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Prevalence of tricuspid regurgitation and its impact on mid-term outcomes: insights from a tertiary referral centre

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

AIMS

To evaluate the prevalence and significance of Tricuspid Regurgitation (TR) from a cohort of patients at a tertiary center and the proportion of patients who meet criteria for intervention.

METHODS AND RESULTS

A retrospective analysis was performed on 6,309 consecutive patients undergoing echocardiography between October 2014 and September 2015 in a single centre in Milan, Italy. The study endpoints included cardiovascular (CV) mortality, major adverse cardiac and cerebrovascular events (MACCE) and net adverse clinical events (NACE, composite of MACCE and re-hospitalization for CV-related events).

A total of 2,336 (37%) patients were found to have TR of any severity, 272 (4.3%) had severe TR, 415 (6.6%) moderate TR, and 1,649 (26.1%) mild TR. Out of 687 patients with at least moderate TR, 147 (21.4%) met criteria for tricuspid valve intervention according to European Society of Cardiology guidelines. From the 272 patients with severe TR, 101 (37.1%) were non-surgical candidates, thus potentially eligible for percutaneous management.

The mean follow-up time of patients with severe TR was 289±142 days. Forty (16.4%) patients suffered CV death, while 53 (21.7%) and 141 (57.8%) developed MACCE and NACE, respectively. In addition, there were 92 (37.7%) patients who were rehospitalized for CV-related events. Patients alive at follow-up were more likely to be in New York Heart Association functional class III-IV (p=0.022) and be on higher doses of loop diuretic (p=0.022).

Multivariable analysis revealed that Blood Urea Nitrogen (BUN, p=0.031) and abnormal liver function blood tests (p=0.010) were independent predictors of mid-term CV mortality. Furthermore, BUN and Tricuspid Annular Plane Systolic Excursion were found to be independent predictors of mid-term NACE.

CONCLUSIONS

TR was found to be a prevalent condition among patients undergoing echocardiography at a third-level referral centre. Severe TR was not uncommon and associated with high mid-term morbidity and mortality. A significant proportion of non-surgical candidates with severe TR may be eligible for percutaneous management.

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10-year follow-up of everolimus-eluting stent in 7,655 consecutive patients: single-centre registry results

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

AIMS

Aim of the study: To assess the performance and clinical outcomes of the everolimus-eluting coronary stent on long-term follow-up in a real-world population.

METHODS AND RESULTS

Methods: A total of 7655 consecutive patients treated with Xience (Abbott Vascular, Santa Clara, CA) stents only were prospectively enrolled in a single-center registry over a decade period (November 2006-December 2015). Patients were clinically evaluated at 1 year and then yearly.

Results: The population (mean age 66±9.8 years) was composed of 6246 (81%) men. Multiple coronary risk factors were present in 56% of the cohort (diabetes 13%, hypertension 21%, dyslipidemia 58%, smoking 10%, family history 20%). Main indication for stenting was elective (angina:70%, positive stress test:23%) for 1- (43%) or 2/3- (57%) vessel disease. Multiple stents (stent/patient ratio: 2.2±0.8) in >1vessel were used in 37.4%, while mean stent segment length was 41.8±29.6 mm. At 1 year, 80% of patients were on dual antiplatelet therapy (DAPT), while 3% only were on DAPT at two years. DAPT duration was reduced to 6 months only after September 2014. A low (5%) 1-year cumulative major adverse cardiaca events (death, MI, angina, Target vessel /lesion revascularization) rate was observed. Overall, stent thrombosis occurred in 17 (0.2%) patients with a prevalence of early (8 patients) over late (3 patients) events. Very late (>2 years) stent thrombosis occurred in 6 (0.08%) patients. Clinically driven target lesion/vessel revascularization were observed in 1.2% of patients, while in 289 (3.8%) a staged procedure or a non-target vessel/lesion PCI was performed during 1-year follow-up. Long-term follow-up, available in 6980 (91%) patients, showed a cumulative major adverse cardiac events rate of 6.2%. Clinically-driven PCI was performed in 2.3% of 3978 (57%) patients with <5-year follow-up and in 7% of 3002 (43%) patients with ≥5-year follow-up.

CONCLUSIONS

These results demonstrate continued safety and effectiveness of the everolimus-eluting Xience stent on long-term follow-up in highly complex, real-world patients.

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Aortic annulus compliance assessment using annular deformation dynamics in TAVI treated patients

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

AIMS

Suitable pressure of the device on the aortic-annulus is critical for sufficient sealing of the neo-valve in TAVI. As it depends on device oversizing and aortic annular compliance (AAC), we thought to offer a novel modus-operandi to measure ACC.

METHODS AND RESULTS

AAC was determined by measuring the absolute change in aortic-annular-area (with ECG-gated-cardiac-CTA) with relation to the corresponding (equivalent % RR-interval) left ventricular and aortic root pressures, measured systematically in the catheterization laboratory. We then evaluated AAC characteristics, associating factors and relation with predefined TAVI outcomes. Forty eight patients with severe aortic stenosis (age: 81 ± 6.4 years, 44% males, STS-PROM: 3.4 ± 1.3 %) were included in the analysis. During the cardiac cycle, the mean increase in LV pressure was 143 ± 42 mmHg, and the concordant increase in aortic-annular area was 50.8 ± 29 mm^2 (13 ± 7.5 %): from 385 ± 81 mm^2 (diastole) to 436 ± 92 mm^2 (systole). Accordingly, AAC [mm^2/mmHg] was calculated to be 12.6 (SD, 8.3) mean; 11.3 [IQR, 6.2-15.9] median; 1.2 to 37.7 range. AAC was associated with age (p=0.001) but independent from other patients' characteristics including gender. ACC was not significantly associated with post procedural para-valvular leak and/or new electrical conduction abnormality post TAVI.

CONCLUSIONS

AAC was found to be associated with Ì´7 mmHg pressure increment for each 1-percent device oversizing, to widely vary between patients, and to decrease with age. AAC measurement method reproducibility, its potential association with outcomes and future clinical utilization needs further investigation.

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Everolimus-eluting stent for left main disease: a long-term, single-centre analysis

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

AIMS

Aim of the study: To assess the performance and clinical outcomes of the Everolimus-Eluting XIENCE® stent (Abbott Vascular, Santa Clara, CA) on long-term FU in unprotected left main coronary artery disease patients.

METHODS AND RESULTS

Methods: A total of 526 consecutive patients treated with Xience stents only were prospectively enrolled in a single-center registry over a decade period (November 2006-December 2015). Patients were clinically evaluated at 1 year and then yearly.
Results: The population (mean age 66±10 years) was composed of 419 (78%) men. Multiple coronary risk factors were present in 45% of the cohort (diabetes 10%, hypertension 31%, dyslipidemia 33%, active smoking 17%, family history 16%). Main indication for stenting was elective (angina:68%, positive stress test:21%) for 1- (21%) or 2/3- (78%) vessel disease. Multiple stents (stent/patient ratio: 1.5±0.9) in >1 vessel were used in 62%, while mean stent segment length was 54±38 mm. At 1 year, 85% of patients were on dual antiplatelet therapy (DAPT), while 5% only were on DAPT at two years.
A low (0.8%) 1-year cumulative MACE (death, MI, angina, TVR/TLR) rate was observed. Long-term (mean 5 years) follow-up, available in 490 (93%) patients, showed a cumulative MACE rate of 11.2%. Overall, ST occurred very late (> 2 years) in 2 (0.4%) patients, with ostial left circumflex involvement. Clinically-driven TLR/TVR was observed in 1.2% of patients, while in 16 (3.2%) a staged procedure or a non-TVR/TLR PCI was performed during the long-term FU.

CONCLUSIONS

In conclusion, for the treatment of patients with unprotected left main coronary artery disease, PCI with the everolimus-eluting Xience stent demonstrated to be safe and effective with respect to the composite of death, myocardial infarction, revascularization at 5 years.

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Transcatheter treatment of degenerated bioprosthetic valves: patients characteristics, procedural details and outcomes - A multicentre Israeli registry

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

AIMS

Transcatheter Valve-in-Valve implantation (ViV) is a less invasive approach to treat patients with bioprosthetic valve deterioration at high risk for redo-surgery. This is the largest registry reporting on ViV experience in Israel.

METHODS AND RESULTS

A datasheet was circulated to multiple Israeli centers involved in ViV. Data from participating centers were collected, analyzed and reported in-line with VARC-2 recommendations. Results: Between March-2010 and Nov-2016, along with a linear growth in procedural volume, a total of 132 patients underwent ViV in the 5 partaking centers: age 77 [SD, 13] years; 38% men; median Society-of-Thoracic-Surgeons (STS) score 6.1 [IQR, 4.1; 10.4] %. Throughout the years there was a shift to treat patients at lower STS-score (9.7% to 7.1%, p<0.01). Follow-up continued up-to 6.5 years [median 2.5 (IQR, 1.1; 3.8) years]. Procedures were performed in the aortic (70%) [mean age 77±12 years, STS-score: 7.8±5.4%], mitral (23%) [mean age 76±12 years, STS-score: 9.5±6.5%], tricuspid (5%) [mean age 69±5.9 years, STS-score: 3.8±1.2%], and combined (2%) positions. Aortic-VIV were performed via the trans-femoral, trans-apical and trans-axillary routes in 92.5%, 2.5% and 5%; respectively, and using self-expandable (94%) or balloon-expandable (6%) devices. Mitral-VIV were performed via the trans-apical route (97.5%) and using balloon-expandable (SXT, 93.5%; S3, 6.5%) devices. The composite end-point of device success rate was 97%, and 30-days stroke rate was 0.9%. Baseline NYHA functional-class was III/IV in most (87%) patients, enhanced to I/II in the majority (91%, at 1-month), and kept well stable in long-term follow-up. Survival rates for all-VIV patients was: 94.5% (30-days), 92%% (1-year), and 75% (3-years).

CONCLUSIONS

The ViV intervention in 5 Israeli TAVI centers is being used to treat a wide range of degenerated surgical valves in different positions. It is safe, effective and expanding. The implications on surgical vs. ViV strategy as optimal management of patients at lower-risk needs further investigation.

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First-in-human evaluation of a novel poly-L-lactide based sirolimus-eluting BRS for the treatment of de novo native coronary artery lesions: MERES-1 trial

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

AIMS

The aim was to assessed safety and performance of a novel Poly-L-Lactide based Sirolimus-eluting BioResorbable Vascular Scaffold (BRS) MeRes100 in patients with *de novo* native coronary artery lesions.

METHODS AND RESULTS

The MeRes-1 is a prospective, multicentre, first-in-human trial of MeRes100 Sirolimus-eluting BRS (Meril Life Sciences, Gujarat, India). A total of 108 patients were enrolled at 13 Indian centres. The primary endpoint was major adverse cardiac events (MACE) composite of cardiac death, myocardial infarction, and ischemia driven-target vessel revascularization (TVR). The secondary endpoints were scaffold thrombosis (ST) and device related serious adverse events at subsequent follow-ups. Clinical follow-ups were scheduled at 1, 6, 12, 24 and 36 months. A total of 108 patients having mean age 50.13 ± 8.82years, 71.3% were males, 41.7% had hypertension and 27.8% had diabetes mellitus. Overall device success per lesion was 100%. No incidence of MACE, ischemia driven-TVR, or ST was noted at 1 year follow-up in patients.

CONCLUSIONS

The preliminary data reflects device feasibility in treating *de novo* native coronary artery lesions. The interim results of MeRes100 BRS are encouraging. Long-term data to assess scaffold safety and efficacy are awaited.

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Two-year outcomes after MitraClip treatment of functional mitral regurgitation in ischaemic and non-ischaemic dilated cardiomyopathy

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

AIMS

Limited data are available regarding MitraClip outcomes comparing inoperable or high-risk patients with ischemic and non-ischemic severe functional mitral regurgitation (FMR) due to dilated cardiomyopathy (DCM).

METHODS AND RESULTS

From 2008-2015, 171 patients received MitraClip for FMR at two institutions. Patients were stratified according to MR aetiology in non-ischemic FMR (n=64) and ischemic FMR (n=107). Preoperative risk factors, operative variables and outcomes up to 2-year were evaluated.

As expected, patients with ischemic FMR had significantly more risk factors and comorbidities, were more male (86% vs. 67%) and with higher Logistic EuroSCORE (21±17 vs. 14±17). Overall procedural success rate was 90% and in-hospital mortality was 3% without significant differences between aetiology. Despite a trend towards a worsening survival in patients with ischemic aetiology, two-year overall (32% vs. 18%, p=0.083) and cardiac (24% vs. 13%, p=0.109) mortality rates were comparable. No differences were detected in terms of re-hospitalization rates (31%), needed for LVAD implantation (4%) and mitral valve surgery (1%). Both groups had significant improvement in MR grade and 6-minute walking test; non-ischemic FMR patients demonstrated a greater reduction in NYHA class and left ventricle volumes. Logistic EuroSCORE ≥13 and LVEDV ≥210 were the strongest independent predictors of 2-year mortality.

CONCLUSIONS

The ischemic or non-ischemic aetiology of DCM did not significantly affect in-hospital and 2-year outcomes after MitraClip in patients with FMR, despite a trend towards a worsening survival is present in those with ischemic DCM.

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Treatment of coronary in-stent restenosis

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

AIMS

The aim of this prospective randomized non-inferiority TIS study was to compare the efficacy of iopromide-coated paclitaxel-eluting balloon catheters (PEB) and everolimus-eluting stents (EES) in the treatment of bare metal stent restenosis.

METHODS AND RESULTS

A total of 136 patients were enrolled in the study. Each treatment group included 68 patients with 74 in-stent restenotic lesions. The primary end-point was in-segment late lumen loss (LLL) at 12 months. Secondary end-points were the incidence of binary in-stent restenosis and 12-month major adverse cardiac events (MACE).

The two-sided 95% CI of LLL difference between treatments (0.149–0.558) was greater than non-inferiority margin (0.12) which demonstrates both non-inferiority and superiority of PEB treatment. Furthermore, the PEB group had significantly less 12-month LLL than the EES group (0.02 vs. 0.19 mm, p=0.0004).

The incidence of repeated binary restenosis (8.7% vs. 19.12%, p=0.078) and 12-month MACE (10.29% vs. 19.12%, p=0.213) were not significant.

12-month LLL was significantly less in the PEB group also in subgroups with in-stent restenosis Ë'10 mm (0.05 vs. 0.26 mm, p=0.0002)and artery diameter <3 mm(0.05 vs. 0.16 mm, p=0.003)compared to the EES groups, but not in the subgroup of diabetic patients(p=0.254). In the EES group, repetitive binary restenosis had a significantly greater chance of occurring (odds ratio = 3.132, 95% confidence interval 1.058-9.269, p=0.039), even when adjusting for other risk factors.

CONCLUSIONS

Treatment of bare metal stent restenosis using PEB led to significantly less 12-month LLL than the implantation of second generation EES.

(ClinicalTrials.gov;https://clinicaltrials.gov; NCT01735825).

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Mortality in patients with cardiogenic shock due to left ventricular failure treated with a percutaneous microaxial pump

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

AIMS

To assess the effect of percutaneous LV unloading by ImpellaCP in standard clinical practice in cardiogenic shock

METHODS AND RESULTS

We investigated all patients (mean age 58 years) with cardiogenic shock presenting at our institution, who received an ImpellaCP microaxial pump for isolated LV support (n=62) between January 2013 and December 2015 (n=62). 61% had been resuscitated before Impella insertion. Overall survival was 48% at hospital discharge. 30-day mortality incrased after out-of-hospital cardiac arrest, with concomitant right ventricular failure, and when Impella implantation was performed after PCI in case of ischemic shock.

Patients in the local registry, who fitted the inclusion/exclusion criteria of the recent SHOCK-II trial had a markedly lower mortality (24% at 30 days) compared to patients from the published trial.

CONCLUSIONS

Active hemodynamic support using ImpellaCP in singular LV failure results in lower than previously published mortality rates with using either no hemodynamic support or only the intra-aortic balloon pump.

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"Off-hours" vs. "on-hours" presentation in STEMI in Singapore and its impact on door-to-balloon time and clinical outcome

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

We evaluated the clinical characteristics, door-to-balloon (D2B) time and clinical outcomes of STEMI patients who underwent primary PCI during "off-hours" and "on-hours'' in our single center registry

METHODS AND RESULTS

From January 2009 to December 2014, 1661 patients (86% male, mean age of 58 $\pm$ 12 years) presented to our hospital for STEMI and underwent Primary PCI. 28% of patients had a known history of diabetes mellitus. Approximately 50% of patients underwent Primary PCI through radial artery access and received DES implantation.

We divided the STEMI patients into 2 groups according to time of presentation to emergency department. "Off-hour PCI" was defined by intervention performed during weekdays from 6 PM-8AM, weekends, and public holidays.Data were collected retrospectively on baseline clinical characteristics, symptom onset to reperfusion time, D2B time, angiographic findings, therapeutic modality and hospital course.

The majority (62%) of STEMI patients in our registry presented during "off-hours".

For the "off-hours" group, there was a higher proportion of male patients (88% vs 83%, p = 0.003) and they tend to be self-presenters (42% vs 36%, p = 0.002). They also have a higher prevalence of hypertension, prior MI and prior PCI compared to "on-hours" group ($p < 0.05$ for all comparisons).

Patients in the "off-hours" group had a longer D2B time (mean 55 $\pm$ 42 mins ; median 56 mins) vs the "on-hours" group (mean 47 $\pm$ 41 ; median 45 mins) (p =0.0002). The proportion of patients achieving D2B time < 90 mins was also significantly lower in the "off-hours" group (80% vs 86%, p =0.005).

However, patients in the "off-hours" group had a shorter symptom to reperfusion time (mean 182 $\pm$ 198 vs 215 $\pm$ 248 mins, p = 0.005).

There was no difference in the types of STEMI, proportion of multi-vessel disease and cardiogenic shock for both groups.

The overall in-hospital mortality was 5.8%. However there was no difference in the rate of in-hospital mortality for both groups ("off hours" : 6.6% vs "on-hours" : 4.6%, p =0.11).

CONCLUSIONS

Our registry showed that patients presenting with STEMI and receiving Primary PCI "off-hours" did not show worse outcomes compared with those arriving during regular daytime working hours. Although the former group had a significantly longer D2B time, they had a significantly shorter symptom-onset to reperfusion time which may have impacted on the observed clinical outcomes.

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TAVR alters expression levels of circulating myocardial microRNAs

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

AIMS

We aimed to explore whether circulating microRNAs (miRs) are differently regulated in response to TAVR-induced acute afterload reduction in patients with impaired and preserved left ventricular ejection fraction (LVEF).

METHODS AND RESULTS

322 patients with severe symptomatic aortic stenosis receiving TAVR were screened for inclusion in the study. To assess circulating miR kinetics in dependence of preinterventional LVEF and LVEF development, 56 patients with impaired LVEF at baseline (39%±12%) and LVEF recovery of ≥15% after three months were compared to 61 patients with preserved LVEF (56%±12%) without LVEF improvement. Despite significant differences in LV function, patient risk scores such as EuroSCORE and STS score were similar in both groups.

Nine circulating miRs representing known biomarkers and effectors of LV function (miR-21, miR-29a, miR-126, miR-133a, miR-199, miR-208a, miR-208b, miR-423, miR-622) were analyzed before, one day, and seven days after TAVR.

Among those, miR-21, miR-29a, miR-423 and miR-622 were significantly regulated after TAVR depending on preinterventional LVEF with increased levels of miR-21 and miR-423 in patients with LVEF improvement. Within the one-year follow-up, patients with preprocedural impaired LVEF and postprocedural LVEF recovery displayed a reduced rehospitalisation rate.

CONCLUSIONS

Circulating miRs are significantly regulated after TAVR depending on preinterventional LVEF. LVEF improvement after TAVR is associated with a reduced rehospitalisation rate and increased postprocedural levels of miR-21 and miR-423.

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CTO coronary arteries are well served by arterial grafts: analysis of 1,333 consecutive bypass operations with 98% arterial conduits

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

AIMS

Chronic total occlusion (CTO) of coronary arteries is a last frontier yet to be conquered by percutaneous coronary intervention (PCI). This study aimed to establish current day surgical treatment of patients with CTOs using mainly arterial grafts.

METHODS AND RESULTS

The study population consisted of 1333 consecutive coronary artery bypass graft (CABG) patients (2003-2016) with 3832 arterial (98%) and 78 venous (2%) grafts (2.93 grafts/patient); 76% patients were given bilateral internal mammary artery grafts (excluding patients with single vessel disease). Two study groups (those with or without CTOs) were compared to determine the relationship of CTO patients, completeness of revascularization and operative survival. CTOs were present in 47% (626 patients) compared with 53% (707 patients) without; 88% of CTOs were able to be bypassed including 100% of occluded left anterior descending arteries. CTO patients had more incomplete revascularization (21% vs. 6%; p<0.001), had worse ventricular function (CTOs: 11% EF<30%; 37% EF30-50%, 52% EF>50%, non-CTOs-5% EF<30%; 22%EF30-50%; 73% EF>50%: p < 0.001) and underwent more re-do surgery (5% vs. 1%; p<0.001). Operative mortality for all 1333 patients was 3.7% (95%CI 2.7, 4.8); for elective patients was 0.55% (3/546 patients). In multivariable logistic regression controlling for urgency and Euroscore, in the non-CTO group incomplete revascularization did not affect operative mortality (3.4% (95%CI -1.1%,8.0%) in incomplete vs. 2.8% (95%CI 1.6,4.0) in the complete revascularization group; p=0.767). However in the CTO group, incomplete revascularization resulted in a trend to increased operative mortality (6.7 (95%CI 3.6,9.7) vs. 3.5% (95%CI 1.8,5.2) respectively p<0.062).

CONCLUSIONS

CTOs are common in the CABG population (47%) and are able to be grafted 88% of the time. The combination of incomplete revascularization and CTOs shows a trend to increased operative mortality but not in the combination of incomplete revascularization and non-CTOs. Because the CTO group also had significantly more impairment of left ventricular ejection, the trend to decreased operative survival may not necessarily be linked to completeness of revascularization in this group but to impairment of left ventricular function. Arterial grafts are an acceptable treatment for CTOs and should be a benchmark against which PCI for CTO should be measured.

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The effect of topical medications on the radial artery spasm in patients undergoing transradial coronary procedures: a systematic review

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THEME: Coronary Interventions
TOPIC(S): NSTEMI

AIMS

The objective of this meta-analysis was to identify the effect of topical medications on radial artery spasm in patients undergoing transradial coronary artery procedures.

METHODS AND RESULTS

A search of the literature aimed to find both published and unpublished radomised and quasi-randomised controlled trials. Trials were included in the review if they included participants over the age of 18 years undergoing non-emergant transradial percutaneous coronary artery procedures and used topical medications prior to commencing transradial approaches to reduce radial artery spasm. Methodological quality of the studies were assessed independantly by two reviewers using a standardised validated instrument. Meta-analysis was conducted using RevMan version 5.2.Only three studies involving 697 participants met the inclusion criteria. there was a statisically significant reduction in the incidence of radial artery spasm in patients treated with Eutectic Mixture of Local Anesthetics (EMLA) compared to topical lidocaine (OR 0.26; 95%CI 0.07, 0.96) However there were no significant differences in radial artery spasm in studies comparing EMLA and placebo or lidocaine and placebo.

CONCLUSIONS

There is currently insuffient evidence to support the use of topical medications to reduce the occurence of radial artery spasm. Further large scale trials are urgently needed.

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Effects of methods used to achieve hemostasis following percutaneous coronary procedures: a systematic review

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

AIMS

To synthesise the best available research evidence related to the effects of methods used to acheive hemostasis on radial artery occlusion rates after percutaneous coronary procedures.

METHODS AND RESULTS

This review considered randomised and quasi-randomised controlled trials that included adult patients (18 years and over) who had a percutaneous coronary procedure via the radial artery. The interventions of interest were the use of various methods to acheive hemostasis and prevent radial artery occlusion. An extensive search was undertaken for the following databases CINAHL, EMBASE, PubMed and the Cochrane Central Register of Controlled trials (CENTRAL). The search for unpublished trials included: Dissertation Abstracts International, World Cat, Clinicaltrials.gov, ProQuest Dissertations & Theses and MedNar. Methodological quality was assessed independantly by two reviewers using the Joanna Briggs Institute Meta-Ananlysis of Statistics Assessment and Review Instrument (JBI-MAStARI) checklist. Quantitative data were extracted from papers included in the review by one reviewer using the standardized data extraction tool from JBI-MAStARI. Data was analysed using review manager.A total of seven trials were included in the review. One trial demonstrated a significant reduction in radial artery occlusion rates in patients who had a mean arterial pressure guided TR band (OR 2.20; 95% CI 0.02, 0.37). A statistically significant reduction the incidence of radial artery occlusion was observed among patients who recieved a biopolymer dressing compared to those who received the TR band (OR 2.20; 95% CI1.20, 4.02). No statistically significant difference in the the incidence of radial artery occlusion was reported between those who recieved the TR band and those who recieved either the elastic bandage (p=0.08) or T band (p=0.76).

CONCLUSIONS

There is limited evidence to support the use of any single hemostatic method to prevent radial artery occlusion rates after percutaneous coronary procedures. Although used extensively there is evidence of no effect og the pneumatic compression method using the TR band on the incidence of radial artery occlusion at discharge or follow up, the time taken to obtain hemostatis and the incidence of hematoma.

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DEB-only angioplasty in CTO, a UK single-centre experience

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

AIMS

CTOs are complex lesions encountered in 15-30% of patients referred for coronary angiography. We report medium term outcomes of Drug Coated Balloon (DCB) - only PCI for CTOs in a UK high volume centre and this is the largest cohort reported so far.

METHODS AND RESULTS

41 consecutive patients with 44 chronic total occlusions treated with DCB angioplasty from 14/12/2011 to 01/06/2016 were identified retrospectively from the hospital data base. No exclusion criteria were set. Patient, lesion and procedural characteristics were obtained from the hospital data base and reviewing angiograms. Clinical outcomes were reported using clinic follow up records and angiographic data. Up-to-date mortality data were obtained from the Demographics Batch Service Bureau of the National Health and Social Care Information Centre.Mean (SD) age of the cohort was 62.3 (9.5). 85.4% were males and 56.1% of patients had a history of previous PCI. 36.6% have had an MI in the past and 29.3% of patients were known to have diabetes mellitus. 29.5% had a Japanese Chronic Total Occlusion (JCTO) score of >= 2 and 45.5% had a score of 1. 81.8% were de novo lesions and 43.2% had multi-vessel disease. 47.7% of lesions were in LAD and 38.6% in the RCA. 22.7% involved a bifurcation. Dual access was gained for 52.3% of procedures and anterograde wire escalation technique was used in all but one procedure. Mean (SD) DCB diameter was 2.8 (0.5) mm and mean (SD) length of treated segment was 41.9 (25.6)mm. In 47.7% of lesions, a DCB with diameter of 3mm or more was used. There were 15 (34.1%) coronary dissections and 2 (4.5%) needed bail-out stenting. 2 (4.5%) lesion had DCB and stents used electively. During a mean (SD) follow up period of 630.1 (347.1) days there were no cardiac deaths. One patient died of traumatic intra cranial and chest injuries 456 days from the index procedure. After a mean (SD) clinic follow up period of 313.3 (304.4) days there were 3 (6.8%) target lesion revascularisations (TLR) and 1 (2.3%) staged target vessel revascularisation (TVR). One patient (2.4%) had a non- target vessel related non ST elevation myocardial infarction (NSTEMI). Major adverse cardiac event (MACE) rate was 9.8%. 17(38.6%) lesions have had repeat angiography and no re occlusions seen.

CONCLUSIONS

DCB-only angioplasty to CTOs appear to be a safe and effective treatment method with acceptable clinical outcomes in the medium term follow up based on this single center experience which is the largest cohort reported so far and the first in the UK.

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Hybrid coronary revascularisation vs. PCI in patients with multivessel coronary disease

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

AIMS

To compare the results of PCI and hybrid coronary revascularization amongst patients with multivessel coronary artery disease.

METHODS AND RESULTS

Patients with multivessel coronary artery disease confirmed by coronary angiography were included in our prospective, single-center, randomized study. Exclusion criteria are chronical total occlusion, left main coronary artery stenosis. We performed analysis of 1-year follow-up of patients with stable coronary artery disease who underwent either PCI or hybrid coronary revascularization. Hybrid coronary revascularization (two-staged intervention) was performed as follows: in the first stage – LIMA grafting to the LAD artery via left anterior mini thoracotomy (MIDCAB) was performed; in the second stage – coronary artery stenting was performed within 1–3 days of admission. We used identical second-generation DESs in both groups, which proved to be effective in multicenter trials (Xience).

Study endpoints included success of the procedure, death, myocardial infarction, stroke, repeat revascularization, and bleeding.There was also combined endpoint (MACCE) which included death, myocardial infarction, stroke, and repeated revascularization.

From January 2014 to december 2015, study sample included 103 patients, 53 patients underwent PCI and other 50 patients underwent hybrid coronary revascularization. There were no significant differences in major clinical and demographic characteristics between the groups. Both groups did not differ significantly regarding EuroScore II scale (PCI group 1.4±1.1%, hybrid revascularization group1.24 ±0.8%, Ñ'=0.15) and SYNTAX score (PCI group 14.3±5, hybrid revascularization group14.4 ±5.5, Ñ'=0.46). There were no significant differences in the success of the procedure, the complication rate, and 1-year outcomes among the groups (MACCE: hybrid coronary revascularization – 16%, PCI – 24.5%, p=0.19).

CONCLUSIONS

There were no significant differences in 1-year outcomes between two groups.The results of our trial show that hybrid coronary revascularization is feasible in select patients with multivessel coronary artery disease.

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First-in-man study of coronary dedicated bifurcation cobalt-chromium sirolimus-eluting stent

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

AIMS

The aim of this first-in-man study is to assess effectiveness and safety of dedicated bifurcation cobalt-chromium sirolimus-eluting stent BiOSS LIM C (Balton, Poland) in patients with stable coronary artery disease (CAD) and NSTE-ACS.

METHODS AND RESULTS

BiOSS LIM C is a coronary dedicated bifurcation sirolimus-eluting balloon expandable stent made of cobalt-chromium (strut thickness 70 μm). It is coated with a biodegradable polymer comprised of lactic and glycolic acids. The polymer releases sirolimus in a time-controlled manner lasting ca 8 weeks. The stent consists of two parts with different diameters connected with two struts of 1.7 mm length. BiOSS LIM C is mounted on a dedicated bifurcation balloon (Bottle, Balton, Poland). The stent delivery is a rapid exchange system.

Our Registry has started enrollment in August 2016 in three invasive cardiology centers (100 patients are planned to be included). Patients with a final diagnosis of stable CAD or NSTE-ACS who sign informed consent are qualified. Patients with STEMI or Medina type 001 bifurcation lesions are excluded from the registry. Provisional T-stenting is the obligatory strategy. Double antiplatelet therapy is planned for 6 - 12 months. An angiographic control with optical coherence tomography is planned at 12 months. The primary end-point is the rate of cardiac death, myocardial infarction, and target lesion revascularization at 12 months. Here are presented preliminary results.Up to now 24 patients with stable CAD or NST-ACS (79.2% vs 20.8%, respectively) were included into this prospective, feasibility and safety assessment registry. The mean age of enrolled patients (75% males) was 66.8 ± 8.95 years. There were 21 (87.5%) patients with hypertension, 7 (29.2%) with diabetes and 12 (50%) with prior MI. Additionally, 10 patients (41.7%) underwent prior PCI, while 12 (16.7%) patients had previous CABG.

In 70.8% of cases the lesion was localized in LMS, followed by 12.5% in LAD, 12.5% in LCx and 4.2% in RCA. According to Medina classification true bifurcations were present in 67%. All BiOSS stents were implanted successfully (avg. pressure 14 atm). The mean nominal stent parameters were as followed: 3.89 ± 0.46 mm x 3.16 ± 0.45 mm x 19.79 ± 3.28 mm. In 5 (20.8%) cases the second stent was implanted within the side branch. There were 95.8% of cases performed from radial access and 4.2% from femoral access. In 2 cases (8.4%) asymptomatic increase in TnI level was observed. At one (n = 24) and three (n = 12) months all patients were uneventful (out-of hospital major adverse cardiovascular events rate - 0%).

CONCLUSIONS

Dedicated bifurcation cobalt-chromium sirolimus-eluting stent BiOSSLIM C is a feasible device with promising safety profile and short-term clinical effectiveness. Long-term data are pending.

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Correlation between iFR and FFR measurements and its impact on the long-term outcome

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

AIMS

Instantaneous wave-free ratio (iFR) is physiological index which can be obtained at rest without hyperemic stimulation. The aim of this study was to analyze the correlation between iFR and FFR measurements and its impact on the long-term outcome.

METHODS AND RESULTS

We prospectively enrolled patients with stable coronary artery disease (CAD) who were qualified for FFR performance between January and August 2015. Patients had to have at least 50% stenosis in at least one coronary artery. FFR measurement was performed with the use of adenosine given in intracoronary boluses (120, 240 or 480 µg) or in intravenous infusion (140 µg/kg/min). Additionally, prior to FFR measurement iFR measurement was performed. FFR and iFR measurements were performed with Verrata Pressure Guide Wire (Volcano). Clinical follow-up was planned at 12 months.We enrolled 112 patients in whom 301 iFR/FFR measurements were performed. The mean age population was 67 ±8 years. Diabetes was present in 31.25% of patients, hypertension – in 62.5%, and the history of prior myocardial infarction had 26.7%. The majority of measurements was performed in left anterior descending artery and its branches (71.4%) followed by left circumflex artery (48.2%), right coronary artery (44.6%) and left main (20.5%). One-vessel disease (1-VD) was found in 13.4%, 2-VD – in 61.6%, and 3-VD – in 25%. Adenosine was given as i.c. boluses in 87.5% of cases.Regarding the lesion severity the correlation between iFR and FFR measurements was r = 0.84 (p<0.01), r = 0.82 (p<0.01), r = 0.79 (p<0.01) for 50-60%, 61-70% and 71-89% lesions, respectively. When analyzing the advancement of the disease the abovementioned correlation was as followed: r = 0.85 (p<0.01), r = 0.84 (p<0.01), r = 0.78 (p<0.01) for 1-VD, 2-VD and 3-VD, respectively. Interestingly, we also found differences in correlation regarding the dose of adenosine given: r = 0.83 (p<0.01), r = 0.82 (p<0.01), r = 0.69 (p<0.01) for 120 µg i.c., 240 µg i.c. and 480 µg i.c., respectively.
At the time of EuroPCR2017 we will present the complete data analyzing the role of iFR and FFR correlation on the long-term outcomes, i.e. the rate of major cardiovascular adverse events defined as cardiac death, myocardial infarction and target lesion revascularization.

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Assessment of intracoronary thrombus type by OCT: in vivo comparison of a computer-based method and visual evaluation

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Analyzing thrombus type *in vivo* may give insight to the pathogenesis of acute myocardial infarction. We aimed to assess intracoronary thrombi using OCT imaging, by a software-based method compared with a consensus classification by two observers.

METHODS AND RESULTS

We included 30 STEMI patients referred for primary PCI enrolled in an optical coherence tomography (OCT) substudy of the TOTAL (ThrOmbecTomy versus PCI ALone) trial. OCT imaging was performed after thrombectomy and restoration of TIMI 2-3 flow in the culprit vessel using the Ilumien™ OCT system and C7 Dragonfly™ catheter (St. Jude Medical, Minnesota, MN, USA). Patients who had any balloon predilatation preceding OCT imaging, were excluded. In addition, a minimum residual thrombus size of 250 μm in ≥3 contiguous frames was required. OCT images were digitally exported for later analysis.For each patient, three largest OCT cross-sectional thrombus areas were selected for assessment. Visual thrombus characteristics were evaluated by two independent readers and by one observer repeatedly after > 4 week period. The thrombi were graded by a six-stage scale from 1 to 6, where value 1 represents least and 6 most attenuation (attenuation score). Attenuation score was used to form two different thrombus type classifications, either with three (scores 1-2=white, 3-4=mixed and 5-6=red) or two (scores 1-3=whitish and 4-6=reddish) classes. Kappa values were 0.60 and 0.62 for three classes and 0.74 and 0.53 for two classes, for inter- and intraobserver comparisons, respectively. Two observer consensus was considered the golden standard for the receiver operating curve analyses.The same OCT cross-sections were analyzed using a special version of QCU-CMS® version 4.69 software (Leiden University Medical Center, LKEB, Division of Image Processing in cooperation with Medis, Leiden, The Netherlands). Thrombus areas were manually drawn and in addition a minimum threshold was applied for attenuation to avoid the inclusion of noise pixels and dark areas at the abluminal side of the thrombus. The software determined the attenuation, backscatter and grayscale intensity values for these areas and several statistical parameters were calculated, including mean and median values. Observer variability of the computer-based method was tested by redrawing the areas and was found to be low.There was a good agreement between the two observer consensus of thrombus type and several parameters measured by the software on the OCT images. By using a receiver operating curve, area under curve values were 0.92 (95% confidence intervals 0.83-1.00) for median attenuation, 0.96 (95% confidence intervals 0.89-1.00) for mean backscatter and 0.96 (95% confidence intervals 0.89-1.00) for mean grayscale intensity. A median attenuation value of 0.57 mm^{-1} (sensitivity 100%, specificity 71%), a mean backscatter value of 5.35 (sensitivity 92%, specificity 94%) and a mean grayscale intensity of 120.1 (sensitivity 85%, specificity 100%) were identified as the best cut-off values to differentiate between red and white thrombi.

CONCLUSIONS

Subjective thrombus assessment can be complemented by computer-based measurement methodology. Attenuation, backscatter and grayscale intensity of thrombus in OCT images can be used to differentiate thrombus types with high sensitivity and specificity. These preliminary results are positive for further development and testing of volumetric OCT analysis of *in vivo* coronary thrombi.

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Five-year results of endovascular treatment of patients with left main coronary arteries bifurcation lesions

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

AIMS

to evaluate long-term results of endovascular treatment in patients with bifurcation left main coronary artery diseases.

METHODS AND RESULTS

Methods: 284 patients were enrolled in the study, which randomized into 2 groups: group I (n=132) were included patients with true bifurcation lesions, which implanted Everolimus-eluting stents, and group II (n=152) – were non-bifurcations (pesudobifurcation), which implanted Paclitaxel-eluting stents. The both groups were additionally randomized into 2 subgroups: subgroup IA, IIA (n=66 in each subgroup) - included patients, who underwent 1-stent bifurcation strategy and subgroup IB, IIB (n=76 in each subgroup) - who underwent 2-stent bifurcation strategy (Culotte and Crush/Mini-Crush). For all patients, who underwent 2 stents in bifurcation, were performing subanalysis, depending on the technique of bifurcation stenting (Culotte vs. Crush/Mini-Crush). Inclusion criteria: true and non-bifurcation (pseudobifurcation) lesions of left main coronary artery (classification A. Medina)+ 1 or 2 vessel diseases (SYNTAX score < 32); hemodynamically significant stenosis of the left main coronary artery, confirmed by FFR<0.8; stable angina classes II-IV (CCS). Primary endpoints: MACE (death, MI, TVR, TLR). Secondary endpoints: restenosis and late stent thrombosis according to digital angiography and IVUS (residual area of the lumen vessel in the proximal segment of left main, zone of bifurcation, the ostia of LAD and LCx). Criteria for restenosis - decrease remaining lumen diameter > 70%. 5-years results were followed in all patients.
Results: in group I, who implanted Everolimus-eluting stents, frequency of MACE was 5.3%. In group II, who implanted Paclitaxel-eluting stents, frequency of MACE was 7.2% (p=0,003). The ratio of restenosis in bifurcation area, according digitalangiographyin both groups was 6.8 and 9.8% respectively (p=0.0024). Ratio of TLR in both groups amounted 4.5 and 6.5% respectively (p=0.004). IVUS-results in subgroup IA and IIA:the average residual lumen area in the proximal part of LMCA was 7,02+0,03 and 7.55+0.02 mm^2 (p>0.05), at the ostia of the LCx - 5,0+0,12 and 5,88+0,01 mm^2 (p=0.02), at the ostia of the LAD - 6,13+0,03 and 6.88+0,04 mm^2 (p=0.03). The frequency of MACE in subgroup IA and IIA was 9.1 and 1.5% respectively (p<0.001). IVUS-results in subgroup IIA and IIB:the average residual lumen area in the proximal part of LMCA was 7,22+0,03 and 7.55+0.02 mm^2 (p>0.05), at the ostia of the LCx - 5,0+0,12 and 5,64+0,01 mm^2 (p=0.024), at the ostia of the LAD - 6,0+0,03 and 6.84+0,04 mm^2 (p=0.027). The frequency of MACE in subgroup IB and IIB was 10.5 and 3.9% respectively (p<0.001).142 patients in the study were implanted two stents at the bifurcation. The distribution of patients according to the stenting technique (Culotte vs. Crush/Mini-Crush) was equivalent, with 70 in each group. The frequency of MACE in Culotte and Crush/Mini-Crushgroups was 0 and 5.7% respectively (p<0.001). Defined stent thrombosis were no significant difference in both groups.

CONCLUSIONS

Everolimus-eluting stents associated with higher efficacy and safety in bifurcation stenting of left main coronary artery, compared with Paclitaxel-eluting stents. Culotte-technique of LMCA bifurcation stenting shows better long-term results, as compared to Crush/Mini-Crush-technique. Two-stent strategy can be the preferred for endovascular treatment of true left main coronary artery bifurcation lesions.

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

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

AIMS

We aimed to present our single-center results on ultrasound-facilitated thrombolysis (UFT) and rheolytic thrombectomy (RT) in patients (pts) with pulmonary embolism (PE) at intermediate-high and high risk (IHR, HR).

METHODS AND RESULTS

Our study was based on the retrospective analysis of the overall 109 pts (F 56, age 60.6±17.5 years) with documented PE who underwent UFT (n=83) or RT(n=26). The systematic work-up including multidetector computed tomography (MDCT), Echo, biomarkers, and PE severity index and its simplified version (PESI, sPESI) were performed in all pts, and Qanadli score (QS) was used as the measure of the thrombotic burden in the pulmonary arteries (PA).

The IHR and HR were noted in 68 and 15 pts of UFT, and in 22 and 4 pts of RT groups, respectively. Clinical and diagnostic measures, and median time delay from symptoms to treatment were comparable between UFT and RT groups ($p>0.05$). Failure in the placement of catheters was experienced in one out of 27 RT attempts but in none of the UFT procedures.Tissue-plasminogen activator (t-PA) dosage was 53,1±28,1 mg, and treatment duration was 25,6±9,7 hours in UFT arm, irrespective of unilateral or bilateral UFT($p > 0.05$). However, adjuvant t-PA (14,6±5,1 mg) was needed in only 5 pts (19,2%) treated with RT. Regardless of the risk status, both UFT and RT resulted in significant improvements in tricuspid annular planary systolic excursion (TAPSE) (mm), PA systolic and mean pressures (mm Hg), QS, right to left ventricle diameter ratio (RV/LV) and right to left atrial diameter ratio (RA/LA), and diameters of main PA, right and left PA branches (mm)($p < 0.001$ for all). Death was documented in 4 pts (4.8 %) of UFT and 2 pts (7.6%) of RT groups. Non-fatal major bleeding was not observed. The RT induced short-term and self-terminating bradycardia or conduction disturbances during activation periods and a gross hemoglobinuria disappearing within one or two days in all pts. However, acute renal failure was not observed in any pts. Post-discharge PE-related morbidity and mortality was not documented during follow-up period for median 310 (68-983) days.

CONCLUSIONS

Irrespective of the risk status, both UFT and RT percutaneous treatment systems facilitate the lysis of thrombotic obstruction in PA and the stabilization of pulmonary hemodynamics and right heart functions with relatively low rates of complications in pts with PE at HR or IHR.

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Prognostic implications of moderate mitral regurgitation and tricuspid regurgitation in patients undergoing transfemoral TAVR - Insights from a multicentre study

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

AIMS

We sought to analyze: 1/The clinical impact of moderate vs. mild/none mitral regurgitation (MR) and its variation following transcatheter aortic valve replacement (TAVR); and 2/The impact of tricuspid regurgitation (TR) in TAVR patients with MR≤2.

METHODS AND RESULTS

Methods: Between August 2007 and January 2015, 1110 consecutive patients underwent TAVR procedure in six different high-volume centers. All patients underwent complete 2D and color-Doppler echocardiography at baseline, before discharge, at 1-, and 6-months of follow up. All images were digitally stored. Offline retrospective analysis of the degree and etiology of MR and TR was performed by an experienced operator in echocardiography blinded to further data of the post-TAVR outcomes. TR and MR degree were assessed following the European Guidelines of Echocardiography and accordingly classified as follows: 0 (none), 1+ (mild), 2+ (non-significant moderate), 3+ (significant moderate) and 4+ (severe).

Results: A total of 813 patients (72.3%) with MR≤2 were included. Mean age was 81±7 years and mean Society of Thoracic Surgeons-score was 6.9±5.1.The self-expandable CoreValve system was used in the 75.8% of the entire cohort. Moderate MR (2+) was present in 37.3% of the patients, which presented comparable in-hospital outcomes and 6-month follow-up mortality (11.9 vs 9.4%, p=0.257). However, patients with MR=2 had more re-hospitalizations (10.4% vs. 3.9%, p=0.008) and worse NYHA-class in the follow-up (9.8% at NYHA III-IV vs. 1%, 0.001) than those with MR<2. Few patients (3.8%) presented an increase in the degree of MR up to 3+. In addition, the rate ofsevere pulmonary hypertension (PHT) was also higher in the MR=2+ group (55.2%) as compared to 39.4% in the none to mild MR group (p=0.001). The presence of concomitant moderate/severe TR in patients with MR≤2 was associated to higher rate of in-hospital (13%) and follow up mortality (34.1%) irrespective of the degree of MR and was, indeed, an independent predictor of mortality with HR=18.4, (95%CI:10.2-33.3), p<0.001.

CONCLUSIONS

Conclusions: The presence of moderate MR did not impact short- and mid-term mortality after TAVR but was associated to more re-hospitalizations and lower functional recovery. The concomitant presence of moderate/severe TR conditioned a higher mortality suggesting that accurate evaluation of the mechanisms of this problem should be performed to determine the best therapeutic strategy and avoid futility of TAVR.

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Comparison between transfemoral and transubclavian access for TAVR: a meta-analysis

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

AIMS

Transfemoral approach is the first choice for TAVR but there is no evidence to support this strategy. We aimed to investigate whether transubclavian and transfemoral approach present comparable major outcomes according to current pooled evidence.

METHODS AND RESULTS

Methods: We systematically searched PubMed, EMBASE, and Cochrane database for studies with symptomatic aortic stenosis patients who underwent TAVR through transfemoral or transubclavian/axillar access from January 2006 to January 2017. Searched terms were: (“aortic stenosis” OR “transcatheter aortic” OR “TAVI” OR “TAVR”) and (“transfemoral” OR “transapical” OR “transaxillary” OR “transubclavian”).

Primary outcome was 30-day mortality. Secondary outcomes were procedural success and 30-day incidence of stroke, major vascular complications, acute kidney injury requiring dialysis, and new pacemaker implantation.

We defined I^2<50% as low heterogeneity and fixed effect analysis when I2 was less than 50% and p value at least 0.10; otherwise we used random effect. Search results yielded 815 studies. Final analysis was made with 6 studies that accomplished all the pre-determined definitions.

Results: A total of 3886 patients received transfemoral access and 618 transubclavian access. Baseline characteristics of compared groups in individual studies were similar, with the exception of a lower prevalence of coronary artery disease with OR=0.67 [95% CI: 0.54-0.83](p=0.0003) and much lower prevalence of peripheral vascular disease with OR=0.07 [95% CI: 0.05-0.11](p<0.00001) found in the transfemoral group.

The trasubclavian group presented comparable 30-day mortality (OR=1.42; [95% CI: 0.88–2.26]; p = 0.15). There was no significant difference among groups for procedural success (OR=0.75; [95% CI: 0.28–2.02]; p = 0.57) and also were comparable the 30-day stroke incidence (OR=0.68; [95% CI: 0.41–1.14]; p = 0.15) the rate of new pacemaker implantation (OR=0.86; [95% CI: 0.68–1.09]; p = 0.22), major vascular complications (OR=1.28; [95% CI: 0.85–1.91]; p = 0.24), and acute kidney injury requiring dialysis (OR=1.32; [95% CI: 0.88–2.00]; p = 0.18).

CONCLUSIONS

Our study suggests that transubclavian approach may be, not only an alternative route to transfemoral approach for TAVR, but even a competitive approach in certain patients with increased risk of vascular injury. Future randomized clinical trials are needed to explore this hypothesis.

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Use of 3D LAA models for optimal pre-procedural percutaneous LAA closure planning

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

Success or failure of percutaneous left atrial appendage closure (LAAC) depends upon accurate LAAC device size selection and implantation. This study aimed to investigate the potential added value of 3D LAA models in the pre-procedural planning.

METHODS AND RESULTS

Based on cardiac multi-slice computed tomography (MSCT), a 3D LAA model was printed of 20 patients planned for LAA closure with the Amulet^{TM} closure device (St Jude Medical, MN, USA). With the use of 2 mm aluminium oxide beads – filled within the patient-specific 3D LAA model – and different LAAC device sizes, three important parameters could be assessed: (1) device embolization; (2) leakage of 2 mm beads during a 60-sec 'shake test'; and (3) the Amulet^{TM} lobe compression rate – as assessed at X-ray angiography. These three parameters were assessed for every 3D LAA model using the full range of available LAAC device sizes (16 mm to 34 mm) and different implantation techniques and/or depths. Based on this 3D model-based pre-procedural planning, the most optimal LAAC device size and 'target' landing zone could be determined. Based on historical data in our center, the average number of LAAC devices used per procedure was 1.4, 1.2 and 1.05 when using transesophageal echocardiography (TEE), MSCT imaging, or MSCT-based 3D models as pre-procedural imaging/tools ($n = 60$; $p = 0.03$), respectively. Based on MSCT imaging with contrast at three months post-procedure, it was shown that only 1/20 patient (5%) of the 3D-model cohort had remaining contrast leakage into the LAA vs. 4/20 (20%) of the MSCT only cohort ($p = 0.339$; no MSCT data available for the TEE cohort).

CONCLUSIONS

Despite the best available pre-procedural LAA imaging, LAAC device size selection remains a challenge as the final implantation result – or 'landing zone' – is not predictable based on imaging alone. The use of 3D LAA models offers the possibility to optimize the LAAC device size selection in combination with the best possible implantation technique and/or depth.

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Impact of radial and femoral approach on the development of contrast-induced nephropathy in patients undergoing coronary angiography and/or PCI

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

AIMS

Contrast induced nephropathy (CIN) is a complication of PCI. Radial approach has become popular and apparently associated with reduction of procedural complications. Aim of the study is to evaluate the impact of angiographic approach on CIN.

METHODS AND RESULTS

Our population included patients undergoing coronary angiography and/or PCI from January 2007 to January 2016. CIN was defined as an absolute ≥0,5mg/dl or a relative ≥25% increase in serum creatinine level at 24-48h after the procedure. Among 4199 patients the total incidence of CIN was 12.4%. We divided our population in two groups, according to the angiographic approach: trans radial (n. 1915) (TR) or trans femoral (n. 2284) (TF). Patients treated with TR approach were more often males ($p = 0.05$), with a previous history of hypertension ($p = 0.005$), and PCI ($p < 0.001$), but with less often history of diabetes ($p = 0.003$), previous myocardial infarction ($p = 0.04$), coronary artery by-pass graft surgery ($p = 0.001$) and cerebrovacular accident ($p = 0.02$). They had a higher ejection fraction ($p = 0.04$), higher prevalence of PCI after coronary angiography ($p < 0.001$), but interestingly lower amount of contrast volume during the procedure ($p < 0.001$) and they were more often in therapy with angiotensin receptor blockers ($p = 0.02$) and beta blockers ($p = 0.005$) but less often with nitrate ($p < 0.001$) and clopidogrel ($p < 0.001$). About biochemical parameters, patients treated with TR approach had higher platelets ($p = 0.003$), Total ($p <0.001$), LDL ($p < 0.001$) and HDL ($p < 0.001$) cholesterol, but lower tryglycerides ($p < 0.001$), glycaemia ($p < 0.001$) and basal creatinine ($p < 0.001$). No significant difference was observed between the two groups regarding the development of CIN (TF 13.2% vs TR 11.7%, $p = 0.16$). The absence of association between angiographic approach and the incidence of CIN was also confirmed at multivariate analysis after correction for baseline confounders (Adjusted OR [95% CI] = 1.2 [0.97 – 1.50], $p = 0.09$)

CONCLUSIONS

This is the first large study showing the absence of relationship between angiographic access and the incidence of CIN

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Subclinical leaflet thrombosis and stent frame geometry in self-expanding transcatheter heart valves

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

AIMS

Subclinical leaflet thrombosis has been reported in several types of bioprosthetic aortic valves; this study assesses the potential relationship between leaflet thrombosis and stent frame geometry in self-expanding transcatheter heart valves (THV).

METHODS AND RESULTS

75 patients with a self-expanding THV were studied with 4D-computed tomography and analysed for hypoattenuating leaflet thickening (HALT), hypoattenuation affecting motion (HAM), as well as overall and regional THV stent frame expansion. There was no difference in THV size, overall THV expansion, eccentricity or implantation depth between patients with or without leaflet abnormalities. Moderate-to-severe regional THV underexpansion was most frequently found at the non- and right coronary cusps with a significant higher incidence of HALT/HAM than in case of full regional THV expansion (25-50% vs. 3%, $p<0.01$). Regional THV underexpansion at the inflow level more often translated into the same issue at the valvular level in THV with intra-annular as compared to supra-annular valve position (54% vs. 17%; $p=0.04$). In addition, regional THV underexpansion occurred less frequently in post-dilated THV as compared to THV that were not post-dilated (18% vs. 43%, $p=0.028$).

CONCLUSIONS

Regional THV stent frame underexpansion is associated with an increased risk of HALT/HAM. Post-dilatation of self-expanding THV seems to reduce the occurrence of this phenomenon. Although the consequences of subclinical leaflet thrombosis are uncertain, this finding may have consequences on the way TAVR procedures with self-expanding THV are performed, on follow-up and medical treatment, as well as on THV-design in the future.

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Vascular access site and outcomes among 26,807 CTO angioplasty cases from the British cardiovascular interventions society national database

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

AIMS

Use of radial access in CTO-PCI warrants further investigation. Using the British Cardiovascular Intervention Society (BCIS) database, access site choice and outcomes after CTO-PCI were assessed.

METHODS AND RESULTS

Data were analysed from the BCIS dataset on all (n=26,807) elective CTO-PCI procedures performed in England and Wales between 2006 and 2013. Multivariate logistic regression was used to identify predictors of access site choice and its association with outcomes. During the study period, there was a significant decrease in femoral artery (FA) utilisation (84.6% in 2006 to 57.9% in 2013, p<0.0001) and a significant increase in dual arterial access use (4.1% to 28.7%, p<0.0001). Although there was a significant increase in dual radial access (RA) (0% to 6.6% during study period, p=0.0045), 93.4% of dual access cases were undertaken using at least one FA. During matured practice years (2012 and 2013) apart from female gender and history of PCI, baseline clinical characteristics did not differ significantly by access site choice. In contrast, the complexity of the intervention was closely associated with access choice with a primary consultant operator, dual arterial access, intra-vascular ultrasound, rotational atherectomy, penetration catheter, micro-catheter, and Crossboss/Stingray use all more frequently observed when FA access was chosen.There was a highly significant association between FA access and the number of CTO devices used (R^2=0.965, p=0.001 for trend), and a highly significant association between dual arterial access and the number of CTO devices used (R^2=0.996, p=0.0001 for trend). Procedural success (75.0 vs. 79.1%, p=0.002) and the number of successful lesions (1.09±0.92 vs. 1.22±0.99, p<0.001) were lower in the femoral cohort. Using multivariate analyses, covariates found to be independently associated with FA access for CTO-PCI in 2012 and 2013 were female gender (odds ratio 1.21, 95% confidence intervals [1.10-1.32], p=0.007), a history of previous revascularisation (1.08, [1.02-1.14], p=0.023), dual arterial access (3.89, [3.45-4.32], p<0.001), Crossboss/Stingray use (1.87, [1.43-2.12], p<0.001), intra-vascular ultrasound use (1.32, [1.21-1.53], p<0.001), and micro-catheter use (1.12, [1.04-1.29], p<0.001). Circumflex CTO intervention was associated with lower use of FA access (0.94, [0.89-1.00], p=0.050). In-hospital complications including an access site complication (1.5 vs. 0.5%, p<0.001), peri-procedural MI (0.5 vs. 0.2%, p=0.037), major bleeding (0.8 vs. 0.2%, p<0.001), blood transfusion (0.4 vs. 0%, p<0.001) and death (0.2 vs. 0.1%, p=0.027) were more frequent in patients undergoing CTO-PCI using FA access. Mortality at 30-days (0.6 vs. 0.1%, p=0.002) was greater in femoral cohort. A femoral access site complication during CTO-PCI was associated with significant increases in transfusion (8.0 vs. 0.1%, p<0.001), acute procedural coronary complication (17.3 vs. 5.8%, p<0.0001), major bleeding (8.4 vs. 0.3%, p<0.001) and mortality at all time points (12-month mortality 4.7 vs. 2.3%, p=0.001). Using individual logistic regression, a strong adverse association of an arterial complication on all clinical events was evident.

CONCLUSIONS

FA access remains predominant during CTO-PCI with case complexity and device size associated with its use. Access site complications were more frequent with FA use and strongly correlated with adverse outcomes.

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The legacy effect of coronary perforation complicating PCI for CTO disease: an analysis of 26,807 cases from the British cardiovascular intervention society database

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

AIMS

Coronary perforation (CP) during CTO-PCI is a rare but serious event. The evidence base is limited and the long-term effects unclear. Using a national PCI database, the incidence, predictors and outcomes of CP during CTO-PCI were defined.

METHODS AND RESULTS

Data were analysed from the British Cardiovascular Intervention Society dataset on all CTO-PCI procedures for stable angina performed in England and Wales between 2006 and 2013. Multivariate logistic regressions and propensity scores were used to identify predictors of CP and its association with outcomes. Using a landmark analysis, 30-day survivors of perforation were matched to non-perforation survivors using 12 baseline variables associated with mortality to investigate for a legacy effect of perforation at 12-months. A total of 376 CP were recorded from 26,807 CTO-PCI interventions (incidence of 1.40%) with an increase in frequency during the study period (p=0.012). The complexity of the intervention was closely associated with coronary perforation with a primary consultant operator, dual arterial access, rotational atherectomy, micro-catheter use, and Crossboss/Stingray use all more frequently observed when perforation occurred. A close relationship between the number of complex strategies utilised and coronary perforation frequency was evident (p=0.008 for trend). Using multivariate analyses, patient-related factors associated with an increased risk of perforation were age (odds ratio 1.02/year, 95% confidence interval [1.01-1.03], 0=0.003), female gender (1.65, [1.26-2.15], p<0.001) and a history of a previous PCI (1.39, [1.09-1.77], p=0.002). Procedural factors associated with an increased risk of perforation were Crossboss/Stingray use (2.92, [1.44-5.93], p<0.001), micro-catheter use (1.64 [1.11-2.42], p=0.007), rotational or laser atherectomy (1.79, [1.08-2.97], p=0.018), and a consultant primary operator (1.46, [1.01-2.10], p=0.042). Tamponade occurred in 16.6% of patients and emergency surgery was required in 3.4% of cases. All in-hospital complications including MI (2.5 vs. 0.5%, p<0.001), major bleeding (16.9 vs. 0.2%, p<0.001), blood transfusion (2.5 vs. 0.2%, p<0.001) and death (1.6 vs. 0.2%, p<0.001) were more frequent in patients with coronary perforation. Mortality at all time points including 30-days (2.4 vs. 0.4%, p<0.001), 12-months (5.8 vs. 2.2%, p<0.001) and 60-months (27.5 vs. 17.2%, p=0.001) was greater in those patients with coronary perforation. Using multiple logistic regression analyses the adjusted odds of all clinical outcomes were higher when a perforation occurred. A legacy effect (i.e. a continued impact of perforation on mortality) was evident with an odds ratio for 12-month mortality of 1.60 compared to those matched patients without a coronary perforation (p<0.0001).

CONCLUSIONS

Using data derived from a national PCI database, coronary perforation as a complication of CTO intervention occurred in 1.4% of cases but with a significant temporal increase in frequency. Independent predictors of coronary perforation included age, female gender, CTO complexity, and consultant operator. Coronary perforation was strongly associated with poor outcomes. A legacy effect on mortality after coronary perforation was observed with a continued excess mortality between 30-days and 12-months.

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Coronary perforation complicating PCI in patients with a history of coronary artery bypass surgery: an analysis of 59,644 cases from the British cardiovascular intervention society database

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

AIMS

The literature on coronary perforation (CP) occurring during PCI in patients with a history of CABG (PCI-CABG) is limited. Using a national PCI database, the incidence, predictors and outcomes of CP during PCI-CABG were defined.

METHODS AND RESULTS

Data was analysed from the British Cardiovascular Intervention Society dataset on all PCI-CABG procedures performed in England and Wales between 2005 and 2013. Multivariate logistic regressions and propensity scores were used to identify predictors of CP and its association with outcomes. Using a landmark analysis, 30-day survivors of perforation were matched to non-perforation survivors using 12 baseline variables associated with mortality to investigate the legacy effect of CP on 12-month survival. The proportion of patients undergoing PCI with a history of CABG increased progressively during the study period from 7.7% in 2005 to 10.2% in 2013 (p<0.001 for trend). A total of 309 coronary perforations were recorded during 59,644 PCI-CABG procedures (incidence 0.52%). The annualised rate of CP rose progressively from 0.32% in 2005 to 0.68% in 2013 (p=0.001 for trend). There was no significant difference in CP incidence between native vessel PCI and graft PCI (0.51 vs. 0.49% respectively, p=0.787). Although CP was significantly more likely in stable angina PCI to native vessels (69.5 vs.60.3%, p=0.008), it was less likely in graft PCI (30.1 vs. 42.5%, p=0.031). Potent anti-platelet therapy and glycoprotein inhibition were not associated with an increased risk of CP. The patient-related factors associated with an increased risk of CP were age per year (odds ratio (OR) 95% confidence intervals 1.04 [1.02-1.05], p<0.001), stable angina presentation (OR 1.28 [1.06-1.52], p=0.005) and female gender (OR 1.25 [1.06-1.47], p=0.007). Procedural factors associated with an increased risk of native vessel perforation included CTO intervention (OR1.60 [1.35-1.90], p<0.001), rotational atherectomy use (OR 1.43 [1.15-1.78], p=0.002), dual arterial access (OR 1.40 [1.1301.75], p=0.002) and micro-catheter use (OR 1.47 [1.12-1.95], p=0.006). In contrast, graft perforation only a history of stroke (OR 1.49 [1.01-1.36], p<0.001) and use of rotational atherectomy (OR 1.56 [1.17-2.10], p=0.003) closely associated with an increased risk. Coronary complications occurred in 14.2% of PCI-CABG procedures with a CP and 3.6% without (p<0.001). Tamponade occurred in 10.0% of patients (9.8% for native vessel PCI and 12.5% for graft PCI, p=0.576). In-hospital clinical complications including Q-wave MI (2.9 vs. 0.2%, p<0.001), major bleeding (14.0 vs. 0.9%, p<0.001), transfusion (3.7 vs. 0.2%, p<0.001), renal failure (1.1 vs. 0.1%, p<0.001) and death (10.0 vs. 1.1%, p<0.001) were more frequent in patients with CP. However, a significant linear reduction in 30-day mortality after CP between 2005 and 2013 was observed (p=0.005). Using multiple logistic regression analyses, the adjusted odds of clinical outcomes indicated a significant impact of CP during PCI-CABG on all short and long term outcomes. A legacy effect (i.e. a continued impact of perforation on mortality) was evident with an odds ratio for 12-month mortality of 1.35 for those with a CP compared to those matched patients without a CP (p<0.001).

CONCLUSIONS

Coronary perforation is an infrequent event during PCI in patients with prior CABG but has a very significant impact on clinical events**.** A legacy effect of perforation on 12-month mortality was observed.

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Peri-procedural myocardial injury depends on transcatheter heart valve type but does not predict mortality in patients after TAVI

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

AIMS

To determine plasma elevation of biomarkers of myocardial injury associated with transfemoral (TF) TAVI, and to evaluate the prognostic value.

METHODS AND RESULTS

In 756 consecutive TAVI patients, cardiac high sensitive troponin I (hsTrop I) and CK-MB-levels were measured at pre-defined time points to assess the occurrence of myocardial injury during the first 72 hours. The primary endpoint was all-cause mortality at 1 year. After TAVI, hsTrop I was elevated in 51.6% and CK-MB in 7.4% of the patients, respectively. Myocardial injury was associated with the prosthesis type: patients receiving a Boston Lotus prothesis suffered more frequently from myocardial injury compared to those with use of another THV. Myocardial injury defined by hsTrop I was not associated with adverse outcomes at 30 days (3.1% vs. 2.7%, p=0.778) and 1 year (16.7% vs. 17.2%, p=0.841). Likewise, a CK-MB increase was not associated with 30-day- and 1-year mortality (5.5% vs. 2.8%, p=0.258; 16.4% vs. 17.3%, p=0.856).

CONCLUSIONS

Myocardial injury is common after TAVI. The extent of cardiac biomarker elevation depends on prosthesis type bit is not associated with adverse short- and long-term outcome after TAVI.

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Mid-term outcomes of underfilling and overfilling balloon-expandable transcatheter heart valves: the OCEAN-TAVI registry

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

AIMS

Modified volume-control techniques (i.e., underfilling and overfilling) are commonly used in TAVI. This study aimed to assess the impact of the modified techniques of THVs on mid-term clinical outcomes and post-procedural follow-up echocardiography.

METHODS AND RESULTS

We evaluated 976 patients with aortic stenosis who underwent TAVI with 23-mm and 26-mm Sapien XTs (SXTs) in nine Japanese centers (Optimized CathEter vAlvular iNtervention [OCEAN-TAVI] registry). Cases were categorized into three groups: underfilling, nominal filling, and overfilling groups (23-mm SXTs: 306, 229, and 99 patients, respectively; 26-mm SXTs: 198, 98, and 46 patients, respectively). We compared the hemodynamics of THVs before discharge and at 6-, 12-, and 24-month follow-up and the mid-term outcomes among three groups. The underfilling group with 23-mm and 26-mm SXTs had the highest mean transvalvular gradients among three groupsbefore discharge (before discharge: 23-mm SXTs; 11.7±4.0 vs. 11.0±3.5 vs. 10.9±3.9 mmHg, p=0.048; 26-mm SXTs; 9.2±3.2 vs. 8.0±2.7 vs. 8.7±3.6 mmHg, p=0.01) and during follow-up (6 months: 23-mm SXTs; 13.1±4.8 vs. 11.3±3.8 vs. 10.8±4.0 mmHg, p<0.01, 26-mm SXTs; 9.8±3.2 vs. 8.3±3.2 vs. 8.5±3.6 mmHg, p=0.01, 12 months: 23-mm SXTs;13.0±5.4 vs. 11.3±3.8 vs. 10.8±3.4 mmHg, p<0.01,26-mm SXTs; 9.5±3.6 vs. 8.0±2.6 vs. 8.6±3.8 mmHg, p=0.06, 24 months: 23-mm SXTs; 14.1±7.8 vs. 11.1±3.5 vs. 10.0±2.3 mmHg, p=0.09; 26-mm SXTs; 9.6±2.7 vs. 8.1±4.8 vs. 7.7±3.6 mmHg, p=0.55). However, the differences in mean transvalvular gradients were subclinical and smaller than those between THV sizes.Indexed effective orifice areas (iEOAs) before discharge were the lowest in the underfilling group with 23-mm SXTs(1.13±0.26 vs. 1.15±0.26 vs. 1.21±0.27 cm^2/m^2, p=0.047), but not significantly different among three groups with 26-mm SXTs (1.25±0.29 vs. 1.28±0.33 vs. 1.27±0.29 cm^2/m^2, p=0.64). Similarly, at 6-month follow-up, iEOAs with 23-mm SXTs were the lowest in the underfilling group (1.07±0.25 vs. 1.12±0.26 vs. 1.20±0.25 cm^2/m^2, p<0.01) andiEOAs with 26-mm SXTswere not significantly different among three groups (1.19±0.31 vs. 1.25±0.30 vs. 1.26±0.30 cm^2/m^2, p=0.33). At 12- and 24-month follow-up, iEOAs with both 23-mm and 26-mm SXTswere not significantly different among three groups.

The incidences of moderate or severe post-procedural aortic regurgitation were not significantly different among the three groups before dischargeand during follow-up. The incidences of severe prosthesis-patient mismatch, which can influence the symptoms and prognoses after TAVI, were not significantly different among the three groups. No significant differences were seen in freedom from all-cause mortality between three groups with 23-mm and 26-mm SXTs (23-mm SXTs: p=0.80; 26-mm SXTs: p=0,86).

CONCLUSIONS

Although slightly higher transvalvular gradients during follow-up were seenin the underfilling group, the differences between the techniqueswere subclinical and smaller than those observed between different THV sizes. The underfilling and overfilling techniques with balloon-expandable THVs did not negatively affect mid-term all-cause mortality and the modified techniquesare safe and valid.

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Invasive hyperemic microvascular resistance predicts adverse clinical outcome and microvascular injury after AMI and is superior to coronary flow reserve: a patient-level pooled analysis

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

We aimed to explore whether hyperemic microvascular resistance (HMR) was a predictor of clinical outcome and to identify the optimal cut-off value for HMR.

METHODS AND RESULTS

A patient-level pooled analysis of combined intracoronary Doppler flow velocity and distal pressure measurements obtained at the completion of primary angioplasty was performed in 176 patients. Clinical outcomes were collected with a primary composite endpoint of death and hospitalization for heart failure. CMR indices were obtained to characterise the infarction and left ventricular function. Median follow-up time was 3.2 years [interquartile range 2.0 to 5.1]. The optimal cut-off value for HMR to predict the primary composite endpoint was 3.0 $mmHg \cdot cm^{-1} \cdot s$. A composite of death and hospitalization for heart failure occurred in 20.3% of the patients (13 of 64 patients) in the group with HMR ≥ 3.0 $mmHg \cdot cm^{-1} \cdot s$, as compared with 2.1% (4 of 112) in the group with HMR < 3.0 $mmHg \cdot cm^{-1} \cdot s$ (hazard ratio, 7.0: 95% confidence interval, 1.5 to 33.7; log-rank $P<0.001$).Patients with HMR ≥ 3.0$mmHg \cdot cm^{-1} \cdot s$ had a worse functional outcome on CMR with larger infarct size as percentage of left ventricle (28.3 [interquartile range 17.9 - 38.1] vs. 16.0 [interquartile range 7.4 - 26.5], $P<0.001$), more frequent microvascular injury (70% vs. 31%, $P<0.001$) and lower left ventricular ejection fraction (45.0 ± 10.3 vs. 49.1 ± 10.5, $P=0.02$) as compared with patients with a low HMR.

CONCLUSIONS

HMR measured immediately following percutaneous coronary intervention for AMI with a cut-off value of 3.0 $mmHg \cdot cm^{-1} \cdot s$, identifies patients at high-risk of long-term adverse clinical and functional outcome after AMI.

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Recovery of renal function after TAVI-associated acute kidney injury and its impact on mid-term clinical outcomes

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

AIMS

The aim of the study was (1) to analyze TAVI-related acute kidney injury (AKI) and (2) to evaluate renal function recovery thereafter, including its impact on clinical outcomes.

METHODS AND RESULTS

TAVI was performed in 1287 consecutive patients (80.8±6.7years, 52.4% female, STS-PROM 6.8±5.0%) from 2008-2014 at a single institution. Patients with chronic hemodialysis were excluded, leaving 1229 patients for analysis. Data were retrospectively evaluated according to the updated Valve Academic Research Consortium (VARC) endpoints. Median follow-up was 354 (IQR 63-812) days. Renal function was calculated as glomerular filtration rate (GFR) using the CKD-EPI formula. Acute kidney injury was defined according to the updated VARC definitions. Renal function recovery was defined as a reversal of GFR deterioration at the time of discharge.

Periprocedural AKI (stages 1-3) was observed in 31.6% of patients after TAVI and was independently associated with increased all-cause mortality (hazard ratio [HR] 1.68). Predictors of AKI included baseline characteristics (impaired renal function [HR 0.87 per 10 ml/min GFR], atrial fibrillation [HR 1.54], male gender [HR 1.51], higher body mass index [HR 1.16 per 5 kg/m^2]) and periprocedural aspects (non-transfemoral approach [HR 2.63], major access site complications [HR 1.86], periprocedural stroke [HR 2.46], blood transfusion [HR 1.69], no device success [HR 1.61]). At discharge, 72.6% of patients with periprocedural AKI had a significant recovery in renal function. Baseline and periprocedural characteristics of these patients were similar to those without recovery. Overall survival at 2 years was similar among patients with renal function recovery and those with persistently impaired GFR (60.0 vs. 62.0 %, Kaplan-Meier p=0.567) but overall significantly worse compared to patients without any AKI after TAVI (77.0%, Kaplan-Meier p<0.001).

CONCLUSIONS

AKI was common after TAVI and it was associated with adverse outcomes, even at mild stage. Several periprocedural and baseline predictors were identified, some of which can be modified. Renal function recovery at discharge occurred in the majority of patients who suffered from periprocedural AKI. Surprisingly, these patients did not benefit in terms of short-term clinical outcomes or mid-term survival compared to those with persistently impaired renal function. Hence, primary avoidance of periprocedural AKI remains essential to improve outcomes after TAVI.

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Transfemoral system for mitral valve reconstruction - Multicentre trial results

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

AIMS

The aim of this multicenter study was to evaluate feasibility, safety and outcomes up to 24 months of Cardioband reconstruction system percutaneous implantation in patients with secondary mitral regurgitation (MR).

METHODS AND RESULTS

Between February 2013 and June 2016, 61 high-riskpatients with significant secondary MR were enrolled at 11 European sites. All patients were screened by a heart team using echocardiography and cardiac CT. Mean patient age was 72±7 years, 44 were males (72%). Mean EuroSCORE II was 7.1%. At baseline, 53 patients (86%) were in NYHA functional class III-IV, with a mean left ventricular ejection fraction of 33±11%. Device implantation was achieved in all but one patient. At discharge, 51 patients (90%) had MR ≤2+. After device cinching, an average 30% reduction in septolateral mitral annular diameter was observed (from 37±4 mm to 26±4 mm; p<0.01). Thirty-day mortality was 3.3% (2 patients; death adjudicated as unrelated to the device).

After Cardioband implantation , 29/31 (93%) and in 11/12 (92%) of patients had MR ≤2+ at 12 and 24 months follow up respectively. 26/33 patients (79%) and 11/15 (77%) were in NYHA functional class I-II at 12 and 24 months follow up respectively. A significant improvement was observed at 12 months in the mean quality of life score (Minnesota Living with Heart Failure Questionnaire) from 41 to 23 (p<0.01); and mean six-minute walk distance changed from 299 to 372 m (p<0.01).

CONCLUSIONS

Transseptal mitral repair with the Cardioband device resulted in significant MR reduction by reconstruction of the mitral annulus. Thirty-day mortality is comparable to other transcatheter mitral procedures. MR severity reduction and clinical benefit remain stable up to 24 months.

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Endovascular treatment of complete occlusion of the superior vena cava with a novel dedicated venous stent: initial clinical experience

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal, Other peripheral interventions

AIMS

We aimed to assess early outcomes of a novel venous stent (Vici; Veniti) for the treatment of complete (Type IV) superior venous cava obstruction (SVCO). The stent has closed-cell designed to provide strength and flexibility in the venous anatomy.

METHODS AND RESULTS

Thirteen patients (6 men; mean age 55.1 years) with symptomatic SVCO who underwent endovascular revascularization between May and December 2016 at our institution were retrospectively reviewed. Etiology of SVCO included malignant expansive mediastinal disease (n=2, 15%) and prolonged indwelling central venous catheter (n=11, 85%). All patients suffered from complete (100%) SVCO with mean lesion length of 27.7±6mm and 4 (30.7%) cases of instent restenosis. Procedural success with deployment of stents in the intended position was 92% without complications. Angioplasty failed in 1 case due to failure of guidewire crossing. One stent was implanted in each case with average diameter and length of 15.2mm and 62.5mm, respectively. Good clinical effect was observed in all (100%) successful cases at discharge with symptoms resolution, and 91.7% at 30-days. One death occurred at 30-days due to sepsis unrelated to the index procedure.

CONCLUSIONS

The Vici venous stent was safe, easy to deploy and showed good early clinical outcomes in the treatment of complex superior vena cava obstruction.

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A comparative study of different imaging modalities for successful percutaneous LAA closure

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

Accurate sizing of the left atrial appendage (LAA) is essential when performing percutaneous LAA closure. This study aimed to compare different LAA imaging modalities and sizing methods in order to obtain successful LAA closure.

METHODS AND RESULTS

Patients that underwent percutaneous LAA closure, a pre-procedural transesophageal echocardiography (TEE) and pre- and post-procedural multi-slice computed tomography (MSCT) were identified. Pre-procedural measurements of LAA ostia and landing zones by TEE, MSCT, and angiography were collected and analysed for those patients with successful LAA closure – i.e. with no contrast leakage at 3-month follow-up MSCT.The study population (n=67) had a mean CHADS-VASc-score of 3.0 and HASBLED-score of 2.7. Of these, 58 patients (87%) were identified to have successful LAA closure. Based on CT-sizing, 48 LAA sizings (83%) resulted in a correct LAA device size choice, whereas in case of 2D-TEE-based sizing, only 33 LAA sizings (57%) led to correct device size selection ($p<0.01$). Using adapted Bland-Altman method, CT-based perimeter-derived mean diameter was shown to be the best parameter to guide device size selection for nitinol “closed-end” devices (Amulet^{TM}, WatchmanFLX^{TM}), whereas maximal diameter was the best parameter for the nitinol “open-end” Watchman^{TM} device.

CONCLUSIONS

Pre-procedural MSCT-based LAA closure device size selection shows to be a more accurate method than conventional 2D-TEE-based sizing. Depending on the LAA device design, perimeter-derived mean *or* maximal diameter could be the better sizing method

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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

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

AIMS

To assess the intermediate term safety, clinical performance and bioabsorption process of the Sirolimus-Eluting Bioabsorbable Magnesium Scaffold (DREAMS 2G) 2-year clinical data and multi-modality imaging outcomes up to 1 year follow-up are reported.

METHODS AND RESULTS

Methods

One hundred twenty three (123) subjects with 123 lesions have been enrolled in BIOSOLVE-II Study. Clinical follow-ups are scheduled at 1, 6, 12, 24 and 36-months. Angiographic follow-up are planned at 6-month and voluntarily at 12-month and 36 month. A subgroup of 30 subjects undergoes additional IVUS and OCT assessment at 6-month and voluntarily at 12-month and 36 month. Vasomotion testing is performed with acetylcholine, followed by nitroglycerine at 6-month and 12-month and 36 month, if subjects consent. Dual antiplatelet therapy was recommended for 6 months. Primary endpoint is in-segment late lumen loss (LLL) at 6-month follow-up.**Results**

Previously published study results showed that the late lumen loss results remained stable from 6 to 12 months: in-segment late lumen loss 0.20±0.21 mm versus 0.25±0.22 mm, p=0.117 and in-scaffold late lumen loss 0.37±0.25 versus 0.39±0.27 mm, p=0.446, respectively.

TLF rate at 24-month was 5.9% including 4 TLRs, 1 peri-procedural MI and 2 death of unknown cause. No definite or probable scaffold thrombosis was observed up to 24-month. All clinical events have been adjudicated by an independent CEC.

Multi-modality imaging data demonstrate vasomotion of ≥ 3% change in mean lumen diameter after administration of acetylcholine or nitroglycerine for 80% (20/25) of the subjects at 6-month demonstrating the uncaging aspect of the absorption process with no further change at the 12-month follow-up.

Six-month virtual histology (VH) data showed a significant decrease in the dense calcium by 14% ($p<0.0001$) remaining stable from 6- to 12-month follow-up. This decrease is interpreted as a surrogate assessment for the bioabsorption process of the scaffold material.

CONCLUSIONS

The 24-months safety results of the DREAMS 2G are encouraging with a TLF rate comparable to existing bioabsorbable scaffolds and no definite or probable scaffold thrombosis.

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Indexed device landing zone calcium volume predicts moderate / severe aortic regurgitation after TAVI with first and second generation self-expandable prosthesis

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

AIMS

Clarify the influence of calcification patterns on the incidence of moderate/severe AR and to assess the performance of different first- and next-generation systems self-expandable prosthesis regarding calcium at the DLZ and residual AR.

METHODS AND RESULTS

Methods

Retrospective, observational study including all patients with severe aortic stenosis submitted to TAVI with self-expandable prosthesis between August 2007 and October 2016. Calcification of the DLZ was quantified for all available contrast scans, using a dedicated software (3mensioValvesTM), with a threshold for calcium detection set at 850 Hounsfield Units. All patients underwent transthoracic echocardiography within 1–3 days following the procedure. We used a Mann Whitney U test to compare DLZ calcium volume between patients with moderate/severe AR and patients with milder degrees of AR after being submitted to TAVI. A receiver operating characteristics (ROC) curve was used to obtain the best cut-off value of DLZ calcium volume to predict ≥moderate AR after TAVI with Self-Expandable Prosthesis. Then DLZ calcium volume was transformed into a categorical variable with 2 groups and a binary logistic regression analysis was conducted to test the strength of prediction of the projected value of DLZ calcium volume to assess development of AR ≥moderate after TAVI.

Results

TAVI with self-expandable prosthesis was performed in 180 patients in our centre (47,8% male, mean age 79.7±7.8 years old). Most of the devices implanted were 1st Generation Self-Expandable Prosthesis (n=112, 62.2%). The incidence of moderate/severe AR after TAVI was 15.8%. Body surface area (BSA) indexed DLZ calcium volume was significantly different between patients with moderate/severe (231.7±53.9) and those with milder degrees of AR (138.4±11.2), (p=0.01). Area under the curve (AUC) for BSA indexed DLZ calcium volume was 0.64 (95% CI 0.53–0.75 p<0,05). We considered the best cut off point for BSA indexed DLZ calcium volume to be 107.1 (sensitivity 73.1%, specificity 52.6%). In a binary logistic regression model, an BSA indexed DLZ calcium volume equal or above 107.1 was associated with 3 times increase in the probability of moderate/severe AR after TAVI with self-expandable prosthesis. Importantly, there were no significate differences in the incidence of moderate/severe AR after TAVI with self-expandable prosthesis, regarding device generation (X^2 (1)=0.1, p=0.83).

CONCLUSIONS

Conclusion

Calcification of the DLZ predicts moderate/severe AR after TAVI with Self-Expandable Prosthesis; the incidence of moderate/severe AR did not differ significantlybetween 1st and 2nd generationdevices.

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Transradial coronary angiography in severe aortic stenosis: left vs. right approach and 5 vs. 6Fr guiding catheters

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

AIMS

Screening coronary angiography is important in patients with severe aortic stenosis (AoS). The aim of the present study was to evaluate the safety and feasibility of using the radial approach and 5 French (Fr) compared to 6 Fr guiding catheters.

METHODS AND RESULTS

200 patients with severe AoS and without previous history of CABG (112 males, aged 73 years) underwent transradial coronary angiography. 136 were performed using the right (R) radial artery and 64 the left (L) radial artery, while 100 were performed using 5 Fr guiding catheters and 100 6 Fr guiding catheters. Thus, four groups of patients were formed (R5, R6, L5, and L6). The primary end-points of the study were procedural success, fluoroscopy time (FT), dose-area product (DAP), number of catheters, and amount of contrast agent. One-way between groups analysis of variance shown statistically significant difference in mean scores of FT and DAP between the four groups [$F (3, 193) = 10.8$, $p < 0.0001$ and $F (3, 192) = 4.8$, $p < 0.05$, respectively]. Post-hoc comparisons using the Tukey HSD test indicated that the mean FT and DAP for group R5 were significantly different from the other 3 groups (6.67±3.10 versus 3.06±1.89 minutes, $p < 0.001$ and 38627±16423 versus 29437±15761 $Gycm^2$, $p < 0.05$, respectively). Among the other three groups, the FT and DAP were not significantly different. There were no significant differences in procedural success, number of catheters, and amount of contrast agent among the 4 groups. Multiple linear regression revealed that radial approach, Fr guiding catheters and Body Mass Index were the independent predictors of FT after controlling for other variables ($R^2 = 0.378$, $p < 0.001$).

CONCLUSIONS

Right radial approach in conjunction with 5 Fr guiding catheters is accompanied by augmented FT and DAP in patients with severe AoS undergoing coronary angiography. Furthermore, left radial approach and right radial approach with 6 Fr catheters may be less FT and DAP consume. These findings imply that catheter size and radial approach should be taken into account in these patients.

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Predilation sizing post-dilation BRS implant in real-world population and complex lesion settings: the REABSORBS registry

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

AIMS
Evaluating safety and efficacy of everolimus eluted BRS Absorb implants with a PSP technique in a real world population.
METHODS AND RESULTS
The single center registry REABSORBS includes all consecutive patients (pt) treated with BRS in our cath lab between 10 December 2012 and 31 December 2016.
Registered endpoints are: cardiac death (CD), target vessel acute myocardial infarction (TV-MI), Academic Research Council scaffold thrombosis (ARC ScT), target vessel revascularization (TVR), target vessel failure (TVF), ischemia driven target lesion revascularization (ID-TLR).
AS is defined as: successful deployment of BRS, residual stenosis (RS) < 30% and final TIMI 3 flow in target vessel.
202 pt of age 58.7 ± 9.7 years (male n=172, 85.1%; diabetics n=32, 15.8%, with ≥ 3 cardiovascular risk factors n=112, 55.4%) were enrolled in the registry, 234 PCI were performed (n=209, 89.3% radial access) on 285 lesions and 350 BRS were implanted.
73 PCI (31.2 %) were hybrid, with BRS and DES implanted in the target vessel, IVUS or OCT was employed in 17 PCI (7.3%).
149 PCI (63.7%) were performed in STEMI, NSTE-ACS or NSTEMI.
Stenoses were localized mainly on left anterior descending artery (n=158, 55.4%), however lesions in any coronary vessel were treated, with the sole exception of the left main; 183 treated lesions (64.2%) were Ellis type B2 or C.
136 pt (67.0%) were on DAPT with ticagrelor, 35 (17.2%) with prasugrel and 32 (15.8%) with clopidogrel.
Preprocedural quantitative coronary angiography (QCA) showed a 83.5 ± 15.2 % diameter and 21.8 ± 11.4 mm lenght stenosis and a 2.89 ± 0.42 mm reference vessel diameter.
Predilatation with non compliant balloon (NCB) at a pressure of 19.7 ± 3.8 atmospheres (atm) was performed in 337 cases (96.3%) with balloon-artery ratio 1:1 in 258 (76.6%).
After careful sizing BRS was released at 13.0 ± 2.7 atm; mean BRS length per vessel was 32.7 ± 18 mm and 29 pt (12.4%) received ≥ 56 mm overlapping BRS on the target vessel.
Marker to marker BRS overlap was present in 184 scaffold (52.6%) while a DES-BRS overlap was present in 41 (17.5%).
Postdilatation with NCB at a pressure of 21.7 ± 4.3 atm was performed in 350 cases (100%) and with balloon diameter 0.5 mm oversized in 147 (42.0%).
Postprocedural QCA showed 12.6 ± 7.9% RS, no RS was > 30%; there were 2 TIMI flow < 3 on target vessel in STEMI pt and 2 BRS implant failure, leading to a 98.9% AS.
We found an inadequate minimal lumen diameter (MLD) in 83 (43.7%) BRS (MLD < 2.5 mm for 2.5-3.0 mm diameter BRS and < 2.9 mm for 3.5 mm ones) without a significant increase in the observed outcomes.
Regarding in-hospital events we had 1 CD (for heart failure, 0.5%) 2 TV-MI (1.0%), 3 TVF (1.5%), 3 TVR (1.5%) and 1 ID-TLR (0.5%).
At a median follow up (FU) of 469 days (interquartile range 208 - 798) in the overall cohort of pt we had 2 CD (both for heart failure, 1.0%), 5 TV-MI (2.5%), 9 TVF (4.5%), 9 TVR (4.5%), 5 ID-TLR (2.5%) and 5 restenosis (2.5%).
We also had 1 definite ARC ScT (0.5%) at 20 months FU leading to an NSTEMI, the BRS was a 2.5 x 28 mm in size and had diffuse restenosis, pt interrupted DAPT 4 months before the event.

CONCLUSIONS
In our experience, with the limitations of the registry's size, PSP implant of BRS Absorb in a real world population with complex lesions seems to have a good AS and a low rate of events at a median FU of 16 months.

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Coronary artery CT as the first imaging test for patients with suspected coronary artery disease and indications for invasive coronary angiography: primary outcomes of the CAT-CAD randomised trial

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Efficacy and safety evaluation of coronary computed tomography angiography (CCTA) as the first choice anatomic test in stable patients with indications to invasive coronary angiography (ICA) due to suspected significant coronary artery disease (CAD).

METHODS AND RESULTS

This is a prospective, randomised, open-label, single centre trial. The study was supported by an Institute of Cardiology in Warsaw, Poland (grant 2.13/III/2015). Between April 23, 2015 and April 28, 2016 we enrolled 120 consecutive stable patients with suspected significant CAD (mean age of 60.6±7.9 years, 42 females). We randomised 60 patients to CCTA group and 60 patients to direct ICA group. Anatomical test results were used to determine the subsequent course of treatment for patients according to routine clinical practice. This included: conservative treatment, subsidiary functional tests, or interventional treatment (PCI/CABG). All patients were monitored for the occurrence of possible primary efficacy and safety outcomes during diagnostic and therapeutic cycle (up to 3 months, or until the last diagnostic/therapeutic procedure was complete). One third of participants 41(34.2%) either had known CAD previously diagnosed on angiography or had previously undergone coronary revascularisation. The patients did not differ significantly with regard to any baseline characteristics, angina symptoms, stress test results, presence and severity of CAD ($p<0.05$ for all characteristics).

The number of patients undergoing catheterisations in CCTA group was reduced by 64.4% as compared to direct ICA group (21 vs 59, respectively), with the median number of invasive procedures in CCTA group significantly lower than in direct ICA group (0[0-1] vs 1[1-2], $p<0.0001$).

The number of patients with non-actionable ICAs (i.e., not directly followed by interventional therapies) was reduced by 88.1% by the CCTA strategy (5 vs 42 respectively, $p<0.0001$).

The composite outcome of myocardial infarction, death, acute coronary syndrome, unplanned coronary revascularisations, cardiovascular related hospitalisation (composed solely of hospitalisations associated with invasive diagnostics or treatment) was reduced by 66.2% in CCTA group as compared to direct ICA group (25 vs 74, respectively, $p<0.0001$). The resulting median length of hospital stay to complete the diagnostic and therapeutic course was significantly lower in CCTA group than in direct ICA group (0[0-2] vs 2[2-5] days, respectively, $p<0.0001$).

Over the diagnostic and therapeutic course, there were no significant differences between both groups regarding the volumes of contrast material (80.3ml [70.0-115.0] vs 90.0ml [70.0-100.0], $p=0.0994$, respectively) while a non-significant trend towards higher radiation in CCTA group was observed (9.9mSv [7.0-22.1] vs 9.4mSv [5.2-14.0], $p=0.0567$, respectively).

ClinicalTrials NCT02591992

CONCLUSIONS

CCTA as the first anatomical diagnostic test in patients with suspected CAD and indications for ICA, may be an effective ‘gatekeeper’ to the cardiac catheterisation laboratory. It allows non-invasive, outpatient based, triage of two thirds of patients without significant or actionable CAD, obviating unnecessary invasive examinations, reducing the number of hospitalisations and its length. Our findings thus seem to bode well for the future role of CCTA, owing to the increasingly recognised relatively low prevalence of actionable, functionally significant CAD in patients with classic indications for ICA.

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A feasibility and safety study of intracoronary haemodilution during primary coronary angioplasty in order to reduce reperfusion injury in myocardial infarction

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Reperfusion injury is a consequence of the restoration of coronary flow during PCI. Dilution of reperfusing blood may help reduce this. We designed a pilot to evaluate the safety and feasibility of a simple approach to haemodilution during PCI.

METHODS AND RESULTS

Ten patients presenting with STEMI underwent intracoronary dilution with room temperature Hartmann’s solution delivered through the guiding catheter during primary angioplasty (PCI). The infusion of perfusate began prior to crossing the occluded artery with the guidewire, continuing until 10 minutes after completion of the balloon and stenting procedure. Infusion was briefly interrupted for contrast injection and pressure monitoring. The outcome measures were safety, including intracoronary temperature reduction and volume of intracoronary perfusate infused, and technical feasibility.There were no significant symptomatic, haemodynamic, ECG ST/T segment or rhythm changes observed during perfusate administration. The median (interquartile range) volume of perfusate administered was 550mls (350-725mls) and the median intracoronary temperature reduction observed was 3.4°Celsius. Myocardial salvage was 0.54 (0.43-0.65).

CONCLUSIONS

Transcatheter intracoronary haemodilution with room temperature perfusate during PCI is feasible and appears safe. Such a strategy is simple and inexpensive, with potential to be widely applied. Further mechanistic and subsequent outcome powered studies are required to evaluate whether such a strategy can reduce reperfusion injury in STEMI.

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Changes in high-sensitivity troponin after DEB angioplasty for DES restenosis

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

AIMS

DEB therapy may be associated with distal embolization of matrix particles, with potential for microvascular obstruction. We aimed to determine if DEB therapy is associated with greater delta troponin post-PCI versus DES or plain balloon angioplasty.

METHODS AND RESULTS

In the ISAR DESIRE 3 trial, patients with limus-eluting stent restenosis were randomized to treatment with a paclitaxel-coated balloon (PCB), paclitaxel-eluting stent (PES) or balloon angioplasty (BA). We included enrolled patients who had pre- and post-intervention high sensitivity troponin (hs-TnT) levels available. Exclusion criteria included target lesion location in the left main stem or in a coronary bypass graft, STEMI within the preceding 48 hours, cardiogenic shock, and severe renal insufficiency. The primary endpoint was delta troponin, defined as the magnitude of change between baseline and peak post-procedural troponin levels, and was compared between the DEB, DES and balloon angioplasty arms. The secondary endpoint was 3-year all cause-mortality according to magnitude of delta troponin by tertile, irrespective of the treatment received.343 patients were included, comprising patients randomised to treatment with PCB (n=115), PES (n=112) and BA (n=116), with a total of 420 lesions. There were no differences the proportion of patients treated as per protocol. Nine lesions in the PEB group were treated with stent implantation; 10 lesions in the PES group were treated with balloon dilatation only; 8 lesions in the balloon angioplasty group were treated with stent implantation (p=0.95). Groups were well-matched in terms of baseline characteristics. Sixty-seven (20.0%) patients presented with ACS at the time of enrolment. There was no difference in delta troponin between patients treated with PCB, PES and BA (36±65, 70±183, and 51±124 ng/L, respectively, p=0.16) in the intention-to-treat analysis. Moreover, there was no significant difference between treatment groups in terms of the proportion of patients with a peak hs-TnT value more than 5 times the 99th percentile upper reference limit of normal: PCB:24 (30.4%); PES:29 (36.7%); and BA:26 (32.9%) patients (p=0.81).The per protocol analysis showed consistent results, with mean delta troponin levels as follows: PCB=34±64; PES=67±182; and BA=42±92 ng/L, respectively (p=0.13). When patients were categorised according tertile of delta hsTnT, there were no significant differences in terms of baseline patient, lesion or procedural characteristics with the exception of a higher proportion of bifurcation lesions in the third tertile and higher mean maximum balloon pressure with each increase in tertile of delta troponin. 3-year mortality was 7.7%, 8.8% and 14.3% for the 1st, 2nd and 3rd tertiles of delta troponin, respectively (p=0.23).

CONCLUSIONS

In patients with in-stent restenosis within a limus-eluting DES, treatment with a paclitaxel-eluting balloon was not associated with a greater troponin rise compared to treatment with DES or balloon angioplasty.

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Slow-speed rotational atherectomy and provisional stenting for bifurcation lesions facilitates procedural success preserving side branch patency

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THEME: Coronary Interventions
TOPIC(S): NSTEMI, Stable CAD, Stents and scaffolds, Left main and multivessel disease, Bifurcation lesion, Other Coronary Interventions

AIMS

Coronary bifurcation lesion (BL) is a hobbyhorse of PCI because commonly suboptimal results are observed. We compare procedural data and stenting technique from patients with BL treated or not with rotational atherectomy (RA)

METHODS AND RESULTS

64 consecutive patients that underwent RA for 87 BL (RA+) were compared with a control group (RA-) of 32 pt with BL non-treated with RA. BL most involved was LAD involving 1st Diagonal branch. Provisional stenting was most used in RA+ than in RA-: 100% vs 59% (p = 0.0.4) We observed a lower need of side-branch treatment in RA+ than in RA- and no acute side-branch happened (p < 0.001) despite the stenting technique used. Less number of stents (p< 0.04) were needed in RA+. Furthermore, TLR and TVR rates were also lower in RA+ (p< 0.01) A higher increase in lumen vessel size and a maximal length stented vessel was observed after RA+: p = 0.009 and p =0.005 respectively

CONCLUSIONS

In a high-risk population slow-speed RAand provisional stenting for BL facilitates procedural success preserving side-branch patency with a low need for side-branch treatment,TLR and TVR rates

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What can intracoronary pressure measurements tell us about flow reserve? Pressure-bounded coronary flow reserve (CFR) and example application to the randomised DEFER trial

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

We propose a new technique called 'pressure bounded coronary flow reserve(pb-CFR)' to bound CFR using only pressure measurements. We apply the technique to the randomized DEFER trial to study the influence of CFR and treatment on high FFR lesions.

METHODS AND RESULTS

While rest and hyperemic intracoronary pressure measurements cannot quantify CFR exactly, they do provide upper and lower bounds. We validated pb-CFR invasively against traditional CFR, then applied it to high FFR (>=0.75) lesions in DEFER randomized to revascularization or medical therapy. pb-CFR showed an 84.4% accuracy to predict invasive CFR<2 or CFR>=2 in 107 lesions. In its proof of concept application to DEFER lesions with FFR>=0.75, the 28 with pb-CFR<2 compared to 16 with pb-CFR>=2 had a non-significant reduction in freedom from angina (61% vs. 71% at 5 years, p=0.75) and a non-significantly higher rate of major adverse cardiac events (MACE, 25% vs. 15%, p=0.34). Lesions with FFR>=0.75 but pb-CFR<2 showed no difference in freedom from angina (61%v vs. 50%, p=0.54) or MACE (25% vs. 38%, p=0.27) between the 28 randomized to medical therapy and the 16 randomized to revascularization.

CONCLUSIONS

pb-CFR offers a novel method for studying FFR/CFR discordances using regular pressure wire measurements. As an example application, DEFER suggested that low pb-CFR with high FFR may be a risk marker for more angina and worse outcomes, but that this risk cannot be modified by revascularizaiton.

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Two-year follow-up of Leaders Free ACS

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

AIMS

This reports on the 2 year results of acute coronary syndrome (ACS) patients from *Leaders Free* randomizing high-bleeding risk patients to a polymer-free BA9-coated stent (BA9-DCS) and a bare metal stent (BMS) with 1-month DAPT.

METHODS AND RESULTS

Leaders Free included 2466 patients undergoing PCI who had at least 1 of 13 pre-defined factors for an increased bleeding risk. Of these, 659 ACS patients were included in *Leaders Free ACS* (BA9-DCS 330, BMS 329). At 24-month follow-up, treatment with the BA9-DCS remained significantly more effective (clinically driven target-lesion revascularization 10.4 vs. 5.0%, HR 0.45 (0.24-0.83), $P = 0.009$) and safer (cumulative incidence of cardiac death, myocardial infarction and probable/definite stent thrombosis, 21.5 vs. 13.0%, HR 0.58 (0.38-0.85), $P = 0.005$) than a BMS.Additionally, definite or probable stent thrombosis tended to be higher in the BMS arm (3.2 vs. 1.3%; $P = 0.1$).

CONCLUSIONS

In high-bleeding risk patients with an ACS a polymer-free BA9-DCS with 1-month DAPT continues to be significantly more effective and safer at 2 years than a BMS. We believe that the BA9-DCS should currently be considered as the device with the strongest evidence to support its use for this indication.

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Thirty-day outcomes in patients treated with a repositionable and fully retrievable aortic valve designed to reduce the incidence of conduction disturbances (RESPOND Extension study)

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

AIMS

The RESPOND Extension Study was designed to assess clinical and device performance outcomes following transcatheter aortic valve replacement (TAVI) with the Lotus Valve with Depth Guard™.

METHODS AND RESULTS

The repositionable and fully retrievable Lotus Valve was evaluated for the treatment of calcific aortic stenosis in routine practice in the 1000-patient RESPOND Post-market Study. Patients from RESPOND demonstrated low 30-day rates of mortality (2.2%) and disabling stroke (2.2%), and exhibited minimal paravalvular aortic regurgitation (PVL) at hospital discharge (92% of patients had no/trace PVL, 7.7% had mild PVL, 0.3% had moderate PVL, and no patient had severe PVL). The rate of new permanent pacemaker (PPM) implantation in RESPOND was 30.0%.The Lotus Valve has undergone recent design changes to reduce the interaction of the valve with the conduction system. The Depth Guard technology, which allows for earlier anchoring of the valve during implantation and minimises interaction of the valve with the left ventricular outflow tract during deployment, in combination with modifications to the valve implant technique, may reduce the need for new PPM implantation.The RESPOND Extension Study enrolled 50 patients at 5 sites in the Netherlands, the United Kingdom, and Poland. The primary endpoint of RESPOND Extension is the rate of all-cause mortality at 30 days post procedure. Additional endpoints include VARC-2 clinical efficacy and safety composites and individual VARC-2 endpoints at 30 days, device performance measures, the grade of pre-discharge PVL, and the incidence of new PPM implantation. Transthoracic echocardiograms are adjudicated by an independent core laboratory.The majority (54%) of patients was female, mean age was 81 years, baseline STS score was 4.4±3.1, and 52% of patients were classified at baseline as New York Heart Association Functional Class III or IV. At baseline, mean aortic valve area was 0.7±0.2 cm^2 and mean aortic valve gradient was 39.1±13.0 mmHg. There were no procedural deaths and no deaths at 30 days, and no instances of life-threatening or disabling bleeding. The rate of disabling stroke at 30 days was 4.0% (2/50 patients). New PPM were implanted in 9/50 patients (18.0%); the site-reported reasons for new PPM implantation were 3rd degree AV block in 8/9 patients (89%), and other (junctional rhythm) in 1 patient. At the time of writing, pre-discharge echocardiographic data were available for 34 patients (68%). Among this cohort of patients, mean aortic valve area was 1.7±0.3 cm^2 and mean aortic valve gradient was 11.7±4.4 mmHg. In this cohort, pre-discharge PVL was absent or trace in 85.3% of patients, 14.7% of patients had mild PVL, and no patients had moderate or severe PVL.Detailed clinical outcome data at 30 days, including echocardiographic data for the full population of patients, will be available at the time of the meeting.

CONCLUSIONS

This report from the RESPOND Extension Study represents the first description of 30-day outcomes in patients treated with the Lotus Valve with Depth Guard, and provides insight into the impact of design and implant technique modifications on the rate of new PPM implantation.

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Real-world use of a repositionable self-expanding transcatheter aortic valve

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

AIMS

We studied the use of the self-expanding Evolut R transcatheter aortic valve (TAV) in routine hospital practice in 1000 patients with symptomatic native aortic valve stenosis or surgical bioprosthetic valve failure.

METHODS AND RESULTS

BACKGROUND: TAVI is considered standard of care at specialized heart centers treating patients with aortic stenosis at high or extreme risk of surgical mortality/morbidity.Clinical evaluations of iterative changes to existing, commercially available valves have studied fewer patients, which has allowed new valves to quickly become available to clinicians. Therefore, clinical outcomes in large patient populations from real-world clinical practice are an important addition to the evidence in support of the use of these new TAVI valves.

METHODS: 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 in a routine hospital setting at 53 centres on 4 continents.The Evolut R TAV is a supra-annular porcine valve in a self-expanding nitinol frame that can be resheathed or fully recaptured to assist with optimal valve positioning. Patients were to have symptomatic native AV or surgical bioprosthesis stenosis and be considered at high or greater risk of surgical mortality/morbidity based on Heart Team assessment. The primary endpoint is all-cause mortality at 30 days compared to a performance goal of 10% (95% confidence interval upper bound) based on a meta-analysis of available literature on the self-expanding CoreValve TAV 30-day mortality. Valve hemodynamics and the incidence of prosthetic valve regurgitation were centrally analysed by an independent core laboratory. The use of the repositioning features of the Evolut R TAV was documented.

RESULTS: Baseline characteristics for the initial 300 patients included mean age 82.0±5.7 years, 67.3% women, with a mean STS score of 5.6±3.8% (83.3% ≤8%) and mean EuroSCORE II of 5.6±4.8%; 72.6% had NYHA III/IV symptoms and 34.1% were considered frail. General anaesthesia was used in 37.0% of patients and most (98.3%) were treated via iliofemoral access. Implanted valve sizes were as follows; 29 mm, 52.5%; 26 mm, 40.5%; and 23 mm, 7.0%. Pre-TAVI balloon valvuloplasty (BAV) was performed in 49% of patients and post-TAVI BAV in 33.4%. The valve was repositioned at least once in 75 patients (25.1%). The AV mean gradient was reduced from 42.5±17.7 mm Hg at baseline to 8.7±6.9 mm Hg at discharge and the mean AV area increased from 0.8±0.3 cm^2 at baseline to 1.9±0.6 cm^2 at discharge. 97.2% of patients had ≤ mild paravalvular leak at discharge. At 30 days, the all-cause mortality rate was 2.0%. The rate of major vascular complication was 2.7%, life-threatening or disabling bleeding was 2.7%, and stage 2 or 3 AKI was 1.0%. A pacemaker was implanted in 15.4% of patients.

CONCLUSIONS

In the initial report from the Evolut R FORWARD Study, the Evolut R TAV was shown to be safe with low incidences of death, bleeding or other complications. Discharge hemodynamics included low single digit mean gradients and exceptionally low rates of moderate/severe paravalvular leak. We plan to present the primary 30-day results from the entire 1000 patient study cohort at the time of the meeting.

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Angiography vs. haemodynamic assessment to predict the natural history of coronary stenoses: an FFR vs. angiography in multivessel evaluation 2 (FAME 2) substudy

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

We aimed to assess the natural history of patients in the FAME 2 trial who received medical therapy only and in whom initial FFR and percentage diameter stenosis (%DS) were discordant.

METHODS AND RESULTS

This study included 607 patients with stable coronary artery disease in whom both FFR and angiographic assessment of %DS by QCA (Quantitative Coronary Analysis) were obtained.

FFR varied from 0.19 to 1.00 (average 0.74 ± 0.16) and %DS (by QCA) varied from 8% to 98% (average 53 ± 15). The primary end point, defined as VOCE (Vessel oriented clinical endpoint), was a composite of cardiac death, vessel-related myocardial infarction, vessel-related urgent and not urgent revascularization. The stenoses were divided in 4 groups according to FFR and %DS values. Positive Concordance (PC: FFR≤0.80; %DS≥50%); Negative Concordance (NC: FFR>0.80; %DS<50%); Positive Mismatch (PM: FFR≤0.80; %DS<50%); Negative Mismatch (NM: FFR>0.80; %DS>50%).

FFR and %DS values were concordant (both positive or both negative) in 534 stenoses (66.8%) and were discordant in (one criteria positive, the other negative) in 265 lesions (33.2%) . A positive concordance (PC: FFR≤0.80; %DS≥50%) was present in 318 lesions (39.8%), a negative concordance (NC: FFR>0.80; %DS<50%) was present in 216 lesions (27%), a positive mismatch (PM: FFR≤0.80; %DS<50%) was present in 152 lesions (19.1%), and a negative mismatch (NM: FFR>0.80; %DS>50%) was present in 113 lesions (14.1%).

The Kaplan Meier Analysis showed the worst outcome in the PC group (Log Rank: X^2=80.96; p=0.001), while in the NC group there was the lowest incidence of events. Moreover, patients of the PM group showed a significant difference in events as compared to patients in the NM group (33% versus 14%; HR, 2.6; 95% C.I., 1.5 – 4.7; p=0.001). Event rates showed little and no significant difference between the PC and the PM groups (both groups with FFR≤0.80) and no significant difference between the NM and NC (both groups with FFR>0.80).

CONCLUSIONS

In patients with stable coronary disease and angiographic-hemodynamic mismatch, FFR assessment more reliably predicts the clinical outcome as compared to the angiographic evaluation.

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Chimney graft technique combined with the endovascular aneurysm sealing technology for complex AAA

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THEME: Peripheral Interventions
TOPIC(S): AAA

AIMS

Chimney graft technique (CGT) was developped to overpass limitations of branched/fenestrated endografts.
We report our experience of the Nellix Endovascular Aneurysm Sealing technology associated with CGT to avoid gutters endoleaks.

METHODS AND RESULTS

Retrospective analysis of prospective data retrieved from 1 center between April 2014 and September 2016 was done. Endpoints were technical success, postoperative morbidity, rate of endoleak and any re-interventions during follow-up.
In this study, 18 patients (mean age 77 years, range 61-88) were identified, including 14 men. The mean aneurysmal diameter was 66mm (range 53-90). Fourteen patients were asymptomatic but 3 patients (18%) were operated in emergency for pain. Mean length of infrarenal neck was 2 mm (range 0-10). Operative time was 214 minutes (range 95-330). Procedural success was achieved in all cases. A total of 43 target vessels (34 renal arteries, 7 superior mesenteric artery and 1 celiac trunk) have been stented using covered balloon expandable stents. Access vessels for the chimneys were the left the left axillary artery in 12 patients and the subclavian artery in 5 cases. In the post-operative period, the only complication observed was acute renal failure in 2 patients and 1 inguinal seroma. No patient died. During the median follow-up of 6 months (range 1-15), 2 re-interventions were performed for 1 type Ib endoleak at 2 months and 1 inguinal seroma at 2 weeks. No type Ia endoleak was observed. The chimney patency rate was 98% (42/43) due to one renal stent occlusion. No death was observed.

CONCLUSIONS

The CGT combined with EVAS is feasible and seems to be safe and effective for the treatment of complex AAA. A low rate of complications and an excellent aneurismal sealing with reduced risk of gutters endoleaks can be obtained with low rate of re-intervention. Moreover, this technique can also be used in case of emergency. More patients and a longer follow-up are required to better define to which population this technique can be effectively proposed.

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Influence of lesion locations on bifurcation lesions treated with two-stent strategy using DES

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

AIMS

We aimed to assess the difference in long-term outcomes of bifurcation lesions treated with the 2-stent strategy using drug-eluting stents (DES) among lesion locations.

METHODS AND RESULTS

We treated 1021 patients with the 2-stent strategy using 502 first-generation DES and 519 second-generation DES between 2004 and 2014. Two-stent strategy was defined as deployment of at least one stent in both the main and side branches of a bifurcation lesion. The primary outcome measure was defined as target lesion revascularization (TLR). Cumulative incidences were estimated by the Kaplan Meier method and compared by the log-rank test. The median follow-up duration was 5.2 years(interquartile range, 3.3 to 7.1 years). Most of the patients were elderly (70.5±10.8 years) and with high rates of diabetes mellitus (41.3%), previous percutaneous coronary intervention (43.2%), and multi-vessel disease (63.7%). Culprit vessels of bifurcation lesions were as follows: left anterior descending artery and its diagonal branch (LAD/Dg, 43.7%), right coronary artery and its branch (RCA/branch, 12.1%), left circumflex artery and its obtuse marginal branch (LCX/OM, 14.6%), and left main coronary artery (LMCA, 29.6%). Nearly all the lesions (91.0%) were true bifurcation lesions according to the Medina classification. Culottes stenting was performed in 65.7% and T-stenting in 34.3%. Intravascular ultrasound was used in 45.8%.The 3-year cumulative rate of TLR was significantly higher in the first-generation DES group than in the second-generation DES group (21.2% vs. 10.9%, log-rank p<0.001). In terms of the 3-year cumulative incidence of TLR, the influence of bifurcation lesion locations on lesions treated with the 2-stent strategy tended to be similar between the first- (log-rank p<0.001, LAD/Dg: 11.6%, RCA/branch: 27.2%, LCX/OM: 32.7%, and LMCA: 27.8%) and second- (log-rank p=0.004, LAD/Dg: 5.3%, RCA/branch: 14.1%, LCX/OM: 19.4%, and LMCA: 13.4%) generation DES groups.

CONCLUSIONS

The long-term outcomes of bifurcation lesions treated with the 2-stent strategy appear to depend on lesion locations in terms of TLR, which was similar in both the first- and second-generation DES groups.

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Activated clotting time guided transradial band removal post-coronary angiography: a pilot study

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

To ascertain whether a rapid release protocol using ACT as a guide to deflate a TR Band decreases total time to wean (TTTW) safely, compared to usual care for patients following radial artery angiography.

METHODS AND RESULTS

This study examined 60 consecutive patients having radial coronary angiography as a day procedure. Patients were randomised to a control or treatment group. The control group followed the usual care using the 4 hour deflation process post TR band application. The treatment group followed an ACT guided rapid release protocol. Baseline clinical characteristics, demographics and procedural characteristics were collected. Complication rates such as bleeding, radial access site haematoma and pain were recorded post procedure. Statistical analysis was carried out to ascertain any differences between the two groups.No statistical difference was found between the control and treatment groups for baseline clinical characteristics. There was a statistically significant reduction in TTTW the TR band in the treatment group 152 minutes $\pm$ *59* vs 231 minutes $\pm$ *26* (mean $\pm$ *SD*); $p<0.001$. 94% of the treatment group (n=30) had ACT levels $\leq$150secs at 120 minutes post application of the haemostatic device allowing removal of the haemostatic device in accordance with the rapid release protocol. Reduction in TTTW in the treatment group was not associated with a statistically significant increase in radial access site bleeding (treatment 7% vs control 0%; p=0.31).

CONCLUSIONS

This study demonstrated that a rapid release TR band protocol using ACT levels as a guide safely reduced total time to wean. A larger study is required to identify whether these results can be replicated in patients requiring higher doses of heparin for coronary intervention.

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Long-term clinical performance of biodegradable polymer-coated sirolimus-eluting stent in unselected real-world Saudi patients - Seven-year results from multicentre SCORES registry

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

AIMS

The purpose of the study was to evaluate long-term safety and clinical performance of Supralimus-Core (Sahajanand Medical Technologies Pvt. Ltd., Surat, India) in unselected real-world complex cohort of saudi patients with coronary artery disease.

METHODS AND RESULTS

SCORES was a multi-centre, observational, non-randomised, post-marketing surveillance registry enrolling patients who had undergone implantation with study stent. The primary end-point of the study was occurrence of major adverse cardiac events (MACE) at 7-years, which is a conglomeration of cardiac death, myocardial infarction, target lesion revascularization (TLR), target vessel revascularization (TVR) and stent thrombosis (ST). A total of 517 patients were intervened successfully with 1044 sirolimus eluting stents. Out of total patients, diabetes and hypertension were observed in 54.0% and 50.5% patients, respectively. The registry involved highly complex lesions, which is demonstrated by 10.5% bifurcation lesion, 13.6% total occlusion, 5.9% restenotic lesions, 8.5% long (>30 mm) lesions, and 14.5% calcified lesions. At least one-year follow-up was completed in 98.3% patients. Median and interquartile follow-up of surviving patients was 5.6 (range, 3.8 - 7.2) years. Long-term follow-up upto 7-year was obtained in 95.5% patients. At 7-year, MACE was found to be 15.2%, which is a composite of 6.9% cardiac death, 6.1% TLR, 1.2% TVR and 0.4% ST. The event free survival by Kaplan Meier method was found to be 84.8%.

CONCLUSIONS

The low incidence of late and very late ST and consequent MACE at long-term follow-up clearly depict excellent safety and clinical performance of Supralimus-Core in unselected real-world complex cohort of saudi patients with coronary artery disease.

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Three-year outcomes of DES in patients with and without diabetes: a pooled analysis of individual patient data from four randomised SORT OUT trials

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Outcome after percutaneous coronary intervention may vary dependent on the type of drug-eluting stent specifically in the presence of diabetes mellitus. The aim was to assess outcome after drug-eluting stents in patients with and without diabetes.

METHODS AND RESULTS

We pooled individual patient-level data from 4 randomized SORT OUT trials (SORT OUT III, IV, V, VI) to assess whether an interaction exists between the presence of diabetes mellitus and treatment with first generation sirolimus-eluting Cypher stent (SES) compared to zotarolimus-eluting Endeavor (ZES-E), zotarolimus-eluting Resolute (ZES-R), biolimus-eluting Nobori/Biomatrix (BES) or everolimus-eluting (EES) Xience/Promus stents. Target lesion failure was defined as the composite of cardiac death, target lesion revascularization (TLR), or definite stent thrombosis.

Of 10,410 patients (diabetic 1,603/non-diabetic 8,807) included in the present analysis, 548/3,216 received SES, 169/993 ZES-E, 254/1,204 ZES-R, 442/2,208 BES and 190/1,186 EES.

In diabetic patients, the zotarolimus-eluting stents ([ZES-E Relative Risk (RR)=1.73, 95% Confidence Interval (CI) 1.18-2.55] and [ZES-R RR=1.68, 95% CI 1.18-2.38]) were associated with an increased target lesion failure rate compared to the first generation SES, while BES [RR=1.00, 95% CI 0.70-1.42] and EES [RR=0.68, 95% CI 0.39-1.18] did not differ significantly from the first generation SES. In non-diabetic patients, only the ZES-R [RR=1.29, 95% CI 1.03-1.62] was associated with an increased target lesion failure rate compared to the SES, whereas ZES-E [RR=1.20, 95% CI 0.94-1.54], BES [RR=1.13, 95% CI 0.93-1.38] and EES [RR=1.07, 95% CI 0.83-1.38] did not differ significantly from the first generation SES. After adjustment for differences in baseline characteristics, none of the newer generation drug-eluting stent improved target lesion failure compared to the first generation SES in non-diabetic patients.

Cardiac death did not differ in diabetic or non-diabetic patients between stent types.

In diabetic patients, rate of definite stent thrombosis did not differ significantly between SES (1.5%), ZES-E (1.8%), ZES-R (1.2%) and BES (1.4%) whereas no definite stent thrombosis were seen in EES treated diabetic patients. In non-diabetic patients, rate of definite stent thrombosis did not differ significantly between SES (1.2%), ZES-E (1.0%), ZES-R (1.1%) and BES (1.2%), however, in non-diabetic patients, EES (0.2%) was associated with a reduced risk of definite stent thrombosis [RR=0.14 95% CI 0.03 - 0.56] compared to SES.

CONCLUSIONS

Compared to the first generation SES, the newer generation drug-eluting stents did not improve outcome in diabetic or non-diabetic patients except for EES, which reduced the risk of definite stent thrombosis.

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A comparison of clinical outcomes between triple antithrombotic therapy vs. DAPT with LAA occlusion in patients with atrial fibrillation undergoing DES implantation

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

There are debates about optimal therapy for patients with atrial fibrillation and PCI. We compared clinical outcomes between triple antithrombotic therapy versus DAPT with LAA closure in patients with atrial fibrililation undergoing DES implantation.

METHODS AND RESULTS

We analyzed total 615 patients with atrial fibrillation who undergoing DES implantation from June 2006 to June 2014. Among 615 patients, we identified 151 patients with triple antithrombotic therapy. We performed matched analysis of 151 triple antithrombotic therapy and 41 patients with DAPT after LAA occlusion using inverse probability weighted model. Primary endpoint was a net clinical outcome, defined as a composite of transient ischemic attack or stroke and major bleeding.
At baseline, patients treated with DAPT after LAA occlusion had higher incidence of diabetes and prior transient ischemic attack or stroke, and higher CHADS2 (2.7 versus 2.11, P=0.005), CHA2DS2-VASC (4.34 versus 2.91, P<0.001) and HAS-BLED score (3.41 versus 1.97, P<0.001). At a median of 36-month follow-up period, the incidence of net clinical outcomes was significantly lower in DAPT after LAA occlusion group than the triple antithrombotic therapy groups despite worse underlying comorbidities (7.41 % vs. 30.2 %, p=0.001, hazard ratio 0.26, 95% confidence interval 0.11 - 0.60), which was mainly driven by reduction of major bleeding (3.7% vs. 12.4%, p=0.01, hazard ratio 0.32, 95% confidence interval 0.14 - 0.76).

CONCLUSIONS

For the patients with atrial fibrillation undergoing DES implantation, DAPT after LAA occlusion was superior to triple antithrombotic therapy with respect to net clinical outcomes which was mainly driven by lower incidence of bleeding. These results suggest that LAA occlusion may be an alternative treatment strategy for patients with atrial fibrillation undergoing DES implantation.

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Transcatheter aortic valve-in-valve implantation using fully repositionable Lotus valve system for failed Mitroflow bioprostheses

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

AIMS

To evaluate the performance and the rate of coronary occlusion of TAVI with Lotus™ Aortic Valve Replacement System (LVS) in patients with degenerated Mitroflow aortic bioprostheses.

METHODS AND RESULTS

Main clinical and procedural data of all “valve-in-valve” (VIV) TAVI with LVS implantation procedures in degenerated Mitroflow bioprostheses performed at our Centre in the last 2 years were collected. The patients had been addressed to valve-in-valve intervention by a local multidisciplinary Heart team. All patients underwent an echocardiographic evaluation on admission and before discharge, as well as a clinical and echocardiographic follow-up at 30 days and 6 months from the procedure.

Thirteen patients (age 77.7±6.6 years, 77% males, STS mortality score 4.8±3.3) were included in the study. All patients had signs and symptoms of advanced heart failure, with 3 patients in NYHA class IV and 10 patients in NYHA class III. VIV TAVI was performed in a 23 mm Mitroflow in 7 cases (53.8%), while the other 6 ones had a 25 mm bioprosthesis. The main indication for surgery was intraprosthetic regurgitation in 5 patients, increased gradients in 3 patients and a mixed defect in 5 patients. A ‘high’ risk of coronary occlusion (as defined by coronary height < 10 mm and/or Valsalva sinus diameter < 30 mm) was recognized in 3 patients.

Implantation success rate was 100%. All procedures were done through femoral access and all required local anaesthesia. Final haemodynamic gradient was 7.4±6.3 mmHg.

There was one case of coronary occlusion (7.7%) occurring two hours after the procedure in a patient judged at high risk (i.e., left main origin at 7.7 mm from the annulus, sinus 29 mm), who was successfully treated by emergency PCI and had a regular uncomplicated clinical course until discharge. In the other two high-risk cases, coronary protection was used but preventative ostial stenting of both RCA and LM was performed in only one case due to slow contrast wash-out from the sinus at final aortogram.

No patients died during the procedure. At discharge echocardiogram all patients who received LVS had a well-seated device and no one had more than mild aortic regurgitation.

At 30 days, there were no deaths or acute cardiovascular events. Only one patient (7.7%) required permanent pacemaker implantation.

CONCLUSIONS

Mitroflow bioprostheses are stented bioprostheses with externally mounted leaflets determining an increased risk of coronary occlusion during VIV interventions. Fully repositionable Lotus Valve System offers the advantage of checking coronary blood flow in all procedural phases. However, coronary protection should be recommended in the presence of high risk features. The occurrence of coronary occlusion in the sub-acute phase, often including the early post-procedural period, is still an issue due to the lack of possible predictors of the timing of this catastrophic event. In patients with Mitroflow bioprostheses and high-risk anatomical features repeat surgery should be considered the first treatment choice.

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RevElution: 12-month clinical outcomes with a novel polymer-free drug-filled stent

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

AIMS

RevElution is the first-in-human clinical trial to evaluate thepolymer-free drug-filled stent (DFS, Medtronic, Santa Rosa, CA). We report for the first time 12-month clinical outcomes from this trial.

METHODS AND RESULTS

Background:

The DFS is formed from a multi-layered wire composed of cobalt chromium for the outer layer, a tantalum middle layer and an inner lumen continuously coated with sirolimus. Small laser-drilled holes on the abluminal stent surface are used to control the rate of drug elution. Previous preclinical studies demonstrate that DFS drug release kinetics and drug tissue levels are similar to conventional polymer-based drug-eluting stents. Additionally, peri-strut inflammation with DFS is similar to bare metal stents in porcine studies.

Methods and Results:

RevElution is a prospective, multi-centre, non-randomised trial which enrolled 101 patients in 2 cohorts with differentiated imaging (OCT, IVUS, angiography) follow-up at 15 clinical sites in 3 countries. Patients were enrolled who had clinical evidence of ischemic heart disease, stable or unstable angina, and up to 2 target lesions in different vessels eligible for treatment with DFS. In the first 50 patient cohort, average age was 66 years old, 76% were male and 30% had diabetes. Fifty-six lesions were treated, of which 76.8% were classified as AHA/ACC type B2/C lesions. The powered primary endpoint, late lumen loss at 9 months, was measured to be 0.26±0.28 mm for DFS compared to 0.36±0.52 mm for Resolute US historical control (p-noninferiority <0.001). The binary angiographic restenosis rate was 0% at 9 months. Median stent strut coverage by optical coherence tomography was 91.4%, 95.6%, and 99.1% at 1, 3, and 9 months, respectively.

CONCLUSIONS

Assessment of 9-month follow up of DFS implantation shows late lumen loss non-inferior to the historical control group. Clinical outcomes at 12 months from 50 patients in the first cohort will be presented for the first time at EuroPCR 2017.

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Three-year clinical outcome following first-generation vs. newer-generation coronary DES implantation: a pooled analysis of the SORT OUT III-VI studies

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

AIMS

We tested the hypothesis that newer-generation drug-eluting stents are superior to the first-generation Cypher sirolimus-eluting stent.

METHODS AND RESULTS

We pooled individual data from the randomized clinical SORT OUT trials III-VI. These trials compared Cypher sirolimus-eluting (C-SES, n=3764 patients), Endeavor zotarolimus-eluting (E-ZES, n=1162), Resolute zotarolimus-eluting (R-ZES, n=1458), Xience V/Promus everolimus-eluting stents (EES, n=1376), and Nobori/Biomatrix biolimus-eluting (BES, n=2650) stents. Stent-related adverse outcome was a composite of cardiac death, target lesion revascularization (TLR), or definite stent thrombosis. C-SES was the comparator stent. The 3-year relative risk (RR) and adjusted RR were calculated. As compared to C-SES, the zotarolimus-eluting stents were associated with increased stent-related outcome (E-ZES: 1.32, 95% CI 1.07-1.62; R-ZES: 1.41, 95% CI 1.17-1.71) whereas no differences were present for BES (1.11 95% CI 0.94-1.32 and EES (0.98, 95% CI 0.78-1.23). TLR was increased for E-ZES (1.62, 95% CI 1.22-2.15) and R-ZES (1.33, 95% CI 1.01-1.77), but not for BES (1.24, 95% CI 0.97-1.58) or EES (0.91, 95% CI 0.65-1.28). All-cause death and cardiac death did not differ between stent types. EES was associated with a major reduction of definite stent thrombosis (0.11, 95% CI 0.03-0.47). Adjustment for baseline characteristics did not change the results.

CONCLUSIONS

In comparison to the first-generation C-SES, none of the evaluated newer-generation drug-eluting stents reduced stent-related adverse outcomes at 3-year follow-up. EES significantly reduced the risk of definite stent thrombosis.

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Initial results from a European wide DEB all-comers registry with an urea-based paclitaxel-coated balloon

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Stents and scaffolds, Left main and multivessel disease, Bifurcation lesion, Other Coronary Interventions

AIMS

This registry investigated the use of drug-eluting balloon (DEB) therapy in daily clinical practice in Europe and aimed to provide further evidence for the safety and efficacy of paclitaxel-coated balloon treatment using urea as inert excipient.

METHODS AND RESULTS

Between December 2013 and December 2015, 757 consecutive patients from 25 European centers treated for all indicated coronary lesions with the In.PACT Falcon balloon (Medtronic, Tolochenaz, Switzerland) were enrolled in this prospective real-world all comers registry. Until yet 700 complete patients data sets with a total of 752 lesions (mean age 66.4 years, 78.7% male) were analysed. Primary outcome measure was the clinically driven target lesion revascularisation (TLR) rate at 12 months. Seconday otucome was major cardiac events (MACE) defined as cardiac death, myocardial infarction, TLR, target vessel revascularisation (TVR). Diabetes mellitus was present in 242 patients (34.6%), hypertension in 526 (75.1%), hypercholesterinemia in 495 (70.7%), renal insufficiency in 90 (12.9%), and 365 (52.1%) had a history of smoking. 288 (41.1%) presented with an acute coronary syndrome with 27 patients with STEMI (3.9%), 149 with NSTEMI (21.3%) and 112 with unstable angina (16%). One vessel disease was present in 322 (46%), two vessel disease in 207 (29.6%) and three vessel disease in 171 (24.4%) patients. 329 (43.8%) out of the 752 lesions were de novo lesions, 397 (52.3%) with DES or bare metal stent (BMS) in-stent restenoses. TLR at 12 month was observed in 5.5% and TVR in 7.7%. MACE occured in 10% with a composite of cardiac death in 0.7% and myocardial infarction in 2.6% plus TLR/TVR. Subgroup analysis confirmed a TLR rate of 6.5% for in-stent restenosis and 4.6% for de novo lesions.

CONCLUSIONS

DEB therapy with a paclitaxel-coated balloon using urea as an inert excipient (In.PACT Falcon) is safe and efficient with a low TLR. The high amount of de novo lesions treated successfully with DEB in this real-world all comers registry indicates that the concept of balloon angioplasty with DEB only is nowadays common and safe with low TLR.

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Online angiography-based FFR assessment during coronary catheterisation

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

FFR_{angio} is a novel technology that uses a patient's routine angiograms to generate a FFR values at each point along the coronary tree. We aimed to explore for the first time the "on-line" application of the system.

METHODS AND RESULTS

The FFR_{angio} system uses the patient's hemodynamic data and routine angiograms to generate a complete three-dimensional coronary tree, with color-coded display of the FFR values at each point along the vessels. We present herein our analysis of the first 35 subjects where FFR_{angio} was used "on-line" in the catheterization laboratory and in comparison to invasive (i.e. pressure wire based) FFR.40 lesions (13/40 significant (≤0.80) were measured with both invasive FFR and FFR_{angio}. Mean FFR was 0.83 (range 0.5 – 0.97). Sensitivity and specificity of the FFR_{angio} were 85% and 100%, respectively.

CONCLUSIONS

The FFR_{angio} system exhibited high usability and generated a FFR_{angio} measure within minutes away from conventional angiography, and a high concordance between FFR_{angio} and invasive FFR was observed. In light of the demonstrated capabilities of the FFR_{angio} system, it should emerge and further validated as a possible alternative for invasive FFR for functional assessment of coronary artery disease.

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TAVI for failed surgical aortic bioprostheses using a self-expanding device: early results from the prospective VIVA post-market study

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

AIMS

The objective of the Valve In Valve trial (VIVA) is to systematically and prospectively collect data regarding use of TAVI with the CoreValve and Evolut R devices in patients with failing surgical aortic bioprostheses at high risk for reoperation.

METHODS AND RESULTS

BACKGROUND: Surgical aortic valve replacement has been the standard of care in symptomatic patients with aortic valve disease. However, bioprosthetic valves degenerate over time, requiring re-do surgery to replace them. As many patients are not candidates for reoperation, a less invasive valve-in-valve procedure using transcatheter aortic valve implantation (TAVI) is an emerging alternative.

METHODS: VIVA is an observational, single-arm, post-market multicentre study conducted at 25 sites in France, Germany, Israel, and Italy, which enrolled 200 patients. Adults with symptomatic degeneration of an aortic bioprosthesis who were acceptable candidates for elective treatment with a self-expanding transcatheter aortic valve were eligible for inclusion. Patients were deemed high-risk for redo surgery by the heart team, and were required to have a logistic EuroSCORE >20% or STS >10%, or presence of comorbidities that contraindicated redo surgery as assessed by at least one cardiac surgeon.

RESULTS: The primary safety endpoint is cardiovascular death at 30 days post procedure, and is expected to be below 10%. The primary efficacy endpoint is lack of significant aortic stenosis (defined as mean gradient > 40mmHg) or insufficiency (defined as > moderate severity) at 1 year post procedure using clinical evaluation and echocardiography. Secondary endpoints are adjudicated according to VARC-II criteria, and include the patient safety composite endpoint and its components, peri-procedural myocardial infarction, major and minor access site complications, major bleeding, stroke, acute kidney injury stage III, new pacemaker implantation, and post-implantation aortic gradient (assessed at each follow-up visit). Patients are assessed at baseline, procedure, discharge, 30 days, 6 months, 12 months, and 24 months. Outcomes at 30 days will be reported at the time of presentation.

CONCLUSIONS

TAVI with a self-expanding device represents a practical alternative for treating patients with failed surgical aortic bioprostheses. This first report from the VIVA study will present 30-day results including the primary safety endpoint.(*both authors contributed equally)

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Safety and efficacy measurements in the global SYMPLICITY registry

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THEME: Interventions for Hypertension
TOPIC(S): Renal denervation

AIMS

The Global SYMPLICITY Registry (GSR) was designed to collect real-world data on the safety and efficacy of renal denervation (RDN). We will report results on a sub-cohort of patients who received treatment of main renal artery and branch vessels.

METHODS AND RESULTS

Background:
GSR is a prospective, multi-centre, non-randomized international registry of RDN. Two key changes in the renal denervation procedure have occurred during the course of enrolment. First, the single electrode Symplicity Flex™ catheter originally used in this study has been replaced by the 4 electrode Symplicity Spyral™ catheter for denervation. This catheter allows simultaneous application of radiofrequency energy in a circumferential pattern designed to treat nerves in all four quadrants around the vessel. In addition, advances in understanding of the renal nerve anatomy has led some sites to extend denervation from just the main renal artery to both main renal artery and branch vessels. Thus, while most data in the registry involves subjects treated in the main renal artery with the Symplicity Flex™ catheter, a subset of patients in GSR were treated with the Symplicity Spyral™ catheter and a group of those patients also had renal artery branch treatment.
Methods and Results:
To date, up to 3000 patients with uncontrolled hypertension have been enrolled. Both short term follow-up on all enrolled subjects and long term follow-up on a subset of these subjects will be presented. Six month safety and efficacy data will be available for ~2500 patients and 3-year data will be available on ~1750 patients. Data from post-hoc analysis of ~270 patients treated with the Symplicity Spyral™ catheter as well as data on ~90 patients who had RDN treatment in both main renal artery and branches will also be available for presentation.

CONCLUSIONS

The Global SYMPLICITY Registry has the largest dataset of renal artery branch treatment reported to date. Non-randomized data from subjects treated with the Symplicity Spyral™ catheter and those with renal artery branch vessel treatment supplement the randomized and sham-controlled SPYRAL HTN-ON MED and OFF MED trials that are currently evaluating safety and efficacy of renal denervation performed in the main renal artery and branch vessels in patients with uncontrolled hypertension.

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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 - BIOSOLVE-II and BIOSOLVE-III

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

AIMS

The 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 6-month post-procedure.

METHODS AND RESULTS

Methods

One hundred eighty four (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 planned during the 12-month follow-up in BIOSOLVE-III. 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.**Results**

117 (63.6 %) men and 67 (36.4 %) women were enrolled at 21 clinical sites in 8 countries in Europe, Brazil and Singapore.

The mean age was 65.5 ± 10.8. Based on preliminary data, 79.3% of the subjects presented with hypertension, 62% with hypercholesteremia, 55.4% were smoker, and 25% diabetics. Type A (41.8%), Type B1 (39.2%), Type B2 (14.8%) and Type C (4.2%) lesions (based on visual estimation) were treated. 32.8% of the lesions were located in the right coronary artery (RCA), 41.8% in the left anterior descending (LAD), 22.8% in the left circumflex (LCx) and 2.6% in the ramus intermedius (RI).

180 subjects had their 1-month clinical follow-ups performed. TLF rate at 1 month is (1.1%) including 1 cardiac death (not device related) and 1 target vessel MI.

No clinically driven TLR, definite or probable scaffold thrombosis have been reported up to 1-month follow-up.

CONCLUSIONS

The full clinical results of the combined BIOSOLVE-II and BIOSOLVE-III studies until 6-month follow-up will be available upon presentation.

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Is the pressure wire useful to predict reperfusion pulmonary oedema after balloon pulmonary angioplasty in chronic thromboembolic pulmonary hypertension?

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

AIMS

To analyze if pressure level distal to target lesions after balloon pulmonary angioplasty (BPA) measured with pressure-wire, correlates or not with the appearance of reperfusion pulmonary edema (RPE) in chronic thromboembolic pulmonary hypertension

METHODS AND RESULTS

BPA is a new therapy for patients with chronic thromboembolic pulmonary hypertension (CTEPH). However, BPA can induce RPE which may lead to mortality. It has been hypothesized that if the mean pressure level of the vasculature distal to the target lesions can be regulated <35mmHg during BPA, this procedure could be performed without risk of RPE.

Methods. From May 2013 to December 2016, 145 consecutive BPA sessions were performed in 45 patients with non-surgical CTEPH at our institution. We started using pressure wire to guide BPA procedures since September 2015. We measured “Pd” value (mean PAP distal to target lesions) after dilation of every branch. The dilation was stopped once the size of the balloon used for dilation reached 90% of the vessel size or, in terms of avoidance of RPE, if the “Pd” value after any dilation, reached 35 mm Hg.

Results. Seventy-three BPA sessions were performed during the initial period, without pressure-wire guidance, and 72 during the latest period, with pressure-wire guidance. Baseline clinical characteristics and hemodinamic parameters were similar between both groups. A total amount of 177 branches were measured with the pressure-wire. In 16 of them pressure-wire was used in unclear lessions, to determine if the angiographic image corresponded to a web or to a bend of the artery. If pressure ratio (FFR) was over 0.80, BPA was not performed because the angiographic image was considered to correspond to a non obstructive web or to a bend of the artery. Mean pressure ratio in those vessels not treated was 0.96. In 161 vessels, pressure wire was used to guide the BPA procedure, trying to maintain “Pd” below 35 mm Hg during BPA. The final mean FFR and final mean Pd measured with pressure-wire after BPA in those lesions treated were 0.52 and 22.9 mm Hg respectively. A final FFR > 0.80 after BPA was very uncommon, as it only was achived in 13 (8%) of BPA treated lesions.

The incidence of RPE of grade 2 or higher was similar in the no-guided sessions and in the pressure-wire guided sessions, 5/73 (6.8%) and 4/72 (5.6%) respectively, without statistically significant differences. A value of Pd > 35 mm Hg after BPA did not correlate with the appearance of RPE: 3/54 (5.6%) in the sessions with Pd ≤35 mm Hg vs 1/9 (11%) in the sesions with Pd > 35 mm Hg, p not significant.

We analyzed which factors were related to the occurrence of RPE of grade 2 or higher. Mean PAP, cardiac output, cardiac index and pulmonary vascular resistance before the procedure; being the first BPA sesión and being on epoprostenol previous to BPA were significantly related to the occurrence of RPE according to univariate analysis. Multivariate analysis using variables with a significant correlation in univariate analysis demonstrated that mean PAP previous to BPA was the only factor related to the occurrence of RPE (p=0.03).

CONCLUSIONS

In pacientes with CTEPH, using pressure-wire to guide BPA procedures did not reduce RPE after BPA compared to sessions without pressure-wire guidance. A value of Pd > 35 mm Hg distal to target lesions after BPA did nor correlate with the occurrence of RPE. Mean PAP before BPA was the only factor related to the appearance of RPE in multivariate analysis.

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Interaction between coronary stents and length of DAPT: a network meta-analysis of 64 randomised controlled trials and 102,735 patients

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

AIMS

Potential differences between type of drug-eluting coronary stent (durable polymer vs. biodegradable polymer vs. bioresorbable) and duration of dual antiplatelet therapy (DAPT) remain to be defined.

METHODS AND RESULTS

Randomized controlled trials comparing different Drug Eluting Stents (DES) and/or length of dual antiplatelet therapy were selected. The primary endpoint was MACE (a composite end point of death, myocardial infarction (MI), and revascularization). Definite Stent Thrombosis (ST) and single components of MACE were secondary endpoints. The following were the arms of interest: BRS (bioresorbable stent) with a DAPT of 12 months (12mDAPT), biodegradable polymer stent with a 12mDAPT, durable polymer stent (everolimus-eluting; EES) with a 12mDAPT, durable polymer stent (zotarolimus-eluting; ZES) with a 12mDAPT, EES/ZES with a DAPT of less than 12 months (DAPT<12m), and EES/ZES with a DAPT of more than 12 months (DAPT>12m).

64 studies with 150 arms and 102,735 patients were included. 59% (39-68) of the patients had stable angina. After a median follow up of 20 months (range 18-30), MACE rates were not different between durable polymer, biodegradable polymer and bioresorbable stents. Among EES/ZES stents however, MACE rates were higher for ZES vs EES with 12mDAPT (OR 1.21; 1.03-1.43) but not with DAPT>12m. In this group there was a reduced risk of ST and MI when compared with other second generation DES.

CONCLUSIONS

MACE rates were not different between durable polymer, biodegradable polymer and bioresorbable stents given 12 months DAPT. EES/ZES with prolonged antiplatelet therapy offered a risk reduction for MI and ST compared to other second generation DES. Type of stent should be considered when choosing appropriate length of DAPT.

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PCI or CABG in left main coronary artery disease: a comprehensive meta-analysis of adjusted observational studies and randomised controlled trials

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

AIMS

PCI has been compared with CABG for patients with ULMCA (Unprotected Left Main Coronary Artery Disease), without conclusive results. Aim of this meta-analysis is to overcome divergences coming from different RCTs and adjusted observational studies.

METHODS AND RESULTS

All randomized controlled trials (RCTs) and observational studies with multivariate analysis comparing PCI and CABG for ULMCA were included. Major cardiovascular events (Maces, composite of all-cause death, MI, definite or probable ST, target vessel revascularization and stroke) were the primary end points, while its single components the secondary ones, along with stent thrombosis, graft occlusion and in hospital death and stroke.. Sensitivity analyses were performed according to Syntax score.

6 Randomized Controlled Trials (4717 patients) and 20 observational studies with multivariate adjustment (14597 patients) were included. After 5 (3-5.5) years, MACE rate was higher for PCI (OR 1.10, 95%CI 1.07-1.14), without difference in death, while more relevant risk of MI was due to observational studies. Coronary stenting increased risk of revascularization (OR 1.52:1.34-1.72). At meta-regression, performance of PCI was improved by use of intra-coronary imaging and worsened by first generation stents, while two arterial grafts increased benefit of CABG. For patients with Syntax score <22, MACE rates did not differ, while for higher values CABG reduced MACE due to lower risk of revascularization. Incidence of graft occlusion was 3.24% (2.25-4.23), while2.13% (1.28-2.98: all CI 95%) of patients. experienced stent thrombosi

CONCLUSIONS

Surgical revascularization reduces risk of revascularization for ULMCA patients, especially for those with Syntax Score>22, with a higher risk of in hospital death. Intra-coronary imaging and use of arterial grafts improved performance of revascularization strategies.

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Femoral vs. radial access for rotational atherectomy - A UK-wide observational study of 8,622 patients

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

AIMS

Published data to support radial access in patients undergoing rotational atherectomy are limited. We compared the early clinical outcomes for patients undergoing rotational atherectomy via the femoral or radial route.

METHODS AND RESULTS

The British Cardiovascular Society-National Institute of Cardiovascular Outcomes Research database identified all patients in the United Kingdom who underwent rotational atherectomy between 1st January, 2005 and 31st March, 2014. The study primary outcome was 30-day mortality. Secondary outcomes were procedural success, in-hospital major bleeding, major access site complications and major adverse cardiac and cerebrovascular events. Multivariable logistic regression analysis was performed to allow a valid comparison of outcomes between patients treated via femoral and radial access sites.8,622 rotational atherectomy cases (5,553 femoral [64.4%] and 3,069 radial [35.6]) were suitable for inclusion in the analysis. The total number of cases and the proportion of patients treated using radial access increased yearly throughout the study period. 30-day mortality was 2.29% in patients undergoing rotational atherectomy using femoral access vs. 2.18% in the radial group. Following adjustment for baseline co-variates, radial access was associated with equivalent 30-day mortality (odds ratio (OR): 1.08, 95% confidence interval (CI): 0.77 to 1.52, p = 0.65), procedural success (OR: 1.01, 95% CI: 0.81 to 1.27, p = 0.91) and major adverse cardiac and cerebrovascular events (OR: 0.98, 95% CI: 0.74 to 1.29, p = 0.86), but markedly lower rates of in-hospital major bleeding (OR: 0.55, 95% CI: 0.35 to 0.85, p = 0.01) and major access site complications (OR: 0.04, 95% CI: 0.01 to 0.28, p = 0.001), compared with femoral access.

CONCLUSIONS

In the largest published comparison of outcomes based on access site for patients undergoing rotational atherectomy, femoral and radial access were associated with equivalent 30-day mortality, procedural success and major adverse cardiac and cerebrovascular events. Radial access was associated with markedly reduced in-hospital major bleeding and major access site complications. We believe radial access should be the default arterial approach for rotational atherectomy, due to equivalent efficacy and superior safety, compared with femoral access.

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Biological safety and efficacy of paclitaxel-coated stent implantation following DEB usage - One-month healthy swine model study

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THEME: Peripheral Interventions
TOPIC(S): Below the knee, Other peripheral interventions

AIMS

The aim of the current study was to determine the biologic and safety effects of the use of bare metal stent (BMS) vs. Zilver PTX (ZPTX) following drug coated balloon angioplasty or plane old balloon angioplasty (POBA).

METHODS AND RESULTS

In a healthy swine model, 4 groups (DCB+ZPTX, POBA+ZPTX, DCB+BMS, and DCB alone) were assessed in the iliofemoral arteries of 12 healthy swine, with sacrifice at 30 days. The vascular and skeletal muscle changes in the downstream (skeletal muscle and coronary band) regions were also assessed. ZPTX showed the highest biological drug effect irrespective of underlying DCB usage or POBA , with the highest medial smooth muscle cell loss in both depth [DCB+ZPTX vs. POBA+ZPTX vs. DCB+BMS vs. DCB only; 4.0 (IQR 4.0-4.0) vs. 3.8 (IQR 3.5-4.0) vs. 3.0 (IQR 2.3-3.9) vs. 2.2 (IQR 1.5-2.6), respectively, p=0.009] and circumferential [4.0 (3.6-4.0) vs. 3.5 (3.1-3.9) vs. 2.0 (1.6-2.6) vs. 1.2 (1.0-1.3), respectively, p=0.007]. The percentage of sections with changes in muscular arteries and arterioles were only seen with the use of DCB. The paclitaxel-associated fibrinoid necrosis in downstream tissues in the DCB+BMS was 26.9% [IQR 17.3-30.8], DCB+ZPTX 14.3% [IQR 0.0-28.6] and DCB only 19.2% [IQR 7.7-36.5]).

CONCLUSIONS

Irrespective of use of DCB or POBA prior to implantation of Zilver PTX, Zilver PTX showed the maximum biologic effects in the neointima and media suggestive of superior drug effect with Zilver PTX. Distal vascular changes were exclusively seen in groups with DCB. Therefore showing the safely and efficacy of Zilver PTX.

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Effects of ticagrelor vs. clopidogrel on myocardial infarct size in patients undergoing primary PCI

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

This study sought to compare the effects of ticagrelor and clopidogrel on myocardial infarct size in patients with ST-segment myocardial infarction (STEMI).

METHODS AND RESULTS

We performed a 2-center, prospective, randomized, open-label, blinded end-point trial. A total of 110 patients with STEMI undergoing primary percutaneous coronary intervention (PCI) were randomly assigned to the ticagrelor group (180 mg loading dose, 90 mg twice daily thereafter) or the clopidogrel group (600 mg loading dose, 75 mg daily thereafter)at a 1:1 ratio. The primary end point was myocardial infarct size assessed by cardiac magnetic resonance imaging (CMR). Evaluable CMRs were available in 45 and 50 patients of the ticagrelor and clopidogrel groups, respectively. Myocardial infarct size was significantly smaller in the ticagrelor group than in the clopidogrel group (21.5±10.9% versus 26.5±11.3%, p=0.03). The extent of microvascular obstruction was also significantly smaller in the ticagrelor group than in the clopidogrel group (3.9±4.1% versus 6.4±6.3%, p=0.02). There was a significant difference in peak creatine kinase-MB level between the 2 groups (170.4 [80.5-267.4] ng/ml versus 232.7 [117.1-310.2] ng/ml, p=0.04). However, there was no significant difference in residual platelet reactivity at the time of PCI (P2Y12 reaction units by VerifyNow; 216.1±83.6 versus 231.0±64.0, p=0.34).

CONCLUSIONS

Ticagrelor was superior to clopidogrel for reducing myocardial infarct size in patients undergoing primary PCI. Our results suggest that the benefit of ticagrelor may be due to its ability to reduce infarct size and prevent recurrent vascular events.

