence of mild PVL on valve durability. We investigated the load acting on the valve at its closure using a patient-specific aortic valve model in the physiologic pulsatile flow circulation system, and also developed an accelerated durability tester which has the system to measure the load at the cyclic speed of 1200 beats/min, to gain an insight into durability of TAVR with a mild PVL.

METHODS AND RESULTS

A patient-specific aortic valve model was constructed from pre-procedural CT data of a patient whose aortic annulus area was 367 mm2 (equivalent to the average of Japanese patient), and who was treated with a 23-mm Sapien XT (Edwards Lifesciences), and whose PVL was mild. By regulating mechanical properties of calcified lesions and aortic wall, aortic annulus areas at systolic and diastolic phases and the stent-frame area of the model were adjusted to those of the patent. As a control, a cylindrical valve model which does not induce PVL was prepared. The Sapien XT was deployed with a nominal volume for each model. We developed a pulsatile flow simulator equipped with the system measuring the load acting on the valve at its closure. Forward flow and aortic pressure were regulated at 4.0L/min and 120/80mmHg, respectively at the 70 beats/min. In parallel, an accelerated durability tester which also has a system to measure the load acting on the valve was developed to investigate whether the acceleration may induce the difference in the loads between the physiologic and accelerated cyclic speed. The accelerated durability tester was operated at 1200 beats/min under the pressure difference of 100 mmHg at the valve closure in accordance with the requirement in the durability test prescribed by ISO 5840.

A micro CT analysis confirmed the presence of the flow tract with the minimal incomplete apposed gap area of 12.6 mm2 between the patient-specific model and the valve stent-frame. No gap was observed in the cylindrical model. The pulsatile flow tests showed that the maximum load acting on the valve at its closure with the patient-specific model was smaller than that with the cylindrical model without the gap inducing PVL (23.6 N vs 36.5 N). These data implied that the PVL reduces the load acting on the valve at its closure and subsequently reduce damage accumulated to the valve.

In the accelerated durability tester, the load acting on the valve was larger than that in the 70 beats/min pulsatile circulation (47.3 N vs 23.6 N). These data indicated that the accelerated durability test condition is severer than the physiologic pulse rate condition even under the same pressure load difference, and considered safer in terms of risk assessment. We confirmed that the valve fully opened and closed at the accelerated condition using a high speed camera.

CONCLUSIONS

Comparison of the maximal load acting on the transcatheter valve at its closure between the patient-specific valve and cylindrical models using the pulsatile flow simulator indicated that PVL has the effect of reducing the

load acting on the valve, which may positively contribute to extending durability of the valve. Moreover, our data indicated that the acceleration of the cyclic speed in the durability test increases the load acting on the valve.

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Paradoxical reduced coronary flow after adenosine in the infarct-related artery in patients with STEMI is dependent on the collateral supply

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Adenosine is used to treat no-reflow due to microvascular injury in the infarct related artery (IRA) during ST-elevation myocardial infarction (STEMI) intervention. However, the coronary physiological effect of adenosine is variable and adenosine derived coronary pressure indices e.g. Fractional Flow Reserve are not recommended in STEMI. We sought to further investigate effects of adenosine on coronary flow in patients presenting with STEMI to determine underlying mechanism.

METHODS AND RESULTS

Seventy-eight patients presenting with STEMI undergoing primary PCI had Pressure wire X (Abbott Vascular) assessment of the IRA after stenting. Coronary flow velocity by thermodilution (transit time–Tmn) and aortic and distal pressure (Pa and Pd) at baseline and after a peripheral infusion of Adenosine (140 Mcg/kg/min) were measured, coronary wedge pressure (Pw) was measured as Pd during balloon coronary occlusion and central venous pressure (CVP) was assumed to be 5mmHg. Off-line analysis was done using Coroflow (Coroventis, Uppsala) to calculate coronary flow reserve (CFR=Tmn baseline/Tmn hyperaemia) and patients' adenosine response was stratified into 3 groups: hyperaemic (CFR>1.1), no effect (CFR=0.9-1.1) and slow flow (CFR<0.9). Index of microcirculatory resistance corrected for collaterals (IMRc) during hyperaemia was calculated as was collateral flow index by pressure (CFIP= (Pw-CVP)/ (Pa-CVP) at rest. Collateral Rentrop grade to the IRA was recorded by angiography. Fifty-eight patients had cardiac MRI (CMR) at 24-48 hours, analysed off-line using CMR42 software (Circle Cardiovascular Imaging, Alberta, Canada). Student's t-test was used to analyse continuous data and Fisher's Exact and McNemar's tests were used for categorical data (IBM® SPSS®, Version 25). A p-value <0.05 was deemed significant.

Mean age of patients was 69±11 years and the majority were male (85%). The territory of the IRA was LAD (67%), RCA (22%) and left circumflex artery (11%). Slow flow after adenosine occurred in 18(23%) patients and these patients had a higher mean Rentrop grade of collaterals supplying the IRA than the hyperaemic group (n=46 patients, 62%): 1.44±0.5 vs. 0.67±0.7, p=0.005 and a higher mean CFIp: 0.24±0.1 vs. 0.16±0.1, p=0.01. Microvascular resistance was numerically higher after adenosine in the slow flow group (IMRc): 54±29 vs. 46±45, p=0.43. CMR evidence of microvascular obstruction (MVO) was apparent in 86% of the slow flow group vs. 39% in the hyperaemic group, p=0.004. The slow flow group also had a larger percentage area of LV subtended by MVO: 2.1±2% vs. 0.6±1%, p=0.009. There was a trend to larger infarct size in the slow flow group compared to the hyperaemic group: 21.8±17g vs. 16.6±15g, p=0.15.

CONCLUSIONS

The response of coronary flow to adenosine in the IRA is heterogeneous and appears to slow when the IRA is subtended by collaterals and there is distal microvascular obstruction. Paradoxical coronary steal phenomenon

may explain disparate effects of adenosine where-by the IRA microcirculation is unable to respond to adenosine but the non-IRA microcirculation retains the ability to vasodilate, diverting blood away from the IRA distal bed via collaterals due to this differential effect. The degree of collateralisation to the IRA should be considered before using adenosine as a therapy for no/slow reflow, to avoid exacerbating the problem.

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The specific characteristics and independent predictors of no-reflow phenomenon, development of a clinically-adaptable risk estimation system

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

No-reflow (NR) phenomenon occurs, when myocardial perfusion is not re-established despite opening the coronary artery during percutaneous coronary intervention (PCI). Our aim was to identify no-reflow specific characteristics, its independent predictors, and to develop a clinically-adaptable risk score.

METHODS AND RESULTS

We have analysed 4085 patient data from two Hungarian cardiovascular centres using the national data of the Myocardial Infarction Database. We included all STEMI/NSTEMI patients underwent PCI (n=3187). 158 patients treated with papaverine or adenosine during PCI formed NR group, while 3029 patients were in control (C) group. Anamnestic parameters, laboratory and operation data were compared. Statistical analysis was carried out with D'Agostino-Pearson normality-, Mann-Whitney-, Fisher test, binary logistic regression, log-rank test and Kaplan Meier survival curve. Based on our results, we designed a risk estimation system, then checked its applicability with ROC analysis.

As for NR-specific characteristics, malignant ventricular arrhythmias (11% vs. 4%, p=0,0031; NR-C consequently) and complications (21% vs. 11%, p=0,064) showed their vulnerability. The increment of glucose (8,1 vs. 7,1 mmol/l, p=0,004), WBC- (12,08 vs. 10,5 G/l, p=0,001), CRP levels (12,46 vs. 7,67 mg/l, p=0,051) and worse LDL profile (3,34 vs. 3,13 mmol/l, p=0,059) supported the pathomechanism of NR. Higher biomarker levels (troponinT: 2040 vs. 510,5 ng/ml; CK-MB: 100,4 vs. 63,65 U/l, p<0,0001) indicated severe perfusion disturbance. Tendency was seen in higher BMI (28,65 vs. 28,03 kg/m2, p=0,12). STEMI dominated in NR (83 vs. 59%, p<0,0001). Lower platelet level (213,3 vs. 228 G/l, p=0,107) and single vessel disease (46 vs. 25%, p=0,0042) characterized NR.

30-day survival was significantly different (85,1 vs. 93,54%, p<0,0001). The mortality rate of NR in STEMI was 69,7% (69,7% vs. 7,94%, p<0,0001) and in NSTEMI 3,7% (3,7% vs. 4,32%).

From the significant differences (BMI, glucose, WBC, CK-MB, hs troponin T, CRP, LDL, LVEF, STEMI), CRP was the independent predictor of NR (OR:1,011, p=0,004; referring to 1 mg/l change). Examining STEMI/ NSTEMI separately, from the significantly different derivations in STEMI (female gender, DM, malignant ventricular arrythmia, glucose, CRP, CK-MB, HR, LVEF) CRP was the independent predictor (OR:1,0092, p=0,036). In NSTEMI, (from LDL, total cholesterol, BMI) LDL (OR:4,23, p=0,021) was the independent factor.

In the risk score, the following 8 parameters were included: BMI/28 kg/m2, glucose>8 mmol/l, WBC>12 G/l, CK-MB>100 U/l, hs troponin T>2000 ng/ml, CRP>12 mg/l, LDL>3,3 mmol/l, STEMI (yes/no), thus maximum 8 points could be reached. Low (0-1 points, 5-20%), moderate (2-5 points, 55-70%) and high risk groups (6-8 points, 41-11%) were formed based on the distribution of score values. Supervising the model with ROC analysis: AUC=0,69, p=0,0026.

CONCLUSIONS

The specific characteristics of NR group were identified, from which CRP was the independent predictor - as well as in STEMI, while in NSTEMI LDL was the independent factor. The 0,69 AUC parameter of our risk estimation system indicates its ability to discriminate effectively between different risk levels of NR. With the elaborated risk estimation system – using anamnestic and routine laboratory parameters – NR could be predicted and unsuccessful PCI could be reduced, resulting in positive therapeutic consequences.

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Primary endpoint results of the world-wide Win registry assessing a self-apposing stent for revascularisation of coronary arteries in routine clinical practice

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

The objective of the Win registry is to assess the long-term safety and efficacy of the Xposition S self-apposing sirolimus-eluting stent in routine clinical practice.

METHODS AND RESULTS

The Win registry is a prospective, non-randomised, multicentre registry with 429 patients enrolled in 25 sites from March 2017 to February 2018. All patients were treated with the Xposition S self-apposing sirolimus-eluting stent in a routine clinical practice. The primary endpoint is the target lesion failure evaluated during the 12-month clinical follow-up and defined as cardiac death, myocardial infarction attributable to the target vessel and clinically-driven target lesion revascularization. The mean age was 64.9±11.5 years-old and 85.8% of the population were male. ACS was reported in 65.3% of patients, with 29.1% presenting STEMI. Patients had multivessel disease in 40.6% of cases. Target lesions were mostly located in the proximal left anterior descending artery (21.3%) and left main coronary artery was involved in 12.8% of the cases. The Xposition S was implanted in 36.4% of lesions located in aneurysm/ectatic vessels and 38.7% in tapered vessels.
During the procedure, pre-dilatation was performed in 79.4% of cases and post-dilatation in 90.7%. The rate of successful implantation of the stent at the target lesion was 93.5%. Clinical follow-up was performed at a mean follow-up time of 370±17 days. A total of 15 patients experienced a target lesion failure which represent 3.5% of cases. Clinically-driven target lesion revascularisation was reported in 2.1%, myocardial infarction attributable to the target vessel in 1.9% and death by a cardiac or unknown cause in 1.9% of patients.
At the time of the interim analysis, the 12 months clinical follow-up data was available for 282 patients. By the time of the EuroPCR congress, all patients will reach the 12 months clinical follow-up time point.

CONCLUSIONS

The preliminary results of the Win registry confirm the safety and efficacy of the Xposition S in routine clinical practice.

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Outcomes of TAVI in patients aged 65 years or younger with multiple comorbidities

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Transcatheter aortic valve implantation (TAVI) has typically been performed in an elderly population. However, over the past decade, TAVI has also been used to treat young patients with severe and/or multiple co-morbidities. The aim of this study was to describe this latter patient population and report the outcomes of TAVI when performed in patients aged 65 years or younger with multiple co-morbidities.

METHODS AND RESULTS

Data on patient and procedural characteristics as well as procedural and clinical outcomes in patients aged ≤ 65 years who underwent TAVI between 2008 and 2017 were retrospectively collected from nine high-volume TAVI centers. Overall, 455 patients underwent TAVR at a mean age of 59.7 ± 6.3 years. The majority of patients was in NYHA class III-IV (81%) and presented with native aortic valve stenosis or mixed stenosis/ regurgitation (86%), pure native aortic valve regurgitation (4%) or a dysfunctional surgical aortic bioprosthesis (10%). A bicuspid aortic valve was present in 20% of patients. Left ventricular ejection fraction < 30% was reported in 83 out of 443 patients (19%). A majority of cases were performed by transfemoral route (86%) and under general anesthesia (64%). The mean calculated STS surgical risk score was 4.0% ± 4.1% with 13% and 19% of patients at high (>8%) and intermediate (4-8%) surgical risk according to STS risk score classification, respectively. Most patients presented with multiple co-morbidities: 34% of patients had previous cardiac surgery, 36% severe lung disease, 27% peripheral vascular disease, 26% severe chronic kidney disease and 13% presented with a body mass index ≥ 35. Despite their young age, 22% of patients were assessed to be clinically frail and 13% had a reduced mobility. Other important reasons to choose TAVI over cardiac surgery were: neurological disorder (15%), immunosuppression (11%), previous chest radiation (10%), liver cirrhosis/ disease (6%), chronic infectious disease (4%), and active malignancy (4%).

Overall device success was 89% with remaining aortic regurgitation ≥ moderate in 13 cases (3.6%), a transprosthetic gradient ≥ 20 mmHg in 22 cases (5.6%) and need for implantation of a second transcatheter heart valve in 13 cases (2.9%). Procedural mortality was reported in three cases (0.7%). Early safety at 30 days was calculated to be 82% with a 30-day mortality rate of 4.0%. In 203 patients with one-year follow-up, one-year mortality was calculated to be 26.1%. Overall, there were 110 deaths reported on a total of 592 patient-years of follow-up. Twenty-five patients (5.5%) underwent a redo-intervention after a median time of 164 days (interquartile range 32 days - 832 days). Clinical outcomes in specific subgroups and predictors of one-year mortality will be presented at EuroPCR 2019.

CONCLUSIONS

This large observational registry indicates that TAVI in patients aged 65 years or younger with severe and/or multiple co-morbidities results in satisfying device and procedural outcomes, but is also associated with a high one-year all-cause mortality. Identification of co-morbidities predictive of one-year mortality will be essential and this should be taken into account in the therapeutic decision making process when confronted with this type of patients.

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The periprocedural and long-term outcome of carotid stenting in patients with carotid artery near-occlusion

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THEME: Interventions for Stroke
TOPIC(S): Carotid stenting

AIMS

The safety and efficacy of endovascular revascularization in patients with carotid artery near occlusion (CANO) remained unknown. We aimed to evaluate periprocedural and long term outcome in CANO patients receiving carotid artery stenting (CAS).

METHODS AND RESULTS

We conducted a retrospective analysis in consecutive carotid artery disease patients who received CAS. Among them, a total of 101 patients had extreme carotid artery stenosis (99%). Based on NASCET diagnostic criteria, 56 patients fulfilled the criteria of CANO and 45 patients had critical stenosis without CANO. The primary measure is 30 days procedural stroke, hyperperfusion syndrome and mortality. The secondary measure is the composite endpoints of total stroke, myocardial infarction and death.

The baseline characteristics were comparable between 2 groups and the procedure success rate was 100%. There were 55.4% patients in CANO group and 46.7% patients in non-CANO group were symptomatic. The incidence of 30 days procedural stroke, hyperperfusion syndrome and mortality in CANO group were 1.8%, 1.8% and 0%, respectively and were 0%, 2.2% and 0%, respectively in non-CANO group.

After median 4.2 years follow-up, there were 3 (Kaplan-Meier rate, 6.1%) patients in CANO group and 1 patient in non-CANO group had ipsilateral stroke including both periprocedural and follow-up period (P=0.433). All these ipsilateral strokes were non-fetal and non-disable strokes. The cumulative incidences of significant in-stent restenosis (>70%) were 1.9% in CANO group and 2.7% in the non-CANO group. The composite endpoints during follow-up periods developed in 21.7% and 30.5% patients in CANO and non-CANO groups, respectively (P=0.977). The major causes of mortality were cancer (50.0%) and pneumonia (25.0%). The short-term and long-term outcomes of carotid stenting were comparable between patient with and without CANO.

CONCLUSIONS

The endovascular stenting is safe and effective in patients with CANO with low perioperative risks and durable long-term outcomes.

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Comparison of neointimal characteristics three months after the six different contemporary metallic stents implantation: a quantitative light property analysis by OCT

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Characterization of neointimal tissue is essential to understand the vascular response to stent implantation. Optical coherence tomography (OCT) provides accurate morphometric data and quantitative measurement of their optical properties may help assess the status of in-stent neointimal tissue. We aimed to analyze the difference among the stents of the light property three months after their implantation.

METHODS AND RESULTS

The study design is a single-center prospective all-comer registry [RESTORE registry] assessing superficial neointimal quality three months after implantation of six kinds of contemporary metallic stents. Quantitative neointimal light property analysis on OCT computed light intensity, light attenuation, and backscatter for superficial neointima full-automatically using dedicated software. [QCU-CMS software version 4.69 (Leiden University Medical Center, Leiden, The Netherlands)]. We analyzed 180 lesions in 152 patients [XIENCETM 31 lesions vs. SYNERGYTM 30 lesions vs. UltimasterTM 33 lesions vs. ResoluteTM 40 lesions vs. OrsiroTM 24 lesions vs. BioFreedomTM 23 lesions].Light intensity of superficial neointima was significantly variant among the stents (XIENCETM 148 [111, 180] vs. SYNERGYTM 128 [94.1, 164] vs. UltimasterTM 114 [98.8, 146] vs. ResoluteTM 161 [124, 204] vs. OrsiroTM 115 [78.8, 148] vs. BioFreedomTM 161 [134, 214], p = 0.003). The light attenuation of superficial neointima showed significant difference (XIENCETM 0.86 [0.77, 0.94] mm-1 vs. SYNERGYTM 0.83 [0.74, 0.93] mm-1 vs. UltimasterTM 0.81 [0.70, 0.92] mm-1 vs. ResoluteTM 1.0 [0.88, 1.2] mm-1 vs. OrsiroTM 0.77 [0.65, 0.88] mm-1 vs. BioFreedomTM 0.85 [0.74, 1.0] mm-1, p < 0.001). Backscatter of superficial neointima were also different according to stents (XIENCETM 5.51 [5.29, 5.67] vs. SYNERGYTM 5.27 [5.04, 5.50] vs. UltimasterTM 5.22 [5.10, 5.53] vs. ResoluteTM 5.68 [5.43, 5.93] vs. OrsiroTM 5.24 [4.78, 5.51] vs. BioFreedomTM 5.62 [5.35, 5.75], p < 0.001).

CONCLUSIONS

Superficial neointimal quality of the coronary three months after stent implantation was significantly different among the contemporary metallic stents in terms of light property on OCT. Further prospective randomized trials should be conducted to evaluate the clinical significance of the present imaging results.

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BuMA Supreme biodegradable polymer sirolimus-eluting stent vs. a durable polymer zotarolimus-eluting coronary stent: three-year follow-up results of the first-in-man PIONEER trial

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

The second iteration of BuMA stent is a sirolimus-eluting stent that has a biodegradable PLGA-polymer coating with electro-grafting base layer on a thin-strut (80 µm) cobalt-chromium platform. The purpose of this report is to provide 3-year results of the PIONEER trial.

METHODS AND RESULTS

The PIONEER randomized controlled trial is a first-in-man trial assessing the efficacy and safety of the BuMA Supreme stent (83 patients) compared with the Resolute zotarolimus-eluting stent (87 patients). The primary endpoint was the non-inferiority of the BuMA stent in terms of the 9-month angiographic in-stent late lumen loss (LLL). At 9 months, the BuMA stent did not achieve non-inferiority of LLL to the Resolute stent (in-stent LLL: 0.29±0.33mm in BuMA and 0.14±0.37mm in Resolute, Pnon-inferiority=0.45, Pinferiority=0.004).Post-hoc QFR analysis was performed in stented vessels in both arms pre-, post-procedural and at 9-month follow-up. The values of QFR distal to the stent (B-SES: 0.89±0.10 vs. R-ZES: 0.89±0.11, p=0.97) and the number of the vessels with QFR <0.8 were not significantly different between the two groups (11.0% vs. 11.6%, p=1.00). QFR gradient across stent (?QFR) at 9 months was also similar between groups (BuMA: 0.03±0.04 vs. Resolute: 0.03±0.07, p=0.95).

At 2 years, device-oriented composite endpoint defined as the composite of cardiac death, target vessel myocardial infarction, and clinically-indicated target lesion revascularization was comparable between two groups (6.0% [5/83] for BuMA vs 5.7% [5/87] for Resolute). The 3-year follow up results will be presented at EuroPCR 2019.

CONCLUSIONS

Despite a significant but “subclinical” difference in in-stent LLL at 9 months, the long-term follow up results will demonstrate whether this difference will impact clinical outcomes.

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The failing Perceval sutureless aortic prosthesis: evaluation and treatment

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Sutureless aortic bioprostehses have been on the market for a decade, but little is known about their failure mechanisms and durability. We report a series of failing Perceval aortic bioprostheses, describe the mechanisms of failure, and discuss the optimal treatment strategy, with special emphasis on transcatheter valve-in-valve implantation.

METHODS AND RESULTS

From March 2011, 835 patients underwent sutureless aortic valve replacement with the Perceval valve at our institution. 28 of these presented with an overtly failing prosthesis during the follow-up period (3 months - 6 years). Prosthesis failure was defined as any alteration of the prosthetic valve function leading to severe aortic stenosis or regurgitation requiring new treatment. All patients were addressed to a multi-imaging assessment including trans-esophageal echocardiography and computed tomography. Valve dysfunction was categorized as structural valve deterioration, non structural valve deterioration, thrombosis, or endocarditis.

4 patients had endocarditis, and underwend redo surgery (two deaths). One patient had a severe paravalvular leakage due to delayed migration of the perceval prosthesis, and underwent successfull redo surgery.

Five patients had major trombosis. The first one underwent successfull valve in valve implantation. The following four were successfully treated with warfarin.

Four patients showed structural valve deterioration, with cusps calcification. Three of them underwent redo open heart surgery (1 death). The fourth patient underwent successful valve in valve implantation.

In fourteen patients, the failing perceval bioprosthesis did not show signs of thrombosis or calcific structural deterioration, and the increased transprosthetic gradient was attributed to reduced cusp motion due to geometric deformation of the stent. In fact the inflow stent of the prosthesis was significantly under-expanded in all patients except one with endocarditis, and was non-circular in all. Twelve of these patients underwent successful valve in valve implantation. The remaining two underwent redo surgery.

Valve-in-valve implantation was always performed with a balloon expandable transcatheter valve, positioned at the level of the inflow stent of the Perceval bioprosthesis via the transfemoral (12) or transapical (2) route. Since there was an extremely poor correlation between the nominal dimension of the implanted bioprosthesis and its actual, in-vivo diameter, sizing of the transcatheter valve was always based on the true in vivo CT measure of the prosthesis virtual basal ring rather than on the valve in valve app recommendations. Valve in valve implantation was highly successful, and there were no major complications.

CONCLUSIONS

According to our observations, early failure (< 6 years) of self-expandable sutureless aortic bioprostheses could be related to excessive oversizing, leading to stent underexpansion / distortion and altered leaflet function.

Valve in valve implantation is safe and extremely effective in patients with failing Perceval bioprosthesis, and

due to the complexity of redo surgery should be considered the treatment of choice for these patients.
Pre-procedural CT scan is mandatory, since in some patients the cause of failure is thrombosis, that can be treated with oral anticoagulants, or delayed migration, that can make valve in valve hazardous. Since this valve has no radial force and can be aggressively oversized, sizing for valve in valve should always be based on CT

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Early experience with a novel temporary pacing guidewire for TAVI

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI, Tricuspid / Pulmonary valve

AIMS

Transcatheter heart valve implantation has generally required temporary introduction of both a ventricular guidewire and a ventricular pacing wire. We describe the initial experience with a purpose-designed Temporary Pacing Guidewire (Teleflex, Maple Grove, Minnesota, USA) which facilitates simulatneous transcatheter valve delivery and bipolar pacing.

METHODS AND RESULTS

The Temporary Pacing Guidewire has a diameter of 0.035”, a length of 280cm, and is fashioned with a 3cm diameter distal pigtail. It is similar to other commercially available pigtail support exchange length guidewires, however it is constructed with an insulated stainless steel core and exposed distal and proximal electrodes allowing bipolar, as opposed to unipolar, pacing. The presence of multiple exposed distal electrodes allows predictable pacing, as only one of these coils needs to be in contact with the myocardium for capture. The wire is supplied with a removable adapter that conveniently attaches to the proximal end of the wire connecting the electrodes to the positive and negative leads of a standard external pacemaker device.

Five patients underwent transcatheter valve implantation under local anaesthetic and conscious sedation using the Temporary Pacing Guidewire. Three patients had transcatheter aortic valve implantation into native aortic valves and two had transcatheter tricuspid valve-in-valve implantation for failed surgical bioprostheses. SAPIEN 3 valve (Edwards Lifesciences, Irvine, California, USA) implantation was successful in all cases; 3 patients also underwent uneventful preparatory balloon valvuloplasty. Pacing was performed at 180bpm in aortic cases and 150bpm in tricuspid cases. Mean pacing threshold was 2.2±0.45mA with no loss of capture in any case. Mean arterial pressure during pacing at was 55.3±8.1mmHg in the aortic group and 74±18.4mmHg in the tricuspid group. No patients required pacing post valve delivery. All cases were discharged without complications.

CONCLUSIONS

The Temporary Pacing Guidewire delivered sustained and effective pacing along with excellent rail support for valve delivery in both aortic and tricuspid positions. It has the potential to make transcatheter valve implantation safer and more efficient for selected patients.

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Fast computational method to predict FFR using routine angiography images and TIMI frame count in intermediate coronary lesions

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

The aim of this retrospective single center study is to assess the ability of Non-Invasive Flow Ratio (vNiFR) and (fNiFR) based on analytical equation in comparison with the wire based FFR.

METHODS AND RESULTS

FFR measurements were performed in patients with intermediate stenosis (40% to 70%) in coronary artery by pressure wire and Then NiFR retrospectively computed from the two-dimensional coronary angiography and TIMI Frame Count (TFC) without the need of pressure wire and adenosine from two computational methods: (1) (Fixed-flow) (2) (Variable-flow) .

Results: In this retrospective study, we evaluate 88 lesions from 86 consecutive patients, who underwent clinically indicated invasive coronary angiography and FFR measurements in a single cardiovascular center. Both fNiFR and vNiFR were tested against wire-FFR. Anatomical severity of epicardial coronary stenosis was generally intermediate, with a mean stenosis degree (44.06+-6.33), Mean FFR value for all lesions was (0.83+-0.08). Of the 88 lesions, 29(33%) were below the ischemia threshold (FFR < 0.8). Sensitivity, specificity and overall diagnostic accuracy were 89.6% (76.9%), 84.7% (92.7%) and 87.5% (85.5%), for vNiFR and(fNiFR), respectively. Also, Correlation with standard FFR were observed for fNiFR and vNiFR ([r = 0.69] and [r = 0.59], respectively).

CONCLUSIONS

This study indicates that Non-Invasive FFR assessment can be safe and reliable to guide coronary revascularization in patients with intermediate stenosis. The final result is pending.

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Association between mitral regurgitation severity, early improvement after TAVI and mortality

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI, Other valvular and structural interventions

AIMS

Concomitant mitral valve disease in patients referred for TAVI is common; up to one-third of patients may have moderate or severe mitral regurgitation (MR). Improvement of MR in the medium term is well documented. However, there are conflicting data regarding the effect of baseline MR severity, as well as MR improvement, on short- and long-term outcomes. We sought to determine predictors of early inpatient MR improvement and the associations between MR severity, MR improvement and mortality.

METHODS AND RESULTS

Patient demographics, echocardiography and procedural data were extracted from routinely collected data in all patients undergoing TAVI at our centre between Jan 2013 and July 2018 (n=629). Clinical outcomes were obtained from linkage with the Scottish Morbidity Record (SMR01), Information Services Division, Scotland.

Moderate or severe MR was present in 82 patients (13%). After excluding patients with unavailable echocardiogram images, 74 patients underwent further image analysis, classifying mitral regurgitation aetiology as primary or secondary.

The median age was 82 (interquartile range [IQR] 78 – 86) years and half were male (n=36, 49%). Mitral regurgitation was moderate in 67 (91%) and severe in 7 (9%). Mitral valve pathology was primary in 20 (27%) and secondary in 54 (73%). Reduced left ventricular ejection fraction was more common in patients with secondary MR (37 (69%) vs 7 (20%), p=0.03).

Mitral regurgitation improved in 58 (78%) patients at a median of 3 (interquartile range [IQR] 3 – 5) days. Multivariable logistic regression analysis, adjusting for age, sex, ischaemic heart disease, left ventricular ejection fraction, MR severity and MR aetiology did not identify any independent predictors of early MR improvement.

Across the entire TAVI cohort (n=629), 30-day mortality was higher in patients with moderate or severe MR at baseline compared to those with no/mild MR (8% vs 2.8%, p=0.032). One-year mortality was numerically higher (18.4% vs 13.3%, p=0.27). These differences were driven by patients with severe MR (30-day mortality 22.2%, 1-year mortality 44.4%). Cox regression models were constructed for mortality as the primary outcome with age, sex, ischaemic heart, ejection fraction and mitral regurgitation severity as independent variables. Ejection fraction <30% (hazard ratio [HR] 1.87, 95% confidence interval [CI] 1.20 – 2.9) and severe MR (HR 4.01, 95% CI 1.57 – 10.2) were independent predictors of overall mortality. In the subgroup of patients with moderate or severe MR, improvement in MR was not an independent predictor of mortality (HR 1.02, 95% CI 0.31 – 3.3).

CONCLUSIONS

Pre-existing severe MR is a poor prognostic marker in patients undergoing TAVI for severe aortic stenosis, independent of left ventricular ejection fraction. A reduction in the severity of MR was observed in the majority of patients following TAVI for severe AS, irrespective of the aetiology of MR, but was not associated with improved survival.

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Assessment of mechanical properties of BRS compared to contemporary DES. Is there a class effect for BRS?

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Stents and scaffolds

AIMS

First-generation bioresorbable scaffolds have been associated with a higher rate of early (0 hours to 30 days) scaffold thrombosis compared to drug-eluting stents. Potential device related factors include larger strut thickness and procedural under-expansion. Advances in polymer technology have enabled the development of second and third-generation bioresorbable scaffolds with thinner struts and improved mechanical properties. The purpose of this evaluation was to assess the performance of these newer generation devices.

METHODS AND RESULTS

Four bioresorbable scaffolds (PLLA-based, magnesium-based, and Tyrocore-based) and 11 drug-eluting stents were systematically evaluated for their design characteristics and mechanical properties. Tests were performed to measure radial strength, longitudinal compression, and flexibility. All testing was conducted in physiologically relevant conditions and in accordance with the manufacturers' device labeling.

The four bioresorbable scaffolds exhibited varied designs based on their structural material (PLLA, Magnesium alloy, and Tyrocore) with the thinnest struts achieved using the Tyrocore polymer. Radial strength testing demonstrated that Tyrocore resorbable scaffolds (TRS) achieve higher radial strength compared to PLLA-based scaffolds and magnesium-based scaffolds despite also having thinner struts. TRS radial strength was similar to certain thin strut, cobalt chromium-based DES. Longitudinal compression and flexibility testing showed a consistent tradeoff between longitudinal strength and flexibility for most stent and scaffold designs. Certain designs were able to achieve sufficient longitudinal strength without a tradeoff in flexibility.

CONCLUSIONS

Advances in material technology can improve BRS characteristics and mechanical properties that are related to early scaffold thrombosis with the first-generation Absorb scaffold. As such, new-generation BRS should be evaluated on their own data and there should not be a class effect applied to all BRS.

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Results of the dedicated coronary bifurcation BiOSS Lim sirolimus-eluting stent in real-world clinical practice

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds, Bifurcation lesion

AIMS

BiOSS® Lim is a bifurcation dedicated sirolimus-eluting stainless steel stent covered with a biodegradable polimer. The stent consists of two parts with different diameters, connected with two struts at the middle zone, and crimped on a bottle-shaped semi-compliant balloon. This design simplifies coronary bifurcation treatment and allows easy access to the side branch. The aim of this study was to assess the performance of this device in a real-world setting.

METHODS AND RESULTS

We conducted a prospective registry of all consecutive patients treated with BiOSS® Lim stent as part of a provisional stenting strategy from 2016 to 2018 at our institution. The primary endpoint was the need for additional side branch stenting at the bifurcation level.

Twenty-three patients were included (median age 73 years, 65% males, 35% acute coronary syndromes). All procedures were performed with 6-French guiding-catheters, and most of them (87%) through radial approach. True bifurcation lesions (Medina types 1,1,1; 1,0,1; 0,1,1) were present in 48%, an angle under 70 degrees in 83%, and median lesion-specific Syntax score was 10 points (interquartile range, IQR: 9-12). Median nominal stent parameters were 3.50 (IQR, 3.25-3.75) x 3.00 (IQR, 2.50-3.00) x 15 (IQR, 15-18) mm.

All implants were successfully performed, achieving adequate postprocedural flow at both branches. In 30% there was no need for side branch wiring. During a median follow-up of 14 months (IQR, 9-21), eight patients (35%) experienced the primary endpoint, six of them at the index procedure. Neither clinical nor anatomical features predicted the need for side branch stenting (p-values>0.05).

CONCLUSIONS

BiOSS® Lim is an effective device for simplified treatment of complex bifurcation lesions. However, additional stenting of side branch may be required in a third of patients during mid-term follow-up.

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Mild prosthetic valve regurgitation is associated with worse long-term outcome in patients at high but not in patients at intermediate/low risk undergoing TAVR

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THEME: Interventions for Valvular Disease

TOPIC(S): Other valvular and structural interventions

AIMS

In PARTNER trials, even mild prosthetic valve regurgitation (PVR) after transcatheter aortic valve replacement (TAVR) was associated with worse outcomes in patients at high surgical risk (PARTNER 1) while only more than mild PVR had a negative prognostic impact in patients at intermediate risk (PARTNER 2). We sought to investigate the impact of mild PVR on long-term clinical outcomes after TAVR in patients at different levels of surgical risk.

METHODS AND RESULTS

From September 2007 to February 2018, 1090 consecutive patients underwent TAVR at our institution. Out of 1046 who survived to 30 days post-TAVR, the severity of PVR was assessed on echocardiography according to the VARC criteria and documented in 987 (94.4%). To assess the prognostic impact of mild PVR, 29 patients with moderate-severe PVR were excluded from the analysis. In the remaining population, PVR was none-trace in 560 (58.5%) and mild in 398 (41.5%). The cumulative incidence of clinical events was estimated using the Kaplan-Meier method in the entire population as well as in patients at low risk (STS score<4; n=462), intermediate risk (STS score 4 to <8; n=339), and high risk (STS score≥8; n=151).

In the overall population, the five-year incidence of the composite of all-cause mortality, aortic valve reintervention, or heart failure hospitalization was not different between none-trace (57.5%) and mild PVR (62.5%, log rank p=0.559). Similarly, the five-year incidence of all-cause mortality, aortic valve reintervention, or heart failure hospitalization was not different between none-trace vs. mild PVR in low risk (48.1% vs. 47.6%, p=0.746) as well as in intermediate risk patients (58.5% vs. 54.9%, p=0.460). On the other hand, mild PVR was associated with increased rate of the composite endpoint in patients at high surgical risk (82.0% vs. 87.5%, p=0.041; hazard ratio: 1.57 [95% CI: 1.02 – 2.41]).

CONCLUSIONS

Mild PVR is associated with increased long-term risk of the composite of all-cause mortality, aortic valve reintervention, or heart failure hospitalization after TAVR in patients at high risk but not in those at intermediate/ low risk.

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Prosthetic valve regurgitation assessed by MRI after TAVR with different next-generation transcatheter heart valves

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Prosthetic valve regurgitation (PVR) is more common after transcatheter aortic valve replacement (TAVR) than after surgical aortic valve replacement. Next generation transcatheter heart valves (THVs) have improved sealing properties but head-to-head comparison of those devices are scarce. We sought to compare PVR assessed by cardiac magnetic resonance imaging (MRI), after TAVR with three of the next generation THVs.

METHODS AND RESULTS

In the period from January 2014 to December 2017, 596 patients underwent TAVR for native aortic valve stenosis with a next generation THV at our institution. The choice of the THV was personalized and left to the discretion of the operator (basically aiming at minimizing the risks of paravalvular leakage, annular injury, coronary obstruction, and permanent pacemaker requirement). Cardiac MRI was performed in 282 patients (76.2% of eligible patients with no contraindications for MRI) at a median(IQR) of 13(8-21) days after TAVR. MRI-derived regurgitation fraction was available for 54 who received the self-expanding Medtronic Evolut R (SE-THV), 194 who received the balloon-expandable Edwards Sapien 3 (BE-THV), and 34 who received the mechanically-expanding Boston Scientific Lotus (ME-THV).

While balloon pre-dilatation was not different between the three groups (29.6%, 24.4%, and 38.2% in SE-, BE-, and ME-THV; p=0.218), balloon post-dilatation was more often required after SE-THV, less so after BE-THV, and least performed after ME-THV (31.5%, 15.5%, and 2.9%; p=0.001). While freedom from PVR on final post-implantation angiography was less after SE-THV (46.3%, 77.2%, and 88.2%; p<0.001), there was no significant difference in freedom from PVR between the three groups on 30 days echocardiography (57.4%, 62.8%, and 70.6%; p=0.730). On MRI, regurgitation fraction was small and not significantly different between the three groups (3.5 [1.7 – 6.1], 3.0 [1.0 – 6.1], and 2.5 [1.4 – 5.3]%, p=0.260).

CONCLUSIONS

In a personalized multi-device based TAVR program, TAVR with the next generation THVs is associated with very low rate of prosthetic valve regurgitation as documented on MRI. However, balloon post-dilatation remains frequently required after TAVR with the SE-THV.

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TAVR with the next-generation balloon-expandable SAPIEN 3 in patients with severe landing zone calcification

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Severe landing zone calcification (LZC) is associated with a lower device success after transcatheter aortic valve replacement (TAVR) with the earlier generation balloon-expandable device. We sought to investigate whether severe LZC would influence the next generation balloon-expandable device success and the role of predilatation in this anatomical setting.

METHODS AND RESULTS

The study included consecutive patients undergoing TAVR with the next generation balloon-expandable device (Sapien 3; Edwards Lifesciences, Irvine, CA) for native tricuspid aortic valve stenosis between March 2014 and February 2018 in our institution. On pre-TAVR multidetector computed tomography, LZC was semiquantitatively assessed on two levels: aortic valve cusp calcification (AVC) and left ventricular outflow tract calcification (LVOTC). Out of 361 patients, MDCT assessment of the LZC was available in 351 (97.2%).

In patients with severe AVC (n=78; 22.2%), balloon predilatation (BPreD) was more frequently performed (49% vs. 20% in patients with non-severe AVC, p<0.001), the extent of device oversizing was lower (5.2[1.6-7.9]% vs. 6.9[3.9-9.0]%, p=0.015), and the rate of balloon post-dilatation (BPostD) was significantly higher (19% vs. 9%, p=0.03). Patients with severe AVC had a higher rate of device failure (3.8% vs. 0.4%, p=0.038).

In patients with severe LVOTC (n=49; 14.0%), BPreD was more frequently performed than in patients with non-severe LVOTC (41% vs. 24, p=0.022), while the frequency of BPostD was not different. In patients with severe LVOTC, device failure was numerically higher (4.2% vs. 0.7%, p=0.093) driven by more PVR (mild: 46% vs. 33%; >mild: 4% vs. 0%; p<0.001).

In total, 106 patients (28.6%) had severe LZC, defined as severe AVC and/or LVOTC. In patients with severe LZC, BPreD was performed in 42.5%. Procedural time (62[52-81] vs. 50[39-71] min, p=0.001), fluoroscopic time (19[15-24] vs. 14[11-18] min, p<0.001), and irradiation area dose product (8221[6733-12146] vs. 7151[4937-9807] cGy*cm2, p=0.027) were all significantly higher in patients who underwent BPreD. Effective orifice area, trans-prosthetic PG, as well as PVR were not different between the two groups. On the other hand, 30-day and one-year mortality were significantly higher in patients who underwent BPreD (8.9% vs. 0%, p=0.030 and 22.3% vs. 7.5%, log rank p=0.030). On multivariable Cox regression analysis, BPreD (HR: 7.76[95% CI: 1.61-37.37]) remained associated with one-year mortality after accounting for STS score (HR: 1.05[95% CI: 0.88-1.27]), prior PCI (HR: 0.61[95% CI: 0.12-3.16]), mean PG at baseline (HR: 0.95[95% CI: 0.91-0.99]), and AR at baseline (mild AR, HR: 1.13[95% CI: 0.26-4.93]; moderate AR, HR: 0.35[95% CI: 0.03-3.82]).

CONCLUSIONS

Device success rate is very high after TAVR with the Sapien 3 THV. However, device success is less in patients with severe LZC, and this was not improved in patients who received BPreD. On the other hand, BPreD increased procedural time and irradiation and was associated with increased early and mid-term

mortality. The association between BPreD and mortality in patients with severe LZC requires further investigation in prospective, large-scale, randomized trials.

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Embolisation in various embodiments of the thrombectomy in ischaemic stroke

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THEME:

TOPIC(S):

AIMS

The variety of different techniques of thrombectomy from the cerebral arteries can not completely exclude the embolism of distal branches and non-target intracranial vessels. Relevant is the answer to the question: what technique to use as a first pass?

METHODS AND RESULTS

During the period 2017-2019 76 consecutive patients underwent thrombectomy with the use of temporary occlusion of the source vessel with a stent Retriever with aspiration of the guide catheter , stent Retriever with aspiration from the distal access catheter, various variants of stent-assisted vacuum-blocked traction, as well as variants of aspiration thrombectomy without occlusion of the mother vessel. The isolated application of the aspiration technique in the first pass was 14.47% (n=11), the stent Retriever with balloon guide catheter occlusion was 50% (n=38), and the stent Retriever with balloon guide catheter occlusion with distal aspiration and the possibility of transition to vacuum-locked traction was 30.26% (n=23). Another 3 patients were excluded from the analysis. In one case, the distal embolism was caused by fibrinolysis prior to the main stage of thrombectomy, and in 3 cases thrombectomy was unsuccessful due to anatomical features. An intragroup risk assessment of embolization was performed using the Chi-square test. A cross-group comparison of the probability of the risk factor influence on the outcome was assessed using the Matel-Henzel criterion. Compare groups on background variables was conducted using the criterion of Mann-Whitney.

The groups were comparable in Albert index, National Institutes of Health Stroke Scale, subtype of ischemic stroke and lesion localization ($p>0.05$).

Any embolism in the primary aspiration group as well as a significant embolism – 100% $p<0.001$, these events may have a connection with the aspiration technique.

Any embolism in the stent Retriever group with balloon guide catheterand distal aspiration was 30.43% $p=0.005$.

When using a stent Retriever with balloon guide catheter, any embolism was 60.53% $p<0.001$, a significant embolism was 44.74% $p<0.001$, and the distribution of an insignificant distal embolism was 15.79%, a significant distal embolism was 39.47%, and a non – target embolism was 5.26% $p<0.001$.

Comparison of stent-Retriever thrombectomy in the group without and with the use of distal access catheter showed that without routine use distal access catheter is more likely embolism 3,505 [1,166-10,539] (OR [95% CI]) , 1,989 [1,019-3,883] (RR [95% CI]).

CONCLUSIONS

Any methodology of thrombectomy may cause embolism. The use of a stent Retriever with distal aspiration and the possibility of transition to vacuum-locked traction can significantly reduce the risk of embolism in thrombectomy.

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The impact of calcified plaque fracture before DES deployment for mid-term neointimal coverage - Insight from OCT analysis

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

The lesion-modification using rotational atherectomy and scoring balloon before stent deployment is recommended to avoid stent-underexpansion in severe calcified lesion. On the other hand, calcium fracture detected by intravascular imaging often occurs by aggressive pre-balloon dilatation, and it leads to stent mal-apposition. In this study, we investigated the impact of calcified plaque fracture before drug eluting stent deployment for mid-term neointimal coverage, using frequency domain-optical coherence tomography (FD-OCT).

METHODS AND RESULTS

We enrolled consecutive 15 patients underwent FD-OCT guided rotational atherectomy and received follow up with FD-OCT between April 2015 and July 2017. We performed FD-OCT analysis and evaluated the incidence of calcified plaque fracture before stent deployment, and distance between mal-apposed stent strut and the surface of calcified plaque (mal-apposed distance) after stent deployment. At mid-term (10-12 months after stent deployment) follow-up, we assessed the presence of neointimal coverage in all stent struts using FD-OCT, and examined cut off values of mal-apposed distance regarding neointimalization at follow-up, using classification and regression tree analysis. Furthermore, we compared the incidence of acute coronary syndrome, target lesion failure (TLF), and stent thrombosis during follow-up period between 2 groups (presence or absence of calcified plaque fracture before stent deployment).

All patients underwent coronary intervention with 2nd or 3rd generation drug eluting stent (DES). The calcified plaque fracture before stent implantation, and mal-apposed stent struts were observed in 7 cases, and there were 385 mal-apposed struts after stent deployment. After follow-up, 111 struts had neointimal coverage. The logistic regression analysis showed that calcified plaque fracture and mal-apposed distance had statistically impacts of poor neointimalization with an odds ratio of 0.030 (95% CI, 0.002-0.191, p=0.002), and 0.996 (95% CI, 0.993-0.999, p=0.022), and multivariable model showed stent deployment on calcified plaque fracture was an independent predictor of poor neointimalization (odds ratio, 0.042, 95%CI, 0.002-0.288, p=0.006). Furthermore, the classification and regression tree analysis revealed that the cut off mal-apposed distance to obtain the neointimalization was 223μm.

There were no events regarding acute coronary syndrome, and stent thrombosis during follow-up period. However, 3 patients without calcified plaque fracture before stent deployment in all cases had TLF during the 1-year follow-up period, although Kaplan-Meier estimates did not show the statistical difference in TLF between 2 groups (log-rank P=0.197).

CONCLUSIONS

This study suggests that calcified plaque fracture before DES deployment is associated with mid-term poor neointimal coverage, although it does not have an influence on TLF, incidence of acute coronary syndrome,

and stent thrombosis during 1-year follow-up period.

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Impact of radiation protection drapes on the patient dose in interventional cardiology

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Because of the increasing number of interventional procedures with fluoroscopy and the corresponding high annual dose for interventionalists, additional dose-protecting measures are desirable. Radiation protection drapes have been shown to be efficient in reducing scattered radiation for operators, but their impact on the patient exposure remains undefined.

METHODS AND RESULTS

We used the fixed interventional radiology equipment and a RANDO phantom simulating a patient of standard sizes. The tube has been placed below the table and fixed on the patient heart to simulate an Interventional Cardiology procedure. The conventionally used 'Collective Protection Equipment (CPE)' were placed to simulate the most frequent cases (low curtains and their vertical extension, as well as the ceiling suspended radiopotection screens).

The phantom skin-dose was measured at three different distances from the ceiling screen (6 cm, 16 cm and 26 cm), with and without radiation protection drapes utilization at two different tube voltages, to simulate the case of a standard size patient (68 kVp) and a corpulent one (125 kVp) and two tube positions (vertical position and LAO 30°). Dose measurements were obtained using ATOMATEX Dosimeter AT1123 in mode fluoroscopy 30 pulses /s during 20 seconds.

At low voltage, the use of the protection drapes increases patient's dose by 13 % in the region situated just near the ceiling screen (6 cm). However, it attenuates the dose by 48 % at 16 cm and 85.5 % at 26 cm form this latter. At high voltage, the dose decreases at all of the three measure points; and the effect of the protection drapes varies depending on the distance from the screen and the tube angle (dose attenuation with protection drapes utilization are at 0° angulation : 6.5% at 6 cm, 31% at 16 cm, 41% at 26 cm and at LAO 30° : 2% at 6 cm, 38 % at 16 cm and 15.5 % at 26 cm).

CONCLUSIONS

Radiation protection drape increases only slighty patient dose near the ceiling screen. However it allows a

significant reduction of the patient dose far the ceiling screen. This could be explained by an attenuation of the « skyshine » effect.
For corpulent patient the protection drape is highly efficient regardless the distance from the ceiling screen.

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Better prognosis after complete revascularisation leaving residual obstructive lesions minimal using contemporary coronary stents in patients with chronic kidney disease

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

The prognostic value of angiographic complete revascularization in patients with chronic kidney disease (CKD) has not been thoroughly investigated, especially for contemporary coronary stents. We compared clinical outcomes of complete and incomplete revascularization with 2nd generation drug-eluting stent (DES), according to the presence of CKD.

METHODS AND RESULTS

From the Grand DES Registry (N=17,286) in Korea, we retrieved 8,471 patients who were treated with 2nd generation DES and having data of glomerular filtration rate and quantitative coronary angiography. Among them, 3,014 (35.6%) patients had CKD and 5,457 (64.4%) had preserved renal function. We defined angiographic complete revascularization when residual SYNTAX score was equal to 0. Primary outcome was patient-oriented composite outcome (POCO) at 3 years, including all-cause death, any myocardial infarction and any revascularization. The rates of POCO were significantly lower after complete revascularization than after incomplete revascularization in CKD population (14.6% vs. 21.8%, adjusted hazard ratio [HR] 0.79, 95% confidence interval [CI] 0.64-0.96, p=0.020) as well as in preserved renal function population (8.0% vs. 12.0%, adjusted HR 0.77, 95% CI 0.63-0.94, p=0.011). The cut-off values of residual SYNTAX scores predicting better POCO were different according to the presence of CKD, i.e. less than 3 in CKD population and less than 8 in preserved renal function population.

CONCLUSIONS

Angiographic complete revascularization led to the better clinical outcomes in both CKD and preserved renal function populations. However, the residual SYNTAX score, predicting better outcome, was lower in CKD population than in preserved renal function population, favoring more aggressive complete revascularization in patients with CKD.

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Could changes in platelet characteristics predict bleeding events following TAVI?

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Aim of the study is to investigate whether total platelet count and platelet reactivity changes might predict early bleeding complications following transcatheter aortic valve implantation (TAVI).

METHODS AND RESULTS

We enrolled 41 consecutive patients with severe and symptomatic aortic stenosis, undergoing TAVI procedure in our institution. All patients who did not have chronic dual antiplatelet therapy, received loading dose of aspirin and clopidogrel one day prior to procedure. Patients' clinical characteristics were collected from medical records. Platelet reactivity was measured using impedance aggregometer (Multiplate® analyzer, Roche, Munich, Germany) in four time points: just before anesthesia induction (T1), 20 minutes after valve implantation or 10 minutes after additional interventional procedures (T2) and on 3rd and 6th postoperative day (T3 and T4, respectively). Three different platelet aggregation agonists were used: arachidonic acid (ASPItest), ADP (ADPtest) and thrombin receptor activating peptide-6 (TRAPtest). Complete blood count was performed prior to TAVI and daily in the following six days. Patients were stratified in two groups (bleeding and control group) according to development of any bleeding based on Bleeding Academic Research Consortium criteria in 6 days following TAVI.

Mean patient age was 82.04 years with majority of patients being male 58.5% (N=24). Mean valve area prior to procedure and mean transvalvular gradient were 0.71 ± 0.19 cm2 and 49.08 ± 18.73 mmHg, respectively. All patients underwent successful TAVI procedure using selfexpandable (N=24; 58.5%) or balloonexpandable valve (N=17; 41.5%). Two patients (4.9 %) underwent transapical TAVI, while transfemoral approach was used in all other patients. Mean postimplantation gradient was 10.75±7.6 mmHg. Nineteen patients (46.3%) had bleeding event. There was no significant difference in basal clinical and laboratory characteristics between groups, with exception of higher haemoglobin level in the bleeding group (136.1 ± 17.5 vs 123.2 ± 14.1 g/L, p=0.013). Mean platelet reactivity on T1 for all studied tests (ASPItest 22.4 ± 22.1 U, ADPtest 41.6±26.5 U and TRAPtest 90.1 ± 33.3 U) did not diverse between groups. On T2, significant reduction in platelet reactivity was observed in all three tests, Δ ASPI –12.8 ± 21.0 U (p=0.001), Δ ADP -18.4 ± 22.5 U (p<0.001) and Δ TRAP -36.3 ± 28.7 U (p<0.001) without any difference between study groups. On T3, platelet reactivity was unchanged compared to previous measurement. Slight recovery of platelet reactivity was observed on T4 although it did not reach basal levels (ASPI 15.2 ± 17.2 U, ADP 27.3 ± 18.5 U and TRAP 68.6 ± 33.2 U). Basal platelet count did not diverse significantly between groups (206.9 ± 77.7 x109/L). Significant reduction of total platelet count was noted in both groups on 1st day after TAVI. Lowest platelet count was reached on day 3 (106.3 ± 13.2 x109/L, p<0.001), with complete recovery of platelet count by day 6 (213.4 ± 102.1 x109/L). Again, no significant difference between bleeding and control group was found.

CONCLUSIONS

Our results indicate that TAVI procedure induces significant decrease in platelet count and reactivity regardless of the platelet activation pathway just after valve implantation. However, these findings do not seem to predict

early bleeding complications after TAVI. Further research on a larger number of patients is needed to confirm these results.

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Target lesion failure after PCI in modern era

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Over the past decade major improvement in stent technology, stenting technique and post PCI medical therapy were made. Aim was this research is to investigate incidence of clinical target lesion failure after percutaneous coronary interventions (PCI) of left anterior descending coronary artery.

METHODS AND RESULTS

Study included 1201 consecutive patients with PCI of left anterior descending coronary artery, performed between 01/2012 and 12/2016 in our institution. Patients were stratified according to PCI with 2nd/3rd generation DES or contemporary BMS (cobalt chrome with thin struts). All procedures were reviewed to determine frequency of direct stenting and non-direct stenting - composed of lesion pre-dilatation and/or stent optimization. Cumulative incidence of clinical target lesion failure (composed of in-stent restenosis and definitive stent thrombosis) was assessed.

Mean patients age was 64.2 years, with majority being men (74.9%, N=896). BMS was implanted in 61.3% (N=741) of cases. DES implantation was more often performed during elective PCI in patients with known coronary artery disease (36.7 vs 19.3%) and during complicated interventions. On the other hand, BMS was more often implanted during emergent interventions (43.4 vs 27.2%), with higher rate of thrombotic occluded vessel (17 vs 9.2%). Final TIMI 3 flow was higher in DES group (94.7 vs 85.7%). Regarding medical therapy there were no significant differences in aspirin (99.3%), P2Y12 inhibitor (99.8%), oral anticoagulation (8.7%), ACE inhibitor (86.5%) and statin (96.3%). However, therapy with beta blocker and ticagrelor were higher in DES group (89.1 vs 84.2%, and 17.8 vs 5.1%, respectively). Non direct stenting was performed more often in DES group (78 vs 55.5%), just as all of its components; lesion pre-dilatation (68.7 vs 48.6%) and stent optimization (45 vs 36.7%). Results also indicate an increase in non-direct stenting in both groups during studied years, although it was continuously higher in DES group. PCI using DES were more often performed from 2nd half of 2015 onwards. Median follow-up was 2.6 years. Target lesion failure was significantly more common in the BMS group (9.3 vs. 4.3%, $p<0.001$). This was mainly due to significant difference in in-stent restenosis (7.8 vs. 3.0%, $p<0.001$). We observed no significant differences in definitive stent thrombosis (1.5 vs 1.3%, $p=0.797$). Regression analysis showed BMS implantation to be the principal risk factor for developing in-stent restenosis and discontinuation of aspirin for stent thrombosis. Odds ratio for developing in-stent restenosis after BMS implantation was 2.7 (95% CI 1.491 to 4.908) compared to DES implantation. Odds ratio for developing stent thrombosis, after discontinuation of aspirin was 22.41 (95% CI 4.297 to 116.961). Multivariable logistic regression models showed no differences between the stenting technique and tested outcomes in overall population, nor in BMS and DES subgroups separately.

CONCLUSIONS

PCI of left anterior descending using contemporary DES provides excellent outcomes in real-world settings with regard to the target lesion failure in long term follow up. PCI with BMS represents principal risk factor for developing in-stent restenosis, while therapy with aspirin provides most important protective factor against stent thrombosis. The utilization of non-direct stenting does not contribute to the reduction of target lesion

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Impact of pre-dilatation with cutting balloons compared to conventional balloons on stent areas: an in vitro study using a hard lesion model.

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THEME: Coronary Interventions

TOPIC(S): Stable CAD, Other Coronary Interventions

AIMS

Cutting balloons are useful type of balloons in a hard lesion or in-stent restenosis for coronary intervention. However, it is unclear whether cutting balloons or conventional balloons are suitable for the pre-dilatation of stent implantations. We hypothesized that an increase in number of cracks at even intervals in the hard lesion would lead to larger stent areas. For that purpose, we used cutting balloon with 3 blades in this study. Using a hard lesion models, we examined the stent area after pre-dilated with cutting balloons or conventional balloons in advance of stent implantation.

METHODS AND RESULTS

Method:

We used a lesion model mainly made from polyvinyl chloride with outer diameter of 3.0 mm, inner diameter of 1.3mm and length of 10 mm. We pre-dilated the lesion model with cutting balloons with 3 blades (WOLVERINE™) or non-compliant balloons at nominal pressure (6 atm for cutting balloon and 11 atm for non-compliant balloon)and implanted same drug-eluting stents (n = 6, each). Then we additionally post-dilated the stent with non-compliant balloons at 20 atm. We counted complete cracks which reach both ends of the lesion model, and measured the cross-sectional stent area before and after post-dilatation with an Optical Frequency Domain Imaging (OFDI).

Result:

In the cutting balloon group, the numbers of complete cracks were almost 3 cracks with even intervals (5 in 6 lesions), while in the non-compliant balloon group were almost 2 cracks with irregular intervals (5 in 6 lesions) ($p = 0.03$). Just after the stent implantations at nominal pressure, the averages of stent areas are 3.28±0.32 mm2 in the cutting balloon group, while 4.57±0.26 mm2 in the non-compliant balloon group ($p < 0.01$). After post-dilatation at 20 atm, the averages of stent areas are 5.87±0.20 mm2 in the cutting balloon group, while 5.23±0.33 mm2 in the non-compliant balloon group ($p < 0.01$). The average ratios of short and long axis diameter in stent areas are 0.94±0.03 in the cutting balloon group, while 0.92±0.04 in the non-compliant balloon group ($p = 0.89$).

CONCLUSIONS

Our results suggested that pre-dilatation with cutting balloons may contribute to an increase in number of cracks and a larger stent area to hard stenotic lesions. However, stent implantations at nominal pressure after pre-dilatation with cutting balloons result in an insufficient cross-sectional stent area, adding a post-dilatation with higher pressure should be considered.

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Combination strategy of quantitative flow ratio and FFR derived from coronary CT angiography for the diagnosis of coronary artery disease

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

This study aimed to investigate the diagnostic performance of the quantitative flow ratio (QFR) compared to the fractional flow reserve derived from coronary computed tomography angiography (FFRCT) and to evaluate the potential benefits of a combination strategy consisting of QFR and FFRCT in the management of coronary artery disease (CAD) patients.

METHODS AND RESULTS

We retrospectively analyzed 149 vessels in 101 patients who had undergone FFRCT assessment, invasive coronary angiography (ICA), FFR measurement, and QFR analysis between July 2015 and September 2017. The diagnostic performance of QFR and FFRCT was evaluated using wire-based FFR as a reference standard.

The mean value of FFR, QFR and FFRCT were 0.78±0.15, 0.76±0.13 and 0.75±0.13, respectively. QFR had a better correlation with FFR than did FFRCT (r=0.81, p<0.001 vs. r=0.66, p<0.001). Applying an FFR cutoff value of ≤0.80 to both QFR and FFRCT, higher accuracy, sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were observed for QFR than for FFRCT: 84% vs. 72%, 90% vs. 80%, 79% vs. 65% and 90% vs. 79%, respectively. The best cutoff values of QFR and FFRCT for FFR ≤0.80 were 0.80 and 0.75, respectively. QFR had a higher area under the curve (AUC) value (0.91, 95% confidence interval [CI]: 0.86-0.96) than did FFRCT (0.8, 95% CI: 0.72-0.88), using an FFR cutoff value of ≤0.80.

A combination strategy of QFR and FFRCT was evaluated based on the results and following criteria: (1) patients with moderate- or high-risk anatomy in CCTA should be assessed by FFRCT; (2) an FFRCT value of >0.80 could be used to defer ICA (NPV of 85%), whereas an FFRCT value of ≤0.80 could be used to perform ICA; (3) a QFR value of ≥0.85 could be used to defer revascularization (NPV of 89% after FFRCT assessment), whereas a QFR value of ≤0.70 could be used to confirm treatment (PPV of 94% after FFRCT assessment); and (4) wire-based FFR would be measured in the vessels with a QFR value between 0.71 and 0.84. With this combination strategy, the ICA incidence rate could decrease by 45% (45/101) and the need for FFR measurement could decrease by 68% (38/56). The agreement with an FFR-only strategy was 92%

CONCLUSIONS

QFR showed better diagnostic performance in detecting ischemia-causing CAD than FFRCT when using FFR as a reference standard. The combination strategy of QFR and FFRCT could decrease ICA incidence and FFR measurement in concordance with an FFR-only strategy for CAD patients. Both image-based FFRs have the potential as an alternative and less invasive method for estimating functional myocardial ischemia.

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The predictors of acute recoil after Orsiro coronary DES implantation

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Acute recoil is a phenomenon that has been observed following deflation of the delivery balloon during the percutaneous coronary intervention (PCI) with metallic stents including drug-eluting stents (DES). Sirolimus-eluting Orsiro stent is an ultrathin stent, but its properties may easily lead to acute recoil after stent implantation. This study investigated the predictors of acute recoil after Orsiro stent implantation based on optical coherence tomography (OCT).

METHODS AND RESULTS

Methods: Of 50 patients treated with Orsiro stent at a single institution between January 2018 and December 2018, forty-four patients were treated with Orsiro stent using OCT during the index procedure. Of the 44 patients, forty patients (treated with 50 stents) who met inclusion criteria were included in the retrospective analysis. All treated lesions were de-novo ones in a native coronary artery with a percentage diameter stenosis >50% and <100%, and a thrombolysis in myocardial infarction (TIMI) flow grade of >0. Patients receiving overlapping Orsiro stent were not included in this study.

Acute absolute recoil by quantitative coronary angiography was defined as the difference between the mean diameter of the last inflated balloon (X) and mean lumen diameter of Orsiro stent immediately after balloon deflation (Y). Acute percent recoil was defined as (X−Y)×100/X. OCT was performed within the culprit lesion. Plaque eccentricity (PE), percent (%) plaque, and calcification grade were assessed using OCT.

We calculated plaque eccentricity index (PEI), which was defined as follows: PEI = (lumen diameter [LD] + the maximum thickness of plaque [Pmax] - minimum thickness of plaque [Pmin]) / (LD - Pmax + Pmin). In addition, calcification grade was scored from 0 to 4 based on quadrants. Based on the median acute stent recoil value, the stents were divided into two groups: low (LAR, n =26) and high acute percent recoil (HAR, n=26).

Results: The mean acute percent recoil was 5.8±4.3%. There were no significant differences between the groups LAR (n=26) and HAR (n=26) with respect to baseline clinical characteristics and ACC/AHA lesion type. PEI, %plaque, and stent/artery ratio were significantly higher in the HAR group than in the LAR group. However, the calcification grade and the diameter of the implanted stent were not significantly different between the groups. In addition, significant differences in acute percent recoil were not observed with respect to the types of stent diameter. In multivariate logistic regression analysis, mean PEI>1.45 in the culprit lesion and mean %plaque volume>75% in the culprit lesion were significant positive predictors for the occurrence of acute percent stent recoil (odds ratio (OR), 19.1; 95% confidence interval (CI), 1.4–81.4, p=0.02; and OR, 5.6; 9 % CI, 1.1–51.0, p=0.043, respectively).

CONCLUSIONS

Acute recoil of Orsiro stent might be influenced by an eccentric plaque with large volume.

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Experience and outcome of LAA occlusion in patients on chronic dialysis - Efficacy of a contrast- sparing approach and mid-term outcome

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THEME:
TOPIC(S):

AIMS

Left atrial appendage occlusion (LAAo) is an established alternative in patients with atrial fibrillation and contraindication against oral anticoagulation (OAC). A considerable contraindication against OAC is severe renal failure with a need for chronic dialysis (CD). Several studies have indicated that severe renal failure is associated with an increased risk for device-related thrombi (DRT) after LAAo. In this single-center analysis, we sought to assess the outcome of LAAo in patients on chronic dialysis.

METHODS AND RESULTS

In this study, 167 consecutive patients that underwent LAAo at our center were included. For the purpose of this study, patients on CD were compared against patients without CD in terms of baseline characteristics, procedural aspects and outcome. All patients underwent preprocedural evaluation and underwent LAAo either with a conventional imaging approach or contrast-free echocardiographic guidance.

Overall, LAAo was performed in 4.8 % of patients (8/167) on CD. Those patients were younger than patients without CD (66 ± 11 vs. 76 ± 8 years, $p < 0.01$) and presented with a lower CHADS-VASC-Score (4 ± 1.7 vs. 4.6 ± 1.3, $p = 0.14$) and slightly better ejection fraction (59 ± 10 vs. 53 ± 12 %, $p = 0.18$). Patients on CD presented with severely impaired renal function, in terms of serum creatinine (5.34 ± 2.41 vs. 1.32 ± 0.6 mg/dl, $p < 0.01$) and glomerulus filtration rate (GFR) (13.3 ± 9.6 vs.59.7 ± 25.3 ml/min/1.73m2, $p < 0.01$). Procedural characteristics revealed that injected contrast volume (CV) was significantly lower in patients on dialysis (14 ± 25ml vs. 67 ± 61 ml, $p < 0.01$). No CV was used in 5 (62.5 %) of patients on dialysis. Hereby, contrast-sparing procedures tended to be significantly shorter (33 vs. 56 min, $p < 0.01$). Overall, device success, technical success, as well as overall complications, were comparable between patients with and without CD in patients without ($p > 0.05$ for all). The incidence of device-related thrombi was 0 % in patients with CD and 9.7 % in those without. One-year follow up was available in 78.4% of patients (131/167 patients). In these patients, one-year mortality tended to be higher in patients on CD: 33 % (2/6) vs. 11.2 % (14/125), $p = 0.11$.

CONCLUSIONS

Chronic dialysis is a major limitation in the treatment of atrial fibrillation, both in OAC and in LAAo and hence presents a patient group with special attention. LAAo appears to be a feasible option in this group, especially when contrast-sparing approaches are utilized. In this single-center study, LAAo in CD patients provided excellent procedural and clinical results. Whereas DRT was not detected in CD patients after LAAo, one-year was found to increased in patients on dialysis. Larger studies will need to assess the true efficacy of LAAo in patients under CD.

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Factors influencing the choice between transcatheter and surgical treatment of severe aortic stenosis in patients younger than 80 years: results from the OBSERVANT study

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Patients treated with transcatheter aortic valve implantation (TAVI), independently of surgical risk score, are mostly older than 80 years. We aimed to analyze the baseline features and clinical outcomes of patients younger than 80 years undergoing transfemoral TAVI or surgical aortic valve replacement (SAVR) enrolled in the OBservational Study of Effectiveness of SAVR-TAVR procedures for severe Aortic steNosis Treatment (OBSERVANT) study, focusing on variables guiding Heart Team decision towards TAVI.

METHODS AND RESULTS

OBSERVANT is a multicenter, observational, prospective cohort study that enrolled patients with symptomatic severe aortic stenosis (AS) who underwent SAVR or TAVI from December 2010 to June 2012 in 93 Italian participating hospitals. For this analysis, baseline characteristics, therapeutic approach and outcomes up to 5 years of follow up of 4801 patients under 80 years of age were collected. Patients were stratified by age classes (<65, 65-74 and 75-79 years).

Patients <80 years of age with severe symptomatic AS undergoing TAVI (n=483) had significantly higher Logistic EuroSCORE (10.84% vs 5.22%, p<0.001) and prevalence of comorbidities compared to subjects undergoing SAVR (n=4318). The decision to perform TAVI over SAVR was driven by anatomical factors, mainly previous cardiac surgery (OR 24.73, CI 12.71-48.10, p<0.001) and the presence of porcelain aorta (OR 17.44, CI 6.67-45.55, p<0.001), and clinical factors, mainly moderate-severe frailty score (OR 5.49, CI 3.33-9.07, p<0.001), oxygen dependency (OR 7.42, CI 2.75-20.04, p<0.001) and need for dialytic treatment (OR 5.24, CI 1.54-17.80, p<0.008). Among patients undergoing TAVI, those under 65 years had the highest baseline risk profile (despite a low Logistic EuroSCORE) and the highest 5-year mortality compared to those 65-74 and 75-79-year-old (65.22% vs. 48.54% vs. 55.24%, log-rank p=0.061).

CONCLUSIONS

Among patients under 80 years of age with symptomatic severe AS, only 10% underwent TAVI. These patients were at higher baseline risk compared to those undergoing SAVR. The decision to perform TAVI was driven by the presence of both anatomical and clinical factors beyond surgical risk scores. Patients under 65 years of age, despite the low Logistic EuroSCORE, had the highest pre-operative risk profile and carried the worse outcome.

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The impact of the ablation by Excimer laser system on the long-term outcome in in-stent restenosis

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

In-stent restenosis (ISR) has been an important issue following the percutaneous coronary intervention (PCI). The drug-eluting balloon (DEB) has considered a potential alternative to the current treatment of ISR. In addition, excimer laser coronary angioplasty (ELCA) treatment is thought to be advantageous for ISR treatment by removing neointima. So, in the present study, we evaluated the impact of ELCA plus DEB treatment on long-term outcome after PCI, focusing on the debulking efficiency of ELCA.

METHODS AND RESULTS

Methods: The clinical outcomes of PCI procedures performed in ISR, between October 2016 and March 2018, at two of our affiliated centers, were prospectively assessed. Forty-patients with ISR who received revascularisation for bare-metal stents (BMS) or drug-eluting stents (first or second generation drug-eluting stent (DES)) restenosis were included. Patients were randomized to ELCA plus DEB or DEB in a 1:1 allocation (ELCA group, N=20; non-ELCA group, N=20).

In the ELCA group, as the initial procedure, the ELCA was performed, followed by a scoring balloon. Finally, a DEB was performed. In the DEB group, a scoring balloon was used, followed by a DEB. Procedures were completed after successful dilatation of the target lesion with a residual stenosis <50%.

After the ELCA, the extent of the debulking in ISR segment was performed using optical frequency domain imaging (OFDI). In addition, the type of ISR on OFDI was classified into homogeneous, heterogeneous and layered type and neoatherosclerosis. Lumen area, stent area, and plaque area and percent (%)-neointima were also analyzed. For the evaluation of the debulking efficiency by the ELCA, the debulking efficiency (DE) value was acquired as the maximum neointima area debulked by ELCA in ISR segment. In addition, a quantitative coronary analysis (QCA) was performed to measure the acute gain and the late lumen loss. At 12-month follow-up, coronary angiography was performed for the evaluation of late lumen loss and target lesion revascularization (TLR).

Results: The average age of the 40 patients was 67± 8 years old. There were no significant differences in age, sex, body weight, lipid profile, glycemic marker, and stent types like BMS between the two groups at baseline. Overall, the incidence of neoatherosclerosis in ISR segment was 10%. The incidence of a homogeneous type of ISR segment in the non-ELCA group was slightly higher than that in the ELCA group. At post-PCI, acute gain on QCA and the changes in the lumen area on OFDI in both groups were similar. At follow up, the occurrences of binary restenosis and TLR in the ELCA group was 15.0 and 20.0%, respectively (N=4 and N=3). On the other hand, the occurrences of binary restenosis and TLR in non-ELCA group were 20.0 and 20.0%, respectively (N=4 and N=4), which were comparable in the ELCA and the non-ELCA groups. Furthermore, the patients in the ELCA group were divided into two groups based on the median value of DE (more DE group, N=10; less DE group, N=10). Interestingly, in ELCA group, three cases from the less DE group of ELCA group resulted in TLR. In addition, the changes in the lumen area on OFDI after DEB dilatation in the less DE group were significantly lower than in the more DE group (2.45±0.17 vs. 3.44±0.83 mm2, P=0.03).

CONCLUSIONS

Though ELCA is an effective technique for the treatment of ISR, the effective ELCA debulking might be required to obtain greater acute gain and a good long-term outcome.

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Renal artery denervation for resistant hypertension: largest Italian single-centre experience

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THEME:
TOPIC(S):

AIMS

To evaluate the impact of renal artery denervation in patients with severe resistant hypertension.

METHODS AND RESULTS

All patients with resistant hypertension who underwent renal artery denervation from 2012 to 2018 were included in the present study. Patients under 18 years old, pregnant women and patients with secondary forms of hypertension were excluded. All the patients underwent an angiogram of the renal arteries to exclude significant stenosis and to evaluate the anatomic features of the arteries. The radiofrequency ablation was performed with the Medtronic Flex catheter and with the Spyral catheter through a retrograde transfemoral approach. Ablations were delivered in multiple spots, in each renal artery, both longitudinally and rotationally within the length of the artery. At 3, 6, and 12 months all patients underwent a clinical follow-up, laboratory test, and 24 H ambulatory blood pressure monitoring. The pressure values at the follow up were compared with the pre-procedural ones using a paired t-test.

The study comprises twenty-eight consecutive patients, they had a median age of 62,3 years old and, 78% were males. Patients had multiple comorbidities: 57% were diabetic, 68% had chronic kidney disease (mean glomerular filtration rate was 46,21 ±24,16 ml/min), and 29% had ischemic heart disease. The majority of patients (78,5%) underwent renal denervation using the Spyralcatheter after 2015. The median duration time of the procedure was 55 ±12,6 min with a mean contrast medium volume of 79,04±44,6 mL. The mean systolic and diastolic pressure values before the procedure were 165,67/86,48 ±23,15/11,83 mmHg, respectively. Follow up data were available for 25, 23 and 18 patients at 3,6 and 12 months respectively. At 3-month follow-up pressure values were 154,80/83,84 ±17,94/13,74 mmHg with a mean systolic blood pressure drop of -12,56 mmHg (p value= 0,02). At 6-month follow-up pressure values were 153,74/83,87 ±18,91/16,40 mmHg with a mean systolic blood pressure drop[MP2] of -10,09 mmHg (p value= 0,08). At 12-month follow-up pressure values were 149.28/82,12 ±18,70/11,70 mmHg with a mean systolic blood pressure drop of -12,83 mmHg (p value =0,01). A non-significant reduction in the diastolic blood pressure was noted at 3-,6-,12-month follow-up. There were no major complications related to the procedure. The renal function has been stable up to 12 months after the procedure.

CONCLUSIONS

Renal denervation is a safe and feasible strategy in patients with resistant hypertension. In our experience renal denervation determine a significant reduction of systolic blood pressure value at 3,6 and 12 months after the procedure and a trend of reduction of the diastolic pressure.

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Comparison of 3-year outcomes between medical therapy and percutaneous revascularisation for surgically ineligible patients

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease

AIMS

This study aims to compare outcomes between PCI and medical therapy for surgically ineligible patients with multi-vessel coronary artery disease.

METHODS AND RESULTS

We determined the composite rate of Major Adverse Cardiovascular Events (MACE, which included all-cause mortality, cardiac death, myocardial infarction, repeat revascularisation, and stroke) amongst patients discussed at a Heart Team meeting following referral for CABG at four tertiary hospitals in the UK and Australia. Patients who were ineligible for surgery were treated with PCI or medical therapy.

Data were collected on a total of 701 patients, including 331 treated with PCI and 370 treated with MT. Rates of Left Main (LM) disease, hypertension and cholesterol were higher in the PCI cohort, whereas rates of immobility and chronic thrombotic occlusions (CTO) were higher in the medical therapy cohort.
30 day MACE-free survival was no different between PCI and medical therapy (88.2% vs 89.2%) whereas 1 year MACE-free survival was better in the group treated with PCI (72.2% vs 61.9%, p=0.0023) as was 3-year MACE-free survival (54.1% vs 20.5%, p<0.0001) with a Hazard Ratio (HR) of 0.58.
Findings were consistent finding across all institutions included in this study.

CONCLUSIONS

Amongst patients with multi-vessel coronary disease ineligible for CABG, PCI offered significant MACE-free survival benefit over MT up to 3 years. This supports the benefits of PCI in high risk groups.

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Treatment of acute pulmonary embolism with rheolytic thrombectomy (early and long-term clinical results)

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THEME: Peripheral Interventions
TOPIC(S): Other peripheral interventions

AIMS

Percutaneous rheolytic thrombectomy with AngioJet catheter can be successfully applied in patients with cardiogenic shock or severe right ventricular dysfunction due to massive pulmonary embolism in experience center.

The aim: to report a single center experience in applying rheolytic thrombectomy treatment of massive pulmonary embolism.

METHODS AND RESULTS

Methods:

Percutaneous rheolytic thrombectomy was performed in 21 patient with acute massive pulmonary embolism between September 2009 and January 2014. All patients had absolute or relative contraindications against systemic thrombolysis.

Twenty one patient (a mean age of 57.6 ± 15.3 years, female n=7 (one of them 22 week of pregnancy) underwent percutaneous rheolytic thrombectomy with AngioJet Xpeedior Catheter. Cardiogenic shock was present in 4 patients (shock index ≥1), severe right ventricular dysfunction was present in 17 patients, Troponin mean value 0.669 ± 0.176 μg/L and Brain Natriuretic Peptide mean value 330.7 ± 87 ng/L.

Selective thrombolysis (mean dose 30 mg) of tissue plasminogen activators was given to 11 patients.

Results:

The rheolytic thrombectomy procedure was technically successful in 20 cases. The perfusion systolic and mean pulmonary pressures improved from mean 56.9±15.8 mmHg to 47.2±14.76 mmHg (systolic) and from mean 34.3±7.56 mmHg to 28.9±6.99 mmHg (mean) ($p< 0.001$).

The shock index decreased from 0.91 to 0.735 ($p=0.001$). All patients survived in hospital stay, hemoptysis was noted in 2 patients (one required blood transfusion) and transient renal failure requiring dialysis in 4 patients. One patient suffered intracerebral hemorrhage (hematoma successfully operated on).

Right ventricular diastolic diameter decreased from mean 3.69±0.57 cm at baseline, to 3.1±0.33 cm 24 hours after rheolytic thrombectomy, to 2.78±0.31 cm at one month, 2.73±0.32 cm at six months ±and 2.68±0.37 cm at one year of follow up.

From 15 patients at one-year follow-up period, free patients (20%) demonstrated evidence of pulmonary hypertension with pulmonary artery systolic pressure (PASP) (measured with Doppler Echo using tricuspid valve velocity) - 40 mmHg, 47 mmHg and 53 mmHg. The pregnant woman successfully delivered a full-term newborn.

From 15 patients at 2–7 years (median 52 months) follow-up period two (13.3%) were with clinical signs of pulmonary hypertension (median PASP 46 mmHg).

CONCLUSIONS

Percutaneous rheolytic thrombectomy using the AngioJet catheter is an effective treatment method for massive pulmonary embolism when systemic thrombolysis is contraindicated. Careful selection of patients is very important. Severe complications were associated with contrast (contrast induced nephropathy) and thrombolytic therapy (even reduced dose of thrombolytic may course severe bleeding complications). Technical success of this invasive treatment correlates with experience of the center. More data with the comparison of this method and systemic lytic therapy in the treatment of acute PE are required.

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Radial or femoral and bivalirudin or unfractionated heparin in ACS patients presenting with advanced Killip class and/or out-of-hospital cardiac arrest

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

To assess whether transradial (TRA) compared with transfemoral access (TFA) and bivalirudin compared with unfractionated heparin (UFH) are associated with consistent outcomes in hemodynamic or electrical vulnerable (HVP) acute coronary syndrome (ACS) patients undergoing invasive management.

METHODS AND RESULTS

In the MATRIX program, 8404 patients were randomized to radial or femoral access and 7213 patients were randomized to bivalirudin or UFH. Among them, 934 (11.1%) were deemed HVP (advanced Killip class=808; cardiac arrest=168; both=42). Major adverse cardiovascular events (MACE) and net adverse clinical events (NACE) were similarly reduced with radial as compared to femoral in HVP or in non-HVP groups (interaction p values=0.77 and 0.89 respectively). TRA provided consistent relative benefits over TFA in terms of all-cause and cardiovascular mortality or BARC 3 or 5 bleeding, but absolute benefits were greater in HVP (absolute risk difference of -1.7%, -1.5% and -2.7% in HVP and -0.4%, -0.4% and -0.6% in non-HVP respectively). The effects of bivalirudin versus UFH on MACE and NACE were also consistent across HVP and non-HVP groups. However, bivalirudin significantly reduced all-cause and cardiovascular mortality exclusively in HVP (all-cause mortality: RR 0.51; 95% CI: 0.31 to 0.84; p=0.007; cardiovascular mortality: RR 0.50; 95% CI: 0.30 to 0.83; p=0.006) with borderline interaction testing (interaction p values=0.056 and 0.060 respectively). Bivalirudin significantly reduced bleeding rates in both HVP and non-HVP groups but the absolute benefit were larger in HVP (risk difference -4.4% vs -0.8%).

CONCLUSIONS

In patients with ACS undergoing invasive management, the effects of randomised treatments were largely consistent in HVP and non-HVP groups but the benefits of radial and bivalirudin trended greater in HVP group, mainly through a greater reduction in mortality and major bleeding.

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Nine-month clinical outcomes of amphilimus DES in an all-comer South-East Asian registry

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Amphilimus-eluting stent (AES) is a novel polymer-free drug eluting stent (DES) that combines sirolimus with fatty acid as antiproliferative drug and has shown promising results in percutaneous coronary intervention (PCI). There is limited data on the safety and efficacy of AES in Asian patients in contemporary clinical registries.

We evaluated the clinical safety and efficacy of AES in an all-comers South-East Asian registry and report on the 9-month clinical outcomes.

METHODS AND RESULTS

Between May 2014 to April 2017, 268 patients (88% male, mean age 60.1 ± 10.8 years) with a total of 291 coronary lesions were treated with AES. The primary endpoint was major adverse cardiac events (MACE) ie a composite of all-cause mortality, target vessel related myocardial infarction (MI), target lesion revascularization (TLR) and stent thrombosis at 9 months follow-up.

The majority of patients presented with acute coronary syndrome (75%) with 75% found to have multi-vessel disease on angiography. Diabetes mellitus was present in 123 patients (46%) with mean HbA1c level of 10.7 + 1.9 (%). 21% of diabetic patients required Insulin therapy for glucose control.Transradial access was used in 84% of cases. The most common target vessel for PCI was left anterior descending artery (43%) followed by right coronary artery (36%), left circumflex (10%) and left main (6%).

The majority of lesions were type B-C (85%) by ACC/AHA lesion classification with chronic total occlusion accounting for 4.5% of cases. Intracoronary imaging was utilised in 11% of PCI and rotablation was used in 5.2% of cases. An average of 1.25 + 0.5 AES were used per patient, with mean AES diameter of 3.1 ± 0.4 mm and average total length of 35 ± 19 mm.

At 9 months follow-up, 4% of patients developed MACE. MACE was mainly driven by all-cause mortality (2%), target vessel related myocardial infarction (2%) and TLR (1.5%). The rate of stent thrombosis was 1.5%.

CONCLUSIONS

In a contemporary all-comers South-East Asian registry with high rate of diabetes mellitus, AES was found to be safe and effective with a low incidence of MACE observed at 9 months follow-up.

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Absolute coronary collateral flow and resistance during STEMI using the controlled flow infusion method

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THEME:
TOPIC(S):

AIMS

Coronary collateral flow provides essential myocardial protection from ischemia in acute and chronic coronary syndromes. While large collateral vessels may be visualized during invasive studies, microvascular collateral function and physiology remain poorly understood, and rigorous hemodynamic quantitation has not been previously possible. This study evaluated microvascular collateral blood flow and resistance using controlled flow infusion in a preclinical porcine STEMI model.

METHODS AND RESULTS

Methods

STEMI was induced in 7 healthy domestic pigs by LAD balloon occlusion for 90 minutes. The controlled flow infusion technology precisely infused a pump driven crystalloid solution distal to epicardial balloon occlusion, measuring the resulting pressure at flow ranges zero (Coronary Wedge Pressure, CWP) through 50 ml/min in incremental steps of 15 sec each. Dynamic Microvascular Resistance, dMVR, is calculated from the known flow infusion rate and coronary pressure, and collateral resistance Rc is derived from CWP, aortic pressure, and microvascular resistance. Collateral flow is the ratio of (Aortic Pressure – CWP) / Rc.

Results

Pre-STEMI mean LAD collateral resistance was 10.16 + 5.30 mWU and collateral flow 5.87 + 2.57 ml/min, while post-STEMI LAD collateral resistance and flow changed to 6.76 + 2.55 mWU and 4.93 + 1.98 ml/min post-STEMI, documenting a collateral resistance drop of 33.5% post-STEMI, a percentage-wise value greater than flow change due to non-zero coronary artery wedge pressure.

CONCLUSIONS

Absolute and quantitative coronary collateral flow (ml/min) and resistance (mWU) calculations are possible using the controlled flow infusion method. Results pre- and immediate post-STEMI collateral flow and resistance in the porcine model is highly dynamic, with marked collateral resistance decrease and corresponding flow increase. Further studies to examine the validity of these methods, including comparison of micro vascular obstruction by CMR, infarct size, myocardial salvage index and severity in this model are warranted.

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Prognostic value of pre-existing atrial fibrillation in secondary mitral regurgitation patients undergoing percutaneous mitral valve repair with the MitraClip system: preliminary results from the Mi-ZU-Br registry

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair

AIMS

The aim of this study was to characterize the prognostic role of preexisting atrial fibrillation in patients with secondary mitral regurgitation, undergoing MitraClip implantation.

METHODS AND RESULTS

Between October 2008 and January 2019, 364 consecutive patients with moderate to severe, symptomatic, secondary mitral regurgitation treated with MitraClip implantation were included. All patients underwent clinical, bio-chemichal and echocardiographic evaluation before MitraClip implantation. Patients were divided into two groups according to the presence or absence of atrial fibrillation. Effectiveness end-point was defined as a composite of all-cause death or re-hospitalization for heart failure. Patients with atrial fibrillation were significantly older (74.3 ±7.9 vs. 69.8 ±10.4, p<0.001), presented a more compromised renal function (estimated Glomerula Filtration Rate: 40.6 [7.3; 73.9] vs. 49.0 [8.1; 89.9], p= 0.021; chronic renal failure: 73.3% vs. 53.7%, p= 0.001) and a higher surgical risk (European System for Cardiac Operative Risk Evaluation II: 14.6 ±10.7 vs. 11.2 ±8.1, p = 0.003). Patients without atrial fibrillation showed less enlarged atrial volume (left atrial volume index: 63.4 ±18.5 vs. 77.0 ±26.3, p= 0.001) and mitral mean annulus (36.1±5.1 vs. 38.0 ±4.4, p= 0.006), less tricuspid regurgitation (1.7 ±1.1 vs. 2.1 ±1.1, p= 0.003), a better right ventricular function (tricuspid annular plane systolic excursion: 18.5 ±4.1 vs. 16.8 ±4.7, p= 0.002; right ventricular dysfunction: 28.5% vs. 34.0%, p= 0.044) and higher pulmonary arterial systolic pressure values (48.9 ±16.9 vs. 44.7 ±14.0, p= 0.047). At 2-years median follow-up, primary effectiveness end-point was significantly different between the two groups (atrial fibrillation 60%; no-atrial fibrillation 49%; p = 0.025). At univariate analysis, N-terminal pro b-type natriuretic peptide >5.000 pg/mL, Logistic European System for Cardiac Operative Risk Evaluation >20%, atrial fibrillation, mean mitral annulus, severe left ventricular dysfunction, tricuspid regurgitationand right ventricular dysfunction were associated with a worse clinical outcome. At multivariate Cox-regression analysis, atrial fibrillation was not identified as an independent predictor, whereas severe left ventricular dysfunction and mean mitral annulus were the only independent predictors (HR 3.266, p= 0.012; HR = 1.127, p= 0.038, respectively).

CONCLUSIONS

Atrial fibrillation can not be considered as a predictor of adverse mid-term outcome after successful MitraClip implantation for secondary mitral regurgitation, but only as an epiphenomenon of advanced heart failure.

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Long-term clinical outcomes in patients with transplanted renal artery stenosis

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THEME: Interventions for Hypertension

TOPIC(S): Renal artery angioplasty, Other hypertension

AIMS

Transplanted renal artery stenosis (TRAS) is the main vascular complication of patients undergoing transplantation. Percutaneous intervention of TRAS is widely accepted as a viable treatment option, but there are few long-term data on patients undergoing angioplasty with or without stent.

METHODS AND RESULTS

Between January 2007 and December 2014, 308 consecutive patients with suspected of TRAS underwent angiography. Of these, 170 presented significant stenosis (>50%) and were submitted to percutaneous transluminal renal stenting (TRAS+ group), 130 had no significant stenosis (<50%) and were treated clinically (TRAS- group). 08 patients had significant stenosis but were not submitted to angioplasty and were excluded from this analysis. Mean follow-up time was 7.6 (4-11) years. Primary endpoints combined were all-cause deaths and graft failure. Secondary endpoints were serum creatinine (Scr), systolic blood pressure (SBP) and diastolic blood pressure (DBP), with one month and one year post arteriography. TRAS+ group were older (42.96±15.03 vs. 37.43±15.96 years, p=0.0026) and had more diabetes(p=0.0493). There was no statistically significant difference between the two groups in the primary outcomes of death and graft failure at follow up (15 vs. 09 deaths and 30 vs. 20 grafts failure, p=0.396). Scr (3.07±2.80 vs. 2.32±1.68 mg/dl, p=0.0029), SBP (153±25 vs. 142±23 mmHg, p=0.0003) and DPB (92±16 vs. 87±16 mmHg, p=0.0026) were significantly higher in the pre intervention TRAS+ group. After 1 month, Scr (2.15±1.39 vs. 2.15±1.37 mg/dl, p=0.346), SBP (138±19 vs. 136±19 mmHg, p=0.257), DPB (82±12 vs. 81±10, mmHg p=0.456) and 1 year, Scr(1.94±1.11 vs. 1.97±1.07 mg/dl, p=0.575), SBP (133±17 vs. 133±22 mmHg, p=0.519), DPB (83±10 vs. 82±10 mmHg, p=0.375), were similar between groups.

CONCLUSIONS

Percutaneous transluminal renal stenting of TRAS was effective in improving renal function and blood pressure levels at 1 month and 1 year. The two groups had similar outcomes of death and graft failure at follow-up.

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Potential benefit of ticagrelor monotherapy for patients with hypertension undergoing PCI: insights from the Global Leaders trial

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THEME: Coronary Interventions
TOPIC(S): STEMI, Stable CAD

AIMS

Hypertension is one of the most frequent modifiable risk factors for coronary artery disease. Due to the increased risk of bleeding associated with it, hypertensive patients might benefit from an antiplatelet monotherapy following percutaneous coronary intervention. We sought to investigate the effect of 1-month DAPT followed by 23-month ticagrelor monotherapy (ticagrelor monotherapy) compared with the reference arm, 12-month DAPT followed by 12-month aspirin monotherapy (standard DAPT), on clinical outcomes in patients with hypertension undergoing PCI.

METHODS AND RESULTS

This is a post-hoc analysis of the prospective, multi-center, open-label, all-comers, randomized controlled trial Global Leaders, that tested ticagrelor monotherapy versus standard DAPT in patients receiving PCI with biolimus A9-eluting stent. Patients were stratified by the hypertension status. The primary endpoint for the present analysis was the patient oriented composite endpoint (POCE - defined as composite of all-cause death, any stroke, any MI, or all revascularization) and safety endpoint of BARC type 3 or 5 bleeding, both at 2 years. Event rates are presented as Kaplan-Meier estimates (%).

In Global Leaders 15,991 patients were randomized, 23 (0.14%) requested complete deletion of their data from the database and 54 (0.34%) had no information on hypertension status. Of the 15,914 (99.52%) included in the analysis 11,715 were hypertensive. In the non-hypertensive patients, comparing ticagrelor monotherapy with standard DAPT, no difference was found regarding POCE (12.17% vs. 12.13%, HR 1.004, 95% CI 0.843 to 1.195, p=0.965) nor bleeding (1.71% vs. 1.72%, HR 1.0, 95% CI 0.628 to 1.592, p=1.0, respectively). In hypertensive patients the experimental treatment of ticagrelor monotherapy resulted in less POCE (13.62% vs. 15.04%, HR 0.898, 95% CI 0.816 to 0.988, p=0.028, p for interaction=0.271) with similar bleeding (2.21% vs. 2.26%, HR 0.976, 95% CI 0.765 to 1.246, p=0.846), compared with the standard DAPT at 2 years.

CONCLUSIONS

In this sub-group analysis of Global Leaders, in patients with hypertension undergoing PCI the experimental treatment of 1-month DAPT followed by 23-month ticagrelor monotherapy may offer ischemic protection without increasing bleeding. The results must be interpreted cautiously as there was no interaction between treatment strategy and the status of hypertension. Thus, the present results are hypothesis generating.

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Incidence and predictors of unplanned hospital re-admission following PCI

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THEME: Coronary Interventions

TOPIC(S): Other Coronary Interventions

AIMS

Unplanned hospital after percutaneous coronary intervention (PCI) is an important problem, which results in a significant burden to the healthcare system and adverse patient outcomes. Understanding the factors that contribute to readmission risk is therefore of substantial interest, and may help to prevent readmissions and improve patient outcomes. In this study, we utilised data linkage from a large multi-centre PCI registry to multiple government administrative databases, to determine the incidence of, and factors associated with unplanned readmissions in the first 30 days following PCI.

METHODS AND RESULTS

This study included 18,065 consecutive patients undergoing PCI from 1 January 2013 to 31 December 2017, enrolled prospectively in the Victorian Cardiac Outcomes Registry (VCOR). Deterministic linkage between VCOR and the Department of Health Victorian Admitted Episodes Dataset (VAED) was used to identify which patients had an unplanned hospital readmission within 30 days of PCI and compared for demographic, presentation and procedural characteristics to those who did not have a readmission.The VAED comprises routinely collected demographic and administrative data on all admitted patients in Victorian public and private hospitals. Of the study cohort, 2,136 patients (11.8%) had an unplanned hospital admission within 30 days of PCI. The primary cause of readmission was cardiac in nature in 36.4% of patients who had a readmission. Overall the median age was 65 years and 4,290 patients (23.7%) were female. Patients who had a readmission were more likely to be diabetic, have stage 4-5 chronic kidney disease, and a history of peripheral vascular and cerebrovascular disease (all $p<0.05$). They were also more likely to have presented with acute coronary syndrome (ACS), have higher lesion complexity on coronary angiography and had an unsuccessful PCI (all $p<0.05$). On multivariable logistic regression analysis, there was an increasing gradient of risk of readmission with increasing number of admissions within the 12 months prior to PCI (>5 readmissions: OR 3.88, 95% CI 3.04 – 4.94; 3-4 readmissions: OR 1.84, 95% CI 1.56 – 2.18, 2 readmissions: OR 1.54, 95% CI 1.31 – 1.81; 1 readmission: OR 1.23 – 1.55; all $p<0.001$). Other independent predictors of unplanned 30-day readmission were age >80 years, female gender, previous cerebrovascular disease, mild-to-moderate left ventricular dysfunction and ACS presentation (all $p<0.05$).

CONCLUSIONS

A substantial proportion of patients undergoing PCI have unexpected readmissions to hospital in the 30 days following PCI. Targeted strategies for patients with risk factors for readmission such as the elderly and those with multiple admissions prior to PCI, may be useful to reduce this significant burden to the healthcare system.

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Characteristics and outcomes of failed PCI in a contemporary Australian clinical registry

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THEME: Coronary Interventions

TOPIC(S): Other Coronary Interventions

AIMS

Since the introduction of percutaneous coronary intervention (PCI) over 40 years ago, substantial development in PCI techniques and adjunctive therapies have occurred, resulting in significant improvements in procedural success rates over time. However, rates of failed PCI are an important quality metric for all PCI operators and centres. There is a paucity of data on the rates of failed PCI worldwide, with less than 5 peer-reviewed publications on this topic. In this study, we therefore sought to examine the incidence, predictors and 30-day outcomes of failed PCI in a multi-centre registry.

METHODS AND RESULTS

This study included 34,383 patients undergoing single-vessel PCI between 1 January 2013 and 31 December 2017 inclusive, enrolled prospectively in the Victorian Cardiac Outcomes Registry (VCOR). VCOR is a large multi-centre Australian registry that collects prospective patient-level data on adult patients undergoing PCI in all public and private hospitals in the state of Victoria. Patients who had a failed PCI were compared to those who had a successful PCI. PCI success was determined for the treated lesion by the operator and a successful PCI was defined as <50% residual stenosis for lesions in which a stent was not able to be deployed in the lesion, or <20% residual stenosis for stented lesions. The primary endpoint was the rate of major adverse cardiovascular events (MACE), defined as a composite of death, myocardial infarction and target vessel revascularisation (TVR). Of the study cohort, 2,080 patients (6.0%) had a failed PCI procedure. Of the failed PCI cases, 30.2% involved PCI to chronic total occlusion lesions. Patients in the failed PCI group were slightly older (67.5 ± 11.8 years vs. 65.5 ± 12.0 years) and were more likely to have a history of stroke, previous PCI, severe left ventricular systolic dysfunction and stage 4-5 chronic kidney disease (all p<0.001). Failed PCI procedures were also more likely to be performed for stable angina and at a private hospital (both p<0.001). The rates of in-hospital and 30-day MACE, mortality and unplanned TVR were all significantly higher in the failed PCI group (all p<0.001). On multi-variable logistic regression analysis, failed PCI was a strong independent predictor of 30-day MACE (OR 3.44, 95% CI 2.75 – 4.30; p<0.001).

CONCLUSIONS

Our study has characterised demographic and clinical characteristics associated with unsuccessful PCI attempts in a large real-world patient cohort undergoing PCI in the contemporary era. Importantly, failed PCI is not a benign event and is associated with significant risk of poor clinical outcomes. Monitoring rates of failed cases among health services and operators is an important quality assurance tool.

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Thrombus aspiration in combination with glycoprotein IIb/IIIa inhibitors with or without stent implantation in patients presenting with STEMI and high-thrombus burden

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

High thrombus burden is an independent risk factor for death and complications, including no reflow, during primary percutaneous coronary intervention (PCI) for STEMI. The aim was to investigate whether a strategy of thrombus aspiration in combination with glycoprotein IIb/IIIa inhibitors without stent implantation is associated with a reduced incidence of slow- or no-reflow, and other thrombotic complications compared with stenting in patients with high thrombus burden.

METHODS AND RESULTS

A total of 210 patients with STEMI and high thrombus burden treated with thrombus aspiration in combination with glycoprotein IIb/IIIa inhibitors with or without stent implantation. Patients were divided into 2 groups: non-stent PCI group (n = 105) and stent PCI group (n = 105). We assessed angiographic and electrocardiographic signs of myocardial reperfusion, as well as clinical outcome. The end points were a myocardial blush grade of 0 or 1 (defined as absent or minimal myocardial reperfusion, respectively) and the postprocedural frequencies of a TIMI flow grade of 3, 48 hours after primary PCI, complete resolution of ST-segment elevation immediately after primary PCI, target vessel revascularization, reinfarction, death, and the combination of major adverse cardiac events by 30 days after randomization.

A myocardial blush grade of 0 or 1 occurred in 26.3% of the patients in the stent PCI group and in 17.1% of those in the non-stent PCI group ($p < 0.05$). Complete resolution of ST-segment elevation occurred in 86.6% and 78.2% of patients, respectively ($p = 0.35$). At 30 days, the rate of death in the stent PCI group and non-stent PCI group was 1.7%, and 1.0%, respectively ($p = 0.33$), and the rate of adverse events was 12.1% and 2.2%, respectively ($p < 0.01$).

CONCLUSIONS

Thrombus aspiration in combination with glycoprotein IIb/IIIa inhibitors without stenting is applicable and effective method in a large majority of patients with myocardial infarction with ST-segment elevation and high thrombus burden. It results in better reperfusion outcomes than conventional PCI with stent, irrespective of clinical and angiographic characteristics at baseline.

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Comparison of a radial dedicated Tig Impulse catheter vs. standard catheters during coronary angiography - a prospective, randomised pilot study

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

The aim of this pilot study was to assess whether using a radial artery dedicated catheter (Tig Impulse, Boston Scientific Corp.) in a big volume catheterization laboratory where the staff has a great experience with standard catheters (Judkins, Boston Scientific Corp.) is a good idea to reduce fluoroscopy time, radiation dose and contrast volume dose in patients underwent coronary angiography?

METHODS AND RESULTS

A total of 46 patients who underwent coronary angiography were prospectively randomised to either radial artery dedicated catheter (Tig Impulse, 5Fr or 6Fr, Boston Scientific Corp.) versus standard Judkins left and right catheters (5Fr or 6Fr Boston Scientific Corp.). The end points of the study included fluoroscopy time, total radiation dose and total contrast volume used. Physicians with a great experience in coronary angiography have been chosen to conduct the procedures in the study.

In the pilot study group 52.4% of patients was in the catheter Tig Impulse subgroup and 47.6% in the Judkins subgroup. Tig Impulse was associated with significant higher fluoroscopy time (297±143 vs 196±254 seconds, p=0.001). Total dose of radiation was also significant higher in Tig Impulse subgroup than in Judkins subgroup and was amounted to 401±207 vs 302±259 mGy, p= 0.017 for Tig Impulse and Judkins subgroup respectively. Moreover total contrast volume was also higher in Tig Impulse subgroup than in Judkins subgroup (76 ± 14 ml vs 64 ± 12 ml, p= 0.023).

Patients' comorbidities were not significantly different between both subgroups.

A total of 9 patients (47%) were crossed over from Tig Impulse catheter to Judkins catheter because of not enough image quality or difficulty in coronary engagement. No patients have to be switched to femoral access. One patient has an artery spasm (in Judkins subgroup) which prolonged procedure but finished the procedure from radial access. In limitations it should be mentioned that our staff had a small experience in Tig Impulse catheters what might have an influence in the results. It is a pilot study and therefore we are planning a larger research to confirm results which should be also focused on complication rate in larger group.

CONCLUSIONS

In conclusion there is no advantage of Tig Impulse – dedicated radial catheter versus standard catheters in reduction of fluoroscopy time, total dose of radiation and total contrast volume. Moreover, in a very experienced team in applying standard catheters there is a significant difference in favor of Judkins catheters using for radial access.

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Two-stent strategy in the management of coronary bifurcations, short- and long-term results

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

To analyze the reality of PCI with bifurcation technique and results on 1 year and longer follow-up. The use of 2 stent techniques are as safe as provisional stent in a "real world" population.

METHODS AND RESULTS

Revised cases from database from January 2009 to July 2018 , selected the PCI with bifurcation technique (either side branch protection guide or need for treatment of side branch). Mayor adverse cardiac events was defined: Cardiac death, myocardial infarction of culprit lesion and new culprit lesion revascularization (TLR). Patient oriented adverse events: Death of all causes, any myocardial infarction and any revascularization. We excluded patients with shock.

380 cases of PCI with bifurcation technique. The age was 63.29 ± 11.15 years, 72.1% men, 36.3% diabetic, 67.4% hypertensive and 16.6% with previous infarction. 70.5% were acute coronary syndromes, 35.5% has STEMI. In 86.1% radial access was used. The predominant segment is Left anterior descending artery/ Diagonal branch (53.4%), Distal left main (25%), circumflex/oblique marginal (14.7 %).

Provisional Stent technique (1-stent PCI) was used in 60%. The 2 stents techniques used are as follows: Minicrushing 36.6%, Culotte 18 %, TAP technique 17.4%, DK Crush 6.8%, T-Stenting 4.3% and Crushing 3.7 %. Final kissing balloon was performed in 69.5%, and proximal optimization technique (POT) in 50.3%. A 1.77 ± 0.83 stent was used, total length 42.8 ± 22.16 mm. We used a DES in 80% of treated main branch and 88.5% to side branch. Success of PCI were achieved in 98.2%.

When comparing 1-stent PCI and 2-stent PCI, only difference was found in previous myocardial infarction (13% and 22%) and previous cardiac revascularization surgery (0.9% and 7.3%); equal location of lesions and treatment of chronic total occlusions between groups. Patient with 2-stent PCI received more DES in the main branch (92% vs 72.2 %), more final kissing balloon was performed (57.2% vs 88.7 %) . There were no differences in the presence of no-reflow (3.5% and 2%) or successful PCI (97.8% and 99.3%).

At 1 year follow-up (254 patients), there was no difference in mayor adverse cardiovascular events (12% vs 11,5%, patient oriented adverse events (16,8% vs 12,6%), nor any of its components.

The longterm mayor adverse cardiovascular events (beyond 1 year) was higher in the 2-stent PCI (3,0% vs 6,6%), mainly driven by greater cardiovascular death (1,3% vs 3,9%) and myocardial infarction (1,7% vs 4,6%), no differences in other outcomes or patient oriented adverse events (25% vs 21,8%). In the logistic regression, the only parameter associated with combined events at 1 year and in the long term was the left main lesion [Mayor adverse cardiovascular events OR: 2.29 (confidence interval: 1.14-4.62); Mayor adverse cardiovascular events at 1 year OR: 3, 4 (confidedence interval: 1.5-7.5)]

CONCLUSIONS

This registry reflects the practice of bifurcation management in our center. The 1-year follow-up confirms the

safety strategy with 2-stent techniques, especially given the greater use and availability of DES. There is a tendency for a lower rate of events in the first year that is diluted and increases in the subsequent follow-up beyond 1 year, it is necessary to clarify if this effect is related to the PCI technique itself, the extension of disease or medical management in follow-up, especially use of double platelet antiaggregation after 12 months.

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12-month results from a prospective randomised trial comparing the safety and effect of a graft preservation solution vs. saline on SVG in patients undergoing isolated CABG

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Left main and multivessel disease

AIMS

Vein graft failure (VGF) remains an issue after CABG reducing long-term clinical outcome. In this trial we evaluated the safety and effect of an intraoperative graft preservation solution (PS) designed to protect against ischemic reperfusion injury and VGF in saphenous vein grafts (SVGs) of patients (pts) undergoing isolated CABG.

METHODS AND RESULTS

Two SVGs for each patient were randomized (within-pt design) to treatment with PS or heparinized saline (hS) with an allocation scheme balanced for (i) alternating target region A (circumflex or diagonal) and B (right coronary or diagonal), and (ii) alternating proximal vs distal segments of the harvested SVG. Multidetector computed tomography angiography (64-slice or better) was done at 1, 3 and 12 months (mo) to assess graft characteristics comprising (change in) wall thickness (WT), lumen diameter (LD), maximum stenosis (MS) and vessel diameter (VD) for the whole graft and the proximal segment (5 cm). Each SVG was evaluated using a semiautomated vessel-tracking algorithm allowing measurements at 10-mm intervals. Adjudicated safety outcomes included early SVG thrombosis, stenosis, occlusion and major adverse cardiac events. 125pts were enrolled (mean age 66.2±6.8 yrs). Most pts had 3-vessel disease (n=104; 83.2%); left main disease was present in 36.8% (n=46). Mean STS score for mortality and EuroSCORE II were 0.85±0.63 and 1.09±0.58, respectively. SVG harvesting was open in 72.8% (n=91) and endoscopic in 27.2% (n=34). Exposure time in PS and hS was similar (36.0±24.3 vs. 36.6±21.3 min). No difference was observed in WT at 3 mo (0.12±0.09 vs 0.21±0.37 mm, p=.29) or in the change between 1-3 mo (0.01±0.05 vs 0.10±0.34 mm, p=.98) for the whole graft. At 12 mo, PS-treated SVGs demonstrated smaller WT in the whole graft (0.12±0.06 vs 0.20±0.31 mm, p=.02) and the proximal segment (0.11±0.03 vs 0.21±0.33 mm, p=.01). Change in WT from 1-12 mo was greater in the proximal segment of hS-treated grafts (0.00±0.03 vs 0.09±0.29 mm, p=.04). No changes were observed in LD. Change in MS (1−12 mo) was larger in the proximal segment for the hS group (0.00±0.04 vs 0.05±0.13%, p=.01). VD was smaller in the PS group at 3 mo (3.34±0.86 vs 3.59±0.77 mm,

CONCLUSIONS

Intraoperative application of a solution developed for graft preservation demonstrated an acceptable safety profile and a favorable effect on SVG morphological characteristics at 12 mo. These data suggest that this solution may have the potential to reduce VGF and warrant further long-term evaluation.

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Comparison of the expanded area and the shape of third-generation DES: an experimental study using a calcified vessel model

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THEME: Coronary Interventions

TOPIC(S): Stents and scaffolds, Other Coronary Interventions

AIMS

Insufficient expansion of stent may cause in-stent thrombosis and in-stent restenosis after implantation of drug-eluting stent (DES). In order to reduce target lesion revascularization after percutaneous coronary intervention, it is necessary to obtain a sufficient expanded area and patency of stents. However, we often encounter the difficulty to expand stents in hard calcified lesions. In this study, we aimed to compare the final expanded area and the cross-sectional shape of third-generation DESs using a calcified vessel model examined with optical frequency domain imaging (OFDI).

METHODS AND RESULTS

We used the calcified vessel model consisting of silicon tube (Outer Diameter (OD) 5.0 mm, Inner Diameter (ID) 3.0 mm, length 40 mm) with two hard semicircular plastic tubes (OD 3.0 mm, ID 1.2 mm, length 10 mm) which we assumed as a hard-calcified lesion inside. We examined Orsiro, Resolute Onyx (Resolute), SYNERGY, Ultimaster, and XIENCE Sierra (Xience) (n=6 each). All stents were 3 mm diameter with a length of 18 mm except SYNERGY had a length of 20 mm. We expanded these stents for 3 times each at nominal pressure and 20 atm. After the expansions, we performed OFDI and obtained the cross-sectional images of hard plastic tube part and proximal non-plastic tube part of the stents and analyzed the area and the shape. The cross-sectional shape deformation was analyzed with ellipticity which was defined as the ratio of the short and long diameters. At nominal pressure, the cross-sectional area in the calcified-like lesion (Ca-LL) was smaller than in the non Ca-LL with a significant difference. SYNERGY had the largest area in the Ca-LL, followed by Resolute, Ultimaster, Orsiro and Xience. All DESs expanded to a nearly perfect circular shape in the Ca-LL at nominal pressure, the mean ellipticity for all DESs was 0.92. At 20 atm, the cross-sectional area of all stents became larger in both Ca-LL and non Ca-LL. Resolute had the largest cross-sectional area (7.33±0.20 mm2) in the Ca-LL, followed by Ultimaster (7.05±0.14 mm2), Orsiro (6.76±0.28 mm2), SYNERGY (6.68±0.44 mm2), and Xience (6.07±0.39 mm2). The area of Resolute was significantly larger than the other stents ($p < 0.05$). In the non Ca-LL, all stents expanded near the perfect circle at both nominal pressure and 20 atm, and the ellipticity was close to 1.00. In the Ca-LL, on the other hands, the shape of stents expanded at 20 atm was more elliptical than at nominal pressure. The ellipticity of SYNERGY was the lowest (0.66), followed by Orsiro (0.68), Ultimaster (0.84), Resolute (0.88) and XIENCE (0.93). Orsiro and SYNERGY had a significantly lower ellipticity compared to the other stents.

CONCLUSIONS

Our experimental study using the calcified vessel model suggested that the cross-sectional areas and the shape of third generation DESs may differ in calcified stenotic lesions. Understanding the difference in stent characteristics is important and it is necessary to examine the influence of the difference in expanded shapes (i.e. circular or elliptic) of DESs in the calcified lesion on clinical outcome.

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Impact of low wall shear stress in coronary aneurysm in patients with STEMI

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THEME:
TOPIC(S):

AIMS

Acute coronary syndrome (ACS) related to coronary aneurysm (CA) is rare and the mechanisms of ACS by CA are not well known. We aimed to investigate how coronary flow in CA related to the occurrence of ACS with computational fluid dynamics (CFD) analysis.

METHODS AND RESULTS

Three cases of ST-segment elevation myocardial infarction (STEMI) with CA were enrolled. CFD analyses using coronary computed tomography angiography (CCTA) were performed in chronic phase after primary percutaneous coronary intervention (PCI). Coronary flow streamline and wall shear stress (WSS) were assessed. Less than 0.2 Pa of WSS was defined as extremely low WSS. Area of extremely low WSS was measured in the vessel with CA.

Clinical presentation of three cases were STEMI. Case 1 presented total occlusion at the proximal left circumflex. Thrombus aspiration was performed at the primary PCI. CCTA was acquired at 13-day after the onset of STEMI. Recirculation flow was observed at CA site. Extremely low WSS area was 182.5 mm2 in left circumflex. Case 2 showed total occlusion at diagonal branch. Primary PCI was performed with drug-eluting stent. CCTA was acquired at 13-day after primary PCI. Recirculation flow was not relevant in CA site. Extremely low WSS area was 312.7 mm2 in diagonal branch. Case 3 presented total occlusion at proximal right coronary artery. Thrombus aspiration and balloon angioplasty were performed for coronary reperfusion. CCTA was acquired 29-day after primary PCI. Recirculation flow was revealed in CA site. Extremely low WSS area was 62.5 mm2.

CONCLUSIONS

CFD analysis revealed the presence of extremely low WSS in CA, which may be associated with the occurrence of ACS.

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Impact of TTVR on kidney and liver function in patients with severe tricuspid regurgitation

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THEME: Interventions for Valvular Disease
TOPIC(S): Tricuspid / Pulmonary valve

AIMS

Tricuspid regurgitation (TR) leads to impairment in renal and hepatic function, which is associated with a worse prognosis. We aimed to assess the impact of transcatheter tricuspid edge-to-edge valve repair (TTVR) of severe TR on kidney and liver functions.

METHODS AND RESULTS

All patients treated with TTVR in our centre between March 2016 and August 2018 were included. Kidney and liver functions were assessed and compared at baseline and at 30-days follow up, in the entire population, and according to whether patients underwent isolated TTVR or combined transcatheter mitral and tricuspid valve repair (TMTVR). Overall, 135 patients underwent TTVR for severe TR (64 (47.4%) isolated TTVR and 71 (52.6%) TMTVR). Mean age was 77.0 ±9.4 years with 65% of women. Most patients presented with functional TR (86.9%), with a TR grade ≥ 3 in 96.9% of cases and a MR grade ≥ 3 in 71 patients (52.6%). Mean LVEF was 50.0 ±13.4%. NYHA class ≥ III was present in 126 cases (96.9%). Mean STS mortality score was 6.1 ±6.5%. TR reduction to a grade ≤ 2+ was achieved in 116 patients (87.7%) and maintained at 30-days in 80.2%. Among patients who survived at 30 days (130 patients, 96.3%), there was no difference between baseline and 30-days renal and liver function tests, except for a reduction in bilirubin level (1.2 vs. 1.0mg/dl, P=0.017). Among patients with moderate to severe CKD (GFR < 59 mL/min/1.73m²; 91 patients, 70.0%), a small but significant improvement in GFR was observed at 30 days (37.9 vs. 42.0 mL/min/1.73m², P=0.019). When considering patients with abnormal liver function at baseline (AST level > 40 U/L, Gamma-GT > 48 U/L, and/or bilirubin > 1.2 mg/dl), there was a reduction in AST level from 54.2 to 39.5U/L (P=0.001), and bilirubin level from 1.8 to 1.5mg/dl (P=0.013).

CONCLUSIONS

TR reduction by TTVR is associated with an improvement in kidney and liver functions among patients with kidney and liver dysfunction. Accordingly, TTVR is an attractive option in these patients, who are at higher surgical risk compared to patients with normal kidney and liver functions.

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Impact of severe aortic stenosis treatment strategy in low-risk patients: a propensity matched analysis of surgical AVR vs. TAVI

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Recent studies suggest that transcatheter aortic valve implantation (TAVI) benefits might extend to lower risk patients. Our goal was to compare the impact of treatment strategy in mortality and peri-procedural complications in a low-risk severe aortic stenosis population.

METHODS AND RESULTS

Single-center retrospective study which screened patients undergoing intervention from June/2009 to July/2016 (682 isolated aortic valve replacement patients) and from June/2009 to July/2017 (400 TAVI patients). Low-risk was defined as EuroScore II < 4% for single non-CABG procedure. After excluding patients with EuroScore II ≥ 4%, previous cardiac surgery and/or undergoing pre-treatment PCI, 544 AVR and 119 TAVI patients were included.

TAVI patients were propensity score paired in a 1:1 ratio with a group of AVR patients, matched by age, NYHA class, diabetes mellitus, COPD, atrial fibrillation, creatinine clearance and LVEF <50% (mean standardized difference <10% for matching variables). All patients completed at least 1 year of follow-up. Outcomes were adjudicated according to VARC2 criteria.

A total of 158 patients (79 AVR and 79 TAVI) were matched (mean age 79 ± 6 years, 79 men). Median EuroScore II was 2.3% (IQR 1.6-3.0%), 46% were in NYHA class ≥ 3 and 91% had preserved ejection fraction. Main comorbidities were hypertension (n=105, 67%), diabetes mellitus (n=48, 30%), COPD (n=35, 22%) and coronary artery disease (n=30, 19%). Most patients had at least mild renal function impairment and median creatinine clearance was 58 ml/min (IQR 43-62 ml/min).

The 30-day mortality was 2.5% (n=2 in each group) and there were no differences in in-hospital complications. During a median follow-up of 3.8 years (IQR 2.1-6.1), 67 deaths occurred (39 on the AVR group and 28 on the TAVI group), and treatment strategy did not influence all-cause mortality (HR 0.97, 95%CI 0.60-1.60, log rank p=0.92). By multivariate analysis, need for dialysis during hospitalization remained the only independent predictor of all-cause mortality (adjusted HR 6.40, 95%CI 1.57-28.14, p=0.01).