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Decompression with implantation of a non-covered stent in the true lumen in patients with aortic dissection after endovascular or surgical treatment and visceral and/or peripheral ischaemia

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

AIMS

after surgical or endovascular treatment of acute aortic dissection the early rate of complications remains high. the aim of the study was to investigate the feasibility for decompression of the true lumen with non-covered stents.

METHODS AND RESULTS

we represent a case series of 8 patients (7 men and 1 woman), mean age 51.9 ± 16 years, age range 15-67 years. all patients had survived acute aortic dissection type A or type B, and had been treated with surgical prosthesis implantation, percutaneous stent graft implantation or medical therapy in the acute period. most of the patients presented in critical general condition, with severe symptoms and evidence of end organ ischaemia after the acute stage of aortic dissection. we performed computed tomography (CT) aortography in all patients. the morphological analysis of the aorta included localization of intimal tears, compression zone, and measurement of true and false lumen diameter before and after decompression. the compression zone was on the level of aortic arch in 25% of the patients, and on the thoracoabdominal level in the rest (75%) of them.

we performed urgent decompression in all patients, using different stent types- with the same immediate result: centralization of the flow and expansion of the true lumen and false lumen thrombosis. true lumen diameter increased from 6.28 ± 4.15 mm before the procedure to 22.63 ± 3.65 mm after decompression, $p < 0.001$, while false lumen diameter decreased from 29.69 ± 9.98 mm to 13.25 ± 15.29 mm, $p = 0.001$. we achieved immediate symptom relief in all patients with restoration of flow in aortic branches. the follow-up period of our patients vary from one year to ten years and there was no mortality during this period

CONCLUSIONS

centralisation of flow and decompression in the true lumen in patients with complicated aortic dissection after endovascular or surgical treatment and visceral and / or peripheral ischemia, can be achieved with implantation of non-covered stents. it appears a safe and effective way of restoring the flow in the aortic true lumen and its side branches, leading to positive aortic remodeling and relieve of end-organ ischemia

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Three-year final outcomes of the phase I mitral valve repair clinical trial (MAVERIC I) using the ARTO system for the treatment of functional mitral regurgitation

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

AIMS

Evaluate the initial safety and feasibility of the ARTO™ System in patients with functional mitral regurgiatation associated with congestive heart failure.

METHODS AND RESULTS

The ARTO™ system percutaneously modifies the mitral annulus to improve leaflet coaptation in patients with functional mitral regurgitation (FMR) and systolic heart failure (HF). This presentation will be the first report of Three Year/Final outcomes from the Phase I of MAVERIC trial.The MAVERIC I trial was a prospective, single arm, first in man study. Key inclusion criteria were symptomatic systolic HF with NYHA Class II-IV, FMR grade ≥ 2+, LVEF ≤ 40%, LVEDD > 50 mm and ≤ 75 mm. Exclusion criteria consisted of clinical variables that precluded feasibility of the ARTO procedure.The primary safety outcome was major adverse event rate at 30 days post-procedure with planned 6 month, and yearly follow-up for 3 years. The primary efficacy outcome was FMR grade change from baseline to 30 days. Secondary outcomes included NYHA Class, LV volumes, and other echocardiographic indices. An independent DSMB monitored the study and a CEC adjudicated all major adverse events.11 consecutive patients were enrolled at a single center between October 2013 and May 2014.Baseline patient characteristics include: mean age 60 $\pm$11; male 81.8%; LVEF 37.5% $\pm$7.7; prior coronary intervention 53.7%, atrial fibrillation 81.8%, COPD 27.3%, 1.1 $\pm$0.7 heart failure hospitalizations in the 2 years prior to treatment and 82% of patients were NYHA Class III/IV.To summarize previously reported safety data: 30 day outcomes reported include 100% procedural success with no deaths, myocardial infarctions, strokes, or renal failure. One patient developed a pericardial effusion which was surgically drained without recurrence. One patient had an asymptomatic dislocation of the coronary sinus T-Bar noted on routine follow-up CT scan and underwent successful elective surgical MV replacement on post procedure day 65. In the first 30 days there were no additional events reported. There were 2 deaths between 1 and 2 year follow-up, 1 cardiac and 1 non-cardiac at approximately 19 months post procedure. Complete 3 year safety data will be presented at EuroPCR 2017.To summarize previously reported efficacy outcomes: From baseline to 30 days, there were meaningful improvements. 90% of patients had MR grade 3+/4+ at baseline and at 30 days, 79% were in Grades 1+ or 2+. Regurgitant volumes decreased from 38.2 ± 12.1 to 16.4 ± 9.7ml. LV end-diastolic volume index improved from 118.7 ± 28.6 to 103.9 $\pm$ 21.2 ml/m2. Mitral annular anteroposterior diameter decreased from 45.0 ± 3.3 to 37.8 ± 2.3mm. Functional status was 82% NYHA functional class III/IV improving to 55% functional class I/II. All of these outcomes were stable or improved over the course of follow-up to 2 years. We intend to present the 3 year efficacy data of the entire Phase I at EuroPCR 2017.

CONCLUSIONS

The MAVERIC I trial establishes the safety and efficacy of the ARTO system in the treatment of FMR associated with systolic HF. Key highlights of the trial include a low rate of adverse events and structural improvements in cardiac function as well as clinical status. Ongoing investigation is underway in the currently enrolling multicenter MAVERIC II trial.

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Transesophageal vs. intracardiac echocardiography from the left atrium for procedural guidance of transcatheter LAA occlusion

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

The purpose was to compare the safety and efficacy of intracardiac echocardiography (ICE) from the left atrium with transesophageal echocardiography (TEE) for procedural guidance of transcatheter left atrial appendage occlusion (LAAO).

METHODS AND RESULTS

A single-centre, observational cohort study of 216 consecutive patients undergoing LAAO with the Amplatzer™ Cardiac Plug or Amulet™. Procedures were guided by ICE from the left atrium with local anaesthesia (n=109) or by TEE using general anaesthesia (n=107). All patients had preprocedural cardiac CT. Primary efficacy outcomes were procedural success, procedure time, and rate and degree of peridevice leak based on TEE 6 weeks after LAAO. The primary safety outcome was a composite of periprocedural complications.

Baseline characteristics and indications for LAAO were comparable between cohorts. CHA_2DS_2-VASc score (TEE: 4.4 ± 1.6 vs. ICE: 4.1 ± 1.6, p = 0.1) and HAS-BLED score (TEE: 4.1 ± 1.1 vs. ICE: 4.1 ± 0.9, p = 0.8) were similar between the ICE and TEE cohort. The LAAO procedural success was 100% and 99.1% in the TEE and ICE cohorts, respectively. A periprocedural complication occurred in 4.7% of the TEE cohort, and 1.8% of the ICE cohort (p = 0.2). The ICE cohort had significantly shorter procedure time (44 vs. 55 min, p < 0.001) and turnover time in the catheter lab. Contrast use and radiation dose were reduced with ICE guidance. The rate and degree of peridevice leak did not differ between cohorts at follow-up TEE.

CONCLUSIONS

ICE from the left atrium to guide LAA occlusion as compared to TEE is safe and effective, without increased procedure-related complications. By the use of ICE, time spent in the catheterization room, contrast use and radiation dose significantly decreases, while the completeness of closure is similar to TEE guided procedures.

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Safety and efficacy of a novel everolimus-eluting stent system in "Real-world" patients with coronary artery disease: a report of six-month outcomes from ongoing ‘SEE-Real' registry

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

AIMS

We aimed to evaluate the clinical outcomes with Tetrilimus, a recently introduced coronary stent system (Sahajanand Medical Technologies Pvt. Ltd., Surat, India), in the treatment of ‘real-world’ patients with coronary artery disease.

METHODS AND RESULTS

The Safety and Efficacy of a novel Everolimus-eluting stents in ‘Real-world’ patients (SEE-Real) registry was a retrospective, singe-arm, open-label, multi-centre registry. All patients who had received Tetrilimus stents between July-2015 and April-2016 at two tertiary care centres in India were analysed. Tetrilimus, the study stent, is a novel biodegradable polymer coated everolimus-eluting cobalt-chromium coronary stent system with ultra-thin (60 μm) strut thickness. After stent implantation, all patients were followed-up at 30 days and at 6 months. Primary endpoint was 6-month incidence of major adverse cardiac events (MACE), which was defined as a composite of cardiac death, myocardial infarction, target lesion revascularization, and target vessel revascularization. The Academic Research Consortium (ARC)-defined stent thrombosis was assessed as additional safety endpoint.

During the study period, 280 Tetrilimus stents (1.4±0.5 stent/patient) were implanted to treat 252 coronary lesions (1.1±0.3 stent/lesion) in 208 patients (mean age: 57.5±11.9 years). Among them, 137 (65.9%) were male, 97 (46.6%) were hypertensive, 52 (25%) were diabetic, 76 (36.5%) were alcoholics, 61 (29.3%) were smokers, 29 (13.9%) were tobacco chewers, 11 (5.3%) had previous revascularization, and 94 (45.2%) displayed multi-vessel coronary disease. Of treated lesions, 170 (67.5%) were complex (i.e. Type B2/C) and 47 (18.7%) had total occlusion. The average length and diameter of implanted Tetrilimus stents were 25.5±8.8 mm and 2.9±0.3 mm respectively. Subsequently, the 30-day MACE were reported in 2 (0.96%) patients; both cases owing to in-hospital cardiac deaths. At 6-month follow-up, MACE were reported in 6 (2.88%) patients, comprising 4 (1.92%) cases of cardiac death and 2 (0.96%) cases of myocardial infarction. Events of stent thrombosis were not reported in any patient, while noncardiac deaths were reported in 2 (0.96%) patients at the end of 6-month follow-up.

CONCLUSIONS

Tetrilimus everolimus-eluting stents demonstrated encouraging safety and efficacy at 6-month follow-up in terms of low MACE rates and absence of stent thrombosis in unselected real-world patients with coronary artery disease, including those with high-risk characteristics and complex lesions.

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The ATI score (Age-Thrombotic burden-Index of microcirculatory resistance) determined during primary PCI predicts final infarct size in patients with STEMI: a cardiac magnetic resonance validation study

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

The age-thrombus score-index of microcirculatory resistance (ATI) score can predict suboptimal myocardial reperfusion in STEMI patients. We aimed to validate the ATI score against cardiac magnetic resonance imaging (cMRI).

METHODS AND RESULTS

The ATI score was calculated using [Age (>50 = 1 point); pre-stenting index of microcirculatory resistance (IMR) (>40 and <100 = 1 point; ≥100 = 2 points) and angiographic thrombus score (4=1 point; 5=3 points)]. cMRI scan was performed within 48 hours from admission and at 6 months follow up to assess the extent of infarct size (IS%) and microvascular obstruction (MVO%).

The ATI score was calculated prospectively in 80 STEMI patients. cMRI scanning was performed within 48 hours in all patients and in 50 patients at six months follow up. ATI score was closely related to final IS%(ATI_{0-1}: 16.5% [8.7 – 22.9], ATI_{2-3}: 28.5% [15.5 – 35.0], ATI_{4-5-6}: 35.5% [22.2 – 44.4], p: 0.001) and with MVO% (ATI_{0-1}: 0.0% [0.0–0.9], ATI_{2-3}: 0.7% [0.0–2.5]and ATI_{4-5-6}: 4.1% [1.2–10.7], p< 0.001). Furthermore, ATI score predicted final IS% at six months follow up (ATI_{0-1}: 12.7% [4.1 – 18.0], ATI_{2-3}-: 16.30% [8.0 – 24.7], ATI_{4-5-6}: 29.5% [19.9 – 49.5], p: 0.02).

CONCLUSIONS

The ATI score performed prior to stenting in patients with STEMI, can predict the likelihood of MVO% and IS% both acutely and at six months follow up cMRI.

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Change in angiogram-derived management strategy of patients with chest pain when some FFR data are available: how consistent is the effect?

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

To assess the consistency in the difference in management resulting from an FFR-directed versus and angiogram-directed strategy.

METHODS AND RESULTS

A methodical search was made using MEDLINE, Current Contents Connect, Google Scholar, EMBASE, Cochrane library, PubMed, Science Direct, and Web of Science. Eight studies were identified using the eligibility criteria. A total of 2468 patients were recommended to have optimal medical therapy (OMT) alone after initial angiographic assessment but, after FFR results were available, a total of 716 (29.0%) were referred for revascularisation (PCI 626 patients (25.36%); CABG 90 patients (3.64%)). Similarly, 3766 patients were originally committed to PCI after initial angiography: of these 1454 patients (38.61%) were reconsidered to be suitable for OMT alone and 71 individuals (1.8%) were deemed suitable for CABG after FFR data were available. Further, of 366 patients referred for CABG based on angiographic data, the availability of FFR data changed the final decision to OMT alone in 65 patients (17.76%) and PCI in 51 patients (13.9%). Overall, the angiogram-derived management was changed in 22-48% of these study populations when FFR data were available.

CONCLUSIONS

Some use of FFR during coronary angiography alters the angiogram-directed management in a remarkably consistent manner. These data suggest that routine use of FFR at the diagnostic angiogram would improve patient care

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Clinical outcomes after BRS implantation with optimisation strategy; insights from Milan experience

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

AIMS

The aim of this study was to investigate clinical outcomes after bioresorbable vascular scaffold (Absorb BVS; Abbott Vascular, Santa Clara, CA) implantation using a dedicated implantation strategy.

METHODS AND RESULTS

518 consecutive lesions (340 patients) treated with BVS between May 2012 and August 2016 were analyzed. The primary endpoint was target lesion failure (TLF) defined as a composite of cardiac death, target vessel myocardial infarction (MI), and target lesion revascularization (TLR). Each of the component of TLF and other endpoints including scaffold thrombosis (ScT) were also investigated.

The mean age of population was 63.0±10.2 years; 25.6% was diabetes mellitus (5.9% was insulin dependent); mean left ventricular ejection fraction was 55.2±8.4%; 23.5% had an acute coronary syndrome. Left anterior descending artery was the most common vessel treated (60.1%), followed by left circumflex artery (20.2%), right coronary artery (16.2%). The majority of target lesion (76.0%) were type B2 or C lesions, involving bifurcation (46.1%) and severe calcification (22.6%). Pre-dilatation was performed in 97.1%, using scoring or cutting balloon (16.4%) and rotation atherectomy (3.7%). The number of scaffolds implanted per patient was 2.3±1.4, of which total length was 53.8±33.5mm. Prevalence of use of 2.5mm BVS per patient was 44.7%. Post-dilation were performed in almost all lesions (99.8%) with non-compliant balloon (balloon/scaffold diameter ratio: 1.03±0.09) at high-pressure (21.0±4.3 atm). In the majority of cases (86.1%), intravascular imaging was performed. Following IVUS further intervention was required in 23.9% of lesions based on the imaging evaluation after post-dilatation. The median follow-up period was 665 (interquartile range 340-1017) days. The cumulative TLF rates evaluated with Kaplan Meier method were 7.1% at 1 year and 12.4% at 2 years. The rates of cardiac death were 1.0% at 1 year and 2.1% at 2 years, target vessel MI 1.6% at 1 year and 2.1% at 2-years, and TLR 6.2% at 1 year and 11.0% at 2 years. Definite or probable ScT occurred in 4 patients (1.2% at 1- and 2-years); 1 acute (day 0), 1 subacute (day 3), and 2 late (day 63 and 143). There was no occurrence of very late ScT.

CONCLUSIONS

Clinical outcomes after BVS implantation are acceptable in a real-world population with high prevalence of complex lesions. The results are likely to be achieved by an optimization strategy with meticulous lesion preparation, post-dilatation, and intravascular imaging guidance.

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Clinical outcomes after hybrid therapy with DEB and DES for the same lesion; international multicentre registry

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

AIMS

The aim of this study was to evaluate clinical outcomes after treatment for the same lesion with combination of DEB and DES.

METHODS AND RESULTS

We retrospectively evaluate the lesions that were partially or completely treated with both DEB (paclitaxel-eluting balloon) and DES in 3 high-volume centers (2 centers in Italy and 1 center in Japan). The primary endpoint was major adverse cardiac events (MACE) defined as composite of cardiac mortality, target vessel myocardial infarction (MI), and target lesion revascularization (TLR).

From June 2009 to December 2015, 1460 lesions (1137 patients) were treated with DEB. Of these, 136 lesions (114 patients) were enrolled for this registry. The mean age of the population was 68.1±9.7 years; 36.0% was diabetes mellitus (DM) (12.3% were insulin dependent); 50.9% with chronic kidney disease (CKD) defined as estimated glomerular filtration ratio <60ml/min./1.73m^2 and mean left ventricular ejection fraction was 52.7±9.6%. Regarding the lesions treated, left anterior descending artery main branch was the most common (35.3%), followed by right coronary artery (19.1%), and left circumflex artery (16.9%). There was one left main trunk lesion and 38 (27.9%) lesions on side branches. The type of lesions were as follows; focal: 16.9%, diffuse: 72.1%, and CTO: 11.0%. Type B2 or C lesions were 85.3% including characteristics such as in-stent restenosis (ISR) (28.7%), calcification (33.1%), bifurcation (33.8%), and small vessel <2.5mm (26.5%). For these lesions, DEB inflation (mean diameter: 2.74±0.45 mm, length: 32.3±6.5 mm) was performed at 10.2±3.6 atm and DES implantation was subsequently required due to bailout for dissection (32.4%), residual stenosis after DEB inflation (39.7%), while in 26.5% was intentionally attempted at the operator's discretion. The majority of DES implanted was Xience/Promus (Boston Scientific, Natick, MA, USA) (41.9%), followed by SYNERGY (Boston Scientific, Marlborough, MA, USA) (16.9%). The lesions where DES implantation partially (20.6%) or completely (79.4%) overlapped the lesions treated with DEB initially. The median follow-up period was 804 (IQR: 378-1655) days. The cumulative rate of MACE evaluated with Kaplan-Meier method was 4.0% at 1 year, and 16.4% at 2 year, which was mainly driven by TLR (4.0% at 1 year, 16.4% at 2 year, respectively). There were no occurrences of cardiac death, target vessel MI and definite/probable stent thrombosis. The patients who experienced TLR were not particular subset regarding comorbidities when compared with total population in this registry (DM: 35.7% and CKD:57.1%), whereas, regarding lesion characteristics, there were higher risks of restenosis including type B2 or C lesions (94.1%) and ISR (58.8%).

CONCLUSIONS

The clinical outcomes after combined therapy with DEB and DES for lesions with high complexity were acceptable at 2-year follow-up. TLR rate gradually increased during follow-up. Further investigations with larger number and long-term follow-up are required to confirm the results from this registry.

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Are NSTEMI patients' perception of illness severity depending on acute versus subacute pathways?

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

AIMS
To explore and compare NSTEMI patients' experiences of different PCI pathways related to acute and subacute invasive treatment and the impact of the different pathways on patients' illness perception.

METHODS AND RESULTS
A qualitative study was conducted with 10 patients suffering from a confirmed NSTEMI. The patients were included from an ongoing RCT. Five patients, who had undergone respectivelyprimary PCI and subacute PCI, were interviewed one month after hospital discharge. A semi-structured interview guide was used. The analysis was conducted according to meaning condensation by Kvale and Brinkmann. To optimise the credibility of the analysis process researcher triangulation was performed.
The analysis of the data revealed three themes illustrating the patients' perceptions of illness from onset of symptoms to discharge from hospital. Overall, at the onset of symptoms patients did not perceive that they had had a severe condition as a heart attack. However, one month after discharge, all patients recognised the severity of their illness. At this time they had experienced physical and mental consequences following their NSTEMI.
The first theme "Management of symptoms" highlights the patients' difficulties interpreting their symptoms. All patients connected their symptoms to earlier experienced symptoms. They did not believe their situation was life-threating, demanding acute contact to the health care system.
The second theme "Experience of intensity during treatment" illustrates how patients experienced the in-hospital treatment different according to urgency and intensity of the PCI procedures. Despite differences in the patients' experiences, this did not impact the patients' perception of illness severity.
The third theme "Facing the future" demonstrates the severity of their illness was clear to all patients one month after discharge. Being at home and living their everyday life with the physical and emotional consequences of the NSTEMI contributed to recognition of the illness severity. All patients were motivated to pursue lifestyle changes due to this.

CONCLUSIONS
Patients with NSTEMI following two different pathways, acute or subacute, did not differ in their perception of illness severity and motivation for lifestyle changes despite different intensity in in-hospital treatment. All patients recognised the severity of their illness one month after discharge. The results from this study do not support previous studies indicating that different modalities in patients presenting with NSTEMI and STEMI impact their illness perception and motivation for lifestyles changes.

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Angiographic and clinical performance of a DEB using butyryltri-n-hexyl citrate as drug carrier compared to a new generation DES eluting a limus analogue in patients with in-stent restenosis - The BIOLUX randomised controlled trial

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

AIMS

DEB may represent an attractive option for patients with restenosis, although it is not known whether they are as safe and effective as new-generation DES eluting limus analogues. We aimed to prove if DEB is angiographic non-inferior compared to DES.

METHODS AND RESULTS

Methods: The BIOLUX-RCT trial is a prospective, multicentre, international non-inferiority, randomized controlled trial enrolling subjects with in-stent restenosis in BMS or DES.Between July 2012 and Jan 2015, 229 subjects stratified for diabetes were randomly assigned 2:1 to DEB (157 subjects) or DES (72 subjects). DAPT was given has per standard at site. Patients had the angiographic follow up at 6 months and clinical follow ups at 6, 12 and 18 months. Angiographic results were analysed by an independent core lab and all clinical events were adjudicated by an independent clinical events committee.

Results: In the intention-to treat population, 171 male (74.7%) and 58 (25.3%) female were enrolled at 14 sites in Germany and Latvia. The mean age was 67.9±9.6. 93.4% of the subjects presented with hypertension, 85.6% with dyslipidaemia, 58.5% with a multi vessel disease, 55.9% with a history of myocardial infarction and 31.4% with diabetes. Majority of lesion were in limus eluting stents (52.0%) and BMS (35.7%); and classified to Mehran class IC (53.3%) and II (27.9%). 36.0% of the lesions were in the RCA, 31.9% in the LAD and 27.6% in the LCX. There was no statistical significant difference in baseline or lesion characteristics between both groups. The primary endpoint late lumen loss at 6-month was evaluated with 0.03±0.40mm for DEB and 0.20±0.70mm for DES (Difference of DEB minus DES = -0.17±0.52mm; 97.5% CI [-Infty;-0.01], p-value for non-inferiority < 0.0001). Target lesion failure based on Kaplan-Meier survival estimates at 18 months was comparable between the two groups (p=0.88) with 82.6% (CI [75.5;87.8]) for DCB and 80.5% for DES (CI [68.5;88.4]). Sub-group evaluation of patients presenting with in-stent restenosis in DES showed similar results with no difference between the two groups.

CONCLUSIONS

DEB using Butyryltri-n-Hexyl Citrate as drug carrier are an attractive treatment option for patients with restenosis in BMS and DES. Angiographic results at 6 months and clinical results up to 18 month are comparable to the results with a new generation DES eluting a limus analogue.

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Clinical and angiographic outcomes of a dedicated sirolimus-eluting stent in patients with de novo coronary bifurcation lesions

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

AIMS

Evaluation of the safety and efficacy of the Nile SIR dedicated sirolimus-eluting stent in the treatment of coronary bifurcation lesions.

METHODS AND RESULTS

This is an observational study of the initial experience with the Nile-Sir stent. Thirty-eight lesions in 37 patients were prospectively included. The in-hospital and 12 month clinical events after stent implantation were evaluated. Data on a subgroup of 15 patients who agreed on having an angiographic control between 6 and 12 months were also analysed.

The mean age of the studied population was 59.7±9.1 years, being 78.4% male, 37.8% of patients with diabetes mellitus, 43.2% with hypertension, 10.8% with dyslipidemia and 29.7% of patient with previous myocardial infarction. Clinical presentation was mostly stable angina 64.9% of patients and unstable angina in 35.1% of the cases.

The target coronary vessels were 74% of LAD/Dg and 26% of LCx/OM. The true bifurcation lesions, described according to the Medina classification, comprised 24% of type 1,1,1; 11% of type 1,0,1 and 13% of type 0,1,1 lesions. There were no procedure complication with a procedure success of 97.3% (one dissection successfully treated with an additional stent) and no adverse cardiac event at discharge.

After a mean follow-up time of 13.4±1.9 months post-procedure, there were no major adverse cardiovascular event (MACE; defined as a composite of myocardial infarction, target lesion revascularization and cardiac death), which was the study primary endpoint.

In the 15 patients with angiographic control at a mean follow-up time of 9.7±3.8 months post-procedure, the in-stent and in-segment diameter stenosis at follow-up were 13.2% and 16.6% in the main vessel and 18.6% and 18.1% in the side branch respectively. The in-stent and in-segment late lumen loss was 0.19±0.27 mm and 0.14±0.21 mm in the main vessel and 0.08±0.21 mm in the side branch.

CONCLUSIONS

This preliminary study with the Nile SIR biodegradable polymer sirolimus-eluting dedicated stent demonstrated encouraging clinical and angiographic results in the treatment of bifurcation coronary artery lesions. The angiographic results showed a very good efficacy of the device with very low in-stent and in-segment late lumen loss at follow-up in all the segments of true bifurcated lesions.

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Clinical outcomes using a balloon occlusion technique for closure of the aortocaval fistula after transcaval TAVR

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

AIMS

Transcaval TAVR has recently been shown to be a valuable alternative to TF-AVR in case of severe iliofemoral disease. Success or failure of transcaval TAVR depends upon successful access and especially closure of the aorto-caval fistula after TAVR

METHODS AND RESULTS

Between December 2016 and January 2017, four consecutive patients with severe aortic stenosis underwent TAVR via transcaval approach using the Portico^{TM} transcatheter heart valve (St Jude Medical, MN, USA). Based on pre-procedural multi-slice computed tomography (MSCT) imaging, a calcium-free window in the aortic wall facing the vena cava inferior (VCI) – around lumbar vertebra #3 and at a minimum distance of 25 mm from the renal arteries – was identified as the target for transcaval crossing. The crossing was performed using a steerable guiding sheath, 0.035” and 0.018” microcatheters, and a 0.014” Confianza Pro 12 coronary guidewire with an amputed tip, while having a 25 mm gooseneck snare in the aorta at the target zone for snaring. After crossing and introducing a stiff Lunderquist wire through the the 0.035” microcatheter from the femoral vein into the ascending aorta, a 18 to 20Fr introducer sheath was inserted and a successful TAVR was performed using a Portico^{TM} transcatheter heart valve. In order to assure a controlled and safe closure of the aorto-caval fistula with a 8x10 mm Duct Occluder (St Jude Medical, MN, USA), a 16 to 20 mm Tyshak-II balloon (NuMED, NY, USA) was inflated in the descending aorta few millimetres above the puncture site during the aorto-caval shunt closure. After closure device deployment, the Tyshak-II balloon was deflated and re-inflated for 30-60 seconds at the site of the closure device to ensure good wall-apposition of the closure device disk. A final abdominal aortogram was obtained to assess aortic wall closure and/or potential presence of a remaining shunt to the VCI or retroperitoneal space. Successful closure and optimal wall-apposition of the closure device disk was confirmed in all four patients by contrast-enhanced MSCT angiography of the aorta two days post-procedure. In one of the four patients, there was still minor residual contrast shunting from the aorta through the closure device into the VCI; there were no signs of retroperitoneal bleeding. The mean hospital length of stay was 2.5 days and all four patients left the hospital in a good clinical condition.

CONCLUSIONS

This new percutaneous adjunctive balloon occlusion technique resulted in controlled, safe, and successful percutaneous closure of the aorto-caval fistula in patients after transcaval TAVR. In addition, a brief balloon post-dilatation of the closure device disk can help in obtaining better wall-apposition of the disk to the inner aortic wall. This technique needs to be tested in a larger patient cohort before it can be recommended as standard technique in transcaval TAVR.

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One-year clinical outcomes of percutaneous treatment with sirolimus-eluting balloons: results from Nanolute prospective registry

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THEME: Coronary Interventions
TOPIC(S): STEMI, Stable CAD, Stents and scaffolds, Left main and multivessel disease

AIMS

We sought to analyse the safety and efficacy of Sirolimus Coated Balloon MagicTouch (Concept Medical Research Pvt Ltd) in patients with the lesions in native coronary vessels in real world.

METHODS AND RESULTS

Total 383 patients were enrolled in this prospective multicentre registry. The primary endpoints included Major Adverse Cardiac Event (MACE), which is defined as composite of cardiac death, Target Vessel-Myocardial Infarction (TV-MI) and Target lesion/ Vessel Revascularization (TLR/TVR) at 6 months. Secondary endpoint of the study was MACE at 12 months.452 devices have been used to treat 408 coronary lesions in 383 patients. 44.91% patients accounted for Diabetes Mellitus whereas 10.97% patients accounted for ST-Segment Elevation Myocardial Infarction (STEMI). Majority of the lesions were located in LAD (47.06%) followed by LCX (24.26%), RCA (24.02%), Ramus (3.68%), graft (0.74%) and LM (0.25%). SCB alone treatment was employed in most of the patients (89.82%). Additional treatment with DES was done 5.74% of the patients. 6 month follow up was completed in 94.25% patients while 12 months follow-up was completed in 87.20% patients. The incidence of primary endpoint i.e., MACE at 6 months was 3.32%. MACE at 12 months was reported as 4.49% mainly driven by TLR/TVR of (3.89%) followed by TV-MI (0.30%) and Cardiac Death (0.30%).

CONCLUSIONS

Our results suggested that treatment of lesions in native coronary vessels with MagicTouch SCB is associated with good clinical outcomes with low MACE rate.

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Clinical implication of the bifurcation angle in left main bifurcation intervention with two-stent technique: wide angle is related with poor clinical outcomes in crush strategy

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

AIMS

We sought to find the impact of bifurcation angles on clinical outcomes in left main (LM) bifurcation percutaneous coronary intervention (PCI).

METHODS AND RESULTS

Patients treated with 2-stent technique for LM bifurcation lesion were included from COBIS [Coronary Bifurcation Stenting] II, EXCELLENT [Registry to Evaluate Efficacy of Xience/Promus Versus Cypher in Reducing Late Loss After stenting], RESOLUTE-Korea [Registry Evaluate the Efficacy of Zotarolimus-Eluting Stent], and SNUH [Seoul National University Hospital] LM registry. Angles between LM and left descending artery (LAD) (LM-LAD), LM and left circumflex artery (LCx) (LM-LCx), and LAD and LCx (LAD-LCx) were measured at left anterior oblique (LAO) caudal view. Primary endpoint was target lesion failure (TLF), a composite of cardiac death, spontaneous myocardial infarction, or target lesion revascularization. A total of 462 patients with LM disease were analyzed in this study. The median (SD) values of angles of LM-LAD, LM-LCx, and LAD-LCx were 80°(64°-102.0°), 151.0°(134.0°-165.0°), and 130.0°(108.1°-138.0°), respectively. Median (SD) follow up duration was 965 (648) days. 167 (36.1%) patients were treated with T-stent strategy, 181 (39.2%) with crush, 81 (17.5%) with kissing, and others (6.9%) with culotte or V-stent strategy. In whole patient population, each angle in LM bifurcation did not affect TLF rate. However, in patients treated with crush technique, LM-LAD angle was significantly associated with TLF. Best cut-off value of LM-LAD angle to determine TLF occurance was 152° (AUC 0.63, 95% CI 0.53-0.73). TLF occurred more frequently in patients with wider LM-LAD angle (≥152°), compared with others (36.9% vs. 15.5%, p=0.005). LM-LCx (AUC 0.51, 95% CI 0.41-0.61) and LAD-LCx (AUC 0.44, 95% CI 0.34-0.53) angles were not associated with TLF. In Cox regression analysis, independent predictors of TLF in crush technique were wide LM-LAD angle (≥152°) (HR 2.78, 95% CI 1.47-5.27), chronic total occlusion of main vessel before procedure (HR 3.38, 95% CI 1.20-9.49) and long lesion of main vessel (≥20mm) (HR 2.04, 95% CI 1.12-3.71). By contrast, in patients treated with T-stent technique, each angle in LM bifurcation was not an important factor for TLF occurrence (LM-LAD AUC 0.49, 95% CI 0.38-0.59, LM-LCx AUC 0.52, 95% CI 0.41-0.62, LAD-LCx AUC 0.51, 95% CI 0.40-0.61). In cox-regression analysis, chronic total occlusion of main vessel (HR 3.30, 95% CI 1.10-9.86) and side branch calcification (HR 3.46, 95% CI 1.55-7.73) were independent predictors for TLF in this patient group.

CONCLUSIONS

Wide angle between LM-LAD (≥152°) was associated with poor clinical outcome in patients treated with crush technique for LM bifurcation lesion.

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Safety and efficacy of novel abluminal coated sirolimus-eluting stent in the treatment of lesions in native coronary vessels

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

AIMS

We sought to assess the safety and efficacy of Abluminus DES+ Sirolimus eluting stent (Envision Scientific Pvt. Ltd.) in the patients with coronary lesions with native coronary vessels.

METHODS AND RESULTS

en-ABL e-registry is prospective, multicentre post marketing registry. We analysed total 1951 patients with lesions in native coronary vessels. The principle endpoints of the study were incidence of Major Adverse Cardiac event (MACE) and Stent Thrombosis (ST) at 1, 9, 12 and 24 months. MACE was defined as composite of cardiac death, target-vessel myocardial infarction, and target lesion/vessel revascularization. ST was defined according to Academic Research Consortium (ARC).Total 2543 Abluminus DES+ devices were employed to treat 2313 lesions in 1951 patients. The study population was dominated by male patients (79%). 36.34% patients presented with diabetes mellitus. Almost half of the patients presented with hypertension (44.44%). Acute myocardial infarction accounted for 35.26% of the patients. Majority of the lesions were located in left anterior descending (48.81%). 80.36% patients completed 1 year follow –up. The incidence of MACE was 2.42% mainly driven by TLR (1.66%), followed by TV-MI (0.51%) and cardiac death (0.26%). ST was reported as 0.76% at 1 year. 2 years follow –up was available for 58.12 % of the patients. There was increment of one MACE at 2 years.

CONCLUSIONS

The treatment of ABLUMINUS® DES+ demonstrated good clinical safety and efficacy. It persistently reduced the rate of revascularization up to 2 years of follow up.

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Differences in FFR after PCI in patients with stable angina, ACS and STEMI

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

AIMS

FFR after PCI is a predictor of late adverse cardiovascular events. Most studies only included patients with stable coronary lesions. The aim of this study was to investigate differences in FFR after PCI in patients with stable angina, ACS or STEMI.

METHODS AND RESULTS

The FFR SEARCH study is a prospective registry in which all consecutive patients underwent FFR evaluation after successful PCI. FFR measurements were performed with a novel over-the-wire monorail catheter (Navvus, ACIST Medical Systems, Eden Prairie, MN) inserted over the previously used coronary guidewire to approximately 20mm distal of the most distal stent edge. FFR measurements were performed in resting conditions and under maximum hyperaemia with intravenous Adenosine. A total of 701 patients (209 with stable angina, 255 presenting with an ACS and 237 with a STEMI) were included with 954 successfully treated and measured lesions. Overall, mean FFR value during resting condition was 0.96±0.04 and 0.91±0.06 under maximum hyperaemia. No significant differences in post PCI FFR between groups were found in resting conditions. Conversely, a significant difference between the groups in post PCI FFR was observed under maximum hyperaemia. The average FFR in STEMI patients was 0.93±0.06, while the average FFR in patients presenting with an ACS was 0.90±0.06 and the average FFR in patients with stable angina 0.89±0.07, $p<0.001$. Post-hoc analysis showed that these differences were significant in patients with STEMI vs. patients with stable angina and in STEMI patients vs. patients presenting with an ACS. Conversely, no difference was found between ACS patients and patients with stable angina.

CONCLUSIONS

FFR values measured directly following successful PCI are significantly higher in patients presenting with STEMI than in patients with ACS or stable angina.

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Characteristics and outcomes of patients ≤75 years undergoing TAVI - Insights from the SOURCE 3 registry

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

AIMS

There is an ongoing discussion whether indications for TAVI should be extended to younger ages, however, little data are available for younger patients.

METHODS AND RESULTS

Thus, the purpose of this study was to analyze characteristics and outcomes of patients ≤ 75 years in the large real-life SOURCE 3 Registry and compare it to the ones in the older, more “typical” TAVI population. Of a total of 1945 patients undergoing TAVI with the Edwards Sapien-3 valve in the SOURCE 3 Registry (transfemoral access, 87.1%; mean age 81.5 ± 6.6 years, female, 48.0%) only 15% (n=291) were 75 years old or younger. They had a significantly lower log. EuroSCORE (13.0% vs. 19.3%, p<0.001) and were less frequently female (37.1% vs. 49.9%, p<0.001).

Younger patients, however, revealed higher rates of current smokers (46.2% vs. 27.2%, p<0.001), COPD (21.6% vs. 15.1%, p=0.007) and diabetes (36.4% vs. 28.3%; p=0.007) as well as more severe coronary heart disease (history of myocardial infarction 17.2% vs. 10.8%, p=0.0029 and CABG 19.9% vs. 9.9%, p<0.001). In turn, atrial fibrillation was less frequently present in younger patients (17.2% vs 23.6%, p=0.019). Of particular note, there was a remarkably higher rate of not risk-score-accounted risk factors such as severe liver disease (5.8% vs. 1.1%), hostile chest (9.6% vs. 2.9%) and porcelain aorta (9.3 vs. 4.0%, all p<0.001).

Regarding intraprocedural parameters, the group of patients ≤75 years differed by a greater number of 29 mm valves implanted (32.6% vs. 20.7%, p<0.001) and slightly shorter fluoroscopy time (13.2 vs. 14.1 min, p=0.001). No significant differences between both groups were detectable in procedural outcomes. 30-day and 1 year outcomes including overall mortality (1.4 vs. 2.4%, p=0.29, and 14.1 vs. 12.3%, p=0.43), cardiovascular mortality (0.7 vs. 1.8%, p=0.18, and 8.3 vs. 12.3%, p=0.82), disabling stroke (0.7 vs. 0.5%, p=0.66 and 1.4 vs. 1.4%, p=0.86), and new pacemaker implantation (9.6 vs. 13%, p=0.11, and 11.1 vs 14.2%, p=0.15) did not significantly differ between age groups. The only exception was less new-onset atrial fibrillation in patients ≤75 years after 1 year of follow-up (3.8 vs 6.8%, p=0.053, and 4.5% vs 8.4%, p=0.026).

CONCLUSIONS

In current practice of TAVI, patients 75 years old or younger still represent a minority. Despite the younger age and a significantly lower risk score their 1-year survival did not differ from the older, higher risk patients. This – as well as their selection for TAVI - may, however, be explained by a worse risk profile not accounted for by traditional scores. These results emphasize the need for more data in this age group to guide the decision between surgery and TAVI.

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Self-expanding DES in coronary bifurcation lesions at 48 months follow-up: long-term results from the OPEN II trial

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

AIMS

We assessed in a real world population the long term efficacy of the STENTYS DES, a self-expanding stent designed for provisional approach, which has shown previously high procedural success and low major adverse cardiac events rate.

METHODS AND RESULTS

In the OPEN II non-randomized study, 207 patients who received the STENTYS Paclitaxel eluting stent in routine coronary bifurcation stenosis were enrolled in 21 European centers between 2011 and 2013. They were followed up prospectively at 6 and 12 months and yearly up to 4 years. Main exclusion criteria included Medina class 0,0,1, chronic total occlusion, unprotected left main artery, and STEMI. Acute and 24 months follow-up clinical endpoints were presented earlier. Revascularization was successful in 99% in the main branch, and 91% in the side branch. Stenting in the side branch was performed in 13% of the procedures. Major adverse cardiac events at 6, 12 and 24 months (resp. 10.1%, 13.0% and 15,7%) confirmed that the STENTYS stent is a true alternative to balloon expandable DES for the provisional approach. Final kissing balloon technique appeared not to be required.

CONCLUSIONS

Long term rate of major adverse cardiac events at 48 months follow-up will be presented. The OPEN II study is the largest study assessing the self-expanding STENTYS DES in bifurcation lesions in a routine clinical setting.

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Transcatheter tricuspid valve reconstruction with a sutureless and adjustable device: initial results from the multicentre first-in-man trial

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

AIMS

The Cardioband system enables percutaneous treatment of functional tricuspid regurgtation (TR). We herein report the initial results from the first-in-man study of the Cardioband system for interventional treatment of TR.

METHODS AND RESULTS

Between October and December 2016, eight patients with symptomatic TR grade III or IV were enrolled at 2 sites in Europe. All patients underwent standardized echocardiographic and cardiac computed tomographic screening procedures. Echocardiographic data were analysed by an independent core-lab. All patients were discussed in the Heart-Teams of the participating centres. All but one patient were female (88%), mean age was 71 years (range 55-81). 88% of patients presented in NYHA class III-IV at baseline. Mean left ventricular ejection fraction was 51% (range 39-60%). Acute procedural success, defined as device successfully implanted with acute reduction of TR to grade ≤2, was achieved in all patients (100%). The septo-lateral diameter was reduced by approximately 25% in all patients after cinching of the Cardioband device. The reduction of septo-lateral diameters remained stable at 30-days follow-up. No major adverse events were reported and no procedural or 30-days mortality occurred.

CONCLUSIONS

Early outcomes suggest high feasibility and a very good safety profile of transcatheter direct tricuspid annuloplasty with the Cardioband system in selected patients with significant and symptomatic TR. Effective acute reduction in TR severity was observed in all patients. Tricuspid annuloplasty with the Cardioband system led to a significant reduction of septo-lateral diameters in all patients. Follow-up is ongoing and the longterm effects of the Cardioband procedure on TR and functional outcomes will be further validated in the ongoing trial.

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Hydrostatic pressure gradient implantable ultrafiltration device: a novel approach for extracellular fluids removal

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

AIMS

We developed a permeable intraperitoneal absorption chamber. A negative hydrostatic pressure is induced in the chamber, prompting fluids ultrafiltration through the peritoneal membranes into the chamber and drained to the urinary system.

METHODS AND RESULTS

A PTFE disk shaped absorption chamber with 15mm diameter one-sided orifice was covered by semi-permeable membrane. The absorption chamber was implanted in the peritoneum cavity of six rats. A micro-catheter that drains the fluids from the chamber was routed to percutaneous port. Drainage and sampling of fluids were conducted for 4 weeks. Extracellular fluids were drained from the chambers at an average rate of 2.8 ± 0.4 cc/kg/hour during intermittent hydrostatic vacuum induction. The fluids electrolytes and proteins were comparable to the serum content. The average drainage rate remained stable throughout 4 weeks of follow up, ranging between 2 to 3.3 cc/kg/hr. Unlike designated chambers, catheter based designs drained only 0.4±0.2 cc/min per square centimeter, 25 folds less than the membrane based devices.

CONCLUSIONS

Implantable absorption chamber enables systemic extracellular fluids removal through the peritoneal membranes, probably due to the direct interface between peritoneal and device’s membranes and negative hydrostatic pressure. More broadly, this study suggests that an implantable absorption chamber system may be used in fluids overload clinical conditions, providing future novel heart failure therapy for diuretic resistance patients.

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New fully bioabsorbable patch-based large hole vascular closure device

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

AIMS

Aim: To assess the safety and clinical performance of a new fully percutaneous patch based synthetic absorbable Large Hole Closure Device (18-24F).

METHODS AND RESULTS

Method: A prospective, multi-centred, non-randomized study was conducted across 6 European centres; patient enrolment was completed on 14 November 2016. Patients undergoing a transfemoral procedure with an arteriotomy in the range 18F to 24F were included. Post procedure follow-up assessments were at discharge, 1, 3 and 12 months. The primary outcome was the incidence of (peri-procedure to 3 months post-procedure) major vascular complications according to the Valve Academic Research Consortium-2 (VARC-2) criteria. The secondary outcomes were the incidence of (peri-procedure to 3 months post-procedure) minor vascular complications (VARC-2) and device technical success rate.Results: 62 patients (70 closures) were enrolled; 42 closures post TAVI procedures, 16 (24 closures, including 8 bilateral closures) post Endovascular Aneurysm Repairs and 4 closures post Thoracic Endovascular Aneurysm Repairs. To date, 62 patients have completed pre-discharge assessments, 55 patients have completed 1-month assessments, 52 patients completed 3-month assessments and 12 patients completed 12-month assessments. There were no major device related complications, no late vascular access site complications and no clinically significant haemodynamic changes on Duplex Ultrasound or CT-angiogram. Three subjects had device related minor complications: one asymptomatic stenosis identified 1 day post implantation (not present at 1-month follow-up); one haematoma on day of implantation and one pseudoaneurysm 1 day post implantation. There have been no other complications related to the closure device reported from all completed follow-up assessments. Device technical success rate was 97%.

CONCLUSIONS

Conclusions: All clinical data to date, including earlier generation device data, has not shown any device related major or minor complication occurring post discharge from any of the 122 subjects treated, of which 103 subjects have 3-month follow-up assessments completed and 55 subjects have completed 12-month follow-up assessments, demonstrating this new closure technology has been consistently safe for percutaneous transfemoral large hole closure.
This new patch based design large arteriotomy Vascular Closure Device is a safe, effective, easy to use, fully absorbable and fully percutaneous option for large transfemoral arteriotomy closure.

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Atrial fibrillation reduction by renal sympathetic denervation (the AFFORD study)

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THEME: Interventions for Hypertension
TOPIC(S): Renal denervation, Other hypertension

AIMS

This study aimed to assess whether renal sympathetic denervation decreases atrial fibrillation (AF) burden in hypertensive patients with symptomatic paroxysmal or persistent AF at 6 months follow-up as measured using an implantable cardiac monitor.

METHODS AND RESULTS

A total of 20 patients with symptomatic paroxysmal or persistent atrial fibrillation (EHRA ≥ 2) and primary hypertension with a mean office based systolic blood pressure of >140mmHg were enrolled. Patients were included between July 2014 and February 2016. After enrollment and 3 months before renal sympathetic denervation (RDN), an ICM was implanted to continuously monitor heart rate and rhythm during the pre-procedural and follow-up period. The ICM monitors atrial tachycardia (AT)/AF burden and ventricular rhythm during atrial arrhythmias. RDN was performed using a dedicated multi-electrode unipolar denervation catheter with the intention to achieve 8 successful ablations per artery. Patients were subsequently followed-up at 1, 3 and 6 months for AF burden, blood pressure control and quality of life assessed using the Atrial Fibrillation Effect on QualiTy-of-life [AFEQT] questionnaire. Yearly follow-up is currently ongoing.

A total of 11 females and 9 males were included, mean age was 64 ± 7yr. At baseline, 75% of the patients presented in EHRA class II and 25% in EHRA class III. Most patients were on rhythm control (19/20) and 4 patients had a history of pulmonary vein isolation. Diabetes was present in 15% of the patients, 40% had dyslipidemia and 10% had a history of stroke. At 3 months no changes occurred in anti-arrhythmic drug regimen.

Office blood pressure decreased from 153 ± 17/88 ± 11mmHg at baseline to 135 ± 15/81 ± 8mmHg at 3 months ($p<0.001$) while mean heart rate on 24h holter monitoring remained unchanged. AF burden decreased at 3 months post treatment. AF minutes/day (median [IQR]) was 1.33 minutes [0-11.0] at baseline versus 0 minutes [0-1.70] at 3 months ($p=0.091$), the number of AF episodes was 1.0 [0-4.0] at baseline versus 0 [0-1.0] at 3 months ($p=0.065$). The total AF minutes/episode was 113 minutes [0-956] versus 0 minutes [0-44.50] at 3 months ($p=0.026$). On 24h holter monitoring no significant change was seen in supraventricular ectopic and ventricular ectopic beats at 3 months. At 3 months 80% of the patients were in EHRA class I ($p<0.001$) and QOL improved with 8.3 ± 17.6/100 points, $p=0.062$. Final 6 months results will be presented at the time of the meeting.

CONCLUSIONS

The preliminary results of this single center pilot study suggest that RDN was able to significantly decrease EHRA class and duration of AF episodes along with a significant decrease in mean systolic blood pressure at 3 months post procedure in hypertensive patients with symptomatic paroxysmal and persistent AF.

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Multivessel disease in patients over 75 years old with STEMI: current management strategies and related clinical outcomes in the ESTROFA MI+75 nationwide registry

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

AIMS

Patients over 75 years old with ST elevated myocardial infarction frequently present multivessel disease (MVD) but current management and prognostic implications of different revascularization strategies are not well known for this population.

METHODS AND RESULTS

Subanalysis of nation-wide database of primary angioplasty in the elderly (ESTROFA MI+75) with 3,576 patients from 31 centers. Patients with MVD were analysed to describe treatment approaches and 2 years outcomes. Of 1,830 (51%) with MVD, 847 (46%) underwent non-culprit lesions revascularization either in acute (51%), staged (44%) or both procedures (5%). Patients with previous infarction and those receiving drug-eluting stents or IIb-IIIa inhibitors were more prone to be revascularized, whereas older patients, females and those with Killip III-IV, renal failure and higher ejection fraction were less likely. Survival free of cardiac death and infarction at 2 years was better for those undergoing non-culprit PCI regardless of Killip class. Non-culprit lesions PCI was independent predictor of cardiac death and infarction at 2 years (HR 0.60, 95% CI 0.40-0.89; p=0.011). Angiographically defined complete revascularization made no difference in outcomes among those patients undergoing non-culprit lesions PCI (HR0.83, 95% CI 0.39-1.77;p=0.64).The best prognosis corresponded to those undergoing staged procedures (HR 0.47, 95% CI 0.26-0.85;p=0.012) but no harm was found for multivessel PCI during primary procedures (HR 0.77, 95% CI 0.48-1.22;p= 0.27).

CONCLUSIONS

Nearly half of patients with MVD underwent non-culprit lesions PCI with similar rate for acute and staged procedures and under factors clearly influencing those decisions. Non-culprit lesions PCI was related with better outcomes specially after staged procedures. Complete revascularization had no influence among those undergoing non-culprit lesions PCI.

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Surgical risk and outcomes of patients undergoing TAVI with the Edwards SAPIEN 3 bioprosthesis: a subanalysis of the SOURCE 3 registry

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

AIMS

TAVI is increasingly being used in patients at lower risk for surgery. We aimed to assess the discrimination value of log EuroSCORE to predict 1-year TAVI outcomes across different risk profile of patients included in the SOURCE 3 registry.

METHODS AND RESULTS

We analyzed the dataset of the SOURCE 3 registry, a multicenter, multinational prospective, consecutively enrolled registry of patients with severe aortic stenosis treated with the commercially available SAPIEN 3™ valve at 33 sites in 10 countries. Follow-up was scheduled at discharge, 1 month and 1 year. Patients were categorized according to baseline log EuroSCORE(low <10; intermediate, 10-20; high >20), and were prospectively followed for adverse events. Out of 1945 enrolled TAVI patients, 1784 were included within current analysis because in 161 patients log EuroSCORE was not available. 29.0% (n=518) were at low-risk (LR, mean log EuroSCORE6.8 +- 2), 38.7% (n=691) at intermediate-risk (IR, mean log EuroSCORE 14+-3), 32.2% (n=575) in the high-risk group (HR, mean log EuroSCORE 33.5+-12.4). The mean log EuroSCORE was 17.8±12.89 and 21.8±14.50 in transfemoral (TF) versus non TF group (p =<0.0001). Patients at IR/LR were 70% and 60% in TF versus non TF group (p=0.0032). Follow-up was complete in 99% of patients. At 1 year, both all-cause mortality (HR 17% in HR group, 11.3% in IR group and 10.3% in LR group, p=0.002 for LR group and p=0.002 for IR group referencing HR group) and cardiac mortality (LR 11.2% vs IR 7.7% vs LR 5.4%, p<0.001 for LR group and p=0.02 for IR group referencing HR group) were significantly different among risk groups, without a significant interaction with TAVI access. The re-hospitalization for valve-related symptoms or worsening congestive heart failure after discharge were also significantly related to the risk of the patients (LR 4.8% vs IR 6.1% vs HR 10.1%, p=0.001), without a significant interaction with TAVI access.Stroke rate and permanent pacemaker implantation were not different among risk groups. The hospital stay (days) was also related to the risk of the patients (9 days in HR vs 8 days in IR and 7 days in LR, p=0.002). Among low risk patients, the prevalence of liver disease (2.7%, p=0.0705) and hostile chest (6.4%; p= 0.0012) was higher than in the intermediate (1.2%/ 2.3%) and high risk (1.2%/3.5%) group and may have driven the Heart Team to favor TAVI over surgical aortic valve replacement (SAVR)despite a low risk score.

CONCLUSIONS

In SOURCE 3 registry, two third of the patients treated by TAVI were at LR or IR as assessed by log EuroSCORE. However the prevalence of additional factors increasing the patient risk profile such as liver disease and hostile chest was higher in the low risk group. The latter showed a good discrimination to identify TAVI patients at high versus intermediate versus low risk for both 1-year mortality and rehospitalization.

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Thickness of retinal layers - A new promising marker of coronary atherosclerosis. A study with retinal OCT and coronary IVUS with virtual histology

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

We tested a relationship between the thicknesses of retinal layers and known risk features for future cardiac events coming from the PROSPECT trial

METHODS AND RESULTS

The PROSPECT trial established features related to future cardiac events: minimal lumen area (MLA) < 4mm2, plaque burden (PB) > 70% and thin-cap fibroatheroma. We tested a relationship between the thicknesses of 10 individual retinal layers (imaged by retinal optical coherence tomography - OCT) and plaque features from virtual histology intravascular ultrasound (IVUS-VH).
In 32 patients with stable angina pectoris, who underwent IVUS-VH for assessing borderline coronary stenoses, retinal OCT was obtained for both eyes. 3 D analysis of coronary plaques was performed in adjecent 5 mm vascular segments covering the entire pullbacks. Retinal OCT was analyzed using Reference Algorithms (Iowa Institute for Biomedical Imaging) yielding average thickness for each of the 10 standard retinal layers. Retinal layers are expressed according to their number (from 1 to 10). Statistical analysis was performed using three types of test for comparisons of continuous indices (Kendall, Pearson, Spearman).
Following plaque risk were related to retinal layers thickness: number of frames with MLA < 4mm2 (layer 1: R=-0.43, p=0.024), smallest MLA in 5 mm vessel segments (layer 1: R=0.47, p=0.012), number of frames with plaque burden > 70% (layer 3: R=0.37, p=0.05, layer 4:R=0.45, p=0.016, layer 7: R=-0.39, p=0.039, and layer 10: R=-0.38, p=0.047), mean plaque area (layer 5: R=-0.38, p=0.03), mean plaque burden (layer 5: R=-0.37, p=0.036), mean necrotic core area (layer 5: R=-0.37, p=0.036), maximal area of necrotic core in 5 mm segments (layer 5: R=-0.4, p=0.038, and layer 6: R=0.38, p=0.044).

CONCLUSIONS

IVUS-VH obtained plaque indices, which exhibit relationships with future coronayr events, correlate with non-invasively acquired indices of retinal layer thicknesses, suggesting the feasibility of predicting future coronary events via non-invasive imaging of the retina.

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SOMVC001, an intraoperative treatment for grafts for the prevention of vein graft failure improves clinical outcomes after CABG - Long-term analysis of 2,436 consecutive patients

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

AIMS

Progressive intimal hyperplasia is known to contribute to vein graft failure (VGF) impairing long-term outcomes after CABG. We assessed the impact of a novel intraoperative treatment (SOMVC001) against VGF on long-term outcomes after CABG.

METHODS AND RESULTS

Between 1996 and 2004 (excluding 2000), a total of 2,436 patients (age: 29-92) underwent CABG with at least one SVG. SVGs were treated with SOMVC001 (anintraoperative, one-time treatment for grafts for the prevention of VGF)in 1,036 patients (treatment-group) and 1,400 patients had *standard-of-care* CABG (control-group). Short-(<30days) and long-term outcomes (≥30days) were assessed for repeat-revascularization (RR), non-fatal myocardial-infarction (MI), death, and major adverse cardiac-events (MACE). Follow-up in the treatment-group (SOMVC001) was 7.2±4.5yearsand 7.7±5.5years in the control-group respectively. Short-term outcomes (<30 days) did not differ between groups and the overall event rate was low. The use of SOMVC001was associated with a significantly lower occurrence of non-fatal MI beginning at 30 days (risk-reduction: 36%) (adjusted Hazard Ratio: 0.64; 95%CI:0.50-0.82; *p*=0.0003) and being even more pronounced after 1000 days onwards (risk-reduction: 50%) (HR: 0.45; 95%CI: 0.41-0.74; *p*<0.0001). Similarly, after 1000 days onwards, a statistically significant 35% and 19% risk-reduction for RR (HR: 0.65; 95%CI: 0.44-0.97; p=0.037) and the occurrence of MACE (HR: 0.81; 95%CI: 0.70-0.94; *p*=0.0051) were detected after SOMVC001treatment. All-cause long-term mortality was comparable between groups.

CONCLUSIONS

We demonstrate that SOMVC001, an intraoperative treatment designed to reduce incidence of VGF significantly improves long-term outcomes in CABG patients. Our data show that the protective effect of SOMVC001on MI starts after 30 days and is most profound after 1000 days (45% risk-reduction) post-surgery. Our study highlights that efficient SVG treatment represents a key-element to reduce VGF post-CABG.

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Percutaneous mechanical thrombectomy in patients with high-risk pulmonary embolism and contraindications for thrombolytic therapy

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

AIMS

High-risk pulmonary embolism is associated with a high early mortality rate. We report our experience with percutaneous mechanical thrombectomy in patients with high-risk pulmonary embolism and contraindications for thrombolytic therapy.

METHODS AND RESULTS

Patients with high risk pulmonary embolism and absolute contraindications for thrombolytic therapy were treated with percutaneous mechanical thrombectomy. From November 2005 to September 2015 we treated 25 patients with mean age of 63±13 years, 64 % were men. The majority of patients were in obstructive shock at presentation with mean maximum lactate levels of 7,8±6,6 mmol/l, vasopressors were used in 77 % and 59 % needed mechanical ventilation, veno-arterial extracorporeal membrane oxygenation was used in one case. Mean simplified Pulmonary Embolism Severity Index was 2,9. Treatment included thrombus aspiration (76 %), fragmentation (60 %) or additional surgical embolectomy (4 %). Local thrombolytic therapy was used in 5 patients (20 %) and salvage systemic thrombolytic therapy was used in 3 patients (12 %). Systemic blood pressure (100±41 mm Hg vs 119±34, p = 0,100) and heart frequency (99±35 min^{-1} vs 87±31 min^{-1}, p = 0,326) did not differ pre and post procedure. Peak systolic tricuspid pressure gradient was significantly lower after the procedure (57±14 mm Hg to 31±3 mm Hg, p = 0,018). Percutaneous mechanical thrombectomy was successful in 20 patients (80 %) and 17 patients (68 %) survived to hospital discharge.

CONCLUSIONS

In patients with high-risk pulmonary embolism who cannot receive thrombolytic therapy, percutaneous mechanical thrombectomy is a promising alternative to effectively reverse acute pulmonary arterial hypertension with right ventricular dysfunction and improve the clinical outcome of these critically-ill patients.

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Compliance with and impact of following a specific OCT stent implantation algorithm: an ILUMIEN III substudy

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

AIMS

In the ILUMIEN III trial, external elastic lamina (EEL) based OCT-guided stent sizing was non-inferior to IVUS-guided stenting. We herein sought to assess the impact of operator compliance with the protocol-directed sizing strategy on acute outcomes.

METHODS AND RESULTS

ILUMIEN III: OPTIMIZE PCI was a multicenter, randomized trial in which patients were assigned 1:1:1 to coronary stent implantation with OCT-, IVUS-, or angiography-guidance. The OCT algorithm included 1) stent sizing based on the smaller EEL diameter of the proximal or distal reference rounded down to the nearest 0.25mm, and 2) iterative high pressure non-compliant balloon dilation to achieve optimal stent expansion (minimum stent area [MSA] >=95% of the closest reference lumen area for both proximal and distal halves of the stent). Operators followed all aspects of the OCT sizing protocol in 65/140 cases (46.4%). The angiographic reference diameter was smaller in vessels in which the protocol was vs. was not followed (2.71±0.45 vs. 2.88±0.52, P=0.03). Optimal stent expansion (MSA >=95% of the reference lumen area; 38.5% vs 14.7%, P=0.001) and acceptable stent expansion (MSA >=90% of the reference lumen area; 56.9% vs 28.0%, P=0.0005) were significantly greater when the protocol-directed algorithm was followed, and absolute MSA (5.64 [4.30, 6.81] vs. 5.79 [5.00, 8.10], P=0.14) was not significantly different despite the smaller vessel size. Moreover, despite the more aggressive sizing strategy, the prevalence of major dissection (length >=3mm or arc 60°) (16.9% vs 10.7%, P=0.28), major malapposition (7.7% vs 13.3%, P=0.28), and major tissue protrusion (tissue protrusion/stent area >=0.1) (12.3% vs 25.3%, P=0.051) were not significantly different in cases in which the algorithm was vs. was not followed.

CONCLUSIONS

The protocol-specified EEL-based OCT stent sizing strategy was followed in half of patients in ILUMIEN III (more commonly in small vessels), but when used, resulted in improved acute stent expansion. Applying this algorithm in all patients (including larger vessels) could further improve MSA.

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Strut coverage and apposition at six and 12 months with metallic DES with resorbable polymers and bioresorbable everolimus-eluting vascular scaffolds

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

AIMS

Direct comparative evaluation for arterial healing between bioresorbable everolimus-eluting vascular scaffolds (BVS) and different metallic drug-eluting stents with bioabsorbable polymers (BP-DES) at various time points results quite pertinent.

METHODS AND RESULTS

Prospective multicenter study in which patients were recruited when requiring stent implantation (without overlapping) in at least two separate lesions of similar morphologic characteristics. Each lesion was randomised to be treated with BVS or BP-DES (Synergy, Orsiro or Biomatrix). After the procedure patients were scheduled sequentially for 6 or 12 months (3:1) evaluation with optical coherence tomography. The proportion of non-covered (NC) struts, non-apposed (NA) struts and NC-NA struts was analysed in a core lab. Finally, 120 patients have been included (61.8 ± 9.8 years old, 30% diabetic and 51.7% with ACS) with 129 BVS and 137 BP-DES implanted. Stent diameter was 3.1 ± 0.42 mm with BVS and 3.05 ± 0.45 mm with BP-DES (p=0.34) and stent length was 18.8 ± 5.1 mm and 19.7 ± 6.8 mm respectively (p=0.22). At 12 months follow up TLR was required in 5 (3.9%) of BVS and 1 (0.7%) of BP-DES (p=0.17). No stent thrombosis were reported. Examination with OCT was obtained at 6 months in 72 patients and at 12 months in 28 patients. At 6 months the rate of NC struts was 1.7±3.2% in BVS and 5.2 ±5.6% in BP-DES (p<0.001), rate of NA struts was 0.82±2.1% and 1.3±2% (p=0.024) and the rate of NC-NA struts was 0.12±0.63% and 0.45 ±1.1% (p=0.044) respectively. At 12 months the rate of NC struts was 0.48±0.72% in BVS and 4.5±5% in BP-DES (p<0.001), rate of NA struts was 0.24±0.83% and 0.9±1.5% (p=0.013) and the rate of NC-NA struts was 0.02±0.12% and 0.4 ±1% (p=0.004) respectively. Significant heterogeneity was found for NC (I^2 60%, p<0.001). The maximal malapposition area at 6 months was 0.61±1.3 mm^2 for BVS and 0.59±0.95 mm^2 for BP-DES (p=0.8) and at 12 months was 0.48±0.9 mm^2 and 0.54±0.9 mm^2 respectively (p=0.7). Evaginations were observed in 3 cases (3%) with BVS and none with BP-DES.

CONCLUSIONS

In this cohort of patients treated simultaneously with both BVS and BP-DES in different but similar lesions the proportions of uncovered and/or malapposed struts at 6 and 12 months were significantly lower with BVS than with BP-DES but significant heterogeneity was observed for non-coverage. Nature of coverage (intima or fibrin) can not be established with OCT. Evaginations were an infrequent finding but only observed in BVS.

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Why hyperaemic (FFR) and resting (PdPa/iFR) indices sometimes disagree and why disagreement need not be disconcerting

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

To understand the physiological mechanisms explaining discordance between hyperaemic (FFR) and resting (iFR/PdPa) indices, using measurements of coronary flow reserve (CFR) and microvascular function.

METHODS AND RESULTS

Discordant cases of stenosis classification were identified among 351 intermediate stenoses assessed as part of the IDEAL study. The IDEAL study is currently the largest collection of stenoses with combined pressure and Doppler flow velocity measurements. Criteria for physiological positivity were, respectively, ≤0.80 for FFR, <0.90 for iFR and <0.91 for PdPa. We measured coronary flow reserve (CFR) and microvascular function by baseline myocardial resistance (BMR), hyperaemic myocardial resistance (HMR) and the resistance reserve ratio (RRR – defined as BMR/HMR).FFR disagreed with iFR in 13% (45/351) of cases: 17 FFR+/iFR- and 28 FFR-/iFR+. FFR disagreed with PdPa in 11% (37/351) of cases: 27 FFR+/PdPa- and 10 FFR-/PdPa+. CFR was significantly higher in the FFR+/iFR- and FFR+/PdPa- versus FFR-/iFR+ and FFR-/PdPa+ groups; median 2.47 (IQR 2.06 to 2.97) and 2.06 (1.74 to 2.54) versus 1.44 (1.29 to 1.86) and 1.63 (1.31 to 1.93), respectively ($p<0.05$). Median (IQR) RRR was significantly higher in the FFR+/iFR- and FFR+/PdPa- versus FFR-/iFR+ and FFR-/PdPa+ discordant groups; 3.31 (2.97 to 3.94) and 3.11 (2.44 to 3.44) versus 1.98 (1.60 to 2.21) and 2.08 (1.50 to 2.13); respectively ($p<0.001$).In FFR/iFR discordant cases, iFR correlated *positively* with microvascular function defined by RRR ($r=+0.76$, $p<0.001$) whereas FFR correlated *negatively* ($r=-0.52$, $p<0.001$). Similar trends were seen for FFR/PdPa discordant cases ($r=+0.77$, $p<0.001$ for PdPa and $r=-0.31$, $p=0.06$ for FFR).

CONCLUSIONS

FFR+ discordant cases are characterized by normal coronary flow reserve and (more) normal microvascular function. Conversely, FFR- discordant cases are characterized by abnormal coronary flow reserve and (more) abnormal microvascular function. Therefore, discordance need not be disconcerting, as it provides the clinician additional physiological information than if hyperaemic and resting indices simply agree.

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Direct implantation of rapamycin-eluting stents with bioresorbable drug carrier technology utilising the Svelte coronary stent-on-a-wire: the DIRECT II study

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

AIMS

The Svelte DES Integrated Delivery System (IDS) is designed to facilitate TRI and '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 DES-on-a-wire utilizes a 81µ thick CoCr stent with bioresorbable amino acid-based (PEA) drug carrier eluting sirolimus mounted on a novel Integrated Delivery System (IDS), which consists of a low-compliant balloon affixed to a 0.014" integrated Asahi wire with shapeable tip. The DIRECT I First-In-Man study (n=30) reported 0% clinically-driven MACE through 30-months. DIRECT II, a prospective, randomized study designed to establish non-inferiority of the Svelte IDS compared with the Resolute Integrity 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 length $\leq$ 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 clinical follow-up continuing through 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 core lab and DSMB.The trans-radial approach was used in 67% of interventions; approximately 40% of the invetigators were first-time users of the Svelte IDS. At 6-months, in-stent LL 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). Also at 6-months, OCT revealed good stent coverage (94.2 $\pm$ 9.0%) and low stent strut malapposition (0.7 $\pm$ 1.9%). 6-month and 1-year rates of target vessel failure (TVF) were similar (4.6% vs. 7.8%; $p=0.469$ at 6-months and 6.5% vs. 9.8%; $p=0.524$ at 12-months) in the Svelte IDS and Resolute Integrity arms, respectively. There were no changes in clinical outcomes between 1 and 2 years. No patients in either arm experienced stent thrombosis through 2 years.A subanalysis of the top 5 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 Integrityarms, respectively ($p=0.039$). In addition, device times were 4 minutes in the Svelte IDS group vs. 11 minutes in the Resolute Integritygroup ($p=.005$). Trends toward reduction in fluroscopy time and contrast use with the Svelte IDS were also observed.Three year clinical follow-up on all patients will be available March 2017.

CONCLUSIONS

This is the first report of 3-year clinical outcomes in the DIRECT II study. DIRECT II demonstrated non-inferiority of the Svelte IDS to the Resolute Integrity DES with respect to LLL at 6-months and TVF at 6,12 and 24-month follow-up. Procedure and device times were reduced with the Svelte IDS, wth trends toward reduction in fluoroscopy time and contrast use. The 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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Final five-year clinical and echocardiographic results of treatment for severe aortic stenosis with a self-expanding bioprosthesis

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

AIMS

The final 5-year clinical and echocardiographic results from the multi-centre, observational ADVANCE study provide long-term safety and durability data in a large real world patient population.

METHODS AND RESULTS

The ADVANCE study enrolled 1015 patients with severe aortic stenosis who underwent femoral, subclavian or direct aortic implantation of the CoreValve self-expanding bioprosthesis. Patients were followed by annual visits and echocardiographic investigations. Endpoint-related events were adjudicated according to VARC-1 definitions by an independent Clinical Events Committee. Baseline characteristics include mean age 81.1±6.4 years, 51% female, and log EuroSCORE 19.4±12.3%. At 5 years, all-cause mortality was 50.7%, cardiovascular mortality was 33.5%, and the stroke rate was 10.2%. All-cause mortality was 40.2%, 51.4%, and 56.5% in patients with a EuroSCORE ≤10%, >10-20%, and >20%, respectively indicating an association between preoperative risk and clinical outcomes ($p<0.001$ for difference among 3 groups). Although 26.3% of the patients received a new pacemaker up to 30 days after TAVI, this did not appear to impact on 5-year survival (52.2% with pacemaker vs. 49.1% without pacemaker, $p=0.470$). There was a significant improvement in New York Heart Association (NYHA) symptom status within one month of valve implantation (class III/IV decrease from 74% to 10%) which persisted through 5 years (19%) post-procedure. Among all patients for whom data is available effective orifice area (EOA) was 1.7±0.4 cm and mean aortic gradient was 8.8±4.4 mmHg. Paired data for discharge and five year follow-up (n=205) confirmed a consistent low mean aortic gradient (8.8±4.4mmHg) at 5 years. Paravalvular aortic regurgitation at 5 years was none in 51.2%, mild in 39.3%, moderate in 9.5% and no patient had severe paravalvular aortic regurgitation.

CONCLUSIONS

The ADVANCE study has demonstrated long-term safety and effectiveness of TAVI through five years. Detailed analysis of valve durability and stratification of data by predicted risk will be presented to provide data relevant to the extension of TAVI to intermediate and lower risk patients with aortic stenosis.

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Selective thrombolysis of peripheral arterial and graft occlusions: immediate and early follow-up results using actilyse

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THEME: Peripheral Interventions
TOPIC(S): Below the knee

AIMS

Hereafter we present our Department experience in the use of selective thrombolysis of peripheral arterial and graft occlusions using Actilyse.

METHODS AND RESULTS

Acute peripheral arterial ischemia results from an abrupt reduction in blood flow to a limb. If flow is not promptly restored, this may lead to tissue death requiring amputation.

From 2009 to present we enrolled 18 patients with acute limb ischemia (ALI) managed with a simplified IAT (intra-arterial thrombolysis) of peripheral arterial and graft occlusions using tissue-type plasminogen activator (rt-PA: Actilyse, Boehringer In). 15 men and 3 women (range 37-90 years of age), all with risk factors for peripheral artery disease (PAD; hypertension, diabetes, dylipidemia, chronic renal insufficiency, smoke, obesity), 1 patient with associated carotid artery disease and 9 with associated coronary artery disease, previously treated. Reported comorbidities were 2 patients with pulmonary and 1 patient with rectal carcinoma in progress, 4 with atrial fibrillation and 2 who had recently undergone hip arthroplasty intervention ipsilateral to the ALI. 6 acute limb ischemia involved femoral-popliteal bypass, 2 were late or very late stent thrombosis and the remaining 10 involved 7 common or superficial arteries, 2 common or external common iliac arteries and 1 popliteal artery. Ten mg rt-PA were infused in bolus and 2.5 mg per hour combined with intravenous (iv) heparin (to ensure Activated Clotting Time > 150) over the next 20-24 h through a 4F diagnostic catheter near the site of the thrombosis, thereafter the extent of thrombolysis was checked fluoroscopically. If complete thrombolysis revealed an underlying stenosis, a percutaneous transluminal angioplasty (PTA) with or without stent delivery was subsequently performed. We reported an ineffective disobstruction and a reocclusion after 6 months who underwent vascular surgery and 2 cases of anemization that required blood transfusions, 1 pseudoaneurysm surgical excluded and 1 retroperitoneal hematoma with no sequelae. The above described complications are known for everyday PAD interventional procedures. No major systemic bleeding or amputations were carried out and doppler ultrasound at 1, 3 months and 1 year follow-up showed patency of the treated arteries or bypass grafts.

CONCLUSIONS

Peripheral arterial thrombolysis was originally performed using iv administration of the drug: relatively high doses were used to achieve therapeutic levels at the site of arterial occlusion. The local thrombolysis allows to use a total of 50 mg of the drug directly onto the thrombosed district in a greater time, with greater chances of success and lower bleeding risk.
Systemic thrombolysis is rapidly injected and less effective because the drug has only 20 minutes half-time, therefore it is completely deactivated in less than 2 hours, while it remains a greater risk of major bleeding in the first hour.
Only a relatively small number of thrombolytic agents (TA) have been used and compared within randomised controlled studies. According to our experience Actilyse appears to be a safe and effective TA with a short half-life and less life-threatening.

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Clinical efficiency of different generation stents in patients with ACS

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

AIMS

To compare clinical efficiency of the coronary stent "Calypso" (Angioline, Russia) and the coronary stent Xience Prime (Abbot Vascular, USA) in cases of acute coronary syndrome.

METHODS AND RESULTS

The study includes 191 patients with unstable angina, myocardial infarction. Patients with alikeclinical picture and anamnesis are divided into 2 groups. Patients of the first group (n = 97) wereimplanted with Sirolimus-Eluting Stent "Calypso" manufactured in Russia. Patients of the second group (n = 94) were implanted with Xience Prime stent. Primary endpoints: MACE. Secondary endpoints: restenosis and late stent thrombosis according to digital angiography. In both groups prevailedone (51.7 ± 0.3%) and two (39.7 ± 0.4%) vascular disease, bifurcation lesion in 8.4 ± 0.9%, pronounced calcification in 26 ± 4.5% of patients. The average length of stented segment is 20 ± 0.3%. The average diameter of the stent 3 ± 0.5 mm. The procedure was successful in two groups, in 100% of cases. Clinical features of the first group interventions: incomplete stent apposition in 2 cases, difficulties of delivery in 1 case, the artery dissection - 2, occlusion of the side branch - 1, acute thrombosis - 1. ð¡linical features of the second group interventions: incomplete stent apposition in 1 case, difficulties in delivery in 4 cases, artery dissection - 1, occlusion of the side branch - 0, acute thrombosis - 1. Hospital outcomes: repeated PCI for 1 patient in each group, death of 1 patient in each group, emergency CABG(Coronary Artery Bypass Graft Surgery)in the second group - 1.

Survival rate in 1 year - 97.88% in both groups. Confirmatory angiography in 12 monthswas done for 81 patients from the first group and 78 patients from the second. The frequency of MACE in both groups was 1.03%. The frequency of restenosis was 5.15% in the first group and 12.4% in the second. This caused repeated revascularization. Stent thrombosis was not diagnosedin both groups.

CONCLUSIONS

No manual differences between the two systems - the Calypso and the Xiencewere found. In both groupsimmediate and long-term results procedures are alike. We believe that long-term results of PCI with the usage of Calypso stent will be comparable to those forpatients with implanted Xience stents.

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Multicentre evaluation of a novel 120µm novolimus-eluting, fully coronary BRS: first report of six-month clinical and imaging endpoints

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

AIMS

The DESolve Cx study is a prospective, multi-center evaluation of the safety and efficacy of the DESolve® Cx Novolimus-Eluting Bioresorbable Coronary Scaffold System (BCSS) using clinical endpoints and multiple imaging modalities.

METHODS AND RESULTS

The DESolve Cx BCSS is a novel, thin strut (120 µm) drug eluting bioresorbable vascular scaffold (BRS) that combines a poly-L-lactide-based (PLLA-based) scaffold coated with a biodegradable PLLA-based polymer and the drug Novolimus, a macrocyclic lactone mTOR inhibitor with potent anti-proliferative properties. The scaffold drug dose is 5 µg per mm of scaffold length, and is currently available diameters of 2.5, 3.0, and 3.5 mm and lengths of 18 and 28 mm.The DESolve Cx scaffold differentiates itself from other BRS with thin struts minimizing areas of flow disturbance, and a shorter bioresorption time (>85% reduction in molecular weight within 6 months, 70% mass loss within 1 year, and bioresorption within 2 years). DESolve Cx scaffold also offers high expansion capacity without strut fracture. More rapid scaffold degradation, as demonstrated in the DEsolve Nx study, allows for the earliest reported vessel and lumen growth and therefore early vascular restoration – the promise of BRS technology.A total of 50 patients with single, de novo coronary artery lesions were enrolled in this prospective, multi-center, single-arm registry. Those patients receiving the study device are being analysed for multiple clinical endpoints including: Major Adverse Cardiac Events (MACE), a composite endpoint of cardiac death, target vessel MI, or clinically-indicated target lesion revascularization (CI-TLR); Device and Procedure Success; Clinically-indicated Target Lesion and Target Vessel Revascularization, (CI-TVR) and Stent Thrombosis assessed at 1, 6 and 12 months and annually to 3 years. Baseline subject characteristics included 68% male, 60.0 ± 10.3 years of age, 20% presented with diabetes mellitus, 26% were current smokers, 84% and 70% had hypercholesterolemia and hypertension respectively. All patients underwent angiographic IVUS and OCT assessment at 6 months. Clinical and multimodality imaging results at 6 month will be presented.

CONCLUSIONS

The 120 µm DESolve® Cx Novolimus-Eluting BCSS offers unique characteristics and has demonstrated safety and efficacy in this study through 6 months. A report of the clinical and multimodality imaging results will be presented.

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Which socioeconomic factors influence presentation delays in the current setting of STEMI networks?

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

The aim of this study was to investigate which socioeconomic factors currently influence presentation delays, in the setting of STEMI networks.

METHODS AND RESULTS

This study is a prospective analysis of a large tertiary primary PCI center's database. 730 patients, presenting with STEMI between January 7th 2013 and August 20th 2016, were included. This tertiary academic hospital is the only 24/24 primary PCI center for a homogeneous region of more than 700'000 inhabitants in the French part of Switzerland.

Patients were classified according to the following pre-defined socioeconomic factors: level of education, marital status, nationality, profession, history of coronary artery disease and primary prevention with drug treatment.

Comparisons between categorical variables were evaluated using Pearson χ^2 test. Student t test was used to compare continuous variables.

Symptom-to-first-medical-contact time was significantly shorter for patients with history of angina pectoris (63.5 minutes vs. 84 minutes, $p<0.05$), prior acute myocardial infarction (55 minutes vs. 94 minutes, $p=0.001$), prior percutaneous coronary intervention (60 minutes vs. 115 minutes, $p=0.001$), prior coronary artery bypass graft (51.5 minutes vs. 83.5 minutes, $p<0.005$) and primary prevention with statin therapy (67 minutes vs. 87 minutes, $p=0.001$). Patients with a low level of education have a significantly longer symptom-to-first-medical-contact time (89.5 minutes vs. 65 minutes, $p<0.05$). In contrast, marital status, nationality, profession and primary prevention with aspirin do not significantly influence symptom-to-first-medical-contact time.

CONCLUSIONS

Socioeconomic factors continue to influence optimal management of STEMI patients, despite the presence of well-developed STEMI networks in a particular region of Western Europe. History of angina pectoris, previous acute myocardial infarction, previous percutaneous coronary intervention, previous coronary artery bypass graft, primary prevention with statin therapy and most of all level of education impact presentation delays. Measures should be taken to heighten awareness of the population and to improve the therapeutic education of vulnerable individuals.

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Prospective, multicentre evaluation of the DESolve Novolimus-Eluting coronary BRS: imaging outcomes and four-year clinical and imaging results

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

AIMS

The DESolve Nx study is a multi-center 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 drug-eluting bioresorbable scaffold combining a PLLA-based scaffold coated with Novolimus, a macrocyclic lactone mTOR inhibitor with potent anti-proliferative properties. The drug dose is 5 µg per mm of scaffold length; the device is 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 revascularization (CI-TLR), the individual components of MACE and stent thrombosis at 1, 6 and annually to 5 years. All patients underwent angiographic assessment at 6 months and a subset of patients underwent IVUS and OCT assessment also at 6 months and multislice computed tomography (MSCT) imaging 12 months. Additionally, at single centers, multi-modality imaging was completed at 18 months and 3 years. Mean age at baseline was 62 years, 32% were females, and 21% diabetics. Lesion length was 11.2 mm, RVD was 3.06 mm, and 18.3% showed moderate-to-heavy calcification. 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 (Δ 10.0%, p = < 0.001)and scaffold areas (Δ 15.7%, p = < 0.001). Serial OCT demonstrated a significant increase in scaffold area (Δ 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 shows minimal lumen change and 3 year OCT imaging reveals the “golden tube” indicating complete resorption of the scaffold. Clinical events remained low (MACE = 5.7%, 7.4%, and 8.2% at 12, 24, and 36 months respectively) with no reports of definite stent thrombosis.

CONCLUSIONS

DESolve demonstrated safety and efficacy with low late lumen loss. Serial imaging indicated early vessel restoration at 6 months. Through 36 months, the clinical event rates remain low. Imaging endpoints at 18 months and 3 years and 4-year clinical results will be presented.

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Multicentre, post-marketing evaluation of the Elixir DESolve novolimus-eluting coronary BRS system: 12-month results from the DESolve PMCF study

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

AIMS

A post marketing clinical follow-up (PMCF) study was conducted evaluating the continued safety and effectiveness of the CE-mark approved DESolve® Novolimus Eluting Bioresorbable Coronary Scaffold System (NEBCSS) (Elixir Medical, Sunnyvale, CA).

METHODS AND RESULTS

The DESolve® NEBCSS is a drug-eluting bioresorbable scaffold combining a PLLA-based scaffold coated with Novolimus, a macrocyclic lactone mTOR inhibitor with potent anti-proliferative properties. The drug dose is 5 µg per mm of scaffold length. A total of 100 patients were treated with the DESolve NEBCSS in de novo, native coronary artery lesions with a reference vessel diameter between 2.25 and 3.5 mm and treatable with a single scaffold. Available diameters were 2.5, 3.0, 3.25 and 3.5 and lengths were 14, 18 and 28 mm. Patient data for the clinical endpoints of major adverse cardiac events (MACE) defined as: cardiac death, target vessel MI, clinically-indicated target lesion revascularization (TLR); target vessel revascularization and stent thrombosis are to be analyzed at 1, 6, 12 months and annually through 5 years. The study was approved by the local Ethics Committees and all patients provided informed consent. Patients were enrolled over a one year period at 10 sites in Germany, and Italy. After the index procedure, patients were contacted at 1, 6 and 12 months either via an office visit or telephonically. The mean age of patients was 62 years; 25.5% were diabetics, 76.5% presented with hypercholesterolemia, 86.3% with hypertension and 15% had unstable angina. Baseline lesion characteristics revealed 50.5% of lesions were type C; the mean reference vessel diameter was 3.0 ± 0.4 mm and lesion length of 17.3 ± 8.7 mm. Clinically, the DESolve NEBCSS demonstrated excellent safety with only two clinical events reported through 6 months (2.0% MACE) with continued low MACE rates through the 12-month follow-up period. Full demographic, lesion and clinical data through 12 months will be presented.

CONCLUSIONS

The DESolve NEBCSS continues to demonstrate excellent clinical safety similar to the clinical safety results seen in the pivotal DESolve Nx Study. Demographic, lesion and clinical results through 12 months will be presented.

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Coronary artery bypass in a BRS implanted segment of a porcine coronary artery

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

AIMS

The purpose of the study was to acutely evaluate the feasibility of performing CABG in porcine coronary arteries previously implanted with a PLLA-based bioresorbable vascular scaffold (BVS).

METHODS AND RESULTS

One year prior to the grafting procedure, the left anterior descending (LAD) coronary arteries of three normal Yucatan mini-swine were implanted with 3.0 x 12 mm BVS using standard procedures. Following sternotomy, a standard off-pump grafting procedure was performed into the BVS-implanted segment of the LAD using the left internal thoracic artery (LITA) as the bypass graft. Procedural feedback from the cardiac surgeon was collected. Angiography and OCT were performed post-procedure to assess patency, overall lumen condition, and to confirm a suitable anastomosis without leakage. The animals were sacrificed, and arteries and distal myocardium were evaluated grossly and histologically to assess local and downstream effects from grafting in the BVS implanted region.Incision into the BVS- implanted LAD felt fibrotic with mild grittiness, unlike entering a hard calcified lesion. The incision into the stented artery could be performed using a standard fine blade. Gross evaluation of the lumen through the incision revealed a smooth lumen surface. The LITA graft was sutured onto the targeted LAD site using a standard needle and 7-0 prolene without difficulty. The procedure was uncomplicated and typical to grafting a mildly fibrotic blood vessel. Post-grafting angiography revealed normal blood flow, a patent and well-sealed anastomosis, and a patent internal thoracic artery graft and LAD lumen. OCT revealed clean, open lumens with no evidence of thrombosis or luminal obstruction by the BVS struts. Gross assessment at necropsy and histological evaluation confirmed that the graft was successfully placed in the scaffolded region and confirmed the retained patency of the graft, anastomosis and scaffolded artery. Histological evaluation of the distal myocardium showed no evidence of thrombo-embolization related to the grafting procedure.

CONCLUSIONS

In a porcine coronary artery model, CABG was successfully performed in scaffolded coronary arteries one year post-implant with a BVS. The grafting procedure was able to be performed by the cardiac surgeon in accordance with standard off-pump procedures without complication. Angiography, OCT, and histology revealed a successful and patent graft, anastomosis, and LAD without evidence of thrombosis in the treated artery or thrombo-embolization in the distal myocardium.

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Additive prognostic value of IVUS parameters to assess clinical outcomes in patients with FFR-guided deferred coronary lesions: up to five-year follow-up

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

AIMS

There is limited data about long-term clinical outcomes and prognostic factors in FFR-guided deferred coronary disease, verified by IVUS. Therefore, we evaluated the clinical outcomes of deferred coronary lesions using FFR & IVUS registry data.

METHODS AND RESULTS

A total of 465 patients with 552 deferred coronary lesions were included in this analysis. Clinical, angiographic and IVUS variables were analyzed. Primary endpoint was major adverse cardiac events (MACE), the composite of including death, myocardial infarction and any revascularization during 5-year follow-up. Secondary endpoint was lesion related events (LRE), the composite of including target-lesion related myocardial infarction and target vessel revascularization.

During follow-up, the rate of MACE was 6.9% and that of LRE was 1.4%. In univariate analysis, diabetes mellitus (DM), acute coronary syndrome, left ventricular ejection fraction (LVEF) ≤40%, plaque burden > 70% and positive remodeling were predictors of MACE. In the multivariate Cox hazard regression analysis, presence of DM (HR 4.270, 95% CI 2.224 – 8.200, p<0.001) and LVEF ≤40% (HR 5.063, 95% CI 1.657 – 15.464, p=0.004) were independent predictors. PB and positive remodeling measured by IVUS showed strong trend of increased risk of MACE. Occurrence of LRE was not also associated with FFR. Positive remodeling was only independent predictor of LRE (HR 7.262, 95% CI 2.099 – 25.130, p=0.002).

CONCLUSIONS

In patients with FFR guided-deferred coronary lesions, overall clinical outcomes were acceptable. Clinical characteristics of patients including DM and LV function were significantly associated with MACE. Neither FFR value nor IVUS parameters could predict the occurrence of MACE independently. However, PB and positive remodeling determined by IVUS could provide additional prognostic information.

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Renal sympathetic denervation in Sweden: a first report from the Swedish registry for renal denervation

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THEME: Interventions for Hypertension
TOPIC(S): Renal denervation

AIMS

This report presents data from the Swedish Registry for Renal Denervation, an investigator driven nationwide registry. The purpose was to assess the safety and efficacy of RDN on patients with resistant hypertension (RH) in a real-world setting.

METHODS AND RESULTS

This nationwide database contains patient characteristics, procedural details and follow-up data on all RDN procedures performed in Sweden. Consecutive procedures between 2011 and 2015 were included.

The data analysis consists of 252 patients (mean age 61±10 years, 38% women; mean 4.5±1.5 antihypertensive drugs). Systolic and diastolic office blood pressure (BP) and 24h ambulatory BP decreased 6 months after RDN (176±23/97±17 to 161±26/91±16 mm Hg, both p<0.001; and 155±17/89±14 to 147±18/82±12 mm Hg, both p p<0.001). Significant office and ambulatory BP reductions persisted throughout the observation period of 36 months. Major procedure related vascular complications occurred in 4 patients. Renal function and number of antihypertenive drugs were unchanged during follow up. Baseline BP was the only predictor for blood pressure response.

CONCLUSIONS

RDN was associated with a sustained reduction in office and ambulatory BP in a real world setting of patients with RH. The procedure proved to be feasible and associated with a low complication rate.

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International multisite Transcatheter Tricuspid Valve Therapies (TriValve) registry: which patients undergo transcatheter tricuspid repair?

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THEME: Interventions for Valvular Disease
TOPIC(S): Tricuspid / Pulmonary valve, Other valvular and structural interventions

AIMS

Transcatheter tricuspid valve therapies are emerging as therapeutic option for patients with a severe symptomatic tricuspid regurgitation (TR). We evaluated their diffusion and initial clinical results using a large, worldwide registry.

METHODS AND RESULTS

The TriValve Registry included 106 high-risk patients (aged 76±9 years; 60.4% female; EuroScore II 7,6±5,7%) from 11 cardiac centers, with severe TR (vena contracta 1,1±0,55 cm; RVol 62,9±27 ml/beat). Mean duration of RV failure symptoms before the treatment was 9 months; 35% of the patients had previous left side valve intervention (surgical in 29/106 patients, transcatheter in 8/106 patients). Right ventricular dysfunction (TAPSE<17 mm) was present in 56.3% of the patients (mean 16±4 mm). Median NT-proBNP was 2253 pg/ml (range 132-70000 pg/ml); 95% of the patients were in NYHA class III-IV. Etiology of TR was functional in 95,2%; mean tricuspid annulus diameter at preoperative 4-chamber view echo was 43,7±9,2 mm. In 25/106 patients (23.5%) a trans-tricuspid lead was present.

In 74.8% of the patients the main location of the regurgitant jet was central. Preprocedural sPAP was 39,7±13,8 mmHg. Inferior vena cava was severely dilated in most of the patients (27,4±6,8 mm).

Implanted devices included: MitraClip (n=58), Trialign (n=17), TriCinch (n=15), FORMA (n=7) Cardioband (n=5), and CAVI (n=3). One case had combined Trialign + Mitraclip.

Patients treated with the different techniques had similar EuroScore II and degree of RV dysfunction. Patients who received CAVI had significantly more dilated tricuspid annulus and inferior vena cava (both $p<0.05$ compared to the other approaches).

All but 1 patient (who received a TriCinch repair) were treated under general anaesthesia.In 68% of the cases the tricuspid intervention was performed as an isolated procedure, while in 32% it was performed concomitantly to a transcatheter mitral treatment. Procedural success (available for 95 patients - defined as patient alive at the end of the procedure with the device successfully implanted and a residual TR≤2+) was achieved in 62% of cases.

At 30-day follow-up (available for 81 patients), all-cause mortality was 3,7% (3 patients: 1 from sepsis, 1 from heart failure and 1 after tricuspid surgery), with an overall incidence of MACCEs of 26%; 58% of the patients were NYHA functional class I/II at 30 days.

CONCLUSIONS

Today, patients who are worldwide treated with transcatheter tricuspid valve therapy are mostly high-risk patients with functional aetiology and very severe central regurgitation, mostly with not severely impaired RV function.

Initial results suggest that transcatheter tricuspid valve therapy is feasible with different techniques. Clinical efficacy is still to be determined.

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Acute and mid-term outcomes of TAVI in patients at low-risk

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

AIMS

There is a paucity of data of transcatheter aortic valve implantation (TAVI) in low-risk populations. We aimed to assess acute and mid-term outcomes of TAVI patients deemed at low-risk according to STS score.

METHODS AND RESULTS

Among 992 patients treated with TAVI from June 2007 to December 2016, we included 226 (22,8%) consecutive patients with STS score<3%. Clinical and procedural outcomes were defined according to VARC-2 criteria

The mean STS mortality score was 2,2 ±0,5 and the mean age was 77,4 ±5,8 years. The approach was mainly transfemoral (98,7%) and transcatheter aortic valves implanted were equally first-generation devices (total 45,1%, Medtronic CoreValve 32,8%, Edwards Sapien XT 12,3%) and second-generation devices (total 54,9%, Medtronic Evolut R 18,1%, Edwards Sapien 3 21,3%, Acurate Neo 11,5%, Others 3%). Device success was 87,7% (84,0% vs 90,7%, 1st generation vs 2nd generation). More than mild PVR was reported in 6,0% of patients, major vascular complications was 4,3%. In-hospital mortality rate was 1,3%. During hospitalization incidence of disabling stroke, LT bleeding and need of permanent PM were 0,4%, 6.6% and 14%, respectively. One-year all-cause and cardiovascular mortality rates were 7,1% and 5,2%, respectively. At 3-year, all-cause mortality rate was 18,4%.

CONCLUSIONS

TAVI in low-risk patients is an effective therapeutic option with low rate of in-hospital complications and favorable outcomes up to 3 years.

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Examination of CTO cases that were switched to antegrade approach after failure of retrograde procedure from the Japanese Retrograde Summit registry

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

AIMS

Success rate of antegrade approach for chronic total occlusion (CTO) after failure of retrograde procedure is relatively low. It was little known about factors related to procedural failure in such situation.

METHODS AND RESULTS

A total of 4866 cases who underwent percutaneous coronary intervention (PCI) for CTO were enrolled in the Japanese Retrograde Summit Registry from 67 centers between 2012 and 2015. We extracted 446 subjects who were switched to antegrade approach immediately after failure of retrograde procedure in the sama session (combined strategy) and examined independent predictors of procedural failure. Two hundred and eighty-four of 446 cases (64%) were successfully treated with combined strategies (S group). Total procedural and fluoroscopy time of the failure group (F group) were significantly longer than those of the S group (244±87 min vs. 220±85, p = 0.006 and 123±58 min vs. 107±46 min, p = 0.005, respectively). Frequency of hemodialysis (F group 12% vs. S group 3%, p = 0.0003), calcified lesion (60% vs. 38%, p<0.0001), tortuous lesion (21% vs. 7%, p<0.0001), and re-attempted case (25% vs. 13%, P = 0.003) were significantly higher in the F group than those in the S group. Multivariate regression analysis demonstrated that calcified lesion (β = 0.173, p = 0.002), tortuous lesion (β = 0.146, p = 0.007), and re-attempted case (β = 0.117, p = 0.03) were independent significant predictors of procedural failure in the combined strategy.

CONCLUSIONS

Complex lesion morphology and previous failure have significant impants on the success rate of the combined strategy for the CTO lesion.

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Long-term clinical results of bioresorbable Absorb scaffolds using the PSP-technique

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

AIMS

Long term follow up up to 3 years of patients having been treated with a BVS using the PSP-technique was analyzed in order to get reassurance in the intriguing concept of bioresorbable vascular restoration therapy.

METHODS AND RESULTS

In this prospective study 319 patients with 420 lesions were enrolled and treated with the Absorb BVS. Pre-dilation was mandatory and post-dilation with a high-pressure balloon was performed in patients with a scaffold length >12mm. The maximal balloon diameter for post-dilatation was the scaffold diameter plus max 0.5mm taking the balloons final size at high pressure into account. This strategy reflects the present discussed optimal scaffold implantation technique (PSP-technique) with predilatation, proper sizing and post-dilatation. Additionally, patients were stratified by the presence of diabetes mellitus and and those not suffering from diabetes mellitus. Patients were clinically followed up to three years. Primary outcome measure was the device oriented endpoint (DoCE) defined as cardiac death, myocardial infarction not clearly related to a non-target vessel and target lesion revascularisation.DoCE was 5.3%, 5.6% and 11% after 12, 24 and 36 months for the total population. Rate of scaffold thrombosis was 0.5%, 0.7% and 1.2% after 12, 24 and 36 months. Rate of DoCE was higher in the diabetic subgroup with 9.4%, 13.0% and 14.7% after 12, 24 and 36 months compared with 4.4% (p=0.14), 3.4% (P=0.01) and 9.7% (p=0.34) in patients without diabetes mellitus.

CONCLUSIONS

Patients treated with the Absorb BVS using the PSP-technique show favorable results up to three years with a lowrate of scaffold thrombosis. Patients suffering from diabetes mellitus show an increased rate of DoCE compared with non-diabetic patients.
Clinical Trial Registration: clinicaltrials.gov NCT01583608

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Acute and chronic effects analysis of transradial coronary intervention on the radial artery by OCT

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI, Stable CAD, Left main and multivessel disease, Other Coronary Interventions

AIMS

We sought to determine the acute and chronic effects of transradial coronary intervention (TRI) on the radial artery (RA) by optical coherence tomography (OCT).

METHODS AND RESULTS

Inmediately after TRI completion, 35 RAs in 35 patients were examined. The sheath was pulled back 2 cm distal to the puncture site, and OCT imaging was performed. The radial artery was divided in 3 segments: proximal (>10 cm from the punture site), mid and distal (5-10 and 0-3 cm from the punture site). The following data were colected: mean diameter, luminal area, area of intima and media layer, intima and media thickening, ITI (intima area/media area ratio), IMR (max intimal thickening/max media thickening), intimal injury, dissection, thrombi, plaques (characteristics), vessel stenosis, spasm.

The acute injuries and intimal thickening were compared between first-TRI RAs (group 1) and repeat-TRI RAs (group 2).

Results: Mean age was 60±12 years, 85% male, 49% smokers (3% former smoker), 9% COPD, 60% hypertensive, 34% dyslipemic, BMI 28±4 (40% obese), 37% ICC, 17% previous ischemic heart disease and 46% had previous radial catheterization.

The diameter used was 6F and all of them by right radial artery. The mean number of attempts at arterial puncture was 1.1±0.4. Catheterization was diagnostic in 60% and 40% therapeutic, the mean fluoroscopy time was 15±13 min, while the cannulated time 39±19 min. By radioscopy the radial diameter was small (<0.3 cm) in 6%. 14.3% were emergency procedures.

The mean number of diagnostic catheters used was 1.8±0.7 and 1.2 ± 0.4 therapeutics. Terumo hydrophilic wire was required in 3% and sheathless catheter in 6% of cases. On the EVO pain scale the mean was 4.3±1.8 points. Midazolam / fentanyl was given in 25% of cases.

Intimal tears were observed in 18% RAs and were more frequent in the proximal than in the distal RA. Medial dissections were uncommon (6.5% RAs). The frequency of acute injury was similar between groups. Intima/medial area (0,28±0,11 vs 0,35±0,15; p=0.03), the máximum intimal thickness/medial thickness ratio (0,37±0,17 vs 0,54±0,26; p=0.01), and percent narrowing were all significantly greater in repeat-TRI RAs in the proximal RA.

CONCLUSIONS

Optical coherence tomography is a safe and usefull technique to evaluate acute and chronic effects of transradial coronary intervention on the radial artery. There are significant acute injuries and chronic intimal thickening of RA after TRI, mainly in the proximal segment. Further study should evaluate the impact of these effects when TRI RAs are subsequently used as conduits, on long-term graft patency and on clinical outcomes after bypass surgery.

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Coronary artery aneurysm: prevalence, management and outcomes in a long-term follow-up

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

AIMS

The aim of this study was to evaluate the incidence, etiology, clinical features, management and long term outcomes of patient with coronary artery aneurysm (CAA).

METHODS AND RESULTS

Coronary artery aneurysm (CAA) was defined as coronary dilatation which exceeds the diameter of normal adjacent segments or the diameter of the patient's largest coronary vessel by 1.5 times. Between Jan 2009-Dec 2015, from 12600 patients who underwent angiography at our centre, 77 ambispectively patients with CAA were included (incidence of 0.61%). Mean age was 69±10 years, 74% male, 42.9% were diabetics, 63.7% smokers (40.3% former/23.4% active), 84.4% hypertensive, 66.2% dyslipidemic, 1.3% with family history of ischemic heart disease, 6.5% Atrial fribrillation, 12.9% COPD, 24.7% prior ischemic heart disease and 10.4% prior PCI or 3.9% CABG, 14.3% PAD, 6.5% CKD (GFR <30 ml/min). 42.9% were on ASA and 10.4% OAC. 28.6% presented some degree of LV dysfunction. Indication for angiography was ACS in almost all cases 81.8% (76% NSTEMI, 24% STEMI). Dominance was right in 83.1%. Up to 75.4% were multivessel, the LM was involved in 15.5%. The most frequently treated artery was the LAD (47%) followed by RCA (17.2%) and Circ (16.1%) and the mid segments were most often affected (47%).

Regarding aneurysm analysis: The most frequent aneurysm type was sacular (53.2%) followed by fusiform (46.8%), with a maximum diameter size of 5.1±1.2 mm by QCA. 7.8% were giant aneurysms. 64.6% had a >50% stenosis in the inmediately proximal o distal spot of the aneurysm. The location was predominently in the LAD (62%), followed by RCA (32.4%), CX (22%), LM (5.1%). 20.7% had multiple aneurysms. 14.3% presented ectasic vessels. Some type of intracoronary imaging technique was performed in 12.9% (5.2% OCT vs 7.8% IVUS). We performed PCI on other lesions in 61%. Regarding the management of CAA, we performed PCI in 53.2% (68% DES; 2.4 BVS; 19.5% BMS; 9.7 CABG) and conservative management in 46.8%. 93.5% were discharged on ASA, 80.5% DATP (mostly with clopidogrel). 10.4% received oral anticoagulation at discharge. The average duration of dual antiplatelet therapy was 10±4.6 months (7.8% indefinite).

During a mean follow-up of 46±28 months, MACE rate was 38.9% (15 deaths: 3 Non CV-deaths, 8 CV deaths, Unknown deaths; 9 Unstable Angina, 5 AMI and 3 non-fatal Bleeding, 2 strokes). The TLR rate on the aneursym was 12% (2 restenosis treated by POBA and 3 new DES implantation). We performed angiographic control in 32.4%.

CONCLUSIONS

In the present analysis, the incidence of CAA is low, with male dominance, predilection for the left anterior descending artery and mostly asociated with atherosclerosis and several cardiovascular risk factors. The Independently of the management, MACE rate was high in a long-term follow-up.

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Nurse led follow-up of a large UK percutaneous mitral valve repair programme demonstrates significant improvement at six weeks in mitral regurgitation, symptoms and quality of life in a consecutive 82 patient cohort

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair, Other valvular and structural interventions

AIMS

We instituted a nurse led follow up programme, with emphasis on clinical and quality of life assessment after MitraClip. We present the 6 week follow up results of this 2 year initiative involving ‘one stop’ nurse led assessment.

METHODS AND RESULTS

Percutaneous mitral valve repair with MitraClip has become a viable option for the treatment of both degenerative (DMR) and functional (FMR) mitral regurgitation in recent years. In the United Kingdom, regular access to MitraClip has been limited to only three centres, with reimbursement provided through the Commissioning through Evaluation (CtE) initiative. As one of the CtE centres, participating in this 2 year programme, we have established a multi-disciplinary heart team responsible for assessment and follow up of patients.

All patients who underwent MitraClip at our institution over a 2 year period were assessed by a specialist nurse before, immediately after and then at pre-specified time intervals of 6 weeks, 6 months and 1 year. In addition to a transthoracic ECHO examination and blood profile, each patient underwent a clinical assessment, 6 minute walk test (6MWT) and completed validated quality of life (QoL) questionnaires. Additionally, owing to the frailty and distances travelled by many of the patients, telephone follow up with assessment of symptoms was employed to optimise patient care, identify deterioration early and improve data collection. Data collected at every time point was entered onto National Institute for Cardiovascular Outcomes Research (NICOR) online database.Results

A total of 82 patients successfully underwent the MitraClip with during the 2 year period with a mean age of 74±11, 60% being male. Data are reported as mean at baseline and 6 weeks ±SD. All patients had been deemed unsuitable for surgical mitral intervention by the Heart Team (55% DMR, 45% FMR). Mean grade of mitral regurgitation (MR) decreased significantly from baseline to 6 weeks (3.8 ± 0.4 vs1.7± 0.9, p<0.001). 6MWT (metres) increased numerically over the same period (297± 85 vs 347± 116, p=0.11). As a subjective measure, we asked patients to rate their overall health from 0-100% (derived from the EuroQol survey). Patients reported a significant symptomatic improvement (48.3% ± 20.1 vs 63.8% ± 21.3, p<0.001).

CONCLUSIONS

We have demonstrated in this real-world series that MitraClip is a safe and effective treatment for MR in non-surgical high risk patients. A dedicated patient-centred follow up programme led by a specialist nurse can be an efficient and effective method of monitoring patients for up to 1 year post-procedure. In our experience, in this group of patients with multiple supervising consultants, the highly targeted and personal follow up offered by the Mitral Nurse ensured continuity, close monitoring and a co-ordinated approach to National Data Collection. Further studies are required to examine the relative merits of nurse led follow up compared to the traditional physician led model. The overall findings of the UK MitraClip CtE programme are awaited.

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Influence of the percentage of patients aged 80 or older on major bleedings after a LAA closure. Results of the II Iberian registry

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

Elders belong to a subgroup of patients with increased risk of events inherent to their old age, after LAA closure. However, there is no clear awareness of major bleeding events and particularly digestive bleeding in the population ≥ 80 years of age.

METHODS AND RESULTS

In the II Iberian Registry, two populations aged < or ≥ 80 years (465 vs 133 patients) were compared. The average age was 71.0 ± 6.8 vs. 83.3 ± 2.6 ($p < 0.001$). CHA_2DS_2-VASc scores were 4.2 ± 1.5 vs 5.1 ± 1.4 ($p < 0.001$) and the HASBLED scores were 3.3 ± 1.2 vs 3.5 ± 1.1 ($p = 0.248$). The percentage of patients with a history of intracranial hemorrhage was low (29.5% vs 19.5%; $p = 0.028$) compared with gastrointestinal bleedings (35.7% vs. 54.9%; $p < 0,001$) and major bleedings (25.8% vs 37.6%; $p = 0.009$). The rest of clinical variables were balanced.

Events are presented as follow-up adjusted rate, since follow-up times were different (<80: 23.5 months; >80: 18.7 months). Deaths: 5.7% vs 13.7% (HR:2.4; p<0.001), Stroke: 1.8% vs 2.5% (HR:1.4; p=0.56), intracranial hemorrhage: 0.7% vs 0.5% (HR:0.7; p=0.64), gastrointestinal bleedings: 2.8% vs 9.1% (HR:3.3; p<0.001), and major bleedings: 4.3% vs 13.3% (HR:3.1; p<0.001) patient-years. However, an important decrease in bleeding events occurs after 1 year, as it happens with patients < 80 years of age (0.5% patients-year vs 2.9% patients-year p= 0.007).

CONCLUSIONS

The percentage of patients aged ≥ 80 in the various series of LAA closure, may significantly influence the incidence of major bleedings beyond than expected by HASBLED, especially due to the high frequency of gastrointestinal bleedings.

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Pacing through the left ventricular wire in balloon-expandable and self-expandable TAVI

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

AIMS

The insertion of a right ventricular lead for rapid or back-up pacing in TAVI is time-consuming and has been associated with vascular complications and right ventricular perforation.

METHODS AND RESULTS

As of April 2016, a strategy of systematic pacing through the left ventricular (LV) wire in patients undergoing TAVI was adopted at our centre.The temporary pacemaker was connected to the stiff wire and a subcutaneous needle using alligator clips. The temporary pacemaker was then tested for rapid (or back-up) pacing using maximal output and minimal sensitivity when the device delivery catheter was positioned close to the aortic valve.No temporary pacemaker was placed at the end of the procedure, unless the patient developed atrioventricular block or if QRS duration was greater than 160 ms,Patients with the following ECG criteria were excluded from the LV-pacing strategy, and received a transvenous temporary pacemaker: complete right bundle branch block (RBBB), complete left bundle branch block (LBBB) >140 ms or bifascicular block with PR interval >240 ms.From April 2016, 184 patients were subjected to this strategy. Patients had a mean age of 83±5.9 years, 52.2% were male, and mean Logistic Euroscore and STS were 16.5±11.6% and 5.3±4.7%, respectively. 97 (52.7%) patients received a balloon-expandable valve and 87 (47.3%) received a self-expandable valve.Left ventricular pacing was performed in 142 patients (77.2%). There were no cases of ineffective pacing requiring a temporary venous pacemaker. In 20 patients (14.1%), a temporary venous pacemaker was required at the end of the procedure due to the occurrence of atrio-ventricular blockand permanent pacemaker was implanted in 16 patients (11.3%). In the 42 patients (22.8%) in which left ventricular pacing was not attempted, the temporary venous pacemaker was left in place at the end of the procedure in 19 cases (45.2%, p<0.0001) and permanent pacemaker was implanted in 15 patients (35.7%, p<0.0001).

CONCLUSIONS

Left ventricular pacing during TAVI is feasible, safe and effective in patients without severe conduction disturbances at baseline.

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Effects of renal denervation on muscle sympathetic nerve activity at rest and during mental stress in patients with resistant hypertension

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THEME: Interventions for Hypertension
TOPIC(S): Renal denervation

AIMS

Studies have shown varying effect of RDN on resting muscle sympathetic nerve activity (MSNA). Mental stress affects sympathetic nerve activity and MSNA. We aimed to assess effects of RDN on MSNA during mental stress in resistant hypertension.

METHODS AND RESULTS

Twenty-three consecutive patients with resistant hypertension (RH) underwent renal denervation (RDN). Multi-unit MSNA, blood pressure (BP) (Finapress ®) and heart rate (HR) at rest and during mental stress (forced arithmetics), were assessed at baseline and 6 months after intervention. The study was approved by the ethics committee at Gothenburg University.

Eleven patients were included into data analysis. Systolic office BP decreased 8 mmHg 6 months after RDN (182±24 vs.174±34 mmHG; p=.27). Mean systolic 24-h ambulatory BP was 163±20 at baseline and 162±24 mm Hg at 6-months follow up (p= .64). Office BP response of > 10 mmHg at follow-up was noted in 5/11 patients. No significant changes in MSNA at rest were noted at follow-up (68±5 vs 73±5 bursts/100hb; p=.43). Mental stress was associated with a significant increase in mean arterial BP both pre- (p=.043) and post-intervention (p=.01). Likewise, HR increased during mental stress (p=.095 and .173, respectively). MSNA, both pre- and post-intervention, was similar before and during mental stress (67±6 vs 61±9 bursts/100hb; p=.325 and 80±7 vs 71±7 bursts/100hb; p=.515, respectively). We did not note any correlation between MSNA and office BP response after RDN.

CONCLUSIONS

MSNA at rest, as well as MSNA- and BP-responses during mental stress, remained unchanged 6 months after renal denervation. The BP-reducing effect of RDN does not appear to depend on lowering of MSNA at rest, nor on a modulation of MSNA responses to stress.

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Conduction dynamics after TAVI and implications for permanent pacemaker implantation and early discharge - The CONDUCT study

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

AIMS
To correlate dynamics in electrical conduction after transcatheter aortic valve implantation (TAVI) with need for permanent pacemaker implantation (PPM) and assess implications for early discharge.
METHODS AND RESULTS
TAVI was performed in 291 consecutive patients with three contemporary transcatheter heart valve designs: Medtronic CoreValve (n=111), Edwards Sapien-XT (n=29) and Sapien 3 (n=72), and Boston Lotus (n=79). We considered two cohorts: A. Patients with normal baseline conduction; and B. patients with conduction disturbances at baseline. Daily ECGs until discharge or to a maximum of 14 days were analyzed. Based on QRS dynamics, three patterns were discerned: stable normal QRS duration (<20 ms change), transient QRS prolongation (>20 ms change but recovery within 20 ms from baseline) and persistent QRS prolongation (>20 ms change). In cohort B QRS dynamics did not correlate with PPM. In contrast, in cohort A QRS dynamics and PPM appeared highly correlated. Neither patients with stable normal QRS duration (0/47), nor patients with transient QRS prolongation required PPM (0/26). All PPMs occurred in patients with persistent QRS prolongation until discharge (27/85). A stable normal QRS duration could be accurately determined as soon as day 1 post TAVI, whereas transient/persistent QRS prolongation fluctuated until at least day 6. Persistent QRS prolongation was typically seen with Lotus (7% stable, 24% transient, 69% persistent) and with CoreValve (28% stable, 16% transient, 57% persistent). ES-XT and ES-3 were typically followed by stable normal QRS duration (51% stable, 13% transient, 36% persistent).
CONCLUSIONS
Three distinct patterns of QRS dynamics can be discerned after TAVI and their predictive probabilities for PPM strongly relate to the baseline conduction status. Patients with normal conduction at baseline and stable QRS duration after TAVI are potentially eligible for early discharge. Patients with pre-existing or newly acquired persistent conduction disorders need prolonged telemetric monitoring because the need for PPM is high.

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Cost-effectiveness of polymer-free drug-coated coronary stents in patients at high bleeding risk: economic evaluation of the LeadersFree trial

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

AIMS

In patients at high risk of bleeding who undergo PCI the biolimus A9 polymer-free drug coated stent (DCS) has shown superior efficacy and safety compared to a bare metal stent (BMS). Our objective was to estimate the cost effectivenss of DCS vs BMS.

METHODS AND RESULTS

The Leaders free-based economic evaluation valued service use and quality of life (QALY) data collected prospectively from the entire trial population. Fully pooled within-trial hospital resources were costed for England, France, Germany, Italy, Scotland, Spain. Country-specific utilities were derived from EQ-5D scores. We estimated incremental cost per incremental event averted and per QALY gained aind explored uncertainty with bootstrap.

Use of DCS resulted in 0.095 fewer cardiac death, target vessel MI, stent thrombosis and revascularization per patient (0.152 vs 0.237 p<0.001). One-year QALYs were non significanltly higher in the DCS group, ranging from 0.671 to 0.790 in the DCS group vs 0.662 to 0.713 in the BMS group. Total costs for the index admission were similar between groups. At 1 year, total average costs per patient in the 6 countries ranged from €4,846-8,593 in the DCS group and €4,845-9,742 in the BMS group. The additional €300 per DCS was offset by reduced repeat admissions. The total 1-year costs, including stent costs, were lower in the drug coated stent group (cost differences: England €-588, France €-339, Germany €-181, Italy €-748, Scotland €-437, Spain €-1,149). In the cost effectiveness analysis, the probability that DCS dominated BMS (cheaper and more effective in terms of events averted and QALYs) was > 50% in all countries. At a threshold of €10,000 per event averted DCS had a 98% probability of being cost effective in all 6 countries. If stakeholders were ready to pay €50,000 per QALY the probability of being cost effective was 70-75% for all countries.

CONCLUSIONS

LEADERS FREE was the first study to directly compare the clinical and economic outcomes of drug coated and bare metal in patients at high risk for bleeding. Use of the drug-coated stent was associated with a better safety and reduced events rate at one year.The Leaders free economic evaluation found that using DCS in patients at increased risk of bleeding was consistently cost-saving and event-reducing in all 6 countries studied. This dominance of drug coated stents was explained by the better results in safety and efficacy: hospital costs were reduced in all countries following fewer and shorter re-admissions, and lower costs. Between-country variations were mostly explained by differences in hospital costs; higher hospital costs were associated with a higher probability of drug coated stents being dominant. In a context where reimbursement prices are discussed separately in every country based on local data, country-specific analyses help decision-makers to assess cost-effectiveness of interventions.

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Cardioprotective effects of intracoronary morphine in patients with STEMI undergoing primary PCI: a prospective, randomised trial

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

We sought to evaluate the effect of intracoronary morphine on myocardial infarct size in patients with ST-elevation myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PCI).

METHODS AND RESULTS

This study was designed as a 2-center, prospective, randomized open-label, blinded endpoint trial. A total of 91 STEMI patients with thrombolysis in myocardial infarction (TIMI) flow grade of 0-1 undergoing primary PCI were randomly assigned to a morphine or control group at a 1:1 ratio. The morphine group received 3 mg of morphine sulfate diluted with 3 ml of normal saline and the control group received 3 ml of normal saline into a coronary artery immediately after restoration of coronary flow. The primary end point was myocardial infarct size assessed by cardiac magnetic resonance imaging (CMR). CMR images were evaluated for 42 and 38 patients in the morphine and control groups, respectively. Myocardial infarct sizewas not different between the 2 groups (25.6±11.2% versus 24.6±10.5%, p=0.77) nor was the extent of microvascular obstruction or myocardial salvage index (6.0±6.3% versus 5.1±4.6%, p=0.91; 31.1±15.2% versus 30.3±10.9%, p=0.75, respectively). There was no difference in peak creatine kinase-MB level, final TIMI flow, myocardial brush grade, or complete resolution of ST-segment.

CONCLUSIONS

Intracoronary morphineadministration could not reduce myocardial infarct size in STEMI patients undergoing primary PCI.

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Early experience with the Trialign system for transcatheter tricuspid valve repair: a multicentre experience

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THEME: Interventions for Valvular Disease
TOPIC(S): Tricuspid / Pulmonary valve, Other valvular and structural interventions

AIMS

Transcatheter tricuspid valve repair technologies are emerging as alternative therapeutic options for high surgical risk patients. We aimed to show the feasibility and efficacy of a transcatheter tricuspid annular repair.

METHODS AND RESULTS

Fourteen patients with severe tricuspid regurgitation underwent tricuspid valve repair with Trialign system (Mitralign, Massachusetts) as a compassionate use using trans-jugular venous access. One or two pairs of pledgets were placed between the antero-posterior and septo-posterior commissures and than cinched together bicuspidizing the tricuspid valve. The following measurements were made on intra-procedural transesophageal echocardiography: vena contracta diameter (VC), effective regurgitant orifice area (EROA) and TV annular area and diameter.

Mean age was 73 ± 11 years and mean log EuroSCORE 16.7 ± 13.7%. Acute procedural success was achieved in all patients with significant improvement in valvular regurgitation and dimensions. The average acute procedural reduction of VC was **–**42% (pre-procedure 10.9 ± 3.4 mm (mean ± SD), post-procedure 5.8 ± 2.4 mm, p=0.013) and EROA was **–**51% (pre-procedure 0.92 ± 0.77 cm^2, post-procedure 0.33 ± 0.16 cm^2, p=0.038). Tricuspid valve annular area (pre-procedure 15.9 ± 6.6 cm^2, post-procedure 9.6 ± 4.1 cm^2, **–**34%, p=0.001) and diameter (pre-procedure 47 ± 7 mm, post-procedure 40 ± 7 mm, **–**17%, p=0.004) were also reduced.

CONCLUSIONS

Transcatheter tricuspid valve repair with Trialign system is feasible and safe, and shows promising results, which have to be confirmed by a larger study.

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Comparison of acute thrombogenicity for metallic and polymeric bioabsorbable scaffolds in a porcine arteriovenous shunt model

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

AIMS

The acute thrombogenicity of Magmaris magnesium BRS and the ABSORB BRS has not been compared. This study assessed acute thrombogenicity of Magmaris compared with ABSORB and the ORSIRO hybrid DES in a porcine arterio-venous shunt model.

METHODS AND RESULTS

An ex-vivo porcine carotid jugular arteriovenous shunt was established and connected to Sylgard tubing containing the Magmaris sirolimus-eluting magnesium bioabsorbable scaffold (140 μm strut thickness), ABSORB everolimus-eluting bioresorbable vascular scaffold (150 μm strut thickness), and Orsiro Hybrid cobalt chromium stent with a sirolimus-eluting bioresorbable PLLA polymer coating (60 μm strut thickness) were inflated to nominal pressure and allowed to run in the shunt for a maximum of one hour. Twelve shunts (2 shunt runs per pig) were run comparing the three scaffolds in alternating order. Nested generalized linear mixed models were employed to compare variables between scaffold groups while adjusting for variability between shunt runs. Confocal fluorescent microscopy costaining CD61/CD42b demonstrated both Magmaris (3.0 ± 0.8%) and Orsiro (5.3 ± 3.4%) had significantly less platelet coverage of the total scaffold compared with ABSORB (20.8 ± 12.6%). Scanning electron microscopy demonstrated significantly less thrombus deposition to Magmaris as a percentage of the total scaffold compared with ABSORB (5.2 ± 0.4% vs 18.5 ± 11.3%, $p<0.05$). Both Magmaris and Orsiro had significantly less PM-1 positive neutrophil and CD14 positive monocyte adherence compared with ABSORB. Magmaris had significantly less monocyte deposition compared with Orsiro. To further determine whether the polymer coating or metal scaffold significantly reduced the thrombogenicity of Magmaris BRS, a stainless steal stent with the same sirolimus-eluting bioabsorbable polymer as Magmaris was created (316-L) with 140 μm strut thickness. When compared in the porcine arteriovenous shunt model, the Magmaris BRS had significantly less platelet (2.6% vs 5.7%, $p<0.0001$) and inflammatory cell coverage ($p<0.001$) compared with the 316-L stent, demonstrating the magnesium biobasorbable stent repels platelets and inflammatory cells.

CONCLUSIONS

Despite a similar scaffold strut thickness, the Magmaris sirolimus-eluting bioabsorbable magnesium scaffold was significantly less thrombogenic compared with the ABSORB BVS in an ex vivo porcine arteriovenous shunt model. We further demonstrated that the magnesium scaffold may help repel platelets and inflammatory cells. Further studies are needed to determine whether the reduced thrombogenicity of Magmaris will result in reductions in major cardiovascular events.

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Rotational atherectomy in severely calcified undilatable coronary artery lesions: a detailed analysis of complications

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

AIMS

Rotational atherectomy (RA) is an effective tool to prepare calcified lesions prior to stent implantation. We assessed the incidence and reasons of complications during RA. It may be useful to prevent future complications in less experienced centers

METHODS AND RESULTS

Out of 10.828 consecutive patients with PCIs, 343 patients (3.2%) underwent RA, performed in 353 vessels. RA was performed only in severely calcified lesion with failed balloon dilation. Procedural success was defined as RA plus stent implantation with residual stenosis <20% and TIMI ≥II without a severe complication. Severe complications were defined as death, Q-wave myocardial infarction, perforation of RV or vessel and urgent CABG.

Mean age of the 343 patients was 70.2 ± 8.2 yrs, 84% were male. Procedure success was achieved in 326 patients (95%). Severe complications occurred in 7 pts (2%).

Patients' demographics and procedural data did not differ between patients with successful vs. non successful procedures. In particular, the number of bifurcation lesions, ostial and CTO lesions, the mean burr size and type of target vessels were not significantly different.

Three patients died (0.9%), one from cardiogenic shock, where RA was performed on LAD despite presence of severe aortic stenosis and hypokinesia of the inferior wall. In this pt. RA should have been omitted to avoid severe hemodynamic compromise. The second pt. died from cardiac tamponade caused by wire perforation in a non rotablated vessel, the third pt. developed a cardiogenic shock of unclear etiology despite successful RA, both seemed not preventable.

Four pts. (1.2%) underwent emergency CABG. Pt. 1 had RA of a highly calcified ostial lesion in the diagonal branch with a 90° angle from the main branch, which resulted in vessel perforation and occlusion of the LAD. This pt. had an unsuitable vessel anatomy and should not have undergone RA. In Pt. 2 we saw burr entrapment within the lesion due to brisk advancement of the rotablator. Pt. 3 showed a temporary pacer induced perforation of the RV by using a non-balloon-tipped catheter. These two complications seemed to be preventable. Pt. 4 had failed wire crossing of a large non-rotablated RPL of the RCA, a complication, which was not preventable.

CONCLUSIONS

In this large cohort of PCI patients RA was performed in 3.2%. Severe RA complications occurred in 2%. The main aspects to reduce the complication rate are respecting the vessel anatomy, exclude patients from RA if this leads to severe hemodynamic compromise, use gentle forth and back burr movement and avoid non-balloon-tipped pacemaker leads. One out of 3 deaths and 3 out of 4 emergency CABG thus could have been avoided.

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Despite the plaque redistribution, stenting of lipid-rich lesions do not cause distal embolisation - Data from combined near-infrared spectroscopy and IVUS imaging

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

AIMS

The present study aimed to characterize the plaque redistribution of lipid-rich lesions after stenting regarding the presence of distal embolization.

METHODS AND RESULTS

The combined near-infrared spectroscopy (NIRS) and intravascular ultrasound (IVUS) imaging analyzed the plaque distribution after the stent implantation in vivo in patients with a stable CAD (n=33) and acute coronary syndromes (n=16). NIRS detected lipids in the lesion and IVUS presented the redistribution of the plaque. NIRS estimated the maximal lipid core burden index in a 4mm long segment (LCBI4mm) before and after the stent implantation, and IVUS determined minimal lumen area (MLA), plaque burden (PB) and plaque volume pre and post implantation.

NIRS-IVUS imaging was performed before and after the implantation of 50 stents in 49 patients. The median plaque volume pre and post implantation was 127.45 (74.5, 186.8) mm2 vs. 99.35 (67.5, 171.5) mm2 (P<0.001) with a median difference 19.25 (3.9, 72) mm2. The median LCBI4mm pre and post stent was 351 (157, 589) vs. 77 (3, 231) (p<0.001) in the treated lesions, and 34 (0, 207) vs. 0 (0, 45) (p<0.04) in segment 4mm long proximally to the stent. PB in 4mm proximally to the implanted stent increased from 46.23±11.79 to 50.36±9.93 post stenting (p=0.02). The difference in the plaque volume pre and post stenting correlated with the value of LCBI4max of the treated lesion (r=0.457, p=0.001). The median difference in the plaque volume was higher for stented lesions with LCBI4mm>265 [8.2 (1.4, 19.3) vs. 24.3 (12.1, 45.0) p=0.012]. Despite the plaque redistribution, none of the PCI was complicated with a no-reflow phenomenon or peri-procedural myocardial infarction.

CONCLUSIONS

Stenting of lipid-rich lesions characterized greater release of the atheroma remnants to the coronary artery lumen as compared to non-lipid rich lesions, but the lack of distal embolization suggested that stenting of lipid-rich lesions was insufficient to trigger distal embolization

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ConfidenHT system safety and performance of diagnostic electrical mapping of renal nerves in hypertensive patients and/or potential candidates for a renal sympathetic denervation (RDN) procedure

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THEME: Interventions for Hypertension
TOPIC(S): Renal denervation, Other hypertension

AIMS

To address one of the major challenges in performing effective renal sympathetic denervation, using the ConfidenHT™mapping system (renal nerve electrical stimulation), and to determine the safety and effectiveness of this system in human.

METHODS AND RESULTS

Ten out of 20 hypertensive patients (63±10.9 years old, 162±18 office systolic BP, 4/6 male/female respectively, and GFR of 75±11.8 mL/min/1.73 m^2) who underwent coronary angiography for diagnostic purpose or were planned for renal denervation were recruited from October 2016 to December 2016 in a prospective, multi-centered study. Following patient recruitment, all patients underwent renal mapping using theConfidenHT™system.

The results shows that electrical stimulation of sympathetic fibers in the renal arteries can elicit a sympathetic response, which in turn drive a transient change in several physiological measurable parameters such as, heart rate and blood pressure.

This technology will improve RDN procedures by providing: (1) better patient selection of RDN responders and non-responders prior to nerve ablation, and (2) intra-procedural guidance and feedback during the procedure for optimal target areas for ablation.

The ConfidenHT™ System consists of two main parts, a catheter and a console.The Console delivers electrical energy to the catheter using a multi-channel stimulator, and a real time intra-arterial Blood Pressure (BP) monitor, which records, analyzes (using a proprietary algorithm) and displays the stimulation outcome (BP and/or HR changes) during the mapping phase.

The ConfidenHT™ catheter is a non-occluding flexible catheter with expendable multi electrode design, compatible with an 8Fr guiding catheter and 0.014" guide wire, for a wide range of renal artery diameters.

CONCLUSIONS

No adverse events intra and/or post procedure were reported. The ConfidenHT™ system procedure showed varying responses to electrical stimulation among patients as well as location dependent response along the artery for a given patient (Hot and Cold spots). The increase in systolic BP ranged from 0 to 26 mmHg.

Currently, 7 patients have their 1 month follow up results for renal function and BP change.

These preliminary results suggest that the ConfidenHT™ system technology is feasible and safe and offers promising diagnostic electrical mapping of renal nerves in hypertensive patients and/or potential candidates for a renal denervation (RDN) procedure. Longer follow up regarding BP changes and renal function is needed in patients after use of the ConfidentH™ system along with testing the RDN efficacy in arterial sites showing better response to electrical stimulation.

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Non-culprit stenosis evaluation using iFR in patients with STEMI

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

AIMS

To examine whether instantaneous wave-free ratio (iFR) is reliable in the acute evaluation of non-culprit coronary stenoses in patients with ST-segment elevation myocardial infarction (STEMI).

METHODS AND RESULTS

Patients with STEMI and non-culprit coronary stenoses were included immediately after successful acute revascularisation of the culprit lesion. Non-culprit lesions were not treated during the acute procedure. Acute non-culprit stenosis iFR was measured during the acute procedure. Follow-up non-culprit stenosis iFR and fractional flow reserve (FFR) was measured at a staged follow-up procedure. The interval between acute and follow-up procedures was left to the discretion of the operator. We considered iFR < 0.90 to be significant. We included 120 patients with STEMI and 157 non-culprit lesions in total. Median time from the acute evaluation to follow-up evaluation was 16 (interquartile range (IQR) 5-32) days. Median acute iFR was 0.89 (IQR 0.82-0.94, n=156). Median follow-up iFR was 0.91 (IQR 0.86-0.96, n=147) and median follow-up FFR was 0.81 (IQR 0.75-0.88, n=146). In 8 lesions with acute iFR ≥ 0.90, follow-up iFR was < 0.90. In 6 lesions with acute iFR ≥ 0.90, follow-up FFR was < 0.75.

CONCLUSIONS

Our results suggest that iFR, an adenosine-free method for stenosis evaluation, may provide reliable evaluation of non-culprit stenoses during the acute phase of STEMI. Thus, iFR may be a valuable method to guide full revascularisation in patients with STEMI.

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Is PCI with BRS more time and resource consuming than with DES? Preliminary results from an international multicentre registry (CAPITAL trial)

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

AIMS

BRS emerged as an alternative to DES but a specific implantation strategy is needed to achieve good results and to reduce scaffold thrombosis. The aim of the study is to clarify if BRS implantation result in greater resource consumption.

METHODS AND RESULTS

In order to compare resource utilization of PTCA using BRS and second generation DES, we retrospectively analyzed procedures performed between 2008 and 2016 in 8 experienced centers in Europe. The procedures were then matched by clinical (patient age, gender, diabetes) and technical (number of stents/scaffolds per procedure, bifurcation or chronic total occlusion, use of intracoronary imaging) factors that may represent confounders in term of material of time consumption. A total of 374 matched procedures were identified (187 in each group). No significant differences were noted in population characteristics regarding age (61.2±9.5 in BRS group vs 61.5±9.5 in DES group; p=NS), renal function (eGFR 67±16 vs 72±26 ml/min; p=NS), male sex (88% vs 89%; p=NS), diabetes (25 vs 28%; p=NS) as well as other common risk factors (hypertension, smoke, previous revascularization). Regarding procedural aspects there were no differences in bifurcation rate (18% vs 16%; p=NS), intravascular imaging use (15% vs 13.4%; p=NS), mean stent number or length (1.9±1 vs 1.9±1 and 44±25mm vs 43±26mm; p=NS). When DES were implanted, a higher number of guidewires were used (2.1±1.2 vs 2.5±1.6; p<0.05). Predilatation rate was significantly higher in the BRS group (97% vs 78%; p<0.05) with a higher (but non significant) number of balloons (2±1.5 vs 1.7±1.6; p=0.06) and plaque-debulking devices such ad scoring balloons (9.1% vs 3.7%; p<0.05); use of or rotational atherectomy (1.6% vs 5.3%; p=0.01) was not different between groups. Procedural success was the same (99.5% vs 99%; p=NS) with slightly but significantly longer procedural and fluoroscopy time in BRS group (104±42min vs 84±37min; p<0,05. 31±18min vs 24±16 min; p<0.05). The amount of contrast media was higher in BRS group (260±113ml vs 223±102ml; p<0.05). Peri-procedural MI incidence (5.3% vs 3.3%; p=NS) and length of hospitalization were not different between groups. At a mean follow-up of 505±292 days, there were no differences in term of ST (1.1% in BRS group vs 0.6% in DES group; p=NS), TLR (7.3% vs 6.4%; p=NS), MACE (9.1% vs 6.4%; p=NS) or TLF (7.5% vs 5.3%; p=NS).

CONCLUSIONS

The preliminary data from this multicenter registry confirm that BRS use seems to be safe and effective in term of procedural and medium-term clinical success as DES in daily practice. However BRS procedures are characterized by a higher consumption of balloons, plaque-debulking devices, contrast media, and by longer procedural and fluoroscopy time. Further investigations and long-term follow-up are needed in order to demonstrate whether the theoretical benefits of BRS justify the need for higher resource utilization.

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Out-of-hospital cardiac arrest: place of post-resuscitation electrocardiogram for coronary angiogram indication

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

AIMS

To determine if immediate post-resuscitation ECG changes after Out-of-Hospital Cardiac Arrest (OHCA) may be useful as a triage method to improve indications for emergency coronary angiogram

METHODS AND RESULTS

Between January2014 and May 2015, we included in a bicentric prospective study all consecutive patients admitted for coronary angiogram after OHCA. Three groups were defined according to ECG obtained after resuscitation: group 1 included ST segment elevation and LBBB; group 2 any other ST/T repolarisation disorder; and group 3 no repolarisation disorder. The primary endpoint was proportion of acute coronary lesion in each groupdefined by acute coronary occlusion (TIMI 0 or 1), thrombotic or critical stenosis and predictor factors of acute coronary lesion were secondarily defined.

The study enrolled 129 patients, 62 patients (50.8%) in group 1, 30 patients (24.6 %) in the group 2 and 30 patients (24.6%) in group 3. Acute coronary artery lesion was confirmed in 55 patients (43 %), mainly in group 1 (n=44, 72.1%). Initial coronary TIMI 0/1 flow was observed in 26 patients (20.1%), more frequently in group 1 than in group 2 (n=25, 57% *versus* n=1, 14%, p=0.009) and was not observed in group 3. Onmultivariate analysis, chest pain before cardiac arrest, ST segment elevation or LBBB on initial ECG were the best predictive factors of acute coronary lesion. Initial ECG without repolarization disorder can exclude acute coronary lesion with NPV of 93.33% and coronary occlusion with a NPV of 100%.

CONCLUSIONS

Considering the high negative predictive values of ECG to exclude acute coronary artery lesions and particularly acute coronary occlusion after OHCA, this study suggests that a delayed coronary angiogram is sage for patients without any repolarization disorder.

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Evaluation of long-term outcomes and arrhythmia burden of a very early discharge strategy (within 48 hours) after primary PCI: an observational study

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

AIMS

Primary PCI (PPCI) has dramatically reduced hospital stay globally and patients are discharged routinely at 72 hours. We aimed to evaluate outcomes and arrhythmia burden of patients discharged very early after their PPCI (within 48 hours).

METHODS AND RESULTS

We enrolled 71 consecutive patients who underwent successful PPCI in a tertiary centre over the summer of 2016. We excluded patients who needed intensive unit care, staged revascularisation procedures including CABG, intra aortic balloon pump insertion, and had out of hospital cardiac arrest and procedural complications. All patients were managed as per ESC guidelines on STEMI and were discharged according to individual clinicians' recommendations. All patients underwent ambulatory ECG monitoring prior to discharge for at least 24 hours and detailed rhythm analysis was done by physiologists blinded to the discharge status. Demographic, procedural and outcome data was collected prospectively and follow up data was collected for six months. Patients were divided into ED: early discharge group (within 48 hours) and RD: routine discharge group (after 48 hours).

We included 44 patients who fulfilled our eligibility criteria and had completeness of the data. The mean age was 65.7 years (±SD12.1) and 55% were men. One third of the patients were smokers and 17% were treated for type 2 diabetes mellitus. Inferior MI was diagnosed in half of the study population and all patients were treated with DES (mean number of stents 1.7±0.9) . Radial access was used in 89% cases and 100% had immediate procedure success with restoration of TIMI 3 flow. None of the patients had major vascular complications or bleeding. All were treated with aspirin and prasugrel as per ESC guidelines and GP IIbIIIa inhibitors were used at operators' discretion. Median duration of hospital stay was 72 hours and 34.1% (n=15) were discharged with in 48 hours (ED group). Patients in the ED group were younger (mean±SD, in years, 55.5±7.5 vs 70.7±11.4, p=0.001) and had better renal function (eGFR, mean±SD, mmol/l, 85.6±11.2 vs 74.2±11.2, p=0.045). Higher proportion of men (73.3% vs 48.3%, p=0.112) and current smokers (80.0% vs 29.4%, p=0.001) were discharged early. There were no differences in CV risk factors such as dyslipidaemia, history of diabetes mellitus and hypertension between the groups. Admission heart rate, blood pressure, call to balloon time, door to balloon time and peak troponin levels were similar between both the groups. left ventricular ejection fraction was similar between both the groups (53.5±8.5 vs 47.3±9.4, p=0.680). Detailed cardiac rhythm analysis showed numerically higher mean heart rates in ED group (mean±SD, beats per minute, 66.1±9.9 vs 73.1±11.7, p=0.060). Life threatening arrhythmias were not noted in any of the patients. Five patients had transient AF (2 ED), one had transient second degree AV block, two patients had less than 3 sec asymptomatic pauses (1ED) and three had non sustained VT (1ED). There was no difference in overall arrhythmia burden between both the groups. All patients were alive and free of MACCE at 6-month follow up. One patient in ED group had re-admission due to non-cardiac chest pain.

CONCLUSIONS

We have shown that significant post MI arrhythmias are rare and very early discharge (within 48 hours) is safe both in short and medium term after successful PPCI. If confirmed in large scale multicentre trials, our findings may have significant implications on management of health care resources and costs.

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Early and late coronary scaffold failure: differences in predictors and mechanisms, impact of implantation technique

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

AIMS

We investigate the incidence and determine the predictors and possible mechanisms of early and three-years coronary scaffold thrombosis and target lesion failure.

METHODS AND RESULTS

662 consecutive patients (62[55-73]years, 79% males, 21% diabetics, 64% acute coronary syndromes) who received 911 coronary bioresorbable scaffolds (BRS) between May 2012 and December 2014 (Abbott Vascular, Santa Clara, CA, USA) were enrolled. Clinical/procedural characteristics as well as clinical outcome data at 1071[910-1206]days (follow-up rate 90%) were collected. Angiographic predictors of scaffold thrombosis were analysed in a nested case-control study (n=69). In a separate prospective case-control study (n=90), the predictive power of 1-year optical coherence tomography (OCT) on the incidence of very late scaffold thrombosis was investigated. Finally, OCT features at the time of early and late scaffold thrombosis (n=6 and 6) were compared.Target lesion failure (composite of cardiovascular death, target vessel infarction and target lesion revascularization) was recorded in 67 patients at 1083[977-1208]days (in 51 cases beyond 30 days and 35 cases beyond 365 days after implantation). Early scaffold thrombosis was observed in 12 cases, late scaffold thrombosis in 5 and very late scaffold thrombosis in another 6. The absence of postdilation at index was an independent predictor of both early target lesion failure and thrombosis (P=0.039, HR=3.1[1.1-9.3]). Diabetes was an independent predictor of late target lesion failure due to in-scaffold restenosis (P=0.016, HR=3.2[1.3-8.4]). No clinical parameter was associated with late scaffold thrombosis.

Quantitative coronary angiography features of late/very late scaffold thrombosis included a larger reference vessel diameter and low footprint, while small reference vessel diameter and high footprint were more frequent in early scaffold thrombosis (both P<0.001). There was no evidence of late luminal gain as possible cause of late scaffold thrombosis (P=0.365). Accordingly, while BRS oversizing at index was associated with early scaffold thrombosis (Log-Rank P<0.001), undersizing was associated with late or very late thrombosis (P=0.03).

OCT features of early scaffold thrombosis included evidence of incomplete expansion while malapposition was the hallmark of late/very late scaffold thrombosis. Dismantling associated with malapposition was found in two cases of very late scaffold thrombosis. Analyzed prospectively, OCT evidence of malapposition at 1 year after BRS implantation was associated with late scaffold thrombosis (Log Rank P=0.002).

Finally, the incidence of probable/definite early scaffold thrombosis and that of late/very late scaffold thrombosis up to three years were reduced respectively from 2.8% to 0.7% and from 3.0% to 1.4% by the introduction of an implantation technique including accurate sizing and pre/postdilation (P=0.011 and P=0.009).

CONCLUSIONS

Early and late events after BRS implantation underlie different mechanisms but can both be significantly reduced with an optimized implantation technique. The presence of malapposition at one year after implantation predicts the risk of very late scaffold thrombosis.

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Long-term follow-up of BRS implantation for complex coronary lesions: a multicentre experience

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

AIMS

Incidence of late BRS thrombosis is of concern. Clinical experiences have shown that ‘dedicated implantation technique’ is a key to decrease ST. The aim of this study was to evaluate the use of ‘dedicated implantation technique’ in the outcome of BRS

METHODS AND RESULTS

We retrospectively analyzed consecutive patients that underwent BRS implantation in three high-volume, experienced centers (2 in Italy and 1 in India) before December 2014, in order to have at least two years of clinical follow-up. A total of 492 patients were identified for a total of 763 lesions implanted with BRS using a dedicated implantation strategy from the beginning. Mean age was 60±11 (male sex 90%), 35% of patients were diabetics, left ventricular systolic function (54±8%) and renal function (eGFR 90±25 ml/min) were preserved. The coronary anatomy was predominantly complex, with type B2 or C lesions in 75%, CTOs in 5.6%, bifurcations in 31% and severely calcific lesions in 13%. The dedicated implantation technique included good lesion preparation and debulking (when necessary): predilatation was performed in 99% of cases (cutting balloon 3.5%, scoring balloon 8%, rotational atherectomy 5%). OCT and IVUS were used in 15% and 37% of cases, respectively. Mean scaffold length was 31±16 mm, with a 1:1 high-pressure (21±4atm) postdilatation rate of 99.9%. Angiographic success was achieved in 99.9% of cases. All patients were discharged with dual antiplatelet therapy (usually ASA and clopidogrel) while a de-escalation therapy with 3 months of prasugrel or ticagrelor followed by 12 months of clopidogrel was prescribed in about 10% of patients. At a mean follow-up of 939±286 days definite or probable scaffold thrombosis occurred in 0.6% (3 pts) of patients, while possible ST occurred in 0.5% (3 pts); notably only 1 case of probable ST occurred more than 1-year after the procedure. Rates of target lesion revascularization (TLR), target vessel revascularization (TVR), MACE (death, any MI, revascularization) and TLF (cardiovascular death, target vessel MI, TLR) were 6.5% and 9.5%, 16% and 5.5% respectively.

CONCLUSIONS

These long-term results from a complex real-world population appear to be reassuring in regards to the incidence of scaffold thrombosis when BVS are implanted by experienced operators with a dedicated implantation technique. In fact, the rate of ST is lower than the one observed in Absorb II trial, despite the higher clinical and anatomical complexity of the treated population. However, longer follow-up data in a larger population are needed in order to support this preliminary evidence.

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IVUS to guide left main stem intervention: a substudy of the NOBLE trial

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

AIMS

We sought to investigate the association between the use and findings of intravascular ultrasound and clinical outcomes in the PCI arm of a randomised trial of left main stem PCI.

METHODS AND RESULTS

The NOBLE trial was a prospective, multi-centre, randomised, open-label trial of patients presenting with stable angina pectoris, unstable angina pectoris, or NSTEMI found to have left main coronary artery disease randomised to treatment by PCI or CABG. Of 580 patients treated by PCI, 430 (74%) underwent post-PCI intravascular ultrasound assessment of which 227 were analysed in a core laboratory.

For a median follow-up of 3 years, major adverse cardiac and cerebrovascular events will be compared between the 430 patients in whom intravascular ultrasound assessment was used to guide stent optimization and the 150 patients in whom angiographic assessment alone was used. Of the 227 patients in whom intravascular ultrasound findings were analysed in the core laboratory, left main stem, polygon of confluence, left anterior descending artery ostial and circumflex artery ostial minimal stented areas were measured. Left main stem minimal stented area was split into tertiles and major adverse cardiac and cerebrovascular events will be compared.

Mean left main stem minimal stented area was 12.5±3.0mm^2. Where measured, polygon of confluence mean minimal stented area was 16.9±4.1mm^2 (n=222), ostial left anterior descending artery 10.1±2.9mm^2 (n=213) and ostial left circumflex artery 9.6±2.9mm^2 (n=52). When compared to previously established minimal stented area thresholds associated with adverse events (left main stem: <8mm^2, polygon of confluence <7mm^2, left anterior descending artery ostial <6mm^2 and circumflex artery ostial <5mm^2 or <4mm^2 if not stented), 20/227 (8.8%) patients had one or more minimal stented area measurements below these thresholds.

CONCLUSIONS

In the NOBLE trial 74% of patients treated by PCI underwent intravascular ultrasound guidance to optimize the result. Of those analysed in the core laboratory, stent expansion appears to be satisfactory.

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Proximal cerebral protection device in carotid artery stenting: safety and efficacy

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THEME: Interventions for Stroke
TOPIC(S): Carotid stenting

AIMS

To evaluate the safety and efficacy of proximal cerebral protection vs distal cerebral protection in patients submitted to carotid artery stenting.

METHODS AND RESULTS

Methods: We retrospectively studied patients submitted to carotid angioplasty in our center from 2000 to 2016. The patients were divided in two groups according to the employed cerebral protection device: group PD (proximal protection device) and group DP (distal protection device). Major adverse cardiovascular events (stroke, ACS or death) were evaluated peri-procedural, at 30 days and one year. Statistical assessment included univariate analysis and survival curves.

Results: This study included 356 patients with a mean age of 71±12 years (76% male). A cerebral protection device was employed in 99% of the population (distal protection in 85% and proximal protection in 14%). Mean age in group PD was 66±21 years (17% female) vs 71±10 years in group DP (24% female) (p=NS). Patients in group DP were more frequently hypertensive (p<0.001) and presented more often with coronary artery disease (p=0.03). Symptomatic severe carotid stenosis was the most frequent indication for carotid angioplasty (64% in group PD vs 43% in group DP). No differences were found in both groups regarding the treated artery. Peri-procedural adverse events occurred in 5% of patients in group PD (3.8% strokes and 1.9% MI) vs 3.3% in DP group (2.6% strokes and 0.7% ACS) (p=NS). There were no differences between groups regarding survival free of major events at 30 days (p=0.78) and one year (p=0.65).

CONCLUSIONS

This study showed that proximal flow blockage is a safe alternative to distal protection in carotid angioplasty. The operator experience associated with an appropriate device choice, considering patient characteristics and anatomic features are key factors for a successful procedure and a low complication rate.

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Local flow patterns after implantation of BRS in coronary bifurcations: novel findings by 3D OCT and computational fluid dynamics

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

AIMS

This study sought to develop a new approach for in-vivo reconstruction of BRS in natural tortuous course and to investigate the impact of BRS implantation in coronary bifurcations on shear stress (SS) distribution and computational FFR.

METHODS AND RESULTS

All patients enrolled in the BIFSORB pilot study with BRS implanted in the main vessels of coronary bifurcation lesions with a side branch ≥ 2.5mm were included. Reconstruction of coronary lumen and BRS was performed by fusion of OCT and X-ray angiography, generating a lumen tree model (LTM) and a hybrid model with BRS (LTMBRS). Meshing and computational fluid dynamics (CFD) using patient-specific pulsatile flow was performed separately on these two models. Main vessel was divided into portions with size representing the thickness of BRS struts (0.15mm×0.15mm) for point-per-point comparison between the two models. Time-average-SS (ASS), average SS gradient (ASSG) that represents heterogeneity of SS, and oscillatory shear index (OSI) were assessed in each portion.

A total of 10 target vessels (7 left anterior descending, 2 left main, 1 left circumflex) with BRS implanted were analyzed. Reconstruction of LTMBRS was successful in all cases. Mean number of side branches crossoverred by BRS was 2.9. SS was assessed in 129167 portions in the stented segments. ASS was higher in LTMBRS than in LTM at the main vessels (2.16±4.08 Pa versus 1.76±2.35 Pa, mean absolute difference: 1.67±3.65 Pa, $p < 0.001$), with remarkable difference at the side branch ostia (12.22±14.80 Pa versus 0.34±1.69 Pa, mean absolute difference: 12.14±14.89 Pa, $p < 0.001$). Both ASSG and OSI were higher in TMBRS than in TM at the main vessels (12.10±38.74 Pa/mm versus 3.88±33.93 Pa/mm, $p < 0.001$, and 0.015±0.037 versus 0.004±0.024, $p<0.001$) and at the side branch ostia (84.15±131.79 Pa/mm versus 3.44±49.58 Pa/mm, $p < 0.001$, and 0.008±0.017 versus 0.001±0.007, $p<0.001$). ASSG was higher at the bifurcation core area (20.20±69.19 Pa/mm) compared with the proximal (12.77±32.71 Pa/mm, $p<0.001$) and distal segments (7.65±16.98 Pa/mm, $p<0.001$). Computational FFR was lower in LTMBRS than in LTM for both the main vessels and their side branches (0.95±0.02 versus 0.97±0.02, $p<0.001$, and 0.91±0.06 versus 0.94±0.05, $p < 0.001$).

CONCLUSIONS

In vivo reconstruction of BRS in natural tortuous course after implantation in coronary bifurcations is feasible. Neglecting BRS in the CFD analysis lead to significant difference in SS assessment and underestimated the heterogeneity of local flow distribution, which was more pronounced at the side branch ostia. The impact of SS as assessed by this novel approach on stent healing and neointima hyperplasia warrants further investigation.

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Impact of delayed initiation of ECMO on the prognosis of patients arriving in cardiac arrest due to ACS

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THEME: Coronary Interventions
TOPIC(S): Other Coronary Interventions, Acute heart failure

AIMS

We sought to evaluate the impact of delay in establishing Extracorporeal membrane oxygenation (ECMO) support on the prognosis of patients arriving in cardiac arrest due to acute coronary syndrome (ACS).

METHODS AND RESULTS

We retrospectively analyzed clinical records of ACS patients who arrived in cardiac arrest and received ECMO treatment between 2006 and 2015. We analyzed clinical indices, including door-to-ECMO time, electrocardiography findings on arrival, 3-, 7-, and 30-day mortality rates, and rate of successful weaning from ECMO. Forty-three patients were investigated, including 4 with critical vasospasm. The mean age was 69.5 ± 11.5 years, and mean door-to-ECMO time was 29.1 ± 24.2 minutes. Door-to-ECMO time was ≤ 30 minutes in 26 patients (60.5%) and > 30 minutes in 17 patients (39.5%). Initial electrocardiographic rhythm was of ventricular tachycardia or ventricular fibrillation in 34.9% and asystole or pulseless electrical activity in 65.1% of the patients. ECMO was initiated in the emergency room for 35 patients (81.4%) and in the catheterization laboratory for 8 patients (18.6%). The mortality rates at 3 days, 7 days, and 30 days after admission in patients with door-to-ECMO times of ≤ 30 minutes and > 30 minutes were 23.1% vs. 52.9% (p = 0.057), 46.2% vs. 82.4% (p = 0.026), and 73.1% vs. 82.4% (p = 0.714), respectively. The incidence of successful weaning from ECMO was 46.2% vs. 29.4% (p = 0.347), respectively.

CONCLUSIONS

Delayed initiation of ECMO contributed to a higher mortality rate in patients arriving in cardiac arrest due to ACS.

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A novel risk score to predict out-of-hospital bleeding on DAPT

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

AIMS

Dual antiplatelet therapy (DAPT) prevents ischemic events after coronary stenting, but increases bleeding. Guidelines support weighting bleeding risk prior to the selection of treatment duration, but no standardised tool exists for this purpose.

METHODS AND RESULTS

We sought to develop and validate a novel score to appraise out-of-hospital bleeding risk during DAPT in a large population treated with coronary stenting. The usefulness of this score was assessed within patients randomized to different DAPT durations to identify the effect on bleeding and ischemia of a long (12-24 months) or short (3-6 months) treatment duration in relation to baseline bleeding risk.

A total of 14,963 patients treated with DAPT after coronary stenting were pooled at a single patient-level from eight multicentre randomized clinical trials with independent adjudication of events. Using Cox proportional hazards regression, we identified predictors of out-of-hospital TIMI major/minor bleeding stratified by trial, and developed a numerical bleeding risk score. The predictive performance of the novel score was assessed in the derivation cohort and validated in 8,595 and 6,172 patients treated with PCI from the PLATelet inhibition and patient Outcomes (PLATO) trial and BernPCI registry, respectively. The novel PRECISE-DAPT score (age, creatinine clearance, haemoglobin, white-blood cell count, prior spontaneous bleeding) showed a c-index of 0.73 (95%CI 0.61-0.85) in the derivation cohort, 0.70 (95%CI 0.65-0.74) and 0.66 (95%CI 0.61-0.71) in the two validation cohorts. The PRECISE-DAPT score was assessed within patients randomized to different DAPT durations (N=10,081) to identify the effect on bleeding and ischemia of a long (12-24 months) or short (3-6 months) treatment in relation to baseline bleeding risk. We observed a significant increase in bleeding with a long rather than short duration of treatment exclusively in patients at high bleeding risk according to the PRECISE-DAPT score (score≥25)(ARD +2.59%, 95%CI +0.82% to +4.34%; NNT: 38) but not in those without a high bleeding risk profile (score<25)(ARD +0.14%, 95%CI -0.22% to +0.49%) (Pint=0.007). Concurrently, longer DAPT duration reduced the composite ischemic endpoint of myocardial infarction, definite stent thrombosis, stroke or target vessel revascularization in those at non-high bleeding risk (ARD -1.53%, 95%CI -2.64% to -0.41%; NNT: 65), but not in those at high bleeding risk, (ARD +1.41%, 95%CI -1.67% to +4.50%) (Pint=0.079). The resulting net effect on bleeding and ischemia suggested a favourable outcome with 12-24 month DAPT in patients at non-high bleeding risk (score<25), and with 3-6 month DAPT in those at high bleeding risk (score≥25).

CONCLUSIONS

The PRECISE-DAPT score, a simple five-item prediction algorithm for the prediction of out-of-hospital bleeding in patients treated with DAPT, identified patients benefitting from a longer treatment with DAPT, and those harmed from such strategy, hence better suited for a short treatment course.

In the context of a comprehensive clinical evaluation process, this novel tool can support clinical decision-making for DAPT duration after coronary stenting.

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Intracardiac echocardiography for LAA closure in patients with a contraindication for transesophageal echocardiography

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

Percutaneous closure of the LAA is commonly guided by transesophageal echocardiography (TEE). Some patients have a contraindication for TEE (severe esophageal pathology) and intracardiac echocardiography (ICE) is an attractive and simple alternative

METHODS AND RESULTS

Six patients with atrial fibrillation and a clinical indication for percutaneous LAA closure according to $CHADS_2$-VASC and HAS-BLED scores had a contraindication for TEE due to severe esophageal disease. An ICE catheter through the femoral vein was used to guide the procedure, initially to facilitate transeptal puncture. Once this was achieved, the ICE catheter was advanced through the same hole (in 3 cases), or in case it was impossible, a second transeptal was performed (in 3 cases). The ICE catheter was directed at the ostium of the LAA, to discard the presence of any thrombus (no patients had LAA thrombi), and to get adequate anatomical measures. After selective angiographies of the LAA were done, the final position of the device before delivery was assessed with ICE. Mean measures of the LAA with angiography and with ICE were not significantly different (24 mm with angio and 25 mm with ICE). In all cases an Amulet® device was implanted (St Jude Medical), with a mean size of 26 mm (22-34 mm). ICE was able to clearly show the lobe and disk position after the implant, as well as distance to the anterior mitral leaflet and the left superior pulmonary vein. All devices were released without any incidence, and were in position at 24 hours and 1-month as assessed by transthoracic echocardiography. After an 8-month follow-up, all patients were well, without embolic or bleeding events.

CONCLUSIONS

Percutaneous closure of the LAA guided by an ICE catheter from the left atrium is a simple procedure, and offers high quality images of the LAA before and after the device implant. This approach is a good alternative for patients where TEE may be contraindicated, though it requires specific training in intracardiac imaging interpretation.

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FFR-guided PCI long-term prognosis in ACS - Can we rely on stable ischaemic heart disease principals?

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

AIMS

PCI guided by FFR in stable ischemic heart disease (SIHD) has shown to be associated with excellent long-term prognosis. Despite its increasing use in ACS, FFR long-term prognosis in this setting has not been well established.

METHODS AND RESULTS

From 2008-2015, patients (pts) with FFR guided PCI in a single tertiary centre were included in a prospective registry. Pts with angiographically intermediate lesions were analysed (total 149: 44 ACS and 105 SIHD). A propensity score matching (PSM) methodology was used to match these groups (44 ACS and 44 SIHD). The primary endpoint was Major Adverse Cardiovascular Events (MACE): death, myocardial infarction (MI) and target vessel failure (TVF). Secondary endpoints consisted on these events individually and on the composite of death/MI. FFR cut-offs were ≤0.75 and ≤0.80.

In the entire cohort (mean age 69.7±10.1, 78.1%males), ACS group presented more smokers (40.9% vs 21.9%, p=0.026) and SIHD group more Diabetes (22.7% vs 45.7%, p=0.010). After PSM, baseline characteristics were not significantly different. In the PSM cohort, follow-up was 2.7±1.8 years. MACE rate and the composite of death/MI were significantly higher in the ACS patients (29.5% vs. 13.6%, 22.7% vs. 6.8%, p<0.05). Moreover, on Cox regression, ACS was an independent predictor for MACE and death/MI (OR 0.23, 95%CI 0.08-0.67, p=0.007 and OR 0.11, 95%CI 0.02-0.53, p=0.006). In the SIHD group, none of the pts with deferred PCI guided by FFR presented MACE or the composite death/MI. However, in the ACS group 44.4% and 33.3% of MACE and 43.6% of death/MI occurred in pts in whom a deferred strategy was conducted by FFR (cut-off 0.75 and 0.80, respectively).

CONCLUSIONS

In a PSM cohort, deferring PCI on the basis of FFR in pts with ACS is associated with significantly worse prognosis than SIHD. In the ACS group more than 30% of pts presenting MACE or the composite of death/MI were considered for a deferred strategy. Carefulness must be taken in using FFR cut-off values derived by SIHD in the acute setting pts.

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Coronary sinus reducer improves myocardial perfusion reserve index assessed by dipyridamole stress cardiac magnetic resonance

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

AIMS

We evaluated the efficacy of the Coronary Sinus Reducer in improving myocardial perfusion assessed by myocardial perfusion reserve index determined from perfusion dipyridamole cardiac magnetic resonance four months after the procedure.

METHODS AND RESULTS

Fourty-four patients with refractory angina despite optimal medical therapy and no coronary revascularization options were successfully treated with Coronary Sinus Reducer implantation. Among them, 12 patients underwent pre-procedural and 4-month follow-up cardiac magnetic resonance perfusion scans at rest and during dipyridamole infusion (0.56 mg/kg infused in 4 minutes) to assess myocardial perfusion reserve index (defined as an index between relative upslope stress/relative upslope rest, with relative upslope defined as the ratio between the maximum upslope of the first pass myocardial perfusion time-intensity curve divided by the maximum upslope of the first-pass left ventricle cavity time-intensity curve) which represents a semiquantitative index that has been demonstrated to be useful for defining and quantifying myocardial ischemia. An increase of myocardial perfusion reserve index was observed in 10 of 12 patients (83%). In 9 of the 10 patients with an increase of myocardial perfusion reserve index, an improvement of at least 1 Canadian Cardiovascular Society angina score was observed; no improvement in angina symptoms was observed in the 2 patients without increase of myocardial perfusion reserve index at follow-up.

Mean myocardial perfusion reserve index increased from 1.42±1.4 to 1.92±2.3, with a mean improvement of myocardial perfusion reserve index per patient of 0.5±0.5 (31.1% increase, p=0.007). When considering only the ischemic myocardial segments, we observed a statistically significant increase in myocardial perfusion reserve index values (from 1.1±0.3 to 1.94±0.8, 73.5% increase, p value=0.002).

CONCLUSIONS

Coronary sinus Reducer implantation is related to an improvement in myocardial perfusion reserve index in refractory angina patients. Moreover, the increase in myocartdial perfusion observed in the ischemic segments of myocardium, shows that Reducer is able to redistribute blood flow to the ischemic territories. Further studies are needed to investigate our findings.

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Coronary sinus reducer implantation for the treatment of chronic refractory angina: a single-centre experience

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

AIMS

To assess the safety and efficacy of the Coronary Sinus Reducer in a real-world cohort of patients with refractory angina refractory to optimal medical therapy and not anemable for conventional revascularization.

METHODS AND RESULTS

Fourty-four patients with refractory angina, objective evidence of myocardial ischemia and unsuitable for revascularization were treated with Coronary Sinus Reducer implantation at our center from March 2015 to December 2016. Safety endpoints included procedural success and no device-related adverse events. Efficacy endpoints, assessed at 4-month follow-up, were a reduction in Canadian Cardiovascular Society angina score, improvement in quality of life assessed by Seattle Angina Questionnaire, improvement in exercise tolerance assessed by six-minute walk test, and reduction in pharmacological anti-anginal therapy.Out of a total of 44 patients who underwent Coronary Sinus Reducer implantation during the study period, complete 4-month follow-up was obtained in 34 patients. Regarding the safety endpoint, procedural success was obtained in all patients and there were no device-related adverse effects observed during the procedure or follow-up period. Regarding the efficacy endpoint, 22 out of 34 patients (65%) had an improvement of at least 2 Canadian Cardiovascular Society classes ($p<0.001$) with a mean reduction of Canadian Cardiovascular Society class of 1.7±0.7 per patient. All Seattle Angina Questionnaire items improved significantly (mean improvement on 100-point scale was 30±7.4). Regarding exercise tolerance, we reported a significant improvement assessed by six-minutes walk test with a mean distance of 411±137 metres at 4 months follow-up compared with the mean distance reported at baseline (258±93 metres, $p = 0.002$). Twenty patients (59%) had a reduction of at least 1 anti-anginal drug and 6 patients (18%) had a reduction of 2 or more anti-anginal drugs.

CONCLUSIONS

In our real-world single center experience, the implantation of the Coronary Sinus Reducer appears safe, and is associated with an improvement in anginal symptoms and quality of life in patients with refractory angina who were not candidates for revascularization.

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Three-year outcomes of BRS in STEMI patients: potential mechanisms and predictors

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

AIMS

The purpose of this study was to identify mechanisms and predictors of outcome at 3-years in patients receiving a bioresorbable scaffold (BRS) for the treatment of ST-segment elevation myocardial infarction (STEMI).

METHODS AND RESULTS

We report on the outcome of consecutive patients who received single- or multi-vessel percutaneous coronary intervention with the current generation everolimus-eluting BRS device (Absorb BVS; Abbott Vascular, Santa Clara, CA, USA) between May 2012 and January 2014. During this period, 342 patients (382 lesions) were enrolled, of which 95 patients (27.7%, 105 lesions) received at least BVS in the setting of a STEMI. The overall median follow-up was 1208[1128-1346] days, and at three years follow up was available in 87%. Primary endpoints included the occurrence of definite scaffold thrombosis (ScT) and device-oriented endpoint (DoCE) at 3-years. Definite ScT occurred in 5 patients (acuteScT=1; lateScT=1; verylateScT=3) (5.26%) and DoCE occurred in 14 patients (14.7%). Univariate analysis identified reference vessel diameter (HR:2.80[1.28-6.11], p=0.01) and ostial lesions (HR:13.1[2.17-79.5], p=0.005) as predictors for ScT; reference vessel diameter (HR:2.03[1.03-3.98], p=0.04) and glomerular filtration rate (HR:0.97[0.95-0.99], p=0.01) were predictors of DoCE. RVD remained an independent predictor of DoCE also in multivariable analysis. Interestingly, while the risk of ScT and DoCE increased for smaller RVDs in stable patients, a larger RVD was associated with increased risk of events in STEMI patients.

CONCLUSIONS

In patients receiving a BRS for the treatment of STEMI in this "real-life" registry ScT, DoCE rates at 3-years are higher than expected. In contrast to stable patients, a larger RVD (probably leading to persistent malapposition) was found to be an independent risk factor for events in STEMI patients.

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Long-term clinical outcomes of patients with multivessel coronary artery disease after treatment with thin strut DES with bioresorbable polymer: four-year results from CENTURY II trial

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

AIMS

To assess safety and efficacy of a bioresorbable polymer sirolimus-eluting stent (BP-SES) in patients with mutivessel disease (MVD) and those with MVD and diabetes comparing it to a permanent polymer everolimus-eluting stent (PP-EES)

METHODS AND RESULTS

In the randomised, multicontinental CENTURY II study, out of 1119 enrolled patients, 546 were diagnosed with MVD and assigned randomly to treatment with BP-SES Ultimaster (275) or PP-EES Xience (271). Out of the 546 patients, 181 (97 in BP-SES and 84 in PP-EES) had simultaneous presence of diabetes mellitus (MVD&DM). The primary endpoint was target lesion failure (TLF), a composite of cardiac death, target vessel related MI and clinically driven revascularization at 9 months. Data was 100% monitored. An independent clinical event committee adjudicated adverse events. While the abtractis based on three-year data, four-year data will be available at the time of presentation.No significant differences were found in baseline patient characteristics. Pertaining to lesion characteristics, comparable rates of bifurcation (14.6% vs 11.2%; p=0.15), ostial lesions (7.2% vs 10.0%; p=0.16) and presence of moderate/severe calcifications (25.2% vs 19.8%; p=0.29) were noted in BP-SES and PP-EES respectively. There was no difference in lesion length (16.8±9.7mm vs 16.4±9.1mm; p=0.59), number of treated lesions per patient (1.5±0.7 vs 1.5±0.7; p=0.60) and number of stents implanted per lesion (1.2±0.4 vs 1.2±0.5; p=0.004).

At 3 years, there was no significant difference noted in the rate of cardiac death (2.9% vs 3.7%; p=0.61), TV-MI (1.8% vs 3.0%, p=0.39), clinically driven TLR (5.1% vs 5.2%; p=0.97) and clinically driven TVR (7.6% vs 7.4%; p=0.91). Composite endpoints such as TLF (9.1% vs 10.3; p=0.62) and TVF (11.6% vs 12.2%; p=0.85) in BP-SES and PP-EES respectively, were also similar. The rate of stent thrombosis followed the same trend (1.1% vs 2.2%; p=0.30) with no very late stent thrombosis in either of the groups.

Among patients with MVD&DM, 22% were insulin-dependent. Lesion characteristics between the two arms were similar with a mean SYNTAX score at baseline of 14.26±.9 in the BP-SES group vs 13.9±7.296 in PP-EES, 88.8% vs 81.8% were type B2/C lesions. The number of lesions detected and lesions treated per patient, was 2.9±1.5 vs. 3.0±1.4 and 1.5±0.7 and 1.6±0.8, in the BP-SES and PP-EES arm respectively. Number of stents implanted per lesion was 1.21±0.5 vs 1.0±0.6, with a total stent length implanted per patient of 34.5±19.4 mm vs 35.2±19.6 mm. At 3 years, the rates of clinical outcomes were: cardiac death: 2.1% in the BP-SES group vs 6.0 % in the PP-EES group (p= 0.18), TV-MI 3.1% vs 6.0% (p= 0.35), clinically driven TLR: 6.2% vs 11.9% (p=0.18), and TVR: 10.3% vs 11.9% (p=0.88) and TLF: 11.3% vs 14.3% (p=0.56). The stent thrombosis rate was 1.0% in BP-SES and 4.8% in PP-EES arm (p=0.13).

CONCLUSIONS

Treatment of patients with multivessel disease despite combination with diabetes mellitus, using BP-SES and PP-EES, resulted in favourable and similar clinical outcomes up to 3 years. Further follow up will provide additional valuable information on the long-term safety and efficacy of the Ultimaster DES. Four-year data will be available at the time of presentation.

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Complete vs. incomplete revascularisation for coronary intervention in STEMI patients with mutlivessel disease - One-year data from the large e-ULTIMASTER registry

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

AIMS

We aimed to compare one-year outcomes of patients with multivessel disease and ST-segment elevation MI undergoing complete versus incomplete percutaneous revascularisation.

METHODS AND RESULTS

Among atotal of 4589 all-comer patients enrolled in the large single-arm, multicentre, e-Ultimaster registry, 464 patients with multivessel disease presented with STEMI. Out of 464 patients, 153 underwent complete revascularisation at baseline procedure (COMP) and 311 patients had incomplete revascularisation (INCOMP). The primary endpoint of the study was Target Lesion Failure (TLF) at 1 year.COMP patients tended to be more often female (22.2% vs 16.1%, NS) had higher incidence ofdiabetes mellitus (27.5% vs 18.3%, p=0.03), hypertension (55.0% vs 51.3%, NS), hypercholesterolemia (50.3% vs 40.4%, NS) and were more often already on dual antiplatelet therapy (80.4% vs 67.5%, p<0.01). The frequency of bifurcation lesions and CTOs were higher for the COMP population (10.1% vs 8.5%, NS and 6.6% vs 2.6%, p<0.05). Percentages of ostial or moderately to severely calcified lesions was similar between groups (5.5% and 17.2%, respectively). Procedural success rate was almost total in both groups (>99%). On average, 2.0±0.8 lesions were treated per patient in the COMP group vs 1.6±0.9 in the INCOMP group (p<0.01), with a total length of stent implanted per patient of 40.34±25.2 mm in the COMP group vs 36.3±22.6 mm (NS) in INCOMP group. Thrombus aspiration and post-dilatation were less often performed in the COMP population (12.0% vs 18.7%, p<0.05 and 34.0% vs 45.1%, p<0.01), whereas direct stenting was performed in 59.5% of COMP vs 41.5% in INCOMP group (p<0.01). At one year, cardiac death (0.7% vs 2.9%, p=0.18) tended to be lower in the COMP group when comparing with the INCOMP group and as expected clinically driven non-target-vessel revascularization was significantly lower (0% vs 2.9%, p<0.05), while the rates of clinically driven TLR (1.9 % for both groups) and stent thrombosis (1.96% vs 1.61%, NS) were similar. The rates of all composite endpoints were lower for the COMP group, without reaching significance: TLF (2.6% vs 4.8%), Patient Oriented Composite Endpoint defined as any cause of mortality, any MI and any revascularization, was 3.9% vs 7.4 %.

CONCLUSIONS

In the e-ULTIMASTER registry, a complete revascularisation approach is associated with numerically lower, though not significant events rate. At the time of presentation one-year clinical outcomes for a larger number of STEMI patients with multivessel disease will be available and will add valuable evidence for this unresolved medical question.

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In-vivo evaluation of the synergic effect of metformin and mTOR inhibitors in the endothelialisation of DES in human coronary arteries of patients with diabetes mellitus

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

AIMS

Animal studies have shown metformin to impair endothelialization of drug-eluting stents (DES). The aim is to evaluate the effect of metformin on the endothelialization of DES in human coronary arteries of patients with diabetes mellitus by OCT.

METHODS AND RESULTS

All patients from the Randomized Comparison of Reservoir-Based Polymer-Free Amphilimus-Eluting Stents Versus Everolimus-Eluting Stents With Durable Polymer in Patients With Diabetes Mellitus (RESERVOIR) trial evaluated by optical coherence tomography (OCT) at 9 months follow-up were included in the current study. The target population consisted of diabetic patients with documented silent ischemia, stable angina, unstable angina or non-ST segment elevation myocardial infarction. Major exclusion criteria included patients with diabetes mellitus treated only with diet and lifestyle changes, ST-segment elevation myocardial infarction, left main or ostial left descending artery stenosis, large bifurcations, severely calcified lesions, stent restenosis, chronic renal failure or left ventricular ejection fraction <30%. TheRESERVOIR trial randomized 116 lesions in 112 patients with diabetes mellitus to amphilimus- or everolimus-eluting stents and included mandatory OCT at 9 months follow-up. OCT results demonstrated that formulation of the drug with an amphiphilic carrier (amphilimus-eluting stents) resulted in non-inferior efficacy as compared to the classic elution from durable polymers (everolimus-eluting stents). In the current study, patients were divided in 3 groups according to the glucose-lowering agents received: 1) No metformin; 2) Metformin in non-insulin dependent patients; 3) Metformin in insulin-treated patients. The primary safety endpoint was the rate of uncovered stents.
From October 2012 to October 2013, 98 patients (101 lesions) were enrolled in the study and evaluated by OCT at 9 months follow-up: 17 patients/19 lesions did not receive metformin, whereas metformin was administered to 53 non-insulin dependent patients (54 lesions) and 28 insulin-treated patients (28 lesions). Baseline characteristics were comparable, although non-insulin dependent patients treated with metformin had better glycemic control ($p<0.01$). By OCT, the rate of uncovered struts was comparable in all groups (3.07 ± 4.80% vs 2.23 ± 4.73% vs 3.43 ± 6.69% respectively, $p = 0.48$). Multivariate models confirmed no effect of metformin on the endothelialization of DES (OR 1.49, 95%CI 0.71 – 3.08, $p = 0.29$). Similarly, quantitative angiography showed no effect of metformin on late lumen loss, whereas patients treated with exogenous insulin had the greater late lumen loss (p 0.02).

CONCLUSIONS

Metformin use does not impair endothelialization of DES in human coronary arteries of patients with diabetes mellitus. Therefore, its use should not be discouraged in these patients.

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Device position and predictors of incomplete occlusion after LAA closure: insights from 3D multislice CT fusion imaging

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

Incomplete occlusion (IO) after LAA closure is common and may be associated to adverse outcomes.

METHODS AND RESULTS

Post-procedural multi-slice computed tomography (MSCT) is a valuable tool to evaluate the presence of IO, but assessment of final device position compared to planned position can be challenging. Fusion of pre- and post procedural MSCT provides better spatial orientation and may provide insight into mechanisms of IO.

A total of 36 patients had pre- and post-procedural MSCT (median 97 days after the procedure, IQR: 87 - 142 days) in our center. For each patient both pre- and post-procedural MSCTs were fused in a unique volume using AW VolumeShare 7 software (GE Healthcare) and analyzed for the presence and mechanisms of IO. Planned and achieved device positions were compared.

Twelve patients (33%) had IO, defined as contrast enhancement of the LAA behind device (a cutoff of 150 Hounsfield units difference between LA and LAA was used, along with a semi-quantitative visual appreciation). Of 30 Amulet patients, 9 had IO (30%), versus 3 of 6 Watchman patients (50%) (p=NS).

Device position was in a significantly larger area than planned. The area of the achieved landing zone was, on average, 29 % larger than the planned landing zone ($p<0.0001$). Consequently, planned versus achieved area oversizing were significantly different (37% vs. 10%; $p=0.05$). In patients with IO, device area oversizing at achieved landing zone was lower than those without IO (2% vs. 16%), but this difference did not reach statistical significance ($p=0.14$). In patients with IO, device orientation was significantly different from planned orientation (angle between planned and achieved position: 21° ±11°; $p=0.0002$). In these patients, the distance between planned and achieved landing zone ranged from 0.7 to 12.6 mm.

The mechanisms of IO included the following: disk malapposition (n=6), disk partially inside LAA (n=2), lobe protrusion outside LAA (n=2), device off-axis compared to neck of LAA (n=1), unclear (n=3). For the Amulet device, patients with IO had a significantly wider angle between the lobe and the disk (9.1° vs. 16.1°; $p=0.03$). Mean device area compression (final area vs. nominal area) was 7.8 ± 11.1%, with no significant difference between patients with and without IO. Mean device circularity index (Dmax/Dmin) was 1.07 ± 0.07, with no significant difference between patients with and without IO.

CONCLUSIONS

As the LAA is a complex three-dimensional structure, closure devices do not necessarily position themselves as intended. Rather, they seem to follow a "path of least resistance", and position themselves in way that results in less-than-intended oversizing, which may have an impact on the occurrence of IO.

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DES with biodegradable polymer in patients with NSTEMI: four-year clinical outcomes of the randomised CENTURY II study

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

AIMS

We aimed to assess long-term outcomes in NSTEMI patients treated with a bioresorbable polymer sirolimus eluting stent, Ultimaster (BP-SES) or a permanent polymer everolimus eluting stent, Xience (PP-EES).

METHODS AND RESULTS

Within the large, single-blind, randomised, multi-centre CENTURY II study, 1119 patients were enrolled of which 203 were diagnosed with NSTEMI and assigned randomly to treatment with BP-SES (97 patients with 127 lesions) or PP-EES (106 patients with 160 lesions). The primary endpoint of the study was Target Lesion Failure (TLF), a composite of certain cardiac death, target-vessel MI and target lesion revascularisation at 9 months four-year follow-up is currently ongoing. All data are 100% monitored and adverse events were adjudicated by an independent clinical event committee.

Baseline patient characteristics such as age, gender, diabetes mellitus, hypertension, dyslipidemia, family history of CAD, smoking, previous MI and previous PCI were similar in both study arms. In BP-SES arm patients presented more often with IDDM (7.2% vs 2.8% p=0.11), history of stroke (3.1% vs 0.0% p=0.07) or cerebrovascular disease (5.2% vs 0.0 % p=0.02) than in the PP-EES arm.

Multivessel treatment was performed in 21.2% of patients and the number of lesions per patient was 1.41±0.70. Radial access was chosen in 77.0% of cases. The rates of complex lesions (type C: 30.3%, type B2: 47.8%), ostial (6.2%), bifurcated (6.9% vs 9.3%), with thrombus (5.8%), and with chronic total occlusion present (1.1%) were similar between treatment arms. Direct stenting was similar in both populations and post-dilatation was performed in 41.9% of implantations.

At 3 years, cardiac death (1.03% vs 2.83 %; p= 0.36), TV-MI (1.0% vs 4.7%; p= 0.12), clinically driven TVR (6.2% vs 6.6%; p=0.90) and TVF (10.3% vs 11.3%; p=0.82) were numerically lower for BP-SES without reaching statistical significance. The stent thrombosis occurred in one patient in each arm.

CONCLUSIONS

Despite the variety of treatment options applied to this high risk population, the treatment with Ultimaster DES with biodegradable polymer or Xience DES with permanent polymer, was associated with favorable clinical outcomes up to 3 years. Four-year results will be available at the time of presentation.

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One-year clinical outcomes of contemporary PCI in patients with renal insufficiency: data from a multicentre registry

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

AIMS

The aim of this study is to assess clinical outcomes of PCI using Ultimaster, a sirolimus-eluted stent with bioresorbable polymer, in patients with renal insufficiency enrolled in a large all-comer 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 representative of real life practice. Of the 4597 patients enrolled and reached 1-year follow up, 321 patients with renal insufficiency (eGFR<60mL/min/1.73m^2) including 26 patients who were on dialysis treatment were enrolled in a pre-specified subset.

Patients in this subset were significantly older (73.7 vs 64.7 years; p<0.001), with more comorbidities (P<0.001 for all) including diabetes mellitus (47.4% vs 25.2%), hypertension (81.4% vs 61.4%), and hypercholesterolemia (61.7% vs 53.7%) compared with the rest of the patients in the registry. Seventy three percent of them were male patients with an average body mass index of 28.2 kg/m^2, which was similar to the rest of the patients. About 10% of patients are current smokers, which is lower than for other e-ULTIMASTER patients (23.9%). Furthermore, more patients in this subset had previous myocardial infarction (MI) (28.6% vs 21.0%, p<0.01) and previous PCI (31.0% vs 24.8%, p=0.02). There were 62.6% of patients with multivessel disease. Compared to the others, patients in renal insufficiency subset had more vessels diseased (1.9 vs 1.6, p<0.01) and more lesions treated (1.6 vs 1.5, p<0.05) per patient. Patients in this subset had similar lesions complexity (60% vs 56% of type B2+C lesions, NS), but more calcified (30.6% vs 19.7%, P<0.01) and ostial lesions (11.7% vs 6.2%, p<0.01). The number of study stent implanted per patient was 1.60±0.95 with a total stent length of 35.83±24.22mm per patient. Study stent was successfully implanted in 99.8% of lesions.

The clinical outcomes at 1 year revealed a higher total death rate (5.9% vs 1.1%, p<0.01) for this subset in comparison with others, with a cardiac death rate of 3.4% vs 0.7% (p<0.01). The rate of MI was 1.25% vs 1.17% (p=0.79), while target vessel related MI was 0.31% vs 0.82% (p=0.51) in this subset in comparison with the others. The target lesion revascularization was 0.62% and 1.22% (p=0.59), target vessel revascularization was 1.25% and 1.66% (p=0.82), the composite endpoint of TLF was 4.36% and 2.20% (p=0.02) and TVF was 4.98% and 2.55% (p=0.02) in this subset and the rest of the patients, respectively. Two patients (0.62%) had stent thrombosis within 1 year follow up (vs 0.82%, p=NS). Ninety-one percent of the patients were on dual-antiplatelet therapy (DAPT) at 3 months follow up while 60% remain on DAPT at 1 year follow up, versus 96% and 68% of patients in the rest of the enrolled patients, respectively p<0.05 for both). At 1 year, 1.87% of the patients had suffered a major bleeding while 1.25% had suffered a minor bleeding, versus 1.83% and 0.59% in the rest of the patients (NS).

CONCLUSIONS

The 1-year clinical outcomes of patients with renal insufficiency in the e-ULTIMASTER registry showed good safety and efficiency of the Ultimaster DES, despite of older age and more co-morbidities of patients. It is recognized that patients with even mild renal dysfunction have an unfavourable prognosis after PCI, while in this subgroup, treatment with DES with bioresorbable polymer demonstrated as an effective therapy with low revascularisation and stent thrombosis rates.

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Five-year outcomes of bifurcation stenting: insights from the SYNTAX trial

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

AIMS

To describe lesion characteristics and stenting techniques as predictors of long-term outcomes after PCI of bifurcation lesions in the SYNTAX trial.

METHODS AND RESULTS

Patients randomized to the PCI arm of the SYNTAX trial were included in the present study if at least one of the treated lesions was reported as a bifurcation (or trifurcation). Primary endpoint was target lesion revascularization (TLR) of the identified lesion at 5 years; secondary endpoint was MACCE at 5 years. Potential predictors included in a multivariate Cox proportional hazards model were: bifurcation type, lesion location, side branch size, severe calcification requiring adjunctive techniques, stenting technique, residual stenosis and TIMI flow in any segment, stent length and number of overlapping stents.

A total of 669 patients and 923 treated bifurcation lesions were identified. Provisional T-stenting technique was selected in 625/923 lesions (67.7%); elective two-stent techniques were selected in the remainder. Patients with "true bifurcation" lesions (1,1,1 or 1,0,1 or 0,1,1) were twice as likely to undergo stenting with an elective 2-stent technique (40.8 vs. 23.2%, p<0.01).

TLR of the treated bifurcation lesion occurred in 75/923 lesions (8.1%) at 5 years. MACCE occurred in 272/669 patients at 5 years (40.7%). When analyzing lesions for TLR, significant univariate predictors were: elective two-stent technique (HR: 2.5 vs. provisional technique; p<0.0001), kissing balloon inflation (HR: 1.9; p=0.006), total stent length (HR: 1.4 per 10 mm increment; p<0.0001) and number of overlapping stents (HR: 1.3 per overlap; p=0.003). In the multivariate model, the independent predictors of 5-year TLR were: elective two-stent technique (HR: 1.92 vs. provisional technique; p=0.02) and total stent length (HR: 1.22 per 10 mm increment; p=0.03). When analyzing patients for MACCE, significant independent predictors in the multivariate model were: elective two-stent technique (HR 1.30 vs. provisional technique; p=0.04) and side branch residual stenosis greater than 30% (HR: 1.93; p<0.0001).

CONCLUSIONS

Provisional T-stenting of bifurcation lesions reduced by half the risk of TLR at 5 years in the SYNTAX trial after adjustment for lesion characteristics and other procedural techniques. Provisional stenting should remain the default strategy in most situations.

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Treatment of bifurcation lesions with a thin strut DES with bioresorbable polymer-long-term clinical outcomes of the CENTURY II trial

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Bifurcation lesion

AIMS

Our aim was to compare the performance of Ultimaster sirolimus eluting stent with bioresorbable polymer (BP-SES) with the Xience everolimus eluting stent featuring permanent polymer coating (PP-EES), in patients with bifurcation lesions.

METHODS AND RESULTS

CENTURY II is a large, randomised, single-blind, intercontinental study comparing Ultimaster BP-SES and Xience PP-EES. Out of 1119 enrolled patients, 194 patients (278 lesions) had at least one bifurcation lesion treated and were randomly assigned to either BP-SES (95) or PP-EES (99) group. The study had 100% on-site source data verification and an independent clinical event committee adjudicated all events. The primary endpoint was target lesion failure (TLF), a composite of cardiac death, target vessel related MI and clinically driven target lesion revascularisation (TLR) at 9 months.
There were no significant differences noted in demographic characteristics. Approximately 18% of the patients were female, 31% had diabetes mellitus, 74% had hypertension and 32% had previous MI. Fifty percent of the patients were admitted with stable angina. Patients treated with BP-SES had more multivessel disease (57.9% vs. 43.4%; p=0.04) and consequently, significantly more multivessel treatment (34.7% vs 20.2%; p=0.02). Most of the bifurcation lesions were classified as 1.1.0 (30%), followed by 1.1.1 (22%) and 0.1.0 (16%) according to the Medina classification and the vessel most frequently treated was LAD (48%), with no significant differences between the study arms. The number of stents implanted was similar, while the total stent length per patient was significantly higher in BP-SES group: 1.8±0.8 vs 1.7±1.0 stents (p=0.33) and 36.0±17.5 mm vs 34.11±23.4 mm (p=0.03), respectively. Clinical outcomes reported at 3 years for patients treated with BP-SES when comparing with PP-EES showed significantly lower rate of cardiac death (0% vs 4.0%; p=0.048) and numerically lower rates for TLF, (7.4% vs 10.10%; p=0.50). The rate of target vessel failure was 8.4% vs 11.1% (p=0.53), MI 3.2% vs 3.0% (p=0.96), target vessel related MI, 1.1% vs 2.0%; p=0.59 and total TLR rate per patient was 6.3% vs 7.1% (p=0.83) in the BP-SES and PP-EES groups respectively. There was one stent thrombosis in BP-SES arm and two in the PP-EES arm.In BP-SES group, 42% and in PP-EES 36% of the patients had more complex or ‘true bifurcation’ withMedina classification 1.1.1, 1.0.1, or 0,1,1. Within this classification, the TLF in BP-SES at 3 years was 2.5%, while in PP-EES groups it was 11.1% (p=0.13).

CONCLUSIONS

Both stents showed good clinical outcomes up to 3 years with a strong trend favoring BP-SES, particularly in true bifurcation lesions, indicating the potential benefit of Ultimaster stent design in the treatment of bifurcation lesions.

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Comparison of a contemporary intravascular vascular closure devices with manual compression in 3,018 patients undergoing transfemoral coronary angiography - Post hoc analysis of a randomised clinical trial

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

AIMS

To assess the value of an intravascular vascular closure device (VCD) compared to manual compression (MC) in patients undergoing transfemoral diagnostic cardiac catheterization within a large-scale, multicenter, randomized clinical trial.

METHODS AND RESULTS

After transfemoral diagnostic coronary angiography, 1509 patients were assigned to arteriotomy with an intravascular VCD and 1509 patients to MC. The primary endpoint was a composite of vascular access-site complications at 30 days. Secondary endpoints were time to hemostasis and repeat manual compression.

At 30 days, there was a significant reduction in vascular access-site complications in patients assigned to the intravascular VCD compared to MC (6% vs. 7.9%, p=0.038). The reduction was driven by a less hematoma > 5 cm in the VCD group (4.3% vs. 6.8%, p=0.003). There was no difference in pseudoaneurysm (1.5% vs. 1.5%, p=0.881), arteriovenous fistula (0.3% vs. 0.1%, p=0.414) and bleeding (0.1% vs. 0.2%, p=0.654). No patient incurred acute ipsilateral leg ischemia or required surgical or interventional treatment. One patient assigned to VCD suffered from local access site infection that was treated conservatively. Time-to-hemostasis was significantly shorter with VCD compared to MC (0.5 [IQR 0.2-1.0] min versus 10 [IQR 10-15] min; p<0.001). More patients in the VCD group required repeat manual compression (1.5% vs. 0.7%, p=0.033).

CONCLUSIONS

This is the largest series of patients that compares a contemporary intravascular VCD with MC within a randomized clinical trial. It shows that in patients undergoing transfemoral diagnostic coronary angiography, the intravascular VCD is superior to MC in terms of vascular access-site complications, driven by less hematoma >5 cm. Comparable safety and increased efficacy supports the use of the intravascular VCD in this population in clinical practice. Further studies are required to assess the value of VCD in patients undergoing PCI.

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Persistent significant tricuspid regurgitation after percutaneous mitral valve edge-to-edge repair impacts outcome

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

AIMS

To analyse whether there is a difference in outcome between patients with improvement of tricuspid regurgitation after edge-to-edge percutaneous mitral valve repair compared to patients without.

METHODS AND RESULTS

Out of 197 consecutive patients undergoing edge-to-edge percutaneous mitral valve repair with the MitraClip device (Abbott Vascular), 133 patients with available follow-up data were included in the study. Concomitant moderate/severe tricuspid regurgitation was present in 58% of patients. Kaplan-Meier analysis showed significantly reduced overall survival for patients with moderate/severe tricuspid regurgitation compared to patients with non/mild tricuspid regurgitation (p=0.003). An improvement of the baseline moderate/severe tricuspid regurgitation was observed in 45.5% of patients at 30-day follow-up. Patients with no improvement of the tricuspid regurgitation after MitraClip procedure had a higher mid-term mortality (mean 428 ± 386 days) compared to patients in whom tricuspid regurgitation improved (40.5% versus 11.4%, p=0.005).

CONCLUSIONS

More than half of patients undergoing edge-to-edge percutaneous mitral valve repair have concomitant moderate/severe tricuspid regurgitation at baseline, which is associated with worse outcome. Moderate/severe tricuspid regurgitation improves 30-days after mitral valve repair in almost half of patients. Patients with no improvement of tricuspid regurgitation at 30-days have a significantly higher mortality at follow-up.

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Prasugrel, ticagrelor and clopidogrel in primary PCI for STEMI: an analysis of comparative clinical outcomes from the United Kingdom BCIS-NICOR national registry

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

AIMS

We to examine comparative outcomes between Prasugrel and Ticagrelor using the United Kingdom national PCI database in patients undergoing primary PCI for ST elevation myocardial infarction.

METHODS AND RESULTS

Prospectively collected data, from January 2007 until December 2014, was used to compare use of P2Y12 antiplatelet drugs in primary PCI in over 89,000 patients. Linkage was performed to the national mortality database. Statistical modeling, involving propensity matching, multivariable logistic regression (MLR) and proportional hazards modeling, was used to study the association of different antiplatelet drug use with all cause mortality. In our main MLR analysis, Prasugrel was associated with significantly lower mortality than Clopidogrel at both 30-days (OR 0.830 95%CI 0.736-0.935, p=0.002) and 1-year (OR 0.829 95%CI 0.749-0.918, p<0.001) post PCI. Ticagrelor was not associated with significantly differences in mortality compared to Clopidogrel at either 30 days (OR 1.057 95%CI 0.934-1.196, p=0.382) or 1 year (OR 1.057 95% CI 0.962-1.162). Ticagrelor was associated with significantly higher mortality than Prasugrel at both time points (at 30 days, OR 1.443, 95% CI 1.274-1.634, p<0.001; at 1 year OR 1.415 95%CI 1.280-1.565, p<0.001) and significantly greater risk of in-hospital MACE but similar in hospital bleeding complications.

CONCLUSIONS

Prasugrel was associated with significantly lower mortality, compared to Clopidogrel and Ticagrelor, when used in primary PCI for STEMI in a contemporary real-world national setting in the United Kingdom.

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Clinical, safety and echocardiographic outcomes from the Nordic Aortic Valve Intervention (NOTION) trial: four-year follow-up data in all-comer patients with severe aortic valve stenosis

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

AIMS

The Nordic Aortic Valve Intervention (NOTION) trial was the first to randomize all-comers with severe native aortic valve stenosis to TAVI or surgical aortic valve replacement (SAVR).This report will focus on 4-year outcomes from the NOTION trial.

METHODS AND RESULTS

The primary outcome of the trial was a composite rate of death from any cause, stroke, or myocardial infarction (MI) at 1 year. Secondary outcomes included safety, efficacy and echocardiographic outcomes. Major inclusion criteria were severe aortic valve stenosis, age at least 70 years old, and suitable for both TAVI and SAVR. Three centres in Denmark and Sweden randomized 280 patients to either TAVI (n=145) or SAVR (n=135), with planned follow-up of 10 years. Baseline characteristics were similar between the TAVI and SAVR groups, respectively: age 79.2±4.9 vs. 79.0±4.7 years old (P = 0.71); male 53.8% vs. 52.6% (P = 0.84); STS score 2.9±1.6 vs. 3.1±1.7 (P = 0.30); NYHA class III or IV 48.6% vs. 45.5% (P = 0.61). At 2 years follow-up, there was no difference in all-cause mortality between TAVI and SAVR patients: 8.0% vs. 9.8%, P = 0.54; cardiovascular mortality was 6.5% vs. 9.1%, P = 0.40. The composite outcome of all-cause mortality, stroke, or MI was also similar between groups (15.8% vs. 18.8%, P = 0.43). Stroke risk was also similar at 2 years (3.6% vs. 5.4%, P=0.46) as well as rate of transient ischemic attack (6.0% vs. 3.3%, P=0.30). Forward-flow haemodynamics at two years were significantly better for TAVI patients compared to SAVR patients: effective orifice area was 1.6 cm^2 vs. 1.3 cm^2 and aortic valve mean gradient was 9.0 mmHg vs. 13.0 mmHg (both P<0.001). However, more TAVI patients had moderate aortic valve regurgitation as compared to SAVR patients (15.4% vs. 0.9%, P<0.001).

CONCLUSIONS

Two-year results from the NOTION trial demonstrated the safety and effectiveness of TAVI in all-comer patients with severe aortic valve stenosis. Four-year follow-up data from the NOTION trial will be presented at EuroPCR 2017.

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Durability of transcatheter and surgical bioprosthetic aortic valves in patients with severe aortic stenosis and lower surgical risk

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

AIMS

The aim of the present study is to evaluate longevity of transcatheter and surgical bioprosthetic aortic valves in the NOTION trial as defined using Valve Academic Research Consortium (VARC) criteria.

METHODS AND RESULTS

TAVI has become a standard treatment for patients with severe aortic stenosis and higher surgical risk. Ongoing controlled trials will help to define the role of TAVI as this therapy seeks to expand toward patients at lower surgical risk. However, longevity of the transcatheter bioprosthetic valve is important when expanding the therapy to these patients with longer life expectancy. The Nordic Aortic Valve Intervention (NOTION) trial was the first to randomise lower risk patients to either TAVI or surgical aortic valve replacement (SAVR).

From December 2009 through April 2013 a total of 280 patients were randomised to TAVI vs. SAVR using bioprosthetic heart valves. Baseline characteristics were similar between the TAVI and SAVR groups, respectively; age 79.2±4.9 years vs. 79.0±4.7 years (P = 0.71); male 53.8% vs. 52.6% (P = 0.84); STS score 2.9±.1.6 % vs. 3.1±1.7 % (P = 0.30); NYHA class III or IV 48.6% vs. 45.5% (P = 0.61).

Based on the VARC criteria, bioprosthetic valve dysfunction (BVD) is classified as structural valve dysfunction (deterioration intrinsic to the prosthetic valve including severe stenosis or intra-prosthetic regurgitation), non-structural valve dysfunction (dysfunction extrinsic to the prosthetic valve, e.g. prosthesis-patient mismatch or prosthetic regurgitation due to mal-positioning, distortion or inappropriate annular seal of the prosthetic valve), prosthetic valve thrombosis, or endocarditis. Bioprosthetic valve longevity is defined as yearly event free rate from the composite of death from a cardiac cause or an unexplained death following the diagnosis of BVD, aortic valve re-intervention or severe haemodynamic dysfunction due to new or progressive BVD in patients with up to seven years of follow-up.

CONCLUSIONS

This will be the first study to provide controlled data on transcatheter and surgical bioprosthetic aortic valve longevity in patients at lower surgical risk. Up to seven-year follow-up data based on VARC defined bioprosthetic valve dysfunction and failure will be presented at EuroPCR 2017.

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When is it appropriate for the scrub nurse to suggest using new balloon?

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

AIMS

Crossing into a side branch (SB) through the side of a stent can be challenging. We noticed balloon tip damage when the balloon had difficulty or failed to pass into the SB. Aim - to establish frequency of balloon tip damage in the clinical setting.

METHODS AND RESULTS

Between December 2014 and April 2016 82 balloons that had attempted to pass or had passed into a side branch through the side of a stent from 50 patients had their tips examined under a microscope. Tip damage was graded as none, mild, moderate and severe. Crossing difficulty was graded as 1. No resistance 2. On first attempt with resistance 3. Crossed after more than one attempt 4. Failed to cross.Of the 82 balloons collected 59 (72%) had tip damage. 35 balloons passed smoothly into the side branch without resistance, of these 19 (54%) had tip damage. Of the remaining 47 balloons which passed with resistance or failed to pass into the side branch 40 (85%) had tip damage.

CONCLUSIONS

When a balloon fails to pass into a side-branch there is a high chance of balloon tip damage. A damaged tip is more likely to catch on a strut preventing crossing or the stent may be distorted. If a balloon will not cross a new balloon should be selected.

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Randomised comparison of JUDKINS vs. TIGER catheter in coronary angiography via the right radial artery: the JUDGE study

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

AIMS

We aimed to assess safety and efficiency of Tiger II (5Fr; Terumo Interventional Systems, Somerset, New Jersey) vs Judkins (5Fr; 3.5L/4R, Medtronic Co) catheters, in coronary angiography via the right transradial route.

METHODS AND RESULTS

This is a prospective, randomized, study of parallel design. Consecutive patients with acute coronary syndrome (ACS), eligible for non-urgent coronary angiography, were randomized after successful cannulation of right radial artery and informed consent to either Tigger II or Judkins 3.5L/4R catheters. In total 337 patients (70.6% males, 27.3% diabetics, 28.8% admitted with myocardial infarction, mean age 66.9±11.1 years) were recruited (161 and 162 in the Tiger and Judkins group respectively). Catheter crossover was required in 28(16.6%) vs 33(19.6%) patients allocated in the Tiger and Judkins group respectively (p=0.5). Severe spasm occurred less frequently with the Tiger compared to Judkins catheters: 6(3.6%) vs 26(15.5%), p<0.001. Dose area product (DAP in $cGy*cm^2$) did not differ significantly between groups: 29527.0(19450.5-41700.5) vs 29180.0(20981.8-41609.5), p=0.6 for Tiger and Judkins respectively). Angiography time (min), radiation time (min) and contrast volume (ml) were lower for Tiger compared with Judkins catheters: 5.6(4.2-7.3) vs 7.1(5.6-10.1), p<0.001, 1.8(1.2-2.8) vs 2.2(1.4-3.7), p=0.01 and 65.5(53.0-81.9) vs 75.2(61.0-94.7), p<0.001 respectively.

CONCLUSIONS

Tiger catheter was found to produce less severe spasm and required less time, radiation time and contrast volume for coronary angiography completion compared with Judkins catheters, without any observed difference in efficiency between the two groups. These findings might have clinical implications in patients with renal impairment and in high-volume cardiac *catheterization laboratories.*

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Lowering of radiation eye dose to nursing staff with use of radiation attenuating patient draps

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI, Stable CAD, Stents and scaffolds, Left main and multivessel disease, Bifurcation lesion, CTO

AIMS

To rectify, discovered higher eye dose to nurses compare to physicians with current shield design.

We measured the radiation attenuation of scrub nurse eye dose using Rad Pad^{tm} sterile drapes.

METHODS AND RESULTS

To simulate procedural conditions a Rando^{tm} phantom was used on our latest Toshiba infinex^{tm} cardiac angiographic system at normal x- ray settings in three common opposing angiographic views to create a varied real world radiation scatter cloud. An Unfors radiation scatter detector at 160 cm height was placed at the secondary operator (scrub nurse) position. Measurements with and without the Rad Pad^{tm} placed over the lower phantom torso were recorded.At the AP position using fluoroscopy we recorded 52.77uGy/hr with the Rad Pad compared to 71.13uGy/hr without. A 26.7% reduction

At the AP position using acquisition we recorded 922.8uGy/hr with the Rad Pad compared to 1150uGy/hr without. A 19.8% reduction

At the Lao40/ Cau40 position using fluoroscopy we recorded 932.7uGy/hr with the Rad Pad compared to 1022uGy/hr without. A 8.74% reduction

At the Lao40/Cau40 position using acquisition we recorded 7713uGy/hr with the Rad Pad compared to 8511uGy/hr without. A 9.38% reduction

At the Rao10/Cra40 using fluoroscopy we recorded 88.16uGy/hr with the Rad Pad compared to 190.4uGy/hr without. A 53.7% reduction

At the Rao10/Cran40 position using acquisition we recorded 769.3uGy/hr with the Rad Pad compared to 1757uGy/hr without. A 56.3% reduction

CONCLUSIONS

The use of the sterile Rad Pad^{tm} patient drapes lowered the effective eye dose at the scrub nurse position from between 9% to 55% over the three measured views. This may correspond with the differing incident x ray beam angles and subsequent scatter cloud and further experimentation in the position of the drapes for such would increase there all round effectiveness. The effective eye dose reduction seen here calls for the use of radiation attenuation drapes to add to the scrub nurse's eye protection.

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An effective method to predict contrast-induced nephropathy in elderly patients undergoing interventional cardiology procedures

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

AIMS

The aim of this study was to evaluate the role of the contrast volume to creatinine clearance ratio in the prediction of contrast-induced nephropathy after percutaneous coronary interventionin elderly patients.

METHODS AND RESULTS

We evaluated serum creatinine (sCr) and creatinine clearance (CrCl) at baseline, and sCr at 24-48 hours and extended to up 5 days (in 40% of pts) after procedurein 685 elderly patients (mean age 79±5.3 years) with mean baseline serum creatinine was 1.09+0.5, and mean baseline creatinine clearance was 60.6+23.3, who underwent coronary angiography and/or percutaneous coronary intervention. Global incidence of ACS was 43% and incidence of diabetes mellitus was 56.5%. In all patients was used iobitridol 350 mg/mL, a low osmolar contrast medium (LOCM) with a mean dose of 237.9±105.5 mL. CrCl was calculated by applying the Cockcroft-Gault and the contrast volume to creatinine clearance ratio (V/CrCl) was calculated by dividing the volume of LOCM used for angiogram and or PCI by the patient's CrCl.All the pts were hydrated with 1 ml/kg/h of saline (0.9%) or 0.5 ml/kg/h for patients with left ventricular EF ≤50%, before and after iobitridol administration. Contrast induced nephropaty (CIN) was defined as rise of 0.5 mg/dL and/or 25% increase in baseline serum creatinine. Following the literature we have chosen to split our patients using a V/CrClIower or greater than 6.5.
CIN were observed in 12.7% of all patients. Patients with V/CrCl ≥ 6.15 were significantly older (81+5.5 vs 78+5 years), with higher ACS as clinical presentation and higher incidence of diabetes mellitus, presented a CIN in 17.8% compared with those with V/CrCl <6.15 that had a CIN in 11.3% ($p<0.04$, chi squared test).

CONCLUSIONS

Our data, as reported in literature, confirm that a volume-to-creatinine clearance ratio ≥6.15 significantly predicts the risk of early post procedural rise in serum creatinine.
Emergent PCI or the presence of diabetes mellitus can predict the onset of CIN suggesting that acute kidney injury may also result from hemodynamic instability or from diabetic nephropaty rather than from CIN.
However our data confirm the good renal tolerance of iobitridol in elderly patients even when a large volume of contrast medium was used, as previously reported in scientific literature.

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Early peripheral endothelial dysfunction predicts myocardial infarct extension and microvascular obstruction in patients with STEMI

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

To evaluate the relation between endothelial dysfunction evaluated by peripheral arterial tonometry (PAT) and both the presence of microvascular obstruction (MVO) and infarct extent in STEMI patients.

METHODS AND RESULTS

Endothelial dysfunction was evaluated by the reactive hyperemia index (RHI), measured by PAT and was defined as an RHI<1.67. Infarct extent was evaluated by troponin I (TnI) release and contrast enhanced cardiac magnetic resonance (ceCMR). MVO was evaluated by ceCMR and by indirect angiographic and ECG indicators. An Echocardiogram was also performed in the first 12 hours. 38 patients were included (mean age 60.0±13.7 years, 29 males). Mean values of RHI were 1.87±0.60 and 16 patients (42.1%) had endothelial dysfunction. Peak TnI (median 118/IQR 186 vs. 67/81, p=0.024) and AUC of TnI (median 2305/IQR2486 vs. 1076/1042, p=0.012) were significantly higher in patients with endothelial dysfunction, which also had a trend for more transmural infarcts (63.6% vs. 22.2%, p=0.06) and larger infarct mass 15.4% vs. 10.3%, p=0.08) in the ceCMR. Left ventricle ejection fraction (LVEF) was lower (Echo: 45.3±8.3 vs. 51.4±4.7. p=0.045; ceCMR: 49.5±7.2 vs. 56.6±8.1, p= 0.025) and wall motion score index (WMSI) was higher (Echo: median 1.77 IQR 0.47 vs. median 1.35 IQR 0.47, p=0.006; ceCMR: 1.53±0.32 vs. 1.28±0.31, p=0.05) in patients with endothelial dysfunction. Global longitudinal strain in the Echo was also higher in these patients (-11.89±2.35 vs. -14.32±1.72, p= 0.014). In the ceCMR, MVO was more frequent in patients with RHI<1.67 (54.5% vs. 11.1%, p=0.03). All angiographic indicators of MVO showed a trend towards worse results if these patients: corrected TIMI frame count was higher (median 19.5 IQR 12.0 vs. median 16.4 IQR 7.0, p=0.07), the prevalence of TIMI myocardial perfusion grade 2-3 was lower (56.3% vs. 86.4%, p=0.09) and the index of microvascular resistance was higher (median 40.5 IQR 54.4 vs. median 26.0 IQR 22.0, p=0.09).

CONCLUSIONS

The presence of endothelial dysfunction evaluated by PAT 24 hours after P-PCI in patients with STEMI is related with larger infarcts, lower LVEF, higher WMSI and higher prevalence of MVO.

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Bifurcation lesion treatment: a contemporary approach using thin-strut DES with bioresorbable polymer

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

AIMS

The purpose of this study is to assess the performance of a thin-strut sirolimus eluting stent with bioresorbable polymer (Ultimaster) in bifurcation lesions from patients enrolled in a large worldwide all-comer registry.

METHODS AND RESULTS

e-ULTIMASTER is a prospective, single-arm, multicentre all-comer registry, designed to further validate the safety and efficacy of Ultimaster in unselected patients enrolled worldwide. Of the 4597 patients enrolled so far and reached 1-year clinical outcome, 672 (15%) patients were enrolled in pre-specified subset of bifurcation treatment.

In this bifurcation subgroup, patients were on average 65 years old, 77% were male, 63% had hypertension and 26% had diabetes mellitus. More than half of the patients (56%) presented with acute coronary syndrome, including ST elevated myocardial infarction (17%). On average, 1.7 lesions per patient were treated, and 33% of patients had PCI in multiple vessels. The number of stent implanted per patient was 1.8±1.1 and the total stent length per patient was 38.3±27.4 mm.

Half of bifurcation lesions were true bifurcation (55%), with the majority classified as Medina 1.1.1 (37%) and the other types according to Medina classification were 1.1.0 (25.0%), 0.1.1 (9.4%), 1.0.0 (7.2%), 1.0.1 (8.6%), 0.0.1 (4.5%) and 0.1.0. (8.6%). In 47% of all cases both, the main and side branches were dilated by balloon or stent. Half of these cases (24%) were treated by double-stent technique: 19% with T-stenting, 15% with TaP, 14% with Crush, 14% with Culotte and 38% with other alternative techniques. Final kissing dilation was performed in 34%, while proximal optimisation technique was used in 33%.

At 1-year follow-up of this subgroup 10 deaths were censored (1.5%), including 6 cardiac deaths (0.9%). Myocardial infarction (MI) was reported in 15 cases (2.2%), including 10 cases with target vessel MI (1.5%). Clinically driven target lesion revascularisation (TLR) was as low as 1.9%, while target vessel revascularisation (TVR) was 3.0%. The composite endpoint of target lesion failure and target vessel failure were 3.9% and 4.8%, respectively. Stent thrombosis (definite+ probable) occurred in 7 cases (1.0%) during 1-year follow-up.

In the 351 patients who had ‘true bifurcation’ withMedina classification 1.1.1, 1.0.1, or 0.1.1, comparable event rates were observed with any death of 1.4%, cardiac death of 0.6%, any MI of 3.1%, target vessel MI 2.0%. Clinically driven TLR and TVR were 2.9% and 4.0% at 1 year respectively, which is slightly higher than for the total bifurcation group, nevertheless within the expected range as true bifurcation is technically more challenging. The stent thrombosis rate was 1.4% in the ‘true bifurcation’ subset.

CONCLUSIONS

One year data from a large worldwide all-comer registry representing contemporary PCI practice confirmed the good safety and efficacy profile of Ultimaster, a thin-strut drug eluting stent with bioresorbable polymer, in the treatment of bifurcation lesions.

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Impact of platelet reactivity on five-year clinical outcomes following PCI: a landmark analysis

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

A large proportion of patients with stable coronary artery disease (CAD) undergoing PCI present high (HPR) or low platelet reactivity (LPR). Wa assessed the impact of pre-PCI suboptimal platelet reactivity on long-term clinical outcomes.

METHODS AND RESULTS

We prospectively enrolled 500 consecutive patients with stable CAD undergoing elective PCI and treated with aspirin and clopidogrel, either a 600-mg loading dose 6 h before intervention or a maintenance dose of 75 mg/day for at least 5 days. After PCI, patients receiving bare-metal stents received clopidogrel 75 mg/day for at least 4 weeks, whereas those receiving drug-eluting stents were prescribed clopidogrel for 12 months. Platelet reactivity was measured immediately before PCI using the VerifyNow P2Y12 assay, with results expressed as P2Y12 reaction units (PRU). HPR was defined in the presence of PRU values ≥240, whereas LPR was defined in the presence of PRU values ≤189. Clinical follow-up data were obtained up to 5 years by means of office visit, telephone interview, or chart review. Primary endpoint of this study was the incidence of ischemic (death, myocardial infarction, target vessel revascularization) or bleeding events (major bleeding according to the Thrombolysis In Myocardial Infarction criteria, or large entry-site hematoma [>10 cm in diameter]) at 1 month and 5 years. Clinical follow-up was complete in 473 (94.6%). Patients experiencing ischemic and bleeding events at 5-year follow-up were 86 (17.2%) and 49 (9.8%), respectively. Ischemic events occurred in 41/162 (25.3%) of patients with HPR and in 45/311 (14.5%) patients without HPR (hazard ratio [HR] 1.87, 95% confidence interval [CI] 1.23-2.86). Bleeding events occurred in 25/150 (16.7%) patients with LPR and in 24/323 (7.4%) patients without LPR (HR 2.36, 95%CI 1.34-4.13). Patients with HPR showed significantly higher rates of ischemic events both during the first month after PCI (HR 2.06, 95%CI 1.02-4.06), and beyond one month compared with patients without HPR (HR 1.73, 95%CI 1.02-2.95). Conversely, patients with LPR presented significantly higher rates of bleeding during the first month (HR 3.67, 95%CI 1.68-8.02) compared with patients without LPR, whereas similar rates of bleeding were observed from 1 month to 5 years (HR 1.37, 95%CI 0.57-3.26).

CONCLUSIONS

Pre-PCI platelet reactivity is able to predict long-term clinical outcomes of stable CAD patients treated with clopidogrel; however, while HPR is associated with increased risk of ischemic events even beyond the first month from PCI, with a continuous divergence between the Kaplan-Meier curves of patients with and without HPR up to 5 years, the association of LPR with bleeding events seems to be confined to the periprocedural period.

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Long-term prognosis of CTO in patients undergoing primary angioplasty

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

AIMS

The aim of this study was to evaluate the long-term prognosis of chronic total occlusion (CTO) in a non culprit vessel in patients with ST-segment elevation myocardial infarction (STEMI) undergoing primary / rescue PCI.

METHODS AND RESULTS

We prospectively included 712 consecutive patients admitted for a STEMI who underwent primary / rescue PCI from 01/06/2009 to 01/06/2015. In order to evaluate the effect of the interaction of a CTO in mortality and readmission we used the Cox regression and binomial models respectively.

The patient mean age of our cohort was 64±22 years old and 80.2% of the patients underwent primary PCI. 82 patients (11.5%) showed a CTO in a non culprit vessel. Patients with a CTO showed a higher percentage of left ventricle systolic dysfunction (<50%), with a higher incidence of cardiogenic shock at the time of infarction. During a median follow-up of 60.7 months (interquartile range: 21-95), no significant differences in reinfarction or rehospitalization for heart failure were observed in both groups. Nevertheless, we observed an increase in inhospital mortality, [12 (5.3%) vs. 29 (5.3%), p <0.001], and during outpatient follow-up, [22 (35.8%) vs. 68 (12.2)%, p <0.001] in patients with a CTO. In multivariate analysis, and after adjusting for clinical and haemodynamic variables, we observed that the presence of a CTO is independently associated with an increased risk of death during the follow-up [hazard ratio (HR) 3.8; 95% confidence interval (CI) 2.0-7.2].

CONCLUSIONS

The presence of a CTO triples the risk of long-term death in patients with a STEMI undergoing primary / rescue PCI, constituting a high-risk subgroup that could also benefit of a complete preventive revascularization.

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Angiographic coronary artery disease burden and 10-year clinical outcomes in patients treated with first-generation DES

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

AIMS

While burden of coronary artery disease assessed by the angiographic SYNTAX score was reported to be associated with greater mortality at 5 years, the predictive ability of the SYNTAX score on long-term outcomes (>5 years) has not been established.

METHODS AND RESULTS

The SYNTAX score was retrospectively calculated in 858 patients enrolled in the SIRolimus-eluting stent compared with pacliTAXel-Eluting Stent for coronary revascularization (SIRTAX) trial (median 11, interquartile range [IQR] 7-17). Follow-up was complete in 763 patients (88.9%) at 10 years. During the 10-year follow-up, 174 (21.9%) patients had died, myocardial infarction (MI) occurred in 76 (9.8%) patients, target lesion revascularization (TLR) in 157 (19.7%) patients, target vessel revascularization (TVR) in 202 (25.4%) patients, and non-target vessel revascularization (non-TVR) in 153 (19.9%) patients, respectively. The SYNTAX score emerged as independent predictor for all-cause mortality (adjusted HR [per 10] 1.23, 95%CI 1.004-1.50, P=0.046), TLR (adjusted HR 1.37, 95%CI 1.12-1.68, P=0.003) and TVR (adjusted HR 1.37, 95%CI 1.14-1.64, P<0.001), and was associated with a trend toward greater adjusted risks for MI (adjusted HR 1.30, 95%CI 0.97-1.74, P=0.08) and non-TVR (adjusted HR 1.22, 95%CI 0.98-1.52, P=0.08), respectively.

We performed stratified analyses according to the median patient age of 62 years (≥62 years: 435 patients, <62 years: 423 patients). The SYNTAX score was higher in older than in younger patients (11 [7-17.75] versus 9 [5.75-15.0], P<0.001). The SYNTAX score independently predicted non-TVR in the younger (adjusted HR [per 10] 1.67, 95%CI 1.20-2.32, P=0.002) but not in older patient group (adjusted HR 1.04, 95%CI 0.75-1.44, P=0.82, $P_{interaction}$=0.049) with significant interaction. Conversely, there was no significant interaction between SYNTAX score and age category for all-cause mortality, MI, TLR and TVR.

CONCLUSIONS

The SYNTAX score was independently associated with 10-year risks of all-cause mortality, TLR and TVR. Among young but not elderly patients, the SYNTAX score independently predicted non-TVR.

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Pressure wire vs. microcatheter for FFR measurement: a head-to-head comparison

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Developed microcatheter can be used instead of pressure wire for FFR measurement. However, the larger profile of this device may lead to lower FFR values. We sought to assess the hemodynamic and clinical impacts of using microcatheter to measure FFR.

METHODS AND RESULTS

Our prospective registry included 110 consecutive patients who underwent invasive FFR measurements for evaluation of mild-to-moderate coronary stenoses as assessed by visual estimate between June 2015 and July 2016. For these procedures, hyperemia was induced by intravenous adenosine infusion. FFR values were obtained first using a pressure wire only (FFR_w), second using a Navvus microcatheter (FFR_{mc}), and finally using the wire with the microcatheter still in the stenosis (FFR_{w-mc}).

Eighty-eight stenoses were suitable for a thorough head-to-head comparison. Mean FFR_w (0.83 ± 0.08) was significantly higher than mean FFR_{mc} (0.80 ± 0.10) andFFR_{mc-w} (0.80 ±0.10). Mean FFR_{mc} and FFR_{mc-w} did not significantly differ. Bland–Altman analysis showed a bias of −0.03 ±0.05 for lower FFR_{MC} values compared to FFR_w values. Vessel reference diameter was significantly correlated with FFR underestimation by the microcatheter (R^2 = 0.047; p = 0.042). Using a dichotomous threshold of 0.80 for FFR, the indication for revascularization would have differed when based on FFR_{mc} versus FFR_w in 20/88 (23%) of the lesions and 18/77 (23%) of the patients.

CONCLUSIONS

FFR measured using a microcatheter overestimates stenosis severity, leading to erroneous indication for revascularization in a sizable proportion of cases.

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Transradial access from femoral artery intervention

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal

AIMS

The purpose of this prospective register was to evaluate the acute success and complication rate of the transradial access for femoral artery intervention.

METHODS AND RESULTS

The clinical and angiographic data of 125 consecutive cases with symptomatic femoral artery stenosis treated via transradial access using 6F sheathless guiding between 2014 and 2016 were evaluated in a pilot registry. Stent implantation was done only in cases of flow-limiting dissection and significant recoil. Secondary access was the popliteal or pedal artery. Inclusion criteria were significant isolated femoral artery stenosis and intermittent claudication (Fontaine IIa-b); or critical limb ischemia (Fontaine III-IV) with viable limb. The exclusion criteria were the conventional contraindications of the radial artery access, lack of distal access site for stenting (occlusion of both main below the knee arteries), acute limb ischemia. Primary endpoint: major adverse events (MAE), target lesion revascularisation (TLR), rate of major and minor access site complications. Secondary endpoints: angiographic outcome of the femoral artery intervention, consumption of the angioplasty equipment, cross over rate to femoral access site and hospitalisation in days. Transradial cases were performed by two interventionalists skilled in transradial technique and lower limb interventions. The radial artery puncture and sheat deployment was successful in 122 cases (97.6%). The procedure from radial artery as single access site was successful in 110 cases (88.0%). The cross over rate to femoral access site was 2,4%. Secondary access was obtained in 10 cases (8.0% - 1 transpopliteal, 9 transpedal). The procedure was finished with good angiographic result in 119 cases (95,2%). In 53 patients (42,4%) CTO recanalisation was performed with a 92,5% success rate. Balloon angioplasty was performed in all patients, but additional stent implantation was done in 33 cases (26.4%). The mean contrast consumption was 108,2±61,7. The mean X-ray dose used was 45.6±165,4 Dyn. The mean procedure time was 34.2±19 min. Minor access site complications were detected in 3 cases (2.4%). Long term MAEs were observed in 4 cases (3.2%) and TLR occured in 2 cases (1,6%).

CONCLUSIONS

Femoral artery intervention can be safely and effectively performed using radial access with an acceptable morbidity and a high technical success rate.

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Pre-dilation, Sizing and Post-dilation (PSP) score for evaluating adverse cardiac events in patients undergoing everolimus-eluting BRS implantation: external validation of the PSP score

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

AIMS

To perform an external validation of the Pre-dilation, scaffold sizing, and post-dilation score models and determine its usefulness in predicting adverse cardiac events in patients undergoing everolimus-eluting bioresorbable scaffolds implantation.

METHODS AND RESULTS

By using the Gauging coronary Healing with biOresorbable Scaffolding plaTforms in EUrope (GHOST-EU) registry population, the pre-dilation, scaffold sizing, and post-dilation (PSP) steps during bioresorbable scaffolds (BVS) implantation were scored according to the hazard model derived from the weight of these variables. Pre-dilation, scaffold sizing, and post-dilation were scored with 0.63, 1.96 and 1.93 points, respectively, if properly performed. After internal validation, this PSP score model was externally validated in the REgistry of PAtients With bioResorbable Device in Daily Clinical prActice (REPARA) registry, an investigator-initiated, prospective, not controlled, multicenter registry conducted at 58 Spanish and Portuguese centers which enrolled 2553 lesions treated by BVS. Primary endpoint was 1-year device-oriented composite endpoint (DoCE) of cardiac death, target vessel myocardial infarction, and target-lesion revascularization. ARC definite/probable scaffold thrombosis was also evaluated. The median value (Interquartile range) of PSP score was 2.59 (1.59 – 2.59). At 1-year, the PSP score was an independent predictor of DoCE (HR 0.76, 95%CI [0.61 – 0.94]; p=0.013). Patients with maximum PSP value exhibited a similar rate of scaffold thrombosis as compared to those patients with a no-maximum score (2.0% vs. 1.9%; p=0.832, respectively).

CONCLUSIONS

In this external validation in the REPARA registry, at 1-year follow-up, the PSP score was an independent predictor of DoCE. Future trials with longer follow-up will be needed to further validate the score.
Clinical Trial Registration: http://www.clinicaltrials.gov. **Unique identifier**: NCT02256449

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Clinical use of FFR-CT in the evaluation of symptomatic patients with intermediate (50-70%) coronary stenosis: can it improve diagnosis and reduce radiation risk and cost?

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS
Investigate whether utilization of FFRct would reduce costs, risk and radiation exposure in symptomatic patients with 50-70% CTA stenosis by reducing the number of “unnecessary” ICA-FFR examinations?

METHODS AND RESULTS
Retrospective analysis of 48 patients with stable chest pain, positive exercise ECG and intermediate (50-70%) CTA stenosis who were referred for ICA and FFR examination. Blinded FFRct analysis. Determination of diagnostic accuracy of FFRct vs CTA using FFR as reference standard. Evaluation of potential impact of clinical adoption of FFRct to guide clinical decision making; “unnecessary” ICA-FFR examinations defined as FFR in all vessels > 0.80.
FFRct had higher diagnostic accuracy than CTA (83% vs 29%) with higher PPV (69% vs 29%) and a six-fold reduction in false positives. Using invasive FFR-guided therapy, 34/48 patients (71%) had non-obstructive CAD (FFR >0.80) and were treated medically; 14 (29%) had FFR ≤0.80 and were revascularized (8 PCI, 6 CABG). There were no major adverse cardiac events. Use of a FFRct-guided strategy would have reduced “unnecessary” ICA-FFR procedures by 85%, thereby reducing the inherent risk of an invasive procedure. Assuming a cost of 1000€ per FFRct analysis, an overall cost reduction of 30% would have been achieved. Furthermore, radiation dose exposure would have been reduced by 63%, assuming an average dose of 2.1 mSv for CTA and 4.8 mSV for ICA.

CONCLUSIONS
Utilization of FFRct analysis in the evaluation of symptomatic patients with intermediate CTA stenosis may result in fewer “unnecessary” invasive ICA-FFR examinations with significantly reduced costs, risks and radiation dose exposure.

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A study of distal renal denervation vs. conventional mode of the intervention for treatment of resistant hypertension: an update

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THEME: Interventions for Hypertension
TOPIC(S): Renal denervation

AIMS

This is an update on the results of our randomized, controlled trial (NCT02667912) of distal denervation in segmental branches of renal artery versus conventional mode of the therapy for treatment of resistant hypertension.

METHODS AND RESULTS

Patients meeting criteria of true resistant essential hypertension were randomized either to “conventional” renal denervation restricted to the main renal artery or to “distal” treatment applied mainly in segmental branches of the artery beyond the bifurcation. Computer-based treatment assignment was performed in the catheterization laboratory at the time of the procedure by the interventional radiologist and remained unknown to patients, investigators, and other outcomes assessors for the entire study period. Baseline antihypertensive pharmacotherapy was maintained as strictly as possible during the follow up.

A total of 55 patients were finally enrolled in the study (28 were treated by distal denervation and 27 – by conventional denervation in main trunk). Per protocol analysis included 51 patient who completed 6 months follow-up. Similar to previous analysis a significantly greater decrease of 24-hour mean systolic BP was found in the distal therapy group (n=27) as compared to the group of conventional renal denervation (n=24): -21.1±19.3 vs -10.3±17.8 mmHg; $P<0.05$. No major safety issues were observed in either group. Doppler flowmetry did not detect any significant change of blood flow in segmental branches of renal artery after distal treatment.

CONCLUSIONS

Distal renal denervation in segmental branches of renal artery is significantly more effective for treatment of resistant hypertension than conventional mode of the therapy in main trunk.

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Comparison of clinical outcomes and long-term mortality for transapical and transaortic TAVI in a tertiary referral centre

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

AIMS

To examine short and long-term clinical outcomes of transapical (TA) versus transaortic (TAO) TAVI in a single tertiary referral centre.

METHODS AND RESULTS

Over an 8-year period, 283 TAVIs were performed under general anaesthesia via transaortic (n=166) or transapical routes (n=117) after Heart Team consensus that transfemoral approach was unsuitable. Valve types used were Sapien XT (43.5%), Sapien (29.0%), S3 (17.7%), Lotus (6.0%), and Symetis (3.2%), with no differences in baseline STS scores (TA 5.4 ± 3.4% vs TAO 6.6 ± 5.5%, p=0.06), mean procedural duration (TA 85.4 ± 42.6 v TAO 92.7 ± 34.0, p=0.13), median (IQR) ICU (1.0 [1.0, 1.8] v 1.0 [1.0,1.0], p=0.08) or total length of hospital stay (9.0 [6.3,16.0] v 9.0 [6.0, 14.5], p=0.99).At 30-days, Euroscore II more accurately predicted mortality than the STS score (AUC 0.62 v 0.60, p=0.03). For TA v TAO, 30-day stroke rates (4.2% v 1.7%, p=0.24), VARC major vascular events (3.0% v 1.7%, p=0.49), and mortality (7.2% v 5.1%, p=0.48) did not differ according to the route of surgical approach. Similarly, there was no difference in mortality at one year (TA 21.1% vs TAO 25.6%, p=0.37) or five-year follow up (TA 42.5% [12 alive] v TAO 25.0% [40 alive], p=0.96).

CONCLUSIONS

For a tertiary centre Heart Team experienced in both surgical TAVI techniques, similar procedural success, clinical outcomes, and 5-year mortality were observed for transapical and transaortic approaches. The results of this study support the use of either approach for patients who are unsuitable for transfemoral arterial access.

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Sheathless transferal and subclavian TAVI in patients with complex vascular anatomies

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

AIMS

Portico valve can be implanted through sheathless TF access, or through left subclavian artery. These two approaches have extended TAVI treatment to patients with complex vascular anatomies while retaining device position accuracy and deliverability

METHODS AND RESULTS

Twentyfive (18 TF sheatless + 7 subclavian) patients (mean age 84.01 ±3,25 years; mean Logistic EuroSCORE 23.14 ±6.11%; STS mortality risk score 12.56 ±2.91%) received St. Jude Medical's PORTICO aortic valve via a common femoral artery by means of a new sheathless approach or by subclavian access. In each patient CT-scan was performed pre-operatively to estimate the dimensions of the aortic annulus and to evaluate the access site vessels and aorta. CT-Imaging revealed calcified and reduced-caliber iliac/femoral arteries (mean access vessel diameters were 5.32/4.52 ±0.19/0.26 mm) and tortuous ilio-femoral axis and aorta. At the end of each TF sheatless procedure, a pre-implanted suture-mediated closure system was used in association to cyanoacrylate glue to obtain full hemostatic control; mean compression time after device withdrawal was 3'30'', while a standard closure device was used for subclavian artery. A Portico aortic valve was successfully implanted in all patients. In fourteen patients (56%) valve re-sheathing was necessary in order to achieve optimal deployment; no VARC-2 (Valve Academic Research Consortium) major vascular complications were observed. Post-operative angiographic and ultrasound control were performed in all cases; paravalvular leaks were observed in 9 patients (36%),none of which was deemed worse than mild. Mean Intensive Care Unit (ICU) stay after TAVI was 23.78 hours and hospitalization lasted 6.79 days on average. All patients were seen 30 days after discharge. They all reported a reduction in dyspnea and/or thoracic pain; in no case was valvular regurgitation worse than mild.

CONCLUSIONS

Our experience shows the feasibility and safety of new-generation TAVI, through TF sheatless or subclavian access. PORTICO's delivery system allows both easy navigation even through complex vascular anatomies and valve retrieval and repositioning, thus enabling structural cardiac surgery to be performed safely and effectively even in high-risk patients. Moreover, the sheathless technique has a low impact on the vascular access site and permits complete hemostatic control through the use of one pre-implanted suture-mediated closure device plus cyanoacrylate glue. Further studies on this specific issue should be conducted in the future.

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Comparison of haemodynamic performance of the balloon-expandable Sapien-3 vs. Medtronic Evolut-R transcatheter valve: a case matched study with independent analysis

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

AIMS

The Sapien-3 and the Medtronic Evolut-R are second-generation transcatheter heart valves, which are designed to further reduce the rate of paravalvular aortic regurgitation. The aim is to compare the hemodynamic performance of both devices.

METHODS AND RESULTS

A total of 203 symptomatic patients with severe aortic stenosis who underwent TAVI with the new-generation valves from 2 centers were eligible. Patients with previous aortic valve replacement, lack of pre-interventional echocardiogram or cardiac CT, or absence of 30-day post-interventional echocardiogram were excluded. Valve type and size were planned before the procedure according to clinical, echocardiographic and Multidetector Computed Tomography (MDCT) data. The matching criteria were (1) aortic annulus diameter derived by perimeter (within 0.5mm of difference) and aortic valve calcium score quartile as assessed by MDCT. A variable number of controls (from 1 up to 3) were allowed, leading to a final sample of 133 patients [Sapien-3 (S3V): 80, Evolut-R (EVR): 63]. All echocardiographic examinations collected at baseline and 1-month follow-up were stored in digital format and centrally analyzed by one independent experienced cardiologist unaware of clinical data. Aortic regurgitation (AR) severity was evaluated using a multiparametric approach and classified following the VARC-2 recommendations.

The mean age of population was 83±6 years and 51% of the patients were women. There were no differences in baseline clinical characteristics and in the matched variables (calcium score: EVR 2531±1782 vs S3V 2503±2015, p=0.93; aortic annulus: EVR 24.8±2.6 vs S3V 24.4±2.4, p=0.43). The two groups were also well balance regarding LVEF, severity of aortic stenosis and rate and severity of AR (p=n.s.). The rate of balloon postdilation after valve implantation was higher in the EVR group (23%) compared with the S3V group (5%), p=0.002. There were no other differences between groups regarding peri-procedural events (p=n.s.). The EVR valve showed a better hemodynamic profile as evaluated by peak aortic gradient (EVR 13±7 vs S3V 20±1, p<0.001), mean aortic gradient (EVR 13±3 vs S3V 11±7, p<0.001), and Doppler velocity index (EVR 0.65±0.2 vs S3V 0.51±0.2, p<0.001). The rate of moderate-severe AR was higher in the EVR group (12%) than in the S3V group (2.5%) p=0.04. Also the rate of any paravalvular AR was higher in the EVR group (50%) than in the S3V group (21%) (p<0,001), with a larger number of paravalvular jets (EVR 1.0±0.9 vs S3V 0.5±0.6, p<0.001).

CONCLUSIONS

In a case matched cohort of TAVI patients, the Sapien 3 valve was associated with a lower rate of paravalvular AR and need of postdilation when compared with the Evolute-R system. The Evolute-R showed a better hemodynamic profile as assessed by lower aortic peak and mean gradients.

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Multicentric registry of BRS in spontaneous coronary artery dissection: a comparison with metallic stents

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

AIMS

To evaluate 1 year outcomes in a multicentric series of in patients with Spontaneous Coronary Artery Dissection (SCAD) that underwent PCI with Bioresorbable Scaffolds (BRS), compared to a cohort of SCAD patients treated with metallic stents

METHODS AND RESULTS

From 2008 to 2015, 30 SCAD patients required PCI in 6 Spanish centres. Of these, 15 were treated with BRS and 15 with metallic stents. Baseline characteristics, peri-procedural and 1 year outcomes of both groups were compared. The primary endpoint was one-year occurrence of a device-oriented composite outcome including: cardiac death, target vessel myocardial infarction and target lesion revascularization (TLR).

There were no significant differences between groups in terms of age, sex, target artery, or other baseline or procedural characteristics. Mean age was 52 years in the BS group and 49 years in the metallic group (p=0.45). Clinical presentation was STEMI in 53% (BRS) and 73% (metallic), all other patients presented with NSTEMI (p=0.26). Mean number of stents implanted was 2.0 (BRS) and 1.67 (metallic)(p=0.47), and the mean of total stent length was 46.5 mm (BRS) and 42.7 mm (metallic)(p=0.91). Intracoronary imaging was used in 12/15 in the BRS group and 10/15 in the metallic group.

Periprocedural complications occurred in 1 patient in the BRS group: LAD perforation solved with balloon dilatation (no complications in the metallic group). During index admission, 4 patients underwent clinically-driven new coronary angiography (CD-CAG), and additional PCI was performed in 2/2 patients from the BRS group and in 1/2 patient from the metallic group, all due to dissection propagation. No other events occurred during admission.

After discharge, 2 patients from the BRS group and 3 from the metallic group underwent CD-CAG. Of these, only 1 patient (metallic group) deemed TLR due to restenosis of 2 overlapped bare metal stents. After 1 year of follow up, all patients were alive with no loses to follow-up. No primary endpoints occurred in the BRS group, whereas only one patient in the metallic group presented the primary endpoint (TLR). There were no stent thromboses in either group.

CONCLUSIONS

BRS seems attractive for those SCAD patients requiring PCI, due to the usually low or absent atheroma burden and predictable artery restoration after the acute event.

In a retrospective multicentric series of SCAD patients requiring PCI, use of bioresorbable scaffolds was feasible and safe, with similar outcomes compared to metallic stents at 1 year of follow-up.

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Real-time IFR-FFR assessment of coronary artery disease in patients with severe aortic stenosis undergoing TAVI

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Bifurcation lesion

AIMS

The aim of the study was to evaluate the variations of iFR measurements before and after the aortic valve replacement and to test the feasibility of a real-time iFR-FFR coronary artery disease assessment in TAVI patients.

METHODS AND RESULTS

Methods and Results. The functional relevance of 141 coronary lesions was assessed by on-line iFR and FFR measurement in 62 patients with severe AS before and after TAVI, during the same procedure. A linear-mixed-model was used to verify interaction of TAVI effect with iFR measurements. A hybrid iFR-FFR strategy was then applied to test the overall diagnostic agreement with the FFR-only strategy. iFR values remained identical before and after TAVI, irrespective of the angiographic severity of the coronary stenosis (0.89±0.12 vs 0.89±0.12, p=0.66). A *"deferral value"* iFR>0.93 yielded a negative predictive value= 98.4% (91.7%-99.9%) to exclude FFR non-significant stenosis (>0.80), and a *"treatment value"* iFR<0.83 had a positive predictive value of 91.3% (72%-98.9%) to identify FFR-significant stenosis (≤0.80). A hybrid decision-making strategy based on iFR and FFR spared 63% of patients from adenosine, while maintaining 97% overall agreement with FFR lesions classification.

CONCLUSIONS

Severe AS did not influence iFR measurements in coronary arteries with different degree of CAD. This supports an iFR pre-intervention physiologic evaluation. A hybrid iFR-FFR diagnostic strategy is feasible in patients with severe AS undergoing TAVI and allows to spare 63% of patients from adenosine, while maintaining an elevated agreement with FFR classification of coronary lesions.

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Long-term follow-up after transcatheter tricuspid valve-in-valve replacement. Haemodynamic performance and clinical outcome

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

AIMS

To evaluate the safety of transcatheter tricuspid valve-in-valve (VIV) replacement by using balloon–expandable aortic valve stents and the long-term hemodynamic and clinical results.

METHODS AND RESULTS

From January 2013 to March 2016, 4 patients underwent transcatheter tricuspid VIV in our center using balloon-expandable Edwards Sapien-XT and Sapien-3 valves. In all cases the procedure succeeded with significant improvement of the tricuspid valve area (from 0.98±0.29cm^2 to 3.1±0.45cm^2, p=0.005), right atrial pressure (from 21±7.78 mmHg to 8.5±2.51mmHg, p=0.025) and mean trans-valvular gradient (from 11.5±4mmHg to 3.32 ±1.28mmHg, p=0.02).
Three out of 4 patients presented a follow up longer than 2.5 years. At median follow up of ~~28~~ 32 months (range 9-47 months) all patients were alive and presented with NYHA class I-II. Only one patient, who presented impaired right ventricular function at baseline, experienced re-hospitalization during the follow-up time. Echocardiographic assessment at long-term disclosed a well-maintained hemodynamic performance with low trans-valvular gradients and no significant valvular regurgitation in all cases.

CONCLUSIONS

In our experience, trans-catheter tricuspid VIV demonstrated good long-term results in terms of valve performance and functional class improvement at 32 months from intervention.

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How do intermediate coronary lesions evolve over time? A morphological and functional retrospective, longitudinal study of 414 stenoses

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

To explore the natural history of intermediate coronary lesions using FFR as surrogate endpoint, describe the clinical significance of longitudinal FFR change (dFFR), its correlation with angiography and identify the predictors of FFR at follow-up.

METHODS AND RESULTS

A retrospective, single-center analysis of all coronary stenoses that were functionally evaluated by consecutive FFR measurements at two time points at least six months apart was performed. Stenoses in vessels that had been revascularized by percutaneous coronary intervention (PCI) and/or coronary artery bypass grafting (CABG) between the two time points were excluded. 414 stenoses from 331 patients were analyzed with a time interval between the FFR measurements of 24 (17, 37) months. FFR follow-up was significantly lower than FFR baseline [0.83 (0.79, 0.90) versus 0.86 (0.82, 0.90), P<0.0001] and the overall dFFR was -0.007 (-0.028, 0.010) per year. Worsening FFR (defined as dFFR <-0.05) was observed in 105 (25%) stenoses, stable FFR (-0.05≤dFFR≤0.05) in 276 (67%) stenoses and improving FFR (dFFR>0.05) in 33 (8%) stenoses. The number of clinically significant stenoses (e.g. FFR≤0.80) was higher at follow-up compared to baseline (33% versus 17%, P<0.0001); dFFR correlated weakly with delta diameter stenosis (DS, ρ=-0.111, P=0.024). In multiple linear regression analysis, FFR baseline andPCI between FFR measurements at a non-index segmentwere the only independent predictors of FFR follow-up (R2=0.2301). In receiver-operator characteristic (ROC) analysis, FFR baseline values were robust predictors of future clinically significant values (FFR follow-up <0.8) with a c-statistic of 0.736 (95% CI: 0.682 – 0.783).

CONCLUSIONS

FFR values decrease at a slow rate over two year follow-up. FFR baseline, but not angiographic indices or clinical characteristics, is a robust predictor of significant longitudinal atherosclerosis progression, predicting which stenoses will require revascularization.

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Angiography alone vs. angiography plus OCT to guide PCI: outcomes from the pan-London PCI cohort

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

AIMS

The superior spatial resolution of optical coherence tomography (OCT) could translate into meaningful clinical benefits. We aimed to determine the effect on long-term survival of using OCT during PCI.

METHODS AND RESULTS

This was a cohort study based on the Pan-London (United Kingdom) PCI registry. In total, 123,764 patients are included in this registry covering London, England, which includes all patients who underwent PCI in National Health Service hospitals in London between January 1, 2005, and May 31, 2015. Patients undergoing primary PCI or pressure wire use were excluded. The primary end point was all-cause mortality at a median of 4.1 years.OCT was used in 1149 patients (1.4%), IVUS was used in 13,356 patients (16.7%) and angiography alone in the remaining 65,372. Overall OCT rates increased over time ($p<0.0001$) with variation in rates between centres ($p=0.002$). The mean stent length was shortest in the angiography-guided group, longer in the IVUS guided group and longest in the OCT-guided group. OCT guided procedures were associated with greater procedural success rates and reduced in-hospital MACE rates. A significant difference in mortality was observed between patients who underwent OCT-guided PCI (7.7%) compared with patients who underwent either IVUS (12.2%) or angiography guided PCI (15.7%, $p<0.0001$), with differences seen for both elective ($P<0.0001$) and ACS subgroups ($p=0.0024$). Overall this difference persisted after multivariate cox analysis (HR 0.37 (95% CI 0.25-0.62) and propensity matching (HR=0.36, 95% CI: 0.18-0.73, $p=0.0005$) (OCT versus angio alone cohort)

CONCLUSIONS

In this large observational study, OCT-guided PCI was associated with improved procedural outcomes and long-term survival compared with standard angiography-guided PCI.

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Prognostic impact of functional assessment with FFR in ACS

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

AIMS

The present study aimed to compare the outcome of stable patients vs those with ACS, especially regarding the ability to safely defer revascularization of lesions with FFR value >0.80.

METHODS AND RESULTS

543 stable patients and 231 with ACS needing functional evaluation of ≥1 lesions using commercially available pressure wires were enrolled. Major cardiac adverse events (MACE), defined as the combination of death, MI and clinically driven revascularization were assessed at a median follow up of 17 months. FFR was used for lesions of ambiguous significance in the absence of a clear culprit vessel (first intention, FI) and for incidental lesions in the presence of a clear culprit vessel (second intention, SI). SIHD and ACS patients were not significantly different for clinical characteristics. As expected, patients studied with FFR in the context of an ACS had a significantly worse prognosis compared to those who were stable. This was even more evident in the subgroup of patients in which FFR was used as FI. In particular, in patients with at least 1 significant lesion, those with ACS had a significantly higher rate of early MACE compared with those with SIHD while among patients with all lesions assessed with FFR>0.80, deferral of revascularization was safe at least up to 12 months; after this timepoint ACS patients showed an increase rate of events. Nevertheless, when FFR was used in SI there was a lack of difference between stable and ACS patients in recurrence of MACE.

CONCLUSIONS

FFR confirms its reliability in safely defer revascularization when it is >0.80 also in ACS patients when used for incidental lesions in the presence of a clear culprit vessel previously treated percutaneously. In those patients in which FFR is used as first intention technique to assess coronary stenosis and in particular to defer revascularization, rate of MACE recurrence is higher in patients with ACS compared to stable ones.

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Prognostic value of FFR, measured after DES implantation

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Stents and scaffolds, Left main and multivessel disease

AIMS

We investigated the potential of post-PCI FFR measurements to predict clinical outcome in patients enrolled in the FAME 1 and FAME 2 trials.

METHODS AND RESULTS

Methods: All patients of FAME 1 and FAME 2 who had post-PCI FFR measurement were included. The primary outcome was vessel-oriented composite end-point at 2 years, defined as the composite of vessel-related cardiovascular death, vessel-related spontaneous (non-periprocedural) myocardial infarction, and ischaemia driven target vessel revascularization (both urgent and non-urgent) and adjudicated by a blinded event committee.
Results: 850 vessels in 644 patients were analyzed. Pre-PCI FFR values did not differ between vessels with versus without vessel-oriented composite end-point (0.66±0.11 vs. 0.63±0.14, respectively; p=0.096). Post-PCI FFR was significantly lower in vessels with vessel-oriented end-point during follow-up (0.88±0.06 vs. 0.90±0.06, respectively; p=0.034). Comparing the tertiles of post-PCI FFR a significant difference was found favoring the upper tertile for the primary end-point (Lower vs Upper 9.0% vs 3.7%; p=0.011; Middle vs Upper 7.9% vs 3.7%; p=0.038) and for target vessel revascularisation (Lower vs Upper 6.9% vs 2.4%; p=0.012; Middle vs Upper 5.2% vs 2.4%; p=0.076). Post-PCI FFR of 0.92 was found to have the highest Youden index, however the positive likelihood ratio did not exceed 1.4.

CONCLUSIONS

A higher post-PCI FFR value is associated with a better vessel-related outcome. However, the predictive value of post-PCI FFR is too low to advocate its use of as a surrogate clinical end-point.

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Explanation of post-procedural FFR below 0.85: a comprehensive ultrasound analysis of the FFR search registry

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

AIMS

FFR after Percutaneous Coronary Intervention PCI is a predictor of adverse cardiovascular events during follow-up. The aim of the present study was to assess the potential reasons for low post procedural FFR values using high definition IVUS.

METHODS AND RESULTS

Methods: FFRsearch is a prospective registry in which post procedural FFR will be assessed in 1000 consecutive all-comer patients after successful PCI. FFR measurements were performed with a novel over-the-wire monorail catheter inserted over the previously used coronary guidewire to approximately 20mm distal of the most distal stent edge. FFR measurements were performed in resting conditions and under maximum hyperemia with intravenous Adenosine. In patients with a post procedural FFR ≤0.85, intravascular high definition ultrasound analysis were performed at a pullback speed of 2.5 mm/sec at 60 MHz to identify potential reasons for a low post procedural FFR. Images were analyzed every 0.5 mm.
Results: IVUS analysis were performed in the first 44 vessels with a post procedural FFR<0.85. Mean post procedural FFR values during resting condition was 0.91±0.05 and 0.79±0.05 under maximum hyperemia.
On IVUS, mean lumen area was 5.99+/-1.33 mm(2) with a minimal lumen area of 2.2+/-0.77 mm(2). Minimum stent area was 4.02+/-1.38 mm(2). Significant focal lesions distal to the stented segment were present in 52% of the vessels analysed while focal proximal lesions were apparent in 43% of the patients. Stent underexpansion was present in 84% of patients according to the MUSIC criteria while malposition was present in 22% of the cases. In 35/44 patients clear focal signs of luminal narrowing were found.

CONCLUSIONS

In patients with a post procedural FFR <=0.85 IVUS revealed focal signs of luminal narrowing in the vast majority of the cases. Whether additional treatment will optimize post procedural FFR values and long-term adverse event rates remains to be determined.

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Routine use of fluoroscopic guided femoral arterial puncture and upfront femoral angiography results in reduced femoral complications in patients undergoing coronary angiographic procedures

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

AIMS

We initiated a quality improvement project recommending that fluoroscopy be used to determine whether upfront femoral angiography performed post sheath insertion to assess for immediate complications reduced the rates of vascular complicaitions.

METHODS AND RESULTS

Methods: Data was collected prospectively on 3653 consecutive patients undergoing femoral coronary angiographic procedures from May 2015 to December 2016. The primary end-point was any access complication, defined as: haematoma ≥5 cm, pseudoaneurysm formation, retroperitoneal haemorrhage, arterial dissection, vessel thrombosis, non-coronary artery bypass graft-related access bleeding requiring transfusion, access site infection, or haemoglobin drop of ≥3 g/dl with an access source or ≥4 g/dl with an unknown source.

Results: 1763 patients underwent angiography prior to the introduction of routine fluoroscopy and upfront femoral angiography and 1890 post. Baseline characteristics, large sheath use, anticoagulant use and PCI rates were similar between the 2 groups. Fluoroscopy-enabled punctures were made in the ‘safe zone’ in over 91% of cases and upfront femoral angiography resulted in management changes i.e procedural abandonment prior to heparin administration in 21 patients (1.1%). These quality improvement measures were associated with a significantly lower incidence of access site complications (0.9% vs. 2.0%, P<0.001). Average length of stay was also significantly lower among patients in the intervention group (1.6 days vs. 2.3, P < 0.001).

CONCLUSIONS

Routine fluoroscopy guided vascular access and upfront femoral angiography prior to anticoagulation leads to lower vascular complication rates and a shorter length of stay.

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Polymer-free DES in high bleeding risk patients with diabetes mellitus: a pre-specified substudy of the LEADERS FREE trial

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

AIMS

Patients with diabetes mellitus (DM) are at risk of poor outcome after PCI and are particularly sensitive to the type of stent and applied antithrombotic regimen. We report characteristics and outcomes of the DM subgroup of the LEADERS FREE trial.

METHODS AND RESULTS

The randomized, double-blind LEADERS FREE trial compared high-bleeding risk (HBR) recipients of either a polymer-free BA9 coated stent (DCS) or a bare metal stent (BMS) with only one month of dual antiplatelet treatment (DAPT) and showed superior safety and efficacy of the DCS up to two years follow-up. The trial included 2466 patients undergoing PCI who had at least 1 of 13 pre-defined factors for an increased bleeding risk. Out of the 2427 patients with a known DM status at baseline, 805 (33.1%) were diagnosed with DM, 262 (32.5%) of which were insulin dependent. Compared to other HBR patients, DM patients were younger (74.4±9.1 vs. 76.2±9.3 years, p<0.001), with a higher prevalence of hypertension, hypercholesterolemia, previous coronary interventions, renal insufficiency, anaemia and multi-vessel disease. Mean number and total length of implanted coronary stents was higher among diabetic patients.

At 2-years follow-up, compared to non-DM patients, diabetics had higher rates of death (15.6 vs. 12.2%, p=0.01), cardiac death (8.3 vs. 5.9%, p=0.02), myocardial infarction (11.1 vs. 7.8%, p=0.009) and definite or probable stent thrombosis (3.1 vs. 1.7%, p=0.01), though clinically-driven target-vessel and target-lesion revascularization rates were comparable to the non-DM population (10.3 vs. 10.5%, p=0.92 and 9.1 vs. 9.5%, p=0.93, respectively).

In patients with DM, treatment with the DCS was more effective than treatment with BMS at 2 years (clinically driven target-lesion revascularization 6.3 vs. 12.2%, p=0.006). The combined primary safety endpoint (cumulative incidence of cardiac death, myocardial infarction, or definite or probable stent thrombosis) at 2-years occurred less frequently in the DCS group compared to the BMS group (14.9 vs. 19.7%, p=0.10), and was significantly lower with DCS in patients with insulin-dependent DM (13.8 vs. 25.4%, p=0.03). Major bleeding rates were high and not significantly different between DM and non-DM patients (10.2 vs. 8.4%, p= 0.20) or in the DCS and BMS groups (9.9 vs.10.5%, p=0.84).

CONCLUSIONS

Diabetic HBR patients accounted for nearly one third of the LEADERS FREE population, and had worse ischemic outcomes but similar bleeding rates compared to non-DM HBR patients at 2 years. For diabetic HBR patients, DCS use was associated with a significant efficacy benefit and showed a strong trend towards a safety benefit. Given the lack of available data for current-generation DES with shortened DAPT in HBR patients with DM, DCS should currently be considered as the device with the strongest clinical evidence to support its use in this complex group of patients.

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Safety and efficacy of minimalist approach in transfemoral TAVR - Insight from OCEAN-TAVI registry

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

AIMS

A monitored anesthesia care utilizing local anesthesia and conscious sedation (minimalist approach: MA) for transfemoral (TF) TAVR has been reported as favorable results. We report our experience from Japanese multicenter registry.

METHODS AND RESULTS

October 2013 and April 2016, a total of 1215 consecutive Japanese patients with symptomatic, severe aortic stenosis undergoing TAVR with self-expandable or balloon-expandable valves were prospectively included in the OCEAN-TAVI registry. Of those, we retrospectively reviewed a total of 921 consecutive patients who had elective TF-TAVR. We evaluate perioperative results of MA-TAVR and non-minimalist approach (NMA) TAVR utilizing propensity matching. 118 patients underwentMA-TAVR and 802 patients had NMA-TAVR (median age: 84 vs. 85, p=0.25, and STS score: 7.6 vs. 6.4, p=0.01). 118 pairs were compared after the propensity matching using multiple variables. In-hospital mortality and stroke/transient ischemic attack were not significantly different between the MA-TAVR and NMA-TAVR group (2.5% vs. 0.8%, p=0.62, and 1.7% vs. 0.8%, p=1, respectively). Major or life-threatening bleeding and transfusion rate were significantly less in the MA-TAVR (3.4% vs. 17%, p<0.0001 and 6.8% vs. 29%, p<0.0001, respectively). Total intensive care unit days and length of hospital stay were significantly less in the MA-TAVR group (p<0.0001).

CONCLUSIONS

MA-TAVR has similar results to NMA-TAVR in terms of mortality and stroke in Japanese multicenter registry. Shorter hospital stay, less major or life-threatening bleeding and less transfusion rate were seen in the MA-TAVR group. MA-TAVR is a safe and effective procedure.

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Lumen boundaries extracted from coronary CT angiography on computed FFR (FFR CT): validation with OCT

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS
The spatial resolution of coronary computed tomography angiography (cCTA) and coronary calcification have been hypothesized to inhibit accurate lumen detection using cCTA, and adversely impact fractional flow reserve (FFR_{CT}) performance.

METHODS AND RESULTS
Fifty-seven patients (118 lesions, 72 vessels) who underwent cCTA and optical coherence tomography (OCT) were enrolled. After co-registration of OCT and cCTA lesion locations, the minimal lumen area (MLA) was measured with both modalities. FFR_{OCT} was calculated using OCT-updated models in which cCTA-based lumen geometry was replaced by OCT-based lumen geometry (Figure 1). All lesions were divided into groups according to Agatston score (AS), and minimum lumen diameter (MLD) using the size of the catheter and guide wire (1.0 mm) as a cut-off value.

Overall, there was no significant difference in the average cCTA MLA and OCT MLA (cCTA MLA: 2.37±1.59 mm^2 vs. OCT MLA: 2.39±1.51, p=0.926). The average absolute difference in MLA measurements between cCTA and OCT was 0.621±0.571 mm^2, with an excellent correlation between imaging modalities (r=0.851, p<0.0001). Bland-Altman plots of cCTA MLA in relation to OCT MLA showed a mean bias of -0.018±1.652 mm^2 with 95% limits of agreement of -1.671 to 1.633 mm^2. For computed FFR, FFR_{CT} tended to be lower than FFR_{OCT} (FFR_{CT}: 0.743±0.151 vs. FFR_{OCT}: 0.790±0.113, p=0.051). There was a significant positive correlation between FFR_{CT} and FFR_{OCT} (r=0.778, p<0.0001). Bland-Altman plots of FFR_{CT} in relation to FFR_{OCT} showed a mean bias of -0.047±0.185 with 95% limits of agreement of -0.231 to 0.138.

When all lesions were divided by AS, good correlations were observed between MLAs from cCTA and OCT in lesions with low-intermediate AS and those with high AS (r=0.873 and 0.787; both p<0.0001). The average absolute error in cCTA and OCT-based MLA measurements were comparable in both groups (p = 0.469). There was a significant correlation between FFR_{CT} and FFR_{OCT}, regardless of AS (r=0.873 and 0.787; both p<0.0001).

When all lesions were divided according to OCT MLD measurements using the size of the OCT catheter and guide wire as a cut-off value (1.0 mm), excellent correlations were observed for MLA comparison (r=0.839, p<0.0001) and for FFR_{CT} and FFR_{OCT} comparison (r=0.918, p<0.0001) in lesions with an MLD above the catheter size (Figure 2). The MLA and FFR_{CT} correlations were observed weak and moderate (r=0.282, p=0.172; r=0.543, p=0.011) in those with an MLD below the OCT catheter size. However, even in this sub-group, the concordance rate of ischemia detection with FFR_{CT} and FFR_{OCT} was 90.5%.

CONCLUSIONS
The spatial resolution of cCTA or calcification does not practically limit the accuracy of lumen boundary identification by cCTA or FFR_{CT} calculations for MLD ≥1.0 mm. The accuracy of cCTA MLA could not be assessed for lesions with MLD<1.0 mm due to the size of the OCT catheter, but had only a modest effect on the concordance rate of ischemia detection between FFR_{CT} and FFR_{OCT}.

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Patients with atrial fibrillation who present with STEMI have different baseline characteristics, clinical outcomes and logistic parameters

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

To examine the baseline characteristics, total ischaemic time and clinical outcomes of STEMI patients presenting to hospital in atrial fibrillation (AF), compared with patients who present in sinus rhythm (SR).

METHODS AND RESULTS

After exclusion of 40 patients with resuscitated out of hospital cardiac arrest, the final study population comprised 372 consecutive patients presenting with STEMI who were revascularized with primary PCI. Clinical characteristics, outcome data and time specific logistic parameters were collected prospectively. Data was categorized according to the presenting rhythm. Patients with AF were compared with those presenting in SR using standard descriptive statistics and univariate analyses.Patients with AF at presentation comprised 7.8% of the cohort. Patients in the AF group were older (71±13 vs 62±12 years; p<0.001), more likely to be female (41% vs 18%; p<0.01) and more likely to have a TIMI risk score >5 (52% vs 18%; p<0.001). Thirty-day mortality (3.8% vs 7.1%; p=0.53) and one-year mortality were not different (7.8% vs 7.1%; p=0.92) but patients with AF required longer hospitalization (7±9vs 4±5 days; p<0.001). Among patients presenting in AF median door-balloon times ($73_{(53-91)}$ vs $64_{(42-89)}$ mins; p=0.21), door-cath lab times ($39_{(22-55)}$ vs $29_{(13-51)}$ mins; p=0.20), and total ischaemic times ($208_{(154-366)}$ vs $182_{(137-309)}$ mins; p=0.26) were modestly prolonged.

CONCLUSIONS

In our series, patients with STEMI presenting in AF had a different clinical profile, required prolonged hospitalization and exhibited a trend toward treatment delay, when compared with those presenting in SR. Continuing investigation will better characterize cath-lab. delays and will clarify the relationship between AF and increased length of stay.

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Baseline predictors of renal failure in TAVI: analysis from the Swiss TAVI registry

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

AIMS

Acute Kidney Injury (AKI) post TAVI is associated with worse short and long term outcomes. We sought to identify significant baseline predictors of AKI and establish a high risk group within patients enrolled in the multicenter SWISS-TAVI cohort.

METHODS AND RESULTS

After excluding patients on hemodialysis, a total of 526 patients were included in our analysis, of which 335 patients underwent TAVI at the university hospital of Zurich and 191 at Cardio Centro Ticino. Within the first week post valve implantation, 9.5% (n=50) of patients had developed AKI as defined by the KDIGO criteria. There was a significantly higher prevalence of Diabetes Mellitus (44.9% vs 27.9%, p=0.020) and Chronic Kidney Disease CKD≥4 (26% vs 13.9%, p=0.035) in patients who developed AKI as compared to those who did not, respectively. However there was no difference in age, gender, BMI, history of dyslipidemia and hypertension between the groups. In a multivariable binary regression analysis, diabetics were at a 1.9 fold increased risk of developing AKI [OR 1.902, 95% CI [1.018 - 3.553], p=0.044], as well as those with high creatinine levels, by a factor of 1.6 with every rise of 1 mg/dl at baseline [OR 1.605, 95% CI [1.111 - 2.319], p=0.012]. To further substantiate our findings we re-evaluated for predictors within the diabetic (n=155, 29.5%) and non-diabetic populations (n=370, 70.5%) where AKI developed in 14.2 %(n=22) and 7.3 % (n=27) respectively. Interestingly enough in non-diabetics, none of baseline Glomerular filtration rate, CKD Grade, STS, Euroscore, ACEF score or even procedural contrast usage were predictors of AKI .On the other hand within the diabetic population an elevation by 1mg/dl in baseline creatinine was an independent predictor of developing kidney injury [OR 2.061, 95% CI [1.154 - 3.683], p=0.015], where more than one third (41%) of the patients who developed AKI in this population had a CKD stage ≥4.

Conclusion: Identifying patients at risk of developing AKI post TAVI is the first of many steps to help implement preventative measures. Diabetics with KDIGO CKD stage≥4 constitute a high risk group within the TAVI patients, where the renal guard system could play a major protective role especially when undergoing concomitant procedures. AKI in Non diabetics on the other hand seems to be more procedure related and less predictable by baseline characteristics.

CONCLUSIONS

Identifying patients at risk of developing AKI post TAVI is the first of many steps to help implement preventative measures. Diabetics with KDIGO CKD stage≥4 constitute a high risk group within the TAVI patients, where the renal guard system could play a major protective role especially when undergoing concomitant procedures. AKI in Non diabetics on the other hand seems to be more procedure related and less predictable by baseline characteristics. Normal 0 false false false EN-US X-NONE X-NONE

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A prospective project for improving renal outcomes among patients receiving radio-contrast media (CM) during cardiac catheterisation procedures: initial results

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

AIMS

A retrospective audit found greater than expected incidence of Acute Kidney Injury (AKI) following CM administration. This prospective investigation aims to better understand our clinical practice to reduce the frequency of AKI in our population.

METHODS AND RESULTS

All patients receiving CM are studied according to a protocol documenting clinical characteristics, previous CM history, fasting and hydration status and procedural CM dose. Plasma creatinine levels and urinary micro-albumin status are tested prior to index procedures afterwards, during pre-specified time periods. For this analysis, renal function was considered impaired when eGFR was < 60 mL/min.283 consecutive patients were studied; the median age was 66 ± 11 years, 74% were males. Diabetes was present in 28% and 59% were treated hypertensives; 19% had received CM in the 30 days prior to catheterization. Patients fasted for a median of 682 ± 264 minutes and received 105 (76 – 155)mL of CM during procedures, 53% of which utilised radial access. Pre-existing kidney injury was present in 25% of patients.The frequency of new AKI in this cohort was 6.7%. When data was dichotomized according to eGFR those with AKI were younger (69 ± 11 vs 74 ± 9 years; P<0.04), and tended to have received iohexol rather than iodixanol (63.2% vs 6.4%; P<0.001). The frequency of AKI was slightly greater among patients who had not received IV hydration (53% vs 47%; P=0.67) with modest differences in the duration of fasting (495 ± 307 mins vs 650 ± 274 mins; P=0.06).

CONCLUSIONS

This ongoing prospective study is defining a contemporary cath-lab. population receiving CM and is documenting the frequencies of pre-existing and new kidney injury. Continuing investigation will seek potential interactions between duration of fasting, duration and volume of IV hydration, and baseline clinical characteristics on renal outcomes with the aim of understanding and managing AKI risk more effectively

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Impact of vascular access on outcome after PCI in patients at high bleeding risk - A pre-specified subanalysis of the LEADERS FREE trial

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

AIMS

To evaluate the impact of a radial vs. a femoral vascular access on 2 years outcome from the LEADERS FREE trial in patients at high bleeding risk (HBR) receiving only one-month dual antiplatelet treatment (DAPT).

METHODS AND RESULTS

Choice of vascular access was left to the discretion of the operator. Among 2432 patients randomized in the trial with recorded vascular access, 1454 (59.8%) were treated via the radial artery (738 with DCS and 716 with BMS) and 978 (40.2%) via the femoral (483 with DCS and 495 with BMS). In the femoral group, there was a higher prevalence of female gender, diabetes, hypertension, renal insufficiency, heart failure, anemia or recent transfusion, prior MI and prior coronary revascularisation. In the radial group, peripheral vascular disease and planned major surgery after PCI were more frequent. Mean age was high (75.7±9.3) and similar in both groups and there were no differences in mean height or body mass index.
When comparing BA9-DCS vs. BMS at 2 years, the unadjusted clinically-driven target lesion revascularization rates in the femoral group were 8.5% for DCS vs. 12.3% for BMS (p=0.04) and 5.8% for DCS vs. 11.8% for BMS in the radial group (p=<0.0001). For the composite primary safety end-point, the rates in the femoral group were 14.1% for DCS vs. 15.3% for BMS (hazard ratio 0.89 [0.64-1.25; p=0.52) and in the radial group 11.5% for DCS vs. 15.2% for BMS (hazard ratio 0.72 [0.54-0.97; p=0.03].
When considering both stent groups together, ischemic events rates in the femoral vs. radial groups respectively were: composite primary safety endpoint [cardiac death, MI or ST] (14.8% vs. 13.4%, ns) all cause death (14.3% vs 12.8%, ns), cardiac death (7.2% vs. 6.4%, ns), myocardial infarction (9.5% vs. 8.5%, ns), definite or probable stent thrombosis (2.2% vs. 2.2%, ns), and target lesion revascularization (10.6% vs. 8.8%, ns). Overall bleeding rates were higher in the femoral vs. radial groups respectively: all reported bleeding (BARC 1-5) 24.9% vs. 20,3% (Hazard ratio 1.33 [1.12-1.58; p=0.001]), and major bleeding (BARC 3-5) 11.7% vs. 7.4% (Hazard ratio 1.68 [1.28-2.20; p=0.0001]). While vascular access bleeding was more frequent in the femoral group (1.8% vs. 0.5% in the radial group, p<0.005), non-access bleeding accounted for the majority of major bleeding events in both groups (10% for the femoral group vs. 6.9% for the radial group, p=0.003).

CONCLUSIONS

Despite important differences in baseline characteristics according to vascular access site, the two-year benefits of BA9 DCS over BMS remain and were broadly similar whatever radial or femoral access is chosen. The femoral route appears to have been often selected for higher risk patients, and its use was associated with markedly higher bleeding complications, irrespective of the type of stent that was used. Remarkably most of the major bleeding did not occur at the vascular access site

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Simultaneous TAVI and LAA occlusion vs. both interventions as stand-alone procedures

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

AIMS

Patients in atrial fibrillation undergoing transcatheter aortic valve implantation (TAVI) have a worse prognosis than those in sinus rhythm. We investigated the feasibility and outcome of simultanous TAVI and left atrial appendage occlusion (LAAO).

METHODS AND RESULTS

Consecutive patients, who underwent either TAVI with Lotus, LAAO with Watchman or both procedures simultaneously were investigated. We compared the procedural characteristics, in-hospital- and 30-day-outcomes defined by VARC-2 criteria in these three groups.

A total of 52 consecutive patients were included in the study. An isolated TAVI with Lotus was performed in 19 patients, an isolated LAAO with Watchman in 23 patients and a combined procedure in 10 patients. Patients in the isolated LAAO cohort were significantly younger (TAVI: 85.1 +/- 4.8 years; LAAO: 75.7 +/- 6.0 years; TAVI + LAAO: 84.2 +/- 5.7 years; p<0.001). There was no significant difference in the amount of contrast medium used between the three groups (TAVI: 89 +/- 29 ml; LAAO: 98 +/- 54 ml; TAVI + LAAO: 86 +/-29 ml; p=0.923). The total procedural time was significantly higher in the combined group than the isolated TAVI or LAAO group (TAVI: 57.1 +/- 18.0 minutes; LAAO: 42.7 +/- 16.0 minutes; TAVI + LAAO: 82.0 +/- 18.6 minutes; p=0.001). Procedural and device success was achieved in all patients. The length of hospital stay was significantly lower in the isolated LAAO group than the isolated TAVI or combined procedure group (TAVI: 9.7 +/- 4.3 days; LAAO: 2.0 +/- 2.1 days; TAVI + LAAO: 10 +/- 4 days; p<0.001). While there was no 30-day mortality in the isolated TAVI or isolated LAAO group, one sudden cardiac death occurred in the combined group at home on day 28. There was one cerebrovascular event in the isolated TAVI group but none in the LAAO or the combined group. Major bleeding occurred in one patient in the isolated TAVI group, but none in the isolated LAAO or the combined group.

CONCLUSIONS

Combining TAVI and LAAO with Lotus and Watchman is feasible and was comparable to both interventions as stand-alone procedures, although procedural time was higher when both interventions were performed simultaneously. Long-term follow-up will show, whether combining TAVI and LAAO improves prognosis in high-risk patients with atrial fibrillation and symptomatic severe aortic stenosis.

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Patients considered to GP IIb/IIIa antagonists and their follow-up - A longitudinal national multicentre perspective

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

AIMS

Current myocardial revascularization guidelines recommend that GP IIb/IIIa antagonists (GPa) should be considered only for ‘bail-out’. We aim to know which patients we currently treat with GPa and their prognosis.

METHODS AND RESULTS

Through the National Registry Investigators of Intervention Cardiology we performed a retrospective, multicenter, observational study with 49680 consecutive patients undergoing PCI (2012-2015). Both stable angina (43.3%) and acute coronary syndrome (STEMI: 30.7%, NSTEMI: 18.9%, Unstable Angina: 7.1%) patients were considered. A total of 3638 (7.3%) patients received a GPa, mainly with STEMI diagnostic (74.4%). Over the years we have seen a progressively reduction in the prescription of GPa (2012: 9.8%; 2013: 8.2%; 2014: 6.3%; 2015: 5.3%). Patients who receive GPa are more frequently women (26.0% vs. 20.1%, p<0.001) and younger (61±12 vs. 65±12, p<0.001). During the procedure, GPa are more frequently initiated in type C lesions (50.2% vs. 35.0%, p<0.001) and bifurcations (10.1% vs. 8.6%, p<0.001). Stent implantation rate is lower (79.5% vs. 84.8%, p<0.001) and mechanical thrombectomy rate higher (53.4% vs. 7.5%, p<0.001). GPa patients have a rate of peri-procedural complications more significant than patients without GPa (7.2% vs. 1.4%, p<0.001), manly no-reflow (2.4% vs. 0.7%, p<0.001). The endpoints considered were in-hospital mortality (GPa: 1.6% vs no GPa: 0.5%, p<0.001) and all-cause mortality at 1 year follow-up (GPa: 1.8% vs. no GPa: 0.7%, p<0.001). Through Cox regression analysis, GPa treatment was an independent predictor of all-cause mortality at 1 year follow-up (OR: 1.62, 95%CI: 1.16-2.24, p=0.004).

CONCLUSIONS

GPa are prescribed in a decreasing number of situations over the years. By this analysis, they are reserved to high risk patients, apparently with a high thrombotic burden (mechanical thrombectomy often used) and in more complex lesions (type C lesions and bifurcations). Patients admitted for ACS who are exposed to PGa present a clearly superior risk profile. The 1-year prognosis is independently marked by higher mortality rates.

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Single-centre early experience using the MitraClip system for transcatheter treatment of tricuspid regurgitation in 34 consecutive patients

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

AIMS

To report the initial experience using the MitraClip system for edge-to-edge repair of the tricuspid valve (TV) in patients wit severe tricuspid regurgitation (TR) and high operative risk.

METHODS AND RESULTS

Patients with high surgical risk, severe TR, and right heart failure underwent isolated or combined (with mitral valve treatment) MitraClip implantation into the TV. Procedural details, success rate, impact on TR severity, and predictors for success are reported. Procedural success was defined as reduction in TR by at least one grade (assessed by echocardiography within 5 days post procedure).

MitraClip™-Implantation in TV position was attempted in 33 patients, in 9 as an isolated TV procedure and in 24 as a combined procedure with MitraClip™-Implantation in mitral valve and TV position.

Age, log EuroScore, NYHA class III/IV and tricuspid annular plane systolic excursion (TAPSE) in these 33 patients were median 75 years (IQR 73-82), 27 ± 19%, 97% and 14 ± 4 mm, respectively. In 3 patients, a right ventricular leads across the TV was present.

In 5 out 33, TV treatment was abounded and no Clip implanted: reasons were insufficient echocardiographic view (n=1), excessive rete chiari and Eustachian valve limiting steerability of the system (n=1), no procedural effect/TR reduction on echocardiography (n=2), inability of appropriate clip placement.

Mean fluoroscopy time was 28 ± 10 minutes. Success rate in patients with clip placement was 93%. In total, 49 clips were implanted into the TV, with a mean number of clips of 1.5 ± 0.8 per patients, 90% of clips between the septal and anterior and 8% between the septal and posterior TV leaflets. Clip implantation into the TV led to a significant reduction in vena contracta (from 13 ± 4 to 8 ± 3 mm; $p<0.001$) and effective regurgitant orifice area (from 60 ± 31 to 31 ± 25 mm^2; $p<0.001$).

In total, there were 4 complications: partial leaflet detachment in two patients, treated by additional clip implantation with adequate TR reduction; Minor anterior leaflet perforation during grasping, but successful reduction in TR by > 50%.

Patients with a predominant TR jet between the anterior and septal leaflet exhibited better results than patients with a predominant TR jet between septal and posterior leaflets ($p=0.035$).

CONCLUSIONS

TV edge-to-edge repair using the MitraClip system is feasible with promising early results of effectiveness.

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CR12 registry: isolated side branch balloon post-dilatation after main vessel stenting in provisional stent technique

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

AIMS

It is not clear whether there is some benefit when post-dilating the side branch (SB) in the provisional stent technique. Objective: To compare PCI of bifurcation lesions with or without SB post-dilatation after main vessel (MV) stenting.

METHODS AND RESULTS

From March 2014 to April 2015 1960 PCI performed in two centres were prospectively registered, of which 296 were PCI of bifurcations with a SB > 2 mm of diameter performed in 268 patients (80.3% male; 66 ± 12 years) with provisional stent technique. In the centre A, systematic SB post-dilation was performed with a small semicompliant balloon independently to the SB stenosis or its TIMI flow after MV stenting. In the centre B, post-dilatation of the SB was only performed in cases with critical stenosis or impaired flow on it. The characteristics of the procedures and major cardiovascular adverse Events (MACE) were analysed after a mean follow up of 24.8 months.

Clinical presentation was stable coronary artery disease in 44.9% of cases and ACS in 55.1%. 33.2% of patients were diabetic. The location of the bifurcation was: left main: 10.2%, left anterior descending (LAD)-diagonal: 53.2%, Circumflex-obtuse marginal: 26.8%, right coronary artery-acute marginal: 5.1% and posterior descending-posterolateral: 10.8%. They were true bifurcations in 39.3%. 142 PCI were carried out in the centre A and 154 in centre B.

In centre A patients presented more frequently as ACS (62% vs 49%; p=0.04), MV lesions were longer (20.7 ± 9.8 mm vs 19.3 ± 7.9 mm; p=0.006), the bifurcation angle smaller (38.4 ± 26.2º vs 51.2 vs 19.2º; p<0.0001), and the rate of postdilatation of the MV was lower (34.5 % vs 53.9%; p=0.001). There were no other significant differences in baseline or procedural characteristics nor in the initial angiographic success (98.6 vs 96.7%; p = 0.47). There was no difference between both centres regarding the percentage of cases in which the SB had a severe stenosis or TIMI flow<3 after MV stenting (A: 44.6% vs B: 49.3%; p = 0.48). The SB was dilated after MV stenting in 87.2% patients of the centre A (55% without severe stenosis or flow restriction in it) and in 1.9% cases of the centre B (p<0.0001).

At the end of follow up, MACE rate was lower in centre A (A: 4.4 vs B: 12.4%; p =0.023). There were no significant differences between both centres regarding cardiac death (A: 2.2% vs B: 4.5%; p=0.34), myocardial infarction (MI) (A: 2.9% vs B: 4.5%; p=0.5), stent thrombosis (ST) (A: 0.7% vs B: 1.3%; p=1) or target lesion revascularization (TLR) (A: 2.2% vs B: 3.2%; p=0.7). There were no significant differences between both centres regarding fluoroscopy time (FT) (A: 17.8 ± 9.7 vs B: 16.1 ± 11.1 minutes; p=0.17), and indeed, mean duration of procedures was higher in centre B (A: 41.7 ± 18.5 vs B: 72.6 ± 29.1 minutes; p<0.0001). In the multivariate analysis, the strategy of systematic SB post-dilation was the only independent factor associated with MACE rate [HR 0.02 CI95% (0.001-0.41); p=0.01]

CONCLUSIONS

Systematic post-dilatation of the SB after MV stenting in the provisional stent technique imply a reduction in MACE rate after a follow-up of 24.8 months. This technique is not associated with higher FT or duration of procedures.

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Mechanisms of stent fracture in patients with stent thrombosis. From the Nordic Intravascular Ultrasound Study (NIVUS)

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

AIMS

To use intravascular ultrasound to assess mechanisms of stent fracture in patients presenting with stent thrombosis. Potential mechanisms leading to stent fracture include repetitive flexing (like a hinge) or repetitive compression.

METHODS AND RESULTS

The Nordic Intravascular Ultrasound Study - (NIVUS) study was conducted between October 2007 and January 2010 in Nordic and Baltic countries as a prospective multicentre registry in which IVUS was performed in patients with stent thrombosis. Total stent fracture was defined as 360Â° disappearance of the stent struts withinÂ the stent in a minimum of two continuous frames and partial stent fracture was defined asÂ > 180Â° disappearance of stent strutsÂ within the stent. To separate repetitive flexing (ie., hinge motions) from compression, we measured stent area proximal and distal to the stent fracture site mm by mm over a 5 mm distal (CSAd-1, CSAd-2, CSAd-3, CSAd-4, CSAd-5) and proximal (CSAd+1, CSAd+2, CSAd+3, CSAd+4, CSAd+5). We pre-specified compression to be the mechanism of fracture if the stent area on the two sides of the fracture - the first image slice with complete stent circumference both proximal and distal to the fracture - was smaller than over the length of the stent 5 mm stent segment proximal and distal to the fracture. If there was no compression and just a repetitive hinge motion, then the stent area should not change over this distance.

In the present analysis, 24 stent fractures (18 total and 6 partial stent fractures)Â were assessed in 124 patients presenting with definite stent thrombosis (19.3%). IVUS findings demonstrated slight stent tapering (gradual decrease in stent area) from proximal to distal over the >10mm long analysis segment - 5 mm long segment distal to the fracture site: CSAd-5: 7.8mm^2, CSAd-4: 8.2mm^2, CSAd-3: 8.1mm^2, CSAd-2: 8.1mm^2, CSAd-1: 8.2mm^2 (p=ns) or 5 mm long segment proximal to the fracture site: CSAd+1:8.7mm^2, CSAd+2: 8.6mm^2, CSAd+3: 8.8mm^2, CSAd+4: 8.7mm^2, CSAd+5: 8.6mm^2) (p=ns). Importantly, comparing the stent area of the first complete stent circumference adjacent to the fracture site vs the mean stent area for the next four frames (1 mm intervals), there was no difference either proximal to the fracture site (8.6mm^2 vs. 8.5mm^2, p=ns) or distal to the fracture site (7.8mm^2 vs. 7.8mm^2, p=ns) - thus excluding the presence of focal stent compression at the fracture site. This pattern did not differ among patients with total or partial stent fracture.

CONCLUSIONS

Stent fracture was a frequent finding in patients with stent thrombosis. However, the mechanism was unlikely to be compression leading to the likely conclusion that a repetitive hinge motion was responsible for stent fracture.

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Transcatheter tricuspid valve repair with a new transcatheter coaptation device for the treatment of severe tricuspid regurgitation - One-year clinical and echocardiographic results

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

AIMS

To report the first-in-man 1 year clinical and echocardiographic outcomes of a novel trans-catheter device, the FORMA device (Edwards Lifesciences, Irvine, CA), for treating high risk patients with severe tricuspid regurgitation

METHODS AND RESULTS

Patients were treated at two centers in Canada and a center in Switzerland under the conditions of compassionate-care programs. These were the first-in-man procedures performed worldwide. Follow-up was done at 30 days and 1 year and included clinical and echocardiography evaluation. One center performed invasive hemodynamic evaluation at 30 days.

18 patients were treated and completed 30 days follow up, 15 patients completed 1 year follow up. Device implantation was successful in 16 (89%) patients, one device dislocated on day 1 and another patient required conversion to open-heart surgery for right ventricle perforation. There were no deaths by 1 year and rates of re-hospitalization for heart failure were reduced significantly (one event).

In 14 patients with a successful device implantation and 1 year follow up, 79% were in New York Heart Association class I/II ($p<0.001$ compared with baseline), the average 6 minute walk test increased by 72 meters ($p=0.04$) and the KCCQ heart failure score improved by 17 points ($p=0.08$) compared with baseline.

Echocardiography showed a reduction of tricuspid regurgitation from severe in all patients at baseline to moderate or less in 11/16 patients (69%) by 30 days ($p=0.001$) and 4/13 patients (31%) by 1 year ($p=0.02$). The diameters of the tricuspid annulus and the right ventricle were both reduced by 1 year (46 ± 6mm vs. 43 ± 4mm, $p=0.12$; 56 ± 7 vs. 50 ± 5mm, $p=0.01$, respectively).

Hemodynamic evaluation at 30 days of right atrial pressures in 6 patients showed that the mean atrial pressure decreased from 15.2 ± 4.6 mmHg to 11 ± 7.0 mmHg ($p=0.08$) and the atrial systolic V wave from 25.1 ± 7.7mmHg to 16.8 ± 10.3mmHg ($p=0.049$). Cardiac output increased by 1.3 ± 1.9 L/min but this change was not statistically significant.

There were no device infections, pulmonary embolisms or significant arrhythmias noted after discharge in all patients. No late dislocations of the devices were observed. There was one case of thrombus noted on a device at 4 months, in a patient with warfarin treatment for atrial fibrillation and non-therapeutic INR measurements. The thrombus resolved uneventfully with resumption of adequate anti-coagulatio

CONCLUSIONS

Our first-in-man experience with the FORMA device in high risk non-operable patients with severe tricuspid regurgitation shows feasibility with a good mid-term safety profile. 1 year follow up revealed significant clinical improvements and reductions in right ventricular dimensions despite variable success in consistently reducing tricuspid regurgitation.

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Predictors and super selective drug infusion treatment of slow-flow / no-reflow during high-speed rotational atherectomy

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

AIMS

Slow-flow/no-reflow is a common complication during high speed rotational atherectomy (HRA). We aimed to identify the predictors of slow-flow/no-reflow and evaluate the effectiveness of superselective drug infusion (SDI) for slow-flow/no-reflow.

METHODS AND RESULTS

We analyzed 1219 lesions (951 patients) undergoing HRA between January 2003 and December 2016, excluding in-stent restenosis lesions. Slow-flow/no-reflow occurred in 82 (6.7%, 78 patients) of the 1219 lesions. Multivariate analysis showed that max deceleration ≥10000 rpm (odds ratio [OR], 2.69; 95% confidence interval [CI], 1.26-5.73; P=0.01), burr-to-artery ratio ≥0.7 (OR, 1.88; 95% CI, 1.10-3.23; P=0.02), and total ablation time ≥60 seconds (OR, 1.63; 95% CI, 1.02-2.61; P=0.04) were significantly associated with slow-flow/no-reflow. SDI is a treatment method using an infusion catheter to infuse drugs directly into the target coronary artery, preventing the drug inflow into the normal coronary arteries and the subsequent coronary steal phenomenon, which may be useful in treating slow-flow/no-reflow. SDI (one-time dose: sodium nitroprusside, 50 μg and dipyridamole, 200μg) was performed on all the 82 slow-flow/no-reflow lesions and was repeated until coronary flow improved. Of the 82 slow-flow/no-reflow lesions, 77 lesions (93.9%) achieved TIMI 3 flow and 5 lesions (6.1%) did not. We examined peak creatine kinase (CK) and CK-MB levels of 897 of the 951 patients, excluding 54 patients diagnosed with acute coronary syndrome. The median CK and CK-MB levels were significantly higher in 73 patients with slow-flow/no-reflow lesions than in 824 patients without slow-flow/no-reflow lesions (CK: 321 U/l vs. 143 U/l, P<0.001; CK-MB: 19.3 ng/ml vs. 7.9 ng/ml, P<0.001). Of the 73 patients with slow-flow/no-reflow lesions, Q wave myocardial infarction occurred in 5 patients (6.8%) and 4 of whom had slow-flow/no-reflow lesions failing to achieve TIMI 3 after SDI. Neither prolonged hypotension nor hemodynamic deterioration occurred after SDI. No other major adverse clinical events were recognized.

CONCLUSIONS

The risk of slow-flow/no-reflow could be reduced by prudent ablation methods including smaller burr sizing, less deceleration and shorter ablation time during HRA. SDI with sodium nitroprusside and dipyridamole is effective and safe in the treatment of slow-flow/no-reflow during HRA.

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Predictors of late (> 48 hours) pacemaker implantation following TAVI

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

AIMS

The aim of our study was to analyse and determine the predictors of late pacemaker (PMK) implantation following TAVI.

METHODS AND RESULTS

Methods: Consecutive patients were identified by retrospective review of a dedicated TAVI database of a single high volume center in Milan, Italy between October 2007 and July 2015. An analysis of the baseline ECG features was performed. Clinical and procedural data were collected to determine predictors of PMK implantation that occurred at least 48 hours after TAVI.
Results: The overall population included 737 patients. We excluded 76 patients who already had a PMK and 51 patients that received a PMK within 48 hours after TAVI. The final analysis included 610 patients. Among this population, the Lotus Valve was implanted in 30 patients (4,9%), balloon expandable valves (Sapien, Sapien XT and Sapien 3) in 311 patients (50,9%), self-expandable valves in 202 patients (33,1%), DirectFlow in 59 patients (9,6%), and other valves in 9 patients (1,4%). In 65 patients, PMK implantation occurred at least 48 hours after TAVI and 545 had no PMK implantation during follow-up. Late PMK implantation was performed after a mean of 6±3.5 days. Reasons for PMK implantation were new onset symptomatic trifascicular block (n=11, 16.9%), symptomatic bradycardia (n=10; 15.3%), Mobitz type II block (n=4; 6.1%), pathological pauses (n=5, 7.6%), asystole (n=3; 4.6%) and complete heart block (n=32; 49.2%). No differences in the demographic characteristics of the 2 populations were found. Patients that received late PMK implantation had a wider QRS width at baseline (113±27msec vs. 105.6±23 msec; p=0.049). Baseline first degree atrio-ventricular block, right bundle branch block and left bundle branch block were not higher in the group implanted with a late PMK after TAVI. Self-expandable valves (Corevalve and EvolutR) were more frequently implanted in the group of late PMK implantation (96.9% vs. 45.4%; p=0.004). New onset left bundle branch block (both transient and persistent) was more frequently present in those patients which experienced late PMK implantation (91.4% vs 33.9%; p=0.0001).
At multivariable analysis, baseline QRS >140 msec [Odds ratio: 3.77 (95% CI: 1.81-12.1); p=0.025], new onset of left bundle branch block [Odds Ratio 3.21 (95% CI: 1.67-6.19); p=0.0001] and self-expandable valves [Odds Ratio 1.86 (95% CI: 1.01-3.46); p=0.049] were independent predictors of late PMK implantation.

CONCLUSIONS

This preliminary analysis indicates that in patients undergoing TAVI, baseline QRS duration >140 msec, new onset left bundle branch block and self-expandable valve implantation are independent predictors of late PMK insertion. In those patients, an early discharge strategy and early removal of temporary PMK should be carefully evaluated.

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Cerebral embolic protection devices during TAVI: a meta-analysis

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

AIMS

The aim of this meta-analysis was to study whether the use of embolic protection devices (EPD) reduces silent ischemic and clinically evident cerebrovascular events associated with transcatheter aortic valve implantation (TAVI).

METHODS AND RESULTS

We conducted a comprehensive search of MEDLINE and EMBASE to identify studies that evaluated patients undergoing TAVI with or withoutEPD. Random-effects meta-analyses were performed to estimate the effect of EPD compared with no-EPD during TAVI using aggregate data.

Sixteen studies involving 1170 patients (865/305 with/without EPD) fulfilled the inclusion criteria. The EPD-delivery success rate was reported in all studiesand was achieved in 94.5% of patients. Meta-analyses evaluating EPD versus without EPD strategies could not confirm or exclude any differences in terms of clinically evident stroke (P=0.26) or 30-day mortality (RR: P=0.30). There were nosignificant differences in number of patients with new-silent ischemic lesions (P=0.60) or number of lesions per patient (P=0.50). The use of EPD was associated with a significantly smaller ischemic volume per lesion (SMD: -0.52, 95%CI: -0.85, -0.20; P=0.002) and smaller total volume of lesions (SMD: -0.23, 95%CI: -0.42, -0.03; P=0.02). Subgroup analysis by type of valve showed a trend towards significant reduction in new-lesions per patient using EPD (SMD: -0.41, 95%CI: -0.82, 0.00; P=0.05), with significant interaction (I^2=85.1%, P=0.01) driven by self-expanding devices.

CONCLUSIONS

The use of EPD during TAVI may be associated with smaller volume of silent ischemic lesions and smaller total volume of silent ischemic lesions. However, EPD may not reduce the number of new-single, multiple or total number of lesions. Moreover, there was only very low quality of evidence showing no significant differences between patients undergoing TAVI with or without EPD with respect to clinically evident stroke and mortality.

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DCB for the treatment of coronary in-stent restenosis: a randomised, multicentre, controlled clinical study

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

AIMS

Drug-coated balloons (DCB) are an established and effective treatment modality for in-stent restenosis. This study compares a new coating formulation with a standard DCB.

METHODS AND RESULTS

AGENT ISR is a prospective, multicentre, 1:1 randomised, non-inferiority study that compares the Agent Paclitaxel-Coated Percutaneous Transluminal Coronary Angioplasty Balloon Catheter (Hemoteq AG, Würselen, Germany; Boston Scientific, Marlborough, MA) to the control SeQuent Please Paclitaxel-Releasing Coronary Balloon Catheter (B. Braun Melsungen AG, Berlin, Germany) for the treatment of coronary in-stent restenosis. The Agent DCB is coated with a formulation of paclitaxel and the highly efficient excipient acetyl tri-butyl citrate in a low drug dose density of 2 µg/mm^2 (compared to 3 µg/mm^2 in SeQuent Please a matrix of Iopromide). Effective drug dose is anticipated to be the same between these two DCBs.Patients: A total of 125 patients (Agent n=65; SeQuent n=60) with in-stent restenosis of a previously-treated lesion of <28 mm in length (in a native coronary artery 2.0 - 3.5 mm in diameter) were enrolled at 11 sites in Germany and France between August 2014 and May 2016. Recommended dual anti-platelet therapy consisted of aspirin in combination with a $P2Y_{12}$ inhibitor for 3 months (minimum 4 weeks). Clinical follow-up continues to 3 years post-procedure. The primary endpoint, 6-month in-stent late lumen loss, was assessed by a blinded, independent angiographic core lab. The rate of 6-month in-stent late loss in the Agent group will be considered non-inferior to SeQuent Please if the two-sided upper 95% confidence bound for the difference between groups is <0.20 mm.Preliminary baseline and procedural data are available on all 125 patients. Mean patient age was 68 years in both groups, women accounted for 22% of Agent patients and 15% of SeQuent Please patients (*P*=0.37); 38% of Agent and 37% of SeQuent Please patients had diabetes (*P*=0.89). Mean target lesion length was 11.5 ± 5.9 mm and 13.1 ± 7.7 mm (*P*=0.92) while pre-procedure minimum lumen diameter was 0.76 ± 0.51 mm and 0.65 ± 0.43 mm (*P*=0.82) in Agent and SeQuent Please, respectively. Technical success was high in both arms (Agent 98.5% vs SeQuent Please 96.7%, *P*=0.94), as was clinical procedural success (98.5% vs 95.0%, respectively; *P*=0.56).Six-month primary endpoint results and secondary clinical, angiographic, and quality of life outcomes in all patients will be presented.

CONCLUSIONS

This is the first head-to-head comparison of two DCBs with different drug formulations. The results will provide insights in optimizing this treatment modality.

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Outcomes after PCI with a bioabsorbable polymer-coated, everolimus-eluting coronary stent in patients with diabetes: three-year results from the EVOLVE II diabetes substudy

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

AIMS

Permanent polymers may induce inflammation and delay arterial healing which can increase late events. Bioabsorbable-polymer DES may reduce these events, but whether late clinical outcomes are improved in patients with diabetes is unknown.

METHODS AND RESULTS

The SYNERGY stent is a novel, thin-strut, platinum chromium stent eluting everolimus from an ultrathin 4μm bioabsorbable poly(DL-lactide-co-glycolide) polymer applied to the abluminal stent surface. The polymer resorbs shortly after everolimus elution is complete at 3 months. SYNERGY was evaluated in the pivotal EVOLVE II randomised controlled trial (RCT) and was non-inferior to the permanent polymer-coated PROMUS Element Plus stent for 1-year target lesion failure (TLF: composite occurrence of ischemia-driven target lesion revascularization [TLR], target-vessel myocardial infarction [TV-MI], or cardiac death). The EVOLVE II Diabetes substudy (N=466) prespecified pooling of patients with diabetes who were randomised to the SYNERGY arm of the EVOLVE II RCT (N=263) and non-randomized patients with diabetes enrolled in the single-arm Diabetes study (N=203) following EVOLVE II RCT completion.Enrolled patients could have up to 3 native coronary artery lesions in up to 2 major epicardial vessels with reference vessel diameter ≥2.25 mm to ≤4.00 mm, and lesion length ≤34 mm. Exclusion criteria included recent (<72 hours) STEMI, left main, vein graft or ostial stenosis, in-stent restenosis, chronic total occlusion, or thrombus. The prespecified Diabetes substudy primary endpoint was 12-month TLF tested against a performance goal (PG) based on TLF rates derived from cohorts of patients with diabetes treated with permanent polymer everolimus-eluting stents in prior studies (PLATINUM, SPIRIT IV, COMPARE, EVOLVE). Dual antiplatelet therapy (aspirin plus a $P2Y_{12}$ inhibitor) was required for ≥6 months, and aspirin was prescribed indefinitely. Patients will be followed for 5 years.At 1 year, the EVOLVE II Diabetes substudy demonstrated a TLF rate of 7.5% (34/451) among SYNERGY treated patients with diabetes (*P*<0.0001 vs 14.5% PG). The rates of TLF at 1 and 2 years were 7.5% and 11.2%; TV-MI were 4.8% and 6.4%; and TLR were 4.4% and 6.8% The rate of definite/probable ST at 1 and 2 years was 1.1%, no ST occurred after day 6 post procedure.

CONCLUSIONS

The EVOLVE II Diabetes substudy demonstrated acceptable safety and efficacy of the SYNERGY stent at 2 years in patients with medically-treated diabetes and successfully supported an expanded label indication. Outcomes to 3 years will be available for presentation for the first time at EuroPCR 2017.

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Transcatheter treatment of native aortic regurgitation using a fully repositionable TAVI system: insights from a pre-clinical model

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

AIMS

Transcatheter valve implantation for treatment of native aortic regurgitation is challenging owing to the absence of calcification to anchor the device, and the majority of currently successful results have been achieved via transapical access.

METHODS AND RESULTS

In order to evaluate the performance of the fully repositionable Lotus Valve System^{TM} (Boston Scientific Corporation, Marlborough, MA, USA) in a calcium-free environment, healthy sheep were used to determine: a) the stability of the transcatheter heart valve after release in the orthotopic position via peripheral arterial access; b) the appropriate degree of oversizing required to avoid embolisation and annular rupture and c) the occurrence of aortic regurgitation intra-procedurally and at follow up. Adolescent Dorset sheep were pre-screened with cardiac CT scans. Orthotopic TAVI was conducted via transfemoral or transcarotid access. Prosthetic valve stability and presence of regurgitation were monitored at implant and termination at 30, 90 or 140d using intracardiac echocardiography and aortography. Oversizing was based on the prosthetic valve-to-native annulus area ratio. Valve deployment was attempted on 51 animals, of which 41 survived to planned termination (n=14 at 30d, n=5 at 90d, n=22 at 140d). All deaths occurred intra-procedurally (n=7), or within 48h post-implant (n=3). Causes included VF (n=6), right coronary obstruction (n=1), pulmonary sepsis (n=1) and device embolisation (n=2). Low implant (n=1) and lack of valve oversizing (<8%, n=1) were deemed contributing factors in the 2 embolisation cases. Moderate paravalvular leak was observed in only 1 case intra-procedurally where valve alignment within the annulus was suboptimal due to model-related anatomical challenges (short ascending aorta). There was no case of annular rupture. Device release without embolisation, leak or rupture was therefore feasible in 94% of attempts (48/51), and planned survival was achieved in >80%. Oversizing in stable implants ranged between 15% and 45% (mean 27.5%). Complete AV block was observed in 5 cases (10%), all of which occurred with >35% oversizing. Repositionability was used to optimise implant position in >85% of cases. At termination, haemodynamic profile of all valves remained within VARC standards. Regurgitation was ≤ mild in 90% (37/41) and moderate in another 3 cases. In these cases, tilting of the prosthetic valve in the annulus was noted and could have been due to the growing anatomy of the adolescent animals.

CONCLUSIONS

To our knowledge, this is the largest dedicated pre-clinical evaluation of transvascular orthotopic TAVI in non-calcified anatomy as a model for aortic regurgitation. In our study, the Lotus Valve could be safely implanted with low complication rates with an area-derived oversizing that ranged between 15% and 35%. With its fully repositionable design and paravalvular leak prevention technology, this system represents a promising avenue to the transcatheter treatment of pure native aortic regurgitation.

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IVUS-guided pulmonary angioplasty in chronic thromboembolic pulmonary hypertension may increase safety of the procedure

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THEME: Interventions for Valvular Disease
TOPIC(S): Tricuspid / Pulmonary valve, Other valvular and structural interventions

AIMS

Pulmonary arterial angioplasty (PA) in chronic thromboembolic pulmonary hypertension is an option for patients rejected for surgical pulmonary endarterectomy. Preliminary results seem encouraging, although high pulmonary injure rates are reported.