CONCLUSIONS

In this low-risk matched population, treatment strategy did not influence mortality neither complications. Older age, higher NYHA class and renal impairment were the main contributors to the predicted low surgical risk. These results suggest that both options are safe for low-risk patients, even though Heart Team remains essential to contemplate other variables that might alter patient management.

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The use of 4Fr diagnostic catheters can minimize radiation exposure through radial approach

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Other Coronary Interventions

AIMS

The use of small catheters for coronary angiography can reduce the risk of vascular complications, but data on radiation exposure comparing the use of 4 French (Fr) diagnostic catheters with larger sized catheters are lacking. The aim of the present study was to evaluate the safety, feasibility, and radiation exposure using 4 Fr diagnostic catheters through radial approach.

METHODS AND RESULTS

120 consecutive patients without previous history of CABG (70 males, aged 66 years) underwent transradial coronary angiography. 60 were performed using 4 Fr diagnostic catheters and 60 were performed using 5 Fr diagnostic catheters. The primary end-points of the study were procedural success, fluoroscopy time (FT), dose-area product (DAP), air kerma (AK), number of catheters, and amount of contrast agent.

Independent-samples t-test indicated that the group of 5 Fr, compared to the group of 4 Fr was characterized by increased FT (3.36±1.10 versus 2.27±0.89 minutes, $p < 0.001$), DAP (30205±9423 versus 22367±5761 mGycm2, $p < 0.001$), AK (443±63 versus 329±51 mGy, $p < 0.001$), and amount of contrast agent (25±3 versus 20±2 ml, $p < 0.05$). There were no significant differences in procedural success and number of catheters between the groups. Multiple regression analysis revealed that the size of diagnostic catheter and weight were independent associated with DAP ($R2 = 0.44$, $p < 0.001$) and AK ($R2 = 0.53$, $p < 0.001$).

CONCLUSIONS

4 Fr diagnostic catheters are associated with decreased radiation exposure in patients undergoing transradial diagnostic coronary angiography, as reflected by decreased DAP, AK, and FT values. These findings imply that catheter size should be taken into account to help minimize radiation dose.

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The use of social media to recruit study participants for a multicentre, randomised, sham-controlled trial for hypertension: insights into the RADIANCE HTN SOLO trial

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THEME: Interventions for Hypertension
TOPIC(S): Other hypertension

AIMS

Great effort is required to recruit potential participants into clinical trials. Using social media to recruit patients for clinical trials may make this process more efficient. The aim of the present study is to evaluate the potential of social media as an approach to recruit hypertensive patients into the RADIANCE-HTN SOLO trial.

METHODS AND RESULTS

RADIANCE-HTN SOLO is a multicenter, randomised (1:1), sham-controlled study that was designed to demonstrate the efficacy and safety of the Paradise Renal Denervation system in subjects aged 18-75 years with essential hypertension on 0-2 antihypertensive drugs. A total of 803 patients were consented in order to enroll 146 patients within 19 months. Study participants were recruited through different methods including social media (Facebook), conventional ads (magazine, brochure/poster, radio, newspaper), web search (the clinical website, craigslist and web-browsing) and physician referral. Facebook ads were targeted towards subjects aged ≥45 years in proximity to a recruiting site (range 20-50 miles), these criteria were modified over time in order to increase response rates [i.e. distance was increased or decreased, age was increased to ≥55 year].

From August to November 2017, we captured information on the efficacy of different recruitment strategies. Campaigns on Facebook reached 5.3 million people in 168 separate campaigns run in proximity to 19 sites in the US and 14 sites in Europe. A total of 182.839 participants (3.4%) clicked on the ad; of those, 10.483 subjects (5.7%) subsequently filled out a dedicated online questionnaire screening patients for entry criteria. This resulted in 3.632 potential candidates for the study. Total cost for the Facebook ads was $152.412, resulting in $907/campaign and $0.83/click.

A total of 285 potential candidates were consented using different recruiting strategies in this specific time period, of which 184/285 came from Facebook at a cost of $828 per consent. Average age of the subjects consented through Facebook was 59±8 years, 51% were male and 82% of the subjects were Caucasian. A total of 27/184 subjects were eventually randomised. When comparing Facebook with one of the conventional methods such as a 7-day radio spot during the same recruiting period, 48 radio spots were launched with a total cost of $2.870; resulting in 9 inquiries with eventually 5 potential candidates, 2 consents ($1.435/consent), and no randomizations.

CONCLUSIONS

Targeted social media was a successful and efficient strategy to find potential candidates for a multicenter blood pressure clinical trial. Based on the high response rates on social media, candidates showed a profound interest for a relatively novel treatment option for hypertension.

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Impact of high-dose statin pre-treatment on contrast-induced nephropathy in patients with chronic kidney disease after coronary procedure

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

The efficacy of statin for prevention of contrast induced nephropathy (CIN) is controversial. The results might be influenced by patient population, type / dose of statin and duration of statin treatment before and after procedure. This study was conducted to evaluate the efficacy of statin pretreatment on CIN in patients with chronic kidney disease (CKD) after coronary procedure.

METHODS AND RESULTS

This study is prospective randomized placebo controlled multi-center trial. All consecutive 70 patients with CKD (eGFR<60 mL/min/1.73m2) were enrolled and randomized into two groups. Group I consist of the patients who treated with statins (pitavastatin 4mg) for 7 days before procedure (n=37, 52.9%) and group II consist of patients who treated with placebo (n=33, 47.1%). After procedure, patients in both group was treated statin. Primary endpoint is incidence of CIN and secondary endpoints are the change of serum creatinine (? sCr) level and eGFR (? eGFR) after procedure.

Mean age was 59.1±13.1 years (men 84%). Baseline sCr levels and eGFR were similar between two groups (1.68±1.03 vs. 1.53±0.62 mg/dL, p=0.575; 46.5±15.1 vs. 49.1±23.9 mL/min/1.73m2, p=0.677, respectively). After procedure, the incidence of CIN was lower in the group I compared than the group II but without statistical significance (5.4% vs. 9.1%, p=0.661). Maximal ? sCr was lower and ? eGFR was higher in the group I rather than the group II but without statistical significance (-0.11±0.53 vs. -0.04±0.33 mg/dL, p=0.678; 4.3±11.2 vs. -2.9±20.4 mL/min/1.73m2, p=0.161, respectively).

CONCLUSIONS

This study showed possibility of clinical benefit of high dose pitavastatin pretreatment for prevention of CIN in patients with CKD after coronary procedure.

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Important role of continuous direct left atrial pressure monitoring for intra-operative decision-making of MitraClips repositioning during transcatheter mitral valve repair

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair

AIMS

Intraoperative decision making during transcatheter mitral valve repair with MitraClip (Abbott Vascular, Santa Clara, CA, USA) is fundamental to predict the long-term outcomes and can be influenced by several factors. Among them, real-time direct monitoring of left atrium pressure (LAP) revealed to be crucial, improving outcomes. The aim of this study was to examine the factors contributing to intraprocedural decision making during MitraClip repair.

METHODS AND RESULTS

From June 2017 to December 2018, 69 patients with symptomatic moderate-severe to severe mitral regurgitation (MR), underwent MitraClip repair with continuous left-sided heart pressure measurements recordings. Left atrium V-wave pressure (LAvP), left atrium mean pressure (LAmP) and left ventricular systolic pressure (LVSP) were measured and stored continuously. Clinical and echocardiographic outcomes were determined. Median age was 78.0 years (IQR 69.5-81.5 years) and 59.4% were male. Pathology included leaflet prolapse/flail (n=45, 65.2%), functional (n=22, 31.9%) and mixed (n=2, 2.9%). Total number of implanted clips was 124 (NT 56 clips, NTR 27 clips and XTR 41 clips) and median number of implanted clips per case was 2.0 (IQR 1.0-2.0). There was a reduction in LAvP [27.0 mmHg (IQR: 19.5-38.0 mmHg) to 17.0 mmHg (IQR: 13.0-23.5 mmHg), P<0.001] and LAmP [13.0 mmHg (IQR: 11.0-19.0 mmHg) to 12.0 mmHg (IQR: 9.0-16.0 mmHg), P=0.15], and significant improvement in LVSP [112.0 mmHg (IQR: 100.5-122.3 mmHg) to 117.0 mmHg (IQR: 107.0-131.3 mmHg), P=0.037]. 66 Clips (53.2%) were implanted with 114 repositioning. Besides 62% (n= 59) transesophageal echocardiography causes (insufficient improvement of MR (n=38, 33.3%), insufficient leaflets grasping (n=13, 11.4%) and increased transmitral gradient (n=8, 7.0%)), decision making of clips repositioning included insufficient improvement of LAP in 48% (n=55).

CONCLUSIONS

This study demonstrates that intraprocedural decision making during MitraClip can be influenced by many factors, among them, the continuous left atrial pressure monitoring proved to be an important one to guide MitraClip device repositioning during procedures.

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Prognostic implications of door-to-balloon time and onset-to-door time on mortality in patients with STEMI treated with primary PCI

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

In patients with ST-segment elevation myocardial infarction (STEMI), timely reperfusion therapy with door-to-balloon time (D2B time) less than 90 minutes is recommended by the current guidelines. However, whether further shortening of symptom onset-to-door (O2D) time or D2B time would enhance survival of STEMI patients remains unclear. Therefore, this study aimed to evaluate the prognostic impact of O2D or D2B time in STEMI patients who underwent primary percutaneous coronary intervention (PCI).

METHODS AND RESULTS

Between November 2011 to December 2015, 5,243 patients with STEMI who were treated with primary PCI were included from Nationwide multicenter prospective registry for consecutive patients with acute myocardial infarction including STEMI. Patients who underwent primary PCI within 24 hours of symptom onset and 6 hours after admission were included for the current analysis. The primary outcomes was all-cause mortality at 1-year after index procedure. The median O2D time was 2.0 hours (Q1-Q3: 1.0-4.2) and the median D2B time was 59 minutes (Q1-Q3: 46-72). 92.2% of total population showed D2B time≤90 minutes and 55.3% were with D2B time ≤60 minutes. In univariable analysis, 1-hour delay of door-to-balloon time was associated with a 55% increased 1-year mortality (HR 1.55, 95% CI 1.40-1.72, p<0.001), whereas 1-hour delay of O2D time was associated with a 4% increased 1-year mortality (HR 1.04, 95% CI 1.02-1.06, p<0.001). In multivariable analysis, D2B showed an independent association with mortality (HRadj 1.64, 95% CI 1.42-1.89, p<0.001). Reducing D2B time within 45 minutes showed further decreased risk of mortality compared with D2B time >90 minutes (HRadj 0.30, 95% CI 0.19-0.42, p<0.001). Every reduction of D2B time by 30 minutes showed continuous reduction of 1-year mortality (D2B time 90 to 60 minutes: absolute risk reduction [ARR] 2.4%, number needed to treat [NNT] 41.9; D2B time 60 to 30 minutes: ARR 2.0%, NNT 49.2).

CONCLUSIONS

In patients with STEMI, shortening D2B time was significantly associated with reduced 1-year mortality. The survival benefit of shortening D2B time was consistently observed, even below 60 minutes.

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Assessment of ostial coronary segments in routine coronary angiography – Are the routinely employed angiographic views adequate?

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Coronary angiography is the gold standard for the diagnosis of coronary artery disease. For a complete angiographic assessment of the coronary tree, orthogonal views of each segment are required. A foreshortened view might lead to misjudgment of a lesion. The correct quantification of ostial lesions is especially challenging. The objective of this study was to evaluate whether the right and the left coronary ostium are adequately assessed during routine coronary angiography.

METHODS AND RESULTS

Coronary CTs and conventional coronary angiographies of 54 patients were analyzed, who underwent both procedures within a week. Based on the CT scan, the “Line of Perpendicularity” (LoP) of the left and right coronary ostium were determined. The LoP represents all projections resulting in an orthogonal view of the coronary segment of interest.

The angiographic views used during the cath procedure were plotted on the same coordinate system as the LoP (RAO/LAO = x-axis, cranial/caudal = y-axis). The angiographic assessment was defined as adequate, when the chosen angiographic views were on the LoP (±10° divergence).

Additionally, a visual assessment was performed by an experienced interventional cardiologist, who classified the chosen angiographic views of the ostial segments into 3 categories - "foreshortened", "slightly foreshortened" and "unforeshortened".

In 42 of 52 (81%) patients, the chosen angiographic views of the left coronary ostium were on the LoP, whereas this was the case for only 21 of 48 (44%) patients for the right coronary ostium.

The visual assessment classified the left and the right ostial segments as “unforeshortened” in 96% (LCA) and in 69 % (RCA) of patients.

In comparison, there was a difference in the assessment of 15% of the left and of 25% of the right coronary ostium between these two methods.

CONCLUSIONS

In 19% resp. 56% of patients no perpendicular projection of the right resp. left coronary ostium was performed during routine angiography. This misalignment was in many cases not recognized by an interventional cardiologist.

Additional effort should be made to choose unforeshortened angiographic views of the left and especially of the right ostium. In case a cardiac CT has been performed before the cath procedure, using the LoP can aid selection of adequate angiographic views.

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Residual shunt after PFO device closure in patients with cryptogenic stroke: serial bubble contrast transoesophageal echocardiography data

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THEME: Interventions for Stroke
TOPIC(S): Other stroke interventions

AIMS

Percutaneous closure of patent foramen ovale (PFO) is an alternative treatment option of medical treatment for secondary prevention for cryptogenic stroke (CS). Despite technical success of procedure, residual shunt (RS) which is a presumable cause for recurrent stroke is observed in some patients. We evaluated the RS with serial follow-up bubble contrast transesophageal echocardiography (BCTEE) after PFO closure.

METHODS AND RESULTS

Among consecutive 47 CS patients who underwent PFO closure, a serial follow-up BCTEE at 3 and 9 months after the index procedure was completed in 38 patients (81%, 46±10 years, 19 men). To evaluate the efficacy of PFO closure, the incidence of any- and significant RS (≥moderate) was assessed.

All PFO closure procedures were successful. The Amplatzer® PFO Occluder (n=19) or the Gore® Septal Occluder (n=19) were used. Any RS was observed in 13 (33%) and 10 patients (26%) at 3 and 9 months after the procedure. Significant RS was observed in 6 (16%) and 4 (11%) patients at 3- and 9-month follow-up BCTEE. Patients who were treated with the Gore® Septal Occluder have a less incidence of any RS in 3 month, and any/significant RS in 3- and 9-month follow-up BCTEE without statistical significance.

CONCLUSIONS

RS grade keeps decreasing after PFO closure, but it remains even after 9 months in some patients. Incomplete sealing of PFO should be taken into consideration in management of CS patients even after technically successful PFO closure.

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The relationship between the severity of coronary artery disease and myocardial blush grade after primary PCI

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

There are no data available about the relationship between Myocardial Blush Grade (MBG) and the severity of CAD with respect to the whole spectrum of LVF impairment. However, despite achieving TIMI 3 flow after PPCI, some patients have less optimal perfusion at the myocardial tissue level, as assessed by Myocardial Blush Grade (MBG), and consequently show adverse outcome.

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METHODS AND RESULTS

This prospective observational study was performed in the National Institute of Cardiovascular Diseases (NICVD), Dhaka from March 2016 to February 2017. Total 274 patients with STEMI who underwent primary PCI and achieved TIMI 3 flow were included. In Group I, 137 patients were taken with mild (GSS≤10) to moderate CAD (GSS>10−≤40) and another 137 patients with severe CAD (GSS>40) were taken in Group II.
Mean age of Group I and Group II were 53.70±9.17 and 51.49±9.41 years respectively (p=0.536). Male to female ratio was 5.7:1. Smoking (59.5% versus 35.1%, p=0.036) and diabetes mellitus (43.2% versus 18.9%, p=0.024) were significantly higher in group II than group I. Multi vessel involvement (24.3% versus 5.4%, p=0.022) and anterior MI (72.9% versus 51.4%, p=0.047) were significantly higher in group II. LVEF was significantly lower in group II than group I (49.92±6.60% versus 58.84±4.55%, p=0.003). The GSS ranged from 2–364. Linear regression analysis revealed a significant correlation between MBG and GSS (r = 0.177, p = 0.02). Patients with mild (GSS≤10) to moderate CAD (GSS>10−≤40) showed MBG 3 or 4. However, in patients with severe CAD (GSS>40), MBG was significantly reduced that is MBG 0 or 1 (p<0.0001) . Interestingly, patients with the same GSS revealed different MBG depending on the left ventricular function (LVF). Patients with preserved LVF (LVF≥50%) showed high MBG compared to those with reduced LVF (LVF<50%) regardless of the GSS. In CAD patients with reduced LVF, MBG was significantly low in patients with mild CAD as compared to patients with preserved LVF (p = 0.001) and showed a stepwise decline with increasing CAD severity.

CONCLUSIONS

The relationship between the severity of CAD and MBG depends on LVF. These findings emphasize the multifactorial interaction between the severity of CAD and MBG.

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Impact of myocardial blush grade on in-hospital outcome after primary PCI

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Primary Percutaneous Coronary Intervention (PPCI) is the optimal reperfusion strategy in patients with ST elevation Myocardial Infarction (STEMI). However, despite achieving TIMI 3 flow after PPCI, some patients have less optimal perfusion at the myocardial tissue level, as assessed by Myocardial Blush Grade (MBG), and consequently show adverse outcome

METHODS AND RESULTS

This prospective observational study was performed in the National Institute of Cardiovascular Diseases (NICVD), Dhaka from March 2016 to February 2017. Total 74 patients with STEMI who underwent primary PCI and achieved TIMI 3 flow were included. In Group I, 37 patients were taken with low MBG (grade 0 or 1) and another 37 patients with high MBG (grade 2 or 3) were taken in Group II.

Mean age of Group I and Group II were 53.70±9.17 and 51.49±9.41 years respectively (p=0.536). Male to female ratio was 5.7:1. Smoking (59.5% versus 35.1%, p=0.036) and diabetes mellitus (43.2% versus 18.9%, p=0.024) were significantly higher in low MBG group than high MBG group. Multi vessel involvement (24.3% versus 5.4%, p=0.022) and anterior MI (72.9% versus 51.4%, p=0.047) were significantly higher in low MBG group. LVEF was significantly lower in low MBG group than high MBG group (49.92±6.60% versus 58.84±4.55%, p=0.003). Among the complications acute heart failure was found significantly higher in low MBG group than high MBG group (8.1% versus 0.0%, p=0.048) along with total adverse in hospital outcome (24.3% versus 5.4%, p=0.041). Total mortality was 2.7% among study population and all were in low MBG group (5.4%). Multivariate logistic regression analysis showed MBG was an independent predictor of adverse in hospital outcome after PPCI (OR 6.553, 95% CI 1.984-21.643, p=0.002).

CONCLUSIONS

Low MBG is associated with more adverse in hospital outcome after PPCI. So, along with TIMI 3 flow following PPCI we have to assess MBG for evaluation of complete reperfusion and further outcome

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Three-year outcome after sirolimus-coated balloon angioplasty for in-stent restenosis

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

In-stent restenosis is one of the major problem associated with stents. Stenting of ISR is often controversial and drug coated balloon emerged as an alternative option to treat ISR. The aim of this registry was to assess the performance of MagicTouch SCB (Concept Medicals, India) in patients with ISR.

METHODS AND RESULTS

NANOLUTE is an all comer, real world registry which enrolled 450 patients from routine clinical practice in India. The primary endpoint of this registry was Major Adverse Cardiac Event (MACE) rate which includes Cardiac Death, Target vessel Myocardial Infarction (TV-MI) and Target lesion Revascularization (TLR) at 1 year. Clinical follow-up of 2 years and 3 years was also calculated to investigate the long-term efficacy and safety of the device.

Out of 450 patients, 211 patients had 225 restenotic lesions and all were treated with 258 MagicTouch SCB. Prevalence of male population was 80.1%. Majority of the lesions were present in left anterior descending (47.6%) followed by right coronary artery (28.4%) and left circumflex (20.9%). 53.8% ISR were focal while 21.8% were classified as diffuse intra-stent ISR. At 1 year, 100% patients completed the follow-up. At 2nd and 3rd year, clinical follow-up of 183 (86.7%) and 158 (74.9%) patients were available. At 1 year, incidence of MACE was 4.8% (TLR: 4.3%, TV-MI: 0.5%). No cardiac death was reported at 1 year. At 2 year and 3 years, incidence of MACE was respectively 6.0% (TLR: 4.9%, TV-MI: 0.5%, cardiac death: 0.5%) and 7.0% (TLR: 5.7%, TV-MI: 0.6%, cardiac death: 0.5%). NANOLUTE study is on-going study so follow-up of rest of the patients is yet to come.

CONCLUSIONS

This multicentre, real world registry demonstrates that the use of MagicTouch SCB is associated with good clinical outcome up to 3-years in patients with coronary ISR.

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Reference vessel diameter for distal radial approach evaluated by ultrasonography in Korean patients

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Since the left distal transradial approach (ldTRA) was introduced, several results for ldTRA were reported. But, there are still concerns about the safety of ldTRA regarding arterial occlusion and vessel injury because there is a lack of evidence for the reference vessel diameter of the distal radial artery (DRA). Therefore, this study aimed to evaluate the reference vessel diameter and predictor for small vessel size by using ultrasonography.

METHODS AND RESULTS

From November 2017 to March 2018, total 1,183 patients who were planned to perform transthoracic echocardiography with arterial ultrasonography were retrospectively enrolled. The outer diameters of both radial artery (RA) and DRA were measured by a perpendicular angle, and the average values were recorded using a linear ultrasound probe (3-4-10.8 MHz). The locations of measurement were 2-3 cm above wrist crease and distal to the extensor pollicis longus tendon between 1st and 2nd metacarpal bone. Average values were compared between men and women. Predictors for a small vessel (<2.3mm) non-compatible with 5-Fr introducer sheath were also analyzed. Total average diameters of right RA, left RA, right DRA and left DRA were 2.94±0.53, 2.90±0.58, 2.34±0.46, 1.02±0.14mm, respectively. Women showed significantly smaller right DRA (2.17±0.41 vs. 2.46±0.45mm, p<0.001) and left DRA (2.22±0.40 vs. 2.51±0.46mm, p<0.001) than men. The proportion of small vessel (<2.3mm) were 39.1% of right DRA, 31.5% of left DRA in men and 64.3% in right DRA, 60.5% in left DRA in women. Predictor for small vessel were women and body surface area in multivariate logistic regression analysis.

CONCLUSIONS

This study provides the reference diameters of radial and distal radial artery in Korean patients. Women showed a smaller arterial diameter than men. Predictors for small DRA were women and body surface area. Evaluation of DRA diameter before puncture is helpful to determine distal radial approach.

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Assessment of antidislodgment capability for contemporary DES

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Stent dislodgment is one of catastrophic complications of PCI, especially in tortuous and calcified lesions. The anti-dislodgment capability of different stent platforms may be varied due to different design. However, data on the anti-dislodgment capability of contemporary stent platforms are still limited. Thus, we aimed to compare the anti-dislodgment capability of different stent platforms with a bench test.

METHODS AND RESULTS

Three types of stent platforms (N=3 for each stent platform) were included in the bench test, including XIENCE Xpedition (3.0*23mm, Abbott), Resolute Integrity (3.0*22mm, Medtronic), and SYNERGY (3.0*24mm, Boston Scientific). The anti-dislodgment capability was assessed by Instron 5943 (Boston, US). Appropriate stent holder was determined according to the measurement of profile of each stent (Inner diameter of stent holder = measured stent profile - 2×structs thickness). The force was recorded during the pullback of stent catheters with the speed of 50.8mm/min. Maximal dislodgement force was defined as the first peak value of the force recorded in first 5 mm pullback. The operators were blinded to the types of stent platforms. Group comparisons were performed using one-way ANOVA with Bonferroni post-hoc test. Data were presented as mean ± standardized deviation.

Maximal dislodgement force for 3 stent platforms was as follows: XIENCE Xpedition group: 10.33 N, 9.76 N, 10.31N; Resolute Integrity group: 6.93 N, 7.00 N, 6.64 N; SYNERGY group: 6.50 N, 6.19 N, 5.48N. There was significant difference among three groups (p for one-way ANOVA < 0.001). Further group comparisons indicated that XIENCE Xpedition had the higher maximal dislodgement force than Resolute Integrity (10.13 ± 0.32 N versus 6.86 ± 0.19 N, p < 0.001) and SYNERGY group (10.13 ± 0.32 N versus 6.06 ± 0.52 N, p < 0.001), while there was no difference between Resolute Integrity and SYNERGY groups (p > 0.05).

CONCLUSIONS

Current bench test found that Anti-dislodgment capability varied among different stent platforms and XIENCE Xpedition may be higher than Resolute Integrity and SYNERGY. Further study is needed to verify this preliminary result.

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Prevalence and determinants of use of invasive physiologic assessment: analysis of large cohort of 40,823 procedures over a 12-year period

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

The actual use of invasive physiology for risk stratification and guiding management decisions of patients undergoing coronary angiography remains largely unknown in the real world. We aimed to describe the prevalence of invasive physiological assessment, its pattern of use and main determinants in a non-selected population of patients in daily practice.

METHODS AND RESULTS

Patient and procedural characteristics were collected using a dedicated electronic database. Overall, 40.823 procedures performed between 2007 and 2018 were included (42% PCI and 58% diagnostic only). Physiology assessment was considered per-procedure.

Over the entire study period, the overall use of physiology was 4.1% (N=1670). According to important landmarks (publication of major clinical trials) the prevalence was 1.3% until 2009, 4.7% between 2010 and 2017 (after FAME-1) and after 2017 (following release of iFR trials) it was 5.3% (

CONCLUSIONS

This multicentre registry clearly indicates that the use of invasive physiologic assessment is very low in routine practice. Strategies are warranted to increase the awareness of the advantages of its integration into patient management algorithms and the implementation of current recommendations.

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Evaluation of drug coating integrity based on different guidewires and side branch protection techniques for interventional treatment of bifurcation lesions

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

Side branch protection techniques are very important to avoid losing side branch for interventional treatment of bifurcation lesions. JWT (Jailed Wire Technique), NJBT (Negative Jailed Balloon Technique) and BSKT (Balloon Stent Kissing Technique) are most common used. But the impact to the drug coating integrity is still unknown and the difference of guide wire design may affect the results. The aim of our study is to evaluate the drug coating integrity based on different guidewires and side branch protection techniques.

METHODS AND RESULTS

The bifurcation vessel fluid model with 3.0mm main branch is designed for JWT, NJBT and BSKT testing. Each side branch protection technique is done with 3 groups of different types of guide wire: full coiled wire (Runthrough NS, Terumo), coiled (45mm from tip) & polymer jacket wire (BMW Universal II, Abbott) and full polymer jacket wire (Whisper MS, Abbott). Each group is with 3 samples. 1.5mm balloon (Traveler, Abbott) is selected for NJBT. 2.0mm balloon (Traveler, Abbott) is selected for BSKT with 8ATM expansion. All the jailed balloons are protruded to main branch with 2mm. The 2nd generation DES (XIENCE, Abbott) is selected for the whole test with 10 ATM expansion. After the procedure, the stent will be taken out of the vessel to exam the coating integrity by SEM (Scanning Electron Microscope). The defects of coating integrity is divided to: no defects (full coating integrity with no metal struts exposed), slight defects (metal struts exposed<100μm), mild defects (100μm≤metal struts exposed<200μm) and severe defects (metal struts exposed≥200μm).
Bench test result shows: there's no difference of the impact to coating integrity from 3 side branch protection techniques. The jailed balloon doesn't contribute any additional defects to the results whether expansion or not. The coating defects come from jailed wire or the wire inside the jailed balloon only. Full coiled wire makes severe defects to the coating (100%). Coiled & polymer jacket wire is superior to full coiled wire and makes mild defects (44.44%). Full polymer jacket wire is superior to both coiled wire and coiled & polymer jacket wire ($P<0.001$) and no mild or severe defects are found.

CONCLUSIONS

NJBT and BSKT is as safe as JBT. The full coiled wire cause 100% severe defects to the drug coating which will may lead to drug lossing or overdosage and might affect the vessel healing, even increase stent thrombus. Full polymer jacket wire should be recommended for all side branch protection techniques.

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Clinical outcomes of patients with non-obstructive coronary artery disease: a single-centre experience

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Other Coronary Interventions

AIMS

Recent studies have shown that the prevalence of non obstructive coronary artery disease in patients undergoing elective coronary angiography is higher than usually estimated. The incidence of major cardiac adverse events (MACE) related to this condition is not negligible.

The objectives of this study are to evaluate clinical outcomes of patients with non obstructive coronary artery disease in terms of angina symptoms or equivalents and occurrence of MACE and to characterize contemporary management (diagnostic and therapeutic) of these patients in our Center.

METHODS AND RESULTS

We enrolled consecutive patients with suspected chronic ischemic heart disease referred to our hospital for “clinically indicated” coronary angiography and with no evidence of obstructive coronary artery disease.

The primary study objective was major cardiac events (MACE, defined as the composite of all-cause death, any myocardial infarction [MI], target vessel revascularization [TVR], stroke and rehospitalization for cardiac reasons). The secondary endpoint was presence of angina symptoms or equivalents at follow up.

From January 2016 to September 2017 a total of 1441 patients underwent clinically indicated coronary angiography in our Center. A total of 1112 patients has been diagnosed at coronary angiograms to have obstructive coronary artery disease; indeed, 329 patients (22.8%) had non obstructive coronary artery disease and were included in the present study. Of these, 61.3% of patients had “normal coronary arteries” (epicardial vessel stenosis < 20%), while 38.6% of patients presented “mild disease” (stenosis of 20% -70% with fractional flow reserve >0.81). Acetylcholine test was performed in 2.7% of patients.

At a median follow-up of 374 days (25%/75% quartile: 491/776 days) the rate of MACE was 20.5% (all-cause death 2.09%; any MI 0.8%, TVR 1.2%, stroke 0.8%, rehospitalizations for cardiac reasons 17.9%), whereas angina symptoms were observed in 27.1% of the patients.

Independent predictors of angina were presence of symptoms at baseline (OR 2.77 [1.13-6.82], p=0.026) and female sex (OR 2.14 [0.99-1.13], p=0.029.

At multivariate analysis, independent predictors of MACE were age (HR 1.04 [1.01-1.07], p=0.005 and the presence of mild disease (HR 1.83 [1.01-3.32], p=0.044.

Regarding the patients with positive acetylcholine test discharged with tailored therapy, none of them had MACE at follow-up.

CONCLUSIONS

In this “real-world” single center study, non obstructive coronary artery disease was a common finding.

The use of functional tests to detect coronary microvascular dysfunction was very low and patients experienced a relatively high rate of angina and MACE at follow-up. Future studies will determine the necessity of a routine assessment of microvascular dysfunction to provide a tailored therapy and improve symptoms and possibly prognosis of these patients.

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One and six-month OCT comparative study among DES with persistent, absorbable or without polymer (Horsepower study)

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

One of the key finding supporing safety of a shorter dual antiplatelet therapy (DAPT) is the early in-vivo detection (1 month) of a low ratio of uncovered/total stent struts, probably the best predictor of late stent thrombosis (LST). We present a prospective, multicenter study to compare the endothelial coverage at 1 and 6 months after DES with persistent, absorbable or without polymer.

METHODS AND RESULTS

A total 90 patients with de novo ¨non complex¨ coronary lesions treated with polymer-free Biolimus A9 (BA9) stent, everolimus-eluting stent with abluminal bioabsorbable polymer (EESb) and everolimus-eluting stent with persistent polymer (EESp) underwent examination with OCT. Blinded analysis was done at an independent core lab. Co-primary endpoints were proportion of struts with coverage and with apposition at 1 and 6 months among this different stents and clinical presentation.

A total of 17995 struts were analyzed. There were no significant differences between groups regarding clinical, angiographic and procedural characteristics; only the mean stent diameter was bigger in the BA9 stent group (BA9 3.3mm vs. EESp 3.0mm vs. EESb 3.1mm, p=0.03). The rate of strut coverage at 1 month (83-88%) and 6 month (97-98%) was similar among the 3 types of DES. We observed significant better strut coverage between 1 vs. 6 months (p<0.001). The percentage of malapposed struts was similar among stents and over the time. We observed more percentage of uncovered struts at 6-month in the acute coronary syndrome (ACS) compared to the stable angina cohort (p=0.01).

CONCLUSIONS

We demonstrated similar degree of intimal coverage and apposition among drug eluting stents with persistent, absorbable or without polymer at 1 and 6 months after implantation. The absence of polymer in DES did not increase the ratio of covered/total stent struts, thus there is no evidence to safetely reduce the DAPT period. We observed more percentage of uncovered struts in the ACS.

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Why thrombus aspiration in acute STEMI fails: could plasminogen activator inhibitor 1 be the culprit?

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

To determine whether the use of thrombus aspiration (TA) during primary percutaneous coronary intervention (PCI) affects plasminogen activator inhibitor 1 (PAI-1) activity levels during acute phase ST elevation myocardial infarction (STEMI).

METHODS AND RESULTS

A total of 87 consecutive acute STEMI patients with symptoms duration of <12 hours were enrolled in the study. Enrolment period was from May 1, 2009 to March 23, 2010. Blood samples were collected prior to PCI and after exactly 24 hours. All PCIs were performed using transfemoral approach, according to contemporary guidelines. Dual antiplatelet therapy consisted of aspirin and clopidogrel. Eptifibatide as well as TA were indicated by interventional cardiologist on duty. Repeated aspirations were allowed. Thrombus burden was determined by thrombolysis in myocardial infarction (TIMI) thrombus grade, and was documented for the initial diagnostic angiogram (TG1), and, in patients with occluded coronary artery, after restoring antegrade flow by means of guidewire advancement or small balloon dilatation (TG2). Endpoints were established after 5 years, and were defined as follows: primary as death, secondary as composite of death, stroke and recurrent acute coronary syndrome.

Study population was predominantly male (72.3%), aged 61.1±12.2, with high prevalence of hypertension (66.8%) and active smoking status (48.3%). TA was performed in 12 patients (13.8%). In TA group, higher PAI-1 activity in second sample (7.32 vs 4.60 U/mL, p=0.019) and higher PAI-1 activity rise (3.25 vs 1.20, p=0.003) were detected, while there was no difference in first sample values. Use of balloon angioplasty was not associated with the difference in PAI-1 activity rise. However, when patients were grouped according to interventional procedures employed (none, balloon angioplasty only, TA only, both), the difference was significant, with the highest value in the group treated with both balloon angioplasty and TA (p=0.015). TIMI thrombus grades (TG1 and TG2) did not correlate with PAI-1 activity rise (for TG1 p=0.289, for TG2 p=0.596). Both TG1 and TG2 values showed no significant difference in groups of patients with or without use of TA (for TG1 p=0.054, for TG2 p=0.966).

There were no differences in primary and secondary endpoints at 5-year follow-up in groups of patients with or without use of TA.

CONCLUSIONS

TA was associated with higher PAI-1 activity rise in acute STEMI patients treated with primary PCI. The clinical implications of this association should be tested in larger studies, and if proved significant, additional efforts to produce and test PAI-1 antagonists should be employed.

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Biomechanical mechanism of high-wall shear stress in the development of ACS

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

Very high wall shear stress (WSS) can increase the vulnerability of coronary plaque. However, biomechanical mechanism of high WSS in the development of acute coronary syndrome (ACS) has not been well-defined in patients with coronary artery disease.

METHODS AND RESULTS

197 lesions were selected from the EMERALD (Exploring the Mechanism of Plaque Rupture in Acute Coronary Syndrome Using Coronary CT Angiography and Computational Fluid Dynamic) study, and anatomical and hemodynamic characteristics of 61 culprit lesions for subsequent ACS were compared with those of 136 non-culprit lesions. Four hemodynamic parameters including WSS, pressure gradient (i.e., pressure drop divided by lesion length), fractional flow reserve (FFRCT), change in FFRCT across the lesion (delta FFRCT) were non-invasively assessed in hyperemic condition from computational fluid dynamics applied to coronary CT angiography (CCTA) data. All data were analyzed by independent CCTA, computational fluid dynamics, and clinical data core laboratories.

The median interval between CCTA and ACS event was 335 days. At the CCTA taken before ACS event, culprit lesions for subsequent ACS were more stenotic than non-culprit lesions (% diameter stenosis, 54±15 vs. 44±15 %, p<0.001), and showed higher WSS (215±111 vs. 141±83 dyne/cm2, p<0.001), pressure gradient (12±9 vs. 6±6 mmHg/cm, p<0.001), delta FFRCT (0.2±0.2 vs. 0.1±0.1 p<0.001) and lower FFRCT (0.7±0.2 vs. 0.8±0.1, p=0.021). In prediction of the culprit for ACS, WSS had better discrimination ability than FFRCT (c-index: 0.71 vs. 0.61, p=0.012). Pressure gradient and delta FFRCT also showed better predictability than FFRCT (c-index: 0.72, vs 0.61, p<0.001; 0.75 vs. 0.61, p<0.001, respectively). Overall, local hemodynamics–WSS, pressure gradient, and delta FFRCT were better parameters than per-vessel parameter–FFRCT in prediction of future ACS. For the relationships among local hemodynamic parameters, WSS was strongly correlated with both pressure gradient and delta FFRCT (r=0.97, p<0.001; r=0.84, p<0.001, respectively). This strong correlation of WSS with pressure gradient and delta FFRCT demonstrates an underlying biomechanical mechanism of high WSS in the development of ACS–WSS is elevated by a large pressure gradient, which is the major force acting on plaques as well as driving flow.

This finding was consistent even when the lesions were divided into the 2 groups according to the presence of high risk plaque characteristics (positive remodeling, spotty calcification, low attenuation plaque, or napkin ring sign). For 81 high-risk plaques, c-index of WSS, pressure gradient, delta FFRCT, and FFRCT were 0.67, 0.70, 0.74 and 0.63, respectively, and there were positive correlations between WSS and both pressure gradient and delta FFRCT (r=0.96, p<0.001; r=0.80, p<0.001, respectively). For 116 non high-risk plaques, c-index of WSS, pressure gradient, delta FFRCT, and FFRCT were 0.71, 0.72, 0.73 and 0.56, respectively, and there were strong correlations between WSS and both pressure gradient and delta FFRCT (r=0.98, p<0.001; r=0.83, p<0.001, respectively).

CONCLUSIONS

High WSS was associated with the increased risk of subsequent ACS, and was strongly correlated with pressure gradient and delta FFRCT. These results demonstrate the biomechanical mechanism of very high WSS in the development of ACS and suggest that measurement of delta FFRCT or invasive delta FFR in daily clinical practice can represent the level of WSS and may help to predict the risk of future ACS.

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Temporal trends and outcomes of radial vs. femoral access in PCI: a study with 158,363 patients from the Brazilian PCI registry (CENIC)

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THEME: Coronary Interventions
TOPIC(S): NSTEMI, Stable CAD

AIMS

Over the last years, several clinical studies have demonstrated the beneficial value of the radial approach in percutaneous coronary intervention (PCI) in comparison with the more traditional femoral route. The purpose of this study is to compare the temporal trends in the utilization of both accesses and their respective in-hospital outcomes in a large cohort of patients treated in Brazilian hospitals.

METHODS AND RESULTS

In a cohort of 158,363 patients treated between June 2006 and March 2016 and included in the Brazilian PCI Registry (CENIC), radial PCI was used in 23.6% patients. Over the years, the proportion of radial PCI increased from 12.4% in 2006 to 49.8% in 2016 (p<0,0001). Radial PCI was associated with a lower in-hospital mortality compared with the femoral PCI (0.5% x 0.9% respectively; p<0.001), wih no difference in in-hospital myocardial infarction (0.4% x 0.3% respectively; p=0.07). In propensity score matching analysis (n=54,242 patients), radial PCI was still associated with lower risk of in-hospital death (OR 0.59; 95% CI 0.47 – 0.74; p < 0.001) and no difference in in-hospital infarction (OR 1.04; 95% CI 0.71 – 1.53; p 0.843).

CONCLUSIONS

This large national registry demonstrates a significant and progressive increase in the use of radial PCI over the last decade. In comparison with femoral approach, radial PCI is associated with lower rates of fatal complications.

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Impact of diabetes mellitus on short-term vascular complications after TAVR: results from the BRAVO 3 randomised trial

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Several clinical and procedural factors have emerged as predictors of adverse events following transcatheter aortic valvular repair (TAVR). However, the impact of diabetes mellitus (DM) on vascular and bleeding complications after TAVR remains unclear. We sought to investigate the impact of DM and the role of insulin use on short term clinical outcomes after trans-femoral TAVR in a large randomized trial population.

METHODS AND RESULTS

The Effect of Bivalirudin on Aortic Valve Intervention Outcomes (BRAVO-3) trial randomized 802 patients undergoing transfemoral TAVR. Overall mortality, cardiac death, stroke, myocardial infarction (MI), major adverse cardiac events (MACE), acute kidney injury (AKI), and, vascular and bleeding complications were examined in-hospital and at 30 days post-TAVR in patients with and without DM. Multivariate analysis was performed according to insulin dependent (IDDM) versus non-insulin dependent DM (NIDDM) status.

A majority of patients with DM (n = 239, 30%) were treated with either insulin (36.4%) or oral medications (34.7%) at baseline. Overall, DM patients had a higher odds of developing a life-threatening bleed, both, in-hospital (OR 1.50 [1.01-2.23], p=0.04) and at 30 days post-TAVR (OR 1.54 [1.07-2.23], p=0.02). Additionally, DM patients also had increased rates of vascular complications at 30 days (OR 1.52 [1.01-2.28], p=0.04). These results were driven primarily by higher rates of bleeding and vascular complications amongst the NIDDM patient subgroup. IDDM patients were more likely to require temporary pacemaker implantation and have unsuccessful vascular closure. There were no differences between subgroups for either in-hospital or 30-day all-cause mortality, MACE, MI, stroke, AKI, or minor vascular complications.

CONCLUSIONS

Patients with DM had higher rates of vascular complications at 30-days post-TAVR, as well as life-threatening bleeds both in-hospital and at 30-days. Overall, however, there was no significant association between DM and early mortality following TAVR.

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First safety and performance report of the routine clinical use of the Fantom scaffold (sirolimus-eluting BRS)

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

The objective of this Analysis was to evaluate the safety and performance of native coronary artery stenting using the novel the Fantom Bioresorbable Scaffold in routine clinical practice. Fantom is manufactured from TyroCore, which is composed mainly of an iodinated, polycarbonate copolymer of tyrosine analogs. Fantom is completely radiopaque with thin struts (125 microns) in the 2nd generation device and as low as 95 micron struts in the 3rd generation version. This is the first report of the routine clinical use of the Fantom Scaffold since it received CE Mark in 2017.

METHODS AND RESULTS

This assessment includes a single center evaluation of the real world use of the Fantom BRS in every-day clinical practice. This analysis includes 54 patients that were treated with a total of 72 implanted Scaffolds over a time period of 16 months. Seven (7) of the patients included in this evaluation were treated with a total of 8 third generation Fantom Encore scaffolds, which has a reduced strut thickness compared to the 2nd generation Fantom scaffold. Reported outcomes include acute technical success, acute procedural success, and a clinical procedural success rate of 97,3% (70/72). There were two incidences of restenosis with no further Major Cardiac Adverse Events (MACE) or scaffold thrombosis through 6 months follow-up among the 41 patients that have reached this time point. 6-month clinical and angiographic outcomes for all 54 patients as well as acute angiographic and OCT results will be presented for the first time at the EuroPCR Course.

CONCLUSIONS

In this first report of routine clinical use of the Fantom sirolimus-eluting bioresorbable coronary, Fantom demonstrated favorable safety and efficacy through 6 months. These results demonstrate the advantages of a thin strut, radiopaque bioresorbable scaffold on procedural success and early clinical outcomes in routine clinical use.

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Clinical characteristics and long-term prognosis of TAVI-associated endocarditis

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

The purpose of this study is to investigate the frequency, clinical characteristics and long-term prognosis of prosthesis endocarditis after transcatheter aortic valve implantation (TAVI).

METHODS AND RESULTS

Consecutive patients undergoing transfemoral TAVI in Bonn University were prospectively enrolled in this study. Transcatheter heart valve (THV) endocarditis was defined according to Duke criteria. The primary outcome was all-cause death within 5-year follow-up.

1448 successful TAVI patients were eligible and 17 patients (1.2%) had THV endocarditis during follow-up period (median 294 days). A multivariate logistic regression analysis identified age (odds ratio [OR], 0.90; 95% confidence interval [CI], 0.85-0.96; P = 0.001) and residual paravalvular leakage (PVL) ≥ 2 after TAVI (OR, 5.15; 95% CI, 1.38-19.19; P = 0.015) are associated with the occurrence of TAVI endocarditis. A Kaplan Meier analysis showed a significantly worse prognosis in TAVI endocarditis than non-TAVI endocarditis patients (log-rank; P = 0.03) within 5-year follow-up, and a multivariate cox proportional hazard analysis revealed TAVI endocarditis as an independent and significant predictor of long-term mortality (hazard ratio, 4.17; 95% CI, 1.91-9.07; P < 0.001).

CONCLUSIONS

The present single center study identified lower age and residual PVL ≥ 2 as predictors for THV endocarditis that was an independent predictor of long-term mortality after TAVI.

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Frequency and determinants of periprocedural myocardial injury after successful percutaneous CTO intervention

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THEME: Coronary Interventions
TOPIC(S): CTO, Other Coronary Interventions

AIMS

This study sought to evaluate the frequency and determinants of periprocedural myocardial injury (PMI) in patients undergoing successful chronic total occlusion (CTO) percutaneous coronary intervention (PCI).

METHODS AND RESULTS

We retrospectively examined 125 consecutive CTO patients who underwent PCI attempt between December 2013 and December 2017 in our Centre. Angiographic success was achieved in 115 patients (92,0%) and measurement of troponin I (Tn-I) values was obtained 12-24 hours after stent implantation. PMI was defined, according to the third Universal Definition of Myocardial Infarction (MI), as an asymptomatic elevation of Tn-I > 5 times the 99th percentile upper reference limit (URL). Baseline demographic, clinical, angiographic and procedural characteristics were compared between groups (Group 1: non-PMI patients; Group 2: PMI patients). Multivariate analysis was performed to determine the independent risk factors of PMI.

Overall, mean age was 67±17 years, 25 patients (21.7%) were female, and 26 CTO (22.6%) were diagnosed following an acute coronary event. Retrograde technique (RT) was used in only 7.0% (n=8) of the procedures. PMI occurred in 41 patients (35.7%) and was more frequent among patients with lower glomerular filtration rate (88.5±29.9 vs. 71.6±25.0 ml/min/1.73m2; p=0.003) and more severe J-CTO score based calcification (20.8% vs. 45.8%; p=0.031); in longer procedures (59.6±59.6 vs. 77.3±39.9 minutes; p=0.008) and fluoroscopy duration (29.0±18.1 vs. 40.0±24.6 minutes; p=0.007); in cases of RT use (2.7% vs. 14.6%; p=0.024), greater total stent length (39.9±20.5 vs. 49.8±22.5 millimetres; p=0.019) or complicated with vessel dissection or mural hematoma (1.4% vs. 24.4%; p=0.001). PMI patients also showed higher rates of 1-year major adverse cardiovascular events defined as a composite of cardiovascular death, non-fatal MI and target lesion revascularization (4.1% vs. 19.5%; p=0.016). Multivessel disease (odds ratio [OR]: 5.1; 95% confidence interval [CI]: 1.0-25.2; p=0.046) and procedure complication with vessel dissection or mural hematoma (OR: 21.7; 95%CI: 1.9-247.3; p=0.013) were identified as independent predictors of PMI. A risk model encompassing these variables showed good discrimination (area under the curve: 0.801; 95%CI: 0.628-0.974; p=0.008) and calibration (Hosmer-Lemeshow, p=0.72).

CONCLUSIONS

In this cohort, asymptomatic PMI following successful CTO-PCI occurred in about one third of the patients and was predicted by the presence of angiographic multivessel disease and iatrogenic vessel dissection or mural hematoma. These patients had worse ischemic outcomes. More research is needed to evaluate the clinical implications of CTO-PCI related PMI.

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Clinical practice and outcomes in high bleeding risk patients undergoing PCI with new-generation DES - Data from a large worldwide registry

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

CAD patients at high bleeding risk (HBR), undergoing PCI represent an overall high-risk population. DAPT reduces the risk of ischemic events, but also increases the risk of bleeding. A careful assessment of these risks should be considered, especially in HBR patients. Current guidelines give a class IIa recommendation for 3-month DAPT in stable patients considered to be at HBR. We aimed to determine the clinical practice and outcomes of PCI with a new generation DES and concurrent DAPT in patients with at least 1 risk factor for bleeding, recruited in a real-world registry.

METHODS AND RESULTS

e-Ultimaster is a prospective, world-wide, multi-centre registry that enrolled patients with coronary artery disease requiring PCI and who were treated with a thin strut sirolimus-eluting stent (Ultimaster) with abluminal biodegradable polymer coating. The primary endpoint of target lesion failure (TLF) at 1 year follow-up is defined as a composite of cardiac death, target vessel (TV) related myocardial infarction (MI) and clinically driven (CD) target lesion revascularization (TLR). An independent Clinical Event Committee reviewed and adjudicated all deaths, myocardial infarctions, revascularizations and stent thromboses. Bleeding was assessed according to BARC definitions.

Among 19,482 patients who reached 1-year follow up, 4903 HBR patients were identified. High-bleeding risk was defined as presence of one or more of following criteria: age ≥75 years, taking oral anticoagulants, previous history of stroke or renal impairment patients on haemodialysis. Mean age of patients was 76 years, with 36% of octogenarians. More than one third of patients were diabetic, 74.4% had hypertension and history of previous PCI or CABG was present in 30.2% and 9.0%, respectively. ACS was present in half of patients, with 13.7% of STEMI patients. Mean number of lesions treated during index procedure was 1.4, with an average total stent length of 33.1 mm. 15.7% of patients had bifurcation lesions, and 4.6% presented with CTO lesions. Left main artery was treated in 4.9% and bypass graft in 2.1% of patients. Radial access was used in 81.1% of patients. Pre-procedure, 74.1% of patients were on DAPT.

At 3 months, 88% of HBR patients were on DAPT and rate of major bleeding (BARC 3-5) was 0.7%. TLF rate at 3 months was 1.7% and definite or probable ST rate was 0.5%. 59.5% of patients was still on DAPT at 1 year and major bleeding rate was 1.2%. One-year TLF rate was 4.5% and definite or probable ST was 0.7%.

Event rates after 3 months up until 1 year were similar in those HBR patients off-DAPT (n=592) at 3 months as compared with those patients still on-DAPT at 3 months (n=4311): TLF (4.1% vs 2.9%, p=0.71), definite or probable ST (0% vs 0.1%; p=0.99) and major bleeding (0.9% vs 0.5%; p=0.20).

CONCLUSIONS

Despite the limitation that not all HBR features were captured for all patients enrolled in this registry, this analysis is valuable to assess safety of earlier discontinuation of DAPT in this specific patient's subset. Patients who stopped DAPT before or at 3 months did not have ST during follow-up until 1-year. These results indicate good safety profile of Ultimaster DES in patients in need to stop DAPT earlier.

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Outcomes of emergent TAVR compared to elective procedures: Assessment of crucial aspects reducing mortality

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Transcatheter aortic valve replacement (TAVR) has been proven as safe and effective in intermediate- and high-risk patients. One of the main factors that conditions the level of estimated risk is the need for emergent intervention; however, this subgroup of patients is highly variable and poorly described to the date. We aimed to assess the current outcomes of emergent TAVR and assess potential key factors improving survival through a meta-analysis.

METHODS AND RESULTS

A systematic search in PubMed and Google scholarship was performed by two independent reviewers for any study comparing emergent vs. elective TAVR. Searched terms were “emergent” and/or “urgent”, “elective”, AND “transcatheter valve replacement” or “severe aortic stenosis”. Definition of emergent/urgent procedures was variable but the consensus was to include those patients who required TAVR in less than 24 hours after an admission through the emergency department. A random-effects model was used. The potential publication bias was assessed by using a funnel plot. As measure of the combined effect for the included studies the Odds ratio (OR) was estimated, valid for prospective and retrospective studies, its confidence interval at 95% and its statistical significance. The homogeneity between studies was contrasted by the QH statistic.

We analyzed a total of 7 studies including 42,057 patients who underwent TAVR (37,934 were elective and 4,123 were emergent procedures). The emergent cases presented higher estimated risk scores (Euroscore 29.3±17.9 vs. 58.8±23.7, <0.001; EuroScore-II 9±11.8 vs 13.4±16.2, p<0.001; STS-score 15.7±12.9 vs 28.76±23.2, p<0.001). A more advanced aortic valve disease was observed in the emergent TAVR cohort with smaller aortic valve areas (0.6±0.2 vs. 0.7±0.2; p=0.034), worse left ventricular ejection fraction (38.3±17.6 vs. 52.5±12.5; p<0.001) and larger left ventricular end-diastolic diameters (55±9 vs 48±7; p<0.001]. Although the reported success rates were comparable (93.6% vs. 92.5%; OR 0.84 [95% CI: 0.74-0.95]; p=0.005), in-hospital mortality rate was higher in patients undergoing emergent TAVR (6.18% vs. 3.03%, p<0.001). No differences existed in the rate of stroke (2.3 vs. 2%, p=0.178), permanent pacemaker (10.7 vs. 10.5%, p=0.644), myocardial infarction (0.38 vs. 0.4, p=0.891), or major vascular complications and bleedings (1.1 vs. 1.2%, p=0.982 and 4 vs. 4.77%, p=0.804, respectively), but patients developed more often acute kidney injury during the hospital stay in the emergent setting (8.4 vs 4.35, p<0.001). The differences in the mortality rate increased at 30 days (6.7% in the elective cohort vs. 18% in the emergent setting). Both, the need for emergent procedure (OR 2.55 [95% CI; 1.14, 5.67]; p = 0.02) and the development of acute renal failure (OR 2.05 [95% CI 1.03, 4.07]; p = 0.04) were independent predictors of 30-day mortality.

CONCLUSIONS

Emergent TAVR procedures were performed in >9% of all patients receiving a TAVR device. This emergent TAVR cohort presented worse baseline risk and a more advanced cardiac disease presenting a 3-fold increase

in the 30-day mortality rate. Emergent procedures and acute kidney injury were associated to increased mortality rate suggesting that implementing mechanical support devices and early hemodyalisis might improve the outcomes in these challenging cases.

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Prognostic significance of troponin I defined periprocedural myocardial injury in patients with successful percutaneous CTO intervention

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THEME: Coronary Interventions
TOPIC(S): CTO, Other Coronary Interventions

AIMS

Limited studies addressed the clinical implication of periprocedural myocardial injury (PMI) following chronic total occlusion (CTO) percutaneous coronary intervention (PCI) and all defined PMI according to creatine kinase myocardial band values. Our aim is to evaluate the prognostic implication of PMI in patients undergoing CTO-PCI using two different troponin I (Tn-I) based definitions.

METHODS AND RESULTS

We retrospectively examined 125 consecutive CTO patients who underwent PCI attempt between December 2013 and December 2017 in our Centre. Angiographic success was achieved in 115 patients (92,0%) and measurement of Tn-I values was obtained 12-24 hours after stent implantation. Two different analysis were performed using two different Tn-I cutoffs to define PMI: A – Tn-I > 5 times the 99th percentile upper reference limit (URL), according to the third Universal Definition of Myocardial Infarction; B – Tn-I > 35 times the URL, according to the Academic Research Consortium-2 definition. Baseline demographic, clinical, angiographic and procedural characteristics were compared between groups according to each PMI definition. Multivariate analysis was performed to determine the correlates of PMI and major adverse cardiovascular events (MACE) at 1-year follow up, defined as a composite of cardiovascular death, non-fatal myocardial infarction (MI) and target lesion revascularization (TLR).

Overall, mean age was 67±17 years, 25 patients (21.7%) were female, and 26 CTO (22.6%) were diagnosed following an acute coronary syndrome. PMI occurred in 41 patients (35.7%) according to definition A and in 8 patients (7.0%) using definition B. Regardless of the definition, PMI was more frequent among patients undergoing retrograde technique (RT) which was used in only 7.0% (n=8) of the procedures (Definition A (non-PMI vs. PMI patients): 2.7% vs. 14.6%, p=0.024; Definition B: 4.7% vs. 37.5%, p=0.011). Both PMI definitions were associated with higher rates of 1-year MACE (A: 4.1% vs. 19.5%, p=0.016; B: 7.5% vs. 37.5%, p=0.028) and non-fatal MI (A: 0.0% vs. 7.3%, p=0.043; B: 0.0% vs. 37.5%, p=0.001) but failed to predict 1-year MACE (p>0.05). Coronary perforation (odds ratio [OR]: 106.61; 95% confidence interval [CI]: 4.68-2428.44; p=0.003) and RT (OR: 19.90; 95%CI: 1.30-304.37; p=0.032) were associated with worse outcome while significant collateralization (RENTROP 3) showed a protective role (OR: 0.07; 95%CI: 0.01-0.69; p=0.023).

CONCLUSIONS

In this study, low rates of PMI following CTO-PCI were observed and it was not associated with worse outcome, regardless of the definition used. Coronary perforation, retrograde technique and collaterals RENTROP 3 showed prognostic significance. More research is needed regarding troponin based PMI definition and prognostic relevance in this scenario.

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Stroke and pacemaker rates in the SHARE-TAVI registry in low TAVI volume centres in the resource-constrained economy of South Africa

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THEME: Interventions for Valvular Disease
TOPIC(S): Other valvular and structural interventions

AIMS

Access to tertiary cardiac services is limited in South Africa's resource-constrained system. SHARE-TAVI, a prospective multi-centre observational registry captures data as part of funding approval processes for all SA TAVI patients to compare outcomes to international data & define local variations in clinical presentation & outcomes.

METHODS AND RESULTS

Potential TAVI patients evaluated at 8 Private/3 State TAVI centres which combined implanted >200 patients in 2018, volumes low due to restrictive funding. Procedural & complications data entered according to VARC-2 criteria, postoperative follow-up 30d & yearly. From Sept 2014 - Dec 2018 inclusive, 894 patients were evaluated. 102 patients await funding decisions (outstanding 2-1185d). Deteriorating patient health during delayed Funder responses resulted in mortality prior to TAVI date for 8 patients whose funding was approved, & ineligibility for TAVI for 9 awaiting decisions (mean wait 115d). Mortality occurred in 21 others awaiting funding approval. 36% of patients declined funding (n=21/59) died within 1 year.

The 663 (15% in State) who received implants are comparable to similar registry & trial populations (GARY, SOURCE 3, & US Corevalve Pivotal) in mean age 80.1±7.2yrs, 54.9% male, mean risk predictions 7.0±7.4% [STSPROM], 23.0±15.7 [logEuroSCORE] & 6.4±5.0% [EuroSCORE 2]. Differences in presentation of risk factors [dialysis, prior CVA/TIA, frailty] at evaluation occur between Private patients [4.0%, 7.8%, 27.7%] and State [0%, 3.2%, 20.8%] but procedural success similar (State 93.1%, Private 93.7%). Mean ICU & total length of stay similar in State [ICU 1.43±1.58d, LOS 4.51±2.87d] & Private [ICU 2.48±1.99d, LOS 5.19±4.24d]. 1-year mortality amongst Frail patients is higher in State than Private [55.6% vs 17.7%] and requires further investigation. All-cause mortality of 10.48% (n=48/458) at 1-year compares favourably to published TAVI populations [14,2% US Corevalve, 12.6% SOURCE 3, 20% GARY], non-cardiac mortality at 33% (n=16/48).

At evaluation 10.6% patients have permanent pacemakers. At 30d new permanent pacemaker implantation needed in 7.5% (n= 50/663) patients, & in 9.85% at 1-year (n=45/458). In 1-year cohort only 15% of the new pacemakers were implanted > 30 days, 40 % of new pacemakers perioperatively (VARC<72hours), 33% postoperatively (VARC>72hours).

Stroke at 30d and 1-year occurs in 3.17% and 4.15% of patients respectively. 1-year outcomes showed stroke occurred predominantly in males (68%), & 26% of strokes occurred in patients with known arrhythmia (16% AFib and 10% other arrhythmias). Diabetes and chronic lung disease history were additional risk factors, contributing to 53% & 32% of strokes, extracardiac arteriopathy in 21% was a greater risk factor than previous CVA/TIA (11%) or dialysis (5%). 21% of strokes occurred perioperatively, 42.1% were postoperative (VARC>72hours) and 31.6% were between discharge & 30 days, compared to PARTNER trial, which demonstrated a very early peak on the 2nd day post-procedure.

CONCLUSIONS

Referral & evaluation protocols are more restrictive in State but frail patients have worse outcomes. Cumbersome TAVI funding processes, & funding resistance, contributes to mortality in appropriately selected patients. TAVI at State and Private centres compares favourably to international best practice standards. Stroke rates are comparable to other registries, but peak postoperatively >72 hours & are independent of centre volume.

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Clinical management and long-term outcomes following grade III coronary perforation: Glasgow natural history of covered stent coronary interventions (GNOCCI) study

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds, Other Coronary Interventions

AIMS

Covered stents (CS) are a potentially lifesaving treatment for grade III coronary perforation but delivery can be challenging, and the long-term durability and safety including risk of acute stent thrombosis are unknown.
AIM: We evaluated procedural and long term clinical outcomes following grade III coronary perforation during percutaneous coronary intervention (PCI). A sensitivity analysis was performed to evaluate outcomes following covered stent insertion.

METHODS AND RESULTS

Retrospective cohort study of 100,253 consecutive invasive coronary procedures (42,740 PCIs) performed from 2000-18. Procedural major adverse cardiac events (pMACE) were defined as a composite of death, myocardial infarction, stroke, target vessel revascularization or cardiac surgery within 24 hours of the index procedure. Stent thrombosis was independently determined by two cardiologists according to academic research consortium (ARC) criterion.
Results: 156 patients experienced iatrogenic coronary perforation (incidence 0.36%). Median follow up was 4.8 years with no patients were lost to follow up. 54 (35%) grade III perforations were identified. Perforation severity was linearly associated with procedural mortality: Ellis I (0%), Ellis II (1.7%), Ellis III (25%), Ellis IIIB (0%), p<0.0001. Covered stent (CS) insertion was attempted in 43 patients. After successful CS insertion, patients were over ten times more likely to suffer acute stent thrombosis at long term follow up (academic research consortium (ARC - probable or definite; 9.7% v 0.9%; RR 10.8; 95% CI 1.2 - 100; P=0.009). Using broader ARC criterion (possible, probable or definite) CS insertion was still associated with greater risk of ST (25.8% v 9.8%; RR 2.6; 1.2 - 6.0; P = 0.021). Angiographic restenosis or target vessel revascularization occurred in 16% of patients with CS insertion. Notably, semicompliant or stent balloons were a more common cause of grade III perforation than non-compliant balloons (43% v 35%). The highest morbidity and mortality was observed when CS implantation failed (n=15, pMACE 80.0% v 21.4%; RR 3.7; p<0.001) with procedural mortality in almost half of cases (47%). Unsuccessful CS deployment was most frequently due to inability to deliver/incompatibility the device with 6F delivery systems including guide catheter extensions (n=6, 40%).

CONCLUSIONS

Grade III coronary perforation is associated with high procedural mortality and significant risk of long term major adverse cardiac events.
Covered stent insertion is a potentially lifesaving treatment option however interventional cardiologists should be aware of size and compatibility issues with early generation covered stents.
Long term safety and durability of covered stents is concerning with over 10-fold higher risk of definite or

probable stent thrombosis at 5 year follow up.

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Peri-prosthetic regurgitation after TAVI: determinants and outcomes

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Significant periprosthetic regurgitation (PPR) is common in patients submitted to Transcatheter Aortic Valve Implantation (TAVI). Several anatomical and procedural aspects have been related to its occurrence, although inconsistently. Its clinical impact, concerning either survival or quality of life, varies widely between registries / cohorts.

This study aims to determine the incidence, predictors and prognostic impact of PPR in patients submitted to TAVI.

METHODS AND RESULTS

All patients that underwent TAVI at our centre between September 2007 and October 2017 were included in the analysis. Clinically significant PPR was defined as more than mild regurgitation (grade II or more by color Doppler analysis). Pre-procedural multi-slice computed tomography (CT) was used to measure valvular dimensions and calcium volume. Post-procedural CT (3 months) were performed to assess prosthesis dimensions, implantation depth, eccentricity and expansion indexes.

A total of 427 patients that underwent TAVI were enrolled, 50.8% were female, and the median age was 81 years (IQR ± 10 years). Mean STS mortality score was 5.86 ± 4.4%. The prevalence of grade ≥ II periprosthetic regurgitation was 55.5% (N=237). This was significantly more frequent among those submitted to aortic balloon valvuloplasty (ABV) post-implantation (76.5% vs 50.3%, p<0.0001), but not observed in those with ABV pre-implantation (52.6% vs 58.5%, p=0.12). Mean pre-procedure aortic valve calcium volume was significantly greater in patients who latter developed grade ≥ II PPR (428.1 ± 402.8 µL vs 210.6 ± 224.3 µL, p< 0.0001). This was also observed for left ventricular outflow tract calcium volume (p= 0.009). Prosthesis type (either auto-expandable or balloon-expandable) did not show to significantly affect the occurrence of grade ≥ II PPR (p= 0.12). Mean prosthesis size did not significantly differ between groups (Mann Withney U test with p value of 0.83). PPR development was not affected by implantation depth (6.91 ± 2.7mm vs 6.87 ± 2.9mm, p= 0.94), nor eccentricity index (12.2 ± 8.3% vs 10.3 ± 8.8%, p= 0.23). The rate of PPR occurrence did not differ in procedures performed in 2007-2012 compared to the last five years' experience, 2013-2017 (49% vs 58%, p=0.07). NYHA functional class of ≥ II/IV on FUP was significantly more frequent among those with this grade of PPR (91.6 vs 83.7%, p= 0.013). All-cause mortality was significantly greater in patients with grade ≥ II PPR, in a median follow-up of 58.7 months (Kaplan Meyer survival curve analysis showed a Log Rank of <0.0001 for grade ≥ II PPR vs. no or mild PPR).

CONCLUSIONS

PPR is a well-recognized clinical problem following TAVI. Its prevalence is significantly affected by anatomical aspects of the aortic valve, mainly peri-valvular calcification. Procedural features (mainly prosthesis type and sizing, aortic balloon valvuloplasty pre and/or post-implantation) seem to have limited to no impact on its occurrence. Advances in prosthesis technology and greater operator experience may yield better results in the

future, although we were not able to document this temporal trend in our cohort. The clinical relevance of this entity is not negligible, with significant impact in terms of medium-term survival and functional status.

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Quantitative flow ratio in non-infarct related arteries after primary PCI: a case series

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THEME:

TOPIC(S):

AIMS

Complete revascularization is recommended for ST-segment elevation myocardial infarction (STEMI). Although physiological evaluation is recommended to evaluate nonculprit lesions, fractional flow reserve (FFR) use in this context is limited. Quantitative flow ratio (QFR) is a novel tool to evaluate functional severity based on angiography. We aimed to evaluate functional changes of nonculprit lesions after the acute phase and QFR/ FFR correlation in noninfarct related arteries.

METHODS AND RESULTS

Methods: All patients with multivessel disease admitted due to STEMI in our institution between January 2016 and December 2017 who underwent staged intervention to treat nonculprit lesions were recruited. Retrospective QFR assessment was performed at index and staged procedures and compared. In addition, QFR/FFR concordance and agreement were prospectively evaluated between January and May, 2018 in a cohort of patients with STEMI and multivessel disease.

Results: A total of 141 lesions in 90 patients were analyzed. During the initial procedure, 93.1% of the lesions were considered significant according to angiography but only 56.3% when assessed by QFR ($P \leq 0.001$). QFR reassessment during the staged intervention demonstrated a reduction in this proportion to 32.1%. All patients with a QFR value over 0.82 during index procedure persisted nonsignificant at staged evaluation. FFR and QFR were compared in 12 patients presenting good agreement with a mean difference of 0.015 ± 0.02 ($P > 0.1$).

CONCLUSIONS

QFR-based physiological assessment of nonculprit lesions in STEMI patients led to consider nonsignificant 40% of those estimated significant by angiography. In addition, QFR significantly increased from the acute phase to the staged procedure suggesting that in patients with QFR ≥ 0.82 in the acute phase a new coronary angiography might not be necessary.

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In dark, follow the light: guiding complex, stent-related lesions with OCT prevents recurrence

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THEME:
TOPIC(S):

AIMS

BACKGROUND: Optimal coherence tomography (OCT) provides accurate characterization of plaque lesions and is very sensitive in detecting suboptimal stent implantation. Possibly, OCT parameters can predict fractional flow reserve (FFR). We aimed to characterize the applicability of OCT in plaque characterization and its usefulness to guide angioplasty. Additionally, we assessed its correlation to FFR.

METHODS AND RESULTS

METHODS: We prospectively included all 80 patients that underwent OCT-guided angioplasty in our centre from November 2014 to October 2018. Clinical, angiographic, OCT and FFR data were collected. The patients were followed up for a median 15 [IQR 7-27] months. Outcomes included all-cause death, acute coronary syndrome (ACS) and heart failure.

RESULTS: Mean age was 64±12 years and 74% were male. Indications for angiography were stable angina in 40% cases, ACS in 43%, and ACS associated angioplasty complications in 7%. Around 10% lesions were associated with heart allograft vasculopathy. Left anterior descending was involved in 64%, the right coronary in 16% and the circumflex in 20%. Stent-related lesion was present in 45% (stent re-stenosis in 29%), fibrocalcified plaque in 40%, thrombus in 7% and spontaneous dissection in 7%. Mean minimal luminal area was lower for left anterior descending lesions (1.8±0.7 mm vs 2.4±0.7mm in right coronary and 2.3±1.1 in circumflex p=0.013 and 0.021). Mean lesion length did not vary between vessels; it was 4.2±2.5 smaller than mean stent length (19.8±4 vs 24.1±5, p<0.001). Mean reference distal diameter did not vary from mean stent diameter (2.9±0.50 vs 2.9±0.45 mm, p=0.07). FFR was performed in 25% cases. MLA had a strong correlation with FFR (r2 0.8, p<0.001) (figure 1). A ROC-derived cut-point of 2.2 cm2 for minimal lesion area had a sensitivity of 71% and specificity of 90% for a FFR value of 0.80. Around 39% cases required OCT-guided post-dilation. At 15 months, ACS rate was 7.2%, heart failure was 8.8% and all-cause mortality was 5.8%. Predictors for ACS included minimal luminal area [HR 0.5 (95% CI 0.4-0.9), p=0.021] and OCT-guided post-dilatation [HR 0.4 (95% CI 0.3-0.8), p=0.013], but not lesion length (p=0.221) or stent diameter (p=0.061).

CONCLUSIONS

CONCLUSIONS: OCT is very useful in assessing stent-related complications and guiding post-dilation. MLA has a strong correlation with FFR, with high specificity. Both minimal luminal area and OCT-guided post-dilation were important predictors of ACS recurrence.

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Clinical outcomes of long-term ticagrelor monotherapy vs. conventional DAPT followed by aspirin after PCI in women and men: a subgroup analysis of the Global Leaders study

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

We aimed to compare clinical outcomes after PCI between women and men and to determine if the efficacy and safety of two antiplatelet strategies after PCI were different between women and men in the Global Leaders study.

METHODS AND RESULTS

Global Leaders study assessed the efficacy and safety of 23-month ticagrelor monotherapy after 1 month of dual antiplatelet therapy (DAPT) versus 12-month conventional DAPT followed by aspirin monotherapy in patients undergoing PCI with biolimus-A9 eluting stent. Clinical outcomes at 2 years after PCI the between women and men in multivariable Cox regression analysis and the interaction between treatment strategies and sex in the outcomes were tested.

The primary outcome of the present study was patient-oriented composite endpoint at 2 years after PCI. Secondary outcomes were the net adverse cardiac and cerebrovascular event, individual components of the composite endpoint and definite or probable stent thrombosis.

Of 15,968 patients randomized, 3714 were women (23.3%) and 12,254 were men (76.7%). Women were older (mean age 67.4 vs 63.7 years old, $p < 0.001$); had higher prevalence of hypertension (79.0% vs. 72.0%, $p < 0.001$, diabetes (28.7% vs. 24.3%, $p < 0.001$) and renal insufficiency (26.1% vs. 12.0%, $p < 0.001$). Women were less commonly smokers than men (22.4% vs. 27.2% $p < 0.001$).

Overall, the risk of 2-year POCE was not different between women and men (HR 0.93, 95% CI 0.84-1.03) in multivariable Cox regression analysis. The risk of NACCE, all-cause death, all-cause death or new Q wave MI, stroke, myocardial infarction, repeat revascularization, definite/probable stent thrombosis were similar between women and men. Women had a significantly higher risk of BARC 3 or 5 bleeding at 2 years when compared with men (HR 1.57, 95% CI 1.19 – 2.07).

When the effect of antiplatelet was taking into account, conventional DAPT strategy trended to increase the risk of BARC 3 or 5 bleeding in men (HR 1.18, 95%CI 0.91-1.54) while it tended to lower the risk of BARC 3 or 5 bleeding in women (HR 0.79, 95%CI 0.54-1.16), (P for interaction 0.09) after PCI. There was no interaction between sex and antiplatelet strategy for other outcomes.

CONCLUSIONS

In this large contemporary PCI study, the risk of POCE and other ischemic endpoints were similar between women and men. However, women had a significantly higher risk of BARC 3 or 5 bleeding at 2 years after PCI.

No significant interaction between antiplatelet strategy and sex was demonstrated.

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Impact of left ventricular outflow tract oversizing on the outcome of TAVI with self-expanding devices

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

To investigate the impact of left ventricular outflow tract (LVOT) oversizing on device success and paravalvular leak (PVL) rates in patients undergoing trancatheter aortic valve implantation (TAVI) with self-expanding devices.

METHODS AND RESULTS

This retrospective single-center study included 337 patients with symptomatic severe aortic stenosis, who underwent TAVI with Evolut-R (N=191, 56.7%), Portico (N=71, 21.1%), and Acurate NEO (N=75, 22.2%) (07/2015 – 12/2018) as well as available computed tomography (CT) angiography measurements of annulus and LVOT (4 mm below the annular plane) perimeter. Device oversizing was calculated as . Optimal oversizing was defined as >9.6%. All patients had optimal annulus oversizing (19.9% ±6.3%) and were divided in two groups according to optimal vs. non-optimal LVOT oversizing.

Thirty-five (10.4%) of 337 patients did not have an optimal LVOT oversizing (4.6 ±3.8% vs. 22.6 ±7.7%; P<0.001). Patients with optimal LVOT oversizing were older (84 ±6 years vs. 77 ±12 years; P=0.004), and had higher ejection fraction (55 ±12% vs. 46 ±14%; P<0.001). Conversely, patients with non-optimal LVOT oversizing had more frequently moderate aortic regurgitation (29% vs 15%; P=0.05), larger annulus area (4.6 ±0.8 cm2vs. 4.3 ±0.9 cm2; P=0.02) and larger LVOT perimeter (84.8 ±7.2 mm vs. 73.1 ±8.4 mm; P<0.001).

Procedural characteristics (access route, predilatation and postdilatation rates, complications of the access site,) were comparable among the two groups; PM implantation rate (15% overall) was similar as well. Thirty-day mortality was 3%.

On predischarge transthoracic echocardiography, patients with non-optimal LVOT oversizing showed significantly higher rates of ³moderate PVL compared to those with optimal LVOT oversizing (29% vs. 12% respectively; P=0.005). Device success rates were consistent (71% vs. 88% respectively; P=0.007).

On ROC analysis, an LVOT oversizing of 18.8% (sensitivity 64%, specificity 56%) predicted the absence of ³moderate PVL (AUC=0.60; P=0.03).

CONCLUSIONS

In patients with optimal annulus oversizing undergoing TAVI with self-expanding devices, adequate LVOT oversizing should be pursued in order to avoid relevant postprocedural PVL and to improve device success.

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The impact of angiographic projection and patient body mass index on X-ray exposure during cardiovascular interventions

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

The number of interventional cardiology procedures is increasing and more complex procedures, requiring longer X-ray exposure are performed on a daily basis. The aim of this study was to evaluate the X-ray exposure in different angiography projections and to identify the safest projections to minimize the patient's and physician's exposure.

METHODS AND RESULTS

Between January 2017 and August 2018 interventional cardiology procedures from one angiography x-ray unit were investigated. The Data of 2600 patients/procedures and over 130000 series (scans) were evaluated. Dedicated monitoring software was implemented for data collection. To investigate the difference of the X-ray exposure between different projections (angulations), projections were grouped in certain intervals with 15 degrees step: from 0 degrees angulation anterior-posterior (AP) to 60 degrees left anterior oblique (LAO) and right anterior oblique (RAO) and 60 degrees cranial (CRA) and caudal (CAU).

The lowest dose projection was AP, with average dose 30 – 40 (Gy x cm)/ms, the highest dose projection was LAO45_CRA15 with average doses of 160 - 260 (Gy x cm)/ms, depending on the type of interventional procedure. From the commonly used projections in coronary interventions, LAO45_CAU0 and LAO0_CAU45 were associated with the relatively low X-ray dose {90 – 110 (Gy x cm)/ms and 90 – 160 (Gy x cm)/ms respectively}. Projections with low degree of angulation (LAO0_CRA15 and LAO0_CAU15) were also found to give less X-ray exposure {110 – 150 (Gy x cm)/ms and 70 – 100 (Gy x cm)/ms respectively}. The data concerning the X-ray dose correlation with patient's weight and angiographic projection will be ready to present at the Congress.

CONCLUSIONS

The safest angiography projections in terms of X-ray exposure are AP, LAO45_CAU0 and low degree angle projections, such as LAO0_CRA15 and LAO0_CAU15.

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Long-term renal function after LAA occlusion - A single-centre analysis

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THEME:

TOPIC(S):

AIMS

Left atrial appendage occlusion (LAAo) is an established alternative therapy in patients with atrial fibrillation (AF) and contraindications against oral anticoagulation (OAC). Several studies have shown that OAC may have a negative impact on long-time renal function, especially in patients with chronic kidney disease (CKD). As CKD is common in AF patients and triggers the indication for LAAo in a substantial amount of patients, assessment of long term renal function is of clinical interest. Therefore, we sought to assess the long-time renal function of patients after undergoing LAAo.

METHODS AND RESULTS

We retrospectively analyzed 70 patients, with available long-term renal parameters. Long-term was defined as the availability of follow-up (FU) renal parameters, which were assessed at least 6 months, preferably between 1-3 years, after LAAo. Median FU was 380 days (Interquartile range [IQR]: 164) from the initial procedure. LAAo patients were at a mean age 76 ± 8 years with increased thromboembolic and bleeding risk (CHADS-VASC-score: 4.7 ± 1.3; HAS-BLED: 3.8 ± 0.9). Postprocedural medical therapy consisted of DAPT for 3-6 months in 60% of patients. Additional OAC for 45 days was given in 17% of patients. All other patients underwent individual regimes.

Overall, mean baseline GFR (glomerular filtration rate) was 56 ± 28 ml/min and mean baseline serum creatinine 1.6 ± 1.2 mg/dl. Of these patients, 41.4% (29/70) revealed CKD stadium I-II whereas 42.9% (30/70) were in stadium III and 15.7% (11/70) were in stadium IV-V. Overall, long-term renal parameters after abovementioned FU did not show a relevant change to baseline (mean deviation from baseline: GFR: -3.3 ± 21 ml/min and creatinine: +0.02 ± 0.63 mg/dl, respectively). Mean change of renal function from baseline was significantly higher at FU in patients with CKD stadium I-II (GFR: -16 ± 20.9 ml/min and serum creatinine: +0.25 ± 0.53 mg/dl) in comparison to patients with CKD stadium III (GFR: +6 ± 18 ml/min and +0.01 ± 0.48 mg/dl) and CKD stadium IV-V (GFR: +4 ± 5 ml/min and -0.59 ± 0.84 mg/dl) ($p < 0.01$).

CONCLUSIONS

Long-term FU of renal function after LAAo did not reveal relevant changes after a median of 380 days. However, changes were more pronounced in patients with mild to moderate CKD ($p < 0.01$). Overall, in contrast to OAC, LAAo does not seem to have a negative impact on long-term renal function. It is however for larger studies to confirm the findings of our single-center analysis.

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Echocardiographic assessment of optimal device position after percutaneous LAA occlusion - Introduction of a novel classification and its impact on outcome

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THEME:
TOPIC(S):

AIMS

Left atrial appendage occlusion (LAAo) is an established therapy in patients with atrial fibrillation and contraindications against oral anticoagulation. However, criteria regarding optimal device position are not well defined making comparability of procedural results virtually impossible. We, therefore, sought to a) introduce a classification describing optimal vs. suboptimal device-position by assessing predefined parameters in transoesophageal echocardiography (TEE) and to b) analyze the impact of device-position on outcome in patients treated with different LAAo devices.

METHODS AND RESULTS

We retrospectively analyzed 120 patients who were treated by LAAo and had undergone follow-up TEEs after 3 or 6 months. Patients were at mean age: 76 ± 8 years; female 40% and presented an increased CHADS-VASC- (4.6 ± 1.4) and HAS-BLED-score (3.7 ± 1). TEE-guidance was performed in all cases.

In 62.5% (75/120) pacifier occluders (PO) (ACP/Amulet, Lambre, Ultraseal) were used, whereas 37.5% (45/120) were treated with non-pacifier occluders (NPO) (Watchman, Wavecrest, Occlutech). To assess device position, TEE images in a commissural view (60-90°) were analyzed and characterised by 1) implantation depth in the left atrial appendage, 2) peridevice flow (PF) and 3) the angle between occluder disc and pulmonal ridge (LUPV). For the purpose of this study, optimal device position was defined as a) ostial (LUPV length <10mm) or slightly subostial position (LUPV length ≤15mm, angle ≥100°) with b) the absence of major PF (>3mm).

Overall, occluders were implanted at a depth of 12 ± 7.8 mm with ostial positioning being achieved in 47.5% (57/120). Major PF was seen in 7.5% (9/120). NPOs were implanted deeper than POs (depth: 15.6 ± 7.1 vs. 9.8 ± 7.4 mm, p<0.01; ostial position: 31.1% vs. 57.3%, p<0.01) and were associated with a higher incidence of major PF (15.6% vs. 2.7%, p=0.01). Also, the depth/angle ratio was higher (i.e. “worse”) in NPOs (18.3 ± 9 vs.14.6 ± 8, p<0.04). As a result, optimal device position was achieved in 48.3% (58/120) of all patients, with lower rates in NPOs than in POs (26.7% vs. 61.3%, p<0.01). Baseline parameters were similar between optimal and suboptimal implantations with lower CHADS-VASC- (4.5 ± 1.4 vs. 4.8 ± 1.3, p=0.14) and HAS-BLED-scores (3.6 ± 0.9 vs. 3.9 ± 1, p=0.07) in optimal implantations. Procedural aspects revealed slight differences in occluder size (optimal: 23.7 ± 3.2 vs. suboptimal: 24.5 ± 3.7 mm, p=0.3), need for repositioning (10.3% vs. 17.7%, p=0.25) and procedural duration (48 ± 36 vs. 52 ± 34 min, p=0.3).

Of interest, device related thrombi (DRT) occurred less frequently in optimally implanted devices (3.4% vs. 12.9%, p=0.06). Hereby, implantation depth and depth/angle ratio were found to be predictors for DRT in ROC-analysis, respectively (AUC: 0.7, 95% Confidence interval [CI]: 0.56-0.84, p=0.05 and AUC: 0.72, 95%CI: 0.58-0.86, p=0.03). Embolization occurred in 4.2% (5/120) patients (optimal: 5.2% vs suboptimal: 3.2%. p=0.59). 1 year survival did also not differ in Kaplan-Meier curves (95.2% vs. 93.7%, p=0.67).

CONCLUSIONS

Echocardiographic classification of device-position is warranted to provide comparability and appears to be

feasible. Based on the novel classification provided, optimal device-position is achieved in 50% and is found more often with the use of POs. DRT appeared to occur more often in suboptimal device-position. It is however for larger studies to validate the provided classification

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Unknown cancer as incidental finding in the evaluation of TAVI candidate patients

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

To describe the incidence, type of neoplastic disease and clinical implication of the finding of malignancy not previously known in pre TAVI evaluation of a group of patients from a single centre.

METHODS AND RESULTS

Descriptive and retrospective observational study of consecutive patients, between the years 2011 and 2018, with severe aortic stenosis or biological aortic prosthesis dysfunction not considered candidates for surgery. We include patients with a computed tomography (chest, abdomen and pelvis) as part of the suitability study for TAVI.

217 patients were included, after the evaluation protocol finally 146 patients were accepted for TAVI. A malignant neoplasm was found in 16 cases (7,4%), median age 82,5 (IQR 4,5), male sex 10 cases (62,5%), EUROSCORE II 5,5±3,6, previous treated cancer 4 cases (23,5%) and in 14 cases (87,5%) the diagnosis was made by computed tomography and the rest of the cases by blood tests.

The location of the disease was digestive system 5 (31%) (gastrointestinal, pancreas and liver); nephrology-urological 4 (25%), hematologic 4 (25%), lung 2 (12,5%) and breast 1 (6%). 3 cases (18,7%) were previous disease recurrences.

The therapeutic decision was in 11 patients (69%) TAVI procedure as first treatment and in 5 patients (31%) definitive TAVI suspension or cancer treatment first, in one of this cases an aortic valvuloplasty was done and another was finally accepted for TAVI several months later.

In an average follow-up of 19,3 months 5 patients (31%) died; 3 patients in the TAVI first group (27%), one cardiac death in a month and two cancer death in six and seventy two moths (just one cancer death in the first year); and 2 patients in the other group (40%) in three and five months from diagnosis date.

CONCLUSIONS

There is a significant number (7,4%) of asymptomatic cancer diagnosis in an old population evaluated for TAVI procedure. The therapeutic decision is a challenge on which treatment to prioritize, it doesn´t mean that these patients must be systematically excluded from performing the procedure.

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New and old devices in defeating calcium

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Other Coronary Interventions

AIMS

Treating patients with calcified lesions is a major challenge in the cath lab. Nurses and technician must be familiar with new inventions that facilitate treatment of these patients.
In 2017 Intravascular lithotripsy with the brand name shockwave gained CE mark and thus has been available throughout Europe.
This technique has potential to help patients who previously was left to medical treatment for their angina pectoris. Furthermore, there is a growing patient population, TAVR patients with calcified iliac arteries who are now able to have their valve treated with femoral access.

METHODS AND RESULTS

Nurses and technicians must assist regularly in the use of this device. In addition, it is important to be familiar with the handling and the treatment of the patients and the equipment to make the daily treatment of these patients as effortless and proficient as possible.
However, we cannot all together dismiss rotational atherectomy it still has its place in selected coronary angioplasty cases.
?The purpose of this presentation is to provide insight surrounding the theoretical background and basic information of the new technique and its uses.
Case stories will be presented to illustrate both the new and the known techniques as well as different indications to use intravascular lithotripsy – shockwave or rotational atherectomy.

CONCLUSIONS

Well educated staff is pivotal in best possible patient care. Even if some cathlabs do not have access to all techniques and care for all types of patients it is important to be acquainted with what is available at other facilities.

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Unstable angina and NSTEMI in the era of high-sensitivity troponin: impact on patient risk profile and management

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THEME: Coronary Interventions
TOPIC(S): NSTEMI, Other Coronary Interventions

AIMS

High-sensitivity troponin assays (HST) entered the clinical arena to facilitate exclusion of ACS in the emergency department (ER) in patients presenting with chest pain. Due to its higher sensitivity there is the potential for an overestimation of the diagnosis of NSTEMI, and possibly ACS overall. We assessed the impact of HST in the classification of ACS (NSTEMI vs UA) and its ability to predict obstructive coronary disease (CAD), in a population of pts referred to coronary angiography (ICA).

METHODS AND RESULTS

Retrospective analysis of 1844 pts with suspected NSTEMI or UA referred for ICA from a single ER between Feb 2013 and Nov 2018. Standard Troponin-I was used until Feb 2016 and HST thereafter. The characteristics of UA and NSTEMI pts before and after the introduction of HST were compared. Multivariate binary logistic regression models were used to access the association of different troponin assays with CAD (> 50% for LM and > 70% for the remaining). Sensitivity, specificity, NPV and PPV for angiographic CAD were also determined.

The relative proportion of patients with UA and NSTEMI was similar between study periods: 31% vs 29% and 69% vs 71%, respectively (p=0.3). Clinical and angiographic characteristics did not differ in UA pts before and after the use of HST. NSTEMI patients in the HST era were less frequently women (39% vs 32%, p=0.026), had higher creatinine (0.93 IQR 0.75-1.3 vs 1.0 IQR 0.82-1.38), higher number of lesions (2 IQR 1-4 vs 3 IQR 1-4) and a lower rate of normal coronary arteries (10.5% vs 3.9%, p<0.001). The prevalence of significant CAD in this population, before and after HST, was 65% and 73%, respectively (p=0.001). However, when clinically relevant characteristics and judgement were accounted for, both standard troponin (OR 0.99, 95% CI 0.99-1.01) and HST (1.0, 95% CI 1.0-1.0) were poor predictors of significant CAD. Sensitivity was 69% vs 72%, specificity 30% vs 30%, PPV 65% vs 73% and NNP 34% vs 28%, respectively. Finally, rates of percutaneous intervention did not differ between the two periods (30% vs 33.5%, p=0.157), nor between ACS types within each period.

CONCLUSIONS

The introduction of HST did not result in an increase of the diagnosis of NSTEM vs UA, suggesting that clinical judgment remains an important determinant of the diagnosis of ACS. Also there was no evidence of an increase in PCI rates, despite worse CAD severity in NSTEMI patients.

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Angiography-based functional assessment of coronary lesions using quantitative flow ratio in patients with severe aortic stenosis undergoing TAVR

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Functional evaluation of coronary stenoses with FFR in patients with severe aortic stenosis (SAS) undergoing transcatheter aortic valve replacement (TAVR) is very limited due to potential risk from coronary instrumentation and the need of vasoactive drugs. Quantitative flow ratio (QFR), a novel functional angiography-based technique, constitutes an attractive method to circumvent these limitations, but its validation in SAS is still pending. Our aim was to investigate the diagnostic performance of QFR in assessing the functional relevance of coronary lesions in SAS patients undergoing TAVR.

METHODS AND RESULTS

This multicenter, international study included 115 patients (138 coronary arteries) with SAS in whom functional relevance of coronary lesions was assessed before TAVR using FFR. Subsequently, QFR was calculated at a central core laboratory, blinded to FFR results. The diagnostic yield of QFR was set using FFR as reference (cutoff 0.80).

Coronary stenoses were angiographically and functionally of intermediate severity (DS% 48±10%, FFR 0.84 [0.77-0.89], QFR 0.82 [0.73-0.89]). Number of functionally significant lesions were 55 (40%) by FFR, and 63 (46%) by QFR (p = 0.315). Overall per-vessel sensitivity, specificity, area under the ROC curve and accuracy of QFR were 84% (95% CI 71-92%), 80% (95% CI 69-88%), 0.88 (95% CI 0.82-0.93) and 81%, respectively. The diagnostic accuracy of QFR significantly decreased in patients with aortic valve area (AVA) <0.60 cm2. A deferring QFR cutoff value ≥0.87 yielded a negative predictive value of 95% (95% CI 82-99%) to exclude FFR-based non-significant stenoses.

CONCLUSIONS

Compared with FFR, QFR has a good diagnostic yield in assessing the functional relevance of coronary lesions in SAS patients undergoing TAVR, particularly when AVA is ≥0.6 cm2. By avoiding the use of hyperemic agents and intracoronary instrumentation, QFR is an accurate alternative tool for coronary stenosis assessment and may facilitate adoption of physiologically-driven revascularization in this fragile population.

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Radiation exposure in complete arm, hybrid and complete femoral vascular access in patients undergoing right heart catheterisation

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THEME: Interventions for Heart Failure
TOPIC(S): Chronic heart failure

AIMS

Right heart catheterization (RHC) is a standard procedure, namely in the workup of patients with terminal heart failure (HF) who are candidates to advanced HF therapies. Complete (arterial and venous) arm vascular access (AVA), is increasingly used in this setting. We aimed to compare procedure duration and radiation exposure for AVA (isolated and hybrid) and femoral alone vascular access (FVA).

METHODS AND RESULTS

Single-centre retrospective analysis of 185 consecutive patients between Feb 2011 and Nov 2018 who underwent RHC. Of these, we compared a total of 171 pts (14 pts were excluded because missing data regarding venous access), that underwent RHC by complete femoral access (FVA; n=70), complete AVA (n=66) and hybrid access (HVA; n= 35) - either intentionally, due to anticipated difficulties, or access failure - concerning procedure duration and radiation exposure. Standard statistics (chi-square, T-student and Mann-Whitney tests) were used according to the tested variables.

Complete AVA entered our practice in 2015 and its use increased progressively, from an initial 29% to 73% of the procedures in 2018. The three groups did not differ significantly in their baseline characteristics.

When compared to complete femoral access, complete AVA procedures exposed both the patient and the operator to significantly less fluoroscopy radiation time (8.49 IQR 6.2-12.4min vs 9.24 IQR 7.6-15.4min, p=0.002) and dose (radiation dose: 2059 IQR 1046-3717 mGy/m2 vs 4246 IQR 2558-10099 mGy/m2, p<0.001; effective radiation dose: 176 IQR 96-369 mGy vs 508 IQR 297-1668 mGy). There was no difference in total procedure duration (55 IQR 45-67min vs 52 IQR 42-68min; p=0.513).

The hybrid procedures were significantly longer than complete femoral access (70min IQR 51-9 vs 52min IQR 43-68, p=0.013) but used less effective x-ray dose (381 IQR 158-495 vs 470 IQR 277-1187, p=0.03).

CONCLUSIONS

Complete arm vascular access is associated with lower radiation exposure despite similar procedure duration.

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Short-term results of ischaemic heart disease endovascular treatment in patients with blood cancer

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Other Coronary Interventions

AIMS

Improvement of the treatment setting for oncohematological diseases allowed to improve the treatment results, to increase the life expectancy, to change life quality. This is one of the factors explaining the tendency of the increase in the incidence of coronary heart disease with oncological disease combination. Aim:to create the algorithm of coronary heart disease endovascular treatment in patients with blood cancer.
The publication has been prepared with the support of the «RUDN University Program 5-100».

METHODS AND RESULTS

A clinical study was based on the analysis of coronary heart disease endovascular treatment results in patients with oncohematological diseases.Our study included two-stage treatment of 54 patients with coronary artery disease and blood cancer. The average age was 64 ± 11.63 years. The 1st stage was performed percutaneous coronary intervention, the 2nd - the treatment of oncopathology (11 patients underwent surgical treatment, 43– chemotherapy/radiation therapy). All patients were prescribed double antiplatelet therapy before revasciarization (acetylsalicylic acid at a dose of 100 mg/day and clopidogrel at a dose of 75 mg /day). Immediately before myocardial revascularization the level of platelet aggregation was assessed by the method of light transmission aggregometry of platelets with adenosine diphosphate (the target level of platelet aggregation before performing percutaneous coronary intervention is less than 45%).We chose the stent type individually based on the duration of the surgical intervention by the reason of cancer, anatomy of the coronary arteries and the nature of coronary arteries atherosclerotic lesions.If surgical intervention was planned for 1 month after percutaneous coronary intervention, then bare-metal stents were preferred. There were no intraoperative and hospital mortality and also no mortality cases due to coronary artery disease during the 1st year after percutaneous coronary intervention.All patients received dual antiplatelet therapy for at least 1 month before performing surgical treatment of oncopathology if bare-metal stents was implanted and 3 months - if drug-eluting stents. Dual antiplatelet therapy was stopped 5–7 days before the surgical treatment replaced by unfractionated heparin to prevent thrombotic and hemorrhagic complications. After the surgery dual antiplatelet therapy was restarted in 6-48 hours. During the 1st year after percutaneous coronary intervention the recurrent angina was observed in 2 patients. Hemodynamically significant 'in-stent' restenoses were identified on the coronary angiography. In 1 patient the recurrent angina occurred 4 months after myocardial revascularization with bare-metal stent implantation. In the 2nd patient the recurrent angina was observed 11 months after previously performed percutaneous coronary intervention with drug-eluting stent.

CONCLUSIONS

Percutaneous coronary intervention is an effective and safe method of myocardial revascularization in patients with coronary artery disease and oncopathology. The use of endovascular myocardial revascularization in cancer patients reduces the risk of developing cardiovascular complications during the oncological treatment.

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FFR-guided PCI on long coronary lesions: five-year clinical results with second or newer generation DES

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Stents and scaffolds

AIMS

The aim of our study was to evaluate the long-term clinical results after FFR guided PCI on long coronary lesions.

METHODS AND RESULTS

A total of 74 consecutive patients with significant (mean FFR 0.61 ± 0.11) coronary artery lesions ≥30 mm in length were included in the prospective study. All patients were treated with FFR guided PCI implanting newer generation Biolimus, Everolimus or Zotarolimus eluting stents. Clinical endpoints were recorded at 1 and 5 years.

PCI was successful in all cases, the mean post procedural FFR was 0.88 ± 0.06. At 5-years, 60 patients were available for follow-up (14 lost due to various reasons, but the total mortality data was available for all patients). 7 (11.7%) patients had ischemia driven target vessel revascularization, 6 of which within the first 12 months. There was no documented target vessel related acute coronary syndrome or definite stent thrombosis in the study group. 7 (11.7%) patients had non-target vessel related myocardial infarction, 13 (21.7%) underwent non-target vessel related PCI. 3 (5%) events of ischemic stroke were documented in the study group. The rate of all-cause mortality was 12.2% (9/74 pts.).

CONCLUSIONS

Although, after FFR guided PCI on long coronary lesions the general rate of major adverse cardiovascular events was high in the patient population with diffuse coronary atherosclerosis, the target vessel revascularization rate at 5 years was relatively low.

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Early coronary stent thrombosis prevention by platelet aggregation management in patients with unstable angina

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

The coronary artery stenting is a common and effective endovascular treatment for various forms of coronary artery disease. In most cases prescribed dual antiplatelet therapy helps prevent stent thrombosis. However, the effectiveness of dual antiplatelet therapy is rarely monitored. Despite there are 0.6-2% chances in the first year of having stent thrombosis with high mortality rate after coronary artery stenting. Aim: to study the effectiveness of platelet aggregation management in early coronary stent thrombosis prevention in patients with unstable angina.

METHODS AND RESULTS

The publication has been prepared with the support of the «RUDN University Program 5-100».

The study included 215 patients with unstable angina. All patients were randomized in II groups. There were 112 patients in group I and 103 patients - in group II. Group I had the platelet aggregation managment based on platelet aggregation test with adenosine diphosphate and group II had not. Percutaneous coronary intervention with stenting perfomed in both groups.

The odds ratio for the development of early coronary stent thrombosis in patients with unstable angina with platelet aggregation management compared with the patients without platelet aggregation management is 3.36 ($p < 0.05$).

CONCLUSIONS

The study shows the importance of platelet aggregation management in the prevention of early coronary stent thrombosis in patients with unstable angina

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Acute outcomes of a novel transcatheter heart valve to treat degenerated surgical valves - The VIVALL multi-centre, single-arm, pilot study

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

The aim of the VIVALL study was to investigate the technical feasibility of the implantation of an ALLEGRA THV into failing surgical aortic bioprosthetical valves and to describe the safety and performance profile.

METHODS AND RESULTS

Between August 2017 and September 2018, 30 patients (78.6± 6.0 years, 50% female. STS score 4.5-± 2.1% and EuroSCORE 9.2 ± 4.3%) with failing surgical aortic bioprostheses and higher surgical risk were treated with the ALLEGRA TAVI system TF. An independent combined DSMB-CEC and corelab adjudicated adverse events, patient safety and echocardiograms, respectively. Primary endpoints were invasive post-procedure mean pressure gradient as assessed by pigtail catheter (performance) and 30-day survival (safety).

Implantation was successful in all but one patient (96.7%) and the pre-procedural pressure gradient was reduced from 37.1 ± 13.8 mmHg to 11.8 ± 6.5 mmHg at post-procedure. At 30 days, all-cause mortality and new implantation of pacemaker were both 0%.

At 30 days, effective orifice area increased from 1.18 ± 0.58 cm2at baseline to 1.4 ± 0.52 cm2, whereas the mean gradient remained significantly reduced form 30.75 ± 12.83 mmHg to 14.75 ± 6.48 mmHg. Paravalvular regurgitation at 30 days was none/trace in 100% of the cases. No mild, moderate and severe PVL was observed.

CONCLUSIONS

The data show that transfemoral implantation of the ALLEGRA THV is feasible and safe in patients with failing surgical aortic bioprostheses and increased surgical risk. Excellent hemodynamic outcomes and a 100% survival rate after 30 days suggest that the device is a valid option for valve-in-valve treatment.

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True coronary artery bifurcations in ACS are associated with longer PCIs, but do not influence clinical outcomes

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THEME: Coronary Interventions
TOPIC(S): STEMI, Bifurcation lesion

AIMS

Percutaneous coronary interventions (PCI) in bifurcation lesions with more than 50% stenosis of both main branch and side branch remain challenging. These “true” bifurcation lesions (TBL) causing acute coronary syndrome (ACS) could pose an additional challenge for adequate treatment since there are no recommended strategies. We investigated the influence of the presence of TBLs as culprit lesions for ACS on the clinical outcomes after PCI.

METHODS AND RESULTS

The study was retrospective and conducted in a high-volume university PCI centre. Study included 256 consecutive patients with native coronary artery bifurcation lesions causing an ACS. Patients with ACS caused by stent thrombosis were not included in the study. All patients underwent PCI of the culprit bifurcation lesion and afterwards were treated according to the appropriate guidelines. Most of the bifurcations were located in left anterior descending 152/256 (59.3%), then in circumflex 66/256 (25.9%) and right coronary artery 38/256 (14.8%). The initial clinical presentation was STEMI in 144/256 (56.2%), then NSTEMI 59/256 (23.1%) and unstable angina in 53/256 (20.7%) patients. TBLs were present in 146/256 (57.0%) patients. TBLs were associated with longer PCI procedural time 48±24min vs. 31±28min ($p<0.05$) and greater contrast volume 177±73 vs. 149±48 ml ($p=0.01$), but not with larger myocardial infarction in terms of magnitude of troponin I release 47.35±73.73 vs 31.07±38.05 ng/ml ($p=0.164$) and LVEF 40±13 vs 42±13% ($p=0.439$), as compared to other bifurcation lesions. The patients were followed for 405±377 days. The MACCE (major adverse cardio-cerebral events: death, myocardial infarction, repeated revascularization and stroke) occurred in 55/256 (21.5%) patients. In univariate regression analysis, provisional PCI strategy was associated with fewer MACCE [OR 0.283 (95 % CI 0.089–0.898)]. However, in the multivariate regression analysis, that included recognized predictors of MACCE (diabetes, LVEF, chronic kidney disease, multivessel disease, provisional PCI strategy, use of ticagrelor, TBLs) only the presence of the multi-vessel coronary artery disease remained an independent predictor of MACCE [OR 5.147 (95 % CI 1.859–14.248)].

CONCLUSIONS

TBLs in acute coronary syndrome are associated with longer PCI duration, but were not associated with larger myocardial infarction and adverse cardiovascular outcomes. The extent of the CAD at presentation predicts the best future cardiovascular events.

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Evolution in one-year mortality in diabetic patients admitted with STEMI in relation to early management and differences in the early management in comparison to non-diabetic patients

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THEME: Coronary Interventions
TOPIC(S): STEMI, Left main and multivessel disease

AIMS

Diabetic patients have important differences in the pathophysiology of coronary artery disease, with impact in the clinical presentation, management and outcomes after ST-segment elevation MI (STEMI).
Our aim was to determine the differences between diabetic and non-diabetic patients in the initial presentation, the use of recommended management, and subsequent morbidity and mortality. Independent predictors of differences in one-year outcomes as well as the evolution of outcomes over time were also assessed.

METHODS AND RESULTS

We used data from 3 one-month French registries, conducted 5 years apart from 2005 to 2015, including diabetic and non-diabetic STEMI patients admitted to coronary or intensive care units.
From 2005 to 2015, diabetic patients had a higher mean age (68.3 vs 62.3 years, p<0.001), and a higher incidence of hypertension, hypercholesterolemia and obesity but a lower incidence of current smoking and heredity. History of prior cardiovascular disease and use of medications was significantly more common in diabetic patients, while they were more likely to present with signs and symptoms of heart failure (11.3% vs 4.9%, p<0.001), but, interestingly enough, they did not differ significantly in terms of symptoms.
However they were less likely to undergo aggressive medical therapy and invasive management (53.7% vs 64.3%, p<0.001), and when they did undergo the latter, they turned out to have more extensive coronary artery disease (60.8% multivessel disease vs 45.1%, p<0.001) and inferior success rate (77.2 vs 84.9%, p<0.001), along with a higher rate of complications and more prolonged hospital stay (9±8.7 vs 7.2±7.1, p<0.001). Clinical outcomes were far inferior for diabetics with more than two-fold mortality in any given time point [Relative risk (RR) 2.12, Confidence interval (CI):1.81 -2.49] for 1-year mortality], which could be partly attributed to greater delays in every step from symptom onset to definitive treatment. In addition, diabetes duration had an impact on outcomes, with a rather U shaped curve, while HbA1c levels were positively correlated and an independent predictor of mortality, even within the grey zone of prediabetes (RR 1.71, CI:1.19 -2.48). Concerning temporal trends, there was an improvement in mortality in diabetic patients between 2005 and 2010, which remained stable thereafter and was in parallel with similar changes in employment of primary PCI.

CONCLUSIONS

Diabetic STEMI patients tend to be older with a higher prevalence of risk factors, prior cardiovascular heart disease and comorbidities. They present more often with heart failure but similar chest pain characteristics, but their management is often delayed and less aggressive. Angiography reveals more extensive disease and revascularization, when attempted, is less frequently successful. All these along with a higher in-hospital complication rate lead to a significant increase in mortality, compared with non-diabetics, and could be

correlated with diabetes duration and levels of HbA1c. Overall there was an initial trend for improvement in mortality which later remained stable, likely mediated by the evolution management strategies (newer antithrombotics and increasing use of recommended medications and mostly primary PCI), underlining the importance of guidelines implementation in diabetic populations as well.

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Prevalence and outcome of patients with prior stroke/transient ischaemic attack and ACS undergoing PCI - A BleeMACS substudy

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

A substantial proportion of patients with acute coronary syndromes (ACS) underwent percutaneous coronary intervention (PCI) presented with a history of stroke/transient ischemic attack (TIA). We aimed to evaluate the impact of prior stroke/TIA on clinical outcomes and assess the efficacy and safety of antithrombotic therapy in these patients.

METHODS AND RESULTS

Methods and results: We conducted an international multicenter study from the Bleeding complications in a Multicenter registry of patients discharged with diagnosis of Acute Coronary Syndrome (BleeMACS) registry. The patients were divided into two groups, with or without prior stroke/TIA. The primary endpoint was the death rate at one-year follow-up. Secondary endpoints include in-hospital reinfarction, in-hospital bleeding, one-year reinfarction and one-year bleeding. Baseline characteristics and one-year follow-up of 15,401 patients with ACS were analyzed. Among them, 5.9% had prior stroke/TIA. Patients with a history of stroke/TIA were more likely to have traditional cardiovascular risk factors and comorbidities, but less likely to receive evidence-based medical therapies and to undergo complete revascularization, despite more multi-vessel disease they had. Patients with prior stroke/TIA had significantly increased in-hospital bleeding (8.7% vs. 5.8%, p<0.001), one-year bleeding (5.2% vs. 3.0%, p<0.001), one-year reinfarction (5.6% vs. 3.8%, p=0.015), and one-year death (8.7% vs. 3.4%, p<0.001) compared with patients without prior stroke/TIA. Prior stroke/TIA was an independent predictor of one-year death after adjustment for confounding variables (odds ratio, 1.705; 95%CI, 1.046-2.778; p=0.032). Dual antiplatelet therapy (DAPT) was associated with the least one-year death (3.1%) compared with other antithrombotic therapies and less bleeding (2.8%) compared with DAPT plus oral anticoagulants (OAC) in patients without prior stroke/TIA. However, no difference of antithrombotic therapies was observed in patients with prior stroke/TIA.

CONCLUSIONS

Conclusions: A history of stroke/TIA was associated with higher one-year death for ACS patients underwent PCI even after adjustment for baseline characteristics. No benefits or harms were observed of DAPT in these patients.

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Invasive assessment of optimal amount of fluid for the management of hypotension in patients with inferior-wall myocardial infarction, complicated by right ventricular infarction

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Fluid replacement along with guideline-directed therapy is recommended in patients of inferior-wall myocardial infarction with right ventricular infarction (IW+RVMI) complicated by low cardiac output (CO) state. However, the optimum amount of intravenous (IV) fluid in such patients has not been studied.

We aim to assess the hemodynamic effect of graded IV fluid infusion and optimal amount of fluid needed to achieve and maintain SBP ≥90 mmHg in hypotensive patients of IWMI with RVMI.

METHODS AND RESULTS

In this single-center prospective study conducted from January to December 2017, patients with first episode of IW+RVMI and SBP <90 mm Hg were analyzed. Subclavian venous access was taken for Swan Ganz CCO catheter to measure pulmonary capillary wedge pressure (PCWP) on GE DASH 500 cardiac monitoring system .Femoral artery access was taken to measure CO and cardiac index (CI) using Edwards Life Sciences Vigilance 1000 platform monitor .The hemodynamic parameters such as heart rate, SBP, CO, CI, and PCWP were measured at the baseline and after each 500 ml normal saline over 15 min until SBP ≥ 90 mmHg was attained. The primary objective was to study the change in CO, CI, and PCWP with response to fluid and amount of fluid needed for ≥10% rise in CO and to maintain SBP ≥90 mmHg was also evaluated. The secondary objectives were to study the need for inotropic support, complications such as acute pulmonary edema, local site bleeding and in-hospital mortality.

Twenty two patients were subjected to graded fluid therapy. The mean baseline PCWP, CO and CI was 8.4±3.0 mm Hg, 2.1±0.7 L/min and 1.3±0.3L/min/m2 respectively. Fluid therapy resulted in significant rise in PCWP, CO and CI to 17.6±1.5 mmHg, 3.7±0.7 L/min and 2.4±0.76 L/min/m2 respectively. The average quantity of fluid needed to increase the CO by 10% over the baseline was 865±462 mL. However, optimal amount of fluid needed to maintain SBP ≥90 mmHg was 2,192 ±560 mL. There were no complications such as local site bleeding and hematoma, acute pulmonary edema or in-hospital death

CONCLUSIONS

Less than a liter iv fluid required for 10% improvement in CO but more than 2 liter fluid needed to treat hypotension in patients with IW+RVMI. However, more study with larger number of patients would be needed to confirm the same.

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Safety and feasibility of balloon mitral valvotomy as a day care procedure using a novel strategy - A single-centre experience

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair

AIMS

Balloon mitral valvuloplasty (BMV) is the most common non-coronary intervention done in developing countries; still there are no clear-cut guidelines regarding the duration of hospital stay for patients undergoing this procedure. Therefore, we intended to define the feasibility of BMV as a day-care procedure.

METHODS AND RESULTS

An uncomplicated BMV in patients of Mitral stenosis (MS) requires a hospital stay of 1-2 days due to concern of vascular haemostasis and related complications. Radial arterial access and femoral venous haemostasis by ‘figure of 8’ stitch has resulted in reduced local site complications, and is preferred, both by operators & patients. We used radial/ulnar arterial access for left heart catheterisation and ‘Figure of 8’ stitch at femoral venous access site and thus assessed safety and feasibility for same day discharge in patients undergoing BMV. Consecutive 103 patients of isolated severe MS, without pregnancy, atrial fibrillation or BMV score >8, were enrolled in the study. Pre-procedural blood investigations, ECG & ECHO (TTE & TEE) were done on OPD basis. During the procedure, arterial access was taken from radial/ulnar artery after introducing 6F arterial sheath. Initial patients had more arterial spasm due to 5F pigtail catheters, later on all remaining patients underwent left heart catheterisation by 4F pigtail catheter. Radial band was applied for arterial haemostasis. Patients were discharged after an observation period of 4-6 hours. Stitches on femoral venous site were removed on Day 3. Primary end point was incidence of local vascular complications at discharge and on follow-up.103 patients (37 males, 66 females, mean age 28.3 years, mean MV area 0.81 cm2) underwent procedure achieving a mean MV area of 1.6 cm2. Five patients needed femoral arterial access (due to inability to gain radial/ulnar access) and were hence excluded from same day discharge protocol. One patient developed severe MR due to leaflet tear and underwent successful MVR. Three patients had observation of 1 day (because of moderate to severe commissural MR in two patients and cardiac tamponade in one patient). Remaining 94 patients were discharged on same day. Two patients had right ulnar, and four had left radial access. Rest 92 patients had right radial access. 32% & 23% of our patients had grade II & grade III spasm respectively. 2.0% of our patients had grade IV spasm and needed multiple measures such as spasmolytics and conscious sedation. The more prevalence of shorter stature and lower BMIs may have contributed to increased incidence of spasm with pigtail catheter in our study (as compared to ~35% incidence in case of PCI through radial route). The incidence of radial artery spasm significantly reduced in patients with 4F pigtail catheter (23%) as compared to patients with 5F pigtail catheter (57%). None of the patients with 4F pigtail had Grade IV spasm. Five patients had radial site hematoma of Grade 2 after the procedure which got resolved on follow-up. None of the patients had significant femoral hematoma. Four patients showed loss of radial pulse at discharge without any symptoms on follow up.

CONCLUSIONS

In patients undergoing BMV, same-day discharge protocol was not associated with any increase in vascular or other complications and appeared to be safe, feasible & cost-effective. Choosing a smaller calibre pigtail

catheter (4F) can further act as a trouble-shooter for the common problem of spasm commonly associated with radial artery access.

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Incidence and procedural predictors of myocardial injury following PCI with rotational atherectomy

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Due to patient`s clinical characteristics, complexity, aggressiveness and presence of pulverized micro debris during rotational atherectomy this procedure is thought to be associated with higher risk of myocardial injury, this however has never been comprehensively demonstrated. This study aimed to assess the incidence and procedural predictors of myocardial injury, described as substantial increase of high sensitivity troponin I levels, following percutaneous coronary interventions with rotational atherectomy.

METHODS AND RESULTS

We prospectively evaluated data of 42 near-consecutive patients who underwent elective percutaneous coronary interventions with rotational atherectomy. Patients with recent myocardial infarction and elevated troponin I levels prior to the procedure were excluded from the study. Blood samples for high sensitivity troponin I measurements were collected directly prior to the procedure and on the following morning (18-24 hours past procedure).

Most of the patients were male (74%), mean age of population was 71 ± 8,9 years and mean left ventricle ejection fraction was 49 ± 11%. Prevalence of traditional risk factors was high and presented as follow: hypertension 93%, diabetes 62%, hyperlipidemia 43%, prior stroke 14%, prior PCI 81%, prior CABG 12%, renal insufficiency 21%, atrial fibrillation 21%.

Radial access site was used in 98% of patients, procedure was successful in 93% of patients. Mean maximal burr size was 1,4 ± 0,19 mm, mean burr speed was 146 000 ± 5 000 revolutions per minute. Mean burr-to-artery ratio was 0,46 ± 0,08. During the procedure operators performed 5,9 ± 4,1 burr runs with 1,13 ± 0,42 burrs. Median total time of burr use reached 114 (79; 222) seconds. Mean 1,4 ± 0,7 stents of 27,6 ± 16,2 mm length were implanted.

In all patients high sensitivity troponin I levels prior to the procedure were below the upper limit of normal (0,057 ng/ml). 18-24 hours post procedure increase of high sensitivity troponin I above the upper limit of normal was present in 79% of patients. Substantial increase (≥5 x upper limit of normal) was present in 55% of patients. Interestingly only one patient (2%) fulfilled the criteria of myocardial infarction type 4a diagnosis (according to 4th universal definition).

Univariate logistic regression models showed total time of burr use (odds ratio 1,9; confidence interval 1,14-3,3; p=0,01) and number of burr runs (odds ratio 1,35; confidence interval 1,06-1,71; p=0,01) to be the only predictors of post procedural myocardial injury described as substantial increase of high sensitivity troponin I levels. Other factors included in statistical analysis (sex, age, diabetes, hypertension, renal insufficiency, left ventricle ejection fraction, prior myocardial infarction, prior PCI and CABG, burr size and speed, burr-to-artery ratio, stent length and number) did not correlate with post procedural myocardial injury.

CONCLUSIONS

Total time of burr use and number of burr runs were the only predictors of procedure related myocardial injury after percutaneous coronary interventions with rotational atherectomy. It's clinical significance needs further evaluation in large population studies. Further studies are also needed to evaluate the impact of different procedural strategies on myocardial injury after rotational atherectomy.

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Impact of the membranous septum and transcatheter heart valve implantation depth on the development of conduction abnormalities after TAVR

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

The inferior membranous septum (MS) border is visible by cardiac CT-scan, functioning as a surrogate for the distance between the native aortic annulus and the atrioventricular conduction system. However, there is limited data on the association between new-onset conduction abnormalities (new-CA) after transcatheter aortic valve replacement (TAVR) and the MS depth (MS-D) as well as the transcatheter heart valve implantation depth (THV-D). The aim was to predict the risk of new-CA after TAVR based on meticulous measurements of the MS-D and THV-D as well as the difference between the two.

METHODS AND RESULTS

Based on pre-procedural CT-scan the MS-D was measured for every 25% of the entire MS width in 192 TAVR-patients without pre-procedural bundle branch block (BBB) or permanent pacemaker. Fifty of these patients also had a post-procedural CT-scan eligible for THV-D assessment corresponding to the sites of MS-D measurements.

New-CA developed in 36.5% of patients (25.0% had new-BBB and 11.5% had new-onset high-degree CA (new-HD-CA)). The MS-D was shorter and the THV-D were greater along the entire MS width for patients with new-CA when compared to patients without new-CA ($p<0.05$ for all comparisons).The difference between the MS-D and THV-D at the edge of the MS closest to the right coronary cusp provided the best predictor for new-CA. In 6 patients the THV did not overlap the inferior MS border at this point and none of these developed new-CA. New-CA developed in 5 out of 25 patients (20.0%; all with new-BBB) where the THV overlapped the inferior MS border by [≥0.0mm; <5.0mm] and in 11 of 18 patients (61.1%; 5 with new-BBB (27.8%) and 6 with new-HD-CA (33.3%)) with THV overlap of the inferior MS border by ≥5.0mm.

CONCLUSIONS

The difference of the THV-D and MS-D measured at the anterior edge of the MS predicted new-CA after TAVR. The risk of new-BBB and successively new-HD-CA increased progressively with greater overlap of the THV over the inferior MS border. Whether this patient specific measurement could result in a higher rate of THV repositioning and lower rate of new-CA needs to be further investigated.

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PrOspective multiCentrE study of cArotid artery steNting Using MER Stent- the OCEANUS study - 30-day and one-year follow-up

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THEME: Interventions for Stroke
TOPIC(S): Carotid stenting

AIMS

The aim of this study was to evaluate the 30-day and one year clinical outcome of non-consecutive patients with high risk of carotid endarterectomy who underwent 5F cylinder- tapered MER open-cells carotid stent implantation.

METHODS AND RESULTS

Presented study is a single-arm, prospective study conducted in four catherization centres. The primary endpoint was the 30-day and one year cumulative incidence of death, stroke and myocardial infarction (major adverse events – MAE). We have recruited 100 patients, with the majority of males (n=61; 61%). The mean age was 68.3±8.2 years and most of the patients were asymptomatic (n=44; 44%). The use of embolic protection devices was mandatory. In 55 (55%) of the cases direct stenting was performed and we have used proximal protection devices in 19 (19%) of the cases. Mean Internal Carotid Artery/Common Carotid Artery stenosis after stent implantation was 12.5±8.7% in the contrary to 81.9±9.1% before stent implantation ($p<0.001$). None of the procedures ended up with failure (success rate =100%). One ischaemic stroke was observed at 30 days follow up. At one year follow we have recorded two myocardial infarctions, three deaths and one stroke.

During 12 months observation 6 major adverse events (MAE) were reported. Altogether 94 patients (94%) were event free. We did not observe differences in MAE between symptomatic and asymptomatic patients ($p=0.258$).

CONCLUSIONS

In our study we have showed safety and efficacy of MER stents during one year follow-up in both symptomatic and asymptomatic patients. Majority of patients were event free, however larger cohort studies are in need to evaluate MER stents in detail.

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A novel pre-operative method for understanding personal coronary anatomy for graft anastomosis in 3D printing heart models based on cardiac CT

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

We hypotized that preoperative 3-D printing heart model and native vessels can play an important role in adjusting graft length and anastomosis sites. 10 patients' CT images who were already undergone bypass surgery via saphenous vein graft were enrolled. In this study first time we studied personal 3-D spatial printing model for better understanding coronary vessel and graft anatomy.

METHODS AND RESULTS

10 patients who had previously undergone bypass surgery were included. Medical 3-D printing consists of some steps: Step 1; collecting medical images with DICOM format from contrast CT images of heart, native vessels, myocardium, and saphenous grafts. Step 2; Image Data Segmentation which was made by using Mimics Innovation Suite 21 Software (Materialise, Leuven, Belgium, CE 0120 Certification) Step 3; data processing in design module and exporting STL file to 3-D printer. Step 4; Printing with 3D printer (Formlabs Form 2, FormlasbsInc. Massachusetts, USA, Laser Specifications: EN 60825-1:2007certified). After obtaining of 3-D models, manual measurements between distal and proximal estimated optimal anastomosis sites were done by cardiologist engineer and cardiovascular surgeon. Actual saphenous graft lengths were measured from CT images by means of CT software. Other measurements of estimated optimal saphenous graft lengths were done between distal and proximal estimated optimal anastomosis sites via command of Fit Centerline in the Module of mimics analyze software after segmentation. And these three measurements compared statistically. There are statistically significant differences between three measurement methods for each saphenous graft length ($P<0.001$). Also, measurements were obtained from 3-D printed models via manually with plastic tube and measurements of segmentation images from Meteralise software are statistically similar for each saphenous graft (Ao-LAD, P=0,53, Ao-LAD-D1, P=0.57, Ao-RCA-PDA P= 0,61, respectively). But There is a significant difference between manual measurements on 3-D models and measurements of CT images ($P<0.001$). Also Meteralise software and CT image measurements comparison has no statically difference ($P<0.001$).

CONCLUSIONS

3D printing heart models and their software can be used to determine optimal saphenous graft length and anastomosis sites for more accurate measurements. Findings revealed from heart models reduces operator dependent variables in graft size and anastomosis location during surgery.

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New-generation stents for primary PCI in patients with AMI: evidence from an individual patient data network meta-analysis of randomised clinical trials

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Drug-eluting stents have shown their superiority in primary percutaneous intervention for treating patients with ST-segment elevation myocardial infarction (STEMI). Nevertheless, to date, no specific stent type has fully proven its superiority over others. We sought to compare the safety and efficacy of coronary artery stents in patients presenting with STEMI undergoing primary PCI through comprehensive network meta-analysis.

METHODS AND RESULTS

We performed an individual patient data (IPD) network meta-analysis of dedicated randomized trial in STEMI patients treated with coronary stents. The protocol of the study was registered in PROSPERO (CRD42018104053). The primary endpoint of interest was the composite outcome of cardiac death, any myocardial infarction (MI) or target lesion revascularization (TLR). Secondary outcomes were the individual components of the primary endpoint, and definite or probable stent thrombosis. Outcomes were analyzed at longest available follow-up. Primary analysis was performed using a one-stage random effects meta-analysis. Hazard ratio (HR) with 95% confidence intervals (CI) were reported for risk estimation.

IPD from 15 randomized trials in STEMI patients were obtained including a total of 10,979 patients. Six different stent types were studied including bare metal stents (BMS), durable-polymer paclitaxel-eluting stents (DP-PES), durable-polymer sirolimus-eluting stents (DP-SES), durable-polymer zotarolimus-eluting stents (DP-ZES), durable-polymer everolimus-eluting stents (DP-EES) and biodegradable-polymer biolimus-eluting stent (BP-BES).

Mean patient age was 60.6 years; 22.7% were female and 16.1% were diabetic. Median symptom onset to balloon time was 210 min. PCI was performed with BMS in 3,409 patients in 9 trials, with DP-PES in 3,173 patients in 6 trials, with DP-SES in 2,044 patients in 11 trials, with DP-ZES in 373 patients in 3 trials, with DP-EES in 1,405 patients in 3 trials and with BP-BES in 575 patients in 1 trial.

At a median follow-up of 3 years (interquartile range 2-4.9 years), patients treated with second generation DES (DP-EES and BP-BES) or first-generation DES (DP-PES, DP-SES and DP-ZES) had significantly lower risk of the primary endpoint than patients treated with BMS (BMS vs. second-generation DES; HR 0.69, 95%CI 0.57-0.82, BMS vs. first-generation DES; HR 0.70, 95% CI 0.61-0.80). The differences were driven by the significant reduction of TLR associated with first- and second-generation DES compared with BMS. Trends towards lower risk of MI with second-generation DES compared with BMS or first-generation DES were observed (BMS vs. second-generation DES; HR 0.79, 95% CI 0.58-1.06, first- vs. second-generation DES; HR 0.75, 95% CI 0.54-1.03). Second-generation DES was associated with significantly lower risk of definite or

probable stent thrombosis compared with BMS (HR 0.62, 95% 0.40-0.97) and first-generation DES (HR 0.55, 95%CI 0.34-0.91). DP-EES and BP-BES had a similar risk of the primary endpoint, individual components of primary endpoint, and definite or probable stent thrombosis.

CONCLUSIONS

In this larger-scale IPD network meta-analysis in STEMI patients, second-generation DES were superior to BMS with respect to long-term efficacy and safety outcomes. Second-generation DES were associated with a significant reduction of stent thrombosis compared with BMS and first-generation DES. Similar long-term outcomes were observed between DP-EES and BP-BES.

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Jailed pressure wire to assess the side branch result for bifurcation lesions treated by provisional stenting strategy: iFR as a new index

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

1.- To analyze the feasibility and efficacy of the jailed pressure wire technique for bifurcation lesions treated by provisional stenting strategy. 2.- To assess the physiological side branch (SB) result using instantaneous wave free ratio (iFR).

METHODS AND RESULTS

Between June 2017 and December 2018, 50 patients who presented a bifurcation lesion considered appropriate for provisional stenting strategy were included in the study (50 bifurcations). Pressure wire was passed to side branch before treatment. Main vessel (MV) and side branch (SB) was predilated at the operator criteria. iFR determination was obtained in the SB baseline and after MV stenting (leaving the pressure wire jailed). Afterwards, the wire was removed to MV ostium to discard the possibility of drift. SB postdilation was performed if SB iFR was £0,89 (according to vessel thresholds established in clinical trials), evaluating the result by a new iFR determination. The mean age was 64 ±10 years and 39 patients (78%) were male. Sixteen patients (32%) had diabetes. Clinical presentation was stable angina in 26 patients (52%), non-STEMI in 19 patients (38%) and STEMI (non culprit lesion) in 5 patients (10%). The most frequent bifurcation type according to Medina classifications was 1,1,0 (21 patients, 42%). Seventeen patients (34%) had a true bifurcation lesion. The MV and SB reference diameter was 3,0 ±0,5 mm and 2,25 ±0,5 mm respectively. Most of the bifurcations were located at the left anterior descending artery/diagonal branch (27 bifurcations, 54%). Ten patients (20%) presented a distal left main bifurcation. Baseline SB iFR was 0,78 ±0,2. Under continuous SB iFR monitoring MV stenting was performed by trapping the pressure wire. After MV stenting, the SB iFR changed to 0,90 ±0,1. We confirmed the presence of drift in 5 patients (10%). In these cases, recalibration of the wire and SB rewiring was performed in 4 cases. In the remaining patient, rewiring was not possible even using specific coronary wires.

According to SB IFR, postdilation was necessary in 14 patients (28%). Final SB iFR was 0,94 ±0,03. A second stent was not necessary in any patient because final SB iFR was higher than 0.89 in all cases. We observed discordance between angiographic and physiological result in 17 cases (34%). All the wires could be removed. Forty wires (80%) were microscopically analyzed. Some grade of microscopic damage was found in 32 wires (80%), all of them distal to the pressure sensor. However, only one of these wires (2%) presented severe damage, and no case of fracture was observed.

After a mean follow up time of 10±6 months only one patient (2%) presented a major cardiac adverse event (acute coronary syndrome due to voluntary cessation of dual antiplatelet therapy).

CONCLUSIONS

The use of jailed pressure wire to monitor SB results for bifurcations treated by provisional stenting seems to be safe. The iFR index seems to provide new physiological information about the significance of the SB

stenosis.

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Step by step of the transseptal puncture in the different approaches to the mitral valve

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THEME: Interventions for Valvular Disease
TOPIC(S): Other valvular and structural interventions

AIMS

The structural cardiac interventions aimed at the percutaneous treatment of the valvular desease have now made possible the access to the left cardiac chambers through the technique of puncturing the interatrial septum which results, in its correctness, to be decisive for a good procedural result.
Even for skilled operators, the procedure is technically demanding and requires a solid understanding of cardiac anatomy.

METHODS AND RESULTS

The transseptal puncture technique originated in 1957 when Dr. John Ross Jr. attempted to measure the inter-atrial defect by inserting balloons of various sizes from the right atrium.
The Brockenbrough needle that is used today for transseptal puncture is available in different configurations. The standard adult needle (BRK) has an angle of 19 ° between the distal curvilinear region and in the body, while the adult BRK-1 needle has an angle of 53 ° and offers greater curvature.
The needles are made of stainless steel with a gauge of 18, tapered to 21 Gauge at the end. Both devices are available in adult lengths of 71 cm, 89 cm and 98 cm. There are pediatric versions with a length of 56 cm and with intermediate curves options (BRKTM and BRK-2TM).
Coupled to this system is usually used the introducer Mullins which is about 60 cm long with a large 180 ° bend on the distal tip and a size of 8 Fr or 10 Fr.
Mitraclip prosthesis implant, Cardioband device implantation, paravalvular leaks closure and occlusion of the Left Atrial Appendage (LAA), require a very precise inter-atrial septum puncture, with different characteristics and positions.
In the first case, the Mitraclip needs a puncture in the upper and posterior region of the septum in order to have sufficient space in the left atrium for movement, angulation and orientation of the catheter with respect to the mitral valve plane.
The height of the puncture with respect to the valvular plane is also of fundamental importance, to allow an optimal freedom of movement of the catheter in the left atrium.
In case of implantation of the Cardioband device, the type of puncture will instead be dictated by the anatomy of the ventricle under examination and will be guided by the CT reconstruction that is performed for each individual patient in the pre-procedure screening phase.
Also in the case of Leak valves and occlusion of LAA the transseptal puncture must be superior and posterior, all guided and established by a previous CT evaluation.
The common denomintor for the transition of the inter-atrial septum will be the optimal achievement of the anatomical area under examination, made possible only through an extremely precise puncture, which will be a predictor of success for the procedure.
The use of the electrosurgical unit during the puncture phase will allow an optimal management of the Brokenbrough needle to reach the lesion target. The main advantage of the RF is negation of mechanical pressure, potentially reducing excessive ‘jump’ and the subsequent complications of catheter exit, a reduction

of puncture and fluoroscopy time.

CONCLUSIONS

The correct puncture of the inter-atrial septum determines a better management of the devices used and a reduction of the procedural and radio exposure times. These factors should therefore be considered as important predictors of success in all transseptal approaches, reducing the rate of adverse events such as iatrogenic defect of the inter-atrial septum (iASD), cardiac tamponade or aortic perforation.

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Safety of distal vs. standard radial artery access for coronary angiography and interventions: a single-centre prospective study

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THEME: Coronary Interventions
TOPIC(S): NSTEMI, Stable CAD

AIMS

To evaluate the incidence of radial artery occlusion with distal transradial access in the anatomical snuffbox versus standard transradial access on the forearm for coronary interventions in patients with ischaemic heart disease.

METHODS AND RESULTS

We conducted a single-center prospective study in patients (n = 246) with acute coronary syndrome and chronic ischaemic heart disease who underwent coronary angiography and/or percutaneous coronary intervention (PCI) via distal (in the anatomical snuffbox) transradial access (n = 169) or standard transradial access (n = 77). Six French sheaths and catheters were used with all patients. Anticoagulation and hemostasis protocols did not differ between two groups. The primary endpoint was a forearm radial artery occlusion in 24–48 hours after the procedure. We assessed radial artery patency using the Doppler ultrasound examination. We found that distal radial access was associated with significantly lower rates of forearm radial artery occlusion in the 24–48 hours following the procedure than standard radial access: 0,6% (n = 1) versus 13% (n=10), respectively (p <0,0001).

CONCLUSIONS

Among patients with acute coronary syndrome and chronic ischaemic heart disease undergoing transradial coronary angiography and interventions, distal radial access is associated with a significant reduction in the incidence of radial artery occlusion.

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Performance of the bioresorbable magnesium-stents Magmaris in ACS: all-comer prospective registry

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

The Magmaris Bioresorbable (BRS) Magnesium-Stent is indicated for improving luminal diameter and stabilize culprit lesions in patients with coronary artery disease including ST-segment elevation as well as Non-ST-segment elevation acute coronary syndrome (ACS). Our objective was to assess the clinical and angiographic characteristics, performance and follow-up of these patients.

METHODS AND RESULTS

A prospective unicenter registry including all patients with ACS treated with Magmaris BRS was done. Baseline demographic and angiographic characteristics, as well as 30-day and 12-month clinical, follow up were prospectively analyzed.

Overall, 26 patients were included (30 lesions including not-culprit ones), 51±9 years-old, 81% (n=21) male, 50% (n=13) hypertensive, 19% (n=5) diabetics, 50% (n=13) dyslipidemics, 70% (n=18) smokers. Most of them presented with STEMI (54%, n=14), followed by NSTEMI (27%, n = 7) and UA (19%, n=5). Only 4% (n=1) underwent previous PCI. During the procedure, other lesions were treated in 23% (n=6). 6F Radial/ulnar access was performed in all patients. 77% of patients were on Ticagrelor, 23% on Clopidogrel.

The most frequent artery treated was LAD (73%, n=19) and RCA (23%, n=6), and the mid segment the most common localization (58%, n=15). Thrombus grade classification was mainly 1-3 (77%, n=20). The QCA analysis revealed 2.76 ± 0.5 mm of ref diameter vessel, 18 ± 5 mm length and 68 ± 10% of stenosis.

In the management, predilatation was performed in 81% (n=21), with Non-Compliant Balloon in 73% (n=19) and postdilatation in 96% (n=25). Mean pressure for predilatation/postdilatation was 14.8 ± 2 and 16.6 ± 2 respectively. Mean scaffold diameter was 3.3 ± 0.3 mm and length 18.7 ± 4.1 mm. Only one case (4%) needed thromboaspiration. One case, (4%) required 2 scaffolds implantation due to distal uncovered plaque. Angiographic success in the target lesion was 100%. Only OCT was used as intracoronary imaging technique, in 50% (n=13) of patients to check/optimize results.

At 1 and 12-month follow-up, the MACE rate was 0% and 4% respectively (1 TLR at 4 month FU managed with metallic-DES implantation). There were no scaffold thrombosis.

CONCLUSIONS

The Bioresorbable Magnesium-Stents “Magmaris” performs extremely well in patients with acute coronary syndrome, with a very low event rate. However, further evaluation in large prospective randomized controlled trials are needed.

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A novel method of local leaflet stress computation on aortic valve bioprosthesis leaflets. In vitro / In silico study

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THEME: Interventions for Valvular Disease

TOPIC(S): TAVI, Other valvular and structural interventions

AIMS

Calcified aortic stenosis is among the most prevalent forms of cardiovascular diseases in the industrialized countries. It is a progressive disease with no effective medical therapy, that ultimately requires aortic valve replacement-either a surgical or very recently transcatheter aortic valve(TAV) implantation. Like traditional surgical bioprosthetic valves, the TAV leaflet tissue calcify and degrade over time. In order to indirectly assess the durability of these valves, a method was developed to estimate local mechanical stress applied on the leaflets, under various hemodynamic conditions.

METHODS AND RESULTS

For in-vitro testing, a double activation simulator was used, with a biological valve (Trifecta 23 mm, St Jude Medical) mounted in the aortic position. Tested heart rate was set to 70bpm, mean aortic pressure to 100 mmHg and stroke volume to 70 ml. A non-contact system based on stereophotogammetry and digital image correlation (DIC) with high spatial and temporal resolution (1000 img/sec) enabled to film and study frame-by-frame the valves' leaflet movement and perform the three-dimensional analysis and deformation measurements. Secondly, the finite element model of the valve was developed, using the microCT scan of tested valve and applying its rheological properties based on experimental data acquired from bi-axial tensile test. Then, an image matching of the numerical and previously analyzed experimental data was made and data transformation was applied using a custom-coded Matlab program. Finally, the deformation obtained from the DIC analysis was applied in the numerical model which allows a realistic opening and closing of each leaflet, in order to calculate the local mechanical stress applied. During the opening, high stress regions were primarily observed in the boundary edge, mostly upper leaflet edge (2.16 MPa), and to a lesser extent at the free leaflet edge (1.16 MPa). During closing, high stress regions were observed at the commissures (1.77 MPa) and to a lesser extent at the belly of the leaflet (0.92 MPa).

CONCLUSIONS

This coupled in-vitro / in-silico method offers a new experimental evaluation of the mechanical stress applied on bioprosthesis leaflets during in-vitro mechanical conditioning, which is important for better understanding and control of the valve durability. This method may be an interesting perspective for percutaneous bioprostheses now rapidly expanding towards lower risk populations, and for which long-term durability remains largely unknown.

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Durable vs. erodable polymer DES in STEMI: an OCT study (DES-OCT study)

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

We sought to compare the healing patterns of biolimus-eluting stents with biodegradable polymer (BES) versus everolimus-eluting stents with permanent polymer (EES) using intravascular OCT in patients presented with STEMI.

METHODS AND RESULTS

Patients admitted for STEMI between October 2013 and June 2015 treated by primary PCI with EES or BES implantation were screened. Patients readmitted in our department, in which an angiographic and OCT control of the culprit lesion was performed at least 6 months after the index procedure, were included in the registry. A total of 20 patients were identified.

The primary endpoint of the study was the difference in percentage of uncovered struts between BES and EES assessed by OCT. Secondary endpoints were percentage of malapposed struts and intimal thickness.

A preliminary analysis of 17 patients was performed and a total of 4306 struts examined (1501 BES vs 2805 EES). BES as compared to EES showed a lower rate of uncovered struts (0.3% vs. 1.7%, $p>0.001$) and malapposed struts (0.3% vs 3.1 %, $p< 0.001$). Moreover, 469 cross sections (CS) were available. The percentage of CS with a ratio of uncovered to total struts > 30% was higher for BES-CS compared to EES-CS (0% vs 2.4%,$p <0.05$). No difference in the intimal thickness was found between the two devices.

The full analysis of the population will be reported at the time of the presentation.

CONCLUSIONS

Little is known about new generation DES in STEMI. This study examine the healing pattern of two new generation devices. Although no final conclusions could be drawn at the moment, BES seem to show a more favourable healing pattern in this setting.

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Impact of coronary calcification on the outcome after intervention with ABSORB coronary artery scaffolds - Insights from the GABI-R Registry

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds, Other Coronary Interventions

AIMS

Metallic drug-eluting stent implantation in patients with calcified lesions is associated with worse clinical outcomes compared to non-calcified lesions. Although implantation of bioresorbable scaffolds in calcified lesions is not recommended, a considerable number of patients with calcified lesions has received such devices and their outcome is not well investigated.

The German-Austrian ABSORB ReglstRy (GABI-R) is the largest registry which enrolled patients treated with Absorb BVS. We sought to investigate the procedural and the mid-term outcomes after BVS implantation in calcified lesions.

METHODS AND RESULTS

Between November 2013 and January 2016, 3326 patients were enrolled in GABI-R. Lesion calcification severity was documented in 96.2% of patients and coronary lesions were classified into moderate to severe (n=1126 lesions), mild (n=1772), and no calcification (n=1375). Patients with more calcification were older (62.44 ± 10.49 vs 61.5±10.9 vs 59.0±11.3 years, Cochran-Armitage test $p < 0.001$), had more diabetes (23.8% vs 20.7% vs 19.2%, p=0.020), more atrial fibrillation (8.8% vs 6.9% vs 5.4%, p=0.005), and more often a previous myocardial infarction (25.2% vs 23.1% vs 19.2%, p=0.002). As expected, lesions were more complex in patients with incremental calcification severity (type B2/C lesions: 52.8% vs 33.4% vs 27.2%, p<0.001). Calcified lesions received more high-pressure predilatations as well as more debulking devices and postdilatations were more frequent with more calcification (75.2% vs. 73.8% vs. 68.5%; p< 0.001). Procedural duration, fluoroscopic time, and amount of contrast medium used were significantly higher in patients with more calcification. Nevertheless, procedural success was achieved in 99% of cases and was not different between the groups (p=0.379).

At 24 months, the rates of cardiovascular death (1.9% vs 0.9% vs 0.4%, p<0.001) and severe bleeding (4.7% vs 3.2% vs 2.0%, p=0.003) were higher with increasing calcification. However, no significant between-group difference was observed in the incidence of definite or possible scaffold thrombosis, target vessel myocardial infarction, target vessel revascularization, or target lesion failure.

CONCLUSIONS

In GABI-R implantation of Absorb BVS in calcified coronary lesions was performed with dedicated lesion preparation and postdilatation and did not result in a higher rate of target lesion failure within 24 months. Nevertheless, coronary calcification severity emerged as a cardiovascular risk marker and was predictive of cardiovascular mortality in the mid-term after coronary intervention.

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Triple therapy post PCI in patients with indication for oral anticoagulation, decision making and guideline adoption in a primary PCI centre

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

To define the decision making process and appropriateness of oral anticoagulation (OAC) and antiplatelet therapy post percutaneous coronary intervention in a real world cohort of patients.

To examine the factors which may contribute to physicians' decision making process with regard to the choice of regimen.

To analyse the initial choice of regime as well as regular assessment throughout the first year of treatment. Appropriateness was then assessed as per the ESC 2017 focused update on dual anti-platelet therapy in coronary artery disease.

METHODS AND RESULTS

This is a single centre retrospective, observational study performed in a primary PCI centre. All emergent and elective patients who had a PCI performed in the year 2017 were extracted from a local database (n=710). The charts of these patients were then reviewed and patients who underwent PCI and also had an indication for oral anticoagulation were identified (n=48).

These patients were then reviewed with regard to choice of antiplatelet and anticoagulation, initially and at one, three, six and twelve months.

Assessment of ischemic and bleeding risks using validated risk predictors (CHADSVASc, HAS-BLED) was performed and patients stratified into three groups; bleeding risk predominating, equipoise and ischaemic risk predominating. The appropriateness of the initial and subsequent strategy was then examined and results presented.

Of the 48 patients eligible for inclusion in the study, bleeding risk predominated in 6, ischaemic risk predominated in 12, and 30 were judged to have balanced bleeding and ischaemic risks.

In the bleeding risk predominant group (n=6), the initial strategy was guideline appropriate in 83% of patients (N=5). After 12 months the strategy was guideline appropriate in 66% of patients (n=4).

In the ischaemic risk predominant group (n=12), the initial strategy was guideline appropriate in 75% of patients (n=9). After 12 months the strategy was guideline appropriate in 50% of patients (n=6).

In the balanced risk group, the initial strategy was guideline appropriate in 93% of patients (n=28). After 12 months the strategy was guideline appropriate in 60% of patients (n=18).

Detailed sub-group analysis was performed and findings will be presented.

CONCLUSIONS

Treatment with antiplatelet agents post PCI is a key principle in reducing ischaemic complications.

Where patients also have an indication for oral anticoagulation the optimal strategy and duration of treatment is uncertain, and guidelines are mainly based on consensus opinion.

At present, in our centre the strategy is based on clinical expertise and experience as well as being mindful of guidelines. Divergence from guidelines increases over time.

Further research in the form of high quality randomised control trials is needed to formulate definite evidence based guidelines for strategy and duration of treatment in patients with indications for OAC and antiplatelet therapy.

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Use of sirolimus-coated balloon in small vessel de novo lesions; short-term follow-up from a single-centre registry

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Use of drug coated balloon (DCB) in de novo lesion is usually preferred in small vessels and the recently reported Basket small 2 trial showed that DCBs were non-inferior to second generation DES. All the available data on DCBs in de novo lesion have been extrapolated from paclitaxcel eluting balloons and the data on limus eluting balloon is lacking. However, when it comes to stents, we prefer limus eluting stent. In this study, we report outcomes from use of limus eluting DCB (MagicTouch, Concept Medical, India) in small vessel disease.

METHODS AND RESULTS

We included all patients treated with MagicTouch DCB between April and October 2018. Results are reported as cardiac death, target vessel myocardial infarction, target lesion revascularisation, target vessel revascularisation and MACE (combination of cardiac death, target vessel MI and TVR).

During the study period, 82 patients (with 97-lesions) with vessel size <3.0 mm were treated with MagicTouch DCB. The mean age of patients were 64.7 ± 11.9 years, 59 (66%) were male and 35% (n=29) had diabetes. Most lesions treated were in the LAD/diagonal system (n=47, 48%) followed by LCx / marginal (n=27; 28%) and RCA/PL/PDA (n=23; 24%). Predilatation was performed in 94% (91-lesions) of cases and of which 42% were with non-compliant balloons and 1% with scoring balloon. Bailout stenting (with DES) was required in 9.3% lesions (n=9) and of which 5 were due to flow-limiting dissections and 4 were due to recoil >50% following DCB use. The mean diameter and length of DCBs were 2.31 mm and 26.1 mm respectively.

During a median follow-up of 144 days (4.8 months) there was no reported cardiac death. Target vessel MI was in 2.4%; n=2, TLR and TVR per lesion were 3% (n=3) and 4% (n=4) respectively. The MACE rate was 6.1%. There were no documented cases of acute vessel closure.

CONCLUSIONS

The short-term outcome from the first ever study on sirolimus eluting balloon in small vessel de novo lesions appears promising with low rates of hard endpoints with no cardiac death or acute vessel closure. The MACE rates appear promising, although we need longer follow-up which is ongoing and we will be able to report outcomes from even longer follow-up during PCR.

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One-year outcomes of long coronary lesions correction with BRS

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Stents and scaffolds

AIMS

To investigate BRS efficacy and safety for long coronary lesions correction and mechanisms of scaffod endotelisation in comparison with DES.

METHODS AND RESULTS

In our single-centre, randomized, prospective clinical study were included 80 patients with chronic stable angina and de-novo stenotic and occlusive long coronary artery lesions (length more than 25mm). All patients were randomized in 2 groups: group 1 (n=40) with BRS Absorb implantation and group 2 (n=40) with DES Xience implantation. Apposition of devices was controlled by coronary angiography and optical coherence tomography (OCT). Extent of the lesion was 39.6 ±12.6mm in group 1 (BRS Absorb) and 36.5±13.0mm in group 2 (DES Xience), length of stented area was 44.9 ±13.5 mm and 41.6 ± 15. 3 mm accordingly. Groups had no statistical difference by demographic and clinical parameters.

Post PCI follow-up included 12 month's observation period. Elective coronary angiography and OCT control were performed after 12 month. In OCT minimal, maximal, mean diameter and area of lumen in stenting zone, amount of malapposed, protruding and uncovered struts, as well as neointima thickness and area were calculated. In addition, peri-strut stent/scaffold evaginations was examined and calculated with every frame of OCT image. STATISTICA 10.0 software was used for processing.

No cases of death and myocardial infarction were observed in 12 month after the lesions correction. There was four cases of target lesion failure in group 1 (BRS): 2 patients with restenosis in BRS, 1 patient with definite scaffold thrombosis (nonocclusive thrombosis on OCT after angina episode) and 1 with probable scaffold thrombosis (reocclusion in scaffold without clinical manifestation). In group 2 (DES) there was three cases of target lesion failure because of restenosis. Difference between groups in target lesion failure was statistically nonsignificant (p>0.5). Cumulative rate of scaffold/stent thrombosis was 2 cases in BRS group and no cases in DES group (p=0.49).

12-month OCT analysis revealed significant reduction of minimal lumen diameter, maximal lumen diameter and mean lumen area in both groups (p< 0.001 in all cases). There was 1.24% of uncovered struts in scaffold group and 9.74% in Xience group, mean neointimal area was 1.18mm2 in scaffold group and 1.42 mm2 in Xience group (p<0.001). OCT-control revealed 12 patients with 53 evaginations in BRS group 1 and 2 patients with 5 evaginations in DES group 2. Mean evagination volume was 11.35mm3 and 2.69mm3 for patient, 3.40mm3 and 0.13mm3 for 40 patients in group 1 and 2 accordingly (p<0.001). The only patient with definite scaffold thrombosis demonstrated the highest evagination volume on OCT – 61.12 mm3, 1.39 mm3 per 1 mm of scaffold with maximal depth up to 1,64mm.

CONCLUSIONS

Both types of implants had equivalent 12 months clinical results. Scaffold/stent thrombosis didn't correlate with neointimal strut coverage, but strongly correlated with extension of peri-strut evaginations. Significantly higher peri-strut evaginations formation rate in coronary vessels with implanted poly-l-lactic acid BRS could be a possible cause of high scaffold thrombosis rate.

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Isolated systolic hypertension in renal denervation using different catheter techniques and technologies - A substudy from the RADIOSOUND-HTN trial

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THEME:
TOPIC(S):

AIMS

Patients with isolated systolic hypertension (ISH) were excluded from recent renal sympathetic denervation (RDN) trials, as they are thought to show a diminished blood pressure (BP) lowering effect following RDN. However, data for a potential interaction between ISH, combined systolic-diastolic hypertension (CH) and different denervation techniques and technologies are scarce, as most as most previous studies used unipolar radiofrequency catheters. Therefore, we used data from the recently published RADIOSOUND-HTN trial comparing three different RDN approaches to investigate this interaction.

METHODS AND RESULTS

One-hundred-twenty patients undergoing RDN in the RADIOSOUND-HTN trial were stratified by having ISH or CH. Of these, 39 underwent radiofrequency ablation of the main renal arteries (MRF-RDN), 39 received a combined ablation of the main renal arteries, branches and accessories (BRF-RDN) and 42 were treated with ultrasound ablation of the main renal artery (US-RDN). Follow up was assessed three months after RDN using ABPM and was available for 117 patients. ANCOVA and logistic regression analysis were used to investigate the interaction between CH/ISH and the used RDN strategy.Patients with ISH were older and had lower systolic and diastolic BP on ABPM at baseline. At 3 months, patients with ISH showed a less pronounced BP lowering effect of RDN as compared to patients with CH (daytime average -5.9 ±11.8 vs. -13.3 ±11.7 mmHg, p = 0.001). This difference was found significant in the MRF-RDN and US-RDN treatment groups (-2.4 ±9.8 vs. -10.6 ±9.4 mmHg and -8.7 ±11.8 vs. -17.3 ±14.2 mmHg for MRF-RDN and US-RDN, p = 0.013 and 0.040 respectively), but did not reach significance level in the BRF-RDN group (-6.3 ±13.1 vs. 10.9±9.2 mmHg, p = 0.24). After adjustment for baseline BP values and age, between-group difference between treatment arms remained significant, while the difference in BP reduction between ISH and CH was not statistically significant (adjusted daytime BP change -10.6 [-13.9 to -7.2] vs. -8.1 [-11.2 to -4.9] mmHg, p = 0.34). Multivariate logistic regression analysis identified CH as the only independent predictor for BP response (defined as drop in daytime ABPM by >= 5 mmHg) at three months.

CONCLUSIONS

Using unadjusted BP values, RDN seems to be more effective in patients with CH than in patients with ISH in this trial, and CH was the only independent predictor for BP response after three months. However, the effect of ISH on daytime BP did not reach statistical significance after adjustment for baseline BP values. Likely, the effect of ISH on RDN outcome has been overestimated in the past. Further research is necessary to investigate the different effects of ISH on BP response for different RDN treatment modalities to optimize preselection and treatment for this patient subgroup ins future RDN trials.

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Impact of target vessel location on procedural and angiographic outcome of rotational atherectomy vs. modified balloons prior to DES implantation in severely calcified coronary lesions: a subanalysis of the PREPARE-CALC trial

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Optimal lesion preparation prior to stent implantation is essential in severely calcified coronary lesions. The impact of lesion location on the differential performance of lesion preparation strategies remains poorly investigated. We sought to compare lesion preparation with either rotational atherectomy (RA) or modified (scoring or cutting) balloons (MB) in lesions located in the left anterior descending (LAD) coronary artery versus non-LAD arteries in the randomized PREPARE-CALC trial.

METHODS AND RESULTS

Patients with documented myocardial ischemia and severely calcified native coronary lesions undergoing percutaneous coronary intervention were randomly assigned to either a strategy of lesion preparation using RA or MB followed by implantation of a new-generation sirolimus-eluting stent with bioabsorbable polymer. The two co-primary endpoints of the trial were: strategy success, defined as successful stent delivery and expansion with attainment of <20% in-stent residual stenosis in the presence of TIMI (Thrombolysis in Myocardial Infarction) 3 flow without crossover or stent-failure, and in-stent late lumen loss at 9 months.

Overall 200 patients were enrolled at two high-volume centers in Germany (n=100 in each treatment group). The mean age was 74.9±7.0 years, 76% were male, and 33.5% had diabetes mellitus. A total of 93 patients had LAD lesions (51 treated with RA and 42 treated with MB) and 107 patients had non-LAD lesions (49 patients treated with RA and 58 patients treated with MB). Strategy success was similar for both strategies for LAD lesions (96.1% in RA group vs. 95.2% in MB group; p=1.00), but procedural (86.2±32.5 vs. 67.3±42.8 minutes; p=0.021) and fluoroscopy time (22.3±10.8 vs. 15.2±10.9 minutes; p=0.004) were longer in the RA group. In contrast, for non-LAD lesions, strategy success was significantly more common with a RA-based strategy compared to a MB-based strategy (100% vs. 70.7%; p<0.001), and procedural (90.3±37.4 vs. 86.7±37.3 minutes; p=0.61) and fluoroscopy time (25.5±13.5 vs. 22.6±14.3 minutes; p=0.31) were comparable. At 9 months, mean in-stent late lumen loss (LLL) was similar for LAD lesions (0.06±0.23 mm in RA group vs. 0.06±0.22 mm in MB group; p=0.87) and non-LAD lesions (0.31±0.41 mm in RA group vs. 0.21±0.45 mm in MB group; p=0.36) according to the lesion preparation strategy, whereas LLL was significantly higher in non-LAD lesions in general compared to LAD lesions (0.25±0.44 mm vs. 0.06±0.23 mm; p=0.001).

CONCLUSIONS

Lesion preparation with either RA or MB before drug-eluting stent implantation in severely calcified coronary lesion is associated with a comparable strategy success rate in LAD lesions. In lesions located outside the LAD, an upfront RA-based strategy may be superior to MB.

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Safety and efficacy of polymer-free biolimus-eluting stents in AMI patients: a RUDI-FREE MI substudy

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(1) ,

THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

New-generation drug-eluting stents (DES) are considered the default treatment in patients with acute myocardial infarction (MI). However, the enhanced thrombotic and inflammatory status of MI would require a DES technology with a particularly high biocompatibility. Among current DES, the polymer-free biolimus-A9-eluting stents (PF-BES) can offer more potent anti-inflammatory and anti-thrombotic effects related to the lack of polymer coatings and to the lipophilic properties of the biolimus. However, safety and efficacy data of PF-BES in acute MI are still limited.

METHODS AND RESULTS

The RUDI-FREE (PolymeR free biolimUs eluting stent implantation in all comers population: analysis of DAPT cessation and clInical outcome after BioFREEdom stent implantation) was a prospective registry including 1,104 all-comer patients treated with PF-BES at 16 Italian centers, between January 2015 and May 2016. The present analysis compared clinical outcomes of patients presenting with MI (n=311) versus those with stable disease/unstable angina (“non-MI”, n=793). The primary endpoint was the composite of cardiovascular death, MI or definite/probable stent thrombosis (ST) at 1 year.

Patients with MI compared with those non-MI were significantly younger (67.1±12.1 vs. 69.3±10.8 years, p=0.004), more frequently smokers (49.8% vs. 42.5%, p=0.03), and less commonly had hypertension (75.6 vs. 81,8%, p=0.02), and dyslipidemia (53.1% vs. 64.4%, p=0.001), while diabetes proportions were similar between the two groups (28.9% vs. 30.4%, p=0.69). More severe symptoms of heart failure (NYHA class 10.3% vs. 2.5%, p<0.001) and lower left ventricular ejection fraction (46.7±10.1 vs. 50.8±10.8%, p<0.001) were observed among MI versus non-MI patients, respectively. The CRUSADE bleeding score was similar between groups. In total 1,667 lesions were treated: 544 (32.6%) in MI and 1123 (67.4%) in non-MI patients. No significant differences in the treated vessel were found according to MI presentation. Among MI versus non-MI patients, more chronic total occlusions were treated (16.7% vs. 8.2%). Proportions of other lesion characteristics (i.e. ostial location, bifurcations, calcifications) were similar between the two groups. With regards to the procedural characteristics, among MI patients a significantly higher rate of stent overlap (40.8% vs. 35.2%, p=0.03) was observed. Finally, at 1 year, 75% of patients in both groups were on dual antiplatelet therapy. No significant differences between the two compared groups were observed for the 1-year rates of the primary endpoint (3.5% in MI vs. 4.3% in non-MI patients, p=0.69) and other ischemic outcomes, despite numerically lower target lesion revascularization and ST occurred in the MI group. The 1-year rates of bleeding tended to be higher in the MI group. At multivariable analysis, the association of MI with lower events was not statistically significant. Moreover, regardless of clinical presentation bifurcation lesions and stent overlap emerged as significant independent predictors of ischemic events.

CONCLUSIONS

The PF-BES has been associated with similar favorable efficacy and safety in patients with and without MI. The 1-year absolute event rates were low among patients with MI, despite the relatively high complexity of the latter population. If this DES technology might offer some advantages in MI patients has to be further investigated.

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Everolimus-eluting BRS for treatment of coronary artery disease in patients with diabetes mellitus: the mid-term follow-up of the prospective ABSORB DM Benelux study

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds, Left main and multivessel disease

AIMS

Percutaneous coronary intervention (PCI) in patients with diabetes mellitus (DM) remains challenging even in the era of second-generation drug-eluting stents (DES) due to high rates of repeat revascularization. Everolimus-eluting bioresorbable scaffold (EE-BRS), might allow for repeat intervention prolonging the time interval of percutaneous treatment options. We intend to evaluate the midterm safety and efficacy for EE-BRS in CAD treatment in DM patients for any indication.

METHODS AND RESULTS

The ABSORB DM Benelux Study is a dedicated prospective, international study in DM patients with anatomically low-risk lesions that underwent treatment with ≥1 EE-BRS. Study endpoints were major adverse cardiac events (MACE): a composite of all-cause death, any myocardial infarction (MI) and ischemic-driven target vessel revascularization (TVR); target lesion failure (TLF): a composite of cardiac death (CD), target vessel MI, and ischemic-driven target lesion revascularization (TLR), as well as definite or probable scaffold thrombosis (ScT). Between April 2015 till March 2017, 150 DM patients and 188 lesions were treated and followed up to three years. Device implantation success was 100%. MACE occurred in 15.2% (event rate of 8.8 per 100 PY) contributed by all-cause death in 3.4%, any MI in 4.9% and ischemic-driven TVR in 9.3%. TLF was reported in 11.7% (7.0 events per 100 PY). CD, target vessel MI, ischemic-driven TLR occurred in 3.4%, 3.6% and 5.5% respectively, while ScT was observed in 1.4%. There were no occurrences of late or very late ScT. In a multivariate Cox regression model adjusted with age, gender and indication angiography, DM treated with insulin showed a trend as predictor for both MACE and TLF (HR 2.01; 95% CI: 0.80-5.04; p = 0.14 and HR 2.54; 95% CI: 0.93-6.97; p = 0.07 respectively).

CONCLUSIONS

EE-BRS for treatment of non-complex CAD in DM patients shows comparable safety and efficacy midterm outcomes when historically compared with modern DES. New-generation EE-BRS might offer an attractive alternative to metallic DES in treatment of fast progressing atherosclerosis population as in DM patients.

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Baseline and post-procedural NT-proBNP predict mortality up to one year better than STS and Euroscore II after TAVI

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Aims: N-terminal pro-brain natriuretic peptide (NT-proBNP) correlates with aortic stenosis severity, but its significance after transcatheter aortic valve implantation (TAVI) is still debated. The aim of the present study is to estimate the prognostic value of NT-proBNP after TAVI.

METHODS AND RESULTS

Methods and Results: A retrospective analysis of 225 consecutive patients referred to Cardiocentro Ticino for TAVI between September 2011 and December 2016 was performed. Baseline and post-procedural NT-proBNP were measured and patients were divided in tertiles. Predictors for one-year mortality were assessed by Cox regression. Areas under the curve of baseline NT-proBNP and post-procedural NT-proBNP for one-year mortality were 0.705 and 0.760 with a p<0.001, compared to 0.632 (p=0.042) and 0.651 (p=0.009) for ESII and STS respectively. Baseline NYHA Class III or IV (p=0.02), Dialysis (p=0.05), STS score (p=0.002), ESII (p=0.042), Creatinine (p=0.04), Hb (p=0.001), CK-MB (0.03), baseline NT-proBNP (p=0.006), post-procedural NT-proBNP (p<0,001), impaired LVEF (p=0,02) were associated with one year mortality. Baseline NT-proBNP (p=0,002), post-procedural NT-proBNP (p=0,001) and LVEF (p=0,007) were associated with one year mortality as well as minor stroke, life-threating bleeding and major vascular complication (p<0.001). Patients with higher baseline NT-proBNP (higher tertile ±680 ng/ml) as well as post-procedural NT-proBNP (higher tertile ±462 ng/ml) had increased risk of all-cause mortality (p=0.015 and p<0.001 respectively) and cardiovascular death up to 1 year (p=0.121 and p=0.013).

CONCLUSIONS

Conclusions: Baseline and post-procedural NT-proBNP as well as LVEF predict mortality in TAVI, particularly in patients with the higher tertiles.

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The use of direct oral anticoagulation compared to vitamin K antagonists (warfarin) in patients with left ventricular thrombus after AMI

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

Current guidelines recommend the use of Vitamin K Antagonist (VKA) for up to 3 – 6 months for the treatment of LV thrombus post- acute myocardial infarction (AMI). However based on evidence supporting the non-inferiority and potential superiority of Direct Oral Anti-Coagulation's (DOAC) compared to VKA for other indications such as atrial fibrillation, DOACs are being increasingly used off licence for the treatment of LV thrombus post AMI. In this study we investigated the effect of DOACs compared to VKA on LV thrombus resolution and their safety profile in patients presenting with AMI.

METHODS AND RESULTS

This was a prospective observational study of 2,328consecutive patients undergoing Percutaneous Coronary Intervention (PCI) for AMI between 2015- 2018, at a UK cardiac centre. Patients' details were collected from the hospital electronic database. The primary end-point was the rate of resolution of LV thrombus with bleeding rates as a secondary outcome.

Left ventricular (LV) thrombus was diagnosed by echocardiography, or cardiac magnetic resonance imaging in 98 (5.1%) patients. Sixty patients (61.2%) were started on VKA and 38 patients (38.8%) on DOAC therapy (Rivaroxaban: 57.9%, Apixaban, 36.8% and Edoxaban: 5.3%). Both groups were well matched in terms of baseline characteristics including age, previous cardiac history (Previous MI, PCI, CABG), and cardiovascular risk factors (Hypertension, Diabetes, Hypercholesterolaemia).

Over the follow up period (median 1.8 years), overall rates of LV thrombus resolution were 86%. There was greater and earlier LV thrombus resolution in the DOAC group compared to patients treated with warfarin (75% vs 53%, p=0.0018, at 1 year), which persisted after adjusting for baseline variables (OR 1.8 95% CI 1.2-2.9). Major bleeding such as intracranial bleed, major GI bleed and bleed requiring hospital admission were lower in DOAC group, compared with VKA group (0% vs 5%, p= 0.030)with no difference in rates of systemic thromboembolism (p=0.388).

CONCLUSIONS

This data suggests improved thrombus resolution in post ACS LV thrombosis in patient treated with DOACs compared to vitamin K antagonists. This improvement in thrombus resolution was accompanied with a better safety profile for the DOAC patients' vs VKA treated patients. This supports the need for randomised controlled trials to confirm this observational data.

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Hybrid coronary percutaneous treatment with metallic stents and everolimus-eluting BRS: two-year results from the GABI-R registry

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

The limitations of the first generation of first-generation everolimus-eluting coronary bioresorbable scaffolds (BVS) against drug-eluting stents (DES) have been demonstrated in several randomized controlled trials. Less data are however available regarding the outcomes of patients receiving hybrid stenting with both BVS and DES.

METHODS AND RESULTS

Patients undergoing BVS implantation from November 2013 to January 2016 at 93 centers in Germany and Austria were prospectively collected in the GABI-registry. Of 3265 patients enrolled and with a 24-months follow up, 435 patients (age 62±10, 19% females) with 970 lesions received at least one BVS and one metal stent (hybrid group). These patients were compared with the remaining 2790 (3308 lesions) who received BVS only. Patients who had received hybrid stenting had more frequently a history of cardiovascular disease and revascularization ($P<0.05$), had more frequently multivessel disease ($P<0.001$), and the lesions treated in these patients were longer ($P<0.001$) and more frequently complex (B2/C type: $P<0.05$). Accordingly, the incidence of periprocedural complications ($P<0.05$) and that of cardiovascular death, target vessel and lesion failure and any PCI at 24 months was lower in the BVS-only group (all $P<0.05$). The 24-months rate of definite + probable scaffold thrombosis was 2.7% in the hybrid group and 2.8% in the BVS-only group, while that of stent thrombosis in the hybrid group was 0.5%. In multivariable analysis, only implantation in bifurcation lesions emerged as predictor of device thrombosis, while device type was not associated with this outcome ($P=0.21$).

CONCLUSIONS

The higher incidence of events in patients receiving hybrid stenting reflects the higher complexity of the lesions in these patients; in patients treated with an hybrid strategy, the type of device implanted did however not influence patients´outcomes.

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Three-year safety and efficacy in the Global Symplicity registry: subgroup analyses

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THEME:
TOPIC(S):

AIMS

The Global Symplicity Registry (GSR) is a prospective, multi-centre, single-arm clinical study to evaluate the safety and efficacy of renal denervation. To better define the long-term safety and efficacy of renal denervation, post-hoc analyses of several subgroups within GSR were completed.

METHODS AND RESULTS

Patients with uncontrolled hypertension and/or conditions associated with sympathetic nervous system activation are enrolled in GSR. Planned follow-up duration is 3 years to assess office blood pressure, 24-hour ambulatory blood pressure, and adverse events. Subgroups analysed include: patients with type II diabetes mellitus, age over 65 years, and baseline eGFR <60 mL/min/1.73m2. There are currently 2,583 patients enrolled in GSR at 196 centres. For the entire cohort, mean age is 60.9 ± 12.0 years, 58.1% male, 38.2% with type 2 diabetes mellitus, and 20.3% with baseline eGFR <60 mL/min/1.73m2. Office and 24-hour systolic blood pressure reductions at 3 years were -16±29 (n=1093) and -9±20 (n=465) mmHg, respectively (both p<0.0001 from baseline). At 3 years, rate of new renal artery stenosis >70% was 0.3% and rate of renal artery reintervention was 0.6% for the entire cohort. Subgroup analyses found similar office systolic blood pressure reductions at 3 years for patients with type 2 diabetes mellitus (-17±27 mmHg, n=426) and age ≥65 years (-18±28 mmHg, n=437), and patients with baseline eGFR<60 had a reduction of -12±30 mmHg (n=230), (p<0.0001 from baseline for all). Mean 24-hour systolic blood pressure reduction at 3 years was similar for patients with type 2 diabetes mellitus (-10±18 mmHg, n=186), age ≥65 years (-9±18 mmHg, n=188), and baseline eGFR <60 (-10±20 mmHg, n=108), all p<0.0001 from baseline. At 3 years, adverse events rates for the entire cohort were 5.4% death, 2.6% myocardial infarction and 4.3% stroke. For noted subgroups, rates of death, myocardial infarction and stroke were 6.9%, 4.1% and 3.5% for patients with type 2 diabetes mellitus; 9.1%, 2.5%, and 5.0% for patients over 65 years old; and 9.3%, 3.3%, and 6.3% for patients with baseline eGFR <60, respectively.

CONCLUSIONS

Follow-up data at 3 years in GSR support the long-term safety and efficacy of renal denervation. Post-hoc subgroup analyses show significant 24-hour systolic blood pressure reductions at 3 years in multiple higher risk sub groups including type 2 diabetes mellitus, age over 65 years, and baseline eGFR <60 mL/min/1.73m2.

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Is rotational atherectomy using the radial access safe in patients with severe aortic stenosis? A propensity matched analysis

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Since the introduction of transcatheter aortic valve implantation (TAVI), percutaneous coronary intervention (PCI) has been increasingly performed in elderly patients with severe aortic stenosis (AS) and a higher incidence of vascular calcification. However, rotational atherectomy (RA) has not been routinely used in patients with AS due to safety concerns. We explored peri-procedural safety and outcomes in patients with severe AS undergoing RA.

METHODS AND RESULTS

Clinical, echocardiographic, procedural and outcome data of patients having RA PCI with the Rotablator® system (Boston Scientific) between January 2012 and July 2018 were retrospectively extracted from a single-centre coronary database. Patients with severe AS undergoing RA PCI were 1:1 propensity matched for age, gender, poor left ventricular ejection fraction (≤30%) and procedural urgency with patients undergoing RA PCI in the absence of AS.

Procedural outcomes were adjudicated by two independent interventional cardiologists and included slow flow/ no-reflow, coronary perforation, coronary dissection, haemodynamic instability, intra-procedural death, 30-day and 1-year mortality. A pre-specified subgroup analysis examined the influence of TAVI on mortality following RA PCI. Kaplan-Meier survival analyses and Cox-regression models were employed. Peri-procedural death(s) were excluded in landmark analyses. All statistical analyses were performed with SPSS 24.0 (IBM Inc. New York USA).

544 patients underwent RA PCI; 478 without AS and 66 with AS. Following echocardiographic analyses, 17 patients with moderate AS according to ACC guidelines were excluded. Propensity matching identified 35 matched pairs with a mean age of 81 and median LVEF of 50% (45, 55). Post-matching, balance in covariates of interest (absolute standardised mean differences <20%) improved, but the baseline characteristics of the two groups did not differ significantly.

Radial access and a sheathless guide catheter were used to perform RA. Burr speeds were 150,000 rotations per minute and the intention was to use a single burr. Elective temporary wire pacing was only performed in one patient. Vasodilators were generally avoided, and drug eluting stents were implanted at the discretion of the operator.

Slow flow/no-reflow, coronary dissection and haemodynamic instability were rare and did not significantly differ between severe AS and non-AS RA patients; 6% vs 0%, 0% vs 3% and 6% vs 0% respectively. One intra-procedural death occurred in a severe AS patient who developed haemodynamic instability secondary to no reflow prior to lesion pre-dilatation. 30-day and 1-year mortality was numerically higher in severe AS patients; 14% vs 0% and 6% vs 26% respectively.

Survival analyses revealed significantly lower 30-day (Log-Rank p=0.02) and 1-year survival (Log-rank p=0.02,

HR 5.24 [95%CI 1.13-24.28]) in the severe AS group. Survival curve separation was evident within 50 days from RA PCI but did not expand thereafter. A subgroup analysis showed that not proceeding to TAVI within a year from RA imparted a 5-fold increase in the hazard of death HR 4.98 [95%CI 1.03-24.1], while the survival probability of patients who had TAVI was not significantly different to the survival probability of RA patients without severe AS HR 1.96 [95% CI 0.28-13.91].

CONCLUSIONS

Radial RA PCI in patients with severe AS was safe and outcomes after TAVI were good. Patients with severe AS that did not proceed to TAVI had poor outcomes despite PCI.

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Impact of body mass index on clinical outcomes in all-comer patients with coronary artery disease undergoing PCI: insights from the Global Leaders study

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

We aimed to assess a relationship between baseline body mass index (BMI) and clinical outcomes at 2 years after PCI and to determine if the outcomes between two antiplatelet strategies depend on baseline BMI.

METHODS AND RESULTS

Global Leaders study compared ticagrelor monotherapy after 1 month of dual antiplatelet therapy (DAPT) with aspirin monotherapy after 12 months of conventional DAPT in patients undergoing PCI with biolimus-A9 eluting stent.

The primary outcome of current study was all-cause mortality at 2 years after PCI. Secondary outcomes were net adverse cardiac and cerebrovascular event (NACCE) and individual components of the composite endpoint.

Relationship between baseline BMI as a continuous variable and outcomes were determined in the Cox regression model. Non-linearity was assessed using restrict cubic spline function. Patients were classified according to WHO BMI categories; underweight (BMI < 18.5), healthy weight (BMI 18.5-24.9), pre-obese state (BMI 25-29.9) and obesity (BMI ≥ 30). The interaction between baseline BMI categories and antiplatelet strategies were assessed with the interaction term in Cox model.

BMI was available in 15,966 out of 15,968 patients (99.99%) with a median of 27.7 kg/m2 (IQR 25.0-30.7). Reverse J-shaped association was found in the relationship between baseline BMI and log-hazard of 2-year all-cause mortality with the lowest hazard at the BMI of 29.8 kg/m2. Baseline BMI was negatively associated with log-hazard of 2-year NACCE. At baseline, 3901 patients (24.4%) were in the group of healthy weight, 79 patients (0.5%) were under-weight, 7220 patients (45.2%) were pre-obese and 4766 patients (29.8%) were obese. Due to very small number of underweight patients, outcomes after PCI were compared among three groups; healthy weight, overweight, and obesity.

Pre-obese and obese patients had lower risk of 2-year all-cause mortality than healthy-weight patients (HR pre-obesity vs. healthy-weight 0.71, 95% CI 0.58-0.88, HR obesity vs. healthy-weight 0.69, 95% CI 0.54-0.87). The risk of 2-year NACCE was similar among three groups (healthy weight vs. pre-obesity; HR 1.04, 95% CI 0.94-1.16, healthy weight vs. obesity; HR 1.04, 95%CI 0.93-1.16). No significant difference in risk of any stroke, any MI, and in BARC3 or 5 bleeding was found among three groups. Pre-obese patients had higher risk of any revascularization than patients with healthy weight (HR 1.19, 95%CI 1.04-1.35). The risk of any revascularization in obese patients was numerically higher than healthy-weight patients (HR 1.14, 95%CI 0.99-1.31).

With respect to the BARC 3 or 5 bleeding at 2 years, ticagrelor monotherapy was more favorable in obese patients (HR reference/experimental 1.63, 95% CI 1.06-2.52) while conventional DAPT strategy was more

favorable in pre-obese patients (HR experimental/reference 0.76, 95% CI 0.55-1.05) with P interaction 0.02. There was no interaction between treatment strategy, BMI categories, and other outcomes.

CONCLUSIONS

Pre-obese and obese patients had lower risk of all-cause mortality at 2 years after PCI than patients with healthy-weight. An obesity paradox, an association between elevated BMI and lower mortality, is still evident in this large PCI population. Effect of two antiplatelet strategies after PCI on bleeding risk may depend on baseline BMI.

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Ischaemic and bleeding prediction with DAPT score in patients with event free at one year in the Global Leaders study

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

We aimed to assess the value of DAPT risk score in predicting ischemic and bleeding in patients who were free from the ischemic and bleeding event within 1 year after PCI. We also evaluated the utility of DAPT risk score to guide antiplatelet strategy at 1 year after PCI.

METHODS AND RESULTS

Global Leaders study compared 2-year efficacy and safety of two strategies of antiplatelet therapy in all-comers patients undergoing PCI with biolimus-A9 eluting stent. One year after PCI, patients in the experimental group continued ticagrelor monotherapy for 12 months while patients in the reference group received aspirin monotherapy for 12 months. Patients who were free from ischemic and bleeding events up to 1 year after PCI were eligible for this analysis.

Primary ischemic outcome was the composite endpoint of myocardial infarction or definite/probable stent thrombosis and primary bleeding outcome was major bleeding defined as BARC 3 or 5 bleeding between 1 and 2 years after PCI.

DAPT score was calculated in eligible patients. Outcomes were analyzed according to low or high DAPT score (< 2 vs. ≥ 2) and antiplatelet strategies (Ticagrelor monotherapy vs. aspirin monotherapy).

Among 15,968 patients enrolled in the Global Leaders study, 14,219 patients were eligible for the analysis; 8,742 patients with a low DAPT score (< 2) and 5,477 patients with a high DAPT score (≥2).

Between 1 and 2 years, patients with high DAPT score had significantly higher rate of ischemic outcome between 1 and 2 years than patients with low DAPT score (1.7% vs. 0.9%, $p < 0.0001$). Between 1 and 2 years, bleeding outcome between 1 and 2 years was similar between patients with high and low DAPT score (high vs. low; 0.6% vs. 0.4%, $p = 0.38$).

The effect of antiplatelet strategy on the risk of ischemic outcome and bleeding outcome were not different between patients with low and high DAPT score.

CONCLUSIONS

Patients with high DAPT risk score had increased risk of myocardial infarction or definite/probable stent thrombosis between 1 and 2 years after PCI when compared with patients with low DAPT risk score. DAPT risk score failed to stratify patients according to the risk of major bleeding. There were no significant differences between ticagrelor monotherapy and aspirin monotherapy in terms of ischemic and bleeding outcomes between 1 and 2 years after PCI in patients with low and high DAPT risk score.

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Predictive ability of the PARIS risk score in all-comer patients undergoing PCI with DES: external validation in the Global Leaders study

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Two models to predict long-term ischemic and bleeding risk in patients treated with drug eluting stent were developed from the PARIS registry. The discrimination of the scores were moderate with adequate calibration in the ADAPT-DES registry. We aimed to externally validate PARIS risk score in the all-comers PCI population.

METHODS AND RESULTS

The Global Leaders study was a prospective randomized, open label trial comparing two strategies of antiplatelet therapy in all-comers patients treated with PCI. The PARIS ischemic and bleeding scores were calculated in 15968 patients in the Global Leaders study. Ischemic outcome was coronary thrombotic event (CTE) defined as myocardial infarction or definite/probable stent thrombosis at 2 years. Bleeding outcome was major bleeding (MB) defined as BARC 3 or 5 bleeding at 2 years. The outcomes were assessed according to the PARIS ischemic and bleeding risk categories. Discrimination was assessed by the C-statistics. Due to the substantial difference between patients in the PARIS registry and Global Leaders study, calibration assessment was performed by applying the regression coefficients of the PARIS model using survival constant and mean values of the predictors in the Global Leaders population.

The 2-year CTE rate were 2.6, 3.9 and 7.0% in the low, intermediate and high risk group according to PARIS ischemic score respectively (p value < 0.001). MB rate at 2 years were 1.5, 2.6 and 6.0% in the low, intermediate and high bleeding risk groups respectively (p value < 0.001). Discrimination for both outcomes were moderate (c-statistic for CTE 0.61, 95%CI 0.59-0.63, c-statistic for MB 0.63, 95%CI 0.59-0.66). Agreement between predicted and observed CTE or MB in majorities of the population were acceptable. Both ischemic and bleeding score overestimated CTE and MB rate in very high risk group. The effect of two antiplatelet strategies on the CTE and MB were not significantly different among patients in the low, intermediate and high risk groups.

CONCLUSIONS

PARIS risk score identified patients with different risk for CTE and MB at 2 years. Overall discrimination of the score for both outcomes were moderate. The scores estimated long-term CTE and MB well in the majorities of the all-comers patients.

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A single-centre experience with paclitaxel DEB in dealing with CTO of the coronary arteries

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

A chronic total occlusion (CTO) is defined as the complete obstruction of a coronary artery, exhibiting TIMI 0 or TIMI 1 flow, with an occlusion duration of >3 months. The prevalence has been described as high as 30% and 13% of cases exhibit more than one CTO. These are a fairly challenging lesion subsets and as such, have been neglected as targets for revascularization. The aim was to study the safety end-points as defined by MACE when dealing with CTO in De Novo lesions as well as In-Stent-Restenosis.

METHODS AND RESULTS

Retrospectively assessed a total of 1536 cases treated with Drug-eluting balloon (DEB) between 2015 and 2017. Out of these cases a total of 143 (9.3%) were noted to have CTO. There were some overlap and in total there were 149 CTO lesions which were treated with DEB, this was due to the fact that 5 patients had more than 1 lesion. Out of the total number of lesions, 112 (75.2%) were De novo lesions and 37 (24.8%) were due to ISR. A residual stenosis post deployment of the DEB was considered successful if it was < 30% by visual assessment and if there were no flow limiting dissections.

It was noted that a high number of CTO cases were noted in males 122 (85%), hypertensive patients 112 (78%), dyslipidemia 87 (61%), diabetes mellitus 86 (60%) and history of smoking accounted for 61 (43%) of cases. It was also noted that the mean age group was 58 ± 10 years which is indicative that the disease process is chronic as expected. Only 12 (8.4%) of cases had a diagnosis of acute coronary syndrome (ACS) prior to coronary angiogram and a majority of these cases were driven by either angina or functional testing. It was noted that diffuse vessel disease is most common vessel characteristic and was seen in 138 (92.6%) of cases. The left anterior descending artery 73 (49%) followed by the right coronary artery 54 (36.2%) were the most common coronary vessels involved. Pre-dilatation of the lesions were performed in all cases with a pressure of 12±5 atmospheres, where the mean vessel diameter pre-dilatation was 2.2 ± 0.6mm. The mean inflation time was 65±31 seconds. The mean DEB diameter and dilatation pressure were 2.5±0.4 mm and 8±3 atmospheres, respectively. Flow limiting dissection was noted in 3 (2%) of cases and was treated with bail-out DES. As what was seen in the PEPCAD 1 Trial, we also noted good results where the major adverse cardiac events (MACE) rate was only 4 (2.8%).

CONCLUSIONS

DEB angioplasty is a safe technique in dealing with CTO in both de novo lesions as well as ISR. MACE was defined as target lesion revascularization (TLR), myocardial infarction and cardiac death, this was seen only in 4 (2.8%) patients at 12 months follow-up. It was also noted that the level of residual stenosis post DEB deployment was 11 ± 13% which falls within the globally accepted standards.

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One-year outcome in STEMI patients treated with primary PCI using cobalt chromium everolimus-eluting stent: XIENCE STEMI registry

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Use of cobalt chromium everolimus-eluting stent (CoCr-EES) with a durable-polymer coat has proven to be clinically effective and safe in patients with STEMI. However, there are no prospective multicenter registry evaluating everolimus-eluting stents in Japanese STEMI patients.

METHODS AND RESULTS

The multicenter registry of very early and late clinical outcomes to everolimus-eluting cobalt-chromium stent in patients with ST-elevation acute myocardial infarction (XIENCE STEMI registry) is a prospective multicenter open-label registry investigated STEMI patients who underwent primary PCI using CoCr-EES. Primary endpoint was the cumulative incidence of target vessel failure (TVF) at 12-months after CoCr-EES implantation. TVF was defined as a composite of target vessel-related cardiac death, target vessel-related recurrent myocardial infarction (MI) and target lesion revascularization (TLR). Between June 2016 to August 2017, total of 390 eligible patients were enrolled from 32 Japanese sites. One-year clinical outcome was available for 372 patients (95.4%). Patient mean age was 66.2 ± 11.7 years, 79.3% were male, 29.5% had diabetics, 94.1% received statins. The number of stent implanted per patient was 1.15. Mean stent length was 21.39 ± 5.13mm. Intracoronary imaging was used in 97.4% for the procedure (IVUS; 76.9% and OCT; 20.5%). At 12 months, the primary endpoint of TVF had occurred in 9 (2.42%) patients. There were 3 (0.81%) cardiac death, 2 (0.54%) MI and 6 (1.61%) TLR. Definite or probable stent thrombosis occurred in 3 patients (0.81%).

CONCLUSIONS

In Japanese patients with STEMI undergoing primary PCI, CoCr-EES demonstrated an excellent safety and efficacy profile at 1 year, with a low rate of stent thrombosis even in STEMI setting.

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Comparison of clinical outcomes in Japanese patients with and without high bleeding risk: observations from the e-ULTIMASTER registry

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Management of coronary artery disease in patients with high bleeding risk (HBR) can be challenging as they often have more extensive and complex disease and are also prone to bleeding complications when receiving antiplatelet therapy. Contemporary drug-eluting stent (DES) has the improved safety and efficacy as compared with bare-metal stents and first-generation DES, whereas clinical outcomes of HBR patients treated with contemporary DES in real world practice remain unclear. We sought to assess clinical outcomes of Japanese patients with and without HBR in the e-ULTIMASTER registry.

METHODS AND RESULTS

The e-ULTIMASTER registry is a large, prospective, single-arm, multi-centre registry that is designed to further validate the safety and efficacy of the Ultimaster drug-eluting stent (DES) (Terumo, Japan) in unselected patients enrolled worldwide. Currently, 721 Japanese patients enrolled in the e-ULTIMASTER registry have completed 1-year follow-up. HBR patient was defined as having at least 1 following feature: age ≥75 years, dialysis, previous stroke, and use of oral anticoagulant. The primary study endpoint was the cumulative incidence of a composite of cardiac death, myocardial infarction, stent thrombosis, and clinically driven target vascular revascularization (CDTVR) at 1-year. Any bleeding events were also assessed. A total of 321 patients (44.5%) had at least 1 HBR, of whom 48 (15.0%) were on dialysis, 67 (9.3%) had previous stroke, and 60 (8.5%) used oral anticoagulant. The use of dual antiplatelet therapy tended to be lower in the HBR group than in the non-HBR group at 3-month follow-up (82.6% vs. 87.6%, p = 0.07), but did not significantly differ at 1-year follow-up (59.7% vs. 63.5%, p = 0.34). The primary study endpoint was not significantly different between the HBR and non-HBR groups (8.1% vs. 5.5%, p = 0.18). The rate of cardiac death was significantly higher in the HBR group than in the non-HBR group (2.8% vs. 0.75%, p = 0.04), but no significant differences in myocardial infarction, stent thrombosis, CDTVR, and any bleeding events were not observed in both group (1.6% vs. 0.50%, p = 0.25; 0.31% vs. 0.25%, p = 1.00; 5.0% vs. 4.8%, p = 1.00; and 0.93% vs. 1.25%, p = 0.74, respectively).

CONCLUSIONS

In real-world practice, Ultimaster DES shows comparable outcomes of Japanese patients with and without HBR, although cardiac death occur more frequently in those with HBR. These results suggest that Ultimaster DES is feasible in Japanese patients with HBR.

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Predictors of health literacy among patients undergoing cardiac catheterisation

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Health literacy among patients undergoing cardiac catheterization has not been comprehensively studied. The literature suggests poor health literacy is associated with readmission, loss to follow-up and lower health related quality of life following myocardial infarction. This study investigated the predictors of health literacy in adult patients prior to cardiac catheterization. It also investigated the correlation between health literacy and anxiety in these patients.

METHODS AND RESULTS

Methods

A cross-sectional survey of adult patients scheduled for cardiac catheterization in a large tertiary teaching hospital in Sydney, Australia was undertaken. Health literacy was measured using a 16 item health literacy screening questionnaire comprising six domains. Anxiety was measured using the Depression and Anxiety Stress Scale. All data was analysed using SPSS version 25.

Results

A total of 198 patients completed the survey. The mean scores for each health literacy domain were; navigation 4.06 (SD 0.92), completing forms 3.84 (SD 0.80), following medication instructions 4.24 (SD 0.72), provider-patient interaction 3.87 (SD 0.80), appointment slips 4.08 (SD 0.88), and family/friend support 4.04 (SD 1.25). The mean score for anxiety was 8.28 (SD 5.94).

Females had significantly higher health literacy in the domain ‘following medication instructions’ compared with males (p=0.049). Unemployed patients compared to employed patients had significantly lower health literacy in the domain ‘completing forms’ (p=0.003) and a significantly lower overall health literacy score (p=0.036). Patients who lived with a partner had significantly higher health literacy in the domain ‘navigation’ compared to patients who did not live with a partner (p=0.017).

Higher anxiety scores significantly correlated with lower health literacy in the domains; ‘completing forms’ (p=0.041), ‘provider-patient interaction’ (p=0.006) and ‘appointment slips’ (p=0.021).

CONCLUSIONS

Demographic predictors are important indicators for health literacy in patients undergoing cardiac catheterization. Anxiety is an additional factor associated with low health literacy in these patients. Targeted screening for health literacy and anxiety in patients receiving cardiac catheterization could improve their treatment outcomes and quality of life.

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Procedural death and need of urgent open surgery during TAVR: a single, high-volume centre experience

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI, Other valvular and structural interventions

AIMS

The aim of our study is to analyse the temporal trends of major procedural complications, during 10 years of experience of a single, high volume, centre and to specify predictors of in-hospital events leading to death and complications requiring conversion to emergency surgery.

METHODS AND RESULTS

Transcatheter aortic valve replacement (TAVR) has wider indications than in the past and is considered a safe procedure, thanks to technological improvements and better operator experience. However, even if with a low incidence (around 1%), major procedural complications requiring conversion to open surgery still occur and have a high mortality rate (around 50%). As a consequence, efforts should be done to understand, predict and manage these complications, in order to decrease mortality and expand even more TAVR indications.

We retrospectively analysed clinical and procedural data of 1348 consecutive patients who underwent TAVR at our Interventional Cardiology Unit in Milan between 2007 and 2017, focusing on in-hospital outcomes, defined according to the Valve Academy Research Consortium (VARC)-2 criteria. We also divided our population in quartiles according to the year in which the procedure was performed in order to evaluate temporal trends in baseline characteristics and outcomes.

Statistical analyses were performed with SPSS 20.0 software (SPSS Inc., Chicago, Illinois).

Overall, in ten years of experience, 47 patients (3.5%) died during hospital stay, 19 patients (1.4%) died within 72h of the procedure and 17 patients (1.2%) needed an emergent conversion to open surgery; among operated patients 7 didn't survive (41.2%), 4 died during or soon after emergency surgery and 3 died later due to subsequent complications.

Conversely than expected, comparing the incidence of endpoints among quartiles we didn't find any significant difference. This result is mainly driven by the occurrence of mechanical complications and heart failure events, whose incidence remained constant along all the study period; on the contrary we observed that intensive care related events decreased over time.

On univariate analysis higher risk scores, old generation devices, worse kidney function, TAVR in TAVR procedures and TAVR performed emergently were associated to adverse outcomes; on the contrary hypertension, dyslipidaemia and more recent procedures seemed to be protective.

On multivariate analysis only recent procedures (those of the third and fourth quartiles) showed a significantly low odds ratio.

CONCLUSIONS

Our results underline as potentially fatal complications of TAVR remain an issue despite improvement in technologies and patient selection, and in most of the cases are unpredictable. Operator experience over time and the improved clinical management of the patient, especially in intensive care, could possibly explain the

protective role of 3rd to 4th quartile.

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Transcatheter mitral valve-in-valve implantation to treat paravalvular leak of surgical bioprosthesis: is it feasible?

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair

AIMS

Transcatheter mitral Valve-in-Valve (mViV) implantation has been used to treat prosthetic mitral stenosis, valvular regurgitation, or both. However, mViV has not been used to treat paraprosthetic leak (PVL).

METHODS AND RESULTS

Methods

We retrospectively examined the perioperative three-dimensional transesophageal echocardiography (3DTEE) of 42 mViV patients performed from 2014 to 2018. The indications of mViV included 15 stenosis, 24 regurgitation and 3 combined. The PVL was quantified by the radial jet width using 3DTEE color datasets with multiplanar reconstruction technique.

Results

Six of 6 the 42 (16.7) patients were identified with PVL. Trans-apical mViV were successfully performed in all of them. For those 2 patients with a jet width of <3mm (2.3mm and 2.2mm), the PVL became trivial and/or disappeared after mViV. For the other 4 patients with jet width of PVL >3mm, the PVL severity remained unchanged after mViV. Transcatheter implantation of occlude devices was needed in 2 of them with large PVL (6.6mm and 5mm) because of persistent hemolysis and/or heart failure. Another 2 patients with PVL jet width of 3.2mm and 3.2mm, respectively, were left untreated because they were asymptomatic and hemodynamically stable.

CONCLUSIONS

PVL with a jet width of <3mm may be reduced after mViV for failed mitral surgical bioprostheses. Those PVL sized 3-5mm may be left untreated if the patients are asymptomatic. However, PVL with a jet width of >5mm may need concomitant occluder therapy.

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A relationship between unrecognised anaemia and the development of type 2 diabetes mellitus in patient with cardiovascular risks

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Studies on anemia in diabetic patients are well known. However, the data of anemia on the development of diabetes mellitus (DM) is very paucity. We aimed to evaluate the impact of anemia on the development of DM and major clinical outcomes in a series of the Korean population during 5-year clinical follow-up.

METHODS AND RESULTS

The patients were retrospectively enrolled using the electronic database of Korea University Guro Hospital from January 2004 to February 2013. A total of 17,515 patients without a history of DM were analyzed. The World Health Organization definition of anemia was used. Patients were divided into ps the anemia group (n=2,907 patients) and the non-anemia group (n=14,608 patients). The primary endpoint was the development of DM. To adjust baseline potential confounders, a propensity score matching (PSM) analysis was performed. After PSM analysis, two matched groups (2,731 pairs) were generated and their baselines were balanced. During 5-year follow up, the anemia group had a higher incidence of type 2 DM [10.7% vs. 7.7%, hazard ratio (HR): 1.356, 95% confidence interval (CI): 1.021-1.802, p=0.035], total death [2.6% vs. 1.2%, HR: 2.449, 95% CI: 1.337-4.486, p=0.004] compared to the non-anemia group.

CONCLUSIONS

In the present study, anemia was an associated with higher rate of the development of DM and mortality during 5-year clinical follow-up. A randomized trial is needed to determine whether this results can be reproducible or not for the final conclusion.

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Innate immunity and peri-procedural myocardial injury: the role of HNP 1-3

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Other Coronary Interventions

AIMS

Pro-inflammatory factors impact myocardial perfusion and procedural success after percutaneous coronary intervention (PCI). The human neutrophilic peptide (HNP) 1-3 has claimed a key role in thrombosis amplification. Contact activation pathway occurs spontaneously in serum but not in plasma samples, explaining higher HNP 1-3 levels in serum. Stent implantation activates the contact pathway, therefore we hypothesized that it might induce HNP 1-3 release, reflected by increased blood levels. We sought to evaluate the role of HNP1-3 on myocardial injury (MI) in patients undergoing elective PCI.

METHODS AND RESULTS

Ninety-five troponin-negative patients were assigned to elective PCI. Troponin T was determined at 0, 6 and 18 hours post-procedure. Baseline serum and plasma HNP 1-3 levels were measured using a sandwich ELISA kit. Periprocedural MI was defined as a troponin T increase of 5 times the upper limit of normal. The prevalence of traditional cardiovascular risk factors was comparable between groups with or without MI. After exclusion of patients with slow flow, side branch occlusion or post-interventional ischemic pain (8 cases) the occurrence of uneventful MI was 9.1%. Plasma HNP 1-3 level in participants with MI was 399 pg/ml, as opposed to 588 in the non-MI group (p=0.12), while the serum HNP 1-3 levels were significantly higher in the MI group (1903 vs. 1006 pg/ml, p=0.004). Serum to plasma HNP 1-3 ratio above 2.4 had a positive predictive value of 37%, negative predictive value of 100%, and specificity of 76% and sensitivity of 100% for MI prediction. None of the previous putative risk markers for MI were significantly related to its occurrence in the study group.

CONCLUSIONS

serum to plasma HNP 1-3 ratio is helpful in predicting MI occurrence following elective coronary stenting. Colchicine is a neutrophil stabilizing agent that diminishes HNP 1-3 secretion, and may serve as a promising therapeutic agent in high risk patients. Prioritizing care according to serum HNP 1-3 levels is a new era in personalized medicine.

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Predictors of radiation exposure during primary PCI for STEMI

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THEME:
TOPIC(S):

AIMS

Radiation exposure during medical procedures is of increasing interest and relevance to both patients and clinicians. Since the advent of primary percutaneous coronary intervention (pPCI) ST elevation myocardial infarction (STEMI) morbidity and mortality rates have significantly improved. However, coronary angiography accounts for a disproportionately high amount of medical radiation in the adult population. We sought to determine the predictors of increased radiation exposure during STEMI cases.

METHODS AND RESULTS

We reviewed all patients presenting for pPCI or rescue PCI for STEMI at a single tertiary centre between January 2011 and December 2018. Fluoroscopy time for all patients as well as air Kerma dosage were recorded using a commercially available digital angiography system (Cannon Medical Systems, Otawara, Japan).

A total of 2,151 patients were reviewed. Mean age was 65.6 (± 13.7) with 21.5% females. The mean body mass index (BMI) was 27.4kg/m2 (± 4.6kg/m2). The median fluoroscopy time was 11.3 minutes (IQR: 8.2-16.7 minutes), whilst the median air Kerma was 810 mGy (IQR: 506.0mGy-1274.3mGy).

Older age was associated with a greater fluoroscopy time ($p<0.0001$), but not with air Kerma ($p=0.70$), whilst female sex was associated with lower fluoroscopy time (12.8 mins vs 14.5 mins, $p<0.0001$) and lower air Kerma (854.8mGy vs 1106.9mGy, $p<0.0001$). A higher BMI was not associated with fluoroscopy time ($p=0.17$) but was associated with a higher air Kerma ($p<0.0001$). pPCI performed during day-time hours (8:00am – 8:00pm) were associated with higher fluoroscopy time (19.3 mins vs 14.1 mins, $p<0.0005$) and a higher air Kerma (1238.4mGy vs 1006.7mGy, $p<0.0005$). Lesion location in the native circulation or coronary bypass grafts were not associated with differences in radiation dosage.

In multivariate analysis, time of day when the procedure was performed remained independently predictive of fluoroscopy time ($p<0.05$) and air Kerma ($p<0.0005$), after correcting for age, sex and BMI.

CONCLUSIONS

During pPCI for patients presenting with a STEMI, age, sex, BMI and timing of the procedure impact the fluoroscopy time and radiation dosage. An appreciation of these factors should be taken into consideration and may identify patients whereby strategies to reduce radiation dosage should be implemented.

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Long-term clinical outcomes of late stent malapposition

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

The relationship between late stent malapposition (LSM) and adverse cardiovascular events is still controversial. Therefore, studies evaluating long-term (>5 years) clinical outcomes of optical coherence tomography (OCT)-detected LSMafter drug-eluting stent (DES) implantation are needed.

METHODS AND RESULTS

We investigated long-term clinical outcomes of OCT-detected LSM in 351 patients who received DESsand were examined by both post-stent and follow-up OCT (175±60 days after DES implantation) from January 2009 to December 2011. LSM was observed in 99 patients (28%). We evaluated the cumulative rate of composite events (cardiovascular death, target vessel-related myocardial infarction, target vessel revascularization, and stent thrombosis).

During 80.1±24.5 months of follow-up, very late stent thrombosis did not occur in any of the patients with LSM. The cumulative rate of composite events was 7.3% in patients with LSM and 10.5% in patients without LSM (p=0.822, log rank test). We further divided patients into the following four groups:patients with both late-persistent and late-acquired stent malapposition (n=23), patients with late-persistent stent malapposition alone (n=45), patients with late-acquired stent malapposition alone (n=31), and patients without LSM (n=252); the cumulative rate of composite events was similar among these four groups (0%, 9.6%, 9.7%, and 10.5%, respectively;p=0.468 by log rank test).

CONCLUSIONS

During long-term follow-up (>5 years), very late stent thrombosis did not occur in patients with OCT-detected LSM. The rates of adverse clinical events were similar between patients with LSM versus those without LSM. Presence of OCT-detected LSM was not associated with unfavorable clinical outcomes.

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Balloon aortic valvuloplasty: does the degree of gradient reduction correlate with echocardiographic or clinical endpoints?

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THEME: Interventions for Valvular Disease
TOPIC(S): Other valvular and structural interventions

AIMS

Percutaneous balloon aortic valvuloplasty (BAV) has been used for symptom alleviation in severe aortic stenosis for patients with multiple comorbidities. Often, an arbitrary reduction in mean gradient of 50% is used to delineate success. However, whether this more aggressive reduction in gradients correlates with an improvement in echocardiographic or clinical endpoints is currently unknown. We sought to determine the clinical and echocardiographic effects of differing reduction in aortic valve gradient following BAV.

METHODS AND RESULTS

We reviewed 119 consecutive patients undergoing clinically indicated BAV therapy at a single high volume centre between March 2010 and November 2018. We subsequently focused our analysis on those patients with severe aortic stenosis defined as having a mean aortic gradient >40mmHg (n=67). We classified a reduction in mean aortic valve gradient (AVG) of >50% as an aggressive reduction, whilst a reduction of <50% was defined as a modest reduction. We reviewed hospital electronic medical records to ascertain mortality, TAVR implantation and unplanned re-hospitalisation rates in patients undergoing BAV. We reviewed echocardiograms performed prior to and following BAV for systolic and diastolic parameters, including mean AVG, aortic valve area (AVA), left ventricular ejection fraction (LVEF), left atrial size (LAS) and tricuspid regurgitant jet (TRJ). Statistical analysis with Log-Rank (Mantel-Cox) tests was conducted using GraphPad Prism 7.0b. Patients were censored from analysis once they received TAVR.

The mean age of patients was 82.2±7.6 with 52% males. Twenty patients went on to undergo TAVR in the total population. The mean AVG in the population was 56.8mmHg, the mean AVA was 0.66cm2 whilst the mean LVEF was 56.7%. A total of 14.3% of patients achieved an aggressive reduction in mean gradient, with 85.7% having a conservative reduction. In patients with an aggressive reduction in mean AVG, there was a significant increase in the percentage change in AVA (48.7±22% n=7 vs 12.9±6% n=40, p<0.05). However there was no difference in percentage change in LVEF (6.4±4% n=8 vs 3.1±3% n=42;p=0.65), LAS (-13.6±5% n=6 vs -1.4±2% n=41;p=0.10) or TRJ (-25.4±19% n=6 vs -3.5±3% n=22;p=0.07). There was no significant difference in unplanned re-hospitalisation or mortality at 90 days (p=0.446).

CONCLUSIONS

Following BAV, a more conservative as compared to a more aggressive reduction in mean AVG does not result in inferior systolic or diastolic echocardiographic indices or worse clinical outcomes. This suggests that in the setting of unfavourable aortic annular characteristics such as eccentric calcification whereby an aggressive reduction in mean AVG is difficult or unsafe to attain, a more conservative reduction does not result in poorer clinical or echocardiographic outcomes. Whilst there is no difference in hospitalisation rates for heart failure, whether the degree of AVG reduction correlates with ambulatory symptom improvement requires further investigation.

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The statin impact for coronary atherosclerotic plaque progression according to high-risk plaque features and luminal narrowing in moderate stenosis lesions by serial coronary CT angiography

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

The protective effects of statins on atherosclerotic plaque progression have been well demonstrated. However, the statin benefits according to high risk plaque (HRP) and luminal stenosis had not been well identified. Therefore, we investigated the plaque progression according to HRP features and diameter stenosis by serial coronary computed tomography angiography (CTA).

METHODS AND RESULTS

The 1,645 intermediate stenosis (25% ~ 70%) coronary artery lesions from 705 patients were evaluated by serial CTA at a ≥2-year inter-scan interval. Atherosclerotic plaques were quantitatively analyzed for annual plaque volume (APV) change according to HRP (positive remodeling, low attenuated plaque, spotty calcification, and napkin ring sign) and diameter stenosis percentages. Compared to those with no HRP lesions, ≥2 HRP lesions showed higher APV changes in both the no statin use (4.90mm3 vs. 10.57mm3, $p < 0.001$) and the statin use (3.35mm3 vs. 7.67mm3, $p < 0.001$) groups (Figure 1). However, in more than 2 HRP lesions, the statin use group showed significantly lower plaque progression than the no statin use group (7.18mm3 vs. 13.04mm3, $p = 0.0021$). While in 61 to 70% of stenosis lesions, statin treatment did not prevent plaque progression (Statin use 8.11mm3 vs. No statin 8.76mm3, $p = 0.954$), and in 25 to 50% of stenosis lesions, plaque progression was significantly reduced by statin therapy (Statin use 4.27mm3 vs. No statin 6.34mm3, $p < 0.001$).

CONCLUSIONS

Our analysis demonstrated that the plaque progression of the intermediate stenosis with HRP lesions could be greatly reduced by statin treatment. However, statin effect could be limited to higher degree intermediate stenosis lesions when compared to lower degree intermediate stenosis lesions.

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Vascular safety of distal renal denervation in segmental branches of renal artery

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THEME: Interventions for Hypertension
TOPIC(S): Renal denervation

AIMS

Distal renal denervation in segmental braches of renal artery demonstrated greater efficacy in terms of blood pressure lowering than main trunk treatment but is it likewise safe for the lower sized distal vasculature?
To assess vascular safety of the distal renal denervation done by most commonly used Symplicity Spyral denervation system.

METHODS AND RESULTS

Optical coherence tomography (OCT) of segmental branches was done before and after the treatment using the following parameters: 30 ml of contrast injected at the rate of 12 ml/min with automatic pullback 20 mm/s. Of 198 mm of segmental arteries studied in 7 patients 109 mm covering 36 treatment points had sufficient quality of pre- and post-treatment imaging. After visual analysis of treated segments for structural changes the lumen area, lumen mean diameter, intima-media thickness (IMT) and cross-sectional area of intima-media layer (area between external basal membrane and lumen) were measured at the specific distances from bifurcation corresponding to the angiographically measured distances between electrode positions and bifurcation during the treatment. No structural changes of arterial wall, dissections or local thrombi were detected after the treatment. However, mean lumen diameter of the branches slightly but significantly decreased (from 4.78+/-0.76 to 4.63=/-0.70 mm, $p<0.0005$) while the IMT increased (from 0,27+/-0,046 to 0,29+/-0,046 mm, $p<0.0001$) indicating angiographically undetected small-scale spasm of arterial wall in response to the treatment.

CONCLUSIONS

Our data show that distal renal denervation by most widely used Symplicity Spyral denervation system is safe for segmental branches of renal artery.

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Safety, feasibility, efficacy and impact on frailty of transradial balloon aortic valvuloplasty: report of the first 100 patients from the SOFTLY-II study

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THEME: Interventions for Valvular Disease
TOPIC(S): Other valvular and structural interventions

AIMS

The spreading of transcatheter aortic valve replacement (TAVR) has paradoxically increased the indications for balloon aortic valvuloplasty (BAV), especially as stratification or bridging tool for TAVR. Nevertheless, BAV-related adverse events are reported in more than 15% of patients with a 9-10% rate of vascular complications. Thus, the reduction of vascular complications could be appealing in these patients that are frequently old and frail.

The present study sought to evaluate whether a transradial mini-invasive approach can reduce vascular complications and improve frailty before TAVR.

METHODS AND RESULTS

The safety and feasibility of transradial mini-invasive balloon aortic valvuloplasty (SOFTLY II, NCT03087552) is a multicentre, observational, prospective study of consecutive patients with symptomatic aortic stenosis undergoing mini-invasive BAV. The present analysis is a preliminary report of the first 100 patients enrolled in the study by 8 Italian centres. The procedure was performed through radial access and without temporary pacemaker implantation (high-rate pacing was performed through the stiff guidewire positioned in the left ventricle). All participating centres received institutional review board approval and all patients gave written informed consent.

Occurrence of vascular complications and clinical adverse events were recorded at the 30-days follow-up visit. The primary endpoint was 30-days incidence of major or minor vascular complications defined by Valve Academic Research Consortium 2 Consensus (VARC2). Frailty was analysed with the essential frailty toolset (EFT) scale before and 30 days after the procedure.

Median age was 86.6 ± 6.9 years. The main indication for BAV was bridge to decision/TAVR in 80% of the cases, followed by destination therapy (17%) and bridge to SAVR (2%).

In the study population we observed a 97% procedural success rate (in only 3 patient radial access was not feasible). Mean invasive gradient was significantly reduced after the procedure (pre-mean gradient: 42 [30-55] mmHg, post-mean gradient: 22 [13-29] mmHg; p= <0.001). At 30-days follow-up, we observed no major vascular complication and 3% minor vascular complications according to VARC2 classification.

Interestingly, 61 patients were mobilized within 12 hours and 28 patients within 24 hours from the procedure. Frailty level measured with EFT scale was significantly reduced 30 days after the procedure with a decrease of the median score from 4 [3-5] before the procedure to 3 [2-4] at 30 days after the procedure (p=0.026).

CONCLUSIONS

Transradial BAV without temporary pacemaker implantation was safe, feasible and with high-procedural success. Vascular complications were reduced when compared to published data with transfemoral conventional approach. Mini-invasive BAV could also reduce frailty status at the moment of TAVR with consequent possible 1-year mortality reduction in this high-risk population. Future trials are warranted to confirm this hypothesis.

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Stereoscopic fluoroscopy: a new concept as imaging guidance in complex structural heart interventions

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI, Other valvular and structural interventions

AIMS

Stereopsis is the most relevant mechanism of human depth perception. As advanced periprocedural imaging is a key factor for complex structural heart interventions, stereoscopic fluoroscopy emerges as a novel approach, combining the advantages of radiographic projection and in-depth vision during cardiovascular transcatheter procedures. The aim of the current study was to assess the feasibility of stereoscopic fluoroscopy in a bench model for structural valve interventions.

METHODS AND RESULTS

A benchtop simulator was created using a 3D printed model of the entire thoracic aorta based on CT segmentation. A transcatheter aortic valve prosthesis (Portico Valve; Abbott, Illinois, USA) was placed in anatomical correct position within the model along with a pigtail catheter (Cordis, California, USA) and a Safari guidewire (Boston Scientific, Massachusetts, USA). Images were acquired in a hybrid operating room setting using a ceiling mounted stationary fluoroscopy unit (Azurion 7M20 FlexMove Clarity, Philips, Amsterdam, Netherlands).

Stereoscopic fluoroscopic image pairs (Stereopairs) were acquired in an anterior-posterior (AP) view, corresponding to LAO (left-anterior oblique) 0°, CRAN (cranial) 0° as left eye image. Following images were acquired going from LAO 1° CRAN 0° to LAO 4° CRAN 0° as right eye imaging pairs to obtain stereopairs with an angle ranging from 1 to 4 degrees. Additional imaging parameters investigated were the focus point of the C-Arm rotational axis and the interpupillary distance.

Fluoroscopic video stereopairs were created using pre-set C-Arm positions. A horizontal rotational sequence starting from AP view to LAO 20° CRAN 0° was obtained as left eye video. Right eye sequences were recorded starting with LAO 1° CRAN 0° to LAO 21° CRAN 0° until LAO 4° CRAN 0° to LAO 24° CRAN 0°, in order to acquire video stereopairs in four different angles. The described method was also applied for acquiring of stereoscopic rotational cranio-caudal sequences.

Depiction and imaging analysis of the created stereopairs was achieved using a passive stereoscopic monitor based on a beam-splitter technology (PluraView, Schneider Digital, Bavaria, Germany) and passive polarizing glasses.

For validation of stereoscopic imaging, 9 test persons were invited to participate in an imaging assessment based on a short-questionnaire, comparing monoplanar and stereoscopic analysis of both image and video samples. Identification of spatial relation between devices was significantly increased due to stereoscopic depiction ($p=0.023$). Improvement of overall spatial orientation due to stereoscopic depiction was reported in 100 % during still image analysis.

CONCLUSIONS

Intuitive perception of depth due to the mechanism of stereopsis augments spatial orientation and recognition

of procedural environment in a structural heart intervention table-top simulator. Orientation and relation of interventional devices was greatly facilitated by stereoscopic video visualization in a viewer assessment. Stereoscopic imaging could be the missing link between monoplanar fluoroscopy, 3D echocardiography, fusion imaging and natural-depth perception as the next step of evolution in the field of hybrid imaging.

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A single-centre experience with paclitaxel DEB comparing scoring balloon and non-scoring balloon for lesion preparation

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THEME: Coronary Interventions
TOPIC(S): NSTEMI, Stable CAD

AIMS

To compare the safety and efficacy of drug eluting balloons (DEB) using scoring balloon and non-scoring balloon for lesion preparation in the treatment of both in-stent restenosis (ISR) and de novo lesions.

METHODS AND RESULTS

We retrospectively studied 624 patients and a total of 719 lesions treated at our institution in 2017 with either scoring balloon or non-scoring balloon lesion preparation followed by paclitaxel-coated SeQuent Please Neo DEB.

179 lesions treated with scoring balloon was compared to 445 lesions treated with non-scoring balloon which included semi-compliant and non complicant balloons for lesion preparation. Endpoints analysed were clinically driven target lesion revascularization rate (TLR) as a primary endpoint and major adverse cardiac events (MACE) at 1 year follow up.

There were 75(37.7%) de novo lesions and 124(62.3%) ISR lesions in the scoring group, compared to 396(76.2%) de novo and 124 (23.8%) ISR lesions in the non-scoring group. The mean age and gender were similar in both groups, 61±10 years old, 135 (84.4%) males in the scoring group and 60±10 years old, 386 (83.2%) males in the non-scoring group. Given the patients were all from the same population, they had very similar cardiac risk factors. The mean vessel size treated was 3.0±0.5mm with a mean lesion length of 26±14mm in the scoring group compared to 2.6±0.5mm with a length of 25±18mm in the non-scoring group.

Percentage of stenosis pre PCI was 87±12% improving to 19±12% post PCI using a scoring balloon as opposed to a pre PCI stenosis of 92±10% improving to 18±14% post PCI in the non-scoring group. There was no statistical significance in this aspect.

There was however a significant increase in flow limiting dissections when scoring balloon was used for lesion preparation, 10(5%) lesions as opposed to only 5 (1%) lesions in the non-scoring group (p=0.02). The scoring group had less non flow limiting dissections 2(1%) lesions compared to 24(4.6%) lesions in the non-scoring group (p=0.023). Those that needed bail out stenting however were similar in both groups, 12(6%) leions in the scoring and 26(5%) lesions in the non-scoring (p=0.576). TLR was required in 3(1.7%) patients in the scoring group and 4(0.9%) in the non-scoring group (p=0.417). MACE at follow up occured in 9(4.5%) patients in the scoring group and 10(1.9%) patients in the non-scoring group (p=0.067).

CONCLUSIONS

Using a scoring balloon for lesion preparation is a promising technique and based on our study, there is no statistically significant difference in terms of TLR and MACE when compared to non-scoring balloons.

Additional numbers are needed to gain further experience in the use of scoring balloons for lesion preparation to achieve more accurate results.

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High-pressure DK crush stenting vs. low-pressure DK crush stenting vs. culotte stenting for left main distal bifurcation lesions: analysis from the 3D left main elastic bifurcated coronary artery models and micro CT

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease, Bifurcation lesion

AIMS

Both DK crush stenting and Culotte stenting are considered efficacious treatment options when a planned 2-stent strategy is deemed necessary for unprotected LM coronary artery disease. However, there are limited data available with regard to the long-term clinical outcomes of each strategy in this setting. This study aimed to investigate the influence of stent implantation technique on the reduction of incomplete stent apposition volume (ISA-volume) between High-pressure DK-crush, Low-pressure DK-crush and Culotte, using a three-dimensional elastic LM coronary artery bifurcated model.

METHODS AND RESULTS

The referenced LM bifurcation angle data of 209 patients were stratified by tertiles focusing on the angle between the LM trunk and left anterior descending artery. Then, a modified-angled bifurcation model with angles of 141°, 122°, and 71° for LM trunk–left anterior descending, LM trunk–left circumflex, and left anterior descending–left circumflex, respectively, was fabricated, with diameters of 4.3mm, 3.3mm, and 3.0 mm for LM trunk, left anterior descending, and left circumflex, respectively; these diameters fulfill Murray's law. A 60% and 50% stenosis were included along the LM trunk–left anterior descending and LM trunk–left circumflex. All in vitro experiments were performed under fluoroscopy in the catheterization laboratory. Six High-pressure DK crush stenting, six low-pressure DK crush stenting and six Culotte stenting were performed using SYNRGY stent. In the high-pressure DK crush group, side branch stent was crushed using 4.0mm non-compliant balloon with 25atm. In the low-pressure DK crush group, side branch stent was crushed using 4.0mm non-compliant balloon with 16atm. The final kissing balloon inflation was performed using 3.5mm semi-compliant +3.0mm non-compliant balloon with 12atm+20atmin the High-pressure DK group, and 6atm+12atm in the Low-pressure DK group. In the Culotte group, stent implantation was performed 6 or 8atm. The final kissing balloon inflation was performed using 3.5mm semi-compliant +3.0mm non-compliant balloon with 6atm+8atm. The main branch ISA-volume, carina ISA-volume and total ISA-volume were quantified using micro-CT. Each case was successfully performed and completed. On the frontal plane, there was no place where the strut was not covered. In addition, extreme strut jailing at the both bifurcation ostium was not observed. Micro-CT analysis showed a higher proportion of ISA-volume into the main branch, carina and total with High-pressure DK-Crush and Low-pressure DK-crush compared to Culotte, respectively (2.80 ± 2.16 mm3vs. 2.72 ± 1.50 mm3vs. 0.24 ± 0.15 mm3; p=0.94, p=0.01 with main branch, 1.18 ± 0.38 mm3vs. 1.30 ± 0.40 mm3 vs. 0.42 ± 0.26 mm3; p=0.73, p=0.001 with carina and 3.98 ± 4.12 mm3vs. 4.02 ± 1.37 mm3 vs. 0.66 ± 0.28 mm3; p=0.97, p=0.002 with total).

CONCLUSIONS

Both high-pressure and Low-pressure DK-Crush stenting increase the proportion of ISA-volume into the three

strut overlapping portions in the main branch and the carina compare to Culotte stenting. It was ineffective even if high pressure expansion was performed in order to reduce the ISA - volume in the DK - Crush stenting. In Culotte stenting, we can achieve good apposition with low pressure KBI.

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Deep-learning-based risk stratification for mortality of patients with AMI

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

Conventional risk stratification models for mortality of acute myocardial infarction (AMI) have been well validated, however, they have potential limitations. This study aimed to develop and validate deep-learning-based risk stratification for the mortality of patients with AMI (DAMI).

METHODS AND RESULTS

The data of 22,875 AMI patients from the Korean working group of the myocardial infarction (KorMI) registry were exclusively divided into 12,152 derivation data of 36 hospitals and 10,723 test data of 23 hospitals. The predictor variables were the initial demographic and laboratory data. The endpoints were in-hospital mortality and 12-months mortality. DAMI was developed using the derivation data and represented the risk of outcome with a score between 0 and 100. We compared the DAMI performance with the global registry of acute coronary event (GRACE) score, acute coronary treatment and intervention outcomes network (ACTION) score, and the thrombolysis in myocardial infarction (TIMI) score using the test data

The areas under the receiver operating characteristic curves (AUROCs) of the DAMI were 0.905 [95% confidence interval 0.902-0.909] and 0.870 [0.865-0.876] for the ST elevation myocardial infarction (STEMI) and non ST elevation myocardial infarction (NSTEMI) patients, respectively; these results significantly outperformed those of the GRACE (0.851 [0.846-0.856], 0.810 [0.803-0.819]), ACTION (0.852 [0.847-0.857], 0.806 [0.799-0.814] and TIMI score (0.781 [0.775-0.787], 0.593[0.585-0.603]). When divided into the risk group, DAMI predicted 30.9% of patients more accurately than the GRACE score. During the 12-month follow-up, the high risk group, defined by the DAMI, has a significantly higher mortality rate than the low risk group (23.2% vs. 1.0%, $p < 0.001$).

CONCLUSIONS

The DAMI predicted in-hospital mortality and 12-month mortality of AMI patients more accurately than the existing risk scores and other machine-learning methods.

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Validation and comparison of contemporary risk scores for post-discharge events after DES implantation: a subanalysis of the ReCre8 trial

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THEME: Coronary Interventions
TOPIC(S): STEMI, Stable CAD

AIMS

Multiple scores have been proposed to guide dual antiplatelet therapy following percutaneous coronary intervention. This study sought to validate and directly compare contemporary risk scores to predict post-discharge events using data from the ReCre8 (Randomized All-comers Evaluation of a Permanent Polymer Zotarolimus-eluting Stent Versus a Polymer-Free Amphilimus-eluting Stent) trial.

METHODS AND RESULTS

A total of 1491 patients (NCT02328898) treated with latest-generation drug-eluting stent implantation were analyzed. Contemporary risk scores for post-discharge ischemic events (PARIS, CREDO) and post-discharge bleeding events (PARIS, CREDO, PRECISE-DAPT) were calculated and directly compared. Calibration and discriminative performance using Harrell's c-statistics, net reclassification index, and decision curve analyses were performed. Post-discharge ischemic events occurred in 116 (7.8%) patients, whereas post-discharge bleeding events occurred in 33 (2.2%) patients. No differences were observed in the discriminative capability of PARIS and CREDO ischemic scores (c-statistic 0.57 and 0.59). CREDO bleeding score displayed modest discrimination (c-statistic 0.67), whereas PARIS and PRECISE-DAPT had marginal discriminative capacity. Net reclassification index and decision curve analysis favored CREDO-derived bleeding risk assessment in terms of predictive performance for post-discharge bleeding events.

CONCLUSIONS

In this cohort, PARIS and CREDO were predictive for post-discharge ischemic events and CREDO was predictive for post-discharge bleeding events in an all-comer population treated with latest-generation drug-eluting stents. With respect to post-discharge bleeding events, CREDO-derived bleeding risk assessment was associated with improved predictive capability

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Lesion-oriented outcomes in small vs. large coronary vessels treated with Absorb BVS or Xience EES - AIDA-trial quantitative coronary angiography substudy

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Stents and scaffolds

AIMS

Absorb bioresorbable vascular scaffold (BVS) implantation in small vessels has been associated with increased rates of adverse events. In this subgroup analysis of the Amsterdam Investigator-Initiated Absorb Strategy All-Comers (AIDA) trial, we evaluated the clinical outcomes of Absorb bioresorbable vascular scaffold (BVS) versus Xience everolimus eluting stent (EES) treated lesions in small versus large coronary vessels.

METHODS AND RESULTS

All AIDA study lesions for which the quantitative coronary angiography (QCA) derived in-segment reference vessel diameter was available were included in this substudy. Coronary vessels with a diameter of <2.25 were defined as ‘small vessels’, and coronary vessels with a diameter of >=2.25 were defined as ‘large vessels’. All included lesions were subdivided by randomization result and by implantation in either a small or a large coronary vessel.

The lesion-oriented composite endpoint (LOCE) of this analysis was defined as a composite of definite device thrombosis, target lesion revascularization (TLR) and target vessel myocardial infarction (TVMI). Event rates are reported as Kaplan-Meier estimates at complete 2-year follow-up.

In AIDA, 2446 lesions were treated of which 1237 in the Absorb BVS arm and 1209 in the Xience EES arm. QCA derived in-segment reference vessel diameter was available in 2243 lesions, of which 1136 in the Absorb BVS group and 1107 in the Xience EES group.

In the small vessel group, LOCE occurred in 9.3% (n=33) lesions in the Absorb BVS group and in 6.6% (n=24) lesions in the Xience EES group (p=0179), whereas in the large vessel group LOCE occurred in 7.6% of Absorb BVS lesions versus 4.6% (n=33) Xience EES lesions (p=0.093, pinteraction=0.966). Furthermore, in the small vessel group, definite device thrombosis occurred in 2.2% (n=8) Absorb BVS lesions versus 0.8% (n=2) Xience EES lesions (p=0.122), whereas in the large vessel group definite device thrombosis occurred in 2.2% (n=17) versus 0.3% (n=2) in Xience EES lesions (p<0.001, pinteraction=0.234).

CONCLUSIONS

In either small or large coronary vessels, we found no significant difference in rates of LOCE between Absorb BVS and Xience EES treated lesions. Rates of LOCE were numerically higher in Absorb BVS lesions in both small and large coronary vessels. Rates of definite device thrombosis were also higher in the Absorb BVS group in both small and large vessels. No significant interaction between small versus large vessels and was found between the two treatment arms.

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Deferred vs. performed revascularisation according to FFR in ACS: insights from the IRIS-FFR registry

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THEME:
TOPIC(S):

AIMS

Real-world clinicians are extrapolating the fractional flow reserve (FFR) cut-off values utilized for stable ischemic heart disease (SIHD) patients to their acute coronary syndrome (ACS) cases. However, their cut-off and usefulness in ACS setting remain controversial. We aimed to determine the mid-term prognostic utility of FFR-guided percutaneous coronary intervention (PCI) in everyday clinical practice for ACS cases.

METHODS AND RESULTS

This study included 1570 native coronary stenosis in 1334 ACS patients who underwent FFR measurement from the prospective multicentre Interventional Cardiology Research In-cooperation Society FFR registry. PCI was deferred for 626 patients (deferred group) and performed for 454 (performed group). The primary endpoint was the rate of a composite of cardiac death, myocardial infarction (MI), and repeat revascularization at 2 yr. The performed group had a tendency toward higher rate of the primary endpoint than the deferred group (4.62% vs. 2.67%, hazard ratio [HR] 1.776, 95% confidence interval [CI] 0.999-3.129, p=0.0505), mainly driven by higher occurrence of MI (1.35% vs. 0.1%, HR 14.216, 95% CI 1.754-115.195, p=0.0129). Both groups had a comparable rate of the primary endpoint when grouped by 0.05 interval of FFR (from =<0.80 through >0.90). In the deferred lesions, the composite outcomes occurred more frequently in those with FFR =<0.80 (HR 2.51), 0.81-0.85 (HR 3.51), and 0.86-0.90 (HR 2.56) compared to lesions with FFR >0.90 (p for trend 0.028).

CONCLUSIONS

FFR-directed PCI did not improve outcome, and deferral strategy based on the FFR cut-off for SIHD patients seemed invalid in the ACS setting.

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Biodegradable polymer-coated thin strut sirolimus-eluting stent vs. durable polymer-coated everolimus-eluting stent in diabetic population

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

The number of patients with diabetes mellitus (DM) presenting with coronary artery disease is increasing and accounts for more than 30% of patients undergoing percutaneous coronary interventions (PCI).The biodegradable polymer drug-eluting stents were developed to improve vascular healing. We sought to determine the 1-year clinical follow-up in patients with DM treated with the thin strut biodegradable polymer-coated sirolimus-eluting (BP-SES) stent versus durable coating everolimus-elutingstent (DP-EES).

METHODS AND RESULTS

We analyzed patients with DM treated with either a BP-SES (ALEX™, Balton, Poland, n=670) or DP-EES (XIENCE™, Abbott, USA, n=884) with available 1-year clinical follow-up using propensity-score matching. Outcomes included target vessel revascularization (TVR) as efficacy outcome and all-causedeath, myocardial infarction, and definite/probable stent thrombosis as safety outcomes. After propensity score matching 527 patients treated with BP-SES and 527 patients treated with DP-EES were selected. Procedural and clinical characteristics were similar between both groups. In-hospital mortality was 3.23% in BP-SES vs. 2.09% in DP-EES group, p=0.25. One-year follow-up demonstrated comparable efficacy outcome TVR (BP-SES 6.64% vs. DP-EES 5.88% p=0.611), as well as similar safety outcomes of all-causedeath (BP-SES 10.06% vs. DP-EES 7.59% p=0.158), myocardial infarction (BP-SES 7.959% vs. 6.83%, p=0.813), anddefinite/ probable stent thrombosis (BP-SES 1.14% vs. DP-EES 0.76%, p=0.525).

CONCLUSIONS

The thin-strutbiodegradable polymer coated sirolimus-eluting stent demonstrated comparable clinical outcomes at 1-year after implantation to the DP-EES. These data support the relative safety and efficacy of BP-SES in diabetic patients undergoing PCI.

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Global impairment of left ventricular function and poor myocardial recovery predict outcome after out-of-hospital cardiac arrest

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Myocardial dysfunction is common after Out of Hospital Cardiac Arrest (OOHCA) but there is limited description of its effect on outcome. We assessed the degree of left ventricular impairment on arrival to a cardiac arrest centre, subsequent myocardial recovery and the relationship with both early and long-term outcome.

METHODS AND RESULTS

Left ventricular ejection fraction (LVEF) was measured on arrival to a U.K. tertiary cardiac arrest centre (within 60 minutes of arrival) and then again at 48 hours. Severely reduced LVEF was classified as <35% (Group A), LVEF 35 – 55% (Group B) and >55% (Group C). Primary end- point was survival at follow-up. Myocardial recovery was classified as an improvement in the LVEF of >10% at interval trans-thoracic echocardiography.

619 patients with OOHCA were admitted at our centre between 1st May 2015 and 31st December 2017. 221 were excluded for having a non- cardiac aetiology. 397 patients (median age 64.2 (IQR 21.3, 25.8% females) were included in the final analysis. 71.3% had VF, 78.9% were witnessed and 77.4% occurred at residence. Mean follow-up was 293 days (+- 468). Patients with incomplete data were excluded from the analysis.

Median LVEF on admission was 40% (IQR 30 – 50%) and LVEF was 29.5% in Group A, 44.6% in Group B and 55.2% in Group C (p<0.001). There was a significant difference in age (65.4 vs, 61.3 vs. 64.5 p 0.049), length of downtime (36.1 mins. vs, 28.5 mins. vs. 26.8 mins. P 0.049), and lactate (6.2. vs, 5.1. vs. 7.2 P 0.006) between the groups. Survival at follow-up was significantly lower in those with in Group A compared with Groups B and C (65.9% vs. 38.5% vs. 57.3% p<0.001). In a multi-variate analysis incorporating age and initial rhythm, Group A was a significant independent predictor of survival at follow-up (OR 0.64 (CI 0.46 – 0.89 p<0.001).

A total of 33.9% of patients showed myocardial recovery (47.1% in Group A, 34.1% in Group B and 8.7% in Group C). In a multi-variate analysis, total downtime was the only factor associated with subsequent myocardial recovery. Only patients in Group A with subsequent myocardial recovery had higher survival at follow-up (67.5% vs. 35.6% p 0.0035) and this trend was not seen in Groups B (73.8% vs. 70.4% p=ns) and C (50% vs. 66.7% p=ns).

CONCLUSIONS

Severely impaired LV systolic function on arrival to the cardiac arrest centre is a potential surrogate marker for prolonged downtime and is associated with lower early and long- term survival. In patients with the most severe LV impairment, myocardial recovery at 48 hours is associated with improved survival in comparison to those without recovery.

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Left bundle branch block after TAVI with Edwards SAPIEN 3 valve: influence of the valve depth implantation

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Left bundle branch block (LBBB) is the most common conduction disturbance after TAVI. The Sapien 3 system (S3) has been associated with a higher incidence of LBBB. A deep valve implant could be related to new-onset LBBB with S3.

The aim of this study is to determine the relation between the valve depth implantation and the new-onset LBBB in patients treated with transfemoral TAVI using S3 prosthesis.

METHODS AND RESULTS

From a total of 214 transfemoral TAVIs, seventy-six consecutive consecutive patients treated with S3 system were included. Electrocardiogram (ECG) registries were recorded at baseline, after the procedure, and before discharge. Valve depth implantation was determined in 40 patients by off-line analysis of the two/three-dimensional transeophageal echocardiogram (TEE) images, with measure of the valve stent percentage under the aortic annulus. Previous and new conduction anomalies were documented; and patient, anatomic and procedural characteristics were retrospectively analyzed.

Complete atrioventricular block (AVB) incidence was 2.9%. LBBB after TAVI appeared in 39% of patients, being transient in almost half of the cases (permanent LBBB rate 20%).

Patients with new-onset LBBB after TAVI were older, with a higher STS Score and a wider basal QRS.

A deep valve position was associated with new-onset LBBB, with a ROC curve establishing a cut-off point of 34% of depth implant as risk factor for new-onset LBBB (sensitivity and specificity 0.8).

CONCLUSIONS

In transfemoral TAVI with S3 prosthesis, a higher valve implantation (<34% of valve stent introduced into the ventricle) may minimize the new-onset LBBB, especially in old and high-risk patients with a wide basal QRS.

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Non-contrast CT scan for the evaluation of the aortic annulus and low-contrast TAVI: results from a small case series of patients with severe chronic renal failure

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

To evaluate the feasibility of non-contrast computed tomography (CT) scan for the assessment of aortic annulus dimensions and minimal dose-contrast transcatheter aortic valve implantation (TAVI) procedure in patients with aortic stenosis suitable for percutaneous valve replacement and severe renal failure.

METHODS AND RESULTS

Consecutive patients with severe aortic stenosis and severe impairment of renal function (glomerular filtration rate <20 ml/min/1.73 m2) were evaluated with non-contrast CT scan prior to TAVI. Aortic annulus dimensions were assessed on the basis of the calcifications of the Valsalva sinuses, which allowed to identify the nadir of each sinus and to trace the annulus perimeter. Annulus measurements were obtained also by transesophageal echocardiography (TEE). The access route was evaluated by Doppler ultrasound. TAVI procedures were performed using the lowest possible dose of iodine contrast medium.

Over a period of 10 months, 3 patients underwent both non-contrast CT and TEE for TAVI evaluation. Annulus analysis was possible in all patients. A self-expandable transcatheter heart valve was implanted in all cases through a femoral access. The procedure was performed in local anesthesia in 2 patients, whereas 1 patient received general anesthesia, as intensive support was needed because of severe respiratory failure. In the 2 patients who received local anesthesia, prosthesis alignment with the aortic basal plane was achieved by positioning two pigtail catheters respectively in the non-coronary and in the left coronary sinus. In the patient who received general anesthesia, only one pigtail catheter was positioned in the non-coronary sinus, and valve positioning and deployment was assisted by intraoperative TEE. An average of 24 ml of iodine contrast medium was administered during the procedure. Device success was achieved in all patients, with mild echocardiographic paravalvular leakage and excellent valve hemodynamics. 2 of 3 patients experienced a peri-procedural advanced atrio-ventricular block with the need of permanent pacemaker implantation. Of these patients, 1 had baseline atrial fibrillation with right bundle branch block and left anterior fascicular block, and 1 had baseline sinus rhythm with left bundle branch block. 1 patient experienced a stage 2 post-procedural acute kidney injury, but despite this, renal function returned to the initial level after 1 month. No other TAVI-related complications according to the Valve Academic Research Consortium 2 definitions occurred.

CONCLUSIONS

Non-contrast CT scan may represent a reasonable option for TAVI sizing in patients with advanced kidney disease. A comprehensive approach with TEE (either preoperative or intraoperative) and Doppler ultrasound is useful. Further data are certainly needed in order to confirm our results.

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OCT in pediatric and adult heart transplantant recipients shows age- and time-dependent differences in the development of cardiac allograft vasculopathy

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THEME: Coronary Interventions

TOPIC(S): Left main and multivessel disease, Other Coronary Interventions

AIMS

Cardiac allograft vasculopathy (CAV) is still one of the leading causes of mortality and graft failure in pediatric and adult patients after heart transplantation (HTx). The high resolution of OCT provides new in vivo insights into CAV. The aim of our study was the evaluation of CAV in pediatric versus adult all-comer patients using optical coherence tomography (OCT) at corresponding intervals between OCT and HTx: ≤5 years, >5 and ≤10 years, and >10 years.

METHODS AND RESULTS

Retrospective OCT-analysis of 33 pediatric (cohort P, median age at HTx 4.5 years [IQR 0.89 -12.15]) and 27 adult HTx patients (cohort A, median age at HTx 48.77 years [39.32 – 54.76]). Cohorts with an interval ≤5 years were defined as P1 (n=11) and A1 (n=9), >5 and ≤10 years as P2 (n=13) and A2 (n=9), >10 years as P3 (n=9) and A3 (n=9). Coronary media thickness (MT) and intima thickness (IT) were measured per quadrant, and intima to media ratio (I/M) was assessed. I/M >1 was considered as relative intimal hyperplasia (IH). Mean values represent overall pathology and maximal values indicate maximal pathology.