METHODS AND RESULTS

Six patients (2 woman) with CTEPH, mean age 65±5,4 uderwent PA. Four patients were in functional class 3, mean TAPSE < 15mm for the hole group. Before the procedure, mean pulmonary pressure (mPAP) was 52 mmHg (±16), BNP 419 pg/ml (±206). All had normal left ventricular ejection fraction and were under OAC. Four were also treated with PD5 agonists and two with endothelin antagonists.In 4 patients we performed PA on 1 segment, 1 on 2 segments and 1 on 3 segments in sequential procedures. Four procedures were done under IVUS guidance in order to precisely estimate the vessel size. Four stents (2 bare metal and 2 drug-eluting) were delivered to correct severe initial recoil. Two patients required stent postdilatation in a second procedure. There were no procedural complications (no regional pulmonary edema, no pulmonary vessel rupture).On follow-up (16.5±6,41months), we observed improvement in functional class (2 patients in class 1, 3 in class 2 and remaining in class 3). We observed discrete improvement in mPAP 48 mmHg (±13) and BPN 374,75 pg/ml (±98). No hospital admission and no deads were seen on follow-u

CONCLUSIONS

Pulmonary angioplasty under IVUS guidance seems to improve the procedure safety in our series, probably avoiding vessel rupture due to a more precise vessel sizing. Stent implantation seems to be safe and had no restenosis.

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Restenosis and its predictors after implantation of everolimus-eluting BRS: results from the GABI-R registry

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

AIMS

Restenosis may limit the efficacy of percutaneous coronary intervention particularly in complex patient populations. Bioresorbable vascular scaffolds (BVS) bare the potential of further reducing its incidence.

METHODS AND RESULTS

Between November 2013 to January 2016, 3170 patients were prospectively enrolled at 93 centers in Germany and Austria and underwent systematic follow-up. At 6-month follow up only 20 patients experienced clinical restenosis (R), defined as target lesion revascularization not related to BVS thrombosis, cumulative incidence 0.6%. Among patients with and without clinical R, the most important differences in clinical profile were: mean age 65.7±9 vs. 60.9±11 (p=0.06); proportion of women 30% vs. 23% (p=0.47), diabetes mellitus 33% vs. 21% (p=0.20), family history of CAD 60% vs. 40% (p=0.08), history of CAD revascularization 10% vs. 30% (p=0.06) and presentation with acute coronary syndrome 40% vs. 52% (p=.53). Regarding procedural data, compared to patients without R, individuals with R Rmore frequently had multivessel CAD, 65% vs. 58% (p=0.66); longer lesions 19.9±8.4mm vs. 17.0±9.2mm (p<0.05), a higher incidence of ostial lesions 3.2% vs. 0.8% (p=0.14); a higher incidence of calcified lesions 61% vs.52% (p<0.05); longer implanted BVS length 30mm [28-46] vs. 23mm [18-30] (p<0.01) and a higher incidence of overlapping BVA 20% vs. 14% (p=0.40). Mean BVS diameter was similar in both groups, median 3.0mm [2.9-3.3] vs. 3.0mm [3.0-3.5] (p=0.75). Considering the small number of patients with R, a Cox regression model was constructed with factors previously identified as R predictors after PCI, but none were identified as independent predictors diabetes mellitus (hazard ratio 1.68, 95% CI 0.65-4.39), ostial lesions (HR 4.29, 95% CI 0.56-33.1), BVS size (hazard ratio 0.89, 95% CI 0.26-2.99), total implanted BVS length (HR 1.01, 95% CI 0.99-1.03).

CONCLUSIONS

In a large clinical cohort with systematic follow-up, clinical restenosis at 6 months after BVS implantation is a rare event and seems to be related with longer length of implanted BVS.

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Angiographic severity scores (BARI and APPROACH) predict revascularisation rates at mid-term follow-up (up to 60-months) after stenting coronary bifurcation lesions insights from intracoronary electrocardiogram and myonecrosis after bifurcation stenting (COSIBRIA&CO)

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

AIMS

To explore the value of BARI and APPROACH scores for myocardial area-at-risk estimation and changes on icECG from PCI wire in the main and side branches and its relation to mid-term post coronary bifurcation PCIs restenosis rates.

METHODS AND RESULTS

Methods: We followed prospectively 80 patients with stable/unstable anginawith complete assessment of myocardial area at risk assessed with BARI and APPROACH risk scores separately. Unipolar icECGs were recorded before, during and after stent placement and at the end of procedure in side branch (SB) and main branch (MB). The coronary wire was placed in all distal vessels with diameter >1.5mm, to “map” the distal zones of ischemia. Provisional T-stenting was default strategy.

Results:From the 80 patients included 71% were males, mean age 67±9, diabetics 35.2%; 42% had previous myocardial infarction and 18% had multivessel disease. The main treated vessel was LAD (78%). True bifurcation lesions (Medina xx1) were 55%. Kissing balloon inflation was performed in 23% of the cases. On univariate analysis significantly associated with target lesion revascularization rates were preinterventional CK-MB values, left-ventricular ejection fraction, percentage increase of troponin concertation, proximal and distal stent diameters at the end of PCI, bifurcation BARI and APPROACH risk scores, as well as occurrence of final main and side branches ST-segment elevation on icECG and main branch R-wave to S-wave ratio. On multivariate Cox proportional hazards model only BIF-BARI or alternatively BIF-APPROACH risk scores were independently associated with TLR rates at 60 months follow-up.

CONCLUSIONS

The myocardial area-at-risk assessed with BARI or APPROACH risk scores are independent predictors of mid-term revascularization rates.

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Thrombocytopenia after TAVR. A comparison between balloon-expandable and self-expanding prosthesis

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

AIMS

To describe the incidence and clinical outcomes related to Transcatheter aortic valve replacement (TAVR) associated thrombocytopenia of patients treated with balloon-expandable (BEV) and self-expanding (SEV) valves.

METHODS AND RESULTS

Consecutive patients who underwent to TAVR from 2012 to 2016 in two tertiary centres were included. Patients with baseline platelet counts <$100x10^9$ and those with procedural death were excluded. VARC-2 criteria were used to evaluate outcomes and complications. Laboratory analyses were performed before the procedure, daily during post-procedural ICU stay and at the physician discretion thereafter. Drop Platelet Count percentage [%DPC= 100 x (baseline platelet count – nadir platelet count) / baseline platelet count] was considered high (hDPC) if resulted >50%. Unfractioned heparin (50-70 units/kg) and adjusted to maintain ACT of >250s was used during the procedure. Standard dual antiplatelet treatment was followed for 3 months and monoantiagregation subsequently unless patient had an indication to oral anticoagulation with vitamin K antagonist.

A total of 188 patients were included in the study. Medium age was 77.7±6.5 and 57.98% males. The valves implanted were BEV in 88 (46%) and SEV in 100 (53.1%) of cases respectively. The transfemoral vascular access was used in 81%. Median days to nadir were 3.08±1.5. Twenty-three (12.2%) of them developed hDPC. Although the rate of hDPC was higher in patients that received a BEV when compared with patients that received a SEV, the difference was not statistically significant (BEV 65.2% vs. 34.7%; p=0,059). The transapical access was related to higher DPC than the transfemoral approach (83.6% vs. 60.8%; p=0.009). Patients that underwent TAVI through a transfemoral approach and received a BEV had the same rate of hDPC when compared with patients that were treated with a SEV (88% vs. 88% p=1.0). The lower rate of atrial fibrillation (4.35% vs. 32.2%, p=0.006) and the lower rate of procedure success (96.9 vs. 82.6%, p=0.003) were the factors significantly associated to hDPC. We did not find any significant differences in mortality at 30 days (hDPC 8.7% vs. non hDPC 2.4%; p=0.33). However, the presence of a high DPC was related to a higher rate of major vascular complications (17.4% vs. 6%, p=0,05), major and life threatening bleeding (17.4% vs. 10%, p=0,004), significant renal injury AKIN 2/3 (6.4% vs. 26.89%, p=0,001) and sepsis (39.1% vs. 4.2%, p<0.001) when compared with no hDPC, respectively.

CONCLUSIONS

In this analysis we did not find differences in the rate of hDPC between both BEV and SEV. The transapical access was related to higher DPC than the transfemoral approach. The hDPC was not associated to higher mortality but it was related to higher rate of major complications.

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Management of aspirin intolerance in patients undergoing PCI: the role of mono-antiplatelet therapy - A retrospective multicentre study

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

AIMS

Aim of our study is to retrospectively evaluate the safety and efficacy of mono-antiplatelet therapy, including new P2Y12 inhibitors, in patients with aspirin intolerance who underwent a PCI.

METHODS AND RESULTS

From January 2006 to June 2016 all patients with a diagnosis of: “aspirin intolerance”, “aspirin hypersensitivity” or “aspirin allergy” and treated by means of PCI in the tree institution involved in the study were included if discharged with a mono-antiplatelet therapy. A twelve month follow-up visit was performed. Data about coronary artery disease, aspirin intolerance and MACE were collected. Moreover, we compared the safety and efficacy on clopidogrel monotherapy with that one of new P2Y12 inhibitors.

We collected 70 patients, 25 (35%) women and 45 (65%) men, with a medium age of 71,8±10,6years. An acute coronary syndrome was the clinical presentation in 47 (67,1%) patients with an NSTEMI in 19 (27,1%) of them. 46 patients (65,7%) were treated with clopidogrel and 24 (34,3%) with a new P2Y12 (15 patients with ticagrelor and 9 with prasugrel). The most common manifestations of aspirin intolerance were skin reactions in 35% of thepatients and asthma in 17% of them. The most used stents were DES in 49 cases (70%). After a follow-up of12months, 18 (25,7%) patients suffered a new MACE, 5 (7,1%) died, 3 (4,3%) required a TVR and 10 (14,3%) patients a TLR. No significant differences were found between patients treated with clopidogrel monotherapy and new P2Y12 inhibitors monotherapy except for TLR(9 vs 0 p: 0,02).

CONCLUSIONS

The monotherapy with a mono anti-platelets therapy seems weighted by a high number of MACE. Current data do not support the use of anti-platelets monotherapy. When desensitization protocols are not applicable a monotherapy with a new P2Y12 seems to perform better than clopidogrel in long term management and target lesion revascularization prevention.

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Clinical and angiographic outcomes of true vs. false lumen stenting of coronary CTO: insights from IVUS

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

AIMS

We evaluated the in-hospital and the long-term clinical and angiographic outcomes of drug-eluting stents (DES) deployed in true versus false lumen of successfully recanalized CTO.

METHODS AND RESULTS

Two independent reviewers analyzed the intravascular ultrasound (IVUS) images of 173 successfully recanalized CTO lesions (157 patients), between August 2011 and October 2012. After successful guidewire crossing, lesions were classified according to IVUS evaluation into 2 groups; (1) true lumen stenting group and, (2) subintimal stenting group; and compared with regards to in-hospital and long-term clinical outcomes. In 154 lesions, DESs were deployed in the true lumen; and in 19 (11%) lesions, DES were deployed in the subintimal space (95% confidence interval: 6.3% to 15.6%). IVUS showed that the prevalence of dissection was two times and intramural hematoma was three times as higher in the subintimal stenting group ($p<0.001$ and $p<0.01$, respectively). Subintimal stenting was associated with a significant increase in minor perforations 6/19 (31.6 % vs. 8.4%, $p=0.002$). At one year follow-up, both groups had a similar cumulative rate of binary restenosis and target lesion revascularization ($p=0.73$ and $p=0.97$, respectively). Six patients (4.6%, 6/129 patients) in the true lumen group and none in the subintimal group died at one year.

CONCLUSIONS

Subintimal stent deployment in a recanalized CTO segments, using second generation DES and IVUS guidance, might have similar success rate and long-term angiographic and clinical outcomes as true lumen stenting.

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Latest generation balloon-expandable vs. self-expanding transcatheter heart valves - A multicentre propensity matched evaluation

HUSSER O.(1), KIM W-K.(2), PELLEGRINI C.(3), HOLZAMER A.(4), WALTHER T.(5), MAYR N.P.(1), JONER M.(1), KASEL A.M.(1), TRENKWALDER T.(1), MICHEL J.(1), RHEUDE T.(1), KASTRATI A.(1), SCHUNKERT H.(1), BURGDORF C.(6), HILKER M.(4), MöLLMANN H.(2), HENGSTENBERG C.(1)

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

AIMS

We compared latest-generation self-expanding Symetis ACURATE neo and the balloon-expandable Edwards SAPIEN 3 through a propensity matching, regarding device failure and the early safety composite endpoint at 30 days.

METHODS AND RESULTS

Between January 2014 and January 2016, 1124 consecutive patients underwent transfemoral TAVI, 311 of whom were treated with the ACURATE neo and 810 with the SAPIEN 3. A 2-to-1 nearest neighbour matching accounting for baseline clinical, electrocardiographic and anatomical differences was performed and identified two patients treated with SAPIEN 3 (n=622) for each patient treated with ACURATE neo. There were no significant differences regarding in-hospital complications, such as stroke (2% vs. 2%; p=0.640), major vascular complications (10% vs. 9%; p=0.376), or life-threatening bleeding (4% vs. 4%; p=0.718). Use of ACURATE neo was associated with a significantly lower incidence of new permanent pacemaker implantations (10% vs. 16%; p=0.024). The incidence of paravalvular leakage (PVL) II+ was higher with ACURATE neo (5% vs. 2%; p=0.008), however postprocedural elevated transvalvular gradients (>20 mmHg) were less frequent (3% vs. 7%; p=0.021) resulting in comparable device failure (11% vs. 10%; OR 1.149 95%CI [0.737-1.793]; p=0.539). All-cause mortality at 30 days was 2% for both prosthesis (p=0.749) and the composite early safety endpoint at 30 days was equivalent in patients treated with ACURATE neo and SAPIEN 3 (16% vs. 16%, HR 1.009 95%CI [0.716-1.423]; p=0.959).

CONCLUSIONS

In a multicentre clinical experience, the self-expanding transfemoral Symetis ACURATE neo proved feasible with equivalent results to the balloon-expandable Edwards SAPIEN 3 regarding overall valve performance and clinical early safety at 30 days. ACURATE neo was associated with a lower rate of new permanent pacemaker implantations and elevated gradients while the rate of PVL II+ was higher compared to SAPIEN 3.

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Incidence and predictors of permanent pacemaker implantation and new conduction abnormalities using a latest generation self-expanding transcatheter heart valve

PELLEGRINI C.(1), HUSSER O.(2), KIM W-K.(3), HOLZAMER A.(4), WALTHER T.(5), MAYR N.P.(2), TRENKWALDER T.(2), JONER M.(2), MICHEL J.(2), RHEUDE T.(2), KASTRATI A.(2), SCHUNKERT H.(2), HILKER M.(4), MöLLMANN H.(3), HENGSTENBERG C.(2)

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

AIMS

We analysed the incidence and predictors of permanent pacemaker implantations (PPI) and new-onset conduction abnormalities (CA) using the Symetis ACURATE neo (NEO) transcatheter heart valve in a multicentre population undergoing transfemoral TAVI.

METHODS AND RESULTS

Between January 2014 and January 2016 276 consecutive patients without prior pacemaker and 225 patients without baseline CA on admission ECG were included in the analysis. Prosthesis oversizing was calculated based on multislice-CT. Implantation depth in the left ventricular outflow tract was assessed in the final aortic angiogram showing the prosthesis in an orthogonal view by a core-lab. ECGs before and after TAVI were evaluated for new-onset CA. Independent predictors for both, PPI alone and PPI/new-onset CA were assessed using multivariable analysis.New PPI was required in 9.8% (27/276). Higher BMI (27±5kg/m2 vs. 30±6kg/m2; p=0.024), complete right bundle branch block (22% vs. 6%; p=0.004) and bradycardia at baseline (<60bpm, 30% vs. 13%; p=0.037) were more frequent in patients who required PPI. PPI/new- onset CA occurred in 27% (51/189) of patients, and were more frequent in patients with higher logistic EuroSCORE (19±12% vs. 16±9%; p=0.030). Mean prosthesis OS for area was 42±10%, and was not different in patients with PPI compared to those without PPI (42±8% vs. 42±10%; p=0.884) or with PPI/new CA compared to those without (41±8 vs. 42±10; p=0.428). PPI rate or PPI/new CA were not affected by implantation depth (7±2mm vs. 7±1mm; p=0.830, 7.4±1.8mm vs. 7.2±1.5mm; p=0.382, respectively). In the multivariable analysis BMI, baseline bradycardia and RBBB persisted as independent predictors of PPI, while neither OS nor implantation depth influenced PPI rates (OR 1.002 CI 95% [0.956-1.050]; p=0.950 and OR 1.021 CI 95% [0.757-1.377]; p=0.890, respectively). Logistic EuroSCORE and severe depressed ejection fraction (<35%) resulted as predictors of PPI/new- onset CA, while neither OS nor implantation depth influenced the rate of PPI/new-onset CA (OR 0.988 CI 95% [0.951-1.026]; p=0.522 and OR 1.113 CI 95% [0.951-1.380]; p=0.329, respectively).

CONCLUSIONS

In this multicenter study with the novel self-expandable NEO, we found a low rate of new PPI and new-onset CA. Degree of prosthesis oversizing or implantation depth, were not associated with an increase in both, PPI alone or PPI/new-onset CA. Using NEO, new PPI rate and new-onset CA seem not to be affected by operator-depending factors, such as sizing or implantation technique, but on patient's characteristics alone.

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Predictors of spasm during transradial PCI - Should we routinely administer prophylaxis for everyone?

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

AIMS

We aimed to identify predictors of radial spasm during transradial coronary angiography, and the effect of spasm prophylaxis on preventing this complication.

METHODS AND RESULTS

Single center prospective analysis of transradial coronary angiography. All patient demographic and clinical data was recorded. The occurence of radial spasm was recorded and graded in every procedure. Spasm prophylaxis was administered according to operator preference. To assess for diferences between groups a T test or chi-square test was used. An independent T test was undertaken to assess the effect of prophylaxis on spasm occurence. A multiple regression analysis was undertaken to identify predictors of radial spasm.

We included 479 patients (51% male, mean age 62 ± 11 years). Spasm occurred in 221 patients (46,1%) and spasm prophylaxis was administered in 144 patients (30,1%). Regarding age, sex and risk factos, there were no diferences between the prophylaxis group and the no prophylaxis group. Radial spasm was significantly lower in the prophylaxis group (79% vs 38%, p < 0,001). A multiple logistic regression model identified older age (OR 0,966; 95%CI 0,943 – 0,989; p = 0,004), female sex (OR 2,859; 95%CI 1,749 – 4,671; p < 0,001) and history of smoking (OR 1,860; 95%CI 1,091 – 3,173; p = 0,023) as independent predictors of radial spasm. In the spasm prophylaxis subgroup, female sex (OR 2,975; 95%CI 1,419 – 6,239; p = 0,004) was the only independent predictor of radial spasm. Nonetheless, considering women only, radial spasm was much lower in the spasm prophylaxis subgroup (84% vs 51%, p < 0,001).

CONCLUSIONS

Spasm prophylaxis strongly reduced the incidence of radial spasm in all subgroups. While a history of smoking and older age were predictors of spasm, their effect was overcome by the use of spasm prophylaxis. Women are particular prone to spasm, but spasm prophylaxis is still useful as it greatly, albeit not completely, reduces the incidence of radial spasm.

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Acute and mid-term outcome following implantation of an everolimus-eluting BRS in patients with AMI: results from the GABI-R registry

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

AIMS

Implantation of BRS in patients with acute myocardial infarction (AMI) has only been analyzed in small-sized studies. We report on outcomes of patients with AMI treated with BRS in the large multicenter German-Austrian Absorb Registry (GABI-R).

METHODS AND RESULTS

A total of 3228 patients enrolled between November 2013 and January 2016 and followed-up for at least 6 months were included in this analysis. Of these, 1283 patients (39.7%) had a myocardial infarction as an indication for percutaneous coronary intervention (PCI) with BRS (560 patients {43.6%} with ST-segment elevation MI). The majority of patients treated in GABI-R were male (76.9%), with no significant difference between AMI and non-AMI patients. Compared to patients without AMI, BRS patients with AMI were younger (58.4±11.1 vs. 62.5±10.6 years, p<0.0001), more often smokers (46.9 vs. 26.9%, p<0.0001), and had less frequently diabetes mellitus (17.9 vs. 23.1%, p<0.001), hypertension (62.8 vs. 80.1%, p<0.0001), hypercholesterolemia (44.9 vs. 64.2%, p<0.0001) and previous cardiovascular interventions. Baseline left ventricular ejection fraction was lower in the AMI group (54.2 vs. 56.9%, p<0.0001).

Overall, 5063 scaffolds were implanted in 4381 coronary lesions (1.36±0.67 lesion/patient), with a larger mean reference vessel diameter and shorter mean lesion length in the AMI group. Thrombus aspiration was used in 12.8% of AMI patients. The rate of balloon-pre-dilatation was not significantly different in the AMI and non-AMI groups (90.9 vs. 91.8% respectively, p=0.29), while the rate of post-dilatation was slightly but significantly lower in the AMI group (70.0% vs. 73.1%, p<0.05). Procedural success was high (99.0% vs. 98.9%, p=0.74) and peri-procedural complications were infrequent (1.2 vs. 1.6%, p=0.27) in both groups. Significantly more patients in the AMI group were discharged on a potent P2Y12 inhibitor (ticagrelor or prasugrel) compared to the non-AMI group (87.9 vs. 34.5%, p<0.001).

An independent clinical events committee adjudicated all clinical events occurring during the follow-up period. Thirty-day all-cause mortality rates were low and comparable in both groups (0.62 vs. 0.46%, odds ratio {OR} 1.35, 95%CI 0.52-3.51, p=0.54). At 6 months, rates of all-cause mortality (1.25 vs. 1.23%, p=0.97), myocardial infarction (1.71 vs. 2.31%, p=0.24), definite or probable scaffold thrombosis (1.43 vs. 1.68%, p=0.58), target-lesion (1.95 vs. 2.31%, p=0.49) and target vessel failure (2.96 vs. 4.22%, p=0.07) were low and not significantly different between AMI and non-AMI patients, respectively.

CONCLUSIONS

In a large and closely followed-up patient population treated with BRS in Germany and Austria, BRS implantation in patients with AMI appears to be as safe and effective as in patients without AMI up to 6 months of follow-up, with a very low overall event rate. Longer-term follow-up up to 5 years is ongoing.

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Predictors of mortality in patients with refractory cardiogenic shock and use of a percutaneous left ventricular assist device

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

AIMS

The aims of the present study were to assess the real world use of the ImpellaCP in patients with refractory cardiogenic shock, to analyze the clinical outcome of these patients and to identify predictors of mortality.

METHODS AND RESULTS

In this retrospective single center study at a cardiological intensive care unit at a university hospital a total of 77 patients (67.9 ± 12.2 years, 68.8% male) with cardiogenic shock receiving temporary mechanical support with an pLVAD were analyzed. The most common cause of cardiogenic shock was myocardial infarction (75.3%). At the time of admission, the majority of patients was mechanically ventilated (74.0%) and underwent cardiopulmonary resuscitation (49.4%). Thirty-day mortality of the overall cohort was 58.4%. Early major cardiac and cerebrovascular adverse events occurred in 3.9% of all patients. Comparing survivors and non-survivors, several differences could be identified. Serum lactate levels of patient in the surviving cohort declined significantly in the first 4 hours after device implantation (lactate clearance -17%, $p < 0.05$). Furthermore, higher norepinephrine dosage at admission was identified as independent predictor of 30-day mortality. Additionally, survival rate after 30 days was numerically higher in patients with infarct-related CS receiving pLVAD before PCI (Pre-PCI group) in comparison with the patients receiving it after PCI (post-PCI group) (50% vs. 40%, $p = 0.48$)

CONCLUSIONS

In the “Dresden Impella Registry” short time mortality of patients with cardiogenic shock remains high despite implantation of a pLVAD, especially after cardiopulmonary resuscitation. Decreasing serum lactate levels as a surrogate for improved microcirculation are associated with a more favorable clinical outcome. Nevertheless, larger randomized controlled trials are necessary to evaluate the benefit of pLVAD support in this severely compromised patient group.

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Perfusion of the hand is preserved by the palmar arches during radial access

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

AIMS

Palmar arch completeness is undetermined in real life patients and non-invasive assessment is considered controversial. We evaluated palmar arch completeness with angiography and the concomitant Modified Allen Test (MAT) and plethysmography

METHODS AND RESULTS

In 234 patients scheduled for a transradial (TR) procedure, angiography of the forearm and handwas performed. Completeness of the palmar arches and other parameters of the collateral vascular supply were visualized by retrograde contrast injection into the radial artery. The MAT and plethysmography were performed pre-procedurally and clinical data were collected prospectively.

Deep Palmar Arch (DPA) completeness was observed in 97% and Superficial Palmar Arch (SPA) completeness in 50% during angiography. Incompleteness of both palmar arches was not observed. Recruitment of interosseous collaterals was present in 31% and was more prevalent in patients with palmar arch incompleteness as compared to patients with palmar arch completeness (37% vs. 24%, p=0.03). Patients with palmar arch incompleteness had a smaller diameter of the ulnar artery (2.24 mm vs. 2.47 mm, p= 0.001) and SPA (1.67 mm vs. 1.89 mm, p<0.001) as compared to patients with palmar arch completeness. Collateral perfusion, measured from the ulnar artery to the thumb, was delayed in patients with palmar arch incompleteness as compared to patients with palmar arch completeness (4.5s vs. 3.8s, p=0.04). Completeness of the palmar arches was significantly associated with the test results of the MAT (p<0.001) and plethysmography (p=0.008). The distribution of the MAT was: normal 52%, intermediate 26%, abnormal 22%. The distribution of plethysmography was: Type A 36%, B 51%, C 9%, D 4%

CONCLUSIONS

Digital perfusion is preserved by the palmar arches, even in those patients with an abnormal MAT or plethymography. Patients with palmar arch incompleteness have a smaller ulnar artery and SPA, resulting in inferior collateral perfusion of the thumb and intensified collateral recruitment during radial access

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Prosthesis oversizing of a balloon-expandable transcatheter heart valve and its influence on device failure and new pacemaker implantations

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

AIMS

Prosthesis oversizing (OS) is needed in TAVI to avoid paravalvular leakage (PVL), however it may result in higher rates of permanent pacemaker implantations (PPI). Therefore we analysed the impact of OS on PPI rate and VARC-2 defined device failure.

METHODS AND RESULTS

804 consecutive patients undergoing transfemoral TAVI with the balloon-expandable Edwards SAPIEN 3 were recruited from three German centres. The cohort presented with a mean age of 81±6 years and a logistic EuroSCORE of 18±13%. OS was calculated on Multislice-CT measurements according to the formula (prosthesis nominal area/patient aortic annular area-1)*100 and grouped into 7 categories for each 5% increase of OS: ([≤ -5%]; [-4 - 0%]; [+1 - +5%]; [+6 - +10%]; [+11 - +15%]; [+16 - +20%]; and [> +20%]) with -4% - 0% as reference. Median degree of OS was +7% [0.25-15]. The overall rate of device failure was 8.8% (71/804). Less OS was associated with device failure (4% [-2-12] vs. 8% [1-15]; p=0.038). The device failure rate was highest in the reference category (14.7%, 17/116). The lowest incidence of device failure was in the [+11 - +15%] category (4.6%, 6/131; OR 0.33 95%CI [0.17-0.64]). While PVL grade II+ occurred in 1.7% (14/804) of cases, there were no cases within +11% to +20% of OS. As a continuous variable (per each % increase), there was no association per unit increase between OS and the risk for device failure, neither in univariate nor in multivariable analyses adjusted for gender, peripheral artery disease, diabetes mellitus, pre-procedural transvalvular gradient, atrial fibrillation, prosthesis model and conscious sedation (OR 0.989 95%CI [0.964-1.015]; p=0.398, per each % of increase). Overall, PPI at 30 days was required in 16.2% (115/709). PPI rates were highest in the [+11% to +15%] and [+16% to +20%] groups. In a multivariable analysis, OS persisted as an important predictor of new PPI, both as continuous (per each % increase) (OR 1.029, 95%CI [1.007-1.0522]; p=0.011) and as categorical variable (per each increase in category) (OR 1.173 95% CI [1.036-1.327]; p=0.012). Other independent predictors for PPI were atrial fibrillation, elevated NYHA functional class, complete right bundle branch block on admission and bicuspid valve.

CONCLUSIONS

Using the SAPIEN 3, increased OS leads to a reduced risk for “device failure”, but raises the risk for PPI. There was no ideal range of prosthesis OS to minimize both, “device failure” and need for new PPI.

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Retrograde recanalisation of radial artery occlusion in patients with need for repeated wrist procedures

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

AIMS

To present a technique of retrograde recanalization of radial artery occlusion in patients with a need for repeated wrist procedures.

METHODS AND RESULTS

METHODS: In our centre during March 2011 –March 2016, 26 807 transradial procedures were performed. Radial artery occlusion (RAO) on angiography was documented in 526 patients. Trans ulnar approach (TUA) was used in 461 and left radial approach (LRA) in 27 patients. During that period we selected 35 consecutive patients for retrograde recanalization of RAO with consequent balloon dilatation. The selected patients were with multiple previous bilateral wrist interventions. We performed retrograde recanalization of RAO in 35 patients. In 5 patients (14%), we didn't manage to cross the occluded segment with the wire. The primary outcome was successfully completed procedure through occluded RA. Secondary outcomes were procedural complications: forearm pain, access site bleeding events, clinically evident hand ischemia. Patients with documented anatomic variations of radial artery from a previous transradial procedure, such as tortuosity of the vessel and high take off, were excluded from this group. All patients had palpable pulse distal of previous puncture site due to collaterals from ipsilateral ulnar and interosseal artery. We punctured the radial artery with an inner metallic needle and a plastic cannula. Using retrograde radial angiography performed with a plastic cannula, we were able to go through the occluded segment with different types of guide wires. After the balloon dilatation, successful catheterization, and percutaneous coronary intervention were achieved.
RESULTS: The primary outcome was achieved in 30 of 35 patients (86%). Forearm pain was present in 20 cases (57%). Minor access site bleeding occurred in 6 patients (17%) EASY score 1 and 2. There was no single case of clinically evident hand ischemia. Two patients had the discharge of embolic material up the arm without clinical consequences. In 1 patient we observed dissection of the interosseal artery. Clinical follow up on 30 days showed normal pulsations of the radial artery up to the forearm after ipsilateral ulnar artery occlusion by hand in 20 patients. 10 patients had no pulsations in the radial artery on 30 days follow up.

CONCLUSIONS

Retrograde recanalization of the radial artery occlusion is safe and feasible in patients with need of repeated coronary angiography procedures. Puncturing the collateral and performing retrograde radial angiography through the cannula is a key factor for successful opening of the RAO.

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Outcome of unprotected left main PCI with concomitant right coronary artery disease

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

AIMS

Left main PCI is now a feasible and favorable option for most patients. We aim by this study to analyze the effect of concomitant RCA disease in LM population and measure its PCI effect.

METHODS AND RESULTS

From a total number of 450 patients received PCI to LM, 424 patients fulfilled our inclusion criteria. All patients received PCI to the LM. The patients were grouped to two groups. Group 1: had no RCA stenosis and group 2 had RCA stenosis >50%. We retrospectively analyzed the study endpoints (death due to any cause and CV death as primary endpoints and composite MACE as secondary endpoints) between the two groups then the effect of RCA PCI was analysed in patients with RCA stenosis >70% excluding RCA CTO. The median duration of follow-up was 2 years with maximum 11 years follow-up duration. 261 patients (62%) had disease in the RCA and 163 (38%) patients had no significant RCA disease. Among the patients with RCA disease, 18% had 50%-70% stenosis, 33.3% of the patients had >70% stenosis and 10.6% had CTO. Although the in-hospital events were higher in patients with RCA stenosis, this difference didn't reach significance. The study endpoints were analyzed by Kaplan Meir curves which shows no significant difference between the primary endpoints. But MACE was significantly higher between the two groups (p70-95% was done. This cohort comprised 141 patients, 29 of them received concomitant PCI to the RCA and the others didn't. In-hospital events analysis showed that the incidence of renal failure and MI was higher in the group who didn't receive PCI to the RCA, but this difference didn't reach statistical significance. The cumulative incidence of outcomes showed that in patients who didn't receive PCI to the RCA has higher incidence of in-hospital events when compared to the other group. This relation was found to be significant ($p<0.05$). Survival analysis for long term study endpoints revealed no significant difference between the two groups.

CONCLUSIONS

Concomitant RCA disease in patients receiving LM PCI significantly affect MACE but not death. Although RCA PCI reduced the in-hospital outcomes, it didn't reduce the long term rates of death and MACE

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Radial vs. femoral access for left main stem intervention: procedural success and short-term clinical outcome

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

AIMS

To compare the survival and procedural success of transradial versus transfemoral percutaneous coronary intervention in patients with left main stem (LMS) disease.

METHODS AND RESULTS

Methods

We analysed data collected at our hospital for all patient who received PCI to LMS from 1/3/2010 to 30/09/2016. This consisted of a retrospective review of case notes, coronary angiograms and data collected prospectively as part of the British Cardiovascular Society (BCIS) audit. We classified the patients into transradial (TRA) and transfemoral (TFA) groups according to access site. Acute failure was defined as peri-procedural death, TIMI flow<3 in one of the treated arteries or unsuccessful PCI strategy. Mortality status was evaluated using the national database.**Results**

403 patients underwent PCI to LMS, including 213 (52.9%) through the radial artery and 305 cases of unprotected left main stem. Patients in the TRA group were more often treated for stable angina (40.9% vs. 24.2%, p<0.01), less likely to have cardiogenic shock (10.3% vs. 26.3%, p<0.01). The rate of 2-stent strategy was not different between the 2 groups (33.8% vs. 36.8%, p=0.94). However, the use of intracoronary imaging was higher in the TRA group (61.1% vs. 34.7%, p<0.01). Procedural success was similar in both groups (94.8% vs. 93.2%, HR 0.74 95%CI (0.32-1.70) p=0.48).

Overall 30-day mortality rate was 8.9% in the TRA group versus 16.3% in the TFA group (HR 0.49 95%CI (0.32-0.75), p<0.01). 6-month mortality rate was 13.1% in the TRA group versus 21.6% in the TFA group (HR 0.41 95%CI (0.26-0.65), p<0.01).

In univariate analysis, acute presentation, femoral access, cardiogenic shock, non-use of intracoronary imaging were associated with increased overall mortality. In multivariable analysis, cardiogenic shock (p<0.01), non-use of intracoronary imaging (p=0.05) were associated with increased 30-day mortality whilst only cardiogenic shock (p<0.01) was associated with higher 6-month mortality.

Adjusted mortality rate according to the presence of cardiogenic shock and use of intracoronary imaging showed no significant difference at 30-days and 6-months (HR 0.71 95%CI (0.48-1.64), p=0.71; (HR 1.03 95%CI (0.62-1.70), p=0.91)).

CONCLUSIONS

Our data suggest that TRA is a safe and effective alternative to TFA access for PCI to LMS. In cardiogenic shock, TFA appears to be favored by operators although even in this unwell group TRA access is associated with similar acute procedural success. The adjunctive use of intracoronary imaging seems to be associated with lower mortality rates. Crude mortality was lower in the TRA group although this was not significantly different when adjusted for cardiogenic shock.

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Length of hospital stay and 30-day mortality in STEMI patients: results from a large tertiary centre

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

AIMS

Our institution advocates early discharge of successfuly treated STEMI patients with left ventricular ejection fraction > 45%. We sought to assess our pathway and identify factors associated with length of hospital stay (LOS) and 30-day mortality.

METHODS AND RESULTS

Methods

We analysed data collected prospectively on all STEMI patients treated with primary percutaneous coronary intervention (PPCI) at our institution between 01/05/2014 – 01/05/2015. Three groups were defined according to LOS where LOS of 2-days indicates short stay, LOS 2-3 days standard stay, and LOS 3 or more days a long stay (>72hr). We analysed 30-day mortality for all the patients and compared mortality rates across the three groups.**Results**

During the two-year period, 1048 patients received PPCI. Of these 869 (67%) were male, median age 65, 161 (12%) were diabetic and 29 (2%) had chronic renal failure. A newer P2Y12 inhibitor (prasugrel or ticagrelor) was used in 87% of cases. 87 (6.7%) were in cardiogenic shock. All patients were treated with parenteral anticoagulation during PPCI (heparin in 60% of cases) and 18% received a GP IIb/IIIa inhibitor. 9% of patients had severe LV impairment after the index event.

The distribution of patients was 460 for short LOS, 282 for standard LOS and 306 for long LOS. Mean LV ejection fraction was 47% for short LOS, 42% for standard LOS and 37% for long LOS.

The median age increased with the increase in length of stay from 62 in short LOS to 67 in long LOS.

The overall mortality rate for our patient cohort was 10%.

We calculated the mortality rates following discharge and compared that across the three groups. No deaths were recorded in the short stay group. The mortality rates for standard LOS and long LOS were 1.8% and 1.4% respectively.

A multi-variable analysis was performed to identify factors associated with longer hospital stay (> 72 hrs). Cardiogenic shock, poor LV function, advanced age and use of GP IIb/IIIa inhibitor were associated with length of hospital stay.

Furthermore, 30-day mortality was significantly higher in patients with long stay of more than 3 days, occluded LAD or occluded LCx.

CONCLUSIONS

A policy of LV function guided discharge appears to be safe and feasible with very low 30-day mortality in low risk patients discharged two days post primary PCI.

Additional factors increasing risk and delaying discharge included LAD occlusion and interestingly occluded LCx possibly as these patients tend to have limited ST segment elevation on ECG and, therefore, have delays in receiving primary PCI

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The AURORAA registry: five-year results of the use of interwoven nitinol vascular mimetic implant in extensive femoropopliteal lesions

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal, Other peripheral interventions

AIMS

We want to see if the long-term or 5 year results of the use of the Supera Vascular Mimetic Implant for the treatment of extensive femoropoliteal lesions are still so durable

METHODS AND RESULTS

MethodsSingle centre, follow-up study of popliteal/distal superficial femoral artery interventions/stenting with Supera vascular mimetic implant (Abbott Vascular, Santa Clara, Cal,US.) over the knee resulting in min 120 patients with 5 year follow-upResultsAll patient underwent a direct post intervention flexion-angiogram that showed no kinking or collapsing of the stent? Technical success was around 97 % . THe majority had very calcified occlusive lesions with average laesion length around 15 cm and stented segment of almost 17 cm

Patients were followed by doppler duplex ar 1, 3, 6, 12, 18 and the every year, all patients had double antiplatelet therapy for at least 3 months

Primary patency at 5 years was still > 60 %

CONCLUSIONS

The 5 year results of the Supera VMI for the treatment of extensive and calcified femoropopliteal occlusive disease showed sustained benefit, with good durability making this, the device of choice to treat this type of lesions

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Temporal trends in frequency, management and outcomes of coronary perforations

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

AIMS

It is unknown how progresses in interventional cardiology in the last decade have affected the occurrence of coronary perforations (CP). This study aimed to compare temporal trends in frequency, management and outcomes of CP.

METHODS AND RESULTS

From a total of 17,566 procedures recorded in our institutional angioplasty registry from January 2003 to December 2015, all instances of CP were identified. Patients were divided in 2 groups according to the frame time in which the CP occurred. CP severity was graded according to Ellis classification. The primary endpoint was the composite of serious events during the index hospitalization, and included final TIMI flow 0-1, cardiac tamponade, emergent cardiac surgery or in-hospital death. Overall, 88 (0.50%) CP occurred in 17,566 procedures. Of these, 17 (0.26%) occurred during the initial period and 71 (0.64%) during the current period ($p<0.001$). CP management also differed between groups, being less proportion of CP sealed by intra coronary devices in the initial period than in the current one (23.5% vs 47.9%, $p=0.068$). Prognostic of CP was significantly better in the current period; the primary endpoint occurred in 69% of the patients in the initial period compared to 31% in the current one (OR 3.18, 95% CI 1.07-9.45, $p=0.037$).

CONCLUSIONS

Expansion of indications and complexity of revascularizations in the current era may be associated to an increased frequency of coronary perforations. However, progresses in techniques and devices have entailed a remarkable improvement in prognosis of this feared complication.

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Incidence, predictors and clinical outcomes of device malposition following TAVI for degenerative bioprosthetic surgical valves

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

AIMS

Transcatheter valve use in failed surgical bioprostheses (Valve-in-valve, ViV) is an alternative to surgery. However, ViV is reportedly associated with device malposition. The incidence, predictors and significance of ViV malposition are unknown.

METHODS AND RESULTS

A cohort of 1,919 patients, undergoing aortic ViV, from the Valve-in-Valve International Data (VIVID) registry was analyzed. Malposition was defined as a position of the valve that resulted in an adverse event directly, such as significant regurgitation, a need for 2nd valve to be implanted because of device location or coronary obstruction. A total of 152 patients (7.9%) had device malposition. In comparison to patients without malposition, those with valve malposition were more likely to have stentless surgical valve (31.8% vs. 18.7%, P<0.001) and predominant aortic regurgitation as a mode of bioprostheses failure (40.7% vs. 29.4%, P=0.01). Device malposition was more frequent with self-expandable vs. balloon-expandable transcatheter valves (11.4% vs. 4%, P<0.001). In patients with malposition, there was a higher incidence of post-dilation (24.1% vs. 12%, P<0.001), need for a second prosthesis (52.4% vs. 0%, P<0.001) and need for a permanent pacemaker implant (12.4% vs. 6.3%, P=0.009). Patients with initial valve malposition had a higher rate of at least moderate aortic regurgitation (14.5% vs. 4.9%, P<0.001) and acute kidney injury (12.2% vs. 5.4%, P=0.001). Multivariate analysis identified predominant aortic regurgitation mode of failure (Odds Ratio, 1.53, CI 1.04-2.2, P=0.03), stentless valves or poorly visible stented devices (Odds Ratio, 2.3, CI 1.5-3.4, P < 0.001), self-expandable THV devices (Odds Ratio, 2.8, CI 1.8-4.4, P < 0.001) and STS score (Odds Ratio, 1.03, CI 1.01-1.05, P=0.002) as independently associated with device malposition. Patients with malposition had significantly higher 30-day mortality in comparison to those without malposition (10.3% vs. 4.2%, P=0.001).

CONCLUSIONS

Transcatheter valve malposition is relatively common when treating failed bioprostheses, especially with regurgitant and stentless surgical valves. Malposition is associated with higher mortality and is caused by anatomic and technical factors, which may be avoided with meticulous procedural planning and technique.

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Use of retrograde vascular access in lower limb interventions: the experience of a single high-volume centre

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THEME: Peripheral Interventions
TOPIC(S): Below the knee, Iliac / Femoral / Popliteal

AIMS

To evaluate the impact of retrograde vascular access on success of endovascular revascularization procedures of femoro-popliteal and below-the-knee (BTK) arteries, analysing the experience of a single high-volume centre.

METHODS AND RESULTS

From January 1st 2012 to December 31st 2016, 3287 patients were treated at our Institution with endovascular revascularization of femoro-popliteal and/or BTK arteries. All cases in whom anterograde crossing of the occlusive lesion was not effective and required the use of a retrograde access to achieve successful revascularization were identified. 151 patients (4.5% of all the cases) treated with endovascular revascularization of lower limb artery chronic total occlusions with use of retrograde approach were selected.

The analysed population presented mean age 71.9 ± 9.2 years, male sex vs. female 78.3% vs. 21.7% and a high rate of Critical Limb Ischemia (CLI) vs. Intermittent Claudication (IC) (62.3% vs. 37.7%). Analysing the whole population, the retrograde access used was popliteal artery in 61.6% of the cases, Dorsalis Pedis artery in 27.2% and Posterior Tibial Artery in 11.2%. The use of retrograde access was determinant to achieve procedural success in 81.5% of femoro-popliteal procedures, in 69% of Anterior Tibial Artery procedures and in 54.5% of Posterior Tibial Artery procedures. The global success of retrograde access in lower limb revascularization was 79.5%, whereas it decreased to 75.5% in CLI patient subgroup.

In the CLI subgroup, we analysed the effect of using a retrograde access to obtain an increased blood flow in the BTK district. Among 50 patients affected by CLI and with occlusion of femoro-popliteal axis treated through retrograde access, 19 (38%) patients received during the same procedure also a percutaneous revascularisation of at least one BTK artery, with effective improvement of foot blood supply.

CONCLUSIONS

In a minority of cases endovascular revascularisation of lower limb arteries may require the helpful hand of a retrograde access to increase the success rate of the procedure. Retrograde access determined an increased success rate of 79.5% in a population in whom anterograde access had been not successful. This could have a higher clinical relevance in CLI patients, who actually constitute the majority of our population. Since in CLI the extent of revascularization and the opportunity to increase blood supply directly to the foot are determinant for patients' prognosis, the use of a retrograde access in this setting should be considered a first-choice strategy.

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To heparin or not to heparin? - That is the radial question

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

We hypothesize that anticoagulation may not be mandatory in contemporary diagnostic radial catheterization. We aim to assess the rate of radial artery occlusion in patients undergoing diagnostic catheterization comparing the anticoagulation approach.

METHODS AND RESULTS

We prospectively included 170 consecutive patients that underwent diagnostic transradial coronary angiography from January 2015, in a comparative prospective observational study. This proof of concept study was designed to include patients in 2:1 ratio (heparin vs no heparin) to better discriminate events in the heparin arm. Anticoagulation strategy was kept constant by the operators during the recruitment period. One operator used a no-heparin strategy, two operators used 2500U and one used 5000U of heparin, as usually performed. A 6Fr sheath was used and hemostasis was achieved with a compression device assuring radial patency throughout. The primary endpoint of the study was radial artery occlusion. Secondary outcome measures included pain, functional limitation, bleeding or hematoma. Radial artery patency was screened using a modified Barbeau's test followed by Doppler study in suspected cases of radial artery occlusion for confirmation.

In 55 patients, no heparin was used and it was used in 115 patients (2500U in 90 and 5000U in 25). The mean age of patients was 65±11 in the no-heparin group vs 64±11 in the heparin group, p=0.65. There were no significant differences regarding prevalence of Diabetes *Mellitus* (21.8% vs 17.4%, p=0.53), smoking habits (12.7 vs 15.7%, p=0.82) and dyslipidaemia (58.2% vs 60.0%, p=0.86). There was a trend toward higher prevalence of hypertension in the no-heparin group (80.0% vs 65.2%, p=0.05).

Using the Barbeau´s test, radial artery occlusion occurred in 15 patients (8.8%). The occlusion was confirmed by Doppler colour in 13 pts (7.6%).

The two groups did not differ regarding radial occlusion rates: 4 (7.3%) in the no-heparin group and 9 (7.8%) in the heparin group, p=0.58. The differences remained non-significant (p=0.67) when patients were stratified by heparin dose. Importantly, absence of heparin was not a predictor of radial artery occlusion.

The rate of local access site complications was not significantly different between both groups (pain 16.4% vs 7.8%, p=0.11; paresthesias 7.3% vs 3.5%, p=0.44; local hematoma 23.6% vs 18.4%, p=0.42).

CONCLUSIONS

In a contemporary cohort of patients undergoing diagnostic transradial catheterizations the rate of radial artery occlusion was low and not significantly different whether heparin was used or not. This proof of concept study highlights the need for inclusion of a no treatment/placebo arm in future heparin for radial artery occlusion prevention trials.

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Prosthesis-patient mismatch of surgical valves significantly impacts survival following aortic valve-in-valve implantation

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

AIMS

Valve-in-valve (ViV) is an alternative for the treatment of failed bioprostheses. It is unknown whether pre-existing prosthesis-patient-mismatch (PPM) is associated with increased post-ViV mortality. This study aims to investigate this association.

METHODS AND RESULTS

Data of 1,168 patients included in the multinational Valve-in-Valve VIVID registry were analyzed. Pre-existing PPM of the surgical valve was defined using the predicted EOA (i.e. the normal reference value of EOA for each given model and size of implanted prosthetic valve) indexed for patient's body surface area and the criteria proposed by VARC 2: i) overall PPM: indexed EOA<0.85 cm^2/m^2 if body mass index <30 kg/m^2 or <0.7 cm^2/m^2 if BMI ≥30 kg/m^2; ii) Severe PPM: indexed EOA <0.65 cm^2/m^2 if body mass index <30 kg/m^2 or <0.6 cm^2/m^2 if BMI ≥30 kg/m^2. Reference EOA values were available for Medtronic Mosaic, Medtronic Hancock II, Medtronic Mosaic, Carpentier-Edwards, Carpentier-Edwards Perimount, Carpentier-Edwards Perimount Magna, St. Jude Epic, St. Jude Trifecta, Sorin Mitroflow, Medtronic Freestyle, St. Jude Toronto SPV, Edwards Prima and Sorin Freedom Solo. The primary study endpoint was 1-year mortality.

Among the 1,168 patients included in the registry, 584 (50%) had moderate pre-existing PPM and 89 (7.6%) of them had severe pre-existing PPM. Mean age was 78.6 ± 8.4 years and mean STS was 9.9 ± 8.7%.Patients with severe PPM had significantly ($p<0.001$) higher 1-year mortality rate (28.6%) compared to patients with no severe PPM (11.9%). After adjusting for surgical valve label size, STS score, renal failure, and diabetes, presence of pre-existing severe PPM was associated with increased risk of 1-year mortality (OR: 1.77; 95% CI: 1.02 - 3.07; $p = 0.04$).

CONCLUSIONS

Pre-existing PPM of the failed surgical valve is strongly and independently associated with increased risk of mortality following ViV. These findings provide strong support for the prevention of severe PPM at the time of the index surgical valve replacement SAVR and for the systematic integration of the assessment of pre-existing PPM in the risk stratification and decision making processes prior to ViV.

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Clinical valve thrombosis after TAVI for degenerated bioprosthetic aortic valves

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

AIMS

Limited data exists on clinical transcatheter valve thrombosis after aortic valve-in-valve (ViV). Our objective was to determine the incidence, timing, clinical characteristics and treatment outcomes of patients diagnosed with ViV thrombosis.

METHODS AND RESULTS

This is a retrospective analysis of prospectively collected data from a multicenter database. Centers were surveyed for thrombosis cases. Post-procedure therapy included dual antiplatelet therapy or oral anticoagulation when indicated. All patients had a pre-defined clinical and echocardiographic follow-up schedule. The following criteria were used to define clinical valve thrombosis: 1) new valve dysfunction (mean gradient > 20 mmHg or increase in mean gradient by >50% from baseline or more than mild transvalvular AR) responding to anticoagulant therapy with complete or partial resolution of the abnormality; and 2) imaging evidence (echocardiography, computed tomography {CT} or both) of prosthetic valve thrombosis in the absence of clinical signs of infection. Definite valve thrombosis was diagnosed if both criteria were met, while probable valve thrombosis was diagnosed if only one criterion was identified.During the mentioned study period, 306 valve-in-valve TAVIs were performed (self-expanding valves = 159; balloon-expandable = 147). Incidence of clinical valve thrombosis was 8.2% (25 patients; 17 definite and 8 probable valve thrombosis). The median time to thrombosis detection was 75 days (range 1 - 2052). In 8 (32%) patients, THV thrombosis was diagnosed within 30 days after valve-in-valve TAVI. 13 (52%) patients had no worsening symptoms at the time of diagnosis. Transvalvular mean gradients were elevated in 21 (84%) patients. The mean transaortic gradient and the mean aortic valve area at the time of diagnosis of THV thrombosis were 36 ± 13.8 mmHg and 0.96 ± 0.36cm2, respectively. Other echocardiographic findings included thrombotic mass on the leaflets (n = 7), thickening of leaflets (n = 6) and reduced mobility (n = 4). Hypoattenuating areas with reduced leaflet motion were observed in 10 out of 11 patients who had CT, with a median of two affected leaflets. 24 patients were treated with oral anticoagulation (20 with warfarin and 4 with novel anticoagulants). Mean aortic gradient decreased significantly during treatment with anticoagulants (16.4 ± 6 mmHg at follow-up echocardiography, $p < 0.001$), and follow-up CT performed in 10 patients after initiation of oral anticoagulation revealed complete (n = 8) or partial (n = 2) resolution of the hypoattenuating areas. There were no deaths or strokes related to valve thrombosis. Of the 25 detected cases of THV thrombosis, 15 had balloon-expandable and 10 had self-expanding valves. The most common surgical valves treated in the thrombosis cohort were the Mosaic (n = 9), Hancock II (n = 5), and the Mitroflow (n = 4).

CONCLUSIONS

Clinical valve thrombosis after transcatheter valve-in-valve implantation for degenerated bioprosthetic aortic valves is common, most frequently detected at an average of three months after valve implantation and characterized by imaging abnormalities and increased gradients. Post procedure anticoagulation appears to be very effective in preventing and treating valve thrombosis.

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One vs. two-stent strategy for the treatment of bifurcation lesions in the context of a coronary CTO: a multicentre registry

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

AIMS

It is not known whether provisional stenting is the choice strategy for bifurcation lesions in chronic total occlusions (CTO). This study aimed to compare the outcomes in patients with bifurcation lesions in CTO treated with 1 vs 2-stent techniques.

METHODS AND RESULTS

This multicentre registry pooled the patients with bifurcations lesions in the context of CTO recanalisation performed at 4 centers. CTO with a side branch reference diameter ≥2.0 mm located in the proximal cap, in the distal cap or within the occluded segment were enrolled. Bifurcation technical success was considered when a residual stenosis of <30% in the main vessel and a final TIMI flow grade III in both branches were obtained. Periprocedural myocardial infarction (MI) was defined according to the third universal definition of MI. Major adverse cardiac events (MACE) were defined as a composite of cardiac death, MI and target lesion revascularisation (TLR). A bifurcation lesion was observed in 263 patients undergoing successful CTO recanalisation. Twenty-nine of them (11%) were excluded due to the impossibility to access to the side branch before or after main vessel stent implantation. The remaining 234 patients were treated by simple approach (n=199) or complex strategy (n=35). No differences were found in the clinical characteristics between both groups of patients. The prevalence of a true bifurcation was higher in the 2-stent group (32, 91% vs 83, 42%; p< 0.01). Additionally, the incidence of an induced dissection affecting the bifurcation site was also higher in this group, compared to patients treated with 1 stent (15, 43% vs 49, 25%; p< 0.05). Bifurcation technical success was similar in both groups: n=34/35 (97%) in complex strategy and 188/199 (94%) in patients treated with provisional stenting. In all cases, the bifurcation failure was due to a TIMI flow at the side branch

CONCLUSIONS

Provisional stenting seems to be the preferred strategy in the majority of bifurcation lesions in the context of CTO recanalisation in order to simplify the procedure. Elective implantation of 2 stents did not penalise the procedure in terms of MACE and it can be required when an important dissection affects the SB origen.

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Stent thrombosis remains a predictor of poor long-term outcome among patients with stent thrombosis undergoing primary PCI for STEMI

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

AIMS

The aim of this study was to characterize ST presenting as STEMI comparing the baseline characteristics, clinical presentation and long-term outcome and relation to ST timing.

METHODS AND RESULTS

This was an observational cohort study of 6153 patients who underwent primary PCI from 2005 to 2016 with follow-up for a median of 4.2 years (IQR range: 1.8-5.4 years). The primary end-point was the first major adverse cardiac event (MACE) defined as death, non-fatal myocardial infarction, or target vessel revascularization.

ST overall accounted for 6.7% (413/6153) of all STEMIs, this included 44 with early ST (1.0%), 38 with late ST (0.9%), and 54 with very late ST (2.0%). The frequency of ST increased over time (2005-2016; P<0.0001). The majority of ST occurred followed stents implemented for acute coronary syndromes (23% NSTEMI and 50.7% STEMI). Independent predictors of stent thrombosis were type II DM, chronic renal failure poor LV Function and small stent diameter (<3mm).

The cumulative incidence of MACE after ST was 43%, which was higher than that for patients without ST (21%; p <0.0001), which persisted after correction for baseline characteristics. Differences existed in the cumulative incidence of MACE between ST timings with significantly lower rates in patients with VLST (25.3%95% CI: 11.2-33.6) compared with those with EST (63.9% 95% CI: 44.7-75.6; P=0.006) or LST (55.5% 95% CI: 36.1-63.3; P=0.010). There was no difference between patients with VLST and patients with native coronary thrombosis (25.6% 95% CI: 13.5-29.5, p=0.475). Early (HR, 2.70; 95% CI: 1.33-3.46; P<0.0001) and late (HR, 1.73; 95% CI: 1.31-2.38; P=0.006) stent thrombosis were independent predictor of MACE after multivariate adjustment however very late stent thrombosis (VLST) was not (HR, 0.84; 95% CI: 0.60-1.56; P=0.466).

CONCLUSIONS

Patients with ST are associated with higher MACE rates than patients without ST. Differences in long-term outcomes between the different timings of ST suggest that the predominant underlying mechanisms might be different.

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The influence of collateral regression post-coronary CTO PCI on donor vessel coronary pressure-derived measurements

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

AIMS

The presence of a concomitant CTO may influence the FFR measurement in a donor vessel. We sought to investigate the influence of collateral regression following successful CTO recanalisation upon donor vessel pressure-derived indices.

METHODS AND RESULTS

34 consecutive patients with symptomatic angina underwent successful PCI to RCA CTOs during the study period. Coronary pressure-derived indices (resting distal pressure/aortic pressure (Pd/Pa), iFR and FFR) were measured in both the donor LAD and Circumflex arteries pre, immediately post CTO PCI, and at 3 months follow up. RCA collateral FFR was also measured at the same timepoints. FFR was measured as previously described FFR=(Pd-Pv)/(Pa-Pv), where Pv is central venous pressure. Hyperaemia was achieved by central administration of adenosine at 140 mcg/kg/min.28 patients completed measurements pre, immediately post and at 3 months follow up after successful CTO PCI. The mean age was 62.0 (± 9.8)years. 89.3% were male, 60.7 % had previous MI, 35.7% had previous PCI, 64.3% had hypertension, and 21.4% had diabetes mellitus. All patients had symptomatic angina, CCS class 1 (10.7%), 2 (39.3%) and 3 (50%). The mean estimated CTO duration was 206.1(± 412.7)weeks and CTO length was 33.4 (± 25.7)mm. Left ventricular ejection fraction on cardiac MRI was 49.5(± 21.1)%, with a mean RCA territory ischaemic burden of 12.5 (±5.0)%. The LAD was the predominant donor vessel in 24 patients and Circumflex artery in 4 patients. Percentage of diameter stenosis on QCA in the predominant and minor donor vessel were 40.6 (±11.7)% and 36.1 (±13.8)% respectively. The overall Rentrop classification grading and collateral connection (CC) Classification grading pre-CTO PCI and at follow-up were (Rentrop grading pre-CTO PCI: 0 (n=0), 1 (n=0), 2 (n=2), 3(n=26), Rentrop grading at follow-up: 0 (n=23), 1 (n=4), 2 (n=1), 3(n=0),) (CC grading pre-CTO PCI: 0 (n=0), 1 (n=3), 2 (n=16), 3(n=9), CC grading at follow-up: 0 (n=23), 1 (n=5), 2 (n=0), 3(n=0).The mean resting Pd/Pa, iFR and FFR pre and post-RCA CTO PCI and at follow-up procedures in predominant donor vessel were (0.893, 0.862, 0.764), (0.907, 0.886, 0.753) and (0.918, 0.901, 0.787) respectively. The mean resting Pd/Pa, iFR and FFR pre and post RCA CTO PCI and at follow-up procedures in minor donor vessel were (0.979, 0.966, 0.890), (0.983, 0.979, 0.880) and (0.981, 0.974, 0.898) respectively. There was a significant increase in predominant donor vessel Pd/Pa, iFR and FFR at 3 months follow up, compared to pre procedure (0.025 ± 0.045 p=0.006, 0.039 ± 0.064 p=0.003, 0.023 ± 0.059 p=0.047) respectively. There was no significant increase in Pd/Pa, iFR and FFR in the minor donor vessel (0.002 ± 0.040 p=0.816, 0.008 ± 0.061 p=0.523, 0.008 ± 0.051 p=0.399) respectively.FFR collateral reduced significantly from 0.305 ± 0.102 pre-CTO PCI to 0.183 ± 0.066 (difference -0.122, 95 % CI -0.157 to -0.0878, p value <0.001).

CONCLUSIONS

Successful recanalisation of a RCA CTO results in a significant reduction of collateral function and concomitant increase in predominant donor vessel coronary pressure-derived indices at 3-month follow-up.This has implications for the timing of coronary physiological assessment and subsequent staged multi-vessel PCI.

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The physiological impact of coronary CTO PCI on donor vessel coronary pressure-derived measurements and the influence of collateral circulation

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

The presence of a concomitant CTO may influence the FFR measurement in a donor vessel.
We sought to investigate the immediate physiological impact of CTO recanalisation on donor vessel pressure-derived indices.

METHODS AND RESULTS

The study participants were patients with angina who had RCA CTO. 34 out of 40 consecutive patients underwent successful PCI to RCA CTOs during the study period and were included in this analysis. Coronary pressure-derived indices (resting distal pressure/aortic pressure (Pd/Pa), iFR and FFR) were measured pre and post-successful RCA CTO PCI in donor vessels and collateral FFR in the CTO vessel. FFR was measured as previously described FFR=(Pd-Pv)/(Pa-Pv), where Pv is central venous pressure.The mean age was 61.7 (±10.5)years.88.2% were male, 61.8 % had previous MI, 41.2% had previous PCI, 64.7 % had hypertension, 26.5 % had diabetes mellitus. All patients had symptomatic angina, CCS class 1(11.8%), 2(35.3%), 3(50%) and 4(2.9%). The mean estimated CTO duration was 175.5 (±379.4)weeks and CTO length was 32.4 (±24.4)mm. Baseline perfusion Cardiac MRI was available in 31 patients. 30 patients had ischaemia in the RCA territory assessed with cardiac MRI. Left ventricular ejection fraction on cardiac MRI was 51.3 (±19.6)%, with a mean RCA territory ischaemic burden of 13.65 (±5.0)%. The LAD was the major donor vessel in 88% (n=30) and Circumflex artery in 12% (n=4). Percentage of diameter stenosis on QCA in the major and minor donor vessel were 41.4 (±12.6)% and 35.1(±13.7)% respectively. The overall Rentrop classification grading and collateral connection (CC) Classification grading pre and post RCA CTO PCI were (Rentrop pre-CTO PCI: 0 (n=0), 1 (n=0), 2 (n=2), 3(n=32), Rentrop post-CTO PCI: 0 (n=3), 1 (n=25), 2 (n=6), 3(n=0),) (CC grading pre-CTO PCI: 0 (n=0), 1 (n=3), 2 (n=22), 3(n=9), CC grading post-CTO PCI: 0 (n=23), 1 (n=10), 2 (n=0), 3(n=1).The mean resting Pd/Pa , iFR and FFR pre and post RCA CTO PCI in major donor vessel were (0.891, 0.858, 0.759) and (0.903, 0.882, 0.746) respectively. iFR in the major donor vessel increased from 0.858 to 0.882 (difference, 0.024 (0.006 to 0.043); P=0.012). There was no significant difference in resting Pd/Pa and FFR pre and post CTO PCI (P =0.109 and P= 0.267 respectively). The mean resting Pd/Pa , iFR and FFR pre and post RCA CTO PCI in minor donor vessel were (0.982, 0.969, 0.894) and (0.985, 0.979, 0.885) respectively. There was no significant difference in resting Pd/Pa, iFR and FFR pre and post RCA CTO PCI in minor donor vessel (p=0.534, p= 0.152, P=0.183 respectively). Change in major donor vessel resting Pd/Pa and FFR correlated with change in mean blood pressure (r=0.462; p=0.007, r= 0.378; p=0.030) but no significant correlation was found with percentage of diameter stenosis, FFR collateral and percent of Ischaemia in RCA territory on Cardiac MRI. The mean pre-RCA CTO PCI collateral FFR was 0.30 (±0.10).

CONCLUSIONS

Successful recanalisation of a RCA CTO results in an increase in iFR of the major donor vessel but no significant difference was seen in resting Pd/Pa and FFR. Complete collateral regression was not observed in all patients immediately post RCA CTO PCI and this may account for the non-significant change in FFR values.

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First look at clinical outcomes of mechanically expanding transcatheter heart valves for failed bioprosthetic aortic valves

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

AIMS

We aimed to evaluate the performance of the new generation Lotus Aortic Valve Replacement System (LVS) in patients with degenerated aortic bioprostheses undergoing transcatheter valve-in-valve (ViV).

METHODS AND RESULTS

Data was collected as part of the VIVID (Valve in Valve International Data) Registry, including a total of 1,944 patients that underwent aortic valve in valve from 142 centres. The patients have been referred to ViV intervention by local multidisciplinary heart team decision. A total of 33 patients undergoing Lotus ViV (age 75.1 ± 11.8 years, 72.7% males, STS PROM 4.4 ± 3.1%) were included in the analysis. Surgical valve label size was 24.4 ± 1.6 mm and none of the devices were small (label size ≤ 21mm). A stented bioprosthesis was treated in the majority of cases (n = 26, 78.8%). Degeneration modes were pure regurgitation in 16 patients (48.5%), predominant stenosis in 6 patients (18.2%) and a mixed failure in 11 patients (33.3%). Most cases were performed using transfemoral access (96.8%) under local anaesthesia (72.7%). Surgical valve predilation was performed in only 2 cases (6.5%), while postdilation was required in none of the cases. In 5 patients (15.6%) initial device position was deemed not satisfactory so that LVS was retrieved and repositioned, without complications. Final positioning was satisfactory in all cases. Final aortic regurgitation was ≥ mild in 11.1% of patients. Post implantation mean gradient was 14.4 ± 5.6 mmHg. The rate of elevated post procedural gradient (mean ≥ 20mmHg) was 12.9%. Median hospital length of stay was 6 days. No patient died within 30 days, however one (3.7%) was diagnosed with a major stroke. Only one patient required a pacemaker within 30 days (4.3%). Major vascular complications occurred in 2 patients (6.5%), while no patients developed acute kidney injury.

CONCLUSIONS

This is the first large multicentre registry of patients treated with aortic valve-in-valve treated by the Lotus System. Clinical outcomes were promising, especially with regard to device positioning, regurgitation and lack of need for post dilatation and will be further evaluated in long-term.

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Preemptive alcohol septal ablation in prevention of left ventricular outflow tract obstruction for TMVR

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

AIMS

To evaluate the impact of preemptive alcohol septal ablation on the neo left ventricular outflow tract surface area in patients identified at extreme risk of left ventricular outflow tract obstruction prior to transcatheter mitral valve replacement.

METHODS AND RESULTS

Methods:
Multi-center retrospective review of patients who underwent preemptive alcohol septal ablation in preparation for transcatheter mitral valve replacement was conducted. Both pre and post alcohol septal ablation multi-detector computed tomography angiography scans were analyzed for predicted neo left ventricular outflow tract surface areas. If no CT was available, pre and post alcohol septal ablation 3dimensional transesophageal echocardiography was utilized to determine predicted neo left ventricular outflow tract surface areas.Results:
Ten patients underwent percutaneous alcohol septal ablation to increase the size of the neo left ventricular outflow tract surface area prior to transcatheter mitral valve replacement. The average increase in the predicted neo left ventricular outflow tract surface area was 160.7+/-121.5mm^2, with a median of 113.6mm^2, and range from 28.7mm^2 up to 419.6mm^2. Baseline mean systolic maximal basal anteroseptal wall thickness by 2dimensional transthoracic echocardiogram was 13.33+/-3.44mm^2. Seven patients subsequently underwent successful transcatheter mitral valve implantation post alcohol septal ablation with a mean peak left ventricular outflow gradient of 13.1+/-20.4mmHg. Two patients required permanent pacemaker implantation post alcohol septal ablation. Two patients are awaiting transcatheter mitral valve replacement procedure. The last patient declined further interventions.

CONCLUSIONS

Preemptive alcohol septal ablation in carefully selected patients can remodel the basal anteroseptal wall of the left ventricular outflow tract and prevent critical left ventricular outflow tract obstruction post transcatheter mitral valve implantation

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Bioresorbable everolimus-eluting vascular scaffolds for type B2/C coronary lesions: a three-year follow-up

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

AIMS

To investigate three-year outcomes in patients treated with bioresorbable everolimus-eluting vascular scaffolds (BRS) for type B2 or C lesions.

METHODS AND RESULTS

The study included a total of 394 lesions in 347 consecutive patients, enrolled between May 2012 and December 2013 (median age 63 [54-73], 79% men, 66.6% with an acute coronary syndrome presentation). One hundred seventy-three lesions in 162 patients were type B2 or C. The primary device-oriented endpoint (Target Lesion Failure) was defined as a combination of cardiovascular death, target vessel myocardial infarction or clinically driven target lesion revascularization. A patient-oriented composite endpoint (death, any infarction, any revascularization) was also collected.

Patients with B2/C lesions where younger (60 [53;72] vs. 66 [56 ; 74] , p = 0.002), otherwise there was no difference in the common cardiac risk factors between groups. 73.3 % of the patients with B2/C lesions versus 61.1% of those without B2/C type lesions presented with an ACS (P=0.022).

Among the procedural characteristics, only the total length per patient was significantly different between the two groups (28.55 (18.21)mm for patients with at least 1 B2/C type lesion versus 23.58 (15.46)mm for patients without, p = 0.007).

Median follow-up was 1199.0 (1113-1327) days. 3-years follow-up was completed in 89.6% of the patients.

The incidence of the primary composite endpoint target lesion failure at 3 years did not differ between patients with type B2/C lesions and those without (22.4% vs. 21.9%, p=0.987). Accordingly, the incidence of scaffold thrombosis was 6.2% and 4.9%, respectively (p=0.752) and that of target lesion revascularization was 14.7% versus 9.0% in the two groups (p=0.143), respectively. B2/C type lesion was associated with a higher rate of Patient-oriented Composite Endpoints between 30 and 365 days (p=0.038; HR 1.791 [1.028-3.119]). On cox regression analysis, B2/C type lesion was not associated with target lesion failure (HR 1.04 [0.21-1.27], p=0.155).

CONCLUSIONS

In a real-world setting, there was no significant difference in the incidence of TLF and scaffold thrombosis between patients with type B2/C stenosis and those without. Reflecting the importance of type B2/C lesions as a marker of disease burden, however, there was a significant difference in the incidence of patient-oriented composite endpoints between 30 days and 365 years.

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Bioresorbable everolimus-eluting vascular scaffold for patients presenting with NSTE-ACS: a three-year follow-up

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

AIMS

To investigate three-year outcomes of patients presenting with nonSTelevation acute coronary syndrome (NSTE-ACS) treated with bioresorbable everolimus-eluting vascular scaffolds (BRS).

METHODS AND RESULTS

The study included a total of 279 lesions in 249 consecutive patients, enrolled between May 2012 and December 2013 (median age 63 [54-73], 80% men. One hundred thirty-nine patients presented with either NSTEMI or unstable angina at the time of enrolling, 110 patients with stable or silent angina. The primary device-oriented endpoint (Target Lesion Failure) was defined as a combination of cardiovascular death, target vessel myocardial infarction or clinically driven target lesion revascularization.

Patients presenting with NSTE-ACS were younger (64.5 vs. 68 years, p=0.312), were more likely to be female (23.0 % vs. 15.5%, p=0.183) and showed more often B2 or C type lesions in the culprit vessel (40.4% vs. 35.3%, p=0.454).

Among the cardiac risk factors, only dyslipidemia and a positive history of prior PCI was significantly more frequent in the stable than in the other group (50% vs. 30.9%, p=0.003, for diabetes, 56.9% vs. 20.1%, p<0.0001, for prior PCI).

Among the procedural parameters, only the total length per patient were significantly different between the two groups (23.6+/-15.1mm versus 28.2+/-19.7mm for NSTEACS vs stable/silent AP, p = 0.003).

Median follow-up was 1199[1113-1327] days. 3-years follow-up was completed in 89.0% of patients.

The incidence of the primary composite endpoint target lesion failure at 3 years was slightly higher but did not differ significantly between groups (NSTE-ACS: 26.1% vs. 17.8%, p=0.163). Accordingly, there was no difference in any of the other endpoints.

CONCLUSIONS

Treatment of NSTE-ACS with BRS appears to be safe and effective. In this group, risk factors for events during follow up did not differ as compared to the general population.

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Learning curve of the transradial approach of percutaneous carotid intervention

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THEME: Interventions for Stroke
TOPIC(S): Carotid stenting

AIMS

We report the learning curve over 7 years in two high-volume interventional centers during the transition from transfemoral (TF) to transradial approach.

METHODS AND RESULTS

Between 2010 and 2016, 2017 patients underwent carotid intervention in our centers. Clinical characteristics, radiation doses, volume of contrast material, screening and procedure times of consecutive patientswere recorded prospectively in a register and restrospectively analysed. Transradial approach was applied in 643 patients, mean age was 68±8 years, 64% of them was male. The ratio of TR has grown from 3 to 7, 25, 43, 48 and 69% of the carotid interventions, during the years respectively. While the duration of the procedure (26, 30, 25, 25, 22.5, 26 min), the fluoroscopy time (11, 11, 10, 8, 8, 9 min), and the applied contrast material (128, 142, 95, 69, 90, 84 ml) has significantly decreased in the first 4 years, then an elevation is observed, as more complicated cases were enrolled. Significant improvement was observed after the first 50 cases, in each parameter. Conversion to TF was needed in 7.5% and did not change significantly. No difference was observed in the incidence of minor or major vascular events and hospitalization days, over the years. Comparing the TR and TF interventions in the overall group, there was no significant difference in fluoroscopy, contrast dose, procedure time, while the radiation was significantly higher in TR group (656.1 vs. 276.6 Gy, $p<0.001$).

CONCLUSIONS

An initial learning curve was observed in the intervention parameters of transradial carotid stenting. The transition from TF to TR approach is achievable in 50 cases in experienced centers. The radiation dose is significantly higher during transradial carotid artery stenting, but no difference in fluoroscopy time, procedure time and contrast consumption.

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The value of the SYNTAX score II in predicting clinical outcomes in patients undergoing TAVI

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

AIMS

To evaluate the value of the SYNTAX Score (SS) II in predicting outcomes in patients undergoing TAVI.

METHODS AND RESULTS

A total of 402 patients with severe symptomatic aortic stenosis undergoing transfemoral TAVI were included. All patients underwent routine coronary angiography prior to TAVI. Pre-procedural angiograms were reviewed and the SS-I and SS-II was calculated using the SS algorithm. Patients were stratified in three groups according to SS-II tertiles. The primary endpoint was all-cause death and MACCE, a composite of all-cause death, cerebrovascular event or myocardial infarction at 1 year.

The median SS-II for PCI and CABG were 40.8 (IQR: 35.4-45.7) and 41.6 (IQR: 37.9-48.1), respectively. The c-statistic for SS-II PCI and SS-II CABG was 0.632 (95% CI 0.524 – 0.740, p = 0.022) and 0.480 (95% CI 0.380 – 0.580, p = 0.728), respectively, for 30-day mortality and 0.625 (95% CI 0.552 – 0.699, p = 0.001) and 0.539 (95% CI 0.466 – 0.612, p = 0.309), respectively, for 1-year mortality. Increased SS-II was associated with higher 30 day mortality (tertiles: 1st 3.7%, 2nd 5.2% and 3rd 11.2%, p=0.036) and major bleeding (p=0.015). The 1-year risk of death and MACCE was higher among patients in the 3rd tertile of SS-II (HR:2.60, p=0.002 and HR:2.66, p<0.001) and similar among patients in the 2nd tertile (HR:1.27, p=0.507 and HR:1.05, p=0.895) compared to patients in the 1st tertile. At four years, a higher SS-II was associated with higher rates of all-cause mortality (p = 0.017), cardiac mortality (p = 0.012) and MACCE (p = 0.017).

CONCLUSIONS

The SS-II, with inclusion of clinical variables as well as angiographic complexity, seems more suited to predict clinical outcomes in patients undergoing TAVI than the SS-I. Increased SS-II was associated with poorer clinical outcomes at one and four years post TAVI. Patients with a SS-II > 44 have a higher risk of cardiovascular death, stroke or MI than patients with a SS-II < 44 independent of the presence of CAD.

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Endothelin-1 receptor antagonism in the prevention of microvascular injury in patients with NSTE-ACS undergoing PCI: the ENDORA-PCI trial

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THEME: Coronary Interventions
TOPIC(S): NSTEMI

AIMS

The aim of the current study was to characterise the coronary microcirculation in patients with NSTE-ACS undergoing indicated PCI and effect of selective inhibition of endothelin-1 (ET-1) with oral ambrisentan.

METHODS AND RESULTS

This was a prospective, double blind, randomised, placebo controlled trial (ACTRN12615000709549) evaluating the effect of pre-procedural ambrisentan (10mg) on the coronary microcirculation in patients with NSTE-ACS. We postulated that impaired index of microvascular resistance (IMR) is associated with poor acute left ventricular (LV) recovery in this context. We further postulated that ET-1 is a significant mediator of coronary MVD through its effect on vasoconstriction and neutrophil activation, and that acute selective ET-1 antagonism may attenuate these effects and thus improve patient outcome. The primary endpoint was the difference in post-procedural changes in IMR (ΔIMR) between the two arms. Secondary end points included changes in myeloperoxidase (MPO; a marker of neutrophil activation) levels and LV systolic function. Coronary physiological parameters were measured immediately before and after PCI with St. Jude Certus^{TM} PressureWire^{TM} under maximal hyperaemia. IMR was derived using Pa x Tmn x (Pd-Pw)/(Pa-Pw). Serial echocardiograms were performed, and global longitudinal strain (GLS) derived as a marker of LV systolic function. Plasma was collected from both the peripheral arterial puncture sites and the culprit coronary arteries to assay peripheral and coronary MPO levels, respectively.52 eligible patients (25 ambrisentan, 27 placebo) were enrolled. Overall, 83% were males, while the mean age was 64.5. 78% of the patients presented with NSTEMI, while the rest had unstable angina. A post-procedural rise in IMR was strongly associated with a decline in patients' LV GLS (ΔIMR vs. ΔGLS, r=-0.42, p=0.004). Ambrisentan however, did not result in any significant difference in post-procedural ΔIMR or GLS.Ambrisentan was associated with a lower pre-procedural coronary MPO ($cMPO_{pre}$; median 116.8 vs. 177.3 ng/L, p=0.039) level, particularly for patients with NSTEMI. Longer symptom-to-balloon time was associated with a higher $cMPO_{pre}$ (r=0.42, p=0.006). In a multivariate model, ambrisentan and symptom-to-balloon time remained the only two independent predictors of $cMPO_{pre}$. Conversely, a longer symptom-to-balloon time was associated with a lower pre-procedural peripheral MPO level (r=-0.37, p=0.017) and remained the only determinant in a multivariate model.Ambrisentan also associated with a reduced post-procedural rise in high sensitivity troponin T (hsTnT; 31.2 vs. 137.7%, p=0.019), although it did not prevent periprocedural myocardial injury (PMI) as defined by the 3rd Universal Definition. Ongoing use of heparin up to the time of PCI was, however, associated with a lower incidence of PMI in our cohort. PMI was not predicted by patients' IMR or MPO levels.

CONCLUSIONS

Ambrisentan was associated with an attenuated intracoronary neutrophil activation and postprocedural hsTnT rise. While MVD predicted a decline in patients' LV function, ambrisentan did not appear to influence patients' IMR or GLS in our NSTEACS cohort. Peripheral MPO levels did not reflect the degree of coronary neutrophil activation, while $cMPO_{pre}$ increased as symptom-to-balloon time rose and may underpin the importance of timely intervention.

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Evaluation of the safety and efficacy of the Cobra PzF NanoCoated Coronary Stent (NCS) in 1,000 all-comer, consecutive, prospective, high-risk patient population: the e-Cobra registry

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

AIMS

The CeloNova COBRA PzF™ NanoCoated Coronary Stent is a *new stent design*, balloon expandable cobalt chromium alloy coronary stent with 71um thin struts that is pre-mounted on a custom rapid exchange balloon delivery catheter.

METHODS AND RESULTS

The alloy stent is surface treated with a nano-layer of Polyzene®-F (PzF) [Poly-bis(trifluoroethoxy) phosphazene]. Polyzene-F is an inorganic polymer with a high molecular weight. In vitro and in vivo studies have indicated that the nano-layer surface treatment is thrombo-resistant, and has anti-inflammatory and rapid endothelialization properties that help prevent tissue reactions. Pre-clinical studies have confirmed the thrombo-resistant and rapid healing properties and initial human studies have shown very promising clinical outcomes with low MACE, low TLR rates and no stent thrombosis at 1 year with 1 month DAPT.

1,000 all comers, consecutive patients, non-eligible for prolonged DAPT, are included from 18 sites. All patients undergoing treatment of "de novo" lesions in native coronary arteries, without limitation of number of stented vessels, saphanous vein graft and/or other bypass conduits were included. Primary objective is the assessment of MACE rate at 12 months (Cardiac death, MI, TLR) and secondary objective is the assessment of ST and TVR at 12 months, DAPT duration, patients in mono-therapy and bleeding per BARC definition. Patients' follow-up is performed at 1 month, 6 months and 12 months.

CONCLUSIONS

1,000 patients have been enrolled to date and 30 days results will be presented.

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Transcatheter aortic valve-in-valve implantation in failed stentless bioprostheses

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

AIMS

Transcatheteraortic valve-in-valve implantation (ViV-TAVI) in failed surgical bioprostheses has emerged as an alternative to re-do surgery. To date, very little is known about the performance of this procedure in degenerated stentless valves.

METHODS AND RESULTS

Out of 45 ViV-TAVI procedures reported in POL-TAVI registry, 20 failed stentless valves (14 stentless prostheses and 6 homografts) were compared with 25 failed stented prostheses. Both groups were also further matched with 45 native transcatheter aortic valve replacement (TAVI) cases. Mean follow-up was 633 (95% confidence interval [CI], 471-795) days and Valve Academic Research Consortium-2 (VARC-2) definitions were applied. At baseline, patients with stentless valves were younger (65.6±16.1 vs. 75.6±8.1 years, *P*=0.017), replacement was required later after surgery (11.5±7.3 vs. 6.2±3.4 years, *P*=0.006) and true internal diameter of surgical valve was larger than in those with stented prostheses (21.6, CI 20.5-22.6 mm vs. 18.7, CI 18-19.4 mm, *P*<0.0001). ViV-TAVI in stentless valves compared with stented ones was associated with longer procedural time (204, CI 144-264 min. vs. 138, CI 115-161 min., *P*=0.043) and larger amount of contrast (211, CI 157-266 ml vs. 135, CI 104-167 ml, *P*=0.017). Using VARC-2 composite endpoints, ViV-TAVI in stentless prostheses was characterized by lower device success (50% vs. 76% in stented vs. 88.9% in native TAVI, *P*=0.01), but comparable early safety (73.7% vs. 84% vs. 81.8%, respectively, log-rank *P*=0.667) and long-term clinical efficacy (72.2% vs. 72% vs. 73.8%, respectively,log-rank *P*=0.963). In the stentless cohort, worse device success was driven mainly by the need for >1 prosthesis (15%) and elevated transvalvular gradients (25%), whereas early safety was mostly affected by acute kidney injury (16%). The frequency of good functional status (NYHA I/II class) in the survivors of in-hospital period was 89.5%, similar to stented and native cohorts (92% and 93.2%, respectively, *P*=0.92).

CONCLUSIONS

Despite technical challenges and lower device success by definition, ViV-TAVI in stentless aortic bioprostheses is characterized by similar safety, efficacy and functional improvement as observed in patients with either failed stented or degenerated native valves.

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Timing of coronary angiography in survivors of out-of-hospital cardiac arrest

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

AIMS

Indications and timing of coronary angiography in patients surviving out-of-hospital cardiac arrest remain controversial. Our aim was to assess the impact of an early invasive strategy in patients presenting with an out-of-hospital cardiac arrest.

METHODS AND RESULTS

Between January 1st 2009 and December 31st 2014 a total 612 all-comer survivors of OHCA were admitted to our institution. No obvious non-cardiac cause could be found in 507 patients. Patients were distributed among three groups. Patients that received cardiac catheterization ≤3 hours were assigned to the 'early invasive' group (n=291), patients receiving cardiac catheterization ≥3 hours were assigned to the 'delayed invasive' group (n=100), and patients that did not receive cardiac catheterization were assigned to the 'non-invasive' group (n=116). Primary endpoint was all-cause mortality at 30 days. Survival status was ascertained using medical records from the hospital or by municipal civil registry.

Patients in the early invasive group presented more often with ST segment elevation, had a lower MAP at admission and were more often in shock. PCI was performed in 72% of the patients in the early invasive group versus 49% of the delayed invasive group. All-cause 30-day mortality was 28.9% in the early invasive group, 13% in the delayed invasive group and 56.9% in the non-invasive group. Cox multivariable regression analyses demonstrated age (HR 1.05; 95% CI 1.02 -1.07) and presentation with cardiogenic shock (HR 5.1; 95% CI 1.8 – 13.9) to be the sole independent predictors of 30-day mortality.

Irrespective of the timing of the invasive strategy, 30 day mortality rate was 31.4% in patients presenting with ST segment elevation versus 32.4% in patients presenting without ST segment elevation (p-value 0.87).

Subgroup analyses in patients presenting with or without ST segment elevation or cardiogenic shock demonstrated that an early invasive strategy was not superior to a delayed invasive strategy in improving 30-day mortality rates. The adjusted HR for an early invasive strategy for 30 day mortality was 0.89; 95% CI 0.34 – 2.37 in patients presenting with ST segment elevation vs. 0.74; 95% CI 0.47 – 1.16 in patients without ST segment elevation at presentation. The adjusted HR for an early invasive strategy for 30 day mortality was 0.83; 95% CI 0.47 – 1.47 for patients presenting in cardiogenic shock.

CONCLUSIONS

An early invasive strategy (<3h) in all-comer survivors of OHCA without obvious non-cardiac causes did not result in a significant benefit in 30 day mortality as compared to a delayed invasive strategy irrespective of the presence of ST segment elevation or cardiogenic shock at presentation.

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Repeat percutaneous edge-to-edge mitral valve repair procedures for the treatment of recurrent mitral regurgitation in patients at high-risk for surgery

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

AIMS

To explore the safety and effectiveness of repeat MitraClip implantation in patients with recurrent and symptomatic moderate-to-severe mitral regurgitation (MR).

METHODS AND RESULTS

From October 2008 to June 2016, a total of 328 patients underwent MitraClip implantation (Abbott Vascular, Santa Clara, CA) at our Institution and were included in the prospective GRASP (Getting Reduction of mitrAl inSufficiency by Percutaneous clip implantation) registry. After a median follow-up of 12 months, 70 patients (21.3%) had recurrent moderate-to-severe MR. Of these, 23 patients with symptomatic MR, anatomic suitability for additional clip implantation and at high-to-prohibitive risk for surgery (median EuroSCORE II of 7.9%, interquartile range [IQR] 4.0-12.2%) underwent repeat MitraClip procedures. Recurrent MR was caused by a partial clip detachment in 4 patients and by a progressive dilatation of the left ventricle (LV) in the remaining cases. Repeat procedures were performed after a median time of 595 days [IQR 303-1106 days] from the first procedure. Procedural success (defined as MR reduction to <2+) was achieved in 100% of patients. No cases of intraoperative death were encountered. At a median follow-up of 65 days [IQR 35-274 days], all-cause mortality was encountered in 7 patients (30.4%).

CONCLUSIONS

Repeat percutaneous mitral valve repair intervention is technically feasible in selected patients with symptomatic recurrent MR due to MitraClip failure. Relevant mortality at short-term follow-up probably reflects the high-risk profile of patients undergoing repeat procedures.

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Assessment of temporal absorption process of second-generation drug-eluting absorbable metal scaffold (DREAMS 2G): OCT insights from the BIOSOLVE-II first-in-man trial

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

AIMS

The novel drug-eluting metal fully absorbable scaffold DREAMS 2G showed a continuous favourable safety profile and stable performance outcomes up to 12 months. We assessed its absorption process using optical coherence tomography (OCT).

METHODS AND RESULTS

The prospective, international, multi-centre, first-in-man BIOSOLVE-II trial enrolled 123 patients with up to 2 de novo lesions with a reference diameter between 2.2 and 3.7 mm. All patients were scheduled for angiographic follow-up at 6 months, and –if subjects consented– at 12 months. Attenuation and backscatter analysis was performed in each analysed OCT cross section using a module developed by LKEB (Leiden University, The Netherlands).

Struts were present post-PCI, but were no more discernible visually at 6 and 12 months. The Maximum Attenuation values were 21.68, 6.59 and 7.16 at post-PCI, 6 and 12 months. The mean absolute difference between post-PCI and 6 months was -15.1 (95%CI: -16.3, -13.9) and between post-PCI and 12 months was -14.5 (95%CI: -15.9, -13.2). In figure 1, standard OCT frames are depicted in the top row; attenuation color-coded images are shown (middle row) at post-PCI (left), 6 (mid) and 12 (right) months; very high and high attenuation values (in red and yellow), which represent the struts, nearly disappear over time. The bottom row images show the whole analysed segment, each color-coded line represent one frame. The Maximum Backscattering values were 9.36, 7.89 and 8.08 at post-PCI, 6 and 12 months. The mean absolute difference between post-PCI and 6 months was -1.47 (95%CI: -1.7, -1.24) and between post-PCI and 12 months was -1.27 (95%CI: -1.45, -1.09).

CONCLUSIONS

The drug-eluting metal absorbable scaffold DREAMS 2G showed a fast absorption process, which is nearly complete at 6 months as shown by the significant reduction in attenuation and backscattering indices from baseline to follow-up. NCT01960504

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Percutaneous techniques for severe tricuspid regurgitation: is there a niche for these patients?

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THEME: Interventions for Valvular Disease
TOPIC(S): Tricuspid / Pulmonary valve, Other valvular and structural interventions

AIMS

The aim of this study is to evaluate the prevalence and characteristics of patients with Severe Tricuspid Regurgitation (STR) dismissed for surgery, who could benefit from novel percutaneous techniques in a high-volume hospital.

METHODS AND RESULTS

We retrospectively analyzed all the patients submitted to echocardiography during 2014 and 2015, and selected those with STR.

A total of 20,643 patients underwent echocardiography for any reason and STR was evidenced in 1.7% (n=348).Mean age was 67.8±12.7year-old and 54.6% were female (n=190). Ninety-seven percent(n=338) of STR were caused by secondary mechanisms such as left heart side valve disease in68.9% (n=240; due to 37.0% mitral, 15.2% aortic and 16.7% mitroaortic affections), ischemic cardiomyopathy in 12.9% (n=45), and pulmonary diseases in 13.2% (n=46). Forty-two patients (12%) had moderate to severe left ventricle systolic disfunction (EF <45%) and severe pulmonary hypertension (PAPs > 60mmHg) was found in 44.8% (n=156).

Patients with prior left heart valve surgery represent a high-surgical risk subgroup that correspond to a 25.9%of the total (n=90). Excluding from this group those pacemaker/defibrillator carriers (n=32) in whom the percutaneous approach may be contraindicated, a 16.6% of patient (n=58) could still benefit from these less invasive techniques.

CONCLUSIONS

A considerable number of patients with severe tricuspid regurgitation and high surgical risk could benefit from newly developed percutaneous techniques.

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Incidence and predictors of one-year outcomes after treatment of multivessel coronary artery disease with a thin strut DES with bioresorbable polymer

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

AIMS

The purpose of this study is to assess the performance of a thin-strut sirolimus eluting stent with bioresorbable polymer (Ultimaster™), in patients with mutlivessel disease (MVD) enrolled in a large worldwide 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 4597 patients enrolled so far and reached 1-year follow up, 2182 patients presented with MVD and were included in a pre-specified subgroup. MVD patients were on average 66 year-old, predominantly male (78%) and presented with the following risk factors: hypertension (65%), diabetes mellitus (30%) hypercholesterolemia (57%), current smoking (22%). Twenty seven % of the patients underwent previous PCI. More than half of the patients (61%) presented with acute coronary syndrome (ACS). The average number of vessel diseased was 2.35±0.48 per patient. Regarding lesion characteristics, 59.2% were complex (B2+C), 7.2% had ostial location, while 23.1% were moderately or severely calcified. In this group, 5.3% of patients had lesions in left main and 18.4% at bifurcation, 6.1% were in-stent restenoses while 50.3% were longer than 25mm. On average, 1.82±0.88 lesions were treated per patient. The number of stents implanted per patient was 1.78±1.06 and the total length of implanted stents per patients was 39.48±26.08 mm.

The clinical outcomes at 1 year were: any death 1.9%, cardiac death 1.3%, MI 1.6% and target vessel related MI 0.9%, clinically driven target lesion revascularization 1.4% and clinically driven target vessel revascularization 2.0%. The composite endpoints of target lesion failure (TLF) and target vessel failure (TVF) were 3.0% and 3.4%, respectively, with 1.1% stent thrombosis (definite+probable). The overall major adverse cardiac events (MACE) rates was 4.6%.

In multivariable stepwise logistic regression analysis independent predictors of death were: age>75 years (odds ratio (OR):2.43, p<0.001), diabetic patients (OR:1.81, p<0.025), renal impairment (OR:3.52, p<0.00001), patients treated for 3 vessels (OR:1.78, p<0.043) and stent diameter (OR:1.86, p<0.023). Predictors of TVF were: renal impairment (OR:1.91, p<0.017), patients treated for 3 vessels (OR: 1.78, p<0.004), total stent length implanted > 25 mm (OR:1.72, p<0.005) and patient having bifurcation lesion (OR:1.70, p<0.01). Predictors of stent thrombosis were: stent diameter (OR:3.35, p<0.0004) and CTO procedures (OR:4.11, p<0.006). Predictors of MACE were diabetic patients (OR:1.5, p<0.001), patients having bifurcation lesion (OR:1.69, p=0.008), patients treated for 3 vessels (OR: 1.9, p<0.001) and stent diameter (OR:1.5 p=0.015).

CONCLUSIONS

In patients with multivessel disease one-year clinical outcomes from a large worldwide registry representing contemporary PCI practice confirmed a good safety and efficacy profile of the Ultimaster™ DES.

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Relationship between OCT derived plaque characteristics and physiological significance determined by FFR

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

To evaluate the plaque composition of coronary stenoses as assessed by OCT according to physiological severity assessed with FFR. To evaluate the impact of plaque composition on target lesion revascularization.

METHODS AND RESULTS

87 de-novo lesions in 75 patients undergoing coronary angiography were included, all lesions were evaluated using FFR and OCT. Lesions were divided into two groups based on FFR values, FFR <0.80 (n= 48) physiologically significant and FFR > 0.8 (n=39) physiologically non significant. OCT analysis included minimum lumen area (MLA), mean and maximum lipid arc, LVI lipid volume index (mean lipid arc multiplied by lipid length), presence of thin cap fibroatheroma (TCFA), minimum and maximum calcium arc, presence of macrophages and microchannels. Clinical and OCT characteristics were compared between groups. Patients were followed up for a median of 69 months (IQR 7-92).There were no differences in clinical characteristics between groups. All lesions assessed were angiographically (diameter stenosis 58.15 ±7.23) and physiologically intermediate lesions (FFR 79.06 ± 10.56). There were no differences in plaque composition between physiologically significant and non-significant groups (calcific, fibrous, lipid: 17 (35%), 19 (40%), 12 (25%) vs 13 (33%), 14 (36%), 12 (31%), p=0.288). There were no differences in OCT characteristics between physiologically significant and non-significant groups including MLA (1.8 ± 1.01 vs. 2.06 ± 0.94, p = 0.223), mean lipid arc (12.83 ± 21.54 vs 22.17 ± 41.4, p 0.203), maximium lipid arc (55.19 ± 72.09 vs. 66.27 ± 90.42, p = 0.534), Lipid length (2.43 ± 3.82 vs 2.8 ± 4.77), Lipid volume index (262.11 ± 443.53 vs. 354.39 ± 717.84 p=0.483), mean calcium arc (28.63 ± 29.49, p 0.236), maximum calcium arc (88.11 ± 68.23, p = 0.359), presence of TCFA (3 vs 6, p 0.288), ruptured plaque (5 vs 1, p 0.218) and thrombus (1 vs 0, p =1). Lesions with positive physiology were treated with PCI while medication was optimized in patients with lesions with negative physiology.Overall MACE rate was 36%, all cause death 8%, myocardial infarction 10.6%, target lesion revascularization 6.6%, all revascularization 26.6%. Target lesion revascularization didn't vary between groups (FFR<0.8 4.17% vs. FFR >0.8 7.69% p=0.653), between plaque types (calcific 7.1%, fibrous 6.1%, lipid 4.3% p=1) or in the presence of TCFA (TCFA 12.5% vs non TCFA 5.1% p 0.487).

CONCLUSIONS

Plaque characteristics as assessed by OCT were not associated with physiological stenosis severity. In this small population plaque composition was not associated with target vessel revascularisation though there was numerically increased TLR in the presence of TCFA.

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Ticagelor is not superior to clopidogrel in patients with ACS - A report from SCAAR

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

AIMS

The aim of this study was to investigate whether treatment with ticagrelor is superior to clopidogrel in patients with ACS in “real-world”.

METHODS AND RESULTS

We used data from the SCAARregistry (Swedish Coronary Angiography and Angioplasty Registry) for the PCI procedures performed in Västra Götaland County in Sweden. The database contains information about all PCI procedures performed at five hospitals (~20% of all SCAAR data). All consecutive procedures between 2005 and 2015 for UA/NSTEMI and STEMI were included. We used multilevel modeling based on complete–case mixed-effects logistic regression to adjust for hierarchical database due to clustering of observations. The following variables were used for adjustment of risk estimates: age; gender; hypertension; hyperlipidemia; smoking status; diabetes; calendar year; indication for PCI; prior MI, CABG and/ or PCI; cardiogenic shock; severity of coronary artery disease; number of implanted stents; completeness of revascularization; type of stent. The primary combined endpoint was death or stent thrombosis at 30 days. The secondary end points were death at 30-days and death at one-year.

The total of 12,168 patients were included in the study of which 2,929 (19%) were treated with ticagrelor. 44% had STEMI. There were 555 events at 30-days of which 53 (9.5%) were stent thromboses. 844 patients were dead at one-year Treatment with ticagrelor was not associated with lower risk for primary endpoint (OR 0.97; 95% CI 0.66 - 1.43; P=0.887). Estimated risk of death at 30-days (OR 1.02; 95% CI 0.59 - 1.76; P=0.937) and one-year (OR 1.01; 95% CI 0.68 - 1.47; P=0.992) was not different between the groups. Sensitivity analysis has shown that for ticagrelor to reach statistical significance for independent association with the primary endpoint, the unmeasured confounder needs to have a relative risk >3 with prevalence of 40% in the ticagrelor group and 10% in the clopidogrel group.

CONCLUSIONS

In this observational study, treatment with ticagrelor was not superior to clopidogrel in patients with ACS treated with PCI.

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Initial experience with an expandable introducer consisting of a mesh and a sheath assembly for transfemoral TAVI

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

AIMS

Report the initial experience with the novel transGlide expandable introducer composed of a mesh assembly and a flexible sheath assembly.

METHODS AND RESULTS

The transGlide expandable introducer was used to facilitate vascular access in a total of 40 patients undergoing transfemoral TAVI with the ACURATE neo transcatheter heart valve. This introducer consists of an expandable mesh assembly and a flexible sheath assembly. The mesh assembly is introduced at 13F and provides a bearing surface for the sheath, which is designed to reduce the axial forces applied to the artery wall while the sheath is being inserted and removed. Vascular access was screened with computed tomography (n = 34) or MRI (n = 6). Mean diameter of the common femoral artery, the external iliac artery, and the common iliac artery was 7.2 +/- 1.2 mm, 7.6 +/- 1.3 mm, and 8.9 +/. 1.6 mm, respectively. A total of 17 patients (43%) had a minimal lumen diameter < 7.0 mm (range 4.1 - 11.9 mm). The degree of vessel calcification was moderate/severe in 27 (68%) and mild in 13 (32%). Five patients (13%) had extreme tortuosity (> 120 degrees). After preclosure with 2 ProGlides, transGlide was successfully inserted using only the mesh (n = 3), or the complete system (n = 37). TAVI was successfully performed in all patients. Patients were discharged after a median of 6 days post TAVI. At 30 day follow-up, there was no mortality and no stroke. The rate of major vascular complications and major bleedings was 1/40 (2.5%).

CONCLUSIONS

This early series shows that use of the transGlide expandable introducer facilitates safe femoral access for large bore catheters resulting in very low vascular complication and bleeding rates.

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Very long-term outcomes following contemporary STAR technique for the treatment of CTO

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

To analyse factors leading to major adverse cardiovascular events (MACE) (a composite of myocardial infarction, cardiac death, or the need for target vessel revascularisation (TVR) and those leading to restenosis in follow-up coronary angiography.

METHODS AND RESULTS

An observational cohort study was performed. The study population comprised consecutive patients who underwent CTO PCI via the contemporary STAR technique at the Interventional Cardiology Unit, San Raffaele Scientific Institute between January 2005 and August 2013. Clinical follow-up was performed by telephone contact or office visit. Angiographic follow-up was usually scheduled post-procedure for reassessment of the outcome. Baseline coronary angiograms and CTO PCIs as well as follow-up angiograms were reviewed. Data were analysed using IBM SPSS Statistics, version 23.0.

The study population comprised 125 patients (133 lesions) who underwent successful CTO revascularisation with the STAR technique and consequent DES implantation. MACE was assessed on a per patient basis whilst angiographic outcomes were analysed on a per lesion basis. Angiographic follow-up was achieved in 108 patients (86.4%). The median follow-up of the study patients was 5.44 years (interquartile range 3.06-7.95 years). During this period, 54% of cases exhibited MACE, mainly driven by TVR (47.6%). Multivariate Cox regression analysis revealed female gender (p= 0.021; OR 2.79, 95% CI 1.17-6.67), chronic kidney disease (p= 0.007; OR 7.58, 95% CI 1.73-33.33) and the occlusion of side branch/ distal vessel during the procedure (p< 0.001, OR 3.23, 95% CI 1.88-5.52) to be the significant predictors of MACE. With regards angiographic follow-up, in-stent restenosis (ISR) was seen in 28.6% of cases, mostly focal in nature. With regards occlusive ISR, they were noted in 27.8%. TIMI flow less than 3 at the end of the procedure (p= 0.034; OR 39.05, 95%CI 1.32-1159.33) was found to be the sole independent predictor of restenosis whilst occlusion of side-branches/ distal vessels (p< 0.001; OR 3.94, 95% CI 1.87-8.33) and final TIMI flow less than 3 (p= 0.002; OR 3.92, 95% CI 1.4-9.35) were statistically significant in predicting reocclusion.

CONCLUSIONS

The current study suggests that female gender together with chronic kidney disease and occlusion of side-branches/ distal vessels results in worsened outcome at long-term follow-up; final TIMI flow less than 3 results in restenosis while occlusion of side-branches/ distal vessels and final TIMI flow less than 3 are predictors of reocclusion. Nonetheless, the STAR technique is a safe and effective bail-out strategy, both in the short- and long-term. Further observational studies are needed to provide more conclusive evidence.

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Optimal assessment of lesion severity in the left anterior descending artery by quantitative flow ratio. The wire-free invasive functional imaging WIFI LAD study

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

We aimed to compare different analysis strategies and propose an optimal QFR analysis algorithm for patients with proximal LAD disease, diffuse LAD disease with multiple lesions or aneurysms and uncertain reference size.

METHODS AND RESULTS

Methods: The study was a pooled analysis of the WIFI I (NCT02795585) and WIFI II (NCT02264717) QFR studies. Cases with lesions or diffuse disease involving the proximal LAD were analysed by QFR using three different analysis protocols. Methods were based on the reference contours fitted either to the LAD (QFR_LAD), the LMCA (QFR_LMCA), or a gender specific reference size in the proximal LAD (QFR_FIX). The analysis with the best fit was evaluated and modified into a new algorithm (QFR_optimal). Two blinded observers applied the algorithm to the pooled data.**Results:** A total of 199 LAD lesions were analysed in the two studies and 63 had diffuse disease involving the proximal LAD. After exclusion of cases with short non-visible left main coronary arteries, severe overlap or no nitroglycerine administration, 40 cases entered analysis.

The mean difference, standard deviation and AUC for the three models were QFR_LAD: -0.03 (SD 0.10), AUC=0.68; QFR_LMCA: 0.05 (SD 0.11) AUC=0.76; and QFR_FIX 0.02 (SD 0.09) AUC=0.84. Diagnostic accuracy was determined by the receiver operator characteristics (ROC) curves and best fit was shown for QFR_FIX. The QFR_optimal algorithm was fitted with a set of rules based on gender specific reference reference size. A total of 34 patients entered QFR_optimal analysis after exclusion of LMCA with no segments above 3.5 mm and one unanalysable case. The first and second observer achieved an AUC of 0.90 and 0.89 and the mean difference between QFR and FFR was 0.02 (SD 0.07) for both.

CONCLUSIONS

Functional evaluation ofprognostic important proximal LAD stenosis by QFR using an optimal analysis algorithm resulted in good precision and diagnostic agreement compared to FFR.

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Bicuspid aortic valve in patients undergoing TAVR

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

AIMS

Data on transcatheter aortic valve implantation (TAVI) in bicuspid aortic valve (BAV) are limited. We sought to determine the prevalence and clinical relevance of BAV in a TAVI cohort using multidetector computed tomography (MDCT).

METHODS AND RESULTS

Out of 2103 consecutive patients with severe native aortic stenosis undergoing TAVI in two centers between June 2011 and November 2016, those without pre-procedural MDCT (n=86) and insufficient diagnostic quality (n=51) were excluded, thus a total of 1966 patients were analysed. After further exclusion of cases with indeterminate phenotype (n=21) and tricuspid aortic valve with acquired fusion (n=60), finally 144/1966 (7.3%) patients were classified as BAV. Using 1-to-1 nearest-neighbor matching, for each patient with BAV (n=144) we identified one control patient with tricuspid valve (n=144). Procedural outcome was adjudicated according to VARC II criteria.

In BAV, aortic regurgitation ≥2° (11.1% vs 2.8%, *P*=0.005), aortic root injury (3.5% vs 0%, *P*=0.024), and malpositioning (14.0% vs 7.0%, *P*=0.054) were more frequent, particularly when non-balloon-expandable or first generation devices were implanted. In contrast, results were similar for the use of balloon-expandable or second generation prostheses. There was no difference regarding 30-day mortality and device success.

Within the BAV-cohort, independent predictors for AR≥2 were malpositioning (OR 12.20 (2.95-50.39), *P*=0.001), the use of first-generation devices (OR 5.26 (1.45-19.17), *P*=0.01), and female gender (OR 6.67 (1.53-29.20), *P*=0.01). Independent predictors for permanent pacemaker implantation were a deep device position (OR 5.55 (1.18-26.19), *P*=0.03) and coronary cusp fusion with a calcium bridge (OR 7.69 (2.08-28.46), *P*=0.002).

CONCLUSIONS

TAVI is feasible in BAV with similar short-term mortality and device success, but may predispose to procedural challenges with an increased need for careful peri-procedural planning. This requires an appropriate identification of BAV based on a sophisticated imaging strategy that includes MDCT with systolic reconstructions and a more attentive appreciation of bicuspid phenotype.

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Intracoronary electrocardiographic parameters predict mortality rates at mid-term follow-up (up to 60 months) after stenting coronary bifurcation lesions insights from intracoronary electrocardiogram (ECG) and myonecrosis after bifurcation stenting (COSIBRIA&CO) (ClinicalTrials.gov Identifier:NCT01268228)

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

The aim of the study is to explore the differences in the rate of procedural ischemia after bifurcation lesion PCI detected with intracoronary electrocardiography (icECG) and the exploration of causation mechanisms.

METHODS AND RESULTS

After placement of intracoronary guidewires in the main branch (MB) and side branch (SB) the uninsulated proximal wire ends were connected to unipolar V leads. Intracoronary unipolar ECGs were recorded before, during and after stent placement and at the end of the procedure. We recorded icECG signal from SB after stent placement in MB. Finally, the coronary wire was placed in every distal vessel with reference caliber >1.0mm, as well as in MB just below the stent, "mapping" zones for ischemia presence and distribution. Changes in ST-segment, QRS complex, QT-interval prior, during and at the end of PCI were analyzed. Provisional T-stenting was the default strategy. The patient population consists of 232 patients with stable/unstable angina: 67% males, mean age 65±9, diabetics 37%, 34% had previous MI, 47% previous PCI and 60% multivessel disease. Main vessel treated - LAD (74%). The true bifurcation lesions (Medina xx1) were 56.7%. SB icECG elevation after stenting the main branch was found in 68,6% pts. After stenting MB, SB diameter stenosis >75% was found in 48,3% (51,6 had STE and 49,4 % did not have STE). On multivariate analysis independent predictors for mortality were parameters of i.c. ECG only: residual icECG ST elevation in the side branch after stent placement in MB, the difference in QRS complex width (pre-post PCI) in SB region, the R/S amplitude ratio of SB QRS complex.

CONCLUSIONS

The distribution of icECG changes in SB are predictive for mortality.

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Interim data from an ongoing study show: pressure-controlled intermittent coronary sinus occlusion results in cardioprotection when given in adjunct to PCI

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Pressure controlled intermittent coronary sinus occlusions (PiCSO) aims at improving microvascular reperfusion after primary PCI for ST-elevation myocardial infarction (STEMI), potentially augmenting infarct size reduction.

METHODS AND RESULTS

Eighty (80) subjects with a first anterior MI were enrolled in a prospective, parallel controlled study at 4 centers in the United Kingdom. First, balloon angioplasty of the culprit lesion was performed to obtain TIMI 2 or 3 flow, after which a PiCSO Impulse catheter (Miracor Medical Systems, Vienna, Austria) was placed in the coronary sinus. After PiCSO therapy was started, coronary stenting was performed. Subjects that met the in-, and exclusion criteria, arriving at the ER on days that a non-PiCSO trained physician was on call, received conventional therapy and were recruited as parallel controls. Left ventricular (LV) function, infarct size (IS) and Microvascular obstruction (MVO) was assessed by cMRI at 5-day post MI.

PiCSO therapy was performed in 35 subjects and 45 subjects served as the control. Baseline characteristics were well matched between groups with the exception of age, gender, height, and pre PCI TIMI flow. At the time of this abstract cMRI data was available in 48 subjects for myocardial function and in 42 subjects for IS analyses.

Significantly fewer PiCSO-treated subjects compared to control had evidence of MVO (4/18 (22.2%) vs. 13/25 (52.2%), p=0.049). At 5-days post MI, subjects treated with PiCSO showed significant improvement of LV function: ejection fraction (LVEF) (52.2% ± 8.3% vs. 46.9% ± 8.6%, p=0.03), LV end-systolic volume (LVESV) (41.1 ± 12.4 vs. 51.2 ± 15.1, p=0.013) and LV end-diastolic volume (LVEDV) (84.5 ± 14.4 vs. 94.8± 17.3, p=0.027). In addition, PiCSO-treated subjects had significantly smaller IS (9.46±8.71 vs. 17.77±12.65, p<0.015). After multivariate analysis to adjust for differences in baseline features, PiCSO was associated with a significant reduction in IS at 5-days by -8.1% (95% CI [-15.2%; -1.0%], p=0.026) compared to the control group.

CONCLUSIONS

Interim analysis of this ongoing study show that PiCSO started immediately after flow restoration in subjects with STEMI and prior to PCI is associated with evidence of reduced MVO and IS with improved left ventricular function measured 5-day post MI.

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Long-term clinical outcomes of BRS to treat all-comer coronary artery disease: single-centre experience

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

AIMS

Multiple studies have proven feasibility and safety of the Absorb bioresorbable vascular scaffold (BVS). Nevertheless, data on medium- to long-term outcomes are limited and available only for simpler lesions.

METHODS AND RESULTS

This was an observational, retrospective, single-center study of consecutive patients treated with the Absorb BVS in a lesion subset representative of daily clinical practice, including calcified lesions, total occlusions, long lesions, acute coronary syndromes, in-stent restenosis and small vessels.

From May 2013 to June 2015, 441 patients with 581 lesions underwent percutaneous coronary intervention with BVS implantation within this period at our institution and were included in the current analysis. Briefly, the mean age was 61± 10.5 years, 76.7% of the patients were male, 22.7% had diabetes and 71.2% presented for acute coronary syndrome (either unstable angina, non-ST elevation acute coronary syndrome or ST-segment elevation myocardial infarction). 29.1% of the lesions were American College of Cardiology/American Heart Association classification type B2/C lesions. Mean number of scaffolds per patient was 1.26 ± 0.59, invasive imaging was used in only 5.4% of the patients, mean total scaffold length was 25.27 ± 13.96 mm and post-dilation rate was 84.2%.

Mean follow-up period was 815.65 ± 243.47days. 64 (14.5%) patients were lost to follow-up. There were 2 cardiovascular deaths (0.5% per patient, 0.3% per lesion),11 scaffold thrombosis (2.5% per patient, 1.9% per lesion), 21 target vessel myocardial infarction (4.8% per patient, 3.6% per lesion) and 32 target lesion revascularization (7.3% per patient, 5.5% per lesion). Using Cox regression multivariate analysis, long lesion >32mm was the only predictive rate of device-oriented composite endpoint (cardiac death, target vessel myocardial infarction and target lesion revascularization), p=0.03, OR=2.4.

CONCLUSIONS

In our study, BVS implantation in a complex patient and lesion subset was associated with an acceptable rate of adverse events in the longer term. Scaffold thrombosis rate is slightly higher than those seen in recent drug-eluting stent cohorts. Long lesions was predictive of device-oriented composite endpoint.

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Comparative efficacy of DES in CTO: a report from the SCAAR

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

AIMS

Our aim was to compare first and second generation DES regarding long-term risk of in-stent restenosis and stent thrombosis.

METHODS AND RESULTS

We used data from the SCAAR registry (Swedish Coronary Angiography and Angioplasty Registry) for the PCI procedures performed in patients with CTO between 2003 and 2015 for stable angina, UA/NSTEMI and STEMI. The database contains information about all procedures performed in Sweden. We compared four groups of DES: paclitaxel- (PES, n=1,557), sirolimus- (SES, n=932), zotarolimus- (ZES, n=1,699) and everolimus-eluting stents (EES, n=2499). We modelled our data with multilevel Cox proportional-hazards regression with stents as the primary observational unit while patients and hospitals were treated as random-effect variables. To adjust for differences in patient's characteristics the following variables were used: age, gender, hypertension, hyperlipidemia, smoking status, diabetes, severity of coronary artery disease, indication for PCI (stable angina, UA/NSTEMI and STEMI), stent length and stent diameter. The primary combined endpoint was time to first occurrence of either stent thrombosis or restenosis.

The total of 6,687 DES were implanted in 1,699 CTO patients. Median follow-up was 3.3 years. The total number of events was 567 of which 112 (19.6%) were stent thromboses. At one-year, unadjusted probability of combined event was 2.6% in ZES, 1.7% in EES, 3.5% in SES and 3.2% in PES group. Treatment with PES (adjusted HR 1.50; 95% CI 1.18 - 1.91; P=0.001) and SES (adjusted HR 1.37; 95% CI 1.06 - 1.77; P=0.018) was associated with higher risk for restenosis or stent thrombosis compared to EES. Similarly, treatment with PES (adjusted HR 2.22; 95% CI 1.32 - 1.70; P=0.002) and SES (adjusted HR 2.11; 95% CI 1.17 - 3.79; P=0.012) was associated with higher risk of stent thrombosis compared to EES. We found no differences between EES and ZES nor between SES and PES.

CONCLUSIONS

In this observational study, treatment of CTO with EES and ZESwas associated with substantially lower risk of in-stent restenosis and stent thrombosis than PES and SES.

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Gender differences in mortality in patients with STEMI - A report from SCAAR

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

AIMS

Debates are ongoing as to whether there exists sex-specific differences in clinical course, diagnosis and management of acute myocardial infarction (AMI) and to what extent these differences can be alleviated by changes in clinical praxis.

METHODS AND RESULTS

We compared all men and women who were treated for AMI at a cardiac care unit in Västra Götaland County between January 1995 and October 2014 by obtaining data from the prospective SWEDEHEARTregistry (Swedish Websystem for Enhancement of Evidence-Based Care in Heart Disease Evaluated According to Recommended Therapies). We performed unadjusted and adjusted Cox proportional hazard and logistic regression analyses on complete case data as well as on imputed datasets.

48.118 patients (35.4% women) were diagnosed with acute myocardial infarction and were included in the analysis. Women as a group had better age-adjusted prognosis than men but this survival benefit was absent for younger women (<60 years) and for women with ST-elevation myocardial infarction (STEMI). Compared to men, younger women and women with STEMI were more likely to develop pre-hospital cardiogenic shock (adjusted OR 1.67, 95%CI 1.30 – 2.16, p<0.001 and adjusted OR 1.31, 95%CI 1.16 – 1.48, p<0.001) and were less likely to be prescribed evidence based treatment at discharge (p<0.001 for beta blockers, angiotensin converting enzyme inhibitor/angiotensin receptor antagonist, statins and P2Y12 antagonists). Differences in treatment between the genders did not decrease over the course of the study period (p>0.1 for all treatments).

CONCLUSIONS

Younger women and women with STEMI have higher risk to develop cardiogenic shock and have worse short- and long-term prognosis after acute myocardial infarction. Women are less likely than men to be prescribed evidence based treatment after acute myocardial infarction.

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Assessment of neointimal healing using OCT at three months after biodegradable polymer DES implantation in AMI: result of randomised comparison of the effect of ticagrelor vs. clopidogrel

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

AIMS

We purposed to compare the effect of ticagrelor and clopidogrel on neointimal healing on DES using OCT in acute myocardial infarction (AMI). We also sought to find relevant factors to have an impact on neointimal healing in AMI.

METHODS AND RESULTS

This study was a prospective, randomized trial conducted in two university hospitals in Korea. Eligible AMI patients were randomly assigned to each treatment arms (clopidogrel vs. ticagrelor) in a 1:1 ratio. Primary endpoint was neointimal coverage on stent struts and neointimal hyperplasia at 3-month OCT. All enrolled patients were treated with biodegradable polymer coated DES (BP-DES; Orsiro, Biotronik AG, Switzerland) for culprit lesions. Post-PCI and 3-month follow up OCT was evaluated for stented culprit lesions and nonculprit lesions. DAPT with aspirin and study drug was continued until 3 month OCT.

Total 107 lesions in 106 patient who underwent PCI were initially included, and total 84 lesions in 83 patients finally finished 3 months OCT evaluation. There was no significant difference in baseline clinical, angiographic, and procedural characteristics between two arms. There was no difference in post-PCI OCT characteristics. Median rate of uncovered struts of the stents were 12% [quartiles, 4%; 20%] and 10% [6%; 20%] in clopidogrel and ticagrelor arms, respectively (p=0.886). Uncovered stents (with uncovered struts ≥6%) were 26 (65%) and 32 (73%) in clopidogrel and ticagrelor arms, respectively (p=0.597). There was also no difference of mean neointimal thickness between two arms (clopidogrel vs. ticagrelor = 48 μm [35 μm; 61 μm] vs. 52 μm [34 μm; 63 μm], p=0.734).

Linear regression analysis showed significant correlations between uncovered strut rates and OCT-defined stent size index defined as a ratio of stent diameter to reference vessel diameter (r=-0.291, p=0.007) and between uncovered strut rates and mean incomplete stent apposition area (r=0.230, p=0.035). Multivariate logistic regression model demonstrated that suboptimal sizing of stent (odds ratio (OR) 4.40 (95% confidence interval, CI 1.46-14.4), p=0.010), stent malapposition at post-PCI (OR 3.49, 95% CI 1.21-10.7, p=0.023) and tapered vessel (OR 3.36, 95% CI 1.12-11.4, p=0.038) were independent predictors of uncovered stent at 3 month OCT.

We determined a total of 35 lipid-laden plaques in nonculprit lesions (15 vs. 25 in clopidogrel vs. ticagrelor arms, p=0.121). There was no difference of fibrous cap thickness measured at baseline and follow-up OCT. Fibrous cap thickness was slightly increased during 3 months, but there was no difference of the change between two arms (19 ± 27 μm and 19 ± 25 μm in clopidogrel and ticagrelor arms, respectively, p=0.987).

CONCLUSIONS

The study demonstrated ticagrelor may have no immediate effect on thickening of fibous cap of nonculprit lipid-laden plaques as well as neointimal healing on BP-DES at culprit lesions in AMI patients. Optimal implantation of DES including correct sizing and sufficient apposition of struts may secure better neointimal healing in AMI patients. Nevertheless, ticagrelor as a more potent antiplatelet should be warranted in AMI patients because PCI may not be easy to be optimally performed in many AMI cases.

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A novel way of performing FFR using a first-in-man dedicated intracoronary adenosine infusion microcatheter

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

AIMS

To evaluate the safety and efficacy of intracoronary (IC) adenosine infusion using the novel HYPEREM™ FFR infusion microcatheter compared with the standard intravenous (IV) adenosine infusion method.

METHODS AND RESULTS

The Hyperemic study is a randomised, single-blinded crossover investigation to evaluate the effectiveness, safety and feasibility of a novel dedicated over-the-wire IC infusion micro-catheter (HYPEREM™IC) for measuring fractional flow reserve (FFR) and comparing it against the standard IV administration of adenosine method.During coronary angiography, if a coronary stenosis was thought to be of intermediate severity and an FFR procedure clinically indicated, then subjects were deemed eligible for randomisation.FFR measurements were performed twice for each stenosis to be studied using a standard IV adenosine (140-180mcg/kg/min) infusion protocol versus the investigational device with a non-weight adjusted IC adenosine infusion (360mcg/min) using the FFR microcatheter. All patients underwent both procedures, and were randomised and blinded to the order in which they received adenosine, with a minimum of 3 minutes washout.The primary endpoint was demonstration of non-inferiority between the IC infusion device versus the IV infusion standard method in measuring FFR. Secondary endpoints were incidence and severity of side effects, time to achieve maximal hyperaemia, and dose and duration of adenosine infusion.Patients were enrolled from 3 sites in the United Kingdom: London, Glasgow and Brighton. A total of 41 patients were suitable for randomisation, 20 to the IC procedure first and 21 to the IV procedure first. All patients received both procedures in the order of randomisation. Two patients were excluded due to failure to achieve hyperaemia.The mean (SD) FFR for each mode of administration was 0.84 (±0.09) IV versus 0.82 (±0.09) IC. There was no evidence of a period effect (p=0.90) or a period/procedure interaction (p=0.75). Within patient differences in FFR (IC minus IV), revealed a mean of -0.02 with a 95% confidence interval of -0.03 to -0.01Time (mean ± SD) in seconds to achieve peak FFR was 84 (±37) in the IV vs. 40 (±24) in the IC infusion arm (p<0.0001). Duration of adenosine infusion was 105 (±33) for IV vs. 57 (±35) for the IC route (p<0.0001). Total mean dose (mcg) of adenosine administered was 21676 (±9667) for IV versus 345 (±209) for IC.Patients experienced more chest discomfort during IV infusion with 32/41 (78.0%) reporting slight to severe chest discomfort compared to 12/41 (29.3%) during the IC procedures. No patients reported severe chest discomfort during the IC procedures compared to 5/41 (12.2%) during the IV procedures.

CONCLUSIONS

IC infusion of adenosine is a reliable, faster and better tolerated method of achieving maximal hyperaemia compared to IV administration. The total IC dose required was about 1.5% of the equivalent IV dose yet achieved a more rapid & stable steady state of maximal hyperaemia. Moreover, FFR values were consistently and statistically significantly lower with the IC infusion. Of note, 4 of the 39 patients were below the 0.8 FFR threshold with IC infusion, but were classified as clinically non-ischemic with IV infusion. No patients with a functionally ischaemic lesion were classified incorrectly by IC infusion. This raises an important question as to whether we may be failing to achieve maximal hyperaemia in a proportion of patients undergoing physiological assessment of coronary artery stenoses.

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Separate assessment of hyperaemic epicardial and microvascular conductance using coronary pressure and flow velocity

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Invasive assessment of the coronary circulation has been largely based on the use of pressure ratios and resistance. Assessment of epicardial- (C_{EPI}) and microvascular conductance (C_{MICRO}), might provide a more coherent and intuitive approach.

METHODS AND RESULTS

Validation of this new approach was performed in a total of 403 both obstructive and non-obstructive coronary vessels interrogated with intracoronary Doppler and pressure in 261 patients with stable angina pectoris. Hyperaemic mid-late diastolic pressure and flow velocity (PV) relationships were calculated from PV loops using an automated algorithm. The slope of the linear PV relationship was first calculated from both aortic and intracoronary pressures and, subsequently, used to derive separately C_{EPI} , C_{MICRO} and zero-flow pressure (Pfz). Median C_{EPI} and C_{MICRO} were 4.56 (IQR 2.18-8.64) and 1.28 (IQR 0.95-1.73) $cm/s^{-1}/mmHg^{-1}$ respectively. Concordance in stenosis severity classification of two validated indices of stenosis severity (FFR and hyperemic stenosis resistance) was used as a robust reference standard to validate C_{EPI}. ROC curves demonstrated an excellent ability of C_{EPI} to characterize significant epicardial stenoses indicating a cut-off of 1.69 (AUC 0.93) with a sensitivity of 93% and a specificity of 82%. Validation of C_{MICRO} (previously reported in endomyocardial biopsies) was not feasible in this population given the lack of a reference standard. Mean Pzf was 29.89±14.16 mmHg.

CONCLUSIONS

A comprehensive assessment of the coronary circulation, based on separate calculation of epicardial- and microcirculatory conductance, is feasible and provides a clear, coherent depiction of coronary haemodynamics in ischaemic heart disease. As part of this novel approach, calculation of zero flow pressure (an index of extravascular compression) can also be performed. The findings should foster the development of simple, reliable methods for its calculation in the clinical arena.

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New smart needle: an easy and cheap way to cannulate antegradely the superficial femoral artery

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THEME: Peripheral Interventions
TOPIC(S): Below the knee

AIMS

Antegrade superficial femoral artery puncture is by far the preferred approach for below the knee (BTK) procedures. We describe a simple and cheap way to selectively cannulate the peripheral artery even in challenging situations.

METHODS AND RESULTS

Angiographic visualization of the vessel to selectively cannulate using a different arterial access (contralateral leg or a brachial artery), is frequently used when direct puncture results to be somehow complex or unsuccessful. However, this approach considerably prolongs procedure time along with radiologic exposure; it implies an adjunctive arterial puncture, therefore increasing the likelihood of unnecessary complications. Finally, it increases contrast utilization. An alternative consists in attempting to visualize the target vessel by an echo scan. Again, this results in significant procedural time prolongation and requires the presence of a dedicated and experienced sonographer in the Cath-Lab, a condition which is not necessarily met in all catheterization laboratories.
We developed a simple, innovative technique based on the use of a pressure-guided antegrade puncture of the superficial femoral artery that proved to be successful in the large majority of challenging cases.
The last consecutive 216 BTK procedures performed in our Centre and documented in our internal database, have systematically employed an antegrade isocurrent approach, possibly combined with retrograde pedal or posterior tibial puncture in more challenging cases. Furthermore, to optimize timing and contrast utilization and to minimize embolic complications, all diagnostic and interventional procedures have been performed using the ACIST – CVi contrast injection system (ACIST Med. Syst. Inc. Eden Prairie MN) that provides in line continuous hemodynamic monitoring and enables real time pressure reading.
We use for the arterial puncture a 70mm 18 Gauge Cook needle (B-Braun AG, Melsungen, FRG), directly connected to the arterial line of the CVi device. The needle is advanced through the skin one inch proximally to the inguinal ligament with a 45° angulation and a slightly medial orientation pointing at the homolateral big toe. As soon as the needle enters the target vessel, the arterial pressure wave appears on the monitor screen, confirming proper vessel cannulation. A few amount of contrast medium is then injected directly through the needle from the ACIST pump, allowing instant visualization of the selected vessel, confirming proper luminal positioning . A guidewire is then advanced according to the standard Seldinger technique and the procedure carried on.
Out of a total of 216 BTK procedures, in 100% of cases we managed to find and successfully cannulate the arterial vessel when patent.

CONCLUSIONS

Pressure guided Cook needle technique is a feasible, reproducible, time and cost effective procedure to selectively cannulate antegradely the superficial femoral artery. We deeply encourage to promote this approach in order to save time , increase cannulation success rate and reduce patient discomfort

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Age-stratified clinical outcome after PCI or CABG for treatment of left main coronary artery stenosis. A NOBLE substudy

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

AIMS

It is unknown if age is an important factor in selecting percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG) for revascularization of patients with left main coronary artery (LMCA) stenosis.

METHODS AND RESULTS

Patients randomized in the NOBLE trial were analyzed according to age under or above 67 years. The main endpoint was the composite of all-cause mortality, non-procedural myocardial infarction, repeat revascularization and stroke (MACCE). Results are 5-year Kaplan-Meier estimates. A total of 1201 patients were randomized in NOBLE and 1184 entered analysis. Patients 67 years and older were treated by PCI (310) or CABG (312) and MACCE was 39% for PCI and 21% after CABG (HR1.74 95% CI 1.22-2.47, p=0.002). Patients younger than 67 years old were treated by PCI (282) or CABG (280) and MACCE was 18% for PCI and 15% after CABG (HR 1.25, 95% CI 0.77-2.00, p=0.36).

CONCLUSIONS

In treatment of LMCA stenosis, outcome after PCI and CABG did not differ in younger patients but PCI was associated with inferior outcome in elderly patients.

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Periprocedural and long-term complications in percutaneous LAA occlusion: impact of echocardiography and angiography sizing agreement

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

To investigate the frequency of sizing agreement between transesophageal echocardiography (TEE) and angiography for LAA occlusion Amplatzer™ devices and whether it have an impact on outcomes and to stablish which of modalities is more reliable

METHODS AND RESULTS

Outcomes of 134 patients with successful device implantation and available TEE-angiography data on LAA dimensions (age 72.8±9.1 years; 70% male) were analyzed. According to TEE/angiography coordination study population divided to agreement (n=76) and disagreement (n=58) groups. Cut-off point for disagreement was defined as more than 2 mm difference for dimensions less than 19 mm, and more than 3 mm for dimensions greater than 19 mm. For further classification, the final device chosen by operator was compared with device suggested by TEE and angiography according to manufacturer sizing chart in each group. The periprocedural (within 7 days after the procedure) major adverse events (MAE) were measured as composite of all cause death, severe pericardial effusion, device/air embolization, cerebrovascular events, myocardial infarction (MI) and vascular complications requiring transfusion or surgical/endovascular intervention. Total device-related peri-procedural adverse events were defined as MAE and pericardial effusion. Long-term events were a composite of cardiovascular death, cerebrovascular events, systemic embolization, major bleeding requiring transfusion or intervention during follow-up.

TEE/angiography agreement existed in 57% patients undergoing LAA closure. Total peri-procedural complications and MAE were significantly higher in the disagreement group (P=0.03 and 0.04, respectively). No significant difference between groups in the occurrence of the long-term events was found (P=0.57). In disagreement group, higher frequency of total peri-procedural adverse events occurred when operators did not follow imaging modalities (29%) compared with angiography-guided (18%) or TEE-guided (0%) device-size selection. In agreement group, it occurred more frequently in patients when bigger device size was selected (12%) compared with same (4%) or smaller (0%) size. TEE was an independent predictor for better periprocedural prognosis (OR=0.15; CI 95%=0.03-0.70; P=0.01).

CONCLUSIONS

Agreement between TEE and angiography could be achieved in 57% of procedures and had better periprocedural prognosis. In case of disagreement, it is therefore recommended to repeat measurements. If closer dimensions between the two modalities cannot be obtained, TEE measurement might be more reliable

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Local intravascular delivery of low-density-lipoprotein cholesterol causes increased neointimal thickening in the healthy porcine coronary model. Insights into development of model of atherosclerosis

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

AIMS

We aimed to evaluate the vascular response after local, intramural delivery of human, highly atherogenic lipids in the healthy domestic swine (DS) coronary arteries with anticipation of development of a reproducible model of atherosclerotic lesions.

METHODS AND RESULTS

A total of 24 coronary artery segments of 10 DS were enrolled. Following triple, 130% balloon overstretch injury (POBA), segments were assigned to local delivery of 2 ml of oxydated human LDL from apheresis (400 mg/dL, n=9), 0.9% NaCl (control, n=7) or to POBA alone. The solutions were infused with the modified, circumferential micro-needle catheter (Peregrine, ASI) into the vessel wall.

Following 28 days, optical coherence tomography (OCT), virtual histology IVUS (VH-IVUS) and NIRS spectroscopy was performed. The vessel segments were harvested for independent pathological analysis.

The balloon injuries expressed as balloon to artery ratios were comparable among groups and the delivery of solutions was feasible in all cases. At 28 days the plaque burden in IVUS was not different between LDL, control and POBA groups respectively (23.4±12% vs. 16.7±9.7%, 16.7±9%; p=0.45) and the % Area Stenosis in OCT was highest in the LDL group (23.6±13 vs. 10.8±7 vs. 8.1±7%; p=0.02). The presence of necrotic core (LDL: 55.5%, Control: 37.5% and POBA: 42.8%; p=0.77) and dense calcium (LDL: 33.3%, Control: 28.5%, POBA: 37.5%; p=0.94) in VH-IVUS were comparable between groups. The Lipid Core Burden index in NIRS was negative in all cases. In histopathology, the injury was comparable between groups (LDL:1.6±0.4, Control: 1.7±0.8, POBA:1.7; p=0.8). In pathology the specimens showed no signs of necrotic core, cholesterol or calcium. The tissue consisted of fibrointimal hyperplasia and proteoglycan-rich matrix in all groups.

CONCLUSIONS

Local delivery of saturated human LDL into the coronary wall was feasible, resulted into higher degree of stenosis caused by neointimal thickening and hyperplasia typical for vascular injury and restenosis, with no atheromatosus lesions. The discrepancy between histopathological findings and VH-IVUS was also noted

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"Cul-de-sac" after percutaneous closure of LAA: clinical implications

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

To evaluate factors that may influence the position of the device in order to avoid residual *cul-de-sac* and to determine its clinical impact on patients (P) with atrial fibrilhation (AF) after left atrial appendage (LAA) closure.

METHODS AND RESULTS

We included 76 P (mean age 74±8 years, 63% male gender), who underwent the closure of the LAA with AMULET/ Amplatzer Cardiac Plug device (ACP) between May 2010 and September 2016. An imaging characterization of LAA was performed with transesophageal echocardiogram (TEE) before, during and up to 12 months after the procedure. In all patients the position evaluated of the device. P divided into 2 groups: G1 (with residual cul-de-sac, N=31, 41%) and G2 (without residual cul-de-sac, N=46%). The mean follow-up time was 21±15 months.AF was permanent in 65%, paroxystic in 30% and persistent in 5%. The embolic and hemorrhagic risk scores were: CHA2DS2VASC 4.7±1.4, HAS-BLED 3.3±1.0. The device used in 58% was AMULET and ACP in the others. The mean size of the implanted device was 23.4±3.0mm, with a success rate of 96%. In two P it wasn't possible to close the LAA because of its small size. During follow-up, one P had an ischemic stroke (12 months after closure) and two P had bleeding complications.

We verified that the existence of residual *cul-de-sac* in P of the G1 did not generate statistically significant differences regarding ischemic (p=0.44) and hemorrhagic (p=0.51) risks, size and shape of the AAE (p= 0.80) and clinical events (p=0.74) compared to G2 during follow-up.

The anomalous position of the device wasn't related to the morphology of LAA (p=0.80) - windsock (68%), chicken wing (13%), cactus (13%), cauliflower (1,7%) - thrombus formation (p=0.22) and occurrence of events (p=0.74).

The maximum and minimum diameters of the neck hole, maximum area of the LAA, the upper and lower length of the LAA, the area between the anatomic and neck orifices, the distances from the LAA and the neck to the mitral valve weren't related to the anomalous position of the device.

CONCLUSIONS

In this study, the success rate of the closure of the LAA was high. We noted that the abnormal position of the device with formation of a 'cul-de-sac' was very frequent, although without clinical impact. The LAA morphology and the echocardiographic parameters studied weren't able to predict the P which 'cul-de-sac' would occur.

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Long-term safety and performance of the EnligHTN renal denervation system in alternative hypertensive populations: 36-month results from the EnligHTN II study

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THEME: Interventions for Hypertension
TOPIC(S): Renal denervation, Other hypertension

AIMS

To examine the real world experience with renal denervation (RDN) in a broader hypertensive population, including patients with severe and moderate treatment-resistant hypertension (rHTN) and chronic kidney disease (CKD).

METHODS AND RESULTS

The EnligHTN II study is a prospective, 3-arm, non-randomized, multi-center clinical investigation on the safety and effectiveness of the EnligHTN™ Renal Denervation System in patients with rHTN. From January 2013 to August 2016, 277 adults (mean age 61.0 [SD:10.9] years, 64% male, mean office systolic blood pressure (SBP) 172.7 [22.3] mmHg) taking an average of 4.6 [1.7] anti-hypertensive medications and with suitable renal vascular anatomy (artery diameter ≥ 4mm and length ≥ 20mm) were recruited from 33 sites. Patients were assigned to one of three groups at baseline:

Group A: office SBP ≥160 mmHg and estimated glomerular filtration rate (eGFR) ≥45 mL/min per 1.73 m^2 (n=147)

Group B: office SBP ≥140-159 mmHg and eGFR ≥45 mL/min per 1.73 m^2 (n=102)

Group C: office SBP ≥140 mmHg and eGFR ≥15 mL/min per 1.73 m^2 (n=28)

All patients underwent multi-electrode radiofrequency RDN (mean number of ablations 17.2 [4.5] per procedure) and had office BP (OBP) and 24-hr ambulatory BP (ABP) assessed at 6, 12, 24 and 36-months follow-up.A total of 62 patients (62% male, mean daily anti-hypertensive medications 4.4 [12.0]) had 36-month follow-up data available for analysis. Overall, patients demonstrated significant mean relative reductions in office SBP/DBP of 10.5/ 7.9% (both p<0.001) and 24-hr ambulatory SBP/DBP of 5.4/5.3% (p=0.003/p=0.01) at 36 months. Baseline office SBP (p=0.0004) and eGFR (p=0.049) were both shown to be independent predictors of response to RDN (defined as a reduction from baseline of >10mmHg in office SBP) at 36 months. Individual patient groups reported varying BP reductions at 36-months as follows:

Group A: 38 patients (mean baseline OBP 174.5/94.7 [19.3/17.9] mm Hg and 24-hour ABP 153.3/86.1 [13.8/13.5] mm Hg) had mean reductions in OBP and 24-hour ABP of 21.8/9.7 [28.6/15.7] mm Hg and 12.0/6.6 [21.1/13.7] mm Hg respectively (all p < 0.001).Group B: 19 patients (mean baseline OBP 159.4/94.0 [15.8/12.9] mm Hg and 24-hour ABP 145.6/88.1 [13.2/11.9] mm Hg) had mean reductions in OBP and 24-hour ABP of 11.3/7.7 [25.6/12.6] mmHg (p = 0.07/p = 0.02) and 4.8/4.1 [18.2/8.5] mm Hg (p = 0.23/p = 0.04) respectively. Group C: 5 patients (mean baseline OBP 169.8/87.2 [23.1/10.4] mm Hg and 24-hour ABP 150.7/77.7 [8.1/11.0] mm Hg) reported mean reductions in OBP and 24-hour ABP of 33.8/9.0 [22.1/10.3] mm Hg (p = 0.03/p = 0.13) and 1.3/2.3 [9.6/5.9] mm Hg (p = 0.75/p = 0.56) respectively.Procedure and/or device-related serious renal artery stenosis occurred in 1.4% of the population. Across each patient group, daily anti-hypertensive medication intake did not change at 36 months compared to baseline (all p>0.40).

CONCLUSIONS

In the clinical setting, RDN was safe and associated with a significant, sustained BP reduction in patients with severe uncontrolled hypertension (Group A). In patients with moderate uncontrolled hypertension (Group B), modest yet significant reductions in ambulatory DBP were observed.

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IABP and peripheral left ventricular assist device for the treatment of cardiogenic shock

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

AIMS

Cardiogenic shock requires assist devices in order to increase systemic blood supply including coronary flow leading to decreased rates of morbidity and mortality. We aimed to investigate the clinical outcomes of devices IABP and pLVAD (Impella)

METHODS AND RESULTS

We searched PubMed, EMBASE, Cochrane databases up to 2016. Primary outcomes included 30 days mortality and CVA. Secondary outcomes studied were leg ischemia, major bleeding, cardiac output and cardiac index.We used fixed or random effect analysis. The pooled data provided a total of 121 patients, 56 receiving IABP and 65 receiving pLVAD. There was no significant difference between groups in regards to 30 days mortality and CVA events. Bleeding complications were significantly less in the IABP group compared to the pLVAD (23% vs. 53%, $p < 0.01$). There were less significant leg ischemia in the IABP group (4% vs. 22%, $p=0.04$). Cardiac output and cardiac index were significantly better in the pLVAD group compared to IABP group ($p<0.05$)

CONCLUSIONS

Our analysis suggested no difference in mortality or neurological events between the two groups. pLVAD can lead to better CO and CI compared to IABP but at costs of increased bleeding and leg ischemia events

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Guidewire vs. device-related grade III coronary perforations: incidence, management, immediate and long-term outcomes

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

AIMS

Grade III coronary perforations (G3CAP) remains a nightmare situation for the interventional cardiologist, with high morbidity and mortality and lack of consensus on optimal treatment strategies.

METHODS AND RESULTS

From 1993 to 2015, 90306 patients (7473 CTO) from 9 European centres undergoing PCI, 224 patients had grade III coronary perforation (0.25%). Most treated lesions were complex (25.0% type B2, 65.6% type C, 26.8% CTO) and within a small vessel (<2.5 mm) in 32% of cases. Intravenous heparin was administered in 96.0% of patients, 4.0% received bivalirudin and a further 11.6% received GPIIb/IIIa Inhibitors. Device-related perforations (DP) occurred in 145 patients (64.7%), more commonly in a proximal segment (69.0%) and were caused more frequently by intracoronary balloons (compliant 32.4%, non-compliant 33.1%, stent delivery balloon 23.4% of cases). Cutting balloons, microcatheters, guideliners and directional atherectomy rarely caused perforation. Guidewires-related perforations (WP) occurred in 79 patients (35.3%), more commonly in the distal segments (69.5%) and were CTO-guidewires related in 72.2% of cases. Immediately following perforations, prolonged balloon inflation (78.0%) with covered stent implantation (59.3%) in DP group and prolonged balloon inflation (66.0%) with coils embolization (31.5%) in WP group were the most commonly adopted strategies to restore haemostasis, while intraprocedural pericardiocentesis was needed in 24% of patients. Emergency ballon counterpulsation (13.8% in DP vs 4% in WP, p=0.019) and cardiopulmonary resuscitation (17% in DP vs 5% in WP, p=0.09) were more frequently required in the DP group, while post-procedural in-hospital pericardiocentesiswas more common in the WP (5.7% vs 13.0%, p=0.049). Emergency CABG and/or surgical repair was performed in 9% (DP) vs. 4% (WP, p=0.15) with low success rate in both groups (46.0% in DP vs 33.0% in WP, p=0,94) but without differences. In-hospital death rate was higher after a DP perforation (15.0% vs.6.3%, p=0.05) while acute stent thrombosis (4.1% in DP vs 1.2% in WP, p=0.33) and in-hospital overall MACE rate (42.0% in DP vs. 35.4% in WP, p=0-33) did not show differences. At clinical follow-up (189 patients, 95%; median 27 months) the overall mortality rate was 9% (DP 10% vs WP 7%, p = 0.49). The target vessel revascularization was 10% in both groups. Subacute, late and very late stent thrombosis were 5% in DP vs 0% in WP.

CONCLUSIONS

This large multicenter registry confirms that G3CAPs still remains a rare but a challenging complication for the interventional cardiologist with high mortality and in-hospital events. Given that DP and WP produces different patterns of perforations, individual strategies for sealing the artery should be adopted depending on the aetiology of the perforation.

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Long-term follow-up of late-acquired incomplete stent apposition in CTO treated with BRS

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

AIMS

Late acquired incomplete stent apposition (LAISA) incidence with 2ºgeneration DES is 0-6.8%. There are few data available regarding the incidence of LAISA with bioresorbable vascular scaffolds(BVS) in CTO and long-term angiographic and OCT follow-up.

METHODS AND RESULTS

Thirty-five true CTO lesions in 33 patients treated with BVS were included in a prospective study during 2013-2014. Scaffolds were deployed after mandatory pre-dilatation and IVUS analysis. Coronary angiography and OCT were performed after BVS implantation, at 12 and 36-month follow-up. Patients were aged 61 ± 10 years with 77% of males (n=27). Cutting balloons were used in 71% (n=25 lesions) and rotational atherectomy was required in 9% (n=3) of cases. All scaffolds were delivered and deployed successfully. The total scaffold length per lesion was of 52 ± 23mm, with 2.17 scaffolds on each CTO.
Post-dilatation was undertaken in 63% (n=22). Post implantation OCT showed all scaffolds well apposed. At 12 months, OCT showed that 94% of struts were well apposed and LAISA was observed in 9% (n=3), due to focal expansive vessel remodelling and/or possible thrombus dissolution. Patients with LAISA were advised to continue with dual antiplatelet therapy and no additional balloon dilatations were performed. At 36 months, OCT confirmed vessel enlargement, partial stent resorption and LAISA resolution by disappearance of the malapposed struts. None of these patients had a MACE during the 3-year follow-up.

CONCLUSIONS

Late acquired incomplete stent apposition is observed after CTO-PCI. In these cases, OCT imaging during follow-up shows a potential benefit of BVS over non-resorbable DES, by resolving LAISA after scaffolds resorption.

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The value of emergency coronary angiography and performance of PCI for patients undergoing therapeutic hypothermia after cardiopulmonary arrest

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

AIMS

The value of emergency Coronary Angiography (CAG) for patients undergoing therapeutic hypothermia after Cardiopulmonary Arrest (CPA) is unknown. We have evaluated the prognosis of emregency PCI and the value of emergency CAG using our facility data.

METHODS AND RESULTS

We have reviewed 86 patients who underwent therapeutic hypothermia between January 2006 and December 2016. We excluded non cardiac event CPAs (n=5) such as asthma attack, asphyxiation, pulmonary embolism and 81 patients were included in this study. 17 patients were STEMI and 64 were others. STEMI patients all went for emergency CAG and PCI was performed. 2 were left main trunk related, 11were multivessel and 4 were single vessel disease. Between STEMI and others group, survival rate was 47.1% vs 82.8% (p=0.05), Cerebral Performance Categories (CPC) was 3.3 vs 2.6 (p=0.25) and Arrival to Therapeutic Hypothermia Time (ATHT) was 169 vs 143 minutes (P=0.001). Among others group, we have compared the outcome between CAG performed (n=25) and unperformed (n=39) group before therapeutic hypothermia. Overall survival rate, CPC, ATHT for emergency CAG performed and not performed group was at 88.0% vs 79.5% (p=0.14), 2.08 vs 2.53 (p=0.22), 139.6 vs 145.1 (p=0.16) respectively. Focusing more on ischemic heart disease, 17 patients were included in others group. The survival rate, CPC, ATHT for emergency CAG performed (n=8) and not performed (n=9) among this group was 87.5% vs 88.9% (p=0.43), 2.25 vs 2.11 (p=0.39), 142.3 vs 166.4 (p=0.13).

CONCLUSIONS

STEMI patients undergoing therapeutic hypothermia after CPA had lower survival and higher CPC rate compared to others group. For non-obvious STEMI patients (others group), Emergency CAG before therapeutic hypothermia did increase survival rate, reduce CPC and even reduce ATHT but was not statistically significant. Although this study reveals that aggressive CAG have no negative effects.

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Impact of BRS-specific implantation technique on device expansion in ACS. A pooled analysis from BVS STEMI First and BVS EXPAND studies

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

AIMS

The aim of the study was to assess the impact of employment of the bioresorbable vascular scaffold (BVS)-specific implantation technique on the scaffold expansion in patients with acute coronary syndromes (ACS) treated with bioresorbable devices.

METHODS AND RESULTS

Patient data were pooled from the BVS STEMI First and BVS Expand studies. The rate of BVS-specific implantation technique employment, defined as predilatation with a 1:1 balloon-to-artery ratio, post-dilatation with a non-compliant balloon avoiding scaffold over-expansion higher than 0.5 mm above device nominal size and scaffold implantation in vessels of diameter within 2.25-3.8 mm, was analyzed. Device underexpansion was evaluated assessing the final minimal lumen diameter (MLD), the %scaled residual diameter stenosis (%sc DS) and the scaffold maximal footprint (MFP), representing the maximal proportion of the arterial circumference covered by scaffold struts.

A total of 285 ACS patients treated with BVS implantation were analyzed. The optimal BVS-specific implantation technique, overall employed in 61 of patients (86 lesions), was associated with a lower rate of scaffold underexpansion expressed by final MLD (2.44±0.36 mm vs. 2.31±0.44 mm, p = 0.007), %scDS (23.37±10.93% vs. 25.51±10.99%, p = 0.120) and MFP (36.35±4.93% vs. 38.35±6.52%, p = 0.003), compared with lesions not treated with the use of the optimal BVS-specific technique of implantation.

CONCLUSIONS

The employment of optimal BVS-specific implantation technique improves scaffold expansion in the setting of acute coronary syndromes.

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Evaluation of frequency-domain OCT versuS Intravascular ultrasound and angloGrapHy to guide percutaneous coronary inTervention - The iSIGHT randomised trial

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

AIMS

To investigate whether OCT-guided PCI can lead to similar minimum stent area (MSA) and stent expansion as those achieved by IVUS, and if both imaging modalities can lead to better stent dimensions than an aggressive angiography-based strategy.