Relative IH peaked early in the pediatric cohort and I/M ratios were comparable at all time points between the pediatric cohorts (mean: P1: 1.84 [1.33 - 3.36], P2: 2.10 [1.75 - 2.23], P3: 2.00 [1.68 – 2.06] and maximal: P1: 5.41 [2.81 – 13.39], P2: 5.09 [3.95 – 6.77], P3: 4.41 [3.35 – 8.74]). As opposed, there was an increase of relative IH in adults depending on post-transplant time (mean: A1: 1.16 [0.87 - 1.46] A2: 1.85 [0.70 - 2.92], A3: 2.10 [1.64 – 3.02] and maximal: A1: 2.29 [1.36 – 3.74], A2: 3.87 [1.76 – 6.09], A3: 5.50 [3.31 - 5.92]).

I/M was significantly higher in P1 than in A1 (mean: p=0.03; maximal: p=0.01) and was comparable between P2 and A2, as well as between P3 and A3.

Absolute values of IT and MT were comparable at all time points between the pediatric cohorts, whereas they showed an increasing trend in adults depending on post-transplant time.

Despite age differences, the absolute IT values were comparable between P1 and A1 (mean: P1: 0.11mm [0.10 - 0.15] vs. A1: 0.09mm [0.08 - 0.23] and maximal: P1: 0.28mm [0.25 - 0.46] vs. A1: 0.16mm [0.12 - 0.72]). They were significantly higher in A2 than in P2 (mean: P2: 0.08mm [0.06 - 0.11] vs. A2: 0.21mm [0.13 - 0.31], p=0.001; maximal: P2: 0.16mm [0.11 - 0.25] vs. A2: 0.44mm [0.28 - 0.73], p=0.009) and in A3 compared to P3 (mean: P3: 0.10mm [0.08 – 0.13] vs. A3: 0.24mm [0.15 – 0.30], p=0.001; maximal: P3: 0.27mm [0.19 – 0.36] vs. A3: 0.46mm [0.35 – 0.54], p=0.02). In addition, mean MT values were comparable between P1 and A1 (P1: 0.07mm [0.05 - 0.09] vs. A1: 0.08mm [0.07 - 0.12]) but significantly higher in A2 than in P2 (mean: P2: 0.05mm [0.04 - 0.07] vs. A2: 0.10mm [0.09 - 0.17], p <0.001) and in A3 compared to P3 (mean: P3: 0.06mm [0.05 – 0.07] vs. A3:0.09mm [0.08 – 1.12], p <0.001).

CONCLUSIONS

To the best of our knowledge, this is the first direct comparison of OCT findings between children and adults at corresponding intervals after HTx. Results show that there is a different age- and time-dependent development

of CAV: Relative and absolute intimal hyperplasia are reaching an early peak in children and progressively increasing in adults. Findings suggest a progressive media involvement in adults starting after 5 years. Serial OCT analyses are needed to correlate findings with risk factors with the aim to optimize individualized CAV therapy

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Assessment of acute thrombogenicity and albumin bindings in the Resolute Onyx zotarolimus-eluting coronary stent system

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Recent clinical studies showed the association between lower rates of early stent thrombosis and a durable polymer drug eluting stents (DES) as compared to bare-metal stents (BMS), which suggests that the presence of polymer and/or drugs may play an important role in decreasing stent thrombosis. Biomaterial studies showed the potential that albumin retention on surfaces is associated with less platelet adhesion. However, thromboresistance and capability of albumin binding in the Resolute Onyx-DES equipped with the biocompatible BioLinx polymer were never investigated relative to BMS.

METHODS AND RESULTS

In an established ex vivo carotid to jugular arteriovenous porcine shunt model, the thrombogenicity of the Resolute Onyx-DES (n=8 stents) was compared with the Onyx BMS platform (n=10 stents). After the stents were bisected, each half was dual immunostained with platelet cocktail (CD61/CD42b) and inflammatory marker for neutrophils (PM1) or monocytes (CD14) which were visually evaluated by confocal microscopy and quantitated by histomorphometry. In a developed in vitro flow loop model, human platelet adhesion and albumin binding of the Resolute Onyx DES were compared with those of the Onyx BMS platform (n=5 for each) using confocal microscopy. Platelet aggregation was significantly less in the Resolute Onyx DES relative to Onyx BMS platform (area percentage 7.04 ± 5.41% vs. 20.49 ± 13.78%, P=0.02). In addition, Resolute Onyx DES showed significantly less inflammatory cell adherence as compared to the Onyx BMS platform for both neutrophils (354 ± 316 vs. 681 ± 293 positive cells/mm2, P=0.04) and monocytes (315 ± 173 vs. 598 ± 217 positive cells / mm2, P<0.01). In an in vitro flow loop model, Resolute Onyx DES also showed significantly less platelet aggregation and albumin coverage on the surfaces as compared to Onyx BMS platform.

CONCLUSIONS

The Resolute Onyx DES equipped with the BioLinx polymer showed a significantly more favorable profile with regard to thromboresistance, less inflammatory cell adherence and greater albumin retention as compared to the Onyx BMS platform. These properties in Resolute Onyx DES may explain why low stent thrombosis rates are observed in Resolute Onyx DES clinical findings.

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Choosing an effective method for assessing the results of PCI in post-myocardial infarction patients

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

to evaluate the effectiveness of cardiac magnetic resonance (CMR) and stress-echocardiography in the assessment of long-term results of percutaneous coronary interventions (PCI) in post-MI patients with dysfunctional myocardium.

METHODS AND RESULTS

Methods: 112 patients were participated in the study. Inclusion criteria: myocardial infarction in previously; angina II-III functional class (CCS); multivessel coronary disease (SYNTAXscore I <32); the presence of segments with abnormality left ventricular local contractility; chronic heart failure I-III functional class (NYHA); left ventricular ejection fraction (LVEF) is less than 45%. All patients underwent stenting of the coronary arteries in the zone of viable myocardium. Only drug-eluting stents were implanted in coronary arteries. Long-term results were followed up 18 months after PCI in all patients. All patients underwent stress-echocardiography and CMR for visualization of myocardium after PCI.

Results: on average, initially accounted for 2.12 ± 0.74 segments with abnormality kinetic per patient according CMR, whereas, according to stress echocardiography, the average number of segments was 1.96±0.42. The average difference was 0.16 segment [0.11-0.18; 95% CI, p=0.003]. In the postoperative period, after 18 months, there was a significant decrease a segments with abnormality kinetics in the zone of hibernated myocardium, from 2.12 to 1.08, according to CMR (the average difference was 1.04 segment) [0.98-1.1; 95% CI, p <0.01], and from 1.96 to 0.98 according to stress-echocardiography (the average difference was 0.98 segments) [0.94–0.99; 95% CI, p = 0.023]. There is a significant discrepancy between the number of identified segments with abnormality kinetics using CMR and stress- echocardiography. There was a significant decrease in the transmurality index from 0.42 to 0.31 (according to CMR). The difference was 0.11 [0.09-0.14; 95% CI, p <0.05]. At the same time, recovery of myocardial function was clearly manifested in patients with a trasmurality index of 0.3–0.5, whereas with a transmurality index of more than 0.5, reliable recovery of myocardial function was not observed.

CONCLUSIONS

CMR allows a more objective analysis of the results of PCI in patients with dysfunctional myocardium, as compared with the stress-echocardiography method.

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Multicentre all-comer registry of in-stent restenosis: clinical, angiographic characteristics, therapeutic management and medium/long-term follow-up

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THEME: Coronary Interventions
TOPIC(S): STEMI, Stents and scaffolds

AIMS

In-stent restenosis (ISR) is one of the major limitations of these devices together with thrombosis. The therapeutic management of these patients is still controversial and very variable depending on each centre. Our objective was to assess the clinical and angiographic characteristics, management and follow-up of these patients.

METHODS AND RESULTS

A multicentre, ambispective registry including all ISR (defined as > 50% stenosis) from January 2014-January 2018 was done. Clinical and angiographic characteristics, therapeutic management and clinical follow-up variables were analysed in all patients for assessment of major cardiovascular events (CV death, TLR, TVR, non-fatal AMI) and stent thrombosis.

Overall, 164 patients were included (2.9% of all PTCA during that period), 67±11 years-old, 78% (n=128) male, 81% (n=133) hypertensive, 63% (n=104) diabetics, 77% (n=127) dyslipidemics, 21% (n=35) smokers / 50% (n=89) former smokers, 19% CKD. 54% (n=88) presented other lesions besides ISR. 7.3% (n=12) were BVS-ISR, 60.4% (n=99) DES-ISR (1st Gen n=18, 2nd Gen n=81) and 32.3% (n=53) of BMS-ISR. The mean time to restenosis was 1878±1836 days (5.1±5.1 years, median 981 [321-3320 days]). There were differences between time to ISR in 2ndGen DES versus 1stGen DES/BMS (3±3.7 vs 7.8±5.1 years, p=0.001) in probable relationship with neoatherosclerosis in the latter.

Most of them presented with unstable angina (29.3%, n = 48), followed by stable angina (28%, n = 46) and NSTEMI (23.8%, n = 39), 21% (n=35) had previous PCI on the same ISR lesion. During the procedure, isolate ISR was treated in 61% (n = 98) and other lesions were treated in 39%. Access was radial/ulnar in 82% (n=135), 18% femoral.

The most frequent artery treated was LAD (37%, n=61) and RCA (28%, n=46), the most frequent angiographic type was Mehran IB "edge" (34%, n=56), presenting angiographic calcification in 52%. The QCA analysis revealed 2.76 ± 0.5 mm of ref diameter vessel, 12.3 ± 7 mm length and 77 ± 17% of stenosis. The initial planned strategy was DES implantation in 76% (n=121) and 18% (n=30) drug-coated-balloon (AngiosculptX or DCB).In the management, predilatation was performed in 71% (n=113), with Scoring Balloon in 32% (n=51) and postdilatation in only 33% (n = 52). Paclitaxel coated balloon was used in 18% (n=29), requiring cross-over to DES only 6% (n=9), and 2ndG DES in 82% (n=134). 10% required 2 or more stents implantation. The success of the procedure (residual stenosis <30%) was achieved in 99% (n=158).

Any intracoronary imaging techniques was used in 23% (n=38), OCT was used in 18% (n=30) and IVUS in 5% (n=8). Neoatherosclerosis was seen in 9 patients (24% of the total imaging subgroup).

At 1-year follow-up, the MACE rate was 6.1% (5 non-CV deaths, 4 CV deaths, 1 TLR, 1 TVR), in a medium extended follow-up to 678 ± 490 days, the MACE rate was 13.4% (7 CV deaths [9 non-CV deaths], 5 non-fatal AMI, 8 TLR, 2 TVR), 2.4% (n = 4) stent thrombosis. There were no differences depending on the nature of the

RIS (BVS / DES / BMS) or the management used (DCB or DES). The female gender (HR 3.8, p = 0.007) and the previous treatment of the same ISR (HR 5.4, p <0.001) were factors related to a higher rate of MACE.

CONCLUSIONS

In-stent restenosis rate is low but it remains a problem of the first magnitude in our usual practice, the clinical profile of these patients is very high risk. Despite DES implantation is preferred to DCB, both are associated with comparable results with a very low long-term event rate.

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DAPT discontinuation after coronary CTO recanalisation and its impact on prognosis: six-month and one-year outcomes

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds, CTO

AIMS

To investigate the clinical and angiographic outcome of patients with coronary chronic total occlusions (CTO), reanalized by antegrade approach, in terms of patient's adherence to DAPT.

METHODS AND RESULTS

Our prospective, single-centre study included 117 patients, who underwent coronary artery CTO recanalization. Different types of drug-eluting stents were used. After 6.1±0.9 months and 12.7±1.6 months all patients were examined by coronary angiography, intravascular ultrasound and optical coherence tomography. Clinical outcomes, coronary arteries patency, the development of restenosis, thrombosis, and other negative events were registered at periods 0-6 months and 6-12 months.

The development of cardiac death did not differ significantly at period 0-6 months and 6-12 months after the CTO recanalization (0.9% vs 1.8%, $p > 0.05$), whereas combined endpoint (all cases of death + myocardial infarction + repeated revascularization) had a tendency to decrease in the second half of the observational period (24.8% vs 15.7%, $p < 0.05$). The frequency of target lesion failure was 23.1% at first half and 13.9% at second half of the year ($p < 0.05$). The observed tendency in decreasing cases of target lesion failure in the second half of observation period was due to decrease of in-stent restenosis (from 18.8% to 13.9%) and stent thrombosis (from 5.1% to 0.9%).

Compared with the first half of the observation period after successful CTO recanalization it was revealed an increase in the discontinuation of therapy with aspirin (from 2.6% to 8.3%, $p < 0.05$), clopidogrel (from 6.8% to 16.7%, $p = 0.0231$) and statins (from 4.3% to 13.9%, $p = 0.0173$). Significant decrease of patient's adherence to DAPT at the period 6-12 months after PCI did not cause increase of late stent thrombosis development in the CTO recanalization zone. The only patient with stent thrombosis at period 6-12 months canceled both aspirin and clopidogrel 5 weeks before the event and all patients with stent thrombosis at 0-6 months period received full DAPT dose. Therefore, stent thrombosis is much more frequent at first 6 months after CTO recanalization and looks more like procedure-dependent, than DAPT-dependent event.

CONCLUSIONS

The obtained data shows good mid-term results after CTO recanalization that makes possible to recommend the interventional techniques for CTO correction in clinical practice. Discontinuation of one component of dual antiplatelet therapy 6 months after CTO recanalization and stenting with DES could be safe in terms of late stent thrombosis.

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Short- and long-term outcomes of a TAVI centre without onsite cardiac surgery: looking beyond experts opinion

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Current guidelines do not recommend performing TAVI at centers without on site cardiac surgery, based in experts opinion but without scientific evidence endorsing it. The aim was to analyse the outcomes of a single-center registry of TAVI without on site cardiac surgery.

METHODS AND RESULTS

Prospective registry of 149 patients (54% male, 84,47 years) undergoing TAVI in a centre without on site cardiac surgery but with a nearby (<200 m) cardiac surgery department of reference. All the patients were evaluated by the local heart-team. Surgical risk classification of patients by STS (mean 5.1 (RIC 25-75: 3.5-8)) and EuroScore (mean 12 (RIC 25-75: 9-20)) was: high in 34%, intermediate 46% and low 20%. All the procedures were performed under general anaesthesia and TEE-guidance and only with self-expandable devices. Fully percutaneous transfemoral access was used in all but 9 patients (surgical access: 6 subclavian and 3 retroperitoneum). Complications that potentially need emergent surgery occurred in 8 cases (5.3%): 2 coronary occlussions, 3 cardiac tamponade and 3 device embolization, but all could be percutaneously solved. Only one patient (cardiac tamponade) underwent surgery at 3 hours of the procedure due to a non-controllable bleeding despite pericardiocentesis. Major vascular complications occurred in 4.7% and major bleeding in 9.4%. Procedure was successful in 94% of cases and 30-day mortality was 96%. In a mean follow-up of 720 days, one-year survival was 90%, three-year survival 75% and five-year survival 63%.

CONCLUSIONS

TAVI procedures with self-expandable devices in a centre without on site cardiac surgery but with possibility of quick transferring to a cardiac surgery department of reference can be performed with similar good short-term and long-term outcomes than in other centres of our environment with on site cardiac surgery. The few complications potentially needing cardiac surgery can be percutaneously solved in the majority of the cases.

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Coronary angioplasty under chronic oral anticoagulation: a safe practice

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THEME: Coronary Interventions
TOPIC(S): STEMI, Stable CAD

AIMS

It is estimated that 6-8% of patients undergoing PCI receive chronic oral anticoagulation (OAC). The withdrawal of OAC a few days before PCI is the usual practice, with heparin bridge therapy in mostly of the patients. This strategy favors both, ischemic events and hemorrhages.

METHODS AND RESULTS

Prospective and longitudinal multicentre registry to know the safety of PCI without withdrawal of OAC (vitamin K antagonists (VKA) or direct anticoagulants (DOAC) in selected patients with stable disease or acute coronary syndrome. Patients included must have taken the OAC without interruption and must show an INR> 1.8 in case of VKA. Antithrombotic strategy during PCI included the use of 50 IU / Kg of unfractionated Heparin in case of DOAC and when INR <1.8. Safety objectives are evaluated during the procedure, at 24 hours, and at 1 month. Between July, 2017 – April, 2018, 40 patients were included (75% Men, 74 ± 8 years, DM 47%, 12.5% ??previous stroke). The mean CHA2DS2-VASC was 4.56 and mean HAS-BLED 2.9; 42.5% received VKA (INR 2.1 ± 0.7) and 57.5% DOAC (32.5% Dabigatran, 15% Rivaroxaban, 7.5% Apixaban, 2.5% Edoxaban), mostly (92.5%) due to atrial fibrillation. The 57.5% of the procedures were performed on an outpatient basis and 97.5% of all the PCI were trans-radial / ulnar. The majority of the procedures were single-vessel PCI with implantation of only 1 DES. Two complications occurred during the procedure: 1 stent edge dissection and 1 occlusion of an small lateral branch. There were no perforations, catheter or devices thrombosis or need to use antidotes. PCI was considered successful in 97.5% of the cases. The only vascular complication was minor, 1 prolonged radial bleeding solved with longer compression. At 1-month follow-up, 97.5% of patients received triple therapy and none presented major adverse cardiovascular events, vascular complication (no radial occlusion) or major bleeding (BARC ≥ III).

CONCLUSIONS

PCI without withdrawal of chronic OAC in selected patients receiving VKA or DOAC, with addition of low doses of heparin is a safe practice, avoiding the ischemic risk of the withdrawal of OAC and the bleeding risk of the bridge therapy.

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Long-term standardised outcomes and cumulative sum of failure analysis in transfemoral TAVI patients

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Transcatheter Aortic Valve Implantation(TAVI) has proved equal to or better than surgery in multiple scenarios. However, the adoption of standardized events definition is still unclear, thus limiting data comparability.
We aim at evaluating VARC-2 single and composite EP according to STS-SCORE stratified risk. Furthermore, we aimed to define the performance of the interventional team for each risk group by means of the Cumulative Sum of Failure (CUSUM) method

METHODS AND RESULTS

Between April 2010 and May 2018, 370 consecutive patients (44% males, aged 81.6±7.4 years) underwent same team TF-TAVI. Mean follow-up was 23,2±21,6m. STS-SCORE varied broadly with a median of 5.2±2.4%, while Logistic Euroscore and Euroscore-II were 19.2±10.8 and 6.0±3.4, respectively. In 100 patients (27%) STS-SCORE was >8% (median 11.0±5.0) for mortality (high-risk), while in 270 patients (73%) STS-SCORE wa

CONCLUSIONS

This single-center single-team analysis confirms the good procedural and long-term clinical results of TF-TAVI. Risk level stratification by STS-score predicts long term hard and composite end-points. At CUSUM analysis, while the DU proved always under control with the need of a limited number of cases for proficiency, ES was more critical for high-risk patients, thus suggesting the referral of these patients to high-volume centers where the learning curve is already in a proficient stage.

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Impact of standardised management of vascular complications following TAVI on short- and long-term outcome

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Vascular and bleeding complications (VC) are the most frequent procedure-related complication following transcatheter aortic valve implantation (TAVI).

The aim of this study was to evaluate the impact of a standardized treatment protocol for procedure-related VC on short- and long-term outcome after TAVI. Bleeding prevention starts with vessel preclosure by two Proglide devices, protamine administration and hemostasis through manual compression plus percutaneous transluminal angioplasty (PTA) or implantation of a covered nitinol stent-graft, if necessary.

METHODS AND RESULTS

Our patient cohort included 1398 consecutive patients undergoing TAVI, of whom 401 (28.7%)
patients underwent TAVI using a standardized access-way management (SAM) protocol.

In the SAM group, a paravasation after vessel closure with the ProGlide System occurred in 194 (48.4%) patients and was treated by manual compression only in 24.9% (n=100), by additional PTA in 10.5% (n=42), whereas a nitinol stent-graft had to be implanted in 11% (n=44) of the patients. Postprocedural major bleeding (MB) was observed in 10 (2.5%) patients.

In the SAM cohort, 30-day and 1-year mortality rates were 2.7 % (11/401) and 7.5% (30/401), still showing a significant association with the bleeding events (30-day mortality: 30% [3/10] for MB vs 2.0% [8/391] for uneventful course, p=0.002; 1-year Mortality: 30% [3/10] for MB vs 6.9% [27/391] for uneventful course, p=0.03).

However, compared to the historical treated cohort (n=997) the use of the standardized access-way management protocol resulted in lower rates of major VC (1.5% (6/401) for SAM cohort vs 4.3% (43/997) for historical cohort, p=0.009) and severe bleeding events (2.5% [10/410] for SAM cohort vs 4.9% [49/997] for historical cohort, p=0.04). Furthermore, the reduction of major complications led to lower mortality rates as compared to the historical group (30-day mortality: 2.7% for SAM vs 5.4% [/997] for historical cohort, p=0.03; 1-year mortality 7.5% [30/401] for SAM vs 20.5% [204/997] for historical cohort, p<0.001).

CONCLUSIONS

In our study, we showed that the occurrence of severe bleeding events is still associated with increased mortality rates. However, a standardized access-way management resulted in lower rates of major vascular complications and severe bleeding events.

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Clinical and imaging assessment of TAVR with the Inovare Proseal with multislice CT

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Transcatheter aortic valve replacement (TAVR) is an established procedure for high-risk patients. The Braile Inovare Proseal was developed to reduce the incidence of paravalvular leakage (PVL). Our aim was to evaluate device performance and additionally pre- and post-operative aortic annulus and the transcatheter prosthesis using multislice computed tomography (MSCT).

METHODS AND RESULTS

Patients were selected by a multidisciplinary heart team and referred for TAVR. MSCT was performed before and after surgery. Measurements of the aortic valve and prosthesis were conducted and correlated with the valve gradient and residual paravalvular leakage. 21 patients were selected for the protocol. Patients had a mean age of 79 years old and 38% were of female sex. Mean EuroSCORE II was 12.5% ± 10.8. Mean gradient was also reduced from 45.8 ± 11.04 mmHg to 5.59 ± 2.61 mmHg and there were no instances of PVL worse than mild. There were no cases of coronary obstruction or procedural death. Circularity was present in all prostheses evaluated. Circularity indexes for the prostheses were: inflow 0.05 ± 0.03, middle third 0.03 ± 0.02 and outflow 0.03 ± 0.02. The mean distance between the prosthesis and the left and right coronary ostia were 14.8 mm ± 3.3 and 17.3 mm ± 3, respectively. The degree of oversizing was appropriate with a mean of 22.14% ± 6.

CONCLUSIONS

Braile Inovare ProSeal transcatheter device has demonstrated good clinical results with low rates of PVL. MSCT was an adequate technique to evaluate device sizing and has demonstrated preserved expansibility and circularity in the evaluated cases.

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Comparison of clinical tools for the prediction of bleeding in elderly patients undergoing PCI

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THEME: Coronary Interventions
TOPIC(S): NSTEMI, Stable CAD

AIMS

Advanced age is associated with an increased risk of both ischemia and bleeding. The identification of specific predictors of bleeding is important for clinical decision making. Our aim was to compare the predictive performance of baseline hemoglobin (HB), PRECISE-DAPT and CRUSADE bleeding risk scores.

METHODS AND RESULTS

We used data from a prospective observational study of all consecutive patients aged ≥ 75 years undergoing percutaneous coronary intervention (PCI) at our institution from 2012 to 2016. The analysis excluded patients with an indication for long-term oral anticoagulation. PRECISE-DAPT and CRUSADE scores were calculated in both elective patients and acute coronary syndromes (ACS). The primary endpoint was the incidence of any major or minor TIMI bleeding.

A total of 367 patients were included, aged 81±4 years, 51% with ACS. Values of HB, PRECISE-DAPT and CRUSADE were 13.0±1.7 g/dL, 31±11 points and 35±14 points respectively. Overall, 71% of the patients showed a high risk PRECISE-DAPT value (score≥25), whereas only 36% a CRUSADE high or very high risk value (score>40) and 26% HB levels below 12 g/dL. During 12 months of follow-up, 43 patients (12.4%) experienced the primary endpoint. The positive and negative-predictive values for bleeding were as follows: 21% and 90% for CRUSADE>40 points, 26% and 92% for HB<12 g/dL, 16% and 92% for PRECISE-DAPT≥25 points. All three measures showed similar modest risk discrimination ability (c-statistic: 0.621, 0.663 and 0.697 respectively, p>0.05 for all comparisons).

CONCLUSIONS

PRECISE-DAPT and CRUSADE risk scores show low positive predictive values in the prediction of bleeding in the elderly, so high values should not justify per se the prescription of softer antiplatelet regimens. Hemoglobin is a widely available parameter that provides similar information in a more simple fashion.

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Automatic coronary angiography analysis using convolutional neural networks: segmentation and quantitative features

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Other Coronary Interventions

AIMS

A software for automatic evaluation of coronary artery angiograms could significantly reduce the time needed to evaluate coronary heart vessels, standardize evaluation of lesion characteristics and make it less operator-dependent The aim of our study is to create a deep learning based algorithm for the automatic analysis of coronary angiograms.

METHODS AND RESULTS

The criteria for image selection were: a) stable coronary artery disease (SCAD), b) optimal image quality (0.1 mg intracoronary nitroglycerine administered before angiogram; diagnostic catheter should be well visible, filled with dye; coronary tree - well visible, near the centre of the angiogram and shown without foreshortening; at least 3 cardiac cycles filled with dye; an angulation with minimal vessel overlapping), c) no previous history of invasive treatment (stenting or CABG). Two-dimensional images of coronary angiograms of thirty SCAD patients were selected for the present analysis. In the next stage, we manually segmented coronary tree using “3D Slicer” software. The following tasks were then performed:

The images and segmentation masks were used to train an U-net based convolutional neural network for contrast-filled vessel segmentation task.
We created an algorithm for skeletonization (creating a 1-pixel width map) of the segmentation masks produced by the neural network created in step 1.
We created an algorithm for the evaluation of pixel location in the skeletonized map (end pixel/bifurcation pixel/ continuous pixel).
We created a code, which uses the output produced in steps 1 and 2 to create a segmentation map of the vessels. The algorithm then has the ability to calculate the local radius by calculating the distance of each edge pixel to the edge pixel on a line perpendicular to the centre line. By extracting the scale which is stored in the DICOM metadata the algorithm is then able to calculate the real radius in millimetres.

CONCLUSIONS

The deep learning based algorithm that we have developed is the initial stage of creating software for automatic evaluation of coronary artery angiograms. The current software code is already able to automatically detect and analyse images of coronary angiograms, create segments based on the pixel locations and automatically measure the mean radius. We plan to eventually develop software for use in everyday clinical practice. Further steps planned: a) detection of the course of individual vessels, b) segmentation of functional segments, c) detection of one anatomical area in different projections of the vessel.

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Comparison of the Evolut-PRO self-expanding transcatheter aortic valve to its Evolut-R predecessor; has there been any PROgress?

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

The self-expanding Evolut-Pro TAVI system has been recently introduced claiming improved features compared to its Evolut-R predecessor. Despite its larger introducer sheath, the last generation device is designed for further improvement in paravalvular leak performance offering increased tissue interaction and favourable healing. However, Evolut-Pro platform is not available for larger anatomies yet, with Evolut R 34mm being the only option for these patients. In the present study, we compare the peri-procedural and one year clinical outcomes between the two devices.

METHODS AND RESULTS

Consecutive patients from the ATLAS (Athens-Tokyo-London Aortic Stenosis) registry, who had undergone transcatheter aortic valve implantation (TAVI) with a self-expandable device (Medtronic, Minneapolis, Minnesota), in four centers were retrospectively studied. Patients receiving a first generation CoreValve platform and those requiring a large 34mm device were excluded from the analysis. In-hospital procedural characteristics and outcomes, such as paravalvular regurgitation (PVR), need for permanent pacemaker (PPM) implantation and bailout techniques required, were recorded and compared among patients receiving the Evolut-Pro and Evolut-R devices respectively. Kaplan-Meier estimated 1-year all-cause mortality was compared between groups.

In total, 222 patients (100pts treated with Evolut-Pro and 122pts with Evolut-R device) were included in the analysis. Baseline demographics (age, gender and coronary artery disease risk factors) were similar between the two groups with the exception of impaired ejection fraction (EF<50%), which was significantly higher in patients treated with the Evolut-R (26.2% vs 13.4% for Evolut-R and Pro respectively, p=0.032).

In terms of peri-procedural and short term outcomes, patients treated with the Evolut-Pro device had significantly lower rates of new PPM implantation (25.9% vs 12.6% for R and Pro respectively, p=0.017), as well as significantly lower rates of bail-out valve-in-valve implantation (4.6% vs 0% respectively, p=0.04). Conversely, the need for balloon post-dilatation was significantly more common for the Evolut-Pro patients (30.2% vs 17.6% for Pro and R respectively, p=0.034). No statistical significant difference was recorded with regards to major bleeding complications despite the larger introducer sheath of Evolut-Pro device. Interestingly, similar rates of at least moderate PVR were detected at hospital discharge with a numeric trend showing Evolut-Pro superiority, yet not statistically significant (3.3% vs 7.3% of moderate+ regurgitation for Evolut-Pro and R respectively, p=0.211).

One year Kaplan-Meier estimated survival was similar between the two groups (91.8% for Evolut-Pro vs. 94.7% for Evolut-R, plog-rank=0.462). Hazard ratio for all-cause mortality (Pro vs R) after adjustment for impaired EF was similar between the groups (HR=0.563; 95%CI 0.17 to 1.8, p=0.332).

CONCLUSIONS

The last generation self-expanding Evolut-Pro device seems to demonstrate reduced rates for PPM implantation and need for bailout valve-in-valve compared to its Evolut-R predecessor. 1-year all-cause mortality does not differ between the two devices. Long-term follow-up is required to establish any potential difference with regards to clinical outcome and prognosis.

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Complex, high and indicated percutaneous coronary indication: does operator volume influence patient outcome?

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, CTO

AIMS

Complex high-risk and indicated revascularisation using PCI (CHIP-PCI) is an emerging concept that is poorly studied. Using the British Intervention Society (BCIS) database, we examined temporal changes in CHIP-PCI volumes, and the relationship between operator CHIP-PCI volume and patient outcomes.

METHODS AND RESULTS

Data were analysed on all CHIP-PCI procedures in England and Wales between 2007 and 2014. Operator volume data was available for 2012-14. CHIP-PCI was defined by either patient characteristics (age >80years, left ventricular ejection fraction <30%, previous CABG, or chronic renal failure) and/or by procedural characteristics (left main PCI, CTO-PCI, use of rotational atherectomy or use of laser atherectomy). Individual operator volume was totalled for the 2012 to 2014 period and operators divided into four quartiles of volume (Q1-Q4). We then performed individual logistic regressions on the imputed data set to quantify the independent association between operator quartile and outcomes. To correct for potential baseline imbalances regarding the volume quartiles and their association with clinical outcomes, we used a propensity score estimation for multiple treatments. CHIP-PCI as a percentage of total PCI increased from 28.1% in 2007 to 36.2% in 2014 ($p<0.001$ for trend). Between 2012 and 2014, a total of 30,268 CHIP-PCI cases were performed with operator volume varying from 1 to 580 cases and a median total operator volume of 29 cases. Higher operator volumes were associated with a greater degree of comorbidity (hypertension, peripheral vascular disease, previous MI and diabetes mellitus increasing across the four quartiles) and with greater baseline disease burden. Additionally, higher operator volume was associated with more complex disease with left main disease increasing from 11.2% in Q1 to 16.7% in Q4 ($p<0.001$) and the presence of a CTO increasing from 40.5% in Q1 to 46.7% in Q4 ($p<0.001$). Higher volume CHIP-PCI operators undertook increasingly complex procedures and were more likely to be perform the procedures using rotational and laser atherectomy, intravascular imaging, micro-catheters and left ventricular support. Increasing CHIP-PCI operator quartile was associated with a greater number of successful vessels, a greater number of successful lesions and a higher likelihood of two and three vessel PCI success. Despite higher baseline disease burden, post-PCI disease burden was similar across operator quartile, with lower degrees of post-PCI disease associated with higher operator quartiles when indexed to baseline disease severity. After adjustment for baseline difference, although in-hospital major bleeding ($p<0.001$ for trend), and access site complications ($p=0.018$) were associated with increasing operator CHIP-PCI volumes, peri-procedural MI ($p=0.007$) and in-hospital MACE ($p=0.015$) rates were lower. Higher volume operators were significantly more likely to discharge patients home the same day than lower volume operators. After adjustment, there were no differences in 12-month mortality between operator volume quartiles. Operator volume was not independently predictive of 12-month survival.

CONCLUSIONS

CHIP-PCI cases represent a large population in contemporary PCI practice. Higher CHIP-PCI operator volumes were associated with more complex patients and procedures and but lower rates of in-hospital MACE. There was no relationship between CHIP-PCI operator volume and 12-month mortality.

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Safety and efficacy of >40mm DES in long coronary lesions: multicentre all-comer registry

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THEME: Coronary Interventions
TOPIC(S): STEMI, Stents and scaffolds

AIMS

The aim of the study is to evaluate the efficacy and safety of very long drug-eluting stents (DES) (> 40 mm) in the treatment of long coronary lesions (> 35 mm) in a "real life" population.

METHODS AND RESULTS

Between January 2014 and May 2018 a prospective, multicenter, "all-comers" registry of consecutive patients with DES> 40 mm was conducted. Their clinical data were prospectively registered. The patient-oriented major adverse cardiac events (MACE) were defined as the occurrence of CV-death, any MI, and any coronary revascularisation.

Overall, 221 patients (246 lesions) were included in the study. The mean age was 64 ± 11 years, 77% male, 34% active smokers, 71% hypertensive, 43% diabetic, 58% hyperlipidemic,8% peripheral arterial disease, 7% previous stroke, 17% CKD (eGFR <60 ml / min), 29% prior PCI, 43% impaired LVEF. The clinical presentation was ACS in 84% (14% STEMI). 74% was radial access and 93% 6F. In half of patients (49%), another lesion was treated, in addition. The most frequent artery treated with a long stent was the right coronary artery (42%) followed by the anterior descending artery (38%) and the middle segments were the most affected (54%). All were type C lesions, 29% bifurcational involvement, 22% ostial, 62% calcified, 16% thrombotic and 21% (n = 47) were CTO.

Predilatation / postdilatation was performed in 89/46% respectively, 3.6% required Rotablator and 5.3% thromboaspiration. By QCA, the mean lesion length was 55 ± 17 mm, proximal ref. diameter 3.1 ± 0.6 mm, distal ref. diameter 2.3 ± 0.5 mm. The proximal diameter of the stent used was 3 ± 0.3 mm and the average length was 48 ± 4.6 mm. The number of stents per lesion was 1.7 ± 0.8, with overlapped stents in 58% of the lesions and a total length (in mm) of stent per lesion of 65 ± 20 mm. Some techniques were used to increase the support during the procedure in 11% of the cases (5.7% GuideLiner, 1.6% Buddy Wire, etc). During the procedure, No-Reflow phenomenon occurred in 2.4% (n = 6), edge dissection in 4.1% (n = 10).

EES (Xience / Synergy) were implanted in 54% of the cases, 39% SES (Biomime / (31%) Biomime Morph) and 7% AES (Cre8).

At 682 ± 435 days (605 median) follow-up:

- 8 (3.3%) CV-deaths (6 non-CV). Most of them in the acute phase of AMI.
- 5 (2%) non-fatal AMI
- 6 (2.4%) TLR
- 10 (4%) Haemorrhages
- 8.6% (n = 19) accumulated MACE rate.
- The rate of stent thrombosis was 1.2% (n = 3).

In the univariate analysis both diabetes (HR = 3.2, 95% CI 1.18-8.86, p = 0.017), previous HF (HR = 4.52, 95%

CI 1.29-15.86; = 0.03), previous bleeding (HR = 6.1, 95% CI 1.39-26.8, p = 0.033), peripheral arterial disease (HR = 5.6, 95% CI 1.74-18.3, p = 0.009), previous stroke (HR = 4.2, 95% CI 1.21-14.7, p = 0.037), femoral access (HR = 3.64, 95% CI 1.24-10.65, p = 0.013).), were predictors of events (CV death, non-fatal AMI and TLR). The use of a rotablator (p = 0.08) and the performance of thromboaspiration (p = 0.07) presented a nonsignificant tendency to higher MACE. In a multivariate analysis, only diabetes (p = 0.039) and previous bleeding (p = 0.033) maintained statistical significance.

CONCLUSIONS

The clinical profile of patients treated with DES> 40 mm is very high risk, with a high percentage of multivessel patients. The safety and effectiveness of these stents is good in the medium to long term although they present a non-negligible event rate. Diabetes, femoral access, peripheral arteriopathy and the previous history of bleeding or stroke were associated with an increased risk of MACE.

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PFO closure: long-term follow-up in a real-world study cohort

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THEME: Interventions for Stroke
TOPIC(S): Other stroke interventions

AIMS

Patent foramen ovale (PFO) closure is the treatment of choice after cryptogenic stroke according to the new S2 guidelines. This recommendation is based on results of several randomized controlled trials; however, the results of these trials might be difficult to extrapolate to a real-world clinical setting. Therefore, the aim of the present study was to evaluate long-term outcome regarding recurrent stroke, migraine, and/or peripheral embolism in patients after PFO closure.

METHODS AND RESULTS

We retrospectively analyzed outcomes of consecutive patients undergoing PFO closure from 2011 to 2018 at two interventional sites with respect to periprocedural events occurring during hospitalization and long-term follow-up. Follow-up data were collected from outpatient visits or telephone interviews.

The analysis included 200 consecutive patients (mean age 52.5 years; 57.8% male). The follow-up rate was 96% and the mean follow-up time was 38 (SD 22) months. The index vascular event leading to PFO closure was stroke (n=181; 91%), including patients with repetitive stroke (n=36), embolic myocardial infarction (n=16; 8%), and migraine (n=3; 1%). One quarter (24.6%) of the population studied had an atrial septal aneurysm (>15 mm). Procedural success was achieved in 98%. There were no procedure-related strokes or deaths. Periprocedural complications occurred in 16 patients (8%): two cases of pericardial tamponade, seven complications at the access site mainly caused by bleeding, two cases of transient atrial fibrillation, and five other complications. The Amplatz Septal Occluder was used in roughly two thirds (64.5%) of the cases and the Gore Cardioform device in one third (28.6%). Four patients (2%) died during follow-up. None of these patients experienced a recurrent stroke. Ten patients (5.6%) experienced a recurrent stroke. Patients with recurrent stroke events were older than patients without recurrent stroke (62.6 yrs. [SD 8.8] vs. 52.2 yrs. [SD 13.8]; p=0.015) and had a higher rate of preexisting cerebrovascular occlusive disease (n=5 [50%] vs. n=10 [6%]; p<0.0001). There was no difference in risk for recurrent stroke between patients with one prior stroke and more than one stroke before PFO closure (p=0.71). Atrial fibrillation occurred in 6.6% of the patients during follow-up, but only one of these patients had recurrent stroke. No other anatomic and vascular risk factors or antithrombotic treatments were identified as being predictive of embolic events after closure.

CONCLUSIONS

In this real-world PFO closure cohort the recurrent stroke rate is low, although it is higher than reported in randomized controlled trials. Recurrent strokes after PFO closure may reflect additional comorbid risk factors such as age or cerebrovascular occlusive disease that are unrelated to the potential for paradoxical embolism.

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Coronary perforation complicating PCI in patients presenting with an ACS: an analysis of 1,013 perforation cases from the British Cardiovascular Intervention Society (BCIS) database

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

The evidence base for coronary perforation (CP) occurring during percutaneous coronary intervention in patients presenting with an acute coronary syndrome (ACS-PCI) is limited with the specific role of acute pharmacology in its clinical presentation unclear. Using the BCIS national PCI database, the incidence, predictors and outcomes of CP during ACS-PCIwere defined.

METHODS AND RESULTS

Data was analysed on all ACS-PCI procedures performed in England and Wales between 2007 and 2014. Multivariate logistic regressions were used to identify predictors of CP and its association with outcomes. During the study period, 1,013 CPs were recorded during 270,329 ACS-PCI procedures (0.37% incidence) with no significant temporal change in its frequency. Patient-related factors associated with an increased risk of perforation were age per year (odds ratio (OR) 95% confidence intervals 1.03 [1.03-1.04], p<0.001), and female gender (OR 1.28 [1.08-1.51], p=0.004). Procedural factors were associated with an increased risk of perforation including CTO intervention (OR 3.08 [2.44-3.89], p<0.001), left main PCI (OR 1.46, [1.00-2.12], p<0.001), vein graft PCI (OR 2.54, [1.53-4.22], p=0.002), number of stents used per stent (OR 1.35, [1.25-1.45], p<0.001), longest stent used per mm (OR 1.01, [1.01-1.02], p<0.001), micro-catheter use (OR 1.97, [1.04-3.73], p=0.37), and rotational atherectomy use (OR 1.88[1.29-2.74], p=0.001). Using propensity score matching to evaluate the association between differing P2Y12 inhibitors, prasugrel was associated with a lower risk of perforation compared to clopidogrel (p=0.007) and compared to ticagrelor (p=0.022,). Glycoprotein inhibitor use was not associated with an excess of coronary perforation when propensity score matching was used (p=0.088). Clinical tamponade occurred in 29.6% of patients although emergency reparative cardiac surgery was undertaken rarely (2.5%). There was a significant reduction in both tamponade and need for surgery over the study period (p<0.001 for both trends). Amongst the independent predictors of tamponade, use of any glycoprotein inhibitor was independently associated with its occurrence (OR 1.50, [1.08-2.06], p=0.014). The adjusted odds ratios for adverse clinical outcomes indicated a significant impact of a CP with emergency cardiac surgery (OR 27.5, [14.09-53.72], p<0.001), transfusion (OR 14.3, [6.67-30.52], p<0.001), in-hospital major bleeding (OR 6.6, [4.88-8.85], p<0.001), in-hospital death (OR 8.2, [6.29-10.51], p<0.001), and in-hospital MACE (OR 8.1, [6.42-10.09], p<0.001) all associated with coronary perforation. Using multi-variate analysis, the independent associates of 30-day mortality in those patients who experienced a coronary perforation included age, shock or ventilation on presentation, and renal disease. Use of any glycoprotein inhibitor was not independently associated with death at 30 days (OR 1.58, [0.86-2.92], p=0.143). Finally, coronary perforation was associated with an excess of 12-month mortality (OR 2.7

[1.69-4.23], p<0.001). Kaplan Meier plots for mortality by perforation status to 12-months confirmed the significant impact of a perforation on patient survival to 12-months (p<0.001).

CONCLUSIONS

Coronary perforation is an infrequent event during ACS-PCI but is closely associated with adverse clinical outcomes.Although potent P2Y12 inhibitors did nt increase the frequency of CP, GPI use increased the risk of tamponade.

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ACS and treatment-risk paradox according to GRACE risk score

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

The aim was to evaluate the incidence of reperfusion therapy in patients with acute coronary syndrome (ACS) stratified according to GRACE risk score

METHODS AND RESULTS

This is a single centre retrospective observational study which included 975 consecutive patients with ACS (612 male (62.8%) hospitalized from 2016 September – 2017 February. Their clinical data and choice of reperfusion were documented and GRACE risk score was calculated and used to divide patients into low (Group1, n=372), intermediate (Group2, n=360) and high risk (Group3, n=243).

Revascularization was performed in 727 out of 975 (74.6%). PCI was performed in 683 patients (70.05%), CABG in 44 (4.51%) and solely medical therapy was applied in 227 (23.28%) patients.

In-hospital mortality was 2.15% (n=21).

There were no deaths in Group1 and mortality rate was significantly ($p<0.001$) lower in Group2 (n=4 (19%) in comparison to Group3 (n=17 (81%).

Paradoxically, the highest incidence of revascularization therapy was noted in Group1 in comparison to Group2 and Group3 (38.8% vs 36.5% vs 24.8% respectively).

146 out of 975 patients (15.1%) had three vessel disease (3VD) with a mortality rate 4.1% vs 1.8% in patients with non 3VD.

CONCLUSIONS

The 'treatment-risk' paradox exists in our daily clinical practice where revascularization procedures are more offered to lower risk patients. All ‘incommers’ included in analysis confirm that higher GRACE risk score and the severity of coronary artery disease is associated with a higher mortality rate. Risk stratification can have a major impact in choosing right interventions at the right time if used on a daily basis

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Silent myocardial ischaemia in patients undergoing peripheral vascular surgery: can selective coronary revascularisation improve survival?

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Silent myocardial ischemia is a marker for adverse cardiac events. Patients who undergo peripheral vascular surgery have increased risk for post-operative AMI/death and reduced long-term survival. Coronary CT angiography-derived FFR (FFRCT) can reliably identify ischemia producing coronary stenosis in patients with chest pain and suspected coronary disease but its value in peripheral vascular patients is unknown. This study aims to determine the prevalence of silent myocardial ischemia in peripheral vascular patients and assess the potential value of FFRCT to improve patient outcome.

METHODS AND RESULTS

Patients with no chest pain symptoms or cardiac history who were cleared for elective carotid, aortic or peripheral vascular surgery were enrolled in a prospective, open-label study approved by an ethics committee. Pre-operative coronary CT angiography and FFRCT analysis were performed with results available to treating physicians in <24 hours. Lesion-specific ischemia was defined as FFRCT ≤0.80 distal to a stenosis in a vessel >2mm in diameter. Patient management was guided by a multidisciplinary team of cardiologists and surgeons. Primary endpoint was major adverse cardiac events (MACE, defined as ACS, cardiac death, urgent revascularization) at 30 days with follow up at 3, 6 and 12 months.

Coronary CT angiography in 123 consecutive patients (age 66±8 years, 80% male, 74% hypertension, 13% diabetes, 40% dyslipidemia, 38% current smoking) revealed ≥50% stenosis in 87 patients (71%). CT image quality was suitable for FFRCT analysis in 114 (93%) despite extensive coronary calcification (mean Agatston score 1125±1095, range 0-4810). FFRCT was ≤0.80 in 77/114 patients (68%) with mean value 0.72±0.16. FFRCT was >0.80 in 32% with mean value 0.91±0.08. FFRCT was ≤0.75 in 69 patients (61%), 9 had left main disease and 46 (40%) had multivessel ischemia. Clinically indicated vascular surgery was performed as scheduled in 115/123 patients (93%) and postponed in 8 patients for coronary revascularization (2) or medical/ other therapy (6). One patient with no FFRCT analysis due to poor CT image quality (motion in the right coronary artery) had AMI 3 days post surgery and had successful emergent PCI. The primary endpoint of MACE at 30 days was 1/123 (0.8%). All patients received optimal medical therapy. Elective coronary angiography was performed 1-3 months post surgery in 60 patients guided by the presence of left main, multivessel ischemia or FFRCT ≤0.75. Significant stenosis was confirmed in each patient with coronary revascularization in 46 patients (PCI in 40, CABG in 6). There have been no cardiac deaths; MACE at 3 and 6 months was 1/123 (0.8%) and at 12 months was 1/77 (1%). Two patients have died of non-cardiac causes, both metastatic lung cancer, first discovered at coronary CT evaluation.

CONCLUSIONS

Two of three patients undergoing elective peripheral vascular surgery have unsuspected, silent myocardial ischemia. Pre-operative evaluation with coronary CT and FFRCT can help guide multidisciplinary team approach for optimal patient management, including planning of elective coronary revascularization.

Favourable early results suggest that focused peri and post-operative cardiac care with selective post-operative revascularization of ischemia-producing coronary lesions may improve survival of vascular surgery patients and suggest the need for prospective controlled outcome studies.

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Contrast-induced acute kidney injury increases the risk of chronic kidney disease progression and mortality at long-term after coronary angiography and intervention

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THEME: Coronary Interventions

TOPIC(S): Other Coronary Interventions

AIMS

The primary end-point of our study was the analysis of chronic kidney disease progression after coronary angiography and/or intervention in a large all-comers population of patients at long-term follow-up. The secondary end-point was the analysis of all-cause mortality.

METHODS AND RESULTS

Our institutional database was interrogated to retrieve all-comers patients who underwent percutaneous coronary angiography and/or intervention between January 2013 and December 2015 with available laboratory data including serum creatinine level at baseline, at 48-72 hours, at 20-40 days and at 12-24 months from contrast medium administration. Renal function was categorized according to the stages set by the National Kidney Foundation. Long-term clinical outcome was assessed with outpatient clinic visits or phone contact.

Contrast-induced acute kidney injury was defined as a relative increase in serum creatinine concentration of at least 25% and/or an absolute increase in serum creatinine concentration of at least 0.3 mg/dL as measured 48-72 hours after contrast medium administration compared with baseline. Chronic kidney disease was defined as an estimated glomerular filtration rate persistently <60 mL/min for at least three months.

Among 655 patients included in our study, contrast-induced acute kidney injury occurred in 106 (16.2%) patients. 71 patients (67%) experienced only transient renal damage, whereas 35 out of 106 patients (33%) demonstrated persistent renal function impairment at 20-40 days.

At a mean follow-up time of 32±11 months, contrast-induced acute kidney injury was associated with a significant progression of chronic kidney disease (OR=2.24, 95% CI 1.31-3.83, p=0.02). Notably, among patients who developed contrast-induced acute kidney injury, those with persistent renal damage experienced a significant progression of chronic kidney disease (OR=4.53, 95% CI 2.11-9.71, p<0.001), whereas those who developed transient renal damage did not progress significantly (OR=0.64, 95% CI 0.19-2.21, p=0.48).

Contrast-induced acute kidney injury was also associated with a significant risk of all-cause death at a mean follow-up time of 32±11 months (HR=4.41, 95% CI 1.97-9.87, p<0.001) at univariate analysis and remained a significant predictor of mortality after adjustment for clinical confounders. No significant difference in mortality was observed between patients who developed persistent renal damage versus transient renal damage (43.7% vs 56.3%).

CONCLUSIONS

Even with several limitations, our study confirmed in a large all-comers population of patients that contrast-induced acute kidney injury, far from simply being a transient and benign laboratory alteration, could be a cause of significant worsening of renal function and a determinant of significantly increased all-cause mortality at long term follow-up.

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Aortic cross-clamp and opening after TAVI: a real issue?

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Patients undergoing TAVI are becoming younger, with lower surgical risk and longer life expectancy. As a consequence, the number of patients treated with TAVI who will require subsequent cardiac surgery will increase. It is debated whether the presence of TAVI devices with a tall stent frame in the ascending aorta may theoretically jeopardize the ability of surgeons to perform aortic cross-clamp and aortotomy.
The aim of this study was to assess the anatomical feasibility of ascending aortic manipulation after TAVI, based on post-TAVI computed tomographies (CT).

METHODS AND RESULTS

117 CTs acquired after TAVI at 3 high-volume centers between October 2008 and May 2017 were retrospectively reviewed.All CT scans were cardiac-gated. As per study design, only TAVI devices with a long tubular stent design were assessed: 101 (86.3%) CoreValve, 16 (13.7%) Portico.
CT-scans revealed that no patient had a distance between the innominate artery and the top of the TAVI stent < 20 mm, the shortest observed measurement being 22 mm in two cases. Eight patients presented an Innominate-TAVI distance < 30 mm (25 mm in four patients, 24 in one, 23 in one, 22 in two). In the remaining cases the Innominate-TAVI distance was more than 3 cm, providing comfortable space for the positioning of the aortic clamp.
The anterior aortic wall presented some contact with the stent of the TAVI prosthesis in all cases assessed. In particular, in 47.9% of cases, there was complete continuous contact between the anterior aortic wall above the sino-tubular junction and the anterior part of the prosthesis stent. The mean distance between the sino-tubular junction and the first possible site for aortotomy, free from the underlying cage of the TAVI device, was 22 ± 7 mm (minimum distance 7 mm in one case).

CONCLUSIONS

Our preliminary CT results suggest that aortic cross-clamp appears to not be an issue when cardiac surgery is needed after TAVI, but a careful and possibly higher aortotomy may be required. If possible, a CT scan should be performed prior to cardiac surgery in patients previously treated with TAVI to plan a secure positioning of the aortic clamp and aortic incision. Large numbers from direct surgical operations will be required to confirm these findings.

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TAVI as bridge therapy to heart transplantation in patients with aortic regurgitation requiring left ventricle assist device

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

The use of TAVI in patients with pure aortic regurgitation (AR) and advanced heart failure (HF) as bridge therapy to ventricular assist device (VAD) implantation or cardiac transplantation is described only in few isolated case reports. The aim of this analysis is to evaluate the feasibility and the impact of TAVI for pure AR on the prognosis of such complex patients.

METHODS AND RESULTS

We analysed 5 consecutive patients treated with TAVI at our centre between July 2012 and June 2018 with advanced HF and severe AR, as bridge therapy to VAD or to cardiac transplantation. In all cases self-expandable Core-Valves were used. The immediate and long-term clinical outcomes were prospectively assessed according to the VARC-2 criteria.

All patients presented advanced HF at the time of TAVI with severe reduction of LVEF (<30%) and NYHA class IV, associated with multi organ failure (MOF) and a prohibitive surgical risk (Log EuroSCORE>40%). All patients were male, and the mean age was 60±5 [51-75]. In 4 patients TAVI was performed as bridge therapy to cardiac transplantation, because of a severe AR secondary to the hemodynamic effect of a previously implanted Heart Mate-II LV-VAD. In one patient, TAVI was performed, as bridge therapy to VAD, to treat a pre-existing degenerative non-calcific severe AR causing terminal HF.

In three patients with LV-VAD, the placement of two valves was required to obtain a successful result: in 2 of them the second valve was pre-planned given the too large size of the aortic annulus, while in the remaining case a second unplanned valve was implanted because of the embolization of the first one in the ascending aorta. A single valve was successfully positioned in the other two cases. None or mild residual AR was detected at the end in all cases, and no procedure-related complications occurred during or after TAVI.

Two patients with LV- VAD died within 30 days of TAVI because of irreversible MOF.

The other two LV-VAD-carriers underwent successful cardiac transplantation after 4 and 6 months respectively, and are alive with NYHA class I without recurrence of clinical events after 6 years and 1 year respectively.

The patient who received TAVI as bridge therapy to LV-VAD underwent device positioning one month after TAVI and is still alive at 6 months, in the waiting list for heart transplant.

CONCLUSIONS

The implantation of self-expandable trans-catheter valves to treat severe AR and advanced HF as bridge to LV-VAD or to cardiac transplantation is feasible and represents a valuable option for the survival of these young and extremely complex patients.

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Is the relationship between the LAA and pulmonary artery a risk factor for pericardial effusion in transcatheter LAA occlusion?

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

Pulmonary artery (PA) perforation with pericardial tamponade is a potentially fatal complication following left atrial appendage (LAA) occlusion. This study aimed to describe the relationship between the LAA and the PA, and the risk of pericardial effusion.

METHODS AND RESULTS

We reviewed 390 consecutive patients undergoing LAA occlusion [ACP: 75 (19.2%), Amulet: 299 (76.7%), Watchman: 12 (3.1%), LAmbre: 4 (1%)] between March 2010 and July 2018. Of these, 344 patients had both preprocedural and 8-weeks follow-up cardiac CT available. All images were analyzed by two blinded investigators. On preprocedural cardiac CT, the distance between the LAA and PA was measured in a cross-sectional view at the predicted landing zone. On follow-up cardiac CT, the measure was repeated in a cross-sectional view through the distal part of the device lobe at the level of the retention hooks. All patients had transthoracic echocardiogram performed before discharge.

The median LAA to PA distance was 5.5 mm (IQR 2.5-11) on pre-CT and 5 mm (IQR: 2.5-8) on post-CT ($p<0.001$). In 41 (12%) patients, the distance between the LAA occluder and the PA was less than 1.5 mm. Tamponade occurred in 6 (1.7%) patients, while minor self-limiting pericardial effusion occurred in 4 (1.2%) patients. In a logistic regression model, the distance between the LAA occluder and PA did not increase the risk of effusion (unadjusted RR 1.05, 95%CI 0.91-1.22, $p=0.492$).

CONCLUSIONS

The left atrial appendage and pulmonary artery are in close anatomical proximity. In 344 cases of LAAO, a small distance between the LAA occluder and the PA, was not a significant risk factor for pericardial tamponade or effusion.

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LAA occlusion with the AMPLATZER and AMULET devices - Long-term outcomes in a high-risk cohort

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THEME:
TOPIC(S):

AIMS

LAA occlusion has become a favorable prophylactic treatment option in patients with atrial fibrillation not suitable for oral anticoagulation therapy. Registries could demonstrate safety and feasibility of implantation of the ACP Amplatzer Occluder devices. Due to its prophylactic character, effectiveness of LAA closure devices should be assessed in long term follow-up periods.

METHODS AND RESULTS

Methods

We found 206 patients, not amenable for oral anticoagulation, treated with the ACP Amplatzer LAA occluder (n=102) or the Amulet device (n=104) between 08/2009 and 04/2016 at our institution. In 192 patients (93%) a standardized follow-up by phone call focusing on data of death, stroke and bleeding events was performed. All of our patients received DAPT for three months post procedural.

Results

206 patients (mean age: 77y) received a Amplatzer or Amulet device at our institution. Patients were at high risk for thromboembolic or bleeding events (prior stroke/TIA 29%; prior bleeding 57 % (whilst on anticoagulation 53%). Mean CHADSvasc score was 5 and HASBLED score was 3. Overall, there was a mean follow-up period of 1244.17 days (±756.70) and a total of 655 patient years.

We observed 22 events later than day 8 post procedure (8 bleeding events, 10 strokes and three TIA and 1 thrombus formation in the LAA).

CONCLUSIONS

We were able to demonstrate a high effectiveness of the Amplatzer/AMULET devices regarding the prevention of stroke and bleedings in a high risk real world cohort during a long-term follow-up period. Overall, we observed remarkably lower rates of stroke and bleedings as predicted with CHADSvasc and HASBLED scores.

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Spatial relationship between LAA occlusion devices and the circumflex coronary artery: A cardiac CT study

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

Compression of the circumflex coronary artery (Cx) caused by left atrial appendage occlusion (LAAO) devices has anecdotally been reported. This study aimed to describe the relationship between the Cx and the implanted LAAO device using pre- and postprocedural cardiac CT imaging.

METHODS AND RESULTS

LAAO was performed in 390 consecutive patients between March 2010 and July 2018. Both preprocedural and 8-weeks follow-up cardiac CT was available in 344 patients. Two blinded investigators retrospectively analyzed all images. On preprocedural cardiac CT, the distance between the LAA and Cx was measured in a cross-sectional view of the landing zone (±5 mm). At follow-up cardiac CT, the shortest distance between the LAAO device and the Cx was measured in a cross-sectional view of the device lobe.

The mean distance between the predicted LAA landing zone and the Cx was 3.9±1.5 mm. A calcified coronary plaque in the Cx was present at the level of the LAA in 151 (44%) patients. At follow-up, the distance between the LAAO device and Cx was 3.1±1.9 mm. One patient had temporary periprocedural ST-elevation and bradycardia, but coronary angiography showed no signs of stenosis.

CONCLUSIONS

The LAAO device and the Cx are closely related, with coronary plaques in relation to the device landing zone being highly prevalent. Our data indicate that despite a close relationship between the Cx and LAA, coronary events are extremely rare.

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IVUS use on CTO PCI

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Impact of Intravascular ultrasound (IVUS) use on chronic total occlusion percutaneous coronary intervention

METHODS AND RESULTS

This was a cohort study that was based on the prospective collection of clinical, angiographic and procedural data of consecutive patients undergoing successful CTO PCI in a tertiary care centre since the onset of a dedicated CTO programme. From June 2012 until November 2018 508 successful CTO PCIs were performed. IVUS was used in 180 (35%) of cases, whilst angiography alone in the remaining 328 (65%) There was a significant rise in IVUS uptake in CTO PCI from 29% in year 1 up to 75% of cases in the most recent year. A ranking propensity score analysis with a nearest-neighbor 1:1 matching algorithm with calipers of 0.2 SDs of the logit of the propensity score was applied to create a matched sample with similar distribution of characteristics that could bias IVUS use. The observed groups of IVUS guided PCI and angiography guided PCI were matched based on the following characteristics: CTO complexity scores including the Japan-CTO and EuroCTO CASTLE scores, Age, chronic kidney disease, previous PCI, and target CTO vessel; and they were balanced for other baseline demographic data such as gender, hypertension, diabetes and hypercholesterolaemia. After matching, two groups of 191 patients each were produced to form the final study population. In the IVUS-guided group the median stent diameter was larger (3.5 vs 3.0mm, IQR 3.0-3.5, p<0.001)., and the median stented segment length was longer compared to the angiography guided group (60 vs 38mm, IQR 33-80, p<0.001). There were no differences in contrast volume (250ml, IQR 197.5-320, p=0.878), radiation (1.78 Gy, IQR 1.1-2.6, p=0.820) and fluoroscopy time (35min, IQR 20-55, p=0.268) between the two groups, whilst IVUS guided group had significantly longer procedural time (135 vs 108 minutes, IQR 90-172, p=0.001)

Multivariate linear regression analysis identified several confounding factors positively associated with implanting larger diameter and longer stented segments. IVUS use and final successful crossing strategy were independent predictors of larger diameter of stent, and these factors also supplemented target CTO, prior CABG, and hypercholesterolaemia as additional predictors of stented length.

CONCLUSIONS

In this observational study, use of IVUS was associated with larger stent diameter and longer stented segments during CTO PCI. This finding might have potential implications regarding long-term outcomes, as IVUS guided CTO PCI could assist to prevent implantation of undersized stents and thus reduce short- and long-term risk for stent failure.

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Impact of blood viscosity on cardiovascular events after PCI

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THEME: Coronary Interventions

TOPIC(S): Other Coronary Interventions

AIMS

Elevated blood viscosity (BV) is an integral component of vascular shear stress that contributes to the site-specific rapid growth of atherosclerotic lesions and their increased propensity to rupture. However, it still remains uncertain whether this value is associated with long-term clinical outcomes after percutaneous coronary intervention (PCI) in patients with coronary artery disease (CAD).

METHODS AND RESULTS

In PCI-treated patients (n = 1,278), BVs were measured with a scanning capillary tube viscometer (BVD Viscometer, Bio-Visco Inc., Jeonju, Korea). Patients were stratified into two groups according to the levels of BVs. The cutoffs at shear rates of 300 s-1 (systolic BV) and 1 s-1 (diastolic BV) were pre-specified as 50 and 350 mP, respectively. MACE was defined as a composite of CV death, non-fatal MI, ischemic stroke and revascularization. : With a median follow-up of 34.6 (IQR: 17.3, 53.3) months, MACE was occurred in 12.8% of the cohort. High levels of systolic and diastolic BVs were observed in 50.7 % and 46.4 %, respectively. The cumulate incidences of MACE did not differ between the groups. On land-mark analysis, the early-term (< 1 year) incidence of MACE was not different between the groups, whereas the late-term (≥ 1 year) incidence of MACE was significantly greater in the high vs. low BV group. In multivariate analysis, high systolic BV (HR 1.68, 95% CI 1.13 to 2.51, p = 0.011) and diastolic BV (HR 1.76, 95% CI 1.17 to 2.61, p = 0.007) were the independent predictors for MACE occurrence after 1 year post-PCI.

CONCLUSIONS

This is the largest cohort study to evaluate the relationship between BV and clinical outcomes in high-risk CAD patients. After PCI, the impact of BV level on MACE occurrence did not make any difference in the early period, but this impact appeared divergent over time (after 1 year).

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Four-year survival of transcatheter compared to surgical AVR in minimal-risk patients lacking EuroSCORE and STS Score comorbidities and signs of frailty

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Transcatheter aortic valve implantation (TAVI) is the method of choice in inoperable, and in high or intermediate risk patients. Randomized trials in low risk patients comparing TAVI and surgical aortic valve replacement (SAVR) are ongoing.

METHODS AND RESULTS

Analyses were based on the TAVI Karlsruhe (TAVIK) registry of 2000 consecutive patients undergoing TAVI and 1050 consecutive patients undergoing isolated SAVR between 05/2008 to 03/2015. Included were patients with an age > 74 and < 86 years and an Ejection Fraction (EF) ≥ 50%. The following exclusion criteria were used to determine minimal risk : redo-operation (valve intervention or coronary artery bypass graft [CABG]), chronic obstructive pulmonary disease, neurological dysfunction, critical preoperative status or emergency operation (EuroSCORE I), pulmonary hypertension (PAsys > 60 mm Hg), serum creatinine > 200 µmol/l, coronary artery disease, mitral valve disease (≥ II°), endocarditis, porcelain aorta, diabetes mellitus (insulin or not insulin dependent), liver cirrhosis with complications, no incurable neoplasm, frailty (no dementia, no immobility, no incontinence, needing, no support for eating or washing). [PDPB1] The only differences in baseline parameters as to EuroSCORE and STS-SCORE were that TAVI patients were older (80.7 vs. 77.4 years; p<0.0001) and more female (72.7% vs. 57.0%; p=0.015). Consecutively the mean EuroSCORE (8.16% vs. 6.43%; p<0.001) and the mean STS score (2.16% vs. 1.72%; p<0.001) were generally low but significantly higher in the TAVI subgroup. Statistically inverse probability of treatment weighting was used to account for baseline imbalances between the 2 groups, with adjustment performed for factors found to differ, age and sex.
132 (6.6%) of 2000 consecutive TAVI patients and 93 (8.9%) of the 1,050 isolated SAVR controls in the same period fulfilled the minimal risk criteria. During a follow up of 4 years 6 SAVR patients (6.7%) and 16 TAVI patients (13%) died (Kaplan Meier survival curves p=0.21); two patients in the SAVR and four patients in the TAVI group died from cardiac reasons. The mean age of the dead patients was 79.09 vs 82.04 years (SAVR vs TAVI, p=0.03). After adjustment for age and gender survival in TAVI patients is superior to SAVR patients (Unadjusted OR at 4-year 0.54 (0.20-1.44) p=0.251; adjusted OR at 4-year 1.92 (1.14-3.24) p=0.014). No patient in both groups had any reintervention regarding the prosthetic valve.

CONCLUSIONS

In elderly minimal risk patients after adjustment for age and gender 4-year midterm survival in TAVI patients is

superior to SAVR patients. From a clinical perspective, these may justify an extension in use of TAVI in this subgroup

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Erythropoietin is an independent predictor for one-year mortality after TAVR: a prospective observational study

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Blood erythropoietin (EPO) level has been shown to independently predict prognosis in cardiovascular diseases such as chronic heart failure and acute coronary syndrome. We investigated the prognostic value of pre-procedural levels of EPO, after adjusting for anaemia and renal function.

METHODS AND RESULTS

A prospective observational study was carried out in 212 consecutive patients undergoing TAVR. Anaemia was defined according to WHO guidelines (Hb <12mg/dl for women, <13mg/dl for men). Renal function was classified in chronic kidney disease (CKD) stages according to estimated glomerular filtration rate (eGFR, mL/min/1.73m2): CKD 1 (>90), 2 (60-90), 3a (45-59), and 3b (30-44). As in previous studies, patients with severe renal failure (CKD 4/5, eGFR <30) were excluded, since EPO production is severely limited in them.

Baseline anaemia and median EPO levels were compared between survivors vs non-survivors. Log-EPO levels were used in a univariate Cox regression analysis of 1-year mortality after TAVR. Other baseline variables found significant in univariate analysis ($p<0.1$) and/or clinically relevant were included in a multivariate analysis. Kaplan-Meier curves were constructed for patients with EPO levels above vs below median value, and for patients with vs without anaemia. Exploratory subgroup analyses were performed in patients with and without anaemia.

Complete data on EPO, anaemia, renal function, and survival were available in 173 eligible patients. Self-expandable (Portico [n=101], Symetis [n=30], and Evolut R [n=18]) and balloon-expandable valves (Sapien 3, n=24) were used. Mean age was 81.8±5.8 years and mean EuroSCORE II was 5.1. Pre-procedurally, 54.3% of patients had anaemia (61.3% male, 38.7% female).

30-day mortality was 4%, and 20.2% patients died at 1 year. Anaemia was significantly associated to 1-year mortality, (30.1% vs 8.7%, $p=0.001$). Higher baseline EPO levels showed a significant association to 1-year mortality ($p=0.001$), with median levels being 20.30 (6.1-231.6) mU/mL vs 12.9 (2.7-136) in non-survivors vs survivors.

High levels of log-EPO significantly predicted 1-year mortality in univariate analysis (HR 5.5, 95% CI 2.3-13.4, $p=0.0001$). Anaemia (HR 3.8, 95% CI 1.7-8.8, $p=0.001$), EuroSCORE II, body mass index, and previous atrial fibrillation were the only other significant factors in the univariate analysis. Multivariate analysis of EPO after adjusting for these factors and eGFR was also significant (HR 2.98, 95% CI 1.03-8.67, $p<0.05$, corresponding to a nearly 3-fold increased hazard rate if EPO levels are 10-fold increased). Kaplan-Meier analyses showed early diverging curves for anaemia vs non-anaemia, whereas the curves for patients with high vs low EPO levels started to diverge at about 3 months after TAVR. In exploratory subgroup analyses in patients with

anaemia, a high EPO level predicted 1-year mortality (HR 3.2, 95% CI 1.1-9.4, p=0.037), whereas it did not achieve significance in patients without anaemia.

CONCLUSIONS

Our study confirmed anaemia to be a strong predictor of short- and mid-term mortality after TAVR. More importantly, excessive EPO synthesis was an independent predictor for higher mortality with its effect not only being driven by pre-existent anaemia or renal dysfunction. Unlike anaemia, EPO could have a specific mid-term predictive value emerging once the acute phase of post-TAVR recovery is over, which could be explained by underlying hypoxia in elderly patients with common chronic co-morbidities.

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Long-term ticagrelor monotherapy in elderly patients aged above 75 years undergoing PCI in the GLOBAL LEADERS study

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THEME: Coronary Interventions
TOPIC(S): NSTEMI, Stable CAD

AIMS

There is a need to identify most effective antiplatelet treatment strategies dedicated to elderly patients undergoing percutaneous coronary interventions (PCI). The study aimed to evaluate the efficacy and safety of ticagrelor monotherapy following PCI in relation to age in the Global Leaders study cohort.

METHODS AND RESULTS

This is a pre-specified analysis from the randomized multi-center Global Leaders trial, comparing the experimental strategy of 23-month ticagrelor monotherapy (after one month of ticagrelor and aspirin) with the reference strategy of 12-month dual antiplatelet treatment followed by 12 months of aspirin monotherapy in 15,991 patients undergoing PCI, divided into elderly (n=2,565) and non-elderly, according to a pre-specified cut-off of 75 years. The primary endpoint was 2-year all-cause mortality or nonfatal, centrally adjudicated, new Q-wave myocardial infarction.

Among elderly patients, the primary endpoint occurred in 7.2% in the experimental arm and in 9.4% of patients in the reference group (rate ratio [RR] 0.75, 95% confidence interval [CI] 0.56-0.99, p=0.041; pint=0.23); the key secondary safety endpoint of Bleeding Academic Research Consortium bleeding type 3 or 5 occurred in 5.0% and 3.9%, respectively (hazard ratio [HR] 1.28; 95%CI 0.88-1.85; p=0.192). Elderly patients in the experimental group had a lower rate of definite (0.2%vs.0.9%, p=0.043, pint=0.03) and definite or probable stent thrombosis (0.4%vs.1.3%, p=0.015, pint=0.01), as compared with patients in the reference group.

CONCLUSIONS

The efficacy and safety of the experimental treatment strategy was not identified as age-dependent for the primary and key safety endpoints among patients undergoing PCI. A potentially more enhanced anti-ischemic efficacy of ticagrelor monotherapy in the elderly (after one month of dual therapy with aspirin), achieved without the trade-off of statistically higher rate of bleeding, warrants careful ischemic-bleeding risk stratification and further investigation in a dedicated study.

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Hybrid carotid artery stenting and cardiac surgery - Do it today or leave it for tomorrow?

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THEME: Interventions for Stroke
TOPIC(S): Carotid stenting

AIMS

Background:
- Evidence supporting the benefits of prophylactic revascularization of asymptomatic carotid stenosis in cardiac surgery candidates to reduce perioperative stroke is lacking.

Aims:
- To evaluate cardiovascular outcomes in patients undergoing hybrid carotid artery stenting (CAS) and cardiac surgery.
- To compare outcomes of CAS previous to cardiac surgery in the same day with staged procedures.

METHODS AND RESULTS

Methods: Single-centre retrospective cohort consisting of 161 patients referred for CAS from February 2001 to December 2017 prior to cardiac surgery either hybrid on the same day or staged. The endpoints evaluated were stroke, myocardial infarction (MI), death and major adverse cardiovascular events (MACE) at 30 days and at 1 year follow up. The sample was further divided in group HYB (hybrid CAS and heart surgery on the same day) and STG (staged CAS prior to heart surgery) to compare both strategies. Event-free survival (MACE) was compared between group HYB and STG by the Kaplan-meier method.

Results: The sample included of 80% (129) males, mean age of 74±8 years old. 66,5% (107) performed CABG while 33,5% (54) performed valvular heart surgery. Group HYB (n=41) and STG (n=111) showed similar cardiovascular risk profile. No statistically significant differences were found between groups in stroke (HYB 0/40 (0%) vs STG 4/110 (3,6%), p=0,222), MI (HYB 0/40 (0%) vs STG 1/109 (0,9%), p=0,543), death (HYB 0/40 (7,5%) vs STG 7/110 (6,4%), p=0,805), MACE (HYB 3/40 (7,5%) vs STG 10/110 (9,1%), p=0,759) at 30 days. The results were also similar at 1 year, stroke (HYB 0/39 (0%) vs STG 5/109 (4,6%), p=0,174), MI (HYB 0/39 (0%) vs STG 5/109 (4,6%), p=0,174), death (HYB 4/39 (10,3%) vs STG 9/109 (8,3%), p=0,705), MACE (HYB 4/39 (10,3%) vs STG 14/109 (12,8)%, p=0,671). Age was the only predictor of MACE at 1 year (odds ratio 1,087 (95% CI 1,005 – 1,175, p=0.038). ROC curve analysis identified 77 years old as a cut off for MACE at 1 year (AUC 0,660 , P=0,02, sensitivity 56% - 95% CI 31-79, specificity 76% 95% CI 68-83). Both groups showed similar event-free survival curves by the Kaplan meier method at one year (HYB 331±16 vs STG 330±10 days, log rank p=0,871).

CONCLUSIONS

The frequency of adverse events following CAS in cardiac surgery candidates is considered low in our series. The hybrid strategy on the same day showed similar results in major cardiovascular risk events and adds the advantage of decreasing the waiting time for surgery and risks associated with the double antiplatelet therapy prior to cardiac surgery. The cut point of 77 years old shows that this strategy may be a good option even for old patients.

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A diagnostic prediction model of coronary artery disease in patient with chest pain

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Chest pain is a major symptom of coronary artery disease (CAD), which can lead to acute coronary syndrome and sudden cardiac death. Accurate diagnosis of CAD in patients who experience chest pain is crucial to provide appropriate treatment and optimize clinical outcomes. This study was to develop a machine learning model which can predict and diagnose CAD in patients complaining of chest pain based on a large real-world prospective registry database and computing power.

METHODS AND RESULTS

A total of 10,177 subjects with typical or atypical chest pain who underwent a coronary angiography at the cardiovascular center of Korea University Guro Hospital, Seoul, South Korea between November 2004 and May 2014 were evaluated in this study. . The generation of the diagnostic prediction model for CAD used the classification application by technical support of MATLAB® R2017a (Mathworks, Natick, MA). The performance evaluation of the learning model generated by machine learning was evaluated by the area under the curve (AUC) of the receiver-operating characteristic (ROC) analysis. The diagnostic prediction model of CAD had been generated according to the user's accessibility such as the general public or clinician (Model 1 - 4). The performance of the models has ranged from 0.78 to 0.96 by the AUC of ROC analysis. The prediction accuracy of the models ranged from 70.4% to 88.9%. The performance of the diagnostic prediction model of CAD by machine learning improved as the input information increased.

CONCLUSIONS

A diagnostic prediction model of CAD using the machine learning method and the registry database was developed. Further studies are needed to verify our results.

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Percutaneous peri-cardioscopy in a population with a high prevalence of tuberculous pericarditis - Improving the diagnostic yield and advancing the time to diagnosis

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THEME: Interventions for Heart Failure

TOPIC(S): Acute heart failure, Chronic heart failure

AIMS

Establishing a definite diagnosis of tuberculous (TB) pericarditis via direct detection of Mycobacterium tuberculosis (MTB) is challenging and not always possible using conventional investigations. Previous studies have demonstrated a low yield using either direct microscopy or mycobacterial culture on pericardial fluid alone. We evaluated the potential advantage of minimally invasive percutaneous pericardioscopic biopsy of the pericardium in the diagnosis of TB pericarditis.

METHODS AND RESULTS

Patients presenting with a moderate-to-large pericardial effusion were offered pericardiocentesis via a standard procedure, followed by percutaneous pericardioscopy and pericardial biopsy. Pericardial fluid evaluation included biochemistry, cell count, smear microscopy and TB culture. Pericardial biopsy specimens underwent direct smear microscopy for acid fast bacilli (AFB's), TB culture and histological examination. Definite TB pericarditis was defined as at least one specimen positive for AFB's, MTB culture, or presence of granulomas on histology. 100 patients participated. 59 were males, mean age 37.9 ±13.5 years, and 60 were HIV infected (mean CD4 = 192.7 cells/μL). Pericardial biopsy could be obtained in 82 participants, and 54 (65,8%) of these had definite pericardial TB. The yield by examining pericardial tissue was significantly higher than by examining pericardial fluid (96,3% (52/54) vs 72,2% (39/54); $p<0.05$). 34 tissue samples were positive by smear and/or histology (11 AFB positive, 12 had granulomas, and 11 had both), whilst 15 tissue samples were only culture positive. Of the 39 culture positive fluid samples, 10 were smear positive.

CONCLUSIONS

Histological and microbiological examination of pericardial tissue resulted in a significantly higher yield than examination of pericardial fluid, with 15 of the 54 confirmed cases (27,7%) identified only on examination of pericardial tissue. In contrast to the assessment of pericardial fluid where a definite diagnosis of TB was mainly dependent on culture, pericardial biopsy enables a more rapid diagnosis by microscopy or histology.

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Sex differences in iFR or FFR guided strategy

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Instantaneous wave-free ratio (iFR)- and fractional flow reserve (FFR)-guided strategy showed comparable clinical outcomes in patients with coronary artery disease. This study sought to evaluate impact of sex on iFR- and FFR-guided treatment.

METHODS AND RESULTS

In this DEFINE-FLAIR (Functional Lesion Assessment of Intermediate stenosis to guide Revascularization) substudy, 601 women and 1,891 men who were randomized to iFR- or FFR-guided strategy were analyzed. iFR≤0.89 and FFR≤0.80 were used as criteria for revascularization. The primary endpoint was 1-year major adverse cardiac events (MACE), defined as the composite of all-cause death, nonfatal myocardial infarction, or unplanned revascularization. There was no sex difference in iFR values (0.91 ± 0.09 vs. 0.91 ± 0.10, p = 0.442), but FFR values were higher in women (0.85 ± 0.10 vs. 0.83 ± 0.09, p = 0.001). In men, iFR-guided strategy was associated with a significantly lower rate of revascularization than FFR-guided strategy (49.3% vs. 57.1%, p = 0.012). However, in women, revascularization rate was not different between iFR- and FFR-guided group (41.4% vs. 42.6%, p = 0.656). At 1 year, MACE rate was not different according to sex (5.49% vs. 6.77%, HR 0.80 95% CI 0.53-1.21, p = 0.282). And there was no significant difference in MACE rates between iFR- and FFR-guided strategy in both women (5.36% vs. 5.61%, HR 0.86, 95% CI 0.40-1.81, p = 0.683) and men (6.55% vs. 7.00%, HR 0.97, 95% CI 0.67-1.41, p = 0.888) (interaction p = 0.76).

CONCLUSIONS

There was no difference in iFR values according to sex, but FFR values were higher in women. iFR- and FFR-guided treatment strategy showed comparable clinical outcome regardless of sex.

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In TAVI the less antibiotics, the better!

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

The pharmaceutical strategy of preventing infections during TAVI is still part of a lively debate. The aim of this study was to assess the impact of the use of antibiotics in the incidence of acute kidney injury (AKI) after transcatheter aortic valve implantation (TAVI) using the ratio of the contrast volume to the respective measure of renal function, which is an independent predictor of contrast induced nephropathy.

METHODS AND RESULTS

We randomized 162 consecutive patients undergoing TAVI between November 2016 and November 2018 (24 months) in our hospital in two groups; in Group A, the patients did not take any antibiotics post TAVI, while in Group B, prophylactic antibiotic treatment post TAVI was given. As for the exact protocol of our hospital, the antibiotic therapy consists of 1gr vancomycin iv bolus 2 hours pre TAVI (Group A) and iv vancomycin 500mg x4 + iv ciprofloxacin 400mg x2 for three days period, starting from 2 hours before the intervention(Group B). Moreover, linezolid was used instead of vancomycin, when glomerular filtration rate (GFR) was lower than 25ml/min. After the application of the exclusion criteria (surgical cut-down approach for transfemoral TAVI or other than femoral access, and permanent peacemaker implantation during hospitalization), the two groups had 52 and 36 patients respectively. Acute kidney injury (AKI) was defined according to the VARC-2 AKIN classification (an absolute increase in serum creatinine of at least ≥0.3 mg/dl or a relative increase of >150-199% within 48 hours after TAVI).

As for the baseline characteristics of the patients, there were no statistically significant differences in mean age (81.7 years vs 81.2 years, p value n.s.), mean weight (71.9kg vs 74.4kg,p value n.s.) and mean contrast volume (CV) (158ml vs 150ml, p value n.s.) , eliminating any possible confusing factors, while the mean contrast volume/glomerular filtration rate (CV/GFR) ratio was 3.5 in Group A and 3.1 in Group B. We considered the 3.5 of the CV/GFR ratio as the cut-off value for AKI, according to the recent international bibliography. While in the Group A , 29% of the patients had CV/GFR ratio > 3.5 (while the same ratio was only 14% in Group B), the use of antibiotics in Group B led to increased incidence of AKI (42%) in comparison with Group A (29%); this difference was statistically significant (p value<0.5). Moreover, the hospitalization duration differed not significantly between the two groups (3.67 days vs 4.06 days in the ICU, p value n.s., and 7.92 days vs 4.06 days, p value n.s. in the hospital), proving that the prophylactic use of antibiotics in Group B did not lead to faster discharge from the hospital.

CONCLUSIONS

After TAVI, AKI may develop due to various reasons. In this study, the prophylactic use of antibiotics post TAVI was found to be correlated with a higher incidence of AKI, without any difference in discharge times. Using as less as possible any nephrotoxic drugs in patients of increased age, like those who undergo TAVI, seems

prudent. Further larger studies are needed to validate these findings.

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Clinical outcomes following coronary artery bifurcation intervention after AMI

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

Bifurcation coronary artery disease(CAD) represents 15-20% in patients undergo coronary angiography. Bifurcation lesions percutaneous coronary intervention (PCI) remain challenging and may be associated with a low success rate especially in acute myocardial infarction (AMI) setting. However, there are limited data concerning the short and long term clinical outcome in this clinical setting.

METHODS AND RESULTS

A total 1402 patients underwent bifurcation lesions PCI were enrolled. Patients were divided into two groups according to clinical presentation: 1) chronic stable angina group (CSA, N=954) and 2) acute myocardial infarction group (AMI, N=448). Major adverse cardiac events (MACE), the composite of total death, myocardial infarction (MI), stroke and revascularization, were compared between the two groups at 39 days and up to 5 years.

Results: At 30 days follow up, the AMI group had significantly higher incidence of total death (HR: 5.901, 95% CI : 1.879 to 18.532; p = 0.002), cardiac death (HR: 6.438, 95% CI 1.743 to 23.781; p = 0.005), MI (HR: 4.736 , 95% CI :1.646 to 13.632; p = 0.004), TLR (HR: 4.300 , 95% CI :1.295 to 14.279; p = 0.017), Stroke (HR: 5.901 , 95% CI :1.879 to 18.532; p = 0.002) and MACE (HR: 4.318, 95% CI : 1.940 to 9.611; p = 0.000) than the CSA group. Moreover, at 5 years follow up, the AMI group had significantly higher incidence of MI (HR: 2.302 , 95% CI :1.283 to 4.130; p = 0.005), TLR (HR: 2.854 , 95% CI :1.831 to 4.448; p = 0.000), Stent Thrombosis (HR: 2.997 , 95% CI :1.205 to 7.451; p = 0.018) and MACE (HR: 1.579, 95% CI : 1.135 to 2.196; p = 0.007) than the CSA group.

Using multivariate logistic regression, and after adjusting for potential confounding factors, the AMI patients had higher incidence of total MACE at 30 days (HR: 3.668, 95% CI 1.572 to 8.558 ; p = 0.003) and at 5 years follow up (HR: 1.693, 95% CI 1.206 to 2.377 ; p = 0.002) including total death, cardiac death, revascularization and stroke.

CONCLUSIONS

Conclusion: In this study, bifurcation lesion PCI in AMI setting was associated with higher incidence adverse clinical outcomes including higher incidence of cardiac death, revascularization, and total MACE at 30 days and up to 5 years.

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New-generation DES vs. BMS in SVG - One-year outcomes by a propensity score ascertainment (SVG Baltic registry)

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Other Coronary Interventions

AIMS

Data regarding the efficacy of percutaneous coronary intervention (PCI)
with new-designed drug eluting stent (new-DES) vs. bare metal stent (BMS)
of saphenous vein grafts (SVG) stenosis is scarce. The primary objective was to compare one-year clinical outcomes of PCI in stenosis of SVG using new-DES vs. BMS in a real-world population.

METHODS AND RESULTS

We carried out a multi-center registry comparing new-DES with BMS
in all consecutive patients undergoing PCI of SVG. The primary composite endpoint was major adverse cardiac and cerebrovascular events (MACCE)
at 1 year. This observation included 792 consecutive patients (mean age 69±8.9y), treated with either new-DES (n=379, 47.9%) or BMS (n=413, 52.1%). In unmatched cohort patients treated with new-DES vs. BMS
had lower MACCE (28.3% vs. 21.4%, HR=0.69, 95%CI 0.50-0.95, p=0.025) as well as myocardial infarctions (MI) (12.1% vs. 6.3%; HR 0.49, 95%CI
0.30-0.82, p=0.005) at 1 year. After propensity score matching similar, significant reduction in MACCE and MI was sustained in new-DES vs. BMS groups (HR 0.66, 95%CI 0.46-0.96, p=0.030; and HR 0.53, 95%CI 0.31-0.92, p=0.020, respectively).

CONCLUSIONS

In patients undergoing PCI of SVG, the use of new-DES is associated with
a reduced 1-year rate of MACCE and MI compared to BMS.

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Comparison between echocardiography and 3D rotational angiography: the implication for successful percutaneous LAA closure

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

Background: In patients undergoing percutaneous left atrial appendage (LAA) closure, the assessment of LAA ostium is critical for sizing of LAA closure device. Three dimensional rotational angiography (3DRA) has recently emerged as an alternative to TEE for LAA ostium assessment. However, the data on comparison between both methods are scarce.

Purpose: First, to compare LAA ostium measurements obtained by TEE versus those obtained by 3DRA. Second, to assess procedural outcome of the TEE- versus the 3DRA-guided sizing of LAA closure device.

METHODS AND RESULTS

Methods: We prospectively studied 67 consecutive patients who underwent LAA closure (age 76±19 years; 42% Female, CHA2DS2-VASc score 4.73, HASBLED score 3.66). Patients were divided into two groups. The 3DRA-guided group consisted of 29 (43%) patients who underwent both 2D/3D TEE and 3DRA during the LAA closure procedure. The 3DRA dataset containing the whole LAA was analyzed to assess LAA ostium size in end systole by an operator blinded to the TEE-derived measurements. In the 3DRA-guided group, the LAA closure device sizing was guided by the 3DRA assessment. In the remaining 38 (57%) patients, the LAA closure device sizing was guided by TEE (the TEE-guided group). In all patients, TEE was repeated at 3-6 months.

Results: The 3DRA-derived maximal diameter of LAA ostium was by 6.7±3.3 mm and 5.3±3.4 mm larger than those derived by 2D and 3D TEE, respectively (both $p<0.05$). Similar trend was observed for LAA minor diameter, 3D area-derived diameter or LAA length. The concordance in LAA closure device sizing between the 3DRA- and the TEE-derived assessment was observed only in 42% of patients. The compressed diameter of the implanted closure device showed a significantly higher correlation with LAA maximal diameter assessed by 3D TEE ($r=0.74$) versus by 3DRA ($r=0.61$) ($p<0.05$). Both the 3DRA-guided and the TEE-guided groups had similar occurrence of periprocedural complications or mild pericardial effusion. At follow-up, the 3DRA versus the TEE-guided group did not show any higher prevalence of significant para device leak (NS) or device-attached thrombus (7.9% vs. 3.4%, $p=0.4$).

CONCLUSIONS

The 3DRA-derived indices of LAA ostium are consistently larger than the TEE-derived ones because of TEE under-sizing or because of 3DRA contrast induced overload. However, neither TEE nor 3DRA appears clinically superior to the other in guiding LAA closure and both modalities show a similar outcome.

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Validation of novel 3D quantitative coronary angiography based software to calculate vessel FFR post-stenting: the FAST POST-study

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

FFR post percutaneous coronary intervention demonstrated to predict future adverse cardiac events. However, FFR assessment requires the insertion of a costly pressure wire in combination with the use of a hyperemic agent, which may contribute to its low adoption in routine clinical practice. The aim of our study was to validate the use of novel dedicated 3D-QCA software to calculate FFR in a consecutive series of patients with post PCI FFR and to assess inter-observer variability.

METHODS AND RESULTS

The present study is an observational, prospective, single-center cohort study. 100 patients from the FFR-SEARCH registry presenting with stable angina or non ST-elevation myocardial infarction who were treated with PCI and stenting and had a post PCI FFR assessment, were included in the present study. Two orthogonal angiographic projections were acquired to create a 3D coronary artery reconstruction of the coronary artery using the CAAS workstation software (Pie Medical Imaging, Maastricht, The Netherlands). vFFR was subsequently calculated offline using the aortic root pressure.

Mean age was 65 ± 12 years and 70% were males. Mean microcatheter based FFR and vFFR were 0.91 ± 0.07 and 0.91 ± 0.06 respectively. A good linear correlation was found between FFR and vFFR ($r = 0.88$; $p<001$). Assessment of vFFR had a low inter-observer variability ($r = 0.96$; $p<0.001$).

CONCLUSIONS

The 3D-QCA derived vFFR has a high linear correlation to invasively measured microcatheter based post PCI FFR and a low inter-observer variability.

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Predictors of diastolic pressure ratio immediately after successful PCI: the dPR SEARCH study

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Fractional Flow Reserve (FFR) assessed post percutaneous coronary intervention (PCI) proved to be a strong predictor of future adverse cardiovascular events. Measuring FFR requires the use of hyperemic agents resulting in additional cost, procedure time and potential patient discomfort. A resting diastolic pressure ratio (dPR) has been introduced as an adenosine free alternative to FFR. The aim of the current study was to assess predictors of post PCI dPR in an all comer population.

METHODS AND RESULTS

The dPR SEARCH study was a post-hoc analysis of the FFR-SEARCH registry, a prospective single center registry in which FFR measurements were performed after angiographically successful PCI in a total of 1000 patients. FFR measurements were performed with a dedicated microcatheter advanced approximately 20mm distal to the most distal stent edge. DICOM pressure waveforms were recorded for offline dPR calculation using recently validated software. Adequate pressure waveform data was available for 735 patients (885 lesions). General mixed linear models were used to assess independent predictors of post PCI dPR.

Mean age was 64±12 years and 75% were male. Mean post PCI dPR was 0.96±0.05 while the mean post PCI Pd/Pa and FFR were 0.97±0.04 and 0.91±0.07 respectively. Post PCI dPR was <0.90 in 14% of the cases, <0.92 in 20% and <0.95 in 38% despite optimal angiographic results. Independent predictors for post PCI dPR were: LAD lesions (-0.06), stent diameter (0.01), in-stent restenosis (-0.03) and pre- and post-PCI reference diameter (0.01 and -0.01 respectively).

CONCLUSIONS

Despite optimal angiographic results, a considerable number of patients end with lower post procedural dPR values than expected. LAD lesions, stent diameter, in-stent restenosis, pre and post reference diameter proved to be independent predictors of post PCI dPR.

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Ultrasound guided vascular access site management and left ventricular pacing are associated with improved outcomes in contemporary TAVI: insights from a single-centre registry

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Transcatheter aortic valve implantation (TAVI) is evolving as the preferred strategy for treatment of aortic stenosis (AS). Vascular complications, major bleeding or pericardial tamponade maybe influenced by procedural practices. The aim of this study was to identify clinical and procedural practice predictors of avoidable complications during TAVI.

METHODS AND RESULTS

The Oxford TAVI (OxTAVI) registry was analysed to identify predictors of avoidable procedural complications in a contemporary cohort of transfemoral TAVI. The primary endpoint was defined as a hierarchic composite of intra-hospital mortality, pericardial effusion/cardiac tamponade, major bleeding and vascular access complications. Individual components of the primary endpoint have been analyzed separately.

Between January 2015 and June 2018, 529 AS patients underwent transfemoral TAVI. Median age was 83(79-86) years and 239(45%) were female. 479(90.5%) of procedures were performed under local anesthesia and conscious sedation. Vascular closure was with 2 Proglide sutures. The primary endpoint occurred in 79(14.9%) patients. 18 (3.4%) patients died in hospital. Pericardial effusion/tamponade was observed in 22(4.1%) patients. Major bleeding occurred in 17(3.2%) and vascular complications in 45(8.5%) patients. Univariate regression analysis identified that female sex (OR=1.78, CI:1.08-2.94, p=0.02) and higher frailty CSHA index (OR=1.36, CI=1.01-1.89, p=0.05) were associated with the composite primary endpoint. Among the procedural variables, ultrasound (US) guided vascular access management (OR=0.35, CI=0.21-0.59, p<0.001) and left-ventricular (LV) rapid pacing (OR=0.46, CI:0.26-0.80, p=0.006) were associated with a reduction in the primary endpoint. In a multivariate model incorporating clinical features, US guided vascular assess management (0R=0.42, CI:0.18-0.99, p=0.048) remained as a predictor of reduced complications.

When the individual components of the primary endpoint were analyzed, US-guidance was associated with a 3-fold reduction in the risk of vascular access complication (OR=0.29, CI:0.15-0.55, p<0.001) and using an LV-guidewire pacing technique was associated with a reduction in the risk of pericardial effusion/tamponade (OR=0.19, CI:0.05-0.66, p=0.009). No significant independent procedural predictors of in-hospital mortality or major bleeding were identified.

CONCLUSIONS

This single centre cohort of transfemoral TAVI using contemporary techniques, identified that female sex and high frailty were associated with a higher risk of death, major bleeding, vascular complication or pericardial tamponade. The use of US-guidance for vascular access management was independently associated with a reduction in complications after adjustment, largely driven by a 3-fold reduction in vascular access

complication. Performing rapid pacing via LV-guidewire was associated with a significant decrease in the risk of cardiac tamponade/pericardial effusion.

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The impact of platelet-fibrin clot strength and endogenous fibrinolytic activity on long-term ischaemic and bleeding events after PCI in patients with coronary artery disease

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

In patients with high-risk coronary artery disease (CAD), the level of on-treatment platelet reactivity has been associated with ischemic and bleeding events. However, the impact of impaired clot-strength and endogenous fibrinolysis on clinical events in these patients remains still uncertain.

METHODS AND RESULTS

In PCI-treated patients (n = 1,775), global hemostasis profiles were measured with thromboelastography (TEG®: Haemonetics Corp, BrainTree, MS, USA). “Platelet-fibrin clot strength” was indicated by MAthrombin (maximal amplitude of the clot dynamics) and “endogenous fibrinolytic activity” was indicated by LY30 (percentage of the clot lysis at 30 min after the time of MA), respectively. We evaluated the cohort’s major ischemic events (cardiac death or MI) and major bleeding episodes (BARC bleeding type 3 or 5) during the follow-up.

With a median follow-up of 23.1 (IQR: 13.3, 35.8) months, the major ischemic and bleeding events were occurred in 5.3% and 2.8%, respectively. Compared with patients with low MAthrombin (< 68 mm), those with high MAthrombin value (≥ 68 mm) showed the greater risk of major ischemic events (9.1% vs. 3.8% at 3 years; HR, 2.10; 95% CI, 1.38 to 3.18; p = 0.001) and the similar chance of major bleeding events (3.3% vs. 2.9% at 3 years; HR, 1.06; 95% CI, 0.60 to 1.88; p = 0.835). High vs. low level of LY30 (≥ vs. < 1.0%) was significantly associated with lower ischemic events (4.6% vs. 7.8% at 3 years; HR, 0.54; 95% CI, 0.36 to 0.82; p = 0.004) and higher bleeding episodes (5.0% vs. 1.7% at 3 years; HR, 2.95; 95% CI, 1.51 to 5.77; p = 0.002). Similar results were obtained when adjusted for clinical covariates.

CONCLUSIONS

This is the first study to show the close linkage of clot strength and endogenous fibrinolytic activity to post-PCI cardiovascular events. Major ischemic events were associated with impaired “clot strength” and “endogenous fibrinolysis”, whereas major bleeding was related with mainly “endogenous fibrinolysis”, which might suggest the different mechanisms of ischemic and bleeding events in PCI-treated patients during antiplatelet treatment.

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Evaluation of epicardial coronary resistance using CT angiography

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

A Fractional flow reserve (FFR) pullback allows assessing the distribution of pressure loss along the vessel. FFR derived from CT (FFRCT) provides a virtual pullback curve that may also aid in the assessment of epicardial coronary resistance in the non-invasive setting. The present study aims to determine the accuracy of the virtual FFRCT pullback curve using a motorized invasive FFR pullback as reference in patients with stable coronary artery disease.

METHODS AND RESULTS

FFR values were extracted from coronary vessels every 1 mm to generate pullback curves. Invasive FFR pullbacks were acquired using a dedicated device at a speed of 1 mm/s. Mixed effect model was used to account for the correlation of FFR values within vessels. A total of 3172 matched FFRCT and FFR values were obtained in 24 vessels. The correlation coefficient between FFRCT and FFR was 0.76 (95%CI 0.75 to 0.78; p<0.001). The area under the pullback curve was similar between FFRCT and invasive FFR (79.0 ± 16.1 vs. 85.3 ± 16.4, p= 0.097); the FFRCT mean curve slope were steeper compared to invasive FFR (p< 0.001). The mean difference in lesion gradient was -0.07 (LOA -0.26 to 0.13) and -0.01 (LOA -0.06 to 0.05) in non-obstructive segments. There were no systematic or proportional differences in FFR gradients either in obstructive or non-obstructive segments.

CONCLUSIONS

The evaluation of epicardial coronary resistance using coronary CT angiography with FFRCT was feasible. FFRCT pullbacks were accurate in the assessment of lesion and non-obstructive gradients. FFRCT can identify the physiological pattern of coronary artery disease in the non-invasive setting.

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A long-term outcome of novel abluminal coated sirolimus-eluting coronary stent in a real-world population: data from all-comer en-ABL e-registry

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Currently, Drug eluting stents are more reliable option to treat coronary heart disease. Although long term safety and effectiveness is not studied extensively. This registry evaluated the safety and clinical outcome of ABLUMINUS sirolimus eluting coronary stent (Envision Scientific) in an all-comers population from routine clinical practice.

METHODS AND RESULTS

en-ABL e-registry is a prospective, all comers and real-world registry. We enrolled 2,500 consecutive patients (2,969 lesions) who underwent PCI using ABLUMINUS. The primary endpoint was a MACE (Major Adverse Cardiac Event); composite of Cardiac Death, Target Vessel Myocardial Infarction (TV-MI), and Target Vessel/ Lesion Revascularization (TVR/TLR) at 1 year. The secondary endpoint was total Stent Thrombosis (ST) and MACE rate up to 2 years.

Mean age of the population was 57.0 ± 12.6 years with male patients accounted for majority of the population (78.9%). 34.4% population had diabetes. 66.8% patients presented with acute coronary syndrome. 83.2% patients had lesions treated in single vessel while 16.7% patients had lesions treated in multiple vessels. Clinical follow-up was available for 2,460 (98.4%), 2,078 (83.1%), 1,545 (61.8%) at 1 year, 2 year and 3 years respectively. At 1 year, MACEs were observed in 55 patients (2.2%) which includes 0.6% cardiac death, 0.4% TV-MI and 1.3% TLR/TVR. Secondary endpoint, total ST at 1 year was found to be 0.6% with no late ST reported. Cumulative MACE rate at 2 years was recorded as 2.7%. 0.7% ST was observed at 2 years. Overall population was subdivided in to 4 subgroups for further investigation. MACE rate for the subgroups at 1 year were: Diabetic group (2.8%), Acute MI group (2.1%), long lesion group (2.8%) and small vessel group (3.1%).

CONCLUSIONS

Long term clinical outcome revealed lower MACE rate in overall population as well as in complex subgroups. The results clinically prove the safety and efficacy of ABLUMINUS sirolimus eluting coronary stent in real world population.

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Antibacterial efficacy of ticagrelor antiplatelet doses against resistant gram-positive infection

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Ticagrelor is a potent oral antiplatelet drug prescribed annually to millions of patients presenting with acute coronary syndrome worldwide. A post-hoc analysis of the large randomized PLATO trial revealed that patients receiving ticagrelor had a lower risk of infection-related death as compared to clopidogrel. In the recent XANTHIPPE study, ticagrelor administration to patients hospitalized for pneumonia was associated with improved lung function. We therefore questioned whether ticagrelor or one of its metabolites could possess antimicrobial properties.

METHODS AND RESULTS

Ticagrelor and its major metabolites were synthetized and tested in time-kill assays against Gram-positive methicillin-resistant S. epidermidis, methicillin-sensitive S. aureus (MSSA), Glycopeptide Intermediate S. aureus (GISA), methicillin-resistant S. aureus (MRSA), and vancomycin-resistant E. faecalis (VRE). Effect on biofilm formation was assessed in vitro with crystal violet staining and in a mouse model of S. aureus polyurethane implant infection.

Ticagrelor and its most abundant metabolite AR-C124910 displayed in vitro bactericidal efficacy against all Gram-positive bacteria tested, including MRSA and VRE. MRSA bacterial growth was promptly delayed in the presence of 5µg/ml ticagrelor. At minimal bactericidal concentrations, ticagrelor killed late exponential phase MRSA cultures with similar efficacy as daptomycin, a last resort antibiotic against S. aureus resistant strains, and it acted more rapidly than the conventional glycopeptide vancomycin. It was superior to vancomycin against MRSE and it killed VRE. Ticagrelor dose-dependently inhibited MRSA, MRSE and VRE biofilm formation. Despite the fact that the effective in vitro antibacterial concentrations are higher than ticagrelor Cmax values for an antiplatelet effect in humans (1.2µg/ml after one 180mg loading dose and 0.75µg/ml at 90mg bid steady-state), treatment of mice with equivalent antiplatelet doses (3mg/kg loading dose, 1.5mg/kg bid), inhibited biofilm growth on S. aureus pre-infected implants and bacteria dissemination in surrounding tissues.

CONCLUSIONS

We uncovered unprecedented bactericidal effect of the antiplatelet drug ticagrelor. Our findings may provide mechanistic explanation for reduced infection-related death for ticagrelor compared to clopidogrel in the PLATO trial and for improvement of lung function by ticagrelor in pneumonia patients of the XANTHIPPE study. This warrants further investigations as well as re-analysis of outcome data in clinical studies on patients receiving ticagrelor.

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Transcatheter treatment aortic valve regurgitation: results from an international registry study using transfemoral ACURATE neo valve

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

This multicenter registry sought to evaluate the self-expandable ACURATE Neo® device in a cohort of patients with aortic regurgitation (AR).

METHODS AND RESULTS

A total of 23 patients with severe AR treated by TAVI between September 2016 and June 2018 in 12 European centers, were included in a dedicated database. Clinical, hemodynamic and procedural data were collected, as well as clinical and echocardiographic follow up. Endpoints and events were codified according to Valve Academic Research Consortium-2 criteria. Mean age was 79.4 (range 50 - 88)years, 61% were female. Mean EuroSCORE II and mean STS score were respectively 3.9% and 3.5%. Device success was 87%. In 3 cases (13%), all with a perimeter oversizing <10%, a second device implantation was necessary to overcame severe perivalvular leak (PVL) after first valve implantation. Post-procedure grade 2 PVL was present in 2 cases (8.7%) among all. All patients with a perimeter oversizing index >10% had only trivial or no PVL.At 30 days, the stroke and all-cause mortality rates were 0% and 4.3%, respectively.

CONCLUSIONS

This multicenter series demonstrates the feasibility and early safety of transfemoral TAVI with the self-expandable ACURATE Neo device in patients with severe AR refused for surgery.

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Outcome of spot vs. full cover stenting for femoropopliteal lesions

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal

AIMS

We aimed to assess the outcomes of femoropopliteal lesions treated by spot stenting, stent implantation at dissection sites alone after plain old balloon angioplasty, in comparison with those treated by full cover stenting.

METHODS AND RESULTS

The study sample consisted of 90 de novo femoropopliteal lesions treated between July 2015 and March 2018 in our institute, excluding lesions in either P2 to P3 segments or the common femoral artery. The 90 lesions were divided into two groups by stenting strategy: 56 lesions treated by full cover stenting and 34 lesions treated by spot stenting. Restenosis patterns were determined by ultrasonography 6 months postprocedure. A focal restenosis pattern was classified into three sites of occurrence: in-stent, stent edge, and nonstented segments. Restenosis was defined as the peak systolic velocity ratio of >2.4. Between the full cover stenting and spot stenting groups, the mean vessel diameter was not significantly different (5.00 ± 0.10 mm vs. 4.71 ± 0.12 mm, p = 0.08), whereas the mean lesion length was significantly longer in the spot stenting group (120.5 ± 11.3 mm vs. 174.8 ± 12.3 mm, p = 0.002); the one-year cumulative rate of primary patency was significantly higher in the full cover stenting group (67.8% vs. 24.3%, p = 0.0009), whereas that of freedom from target lesion revascularization was not significantly different (72.6% vs. 64.3%, p = 0.84). In the spot stenting group, a focal restenosis pattern was observed in 11 lesions, and the sites of occurrence were as follows: in-stent, 2 lesions (18.2%); stent edge, 5 lesions (45.4%); and nonstented segments, 4 lesions (36.4%).

CONCLUSIONS

One year postprocedure, spot stenting was significantly associated with restenosis, but not with target lesion revascularization. The common sites of focal restenosis after spot stenting may be stent edge and nonstented segments.

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Distribution of epicardial coronary resistance by angiography-derived FFR (FFRangio): preliminary results

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Angiography-derived fractional flow reserve (FFR) has emerged as a novel technique to detect hemodynamic significant epicardial stenoses using conventional coronary angiography. The FFRangio system creates a three-dimensional (3D) reconstruction of the entire coronary tree that enables the extraction of FFR values along the length of the vessel allowing to identify the physiological pattern of CAD. The present study aims at investigating the accuracy of FFRangio to determine the distribution of epicardial resistance using a hyperemic motorized FFR pullback as reference.

METHODS AND RESULTS

Prospective, single-center registry of stable patients referred to coronary angiography. Patients with intermediate coronary stenosis underwent FFR evaluation using a motorized device at a speed of 1mm/s. For the calculation of FFRangio, coronary geometries were created using two or more angiographic projections with a minimum separation of 30° utilizing epipolar ray tracing together with mathematical constraints enforcing the tree's structure modeled as an electrical circuit with each segment acting as a resistor. FFRangio values were extracted with an interval of 1 mm. Invasive and FFRangio values were co-localized using the position of the pressure sensor as landmark. FFR pullback curves were created to depict the physiological pattern of CAD. An independent core laboratory perform the FFRangio analysis and adjudicated the physiological pattern of CAD. CAD patterns were classified as focal, diffuse, or with a combined mechanisms. Adjudication was performed by visual assessment of FFRangio and invasive FFR pullback curves. Agreement between methods was assessed using Bland-Altman and Passing-Bablok regression. Fleiss' Kappa was used to assess the agreement on the CAD pattern (i.e. focal, diffuse and combined). Mixed effect model was used to account for the within-vessel correlation of FFR values. A total of sixteen vessels were included. Two vessel were excluded due to inadequate invasive FFR pullback curve. Overall, 1.210 matched FFR values were analyzed. The mean invasive FFR value was 0.90±0.10 whereas mean FFRangio was 0.86±0.11. The correlation between modalities was high (correlation coefficient 0.78; 95% CI 0.76 to 0.80) with a mean difference of 0.037 (limits of agreement -0.096 to 0.170). There was a systematic and proportional overestimation of disease severity with FFRangio (Intercept A -0.18; 95% CI -0.22 to -0.13; Slope B 1.16; 95% CI 1.11 to 1.21). The agreement on the physiological pattern of CAD between FFRangio and invasive FFR pullbacks was fair (Kappa coefficient 0.42; 95% CI 0.06 to 0.79). Using the distal invasive FFR value as reference, the diagnostic performance of FFRangio revealed an accuracy of 86%, sensitivity 100%, specificity 78%, positive predictive value 71% and negative predicted value 100%.

CONCLUSIONS

FFRangio derived from the coronary angiogram alone was accurate in detecting the distribution of epicardial resistance in coronary vessels. FFRangio has the potential to refine patient selection for revascularization.

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Long-term prognostic impact of successful CTO revascularisation in all-comer patients

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Our aim was to determine the prognostic impact of successful PCI CTO procedure on long term survival and major adverse cardiovascular events (MACE) in unselected, all-comer patients in a single tertiary centre.

METHODS AND RESULTS

We identified 261 consecutive patients who underwent PCI CTO procedure at our institution between 1st January 2010 and 31th December 2016. Indications for coronary angiography were as follows: angina pectoris (46.4%), acute coronary syndrome (38.7%) and heart failure (8.4%). All patients undergone full revascularization of non-CTO coronary arteries prior to attempted PCI CTO. Anterograde and retrograde approaches were used. PCI CTO success rate was 55.2%. Median follow-up time was 50 months (IQR 40 months). There was no significant difference in all-cause (p=0.581) and cardiovascular (p=0.804) mortality between successful and unsuccessful PCI CTO groups. We also found no difference in subgroup analyses conducted in patients with heart failure (EF<40%), diabetes and chronic kidney disease and according to the affected coronary artery. Successful PCI CTO was associated with less MACE (27.8% vs 38.5%, p=0.007, HR=1.82). This was due to less frequent target lesion revascularizations (7.6 vs. 15.4%, p=0.045, HR=2.31) and less frequent PCIs in non-CTO coronary arteries (2.8 vs. 9.4%, p=0.021, HR=3.53). Most revascularizations during follow up were indicated because of stable angina (74.3 %). There was no difference in the incidence of acute coronary syndrome (p=0.389).

CONCLUSIONS

In unselected, all-comer patients, successful PCI CTO procedure has no prognostic impact on all-cause and cardiac mortality. However, it is associated with less revascularizations, even in previously fully revascularized non-CTO coronary arteries.

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Magnesium BRS implantation in ACS - A single-centre experience

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THEME: Coronary Interventions
TOPIC(S): NSTEMI, Stents and scaffolds

AIMS

Bioresorbable vascular scaffolds (BRS), the newest coronary stent technology seems to be especially interesting treatment option in the setting of acute coronary syndromes (ACS).

METHODS AND RESULTS

The first 100 consecutive patients who underwent percutaneous coronary intervention (PCI) with the Magmaris BRS in the settings of ACS were enrolled for analysis as a part of the Magmaris-ACS Registry. Baseline demographic and angiographic characteristics were prospectively collected. Clinical 30-day follow-up (FU) was obtained by telephone contact. The mean age of the analysed group was 63.2±8.2 years, 86% male with typical risk factors of ACS and following clinical presentation: 17%-Unstable angina and 83% Non-ST-segment myocardial infarction; 90% TIMI-3 flow; 93% single lesion disease, 77 % type A + B1 lesion according to AHA/ ACC classification. Scaffold implantation and sizing were done under the Magmaris instructions-for-use (IFU) document. Predilatation was performed in 100% lesions with a noncompliant balloon. In total, 107 scaffolds at mean diameter 3.2±0.3 mm and length 21.1±3.3 mm were implanted for de novo lesions located in LAD (39%), LCX (22%), and RCA (39%), respectively. Six lesions required implantation of two overlapping scaffolds. Postdilatation was performed in 99% lesions, with the noncompliant balloon 0.25–0.50 mm larger than the scaffold size. Preprocedural MLD was 0.96 mm, with mean 67.3 % DS. Postprocedural MLD was 2.44 mm, resulting in an acute gain of 1.48 mm. Angiographic success in the target lesion was 100%. OCT-guided PCI confirmed the significant proximal (3%) or distal (1%) edge dissection, and a regular metallic DES overlapping BRS or additional BRS were implanted for four cases (4%). Three cases (3%) of interim small side branch (SB) occlusion after implantation of BRS occurred. No bail-out stenting of SB was needed. The mean hospital stay was 2.5 days (range 1 to 7) and one case of ischemia-driven target vessel revascularization (ID-TLR) was reported. No other in-hospital events were observed (procedural success of 99%). Patients received dual antiplatelet therapy (DAPT) for 12 months. Thirty-day FU showed none device-oriented endpoints such as cardiac mortality, target vessel myocardial infarction or target vessel revascularization were noticed. None early scaffold thrombosis was reported.

CONCLUSIONS

Bioresorbable vascular scaffolds (BRS), the newest coronary stent technology seems to be especially interesting treatment option in the setting of acute coronary syndromes (ACS).

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Six-month clinical outcomes of world's thinnest (50 µm) biodegradable polymer-coated everolimus-eluting coronary stent in patients with coronary artery disease

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

The aim of the study was to determine the safety and performance of ultrathin (50 µm) strut biodegradable polymer coated Evermine 50™ everolimus-eluting coronary stent system in patients with coronary artery disease.

METHODS AND RESULTS

This was a prospective, single-arm, multi-center study. A total of110 patients at nine clinical sites across India were enrolled and implanted with Evermine 50™ everolimus-eluting stent for the treatment of coronary artery disease. Study end-points were major adverse cardiac events, defined as a composite of cardiac death, myocardial infarction and ischemia-driven target lesion revascularization, at 6-month follow-up.

Out of 110 enrolled patients (mean age: 57.87 ± 11.63 years), 87 (79.1%) were male, 55 (50.0%) patients had hypertension, and 44 (40.0%) had diabetes. A total of 128 lesions were treated with Evermine 50 stent (1.16 lesions per patient). The baseline angiographic data revealed that 64 (58.2%) patients had multi-vessel disease. Amongst the 110 enrolled patients, 58 (52.7%), 29 (26.4%) and 23 (20.9%) patients were diagnosed with ST-segment-elevation myocardial infarction, non-ST-segment-elevation myocardial infarction and unstable angina, respectively. Major adverse cardiac event at 6-month follow-up was one (0.9%); there was no stent thrombosis or myocardial infarction.

CTRI number- CTRI/2017/02/007781

CONCLUSIONS

The present study demonstrated the favourable safety and performance of ultra-thin strut Evermine 50 everolimus-eluting coronary stent in real-world patients with coronary artery disease at 6-month follow-up.

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Effect of coronary sinus size upon myocardial ischaemia improvement after coronary sinus reducer implantation. "One size to fit them all ?"

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Coronary sinus (CS) Reducer System is a balloon-expandable mesh, implanted percutaneously in the CS to create a controlled narrowing of the lumen and establish a pressure gradient across it. Reducer implantation has been shown to improve angina and quality of life of patients with coronary artery disease having angina refractory to medical therapy and not amenable to any further revascularization. However, there are patients not responding to Reducer therapy. Aim of the study was to evaluate the role of the CS size in the effectiveness of the Reducer device.

METHODS AND RESULTS

Prior to device implantation and at 4-months, all patients underwent dipyridamole stress cardiac magnetic resonance (CMR) and clinical assessment with evaluation of CCS class and six-minute walk test (6-MWT). Stress-CMR was analyzed to extract quantitative analysis of myocardial perfusion reserve. Quantitative coronary analysis (QCA) was performed to assess the CS size at the implantation size.

Nineteen patients (18 males/1 female, 66±10 years), underwent successful Reducer implantation. Sixteen patients improved by at least≥ 1 CCS class. Eight patients experienced 1 CCS class reduction, 7 patients 2 CCS class reduction, 1 patient 3 CCS class reduction and 3 patients did not experience any benefit in angina class. The 6MWT was also improved 4 months after Reducer implantation (from 319±77 to 418±107 meters, p=0.002).

Stress-CMR demonstrated an improvement in myocardial perfusion reserve index (MPRI) (from 1.2±0.38 to 1.61±0.79, p=0.011) 4 months after the Reducer implantation. MPRI increased in 13 patients (Responders: presenting a 65±44 % increase), while in 6 patients did not improve at all (Non Responders: presenting a -16±15 % decrease). The CS size was significantly smaller in the group of Responders (6.6±1.6 vs 8.2±1.4 mm, p=0.04) and the CS size was well correlated with the MPRI increase (r= - 0.71, p=0.001).

CONCLUSIONS

CS Reducer implantation improved angina symptoms, functional capacity and myocardial perfusion in patients with refractory angina. Patients with large CS size did not present any significant improvement in myocardial perfusion. The hypothesis generating results of this study indicate that CS size could affect the efficacy of the device and that a more tailored approach by assessing the CS size could increase the responders of the procedure.

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Percutaneous closure of paravalvular leaks requiring several devices: never too big

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THEME: Interventions for Valvular Disease
TOPIC(S): Other valvular and structural interventions

AIMS

Percutaneous closure of paravalvular leaks (PVL) is a complex procedure, especially in the presence of large or several dehiscences. In some interventions it may desirable to implant more than 1 device, increasing the risk of interference with the discs in cases of mechanical prosthesis.
Consecutive procedures of PVLs closure were analyzed, collecting the cases where more than one device was implanted.

METHODS AND RESULTS

29 percutaneous transfemoral PVLs closure were analyzed (1 tricuspid,21 mitral,7 aortic). The mean age of the patients was 64.8+8.2 years, and 63% presented at least two previous cardiac surgeries.
38 VP 3 and 1 VSD device were implanted. 8 patients required ≥2 devices (3 devices were used in 2 of these cases), 7 of them for the treatment of PVLs in the setting of mechanical prosthesis (1 aortic and 6 mitral).
In 5 patients 2 simultaneous devices were used in the same leak (parallely delivered). The remaining 3 were treated with 2 VP3 implanted in different location.
Patients requiring 2 or more devices presented more frequently cardiac failure as index symptom compared to patients treated with only one device.
1 patient with an aortic PVL was treated with a left main stent to avoid the protrusion of the VP 3 in the LM. One patient was treated with two VP3 in a mitral PVL in the immediate postoperative period (5th day after surgery), due to refractory heart failure. A second one presented cardiac arrest after the anesthesia, requiring BCIAO to perform the procedure. One patient with a semilunar 180º defet presented reisdual leak>grade 3 after the closure, and was reoperated a few days after the procedure, with exitus in the 8th day after surgery.
In 3 cases a significant interference of the VP3 with the disc prosthesis was observed; in these patients the VP 3 was repositioned inside the dehiscence to avoid the disc interference with an accurate final result. There were not major complications related to the procedure and a good result (with residual leak<2) was achieved in all cases except one.

CONCLUSIONS

Percutaneous closure of PVLs with ≥2 devices is safe allowing the attempt of large or several defects. VP 3 devices present an accurate deformability enabling different positions inside the dehiscence tunnel, minimizing the disc interference. In cases of several devices implant, a wire-maintaing technique is desirable, to eneable the implant of the second device.

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Clinical experience after implantation of ultrathin strut biodegradable polymer-coated everolimus-eluting stents for treatment of atherosclerotic lesions: all-comer single-centre registry with a subgroup analysis of patients with ultra-long stents

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

The registry investigated clinical outcomes after 12 months of implantation of ultrathin strut (60 µm) biodegradable polymer coated Tetrilimus everolimus-eluting stents (EES) [Sahajanand Medical Technologies Pvt. Ltd., Surat, India] in patients with atherosclerotic coronary lesions. In addition, sub-group analysis was performed to evaluate the outcomes of ultra-long (44/48 mm) EES in patients with long atherosclerotic coronary lesions.

METHODS AND RESULTS

This was an observational, single-center, single-arm and investigator initiated retrospective registry. In this all-comers registry, 558 patients who underwent implantation of the Tetrilimus EES for the treatment of coronary artery disease during routine clinical practice between February-2016 and August-2016 at a tertiary care center of India were examined. Patients who had been implanted with some other stents were excluded. Patients' data were obtained from medical records. Follow-up was achieved by either clinical database review or telephonic follow-up for clinical events. Primary endpoint was occurrence of any major adverse cardiac event (MACE) up to 12-month follow-up. MACE was considered as a composite of cardiac death, Q-wave or non-Q wave myocardial infarction (MI), emergent coronary artery bypass graft (CABG) and clinically driven target lesion revascularization (TLR). The occurrence of stent thrombosis (ST) was also analysed as per the Academic Research Consortium. In subgroup analysis, clinical outcomes were assessed for 143 patients with long atherosclerotic coronary lesions who were implanted with long (44/48 mm) Tetrilimus EES.

Total 766 stents were implanted to treat 695 lesions in 558 patients, with an average of 1.3±0.5 stents per patient. Out of 558 patients, 393 (70.4%) were males and mean age was 57.0±10.2 years. There were 215 (38.5%) diabetics and 273 (48.9%) hypertensives. Non-ST-elevation myocardial infarction (n=197; 35.3%) was the most prevalent clinical presentation, followed by stable angina (n=153; 27.4%). Of treated lesions, 79 (11.4%) lesions were type B2 and 544 (78.3%) were type C lesions, including 73 (10.5%) totally-occluded lesions. The average stent length and diameter were 33.5±10.7 and 2.8±0.3 mm respectively. At 12 months follow up, 4 (0.7%) incidences of cardiac death, 8 (1.4%) incidences of MI, and 2 (0.4%) incidences of TLR were reported, resulting to 12 months MACE of 2.5%.

In sub-group analysis of 143 patients who underwent implantation of 44 or 48 mm long Tetrilimus EES, 65 (45.5%) were males and average age was 58.9±9.5 years. The rates of hypertension and diabetes were 53.8% and 40.6% respectively. A total of 155 long coronary lesions were intervened successfully with only one stent been implanted per lesion. There were 12 (7.7%) totally occluded lesions and the average stent length and diameter were 46.3±2.0 mm and 2.8±0.3 mm respectively. MACE at 12 months follow-up was 2.8% with 1

(0.7%) incidence of cardiac death, 2 (1.4%) incidences of MI, and 1 (0.7%) incidence of TLR.

CONCLUSIONS

The 12-month clinical data demonstrated good safety and performance of the Tetrilimus EES even in high-risk patients and complex coronary lesions in routine clinical practice. Moreover, subgroup analysis supported the use of long Tetrilimus EES in the treatment of long atherosclerotic lesions, with excellent procedural performance and clinical outcomes.

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A systematic review on the LAmbre atrial appendage closure device

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THEME:
TOPIC(S):

AIMS

The LAmbreTM LAA-occluder is a novel device characterized by full retrievability, repositionability during the implantation process, and the characteristic umbrella with hooks directed towards the LAA, which act synergistically to prevent from LAA perforation. In this systematic review, we summarized the safety and therapeutic success of LAAC using the LAmbreTM occluder evaluating the published data.

METHODS AND RESULTS

A systematic search of the literature retrieved n=10 publications, encompassing n=403 NVAF patients treated with a LAmbreTM LAAC, with relevant data regarding safety and therapeutic success of the procedure.The majority of the publications were prospective monocenter observational registries, while 4/10 publications were multicenter registry publications. The mean age was 73.6 + 4.0 years, 58% of the treated patients were male, and their mean LVEF was 56.9 ± 5.3%. The mean CHA2DS2-VASc Score was 4.0 + 0.9, and the HAS-BLED score was 3.4 + 0.5. The reported implant success was 99.7%, with a mean procedure time of 45.4 ± 18.7 min, and a mean fluoroscopy time of 9.6 ± 5.9 minutes, with mean contrast agent volume of 96.7 ± 0.7 ml per LAAC procedure. The anticoagulation regime was switched to DAPT post procedure in the majority of the patients (96.8%). Partial recapture was reported in 45.5%, full recapture was done in 25.6%, and resizing of the device was undertaken in 3.6% of the patients, respectively. Major complications were reported in 2.9%, with 0.3% mortality, 1.7% pericardial tamponade, 0.3% stroke, and 0.6% major bleeding complications. During follow up at 6 or 12 months, major adverse cardiovascular events were reported in 3.3%: Stroke or TIA in 1.7%, thrombus formation on the device in 0.7%, and residual flow >5 mm in 1.0 %. No major bleeding or device embolization events were reported. In some publications, the favorable implant properties of the LAmbreTM for difficult anatomies such as shallow or multilobular LAA anatomies were described.

CONCLUSIONS

This systematic review on the LAmbreTM LAA-occluder n=403 NVAF patients from various centers and countries summarizes an excellent implant success rate, low periprocedural complications, favorable implant properties for difficult LAA anatomies, and promising follow up clinical outcome. Further larger prospective multicenter registries and randomized trials are warranted to scrutinize the value of LAmbreTM LAA-occluder, comparing its feasibility, safety and efficacy with other LAAC devices.

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Impact of treatment strategies on long-term outcome of CTO patients

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

The percutaneous treatment of chronic total occlusions (CTO) represents a major challenge in contemporary interventional cardiology and the potential long-term benefits of CTO PCI remain controversial. Therefore, the aim of the current large-scale observational multi-center registry was to compare the long-term outcome of CTO patients with successful interventional revascularization, surgical revascularization, failed CTO recanalization versus CTO patients under optimal medical therapy (OMT).

METHODS AND RESULTS

We enrolled CTO patients from two tertiary-care centers to compare different treatment strategies. All procedures were performed by highly experienced CTO operators. CTO-PCI was based on at least one of the following conditions: (i) inducible myocardial ischemia evaluated by stress echocardiography, (ii) presence of viable myocardium on cardiac magnetic resonance imaging, and (iii) presence of angina symptoms.

A total of 6631 patients underwent CTO-PCI with successful revascularization in 3906 patients and failed revascularization in 1480 patients, 412 patients underwent CABG surgery and 833 patients were treated with OMT. During the 5-year follow-up period, 1019 patients died. In the Kaplan-Meier analysis patients undergoing revascularization with PCI or by CABG had significantly better long-term outcome compared to patients with failed CTO-PCI or exclusively under OMT (log-rank P<0.001). In the multivariate Cox-regression analysis successful CTO-PCI was associated with significantly improved long-term outcome compared to patients under OMT independent of a clinical confounder model encompassing age, bmi, diabetes, kidney function and left ventricular function (crude HR 0.39, 95%CI 0.33-0.45, P<0.001; adj. HR 0.68, 95%CI 0.54-0.86, P=0.001).

CONCLUSIONS

Successful revascularization in CTO patients was associated with improved long-term outcome independent of established clinical risk factors in this large-scale multicenter study. These findings suggest that CTO revascularization, when indicated, should not be withheld from patients owing the complex nature of the intervention.

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Two-year follow-up of a real-world multicentre study assessing sirolimus-coated balloon in small coronary vessels: insights from the NANOLUTE registry

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Treatment of small coronary vessel (<2.75 mm) with drug eluting stents remains a challenge with higher rates of stent failure due to repeat revascularization and subsequent adverse events. Drug coated balloon emerged as a potential new treatment modality for small coronary vessels. The aim of this registry was to assess the safety and efficacy of MagicTouch SCB (Concept Medicals, India) in small coronary vessels.

METHODS AND RESULTS

NANOLUTE registry enrolled 450 patients from routine clinical practice from multiple Indian centres. The primary endpoint of the study was Major Adverse Cardiac Event (MACE) rate which included Cardiac Death, Target Vessel Myocardial Infarction (TV-MI) and Target Lesion Revascularization (TLR) at 1 year.

Out of 450 patients, 197 patients had lesions located in small coronary vessels. Average age of the population was 59.01 ± 10.30 years with 82.7% of males. 30.2% lesions were in the left anterior descending artery, followed by 21.0% in diagonal branches. The mean length and diameter of the device were 22.12 ± 7.54 mm and 2.33 ± 0.26 mm respectively.

197 (100.0%) patients completed the clinical follow-up at 1 year. Cumulative MACE rate was 3.6% which comprises of 2.5% TLR and 1.0% cardiac death. 179 (90.9%) patients completed the clinical follow-up at 2 years and the incidence of MACE was 3.9% (2.8% TLR and 1.1% cardiac death). No TV-MI was recorded at 2-years.

CONCLUSIONS

In this small coronary vessel subgroup of the Nanolute registry, angioplasty with SCB showed a good clinical outcome. Low MACE rate and the absence of TV-MI after 2 years demonstrates that MagicTouch is a potential candidate to treat small coronary vessels

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Prediction of functional significance of coronary bifurcation lesions by means of use of FFR (results from FIESTA registry)

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

To determine which factors are associated with functionally significant coronary bifurcation stenosis (FFR

METHODS AND RESULTS

102 patients with stable and unstable angina (troponin negative) and coronary bifurcation lesions were included. 57 patients (55%) had at least one FFR significant lesion in side or main branches. The mean age was 65 vs 67 years, 68% vs 60% males, 47% vs 40% diabetics, 60% vs 40% smokers, 30% vs 33% with renal failure (GFR<60 ml/kg/min), 28% vs 21% previous AMI, 51% vs 56% with previous PCI (all p>.05) in FFR (+) vs FFR (-) bifurcation lesions. The following factors were associated with FFR(+) results: proximal MB%DS (percentage diameter stenosis)>60%, c-statistic=.792, sensitivity 90%, specificity 50%, p65%, c-statistic=.798, sensitivity 68%, specificity 78%, p12, c-statistic=.823, sensitivity 68%, specificity 80%, p1.5 mmol/l, c-statistic=.655, sensitivity 60%, specificity 61%, p=.009. The 4 point score (FIESTA score) summing all significant correlates had a good discriminatory ability, c-statistics=.835, p2, with overall accuracy 78%. The presence of atrial fibrillation also was significantly associated with FFR(+) result (17% vs 35% in FFR(+) vs FFR(-) group, p=.024), but did not improve the accuracy of prediction model. At median follow-up of 24 months (IQR 20-36 months) the rates of mortality were 16.1% in FFR(+) group (treated with stenting) vs. 4.4% in FFR (-) group, p=.058.

CONCLUSIONS

Almost half of coronary bifurcation lesions are not functionally significant. This is especially true if one of main vessel segments (proximal or distal main branch assessed separately) has a stenosis less than 60%. Taking into account a strong trend for difference in mortality at two years, assessment of functional significance of bifurcations is strongly recommended, especially in patients with FIESTA score <3.

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Acute effects of the new generation of percutaneous MitraClip implantation on mitral valve geometry assessed by peri-procedural 3D transoesophageal echocardiography: NTR/XTR System vs. NT system

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair, Other valvular and structural interventions

AIMS

MitraClip (MC) implantation is a validated alternative treatment of significant mitral valve (MV) regurgitation (MR) in symptomatic patients at high surgical risk.The effect of MC on geometry and function of the MV remains largely unexplained.New models of MC (NTR, XTR) are now available, with easier delivery system and longer arm, allowing easier grasping, and improved leaflet capture.The aim was to evaluate the acute changes in MV geometry after MC implantation assessed by 3D transesophageal echocardiography (TEE), with eventual differences between the “old”-NT and the “new”-NTR/XTR systems.

METHODS AND RESULTS

Materials and methods:

In our study we enrolled 30 consecutive patients who underwent MC implantation for significant MR (mean age 77±7 yrs, 10 females), 15 pts with first generation of MC (NT), and 15 pts with NT/XTR MC.

Intraoperative 3D TEE images were acquired immediately before and after the procedure, and 3D analysis of the MV geometry (annular diameters, area and perimeter, angle of the anterior (AML) and posterior (PML) leaflets, nonplanar angle, annulus excursion) using a semi-automated software (MVQ GE) was performed.

Results:

No significant difference regarding the demographic characteristics and main echocardiographic parameters were observed between the 2 groups; functional MR was present in 12 pts in NT Group (80%), and in 9 pts in NTR/XTR Group (60%).

After the procedure a significant reduction of antero-posterior annular diameter (36.7±4.4 mm vs 33.1±8.1 mm,

CONCLUSIONS

The 3D TEE analysis allowed an accurate identification of minimal changes of the MV geometry after MC implantation.

To our knowledge, this is the first study who evaluated the behavior of the new generation of Mitraclip.

We identified a lower reduction of the nonplanar angle and greater annulus stability that could be explained by a reduction of the annulus excursion due to a more homogeneous traction of the leaflets, obtaining a conformation that is closer to the normal valve.

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One-year clinical outcomes of world's thinnest (50 µm) strut biodegradable polymer coated everolimus-eluting coronary stent system in real-world patients

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

This study aimed to evaluate the safety and performance of ultrathin (50 µm) strut biodegradable polymer coated Evermine 50™ everolimus-eluting coronary stent system in real-world patients with coronary artery disease.

METHODS AND RESULTS

This was a prospective, single-arm, single-center study in real-world patients. A total of 251 patients with de novo coronary artery lesion (lengths < 44 mm) and/or in-stent restenosis were enrolled and implanted with at least one Evermine 50 everolimus-eluting coronary stent system. The safety endpoint was major adverse cardiac event, composite of cardiac death, myocardial infarction attributed to the target vessel and clinically-driven target lesion revascularization, at 6 and 12 month follow-up. Out of 251 patients (mean age: 58.20 ± 9.92 years), 193 (76.9%) were male, 122 (48.6%) were diabetic, and 114 (45.4%) were hypertensive. A total of 343 lesions were intervened successfully with Evermine 50 (1.37 stents per patient). Average stent length and diameter were 23.50 ± 12.21 mm and 2.83 ± 0.23 mm, respectively. At 6-month follow-up, major adverse cardiac event reported was 2 (0.8%), in the form of one (0.4%) cardiac death and one (0.4%) clinically-driven target lesion revascularization. At 12-month follow-up (N=197), major adverse cardiac events were 3 (1.5%) which included 2 (1.0%) cardiac deaths and one (0.5%) clinically-driven target lesion revascularization. There was no stent thrombosis reported up to 6 and 12-month follow-up.
CTRI No: CTRI/2017/03/008173

CONCLUSIONS

The present study demonstrated the favourable safety and performance of ultra-thin strut everolimus-eluting coronary stent in real-world patients with coronary artery disease.

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Early vascular responses after ultrathin strut biodegradable polymer-coated sirolimus-eluting stent implantation: SiBi OCT study

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Recent optical coherence tomography (OCT) studies revealed that the lack of stent strut endothelial coverage is associated with late stent thrombosis after drug-eluting stent implantation. Nonetheless, the data regarding sequential changes of stent strut endothelial coverage for biodegradable polymer-coated stent remain limited. The aim of this study was to evaluate neointimal coverage in the early phase after ultrathin strut (60 μm) biodegradable polymer-coated Tetriflex (Sahajanand Medical Technologies Pvt. Ltd., Surat, India) sirolimus-eluting stent (SES) implantation using OCT.

METHODS AND RESULTS

Between January 2018 and April 2018, we enrolled consecutive patients with multi-vessel disease who underwent percutaneous coronary interventions (PCI) of the culprit lesion with Tetriflex SES followed by a staged PCI of other lesion(s) 4–6 weeks later. During the staged PCI for other lesions, an OCT examination of Tetriflex SES was also performed. The OCT was performed using a C7 Dragonfly™ imaging catheter (St. Jude Medical Inc., USA). All OCT images were analysed at an independent core laboratory (Cardiovascular Research Center, São Paulo, Brazil) by analysts who were blinded to patient and procedural information. During the study period 25 patients underwent PCI with at least 1 Tetriflex SES (27 stents in 25 lesions) and underwent OCT analysis after 35.3±5 days of Tetriflex SES implantation. The mean age of patients was 48.7 years, 61.5% were male, and diabetes was present in 42.3% of patients. A total of 14,024 stent struts in 1520 cross sections were analyzed. The mean analyzed length of stented segment was 30.09 ± 11.19 mm and mean stent area was 6.06 ± 1.91 mm2. Strut tissue coverage was observed in 91.26 ± 5.53 % of struts and malapposed struts were seen in 0.89 ± 1.67 %. The mean neointimal hyperplasia (NIH) thickness on the covered struts was 50 ± 30 μm.

CONCLUSIONS

In the present study, Tetriflex SES demonstrated an excellent healing profile with a mean of 91.26% strut coverage after 35.3±5 days of the index procedure. Furthermore, the elevated percentage of strut coverage was accomplished with very thin layer of NIH at only 50 microns in thickness evenly distributed along the stent length.

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Percutaneous closure of mitral paravalvular leaks in patients with aortic prosthesis, is the retrograde approach safe?

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THEME: Interventions for Valvular Disease
TOPIC(S): Other valvular and structural interventions

AIMS

Percutaneous closure of mitral paravalvular leaks (PVL) is a complex procedure,specially in patients with aortic valve prosthesis (AVP). In this context,some authors dismiss the retrograde approach to avoid the AVP crossing recommending a transapical PVL closure that has, however, been related to higher morbidity and hospital stay.

Transfemoral percutaneous closure of mitral PVLs in the presence of an AVP were collected and analyzed in one center.

METHODS AND RESULTS

28 consecutive closures of PVLs were recorded, 21 corresponding to mitral PVL and 8 of them with AVP.Clinical characteristics and procedural details were analyzed. Mean age of the patients was 64.3 ± 7.9 years, with a Euroscore of 16.7± 7.3, and 62% of patients with more than 2 previous surgeries.

All patients were treated with retrograde approach, crossing the AVP with 5/6 French catheters (JR/IMA/AL/ Vertebral) with a good hemodynamic tolerance except in 2 cases. 1 patient with a 16 ATS AVP was treated with anterograde approach advancing a high-support wire to the LV avoiding the AV loop; and one patient with a monoleaflet AVP could be managed advancing a low-profile catheter (4 French Vertebral) in a different position. 1 patient with severe pulmonary hypertension presented cardiac arrest after the general anesthesia,requiring IBP insertion to enable the procedure. 1 patient was treated in the immediate postoperative period (5th day after surgery) due to refractory heart failure.

13 Vascular Plug 3 devices were implanted (one patient required 3 VP3 and 3 cases were treated with 2VP3). There were not complications and a good result was obtained in all cases with residual shunt<2. .

CONCLUSIONS

Retrograde closure of mitral PVLs in patients with AVP is safe.Low profile catheters and anterograde approach with high-support wires in cases of hemodynamic instability may be usefull in selected cases.

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Early experience of transnasal micro-transoesophageal echocardiography to guide LAA closure under conscious sedation

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

Percutaneous left atrial appendage closure (LAAC) is typically performed utilizing transesophageal echocardiography (TEE) and fluoroscopy under general anesthesia (GA) or intracardiac echocardiography (ICE) under conscious sedation. Transnasal microtransesophageal echocardiography (micro-TEE) is a recently described technique to guide structural heart interventions eliminating the need for GA, which is beneficial for all, especially older patients. In this series, we report our initial experience with this novel technique to guide LAAC.

METHODS AND RESULTS

Between June 2018 and January 2019, we performed 30 consecutives LAAC (mean age 80,2 years old) with the Amplatzer AMULET in whom we considered using transnasal micro-TEE under conscious sedation instead of TEE under GA. All patients had a CT prior to the procedure to assess anatomy suitability and to rule out thrombus as well as a follow-up CT performed at 3 months post-LAAC to confirm complete sealing. Three patients had TEE instead of micro-TEE for various reasons (patient preference, cognitive impairment, INR > 2). We observed one cross-over to TEE+GA because of a failed esophageal intubation under conscious sedation. Device implantation success rate was 100%. Imaging quality was quoted either good or excellent in 25 of the 26 patients with the remaining being quoted as suboptimal. Patient tolerance was either good or excellent in 24 of the 26 cases. There was fives epistaxis noticed, one requiring nasal packing. No device embolization, no significant peri-device leak, no tamponade occurred in any patient during this period. At 3 months, there was no prosthesis thrombosis observed and 23% (6/26) had partial opacification of the LAA behind the prosthesis.

CONCLUSIONS

In this series, transnasal micro-TEE was feasible, safe, well tolerated and provided sufficient imaging quality to guide LAAC with the Amplatzer AMULET under conscious sedation. The cheaper cost and the wider field of view of micro-TEE over ICE are potential advantages that could impact the organization of LAAC programs especially when these interventions are planned in the elderly in whom GA carries a significant risk.

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Impact and performance of abluminal coated sirolimus-eluting stent in diabetic population: results from en-ABL e-registry

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Percutaneous coronary intervention (PCI) of the diabetic patients remains a challenging procedure as these patients have generally longer lesions and diffuse disease. The focus of this registry was to evaluate the performance of ABLUMINUS – sirolimus eluting stent (Envision Scientific) in diabetic patients against non-diabetic patients. Abluminus possesses unique fusion and abluminal coating possibly able to address the complexity of longer and diffuse lesions.

METHODS AND RESULTS

en-ABL e-registry was prospective, multicenter, all comers, real world study enrolling 2,500 patients from 35 Indian sites. The primary outcome was of the study was the incidence of Major Adverse Cardiac Event (MACE) rate [defined as the combination of Cardiac death, Target vessel Myocardial Infarction (TV-MI) and Target Vessel/Lesion Revascularization (TLF/TVF)] at 1 year. Secondary outcome was total stent thrombosis (ST) at 1 year.

Amongst 2,500 patients, diabetes mellitus (DM) was present in 859 (34.4%) while 1641(65.6%s) patients did not have the documented history of DM. 1-year clinical outcome data was available for 844 (98.3%) and 1,616 (98.5%) for diabetic patients and non-diabetic patients respectively. The incidences of MACE were: 2.8% vs.1.9%, [p=0.148] for diabetic and non-diabetic patients, respectively. Total ST was reported as 0.8% (diabetic group) vs. 0.4% (non-diabetic), p=0.260, respectively. Further, DM group was divided into Insulin dependent DM (IDDM) and non-insulin dependent DM (non-IDDM). MACE rate for both cohorts at 1 year were found to be 4.4% vs. 2.5% [p=0.253], respectively.

CONCLUSIONS

In the current study, ABLUMINUS – sirolimus eluting stent displays similar outcomes in diabetic patients compared to non-diabetic patients. Analysis of IDDM and non-IDDM groups demonstrates positive impact of ABLUMINUS in complex DM patients. The results of the present registry support the concept that the performance of Abluminus is not negatively affected by the presence of Diabetes.

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Performance of novel abluminal coated sirolimus-eluting stent in small and large coronary vessels: subgroup analysis from en-ABL e-registry

TESTA L. (1), DANI S. (2), DESAI D. (3), PANDYA R. (4), PAREKH P. (5), VASAVADA A. (6), BHALANI N. (7), SHARMA A. (7), SHETH C. (7), SHAH D. (8)

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Percutaneous coronary intervention (PCI) of small coronary vessel (≤ 2.75 mm) is associated with higher rate of restenosis and repeat revascularization. We evaluate the performance of ABLUMINUS – sirolimus eluting stent in patients with small coronary artery disease (≤2.75mm) compared to larger vessels in the population enrolled in the en-ABL registry.

METHODS AND RESULTS

The en-ABL e-registry enrolled 2,500 all comers patients. Among them, 1,253 patients had small vessel (SV) disease while 1,247 patients had large vessel (LV) disease. The primary outcome was Major Adverse Cardiac Event (MACE) which includes Cardiac death, Target Vessel Myocardial Infarction (TV-MI) and Target Vessel/ Lesion Revascularization (TVR/TLR) at 1 year. The secondary outcome was total Stent Thrombosis (ST) at 1 year.

The demographic characteristics were almost similar for both the groups. While comparing the target vessel, in SV group 47.7% lesions were present in left anterior descending (LAD) and in LV group 49.9% lesions were present in LAD. The prevalence of diabetes mellitus was higher in small vessels compared to large vessels 43% vs 25.7%. The mean diameters were 2.61 ± 0.23 mm and 3.27 ± 0.32 mm for SV and LV, respectively. At 1 year, 97.7% clinical follow-up was achieved in SV group while 99.1% achieved in LV group.

MACE rate at 1 year was calculated as 3.1% vs 1.4%, [p=0.004] in SV vs LV groups, respectively. Cardiac death [0.7% vs. 0.5%, p=0.605], TV-MI [0.4% vs. 0.3%, p=0.752] and TVR/TLR [2.0% vs. 0.6%, p=0.001] were recorded at 1 year. Total ST at 1 year was (0.7% vs 0.4%, p=0.298]. At 1 year, MACE rate and TLR/TVR were significantly higher in small vessel group compared to large vessel group.

CONCLUSIONS

The MACE and TLR/TVR rates were higher in small vessels although absolute numbers were encouragingly low. No differences were found in terms of ST and TV-MI between SV and LV groups.

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Diagnostic accuracy of attenuation-compensated OCT compared to conventional OCT with histology as gold standard for detection of plaque composition

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Attenuation-compensated technique has been introduced by correcting light attenuation to enhance contrast and penetration depth of optical coherence tomography (OCT) imaging. We aim to compare the diagnostic accuracy of attenuation-compensated OCT compared to conventional OCT for detection of coronary plaque composition.

METHODS AND RESULTS

We analysed 200 OCT frames from randomly selected native coronary arteries of 16 patients who underwent OCT imaging for clinical purposes. The acquired OCT frames were processed using the attenuation-compensated technique. This was also applied to 30 ex-vivo OCT frames acquired from 6 patients with matching histology cross sections stained with haematoxyline & eosin which were used as reference. The histology cross-sections were analysed by a skilled cardiac pathologist, while two experts in intravascular imaging analysed the OCT and attenuation-compensated OCT images for presence of calcium and lipid tissue. When these tissues were detected - their circumferential extent were defined.

A high inter- and intra- observer agreement was noted in the conventional and the attenuation-compensated methodology ($\kappa>0.868$, and ICC>0.892, $P<0.001$ in all estimations) for the detection of the calcific component in the native coronary arteries. In addition, the agreement of the two methodologies for the presence and circumferential extent of calcific tissue was also high ($\kappa=0.825$, $P<0.001$ and ICC 0.969, $P<0.001$). Conversely, the inter- and intra- observer agreement was moderate for the presence of lipid tissue in the conventional and attenuation-compensated OCT imaging (0.7520.915, $P<0.001$ for all estimations). More importantly, there was a weak agreement between the two techniques for the presence of lipid tissue ($\kappa=0.472$, $P<0.001$). Analysis of ex-vivo OCT imaging with matching histology demonstrated that conventional OCT was superior to attenuation-compensated OCT imaging for the detection of lipid tissue ($\kappa=0.545$, $P=0.002$ vs $\kappa=0.296$, $P=0.091$) and the estimation of its circumferential extent (ICC 0.874 vs 0.514).

CONCLUSIONS

Previous studies have shown the potential added value of attenuation-compensated technique in identifying external elastic lamina which may facilitate stent selection and optimal stent deployment. Our analysis confirmed its efficacy for detecting calcific plaques but raises concerns about its accuracy in detecting lipid rich plaques. Combined conventional and attenuation-compensated imaging may enhance the value of OCT in the assessment of plaque composition and treatment planning.

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cARTHAGE-ACS trial Impact of Aspirin Regimen on THrombin Generation in diabEtic patients with ACS

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THEME: Coronary Interventions
TOPIC(S): NSTEMI

AIMS

In our study, we used for the first time Thrombin Generation test (TGT) to compare the biological efficacy of aspirin given once a day (100mg or 160 mg OPD) with aspirin divided twice per day (100mg*2 per day) in a population of diabetic patients suffering from non ST elevation myocardial infarction (NSTEMI).

METHODS AND RESULTS

Methods: Our study was prospective, descriptive, analytic and monocentric including 59 consecutive diabetic patients admitted in the cardiology department of Abderrahmen Mami hospital for NSTEMI. Patients were randomly treated with aspirin 100 mg once a day (GA100), aspirin 160 mg once a day (GA160) or aspirin 100 mg twice a day (G2100).The main outcome was Endogenous Thrombin Potential (ETP) measured by calibrated automated thrombogram (CAT) at discharge and 6 months after the NSTEMI.

Results: The baseline clinical and biological characteristics were comparable between the three groups. NSTEMI was associated in our population with an increase in thrombin generation compared to the control group .This increase was persistent up to 6 months after the acute event (ETP 6 month: 1069,93±349,99 vs ETP control: 764,37±304,55, p<0,001). When aspirin 100 mg was administered once a day, there was no significant effect on thrombin generation as attested by ETP variation at 6 months (1150,46±504,84 versus 1087,63±454,18, p=0,794). An increase in aspirin dose with a second daily administration of 100mg was associated with a significant reduction in ETP at 6 months after NSTEM (1004,87±196,2 versus 1233, 63±333,5;p=0.003).

An intermediate response was seen in the group GA160. In fact, thrombin generation decreased from 1173, 8 ±388, 07 to 1053, 64±269, 93 at 6 months; but without significant difference (p=0,117).

CONCLUSIONS

Diabetic patients are associated with a persistent thrombotic state after NSTEMI. Aspirin given twice a day (100mg*2 per day) decrease thrombin generation up to 6 months after a NSTEMI compared to a single daily dose (100mg or 160 mg OPD).This result should be supported by other studies on a larger scale.

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Percutaneous vs. surgical cut-down approach in transfemoral TAVR: a systematic review and meta-analysis of randomised controlled and propensity-matched studies

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

There is conflicting evidence as to whether or not percutaneous vascular access (PC) is superior to surgical cut-down (SC) in patients undergoing transfemoral transcatheter aortic valve replacement (TF-TAVR). This study aimed at comparing PC and SC in TF-TAVR using a systematic review and meta-analysis.

METHODS AND RESULTS

We searched EMBASE, MEDLINE and CENTRAL, from inception of each database up to January 2019. The primary analysis only looked at randomized controlled (RCT) and propensity-matched (PSM) studies. Observational unadjusted studies were included as a secondary analysis. The primary endpoint were major vascular complication and major bleeding according to the VARC definition. Secondary endpoints included minor vascular complications, minor bleeding, mortality, and length of hospitalization. This systematic review was registered to the PROSPERO register (CRD42018093873). A total of 6279 patients enrolled in 14 studies (1 randomized controlled trial, 5 propensity-matched observational studies, 8 unadjusted observational studies) were included. In the primary analysis including only RCT and PSM studies, PC approach was not associated with a statistically lower rate of major complication (OR 0.79, 95% CI 0.60-1.05) (Figure 1). However, PC was associated with a lower rate of major (OR 0.45, 95% CI 0.29-0.71) and minor bleeding rate (OR 0.59, 95% CI 0.37-0.93). No difference in minor vascular complication, life-threatening bleeding nor mortality was observed between the two strategies. PC approach was associated with a shorter length of hospitalization (MD -1.07, 95% CI -2.10; -0.03) when all studies were included.

CONCLUSIONS

In this meta-analysis, which is the largest ever reported in the literature, a PC approach in TF-TAVR showed a similar rate major vascular complications to a SC approach but was associated with a lower rate of both major and minor bleeding.

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Novel dose-reducing fluoroscopic system decreases patient but not occupational radiation exposure in CTO intervention

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THEME: Coronary Interventions
TOPIC(S): CTO, Other Coronary Interventions

AIMS

Several novel dose-reducing fluoroscopic systems have appeared in recent years, however there are only a few clinical studies that validate manufacturer data. Particularly, it is often assumed that lower patient exposures correlates with lower operator exposure although specific data is scarce. This study aimed to assess both patient and operator radiation exposure during CTO PCI, comparing a standard system fluoroscopic (STS) with a low-dose system (LDS).

METHODS AND RESULTS

We included all consecutive CTO PCI cases performed by our team of 4 CTO expert operators since the LDS was installed (excluding cases performed by non-CTO operators), making a total of 120 CTO PCI procedures. All CTO cases in our institution are incuded in a prospective CTO registry having demographic, clinical and angiographic available. Exposure data was as well prospectively collected by our Radiophysics department with an integrated management system including multiple digital dosimeters, however operator digital dosimetry was introduced later in the study and was available for 78/120 cases (65%) only. Patient exposure was assessed by the dose area product (DAP) and the total air kerma (AK). Occupational exposure was assessed by the operator dose (the highest in case of 2 operators) and scatter dose (measured from a dosimeter in the C-arm). Radiation dose parameters had non-normal distributions and were compared with the Mann-Withney U test.

Sixty CTOs were treated in a LDS cath lab and 60 in the other two SDS labs; biometrics, demographics and CTO variables as well as operators were distributed evenly between the LDS and the SDS labs (all p values >0.05). The CTOs had a median J-CTO score of 2 (93.3% ≥1), and the procedures were performed with bilateral injection in 86.7% and were successful in 81.7% (final successful retrograde approach in 16.7%). Fluoroscopic acquisition was similar in both groups: median fluoroscopy time was 33.7 min in LDS vs. 30.45 min in SDS (p=0.94) and median number of cine frames were 1879 LDS vs 2246 SDS (p=0.94). Patient radiation exposure measurements were lower in LDS than SDS: median PDA 78.7 Gy*cm2 in LDS vs. 123.7 Gy*cm2 in SDS (p<0.001) and median AK 1200 mGy in LDS vs. 2261 in SDS (p<0.001). The LDS effectively decreased PDA by 36% and AK by 47%. However, occupational data showed no statistical differences between the LDS and the SDS: median scatter dose measured at the C-arm was 1.02 mSv in LDS vs. 0.95 in SDS (p=0.63) and median operator dose was 0.096 mSv in LDS vs 0.11 in SDS (p=0.6).

The median operator occupational dose was within safe values, however the values were no different in the LDS in spite of patient dose reduction. A plausible explanation of this phenomenon is that the LDS uses less radiation amount but with higher energy (due to additional filtration) compared to SDS, therefore increasing the scatter dose that is absorbed by the operator but not by the patient. When comparing in a scatterplot the C-arm

scatter dose with the DAP we found that scatter dose with the LDS (0.0123 mSv/Gy*cm2) was 36% higher than LDS (0.0079 mSv/Gy*cm2?).

CONCLUSIONS

Using a LDS for CTO PCI was safer for patients, reducing PDA by 36% and AK by 47%. However, occupational parameters were not lower in the LDS. This effect might be due to higher energy beams used by LDS and increased scatter radiation. Therefore, radiological protection measures must be kept maximized even in LDS.

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Potential value of quantitative flow ratio in assessing a novel cardiovascular magnetic resonance quantitative perfusion mapping technique

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Quantitative Flow Ratio (QFR) is an angiography based functional assessment that has shown to have good diagnostic accuracy in assessing functionally significant intermediate coronary artery lesions. In the present study, we aim use QFR to examine the accuracy of a novel cardiovascular magnetic resonance (CMR)-based technique - CMR perfusion mapping, which has been developed to accurately quantify myocardial blood flow (MBF) with no modification of image acquisition and minimal user input.

METHODS AND RESULTS

We retrospectively analysed data from 71 patients (213 vessels) who underwent CMR with perfusion mapping prior to invasive coronary angiography. The MBF and the myocardial perfusion reserve (MPR, the stress:rest MBF ratio) for each coronary territory was calculated from the perfusion maps. Coronary angiograms were reviewed and QFR assessment was performed by a trained expert. Epicardial coronary arteries with at least intermediate stenosis (>30%, n=100) were included in the analysis. Receiver operator characteristic (ROC) curves were generated for stress MBF and the MPR to examine the efficacy of the two modalities in detecting flow limiting stenoses. 36 vessels had a QFR£0.80 and were considered functionally significant. Compared to the non-ischaemic myocardium, the ischaemic myocardium had a significantly lower MBF (1.96 vs 1.16ml/g/min, $p<0.001$) and MPR (2.21 vs 1.44, $p<0.001$). Stress MBF and MPR showed good accuracy for the detection of functionally significant coronary artery stenoses (stress MBF AUC 0.88 (95% CI 0.80-0.96) and MPR AUC 0.80 (95% CI 0.70-0.90)). The diagnostic accuracy of stress MBF was statistically higher when compared to MPR, $p=0.03$. The threshold of stress MBF to detect functional significant coronary stenoses was 1.65 ml/g/min with a sensitivity and specificity of 86% and 71% respectively.

CONCLUSIONS

Computational modelling and in particular, QFR can be used to retrospectively process angiographic data to accurately identify flow limiting stenoses with minimal cost. This allows QFR to be used as an assessment tool to study potential emerging methodologies to detect myocardial ischemia. Here, QFR demonstrated that the novel CMR perfusion mapping technique allows accurate detection of functionally significant coronary artery disease.

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Prognostic impact of PCI in octogenarians with NSTEMI: a report from SWEDEHEART

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Studies have shown that percutaneous coronary intervention (PCI) improves morbidity and mortality in non-ST elevation acute coronary syndromes (NSTE-ACS). Octogenarians, however, were underrepresented in these trials and the optimal treatment strategy remains a subject of debate. This study aimed to assess the effect of PCI in patients ≥ 80 years during the first year of follow–up.

METHODS AND RESULTS

We used data from the SWEDEHEART registry for all hospital admissions at eight cardiac care centers within Västra Götaland County. The database contains >100 clinical variables documenting the entire process of acute coronary hospital care. All consecutive patients ≥ 80 years, admitted for NSTE-ACS during the period January 2000-December 2011 were included in the analysis. We performed instrumental variable analysis with propensity score to adjust for measured and unmeasured confounders. Treatment preference variable was the calendar year. The primary endpoint was all-cause mortality at 30 days and one-year after index hospitalization.

During the study period a total of 5200 patients fulfilled the inclusion criteria. The number of patients ≥ 80 years treated with PCI increased by 2,2 % per calendar year between 2001 and 2011. In total, 586 (11.2%) patients underwent PCI; the remaining 4614 patients were treated conservatively. Total mortality at 30 days post PCI was 19.4 % (1,007 events) and 39.4 % (1,876 events) at one-year. 30-days mortality was 20.7 % in the conservatively treated patients and 8.5% in the PCI treated patients (adjusted OR 0.34; 95% CI 0.12-0.97, p = 0.044). One-year mortality was 42.1 % in the conservatively group and 16.3% in the PCI group (adjusted OR 0.97; 95% CI 0.36-2.51, p = 0.847)

CONCLUSIONS

In this observational study, treatment with PCI in octogenarians with NSTE-ACS was associated with a lower risk of mortality at 30 days. However, this short-term survival benefit was not sustained one year after the index hospitalization.

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Impact of physiological evaluation on the identification of the pattern of coronary artery disease

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Using conventional angiography, a diffuse or focal CAD pattern can be identified and this pattern has shown to influence treatment decision making. CAD patterns can be physiologically evaluated by means of invasive pressure-wire pullbacks. The incremental value of a FFR pullback on the classification and agreement on CAD patterns remains to be determined. The current study aimed at investigating the impact of a systematic FFR pullback assessment on CAD pattern classification and to examine the inter-observer variability on the CAD pattern using conventional angiography and FFR pullback curves.

METHODS AND RESULTS

Prospective, multi-center registry of stable patients undergoing coronary angiography and FFR evaluation. Vessels were assessed using a motorized FFR pullback at a speed of 1 mm/sec during continuous adenosine infusion. An independent core laboratory adjudicated the anatomical and physiological CAD pattern. CAD patterns were classified as focal, diffuse, or with a combined mechanism. Adjudication was performed by visual assessment of conventional angiography and invasive FFR pullback curves. Agreement was assessed using Fleiss' Kappa coefficient. Overall, 116 patients (158 vessels) were included; 23% were females and 30% diabetics. Adequate pressure tracings and motorized FFR pullback curves for analysis were available in 92 vessels. The target vessel was LAD in 72%, LCX in 13% and RCA in 15%. Using coronary angiography alone, 63% of vessels were classified as having a focal disease pattern, 26% as diffuse disease and 11% as a combined pattern. The inter-observer agreement on the pattern of CAD based on conventional angiography alone was moderate (Fleiss' Kappa coefficient 0.45; CI 0.29 to 0.61). After the evaluation of the FFR pullback curve, 53% of the vessels were identified as focal disease, 20% as diffuse disease and 27% showed a combined pattern of pressure drop. The inter-observer agreement based on the physiological CAD pattern was substantial (Fleiss' Kappa 0.76; CI 0.67 to 0.87). Of the patients identified with anatomical focal disease, 26% was reclassified to a diffuse or combined CAD pattern whereas 13% of anatomical diffuse disease was reclassified as focal CAD. Although, the agreement increased with the inclusion of the functional component, a discrepant classification of the CAD pattern remained in 19% of the cases.

CONCLUSIONS

Using conventional angiography, moderate agreement was observed concerning the identification of the CAD pattern. The inclusion of the physiological component reclassified 35% of the cases and increased the inter-observer agreement on the pattern of CAD. However, in one fifth of the cases observers disagreed. A quantitative metric to evaluate the pattern of CAD is required.

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Percutaneous transseptal mitral valve-in-valve and valve-in-ring procedure in high-risk patients: procedural, early and late outcomes in a two-centre initial experience

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair

AIMS

Percutaneous transeptal mitral valve implantation in degenerated bioprosthetic valves (TSMVIV) or failed ring anuloplasty (TSMVIR) is emerging as a valid therapeutic alternative to surgical re-do in high risk patients. Immediate outcomes are favorable, but data on subsequent outcomes are lacking. The aim of this study is to report interventional techniques, early procedural outcomes and 1-year outcomes of transeptal balloon-expandable transcatheter heart valve implantation in failed mitral bioprosthesis, ring annuloplasty in a initial two centers experience in the Veneto region, Italy.

METHODS AND RESULTS

In this registry we prospectively enrolled all patients who underwent transseptal mitral valve implantation with balloon expandable bioprosthesis for failed previous surgical correction of mitral valve disease from January 2017. Demographics, clinical, procedural informations and data of early outcomes were collected. Follow up is scheduled at 30 days, 6 months and 1 year.

Of the 22 patients enrolled in our study, 21 received TMVIV and 1 received TMVIR implantation, 9 were female (40,9%). Mean age was 80 years old (32-87), mean Euro score II was 10 (3-50) . 17 (77,2%) procedures were performed under general anesthesia, 5 implant under conscious sedation all the procedure were performed via transseptal approach. Procedural success, defined as successful valve implantation without complications and absence of residual significant valve insufficiency, was achieved in 21 patients (95,4%). One patient died for pericardial tamponade due to cardiac perforation. One patient died few days after the procedure, during hospital stay, because of intracranial bleeding. Average procedural time was 115 min (55-190). Mean ICU stay was 1,4 days. 20 of 22 patients (90%) were discharged without in hospital complications and where evaluated at 30 days reporting improvement of functional class (NYHA) without hospital readmission. At 1 year overall mortality rate was 13,2%, cardiovascular mortality was 9%, and the 18 of 19 patients still alive (94,7%) were in CF NYHA I or II. The 1-year mean gradient post was 6 (3-9) mmHg and PVL >2 rate was 0.0%.

CONCLUSIONS

Percutaneous transeptal implantation of balloon expandable bioprosthesis in degenerated mitral valve bioprosthesis or in patient with failed surgical ring anuloplasty represent an effective option to avoid high risk surgical re-do. The two centers initial experience reported in this study is in line with previous published data in terms of procedural safety/efficacy and early and late outcomes.

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Trends in outcomes in patients with acute post-infarct heart failure: a report from the Swedish Coronary Angiography and Angioplasty Registry (SCAAR)

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THEME: Interventions for Heart Failure
TOPIC(S): Acute heart failure

AIMS

Acute ischemic heart failure (AIHF) is the most common cause of death for patients with ST-elevation myocardial infarction (STEMI). The most severe form of AIHF, cardiogenic shock, carries a particularly poor prognosis. We sought to determine whether the incidence and prognostic impact of AIHF and CS in STEMI have been reduced over the last eight years.

METHODS AND RESULTS

Using the nationwide Swedish Angiography and Angioplasty Registry (SCAAR) we identified patients who underwent primary PCI due to STEMI in Sweden between January 2010 and April 2018. We defined IAHF as Killip class ≥2 and cardiogenic shock as Killip class 4. The primary endpoint was mortality at 30 days.

We identified 40,701 patients who underwent primary PCI during the study period with known vital status at 30 days, for whom Killip class was reported for 40,365 (99.2%). AIHF occurred in 3,456 (8.6%) of these patients, and 955 (2.4%) developed cardiogenic shock. Thirty-day mortality for the overall STEMI cohort was 5.9%, whereas 30-day mortality for patients with AIHF and CS were 27.7% and 48.8%. respectively. The incidence of AIHF decreased somewhat (ptrend=0.006), whereas the incidence of CS did not (ptrend=0.77)(Figure). In contrast, we observed an improvement over the study period in the prognosis of CS (ptrend=0.004) but not AIHF (ptrend=0.065).

CONCLUSIONS

The incidence and prognostic implications of AIHF among patients with STEMI have improved slightly over the eight years. However, AIHF, and particularly CS, is still associated with a very high risk of dying.

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The impact of strut design on the haemodynamic behaviour of various BRS

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

The hemodynamic environment after BRS deployment plays an important role in the mid- to long-term efficacy of these devices. Scaffold regions exposed to flow recirculation and low Time Averaged Wall Shear Stress (TAWSS) are prone to develop increased neo-intima formation. We aimed to compare the hemodynamic behaviour of 3 different BRS with rectangular struts of varying height, namely the Fantom (125μm), Fantom Encore (98μm), and Absorb (157μm) and one BRS with rounded struts, the Magmaris (150μm). We performed in vitro scaffold deployment to study the TAWSS and circulation zones in 2D and 3D.

METHODS AND RESULTS

BRSs were deployed in plastic tubes and were imaged with high resolution microCT. From the microCT data, both 2D and 3D geometrical models of the deployed scaffolds in the tube were reconstructed by first extracting the centreline of the scaffolds (Mimics software) and second reconstructing the surface models (Rhinoceros software). Based on these models, Computational Fluid Dynamics (CFD) was performed with FLUENT, using a time-dependent inflow profile. The size of the recirculation zone and the minimal TAWSS were largest for the Absorb (240 μm and -0.18 Pa), followed by the Magmaris (170 μm and -0.15 Pa), the Fantom (140 μm and -0.14 Pa) and the Fantom Encore (100 μm and -0.13 Pa). For the rectangular scaffolds, the 2D models showed that a larger strut height was linearly correlated with a larger size of the recirculation zone and lower values of minimal TAWSS. The Magmaris had a smaller recirculation zone than expected based on the strut thickness, due to the rounded strut edges. Whilst the hemodynamic behaviour in 2D depended on strut size and shape, in 3D, stent design and strut lay-out played a role as well. For the BRS with rectangular struts, the percentage area with adverse TAWSS (<0.5 Pa) was highest for the Fantom (59%) and lowest for the Fantom Encore (30%). The Absorb had a more open strut design with reduced coverage of the stented region compared to the Fantom scaffold, resulting in a smaller region with adverse TAWSS (57%). Lastly, the Magmaris had both less coverage of the stented region as well as rounded strut edges, leading to the smallest region of adverse TAWSS (20%).

CONCLUSIONS

In BRS with rectangular shaped struts, Fantom Encore showed the smallest recirculation zone and lowest value of minimal TAWSS in 2D. Due to the impact of stent design and strut lay-out both the Fantom Encore and the Magmaris showed smaller TAWSS in 3D as compared to the thicker strut Fantom and Absorb BRS. This study shows the benefit of CFD to disentangle the effect of strut height and layout on the hemodynamic performance of coronary stents.

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A novel methodology for accurate reconstruction and assessment of the local haemodynamic forces in metallic-stented coronary artery segments

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Stents and scaffolds

AIMS

To develop and validate a novel in vivo methodology that enables reliable coronary artery reconstruction of stented segments which relies on separate reconstruction of vessel and stent geometry.

METHODS AND RESULTS

Five coronary arteries implanted with Xience Alpine everolimus eluting stent that were assessed by optical coherence tomography (OCT) imaging immediately after stent implantation were included in this study. The stented segment were reconstructed using two angiographic projections and OCT images using two methodologies - 1. Conventional methodology, which assumes that stent struts are well apposed and generates a surface of the combined lumen and strut geometry - 2. Novel methodology, where the lumen and stent geometry are reconstructed separately and then the two reconstructions are fused to generate the final geometry of the stented segment. Pulsatile blood flow simulation was performed and the endothelial shear stress (ESS) distribution and shear rate were compared in the models obtained by the two reconstruction approaches. The conventional methodology was unable to reconstruct strut architecture in segments with strut malapposition and appeared to underestimate areas exposed to low ESS <1Pa (21±12% vs 27±13%, P<0.001) and lumen volume exposed to high shear rate >1000s-1 (0.72 mm3 vs 1.17 mm3, P=0.07) in these segments compared to the novel methodology. In cases of bifurcations, the novel methodology enabled a better assessment of flow dynamics and the flow disturbances caused by the protruded struts that resulted in a higher shear rate compared to the conventional method (1440 s-1 vs 1300 s-1, P<0.001).

CONCLUSIONS

The new methodology allows more reliable reconstruction of stent struts and accurate estimation of local haemodynamic forces, especially at the bifurcations and when malapposed stent struts are present. This optimised novel methodology may provide invaluable information on predictors of stent failures and vascular response after stenting.

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Clinical outcomes at two years of the Absorb BRS vs. the Xience drug-eluting metallic stent in diabetic or non-diabetic patients in routine PCI - AIDA trial substudy

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds, Other Coronary Interventions

AIMS

In this pre-specified subgroup analysis of the Amsterdam Investigator-Initiated Absorb Strategy All-Comers (AIDA) trial, we evaluated the clinical outcomes of Absorb bioresorbable vascular scaffold versus Xience everolimus eluting stent treated diabetic or non-diabetic patients in a population which reflects daily clinical practice.

METHODS AND RESULTS

This analysis includes the 2-year outcomes of all 1845 patients randomized in the AIDA trial subdivided by clinical presentation, a pre-specified subgroup analysis. We compared patients presenting with diabetes with those presenting without diabetes (diabetic patients versus non-diabetic patients). Patients presenting with diabetes were further sub-categorized according to insulin treated diabetes versus non-insulin treatment The primary outcome of this analysis is target vessel failure (TVF) (composite of cardiac death, target-vessel myocardial infarction or target-vessel revascularization).

In AIDA, 324 patients were diabetic, of which 171 in the Absorb group (insulin treatment = 65), and 153 in de Xience group (insulin treatment = 45). At baseline, patients with diabetes were generally younger, less often male, and had less more often hypercholesterolemia and hypertension.

Patient level procedural characteristics were well balanced between the two treatment groups. On lesion level, diabetic patients within the Absorb group, had higher rates of moderate to severe calcification, and a higher percentage diameter stenosis post-procedure, and a lower post-procedure in-segment minimum lumen diameter, whereas, in the Xience group, diabetic patients had higher rates of moderate to severe calcification.

The rates of the 2-year primary endpoint of target vessel failure (TVF) were similar after treatment with Absorb or Xience in diabetic patients (14.4% versus 14.3% respectively; p=0.997) and in non-diabetic patients (10.2% versus 9.0% respectively; p=0.672).

No statistically but numerically significant difference in definite device thrombosis in diabetic Absorb or Xience patients was found (2.4% versus 0.7%, respectively; p=0.218). Definite device thrombosis occurred statiscally more frequently with Absorb compared to Xience in non-diabetic patients, however, (3.0% versus 0.5% respectively, p<0.001). There were no statistically significant interactions between clinical presentation and randomized device modality for TVF (p=0.672) and for the endpoint of definite or device thrombosis (p=0.720).

In orally treated diabetics, TVF occurred in 10.8% of Absorb patients and in 12.5% of Xience patients (p=0.740), whereas in insulin treated patients TVF occurred in 20.3% and 20.9% Absorb or Xience patients (p=0.954), respectively. Rates of definite device thrombosis with Absorb compared to Xience in orally treated

diabetics were similar (1.1% versus 1.0% respectively, p<0.985). In insulin treated diabetics TVF occurred in 20.3% of Absorb patients and 20.9% Xience patients (p=0.788), whereas rates of definite device thrombosis were 4.8% for Absorb versus 0% for Xience , p=0.145.

CONCLUSIONS

In diabetic patients, we found no difference in rates of TVF between the Absorb and Xience groups. Rates of definite or definite device thrombosis were higher in the Absorb group throughout all clinical presentations. No significant interaction between diabetic and non-diabetic patients and the occurrence of TVF or definite device thrombosis was found between the two treatment arms.

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PCI in patients with complex coronary artery disease when surgical revascularisation is rejected

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease

AIMS

Patients with complex coronary artery disease that are rejected for or refuse surgical revascularization compose a high-risk population. We sought to examine clinical outcomes of percutaneous coronary intervention (PCI) in such high-risk patients.

METHODS AND RESULTS

We retrospectively included 34 consecutive patients that underwent non-emergency PCI from a single-center cohort from September 2014 to November 2017 after having been rejected by cardiac surgeons or having refused surgical treatment. Median follow-up period was 18 months. Primary outcome was the composite endpoint of mortality, acute myocardial infraction, cerebrovascular accident and target lesion revascularization. Mean age was 70.9±10 years. Most patients presented with acute coronary syndrome (64.8%). The documented reason for coronary artery bypass graft (CABG) rejection was high surgical risk in 23 patients (67.6%), poor surgical targets in 4 patients (11.8%) and patient preference in 7 cases (20.6%). Left main or three-vessel disease was present in 29 patients (85.3%). Median Euroscore II and median Syntax score were 3.05%(1.72-7.4%) and 28.5(24-34.5), respectively. A single procedure or staged revascularization was performed aiming at complete revascularization when technically possible. In-hospital clinical course was uncomplicated in all cases. During long-term follow-up, the primary composite outcome was observed in 7 patients (20.6%). In specific, primary endpoint was driven by 3 cases of death (8.8%), 3 cases of target lesion revascularization (8.8%) and 1 case of acute myocardial infraction (2.9%).

CONCLUSIONS

PCI in patients with complex coronary artery disease after CABG rejection appears to be feasible with uncomplicated in-hospital course. However, a high rate of major cardiovascular events should be anticipated in the long-term and close follow-up of these patients is warranted.

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Haemodynamic and clinical impact of ANOmalous connections of CORonary arteries using CT-derived FFR from the ANOCOR registry

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Other Coronary Interventions

AIMS

Aims

With the emergence of coronary computed tomography angiography (CCTA), ANOmalous connections of CORonary arteries (ANOCOR) are more frequently diagnosed than previously reported. CT-derived Fractional Flow Reserve (FFRCT) is a non-invasive functional test providing anatomical and functional evaluation of the overall coronary tree. These unique features could help for the management of patients with ANOCOR. We aimed to retrospectively evaluate the clinical impact of FFRCT analysis in the ANOCOR registry population with 3 year-follow-up.

METHODS AND RESULTS

Methods and results:

The ANOCOR registry included adult patients with ANOCOR detected during invasive coronary angiogram or CCTA performed between January 2010 and January 2013. Among 472 patients included, 105 patients had a cardiac CT during the inclusion period.

We retrospectively performed FFR-CT and obtained successful analyses in 54 patients of 60 ± 13 years with a complete 3-year clinical follow-up. Thirty-six (67%) patients had conservative treatment and 18 (33%) patients had coronary revascularization after the CCTA. FFRCT analysis showed that ANOCOR course slightly reduces the mean FFRCT value of 1 at the ostium to 0.90 ± 0.10 downstream the abnormal course and had a distal vessel mean FFRCT value 0.82 ± 0.11. No statistical difference of FFRCT values were observed between ANOCOR at risk and non at risk and between conservative and revascularization groups. At 3 years of follow-up, only one patient had unplanned revascularizations of ANOCOR vessel in the conservative strategy group.

CONCLUSIONS

Conclusions

We observed favorable FFRCT values of ANOCOR and non ANOCR vessels. Patients treated conservatively and revascularized had excellent clinical outcome at 3 years of follow up.

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Transcatheter implantation of balloon-expandable valve for severe aortic stenosis in large and very-large native aortic annuli

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

We report our two-center experience implanting the transcatheter aortic Edwards SAPIEN 29mm valve in native annuli that exceed the manufacturer`s recommendations regarding maximum annulus size.

METHODS AND RESULTS

Methods

The largest recommended annulus area for the implantation of a 29mm Edwards SAPIEN S3 (ES3) valve is 683mm2. All patients undergoing transfemoral implantation of a 29mm ES3 valve and with a native valve annulus > 683mm2 at our two centers between the years 2014-2018 were included. Pre-procedural computed tomography (CT) was routine. Thirty-day outcomes are reported.

Results

During the respective period, 191 patients underwent implantation of a 29mm ES3 valve. A total of 17 patients met the inclusion criteria. All patients were male, with a median age of 80 years (IQR 77-84). The median annulus area was 729mm2 (IQR 715-773). Two patients had an annulus area ≥800mm2. No major procedural complications occurred. At 30 days, trivial and mild paravalvular leak (PVL) was found in 10 and 4 patients, respectively. Three patients had none. No mild-to-moderate PVL was recorded. Median mean transvalvular gradient was 8mmHg (IQR 5.5-9.5). Two patients (12%) received a permanent pacemaker.
At 30-days, no stroke occurred and all patients were alive.

CONCLUSIONS

In patients with large native aortic annuli (up to 817mm2), implantation of the 29mm ES3 valve resulted in excellent hemodynamic and clinical outcomes at 30 days.

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Comparison of contrast-induced nephrotoxicity of iodixanol and iopromide in patients with renal insufficiency undergoing coronary angiography

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Aims: This monocentric, randomised, double-blind study compared the nephrotoxicity of low-osmolar, low-viscous iopromide and iso-osmolar, high-viscous iodixanol in patients at high risk (Mehran score≥6), after coronary angiography or percutaneous coronary intervention (PCI).

METHODS AND RESULTS

Methods: The primary endpoint was contrast-induced nephropathy (CIN) on day 2 or 3, defined as a post-dose absolute increase in serum creatinine (SCr) of ≥ 0,5 mg/dl from baseline or a relative increase of 25%. All patients were rigorously hydrated from 12 hours before intervention.

Results: A total of 102 patients (51 in each group) were enrolled into the study (from 187 recruited). No difference was observed in baseline patients characteristics between Iopromide group and Iodixanol group except in baseline creatinine serum level (157.1±36 vs. 181.5±55.7 µmol/l, respectively; p=0.01), whereas creatinine clearance (37.2±10.8 vs. 34.2±10.2 ml/min; p=0.147) as well as Mehran score (9.2 ± 2.4 vs. 9.9 ± 2.6; p=0.168) were similar between the two groups. Regarding contrast load, a trend was observed in Iopromide group vs. Iodixanol group (63.6±36.7 vs. 51.2±2.9ml; p=0.077). Nine patients experienced CIN for an overall incidence of 8.8%. No difference in CIN occurrence was found between the two groups (7.8 vs. 9.8%; p=0.727). No death or need for dialysis was noticed during in-hospital stay or at 3-month follow up in both groups.

CONCLUSIONS

Conclusions: With rigorous hydration, the CIN incidence was very low in patients at high risk for CIN (Mehran score≥6) who underwent coronary angiography or PCI. No difference in nephrotoxicity was found between iopromide and iodixanol

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Ischaemic efficacy and bleeding safety of ticagrelor monotherapy in patients with multivessel PCI: insights from the GLOBAL LEADERS trial

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THEME: Coronary Interventions

TOPIC(S): Left main and multivessel disease

AIMS

The aim of the present study is to evaluate the impact of the experimental strategy (1-month DAPT followed by 23-month ticagrelor monotherapy) vs. the reference strategy (12-month DAPT followed by 12-month aspirin monotherapy on clinical outcomes in patients with multivessel percutaneous coronary intervention (PCI).

METHODS AND RESULTS

This is a post-hoc analysis of the Global Leaders trial and included 15,845 patients, of whom 3,578 patients received multivessel PCI. The primary endpoint was the composite of the all-cause death and new Q-wave myocardial infarction (MI). The key secondary endpoint was Bleeding Academic Research Consortium (BARC) defined type 3 or 5 bleeding. In addition, the Academic Research Consortium 2- defined patient-oriented composite endpoint (POCE) (defined as the composite of all-cause death, any stroke, any MI, and any revascularization) and the net adverse cardiovascular events (NACE) (defined as the composite of POCE and BARC type 3 or 5 bleeding) at two years were assessed. In patients with multivessel PCI, the experimental strategy, when compared with the reference one, significantly reduced a rate of primary endpoint (3.11% vs. 4.85%, p=0.003, p-value for interaction=0.016) at two years, while a risk of BARC type 3 or 5 bleeding at two years was statistically similar (2.44% vs. 2.65%, p=0.689, p-value for interaction=0.657). An additional post-hoc analysis has demonstrated that, in patients with multivessel PCI, the experimental treatment had a significant risk reduction in POCE (13.37% vs. 16.79%, p=0.006, p-value for interaction=0.011) and NACE (14.64% vs. 18.42%, p=0.003, p-value for interaction=0.007) at two years, as compared with the reference one.

CONCLUSIONS

The experimental strategy had a significant risk reduction in the primary endpoint as well as POCE and NACE with a significant treatment effect while maintaining a similar risk of BARC type 3 or 5 bleeding in patients with multivessel PCI, as compared with the reference one. Further large-size investigations are warranted to confirm these findings

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Lipid rich plaques detected by near infrared spectroscopy are more frequently located in regions of high shear stress

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THEME:
TOPIC(S):

AIMS

Lipid rich plaques (LRP) as detected by near infrared spectroscopy (NIRS) have been linked to future adverse cardiac events. Shear stress, caused by blood flow along the vessel wall, is known for its involvement in the initiation, progression and destabilization of atherosclerotic plaques. High shear stress regions are related with destabilization and even rupture of plaques. The aim of the present study was to assess the colocalization of NIRS-detected LRP and high shear stress in non-culprit coronary arteries of patients with an acute coronary syndrome.

METHODS AND RESULTS

The IMPACT study is a prospective, single center study investigating the relation between atherosclerosis and shear stress in coronary arteries. Patients with acute coronary syndrome, treated with PCI, underwent NIRS-IVUS imaging and intravascular doppler flow measurements of at least one non-culprit coronary artery along with CT coronary angiography at 1 month follow-up. 3D reconstructions of the vessels were performed using fusion of IVUS derived lumen contours and CT derived vessel centrelines. Detailed time average wall shear stress (TAWSS) computations were subsequently executed by means of computational fluid dynamics in the 3D reconstructions applying invasive flow measurements. For each vessel, the TAWSS was subdivided into tertiles (low, mid, high). We compared the TAWSS distribution at NIRS positive and NIRS negative plaques (wall thickness> 0.5 mm). 32 vessels out of 31 patients (mean age 60±10 years, 87% male) were analyzed. A positive NIRS signal was observed at 10% of the plaque surface. The average wall thickness of NIRS positive plaque regions was slightly higher than the wall thickness of NIRS negative plaque regions (0.73 ± 0.19 mm vs 0.82 ± 0.23mm, T-Test $p<0.05$). The frequency with which NIRS positive regions were exposed to low, mid and high TAWSS differed significantly from the NIRS negative regions (NIRS negative: 33%, 33%, 34% vs NIRS positive: 25%, 33%, 42%, respectively, two-way ANOVA $p<0.05$). These data demonstrate that NIRS positive plaques were more frequently colocalized with high shear stress compared to NIRS negative plaques (42% vs 34%).

CONCLUSIONS

In this study we assessed the colocalization of lipid rich coronary plaques with high shear stress. LRP as detected by NIRS are more often located at regions exposed to high shear stress as compared to plaques with no detectable lipids. Regions that display both high shear stress and NIRS positive signal are potentially at risk for future plaque destabilization and rupture. Combining the knowledge of these two features may be of added value in risk stratification.

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PCI performance in spontaneous coronary artery dissection: insight from an Italian multicentre registry

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds, Other Coronary Interventions

AIMS

Spontaneous coronary artery dissection (SCAD) optimal treatment is still unclear. However, when Percutaneous Coronary Intervention (PC)I is attempted, techniques and devices used to ensure true lumen recanalization may be different compared to a standard PCI in atherosclerotic disease

METHODS AND RESULTS

DISCO (DIssezioni Spontanee COronariche) is an italian multicenter registry enrolling patients admitted with a diagnosis of SCAD. Baseline, procedural characteristics, in–hospital management and outcomes of SCAD patients were collected. Among 170 patients included, women were 77.6% with a mean age of 53±12 year. 70 (41.2%) cases underwent PCI as a first approach. Besides, 7 (4.1%) patients initially managed conservatively required an urgent PCI due to retrograde propagation of dissection including left main abrupt occlusion in 1 case. A TIMI (Thrombolysis in Myocardial Infarction) flow was 0-1 in the most of the cases (n=43, 55.8%) and Left Anterior Descending artery was mainly the target (n=44; 57.1%). A workhorse guidewire was adeguate in the majority of cases (n = 63, 81.8%). PCI with stent implantation was necessary in 56 (77.2 %) of cases (with DES n= 49, 87.5%; only BRS n=3 5.4%; hybrid DES-BRS n=2 3.6%) with a median stent/scaffold length of 38 mm (IQR range 23-63). Remaining cases required only balloon-angioplasty, including 2 cases with successful hematoma fenestration using an undersized cutting-balloon. An Imaging technique to optimize the PCI result was performed only in 16 cases (20.8%). Overall, TIMI 3 flow at the end of PCI was obtained in 49 patients (70%). PCI failure occurred in 16 patients (23%): in three of them a second PCI procedure was accomplished after discharge (> 1 month), while the others cases where managed conservatively. In-hospital events occurred in 10 patients (13%, cardiac death = 1 ; non-fatal MI = 5, any PCI=8). Follow-up after discharge was to-date available in 55 patients (71.4 %) with a mean lenght of 25 +- 26 months. A total of 13 MACE (17%) was registered (cardiac death = 1 ; non-fatal MI = 7, unplanned PCI=10).

CONCLUSIONS

PCI in case of SCAD continue to be hampered by a non-negligible rate of failure or subsequent hard events. Different techniques like only-balloon, cutting balloon or BRS could be considered in order to limit extensive stenting in such young population.

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Impact of recruitment and retention on all-cause mortality in a large all-comer trial: insights from the GLOBAL LEADERS trial

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Selective recruitment and lack of retention in clinical trials may bias the results and subsequently complicate their interpretation and validity. We soughttoevaluate the impact of recruitment and retention on all-cause mortality in a large all-comers randomized controlled trial (RCT).

METHODS AND RESULTS

The recruitment rate in each investigating center of the Global Leaders trial was assessed and the 130 participating centers were subdivided into low and high recruiters according to the median of the recruitment rate. The risk of all-cause mortality was compared between the low vs. high recruiters. With the data on vital status obtained from public domains in patients with incomplete follow-up, we also evaluated all-cause mortality according to the study follow-up status.

The trial randomized 15,991 (mean:7.86%, median:6.68%) of 203,483 patients treated with percutaneous coronary intervention (PCI) during the recruitment period, of whom 15,267 (95.47%) completed follow-up, 23 (0.14%) patients withdrew consent and formally requested to be deleted from the database; 183 (1.14%) withdrew consent but only objected to future data collection; 303 (1.89%) discontinued the study; and 215 (1.34%) were lost to follow-up. Vital status was finally obtained from public records in all but 31 patients (99.81%). Our analysis has found that low recruiters had a significantly lower all-cause mortality, compared with the high ones (2.26% vs. 3.24%, p=0.002). Likewise, there was a significant difference in all-cause mortality among the incomplete follow-up groups (log-rank p< 0.001) with a significantly higher mortality in the 183 patients who withdrew consent than those who completed follow-up (7.10% vs. 2.99%, p=0.002).

CONCLUSIONS

Patterns of recruitment and retention significantly impacted all-cause mortality in a large “all-comers” RCT. Future “all-comers” trials should comply with strict conditions to prevent jeopardizing their validity. Search for vital status through public domains is of paramount importance in the interpretation and validity of large clinical trials.

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Coronary OCT pattern five years after implantation of BRS compared with everolimus- and biolimus-eluting coronary stents: insights from the randomised EVERBIO II trial

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Although bioresorbable vascular scaffolds (BVS) are currently considered inferior to metallic drug-eluting stents (DES), long-term data are limited. We sought to compare the optical coherence tomography (OCT) findings 5 years after implantation of bioresorbable vascular scaffolds (BVS), everolimus-eluting persistent polymer stents (EES) and biolimus-eluting stents with bioabsorbable polymer (BES).

METHODS AND RESULTS

EVERBIO II was a single-center, assessor-blinded, randomized study. Between November 2012 and November 2013, the EVERBIO II trial recruited 240 patients randomly allocated to BVS (n = 80), BES (n=80) and EES (n=80). For the purpose of the present study, all patients included in the EVERBIO II trial were screened to undergo an OCT examination of the scaffold and stent segment during the 5-years angiographic follow-up. We present here the findings in 93 lesions from 86 patients. At 5 years, no BVS struts could be delineated. Thererfore the platinum markers were visualized and used for comparison with DES. Mean lumen area was significantly higher in BVS (7.05±2.45mm2) than in those threated with metallic drug-eluting stents (DES) (5.83±2.24 mm2, p= 0.03). OCT showed no malposition and a complete strut resorption in the vessel wall for the BVS group. In-stent eccentricity index and asymmetry index were similar between the groups.

CONCLUSIONS

At long-term OCT follow-up, a complete resorption of the BVS was observed. This was associated with positive lumen remodeling in comparison with DES.

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Impact of ticagrelor monotherapy on two-year clinical outcomes in patients with increasing stent length: insights from the GLOBAL LEADERS trial

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Data on the efficacy and safety of different antiplatelet regimens after percutaneous coronary intervention (PCI) are limited in patients with increasing total stent length (TSL).The aim of this study was to evaluate the impact of the experimental strategy vs. the reference one on clinical outcomes in patients with increasing TSL.

METHODS AND RESULTS

This is a post-hoc analysis of the Global Leaders trial, which examined the efficacy and safety of the experimental strategy (1-month dual antiplatelet therapy [DAPT] followed by 23-month ticagrelor monotherapy) vs. the reference strategy (12-month DAPT followed by 12-month aspirin monotherapy) in “all-comers” population. The primary endpoint was the composite of all-cause death and new Q-wave myocardial infarction (MI) and the key secondary endpoint was Bleeding Academic Research Consortium (BARC) type 3 or 5 bleeding at two years. Other exploratory endpoint was Academic Research Consotium-2 defined the patient-oriented composite endpoint (POCE) (defined as the composite of all-cause death, any stroke, any MI, and any revascularization) and the net adverse cardiovascular events (NACE) (the composite of POCE and BARC type 3 or 5 bleeding) at two years.

The cohort of 15,234 patients treated with the uniform use of biolimus-eluting biodegradable polymer stents included in this analysis were divided into quartiles according to TSL per patient. In patients with the longest TSL group (defined as TSL ≥ 43 mm), the experimental strategy significantly reduced a rate of the primary endpoint (3.61% vs. 5.46%, p=0.004, p-value for interaction=0.030). Also, the experimental treatment had a significant risk reduction in POCE (14.00% vs. 18.15%, p<0.001, p-value for interaction =0.001), and NACE (15.54% vs. 19.50%, p=0.001, p-value for interaction =0.003) with a statistically similar risk of BARC type 3 or 5bleeding (2.49% vs. 2.24%, p=0.415, p-value for interaction =0.539), as compared to the reference treatment.

CONCLUSIONS

In patients with the longest TSL, the experimental strategy significantly reduced a risk of the primary endpoint as well as POCE and NACE while avoiding an increased risk of BARC type 3 or 5 bleeding at two years.

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Clinical outcomes of an ultrathin strut sirolimus-eluting stent with biodegradable polymer in all-comer patients undergoing coronary intervention

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Thin stent struts may be associated with reduced vessel injury and use of biodegradable polymers may further improve long term outcomes but data with earlier stents has been inconsistent; thus further studies with newer devices are needed. We evaluated the efficacy and safety of a new ultra-thin (65um) strut cobalt chromium sirolimus eluting stent with a hybrid design (closed cell at ends and open cells in middle to reduce edge injury and optimise conformability) in all-comers patients undergoing percutaneous coronary intervention (PCI).

METHODS AND RESULTS

We enrolled 752 patients from 14 sites undergoing PCI into a prospective, non-randomized, multi-centre, open-label, observational registry. Inclusion of patients with complex anatomy (long stent lengths, bifurcations and chronic total occlusions) was encouraged. Clinical follow-up was scheduled at 1, 9, 12 and 24 months. The primary endpoint was incidence at 9 months of major adverse cardiac events (MACE) defined as cardiac death, non-fatal myocardial infarction (MI) or target vessel revascularisation (TVR) .

Mean patient age was 64.7±12.2 years, 20.7% had diabetes, 58.8% had dyslipidemia, 40.4% had multi-vessel disease, 22% had previous PCI, 4.7% had previous coronary-artery bypass graft, and 19.6% had a clinical history of previous MI. Mean lesion length was 25.7±17.3 mm. The primary endpoint of cumulative MACE up to 9 months (from 578 patients reaching 9 months follow-up) occurred in 12 patients (2.08%), including 6 (1.04%) cardiac death, 5 (0.87%) MI and 6 (1.04%) TVR. Definite stent thrombosis was reported in 3 patients (0.52%) and probable stent thrombosis in 2 patients (0.35%).

CONCLUSIONS

Use of an ultra-thin strut biodegradable polymer sirolimus-eluting stent in all-comers patients undergoing PCI was associated with good clinical efficacy and safety.

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DynamX novolimus-eluting bioadaptor, an innovative device that adapts to patients' physiology, for PCI treatment of coronary artery disease

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Drug Eluting Stents (DES) are the mainstay in coronary artery disease treatment. The DynamX Bioadaptor System is a novel, thin strut bioresorbable polymer coated drug eluting bioadaptor releasing Novolimus, a macrocyclic lactone mTOR inhibitor with anti-proliferative properties. The DynamX Bioadaptor offers the acute performance of a current generation DES and with its uniquely designed uncaging elements offers the potential advantages of minimizing compliance mismatch and geometric distortion, providing physiologic coronary pulsatile motion and supportsearly adaptive remodeling.

METHODS AND RESULTS

The DynamX Bioadaptor contains a drug dose of 5 µg of Novolimus per mm of bioadaptor length with device availability in multiple diameters (2.5 – 3.5 mm) and lengths (14, 18 and 28 mm). In a non-randomized, mechanistic clinical study, 50 patients were enrolled at 6 sites in Belgium and Italy to assess the safety and performance of the DynamX Bioadaptor. Patients were analyzed for multiple clinical endpoints including: device and procedure success; target lesion failure (TLF), a composite endpoint of cardiac death, target vessel MI, or clinically-indicated target lesion revascularization (CI-TLR), the individual components of TLF, and bioadaptor thrombosis at 1, 6 and 12 months and annually to 3 years.

Mean age at baseline was 65.8 ± 8.9 years, 76% were male, and 26% diabetics. Physician visual assessment showed an average reference vessel diameter of 3.2 ± 0.3, lesion length of 12.8 ± 4.6, a pre-procedure percent diameter stenosis (% DS) of 78.1 ± 9.9, and 50% of lesions were type B1/B2. Pre-dilatation was performed in 98% of patients and post-dilatation in 64% of lesions. The average DynamX deployment pressure was 12.2 atm.

At 30 days, there were no device-related events reported. Longer-term clinical data will be presented.

CONCLUSIONS

The DynamX Novolimus Eluting Coronary Bioadaptor System is a novel medical device which combines the acute attributes of metallic DES with longer term attributes of normal vessel compliance and pulsatile motion and supporting early adaptive remodeling for a more complete revascularization. To date no device-related clinical events have been reported. Longer-term clinical data will be presented.

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Correlation and diagnostic accuracy between resting full-cycle ratio and resting Pd/Pa in moderate coronary artery stenosis

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

The aims of this study was to assess the correlation and diagnostic accuracy between resting full cycle ratio (RFR) and resting Pd/Pa in moderate coronary artery.

METHODS AND RESULTS

Between September 2018 and January 2019, we retrospectively assessed 53 moderate coronary stenosis in 42 patients with FFR, resting full-cycle ratio (RFR), and resting Pd/Pa. The correlation between resting full-cycle ratio and resting Pd/Pa was assessed by correlation coefficient. Receiver operating curve (ROC) analysis was performed to examine the optimal binary cut-off value of RFR and resting Pd/Pa, which predict FFR value of 0.80. The median RFR and resting Pd/Pa were 0.91 ± 0.10 and 0.95 ± 0.64, respectively. Quantitative coronary analysis showed median diameter stenosis was 51±12% and lesion length was 18.8 ± 8.2 mm. There was a significant liner correlation between RFR and resting Pd/Pa (R2= 0.967, P< 0.001, Pd/Pa = 0.41 + 0.59x). ROC analysis revealed optimal binary cut-off value of RFR predicting FFR value of 0.80 was 0.89 (area under curve [AUC] 0.712, 95% confidence interval [CI]: 0.57-0.85), and Pd/Pa was 0.93 (AUC 0.712, 95% CI 0.56-0.85).

CONCLUSIONS

There was a highly correlation between RFR and resting Pd/Pa with a equal diagnostic accuracy which predicts FFR value of 0.80 in moderate coronary artery stenosis.

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Impact of renin-angiotensin system inhibitors on clinical outcomes in patients with severe aortic stenosis undergoing TAVR: an analysis from the PARTNER 2 trial and registries

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Left ventricular pressure overload is associated with activation of the cardiac renin-angiotensin system, which may contribute to myocardial fibrosis and worse clinical outcomes. We sought to assess the association between treatment with angiotensin-converting enzyme inhibitors (ACEIs) or angiotensin II receptor blockers (ARBs) at baseline and clinical outcomes in patients with symptomatic, severe aortic stenosis (AS) undergoing transcatheter aortic valve replacement (TAVR) in the PARTNER 2 trial and registries.

METHODS AND RESULTS

A total of 3979 intermediate, high, or prohibitive risk patients who underwent TAVR in the PARTNER 2 trial and registries were included in the study. Clinical outcomes from discharge to 2 years were compared according to baseline ACEI/ARB treatment status using Kaplan Meier event rates and study-stratified multivariable Cox proportional hazards regression models. Sensitivity analyses were conducted using propensity score matching and instrumental variable analysis. Of 3979 patients who were included in the current analysis, 1736 (43.6%) were treated and 2243 (56.4%) were not treated with ACEI/ARB at baseline. Treatment with ACEI/ARB was associated with lower 2-year all-cause mortality (18.6% vs 27.5%, p<0.0001), cardiovascular mortality (12.3% vs 17.9%, p<0.0001), and non-cardiovascular mortality (7.2% vs 11.7%, p<0.0001). ACEI/ARB treatment at baseline remained independently associated with a lower hazard of 2-year all-cause and cardiovascular mortality after multivariable adjustment, propensity score matching and instrumental variable analysis.

CONCLUSIONS

In a large cohort of patients with severe symptomatic AS from the PARTNER 2 trial and registries, ACEI/ARB treatment at baseline was independently associated with a lower risk of 2-year all-cause and cardiovascular mortality.

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Intracoronary tirofiban delivered by controlled flow infusion: marked reduction of microvascular obstruction in a porcine STEMI model

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Microvascular obstruction (MVO) is a major problem in acute coronary syndromes, and impacts both short- and long-term prognosis. No clinical pharmacology-based trials to date show efficacy against MVO. This study thus evaluated a multi-modal therapy to MVO using a combined pharmacologic and fluid-dynamic strategy. This MVO therapy was designed to 1) disaggregate platelet thrombi and 2) reverse microvascular collapse due low perfusion pressure. The approach thus targeted both mechanical and biochemical microvascular congestion.

METHODS AND RESULTS

Methods

Controlled flow infusion (CoFITM) was employed using tirofiban, a GP IIb/IIIa inhibitor precisely infused by digital pump. The CoFITM system utilizes proximal an epicardial coronary balloon occlusion and distal controlled flow infusion to generate therapeutic pressures to open collapsed dysfunctional micro vessels.

12 domestic pigs underwent STEMI by 90-minute LAD balloon occlusion, followed by reperfusion. CoFITM infusion used either tirofiban (n=5) or no infusion (n=7). Tirofiban 25µg/kg was infused within 3 sequences (30 ml/min). Cardiac MRI (CMR) post reperfusion (6 hrs) was performed to evaluate MVO presence and extent.

Results

CMR in untreated pigs showed MVO (% LV Mass) of 2.3 ± 1.1%, while tirofiban-infused pigs had 0.15 ± 0.3% ($p < 0.01$). Microvascular resistances measured at 30 ml/min after reperfusion, were 1.30 ± 0.16 mWU vs. 0.97 ± 0.11 mWU ($p < 0.01$) in the treated animals.

CONCLUSIONS

MVO is a critical, multifaceted problem, with uniformly poor therapeutic response displayed across many pharmacologic trials. The combination of a targeted, local platelet disaggregating agent delivered using restorative hemodynamic infusion (CoFI) shows promising preclinical results and simultaneously provides diagnostic physiologic data. Further preclinical studies are warranted by these early data.

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Short- and long-term clinical impact of urgent TAVR: a propensity-score matched single-centre study

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

High risk severe aortic stenosis patients can present to the emergency department because of acute decompensated heart failure (ADHF). When resistant to medical therapy, it mandates an urgent intervention. Urgent TAVR may be a safe and efficacious approach, but data regarding long-term follow up is missing. Our aims were to report our experience with urgent TAVR and to assess the short and long-term clinical impact of urgent TAVR in a propensity-matched population.

METHODS AND RESULTS

Retrospective study of 338 severe aortic stenosis patients submitted to TAVR between 08/2007-10/2016. Urgent TAVR group was defined by: ADHF secondary to severe aortic stenosis, resistant to medical therapy, with TAVR performed in the same hospital stay. Propensity score matching analysis (2:1 ratio) was performed to adjust for the following baseline variables: gender, EuroSCORE II, LVEF, NYHA class, coronary artery disease, carotid disease, anemia, atrial fibrillation and type of transcatheter aortic valve. 338 patients were enrolled (age 79.1±7.7 years; 51.5% females; mean EuroSCORE II 6.2±5.7%). In the majority of patients of both groups the procedure was performed by femoral access (88%). The following devices were used: self-expandable prosthesis 60% (n=203) and balloon expandable prosthesis 40% (n=135). The propensity matching analysis identified 146 matched pairs (56 urgent TAVR patients and 90 elective TAVR patients). All patients from both groups sucessfully received a TAVR device. The operators performed less predilatation in the urgent group (42.9 vs 61.9%, p=0.02), with a statistical tendency for more repositioning (5.4 vs 0%, p=0.05), without differences in post-dilatation (21.4 vs 16.9%, p=0.51). The acute device success (urgent 80.4 vs elective 76.7%, p=0.683), and safety (76.8 vs 83.3%, p=0.38) were similar. There was similar procedural mortality (1.8 vs 2.2%, p=0.85). No significant differences were found in post procedural PVL (>mild: 12 vs 10.5%, p=0.33) or in mean gradients (12.3 vs 13.1mmHg, p=0.52). There were more major vascular complications in the urgent group (16.4 vs 6.7%, p=0.02); no differences in acute kidney injury (22.6 vs 22%, p=0.92), major bleeding (11.8 vs 12.5%, p=63), cardiogenic shock (7.3 vs 6.7%, p=0.889) or stroke/transient ischemic attack (8.9 vs 7.9%, p=0.82). The urgent TAVI group had significantly longer hospital stays (16 vs 9 days, p<0.01). 30 day all-cause mortality rates were similar (7.1 vs 5.7%, p=0.72), as was cardiovascular mortality and major adverse cardiovascular events. In a median follow up period of 428 (IQR 210-910) days, overall 36.3% reached the endpoint all-cause mortality and no differences were found between the urgent and the elective matched-TAVR group (log-rank test p=0.616).

CONCLUSIONS

Urgent TAVR procedures were safe and effective in unstable severe aortic stenosis patients. Despite increased major vascular complications and hospitalization time, appropriately selected urgent TAVR patients had similar short and above one year safety profiles.

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A novel shock grade is associated with long-term survival and mode of death after out-of-hospital cardiac arrest

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Cardiogenic shock is common after Out of Hospital Cardiac Arrest (OOHCA) with several potential causes early in the clinical course. The severity of shock influences early clinical decision-making. We developed a novel shock grade based on a practical combination of haemodynamic data and ionotrope requirement and evaluated the relationship of this grade with clinical outcome.

METHODS AND RESULTS

A novel shock grade on patient arrival at the cardiac arrest centre was developed. Grade A: systolic blood pressure >90mmHg and no requirement for ionotropes; Grade B: Requirement for bolus of ionotropes to maintain above 90mmHg; Grade C: Requirement for ionotrope infusions to maintain systolic blood pressure above 90mmHg; Grade D: inability to maintain above 90mmHg despite the use of one ionotrope infusion. The primary end- point was survival at follow- up (Cerebral performance category 1- 2). Secondary end- points were cause of death - classified as neurological, multi-organ dysfunction syndrome or cardiogenic. Patients with incomplete data were excluded from the analysis (2 patients).

619 patients with OOHCA were admitted at our centre between 1st May 2012 and 31st December 2017. 221 were excluded for having a non- cardiac aetiology. 397 patients (median age 64.2 (IQR 21.3, 25.8% females) were included in the final analysis. 71.3% had ventricular fibrillation, 78.9% were witnessed and 77.4% occurred at residence. Mean Follow-up was 293 days (+-468).

148 (37.3%) were in Grade A, 120 (30.2%) in Grade B, 92 (23.2%) in Grade C and 35 (9.3%) in Grade D on admission.

There was a step-wise difference between the Shock Grades in mortality at discharge (Grade A 37.8%; Grade B 48.3%; Grade C 59.8% and Grade D 85.7% $p<0.001$), long-term mortality (Grade A 37.8%; Grade B 50.0%; Grade C 62.0% and Grade D 85.7% $p<0.001$) and survival with good neurological recovery (Grade A 55.5%; Grade B 42.0%; Grade C 30.4% and Grade D 14.3% $p<0.001$).

While the rates of mortality were lower Group A and rose step-wise across the shock grades to Grade D, the modes of death were significantly different between the different Grades. In those that died, neurological death was most common mode of death in Grade A (Grade A 75.0%; Grade B 64.0%; Grade C 50% and Grade D 16.7% $p<0.001$). Multi-organ dysfunction was most common in Grades C and D (Grade A 8.3%; Grade B 0%; Grade C 0% and Grade D 4.2% $p<0.001$). Cardiogenic death was most common in Group D (Grade A 2.1%; Grade B 10.2%; Grade C 10.7% and Grade D 50.0% $p<0.001$).

CONCLUSIONS

A novel, simple and practical shock grade which can be applied on admission to patients with primary cardiac aetiology OOHCA is associated with long-term survival and mode of death. This shock grade has the potential to be used to prognosticate patients and to guide targeted therapies on arrival to a cardiac arrest centre.

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Immediate and mid-term follow-up of patients with unprotected left main PCI - Single-centre experience

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease

AIMS

Contemporary clinical trials, registries and meta analyses have established PCI of left main (LM) as a safe alternative to CABG in patients with low and intermediate complexity. We analyzed immediate and mid-term results after unprotected LM (ULM) PCIs in our center.

METHODS AND RESULTS

For the period March 2013 – October 2018 we performed 225 PCIs of patients (pts) with LM disease. Of them 170 patients with PCI of ULM stenosis, 13,3% (30/225) were patients with previous CABG (protected LM PCI), 11% (25/210) were STEMI pts.We analyze the major adverse cardio-vascular events (MACE) rate and time-to-first MACE of 170 pts with ULM stenosis. They were divided into 2 groups, according to their Syntax Score (SS), low - < 32 and high SS > 32. 103 pts had low SS and 67pts had high SS.MACE is defined as mortality, stroke and ischemia driven TLR at discharge, on the 1st -, 6th - and 12th – month and yearly after.The pts mean age was 67,25 ± 11,03. 67,6 % (115/170) of them were males with no difference in demographic data between 2 groups. No difference in clinical data except: history of previous MI, LVEF and EuroSCORE. There are more significant differences in angiographic and procedural characteristics. Average follow up was 26,6±19,1 months (30,9±19,7 for low SS group and 19,9±16,3 for high SS group). MACE rate for the whole amount of pts was 12,4% (21/170) with no significance between groups (low SS - 15,5% (16/103) vs high SS-7,5% (5/67)(p=0,118)). All cause mortality was 8,2% (14/170) (11,7% (12/103 vs 3% (2/67)(p=0,045)) with a trend to be higher in pts with low SS. There was no significance in TLR (respectively 4,9% (5/103) vs 6%(4/67)p=0,740,). Only 1 pt (0,6%) from low SS group had stroke during FU. Average time-to-first MACE was 60,04 mo vs 58,60 mo (95%CI:55,89 - 64,17) and was also no statistically different (LogRank test ,p=0,205).

CONCLUSIONS

LM PCI has high procedural success rate and good mid-term results, even in pts with complex anatomy. For ULMD patients, high anatomical complexity as defined by a SYNTAX score > 32 is not predictive for poor clinical outcome after PCI.

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Factors associated with high cumulative cardiovascular sequential organ failure assessment scores in the first 72 hours after out-of-hospital cardiac arrest

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Cardiogenic shock and Systemic Ischaemic Reperfusion Syndrome are common after Out of Hospital Cardiac Arrest (OOHCA). Prediction of the development of these syndromes could guide provision of acute treatments, including PCI or use of mechanical LV support devices. We evaluated the factors associated with adverse haemodynamics and raised ionotrope requirements after OOHCA.

METHODS AND RESULTS

The Cardiovascular Sequential Organ Failure Assessment score (SOFA) incorporates the mean arterial pressure and highest ionotorope requirement in a 24 hour period. This was calculated for the first 72 hours after OOHCA and the sum was calculated in order to obtain the Cumulative SOFA (C-SOFA) score. C-SOFA scores ranged from 0 – 32 with a median of 5.0 (IQR 1 – 11). Patients with a C-SOFA score greater than 11 were classified as high shock grade.

619 patients with OOHCA were admitted at our centre between 1st May 2012 and 31st December 2017. 222 were excluded for having a non- cardiac aetiology. 397 patients (median age 64.2 (IQR 21.3, 25.8% females) were included in the final analysis. 71.3% had ventricular fibrillation, 78.9% were witnessed and 77.4% occurred at residence. Mean follow-up was 293 days (+-468). Patients with incomplete data were excluded from the analysis.

89/397 patients (22%) were classified as a High C-SOFA Shock Grade. Patients with a high shock grade had higher adrenaline dose (2 vs. 1 p<0.001), lower systolic blood pressure on arrival (110mmHg vs. 113mmHg) and lower left ventricular ejection fraction (40% vs. 45% p=0.0061). Patients with a high C-SOFA shock grade had a trend to higher in- hospital mortality (46.1% vs. 35.2% p=0.076), driven by a higher rate of cardiogenic death (6.7% vs. 0.0% p=0.002).

In a multi-variate regression model, British Cardiovascular Interventional Society Myocardial Jeopardy score (1.28 (CI 1.08 – 1.53 p=0.05) and two cardiac arrests sustained before arrival (2.09 (CI 1.02 – 4.30 p=0.045) were significant predictors of a high C-SOFA shock grade.

CONCLUSIONS

British Cardiovascular Interventional Society Myocardial Jeopardy score and two arrests before arrival to the cardiac arrest centre are associated with a high C-SOFA shock grade after OOHCA, which in turn is associated with in- hospital cardiogenic death. These features may be considered for used on arrival to the cardiac arrest centre to guide provision of mechanical LV support devices.

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Ticagrelor monotherapy in patients undergoing PCI for stable coronary artery disease in the GLOBAL LEADERS study. Impact of COPD

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THEME: Coronary Interventions
TOPIC(S): NSTEMI, Stable CAD

AIMS

Data on long-term safety and efficacy of ticagrelor in patients with stable coronary artery disease (CAD) and chronic obstructive pulmonary disease (COPD) who undergo percutaneous coronary intervention (PCI) are limited. The study aimed to evaluate the impact of COPD and dyspnea as a drug adverse effect on clinical outcomes in stable CAD patients treated with ticagrelor monotherapy after PCI.

METHODS AND RESULTS

This is a post-hoc analysis of the safety and efficacy of ticagrelor among patients with stable CAD enrolled in the randomized multicentre open-label Global Leaders study (n=15991), comparing the experimental strategy of ticagrelor monotherapy following one-month dual antiplatelet therapy (DAPT) with the reference strategy of 12-month aspirin and clopidogrel DAPT. The impact of COPD and occurrence of dyspnea reported as an adverse event on clinical outcome was evaluated up to 2 years of follow-up. The primary endpoint was a composite of 2-year all-cause mortality or nonfatal, centrally adjudicated, new Q-wave myocardial infarction. Patient-oriented composite endpoint (POCE: all-cause mortality, any stroke, MI or revascularization) and net adverse clinical events (NACE: POCE and bleeding type 3 or 5 according to the Bleeding Academic Research Consortium [BARC]) were reported at two year after PCI.

In 8481 patients with stable CAD, the experimental as compared to the reference treatment was associated with a similar rate of primary endpoint [3.7% vs. 4.2%, rate ratio 0.87; 95% confidence interval (CI) 0.70-1.09; p=0.218] and safety endpoint BARC type 3 or 5 bleeding (2.1% vs. 1.6%, hazard ratio (HR) 1.32; 95%CI 0.96-1.80; p=0.086).

Among patients with COPD, the primary endpoint had occurred in 11.3% of patients in the ticagrelor group and in 8.8% of patients in the clopidogrel and aspirin group (rate ratio 1.32; 95% CI 0.72-2.41; p = 0.373) at 2 years.

Patients with COPD treated with ticagrelor had a comparable rates of all-cause death (9.60% vs. 8.0%; rate ratio, 1.21; 95%CI 0.65-2.24, p = 0.538), POCE (18.7% vs. 18.5%; rate ratio, 1.04; 95%CI 0.68-1.59, p = 0.850), and NACE (21.3% vs. 21.1%; rate ratio, 1.01; 95%CI 0.64-1.58, p = 0.970), when compared to patients treated with clopidogrel and aspirin

In the COPD patient subset, a non-significantly different rate of bleeding BARC type 3/5 bleeding was found in both treatment groups (2.70% vs. 4.30%; rate ratio, 0.62; 95% CI 0.22-1.73, p = 0.358).

Dyspnea was reported in 17.8% and 6.6% of patients in the experimental and reference groups (p=0.001),

respectively, with a higher frequency among patients with COPD in both groups (27.4% on ticagrelor vs. 10.1% on clopidogrel and aspirin, rate ratio, 3.05; 95%CI 1.91-4.89; p = 0.001). Among patients experiencing dyspnea the rates of primary endpoint (3.2% vs. 3.8%; rate ratio 0.83, 95%CI 0.53-1.28; p=0.394) or other outcome variables in ticagrelor-treated patients with stable CAD were not significantly higher, as compared with patients without dyspnea.

CONCLUSIONS

Among patients with stable CAD, including those with COPD, ticagrelor monotherapy (after one month of ticagrelor and aspirin) was safe and comparable with 12-month clopidogrel and aspirin DAPT. Although dyspnea was more frequent particularly among COPD patients treated with ticagrelor, the efficacy or safety was not affected among patients with stable CAD.

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Percutaneous LAA occlusion in patients with and without chronic kidney disease: immediate and one-year results

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THEME:
TOPIC(S):

AIMS

There is scarce evidence on best stroke prevention in atrial fibrillation patients with chronic kidney disease due to increased bleeding complications both with vitamin K antagonists and non-vitamin k-antagonist oral anticoagulants. Percutaneous left atrial appendage (LAA) closure is associated with a reduction in thromboembolic risk in patients with atrial fibrillation. The aim of this study was to analyze the immediate and one year results after LAA closure in patients with non-valvular atrial fibrillation with and without chronic kidney disease.

METHODS AND RESULTS

50 patients (35 chronic kidney disease vs. 15 non-chronic kidney disease) who underwent LAA closure were prospectively included in this single center registry. Follow up at 1-6 months and at 1 year with serum creatinine (mg/dl), hemoglobin (mg/dl) and estimated glomerular filtration rate (ml/kg/1.73m2) values were recorded. TEE was performed for screening (70%), intraprocedure (89%) and at 1-month (100%). Intracardiac echocardiography was performed in 6% of patients. 80% were discharged with one antiplatelet therapy during 30 days. Follow up was available in 100% of patients.

Mean age was 75.9 ± 9.0 (female 42%). Chronic kidney disease patients had a higher prevalence of hypertension, diabetes, heart failure, coronary artery disease, and labile INR. The prevalence of previous stroke was higher in no-chronic kidney disease group. Previous major bleeding was similar. CHA2DS2-VASc and HAS-BLED were similar (4.7 ± 1.6 in chronic kidney disease vs. 4.8 ± 1.8, and 4.1 ± 0.9 vs. 4.0 ± 1.2, p ns for both comparisons). 10 patients were on dialysis and 2 patients had a previous renal transplantation. The device size was similar in both groups 26.7 ± 2.7 in chronic kidney disease vs. 25.1 ± 3.6 (p=0.09). 69.4% of patients received a Lambre™ device that was successful in 98% of cases. Procedural complications resulted in 1 patient presented cardiac tamponade, 2 major bleeding (requiring transfusion) and 1 death related to the procedure. No other periprocedural complications (vascular surgery or stroke) were reported. Acute Kidney injury at 24-48 hours was observed in 5 patients (10%, chronic kidney disease group) but renal recovery based to baseline estimated glomerular filtration rate was observed in all these patients at follow-up. Average length of stay was 2 days (no differences between groups). The events during follow-up (373 ± 283 days in chronic kidney disease vs. 509 ± 297, p=0.12) were: 3 non-cardiac deaths; 1 ischemic stroke (chronic kidney disease group); 1 severe bleeding (non-chronic kidney disease group); no other events were recorded. At one year follow-up there was an increase in hemoglobin and estimated glomerular filtration rate compared to baseline in chronic kidney disease patients (12.5 ± 2.1 vs. 11.6 ± 1.7, p = 0.05, and 27.7 ± 17.2 vs. 33.2 ± 29.9, p = 0.04, respectively). These results were not observed in non-chronic kidney disease group.

CONCLUSIONS

Percutaneous LAA closure results a plausible treatment for patients with atrial fibrillation and need for stroke

prevention. Patients with chronic kidney disease is a heterogeneous population, characterized by both an increased risk of bleeding and a hypercoagulability state. We observed improvement of hemoglobin and estimated glomerular filtration rate in one year follow-up in pacients with chronic kidney disease and atrial fibrillation after percutaneous LAA closure.

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Early outcomes after percutaneous closure of access site in transfemoral TAVI using the novel vascular closure device plug-based MANTA

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

A new collagen-based MANTA TM vascular closure device (VCD), was developed for closing large-bore arteriotomies after transfemoral transcatheter aortic valve replacement (TAVI).

We evaluated safety and feasibility in terms of vascular complications, bleedings and 30 days outcomes of the collagen-based VCD, MANTA TM VCD compared with the suture-based VCD, Prostar®XL in a cohort of patients undergoing transfemoral TAVI.

METHODS AND RESULTS

A retrospective comparative study of consecutive patients who underwent transfemoral TAVI and percutaneous closure in a tertiary hospital between January 2015-April 2018. A total of 366 patients were included. MANTA TM VCD was used in 168 patients and Prostar®XL VCD in 198 patients.

Vascular access site closure with the MANTA TM VCD was successful in 98.8% and in 98.5% with the Prostar®XL in the treated patients.

VARC-2 defined major vascular complication and major bleeding was similar in both cohorts (MANTA TM vs Prostar®XL): 0.6% vs 1.0% (P=0.661) and 0.6% vs 1.5% (P=0.102) respectively. Minor vascular complications and minor bleeding, however, were significantly more frequent (10.7 vs 18.8 %, P=0.003), and (13.7 vs 19.7%, P=0.080) respectively) in the Prostar®XLcohort. Thirty-days all-cause mortality was 2.7%, without significant difference between the groups.

CONCLUSIONS

The MANTA TM device is a safe and feasible option for vascular access closure in patients undergoing transfemoral TAVI.

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Revascularisation strategies in patients presenting with STEMI and multivessel disease

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THEME: Coronary Interventions
TOPIC(S): STEMI, Left main and multivessel disease

AIMS

The optimal revascularization strategy to manage residual coronary stenosis following primary PCI in patients with STEMI and multivessel disease remains controversial. We aimed to compare clinical outcomes between patients undergoing primary PCI of the culprit artery only or received multivessel revascularization (MVR), either acutely or staged.

METHODS AND RESULTS

This is a retrospective single-center study evaluating patients with STEMI and multivessel disease presenting from January 2010 to March 2017. Patients with cardiogenic shock, chronic total occlusions or out-hospital cardiac arrest were excluded. Based on the revascularization strategy, three groups were identified: culprit only (CO), ad-hoc multivessel revascularization, staged revascularization of the non-culprit vessels. The primary outcome was patient-oriented composite endpoint (POCE), a composite of overall death, myocardial infarction and repeat revascularization at 3 years.

A total of 958 patients were evaluated (488 in CO group, 254 in de ad-hoc group an 216 in staged group). Median follow-up was 1110 days (IQR 226 - 2144). In the staged group, 65.3% received a planned PCI and 9.6% planned CABG; the planned treatment of the remaining lesions was aborted due to re-assessment of the lesions with FFR or intracoronary imaging (8.8%) or an earlier event that led to sooner revascularization (16.2%). At 3 years follow-up, the cumulative incidence of the POCE was 41.6%, 34.5% and 19.7% for CO, staged and ad-hoc groups respectively (P<0.001). The ad-Hoc group had a significantly lower risk of POCE as compared to CO group [HR 0.60 (0.41-0.88) p 0.010] and as compared to staged group [HR 0.43 (0.26-0.70) p 0.001] mainly driven by a lower risk of repeat revascularization. There was no difference in POCE at 3 years between the staged and CO groups [HR 1.10 (0.76-1.60) p 0.586].

CONCLUSIONS

Ad-hoc multivessel revascularization in patients presenting with STEMI and MVD was associated with a lower risk of adverse cardiac events at long-term follow-up as compared to culprit only revascularization or staged revascularization of the non-culprit vessels.

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Two-year clinical outcomes after implantation of an everolimus-eluting BRS in stable angina and ACS patients. Single-centre real-life registry data for N=354 patients

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Stents and scaffolds

AIMS

The aim of this long-term registry data was to evaluate two-year clinical and angiographic outcomes after implantation of everolimus-eluting bioresorbable scaffolds.

METHODS AND RESULTS

All patients (n=354) had PCI following bioresorbable scaffold implantation. First analysed hospital outcomes as hospital death, hospital myocardial infarction and hospital scaffold thrombosis. At two years, clinical parameters and outcomes were analysed; all-cause death, cardiovascular death, myocardial infarction, target lesion revascularization, target vessel revascularization, scaffold thrombosis, cerebral infarction, repeat PCI.

Clinical follow-up at two years reached 98.0%. Male population was 46.9% and female 53.1%. Mean patient age 57.5 ± 11.4 years. Hypertension was in 84.2%, dyslipidaemia in 79.1% and diabetes in 16.4% of patients. Previous myocardial infarction was in 31.6% of patients, previous PCI 44.4 %. Stable angina were in 78.8%, NSTEMI 5.1% and STEMI 7.9% and unstable angina in 8.5% of patients. Multi-vessel disease by coronary angiography was diagnosed in 67.5% of patients.

Left anterior descending artery was stented in 50.8% of cases, right coronary artery in 30.5% of cases and left circumflex in 11.9% of cases. Mostly stented area was located in middle part of artery - 63%, proximal part was stented in 58.8 % of cases. Elective PCI was done in 84,5% of cases. Radial approach used in 77,4%. IVUS guidance use in 13% of cases.

Lesion pre-dilatation was done in 94%. Mean scaffold length was 20,7 ± 7,8 mm. Mean scaffold diameter used 3,2 ± 0.4 mm, Mean post-dilatation balloon diameter was 3,5 ± 0.4 mm. Post-dilatation was done in 93% of cases.

In-hospital death occurred in 0,6% (n=2) patients, one patient had in-hospital myocardial infarction - 0.3%. At two years, the rate of all-cause death was 3.1 % (n=11), cardiovascular death in 1,4% (n=5), myocardial infarction 2,5% (n=9), target lesion revascularization 2,8 % (n=10), TVR 7,1% (n=25). Repeated PCI was done in 26,6 % (n=94) but mainly due to staged second PCI. Cerebral infarction occurred in 1,7% (n=6). Between hospital discharge and two-year follow up scaffold thrombosis occurred in 1.1% (n=4). In-hospital scaffold thrombosis occurred in 0.3% (n=1) due to clopidogrel resistance.

CONCLUSIONS

Everolimus-eluting bioresorbable scaffolds showed acceptable efficacy (target lesion revascularization) and safety (cardiac death, myocardial infarction, and scaffold thrombosis) results at mid-term follow-up in stable angina and acute coronary syndrome patients.

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BRS in coronary CTO. Clinical, vasomotor and OCT findings at three-year follow-up (ABSORB-CTO study)

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds, CTO

AIMS

Percutaneous treatment of coronary chronic total occlusion (CTO) is associated with important arterial remodeling after successful recanalization. Bioresorbable vascular scaffold (BVS) implantation in CTO has been shown feasible and can be of interest when the scaffold achieves complete bioresorption. We sought to evaluate the 3-year results in terms of clinical events, serial imaging outcomes and the vasomotion response in CTO lesions successfully treated with BVS.

METHODS AND RESULTS

A total of 33 patients (35 CTO lesions) successfully treated with BVS were included in ABSORB-CTO study. Clinical outcomes, quantitative coronary angiography (QCA) and optical coherence tomography (OCT) assessment were the vasomotion at 1-and 3-year follow-up. Vasomotion examination was also performed at 3 years.

At 3-year, cumulative target vessel re-occlusion was observed in 4 lesions(11.4%). By QCA, in-scaffold segment presented a lumen loss of 0.23±0.46 mm compared with baseline procedure (p=0.001) and a lumen gain of 0.05±0.29 mm between 1 and 3 years (p=0.220).

By OCT the mean neointimal area stenosis progressed from 11.45% at 12 months to 17.10% at 36 months (p<0.001)and mean scaffold area increased continuously at 12 (+12%;p<0.001) and at 36 months (+14.85%;p=0.001).Late acquired incomplete scaffold apposition (LAISA) observed at 12 months in 3 patients was completely undetectable at 3 years. Most of the cases responded to endothelial-dependent vasomotor stimuli (69%). Vasoconstriction to acetylcholine was the predominant response (45%).

CONCLUSIONS

Successful recanalization of coronary-CTO with BVS implantation is associated with favorable clinical and imaging outcomes.Despite vessel motility restoration, successfully treated CTO remain with signs of endothelial dysfunction

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Outcomes after double valve implantation during TAVI

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Implantation of two valves in the same patient in the setting of TAVI is a rare event. This may be a pre-planned off-label strategy or a bail-out option due to unexpected complications related to the placement of the first prosthesis. Clinical and echocardiographic outcomes in this setting are limited to few single case reports. The aim of this study is to analyse the short, mid and long-term outcome of a single-centre series of patients treated with two valves.

METHODS AND RESULTS

Between July 2011 and May 2018, patients scheduled for TAVI that received 2 valves (either planned or as bail-out strategy) to treat severe aortic stenosis (AS) or severe pure aortic regurgitation (AR) were followed prospectively. Self-expandable and balloon-expandable valves were used. Thirty-day and 1-year echocardiographic and clinical data were collected according to VARC-2 criteria.
Eight patients out of a total of 553 procedures required a second valve. The mean age was 78±8 years, mean Log-EuroSCORE was 32±8%. TAVI was performed to treat severe pure AR in 6 patients and severe AS in 2. In 2 cases the second valve was planned before-hand. Among the 6 patients with AR, 3 were VAD-carriers, for 2 of them the double valve strategy (like a valve-in-valve procedure) was planned because of the too large size of the aortic annulus compared to the largest size of the available valves, in order to minimize the residual perivalvular regurgitation (PVR). In the other case the second valve was implanted after the embolization of the first one in the ascending aorta. The 3 patients without VAD required a second unplanned valve because of severe residual PVR after the implantation of the first valve in 2 cases (valve-in-valve) or the embolization of the first valve in the ascending aorta in the last case. Both patients with AS required a double valve as consequence of procedure-related complications: an embolization of a balloon-expandable valve implanted in the abdominal aorta, and a severe leak, due to a leaflet malfunction that required a second bail-out valve.
At 30-day 2 patients (25%) died because of irreversible heart failure, one was VAD carrier. Two patients needed a single haemodialysis treatment to treat AKI, and 3 required pace maker implantation; no other clinical complications occurred. The 6 survivors were discharged in NYHA class I-II with echocardiographic evidence of a well-functioning prosthesis:mean gradient (MG) 9,3±2,4 mmHg and a mean left ventricular ejection fraction (LVEF) improved to 44±8,5%. At 1-year the 6 patients were alive, presenting stable functional class (NYHA I-II) and no clinical recurrences. Of note, the two remaining VAD-patients underwent successfully heart transplantation. Echocardiography at 1-year follow-up confirmed stable MG of 7±1 mmHg, no or mild PVR, and a further increment of the LVEF (61±6%). Longer follow up are available at 5, 6 and 7 years, with unchanged hemodynamic performance of the valves as assessed by echography.

CONCLUSIONS

In this small series, the implantation of a second valves to treat severe pure AR, severe residual PVR or first valve embolization does not seem to impact the hemodynamic efficacy of TAVI at long term, showing results comparable to larger cohorts. Until larger studies become available, this option may be life-saving in very

critical cases.

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Influence of ultrathin non-polymeric stent design on non-apposed strut coverage evaluated with OCT

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

To compare the strut coverage of non-apposed struts between an ultrathin non-polymeric sirolimus eluting stent and a thin biorresorbable polymeric sirolimus eluting stent.

METHODS AND RESULTS

In the FRIENDLY-OCT trial 70 patients were included to compare the early (3 months) strut coverage between 2 sirolimus eluting stents, the Coroflex ISAR (ultra-thin strut, with non polymeric drug elutin technology based on probucol) and the Terumo Ultimaster (thin strut, resorbable PLLA polymer), with OCT.

The trial population was a cohort of patients with 2 angiographically similar lesions, treated with PCI. We applied an intrapatient randomization scheme: the first lesion to be treated was randomized and assigned to be treated with one of the study stents; then the second lesion would be treated with the other device. Struts were considered covered if a tissue layer ≥20μm thick was observed above them, based on the axial resolution of the OCT technology. Otherwise we defined them uncovered if no tissue at all (0 μm) was observed, as many previous trials have reported. OCT and statistical analysis were blinded.

59 patients completed the trial protocol. The results showed a significant (p 0.00) benefit for of the ultrathin, probucol based, non-polymeric stent, with an absolute 8.2% higher proportion of (≥20μm) covered struts (87.3% vs 79.1%) and a 2.2% absolute lower proportion of uncovered (0μm) struts (96.9% vs 94.7%).

For this abstract we have evaluated the coverage of the non-apposed struts. A total of 668 struts fulfilled the non-apposition criteria (2.51% of the stent struts); 222 bifurcation struts and 446 malapposed struts (1.7%). As expected, the strut coverage of the non-apposed struts was significantly lower (34.5% vs 82.99% , p 0.00), and uncoverage was significantly higher (34.1% vs 4.3%, p 0.00).

With regards to the stent type, the 349 Terumo stent struts showed a 32.9% uncoverage rate, compared to the 35.4% of the 319 Coroflex ISAR struts (p .48). More the ≥20μm strut coverage was almost significantly higher for the Coroflex ISAR stent (37.9% vs 31.4%, p .07). As we observed that it seemed that the thicker the layer width, the more pronounced the difference between the stents, we explored what happened at the 30 μm cut-off point. We found a statistically significant (p 0.006) higher proportion of coverage (21.6%. vs 13.5) with the Coroflex ISAR stent.

Finally, we also explored whether there was or not any difference between the bifurcation struts or the malapposed struts. We observed that the strut coverage proportion was significantly higher in the bifurcation struts compared to the malapposed struts (41 vs 31.3%, p 0.01). When we analysed the coverage proportion of each stent type separatedly for both bifurcation and malapposed struts, we observed a non-significant association to a better strut coverage with the Coroflex ISAR (44.4% vs 38.6% in bifurcations, p 0.35; 35.7 vs 26.7% in malapposed struts, p 0.2).

CONCLUSIONS

The non-apposed struts show a lower coverage rate than apposed struts, that is more pronounced for malapposed struts compared to those hunging in bifurcations. The results show a higher strut coverage with the non-polymeric ultra-thin strut compared to the polymeric thin strut stent, similar and in parallel to what was observed in the whole cohort of the FRIENDLY-OCT trial. Statistical significance was not achieved, due to the lack of power, but the trend is in our opinion highly robust.

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Computer-assisted interpretation of FFR pullback curves for guiding coronary revascularisation

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Fractional flow reserve (FFR) pullback measures the distribution of pressure drop generated by coronary artery disease along the vessel and provides more relevant hemodynamic information that a one point distal measure. Interpretation of pullback curves is operator-dependent and poorly reproducible. Therefore, we aimed to investigate the diagnostic performance of a computer-based algorithm to detect significant pressure drop and guide myocardial revascularization, compared to the effective treatment strategy.

METHODS AND RESULTS

Pullback FFR curves were recorded under continuous intra-venous adenosine infusion at 140 µg/kg/min in patients with intermediate coronary stenosis and included into a single center registry. Pullback of FFR wire (PressureWire X, St Jude Medical, Mineapolis, United States) was performed by using a motorized device working at a speed of 1 mm/s (Volcano R 100, San Diego California, United States). Then, an off-line analysis of the curves was performed by an in-house developed algorithm (JD, Mathematica v.11.3.0). Briefly, the derivative function of the smoothed FFR signal were applied to first, discriminate a stepwise from a slow progressive decrease of FFR, and secondly, to propose a stent length able to correct a significant stepwise decrease of FFR signal. A concordance analysis between effective and computer based revascularization was performed. Only curves with distal FFR ≤ 0.85 were included into the analysis.

53 vessels from 47 patients (75% LAD, 10% Cx, 15% RCA) with a distal FFR of 0.78±0.08 were assessed. A revascularization was performed in 30 vessels (24 PCI, 6 CABG). Compared to the effective treatment, a similar proportion of vessels were referred for revascularization by computer-based algorithm (66 vs. 56% respectively, Chi2 0.63, p NS). Agreement between operator and computer-based approaches, regarding the need of a revascularization, was observed in 79% of cases. Observed Cohen's Kappa coefficient was 0.6 (CI 95%: 0.33-0.8). When a mismatch between operator and computer guided strategy was observed, the distal FFR was significantly higher compared to the group without mismatch (0.81±0.04 vs. 0.77±0.09, respectively, t-test $p<0.05$). Stent length proposed by the computer approach did not differ from the cumulative stent length really used, but a trend towards a stent length underestimation was observed (24.2±15 vs. 31.3±16 mm, t-test $p= 0.09$).

CONCLUSIONS

Computer-based algorithm for interpretation of FFR pullback curves showed a moderate to good agreement with real practice revascularization. Most of observed disagreement was found in vessels with distal physiologically intermediate FFR values (0.80 to 0.85). Stent length prediction was concordant with the real practice.

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Procedural and clinical outcomes following treatment with rotational atherectomy or modified balloons prior to DES implantation in diabetic patients with severely calcified coronary lesions: a subanalysis of the PREPARE-CALC trial

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Balloon dilatation or debulking seems to be essential to allow successful stent implantation in calcified coronary lesions. We sought to investigate the impact of diabetes mellitus (DM) on lesion preparation with either rotational atherectomy (RA) or modified (scoring or cutting) balloons (MB) followed by drug-eluting stent implantation in the randomized PREPARE-CALC trial.

METHODS AND RESULTS

Patients with documented myocardial ischemia and severely calcified native coronary lesions undergoing percutaneous coronary intervention were randomly assigned to either a strategy of lesion preparation using RA or MB followed by implantation of a new-generation sirolimus-eluting stent with bioabsorbable polymer. The two primary endpoints were: strategy success, defined as successful stent delivery and expansion with attainment of <20% in-stent residual stenosis in the presence of TIMI (Thrombolysis in Myocardial Infarction) 3 flow without crossover or stent-failure, and in-stent late lumen loss at 9 months.

Overall 200 patients were enrolled (n=100 in each treatment group). Mean age of the entire study population was 74.9±7.0 years, 76% were male, and 33.5% had DM. In total, 67 patients had DM (33 treated with RA and 34 treated with MB) and 133 patients did not (67 patients treated with RA and 66 patients treated with MB). In patients with and without DM, strategy success was significantly more common with a RA-based strategy compared with a MB-based strategy (97.0% vs. 73.5%; p=0.013 and 98.5% vs. 84.9%; p=0.004). At 9 months, mean in-stent late lumen loss was similar for both lesion preparation strategies in diabetic (0.21±0.41 mm in RA group vs. 0.22±0.37 mm in MB group; p=0.91) and non-diabetic patients (0.16±0.32 mm vs. 0.11±0.37 mm; p=0.50).