METHODS AND RESULTS

We recruited patients ≥ 18 years old, from a single tertiary institution undergoing PCI for ≥1 lesions located in native coronary arteries with a visually estimated reference diameter of 2.25 to 5.00 mm. Lesions located in the left main, ostial right coronaries and bypass grafts were excluded, as were chronic total occlusions, planned two-stent bifurcation lesions, acute ST segment elevation myocardial infarction, and patients with an estimated creatinine clearance < 45 mL/min. Patients were randomized 1:1:1 in blocks of 9 to OCT-guided, IVUS-guided or angiography-guided PCI. Stents were sized by OCT according to the mean external elastic lamina (EEL) reference vessel diameter when the EEL was visible in at least 270 degrees of the vessel circumference or to the maximum reference lumen diameter when the EEL was visible in <270 degrees of the vessel circumference. Stent size was selected by IVUS according to the mean EEL reference vessel diameter when the reference vessel plaque burden was <50% or to the maximum reference lumen diameter when the reference vessel plaque burden was >50%. In the angiography group stents were sized according to standard practice. In all modalities, when a discrepancy ≥ 0.75 mm existed between the proximal and distal references, stents were sized according to the smaller reference and proper post-dilatation was performed with adequately sized balloons to match to the stent size to the other reference diameter. High-pressure balloon post-dilatation was highly recommended in all groups aiming to achieve a MSA ≥ 80% of the average of the distal and proximal references or the MSA in each half of the stent reaching ≥ 90% of each reference maximum lumen area. In the angiography group use of angiographic enhancement modalities and multiple angiographic planes were highly recommended for post-dilatation. Final OCT, IVUS, and angiography were performed in all cases after the procedure. Analyzes are being conducted in an independent imaging core laboratory, and at this moment the investigators are blinded to group assignments. A total of 150 patients were included, with 70.6% of males, 38.6% of diabetics, and a mean age of 59.22 ± 9.75 years. Acute coronary syndrome was the most common (57.3%) indication for the procedure. Most procedures (75.3%) were performed by the radial route, with a mean total contrast volume of 90.93 ± 38.13 mL. A total of 154 lesions were treated with a mean stent length of 28.64 ± 11.94 mm. Only second-generation drug-eluting stents were used. Post-dilatation with non-compliant balloons was performed in 98.1% lesions with a mean of 1.23 balloons per lesion.

CONCLUSIONS

The iSIGHT randomized trial investigated the role of OCT-guided PCI in comparison to IVUS-guided and an optimized angiography-guided PCI. The incremental role of both invasive imaging methods against an aggressive angiography-based strategy will be evaluated. Complete study results will be available at the time of presentation.

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Regret in patients with acute and chronic conditions recruited to stem cell clinical trials

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

AIMS

We examined decisional regret in patients recruited to trials of acute and chronic conditions. We explored whether there is a difference in regret in acute versus chronic cohort, and also whether regret is attributable to lack of personal benefit.

METHODS AND RESULTS

This was a qualitative-quantitative study of 92 patients (n=51 acute and n=41 chronic) recruited to the bone marrow derived adult stem cell (REGENERATE) trials between October 2012 and July 2013. A questionnaire survey and semi-structured interview were used to examine patient attitudes towards consent, motivations for participating and reflections on trial participation. Data was analysed using descriptive statistics and thematic analysis.We found that abbreviated consent was not associated with increased decisional regret. Regret was evident among individuals who suffered complications, but there was no significant difference between the acute and chronic groups. Patients in the chronic group more frequently considered themselves fully informed and had a better understanding of risk. Regret in the chronic group was not associated with lack of personal benefit. Furthermore, patients' understanding of risk was highly individual. Lastly, altruism emerged as a prominent theme in both cohorts.

CONCLUSIONS

We conclude that our study did not show an increased incidence of regret in the acute cohort despite data showing that the patients in the acute trial did not feel as well informed as patients in the chronic trial. Further research must examine patients' understanding of risk in clinical trials.

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Performance and healing patterns after implantation of a novel sirolimus eluting BRS. Nine-month follow-up by OCT in the FANTOM II study

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

AIMS

The novel Fantom bioresorbable scaffold (BRS) (Reva Medical, USA) has separating properties. We report the 9-month follow-up by optical coherence tomography in the FANTOM II multicenter study.

METHODS AND RESULTS

The Fantom BRS has a polycarbonate polymer platform with covalently bound iodine making it radiopaque, a strut thickness of 125 µm, a crossing profile of 1.3 mm, full degradation within 12-18 months and absorption is complete within 36-42 months. A total of 240 patients with stable angina pectoris and indication for revascularization were enrolled in 28 centers. Cohort B comprised 123 patients with planned 9-month angiographic follow-up and optional optical coherence tomography (OCT) scans. OCT recordings are analyzed systematically by experienced observers in an independent core laboratory using validated methods. Baseline and follow-up scans are matched at frame level by multiple corresponding landmarks. OCT scans are analysed for mean and minimal stent area and lumen area, strut malapposition, strut tissue coverage and neointimal thickness. Strut fracture, and discontinuity analysis are performed by 3D OCT. Analysis is ongoing and follow-up is complete by February 2017.

CONCLUSIONS

The novel Fantom bioresorbable scaffold poses separating features aimed at improving feasibility during implantation, reduce flow disturbance and facilitate healing. Completed 9-month OCT results to be presented at EuroPCR 2017.

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Three-dimensional transoesophageal echocardiography during percutaneous direct tricuspid valve annuloplasty with the TR Cardioband device

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

AIMS

We established a three dimensional guiding to enable the first percutaneous direct tricuspid ring annuloplasty using the new TR Cardioband system (Valtech, Israel) in human implant procedures and to analyse first in man (FIM) experience.

METHODS AND RESULTS

The procedure is performed under general anesthesia under both fluoroscopic and 3 D transoesophageal (TEE) guidance. The implant device is delivered via a transvenous transfemoral approach in the right atrium starting from the anterior leaflet tricuspid ring at a distance of 2.7 to 3 cm of the center of the Aortic valve to the posterior leaflet tricuspid ring at the level of the coronary sinus. The triangel of Koch is spared to avoid AV conduction delay. The right coronary artery is marked with a coronary wire to avoid interaction with the 15 to 17 metal anchors used to secure the band to the annulus interventionally. Interventional guidance is achieved through biplane fluoroscopy in LAO caudal and RAO cranial projections predefined by a cardiac CT 3D procedural sizing and planning. A predefined protocol ist used with patient anatomy and valve position related use of transosophageal or transgastric views. The height and delivery catheter angulation is crosschecked with both MP fluoroscopy and MP 2D biplane and MP R 3D echocardiography. Predefined distances to the hinge point of the Tricuspid valve leaflets oriented to the center of the valve (TV) as well as to the right coronary artery (RCA) is confirmed before anchor deployment of each ot the 15 to 17 anchors. After successful implantation of the last anchor the band is released and cinched under echocardiographic control to achieve a 20 to 30% ring reduction of the annulus diameters and a 60 to 100% reduction in functional TV regurgitation. Up to January 2016, 14 patients have been treated worldwide in both compassionate use FIM implants and in the TR REPAIR ce approval study. Device implantation rate has been 100% with an device implant time of 2 to 4 hours at 5 centers worldwide and acute and short term reduction in annular dimension, improved reduction of leaflet gaps and acute decrease in TR. Thirty-day and 6 month efficacy and outcome date is to follow soon.

CONCLUSIONS

Percutaneous transcatheter direct tricuspid valve annuloplasty can now be performed effectively using a standardized imaging protocol. 3D echocardiography and fluoroscopy are mandatory to achieve the high procedural success of 100% in this early first in man experience. The interventional approach shows acute tricuspid annular ring reductions and significant decrease in tricuspid valve regurgitation volumes.

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Long-term safety and efficacy of PCI with DES vs. CABG in patients with left main coronary artery disease: a frequentist pair-wise meta-analysis of randomised clinical trials

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

AIMS

Left main coronary artery disease is associated with the highest mortality. CABG has been the standard of care for a long time but due to significant advances PCI has emerged as alternative. We compared long-term outcomes of PCI with DES vs CABG.

METHODS AND RESULTS

We searched main PubMed, ScienceDirect, Scopus, EMBASE and Web of Knowledge electronic database from December 18th, 2001 to December 1st, 2016. We included trials fulfilling all the following criteria: i. randomised clinical trial; ii. PCI versus CABG; iii. exclusive use of DES; iv. left main coronary artery disease; v. clinical follow-up ≥3 years. The primary endpoint was defined as a composite of all-cause death, myocardial infarction or stroke. The main secondary endpoint was repeat revascularisation. We pooled trial-level data as log hazard ratio (HR) and corresponding standard error by using fixed-effect and random-effects models with inverse variance weighting. Risk measures were expressed as HR and 95% confidence interval (CI). We assessed heterogeneity across trials by using between-trial variance τ^2 and I^2 statistics. We identified 4 randomised clinical trials. With respect to the primary endpoint, PCI and CABG showed comparable outcomes (random-effects model, HR 1.06, 95% CI 0.85-1.32, p=0.597) with a moderate degree of heterogeneity (I^2=42.5%, p=0.154). The EXCEL trial had the highest relative weight in the analysis (35.9%). At influence analysis heterogeneity was mainly due to the NOBLE trial (omitting NOBLE trial, HR 0.96, 95% CI 0.80-1.15, p=0.660; I^2=0%). The results of a sensitivity analysis including only patients with SYNTAX score 1-32 were consistent with main analysis. With respect to the main secondary endpoint, PCI was associated with as significant risk increase as compared with CABG (HR 1.70, 95% CI 1.42-2.05, p<0.0001). Effect size across trials was consistent across trials (I^2=0%, p=0.872). Although the grouping of trials according to the predominant DES generation used did not show significant differences between groups with a significant increase in repeat revascularisation regardless the device used, second-generation DES patients (HR 1.63, 95% CI 1.29-2.06, p<0.0001) had a slight risk reduction as compared with first-generation DES patients (HR 1.83, 95% CI 1.37-2.45, p<0.0001).

CONCLUSIONS

In patients having coronary artery disease with left main coronary artery involvement and predominantly low to intermediate anatomic disease complexity, PCI and CABG are associated with comparable risk of a composite of all-cause death, myocardial infarction, or stroke at long-term follow-up. However, patients treated with PCI present a higher risk of repeat revascularisation as compared with CABG.

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Acute and long-term outcomes after polytetrafluoroethylene (PTFE) or pericardium covered stent for grade 3 coronary artery perforations: insights from G3CAP registry

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI, Stable CAD, Stents and scaffolds, Left main and multivessel disease, Bifurcation lesion, CTO

AIMS

Covered stent implantation is considered a useful device in the setting of Grade III Coronary Perforation (G3-CAP), one of the most harmful PCI complication. However data regarding efficacy of this device and clinical outcomes are still limited.

METHODS AND RESULTS

From 1993 to 2015, among 90306 patients from 9 European centers undergoing PCI (7473 CTO), 224 patients had G3-CAP (0.25%) and 102 patients were managed with covered stent implantation (96 with PTFE, 6 with pericardium). Long term follow up was obtained in 82/102 (94%) of patients (median follow-up 30 months). Device oriented composite endpoint (DOCE), a composite of cardiac death, target vessel revascularization and stent thrombosis at 30-days and long term follow-up were evaluated.

G3-CAP perforations were successfully sealed with covered stent in 88 patients (86%) with need of intraprocedural pericardiocentesis in one-third of cases. Protamine as heparin reversal agent was administered in 36 (35%) of cases. Angiographic follow up was available in almost one-third. The cumulative incidence of DOCE at 30-days follow-up was 21.5% (22/102): cardiac death 14.7%, TLR 1.0%, stent thrombosis 5.8%. At long term follow-up DOCE rates occurred in 14.7% (12/81): cardiac death 6.0%, TLR 5.0% and stent thrombosis 3.7%. Only 14/82 (17%) of patients received lifelong DAPT: three of them presented an episode of late stent thrombosis. Most of patients received 12-months DAPT 43/81 (52.0%) with long term DOCE of 16%, and 21/81 (18.5%) received 1 to 6 months of DAPT with long-term DOCE of 11.0%.

CONCLUSIONS

Use of covered stent was successful in sealing G3-CAP in the majority of cases.

Beside the high rate of clinical events at short and long-term, stent thrombosis remains the leading cause of device failure, even when DAPT was prolonged lifelong.

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Low rates of Absorb BRS thrombosis beyond 12 months in patients treated with aggressive pre- and post-dilatation using highly non-compliant balloons

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

AIMS

Recent studies have raised serious concerns regarding the high rates of scaffold thrombosis (ScT) in patients treated with the Absorb BRS. We describe our long-term experience using aggressive pre-and post-dilatation when implanting Absorb BRS.

METHODS AND RESULTS

Between 2013 and 2016 a total of 557 patients with coronary artery disease received Absorb at our institution. The mean age of the study population was 63±10 years. The indication for coronary revascularization was stable angina in 205 patients (37 %) and ACS in the rest of the patients (86 patients had STEMI). After the publication of the GHOST-EU study, all scaffold were implanted using a new protocol, which included aggressive pre- and post-dilatation using highly non-compliant balloons.Mean follow-up was 496±256 days and 378 patients had a follow-up > 365 days.
Scaffold thrombosis occurred in a total of 8 patients (1.4 %): 5 were early (<30 days post PCI), 2 were late (between 30-365 days post PCI) and 1 patient had an acute (1 hour post PCI) and a very late ScT (603 days) post PCI. ScT rates 12 months post implantation was 0.3 % (n=1).

CONCLUSIONS

Our results demonstrate that the Absorb BVS is a safe device when implanted using highly non-compliant balloons to pre- and post-dilate aggressively. ScT rates beyond 12 months were extremely low in our population and contradict the results of the Absorb-II trial.

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Improved safety and efficacy profile of thin struts biodegradable coated sirolimus-eluting stents when compared to durable everolimus-eluting stents implanted in all-comer patient population

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

AIMS

The aim of this study was to evaluate long-term safety and efficacy of biodegradable sirolimus eluting (SES) Alex™ stent (Warsaw, Poland) implanted in all-comers patient population with coronary artery disease (CAD).

METHODS AND RESULTS

This is a multicenter retrospective registry of 1717 patients with CAD, in whom percutaneous coronary intervention (PCI) utilizing SES or EES was performed. The ALEX stent was compared with reference article, an everolimus eluting stent (EES, Xience V). One thousand two hundred and thirty two sirolimus eluting stents (SES, Alex™), and 485 everolimus (EES, Xience V) were implanted. Patients where controlled after 3, 6, 12 and 24 months.

The study groups were comparable with regard to baseline demographic clinical and procedural characteristics, however there were less incidents of UA (40,5% vs. 49,7%; p=0,003) in SES group. There were no differences in mortality and major adverse cardiovascular and cerebrall events (MACCE) in the periprocedural period between the groups. At two-year follow up the incidence of MACCE (13,5 vs. 19,1%; p=0.079), any cause mortality (3,4 vs. 4,6%; p=0.83), miocardial infarction (5,2 vs. 7,9%; p=0,83) and repeated revascularization (8,0 vs. 9,9%; p=0,65) were non-inferior when compared with reference. There was also no difference in definite stent thrombosis (ST) defined by Academic Research Consortium (ARC) (2,1% vs. 1,3%; p=0,18). Propensity Score Matching (PSM) was performed, as a result two groups with identical baseline were paired. In propensity score matched groups a lower incidence for MACCE (7,2 vs. 12,7%; p=0,09) was observed in ALEX™ group.

CONCLUSIONS

The ALEX™ – a biodegradable polymer-coated, sirolimus-eluting stent demonstrates good safety profile at long-term follow-up and was non-inferior when compared with EES.

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Everolimus-eluting BRS: impact of lesions complexity on clinical outcome and predictors of adverse cardiac events at long-term follow-up

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds, Bifurcation lesion, CTO

AIMS

to evaluate the long term follow up of a cohort of patients treated with biorresorbable vascular scaffold (BVS), and to look for predictors of mayor adverse cardiac events.

METHODS AND RESULTS

From January 2012 to July 2016, 870 patients with 1056 coronary lesions were treated with BVS in two high volume centres. Pre-dilatation was done according to operator discretion. The scaffold diameter was selected by visual estimation according to the proximal angiographic reference. Post-dilation was performed if intracoronary image techniques showed incomplete scaffold apposition (≥ 200 µ), or under-expansion of the platform was observed (the balloon of the BVS was not totally expanded, or if the intracoronary images techniques detected a minimal lumen area (MLA) ≤ 30% than the point of ideal expansion). The balloon selected for post-dilation was a non-compliant balloon, not exceeding more than 0.5 mm the diameter of the scaffold. Clinical follow up was achieved by medical outpatient visits or telephone calls. Most of the patient were male (85%), with hypertension (54%) and hyperlipidaemia (59%) and almost one third of them (25%) were diabetic. The main clinical condition was an acute coronary syndrome (75%). According to AHA classification, 643 lesions (61%) were complex (Type B2 or C). There were 377 bifurcation lesions, (170 of them (45%) true bifurcations), 86 chronic total occlusion lesions, 360 diffuse lesions (> 20 mm) and 65 in stent restenosis lesions. In 192 instances the lesion combined at least 2 types of complexity. Predilation was performed in 482 (45.6%) lesions, and postdilation in 484 (45.8%). OCT or intracoronary ultrasound study was performed in 526 lesions (49%) to assess final result. After a follow up of 29±13 months there were 16 deaths (8 cardiac death) , 12 myocardial infarction (1.1%), 47 TLR, and 3 CABG (0.3%), with a global MACE of 8.9%. There were 15 thrombosis (1.4% per lesion and 1.7 per patient) , 7 definitive, 7 probable, and one possible. According to AHA classification, there were not significant differences in terms of TLR (type A lesions 4.5%, in B_1 3.7%, in B_2 5.2% and in C type 4.3% ,p: 0.8) or thrombosis (type A lesions 1.5%, in B_1 0.9%, in B_2 2.4% and in C type 1% ,p: 0.4). Diabetes, (12% vs. 6.8%) a smaller size of the vessel (2.9±0.4 vs. 3.1±0.4, p<0.05), a smaller MLD post (2.66±0.45 vs. 2.81±0.49, p<0.05) or the use of clopidogrel instead of ticagrerol or prasugrel (12.5% vs 6.6%) was associated to MACE at follow up. Regarding predictors of thrombosis, diabetes (3% vs 0.9%, p<0.01), and the use of clopidogrel (2.8% vs 0.8%) also increased the risk of thrombosis.

CONCLUSIONS

Treatment of complex lesions with biorresorbable vascular scaffold is feasible, with a low rate of MACE after 29 months of follow up. Diabetes and the use of clopidogrel instead of new antiplatelet agents increased the risk of MACE and thrombosis

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Clinical and imaging predictors of permanent pacemaker implantation after TAVI: an analysis from the PARTNER II SAPIEN 3 study

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

AIMS

Cardiac conduction disturbances requiring permanent pacemaker implantation are a frequent complication of TAVI. We aimed to identify clinical and imaging predictors of pacemaker implantation in the PARTNER II SAPIEN 3 study.

METHODS AND RESULTS

The study included 1023 patients from the PARTNER II SAPIEN 3 High and Intermediate Risk registries, who underwent TAVI with placement of 1 prosthesis and had core laboratory interpretation of baseline electrocardiograms, echocardiograms and cardiac computed tomography angiography (CTA). 156 patients were excluded due to the presence of a permanent pacemaker at baseline. Depth of implantation was assessed by the echocardiographic core laboratory based on post-TAVI discharge or 30-day echocardiograms and was available in 614 patients. Aortic annulus oversizing was defined as prosthesis 100*[(area/annulus area)-1] by CTA and LVOT oversizing was defined as prosthesis 100*[(diameter/LVOT diameter)-1] by echocardiography. Univariate and multivariable analysis was performed to identify clinical and imaging predictors of new pacemaker implantation within 30 days of TAVI.Within 30 days of TAVI, 118 patients (13.6% of those without prior pacemaker or 11.5 % overall) required new pacemaker implantation. Those requiring a pacemaker were significantly older (83.6 vs 81.8 years, p=0.006) with more frequent CAD (77.1 vs 66.9%, p=0.03) and a numerically higher STS score (5.9 vs 5.5, p=0.09). The pacemaker group also had significantly more frequent baseline EKG findings of first degree atrioventricular block (19.5 vs 12.8%, p=0.05) and right bundle branch block (30.5 vs 9.3%, p<0.001) and CT findings of moderate to severe annular calcification (33.9 vs 22.3%, p=0.006) and subannular calcification (31.4 vs 20.2%, p=0.006). With respect to the TAVI procedure, pacemaker recipients were more likely to be treated in the first half of each enrolling site's experience (58.5 vs 47.3%, p=0.02), to have an implant depth >6mm (83 vs 72%, p= 0.04) and to be treated with a large (26 or 29 mm) SAPIEN 3 valve (76.3 vs 60.4%, p<0.001) with a greater degree of annulus oversizing (11.5 vs 8.4%, p=0.003) and left ventricular outflow tract oversizing (19.1 vs 16.5% vs p=0.008).Multivariable analysis was performed in the population with depth of implantation available and resulted in a final model with an AUC of 0.74. Independent predictors of pacemaker at 30 days included right bundle branch block (OR 5.1, p <0.001), moderate to severe annular calcification (OR 2.4, p=0.001), use of a 26 or 29 mm prosthesis (OR 2.7, p=0.012) and annulus oversizing (OR 1.3 per 0.1, p=0.032).

CONCLUSIONS

In a large cohort of patients from the PARTNER II SAPIEN 3 study with core laboratory adjudication of imaging studies, 13.6% of patients required new pacemaker implantation at 30 days. Independent predictors of new pacemaker included RBBB, moderate or severe annular calcification, treatment with a large prosthesis (26 or 29mm), and annulus oversizing by CTA. Careful consideration of these risk factors may help to guide the management of TAVI patients at high risk for cardiac conduction disturbances.

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Assessment of long-term safety outcomes after PCI with DES vs. CABG: a comprehensive frequentist pair-wise meta-analysis of randomised clinical trials

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

AIMS

CABG has been the standard of care for coronary artery disease for decades but more recently PCI has emerged as acceptable alternative. We pooled long-term safety outcomes of randomised trials comparing PCI with DES and CABG.

METHODS AND RESULTS

We searched PubMed, ScienceDirect, Scopus, EMBASE and Web of Knowledge electronic databases from December 18th, 2001 (first-in-man with DES) to December 1st, 2016. We included trials fulfilling all the following criteria: i. randomised clinical trial; ii. PCI versus CABG; iii. exclusive use of DES; iv. clinical follow-up ≥3 years. Pooling of data was performed taking left main coronary artery involvement into account by stratifying data according to the anatomic subset and testing for difference between subgroups. The primary endpoint was a composite of all-cause death, myocardial infarction or stroke. The secondary endpoints were the individual components of the primary endpoints. We pooled trial-level data as log hazard ratio (HR) and corresponding standard error by using fixed-effect and random-effects models with inverse variance weighting. We assessed heterogeneity across trials by using between-trial variance τ^2 and I^2 statistics. A total of 6 randomised clinical trials were identified. The SYNTAX trial had randomisation stratified according either to left main coronary artery disease or three-vessel disease without left main stenosis and was considered as two cohorts. Weighted trial-level values of baseline SYNTAX score were similar (left main: 25.8; multi-vessel: 26.3). With respect to the primary endpoint, PCI was associated with a higher risk as compared with CABG (random-effect, HR 1.21, 95% CI 1.10-1.37, p=0.002). However, subgroups resulted heterogeneous (p=0.036). Indeed, the two revascularisation techniques showed comparable risk in the group of patients with left main disease (random-effects; HR 1.06, 95% CI 0.85-1,32, p=0.476) while the group of patients with multi-vessel disease without left main involvement (random-effects, HR 1.42, 95% CI 1.02-1.45, p=0.029). PCI was associated with an increased risk of death as compared with CABG (HR 1.21, 95% CI 1.01-1.46, p=0.042). Similarly, whereas there was no difference between treatments in the left main group (random-effects, HR 1.04, 95% CI 0.81-1.33, p=0.772), risk of death was increased after PCI in the multi-vessel group (random-effects, HR 1.43, 95% CI 1.16-1.76, p<0.001). PCI was also associated with a significantly increased risk of risk of myocardial infarction (random-effects, HR 1.77, 95% CI 1.20-2.59, p=0.0004). In the left main disease group the risk of myocardial infarction between PCI and CABG was comparable (random-effects, HR 1.48, 95% CI 0.85-2.58, p=0.172) while in the multi-vessel disease group it was significantly higher after PCI (random-effects, HR 2.14, 95% CI 1.47-3.12, p<0.0001). With respect to stroke by no difference between PCI and CABG was observed (random-effects, HR 0.78, 95% CI 0.49-1.26, 0.622).

CONCLUSIONS

Despite similar baseline SYNTAX score, very long-term risks of death and myocardial infarction tend to differ between patients with coronary artery disease involving left main—in which PCI and CABG present comparable safety—and patients with multi-vessel disease without left main involvement—in which PCI is associated with a higher risk.

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CAFE-contrast (Contrast Agent Follow-up and Economy)

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

AIMS

To reduce the hospital use of contrast media below the national average level, reduce the extremely huge waste of contrast media and soften the footprint of the hospital in the environment.

METHODS AND RESULTS

We have followed up the delivery of Contrast Media to the Cath lab (pharmacy data), calculated and registered the used contrast volumes by procedure (INFOHOS and CCW softwares).Between January-June 2012, 2164 procedures with contrast media use were selected and analysed (provisioned, used, registered volumes of contrast media and wasted quantities). The Cathlab team was informed and sensitized about the project.Consequently, a new contrast saving system with an anti-backflow valve was designed and produced touse a bigger contrast bottle of 500 ml instead of 50, 100 and 200ml.

After a period of six months, the new system was evaluated in relation to the effectively used volumes, wasted product and saved quantity. During the same period, it was also checked whether the contrast volume roof per patient had not been exceeded.

Before the use of the Contrast Saver System, 115.73 litres(100%) of contrast were monthly deliveredof which only 75.57 litres (65%) were used and 40.16 litres(35%) thrown in the garbage. In addition, the cost of contrast per procedure was 30-50 € more compared to the national standard.

With the new Contrast Saver System, the contrast media waste was reduced from the original 35% to 10-15%by using it sparingly. At the same time, the use of contrast by each cardiologist was followed. This showed that Cardiologists in training are using more contrast than senior physicians while working alone. Also the used quantity is proportional to the x-ray time. In general, the used contrast volume by patient is below the ideal allowed volume, considering contrast nephrotoxicity.

CONCLUSIONS

By creating and implementing a new contrast saver system, contrast waste could be reduced to the minimum. The new contrast saver system guarantees a safe and comfortable way of working for physicians and nurses:it is a bare change- over for a better care for the patient, the hospital and the environment.

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Five-year durability and haemodynamic performance of transcatheter aortic valves vs. surgical bioprotheses

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

AIMS

We aim to analyze and compare the hemodynamic performance of percutaneously implanted bioprothesis with surgical implanted bioprothesis (SAVR) at 5 years.

METHODS AND RESULTS

Prospective, single center study of 49 consecutive patients reaching a 5-year survival, between April 2008 and December 2011, compared to a cohort of 50 high or intermediate risk patients that underwent a surgical bioprothesis implantation reaching similar survival. Prosthesis hemodynamic behavior was evaluated using echocardiographic Doppler derived parameters at discharge and at 5 years. Comparisons between echocardiographic assessments were performed using Wilcoxon Signed test and between cohorts with the Mann Whitney test.

Mean age of was 78±7,6 years, 54% were female and mean Euroscore II was 4,9±3,7. In both cohorts there were no significant differences in peak velocity, mean gradient and VTI ratio between baseline and 5 year echocardiographic assessment, however the LVEF decreased in both groups (Table 1.) The distribution of the absolute difference between baseline and 5-year peak velocity, mean gradient, VTI ratio and LVEF did not differ across the overall population; the median peak velocity variation was 0.03m/s IR[-0.1 to 0.27] in TAVI and -0.1m/s IR[-0.4 to 0,5] in SAVR, p=0.25; the median mean gradient variation was 0mmHg IR[-3.5 to 1.5] in TAVI and -2.5mmHg IR[-4.7 to 5.5] in SAVR, p=0.41; the median VTI ratio variation was -0.1 IR [0.11 to 0.05] in TAVI and -0.2 IR[-0.15 to 0,06] in SAVR, p=0.86; and the median LVEF was -1% IR[-7.5 to 2] in TAVI and -5% IR[-8 to -1] in SAVR, p=0.46.

CONCLUSIONS

Percutaneous and surgical bioprothesis showed similar long-term hemodynamic profile. No significant structural deterioration was seen in our population at 5 years.

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Transradial vs. transpedal vs. dual radial-pedal access approach for endovascular intervention of superficial femoral artery CTO

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal

AIMS

Improved techniques have resulted in use of radial (TR) or pedal (TP) approach for superficial femoral artery (SFA) CTO intervention instead of femoral approach. TP, TR and dual TP-TR for SFA-CTO intervention have not been compared.

METHODS AND RESULTS

Methods: We performed as treated analysis on prospectively collected data of 184 SFA CTO interventions in 161 patients from 01/2014 to 12/2016 using either TR, TP or dual TR-TP (operator discretion) at two institutions. Primary end point was 30 day major adverse event (MAE) - death, amputation or target vessel revascularization.**Results:**Primary TR was used in 46 patients (Rutherford class 3-6 94%) with 47 CTO lesions (TASCII A 38%, B 23%, C 17%, D 22%). Primary TP was used in 115 patients (Rutherford class 3-6 100%) with 137 CTO lesions (TASCII A 7%, B 18%, C 35%, D 40%). Primary crossing success rate was higher with TR compared to TP (76% vs 54%, p=0.009). Primary procedural success rate was 74% with TR, 54% with TP (100% when the lesions crossed). For lesions with unsuccessful crossing, dual TR-TP was used in 59 patients (Rutherford class 3-6 98%) with 72 CTO lesions (TASCII A 12%, B 17%, C 31%, D 40%). Crossing success rate was 99% and procedural success rate was 96%. The 30 day MAE (as treated) was 5% (1 death, 1 amputation) in TR group vs 0% in TP group vs 2% (1 death) in dual TR-TP group (p=0.16). There were no vascular complication in either groups and access sites were patent, confirmed by ultrasound at 1 month.

CONCLUSIONS

Conclusion: The treatment of SFA CTO is feasible and safe using TR, TP or dual TR-TP approach when needed, providing high success rates and no access site complications.

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OCT and histopathological pre-clinical evaluation of an enhanced polytetrafluoroetylene-covered stent in a peripheral swine animal model: addressing the anatomical challenges of the lower limb stenting procedure

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THEME: Peripheral Interventions
TOPIC(S): Below the knee, Iliac / Femoral / Popliteal, Other peripheral interventions

AIMS

We aim to evaluate the performance and vascular response of a novel, high flexibility, high biocompatibility peripheral covered stent in a porcine restenosis model.

METHODS AND RESULTS

Six domestic swine were included in this study (45±1 kg). Based on angiographic QVA, the superficial femoral arteries were randomized for either the implantation of a Solaris (Scitech, Sao Paulo, Brazil) or Fluency (Bard, Tempe, AZ) 40 mm long stent grafts with 110% overstretch. Subsequently, animals were followed for 30 days. At terminal imaging, all stents were evaluated with optical coherence tomography (OCT), explanted and subjected to stent integrity analysis and histopathological evaluation. A total of 11 stents were evaluated (Solaris n=6, Fluency n=5). Solaris stent demonstrated improved deliverability when compared to the reference stent graft. At 30 days, OCT revealed a similar stent area for both groups (Solaris 25.8±4.7 vs Fluency 24.7±5mm^2; p=0,7). There was a trend toward higher lumen area in the Solaris stent (18±4.2mm vs Fluency 13.9±3.4mm^2;p=0.11) as a consequence the neointimal hyperplasia was lower as expressed as lower percentage stenosis in the study group (Solaris 31.9±7 vs Fluency 44.8±6%; p). The integrity analysis of the stents via radiographs revealed no fractures in any stent from either group. The results of the histopathological evaluation will be presented in the meeting.

CONCLUSIONS

The Solaris PTFE-covered peripheral stent demonstrated a resistance to fracture with increased flexibility and navigability and better conformability to artery curvature. The release system allowed for an accurate geographical delivery and the components of the device produced a lower OCT morphometrically-assessed neointimal response when compared to the control group.

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Gender specific clinical outcome after PCI or CABG for treatment of left main coronary artery stenosis. A NOBLE substudy

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

AIMS

Gender is known to influence prognosis in coronary artery disease. We aimed to determine the gender specific outcomes after PCI or CABG for revascularization of patients with left main coronary artery (LMCA) stenosis.

METHODS AND RESULTS

Patients randomized in the NOBLE trial (NCT01496651) were analyzed according to gender. The main endpoint was the composite of all-cause mortality, non-procedural myocardial infarction, repeat revascularization and stroke (MACCE). Results are 5-year Kaplan-Meier estimates. A total of 1201 patients were randomized in NOBLE and 1184 entered analysis. Females (256, 22%) were treated by PCI (116) or CABG (140) and MACCE was 32% for PCI and 14% after CABG (HR 2.06% CI 1.08-3.91, p=0.026). Males (928, 78%) were treated by PCI (476) or CABG (452) and MACCE was 27% for PCI and 20% after CABG (HR 1.38, 95% CI 1.01-1.90, p=0.043).

CONCLUSIONS

In treatment of LMCA stenosis, 5-year outcomes after PCI or CABG was in favor of CABG for both genders but in particular for woman.

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Is there a measurable attrition in survival due to fatal development of complete atrioventricular block during the first 30 days post-discharge from hospital after TAVI? Insights from the UK TAVI registry 2007 to 2015

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

AIMS

To determine whether the presence of a permanent pacemaker confers a survival benefit during the first 30 days post discharge from hospital following an admission for transcatheter aortic valve implantation (TAVI) in a real-world patient population.

METHODS AND RESULTS

The United Kingdom TAVI registry has recorded characteristics and clinical outcomes for every single patient treated by TAVI since its inception in January 2007. Those patients treated in England and Wales are also linked to the Office of National Statistics, thereby providing a robust system for tracking all-cause mortality.We performed a retrospective observational cohort analysis of all those patients for whom validated life status data were available. We documented survival of these patients in the first 30 days post discharge from hospital after TAVI in relation to permanent pacemaker (PPM) implantation status; the assumption being that a PPM would protect against sudden cardiac death due to complete atrioventricular block.Range checks were used during cleaning of the UK TAVI dataset to look for extreme values and assessments of internal consistency were applied. Death before hospital discharge was self-reported by the participating centre. Death post hospital discharge was taken from national census data. Missing data were not included in the analysis.From January 2007 to the end of June 2015, all-cause mortality and PPM status data were available for 7691 patients. The average age of the cohort was 81.1 years (standard deviation, SD ±7.6). There were 4137 men (54%) and 3531 women (46%). Of these, 1457 patients had a PPM in situ (19%) - 614 were implanted at some point pre-TAVI (8%); 74 during TAVI (1%) and 769 during the index hospital admission post TAVI (10%). A total of 369 patients (4.8%) died during the index hospital admission. Of those that survived to hospital discharge (n=7322), 107 patients (1.5%) died within the first 30 days whereas 7215 individuals survived (98.5%) beyond this time point.Of those that died within 30 days post discharge, 22 patients (20.6%) had a PPM in situ and 85 patients (79.4%) did not have a PPM. Of those that survived beyond 30 days, 1372 patients (19.0%) had a PPM in situ and 5843 individuals (81.0%) did not have a PPM. In effect, the death rate of those with a PPM within the first 30 days post discharge was 1.58% compared with a death rate of 1.43% in those that did not have a PPM during the same time period. A Chi-square test to determine the independence of these categorical data (i.e. all-cause mortality with PPM status 30 days post discharge following TAVI) confirmed the null hypothesis (p=0.6862; odds ratio 1.102; 95% confidence interval 0.685 – 1.747).

CONCLUSIONS

Atrioventricular block requiring PPM is recognised as the most common complication after TAVI. The PPM is implanted during the index hospitalisation in the vast majority of patients, with median time to PPM being 3 days according to the literature. With patients now being increasingly discharged earlier than this median time point of 3 days, it would seem prudent to determine whether there is an excess of death caused by fatal development of complete atrioventricular block in the 30 days immediately after discharge from hospital. The present analysis of a large national real-world patient population

treated with TAVI would suggest there is no significant measurable attrition in survival due to fatal development of complete atrioventricular block.

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A prospective single-centre registry, evaluating real-world usage of the Tryton dedicated bifurcation stent: procedural success and three-year clinical outcome

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

AIMS

We assessed in a prospective all comers' single centre registry, long term (3 year) safety and efficacy of the Tryton dedicated side branch stent. Tryton is a dedicated coronary bifurcation stent having favourable medium term outcomes.

METHODS AND RESULTS

MethodsWe evaluated the data from our centre's prospective Tryton registry from January 2009 to August 2016. The procedural data was assimilated from British Cardiac Intervention Society database, clinical follow up information obtained by reviewing electronic hospital data base and mortality information verified from the Welsh Demographic national statistics database.

The primary endpoint was 3-year device oriented composite endpoint [DOCE: cardiac death, target vessel myocardial infarction (TV-MI) and target lesion/vessel revascularisation (TLR/TVR)]. Secondary endpoints were technical and procedural success (respectively defined as successful implantation of Tryton at the intended lesion and successful performance of the whole procedure with Tryton without in-hospital MACE).**Results**A total of 83 patients had Tryton stents implanted during the study period, with a mean follow up of 37(+/-2) months. Mean age was 66(+/-10) years, 80% were men, 16% had moderate to severe LV dysfunction, 25% had DM and 25% had past MI. Indication for PCI was predominantly ACS (69%) including STEMI (10%) and cardiogenic shock (3.6%). 93% of the procedures were done via radial access using 6F sheath. 98% of the lesions were true bifurcations (MEDINA 1,1,1; 1,0,1 or 0,1,1) with LAD/Diagonal bifurcation being the commonest (71%). LMS bifurcation compromised 9% of the lesions.Technical and procedural success (secondary endpoint) was achieved in 98.8% and 97.6% patients respectively. All-cause mortality at 30 days, 12 months and 3year was 3.6%, 7.23% and 10.84% respectively. Cumulative DOCE (primary endpoint) at 37 months was 9.6% (cardiac death 3.6%, TV-MI 3.6%, definitive ST 1.2%, possible ST 2.4% and TLR/TVR 3.6%).

CONCLUSIONS

In the real world setting in a single -centre registry the use of the Tryton dedicated bifurcation stent is associated with good technical and procedural success along with long term clinical results that compare very favourably with historical bifurcation studies.

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A change in the practice of intra-aortic balloon implantation over 18 years: a single tertiary centre experience

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

AIMS

To evaluated Intra-aortic balloon pump conterpulsation (IABP) usage over an 18 year period at a single tertiary care centre to establish the influence of guidelines and trails (IABP-SHOCK II Trail) on real world practice.

METHODS AND RESULTS

Methods: We analysed the data from our electronic database, which was recorded prospectively from 1998 to 2015. This is an “all comers” database of patients undergoing IABP therapy for clinically indicated conditions. The mortality tracking information was collected via a national demographic database.**Results:**A total of 1759 patients received IABP therapy over this period with an average of 98 cases per year. The mean age was 68 years, 1224(70%) were men, and 1623 (92%) of them were inserted via femoral arterial access. The indications were preoperative support in 576(33%), post-operative support in 439(25%), supported angioplasty in 321(18%) and cardiogenic shock in 214(12%). The number of IABP insertions steadily increased from 1998 to 2012 with a peak (155) in 2012, with the rate declining from 2013 onwards with lowest implantation in 2014. Post 2013 there were less implantations for cardiogenic shock and post-operative support in comparison to earlier years. The mortality on day 0, 7 days, 30 days, 1 year and 5 years was 5%, 20%, 27%, 34% and 47% respectively. Day 0 mortality was highest in cardiogenic shock (25%) and post-operative (29%) patients. Mortality rates with IABP usage have not changed significantly over the 18 year period.

CONCLUSIONS

This study reflects the real world practice of IABP treatment and the change in usage with emergence of new evidence. Post-operative IABP implantation remains the most common indication for usage and is associated with highest in patient mortality.

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Impact of CTO in non-culprit artery on in-hospital and post-discharge mortality in patients with STEMI undergoing primary PCI

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

AIMS

Previous studies have indicated poor clinical outcome in patients with STEMI and chronic total occlusion (CTO) in non-culprit artery. Our aim was to investigate the impact of non-culprit CTO on mortality in different time periods after primary PCI.

METHODS AND RESULTS

The analysis included 4340 patients with STEMI who were treated with primary PCI within 24 hours of symptoms onset, during 2009 – 2012, in a high-volume catheterization laboratory. Kaplan Meier cumulative mortality curves were used to compare the impact of non-culprit CTO vs. no CTO on all-cause mortality during 3-year follow-up, with landmarks set at hospital discharge, 1 and 2 years. Cox regression models were constructed to assess mortality risk of non-culprit CTO in different time intervals. Non-culprit CTO was present in 10.1% of included patients (n=439). Patients with non-culprit CTO had more frequently prior MI (33.3% vs. 12.9%, p<0.001), prior CABG (7.5% vs. 1.4%, p<0.001), Killip 2-4 on admission (31.5% vs. 15.8%, p<0.001) and lower ejection fraction (40.0% vs 49.0%, p<0.001). Presence of non-culprit CTO was also associated with higher rates of diabetes, renal failure and prior stroke at baseline (30.7% vs. 22.9%, 7.8% vs. 2.8% and 11.1% vs. 6.3%, respectively, p<0.001 for all comparisons). Percutaneous revascularization during index hospitalization was attempted in 38 patients and was successful in 17, without significant impact on the prognosis. At 3 years, patients with non-culprit CTO had significantly higher rate of all-cause mortality compared with no CTO patients (30.3% vs. 11.6%, respectively, logrank p<0.001). Significantly more deaths occurred already during index hospitalization for STEMI, in patients with non-culprit CTO (13.0% vs. 4.4%, p<0.001). Landmark analysis showed that higher cumulative mortality rates in patients with non-culprit CTO were maintained after discharge from hospital and also in the time-periods after the first and second year post primary PCI (17.6% vs. 7.0%, 8.3% vs. 2.8% and 5.9% vs. 1.4%, respectively, logrank p<0.001 for all comparisons). Even after adjusting for the described baseline differences, non-culprit CTO was associated with continuously increased post-discharge mortality risk (after discharge: HR 2.0, CI95% 1.5-2.8, p<0.001; after the first year: HR 2.0, CI95% 1.2-3.4, p=0.012; after the second year: HR 2.9, CI95% 1.4-5.9, p=0.003).

CONCLUSIONS

Non-culprit CTO is independently associated with continuously increased mortality risk up to three years after primary PCI. Our findings seem to be clinically relevant amid discussions about the timing of non-culprit PCI in STEMI patients, since they indicate that patients with CTO in non-infarct-related artery may potentially benefit from revascularization also at a later time point, even years after primary PCI.

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Transapical off-pump mitral valve repair with Neochord implantation: first-year results in a multicentric experience

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

AIMS

The goal of this study was to evaluate the feasibility, safety and up to 12 months outcome of the NeoChord DS1000 system in patients with primary mitral regurgitation (MR) due to leaflet(s) prolapse or flail.

METHODS AND RESULTS

Methods

Form July 2015 to November 2016 34 patients with severe primary MR were selected for transapical implantation of Neo-Chordae at 2 centers in Italy. Mitral Valve Academic Research Consortium (MVARC) procedural success criteria at 30 days were evaluated in all patients along with follow-up at 6 and 12 months.

Results:

The mean age was 64.7 ± 11 years, 26 were male (76%) and mean STS repair score was 1.06% (IQR 0.46-1.12). Twenty five patients had isolated central PML (P2) disease and 9 patients had other or multisegment disease involvement. At baseline 11 patients were in NYHA class III (32.4%) and 20 patients in NYHA class II (58.8%). Thirty days MVARC procedural success obtaining MR ≤ moderate was achieved in 31 of 34 patients, one patient had died of respiratory failure during early postoperative period (in hospital mortality 2.9%), and 2 patients had undergone conversion to traditional valve surgery due to functional failure and residual significant MR. At discharge 25 patients (80,6%) had MR ≤ mild and 6 patients had moderate MR. Two patients experienced early device failure with recurrent sever MR and had undergone additional valve surgery (at 61 and 129 days after implantation). Of the remaining 29 patients 22 reached 6 month follow up, all had MR≤ moderate and showed significant improvement in NYHA functional class (P<0.001, figure A). Ten patients reached 12 month follow up, all had MR ≤ moderate and 9 (90%) had NYHA class I.

CONCLUSIONS

Mitral valve repair with the NeoChord DS1000 system for primary MR due to leaflet(s) prolapse or flail is feasible and safe. Its efficacy is maintained up to 1 year showing significant clinical benefit and functional class improvement .

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Investigation of an optimal deployment method of polymer BRS to gain acute expansion using a stenotic mechanically-equivalent coronary artery model

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

AIMS

It is important to sufficiently expand polymer bioresorbable vascular scaffold (BRS) to prevent scaffold thrombosis. This study aimed to find out optimal expansion method to gain larger diameter during interventional procedure.

METHODS AND RESULTS

We previously developed a diseased coronary artery model which equipped a concentric 75 % stenosis in 3.0 mm reference diameter. Mechanical properties of the stenotic lesion model were regulated to match stent delivery balloon underexpansion and stent recoil between in-vivo and in-vitro data. Using the model, effectiveness of sequential 3-times metallic DES expansion has been demonstrated at bench and its usefulness has been proven in real world clinical practices. In this study, influences of sequential expansion of PLLA BRS (Absorb GT1 3.0×18 mm, Abbott Vascular) on minimal lumen diameter (MLD) were investigated.

A total of 18 BRS were tested. BRS were deployed in the model filled with 37°C-regulated phosphate buffered saline (PBS) using the delivery balloon (DB) with inflation pressure (IP) of 12 atm (n=6) and 16 atm (max. IP) (n=6). Additional sequential 2 times expansion with the same IP were conducted. Each retention time at the target IP was regulated in 20 sec for consistency. In parallel, after deployment of BRS with 12 atm for 1 time, post-dilatation using a non-compliant (NC) balloon (NC TREK 3.0×20 mm, Abbott Vascular) at 18 atm (maxim inflation pressure) were conducted 3 times (n=6). The MLD after 1-time, 2-times, and 3-times expansion at 12 atm were 2.47±0.06 mm, 2.61±0.03 mm, and 2.68±0.04 mm, respectively. The scaffold gained larger lumen diameter using 2-times and 3-times DB expansion (1-time vs 2-times: p=0.027, 1-time vs 3-times: p<0.001, 2-times vs 3-times: p=0.111). In case of BRS expansion at16 atm, the MLD after 1-time, 2-times, and 3-times were 2.69±0.10 mm, 2.82±0.08 mm, and 2.92±0.07mm, respectively. The scaffold expanded more at 16 atm and effectiveness of 3-times expansion was consistent (1-time vs 2-times: p=0.038, 1-time vs 3-times: p=0.001, 2-times vs 3-times: p=0.199). When post-dilatation was conducted using the NC balloon, the MLD after 1-time, 2-times, and 3-times were 2.77±0.04 mm, 2.86±0.03 mm, and 2.89±0.04mm, respectively. Sequential expansion using the NC balloon was also effective (1-time vs 2-times: p=0.009, 1-time vs 3-times: p<0.001, 2-times vs 3-times: p=0.098). The MLD after 3-times expansion was comparable between the DB with 16 atm and the NC balloon with 18 atm. However, the deviation of diameter in 6 tests was smaller in use of the NC balloon. In one scaffold deployed at 16 atm using DB, scaffold fracture was observed.

Due to viscoelastic creep property of the polymer PLLA scaffold, the MLD after 3-times expansion with the NC balloon immediately decreased by 0.16±0.02 mm (5.9±0.6 %) in 24 hours, and 0.23±0.02 mm (8.0±0.5 %) in one month under 37°C-regulated PBS. The MLD reduction was also observed by 0.29±0.04 mm (9.8±1.3 %) in 24 hours, and 0.33±0.03 mm (11.3±0.8 %) in one month after 3-times expansion at 16 atm using DB.

CONCLUSIONS

This study indicated that 3-times expansion of BRS was effective for larger diameter gain, regardless of delivery balloon with different inflation pressures and NC balloon. Post-dilatation using NC balloon after BRS deployment at intermediate IP was considered feasible to reduce the procedural-related risk of scaffold fracture. Acquisition of procedural larger acute gain would be crucial for BRS due to time-dependent diameter reduction.

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Pre-medication to reduce anxiety in patients undergoing coronary angiography and PCI

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

AIMS

There is limited evidence supporting the use of premedication to reduce anxiety. In this study we examined the effects of routinely administration of different benzodiazepines or no premedication on reducing periprocedural anxiety.

METHODS AND RESULTS

In this open label study, we enrolled 1683 patients undergoing coronary angiography (CAG) or percutaneous coronary interventions (PCI). Randomization was simulated by systematically allocating patients in monthly periods to lorazepam 1mg/sl, oxazepam 10mg/po, diazepam 5mg/po, midazolam 7.5mg/po or no premedication. Anxiety was measured at four different time points using the one-item Visual Analogue Scale for Anxiety (VAS score) ranging from 0 to 10. The primary outcome was the reduction in anxiety from pre-procedure to post-procedure.

Anxiety reduction was larger in patients premedicated with lorazepam (VAS= -2.0, SE= 1.6,*P* = 0.007) and diazepam (VAS=-2.0, SE= 1.5, *P* = 0.003)compared to patients who did not receive any premedication (VAS = -1.4, SE= 1.2). Midazolam and oxazepam did not lead to a significant reduction in anxiety compared to patients receiving no premedication. Additionally, a high number of patients treated with midazolam (N=39, 19.8%) developed side effects.

CONCLUSIONS

In this study, lorazepam and diazepam were both associated with significant, but small, anxiety reduction in patients undergoing CAG or PCI. This study does not support the standard use of oxazepam or midazolam as premedication to reduce anxiety.

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Very late stent thrombosis in a large cohort of patients treated with DES in daily practice

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

AIMS

The occurrence of stent thrombosis after DES is considered a relatively rare event, but may occur overtime. Our objetice was to report of the incidence and predictors of stent thrombosis in a large cohort treated with DES in daily practice.

METHODS AND RESULTS

A total of 6943 patients undergoing elective, urgent or emergent percutaneous intervention with DES as default strategy were enrolled in the DESIRE (Drug-Eluting Stents In the REal World) Registry between May/02 and Oct/16 at a single institution in Brazil. Clinical FU was performed at 1 and 6 months, and yearly up to 14 years (95%). ST was defined according to the propositions of the Academic Research Consortium. Overall, mean age was 64.7 yrs, 32% had diabetes, 63% dyslipidemia, and 18% presented with recent MI (<30 days). There were 1.7±0.8 lesions per patient and 1.8±1.0 DES implanted per patient (total=12261) - 46% first and 54% second generation DES. Mean lesion length and reference diameter were 21.1±7.3 mm and 2.86±0.56 mm, respectively. At late follow-up up to 14 years (mean time 5.5±3.8 years), the cumulative incidence of stent thrombosis was 2.5%; very late ST represented 60% of events, and def./prob. ST >1 year represented 30%. The independent predictors of def./prob. stent thrombosis identified in the multivariate model were: target vessel in saphenous vein graft (HR=3.9, 95% CI 2.0-7.8, p<0.001), clinical presentation of recent MI (HR=2.7, 95% CI 1.3-5.6, p=0.007), residual stenosis per % by QCA at postprocedure (HR=1.0, 95% CI 1.0-2.0, p=0.01), total stent length (HR=1.0, 95% CI 1.0-1.0, p=0.08), and solely use of second generation DES (HR=0.4, 95% CI 0.2-0.8, p=0.02).

CONCLUSIONS

The occurrence of definite or probable stent thrombosis after in the very long-term follow-up (up to 14 years) in daily practice was relatively low, and associated with saphenous vein graft, recent MI, stent underexpansion, stent length and the use of first generation DES.

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Caval Valve Implantation (CAVI) as interventional treatment option for severe tricuspid regurgitation - results from the CAVI-TricValve-Registry

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

AIMS

Transcatheter caval valve implantation (CAVI) is considered as treatment option for inoperable patients with severe tricuspid regurgitation (TR) and venous congestion. The procedure involves the catheter-based deployment of bioprosthetic stent valves in the inferior (IVC) and/ or superior (SVC) vena cava to treat symptoms of right heart failure. Herein, we summarize the up-to-date experience with this treatment approach in a multicenter registry.

METHODS AND RESULTS

The CAVI-Registry included 23 (mean age 74.2±8.0; female 60.9%) patients from 7 cardiac centers across Germany and Canada. Procedural and interventional data as well as information on adverse events at 30 days and during long-term follow-up was collected using standardized report forms.

Patients were treated with single valve implantation (IVC only; n=19, 82.6%) or bicaval valve implantation (IVC+SVC, n=4, 17.4%). In these patients, either ballon-expandable (Sapien XT or Sapien 3: n=18, 78.3%) or self-expandable valves (TricValve n=5; 21.7%, Directflow n=1, 4.3%) were used for either single IVC- or bicaval-valve implantation. When self-expandable valves were used different techniques of IVC landing-zone downsizing were applied including pre-stenting with ≥1 self-expandable stents (n=16) or surgical banding (n=2). In all patients immediate procedural success (defined as successful valve delivery in intended position) was reported. 30d-survival was 82.6% (n=19), long-term survival was reported in 8 patients with an overall median survival 98d (1-1429d). Causes of early mortality included respiratory (n=1) or multiple organ failure (n=3) during the postoperative course and were not linked to the procedure. Early valve migration requiring surgical intervention occurred in one patient.

CONCLUSIONS

Transcatheter caval valve implantation for treatment of severe TR is associated with a high procedural success rate and consistently results in the resolution of caval backflow. Safety and efficacy concerns include sufficient anchoring of valves in dilated caval veins as well as patient selection. As the clinical benefit of the CAVI-concept is still undetermined data from ongoing randomized studies is awaited.

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Bioresorbable everolimus-eluting vascular scaffold for the treatment of long coronary lesions: the Long-ABSORB registry

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

AIMS

This study aimed to describe the results of using bioresorbable Vascular Scaffold (BVS)to treat long and very long lesions in a real world patient population. We assessed one year anatomic evaluation either by coronary angiogram or MultiSlice Computed Tomography (MSCT).

Whereas initial studies with BVS avoided long lesions, recent reports have shown good early results. Two years follow-up of long and very long lesions has not been published. Little is known about one year MSCTevaluation of long BVS segments.

METHODS AND RESULTS

We conducted a prospective single-centre registry including all consecutive long lesions treated by BVS with a meticulous protocol.One year anatomical evaluation (coronary angiogram and mainlyMSCT)was obtained in almost allpatients.Target lesion failure (TLF)and stent thrombosis (ST) were assessed at one and two years.

113patients were enrolled with a mean age of 62±11.2 years. The PCI scenario was: 79% stable angina21% acute coronary syndrome. A total of 116 lesions were treated with 201 Absorb BVS. Mean lesion length was 35.2±14.1 mmwith 42%of very long lesions (>34 mm). The overall procedural success was 97.4 %.The cumulated TLF at one and two yearswas 7.1 %and 9.7% respectively. The cumulative incidence of ST was 0.88 % at 30 days and 1.77 % at 18 months. 90 % of patients underwent anatomical one year control. We detected 5.9 % of in-scaffold restenosis.

CONCLUSIONS

BVS PCI for long and very long lesions appear to be effective and safe with low rates of ST. MSCT permits the non invasive evaluation of BVS patency at one year. Long-term data are awaited.

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Major coronary evaginations following implantation of BRS - Clinical and OCT characteristics

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

AIMS

The aim of this study was to clarify the clinical manifestation, extent and time course of coronary artery remodeling in vessel segments that develop angiographically detectable evaginations following BRS implantation through OCT analysis.

METHODS AND RESULTS

In 8 patients, 10 BRS which displayed coronary evaginations in clinically driven invasive coronary angiograms following implantation of BRS (Absorb, Abbott Vascular, Santa Clara, CA, USA) were identified. Vessel and device geometry was analyzed in serial OCT cross-sections at a spacing of 200µm. Measured BRS dimensions were normalized to the original implant size. Results were analyzed in relation to the time interval since BRS implantation and findings were compared to 10 BRS without coronary evaginations.

The mean time interval since implantation was 20±10 months (4-33 months). 7 of 8 patients both with evaginations and in the control group presented with stable angina, 1 patient in each group with NSTEMI. In OCT, major evaginations on average affected 24±19% of the scaffold length. Scaffolds with major evaginations had a significantly larger lumen area than scaffolds without evaginations (mean normalized lumen area 1.19±0.58 vs. 0.77±0.38; p<0.001), and also displayed significantly larger scaffold area (mean normalized scaffold area: 1.36±0.6 vs. 1.13±0.43; p<0.001), and scaffold diameter (mean normalized scaffold diameter: 1.17±0.33 vs.1.04±0.19; p<0.001). In BRS segments with evaginations, normalized scaffold area (1.37±0.45 vs. 1.36±0.64; p=0.01) and normalized scaffold diameter (1.18±0.33 vs. 1.16±0.20; p=0.03) were significantly, but only very slightly larger than in segments without evaginations. BRS segments with evaginations showed significantly higher rates of strut fracture (rate per cross section: 0.08±0.11 vs. 0.02±0.18; p=0.03) and malapposed struts (0.13±0.24 vs. 0.03±0.07; p=0.006) compared to areas without evaginations. There were no significant differences regarding edge dissections or scaffold eccentricity between scaffolds with and without evaginations. Lumen area (r=0.47; p<0.001), scaffold area (r=0.52; p<0.001), and scaffold diameter (r=0.76; p<0.001) in the evagination group were positively correlated to the time since scaffold implantation.

CONCLUSIONS

Coronary evaginations following BRS implantation are associated with an increased scaffold area, indicating that the scaffold follows the outward remodeling of the artery. The process affects the entire scaffold length and seems to be continuously progressing following implantation. The occurrence of evaginations is associated with higher rates of strut fracture and malapposed struts.

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Feasibility and safety of transfemoral sheathless Portico implantation: TAVR with the lowest profile delivery system

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

AIMS

The use of the Portico system without delivery sheath results in the lowest profile delivery system for TAVR currently on the market. We herein report our single center experience, feasibility and safety of such an approach.

METHODS AND RESULTS

The Portico valve (St. Jude Medical, Minneapolis, Minnesota) was implanted sheathless in 81 high-risk patients with severe aortic stenosis utilizing percutaneous femoral access. Mean diameter of the common femoral artery was 7.06±1.89 mm. In most cases a multidetector computed tomography was performed before the intervention to assess the feasibility of vascular access and for aortic annulus measurements. The vascular access site was preclosed using two ProGlide suture systems.
Device implantation was successful in all patients. Valve recapturing and repositioning as well as valve-in-valve deployment was performed in only one case (1.2%). There were no infarctions, 2 strokes (2.4%) and 2 acute kidney failure (2.4%), 1 major vascular complication1 (1.2%) 4 major bleedings (4.9%), 11 conductions disturbances and relative pace-maker implantations (13.5%). The mean gradient decreased from 42.33±17 to 6.28±2.78mmHg. Paravalvular regurgitation as assessed by TTE at discharge was absent or trivial in 19 patients, mild in 60 and moderate 1. Thirty-day mortality was 2.4%.

CONCLUSIONS

Sheathless use of the Portico valve is feasible and appears to be safe, with excellent rates of complications and mortality in the short-term. Such an approach has the potential to further expand feasibility of transfemoral TAVR to patients with severe peripheral arterial disease.

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Efficacy of rotational atherectomy to treat in-stent restenosis lesions

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

AIMS

We have occasionally encountered restenosis due to under-expansion of drug-eluting stent (DES) implanted in severely calcified lesions. The aim of this study is to evaluate the efficacy of rotational atherectomy to treat in stent restenosis lesions.

METHODS AND RESULTS

In patients who were suffered from repetitive in stent restenosis, rotational atherectomy was performed to ablate the under-expansion stent struts and the calcified plaques behind them. Then new DES was implanted in these lesions. We measured these minimum lumen area (MLA), minimum lumen diameter (MLD), minimum stent area (MSA) and minimum stent diameter (MSD) by using intravascular ultrasonography (IVUS) before and after percutaneous coronary intervention (PCI).

We experienced ablation of the under-expansion stent struts and the calcified plaques behind them in 9 cases who were suffered from repetitive in stent restenosis because of the original calcified plaque.
It was accomplished good stent expansion in the cross-sectional IVUS images. MSA was significantly bigger than MLA (2.89±0.65 mm^2 vs 7.78±1.28 mm^2; P = 0.0004). However there was no significant difference in MSD and MLD (2.74±0.44 mm vs 1.64±0.21 mm; P = 0.84).

CONCLUSIONS

Rotational atherectomy might be a safe and promising option for the treatment of restenosis lesions caused by the crushing of DES in severely calcified lesions.

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Clinical implication according to spasm type of single coronary artery provoked by intracoronary ergonovine tests in Korean patients

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

AIMS

This study aimed to evaluate clinical implications of single vessel coronary spasm provoked by intracoronary ergonovine provocation test in Korean population.

METHODS AND RESULTS

A total of1,248patientswho presented with single vessel coronary artery spasm induced by intracoronary ergonovine provocation test,excluding 1,712 with multiple and mixed coronary artery spasms among 2,960 patients in the VA-KOREA (Vasospastic Angina in Korea) registry, were classified into diffuse (n=705) and focal (n=543) groups. The 24-month incidences of a composite primary endpoints (cardiac death, new-onset arrhythmia, and acute coronary syndrome) were determined.

Over a medianfollow-up of 30 months, the composite primary end point occurred more frequently in the focal type patients than in the diffuse type patients (primary endpoint : adjusted hazard ratio [aHR], 1.658; 95% confidence interval [CI] 1.272 to 2.162,p<0.001). Especially, unstable angina in ACS components played a major role in this effect (hazard ratio [HR], 2.365; 95% confidence interval [CI] 1.100 to 5.087,p=0.028).

CONCLUSIONS

Focal typeof single vessel coronary artery spasm in vasospastic angina (VSA) patients is found to be associated with worse clinical outcomes. It is thought that the effect is stemmed from unstable angina among ACS rather than the other components of primary endpoint. Therefore, focal type of single vessel coronary artery spasm in patients with VSA should be more carefully assessed and managed with appropriate medication.

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BRS as a treatment option for left main lesions

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

AIMS

We aimed to explore the use of current generation bioresorbable vascular scaffolds (BVS) as a treatment option for left main (LM) lesions.

METHODS AND RESULTS

We analyzed 60 patients treated with BVS for LM lesions from 12 centers (out of a total of 2765 LM percutaneous coronary interventions) between June 2012 and December 2015. The primary endpoint was target lesion failure (TLF), which was defined as a composite of cardiac death, target vessel myocardial infarction and ischemia-driven target lesion revascularization (TLR). From the cases analyzed, 14 (23.3%) involved isolated LM shaft stenting, and the remaining 46 (76.7%) cases involved the LM bifurcation. Of the 46 bifurcation cases, 37 (80.4%) had BVS implanted with a provisional strategy. Crossover from an initial provisional to a 2-stent strategy occurred in 4 out of 37 patients (10.8%). The remaining 9 (19.6%) underwent an elective 2-stent strategy (2 mini-crush, 3 V-stenting, 4 T-stenting). Of the 13 cases in which a stent / scaffold was implanted in the side branch, a BVS was used in 10 cases and DES in the remainder (n=3). The median follow-up time was 593 days (Interquartile range 230–817 days). In the overall cohort, the primary endpoint occurred in 14.9% (n=7) and 25.0% (n=10) of patients at 1 and 2 years respectively. The ischemia-driven TLR rate was 13.4% (n=6) and 23.6% (n=9) at 1 and 2 years respectively. The cardiac death rate was 1.8% (n=1) and there were no incidences of myocardial infarction or definite/probable device thrombosis at 2-years. For isolated LM shaft stenting, the 2-year TLF rate was 16.7% (n=1), and for bifurcation stenting 27.5% (n=9) at 2-years (p=0.39).

CONCLUSIONS

In this preliminary experience, the implantation of BVS in highly selected patients with LM disease appears feasible and was not associated with myocardial infarction or device thrombosis at midterm follow-up. However, the ischemia-driven TLR rate at 2-year follow-up was high, which probably reflect limitations of current generation BVS.

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Prognostic value of the CHADS2 score for adverse cardiovascular events in coronary artery disease patients without atrial fibrillation

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

AIMS

The $CHADS_2$ score has been used to predict cerebrovascular accidents in patients with atrial fibrillation (AF). We wished to investigate the value of the $CHADS_2$ score in predicting cardiovascular events in coronary artery disease patients without AF.

METHODS AND RESULTS

This was a multicenter, observational cohort study. The subjects had been admitted to one of the participating institutions with a cardiovascular event requiring percutaneous coronary intervention (PCI). We calculated the CHADS2 scores for 7082 CAD patients (mean age, 69.7 years; male, 71.9%) without clinical evidence of AF using data collected in the registry database. Subjects were subdivided into low- (score 0-1), intermediate- (score 2-3), and high-risk (score 4-6) groups, and followed for one year. The endpoint was a composite of cardiovascular and cerebrovascular death, nonfatal myocardial infarction, and ischemic stroke at 1-year follow-up after PCI. The rates of triple-vessel or left main trunk (LMT) disease correlated positively with CHADS2 score categories. The mean CHADS2 score among single, double, and triple-vessel or LMT coronary artery disease were (mean[standard deviation]) 1.82(1.15), 2.05 (1.16), and 2.35 (1.2), respectively($P < .001$). A total of 194 patients (2.8%) had a cardiovascular event, and Kaplan-Meier analysis demonstrated a significantly higher probability of cardiovascular events in proportion to a higher CHADS2 score (log-rank test: $P < .001$). Multivariate Cox hazard analysis identified CHADS2 score (per 1 point) as an independent predictor of cardiovascular events (HR, 1.28; 95% CI, 1.15-1.44; $P < .001$).

CONCLUSIONS

This large cohort study indicated that the $CHADS_2$ score is useful for the prediction of cardiovascular/cerebrovascular events in CAD patients without AF.

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Feasibility of magnetic resonance-guided coronary catheterisation: initial results from a mini-pig model

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

AIMS

X-ray guided coronary catheterization comes at the cost of exposure to radiation. Since MRI does not use radiation, provides tissue contrast, and allows functional measurements, we aim to show feasibility of MR-guided catheterization in a pig model.

METHODS AND RESULTS

Female Göttingen minipigs (24 month of age, about 40 kg) were anaesthetized and mechanically ventilated. An 8F vascular access was surgically inserted in the right femoral artery, then the animal was transferred into a clinical 3T MR scanner (Siemens PRISMA, Germany). From a 3D data set acquired in the beginning, images of the left main stem were reformatted in both double-oblique transversal and coronal view. These images were then used as reference planes for realtime guidance. As standard coronary catheters show unfavorable properties for MR due to artifacts caused by incorporated metal braiding and invisible catheter tips, we custom-build an active coronary catheter providing a hyperintense signal at its tip to improve guidance. The active catheter was advanced to the aortic root using a hydrophilic guidewire. After removal of the wire, engagement of the left coronary artery was repeatedly successful under MR realtime-guidance. We advanced an MR-compatible guidewire (MaRVis Medical GmbH, Germany) into the coronary artery to set the basis for future stent placement. Having selectively intubated the coronary vessel, we performed a perfusion study injecting gadolinium contrast agent through the catheter lumen, which allowed to identify the myocardial segments supplied via the left coronary artery.

CONCLUSIONS

In this study, we show that active visualization of modified commercial catheters for MR-guided percutaneous coronary interventions is feasible in a minipig model. Our approach allows reprodrucible engagement of the left coronary artery under real-time MR-guidance, as well as selective coronary perfusion imaging for assessment of myocardial blood supply.

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Treatment of aortic and iliac artery aneurysms with multilayer flow modulator: single-centre experiences

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THEME: Peripheral Interventions
TOPIC(S): AAA, Iliac / Femoral / Popliteal

AIMS

Presenting early and midterm results of aortic and iliac artery aneurysms treated with Multilayer Flow Modulator (MFM) stent.

METHODS AND RESULTS

Cardiatis MFM stent was used throughout the stent implementation procedure. MFM stent placement in the aneurysm region without complication was defined as successful intervention. Patients were followed up for 6 months in terms of development of clinical complications.The procedure was successfully completed in 16 out of 18 patients (15 men, 3 women). 13 of the remaining 16 patients were thoracoabdominal aortic aneurysm and 3 of them were iliac artery aneurysm. In all the remaining patients, the procedure was performed via the main femoral artery. 1 patient (70 years old male) died during the hospitalization period on the third day due to acute renal failure, 1 patient (72 years old male) died at the end of the first month because of superior mesenteric artery and celiac artery thrombosis and one patient (78 years old male) died at the end of the third month due to the acute anterior myocardial infarction. Remaining 13 patients were uneventful for first 6 months.

CONCLUSIONS

In the treatment of aorta and iliac artery aneurysms whose significant side branches, MFM stents are effective and safe. Our results have shown that MFM stents can be a good alternative for the treatment of aortic and iliac artery aneurysms with important side branches.

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Evaluation of outcomes in left main stem PCI in a non-surgical centre

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

AIMS

Coronary bypass grafting is considered as the gold standard treatment. The aim of this study was to evaluate the clinical efficacy and safety of unprotected LMS PCI in a non-surgical centre.

METHODS AND RESULTS

For this retrospective study, the data on the LMS PCI cases performed between **June 2011 and November 2015**, was collected from the local database and discharge summaries. In-hospital mortality and 6 month major adverse cardiovascular events (MACE) were also recorded.

The total number of patients were 192 including 142 males and 50 females with an average age of 68.2 (39-91) years and multiple risk factors .12.5% (24) of patients had functional grafts.45% were elective procedures 33.8% NSTEMI and 15%PPCI. Bail out stenting was required in 1.5%.Over 70% of the procedures were performed trans-radially. The average **EURO score was 3.59 % (0.55-34.7%).**

The anatomical distribution was: 50% distal, 26% mid and 23% ostial .Of the total number of lesions 50% were isolated LMS lesions. Additional imaging was performed in approximately 41% of the PCIs.The mean **Syntax score** was 31.9(11-73).The mean dimensions of LMS was 3.47(2.5-4.5) mm by 19.8(8-38) mm. Total number of stents used were 312: 64% were drug eluting stents, 15% drug eluting balloons, 7.3%bare metal stents and 6.7% combination Sirolimus-eluting endothelial progenitor cell capture stents .6% of patients were in cardiogenic shock and had Intra-aortic balloon pump inserted GpIIbIIIa was used in 25% of patients.

97% of the cases had post–procedural stenosis of <50%. TIMI III flow was achieved in 94.7% and procedural success reported in 97.4%. In-hospital MACE was 5.2% and at 6 months 12.5%. There were in total 8 (4.1%) in-hospital deaths recorded.

CONCLUSIONS

The study revealed a procedural success of over 95% with a low in-hospital mortality of 4%.The 6 month MACE rate was 12.5 % comparable to the reported data, leading us to conclude that PCI in LMS lesions in a non-surgical centre is both safe and effective when performed in appropriate patients.

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Final results from the PROMUS Element European Post-Approval (PE-Prove) registry: five-year outcomes in 1,010 unselected patients treated with a platinum-chromium everolimus-eluting stent

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

AIMS

The prospective, open-label PROMUS Element European Post-Approval Surveillance Study (PE-Prove) assessed the platinum-chromium everolimus-eluting PROMUS Element stent in an unselected patient population. Here we present 5-year outcomes from PE-Prove.

METHODS AND RESULTS

PE-Prove enrolled 1010 patients at 40 European sites who underwent coronary artery stenting with the PROMUS Element stent. The majority (75%) of patients was male; at baseline, 25.0% had medically-treated diabetes and 20.5% had unstable angina. AHA/ACC Type B2 or C lesions were present in 50% of patients, and 8.5% of patients had total occlusions. The primary endpoint of PE-Prove was the target vessel failure (TVF) rate (overall and PROMUS Element stent-related) 1 year after stent implantation. The TVF rate was defined as cardiac death, myocardial infarction related to target vessel, and target vessel re-intervention. As previously reported, the 1-year overall and study stent-related TVF rates were 6.2% (60/975) and 3.4% (33/976), respectively.

At 5 years, clinical follow-up was available for 942/1010 patients (93.3%). By Kaplan-Meier analysis (N=1010), the overall 5-year TVF rate was 14.9% (n=145), and PROMUS Element stent-related TVF was 7.0% (n=67). The overall mortality rate at 5 years was 9.7% (n=95); cardiac mortality was 5.0% (n=48). Myocardial infarction, which was assessed according the definition used in the Platinum study, occurred in 6.1% (n=59) of patients; 3.2% (n=31) of MI were considered related to the study stent. A total of 10.0% of patients (n=95) underwent target vessel revascularisation (TVR); 5.7% (n=54) were reported as being related to the study stent and were considered target lesion revascularisations (TLR). At 5 years, ARC definite/ probable stent thrombosis was 1.0% (n=10; all instances were considered related to the PROMUS Element stent). The annualised incidence of stent thrombosis was 0.2% per year. Among patients with medically-treated diabetes, the overall and study stent-related TVF rates were 24.5% and 12.9%, respectively. In patients with long lesions (≥28mm), the overall and study stent-related TVF rates were 16.4% and 9.8%, respectively. Additional results for high-risk subgroups will be reported at the time of the meeting.

CONCLUSIONS

Five-year results from the multicentre PE-Prove Registry demonstrate favourable outcomes and low rates of adverse events with the PROMUS Element everolimus-eluting stent when used in routine clinical practice in an unselected patient population.

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Carotid artery stenting in elderly patients

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THEME: Interventions for Stroke
TOPIC(S): Carotid stenting, Ischaemic stroke

AIMS

We tried to determine the influence of age on complication rates of carotid artery stenting.

METHODS AND RESULTS

From April 2014 to December 2015, 52 patients aged ≥65 years underwent 69 procedures. Patients had either symptomatic stenosis ≥50% or asymptomatic stenosis ≥70%. All patients underwent carotid and cerebral CT angiography to determine anatomic suitability and stent risk. Demographic and outcome data were entered into a database; other data were obtained retrospectively. Independent neurology evaluation was performed before and at 24 hr after the procedure. The mean age was 75.2 years, 73.7% were male, 70.5% were symptomatic, 3.5% had postcarotid endarterectomy restenosis, and 8.0% had contralateral internal carotid artery occlusion. **Results:** CS was successfully completed in 67 procedures (98.7%). There are two procedural failures. One patient had a distal filter stuck in the stent which can not to be removed. This patient underwent emergency surgery under regional anesthesia. Another patient common carotid artery dissection during sheath placement, deployed one more stent. There were no intracranial hemorrhages or periprocedural myocardial infarctions. One patient had minor conrtlateral stroke in-hospital with good recovery. Thus the overall 30-day stroke rate was 1.44%.

CONCLUSIONS

CS can be performed safely in anatomically suitable elderly patients with low adverse event rates. CS should remain a revascularization option in appropriately selected elderly patients.

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Circadian rhythm in Southeast Asian patients with STEMI and the differences in clinical characteristics and outcomes

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

AIMS

We evaluated the circadian rhythm of STEMI, differences in clinical characteristics and its impact on clinical outcome in our South-East Asian cohort of patients.

METHODS AND RESULTS

We studied 1,441 STEMI patients (86% male, mean age of 58 ± 12 years) who underwent primary percutaneous coronary intervention (PPCI) at our institution in Singapore from January 2009 to December 2014. 28% of patients had history of diabetes mellitus. Approximately 50% of patients underwent PPCI through radial artery access and received DES implantation.Patients were categorized by time of symptom onset into four 6-hour intervals: 00:00 – 06:00, 06:00 -12:00, 12:00 – 18:00, and 18:00 – 24:00. Patients' clinical characteristics, reperfusion time and inhospital mortality in each subgroup were analysed.A significant circadian variation in the timing of symptom onset of STEMI was observed : early morning peak (31%) between 06:00-12:00 and trough (21%) between 18:00-2400.There were no age, gender, multi-ethnic and socio-economic differences between the 4 subgroups. There was also no difference in the prevalence of cardiovascular risk factors between the 4 subgroups except for hypertension. Patients in the time interval of 18:00-24:00 has the highest proportion (55.3%) of antecedent hypertension followed by those (52.2%) in the time interval of 00:00-06:00.Patients in the time interval of 06:00-12:00 have the shortest median door-to-balloon (D2B) time (46.5 mins) while those in the time interval of 00:00-06:00 has the longest median D2B time (57 mins).Incidence of anterior STEMI was highest (57%) in the time interval of 00:00-06:00 followed by patient subgroup (49.3%) in the time interval of 18:00-24:00. There was no difference in the rates of cardiogenic shock across the 4 subgroups.For inhospital mortality, patient subgroup in the time interval of 00:00-06:00 has the highest mortality (7.5%) followed by those (6%) in the time interval of 18:00-24:00.

CONCLUSIONS

We observed a circadian peak presentation of STEMI in our South-East Asian cohort with differences observed for baseline clinical characteristics, reperfusion time and inhospital mortality. The highest rates of anterior STEMIs and inhospital mortality were observed in the two time intervals (00:00-06:00 and 18:00-24:00) and this could represent a potential target for preventive strategies.

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Comparison of on- vs. off- hour management of patients with NSTEMI and their outcomes: a single-centre experience in Ireland

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THEME: Coronary Interventions
TOPIC(S): NSTEMI

AIMS

The aim of this study was to determine whether invasive management of NSTEMI patients was in concordance with the ESC guidelines, and to analyze the difference in the timing of invasive management between on- and off- hours and their outcomes.

METHODS AND RESULTS

The 2015 European society of Cardiology (ESC) guidelines on management of Non-ST-elevation myocardial infarction (NSTEMI) in high-risk patients (rise or fall in cardiac troponin compatible with MI) recommend an early invasive strategy i.e., coronary angiography within 24-hours of hospital admission. We retrospectively enrolled 191 NSTEMI patients in this study, who presented to University hospital Limerick from January to November 2016. The time interval from presentation to invasive management and the outcomes of patients presenting during weekdays 9:00 a.m. to 5:00 p.m. (on-hours) were compared with those presenting during off-hours. The Mann-Whitney U test was used to compare medians across groups (on- and off- hours). Spearman's correlation coefficient was used to measure the strength of the association between numeric variables. A 5% level of significance was used for all tests.The mean age of the patients was 65 years (SD 11.6, range 24 to 91). The majority (73.3%) were male and 106 (55.5%) presented out of hours. There was considerable variation in time from presentation to invasive management (range 0.5 to 266.5 hours) and these times were negatively correlated with the change in troponin levels ($r=-0.24$, $p<0.001$), positively correlated with age of the patient ($r=0.22$, $p=0.002$) and strongly positively correlated with total inpatient length of stay (LOS) ($r=0.51$, $p<0.001$).
Median time from the Emergency Department to the ward was 9 hrs for on-hours and 10.25 hrs for off- hours presentations ($p=0.32$). Median time from presentation to invasive management was 30.5 hrs for on- hours and 37.6hrs for off- hours presentations ($p=0.77$). Overall, 70 (36.5%) patients had coronary angiography within 24-hours of presentation. Median LOS was similar for patients who presented during on- and off-hours (median LOS of 4 days for both groups, $p=0.38$). Readmission rates within 30 days did not show a statistically significant difference11.1% for in hours vs. 18.6% for out of hours, $p=0.16$). There were no inpatient deaths and only one patient (who presented in hours) died within 30 days.

CONCLUSIONS

The invasive management of NSTEMI in our hospital is not in concordance with the guidelines. Waiting times and outcomes are similar for on- and off- hours presentations. Longer times from presentation to invasive management are associated with older patients and smaller changes in the level of troponin.

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TAVI futility risk model development and validation among treated aortic stenosis patients

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

AIMS

Optimal patients' selection for TAVI is still unclear. A sizeable group of patients do not benefit from the intervention despite successful procedure. We sought to develop a risk model in order to predict those ‘futile’ TAVI procedures.

METHODS AND RESULTS

We included all patients that underwent TAVI in our medical center with device success and with no major and/or debilitating complications as defined by the Valve Academic Research Consortium-2, leaving those with an uncomplicated optimal TAVI for the present analysis. We examined various demographic data, clinical details and echo-cardiographic findings, including patients’ frailty assessment. The outcome was defined as 1-year composite score of mortality, stroke, functional-class lack of improvement (vs. baseline), and repeat (≥1 month) cardiovascular admissions. We used logistic regression and support vector machine (SVM, a machine learning method) to fit the prediction model. We used 10-fold cross-validation to verify our results. Out of 567 patients, 482 met the inclusion criteria. Mean age 82 (±6.5) years, 56% females. At 1-year, 102/482 (21%) patients experienced the adverse futility related outcome. The final model included age, sex, weight, height, frailty, albumin, creatinine, hemoglobin, aortic and mitral insufficiency grade, history of diabetes, pulmonary disease, and baseline conduction-delay. Using a regression model, the area under the curve (AUC) was 0.75 and was reduced to 0.69 after validation, with 96% specificity and 2.9% false (+). With SVM, the AUC after validation was also 0.69, but specificity rose to 99.7% with only one patient misclassified as false-positive, and with positive/negative predictive values of 0.97/0.85, respectively. Using the model could identify futile TAVI upfront in a third of the cases (31% sensitivity).

CONCLUSIONS

Without depriving treatment from those who may need it, the TAVI futility model could provide important insight and aid identifying patients who, despite successful/uncomplicated procedure, might not derive benefit and/or longevity following TAVI.

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One-stent vs. two-stent strategy in STEMI patients with bifurcation lesion undergoing primary PCI: COBIS (Coronary Bifurcation Stenting) registry II

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

AIMS

This study aimed to compare the clinical outcomes between the 1-stent and 2-stent strategies in ST elevation myocardial infarction (STEMI) patients with bifurcation lesion undergoing primary percutaneous coronary intervention (PCI).

METHODS AND RESULTS

Coronary bifurcation stenting (COBIS) II registry is a retrospective multicentre registry of consecutive 2,897 patients with bifurcation lesions undergoing PCI with drug-eluting stents in Korea. Among the registered study population, 367 (12.7%) patients had STEMI, which consisted of 304 (82.8%) patients received 1-stent and 63 (17.2%) patients received 2-stent strategy. The inverse probability of treatment weighted method was used to adjust for confounding factors. The primary outcome was major adverse cardiac event, a composite of cardiac death, myocardial infarction, target lesion revascularization, and stent thrombosis. The median follow-up duration was 38 months (interquartile range 26 to 50). After performing inverse probability of treatment weighted methods, the rate of occurrence of major adverse cardiac event was significanlty higher in 2-stent strategy group than in 1-stent strategy group (hazard ratio 1.85, 95% confidence interval 1.19 to 2.87, p=0.006) mainly driven by target lesion revascularization (hazard ratio 2.17, 95% confidence interval 1.29 to 3.63, p=0.003) and stent thrombosis (hazard ratio 19.83, 95% confidence interval 3.04 to 129.41, p=0.002). Post procedural side branch diameter stenosis was significanlty different between the two groups (1-stent vs. 2-stent, 42.7% vs. 9.7%, p<0.001)

CONCLUSIONS

In STEMI patients with bifurcation lesion undergoing primary PCI, 2-stent strategy had significantly higher rates of major adverse cardiac event mainly driven by target lesion revascularization and stent thrombosis compared to 1-stent strategy despite more procedural success in side branch.

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A decade trends in PCI practice: insights from a 18,641 patients registry

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

AIMS

To evaluate the trends accompanying percutaneous coronary intervention (PCI) practice and outcomes during the last decade.

METHODS AND RESULTS

Between Jan-2004 and Dec-2016, 18,641 consecutive PCI's at our medical center were divided into time quarters according to procedural date (Q1: 2004-2006, n= 4,865; Q2: 2007-2009, n= 4,977; Q3: 2010-2012, n= 4,230; Q4: 2013-2016, n= 4,569). Temporal trends regarding patients' characteristics, procedural issues and outcomes were analyzed. Results: Mean patients age was 65 (±11) years, 4242 (22.8%) females, 10,926 (58.6%) of the procedures carried out in acute-coronary-syndrome (ACS) settings. Throughout the years, octogenarians constituted a larger part of the population (from 10.7% to 15.5%, p<0.001), and although the burden of hypertension (p<0.001) and smoking history (p<0.015) decreased, the burden of most co-morbidities increased, including baseline left-ventricular (≥moderate) and chronic kidney dysfunction (from 13% and 18.1% to 17.2% and 21.7%, respectively, p<0.001 for both). Despite 2-times complex procedures amplification (from 11.2% to 22.6%, p<0.001) and 3-times escalation in unprotected left-main angioplasty (from 1.1% to 3.6%, p<0.001), the shift to radial approach was prominent (from 2% to 63.5%, p<0.001) and was accompanied by a decrease in in-hospital bleeding in ACS (but not in stable coronary disease) patients (p=0.02). Regarding stents utilization, DES implantation increased from 43% to 83% on the expense of BMS application, and accompanied by DEB sprout to 1.8%, p<0.001. Over the years, Kaplan-Meier survival curves revealed a time-based enhanced outcome, with a decreased rate of death, MI, target vessel revascularization and CABG after the PCI (Figure), which remained significant in subgroup analysis for ACS and non-ACS patients.

CONCLUSIONS

In the last decade, PCI had evolved to offer better prognosis to more elderly, sicker patient population, with more complex coronary disease. The shift to DES and to enhanced PCI techniques may explain part of this progress.

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BIOFLOW-III an all-comer registry with a sirolimus-eluting stent, presentation of three-year target lesion failure data in patients with complex lesions

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

AIMS

The aim of this registry is to evaluate the clinical performance of a new generation Sirolimus eluting stent system (Orsiro) in a large patient population in standard clinical care.

METHODS AND RESULTS

Between August 2011 and March 2012, 1,356 subjects were enrolled consecutively in this international, multicentric BIOFLOW-III all-comers registry using the Orsiro Sirolimus eluting stent.
Primary endpoint is Target Lesion Failure (TLF) at twelve months follow-up. A subgroup analysis has been conducted in patients presenting with diabetes, acute myocardial infarction, CTO and small vessels.Nine hundred seventy one men (72%) and three hundred eighty five women (28%) were enrolled at 43 sites in 14 countries. The mean age was 66.1 ± 10.7, ranging from 29 - 91 years. The majority of subjects presented with hypertension (76%), hypercholesteremia (60%), diabetes (30%) and as smokers (55%). 48% of all stented vessels had a diameter ≤2.75mm, 4.0% presented with chronic total occlusion, 10.6% with acute myocardial infarction, 77.5 % with multi-vessel disease and 52% with B2/C lesions.
In this all-comers setting a TLF rate of 7.4% was observed within the first 36 months for the overall cohort. The low TLF rate was also confirmed for the subgroups at the 3 years follow-up: diabetics (9.8%), acute myocardial infarction (9.9%), small vessels (7.3%) and CTO (1.8%).

CONCLUSIONS

The results observed in this “real world” population demonstrate a low TLF rate comparable to other state of the art DES at 36-months not only in the overall cohort but also in patients with complex lesions which have a higher risk of experiencing an adverse event.

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BIOTRONIK-safety and clinical performance of the drug-eluting Orsiro stent in the treatment of subjects with single de novo coronary artery lesions-II (BIOFLOW-II) - Four-year clinical results

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

AIMS

In this randomized controlled study we compare the clinical efficacy of the Orsiro Drug Eluting Stent with the Xience Prime™ Everolimus Eluting Stent at 4 Years in the complete study population as well as in the diabetic and small vessel subgroups.

METHODS AND RESULTS

A total of N=452 subjects (age 63.4 ± 10.1, 36-80 yrs) were enrolled in the Intention to Treat population of the BIOFLOW-II study. All subjects were randomly assigned (2:1) to receive the Orsiro or the Xience Prime stent, respectively. The randomization was stratified for diabetes. The diabetic subgroup accounted for 28.3% (Orsiro N=84, Xience Prime N=44) of all subjects. The small vessel subgroup included all subjects with a reference vessel diameter ≤2.75mm, accounting for N=259 (57.3%) of the cohort (Orsiro N=168, Xience Prime N=91).

Clinical follow up visits are performed at 1, 6, and 12 months and annually thereafter up to 5 years post index procedure. All angiographic images were analyzed by an independent Corelab. All clinical events were adjudicated by an independent clinical events committee.All three study groups showed comparable populations in both randomization arms in terms of demographics, current risk factors, clinical history and lesion/vessel characteristics. The TLF rate at 48 months was 10.2% for the Orsiro vs 11.3% for the Xience (p= 0.6699) for the overall cohort, 15.0% for the Orsiro vs 9.1% for the Xience (p=0.3888) for the diabetic subgroup and 11.3% for the Orsiro vs 15.5% for the Xience (p= 0.3028) for the small vessel subgroup. No definite or probable stent thrombosis occurred through 48 months.

CONCLUSIONS

Preliminary data of the 4 year follow-up of this randomized controlled trial demonstrates that the clinical event rates of the Orsiro SES with a biodegradable polymer were low and comparable to the Xience Prime™ in all three analyzed populations.

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Three-year clinical outcomes of BioMime sirolimus-eluting coronary stent system with a biodegradable polymer in coronary artery disease patients: a long-term follow-up of the MERIT-2 study

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

AIMS

Aim: The aim of the meriT-2 study was to determine the long-term safety and performance of the BioMime Sirolimus-Eluting Coronary Stent System (Meril Life Sciences Pvt. Ltd., Gujarat, India) for the treatment of coronary artery disease patients.

METHODS AND RESULTS

The meriT-2 was a prospective, multicenter study conducted in 250 patients at 11 Indian sites. The primary endpoint was major adverse cardiac events (MACE) defined as a composite of cardiac death, myocardial infarction (MI) and target lesion revascularization (TLR) at 30 days after the procedure. The primary efficacy endpoint was in-stent late lumen loss (LLL) at eight months. The secondary endpoints were MACE and stent thrombosis (ST) at one-year follow-up. The clinical follow-up was performed at the following time points: 30 days, six months, one year, and three-year after index procedure. Recently, follow-up was performed at three-year and the resultant cumulative MACE was analyzed. Follow-up at three-year was available for 242 patients (96.8%). Among those 123 (49.2%) patients had hypertension and 91 (36.4%) patients with diabetes mellitus. Out of 355 lesions, 63.4% lesions were type B2/C as defined by the ACC/AHA guidelines. The cumulative MACE was 18 (7.4%), including 2(0.8%) cardiac deaths, 4 (1.6%) MI, and 12 (4.8%) any-TLR. Stent thrombosis was observed in 3 (1.2%) patients.

CONCLUSIONS

Long-term clinical outcomes of BioMime SES at 3 year follow-up demonstrated excellent safety and performance in a coronary artery disease patient population with a high prevalence of hypertension, diabetes and complex lesions.

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One-year clinical outcomes of biodegradable polymer sirolimus-eluting coronary stent system in patients with coronary artery disease

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

AIMS

The aim of the present study was to evaluate the safety and performance of Metafor Sirolimus-eluting Coronary Stent System (SES) in consecutive patients with coronary artery disease (CAD) in a real-life scenario.

METHODS AND RESULTS

This was a retrospective, observational, postmarketing study conducted in 251 patients with CAD who were implanted with Metafor SES (Meril Life Sciences, Pvt .Ltd., Gujarat, India) and followed clinically/telephonically at one-year. The primary endpoint was a major adverse cardiac event (MACE) defined as the aggregate of cardiac death, myocardial infarction (MI), and any target lesion revascularization (TLR) at one year. Also, stent thrombosis (ST) was observed at one-year patients follow-up. Out of them 251 participants, 191 (76.1%) were male, 95 (37.8%) patients had diabetes, 153 (61%) had MI, 161 (64.1%) had stable angina, and 134 (53.4%) had hypertension which is suggestive of a real-life scenario. Mean patient age was 56.35 ± 11.23 years and 17 patients underwent primary percutaneous coronary interventions (PCI). A total of 295 lesions were treated, out of which 13.6% of the lesions were long lesion of ≥ 40mm. At one-year, MACE occurred in 4 (1.6%) of 251 patients, consisting of 2 (0.8%) cardiac deaths, 2 (0.8%) MI, and 0 (0%) TLR. Stent thrombosis was reported in one patient (0.4%).

CONCLUSIONS

This retrospective data demonstrated excellent safety and performance of Metafor SES in the “real-life” consecutive CAD patients, indicating low rates of MACE and ST at one-year follow-up.

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Quantitative angiographic analysis in patients with de novo native coronary artery lesions treated with novel poly-L-lactide based sirolimus-eluting BRS: MERES-1 trial

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

AIMS

The aim of this first-in-man study was to report the six-month angiographic results of a MeRes100 BRS (Meril Life Sciences, Gujarat, India) applied for the treatment of *de novo* native coronary artery lesions.

METHODS AND RESULTS

A total of 108 patients with coronary artery lesion related to a single *de novo* lesion length up to 20 mm in length in native coronary artery or a maximum of two such lesions in different epicardial vessels with vessel diameter between 2.75 and 3.50 mm. The primary endpoint of the study was in-scaffold late lumen loss at six-months. The secondary endpoints include in-scaffold and in-segment restenosis and % diameter stenosis (DS). Angiographic follow-ups were scheduled at 6 and 24 months. The Quantitative Coronary Angiography (QCA) results were available in 37 patients (41 lesions) at six-months. QCA results post procedure showed an In-segment acute gain of 1.71 ± 0.50mm and the late lumen loss was observed as 0.14 ± 0.22mm at 6 month follow-up (FU). The In-scaffold acute gain was 1.86 ± 0.42mm and the late lumen loss at 6 month FU was 0.15 ± 0.23mm. In-scaffold RVD was observed as 3.14 ± 0.38 and 3.06 ± 0.39 at post-procedure and 6-months respectively while MLD was observed as 2.82 ± 0.32 and 2.67 ± 0.40 at post-procedure and 6-months respectively. Whereas, in-scaffold and in-segment % DS rates were 12.68 % and 13.87%, respectively and angiographic binary restenosis rate at 6 months was 0 (0%).

CONCLUSIONS

The preliminary data from QCA reflects device feasibility in treating *de novo* native coronary artery lesions in terms of low late lumen loss and absence of restonesis at 6 month FU. Long-term QCA (24 month FU) results are awaited.

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MERES-1 trial: six-month IVUS follow-up outcome of novel poly-L-lactide based sirolimus-eluting BRS

SETH A.(1), NANJAPPA M.(2), MAHAJAN A.(3), KUMAR V.(4), GOEL P.(5), CHANDRA P.(6), WANDER G.(7), BAHL V.(8), KALARICKAL M.(9), KUMARAN A.(10), KAUL U.(11), RATH P.(12), MISHRA A.(13), TREHAN V.(14), GANESHWALA G.(15), KOSHY A.(16), ONUMA Y.(17)

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

AIMS

In present study, we evaluate safety and efficacy of a novel Poly-L-Lactide based Sirolimus-eluting BRS MeRes100 in patients with de novo native coronary artery lesions.

METHODS AND RESULTS

The MeRes-1 is a prospective, multicentre, first-in-human trial of MeRes100 Sirolimus-eluting BRS (Meril Life Sciences, Gujarat, India). A total of 108 patients were enrolled at 13 Indian centres. Twelve patients were followed up for six months after the procedure. Each patient was analyzed by intravascular ultrasound (IVUS) catheters in paired angiographic views after the procedure and at follow-up. IVUS follow-ups were scheduled at 6 and 24 months. The IVUS subset analyses at six months showed limited in-scaffold neo-intimal hyperplasia (NIH) area ($0.14mm^2$). Overall the scaffold area remained consistent. There were no significant changes observed in mean scaffold area (6.17 to 6.47 mm^2) and mean lumen area (6.14 to 6.25 mm^2). No malapposition or late-acquired incomplete strut apposition was observed till six months.

CONCLUSIONS

At 6 month FU by IVUS, there were no significant changes in scaffold area and lumen area and minimal neo-intimal hyperplasia. MeRes100 BRS seems an attractive option for the treatment of *de novo* native coronary artery stenosis.

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Conscious sedation as the default anesthetic approach for TAVI

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

AIMS

TAVI has traditionally been performed under general anesthetic (GA). Our default has been to perform TAVI under conscious sedation (CS) .We determined the efficacy, safety and cost savings of this approach.

METHODS AND RESULTS

We reviewed our program at St James's Hospital and Blackrock Clinic, Dublin from commencement in September 2008 to December 2014. Mean EURO II score, 30 day and one year mortality; cerebrovascular complications, vascular and major bleeding complications (drop in Hb> 2g/dl), acute kidney injury (AKI) and length of stay were compared between GA and CS groups.The mean age for CS patients was 82 ± 4.8 and 83 ± 4.4 for GA patients (p=0.2). The mean EUROII score for CS was 9.1 ± 0.6 verus 9.7 ± 0.9 for GA (p=0.6). The total length of stay was significantly lower for CS patients 7.5 ± 8.1 days versus 15.4 ± 37 days for GA patients(p=0.01). There was no difference in one year mortaility which was 21% for GA and 17% for CS (p=0.6). There was a trend for lower rates of major bleeding and vascular complications with CS procedures. Major bleeding occured in 13% of CS patients and 15% of GA patients (p=0.4), whilst vascular complications occured in 9% of CS patients and 14% of GA patients (p= 0.2).There was no significant differences in stroke or pacing rates between groups.CS was associated with a significantly decreased incidence of acute kidney injury (5% for CS and 18% for GA,p=0.01). Addionally at a cost per night of 1000 euro per patient the shorter length of stay for CS generated significant cost savings when compared to GA.

CONCLUSIONS

TAVI using conscious sedation is associated with a much shorter post procedural hospital stay, significant cost savings and similar procedural success. Conscious sedation should be the default anesthetic approach for non-surgical access

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The efficacy of using Lacrosse NSE balloon before stenting for the severe calcified coronary lesion

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

AIMS

Assessment of the efficacy of using Lacrosse NSE Balloon(NSE) before stenting for the severe calcified coronary lesion

METHODS AND RESULTS

Methods; This was a single center retrospective observational study. Consecutive 34 lesions(32 patients) underwent NSE angioplasty before drug-eluting stent(DES) implantation for the severe calcified coronary lesion(defined as calcium arc =>180° and calcium length =>1.0mm) at our hospital from June 2015 to November 2015. At 6-12 months, the follow up coronary angio graphy(CAG) was performed. Clinical events were collected until November 2016. Patients were divided into two groups based on the number of crack : 13 lesions(12 patients)=<1 crack group(no/1 crack group) and 21 lesions(21 patients) =>2 crack group(multiple crack group) on the intravascular ultrasound (IVUS) image. The primary outcomes were acute lumen gain and acute symmetry index gain(defined as post symmetry index% – pre symmetry index%). The second outcomes were targeted lesion revascularization(TLR) and stent thrombosis(ST).

Results; There were no clinically significant differences between both groups with respect to clinical presentation(mostly stable angina), cardiovascular risk factors, but the value of estimated glemerular filtration rate(eGFR) was significantly lower in the multiple crack group. Patients were well balanced according to lesion location, morphology, all pre-procedural quantitative coronary angiographic analysis(QCA) variables. The number of arc of calcium=>270°was numerically higher in the multiple crack group(8 vs. 15 lesions, p=0.70), on the other hand, the number of 270°>arc=>180°was similar in both groups(5 vs. 6 lesions, p=0.70). There were no significant differences with regard to NSE size, post-dilatation balloon size and pressure atmosphere between the two groups. Acute lumen gain and acute symmetry index again of the primary endpoint were numerically higher in the multiple crack group(4.18±2.16 vs. 2.88±1.54mm, p=0.06, and 8.50 vs. 3.01, p=0.25). The number of TLR of the second outcome were numerically higher in the no/1 crack group(2 vs. 0, p=0.27). There was no ST in either group.

CONCLUSIONS

Although statistically significant difference was not, using NSE before stenting for the severe calcified coronary lesion had tendency to result in better stent expansion in the multiple crack group.

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Radiation exposure optimisation in the cathlab

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

AIMS

We analysed whether fine-tuning of radiation protocols together with increased awareness reduces radiation exposure in the cathlab.

METHODS AND RESULTS

Since January 2016, in close collaboration with the general electric engineer, we added a new radiation protocol in our cath lab with less radiation, including, low frame rate fluoroscopy at 7.5 frames/second. In addition, the cathlab staff were sensitised to reduce radiation exposure as much as possible by applying the lowest radiation protocol. Maximal collimation and optimal X-ray tube/patient/detector distances were recommended too.

From October 2015 to February 2016, 170 consecutive patients (110 percutaneous coronary interventions (PCI)) who underwent coronary angiography in our institution were retrospectively collected and then divided into two groups according to the data of the cardiac catheterization: Before January, the lowest radiation group (group A) and after January, the traditional protocol group (group B).After optimization, lowest radiation protocol was used 97% of the time. Most of the procedures were performed by radial approach in both groups (group A 87.5% vs group B, 86.4%, p=0.8). There were no significant differences in patient backgrounds; complexity of the lesions or complications rate of both groups. The same operators performed the procedures in both groups.

Contrast volume (152±115 vs 161 ± 121 ml, p=0.4) and fluoroscopy time (13.5±14 vs 12.9±13 min, p=0.7) were also not different between both groups; However the entrance dose at the patient plane (EFD) was reduced by 44.6% mGy (CI 95% 18.4%-70.8%) in overall procedures and by 48.3% mGy (CI 95% 21.2%-75.4%) when only PCI were analyzed. The Dose-area product (DAP) was reduced by 71.1% Gy·cm2 (CI 95% 30.2%-90.1%) in PCI procedures. The ratio EFD / Fluoroscopy time was highly significantly reduced in group A (39.9±22 vs 54.3±22, p<0.0001).

Subgroup analysis showed that radiation differences were found among PCI cases but not when we analyzed only diagnostic procedural cases.

CONCLUSIONS

Optimization of radiation programmes together with the active sensitisation of the staff resulted in a significant reduction in radiation exposure in the cath lab. We should be willing to optimize radiation protocols to improve the safety of patients and medical staff.

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Safety and efficacy of biolimus-eluting stents in patients undergoing complex PCI

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

AIMS

The purpose of this study was to compare the 2-year safety and efficacy of biolimus-eluting stents with biodegradable polymer (BP-BES) versus everolimus-eluting stents with durable polymer (DP-EES) in patients undergoing complex PCI.

METHODS AND RESULTS

This is the sub-study of the SMART-DESK registry, which is multicenter, nonrandomized, open-label trial comparing BP-BES with DP-EES in patients scheduled for PCI using drug-eluting stent among 16 major cardiovascular centers in Korea. Study population was categorized according to the presence or absence of complex PCI, which was defined as the composite of left main coronary artery as target vessel, ≥2 lesions treated, total length of stent implanted >55mm, or minimal diameter of stent implanted <2.75 mm. The primary endpoint was major adverse cardiovascular events (MACE) defined as a composite of cardiac death, target vessel myocardial infarction (TV-MI), or target lesion revascularization (TLR) at 2 years of follow-up. Of 1,999 patients included in the registry database, 916 (45.8%) underwent complex PCI. Patients who underwent complex PCI were older and had higher prevalence of diabetes mellitus, previous MI, and lower hemoglobin. In terms of clinical presentation, patients undergoing complex PCI had higher prevalence of ACS presentation. Patientswho underwent complex PCI had more complex coronary artery disease with higher prevalence of American College of Cardiology/American Heart Association type B2/C lesions. BP-BES were used in 44.4% and 54.7% in the complex PCI and non-complex PCI groups, respectively. Compared with non-complex PCI, patients who underwent complex PCI showed a tendency to have a higher 2-year risk of MACE (adjusted hazard ratio [HR]: 1.59; 95% confidence interval [CI]: 0.95 to 2.68; $P = 0.08$), driven by a higher risk of TLR (adjusted HR: 4.96; 95% CI: 1.68 to 14.64; $P = 0.004$). However, complex PCI was not independently associated with higher risks of cardiac death (adjusted HR: 1.05; 95% CI: 0.56 to 1.99; $P = 0.88$), TV-MI (adjusted HR: 1.57; 95% CI: 0.37 to 6.62; $P = 0.54$), or definite or probable stent thrombosis (adjusted HR: 1.67; 95% CI: 0.40 to 7.01; $P = 0.49$). The magnitude and direction of the effect and safety of BP-BES compared with DP-EES on clinical outcomes was uniform between complex PCI and non-complex PCI patients, without evidence of interaction for the studied endpoints ($P_{interaction}$ for MACE = 0.50; $P_{interaction}$ for cardiac death = 0.84; $P_{interaction}$ for TV-MI = 0.67; $P_{interaction}$ for TLR = 0.12; or $P_{interaction}$ for stent thrombosis = 0.95).

CONCLUSIONS

Patients undergoing complex PCI remain at higher risk of adverse events. The long-term safety and efficacy of BP-BES versus DP-EES are constant among complex and non-complex percutaneous revascularization procedures.

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Bivalirudin plus prasugrel in primary angioplasty

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Our aim was to determine if prasugrel plus bivalirudin in primary percutaneous coronary intervention (PCI) would reduce cardiovascular events without increasing bleeding complications compared to clopidogrel plus bivalirudin.

METHODS AND RESULTS

224 consecutive patients with an acute ST-segment elevation myocardial infarction who were treated by primary PCI within 12 hours of the onset of symptoms received bivalirudin plus clopidogrel (Group A) or bivalirudin plus prasugrel (Group B). We compared the groups using propensity score matching.

The primary endpoints were MACE at 30 days and 12 months defined as composite cardiac death, stent thrombosis (ST), acute myocardial infarction, and cerebrovascular accident. Secondary endpoints were: probable/confirmed ST and bleeding complications.After propensity score matching no differences in baseline characteristics were observed between both groups (n=174). The mean age of the patients was 57.3 ±9 years old (57.6±9 in group A versus 57±10, p=0.7); 25% were diabetics (23% vs 27.6%, p= 0.48) and left ventricular ejection fraction was 54.4 ±10 (53.7±10 vs 55±9, p=0.78); . The approach was preferentially radial in both groups (93.1% vs 95%, p=0.5) and the prevalence of anterior myocardial infarction was 41.4% in group A versus 41.4% in group B (p=1). MACE at 30 days were significantly increased in group A (4.6% vs 0%, p=0.042). Cardiovascular events were increased mainly at the expense of ST. The rate of acute and subacute ST was 3.4% in Group A and 0% in Group B (P = 0.12). The total mortality and rate of major bleeding complications at 30 days were 0% for both of the groups. MACE at one year were not significantly reduced in group B (6.9% vs 2.3%, p=0.14). ST at one year was 4.6% in group A versus 1.1% in group B (p=0.17).

Neither minor (6.9% vs 1.1%, p=0.06) nor major bleeding complications (2.3% vs 1.1%, p=0.16) were increased in group B compared to group A at one year follow-up.

CONCLUSIONS

The administration of bivalirudin plus prasugrel in primary PCI, with a preferentially radial approach, reduces cardiovascular events at 30 days compared to bivalirudin plus clopidogrel without increasing neither bleeding nor ST.

However a lack of benefit was observed at one year follow-up.

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Dual lumen catheter in CTO: not only for bifurcation cases

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

AIMS

Dual lumen catheters (DLC) were designed with the purpose of managing bifurcation lesions. Beyond this scenario these catheters could be a useful tool in chronic total occlusions(CTO). Our aim was to analyse CTO cases in which DLC was used

METHODS AND RESULTS

A retrospective multicentric study was carried out, including all cases of CTO PCI in which a DLC was used between January 2013 and January 2016

Result:

During the period of the study a DLC was used in 13 CTO percutaneous coronary intervention (PCI) cases with a successful final result in 77% of them (10/13). The mean age of the patients was 71±12 years old; 84% were males; 25% were diabetics and mean left ventricular ejection fraction was 47±12%; J CTO score was 1.92±0.9

Most of the cases were CTO bifurcation cases (8/13). In the rest of cases the DLC was used as bailout strategy, after other techniques failed, as part of modified see-saw technique and one case was an in stent CTO with a previous failed attempt t in which the DLC was used to successfully direct a second wire to the center lumen, away from abutting the stents struts and then was used to treat the distal bifurcation.

Regarding the bifurcation cases all of them involved the distal bifurcation and the secondary branch had at least 2mm. 50% of them were true bifurcations. A dissection that involved the bifurcation during the PCI occurred in 62.5% (5/8).The most frequent strategy for bifurcation treatment in these cases was wiring and predilate the secondary branch. The bifurcation treatment success (less than 30% residual stenosis and a TIMI flow grade 3) was 87.5% (7/8).

There were no major procedural complications. On 12 months follow-up there was one cardiac event (1/13): A myocardial infarction in a CTO PCI failure. 100% of the patients with successful recanalization of a CTO were free of events at follow-up.

CONCLUSIONS

DLC are easy and reliable to use and can be useful and safe in CTO PCI cases, especially, but not only in CTO bifurcation cases.

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Treatment of bare-metal stent restenosis using different paclitaxel-eluting balloon catheters

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

AIMS

Our study aimed to compare the efficacy of seal-wing paclitaxel-eluting balloon catheters (PEB) with iopromide-coated PEB and everolimus-eluting stents (EES) for treating bare metal stent restenosis (BMS-ISR).

METHODS AND RESULTS

We enrolled 64 patients with 69 BMS-ISR. The control group comprised patients from the iopromide-PEB and EES arms of a previous TIS study. The primary end-point was 12-month in-segment late lumen loss (LLL). Secondary end-points included incidence of binary in-stent restenosis and 12-month major adverse cardiac events (MACE).

Compared to iopromide-coated PEB, seal-wing PEB was associated with significantly lower 12-month minimal lumen diameter (MLD; 1.68 vs. 2.13 mm; p=0.0006) and significantly higher 12-month LLL (0.30 vs. 0.02 mm; p<0.0001), repeated binary restenosis (28.12% vs. 8.7%; p=0.012), 12-month MACE (26.98% vs. 10.29%; p=0.003), and target vessel revascularization (TVR; 20.63% vs. 7.35%; p=0.009).

Seal-wing PEB was also associated with significantly lower 12-month MLD (1.68 vs. 2.23 mm; p=0.003) in comparison with EES, but no significant differences were found in the 12-month LLL, repeated binary restenosis, or 12-month MACE (p=1.000 for all).

CONCLUSIONS

BMS-ISR treatment using seal-wing PEB led to significantly higher 12-month LLL, repeated binary restenosis, MACE, and TVR compared to iopromide-coated PEB and significantly lower MLD in comparison with EES.

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Key predictors of severe or obstructive coronary artery stenosis among asymptomatic and zero or extremely low coronary calcium score populations

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

AIMS

Coronary artery calcium (CAC) correlates with severity of coronary artery disease (CAD). However, significant CAD has been detected in patients with very low CAC. We aimed to evaluate key predictors of severe or obstructive CAD in those populations.

METHODS AND RESULTS

In this study, 1922 consecutively enrolled asymptomatic subjects without previous history of CAD underwent calcium scans and coronary computed tomography angiographies (CTA). Among those populations, 638 subjects with zero or very low (<10) calcium scores were analyzed for coronary artery stenosis by using CTA. The very low CAC score group was defined by having a less than 10 CAC score. Obstructive and Severe stenosis were defined by having more than 50% and more than 70% stenosis in any of the major coronary arteries respectively. Age, gender, body mass index (BMI), hypertension (HTN), Type II diabetes (DM), dyslipidemia, lipid profile, creatinine, and smoking status were evaluated as predictors for severe CAD. Among the 638 subjects, 10.3% (n=66) showed obstructive stenosis (≥50%) and 4.5% (n=29) showed severe stenosis (≥70%). In addition, 46.7% (n=298) were male and the mean age was 57.2 ± 12.6. The mean CAC score was 0.73 ± 2.02 and the zero calcium score was 84.0% (n=536). Among evaluated risk factors, age (OR 1.04, 95% CI 1.01-1.06, p=0.005), male (OR 2.06, 95% CI 1.13-3.75, p=0.018), and low HDL cholesterol (OR 0.98, 95% CI 0.96-0.993, p=0.043) were significantly associated with obstructive CAD in multivariate analysis. On the other hand, for severe CAD, age (OR 1.04, 95% CI 1.01-1.08, p=0.015), low HDL (OR 0.95, 95% CI 0.92-0.98, p=0.002), and current smoking status (OR 2.58, 95% CI 1.01-6.58, p=0.048) were found to be significantly associated in multivariate analysis. Improvement of discrimination power for predicting severe CAD was observed when smoking and HDL cholesterol were serially added into the age model. The AUC value was higher in the ‘Age + Smoking + HDL cholesterol’ model when compared to the ‘Age + Smoking’ model (AUC 0.80, 95% CI 0.76-0.83 vs. AUC 0.70, 95% CI 0.66-0.74, p=0.009).

CONCLUSIONS

Our analysis demonstrated that smoking showed significant correlation with severe CAD even in the extremely low CAC scored asymptomatic population. Low HDL cholesterol level also proved to be a powerful predictor of either obstructive or severe CAD in the same subjects. These factors might be useful to consider when screening CAD in asymptomatic subjects.

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Clinical and echocardiographic outcomes after percutaneous transluminal septal myocardial ablation for hypertrophic obstructive cardiomyopathy: a 16-year single-centre Australian experience

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

AIMS

Percutaneous Transluminal Septal Myocardial Ablation (PTSMA) is a recognized option for the relief of symptoms in patients with HOCM. However, data are limited regarding long-term procedural safety and efficacy.

METHODS AND RESULTS

We report long-term clinical and echocardiographic outcomes in patients undergoing PTSMA in a tertiary centre. Consecutive patients undergoing PTSMA from 2000-2016 were included in a retrospective analysis. All procedures were performed by a single experienced operator, under general anesthesia with transesophageal myocardial contrast echocardiographic guidance to enable anatomical selection of appropriate sub-branches of septal perforators. Clinical follow-up and echocardiography was performed post-procedure, at 2 days, 6 weeks, 6 months, 12 months and yearly thereafter.76 patients (mean age 60±15 yrs; 50% male) underwent PTSMA during the study period [median FU 90 (range 3-182) months]. Long-term data were not available on 10 patients. Mortality was 1.3% (1/76) in hospital. Survival at most recent follow up was 93.4% (61/66). Of the 5 deaths, 2 were cardiovascular (CV) and 3 non-cardiovascular; the 2 CV deaths were due to heart failure and not late ventricular arrhythmias. New PPM implantation was 24.2% (15/62) in hospital; only 2 further patients received a PPM at most recent follow up. Compared to baseline (19.8±4.4mm), post-procedural septal thickness was significantly reduced at all intervals (6wk - 18.4±4.9mm, p=<0.001); 6mnth - 17.7±5.5mm, p=0.008; 1yr - 17.7±5.8mm, p=<0.001; most recent - 16.0±4.9mm, p=0.002) indicating progressive remodelling. Compared with baseline (81.7±49.6mmHg), post-procedural resting LVOT gradients were significantly reduced at all points (2 days - 51.4±40.9mmHg, p<0.001; 6wk - 31.8±37.4mmHg, p<0.001; 6mnth - 28.5±30.4mmHg, p<0.001; 1yr - 27.4±32.4mmHg, p<0.001; most recent - 11.8±21.1mmHg, p<0.001). At most recent follow up, median NYHA class improved from 3 to 1 (p=0.004) and median CCS class from 2 to 1 (p=0.08).

CONCLUSIONS

In selected patients, PTSMA is a safe and effective treatment for relief of symptoms in patients with HOCM. Our data demonstrates sustained reductions in both IVS wall thickness & resting LVOT gradients up to 8 years post-procedure.

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Percutaneous transluminal septal myocardial ablation, is it safe? A 16-year single-centre Australian experience of immediate procedural outcomes

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair, Other valvular and structural interventions

AIMS

Percutaneous Transluminal Septal Myocardial Ablation (PTSMA) is designed to relieve symptoms of HOCM. We report immediate procedural outcomes in patients undergoing PTSMA in a regional tertiary centre over a 16-year period.

METHODS AND RESULTS

Consecutive patients presenting for PTSMA from 2000-2016 were included in a retrospective analysis. All underwent coronary angiography to assess for the presence of suitable sub-branches of septal perforators. If appropriate, PTSMA was scheduled separately under general anesthesia with transesophageal myocardial contrast echocardiographic (MCE) guidance.85 patients (mean age 60±15yrs, 52% male) were considered for PTSMA; of these 2 (2.4%) were unsuitable due to very small septals, 2 (2.4%) were abandoned because balloons could not be delivered into inaccessible septal anatomy, & 5 (5.9%) were unsuitable after septal interrogation revealed echocardiographic opacification of inappropriate myocardium due to extensive septal collaterals. 76 patients (89.4%) proceeded to PTSMA. Mean procedural time was 106±24 mins. An average of 2.2±0.6ml alcohol was injected into 1.1±0.4 septal perforators. Acute intra-procedural ventricular arrhythmias necessitating DC cardioversion occurred in 3 patients (3.9%). Anterior MI due to LAD artery no reflow occurred in 2 patients (2.6%) & tamponade occurred in 1 patient (1.3%) after removal of the temporary pacing wire. 14/64 patients (21.9%) experienced complete heart block & required PPM implantation. There were no ventricular septal ruptures, & no intra-procedural deaths although one patient (1.3%) suffered a hemorrhagic stroke & died 3 days post procedure. Compared with baseline, PTSMA led to an immediate significant reduction in both resting (51±41 vs 82±50mmHg; p=0.0001) & provoked (65±44 vs 96±37mmHg; p=0.0002) LVOT gradients. Mean peak troponin & CK post PTSMA were 33±27 (ug/L) and 1295±792 (U/L) respectively.

CONCLUSIONS

Sub-selective PTSMA guided by MCE is an effective treatment for reducing LVOT gradients in symptomatic patients with HOCM. It is technically feasible in most patients assessed, & in carefully selected anatomy, procedural success can be achieved with 2.2ml of alcohol with low complication rates.

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The risk of rhythm disturbances and ventricular arrhythmias after and during percutaneous transluminal septal myocardial ablation for hypertrophic obstructive cardiomyopathy

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

AIMS

Percutaneous Transluminal Septal Myocardial Ablation (PTSMA) is an effective treatment for symptomatic HOCM but may be associated with conduction disturbances & arrhythmias. We analysed their incidence in a single tertiary centre undertaking PTSMA.

METHODS AND RESULTS

Consecutive patients undergoing PTSMA from 2000-2016 were included in a retrospective analysis. All procedures were performed by a single experienced operator, under general anesthesia with transesophageal myocardial contrast echocardiographic guidance for anatomical selection of appropriate sub-branches of septal perforators. A temporary pacing wire remained in-situ for 24-48 hours and patients were monitored in hospital for 5 days post-procedure. 12-lead ECGs were recorded at baseline and daily thereafter until discharge, and were systematically analyzed for conduction disturbances.76 patients (mean age 60±15yrs, 50% male) underwent successful PTSMA. Intra-procedural ventricular arrhythmias necessitating DC cardioversion occurred in 3/76 patients (3.9%) - 1 of these occurred during septal wiring and 2 during injection of the echo contrast agent. Post-procedure, 14/64 patients (21.9%) developed complete heart block (CHB) and required permanent pacemaker (PPM) implantation. CHB was not associated with volume of alcohol infused (2.1±0.8 vs 2.0±0.8ml, p=0.44) or number of septal perforators injected (1.1±0.3 vs 1.1±0.4, p=0.77), but was more likely in patients with pre-existing LBBB (21.4 vs 4.0%; p=0.06). In patients not requiring a PPM (n=50), the most common new conduction abnormalities were RBBB (n=15, 30%), 1st degree AV block (n=9, 18%) & LBBB (n=5, 10%).

CONCLUSIONS

Conduction disturbances (but not ventricular arrhythmias) are common after PTSMA for selected patients with symptomatic HOCM. Pre-existing LBBB is a predictor for the development of CHB and the need for a PPM.

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Incidence of symptom-driven coronary angiographic procedures post-DEB treatment of coronary artery DES in-stent restenosis - Does it matter?

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

AIMS

We aimed to describe the incidence of incidence of symptom-driven coronary angiography (SDCA) after drug-eluting balloon (DEB) coronary intervention for drug-eluting in-stent restenosis (DES-ISR).

METHODS AND RESULTS

We retrospectively identified all patients (n=28) who had DEB-treated DES-ISR at University Hospital Limerick between 2013-2015 and evaluated the incidence of subsequent SDCA as the primary endpoint. Data were expressed as mean ± SD and %. Baseline demographics demonstrate a mean age 63 ± 9 years with 61% of DEB-treated DES-ISR presenting with acute coronary syndrome. Mean number of ISR per patient and number of DEB per lesion was 1.2 ± 0.6 lesions and 1.2 ± 0.6 balloons, respectively. The incidence of SDCA was 54% after mean follow-up duration of 179 ± 241 days. 67.8% of patients had follow-up data beyond 12 months. Within the first year of follow-up, the incidence of SDCA with and without target lesion revascularization (TLR) was 11% and 36% respectively. Among patients with SDCA without TLR, 30% had an acute coronary syndrome not requiring percutaneous coronary intervention.

CONCLUSIONS

A high incidence of SDCA was observed, particularly within the first 12 months after DEB-treated DES-ISR. This under-reported metric may represent a cohort at higher cardiovascular risk but requires further confirmation in larger studies.

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Transcatheter LAA occlusion for stroke prevention in patients with atrial fibrillation: the Belgian registry

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

This study aimed at assessing the safety and efficacy at mid-term follow-up of transcatheter left atrial appendage occlusion using different devices, in the real life in Belgium.

METHODS AND RESULTS

Between June 2009 and November 2016, 457 consecutive patients (63% males, 75±12 yrs, CHA_2DS_2-VASc 4±0.6, HASBLED 3.5±0.7) undergoing left atrial appendage occlusion in 21 centers, were included in the study. Technical success was 97.1%. There were 19 periprocedural major adverse events (4.1%) including three death (0.6%), nine tamponades (1.9%), four major bleedings (0.8%) and two device embolizations (0.4%). The procedural outcome was similar between patients implanted with the Watchman device (N = 139) and those treated with the ACP/Amulet prosthesis (N = 318).

Among patients successfully implanted with a complete follow-up (672 patient-years, median follow-up 1273 days), the actual annual stroke rate was 1.2%, lower than the expected stroke risk (4%, 70% reduction). The observed bleeding rate was 2%, while the calculated risk was 3.7% (46% reduction).

Kaplan-Meier analysis showed a similar overall survival (91±3% and 87±4% versus 93±2% and 87±3% ; p = 0.35) and event-free survival (88±3% and 80±5% versus 92±2% and 84±3% ; p = 0.17) at 1 and 2 years, for the Watchman versus the ACP/ Amulet groups of patients, respectively.

At last follow-up, 90% of patients were left untreated by any anticoagulants : medication was limited to aspirin in 65% or to nothing in 5.7% of cases.

CONCLUSIONS

The data of the Belgian left atrial appendage occlusion registry suggest that the procedure is safe and effective in a real world setting, to prevent atrial fibrillation-related thromboembolism at mid-term follow-up, using either the Watchman or the ACP/Amulet device.

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Bivalirudin vs. unfractionated heparin during PCI in patients with ACS without ST-segment elevation: 12-months follow-up

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THEME: Coronary Interventions
TOPIC(S): NSTEMI

AIMS

to evaluate the efficacy of various anticoagulants used in percutaneous coronary interventions in patients with acute coronary syndrome without ST-segment elevation.

METHODS AND RESULTS

METHODS: 346 patients were randomized in 2 groups. In group I (n=155) - PCI was performed with the use of bivalirudin and in group II (n=191), using unfractionated heparin. Additional randomization of patients in group I: in subgroup A (n=77) - the bivalirudin infusion was continued for 4 hours after intervention and in the subgroup B (n=78) - infusion was discontinued in the CathLab.

Inclusion criteria: patients ACS without ST-segment elevation with multi-vessel coronary bed lesion (risk SYNTAX score=23-32); high and medium risk on GRACE scale; the absence of a history of myocardial revascularization. Exclusion criteria: patients with very high risk on GRACE scale; the lesion of the main left coronary artery.

RESULTS: during hospitalization, the combined incidence of intra - and postoperative cardiovascular complications was not significantly different in two groups and was 7.1% and 8.4%, respectively (p=0,6423). Serious bleeding (BARC 3 and 5) was significantly more often in patients from group II. The groups also did not differ in the incidence of acute stent thrombosis. In the subgroup A was less significant to have serious cardiovascular complications, compared with patients from the subgroup B (1,3 and 13%, respectively; p=0.001), and the incidence of bleeding was also not significantly increased. Patients in group I with transradial arterial access, bleeding and cardiovascular complications were 0 and 2.9%, respectively, while patients with transfemoral arterial access, these figures were significantly higher and was up to 3.3 and 10%, respectively (p<0.001). Similar trend was observed in the second group with transradial arterial access - 6 and 4.6%, respectively, while with transfemoral arterial access were 33.7 and 11.9%, respectively (p<0.001). Comparing these parameters between groups it was revealed that regardless of the selected arterial access, cardiac events were not significantly different in the group which got bivalirudin or heparin, although bleeding was observed significantly more often in the heparin group (p<0.001). The long term results of treatment (mean period of 12±0.14 months) were assessed in 192 patients, of which 91 patients from group I and 101 patients from group II. The total incidences of cardiovascular complications was significantly lower in group I compared to group II and was up to 2.2% and 6%, respectively (p=0,0312).

CONCLUSIONS

the use of a direct thrombin inhibitor - Bivalirudin during PCI in patients with ACS without ST-segment elevation, reduces the risk of hemorrhagic complications in the immediate postoperative period, and has a positive influence on long-term prognosis of these patients. The implementation of PCI by radial arterial access and the prolongation of the bivalirudin infusion for 4 hours after PCI are additional factors favorable for endovascular treatment of patients (ACS) without ST-segment elevation.

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Polymer-free sirolimus-eluting stents in a large scale all-comer population

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

AIMS

The purpose of this all comers study was to assess the safety and efficacy of a polymer-free sirolimus coated, ultrathin strut drug eluting stent (PF-SES). Stable coronary artery disease (CAD) patients with short (<= 6 months) vs. long (> 6 months) DAPT were also studied.

METHODS AND RESULTS

Patients with ACS and stable CAD received PF-SES in an unselected large scale, international, all-comers study. The primary endpoint was the 9-month TLR rate whereas secondary endpoints included the 9-month MACE and procedural success rates. Various a priori defined subgroups such as patients with ACS, diabetes, lesion subsets and procedural characteristics and DAPT duration were also investigated.

A total of 2877 patients of whom 1083 had ACS were treated with PF-SES (1.31+/- 0.75 stents per patient). At 9 months, the TLR rate was 2.3% (58/2513) whereas there were no significant differences between ACS and stable CAD patients. The overall MACE rate was 4.3% (108/2513) with a higher MACE rate in ACS patents as compared to the stable CAD subgoup (6.1% vs. 3.2%, p<0.001). Accumulated 9-month stent thrombosis rates (probable, definite) were not different between groups (0.8% vs. 0.6%, p=0.424).

Logistic regression analyses revealed that the absence of preloading and DAPT durations did not have predictive value for 9-month TLR in ACS and stable CAD patients.

CONCLUSIONS

PF-SES are safe and effective in daily clinical routine with low rates of TLR and MACE in an unselected patient population. Our data suggest that extended DAPT duration beyong 6 months do not improve MACE or TLR at 9 months in patients with stable CAD (ClinicalTrials.gov Identifier NCT02629575).

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Single-centre experience of endovascular treatment of symptomatic femoropopliteal disease by antegrade-intraluminal technique. Acute and long-term outcomes

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THEME: Peripheral Interventions
TOPIC(S): Below the knee, Iliac / Femoral / Popliteal

AIMS

Endovascular treatment has proved equivalent to surgery in peripheral artery disease (PAD). We sought to evaluate the clinical outcomes in patients (pts) with PAD treated utilizing intraluminal technique and only balloon angioplasty.

METHODS AND RESULTS

Pts with FP complete occlusion and intermitten claudication represented the studypopulation. Our technical approach is ipsilateral antegrade puncture of the common femoral artery and introduction of a short 6-Fr sheath. The intended procedure was intraluminal recanalization using alternately an 0.018-in. guide wire (V18 Control Wire; Boston Scientific, Natick, MA, USA) and 0,014-in coronary guidewire Hi-Torque Pilot 200 (Abbott Vascular, Abbott Park, IL, USA) supported by 4Fr Ber2 catheter (Cordis; J&J company, Miami Lakes, FL, USA). Between January 2014 and December 2015 65 consecutive pts underwent endovascular treatment of FP disease by antegrade intraluminal approach. Baseline clinical characteristics were: mean age 76±5,9 yo; 73,8 % (48/65) male; smoking 80% (52/65), diabetes 67,9% (44/65); hypercholesterolemia 84,6% (55/65) and hypertension 73,8 % (48/65). Angiographic characteristics were: mean length of stenosis 12,6±3,8 cm; segments treated were 43,3% (28/65) TASC A, 30,7% (20/65) TASC B, 15,3% (10/65) TASC C and 10,7% (7/65) was TASC D. Below the knee disease was present in 18,4% (12/65) of cases. Procedural success was 89,2% (58/65) and any periprocedual complication was recorded. We implanted stent only in presence of residual stenosis >30% and/or flow limiting dissection following prolonged balloon dilatation (≥ 120 sec.). The recanalization with intraluminal techniques failed in only seven pts with TASC D occlusion; We tried again a month after getting the success with traditional subintimal technique and stent implantation. We had no periprocedural complication and the mean follow-up duration was 22±12,2 months and was avalaible in 100% of pts. Improvement of recurrence of intermittent claudication was 6% (4/65); re-hospitalization was 7,6% (5/65); surgical femoralpopliteal by-pass and death were both 0%.

CONCLUSIONS

Our study demonstrates that endovascular treatment of FP disease with intraluminal techniqueand only balloon angioplasty is safe and effective also in complex lesions and, although larger studies and longer follow-up are needed, can represents an alternative of subintimal recanalization and primary stent implantation in term of acute and long clinical outcomes.

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Kinetics of circulating microRNAs in response to cardiac stress in patients with coronary artery disease

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Circulating microRNAs (miRNAs) are regulated in patients with coronary artery disease (CAD). We aimed to investigate circulating miRNA kinetics in response to cardiac stress in patients with or without significant coronary stenosis.

METHODS AND RESULTS

80 out of 105 screened patients with stable CAD underwent dobutamine stress echocardiography (DSE) before coronary angiography. Nine vascular, myocardial and platelet-derived miRNAs - miRNA-21, miRNA-26, miRNA-27a, miRNA-92a, miRNA-126-3p, miRNA-133a, miRNA-222, miRNA-223, and miRNA-199-5p - were quantified in plasma by reverse transcription polymerase chain reaction before, immediately after, at 4 hours, and at 24 hours after DSE. QPCR revealed increased miRNA-126 and -21 levels at 4 and 24 hours after DSE in all patients. In coronary angiography, significant coronary artery stenoses (>80% diameter stenosis) were found in 41 patients. Stratifying the patients according to the prevalence of significant stenoses, patients with stenosis showed an increase of circulating miRNA-21, -26, -126, and -222 in response to cardiac stress. In patients without significant stenoses (<50% diameter stenosis), miRNA-21 levels were increased at 4 hours after cardiac stress and decreased to baseline at 24h. In contrast, miRNA-92 levels gradually increased in response to cardiac stress.

CONCLUSIONS

Vascular and myocardial miRNAs are distinctly released into the circulation in response to cardiac stress depending on the prevalence of significant coronary stenoses.

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Clinical outcomes following primary PCI: a comparison of clopidogrel, prasugrel and ticagrelor

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

We assessed the association of procedural oral P2Y12-inhibitor with clinical outcomes in primary percutaneous coronary intervention (primary PCI) for ST-segment elevation myocardial infarction (STEMI), in a large consecutive patient-series.

METHODS AND RESULTS

Demographic and procedural data for all patients undergoing primary PCI in a single 24/7 UK tertiary centre between 1-1-2009 and 31-12-2011, and 1-1-2013 and 31-12-2013, were collected prospectively. Minimum 30-day follow-up data were collected for all patients. Patients with pre-procedural cardiogenic shock and/or cardiac arrest were excluded. Clinical endpoints were 30-day major adverse cardiovascular event (MACE) - defined as all-cause mortality, myocardial infarction (MI) and repeat coronary revascularisation, and 30-day major bleeding (HORIZONS criteria). Multivariable analyses for MACE and major bleeding were performed with Cox proportional hazards models, adjusting for major cardiovascular risk factors.

4056 patients underwent primary PCI during the study period, 464 of whom were excluded due to pre-procedural cardiogenic shock and/or cardiac arrest. Data for 30-day bleeding and MACE were available for 3381 of 3592 (94.2%) patients. After multivariable analysis, there was no significant difference in MACE or major bleeding between patients pre-treated with clopidogrel (n=1492; MACE 10.8%; bleeding 7.6%), ticagrelor (n=737; MACE 9.5%; HR 0.84 (0.53-1.32) vs clopidogrel; bleeding 5.3%; HR 0.76 (0.41-1.41) vs clopidogrel), and prasugrel (n=1152; MACE 5.3%; HR 0.82 (0.56-1.20) vs clopidogrel; HR 0.97 (0.60-1.58) vs ticagrelor; bleeding 5.1%; HR 1.25 (0.83-1.87) vs clopidogrel; HR 1.64 (0.88-3.05) vs ticagrelor). However, there was a significantly lower adjusted probability of 30-day MI with ticagrelor compared to clopidogrel (HR 0.38 (0.17-0.84)). The differences in adjusted 30-day MI between prasugrel and clopidogrel (HR 0.59 (0.33-1.04)), and prasugrel and ticagrelor (HR 1.55 (0.67-3.61)), were not statistically significant. There were no statistically significant differences in mortality between clopidogrel and ticagrelor, between prasugrel and ticagrelor, and between ticagrelor and prasugrel.

CONCLUSIONS

This large consecutive real-world series has shown that pre-treatment with ticagrelor was associated with lower probability of 30-day MI compared to clopidogrel, with no overall difference in bleeding, MACE or mortality. There was no significant difference in bleeding, MACE or mortality between ticagrelor and prasugrel, or between prasugrel and clopidogrel.

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Predictors of neoatherosclerosis formation in stent restenotic neointimal tissue after DES implantation

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

AIMS

Several reports have demonstrated the development of neoatherosclerosis inside drug-eluting stents (DES). We aimed to investigate the predictors of neoatherosclerosis formation in stent restenotic neointimal tissue after DES implantation.

METHODS AND RESULTS

We enrolled 51 consecutive patients with in-stent restenosis requiring revascularization after DES implantation between January 2008 and December 2015. In advance, we excluded the patients with recurrent restenosis, thrombotic lesions, and total occlusion. For evaluation of in-stent tissue components, integrated backscatter intravascular ultrasound (IVUS) was performed. We carried out simple and multiple linear regression analysis to assess the relationship between percent lipid or fibrous tissue volume and various parameters (age, gender, coronary risk factors, interval from stent implantation, continuous smoking, stent fracture, and medication) on volumetric integrated backscatter IVUS analysis. After adjustment for confounding factors, stent fracture and continuous smoking were positively correlated with the percentage of lipid tissue volume and negatively correlated with the fibrous tissue volume ($\beta = 0.35$, $p = 0.03$, and $\beta = -0.32$, $p = 0.04$; $\beta = 0.36$, $p = 0.03$, and $\beta = -0.33$, $p = 0.04$, respectively). Stent fracture was defined as complete or partial separation of stent segments observed using plain fluoroscopy without contrast injection or IVUS. Of these enrolled patients, stent fracture was observed in 17 (33.3%) and 13 (25.4%) were current smokers.

CONCLUSIONS

Stent fracture and continuous smoking were associated with larger lipid tissue volume within the neointima after DES placement, suggesting the development of neoatherosclerosis and vulnerable neointima. Thus these factors might contribute to future adverse coronary events.

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Impact of adenosine A2a receptor polymorphism rs5751876 on platelet reactivity in ticagrelor-treated patients

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

AIMS

The role of genetics on platelet inhibition with ticagrelor is still unclear. We investigated the impact of rs5751876 C>T polymorphism of adenosine A2a receptor (ADORA2a) on platelet reactivity in patients during chronic treatment with ticagrelor.

METHODS AND RESULTS

We included patients treated with ASA and ticagrelor for a recent ACS or elective coronary revascularization. Platelet reactivity was assessed at 30-90 days post-discharge by multiple-electrode aggregometry. HRPR for ticagrelor was defined as ADP-test results >417 AU*min. Genetic analysis was performed to assess the presence of rs5751876 C>T polymorphism of ADORA2a receptor.

We included 244 patients in our study, 174 (71.3%) patients carried the ADORA2a-T allele, 51 (20.9%) of them in homozygosis. C-allele carriers showed no difference in baseline characteristics but for lower HDL-cholesterol (p=0.01). An absolute lower rate of HRPR on Ticagrelor was observed in homozygotes T/T (p=0.03). At multivariate analysis, C allele carriage was independently associated with the rate of HRPR on ticagrelor (adjusted OR[95%CI]= 4.63[1.02-21.01], p=0.048).

CONCLUSIONS

Our study results showed a significant independent association between rs5751876 allele C carriage and a higher rate of high residual platelet reactivity in patients on Ticagrelor after a recent ACS or PCI.

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Impact of pre-procedural DAPT on periprocedural myocardial infarction in patients undergoing PCI with adjunctive tirofiban

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

AIMS

Suboptimal platelet inhibition enhances the risk of complications as periprocedural myocardial infarction (PMI). We evaluated the impact of platelet reactivity and pre-procedural DAPT on PMI in patients undergoing PCI with adjunctive tirofiban.

METHODS AND RESULTS

In a consecutive cohort of patients undergoing PCI with tirofiban (intracoronary/intravenous ± prolonged infusion), periprocedural myonecrosis was defined as troponin I increase by 3 times the ULN or by 50% of an elevated baseline value, whereas PMI as CKMB increase by 3 times the ULN or 50% of baseline. Platelet function was assessed by impedance aggregometry.

A total of 168 patients were included, 77 (45.8%) of whom were on DAPT at the time of PCI. Patients on DAPT had more often a history of previous PCI (p=0.03), higher ACS at admission (p<0.001) and creatinine levels (p=0.03). Coronary calcifications and type C lesions were more frequent in patients without DAPT (p=0.02 and p=0.03, respectively), as much as TIMI flow < 3 (p=0.03), whilst procedural characteristics were comparable. Baseline platelet reactivity was significantly reduced in DAPT treated patients (p<0.001 for ASPI, COL and ADP tests). However the rate of periprocedural myonecrosis did not differ according to pre-procedural DAPT (68.4%vs 67%, p=0.87; adjusted OR[95%CI]=1.34[0.71-2.53],p=0.36) and neither the occurrence of PMI (13.3% vs 12.6%, p=0.99; adjusted OR[95%CI]=1.24[0.51-3.1],p=0.64). Moreover, baseline platelet reactivity was similar in patients with and without PMI/myonecrosis with no relationship between platelet function and Troponin I peak.

CONCLUSIONS

In patients undergoing PCI with adjunctive tirofiban, preprocedural DAPT and baseline platelet reactivity are not associated to the risk of periprocedural myocardial infarction or myonecrosis.

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Impact of early culprit vessel localisation in electrocardiogram on door-to-balloon time in STEMI patients

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

The objective of this study was to investigate the impact of culprit lesion location among the three major coronary arteries on Door-to-balloon (DTB) time in ST-segment elevation myocardial infarction (STEMI) patients.

METHODS AND RESULTS

The 429 consecutive STEMI patients who underwent pPCI between January 2008 and December 2015 were evaluated groups involving, 221 patients with the culprit lesion located in left anterior descending artery (LAD group); 39 patients with the culprit lesion located in left circumflex artery (LCX group); 169 patients with the culprit lesion located in right coronary artery (RCA group). The DTB time in LCX group (55.5±20.6 min) was markedly longer than other 2 groups (43.1±21.6 min in LAD group and 39.7±20.8 min in RCA group, $p<0.01$). Moreover, the door-to-catheter laboratory time in LCX group (33.8±19.3 min) was markedly longer than other 2 groups (24.1±18.9 min in LAD group and 22.5±16.3 min in RCA group, $p<0.01$). However, the procedure time of pPCI and the 30-day mortality were similar among 3 groups.

CONCLUSIONS

DTB was significantly longer, when culprit lesion is located in the LCX. Early diagnosis for STEMI and culprit lesion localization with electrocardiogram in emergency room for those patient is considered important for further improvement in DTB.

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Out-of-hospital cardiac arrest and stent thrombosis: ticagrelor vs. clopidogrel in patients with primary PCI under mild therapeutic hypothermia

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

AIMS

To compare the incidence of ST (Stent Thrombosis) and bleeding events between ticagrelor and clopidogrel, in patients with ACS (Acute Coronary Syndrome) under MTH (Mild Therapeutic Hypothermia) after an OHCA (Out-of-Hospital-Cardiac-Arrest)

METHODS AND RESULTS

From January 2010 to August 2016, 144 patients underwent MTH after an OHCA. Overall, 114 had an ACS (79%) and 98 (67,3%) were treated with primary percutaneous coronary intervention (PCI) and stent implantation. Among them, 61 (62,2%) were treated with clopidogrel, and 32 (32,6%) with ticagrelor. During hospitalization, the incidence of probable or definite ST was significantly higher in patients receiving clopidogrel compared to ticagrelor (11,4% vs. 0%; p: 0.04), and no significant differences in any (28,6% vs. 25%; p: 0.645) or major bleeding (BARC 3 or 5) (11,4% vs. 12,5%; p: 0.685) were found. Hospital mortality did not differ between groups (26,2% vs. 25%; p: 0.862).

CONCLUSIONS

In this study, as compared to clopidogrel, ticagrelor was associated with a lower rate of ST, without differences in haemorrhagic events in patients with OHCA for an ACS under MTH. Similarly to other settings, ticagrelor might be a valid alternative to clopidogrel in these patients.

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Three-year follow-up of hybrid interventions in patients with critical limb ischaemia

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THEME: Peripheral Interventions
TOPIC(S): Below the knee, Iliac / Femoral / Popliteal

AIMS

to evaluate the effectiveness of the hybrid operation in patients with critical lower limbs ischemia.

METHODS AND RESULTS

142 patients included in the study. Inclusion criteria: multilevel arterial disease of the lower limb; critical limb ischemia; no operations and interventions on the low limb arteries in the history. Patients were divided into 2 groups. Group I included 78 patients who underwent hybrid surgery on the arteries of the lower extremities, and II group (control) included 64 patients who underwent only open surgery. During an open stage were mainly performed femoral-popliteal bypass and in some cases were performed endarterectomy of the superficial femoral artery. Endovascular stage included stent implantation in the iliac arteries, and the implementation of preferential balloon angioplasty on lesions localized below the infrainguinal area. Stent implantation was performed in the presence of dissection type D-F. Clinical criteria for evaluating the immediate results of the intervention: regression of pain, increased pain-free walking distance. Angiographic criteria for successful intervention: restoration of the main blood flow in the arteries below the knee joint gap, the lack of heavy dissections type D-F. Criteria for assessing the long-term results: the frequency of amputations, the frequency of repeated interventions. Arteriography of the lower limbs was performed in the presence of limb ischemia IIb.

The average age of patients was 67 ± 5.5 years. In I group, femoral-popliteal bypass were performed in 68 patients (87,2%), endarterectomy from superficial femoral artery were performed in 10 patients (12,8%). The stents in the superficial femoral artery were implanted in 13 patients (16.6%). In group II, femoral-popliteal bypass was performed in 53 patients (82,8%), and endarterectomy - in 11 patients (17,2%). Interventions in the tibialis arteries were included only balloon angioplasty procedures. Stent implantation was not necessary in any case.At the hospitalization period all patients had regression of pain and a significant increase in pain-free walking distance (from 12.54 ± 2.24m to 2,14m 150.2 ±; p <0.05 - in group I, and 15.42 ± 1,63m to 148,25 ± 1,89m; p<0.05 - in group II). Angiographic success in group I were achieved in 95.6% of cases. Long-term results after 36 months were followed up in 68 patients of group I, and 58 patients in group II. The frequency of amputations in patients from group I was 4.4% and in group II - 15.5 (p<0.05). Repeated interventions were also significantly more often performed in group II and formed 14.7 and 31.03% respectively(p<0.05).

CONCLUSIONS

the one-step hybrid arterial reconstructions most effectiveness methods of surgical treatment in patients with critical limb ischemia and multilevel lesions in comparison with non-hybrid treatment strategyand can improve the prognosis of this patients.

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DEB-only angioplasty in left main stem disease, a stentless approach

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

AIMS

PCI with stents has similar mortality compared to CABG in left main stem (LMS) disease, but with greater risk of repeat revascularisation. We report medium term outcomes of drug coated balloon (DCB)-only PCI, a novel approach in this cohort.

METHODS AND RESULTS

24 patients underwent DCB-only angioplasty for LMS disease from 19/07/2011 to 19/05/2016 at Norfolk and Norwich University Hospital NHS Foundation Trust, UK. Patient, procedural and clinical follow up data were obtained from trust data base, angiograms and clinic follow up records. Up-to-date mortality data were tracked via Demographics Batch Service Bureau of the Health and Social Care Information Centre.

Mean (SD) age of the cohort was 68.0 (11.5) years and 19 (79.2%) were male. 16 (66.7%) were unprotected LMS whilst 19 (79.2%) were de novo lesions. During a mean (SD) follow up of 674.6 (521.7) days there were no cardiac deaths. No target lesion revascularisations, target vessel revascularisations or cerebrovascular accidents were reported for a mean (SD) clinic follow up period of 367.6 (331.0) days. 1 (4.2%) patient had a myocardial infarction unrelated to the previously treated segment. No treated lesion thrombosis and acute vessel closure.

CONCLUSIONS

DCB-only angioplasty to LMS disease appears to be a safe and effective treatment at medium-term follow up. Further studies comparing conventional PCI to this novel stentless approach with DCB are indicated.

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Long-term follow-up of patients with coronary slow flow phenomenon

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

AIMS
Although about 1% of patients with chest pain who underwent coronary angiography have coronary slow flow phenomenon (CSFP), the long-term outcome data are limited. The aim of this study was to investigate the clinical outcome of patients with CSFP.
METHODS AND RESULTS
We prospectively enrolled 11 patients (8 males, mean age 57.5 ± 12.4 years) with CSFP between September 2007 and May 2009, and could collect the long-term (>4 years) follow-up data in 7 patients (4 males, mean age 57.7 ± 14.4 years). CSFP was defined on the basis of angiographically normal or near-normal epicardial coronary arteries and thrombolysis in myocardial infarction (TIMI)-2 flow in at least one major vessel. All patients had chest pain and 4 had some ischemic findings. On the coronary angiography, the coronary flow was improved after the administration of isosorbide dinitrate or nicorandil, and delayed after the subsequent contrast injection in all patients. The CSFP was observed in the left anterior descending artery, the right coronary artery, the circumflex artery in 5, 3, 2 patients, respectively. The median follow-up period was 2511 (range, 1703-3303) days, and calcium channel blockers were administered in 5 patients. There was no major cardiovascular event, while one patient died by drowning. No patient underwent repeat coronary angiography, but 2 patients were examined by non-invasive imaging tests because of atypical chest pain.

CONCLUSIONS
Long-term prognosis in patients with CSFP was good. Calcium channel blockers might play some role in the course, because the coronary flow change after the administration of agents suggested that the microvascular spasm was the main factor of CSFP in our patients.

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Short term effect of PCSK9 antibody against familial hypercholesterolemia developing ACS. Three cases of plaque analysis in target vessel measured by intravascular ultrasonography

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Familial hypercholesterolemia (FH) is well known for its poor prognosis.
PCSK9 antibody remarkably decreases serum LDL-C, however, it is little known about its short-term effects in FH patients developing acute coronary syndrome.

METHODS AND RESULTS

We experienced 3 cases of familial hypercholesterolemia developing acute coronary syndrome and analyzed the effectiveness of PCSK9 antibody (evolocumab) to each coronary atherosclerotic plaque in target vessel.
After PCI, evolocumab 280 mg was administered monthly via subcutaneous injection adding to take rosuvastatin calcium (20mg) and ezetimibe (10mg) orally. 12 weeks later, we performed coronary angiography and IVUS followed by analysis every 1mm slice in each atheroma plaque.
Serum level of LDL-C was significantly decreased (mean 48 mg/dl) and major adverse cardiovascular events were not occurred in all cases. IVUS analysis showed plaque volume (burden) was not significantly decreased (control 48.6% vs after 46.7%), however, lipid component of atheroma plaque was significantly decreased (control 63.2% vs 52.9%) totally in every indicating that PCSK9 antibody could modify plaque vulnerability.

CONCLUSIONS

It is possible that short duration of PCSK9 antibody may stabilize vulnerable plaque in acute coronary syndrome in familial hypercholesterolemia.

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Single-centre experience with DEB in the treatment of de novo small vessel coronary artery disease

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

AIMS

To report the outcome of Paclitaxel-Drug Coated Balloon (DCB) angioplasty in the treatment of de novo small vessel coronary artery lesions.