CONCLUSIONS

In patients with severely calcified lesions, lesion preparation with upfront RA before drug-eluting stent implantation is more commonly successful as a primary strategy compared with MB in patients with and without DM. In-stent late lumen loss was not significantly different between both strategies regardless of the presence or absence of DM.

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Novel methodology for imaging-based retrospective gating of NIRS-IVUS imaging data and implication of the acquisition frame rate on its estimations

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THEME:
TOPIC(S):

AIMS

Combined NIRS-IVUS imaging has been recently introduced in the clinical arena to characterize more accurately plaque composition and identify plaques that are likely to progress and cause events. The ECG signal that is needed for image gating is not incorporated in to NIRS-IVUS. NIRS-IVUS analysis is performed ignoring the longitudinal motion of the catheter during the cardiac cycle which can affect volumetric measurements. In this study we introduce a novel methodology that enables retrospective imaging based cardiac gating of NIRS-IVUS and examine its performance at different frame rates.

METHODS AND RESULTS

The proposed method looks for the image texture difference between two adjacent frames in a predefined region of interest. Based on the frame rate, the texture difference signal is analyzed to predict the base ECG signal. A frame is selected as end-diastolic when the difference between two frames is the smallest in a selected time window.

The developed methodology was incorporated in the QCM-CMS software (Leiden University Medical Centre, Leiden, The Netherlands) and used to retrospectively process NIRS-IVUS data acquired in 41 native vessels [8 right coronary (RCA), 14 left anterior descending (LAD) and 18 Left cirumflex (LCx) coronary arteries and 1 intermediate, 165,373 frames] using the combined high resolution (50MHz) MC10 imaging catheter (Infraredx Inc, Burlington, MA). Pull-back was performed at a speed of 0.5mm/s while the acquisition frame rate was 30fps. Retrospective gating was performed in the entire pull-back sequences and in artificial sequences with a frame rate of 15fps that were constructed after selecting from the original data one out of every two frames. The estimations of the developed approach were compared in the two datasets and with the estimations of an expert observer who manually identify the end-diastolic NIRS-IVUS frames.

Retrospective NIRS-IVUS gating was feasible in all the studied sequences. The mean time needed to extract the end-diastolic frames was only 2.3±1.0s per sequence.There was a moderate agreement (65.6±18.2% of the cases) between the estimations of our approach and the expert operator in the original data. The agreement between the method and the operator for the end-diastolic frame was numerically higher in the LCx (72.2±15.5%) and RCA (64.3±13.2%) compared to the LAD (58.3±20.8%); this difference however did not reach statistical significance (P=0.121).

The overall agreement between our method and the expert was lower than the agreement between the estimations of our approach in the original data and in the sequences with a frame rate of 15fps (65.6±18.2% vs 81.7±9.9%, P<0.001). The studied vessel did not appear to affect the agreement between the estimations of our approach in the sequences with frame rate of 30fps and in those with a rate of 15fps (LAD: 83.4±6.4%, LCx: 81.6±12.1%, RCA: 78.3±10.0%; P=0.837).

CONCLUSIONS

Imaging based retrospective gating of NIRS-IVUS is feasible and can be performed within few seconds. The high agreement of our method's estimations in the original data and the pull-backs with a frame rate of 15fps indicates that the proposed approach may have a value for the retrospective processing of data acquired by catheters with a lower temporal resolution. Further validation of the developed method in NIRS-IVUS data with the ECG signal available is needed before its broad use in the clinical arena.

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Three-year clinical outcomes after implantation of an everolimus-eluting BRS in stable angina and ACS patients. Single-centre real-life registry data for N=283 patients

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THEME: Coronary Interventions
TOPIC(S): STEMI, Stents and scaffolds

AIMS

The aim of this long-term registry data was to evaluate three-year clinical and angiographic outcomes after implantation of everolimus-eluting bioresorbable scaffolds.

METHODS AND RESULTS

All patients n=283 had PCI following bioresorbable scaffold implantation. First analysed hospital outcomes as hospital death, hospital myocardial infarction and hospital scaffold thrombosis. At three years, clinical parameters and outcomes were analysed; all-cause death, cardiovascular death, myocardial infarction, target lesion revascularization, target vessel revascularization, scaffold thrombosis, cerebral infarction, repeat PCI.

Clinical follow-up at two years reached 97,5%. Male population was 48% (n=135) and female 52% (n=147). Mean patient age 57.0 ± 11.8 years. Hypertension was in 83.3% (n=235), dyslipidaemia in 78,7% (n=222) and diabetes in 16.7% (n=47) of patients. Previous myocardial infarction was in 33% (n=93) of patients, previous PCI 43.3% (n=122). Stable angina were in 76,6% (n=216), NSTEMI 5.0% (n=14) and STEMI 8,5% (n=24) and unstable angina in 9,2% (n=26) of patients. Multi-vessel disease by coronary angiography was diagnosed in 66.7% (n=188) of patients.

Left anterior descending artery was stented in 48,9% (n=138) of cases, right coronary artery in 30.1% (n=85) of cases and left circumflex in 12,9% (n=36) of cases. Mostly stented area was located in middle part of artery - 62%, proximal part was stented in 63 % of cases. Elective PCI was done in 83,7% of cases. Radial approach used in 79,1%. IVUS guidance use in 14% (n=39) of cases and optical coherent tomography was used in 11% (n=31).

Lesion pre-dilatation was done in 93%. Mean scaffold length was 20,1 ± 6,2 mm. Mean scaffold diameter used 3,2 ± 0.4 mm, Mean post-dilatation balloon diameter was 3,5 ± 0.4 mm. Post-dilatation was done in 92% of cases.

In-hospital death occurred in 0,7% (n=2) patients, one patient had in-hospital myocardial infarction - 0.3%. At two years, the rate of all-cause death was 4,6 % (n=13), cardiovascular death in 1,8% (n=5), myocardial infarction 3,9% (n=11), target lesion revascularization 3,9 % (n=11), TVR 8,5% (n=24). Repeated PCI was done in 26,2 % (n=74) but mainly due to staged second PCI. Cerebral infarction occurred in 2,1% (n=6). Between hospital discharge and two-year follow up scaffold thrombosis occurred in 0,7% (n=2). In-hospital scaffold thrombosis occurred in 0.3% (n=1) due to clopidogrel resistance.

CONCLUSIONS

Everolimus-eluting bioresorbable scaffolds showed acceptable efficacy (target lesion revascularization) and safety (cardiac death, myocardial infarction, and scaffold thrombosis) results at long-term follow-up in stable angina and acute coronary syndrome patients.

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Percutaneous mitral valve repair vs. stand-alone medical therapy in patients with functional mitral regurgitation and heart failure: a meta-analysis of mid- and long-term survival outcomes

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair

AIMS

Functional mitral regurgitation (FMR) is a common finding among patients with heart failure (HF) and it is related to adverse events. Outcomes in patients undergoing transcatheter mitral valve repair (TMVR) are still a matter of debate. We performed a meta-analysis to assess mid- and long-term outcomes of patients with FMR treated with MitraClip® compared to medical management.

METHODS AND RESULTS

We conducted an electronic database search of all published data PubMed Central, Embase, the Cochrane Central Register of Controlled Trials, ClinicalTrials.gov, and Google Scholar databases. The primary end-point was all-cause mortality. The secondary end-points were hospitalizations for HF, need for heart transplantation or left ventricular assist device, unplanned mitral valve surgery, myocardial infarction and stroke. Odds ratios (ORs), Hazzard ratios (HR), and 95%con?dence intervals (CIs) were computed. Random effects model was used and heterogeneity was considered if I2 >25.

Five studies (n= 1513 patients) were included in the analysis. The summary estimate including all the available studies showed a statistically significant reduction in all-cause mortality favoring MitraClip® (HR 0.56, CI95% [0.38-0.84]) and HF hospitalizations (HR 0.65; CI95% [0.46-0.92]). A significant reduction in the indication for advanced HF therapies (OR 0.48; CI95% [0.25-0.90]) or the need for unplanned mitral valve surgery (OR 0.20; CI95% [0.07-0.57]) was also found in the group of patients that underwent TMVR. No differences in the incidence of myocardial infarction or stroke were found between both groups of treatment. No publication bias was detected.

CONCLUSIONS

TMVR with MitraClip® system was related to a significant reduction in all-cause mortality, hospitalizations for HF and the need for HF transplant, left ventricular assist device or unplanned surgery.

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STEMI network - Where to improve? Experience of a country

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Introduction: Primary angioplasty (PA) is a cornerstone in the ST elevation myocardial infarction (STEMI) treatment. Time is myocardium and STEMI network was designed to reduce time lost and offer PA as early as possible

Purpose: To characterize STEMI network in a country and its regions and identify gaps/flaws that lead to delay in STEMI treatment

METHODS AND RESULTS

Methods: Retrospetive and multicenter study, based on a national register from 30/10/2010 to 09/19/2017. All patients with revascularized STEMI within the first 12 h of pain were included. 4 groups were established: Northern (I); Center (II); South (III); Algarve and Islands (IV). Univariate analysis was performed of the clinical history, times until PA and hospitalization data.

Results: It was obtained 4683 patients, 1401 of I (29.9%), 971 of II (20.7%), 1033 of III (22.1%) and 1278 of IV (27.3%). The mean age was 62 years and 77% were men.
Admission by STEMI network was performed in 36.2% of cases in country, 38.0% in I, 20.1% in II, 23.4% in III and 56.3% in IV. The hospital admission was directly in the catheterization laboratory (cath lab) in 41.3% in country, 48.6% in I, 30.1% in II, 12.6% in III and 64.8% in the IV.
The time symptoms (S)-1st medical contact (MC) was 145m in the country, 137m in I, 146m in II, 141m in III and 154m in IV. The time S-balloon(B) in the country was 279m, 279m in I, 320m in II, 277m III and 249m in IV. The time 1st MC-B in the country was 132m, 142m in I, 559m in II, 138M in III and 95m in IV. The time door(D)-B in the country was 98m, 103m in I, 123m in II, 119m in III and 54m in IV.
The percentage of patients admitted in Killip –Kimball class (KK)>1 was 12.2% in the country, 15.4% in I, 13.1% in II, 11.2% in III and 9.0% in IV. Left ventricular ejection fraction (LVEF) at discharge was 51% in the country, 44% in I, 51% in II ,51% in III and in 57% in IV.
The rate of in-hospital mortality (IHM) was 3.5% in the country, 2.9% in I, 5.5% in II, 3.3% in III and 3.0% in IV. The rate of MACE (composite endpoint: IHM, re-infarction, nonfatal stroke) was 4.7% in the country, 4.6% in I, 6.5% in II, 4.1% in III and 3.8% in IV.

CONCLUSIONS

This analysis of the STEMI network we can conclude the following:
- The admission by STEMI network and/or admission in LH is generally low, with Algarve and Islands being the only region with percentages > 50%.
- Time S-1st MC is greater than 2h in all regions of the country, especially in the Algarve and Islands (154 min). The times 1st MC-B and D-B are high in all regions of the country, with exception of Algarve and Islands.
- On the whole the time S-B was 279m, more higher in the Center (320m) and lowest in Algarve and Islands

(249m). This had prognosis impact with mortality and MACE rates of 5.5% and 6.5% in Center region and 3.0% 33.8% in Algarve and Islands respectively (3.5% and 4.7% in the country).

- Focus of intervention in North, Central and South should be development of local STEMI network and the development of strategies to reduce the times 1st MC-B and D-B. In turn, the focus of Algarve and Islands should be education and intervention in the population in order to reduce the time S-1st MC.
- All country and all services of Cardiology should invest and optimize all stakeholders and steps from STEMI network because time is myocardium.

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Short- and mid-term outcomes following BRS implantation: a single-centre experience

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

This study was conducted to assess short and mid-term clinical outcomes of patients who underwent percutaneous coronary intervention (PCI) with bioresorbable vascular scaffold (BRS) implantation in a single centre.

METHODS AND RESULTS

All patients treated with BRS at the centre from August 2013 to February 2016 were included in this retrospective observational study. The decision for BRS implantation was at the discretion of the operator. Clinical outcomes were assessed at 6 months, 1 year and 2 years.

Sixty seven patients were included in the study. Mean (±SD) age was 64 (±10) years, 84% were male. Mean follow up period was 29 months. 53 patients (79%) had normal LVEF whilst 6 patients (9%) had LVEF of 45% or less. 20 patients (30%) had diabetes mellitus. All except one patient had an estimated glomerular filtration rate of more than 50ml/min. Indications for the procedure were acute coronary syndrome in 12 patients (18%), stable angina in 43 patients (64%) and staged procedure in 12 patients (18%). PCI involved the left anterior descending artery in 59 patients (88%). In total, 107 BRS were used to treat 76 lesions, of which 41 lesions (54%) were type 2C, 20 lesions (26%) were type 1B and 15 lesions (20%) were type 1A. Mean (±SD) diameter and length of the BRS was 3.00(±0.39) mm and 23(±6) mm respectively. Intracoronary imaging (IVUS or OCT) was used in 38 patients (57%). Angiographic success was achieved in all patients. There were no cardiac deaths or scaffold thrombosis during the follow up period. The rate of target vessel failure (due to instent restenosis requiring target lesion revascularization) was 3.0% at 6 months, 6.0% at one year and 7.5% at two years. Apart from one patient who developed an apical VSD, due to closure of septal arteries during stenting, there were no procedural complication observed.

CONCLUSIONS

This single centre experience with BRS demonstrates excellent procedural success and acceptable rates of target vessel failure in the short to mid-term. No scaffold thrombosis occurred during 2 years of follow up.

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The in-hospital clinical outcomes of immediate coronary angiography and PCI after out-of-hospital cardiac arrest

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS
Survivors of out-of-hospital cardiac arrest have a significantly high mortality and morbidity. Out-of-hospital cardiac arrest is frequently attributed to coronary artery disease and the current guidelines recommend coronary angiography for survivors of out-of-hospital cardiac arrest. The objective of the study was to assess 30-day clinical outcome of patients who underwent emergency coronary angiography after having had a successfully resuscitated out-of-hospital cardiac arrest.

METHODS AND RESULTS
We assessed the outcome in consecutive patient cohort from January 2016 to December 2017, admitted to a high-volume tertiary cardiac centre for emergency coronary angiography after successfully resuscitated out-of-hospital cardiac arrest within 24 hours after cardiac arrest. The primary endpoint was 30-day mortality. The demographic and clinical data were collected from the electronic medical records.

Using the database, we identified 90 consecutive patients admitted after successful resucitation from out-of-hospital cardiac arrest because of ventricular fibrillation (95.5%), pulseless ventricular tachycardia (2.2%), and pulseless electrical activity (2.2%). Only 12 (13.3%) patients complaint of chest pain prior to collapse. Post return-of-spontaneous circulation (ROSC) electrocardiograpghy demonstrated ST-segment elevation/LBBB in 43 (47.7%). On admission, GCS was 3/15 in 80 (88.8%), mean pH was 7.16±0.15 and mean lactate was 6.05±4.41.

Prior history of myocardial infarction was found in 6 (6.6%), prior CABG in 1 (1.1%) and prior PCI in 2 (2.2%). The left ventricular systolic function was found to be severely impaired in 19 (21.1%). Coronary angiography revealed unobstructed coronaries in 24 (26.6%), moderate disease in 6 (6.6%) and severe coronary artery disease in 60 (66.6%). Significant (≥70%) single vessel coronary artery disease was found in 43 (47.7%), two-vessel disease in 12 (13.3%) and three-vessel disease in 5 (5.5%). Left anterior descending (LAD) artery was found to be the culprit vessel in 38 (42.2%), followed by right coronary artery (RCA) in 26 (28.8%), left circumflex (LCx) in 9 (10.0%) and left main stem (LMS) in 7 (7.7%). Acute coronary artery occlusion was seen in 39 (43.3%). Successful percutaneous coronary intervention was performed in 56 (62.2%) of the cases. Fifty-four (60%) patients were discharged alive from the intensive care unit, out of which 4 (4.4%) had significant hypoxic brain damage. Thirty-one (34.4%) died in hospital (5.5% in cardiac catheterization laboratory, 28.8% on intensive care unit). The mean hospital stay was 10.67±10.62 days.

CONCLUSIONS
In our cohort of patients, two-third of the patients were found to have severe coronary artery disease and underwent successful coronary intervention and over half of the patients had a successful 30-day outcome with complete neurological recovery. Immediate bystander resuscitation, ROSC and emergency coronary angiography with a view to revascularization are the best markers of a positive outcome in this group of

patients.

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Efficacy and safety of ispilateral transulnar crossover following transradial access failure

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Transradial access has become the gold standard for coronary interventions due to lower rates of access site complications. Nevertheless, in approximately 6% of cases an access site crossover may be required. Coronary interventions using a transulnar access have demonstrated similar efficacy and safety; however, there is little evidence whether the ipsilateral ulnar artery should be the preferred choice in the case of transradial access failure. We aimed to evaluate the efficacy and safety of ipsilateral transulnar crossover in this setting.

METHODS AND RESULTS

We performed a retrospective analysis of all cardiac catheterizations with an initial radial approach performed in our centre from April 2016 to January 2019. Patients with radial access failure were identified and those with an ipsilateral ulnar crossover site (IU group) were further evaluated and compared to patients with a contralateral (radial or femoral) crossover site (CC group).

During the study period, 4147 patients with an initial transradial approach were identified (3812 right radial and 335 left radial). There were 150 patients (3.6%) with access site failure and among them 41 patients had ipsilateral ulnar crossover (36 right and 5 left ulnar approach). Second access success was achieved in 35 patients (85.4%) in the IU group compared to 102 patients in the CC group (93.6%) (p=0.188). There was no significant difference in forearm hematomas (83% EASY classification I and 17% EASY classification II) between patients in the IU group and the CC group (19.5% vs. 12.8%, p=0.304). No cases of early hand ischemia were reported. Patients in the IU group had significantly lower screen times [5.3(IQR:3.5-9.2) min vs. 10.6(IQR:4.6-21.8) min, p=0.003] and received lower contrast volume [100(IQR:80-160) mL vs. 150(IQR:80-200) ml, p=0.026] compared to patients in the CC group. There was no significant difference in radiation dose between the two groups [2076(IQR:1238-4599) uGym2 vs. 3260 (IQR:1614-6232) uGym2, p=0.110].

CONCLUSIONS

In the case of radial access failure, crossover to the ipsilateral ulnar artery is a safe and effective option for the experienced transradial operator.

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STEMI network - Portrait of a country

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Introduction: Primary angioplasty (PA) is a cornerstone in the ST elevation myocardial infarction (STEMI) treatment. Time is myocardium and STEMI network was designed to reduce time lost and offer PA as early as possible

Purpose: To characterize STEMI network in a country and its regions and identify independent predictors (IP) to increase or decrease the times symptoms-1st ECG (S-ECG), 1st ECG - balloon (ECG-B), symptoms-balloon (S-B) and door-to-balloon.

METHODS AND RESULTS

Methods: Retrospetive and multicenter study, based on a national register from 30/10/2010 to 09/19/2017. All patients with revascularized STEMI within the first 12 h of pain were included. 4 groups were established: Northern (I); Center (II); South (III); Algarve and Islands (IV). Univariate and multivariate analysis was performed of the clinical history, times until PA and hospitalization data.

Results: It was obtained 4683 patients, 1401 of I (29.9%), 971 of II (20.7%), 1033 of III (22.1%) and 1278 of IV (27.3%). The mean age was 62 years and 77% were men.
Admission by STEMI network was performed in 36.2% of cases in country, 38.0% in I, 20.1% in II, 23.4% in III and 56.3% in IV. Direct admission in catheterization laboratory (cath lab) was 41.3% in country, 48.6% in I, 30.1% in II, 12.6% in III and 64.8% in the IV.
S-ECG time was 158 minutes (m) in country, 155m in I, 187m in II, 161m in III and 138m in IV. IP for increase S-ECG time were transport through own or ambulance without doctor, females (FS), increased age (IA) and belong to group II ($p<0.01$). The admission by STEMI network was IP for decrease S-ECG time ($p<0.01$).
ECG-B time was 121m in country, 124m in I, 134m in II, 116m in III and 111m in IV. IP for increase ECG-B time were transfer from another hospital, admission in coronary care unit (CCU) or emergency service and IA ($p<0.01$). Belonging to group IV was IF for decrease ECG-B time ($p<0.01$).
S-B time was of 279m in country, 279m in I, 320m in II, 277m in III and 249m in IV. IP for increase S-B time were transport through own or ambulance without doctor, transfer from another hospital, FS, IA, belonging to group II ($p<0.01$) and admission in CCU. Direct admission in cath lab was IP for decrease S-B time.
P-B time was 98m in country, 103m in I, 123m in II, 119m in III and 54m in IV. IP for increase S-B time were transfer from another hospital, admission in the emergency service, FS and IA ($p<0.01$). Medical transport, admission by STEMI network and belong to groups I and IV were IP for decrease P-B time ($p<0.01$).

CONCLUSIONS

Conclusion:
STEMI network admission and/or admission in cath lab were IP in decrease of times until PA. By contrast, transport by other means and admission at other locations contributes to its increase.

FS and IA were IP for increase of the times until PA.
Northern and Algarve and Islands regions had a STEMI network more effectively than the rest of the country being IP in the decrease P-B (North and Algarve and islands) and ECG-B (Algarve and islands) times.
Central region is one that requires greater intervention and restructuring because it is where the S-ECG and S-B times were significantly higher.

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Intracoronary lithotripsy for lesion preparation in calcified coronary lesions: a prospective, observational single-centre study

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Calcified non-dilatable coronary lesions remain a challenge for interventional cardiologists. Percutaneous coronary intervention (PCI) of calcified lesions is associated with a higher prevalence of target vessel revascularization and myocardial infarction. Intravascular lithotripsy (IVL) has been recently proposed for the treatment of calcified coronary lesions. IVL can modify calcified plaques and promise low pressure PTCA and subsequently lower rate of complication. Its effectiveness in variable clinical situations in an all-comers cohort with severely calcified stenosis is widely unknown.

METHODS AND RESULTS

Patients with moderate and severely calcified coronary lesions were screened in our center starting May 2018. Until December 2018, 42 patients with 47 lesions were eligible for coronary lithotripsy. Patients were assigned to the following groups: A) Primary lithoplasty therapy for patients with circularly calcified de-novo coronary lesions (n= 22 lesions), B) Secondary lithoplasty therapy for patients with moderate or severe calcified coronary lesions in which conventional non-compliant balloon dilatation failed (n=11 lesions) and C) Tertiary lithoplasty therapy in patients with in-stent stenosis due to
stent underexpansion after previous stenting (n= 14 lesions). The investigational Shockwave C2 balloon device (Shockwave Medical Inc., USA) for intravascular lithotripsy was prepared and used according to instruction for use. Primary endpoint was strategy success and safety outcome. Strategy success was defined as successful stent delivery and expansion with attainment of < 20% in-stent residual stenosis of the target lesion. Safety outcome were procedural complication, defined as coronary dissection, slow or no reflow, new coronary thrombus formation during PCI, abrupt vessel closure and device failure (inability to place the balloon, malfunction, or burst) and in hospital MACE. 42 patients with 47 calcified lesions were treated with coronary lithotripsy by using Shockwave C2. Target vessel were in 20 cases LAD (47.6 %), in 16 cases RCA (38.1 %), in 9 cases left main vessel (21.4 %) and in 2 cases RCX (4.8 %). The overall average of applied Shockwave pulses was 62.0 ± 21.0. Average diameter of calcified stenosis was 82.5 ± 9.9 % at baseline and decreased significantly to 17.7 ± 12.53 % (p-value: 0.01) after PCI. MLD was 1.3 ± 0.5 mm at baseline and significantly increased after Shockwave procedure (2.9 ± 0.6 mm, p-value < 0.001). Strategy success was reached in 38 of 42 patients. Device delivery and lithotripsy treatment of target lesion could be performed in all cases. In 4 lesions type B dissection occurred, which were successfully treated with stent implantation. Four shockwave balloons ruptured after 20, 40, 60, and 70 shocks, respectively, mostly after repositioning of the balloon within the calcified lesion without further sequelae.

CONCLUSIONS

Intracoronary lithoplasty provides an alternative strategy for lesion preparation in severely calcified coronary lesions in an all- comers cohort. Larger studies are warranted before the use of the Shockwave lithoplasty can be generally recommended.

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The role of IVUS in CTO PCI

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

We aimed to assess the frequency of use and indication for intravascular ultrasound (IVUS) imaging in contemporary CTO PCI at a university cathlab.

METHODS AND RESULTS

We analysed clinical and procedural characteristics of all consecutive patients who underwent CTO PCI performed by two dedicated CTO operators at our centre in 2018. We evaluated the leading indication for IVUS imaging (20 MHz probe Eagle Eye, Phillips) and assessed the role of IVUS imaging during CTO PCI. During the study period, we performed 41 CTO PCI of 38 lesions in 36 patients (second attempt in 3 patients, 2 patients had 2 CTOs). The mean age was 68.3 ± 8.9 years, 86% were men. The mean LVEF was 51 ± 12%. The population demonstrated a high prevalence of cardiovascular risk factors, 19.4% had previous CABG and 50% previous non-CTO PCI. Reversible ischemia was demonstrated by single photon emission computed tomography (SPECT) in 61% of patients with a mean extent of ischemia 16 ± 6.6% of left ventricular myocardial mass. The right coronary artery (RCA) was the most frequent CTO PCI target vessel (47.4%), followed by the left anterior descending (31.6%), and the left circumflex (21%) arteries. The average Japanese CTO (J-CTO) score was 1.87±1.24. The overall technical success rate was 80.5% per PCI and 86.8% per lesion with the retrograde approach used in 43.9% cases. IVUS was performed in 41.5% (17/41) of CTO PCIs. IVUS was used primarily for facilitation of guidewire crossing in 9 cases (52.5%), whereas it was indicated for PCI guidance after successful CTO crossing in 8 cases (47.5%). IVUS imaging was used less frequently in antegrade only cases as compared with retrograde cases (17.4% versus 72.2%, p<0.01). Cases with IVUS utilisation were significantly more complex (J-CTO score 2.41±1.37 versus 1.5±1.02, p <0.01) than cases performed without IVUS. IVUS-guided cases had longer mean occlusion length (18.1±9.5 versus 12.5±7.5 mm, p <0.01), more frequently had a blunt/ambiguous proximal cap (76% versus 42%, p <0.01) and significant (> 45°) bending inside the CTO segment (35% versus 8%, p <0.01) as compared to angiography-guided cases. Use of IVUS was associated with longer mean procedure duration (214±64 versus 129±63 minutes, p<0.01), fluoroscopy time (84±33 versus 47±31 minutes, p<0.01), higher mean air kerma radiation dose (3.9±2.9 versus 2.3±1.3 Gray, p<0.01) and higher mean contrast volume used (277±76 versus 231±62 ml, p<0.01) as compared with angiography-guided cases. Despite higher lesion complexity, technical success rate of IVUS-guided cases was similar to cases without IVUS guidance (76.5% versus 83.3%, p=NS). The final crossing strategies in the IVUS-guided group were as follows: antegrade wire escalation (AWE) in 31%, antegrade dissection and re-entry (ADR) in 8% and retrograde in 61% of cases. In the non-IVUS group, AWE was the predominant successful crossing strategy (80%), followed by retrograde crossing (20%). One patient in the IVUS group developed periprocedural cardiac tamponade successfully treated by pericardiocentesis, no other in-hospital major adverse events were observed.

CONCLUSIONS

Despite the use of IVUS in more complex CTOs, requiring frequent utilization of retrograde techniques, cases performed with adjunctive intravascular imaging achieved similar success rates to anatomically less

challenging angiography guided cases.

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Incidence and prognostic implications of late bleeding events after percutaneous mitral valve repair

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THEME: Interventions for Valvular Disease

TOPIC(S): Mitral valve replacement and repair

AIMS

MitraClip is an established therapy for patients with mitral regurgitation (MR) that are considered of high-risk or inoperable. However, late bleeding events (BE) after hospital discharge and their impact on progno- sis in this cohort of patients have been poorly investigated. Our purpose is to address the incidence, related fac- tors and clinical implications of BE after hospital discharge in patients treated with MitraClip.

METHODS AND RESULTS

Prospective registry of all consecutive patients (n = 80) who underwent MitraClip implantation in our Institution between June 2014 and December 2017. BE were defined according to MVARC definitions. A com- bined clinical end-point including admission for heart failure (HF) and all-cause mortality was established to an- alyze prognostic implications of BE.

During a median follow up of 523.5 days, 41 BE were reported in 21 patients. Atrial fibrillation (AF, HR 4.54, CI95% 1.20–17.10) and combined antithrombotic therapy at discharge (HR 3.52, CI95% 1.03–11.34) were independently associated with BE. In the study period, 15 (18.8%) patients died, 20 (25%) were admitted for HF and 29 (36.3%) presented the combined end-point. After multivariable adjustment BE remained independently asso- ciated with an adverse outcome (HR 3.80, CI 95% 1.66–8.72). In the subgroup of patients with AF, HAS-BLED score was higher among subjects with BE (3.1 ± 1.3 vs 2.1 ± 0.9, p = 0.003). HAS-BLED score had a significant discrim- ination power for the occurrence BE (AUC: 0.677 [0.507–0.848]) in this subgroup.

CONCLUSIONS

BE are common after MitraClip and are associated with an impaired outcome. Strategies to reduce bleeding events are paramount in this cohort of patients.

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Impact of recent heart failure hospitalisation on clinical outcomes in patients with severe aortic stenosis undergoing TAVR: an analysis from the PARTNER 2 trial and registries

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Heart-failure (HF) hospitalization prior to transcatheter aortic valve replacement (TAVR), has been shown to be associated with increased post-procedural mortality. We sought to assess the association between recent (≤6 months) HF hospitalization and long-term adverse outcomes in patients with symptomatic, severe aortic stenosis (AS), undergoing TAVR in the PARTNER 2 trial and registries.

METHODS AND RESULTS

We analyzed Intermediate to high or even prohibitive risk patients who underwent TAVR in the PARTNER 2 trial and registries. Clinical outcomes at 30 days and 2 years were compared between patients according to whether they were recently hospitalized for HF, using Kaplan Meier event rates and study-stratified multivariable Cox proportional hazards regression models. Sensitivity analysis was conducted using propensity score matching. Of 3988 patients (99.8%) with available information on recent HF hospitalization, 1622 patients (40.7%) were hospitalized for HF symptoms during the 6 months prior to TAVR. Recent HF hospitalization was associated with older age, lower body mass index and higher STS score. After multivariable adjustments, recent HF hospitalization was associated with increased all-cause mortality at 30 days (adj HR 1.63 95% CI 1.07 to 2.48, p=0.02) and 2 years (adj HR 1.30 95% CI 1.13 to 1.49, p=0.0003), which was driven by increased cardiovascular mortality. Infective endocarditis rate at 2 years was also higher in patients with recent HF hospitalization (adj HR 2.35 95% CI 1.38 to 4.01, p=0.002). These results remained consistent when propensity score matching was used.

CONCLUSIONS

In a large cohort of patients with severe symptomatic AS from the PARTNER 2 trial and registries, all-cause and cardiovascular mortality, as well as infective endocarditis rates at 2 years, were higher in patients with recent HF hospitalization.

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Impaired peripheral endothelial function is associated with increased infarct size, decreased coronary flow reserve and inflammatory parameters in patients with STEMI

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THEME: Coronary Interventions
TOPIC(S): STEMI, Other Coronary Interventions

AIMS

It has been proposed that at the acute moment of ST-elevation myocardial infarction (STEMI), peripheral endothelial function (PEF) is impaired. PEF can be measured by reactive hyperemia-pulse amplitude tomography (RH-PAT). There is a negative correlation between PEF and troponin levels in STEMI. In stable coronary artery disease, there is a relationship between PEF and coronary flow reserve coronary endothelial function. The primary aim of our study was to assess acute and follow-up PEF and their relationship with infarct characteristics in a relatively large population of patients with STEMI.

METHODS AND RESULTS

We included 110 STEMI patients with acute and follow-up (day 30, 1, 2 year follow-up) RH-PAT. To determine PEF, we calculated the reactive hyperemia index (RHI) which is the ratio of the average post-occlusive pulse volume amplitude to the average pre-occlusion pulse volume amplitude corrected for baseline tonus. Intracoronary hemodynamic measurements in the culprit vessel at the acute moment and 1-month follow-up were done. We performed CMR at 2-7 days and 1 month post primary PCI.

There was a significant correlation between the acute and follow-up RHI (rho 0.32, p=0.001). Acute RHI was significantly decreased at the acute moment versus follow-up (1.84±0.80 versus 1.98±0.67, p=0.04). Bland-Altman analysis of RHI showed a bias of 0.14 (SD of 0.86). There were higher leukocyte levels (12.0±3.5 vs. 10.1±3.1 /L, p=0.01) in patients with decreased acute RHI (≤Q1, 1.44). There was a correlation between acute RHI and coronary flow reserve (CFR) in the culprit vessel (rho 0.24, p=0.02). Acute RHI was significantly lower in patients with acute culprit CFR<2.0 compared to CFR≥2.0 (1.65±0.36 versus 2.04±1.15 respectively, p=0.04). At follow-up, RHI was significantly lower in patients with a larger final infarct (as % of LV)(rho -0.26, p=0.01). There was a significant correlation between follow-up RHI and troponin peak values (rho -0.27, p=0.006) and CK-MB peak values (rho -0.20, p=0.04). After multivariate analysis, RHI remained an independent predictor of infarct size as %LV (B=0.24, p=0.02).

CONCLUSIONS

There was correlation between acute- and follow-up RHI, with a significantly decreased acute RHI. Patients with a decreased acute CFR in the culprit vessel, experienced peripheral endothelial dysfunction. In patients with increased inflammatory parameters, endothelial function was impaired and related to infarct size. Interestingly, after multivariate analysis, RHI remained an independent predictor of infarct size.

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Long-term efficacy of DEB for the treatment of de novo coronary artery lesions

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds, Other Coronary Interventions

AIMS

To evaluate the long-term efficacy of the three most commonly used drug coated balloons (DCB) for the treatment of de novo coronary lesions in Sweden.

METHODS AND RESULTS

This was an analysis of prospectively collected data from the Swedish Coronary and Angioplasty Registry. Between January 2009 and December 2017, all DCBs used for the treatment of a de novo coronary lesion in Sweden were identified. The three most commonly used DCBs (95% of all DCBs used for de novo coronary lesions) were included in the present analysis. Outcomes included clinically driven restenosis and target lesion thrombosis (TLT) (per DCB) and major adverse cardiac events (MACE) including death, myocardial infarction (MI) or target vessel revascularization (TVR) (per patient). Patients were followed up to 4 years and Cox regression models were used to adjust for differences between the groups.

We identified and included 6715 DCBs, 4483 SeQuent® Please (Se-DCB), 1071 In.Pact Falcon (In-DCB) and 1161 Pantera® Lux (Pa-DCB), in 5670 patients.

Patients had a high-risk profile. The mean age was 68y, 28% had diabetes, 37% a previous MI and 41% a previous percutaneous coronary intervention (PCI). The indication for PCI was an acute coronary syndrome in 60% of the cases.

The mean (standard deviation, SD) DCB diameter was 2.43mm (0.44). Left anterior descending was the target vessel in 50% of the cases. More than half of the lesions (53%) were classified as B2/C lesions. Employment of a DCB plus a stent in the same lesion occurred in 6.7% of lesions. Angiographic success was very high, 98.5%.

The cumulative rate of restenosis was 5.5% (299 events), with no difference between the three studied DCBs, before or after adjustment (In-DCB vs Se-DCB, adjusted hazard ratio (HR) 0.94; 95% confidence interval (CI) 0.67- 1.31 and Pa-DCB vs Se-DCB adjusted HR 0.87; 95% CI 0.63- 1.22).

The cumulative rate of TLT was 0.8% (44 events), with no difference between the three studied DCBs (In-DCB vs Se-DCB, HR 1.03; 95% CI 0.45- 2.36 and Pa-DCB vs Se-DCB HR 1.30; 95% CI 0.62- 2.76)

The cumulative rate of MACE was 27% (1251 events). The risk for MACE did not significantly differ between the three studied DCB groups before or after adjustment (In-DCB patients vs Se-DCB patients, adjusted HR 1.05; 95% CI 0.89- 1.22 and Pa-DCB patients vs Se-DCB patients, adjusted HR 1.08; 95% CI 0.91- 1.28). Similarly, there was no significant difference in the risk for the individual components of MACE, between the three studied DCB groups.

CONCLUSIONS

We showed that DCB angioplasty for de novo coronary lesion was feasible with low risk for long-term restenosis and TLT. Furthermore, we found similar long-term efficacy between the three most commonly used DCBs in Sweden

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Successful edge-to-edge mitral valve repair reduces ventricular arrhythmic burden in patients with functional mitral regurgitation and implantable cardiac devices: an observational bicentre study

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair

AIMS

to evaluate ventricular arrhythmic (VA) burden before and after percutaneous mitral valve repair (PMVR) in patients with implantable cardiac devices. We hypothesized that hemodynamic improvement after PMVR might have a positive impact in the frequency of VA.

METHODS AND RESULTS

prospective registry of all consecutive patients (n=34, age 69.0 ± 12.2 years, 76.5% male) with functional mitral regurgitation (FMR) grade 3+ or 4+ who underwent MitraClip implantation in two Spanish centers between June 2014 and July 2018. VA burden was defined as the total number of events during device follow-up time frame presented on a per month basis before and after PMVR. Among patients who presented VA during follow-up before or after PMVR, device success at hospital discharge (16/19 [84.2%]) was related to a significant reduction in the incidence of Non-Sustained ventricular tachycardia (VT, p = 0.002) and any sustained VT or rapid VT/VF (p = 0.034). Regarding ICD therapies, successful PMVR was related to a reduction in incidence of either ATP or appropriate shocks (p = 0.045) and in the occurrence of any defibrillation shocks (p = 0.045). Overall, effective repair lead to a significant reduction in the VA burden, with a significant decrease in the occurrence of any VA (p = 0.004) and any ICD therapies (p = 0.045).

CONCLUSIONS

device success after PMVR was related to a reduction in overall arrhythmic burden and ICD therapies in our cohort

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Transcatheter vs. surgical pulmonary valve replacement - A meta-analysis

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THEME: Interventions for Valvular Disease
TOPIC(S): Tricuspid / Pulmonary valve

AIMS

We performed a meta-analysis to assess the safety of transcatheter pulmonary valve replacement (TPVR), compared with the surgical approach.

METHODS AND RESULTS

We search the MEDLINE and Cochrane Library electronic databases for publications comparing the outcomes of TPVR with surgical pulmonary valve replacement (SPVR). To be included in the analysis the studies needed to provide data regarding peri-procedural mortality for TPVR and SPVR. The primary endpoint was peri-procedural mortality. Secondary outcomes included length of hospital stay and costs, as well as the occurrence of infective endocarditis during follow-up. The main baseline demographics were also assessed and compared between groups.

The initial research provided 103 publications, of which 5 were included in the final analysis, yielding a total of 3161 patients (740 in the TPVR group and 2421 in the SPVR group). Cincerning the baseline characteristics, patients in the TPVR group were older (mean difference 2.38 years, 95% CI 0.26-4.51, P=0.03, I2=90%) and less frequently had tetralogy of Fallot (pooled OR 0.50, 95% CI 0.25-0.97, P=0.04, I2=86%); there were no differences in gender between groups.

There was a non-significant trend to a lower mortality in the TPVR group (0.00% vs 0.95%, pooled OR 0.30, 95% CI 0.07-1.35, P=0.12, I2=0%). Data regarding the length of hospital stay was available in four studies and the pooled analysis of this data showed a significantly lower length of stay in the TPVR group (mean difference -3.53 days, pooled OR -5.06 to -2.00, P<0.001, I2=100%). However, data regarding total hospital costs, which was available in three studies showed that expenses were significantly higher in the TPVR group (mean difference $5668.19, 95% CI 687.18-10649.21, P<0.001, I2=91%). The incidence of endocarditis during follow-up was reported in only two of the studies; the pooled results of these studies showed a non-significant trend towards a higher incidence of endocarditis in the TPVR group (3.9% vs 0.9%, pooled OR 3.31, 95% CI 0.82-13.28, P=0.09, I2=0%).

CONCLUSIONS

Our results show that TPVR is a safe procedure when compared to SPVR (no mortality was observed in TPVR group) and is associated with a shorter hospital stay. Nevertheless, costs were higher with TPVR and there was a trend towards an increased risk of endocarditis during follow-up.

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Multicentre registry of the first Brazilian DES

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Evaluate the safety and effectiveness of the Sirolimus eluting coronary stent in "real world" patients.

METHODS AND RESULTS

Material and Methods: Patients with 18 years or older, that presented with severe coronary lesion treated with sirolimus drug eluting stent in a nine multi centric registry, from June of 2017 to November of 2018. Eligible patients included in the registry were considered the ones in witch each lesion was no more than 34 mm in length with a reference vessel diameter of 2.5 to 3.5 mm on visual assessment. The primary endpoint was a composite of major adverse cardiac and cerebrovascular events (MACCE) that included, all cause of death, myocardial infarction, target vessel revascularization, target lesion revascularization and stent thrombosis during hospital stay and in 30 days. Secondary outcome was each one of the above endpoints evaluated individually.

Results: 543 patients were included in the registry, with 628 lesions treated. The mean age was 63.8 ± 10.6, male were majority, 63.7%. Main cardiovascular factors observed were, hypertension in 76.6% and diabetes mellitus in 43.5% of patients. Clinical presentation were stable angina in 45.9%, acute coronary syndrome in 45.5%, silent ischemia in 3.3% and unknown in 5.3% of cases. Related coronary were, left anterior descending in 40.6%, circumflex in 23.6% , right coronary in 35.2% and left marginal in 0.6%. Lesion diameter was 2.9 ± 0.5mm and length 18.5 ± 8.5mm. Procedure success was achieved in 100% of cases . In-hospital major adverse cardiac events were observed in 0.2% of patients, due to non-cardiac death (1 case) . No other outcome was reported during hospital stay. At 30 days MACCE was observed in 0.7% of patients. There were 2 non-cardiac and 1 cardiac death. One myocardial infarction occurred in 30 days. There was one case of target vessel and one case of target lesion revascularization. Stent thrombosis occurred in one patient at 30 days of follow up.

CONCLUSIONS

This registry findings suggests that the first Brazilian drug eluted stent implanted in a multi centric strategy is safe and effective in a real world patient, most of them with an unstable presentation and high risk profile for thrombotic events.

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Infective endocarditis caused by staphylococcus or enterococcus after TAVI - A comparison between the two most common microbiological findings

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Infective endocarditis (IE) after transcatheter aortic valve implantation (TAVI) is a severe complication associated with a high mortality. The two most common microbiological findings are staphylococci and enterococci. We aimed to compare the baseline characteristics and outcome between patients developing IE due to staphylococci (IEst) or enterococci (IEen) after TAVI.

METHODS AND RESULTS

Patients receiving TAVI between 2007 and 2017 and afterwards developing IE caused by staphylococci or enterococci were included this analysis. The 1-year mortality was the primary outcome measure of this retrospective single center analysis. The complication rate during IE treatment was recorded.

Overall, 37 IEst and 32 IEen were included. Patients were comparable with regard to age (IEst: 79 (74; 84) vs. IEen: 80 (77; 85), p=0.37), sex (male: 50% vs. 51%, p=0.91) and most baseline comorbidities except for coronary artery disease (IEst: 60% vs. IEen: 31%, p=0.02). Self-expanding valves were affected in 66% in IEst and 65% in IEen (p=0.55). Early IE, e.g. within the first year, occurred in 75% and 63% in IEst and IEen, respectively (p=0.27). Assessed by transoesophageal echocardiography (TEE), an affected prosthesis was found in 53% in IEst and 68% in IEen (p=0.21). There was no difference in the rate of periannular abscess (IEst: 32% vs. IEen: 19%, p=0.25). A negative TEE imaging for vegetation was evident in 17% in IEst and 23% in IEen (p=0.24). Despite a high proportion of patients having a formal indication for operation (IEst: 81% vs. IEen: 71%, p=0.36), only a minority of patients underwent cardiac surgery (IEst: 27% vs. IEen: 25%, p=0.85).

The rate of any complication during IE treatment was higher in IEst (83%) compared to IEen (58%) (p=0.02), mainly driven by a higher rate of dialysis dependent renal failure (IEst: 42% vs. IE en: 19%, p=0.05). In-hospital (IEst: 68% vs. IEen: 53%, p=0.05) and 1-year mortality (IEst: 81% vs. IEen: 64%, p=0.05) was higher in IEst compared to IEen. Adjusting for age and sex, IEst was associated with increased 1-year mortality (HR 1.81 95%-confidence interval 1.02-3.2, p=0.04).

CONCLUSIONS

Both IEst and IEen are associated with a devastating high in-hospital and 1-year mortality. The results of this analysis implicate that IEen might be associated with a slightly better prognosis compared to IEst.

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Outcomes following urgent vs. elective percutaneous mitral valve repair

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair

AIMS

Mitral regurgitation (MR) is the most common valvular heart disease observed in patients with acute decompensated heart failure (ADHF). Percutaneous mitral valve repair (PMVR) has proved to effectively reduce MR in patients at high risk for open heart surgery. Data regarding urgent PMVR are limited to a few case reports. Our aim was to examine procedural and clinical outcomes among patients undergoing PMVR within an admission for ADHF.

METHODS AND RESULTS

Prospective registry of all consecutive patients with symptomatic MR grade 3+/4+ who underwent PMVR in our center between June/14-March/18. A patient was considered for urgent PMVR in case of recurrent episodes of pulmonary edema or cardiogenic shock. Adverse events during followed up were defined according to Mitral Valve Academic Research Consortium.

Eighty-five patients were treated within the recruitment specified period. Among them, seventeen patients (20%) underwent MitraClip implantation within an admission for ADHF. Six patients (35.3%) presented cardiogenic shock and eleven subjects underwent urgent PMVR due to recurrent pulmonary congestion. The subgroup of patients who underwent urgent PMVR had higher prevalence of peripheral artery disease (p=0.039), prior myocardial infarction (p=0.023) and percutaneous coronary intervention (p=0.044), consistent with more predominantly functional MR of ischemic etiology (p=0.030) compared to those electively intervened. Those patients had a worse NYHA functional class (p<0.001); higher levels of NT-pro Brain Natriuretic Peptide (p=0.035) and high-sensitive Troponin (p=0.008); and required more frequently iv diuretics (p<0.001), inotropes/vasopressors (p<0.001), mechanical ventilation (p<0.007) or intraaortic balloon pump (p<0.001) before PMVR.

At least one MitraClip was successfully implanted in all patients who underwent urgent PMVR and more than one clip was used in 6 (35.3%) cases. No differences in device time or the number of clips implanted were found among elective and urgent procedures. Patients who underwent an elective procedure were hospitalized for a shorter period of time (p<0.001), including a shorter preprocedural stay (p<0.001) and admission in a cardiac critical care Unit (p<0.001), and were also discharged sooner after PMVR (p=0.022). Nevertheless, most of patients (64.7%) who received a clip within an admission for ADHF could be stably discharge in the following week. There was a significant higher incidence of acute renal failure grade 2 or 3 in patients who underwent urgent PMVR (p =0.029). No differences in the incidence of any other procedural complication was found between elective and urgent cases. Both approaches have similar rates of technical, device and procedural success. During a median follow up of 691 [467-1006] days, 19 (22.4%) patients died, 14 (16.5%) due to a cardiovascular cause. Cumulative estimated survival free from all-cause death was 92.9% (82.4% vs 95.6%), 89.4% (82.4% vs 91.1%), 76.3% (82.4 vs 74.9%) at 6 months, 1-year and 2-years, respectively, with no significant differences between urgent or elective PMVR (log-rank test p = 0.769). None of the patients with MR as complication of an acute or recent (within 90 days) MI (8 urgent cases) died during a median follow up

of 785 [589-1058] days.

CONCLUSIONS

MitraClip® implantation can be considered as an urgent therapy during admission for ADHF in patients with recurrent pulmonary edema and/or cardiogenic shock in which MR is deemed to be the main cause of decompensation.

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Outcomes of 626 echocardiographically-guided peri-cardiocenteses over a 10-year period in a low-to-middle income country tertiary referral centre

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THEME: Interventions for Heart Failure

TOPIC(S): Acute heart failure, Chronic heart failure

AIMS

Echocardiographically-guided percutaneous pericardiocentesis (EGPP) is well established as a safe procedure with a low rate of complications in high-income countries. Its feasibility and safety is poorly described in resource-limited regions. The objective of this study was to evaluate the major and minor complications associated with EGPP in a large South African tertiary centre, and to compare the rate of complications with internationally accepted standards. Secondary objectives included evaluating the optimal route of access and identifying risk factors for procedure-related complications

METHODS AND RESULTS

All EGPP performed between 01/01/2008 and 31/10/2018 were included. Pericardiocentesis procedural reports and clinical notes were evaluated to determine the aetiology of the pericardial effusion, pericardial access site, procedural success, volume of fluid aspirated, and procedure related minor and major complications.

During the 10-year study period, 626 EGPP were performed on 558 patients (mean age: 40 ± 15 years). The leading aetiology was tuberculous pericarditis (81.0%); iatrogenic, cardiac catheterisation-related effusions comprised only 1.3%. Overall, EGPP procedural success rate was 95%, with a total procedure-related complication prevalence of 6.5% (95% CI: 4.5 – 8.9%); (major: 1.7%; minor: 4.8%), compared to a complication rate of 4.7% (major: 1.2%; minor: 3.5%) in the largest series from the Mayo Clinic. The preferred site of access, guided by the largest pool of fluid identified on ultrasound, was the trans-apical route (55%). After adjusting for confounding variables in a multivariate analysis, multiple punctures was associated with procedure related complications (Odds Ratio 7.0 (95% confidence interval (CI): 3.30–14.90) whilst low-volume effusions (<300mL) and apical route of access had a marginal but non-significant effect.

CONCLUSIONS

EGPP is associated with a low prevalence of complications in our centre (in a resource-limited African country), with a major procedure related complication prevalence comparable to that of a leading centre from a high-income country. After adjusting for confounders in a multivariate analysis, multiple punctures was highly associated with an increased risk of procedure-related complications.

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FFR derived from coronary CT compared to conventional FFR

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Coronary computed tomography has become one of the main tests performed in patients with suspected ischaemic heart disease. While it has an excellent negative predictive value, it has a worse positive predictive value and the limitation for evaluating the functional repercussion of a coronary artery stenosis.

We have compared the correlation between fractional flow reserve derived from coronary computed tomography (FFR-CT) and conventional (invasive) fractional flow reserve by coronary angiography (FFR-CA).

METHODS AND RESULTS

We analysed retrospectively the coronary computed tomography of those patients in which we had performed FFR to evaluate intermediate lesions found in invasive coronary angiography. We calculated the FFR-CT in those vessels, and used ≤0,80 as the cut-off point for a significant stenosis by both methods.

We evaluated a total of 38 vessels in 32 patients (84% men, mean age 67±9 years) with intermediate coronary lesions in coronary angiography, in which FFR was performed to guide treatment. Pressure wires used were X-Wire (Abbott) in 79% and Verrata Plus (Philips Volcano) in 21%. The CAD-RADS score in the CT was between 3 and 4 in all patients. The FFR-CT was calculated with an investigational software (ctFFR, syngo.via Frontier, Siemens Healthineers). One vessel was excluded because it had a formerly implanted stent.

In the vessel analysis, we found a median of 0,83 in FFR-CT group and 0,85 in FFR-CA group. The medium coronary calcium score was 846 ±973. The sensitivity, specificity, positive predictive value and negative predictive value were 37%, 86%, 66% and 65% respectively, of the FFR-CT compared to the FFR-CA.

CONCLUSIONS

In patients with intermediate coronary stenosis (CAD-RADS 3-4), the median FFR-CT values obtained are close to those obtained by invasive FFR-CA. This could be used as a tool to identify the patients that could benefit the most from invasive coronary angiography.

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First clinical validation of automated quantitative assessment of coronary calcification using IVUS

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Coronary calcifications can negatively affect stent expansion and are related to future adverse cardiac events. IVUS is known for its high sensitivity to detect coronary calcifications and to assess their angular extent. In this work, we present an optimized framework for fast and accurate automated detection and quantification of the presence and extent of calcifications in coronary atherosclerosis as seen by IVUS.

METHODS AND RESULTS

36 IVUS pullbacks (Infraredx TVC, Burlington MA, USA; pullback speed 0.5 mm/s) of non-culprit coronary arteries from 35 ACS patients were analysed. Frames were manually annotated by a trained expert at 1 mm (32 frames) intervals and calcium arcs were drawn on a frame-level ending up in calcium annotated in 360 1°-sectors per frame, relative to the catheter as the centre of the image, and labelled as calcified or not. Sections of guiding catheter were excluded. The annotations were transformed into polar coordinates such that each A-line was labelled. We trained a support vector machine (SVM) to automatically identify calcium per A-line based on histogram features and other statistical parameters representing its amplitude distribution. In order to study the potential improvement in the algorithm, additional post-processing was performed to exclude the guidewire and isolated pixels from the SVM detection. 30 pullbacks were randomly chosen for feature selection and model training, and the remaining 6 pullbacks were used for testing. Using the detection results, we defined an IVUS-calcium score to be:

1000 × [(number of CA-positive pixels)/(total number of pixels)]

Computed in the carpet view (unfolded 2-dimentional view along pullback lengths and angles), which is also used to display the detection result. The IVUS-calcium scores were reported as mean and standard deviations. The linear relationship between scores estimated using the algorithm and that using the manual labelling was reported by Pearson correlation (r).

Results showed that the trained SVM classifier can automatically detect calcified lesions with a high accuracy in both validation data (Sensitivity 0.82, Specificity 0.95, Accuracy 0.95, PPV 0.45 and NPV 0.99) and testing data (Sensitivity 0.90±0.03, Specificity 0.94±0.04, Accuracy 0.94±0.04, PPV 0.36±0.22 and NPV 1.00±0.00, calculated per pullback). Feature selection showed that the significant contributors are a) histogram frequencies of lower to middle high intensities, b) lower and upper quantiles, and c) the A-line maximum intensity. Furthermore, post-processing changed the outcomes to be; Sensitivity 0.62±0.24, Specificity 0.97±0.05, Accuracy 0.96±0.04, PPV 0.53±0.30 and NPV 0.99±0.01. The calcium scores for the total 35 pullbacks (one outlier removed) are; manual label: 42.53±55.62, detection before post-processing: 67.83±58.23 (r=0.89), and detection after post-processing: 43.10±55.58 (r=0.96). Performance of post-processing can be further improved in the future by retrospective cardiac gating, accounting for the occasional absence of a guidewire, and other image correction steps.

CONCLUSIONS

Intracoronary calcified plaques can be automatically detected with high accuracy using machine learning techniques. The detected calcium can be shown in a “carpet” view and quantified as calcium score, introduced here, which allows for a quick overview of the calcium distribution in coronary arteries. This might be help in improving PCI risk classification and outcome.

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Clinical characteristics and outcomes after TAVI in patients reclassified to moderate aortic stenosis by integration of multimodality imaging and pressure recovery

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

This study assessed whether the combination of imaging data from transthoracic echocardiography (TTE) and multidetector computed tomography (MDCT) affects the grading of aortic stenosis (AS) severity under consideration of the energy loss index (ELI) in patients undergoing in patients undergoing transcatheter aortic valve implantation (TAVI).

METHODS AND RESULTS

197 patients diagnosed with severe AS were included in this study. Left ventricular outflow tract (LVOT) area derived from TTE was smaller than the planimetric area in MDCT due the ovoid shape of the LVOT (3.4±0.12 cm2 vs. 4.5±0.23 cm2; p<0.01). The sinotubular junction (ST-junction) diameter measured in TTE method was similar to maximal, minimal, and mean diameters determined by MDCT. The sphericity index confirmed an almost circular anatomy of ST-junction, and its area derived from LTL diameter in TTE was similar to the planimetric area in MDCT. Fusion aortic valve area index (fusion AVAi) assessed by inserting MDCT derived planimetric LVOT area in the continuity equation was significantly higher in all patients compared to conventional AVAi. 62 patients were reclassified from severe to moderate AS because fusion AVAi was >0.6 cm2/m2. ELI was calculated for conventional AVAi and fusion AVAi each with ST-junction area determined by TTE and MDCT. Calculating ELI with fusion AVAi resulted in significantly larger effective orifice area, with values >0.6 cm2/m2in 83 patients (ST-junction area from echo) and 85 patients (ST-junction area from MDCT). Calculating ELI with conventional AVAi resulted in significantly larger effective orifice area irrespective of whether the ST-junction area was determined by TTE or MDCT. Calculating ELI with fusion AVAi resulted in even larger effective orifice area, with values >0.6 cm2/m2in 83 patients (ST-junction area from echo) and 85 patients (ST-junction area from MDCT). Reclassified patients had lower mean transvalvular pressure gradients, lower myocardial mass, less symptoms according to NYHA classification, and lower proBNP levels at baseline. While both groups exhibited improvement of functional status 1 year, the survival rate 3 years after TAVI was higher in patients reclassified to moderate AS (81% versus 66%; p=0.02).

CONCLUSIONS

TTE underestimates LVOT area as compared to MDCT, while both modalities are comparable with regard to ST-junction area. Integration of TTE and MDCT derived values for calculation of ELI reclassifies the severity of AS in 43% of patients initially diagnosed with severe AS. While reclassified patients display less advanced valve disease at baseline, TAVI results in functional improvement in all patients.

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Methods of calculating coronary flow reserve from data obtained during intracoronary pressure measurement

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

The fractional flow reserve (FFR) determined from hyperemic pressure ratios is the indicator primarily recommended to assess the hemodynamic significance of the stenosis. Coronary flow reserve (CFR) has been proved to be an additional prognostic parameter to describe the combined capacity of epicardial flow and microcirculation. Since its direct measurement is technically difficult to perform, it is not routinely used in clinical practice.

In our study we compared the calculated CFR values determined from coronary angiography and the pressure data measured during rest and vasodilatation.

METHODS AND RESULTS

FFR measurements were performed in 59 cases. In 50 patients, the CFR was calculated using the "frame count reserve" (FCR) and "pressure-bounded" CFR (CFRpb) method where was published earlier and the "simple CFR" (CFRsim) evaluated using our new technique. In order to calculate the CFRsim value, the 3D morphological parameters of the given stenosis and the pressure gradients resulting from FFR measurement were used to solve the classic fluid dynamic equations. In 9 cases we carried out finite element analysis to perform detailed flow modelling with the help of Navier-Stokes equations, using the results of 3D coronary artery reconstruction and measured values of pressure gradients.

We found significant correlation between the FCR and CFRsim ($r=0.87$, $p<0.0001$).The correlation between CFR and CFRsim calculated by the ANSYS software using Navier-Stokes equations proved to be even stronger ($r=0.97$; $p<0.0001$). Using the CFRpb to classify patients below or above CFR 2 (considered as threshold value) was possible only in 46% of the cases (23/50), as in the case of the remaining 54% the CFR interval calculated with this method incorporated the cut off value.

CONCLUSIONS

Considering the time and special software requirements of the various methods used to calculate the value of CFR, we suggest the application of the CFRsim method described above to determine the pressure-based CFR.

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A trust-worthy indice for the classification of aortic stenosis severity in symptomatic patients

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Aortic valve area (AVA fusion) as assessed using CT estimated left ventricle outflow tract (LVOT) area is used in order to evaluate the severity of aortic stenosis in borderline patients with mild symptomatology. This is due to the inability of 2D echocardiography to accurately evaluate the oval shape and the calcified borders of LVOT area. Whether this has also any significant impact on patients with severe symptomatic aortic stenosis or not, has not been fully elucidated.

METHODS AND RESULTS

Seventy-three patients consecutive patients (81±6 years, 44 males (60.3%)) with symptomatic aortic stenosis were evaluated for the severity of aortic stenosis with ultrasound echocardiography and MSCT. Ultrasound echocardiography was used in order to assess LVOT in long-axis 2D view and VTI in aortic valve and in LVOT using color-Doppler. MSCT was used in order to evaluate LVOT area. Using the equation of continuity AVA as well as AVA fusion were evaluated as follows: Echo AVAi: (π*(LVOT/2)2* Echo VTI PW LVOT / Echo VTI CW Aortic valve and Fusion AVAi: (LVOTarea*Echo VTI PW LVOT) / Echo VTI CW Aortic valve. MSCT was also used in order to measure the total calcium score (TCS). Patients were separated into two groups according to TCS values. (Group I: TCS<1600 for women and <3000 for men, Group II: TCS≥1600 for women and ≥3000 for men). Mean values of Fusion AVAi (0.65±0.27 cm2/ m2 vs 0.35±0.08 cm2/ m2, p=0.001) differed significantly when compared with mean values of Echo AVAi. Finally, CTA LVOTarea and US LVOTarea differed significantly both in Group I (5.52±1.32 cm2 vs 3.13±0.77 cm2, p<0.001) and in Group II (5.41±1.64 cm2 vs 2.88±0.63 cm2, p<0.001).

CONCLUSIONS

In conclusion, MSCT needs to be performed for the proper evaluation of LVOT area and consequently of AVAi in symptomatic aortic stenosis patients.

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Prospective, multicentre evaluation of the DESolve novolimus-eluting BRS: imaging outcomes and five-year clinical and imaging results

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

The DESolve Nx study is a multi-centre evaluation of the safety and efficacy of the DESolve Novolimus Eluting Bioresorbable Coronary Scaffold System (NEBCSS) in patients with single, de novo, native coronary artery lesions.

METHODS AND RESULTS

The DESolve® NEBCSS is a novel drug-eluting bioresorbable scaffold (BRS) combining a PLLA-based scaffold coated with Novolimus, a macrocyclic lactone mTOR inhibitor, and a PLLA-based biodegradable coating, and differentiates itself from other BRS with a shorter bioresorption time [>90% reduction in molecular weight within 6 months with near complete bioresorption by 1 year (~70% mass loss) in preclinical studies while offering high expansion capacity without strut fracture. The drug dose is 5 µg per mm of scaffold length and was available in multiple diameters (2.5 – 3.5 mm) and lengths (14, 18 and 28 mm).

A total of 126 patients were enrolled in this prospective registry. Patients receiving the study device were analysed for multiple clinical endpoints including: device and procedure success; Major Adverse Cardiac Events (MACE), a composite endpoint of cardiac death, target vessel MI, or clinically-indicated target lesion revascularisation (CI-TLR), the individual components of MACE and stent thrombosis at 1, 6 months and annually to 5 years. All patients were to undergo angiographic assessment at 6 months; a subset of patients also underwent IVUS and OCT assessment at 6 months and multislice computed tomography (MSCT) imaging at 12 months. Additionally, at two separate single centres, multi-modality imaging was completed at 18 months and 3 years.

Six-month QCA demonstrated low mean in-scaffold late lumen loss (0.20 mm), 18.3 %DS and an MLD of 2.45 mm. Serial IVUS at baseline and 6 months demonstrated a significant increase in mean lumen (? 10.0%, p = < 0.001) and scaffold areas (? 15.7%, p = < 0.001). Serial OCT demonstrated a significant increase in scaffold area (? 16.9%, p = < 0.001) with 98.8% neointimal coverage of the scaffold at 6 months. Twelve-month MSCT demonstrated lumen maintenance from 6 to 12 months. QCA at 18 months showed minimal lumen change and 3 year OCT imaging revealed the “golden tube” indicating complete resorption of the scaffold. Clinical events remained low (MACE = 5.7%, 7.4%, 8.2% and 9.0% at 12, 24, 36, 48 months, respectively) with no reports of definite scaffold thrombosis.

CONCLUSIONS

DESolve demonstrated safety and efficacy with low late lumen loss. Serial imaging indicated early vessel

restoration at 6 months. Through 48 months, the clinical event rates remain low. Full imaging data from 6, 18 and 36 months as well as final 5-year clinical results will be presented.

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30-day mortality predictors in a high-risk population of patients with complex coronary artery disease treated with PCI and percutaneous mechanical circulatory support

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

Increasing number of patients with complex coronary artery disease (CAD) present high-risk features that are unsuitable for surgery. Such high-risk percutaneous coronary interventions (PCI) may benefit from percutaneous mechanical circulatory support (pMCS), as Impella and veno-arterial extracorporeal membrane oxygenation (V-A ECMO), especially in patients with cardiogenic shock (CS) or cardiocirculatory arrest (CA). The aim of this study was to evaluate clinical and hemodynamic predictors of 30-days mortality in a cohort of high-risk patients with CAD undergoing PCI under pMCS.

METHODS AND RESULTS

All the consecutive patients who underwent a protected PCI with pMCS, due to complex CAD associated with hemodynamic instability, were enrolled in our prospective single center registry from July 2007 to December 2018. Thirty-eight patients (82% male, mean age 69,6±11,5 years; mean left ventricle ejection fraction 29,3±8,1%) were enrolled. ACS was the admission diagnosis in 87% of cases, of which 51% STEMI. Chronic ischemic cardiomyopathy was present in 18 (47%) patients. Twenty-one patients (54%) presented severe hemodynamic instability at the admission (26% CS and 28% CA), requiring V-A ECMO, Impella CP and Impella 2,5 in 11 (29%), 4 (11%) and 26 (68%) patients, respectively. Two patients received both Impella and V-A ECMO support. All patients presented critical multivessel and/or left main CAD (mean SYNTAX score 32±13%); BCIS Jeopardy score 10,3±3). Eighty-seven percent of the patients presented lesions in the left main or in the proximal tract of the anterior descending coronary artery. The use of the Rotablator was deemed necessary in 9 (24%) patients and 19 were complex bifurcations. An average of 2,2±1 vessels per patients were treated. Complete revascularization was achieved in 21 (56%) of the patients. Multiple mortality risk scores were calculated in the overall population (GRACE score 178±38,5; Additive EUROSCORE 17±9,5%; EUROSCORE II 18±13%; ACEF Score 2,6±0,9; Clinical SYNTAX Score 114,3±86,8; SYNTAX Score II 48,5±12%). Our high-risk cohort of patients presented mortality rates in line with the calculated risk scores, 7 (18%) patients died within 30-days, while other 4 patients died within one year post-procedure. Cardiac arrest at the admission and post-procedure incomplete revascularization were found to be predictors of 30-days mortality (HR 7,3 95% CI: 0,1-0,9; p=0,017 and HR 9,1 95% CI: 0,013-0,92; p=0,042 respectively).

CONCLUSIONS

In our population of high-risk patients, pMCS helped in performing PCI with a good in hospital survival and rate of complete revascularization. The presence of cardiac arrest at the admission and an incomplete revascularization correlate with 30-days mortality, regardless of the type of pMCS used; therefore, efforts should be focused on tight follow-up, considering additional interventions after discharge.

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Left circumflex coronary in Cardioband transcatheter mitral direct annuloplasty: is it a real issue? A pre- and post-implant CT analysis

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair

AIMS

One of the main limitations of the Cardioband implant is the close course of the circumflex coronary artery (Cx) in the region between the anterolateral commissure and the posterior segment of the mitral annulus corresponding to p1, given the risk of impingement. The aim of the study is to compare the pre- and post-implantation course of the circumflex artery in this particular region, in systoles and diastoles, by CT scan analyses.

METHODS AND RESULTS

A total of 11 patients with severe functional MR (mean age 73 ± 9.2 years, 65% men) who underwent CT prior and post transcatheter direct mitral annuloplasty with Cardioband were evaluated. A minimun distance of 4 mm (from left ventricular endocardium to the anchor) with an angle of anchor's penetration of 45° was set in these patients during CT analyses. The minimum distance from the projected anchor to Cx was measured, in end-systole and end-diastole, analysing every 30° several points occurring from the anterolateral commissure to the end of the P1 region, in a counterclockwise fashion.

In 10 out of 11 patients a right coronary dominance was present. The narrowest course of the Cx from the projected anchor was found during diastole, at the initial and middle portion of P1 segment, with a minimal distance of 3.95 mm (IQR 2.9-5.6). Median Cx excursion in P1 between systole and diastole was 1.85 mm (IQR 1.1-2.3). At the level of the anterolateral trigone minimal distance of Cx from the projected anchor was 5.9 mm (IQR 4.7-8.1), with Cx displacement of 0.7 mm (IQR 0.4-1.3). In Cardioband's pre- and post-implant CT analyses comparison, the mean distance of Cx from the projected anchors increases of 3.3 ± 0.5 mm in systole and of 2.5 ± 0.2 mm in diastole. These measurements were reproducible in all patients, regardless of left coronary dominance.

CONCLUSIONS

This is the first systematic dynamic CT study reporting the distance and displacement of the Cx during the cardiac cycle, comparing pre- and post Cardioband implantation. The narrowest areas of Cx in correspondence of P1, embedded in epimyocardial tissue, increases its distance from the anchors after Cardioband cinching, when compared with baseline. This reveals a potential negligible risk of coronary impingement with Cardioband transcatheter mitral direct annuloplasty.

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Characterisation of neoatherosclerotic tissue inside coronary stents in patients with ACS caused by in-stent restenosis

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

According to recent data, development of neoatherosclerotic tissue inside the implanted coronary stens could be responsible for triggering acute coronary events resulting from stent thrombosis. The aim of this study was to compare the characteristics of the neoatheromatous plaque evidenced by Multislice Angio Computed Tomography, Optical Coherence Tomography (OCT) and Virtual Histology Intravascular Ultrasound (VH-IVUS) with the characteristics of de-novo lesions in native coronary vessels of patients with ISR.

METHODS AND RESULTS

In total, 25 patients with coronary BMS presenting with acute coronary syndrome (medium age 61.26 +/- 11.3, 56% females) were included in the study, in whom 25 ISR lesions and 39 de novo lesions were identified and analysed using angio CT, IVUS and OCT.

Results: From the total population, 56% were dyslipidemic, 44% were smokers, 32% were obese, 36% were hypertensive and 32% diabetic. At CT examination, 48% of ISR lesions had unregular shape compared with 25.6% from de novo lesions. ($p=0.006$, OR=2.67, %CI:0.92-7.7). By OCT, ISR lesions were heterogenous in 24% compared to 15.3% heterogenous de novo lesions ($p=0.05$). At VH-IVUS examination, necrotic core was 22.92+/-5.14 mm3 in ISR lesions compared to 11.10+/-4.93 mm3 in de novo lesions ($p<0.0001$). Similarly, plaque volume was 34.76+/-8.76 mm3 in ISR lesions, significantly higher than plaque volume in de novo lesions, which was 17.41+/-5.45 mm3, $p<0.0001$.

CONCLUSIONS

In case of ISR restenosis with clinical presentation as acute coronary syndrome, ISR lesions a distinct pattern which is similar to the one of vulnerable coronary plaques. Vulnerability markers are significantly more expressed in neoatherosclerotic tissue as compared to de novo lesions in native vessels of the same patients.

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Decrease of coronary shear stress following implantation of BRS - First results of a one-year follow-up pilot study

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Coronary shear stress (CSS) has been recently recognized to play a significant role in coronary plaque progression and vulnerabilisation. However, the evolution of CSS after implantation of different types of coronary stents is still under investigation. The aim of this study was to assess the evolution of the CSS along the coronary lesions following implantation of bioabsorbable vascular scaffolds (BVS), in order to assess the impact of BVS on coronary flow haemodynamics.

METHODS AND RESULTS

This was a single center prospective pilot study which enrolled 15 patients (aged 58.35 +/- 7.79 years, 13 males) with coronary artery disease undergoing BVS implantation in a major epicardial vessel. In all patients, angio CT scanning (Siemens Somatom Sensation scanner, Erlangen, Germany) was performed prior to the BVS implantation and repeated after 12 months. Plaque analysis was performed using the QAngioCT RE software (Medis, Netherlands) and coronary shear stress was calculated using computational fluid dynamics analysis by Wall Shear Stress Computation in Coronary Arteries software. All shear stress calculations was performed at baseline and repeated after 1 year. Average CSS was determined proximal, distal and at the level of minimal lumen area (MLA). Average CSS along the stented segment significantly decreased after BVS implantation, from 2.87 +/- 1.64 Pa at baseline to 1.9 +/- 0.49 at 1 year (p=0.0001). Maximum CSS along the segment also exhibited a significant decrease, from 11.78 +/- 10.06 Pa to 6.35 +/- 3.08 Pa (p=0.0009). At the level proximal to the MLA, CSS significantly decreased after BVS implantation, from 3.39 +/- 1.93 Pa at baseline to 1.91 +/- 0.68 Pa at 1 year (p<0.0001). However, this decrease in SCS was not significant at the level distal to MLA (1.3 +/- 0.72 Pa vs 1.59 +/- 0.65 Pa, p=0.9).

CONCLUSIONS

Implantation of BVS leads to a significant decrease of CSS after 1 year, which is especially encountered at the segments located proximal to the stenosis. This underlines the role of BVS in re-establishing a physiological pattern of coronary flow after implantation in diseased coronary vessels.

The feature (mentioned herein) is not commercially available. Due to regulatory reasons its future availability cannot be guaranteed.

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Percutaneous treatment options after failed surgical mitral repair

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair

AIMS

Surgical mitral repair remains the gold standard for patients with degenerative mitral regurgitation (MR). For patients at high surgical risk, percutaneous repair with the MitraClip may be considered. There is no guidance on how to manage patients with previous surgical mitral repair with recurrent severe MR. This group is usually high risk for redo surgery due to previous sternotomy and coexisting comorbidities.

We present a series of patients with severe MR after surgical mitral repair who underwent transcatheter mitral valve-in-ring (TMVIR) or valve repair with the MitraClip device.

METHODS AND RESULTS

Patients with previous surgical mitral repair including implantation of an annuloplasty ring with recurrent symptomatic severe mitral regurgitation who underwent percutaneous intervention at our institution were included in this analysis. Choice of therapy was at the discretion of the operator. Baseline, procedural, discharge and 30-day echocardiography and outcome data were collected.

For patients undergoing TMVIR, the Sapien 3 valve was used and sizing was determined using TEE and CT measurements, including prediction of the neo-LVOT area (minimum 250mm2 for this technique to be considered). The implantation itself was carried out using femoral venous access and a transseptal approach under TEE guidance. For patients undergoing the MitraClip procedure, this was carried out in the standard fashion, via the femoral vein and a transseptal approach.

Between 2015 and 2018 26 patients with previous surgical mitral repair and recurrent severe MR underwent percutaneous mitral intervention; 9 (35%) patients had TMVIR and 17 (65%) had valve repair with the MitraClip device. The procedure was completed successfully in all patients.

In the TMVIR group, the device used was the Sapien S3 in 8 (89%) patients and the XT in one (11%) patient. Five patients required deployment of a second valve due to paravalvular leak. There was no valve embolization. One patient (11%) required redo surgery within 30 days due to haemolysis after TMVIR, and subsequently recovered without further complication. One patient (11%) died within 30 days due to multi-organ failure.

In the MitraClip group, median number of clips was 1 (range 1-3) and median mean mitral gradient at the end of the procedure was 3 (range 1-7). 13/17 patients had post procedure mitral gradient ≤5 mmHg. Two patients required closure of iatrogenic ASD. No patients died within 30 days.

Comparing the two groups, baseline characteristics were similar. Mean left ventricular ejection fraction was 47% and 53% in the TMVIV and MitraClip groups respectively (p=0.46) with 44% and 29% having LVEF ≤

40%. Baseline mean mitral gradient was 5.4 vs. 4.3 mmHg (p=0.17). Time since mitral valve surgery was 6.3 vs 5.9 years (p=0.83) and median size of annuloplasty ring was 29 vs. 32 mm (p=0.02). On discharge TTE 88.9% of patients in the TMVIR group had mild or less residual MR versus 76.5% in the MitraClip group. Mean mitral gradient was 6.9 in the TMVIR group versus 4.9 mmHg in the MitraClip group (p=0.04).

CONCLUSIONS

TMVIR and MitraClip can be considered to treat patients with recurrent severe MR after surgical mitral repair. Both technologies offer an acceptable reduction in MR. Choice of procedure should depend on valve characteristics, particularly baseline mitral gradient, and local procedural expertise.

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Cryoablation method for pulmonary artery sympathetic denervation in patients with pulmonary hypertension secondary to left-sided heart disease

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THEME: Interventions for Hypertension
TOPIC(S): Other hypertension

AIMS

To study the influence of innovative pulmonary denervation cryoablation method on pulmonary artery pressure in patients with pulmonary hypertension secondary to left sided heart disease.

METHODS AND RESULTS

Materials and methods. 15 patients with pulmonary hypertension were included in the study. The procedure of pulmonary artery cryodenervation was performed at the bifurcation level of the main pulmonary trunk using single-point cryoablation catheter. The cryoablation was applied in a circular way around the pulmonary trunk at the bifurcation level, rotating the catheter tip with the pace of 2 mm with temperature minus 80°C and time 120 s at each spot. The study endpoints were the changes in systolic pulmonary artery pressure, mean pulmonary artery pressure, pulmonary vessel resistance and 6 min walking test before and immediately after procedure.

Results.We analyzed intermediate results of sympathetic fibres cryodestruction, located in the bifurcation of main pulmonary trunk. The mean systolic pulmonary artery pressure decreased from 40±8 to 31±4 mm Hg ($p<0.01$), pulmonary vessel resistance decreased from 5.7±2.1 to 3.8± 2.5 WU ($p<0.01$) and improvement of 6 min walking test from 269±73 to 305±55 m ($p<0.01$) was observed. There were no cases of early deaths and specific complications.

CONCLUSIONS

The cryoablation pulmonary denervation is a new promising treatment in patients with pulmonary hypertension. First clinical results demonstrate the safety of this procedure. Further randomized studies are required to confirm the efficacy of this procedure.

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Behavioral determinants for the adoption of FFR and iFR physiological assessment technologies

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Background: Assessment of physiological significance of coronary stenosis with FFR or iFR is recommended (class I A). However, adoption of coronary physiology techniques in determining appropriateness for revascularization is poorly adopted. Global estimates suggest that half of all patients undergo a PCI without proof of physiological severity. Currently, clinical implementation of FFR or iFR flow techniques is stagnant at 11%.

Aims: Our principal aim was to assess physician level behavioral factors that influence their adoption of coronary physiology techniques in practice.

METHODS AND RESULTS

Methods: Using the Theoretical Domains Framework (TDM) developed by Michie and colleagues, we developed a survey instrument. TDM encompasses information of 33 behavior change theory constructs divided into 12 behavioral factor domains that explain human behavior. The survey developed included 23 targeted questions to explain the behavior of physicians culled from 11 of 12 relevant domains. The behavioral determinants were analyzed by factor analysis, in an effort to assess correlations of multiple outcomes as one factor. Regression analysis was used to define variance in the adoption rate, a function of the behavioral factors defined in the factor analysis. The influence of experience, demographics and provider structures were also tested as variables correlating with adoption.

Results: Of 150 surveys requested, 93 interventional cardiologists completed the survey. Participation was international, however Germany (15.4%), Italy (11.5%), and UK (21.2%) led the country lists of response. The predictor variables Ease, Constraints, and Recommendation together explain 30% ($p<0.001$) of the variance in the adoption rate. Ease is defined by efficiency, confidence in skillset, behavior and memory. Recommendations refer to the knowledge of the clinical practical guidelines. The only significant (negative) driver on the motivation to adopt coronary physiology is Constraints which is defined by the question: ‘No incentives available’. Demographic, experience or provider structure factors have no significant correlation with the adoption rate. Interestingly, it was expected that eminence would play a role in the non-acceptance of coronary physiology techniques, however this study suggests differently.

CONCLUSIONS

Conclusion: This study proves that Ease and Recommendations positively, and Constraints negatively, influences the adoption rate of FFR/iFR. More research is required on behavioral drivers to ensure the acceptance of evidence based practice.

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LAA occlusion: to tug or not to tug?

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THEME:
TOPIC(S):

AIMS

Left atrial appendage occlusion, a percutaneous stroke prevention technique for atrial fibrillation patients, sometimes involves a “tug test,” in which implanters pull on the delivery cable used to place the device to ensure stable device placement. Since current clinical knowledge of the benefit and safety of this test remains unclear, the aim of this study is to evaluate the use of the tug test, by comparing the forces exerted on the device during deployment and subsequent tug test.

METHODS AND RESULTS

The AMPLATZERTM Amulet device was used for occlusion (Abbott). The device consists of a lobe, which inserts into the left atrial appendage neck, and a disc, which seals the entrance to the appendage from the atrial side of the heart. Forces were measured during device placement in six patients. A bending beam force transducer coupled to a clamp was used to record forces in the delivery cable during deployment and subsequent tug test. Maximum average force was compared during deployment and tug test. Analysis of data showed device disc unfolding forces exceeded tug test forces ($p=0.01$, two-tailed, paired t-test), implying that the tug test is not necessary to validate stability and may only increase risk of tissue damage or device embolization. Additional patient studies will be performed using a variety of device sizes to examine trends across the available size range of the AMPLATZERTM Amulet device.

CONCLUSIONS

To date, there remains disagreement among LAA implanters in regard to the necessity of the tug test, and this data clarifies existing recommendations. This study demonstrated that the forces on the Amulet device during implantation in patients were consequently higher during disc deployment than during the tug test. These observations suggest the tug test to be unnecessary for stability testing.

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STEMI - Makes a difference being a woman?

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS
Introduction: ST elevation myocardial infarction (STEMI) in women has been associated to poor prognosis in several studies and records.

Purpose: Evaluate the differences of STEMI treatment between men and women and to assess the impact of the female sex (FS) in prognosis

METHODS AND RESULTS
Methods: Retrospetive and multicenter study, based on a national register from 30/10/2010 to 09/19/2017. All patients with STEMI were included. Two groups were established, men and women. It was carried out univariate and multivariate analysis of clinical history, hospitalization dat and treatment strategies.

Results: Analysis identified 6757 patients, 5094 men (75.4%) and 1663 women (24.6%).
Women, comparing with men, had higher age (70vs61years, p<0.01), were less frequently: pre-hospital medical transport, admission by STEMI network and admission directly in the catheterization laboratory (cath lab). Women were less frequently subjected to reperfusion therapy (76.5%vs85,1%, p<0.01), had higher times symptoms-balloon and door-to-balloon (D-B). In coronary angiography radial access coronary was used less often and women were submitted to coronary angioplasty (PCI) with less frequently than men (80.4%vs89,2%, p<0.01). The left ventricular ejection fraction (LVEF) <50% was more frequent in women and the rate of complications (intra-aortic balloon, temporary pacemaker, mechanical ventilation, congestive heart failure (HF), cardiogenic shock, atrial fibrillation, mechanical complication, AV block and major bleeding).

FS was associated to an increase in intra-hospital mortality (IHM) (9,2vs3,8%, p<0.01), stroke (1.8%vs0,5%, p<0,01) and MACE (composite endpoint: IHM, re-infarction, nonfatal stroke (11,2%vs5,0% p<0.01).
In multivariate analysis the FS was not an independent predictor (IP) of IHM (p=0.6; OR 0,73-1,75), MACE (p=0.4; 0.81-1.67), HF (p=0.2; OR 0,94-1,40), re-infarction (p=0.5; OR 0,33-1,70), and LVEF <50% (p<0.01; OR 1,99-8,66) and was IP of stroke (p<0.01; OR 1,99-8,66).
FS was IP to not be admitted by STEMI network (p<0.01, OR 0,58-0,79), not be admitted directly in the cath lab (p=0.03, OR CI 0.73-0.98), had a time D-B >90min (p<0.01, 1.07-1.47), anddo not perform reperfusion (p=0.04, 0.70-0.99) and PCI (p<0.01, 0.44-0.83).

CONCLUSIONS
Conclusions:
In patients with STEMI:
- Female sex was associated with worse prognosis and greater number of complications.
- Female sex was not a IP of poor prognosis (death, MACE, re-infarction, HF, LVEF<50%), except for the increase rate of stroke.

- Being women was IP to not be admitted by STEMI network, not be admitted directly in the cath lab, had a time P-B >90min and do not perform reperfusion and PCI. All these factors known to negatively influence the prognosis of STEMI.
- In this study, we can conclude that in this population the worst prognosis associated with female sex is not due to the genre itself, but the worst treatment given to women with STEMI.

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Long-term clinical outcomes of elderly Korean patients with multivessel disease who underwent PCI with DES

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease

AIMS

Percutaneous coronary intervention (PCI) for multi-vessel disease has been widely used as a revascularization option for elderly patients with development of contemporary drug-eluting stents (DES). However, there are limited data regarding long-term clinical outcomes following successful PCI in elderly Korean population.

METHODS AND RESULTS

A total of 942 patients underwent PCI ≥ 2 vessels were included. Patients were divided into two groups; 1) <70 years group (N=648) and 2) >70 years group (N=294). Individual and composite major clinical outcomes including major adverse cardiac events (MACE), the composite of total death, myocardial infarction (MI), repeat revascularization and stent thrombosis were compared between the two groups up to 5 years.
Results: At 30 days follow up, >70 years group had signficantly higher incidence of total death (HR: 5.077, 95% CI: 2.207 to 11.676; p < 0.001), cardiac death (HR: 4.182, 95% CI: 1.669 to 10.483; p = 0.002), revascularization (HR: 3.466, 95% CI: 1.724 to 6.968 ; p = 0.000) and all MACE (HR: 3.384, 95% CI : 1.721 to 6.654; p = 0.000) than <70 years group (Table 1). Using multivariate logestic regression, and after adjusting for potential risk factors, there was no significant difference between two groups in all MACE (HR: 1.430, 95% CI : 5.104 to 0.965; p = 0.582). At 1 year follow up, >70 years group had signficantly higher incidence of total death (HR: 3.268, 95% CI: 1.684 to 6.339; p = 0.000), cardiac death (HR: 2.519, 95% CI: 1.150 to 5.522; p = 0.021), however no significant difference between two groups in MACE (HR: 1.275, 95% CI : 0.888 to 1.829; p = 0.188). At 5 years follow up, >70 years group had signficantly higher incidence of total death (HR: 2.715, 95% CI: 1.446 to 5.095; p = 0.002), cardiac death (HR: 2.776 , 95% CI: 1.200 to 6.427; p = 0.017), however no significant difference between the two groups in all MACE (HR: 1.095, 95% CI : 0.818 to 1.465; p = 0.542).

CONCLUSIONS

Elderly (>70 years) Korean patients with multivessel disease treated with DESs showed a higher incidence of total death and cardiac death than younger patients. However, there was no significant difference in MI, revascularization and all MACE between the two groups up 5-year follow up.

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A prospective single-centre registry, evaluating real-world usage of the AXXESS bifurcation stent: procedural success and long-term clinical outcomes

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

Percutaneous Coronary Intervention (PCI) for coronary bifurcation lesions (CBL) remains hampered by suboptimal results, mainly in the side branch (SB), even with the use of drug-eluting stents (DES). AXXESS is a self-expandable dedicated bifurcation stent having a unique design allowing scaffolding of SB ostium and gives the flexibility of both provisional and two stent approach. It has been reported to have favourable medium term outcomes. We assessed in a prospective all comers' single centre registry, long term (mean FU 3.9 years) safety and efficacy of the AXXESS stent.

METHODS AND RESULTS

Methods: Data was evaluated from our centre's prospective AXXESS registry from November 2013 to July 2017. The procedural data was obtained from British Cardiac Intervention Society database, clinical follow up obtained from electronic hospital data base and mortality information from the Welsh Demographic national statistics database. Primary endpoint was device oriented composite endpoint (DOCE: combination of cardiac death, MI and TLR/TVR). Secondary endpoints were technical (successful AXXESS implantation) and procedural success (successful procedure with AXXESS without in-hospital MACE).

Results: 43 patients had AXXESS stents implanted in our centre, with mean follow up of 3.9±1.1 years (minimum 18 months, maximum 5 years). Mean age was 62+/-10 years, 67% were men, 14% had moderate to severe LV dysfunction, 14% had DM and 44% had past MI. Indication for PCI was predominantly ACS (69%) with 97% of the procedures performed via radial access. 95.4% of the lesions were true bifurcations (MEDINA 1,1,1 / 1,0,1 or 0,1,1) with LAD/Diagonal bifurcation being the commonest (79%). This was 1 case of coronary perforation leading to tamponade that was successfully managed. Post-PCI no further in-hospital MACE was documented. Technical and procedural success was achieved in 97.6% of patients. All-cause mortality at end of follow up years was 2.3 % (cardiac death 0%, non-cardiac death 2.3%). Cumulative DOCE was 6.9 % (non-hierarchical events: cardiac death 0 %, MI 4.6%, stent thrombosis 2.3% and TLR/TVR 4.6%). Landmark analysis beyond 1 year revealed 1 possible TV-MI but no stent thrombosis, TLR or TVR.

CONCLUSIONS

In the real world setting in a single -centre registry the use of the AXXESS dedicated bifurcation stent is associated with good technical and procedural success along with long term clinical results with no very late stent thrombosis and no TLR beyond 12 months.

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DynamX novolimus-eluting bioadaptor - Engineering design and pre-clinical evaluation of an innovative device that adapts to patients' physiology, for PCI treatment of coronary artery disease

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Drug Eluting Stents (DES) are the mainstay in coronary artery disease treatment. The DynamX Bioadaptor System is a novel, thin strut bioresorbable polymer coated drug eluting bioadaptor releasing Novolimus, a macrocyclic lactone mTOR inhibitor with anti-proliferative properties. The DynamX Bioadaptor offers the acute performance of a current generation DES and with its uniquely designed uncaging elements offers the potential advantages of minimizing compliance mismatch and geometric distortion, providing physiologic coronary pulsatile motion and supportsearly adaptive remodeling.

METHODS AND RESULTS

The DynamX Bioadaptor contains a drug dose of 5 µg of Novolimus per mm of bioadaptor length with device availability in multiple diameters (2.5 – 3.5 mm) and lengths (14, 18 and 28 mm). The device was evaluated on the bench for acute performance as compared to the 2nd Gen DES, assessed for conformability and geometric distortion pre and post uncaging of the device, and flexibility to improve fracture resistance. In vivo safety was assessed following implantation in a porcine coronary artery model.

Bench data showed that the acute performance of the DynamX bioadaptor matched with that of the 2nd Gen DES. Long term in vivo safety was evaluated post uncaging by OCT imaging and histopathology.

CONCLUSIONS

The DynamX Novolimus Eluting Coronary Bioadaptor System is a novel medical device which combines the acute attributes of metallic DES with longer term attributes of normal vessel compliance and pulsatile motion and supporting early adaptive remodeling for a more complete revascularization. Bench acute performance data and long term in vivo safety data in a preclinical model will also be presented.

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Durability of stroke prevention using routinely the MicroNet-covered embolic prevention stent system to perform carotid revascularisation in symptomatic and increased stroke-risk asymptomatic patients: three-year clinical and duplex evidence

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THEME: Interventions for Stroke
TOPIC(S): Carotid stenting

AIMS

We aim to provide long-term clinical (including neurologic) and duplex ultrasound (DUS) evaluation of the CGuard embolic prevention stent system (EPS) routine use to perform CAS in all-comer (no exclusion criteria) patients with symptomatic or increased-stroke-risk asymptomatic carotid stenosis recommended for revascularization by the NeuroVascular Team (neurologist + angiologist + vascular surgeon + cardiologist) in a large cohort of consecutive CAS patients.

METHODS AND RESULTS

PARADIGM-Extend is a non-industry-funded, prospective academic study in all-referrals-tracked symptomatic and asymptomatic carotid stenosis. Independent neurologist evaluation and DUS are performed before CAS, at 48h, 30 days, and then every 12 months. There is external source data verification, external angiographic corelab, and external statistical analysis.

Currently 325 patients (48-87 years, 54.2% symptomatic) with 344 arteries recommended for revascularization by the NeuroVascular Team crossed the trial first follow-up window. There has been 100% CGuardEPS use. Angiographic diameter stenosis was reduced from 84±8% to only 6.9±5% ($p<0.001$, 'CEA-like' effect of CAS).

Peri-procedural death or major stroke rate was 0%. One event (extension of prior cerebral infarct on imaging, in a patient with prolonged hypotension) with no change in NIH-SS or Rankin scale and no clinical sequel, was Clinical Events Committee-adjudicated as minor stroke (0.3%), and there was one (type2) MI (0.3%). By 30 days there was one haemorrhagic transformation of prior ischaemic cerebral infarct leading to death (0.3 %) and one bleeding-related death (0.3%). Thus total death/major stroke/minor stroke rate at 30 days was 0.9%, and total death/major stroke/minor stroke/MI rate at 30 days was 1.2%.

At 1- 12 months were no strokes or stroke-related deaths (0%). At 12-24 months there was one cerebellar stroke in an AFib patient that was confirmed on MRI imaging but no carotid-territory stroke or stroke deaths (0%).

By 12 months there was one asymptomatic in-stent restenosis that was treated with drug-eluting balloon angioplasty and one clinically silent stent occlusion in a patient who initiated neck radiotherapy course 2 months after CAS due to cancer relapse. External carotid artery patency rate was normal at 98.6% prior to CAS, 97.1% post CAS and at 30 days, and 96.9% at 12 months.

By 24 and 36 months there was one posterior circulation (cerebellal) infarct but no cerebral infarctions.

Post-procedural in-stent velocities were normal and remained normal throughout the 36-month follow-up period (peak-systolic/end-diastolic velocity 0.69±0.29/0.18±0.09 m/s at 30 days, 0.82±0.47/0.22±0.13m/s at 12 months, 0.73±0.31/0.19±0.09m/s at 24months and 0.80±0.31/0.21±0.11 at 24months), indicating normal device healing and lack of any device-related issues.

CONCLUSIONS

PARADIGM-Extend accumulating 36-month clinical and DUS evidence is consistent with unprecedented, sustained safety and cerebral embolism prevention efficacy of the CGuard™ MicroNET-covered embolic prevention stent system used routinely for stroke prevention in symptomatic and increased-stroke-risk asymptomatic subjects with carotid stenosis.

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Experimental investigation of local flow dynamics in the vicinity of jailed stent struts using a left main coronary bifurcation model

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds, Bifurcation lesion

AIMS

Presence of stent struts over the flow tract of the left circumflex artery (LCx) ostium at left main bifurcation is a concern for future thrombus formation, neointimal formation, and late narrowing of the LCx ostium. The aim of this study is to investigate factors inducing larger incomplete stent apposition (ISA) areas at the flow tract of LCx ostium, and to investigate local flow dynamics potentially influenced by the presence of jailed stent struts at the LCx ostium after a single stenting plus kissing balloon inflation (KBI) using a left main coronary bifurcated artery model

METHODS AND RESULTS

A left main coronary bifurcation model with the diameters of 4.3 mm at left main trunk (LMT) artery and 3.3 mm at left anterior descending artery (LAD) and 3.0 mm at LCx ostium were fabricated using slicone. The diameters of these arteries meet the Murray's law. We used the mean left main bifurcation angle data from 209 de novo patients who underwent 64 multi-slice computed tomography. The angles between LMT and LAD, and between LMT and LCx were 141° and 122°, respectively. A 80 % stenosis was equipped along from the LMT to the LAD. The flow tract from the LMT to the two distal bifurcated arteries was angled 10°. Stent deployment procedures were conducted in the catheterization laboratory under the angiography. Ultimaster (n=6) and Xience Alpine stents (n=6) with 3.5/18 mm were used. After single stent deployment along LMT-LAD, proximal optimization technique and simultaneous kissing balloon inflation (KBI) were conducted. The incomplete stent apposition area (ISA) formed between the jailed stent struts and LCx ostium was investigated using a micro CT, and the ISAs were compared between the two stents. To investigate influences of the jailed struts on local flow dynamics, flow visualization study was conducted using particle image velocimetry. In the bifurcation models where stents were deployed as described above, a physiologic flow waveform with a smaller peak in the systolic phase and a larger peak in the diastolic phase under the mean flow rate of 60 mL/min and an aortic pulse pressure of 120/80 mmHg were duplicated. The ISA areas of Ultimaster was smaller than those of Xience Alpine stents (0.59±0.40 mm2 vs 1.50±0.43 mm2: $p<0.01$). At the ISA regions, links of the stents were always protruded into the flow tract of LCx ostium in the Xience Alpine stents (6/6), whereas those were present in 3/6 in the Ultimaster stents. It was suggested that the number of links of the stent design influenced the occurrence of the protrusion of the links into the flow tract. The protrusion induced the larger ISAs as compared with those without the link protrusion ($p<0.01$). Flow study revealed that the jailed struts altered flow velocity field at the LCX ostium and decreased flow velocity in the vicinity of the jailed struts. Distinct slow flow regions were observed behind the jailed struts. Compared with the carina side, influences of jailed struts on the flow velocity reduction was distinct in the LCx shoulder side

CONCLUSIONS

Our data indicated that protrusion of the stent links into the flow tracts was a primal factor inducing the

incomplete stent apposition. The flow study revealed the presence of the abnormal slow flow regions behind the protruded stent struts, which may become a potential source of thrombus formation. Further study is needed for finding better technique or designing a bifurcation-specific stent in the left main bifurcation.

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Early experience of right transaxillary TAVR with the SAPIEN 3 valve using the "Flip-n-Flex" technique

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Transaxillary transcatheter aortic valve replacement (TAx-TAVR) is less invasive compared to other alternative access routes. Right TAx-TAVR is rarely performed due to challenging vascular tortuosity and unfavorable implantation angle, particularly with balloon-expandable valves. We explored right TAx-TAVR approach with the SAPIEN 3 valve and developed a simple technique, 'flip-n-flex' maneuver, to facilitate device insertion and coaxial valve alignment (Eurointervention, Epub ahead of print). The safety and effectiveness of the 'flip-n-flex' technique was investigated.

METHODS AND RESULTS

Methods: We have performed our first 10 right TAx-TAVR cases from 2016 to 2018 using the SAPIEN 3 valve. Patients' preoperative characteristics, intraoperative fluoroscopy times, procedural outcomes, and clinical outcomes were studied. Data were presented as mean ± SD and as percentages for continuous and categorical variables, respectively. Intergroup comparison was performed using Student's t test for continuous variables.

Results: Mean age of the patient cohort was 81.8 ± 8.7 years and 5/10 (50%) patients were female. Mean STS-PROM was 12.0 ± 9.5%. Access conversion was 0%. Procedural success was achieved in 100% of cases. Vascular complication was 0%. Paravalvular leak was absent or mild in all patients. Two patients required permanent pacemaker implantation (2/10, 20%). The median post-operative hospital stay was 4 days (range 2-13 days). The 30-day mortality was 0%. There was a reduction in mean transvalvular gradient from 38.4 ± 12.6 mmHg preoperatively to 9 ± 4.4 mmHg postoperatively (P< 0.001). Patients' symptoms were all improved according to the New York Heart Association (NYHA) classification. Fluoroscopy times decreased from 38.3 and 49.9 minutes of the first 2 cases to an average of 17.4 ± 2.9 minutes for the rest of cases (n=8). The decrease in the fluoroscopy time correlated with the use of the "flip-n-flex" technique. With the use of optimal operative techniques, the fluoroscopy time of right TAx-TAVR was similar to that of left TAx-TAVR performed in the study period (P=0.128).

CONCLUSIONS

Conclusions: Our early experience of right TAx-TAVR using the SAPIEN 3 valve demonstrated the technical feasibility of this approach. The "flip-n-flex" technique attributed to our steep learning curve as exhibited by the reduction in fluoroscopy time. With technical refinement, right axillary/subclavian approach has the potential for a broader use as an alternative TAVR access.

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VSD endovascular closure with a new multifunctional device

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THEME: Interventions for Valvular Disease
TOPIC(S): Other valvular and structural interventions

AIMS

Transcatheter ventricular septal defect (VSD)closure is an effective, safe and challenging procedure. The multifunctional occluder is a new soft woven mesh self expanding device with two discs joined by an articulated waist wich can be either anterogradely or retrogradely positioned.
Our purpose is to asses the feasibility use of this device as well as the short and mid-term results of Gerbode's perimembranous VSD closure with the multifunctional occlude

METHODS AND RESULTS

From october 2017, 23 patients with perimembranous and muscular VSD have been included to perform endovascular closure with the multifunctional device. All patient were >2,5kg in weight and had clinical VSD closure indication, 4 of them had left ventricle-right atrium residual post surgical closure shunt. The procedures were guided by trans thoracic or transesophageal echocardiography(TEE).
VSD closures have been performed in 22 of 23 patients. Three patients weighed less than 5kg and had associated complex congenital heart diseases. Median age 12,67 years (1,11 to 37 years); weight 39,96kg (3-89kg). VSD type were 16 perimembranous and 7 muscular. Gerbode type were 4 of them with residual post surgical shunt because of aneurysm with 2 right orifices or detached patch.The waist device diameter was 2 mm larger than the maximum diameter of the right orifice of the defect. The average of right waist was 5,07mm (+-1,52) the left waist was 7,07mm(+-1,52). The most frequently size used was 7-5.The multifunctional device was implanted in anterograde way in 3 Gerbode type VSD and in retrograde way in one.
Procedures were succesful in 22 of 23 patients with trivial or not residual (95%). The failed procedure was in a large muscular VSD but transient AV Block was present.
The average follow up was 6,8 months (1 to 15 month). Neither residual shunt, AV block, hemolysis nor any other major complication were observed.

CONCLUSIONS

VSD closure using the multifunctional occluder is feasible in both congenital and residual postoperative VSD even in Gerbode VSD type. It offers more options in terms of approaches of different types of VSD and allows closure of large defects even in low weight patients.
There will be necessary longer follow up to let us know more details.

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Homemade coronary incidences simulator

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Predictors of suboptimal post-PCI FFR from pre-PCI OCT characteristics

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THEME: Coronary Interventions

TOPIC(S): Stents and scaffolds, Other Coronary Interventions

AIMS

Post-percutaneous coronary intervention (PCI) functional assessment has been shown to have prognostic significance with a higher post-PCI FFR correlating with better clinical outcome. In this study, we sought to investigate the impact of vessel and plaque characteristics from pre-PCI OCT on post-PCI FFR.

METHODS AND RESULTS

165 lesions (164 patients) treated with a DES, evaluated with pre- and post-PCI OCT and FFR were included from an anonymized imaging database at the cardiovascular imaging core laboratory. Two independent readers did all imaging analysis. The lesions were divided into 2 groups using a post-PCI FFR cutoff of <0.86, in keeping with published data, resulting in¬†36 lesions in the suboptimal FFR (FFR<0.86) and 129 lesions in the optimal FFR group (FFR,â•0.86). Patient demographics, clinical parameters, vessel and lesion metrics were compared.¬†We used the recently proposed OCT-derived calcium scoring for calcified lesions. The mean age (65.1¬±10.7 years), gender (76.4% males), BMI (27.5¬±5.9 Kg/m¬?) and co-morbidities were statistically similar between the groups. The most common presentation was stable angina followed by unstable angina and NSTEMI with no difference between the groups (p=0.107). Left anterior descending artery involvement was more common in the suboptimal FFR group (91.7% vs. 45.7%; p<0.001).¬†¬†The use of post-dilation was not different between the groups (69.4% vs. 55%; p=0.121). The suboptimal FFR group had lower pre-PCI FFR (0.67¬±0.11 vs. 0.77¬±0.12; p<0.001), longer lesion length (26.8¬±9.4 mm vs. 21.6¬±8.4 mm; p=0.002), smaller reference lumen area (5.6¬±1.7 mm¬? vs. 7.0¬±2.7 mm¬?; p=0.012), smaller mean lumen area (3.6¬±0.8 mm¬? vs. 4.6¬±2.1 mm¬?; p=0.005) but similar minimal lumen area (MLA) (1.6¬±0.5 mm¬? vs. 1.7¬±0.9 mm¬?; p=0.502). In terms of plaque characteristics, suboptimal FFR group had higher frequency of calcified plaque (80.6% vs. 60.5%; p=0.026), with larger maximum calcium arc angle (227.5¬±108.7¬? vs. 132.4¬±71.5¬?; p<0.001), maximum calcium length (10.0¬±6.6 mm vs. 6.3¬±3.6 mm; p<0.001) and maximum calcium thickness (881.7¬±286.8 ¬µm vs. 749.1¬±218.2 ¬µm; p=0.012); reflecting a higher overall calcium score (p<0.001). The frequency of lipid plaque and the maximum thickness of fibrous cap were not different between the groups but there was larger maximum lipid arc angle (213.8¬±85.5¬? vs. 165.8¬±71.0¬?; p=0.003) in the suboptimal FFR group. In contrast, maximum fibrotic angle was smaller in the suboptimal FFR group (163.4¬±72.9¬? vs. 212.8¬±119.2¬?; p=0.028) while the frequency of presence of fibrotic component was same.

CONCLUSIONS

Our analysis shows that LAD lesions, longer lesions, lower pre-PCI FFR, and presence of calcified lesions with longer, thicker and more circumferential calcification as well as larger lipid arc angle can predict a suboptimal post-PCI FFR.¬†This is the first study in our knowledge to investigate the association of OCT-based plaque characteristics with post-PCI FFR. Identification of high-risk vessel and plaque features using OCT can predict poor functional outcome of revascularization, which may have significant clinical implications.

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Proximal anchoring technique attenuates longitudinal stent elongation caused by post-dilatation

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds, Bifurcation lesion

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Main branch stent malapposition after mini-culotte procedure is highly related to the design of side branch stent

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THEME: Coronary Interventions

TOPIC(S): Stents and scaffolds, Bifurcation lesion

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Super elastic sizing device

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THEME: Interventions for Valvular Disease
TOPIC(S): Other valvular and structural interventions

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Implications of a simultaneous 18-lead electrocardiogram patch in cardiac care

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Coronary intervention through left distal transradial artery approach in third-world country

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THEME: Coronary Interventions
TOPIC(S): STEMI, Stable CAD

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Innovative technique for aorto-ostial left main imaging with OCT

BHOOPALAN K. (1), DABROWSKI M. (2), JAGIELAK D. (3), KOCHMAN J. (4), GRYGIER M. (5), HAWRANEK M. (6), BUSZMAN P. (6), WITKOWSKI A. (2), DUDEK D. (7), WOJAKOWSKI W. (6)

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Sandwich stent - as an alternative to covered stent

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds, Other Coronary Interventions

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Real-time peripheral vascular imaging by photoacoustic method

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THEME: Peripheral Interventions
TOPIC(S): Below the knee

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Novel technique to tackle flush superficial femoral artery CTO

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THEME: Peripheral Interventions

TOPIC(S): Iliac / Femoral / Popliteal

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Ultrathin, polymer BRS - Preservation of molecular weight

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Regenerative stents: minimally invasive vascular restoration

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THEME: Peripheral Interventions
TOPIC(S): Below the knee, Iliac / Femoral / Popliteal

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Two-year clinical results with the Angiolite DES: the Anchor study

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Pre-clinical results of a novel open-cell, thin strut, durable polymer, laser cut cobalt chromium sirolimus-eluting stent (Angiolite) were promising. The aim of the study as to evaluate the 24-month clinical outcomes associated with percutaneous coronary intervention (PCI) with the Angiolite stent.

METHODS AND RESULTS

This was a prospective multicenter registry including a total of 103 patients (mean age: 65±10 years, 76% men) with de novo coronary lesions who underwent PCI with the Angiolite stent. Angiographic restenosis was evaluated at 6-month follow-up and target lesion failure [TLF] (cardiac death, target vessel myocardial infarction, clinically-driven target lesion revascularization, stent thrombosis) was determined at 24-month follow-up.

The Angiolite stent was successfully implanted in all patients, without periprocedural complications. At 24-month follow-up, the rate of TLF was 1%, with no cases of cardiac death, myocardial infarction or stent thrombosis. Target lesion revascularization (TLR) occurred in one patient (1%). A total of two (2.3%) patients died from noncardiac-related death and no case of late adverse events related to the device were observed (TLF and TLR occurred within the first 12-month of follow-up).

CONCLUSIONS

PCI with the Angiolite stent was safe and 24-month clinical data shown favorable results characterized by the absence of binary in-stent restenosis, stent thrombosis, myocardial infarction or cardiac death, suggesting a highly efficacious DES platform.

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Feasibility and safety of distal radial artery access in ACS patients

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

The radial artery access is recommended in patients with acute coronary syndromes (ACS) qualified to coronary angiography. The distal radial artery (DRA) access may offer additional benefits to patients and operators. We aimed at assessing the feasibility and in-hospital safety of DRA access for PCI in patients with ACS using dedicated hydrophilic distal radial sheaths.

METHODS AND RESULTS

This is a single arm, prospective, single-centre study evaluating the feasibility and safety of cardiac catheterization through DRA in acute coronary syndrome (ACS) patients. diagnostic and guiding catheters. Arterial access was achieved using a dedicated, 20 cm length, 5 and 6 F hydrophilic radial sheaths. Haemostasis was achieved with a radial band. Feasibility was defined by the ability to cannulate the DRA and completing the PCI procedure. The safety point included bleeding, vascular complications or neuropathy. ? DRA was attempted in 78 ACS patients (61% male, aged 66+/-10 years). Among them 15 patients were diagnosed with STEMI. 74 patients had successful completion of the procedure through DRA. Conversion occurred in 4 patients due to failed wire passage, requiring a unilateral radial artery access to complete the procedure (94.6% feasibility). 6 F sheaths were used in 78.2% of patients. 68 patients required percutaneous coronary intervention with DES implantation. The bleeding complication occurred in 1 patient (1.3%) as forehand haematoma not requiring surgery caused by band dislocation. No vascular complications or neuropathy were observed. In-hospital survival was 100%. All interventions were performed in optimal operator working position.

CONCLUSIONS

Distal radial access is safe and feasible in majority of patients with ACS requiring coronary intervention. Dedicated hydrophilic distal radial sheaths allow the use of 6 F catheters in 78.2% of cases.

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Role of multilayer stents in treatment of complex descending aortic pathologies - A single-centre experience

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THEME: Peripheral Interventions
TOPIC(S): AAA

AIMS

While treatment of descending aortic disease remains a challenge, the development of multi-layers stents represents a therapeutic option which may improve branches' permeability after endo-vascular treatment.

METHODS AND RESULTS

Prospective, observational, single-center study. Primary endpoint was ischaemic events within the first 30 days of the intervention. Secondary endpoints included procedural success, procedural-related mortality, long-term permeability of the coated collateral vessels evaluated by computerised fluid dynamics (CFD), and presence of major ischaemic events during follow-up (average of 18 months). 38 patients with complex thoraco-abdominal aortic pathologies were classified into 3 groups: group-I (type B aortic dissection, N = 16), group-II (residual dissection after type A surgery, N = 4), and group-III (thoraco-abdominal aortic aneurysms, N = 18). All patients underwent multilayer flow modulator (MFM) stent implantation and had descending aorta fully coated, with coverage of all thoraco-abdominal branches (bronchial, oesophageal, intercostal, supra-diaphragmatic, celiac, renal and genital arteries). CFD analysis was performed and then repeated in all patients during follow-up.
Results: No ischaemic events were documented within the first 30 days of follow-up. Procedural success was obtained in all patients. No late branch occlusion or procedural-related mortality was reported during follow-up period (maximum of 36 months). CFD analysis confirmed flow lamination in collinear branches with dissection remodelling and reduction of false lumen's diameter.

CONCLUSIONS

MFM is safe and effective in the treatment of complex descending aortic pathologies, with promising results regarding branch permeability and ischaemic complications.

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Multicentre, prospective, randomised, evaluation of a novolimus-eluting coronary stent system with a durable polymer coating compared to a zotarolimus-eluting coronary stent system: five-year clinical follow-up from the EXCELLA II study

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

To evaluate the long term safety and efficacy of the DESyne Novolimus Eluting Coronary Stent System with an ultra-thin durable polymer coating compared to the Endeavor Zotarolimus Eluting Coronary Stent System

METHODS AND RESULTS

The DESyne Stent System was specifically designed to provide a highly flexible and deliverable cobalt chromium-alloy stent, delivering Novolimus, a metabolite of sirolimus, developed to provide similar efficacy as other currently available agents at a lower dose (5 mcg/mm of stent length) and using an ultra-thin (< 3 µm) durable polymer coating.

The EXCELLA II Trial was a randomised, prospective, multicentre, single-blind, non-inferiority study evaluating the DESyne Novolimus Eluting Coronary Stent System (NES) compared to the Endeavor Zotarolimus Eluting Coronary Stent System (ZES) in the treatment of up to two de novo native coronary artery lesions. The primary efficacy endpoint was in-stent late lumen loss and the principal safety endpoint was a device-oriented composite endpoint (DoCE) comprised of cardiac death, myocardial infarction (MI) not clearly attributable to a non-intervention vessel, and clinically-indicated target lesion revascularisation (TLR). A total of 210 patients were enrolled at 21 International sites.

The EXCELLA II Trial demonstrated both non-inferiority but also superiority of the DESyne Novolimus Eluting Stent to the Endeavor Zotarolimus Eluting Stent for the primary endpoint of in-stent late lumen loss (0.11 ± 0.32 mm vs. 0.63 ± 0.42 mm; p=0.001). Additionally, at 5 years, the DESyne stent demonstrated a significant improvement in safety with a 61% decrease in the composite clinical endpoint inclusive of cardiac death, target vessel MI and clinically indicated TLR (Kaplan-Meier (KM) 8.1% vs. 21.3%, p=0.01) as well as significantly lower (63% decrease) clinically-indicated TLR (KM 4.4% vs. 11.8%, p=0.05). There was no difference in cardiac death or target vessel MI; definite and probable stent thrombosis rates were also similar.

CONCLUSIONS

Following the demonstration of superiority of the DESyne Novolimus Eluting Coronary Stent System vs. the control for in-stent late lumen loss at 9 months, the final 5-year results from the EXCELLA II Clinical Trial demonstrated substantially lower DoCE events and clinical indicated TLR for the DESyne Novolimus Eluting Coronary Stent System vs. the control supporting the long term safety and efficacy of the DESyne stent.

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The right heart catheterisation and the role of a nurse

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

The right heart catheterization enables measurement of pressure in the right ventricle, pulmonary artery and pulmonary capillaries. It is important to take blood samples for analysis and determine oxygen saturation, which allows us to determine the intracardial level.

METHODS AND RESULTS

The catheterization is performed by the puncture of femoral, subclavian, internal jugular or cervical veins. A balloon-tipped flotation catheter-originally designed by Swan and Ganz is the most commonly used balloon catheter. The balloon tip allows the catheter to float through the right side of the hearth safely and easily. The balloon wedges in the distal side of catheter helps to measure the pulmonary artery pressure. Other known catheter types that are still used are Cournand catheter, Berman catheter, Corodyn catheters

Right heart rate catheterization is most commonly used for measuring right atrium, right ventricular, pulmonary artery and pulmonary capillary pressure. Also is useful for assessing pulmonary vascular resistance, tricuspidal and pulmonary function, and right ventricular pressure. Right ventricule pressure measurement helps diagnose cardiomyopathy, constrictive pericarditis, and heart buffering in case non-invasive tests do not indicate a true diagnosis. The test is performed by the puncture of femoral, subclavian, internal jugular or cervical veins.

Indications for Cardiac Catheterization are suspected or known coronary artery disease, myocardial, sudden cardiovascular death, valvular heart disease, congenital heart disease, aortic dissection, pericardial constriction or tamponade, cardiomyopathy, initial and follow-up assessment for heart transplant. Right-sided heart catheterization is indicated for patients with a history of dyspnea, valvular heart disease, or intracardiac shunts.

Absolute contraindication is inadequate equipment or catheterization facility. Relative contraindications are acute gastrointestinal bleeding or anemia, anticoagulation (or uncontrolled bleeding diathesis), electrolyte imbalance, infection and fever, medication intoxication (digitalis, phenothiazine), pregnancy, recent cerebrovascular accident, renal failure, uncontrolled congestive heart failure, high blood pressure, arrhythmias, uncooperative patient. Complicatons that may occure are: complications od vascular access, pulmonary infarction, pulmonary artery rupture, injury to chordae in right ventricle, tricuspid regurgitation, right bundle-branch block, dislodgement of pacemaker leads.

The patient's preparation for right heart catheterization is the same as preparation for other heart catheterizations. The nurse must know the RHC protocol and must take part in the catheterization performance. It must know the normal values and appearance of the pressure curves in the heart cavities and ecg. The nurse needs to have knowledge of hemodynamic patient monitoring system and record, mark and analyze the pressure values. The nurse takes care of proper blood sampling during catheterization and proper labeling and transport of samples to the laboratory. The nurse have the skill to recognize and observe artefacts and pathological changes in vital function monitoring and timely and properly respond to them.

CONCLUSIONS

The right heart catheterization is a gold standard for the detection of pulmonary hypertension. The role of a nurse is very important, and as such nurses are the inevitable members of a team.

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Effect of coronary sinus reducer implantation on myocardial function of patients with coronary artery disease and refractory angina

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Coronary sinus (CS) Reducer is a balloon-expandable mesh, implanted percutaneously in the CS to create a narrowing of the CS lumen and to establish a pressure gradient across it, which in turn has been shown to improve refractory angina of patients with coronary artery disease (CAD) not amenable to further revascularization. Aim of this study was to investigate the effect of CS Reducer upon left ventricular performance of CAD patients with refractory angina.

METHODS AND RESULTS

Prior to device implantation and at 4-months, all patients underwent clinical assessment with evaluation of Canadian Cardiac Society (CCS) class and evaluation of resting ventricular volumes and function by CMR. Myocardial perfusion reserve was evaluated by Stress-CMR.

Nineteen patients (18 males/1 female, 66±10 years), underwent successful Reducer implantation. Sixteen patients improved by ≥ 1 CCS class. Eight patients experienced 1 CCS class reduction, 7 patients 2 CCS class reduction, 1 patient 3 CCS class reduction and 3 patients did not experience any benefit in angina class. Myocardial perfusion reserve index (MPRI) increased significantly 4 months after Reducer implantation (from 1.2±0.38 to 1.61±0.79, p=0.011). We did not observed any significant correlation between angina class and myocardial perfusion improvement; patients that had ≥2 CCS class improvement presented a 54±47 % MPRI increase versus a 28±58 % increase in patients with 0 or 1 CCS class change (p=0.316).

Four months after Reducer implantation, we noticed a significant improvement in LV ejection fraction (LVEF) (from 59±15 to 64±13 %, p=0.015), a reduction in LV end-diastolic volume/Body surface area (BSA) (from 72±16 to 66±19 ml/m2, p=0.044) and a reduction in LV end-systolic volume/BSA (from 30±15 to 21±10 ml/m2, p=0.009). LV end-diastolic mass did not change (from 108±16 to 104±23 gr, p=0.24).