METHODS AND RESULTS

A total of 636 patients with 715 coronary lesions treated with DCB (SeQuent Please) were reviewed between January 2012 – December 2015. Three hundred and twenty two (51%) patients with 371 (52%) lesions had in-stent restenosis (ISR). We evaluated the remaining 314 (49%) patients with 344 (48%) de novo coronary artery lesions. Mean age was 59±10 years with a predominance of males (n= 265, 84%). Majority were hypertensive (n=237, 76%) and diabetes mellitus accounted for 165 (53%) of cases. Sixteen percent presented with acute coronary syndrome (ACS), 6% had STEMI, 5% had NSTEMI and 5% unstable angina. Diffuse vessel disease were present in 174 cases (51%). Majority of the stenotic lesions were in the left coronary artery; left anterior descending artery, n=139, (40%) and left circumflex artery, n=111 (32%). Eighty nine (26%) lesions were in the right coronary artery and 6 were in the bypass grafts (2%). Total occlusions were found in 47 cases (14%). There were 45 (13%) ostial lesions and 29 (8%) bifurcation lesions. Majority of the lesions were type B2 and C lesions (n=226, 66%). The mean reference diameter of the lesion was 2.5±0.4 mm and mean lesion length treated was 26±18 mm. The mean lesion stenosis was 87±12%. Predilatation of the lesions were performed in majority of cases (n=338, 98%) with a pressure of 11±4 atmospheres. The mean DCB diameter and dilatation pressure were 2.4±0.4 mm and 9±4 atmospheres, respectively. The mean inflation time was 59±15 seconds. Lesions that were bailed out with stents were 9 (2.6%). Two hundred and fifty one (81%) patients received both Aspirin and Clopidogrel on discharge.Clinical follow-up were available in 303 (97%) patients with a mean of 17±11 months. There were no complications of acute or subacute vessel thrombosis following treatment and all remained free of vessel thrombosis on follow-up. Major adverse cardiac events (MACE) were observed in 8 (3%) cases with 2 (1%) cardiac death and TLR occurred in 6 (2%) cases.Out of 344 lesions, 98 (29%) cases treated with DCB had a diameter of ≤ 2.25 mm. Dissection in vessels ≤ 2.25 mm and > 2.25 mm were in 9 (9.2%) and 10 (4.1%) cases respectively (p=0.061). Flow limiting dissection was significant in vessels ≤ 2.25 mm as compared to vessels > 2.25 mm (p=0.018), which occurred in 6 (6.1%) and 3 (1.2%) cases respectively. TLR in vessels ≤ 2.25 mm were 1 (1.1%) and 5 (2.3%) in vessels > 2.25 mm, which was not significant. Overall freedom from MACE at 1, 2 and 3 years were 98%, 95% and 95%, respectively. Freedom from MACE at 1 and 2 years in vessels ≤ 2.25 mm was 99% and 93%, respectively and in vessels ≥ 2.25 mm was 98% and 96%, respectively (p=0.931).

CONCLUSIONS

PCI using DCB in the treatment of de novo 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 smaller vessel coronary artery disease.

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Impact of statin therapy and optimal treatment for diabetes on long-term outcomes after everolimus-eluting stent implantation in diabetic patients

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

AIMS

The aim of this study was to clarify the impact of statin therapy and optimal treatment for diabetes on long-term target lesion revascularization (TLR) after everolimus-eluting stent (EES) implantation in Japanese diabetic patients.

METHODS AND RESULTS

The study subjects were 559 diabetic patients (654 lesions) who were treated with EES between February 2010 and September 2015. We investigated clinically-driven TLR within 5 years and assessed predictors of TLR by multivariate analysis in Cox's proportional hazards model. Moreover, we elucidated the efficacy of the statin therapy and the influence of follow-up HbA1c levels (FU-HbA1c) on the TLR after EES implantation. The patient characteristics were 70.7±9.0 years, 75% male, 14% insulin-use, 32% DPP4 inhibitor-use, 19% pioglitazone-use and 69% statin-use. The lesion characteristics were 89% type B2/C lesion, 35% true bifurcated lesion and 17% in-stent restenotic lesion. The number of stents per lesion was 1.36±0.68, mean stent size/ length were 2.93±0.40/ 30.7±20.4mm and multiple stents were implanted in 27% lesion. IVUS-guided PCI was performed in 98.5% lesion. Mean minimum stent area assessed by IVUS was 5.51±2.15mm^2. Median clinical follow-up period was 4.6 years (IQR: 3.3-5.0). The cumulative incidence of TLR at 5 year was 7.4% (44/654 lesion). The incidence of TLR was lower in statin group than that in non-statin group (4.2 vs. 14.2%, p< .0001). The mean FU-HbA1c was 6.9±1.1% (mean duration of follow-up laboratory tests was 1.5±0.6 years). The incidence of TLR was lower in FU-HbA1c<6.9% group than that in FU-HbA1c≥6.9% group (3.7 vs. 13.4%, p< .0001). On multivariate analysis, the independent predictors of TLR were statin-use (HR=0.26, 95%CI 0.13-0.49, p< .0001), FU-HbA1c<6.9% (HR=0.29, 95%CI 0.14-0.58, p=0.0004), multi-stent (HR=2.64, 95%CI 1.43-4.85, p=0.002) and in-stent restenotic lesion (HR=2.02, 95%CI 1.01-3.84, p=0.046). As a result, in those with non statin-use and in those with FU-HbA1c≥6.9% the risk of TLR increased about 14-fold compared to those with statin-use and FU-HbA1c<6.9% (HR=14.18, 95%CI 5.74-42.62, p< .0001).

CONCLUSIONS

In this retrospective study, 5 year-clinically-driven TLR rate after EES implantation for diabetic patients was exceedingly low. It was obvious that statin therapy and optimal treatment for diabetes were effective for preventing long-term TLR after EES implantation in diabetic patients.

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Invasive management of complex coronary artery disease in a hospital without on-site cardiac surgery

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Stents and scaffolds, Left main and multivessel disease

AIMS

To assess the invasive management of complex coronary artery disease in a hospital with a high PCI volume without on-site cardiac surgery.

METHODS AND RESULTS

We analyzed the characteristics of patients with left main (LM) or 3 vessels disease (3VD) studied in our center and the differences of the invasive treatment performed in them: PCI vs CABG.

Between March 2014 and November 2016, 3893 consecutive patients underwent a coronary angiography in our center. Among them, 788 patients (20.2%) had severe LM or 3VD. 72.1% were male with a mean age of 70.2 ± 11 years. 51.7% were diabetic and 32.4% had ventricular dysfunction. Mean Syntax score was 31.5 ± 15.3 and mean Euroscore 8.28 ± 10.8%. 28.1% had CTO of at least one vessel. Clinical presentation was stable ischemic heart disease in 35.4% and 64.6% acute coronary syndromes. PCI was performed in 86.3% and CABG in 13.1% of these patients. The patients who were sent to surgery had a higher syntax score (38.1 ± 16.3 vs 29.9 ± 14.8; $p < 0.0001$) but did not show a significantly different Euroscore (9.1% vs 8.5%; $p = 0.6$). Patients with isolated LM or LM+1 vessel were sent to surgery significantly less than patients with multivessel disease (6.4% vs 14.1%; $p = 0.04$). Patients with previous PCI were revascularized preferably with new PCI (93.9% vs 6.1%; $p = 0.001$). The clinical presentation of the patients who were sent to CABG was stable ischemic heart disease in the majority of cases (65.2% vs 34.7%; $p = 0.02$). Angiographic PCI success was 96.4%. No patient died and only 25 patients (3,7%) had complications (periprocedural myocardial infarction: 2 patients, recovered cardiac arrest during the procedure: 10 patients, cardiogenic shock: 5 patients, coronary dissection: 3 patients, coronary perforation: 4 patients and vascular access complication: 1 patient).

CONCLUSIONS

In a high-volume PCI hospital without on-site cardiac surgery, only 13.1% of patients with complex coronary artery disease are sent to CABG. These patients have more frequently multivessel disease (instead of isolated LM or LM+1 vessel disease), a higher syntax score, and stable ischemic heart disease without previous PCI. The EuroSCORE was not a variable associated with the indication of CABG. Despite the complexity of coronary artery disease, the good results of PCIs are remarkable with a low rate of complications.

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Effects of successful PCI of CTO on myocardial perfusion and left ventricular function

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

PCI of a CTO is technically challenging and its salutary effects are questioned. The aim of the present study was to investigate the effects of successful PCI CTO on absolute myocardial blood flow (MBF) and functional recovery.

METHODS AND RESULTS

Methods: Patients with a documented CTO were prospectively examined for ischemia and viability with $H_2{}^{15}O$ positron emission tomography (PET) and late gadolinium enhancement cardiac magnetic resonance imaging (LGE-CMR). Sixty-nine consecutive patients, in whom PCI was successful, underwent follow-up PET and CMR after approximately 12 weeks to evaluate potential improvement of MBF as well as regional and global systolic function.

Methods: After PCI, stress MBF in the CTO area increased from 1.22±0.36 to 2.40±0.90 $mL \cdot min^{-1} \cdot g^{-1}$ ($p<0.001$), whilst stress MBF in the remote area also increased significantly between baseline and follow-up PET (2.58±0.68 to 2.77±0.77 $mL \cdot min^{-1} \cdot g^{-1}$, $p=0.01$). The ratio of stress MBF between CTO and remote area was 0.49±0.13 at baseline and increased to 0.87±0.24 at follow-up ($p<0.001$). MBF defect size of the CTO area decreased from 5.12±1.69 to 1.91±1.75 myocardial segments after PCI ($p<0.001$). Left ventricular ejection fraction significantly increased (46.4±11.0 vs. 47.5±11.4%, $p=0.01$) at follow-up, whereas mean systolic wall thickening of the myocardium subtended by the CTO artery did not improve after PCI ($p=0.18$). There was no relation between the extent of LGE (%) and change of systolic wall thickening at follow up ($R=0.01$, $p=0.69$), nor was improvement in stress MBF associated with recovery of systolic wall thickening ($R=0.08$, $p=0.53$).

CONCLUSIONS

The vast majority of CTO patients with documented ischemia and viability showed significant improvement in stress MBF and a reduction of ischemic burden after successful percutaneous revascularization with only minimal effect on left ventricular ejection fraction.

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Does extracorporeal cardiopulmonary resuscitation prolong door-to-balloon time compared to conventional cardiopulmonary resuscitation?

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Does extracorporeal cardiopulmonary resuscitation prolong door to balloon time compared with conventional cardiopulmonary resuscitation?

METHODS AND RESULTS

Patients who were treated with 1) ECPR or CCPR, 2) immediate coronary revascularisation, and 3) targeted temperature management between 2012 and 2016 were enrolled in this retrospective study. The patients were divided into 2 groups according to whether they were treated with ECPR or CCPR. The baseline characteristics and in-hospital findings including D2BT were compared between the 2 groups. Among the study patients, 37 patients (ECPR group) were treated with ECPR and 11 patients (CCPR group) were treated with CCPR. The age of the study patients was 66 (63 – 71) y and 71 (61 – 77) y (P = 0.30); men comprised 30 (81%) and 8 (73%) patients (P = 0.68); the initial shockable rhythm was present in 7 (64%) and 21 (57%) patients (P = *****); and the time interval from collapse to return of cerebral circulation was 50 (23 – 62) min and 25 (19 – 40) min (P = 0.08) in the ECPR group and the CCPR group, respectively. Extracorporeal membrane oxygenation (ECMO) was initiated in the catheter laboratory in all patients in the ECPR group. None of the patients in the CCPR group underwent mechanical chest compressions at the time of coronary angiograms. The D2BT was similar between the 2 groups (median, 58 [interquartile range, 36 – 75 min] in the ECPR group vs. 67 [53 – 70] min in the CCPR group, P = 0.36). In the ECPR group, the door to initiation of ECMO was 36 [26 – 56] min and the time interval from the catheter laboratory to initiation of ECMO was 10 (6 – 15) min. The catheter laboratory to balloon time showed a tendency toward being longer in the ECPR group (30 [26 - 45] min vs. 21 [18 - 32] min, P = 0.07). All patients whose D2BT was > 90 min (N = 6) died within 30 days.

CONCLUSIONS

ECPR was associated with a longer time interval from catheter laboratory to balloon time than was CCPR, but not with longer D2BT. This might be because of the shorter interval from hospital arrival to the catheter laboratory. Further studies are necessary to clarify the role of D2BT in CCPR and ECPR.

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Learning curve for interventional annuloplasty for functional mitral regurgitation with the Cardioband system

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

AIMS

The Cardioband system is a novel transvenous, trans-septal direct annuloplasty device. We aimed to evaluate the learning curve in the first 23 patients treated with the Cardioband device and its influence on procedural and patient´s outcomes.

METHODS AND RESULTS

23 patients underwent interventional annuloplasty with the Cardioband device at the University of Bonn. Procedure duration and fluoroscopy times were documented. All patients underwent standardized transthoracic echocardiography before and 6 months after the procedure. Clinical evaluation comprised a 6 minutes walking test (6MWT) as well as evaluation of NYHA status. We parted the patient cohort and analyzed the first 12 and the second 11 patients separately for evaluation of the learning curve and its impact on functional and procedural outcomes.23 consecutive patients (age 73.9±7.2years, 39% female gender, EuroScore II 25.6±7.3%) with symptomatic moderate (22%) or severe (78%) functional MR were prospectively included. There were no differences regarding baseline demographic or echocardiographic parameters between the patient groups except for the left ventricular diastolic diameter (LVIDd), which was significantly larger in the second half of patients (57.9±6.1mm, 67.9±10.4mm, p=0.02). There were no differences in left ventricular ejection fraction (LVEF, p=0.8) or MR grade (p=0.8). Of note, functional capacity as measured by 6MWT showed no differences (p=0.1) and functional NYHA class, as well, was not statistically different (p=1.0).

We found statistically significant shorter procedure durations in the second half of treated patients (162.5±50.6min, 111.3±34.3min, p=0.01) as well as a shorter fluoroscopy time (66.5±33.1min, 41.3±12.9min, p=0.03).

There was one pericardial effusion needing pericardiocentesis in the first 12 patients.

Acute procedural results were favorable with significant reduction of MR grades (p=0.001) and annular septo-lateral diameters in both groups (first 12: 35.6±3.2mm, 25.4±3.6mm, p<0.001, second 11: 39.3±5.1, 30.8±6.5, p<0.001). Of note, there was no difference in septo-lateral diameters at baseline (p=0.07) or after the procedure (p=0.6) between the groups.

At 6 months follow up, 6MWT increased in the first 12 patients (178.1±66.5m, 301.8±136.9m, p=0.2) as well as in the second 11 patients (276.9±144.6m, 405±90.5m, p=0.5), albeit not statistically significant in both groups. NYHA class was significantly improved in both groups (first 12: p=0.001, second 11: p<0.001) as well as MR grades (first 12: p=0.01, second 11: p=0.02).

However, there was no difference in functional outcomes between the two groups as assessed by 6MWT (p=0.4) or functional NYHA class (p=0.9).

CONCLUSIONS

Interventional annuloplasty with the Cardioband is a challenging intervention for structural heart disease. The learning curve for Cardioband for treatment of functional MR is characterized by a sequential reduction in procedure and fluoroscopy time. The rate of procedural complications as well as 6 months functional results are favorable.

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PCI of CTO of the left main coronary artery after bypass grafting: a feasible option in select cases

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

To determine the feasibility of PCI in patients with a previous CABG due to LMCA disease with an occlusion of one graft and progression of the LMCA to a CTO in the presence of demonstrated ischemia in the area of the compromised perfused artery.

METHODS AND RESULTS

Of 620 patients with some CTO diagnosed in our centre we identified, for a retrospective case series, 5 with a previous CABG due to LMCA disease, that had an occlusion of one graft and progression of the LMCA to a CTO. All five underwent PCI. Each patient received a functional classification for angina, myocardial ischemic tests such as cardiac-MRI (cMRI), myocardial perfusion gammagraphy scintigraphy, and a follow-up coronary angiogram during a median of 63 months follow-up. Median age was 65 years, and all patients were male. All of them had at least three traditional cardiovascular risk factors and 1 had chronic renal disease.

The coronary angiogram showed CTO of LMCA semiprotected lesions with 2 CABG previously performed in all patients, one occluded and the other permeable. Severe left ventricular dysfunction (LVD) was found in 1 patient, and moderate LVD was found in three. Ischemia and viability were demonstrated in all patients by cMRI with adenosine or perfusion gammagraphy scintigraphy. The surgical option was dismissed either because of patient rejection or because of high surgical risk.

PCI of CTO of LMCA with drug-eluting stents was performed in all patients, using an anterograde approach in four cases and retrograde access in one patient. In a 5-year follow-up period, 4 patients remained asymptomatic (CCS Class I for angina and NYHA I) and event free (no major adverse cardiac events). One death occurred 1.4 years post-PCI due to a non-cardiovascular cause.

CONCLUSIONS

PCI of CTO of LMCA after CABG can be successful, safe and can provide sustained clinical improvements in patients with a previous CABG due to LMCA disease with an occlusion of one graft and progression of the LMCA to a CTO in which the surgical option was dismissed either because of patient rejection or because of high surgical risk.

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Current practice of transradial approach for coronary procedures: a survey by the Italian Society of Interventional Cardiology (SICI-GISE) and the Italian Radial Club

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

AIMS

Transradial approach (TRA) for percutaneous coronary procedures is associated with improved patient outcome and is being increasingly adopted worldwide. We conducted a survey in order to investigate the current practice of TRA in Italy.

METHODS AND RESULTS

A web-based questionnaire was emailed to all members of the Italian Society of Interventional Cardiology. The survey was taken by 508 respondents, mostly working in high-volume Centers with high rate of TRA. Cardiogenic shock and CTO represented the principal limitations to TRA, whereas end-stage renal failure was perceived as a contraindication for TRA by only 21% of operators. Complex PCI, such as rotational atherectomy, left main PCI, bifurcation lesions needing 2-stent techniques were managed transradially by most operators (78%), the remaining shifting to femoral approach. Right TRA was the default approach for 81% of respondents. Both diagnostic and interventional procedures were routinely performed through 6 Fr sheaths (83% and 93%, respectively); dedicated TRA curves were used in 11% of diagnostic and in about 3% of interventional procedures. Almost 70% of the operators did not assess dual hand circulation. In case of crossover, the contralateral radial artery was the preferred site (57%). Radial artery hemostasis was mostly achieved by pneumatic bracelet (64%) and patency of the radial artery during hemostasis was ensured in 60% of cases. Pre-discharge patency of the radial artery was routinely assessed by almost 60% of respondents. For diagnostic procedures, adequate heparin anticoagulation (5000 IU) was only given by 45% of operators. Most respondents believed that TRA is associated with greater radiation exposure for both the patient (82%) and the operator (98%) as compared to transfemoral approach; however, additional anti-X protective devices were routinely used by less than 20% of operators. Day-Hospital or Day-Surgery programs for TRA diagnostic or diagnostic/interventional procedures were only implemented in 21% and 13% of centers, respectively, although the majority of operators declared to be in favor of them; a possible explanation for this discordance may be represented by administrative issues (e.g. lack of reimbursement).

CONCLUSIONS

This survey provides contemporary data about the adoption of TRA in Italy and gives interesting insights about several technical and clinical issues related to the practice of this vascular approach for coronary procedures.

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Use of iFR in current clinical practice

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

AIMS

iFR was recently proposed as a vasodilator-independent index of coronary stenosis severity. To test the accuracy of iFR, lesions of intermediate severity were assessed with both iFR and FFR.

METHODS AND RESULTS

iFR and FFR were measured in 83 lesions of 76 patients using the Volcano Verrata Pressure Wire and software. FFR was measured in maximum hyperemia achieved with adenosine IV. Adenosine was administered IV via an antecubital or femoral vein at 150-170μg/kg/min. iFR cut off points of 0.89 and 0.90 and hybrid strategies using different adenosine zones, which were used in ADVISE II and RESOLVE studies, were tested for their accuracy compared to FFR values. A different adenosine zone proposed by our department was also tested for its accuracy. Using an iFR cut off point of 0.89, 78.3% (65/83) of the lesions were correctly classified with a sensitivity: 75.9% and specificity: 79.6%. Using an iFR cut off 0.90, 78.3% (65/83) of the lesions were classified correctly with a sensitivity: 70.3% and specificity: 84.4%. Using an adenosine zone of iFR 0.86-0.93 (used in ADVISE II) the proportion of lesions properly classified by iFR outside the pre-specified treatment (<0.86) and deferral (>0.93) values was 86.7% (39/45) and adenosine was needed in 45.8% (38/83). Using an adenosine zone of iFR 0.89-0.96 (used in RESOLVE) the proportion of lesions properly classified outside the pre-specified treatment (<0.85) and deferral (>0.96) values was 82.9**%** (29/35) and adenosine was needed in 57.8% (48/83). Using another adenosine zone of iFR: 0.85-0.95, proposed by our department the proportion of lesions properly classified by iFR outside the pre-specified treatment (<0.85) and deferral (>0.95) values was 87.9**%** (29/33) and adenosine was needed in 60.2% (50/83).

CONCLUSIONS

The results of ADVISE II and RESOLVE are not well reproducible in real life practise. We propose a different hybrid strategy using an adenosine zone of 0.85-0.95 which offers a better accuracy (87.9%). A large proportion of the lesions still need FFR and adenosine IV, with any of the different adenosine zones used.

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The efficacy and durability of femoropopliteal stenting compared with balloon angioplasty after one year

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal, Other peripheral interventions

AIMS

Several studies have shown the efficacy of femoropopliteal (FP) stenting compared with balloon angioplasty (BA) alone at 1 year. However, the efficacy of FP stenting compared with BA alone after 1 year has not yet been thorpughlt addressed.

METHODS AND RESULTS

This study was an observational study examining consecutive patients performing endovascular therapy (EVT) for de novo FP lesion from July 2004 to March 2015. Study population included 1371 patients 1799 limbs with stent (n=984) or without stent (n=815). Kaplan-Meier analyses about restenosis, target lesion revascularization (TLR), and major adverse limb event (MALE) were performed. Landmark analyses were also performed at 1 year to investigate the efficacy of FP stenting after 1 year compared to BA alone.

The incidence of restenosis at 1 year was significantly lower in stent group than BA alone group (27.3% versus 31.1%, p=.026). The incidence of MALE were also lower in stent group (22.7% versus 26.4%, p=.034). On the other hands, there was no significantly difference between two groups in TLR (20.5% versus 22.2%, p=.26). After adjustment for confounders, the risk for restenosis in stent group was significantly lower than that in BA alone group at 1 year (hazard ratio: 0.73, 95% CI: 0.58 to 0.92, p=.008). However, there were no significant differences in the incidences of restenosis (20.2% versus 22.2%, p=.81), TLR (25.8% versus 27.0%, p=.83), and MALE (16.1% versus 14.7%, p=.33) at 3 year between two groups in the 1-year landmark analysis. In subgroup analysis, the efficacy of FP stenting after 1 year was not statistically evident in all subgroups.

CONCLUSIONS

Our study suggests FP stenting is associated with better 1-year EVT outcomes in FP lesions as previous studies. However, landmark analyses did not suggest FP stenting has apparent clinical benefits compared to BA alone after 1 year of index procedure.

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Comparison of radial and femoral approaches for diagnostic angiography and intervention among patients with coronary bypass graft

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Radial approach is gaining the momentum as a default technique for coronary procedures. Limited trails are available for post CABG patients to compare the merits of femoral & radial access.

METHODS AND RESULTS

It is a single-center study conducted in between January, 2013 to December, 2015 in a relatively high volume canter of Dhaka, Bangladesh where radial approach is the preferred approach for coronary procedures in more than 95% cases for last 4 years. During this study period, post CABG patients were blindly assigned to its five high volume operators. Coronary angiography & intervention procedures were performed by left radial or femoral approach as per assigned operator's choice. The patient with acute STEMI needed primary PCI & the patients with absent or abnormal access either radial or femoral was excluded from the study. Contrast volume was the primary endpoint whereas the procedure & fluoroscopy time, procedural success, access site major bleeding, pre discharge MACE were the secondary endpoint both for CAG & PCI. Baseline patient characteristics were also compared.Total 380 post CABG patients were included in this study period. Radial access (n=155) was lower than femoral access (n=225). Compared with femoral access, diagnostic coronary angiography required relatively lower contrast volume though statistically not significant via radial access (70±64 vs. 72±80 ml, p=0.267). Procedure time (25.2±10.7 vs. 26.9±6.8 min, p=0.735), fluoroscopy time (10.7±5.5 vs. 9.5±4.7 min, p=0.424) were almost similar in both access for CAG. Other secondary clinical endpoints were similar among both groups. Interestingly, adhoc PCI was more frequent in radial group (n=54 out of 155, 34.8%) than in femoral group (n=44 out of 225, 19.6%) with pË'0.01. Contrast volume in between two groups was pretty similar with p=0.267. The incidence of other secondary endpoints was also not statistically significant. No incidence of access crossover was surprisingly present among these two groups. Learning curves for choosing the access site among the operators were distinct. In first year of the study, 81.5% of the cases were performed by femoral access. In second year, it was 66.5% with femoral access. In the last year of the study period, choice of the operator shifted abruptly towards radial access with 25.7% in the femoral & 74.3% in radial group.

CONCLUSIONS

Coronary angiography for post CABG patients through left radial approach seems to be effective, noninferior in terms of contrast volume, procedure & fluoroscopy time & other clinical endpoints comparing to femoral access. Learning curve of the operators for radial approach is an important predicator of effective results especially of this type of study population.

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Impact of Tricuspid Annular Plane Systolic Excursion (TAPSE) on outcomes in patients undergoing TAVI

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

AIMS

TAPSE is an echocardiographic parameter reflecting right ventricular (RV) function. The aim of this study was to investigate the impact of TAPSE on short- and mid-term outcome after TAVI in high-risk patients with severe aortic stenosis.

METHODS AND RESULTS

Between June 2008 and June 2016, TAVI and echocardiographic evaluation of RV function at baseline were performed at our hospital in a total of 613 patients with severe AS. The analyzed patients were divided into those with a TAPSE ≥16 mm (n=431, 70%) and those with a TAPSE < 16mm (n=182, 30%).

Regarding the baseline characteristics (47% men; 81±7 years old; logistic EuroSCORE 22±16%; STS PROM 5.1 (median; IQR 3.4-8.2)) significant differences were found between the two groups (Table 1). Patients with impaired RV function came up with an increased incidence of ischemic cardiomyopathy and reduced left ventricular function (TAPSE ≥16mm vs. <16mm: 55±10% vs. 42±15%; p<0.001), impaired renal function (TAPSE ≥16mm vs. <16mm: 55% vs. 66%; p=0.012), higher incidence of at least moderate mitral (TAPSE ≥16mm vs. <16mm: 4% vs. 14%; p<0.001) and tricuspid regurgitation (TAPSE ≥16mm vs. <16mm: 3% vs. 11%; p<0.001), and concomitant pulmonary hypertension (TAPSE ≥16mm vs. <16mm: 14% vs. 30%; p<0.001). Patients with decreasing TAPSE at baseline had significantly lower all-cause mortality at discharge (TAPSE ≥16mm vs. <16mm: 3% vs. 7%; p=0.027) and at 1 year after TAVI (TAPSE ≥16mm vs. <16mm: 8% vs. 23%; p<0.001; Figure 1). There were no other differences in clinical outcomes regarding the VARC-2 criteria.

	TAPSE ≥16mm (n=431)		**TAPSE <16mm (n=182)**		**total (n=613)**		**p**
Male gender, n (%)	199	(46)	92	(51)	291	(47)	0.331
Age, mean ± SD (years)	82	±7	81	±8	81	±7	0.156
Log. EuroSCORE, mean ± SD (%)	19	±13	29	±19	22	±16	<0.001
STS-PROM, Median (IQR) (%)	5	(3-14)	6	(4-29)	5	(3-19)	<0.001
Art. hypertension, n (%)	360	(84)	146	(80)	506	(83)	0.352
Coronary artery disease, n (%)	242	(56)	124	(68)	366	(60)	0.007
Previous cardiac surgery, n (%)	45	(10)	48	(26)	93	(15)	<0.001
Impaired renal function, n (%)	237	(55)	120	(66)	357	(58)	0.012
Chronic dialysis, n (%)	11	(3)	9	(5)	20	(3)	0.139
Atrial fibrillation, n (%)	169	(39)	112	(62)	281	(46)	<0.001
Peripheral vascular disease, n (%)	74	(17)	49	(27)	123	(20)	0.008
COPD, n (%)	64	(15)	29	(16)	93	(15)	0.714
History of stroke, n (%)	68	(16)	26	(14)	94	(15)	0.713
Pulmonary hypertension, n (%)	59	(14)	55	(30)	114	(19)	<0.001
LV ejection fraction, mean ± SD (%)	55	±10	42	±15	51	±13	<0.001
Aortic valve area, mean ± SD (cm²)	0,79	±0,23	0,77	±0,24	0,79	±0,24	0.296
Mean pressure gradient, mean ± SD (mmHg)	69	±24	53	±21	64	±25	<0.001
Peak aortic velocity, mean ± SD (m/sec)	4,13	±0,81	3,62	±0,77	3,97	±0,83	<0.001
Aortic regurgitation ≥2, n (%)	12	(3)	6	(3)	18	(3)	0.794
Mitral regurgitation ≥2, n (%)	16	(4)	25	(14)	41	(7)	<0.001
Tricuspid regurgitation ≥2, n (%)	11	(3)	20	(11)	31	(5)	<0.001

Table 1. Baseline characteristics. Impaired renal function defined as GFR <60 mL/min/1.73m²; COPD = chronic obstructive pulmonary disease; Pulmonary hypertension = systolic PAP ≥60mmHg.

Figure 1. Freadom from death from any cause regarding to RV funktion.

CONCLUSIONS

These results demonstrate that reduced TAPSE at baseline, reflecting impaired RV function, might be accompanied by a significantly aggravated short- and medium-term outcome in patients after TAVI.

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TAVI in patients with aortic stenosis and chronic dialysis

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

AIMS

Less is known about patients with chronic dialysis undergoing TAVI. The aim of this study was to describe the procedural results and the short-term outcomes of those patients.

METHODS AND RESULTS

A total of 1565 high-risk patients with severe AS underwent TAVI at our hospital between July 2008 and January 2016with 53 (3.4%) chronically dependent on dialysis. The baseline characteristics (72% men; 75±8 years old; logistic EuroSCORE 34±23%; STS PROM 25±14%) are listed in Table 1. TAVI was performed using either transfemoral (Corevalve n=14, Edwards Sapien n=21, Portico n=2, DirectFlow n=1, Lotus n=2), transapical (Edwards Sapien n=3, Jena Valve n=4), or transaxillary access (Corevalve n=5, Edwards Sapien n=1). Regarding the VARC-2 criteria, acute procedural success was achieved in 48 (91%) patients. Conversion to open heart surgery was necessary in 1 patient due to embolization of the prosthesis. Implantation of a second valve prosthesis was performed in 2 (4%) patients because of severe untreatable paravalvular regurgitation. Seven (13%) patients died post-procedurally in-hospital. An ischemic stroke occurred in 2 (4%) patients during the hospital stay. In 3 (6%) patients major vascular complications, in 8 (15%) patients minor vascular complications, in 7 (13%) life-threatening bleedings, and in 11 (21%) major bleedings were documented. A new onset of a total AV-Block III° was diagnosed in 8 (15%) patients; in 11 (21%) patients implantation of a permanent pacemaker was necessary. All-case mortality at one year after TAVI procedure was 51% (Figure 1).

Male gender, n (%)	38	(72)
Age, mean ± SD (years)	75	±8
Log. EuroSCORE, mean ± SD (%)	34	±22
STS-PROM Score, mean ± SD (%)	25	±14
Art. hypertension, n (%)	46	(87)
Coronary artery disease, n (%)	38	(72)
Previous cardiac surgery, n (%)	13	(25)
Porcelain aorta, n (%)	13	(25)
Peripheral vascular disease, n (%)	22	(42)
Diabetes mellitus Type II, n (%)	27	(51)
Atrial fibrillation, n (%)	23	(43)
COPD, n (%)	11	(21)
History of stroke, n (%)	11	(21)
Pulmonary hypertension, n (%)	22	(47)
LV ejection fraction, mean ± CD (%)	46	±15
Aortic valve area, mean ± SD (cm^2)	0.82	±0.20
Mean pressure gradient, mean ± SD (mmHg)	63	±20
Peak aortic velocity, mean ± SD (m/sec)	4.03	±0.65
Aortic regurgitation ≥2, n (%)	1	(2%)
Mitral regurgitation ≥2, n (%)	4	(8%)
Tricuspid regurgitation ≥2, n (%)	4	(8%)

Table 1. Baseline characteristics. COPD = chronic obstructive pulmonary disease; Pulmonary hypertension = PASP ≥60mmHg.

Figure 1. Freedom from death from any cause in patients with chronic dialysis.

CONCLUSIONS

These results demonstrate that TAVI is feasible in patients with severe AS requiring chronic dialysis. Due to the underlying pathophysiology of terminal kidney injury and usually multiple comorbidities, increased mortality must be expected. Strategies to improve the outcome in these patients need to be developed in larger patient populations.

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Intracardiac ultrasound in atrial septum defect closure procedure

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

AIMS
The aim is to evaluate the benefits of intracardiac echo guidance in closure procedures.

METHODS AND RESULTS
Methods
Procedures were performed in the Philips Allura cathlab with a local or general anaesthesia, depending on age. To perform an intracadiac ultrasound guidance we used the iLab device by Boston Scientific and the "ULTRA-ICE" probe in 29 patients, including 4 males. The average age was 14.6±9.6 years old.

Two planes of the fossa ovals are necessary to select the appropriate occluder device. The first plane was taken when the probe enters the superior vena cava and was directed down manually, scanning the cardiac structure. The optimal movement speed is 0.2–0.5 cm per second. Most cardiac structures, including valves, can be analysed in the axial views: great vessels, superior vena cava, right atrium, aortic valve, cavotricuspid isthmus. Two specific landmarks are: 1) the crista terminalis, a thick structure located at the junction between the posterior smooth part and the anterolateral trabeculated portion of the RA; 2) the right atrial appendage which is a nose-like structure.

The second plane, the long-axis view, was obtained with a 55° precurved introducer sheath advanced up to the septal defect and turned posterior and leftward, to longitudinally scan the atrial septum. On this plane, it is possible to visualise the both atria, both atrial auricles, tricuspid and mitral valves. Moreover, the atrial septum is longitudinally scanned and the fossa ovalis with its inferior–anterior and superior–posterior rims can be well estimated.

The systolic and diastolic longitudinal atrial septal diameters, the dimensions of the defect and the fossa ovalis, the fossa ovalis distances to the inlet of the inferior vena cava (postero-inferior rim) as well as the coronary sinus or atrioventricular junction (antero-inferior rim) have been measured accurately. The occluder size can be calculated by Onorato formula, were size of the device is square root of multiplied two “muscular to muscular” defect sizes in planes defined above. Device sizes were 9 to 24 mm with mean 17.9±6.1.

The iLab internal software allows adjusting virtually occluder size to the septum. After this check was performed the final stage of the occluder.

Results
No complications occurred in the early postoperative period. Patients were in good clinical conditions and 6 months follow-up showed the absence of residual shunting through the atrial septum in most all cases. One patient with multiple defects had 4 mm residual shunt. No major complications (death, device embolization or need for surgery) occurred.

CONCLUSIONS
Intracardiac guidance has benefits such as: 1. Appropriate selection of the device type and size and possible without balloon sizing; 2. Optimal monitoring of device deployment, because of its ability to provide 360° view from inside; 3. Procedure can be performed with local anaesthesia with minimum patient’s discomfort for a relatively prolonged time period; 4. It is easy to use technique by the single interventional cardiologist, who have possibility to perform the closure the ASD and navigation by himself; 5. Learning curve is 15 procedures.

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PCI to CTO lesion through transradial approach using 5Fr vs. 6Fr guide catheter

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Treating CTOs by antegrade approach needs skill and appropriate devices. Guide catheter is an important factor for success.5 F guide catheter for treating CTO is an alternate choice for diabetic population with narow calibred radial artery.

METHODS AND RESULTS

In an absolute radial ceter like ours, PCI to CTO lesion for last 1 year since July 2015 to June 2016 were evaluated retrospectively by antegrade approach through transradial access. Total 147 CTO lesion was attempted by this period of time. Using 5 For 6 F guide catheter was operator's choice.Out of 147 CTOs in diabetic patients, 66 (45%) was by by 5 F guide catheter and 81 (55%) was by 6 F guide catheter. Success rate in both group was almost similar(63.95% vs 65.4%, p=0.82).Smaller profile balloon support was needed in both groups in similar number 66.7% vs 69.1 %,p=0.75). Workhorse CTO guide wire in our lab was thin hydrophilic PT2 (Boston) and used in similar percentage (93.9% vs 88.9%,p=0.3). Only in 5 cases each, microcatheter was used. CTO of LAD was more in 5 F group (45.5% vs 34.6%, p=0.30). CTO lesion of RCA was 35% vs 40%. Contrast volume is lower in 5F group though not statistically significant (152 vs 165,p=0.26). Flouroscopy time was similar in both group.

CONCLUSIONS

Backup support of guide catheter is an important prerequisite for PCI to CTO." Active back up support" by 5 F guide catheter is better in our experience specially for left system. Orther than using bulky devices like IVUS catheter and rotablation, 5 F guide catheter can be feasible comfortable choice for CTO PCI.

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How to improve clinical status of patients with CTO and low LVEF

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Analyze the impact on the heart failure status (New York Heart Association (NYHA), angina (Canadian class, CCS), Brain natriuretic peptide (BNP) and ventricular function of a CTO PCI in patients with left ventricular ejection fraction (LVEF) < 40%.

METHODS AND RESULTS

Methods: prostective, monocenter study of consecutive patients who had a CTO and LVEF < 40%. At baseline we registered NYHA and CCS class, BNP, cardiovascular risk factors and several clinical and angiographic scores [ACEF (age creatinine and ejection fraction), SYNTAX, residual Syntax score]. All patients underwent a MRI to demonstrate viability/ischemia at two consecutive segments in the territory supplied by the occluded vessel. If the study was positive we performed the CTO PCI and PCI in non CTO vessels with >70% stenosis. After 6 months follow up the same parameters were checked

RESULTS: 39 patients were included, aged 59,8±9,6, 87% men. Cardiovascular risk factors: 41% hypertension, 56.4% dyslipidemia, 34% diabetes mellitus, 64% smoker. FVEF was 29,8±7,8. Other findings: 53.8% had a previous STEMI, 15.4% a previous CABG and 33.3% previous PCI. ACEF score 2,2±0,8 basal BNP 308±573. Basal clinical status: 60% were in CCS 1. NYHA class: 2.6% I, 69.2% II, 28.2% III, 0% IV.

Angiography: 49 CTO, 72% patients had one CTO, the most common occluded vessel was right coronary artery (43%), 84% had multivessel disease (28% 3 vessel). Syntax score 22,7±10,2.

Viability was found at the territory supplied by 43 CTO. Occlusion length was 24±14 mm. Procedure CTO PCI: success rate was 82%, duration 81,4±47,5 min, irradiation 31±16,7 min, contrast volume 215,7±114,7ml. We performed 17 PCI in non CTO lesionsso 77% of patients reached a complete revascularization. Any complication was detected during the procedure or index hospitalization.

6 months follow-up: RRI showed: improvement of LVEF in 6 points [32(26-37) to 39(35-43)], decrease of systolic volume (160±54 to 143±58ml) and improvement of contractility.Number of segments with normal motion or mild/moderate hypokinesia improved after successful CTO-PCI (8.5 ± 4.5 vs. 11.2 ± 3.5; p = 0.001). Number of segments with severe hypokinesia-akinesia- dyskinesia was significantly reduced (8.3 ± 4.6 vs. 5.7 ± 3.5; p = 0.002). The same changes were seen when the analysis was restricted to recanalized CTO-dependent myocardial segments[segments normal - mild hipokinesia (2,9±2,2 to 3,6±2, p: 0,011), segments with severe hipokinesia - akinesia (3,9±1,8 to 3,3±1,3, p 0,029)]. A significant reduction was observed in the proportion of patients with angina (34.4% vs. 3.1%; p = 0.002) and in BNP levels (323 ± 657 pg/ml [IQR 60.4-238.2] vs. 123 ± 151 pg/ml [IQR 40.6-154.5]; p = 0.004). NYHA functional class for dyspnea improved significantly, with a higher proportion of patients in NYHA I and II at follow-up (72% vs. 100%; p = 0.004).

CONCLUSIONS

To our knowledge, this is the first study evaluating the benefits of CTO-PCI in patients with heart failure,an improvement in angina and NYHA functional class, along with a decrease in BNP levels were seen after CTO recanalization.

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Acquired intracardiac shunts following TAVR

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

AIMS

Acquired intra-cardiac shunts (AICS) represent an infrequent and under-explored complication following TAVR. We sought to evaluate the baseline and procedural characteristics, mechanism, management and outcomes of this complication.

METHODS AND RESULTS

Methods

Between January/2009 and December/2016 all cases of AICS following TAVR were gathered in 9 European centres that systematically performed recording and follow up for all TAVR recipients. Both, infective and non-infective aetiology were included.

Results

A total of 25 cases with AICS were found, representing an incidence of ~0.8%, with non-infective aetiology in 18 cases (72%, incidence 0.6%) and suspected endocarditis in 7 cases (28%, incidence 0.2%). Mean age was 81±8 years and 60% were women; logistic euroSCORE was 12.5±9.8%. Computed tomography determined a mean aortic annulus area of 416.08±115 with median of 4002 Agatston units of calcium [IQR:3304-4804]. In up to 36% an asymmetric calcium distribution with extension to the left ventricular outflow tract (LVOT) was detected.

Most patients were treated with balloon-expandable prostheses (56%) through transfemoral (76%) or transapical (24%) approach. Pre-dilation was performed in 88% and post-dilation in 52 % of the patients. Complete atrioventricular block occurred in a 24% of the patients and aortic regurgitation ≥2 in 20%.

Non-infective AICS (18 patients) were detected at a median time from TAVR of 3 days [IQR:0.75-17]. The most common location was ventricular septal defect (55.6%) followed by LVOT-right atrium (16.7%), aortic root-right ventricle (16.7%), aortic root-left ventricle (11.1%), and the mean size of the shunt was 4.56±2.12 mm. Up to 91.6% of the patients had heart failure symptoms. Percutaneous closure of the AICS was performed in 7 symptomatic patients (39%) presenting mean Qp/Qs=2.3 with Nit-Occlud PDA (pfm Medical) in 3 patients, Amplatzer vascular Plug II (St Jude Medical) in 2 patients, IMWC-5 PDA occluder and Amplatzer ASD Occluder in one patient each. Percutaneous closure complicated with pericardial effusion in 2 patients and at a mean follow up of 0.35±0.1 years 6 of them (85.7%) had died due to complications related to the shunt. One more patient was treated with open surgery and the remaining 10 patients, with a mean Qp/Qs=1.86 were medically treated with a 50% of mortality at a mean follow up of 1.7±0.3 years.

AICS with suspected infective aetiology (7 patients) were located as follows: anterior mitral leaflet perforation (4 cases), aortic root-left ventricle (2 cases), LVOT-right atrium (1 case). Cultures were positive for coagulase-negative staphylococci in 4 patients, enterococci in 1 case, methicillin-resistant Staphylococcus aureus in 1 case, and polymicrobial infection in 1 more case. All patients presented heart failure and onset of symptoms occurred much later than non-infective AICS (257±110 days from the procedure). All of them were medically treated and all but one died during the index hospitalization.

CONCLUSIONS

AICS following TAVR are uncommon with 3/4 due to mechanical compression and 1/4 due to infective endocarditis. Prognosis was especially poor for those patients who presented AICS due to infection or with symptoms of heart failure, more common in those with larger shunts and higher Qp/Qs values. Medical treatment was clearly unsuccessful for those with infective endocarditis whereas further research in needed to improve the results of percutaneous closure in aseptic AICS.

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Lower level of low-density lipoprotein cholesterol is associated with a larger increase in FFR in patients with fixed-dose rosuvastatin

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

FFR reflects on diffuse atherosclerosis per coronary artery. It is unknown whether the statin therapy affects the long term FFR after PCI. The aim of this study was to evaluate the long term FFR after PCI in patients taking statin.

METHODS AND RESULTS

A total of 22 patients with stable angina pectoris were enrolled. The values of FFR, coronary flow reserve (CFR), and index of microcirculatory resistance (IMR) were measured before, immediately after, and 18 months after (follow-up day) everolimus eluting stent (EES; Promus Element™ or Promus Element Plus™) implantation. All coronary angioplasties were performed according to standard techniques using OCT or/and IVUS. A fixed dose of rosuvastatin 5 mg/day was administrated in all patients. In 22 patients, 2 were excluded because of adverse effect of rosuvastatin and in-stent total occlusion after EES implantation. Overall, the values of FFR, CFR, and IMR immediately after and 18 months after EES implantation did not show significant change (0.90 ± 0.05 to 0.88 ± 0.06, $p = 0.16$; 2.29 ± 1.36 to 2.96 ± 1.48, $p = 0.15$; 22.5 ± 11.7 to 19.4 ± 7.2, $p = 0.21$, respectively). There was an equal or increase in the FFR values 18months following procedure compared to the post procedure values in half of evaluated patients (Preserved FFR group, n = 10), and a decrease in others (Decreased FFR group, n = 10). The LDL cholesterol level at follow up in Preserved FFR group was significantly lower than that of Decreased FFR group. Additionally,there was a significant negative correlation between low density lipoprotein (LDL) cholesterol level at follow-up day and changes in the value of FFR ($p = 0.01$, r = -0.74). There was an increase in the value of FFR after stenting in 8 out of 9 patients with LDL cholesterol level below 75 mg/dl (area under the curve 0.92, $p = 0.0005$).

CONCLUSIONS

LDL cholesterol level was associated with the change in the value of FFR in patients following stent implantation. Lower LDL cholesterol tended to improve in the long-term FFR, underscoring the importance of LDL cholesterol lowering to prevent the progression of coronary atherosclerosis.

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Tiomax: a Spanish multicentre registry of the real-world use of the new tItanium cobalt-chromium bioactive stent

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

AIMS

The TIOMAX registry analysed 784 patients who underwent PCI in 21 Spanish hospitals to compare the safety and efficacy of the new cobalt-chromium bioactive stent Titan Optimax with its predecessor, Titan2.

METHODS AND RESULTS

Analysis of all patients in the registry without exclusion criteria, candidates for revascularisation and treated between March 2013 and July 2014. Initially 273 patients received Titan®2, and the next 511 received the Optimax® after its launch. Mean age was 65.8±13.0 (78.1% men); 49.2% were STEMI patients (n=322), 29.8% NSTE-ACS, and the remaining 27.3% had stable angina or silent ischemia. Most STEMI patients (76.4% of n=322) were treated <24 h after developing symptoms. All-cause death, cardiac death, acute myocardial infarction and stent thrombosis at 1 month were 1.1%, 0.8%, 0.1%, and 0.5%, respectively, with no significant differences between groups. At 1 year, death was 5.5% in Titan-2 vs 4.1% in Optimax group, cardiac death was 1.8% for both groups, stent thrombosis 1.1 vs. 0.6%, new acute myocardial infarction 3.3 vs. 2.5% and target lesion revascularization 3.7 vs. 2.9%. Primary endpoint of the composite event of death/acute myocardial infarction/target lesion revascularization/stent thrombosis occurred in 10.3 vs. 7.6% (p=0.211). Patients with STEMI (N=322: Titan-2/Optimax: 103/209) had better outcomes for secondary events, the deviced oriented failure (cardiac death/acute myocardial infarction/target lesion revascularization (7.8% vs 5.0%; p=0.330), and for the non-fatal composite event of acute myoradial infarction/stent thrombosis/target lesion revascularization (7.8% vs.2.7%, p=0.039) .

CONCLUSIONS

The Titan Optimax retains the efficacy and safety of Titan 2. It appears to perform better in the subgroup of STEMI patients, by reducing the non-fatal composite event of: acute myocardial infarction/stent thrombosis/target lesion revascularization.

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Early vascular responses after everolimus-eluting stent implantation assessed by serial observations of intracoronary OCT

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

AIMS

The present study evaluated the vascular responses of neointimal formation and malapposition at 2, 4, and 12 weeks after EES implantation by using OCT.

METHODS AND RESULTS

Serial OCTs were performed in 35 patients with 35 EES treated de-novo lesions at 0, 2, 4, and 12 weeks after EES implantation. Serial changes in quantitative parameters of the neointima (neointimal thickness, stent strut coverage, and apposition of each strut) were analyzed. Mean neointimal thickness significantly increased from 35.9 to 51.8 and 108.2 μm at 2, 4, and 12 weeks, respectively ($p<0.001$ for all), and the percentage of uncovered stent struts significantly decreased from 74.7% to 19.5 % and 0.4 % ($p<0.001$, respectively). There was no stent malapposition at 4 weeks compared with immediately post-intervention (0% vs. 5.4 %, $p=0.031$).

CONCLUSIONS

This OCT study demonstrates that neointimal coverage of stent struts progresses to about 80% and malapposition of stent struts completely disappears at 4 weeks after EES implantation. Additionally, neointimal coverage of stent struts was almost complete within 12 weeks.

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Current interventional trends in translational development of multifunctional nanomedicine for regression of atherosclerosis

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

AIMS
The purpose of this study was to evaluate how nanotechnologies meet the needs of the real clinical practice in the theranostics of the coronary atherosclerosis with the ultimate idea to reverse atherogenesis and dramatically reduce mortality.

METHODS AND RESULTS
We investigated the available sources of the information published in PubMed/ Medline, Google Scholar, ResearchGate, and SCOPUS between January 1980 and August 2016. The bench studies and bedside trials were examined for the clinical relevance to the main three targets: (1) lumen stenosis, (2) (athero-)thrombosis, and (3) atherogenesis. The scope was limited by the translational technologies and strategies with a clinical potential for imaging, treatment and theranostics of atherosclerosis. The number of papers testing any approaches for the management of atherosclerosis achieved 109,801 (database of Pubmed) during 36 overviewed years. The key-word ‘nanoparticle’ was revealed in 133,016 articles since 1980 which is a 21.14 per cent higher than in case of ‘atherosclerosis’. In fact, the age of nanomedicine started in 2000 with a further soaring pattern of publications up to 14,010 manuscripts totally by September 2016. Regretfully, the progress of nanomedicine for needs of cardiology and particularly atherosclerosis was not that bright, and characterized by only 512 papers since 2005 which weighs just about 3.65% of nanomedicine and a 0.38% of the entire nanoindustry. After detailed verification of the revealed articles strictly within the scope of the review we assigned 135 papers (a 26.37% of 512; 377 articles were excluded because were not in scope of the systematic review) with 120 studies introducing technologies for the special analysis through the prism of systems biomedicine in order to adjust this data array by the main clinical targets. We have identified 79 studies (65.83%) of nanotechnologies with a focus on atherogenesis (cholesterol/ lipid metabolism and immune response), 23 studies (19.17%) targeting lumen stenosis (mostly, medical devices), and 18 studies (15%) examining atherothrombosis. The majority of papers pays attention to imaging and therapy of atherogenesis with a targeting of the diverse molecular metabolic mechanisms. Notwithstanding, there is a lack of solutions for lumen stenosis and thrombosis nothing to talk about synergistic approaches such as multifunctional nanoformulations and medical devices. The bench science still disregards the needs of the real clinical practice being converged exceptionally on reversal of atherosclerosis.

CONCLUSIONS
The number of achievements in nanomedicine is rocketing today, but without clear destination for the real world cardiovascular medicine. The tools of the systems biomedicine reveal the lack of the proper multifunctional nanoformulations and medical devices in order to reach all the clinical expectations.

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Predictors of new heart block requiring pacemaker implantation in patients undergoing TAVI

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

AIMS

Conduction abnormalities (CA) requiring permanent pacemaker (PPM) implantation, are frequent complications after TAVI in patients with severe aortic stenosis (AS). The objective of this study was to determine predictors of AVB III after TAVI.

METHODS AND RESULTS

This study included patients without prior CA/PPM who underwent TAVI. Of 610 patients who had undergone TAVI at our institution between July 2008 and January 2016, 116 (81±7 years, 264 men [43%], logistic EuroSCORE 20.7±14.5%, STS PROM 6.9±7.6%) developed a permanent AVB III post-TAVI. In a multivariable logistic regression analysis, two independent predictors for new AVB III after TAVI were identified: use of a Medtronic CoreValve prosthesis (Odds ratio [OR] 3.07; 95% CI 1.95-4.81; p<0.001) and moderate/severe tricuspid regurgitation (TR) (OR 1.58; 95% CI 1.02-2.45; p=0.040; figure 1). Moreover, patients with increasing severity of TR showed increases in left and right ventricular overload: left ventricular (LV) end-diastolic diameter, LV end-diastolic pressure, pulmonary pressures, NT-proBNP, and the prevalence of mitral regurgitation ≥II increased, whereas LV ejection fraction, TAPSE and cardiac output decreased.**Figure 1:**Incidence of atrioventricular block (AVB) III after TAVI according to the severity of tricuspid regurgitation (TR).

CONCLUSIONS

PPM implantation is a frequent complication in patients undergoing TAVI. Increasing severity of TR seems to be a consequence of left and right ventricular overload caused by severe AS and is a significant predictor of new AVB III after TAVI. In patients with moderate/severe TR utmost care should be taken to avoid procedural factors conducive to mechanical irritation of the conduction system, resulting in pacemaker dependency.

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Changes of global afterload / valvuloarterial impedance in patients undergoing TAVI

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

AIMS

Patients with severe aortic stenosis (AS) often have increased global afterload/valvuloarterial impedance (Zva). The objective of this analysis was to evaluate the impact of ΔZva (post-TAVI – pre-TAVI) on outcome after TAVI.

METHODS AND RESULTS

A total of 984 patients with symptomatic AS and hemodynamic assessment by right heart catheterization during TAVI were included. Zva was measured before and after TAVI. Patients were divided into two groups: ΔZva = Zva[post-TAVI] – Zva[pre-TAVI] <0 (n=493) vs. ≥0 (n=491) mmHg/mL/m². The primary end-point was clinical outcome according to the VARC-2 definition.

Baseline characteristics of the 984 patients (448 [45.5%] men; 81±7 years; logistic EuroSCORE 22.2±16.2%; STS PROM 5.1 [median, IQR 3.4-8.2]) were not significantly different between both groups. Patients with decreasing Zva after TAVI (ΔZva <0) came up with significantly lower all-cause mortality at discharge (3.2% vs. 6.7% in patients with ΔZva ≥0; p=0.013) and 1 year after TAVI (16.3% vs. 25.5%, respectively; p=0.004; Figure 1). There were no differences in clinical outcomes according to the VARC-2 criteria (acute device success in 94.1%). On multivariate analysis, patients with ΔZva ≥0 (as opposed to patients with ΔZva <0) had a hazard ratio (HR) of 1.57 [95% CI, 1.06-2.33; p=0.024] for death at 1 year. Other independent predictors of 1-year mortality were impaired renal function (HR 1.73 [1.17-2.57]; p=0.006), systolic pulmonary artery pressure ≥60 mmHg(HR 1.86 [1.26-2.75]; p=0.002), LVEF ≤50% (HR 1.59 [1.09-2.32]; p=0.017), stroke volume index ≤35 mL/m^2 (HR 1.72 [1.17-2.53]; p=0.006), acute kidney injury of stage 2/3 (HR 2.14 [1.31-3-50]; p=0.002), and life threatening or disabling bleeding(HR 3.33 [1.99-5.58]; p<0.001).**Figure 1**: Time-to-event curves of death from any cause. Event rates were calculated with the use of Kaplan–Meier methods and compared with the use of the log-rank test; population were divided into groups: ΔZva <0 vs. ΔZva ≥0 mmHg/mL/m2.

CONCLUSIONS

Increasing end-procedural valvuloarterial impedance/global afterload is associated with an elevated risk of mortality both at discharge and at one year after TAVI. The identification of treatable causes of elevated global afterload may represent an opportunity to improve the clinical outcome of these patients.

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DES acute recoil rate following proximal segment post-dilation in PCI

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

AIMS

In tapering lesions (TL), post-dilation (PD) of proximal segment of stent is recommended. Such partial PD often requires significant oversizing of the balloon.The present study evaluated acute recoil (AR) after proximal PD of stent in TL.

METHODS AND RESULTS

Of 840 stents of 671 patients treated with metallic drug-eluting stent (DES) between January 2015 and September 2016, 146 consecutive drug-eluting stents (DESs) implanted in TL were enrolled. Stent designs included Biodegradable polymer (BP)-sirolimus eluting stent (Ultimaster), BP-everolimus eluting stent (Synergy), PtCr-everolimus eluting stent (Promus Premier), Zotarolimus-eluting stent (Resolute Integrity), and Everolimus-eluting stent (Xience) and totaled 25, 39, 25, 27, and 30 stents, respectively. Mostly metallic DES platforms consist of two or three different stents sizes with differing deploying balloon sizes to reflect the different size vessels. In this study, the stent implanted with the expansion of more than [0.8×("the maximum diameter of the stent"-"the smallest nominal diameter of the same stent platform(X)")+X] at PD was classified as over-dilatation (OD) group based on 3rd quartile, otherwise as non-OD group. TL was defined as proximal reference diameter greater than 0.5mm that of distal reference diameter on optical coherence tomography (OCT). Calcification, balloon/reference diameter ratio, and OD were assessed regarding influential factors on AR. Calcification at PD site was graded from score 0 to 4 according to quadrants using OCT as follows:score 0, no calcification; score 1, <1 quadrant; score 2, ≥1 but <2 quadrants; score 3, ≥2 quadrants but <3 quadrants; and score 4, ≥3 quadrants.
On quantitative coronary angiography, %AR was calculated as ("minimum diameter of inflated balloon at PD(Y)"-"minimum lumen diameter of DES immediately after balloon deflation")×100/Y. The mean age was 68.6±10.8 years old. 25 stents were implanted in acute coronary syndrome and 121 stents in stable angina. Calcification grade was 0.54±0.34. In addition, balloon/reference diameter ratio was 1.06±0.04. Overall, the mean stent size and length were 3.0 and 25.4mm, respectively. In addition, the mean size and length of the PD balloon were 3.72 and 9.77mm, respectively. Furthermore,there were not significant differences in not only the size and length of the implanted stent but also the procedural factors such as calcification grade, balloon/reference diameter ratio and the size and length of the PD balloon among 5 stent designs.
Overall, mean AR was 7.8±3.4%. No significant differences in AR were observed among stent designs. But, only in OD group, AR of Resolute Integrity and Synergy were significantly lower than that of Ultimaster and Xience (6.5±2.9, 5.9±2.7, 9.4±3.2, 9.1±3.6%, p=0.03, respectively).
Multivariate logistic regression analysis revealed that only stent designs was an independent predictor for predicting AR in OD group (P=0.04).

CONCLUSIONS

Stent choice should include consideration of stent design as well as OD of the stent, particularly for TL.

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Clinical utility of PARIS score for the patients with atrial fibrillation undergoing PCI: a multicentre registry

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

AIMS

PARIS Score can predict thrombotic and bleeding event separately for the patients with percutaneous coronary intervention (PCI).
The aim of this study was to validate PARIS Score to the patients with atrial fibrillation (AF) undergoing PCI.

METHODS AND RESULTS

Five hundred ninety two consecutive patientswith AF undergoing PCI from January 2011 to December 2014 were registered at 8 medical centers in Japan. Among them, 35 patients were excluded because of missing data for PARIS Score. Finally, 557 patients were examined. The study endpoints were incidence of major adverse cerebro-cardiovascular events (MACCE; All cause death, non-fatal myocardial infarction and stroke) and bleeding events (including TIMI criteria major and minor bleeding).
The mean age of whole study population was 73.3±8.8 years old, 79.4% of them were male, 41.4% of them were suffered from diabetes mellitus and 50.0% of them showed impaired renal function (eGFR<60 mL/min/1.73m2)). The mean CHADS2 score and HAS-BLED score were 2.4±1.3 and 2.5±0.9, respectively. The patients who took DAPT consisted of aspirin plus thienopyridine without oral anticoagulation were 31.8% and DAPT plus oral anticoagulation (triple therapy) were 64.4%.
Based on PARIS Score, the patients were scored for thrombotic risk and bleeding risk separately. To evaluate thrombotic risk, diabetes mellitus, acute coronary syndrome, current smoking, impaired renal function, prior PCI and prior CABG were scoring items. The scores ranged from 0 to 10, and patients were categorized at low (0 to 2), intermediate (3 or 4), and high (≥5) risk groups. The numbers of patient at low-, intermediate-, and high-risk group were 326 (58.5%), 159 (28.5%) and 72 (12.9%), respectively. Analogously, high age, body mass index, current smoking, anemia and triple therapy on discharge were the scoring items for bleeding risk. The range of scores was 0 to 14, and patients were also categorized at low (0 to 3), intermediate (4 to 7) and high (≥8) bleeding risk groups. The numbers of patient at low-, intermediate-, and high-risk group were 34 (6.1%), 306 (54.9%) and 217 (39.0%), respectively.
Kaplan-Meier analysis both on MACCE and bleeding events were performed separately. In terms of MACCE, three-year event rates were 13.8%, 16.9% and 39.4% in low-, intermediate- and high-risk group, respectively (Log-rank p<0.001). Cox proportional hazard analysis showed that high-risk group had a significantly worse clinical outcome compared with the other two groups. (high-risk vs. Intermediate-risk, hazard ratio 2.2, 95% confidence interval 1.17-4.03, p=0.01 and high-risk vs. low-risk, hazard ratio 2.7, 95% confidence interval 1.56-4.69, p<0.001). On the other hand, three-year bleeding event rates were 0.0%, 14.6% and 20.1% in low-, intermediate- and high-risk group, respectively (Log-rank p=0.047).

CONCLUSIONS

PARIS Score might be useful to evaluate the thrombotic and bleeding risk in patients with AF undergoing PCI, which were thought to be a high-risk subset in current daily practice.

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Systemic inflammatory response syndrome following TAVI: what role do "next-generation" transcatheter heart valves play?

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

AIMS

With respect to continuously further technological improvements, in particular the advent of "next generation" protheses with specific biomechanical properties, the question arises to what extent they contribute to the occurrence of SIRS.

METHODS AND RESULTS

In 758 TAVi patients, pro-inflammatory biomarkers were measured at pre-defined time points and SIRS was assessed clinically. The primary endpoint was all-cause mortality at one year after TAVI. 41.4% underwent TAVI with use of a "next generation" prothesis. Approximately 15% of these patients developed SIRS within the first 48h after TAVI. The patients with development of SIRS showed an increased inflammatory activity already at baseline. In a ROC curve-based cut off analysis, a leukocyte count > 8G/L, CRP > 13.3 mg/L and IL-6 > 4.9 pg/mL were chosen to be the optimal cut-off values to identify patients at high risk for SIRS. Major vascular complications and acute kidney injury were associated with the occurrence of SIRS. History of stroke and acute kidney injury were independent predictors of SIRS. In "next generation" THV patients, SIRS was related to 30-day, 1-year and 3-year mortality (13.3% vs. 0.7%, 28.9% vs. 8.9%, and 37.8% vs. 13.0%, respectively; $p<0.001$).

CONCLUSIONS

With "next generation" THVs, the occurrence of SIRS could be reduced significantly, but is still associated with mortality.

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Cardiac biomarkers and clinical scores for risk stratification in patients with severe symptomatic aortic stenosis undergoing TAVI - Which ranks first now?

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

AIMS

To identify biomarkers to identify TAVI patients at high risk for adverse outcome, and to assess whether a combined multi-marker strategy might have an impact on clinical decision making for risk stratification.

METHODS AND RESULTS

In 535 TAVI patients, cardiac biomarkers (leukocytes, creatinine, CRP, PCT, IL-6, IL-8, NT-proBNP, Galectin-3, BNP, Troponin I, hsTroponin I, NGAL) were measured at baseline. The primary endpoint was all-cause mortality at 1 year. 30-day and 1-year mortality were 5.2% and 23.6%, respectively. Non-survivors at 1 year had higher risk scores and increased median biomarker levels. For the prediction of the procedural result in form of 30-day mortality, the logistic EuroSCORE (LES) was superior to any kind of biomarkers. However,LES and PCT had the highest predictive value for 1-year mortality. Their combination offered a slight improvement in model performance with the overall highest area under the curve (AUC 0.703 (0.649-0.757)) for the prediction of 1-year mortality. In multivariate analysis, LES and PCT showed the strongest associations with 1-year mortality.Combinations of increasing tertiles of LES results and PCT levels allowed the stratification of the TAVI patient into subgroups with 1-year mortality rates ranging from 11% up to 60%.

CONCLUSIONS

For outcome prediction, biomarkers were inferior to risk scores. However, PCT besides the logistic EuroSCORE was an independent predictor of 1-year mortality. A combination of both might allow the development of a risk assessment strategy that is tailored to be applied with TAVI patients to better predict procedural risk and outcome and to identify futile patients.

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Predictive factors for high platelet reactivity in patients treated with DES implantation

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

AIMS

High platelet reactivity (HPR) of P2Y12 receptor inhibitor is now recognized to be a predictor of stent thrombosis and myocardial infarction. We investigated predictive factors which are related with HPR despite dual antiplatelet therapy (DAPT).

METHODS AND RESULTS

We enrolled all comer patients who were successfully treated with drug eluting stent (DES) and DAPT. All patients were assessed platelet reactivity at 12-48 hour after DES implantation using VerifyNow point-of care assays and were taken a general blood test at before and after procedure. HPR was defined as P2Y12 reaction unit (PRU) >208. Between January 2016 and Aug 2016, 152 consecutive patients were prospectively enrolled. Of these, 53 patients (35%) had acute coronary syndromes and prasugrel was used in 111 patients (73%). 71 patients (47%) received a loading dose of P2Y12 receptor inhibitor. The mean PRU was 169±77 and HPR was seen in 50 patients (33%). Poor but significant negativecorrelation with PRU was observed hematocrit ($r = -0.40$, $p < 0.01$) and estimated glomerular filtration rate ($r = -0.20$, $p < 0.01$). The multivariable analysis was identified that diabetes mellitus (OR 3.06, $p < 0.01$), clopidogrel administration (OR 3.06, $p = 0.01$), female sex (OR 2.81, $p = 0.04$) and hematocrit level ≤40.7 % (OR 2.80, $p = 0.01$) were independent predictors of HPR. On the other hand, smoking was a negative predictor of HPR (OR 0.324, $p = 0.01$).

CONCLUSIONS

The finding from this study have shown the possibility to predict HPR using simple factors in patients after implantation of DES. These predictors may help in the selection of more prompt acting P2Y12 receptor inhibitor.

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The level of average 24-hour ambulatory systolic blood pressure as a predictor of the best response to renal denervation

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THEME: Interventions for Hypertension
TOPIC(S): Renal denervation, Other hypertension

AIMS

The predictors of best response to renal denervation (RDN) are still not found.The aim of our study was to find the predictors of best response to RDN in patients with refractory hypertension.

METHODS AND RESULTS

92 patients with RH included, the average age was – 52 [19; 68]. All patients underwent RDN. Procedure performed by an experienced electrophysiologist at the renal arteries (RA) using specialized electrode Symplicity: capacity of 8 - 10 W at 55 ° C, for rightRA – 6, 8±2,8 points, for left RA – 6,9±2,8 points,for 2 minutes per point. Office systolic blood pressure (SBP) and diastolic blood pressure (DBP), 24-hour ambulatory blood pressure monitoring (ABPM) measured before and at 3, 6 and 12 months of follow-up.The ROC - analysis performed to assess the threshold of the baseline ambulatory BP.ABPM baseline and 12 months after the RDN analyzed. Their values were significantly different. The thresholds determined for average 24-hour SBP and DBP. High probability of significant reduction in average 24-hour SBP was registered at the threshold level of the baseline average 24-hour SBP p> 153.3 mmHg (sensitivity 75.68%, specificity 83.87%), AUC (area under ROC curve) = 0.84 [0.73; 0.92], p <0,0001. Threshold p>96 mm Hg was also determined for baseline average 24-hour DBP. High probability of significant reduction in average 24-hour DBP was registered at the threshold level of the baseline average 24-hour DBP p>96 mmHg (sensitivity 58.33%, specificity 77.27%), AUC = 0.69 [0,58; 0,80], p <0,0024.

CONCLUSIONS

The study confirmed the prognostic significance of initial data of ambulatory blood pressure. New prognostic criteria were identified - the baseline average 24-hour SBP and DBP. The baseline average 24-hour SBP/DBP threshold as 153.3/96 mm Hg is strong predictor of efficiency of RDN procedure.

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Diabetic patients with CTO: can percutaneous revascularisation change the prognosis?

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

AIMS

Little is known about prognosis in diabetic patients who carry a CTO. We aim to analyze what kind of revascularization can influence mortality in these patients.

METHODS AND RESULTS

METHODS: between June 2010 - April 2014 we conducted a monocenter registry of consecutive diabetic patients sent for coronary angiography with a CTO. Clinical and angiographic characteristics and risk scores were analyzed. After a long term follow-up we made multivariate analysis of factors that can influence the prognosis.

RESULTS: 443 patients were included. Global clinical characteristics were: average age 68.4±10 years, 20% were women, 83.5% had hypertension, 71% dyslipidemia, 50% were smokers. 31% had previous STEMI, 10 % had previous CABG, 16% were admitted for STEMI. We found multivessel disease in 85%. LVEF was 44±13.7%. Average ACEF score was 1.83±0.81 and Syntax 25.3±11.8. Treatment decision was let to cardiologist criteria. We divided the population according to the treatment given to the CTO in 3 groups: patients managed by medical therapy 237 (group I), patients sent to CTO PCI 104 (group II) and patients sent to CABG 102 (group III). CTO PCI success rate was 61%. Patients sent to medical therapy had the worse clinical profile: older (70.3±10.2, vs 66.2±10.1 group II and 66.2 ± 9.2 group III (p<0.001), had lower LVEF (42.7± 13.7% vs 46±13.6 group II and 48±13 group III, p=0.003) and higher ACEF score (1.99±0.86, vs 1.75±0.8 group II and 1.54±0.58 group III, p<0.001). Group III patients had the most complex coronary anatomy: tree vessel disease (63% vs 44.5% group I and 36.5% group II, p=0.003) and left main disease (30.4% vs 10% group I and 5.8% group II, p<0.001).

During the follow-up (2,9±1.35 years) cardiac death happened in 22.5 % of patients in group I vs 12,5 % group II and 7.8% group III (p<0.001). Predictive factors of cardiac death on multivariate analysis were: age [HR1,05, IC 95%(1.02-1.08) p=0.001]; ACEF score [HR 2,45,IC95% (1.9-3.1), p<0.001] and left main disease [HR 2,4, IC 95%(1.3-4.3, p=0.004]. CABG was a protective factor [HR 0.44, IC95% (0.2-0.97, p=0.044]. All causes of mortality reached 34.7% in group I, 17.3% in group II and 10.8% in group III (p<0.001) Independent predictive factors of all causes of death were: age [HR 1.041, IC 95%(1.018-1.065), p<0.001], creatinine [HR 1.09, IC 95%(1.005-1.17), p=0.038] ACEF score [HR 2.056, IC 95% (1.66-2.54), p<0.001], Syntax score [HR 1.032, IC 95% (1.015-1.050), p<0.001]. CABG [HR 0.36, IC 95% (0.18-0.07), p=0.002] and CTO PCI [HR 0.49, IC 95% (0.29-0.84), p=0.009] were protective against all causes of death.

CONCLUSIONS

CONCLUSIONS: Patients sent to medical therapy had the worst clinical profile and the highest rate of cardiovascular death and all causes of death during the follow-up. Patients sent to CABG had the most complex coronary disease but the best prognosis due to a significant reduction on cardiac death (not significantly influenced by PCI). Revascularization (both CABG and PCI) seems to protect against all causes of death.

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Transcatheter aortic valve-in-valve treatment of degenerative bioprosthetic Freedom Solo valves: a single-centre experience

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

AIMS

To report the results of percutaneous valve-in-valve therapy in failed stentless Freedom Solo (FS) surgical bioprostheisis, the highest risk for coronary occlusion.

METHODS AND RESULTS

6 patients with FS valves (mean age 78.5 years, 50% males). 5 had valvular restenosis (peak gradient 87.2mmHg, valve area 0.63cm^2), 1 had severe regurgitation (AR). Median time to failure was 7 years.Patients were high risk (mean STS/ Logistic EuroScore 10.6 15.8, respectively). FS valves ranged from 21-25mm. Successful ViV-TAVI was achieved in 4/6 patients (67%). Of the unsuccessful cases, (patient 1 and 2 of series) patient 1 underwent BAV with simultaneous aortography which revealed left main stem occlusion. The procedure was stopped and the patient went forward for repeat surgery. Patient 2 underwent successful ViV- TAVI with a 26mm CoreValve with a guide catheter in the left main, but on removal coronary obstruction occurred, necessitating valve snaring into the aorta. Among the successful cases, (patients 3, 4, 5, 6) the TAVIs used were CoreValve Evolut R 23mm (n=3), and Lotus 23mm (n=1). In the successful cases the peak gradient fell from 83.0mmHg to 38.3mmHg. No patient was left with >1+ AR. One patient had a stroke on Day 2, with full neurological recovery. Two patients underwent semi-elective pacing for LBBB and PR >280ms.

CONCLUSIONS

ViV-TAVI in stentless Freedom Solo valves is high risk. The risk of coronary occlusion is high. The smallest possible prosthesis (1:1 sizing) should be used, and strategies to protect the coronary vessels must be considered.

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Safety of endovascular therapeutic hypothermia as an adjuvant therapy in acute STEMI

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

AIMS

Evaluation of safety in the development of a standard protocol for endovascular therapeutic hypothermia in STEMI patients, awaken and without the need for intubation or mechanical ventilation.

METHODS AND RESULTS

Therapeutic hypothermia (TH) reduces the damage by ischemia/reperfusion cell syndrome in cardiac arrests, however its role in STEMI remains controversial.Patients admitted to the emergency department with up to 6 hours of the onset of chest pain, presenting STEMIs in anterior or inferior wall with ST segment elevation greater than 1mm in 2 or more contiguous leads, and eligible for percutaneous intervention procedures (PCI). Administration of anti-shivering drugs (buspirone and meperidine) and TH induced by the administration of 1L of cold saline solution at 4°C together with implant of Proteus® Endovascular System to induce therapeutic hypothermia as an adjuvant treatment to primary PCI, by cooling for at least 18 minutes before the recanalization of the occluded coronary artery at target temperature of 32°C before PCI. Maintenance of TH for 3 hours and active rewarming at rate of 1ºC/h for 4h. The primary safety endpoints included death, reinfarction, need for target vessel revascularization (MACE), ventricular arrhythmias or major bleeding within 72 hours after infarct onset.

Results: TH induction was induced in 12 patients with a target temperature of 32°C, which was reached after a median of 29 min. There was successfull cooling in all of them (100%). By administration of buspirone and meperidine, patients remained conscious and comfortable during the angioplasty procedure at all stages of HT and rewarming in intensive care unit (ICU). All patients received unfractionated heparin (100 IU/kg) and dual anti-platelet aggregation with 600mg of clopidogrel and 300mg of aspirin. The mortality rate was 8,3% (n = 1). Ventricular arrhythmias occurred in 16,7% of patients during TH (n = 2). Absence of bleeding or severe complications in 91,7% of patients (n = 11). In all patients, there was no delay in door-to-balloon time to primary angioplasty, which occurred in a timely manner (less than 90 minutes), and maintenance of TH successfully in the ICU (temperature of 32 ± 0.5°C).

CONCLUSIONS

The therapeutic hypothermia protocol in awaken STEMI patients is feasible and safe. There were no delays in the door-to-balloon time in endovascular TH as an adjuvant therapy to primary PCI.

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Long-term survival after unprotected left main PCI according to indication

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

AIMS

We investigated long term survival of patients undergoing unprotected left main (ULM) PCI according to different indications which prompted the intervention.

METHODS AND RESULTS

A total of 147 consecutive patients in whom ULM PCI was performed by a single operator between 2004 and 2015 were investigated. Patients had either stable coronary disease (48%), NSTE-ACS (34%), STEMI (11%) or resuscitated cardiac arrest (7%). Distal ULM stenosis was present in 69% and true bifurcation (Medina 1,1,1) in 22%. Diameter stenosis was 79±14% with FFR confirmation in 11%. PCI was guided by IVUS/OCT in 19%. DES was used in 82% with wire recross/ kissing in 36% and two stent technique in 13%. Good angiographic result was obtained in 99%. Concomitant multivessel PCI was performed in 57%. Periprocedural intraaortic balloon pump was used in 21% and mechanical ventilation in 12%.

For analysis of long-term survival, patients were divided into 3 groups according to the indication for ULM PCI. Group A consisted of patients who were considered as appropriate PCI candidates by the »heart team« (n=48). Group B consisted of patients in whom “heart team” estimated that the risk of CABG would be prohibitive (n=64). Group C consisted of patients in whom rescue ULM PCI was performed based only on intraprocedural decision by interventional cardiologist (n=35) in case of ACS with ULM as a culprit or ULM as concomitant critical stenosis, comatose survivor of cardiac arrest or iatrogenic LM dissection. Euroscore II was 2.74±3.99 in group A, 14.03±14.37 in group B and 11.12±9.96 in group C ($p<0.5$ for group A versus B and C). After a mean of 1221 days of follow up which was completed in 96%, survival was 93%, 49% and 76% in groups A, B and C, respectively ($p<0.05$ for all comparisons). Clinically-driven target vessel revascularization was 6%, 9% and 14% (NS). No definite stent thrombosis was documented.

CONCLUSIONS

In all-comer population, long-term survival of patients undergoing ULM PCI is significantly different according to the indication. In view of high and comparable angiographic success and low target vessel revascularization/stent thrombosis between different subsets of patients, survival seems to depend on index comorbidities evaluated by Euroscore II.

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CT-based 3D printing for sizing, device positioning and prediction of device compression in the context of LAA occlusion - A comparison to transesophageal echocardiography

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

To determine whether the use of 3D-printed models of patient-specific LAA anatomy based on pre-procedural computed tomography (CT) can aid in device sizing and can predict device compression in the context of LAA closure using the WATCHMAN® device.

METHODS AND RESULTS

18 consecutive patients (73±9 years, 50% male) with atrial fibrillation requiring anticoagulation, but at high bleeding risk underwent LAA closure using the WATCHMAN® device. All patients underwent pre-procedural TEE and contrast-enhanced third-generation dual source CT imaging of the LAA. Based on CT anatomy, replicas of LAA anatomy were created by 3D printing and used to shape silicon moulds to create a hollow model of patient-specific LAA anatomy on a 1:1 scale. Pre-procedural simulation of device implantation was performed in these models. A CT scan of the occluder implanted in the 3D model was used to determine the degree of device compression. In addition, appropriate device size was estimated based on pre-procedural TEE of the LAA. LAA occlusion was performed under TEE guidance and angiographic visualization. Final implant size was compared to CT-based and TEE-based prediction. Implantation was successful in all patients. In one patient, pericardial effusion required drainage. Mean ostium diameter based on TEE was 22.2±3.9 mm, mean ostium diameter based on 3D-CT was 24.4±3.5 mm (p=0.072). 3D-CT based sizing was equal to the finally implanted device in all patients. Based on TEE, the device would have been undersized in 5/18 patients (28%, p=0.045). Compression of implanted occluders was 17.3±4.6% in TEE, which corresponded to the degree of compression determined by in the 3D-CT-model (15.1±3.1%, r=0.533, p=0.023).

CONCLUSIONS

Models of patient-specific LAA anatomy created by CT-based 3D printing may assist in device selection and can predict device compression in the context of interventional LAA closure.

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Does baseline anaemia lead to a differential effect of completeness of revascularisation and mortality after ACS-PCI compared to patients without anaemia?

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THEME: Coronary Interventions
TOPIC(S): NSTEMI

AIMS

Anaemia is associated with adverse outcomes in patients presenting with an acute coronary syndrome. The influence of baseline anaemia on patient demographics, PCI procedures and outcomes is poorly defined.

METHODS AND RESULTS

Data was analysed on all patients presenting with an ACS between 2012 and 2014 and then undergoing PCI at a single large national university hospital performing in excess of 1,500 PCI procedures for all indications per year. The standard WHO haemoglobin thresholds were used to define anaemia. A total of 1,731 patients were included analysis with 468 (26.9%) patients meeting the criteria for baseline anaemia. The mean baseline CRUSADE scores were higher for those patients with anaemia (34.6±16.9 vs. 24.6±13.4, p<0.001) with every component of the score apart from heart rate higher with anaemia. The baseline GRACE scores were also significantly higher for those patients with anaemia (165.8±44.9vs. 141.6±40.1, p<0.001) with every component of the score apart from troponin status associated with anaemia.Patients with anaemia were significantly more likely to have a high/very high CRUSADE score combined with a high GRACE score than patients without anaemia (69.3 vs. 48.3%, p<0.001). Patients with baseline anaemia were more likely to have left main disease (4.3 vs.2.3%, p=0.023) or a CTO (66.3 vs. 60.3, p=0.024), and a greater number of diseased vessels at baseline (1.62±0.78 vs. 1.49±0.69, p=0.001) than patients without anaemia. However, patients with anaemia were less likely to undergo proximal left coronary revascularisation, did not have more vessels treated or receive more stents, and were more likely to be treated with bare metal stents or balloon angioplasty only (36.7 vs. 28.9, p=0.003). As a result, the percentage of patients with residual disease (41.2 vs. 30.7%, p<0.0001), the number of residual diseased vessels (0.59±0.83 vs. 0.42±0.72, p<0.0001), and the percentage with a residual CTO (62.4 vs.56.4%, p=0.036) were all higher than in non-anaemic patients. However, baseline anaemia was not independently predictive of incomplete revascularisation, with age and baseline disease severity (such as the number of disease vessels and graft PCI) being the most important predictors. Amongst patients with baseline anaemia, peri-procedural myocardial infarction (5.3 vs. 2.8%, p=0.011) and in-hospital death (5.3 vs. 2.4%, p=0.004) occurred more frequently. At 12-month follow up, definite stent thrombosis (4.5 vs. 1.1%, p<0.0001) and mortality (14.8 vs. 4.4%, p<0.0001) occurred much more frequently in patients with anaemia compared to those without. The strongest independent predictors of 12-month mortality for the whole cohort were age, baseline anaemia, chronic renal disease and the number of residual untreated vessels. In multivariate analysis by anaemia status, in patients without baseline anaemia, age (OR 1.09 (1.05-1.13), p<0.0001) and the number of residual vessels (OR 1.69 (1.14-2.51), p=0.008) were the strongest predictors of 12-month mortality. In patients with baseline anaemia, age (OR 1.04 (1.01-1.08), p=0.014) and the number of residual vessels (1.42 (1.01-2.02), p=0.047) were the strongest predictors of 12-month mortality.

CONCLUSIONS

Patients with anaemia present a significant clinical challenge with high bleeding and ischaemia scores, complex coronary disease and receive incomplete PCI. However, incomplete revascularisation was associated with increased 12-month mortality regardless of anaemia status.

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Determination of optimal fluoroscopic angulations for coronary ostial interventions from coronary CT angiography

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

AIMS

This study aimed to determine the distribution of optimal C-arm positions for visualization of coronary ostia with minimal overlap of the aortic root and minimal foreshortening using coronary computed tomography (CT) angiography.

METHODS AND RESULTS

Retrospective analysis of 150 consecutive patients (excluding patients with an abnormal coronary artery origin, ascending aorta aneurysm, coronary bypass grafts or an artificial aortic valve) who underwent coronary CT angiography using a third generation dual-source CT scanner due to suspected coronary artery disease. For identification of optimal aorto-left main coronary artery and aorto-right coronary artery projections, the angulation of the image plane with the proximal coronary artery perpendicular to the aorta was determined. If this projection was not achievable due to mechanical constraints of the C-arm system (maximum of 45° cranial and caudal angulations), the best obtainable aorto-coronary projection was determined by finding the image plane with the angle between the proximal coronary artery and the aorta most closely to 90°. Mean patient age was 62±16 years, 53% were males. For the left main coronary ostium, projections within clinical reach of the C-arm that provide orthogonal visualizationcould bedetermined in 124/150 patients (83%). 90% of these projections were in LAO/cranial angulation (LAO 22±24°, cranial 21±16°). In contrast, only 39 patients (26%) had angulations that would provide an orthogonal view of the right coronary ostium within the C-arm range (90% of them in LAO/cranial angulation, mean: LAO 48±36°, cranial 31±21°). In the remaining 105 patients (70%), the obtainable projections most closely to orthogonal visualization were also in LAO cranial position (mean: LAO 50±45°, cranial 41±19°). Overall, a LAO/cranial angulation was optimal or best obtainable for the right coronary ostium in 87% of all patients.

CONCLUSIONS

An optimal view on the left coronary ostium can be reached in most cases in LAO/cranial angulation. The distribution of optimal views on the right coronary ostium is rather sparsely. If optimal angulations cannot be reached, best obtainable angulations may serve as an alternative.

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Temporal changes in outcomes following transfemoral implantation of a fully retrievable and repositionable transcatheter aortic valve prosthesis without routine pre-dilatation for the management of severe aortic stenosis

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

AIMS

The Lotus valve is associated with favourable valve function but higher vascular complications and pacemaker requirements. The aim of this study was to evaluate if greater operator experience resulted in improved procedural and clinical outcomes.

METHODS AND RESULTS

Patients that underwent TF TAVI for native severe aortic valve stenosis at the John Radcliffe Hospital, Oxford, United Kingdom between April 2015 and September 2016 that were treated with the Lotus device were retrospectively identified. All patients were discussed by the 'Heart Team' and underwent pre-procedural echocardiography and computed tomography (CT) to determine suitability of TF access and in prosthesis sizing. Baseline, procedural and 30-day clinical follow-up data were collected. The primary endpoint was 30-day safety according to the Valve Academic Research Consortium 2 (VARC-2) definition.146 consecutive patients were treated with the Lotus valve. The first 49 patients treated were allocated to the early group and the last 49 patients to the late group. There were no differences between the groups with regards to age (81.5±7.2 vs. 81.8±7.2, p=0.81), male sex (53.1% vs. 46.9% p=0.69), logistic EuroSCORE (15.9±10.3 vs. 15.1±10.3, p=0.7).Procedural success was achieved in all patients in both groups. 3 (6.1%) valve failures during deployment occurred in the early group and 1 (2%) in the late group p=0.62, in each case the valve was fully retrieved and a second valve implanted without complication. 1 patient had residual moderate AR in the late group and there were no instances of residual severe AR. The incidence of mild residual AR was similar between groups (18.4% vs. 22.4%, p=1.0). There were significantly more major vascular complications (14.3% vs. 2.2%, p=0.03) in the early group and a trend toward more major or life-threatening bleeding events (2% vs. 0%, p=0.4) early in our experience. No patients suffered coronary obstruction and one patient in the late group required emergency cardiac surgery for the management of cardiac tamponade secondary to left ventricular perforation (p=1.00). There was a trend toward shorter procedure times (97.6±44.3 vs. 86.8±31.4 minutes, p=0.14) and the administration of less contrast (104.4±45.2 vs. 91.7±37.6 millilitres, p=0.16) in the late group. Pacemaker implantation rates were similar between groups (32.7% vs. 28.6%, p=0.83). There were no differences between groups with regards to median length of stay (6.2 vs. 5 days, p=0.9).At 30-day clinical follow up all there were no deaths in either group and no differences in the rates of disabling (4.1% vs. 2%, p=1.00) or non-disabling stroke (4.1% vs. 4.1%, p=1.00).

CONCLUSIONS

The use of the fully repositionable and retrievable Lotus TAVI prosthesis is feasible and safe in an unselected contemporary patient group presenting with native severe aortic stenosis. Greater operator and institutional experience resulted in a significant reduction in the number of vascular complications and a trend to towards shorter procedure times and reduced contrast administration.

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Comparison of different imaging modalities for device size selection for percutaneous LAA closure

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

This study compares different pre-procedural left atrial appendage (LAA) imaging modalities to guide device size selection. 3 months post-procedural multi-slice computed tomography (MSCT) were used as reference.

METHODS AND RESULTS

Methods. Patients who underwent LAA closure with pre-procedural transesophageal echocardiography (TEE), MSCT, and fluoroscopy measurements were identified. LAA device landing zone (maximal diameter measuring at 2mm distal from the orifice at the level of mitral valve annulus for WATCHMAN^{TM} and WATCHMANFLX^{TM} and 10 mm within the orifice at the level of circumflex artery for Amulet^{TM}) measured by all 3 imaging modalities were compared. Post-procedural MSCT was used to assess device expansion.**Results.**67 patients (44 with Amulet^{TM}, 11 with WATCHMAN^{TM}, and 12 with WATCHMANFLX^{TM}) were included in the study. Mean age was 74.0$\pm$7.0 years, mean CHA_2DS_2-VASc-score of 3.0 and mean HASBLED-score of 2.7. For device landing zone, pre-procedural mean maximal measurements were 26.8 ± 6.0 mm with MSCT, 21.8 ± 4.8 mm TEE, and 21.0 ± 4.9 mm fluoroscopy ($P < 0.05$)

Bland-Altman analysis of maximal diameters of device landing zone between pre-procedural MSCT and TEE showed a mean difference of 4.8 mm with a limit of agreement (LoA) of Δ9.6 mm ($p<0.005$). The pre-procedural flouroscopic and TEE maximal diameters were showed a mean difference of 1.3mm with LoA of Δ7.6 mm ($p=0.839$). Based on MSCT measurements, the landing zone changefrom elliptic at baseline to circular after device implantation (ellipticity from 1.48 at baseline to 1.05).

CONCLUSIONS

MSCT consistently provided the largest measurements, followed by TEE and fluoroscopy. This should be taken into consideration when choosing device size based on a certain imaging modality. Post-procedural MSCT shows adaptation of LAA to the device with decrease in ellipticity overtime.

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Relation between one-year clinical outcome of deferred patient and physiological severity based on FFR - Japanese single-centre experience

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

AIMS

The purpose of this study was investigate relation between the outcome of the patients who deferred PCI and physiological severity based on FFR.

METHODS AND RESULTS

This was a prospective single-center study enrolling 218 patients (254 lesions) from September 2013 to June 2015, who had stable coronary artery disease and were deferred PCI. All enrolled patients were measured FFR. Patients with ACS, cardiogenic shock, CTO, and malignant neoplasm were excluded. The primary end point was one-year composite of death, ACS, target lesion revascularization (TLR), and target vessel revascularization (TVR). The completion rate of one-year follow up was 99.1% (216/218 patients). The baseline FFR value in analyzed patients was 0.85±0.06, in whom 58 lesions (22.7%) of FFR≤0.80 and 20 lesions (7.8%) of FFR≤0.75 were included. One-year cardiovascular death, non-cardiovascular death, ACS, TLR, and TVR were 0.5%, 0.9%, 1.9%, 7.8%, 8.8%, respectively. In only FFR≤0.80 group, non-cardiovascular death, ACS, TLR, and TVR were 1.9%, 1.9%, 18.5%, 20.4%, respectively. TLR and TVR were higher rate in FFR≤0.80 group than in FFR>0.80 group (TLR: 4.9%, p=0.013, TVR: 6.1%, p=0.009). FFR≤0.80 group included more hypertension and hemodialysis patients than FFR>0.80 group (hypertension: 85.5% vs 73.1%, p=0.038, hemodialysis: 14.5% vs 1.8%, p=0.012). The major reasons for deferment PCI in spite of FFR≤0.80 were "pressure recovery was gradual pattern", "necessity of left main stenting", and "absence of typical symptom". 57.1% of all deferred lesions were angiographical severe stenosis as %diameter stenosis (%DS) by quantitative coronary analysis (QCA)>50%. There were no significant difference between %DS≤50% group and %DS>50% group in baseline patients characteristics and one-year outcome. All TVR patients excluding 4 patients with ACS and one patient with contrast delay were measured FFR just before revascularization, and FFR≤0.80 was shown in 13 out of 14 patients. On multivariate logistic regression analysis, hemodialysis (p=0.038, odds ratio [OR]: 4.631, 95% confidence interval [CI]: 1.092 to 19.641) and FFR≤0.80 (p=0.012, OR: 3.977, 95%CI: 1.347 to 11.736) were the independent predictors of TLR. While, the predictor of TVR was only FFR≤0.80 (p=0.001, OR: 5.074, 95%CI: 1.919 to 13.419).

CONCLUSIONS

A need for revascularization after deferral of PCI depends on physiological severity of the lesion rather than anatomical severity of stenosis.

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Efficacy of the combination therapy using a non-slip element balloon and rotational atherectomy for symmetrical DES expansion

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

AIMS

We evaluated the combination therapy using a Non-Slip-Element (NSE) balloon with 3 nylon elements or a dual wire balloon after rotational atherectomy (RA) for calcified lesions before implantation of drug-eluting stent (DES).

METHODS AND RESULTS

70 consecutive lesions which need rotational atherectomy (RA) because of heavily calcified lesion, were evaluated. 35 lesions were excluded because of chronic total occlusion, <2.75mm drug-eluting stent (DES) implantation or no intravascular ultrasound (IVUS) data during the procedure. Finally, 10 lesions treated with a combination therapy using a NSE balloon after RA, 13 lesions treated with a combination therapy using a dual wire balloon after RA, and 12 lesions treated with RA alone, could be examined. All lesions were successfully implanted DES. Just after RA or a scoring balloon dilatation, the section with smallest luminal cross sectional area (CSA) with an angle of more than 180 degree calcification was identified by IVUS and the following measurements made at the same lesion. Quantitative IVUS assessment was performed three times and the average data was compared. Angiographic findings were examined just after treatment and 11 months after treatment. Baseline patient characteristics, lesion characteristics calculated by quantitative coronary angiography, procedure devices and postdilatation procedures were not different among three groups. The scoring balloon catheter could be advanced to the calcified lesion after RA in all cases. However, 3 cases using a NSE balloon need a guiding extension catheter for the advancement of the balloon. After the implantation of DES, the minimal stent diameter (2.9±0.3mm vs. 2.5±0.4mm, P<0.05) and the minimal stent CSA (8.1±1.5mm^2 vs. 6.6±1.4mm^2, P<0.05) were significantly larger in patients treated with a NSE balloon compared to patients treated with RA alone. However, those were not significantly different between the patients treated with a NSE balloon and a dual wire balloon.

Moreover, symmetrical expansion ratio (mean ratio calculated by dividing the shortest diameter by the longest diameter at the site of the minimal stent CSA) was significantly higher in patients with a NSE balloon (0.86±0.07) than those with a dual wire balloon (0.80±0.05, P<0.05) and RA alone (0.76±0.06, P<0.05). Although in-stent restenosis was observed in patient treated with RA (N=2, 28.6%), there was no in-stent restenosis in patients treated with a dual wire balloon and a NSE balloon.

CONCLUSIONS

The combination therapy using a NSE balloon after RA, accomplished the adequate stent expansion and follow-up result. This combination therapy is feasible procedure for the treatment of severe calcified lesions.

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Facilitation of stent delivery with the GuideLiner catheter: the RUHL study

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

AIMS

This registry Of University Hospital Limerick (UHL) recorded 118 consecutive cases of Guideliner facilitated PCI to assess safety, feasibility and use of “anchor-balloon technique” in terms of distal stent delivery.

METHODS AND RESULTS

The study was conducted at (UHL), Ireland. Clinical and angiographic records were searched using administrative and clinical databases at (UHL) to identify all patients that underwent GL assisted PCI with the indication of facilitating stent delivery and deployment at our institution from August 1, 2012, to July 1, 2016. All other cases involving use of GL for reasons such as contrast delivery or thrombectomy were excluded.

Results

Among 118 patients studied , median age was 69 years. Clinical indication for PCI was stable Angina in 60%(70/118) and acute coronary syndrome in 40%(48/118) . It was predominantly Trans-radial intervention 63%(74/118) compared to 37% (44/118) trans-femoral . Most of the lesions were complex and had American Heart Association/American College of Cardiology (AHA/ACC) classification of B or C; (93%). The primary indication in all cases was to facilitate stent delivery. The use of the “anchor-balloon technique” to facilitate deep intubation and stent delivery was used in 25% (29/118). Device success rate was 86% (101/118). There were six cases of edge dissection all of which were stented successfully. in addition to two cases where the stents were damaged at the transition zone.

CONCLUSIONS

This is a large registry for the use of GL to facilitate difficult PCI. GL use resulted in increased back-up and guide catheter alignment for stent delivery in unfavorable tortuous coronary anatomies and complex, heavily calcified, and often distally located lesions, which otherwise may have been considered unsuitable for PCI. Procedural success rate was high, especially when anchor balloon is used, and apart from few minor complications the device was otherwise safe.

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Moderate/severe aortic regurgitation after TAVI with CoreValve: is it anatomically or procedurally determined? - A MCDT study

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

AIMS

AIM: To investigate the determinants of moderate/severe aortic regurgitation (AR) occurring after transcatheter aortic valve implantation (TAVI) with CoreValve.

METHODS AND RESULTS

Methods

Retrospective, observational study including all patients with severe aortic stenosis and submitted to TAVI with CoreValve prosthesis between August 2007 and October 2016. TAVI with CoreValve was performed in 112 patients with severe aortic stenosis (50% male, mean age 79.4±8.8 years old, mean EuroSCOREII 6.3±69) between August 2007 and October 2016. Contrast-enhanced electrocardiogram (ECG)-gated multidetector computed tomography (MDCT) was performed before and after TAVI. Indexed aortic valve (AV), left ventricular outflow tract (LVOT) and device landing zone (DLZ) calcification was quantified by a standard Agatston methodology for all available pre-procedure contrast-enhanced MCDT, with a threshold for calcium detection set at 850 Hounsfield Units. Annular diameter, indexed annular perimeter and area, ellipticity index and transcatheter heart valve (THV) oversizing were determined using post-procedure contrast-enhanced MCDT data, during late systolic phase. Procedure and pre-discharge echocardiographic data were also collected.**Results**

TAVI with CoreValve was performed in 112 patients in our centre (50% male, mean age 79.4±8.8 years old, mean EuroSCOREII 6.4±6.8). The incidence of moderate/severe AR after TAVI was 15.1%. Balloon post-dilation was performed in 21.8% of patients. Indexed AV, LVOT and DLZ calcification; annular diameter and indexed annular perimeter and area were significantly different between patients with moderate/severe post-procedure AR and those with milder degrees of AR. The were no significant differences in THV oversizing and ellipticity index between the two groups. After multivariate analysis was performed, only indexed DLZ calcification and indexed annular area remained independent predictors of moderate/severe post-procedure AR.

CONCLUSIONS

Conclusion

In the present study, only anatomic parameters assessed by ECG-gated contrast-enhanced MDCT (indexed DLZ calcification and indexed annular area) were independently associated with the development of moderate/severe AR occurring after TAVI with CoreValve. The intraprocedural parameters assessed did not independently predict of the outcome.

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Usefulness and safety of the "radial ultrasupport technique" to enhance guiding catheters support: a prospective randomised pilot study vs. anchoring technique

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

AIMS

The “Radial Ultra Support technique” is a new technique, it provides active support by deep pass of the coronary wire into the left ventricle and aorta. We aimed to assess its feasibility and safety in clinical practice versus anchoring technique.

METHODS AND RESULTS

Methods

The present study was a single-center, prospective, randomized study. Patients with stable angina and complex coronary stenosis included into the clinical trial .

After unsuccessful attempt at crossing the stenosis/occlusion either with a minimal size balloon (1.25×10mm) or with a stent if predilatation with non-compliant balloon was obtained, patients could be included in the study. Patients were randomized in two groups according to the support technique: “anchoring” technique, and “Radial Ultra Support” technique.

INTERVENTIONAL PROCEDURES

The right radial access and appropriate 6 Fr guiding catheters (Extra Back Up, Amplatz) were used systematically.

In the “Radial Ultra Support” technique a soft hydrophilic wire was smoothly advanced through the invisible small vessels at the distal parts of all major epicardial coronary arteries into the left ventricle. Often the wire goes through the left ventricle into the aorta arch. Thus the stiffest part of the wire becomes staying on all length of artery, straightening bends and giving a maximum support. Balloons and stents could then be delivered on the wire using the enhanced support.

STUDY ENDPOINTS AND DEFINITIONS

The primary endpoint was the procedural success rate, defined as successful implantation of the intended stent without the occurrence of in-hospital Major Adverse Cardiac Events.

Results

The demographic characteristics of the study population were well balanced between the two groups. Target lesions were highly complex and were all type C. A total of 86% of lesions were calcified. Mean lesion length was more than 30 mm in both groups. The number and diameter of stents, and the length of stenting segment per patient were similar in both groups. Contrast volume and procedure time were not different between groups.

The device success and procedural success rates were similar in both groups (96 vs. 93%; p=1.0 and 96 vs. 89%;p=0.8, respectively).

CONCLUSIONS

The use of the "Radial Ultra Support" technique resulted in an increased back-up support and guide catheter alignment for stent delivery in the presence of unfavorable tortuous coronary anatomies and in complex, heavy calcified lesions, which otherwise may have been either considered unsuitable for PCI or would have required additional expensive tools for successful implantation. The procedural success rate of "Radial Ultra Support" technique was high without major complications.

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Indexed device landing zone calcium volume predicts the need for balloon post-dilation in TAVI procedures with self-expandable prosthesis

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

AIMS

his study sought to evaluate the relationship of DLZ calcium volume with the need for BPD during TAVI with 1st and 2nd generation self-expandable prosthesis.

METHODS AND RESULTS

Retrospective, observational study including all patients with severe aortic stenosis and submitted to TAVI with self-expandable prosthesis between August 2007 and October 2016. Calcification of the DLZ was quantified for all available contrast scans, using a dedicated software (3mensioValvesTM), with a threshold for calcium detection set at 850 Hounsfield Units. TAVI with self-expandable prosthesis was performed in 180 patients in our centre (47,8% male, mean age 79.7±7.8 years old). Most of the devices implanted were 1st Generation Self-Expandable Prosthesis (n=112, 62.2%). BPD was performed in 40 TAVI procedures (22.5%). Body surface area (BSA) indexed DLZ calcium volume was significantly different between patients with and without need for BPD during TAVI procedures: 259,1±45,1 v*s.* 126,6±9,5 (p<0.01). Area under the curve (AUC) for BSA indexed DLZ calcium volume was 0.70 (95% CI 0.60–0.79 p<0,01).
We considered the best cut off point for BSA indexed DLZ calcium volume to be 93.3 (sensitivity 84.2%, specificity 49.6%). In a binary logistic regression model, an BSA indexed DLZ calcium volume equal or above 93.3 was associated with 3 times increase in the probability BPD need during TAVI procedures with self-expandable prosthesis. There were no significant differences in the incidence of moderate/severe AR after TAVI with self-expandable prosthesis, regarding device generation (X^2 (1)=007, p=0.85).

CONCLUSIONS

Calcification of the DLZ predicts the need for BPD in TAVI Procedures with Self-Expandable Prosthesis, both in 1st and 2nd generationdevices.

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Prospective evaluation of the development of contrast-induced nephropathy in patients with ACS undergoing rotational coronary angiography vs. conventional coronary angiography: CINERAMA study

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

AIMS

The aim of the study is to evaluate the impact of rotational coronary angiography, for the first time in medical literature, on contrast-induced nephropathy after an acute coronary syndrome.

METHODS AND RESULTS

From April to September 2016, patients suffering acute coronary syndromes underwent diagnostic coronary angiography, with possibility of ad hoc coronary angioplasty, were recruited. According to operator criteria, patients received rotational coronary angiography or convencional coronary angiography. Contrast-induced nephropathy (primary endpoint), analytic, angiographic and clinical endpoints were compared between groups.

From a total of 235 patients, 116 patients received rotational coronary angiography and 119 patients received conventional coronary angiography. Patients in rotational coronary angiography group were older (years: 64.0±11.8 vs. 59.7±12.1; p=0.006), had higher percentage women (44.8% vs. 17.6%; p<0,001), lower glomerular filtration rate (mL/min: 73±25 vs. 85±27; p<0.001), and lower coronary angioplasties(p<0.001) compared with conventional coronary angiography group. Furthermore, rotational coronary angiography group, received less iodinated contrastin total (mL: 113±92 vs. 169±103; p<0.001), also in diagnostic procedures (mL: 54±24 vs. 85±56; p<0.001), and diagnostic-therapeutic procedures (mL: 174±64 vs. 205±98; p=0.049) compared with conventional coronary angiography group. Rotational coronary angiography group presented less contrast-induced nephropathy (4.3% vs. 22.7%; p<0.001) as compared to conventional coronary angiography group, maintaining the gap in the regresión analysis (Adjusted relative risk [95% CI]: 0.868 [0.794-0.949]; p=0.002). There were no differences in clinical endpoints between groups.

CONCLUSIONS

Rotational coronary angiography was associated with lower administration of iodinated contrast during invasive coronary procedures in acute coronary syndrome patients, resulting in lower incidence of contrast-induced nephropathy, in comparison with conventional coronary angiography.

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Impact of rotational coronary angiography in the amount of contrast and exposition to ionising radiations in patients undergoing invasive coronary procedures: a systematic review and meta-analysis

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

AIMS

The aim of the systematic review and meta-analysis is to assess the impact of RCA in the amount of iodinated contrast and the dose of ionizing radiations during invasive coronary procedures.

METHODS AND RESULTS

Invasive coronary procedures involve the administration of iodinated contrast and the use of ionizing radiations, increasing morbidity and mortality. The rotational coronary angiography allows acquiring multiple projections with a unique injection of iodinated contrast. To date, there were no meta-analysis specifically comparing rotational coronary angiography and conventional coronary angiography in patients undergoing invasive coronary procedures, whether diagnostic or diagnostic and therapeutic.A search in PubMed and Ovid databases was conducted to identify studies, diagnostic and diagnostic and therapeutic studies, comparing rotational coronary angiography and conventional coronary angiography. The manuscripts were evaluated on quality and biases and included if they studied any of the following endpoints: volume of contrast and doses of ionizing radiations measured as dose-area product, Kerma-air or fluoroscopy time.Sixteen studies, with a total of 2327 patients, were included in the final analysis (1146 patients underwent rotational coronary angiography and 1181 patients underwent conventional coronary angiography), detecting significant differences in volume of contrast (standard difference in means [95% confidence interval]; 1.887 [-2.472 to -1.302]; p <0.001), dose-area product (-0.726 [-1.034 to -0.418]; p <0.001), Kerma-air (-0.842 [-1.104 to -0.581]; p <0.001), and fluoroscopy time (0.263 [-0.496 to -0.030]; p = 0.027), favoring rotational coronary angiography.

CONCLUSIONS

Rotational coronary angiography reduces the volume of contrast and the dose of radiation, evaluated as dose-area product, Kerma-air and fluoroscopy time, in patients undergoing invasive coronary procedures, in comparison with conventional coronary angiography.

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Long-term clinical outcomes after primary percutaneous angioplasty in elderly patients with STEMI: a single-centre experience

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

This study sought to determine the long-term clinical outcomes of patients aged ≥ 75 years who underwent primary percutaneous coronary intervention (PPCI) for STEMI.

METHODS AND RESULTS

From January 2014 to December 2014 all consecutive patients ≥ 75 years with STEMI treated with PPCI in our hospital were enrolled.Patients were followed up over 2 years by clinical observation.Clinical outcome was measured by taking the primary endpoint of major adverse cardiac and cerebrovascular event (MACCE), a composite of cardiovascular death, any-recurrent myocardial infarction (MI), target vessel revascularization (TVR) and stroke during follow-up.Among 198 STEMI patients admitted for PPCI, 44 (22.2%) were ≥ 75 years. Mean age was 77.9 ± 3.1 years, 54. 5% were male patients and 40.9 % were diabetics. Killip class III-IV at admission was 15.9% and the median time of symptoms onset to PPCI was 261 minutes (25th-75th:198-321).The culprit lesion was most often found in the right coronary artery (54.5%). The radial approach was used in 75% of cases. Stent implantation was performed in 95.5 % of cases (43.2% BMS, 52.3 % DES) and plain old balloon angioplasty in 4.5 %. The procedure was successful in 88.6%. The overall 30-day cumulative mortality was 9.1 %. Cumulative MACCE rate at 2 years was 27.3%, with 15.9 % cardiac death, 6.8% MI, 6.8% TVR and 2.3 % of stroke. 1 patient (2.3%) had a stent thrombosis. Major bleeding occurred in 2 patients (4.5%).The MACCE rate at 2 years did not significantly differ between DES-treated patients than in BMS-treated patients (26.1% vs. 26.3 %, p=0.74).

CONCLUSIONS

In this series of patients with STEMI who were older than 75 years, PPCI had high procedural success and provided good clinical outcomes in this high risk subset of patients demonstrated by the low MACCE rates at long-term follow-up.

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The effect of side branch predilation in coronary bifurcation stenting with the provisional approach

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

AIMS

We investigated the effect of SB predilation on procedural and long-term clinical outcomes in coronary bifurcation lesion treated by the provisional approach.

METHODS AND RESULTS

A total of 1,083 patients with true bifurcation lesion undergoing percutaneous coronary intervention were evaluated. The primary outcome was a major adverse cardiovascular event (MACE; cardiac death, myocardial infarction, or target lesion revascularization). SB predilation was performed in 437 (40.4%) patients. Abrupt (10.5% vs. 11.3%; P=0.76) or final SB occlusion (2.7% vs. 3.9%; P=0.41) during the procedure showed no differences between the predilation and no predilation groups. The angiographic success, defined as final TIMI 3 flow and < 30% residual stenosis in MV and < 50% residual stenosis in SB, was significantly higher in the predilation group (69.1% vs. 52.9%, P<0.001), which was mainly driven by higher rate of SB stent implantation in the predilation group (28.4% vs. 14.7%, P<0.001).During a median follow-up of 36 months, there was no significant difference between the groups in the rate of MACE (11.7% vs. 9.1%, hazard ratio [HR], 1.12; 95% confidence interval [CI], 0.75-1.67; P=0.58). In a propensity score-matched population, the rate of MACE was similar between the groups (11.2% vs. 9.0%; HR, 1.00; 95% CI, 0.61-1.65; P=0.99). In the subgroup analysis, patients with minimal luminal diameter of parent vessel less than or equal to 1mm got a benefit from SB predilation in terms of abrupt SB occlusion (P for interaction = 0.04).

CONCLUSIONS

For the treatment of true bifurcation lesion, selective SB predilation might be associated with a favorable outcome.

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Prediction of side branch occlusion in PCI by coronary CT

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

AIMS

We investigated whether preprocedural coronary computed tomography angiography (CCTA) could predict intraprocedural SB occlusion.

METHODS AND RESULTS

A total of 260 bifurcation lesions were enrolled from 246 patients who underwent CCTA before elective PCI for bifurcation lesion. Quantitative plaque analysis was done in both main vessel (MV) and SB. SB occlusion was defined by loss of anterograde flow with thrombolysis in myocardial infarction flow (TIMI) grade 0 or 1 immediately after ballooning or stent implantation. Intraprocedural SB occlusion occurred in 42 lesions (16%). These lesions could be characterized by SB plaque length ³5mm, calcified plaque in the MV, low attenuation plaque in main proximal segment or SB, and the ratio of MV to SB ostium area > 4.3, which constituted point-based CT bifurcation score.CT bifurcation score was cross-validated and outperformed (c-statistics = 0.751) any angiographic Medina classifications or angiographic RESOLVE score (c-statistics=0.631 to 0.551; $p < 0.05$, all). The risk of SB occlusion proportionally increased from 5% to 64% according to CT bifurcation score of 0 to 3. The sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of CT bifurcation score ≥1 was 86%, 54%, 26%, 95%, and 59%, respectively.

CONCLUSIONS

Comprehensive CCTA assessment could predict intraprocedural side branch occlusion better than current angiographic classification or scoring system. CT bifurcation score might be helpful for the guidance of optimal PCI strategy for bifurcation lesion.

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Inter-modal and clinical validation of intraprocedural echocardiographic and angiographic assessments of aortic regurgitation after TAVI

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

AIMS

We aimed to investigate the relationship between intraprocedural echocardiographic and angiographic assessments of the severity of aortic regurgitation (AR) after TAVI and the predictability of outcomes of both techniques.

METHODS AND RESULTS

Seventy-one patients with symptomatic severe aortic stenosis underwent TAVI in our hospital from Apr 2014 to Dec 2016. For the echocardiographic assessment, we measured circumferential extent (CE) of the paravalvular regurgitant jet arc in accordance with VARC-2 criteria. To improve its reproducibility, we made the measurement of CE at the end of E wave of trans-mitral flow. Subsequently, we graded the severity as follows: none-trace 0≤CE<5 (%); mild 5≤CE<10 (%); moderate 10≤CE<30 (%); severe 30≤CE (%). We investigated reproducibility of the echocardiographic method between two trained observers in 30 randomly-selected patients.

For angiographic assessment, we performed the final angiogram with fixed catheter size, contrast volume and injection speed, and complete stop breathing. AR was quantitated using a contrast videodensitometry software which can calculate the ratio of the time-contrast density of region of interest (ROI) to that of ascending aorta. Especially, we focused on the left ventricular outflow tract (LVOT-AR) as a ROI.

We did the time to event analysis defining all-cause death and re-hospitalization due to heart failure as a composite endpoint, and investigated the predictability of this endpoint by receiver operating characteristic (ROC) curve analysis.

On echocardiography, the prevalence of AR after TAVI was as follows: none-trace 17(23.9%); mild 25(35.2%); moderate 29(40.9%).

Inter-observer variability of %CE was low (mean difference ± standard deviation0.39 ± 2.6), and intra-class correlation coefficient was excellent (0.92) as the agreement on the grade of AR (weighted-kappa 0.89).

Median follow-up time was 311 days, and there were 7 all-cause deaths and 11 re-hospitalizations due to heart failure up to 1-year. Patients with >mild AR (n=42) had a significantly increased risk of the composite endpoint at 1-year, compared to patients with none-mild AR (n=29) [45.1% vs 11.2%, Hazard Ratio (HR), 95% confidence intervals (CI) 2.81(1.07-7.37), p=0.0217].

Forty-five angiograms were analyzable for LVOT-AR. The distribution of LVOT-AR across the echocardiographic grades of AR was [median(IQR)]: none~trace 0.07(0.06-0.14); mild 0.13(0.09-0.16); moderate 0.19(0.15-0.22). Based on cut-off point (LVOT-AR>0.17) which was previously reported to correspond to moderate AR on echocardiography, we divided this population into 2 groups. Patients with LVOT-AR>0.17 (n=12) had a significantly increased risk of composite endpoint at 1-year, compared to patients with LVOT-AR≤0.17 (n=33) [100% vs 41.0%, HR, 95% CI .3.73 (0.78-17.76), p=0.0069].

There was a moderate correlation between the two techniques of AR assessment (r=0.70, p<0.0001) with no significant difference in the predictability of outcomes on ROC curves (p=0.7599), although both predictabilities were not statistically significant.

CONCLUSIONS

Accurate and reproducible intraprocedural assessment of AR is possible and comparable using careful transesophageal color Doppler as well as quantitative angiography.

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Long-term clinical outcomes following ultrathin, biodegradable polymer-coated sirolimus-eluting stent implantation in diabetic vs. non-diabetic patients: results from the SCODA registry

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THEME: Coronary Interventions
TOPIC(S): Stents and scaffolds, Left main and multivessel disease, Other Coronary Interventions

AIMS

Aim of this registry was to compare the long-term (up to 7 years) clinical outcomes after implantation of the Supralimus-Core; ultrathin-strut (60 µm), biodegradable polymer coated sirolimus-eluting stent (SES); in diabetic and non-diabetic patients.

METHODS AND RESULTS

We conducted a retrospective, singe-arm, open-label, multicenter registry of 517 patients, who had treated exclusively with the Supralimus-Core SES (Sahajanand Medical Technologies Pvt. Ltd., Surat, India), between April-2008 and May-2015 at two centers in Saudi Arabia. Of these, 279 patients were diabetic, whereas 238 had non-diabetic. The primary endpoint was long-term (up to 7 years) combined major adverse cardiac events (MACE) including cardiac death, myocardial infarction (MI), target lesion revascularization (TLR), target vessel revascularization (TVR)/ coronary artery bypass graft (CABG) and stent thrombosis; according to ARC definitions. A total of 517 patients [279 (54.0%) diabetic patients and 238 (46.0%) non-diabetic patients], with mean age of 55.0±10.2 years, were evaluated in this registry. Diabetic patients had a higher prevalence of arterial hypertension (59.5% vs. 39.9%, p<0.001), hyperlipidemia (71.7% vs. 40.8%, p<0.001) and unstable angina (40.9% vs. 29.8%, p=0.009) compare to non-diabetic patients. There were no significant differences in lesion complexity like long lesions (≥30mm), bifurcation lesions, calcified lesions, restenotic lesions, and total occlusion between diabetic and non-diabetic patients. A median follow-up of 5.6 years; interquartile range: 3 to 7 years was achieved in 95.6% of patients (494/517) and during follow-up, the cumulative incidence of MACE in patients with diabetes was comparable to that of non-diabetics [46 (17.2%) vs. 29 (12.8%), p=0.169]. Diabetic patients had higher risks of cardiac death [25 (9.4%) vs. 9 (4.0%), p=0.018] during follow-up compared with non-diabetic patients. However, the rates of TLR [15 (5.6%) vs. 15 (6.6%), p=0.656] and TVR/CABG [4 (1.5%) vs. 5 (2.2%), p=0.560] were not significantly different between diabetic and non-diabetic patients during follow-up. Also, there was no difference in stent thrombosis between diabetic and non-diabetic patients [2 (0.7%) vs. 0 (0), p=0.502)].

CONCLUSIONS

Despite complex lesion morphology, this registry demonstrates satisfactory and sustained long-term clinical outcomes as evidenced by the low rates of MACE, for the Supralimus-Core SES, in diabetic and non-diabetic patients.

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Comparative analysis of balloon- vs. mechanically expandable transcatheter heart valves considering landing zone calcification

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

AIMS

We sought to compare functional and clinical outcomes in patients after TAVI using balloon-expandable (BE) or mechanically-expandable (ME) transcatheter heart valves (THV) under consideration of the aortic valve complex (AVC) calcification load.

METHODS AND RESULTS

The analysis comprises 303 consecutive patients with severe symptomatic aortic stenosis treated with BE Sapien 3 (Edwards Lifesciences, USA; N=212) or ME Lotus (Boston Scientific, USA; N=91) THV from 2014-2016 via transfemoral access. Outcomes were retrospectively assessed according to Valve Academic Research Consortium (VARC)II definitions. Rate of paravalvular leakage (PVL), periprocedural stroke and permanent pacemaker implantation (PPI) was adjusted for calcification load of the AVC as calculated by multi-slice computed tomography (MSCT) using a semi-automated volume-scoring tool.

Baseline characteristics were similar between groups (all comparisons BE vs. ME: age 80.6±7.2 vs. 80.5±7.5 years, male gender 51.9% vs. 50.6%, STS PROM 5.9±5.6% vs. 4.8±2.6%, all p=n.s.). Calcification load of the AVC was lower in the BE group (annular plane calcification: 671.5±542.4 mm^3 vs. 855.3±665.9mm^3, p<0.05; LVOT calcification: 60.5±124.2 mm^3 vs. 161.6±544.3 mm^3, p<0.05).There was no difference in rate of device success (95.3% vs. 95.1%, p=n.s.), 30-day mortality (1.9% vs. 4.3%, p=n.s.), periprocedural disabling stroke (1.4% vs. 3.3%, p=n.s.) or major access site complications (9.4% vs. 6.3%, p=n.s.). PPI was more (19.4% vs. 30.8%, p<0.05) and ≥mild PVL was less frequent (17.6% vs. 7.5%, p<0.05) after ME THV implantation. For both THV, extent of AVC calcification was associated with increased risk for PVL ≥mild (OR 1.21, 95%CI 1.03-1.42, p<0.05). No association was found between AVC calcification and periprocedural stroke rate (OR 1.19, 95%CI 0.92-1.54, p=n.s.) or need for PPI (OR 1.04, 95%CI 0.91-1.18, p=n.s.) in the overall patient cohort. After adjusting for AVC calcification, risk for PVL ≥mild was reduced with ME THV (OR 0.15, 95%CI 0.02-0.54, p<0.05).

CONCLUSIONS

Both THVs yield similar clinical outcomes except for a significantly higher PPI rate with ME THV – a finding that is independent from the extent of AVC calcification. The extent of AVC calcification is associated with an increased risk for significant PVL for both THV. However, after adjusting for AVC calcification this risk is significantly reduced with ME THV.

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Efficacy and safety of new generation P2Y12 inhibitors in Korean myocardial infarction patients; a nationwide registry based analysis

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

AIMS

Current guidelines recommend that new oral P2Y12 inhibitors should be used in myocardial infarction (MI) patients. We evaluated the efficacy and safety of new oral P2Y12 inhibitors from a nationwide registry of Korean acute MI patients.

METHODS AND RESULTS

Patients were enrolled from the Korea Acute Myocardial Infarction Registry (KAMIR). Patients who received any dual antiplatelet agent therapy (aspirin with clopidogrel (AC group), aspirin with prasugrel (AP group), or aspirin with ticagrelor (AT group)) at discharge, and took a successful 1-year follow-up were included for this study. The 1-year efficacy endpoint was the major adverse cardiac and cerebrovascular event (MACCE, a composite of cardiac death, myocardial infarction, stent thrombosis and stroke) and the 1-year safety endpoint was bleeding events, including type 2, 3, 5 Bleeding Academic Research Consortium bleeding events.

A total of 9,112 patients were analyzed (6,411 (70.4%) patients in the AC group, 993 (10.9%) in the AP group and 1,708 (18.7%) in the AT group). Baseline characteristics showed distinct clinical characteristics among three groups. Crude analysis of clinical events showed that 1-year MACCE was most common in the AC group (4.1% vs. 2.6% vs. 2.3%, p<0.001, in the AC, AP, AT group), and bleeding events were least in the AC group (4.1% vs. 7.2% vs. 9.0%, p<0.001). However, the Cox regression multivariate analysis showed that new oral P2Y12 inhibitors could not reduce risk of 1-year MACCE, whereas increased bleeding risk (AP vs AC: HR 2.14, 95% CI 1.53 – 2.99, p<0.001, AT vs AC: HR 2.26, 95% CI 1.73 – 2.95, p<0.001).

Due to the distinct baseline characteristics, a propensity score matching analysis and inverse probability weighting regression analysis was done. A 1:1:1 propensity score matching for each antiplatelet agent yielded 572 matched triplets. Outcome analysis revealed no difference in 1-year MACCE between antiplatelet agents, whereas bleeding events was still significantly increased for each new generation antiplatelet agent (AP vs. AC: HR 2.62, 95% CI 1.52-4.51, p<0.001; AT vs. AC: HR 2.65, 95% CI 1.53-4.56, p<0.001). The inverse probability weighting regression model also showed that both the AP group and AT group could not reduce 1-year ischemic outcomes compared to the AC group only to significantly increase bleeding events.

The KAMIR had a few missing values due to the nature of registry data, leading a decreased sample size in analysis. After multiple imputations, we could analyze the total data set of 9,112 patients. Pooled analysis of 5 data sets showed that DAPT group was insignificant factor for predicting 1-year MACCE, whereas the AP and AT group had a significantly higher risk of bleeding (AP vs. AC: HR 2.28, 95% CI 1.73 – 3.00, p<0.001, AT vs. AC: HR 2.47, 95% CI 1.98 – 3.08, p<0.001).

For subgroup analysis, we analyzed those without the triple contraindications for prasugrel (patients > 75 years old, weight < 60 kg, and with a history of stroke), including 5,399 patients (57.7%). Even in this low-risk population, the usage of new generation antiplatelet agents was neutral for ischemic outcomes, but significantly increased bleeding events.

CONCLUSIONS

From the KAMIR registry, usage of new P2Y12 inhibitors did not reduce 1-year ischemic outcomes, whereas increased bleeding events in Korean acute MI patients. Further studies are warranted to adopt current Western guidelines for new generation P2Y12 inhibitors in East Asian population.

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Comparison of biodegradable polymer (Everoflex) vs. permanent polymer (Xience Pro) coated everolimus-eluting coronary stent systems in all-comer patient population at a tertiary care hospital - One-year outcome study

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

AIMS

We sought to evaluate safety and efficacy of Everoflex (Sahajanand Medical Technologies Pvt Ltd, Surat, India) and Xience Pro (Abbott Vascular, Abbott Park, Illinois) coronary stents in daily clinical practice at a tertiary care center.

METHODS AND RESULTS

It is a single-center, non-randomized, prospective registry consisting of two cohorts – Everoflex and Xience Pro. Each cohort consisting of 327 consecutive patients who underwent percutaneous coronary intervention with Everoflex and Xience Pro stents respectively between January and December, 2015. The primary end-point was incidence of cardiac death, myocardial infarction and target lesion revascularization. Secondary endpoint was composite of device oriented end-points as well as patient oriented outcomes comprising overall mortality, any myocardial infarction and repeat revascularization. The mean age of the Everoflex and Xience Pro groups was 56.7±10.4years and 55.6±9.7 years (p=NS) respectively. Both the groups were matched in terms of gender, risk factors, ejection fraction, severity of the disease and infarct related artery. The average diameter and length of stents were 2.83±0.29mm and 25.12±8.70 mm in Everoflex group, 2.82±0.31 mm and 19.81±7.61 mm in Xience Pro group. Device related outcomes at 1-year follow up: Cardiac death, myocardial infarction, target vessel revascularization (TVR) and target lesion revascularization (TLR) were reported in 02 (0.6%), 07 (2.2%), 06 (1.8%) and 06 (1.8%) patients in Everoflex group whereas in Xience Pro group it was 05 (1.5%), 7 (2.1%), 04 (1.2%) and 04 (1.2%) respectively. In Everoflex group, Stent thrombosis was reported in 03 (0.9%) patients, of which 01 (0.3%) was sub-acute and 02 (0.6 %) were late where as in Xience Pro group it was reported in 02 (0.6%) patients and both were late. In-stent restenosis was found in 03 (0.9%) and 02 (0.6%) patients in Everoflex and Xience Pro groups respectively. At 1-year follow-up, overall mortality was 0.6% and 1.5%; and survival rate was 99.4% and 98.5% in Everoflex and Xience Pro groups respectively.

CONCLUSIONS

At 1-year follow-up, Everoflex and Xience Pro stents are safe with low risk of stent thrombosis, in-stent restenosis and higher survival rates in all-comers patient population. Everoflex group showed a slightly higher mortality benefit than Xience Pro, this finding may be because of thinner strut size and biodegradable polymer used in Everoflex. A larger multi centric study with longer follow-up will be useful to establish these findings.

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TAVI in conjunction with mitral edge-to-edge repair in surgical high-risk patients - Procedural, clinical and haemodynamic outcomes

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

AIMS

We sought to analyze procedural, clinical and acute hemodynamic outcomes after TAVI and concomitant percutaneous mitral edge-to-edge repair in patients with severe aortic stenosis and mitral regurgitation (MR).

METHODS AND RESULTS

All patients who underwent simultaneous transfemoral TAVI and MitraClip™ implantation at 3 European sites were included in the analysis (N=20). All endpoints were assessed in accordance with the current (mitral) valve academic research consortium definitions. Cardiac output (CO) was measured by right heart catheterization using the method of thermodilution.
Mean age was 81.2±7.0 years and surgical risk (mean LogEuroSCORE I 29.4±15.1%) was high. At baseline, aortic valve effective orifice area (EOA) was 0.8±0.2 cm^2 and all patients displayed severe MR (70.0% of the patients presented with MR 4+). MR was predominantly of degenerative or mixed etiology (12/20; 60%) and mean left ventricular ejection fraction at baseline was 44.8±14.1%.TAVI was performed in 19 out of 20 patients before MitraClip™ implantation and mean procedural time was 173.3±44.2 min. Rate of device success (combined TAVI and MitraClip) was 90.0% (18/20). Reason for device failure was moderate PVL after TAVI (31 mm CoreValve) in one and MR 3+ after MitraClip in another patient. There was no procedural death, but 2 patients died during the following 30 days after the procedure. Causes of death were refractory pneumonia in a 95 year old patient on day 20 and cardiac arrest of unknown cause in an 82 year old patient on day 21 after the procedure. No peri-procedural stroke or myocardial infarction was observed. One patient (5.0%) required a permanent pacemaker and one patient (5.0%) had a major access site complication. CO increased from 3.7±1.2 l/min at baseline to 4.2±1.4 l/min after TAVI, but showed no further improvement after MitraClip™ implantation (4.2±1.3 l/min). However, there was a reduction of v-wave from 37.7±15.4 mmHg to 19.5±4.1 mmHg after MitraClip™ implantation. At discharge EOA had increased to 2.1±0.2 cm^2 and MR was <2+ in 90.9% (10/20) of the patients.

CONCLUSIONS

In high-risk patients suffering from both, severe aortic stenosis and mitral regurgitation, a combined interventional treatment approach with TAVI and percutaneous mitral edge-to-edge repair is feasible but time consuming even for experienced operators. Whereas TAVI entails acute improvement of CO, such an acute effect is not observed after mitral repair. A larger study is needed to investigate if the combined treatment approach translates into improved long-term patient outcome.

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Extended anticoagulation after primary PCI in patients with coronary microvascular obstruction and TIMI flow 3

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Microvascular obstruction (MVO) can be related to different factors such as thrombus embolisation and yields a worse clinical outcome in ACS. Objetive: To identify MVO patterns after successful primary PCI and assess extended anticoagulation.

METHODS AND RESULTS

We included 18 patients who underwent primary PCI successfully, culprit left anterior descending artery and final TIMI 3 flow. We selected patients with one of the following inclusion criteria: 1) No complete ST resolution or 2) Coronary blood flow patterns by doppler-flow wire (systolic flow reversal, diastolic deceleration time < 600 ms or coronary flow velocity reserve –CFVR- <2 with hyperaemic microvascular resistence –HMR- ³1,9 mmHg/cm/s). We prolonged anticoagulation for 48 hours and compared them with a control group with stantard treatment at discharge and at 6 mounths.

Results: 6 patients (30%) had no MVO patterns by doppler-flow wire and 6 patients was included with no ST resolution. 7 cases received extended anticoagulation (group A) and 5 received standard treatment (group B). No differences were observed in mean age (57,7±10,7 group A and 64±15, p=0,189), sex (71,42% male group A and100% group B, p=0,19) or cardiovascular factors. Thrombus extractor was used in 3 patients, all of them in group A. Predilatation was performed in 1 patient in group A and 3 patients in group B. Mean diameter and length stent were similar in both groups. No signifficant difference was observed in mean Creatinine protein kinase (2719±1650 U/L in group A and 18,46±1160 U/L in group B, p=0,269) and high-sensibility troponin (6283±3166 ng/ml and 5310±3489 group B, p=0,235). 5 patients were treated with ticagrelor in grupo A and 3 in group B. All the patients who underwent doppler-flow wire had FFR ³0,80 and had high microvascular resistence (Hyperaemic Microvascular Resistence -HMR > 1,8 mmHg/cm/second in 6 patients, 4 of them > 3,2, mean HMR 2,85±0,54 in group A and 3,2±1,6 in group B, p=0,292). 4 Cases had sistolic flow reversal and diastolic deceleration time < 600 ms was observed in 7 cases. 3 patients improved left ventricular ejection fraction at 6 mounths in group A and 1 in group B but all the patients in group B normalized the HMR values in the follow-up.

CONCLUSIONS

In this pilot study, the extended anticoagulation in patients with apparently restored epicardial flow but MVO didn´t provide significant benefits but was shown safe with no complications.Larger studies would be necessary to confirm these results.

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Prognostic value of atypical chest pain in non-diabetic patients with AMI

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

AIMS

Patients with atypical chest pain can be easily misdiagnosed and undertreated even in non-diabetic patients. Therefore, we assessed the prognostic value of atypical chest pain in non-diabetic acute myocardial infarction (AMI) patients.

METHODS AND RESULTS

Total 8,324 subjects with AMI were analyzed from KAMIR-NIH registry between Nov. 2011 and Nov. 2015. Patients with diabetes mellitus, missing values for door-to-balloon time and missing values for TIMI flow were excluded. Chronic kidney disease (CKD) was defined as eGFR<60 ml/min/1.73m^2. This research was supported by a fund(2013-E63005-02) by Research of Korea Centers for Disease Control and Prevention. Mean age was 62.8±13.0 years and male was 6463 (77.6%). Atypical chest pain group was older and had more history of hypertension, chronic kidney disease, dyslipidemia, heart failure, cerebral ischemia, cerebral hemorrhage and less current smoking. The incidence of non-ST segment elevation myocardial infarction (NSTEMI) and lower systolic blood pressure (SBP), higher Killip classification, and lower left ventricular ejection (LVEF), multivessel disease, left anterior descending territory, pre-TIMI flow 0 or 1 and post-TIMI flow 0 or 1 were significantly higher in atypical chest pain group. In multivariate logistic regression analysis for in-hospital death, atypical chest pain (odd ratio [OR] 2.148 ; 95% confidence interval [CI] 1.479-3.121 ; p<0.001) was an independent predictor as well as age, CKD, history of cerebral ischemia, SBP, Killip≥2, LVEF and post-TIMI flow 0 or 1.

CONCLUSIONS

In this registry, patients with atypical chest pain in non-diabetic AMI had higher proportion of classical cardiovascular risk factors than patients with typical chest pain. Moreover, atypical chest pain itself was a significant prognostic factor for predicting in-hospital death in multivariate logistic regression analysis.

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The effect of QTU prolongation on hyperemic-iFR value

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

It is unknown whether QTU interval prolongation affects iFR measurement enough. We investigated the relationship between QTU interval and iFR value at hyperemia.

METHODS AND RESULTS

Fourty-one consecutive patients, age 70±10 years, with intermediate stenosis in Left anterior descending artery at coronary angiography were enrolled in this study. Physiological assessment was performed in each patient using intravenous adenosine triphosphate (ATP) and intracoronary papaverine. The FFR and hyperemic-iFR value were measured continuously using iFR scout without changing the wire position. The study subjects were divided into tertile ranges according to QTUc ATP / papaverine ratio during maximum hyperemia. (T1: 0.67-0.85, T2: 0.88-0.98, T3: 0.99-1.13)

There is no significant difference between the FFR value of ATP and papaverine in the 3 groups. However, the difference of the hyperemic-iFR value between ATP and papaverive has a significant difference in the 3 groups (T1; 0.46±0.06, T2; -0.01±0.03, T3; -0.03±0.05, anova P<0.001). Furthermore, hyperemic-iFR value significantly decreased with stimuli that reveald longer QTUc in T1 and T3, respectively.(T1; ATP 0.74±0.15, papaverine 0.69±0.17, P<0.001, T2; ATP 0.71±0.10, papaverine 0.72±0.11, P=0.320, T3; ATP 0.74±0.13, papaverine 0.77±0.13, P<0.001)

CONCLUSIONS

The FFR value of ATP and papaverine were equivalent regardless of QT interval prolongation. However, prolongation of the QTUc was associated with the decrease of the hyperemic-iFR value. The resistance might not decrease adequately by the presence of the T-U wave during wave free period and would lead to the decrease of the hyperemic-iFR value.

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Impact of the balloon inflation time and pattern on the coronary stent expansion

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

AIMS

To assess stent expansion defined as IVUS and OCT-derived in-stent lumen diameter and cross-section area (CSA) by using different balloon inflation times and pressures to commercially available coronary stents of different manufacturers.

METHODS AND RESULTS

Ten pairs of different stents (drug-eluting and bare-metal) were used. Every stent mounted on the dedicated balloon was deployed in contrast medium without any phantom tube to avoid any influence of external forces. Each pair of same stents was subsequently deployed under nominal pressure. First paired stent was expanded to 5, 10, 20, 30 seconds of total time. After 30 seconds of total deployment time stents were left for 15 minutes. Then the second paired stent was partially placed in the first stent to create double and single layer of stent struts and then expanded directly for 30 seconds. Finally, balloon positioned in the second paired stent (at overlapping and single segment) was inflated at rated burst pressure for 30 seconds. After each given time-point, in-stent lumen image acquisitions by OCT and IVUS were performed in 3 different points- distal, proximal and central and then averaged. For the second paired stent measurements were done at the overlapping segment and at non-overlapping segment. Due to different dimensions of the used stents measured diameters and CSA were calculated as percentages of the nominal values. Validation of OCT and IVUS measurements was performed using phantom metallic tube with defined inner diameter. Both in-stent diameters and CSA of the paired stents deployed under nominal pressures measured by OCT at all sequential time-points were significantly smaller compared to given chart's values. Significant increase of in-stent diameter and CSA was observed across step-by-step deployment pattern, regardless of the imaging technique. In-stent lumen measurements after 30 seconds of deployment time were significantly larger, when sequential deployment pattern was applied (CSA_{IVUS}=102%, CSA_{OCT}=88%) compared to direct deployment (CSA_{IVUS}=95%, CSA_{OCT}=81%, p_{IVUS}<0.05, p_{OCT}<0.05). In-stent lumen measurements were also larger when comparing expanded directly for 30 secondstime in the single-layer segment with the overlapping segments in the nominal pressure (CSA_{IVUS}=95%, CSA_{OCT}=81% vs. CSA_{IVUS}=86%, CSA_{OCT}=74%, p_{IVUS}<0.05, p_{OCT}<0.05) and the rated burst pressure (CSA_{IVUS}=100%, CSA_{OCT}=85% vs. CSA_{IVUS}=94%, CSA_{OCT}=80%, p_{IVUS}<0.05, p_{OCT}<0.05). When comparing in-stent lumen measurements directly after 30 seconds total deployment time (CSA_{IVUS}=102%, CSA_{OCT}=88%) and after 15 minutes rest(CSA_{IVUS}=101%, CSA_{OCT}=86%), no significant differences were found. Validation of the imaging methods using calibrated 2.51mm metallic tube (CSA 4.95 mm^2) revealed perfect reproducibility with OCT (4.93mm^2) and overestimation with IVUS (5.37mm^2). This difference between both imaging methods was consistent across all study measurements.

CONCLUSIONS

Stent diameter after deployment is time-dependent and not only pressure-dependent, supplementing stent specifications with information on time-dependent deployment diameter should be considered. Different stent expansion behavior, depending on the applied deployment pattern (sequential and non-sequential) or environment (single-layer and double-layer) regardless of the stent type was observed. Additionally, our study confirms previous observations, that IVUS-derived in-stent dimensions are overestimated.

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Impact of CTO in a non-infarct-related coronary artery on myocardial injury assessed by cardiac MRI in patients with STEMI

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

AIMS

Aim of this study was to investigate the association of a CTO in a non-infarct-related artery (non-IRA) with myocardial damage assessed by Cardiac magnetic resonance (CMR) in patients with STEMI treated by primary PCI

METHODS AND RESULTS

Methods: The AIDA-STEMI (*Abciximab Intracoronary versus intravenously Drug Application in STEMI*) trial randomized 2,065 patients to intracoronary or intravenous abciximab. Of these 795 patients were enrolled in the predefined AIDA-STEMI CMR substudy. CMR was completed within 1 week after ST-segment elevation myocardial infarction using a standard infarction protocol for assessment of infarct size, myocardial salvage and microvascular obstruction. Patients in the AIDA-STEMI CMR substudy were divided according to presence or absence of a CTO in a non-IRA into 2 groups. The primary clinical endpoint of the study was the occurrence of major adverse cardiac events (MACE: death, re-infarction, re-admission for heart failure) within 12 months after the index event.

Results: A CTO in a non-IRA was present in 74 (9%) patients. Patients with non-IRA CTO had a higher incidence of 3-vessel coronary disease otherwise there was no significant difference in patient characteristics between the 2 groups. Patients with a CTO in a non-IRA had larger infarcts (21 %LV vs 16 %LV, p=0.007), lower myocardial salvage index (42 vs 52, p=0.02), and lower LV- ejection fraction (44% vs 51%, p<0.001). MO was numerically larger in the CTO non-IRA group without reaching statistical significance. In Cox regression analysis, a coronary stenosis >75% in the non-IRA was an independent predictor of MACE [hazard ratio 2.10, confidence interval CI 1.22-3.62, p=0.007].

CONCLUSIONS

In patients with acute reperfused STEMI, the presence of CTO in a non–IRA was associated with larger infarct size, lower myocardial salvage index and lower ejection fraction. The relationship of CTO in a non-IRA with prognostic CMR markers of myocardial damage may explain the strong association with clinical outcome.

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Complex coronary CTO - Bilateral radial access does not affect success rates, procedure time or contrast use

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

The aim of this study was to investigate whether using bilateral radial access as opposed to standard femoral access resulted in a difference in success rates of complex CTO recanalization along with measures of procedure time and contrast use.

METHODS AND RESULTS

International registry data of chronic total occlusion (CTO) percutaneous coronary intervention (PCI) consistently report a success rate of approximately 50-75%, with the majority of hospitals using bilateral femoral access. While transradial PCI has been shown to reduce complication rates compared to femoral in everyday PCI, there has been a very paltry application of bilateral radial access for complex CTO PCI, likely due to possible compromise of catheter support and certain device utilization as well as radiation exposure.We performed a retrospective analysis of all CTO procedures from January 2014 to December 2015 in two centres to investigate the difference in success rates and resource use between the two strategies. We included all CTOs performed by one lead operator in the 2 centres; a large public teaching hospital and a private hospital. For the purposes of this study we only included those occlusive lesions which were present for more than 1 year, longer than 20mm and required bilateral access and hybrid techniques. A successful procedure is defined as recanalisation of the target artery to <50% stenosis with successful stenting.During the two year period we identified 104 cases of complex PCI CTO involving 92 patients. There were 12 patients who had a procedure failure with a reattempt at a later date. The average age was 69 years, 91 (88%) were men, 40 (38%) had a previous myocardial infarction, 25 (24%) had diabetes mellitus, 62 (60%) had hypertension/dyslipidaemia. The target artery was the right coronary artery in 79 cases (76%), the left anterior descending in 14 cases (13%) and the circumflex in 11 cases (10%).The number of successful cases over the two years was 88 (84%). The 16 procedure failures involved 15 patients, with 10 patients having a successful reattempt at a later date, 1 patient had two failed attempts and 4 patients who were awaiting re-attempt by December 2015. Thus the overall success rate per patient after reattempt is 96%. Bilateral radial access (mostly 6F but some 8F also) was used in 61 (59%) of the 104 attempted, with a success rate of 87%, in a mean duration of 139 minutes and a mean contrast dose of 355ml.Combined femoral/radial or femoral/femoral was used in 43 cases, with a success rate of 81%, in a mean duration of 161 minutes and a mean contrast dose of 390ml. Anterograde wire escalation, including knuckle wiring, was the successful technique in 40 (45%) of the procedures. Combined anterograde / retrograde techniques, including anterograde dissection re-entry (ADR), was the successful technique in 48 (55%). The average stent length was 83mm confirming the complexity of these cases.

CONCLUSIONS

Bilateral radial access did not compromise success rates, duration or contrast use during complex CTO. Accordingly bilateral radial access is now our default initial strategy for all CTO. Larger studies would be valuable in establishing the global efficacy and possible reduction in complications of bilateral radial access for complex CTO procedures.

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Impact of dyslipidemia on five-year clinical outcomes in patients with significant coronary artery spasm

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

AIMS

Dyslipidemia is a risk factor of coronary artery disease (CAD). Coronary artery spasm (CAS) is known to be a cause of myocardial ischemia. However, whether dyslipidemia adds any long-term clinical risk in CAS patients (pts) is largely unknown.

METHODS AND RESULTS

A total of 2,797 consecutive pts without significant CAD who underwent acetylcholine (Ach) provocation test between Nov 2004 and Oct 2010 were enrolled. Pts were divided into two groups according to the existence of dyslipidemia (Dyslipidemia group: n=241, Normal group: n=1368). Major clinical outcomes were compared between the two groups up to 5 years.
At baseline, pts with dyslipidemia had a higher incidence of elderly, hypertension, diabetes and fixed coronary lesion than pts without dyslipidemia. During Ach provocation test, there was no difference in angiographic and clinical parameters between the two groups. At 5 years, the dyslipidemia group had higher incidence of recurrent chest pain (9.9% vs. 5.7%, p=0.012) and major adverse cardiac & cerebrovascular events (MACCE) including all-cause mortality, myocardial infarction, coronary revascularization and cerebrovascular accidents (2.0% vs. 0.5%, p=0.023). However, the only remaining difference was shown in the incidence of recurrent chest pain which was higher in the dyslipidemia group before (HR; 1.82, 95%C.I; 1.11-2.98, p=0.016) and after propensity score matching analysis (HR; 2.86, 95%C.I; 1.29-6.30, p=0.009).

CONCLUSIONS

In this study, pts with dyslipidemia showed significant association with higher incidence of recurrent chest pain up to 5 years clinical follow up, suggesting higher chance of profound endothelial dysfunction requiring intensive anti-anginal management and close clinical follow up.

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Difference in non-uniform strut distribution among DES evaluated by optical frequency domain imaging

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

AIMS

The aim of our study was to compare the longitudinal nonuniform strut distribution (NSD) among different drug-eluting stents (DES) using reconstructed carpet image obtained by optical frequency domain imaging.

METHODS AND RESULTS

A total of 32 DES including Xience Xpedition (n=8), Promus Premiere (n=7), Resolute Integrity (n=7), and Nobori (n=10) were analyzed. Reconstructed carpet images were divided into subsegments by 2.0 mm width, and strut area was measured in each subsegment. Longitudinal NSD was defined as the coefficient of variation (CV) of strut area among all subsegments. There was no significant difference in the baseline lesion characteristics and stent profile among the groups. The mean value of CV was significantly lower in Resolute Integrity group (0.061 ± 0.037) and Promus Premiere group (0.069 ± 0.022) than Nobori group (0.101 ± 0.024, $p<0.01$ vs Resolute Integrity group, $p=0.021$ vs Promus Premiere group). There was no significant difference in CV value between Xience Xpedition group (0.084 ± 0.024) and other groups.

CONCLUSIONS

There were difference in longitudinal NSD among several types of DES. Resolute Integrity and Promus Premiere showed less longitudinal NSD as compared with Nobori, possibly having an impact on drug delivery efficacy.

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Impact of ultralong (44mm/48mm) biodegradable polymer-coated sirolimus-eluting stents in patients with complex, long coronary artery lesions: one-year results from the real-world FLEX-LONG study

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

AIMS

We aimed to assess the safety and procedural outcomes of ultra-long (44mm/48mm) biodegradable polymer coated Supraflex sirolimus-eluting stents (SES) in real-world patients with complex, long coronary artery lesions.

METHODS AND RESULTS

This was a single-centre, observational study which assessed one-year results of 141 patients who had undergone stenting using single ultra-long (44mm/48mm) Supraflex SES (Sahajanand Medical Technologies Pvt. Ltd., Surat, India) per lesion, between August-2014 and June-2015 in India. Baseline clinical data with procedural outcomes were obtained by case-note review and follow-up data were recorded prospectively. The incidence of major adverse cardiac events (MACE), a composite of cardiac death, myocardial infarction (MI), target lesion revascularization (TLR) or target vessel revascularization (TVR), at one-year follow-up was the primary outcome of this study. Stent thrombosis according to Academic Resource Consortium was also analyzed as a safety endpoint. All patients were prescribed one-year dual antiplatelet therapy. The mean age of the study population was 56.2±9.6 years and 78.0% (110/141) were male. The study analyzed high risk patients, including 44.0% (62/141) hypertensive patients and 42.6% (60/141) diabetic patients. The indication for the procedure was stable angina in 23 (16.3%), unstable angina in 31 (22.0%), ST-elevation MI in 20 (14.2%) and non-ST-elevation MI in 67 (47.5%) patients. A total of 147 target lesions were treated, including 25 (17.0%) total occlusions. An entire of 51 (34.7%) and 96 (65.3%) 44mm and 48mm Supraflex SES were implanted, respectively. The average stent length and diameter were 46.6±1.9 mm and 3.4±0.2 mm, respectively. Device success was achieved in 99.3% of patients and there were no procedural complications during implantation. The one-year clinical follow-up data were obtained in 100% of patients and there was one probable stent thrombosis resulting in 0.7% cardiac death at week three. At one-year follow-up, 99.3% of patients remained event-free with no TLR.

CONCLUSIONS

The results of the FLEX-LONG study support the use of ultra-long (44mm/48mm) Supraflex SES, in the treatment of long coronary artery lesions. The stent appeared to be safe and effective at one-year with low clinical events in high risk real-world patients.

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PCI of diabetics patients: an analysis of 6,630 cases

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

AIMS

Despite the advances in revascularization techniques and adjunct antithrombotic therapies, patients with diabetes show more unfavorable clinical outcomes. The aim of this study was to evaluate the long-term outcome after PCI in diabetic patients.

METHODS AND RESULTS

All diabetic patients (18576) who underwent PCI in our hospital from January 2008 to December 2015 were included in this study. Follow-up was done by a telephone interview. Clinical information was collected from patients by a telephone interview. Information on mortality was obtained from phone contact with relatives of the patient.During this period18576 patents underwent PCI in our hospital. Of them 6630 (35.7%) patients were diabetic. Mean age of the patients was 55.2±9.6 years. Most patients were male (81% vs 19%). Most common clinical manifestation was stable angina. Most patients (62.2%) were with good left ventricular systolic function. Most patients had multi-vessel disease (68%), followed by single vessel disease (32%). In almost all cases drug-eluting stents (DES) were used (94.92 % vs 5.08%). 2.5 mm stent was used in 23% cases. More than 20 mm stent was used in 70% patients. Mean duration of follow-up was 36.4 months. Lost of follow-up was 19.6%. Mortality rate was 2.25%. Mortality due to cardiac cause is 65%. Lowest mortality rate was in patients with everolimus-eluting stent(1.5%). followed by zotarolimus –eluting stent (1.9%).

CONCLUSIONS

PCI in diabetic patients with DES is feasible with good long-term result.

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GABI-R Russia: six-month clinical outcomes in patients with ABSORB implantation

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

AIMS

This study aimed to investigate the clinical efficacy and safety of Absorb bioresorbable vascular scaffold implantation under real-world conditions in an all-comers population of patients in Russia.

METHODS AND RESULTS

Methods

A cohort of 500 consecutive patients who underwent PCI for stable chest pain or acute coronary syndromes, with implantation of at least one BRS(Absorb) and who were followed up by telephone interview and review of medical charts, were included in a single-center, prospective, all-comers, First-in-Russia registry. The mean age was 61.26 ± 8.57 years, male - 78%, current or ex-smoker - 25.2%. Comorbidities were presented as arterial hypertension in 90.6%, Atrial fibrillation – 12%, Diabetes - 22%, history of MI – 47%. 45.4% had prior coronary revascularization, 6% had chronic renal failure. The primary outcomes were Target Lesion Failure (TLF), defined as the combination of cardiac death, target vessel myocardial infarction (TVMI), or clinically driven target lesion revascularization (CD-TLR) and individual endpoints of MACE such as cardiovascular death, MI, CD-TLR and scaffold thrombosis. Secondary outcomes were Procedure success defined as the achievement of residual is less than 30% in the ABSORB covered lesion segment at the end of the procedure and Clinical success defined as the absence of in-hospital complications.Results

A total of 500 patients with coronary artery disease (Stable Angina pectoris - 47%, ACS - 45.6%, 7.4 - other) presenting with 1-vessel CAD in 40.8%, 2-vessel CAD in 32.8% and 3-vessel CAD in 26.4%, received 664 scaffolds and 55 metallic stents in 603 stenoses (mean length 23.33 ± 9.85 mm, mean % of diameter stenosis - 85.17 ± 11.68%) 99.8% of lesions were pre-dilated, 94.4% underwent post-dilatation. Stenosis morphology was type A - 6.8%, B1 - 38.6%, B2 - 10.0%, C1 - 35.5%, C2 - 9.1%. 8% of lesions were bifurcational, 13.7% were CTOs, 7.1% were calcified and 4.1% presented as in-stent restenosis. Procedure success, was in 98.5% of cases. Clinical success was achieved in 99.4% of patients: 1 peri-procedural coronary artery perforation (0.2%) 1 stroke (0.2%) and 1 non-TLF requiring PCI (0.2%) were observed during hospitalization . All patients were alive at discharge.

At 6-month follow-up 95.2% (476) of patients were included. The 6-month cumulative rate of TLF was 4% (20 cases). Rates of cardiac death, MI, and ID-TLR were 1% (5), 2.2% (11) and 2.4% (12) respectively. The cumulative 6-month rate of definite/probable scaffold thrombosis was 2.41% (12).

CONCLUSIONS

In an all-comers population of patients in Russia, treatment with a bioresorbable vascular scaffold is feasible and safe in the short term. Longer term follow up is required to confirm this.

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Real-world performance of the iFR for guiding coronary revascularisation

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

AIMS

iFR is a new physiological index that is calculated without vasodilator stimuli. The aim of this study is to assess the performance of iFR in a consecutive series of patients with intermediate coronary stenoses.

METHODS AND RESULTS

we conducted a registry of 152 consecutive patients (mean age 67,8±13,2, 79,6%) from October 2013 to April 2015. Two hundred and twelve intermediate coronary stenoses were assessed by iFR and FFR (both measures perfomed in 113 lesions). An iFR ≤0,90 and a FFR ≤0,80was considered significant. In the case of the value of the obtained iFR was between 0.90 and 0.93, FFR was used to guide the decision. Those patients where iFR (or the hybrid strategy) dictated conservative management were clinically followed to evaluate the presence of death, myocardial infarction and target lesion revascularization.

The most frequent indication for physiological assessment was the evaluation of patients with unstable angina and intermediate coronary stenoses (15.9%). Forty-eight percent of patients had multivessel disease. Mean quantitative coronary analysis (QCA), FFR and iFR of lesions assessed were 45.5±9.5%, 0.86±0.1 and 0.92±0.1, respectively. iFR and FFR showed a significant positive correlation (r=0,66, p<0,001). Discordance between iFR and FFR was observed only in 18 stenoses (8.4%). The value of iFR to predict a FFR <0.8 was assessed by means of ROC curves. AUC was 0.88 (CI95% 0.72-0.98; p=0.004). Based on iFR/FFR 55 lesions were stented (26.3%). After a median of 9.0 month (IQR 3.6-13.2)of follow-up none of the patients with iFR >0.90 experienced any of the clinical end-points analyzed.

CONCLUSIONS

iFR and FFR indexes showed a good correlation and defer coronary revascularization based on iFR measurement has proved to be a safe and effective strategy in our cohort.

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Left main optimising outcomes in 2016 and our experience

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

AIMS

Patients with stenosis of the left main coronary artery present difficult challenges. Here we describe our experience regarding PCI in left main disease.

METHODS AND RESULTS

This prospective observational study was done fromJanuary 2015 to October-2016 in our hospital. Total 448 patients of both sex who underwent left main PCI during this period were included in the study. They were studied for clinical characteristics and angiographic profile and management strategy.Most patients were male (85%), female were 15%. Mean age of the patients was 55.07±11.3 years. Smoking was the most common risk factor in male and DM in female. Stable anginawas most common clinical manifestation (56%). Majority of the patients (57.1%) had good left ventricular systolic function.Isolated left main disease was in 17.2%. Right dominant circulation was 78.8% and left dominant circulation was 21.2%. Most patients had unprotected left main disease (87.9%). Distal left main disease was in 81% patients. Most patients had Medina 1.1.1. lesion (55%).Single stent technique was done in most cases (84.2%) for distal left main disease. IVUS was done in 16% patients, FFR in 0.9% and rotablation in 4% patients. Mean follow-up period was 11.5±6.83 months. Overall MACE was 3.12%.

CONCLUSIONS

In patients with LM CAD, have allowed PCI to become a viable and safe alternative to CABG in appropriately selected patients with favorable anatomy and/or high surgical risk.

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Mechanical and pharmacological revascularisation strategies for prevention of microvascular dysfunction in STEMI: analysis from index of microcirculatory resistance registry data

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Microvascular dysfunction (MVD) after STEMI is correlated with infarct size and long-term prognosis. We aimed to identify mechanical and pharmacological revascularization strategies correlated with index of microcirculatory resistance (IMR) in STEMI

METHODS AND RESULTS

STEMI patients who underwent primary PCI were enrolled. Baseline characteristics including clinical and angiographic characteristic were investigated. The IMR was measured with a pressure sensor/thermistor-tipped guidewire immediately after primary PCI. The patientwith MVD was defined as values of ≥ 66^{th} percentile of IMR in enrolled patients. A total of 160 STEMI patients were analysed (MVD in 52 patients). The IMR value was 47 ± 19 in MVD (+) group and 18 ±7 in MVD (-) group. The MVD (+) group was older (60 ± 11 vs. 54 ± 11, p<0.001) and high incidence of multi-vessel disease (51 vs. 26%, p=0.07), Killip Class II~IV (23 vs. 18%, p=0.10) and initial TIMI flow grade 0~1 (75 vs. 58%, p=0.04). In logistic regression analysis adjusted by confounding factors (age, multi-vessel disease, Killip Class, initial TIMI flow), pre loading of ticagrelor (adjusted odds ratio = 0.43, CI 0.19 ~ 1.00, p=0.05) and use of morphine (adjusted odds ratio = 0.68, CI 0.33 ~ 1.42, p=0.31) were associated with lower incidence of MVD. However aspiration thrombectomy (adjusted odds ratio = 1.02, CI 0.48 ~ 2.13, p=0.95) and use of glycoprotein IIbIIIa inhibitor (adjusted odds ratio = 1.19, CI 0.49 ~ 2.87, p=0.69) was not correlated with prevention of MVD

CONCLUSIONS

In term of mechanical and pharmacological revascularization strategies, pre loading of ticagrelor and use of morphine revealed a trend of MVD prevention, whereas aspiration thrombectomy and glycoprotein IIbIIIa inhibitor was not correlated with MVD prevention estimated by IMR

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Low-concentration sodium bicarbonate vs. saline for the prevention of contrast-induced nephropathy: a retrospective propensity-matched analysis

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

We aimed to compare low-concentration sodium bicarbonate infusion with saline infusion for preventing contrast-induced nephropathy.

METHODS AND RESULTS

In total, 1514 consecutive patients undergoing elective PCI at our hospital from November 2013 to May 2016 were screened. Exclusion criteria were pre-existing dialysis and acute coronary syndrome. We used BICANATE (Otsuka Pharmaceutical Factory, Inc., Tokushima, Japan), which includes sodium bicarbonate 28 mEq/L in one infusion bag, or saline. The choice of BICANATE or saline was at the discretion of the PCI operators. In the sodium bicarbonate group, a continuous 12-h infusion was given at a rate of 40 mL/h before PCI, followed by an infusion of 40 mL/h for 24 h after PCI, whereas in the saline group, a continuous 24-h infusion was given at a rate of 40 mL/h only after PCI. The patients were matched using a propensity score based on age, sex, baseline serum creatinine levels and amount of contrast used. The primary endpoint was the incidence of contrast-induced nephropathy, which was defined as an increase in serum creatinine levels ≥ 0.5 mg/dL or ≥25% above baseline within 72 h of administration of contrast.The secondary endpoint was defined as a ≥25% increase in serum creatinine levels above baseline at 180 to 540 days after administration of contrast (mid-term follow-up). We compared the incidence of contrast-induced nephropathy and a ≥25% increase in serum creatinine levels above baseline during the mid-term follow-up between the two treatment groups before and after propensity score matching. Of the 1514 patients screened for the study, 234 were excluded. Of the remaining 1280 patients, 205 patients (16%) received sodium bicarbonate and 1075 (84%) received saline. Patients receiving sodium bicarbonate were significantly older (73.4 ± 9.2 vs 69.6 ± 10.2 years, $P < 0.001$), had significantly higher serum creatinine levels (1.25 ± 0.36 vs 0.83 ± 0.22 mg/dL, $P < 0.001$) and received significantly less contrast volume (110.9 ± 78.0 vs 130.9 ± 64.4 mL, $P < 0.001$). The percentage of female patients was not significantly different between the two groups (18.0% for sodium bicarbonate vs 23.9% for saline, $P = 0.082$). In an unmatched comparison, there was no significant difference in the incidence of contrast-induced nephropathy between the two groups (4.9% for sodium bicarbonate vs 2.5% for saline, $P = 0.10$); 106 patients who received sodium bicarbonate and 106 who received saline were matched to their outcomes (1:1 ratio; caliper distance = 0.05). In this matched comparison, no significant difference was found in the incidence of contrast-induced nephropathy (5.7% for sodium bicarbonate vs 1.9% for saline, $P = 0.28$). Of the 859 patients receiving mid-term follow-up, 67 who received sodium bicarbonate and 68 who received saline were matched to their outcomes. In this matched comparison, no significant difference was found in the incidence of a ≥25% increase in serum creatinine levels above baseline during the mid-term follow-up (10.4% for sodium bicarbonate vs 4.4% for saline, $P = 0.21$).

CONCLUSIONS

This retrospective analysis found no significant difference in the incidence of contrast-induced nephropathy between the use of low-concentration sodium bicarbonate and saline.

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PCI vs. CABG for left main coronary artery disease: a systematic review and meta-analysis

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

AIMS

To investigate safety and efficacy of percutaneous coronary intervention (PCI) compared to coronary artery bypass grafting (CABG) for the treatment of unprotected left main stem coronary artery disease (LMS-CAD).

METHODS AND RESULTS

A search of PubMed, Google Scholar, Science Direct, Web of Science, MEDLINE and EMBASE was conducted to identify trials in patients with significant LMS-CAD randomized to revascularization by PCI or CABG to evaluate mortality or major adverse cardiovascular events (MACE), myocardial infarction (MI), stroke, repeat revascularization, stent thrombosis or graft occlusion or major bleeding. Random effects meta-analysis was used to estimate the risk of adverse outcomes. Six trials including 4700 participants were identified. There were no significant differences in mortality (OR: 0.99, 95%CI: 0.76-1.29; 6 studies) but significantly greater overall MACE (OR: 1.25 95%CI: 1.02-1.54) and repeat revascularization (OR: 1.77, 95%CI: 1.46-2.14; 6 studies) in PCI compared to CABG. Sensitivity analysis was performed considering diabetes, bifurcation involvement, SYNTAX score and follow up duration. There was no significant difference for MACE for diabetic patients (OR: 1.23, 95%CI: 0.89-1.71) and patients with bifurcation involvement (OR: 1.07, 95%CI: 0.83-1.38). There was only significantly increased risk of adverse outcomes in the PCI group for SYNTAX score ≥33 (OR: 1.58, 95%CI: 1.16-2.16). In terms of follow up time, there was a significantly lower mortality with PCI at 1 year (P=0.03), but this was not significant at 2-3 years (P=0.74) and >5 years (P=0.41). By contrast, there was initial decreased odds of MACE in the PCI group at 30 days (OR: 0.54, 95%CI: 0.35-0.83; P=0.005), but at >5 years follow up, the PCI group had significantly more events than the CABG group (OR: 1.34 95 CI: 1.04-1.72; P=0.03). No significant difference in rates of stroke, stent thrombosis or graft occlusion and major bleeding for PCI compared to CABG group were observed over different time points, but there was significantly higher repeat revascularization and MI in the PCI group with longer-term follow up.

CONCLUSIONS

Our analysis suggests that patients with significant LMS-CAD with low and intermediate anatomical complexity (SYNTAX score 0-32) can be safely treated with PCI and achieve similar outcomes as compared with CABG in the short and medium term. These results may help determine whether an update of the current international guidelines for optimal LMS-CAD revascularization strategy should be revisited. Individualized patient treatment should be based on a multidisciplinary evaluation around comorbidity burden, procedural risks and patient's preference, as well as the expertise contained within an individual centre, and PCI should only be undertaken when complete revascularization can be offered.

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Coronary sinus reducer for the treatment of refractory angina - A single-centre experience

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

AIMS

The coronary sinus Reducer is a novel hourglass-shaped stent used for the treatment of refractory angina. Implantation has been shown to improve Canadian Cardiovascular Society (CCS) class however little is reported on psychosocial outcomes.

METHODS AND RESULTS

Out of 31 patients reviewed in our service for Reducer implantation, 13 were considered suitable on the basis of continuing angina despite optimised medical therapy, no option for conventional revascularisation and demonstrable left coronary territory ischaemia. Currently, 6 patients had complete data at 6-month follow-up and are presented here. Data collected included patient demographics, previous coronary intervention and pre- and post-Reducer psychological and quality of life scores, functional testing and number of anti-anginal medications.All six patients were male and all had previous revascularisation by either PCI (n=4), CABG (n=6) or both (n=4). Reduction in CCS class was observed in 66.7% of patients (n=4), two of whom improved by two of more classes. Improvements were also observed in psychological outcomes. For both anxiety and depression, 2 out of the 3 patients with borderline/affected scores improved to sub-threshold scores after Reducer implantation. Encouragingly, the majority of cases demonstrated a reduction in reversible ischaemia after device implantation (66.7%; n=4). Furthermore, 50% of patients (n=3) had a reduction in the number of anti-anginal medications with the other half having no change (n=2) or an increase in number (n=1).

CONCLUSIONS

This small case series suggests that Reducer implantation can achieve improvements in symptomatology and psychological outcome for appropriately selected patients with refractory angina, a challenging patient cohort for whom innovative treatments are needed. By narrowing the coronary sinus and increasing venous pressure, perfusion is thought to be diverted to ischaemic myocardium. This mechanism is further supported by improvements in ischaemic burden on functional testing and a reduction in the number of anti-anginal medications required by patients. Further studies are required however to confirm the benefit of the coronary sinus Reducer. These should include not only measures of quality of life but also psychosocial outcomes, which are a major source of morbidity and an important focus of management in refractory angina.

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Chronic mechanical performance of a novel polymer-free drug-filled coronary stent: comparison with current generation DES

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

AIMS

The objective of the current study was to investigate the fatigue resistance of the drug-filled stent (DFS, Medtronic, Santa Rosa, CA) compared with current generation drug-eluting stents (DES) under conditions similar to those in vivo.

METHODS AND RESULTS

Background:

The DFS provides controlled drug elution from an internally-coated drug platform without using a polymeric matrix, thus avoiding inflammation and adverse vascular responses associated with polymers. The unique polymer-free DFS has an outer cobalt chromium layer, a middle tantalum layer, and an inner lumen coated with sirolimus. Small, laser-drilled holes on the abluminal stent surface control drug elution. Previous independent testing of DFS demonstrated radial strength comparable to the current generation Resolute Onyx DES.Methods & Results:

Accelerated cyclic bending fatigue testing was performed by an independent test facility (Medical Device Testing, Minnetonka, MN). The stent samples were deployed in a curved mock artery with a bending angle varying between 85 and 130 degrees. Three different stent designs were compared: DFS, Resolute Integrity DES, and Xience Pro DES. Routine inspections were conducted throughout 20 million bending cycles (corresponding to approximately 6 months in vivo).No fractures for DFS or Resolute Integrity were observed. However, fractures were detected in Xience Pro from 0.5 million through 20 million cycles on multiple tested samples (average 2.7 fractures per Xience Pro sample at 20 million bending cycles, $p<0.05$).

CONCLUSIONS

The chronic resistance to bending fatigue of the novel DFS is comparable to current-generation DES platforms.

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Land-mark analysis of clinical outcome following first-generation vs. newer-generation coronary DES implantation: a pooled analysis of SORT OUT III-VI studies

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

AIMS

We tested the hypothesis that newer-generation drug-eluting stents (DES) are superior to the first-generation Cypher sirolimus-eluting stent (C-SES) beyond 12-month follow-up.

METHODS AND RESULTS

We pooled individual data from the randomized clinical SORT OUT trials III-VI. These trials compared C-SES (n=3764 patients), Endeavor zotarolimus-eluting (E-ZES, n=1162), Resolute zotarolimus-eluting (R-ZES, n=1458), Xience V/Promus everolimus-eluting stents (EES, n=1376), and Nobori/Biomatrix biolimus-eluting (BES, n=2650) stents. Stent-related adverse outcome was defined as the composite of cardiac death, target lesion revascularization (TLR), or definite stent thrombosis. The analysis was divided into 0-12 months and >12-36 months. C-SES was the comparator stent. Relative risk (RR) and adjusted RR were calculated. At 12-month follow-up, C-SES was associated with fewer stent-related adverse outcomes than newer-generation stents (E-ZES: 2.08; 95% CI 1.55-2.79; R-ZES: 1.95, 95% CI 1.47-2.59; BES: 1.50, 95% CI 1.16-1.95; EES: 1.42, 95% CI 1.03-1.97). The landmark analysis (>12-month) showed that EES, but none of the other newer-generation DES were associated with significantly better late outcome (E-ZES: 0.86 [0.61-1.19], R-ZES: 1.09 [0.83-1.44], BES: 0.88 [0.69-1.12], EES: 0.70 [0.50-0.99]. Adjustment for baseline characteristics did not change the results.

CONCLUSIONS

The first-generation C-SES had fewer stent-related adverse outcomes than newer-generation DES at 12-month follow-up. Between 12-36 months, EES reduced stent-related adverse outcomes by 30%, while the other newer-generation DES failed to show superiority.

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Safety of uninterrupted oral anticoagulation in diagnostic transradial cardiac catheterisation of patients receiving novel direct oral anticoagulants

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

AIMS

There is still lack of evidence about the safety of performing cardiac catheterization without interruption of novel direct oral anticoagulants (NOA´s).

METHODS AND RESULTS

Prospective and longitudinal case-control study comparing 3 groups of consecutive patients undergoing transradial diagnostic catheterization: A: without interruption of NOA´s; B: Uninterrupted VKA; C: without oral anticoagulation. Unfractioned heparin (UFH) (50-70 UI/Kg) was used in all patients of group C and only in those with INR < 2 or those with last dose of NOA forgotten. Safety variables during and after the procedure were recorded. All patients were followed during 1 month.

Overall, 96 patients were included in the study (32 in each group). Patients in group A were more frequently male and older, without other differences for the rest of baseline characteristics. A hydrophilic 5 French sheath was used in all patients and for hemostasis after the procedure, compression with elastic bands during 2 hours. No catheter-related thrombosis, stroke, embolism nor major bleeding was recorded during the procedure. After removal of the bands, 4 radial occlusions were noted (4.16%), 2 in group B and 2 in group C, without hand ischemia. Only one patient (1.04%) needed for new compression due to bleeding after removal of the band (group B). In the follow-up, no patients developed hematoma >5 cm, fistula, pseudoaneurism and new occlusion. The four occlusions persisted.

CONCLUSIONS

Performing diagnostic transradial cardiac catheterizations without interruption of NOA´s is as safe as those performed without interruption of VKA or in patients without oral anticoagulation.

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Comparison of accuracy of iFR and FFR to non-invasive methods of myocardial ischaemia detection for assessment of intermediate coronary stenoses

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

The aim of our study was to compare the diagnostic value of iFR and FFR to traditional non-invasive methods used to detect myocardial ischemia in patients with intermediate coronary artery stenoses.

METHODS AND RESULTS

60 patients with stable coronary artery disease and intermediate coronary artery stenoses (50-69%) were included in study. In the first phase of study values of iFR and FFR were measured during coronary angiography. At the second stage of study stress echocardiography and single-photon emission computed tomography were performed in all patients. A non-invasive surrogate standard was used for verifying the myocardial ischemia. We considered the stenosis functionally significant if at least one of the noninvasive tests had a positive result, and non-significant if both noninvasive tests were negative.
87 borderline coronary stenosis were identified in selected group of patients. The average degree of coronary artery stenosis was 59.8±6.4%. The results of non-invasive surrogate standard were positive in 17 (28%) of patients and negative in 43 (72%). iFR showed excellent reproducibility (standard error <1.5%). According to the results iFR optimal cut-point was 0.92 (sensitivity 100%, specificity 85%). At the same time, FFR optimal cut-point was 0.81 (sensitivity 100%, specificity 73%). Comparison of iFR and FFR ROC-curves shown no significant difference (ROC AUC iFR 0.96 (95% CI: 0.89 to 0.99) vs. FFR 0.92 (95% CI: 0.83 to 0.97), p=0.25).

CONCLUSIONS

Diagnostic accuracy of iFR is not inferior to FFR in comparison with non-invasive tests commonly used to detect myocardial ischemia in patients with intermediate coronary artery stenoses.

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Shorter duration of balloon inflation time results in greater malapposition during PCI with DES in patients with stable coronary artery disease: a randomised control trial of the second STent OPtimisation using optical frequency domain imaging (OFDI) - STOP2 study

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

AIMS

Outcomes of PCI are poor in those with stent malapposition. It is unknown if prolonged duration of balloon inflation during PCI will result in better stent apposition and thereby reduce future adverse events.

METHODS AND RESULTS

We studied 40 patients with de-novo coronary lesions and stable angina pectoris in our randomised blinded controlled trial (STOP-2 study: Second STent Optimisation study) . Patients were randomised to short inflation group (5-15secs) and long inflation group (30-60secs). All stable patients with a native vessel lesion requiring single stent were included and those with longer lesions, left main stem or bifurcation lesions, and heavy calcification were excluded. After lesion preparation using standard protocol, vessel segment was analysed using Optical Frequency Domain Imaging (OFDI). Promus Premier drug eluting stent was deployed after randomisation. Operators were blinded to post stenting OFDI and further post dilatation OFDI was performed. Detailed blinded OFDI image analysis was done using validated software. All but one patient in the short group had OFDI images of excellent quality and were included for the final analysis.

Results:

Patients were divided into short inflation group (n=19) and long inflation group (n=20). Baseline characters were similar between both the groups. Both the groups were well matched in age {in years, median(IQR); 69(58-75) vs. 65(62-75), p=0.639}, gender (11 men in each group) and history of smoking (27.8% vs 28.6%, p=1.000). The lesion characteristics were similar between short and long groups {lesion length, mm, Median (IQR), [27(21.7-32.6)] vs [26.6(19.2-32.67)], p value =1.0; with no difference in vessel diameter. There were neither geometrical deformations nor any damage to stent struts with longer inflation. The eccentricity index was similar in both groups. Total malapposed area of the stents was higher in short inflation group {sq.mmX10^{-2}, median(IQR), 10.35(5.64-17.48) vs. 5.90(3.15-11.04), p=0.021) but improved after post dilatation {7.30(4.61-8.68) vs. 5.00(2.30-6.95), p=0.0740}. Maximum distance of malapposition was higher in short inflation group {microns, median(IQR), 469.9(311.2-583.3) vs 665.0(427.2-747.5), p=0.021} and has improved to similar levels as seen in the long inflation group after post dilatation {445.3(320.0-483.0) vs. 461.4(362.5-550.0), p=0.089}. Shorter inflation time had more malapposed struts {median(IQR), 89 (30-149) vs 39(25-80), p=0.071) and improved after post dilatation {median(IQR), 39(19-62) vs. 37(14-66), p=0.945}. Percentage of malapposed struts were higher in those who had short inflation time compared to long inflation time (median(IQR), 15.41%(12.03-20.55) vs 8.14%(3.26-12.98), p=0.0001}. This improved in both the groups and was similar after post dilatation {median(IQR) 8.22%(6.57-9.54) vs. 6.95%(2.65-12.01), p=0.558). There were no complications d and no major adverse events at 30 days after the procedure. All patients were alive at one year after the study.

CONCLUSIONS

Patients who had PCI with drug eluting stents with shorter balloon inflation times had significantly higher indices of malapposition compared to those who had longer inflation time and this was overcome by mandatory post dilatation. Clinical benefits of longer duration of balloon inflation strategy have to be proven in large scale studies.

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Is aspirine needed after TakoTsubo syndrome? A propensity score subanalysis of INTER-TAK registry

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

AIMS

The efficacy of after discharge treatment with aspirin for patients admitted Takotsubo Syndrome (TTS) remains to be defined.

METHODS AND RESULTS

Consecutive patients from the InterTak registry were included and divided according to use or not of aspirin at discharge. Analysis was performed before and after propensity score with matching. Recurrence of TTS at one year was the primary endpoint, while that at 30 days, 5 and 10 years were the secondary one, along with MACE (a composite mutual exclusively endpoint of death, myocardial infarction and stroke). Subgroup analysis was performed for patients with coronary artery disease (CAD) and diabetes mellitus (DM) and according to therapy at discharge.Out of 1533 patients included in the total cohort, nearly two-thirds (67%) were discharged on aspirin. TTS was typical for about 80% of the patients in both groups, with physical stress as trigger in one third of them. After propensity score, 293 patients were included in each group with similar baseline and risk profiles. At one year, recurrence of TTS did not differ among the two groups (0.7% vs 0.3%, p 1.000) as at 30 days (0% vs. 0.3%, p 1.000) and at 5 and 10 years (respectively 2.7% vs 2.4%, p 0.704 and 3.8% vs 2.4%, p 0.338). Similarly, MACE and its single components were not influenced by use of aspirin. In parallel, aspirin did not reduce the risk of TTS recurrence or MACE for patients with CAD, DM and discharged without betablockers and ACE-inhibitors.

CONCLUSIONS

Aspirin treatment at discharge does not reduce the risk of TTS recurrence or adverse events in patients admitted for TTS, independently from the presence of CAD, DM and other treatment at discharge.

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Bivalirudin vs. heparin in primary PCI: clinical outcomes and cost analysis

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

AIMS

Aims:We aimed to analyze the safety and cost-effectiveness following reintroduction of heparin instead of bivalirudin as the standard anticoagulation for primary PCI (PPCI) in a high volume center.

METHODS AND RESULTS

Methods:This analysis was an open-label, prospective registryincluding all patients admitted to our center for PPCI from May 2014 to May 2016.Two periods were defined; Cohort B encompassed all PPCI patients admitted from 1st May 2014 to 30st April 2015. During this period bivalirudin was used as the standard for anticoagulation in PPCI, unless contraindicated. Cohort H included patients treated by PPCI between 1st May 2015 & 30st April 2016 following an institutional protocol amendment resulting in the use of unfractionated heparin as the standard peri-procedural anticoagulant.Bivalirudin was started as soon as possible during the PPCI and was given as a bolus of 0.75 mg per kilogram of body weight, followed by an infusion of 1.75mg per kilogram per hour for 4 hours following the procedure. Heparin was given at a dosage of 70-100IU per kg (operator preference) and then guided by activated clotting time (ACT) results, aiming to maintain an ACT of >250 seconds.Bailout use of a Gp2b3a inhibitor was allowed in the event of high thrombus burden or microvascular obstruction (no reflow).

Results:During the 2 years 1291 patients underwent a PPCI, 662 in the Bivalirudin protocol period (Cohort B) and 629 in the heparin protocol period (Cohort H). Baseline and procedural characteristics were not significantly different, except for a higher use of thromboaspiration (44.9% vs. 12.4%, p<0.01) and femoral access route (12.6% vs. 19.8%, p<0.01)in the earlier Cohort B. Regarding the antiplatelet strategy, we observed that clopidogrel was less frequently used in the Cohort H (11.9% vs. 20.2%, p<0.01). The use of Gp2b3a inhibitors was significantly higher in the Cohort H (28.0% vs. 23.0%, p), mostly driven by more frequent use of abciximab (24.6% vs. 17.5%, p<0.01). We did not observe any differences in death at 30 days (9.4% in Cohort B vs. 8.9% in Cohort H; HR 95%CI 1.05 (0.75 – 1.49), p=0.77) and 180 days (11.03% vs. 11.29%; HR 95%CI 0.98 (0.72 – 1.33), p=0.88). The incidence of any bleeding complications at 30 days did not differ between the 2 periods (21.9% vs. 21.9%, p=0.99).The cost related to the anticoagulants amounted to £246236 in the Cohort B vs. £4483 in the Cohort H (p<0.01), corresponding to £372.00 per patient vs. £7.10 per patient.

CONCLUSIONS

Conclusion:We did not find clinically relevant changes in patient outcomes including bleeding complications with reintroduction of heparin in our PPCI protocol. However, the use of heparin was associated with a major reduction in treatment costs.

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TAVI in intermediate-risk patients performed in centres without on-site cardiac surgery

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

AIMS

The efficacy and safety of TAVI in centres without on site cardiac surgery is controverted, mainly in low and intermediate-risk patients.

METHODS AND RESULTS

We assess the outcomes of patients undergoing TAVI included in a multicentre registry of centres without on site cardiac surgery, according to the risk-profile. Group A was defined as high risk (STS ³8 or EuroScore ³20) and Group B as intermediate risk (STS < 8 or EuroScore < 20). Other features as porcelain aorta, frailty, liver disease, hostile chest and extreme age were also taken into account. Each heart team decided all the cases.

Overall, 210 patients were included. Group A included 69 patients (STS 8.4±4 and EuroScore 26±10) and Group B 141 (STS 3.5±1, EuroScore 8±4). Procedures were longer and with more radiation exposure in Group A and predilatation was more frequently performed in Group B (55% vs. 82%, p=0.001). There were not differences for in-hospital complications: Major BARC bleeding (10% in each group), vascular (5.8% vs. 2.8%, p: NS), pacemaker implantation (23 vs. 28%, p: NS), mortality (5.8% vs. 4%, p: NS). At 1-year follow up, patients in group A presented a worse course, with a survival free of events (death or cardiovascular admission) 57% vs. 78% in Group B (p=0.019, log rak 0.02).

CONCLUSIONS

Intermediate-risk patients but with some other risk feature, undergoing TAVI in centres without on site cardiac surgery, have good long-term prognosis. The results are similar to those published by centres with on site cardiac surgery. The prognosis of these patients is clearly better than high-risk patients.

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Impact of percutaneous mitral valve repair in ventricular arrhythmic burden of patients with severe mitral regurgitation and heart failure

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

AIMS

Ventricular remodeling and volume overload can lead to electrical instability in patients with LV dysfunction and severe mitral regurgitation (MR). We sought to investigate the impact of Mitraclip in the arrrythmogenic burden in such patients.

METHODS AND RESULTS

Prospective single-center registry of consecutive patients treated with MitraClip® at our Institution between June 2014 and December 2016. Clinical, echographic and electrophysiological variables were recorded. The main outcome was the change in major ventricular arrhythmias (MVA, a composite of non-sustained ventricular tachycardia-NSVT-, device shock or antitachycardia pacing-ATP-) in the prior year to MitraClip implantation and during follow-up.

During this period a total of 54 patients (mean age 72.9± 8.9 ; 72.2% male) have undergone percutaneous mitral valve repair. Among them, 17 patients (mean age 73.8±9.2, 64.7 % male) had received a cardiac device with continuous cardiac monitoring prior to MitraClip ® implantation (70.5 % defibrillator, 14 % CRT, 15.5% pacemaker). Mean ejection fraction was 33 ±12.9 %, mean end-diastolic volume was 182.8±53 ml and all of them had severe functional MR. All patients were in NYHA functional class III-IV prior to procedure. MitraClip ® was successful in 94.1 % of the cases with 41.2% of patients receiving ≥2 clips.

A total of 25 MVAs were recorded in the year prior to device implantation (NSVT 12, shocks 2 and ATP 11). Notably, only 1 NSVT was recorded during a median follow up of 452 days (IQR 189-600), being this difference statistically significant (p=0.042). No differences were observed in the rate of atrial arrhythmias (3 episodes prior to clip vs. 1 episode after, p=NS).

CONCLUSIONS

Mitraclip® therapy might be associated with a reduction in the burden of ventricular arrhythmias in patients with LV dysfunction and severe functional MR.

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Immediate and long-term results of stenting of the proximal branches of the aortic arch

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THEME: Interventions for Stroke
TOPIC(S): Carotid stenting, Ischaemic stroke

AIMS

To evaluate long-term clinical results of stenting of the proximal segments of the aortic arch branches depending on risk factors and comorbidities

METHODS AND RESULTS

From November 1999 to October 2015 consecutive 167 patients with occlusive-stenotic lesions of the supra-aortic trunks were 179 endovascular interventions. In all the clinical cases were implanted balloon-expandable and/or self-expanding stents and/or stent-graft. Some patients were operated several times. Reasons for repeated reconstructions of 8 observations was staged correction of multiple lesions. In 3 cases the intervention was retried due to the destruction of a previously installed stent and the return of symptoms of vertebrobasilar insufficiency

CONCLUSIONS

Stenting of the supra-aortic trunks should be considered as first method of choice of treatment, since high performance has a low risk of complications and good long-term results.
Stenting of the innominate artery should only be performed using systems preventing the brain from embolism.
Restenosis and stent degradation do not always lead to the development of the clinic vertebrobasilar insufficiency, therefore, to the necessity of repeated interventions.

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Atrial fibrillation sufferers have lower rates of invasive therapy in ACS at the expense of mortality, morbidity and length of hospital stay

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

AIMS

There is a clear interplay between AF and ACS in terms of selection for antiplatelet therapy and bleeding risk. Little is known on how treatment modality (invasive or medical) is influenced by AF, and how AF affects length of stay and major outcomes

METHODS AND RESULTS

We investigated the impact of AF on morbidity, mortality and length of stay (LoS) amongst 18,444 ACS patients between Jan-2010 and Dec-2014 using the Secure-Anonymized-Information-Linkage (SAIL) databank. Demographics, admissions and comorbidities were identified using coded data. Propensity-matched cohorts were used to study outcomes.There were a total of 5,037 out of 18,444 patients who had pre-morbid AF. Of the remaining 13,407 patients, 664 developed AF within the first year after ACS. The mean LoS (± standard-deviation) in propensity-matched patients without AF was 12.3±17.9 days. This was significantly higher ($p<0.001$) in patients with premorbid AF 17.3±22.8, who were also 24% (95%-CI: 18-29%) less likely to undergo invasive-therapy, and 30% (95%-CI: 10-50%) more likely to experience re-infarcts ($p<0.01$). ACS patients with AF had worse one-year net adverse cardiac events in both pre-morbid (HR 1.20, 95%-CI: 1.10-1.30) and post-morbid onset (HR 3.2, 95%-CI: 2.6-4.0), driven mainly by all-cause mortality, but not bleeding or strokes.

CONCLUSIONS

ACS patients with pre-morbid or post-morbid AF have higher mortality rates and poorer outcomes. Pre-morbid AF is associated with prolonged LoS and fewer invasive treatments, together with more frequent re-infarctions. Clinicians' awareness of these findings is needed to reduce the risk for patients and financial burden for the health-service.

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Impact of calcification pattern and implantation depth on permanent pacemaker implantation and paravalvular leakage after TAVI with a next generation self-expanding device

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

AIMS

Our aim was to identify predictors for paravalvular leakage and permanent pacemaker implantation following TAVI by taking pre-procedural calcification pattern and device implantation depth into consideration.

METHODS AND RESULTS

This analysis by two high-volume TAVI centers comprises 143 consecutive patients treated for severe aortic stenosis with a novel self-expanding transcatheter heart valve, the ACURATE *neo*™ transcatheter heart valve (Symetis SA, Ecublens, Switzerland). Valvular- and sub-valvular calcification was analyzed in pre-procedural multi-slice computed tomography and the relative implantation depth was derived from post-implantation root angiography (relation of infra- to supra-annular part of the device, measured from the upper crown to the ventricular end of the transcatheter heart valve).

After exclusion of patients with previous pacemaker implantation, 130 patients remained for further analysis. Permanent pacemaker implantation rate was 13.01% (88.2 % atrioventricular block °III, 5.9% left bundle branch block, 5.9% bradyarrhythmia). The relative implantation depth of the device (percent of the transcatheter heart valve in the left ventricular outflow tract) was similar in patients with and without the need for permanent pacemaker implantation (31.3±10.9 vs. 30.7±10.4%; P=0.702). Total device landing zone calcium volume did not differ between patients with and without permanent pacemaker implantation (666±452 vs. 667±453 mm^3; P=0.864). However, an elevated calcium load of the left ventricular outflow tract (LVOT) in the area below the left-coronary cusp ($LVOT_{LC}$) was associated with increased risk for permanent pacemaker implantation. Patients with elevated $LVOT_{LC}$ calcification had a permanent pacemaker implantation rate of 30.8% compared to 9.4% in patients without relevant $LVOT_{LC}$ calcification (P=0.044). Multivariate analysis derived no significant association of implantation depth (P=0.829), total valvular- or individual cusp calcification (P=0.298 for total valvular calcification) and the need for permanent pacemaker implantation. Interestingly, a significant association of $LVOT_{LC}$ calcification and the need for pacemaker implantation could be shown in our cohort (p= 0.020).

Paravalvular leakage was none/trace in 41%, mild in 53% and moderate in 6% of patients. Total device landing zone calcium volume was 507±385 mm^3, 661±400 mm^3 and 924±608 mm^3 in patients with none/trace, mild and moderate paravalvular leakage, respectively (P=0.002). The relative implantation depth of the device ranged from 6.1% to 57.0% of total stent length, with no association with the degree of paravalvular leakage (P=0.342). However, there was a good correlation in a linear regression analysis between the burden of total device landing zone calcification and the degree of paravalvular leakage (P=0.002). Patients in the upper tercile of calcification had higher rates of mild and moderate paravalvular leakage compared to patients in the lower tercile (P=0.008).

CONCLUSIONS

Our study suggests that in TAVI with the ACURATE *neo*™ transcatheter heart valve (I) LVOT calcification is an important predictor for the post-interventional permanent pacemaker implantation rate and (II) the burden of valvular calcification is an important predictor for paravalvular leakage. Therefore, our study underlines the importance of careful pre-procedural planning and emphasizes the need for careful prosthesis selection in each individual patient.

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Carotid artery stenting for the patients in the acute post-stroke phase

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THEME: Interventions for Stroke
TOPIC(S): Ischaemic stroke

AIMS

The efficacy of Carotid artery stenting (CAS) for the patients with recent ischemic stroke has not been established. We investigate the outcome of the CAS underwent during acute phase.

METHODS AND RESULTS

We enrolled all patients who underwent CAS for symptomatic ICA stenosis in our institution from April 2012 to July 2016. The patients underwent CAS within 3 days from onset/ neurological deterioration were identified with the ‘early group’ and the other patients were identified with the ‘delayed group’. All procedures were underwent with embolic protection devices. All data were collected retrospectively from medical records.

In a total of 149 patients, 162 CAS procedures were performed at our institution during the study period. Fifty-seven procedures including CAS for asymptomatic lesions, iatrogenic dissection, requiring additional intervention, re-stenosis of the CAS and chronic total occlusion were excluded. The median time interval between symptom onset/ neurological deterioration and the CAS procedure was 1.0 days in the early group and 12.0 days in the delayed group. There were no significant differences between the groups regarding age, gender, the type of stents used in CAS. The overall major adverse event (MAE) rate was 4.8% during their hospitalization. There was no significantly increased perioperative MAE in early group compared with delayed group (2.5% vs 6.5%, P = 0.65). Among the early group, twenty-five of 40 patients (62.5%) at their discharge and 23 of 36 patients (63.9%) at 90 days were functionary independent (score of 0 to 2 on the modified Rankin Scale). Compared to the patients with poor outcome (modified Rankin Scale 3-6) , the patients with functionary independent were significantly younger, higher prevalence of TIA and lower frequency of appearance new diffusion weighted image high lesion.

CONCLUSIONS

CAS performed within 3 days from last ischemic event may be safe, even in patients with progressive neurological symtoms. Early CAS is a useful option for the symptomatic extracranial carotid artery stenosis.

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Primary PCI with DEB-only angioplasty, first UK experience

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

AIMS

Primary PCI (PPCI) for ST elevation myocardial infarction (STEMI) accounts for about 27% of all PCIs in the UK. It is a high risk group; the UK 30 day mortality is 6.9%. We report outcomes of DCB-only angioplasty in PPCI for the first time in the UK.

METHODS AND RESULTS

253 consecutive patients (267 lesions) treated with DCBs were identified. Up-to-date mortality data were available for 252 (99.6%) patients from the Demographics Batch Service Bureau of the Health and Social Care Information Centre. Minimum duration mortality follow up was 379 days. Other clinical outcomes were obtained from hospital clinic records and reviewing angiograms.

Mean (SD) age 65.5 (13.4), 74.7% male, 21.7% prior myocardial infarction, 22.1% previous PCI. 4% in cardiogenic shock and 6.7% were out of hospital cardiac arrests. 84.3% were de novo lesions. The left anterior descending was treated in 44.6%. Mean (SD) DCB diameter was 3.2 (0.6) mm and length of treated segment was 25.4 (13.6) mm. 91% had DCB-only PCI. 0.75% returned with acute vessel closure requiring bail-out stenting. 30 day mortality was 2.4% and for first 379 days from the index procedure was 6.3%. Clinical outcomes obtained from hospital records for a mean (SD) 261.4 (228.9) days were, MI 6 (2.62%), target lesion revascularization 8 (3.3%) and target vessel revascularization (non TLR) 5 (2.1%) for 90.5% of patients.

CONCLUSIONS

DCB-only angioplasty in PPCI appears to be safe and effective at medium term follow up.

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Perfusion-balloon valvuloplasty of aortic valve stenosis without rapid pacing: results of the TRUE-FLOW study

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

AIMS

TRUE-FLOW was a prospective study designed to assess acute performance and safety of the True^{TM}Flow Valvuloplasty Perfusion Catheter in providing stationary, effective, longer-term inflation of a stenotic aortic valve without rapid pacing.

METHODS AND RESULTS

Twenty-four patients undergoing TAVI for aortic valve stenosis were enrolled at the University of Leipzig – Heart Center (Leipzig, Germany) in this observational study. The test device (i.e., True^{TM}Flow Valvuloplasty Catheter, Bard Peripheral Vascular) consisted of eight individual balloons encapsulated in a fiber-based non-compliant shell mounted on an over-the-wire catheter. The open chamber between the individual balloons was designed for blood flow, allowing for inflation with low hemodynamic resistance. The primary performance measure was stationary inflation of the balloon with clinically acceptable intraventricular pressure with or without rapid pacing. Safety was measured as freedom from device-related death, stroke, annulus rupture, coronary occlusion, or ventricular perforation during the dilation procedure. Baseline data were collected and pressure measurements were taken prior to inflation, at the time of balloon inflation, and immediately thereafter.Patients in the TRUE-FLOW study were 79.8 $\pm$ 4.3 years old; 70.8% were male with a mean STS score of 7.8 $\pm$ 5.9%. The ejection fraction prior to the procedure was 53.1% $\pm$ 13.9, and 54.2% of patients were classified as NYHA Class III. The total time of balloon inflation was 5.4 $\pm$ 2.3 sec, and all procedures except one (95.8%) were completed without rapid pacing. Movement of the balloon during inflation, while inflated, and during deflation were 4.2 $\pm$ 5.0, 2.0 $\pm$ 4.5 and 5.9 $\pm$ 6.1 mm, respectively. The mean pressure gradient between the left ventricle and the aorta before, during, and after inflation was 43.9 $\pm$ 18.9 mmHg, 38.3 $\pm$ 14.3 mmHg, and 29.0 $\pm$ 13.6 mmHg, respectively. The peak-to-peak gradient before, during, and after inflation was 54.9 $\pm$ 24.7 mmHg, 63.7 $\pm$ 24.1 mmHg, and 40.3 $\pm$ 18.5 mmHg while the mean ventricular end diastolic pressure was 17.8 $\pm$ 10.9 mmHg, 13.4 $\pm$ 11.3 mmHg, and 17.5 $\pm$ 10.5 mmHg, respectively. There were no reports of device-related safety events (i.e., death, stroke, annulus rupture, coronary occlusions, or ventricular perforation).

CONCLUSIONS

Data from this feasibility study demonstrate that the True^{TM}Flow Valvuloplasty Catheter can treat aortic valve stenosis with minimal movement during inflation in the absence of rapid pacing (96% of cases), no increase in left-ventricular end-diastolic pressure, and with no device-related adverse events. Further studies are necessary to elucidate whether the avoidance of rapid pacing during valvuloplasty reduces ischemia of the myocardium, ischemia-related arrhythmias, and decompensations especially in patients with poor LV function.

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OCT assessment of second-generation drug-eluting absorbable metal scaffold (DREAMS 2G): insights from the BIOSOLVE-II first-in-man trial

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

AIMS

We assessed the baseline, 6-month and 12-month optical coherence tomography performance of this novel device which may provide a mechanistic explanation for the optimal clinical results.

METHODS AND RESULTS

The prospective, international, multi-centre, first-in-man BIOSOLVE-II trial enrolled 123 patients with up to 2 de novo lesions with a reference diameter between 2.2 and 3.7 mm. All patients were scheduled for angiographic follow-up at 6 months, and –if subjects consented– at 12 months. Unlike the published 1 year data (n=11), a larger OCT population (n=65) was available for this report. Mean and minimum lumen areas decreased significantly from baseline to 6 and 12 months, but it remained nearly unchanged between 6 and 12 months. Mean Stent Area (mm2) was 7.60 post-procedure. Struts were no more discernible at 6 and 12 months.

Post-procedure, 6-month, 12-month
Absolute Diff: 6-month vs post* [95% CI]
Absolute Diff: 12-month vs post** [95% CI]
Absolute Diff: 6-month vs 12-month*** [95% CI]

Mean Lumen Area (mm2) 7.62, 6.34, 6.46
-1.28 [-1.68,-0.88]
-1.66 [-2.26,-1.05]
-0.20 [-0.48,0.35]
Minimum Lumen Area (mm2) 6.32, 4.53, 4.81
-1.79 [-2.17,-1.42]
-2.04 [-2.59,-1.49]
-0.27 [-0.62,-0.09]
Minimum Lumen Diameter (mm) 2.86, 2.49, 2.55
-0.36 [-0.45,-0.27]
-0.41 [-0.53,-0.28]
-0.01 [-0.09,0.11]

CONCLUSIONS

The novel drug-eluting metal absorbable scaffold DREAMS 2G showed a continuous favourable and stable lumen size parameters between 6 and 12 months. NCT01960504

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Long-term follow-up (three year) of different strategies for treatment of multivessel disease with CTO

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

To Show the comparison of events of CTO with successful stent treatment versus unsuccessful stent treatment, surgical and medical treatment at a three year follow up in an Institution in Mexico.

METHODS AND RESULTS

In a longitudinal retrospective, non randomized cohort of the interventional cardiology department 221 patients with coronary angiography in the period between January 2010 and December 2014 with multivessel disease and at least one CTO. After the decision of the heart team they were treated with stent (112 patients), surgical (63 patients) or medical treatment (46 patients). After the treatment, 4 groups were created: 1) Successful stent treatment (n= 85), 2) Unsuccessful stent treatment (n= 27), 3) Surgical treatment (n= 63) and 4) medical treatment (n=46). The Syntax score > 33 was 7%, 22%, 60% and 54% for each group respectively (p= 0.001). The presence of multiple CTO was more frequent in the surgical group 33.3% and lesser in the successful stent group 16.5%. The ejection fraction less than 30% was significantly higher in the surgical and medical treatment group (17.5% and 32.6%). In the primary endpoint of cardiovascular adverse events at 3 years the prevalence was 6.1% for Group 1, 30% for the unsuccessful stent (group 2) , 16% in the surgical treatment group (Group 3) and 25% in the medical treatment group (Group 4) (p= 0.001 for group 1 vs all groups and < 0.05 for group 3). In the secondary endpoints of adverse events at 1 year the difference was found in favour of the group 1 and 3 (6.1% p=0.001 and 1.8% p=0.001). There were non significant difference between the groups in the adverse events in hospital and at 30 days. The death of all causes at 3 years was 4.7%, 19.1%, 15% and 14% for each group.(p=0.013 for group 1). The hospitalization rate was higher for the medical treatment group (56% p= 0.001). In the comparison between the strategies of treatment (Successful stent vs Surgery) there were no differences in the rate of the composite of cardiovascular adverse events at 1 and 3 years or death of all causes. When the complete revascularization was analysed between this two strategies, in the composite endpoint there were no differences in the surgical treatment group (18% vs 10% p=0.035), but in the successful stent group there was a significant difference (3.07% vs 15%). The rate of complete revascularization was higher in the stent group (81.5%) vs surgical group (52.38%).

CONCLUSIONS

This is a sample of the evolution of a cohort of patients in a reference institution in Mexico. The characteristics of high risk (Syntax score > 33, left ventricle ejection fraction < 30%) were more prevalent in the surgical and medical treatment group. The successful stent implantation and the surgical treatment had a better prognosis than the unsuccessful stent and medical treatment. Also the complete revascularization was a better predictor of a good outcome.

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Risk factors for cardiovascular events up to five years in near-normal coronary artery

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

AIMS

Coronary artery disease (CAD) is a well-known risk factor for long-term cardiovascular events (CVE). We wanted to evaluate baseline risk factors for CVE in patients who have near-normal coronary artery assessed by coronary angiography (CAG).

METHODS AND RESULTS

A total of 5,852 patients with chest pain, but without significant CAD were prospectively enrolled in this study. Mean follow-up duration was 3.4 years. Thirty eight (0.9 %) patients developed major adverse cardiac events (MACE), and 309 (8.1 %) patients developed sustained angina pectoris (AP), both within 5-years. MACE was defined as composite of death, myocardial infarction and de novo percutaneous coronary intervention (PCI).

In multivariable Cox-proportional hazard model analysis, MACEs was significantly associated with age [per 5-year, hazard ratio (HR); 1.29, 95 % confidence interval (CI); 1.09-1.52] and mild to moderate coronary stenosis [mild (30-50%), HR; 2.62, 95% CI; 1.09-6.29 and moderate (50-70%), HR; 3.48, 95% CI; 1.50-8.07]. Also, sustained AP was significantly associated with age [per 5-year, HR; 1.05, 95% CI]; 1.00-1.11], alcohol drinking [HR; 0.74, 95% CI; 0.55-0.98], mild to moderate coronary stenosis [Mild- HR; 1.73, 95% CI; 1.18-2.53 and Moderate-HR; 3.50, 95% CI; 2.53-4.84], coronary spasm [CAS, HR: 1.39, 95% CI; 1.09-1.78] and myocardial bridge [MB, HR: 1.39, 95% CI; 1.05-1.84]. [Table]

CONCLUSIONS

In patients without no significant CAD, coronary artery stenosis less than 70 % is a strong predictor for future long-term CVE. Aging, CAS and MB are also strongly associated with future APs.

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Impact of diabetes on the three-year clinical outcomes in left main disease patients treated with DES

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

AIMS

Drug-eluting stents (DES) is one of the treatment methods for treating patients (pts) with coronary artery disease. However, whether PCI using DES affects left main (LM) pts with diabetes mellitus (DM) differently than those without DM is limited.

METHODS AND RESULTS

A total of 252 consecutive LM percutaneous coronary intervention (PCI) pts were divided into two groups according to the presence of DM: Non-DM group (n=104) and DM group (n=148). Major clinical outcomes were compared between the two groups up to 3 years.

At baseline, the DM group contained a higher prevalence of patients with hypertension, chronic kidney disease, MI, dissection and more ARB prescription than the non-DM group. Kaplan-Meier analysis showed that the two groups exhibited no significant difference in regards to individual and composite clinical outcomes up to 3 years. Multivariate Cox Regression Analysis showed that after baseline adjustment, only left ventricular ejection fraction (LVEF) was a significant risk factor of total MACE (HR: 0.961, 95% CI: 0.942-0.981).

CONCLUSIONS

DM patients with LM disease treated with DESs showed similar individual and composite major clinical outcomes than non DM patients up to 3 years. Left ventricular function was the sole independent predictor of 3-year total MACE.

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The impact of metformin on long-term clinical outcomes in diabetes mellitus patients undergoing acetylcholine provocation test: five-year follow-up results

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

AIMS

Metformin is one of the major anti-diabetic drug. Limited studies suggests metformin may prevent the cardiovascular disease. However, there is limited data regarding the effects of metformin on the cardiovascular events in DM patients (pts).

METHODS AND RESULTS

A total 459 DM pts who underwent intracoronary acetylcholine (Ach) provocation test were enrolled. Provocation test was performed by incremental dosages (20, 50, 100ug) of Ach until get significant response (>70% narrowing). The study population were divided into anti-diabetic drug treatment group without Metformin (Control group; n=551) and Metformin treatment group (Metformin group; n=92). Angiographic and clinical parameters during Ach provocation test were compared between the two groups. We investigated the clinical outcomes in DM pts in both groups throughout 5 years.

Baseline characteristics were similar between the two groups except serum cholesterol and Low-density lipoprotein level. During Ach provocation test, angiographic parameters and clinical parameters are not different between the two groups. Five-year individual and composite clinical outcomes were not different between the two group except that metformin treatment group showed higher incidence of major adverse cardiac event (MACE; 0.4% vs. 4.3%,*p* <0.001). After the multivariate analysis, Metformin treatment in DM pts was not an independent predictor for recurrent chest pain. However, cerebrovascular accident was an independent predictor and current alcoholics was the negative predictor of recurrent chest pain.

CONCLUSIONS

Although the metformin was a well-known drug thatameliorate cardiovascular morbidity in DM pts, metformin treatment was not associated with five-year adverse clinical outcomes.

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First experience after implantation of ultrathin-strut biodegradable polymer-coated long (44/48 mm) everolimus-eluting stents for treatment of long atherosclerotic lesions in real-world scenario

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

AIMS

The study investigated procedural and clinical outcomes after 6 months of implantation of ultrathin-strut (60 µm) biodegradable polymer coated long (44/48 mm) everolimus-eluting stents in real-world patients with long atherosclerotic coronary lesions

METHODS AND RESULTS

This was a real-world, single-center, observational study that incorporated 105 patients who underwent implantation of Tetrilimus everolimus-eluting stent (Sahajanand Medical Technologies Pvt. Ltd., Surat, India) for treatment of coronary artery disease between February, 2016 and July, 2016 at a tertiary care center of India. Data were sourced from clinical notes, angiogram reports and procedural reports. All patients in whom 44/48 mm Tetrilimus stent was implanted during routine clinical practice were included in the study, except those in whom already some other stent had been implanted. The patients were followed up to six months after the index procedure. Follow-up of all patients was achieved by either clinical database review or telephone follow-up for clinical events, depending upon the length of follow-up achieved clinically. Occurrence of any major adverse cardiac event (MACE) up to 6-month follow-up was the primary endpoint of the study. The MACE was considered as a conglomerate of cardiac death, myocardial infarction (MI), target lesion revascularization (TLR) and target vessel revascularisation (TVR). The occurrence of stent thrombosis (ST) was also analysed as per the Academic Research Consortium.

The study population included 64 (61.0%) males and average age was 58.2±10.0 years. The rates of hypertension and diabetes were 52.4% and 37.1%, respectively. Of total patients, 24 patients were current smokers. Thirty-four (32.4%), 33 (31.4%), 24 (22.9%), and 14 (13.3%) patients presented with non-ST-elevation myocardial infarction, stable angina, unstable angina, and ST-elevation myocardial infarction, respectively. There were 14, 45, and 55 lesions located in left circumflex artery, left anterior descending artery, and right coronary artery, respectively. There were 11 (9.6%) totally occluded lesions. A total of 114 lesions were intervened successfully with only one stent been implanted per lesion. The average stent length and diameter were 46.3 ± 2.0 mm and 2.8 ± 0.3 mm, respectively. All lesions were pre- and post-dilated. Device success rate, lesion success rate, and procedural success rate were all 100%. Six-month follow-up was attained in all patients. There was no incidence of MACE up to 6-month follow-up.

CONCLUSIONS

Implantation of long Tetrilimus stents was associated with excellent procedural performance and clinical outcomes with no incidence of MACE up to 6-month follow-up. Long-term follow-up would provide base for more widespread use of long drug-eluting stents in complex coronary artery lesions in contemporary clinical practice.

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24-month outcome with the repositionable and retrievable Boston Scientific Lotus valve compared with the balloon-expandable Edwards Sapien 3 valve in patients undergoing TAVR

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

AIMS

We compared 30 days, 12 and 24 months outcome of the Boston Scientific Lotus valve (Lotus) and the balloon-expandable Edwards Sapien 3 (ES3) valve. Primary endpoint was all-cause mortality or disabling stroke within 12 and 24 months.

METHODS AND RESULTS

Between 2014 and 2016 537 patients were enrolled (clinicaltrials.gov NCT02162069), 202 patients received Lotus and 335 ES3. There was no residual moderate or severe AR. Rate of mild AR was lower with the repositionable and retrievable Lotus valve. Rate of pacemaker implantation was significantly higher with Lotus compared with ES3 (36.1% versus 14.9%, $p<0.01$). VARC-2 early safety endpoint at 30 days was 7.4% with both devices with no difference in all-cause mortality (Lotus 1.9%, ES3 1.8%, $p=0.87$) and rate of disabling stroke (Lotus 2.9%, ES3 2.9%, $p=0.99$). The primary endpoint at 12 months was similar with no difference in exploratory subgroup analyses. In a propensity score matched comparison there was no difference in the primary endpoint within 12 months (Lotus 16.6%, ES3 20.6%, $p=0.47$) and 24 months (Lotus 38.3%, ES3 33.3%, $p=0.58$) except for a significant higher need for pacemaker implantation with the Lotus valve.

CONCLUSIONS

TAVR with the Edwards Sapien 3 and the Boston Scientific Lotus Valve were associated with similar 30 days, 12 and 24 months clinical outcome. Need for permanent pacemaker implantation was significantly higher with the repositionable Lotus device.

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Cerebral emboli protection during TAVR significantly reduces death and stroke compared to unprotected procedures

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

AIMS

The aim of this study was to evaluate the impact of cerebral emboli protection with the Claret Sentinel device on stroke in patients undergoing transfemoral aortic valve replacement (TAVR).

METHODS AND RESULTS

A total of 681 patients was enrolled. The Sentinel cerebral emboli protection device (Claret Medical Inc. CA, USA) was used in 25.6% (N=174) of consecutive patients. In 74.4% (N=507) TAVR was performed in the identical setting except without cerebral emboli protection. Neurological follow-up was done within seven days post procedure. The primary endpoint was a composite of all-cause mortality or all stroke according to Valve Academic Research Consortium (VARC)-2 criteria within seven days.

The device was successfully positioned in 174/186 (93.5%) patients. With use of the cerebral emboli protection device rate of disabling and non-disabling stroke was significantly reduced from 4.3% to 0.6% (p=0.02; odds ratio 0.13, 95% confidence interval 0.02-0.95). The primary endpoint occurred significantly less frequent with 1.2% (N=2/174) in the protected group compared to 6.7% (N=34/507) in the control group (p=0.01; odds ratio 0.16, 95% confidence interval 0.04-0.68). In multivariable analysis only STS score for mortality (p<0.01) and TAVR without use of cerebral emboli protection (p<0.01) were independent predictors for the primary endpoint.

CONCLUSIONS

In patients undergoing TAVR use of a cerebral emboli protection device demonstrated a significant clinical benefit with a lower rate of death and stroke compared with unprotected TAVR.

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Long-term outcome of patients with mixed aortic valve disease undergoing TAVR

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

AIMS

The aims of this study were to assess feasibility of transfemoral aortic valve replacement in mixed aortic valve disease and evaluate impact on short- and long-term outcome.

METHODS AND RESULTS

Between 2014 and 2016 734 patients were enrolled (clinicaltrials.gov NCT02162069), 665 had aortic stenosis, 69 presented with MAVD. Mixed aortic valve disease was defined as severe aortic stenosis with coexisting moderate to severe aortic regurgitation. Primary endpoint was all-cause mortality or disabling stroke within 12 and 24 months.VARC-2 early safety endpoint at 30 days was 8.1% in isolated AS and 10.1% in MAVD (p=0.57) with no significant differences in all-cause mortality (AS 1.8%, MAVD 4.3%, p=0.16) and rate of stroke (AS 3.9%, MAVD 2.9%, p=0.71). The primary endpoint at 12 months (AS 18.3%, MAVD 23.9%, p=0.36) and 24 months (AS 30.4%, MAVD 34.6%, p=0.67) were similar. Rate of rehospitalization for congestive heart failure did not differ between groups. In multivariate analyses STS for mortality (p<0.01) and atrial fibrillation (p=0.02) were independent predictors for the primary endpoint at 12 months, but not AS or MAVD, diabetes mellitus, history of bypass surgery, prior stroke, gender, predilation or reduced left ventricular ejection fraction.

CONCLUSIONS

TAVR in patients with mixed aortic valve disease is associated with similar 30 days, 12 and 24 months clinical outcome compared to patients undergoing TAVR for aortic stenosis.

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Bilateral occlusion of the femoral veins: does it constrain a Melody implantation?

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

AIMS

To present an experience of transcatheter valve implantation in patient with right outflow tract dysfunction without vascular approach.

METHODS AND RESULTS

Methods: a 16-old boy, 46 kg, with repaired complex D-transposition of the great arteries (D-TGA, VSD, LVOTO) was admitted after Rastelli procedure with RVOT reconstruction using xenograft, initially modified B-T shunt was performed at the age of 1 month. After 1 year of complete repair, a conduit reimplantation has been performed due to gradually increasing gradient. 3 years later, he underwent LVOT reconstruction with expansion of the tunnel from LV to aorta using pericardial patch. Within next 4 years, he has undergone another two reconstructions of the RVOT with homografts. Following the 5-year period without hospitalization, the severely increased gradient on the homograft required reintervention and balloon dilatation has been performed through right jugular vein due to bilateral femoral veins thrombosis. Patient was discharged with satisfying result – RV pressure was decreased from 90% to 50% from systemic pressure. After 1 year, pressure gradient on RVOT was increased to 80 mmHg. The reoperation risk was very high and for the reason of absence of vascular access, the hybrid approach was chosen.
Results: Melody valve implantation through the parietal wall of the RV was performed. Initially obstructed area was dilated with 18x40 mm balloon. On angiography there was laminar flow through the pulmonary valve, right ventricular pressure was 46/3 mmHg. According to TTE peak pressure gradient on conduit was 27 mmHg.

CONCLUSIONS

Femoral veins thrombosis does not restrain transcatheter reconstruction of the right outflow tract. Using of the transventricular hybrid approach for pulmonary valve implantation is an acceptable alternative in absence of vascular access.

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The drug-eluting absorbable magnesium scaffold in complex coronary bifurcations: insights from a pre-clinical multimodality imaging study

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

AIMS

This acute pre-clinical animal study sought to provide insights regarding the feasibility of performing complex bifurcation stenting with the Magmaris bioresorbable magnesium-alloy scaffold(Biotronik AG, Bülach, Switzerland).

METHODS AND RESULTS

Twenty-five New-Zealand white rabbits underwent stenting of the non-diseased aorto-iliac bifurcation with Magmaris using provisional (PS, n=5), culotte (n=6), modified-T (n=6), or T-and-protrusion (TAP, n=8) stenting techniques. Angiography, optical coherence tomography (Optis IVOCT system, St Jude Medical, St Paul, MN, USA)and micro-computed tomography (SkyScan 1076/Bruker-microCT, Kontich, Belgium)were performed. Angiographic results were excellent without evidence of dissection or side-branch (SB) compromise. In the 25 procedures carried out with 45 scaffolds, 7 single and 2 double fractures were identified, when using 2-stent techniques. In only 2 cases minimal luminal compromise at the level of the bifurcation was observed. PS optimally opened the SB ostium with excellent scaffold expansion and no evidence of scaffold compromise or fractures. Culotte stenting resulted in complete bifurcation coverage, extensive segments of double-layered struts, and excellent scaffold expansion. There were single strut fractures in 3/6 and double fractures in 1/6 culotte procedures. Modified-T and TAP resulted in complete bifurcation coverage, minimal double-strut layers at the neocarina and excellent scaffold expansion. In 2/6 Modified-T procedures strut fractures were present with SB scaffold deformity present in an additional 2/6 procedures. In 3/8 TAP procedures single strut fractures were present with no compromise of overall scaffold integrity. Although in-vivo pre-clinical testing provides valuable insights that may aid in improving clinical practice, the non-diseased model used may not accurately predict scaffold behavior in human subjects. Furthermore, as it is an acute performance study, the long-term outcomes following scaffold degradation still need to be assessed.

CONCLUSIONS

In this acute in-vivo study,bifurcation stenting using Magmaris appears feasible with excellent angiographic results. PS with additional TAP whenever needed seems a reasonable approach. Whenever a 2-stent technique is required from the outset, TAP appears most favorable whilst modified-T and culotte stenting should probably be avoided.

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Role of deferred stenting in patients with STEMI treated with primary PCI: a systematic review and meta-analysis

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

AIMS

We conducted a meta-analysis of studies comparing deferred stenting strategy versus the conventional approach with immediate stenting in STEMI undergoing primary percutaneous coronary intervention (pPCI)

METHODS AND RESULTS

Searches in electronic databases were performed. Comparisons between the two strategies were performed for both hard clinical endpoints (all cause-mortality, cardiovascular mortality, unplanned revascularization, myocardial infarction and readmission for heart failure) and surrogate angiographic endpoints (TIMI flow<3 and myocardial blush grade (MBG) <2).

Eight studies (3 randomised and 5 non-randomised) were deemed eligible, accounting for a total of 2,101 patients. No difference in terms of hard clinical endpoints was observed between deferred stenting and immediate stenting (OR [95 %CI]: 0.79 [0.54-1.15], for all-cause mortality; odds ratio (OR) [95 %CI]: 0.79 [0.47-1.31] for cardiovascular mortality; OR [95 %CI]: 0.95 [0.64-1.41] for myocardial infarction; OR [95%CI]: 1.37 [0.87-2.16], for unplanned revascularization and OR [95 %CI]: 0.50 [0.21-1.17] for readmission for heart failure). Notably, the deferred stenting approach was associated with improved outcome of the surrogate angiographic endpoints (OR [95 %CI]: 0.43 [0.18-0.99] of TIMI flow<3 and OR [95 %CI]: 0.25 [0.11-0.57] for MBG<2.

CONCLUSIONS

A deferred stenting strategy could be a feasible alternative to the conventional approach with immediate stenting in “selected” STEMI patients undergoing pPCI.

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Thrombus aspiration in patients with STEMI presenting late after symptom onset - Two-year clinical outcome of a randomised trial

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

AIMS

In the so far only randomised trial on thrombus aspiration in STEMI patients presenting late after symptom onset, thrombectomy did not improve reperfusion success. Aim of the current analysis is to report the first data on long-term clinical outcome.

METHODS AND RESULTS

STEMI patients (n=144) presenting ≥12 and ≤48 hours after symptom onset were randomised to primary PCI with or without manual thrombus aspiration in a 1:1 ratio. For the predefined long-term follow-up, we assessed the incidence of clinical events at 2-year follow-up. Major adverse cardiac events (MACE) were defined as the composite of death, myocardial re-infarction, and target vessel revascularisation (TVR). Post-hoc subgroup analyses were performed for gender, presence or absence of diabetes mellitus, TIMI thrombus grade (0-4 vs. 5), TIMI flow before PCI (0-1 vs. 2-3), and collateralization (Rentrop 0 vs. 1-3).

Data on clinical outcome were available in all patients. Follow-up was completed at a median of 24 months (interquartile range 14-34). MACE occurred in 9 patients in the thrombectomy group and in 8 patients randomised to standard PCI (12.9% vs. 10.8%, p=0.80). The rates of death (5.7% vs. 8.1%, p=0.54), myocardial infarction (5.7% vs. 2.7%, p=0.45), and target vessel revascularisation (5.7% vs. 1.4%, p=0.18) were similar in both groups. The results with respect to MACE and secondary endpoints were consistent across all subgroups (all p>0.05).

CONCLUSIONS

In patients with STEMI presenting late after symptom onset, routine thrombus aspiration before PCI failed to show a clinical benefit at long-term follow-up.

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Impact of one radiation protection device on radiation doses for both operator and patient in interventional cardiology

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Image-guided surgeries have increased over the last twenty years. The goal of this study is to measure the effectiveness of *radioprotective drapes* during interventional cardiology procedures to protect both workers and patients.

METHODS AND RESULTS

In this study we worked with an anthropomorphic phantom RANDO which simulates a human body and we reproduced X-ray beam incidences used during interventional cardiology procedures. For the experimentation classical protective equipment such as a lead*curtain*, *screen* and *aprons* were used and we have established X-ray beam angles producing the highest scattered radiations for the operator. Operator effective dose and operator's lens dose were measured respectively with a Radcal ionization chamber 1800 cc and with an Unfors dosimeter EDD-30. For each beam incidence a measure was performed without and with a radioprotective drape RADPAD and a lead cap (0.5 mm Pb). In the same way, skin dose and deep dose were measured according to a specific protocol using Unfors dosimeter EDD-30 for the patient.

CONCLUSIONS

For operator we already have an improvement with RADPAD in fact doses have been reduced by 50% to the lens and 43% to the whole-body. In contrast, the *lead cap* reduce dose to the operator head until 97%. For patients experiments are currently held so we don't have the result for now but we are also expecting a good reduction.

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Outcomes after staged intervention for non-culprit disease in patients with multivessel disease undergoing primary PCI for STEMI

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

AIMS

We aim to determine if the timing of staged PCI to non-infarct arteries in patients with STEMI and multi-vessel coronary disease has an impact on cardiovascular outcomes.

METHODS AND RESULTS

250 patients who presented with STEMI to a regional cardiovascular centre, and underwent a staged PCI procedure to non-infarct arteries (bystander PCI), between 2012 and 2016 were identified. Patients with cardiogenic shock were excluded. Major adverse cardiovascular events (MACE) were recorded retrospectively. Patients were divided according to whether they underwent inpatient or outpatient bystander PCI and outcomes were compared using Kaplan-Meier survival analysis.76 patients underwent inpatient bystander PCI and 174 patients had outpatient PCI. There was no significant difference between the groups in age, sex, smoking history or diabetes. The mean time between STEMI and bystander PCI was 3.99 days (SD 2.92) for inpatients and 60.47 days (SD 44.44) for outpatients. On Kaplan-Meier analysis there was no significant difference in MACE between the inpatient and outpatient cohorts (p-value 0.78). Age-adjusted Cox analysis demonstrated no difference in outcomes between inpatient and outpatient procedures (HR 0.84 [95% CI 0.67-1.81)), which persisted after multivariate adjustment ((HR 0.77 [95% CI 0.72-1.96).

CONCLUSIONS

In this study we observed that the timing of bystander PCI after STEMI has no effect on cardiovascular outcomes. Our results suggest that patients with STEMI who are found to have multi-vessel disease could be promptly discharged and have bystander PCI as an outpatient. This could have a significant impact on length of stay and reduce the cost of managing patients with myocardial infarction.

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Intervention in coronary bypass grafts or native vessels? Results from single-centre CABG registry

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

AIMS

Current practice guidelines do not give any direct answers on how to treat patients with CABG who present with a need for another PCI – should we treat the graft or the native vessel? We present results from a single-center CABG registry.

METHODS AND RESULTS

We analyzed 138 consecutive patients (aged 71,4 ±10,0 years, 18 % females) with existing coronary artery bypass grafts who presented to our catheterization laboratory for coronary angiography between January 2013 and April 2015. Fifty percent of the patients presented with acute coronary syndrome, 17 % for stable angina and 23 % with other indications. PCI of the SVGs was performed in 14 % of the patients (no interventions on LIMA-LAD), while PCI of the native vessels was performed in 30 % of the patients. Of those patients that had had PCI of one of the SVGs 9 (47 %) had another coronary angiography in the following years while 17 patients (41 %) who had had PCI of the native vessels had another coronary until July 2016 (P = 0,67). Three of the patients (33 %) with previous PCI of one of the SVGs had another PCI – all of them in the same SVG as previously (DES were used at index procedure); none of them had an intervention in native vessels. In the group of patients who were previously treated with PCI of native vessels 10 patients (59 %) needed another intervention – three of them were treated with PCI of SVGs, the others had a re-intervention in the native vessels. Five of those patients (50 %) had a re-intervention in the same vessel as at the index procedure.

CONCLUSIONS

In our group of patients intervention in native vessels was more common than PCI of the SVGs, yet repeated coronary angiography seems to be equally common in both groups of patients with a somehow higher rate of re-intervention among those with PCI of the native vessels at the index procedure. Further preferentially randomized studies are needed to give better answers on how to tackle patients after CABG and a need for percutaneous intervention.

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The patient's own perspective on COronary RevascularisatioN - the POPCORN study

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Left main and multivessel disease, Other Coronary Interventions

AIMS

To explore how patients would interpret key features related to CABG and PCI provided both would be feasible in a given hypothetical left main (LM) stenosis and whether particular personality traits or distress levels would impact their preference.

METHODS AND RESULTS

All patients (1145) who visited the outpatient clinic of the Erasmus Medical Center for stable coronary artery disease from June 2010 to August 2011 were eligible for this study. Patients were asked to complete a case vignette-questionnaire on a hypothetical significant LM stenosis amenable to PCI or CABG. Using this vignette, patients were asked to rate the importance of treatment strategy related consequences and relevant potential adverse clinical events. To assess the individual's personality disposition and general distress level, each patient had to complete a set of 4 standardized, validated questionnaires with psychometric properties.Overall 89% of patients preferred PCI to CABG in reply to the case vignette-questionnaire. In comparison with patients who preferred CABG, patients who chose PCI gave higher ratings to the risk for stroke (4.09 vs. 3.30, $p<0.001$) and bleeding (3.56 vs. 3.01, $p<0.001$). In contrast, duration of in-hospital stay and recovery time were considered as not important to patients who would prefer CABG (2.01 vs. 2.93, $p<0.001$ and 2.32 vs. 3.06, $p<0.001$ respectively). Type D personality, depression and anxiety were all associated with a relatively higher preference for CABG as revascularization strategy.

CONCLUSIONS

1. PCI is the preferred strategy despite having a higher risk for repeat revascularization and the need for more medication (DAPT).
2. Risk for stroke was the most important argument to opt for PCI over CABG.
3. Patients with type D personality grant particular weight to the risk for repeat revascularization, in-hospital stay, recovery time and need for additional medication.

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Is J-CTO score a good predictor of results in CTO percutaneous interventions?

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

To estimate the prevalence and demographic profile of chronic total occlusions (CTOs) in our centre. To evaluate the accuracy of J-CTO score to select best approach and predict results in percutaneous treatment of CTOs.

METHODS AND RESULTS

A retrospective study was performed in our centre in patients in whom a coronary angiography was indicated by their physician, after a diagnosis of stable angina or an acute coronary syndrome. Those patients in which a CTO was observed and a percutaneous treatment attempt was performed between January 2015 and December 2016 were included.

The J-CTO score had been calculated in all of the patients before treatment attempt, so as to assess the potential difficulty of the procedure and better select the most appropriate approach (antegrade, retrograde or both).

A total of 83 patients, median age 66 years old (IQ 56-74) and 82% males, were included. This represents 9.2 CTO treatment attempts for every 100.000 inhabitants a year.

The prevalence of one vessel (32%), two vessels (34%) and three vessels (34%) disease was similar in all of the patients. The prevalence of multiple CTOs in a patient was 17%, and its frequency was particularly high in patients with three vessels disease that had undergone previous CABG.

The two coronary arteries that were occluded in most of the cases were LAD (in 41% of the patients) and RCA (in 53% of the patients).

Medium J-CTO score was 1.4 (SD 0.94) and more than half of the patients (53%) showed a J-CTO score 0 or 1, that revealed a low or intermediate degree of technical difficulty. According to the level of complexity, an antegrade or mixed (antegrade and retrograde) approach was selected in most of the cases (95%).

Technical success, defined as TIMI 3 flow after stent implantation or balloon angioplasty, was more frequently reached in patients with low J-CTO score (0-1) (88.6%) compared to those with high J-CTO score (2-4) (46,1%) $p<0.0001$. No major complications were registered.

CONCLUSIONS

There is an increasing tendency in attempting to treat CTOs, in relation with recent advances in techniques and materials and the reduction of major complications.

The J-CTO score is an useful tool that allows to select the most appropriate approach and technique and predicts the probability of success when attempting to percutaneously treat a CTO.

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Impact of diabetes mellitus on five-year clinical outcomes after everolimus-eluting stent implantation

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

AIMS

We aimed to compared the clinical outcomes up to 5 years after EES implantation in diabetic and nondiabetic patients.

METHODS AND RESULTS

The study population comprised 1218 consecutive patients undergoing the first EES implantation between January 2010 and December 2011: non-DM patients, 738; patients with noninsulin-dependent DM (NIDDM), 345; and those with insulin-dependent DM (IDDM), 135. The mean follow-up period was 1659 ±597 days. The rate of major adverse cardiac event (a combination of all-cause mortality, myocardial infarction, and TLR) was significantly higher in NIDDM and IDDM groups than those of non-DM group (34.4% vs. 47.1% vs. 26.1%, P <0.0001). Compared with the non-DM group, the rates of target vessel revascularization and target lesion revascularization of the NIDDM group were not significantly different (18.5% vs. 21.9%, P=0.16 and 11.0% vs. 14.9%, P=0.09), whereas those of the IDDM group were significantly higher (18.5% vs. 29.8%, P=0.002 and 11.0% vs. 24.1%, P=0.0002).

CONCLUSIONS

IDDM was associated with higher rates of adverse clinical outcomes for 5 years after EES implantation.

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PCI in patients with completely occluded culprit artery after pre-hospital thrombolysis

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

To evaluate in-hospital outcomes of percutaneous coronary interventions (PCI) in patients with acute ST-elevation myocardial infarction (STEMI) with completely occluded culprit artery after prehospital thrombolysis (PT).

METHODS AND RESULTS

Data were collected on all patients (n = 1103) with STEMI admitted to the coronary care unit and submitted to PCI from 2006 to 2014. Seven hundred twenty-two (65.5%) patients with completely occluded culprit artery (TIMI thrombus grade score 5) were included in the analysis. Seventy eight patients received PCI after PT were compared with 644 patients received primary PCI. The clinical and angiographic characteristics, in-hospital outcomes, as well as predictors of no-reflow phenomenon were analyzed. The composite of in-hospital death, recurrent myocardial infarction and stent thrombosis were defined as major adverse cardiac events (MACE).

Baseline clinical and angiographic characteristics were comparable between both groups. The median “pain to needle” time was 80 [50; 222.5] minutes in the PCI after PT group. The median “door-to-balloon” time was 66 [50; 95] minutes in the primary PCI group. The rates of transradial approach was comparable between groups (55.1% vs 51.6%; p=0.551). The rates of no-reflow (14.1% vs 6.2%; p=0.010) and recurrent myocardial infarction (5.1% vs 1.2%; p=0.032) were significantly higher in the PCI after PT group. The rates of death (5.1% vs 5.4%; p=0.910), stent thrombosis (3.8% vs 1.2%; p=0.106), as well as MACE (9% vs 7.1%; p=0.558) were comparable between the groups. After multivariate adjustment, completely occluded culprit artery after prehospital thrombolysis remained an independent predictor of no-reflow (odds ratio (OR) 2.5; 95% confidence interval (CI) 1.2-5.2; p=0.016) along with age (OR 1.03; 95% CI 1.003-1.06; p=0.031) and blood glucose level (OR 1.17; 95% CI 1.08-1,25; p<0.001).

CONCLUSIONS

PCI in patients with STEMI and completely occluded culprit artery after prehospital thrombolysis associated with higher level of no-reflow and recurrent myocardial infarction. Completely occluded culprit artery after prehospital thrombolysis was an independent predictor of no-reflow during PCI.

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Polymer-free biolimus-A9-coated stent for patients at high bleeding risk: one-year results from the BioFreedom Japan trial

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

AIMS

The aim of this study was to test in a Japanese population the hypothesis that safety and efficacy of the BioFreedom BA-9-coated stent in patients at high bleeding risk (HBR) and 1-month DAPT are similar to the results of the LEADERS FREE trial.

METHODS AND RESULTS

This study was designed as a companion trial to the randomized double-blind LEADERS FREE trial. It used a very similar protocol that included the same patient selection criteria for high bleeding risk, DAPT regimen of 1 month, endpoint definitions, follow-up time points, adjudication principles, and statistical analysis methods. The study sought to confirm the hypothesis that in a Japanese patient population the safety of the BioFreedom stent is non-inferior, and the efficacy is superior to the bare-metal stent arm of LEADERS FREE.

A total of 140 patients were enrolled and received on average 1.6 stents/patient. The leading criteria for rendering patients to be at HBR were age>75y (62%), need for oral anticoagulation on top of DAPT (31%), poor renal function (18%), anemia (18%), and major surgery planned within 1y (13%). Many patients qualified through several criteria.

The mean age of the selected HBR population was 76.2y, 43.6% had multivessel disease, 39.3% were diabetic, 25.7% had atrial fribrillation, 29.3% had a prior PCI, and 16.4% had a history of stroke.

The main indication for PCI was stable angina (60.7%), followed by silent ischemia (25%), unstable angina (8.6%), NSTEMI (4.7%), and STEMI (1.4%). The majority of procedures were done through the radial access. Patients were prescribed with 1 month of DAPT.

Patients adhered very closely to the DAPT regimen. Only 2.1% discontinued before 1 month, and 1.4% stayed on DAPT for >1 month. At 1y follow-up, the incidence of cardiac death was 0/140 (0%), non-cardiac death 3/140 (0.69%), myocardial infarction 1/140 (0.71), definite/probable stent thrombosis (ST) 0/140 (0%), and BARC 3-5 bleeding 7/140 (5.0%). The primary safety endpoint, a composite of cardiac death, myocardial infarction, and definite/probable stent thrombosis was reached by 1 patient (0.71%). The primary efficacy endpoint, clinically driven target lesion revascularization (TLR), was reached by 2/140 (1.4%) of patients.

Thus, the study results confirmed the hypothesis of non-inferiority for safety and superiority for efficacy in comparison with the bare-metal stent arm of LEADERS FREE.

CONCLUSIONS

In this study, the BioFreedom drug-coated stent showed similar and favorable outcomes for safety and efficacy in a Japanese population of patients at high bleeding risk and only 1 month of DAPT, in comparison with the randomized double-blind LEADERS FREE trial.

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The natural course of non-culprit coronary artery lesions; analysis by serial quantitative coronary angiography

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

AIMS

Nonculprit lesions are the major cause of future cardiovascular events. However, the natural course of nonculprit lesions and angiographic predictors of plaque progression are not well-studied.

METHODS AND RESULTS

From July 2008 to March 2013, we retrospectively identified 320 patients with 640 nonculprit lesions that had received two serial angiographic follow-ups at 9-months and 24-months from the index PCI procedure at a single institution. Patients with a lesion length of ≥2mm and luminal narrowing ≥ 30% at baseline angiography were included in the analysis.Quantitative coronary angiography(QCA) analysis was performed for all lesions. The study endpoints were nonculprit-ischemia driven revascularization (IDR) and the rate of diameter stenosis (DS) progression during the follow-up period. Those with progression of DS more than 12% per year were defined as ‘rapid progressors’.

Baseline QCA of the 640 lesions revealed a lesion length of 11.4±7.7mm with a DS of 45.1±10.5%, 29.8% had a DS>50%, and 2.5% had a DS>70%.

During the median follow-up period of 737 days (640.3 patient-years), 20 lesions in 20 patients (6.3%) required nonculprit-IDR. Independent predictors of nonculprit-IDR were diabetes (hazard ratio [HR] 2.93, 95% confidence interval [CI] 1.07 – 8.01, p=0.036) and lesion type B2/C (HR 4.02, 95% CI 1.61 – 10.00, p=0.003). The initial DS was 45.1±10.5% and the rate of DS progression was 2.19±5.47%/year. The presence of one or both of the two major risk factors was associated with significant DS progression (3.0±6.8% vs. 3.5±6.1% vs. 6.8±9.9% for lesions with 0, 1 and both risk factors, p<0.001).

Using a multiple logistic generalized estimating equations modelfor repeated measures, patients with diabetes mellitus and type B2/C lesions showed faster progression of angiographic stenosis compared with those without these factors. According to the presence of 0, 1 or 2 risk factors, the final DS was 46.0±9.7% vs. 49.5±12.0% vs. 55.5±14.6%, p<0.001 and the delta DS was 3.0±6.8% vs. 3.5±6.1% vs. 6.8±9.9%, p<0.001, respectively.

Among the 640 lesions, 38 lesions (5.9%) in 33 patients were defined as rapid progressors. Predictors of rapid progressors were lesion type B2/C (HR 1.998, 95% CI 1.006 – 3.791, p=0.048) as a lesion-related risk factor and diabetes mellitus (HR 3.725, 95% CI 1.937 – 7.538, p<0.001) as a patient-related risk factor. Lesions with both risk factors of diabetes and lesion type B2/C were at the highest risk of rapid progression (13/273 [4.8%] vs. 12/283 [4.0%] vs. 13/84 [15.5%], p<0.001 for lesions with 0, 1, and 2 risk factors, respectively), with an odds ratio of 3.250 (95% CI, 1.451–7.282), compared to type A/B1 lesions in non-diabetic patients.

CONCLUSIONS

Nonculprit-IDR was not uncommon during the 2-year follow up period in our population. The major risk factors of nonculprit lesion progression were diabetes and lesion type B2/C.

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A sirolimus-coated balloon in the treatment of coronary lesions in patients with ACS

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

AIMS

The purpose of the study was to evaluate the clinical outcomes of sirolimus-coated balloon DEVOIR in patients with acute coronary syndrome (ACS) in a real-world setting.

METHODS AND RESULTS

In this real-world observational study, 184 patients with ACS were enrolled (196 lesions). Male patients were 79.9% of the total study population and 47.8% of patients had hypertension. Unstable angina accounted for 65.2% of patients, ST segment elevation myocardial infarction (STEMI) for 22.8% of patients and non-STEMI for 12.0% of patients. The majority of the lesions was located in LAD (46.9%) followed by LCx (26.5%) and RCA (21.9%).

The primary endpoint of the study was major adverse cardiac events (MACE) rate at 12 months. MACE was defined as a composite of cardiac death, target vessel myocardial infarction (TV-MI) and target lesion/vessel revascularization (TLR/TVR).

One year follow-up was completed in 87.5% of the patients. The incidence of MACE was 5.6%. The events included 5.0% of TLR and 0.6% of TV-MI with no cardiac death reported at 1 year.

CONCLUSIONS

The results showed that treatment of patients presenting ACS is safe and effective with the DEVOIR sirolimus-coated balloon. Indeed, a low rate of MACE with no cardiac death was reported at one-year.

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Treatment of coronary in-stent restenosis with sirolimus-coated balloon catheter

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

AIMS

In recent years, drug-coated balloon (DCB) has emerged as an alternative option for the treatment of in-stent restenosis (ISR). We aimed to evaluate the safety and efficacy of the sirolimus-coated balloon DEVOIR in patients with coronary ISR.

METHODS AND RESULTS

One hundred and seventy-two patients with coronary ISR were treated with the sirolimus-coated balloon DEVOIR in a prospective, multi-centre and post-marketing study. The primary endpoint of the study was the rate of major adverse cardiac event (MACE), which is defined as the composite of cardiac death, target-vessel myocardial infarction (TV-MI) and target lesion/vessel revascularization (TLR/TVR) at one year.

Male population constitutes 79.7% of the study total population. More than half of the patients presented with diabetes mellitus (53.5%) and 46.5% with acute coronary syndrome. According to Mehran classification, the ISR lesions were categorised as focal (61.4%), diffuse intra-stent (17.9%), diffuse total occlusion (9.8%) and diffuse proliferative (8.7%). To date, 154 (89.5%) patients completed one-year clinical follow-up. The incidence of MACE is 5.8%, mainly driven by 5.2% of TLR/TVR and 0.6% of TV-MI. No cardiac death was reported at one-year.

CONCLUSIONS

The use of sirolimus-coated balloon DEVOIR for the treatment of coronary ISR is safe and effective with a low rate of events including repeat revascularization up to one-year clinical follow-up.

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Comparison of clinical outcomes after treatment with a sirolimus-coated balloon in patients with coronary lesions in small vessels vs. large vessels

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

AIMS

To compare the clinical outcomes of the patients with small coronary vessels versus patients with large coronary vessels after PCI with the sirolimus-coated balloon DEVOIR.

METHODS AND RESULTS

Patients from a real-world population with small vessels (reference vessel diameter ≤2.75 mm) and with large vessels (reference vessel diameter ≥3 mm) were enrolled in this non-randomized, prospective multicentre study. The primary endpoint of the study was major adverse cardiac event (MACE) rate at 12 months. MACE was defined as a composite of cardiac death, target vessel myocardial infarction (TV-MI) and target lesion/vessel revascularization (TLR/TVR).
A total of 248 patients presented a small vessel (SV) lesion and 135 patients presented a large vessel (LV) lesion. A high proportion of patients was diabetic in both groups (42.7% vs. 48.9%, p=0.25). Patients with acute coronary syndrome also accounted for almost half of the population in both groups with no significant difference (47.6 % vs. 48.9 %, p=0.81). The mean stent diameter and length for SV group were 2.39±0.25 mm and 21.51±7.14mm. While in LV patients group, the mean stent diameter and length were 3.18±0.28 mm and 22.58±6.20mm. The 12 months follow-up was completed in 86.3% of the SV group and 88.9% in the LV group. The incidence of MACE in both groups was comparable (5.1 % vs. 3.3%, p=0.44). The most reported event in both groups was TLR (4.7% vs. 2.5%, p=0.39).

CONCLUSIONS

The results suggest that the use of the DEVOIR sirolimus-coated balloon is associated with good clinical outcomes whether in small or large vessel lesions. There was no significant difference reported between the two groups in terms of MACE.

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The South African Heart Association (SHARE) -TAVI registry

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

AIMS

The South African Heart Association TAVI Registry, the first of its kind in Africa ,was set up to prospectively study all patients receiving TAVI in South Africa, delineating the unique challenges faced and compare outcomes to international data.

METHODS AND RESULTS

The SHARE - TAVI registry is a prospective multicentre registry, designed to capture data for all patients undergoing TAVI across South Africa in a dedicated web-based database.
Eleven centres performing TAVI in South Africa are actively capturing data into the registry. Nine of the 11 centres perform less than 20 implants/ year.
Outcomes are reported as defined by the VARC-2 criteria.
From Sept 2014 to Jan 2017, a total of 328 patients were entered [this is not the total number of patients considered for TAVI] and 238 of these received implants. Of the 96 patients who did not receive an implant, the reason in the vast majority was due to declined funding.
The mean age was 80 yrs and mean risk prediction values were 7.8% [STS PROM]; 22.8 [logEuroSCORE] and 7.4% [EuroSCORE 2], making the population comparable to the US Corevalve Pivotal trial population and the German Aortic Valve registry [GARY].
Transfemoral access was used in 90% with overall procedural success in 93%. Peri-operative mortality was 4.62 and complications included stroke [0.8%], bleeding [6.7%], vascular complication [7.56%] and pacemaker implantation of 6.3% was lower than in comparable registries.
Mean ICU stay was 2.3 days and hospital stay 5.5 days. 30-day all-cause mortality was 10.7% [compared to 3.4% in US Corevalve and 5.6% for GARY] and 1-year mortality was 15.63% [compared to 14,2% in US Corevalve and 20% for GARY].

CONCLUSIONS

In resource-constrained economies, funding remains a major challenge for the appropriate use of TAVI. The outcomes for predominantly low volume centres were worse in the short term but comparable to international figures at 1 year.

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Patient specific computer simulations to elucidate the role of contact pressure in the development of new conduction abnormalities after catheter-based implantation of a self-expanding aortic valve

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

AIMS

Patient-specific computer simulations are used to quantify and compare the contact pressure generated by an aortic device on the atrioventricular conduction pathway in patients with and without new conduction abnormalities after TAVI.

METHODS AND RESULTS

One-hundred-twelve patients underwent TAVI with a self-expanding CoreValve (n=95) or CoreValve Evolut R (n=17) (Medtronic, MN, USA). A 3D patient-specific aortic model, including the (calcified) native leaflets, left ventricular outflow tract and ascending aorta,was segmented for each patient from preoperative cardiac CT images (Mimics v18.0). Also the inferior boundary of the membranous septum was identified and used as anatomical landmark for the His bundle and the take-off of the left bundle branch. Starting from this boundary, a region of interest in vicinity of the atrioventricular (AV) conduction system was defined that includes the proximal part of the left bundle branch. Finite-element simulations were performed in Abaqus (Abaqus v12.0) to virtually implant the Medtronic CoreValve or CoreValve Evolut R devices at the same implantation depth as done in reality for each patient. From each simulation, the force experienced by the aortic surface due to the contact with the device frame was extracted. From this contact force and the area where it was exerted, the following parameters were assessed: (i) maximum contact pressure in the region of interest, and (ii) contact pressure index (i.e. the percentage of the region of interest in the vicinity of the AV conduction system subjected to contact pressure). A 2-tailed Mann-Whitney test was performed (SPSS) to determine differences in contact pressure levels and contact pressure index between patients with and without new conduction abnormalities (new CA), with the significance level at 0.05. Receiver-operating characteristic (ROC) curve and sensitivity-specificity analysis were performed for the investigated parameters.

Sixty-two patients (55%) developed new TAVI-related left bundle branch block or high degree atrioventricular block (second degree AVB Mobitz 2 or third degree AVB). In those patients, maximum contact pressure and contact pressure index were both significantly higher in comparison to patients without new CA: 0.47 MPa vs 0.25 MPa and 33% vs 13% ($p<0.001$), respectively. ROC curve analysis revealed an area under the curve (AUC) of 0.79 and 0.78 for maximum contact pressure and contact pressure index. A cut-off value of 0.36 MPa for the maximum contact pressure was associated with a sensitivity, specificity, PPV, NPV and accuracy of 84%, 66%, 75%, 77% and 76%. This was 97%, 52%, 71%, 93% and 77%, respectively for a contact pressure index of 14%. The accuracy of prediction further increased when combining both contact pressure parameters.

CONCLUSIONS

Contact pressure generated by the valve on the AV pathway can be quantified pre-operatively by patient-specific computer simulations which help to predict which patients will or will not develop new CA after TAVI. Future prospective studies will investigate the impact of these CT-based computer simulations to assist TAVI operators in their pre- and peri-operative decision-making.**Acknowledgement**

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Baseline and dobutamine stress haemodynamic physiology of the severely stenotic aortic valve before and after TAVI

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

AIMS

Although symptoms from aortic stenosis (AS) arise during exercise, physiologic assessment almost always takes place at rest. Stress hemodynamics might more accurately identify patients who benefit from intervention.

METHODS AND RESULTS

This study described the relationship between transvalvular pressure gradient (DP) and transvalvular flow (Q) before and after transcatheter aortic valve implantation (TAVI). We recruited routine TAVI's but excluded valve-in-valve procedures or concomitant moderate-to-severe disease of other valves. During graded dobutamine infusions both before and after TAVI, 0.014" pressure wires in the aorta and left ventricle (LV) continuously measured DP while a pulmonary artery catheter regularly assessed cardiac output by thermodilution. 16 subjects underwent assessment. Before TAVI, DP did not display a consistent relationship with Q. Neither linear (median R^2 0.16) nor quadratic (median R^2<0.01) models at rest predicted stress observations, implying that a severely stenotic valve does not behave like a pure resistor or orifice. Under stress conditions, the unitless ratio of aortic to left ventricular pressures during systolic ejection correlated best with post-TAVI flow improvement. After TAVI, we observed a highly linear relationship (median R^2 0.96) indicating a valid valve resistance, median 0.645 (interquartile range 0.405 to 1.152) Woods units.

CONCLUSIONS

The existing Gorlin orifice model does not correctly describe AS pathophysiology. Resting assessment cannot reliably predict stress hemodynamics, suggesting that some patients with exertional symptoms may be missed without routine provocative maneuvers. The logical consequence would be a trial of TAVI in patients who are not current candidates due to insufficient gradient at rest but with an abnormal stress aortic valve index (SAVI), measured as the stress aortic/LV systolic pressure ratio.

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The impact of PCI in octogenarian patients: a report from Nationwide Real World Database of 18,288 patients enrolled in the Japan Acute Myocardial Infarction Registry (JAMIR)

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

AIMS

The Japan AMI Registry (JAMIR) has been established to provide nationwide real-world database of Japanese patients, who have the longest life expectancy in the world. We sought to investigate the impact of PCI in octogenarian AMI patients.

METHODS AND RESULTS

The JAMIR consists of a total of 18,288 AMI patients (male/female 13,763/4,525, age 68.4±13.2 years) hospitalized between 2011 and 2013. This retrospective, multicenter, observational study showed 89.0% of patients undergoing direct PCI and 7.2% of in-hospital mortality. The JAMIR included 3,681 (20%) octogenarian patients, of whom, 3,043 patients (82.7%) underwent PCI. The rate of patients undergoing PCI (82.7% vs 90.8%, P<0.001) was lower, and the in-hospital mortality (13.9% vs 4.9%, P<0.001) was higher in octogenarians compared with younger (<80 year-old) patients. Additionally, octogenarians undergoing PCI had a significantly lower rate of in-hospital mortality than those without PCI (10.6% vs 30.0%, P<0.001). In multivariate analysis, anterior wall infarct (odds ratio [OR]: 1.69; 95% confidence interval [CI]: 1.22–2.34; P=0.002), ST-segment elevation myocardial infarction (OR: 1.6; 95% CI: 1.028 – 2.49; P=0.037), Killip II (OR: 2.37; 95% CI: 1.53–3.68; P=0.027), Killip IV (OR: 12.25; 95% CI: 8.13–18.45; P<0.001), and non-PCI (OR: 2.27; 95% CI: 1.40–3.68; P<0.001) were independent predictors of in-hospital death in octogenarians.

CONCLUSIONS

In this large registry of JAMIR characterized as the advanced age of the study population (including 20% of ≥80 year-old patients), the reasonable in-hospital outcomes may justify consideration of PCI for octogenarians with AMI.

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Clinical outcomes in diabetic patients treated with sirolimus-coated balloon: results from Nanolute registry

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

AIMS

We sought to assess the influence of diabetes on the safety and efficacy of the new treatment modality called MagicTouch SCB (Concept Medical Research Pvt. Ltd.) angioplasty for the reduction of restenosis in patients with coronary artery disease.

METHODS AND RESULTS

We analysed one hundred seventy two patients with Diabetes Mellitus with lesions in native coronary vessels. Nanolute is the multi-centre prospective real world registry. The principle endpoints of the study were Major Adverse Cardiac Event (MACE) at 6 months and 12 months. MACE is defined as a composite of Cardiac Death, Target Vessel Myocardial Infarction (TV-MI) and Target Lesion/Vessel Revascularization (TLR/TVR).Total 210 MagicTouch SCB devices were employed to treat 185 lesions in 172 diabetic patients. The study was dominated by male population (80.81%). More than half of the patients had hypertension (65.7%). 59.9% patients has previous history of Percutaneous Coronary Intervention (PCI). Diabetes is associated with diffused long lesions. In this study 32.43% patients had long lesions and 63.24% had small vessel lesions. 98.26% patients completed 6 months follow-up. The incidence of MACE at 6 months was 2.96% at 6 months. 12 months follow-up was available for 89.53% of the patients. MACE rate was reported as 4.55%, mainly comprised of TLR (3.9%) and cardiac death (0.65 %.) at 12 months.

CONCLUSIONS

1 year clinical results after treatment of MagicTouch SCB demonstrated low rates of MACE in diabetic patients hence proving its efficacy and safety in this setting.

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The coronary collateral flow index is correlated with the palmar collateral flow index, indicating systemic collateral coherence in individual patients

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

AIMS

Experimental data show that the extent of the collateral circulation in different organs is interrelated specific mouse strains. The aim of this study is to investigate whether this interrelation is also present in individual patients

METHODS AND RESULTS

Methods: In 50 patients with a chronic total occlusion both the coronary collateral flow index (CFI) and the palmar CFI was measured. The coronary CFI determined as the ratio [coronary wedge pressure −5mmHg] / [mean aortic pressure – 5mmHg]. The palmar CFI was determined as the ratio [average blood pressure of the thumb during radial artery occlusion] / [blood pressure of the thumb prior to occlusion]. The correlation between both CFI's was determined. Also the relation with both indices with clinical variables was investigated using uni- and multivariate analysis.

Results: Mean coronary CFI was of 0.51±0.16 and mean palmar CFI was 0.82 [0.73-0.91]. The coronary CFI and palmar CFI were significantly correlated (Spearman's Rho=0.48, p=0.001). Coronary CFI was 22% lower in patients with a low palmar CFI (<0.82) as compared to patients with a high palmar CFI (≥0.82; 0.43±0.12 versus 0.57±0.18, p=0.03). In multivariate analysis coronary CFI was significantly positively correlated with the palmar CFI and the duration of angina pectoris. Coronary CFI was negatively correlated with peripheral artery disease and systolic blood pressure.

CONCLUSIONS

The coronary- and palmar CFI are significantly correlated, implicating collateral coherence between different vascular beds in humans.

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Effect of renal denervation on coronary flow reserve in patients with resistant hypertension

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THEME: Interventions for Hypertension
TOPIC(S): Renal denervation

AIMS

Renal denervation has shown effects on several cardiovascular surrogate markers. Coronary flow reserve (CFR) is impaired in hypertension. However, there are no data on the effect of RDN on CFR. The objective was to assess the effect of RDN on CFR.

METHODS AND RESULTS

Twenty-six consecutive patients with RH (9 female and 17 male; mean age 62±8 years; mean number of antihypertensive drug 4.2±1.6) underwent bilateral RDN. CFR was assessed at baseline and 6 months after intervention. Mean flow velocity was measured in the left anterior descending artery by transthoracic Doppler echocardiography at baseline and during adenosine infusion. Furthermore, we assessed carotid artery intima-media thickness (CIMT) at baseline and 6 months post-intervention.
Systolic office blood pressure (BP) was reduced at follow-up (174±24 vs. 162±27mmHG; p=0.01).
CFR remained unchanged six months after intervention (2.7±0.6 vs 2,7±0.7; p=0.67). No significant reduction in CIMT (0.70±0.24 mm vs 0.73±0.24 mm; p=0.29) was noted 6 months post-procedure.

CONCLUSIONS

Although RDN was associated with a reduction in systolic office BP, CFR and CIMT remained unchanged 6 months after intervention.

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Impact of manual thrombus aspiration on coronary blood flow recovery and left ventricular remodeling in patients with STEMI

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

The aim of our study was to evaluate the use of manual thrombus aspiration in patients with STEMI undergoing primary (pPCI) or rescue PCI (rPCI).

METHODS AND RESULTS

The study included 160 STEMI patients with primary (n=80) and rescue (after unsuccessful thrombolytic therapy, n=80) PCI. Patients in both groups were prospectively randomized 1:1 to either standard (n=40) or thrombus-aspiration (n=40) PCI. Post-procedural myocardial perfusion was assessed with TIMI flow grade and Myocardial Blush Grade (MBG). At discharge and at one-year follow-up all patients underwent echocardiography for evaluation of the left ventricular remodeling process (left ventricular end diastolicand systolic volumes (LVEDV, LVESV) and ejection fraction (EF)). It was found that in patients with pPCI the use of thrombus aspiration resulted in better MBG (MBG 3, 60% vs 35%, p=0.08) and TIMI flow grade (TIMI 3, 82.5% vs 55%, p=0.025) compared with the standard PCI. The incidence of ST-segment resolution (≥70%) was 75% and 42.5% in the thrombus-aspiration and standard PCI subgroups, respectively (p=0.03). The results of the manual thrombus aspiration use in the rPCI group were quite the opposite. Thus, post-procedural myocardial perfusion in the thrombus-aspiration subgroup was significantly worse than in the standard PCI subgroup (MBG 3,47.5%vs70%, respectively, p=0.03; TIMI 3, 25% vs 50%, respectively, p=0.021).The incidence of ST-segment resolution (≥70%) was lower in the thrombus-aspiration PCI subgroup (35% vs 55%in the standard PCI subgroup, p=0.075).

At one-year follow-up a greater improvement in LV ejection fraction was observed after pPCI in the thrombus-aspiration subgroup comparedwith the standard PCI subgroup (4.95% vs 1.39%, respectively, p=0.191). An increasein LVEDV was 5.97 ml in the thrombus-aspiration PCI subgroup and 17.15 ml in the standard PCI subgroup, p=0.016. There were no changes in LVESV in case of manual thrombus aspiration use; however in the standard PCI subgroup LVESV increased by 3.05 ml, p=0.624.

By contrast, in the rPCI group the use of thrombus aspiration led to 0.6% ejection fraction decrease compared with its 2.02% increase in the standard PCI subgroup, p=0.009. LVEDV increased by 24.77 ml and 15.12 ml in the thrombus-aspiration and standard PCI subgroup, respectively (p=0.051). LVESV increase was 7.85 ml vs 5.1 ml, respectively (p=0.02).

CONCLUSIONS

In patients with primary PCI the use of thrombus aspiration improves myocardial perfusion withfavorable effect on the left ventricular remodeling in the long term follow-up.On the other hand, in the rescue PCI group the use of manual thrombus aspirationled to the deterioration of myocardial perfusion and left ventricular contractile function.

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Impact of diabetes mellitus on post-procedural FFR in patients undergoing PCI

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

AIMS

FFR after PCI is a predictor of cardiovascular events at follow-up. FFR in patients with diabetes might be influenced by microvascular dysfunction. Our aim was to investigate the differences in FFR after PCI in patients with and without diabetes.

METHODS AND RESULTS

We conducted a registry in which all consecutive patients underwent FFR evaluation after successful PCI. FFR measurements were performed with a novel over-the-wire monorail catheter (Navvus, ACIST Medical Systems, Eden Prairie, MN) inserted over the previously used coronary guidewire to approximately 20mm distal of the most distal stent edge. FFR measurements were performed in resting conditions and under maximum hyperaemia with intravenous Adenosine. Diabetes mellitus was defined as treatment with either oral hypoglycaemic medication or insulin. A total of 701 patients (131 with diabetes mellitus, 19%) were included with 954 successfully treated and measured lesions. Overall, mean FFR value during resting condition was 0.96±0.04 and 0.91±0.06 under maximum hyperaemia. Average FFR during resting condition was 0.95±0.05 in patients with diabetes mellitus vs. 0.96±0.04 in non-diabetics, $p<0.001$. Mean FFR under maximum hyperaemia was 0.89±0.07 in patients with diabetes mellitus vs. 0.91±0.06 in non-diabetics, $p=0.002$. Furthermore, out of the 131 diabetic patients, 11 patients had at least 1 lesion with an FFR ≤0.80 (8.4%) after angiographic successful PCI, as compared to 23 out of the 547 patients without diabetes mellitus (4.2%), $p=0.036$. Of note, no differences in FFR were found between diabetic patients taking oral hypoglycaemic medication (n=77) and insulin dependent patients (n=54).

CONCLUSIONS

FFR values directly measured after successful PCI are significantly lower in diabetic patients and may mimic microvascular dysfunction.

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Do we need urgent vascular surgical backup to perform lower limb endovascular interventions? A cardiologist point of view

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal

AIMS

This retrospective study aimed to assess the need for vascular surgical back up during lower limb peripheral endovascular interventions.

METHODS AND RESULTS

902 patients were included in this study from January 2004 to February 2014, 60 % of patients presented with critical limb ischemia (CLI), 40 % of patients with claudication

DATA COLLECTION AND ANALYSIS:

Thirty nine percent of lesions were supra inguinal, 27 % were infra inguinal, and 34 % were infra-genicular lesions. TASC were A=40%, B=30%, C=18% and D =12%.

The success rate was 92.3% (833/902 patients) with good immediate outcome.

Â' 20 patients (2.2%) had in-hospital mortality (16 patients (1.7%) cardiac death and 8 patients 0.84%) due to septicemia.

Â' The in-hospital morbidity occurred in 55 patients (6%), mainly related to access site complication, 37 patients (4.1%) hematoma, 13 patients (1.4%) dissection and treated with stenting.

Â' There was no need for urgent surgical intervention in any case.

CONCLUSIONS

This single center experience concluded that peripheral vascular intervention does not necessitate the presence of onsite surgical backup.

Instead it seems enough to have a protocol for transfer of patients to vascular surgical center if needed

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Platinum-chromium vs. cobalt-chromium durable polymer everolimus-eluting stents in calcified lesions: a patient-level pooled, propensity score-adjusted analysis in participants of clinical trials

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

AIMS

The risk of adverse events following coronary stenting is increased in severely calcified lesions, related to impaired stent expansion, incomplete stent apposition, and decreased stent visibility in severely calcified lesions.

METHODS AND RESULTS

Refinements in stent design may be particularly important for the treatment of severely calcified lesions. The Xience V everolimus-eluting stent (EES) has a cobalt-chromium backbone, while the more recently introduced Promus Element EES has a novel, platinum-chromium alloy that increases radial force and visibility. In the present patient-level pooled analysis of participants in the TWENTE and DUTCH PEERS trial, we assessed post-hoc the impact of the type of EES on clinical outcome in patients treated for severely calcified lesions. We assessed patients who had been treated by the same operators at Thoraxcentrum Twente for non-ST-elevation acute coronary syndromes or stable angina. Three-year follow-up was evaluated for the composite clinical endpoint target vessel failure (TVF) and the individual components thereof: cardiac death, target vessel myocardial infarction (MI), and target vessel revascularization.

We assessed clinical outcome of all 282 (23.1%) trial participants with severely calcified lesions, who had been treated at Thoraxcentrum Twente with Xience V EES (n=149) or Promus Element EES (n=133). A significantly lower rate of target vessel MI was observed in patients treated with Promus Element versus Xience V (2.0% vs. 9.1%; p-Logrank=0.02, adjusted p-Logrank=0.03). The rates of cardiac death and target vessel revascularization were similar for both EES; as a result, there was only a numeric difference in TVF that did not reach statistical significance (14.8% vs. 18.9%; p-Logrank=0.33). Definite-or-probable stent thrombosis rate did not differ between both EES (2.0% vs. 2.3%; p-Logrank=0.89).

CONCLUSIONS

In patients with severely calcified target lesions, the 3-year rate of target vessel MI was lower for Promus Element versus Xience V EES. Target vessel failure and other individual components thereof showed no statistically significant between-EES difference.

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Ultrathin strut biodegradable polymer sirolimus-eluting stent vs. durable polymer everolimus-eluting stent for coronary revascularisation

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

AIMS

Biodegradable polymer SES (BP-SES) have been reported to be non-inferior compared with durable polymer EES (DP-EES) in RCT. We aim to validate the efficacy and safety of BP-SES compared with DP-EES in an all-comers population.

METHODS AND RESULTS

Among 6001 consecutive patients (9978 lesions) who underwent PCI at Bern University Hospital between March 2011 to June 2014, 3602 patients (5961 lesions) were exclusively treated with BP-SES (N=1430, 2390 lesions) or DP-EES (N=2172, 3569 lesions). After propensity score (PS) matching, the final study population consisted of 1111 matched pairs (BP-SES 1844 lesions, DP-EES 1829 lesions). The primary device-oriented composite endpoint (DOCE) included cardiac death, target-vessel myocardial infarction (MI) and target lesion revascularization (TLR) at 1 year. Clinical indication to undergo PCI was well balanced between the two groups, including STEMI in 466 patients (21.0%), NSTEMI in 596 patients (26.8%), unstable angina pectoris (uAP) in 128 patients (5.8%) and stable coronary artery disease (CAD) in 1032 patients (46.4%). Clinical follow-up information was obtained in 94.9% of patients at 1 year. BP-SES as compared with DP-EES was associated with a similar cumulative incidence of DOCE (6.0% versus 7.9%, HR 0.76, 95%CI 0.55-1.05, P=0.09). There were no significant differences with regards to cardiac death (HR 0.68, 95%CI 0.41-1.14, P=0.15), target-vessel MI (HR 0.84, 95%CI 0.50-1.40, P=0.51), and TLR (HR 0.87, 95%CI 0.52-1.45, P=0.59). The rate of definite stent thrombosis was low within 1 year in both groups (BP-SES: 0.8% versus EES 0.9%, HR 0.90, 95%CI 0.36-2.21, P=0.82). A positive interaction suggesting a potential benefit of BP-SES was observed among female patients ($p_{interaction}$=0.018).

CONCLUSIONS

In this consecutively enrolled all-comer population, BP-SES was associated with a similar efficacy and safety as compared with DP-EES.

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Six-months outcome of the ELECT trial: Sapien 3 vs. CoreValve device for TAVI

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

AIMS

The difference between the SAPIEN-3® and CoreValve® system regarding paravalvular aortic regurgitation (PVL) and clinical outcome is not elucidated yet.

METHODS AND RESULTS

The ELECT study is a single-centre, randomised controlled trial, with main focus on comparing PVL between the balloon-expandable Edwards Sapien 3® (S3) and the self-expanding Medtronic CoreValve® (MCV).
Primary endpoint was quantitative assessment of differences in the severity of post-TAVI PVL, using three different novel imaging modalities; (3D) transesophageal echocardiography (TEE), quantitative contrast angiography and magnetic resonance imaging (CMR).
Secondary endpoint included clinical outcomes according to Valve Academic Research Consortium-2 criteria.
56 consecutive adult patients suitable for trans-femoral TAVI were randomly assigned to receive either the S3 (n=29) or the MCV (n=27). Inclusion criteria were: aortic annulus diameter between ≥18 and ≤29 mm and anatomy suitable for trans-femoral TAVI.Results showed that the severity of post-TAVI PVL was non significantly higher for the MCV compared to S3 by CMR (regurgitation fraction 4.2%[IQR:2.7-10.4] vs. 2.6%[IQR:1.74-7.2]; p=0.088), quantitative contrast angiography (44% vs. 69% none/trace, 44% vs. 31% mild, 12% vs. 0% moderate; p=0.062) and TEE (67% vs. 85% none/trace, 22% vs. 15% mild, 11% vs. 0% moderate; p=0.414).Clinical outcomes at six months showed a higher incidence of stroke (19% vs. 0%; p=0.021) and mortality (19% vs. 0%; p=0.021) and a lower device success rate (85% vs. 100%; p=0.048) for MCV. No significant differences were found for TIA (0% vs. 7%), myocardial infarction (0% vs. 0%), pacemaker implantation (26 % vs. 17%), vascular complications (major: 11% vs. 4%; minor: 15% vs. 21%), bleedings (life threatening: 11% vs. 0%) or rehospitalisation (30% vs. 28%). NYHA class improvement at 6 month was significantly lower for MCV (mean improvement: 0.67 class (95%CI:0.30-1.03) vs. 1.3 class (95%CI:0.97-1.65); p=0.041).

CONCLUSIONS

The ELECT-trial is the first randomised quantitative comparison of post-TAVI PVL between S3 and MCV. S3 was associated with lower post-procedural PVL and demonstrated superiority in clinical outcomes at six months with respect to mortality rate, stroke, NYHA class improvement and device success rate. (ClinicalTrials.gov number NCT01982032).

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Occurrence and predictors of acute stent recoil, comparison between the Xience Cobalt Chromium stent and the Promus Premier Platinum Chromium stent

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

AIMS

Acute stent recoil is frequently observed after PCI. Different stent designs may result in varying degrees of acute recoil. Aims of this current study were to compare recoil in 2 different stent types and identify predictors of significant recoil.

METHODS AND RESULTS

From a large registry of “all-comers” treated with either the Xience Cobalt Chromium stent (Abbott Vascular, Santa Clara, CA, USA) and the Promus Premier Platinum Chromium stent (Boston Scientific, Natick, MA, USA), a random sample of 100 patients was drawn. Quantitative coronary angiography analysis was performed and Acute stent recoil was defined as the minimal luminal diameter (MLD) of the last inflated balloon minus the MLD after, divided by the MLD of the last inflated balloon. Significant acute stent recoil was defined as recoil ≥10%. A total of 123 successfully treated lesions (61 Xience vs. 62 Promus) in 100 patients (70% men) were analysed. No differences in lesions characteristics, number of stents or stent length were observed between the 2 groups. Neither any differences in treatment strategy (maximum balloon size, pre- and/or post dilatation, bailout stenting) existed between the groups. Acute stent recoil of 8.6%±4.9% was observed in the Xience group vs. 8.7%±4.2% in the Promus group, p=0.970. In a multivariate model for the occurrence of significant acute stent recoil, only a stent/vessel ratio ≥1 (hazard ratio 3.53 [1.58-7.85], p=0.002) and a balloon/stent ratio >1 (hazard ratio 4.07[1.22-13.60], p=0.022) were identified as significant predictors.

CONCLUSIONS

In this population of “all-comers”, no significant differences were observed in the extent of acute stent recoil between patients treated with the Xience Cobalt Chromium stent and the Promus Premier Platinum Chromium stent. A larger stent/vessel ratio and a larger balloon/stent ratio were associated with a higher chance of significant acute stent recoil ≥10% after successful PCI.

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One-year outcomes after a biodegradable-polymer sirolimus-eluting stent implantation in patients with long coronary artery lesions

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

AIMS
We sought to evaluate the long-term clinical outcomes of the Amazonia SIR stent for the treatment of long coronary artery lesions in real-world population.

METHODS AND RESULTS
In this study, a total of 1098 patients with 1188 long coronary artery lesions (≥28mm) were treated with the Amazonia SIR biodegradable-polymer sirolimus-eluting stent. The primary endpoint was the rate of major adverse cardiac events (MACE) at one year, defined as a composite of cardiac death, target vessel myocardial infarction(TV-MI), and target lesion/vessel revascularization (TLR/TVR). Secondary endpoints include stent thrombosis (ST) and MACE rates up to three years. Clinical follow-ups of this study are on-going.
Among the 79.8% patients who reached the one-year clinical follow-up, the rate of the cumulative incidence of MACE was 3.3% (29 patients). The MACE was driven by cardiac death (0.3%), TV-MI (0.7%) and TLR/TVR (2.3%). ST occurred in 1.0% of cases. To date, the 2-year clinical follow-up data (58.7% of patients) include a single additional TLR/TVR.

CONCLUSIONS
The use of Amazonia SIR stent showed a low MACE rate at one-year clinical follow-up for the treatment of long lesions in a real-world population.

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New pacemaker timing after TAVI

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

AIMS

TAVI is frequently complicated by high-grade atrioventricular block, requiring a permanent pacemaker. This study aimed to investigate the minimum required admission time to discharge patients post TAVI safely regarding need for permanent pacemaker.

METHODS AND RESULTS

A retrospective analysis of all patients who underwent a TAVI in a single centre from 2008 till august 2016 (n=532) with either a balloon-expandable valve (Sapien, Sapien XT or Sapien 3, Edwards Lifesciences Inc., Irvine (SAPIEN)) or a self-expandable valve (CoreValve, Evolut R, Medtronic Inc., Minneapolis (MCV)). Thirty four patients with pre-procedural permanent pacemaker or already scheduled to undergo a pacemaker implant were excluded.

Of all patients that received a permanent pacemaker implantation (PPI) before discharge, we evaluated electrocardiograms (ECGs) at baseline, and ECGs and clinical records of telemetry post-TAVI to identify high-grade atrioventricular block (AVB).Out of 498 patients, 54 patients (9,2%, 80±7 years, EuroSCORE I: 18±10) received a PPI before discharge. In the Sapien group 9.3% (34/364), in the MCV group 14.9% (20/134).

Conduction abnormalities in PPI patients developed after TAVI in 70% (38/54) within 48 hours, in 21% (5/54) between 48 and 72 hours, in 5.6% (3/54) between 72 and 96 hours, and in 3.7% (2/54) between 96 hours and discharge on day 5. There was no statistically significant differences between the two valve types.Predisposing factors for early development of conduction disorders leading to PPI were investigated.

After TAVI, these conduction disorders arose in patients with baseline right bundle branch block (BBB) within 48 hours (100%, 15/15, p=0.002). And in case of baseline first-degree AVB, in the Sapien group within 48 hours (100%, 5/5, p=0.28), and in the MCV group within 72 hours (100%, 4/4, p=1.0).

Baseline atrial fibrillation was no significant predisposing factor. The baseline Left BBB group was too small for analysis (n=6).

CONCLUSIONS

Most PPI indications (91%) are seen within 72 hours after TAVI. Patients that received a Sapien valve with pre-procedural RBBB and/or first-degree AVB, did not develop conduction disorders leading to pacemaker implantation after 48 hours of TAVI. Therefore, these patients might be safely discharged after 48 hours. This algorithm should be validated in a larger patient population.

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Safety and efficacy of BRS implantation in very long left anterior descending stenoses: medium-term follow-up results

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

AIMS

Extensive stenting and vessel “caging” in case of very long Left Anterior Descending PCI is burdened by a non-negligible increased risk of adverse outcomes. In this setting the implantation of bioresorbable scaffolds could be an actractive option.

METHODS AND RESULTS

All consecutive patients undergoing PCI with implantation of overlapped Bioresorbable Scaffolds (BrS, ABSORB, Abbot vascular) in very-long coronary lesions (defined as ≥35 mm) on LAD, between September 2014 and January 2016, were prospectively included. One-year angiographic follow-up was planned.
Rate of DOCE (device-oriented combined endpoint) a composite of cardiac death, target-vessel myocardial infarction (MI) and target-lesion revascularization (TLR), at a medium term follow-up, was recorded. Any individual components of DOCE, non-target vessel revascularization (non-TVR) as well as major vascular bleeding were also registered.
Thirty-six patients were included in our analysis. They were mainly males (88.9%) with a mean age of 60.1±8.4 years and presented low rate of diabetes (13.9%) and chronic kidney disease (5.6%). STEMI (39.0%) and NSTACS (39.0%) were the most common admission diagnoses, followed by stable CAD (22%).
Mean LAD lesion length was 59.8 ± 15.4 mm treated with a mean of 2.53 ± 0.65 Bioresorbable Scaffold. A <2mm overlapping technique was the most preferred strategy (91,7%). BrS predilatation and postidilatation were performed in 91.7% and 100% of patients, respectively, while use of intravascular imaging (IVUS or OCT) was fairly low (27.8%). Bifurcations were involved in BrS treatment in more than half patients (61.1%) with provisional stenting as the most adopted technique (94.0%). One-fourth of patients underwent a hybrid procedure on LAD, with a concomitant implantation of a DES or BMS in 19.4 % and 5.6% of patients, respectively. Dual antiplatelet therapy was prescribed at discharge in the great majority of patients (97.2%).
At a mean follow-up of 229±87 days (including 8 angiographic follow-up up to date available), DOCE occurred in 2.8% of patients, driven by a single TLR (proximal BrS edge restenosis); neither cardiac death, nor target vessel-MI were recorded. Non-TVR occurred in 8.3% of patients, while major vascular bleeding in 2.8% of them.

CONCLUSIONS

Treatment of very-long LAD stenoses with overlapped Bioresorbable Scaffolds appears feasible, safe and effective, even without a systematic adoption of intraprocedural imaging techniques. Longer follow-up data are required to confirm these results.

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Exploratory study of the added value of patient-specific computer simulation in the planning and evaluation of TAVI

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

AIMS

Due to an increasing number of valvetypes and sizes,outcome of TAVI will depend more on device-host interactions necessitating a patient-tailored approach.We aimed to explore the added value of patient-specific computer simulation to predict outcome.

METHODS AND RESULTS

55 patients underwent TAVI between November 2005 and May 2013 with the Medtronic CoreValve System. In all patients patient-specific computer simulation was performed after TAVI. The objective was to assess to what extent optimal valve size according to computer simulation differs from the MD driven decision based upon multi-slice computer tomography (MSCT) pre-TAVI that was also used for computer simulation. Since simulation may propose different valve sizes and depth of implantation in relation to paravalvular leakage (PVL), the proposed (i.e. computer simulation) valve size that was associated with the least amount of PVL was chosen as optimal valve size according to computer simulation. 32 patients (58%) received the same valve size as proposed by the simulation. In 23 patients (42%) the simulation proposed another size than the implanted size. In 20 out of these 23 patients, the simulation proposed a larger valve size and in 3 a smaller one. In 4 out of the 32 and 6 out of the 23 patients, echocardiography disclosed ≥ moderate aortic regurgitation. The computer simulation observed less PVL when the valve would have been implanted at a mean depth of 8.1 ± 3.0mm at the left coronary cusp and 7.9 ± 3.3mm at the right coronary cusp.

CONCLUSIONS

In a substantial proportion of patients (42%) computer simulation proposed a different valve size that is associated with less PVL, thereby underscoring its potential added clinical value and support for patient-specific treatment planning.

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Percutaneous LAA occlusion: impact of device positioning on peri-procedural and long-term outcomes

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

To investigate the effects of LAA closure device (Amplatzer™ Amulet™) disc position on periprocedural and long-term outcomes.

METHODS AND RESULTS

Outcomes of 87 patients (age 73.4±9.7 years; 72% male) with successful LAA closure were analyzed according to Amulet disc position: group A (n=45) had complete LAA ostium coverage; group B (n=42) had incomplete LAA ostium coverage secondary to disc retraction. The periprocedural (within 7 days after the procedure) primary endpoint was defined as major adverse events (MAE) and measured as composite of all cause death, tamponade, device/air embolization, cerebrovascular events, myocardial infarction (MI) and major bleeding not related to vascular access complications. The long-term primary endpoint was defined as composite of cardiovascular death, cerebrovascular events, systemic embolization, major bleeding requiring transfusion or intervention during follow-up. Secondary endpoints were defined as total device-related periprocedural adverse events defined as MAE and pericardial effusion of any severity if not reported before procedure, Follow-up echocardiographic findings such as device thrombosis and peri-device leakage of at least 3mm and any individual component of the primary endpoints.

Mean CHA2DS2-VASc score was 4.0±1.6 and mean HASBLED score was 3.4±1.3. Baseline characteristics were similar between groups with the exception of male gender and body mass index (BMI) which were more frequent in group B. The main indications for device closure of LAA was previous major bleeding (48%) followed by cardiovascular intervention requiring triple therapy (22%). The most common LAA anatomy detected by fluoroscopy was Chicken-wing (48.3%), followed by Cactus (23.0%) and Windsock (17.2%).The most commonly used device size was 22 mm (34.5%). The majority of patients (78.2%) were discharged with DAPT, with 14.9% of patients discharged with anticoagulants only. In the periprocedural period new detected pericardial effusion developed in three cases (3.4%) and was mild in one case. All 3 patients with pericardial effusion were in group B with a trend towards higher frequency (P=0.07).

One patient in group B experienced altered level of consciousness without focal neurological defect. MRI was done which documented new multifocal, bilateral hyperintensity lesions in ponto-mesencephalic reticular formation suggestive of ischaemia with embolic source. Deep implantation of Amulet device was associated with significant total device-related periprocedural adverse events (P=0.03). Periprocedural MAE tended to be higher in group A (P=0.07).

Median follow-up days was 234 days (interquartile range 150-436 days). No significant difference of primary long-term clinical outcomes (P=0.57) and secondary endpoints was found between groups.

CONCLUSIONS

Suboptimal device position appears to be associated with worse periprocedural outcomes. Our study suggests that attempt to achieve optimal in comparison to suboptimal position of Amulet device is reasonable. These findings should be confirmed with larger prospective studies with longer follow-up.

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One-year mortality and hospitalisations in patients with new-onset conduction disturbances after TAVI: an updated meta-analysis

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

AIMS

There is continued debate about the impact of permanent pacemaker implantation (PPMI) or new-onset left bundle branch block (LBBB) after TAVI. We compared one year outcomes in patients with or without PPMI or new-onset LBBB in this population.

METHODS AND RESULTS

We performed a literature search in PubMed, Embase, and Cochrane databases for the terms ´pacemaker´, ´left bundle branch block´, ´transcatheter aortic valve´, and iterations up to January 10th 2017. Only studies published in peer-reviewed journals were eligible. Clinical data and outcomes at one-year were extracted and random effect models were used to assess differences among groups. We identified 15 comparative studies with a total of 18436 patients to assess the effect of PPMI, and 11 comparative studies with a total of 5125 patients to assess the effect of new-onset LBBB. We observed no difference in the risk of all-cause mortality (pooled risk ratio [RR] = 1.06; 95% confidence interval [CI], 0.96-1.16; p = 0.27), cardiovascular mortality (RR = 0.93; 95% CI, 0.76-1.14; p = 0.48), or hospitalizations (RR = 1.09; 95% CI, 0.93-1.28; p = 0.28) in patients who required PPMI after TAVI. This lack of effect remained when analyzing studies excluding patients with chronic LBBB (RR for all-cause mortality = 1.17; 95% CI, 0.94-1.45; p = 0.17). Conversely, we observed an increased risk of all-cause mortality (RR = 1.21; 95% CI, 1.05-1.39; p = 0.01) and cardiovascular mortality (RR = 1.38; 95% CI, 1.10-1.74; p = 0.01) in patients who presented new-onset LBBB after TAVI, but no effect on hospitalizations (RR = 1.25; 95% CI, 0.91-1.71; p = 0.17). In sensitivity analyses excluding comparative studies that did not exclude patients with new-onset LBBB with PPMI before discharge (2 studies including 796 patients), a significant increase in cardiovascular mortality remained in patients with new-onset LBBB (RR = 1.39; 95% CI, 1.10-1.74; p = 0.006), however the difference was no longer significant for all-cause mortality (RR = 1.17; 95% CI, 1.00-1.37; p = 0.052). Heterogeneity was low among studies in all meta-analyses ($I^2 \leq 12\%$, $p > 0.33$ for all).

CONCLUSIONS

Among patients undergoing TAVI, those who developed new-onset LBBB after the procedure exhibited an increased risk of all-cause and cardiovascular mortality at one-year. We did not observe an effect on clinical outcomes at one year in patients who underwent permanent pacemaker implantation after TAVI.

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Right ventricular function and TAVR: a meta-analysis on clinical outcomes and echocardiographic changes

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

AIMS

We aimed to compare one-year all-cause mortality after TAVI among patients with pre-procedural normal and abnormal right ventricular (RV) systolic function. Moreover, we assessed changes on RV systolic function at 1 to 3 months, and 6 to 12 months.

METHODS AND RESULTS

We performed a literature search in PubMed, Embase, and Cochrane databases for the terms ´right ventricle´, ´transcatheter aortic valve´, and iterations up to January 10th 2017. Only studies published in peer-reviewed journals were eligible. Clinical data, RV systolic function, echocardiographic findings, and outcomes at one-year were extracted and random effect models were used to assess differences among groups and changes in quantitative variables. Longitudinal changes in RV systolic function were assessed by echocardiography with tricuspid annulus plane systolic excursion (TAPSE) and the RV peak systolic velocity (PSV) with tissue Doppler imaging. We identified 5 comparative studies with a total of 2,056 patients to assess the effect of RV function on one-year mortality, and 12 longitudinal studies with a total of 1,039 patients to assess the effect TAVI on RV systolic function. We observed an increased risk of all-cause mortality (pooled risk ratio = 1.58; 95% confidence interval [CI], 1.30-1.92; $p < 0.001$) in patients who presented with RV dysfunction before TAVI. When all available studies were analyzed, right ventricular systolic function seem to improve after TAVI relative to baseline at 1 to 3 months (TAPSE: mean difference [MD] 1.81 mm; 95% CI, 1.32-2.30 mm; $p < 0.001$; PSV: MD 1.53 cm/s; 95% CI, 0.52-2.54 cm/s; $p = 0.003$), and at 6 to 12 months (TAPSE: MD 1.87 mm; 95% CI, 1.52-2.23 mm; $p < 0.001$; PSV: MD 2.38 cm/s; 95% CI, 0.07-4.78 cm/s; $p = 0.044$). Notwithstanding, sensitivity analyses showed that statistical significance in the observed changes was driven by one study including 50 patients. When excluding this study, changes were no longer significant at 1 to 3 months (TAPSE: MD 0.05 mm; 95% CI, -2.19-2.30 mm; $p = 0.966$; PSV: MD 1.36 cm/s; 95% CI, -0.51-3.23 cm/s; $p = 0.155$), and at 6 to 12 months (TAPSE: MD 0.55 mm; 95% CI, -1.96-3.05 mm; $p = 0.67$; PSV: MD 1.0 cm/s; 95% CI, -1.27-2.37 cm/s; $p = 0.388$). Heterogeneity was low among studies in all meta-analyses ($I^2 \leq 12.7\%$, $p > 0.43$ for all).

CONCLUSIONS

Among patients undergoing TAVI, those who present with right ventricular systolic dysfunction exhibit an increased risk of all-cause mortality at one-year. Baseline right ventricular systolic function does not change at mid-term follow-up after TAVI.

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Long-term follow-up of complex coronary bifurcation lesions treated with a dedicated self-expanding biolimus-eluting stent

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

AIMS

Aims: Dedicated bifurcation stents have been used for treatment of coronary bifurcation lesions. We assessed long-term clinical outcomes with a dedicated self-expanding biolimus-eluting stent (BES).

METHODS AND RESULTS

Methods and Results: Between 2004 and 2013, 123 patients with complex bifurcation lesions were treated in a single center with a dedicated bifurcation self-expanding BES in the proximal main vessel (MV) and additional drug-eluting stents in the side branches when required. Follow-up was performed at 1-month, 1, 3 and 5-years post-procedure. Primary clinical endpoint was the rate of major adverse cardiac events (MACE). Secondary endpoints included MACE components [cardiac death, non-periprocedural myocardial infarction (MI), target lesion revascularization (TLR) and stent thrombosis (ST)] as well as all cause death, target vessel revascularization (TVR) and non-TVR.
At 5 years, 11 patients (8.9%) had a MACE, of whom 2 patients (1.6%) suffered cardiac death, 2 (1.6%) had a non-periprocedural MI (followed by TLR), and 7 others underwent elective TLR (5.7%). There were no ST. All-cause death occurred in 9 patients (7.3%), TVR in 11 patients (8.9%) and non-TVR in 11 patients (8.9%). Patients treated for left main (LM) bifurcation lesions, were more likely to experience MACE when compared with non-LM bifurcation lesions (25% vs 6.5%, *p=0.04*). LM bifurcation lesions were an independent predictor for MACE and TLR [HR: 3.94, 95% CI (1.2-13.5), p=0.04 and HR: 5.36, 95% CI (1.4-19.9), p=0.02, respectively].

CONCLUSIONS

Conclusions: Percutaneous complex coronary bifurcation lesion revascularization with a dedicated self-expanding BES is a safe procedure with excellent 5-year results in terms of survival and MACE, especially in non-LM lesions.

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A single-centre registry looking at four-year comparing the outcome of diabetic and non-diabetic patients after PCI with DCB for de novo lesions

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

AIMS

To report our outcome with Paclitaxel drug coated balloons in the treatment of de novo lesions in diabetics versus non diabetic patients

METHODS AND RESULTS

A total of 636 patients with 716 coronary lesions treated with DCB (SeQuent Please) were reviewed from January 2012 -December 2015 and only 314 patients with 344 de novo lesions were evaluated. Out of this,165 (52.5 %) of the patients were diabetics . The mean age of patients were 59 Ã"Ã'Â± 10 years with a predominance of males (85%, n=265). Majority of the patients in the diabetic group were also hypertensive (84.2%, n=237) . 21 patients in diabetic subgroup presented with acute coronary syndrome (STEMI, NSTEMI and unstable angina) compared to 12 in the non diabetic group(p=0.01) The target vessel, lesion type, length and degree of stenosis were fairly matched in both groups with no statistically significant differences. Majority of the lesions were Type B1 and C (85% n=294). Ã"Ã'Â The mean reference diameter of the lesion was 2.5 Ã"Ã'Â±0.4 mm and the mean lesion length was 26 Ã"Ã'Â±18mm. The mean lesion stenosis was 87 Ã"Ã'Â±12 %. Predilatation was done in majority of cases (98%, n= 338). The mean DCB diameter and dilatation pressure were 2.4Ã"Ã'Â±0.4 mm and 9Ã"Ã'Â±4 atmospheres, respectively. The mean inflation time was 59Ã"Ã'Â±15 seconds. Clinical follow-up was available in 303 (97%) patients with a mean of 17Ã"Ã'Â±11 months. Major adverse cardiac events (MACE) of cardiac death, target lesion revascularization and myocardial infarction in the diabetic group were 8 cases compared to the non-diabetic patients which had none. Ã"Ã'Â Out of these 8 cases, 2 were of cardiac death and 6 were TLR Ã"Ã'Â . Freedom from MACE at 1 ,2 and 3 years in the non-diabetic group was 100%, and in the diabetic group it was 96.7% at 1 year, 90.6 % at 2 years and 90.6 % at 3 years.

CONCLUSIONS

PCI using only DCB in the treatment of de novo coronary artery disease in the diabetic group had a statistically significant higher rate of MACE. However further analysis of the individual MACE events in the diabetic group indicate this is due to factors such as diffuse pattern of coronary artery disease, multi vessel lesions, statistically higher percentage of acute coronary syndrome presentations at the time of revascularisation, poor left ventricular function and the presence of other co-morbities such as hypertension. Therefore this diabetic group of patients may still benefit from the use of DCB in selected cases such as small vessel disease, or benefit from other hybrid strategies such as using DCB and DES in different segments of diffusely diseased and in cases of multi vessel coronary lesions who are not suitable candidates for other options of treatment such as coronary bypass surgery.

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Coronary ostia height: implications for percutaneous coronary access following TAVI

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

AIMS

Approximately 50% of patients who undergo TAVI have coronary artery disease. In patients with low coronary height, the TAVI valve sealing skirt and frame may lie adjacent to the ostia, making percutaneous coronary access challenging.

METHODS AND RESULTS

Computed tomography angiography scans were analysed from 252 consecutive patients referred for TAVI. The dimensions of the aortic annulus were recorded. The minimum/maximum/average height and area of the left main coronary artery (LMCA) and right coronary artery (RCA) were recorded. Modelling was performed with an appropriately sized Medtronic Evolut R, Edwards SAPIEN 3 and Boston Scientific Lotus valve to determine if the coronary ostia would lie at least partially or completely below the TAVI valve sealing skirt and frame. The average aortic annulus diameter was 24±3mm. The average LMCA height was 17±4mm and area 16±9mm^2. The average RCA height was 20±3mm and area 7±6mm^2. Modelling predicted that the LMCA would lie at least partially below the TAVI valve sealing skirt in 4% of Evolut R, 1% of SAPIEN 3 and 3% of Lotus implants and would lie completely below the TAVI valve sealing skirt in 1% of Evolut R, 0% of SAPIEN 3 and 1% of Lotus implants. The RCA would lie at least partially below the TAVI valve sealing skirt in 1% of Evolut R, 0% of SAPIEN 3 and 1% of Lotus implants, but would not lie completely below the sealing skirt in any patient. The LMCA would lie at least partially within the TAVI valve frame in 100% of Evolut R, 55% of SAPIEN 3 and 74% of Lotus implants and would lie completely within the TAVI valve frame in 100% of Evolut R, 9% of SAPIEN 3 and 20% of Lotus implants. The RCA would lie at least partially within the TAVI valve frame in 99% of Evolut R, 18% of SAPIEN 3 and 34% of Lotus implants and would lie completely within the TAVI valve frame in 99% of Evolut R, 3% of SAPIEN 3 and 9% of Lotus implants.

CONCLUSIONS

A small minority of patients have very low coronary ostia. Following a TAVI procedure, their coronary ostia will lie at least partially below the sealing skirt, making percutaneous coronary access challenging. The majority of LMCA ostia and a significant minority of RCA ostia will lie at least partially within the TAVI valve frame. Percutaneous coronary access in these patients is likely to remain feasible with the Evolut R and SAPIEN 3 valves, as they have an open frame geometry, but may be challenging with the Lotus valve because of its dense frame geometry.

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STEMI and multivessel disease: predictors of non-culprit lesion revascularisation

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

We investigated the timing and the predictors of non-culprit lesion revascularization in STEMI patients with multivessel disease undergoing primary-PCI and their related impact on clinical endpoints.

METHODS AND RESULTS

Methods: All consecutive patients undergoing pPCI from 2012 to 2014 at our cath-lab were included. Multivessel disease was defined as the presence of ≥50% stenosis in at least one nonculprit vessel. Main objective of the study was the evaluation of the predictors of any early revascularization performed in nonculprit lesions (within 30 days with PCI or two months with CABG) from the index procedure. Possible association between clinical, angiographic and procedural factors with early revascularization was explored with logistic regression analysis. Secondary endpoints were the occurrence of major adverse cardiovascular events (MACE: composite of all-cause death, myocardial infarction, recurrent revascularization) and of the individual MACE components at 12 months follow-up, analyzed by Coxregression analysis.

Results: Out of 493 consecutive patients with ST-elevation myocardial infarction screened, we enrolled 304 (62%) presenting with MVD. Early revascularization of nonculprit lesions was performed in 120 MVD patients (94% with PCI, 6% with CABG): 125 lesions treated, consisting of 1 left main (LM) (1%), 54 left anterior descending artery (LAD) (43%), 38 left circumflex artery (LCx) (30%), 32 right coronary artery (RCA) (25%). Most of the nonculprit lesion revascularizations (78%) occurred within the first 3 days from the pPCI. Dyslipidemia ($p<0.01$), % diameter stenosis of nonculprit vessels ($p<0.01$) and rate of 2 vessel disease with LAD involved ($p<0.01$) or 3 vessel disease ($p<0.01$) were significantly associated to the primary endpoint at the univariate analysis. At the multivariate analysis, a significant association was observed only with dyslipidemia and with % diameter stenosis of nonculprit lesions. A mean followup of 15±13 months was obtained in 188 patients (62%). At the adjusted Cox regression, early revascularization of nonculprit lesions was not associated with MACE or any of the individual endpoints. No interaction was observed between timing of revascularization of non-culprit lesions and MACE.

CONCLUSIONS

Revascularization of non-culprit lesions was mostly guided by the angiographic stenosis severity and was performed within 3 days from pPCI. We did not confirm an improved clinical benefit from the performance of early revascularization of nonculprit lesions.

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New score to predict outcomes in elderly patients undergoing primary angioplasty in cardiogenic shock

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

AIMS

Patients over 75 years old presenting with ST elevated myocardial infarction in cardiogenic shock suffer from very high mortality but prognostic predictors for these patients undergoing contemporary primary angioplasty are not well established.

METHODS AND RESULTS

This is a subanalysis of the nationwide database of primary angioplasty in the elderly (ESTROFA MI+75) with 3,576 patients included in 31 centers. Characteristics and outcomes of the subgroup of patients in cardiogenic shock were analyzed. A total of 332 patients were included in the analysis (9.3%), age 81±4 years, 39.5% women, 35.8% diabetics, 49% with anterior infarction, ejection fraction 39 ±14% and 34% with > 6 hours since pain onset. The procedure was done through radial access in 27%, with bivalirudin in 7%, abciximab in 32%, thrombus aspiration in 54%, drug-eluting stent in 21% and intra-aortic balloon in 45%. In hospital mortality was 54%. Baseline independent predictors for mortality were anterior myocardial infarction (HR 2.8, 95% CI 1.4-6; p=0.005), LVEF < 40% (HR 2.3, 95% CI 1.14-4.5; p=0.018) and time from symptoms onset to PCI > 6 hours (HR 3.2, 95% CI 1.6-7.5; p=0.001). A score was designed including these 3 factors (Score “6-ANT-40”), assigning 1 point for meeting each. Survival rates at 12 months were 54.5%, 32.3%, 27% and 17% for patients with score values from 0 to 3 respectively (p=0.005).

CONCLUSIONS

In patients over 75 years referred for primary PCI with cardiogenic shock, baseline independent predictors for mortality were a presentation with more than 6 hours after symptoms onset, anterior myocardial infarction and LVEF < 40%. A significantly different risk of mortality was observed for a scoring based on these factors

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Self-expandable sirolimus-eluting stent in STEMI: long-term OCT follow-up results from the APPOSITION IV trial

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

AIMS

We sought to investigate the impact of the self-apposing, sirolimus-eluting STENTYS stent on long-term stent apposition and strut coverage in STEMI patients undergoing primary PCI.

METHODS AND RESULTS

TThe APPOSITION IV trial randomized 152 STEMI patients between self-apposing STENTYS SES and Resolute zotarolimus eluting stent (3:2), with angiographic and OCT follow-up at either 4 or 9 months post procedure. The results of this study have been previously reported and showed significantly better stent apposition and strut coverage for patients in the STENTYS SES group at 4 month follow-up, as well as a lower Late Lumen Loss (LLL) at 4 and 9 months follow-up, as compared to patients in the control group. In order to assess whether low LLL, limited intimal proliferation, and continued optimal apposition are maintained on the long term, the protocol was extended and the patients from the STENTYS SES group from 5 sites were asked to participate in this extended protocol requesting angiographic and OCT follow-up at 2.5 years post procedure (+/- 6 months). QCA and OCT analysis from follow-up data of 16 patients could be performed, with a mean follow-up duration of 2.9 years (+/-0.2). QCA paired analysis (15 patients) show a stable mean lumen diameter on the long term (3,12 mm post procedure vs 3,27 mm at the long term follow-up) and a low LLL (0.24mm at the long term followup). The OCT paired data (14 patients) confirm long term optimal apposition with 0.05% of malapposed struts and a mean incomplete stent apposition volume of 0.03 mm^3, and a stent expansion which remains limited.

CONCLUSIONS

QCA and OCT data confirm long term apposition, stable MLD, and low LLL. This is the first report on systematically collected invasive data beyond 6 months follow-up for the STENTYS self-apposing stent in STEMI patients.

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Long-term outcomes of 560 consecutive patients treated with TAVI and propensity score matched-analysis of early- vs. new-generation valves

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

AIMS

To evaluate temporal changes in TAVI characteristics, predictors of 1 year and long-term outcomes, and to compare the performance of the early and new generation valve systems

METHODS AND RESULTS

We carried out an Analysis of 560 consecutive patients who underwent TAVI at our institution between 2008 and 2016. Patients were distinguished by access (transfemoral versus alternative) and divided to three equal groups with respect to TAVI date to evaluate temporal changes in TAVI and long-term outcomes. Propensity-score matched analysis was preformed to compare the outcomes of the early and new generation valve systems. With time, we have adopted lower risk threshold for patient selection (mean STS declined from 8.5 ± 5.1 to 4.7 ± 3.4 in the first and last patient tertile respectively, $p<0.001$), and have been using conscious sedation and trans-femoral access preferentially ($p<0.001$ for both). The incidence of greater than mild PVL declined from 16% to 7.6% in the 2nd and last patient tertile respectively, ($p=0.029$). Within 30 days, all cause death rate reached 3.4%, and disabling stroke rate reached 2%. Within 5 years, 47% of the patients died, the majority (78%) due to non-cardiac causes. Independent predictors of 1 year death included peri-procedural aspects (i.e. vascular complications, stroke and PVL), while death occurring later than 1 year was solely related to baseline comorbidities. Transvalvular gradients and residual regurgitation remained non-clinically significant for up to 5 years of follow-up. New generation valves were associated with less PVL compared to propensity-score matched early generation valves ($p<0.001$).

CONCLUSIONS

TAVI utilization at our institution has progressed to include lower risk patients with transfemoral access becoming applicable in the great majority. Poor long term survival is attributable to population factors rather than to procedural factors. Intermediate and long-tem hemodynamics are excellent. PVL has diminished significantly with the new generation valves. Efforts to improve long and short term outcomes remain a therapeutic challenge.

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An everolimus-eluting platinum chromium stent with durable polymer evaluated in an all-comer diabetic cohort from the P-SEARCH registry

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

AIMS

The aim of the current study was to compare the safety and efficacy of an everolimus-eluting platinum-chromium stent (EePCS) with an everolimus-eluting cobalt-chromium stent (EeCCS) in an all-comer cohort of patients with diabetes.