CONCLUSIONS

CS Reducer implantation improved angina symptoms, myocardial perfusion and left ventricular function in patients with refractory angina. The observed increase of myocardial perfusion could be the underling mechanism for the improvement of left ventricular function of patients with refractory angina amenable to CAD.

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Multicentre, prospective, randomised, evaluation a novolimus-eluting coronary stent system with bioabsorbable polymer compared to a zotarolimus-eluting coronary stent system: five-year follow-up from the EXCELLA BD study

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

To evaluate the long term safety and efficacy of the Elixir DESyne BD Novolimus Eluting Coronary Stent System (CSS) with a bioabsorbable polymer compared to the Endeavor Zotarolimus Eluting Coronary Stent System

METHODS AND RESULTS

149 patients were randomised 3:1, either to the Elixir DESyne BD Novolimus Eluting CSS loaded with 5 mcg per mm of stent length of Novolimus, a sirolimus metabolite, eluted via a bioabsorbable polylactide-based polymer, or to the Endeavor Zotarolimus-eluting CSS loaded with 10 mcg per mm of stent length of Zotarolimus eluted via a durable phosphoryl choline polymer. All patients were analyzed for the primary endpoint of in-stent late lumen loss (LLL) assessed by qualitative coronary angiography (QCA) at 6 months. Moreover, all patients underwent evaluation for the secondary endpoints including the Device-orientated Composite Endpoint (DoCE) defined as: cardiac death, MI not clearly attributable to a non-intervention vessel, and clinically-indicated target lesion revascularisation; clinically-indicated Target Vessel Revascularisation (TVR), and stent thrombosis at 1, 6, 9, and 12 months and annually through 5 years. Lesions were also evaluated for angiographic endpoints at 6 months including: in-segment LLL, percent diameter stenosis, minimal lumen diameter post-procedure, and angiographic binary restenosis (ABR) (≥50%). A subset of patients underwent intravascular ultrasound (IVUS) evaluation including percent (%) neointimal obstruction at 6 months. The study met the primary endpoint demonstrating both non-inferiority and superiority of the DESyne BD compared to the control (0.12 ± 0.15 mm vs 0.67 ± 0.47 mm, $p<0.001$), additionally, in-stent ABR was significantly lower for DESyne BD (0% vs 7.9%, $p=0.003$). Excellent clinical results at 6 months were demonstrated for both devices (DoCE 2.7% vs. 3.2%, $p= 1.00$). Sustained low event rates were observed at 1 and 2 years (DoCE - 2.7% vs 3.2% $p=1.0$), as well as through 3 and 4 years (DoCE 5.4% vs 6.5% $p=0.68$ and 6.3% vs 9.7% $p=0.11$). Final clinical results through five years and complete angiographic and IVUS results will be presented.

CONCLUSIONS

Final report of the 5 year clinical results and complete angiographic and IVUS results of the DESyne BD Novolimus Eluting Coronary Stent with biodegradable coating will be presented.

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Routine use of the ACURATE neo self-expanding TAVI valve is associated with improved procedural outcomes and reduced post-operative length of stay: Insights from a single-centre registry

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Published outcomes from self-expanding TAVI valves differ, but there are few comparative series. We explore peri-procedural complications and their association with length of stay (LoS) in a contemporary single-centre series of CoreValve Evolut R (Medtronic, Minneaoplis MN) and Acurate Neo (Boston Scientific, Maple Grove, MN).

METHODS AND RESULTS

Clinical, imaging, procedural and outcome data of patients undergoing transfemoral percutaneous (pTF) TAVI between March 2017 and September 2018 were extracted from a single-centre database. Procedural outcomes were: successful valve deployment, pericardial effusion/tamponade, periprocedural acute kidney injury (AKI), cerebrovascular accident (CVA), major vascular complications, major/life threatening bleeding, new permanent pacemaker (PPM) implantation, post-deployment significant aortic regurgitation (AR) and in-hospital, and 30-day mortality. These were adjudicated by two independent interventional cardiologists using where applicable valve academic research consortium 2 (VARC-2) criteria. We explored the influence of valve system on procedural outcomes and post-operative LoS using univariate and multivariate logistic and linear regression models respectively. Univariate predictors with p-value ≤0.1 were included in multivariate models. Maximally adjusted odds ratio (OR) with 95% confidence intervals (CI) were estimated. All statistical analyses were performed with SPSS 24.0 (IBM Inc. New York USA).

231 patients underwent pTF TAVI (143 Acurate Neo, 88 with Evolut R). The median age was 83 (79, 86) with 100 (48%) female patients. All femoral access was ultrasound guided. 213 (92%) implantations were performed with a left ventricle guidewire or PPM pacing. Pre-implantation valvuloplasty was performed in 137 (96%) Acurate Neo implantations and 12 (14%) Evolut R implantations. 30 (13%) patients had pre-existing PPMs with no difference between the Acurate Neo and Evolut R cohort (15% vs 10%, p=0.34). Successful valve deployment (99% vs 98%), post-dilatation rate (20% vs 15%), pericardial effusion/tamponade (1% vs 0%), CVA (3% vs 0%), in-hospital (3% vs 2%) or 30-day mortality (3% vs 2%) were similar in both cohorts. The Acurate Neo cohort was associated with less major vascular complications (1% vs 9%, OR 0.14 95% CI [0.03-0.68]), life-threatening bleeding (1% vs 8%, aOR 0.14 95% CI [0.01-0.68]) and new PPM implantation (10% vs 29%, aOR 0.53 95% CI [0.36-0.79]. Post-operative LoS was also reduced with the Acurate Neo system; 3 (2,4) vs 3 (2,5), p=0.02, with 64 (45%) patients in the Acurate Neo and 27 (31%) of the Evolute R cohort being discharged within 2 days (x2=4.90, p=0.03). Univariate linear regression identified age, year of operation, procedural urgency, valve model, new PPM and a composite of peri-procedural complications as predictors of LoS. A multivariate linear regression model identified periprocedural complications (b=4.87, p<0.001) and new PPM (b=3.49, p<0.001) as independent predictors of post-operative LoS (R2=0.23).

CONCLUSIONS

In our experience, use of the Acurate Neo valve is associated with reductions in major vascular complications, major/life threatening bleeding and new PPM implantations compared to the Evolut R platform. The improvements in procedural outcomes are associated with reductions in post-operative LoS. We await the results of ongoing randomised trials with interest.

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Prognostic impact of contrast FFR

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Contrast-FFR (cFFR) is an adenosine-free alternative to conventional FFR. Although a cFFR value of <0.85 can predict an “ischemic” FFR value of <0.80 quite accurately, some discordance between these two indexes can exist. The clinical impact of this discordance is unknown. We aimed to compare the incidence of MACE (death, myocardial infarction and urgent target vessel revascularization (TVR)) in patients undergoing functional evaluation with both FFR and cFFR based on the results of the two indexes.

METHODS AND RESULTS

we retrospectively analyzed, at a maximum follow-up of 60 months (mean 22,2±14,5 months), the incidence of MACE in 488 patients who underwent functional evaluation with FFR and cFFR between June 2012 and June 2018. Discordance between FFR and cFFR findings was observed in 11% of cases. Based on FFR and cFFR values patients were divided into four groups: group 1 (negative concordance: FFR >0.80 and cFFR >0.85, n=298), group 2 (positive concordance: FFR ≤0.80 and cFFR ≤0.85, n=134); group 3 (negative discordance FFR>0.80 and cFFR≤ 0.85, n=31) and group 4 (positive discordance: FFR ≤0.80 and cFFR >0.85, n=25). All patients were treated on the basis of FFR value. Moreover, in 80 patients a concomitant PCI was performed on an angiographic basis. Incidence of MACE at follow-up was 8.3% in group 1, 14.0% in group 2, 16.0% in group 3 and 8.0% in group 4 without a significant difference among the 4 groups (p=0.2). Similarly the incidence of the individual endpoints was equally non significant. Nevertheless, at landmark analysis, we found a significant difference in the rate of TVR between group 1 and group 3 (5.7% vs 16.0%; p=0.027) after 24 months.

CONCLUSIONS

cFFR is confirmed accurate in predicting FFR and consequently reliable in guiding coronary revascularization. In the rare case of discordance, while positive discordance shows a prognosis similar to negative concordant, negative discordance is associated to a prognosis similar to positive concordance. This result can suggest that cFFR is a potentially more sensitive index than conventional FFR to avoid late events. Further studies are warranted to confirm this retrospective finding.

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Cost-effectiveness of TAVI in patients at intermediate surgical risk: a model-based analysis based on the SURTAVI trial using contemporary cost data

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Clinical non-inferiority between transcatheter aortic valve implantation (TAVI) and surgical aortic valve replacement (SAVR) has previously been demonstrated in patients with severe aortic stenosis at intermediate surgical risk. While the cost-effectiveness of TAVI has been studied in other – typically high or extreme risk – cohorts, additional data about the health-economics of TAVI in intermediate risk patients are desirable.

METHODS AND RESULTS

Mortality, clinical event rates, and rehabilitation resource utilization were derived from the SURTAVI trial (N=864 TAVI and N=796 SAVR patients with an STS PROM score of 4.5±1.6%). The patients' mean age was 79.8±6.2 years. Cost data for the index procedure and adverse events were based on an analysis of real-world data for TAVI and SAVR procedures from the US Medicare population in 2017 (Medpar inpatient dataset, N=38,120 TAVI and N=40,046 SAVR patients), with reported charges adjusted to cost using site-specific cost-to-charge ratios. Rehabilitation and long-term follow-up costs were derived from Medicare fee schedules as a proxy for true cost and data from the published literature. All costs were inflated to 2018 costs using the medical consumer price index.

Costs and effectiveness as quality-adjusted life years (QALYs) were projected to lifetime via a decision-analytic model calibrated to 24-month incidences of all-cause mortality and stroke from the SURTAVI trial. Several scenarios were considered where after either 24-month data or an assumed catch up of mortality at 48 months, relative mortality risks were maintained, or would gradually fade out over time. The discounted incremental cost-effectiveness ratio (ICER) was compared to a willingness-to-pay (WTP) threshold of $150,000 per QALY gained, as per the American Heart Association/American College of Cardiology guidelines.

Index hospitalization costs were slightly lower for TAVI than SAVR ($57,782 vs. $59,899: difference: -$2,118). When considering rehabilitation (mean of 1.30 and 4.30 days for TAVI and SAVR, respectively), TAVI resulted in lower costs at the 30-day follow-up ($59,794 vs. $66,287; difference: -$6,493). Lower TAVI cost were maintained through lifetime. Depending on the long-term mortality scenario used, TAVI, compared to SAVR, either gained or lost a small amount of QALYs.

CONCLUSIONS

TAVI in intermediate risk patients was found to be associated with lower cost compared to SAVR based on contemporary cost and resource utilization data from the United States. Follow-up analyses considering longer-term survival data would be desirable to further corroborate long-term cost-effectiveness.

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Implant success and safety of LAA occlusion in end-stage renal disease patients: peri-procedural outcomes from an Italian dialysis population

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THEME:
TOPIC(S):

AIMS

The high haemorragic risk in patients with end-stage renal disease (ESRD) undergoing chronic dialysis and suffering from nonvalvular atrial fibrillation (NVAF) represents the main problem faced by nephrolgist. The aim of this study is to estimate the safety and the efficacy of Left Atrial Appendage Occlusion (LAAO) in patients with end-stage renal disease (ESRD) on chronic dialysis, with NVAF and contraindication to oral anticoagulation.

METHODS AND RESULTS

This is a prospective cohort study. Primary endpoints are i) incidence of peri-procedural complications, ii) cumulative incidence of two-year thromboembolic events iii) cumulative incidence of two-year bleedings iiii) mortality at two years. Adverse events (AE), defined as stroke, systemic thromboembolism, bleeding, pericardial effusion, device embolization and death within 30 days of the procedure were recorded. Adverse events (AE), defined as stroke, systemic thromboembolism, bleeding, pericardial effusion, device embolization and death within 30 days of the procedure were recorded.

Results: Between May 2014 and November 2018, we recruited 89 consecutive patients (76% male) undergoing chronic dyalisis and treated with LAAO. The patient's mean age and dialysis duration were 71.9(9.9) years and 48.9(62.4) months, respectively. Sixty percent of patients suffered a major bleeding and 10% an ischemic stroke or systemic thromboembolism. CHA2DS2VASCs and HASBLED scores were 3.9(1.4) and 4.4(0.8), respectively. Most patients (88%) were hypertensive, 30% was diabetic, 37% had a history of heart failure and 48% of coronary artery disease; 85% showed atrial dilatation and 24% had left ventricular ejection fraction <50%. Forty six percent patients had permanent and 36% paroxysmal NVAF. Here we report results about incidence of peri-procedural complications and adverse events within 30 days. The procedure was successful in 98.8% of cases, while in one patient there was an intra-procedural device displacement, without other complications and with uneventful implantation performed in the same session. Concerning adverse events, two major [2.2%] (a pericardial effusion with cardiac tamponade requiring pericardiocentisis and a femoral artery damage, with subsequent acute ischemia of the lower limb), and three [3.3%] minor events (peri-procedural access site bleeding, requiring no transfusion) were reported. At discharge 57% of patients were on DAPT, 27% on single antiplatelet regimen, 4% on aspirin plus anticoagulation. DAPT was stopped at 3 months, based on transesophageal echocardiography exclusion of device related thrombus or important pericardial leaks (>5mm). During the 30-day follow-up there were no major or minor bleedings, no deaths or other AE.

CONCLUSIONS

In patients with ESRD and NVAF, undergoing chronic dialysis, direct oral agents are contraindicated and warfarin does not fully prevent embolic events while increasing the bleeding risk. Evidence in literature on the safety and efficacy of LAA closure in this very high-risk population are lacking. Our preliminary data suggest the feasibility and safety of LAA occlusion in ESRD patients undergoing dialysis, with an acceptable incidence of peri-procedural complications, and no death, no bleeding or other adverse events at 30-day follow-up.

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Outcomes of proximal left anterior descending artery angioplasty using a bioresorbable polymer coating sirolimus-eluting stent: analysis of the large multicentre prospective e-ULTIMASTER registry

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THEME: Coronary Interventions

TOPIC(S): Stable CAD, Stents and scaffolds

AIMS

Current guidelines recommend heart team discussion and CABG consideration in patients with proximal left anterior descendant (LAD) artery stenosis. Emerging evidence suggest that angioplasty outcomes of patients with proximal LAD stenosis are not different from those with non-proximal LAD disease. We aimed to determine outcomes of patients undergoing PCI in the proximal LAD segment in comparison to non-proximal LAD angioplasty treated with an ultrathin bioresorbable polymer DES and enrolled in the large, multicenter, all-comer international e-Ultimaster registry.

METHODS AND RESULTS

Patients enrolled between 2014 and 2018 in the e-Ultimaster, all-comer multinational real-world registry, who completed 1-year follow-up, were included. The primary endpoint of target lesion failure (TLF) at 1 year follow-up was defined as a composite of cardiac death, target vessel (TV) related myocardial infarction (MI) and clinically driven (CD) target lesion revascularization (TLR). An independent Clinical Event Committee reviewed and adjudicated all deaths, myocardial infarctions, revascularizations and stent thromboses. Among 19,482 patients who reached 1-year follow up, 5452 patients in which stents were implanted in the proximal LAD segment were compared to a control group of all those in which stents were implanted in non-proximal LAD locations (n=12353). Patients with left main segment involvement and those with previous CABG were excluded.

Mean age of patients was 64.2 years and 76% were men. At baseline the rates of hypertension (60.6 vs 63.8%; p<0.001), hypercholesterolemia (52.9 vs 56.7%; p<0.001), previous MI (17.1 vs 20.8%; p<0.001) and previous PCI (19.0 vs 25.8%; p<0.001) were different in patients with proximal LAD lesion treated in comparison to those without.

Multivessel disease (48.7% vs 43.5%; p<0.001) was more prevalent and a higher number of lesions were treated (1.92 vs 1.79; p<0.001) in the proximal LAD group. Patients in the proximal LAD group had higher rates of type C lesions (30.8 vs 27.8%; p=0.002), bifurcations (18.8%vs 9.2%; p<0.001), ostial lesions (8.7 vs 5.1%; p<0.001) and calcified lesions (20.5 vs 17.2%; p<0.001).

After propensity score matching in a 1 to 1 proportion (n=5351), to correct for differences in baseline characteristics, there were no differences in mortality rates, rates of TV-MI or revascularizations at 3 months. TLF was 1.42% in proximal LAD group as compared to 1.44% in the other patients (p=0.94). At 1-year follow-up in the propensity-matched population, cardiac death (1.4 vs 1.2%; p=0.49), TV-MI (0.80 vs 0.9%; p=0.47) and CD-TVR (2.4 vs 1.9%; p=0.06) were similar between the two groups while rates of CD-TLR (1.9 vs 1.3%; p=0.02) were higher in proximal LAD group. No differences were observed in TLF (3.4 vs 2.8%; p=0.11) and patient-oriented composite endpoint of all-cause mortality, any MI or any revascularization (6.0 vs 5.7%; p=0.54). Rates of definite and probable ST were similar.

CONCLUSIONS

In this real-world analysis, we report good clinical safety and procedural efficacy of newer generation thin-strut DES (Ultimaster stent) independent of stenting location and strategy. Stenting of the proximal LAD did not confer a different prognosis, questioning whether indeed it should be regarded differently from stenting of any other coronary artery lesion location.

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Mechanisms provoking myocardial hyperaemia: does adenosine mediate saline-induced hyperaemia?

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

In the coronary arteries adenosine binds to A2A receptors and is a potent vasodilator, while in the kidney, adenosine binds to A1 receptors and is an afferent arteriolar vasoconstrictor. We have shown previously that saline infused using a dedicated catheter in the proximal part of an epicardial or a renal artery at the rate of 20 mL/min induces maximal microvascular dilatation The mechanism responsible for the induction of hyperemia during saline-infusion remains to be determined. The present study aimed at determining the impact of adenosine on the hyperemic state achieved by saline infusion

METHODS AND RESULTS

Selective renal artery catheterization was performed. a Doppler wire (FloWire, Volcano) was used to monitor the intracoronary Average Peak Velocity (APV). A dedicated monorail infusion catheter (RayFlowTM, Hexacath, Paris, France) was advanced over a pressure/temperature wire (PressureWire X, Abbott, USA) and used to infuse saline in the proximal part of the renal artery. APV and thermodilution-derived absolute flow were measured in the following experimental situations: (1) at baseline; (2) after a bolus of 200 µg intrarenal (IR) adenosine; (3) during saline infusion at 10 mL/min; (4) after IR adenosine on top of saline infusion at 10 mL/min; (5) during saline infusion at 20 mL/min; and (6) after IR adenosine on top of saline infusion at 20 mL/min.

Twelve patients (23 renal arteries) with normal GFR (70±16 mL/min/1.7m2) were studied. Compared to baseline, intrarenal infusion of saline at 20 ml/min significantly increased renal artery APV (51±8%). In contrast, no increase in APV was noticed with saline at 10 mL/min (4±4%). Intrarenal adenosine reduced APV at rest and during infusion of 10 mL/min of saline by 65± 5%, and 43±16%, respectively. Intrarenal adenosine administered during saline infusion of 20 mL/min had no effect on renal APV (Delta 7±2%), indicating that the hyperemic effect of saline infused at 20 mL/min offsets the vasoconstrictive effect of Adenosine.

CONCLUSIONS

The present data suggest that the Adenosine pathway might not be involved in the mechanism of saline-induced vasodilation in the renal artery. This finding can be translated to the coronary microcirculation. It can be hypothesized that a local, intra-organ, neural pathway could be responsible for the translation between large and small arteries

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Intra-aortic balloon support for myocardial infarction with cardiogenic shock - A report from the Swedish Coronary Angiography and Angioplasty Registry (SCAAR)

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

Cardiogenic shock (CS) remains the leading cause of in-hospital death in acute myocardial infarction (MI) and is associated with a mortality rate of ~50%. Intraaortic balloon support (IABP) was class I ESC guideline recommendation for treatment of CS for many years, but this recommendation was changed to class III after the IABP-SHOCK II study. The aim of this large prospective observational study was to evaluate the impact of IABP on 30-days mortality and in-hospital complications in patients with CS.

METHODS AND RESULTS

We used data from the Swedish Coronary Angiography and Angioplasty Registry (SCAAR), which contains information about all PCI procedures performed in Sweden (31 hospitals). We included all procedures from 2005 to 2018 in patients with CS due to MI and divided the patients according to whether or not they were treated with IABP. We used instrumental variable analysis to adjust for differences in patient characteristics and hidden bias. Treating hospital was used as a treatment-preference instrumental variable using two-stage least squares regression. Multilevel modeling was used to adjust for clustering of observations in a hierarchical database. In-hospital complication was defined as the occurrence of any of the following events: major bleeding, minor bleeding, extended compression of the access artery, blood transfusion, surgical revision of the access artery, neurologic complication.

In total, 2,991 patients with CS were included in the study. Of these, 737 (25%) were treated with IABP. In the combined cohort, there were 1,554 (52%) deaths 30 days after PCI and 1,239 (41%) cases of in-hospital complications. IABP was not associated with death at 30 days (risk reduction [RR] -1.1 %; 95% confidence interval [CI] -15.7;13.5; P= 0.881). However, IABP was associated with a higher risk of in-hospital complications (RR 35.4%; 95% CI 17.7-53.1; P<0.001).

CONCLUSIONS

In this observational study, treatment with IABP, was not associated with 30-days mortality in patients with CS. However, the risk of in-hospital complications was substantially higher in patients with CS who were treated with IABP. Our observational study supports class III recommendation by the current ESC guidelines for the use of IABP in CS.

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The prognostic value of diastolic pressure ratio immediately after successful PCI in all-comer patients

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Fractional Flow Reserve (FFR) assessed post percutaneous coronary intervention (PCI) proved to be a strong predictor of future adverse cardiovascular events. Measuring FFR requires the use of hyperemic agents resulting in additional cost, procedure time and potential patient discomfort. A resting diastolic pressure ratio (dPR) has been introduced as an adenosine free alternative to FFR. The aim of the current study was to assess the predictive value of post PCI dPR on the incidence of a combined endpoint of cardiac death, myocardial infarction and target vessel revascularization at 2 years.

METHODS AND RESULTS

The FFR SEARCH study is a prospective registry in which 1000 consecutive patients underwent post PCI FFR between March 2016 and May 2017. FFR measurements were performed with a dedicated microcatheter advanced approximately 20mm distal to the most distal stent edge. DICOM pressure waveforms were recorded for offline calculation of dPR using recently validated software. Adequate pressure waveform data was available for 735 patients (X lesions).

Mean age was 64±12 years and 75% of the population was male. Mean post-PCI FFR was 0.91±0.07 and dPR was 0.96±0.05. Clinical follow-up is currently ongoing, final results will be presented at the meeting.

CONCLUSIONS

The present study will provide potential important insights into the prognostic value of the adenosine-free resting pressure gradient dPR on post PCI outcome.

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Intracardiac vs. transoesophageal echocardiography for guidance of percutaneous LAA occlusion - A meta-analysis

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

We performed a meta-analysis to compare the safety and efficacy of intracardiac echocardiography versus transoesophageal echocardiography for guidance of percutaneous left atrial appendage occlusion.

METHODS AND RESULTS

A comprehensive search of the literature was performed, from inception to December 2018 using the MEDLINE, Cochrane Library and Google Scholar electronic databases, as well as references from other articles. We included in the analysis all publications comparing intracardiac and transoesophageal echocardiography for guidance of percutaneous left atrial appendage occlusion. The primary efficacy endpoint was procedural success and the primary safety endpoint was procedure related complications. Secondary endpoints included procedural and fluoroscopy time. Five studies met the inclusion criteria, yielding a total of 1122 patients. Procedural success was similar with both techniques (pooled OR 1.46, 95% CI 0.77-2.75, P=0.24, I2=0%). A non-significant trend for less procedure related complications was observed in the intracardiac echocardiography group (pooled OR 0.57, 95% CI 0.31-1.05, P=0.07, I2=0%). Procedural (mean difference -1.64 minutes, 95% CI -16.42-13.14, P=0.83, I2=96%) and fluoroscopy time (mean difference +1.29 minutes, 95% CI -1.38-3.97, P=0.34, I2=76%) were similar between groups.

CONCLUSIONS

Intrachardiac echocardiography is a safe and effective alternative to transoesophageal echocardiography for guidance of percutaneous left atrial appendage occlusion.

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Long-term outcomes in patients with new-onset persistent left bundle branch block following TAVR

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THEME: Interventions for Valvular Disease
TOPIC(S): Other valvular and structural interventions

AIMS

The aim of this study was to determine the impact of new-onset persistent left bundle branch block (NOP-LBBB) on long-term (>2 year) outcomes after transcatheter aortic valve replacement (TAVR).

METHODS AND RESULTS

Methods: A total of 1020 consecutive patients without pre-existing LBBB or permanent pacemaker implantation (PPI) undergoing TAVR were included. NOP-LBBB was defined as any new LBBB post-TAVR that persisted at hospital discharge. Follow-up clinical and echocardiographic data were obtained at a median of 3 years (interquartile range: 2 to 5 years) post-TAVR.

Results: NOP-LBBB occurred in 212 patients (20.1%) following TAVR. There were no differences between NOP-LBBB and no NOP-LBBB groups, except for a higher use of the self-expandable CoreValve system in the NOP-LBBB group (p<0.001). At follow-up, there were no differences between NOP-LBBB and no NOP-LBBB groups in global mortality (45.3% vs. 42.5%; adjusted HR:1.09; 95% CI: 0.82 to 1.47; p=0.54), cardiovascular mortality (14.2% vs. 14.4%, adjusted HR: 1.02, 95% CI: 0.56-1.87, p=0.95), or heart failure rehospitalization (19.8% vs. 15.6%, adjusted HR: 1.44, 95% CI: 0.85-2.46, p=0.18). NOP-LBBB was associated with an increased risk of PPI at follow-up (15.5% vs. 5.4%, adjusted HR: 2.45, 95% CI: 1.37-4.38, p=0.002), with the highest risk within the first 12 months. LVEF increased over time in patients with no NOP-LBBB but slightly decreased in those with NOP-BBB (p<0.001 for changes in LVEF between groups).

CONCLUSIONS

After a median follow-up of 3 years post-TAVR, NOP-LBBB was not associated with a higher mortality or heart failure rehospitalization. However, NOP-LBBB increased the risk of PPI and negatively impacted left ventricular function over time. These results should inform future efforts for improving the management of patients with NOP-LBBB post-TAVR.

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Comparison of the new-generation balloon-expandable and self-expanding valves in the large multicentre ATLAS (Athens Tokyo London Aortic Stenosis) registry

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

In the present study, we compared the peri-procedural and one year clinical outcomes between the contemporary balloon expandable SAPIEN S3 and the self expanding Evolut PRO and Evolut R 34mm devices.

METHODS AND RESULTS

Consecutive patients from the ATLAS (Athens-Tokyo-London Aortic Stenosis) registry who had undergone transcatheter aortic valve implantation (TAVI) with new generation devices in four centers were retrospectively studied. In-hospital procedural characteristics and outcomes, such as paravalvular regurgitation (PVR), need for permanent pacemaker (PPM) were recorded and compared among patients receiving the balloon expandable (SAPIEN S3) and the self-expanding (Evolut PRO and Evolut R – 34mm) devices respectively. Kaplan-Meier estimated 1-year all-cause mortality was compared between groups.

In total, 362 patients were included in the analysis, 201 patients treated with S3, and 161 with new self-expanding valves (100 treated with Evolut-Pro and 61 with Evolut R 34mm). Baseline demographics (age, gender), revascularization history (previous CABG, PCI), diabetes, COPD and history of liver and kidney disease were similar between the two groups. Patients treated with self-expanding valves however had a higher prevalence of previous MI (13% vs. 4.5%, p=0.004) and reduced LV EF (<50%) (23.9% vs. 19%, p=0.011). Patients treated with S3 had higher prevalence of 2- or 3-vessel coronary artery disease (17.4% vs. 5.5%, p=0.002).

Of the 201 S3 cases 92% were transfemoral and 8% transapical whereas in the self-expanding group 99.3% of cases were transfemoral and 0.7% subclavian.

In terms of peri-procedural and short-term outcomes, patients treated with S3 had lower rates of moderate/ severe paravalvular leak (0% vs 4.7%, p=0.002) yet higher rates of new pacemaker implantation (18.2% vs. 12.9%, p<0.001). Both valves demonstrated similar rates of periprocedural stroke (4.5% S3 vs 2.1% Evolut PRO/R34, p=0.223), major vascular access complications (2.5 vs. 2.1%, 0.223) and in-hospital mortality (4% vs. 1.9%, p=0.248). There was a significantly lower valve gradient in patients treated with self-expanding valves (17.6mmHg vs. 7.07mmHg, p<0.001)

One year Kaplan-Meier estimated survival was similar between the two groups (89% for S3 vs. 90.9% for self-expanding, plog-rank=0.953). Hazard ratio for all-cause mortality (Evolut PRO/R34 vs S3) after adjustment for EF, coronary artery disease and previous MI was similar between the groups (HR=0.87; 95%CI 0.40 to 1.87, p=0.717).

CONCLUSIONS

The last generation self-expanding Evolut Pro/Evolut R 34mm devices seem to demonstrate slightly higher rates of moderate/severe paravalvular leak, reduced rates for PPM implantation and lower post implantation

mean gradients compared to the balloon-expandable SAPIEN 3 valve. 1-year all-cause mortality does not differ between the two devices.

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Prospective, observational, Italian, multicentre registry of self-apposing coronary stent in patients presenting with STEMI: the iPOSITION registry. Procedural and one-month follow-up results

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THEME: Coronary Interventions
TOPIC(S): STEMI, Stents and scaffolds

AIMS

The aim of this registry is to collect clinical data to evaluate the safety and efficacy of a nitinol, self-expanding, sirolimus DES, pre-mounted on a novel balloon delivery system, in de novo lesions of native coronary arteries of patients presenting with STEMI.

METHODS AND RESULTS

This was a prospective, multi-centre, post-market, observational registry. The study population consisted of 247 consecutiveSTEMI patients, enrolled from June 2016 to July 2018.Mean age was 61 (±11) years, with the majority being male (82.6%).As per operator's assessment, they received PCI in the target vessel, limited to the culprit lesion, with a nitinol, self-expanding, sirolimus DES.

Inclusion criteria were: age ≥ 18 years, symptoms of STEMI lasting less than 12 hours in duration, with a ≥ 2 mm elevation in ST segment in > 2 contiguous leads on the electrocardiogram. Exclusion criteria were: cardiogenic shock, multiple lesions requiring stenting in the target vessel, highly calcified lesions or excessive tortuosity at target lesion site, intra-stent pathology, inability to take or comply with DAPT as recommended in guidelines, pregnancy, life expectancy less than 1 year for comorbidities, inability to provide written informed consent or known allergies to stent component.

Few patients were pre-treated with acetylsalicylate (26%) or P2Y12inhibitor (6.5%).In most of cases patients were in Killip Class I (88.7%), with symptom-onset-to-sheath time inferior to 6 hours (84.3%) and a mild culprit lesion thrombotic burden (72.8%). Pre-procedural TIMI flow 0/1 was seen in 58.3% of patients, TIMI flow 2 in 32.4%, with culprit lesion found predominantly in right (43.3%) and left anterior descending (40.9%) coronary artery.

Thrombus aspiration was performed in 29.6% of patients and pre-dilatation in 82.6%. Post-dilation was performed in 75.3% of patients. 93% of the patients had TIMI 3 flow on their final angiogram. Few procedural complications have been observed: 3 cases of coronary dissection, 4 cases of side branch occlusion and 9 cases of no-reflow phenomenon.

Sample size calculation was performed for non-inferiority on a "target lesion failure at 12-months post-procedure" primary endpoint, defined as a composite of cardiac death, recurrent target lesion related myocardial infarction or clinically driven target lesion revascularization via CABG. Target lesion failure at 30 days post-procedure was verified as a secondary endpoint, as procedural success without the occurrence of death and repeat ischemia-driven revascularization of the target lesion during the hospital stay, death from any cause and stent thrombosis rate at 30 days, classified according to Academic Research Consortium definition.

Preliminary data on 30 days follow-up show 99.2% rate for both procedural and device success, with no major

adverse cardiac event observed.
Twelve months follow up will end on 31 July 2019, providing definitive outcomes results.

CONCLUSIONS

To best of our knowledge this is the first multicentre Italian registry evaluating the performance of the nitinol self-apposing DES in a STEMI population and the first worldwide study weighing up the self-apposing DES novel balloon delivery system. The procedural success rate and 30-day follow-up have been excellent. Definitive results and the primary endpoint analysis will be available at the end of 2019.

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Clinical effectiveness of thrombus aspiration during PCI for stent thrombosis

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THEME: Coronary Interventions
TOPIC(S): STEMI, Stents and scaffolds

AIMS

Routine thrombus aspiration during percutaneous coronary intervention (PCI) for acute myocardial infarction (AMI) has not been shown to be associated with improved clinical outcomes. In patient subgroups with an angiographically high thrombus burden, however, thrombus aspiration has shown a trend towards improved cardiovascular outcomes. In this study we sought to assess the effect of thrombus aspiration on clinical outcomes in patients with stent thrombosis.

METHODS AND RESULTS

We studied all consecutive patients admitted to our institution with definite stent thrombosis between June 2015 and November 2018. Definite stent thrombosis was diagnosed on the basis of clinical and coronary angiography findings in accordance with the Academic Research Consortium (ARC) consensus definition. Data on baseline and procedural characteristics, and outcome data on mortality and target vessel revascularisation (TVR), were collected prospectively. Propensity score matching (1:1), using a nearest neighbour algorithm and no replacement, was performed to match patients who underwent thrombus aspiration (TA group) to those who did not have thrombus aspiration performed (n-TA group). Patients were matched on the following characteristics: type of stent thrombosis, type of ACS (STEMI vs. NSTE-ACS), type of treatment for stent thrombosis (PCI with stent vs. non-stent treatment), initial TIMI flow, cardiogenic shock, diabetes mellitus and use of IIb/IIIa antagonists. Kaplan-Meier analysis was used to compare outcomes between the two groups. The primary study endpoint was final TIMI flow. Survival free of cardiac death (CD) or TVR was a secondary endpoint.

During the 41-month study period, 138 patients were admitted to our institution with stent thrombosis. 2 patients who presented with stent thrombosis of covered or bioresorbable stents were excluded from the study. Of the 136 patients included, 85% were male and the mean age was 66 years. 88% of the patients presented with STEMI and the remaining 12% had NSTE-ACS. All patients underwent coronary angiography; 85 patients (62%) had PCI with implantation of a drug-eluting stent, 49 patients (36%) had balloon angioplasty only and 2 patients (2%) were managed medically. Thrombus aspiration was performed in 56% of patients. Following propensity score matching, 60 patients were included in the final outcome analyses. The two groups were well-balanced on all matched characteristics, and all other baseline demographic characteristics. Patients in the TA group were more likely to achieve TIMI 3 flow compared to patients in the n-TA group, but the difference between the two groups did not reach statistical significance (86.7% vs 76.7%, p = 0.32). At a mean follow-up of 1200 days, there was no statistically significant difference in survival free of CD or TVR (p=0.47) between the two groups.

CONCLUSIONS

Thrombus aspiration during PCI for stent thrombosis was not associated with improved clinical outcomes in this study. There was, however, a trend towards improved final TIMI flow in the thrombus aspiration group and

this provides a rationale for future trials in a larger cohort of stent thrombosis patients with improved thrombus aspiration technologies.

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Clinical consequence of new-onset left bundle branch block following TAVR: an analysis of pooled clinical trial cohorts with self-expanding valves

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

The current body of clinical evidence yields inconsistent findings as to the prognostic significance of new-onset left bundle branch block (LBBB) following transcatheter aortic valve replacement (TAVR). The aim of this analysis was to pool patients from controlled clinical trials of self-expanding transcatheter valves and to assess the incidence and long-term clinical impact of new-onset LBBB.

METHODS AND RESULTS

There were 3,757 patients in the CoreValve Pivotal Extreme Risk, CoreValve Pivotal High Risk, and CoreValve Pivotal Continued Access studies that underwent TAVR with a self-expanding device and had a 12-lead ECG at baseline. Patients that died in-hospital or withdrew from the trial (n=47), had a right bundle branch block at baseline (n=550), had a permanent pacemaker at baseline (n=727), or had a new post-TAVR permanent pacemaker at the time of hospital discharge (n=500) were excluded. The resulting analysis cohort of 1,934 patients was divided into three groups: patients with a new-onset LBBB at the time of hospital discharge (n=504), patients with no LBBB at discharge (n=1,267), and patients with LBBB that was present at baseline (n=163). The incidence of new-onset LBBB at discharge was 28.5%. The rate of new permanent pacemaker implantation between 30 days and 5 years post-TAVR was significantly different between these patient groups (new-onset LBBB 33.3%, no LBBB 13.4%, baseline LBBB 29.5%; log-rank P value <0.01). At 5 years following TAVR, the rate of all-cause mortality in patients with new-onset LBBB was 64.2%, 65.8% in patients with no LBBB, and 75.3% in patients with baseline LBBB (log-rank P value=0.06).

CONCLUSIONS

In this large cohort of high and extreme surgical risk patients having undergone self-expanding TAVR, pre-existing and new-onset LBBB were equally associated with a higher need for permanent pacemaker implantation after 30-days but not with higher all-cause mortality as compared to patients without LBBB.

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Impact of peri-procedural biomarker elevation on mortality in stable angina pectoris patients undergoing elective coronary stenting

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

While controversies are still existing over the appropriate definition for periprocedural myocardial infarction (PMI), several studies have evaluated the relationship of cardiac biomarkers elevations after percutaneous coronary intervention (PCI) and the subsequent risk of death. Nevertheless, uncertainty remains regarding the exact prognostic impact of such elevation and its association with mortality. We sought, therefore, to evaluate the effect of PMI on the subsequent mortality risk following PCI in patients with stable angina pectoris (SAP).

METHODS AND RESULTS

We conducted a meta-analysis of studies with postprocedural cardiac biomarkers data. All-cause mortality and cardiac death were evaluated in subjects with SAP who underwent an elective coronary intervention.

Thirteen studies with 19,072 patients were included (mean age of 64 years ± 9.8, 75% men). The mean duration of follow-up was 22.6 months ± 17.7. PMI, based on study specific biomarker criteria, occurred in 19.9% of the patients. The incidence of PMI conferred a statistically significant increase in the risk of all-cause mortality [odds ratio (OR): 1.53; 95% confidence interval (CI): 1.19 to 1.96; p = 0.0008; I2 = 0%] and even a more significant increase in cardiac death (OR 2.77; CI 1.6 to 4.8; p = 0.0003; I2 = 0%).

CONCLUSIONS

The incidence of PMI after an elective PCI in patients with SAP is associated with a statistically and clinically significant increase in the subsequent risk of all-cause mortality, and cardiac death.

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Distal radial artery access using slender technique for superficial femoral artery intervention

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal

AIMS

The purpose of this pilot study was to evaluate the acute success and complication rate of the distal radial artery access for femoral artery intervention.

METHODS AND RESULTS

The clinical and angiographic data of 195 consecutive cases with symptomatic superficial femoral stenosis, treated via distal radial (DR) or proximal radial (PR) access using 6F sheathless guiding between 2014 and 2018, were evaluated in a pilot study. Secondary access was achieved through the pedal artery. Primary endpoint: major adverse events (MAE), rate of major and minor access site complications. Secondary endpoints: angiographic outcome, procedural factors, cross-over rate to femoral access site, and duration of hospitalization. Overall technical success was achieved in 186 patients (95.4%) with 25/26 (96.1%) success in DR and 161/169 (95.2%) success in PR group (ns). The cross over rate to femoral access site was 3.8 % in DR and 4.7 % in PR group (ns), while dual (transradial and transpedal) access was used in 9/26 (34.6%) patients in DR and 39/169 (23%) patients in PR group ($p<0.05$). Stent implantation was necessary in 8/26 (30.7%) cases in DR and in 42/169 (24.8%) cases in PR group (ns). CTO recanalization was performed in the DR and PR group with 94.1% (16/17) and 92.6% (79/81) technical success rate. The mean contrast consumption, fluoroscopy time and procedure time was in the DR and PR group was: 93.4 [78-108]ml vs 120 [108-131]ml, 662 [501-822]vs 769 [671-866]min, and 33.4 [27-39]vs 36.5 [32-40]min (ns), respectively. The rate of access site complications in the DR and PR group was 0% and 4.7% (0% major, 4.7% minor) (p $p<0.001$), respectively. The cumulative incidence of MAE at 3 months in the DR and PR group was 3.8 % vs 10.6% ($p<0.05$).

CONCLUSIONS

Femoral artery intervention can be safely and effectively performed using transradial access.

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Consecutive intravascular imaging assessment up to three years following implantation of resorbable magnesium scaffolds

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

There is limited understanding of the process of vessel healing, especially after complete resorption of resorbable magnesium scaffolds (RMS).

In the present study, we used optical coherence tomography (OCT) imaging for characterization of atherosclerotic plaque progression up to 3 years after RMS implantation.

METHODS AND RESULTS

Corresponding OCT data at the time points of post implant and 3 years follow-up was available for 21 patients collected from 9 centres and co-registered using anatomical landmarks along with topographic information. Qualitative analysis for each circumferential quadrant was performed at a frame rate of 0.2 mm. Quadrants in post implant cases were classified as non-diseased or diseased based on the presence of lipid pool with/ without macrophages or fibrocalcific plaque; quadrants at follow-up were classified using the same criteria.

Disease state frequency obtained from corresponding post implant and 3 year follow-up quadrants was compared using pairwise Wilcoxon signed-rank test. Progression or regression of disease was subsequently determined by comparison of disease state frequencies between baseline and follow-up (cases with >5% difference).

Mean age of our 21 case cohort was 68.3±8.6 years. Amongst them 47.6% cases were females, while 19.0% had diabetes mellitus. OCT imaging was available at a median of 1,099 days post implant. A total of 944 (11.2%) diseased quadrants were discovered at index procedure, while at follow-up, we observed 813 (9.5%) diseased and 793 (9.3%) non-diseased quadrants.

Direct comparison of diseased quadrants at index procedure and follow-up yielded a mean difference of -1.71% (p= 0.20). A total of 13 cases with a median of -0.23% decrease in diseased quadrants (Interquartile range [IQR] -1.45%; 3.08%) were adjudged to be stable at 3 year follow-up. On the other hand, 3 cases with a median 5.23% increase in diseased quadrants (IQR 5.20; 5.55%) were classified as cases with disease progression while 5 cases with a median -8.26% decrease (IQR, -10.79; -7.47%) were classified as cases with disease regression.

An independent second read aimed at replicating our quadrant based qualitative assessment is underway and the results will be available for presentation during EuroPCR 2019.

CONCLUSIONS

Disease state comparison between baseline and 3 year follow-up suggests favourable vascular healing and stable disease in 13 cases (61.9%), while 5 cases (23..8%) displayed disease regression in a cohort of 21 cases implanted with resorbable magnesium scaffolds.

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Discrepant FFR/iFR results associated with lower levels of haemoglobin - Findings from the FiGARO registry

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

FiGARO registry collects data from both fractional flow reserve (FFR) and instantaneous wave-free ratio (iFR) measurements of coronary lesions in five Czech, one Japanese and one Argentinian cathlabs. The main objective is to analyze possible clinical predictors of discordant measurements between FFR and iFR.

METHODS AND RESULTS

Data has been collected since 2016, up to date 1732 combined FFR and iFR measurements in 1395 patients were analyzed. Present data comes from completed database of 1349 measurements in 1074 patients.
Correlation between FFR and iFR was high ($r=0.91$, $p<0.0001$). Discordant FFR/iFR measurement was observed in 311 cases (23.1%) – FFR positive/iFR negative type (FFR+/iFR-) of was discrepancy was more frequent (222 measurements, 16.5%) than FFR negative/iFR positive (FFR-/iFR+) type of discrepancy (89 measurements, 6.6%).
FFR-/iFR+ type discrepancy was significantly more frequent in patients with lower level of hemoglobin ($p=0.04$, 131.1 vs. 135.0 g/l). There was no significant difference ($p=0.4$) between the group of FFR+/iFR- measurements and the concordant cases.

CONCLUSIONS

We identified low level of hemoglobin as a possible predictor for FFR-/iFR+ type of discrepancy. One theoretical explanation of this relationship is increase of blood flow in patients with chronic anemia, which can lead to lower iFR results. While the basal flow is increased, hyperemic coronary flow after adenosine administration remains unchanged or similar, therefore FFR value increases.

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Influence of sex on relationship between total anatomical and physiologic disease burden and their prognostic implications in patients with coronary artery disease

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Total atherosclerosis disease burden is associated with clinical outcomes in patients with coronary artery disease. However, the influence of sex on the relationship between total anatomical and physiologic disease burden and their prognostic implications have not been well defined.

METHODS AND RESULTS

A total of 1,136 patients who underwent fractional flow reserve (FFR) measurement in all 3 major coronary arteries were included in this study. Anatomical and physiologic total disease burden was assessed by SYNTAX (Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery) score, residual SYNTAX score, a total sum of FFR in three vessels (3-vessel FFR), and functional SYNTAX score. The primary endpoint was major adverse cardiac events (MACE), a composite of cardiac death, myocardial infarction and ischemia-driven revascularization at 2 years. There were no differences in angiographic diameter stenosis, SYNTAX score and residual SYNTAX score between women and men. However, both per-vessel FFR (0.89 ± 0.10 vs. 0.87 ± 0.11, P < 0.001) and 3-vessel FFR (2.72 ± 0.13 vs. 2.69 ± 0.15, P < 0.001) were higher in women. Multivariable Cox regression analyses showed that total anatomical and physiologic disease burden were significantly associated with 2-year MACE, and there was no significant interaction between sex and total disease burden for clinical outcomes.

CONCLUSIONS

Despite similar angiographic disease severity, both per-vessel and per-patient physiologic disease severity was less in women than in men. There was no influence of sex on prognostic implications of total anatomical and physiologic disease burden in patients with coronary artery disease.

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Clinical and electrocardiographic predictors of atrioventricular conduction recovery after three months in patients with pacemaker implantation after transfemoral aortic valve implantation

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Permanent pacemaker implantation after transcatheter aortic valve implantation (TAVI) is the most common postprocedural complication. It is known, that there is a recovery of conduction over the course of time. In patients with need for permanent pacemaker implantation after TAVI, we aimed to identify factors able to predict complete restoration of atrioventricular conduction without further need for ventricular stimulation at pacemaker follow-up three months after TAVI.

METHODS AND RESULTS

764 consecutive patients who underwent transfemoral TAVI for treatment of severe symptomatic aortic stenosis at our institution were evaluated. 192 patients needed permanent pacemaker implantation after the procedure (25.1%). Patients who received a cardiac resychronization therapy device were excluded from the analysis, leaving 181 patients for evaluation. Indication for pacemaker implantation were a higher degree atrioventricular block (74%), bradyarrhythmia absoluta (14.9%), trifascicular block (5%) and first degree atrioventricular block in combination with complete large left bundle branch block (6.1%). We analyzed baseline data, 12-lead-ECG before and after the procedure as well as ventricular stimulation rate at three months and compared patients with 0% stimulation at three months (17.7%) with those who had more than 0% ventricular stimulation (82.3%). Patients with 0% ventricular stimulation had significantly less history of atrial fibrillation (18.2% vs. 41.2%, p=0.043), more often sinus rhythm in the ECG prior TAVI (100% vs. 73.3%; p<0.01), absence of complete right bundle branch block at baseline (0% vs. 24.8%; p=0.013) and lower rates of higher degree atrioventricular block as indication for pacemaker implantation (50% vs. 78.4%; p<0.01). There was a trend of a longer time interval between TAVI and pacemaker implantation in patients with 0% ventricular stimulation (5.5±2.3 days after TAVI vs. 3.9±3.8 days after TAVI, p=0.08), which became significant with a cut-off point at three days after TAVI: patients with 0% ventricular stimulation after 3 months had pacemaker implantation significantly more often later than the first three days after TAVI (80.1% vs. 44.4%, p=0.002). There was no significant difference between valve type (Boston Lotus/Lotus Edge vs. Edwards Sapien XT/ES3) in terms of ventricular stimulation rate at three months (35.1±41.0% vs. 29.6±39.7%, p=0.68).

CONCLUSIONS

In patients with need for permanent pacemaker implantation, initial sinus rhythm, absence of right bundle branch block at baseline, a longer time interval between TAVI and pacemaker implantation and indications other than higher degree atrioventricular block for pacemaker implantation had significantly more often 0% ventricular stimulation at follow-up after three months. To prevent unnecessary pacemaker implantation in those patients temporary-permanent pacemakers could be an option.

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Performance of quantitative flow reserve against combined near-infrared spectroscopy and IVUS

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Recently, QFR has emerged as a non-invasive tool to perform functional testing of coronary stenosis during the standard angiography. It not only gives a functional assessment of coronary lesions but also proves the simulated image of the vessel's anatomy. The presented study aimed to compare QFR results with IVUS-NIRS results acquired simultaneously in the same coronary lesion.

METHODS AND RESULTS

We retrospectively enrolled 66 patients in whom coronary lesions were assessed by NIRS-IVUS. The PCI was performed under angiography guidance and neither NIRS-IVUS data nor QFR data were not used PCI guidance. The combined NIRS-IVUS imaging assessed the minimal lumen area (MLA), plaque volume (PV), plaque length (PL) and maximal lipid core burden index in 4mm segment (maxLCBI4mm) of the target lesion. QFR was obtained for every lesion based on two X-ray angiographic projections acquired at different by 25? angles. The contrast frame count was performed in an angiographic run. Frame count based contrast-QFR was used for all analysis. The QFR analysis was performed offline by one blinded observer. Patients were divided into two groups based on QFR results (≤0.8 were included into QFR positive group (n=37) and rest into QFR negative group (n=29).

In our study, 56.1% (n=37) of patients had significant stenosis based on QFR and they were included in QFR-positive group. In QFR-positive group lesions were not significantly longer than in QFR-negative group (27.7 ± 10.74 vs. 22.91 ± 11.02, p=0.48). QFR-positive group characterizes smaller Minimal Lumen Area (2.2 ± 0.42 vs. 3.12 ± 1.44; p=0.007) and Minimal Lumen Diameter (1.5 (1.5, 1.6) vs. 1.7 (1.5, 1.9); p = 0.001) as compared to QFR-negative group. In QFR-positive group 91.89% lesions met the criteria for MLA threshold < 3.0mm2 but only 59.5% lesions characterized diameter stenosis >70% measured by 2D-QCA. In QFR-positive lesions the maxLCBI4mm was significantly higher than in QFR-negative lesions (450.12 ± 251.0 vs. 329.47 ± 191.14, p=0.046). According to Plaque Volume and Plaque Burden there were no significant differences comparing both groups (respectively p = 0.252, p = 0.286). There was also no difference in lumen volume and EEM volume in both groups (respectively p=0.737, p=0.658).

In QFR-positive group there was no correlation between vessel QFR and MLA (r = 0.151, p = 0.721), MLD (r = 0.064, p = 0.722), Plaque Volume (r = -0.229, p = 0.173), nor PB (r = -0.227, p = 0.176).

CONCLUSIONS

The major finding of the present study showed that QFR-positive lesions characterizes higher maxLCBI4mm as compared to QFR-negative group. Additionally we observed a smaller MLA and MLD in QFR-positive group. Also 91.89% of these lesions met the criteria for MLA threshold < 3.0mm2 but only 59.5% had diameter stenosis >70%. In QFR-positive group there was no correlation between vessel QFR and Minimal Lumen Area, Minimal Lumen Diameter, Plaque Volume or Plaque Burden.

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The influence of lipid plasma levels on maximal lipid core burden index assessed by near infrared spectroscopy

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Previous studies suggested that higher plasma concentrations of several lipid molecules are associated with higher lipid core burden index (LCBI) NIRS imaging. The aim of this study was to investigate whether association between plasma lipids depends on the plaque morphology (TCFA vs. non-TFCA) measured by NIRS-IVUS.

METHODS AND RESULTS

All patients diagnosed with SCAD or ACS between 2012 and 2015 in cardiology department who underwent NIRS-IVUS imaging were selected for this study. The PCI was performed under angiography guidance and NIRS-IVUS data were not used for this purpose. Analyzed segments were target ones in the imaged artery by NIRS-IVUS. Before the percutaneous coronary intervention blood samples were collected from every patient on day 1 after fasting for the measurement of serum levels of total cholesterol (C), LDL-C, HDL-C and triglyceride. All of them were measured enzymatically using standard methods. The study group consists of 64 lesions analyzed in 64 patients. Patients were divided into two groups based on maxLCBI4mm results. Those with maxLCBI4mm ≥323 were included into TCFA group (n=35) while others into non-TCFA (n=29).

All patients in both groups suffered from dyslipidemia. TCFA lesions were significantly longer than non-TCFA lesions (25.66 ± 9.56 vs. 17.03 ± 9.22, p=0.001). TCFA characterizes greater plaque burden (78.4 (70.9, 82.2) vs. 72.70 (64.77, 76,05); p=0.021) and plaque volume (176.1 (110.75, 247.5) vs. 68.1 (55.58, 143.35); p = 0.000) as compared to non-TCFA. The values of lumen volume (114.800 (86.100, 137.90) vs. 75.10 (55.75, 128.60); p = 0.05) and EEM volume (301.6 (212.9, 393.7) vs. 153.2 (105.85, 272.1); p = 0.003) were also higher in TCFA group. According to Minimal Lumen Area and Minimal Lumen diameter there were no significant differences comparing both groups (respectively p = 0.69, p = 0.334). We did not find a difference in RI in both groups as well (1.02 (0.8, 1.27) vs. 1.00 (0.84, 1.44); p = 0.69).

Comparing TCFA to non-TCFA group, the differences in the levels of LDL-C (80.00 (69.00, 111.00), vs. 72.00 (58.50, 97.50); p = 0.43), HDL-C (39.50 (35.75, 46.00) vs. 42.00 (33.50, 53.00) p = 0.47), TCH (146.00 (122.00, 181.00) vs 140.00 (120.50, 167.50) p = 0.80) and TG (119.00 (74.00, 160.00) vs. 102.00 (83.50, 120.50); p = 0.34) were not statistically significant. In non-TCFA group there was no correlation between maxLCBI4mm and LDL levels (r = -0.55, p = 0.783), TCH levels (r = -0.133, p = 0.498) nor HDL-C levels (r = -0.062, p = 0.754). In TCFA suspected lesions there was also no correlation between maxLCBI4mm and LDL levels (r = 0.105, p = 0.549) nor TCH levels (r = -0.035, p = 0.844) but we found a negative correlation between HDL-C and maxLCBI4mm (r = -0.453, p=0.007).

CONCLUSIONS

Our study showed that there was no correlation between plasma LDL-C, TCH and TG level and the amount of lipids in coronary plaque assessed by NIRS in both TCFA and non-TCFA group. Only HDL-C correlated with maxLCBI4mm in TCFA lesions. There was also no difference in LDL-C, HDL-C, TCH and TG in patients with TCFA comparing to those with non-TCFA lesions. Based on IVUS analysis TCFA characterized greater values of plaque volume, plaque burden and stenosis length.

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Long-term outcome following primary PCI in elderly patients

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THEME: Coronary Interventions
TOPIC(S): STEMI, Other Coronary Interventions

AIMS

Primary PCI is the preferred treatment of choice in an acute STEMI situation even in the elderly age group, despite of lack evidence in this cohort as most of the randomised studies have excluded octogenarians and above. A retrospective study to analyse and provide insight into the long-term outcome, including mortality and major adverse cardiovascular events among very elderly patients (≥80 years old) versus the younger age group undergoing primary PCI for ST-elevation myocardial infarction (STEMI) including all comers over 6 years period in a high volume district general hospital.

METHODS AND RESULTS

Between 2006 and 2012, a total of 853 patients (average age 65.6, maximum age 92, minimum age 32) underwent primary percutaneous coronary intervention (PCI) at our centre. Patient outcomes after 1 year, 2 years were recorded and analysed in terms of incidence of recurrent MI, cerebrovascular event, or death. There were 127 patients in very elderly group of ≥ 80 years old (56.7% male) versus 726 patients in < 80 years old group (77.7% male).

The 1 year MACE outcome including recurrent MI, Cerebrovascular events (CVE) is almost doubled (10.2% vs 5.09%, p=0.00004) between the very elderly and <80 years age group respectively and the 1 year mortality rate in very elderly patients was 19.7 % (25 patients) vs 8.5 % (99 patients)(p=0.000129) in <80 years of age group. Despite the statistically lower 2 years MACE in elderly group than in <80 years age group (2.36 % vs 3.165, p= 0.000925), we noted a significantly higher 2 years mortality rate (7.1 % vs 0.8%, p=0.000001) in the very elderly group as compared to <80 years age group.

CONCLUSIONS

We are aware that elderly population are not recruited in most trials and Primary PCI the preferred treatment of choice but our analysis of real world data showed that by the end of 2 years the adverse events are slightly lower in very elderly age group, however, the mortality is significantly higher in comparison to the population <80 years old, which reflects overall poor outcome of PPCI in octogenarians.Future randomised-controlled trials should consider including the elderly population which would help in identifying the treatment of choice for the icreasing cohort of elderly patients with acute myocardail infarction.

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Prognosis of patients with chronic coronary artery disease undergoing PCI (five-year follow-up)

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

to evaluate the prognosis of patients with chronic ischemic heart disease, who underwent percutaneous coronary interventions (PCI) and were only on optimal medical therapy (OMT).

METHODS AND RESULTS

Methods: measurement of the fractional flow reserve (FFR) was performed for 432 patients. According to the measurement results, all patients were randomized in 2 groups (1:2): Group I (n=168) – included patients, who had a FFR <0.8 and were followed by PCI; Group II (n=264) – included patients with FFR >0.8 - received OMT and were under monitoring for to 5 years. Inclusion criteria: stable angina II-III FK, post-MI, silent myocardial ischemia. Concomitant diseases: diabetes mellitus (19.2%), multifocal atherosclerosis (21%), hypertension (27%), post-MI (24%), PCI in previously (15%). According to angiography, 44% had a one-vessel disease, 35% had two-vessel diseases, and 21% had a three-vessel disease. Primary endpoints: MACE (death, MI, repeated interventions). Observation periods: 6, 12, 24, 36, 48, 60 months. Long-term results were evaluated by repeated coronary angiography and measurement of FFR.

Results: during 6 and 12 months there were not a single case of MACE in both groups. By the 18th month, 7% of cases conversion from the OMT to the PCI group on the basis of FFR measurements was recorded. By the 24th and 36th months in the OMT, PCI group was performed in 12 and 21% of patients, respectively. By the 48th and 60th month, the number of such patients was 24 and 31%, respectively. Among the total number of performed PCI in Group II, 20% of them were due to unstable angina. Thus, over the entire observation period, 149 patients from group II (56%) had PCI performed. The frequency of MACE in group I to 36 months was 2.4%, and in group II - 18%, respectively (p <0.001). By the end of the observation period, the frequency of MACE in groups I and II was 4.2 and 31%, respectively (p <0.001). Multifactor analysis showed that with SYNTAX score> 28, multifocal atherosclerosis, diabetes mellitus, MACE was significantly more frequent and there was a need to perform PCI in the long-term period.

CONCLUSIONS

the prognosis of patients with chronic coronary artery disease undergoing percutaneous coronary intervention, performed using measurement of FFR, is significantly better than in patients who were only on optimal medical therapy.

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Effect of post-PCI bivalirudin infusion on net adverse cardiovascular events and stent thrombosis: a post-hoc analysis of the Global Leaders study

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

To investigate the association between post-percutaneous coronary intervention(PCI) bivalirudin infusion and the risk of net adverse cardiovascular events (NACE)in patients with stable coronary artery disease (SCAD) or acute coronary syndrome (ACS).

METHODS AND RESULTS

GLOBAL LEADERS study evaluated the efficacy and safety of ticagrelor monotherapy after 1 month dual-antiplatelet treatment in patients undergoing PCI with biolimus-A9 eluting stent.Allpatients who received bivalirudin-assisted PCI were stratified into two groups according to the use of bivalirudin infusion post procedure. The primary endpoint of the present study was NACE (defined as a composite of all-cause death, any stroke, any MI, all revascularizationand BARC type 3 or 5 bleeding). The secondary endpoint was definite and/or probable stent thrombosis at 30 days.

Of 15,968 patients, 13,870 (7281 with SCAD and 6589 with ACS) underwent bivalirudin-assisted PCI. 7148 (51.5%) were treated with bivalirudin infusion after procedure, whereas 6722 patients (48.5%) were not. The indications for bivalirudin infusion after procedure were as follows: routine use (93.5%), residual thrombus in coronary artery (1.7%), untreated coronary dissection (0.7%), oral antiplatelet agents not given or vomited (0.3%), systemic anticoagulation (0.1%) and others (4%). The 30-day NACE rate was 2.93% (n=210/7148) in patients with bivalirudin infusion and 2.75% (n=185/6722) in patients without bivalirudin infusion (P=0.508). The incidence of definite and/or probable stent thrombosis was 0.63%(n=45/7148) in patients with bivalirudin infusion and 0.45%(n=30/6722) in patients without bivalirudin infusion (P=0.165).After adjustments for baseline characteristics, two groups had comparable outcomes in terms of NACE (hazard ratio 1.09, 95% CI, 0.87-1.36, P=0.469)and definite and/or probable stent thrombosis (hazard ratio 1.36, 95% CI, 0.86-2.17, P=0.190)at 30 days.

CONCLUSIONS

In an all-comers population undergoing PCI, 30-day NACE and definite and/or probable stent thrombosis rates were not significantly different between patients with or without bivalirudin infusion after PCI.

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Alternative technique to cross CTO in above and below-the-knee lesions using a new dedicated device

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THEME: Peripheral Interventions
TOPIC(S): Below the knee

AIMS

Crossing peripheral calcific CTO continues to be challenging and time consuming. Many companies in this market develop and improve sophisticated guidewires, support catheters and expensive CTO specialty devices which increase time to cross CTO and often compromise safety.
The purpose of this study was to evaluate safety and efficacy of a balloon catheter with two guidewire lumens to recanalize peripheral CTO.

METHODS AND RESULTS

After unsuccessful CTO luminal crossing and subintimal re-entry using conventional methods for minimum of 10 minutes of fluoro time, a guidewire was placed subintimal and distal to the CTO (first guidewire). A balloon catheter was introduced over the first guidewire and positioned in subintimal space over the distal CTO cap. The balloon catheter was then inflated and deflated to create a
transient fenestration between subintimal space and the true lumen. A second guidewire was introduced into the second guidewire lumen within the balloon catheter and navigated through the fenestration to re-enter into the distal true lumen. Then, the balloon catheter and the first guidewire were removed and intervention was continued using the second guidewire positioned in the true lumen. The primary safety end point of the study was safety defined as no occurrence of vessel perforation or dissection. The primary efficacy endpoint was the succesfull the re-entry of the guidewire in the true
distal lumen using this approach.
Between May 2018 and December 2018, we used the balloon catheter with two guidewire lumens to cross calcific peripheral CTO after failed attempts with conventional guidewire techniques in 12 patients (12 CTO). All patients had critical limb ischemia and Rutherford scale scores from 4 to 6. Five patients had infrainguinal CTO and seven patients had CTO below the knee.
The mean age of all 12 patients was 75.5 ±5.7. The mean infrainguinal CTO length was 157 mm ±53mm and mean CTO length below the knee was 121 mm ±32mm. The primary safety and efficacy end points were achieved in all patients.
succesful direct flow to the foot was obtained in all patient using a plain balloon in all patients.

CONCLUSIONS

In our preliminary experience, subintimal calcific CTO recanalization using a balloon catheter with two guidewire lumens for re-entry in the true lumen has proven to significantly decrease procedure time, is safe and achieve a high success rate. A larger multi-center clinical study is required to validate this new approach.

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Short- and long-term prognosis of patients undergoing urgent TAVI - A report from the nationwide SWENTRY registry

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

The aim of this study was to compare the short- and long-term prognosis of patients undergoing urgent to elective TAVI (transcatheter aortic valve implantation) procedure. An urgent procedure is defined as a procedure where the patient is not able to be discharged from hospital due to decompensated left ventricular function.

METHODS AND RESULTS

All TAVI procedures performed in Sweden have been registered in the SWEdish traNscatheter cardiac intervention regisTRY (SWENTRY). 3,686 TAVI procedures were performed between 2008 and 2017 of which 395 (11%) were classified as urgent. The patients undergoing an urgent procedure were similar to elective patients regarding gender (51% male), body mass index (BMI) (mean 26 kg/m2) and the maximum pressure gradient over the aortic valve (mean 79 mmHg). Patients undergoing an urgent procedure were younger (mean 80 vs 81 years), had worse kidney function (mean Serum-Creatinin 127 vs 105 mmol/L), more often a previous myocardial infarction within 3 months (15% vs 5%), more often atrial fibrillation (43% vs 37%), higher level of NT-proBNP (mean 11469 vs 3899 ng/L), more common left ventricular ejection fraction <50% (63% vs 37%) and more often right ventricular pressure >60 mmHG (27% vs 15%).

The Kaplan Meier estimates for mortality at 30 days and at 365 days were higher for urgent compared to elective procedures (9.3% vs 4.4%, log-rank test p<0.01 and 26% vs 12%, log-rank test p<0.01 respectively).

Logistic regression adjusted for propensity score created from baseline variables (age, gender, diabetes, chronic pulmonary disease, previous stroke, atrial fibrillation, BMI, previous surgical biologic aortic prothesis and treating hospital) did not show a significant increase for risk of death at 30-days (OR 1.52; 95% CI 0.96-2.42) but a significant increased risk for death at 1 year (OR 1.84; 95% CI 1.38-2.44).

CONCLUSIONS

In this study, patients undergoing urgent TAVI procedures compared to elective procedure have similar short and increased long term risk of death. The results imply that urgent TAVI is feasible but a careful evaluation of prognostic risk factors is of even more importance in patients with decompensated left ventricular function due to aortic valvular stenosis before patients are treated.

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Prevalence, clinical characteristics and prognosis of patients referred for primary PCI without obstructive coronary disease

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

A proportion of patients with suspected STEMI that are referred for emergent coronary angiography and primary PCI (PPCI) suffer from conditions other than acute coronary obstruction. We aimed to characterize such a population and compare its short-term prognosis with that of confirmed STEMI patients.

METHODS AND RESULTS

Retrospective analysis of 2226 pts with suspected STEMI referred for emergent invasive coronary angiography in a single PPCI reference hospital between January 2012 and November 2018. Patients with cardiorespiratory arrest were excluded. Baseline, procedural and 30-day outcome data was prospectively collected in a local dedicated Cath-lab database for patients admitted to the reference centre, while data regarding diagnosis and outcome of patients without confirmed STEMI finally admitted to referral institutions was captured from the national health system clinical registry. Baseline characteristics and 30-day mortality were compared between those with and without a definitive diagnosis of STEMI.

72 pts (3.2%) referred for PPCI presented with non-obstructed coronary arteries. These patients were younger (55 IQR 42-66 vs 64 IQR 54-73), had a lower prevalence of hypertension (35% vs 58%, p<0.001), diabetes (10% vs 23 %, p=0.006), smoking (36% vs 49%, p=0.041) and of clinical background of coronary artery disease (myocardial infarction or coronary revascularization, p<0.001). The most common EKG finding was ST elevation in inferior leads (31%), while left bundle brunch block was present in 7 patients (10%). Forty-sixt percent of the patients (n=33) had a cardiac condition, 37% without coronary involvement. The most frequent final discharge diagnosis were miopericarditis (n=14;19%), Takotsubo syndrome (n=8;11%), musculoskeletal diseases (n=6;8%), myocardial infarction assumed to be due to coronary artery spasm or with spontaneous revascularization (n=6; 8%), acute heart failure with new onset LBBB (n=5; 7%), gastro-intestinal diseases (n=4; 6%) and drug abuse (n=3; 4%).

At 30 days, none of the patients that presented with suspected STEMI died; conversely, patients with confirmed STEMI had an overall 30-day mortality rate of 3.5% (n=76).

CONCLUSIONS

In a contemporary PPCI population, the prevalence of “normal” coronaries (without severe stenosis or complete obstruction) is trivial. A significant proportion of patients (46%) had a cardiac condition mimicking STEMI. The short-term prognosis is good.

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The CAMI1 study: selective CRP apheresis as a new treatment option in AMI

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

In patients with STEMI, C-reactive protein (CRP) is a marker of poor prognosis and independently predicts 30-day mortality. In STEMI, CRP may be involved in myocardial damage by activating the complement system in the ischemic tissue. In animal experiments, CRP removal after STEMI reduces infarct size and results in a significantly better LVEF. Recently, a new CRP adsorber has been demonstrated to efficiently and selectively lower CRP plasma levels in humans. We present preliminary data of the ongoing human multi-center matched-control pilot study on CRP apheresis in STEMI (CAMI1).

METHODS AND RESULTS

Methods: Up to the present day, 83 STEMI patients were enrolled in the study following complete coronary revascularization. 43 patients received CRP apheresis, whereas 40 patients treated by standard protocols served as controls. CRP apheresis started 24 ± 12 h after onset of symptoms. In case of a rapid increase in CRP plasma levels following the 2nd session, a 3rd session was carried out another 24 h later. In each apheresis session, 6000 ml plasma was treated via peripheral venous access. Primary study endpoint was myocardial infarction size as determined by Cardiac Magnetic Resonance Imaging (MRI) 5 ± 3 days and 12 ± 2 weeks after STEMI.

Results: Apheresis sessions were well tolerated with no relevant side effects. Peak CRP plasma levels after STEMI ranged from 9 mg/l to 279 mg/l. An area under the curve calculated from the CRP plasma level between 12 and 72 h after the onset of symptoms of ≤ 1000 was associated with a significantly smaller myocardial infarct size. CRP apheresis resulted in an average 64% reduction in CRP plasma levels. 5 ± 3 days after STEMI, myocardial infarct size in the CRP apheresis group that reached an AUC ≤ 1000 was 35% smaller (p=0.012) compared to controls (AUC > 1000). Moreover, LVEF was 10% (p=0.024) better and circumferential strain was 14% (p=0.019) better in the CRP apheresis group. In the follow-up period (≤12 months), 2 major adverse cardiac events (MACE) occurred in the control group and none in the CRP apheresis group.

CONCLUSIONS

Here, an unequivocal association between infarct size and CRP is demonstrated for the first time. CRP apheresis following STEMI is feasible and safe. Our preliminary results in a small cohort show a significant beneficial effect of CRP apheresis on myocardial infarction size and wall motion. Selective CRP apheresis may emerge as a new therapeutic approach in the treatment of acute myocardial infarction but it needs to be

mentioned that the trial was not yet adequately powered to reveal an unambiguous significance.

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Impact of mitral stenosis in the outcomes of patients undergoing TAVR. A multicentre study

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

This study sought to analyze the impact of mitral stenosis (MS) in patients with severe aortic stenosis (AS) undergoing transcatheter aortic valve replacement (TAVR).

METHODS AND RESULTS

METHODS: Between 2008 and 2018, 2866 consecutive patients with diagnosis of AS underwent TAVR across 10 centers. All patients underwent complete 2-dimensional and color doppler echocardiography at baseline, before discharge and at 1 year after TAVR. Patients were classified according of presence of moderate-severe MS or not. Any prior mitral intervention (percutaneous valvuloplasty or surgery) was recorded. The primary outcome was a composite of all-cause mortality and stroke. The secondary endpoints were NYHA functional class, re-admission, tricuspid regurgitation degree, and pulmonary hypertension in the follow up.

RESULTS: Mean age was 80.8±7.2 years and 53,9% were women. Moderate or severe MS was present in 89 patients (3,1%). The rheumatic etiology was the most frequent (69%) and 75% were successfully treated with mitral valvuloplasty either before (25%) or after (50%) TAVI, requiring surgical mitral replacement 39% of the cases. Degenerative etiology was mostly treated conservatively (76.9%) without differences in global mortality rate at 1-year follow up (0% in rheumatic MS vs. 20% in degenerative cases, p=0.542). Patients with MS were younger (78.8±8.8 vs. 80.4±7.1, p=0.001), with higher surgical risk according to EuroSCORE (16±12 vs. 21±14%, p=0.04), and higher rates of prior cardiac surgery (37 vs. 12.7%, p<0.001) atrial fibrillation (62.9% vs. 29.8%, p<0.001), pulmonary hypertension (50.17±16 mmHg vs. 44.94±18mmHg, p=0.024), and significant tricuspid insufficiency (30.5% vs. 15.8, p=0.003). Concomitant MS and significant tricuspid insufficiency were related to higher rate of pulmonary hypertension, worse NYHA class, and greater mortality. A total of 308 (10.8%) and 473(16.5%) patients had died at 1- and 3-year follow-up. Higher EuroSCORE, the pulmonary systolic pressure, and atrial fibrillation were associated to worse prognosis at both timepoints but MS was neither associated to an increased mortality (OR=1.23 at 1-year and OR=1.07 at 3-year, p=NS), nor to greater stroke rate (OR=0.793 at 1-year, p=NS). The combined endpoint of death and stroke did not show differences. Conversely, MS patients presented a trend towards worse NYHA functional class (NYHA II-III 18.5 vs 10.6%, p=0.062) and greater need for oral diuretics (81.5% vs. 69.2%, p=0.018) at 3-year follow up.

CONCLUSIONS

Moderate-Severe MS is uncommon in TAVR recipients (~3%), and in 2/3 due to rheumatic disease in our population. Most of them received successful percutaneous valvuloplasty whereas degenerative MS was managed conservatively before TAVR without differential outcomes at 3-year follow up. MS was not

independently associated to worse mortality after TAVR but the poorer clinical recovery suggests that newer approaches for this combined problem are required.

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Impact of varying severities of femoropopliteal artery calcification on 12-month outcomes after paclitaxel DEB angioplasty

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal

AIMS

We performed an independent angiographic core lab analysis to quantify the femoropopliteal artery (FPA) calcium burden assessed by standard fluoroscopy and its impact on loss of 12-month primary patency in a patient level de-identified data set of 1,184 lesions in 1,135 claudicants treated with a drug-coated balloon.

METHODS AND RESULTS

We analyzed demographic and angiographic de-identified data from 1,135 patients enrolled in DCB arms of the IN.PACT SFA, IN.PACT Japan, and ILLUMENATE Pivotal randomized controlled trials, the pre-specified long lesion and chronic total occlusion cohorts of the IN.PACT Global study, and the ILLUMENATE Global study. Study data sets were sent to a central statistical analysis center. The respective IN.PACT and ILLUMENATE core laboratories provided the initial angiographic analyses for reference vessel diameter (RVD), % diameter stenoses (%DS) and dissection grades. Angiograms were then reviewed at a Central Core Laboratory using a novel fluoroscopy-based vascular calcification scoring system by blinded observers. 1,184 lesions were analyzed with co-registration of 12-month target lesion assessment of primary patency adjudicated by an independent duplex-ultrasound core lab.

Lesion length was defined in mm as the distance between the most proximal and distal > 20%DS. Treatment length was defined as the distance between the most proximal and distal balloon inflation.RVD was determined by the average of the proximal and distal non-diseased segments. Minimal lumen diameter (MLD) was the smallest diameter within the treated segment. %DS = (1 – MLD /RVD)* 100. Total occlusions were those with 100%DS and no antegrade flow.

Primary patency failure (PPF) was the primary endpoint of this analysis. Univariate predictors of PPF were identified and a multivariate logistic regression model was constructed using candidate variables with univariate p-value <0.10. Backward selection with a significance level of 0.20 was required for a variable to stay in the model (SLSTAY=0.20). A $p < 0.05$ was considered significant.

The mean patient age was 68.5 ± 9.8 years; there was a high prevalence of men, hypertension, hyperlipidemia, and diabetes mellitus. The mean target limb ankle brachial index of 0.71 ± 0.21 and 67.1% of patients had a Rutherford Category 3 or greater. The mean lesion length was 109.9 ± 80.6 mm and mean treatment length 142.9 ± 86.5 and 38.6% total occlusions. The baseline %DS was 83.0 ± 17.0% with a 20.5 ± 12.7% final post-procedure %DS

Lesion calcium severity was determined by a quantitative assessment of the length of bilateral calcium measured at the lesion and normalized to both lesion length and treatment length. The overall 12-month PPF calculated on a proportion basis was 23.0%. The multivariate analysis predictive of 12-month PPF included the presence of total calcium length normalized by treatment length (OR 1.004; p=0.028) and total bilateral calcium length normalized by treatment length (OR 1.01; p=0.013).

CONCLUSIONS

Our angiographic core lab adjudicated analysis of a large de-identified patient-level dataset identified that the total femoropoliteal lesion calcification defined by a novel fluoroscopy-based calcification scoring system was an important independent predictor of 12-month loss of primary patency after DCB angioplasty.

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Predictors of length of hospital stay after TAVI

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

There is an increasing trend towards shorter hospital stay after transcatheter aortic valve implantation (TAVI), especially for patients undergoing the procedure via transfemoral access. In the current era of cost containment hospitalization, duration is of particular importance. Prolonged hospitalization can be associated with increased costs and resource utilization. The aim of this study was to identify predictors for the length of hospital stay after TAVI implantation.

METHODS AND RESULTS

A total of 1058 patients who underwent TAVI between March 2012 and January 2018 at our center were enrolled in this retrospective analysis. The primary endpoint was the length of hospital stay after TAVI implantation. We defined “early discharge” ≤ 7 days and “late discharge” > 7 days post-TAVI. Baseline characteristics and peri- as well as postprocedural variables were analyzed to the primary endpoint. Multivariate models were created to identify various factors and outcomes associated with delayed discharge.

Among 1058 patients, 671 (63.4%) were discharged late. The mean hospital stay was 10 days (SD +/-5.8). With the exception of a previous pacemaker implantation there were no significant differences in baseline characteristics between the early discharge and prolonged stay group. Multivariate predictors that were significantly associated with higher likelihood for late discharge were: post-operative bleeding (OR: 0.6; 95%CI: 0.45-0.81; P = 0.001), blood transfusion (OR: 1.19; 95%CI: 1.04-1.35; P 0.01), stroke or TIA (OR: 1.44; 95%CI: 1.11-1.89; P = 0.006), acute kidney injury (OR: 1.41; 95%CI: 1.15-1.72; P = 0.001) and implantation of a new permanent pacemakers (OR: 1.2; 95%CI: 1.1-1.33; P < 0.001). From 671 patients who were discharged home delayed, 413 Patients (61.5%) had no periprocedural complications.

CONCLUSIONS

TAVI related complications like bleeding, transfusions, cerebrovascular events, acute kidney injury and conduction disturbances needing a permanent pacemaker can perpetuate prolonged hospital stay. However, there still is a substantial number of patients who remain hospitalized for monitoring purposes, despite the absence of critical medical ground. Unified and adjudicated Standard operating procedures could help identify patients eligible for early discharge thereby minimizing unnecessary use of personnel and medical resources hence considerably decreasing economic burden on both patient and hospital.

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Prognostic impact of post-procedure TIMI flow on in-hospital mortality in STEMI patients undergoing pharmaco-invasive strategy

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Suboptimal post-procedure TIMI flow (TIMI flow < 3) has been identified as an important predictor of in-hospital mortality following primary PCI in STEMI patients. This association in the setting of pharmacoinvasive approach for the management of STEMI has not been investigated.

METHODS AND RESULTS

Between March 2010 and October 2016, 1,652 STEMI patients were treated with a pharmacoinvasive strategy, and consecutively included in a prospective, single-center registry. Multivariate logistic regression analysis was conducted to investigate the association between suboptimal final TIMI flow and in-hospital mortality. Final suboptimal TIMI flow occurred in 307 patients (18.5%). Patients with suboptimal TIMI flow were older (60.5 ± 11.9 vs. 57.4 ± 11.6 years, p<0.001), had higher GRACE scores (153.8 ± 45.5 vs. 140,8 ± 37.3, p<0.001), and lower left ventricular ejection fraction (44.4 ± 12.3 vs. 49.5 ± 11.9%, p<0.001) than patients with normal (TIMI 3) coronary flow. In comparison to patients with final TIMI 3 flow, patients whith suboptimal TIMI flow had significantly higher in-hospital mortality (13.4% vs. 3.2%, p<0.001) and non-fatal myocardial infarction (5.0% vs. 1.4%, p<0.001). The independent predictors for in-hospital mortality were Killip class IV at admission [odds ratio (OR): 28.32; 95% confidence interval (CI): 13.27-60.47, p<0.001], suboptimal final TIMI flow (OR: 3.80; 95% CI: 1.78-8.13, p=0.001), female gender (OR: 2.18; 95% CI: 1;03-4.62, p=0.042), age (OR: 1.05; 95% CI: 1.02-1.09, p=0.001), maximum troponin rise (OR: 1.03; 95% CI: 1.01-1.06, p=0.039), and admission heart rate (OR: 1.02; 95% CI: 1.01-1.04, p=0.020).

CONCLUSIONS

In STEMI patients managed with pharmacoinvasive strategy in this large and prospective registry , suboptimal post-procedure TIMI flow was relatively frequent and identified as an independent predictor of in-hospital mortality. Strategies aiming to further improve the rates of normal coronary flow in this high-risk population could have an important prognostic impact.

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The SELECT RBBB multicentre registry - SELECTion of transcatheter heart valves in patients with pre-existent Right Bundle Branch Block and impact on pacemaker implantations

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Complete pre-existing right bundle branch block (RBBB) is the strongest patient-related predictor for new permanent pacemaker implantation (PPI) after transcatheter aortic valve replacement (TAVR). RBBB results in an up to 12-fold risk increase with PPI rates of up to 40%. For newer generation transcatheter heart valves (THV), no comparison with regard to PPI in patients with RBBB exists. We aimed to evaluate the impact of ACURATE neo (NEO) versus SAPIEN 3 (S3) on PPI in patients with RBBB.

METHODS AND RESULTS

The SELECT RBBB registry includes 4305 consecutive patients treated with TAVR using the NEO or the S3 for severe symptomatic aortic stenosis in 7 centers in Germany and Switzerland between January 2014 and July 2017. Of these, 296 displayed a pre-existent complete RBBB no permanent pacemaker at baseline and had evaluable CT data and formed the study population. The effect of THV (NEO vs. S3) on the primary endpoint new PPI before discharge was evaluated using 3 different appraoches: a binary logistic regression analyses, inverse probability treatment weighting (IPTW) and by creating a propensity matched population. Overall, PPI rate was 37.8% in the entire study population. NEO was associated with a lower PPI rate and risk compared to S3 (29.8% vs. 41.9%, p=0.040, odds ratio (OR) 0.58 95% confidence interval (CI) [0.34-0.97], p=0.041), after multivariable adjustment (OR 0.50 95%CI [0.28-0.90], p=0.022) and in the IPTW analysis (OR 0.38 95%CI [0.25-0.56], p<0.001, figure 1 right panel). There was no difference between NEO and S3, in terms of device failure (8.2% vs. 6.2%, p=0.792). Postprocedural mean transaortic gradients were significantly lower with NEO (8 mmHg vs. 11, p<0.001). In-hospital complications were comparable between both THV. Results from the entire population analysis were confirmed in a propensity matched population. Here, PPI rate was also lower with NEO vs. S3 (23.1% vs. 49.2%, p=0.001, OR 0.31 95% CI [0.14-0.65], p=0.002), while no difference in rate and risk of device failure was observed (9.2% vs. 6.2%, p=0.742, OR 1.55 [0.42-6.33], p=0.513).

CONCLUSIONS

In patients with pre-existent RBBB, the present SELECT RBBB registry suggests the possibility of a patient-tailored THV therapy to reduce PPI rate after TAVR.

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LAA occluder real-life data from Europe: final two-year results of the prospective, multicentre 1,020 patients. EWOLUTION registry including subgroup analysis

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THEME:
TOPIC(S):

AIMS

According to the latest ESC guidelines LAA (left atrial appendage) occluder therapy is recommended for all patients with atrial fibrillation at increased stroke risk, where effective longterm oral anticoagulation is not feasible. EWOLUTION reports the safety and efficacy of the WATCHMAN LAA occluder in this setting.

METHODS AND RESULTS

1020 patients scheduled for elective LAA occluder therapy were consented for participation in the registry and followed for 2 years; at least 83% of sites recruited consecutive patients. 1005 patients received a successful implant. Over the 2 year study period, 161 patients died, 18 patients withdrew and 42 were lost to follow-up. TEE follow up data is available for 835 patients (83%). Completed follow-up data set is available for 784 patients (78%). Mean CHA2DS2-VASc for the overall population was 4.5, mean HAS-BLED was 2.3 with an expected annual rate of ischemic stroke w/o oral anticoagulation of 7.2/100 patient-years (PY)and major bleeding rates on VKA of 5.0/100 PY, respectively. The observed rate in the whole stud population for ischemic stroke was 1.3 per 100 PY, the observed non-procedural major bleeding rate was 2.7 per 100 PY. Patients with a history of ischemic (n=311) or hemorrhagic (n=153) stroke had an observed rate of 2.3 and 1.8 strokes and 3.2 and 1.8 major bleeds per 100 PY, respectively. Patients with abnormal renal function (n=162) had 1.2 ischemic stroke events and 6.7 major bleeds per 100 PY. Lower risk patients who transiently received oral anticoagulation post-implant (n=274) had 0.6 ischemic stroke and 1.9 non-procedural major bleeds per 100 PY. Higher risk patients with transiently prescribed DAPT post-implant (n=608) had 1.5 ischemic stroke and 2.7 major bleeds per 100 PY. Lastly, the subgroup of patients switched to single antiplatelet therapy or no therapy (n=766) experienced 1.3 ischemic stroke and 1.3 major bleeds per 100 PY after medication switch.

CONCLUSIONS

Following WATCHMAN LAA occluder therapy, the observed rate of ischemic stroke and major bleeds in AFib patients followed over a 2 year time frame is between 1-2% and 2-7%, respectively. Both for the overall population as well as for various subgroups the observed event rates are consistently lower than previously reported in such patient cohorts w/o longterm oral anticoagulation providing additional evidence of the efficacy and safety of this device in interventional stroke protection.

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Zwolle score as a predictor of contrast-induced nephropathy after primary angioplasty

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THEME:
TOPIC(S):

AIMS

Contrast-induced nephropathy is an important complication after invasive cardiac procedures, as it is associated with short- and long-term morbidity/mortality, as well as longer hospitalizations and higher hospital costs.

The Zwolle primary PCI index (ZS) is a risk score that has been used to identify low-risk patients with ST-elevation myocardial infarction (STEMI) undergoing primary PCI (PPCI). We questioned whether this score could predict the development of Contrast-induced Nephropathy (CIN).

METHODS AND RESULTS

Methods

This retrospective study is composed of a sample of 3462 patients, derived from a national multicentre registry, that were admitted in the catheterization laboratory with STEMI and underwent PPCI.

The ZS (16 points (p) total) is characterized by:

-Killip 1: 0p; Killip 2: 4p; Killip 3-4: 9p

-TIMI 3 flow post: 0p; TIMI 2: 1p; TIMI 0-1: 2p

-Age <60: 0p; ≥60: 2p

-3-vessel disease: 1p

-Anterior MI: 1p

-Ischaemia time >4h: 1p

The variable CIN was defined as an increase of 25% or 0.5mg/dL relative to baseline serum creatinine in the first 72 hours after contrast administration.

After population characterization, we have performed a ROC curve analysis between the outcome CIN and ZS, reporting AUC, optimal c-statistic and its epidemiological data.

We also have performed a multivariate analysis reporting OR with plausible variables.

Results

The sample mean age is 63 ± 13, and it is composed by 77,1% of males. The majority of patients presented Killip Class I (87,1%). The STEMI was anterior in 49.6% of patients and inferior in 49.9% of patients. The mean serum creatinine at admission was 1 ± 0.5md/dL, and 17.2% (597) developed CIN.

The mean ZS was 2.8 ± 2.5 p in patients without CIN and 4.4 ± 3.3 p in patients with CIN.

The ROC curve analysis between CIN and ZS revealed an c-statistic of 0.824 and an Youden index of 3.5p (optimal cut-off point: specificity 68%, sensitivity 84%, negative predicting value 94%, positive predicting value 42% and accuracy 72%).

We also have performed a multivariate analysis model which included the variables ZS ≥3.5p, left-ventricle

ejection fraction (LVEF) <50%, NT-proBNP > 500pg/mL, cardiovascular risk factors, past history of heart failure (HF) and chronic kidney disease (CKD). An OR of 8 (95% CI 2,2 – 28,8; p=0.002) for the variable ZS ≥3.5p was obtained. Past history of HF had an OR of 2.26 (95% CI 1.25-4.08; p=0.007), LVEF <50% had an OR of 1.89 (95% CI 1.55-2.3; p<0.001); CKD had an OR of 1.83 (95% CI 1.15-2.9; p<0.011).

CONCLUSIONS

We conclude that the ZS is a good test to rule out CIN in our population of patients submitted to PPCI, as it is shown by its very high negative predicting value at optimal cut-off point (94%). A ZS ≥3.5 is the optimal cut-off point to predict the studied outcome and represents an increased risk of CIN by 8 times.

The calculation of the Zwolle score during PCI could allow the initiation of preventive measures to limit the renal damage associated with this intervention. It can also be used for risk stratification in this population of patients.

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Intracoronary nitroglycerin plus non-ionic contrast accurately predict FFR result

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Functional assessment of coronary artery stenosis is performed by measuring FFR or by measuring iFR. However both methods have limitations: the use of adenosine has some potential drawbacks and iFR requires an specific software.

We sought to investigate the relationship and correlation between FFR and three free-adenosine indexes that not require a specific sofware: Pd/Pa ratio during submaximal hyperaemia induced by non-ionic contrast medium(cFFR); the Pd/Pa value obtained just after the intracoronary infusion of nitroglycerin plus non-ionic contrast(cFFR-NTG) and resting baseline Pd/Pa.

METHODS AND RESULTS

From Jan 2017 to Dec 2018, 199 patients with 235 angiographic coronary stenosis functionally evaluated by pressure wire were prospectively enrolled in the three participating centers. Mean age was 66.8±11.9 years and 78.9% were males. The majority of patients had stable coronary artery disease or atypical chest pain (60.4%) the rest were acute syndromes, including 11.5% of STEMI in which the functional assessment was performed in a second-stage procedure to evaluate a non-culprit lesion.

The most frequently studied vessel was the left anterior descending (51.9%) and the mean angiographic stenosis measured by QCA was 52±13.9%. An angioplasty of the studied lesion was performed in 40.5% (95/235).

Resting baseline Pd/Pa value was 0.6 to 1 (0.91±0.07), cFFR was 0.48 to 0.99 (0.85±0.08), cFFR-NTG was 0.48 to 0.98 (0.84±0.07) and FFR was 0.43 to 0.99 (0.81±0.08). The four indexes, including FFR, were significantly but weakly correlated to angiographic stenosis ($r \leq 0.4$, $p<0.05$ for all). A significant strong correlation was found between FFR and the three indexes analyzed: Pd/Pa ($r=0.77$, $p<0.001$); cFFR ($r=0.88$, $p<0.001$) and cFFR-NTG ($r=0.91$, $p<0.001$).

The ROC curves using a FFR≤0.80 showed an area under the curve (AUC) of 0.91 (95% CI 0.87-0.94, $p<0.001$) for resting Pd/Pa; 0.93 (95% CI 0.90-0.96, $p<0.001$) for cFFR and 0.96 (95% CI 0.94 – 0.99, $p=0.019$) for cFFR-NTG. The ROC curves using a FFR<0.75 showed an AUC of 0.88 (95% CI 0.83-0.92, $p<0.001$) for resting Pd/Pa; 0.91 (95% CI 0.87-0.95, $p<0.001$) for cFFR and 0.95 (95% CI 0.91 – 0.98, $p=0.019$) for cFFR-NTG.

According to youden index, the optimal cutoff values for a FFR>0.8 of resting Pd/Pa, cFFR and cFFR-NTG were >0.9, >0.85 and >0.83 respectively. These cutoff values were present in a 39.3%, 49.6% and 40.6% of the total lesions respectively and showed a negative predictive value (NPV) of: 79.5%, 89.6% and 93.1% respectively, a sensitivity of: 90%, 84% and 94% ; a specificity of 74%, 90% and 90% and an accuracy of: 87%, 86.5% and 92.3% respectively.

CONCLUSIONS

Induction of submaximal hyperaemia using intracoronary standard radiographic contrast medium just after the intracoronary infusion of nitroglycerin (cFFR-NTG), accurately predicts FFR, significantly better than resting Pd/Pa and cFFR. This simple and independent index may allow limiting the use of adenosine for coronary functional assessment

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The timing of new left bundle branch block predicts the need for permanent pacemaker implantation in patients undergoing TAVI

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

New left bundle branch block (LBBB) frequently occurs during transcatheter aortic valve implantation (TAVI). Little is known about the relevance of its timing. We sought to determine if the timing of new LBBB during TAVI influences the need for permanent pacemaker implantation.

METHODS AND RESULTS

Consecutive patients with normal QRS at baseline and new LBBB during TAVI were analyzed. Patients with new LBBB before valve deployment (insertion of the stiff wire or predilatation) were compared to patients with new LBBB after valve deployment (valve deployment or postdilatation). A total of 126 patients (mean age 81 ± 7 years, 51% female) were enrolled.

New LBBB occurred before valve deployment in 67 (53%) patients and after valve deployment in 59 (47%) patients. Resolution of LBBB until discharge was observed in 47 (70%) of patients with LBBB before valve deployment and in 33 (56%) of patients after valve deployment (p= 0.15). Implantation of a new permanent pacemaker in patients with LBBB occurring before valve deployment was required in 1 (2%) compared to 7 (12%) of patients with LBBB after valve deployment (p= 0.03). One year mortality did not differ.

CONCLUSIONS

Patients with new LBBB during insertion of the stiff wire or predilatation required implantation of a permanent pacemaker less often compared to patients with new LBBB during valve deployment or postdilatation. This may indicate that trauma occurring before valve deployment may be reversible and may have important implications for postprocedural management.

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Differences in the degree of acute stent recoil and in-stent lumen areas of third-generation DES: an experimental study using a calcified stenotic vessel model

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THEME: Coronary Interventions

TOPIC(S): Stents and scaffolds, Other Coronary Interventions

AIMS

We often experience the stent deformation immediately after deflation of stent delivery balloons, called acute stent recoil. The stent struts of drug-eluting stent (DES) are getting thinner, but thin stent struts of DESs may reduce radial strength and lead to an increased risk of stent recoil especially in severe calcified lesion. In this study, we aimed to evaluate differences in the degree of acute stent recoil, in-stent lumen areas and shape of third-generation DESs using a calcified stenotic vessel model.

METHODS AND RESULTS

We used the calcified vessel model consisting of silicon tube (Outer Diameter (OD) 5.0 mm, Inner Diameter (ID) 3.0 mm, length 40 mm) with two hard semicircular plastic tubes (OD 3.0 mm, ID 1.2 mm, length 10 mm) which we assumed as a hard-calcified stenotic lesion inside. We examined Orsiro, Resolute Onyx (Resolute), SYNERGY, Ultimaster, and XIENCE Sierra (Xience) (n=6 each). All stents were 3 mm diameter with a length of 18 mm except SYNERGY had a length of 20 mm. We expanded these stents for 3 times at nominal pressure and 20 atm. We obtained microscopic digital images of the vessel model during the final inflation of stent delivery balloons and after the deflation of each expansion pressure. We measured the outer diameter of silicon tube and calculated the shortening rate which we considered as an indicator of acute recoil. We also performed optical frequency domain imaging (OFDI) and obtained the cross-sectional images of hard plastic tube part (assumed calcified stenotic lesion) and proximal non-plastic tube part of the stents and analyzed the lumen areas and the shape. The cross-sectional shape deformation was analyzed with the short and long diameters.

The shortening rate of the silicon tube diameter in calcified like lesion (Ca-LL) was greater than in non Ca-LL. The mean shortening rate of examined DESs in Ca-LL was larger at 20 atm (5.8±3.0 %) than at nominal pressure (1.7±0.7 %). At 20 atm, XIENCE (2.5±1.5 %) had the smallest shortening rate in Ca-LL, followed by Resolute (2.9±0.4 %), Ultimaster (5.0±1.3 %), SYNERGY (8.6±1.2 %) and Orsiro (9.9±1.8 %). XIENCE and Resolute had significantly smaller shortening rate than SYNERGY and Orsiro ($p<0.05$). In the study at OFDI, Resolute had the largest short-diameter (2.99 mm), followed by Ultimaster (2.86 mm), XIENCE (2.82 mm), Orsiro (2.60 mm), and SYNERGY (2.53 mm) in Ca-LL at 20 atm. On the other hands, the long-diameter was the largest in SYNERGY and Orsiro (3.85mm), followed by Ultimaster (3.41 mm), Resolute (3.39 mm) and XIENCE (3.03 mm). XIENCE and Resolute expanded to near circle shape, but Orsiro and SYNERGY expanded to elliptical shape. The lumen area of the DESs in Ca-LL was always smaller than the area in non Ca-LL. At 20 atm expansion, Resolute had significantly smaller difference (8.2±4.0 %) in stent lumen area between in Ca-LL and non Ca-LL than the deference of SYNERGY (21.1±6.8 %), Orsiro (18.0±2.3 %) and Xience (16.3±5.2 %) ($p<0.05$).

CONCLUSIONS

This experimental study suggested that DESs with larger acute recoil at 20 atm may have larger difference in

in-stent lumen areas between in calcified lesion and non-calcified part and expanded to elliptical shape. Further study is necessary to examine the influence of the differences in prone to recoil and deformation of DESs on clinical outcome.

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Mechanical chest compression with AutoPulse in patients with shock-resistant ventricular fibrillation transported directly to a cathlab during cardiopulmonary resuscitation: a one-year prospective observational study

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

Sudden cardiac arrest is one of the most common causes of death. In cases of shock-resistant ventricular fibrillation (VF), immediate transport of the patient to the hospital is essential and made possible with the use of devices for mechanical chest compression. The aim of this study was to report on the efficacy of the AutoPulse™ system for mechanical chest compression in patients with shock-resistant VF transported directly to a catheterisation laboratory during cardiopulmonary resuscitation.

METHODS AND RESULTS

This was a one-year prospective observational study conducted in an area with a population of 480,000. A total of 192 cases of out-of-hospital cardiac arrest were reported. The study included patients with shock-resistant VF defined as a sudden cardiac arrest secondary to VF requiring 3 or more consecutive shocks. Eventually, 18 patients met the study eligibility criteria.

The mean duration of cardiopulmonary resuscitation was 48.4±43 minutes, 55% of the patients were handed over to the catheterisation laboratory while still in cardiac arrest, 83.3% of the patients underwent coronary angiography and in 93.3% of them myocardial infarction was confirmed. PCI was continued during mechanical cardiopulmonary resuscitation in 50.0% of patients, with 60% of the patients surviving the procedure, and 27.8% of the initially enrolled patients survived to discharge.

CONCLUSIONS

Resistant VF suggests a high likelihood of a coronary component to the sudden cadiac arrest. AutoPulse™ is helpful in conducting cardiopulmonary resuscitation and allows to reduce the time from cardiac arrest to the arrival at a catheterisation laboratory.

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Predictors of outcome after successful management of stent thrombosis in the era of new-generation DES: insights from the Essex Stent THrombosis Investigation Registry (ESTHIR)

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

We aimed to investigate contemporary predictors of mortality in patients with stent thrombosis (ST) after successful interventional management.

METHODS AND RESULTS

The ESTHIR registry comprises of patients with ST who were managed at the Essex Cardiothoracic Centre since 2015. From this registry, we studied patients with either DES or BMS ST. All patients' angiograms were reviewed and modes of management after angiogram were classified as PCI with stenting and non-stent treatment (balloon-angioplasty or medical management, including any combination of antiplatelet and antithrombotic therapy, with or without repeat angiography). Successful management was defined by angiographic criteria as residual stenosis <10% with TIMI-flow ≥2 in the culprit vessel and no significant side-branch occlusion or flow-limiting dissection after intervention. Follow-up was performed to document all-cause death (ACD) and target vessel revascularization (TVR), which was used for censorship in Cox-regression analysis of survival free of ACD.

136 patients (85% male, mean age 66±11 years), 94 with DES and 42 with BMS were studied. Mode of presentation was STEMI in 88% and UA/NSTEMI in 12% of the patients. ST was classified as acute, subacute, late and very late in 7%, 4%, 4% and 85% of the cases respectively. Intravascular imaging was performed in 33% and thromboaspiration in 56% of the patients. Management was PCI with stenting in 85 patients (a new generation DES was used in all cases), balloon-angioplasty in 49 and medical in 2 patients. The mechanism of ST was determined, based on angiographic and intravascular imaging data, in 41% and 51% of the patients managed with stent and non-stent treatment respectively (p=0.3). After a mean follow-up of 1040 days, there were 21 ACDs (7 in-hospital) and 8 TVRs. TIMI 3 flow after intervention was achieved in 87% of the patients and 4 patients who did not fulfil criteria for successful intervention were excluded from survival analysis. In-hospital-ACD predictors were: presentation with cardiogenic shock (HR 7.5, 95% CI 1.7-33.8, p=0.008) or cardiac arrest (HR 18.8, 95% CI 3.6-97,2, p<0.001), mechanical ventilation on admission (HR 12.2, 95% CI 2.7-54.9, p=0.001) and LVEF (HR 0.9, 95% CI 0.86-0.97, p=0.004). In patients discharged alive, ACD-predictors were: TIMI-flow 2 in the culprit vessel (HR 2.4, 95% CI 1.3-4.4, p=0.003), non-stent treatment (HR 1.8, 95% CI 1.1-3.2, p=0.03) and glomerular filtration rate < 60 ml/min (HR 1.9, 95% CI 1.1-3.2, p=0.02).

CONCLUSIONS

In a contemporary treatment setting, the mode of treatment of ST was a significant mortality predictor in patients discharged alive, but further studies are required to determine if this novel observation relates to patient/lesion characteristics or the treatment itself.

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The index of microcirculatory resistance after primary PCI predicts long-term clinical outcomes in patients with STEMI

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THEME:
TOPIC(S):

AIMS

Microvascular dysfunction after primary percutaneous coronary intervention (PCI) in patients with ST-segment elevation myocardial infarction (STEMI) is associated with poor outcomes. The index of microcirculatory resistance (IMR) is a simple invasive method of microvascular function available at the time of primary PCI. The long-term prognostic value of IMR is still unknown. The aim of this study is to determine whether IMR predicts clinical outcomes in STEMI.

METHODS AND RESULTS

A total of 317 patients with STEMI who underwent primary PCI from 2005 to 2017 were enrolled in this study. The IMR was measured with a pressure sensor/thermistor-tipped guidewire after primary PCI. The primary endpoint was the rate of death or hospitalization for heart failure during a mean follow-up period of 65 months.
The mean corrected IMR was 29.4 ± 20.0. Patients with an IMR >29 had a higher rate of the primary endpoint compared to patients with an IMR ≤29 (10.3% vs. 2.1%, p = 0.001). During a mean follow-up period of 64.7 months, 13 (4.1%) patients were died and 6 (1.9%) were hospitalized for heart failure. An IMR >29 was associated with an increased risk of death or hospitalization for heart failure (HR 5.378, p = 0.004). On multivariable analysis, IMR >29 (HR 3.962, p = 0.022) remained an independent predictor of death or hospitalization for heart failure with age (HR 1.048, p = 0.049) and symptom-to-balloon time (HR 1.002, p = 0.049).

CONCLUSIONS

IMR can predict long-term clinical outcomes in STEMI patients.
High IMR measured after primary PCI significantly can predict poor long-term outcomes in STEMI patients.

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Incidence of late device-related thrombi formation in patients undergoing LAA occlusion - a single-centre study

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THEME: Interventions for Stroke
TOPIC(S): LAA closure, Ischaemic stroke

AIMS

Device-related thrombi (DRT) are a relevant complication in patients after left atrial appendage occlusion (LAAo), occurring in 5-15 % of cases. The clinical relevance of DRT is heavily disputed with recent studies indicating an impact on stroke and systemic embolism in patients who develop DRT. With ongoing clinical interest in this issue, we sought to assess the timing incidence and relevance of late DRT.

METHODS AND RESULTS

In this study, we investigated 120 patients, in whom LAAo had successfully been conducted and who underwent at least one transoesophageal echocardiographic (TEE) follow-up (FU) for DRT screening. Late DRT was defined as the occurrence of a DRT > 6 months after the initial procedure. Early clinical and echocardiographic FU within the first three months was conducted in 97/120 (80.8 %) patients (mean: 80 ± 24 days) and the second FU within six months in 57/120 (47.5 %) patients (mean 183 ± 28 days). Additional long-term FUs were conducted frequently in 49/120 (40.8 %) patients (mean 572 ± 398 days).

Overall, DRT occurred in 11/120 (9.2 %) patients after a mean 155 ± 230 days after LAAo. While 8/11 (72.7 %) DRTs were found within the six-month frame (mean: 58 ± 35 days), late DRTs were found in 3/11 patients (27.3 %) after a mean of 415 ± 315 days. Two of these late DRT occurred shortly after 6 months at 199 and 226 days. The third, however, was detected during a long-term FU at 820 days. All of these patients had undergone early FU at 3 months with TEE performed in 2/3 (66.6 %) and no evidence of DRT.

Patients with late DRTs trended to be older at baseline than patients with early DRT (82 ± 6 vs. 75 ± 7 years). Postprocedural therapy was similar in patients with early and late DRT. Hereby dual antiplatelet therapy (DAPT) was given for 3 months in 6 patients and DAPT for 6 months in 5 patients. All three patients with late DRT had received initial DAPT for 3 months. No differences were found in postprocedural aspects as device and technical success (100 %). Furthermore, occluder size (23.4 vs 22.3 mm) and implantation depth (measured along the left upper pulmonary vein ridge: 17 ± 5.6 vs. 16 ± 7.4 mm) did not differ between patients with late DRT and early DRT.

CONCLUSIONS

The incidence of DRT is a common complication (9.2 %) after LAAo. While most DRT in our study occurred shortly after LAAo (72.7 %) and can be found in early standardized follow-ups within the first postprocedural months, almost a third of DRT (27.3 %) appear to form later. Although further studies are required to support the findings our study, our results indicate the necessity of echocardiographic DRT screening beyond a time span of 6 months.

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Stent strut condition after imaging-guided vs. angiographic-guided emergency PCI with DES in ACS patients: OCT study

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THEME:

TOPIC(S):

AIMS

To evaluate the stent strut condition of drug-eluting stents(DESs) implanted in the culprit lesion of acute coronary syndrome (ACS) cases in comparison with imaging- and angiographic-guided percutaneous coronary intervention (PCI)by using optical coherence tomography(OCT) at 8-month follow-up angiography.

METHODS AND RESULTS

We studied 43 consecutive patients (68.4±10.1 y/o) who had received emergency PCI with second generation DESs due to ACS (acute myocardial infarction and unstable angina pectoris) and OCT study at 8-month follow-up. At initial PCI, 29 patients were performed with imaging guidance (Imaging group; 2 OCT use and 27 intravascular ultrasound use) and 14 patients were performed with angiographic guidance (Angio group). The apposition and neointimal coverage of the stent strut in 1mm interval cross-section were assessed on OCT images obtained at follow-up angiography. Malapposed strut was defined as a strut detachment from the inner vessel wall at a distance greater than the each stent strut thickness including the polymer plus the resolution limit of OCT (20 μm).A covered strut was defined as a neointimal thickness (NIT), defined as the distance between the center of the strut and the neointimal surface, of more than 30 μm based on previous papers.

In terms of patient and lesion characteristics, there were no significant differences between the two groups. Most patients of the both groups were continued dual antiplatelet therapy until follow-up period (Imaging group 96.6% vs. Angio group 85.7%, p=0.19). Post dilatation after stent implantation was more frequently performed in the Imaging group (57.1%) than in the Angio group (7.14 %, p<0.01). However, as for stent strut condition at the follow-up OCT image, the rate of malapposed struts(Imaging group 1.80±2.11% vs. Angio group 4.56±6.23%, p=0.51) and uncovered struts (Imaging group11.7±12.8% vs. Angio group 17.9±15.4%, p=0.26) were similar between the two groups. Thrombus was detected on only one lesion of the Imaging group.

CONCLUSIONS

At the PCI using intravascular imaging, post dilatation after stent implantation was often performed compared to angiographic-guided PCI.

On the other hand, there were no differences in the apposition and neointimal coverage of the stent strut between imaging-guided PCI and angiographic-guided PCI to the culprit lesion of ACS at mid-term follow-up.

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Feasibility of distal radial access for carotid interventions: the RADCAR-DISTAL pilot study

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THEME: Interventions for Stroke
TOPIC(S): Carotid stenting

AIMS

The aim of our study was to demonstrate the feasibility and safety of the distal transradial approach (DTRA) for carotid artery stenting (CAS).

METHODS AND RESULTS

We included 209 consecutive patients (151 Trans-Radial Access (TRA) and 58 DTRA) treated in a single center by CAS with cerebral protection between 2016 and 2018. DTRA punctures were performed by ultrasound guidance, and the carotid artery cannulations were done using a 6.5 F coronary sheathless guiding catheter. The groups showed similar demographic profile regarding age, gender and comorbidities, however the proportion of symptomatic patients was significantly higher in the DTRA cohort (DTRA: 75,86 % vs. TRA: 46.36% $p < 0.001$). Procedural success rate was similarly high in both groups, while the overall complication rate was very low, with no major adverse events and only a few vascular complications. The cannulation times were similar, while the overall procedure length was slightly higher in the DTRA group. The cumulative X-ray dose was similarly low regardless the access used.

CONCLUSIONS

DTRA is a safe and effective alternative of conventional trans-radial approach for CAS, with a potential to further improve the patient comfort.

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Distal transradial approach for primary PCI for AMI: a multicentre study

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

The distal transradial approach (dTRA) for coronary catheterisation is a newly introduced alternative to the conventional transradial approach. This technique is expected to decrease the incidence of haemorrhagic complications and improve patient comfort. However, limited data are available regarding the application of this technique in patients with acute myocardial infarction (AMI). This study investigated the feasibility and safety of the dTRA for primary percutaneous coronary intervention (PCI) in patients with AMI.

METHODS AND RESULTS

Methods

This study included patients with AMI who underwent primary PCI via the distal radial artery across 3 Japanese hospitals between January 2018 and December 2018. Patients' background, procedural characteristics, and clinical outcomes including the incidence of haemorrhagic complications were analysed.

Results

This study enrolled 89 consecutive patients with AMI, including 64 patients (71.9%) with ST-segment elevation myocardial infarction (STEMI), in whom distal radial artery puncture was attempted for primary PCI. The patients included 65 men, and the mean age was 72.5 years. Among these patients, cannulation was successfully performed in 83 patients (93.3%). A 5-, 6-, or 7-French sheath (conventional or slender) was used in this study. Cannulation was performed using a forearm radial artery approach in patients in whom dTRA failed.

PCI was successfully performed in all patients. The meantime to achieve haemostasis was 6.4 ± 5.3 hours, and no major bleeding complications occurred. Based on The Early Discharge After Transradial Stenting of Coronary Arteries trial haematoma scale, grade I, II, and III subcutaneous haemorrhages were observed in 15 (18.1%), 4 (4.8%), and 1 patient (1.2%), respectively. No patient developed a haematoma > grade IV.

In patients with STEMI, the mean door-to-balloon time was 40.2 ± 32.7 min, and the mean puncture-to-balloon time was 20.4 ± 14.4 min.

CONCLUSIONS

The distal radial approach is feasible and safefor primary PCI in selected patients with AMI.The application of the dTRA may serve as a less invasive strategy for the treatment of patients with AMI

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Patient pre-hospital delays in AMI - A nationwide patient survey. "Heart attack - Time is life" campaign

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THEME: Coronary Interventions
TOPIC(S): STEMI, Other Coronary Interventions

AIMS

A minimal delay from symptom onset to reperfusion therapy is essential in the management of acute myocardial infarction. The patient's response to initial symptoms (patient delay) substantially affects the delay. Nevertheless, predictors of patient-related delays are less clear. The aim of the study was to compare knowledge and awareness of heart attack symptoms and reactions to it in a general Polish population.

METHODS AND RESULTS

In this cross-sectional study, 1 376 persons aged 18 years or older enrolled in an Internet survey (computer assisted web interview). Heart attack knowledge, self-efficacy for recognizing and responding to heart attack symptoms, and perceived risk for a future heart attack were measured. Primary exclusion criteria were: prior myocardial infarction or family history of myocardial infarction. The survey was carried out as a part of the nationwide “Heart attack – time is life” Campaign. Based on the Polish Registry on Acute Coronary Syndromes (PL-ACS) the median total ischemic time in Poland is 260 minutes, whereas the median patient delay is 142 minutes. The main factors associated with long time delays include interhospital transfers, symptoms presentation during the night, age >65years, inhabitants of rural areas, diabetes mellitus, first-ever myocardial infarction, female sex. The survey demonstrated that 73.8% of respondents recognize that chest pain may be associated with myocardial infarction, but only 22.2% of them would call the emergency medical services. Only 23% of these respondents would make the call immediately, whereas 31.7% would wait at least 3-4 hours (in some cases event until the next day). 66.4% of the surveyed population would ignore the chest pain main reason being “nothing serious” or “a result of extreme emotions”. Notwithstanding, the majority of the surveyed population is aware of the seriousness of the acute myocardial infarction-related complications (heart failure, disability, rehospitalizations, death).

CONCLUSIONS

These findings highlight the urgent need to develop effective, tailored campaigns to close the knowledge gap and, primarily, to educate the Polish society about the correct response to chest pain. Young age, higher education, and high income were not predictors of common sense and correct responses.

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Immediate vs. delayed coronary intervention in patients with transient STEMI: one-year follow-up of the randomised clinical TRANSIENT trial

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

Up to 24% of acute coronary syndrome patients present with ST-elevation but show complete resolution of ST-elevation and symptoms before revascularisation. This transient ST-segment elevation MI (STEMI) poses a therapeutic challenge, as current guidelines do not clearly state whether these patients should preferably be treated with immediate or delayed coronary intervention. The aim of the present study is to determine the effect of an immediate versus a delayed invasive strategy on infarct size measured by 4-month cardiac magnetic resonance imaging (MRI) and clinical outcome up to one year.

METHODS AND RESULTS

In this multicenter trial, 142 transient STEMI patients were randomised in a 1:1 ratio to either immediate or delayed intervention. Cardiac MRI was performed at four days and at 4-month follow-up to assess infarct size and myocardial function. Clinical follow-up was performed at four months and one year.

Both in the immediate (0.4 h) and the delayed invasive group (22.7 h) MRI-derived infarct size at four months was very small (0.4 [0.0-3.5%] versus 0.4 [0.0-2.5%], p=0.79) and left ventricle ejection fraction (LVEF) was good (59.9±5.4% versus 59.3±6.5%, p=0.63). In addition, major adverse cardiac events, a composite of death, recurrent infarction and repeat revascularisation of the culprit lesion, at one year were low and not different between both groups (4.4% versus 5.7%, p=1.00).

CONCLUSIONS

We demonstrated that patients with transient STEMI have limited myocardial injury and well preserved left ventricular function and that an immediate or delayed approach has no effect on clinical outcome up to one year. Therefore, patients with transient STEMI can be treated with both an immediate or a delayed invasive strategy with similar outcome. These findings extend our current knowledge about the optimal timing of coronary intervention in patients with transient STEMI and complement the guidelines.

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Minimalistic approach in TAVR protects from post-operative delirium, mechanical ventilation and prolonged intensive care unit stay

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Patients with postoperative delirium (POD) after transcatheter aortic valve replacement (TAVR) are ventilated and hospitalized longer and suffer an increased risk of in-hospital mortality. This study hypothesized whether a minimalistic approach with conscious sedation during transfemoral aortic valve replacement (TF-AVR) protects from delirium, prolonged mechanical ventilation, and prolonged time on ICU compared to TF-AVR with intubation anesthesia.

METHODS AND RESULTS

TF-AVR was performed in 245 patients with intubation anesthesia and in 63 patients with conscious sedation in our center between January 2013 and August 2017. The operative risk estimated by the logEUROScore was similar in both groups (intubation: 13.28 +/- 9.06 %, conscious sedation: 12.24 +/- 6.77 %). In the conscious sedation group length of the procedure was shorter (0.61 +/- 0.91 h vs. 1.75 +/- 0.96 h). The risk for intraprocedural complications was not influenced by the anesthesia method (OR conscious sedation instead of intubation 1.66, $p = 0.117$). Both days on ICU (-2.21days, $p < 0.0001$) and minutes of mechanical ventilation (-531.2min, $p < 0.0001$) were reduced. Furthermore, the risk for a POD was significantly decreased when TF-AVR was performed in conscious sedation (6.35 % vs. 18.18 %, OR 0.29, $p < 0.05$).

CONCLUSIONS

Time of mechanical ventilation, risk of POD, and days on ICU were significantly reduced in patients which underwent TF-AVR in conscious sedation in comparison to an intubated approach in this retrospective single center study. Our data suggest that TF-AVR with conscious sedation is safe with a beneficial postoperative course in clinical practice, and should be the favored approach.

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Update of the world-wide Sizing registry results assessing a self-apposing stent in challenging lesions with vessel diameter variance

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds, Other Coronary Interventions

AIMS

The worldwide Sizing registry is designed to assess the safety and efficacy of Stentys stents in a real-world population. We evaluated the Xposition S self-apposing sirolimus-eluting stent in lesions subsets with significant vessel diameter variance (e.g. left main coronary, ectatic/aneurysmatic vessels, bifurcations, vessels with high thrombus load, significantly tapered vessels and vein grafts).

METHODS AND RESULTS

Since June 2012, 1745 patients were enrolled in 53 sites after treatment with different generations of the Stentys self-apposing stents. The primary endpoint is the rate of major adverse cardiac events evaluated during 12 months follow-up. It is defined as cardiac death, target vessel related myocardial infarction, clinically-indicated target lesion revascularization or emergent CABG. Major adverse cardiac events were independently adjudicated. An interim analysis was performed on the 950 patients treated with the latest generation of Stentys self-apposing stents, Xposition S. The mean age was 65.3±12.6 years-old and 83.3% of the population were male. Most of the patients had ACS (66.9%) which included 32.3% of STEMI. The main anatomical subset treated was aneurysmatic/ectatic vessel, which represented 22.7% of the population. Other anatomical subsets included notably 17.5% of left main coronary or bifurcation lesions, 16.5% of thrombus containing lesions, 12.1% of tapered vessel, 8.6% of SVG and 4.4% of CTO. The procedure success (defined as <30% residual stenosis with no peri-procedural complications) was reported in 95.0% of patients.

The cumulative and hierarchical MACE rate at a mean follow-up duration of 368±46 days was 4.84%, which included 1.47% of death from a cardiac or unknown cause, 2.21% of target vessel related myocardial infarction and 2.21% of clinically-indicated target lesion revascularization. The definite/probable stent thrombosis rate was 0.84%. In the anatomical subset analysis we observed a MACE rate of 4.2% in the vessel diameter variance subgroup, 3.6% in the large vessel subgroup (≥4.5mm) and 9.8% in SVG lesions.

By the time of the EuroPCR congress, we expect to have an analysis on a thousand patients treated with the Xposition S.

CONCLUSIONS

In the largest data analysis reported on the Xposition S to date, we observed low clinical event rates despite specific inclusion of a broad set of challenging lesions. These interim results of the Sizing registry confirm the safety and efficacy of the Xposition S stent in the challenging anatomies where vessel diameter varies.

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One-year safety and efficacy results after the implantation of a biodegradable-polymer sirolimus-eluting stent for the treatment of lesions in native coronary arteries in a real-world clinical practice

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

The objective of the Siregistry is to assess the safety and efficacy of the Amazonia Sir sirolimus-eluting stent for the treatment of lesions in native coronary arteries in a real-world clinical practice.

METHODS AND RESULTS

In this prospective, multicentre ongoing registry, 350 patients with 405 coronary lesions were treated with the Amazonia Sir biodegradable-polymer sirolimus-eluting stent. The primary endpoint is the rate of major adverse cardiac events at one year, defined as a composite of cardiac death, myocardial infarction and target lesion revascularisation. The mean age is 57.1±9.9 years-old and 80.3% of the population were male. Patients had ACS in 64.9% of cases which included 30.3% of STEMI patients. Most of the lesions were located in the left anterior descending artery (52.8%) with a mean length of 24.6±10.7 mm.

During the procedure, 93.6% of the lesions were pre-dilated and 82.7% post-dilated. Procedural success was reported in all cases but two (99.4%). One-year clinical follow-up was performed in 98.6% of patients at a mean follow-up time of 12.9±1.3 months. There were three cardiac death (0.9%), seven myocardial infarction (2.0%) and only one target lesion revascularisation (0.3%), leading to a very low rate of major adverse cardiac event (3.2%) at one-year after the implantation of the Amazonia Sir. Stent thrombosis was reported in two patients (0.6%), one definite and one probable.

CONCLUSIONS

In a real-world clinical practice, the use of Amazonia Sir stent showed a very low rate of major adverse cardiac event at one-year clinical follow-up.

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Comparison of transradial vs. femoral access in contemporary real-life PCI practices – A propensity weighted matching analysis from a worldwide registry

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

To compare the procedure and one-year outcomes of patients treated using transradial (RAD) vs transfemoral (FEM) approach in a large all-comer registry representative of contemporary real-life PCI practice.

METHODS AND RESULTS

We analysed data of patients treated with Ultimaster DES in the worldwide e-Ultimaster registry in more than 300 centres world-wide and compared clinical outcomes of transradial and femoral approach. Ultimaster is a thin strut (80um) cobalt chromium stent coated with sirolimus-eluting bioresorbable polymer. In order to reduce baseline differences between patients treated using radial and femoral access, we applied weighted propensity score matching (PSM) method for this comparison.

The population enrolled in e-Ultimaster registry that reached 1-year follow up at the time of the analysis, included 3390 FEM patients (18%) and 15680 RAD patients (82%). Baseline characteristics in the two groups were comparable after propensity weighted matching. The mean patient age was 64.1 years and 75.0% were male patients in both groups. In both groups, 33% were diabetic and 21% current smokers. At enrolment, 50% of patients presented with acute coronary syndrome, while 26% had a history of previous PCI. The number of treated lesions was 1.40±0.68 per patient in both groups with 50% of patients having multi-vessel disease. Regarding lesion complexity, 60.3% of patients in FEM group and 62% of patients in RAD had complex lesions (type B2+C), 14.2% patients in FEM group and 14.3% in RAD group were treated for bifurcation, and 19% of patients in both groups had moderate to severely calcified lesions.

At the time of hospital discharge, more patients in FEM group had experienced bleeding (0.8% vs 0.4%, p<0.001) and access site related complications (2.6% vs 0.8%, p<0.001) than RAD group. The difference in bleeding between two groups disappeared by 12 months (2.0% vs 2.1%, p=0.68).

The adjusted propensity weighted clinical outcomes at 1 year showed 3.2% mortality in the FEM group versus 2.0% in the RAD group (p<0.001), with cardiac death rate of 2.1% in FEM and 1.2% in RAD group (p<0.001). The target vessel related myocardial infarction rate was 0.9% in both groups (p=0.81). The total target lesion revascularization rate was also similar in both FEM and RAD group (1.7% vs 1.7%, p=0.93). Composite endpoint target lesion failure (TLF) rate was 4.1% vs 3.3% in FEM and RAD group respectively (p=0.019) while the target vessel failure (TVF) rate was 4.6% vs 3.8% (p=0.035). Stent thrombosis (definite + probable) occurred in 1.0% FEM patients and 0.5% RAD patients (p<0.001).

CONCLUSIONS

The data from this large world-wide registry showed a more than ¾ of patients underwent RAD PCI. After propensity matching, radial access was associated with lower in-hospital bleeding and access site complications as well as mortality. The mortality benefit of RAD over FEM PCI persisted at 1 year.

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Revascularisation strategy of multivessel PCI in STEMI patients enrolled in a real-world registry

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Urgent revascularization of the culprit lesion is the initial strategy in STEMI patients. About 40 to 60% of STEMI patients present with multivessel disease (MVD). Optimal revascularization strategy in these patients remains a topic of debate. Current 2017 European Society of Cardiology (ESC) guidelines gives a class IIa recommendation for revascularization of the non-infarct-related artery in MVD STEMI patients. We analysed data from a large, real-world registry to assess the effect of revascularization strategy on clinical outcomes in these high-risk patients.

METHODS AND RESULTS

e-Ultimaster is a prospective, world-wide, multi-centre registry that enrolled patients with coronary artery disease requiring PCI treated with a thin strut sirolimus-eluting stent (Ultimaster) with abluminal biodegradable polymer coating. The primary endpoint of target lesion failure (TLF) at 1 year follow-up is defined as a composite of cardiac death, target vessel (TV) related myocardial infarction (MI) and clinically driven (CD) target lesion revascularization (TLR). An independent Clinical Event Committee reviewed and adjudicated all deaths, myocardial infarctions, revascularizations and stent thromboses. Among 19,482 patients who reached 1-year follow up, 1311 STEMI patients presented with MVD.

Mean age was 62.8 years, 80.8% were male, 34.1% smokers and mean body mass index was 27.3 kg/m². Diabetes was present in 22.3%, hypertension in 59.8% and 49.2% of patients had hypercholesterolemia. Out of 1311 patients, 407 were completely revascularized (at index or at staged procedure before discharge) and 904 were incompletely revascularized at index procedure. Pre-intervention TIMI-flow grade 0/1 was less frequent in completely revascularized patients (43.9 vs 65.0%; p<0.001). Post-intervention, 98.6% versus 97.9% (p=0.44) of patients in the complete versus incomplete revascularization group reached TIMI-flow grade 3.

A significantly higher rate of patients were angina-free in the complete revascularization group as compared with the incomplete revascularization group at 3 months (95.7% vs 88.9%; p<0.001) and at 1 year (97.2% vs 88.7%; p<0.001). At 1-year follow-up all-cause mortality was 3.2% in the completely revascularized group as compared to 5.3% in incompletely revascularized patients (p=0.12). Similar rates of TV-MI (0.7 vs 0.8%; p=0.99) and target lesion (1.7 vs 1.4%; p=0.81) and vessel revascularization (2.5 vs 2.6%; p=0.99) were observed. Rate of non-target vessel revascularization occurred in 0.7 vs 2.1% (p=0.10) of completely vs incompletely revascularized patients. TLF rate at 1 year was 3.9% versus 5.1% (p=0.40) and patient-oriented composite endpoint of all-cause mortality, any MI or any revascularization was 7.1 versus 9.7% (p=0.14) in complete versus incomplete revascularization group. Definite and probable stent thrombosis rate at 1 year was 1.2% versus 1.6% (p=0.81). Results after propensity matching to adjust for differences in baseline characteristics confirmed these results.

CONCLUSIONS

In STEMI patients with MVD, complete revascularization was associated with a lower rate of angina during

follow-up. Although cautious interpretation is necessary because this is a sub-analysis of an observational registry, these findings suggest that physician-directed selective use of complete revascularisation results in good clinical outcomes in STEMI patients with MVD.

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The role of intravascular imaging in the contemporary management of patients with stent thrombosis: results from the Essex Stent THrombosis Investigation Registry (ESTHIR)

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

We aimed to evaluate the clinical role of intravascular imaging (IVI) in the treatment of stent thrombosis (ST) in the era of new generation DES.

METHODS AND RESULTS

The initial patients' pool consisted of the patients included in the ESTHIR registry, where all patients with ST managed at the Essex Cardiothoracic Centre since 2015 are registered. Excluding 2 patients with bioresorbable and covered stent thrombosis, the initial population of this study included 136 patients with either BMS or DES ST. We implemented 1:1 propensity score matching using a nearest neighbor algorithm without replacement to match patients with and without use of IVI for the following characteristics: type of ST, presenting ECG, type of stent, presentation with cardiac arrest, cardiogenic shock, type of management (stent vs. non-stent treatment) and age. After matching, two groups of 30 patients each were produced and formed the analysed population. Follow-up was performed to establish all-cause death (ACD), cardiac death (CD) and target vessel revascularization (TVR). Kaplan-Meier and Cox-regression analysis was used to compare survival free of ACD, CD and CD or TVR between these two groups and adjust for confounders, with TVR being used for censorship in mortality analyses.

The two groups were well balanced on all matched characteristics (standardized mean differences < 10%), as well as on all other baseline demographic characteristics, including rates of initial TIMI flow < 2, which were identical between the two groups (86.7%). The IVI group had more frequent use of thromboaspiration (77% vs. 43%, p=0.01). The mechanism of ST was identified in 26 and 7 patients in the IVI and non-IVI use groups respectively (p<0.001). IVI was performed by OCT in 18 patients, IVUS in 11 and both OCT and IVUS in 1 patient. Specific treatments within each group (IVI vs. non-IVI) were as follows: new generation DES 63% vs. 60%, balloon-angioplasty 37% vs. 37%, medical management 0% vs 3%. TIMI 3 flow rates after intervention were non-significantly higher in patients treated with IVI use (90% vs. 73%, p=0.09). At 1000 days of follow-up, 14 ACDs, 13 CDs and 3 TVRs (all with CABG) were observed. In Kaplan Meier- analysis, the IVI use group had significantly better event-free survival with regards to CD or TVR (p=0.03) and similar survival with regards to ACD (p=0.2) and CD (p=0.09). The difference in survival free of CD or TVR remained significant after adjustment for LVEF, status of renal function, end TIMI flow achieved and cardiac arrest on presentation.

CONCLUSIONS

The use of IVI in the context of contemporary management of ST, including new generation DES,

demonstrated significant benefit with regards to a combined clinical end-point, compared to management using only angiographic data.

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Angiography-derived functional assessment of left main coronary stenoses

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THEME: Coronary Interventions

TOPIC(S): Stable CAD, Left main and multivessel disease

AIMS

Quantitative Flow Ratio (QFR) is a promising angiography-based tool in establishing the functional relevance of coronary stenoses. However, no data is available on its diagnostic value for stenoses located in the left main (LM) coronary stem. The aim of this study was to evaluate the diagnostic yield of QFR in assessing the functional relevance of LM stenoses, using FFR as a reference.

METHODS AND RESULTS

Methods

This was a retrospective, observational, multi-center, international (Spain, Japan and South Korea) study including patients with intermediate LM stenoses undergoing FFR assessment. Ostial LM stenoses were excluded from the study. QFR was calculated from the coronary angiogram in a blinded fashion with respect to FFR values. Bayesian statistics were used to estimate the diagnostic value of QFR.

Results

A total of 62 patients with LM stenoses were included. Most stenoses were located at the LM bifurcation (53[85%]). On average, LM lesions had intermediate severity, both from angiographic (mean diameter stenosis [%DS] 44.1 ± 11.1 %) and functional (mean FFR 0.755 ± 0.105) perspective. Mean QFR was 0.728 ± 0.162. Correlation between QFR and FFR was moderate (r= 0.578). Positive and negative predictive value, sensitivity and specificity were 84.8%, 68.2%, 84.8%, and 68.2% respectively. Classification agreement of QFR and FFR in terms of functional severity was 79.4%. Diagnostic performance of QFR was acceptable (AUC 0.82 [95% CI, 0.71-0.93]).

CONCLUSIONS

Despite an acceptable diagnostic yield in assessing functional relevance of LM stenoses, the diagnostic efficiency of QFR was markedly lower than that reported in previous studies enrolling non-LM stenoses only. LM location pose major challenges for QFR assessment, like significant caliber mismatch between LM and LAD/left circumflex (LCX), and unavoidable overlap between LAD and LCX; these factors probably account for the lower QFR accuracy in LM stenoses. Further research may contribute to elucidate this and to introduce correcting measures in QFR algorithms.

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Clinical implication of run-off in long-term follow-up after femoropopliteal endovascular treatment

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THEME: Peripheral Interventions
TOPIC(S): Other peripheral interventions

AIMS

Clinical outcomes after percutaneous transluminal angioplasty (PTA) at the femoro popliteal (FP) segment are influenced by several factors. Run off is a well-known variable that influence critical limb ischemia prognosis, but its impact on outcomes remains unclear for claudicant patients.
The purpose of this study was to assess the long term clinical impact of run off after FP PTA in claudicant patients.

METHODS AND RESULTS

Methods
A prospective database of patients undergoing endovascular treatment between 2010 and 2018 was analyzed. Patients with Rutherford classification 1, 2, and 3 were selected.
Claudicant patients that received FP PTA were included. The technical success of PTA and the patency of calf arteries were assessed by angiography. Run off at the tibial level was determined by the number of patent vessels present with a maximum of 3 (scored as 0, 1, 2, or 3), and for clinical end points we divided the population in group A (run off 0 or 1) and group B (run off 2 or 3). TransAtlantic Inter-Society Consenus II classification (TASC) was used to characterize the lesions treated. Patients with concomitant infrapopliteal angioplasty as well as critical limb ischemia were excluded. Death, amputation, or TLR was the predefined combined endpoint.
For comparative tests we used parametric and non-parametric tests according to the type of distribution of the variables. Epi Info 2000 was used for analysis and a value of $p<0.05$ was considered as significant.

Results
446 patients were included (mean age 67 years, 73,5% male, 26% were smokers). Diabetes mellitus was higher in group A (46,1% vs 36,1%, p= 0.036). TASC classification was similar in both groups (TASC type A or B: 76,4% vs 78,3% in group B, p 0.5). More than half of the patients received auto expandable stents (p=0.09) and 20% used drug eluting balloons in both groups (p=0.10).
The mean follow-up period was 24 ± 21 months. Group A had less meters walked after revascularization (874 meters vs 2160 meters in group B, p=0.0009). Target lesion revascularization (TLR) was similar between groups (16.8% vs 12.6%, p=0.24), however the time to TLR was shorter for patients with worse run off (337 days and 695 days in group B, p=0.005). Five patients required amputation during follow up (group A 3,5%, group A 0.5%, p=0.001). The combined end point was significant higher in group A (group A 23,9 vs group B 13,9%, p=0,01).

CONCLUSIONS

A poor run off after FP PTA was associated with worse long term clinical outcomes in claudicant patients.

Further investigation should be done in order to indicate differentiated treatment modalities in this increased risk subgroup of patients.

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PCI treatment of coronary artery disease patients with diabetes – Insights from a worldwide prospective registry

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THEME: Coronary Interventions
TOPIC(S): Left main and multivessel disease

AIMS

Historically, patients with Diabetes Mellitus (DM) are thought to be at increased risk for adverse events following percutaneous coronary intervention (PCI). A subgroup analysis of a world-wide registry of patients undergoing PCI was undertaken to assess safety and performance of the new generation contemporary sirolimus-eluting Ultimaster stent in these high-risk patients.

METHODS AND RESULTS

e-Ultimaster is a prospective, multi-centre registry recruiting patients undergoing PCI from 50 countries world-wide treated with a thin strut sirolimus-eluting stent with abluminal biodegradable polymer coating. The primary endpoint of target lesion failure (TLF) at 1 year follow-up was defined as a composite of cardiac death, target vessel (TV) related myocardial infarction (MI) and clinically driven (CD) target lesion revascularization (TLR). An independent Clinical Event Committee reviewed and adjudicated all adverse events.

Among 19,482 patients who reached 1-year follow up, 5488 patients with diabetes (28.2%) were included with mean age of 65.9±10.4 years and body mass index of 28.8 kg/m². The majority of patients were male (73.5%). 22.4% of diabetic patients were treated with insulin, and 79.7% of patients were on statin treatment. Almost 50% of patients presented with acute coronary syndrome and 52% had multivessel disease (MVD). Small vessels were treated in almost half of patients, left main lesions were present in 3.8%, CTO in 6.2% and in-stent restenosis in 6.8% of patients. Mean number of stents implanted per patient was 1.5, with a mean total stent length of 33.4 mm.

At 1-year follow-up, after propensity score matching to correct for differences in baseline patient and lesion characteristics rate of TLF was 3.0 versus 4.5% in patients without vs with DM, with rate of cardiac death 1.3% vs 2.1% ($p<0.001$), TV-MI 0.9 vs 1.0% ($p=0.39$) and CD-TLR of 1.3 vs 2.2% ($p<0.001$). Patient-oriented composite endpoint (POCE; all-cause mortality, any MI or any coronary revascularization) occurred in 6.0 vs 7.6% ($p<0.001$) of patients without vs with DM. Rate of definite or probable ST was 0.6% in patients without DM and 0.7% in patients with DM ($p=0.21$). Propensity-weighted 1-year TLF rate was significantly different between non DM, non-insulin dependent DM and insulin-dependent DM of (2.8 vs 4.1 vs 5.5%; $p<0.001$). Rates of TV-MI were similar (0.9 vs 1.0 vs 1.3%; $p=0.24$), but CD-TLR (1.3 vs 2.0 vs 3.0%; $p<0.001$) and TVR (1.9 vs 2.6 vs 4.1%; $p<0.001$) differed significantly between non-DM, non-insulin dependent DM and insulin dependent DM. Rates of POCE were 5.8 vs 7.1 vs 8.2% ($p<0.001$) and 0.6 vs 0.7 vs 0.9% ($p=0.33$) for definite and probable ST in these 3 groups.

CONCLUSIONS

Ultimaster stent is associated with low event rates in the high risk DM population. Nevertheless, despite treatment with a new 3rd generation DES platform, patients with DM have worse medium term outcomes, particularly those treated with insulin. Patients with DM should be considered a higher-risk cohort, even in contemporary practice.

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The use of ECMO cardiopulmonary resuscitation within a primary angioplasty service, a single-centre experience in the UK

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

ECPR has recently been shown to be a safe and effective intervention for patients suffering intractable cardiac arrest that is not responsive to traditional Advanced Life Support wherein historically their prognosis would be grave . The resuscitation Council (UK) guidelines now suggest that ECMO should be considered where available and appropriate.
Our unit provides quaternary cardiac and transplant services for the north of England, as well as a 24/7 primary angioplasty service for STEMI, covering 3.8 million patients coupled with an inhouse capacity to deliver veno-arterial ECMO (VA ECMO).

METHODS AND RESULTS

A retrospective data analysis of all ECPR cases was undertaken to review the patient demographics, arrest aetiology, intervention undertaken, length of stay, metabolic markers from arterial blood gasses (ABG) and clinical outcomes. Patients who presented with an acute coronary syndrome (ACS) as the aetiology of their arrest were included in the study.

The ECPR service commenced in April 2016 and a total of 17 ECPR cases have been undertaken up until 31st December 2018. 12 patients met the ACS inclusion criteria. The mean age was 49 with 92% being male .Five patients were commenced on VA ECMO in the cardiac catheter lab with the remaining seven being established on VA ECMO in the Emergency Department. The mean time to establish ECMO in the catheter lab was 22.6 minutes. 10/12 were out of hospital cardiac arrests pre-alerted from the ambulance service. All 12 were brought to the lab for primary coronary intervention.
All patients were transferred to the intensive care unit following their procedure. Mean baseline lactate was 12.8mmol/L, with a mean reduction 8.72 mmol/l 24 hours post treatment.
Overall survival rate was 16.6%, with cause of death multi-organ failure in six cases, one acute cardiac failure, two hypoxic brain injuries and one case of cerebral herniation.Two patients survived to hospital discharge neurologically intact.

CONCLUSIONS

This data suggests that ECPR delivered in conjunction with a primary angioplasty service has the potential to improve patient outcomes for those in cardiac arrest refractory to traditional resuscitative measures in the context of STEMI/ACS. Initiatives should be concentrated towards developing protocols within the cardiac and prehospital networks to improve celerity for arrest to ECMO times. More research is also needed to establish if ABG metabolic markers are prognostically indicative in this patient group.

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High procedural radiation dose to lower legs found for scrub nurse (secondary operator) compared to physician (primary operator). Discovered deficiencies in current, below table shielding

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

To measure the x-ray scatter dose of the lower legs (below the average lead gown coverage) of both the primary and secondary operator positions in the usual cardiac imaging views. And to measure the effectivness of the average current below table lead shielding in both these staff procedural positions.

METHODS AND RESULTS

In considering the ocupational radiation dose to the lower long bones and feet.
We used a chest phantom of average patient BMI (25) and a Unforstm radiation detector at 50cm above floor height.
We mesured the absorbed x-ray scatter dose at
1st operator position (Physician), 80 cm from patient ISO centre and 235 Deg from table alignment and
2nd operatior position (Nurse), 150cm from patient ISO centre and 212.5 Deg from table alignment.
We conducted dose mesurements at AP, Rao 30 / Cra 30,Rao 30 / Cau 30, Lao 30 / Cra 30 and Lao 30 / Cau 30 angiographic positions.
We found that the current shielding design whilst effective for the 1st operator position. Was quite inneffective for the 2nd operator position.
With the 2nd position (Nurse) recieving 2 to 20 times the total lower leg dose than the 1st position (Physician) depending on cardiac angiographic view.
We found the under table lead shield gave a 97 to 99% reduction in dose for the primary operator,
but only a 1 to 4.4% reduction for the 2nd operator depending on cardiac imaging view.
The large variance found in the lower leg dose depending on cardiac angiographic view was greater than expected.
From 138nSv/Sec for the Lao 30/ Cau 30 view as the lowest, to 1848nSv/Sec for the Lao 30/ Cra30 view, over 10 times higher.

CONCLUSIONS

From this experiment we found that the current average under table lead shielding whilst very effective for the primary operator is quite ineffective in reducing x-ray scatter to the lower legs of the 2nd operator.
From this we are purchasing a wider lead under table shield and considerating lead shin pads for the 2nd ooperator.
We recommend that all cardiac labs do similiar x-ray scatter surveys for staff saftey.

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Clinical experience with TAVI at a tertiary hospital in the Republic of Ireland

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THEME: Interventions for Valvular Disease

TOPIC(S): TAVI, Other valvular and structural interventions

AIMS

A paucity of published data on clinical outcomes for patients undergoing trans-catheter aortic valve implantation (TAVI) exists in the Republic of Ireland. We sought to examine the clinical outcomes in a sizable cohort of patients with medium-term follow-up treated with TAVI at an Irish tertiary referral centre.

METHODS AND RESULTS

A prospective TAVI registry was used to assess the baseline demographics, procedural variables, and clinical outcomes of patients treated with TAVI between the inception of the program in 2008 and 2017. Kaplan-Meier estimates were used to estimate overall freedom from death and compare freedom from death and/or stroke between valve types (self-expandable v's balloon expandable) and the main access routes (transfemoral v's transapical).

A total of 354 patients (mean age 80.9 ± 8.1 years, 58% male, mean STS score 6.1 ± 4.3%) were treated during the study period. Treatment of degenerative calcific disease on a tricuspid aortic valve was the dominant clinical indication (n=334, 94%). The trans-femoral access route and balloon-expandable TAVI valves were used in 88% and 83% of patients, respectively.

Major in-hospital outcomes included: in-lab death (n=2, 0.6%), stroke (n=8, 2.2%), device embolization (n=4, 1.2%), permanent pacemaker implantation (n=22, 6.2%) and major vascular complication (n=2, 0.6%). The median length of hospital stay was 4 days (IQR 2 - 8 days).

The median follow-up for the cohort was 228 days (IQR 45 – 825 days). Kaplan-Meier estimate of freedom from death at 30-days and 1 year for the entire cohort was 97% ± 1% and 85.4% ± 2.3% respectively. Trans-femoral access was associated with a significantly lower rate of death and/or stroke at 1-year compared to trans-apical access (87.6% ± 2.3% versus 70% ± 8.4%, p=0.0005). There was no significant difference in the rate of death and/or stroke at 1-year between balloon expandable and self-expandable valves (85 ± 2.4% versus 89% ± 6.5%, p=0.63). The Kaplan-Meier estimate of survival at 3 years was 66% ± 4%.

CONCLUSIONS

This study documents acceptable complication rates and favourable rates of survival following TAVI in a consecutive series of patients undergoing TAVI at a tertiary referral centre in the Republic of Ireland. These data support the application of this therapy in the Irish context.

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Mortality in infarct-related cardiogenic shock patients treated with an Impella microaxial pump – influence of timing and predicted risk

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THEME: Interventions for Heart Failure
TOPIC(S): Acute heart failure

AIMS

We compared observed to individually predicted mortality using CardShock-, Shock II-, and SAVE-scores in acute myocardial infarction-related cardiogenic shock (AMI-CS)patients treated between 2013 and 2017 with an Impella microaxial pump, who met the IABP-Shock II-trials inclusion/exclusion criteria in order to determine whether standardised use of an Impella microaxial flow-pump in AMI-CS is associated with lower than predicted mortality rates and whether timing of implantation or selecting patients based on predicted risk is meaningful.

METHODS AND RESULTS

We analyzed data from 166 consecutive AMI-CS patients meeting the inclusion/exclusion criteria of the IABP-Shock II-trial (age 65±12 years), who received an Impella microaxial pump and compared observed vs. individually predicted mortality using CardShock-, Shock II-, and SAVE-scores. 39% (n=65) had been resuscitated before Impella implantation.

Overall 30-day mortality was 43%. Mortality was higher in resuscitated patients (50% vs. 36%, p=0.0324) and when Impella was implanted post-PCI (Impella-pre-PCI: 29%, Impella-post-PCI: 50%, p=0.0130). In all score systems predicted mortality was significantly higher than observed mortality on Impella support for individuals with highest predicted risk (IABP-Shock II predicted 77% vs observed 44%, p=0.010; CardShock predicted 77% vs observed 51%, p=0.017; SAVE predicted 81% vs observed 56%, p<0.001).

CONCLUSIONS

In the absence of prospective trials, our retrospective analysis encourages the use of active mechanical circulatory support by Impella microaxial pumps in high-risk patients with AMI-CS and supports the concept of early implantation prior to PCI.

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Indication and outcomes of TAVI in intermediate-risk population. Latin American real-world registry (TRYTOM)

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

The majority of patients eligible for surgery are low risk. Intermediate risk population represents only 14%. Transcatheter aortic valve implantation (TAVI) is an accepted alternative to surgery in patients with severe aortic stenosis who are at high surgical risk.

The purpose of our study is to define the characteristics and outcomes of a real-world intermediate risk population, that were selected for TAVI after a heart team decision.

METHODS AND RESULTS

Methods

Consecutive patients were included in 8 Latin American valve centres during 2010 - 2017. Patients were assessed by a local heart team, which used a guideline that was based on a risk model developed by the Society of Thoracic Surgeons (STS) to estimate the risk at 30 days after surgery. Intermediate risk correspond to a STS from 4 to 8% in line with guidelines. We divided the population in two groups; intermediate risk (IR) and high risk (HR) to compare and evaluate population treated and outcomes between the groups.

Results

658 patients underwent a TAVI procedure after a heart team decision. IR population represent 43,6% (mean STS 5,8±1,2) and HR 30,5% (mean STS 14,3% ±5,4). Most of the procedures were elective in both groups (IR 77,3% vs HR 71,5%, p 0,06). Despite HR group were older (IR 81,6±6,4 vs 82,1±6,5, p 0,01), above 80 y-o there were no significant differences between groups (p0,8). Baseline characteristics were similar between the groups; coronary disease (IR 50,5% vs HR 57,7%, p0,29), complete revascularization (IR 61,8% vs HR 62%, p0,98), vascular disease (IR 22,3% vs HR 19,9%, p0,07), porcelain aorta (IR 3,8% vs HR 4%, p0,7), atrial fibrillation (IR 15% vs HR 21%, p0,18), however HR group had high prevalence of pre CABG (IR 11,5% vs HR 26,4%, p0,001), COPD (IR 26,8% vs HR 32,3%, p0,001) and higher serum creatinine (IR 1,33±1 vs HR 1,56±1,8, p0,001). There was no differences in type of valves implanted (auto expandable 74%). Technical success was 90,6% in IR and 92% in HR, p0,77. The rate of death (IR 6,3 vs HR 8,5, p0,23), major vascular complication (IR 5,6% vs HR 7%, p49), disabling stroke (IR 1% vs HR 1,5%, p0,178), moderate-severe paravalvular leak (IR 4,9% vs HR 5%, p0,49) and permanent pacemaker (IR 19,2% vs HR 18,1%, p0,94) were similar between the groups.

CONCLUSIONS

Heart team Intermediate risk patients selection in a real world registry, gathered an enhanced ¨moderate risk¨

subgroup that worked as an alternative to surgery for not eligible patients. However, further investigation should be done to incorporate all intermediate risk patients for TAVI.

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Safety and performance of the magnesium-based resorbable scaffold in patients with de novo coronary lesions: a prospective, observational, real-world setting Spanish registry - MAGMARIS-ES

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds, Other Coronary Interventions

AIMS

The aim of this registry is to evaluate the feasibility and safety of the Resorbable Magnesium Scaffold in the daily clinical practice in patients with stable angina, documented silent ischemia or acute coronary syndrome (STEMI patients are excluded) undergoing a coronary percutaneous revascularization. Up to 445 number of patients in up to 31 number of sites in Spain will enroll in this study. This analysis includes 12 months follow up data of the first 50 enrolled patients.

METHODS AND RESULTS

Between July 2017 and November 2018, 204 subjects with a maximum of two de novo lesions have been enrolled in the Magmaris Registry. The primary end point is MACE rate at 12 month FUP. Clinical follow-up is scheduled at 1, 12 and 24 months. Dual antiplatelet therapy is recommended for one year. By November 2018, 50 patients, at 19 sites, completed the 12 month FUP. The mean lesion length and vessel diameter were 16mm and 3.2mm, respectively. Patient mean age was 75+10 years old (82% male). Analysis of this population shows that 44% of the subjects had hypertension, 46% hypercholesteremia, and 20% were diabetics. Procedure indication was stable angina in 35% and unstable angina or NSTEMI in 65% of patients.

12 month data of the first 50 patients on TLF rate, cardiac death, myocardial infarction, TLR, scaffold thrombosis, device and procedure success will be available upon presentation.

CONCLUSIONS

The study results will provide important information on the safety and performance of Magmaris at 12 months

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FANTOM II long lesion study: initial safety and performance study of the Fantom sirolimus-eluting bioresorbable coronary scaffold in long lesions - First report: 30-day outcomes

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Stents and scaffolds

AIMS

The primary objective of the FANTOM II Long Lesion study was to evaluate the safety and performance of native coronary artery stenting of lesions ≥ 20mm in length using one or more Fantom Sirolimus-Eluting Bioresorbable Coronary Scaffolds. Fantom is a fully resorbable scaffold, manufactured from TyroCore, which is composed mainly of an iodinated, polycarbonate copolymer of tyrosine analogs. Fantom is completely radiopaque enabling multiple scaffolds to be placed in a precise edge to edge configuration allowing for complete coverage of longer target lesions.

METHODS AND RESULTS

The FANTOM II Long Lesion study is a prospective, multicenter trial which enrolled 33 patients with de novo coronary stenosis with reference vessel diameters between 2.5 to 3.5 mm in diameter and lesion lengths ≥ 20mm. In this study all lesions were pre-dilated using a 1:1 NC balloon and then subsequently assessed to determine vessel diameter and lesion length. Once sizing was complete, either one or two scaffolds were selected to enable complete target lesion coverage. In this study acute technical success, acute procedural success and clinical procedural success rates as defined in the clinical protocol were 100% (33/33) in all cases. No incidence of a Major Cardiac Adverse Event or scaffold thrombosis was reported in the initial 30 day follow-up time period. Acute angiographic and OCT analysis is currently in process at the designated core lab and will be presented along with the MACE and scaffold thrombosis results for the first time at the EuroPCR Course. Additionally, the initial angiographic imaging results from the first 10 patients through 6 months of follow-up will also be presented.

CONCLUSIONS

As in the Fantom II Trial which was used as a basis for obtaining CE Mark, the Fantom sirolimus-eluting bioresorbable coronary scaffold demonstrated favorable initial acute safety in this first cohort of patients with more complex lesions. A qualitative angiographic assessment will be performed in all patients at 6 months and all patients will be followed through 5 years.

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The strategy for intraprocedural stent thrombosis during primary PCI in Japanese ACS patients

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds

AIMS

Intraprocedural stent thrombosis (IPST) during percutaneous coronary intervention is a rare complication leading to poor outcome. It is not clear how to treat for IPST. The aim of this study was to evaluate appropriate strategy for IPST.

METHODS AND RESULTS

This was single center retrospective observation study. Between April 2007 and August 2017, 1604 consecutive acute coronary syndrome (ACS) patients were treated by percutaneous coronary intervention in our institute. In those patients, IPST was observed in 50 cases. Until 2013, our phase1 strategy for IPST was mainly stent deployment. After we can use perfusion balloon in 2014, long balloon inflation became our phase2 strategy for IPST. We compared the primary PCI strategy for ACS, the strategy for IPST and their outcomes between phase1 strategy group (n=25) and phase2 strategy group (n=25). The type of thienopyridine loading was clopidogrel (76%) in phase1 group and prasugrel (64%) in phase2 group (P<0.01). The type of stent in primary PCI strategy was BMS (84%) in phase1 group and DES (84%) in phase2 group (P<0.01). In the strategy for IPST, we use IABP (phase1 vs phase2: 84% vs. 72%), urokinase (12% vs. 8%), cilostazol add on (48% vs. 32%), primary stent (64% vs. 12%, P<0.01), and long balloon inflation (1% vs. 36%, P<0.01). At 1 year, MACE rates were 52% and 20% (P=0.03) and Stent thrombosis were 30% and 8% (P=0.07).

CONCLUSIONS

Phase2 strategy in that we use prasugrel loading, DES and long balloon inflation might be better strategy for IPST.

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The use of angiogenic proteins in refractory angina: a systematic review and meta-analysis

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Refractory angina (RFA) effects up to 100,000 new patients in Europe per year. Patients experience chest pain, multiple hospitalizations and a low quality of life with few treatment options. Angiogenic therapy as recombinant proteins or gene therapy has the potential to stimulate new vessel growth. Studies have been phase I-II trials and effects on cardiovascular outcomes (mortality, MACE) and secondary measures of angina remain unclear. We therefore performed a meta-analysis of randomized controlled trials (RCTs) to evaluate the effect of angiogenic protein therapy in patients with RFA .

METHODS AND RESULTS

We performed a systematic review and meta-analysis of randomized controlled trials (RCTs) comparing according to the PRISMA statement and prospectively registered on the PROSPERO website (CRD42018107283). A comprehensive search of PubMed, CENTRAL, EMBASE, Cochrane, ClinicalTrials.gov, Google Scholar databases of RCTs and scientific session abstracts was performed. Studies were deemed eligible if they: (i) were full-length publications in peer-reviewed journals; (ii) evaluated the use angiogenic proteins; (iii) had patients with no further revascularisation options; (iv) had patients in whom angina was treated with optimal medical therapy; (v) had on-going stable angina (equivalent to CCS class II – IV); (vi) had a placebo/control arm. We calculated risk ratios (RR) for all-cause mortality, combined MACE events, non-fatal MI, and need for revascularization. We assessed heterogeneity using chi-squared and I2 tests.

We identified 1536 citations with 15 RCTs meeting inclusion criteria involving 1083 patients. Outcomes pooled were MACE, mortality, ejection fraction and indices of angina (Canadian Cardiovascular Society [CCS] angina class, exercise tolerance). Our analysis showed a decreased risk of MACE (OR 0.77; 95% CI, 0.63−0.95) but not mortality (OR 0.67; 95% CI, 0.29−1.52) in treated patients compared with patients on maximal medical therapy.

This was supported by improvements in surrogate endpoints of angina episodes, use of anti-anginal medications, CCS class, and exercise tolerance.

CONCLUSIONS

Angiogenic therapy is a promising treatment when given in patients with RFA which improves MACE outcomes. However, larger clinical trials are needed to evaluate the best delivery method, vector and protein type before the therapy can be used as standard clinical practice.

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Benefit of vasodilating beta-blockers on cardiovascular outcomes after PCI in patients with AMI: nationwide multicentre cohort study two-year follow-up

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

Although current guidelines recommend using β-blocker after acute myocardial infarction (AMI), the benefit of β-blocker, which are currently prescribed in clinical practice, is equivalent across the entire class is unclear. We conducted this study to investigate the long-term benefit of vasodilating β-blockers over conventional ones in patients with AMI.

METHODS AND RESULTS

With national wide multicentre Korean Acute Myocardial Infarction Registry data, we analysed clinical outcomes of 7,489 patients with AMI, who underwent percutaneous coronary intervention (PCI), and took β-blocker. To adjust differences of baseline characteristics, propensity score matching method was used. Primary endpoint was composite of cardiac death, myocardial infarction (MI), or hospitalization for heart failure (HF).

In 3174 pairs (6348 patients) of propensity score matched patients, composite outcome occurred in significantly less in vasodilating β-blockers group compared with in conventional β-blockers group during 2-year follow up (6.2% vs 7.7%, Log-rank P = 0.025). Although statistical significance was not met, cardiac death occurred in less in vasodilating β-blockers group compared with conventional β-blockers group (2.7% vs 3.5%, Log-rank P = 0.072). Incidences of MI or hospitalization for HF were not different between two groups (P > 0.05 for each).

CONCLUSIONS

At 2 years, vasodilating β-blocker therapy resulted in better clinical outcomes compared with conventional β-blocker therapy did in patients with AMI in patients who underwent PCI.

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Impact of different anaesthesia protocols in TAVI outcome

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Transcatheter aortic valve implantation (TAVI) is currently recommended for elderly patients with symptomatic severe aortic stenosis at prohibitive or elevated operative risk. Growing TAVI volume mandate more streamlined TAVI programs. The aim of this study was to evaluate and compare the frequency of post procedure infection and delirium and overall hospitalization duration between patients treated under general anesthesia, conscious sedation and local anesthesia.

METHODS AND RESULTS

The study included 896 consecutive transfemoral TAVI patients. All patient data are collected in a dedicated prospective database. Statistical analysis consisted of Chi Square and Logistic Regression. Overall, mean age was 79 years, mean STS of 4.4 and 52.6% were males. A total of 442 patients (50.1%) were treated under general anesthesia, 197 (22.3%) with conscious sedation and 243 (27.6%) with local anesthesia. A total of 96 (10.9% of total) patients suffered a delirium; respectively 50 (11.3%) in general anesthesia cohort, 29 (14.7%) in conscious sedation cohort, and 17 (7%) in local anesthesia cohort (p=0.032). The overall rate of infections was 14.4% (n=127), respectively 87 (19.7%) in general anesthesia cohort, 27 (13.7%) in conscious sedation group, 13 (5.3%) in local anesthesia cohort (p<0.0001). Overall, 140 patients (16%) had prolonged hospitalization (≥ 7 days), respectively 103 (23.5%) in general anesthesia cohort, 26 (13.4%) in conscious sedation cohort, 11 (4.5%) in local anesthesia cohort (p<0.0001). On multivariate analysis, general anesthesia and conscious sedation were associated with delirium (general anesthesia vs local anesthesia: OR, 1.768, 95% CI 0.990-3.159, p = 0.054; conscious sedation vs local anesthesia: OR 2.378, 95% CI 1.256-4.506, p=0.008), and infections (general anesthesia vs local anesthesia: OR 4.063, 95% CI 2.208-7.477, p < 0.0001; conscious sedation vs local anesthesia: OR 2.851, 95% CI 1.389-5.853, p=0.004).

CONCLUSIONS

General anesthesia is associated with more delirium and infections post TAVI and prolonged hospital stay. A transition to simplified TAVI under local anesthesia may considerably improve TAVI practice.

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How to become a "snuffboxer": Data from the BAR-TAB Registry (Barmbek Tabatiere Registry) demonstrating the feasibility and safety of the distal transradial access via the anatomical snuffbox

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

Over the recent years transradial access has become the primary route for coronary angiography (CAG) and interventions (PCI) and has achieved class I recommendations in European and American Guidelines. Recently a new puncture site more distally on the dorsal side of the hand in the area of the anatomical snuffbox has been developed and seen widespread use. With this registry we want to demonstrate the feasibility and safety of the distal transradial access.

METHODS AND RESULTS

From November 2017 until January 2019, we documented the characteristics of all patients scheduled for CAG or PCI via the right or left distal transradial access (dTRA). Patients with a palpable pulse at the distal and proximal radial artery were included. Ultrasound was not used for screening or puncture guidance. Primarily we have used dTRA only in selected cases, especially for access via the left arm since the placement of the arm for distal access is a lot more comfortable for the patient and the examiner than the standard proximal transradial access (pTRA).

In our cohort (N= 115, 87/115 = 75% male, average age: 74 years) patients with coronary artery bypass grafts (CABG) especially with usage of the left arteria mammaria interna represent the largest subgroup (N=40). Patients with advanced chronic kidney disease were another group of patients that we chose for dTRA since the first registries documented a significantly lower rate of chronic radial artery occlusion (RAO), thus the radial artery could be used for a later shunt implantation (N = 7). Other reasons we have chosen dTRA were orthopedic reasons (N = 17), weak proximal pulse or RAO of the contralateral arm (N= 24) use of the non-dominant arm and known kinking of the ascending aorta or the truncus brachiocephalicus (N= 22). CAG or PCI was performed using the right arm in 33 cases and via the left arm in 82 cases.

Indications were acute coronary syndroms in 91 cases. Other indications including stable coronary disease, valvulopathies or reduced left ventricular function were present in 24 cases. PCI was performed in 42% of the patients (N = 48/115). A crossover to another site became necessary in 12 cases and we used the ipsi- or contralateral pTRA (N= 6) or the femoral artery (N=6).

Overall the puncture success rate was 94% (108/115) and the completion rate of the planned procedure was 91% (105/115). As expected, our data show a learning curve with a puncture success rate in the first 50% of the patients of 90% (51/57) and in the second half of the patients we achieved a nearly perfect puncture success rate of 98% (57/58). The puncture time from holding the puncture needle until placement of the sheath was measured in 60 cases and was 64 sec. Only minor hematomas (<2cm) were encountered in two cases at the puncture site and one larger hematoma (<5cm) on the forearm that could be handled with compression. No other complications or RAO were discovered.

CONCLUSIONS

After more than a year of using the distal radial access in over 100 cases we can conclude that the method is feasible and can be apprehended after a learning curve of about 30 patients and lead to a near perfect puncture success rate. In our registry we haven't encountered any major complications, although naturally it requires trials with longer follow ups to compare the safety of the dTRA with the standard pTRA. If the first data showing a lower rate of RAO can be proven in a randomized trial the distal radial access could develop into the standard approach.

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The impact of plaque characteristics on volumetric stent expansion assessed by OCT

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THEME: Coronary Interventions

TOPIC(S): Stents and scaffolds, Other Coronary Interventions

AIMS

The evaluation of coronary stent expansion by a recently described novel optical coherence tomography (OCT) based volumetric method proved to be superior to the conventional method. This method makes it possible to precisely evaluate the relationship between pre-percutaneous coronary intervention (pre-PCI) plaque characteristics and stent expansion. This study sought to investigate the relationship between plaque characteristics and volumetric stent expansion utilizing OCT, in patients after drug eluting stent implantation.

METHODS AND RESULTS

164 patients with 165 lesions evaluated with pre- and post-PCI OCT and final FFR were enrolled. The volumetric method was used on post-PCI OCT pullbacks to evaluate stent expansion. Under-expansion was defined when Minimal Expansion Index (MEI) was <0.80. A comparison of plaque characteristics (calcium [maximum angle, maximum thickness, and minimum depth], lipid [maximum angle and minimum fibrous cap thickness], fibrous [maximum angle and maximum thickness]) from co-registered pre-PCI OCT between under-expanded (UE) lesions and well-expanded (WE) lesions was made. The UE lesions were further divided into UE and WE ‘segments’ based on EI at the frame level and the plaque characteristics were compared between the two groups within the UE lesions.

Out of the 165 lesions, 72 were UE and 93 were WE. Left anterior descending artery involvement was significantly more common in the UE group. At the lesion level, the frequency of plaque components was higher in the UE group [Calcium (77.8% vs 55.9%; p=003), fibrous (95.8% vs 76.3%; p=<0.001) and lipid (79.2% vs 68.8%; 0.094)]. Moreover, the UE group had larger calcium angle (167.04 ± 97.83º vs 132.31 ± 72.41º; p=0.04) and smaller lipid minimum fibrous cap thickness (112.95 ± 64.95 µm vs 147.81 ± 69.98 µm; p=0.005). In 72 UE lesions, UE ‘segments’ accounted for 21.2% of all the analyzed frames within the stent. Comparison of UE segments versus WE segments revealed significantly smaller minimum calcium depth (47.64 µm vs 82.78µm, p=0.012), lipid minimum fibrous cap thickness (75.11µm vs 111.25 µm, p=0.002), maximum fibrous angle (131.04° vs 161.75°, p=0.015) and maximum fibrous thickness (541.39µm vs 669.03µm, p=0.022) in the UE segments.

CONCLUSIONS

The UE lesions had a higher presence of all plaque components as well as a significantly larger calcium angle and smaller lipid minimum cap thickness. Within the UE lesions, the under-expanded segments were found to have significantly lower depth of calcium and lipid plaques as well as smaller fibrous angle and thickness. The elastic and compressible property of fibrotic tissue plays an important role in lumen gain and stent expansion, in the presence of other plaque components. Co-registered segmental analysis is helpful in identifying the baseline plaque characteristics that may result in stent under expansion.

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In-hospital mortality in STEMI with primary PCI: is it a huge umbrella hiding many entities? A high-volume centre one-year analysis

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Acute myocardial infarction represents the global leading cause of mortality in cardiovascular patients. We aim to analyze one-year data of in-hospital mortality of STEMI patients treated with primary percutaneous intervention (pPCI) in a high-volume center (1050 pPCIs / year, 5000 various procedures / year) with on-site cardiac surgery but no left-ventricular assist devices available.

METHODS AND RESULTS

We analyzed data from 1050 STEMI patients which were admitted and treated in a primary PCI center from Romania in 2018. Our center is the only one 24/7 available for at least 8 million inhabitants from east Romania. The mean age was 60 ± 8.81 years of whom 61% were males. The most prevalent cardiovascular risk factors were hypertension (69%), diabetes (25%), smoking (42%), and dyslipidemia (53%). Total all-cause in-hospital mortality was 5.9% (n=62). Significant corelations were found with older age ($p<0.001$), female gender ($p<0.001$), diabetes ($p<0.04$), depressed left ventricular ejection fraction <35% ($p<0.001$), Killip class at admission >I ($p<0.001$) and delayed presentation time >12h ($p<0.001$). No recordings of in-hospital mortality due to iatrogenic PCI complications (such as coronary perforation, rupture, aortic dissection or cardiac tamponade) were done. In other words, mortality due to PCI was zero. 12% of all admitted patients had cardiogenic shock and this was the main cause (92%) of all in-hospital deaths. Furthermore, this condition was associated with triple vessel disease (47%, p=0,0021), culprit left main (21%, p=0.0015), culprit proximal left anterior descending artery (57%, p=0.0023), acute in-stent thrombosis (4.83%, p=0.003) and mechanical complications (13%, $p<0.001$). Another important factor associated with in-hospital mortality was unsuccesfull PCI in patients presenting with cardiogenic shock ($p<0.001$). This was most frequent due to sudden haemodynamic instability during the procedure or due to anatomic complexity (severe calcifications, extreme tortuosity, multivessel disease). A subgroup of patients (2.38%, n=25) developed cardiogenic shock after successful primary PCI, possibly due to acute reperfusion injury. This can be considered generated by the procedure itself and was associated with delayed presentation time (>12h) and triple vessel disease with left main involvement. Mortality in this subgroup was very high (72%, n=18) mostly due to recurrent incessant ventricular tachyarrythmias. Data analysis of time from admission to in-hospital death revealed that ventricular free wall rupture and culprit left main were associated with first-day mortality, while triple vessel disease and proximal left anterior descending artery were more prevalent in the 24h-7days interval. The average in-hospital mortality time was 3 ± 4.1 days.

CONCLUSIONS

Our analysis revealed that in-hospital mortality of STEMI pPCI patients is a broad term, covering different clinical scenarios. While de-facto mortality in the cath-lab for primary PCI was zero (no iatrogenic major complications), almost all patients who died had cardiogenic shock. Late interventions, multivessel disease, severe left ventricular disfunction and complex procedures with no/slow-flow were main causes for a high incidence of cardiogenic shock. In order to improve quality of care and reduce the incidence of death, it is not

enough to report an unspecific percentage of mortality, but to identify the main causes and tackle them accordingly.

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The kissing WATCHMAN - Data from the co-LAA register

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THEME:

TOPIC(S):

AIMS

LAAC is an established treatment strategy to reduce the risk of stroke in patients with atrial fibrillation and contraindications for oral anticoagulation. In some cases, the atrial appendage is so large that it cannot be closed with a single occluder, so that there is a second session after a partial ingrowth of the first occluder with the implantation of a second occluder necessary.

The aim of this study was to evaluate the feasibility and safety of the staged 'kissing-Watchman' technology to occlude the LAA with complex anatomy.

METHODS AND RESULTS

Since December 2015 nearly 500 patients were included in the “Coburger LAA-Register” (COLAA) after implantation of an LAAC device from different companies. In this time 8 complex LAAs were implanted in double devices technic using staged Watchman procedures. The anatomic morphology, procedure characteristics and safety were analyzed.

We report about 8 patients (6 men, mean age 79,6 years, CHADS-VASC Score 3, HASBLED Score 4), in which we performed a LAAC using two Watchman Device (Boston Scientific) in staged procedure. Each LAA, the anatomic morphology includes 3 cauliflowers, 2chicken wings and 3 windsocks, had 2 big lobes with a large common ostium. After the implantation of the first device and a six weeks depending partial ingrowth a second device was implanted in the second lobe. After implantation a dual platelet therapy was used with ASS und Clopidogrel. All the procedures were successful, no severe complications or major adverse events were reported in both procedures. In the 3 month follow-up no dislocations, thrombosis or leakage were seen.

CONCLUSIONS

Our preliminary data show that the kissing watchman is a safe and effective therapeutic option, which might provide a strategy to occlude the LAA with complex anatomy when an incomplete closure is inevitable with a single device.

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Correlates of depression anxiety and stress in patients undergoing transradial cardiac catheterisation

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THEME: Coronary Interventions
TOPIC(S): NSTEMI, Stable CAD

AIMS

Transradial cardiac catheterization is being increasing used as a diagnostic or interventional procedure for coronary heart disease. However, the presence of depression, anxiety and stress during cardiac catheterisation is associated with worse cardiovascular outcomes. In addition the presence of anxiety has been associated with radial artery spasm and reduced patient comfort. Therefore the objective of this study was to investigate the prevalence of depression anxiety, and stress among patients scheduled for elective transradial cardiac catheterisation.

METHODS AND RESULTS

Following obtaining informed consent, patients scheduled to have elective transradialartery cardiac catheterisation completed a survey consisting of demographic questions and the 21 question version of the Depression Anxiety Stress Scale (DASS21)Data analysis was done using SPSS statistical software.

Completed questionnaires were received from 194 patients (123 Males and 71 Females). The mean scores for depression, anxiety and stress were 6.2 (±5.6), 8.2(±5.9), 10.2 (±6.6). Approximately 30% of the patients were identified as having mild to moderate depression, 50% had anxiety and 20% had stress prior to the procedure.The female gender, and smoking status were significant correlates of anxiety, depression, and stress. In addition, lower education level and unemployment were significant correlates of anxiety and depression.

CONCLUSIONS

A large proportion of patients having transradial PCI experience some level of anxiety prior to the procedure hence tailored strategies to minimise the anxiety levels and thus reduce the risk of PCI failure need to be implemented. Screening should also focus on identifying depression and stress in addition to other traditional risk factors for coronary heart disease.

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Procedural and clinical outcomes of newer-generation transcatheter aortic valves vs. first-generation transcatheter aortic valves in Latin America. Latin American real-world registry (TRYTOM)

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

OBJECTIVES: To compare procedural and clinical outcomes of the first generation transcatheter aortic valves (FGTAVR) (Core valve Medtronic, Minneapolis, MN, USA and Edwards XT) implantations with the 2nd generation transcatheter aortic valves (SGTAVR) (Evolut R, Edwards Sapien 3, Acurate Neo, Lotus). Main endpoints include 30 days mortality all-cause and cardiovascular death, paravalvular regurgitation, major vascular complications, stroke, and pacemaker implantation.

METHODS AND RESULTS

BACKGROUND: The evolution of transcatheter aortic valve replacement (TAVR) procedures was possible due to various technical improvements, including the procedure itself and the devices. Nonetheless, little is known on real benefits in clinical practice of the performance of such newer devices in relation to the first generation.

METHODS

A multicentre observational registry from 8 centers spread in 4 countries in Latin America with a total of 717 patients included from 2009 and 2018, all of them with severe symptomatic aortic stenosis or dysfunction bioprosthesis, that were treated with the first generation THV (Core Valve and Edwards XT) and the newer generation devices (Evolut R, Edwards Sapien 3, Acurate Neo, Lotus). Procedural and clinical outcomes were compared according to definitions of the Valve Academic Research Consortium-2

RESULTS:

A total of 717 patients whit FGTAVR and SGTAVR were included in this study, with an average of 80.4 ± 7 years, male gender 49,4%, HTA 83,6% and Diabetes mellitus 26,2%. 67,1% were in NYHA CF III-IV. The mean Euro score II was 7.8 and STS score 7.7%.

FGTAVR was used in 505 patient (70, 5%) and 212 (29, 5%) patient were treated with SGTAVR.

Devices investigated in the registry were the following: classic Core valve Medtronic (n=422; 58,9%), Edwards XT (n=83; 11,6%), Edwards SAPIEN 3 (n= 41; 5,7%), Lotus Valve (n=47; 6.7 %), Symetis Acurate Neo (n=50; 7,0%), and Evolut R (n=73; 10,2%). Valves in Valve procedure was performed with 4.2% FGTAVR and 12,2% with SGTAVR (p=0,002).The FGTAVR and SGTAVR Thirty-day all-cause and cardiovascular death were 6,2 % and 6,6 % (p=0,8), respectively; Any stroke occurred 10% and 5,4% (p=0,026) respectively; life-threatening bleeding occurred in 12,3% and 5,7% respectively, taponade 5,3 and 1,9% respectively(p=0,038%); major

vascular complications 12,3% and 5,7% (p=0,008) respectively, permanent pacemaker implantation 20,6% and 15,2% (p=0,099) respectively; moderate or severe aortic regurgitation 11,4% and 9,3%,(p=0.09), Percutaneous Access 61,4% vs. 80,2 % (p<0,001). The length of stay in UTI was 4,08 vs 3,65 (p=0,37) and total hospital stay length was 8,63 and 7,15 days respectively.(p=0,024).

CONCLUSIONS

TAVR with second generation valves is safe and effective with a similar rate in in-hospital and at 30 days mortality with fewer stroke, vascular complications, life-threatening bleeding, pacemaker implantation and hospitalization days.

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Long-term outcomes of complete vs. incomplete revascularisation in STEMI in patients with multivessel coronary artery disease

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Multivessel coronary artery disease (MVD) in ST elevation myocardial infarction (STEMI) patients is common. Data whether STEMI patients with MVD should undergo additional percutaneous coronary intervention (PCI) of the nonculprit coronary artery shortly after primary PCI are conflicting. The aim of our study was to evaluate the impact of complete revascularization during index hospitalization on long-term survival in STEMI patients with MVD.

METHODS AND RESULTS

We identified 258 STEMI patients, of which 23 (9%) patients were excluded due to unsuccessful PCI of culprit coronary artery or urgent surgical revascularization. A total of 235 patients constitute the study cohort (70 (27%) patients had CR and 165 (64%) had IR). Median follow up was 7.03 years (QD 6 – 8.24 years). There were no significant differences in baseline characteristics between both groups. On long-term follow up, patients with CR had lower all-cause mortality (15.7% vs. 35.8%, log rank P=0.003) and lower CV mortality (12.9% vs. 23.6%, log rank P=0.046) compared to patients with IR. Cox regression analysis showed that patients with CR during index hospitalization had lower all-cause mortality (HR 0.386 at 95% CI; P=0.004) and a trend towards lower CV mortality (HR 0.486 at 95% CI; P=0.051). In competing risk analysis for rehospitalization and all-cause mortality for patients that did not need rehospitalization in CR group had lower risk for an event than patients in IR group (P=0.003). While competing risk analysis for rehospitalization and cardiovascular mortality revealed a trend toward lower risk of an event for patients in CR group that did not need rehospitalization (P=0.071). The rate of rehospitalization between CR and IR group during follow up was the same (P=0.9).

CONCLUSIONS

In our study cohort, patients with STEMI and MVD who were treated with CR during index hospitalization showed better long-term survival compared to patients with IR.

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Long-term follow-up results of percutaneous endoatherectomy of heavily calcified lesion in non-stent zone with sheathless guiding catheter and bioptome (BRAVO)

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal

AIMS

Previously, we presented the effectiveness of BRAVO technique (Bioptome assisted by RAMBO Via OPTIMO: percutaneous endoatherectomy using 7Fr sheathless guiding catheter with protection balloon on its tip (OPTIMO), and bioptome.) for heavily calcified lesion in common femoral artery (CFA). This time, we evaluated the long-term follow up results of the cases including superficial femoral artery (SFA).

METHODS AND RESULTS

"BRAVO" procedure is consisted with 2 parts. 1) Double vended hard guidewire and Crosser was introduced to peel off calcified plaque from the vessel wall (“RAMBO” technique), 2) calcified plaque was scraped off by bioptome under OPTIMO protection introduced from frontal superficial femoral artery (SFA) puncture.

We underwent angioplasty for 16 cases of heavily calcified total occlusion in 15 CFA and 5 SFA with BRAVO technique. 15 cases were done successfully including all CFA cases, and 1 SFA case needed stent graft because of perforation. After procedure, angiogram showed no residual stenosis. Hemostasis of OPTIMO was done safely by hemostasis device with assistance of long balloon inflation from inside via contra-lateral femoral and outer compression device from outside.

We followed up all the cases with ABI, Duplex or CT angio.

Mean follow up duration was 13.0 months, followed by 1 CT, 5 ABI, 6 Duplex, and 2 angiography.

15 cases had no restenosis, except 1 CFA case, which had restenosis at 19 months, and IVUS revealed no more calcified plaque proliferation compared with final IVUS at initial EVT. This case needed only simple balloon angioplasty to achieve revascularization.

CONCLUSIONS

We confirmed not only initial results, but long-term follow up results also seemed fairly good.

This procedure may represent one of the promising option for revascularization of heavily calcified lesion including joint position via EVT alone, without surgical endoatherectomy.

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Radiation dose reference levels for primary operators in the cardiac catheter Laboratory.

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Radiation from X-ray guided procedures undertaken in cardiac catheter laboratories (CCL) is harmful to both patients and the staff performing the procedure. Patient radiation doses should be continually monitored and compared to established benchmarks.

Primary operator radiation dose is relatively high and should be carefully monitored but it is difficult for operators to know what dose should be expected for different procedure.

The aim of this study was to establish primary operator radiation dose benchmarks for procedures undertaken in a modern tertiary catheter laboratory.

METHODS AND RESULTS

With the advent of real time digital dosimeters (RTDD), it is possible for the dose of the operator to be recorded at the end of each procedure. With sufficient procedure numbers, dose benchmarks for operators can be established.

For a period of three years, in a single tertiary institute, the RTDD (Raysafe i2 dosimeter - Unfors, Billdal, Sweden) was worn by the primary and secondary operator for CCL procedures and recorded at the end of each procedures. Fluoroscopy time, dose area product (DAP), air kerma, body mass index (BMI), X-ray system used, access route and procedure type were also recorded. Procedures were grouped into 8 different categories. Only procedure categories with >50 individual procedures were included. Operator effective dose was calculated from the RTDD readings. An operator dose reference level (ODRL) was then established for the median and 75th percentile of the effective dose. As operator dose has a direct relationship to the radiation dose to the patient (DAP), a RTDD to DAP ratio was created to account for variances in DAP between procedure types.

Of 10317 procedures performed, the RTDD was worn for 7639. Of the 8 procedure categories, diagnostic procedures were the most numerous with 5188 procedures. CTO procedures had the highest median ODRL-1.52 uSv (IQR=0.67-3.71) and right heart catheterisation the lowest at 0.05 uSv (IQR=0.00-0.24) ($p<0.001$). Access route significantly impacted on median RTDD readings so a different ODRL is established for radial and femoral access (0.38 (0.14-1.00 radial vs 0.24 (0.10-0.64) femoral ($p<0.001$)).

RTDD to DAP ratio (RTDD/DAP) was calculated for each procedure type and cardiac biopsy procedures were demonstrated to have the highest RTDD/DAP ratio. There was a significant difference between individual operators with regard to the RTDD/DAP ratio ($p<0.001$), demonstrating that there is a significant variance in the dose to the operator per DAP unit from the X-ray system based on the individual operator.

CONCLUSIONS

This large cohort study has established dose reference levels for primary operators (ODRLs) for different procedure types undertaken in the CCL and is the first such study to do so. The RTDD/DAP ratio normalises the operator dose for the different procedure types. In the same manner as exists for patient dose reference levels; an ORDL or RTDD/DAP ratio for operators consistently above the 75th percentile should be

investigated.

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Depth of implantation of a transcatheter aortic valve on different angulations and its correlation with new conduction disturbances

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Using post-implant multi-detector computed tomography (MDCT) scans, this study explores how different fluoroscopic viewing angles may influence the measured implantation depth after transcatheter aortic valve replacement (TAVR) and how will this measurement difference translate to new conduction disturbances.

METHODS AND RESULTS

We retrospectively selected 60 patients (33 with bicuspid aortic valves) who received a self-expanding transcatheter aortic valve (CoreValve [Medtronic, Minneapolis, Minnesota], or Venus A-Valve [Venus MedTech Inc., Hangzhou, China]) and underwent a post-procedural MDCT scan. The viewing angle providing actual depth measurements should show the valve stent inflow plane and aortic valve annulus both in plane. After segmenting the native annulus and the prosthesis stent inflow plane, the viewing angle where both structures were in plane was recorded and used to measure the actual implant depth. The shorter distance (i.e. the actual minimal depth, referred as Dmin) and the longer distance (i.e. the actual maximal depth, referred as Dmax) were measured in this view. The distance between the non-coronary cusp and the lower edge of the stent at the projection where valves were deployed was measured as the conventional depth of implantation retrospectively on fluoroscopy (referred as Dangio). New atrioventricular block (AVB), left bundle branch block (LBBB) and right bundle branch block (RBBB) post-TAVR were recorded. The mean (95% confidence interval [CI]) fluoroscopic view angle used for valve deployment was LAO 0 CAUD 13 (RAO 5 – LAO 6; CAUD 8 – CUAD 18), whereas the mean (95% CI) fluoroscopic view angle where both the annular and stent inflow planes were in plane was RAO 14 CAUD 18 (RAO 6 – RAO 23; CAUD 12 – CAUD 25). Dangio (8.1±4.3 mm) was approximately 2 mm apart from Dmin (5.7±4.0 mm) and Dmax (10.4±3.4 mm) ($P<0.001$). In 59 patients naïve of pacemaker, 10 had new first degree AVB, 4 had new third degree AVB, 16 had new LBBB and 5 had new RBBB. Among the three depth measurements and any new conduction disturbances, only Dmin had statistically significant impact on new LBBB (odds ratio [95% CI]: 1.2 [1.0 – 1.4], $P=0.046$).

CONCLUSIONS

The best fluoroscopic viewing angle for appreciating actual minimal/maximal depth of implantation of transcatheter aortic valves in average lies in the RAO and CAUD quadrant. When measuring the depth of implantation on fluoroscopy with only the annulus in plane might either under- or over-estimate the depth. This measurement difference may lead to a mismatch of implant depth and event of conduction disturbances.

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Prognostic impact of deterioration in nutrition status after TAVI

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Nutrition status was important for prognosis but not adequately assessed for patients who underwent transcatheter aortic valve implantation (TAVI), especially about change before and after TAVI. Our aim was to assess the prognostic impact of deterioration in nutrition status after TAVI.

METHODS AND RESULTS

Consecutive 212 patients who underwent TAVI from February 2014 to October 2017 were enrolled. Nutrition status was assessed with CONUT score which involves protein reserve depletion, caloric depletion, and impaired immune defenses. CONUT score was calculated before and 3 to 6 months after procedure. Enrolled patients were divided into two groups whether nutritional status deteriorated or not. Primary endpoint was mortality within 1 year after TAVI assessed with Kaplan-Meier analysis and predictors were assessed with cox proportional hazard model.

Deterioration of nutrition status was observed in 85 patients (40.1%; deterioration group). Baseline characteristics including nutritional status before TAVI were similar between two groups. Mortality rate was significantly higher in deterioration group than no deterioration group (30.5% vs. 2.9%, p?0.001). As a result of multivariate analysis including known prognostic factors, poor prognosis after TAVI was independently associated with deterioration of nutritional status (HR: 23.9, 95% CI: 9.03-78.1. p<0.001), frailty (clinical frailty scale?5) (HR: 2.40. 95%CI: 1.01-5.87, p=0.04) and surgical high risk (STS score?8) (HR: 3.74. 95%CI: 1.60-9.12, p=0.002). Deterioration of nutritional status after TAVI was only predicted with transapical approach (OR: 2.25, 95%CI: 1.09-4.79, p=0.03).

CONCLUSIONS

Deterioration of nutrition status after TAVI was associated with poor prognosis after TAVI. Transapical approach should be avoided possible in the view of nutritional status.

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Newer antiplatelet agents in patients with chronic kidney disease and STEMI: insights from the TOTAL trial

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

In patients with Acute Coronary Syndrome (ACS), the presence of chronic kidney disease (CKD) is associated with poor outcomes. We aimed to compare outcomes in patients with ST Elevation Myocardial Infarction (STEMI) ± CKD and analyse the effect of newer antiplatelet agents on the outcomes.

METHODS AND RESULTS

We included patients enrolled in the TOTAL trial. The TOTAL Trial was a randomized trial of routine manual thrombectomy vs. Primary Percutaneous Coronary Intervention (PPCI) alone in STEMI. Patients were divided based on the eGFR (<60ml/minute or ≥60ml/minute). In patients with low eGFR <60ml/minute, the primary outcome (composite of cardiovascular death, MI, or stroke) at 1 year was higher compared to patients with normal eGFR (15.1% vs 4.6%, p<0.0001). On comparison of the effect of newer antiplatelet agents, in patients with low eGFR <60ml/minute (n=1318), the primary outcome was no different between those on a newer antiplatelet agent or clopidogrel (11.6% vs.16.2%, HR 0.81 (0.56-1.16) respectively, p=0.24). Similarly, in patients with eGFR ≥60ml/minute (n=8201), there was no difference in primary outcome between those on newer antiplatelet agents and those on clopidogrel (3.9% vs. 5.0%, HR 0.87 (0.70-1.09), p=0.23).

Patients with low eGFR had similar rates of secondary outcomes (composite of cardiovascular death, MI, cardiogenic shock, new or worsening class IV heart failure, stent thrombosis and TVR at 1 year) irrespective of whether a newer antiplatelet agent or clopidogrel was used (17.1% vs. 21.9%, HR 0.89(0.66-1.20), p=0.42). However, in patients with eGFR ≥60ml/minute, the secondary outcome was significantly lower in those patients on a newer antiplatelet (7.5% vs. 10.1%, HR: 0.79 (0.68-0.93), p=0.005, table 4) driven mainly by reduction in class IV heart failure.

CONCLUSIONS

In this post-hoc analysis of the TOTAL trial, overall composite primary outcome rates in patients with CKD were higher compared to those without CKD. Despite this higher risk, the use of newer antiplatelet agents was not associated with a reduction in primary or secondary event rates in STEMI patients with CKD.

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Detection of device-related thrombosis following LAA occlusion: a comparison between cardiac CT and transoesophageal echocardiography

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

Device-related thrombosis (DRT) following left atrial appendage occlusion (LAAO) is a rare, but feared complication. This study sought to evaluate the clinical value of cardiac CT for detection of DRT using transesophageal echocardiography (TEE) as the reference standard, and to provide insights into the causes, natural history and risk of DRT.

METHODS AND RESULTS

We reviewed 301 consecutive patients undergoing LAAO between 2010 and 2017. Of these, 256 patients had cardiac CT and TEE imaging available at 8-weeks follow-up; 143 had complete 12-month imaging. A blinded investigator analyzed all images. On TEE, an echo-dense mass attached to the device was defined as DRT. Cardiac CT was analyzed for presence of hypo-attenuated thickening (HAT) on the device, which was sub-classified as low-grade or high-grade. High-grade HAT was considered as definite DRT.

At 8-weeks, TEE detected 5 (2%) cases with DRT; and cardiac CT 6 (2.3%) cases with high-grade HAT. At 12-months, both TEE and cardiac CT detected 2 (1.4%) cases with DRT or high-grade HAT, respectively. Cardiac CT demonstrated low-grade HAT in 9 (3.5%) cases at 8-weeks; and 13 cases (9.1%) at 12-months. High-grade HAT/DRT was associated with thromboembolism in 2 cases, while low-grade HAT was not related to embolic events. Low-grade HAT resolved spontaneously over time.

CONCLUSIONS

Cardiac CT appears equally good as TEE for detection of DRT. In addition, cardiac CT demonstrates cases with low-grade HAT, not visualized by TEE. The clinical significance hereof requires further investigation.

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Acute and long-term clinical outcomes after AMPLATZER LAA closure via a PFO vs. transseptal puncture

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THEME:
TOPIC(S):

AIMS

Transseptal puncture (TSP) in an infero-posterior location is the preferred access for device positioning in left atrial appendage closure (LAAC) with Amplatzer devices. Using a patent foramen ovale (PFO) potentially avoids complications of TSP and allows ad hoc PFO closure. Aim of this study was to compare acute and long-term clinical outcomes of PFO versus TSP access for LAAC with Amplatzer devices.

METHODS AND RESULTS

Retrospective study of 462 consecutive patients, which were enrolled from July 2009 to April 2018, into the Amplatzer registries Bern-Zurich, Switzerland and Coburg, Germany. A 1:3 propensity score matching was performed to adjust for all prognostically relevant baseline characteristics. The predefined primary efficacy endpoint of all-cause stroke, systemic embolism, and cardiovascular/unexplained death and the primary safety endpoint of major, periprocedural complications and major or life-threatening bleedings were analyzed according to the intention-to-treat principle. A total of 337 patients (91 PFO vs 246 TSP) with a mean follow-up of 2.6 ± 1.6 and 2.5 ± 1.4 years were included. Events are reported per 100 patient-years. The PFO was simultaneously closed in 54/91 patients (59.3%). Echocardiographic guidance was used in 28.6% of the PFO and 39.8% of the TSP patients and fluoroscopy time was 17.0±13.0 and 14.2±9.1 minutes, respectively. Age (74.4 ± 10.9 [PFO] vs 75.2 ± 8.7 [TSP] years, p=0.50), stroke (CHA2DS2-VASc score 4.3±1.4 vs 4.5±1.6, p=0.47), and bleeding risk (HAS-BLED score 3.3±0.94 vs 3.3±1.01, p=0.87) were comparable between the groups. The rates of device success (97.8% [PFO] vs 97.6% [TSP], p=0.90) and major, periprocedural complications (4.4% [PFO] vs 4.5% [TSP], p =0.98) did not differ. Major bleedings were documented in 7/233 (3.0% [PFO] vs 14/603, 5.7% [TSP], HR, 1.3; 95% CI, 0.50 - 3.4, p=0.30) patients. All-cause stroke and TIA occurred in 4/233, (1.7% [PFO] vs 16/603, 2.7% [TSP], HR, 0.62; 95% CI, 0.25 - 1.7, p=0.39) patients. Also, the rates of cardiovascular or unexplained death were comparable (18/233, 7.7% [PFO] vs 42/603, 7.0% [TSP] hazard ratio [HR], 1.1; 95% confidence interval [CI], 0.63 - 2.0, p=0.70) between the groups. The co-primary endpoints of efficacy (21/233, 9.0% [PFO] vs 46/603 [TSP], 10.3, HR, 1.2; 95% CI, 0.69 - 0.85, p=0.54) and safety (11/233 [PFO], 4.7% vs 24/603 [TSP], 4.0%; HR, 1.4; 95% CI, 0.52 - 3.6, p=0.49) did not differ.

CONCLUSIONS

Use of a PFO access for LAAC with Amplatzer devices offers equal acute and long-term clinical outcomes as a transseptal puncture. Simultaneous PFO closure does not increase risk but confers a potential protective benefit.

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Mid-term clinical outcomes of ACP vs. Amulet AMPLATZER occluders for LAA closure

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THEME:
TOPIC(S):

AIMS

The Amplatzer Cardiac Plug (ACP) and its successor Amulet have shown similar short-terms results for left atrial appendage closure (LAAC). To investigate clinical mid-term outcome of ACP versus Amulet devices for LAAC.

METHODS AND RESULTS

Three real-world, Amplatzer registries (Bern, Coburg, Zurich), enrolling consecutive patients from July 2009 to April 2018, were retrospectively analyzed. The primary endpoint of safety was a composite of major periprocedural complication and major bleedings, the primary endpoint of efficacy included stroke, systemic embolism, and cardiovascular or unexplained death, and the net clinical benefit was a combination of all above mentioned hazards. Furthermore, incidence of device-related thrombus (DRT) was assessed. A total of 563 patients (344 ACP vs 219 Amulet) with a mean follow-up of 2.9 ± 1.6 and 1.9 ± 0.9 years were included. All events are reported per 100 patient-years. Age (74.4 ± 9.9 [ACP] vs 74.4 ± 9.1 [Amulet] years, p=0.93), stroke (CHA2DS2-VASc score 4.4 ± 1.6 [ACP] vs 4.6 ± 1.7 [Amulet], p=0.43), and bleeding risk (HAS-BLED score 3.2 ± 1.1 [ACP] vs 3.2 ± 0.9 [Amulet], p=0.96), such as all other prognostically relevant baseline characteristics were comparable between both groups. The rate of major periprocedural complications was similar (4.9% [ACP] vs 4.1% [Amulet], p=0.65). Major bleedings occurred in 24/998, 2.4% [ACP] vs 9/417, 2.1% [Amulet] (hazard ratio [HR], 1.2; 95% confidence interval [CI], 0.56 - 2.6, p=0.64) patients. All-cause stroke and TIA were documented in 21/998, 2.1% [ACP] vs 12/417, 2.9% [Amulet] (HR, 0.56; 95% CI, 0.25 - 1.3, p=0.16) patients. Also, cardiovascular or unexplained death were comparable (93/998, 6.3% [ACP] vs 23/417, 7.7% [Amulet] (HR, 0.6; 95% CI, 0.54 - 1.4, p=0.51). The co-primary endpoints of efficacy (72/998, 7.2% [ACP] vs 43/417, 10.3% [Amulet] (HR, 0.67; 95% CI, 0.44 - 1.02, p=0.062), safety (40/998, 4.0% [ACP] vs 18/417, 4.3% [Amulet] (HR, 1.15; 95% CI, 0.53 - 2.51, p=0.72), and the net clinical benefit (101/998, 10.1% [ACP] vs 55/417, 13.4% [Amulet] (HR, 0.73; 95% CI, 0.49 - 1.07, p=0.11) did not differ between the two devices. The rate of DRT (3.4% [ACP] vs 3.2% [Amulet], p=0.69) was similar.

CONCLUSIONS

On mid-term, ACP and Amulet provided similar efficacy, safety and net clinical benefit.

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Different dynamics of electrical conduction abnormalities after balloon-and self-expandable TAVI

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

To compare the dynamics of new onset conduction abnormalities after TAVI between balloon-expandable (BEV) and self-expandable (SEV) valve prostheses and to assess the consequences on ECG-based decision making for permanent pacemaker implantation (PPMI) and early discharge.

METHODS AND RESULTS

This single-center study enrolled all consecutive TAVI patients with SEV or BEV implanted between January 2011 and January 2018. Patients with pre-existent pacemaker implantation, procedural death or incomplete ECG registration were excluded. Standard twelve lead ECG was performed before the procedure, immediately after, daily until discharge and at 1 and 6 months. The need for PPMI was assessed at 12 months after TAVI. Overall, 133 patients were included: 31 SEV (Medtronic EVOLUT or EVOLUT PRO) and 102 BEV (Edwards SAPIEN XT or SAPIEN 3). There were no significant differences in baseline demographic or ECG characteristics between the BEV and SEV patients. In SEV patients, the PR-interval did not show a significant increase in the first 24 hours (172±30 vs 175±32ms, p=0.787) but prolonged significantly after 24 hours and peaked at 6 days post TAVI (175±32 vs 203±25ms, p=0.022). In BEV patients, PR-interval increased immediately after TAVI (187±34 vs 197±35ms, p=0.210) and remained stable during hospitalisation (delta PR 1.1±21ms, p=0.980). QRS duration increased immediately after TAVI in SEV patients (104±25 vs 121±27ms, p=0.020) and BEV patients (109±25 vs 119±30ms, p=0.211) and remained stable during further hospitalisation in both groups. At one month post-TAVI, PR-interval and QRS duration decreased again in both groups. However in SEV patients, the PR-interval and QRS duration remained significantly increased compared to baseline (194±20 vs 172±30ms, p=0.022 and 117±23 vs 104±25ms, p=0.028 respectively). New-onset LBBB was seen in 18.5% of BEV and 30.7 % of SEV (p=0.120) and persisted at 30 days in 14.0% of BEV and 26.9% of SEV (p=0.066). PPMI after 1 year was needed in 12.7% of BEV and 35.4% of SEV (p=0.001). Both for BEV and SEV patients, no PPMI was needed if no changes occurred in PR-interval and QRS duration in the first 48 hours (delta PR and delta QRS ≤ 0ms).

CONCLUSIONS

New onset conduction abnormalities after TAVI reveal different time patterns in relation to valve design. PR-interval prolongation in SEV is more pronounced and occurs later as compared to BEV. Independent of these different dynamics, absence of PR prolongation and QRS widening at 48 hours precludes the need for PPMI. Our findings suggest that patients with SEV require ECG evaluation at least until 48 hours after TAVI.

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Long-term impact of conduction disturbances on left ventricular remodeling and mass regression following TAVR

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

Left ventricular (LV) reverse remodeling and mass regression after valve replacement for aortic stenosis (AS) is a favorable outcome suggesting LV unloading. The aim of this study was to compare the difference of long term LV remodeling and mass regression between the patients with and without conduction disturbances (CD) following trans-catheter aortic valve replacement (TAVR).

METHODS AND RESULTS

We conducted a prospective analysis of 152 consecutive TAVR patients in National Taiwan University Hospital. The echocardiography was performed at baseline, 1 and 3 years follow-up visit. LV mass was calculated and indexed to body surface area.

53 patients (34.9 %) had CD following TAVR, including 30 (56.6%) permanent pacemaker implantation and 23 (43.4%) new left bundle branch block. Male gender, CoreValve/Evolute R and low implantation were associated with post-TAVR CD. In 123 patients completing 1-year follow-up, post-TAVR non-CD group (N=85) had significant improvement of LV ejection fraction (Baseline vs 1-year: 65.1±13.2 vs 68.7±9.1, P=0.017) and reduced LV end-systolic volume (39.8±25.8 vs 34.3±17.1, P=0.011), which was not found in CD group (N=38). Both groups had significant decrease in LV mass index (baseline vs 1-year: 148.6±36.9 vs. 136.4±34.7 in CD group, p=0.023; 153.0±50.5 vs. 125.6±35.1 in non-CD group, p<0.0001). But in 46 patients completing 3-year follow-up, only non-CD patients (N=28) had statistically significant decrease in LV mass index (Baseline vs 3-year: 180.8±58.8 vs 129.8±39.1, p=0.0001), and a trend toward reduced LV end-diastolic volume (125.5±39.1 vs 110.5±39.5, p=0.082) with LV end-systolic volume reduction > 10% (50.8±31.5 vs 41.1±29.7, P=0.191), not in CD patients (N=18).

CONCLUSIONS

In patients with severe AS receiving TAVR, the improvement of left ventricular systolic function at 1-year, and sustained LV reverse remodeling and mass regression at 3-years could only be observed in patients without post-TAVR CD.

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Some wounds never heal: stent thrombosis beyond five years

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

It remains unknown whether the risk of stent thrombosis (ST) eventually abates over time or persists indefinitely. There are a few reported cases of very very late stent thrombosis (VVLST) (> 5 years). We describe the largest series of VVLST reported so far.

METHODS AND RESULTS

From January´09 to December´18, 58 patients presented 59 definite VVLST at the 4 participating centers and were included in the study. The mean age was 62.7±11, 89% were males, 79% had hyperlipidemia, 69% had prior tobacco abuse, diabetes was present in 31%. The mean left ventricular ejection fraction was 52.8±11.The median interval between stent implantation and VVLST was 8.1 [IR 5.6-9.4] years.

Regarding thrombosed stent characteristics:Thrombosed stent was a bare metal stent (BMS) (42.5%), in three cases (5%) the stent was unknown and the rest(52.5%) were drug eluting stent (DES) (65% of them first-generation DES and the rest second-generation DES); stent mean diameter was 3.2±0.4mm, thrombosed stent was involving a bifurcation (8.5%) and more than one stent was overlapped in 22% cases; average stent length was 21.5±7mm. The initial stent was deployed to treat a reestenosis in 12 patients (21%), 11 of them(92%) a BMS-reestenosis.

Seventy-six percent of patients (44/58) were taking aspirin but only 8 of them were still taking clopidogrel (14%) at the time of VVLST. 9/58 patients (15.5%) had discontinued any antiplatelet treatment in the last month (66% of them P2Y12) and 10/58 patients (17%) discontinued any antiplatelet therapy during the last 3 months, one patient discontinued oral anticoagulation.

The mean LVEF post VLSTT was 45±13, significantly lower than the previous one (p=0.001) and the mean LVEF reduction was 10.5±14. Most patients presented as a STEMI (88%, 51/58). Three patients presented in cardiogenic shock and two of them died (3.5%). Four patients (6.8%) suffered a re-ST on follow-up and other 3(5%) patients suffered a ST in another vessel.

CONCLUSIONS

The risk of ST persist beyond 5 years after BMS, first- and second –generation DES implantation and cause serious clinical consequences. A high incidence of classical cardiovascular risk factors and previous stent reestenosis were frequently found in these patients and they could be some of the factors related to VVLST.

It is noteworthy that after a mean of 8.1 years since stent implantation, 14% patients suffered a ST related to antiplatelet therapy discontinuation (mainly P2Y12) pointing once again the controversy about dual antiplatelet therapy (DAPT) duration. Some patients may benefit from indefinite DAPT, however the patients who would benefit remains to be further clarified.

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Diagnostic accuracy of 320-detector CT for characterizing coronary atherosclerotic plaques: comparison with intravascular OCT

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Multi-detector computed tomography has shown variable results in defining tissue characteristics based on optical coherence tomography findings. This study sought to determine the diagnostic accuracy of 320-detector computed tomography for characterizing coronary atherosclerotic plaques in comparison with optical coherence tomography.

METHODS AND RESULTS

From 32 patients, 42 coronary segments were evaluated and co-registered by both 320-detector computed tomography and optical coherence tomography. 320-detector computed tomography vulnerable plaque characteristics included low attenuation plaque (<30HU), napkin-ring sign, positive remodeling and spotty calcification. The presence of macrophage, neovascularization and cholesterol crystals was also determined by optical coherence tomography. Minimal lumen area was 2.78±1.23mm by optical coherence tomography and 3.29±1.49mm by 320-detector computed tomography (p<0.001). Accuracy of 320-detector computed tomography to classify coronary stenosis severity was low (42.1%; 95%CI 25.3-58.9), whereas agreement was moderate (AC=0.64; 95%CI 0.46-0.82; p<0.001). Noncalcified plaques were classified accordingly by both methods in 88.2% of the cases (p=0.005). There was no association between any 320-detector computed tomography plaque type and optical coherence tomography fibroatheroma (p=0.62). The combination of 2 or more of the 320-detector computed tomography vulnerable plaque characteristics was associated with the presence of macrophage (74.2 vs. 25.8%; p=0.034) and cholesterol crystals (85.7 vs. 14.3%; p=0.04), but not with neovascularization (p=0.65). The presence of all four characteristics demonstrated the highest accuracy (75.1%) for detecting optical coherence tomography fibroatheroma.

CONCLUSIONS

320-detector computed tomography is useful for non-invasive evaluation of calcified and noncalcified tissue characteristics of coronary atheroma. The presence of low attenuation plaque, napkin-ring sign, positive remodeling and spotty calcification on 320-detector computed tomography showed a high diagnostic accuracy of optical coherence tomography-defined fibroatheroma

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Coronary plaque rupture in stable coronary artery disease and ACS: an OCT study

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Plaque rupture (PR) is the main cause of coronary thrombosis in the acute coronary syndromes (ACS), but can also be found in patients with stable coronary artery disease (SCAD). Our study aimed at comparing the morphology and the local inflammatory activity of ruptured plaques between SCAD and ACS patients using the highest resolution in vivo imaging technique: frequency domain optical coherence tomography (FD-OCT).

METHODS AND RESULTS

We retrospectively evaluated 70 plaques with evidence of PR at the FD-OCT: 25 in SCAD and 45 in NSTEMI patients. Main clinical, angiographic and morphological features (including plaque inflammation by a quantitative assessment of the macrophages density) were compared between the two groups. Beside an overall equivalence in clinical and angiographic features (except for an higher percent of active smokers among NSTEMI patients), some important FD-OCT differences in plaque morphology emerged. In particular, PR in NSTEMI was characterized by higher rate of macrophage infiltrates (78% vs 20%, $p<0.001$) and intraluminal thrombosis (84% vs 48%, $p=0.002$). Quantitative analysis showed a higher density of macrophages in NSTEMI than in SCAD patients (Normalized standard deviation: 0.0923+/-0.0102 vs 0.0721+/-0.0082, $p=0.043$). The majority of ruptured plaques were fibro-lipidic with a thin fibrous cup and these features did not differ between SCAD and NSTEMI. Main FD-OCT quantitative parameters like minimal lumen area or plaque length were also equivalent between the two groups.

CONCLUSIONS

Some differences in morphological features of PR are present between SCAD and NSTEMI patients, suggesting that local inflammation contributes to the unstable fate of the atherosclerotic plaque.

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The safety of next-day discharge after transfemoral TAVR with a self-expandable vs. balloon-expandable valve prosthesis

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI

AIMS

The safety of next-day discharge (NDD) after transfemoral transcatheter aortic valve replacement (TF-TAVR) with a self-expandable valve is unknown. We investigated the safety of NDD after TAVR in patients who received a self-expandable valve or balloon-expandable valve.

METHODS AND RESULTS

We retrospectively evaluated consecutive patients who underwent elective minimalist TF-TAVR between January 2017 and July 2018. We identified predictors of NDD after TAVR. Ninety-day and 1-year outcomes in patients managed with NDD after ACURATE neo or SAPIEN 3 placement were compared.

In 315 elective TAVRs, 249 patients received an ACURATE neo (n = 146) or SAPIEN 3 (n = 103) valve. There were no differences in baseline characteristics. In the ACURATE neo and SAPIEN 3 groups, NDD was achieved in 60% (87/142) and 55% (57/103) of patients, respectively (p = 0.50). Predictors of NDD included COPD (odds ratio [OR]: 0.49; 95% confidence interval [CI]: 0.25 to 0.94) and low pre-TAVR hemoglobin (OR: 0.98; 95% CI: 0.96 to 0.99), but not valve type (OR: 1.20; 95% CI: 0.71 to 1.98). After excluding non-NDD cases, there were no significant differences in 90-day post-mortality (0% vs. 0%, p = 1.00), or new pacemaker implantation (1% vs. 0%, p = 0.40). No significant difference in 1-year mortality between ACURATE neo and SAPIEN 3 groups (8% vs. 10%; log-rank, p= 0.86) was observed.

CONCLUSIONS

The safety of NDD was similar after ACURATE neo or SAPIEN 3 valve, with comparable 90-day and 1-year outcomes.

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Pacemaker dependency after TAVI: incidence, predictors and long-term outcomes

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THEME: Interventions for Valvular Disease

TOPIC(S): TAVI, Other valvular and structural interventions

AIMS

To determine the appropriateness of permanent pacemaker implantation (PPI) after TAVI through an analysis of PM dependency at follow-up, and to assess long-term outcomes of patients undergoing PPI after TAVI.

METHODS AND RESULTS

From June 2007 to February 2018, 1116 consecutive patients without prior PM underwent TAVI in our Institution. We assessed incidence and predictors of PM dependency of patients who underwent PPI within 30 days, and 6-year outcomes among patients who underwent and did not undergo PPI at 30 days.

At 30-day PPI was reported in 141 patients (11.4%).Rates of PM dependency were 35.7%, 35.8% and 33.3% at 1-, 6- and 12-month, respectively. Analysing PPI timing, implantation on day 1 was found a predictor of PM dependency at 6 months (OR 20.7 [CI 3.4-126.7]; p=0.001) and 12 months (OR 7.5 [CI 1.4-40.2]; p=0.019). An interaction between PM dependency and the presence of baseline right bundle branch block (RBBB) at 6 months (pinteraction=0.024) and 12 months (pinteraction=0.028) was reported when PPI was performed on the same day of TAVI.

At 6-year, patients who received a PM at 30 days showed a higher all-cause death rate (KM estimate 41.7% vs. 57%; plog-rank=0.034).

CONCLUSIONS

Among patients receiving PPI after TAVI, PM dependency rates were about 33-36% at 1-year. Patients with a baseline RBBB undergoing PPI at day 0 or at day 1 when severe CDs persisted for 24 hours after TAVI, irrespectively from baseline CDs, had higher chances to be PM dependent at follow-ups. Finally, PPI after TAVI was associated with increased 6-year mortality.

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An experimental study of paclitaxel embolisation during DEB angioplasty of peripheral arteries

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THEME: Peripheral Interventions
TOPIC(S): Below the knee, Iliac / Femoral / Popliteal

AIMS

Drug-Coated Balloons (DCB) improve the patency of femoro-popliteal angioplasty but remain debatable in infrapopliteal lesions since Paclitaxel (PTX) particles embolisation was suspected. The aim of this study was to compare experimentally five DCBs in terms of distal embolism of PTX.

METHODS AND RESULTS

Twenty-five New Zealand rabbits were divided into five groups according to the DCB used: LutonixÒ (Bard), In.PactÒ (Medtronic), Passeo-18 LuxÒ (Biotronik), RangerÒ (Boston Scientific) and StellarexÒ (Spectranetics) (n=5 in each group). After ligation of the right common iliac artery, a 4x40 mm DCB was inflated in the infrarenal aorta for 180 seconds. Rabbits were euthanized two hours after the DCB inflation. The infrarenal aorta, a blood sample and three left hind leg muscles [tensor fasciae latae (TFL), vastus lateralis (VL) and tibialis anterior (TA) muscles] were harvested for blind measurement of PTX concentrations and histological analysis (PTX emboli count).

In the TA muscle (the most distal one), concentrations of PTX were significantly lower for the Rangerâ (0.067 ng/mg) than for the Lutonixâ (0.342 ng/mg; p=0.008), In.Pactâ (0.370 ng/mg; p=0.012) and Passeo-18-Luxâ (0.160 ng/mg; p=0.021) DCBs. Similarly, concentrations of PTX were significantly lower for the Passeo-18-Luxâ than for the In.Pact (p=0.028). Concentrations of PTX were not significantly different between DCBs in TFL and VL muscles. Concentrations of PTX were found to be significantly higher in the plasmas, lower in the aortas and on the DCBs after use with the Lutonixâ than with the 4 others DCBs. Histological analysis revealed evidence of embolised PTX crystals in small arterioles of all muscle tissue samples without any significant difference between the DCB

CONCLUSIONS

This study suggests some differences regarding distal embolisation profiles between the five assessed DCBs. Although clinical implications remain to be demonstrated, our results may have implications while choosing a DCB, especially in a critical limb ischemia setting.

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Multicentre experience with the chimney technique for complex AAA

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THEME: Peripheral Interventions
TOPIC(S): AAA

AIMS

The chimney technique (ChEVAR) allows extending the proximal landing zone for endovascular repair of complex aortic aneurysms. Beyond studies originating from expert centers, scant data reflects real-life practice results. Our goal was to assess ChEVAR outcomes in French university hospital centers.

METHODS AND RESULTS

All centers were contacted and entered data in a computerized online database on a voluntary basis. Clinical and radiological data from all consecutive ChEVAR patients operated in 14 centers between 2008 and 2016 were collected. Factors associated with early (30-day or intrahospital) mortality and type 1 endoleak (T1E) were calculated using a multivariate analysis.

In total, 257 patients with 415 target vessels were treated. There were 109 pararenal (42.7%), 103 juxtarenal (40%), 13 type 4 thoracoabdominal (5%) aneurysms and 32 (12.4%) proximal failures of prior repairs. Preoperative diameter was 66.2±15.9 mm and 36 (14%) ChEVAR were performed in emergency. There were 26 (10.3%) unplanned intraoperative procedures, mainly related to access issues. The rate of early deaths was 11.2% (N=28). Ten patients (3.9%) presented a stroke. The rate of early proximal T1E was 12%. Survival was 84.2%, 81.1%, 73.7%, 69.5% at 6, 12, 18 and 24 months, respectively. Primary patency of chimney stents was 97.7%, 97.1%, 95.9% and 94.2% at 6, 12, 18 and 24 months, respectively. Preoperative chronic kidney disease (CKD; OR 3.7 [1.4-9.8]) and unplanned intraoperative procedures (OR 4.4, [1.6-12.2]) were identified as independent predictors for postoperative mortality. A number of chimney stents ≥2 was associated with postoperative T1E (OR 2.6 [1.1-6.0])

CONCLUSIONS

In this large national ChEVAR series, early results were concerning and worse than those reported in previous works. Future research should focus on improvements in preoperative planning and intraoperative technical aspects. Until such improvements are available, ChEVAR should be considered with caution in patients with CKD or challenging iliac accesses.

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Distal (snuffbox) vs. traditional radial approach for coronary angiography: a randomised study

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

This is the first randomized study to evaluate the efficacy and safety of distal/ snuffbox radial (DR) versus traditional radial (TR) approach during coronary angiography.

METHODS AND RESULTS

Two hundred patients scheduled to undergo transradial coronary angiography were randomized between the two approaches. Primary endpoint of the study was switching to another access site due to inability of successful target artery cannulation. Secondary endpoints were time to cannulation, total procedure duration, number of attempts, number of skin punctures and duration of manual hemostasis. Secondary safety endpoints were the rate of moderate or severe spasm, arm hematoma EASY (Early Discharge After Transradial Stenting of Coronary Arteries) class III or more and radial artery occlusion at discharge. Quality of life endpoint was the patient's preference of cannulation method at 30 days. The primary endpoint was met in 30 patients (30%) from the DR group and in 2 patients (2%) from the TR group ($p < 0.001$). The time of cannulation was longer in the DR group compared to the TR group (269 ± 251 s vs 140 ± 161 s, $p < 0.001$), but this did not affect the total procedural duration (925 ± 896 s vs 831 ± 424 s, $p = 0.494$). The number of attempts and the number of skin punctures were more in the DR group compared to the TR group (6.8 ± 6.2 vs 3.4 ± 4.5, $p < 0.001$ and 2.4 ± 1.7 vs 1.6 ± 1.2, $p < 0.001$, respectively). However, DR treated patients had faster manual hemostasis time compared to TR treated patients (568 ± 462 s vs 841 ± 574 s, $p = 0.002$). There were no differences recorded in the safety endpoints of moderate or severe spasm, EASY grade III or more radial hematomas or the incidence of radial artery occlusion after the procedure. Patients' preference to the randomized puncture sites was the same (79% vs 85%, $p = 0.358$).

CONCLUSIONS

Distal radial approach is associated with lower successful cannulation rates and shorter manual hemostasis time compared to the traditional radial approach.

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Comparing invasive haemodynamic responses to adenosine vs. physical exercise stress in patients with stable angina and coronary stenosis

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Adenosine stress is commonly used as a pharmacological alternative to exercise stress. The aim of this study was to compare invasive systemic, coronary and microcirculatory hemodynamics between adenosine versus exercise stress in patients with stable angina and coronary stenosis.

METHODS AND RESULTS

Twenty-three patients (mean age, 60.7±8.2 years) with single-vessel coronary stenosis underwent cardiac catheterization. Continuous trans-stenotic coronary pressure-flow measurements were performed during: i) maximal adenosine hyperemia, and ii) maximal physical exercise using a catheter-table-mounted supine ergometer. The order of adenosine and exercise was randomly assigned. Systemic, coronary and microcirculatory hemodynamic responses were compared between adenosine and exercise stresses.

Mean stenosis diameter and FFR were 74.4%±10.0 and 0.63±0.18, respectively. At maximal adenosine versus maximal exercise stress, mean aortic pressure (Pa, 91±16 mmHg vs 99±15 mmHg, p<0.0001), distal coronary pressure (Pd, 58±21 mmHg vs 69±24 mmHg, p<0.0001), trans-stenotic pressure ratio (Pd/Pa, 0.63±0.18 vs 0.69±0.19, p<0.0001), microvascular resistance (MR, 2.9±2.2 mmHg.cm-1.sec-1 vs 4.2±1.7 mmHg.cm-1.sec-1, p=0.001), heart rate (HR, 80±15 bpm vs 85±21 bpm, p=0.02) and rate-pressure product (RPP, 7522±2335 vs 9077±3200, p=0.0001) were all lower. Conversely, coronary flow velocity (APV, 23.7±9.5 cm/s vs 18.5±6.8 cm/s, p=0.02) was higher. Additionally, temporal changes in Pa, Pd, Pd/Pa, MR, HR, RPP and APV during adenosine versus exercise stress were all different (p<0.05 for all).

CONCLUSIONS

In patients with stable angina and coronary stenosis; invasive systemic, coronary and microcirculatory hemodynamics were markedly different between adenosine and exercise stress.

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Long-term patient prognostication by coronary flow reserve and index of microcirculatory resistance: international registry of comprehensive physiologic assessment

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Long-term prognostic implications of microvascular conditions by invasive physiologic assessment in patients subjected to fractional flow reserve (FFR) measurement and deferred revascularization have yet to be clarified. We evaluated clinical implications of coronary flow reserve (CFR) and index of microcirculatory resistance (IMR) in patients with coronary artery disease.

METHODS AND RESULTS

A total of 867 patients (1152 vessels) consigned to deferred revascularization who underwent comprehensive physiologic assessments (FFR, CFR, and IMR) were enrolled from three countries (Korea, Japan, and Spain). Patients with high FFRs (>0.80) were categorized by CFR (≤2) and IMR (≥23 U) as high CFR/low IMR (55.5%), high CFR/ high IMR (20.8%), low CFR/low IMR (13.0%), or low CFR/high IMR (10.6%). Clinical outcome was assessed by patient-oriented composite outcome (POCO), a composite of any death, myocardial infarction [MI], and revascularization. Median follow-up was 1854.5 days (Q1-Q3: 763.5-1855.0 days). Most patients presented with stable ischemic heart disease (86.7%) and intermediate epicardial coronary stenosis (mean diameter stenosis 40.9±15.6%, mean FFR, 0.88±0.07). Correlation (r=0.113, p<0.001) and categorical agreement (kappa=0.095, p<0.001) between FFR and CFR were modest, and 268 patients (30.9%) showed discordance. Patients with low CFR (≤2) showed significantly greater risk of POCO than those with high CFR (>2) in both high-FFR (14.9% vs. 8.6%, HR 1.846, 95% CI 1.083-3.146, p=0.024) and low-FFR (34.8% vs. 14.0%, HR 2.383, 95% CI 1.066-5.329, p=0.034) groups. In patients with high FFR, those with low CFR and high IMR (overt microvascular disease) displayed the greatest risk of POCO overall (p=0.015), surpassing those with high CFR and low IMR (HR 2.873, 95% CI 1.476-5.594, p=0.002) and showing significantly greater risk of cardiac death or MI (HR 5.662, 95% CI 1.984-16.154, p=0.001). Overt microvascular disease was found independently associated with occurrence of POCO in the high-FFR population (HR 2.282, 95% CI 1.176-4.429, p=0.015).

CONCLUSIONS

Among patients with deferred revascularization, those with low CFR showed significantly greater risk of POCO than those with high CFR, regardless of FFR. In patients with high FFR, those with overt microvascular disease (low CFR and high IMR) showed significantly greater risk of POCO and cardiac death or MI during 5-year follow-up, compared with the others.

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Clinical outcome of lesions with discordant results among different invasive physiologic indices: resting distal coronary to aortic pressure ratio, resting full-cycle ratio, diastolic pressure-ratio, iFR, and fractional flow

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Current guidelines recommend the use of invasive physiologic indices such as fractional flow reserve (FFR) or instantaneous wave-free ratio (iFR) to guide the treatment strategy for patients with coronary artery disease. However, about one fourth of interrogated lesions show discordant results between resting and hyperemic physiologic indices, and there are limited data regarding clinical outcomes of lesions with discordant results among different physiologic indices.

METHODS AND RESULTS

The current study evaluated 2-year clinical outcomes of lesions with discordant results among the resting and hyperemic pressure-derived physiologic indices including resting distal to aortic coronary pressure (resting Pd/Pa), iFR, resting full-cycle ratio (RFR), diastolic pressure ratio (dPR), and FFR. Two-year clinical outcomes of 1,024 vessels (435 patients) with available resting Pd/Pa, iFR, RFR, dPR, and FFR were analyzed according to 4 group classification using known cut-off values (resting Pd/Pa≤0.92, iFR≤0.89, RFR≤0.89, dPR≤0.89, and FFR≤0.80): Group 1 (concordant normal), Group 2 (high resting index and low FFR), Group 3 (low resting index and high FFR), and Group 4 (concordance abnormal). Clinical outcomes according to the discordance between iFR and other resting indices were also investigated. The primary outcome was vessel-oriented composite outcomes (VOCO, a composite of cardiac death, vessel-related myocardial infarction and vessel-related ischemia-driven revascularization) in deferred vessels. Mean angiographic diameter stenosis was 44.3 ± 17.5% and mean values of physiologic indices were 0.96 ± 0.07, 0.94 ± 0.10, 0.92 ± 0.09, 0.93 ± 0.09, and 0.87 ± 0.11 for resting Pd/Pa, iFR, RFR, dPR, and FFR, respectively. In comparison of VOCO risk among 4 groups classified according to FFR and 4 resting physiologic indices, Group 4 (concordant abnormal) consistently showed a significantly higher risk of VOCO than Group 1. Comparison of VOCO risk among 4 groups classified according to iFR and other resting physiologic indices also showed the same results, and only Group 4 showed a significantly increased risk of VOCO than the other groups. The presence of discordance, either between hyperemic and resting indices or among resting indices, was not an independent predictor for VOCO.

CONCLUSIONS

The discordant results between resting physiologic indices and FFR and among resting indices were not associated with the increased risk of VOCO.

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Mortality and myocardial infarction reduction with CABG or coronary stenting compared with optimal medical therapy in patients with stable coronary artery disease

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Stents and scaffolds

AIMS

The prognostic role of coronary revascularization in patients with stable coronary artery disease is still controversial. We investigated whether coronary revascularization with either coronary artery bypass grafting or percutaneous coronary intervention with stenting reduce the risk of all-cause death and myocardial infarction compared with optimal medical therapy in patients with stable coronary artery disease.

METHODS AND RESULTS

We performed a systematic review and network meta-analysis of contemporary randomized controlled trials comparing optimal medical therapy, coronary artery bypass grafting and different stent types. Studies were identified through Medline, Cochrane library and international meeting proceedings. Stents of interest were: bare metal stent, durable polymer-paclitaxel-eluting-stent, durable polymer-sirolimus-eluting-stent, durable polymer-Endeavor-zotarolimus-eluting-stent, durable polymer-Resolute-zotarolimus-eluting stents, durable polymer-cobaltum-chromium-everolimus-eluting-stent, durable polymer-platinum-chromium- everolimus-eluting-stent, bio-absorbable-polymer-biolimus-A9-eluting-stent, bio-absorbable-polymer-platinum-chromium-everolimus-eluting-stent, bio-absorbable-polymer-sirolimus-eluting-stent, bio-absorbable-polymer-cobaltum-chromium-sirolimus-eluting-stent, polymer-free-sirolimus-eluting-stent. Primary endpoints were all cause mortality and myocardial infarction. Secondary endpoint was subsequent revascularization. Ninety-nine trials including 76845 patients with a mean follow up of 41 months were analyzed. Compared to optimal medical therapy, coronary artery bypass grafting was associated with a lower risk of all-cause mortality (odds ratio = 0.84; 95%, confidence interval 0.71-0.97) and myocardial infarction (odds ratio = 0.84; 95%, confidence interval 0.72-0.97) on main analysis. On sensitivity analysis, after exclusion of trials enrolling only patients with left main and/or multivessel disease the survival benefit was not any longer statistically significant (odds ratio = 0.88, 95%, confidence interval 0.74-1.05). Among stent types only bio-absorbable-polymer-cobaltum-chromium-sirolimus-eluting-stent was associated with a lower risk of all-cause death (odds ratio = 0.59 95%, confidence interval 0.34-1.00) and myocardial infarction (odds ratio = 0.47, 95%, confidence interval 027-0.81). However, these findings stemmed only from indirect evidence. The risk of revascularization was reduced by any of the interventions analyzed.

CONCLUSIONS

In patients with stable coronary artery disease, coronary artery bypass grafting and percutaneous coronary intervention with latest generation bio-absorbable-polymer-cobaltum-chromium-sirolimus-eluting-stent reduce the risk of mortality and myocardial infarction compared to optimal medical therapy.

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Application of non-pharmacological method of the radial artery occlusion recanalisation after interventional procedures

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

to compare the effectiveness of non-pharmacological method of recanalization of the acute radial artery occlusion in two groups: with short-time (3-5 hours) and long-time (6-12 hours) hemostasis. Additional, to identify predictors of early and late radial artery occlusion.

METHODS AND RESULTS

Methods: The study included 1000 patients, age 62.2 ± 10.1 (81.8% male) with stable angina who underwent coronary angiography or PCI through the radial access, and were divided into two groups. In group 1 (500 patients), the compression bandage was removed in the interval from 6 to 12 hours after the procedure. In group 2 (500 patients), the bandage was removed after 3-5 hours. A reverse Barbeau's test with a pulse oximeter was used to check the patency of the radial artery. If the occlusion was detected, patients were subjected to compression of the ipsilateral ulnar artery with a dosed-compression device for 60 minutes, followed by Barbeau's repeated test. Late radial artery occlusion was observed in case of negative Barbeau's test and absence of recanalization.

Result: The frequency of the acute radial artery occlusion in group 1 and group 2 was 51 (10.2%) and 16 (3.2%), respectively (P <0.0001). The incidence of late occlusion was 51 (10.2%) and 7 (1.4%) (P <0.0001). In group 1, the compression technique of the ipsilateral ulnar artery failed to recanalize any occlusions, in group 2 the patency of the radial artery was restored in 9 patients. The frequency of bleeding was not significantly different. Diabetes mellitus (OR 0.45, 95% CI 0.25-0.83, P = 0.009) and long-term hemostasis (OR 8.78, 95% CI 4.19-21.5, P <0.0001) were predictors of the late radial occlusion. The predictors of the onset of early radial artery occlusion were also diabetes mellitus (OR 0.6, 95% CI 0.34-1.08, P = 0.0912) and smoking (OR 0.64, 95% 0.38-1.08, P = 0.0812). The interaction of both factors increases the likelihood of detecting early radial artery occlusion (OR 18.1, 95% CI 12.7-26.7, P <0.0001).

CONCLUSIONS

Compression of the ipsilateral ulnar artery is a simple and effective method of non-pharmacological recanalization of acute radial artery occlusion in patients with a short-time hemostasis. To reduce the incidence of radial artery occlusion after coronary angiography and PCI, it is necessary to reduce the time of compression less than 4 hours. Smokers and diabetic patients are at risk for radial artery occlusion after interventional procedures performed through the radial access.

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Incidence and predictors of radial artery occlusion after transradial coronary catheterisation

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THEME: Coronary Interventions

TOPIC(S): Stable CAD, Stents and scaffolds

AIMS

To assess the incidence and predictors of radial artery occlusion (RAO) after transradial coronary catheterization.

METHODS AND RESULTS

A prospective study enrolled 164 patients undergoing diagnostic coronary study and percutaneous coronary interventions (PCI) via the transradial approach (TRA) using 6-F catheters. Doppler ultrasonography assessment of the radial artery (RA) was conducted on day 1 and 6 months following the procedure. RAO was defined as the absence of antegrade flow on Doppler study. Predictors of RAO were evaluated by multivariate logistic regression analysis.

The studied group included 104 male (63.4%) and 60 female (36.6%) patients with mean age 57.7 ± 8.8 years and mean RA diameter 2.8 ± 0.5 mm . On day 1, Doppler ultrasound examination revealed RAO in 54 patients (32.9%). After 6 months, RAO was detected in 49 patients (29.9%). Interestingly, only 1 new case (0.9%) of RAO was noted and 6 patients (11.1%) had regained their RA patency indicating spontaneous recanalization of the RA. All patients with RAO remained asymptomatic.

On univariate analysis, female sex, age, number of catheters used, hemodynamically compromising events (such as ventricular arrhythmia or sudden drop in blood pressure) during the procedure, manual RA compression and RA diameter were predictors of RAO. Surprisingly, procedure duration was not a significant predictor of RAO. On multivariate analysis, female gender, age, manual compression and RA diameter emerged as independent predictors of RAO. Using TR band for hemostasis for only 2 hours was recognized as a potent independent predictor of RA patency on day 1 and 6 months after the procedure (n=2, 3.7% in the RAO group vs. n=23, 20.9% in the non-RAO group, p=0.004), compared to TR band compression for 6 hours which was associated with statistically non-significant difference (n=5, 9.3% in the RAO group vs. n=17, 15.5% in the non-RAO group, p=0.274).

CONCLUSIONS

RAO, although clinically a silent issue, has been the main concern following TRA and its long term impact requires further investigation. Female gender, age, manual RA compression and RA diameter were found to be the strongest independent predictors of RAO. Patent hemostasis using TR band for 2 hours is highly effective in reducing the incidence of RAO.

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A new technique to overcome difficulties of radial approach

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

The radial artery is smaller and thinner than the femoral artery and some patients have a radial artery that is smaller than a 6F introducer, which sometimes makes angioplasty difficult.

Purpose: This study reports our initial experience with the 5Fstraight(STR) flush catheter, which can be used as a “child” type rapid exchange catheter inside the 6Fguiding catheter, creating a distal tip transition, facilitating angioplasty in transradial coronary interventions when the radial artery is small or tortuous that impedes advancement of guiding catheter after successful angiography with 5Fcathete

METHODS AND RESULTS

Methods: We analysed, retrospectively, 1510 STEMI patients (pts) admitted in our catheterization laboratory, from August of 2010 to October 2017. Of these patients, 95 (6.3%) pts with problems in advancing a 6F guiding catheter, were submitted to this technique and a direct crossover to a femoral approach was performed in 36 pts (2.4%). This technique consists in the use of longer 5F STR flush catheter in order to overcome the larger distal tip of the 6F guiding catheter through the radial access, employing a 5-in-6 F technique.

Results: In 89 of 95 patients (93.7%), this new technique was successful, with a mean reperfusion time since arrival to the catheterization laboratory of 24.5 ± 9.9 minutes. Of the pts submitted to this technique the majority were female 51 (57.3%) and the mean age was 67 ± 14.3 years. Angioplasties were performed in the left main (2; 2.3%), left anterior descending (36; 40.4%), left circumflex artery (8; 9.0%), right coronary artery (40; 44.9%), right posterior descending artery (1; 1.1%) and obtuse marginal branch (2; 2.3%). No complications in arterial access were seen. Throughout these years of study, the need for crossover to femoral approach has decreased with the learning of this technique. The time until reperfusion since catheterization laboratory arrival was 29.3 ± 9.5 minutes when there was a crossover, being statistically higher than with the radial procedure with the STR technique ($p < 0.017$).

CONCLUSIONS

This new technique may be a simple and useful approach to perform primary PCI through transradial access in patients with small diameter radial arteries, allowing a reduction of crossover to femoral access, which translates into a lower risk of vascular complications and shorter reperfusion time, that may influence the prognosis of STEMI patients.

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Reappraisal of intra-aortic balloon pump in cardiogenic shock: gender difference and determining factors for survival

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions

AIMS

Intra-aortic balloon pump (IABP) is the most widely used form of mechanical circulatory support in cardiogenic shock. Although the determining factors for IABP survival have been documented in current guidelines, it is unknown whether IABP delivery disparities exist based on victim gender. We investigated IABP use by gender in a single medical center, hypothesizing that females would be less likely than males to receive IABP for cardiogenic shock, with an associated difference in survival to hospital discharge.

METHODS AND RESULTS

Methods

This retrospective study reviewed a total of 248 patients (193 male, age 64.1 ± 14.1) using IABP between June 1, 2008, and January 31, 2015, at National Taiwan University Hospital. The underlying disease of cardiogenic shock, the first laboratory data at the emergency department or intensive care unit (ICU), and the complications were investigated. The predictors of survival were assessed using a multivariable analysis.

Results

The cause for cardiogenic shock with IABP use included coronary artery disease(CAD) (212, 85%), dilated cardiomyopathy (DCM) (6, 2.8%), and other causes (7 patients with acute myocarditis, 7 with congestive heart failure, 3 with severe mitral reguirgitation, 1 with severe aortic stenosis, 9 with mixed septic shock, 1 with mixed anaphylactic shock, 1 with ventricular arrhythmia, and 1 with complete atrioventricular block).

The overall survival was 81.0% and the major complication rate was 5.6% mainly due to infection but not bleeding or limb ischemia. Multivariate analyses with logistic regression determined that the independent predictors were old age (hazard ratio 1.04, 95% CI: 1.01-1.07) and higher lactic acid levels (hazard ratio 1.08, 95% CI: 1.02-1.16). The Kaplan-Meier curve with log-rank test showed that patients with high lactic acid levels and older age had the highest mortality. The ROC curves showed good prediction with AUC 0.864 (95% CI, 0.80-0.92) combining with age, causes, prior CAD, preexisting DM, revascularization, ventilator use, left ventricular ejection fraction, hemoglobin, albumin, BUN, and APACHE score.

Women had significantly older age, higher incidence of mechanical complications, and higher NT-proBNP level, more dilated left ventricular end-diastolic diameter (LVEDD), and higher homocystein level. There was no significant difference but time-dependent varying hazard ratio between genders. However, the hazard ratio before 8 days of ICU stay was 0.524 (p=0.077) and after 8 days was 6.629 (p=0.074), with significant interaction (p=0.023).

CONCLUSIONS

Intra-aortic balloon pumps are widely applied as hemodynamic support in various types of cardiogenic shock. The overall survival rate is high and complications could be lower if properly managed. There are gender disparities in IABP users. Women tend to have older age, more advanced heart failure and mechanical complications in clinical presentation. Women have higher mortality than men in the first 8 days of IABP use. However, the overall 30-day survival has no significant gender difference. Older age and high lactic acid levels

are the strongest predictors of mortality associated with the use of IABP in both genders.

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Ticagrelor vs. clopidogrel in long-term outcomes of Taiwanese diabetic patients with ACS undergoing successful revascularisation

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI

AIMS

Although previous clinical trials demonstrated that, compared with clopidogrel, ticagrelor can reduce cardiovascular events and mortality in patients with acute coronary syndrome (ACS), the long term real world evidence of its clinical effects on East Asian diabetic patients has not been thoroughly investigated. In this study, we compared long term outcomes among Asian diabetic patients with ACS undergoing successful revascularization and discharged with prescriptions for ticagrelor vs clopidogrel.

METHODS AND RESULTS

Between November 2013 and June 2015, 1534 patients were recruited into the Acute Coronary Syndrome–Diabetes Mellitus Registry of the Taiwan Society of Cardiology (TSOC ACS-DM registry). After matching patients, we examined a total of 690 patients undergoing successful revascularization and discharged with prescriptions for ticagrelor (n=345) or clopidogrel (n=345). The primary endpoint was all-cause mortality. The safety end points were major/minor bleeding and blood transfusion during hospitalization according to the Thrombolysis in Myocardial Infarction (TIMI) Score. The all cause of death with ticagrelor vs. clopidogrel were 2.3 vs. 7.5% (adjusted Hazard Ratio 0.39, 95% confidence interval =0.17-0.87; p=0.0209) at 24 months. The TIMI major bleeding that required blood transfusion were 0.6 vs 1.7% (p=0.286)

CONCLUSIONS

For diabetic patients with ACS, ticagrelor was associated with a greater survival benefit than clopidogrel without an increase in the major bleeding during 24 months after successful percutaneous coronary intervention. This study of long-term survival in real-world circumstances provides valuable complementary data that externally validate PLATO findings, specifically in an Asian diabetic population.