METHODS AND RESULTS

The P-Search registry consists of 2,000consecutive all-comer patients treated with either an EePCS (Promus Premier™, Boston Scientific, Natick, Massachusetts) or an EeCCS (Xience Prime™, Abbott Vascular, Santa Clara, California) between April 2012 and October 2014. Patients were clinically followed for 1 year. Within the registry 414 patients (20.7%) were diabetics, 219 were treated with the EePCS and 195 with the EeCCS. Mean age was 66±11 years. A total of 60.8% of the patients presented with an acute coronary syndrome. The mean number of stents per patient was 1.9±1.2. Total stented length was 37±26mm. Lesion classification was B2/C in 75.1% of patients. At 1 year the primary endpoint of major adverse cardiac events (MACE) (all-cause mortality, myocardial infarction [MI], ischemia-driven target vessel revascularization [TVR]) was reached in 13.4% in the EePCS cohort and 17.9% in the EeCCS cohort (adjusted HR 0.59 [0.35–0.99]; p=0.045). No significant differences were noted in the individual clinical endpoints all-cause mortality (8.8% versus 8.7%), MI (1.9% versus 3.3%), and stent thrombosis (0.9% versus 3.3%). There were fewer TVR (4.9% versus 10.4%; adjusted HR 0.42 [0.19-0.91]; p=0.028) and fewer target lesion revascularizations (TLR) (3.3% versus 9.3%; adjusted HR 0.33 [0.14-0.80]; p=0.014) in the EePCS patients.

CONCLUSIONS

In all-comer patients with diabetes, after 1 year the use of EePCS was associated with lower rates of MACE, TVR and TLR.

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Coronary perforation - A single-centre experience

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI, Stable CAD, Stents and scaffolds, Left main and multivessel disease, Bifurcation lesion, CTO, Other Coronary Interventions

AIMS

Iatrogenic coronary artery perforation (CAP) is a rare but potentially lethal complication of percutaneous coronary intervention (PCI). We present an updated report on the incidence and clinical characteristics of CAP.

METHODS AND RESULTS

We analysed the PCI databasefrom the period between February 9 2005 and May 14 2016 and out of 20,376 PCI procedures 140 CAP cases (0.69%) were identified. Mean age of the CAP patients was 73±11 years and 62.1% were male. The indication for PCI was stable angina in 44.3%, non-ST-elevation acute coronary syndrome in 28.6%, ST-elevation myocardial infarction in 25.7%, ischemic heart failure in 0.7% and analysis of the perfusion of an intrapericardial glomus tumor in 0.7%. Treated lesion type was B2/C in 94.9% with calcifications in 61.8% and 30.0% were chronic total occlusions. Stenting was performed in 77.9% with the use of non-workhorse guidewires in 73.8%. CAP types were classified as Ellis-I in 3.2%, Ellis-II in 41.5%, Ellis-III in 53.2 and Ellis-III-Cavity Spilling in 2.1%. CAP treatment was conservative in 75.7%, including prolonged balloon inflation, use of covered stents in 23.6% and coiling in 0.7%. The subsequent in-hospital course was characterized by tamponade in 42.1%, pericardial drainage after initial conservative treatment in 44.3%, emergency cardiac surgery in 13.6%, periprocedural myocardial infarction in 35.0%, secondary coronary artery bypass grafting in 4.3% and death in 7.9%. All-cause mortality was 10.0% at 30 days and 16.7% at 1 year.

CONCLUSIONS

CAP is a rare complication of PCI, but it comes with considerable morbidity and mortality. Early recognition and timely and proper treatment of CAP is of paramount importance.

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Comparison of OCT vs. IVUS assessment of stent edge dissections

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

AIMS

Optical coherence tomography (OCT) has a higher resolution compared to intravascular ultrasound (IVUS). We aimed to compare the prevalence and severity of stent edge dissections including intramural hematomas (IMH) between IVUS and OCT.

METHODS AND RESULTS

We retrospectively analyzed 492 patients with coronary artery disease (44.1% ACS) who underwent stent implantation followed by both IVUS and OCT. Stent edge dissection was assessed at the proximal and distal 5-mm reference segments. The median patient age was 66 years with 81.5% males and 33.5% diabetics. Total stent length and minimal stent cross-sectional area (CSA) by OCT were 23.4 [18.4, 31.6] mm and 6.9 [5.6, 8.7] mm^2, respectively. An OCT dissection was observed in 39.6% of cases (29.5% proximal stent edge and 24.9% distal stent edge) with a lumen area at the site of the dissection of 5.5 [4.1, 7.7] mm^2. Overall, OCT detected four times the number of dissections compared with IVUS (39.6% vs. 10.0%, P<0.001), including intimal dissection (24.6% vs. 3.0%, P<0.001), medial dissection (7.7% vs. 2.4%, P<0.001), and IMH (7.3% vs. 2.7%, P<0.001), whereas extra-medial dissection was described by only IVUS (0% vs. 1.6%). In particular, severe dissections (angle ≥60° or length ≥3mm, 16.9% vs. 6.3%, P<0.001) were better detected by OCT as compared to IVUS. Most (12/14) IVUS-detected IMH were also detected by OCT; and in the 12 IMH that were detected by both IVUS and OCT, the OCT-measured angle (147 [116, 178]° vs. 109 [80, 130]°, P=0.008) and length (4.1 [2.1, 7.6] mm vs. 2.9 [1.7, 4.1] mm, P=0.028) were greater than measured by IVUS. Further, in 24 IMH detected by only OCT, re-review of the IVUS still failed to recognize the IMH. Conversely, out of 8 IVUS-detected extra-medial dissection, 6 were missed by OCT because there was a thick plaque on top of the extra-medial dissection; and 2 were diagnosed as IMH by OCT.

CONCLUSIONS

In general OCT detected and better quantified dissections that were missed by IVUS, especially severe and clinically important dissections and IMH. Conversely, uncommon extra-medial dissections were better detected by IVUS.The prognostic importance of severe edge dissections by OCT in comparison to IVUS warrants further investigation.

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Lower need of side-branch treatment if slow-speed rotational atherectomy was used for treatment of bifurcation lesions

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

AIMS

Coronary bifurcation lesion (BL) is one of the most challenging settings for percutaneous coronary interventions (PCI) We compare procedural data from patients with BL treated or not with rotational atherectomy (RA)

METHODS AND RESULTS

64 consecutive patients that underwent RA for 87 BL (RA+) were compared with a control group (RA-) of 32 pt with BL non-treated with RA. BL most involved was LAD involving 1st Diagonal branch. In our study we observed a lower need of side-branch treatment in RA+ than in RA- and no acute side-branch happened ($p < 0.001$) despite the stenting technique used. Less number of stents ($p< 0.04$) were deployed in RA+. Furthermore, TLR and TVR rates were also lower in RA+ ($p< 0.01$) A higher increase in lumen vessel size and a maximal length stented vessel was observed after RA+: $p = 0.009$ and $p =0.005$ respectively.

CONCLUSIONS

In a high-risk population slow-speed RAfor BL facilitates procedural success preserving side-branch patency with a low need for side-branch treatment,TLR and TVR rates. In this cohort, unstable high-risk patients with left ventricle dysfunction, multivessel disease and distal LM bifurcation most benefit.

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TAVI with or without percutaneous coronary artery revascularisation strategy: a systematic review and meta-analysis

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

AIMS

We performed a systematic review and meta-analysis to study the clinical outcomes of patients with coronary artery disease and underwent revascularization versus without revascularization prior to transcatheter aortic valve implantation (TAVI).

METHODS AND RESULTS

We conducted a search of MEDLINE and EMBASE to identify studies that evaluated patients who underwent TAVI with and without percutaneous coronary intervention (PCI).Random-effects meta-analyses with the inverse variance method were used to estimate the rate and risk of adverse outcomes.

Twenty-four studies were included in the systematic review and 9 studies with 3,858 participants in the meta-analysis. Meta-analyses evaluating outcomes showed that those who underwent revascularization with PCI had a higher rate of major vascular complications (RR: 1.79, 95%CI: 1.31-2.45, P=0.0002) and an increased 30-day mortality (risk ratio: [RR] 1.39, 95% confidence interval: [CI] 1.08-1.79, P=0.010). No statistically significant differences in terms of 30-day cardiovascular mortality (RR: 1.03, 95%CI: 0.37-2.87, P=0.96), myocardial infarction(RR: 0.86, 95%CI: 0.14-5.17, P=0.87), major bleeding(RR: 0.87, 95%CI: 0.58-1.29, P=0.48), acute kidney injury (RR: 0.89, 95%CI: 0.47-1.71, P=0.73), stroke (RR: 1.06, 95%CI: 0.39-2.86, P=0.90) or 1-year mortality (RR: 1.03, 95%CI: 0.79-1.34, P=0.83). Meta-analyses evaluating *a priori* PCI versus concomitant revascularization strategies showed no statistically significant differences in terms of 30-day mortality (RR: 1.23, 95%CI: 0.46-3.29, P=0.67), major or life threatening bleeding (RR: 0.50, 95%CI: 0.20-1.25, P=0.14) or major vascular complications (RR: 0.32, 95%CI: 0.05-1.94, P=0.21). A meta-regression analysis suggests that differences in the prevalence of CAD did not appear to significantly influence all outcomes of the meta-analysis.

CONCLUSIONS

Our analysis suggests that revascularization before TAVI confers no clinical advantage with respect to many patient-important clinical outcomes, and may be associated with an increased risk of major vascular complications and 30-day mortality. In the absence of definitive evidence derived from randomized-trial, careful evaluation of patients on an individual basis by a dedicated heart team is of paramount importance in identifying patients that may benefit from elective revascularization.

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Gender-specific angiographic and clinical outcomes after BRS implantation during daily practice

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

AIMS

The aim was to investigate gender-specific differences of patients undergoing bioresorbable scaffold (BRS) implantation and thus angiographic and clinical outcomes of female and male patients were analyzed.

METHODS AND RESULTS

Consecutive patients treated with BRS at two centers in Munich, Germany were included. In a post-hoc analysis, patients were analyzed according to gender. Routine angiographic surveillance was scheduled after 6-8 months and clinical follow-up was conducted to 24 months. The primary endpoints of interest was the composite of death/ myocardial infarction/target lesion revascularization, target lesion revascularization, scaffold thrombosis according to ARC criteria and in-scaffold late lumen loss. A total of 98 female patients were compared with 321 male patients. Female patients were significantly older (73 vs. 67 years; p<0.001), less often smokers (13.3% vs. 24.0%; p=0.02) and less likely to have had prior myocardial infarction (14.3 vs. 29.6%; p=0.002). Lesion and procedural characteristics were comparable in both groups. At angiographic follow-up, in-scaffold late lumen loss was numerically lower in females (0.19mm vs. 0.28mm,vp=0.71). The rate of the primary composite endpoint (16.4% vs. 24.0%, p=0.74), target lesion revascularization (10.1% vs. 18.4%, p=0.59) and scaffold thrombosis (2.1% vs. 4.5%, p=0.57) was comparable in both groups.

CONCLUSIONS

In patients undergoing BRS implantation in routine practice, gender was not a determinant of clinical or angiographic outcomes.

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Development of a high-volume, multiple-operator programme for percutaneous coronary CTO revascularisation: procedural, clinical and cost-outcomes

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Although CTOs are commonly found in coronary angiography, percutaneous revascularisation has been underused. We sought to review the outcomes of the development of a new dedicated CTO revascularization program in a single tertiary center.

METHODS AND RESULTS

A CTO interventional program was initiated in our center in June 2012 by three experienced percutaneous coronary intervention (PCI) operators. That followed an on-site period of proctorship with a further proctor visit in December 2012. All operators adopted the hybrid approach since the onset of the program. An annual teaching/training CTO day with the presence of international CTO expert operators was established. 441 consecutive CTO PCI procedures were performed between June 2012 and December 2016. Mean age of the cohort was 65 years and 19% of the patients had previous coronary artery bypass grafting (CABG) procedure. Right Coronary Artery was the most common attempted vessel (66%), followed by Left Anterior Descending (LAD) (24%) and Circumflex (Cx) (7%). 61% of the patient had a Japanese CTO (JCTO) score of 2 or higher. The most common initial procedure strategy was antegrade wire escalation (AWE), attempted in 70% of the cases. AWE was the successful strategy in 67% of the cases, antegrade dissection re-entry (ADR) in 13% and retrograde [retrograde wire escalation (RW) or retrograde dissection re-entry (RDR)] in 19%. Technical success rate (defined as TIMI 3 flow and < 30% stenosis) per procedure was 74% and per patient 84%. Average procedure time was 133 minutes. Average contrast dose was 262 ml and average radiation dose 20506 cGycm2. In hospital mortality was 0.2 % and stroke rate 0.2%. The average cost of the equipment used was 2,699.66 pounds.

CONCLUSIONS

The development of a dedicated CTO program is feasible, with high success and low complications rates at a reasonable cost.

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Strut coverage and apposition at six months with different metallic DES with bioabsorbable polymers

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

AIMS

Direct comparative evaluation for arterial healing between different models of metallic drug-eluting stents with bioabsorbable polymers is relevant to define safety profile under shorter periods of dual antiplatelet therapy (6 months).

METHODS AND RESULTS

Prospective multicenter study in which patients were sequentially treated with drug-eluting stents with bioabsorbable polymers: Synergy, Orsiro and Biomatrix. After the procedure patients were scheduled for evaluation with optical coherence tomography at 6 months. The proportion of non-covered (NC) struts, non-apposed (NA) struts and NC-NA struts was analysed in a core lab. Finally, 85 patients have been included (61.5 ± 9.5 years old, 28.3% diabetic and 53% with ACS). Examination with OCT at 6 months was obtained in 72 patients, 32 treated with Synergy, 20 with Orsiro and 20 with Biomatrix. No differences were found in stent diameter (3.05 ± 0.45 mm) and stent length (19.7 ± 6.8 mm). At 6 months the rate of NC struts was 4.5 ±5.2% with Synergy, 4.7 ± 4.9% with Orsiro and 6.9 ± 6% with Biomatrix (p=0.01); the rate of NA struts was 1.4 ±2.2%, 1.2 ±2% and 1.1 ±1.8% (p=0.2) respectively and the rate of NC-NA struts was 0.2 ±0.5%, 0.6± 1.5% and 0.2 ±0.6% (p=0.7) respectively.

CONCLUSIONS

In this cohort of patients treated alternatively with different drug-eluting stents with bioabsorbable polymers, Synergy and Orsiro showed similar low rates of non-coverage both being significantly lower compared to Biomatrix. Rates of malapposition resulted comparably low in all models.

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Everolimus-eluting and novolimus-eluting BRS in daily clinical practice

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

AIMS

Two bioresorbable scaffold (BRS) of which one is eluted with everolimus (e-BRS) and another one with novolimus (n-BRS) are available und thus we aimed to compare clinical outcomes of patients undergoing implantation of those BRS during daily routine.

METHODS AND RESULTS

Consecutive patients who were treated with either e-BRS or n-BRS until were included. Patient and lesion related factors, as well as pre- and postdilatation . were considered for a propensity matching in a 2:1 ratio. The primary endpoint was the composite of cardiac death, target-vessel myocardial infarction and target lesion revascularization (TLR). In addition, individual components of the composite and scaffold thrombosis according to ARC criteria were assessed.A total of 212 patients treated with e-BRS and 106 patients treated with n-BRS were included. Overall, the baseline characteristics were well matched and no relevant differences were found. The mean age in the e-BRS group was 62.9 years and 63.1 years in the n-BRS group. Diabetes was present in 29.7% in the e-BRS group and 27.4 % in the n-BRS group. Predilatation was performed in nearly all patients in both groups (99.5% vs. 98.1%) and postdilatation was performed in 84.4% and 86.8%. After one year of follow-up, outcomes of the e-BRS and n-BRS group were similar regarding the composite endpoint (5.8 vs. 4.5%; p=n.s.), TLR (2.6 vs 3.5%; p=n.s.) and scaffold thrombosis (2.0 vs. 1.0%; p=n.s.).

CONCLUSIONS

In this study, both BRS types offer reasonable clinical outcomes at one year without relevant differences. However, future randomized controlled-trials will be required.

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Feasibility and clinical outcome of rotational atherectomy in patients presenting with an ACS

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

AIMS

To compare clinical outcome of patients admitted for ACS and treated with rotational atherectomy for the culprit lesion with patients treated with rotational atherectomy for stable coronary artery disease

METHODS AND RESULTS

Between November 2002 and July 2015, a total of 588 patients were treated with rotational atherectomy at a single institution. Of these, 113 patients received rotational atherectomy for 123 culprit lesions in the setting of ACS (12 patients with STEMI, 39 with NSTEMI and 62 with unstable angina), and 433 patients received rotational atherectomy for 472 lesions in the setting of stable coronary artery disease. We excluded ACS patients treated with rotational atherectomy on a non-culprit lesion. Overall, the mean age of the study population was 71.6 +- 9 years and 73.3% were male. Patients with ACS were older (73.3 +- 9 years vs. 71.2 +- 9 years; p=0.03) and had lower left ventricular ejection fraction (49.6 +- 13% vs. 52.5 +- 12%; p=0.03). Other baseline characteristics were not significantly different between the groups. In general, rotational atherectomy was performed electively in 60% of treated lesions (59.9% vs. 60.8%; p=0.43). However, in patients with myocardial infarction planed rotational atherectomy was only perfomed in 35.2% of lesions. More CTO were noted in the stable coronary artery disease group (2.4% vs. 7.4%; p=0.04), whereas ostial location was numerically more frequent in the ACS population (30.9% vs. 22.7%; p=0.06). Procedural outcome was characterized by a high rate of angiographic sucess in both treated groups (96.7% vs. 96.4%; p=0.85). Procedural complications such as persistent slow flow (0.8% vs. 2.7%; p=0.21), coronary dissection (7.3% vs. 7.2%; p= 0.96) and perforation (0.8% vs. 1.7%; p=0.47) were not significantly different between both groups. In hospital major adverse cardiac events (MACE) defined as the composite of all cause mortality, target vessel revascularisation and myocardial infarction was significantly higher in the ACS group (12.4% vs. 6.2%; p=0.017), mainly driven by a higher in hospital mortality (6.2% vs. 0.46%, p<0.001), which occurred in 5 patients with STEMI and 2 patients with NSTEMI. Long term follow-up was available for 93% of the study population. The Kaplan-Meier estimated rate of MACE at two years was higher in the ACS group compared to stable coronary artery disease group (43.0% vs. 24.4%; log-rank p<0.001; HR: 2.03, 95%CI: 1.41-2.93). Mortality at two years was also significantly higher in the ACS group (19.0% vs. 10.9%; log-rank p=0.024; HR: 1.74, 95%CI: 1.29-3.94) as well as spontaneous myocardial infarction (7.4% vs. 2.7%; log-rank p=0.05; HR:2.64, 95%CI 0.95-7.24)

CONCLUSIONS

Despite the technical feasibility of rotational atherectomy in a population of high risk patients with severe calcified lesions presenting with ACS, the rate of in hospital and long term mortality and MACE remain high compared to patients with stable disease.

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HsCRP is an independent predictor of microvascular injury

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

AIMS

Inflammation and microvascular dysfunction (MVD) are independently associated with the adverse cardiovascular outcomes amongst patients with ischaemic heart disease. This study aimed to assess the relationship between inflammation and MVD.

METHODS AND RESULTS

Methods

Coronary microvascular function was assessed using the index of microvascular resistance (IMR) by a pressure-temperature sensor-tipped wire. IMR was calculated as the distal coronary pressure divided by the inverse of mean transit time at maximal hyperaemia (IMR = Pa_{Hyp} x Tmn_{Hyp} (Pd_{Hyp}–Pw/Pa_{Hyp}-Pw)). IMR was measured pre-PCI in an angiographically normal reference vessel and a culprit vessel in 74 patients undergoing elective and emergent PCI between April 2010 and June 2013. Serum High-sensitivity C-Reactive Protein (HsCRP) level was quantified by rate turbidimetry on a Beckman Coulter AU Analyzer. Demographics and procedural characteristics data were collected. HsCRP and troponin values were log-transformed in the analysis. Significant MVD was defined as IMR>30. A Pearson product-moment correlation coefficient was computed to assess the relationship between inflammation (HsCRP levels), degree of myocardial injury (peak troponin post PCI/infarct) and microvascular injury (IMR) of culprit vessel. Interactions with cardiovascular risk factors were tested through multivariate logistic regression and two-way analysis of variance (ANOVA).**Results**

The mean age was 60.2±10.8 years and 73% were males. ACS represented 49% of the total cohort (37% NSTEMI and 12% STEMI). A significant proportion of the study population had cardiovascular risk factors which included 66% smokers, 73% hypertension, 65% dyslipidaemia, 30% diabetes, 42% family history of ischaemic heart disease and 23% previous AMI. Demographic characteristics were similar between ACS and non-ACS groups except for history of smoking (66% vs. 34%, p=0.014) and prior history of AMI (23% vs. 77%, p=0.005). Mean HsCRP and IMR levels were significantly elevated in the ACS group compared to the non-ACS group (15.1mg/L vs. 3.1mg/L and 28.9 vs. 17.4 respectively; p=0.001). There was a strong positive correlation between HsCRP and IMR (r=0.85, p<0.0001) and a moderate correlation between HsCRP and troponin (r=0.59, p<0.0001), independent of age, gender, clinical presentation and traditional cardiovascular risk factors. HsCRP level was 2.5 times higher (16.0mg/L vs. 6.4mg/L, p=0.02) in patients with significant MVD (IMR>30). Two-way ANOVA demonstrated significant interaction effects between diabetes and hypertension (F(1,70)=4.08, p=0.04) on IMR. Patients with significant MVD were more likely to have prior history of hypertension (OR 8.7, p=0.009) and hypercholesterolaemia (OR 4.1, p=0.04). HsCRP was an independent predictor of high IMR (OR 2.1, p=0.02).

CONCLUSIONS

Inflammation as measured through HsCRP is associated with microvascular dysfunction and myocardial injury and is an independent predictor of significant microvascular injury. Inflammation may serve as a common link between epicardial and microvascular disease. Future studies are warranted to affirm this association and to establish the potential of HsCRP in tailoring risk modification strategies to manage cardiovascular disease.

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Final five-year results of the first-in-human evaluation of a sirolimus-eluting coronary stent on an integrated delivery system: the DIRECT study

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

AIMS

The DIRECT study is a first-in-human evaluation of the safety and efficacy of the Svelte sirolimus-eluting coronary stent-on-a-wire Integrated Delivery System (IDS).

METHODS AND RESULTS

The Svelte IDS permits easy delivery, deployment and post-dilatation of a cobalt chromium stent eluting sirolimus from a fully bioabsorbable amino acid coating. The IDS is ultra-low profile, indicated for use with diagnostic (≥ 5F / ID 0.047") and designed to extract the steps, time and cost associated with stenting procedures.Patients with symptomatic ischaemic heart disease and single *de novo* native coronary
lesions suitable for percutaneous coronary intervention were prospectively enrolled at four sites in New Zealand. Lesion lengths were <23 mm and vessel reference diameters were 2.5-3.5 mm. The primary safety and efficacy endpoints were target vessel failure (TVF) and angiographic in-stent late lumen loss (LLL) at 6 months, respectively. Twenty-nine of 30 enrolled patients completed 6-month follow-up. Clinical follow-up continues through 5 years.At 6 months, clinically-driven MACE was 0% and in-stent LLL was 0.22±0.27 mm. Neointimal volume was 3.3±4.4 mm3 and volume obstruction was 2.7±4.5% as measured by intravascular ultrasound, and optical coherence tomography showed 98±4% strut coverage at a depth of 0.12±0.06 mm, also at 6 months. No patients developed stent thrombosis. Through 4 years, clinically-driven MACE remains 0%.Final 5-year clinical follow-up will be completed for all patients by April 2017, with all clinical and angiographic data as well as illustrative case examples available for presentation.

CONCLUSIONS

Percutaneous coronary intervention using the Svelte sirolimus-eluting coronary stent IDS is safe and effective in *de novo* coronary artery lesions, with minimal in-stent proliferation and excellent stent strut coverage at 6 months and durable clinical outcomes through 5 years.

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Evolution of TAVI within a time horizon of seven years - A single-centre experience in 2,000 patients (TAVIK registry)

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

AIMS

TAVI has ever increasing importance for the treatment of patients with severe aortic stenosis (AS). The aim of this study was to fully characterise the changes which have taken place regarding the evolution of TAVI over time between 2008 and 2015.

METHODS AND RESULTS

METHODS- Prospective, single center registry of 2,000 consecutive patients undergoing TAVI between May 2008 and March 2015. Patients were divided into four cohorts of 500 consecutive implantations each: cohort I: 04/2008–07/2010; cohort II: 07/2010–04/2012; cohort III: 04/2012–10/2013; cohort IV: 10/2013–03/2015

RESULTS- The mean age was 81.8 ± 5.5 years with no significant variation between the four cohorts (p=0.4). The proportion of females was higher for cohort I (62.8%) than for the later three cohorts (50 to 52.4%, p<0.001). The mean EuroSCORE I decreased from cohort I (24.3 ± 16.7) through cohorts II (21.7 ± 15.6), III (19.6 ± 14.3) and IV (18.7% ± 13.7) (p<0.001). The proportion of patients who were frail decreased steadily from cohort I to cohort IV (48.6 to 17.2%, p<0.001). There were definite trends in the access routes used for TAVI over time, with transapical access decreasing from 43.6% in cohort I to 29.0% in cohort IV (p<0.001). The use of balloon expandable valves increase over time (I: 85.4, II: 77.8, III: 77.5, IV: 89%, p<0.001) caused through a portion of 64.4% SAPIEN 3 in the last cohort. Device success according to VARC-2 criteria increased slightly from cohort I to II (86.2% to 91.4%; p=0.012) with no significant further changes in cohorts III and IV (89.6% and 90.2%). During the first 30 days after the TAVI procedure, there was a non-significant trend towards reduction over time of the proportion of patients who experienced 1 or more event included in the VARC-2 early safety composite endpoint (cohort I: 16%, cohort IV:12%, p=0.068). This was mainly driven by a fall in the proportion of patients experiencing life-threatening bleeding (from 7.0% in cohort 1 to 3.0% in cohort IV, p=0.004) and major vascular complications (5.4% and 1.8%, respectively, p=0.002). There were no significant differences in all-cause mortality between the four cohorts, though cardiovascular mortality decreased from 4.4% in cohort I to 1.8% in cohort IV (p=0.018). Moderate/severe valve regurgitation also decreased over time (cohort I vs. IV: 3.2% vs. 0.0%; p<0.001). Rates of stroke, acute kidney disease (state II/II) and new pacemaker implantations did not show any trends over time.

CONCLUSIONS

Over a time of seven years of TAVI patients have less comorbidity regarding EuroSCORE and frailty. The use of transfemoral implantations rise up significantly and there are significant improvements in cardiovascular mortality, device success, bleeding and vascular complications and moderate/severe valve regurgitation. The stroke and pacemaker rates shows no changes and are further an unresolved problem.

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Sirolimus analog lipophilicity dictates release kinetics and tissue retention after implantation of polymer-free drug-coated stents

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

AIMS

We examined the sensitivity of DCS release kinetics and arterial tissue retention with differing sirolimus analog type in a number of animal models.

METHODS AND RESULTS

Biolimus A9 is a highly lipophilic sirolimus analog (13-fold the lipophilicity of the parent drug) that was specifically designed for local-drug delivery. Biolimus A9 and Sirolimus PF DCS stents (Biosensors International) were coated with the same drug load (225µg) via the same abluminal surface texturing and spray coating processes of stainless steel BioFlex II stents. NZW Rabbits were fed a normal (n=6) or high fat, high cholesterol diet (n=5, HFHC). Bilateral iliac arteries were balloon injured after 14 days on either diet. A Biolimus A9 PF DCS and a sirolimus PF DCS were implanted in the injured arteries of each animal after an additional 14 days. Whole blood samples were analyzed for drug content immediately after implantation, at 1h and 24h, and serum cholesterol measured every 2 weeks. Animals were sacrificed 14 days after stent implantation. Stents and arteries were separated and analyzed for drug content and adjacent nonstented proximal and distal sections evaluated histopathologically.After 4 weeks, whole blood cholesterol levels were 21-fold higher in the HFHC than in the normal diet rabbits after stent implantation (970 vs. 45mg/dL, P=0.002). Histologic findings were comparable save for slightly greater neointimal foam cell accumulation and incidence with HFHC. But in each diet group drug liphophilicity had a dominant effect releasing more sirolimus into the blood and retaining more Biolimus on the stent and adjacent tissue. Residual drug per stent at 14 days was 165-fold higher for the PF DCS coated with Biolimus A9 vs. sirolimus (16.5±5.8% vs. 0.1±0.2%, P<0.001), suggesting a dissolution mediated release process. And arterial tissue retention 14 day post treatment was 8.3-fold higher levels after treatment with Biolimus A9 PFDES than sirolimus PF DCS (75.7 vs. 9.1 µg/g, P<0.001). The faster release of sirolimus resulted in consistently higher whole blood levels compared to Biolimus A9, 11-fold at the 1h peak (36.8 vs. 3.0 ng/mL, P<0.001) and 5-fold at 24h (7.2 vs. 1.3 ng/mL, P<0.001).

CONCLUSIONS

Polymer-free DCS avoid the concern for inflammatory material responses, but are challenged to provide controlled drug release and sustained tissue retention. Release of sirolimus from identically prepared PF DCS occurred faster than Biolimus A9 and achieved significantly higher plasma levels, but significantly lower sirolimus tissue levels than Biolimus A9 in stented arteries under both normal and high fat diets. Thus, the sirolimus analog lipophilicity determines the rate of drug release from PF DCS and the corresponding tissue retention, providing a mechanistic underpinning for the sustained efficacy achieved with Biolimus A9 released from the BioFreedom DCS.

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PARIS score does not predict clinical outcomes in haemodialysis patients on prolonged DAPT after coronary intervention

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

AIMS

PARIS score could predict coronary thrombotic events and major bleeding after PCI with DES. In this study, we aimed to validate the impact of PARIS score in predicting clinical outcomes of hemodialysis patients as a population at the highest risk.

METHODS AND RESULTS

This study included 250 consecutive patients (derived cohort; mean age 65.0± 10.6 years; male 78.6%; diabetes mellitus (DM) 69.8%; insulin dependent DM 41.5%) on regular hemodialysis who underwent PCI with DES from January 2010 to June 2014. All patients received thienopyridine and aspirin for at least 12 months after PCI.

PARIS score was calculated at the time of PCI. Score for coronary thrombotic events (CTEs) consist of integer risk variables, such as insulin-dependent DM, history of ACS, current smoking, CrCl <60ml/min, prior PCI, and prior CABG. The prediction rule assigned 0 to 3 points for each variables, and PARIS score for CTEs was graded from 0 to 10 points. Score for major bleeding (MB) events consist of integer risk variables, such as body mass index, current smoking, presence of anemia, CrCl <60ml/min, and triple therapy on discharge. The prediction rule assigned 0 to 4 points for each variables, and PARIS score for MB was graded from 0 to 14 points.

During a median follow-up period of 973 days, the incidence of CTEs including stent thrombosis and myocardial infarction, the incidence of major adverse cardiac event (MACE) including cardiovascular death, target vessel revascularization, stent thrombosis, and myocardial infarction were compared between patients with PARIS CTEs low score (score ≤2, n=24), intermediate score (3≤ score ≤4, n=70), and high score (5≤ score, n=156) group. The incidence of MB was also compared between patients with PARIS MB low score (score ≤3, n=14), intermediate score (4≤ score ≤7, n=87), and high score (8≤ score, n=149) group.

Over 3 years of observation, CTEs occurred in 12 patients (4.8%), MACE occurred in 94 patients (37.6%), and MB occurred in 12 patients (4.8%). After classification by PARIS score, Kaplan-Meier analysis revealed that the incidence of CTEs during entire study period was 0%, 3.5%, and 8.4% in the low, intermediate, and high coronary thrombosis risk score group, respectively. The incidence of MACE was 25.0%, 35.7%, and 40.4% in the low, intermediate, and high coronary thrombosis risk score group, respectively. Kaplan-Meier analysis also revealed that the incidence of MB was 0%, 5.2%, and 5.4% in the low, intermediate, and high major bleeding risk score group, respectively.

In statistical analysis, CTEs rates showed no significant difference between low and high coronary thrombosis score group (0% vs. 8.4% : Log rank p=0.22). MACE rates showed no significant difference between low and high coronary thrombosis score group (25.0% vs. 40.4% : Log rank p=0.14) either. MB rates also showed no significant difference between low and high major bleeding score group (0% vs. 5.4% : Log rank p=0.40). Furthermore, no significant difference was observed between any other risk score groups in CTEs, MACE, and MB rates.

CONCLUSIONS

PARIS score tended to get higher score in hemodialysis patients, because of the high prevalence of renal dysfunction, anemia, and insulin dependent DM. PARIS score was hardly adapted to the hemodialysis patients in predicting ischemic and bleeding events, and also determining optimal duration of Dual Antiplatelet Therapy after PCI with DES.

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Tips of the dual lumen microcatheter-facilitated reverse wire technique in PCI for markedly angulated bifurcated lesions

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Bifurcation lesion

AIMS

This study aimed to discuss tips about the dual-lumen micro catheter (MC)-facilitated reverse wire technique in percutaneous coronary intervention (PCI) for markedly angulated bifurcated lesions.

METHODS AND RESULTS

Between January 2013 and July 2016, we performed a total of 1338 consecutive PCI procedured. Among the cases, 366 (27.4%) included bifurcated lesions as targets for intervention. Of these, we encountered 12 cases (3.3% of total PCI) who underwent PCI with dual-lumen MC-facilitated reverse wire technique. We retrospectively investigated the lesions' characteristics and the details of the PCI procedures, and provided tips about the use of this technique.

We classified the type of bifurcation according to the combination of the take-off angle and the carina angle. The bifurcation that exhibits both a smaller take-off angle (<90 degrees) and a larger carina angle (>90 degrees) are considered to be the most suitable candidates for this technique. All 6 cases with this type of highly angulated bifurcation required reverse wire technique for guidewire crossing to the side branch. The first step of this technique involves the delivery of the reverse wire system to the target bifurcation. However, most cases with bifurcated lesions exhibit significant stenosis at proximal to the target bifurcation (10/12 cases), which often hampers the delivery of the reverse wire system. Although there has been debate regarding whether roundly or sharply curved guidewires are most suitable for this technique, we consider that a sharply curved guidewire is more appropriate than the other because of its superiority in the system crossability based on the slenderer profile. As a result, we used a polymer-jacket hydrophilic-coated guidewire with a sharp reverse bend curve in the majority of our cases (10/12 cases), and we successfully performed all PCI procedures without any complications.

CONCLUSIONS

The dual-lumen MC-facilitated reverse wire technique is considered to be the method of last resort for inserting a guidewire into a highly angulated side branch. We recommend the use of a polymer-jacket hydrophilic-coated guidewire with a sharp curve for the reverse wire technique. However, it is important to modify the details of this procedure on a case-by-case basis according to the lesion's characteristics.

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Comparison of orbital and rotational atherectomy in calcified lesion in patients undergoing PCI

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

AIMS

We aimed to compare the safety and efficacy of orbital and rotational atherectomy (OA and RA) among all-comer population under going PCI in terms of in-hospital complication and elevation of cardiac biomarkers.

METHODS AND RESULTS

We included all patients undergoing PCI with OA or RA in our institute from 10/2013 until 10/2016. Baseline characteristics, along with procedural aspects were compared, in addition to the acute complications rates and post-procedural cardiac enzyme elevation.

Among 248 patients, 191 underwent RA and 57 underwent OA. There were no significant differences in baseline characteristics between both groups with the exception of creatinine clearance, which was lower in patients with OA (55±29 vs. 67±28ml/Kg, p=0.01). OA was used more frequently in LAD lesions (40% vs. 27%, p=0.02), while RA was more commonly used in RCA lesions (42% vs. 25%, p=0.01). In addition patients with OA had higher rates of drug eluting stent utilization (87% vs. 77%, p=0.04). Intracoronary imaging rates were similarly high between OA and RA groups (61% vs. 62%, p=1.0). There was a higher rate of coronary dissections with OA compared with RA (5.7% vs. 0.4%, p=0.003) but there no difference in peri-procedural clinical events. Post procedural maximal troponin levels were similar among both groups (median peak troponin of 1.48 IQR[3.5-0.26] for OA vs. 2.8 IQR[3.2-0.35] for RA, p=0.11).

CONCLUSIONS

RA and OA have similar safety and efficacy profile in treating calcified coronary lesion and intracoronary imaging is highly beneficial to identify coronary injuring following atherectomy procedures.

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Carotid artery stenting in high-risk patients

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THEME: Interventions for Stroke
TOPIC(S): Carotid stenting

AIMS

to evaluate if patients with contralateral carotid occlusion (characteristic that defines them as high surgical risk patients) have a different final result of the stenting procedure than patients with patent contralateral carotid.

METHODS AND RESULTS

We performed a retrospective analysis of 798 patients (mean age: 71.6 ± 7.9 years old)performed between January 2004 and December 2015.

Results: symptomatic patients with carotid artery stenosis > 80% were 38%. Contralateral stenosis was present in the 33.1% of the patients, the contralateral carotid was patent or with non significative stenosis (< 50%) in the 58.4% of the patients and 8.5% of patients presented a contralateral carotid occlusion. The presence of risk factors was: diabetes (33%), hypertension (79.7%), smoke (39.1%), dyslipidemia (68.7%). Associated comorbidity were: coronary artery disease (69.8%), chronic obstructive pulmonary disease (8.3%), chronic peripheral artery disease (20.7%), renal failure (12.9%). The embolization risk associated to the type of plaque was low in 64.7% of the patients while 17% of the patients presented soft plaque or heavy calcified plaque and they were considered at high risk of embolization. Successful immediate angiographyc result occurred in 96,5% of the patients. Major complications occurred in 11 patient (1.9%) and included: death (1 fatal stroke), major stroke (3), intracerebral hemorrhagic stroke (1), minor stroke (5), acute in-stent thrombosis (1 patient treated with thromboendoarterectomy and stent removal). Puncture site hematoma occurred in 4 patients treated with vascular surgical repair, one patient died for hemorrhagic shock. Successful immediate angiographyc result is not associated with the presence of contralateral occlusion: unsuccessful immediate result was 3.4% in the group without contralateral occlusion and 4,4% in the group with contralateral occlusion (p=0.937). Final result is not associate to the type of plaque too (p=0.323).

CONCLUSIONS

in our experience, if performed by skilled operators, Carotid artery stenting immediate result is not affected by the presence of contralateral carotid occlusion, in fact immediate successful result in high risk patients is not inferior to the immediate result in patients with patent contralateral carotid artery.

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Diagnostic performance of quantitative flow ratio compared with FFR derived from coronary CT angiography

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

The aim of this study was to evaluate the diagnostic performance of quantitative flow ratio (QFR) compared with FFR derived from coronary computed tomography angiography (FFR_{CT}) to detect functionally significant coronary artery stenoses.

METHODS AND RESULTS

We retrospectively analyzed a total of 100 vessels in 63 patients who had undergone FFR_{CT} assessment, invasive coronary angiography, FFR assessment and QFR analysis between July 2015 and April 2016. The diagnostic performance of QFR was compared with FFR_{CT} using invasive FFR as a reference standard. QFR had a higher correlation with FFR than FFR_{CT} ($r = 0.84$, $p<0.001$ and $r = 0.71$, $p<0.001$). Applying to the FFR cutoff value of ≤0.8 to both QFR and FFR_{CT}, higher accuracy {82% (95% confidence interval [CI]: 74-88) and 69%, (95% CI: 60-76)}, higher specificity {89% (95% CI: 81-94) and 63% (95% CI: 55-69) } and higher positive predictive value {85% (95% CI: 75-92) and 59% (95% CI: 51-66)} were observed for QFR than FFR_{CT} respectively. The best cutoff value of QFR and FFR_{CT} for FFR≤0.8 was 0.81 and 0.77. QFR had a higher area under the receiver operating characteristic curve than FFR_{CT} (0.92 and 0.84, $p = 0.0046$), using FFR cutoff value of ≤0.8.

CONCLUSIONS

This study showed that QFR had a higher correlation with invasive FFR and a higher performance for diagnosis of ischemia-causing coronary artery disease than FFR_{CT}.

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The association between periprocedural factors and the one-year mortality of transcatheter edge-to-edge mitral valve repair in patients with mitral regurgitation

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

AIMS

The aim of this study was to investigate the correlation between periprocedural factors and mortality in mitral regurgitation (MR) patients who were treated with transcatheter mitral valve repair using MitraClip.

METHODS AND RESULTS

Between October 2005 to August 2015, a total 320 patients with severe MR were treated with MitraClip in single centre. The patients who had incomplete pre-procedural echocardiographic findings and periprocedural haemodynamic measurements including pre- and post- cardiac output (CO), cardiac index (CI), mean left atrial pressure (LAP) and v-wave, mean pulmonary arterial pressure (PAP), and systolic PAP were excluded from this retrospective study. Therefore, 290 patients were included for final analysis. These patients were divided into 2 groups according to survival status at 12-months after index procedure. The baseline characteristics, echocardiographic data, and haemodynamic parameters were being compared between both groups. During a mean follow up of 311.5±100.5 days, 45 (15.5%) patients died. Those patients who died had higher the society of thoracic surgeons' risk (STS) score (14.2±9.1 vs. 9.8±7.3), higher incidence of hypertension (87% vs. 71%), higher history of previous cardiac surgery (57.8% vs. 33.5%), worse kidney function (creatinine level of 1.82±1.10 vs. 1.39±0.94 mg/dL), more often received cardiac resynchronisation therapy 13% vs. 5%), lower left ventricular ejection fraction (46.3% vs. 52.8%), and more severe of baseline tricuspid regurgitation (grade 3+ or more tricuspid regurgitation (TR) 38% vs. 19%). According to periprocedural hemodynamic data, the decedents had significantly higher in both pre-procedural and post- mean LAP (pre 23.4±9.1 vs. 18.7±7.9 mmHg, post 16.9±5.2 vs. 14.8±7.9 mmHg) and v-wave (pre 38.3±15.1 vs. 31.7±15.6 mmHg, post 24.1±7.8 vs. 21.0±8.4 mmHg), mean PAP (pre 32.8±10.2 vs. 28.9±10.8 mmHg, post 30.2±9.1 vs. 27.1±8.5 mmHg), and systolic PAP (pre 46.5±16.8 vs.41.1±15.6 mmHg, post 44.6±14.6 vs. 39.7±12.4 mmHg). The LAP after MitraClip procedure was significantly reduced in both groups (mean LAP reduction 6.5 mmHg in death group and 3.8 mmHg in survival group; v-wave reduction 14.2 mmHg in death group and 10.7 mmHg in survival group, paired t-test $p<0.001$). A multivariate cox proportional hazards model revealed that increased pre-procedural mean LAP (hazard ratio (HR) 1.11, 95% confidence interval (95% CI) 1.01-1.21, p-value=0.026) and baseline TR 3+ or more (HR 2.01, 95% CI 1.04-3.89, p-value=0.039) were independently associated with all-cause mortality at 12-months.

CONCLUSIONS

In the patients who underwent MitraClip procedure for severe MR, higher pre-procedural mean LAP and baseline grade 3+ and 4+ TR were the independent predictors of all-cause death during 12-months follow-up.

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The radiation dose reduction by using low-frame rate fluoroscopy during PCI

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

AIMS

The aim of the present study was to evaluate the efficacy of using low rare fluoroscopy at 3.0 frames/s (FPS) and store of fluoroscopic images compared with conventional 7.5 FPS for reduction of patient radiation dose during PCI.

METHODS AND RESULTS

From January 1, 2014 to June 30, 2014, 161 consecutive patients with coronary artery disease who underwent PCI (primary or ad-hoc) in our institution were enrolled into the prospective, non-randomized, single center clinical study. The patients with chronic total occlusion or acute coronary syndrome with shock vital requires percutaneous cardiopulmonary support (PCPS) were excluded. The patients were divided into the following two groups: the low frame rate (3.0 FPS) fluoroscopy group (n=37) and the conventional frame rate (7.5FPS) fluoroscopy group (n=124). In the patient's characteristics, gender was significant different between the two group (94.5% male in the low frame rate group versus 80.0% male in the conventional frame rate group, P=0.044). In the procedural characteristics, the median fluoroscopic time (27.4 min interquartile range 21.3-41.2 min vs 29.6 min interquartile range 21.5-41.1 min, P=0.81) and contrast volume (174.5 ml interquartile range 146.0-200.5 ml vs 163.0 ml interquartile range 120.0-200.7 ml, P=0.221) and procedural success rate (100% vs 98.3%) were no significant difference. The median total radiation dose (1056.9 mGy interquartile range 801.5-1377.8 mGy vs 1725.8 mGy interquartile range 1186.5-2884.6 mGy, P<0.001) was significant difference.

CONCLUSIONS

The patient radiation dose could be reduced significantly using low frame rate fluoroscopy and store of fluoroscopic images during PCI. We should be considered for the reduction of the patient radiation dose.

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PCI of coronary bifurcation lesions in current real practice

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI, Stable CAD, Stents and scaffolds, Bifurcation lesion

AIMS

Optimal treatment for bifurcation coronary lesions is still debated. Many studies include small side branches, dismiss the left main (LM) and do not have the contemporary therapeutic tools. To describe bifurcation lesions PCI in current practice.

METHODS AND RESULTS

From March 2014 to April 2015 1960 consecutive PCI performed in two centres were prospectively registered, of which 382 were PCI of bifurcation lesions with a side branch> 2 mm of diameter (19.5%), performed in 353 patients (78.8% male, 65.8 ± 12.5 years). The characteristics of the procedures and major adverse cardiac events (MACE) were analysed after a mean follow up of 24.8 months.

In 45.4% clinical presentation was stable coronary artery disease and in 54.6% acute coronary syndrome (ACS). 33.1% of patients were diabetic, and mean left ventricle ejection fraction (LVEF) was 52 ± 12%. Radial or ulnar approach was chosen in 55.5% of cases and femoral in 44.5%. The location of the bifurcation was: left main: 14.2%, left anterior descending (LAD)-diagonal: 51.7%, Circumflex-obtuse marginal: 20.1%, right coronary artery-acute marginal 4% and posterior descending-posterolateral: 8.2%. 46.3% were true bifurcations.

Provisional stent technique was performed in 93.7% of lesions, and an initial 2-stent technique (2ST) in only 6.3%. Side branch (SB) was predilated in 9.3% of cases and postdilated in 51.3%. The main vessel (MV) was postdilated in 48.7% and final kissing balloon was performed in 5.9% of the PCI with one stent and in 100% of PCI in which two stents were used. Intracoronary imaging techniques were used in 5.7% of cases and FFR in only 1.3%. Bare metal stents were used in 8.4% of cases and DES in 91.6%. Only 2 lesions were treated with dedicated stents and 15 with bioresorbable scaffolds. Angiographic success rate (stenosis <20% and TIMI 3 in both vessels) was 97.6%. Angiographic follow-up was performed in 13% of cases. The adverse event rate at the end of follow-up was 15.5%: 31 deaths (8.3%), 16 cardiac deaths (4.3%); the majority of them in the context of ACS and cardiogenic shock, 14 myocardial infarctions (3.7%), 3 stent thrombosis (0.8%) (2 acute and one very late) and 13 cases with need of target lesion revascularization (3.5%).

A higher MACE rate at the end of follow up was observed in women (72.2% vs 12%; p=0.009), true bifurcations (21.1% vs 9.8%; p= 0.015), higher ostial stenosis and lesion length of the SB (61.6 ± 36.1% vs 42.1 ± 37.9% and 9.6 ± 8.5 mm vs 6.1 ± 7.6 mm respectively) and the presence of stenosis >75% or TIMI <3 flow in the SB after MV stenting (23.3% vs 8.2%; p=0.001) regardless its management. There was a trend towards higher MACE rate in patients presenting with ACS (19.5% vs 11.4%; p =0.08), 2ST (27.3% vs 13.8%; p=0.09), higher age (70.4 ±12.1 vs 66.2 ±12.2 years; p =0.055), lower LVEF (46 ±15 % vs 52 ± 11%; p=0.08) and smaller MV stent diameter (2.9 ± 0.3 mm vs 3.1 ± 0.4 mm; p=0.08).

CONCLUSIONS

Currently, most bifurcation lesions affect the LAD and are treated with provisional DES technique with high success rate and very favorable results after 24.8 months follow-up. Higher MACE rate was observed in women with true bifurcations, higher ostial stenosis and lesion length of the SB, and a stenosis>75% or TIMI3 flow in SB after MV stenting.

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Do we need additional stenting for PCI for very late stent thrombosis?

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

AIMS

The optimal treatment for Very late stent thrombosis (VLST) remains unknown. We compared clinical and angiographic outcomes between additional DES implantation and only plain old balloon angioplasty (POBA) in the timing of PCI for VLST.

METHODS AND RESULTS

A total of 75 patients with 78 lesions underwent DES implantation or POBA for VLST in our institution between January 2001 and December 2016. There were 40 patients with 42 lesions in the DES group and 35 patients with 36 lesions in the POBA group. We evaluated the clinical outcomes including all-cause death, recurrent stent thrombosis, and target lesion revascularization (TLR) at 3 years. Furthermore, quantitative coronary angiographic analysis was performed at follow-up coronary angiography 6 to 8 months after PCI for VLST. All-cause mortality was similar between the DES and POBA groups(20.0% vs. 14.3%, p=0.60). The cumulative incidences of recurrent stent thrombosis and TLR were also similar between the 2 groups (7.1% vs. 6.6%, p=0.81; 20.0% vs. 15.3%, p=0.61; respectively). Follow-up angiography was performed in 63 lesions (DES: 34 lesions, POBA: 29 lesions). Postprocedural diameter stenosis was significantly smaller in the DES group (17.1±10.2% vs. 23.2±12.5%, p=0.04). However, at the follow-up angiography, minimum lumen diameter and diameter stenosis were similar between the 2 groups (2.09±0.85 mm vs. 2.10±0.72 mm, p=0.96; 34.7±21.4% vs. 35.3±18.4%, p=0.91; respectively). There was no significant difference in the binary restenosis rate (14.7% vs. 13.8%, p=1.0) and late lumen loss (0.65±1.06 mm vs. 0.38±0.69 mm, p=0.23) between the 2 groups.

CONCLUSIONS

The clinical and angiographic outcomes were comparable after additional DES implantation and only POBA for VLST. Additional stenting may not be necessarily required in PCI for VLST.

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One-year follow-up of patients treated with extra-long (40 to 60 mm) sirolimus-eluting stents

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

AIMS

To assess the clinical outcome of one year follow-up in a real world population of patients with diffuse long lesions treated with extra-long sirolimus-eluting stents.

METHODS AND RESULTS

Between March 2014 to February 2016 85 consecutive patients with (40 to 60 mm) BioMime stents (Meril Life Sciences, India) implantation were prospectively included. Mean age was 62.67±9.84 years, 22 (25.9%) were diabetics, 24 (28.2%) had a previous PCI or CABG, and 58 (70.7%) had 2 or 3 vessels disease. Chronic total occlusion was treated in 40 (47.1%) of cases. The target vessel was left anterior descending artery in 30 (35.3%) patients, right coronary artery in 45 (52.9%) and left circumflex/obtuse marginal artery in 10 (11.8%). The mean reference artery diameter was 3.12±0.69 mm and the mean target lesion length was 52±9.4 mm. All procedures were performed through radial approach. Angiographic success defined as residual stenosis <20% in the target vessel with TIMI flow 3 and procedure success (angiographic success without major cardiac events during hospitalization) were achieved in all patients. Totally 85 stents were implanted. The additional guide catheter back-up support for the stent delivery was used in 8 (9.4%) patients, including «buddy wire» technique in 6 (7.3%) and Guidezilla guide extension catheter in 2 (2.1%). Cumulative MACE rate at 12 months was 8.1% with 1.1% myocardial infarction and 5.9% TLR. One patient died 6 month after stent implantation from pulmonary thromboembolism. None of the patients had subacute or late stent thrombosis. Follow-up coronary angiography was performed in 48 (68.5%) of cases, binary restenosis was detected in 5 (10.4%) patients.

CONCLUSIONS

The use of extra-long sirolimus-eluting stents in complex real-world patients with long lesions is associated with good procedural and one-year clinical outcomes.

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Difference in the percentages of events during the follow-up according to the indication for the LAA closure. Results of the II Iberian registry

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

The percentages of events during the follow-up of patients undergoing left atrial appendage closure might vary according to the indications for intervention.

METHODS AND RESULTS

In the II Iberian Registry, 598 patients were recruited from 13 hospitals (10 from Spain and 3 from Portugal) between March 02, 2009 and December 18, 2015. Thromboembolic and bleeding events were compared according to the two main indications for intervention, gastrointestinal bleeding and intracranial hemorrhage (238 and 150 patients respectively).

Patients with a history of gastrointestinal bleeding were older (76.1 ± 7.5 vs 73.5 ± 7.8; p<0.001) and had a higher prevalence of diabetes (41.2 vs. 24.7%; p=0.001) than those with intracranial hemorrhage. There were no gender differences between groups. The prevalence of permanent atrial fibrillation (54.2 vs 49.3%; p=0.354) and the CHA_2DS_2-VASC and HASBLED scores (4.5 ± 1.5 vs. 4.6 ± 1.5 and 3.6 ± 1.2 vs. 3.6 ± 1.1) were similar. Prior stroke was present in 22.3% of patients with gastrointestinal bleeding and in 52.7% of patients with intracranial hemorrhage (p<0.001).

The rates of ischemic stroke were 1.4 vs. 2.0 per 100 patient-years (HR: 1.9; p=0.298), those of intracranial hemorrhage were 1.8 vs 0.5 per 100 patient-years (HR: 0.3; p=0.158) and those of gastrointestinal bleeding were 1.4 vs. 6.8 per 100 patient-years (HR: 5.2; p=0.001) in patients with intracranial hemorrhage vs. gastrointestinal bleeding, respectively, during a mean follow-up of 25 months.In the multivariate analysis, a history of stroke was the main predictor of stroke during the follow-up (HR: 9.97; 95% CI: 2.28 to 43.47; (p = 0.002). A history of intracranial hemorrhage was the main predictor of intracranial hemorrhage during the follow-up (HR: 5.03; 95% CI: 0.92 to 27.5; p = 0.062) and a history of gastrointestinal bleeding was the main predictor of gastrointestinal bleeding during the follow-up (HR: 4.27; 95% CI: 1.87 to 9.73; (p = 0.001); (all age-adjusted)

CONCLUSIONS

The percentages of events during the follow-up after LAA closure vary depending on the indication, being especially remarkable gastrointestinal bleeding recurrence in patients with an indication for this cause. The choice of the post-implant treatment should be adjusted according to the various profiles.

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PCI without P2Y12 inhibitor pretreatment: a real-life prospective study

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

AIMS

The aim of this study was to assess the safety of performing PCI immediately after the coronary angiography with an exclusive "on the table" $P2Y_{12}$ inhibitor loading dose by evaluating ischemic and bleeding complications in unselected patients.

METHODS AND RESULTS

Recent studies have challenged systematic pretreatment with a $P2Y_{12}$ inhibitor before percutaneous coronary intervention (PCI) in elective and non-ST segment elevation myocardial infarction (NSTEMI) patients.
In this bicentric, prospective, observational study, consecutive patients admitted for elective PCI or NSTEMI were included and received a $P2Y_{12}$ inhibitor only after the coronary angiogram when PCI was decided. The primary composite endpoint was the first occurrence of cardiovascular death, myocardial infarction, stroke, urgent revascularization, or bailout glycoprotein II_b/III_a inhibitors at 30 days after PCI. Stent thrombosis and bleedings according to BARC criteria were also evaluated.
Among 299 included patients, 188 patients were admitted for elective PCI and 111 for NSTEMI setting. The incidence of the primary endpoint was 8.5% (95%CI [5.7 - 12.4%]). No definite stent thrombosis occurred on the whole population. Three independent predictive factors associated with the primary endpoint were highlighted: NSTEMI setting (OR: 5.61 95%CI=[1.75-17.98),thrombotic coronary lesion (OR: 4.26 (95%CI=[1.45-12.54]) and longer procedure duration (OR: 1.06 (95%CI=[1.03-1.09]). Clinically relevant bleedings (BARC type 2, 3 or 5) occurred in 5.4% of patients.

CONCLUSIONS

In an unselected population addressed for elective PCI or NSTEMI in real life, administration of a $P2Y_{12}$ inhibitor only after coronary anatomy is known is associated with low rate of both ischemic and bleeding events at 30 days.

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Transcatheter vs. surgical AVR in patients with pre-existing liver disease: favorable outcome for transfemoral transcatheter approach

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

AIMS

The optimal treatment of severe aortic stenosis in patients with liver disease is still debatable. This study reports the outcome of patients with liver disease undergoing surgical aortic valve replacement, transapical or transfemoral TAVI.

METHODS AND RESULTS

Baseline characteristics and mortality outcome of 49 patients with pre-existing liver disease were analyzed retrospectively, who underwent either transfemoral TAVI (TF, n=30) and transapical TAVI (TA, n=13) or surgical aortic valve replacement (SAVR, n=6) at our institution between March 2004 and August 2016. Diagnose of liver disease was confirmed prior intervention by sonography, laboratory testing, computed tomography or magnetic resonance imaging. Because of underlying active endocarditis fourteen patients with SAVR were excluded from our study.

Mean follow-up period was 486.2±594.6 days with a mean patients' age of 74.2±10.6 years (17 female, 34.7%). Most frequently etiology of liver disease (Child-Pugh B 73.5%, median MELD-score 14.0) was unknown (36.2%), followed by liver cirrhosis (23.4%) and fatty liver disease (12.8%). In comparison to SAVR rates of postoperative kidney failure (p=0.012), hemodialysis (p=0.001), sepsis (p=0.09), delirium (p=0.020), rate of re-operation (p<0.001) and inotropic support (p<0.001) was reduced significantly as well as length of in-hospital stay (p=0.001; p=0.046) and need of any blood products (both p<0.001) after SAVR compared to TF-TAVI and TA-TAVI respectively. Furthermore in TA-TAVI patients, sepsis (p=0.004), delirium (p=0.046) and rate of re-operation (p=0.001) occurred less frequently and ventilation-time was shorter (p=0.002) compared to SAVR patients.

Thirty-day and 6-month mortality of the overall cohort were 14.3% and 22.4% with no significant differences between the study groups. Only TF-TAVI patients (log-Rank, p=0.005), but not TA-TAVI patients (log-Rank p=0.275) showed favorable long-term survival compared to SAVR. In TAVI procedures, overall survival improved almost significantly if transfemoral approach was performed (log-Rank p=0.068). All 6 patients undergoing SAVR had severe bleeding complications and required re-thoracotomy and re-operation. Preoperative ascites and postoperative sepsis were revealed as multivariable predictors for 30-day mortality. Only postoperative sepsis was found as multivariate predictor for long-term mortality. Neither EuroSCORE-II, STS-, MELD- nor Child-Pugh-Score could reliably predict 30-day mortality (ROC-analysis, p>0.05).

CONCLUSIONS

Independent of the chosen treatment approach, the periprocedural risk and 30-day mortality in patients with liver disease undergoing aortic valve replacement is dramatically increased. Long-term outcome after TF-TAVI seems to be superior in comparison to TA-TAVI and especially to SAVR. Although our cohort of patients undergoing SAVR was very small, there is a clear tendency for a significant benefit in long-term survival for patients receiving TF-TAVI. However to date, there is no current risk score to predict mortality and morbidity in this special patient selection.

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Influence of the presence of thrombus in the occlusion device on ischaemic events after LAA closure. Results of the II Iberian registry

LóPEZ-MíNGUEZ J.R.(1), NOGALES-ASENSIO J.M.(1), INFANTE DE OLIVEIRA E.(2), DE GAMA RIBEIRO V.(3), RUIZ-SALMERóN R.(4), ARZAMENDI D.(5), COSTA M.(6), GUTIéRREZ-GARCíA H.(7), FERNáNDEZ-DíAZ J.A.(8), MARTíN-YUSTE M.(9), RAMA-MERCHáN J.C.(10), MORENO-GóMEZ R.(11), íñIGUEZ-ROMO A.(12), BENEDICTO-BUENDíA A.(13)

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

There is some controversy about whether the presence of thrombus in the occlusion device in patients undergoing left atrial appendage closure is a predictor of stroke. Our aim was to clarify this issue.

METHODS AND RESULTS

The II Iberian Registry (598 patients recruited from 13 hospitals, 10 from Spain and 3 from Portugal) was analyzed to determine the incidence of thrombus in the device (4.7%). The percentage of patients receiving ACP, Amulet or Watchman devices was 46.5%, 34.9% and 18.6%, respectively.

No significant differences were found between the non-thrombus and thrombus groups regarding prior stroke (31.2 vs 37%; p = 0.521) age (74.2 ± 8.1 vs 73.7 ± 7.4; p = 0, 782) CHA_2DS_2VASc (4.4 ± 1.5 vs 4. 5 ± 1.8; p = 0.704) or permanent atrial fibrillation (51.1% vs 59.3%; p = 0.409). The rest of clinical variables were also balanced in both groups with the exception of a higher incidence of gastrointestinal bleedings prior to implant (38.9% vs 59.3%; p = 0. 035).

Patients with a device thrombus had a higher incidence of stroke (11.1 vs. 2.8%; p = 0.049). The incidence of thrombus was significantly higher in the ACP device compared with the AMULET (7.6% vs 2.4%; p = 0.019) or Watchman devices (0.9%; p=0.013), without significant differences between the last two (p = 1).

In the multivariate analysis of the "device thrombus" variable, prior stroke (HR: 2.5; p = 0.05) and the presence of thrombus in the device (HR: 4.2; p = 0.033) were the variables independently related with the incidence of stroke during the follow-up. The presence of leakage (9.4%) did not improve the differentiation.

CONCLUSIONS

Prior stroke and the presence of thrombus in the device in patients undergoing LAA closure may be associated with an increased incidence of stroke during the follow-up. Amulet and Watchman devices seem to have a lower incidence of thrombus compared with the ACP device.

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Pre-diabetes in patients undergoing PCI: extensiveness of coronary disease and repeat revascularisation risk after treatment with contemporary DES

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

AIMS

We examined in all-comers, who underwent percutaneous coronary intervention (PCI), the relationship between glycaemic state and the extensiveness of coronary artery disease as well as the need for repeat target vessel revascularisation.

METHODS AND RESULTS

In the large-scale, multicentre, investigator-initiated BIO-RESORT (clinicaltrials.gov NCT01674803)trial, 3514 all-comer patients were treated with modern drug-eluting stents (DES), of whom glycaemic state was known in 2645 (75%). In 2021 non-diabetic patients, HbA1c was determined to identify pre-diabetes (HbA1c 42-47 mmol/mol) and newly diagnosed diabetes (HbA1c >=48 mmol/mol); another 624 patients had known diabetes mellitus. We assessed the extensiveness of coronary disease and the need for repeat target vessel revascularisation until 1-year follow-up.Pre-diabetes was present in 228 (9%) patients and normo-glycaemia in 1713 (65%). Diabetes (known or new) was present in 704 (27%) patients, of whom 80 patients were newly diagnosed based on HbA1c at admission. Patients with diabetes and pre-diabetes had similar cardiovascular risk profiles that differed significantly from that of normo-glycaemic patients. Pre-diabetic patients had significantly more severely calcified lesions than diabetic and normo-glycaemic patients (24.7% vs. 22.0% and 18.7%, respectively, p=0.01) and a higher prevalence of chronic total occlusions (3.8% vs. 4.3% and 2.6%, respectively, p=0.03). During 1-year follow-up, repeat target vessel revascularisation was more often required in pre-diabetics than in diabetics and normo-glycaemic patients (5.0% vs. 3.0% and 1.5%, p=0.001), and mortality was higher in pre-diabetics and diabetics than in normo-glycaemic patients (3.5% and 3.1% vs. 1.2%, p=0.001). Multivariate analysis showed that the presence of pre-diabetes was an independent predictor of target vessel revascularisation (pre-diabetic vs. normo-glaecemic patients: adjusted OR 3.24, 95%CI:1.48-7.07).

CONCLUSIONS

In this large-scaled all-comer PCI study, patients with pre-diabetes had more advanced coronary disease than normo-glycaemic patients. Pre-diabetes was demonstrated to be an independent predictor of repeat target vessel revascularisation. In non-diabetic patients, routine assessment of HbA1c prior to PCI may be of great value.

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Very long coronary lesions treated with 48mm everolimus-eluting stent and sirolimus-eluting stent: clinical outcomes in a real-world population

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI, Stents and scaffolds, Left main and multivessel disease, CTO, Other Coronary Interventions

AIMS

To assess the clinical outcome of real-world patients with long coronary lesions treated with the 48 mm Xience Xpedition (Abbott Vascular) everolimus-eluting stent (EES) and the 48 mm Biomime (Palex Medical) sirolimus-eluting stent (SES).

METHODS AND RESULTS

Consecutive patients presenting with a very long coronary lesion (>35 mm) treated by percutaneous coronary intervention with at least one implanted 48 mm EES or SES were enrolled in the study. Their clinical data were prospectively registered. Major adverse cardiac events (MACE) were defined as a composite of cardiac death, nonfatal myocardial infarction (according to the Universal Definition) and target lesion revascularization. Stent thrombosis was defined according to the Academic Research Consortium criteria.

Results: Overall, 80 real-world patients with 92 (48 mm) DES (76% men, 63±10 years, 53% smoker, 74% hypertensive, 44% diabetic, 59% hyperlipidemic, 22% CKD, 42% prior ischemic heart disease, 33% prior PCI and 5% prior CABG, 45% LVEF impairment) were enrolled in the study. Clinical presentation was ACS in 80% (17% STEMI). 82% were multivessel and complete revascularization was performed in 76%. 27% were CTO.

47 EES in 45 patients (group 1) and 45 SES in 35 patients (group 2) were inluded. Basal characteristics were similar between groups. At 1.3±0.8-year follow-up, 4 (5.0%; 6.6 vs 2.8%;p=0.43) patients had died from cardiac causes, 1 (1.25%; 2.2 vs 0%; p=0.35) had a nonfatal myocardial infarction and 3 (3.75%; 4.4 vs 2.8%;p=0.65) underwent target lesion revascularization, yielding a 10% cumulative rate of MACE. One patient had a subacute stent thrombosis (2 overlapped SES stents). No significant differences in event rates were found between patients with and without an additional stent implanted overlapping the 48 mm one.

CONCLUSIONS

The use of a new-generation polymer-based 48 mm EES and SES in a real-world population with unselected very long lesions is associated with excellent procedural results and good clinical outcomes at 1.3±0.8-year follow-up.

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TAVI with a single femoral approach: preliminary single-centre experience

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

AIMS

To describe our initial experience with the transradial approach as secondary access site in TAVI.

METHODS AND RESULTS

As of April 2016, a strategy of systematic transradial approach as secondary access site for TAVI was adopted in our centre. A 5 F 125 cm multipurpose catheter was navigated from the left or right radial artery into the common iliac artery to assist in main access puncture. The catheter was then exchanged for a pigtail, which was positioned on the aortic valve to guide TAVI.The multipurpose catheter was used again at the end of the procedure to assess ilio-femoral integrity. In case of an iliac or femoral access complication, the radial sheath was exchanged for a 120 cm long 5F sheath. A 0.018'/400 cm nitinol guidewire was introduced beyond the lesion and a compatible long shaft (180 cm) 5F balloon or nitinol self-expandable stent was introduced and used accordingly. In case of a perforation, a balloon was inflated proximal to the lesion in order to stop the bleeding and contralateral femoral access was obtained in order to deploy a covered stent via a 6F sheath.From April 2016, 184 patients underwent TAVI using this strategy. Patients had a mean age of 83±5.9 years, 52.2% were male, mean Logistic Euroscore and STS score were 16.5±11.6% and 5.3±4.7%, respectively. 97 (52.7%) patients received a balloon-expandable valve and 87 (47.3%) received a self-expandable valve.All procedures were performed under local anaesthesia and conscioussedation. Transradial access as secondary approach was not used in 30 of 184 patients (16.3%) for the following reasons: absence of radial pulse or unsuitable artery size (n=14; 7.6%), prohibitive patient height (n=1; 0.8%), physician preference n=15; 8.1%).TAVI was successful in all cases.No complications occurred due to transradial access. Transfemoral vascular access site complications occurred in 8 cases (4.3 %): three occlusion, two flow-limiting stenoses and three perforations of the common femoral artery. Five complications were successfully managed using self-expanding stents from the transradial access. The 3 cases of perforation (1.6%) were successfully treated with a covered stent delivered via femoral crossover. There were no additional major vascular complications at 30 days.

CONCLUSIONS

Use of the radial approach for secondary access in TAVI is safe and feasible. Most primary access site complications were manageable from the radial access site. A low rate of crossover to the contralateral femoral approach (1,6 %) was neccesary. Further large-scale studies are necessary to confirm the benefits of this approach.

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Clinical outcomes of male vs. female patients undergoing aortic valve-in-valve implantation

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

AIMS

Valve-in-valve (ViV) is an alternative to redo open heart surgery for patients with a failing aortic bioprosthesis. We compared clinical outcomes after ViV-TAVI performed in male vs. female patients for failing bioprostheses using a large registry.

METHODS AND RESULTS

A total of 1646 aortic ViV procedures from the ViV International Data (VIVID) registry were investigated (950 male, 696 female). Male patients were younger at the time of ViV procedure (76.4 ± 10.1 vs. 79.5 ± 8.2 years) and had larger surgical bioprosthesis (true internal diameter 20.9 ± 2.3 vs. 19.1 ± 2.1 mm). Male patients had lower baseline risk vs. females based on logistic EuroSCORE (27.6 ± 17.5 vs. 31.3 ± 16.3), EuroSCORE II (13.6 ± 8.4 vs. 15.8 ± 8.8), and STS mortality (8.7 ± 7.6 vs. 10.5 ± 9.3). Bioprosthetic failure was due to isolated stenosis in 46% of females compared to 33.5% of males ($p < 0.001$). Major bleeding was more common in females (7.7% vs. 5%, $p = 0.02$) but there was otherwise no significant difference in procedural complications. Though similar device types were used, transcatheter prosthesis size was larger in males (25.2 ± 2.2 vs. 24 ± 1.8 mm). Post procedural valve hemodynamics were more favorable in males with greater final aortic valve area (1.54 ± 0.5 vs. 1.37 ± 0.44 cm2, $p < 0.001$) and lower mean gradient (15.4 ± 8.5 vs. 17.3 ± 9.3 mmHg, $p <0.001$). Additionally, female patients had higher 30-day all-cause mortality (6.2% vs. 4.2%, $p = 0.07$) and higher 30-day cardiovascular mortality (5.9% vs. 3.7%, $p = 0.04$).

CONCLUSIONS

All cause and cardiovascular mortality at 30 days post ViV TAVI was higher in female patients compared to males. Male patients undergoing ViV TAVI for failing aortic bioprothesis had more favorable valve hemodynamics as compared to female patients despite similar procedural technique and device type.

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Clinical outcomes of diabetic patients treated with an amphilimus-eluting stent and a short duration of DAPT in routine clinical practice: results of the Utrecht Cre8 (U-Cre8) registry

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

AIMS

Diabetic patients represent one of the most challenging scenarios of DES. Hence, we compared an amphilimus-eluting stent with 3 months of dual antiplatelet therapy to a zotarolimus-eluting stent in the complex setting of (troponin negative) diabetes.

METHODS AND RESULTS

In this observational study, we analyzed all consecutive patients with DM referred to our center from December 2012 to December 2014. The device-oriented primary endpoint was target lesion failure (TLF) as defined by the Academic Research Consortium at 1-year follow-up. A total of 165 consecutive diabetic patients underwent PCI with AES or ZES for stable coronary artery disease in our tertiary center. At 1-year follow-up the cumulative incidence of TLF was 6.7% (5.9% AES versus 7.5% ZES, p=.48). Major Adverse Clinical Event free survival at 1-year follow-up was similar in both AES and ZES (88.2% versus 85.0%, p=.54). Interestingly, we did not find any cases of definite-, and only one case of probable stent thrombosis in this high risk cohort.

CONCLUSIONS

In this real-world registry, both third-generation AES and ZES are associated with promising 1-year safety outcomes in the complex setting of DM. Our finding of no cases of definite-, and only 1 case of probable stent thrombosis despite an extensive risk profile and short DAPT should be further investigated in a large randomized clinical trial.

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Clinical outcomes of valve-in-valve TAVI in degenerated sutureless bioprostheses

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

AIMS

Sutureless valves have a unique frame structure design and an elastic stent body. Our aim was to evaluate the safety and efficacy of performing transcatheter valve-in-valve (ViV) inside failling sutureless surgical valves.

METHODS AND RESULTS

A cohort of 1,919 patients, undergoing aortic ViV, from the Valve-in-Valve International Data (VIVID) registry was analyzed. An international, multicenter registry was developed to collect data on ViV cases performed in sutureless surgical valves as part of the Valve-in-Valve International Data (VIVID) Registry. A total of 24 patients with failing sutureless valves treated by ViV were evaluated: Age 80.3 ± 8 years, 78.2% female (STS-PROM 9.4 ± 5.3%). Sutureless surgical valve sizes ranged from 21 to 25 (median 23) mm and included the Perceval (n = 21) and the ATS 3F (n = 3). The indication for ViV was significant stenosis (n = 4), regurgitation (n = 5) or a mixture of the two (n = 15). The ViV was attempted via the trans-femoral (n = 17) and trans-apical (n = 7) approaches with the SAPIEN XT (n = 9), Sapien 3 (n = 7) and CoreValve (n = 8), sizes 23mm to 29 mm (median 23 mm). There were two cases (10%) with a need for permanent pacemaker implantation, one case with major vascular complication and1 case with major/life threatening bleeding. Implantation was successful in all patients, with a mean postprocedural mean gradient of 14.3 ± 8.8 mmHg. There were no cases with AR > moderate and no need for 2nd prosthesis implantation. There was no coronary obstruction in any of these cases and only one patient died during 30 days of follow-up (4.2%).

CONCLUSIONS

ViV implantation inside selected failed sutureless surgical valves is feasible and associated with reasonable post procedural hemodynamics. The safety of this approach will be further studied.

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Influence of using guide extention catheter on the total amount of contrast agent under PCI with OCT

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

It is recommended to use a contrast medium when performing OCT examination. We investigated wheter the amount of contrast medium can be reduced by using guide extention catheter when treating with OCT.

METHODS AND RESULTS

There are 446 PCI cases treated with OCT from 2013 to 2016. 91 cases using guide extention catheter(group G) and 375 cases of non-use guide extention catheter(group N). In all cases ,CAG and PCI are done simultaneously. In OCT examination,One dose of contrast media was 10ml(2.5ml/s) in group G and 16ml(4ml/s) in group N. 56 cases with mild renal dysfunction(Cr1.2-2.0)(group G 17, group N 74). The amount of the contrast medium was used 202.48ml in group G ,242.88ml in group N(p= 0.0007).
Compare to the group N, the amount of the contrast medium was small in group G.

CONCLUSIONS

In this study,we examined whether reducing the amount of contrast medium by using guide etention catheter. This device can make selectively contrasted,it was possive to treat less contrast agent at total amount.

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Survival advantage of percutaneous mitral valve repair over medical treatment in patients with mitral regurgitation: a meta-analysis

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

AIMS

MitraClip has shown promising results for percutaneous mitral valve repair in patients at high-risk for surgery. *AIM*: to assess the effect of MitraClip on survival in patients with significant mitral regurgitation compared to medical therapy alone.

METHODS AND RESULTS

A meta-analysis on percutaneous mitral valve repair with MitraClip device versus stand-alone medical therapy in patients with symptomatic mitral regurgitation was carried out. The MOOSE statement for reporting systematic reviews and meta-analyses of observational studies was applied.

We conducted a literature search of common electronic databases for studies published from January 2005 to October 2016. Search keywords included a combination of “MitraClip”, “mitral clip”, “percutaneous edge-to-edge repair”, “percutaneous mitral valve repair”, “transcatheter mitral valve repair” and “medical therapy alone”. Reviewers independently examined publications identified by the described search strategy to determine inclusion or exclusion, and extract data for the analysis.

The search strategy identified a total of 658 potential articles. Duplicate reports, abstracts, studies that did not compare survival after PMVR with medical treatment alone, and narrative or systematic reviews were removed. Primary outcome was 30- day and 1-year mortality.

The collected data were summarized across treatment arms using Mantel–Hansel odds ratio (OR) fixed effects model when I^2 was below 25% and heterogeneity p value over 0.05. Otherwise we used random-effect analysis.

No randomized controlled trial was reported. We included 5 observational reports that enrolled a total of 1271 patients: 720 underwent percutaneous mitral valve repair and 551 were managed conservatively. A total of 49 all-cause mortality events were reported at 30 days: 3.05% (22/720) in the MitraClip arm and 4.90% (27/510) in the conservative group, with no significant differences in all-cause mortality (OR 0.64, 95% CI 0.36-1.14, p = 0.13; heterogeneity: I2 = 14%, p 0.33). A total of 269 all-cause mortality events at one year were reported: 15.14% (109/720) in the MitraClip arm and 29.04% (160/551) in the conservative group. A significant difference favoring percutaneous edge-to-edge repair over medical therapy alone was observed at one year follow-up (OR 0.44, 95% CI 0.30–0.64, p < 0.0001; heterogeneity: I2 = 37%, p 0.18). Neither significant between study heterogeneity using the one-study-out method (p=0.18) nor publication bias estimated by funnel plots and the Egger’s linear regression test (p=0.3) were detected.

CONCLUSIONS

Percutaneous mitral valve repair with MitraClip® system may be associated with an improvement in one-year survival compared to stand-alone medical management.

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Measurement of circulating endothelial progenitor cell and endothelial microparticles can detect the coronary spasm

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

AIMS

Endothelial microparticles (EMP) are small vesicles shed from activated or apoptotic endothelial cell. We wonder elevated EMP and EPC level is possible to detect the coronary spasm, by detecting the endothelial dysfunction

METHODS AND RESULTS

Methods

total 125 patients (age 63±11, male 255(72%)) were enrolled. EMP and endothelial progenitor cells(EPC) are determined in peripheral blood by anti CD31-PE and anti CD42-FITC. MPs were defined as CD31+/CD42- particles with a diameter <1.5μm, being MP size calibrated with flow cytometry size calibrations. The values of EMP, EPC, and EMP/EPC ratio in patients with coronary spasm were compared with control group.**Results**

Variant angina(n=85, meanage 64±11) and forty patients shown in no stenotic lesion or spasm (mean age 64±10)were compared as control. There were no significant differences in age and other risk factors between two groups. The level of EMP(%) [(1.33 ± 0.71) in spasm, (1.54 ± 0.96) in control, *p*=0.09]were not different between two groups, EPC values were similar between two groups. [(0.042 ±0.016) vs (0.049 ± 0.022, *p*=0.11)] and EMP/EPC ratio [(62.1 ± 22.2) in spasm, (49.4 ± 24.3) in control, *p*=0.02] were significantly different. Also, in subgroup analysis, the lowest quartile of EPC values groups, EMP/EPC ratio had significant predictive value to detect coronary spasm (OR, 1.88. 1.32-1.99, p=0.01)

CONCLUSIONS

. Variant angina patients with lower EPC level had significantly higher level of EMP/EPC ratio. Compared to no spasm patient. EMP/EPC ratio might had predictive value to detect coronary spasm.

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Interplay of previous mitral surgical prostheses and TAVI - A multicentre study

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

AIMS

Transcatheter aortic valve implantation (TAVI) in patients with previous mitral prostheses (PMP) presents specific risks that are still poorly understood and we aimed to clarify this point.

METHODS AND RESULTS

METHODS: We performed a large real-world multicenter registry between April/2008 and March/2016, of patients with severe symptomatic aortic stenosis who underwent TAVI across 9 centers. We determined the proportion, main characteristics, and outcomes of TAVI recipients according to the presence or absence of PMP.**RESULTS:** The mean age of the study population (n=2396) was 80.58±7.6 years and 48.8% were males. A total of 73 patients (3.1%) had PMP. They were more commonly women (75.3%), younger (74.45±8.7 vs. 80.78±7.6; p<0.001), and with higher surgical risk (LogEuroscore: 29.3±16.2 vs. 20.3±13.4, p<0.001).

From PMP cohort (n=73), 21 patients carried biological prostheses and in 71.2% it was mechanical. Median time between PMP procedures and TAVI was 14 years. Vitamin K inhibitors were used at baseline in 68 patients (93.1%). Bridging therapy with low molecular weight heparin (LMWH) or unfractionated heparin (UFH) was administered in 78.6% (22 patients) and 24.2% (7 patients), respectively. Following the TAVI procedure anticoagulation was re-started within the first 24 hours in 86.7% (26 patients) and at discharge the rate of patients under triple antithrombotic regime was higher (41.1 vs. 9.8%, p<0.001).Most patients (1846, 77,1%) underwent TAVI through transfemoral approach, and the preferred device was the balloon-expandable in 1082 patients (45.2%). The procedure was successful in 94.7% of the global population and an in-hospital mortality rate was 6.6% (128 patients). In patients with PMP transfemoral approach was preferred (93.2% vs. 76.6%, p<0.001). Patients with PMP presented a higher rate of in-hospital complications including vascular complications (19.2 vs. 11.4%, p=0.042) and interaction between the TAVI and the mitral prostheses leading to valve embolization (5.48 vs 1%, P=0.007) that required second valve implantation. None of these patients underwent subsequent surgery. To remark, the rate of bleeding after the procedure and the length of stay were larger for PMP patients.

They use of self-expandable TAVI but not the presence of PMP (35.6% vs. 29.5%, p=0.261) were associated to higher 1-year mortality rate. However, PMP patients remained more often in NYHA class III or IV at 1year of follow-up (21.6% vs. 10.8%, p=0.038).

CONCLUSIONS

The rate of TAVI recipients with PMP remains low. Despite their higher surgical risk, mortality rate was similar at short- and mid-term but with higher rate of complications and limited functional recovery. In particular, vascular injury occurred more often maybe in relation with the more aggresive antithrombotic treatment.Finally, the use of self-expandable prostheses was associated to higher mortality in the PMP group.

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Identification of a subset of patients who may benefit of a direct left transradial approach

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

AIMS

We aim to study predictors of right TRA failure in order to identify a subset of patients who may benefit of a direct left TRA approach

METHODS AND RESULTS

We evaluated all patients referred for coronary angiography or percutaneous coronary intervention from January 2014 to October 2016 at a tertiary care center. We excluded patients whom first access site was TFA or left TRA. We considered failed right TRA those procedures where a coronary angiogram or a PCI was not possible to complete adequately and there was need to switch to another access.

We compared epidemiological variables in patients with a failed right TRA (first attempt) with those successfully catheterized via left TRA or TFA (second attempt) in order to find predictors of right TRA failure.

A total of 3319 patients whom first access site was right TRA were included. Out of those, 3156 (95.1%) were successfully catheterized and in 163 (4.9%) there was need of an alternative access. Second access was left TRA in 73 patients (46.8%) and TFA in 75 patients (46.0%).

Mean age was 69 years (SD=12.7) and 32.5% were women. Significant differences were found between groups. In the group of right TRA failure, patients were older (71.2 vs 68.9 years, p =0.024), shorter (162 vs 165cm, p 0.006) and with smaller body surface area (1.84 vs 1.90m2). Furthermore, there was a higher proportion of women (49.1 vs 31.7%, $p < 0.001$) and patients with hypertension (82.7 vs 74.5, $p = 0.017$). We found 165 cm (ROC area 0.5741) and 75 years (ROC area 0.6534) as suitable cut-off values for height and age, respectively.

CONCLUSIONS

In an experienced radialist tertiary center, right TRA was successful in 95% of patients. Patients older than 75 years, shorter than 165 cm and with a BSA smaller than 1.67 cm2, have a higher rate of right TRA failure. A direct left TRA may expedite the procedure in this subset of patients. This time-saving approach is particularly relevant in primary PCI scenario where any delay means less myocardial salvage.

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Impact of antithrombotic regimes on clinical outcome after TAVI

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

AIMS

Given the high bleeding risk of TAVI patients, selection of optimal antithrombotic therapy is challenging. The aim of this study was to compare different antithrombotic regimes and to assess its impact on clinical outcomes in TAVI patients.

METHODS AND RESULTS

A total of 1663 patients underwent trans-femoral TAVI from January 2007 to October 2016 using 23.1% self-expandable, 6.1% repositionable and 70.8% balloon-expandable prosthesis. Maintenance antithrombotic therapy at discharge was: dual antiplatelet (DAPT, n=1037), vitamin k antagonists (VKA, n=365) and new oral anticoagulants (NOACs, n=261). Thirty-day follow-up was available for all patients. Outcomes of interest were incidence of BARC bleeding ≥3 and mortality at 30 days after TAVI procedure. Treatment groups were comparable regarding baseline characteristics (mean age 81.2 years, 52.3% women) except of the proportion of patients with chronic kidney disease (44.4%% vs. 52.9% vs. 53.6%, p<0.01). Incidence of 30 day BARC bleeding ≥3 was increased in DAPT and VKA group compared to NOACs (24.7% vs. 21.6% vs. 18.0%, p= 0.06), while rates of VARC-2 major vascular complications were 9.3% vs. 9.3% vs. 5.4%, respectively (p=0.05). Unadjusted 30-day mortality was numerically higher in the DAPT group (4.1% vs. 1.6% vs. 2.6%, p=0.06).

CONCLUSIONS

In this descriptive analysis patients receiving DAPT therapy after TAVI seems to have higher unadjusted mortality compared to those receiving anticoagulation. The mechanism behind this finding needs further investigation.

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Paravalvular leak predicts long-term mortality in young but not in old elderly patients undergoing TAVI

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

AIMS

The present study was designed to identify and compare predictors of long-term mortality in young elderly (YE, ≤80 years) and old elderly (OE, >80 years) patients treated with TAVI in contemporary clinical practice.

METHODS AND RESULTS

A total of 1376 consecutive patients undergoing transfemoral TAVI were included. The primary outcome of interest was 3-year all-cause mortality and its age-dependent predictors. Interaction-term analysis was utilized to identify and compare independent predictors of long-term mortality between YE (n=600) and OE (n=776) patients. YE experienced lower mortality compared to their OE counterpart (3- year actuarial mortality rate 33.8% vs. 39.3%; log rank test p=0.001). Predictors of long-term mortality differed between the two groups - any paravalvular leak was a significant predictor of mortality only in YE (YE, HR = 2.04 1.34-3.12 and OE, HR = 1.18 0.86-1.63; p for interaction=0.037), while any bleeding complication predicted mortality only in OE patients (YE, HR = 0.84 0.54-1.33 and OE, HR = 1.76 1.33-2.33; p for interaction=0.007).

CONCLUSIONS

Among predictors of long-term mortality risk after TAVI, modifiable procedure-related factors demonstrate an age-dependent distribution. Presence of any paravalvular leak doubles the risk of death in young, but not in old elderly patients. This identifies avoidance of this complication as an essential task to be resolved prior to expansion of TAVI indication into young patient populations.

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Optimisation and first-in-man clinical evaluation of combined photoacoustic and duplex ultrasound imaging for carotid atherosclerosis and vulnerable plaques detection

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THEME: Interventions for Stroke
TOPIC(S): Carotid stenting

AIMS

The overall aim of this study is to optimise and clinically evaluate the combined photoacoustic (PA) and duplex ultrasound (DUS) imaging for structural and functional assessment of carotid atherosclerosis and vulnerable plaque detection.

METHODS AND RESULTS

An integrated PA and DUS imaging system was optimised for clinical imaging. The system consisted of linear-array transducer coupled to a tunable Nd:YAG laser. *In vivo* imaging of the carotid artery was performed to see the feasibility, appropriateness and performance of combined PA and DUS imaging. Multi-wavelength co-registered PA/DUS structural (microvaculature maps) and functional (oygen saturation (sO_2), haemoglobin concentration (HbT)) images of the carotid artery were obtained. The linear-array based co-registered PA/DUS imaging has been found promising in terms of non-invasiveness, high spatial and temporal resolution at sufficient depths, sensitivity, adaptability and imaging speed for the carotid artery imaging. The high optical contrast provided by PA imaging co-registered with high resolution DUS imaging allows real-time *in vivo* imaging of carotid artery with detailed anatomical analysis.

CONCLUSIONS

PA imaging combined with DUS imaging can be used to visualize molecular tissue changes, not only stenosis, and relates to the evaluation treatment protocols and or post-procedural follow up. Multi-spectral PA imaging can be used to distinguish between different absorbing structures, which provides a more direct assessment of morphology.

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Vascular complications after percutaneous mitral valve repair using the MitraClip system after venous access closure using a suture or Proglide technique

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

AIMS

Aim of this study is to evaluate vascular complications using a standard suture technique as compared to ProGlide in patients receiving percutaneous MitraClip implantation.

METHODS AND RESULTS

Between 2009 and 2015 two hundred and seventy seven consecutive high-risk patients with severe mitral regurgitation (MR) treated with percutaneous MitraClip at our institution were included. Duplex sonography was performed in every patient the day after the procedure. Vascular access site and access site related complications were defined and classified according to the Valve Academic Research Consortium (VARC) criteria. Major vascular complications were vascular injury, unplanned endovascular or surgical interventions associated with death, bleeding or ischemia. Minor vascular complications were vascular injury, unplanned endovascular or surgical interventions not meeting the criteria for major vascular complications. In 275 patients venous access with the 24F sheath was performed from the right femoral vein, in 2 patients from the left side. Functional MR was observed in 31% of the patients with standard suture (n=159) and in 52% of the patients with ProGlide (n=127). Patients receiving sutures were comparable to those receiving ProGlide referring to age, gender, NYHA classification and severity of MR. VARC2 major and minor complications were similar after closure with the suture technique as compared to ProGlide (4% versus 3%, P=0.7; 21% versus 19%, P=0.7). None of the patients suffered from venous thrombosis or local stenosis assesed by ultrasound.

CONCLUSIONS

ProGlide use after percutaneous MitraClip implantation is feasible and safe. However, there is no benefit as compared to the suture technique according to VARC2 major and minor complications.

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Assessment of the non-culprit lesion in patients with STEMI: a comparison between iFR and FFR

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

AIMS

Immediate PCI of the non-culprit vessel in STEMI is associated with improved clinical outcome. The aim of our study was to investigate the value and reliability of FFR and iFR in the acute moment compared to 1 month follow-up in STEMI patients.

METHODS AND RESULTS

43 patients presenting with STEMI and an additional non-culprit coronary lesion, were included. Immediately following successful primary PCI, resting and hyperaemic intracoronary pressure measurements were performed. These measurements were repeated at one-month follow-up. FFR and iFR were calculated retrospectively. FFR significantly decreased between baseline and follow-up (0.89±0.07 versus 0.87±0.08, p=0.003). iFR significantly increased between baseline and follow-up (0.94±0.07 versus 0.95±0.05, p=0.025). Bland-Altman analysis (with follow-up as true value) showed a bias of 0.024 (FFR) and -0.021 (iFR) with a 95% CI interval ranging between -0.079 and 0.126, and -0.136 and 0.094, respectively. Between baseline and follow-up, the number of discordant values was higher for FFR as compared to iFR (23.3% versus 11.6%, p=0.007).

CONCLUSIONS

In the acute setting of STEMI, FFR-values are slightly higher as compared to follow-up. In contrast, iFR-values are slightly lower in the acute setting as compared to follow-up. When applying custom cut-offs, iFR has the lowest percentage of discordant values.

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Treatment of in-stent restenosis with thin strut DES with bioresorbable polymer

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

AIMS

To present one year clinical outcomes of patients with in-stent restenotic lesions treated with Ultimaster, a thin strut sirolimus-eluted stent with bioresorbable polymer in patients enrolled in a large all-comer registry (e-Ultimaster).

METHODS AND RESULTS

e-Ultimaster is a prospective, single-arm, multicentre registry, designed to further validate the safety and efficacy of the Ultimaster drug eluting stent (DES) in unselected patients representative of real life practice. Of the 4597 patients enrolled worldwide in e- Ultimaster registry that have reached 1-year clinical follow-up, 252 patients with at least one treated intrastent restenosis (ISR) were included in this pre-specified subgroup. The mean age of this subgroup population was 66.8 years (77.8% male), 34.1% had diabetes mellitus, 78.5% had hypertension, and 67.2% had hypercholesterolemia. About 14.0% of the patients were current smokers and 10.7% had renal impairment. Bare metal stent (BMS) ISR accounted for 40% of the cases while 60% were treated for ISR after DES implantation. Moreover, 52.4% of patients had multivessel disease, and 48.8% presented with acute coronary syndrome. The number of lesions identified and treated per patients was 1.9±1.1 and 1.6±0.9, respectively. In total, 62.1% of the patients had complex lesions (type B2/C), and 18.5% had moderate or severe lesion calcification. The number of study stent implanted per patient was 1.54±0.88 with an average stent length of 35.6±22.0mm. Of note, 5.5% of ISR lesions were pre-treated with cutting balloon and 2.6% required microcatheter support for successful stent delivery. The study stent was successfully implanted in all target lesions. At least one intracoronary imaging technique was used during the procedure in 31 patients.

At 1 year follow-up, 1.2% of patients died, all from non-cardiac causes while 2.0% had myocardial infarction (MI), all target-vessel related. The rate of clinically driven target lesion revascularization and target vessel revascularization was 2.4% and 3.6%, respectively. The rate of patient oriented composite endpoint was 4.8%, and stent thrombosis (definite+probable) was reported in 2 patients (0.79%). In this group of patients, 95.0% were on dual-antiplatelet therapy (DAPT) at 3 months follow-up while 73.5% remained on DAPT at 1 year follow-up. At 1 year, the rate of major and minor bleeding was 2.0% and 0.79%, respectively.

CONCLUSIONS

Use of the Ultimaster DES for the treatment of ISR appears to be safe and effective, as reflected by low rates of revascularization and stent thrombosis at 1 year follow-up.

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Stent Pattern Qualitative Recognition (SPQR): a study with OCT image fusion

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

AIMS

Usefulness of 3D optical coherence tomography has been shown clinically useful for treatment of bifurcations and as guide in treatment of ST-segment elevation ACS. We aimed to describe the feasibility of using 3D-OCT to recognize implanted stents

METHODS AND RESULTS

Between February 2016 and July 2016, 29 patients carriers of previous metallic stent underwent OCT with 3D reconstruction. A total of 59 stents previously implanted were analysed. The OCT acquisitions were realized using *Dragon Fly Catheter*, (LightLab, St. Jude Medical, St. Paul, Minnesota). After unfractionated heparine use and intracoronary nitroglicerine, the catheter was advanced, through a 0.014´ wire, distal to the stent previously implanted. Automatic injection of contrast was use to remove blood from the vessel and OCT pullback was done. 3D reconstruction was performed. Off-line blinded analysed of each stent was Cohen´s kappa index. A specific kappa index was also calculated for each stent type. A flow chart with key sequential findings helpful to identify stent types was performed.Of 59 analysed stents, 5 (8.5%) were unrecognizable according to the observer 1 and 1 (1.7%) according to the observer 2. A total of 112 observations were performed. The most commonly recognised pattern was “Xience” in 47.32%, followed by “Resolute/Intergrity” (14.29%), “Orsiro” (12.50%), “Promus” (9.82%), “Taxus” (6.25%) and “Biomatrix” (6.25%). The agreement between both observers evaluated by kappa index was 79.54%. The pattern with higher agreement degree was “Promus” (kappa index 89.98%) whereas “Biomatrix” showed the poorest agreement (kappa index 54.5%).
The sequential key features for the stent type characterization according to this novel flow chart were: First, determine if the pattern is on phase (concordance between peaks and valleys) or out-of-phase. Second, identify the connector, mandatory to distinguish between peak-to-peak or peak-to-valley. Third, identify specific features of each platform form a list, as interdigitated appearance in Taxus or S-shaped connector in Biomatrix

CONCLUSIONS

A growing number of patients with previous coronary stent implantation need repeated coronary angiography. Due to the wide expansion of catheterization laboratories and migration movements of population, in some cases the information of previous intervention is not available. In case of intra-stent restenosis the most accepted strategy is “switch strategy” in order to change the drug eluting from the stent. Therefore, our research demonstrates that 3D OCT technology can be useful to recognize the previously implanted stent allowing “switch strategy”. “Promus” presented the most easily recognizable pattern by 3D OCT

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Transradial secondary access for TAVI

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

AIMS

Vascular complications from transfemoral TAVI are common; secondary vascular access, usually also transfemoral, is responsible in up to a quarter of cases. We compare our experience of transradial versus transfemoral secondary access during TAVI.

METHODS AND RESULTS

138 consecutive TAVI cases with single secondary access were studied. 14 used non-transfemoral primary access (9 transaortic, 4 transapical, 1 subclavian); all used successful transradial secondary access to perform aortography. 124 used transfemoral primary access; 57 (46%) planned transfemoral secondary access and 67 (54%) planned transradial secondary access. Radial access failed in two of these cases (small calibre artery (1 case) and radial loop (1 case); transfemoral secondary access was used instead. There were therefore 65 transfemoral TAVI cases with successful transradial access and 59 with successful transfemoral access.A “radial bailout kit” was available including a 400cm 0.018” wire (Plywire Soft Tip, Optimed) and long-shaft 0.018” compatible over-the-wire peripheral angioplasty balloons: Pacific Plus balloons (Medtronic) and Advance 18LP (Cook Medical). This combination of equipment allowed access for intervention above, at, or below the arteriotomy site.In the transradial secondary access group, haemodynamic monitoring and aortography was performed in all cases. During transfemoral TAVI cases, selective iliac angiography to guide femoral access puncture was performed in 19 (29%) cases and following sheath removal in 17 (26%) cases. Percutaneous vascular intervention was performed via transradial secondary access in 9 cases (15%); this was successful in 7 cases (balloon tamponade for primary access site bleeding (4 cases), prophylactic balloon tamponade in a patient at high-risk of primary access site bleeding (1 case) and deployment of a ‘safety wire’ down the femoral artery in case further intervention was required (2 cases)). Two cases of occlusive femoral artery dissection underwent unsuccessful percutaneous intervention from the radial approach and required surgical repair. There were no secondary access complications and no unplanned transfemoral secondary access was required in any of the cases.In the transfemoral secondary access group, one case suffered bilateral secondary access complications (femoral artery dissection of initial contralateral femoral secondary access; second femoral access complicated by intraluminal deployment of the Angioseal closure device (St Jude Medical) requiring surgical repair).There was no difference in contrast dose, radiation dose, screening time or procedural time between the two cohorts.

CONCLUSIONS

Transradial secondary access during TAVI is safe and feasible; unplanned transfemoral access was not required in any cases. In non-transfemoral TAVI, transradial secondary access should be considered default practice. For transfemoral TAVI, with appropriate equipment, significant peripheral vascular complications can be managed without the need for unplanned contralateral transfemoral secondary access.

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Impact of atrial fibrillation on cerebral infarcts during TAVI

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

AIMS

TAVI is associated with the risk of cerebral infarcts as evident from diffusion-weighted MRI. We investigated the impact of atrial fibrillation on the incidence of cerebral infarcts in patients undergoing TAVI.

METHODS AND RESULTS

A total of 356 consecutive patients (mean age 82 ± 7 years, EuroSCORE 20.5 ± 12.8%, 50% male), who underwent TAVI and received a cerebral diffusion-weighted MRI 3-5 days after TAVI to detect cerebral infarcts were enrolled. Patients who underwent TAVI under cerebral protection were excluded.

New cerebral infarcts were found in 71.3% of patients. The prevalence of atrial fibrillation at baseline was 34.3% (122/356). Out of 234 patients in sinus rhythm, 11 patients had a periprocedural atrial fibrillation (4.7%). The incidence of cerebral infarcts was comparable between patients with baseline or periprocedural atrial fibrillation compared to patients without atrial fibrillation (73.7% versus 70%, p=0.47).

CONCLUSIONS

Compared to patients in sinus rhythm, the incidence of cerebral infarcts is not higher in patients with baseline or periprocedural atrial fibrillation.

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Performance of >40 mm DES in very long (>35 mm) coronary lesions

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

AIMS

To assess the clinical outcome of real-world patients with long coronary lesions treated with >40 mm drug eluting stents.

METHODS AND RESULTS

Consecutive patients presenting with a very long coronary lesion (>35 mm) treated by percutaneous coronary intervention with at least one implanted 40 mm EES or SES were enrolled in the study. Their clinical data were prospectively registered. Major adverse cardiac events (MACE) were defined as a composite of cardiac death, nonfatal myocardial infarction and target lesion revascularization. Stent thrombosis was defined according to the Academic Research Consortium criteria.

Results: Overall, 94 real-world patients with 113 lesions (80% male, 63.8±10 years, 55% smoker, 77% hypertensive, 41.5% diabetic, 58% hyperlipidemic, 19% CKD, 40% previous ischemic heart disease, 32% prior PCI and 4.3% prior CABG, 43% LVEF impairment) were enrolled in the study. Clinical presentation was ACS in 80% (17.5% STEMI). 82% were multivessel and complete revascularization was performed in 80%. The most frequent artery treated with long stent was LAD (39%) followed by RCA (35%) and mid segments were the most frequently affected (58%). All lesion were type C. Bifurcation lesions account 44%, ostial 32%, calcified 87%, thrombotic 20.6% and 22.7% were CTO.

Predilatation/postdilatation was performed in 95/36% respectively. Debulking was performed in 8%. Mean lesion length was 41.5±9.8 mm, and mean stent lengthwas 46±2.5 mm. The number of stents per lesion was 1.7±0.7, with overlapped stents in 59%. The total length (in mm) of stent per lesion was 64±21 mm.

EES (Xience Xpedition) were implanted in 54% cases and 46% were SES (Biomime). At 14.8±11month follow-up, 4 (4.3%) patients had died from cardiac causes (also 4 died for Non-CV cause), 2 (2.1%) had a nonfatal myocardial infarction and 3 (3.2%) underwent target lesion revascularization, yielding a 9.6% cumulative rate of MACE. One patient had a subacute stent thrombosis (2 overlapped SES stents=1.1%). No significant differences in event rates were found between patients with and without an additional stent implanted overlapping the >40 mm one.

CONCLUSIONS

Patients with complex very long coronary lesions in a real-world population treated with long DES (>40 mm) are associated with excellent procedural results and good clinical outcomes at 14.8±11month follow-up.

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Very long-term (up to 24 years) follow-up after mitral balloon valvuloplasty in rheumatic mitral stenosis

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

AIMS

This study sought to access the very long-term outcomes after successful percutaneous mitral balloon valvuloplasty due to severe symptomatic rheumatic mitral stenosis.

METHODS AND RESULTS

This is a single center analysis of all consecutive patients who underwent successful percutaneous mitral balloon valvuloplasty (PBMV) (post-procedural valve area ≥ 1.5 cm^2 and moderate or less residual regurgitation, without in-hospital major adverse cardiac and cerebrovascular events) between 1987 and 2011. The primary endpoint was the incidence of major adverse cardiac events (MACE), including global death, need for mitral surgery or repeat PMBV up to 23 years after the procedure.Among all 1582 patients, success was achieved in 90.9% (1438 patients). The independent predictors of success were left atrium size (HR: 0.96, 95% CI: 0.93-0.99, p=0.045), Wilkins-score ≤ 8 (HR: 1.66, 95% CI: 0.48-0.93, p=0.02) and age (HR: 1.02, 95% CI: 1.02-1.04, p=0.006). Long-term follow-up (mean 15.6 ± 4.9 years; IQ range 1-24 years) was obtained in 979 cases (68%). The incidence of the primary endpoint was 19.1% (95% CI: 17.0-21.1). The rate of overall mortality, need for mitral surgery or repeat PMBV was 0.6% (95% CI: 0.3-1.2), 8.3% (95% CI: 7.0-9.9), and 10.0% (95% CI: 8.5-11.7), respectively. The mean MACE-free survival time was 18.9 years (95% CI: 18.4-19.35 years). Cumulative MACE-free survival rate at 24 years was 76.4%. At multivariate analysis, NYHA functional class III-IV (HR: 1.62, 95% CI: 1.26-2.09, p<0.001), age (for each 1 year HR: 0.97, 95% CI: 0.96-0.98, p=0.028) and mitral valve area ≤1.75 mmHg after procedure (HR: 1.67, 95% CI: 1.28-2.11, p=0.028) were identified as independent predictors of the primary endpoint.

CONCLUSIONS

Twenty-four years after successful percutaneous mitral valvuloplasty over 75% of followed patients still exhibit sustained results. Prediction of late favorable results is multifactorial and strongly determined by age and previous symptoms.

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Impact of gender in patients undergoing BRS: a high-volume single-centre study with long-term follow-up

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

AIMS

Few data exist about clinical outcomes according to gender in patients treated with BRS in daily clinical practice.

METHODS AND RESULTS

The study was a retrospective, single, high-volume PCI center registry using Absorb BRS in both stable angina (30.5%) and acute coronary syndrome (STEMI: 29.5%, NSTEMI: 24.2%, Unstable Angina: 15.9%) patients. We include 302 consecutive BRS patients enrolled from September 2013 to September 2016 (mean age 55.3±10.4 years, 83.8% male). We compare both genders looking for predictors of adverse events. Regarding baseline characteristic we found higher rates of hypertension (67.4% vs. 47.6%, p=0.013) in females and higher rates of smoking habits (35.9% vs. 22.4%, p<0.001) in males. There were no other significant differences in lesion characteristics, number of devices, device diameter or length, rates of post-dilatation, bifurcation lesions and use of intravascular imaging between genders. We follow 187 patients (61.9%) during 613±296 days. During this long-term follow-up, males had lower rates of recurrent angina (7.9% vs 26.5%, p=0.005) and were less frequently submitted to coronary angiography (31.3% vs. 52.2%, p=0.057). The composite endpoint of long-term follow-up events occurred in 51 (27.3%) patient [all-cause mortality (n=6, 3.2%), cardiovascular hospitalization (n=11, 5.9%), recurrent angina (n=21, 11.2%), myocardial revascularization (n=24, 12.8%) or stent thrombosis (n=7, 3.7%)]. Through logistic regression model we found that gender is an independent predictor of the composite endpoint (female: 47.1% vs. male: 22.9%; OR: 0.33, 95%CI: 0.15 – 0.73; p=0.006].

CONCLUSIONS

During this long-term follow-up with bioresorbable coronary devices, we found few adverse events, particularly low mortality rate and stent thrombosis. Regarding on gender comparison, no significant differences about procedures. Higher rates of adverse events in females should be considered in analysis of future clinical trials with BVS devices.

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Comparison of transradial vs. transfemoral access for aorto-iliac and femoral interventions. A single-centre experience

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal, Other peripheral interventions

AIMS

To compare the procedure and safety outcomes of the transradial (TR) approach with the transfemoral (TF) approach for treating aortoiliac and femoro-popliteal stenoses and occlusions.

METHODS AND RESULTS

A single-center retrospective study was conducted involving 1215 patients (mean age 67.2±12.2 years) with lower limb claudication or critical limb ischemia who underwent aorto-iliac (459, 37.8%) or femoral (792, 65.2%) interventions over a 3-year period. Operator discretion determined TR suitability; exclusions included Raynaud's disease, upper limb occlusive disease, previous TR difficulties, or planned hemodialysis. Lesion characteristics, clinical endpoints (MAE, MACCE), vascular complications (procedural and access) were compared. Good angiographic result was reached in 278 patients (98%) in the TR and in 886 patients (95%) in the TF group (p=ns). CTO recanalization was performed in 72 patients (25.35%) in the TR and in (36.5%) patients in the TF group (p=0.001). Dual access was used in 6.3% in the TR and in 6.8% in the TF group (p=ns). The one year MAE rate in the TR and TF group was 35.56 % and 43.18 % (p=0.02), while the one year MACCE rate in the TR and TF group was 16.90 and 18.90% (p=ns), respectively. The rate of all vascular complications were 2.11% and 3.26 % (p=ns) in the TR and TF group. Access site complications were encountered in 32 patients (11.2%) in the TR and in 103 patients (10.65%) in the TF group (p=ns), but the rate of major access site complications were significantly lower in the TR group (2/34, p=0.008).

CONCLUSIONS

The transradial approach for aortoiliac and femoropopliteal interventions is safe and efficacious compared with the transfemoral approach for a range of lesion subtypes and the radial access is associated with less major access site complications and long term MAEs.

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Clinical outcomes of patients treated with everolimus-eluting BRS in real-world: the antiplatelet therapy perspective

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

AIMS

An increasing number of patients have been treated with everolimus-eluting bioresorbable vascular scaffolds (BRS). Long-term outcome data are limited, particularly which antiplatelet therapy is associated with less adverse events.

METHODS AND RESULTS

The study enrolled 302 patients treated with BRS (Absorb) from September 2013 to September 2016 (mean age 55.3±10.4 years, 83.8% male). Most patients presented with acute coronary syndromes (n=210, 69.5%). We compare both antiplatelet therapies (clopidogrel and ticagrelor) in complement to aspirin, as dual antiplatelet therapy prescribed after procedure, looking for predictors of adverse events. There were no significant differences in lesion characteristics, number of devices, device diameter or length, bifurcation lesions and use of intravascular imaging between clopidogrel and ticagrelor. During the enrolment period we assist a progressively increase in ticagrelor prescription (ticagrelor: 1st year: 10.3%, 2nd year: 39.4%, 3rd year: 68.8% vs clopidogrel: 1st year: 89.7%, 2nd year: 60.6%, 3rd year: 31.2%; p<0.001). Clinical follow-up was available in 187 patients (61.9%) and was performed during 613±296 days. Additional angiographic (n=37, 12.3%) and coronary computed tomography angiogram follow-up (n=35, 11.6%) were performed. Clinical endpoints of interest included the composite of all-cause mortality (n=6, 3.2%), cardiovascular hospitalization (n=11, 5.9%), recurrent angina (n=21, 11.2%), myocardial revascularization (n=24, 12.8%) or stent thrombosis (n=7, 3.7%). We report one case of subacute scaffold thrombosis, 2 cases of late and 4 cases of very late thrombosis. No significant differences between both antiplatelets regarding composite endpoint or each individual endpoint except stent thrombosis: no thrombosis occurred under ticagrelor treatment (p<0.001).

CONCLUSIONS

Clinical results of everolimus-eluting BRS in a real-world-scenario demonstrate satisfactory clinical outcomes. The incidence of very late scaffold thrombosis is a signal that warrants further careful monitoring and investigation. Dual antiplatelet therapy with ticagrelor appears to be less associated with stent thrombosis.

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A novel right heart assist device - The PERKAT RV system

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

AIMS

Right ventricular failure is a clinically challenging problem with a high mortality. Temporary mechanical right ventricular support offers a treatment option. Thus, we developed a pulsatile assist device for rapid percutaneous implantation.

METHODS AND RESULTS

The PERKAT RV („PERkutane KATheterpumptechnologie“) device consists of a self-expanding nitinol pump chamber which is covered by foils carrying multiple inflow valves. A flexible outlet tube with a pigtail-shaped tip and outflow valves is attached to its distal part.

The system is designed for 18F percutaneous implantation via the femoral vein. Pulling back the sheath unfolds the nitinol chamber in the inferior vena cava while the outlet tube bypasses the right atrium and ventricle with the pigtail tip in the pulmonary trunk. A standard IABP balloon is placed into the pumping chamber and is connected to an external IABP console. Balloon deflation generates a blood flow from the vena cava into the chamber through the foil valves. During balloon inflation blood is guided through the tube into the pulmonary arteries.

In an in vitro setting the PERKAT RV device was placed in a reservoir with pre-specified blood analogue levels simulating the inferior vena cava. The flexible outflow tube was adjunct to a higher blood analogue reservoir simulating various afterload situations (30 cm= 22 mmHg; 60 cm= 44 mmHg; 90 cm= 66 mmHg). After initiation of pump support, the flow (in l/min) was analyzed at constant pump rates of 60, 70, 80, 90, 100, 110, and 120/min. Using a 40 ml IABP balloon, the PERKAT RV device generated a flow of 2.3; 2.6; 3.0; 3.3; 3.6; and 3.7 l/min, respectively in the 22 mmHg afterload setting.

Acute right ventricular failure was induced by venous injection of Sephadex (macroscopic beads synthetically derived from the polysaccharide dextran) in seven sheep for in vivo evaluation of the device. PERKAT RV was implanted in the inferior vena cava via percutaneous approach through the right femoral vein. The device was able to improve the hemodynamic situation immediately generating a median increase in cardiac output of 47 %. Longer pump support was evaluated in a second animal study. Two sheep were supported by PERKAT RV for 8 h without any problems. It was possible in both animals to explant the device by pulling back into the 18F sheath without any problems.

CONCLUSIONS

The novel, percutaneously implantable PERKAT RV device for acute mechanical circulatory support of the right ventricle offers sufficient in vitro flow rates of up to 3.7 l/min. Based on the in vitro results, preclinical sheep studies proved beneficial hemodynamic effects of the device in acute right ventricular failure. Ongoing animal experiments will further evaluate the performance of PERKAT RV before first-in-man implantation. The novel PERKAT RV system offers easy and safe treatment in acute right ventricular failure.

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Predictors of coronary collateral development in late presentation myocardial infarction: hemogram parameters may play a role

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

AIMS

We aimed to identify predictors of well-developed coronary collateral circulation in patients with a late presentation (>24 hours) myocardial infarction (MI).

METHODS AND RESULTS

Ambispective multicenter longitudinal study on 107 patients with a LPMI and angiographic evidence of a thrombotic occlusion (TIMI 0) of a major coronary artery from 2009 to 2015. Exclusion criteria were: Previous coronary artery bypass grafting (CABG); a chronic total occlusion or a critical stenosis in a major coronary artery; left main disease and other severe comorbidities.

The Rentrop and Werner score were used for the angiographic categorization of collateral circulation (CC). Patients in Rentrop grades 0 and 1 were classified as poor CC, and grades 2 and 3 were classified as good CC. Two experienced cardiologists retrospectively evaluated the angiographies in a blinded manner to classify the CC into grades. The angiographies had enough quality in 88 patients that were finally included. The Kappa index of agreement was used to evaluate the interobserver variability for the classification of patients into one group or the other in a single random sample of 33 patients. The study protocol was approved by the local ethics committee.Poor CC was detected in 49 patients (56%). The Kappa indices of agreement for variability was

excellent (k = 0.88; 95% CI, 0.82-1.00). Patients with good CC more commonly had a right coronary (RC) occlusion but less often had a left anterior descending occlusion ($p<0.05$ for both) and had a non-significant trend for a longer time between symptom onset and catheterization (8.4±7.8 vs 5.6 ±7.2 days, p=0.1).

Poor CC patients showed a higher maximal ST-segment elevation (2.3±1.7 vs 0.8±1.1 mm, p=0.0003); a higher number of leads with ST segment elevation greater than 1 mm (1.6±1.7 vs 3.6±1.9, p=0.0001) and had more frequently ST-elevation at presentation (88% vs 50%, p= 0.01) compared to good CC patients.

There were no significant differences between good and poor CC groups in baseline characteristics (Sex, age, cardiovascular risk factors, previous treatment and comorbidities). Patients with good CC had a non-significant trend for a higher prevalence of smoking (55% vs 68%, p=0.15).

Peak serum creatine kinase (CK) had a non-significant trend to be higher in poor CC patients (1829±1536 vs 1138±1739 ng/ml, p=0.08). Eosinophils (EOS) count (0.11±0.1 vs 0.25±0.2 mgr/dl, p=0.001) and EOS percentage (0.8±1.4 vs 1.5±1.5 %, p=0.054) were higher in good CC patients. Neutrophils count (9.02±3.8 Vs 7.17±2.9 mgr/dl, p= 0.02) and neutrophils percentage were significantly reduced (72±12 vs 66±9 % ,p=0.02) in good CC compared to poor CC patients.

RENTROP and Werner classification were moderated but significantly correlated to EOS count (r=0.29, p=0.013 and r=0.23, p=0.04 respectively).

The result of receiver-operating characteristic (ROC) curve analysis for the EOS count in the prediction of good CC was AUC: 0.727 and 95% CI: 0.60–0.84 with 87.5% sensitivity and 61.0% specificity

CONCLUSIONS

Late presentation MI with good CC more commonly have a RC occlusion and present without ST-segment elevation compared to poor CC patients.

Neutrophils but especially eosinophils were significant predictors of good CC in late presentation MI patients suggesting that inflammatory cells may play a role in the formation of CC in late presentation MI patients.

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There is still place for bare-metal stents?

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

AIMS

Purpose:

The aim of the study was to determine independent predictors for use of BMS and assess the impact of their use in the prognosis of patients with ACS.

METHODS AND RESULTS

Methods:

A retrospective study was conducted encompassing all patients admitted for ACS treated with DES or BMS in a cardiology service of 1 October 2010 to 31 August 2015. Baseline characteristics of patients, data on admission and therapeutic strategies were evaluated. It was performed univariate and multivariate analysis of mortality and hospitalization rates in follow-up of 1 year. For statistical analysis, we used SPSS.**Results:**

In the study period, 1941 patients with ACS were undergoing angioplasty with stenting, 1548 (80,5%) with DES and 376 (19,5%) with BMS.

There was an association with DES use with: younger age (p<0,01), dyslipidemia (p=0,04), familiar history of coronary heart disease (p=0,04). There was an association with BMS use with: older age (p<0,01), valvular disease (p<0,01), heart failure (p=0,03), pulmonary disease (p<0,01), dementia (p<0,01), lower ejection fraction of left ventricle (LVEF) (p<0,01) and longer ischemia time (onset of symptoms until revascularization) (p=0,01).

During hospitalization, BMS use was associated with increased hospital mortality (6,4%vs1,2%, p<0,01) and higher rate of complications: major bleeding (p=0,01), cardiac arrest (p<0,01), ventricular tachycardia (p<0,01), auriculo-ventricular block (p<0,01), atrial fibrillation (p<0,01), heart failure (p<0,01) and need for mechanical ventilation (p<0,01).

In the follow-up of 1 year BMS use was associated with higher mortality rate (9,5%vs2,4%, p<0,01) and hospitalization rate (18,4%vs12,9%, p=0,02).

In multivariate analysis were identified as independent predictors for BMS use: older age (p<0.01), lower LVEF (p=0,02) and a longer ischemia time (p<0,01). In 1 year follow-up use of BMS was an independent predictor of mortality (p=0,04), but not of hospitalization (p>0.05).

CONCLUSIONS

Conclusions:

1 – ACS patients treated with BMS (vs DES): were more older and had more morbidities; had a higher hospital mortality and more complications; in 1 year follow had higher rates of mortality and hospitalization.

2 - Older age, longer ischemia time and lower LVEF were independent predictors for BMS use.

3 – BMS use was an independent predictor of mortality at 1 year.

4- In spite of the differences between populations, BMS use did not show any benefit compared with DES, rather, was a predictor of mortality.

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PFO detected by transoesophageal echocardiography post-Watchman implantation for atrial fibrillation - A cause for concern?

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

Incidence of patent foramen ovale (PFO) post-Watchman implantation for atrial fibrillation, remains unknown. We aimed to observe the incidence of PFO detected by transoesophageal echocardiography (TOE), post-Watchman implantation.

METHODS AND RESULTS

We retrospectively identified all patients (n=73) who had a Watchman device implanted between 2014-2016 at Beaumont Hospital. Within this cohort, patients who had undergone post-procedural TOE were analyzed for evidence of de novo PFO and compared with pre-procedural imaging. Data were expressed as mean ± SD and %. Baseline demographic of all patients were age, 77 ± 7 years; male, 71%; CHADSVASC2 score, 4.3 ± 1.4; with left ventricular ejection fraction 49 ± 8%. All patients had a 14F catheter across the inter-atrial septum to fascilitate Watchman device delivery. 66% (n=48) had post-procedural TOE performed with mean duration from time of implant of 5.3 ± 4.2 months. Incidence of PFO pre-Watchman implantation was 16%. There was a 17% (n=8) incidence of de novo PFO post-Watchman implant after comparison with pre-procedural TOE. Mean PFO size pre- and post-Watchman was 0.12 ± 0.38 vs 0.29 ± 0.58 cm, respectively. This change in PFO size of 0.13 ± 0.57 cm trended towards significance (p=0.09).

CONCLUSIONS

A modest incidence of PFO was detected by TOE post-Watchman implantation. The relevance of this finding requires further investigation.

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Safety and faesibilty of PFO closure under transoesophageal echo and sedation without anaesthesiologist

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THEME: Interventions for Stroke
TOPIC(S): Ischaemic stroke, Other stroke interventions

AIMS

Transoesophageal echo (TOE) guided PFO closure generally is performed under general anaesthesia.
The aim of our study is to compare safety and faesibility of PFO closure with TOE “under general anaesthesia” (UGA) versus “under sedation” (US).

METHODS AND RESULTS

We performed a observational retrospective study on 150 consecutive patients treated in our centre. General anaesthesia was performed with propofol administered by anaesthesiologists. Sedation was performed with midazolam and fentanyl administer by cath-lab nurses, after a specific training and following a protocol shared with anaesthesiologists (but without anaesthesiologists in cath lab).
We treated 150 patients (age 55±5). 40% were in UGA gruop and 60% were in the US group.
We had 4 complications: 2 air embolization in right coronary artery with transient ST elevation and 2 sopraventricolar tachicardia. Complication rate did non differ in the two group. Only two patients, with a weight more than 110 Kg, in the US group required propofol.
Any patient in both group required orotracheal intubation.
Any patient in both group suffered ab-ingestis pneumonia.
All patient in the US group were treated with anexate after the procedure.

CONCLUSIONS

PFO closure TOE guided under sedation is feasible and safe. Midazolam and fentanyl under trained Cath-lab nurses control permit to perform the procedure without anaesthesiologist and without adverse events.

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Safety and efficiency of switching of adenosine diphosphate receptor inhibitor from ticagrelor to clopidogrel at one month after hospital discharge among all coming patients treated by PCI

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

AIMS

In clinical practice, there is a frequent need to switch between P2Y12 receptor inhibitors.To date, the PD effects of switching from ticagrelor to clopidogrel have yet to be investigated.

METHODS AND RESULTS

This prospective study was carried out in the department of cardiology, during a period from August 2015 to October 2016. A total of 456 consecutive patients with STEMI/NSTEMI undergoing percutaneous coronary intervention were included in the study.We examined GUSTO moderate or severe bleeding, major adverse cardiovascular events (MACEs), and definite stent thrombosis events around the time of the switch and after a mean follow up of 227+/- 94 days. The patients take ticagrelor for 30 days from PCI and switch to clopidogrel in day 30 taking ticagrelor and clopidogrel in this same day. Switching occurred at a median of 30 days postdischarge. Comparing the 7 days preceding and following the switch to clopidogrel, we don’t not any upsurgeof MACE or modification of GUSTO moderate or severe bleeding event and any stent thrombosis.

CONCLUSIONS

Postdischarge ADPri switching can occure frequently from ticagrelor to clopidogrel within the first days post-PCI and was not associated with significant MACEs or bleeding events after switching at one month in our study.

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Clinical impact of persisting iatrogenic atrial septal defect following percutaneous mitral valve repair

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

AIMS

Iatrogenic atrial septal defect after MitraClip implantation is not routinely closed and data about its impact on outcomes are scarce. AIM: to assess prognostic implications of persisting atrial septal defect after percutaneous mitral valve repair.

METHODS AND RESULTS

Prospective registry of all consecutive patients treated with MitraClip between June/2014-November/2016 in our Institution was carried out. Baseline characteristics and clinical and echocardiographic follow up were analyzed. Primary endpoint was defined as a combination of cardiovascular mortality, re-admission for heart failure and advanced NYHA functional III or IV at last clinical follow up. Persistent left atrial septal defect was defined by the presence of spontaneous interatrial septal shunt evaluated by color doppler at two months echocardiographic follow up after the procedure. Multivariate COX regression analysis was performed to assess prognostic implications of persisting atrial septal defect after percutaneous mitral valve repair in clinical outcomes.

In this period, 51 patients (mean age 73.6±10.1 years old, male 68.6 %) with symptomatic mitral regurgitation were treated percutaneously with MitraClip device in our Institution. Logistic EuroScore was 22.6±15.9%, 76.5% presented functional mitral regurgitation and mean ejection fraction was 38.5±15.2%. 88.2% of patients had been previously admitted for heart failure within previous year and 86.3% were in functional class NYHA III-IV before the procedure.

Successful percutaneous mitral valve repaired, defined as residual mitral regurgitation grade I or II, was performed in 94.1% of the patients and more than one clip was implanted in 46.3% of the cases. Clinical follow-up was performed during a median of 370 (179-533) days in 49 patients. At two months echocardiographic follow up, an interatrial septal defect was observed in 16/49 patients (32.7%). No significant differences were found regarding age, mean left ventricular ejection fraction, seattle heart failure risk score or residual mitral regurgitation after MitraClip implantation between the two groups of patients with or without post-procedural interatrial septal defect.

Persisting iatrogenic interatrial septal defect was related to a higher incidence of the primary end-point (56.2% vs 18.2%, p = 0.010). Furthermore, the presence of echocardiographic interatrial shunt was associated with higher levels of pro-BNP at six months follow up (mean proBNP 6445 vs 1971, p = 0.039). Multivariate COX regression analysis showed a significant increase in the risk of the primary endpoint in patients with persisting atrial septal defect (HR 4.586, CI 95% 1,356-15.386, p = 0.014).

CONCLUSIONS

Persistence of interatrial septal defect at two months after percutaneous mitral valve repair with MitraClip device was associated with adverse clinical outcomes in our series.

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Relationship between platelet activation and ST-segment resolution after primary PCI

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

We aimedto investigate the relationship between platelet reactivity(PR) measured at the moment of primary percutaneous coronary intervention(PPCI) and ST resolution(STR).

METHODS AND RESULTS

STEMI patients undergoing PPCI underwent P2Y12 PR measurement at the moment of PPCI using Verify Now.STR was defined as ST regression more than 50% at 90mn after PPCI.
140 patients with STEMI were included. They were divided into 2 groups: a low PR group (LPR)defined by PR<209 PRU(n 47) and high platelet reactivity group (HPR) defined by PR>209PRU*n 93). There were no differences between LPR and HPR groups for baseline characteristics,no STR was significantly more frequent in HPR group 44(47.3%) vs 9(19.1%) p=0.0012. Mean PR was higher in patients with no STR compared with patient with STR: 268.3 ±53 vs 223.8 ± 50.1 PRU, p=0.002.In multivariate analysis, HPR level was an independent predictor of no STR.

CONCLUSIONS

High P2Y12 platelet reactivity measured at the moment of PPCI is associated independently to no STR.

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Intra-procedural characterisation of estimated peak skin dose during PCI of CTO using a new patient dose mapping technology: the Dosemap study

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

AIMS

To reduce the patient peak skin dose (PSD) during percutaneous coronary angioplasty of chronic total occlusion (CTO-PCI) using an on-line estimated PSD software (DoseMap, GE Healthcare, UK).

METHODS AND RESULTS

DoseMap is a on-line software providing a record and display of patient local skin dose during PCI. From Nov 2015 to Oct 2016, 100 consecutive patients with CTO (TIMI =0, occlusion duration > 3 months) were prospectively enrolled at 2 sites. All along the procedure, the distribution of the local cumulated skin dose, as well as the current projection of the beam was displayed in-room as a map from 1Gray (Gy) cumulated Air Kerma (CAK) and updated every 0.5 Gy CAK increment. Clinical, angiographic and procedural outcomes were collected. Operator actions to minimize deterministic risks following map notification were also collected. To check for tissue reaction, clinical follow-up was performed at 3 months after the procedure. Finally, a comparison with our historical radiation data (208 patients from January 2013 to July 2014), in CTO patients was performed.

Patients were 62.5±8.8 years, 93% were male, body mass index 28.9±4.3 kg/m². Risk factors were smoking in 39%, hypercholesterolemia 75%, family history 14 %, hypertension 62 %, diabetes 34% and obesity 37%. Indication for CTO-PCI was typical angina in 59 % of cases, cardiac failure in 8% or documented ischemia in 33%. CTO complexity, defined by J-CTO score was 2.1±1.1 and occlusion length was 27.4±13.9mm. CTOs were located in the right coronary artery in 52% of cases, left anterior descending artery in 34% and circumflex in 14%. Revascularization approach was mostly antegrade (75%), followed by hybrid (14%) and retrograde (11%). Procedure duration was 86.0±43.6 min and total amount of contrast media 225±113 ml. Procedural success was obtained in 80% of cases. Complications were transient ischemic attack in 1% and tamponade in 2%. They were no myocardial infarction, no death or emergency cardiac surgery. Procedural parameters are reported as a median with interquartile range. Fluoroscopic time 40.8 (21.6-60.3) min, CAK 1884 (1144-3231) mGy, estimated PSD 962 (604-1474) mGy, dose area product 115.8 (71.5-206.7) Gy.cm². CAK was > 3Gy in 28% of cases. In 19/28 cases (68%) there was at least one action taken by operator after map notification to optimize skin dose distribution. Among those 28 cases, only 6 cases (21.4%, 6% of the total cohort) had a peak skin dose greater than 3 Gy at the end of the procedure. Main changes taken by operator after map notification were: gantry angulation (47%), Field of view (23%), collimation (11%), technical measures (17%),swich of details setting from «normal » to « low »(2%). No skin injuries were observed at 3 months follow-up. In comparison with our CTO historical radiation data, median CAK and DAP have been reduced respectively by 31% and 33% (both with p<.001) with no statistical difference in fluoro time (p=0.275).

CONCLUSIONS

The use of an online skin dose mapping software helped to distribute patient skin dose during complex PCI procedure and therefore minimize risk for skin injuries.

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Balloon tip damage and side branch access. A clinical and bench study

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

AIMS

To examine clinically, balloon catheter tip damage caused by attempted crossing through the side of a stent. Damage may prevent crossing or damage the stent.
To compare tip widths of same-design balloons of different nominal inflation diameters.

METHODS AND RESULTS

A total of 82 balloon catheters were examined microscopically after clinical attempted side-branch access through the sides of stents. Of balloons that crossed smoothly, there was tip damage in 18 (53%). Of those that failed to cross, tip damage was found in 31 (89%) (p=0.002).
In a bench study, balloon tips of 2.5 and 3.5 mm nominal inflation diameters from 10 different designs were measured microscopically. Three were of semi-compliant design and seven were non-compliant.
Results showed a mean tip diameter difference of 0.003 mm ± 0.01 between 2.5 mm and 3.5 mm balloon catheters. There was no significant difference in widths of tips for any balloon design. Furthermore, there was no significant difference in width of tips between semi-compliant and non-compliant balloons.

CONCLUSIONS

Balloon tip damage is common with attempted side-branch access through the side of a stent. The balloon may need changing to successfully cross and to prevent stent distortion. As the tip widths of all nominal balloon of the same design are the same, a smaller nominal balloon diameter of the same design may not be more likely to cross than a larger one.

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Outcome after hybrid implantation of everolimus-eluting BRS and drug-eluting metallic stents: six-month results from the GABI-R registry

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

AIMS

The outcome of patients receiving hybrid treatment with both everolimus-eluting bioresorbable vascular scaffolds (BRS) and drug-eluting metallic stents (DES) has not been systematically evaluated.

METHODS AND RESULTS

Data of patients undergoing BRS implantation from November 2013 to January 2016 were prospectively collected at 93 centers in Germany and Austria. Of 3170 patients enrolled (6-month follow up available in 100%), 437 patients (age 62+/-10.4, 20% females) with 975 lesions received hybrid therapy (633 BRS and 612 stents). The outcome of these patients was compared with the remaining 2733 patients who received BRS only (3343 lesions, 3760 BRS). Patients who had received hybrid stenting more frequently had a prior history of cardiovascular disease and revascularization (P<0.05), more frequently had 3-vessel disease (44.4% vs. 24.5%, P<0.0001), and lesions treated in these patients were longer (18.7+/-10.4mm vs. 16.6+/-8.8, p<0.0001) and more frequently complex (B2/C type: 44.3% vs. 34.1%, P<0.0001). Accordingly, the incidence of periprocedural complications (3.0% vs 1.2%, P<0.01) and that of death at 6 months (2.3% vs 1.1%, P<0.05) was significantly lower in the BRS-only group, while 6-month overall target lesion failure was more frequent in the hybrid group (3.7% vs 2.0%, P<0.05). The 6-month rate of definite and probable scaffold thrombosis was 2.1% in the hybrid group and 1.5% in the BRS-only group (P=0.38), while that of stent thrombosis in the hybrid group was 1.1% (P=0.0455 for the comparison between BRS and metal stents within the hybrid group).

CONCLUSIONS

Reflecting the higher complexity of the lesions, the incidence of events was higher in patients receiving hybrid treatment including both BRS and metal stents. In patients treated with a hybrid strategy, the incidence of scaffold thrombosis was higher than that of metallic stent thrombosis.

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How can we predict and reduce the renal dysfunction in high-risk patients undergoing coronary procedures?

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

AIMS

Aim of this study was to evaluate the predictive role of the contrast volume to creatinine clearance ratio and the safety of administration of a water-soluble, non-ionic, monomeric, low-osmolar, iodine-based contrast medium in high risk patients

METHODS AND RESULTS

We evaluated serum creatinine (sCr) and volume of iobitridol 350mg/mL and the creatinine clearance ratio (V/CrCl) at baseline, and sCr at 24-48 hours and extended to up 5 days after procedure; CrCl was calculated by applying the Cockcroft-Gault and the V/CrCl ratio was calculated by dividing the volume of LOCM used for PCI by the patient's CrCl. We evaluated 246 patients (mean age 82±5.4 years) who underwent a percutaneous coronary angioplasty, divided into two groups: group A (120 pts, 53% male, mean BSA 1,71) in which it was administered less than 200 ml of iobitridol (mean 151,5±35,34 ml), and group B (112 pts, 56.8% males, mean BSA 1,72) in which it was administered more than 200 ml of iobitridol (mean 295,6±83,87 ml). Global incidence of ACS was 38% and of diabetes mellitus was 58% with similar distribution in two group. All the pts were hydrated with 1 ml/kg/h of saline (0.9%) or 0.5 ml/kg/h for patients with left ventricular EF ≤50%, before and after iobitridol administration. CI-AKI was defined as a postprocedural increase in serum creatinine more than ≥0,5 mg/dL or a >25% elevation from baseline over the course of hospitalization. The Student's t test and chi $\chi 2$ test were used to compare variables between the two groups.

CONCLUSIONS

- As renal dysfunction was more frequent in patients with V/CrCl ratio greater than 4 (22/232) the evaluation of this simple parameter may be an useful method for predicting the onset of a renal failure by contrast in patients at higher risk during interventional cardiology procedures.
- However our data confirm the good renal tolerance of iobitridol in high-risk patients even when a large volume of contrast medium was used, as previously reported in literature.
- Incidence of kidney disfunction in elderly patients supports the use of hydration and it is always necessary to limit the amount of contrast agent during the procedure in high risk patients

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Provisional stent vs. two-stent techniques: outcomes in a real-world population

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

AIMS

To compare the “provisional stent” technique with two-stent techniques in percutaneous coronary intervention (PCI) of bifurcations.

METHODS AND RESULTS

Methods: Single centre cohort analysis of 335 consecutive PCI in 303 patients, between 2010 and 2015. We defined 2-stents techniques as stent implantation in both the main and side vessels, including dedicated bifurcation stents. We classified all other cases as provisional stent.

We analysed which characteristics of coronary anatomy impacted on the choice between PS and 2-stents techniques. We then analysed impact of both techniques on short and long term follow-up. The primary endpoint was a composite of death, acute coronary syndrome (ACS), coronary artery disease progression and hospital admittance due to heart failure; the secondary endpoint was in-hospital mortality.

Results: Our sample consisted of 303 patients, with a mean age of 68±11 years (75% male). Mean follow-up time was 3.3±1.8 years. In-hospital mortality was 1% and the primary endpoint occurred in 32% of the patients. Two-stent techniques were used in 27% of the patients - mainly dedicated stent (42%), mini-crush (23%) and T-stent (18%) techniques.

The main variable that impacted on the choice between provisional stent and 2-stent techniques was the presence of significant lesions in both the main and side vessels (96 vs 70%, P<0.01).

There was no difference in in-hospital mortality between the provisional stent and 2-stent techniques groups.

There was a non-significant trend for an increase in the primary endpoint with the 2-stent techniques (42 vs 29%, P=0.06), mainly due to an increase in coronary artery disease progression (22 vs 11%, P=0.01) and ACS (17 vs 7%, P=0.02). There was significant association between dedicated stents and the primary endpoint (56 vs 30%, P=0.01). Of note, there was no association between non-dedicated stents 2-stent techniques and the primary endpoint.

In multivariate analysis models adjusted for age, chronic kidney disease, left anterior descending artery lesions, bare metal stent and left femoral artery as arterial access (the main variables associated with the PE in the univariate analysis) both overall 2-stent techniques(P=0.01) and dedicated stents (P<0.01) remained significantly associated with the PE. However, when adjusting for non-drug eluting stents (which includes the tryton stent, used in 33% of 2-stent techniques), neither overall 2-stent technique nor dedicated stents remained associated with the primary endpoint.

CONCLUSIONS

In our-real world population, 2-stent techniques not including dedicated bifurcation stents and the provisional stent technique seem to have comparable outcomes in both short and long time follow-up. However, the use of dedicated bifurcation stents was associated with a worse long-term prognosis, apparently due to an over utilization of non-drug eluting stents.

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Increased troponin I after bifurcation angioplasty - What does it really tell us?

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Bifurcation lesion

AIMS

i) to assess if post-procedure troponin I levels influence outcome after percutaneous coronary intervention (PCI) of bifurcated lesions and ii) to study which variables are associated with an increased post-procedure troponin I.

METHODS AND RESULTS

Methods: Single centre, observational and longitudinal study of 85 consecutive patients who underwent planned PCI of at least one bifurcation between 2010 and 2015 and who had available post-procedure troponin I values. Planned PCI was defined as PCI not undertaken in the context of an acute coronary syndrome.

We first analysed the impact of troponin I values on in-hospital mortality, 30-days mortality and a composite endpoint of progression of coronary artery disease, acute coronary syndrome, hospital admission due to heart failure and all-cause mortality.

Since troponin I influenced only the composite endpoint, we identified the troponin cut point with a highest sensitivity and specificity to predict CE using a ROC curve.

Then we identified which variables were associated with higher troponin values.

Results: The sample consisted of 85 patients with a mean age of 71±10 years, 85% of which were male. Mean follow-up time was 3.0±1.8 years.

No patients died during hospital stay. 30-days mortality was 4% (3 patients) and the frequency of the composite was 36%. Troponin values were relevant only in predicting the composite endpoint (5.7±14,1 vs 1.1±2,2 pg/dL, *P*=0.02) and the area under the curve was 0.63 (95% CI 0.50-0.76).The troponin I cut-off with highest accuracy for predicting the composite endpoint was 0.28 pg/dL (sensitivity=72% and specificity=52%). Troponin values above this cut-off were associated with a higher incidence of the composite endpoint (46 *vs* 23%, *P*=0.04).

The main variables associated with an increased troponin were age (73 *vs* 68 years, *P*=0.02), the presence of significant stenosis of both the main and side vessels (63 *vs* 29%, *P*=0.02), the use of two-stent techniques (75 *vs* 50%, *P*=0.04), of two guide-wires for side-branch protection (63 *vs* 31%, *P*=0.02) and of more than 3 stents, including concomitant lesions treated at the same time (90 vs 53%, *P*=0.03). In a multivariate analysis adjusted for all of these variables, only age (*P*=0.016) and the utilisation of two guide-wires (P=0.03) remained significantly associated with an increased troponin. None of these variables were associated with an increased prevalence of the composite endpoint.

CONCLUSIONS

Post procedure troponin I values after bifurcation PCI had prognostic value on the long term, but not on the short term . Older age and use of two guide-wires were associated with higher post procedure troponin levels.

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PCI: clinical and anatomic determinants of procedure failure

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI, Stable CAD, Left main and multivessel disease, Bifurcation lesion, CTO, Other Coronary Interventions

AIMS

With growing experience, percutaneous coronary intervention (PCI) has become associated with a greater success rate. However, there is still a non-negligible number of failed PCI .

METHODS AND RESULTS

Aims: To identify clinical and anatomic lesions associated with failed PCI.
Methods: We performed a retrospective analysis of 4061 consecutive PCIs performed between 2010 and 2015. We analysed all coronary lesions treated and registered their anatomical features as well as the patients' clinical characteristics. Univariate and multivariate analysis were performed. PCI failure was defined as residual stenosis >50%.
Results: The sample consisted of 5752 lesions treated, involving a total of 3498 patients. 63% of PCIs were performed on male patients and mean age at the time of intervention was 68±11 years. The incidence of PCI failure was of 1.2%.
In the univariate analysis, the clinical characteristics with impact in PCI failure were history of previous coronary artery bypass grafting (CABG) and dyslipidaemia. The prevalence of failed PCI was higher in the CABG group (2.5 *vs* 1.1, *P*=0.05) and lower in the dyslipidaemia group (0.9 *vs* 1.6%, *P*=0.02). Also, patients who underwent PCI in the context of an acute myocardial infarction had a higher prevalence of PCI failure (1.8 *vs* 0.7%, *P*<0.01).
Concerning coronary anatomy, type C lesions (2.5% *vs* 0.6%, *P*<0.01), total occlusions (6.1% *vs* 0.5%, *P*<0.01), lesions of the marginal arteries (2% *vs* 1.1%, *P*=0.04) and the presence of 3 or more lesions (1.7% *vs* 0.5%, *P*<0.01) were more often associated with failed PCI. On the other hand, lesions of the left anterior descending artery (0.6% *vs* 1.5%, *P*<0.01), bifurcated lesions (0% *vs* 1.2%, *P*=0.02) and lesions >20 mm (0.4% vs 1.3%, *P*=0.02) were associated with a lower incidence of PCI failure. Local complications, defined as thrombus formation or coronary dissection, were strongly associated with PCI failure (14% *vs* 1.1%, *P*<0.01).
In the multivariate analysis, total occlusions (OR 5.12, *P*<0.01), the presence of 3 or more lesions (OR 5.41, *P*<0.01), and type C lesions (OR 7.821, *P*<0.01) were independently associated with a failed PCI, while dyslipidaemia (OR 0.37, P<0.01) and lesions >20 mm (OR 0.08, *P*=0.02) remained independently associated with a lower risk of PCI failure, in a model adjusted for acute myocardial infarction presentation, history of CABG, bifurcated lesions and lesions of the left anterior descending artery.

CONCLUSIONS

Our real world data shows that anatomic features are the main determinants of PCI failure. Dyslipidaemia appears to be associated with better outcomes, possibly because these patients are more often treated with statins.

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Influence of PCI in CTO long-term outcomes

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

AIMS

To investigate the overall success rate of PCI as a treatment for CTO and to determine the predictive factors of technical success and of major cardiac events (MACE) occurrence.

METHODS AND RESULTS

Retrospective analysis of 135 consecutive patients (pts) (mean age 65±12 years, 81% men) who underwent PCI for CTO consecutively in a single center. Pts were divided into 2 groups: procedural success and procedure failure. We compared baseline demographic, clinical and angiographic characteristics and occurrences of major cardiac events (MACE) [cardiac death, non fatal myocardial infarction (MI) and target-lesion revascularization (TLR)].

Successful revascularization was achieved in 101 pts (74,8%). There were no significant differences in baseline demographic characteristics, comorbidities, target vessel, complexity of lesion and number of diseased vessels between the groups PCI success vs PCI failure, and none of these variables predicts procedural success. Intervention's complications (clinical or angiographic) was 13,4%, with no significant difference between the 2 groups (p=0,865). During the follow-up period (22±16months), occurred at least one MACE in 18,3% of patients (7% cardiac deaths, 5,5% non fatal IM, 8,8% TLR), and their occurrence was significantly lower in the procedural success group (12,9%vs37,0%, p<0,005). Upon multivariable analysis, the only predictor of MACE was technical failure of CTO PCI.

CONCLUSIONS

In our study, the CTO PCI was an effective and safe procedure, and its success has a huge impact on prognosis.

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Comparison of blood gas assessment of systemic hypoperfusion vs. clinical risk score to predict mortality in cardiogenic shock post-STEMI

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

AIMS

Cardiogenic shock (CS) in STEMI is associated with high mortality. Registry data suggest the rate of lactate clearance predicts outcome. We compare the correlation of blood gas markers of hypoperfusion vs premorbid risk factors with mortality.

METHODS AND RESULTS

Retrospective assessment of patients presenting with cardiogenic shock (STEMI with hypoperfusion and lactate > 2.0 mmol/L) to a tertiary primary PCI service. Sequential blood gas samples were taken for 48 hours after admission. Statistical comparison of pH and lactate in patients who were discharged alive vs those who died in-hospital was performed. The North West Quality Improvement Programme in Cardiac Interventions (NWQIP) score was also calculated for each patient. This was based on age, gender, presence of cerebrovascular disease, cardiogenic shock, urgent or emergent PCI, and the presence of left main stem or graft lesions, and expressed as a predicted percentage risk of major acute cardiovascular events.Patients were divided into those who survived to discharge (n=22) and those who died in-hospital (n=16). Linear regression was used to determine the gradient of lactate clearance and pH over time. There was no significant difference in admission lactate (p=0.63), lactate clearance (p=0.60), admission pH (p=0.59), pH clearance (p=0.60), ratio of pH to lactate on admission gas (p=0.91), or age (p=0.06) between groups. The patient's pre-test probability of mortality based on risk profile, as determined by the NWQIP score, showed that the anticipated risk of death was significantly higher in those who succumbed versus survivors (49.4±6.0 vs 37.9±2.2%, p = 0.04).

CONCLUSIONS

In patients presenting with myocardial infarction complicated by CS, markers of systemic hypoperfusion derived from an arterial blood gas collected on and after the acute presentation were not predictive of subsequent mortality. Conversely demographic factors and risk profile, when combined to form a pre-test probability of death in a previously described multivariate prediction model, indicated a significantly higher risk score in non-survivors. This highlights the relative importance of a patient's premorbid state, compared to blood gas markers of hypoperfusion, in predicting outcome in CS.

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Impact of the SYNTAX score on long-term outcomes after percutaneous revascularisation of CTO: insights from a contemporary multicentre registry

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

AIMS

The prognostic utility of the SYNTAX Score (SS) in the specific subset of patients with CTO has not been definitively established. We aimed to evaluate the impact of SS on long-term outcomes after successful CTO PCI.

METHODS AND RESULTS

This multicenter registry pooled all consecutive patients treated with successful CTO PCI at 5 institutions. The primary endpoint was long-term major adverse cardiac event (MACE, a composite of cardiac death, myocardial infarction, and target-lesion revascularization) in patients with intermediate-to-high (>22) versus low (≤22) SS. Multivariate Cox regression analysis was used to adjust for potential confounders.

A total of 544 patients undergoing successful CTO PCI were included. At a median follow-up of 693 days (interquartile range 399-967), patients with SS >22 had a higher rate of MACE (10.4% vs. 4.2%; p=0.007) and cardiac death (4.3% vs. 1.4%; p=0.049). After adjustment for clinical (adjusted HR 2.24, 95% CI 1.08-4.65, p=0.031), angiographic (adjusted HR 4.52, 95% CI 2.07-9.85, p<0.001), procedural (adjusted HR 2.60, 95% CI 1.30-5.22, p=0.007), or combined confounders (adjusted HR 2.32, 95% CI 1.15-4.65, p=0.018), the risk of MACE remained significantly higher in patients with SS >22.

CONCLUSIONS

Intermediate-to-high SS (>22) was independently associated with an increased risk of long-term MACE after successful CTO PCI. Further studies are needed to define the optimal management strategy in patients with CTO in the context of diffuse CAD.

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The Polish interventional cardiology TAVI survey: adoption and practice of TAVI in Poland

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

AIMS

Few studies assessed the development of TAVI in Poland since its introduction in 2008. Our aim was to assess the dynamics of TAVI adoption in Poland and to detect differences among Polish centres in TAVI practice and decision-making.

METHODS AND RESULTS

The Polish Interventional Cardiology TAVI Survey (PICTS) was approved by the Polish Association of Cardiovascular Interventions and presented to all 21 national TAVI centres. Between 2008 and 2015 the cumulative number of TAVI performed in Poland was 2189. The annual number of TAVI rose from 8 in 2008 to 670 in 2015 (0.21 to 17.4 implants per million inhabitants, correspondingly). The median TAVI experience per centre was 80 procedures (95% CI 38.1 – 154.6). In 2015 the TAVI penetration rate reached 5.12 % of the estimated eligible Polish population. Inoperable and high-risk patients are treated with TAVI in all centres, with 52% of Heart Teams qualifying also medium-risk patients. The rate of transfemoral implantations increased to 83.2% of all procedures in 2015, while transapical implantations decreased to 12%. The frequency of subclavian, direct aortic or transcarotid routes in 2015 were below 3% each.

CONCLUSIONS

The PICTS survey observed a positive, but slow rate of adoption of TAVI in Poland. When compared to Western European countries, our findings highlight a significant treatment gap in high or prohibitive surgical risk patients with severe aortic stenosis. Remarkable variations in TAVI practices among Polish TAVI centres warrant publication of joint national guidelines and recommendations.

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Initial experience with intracardiac echography in LAA occlusion: the tip of the iceberg

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

To compare the outcomes of patients who underwent percutaneous left atrial appendage (LAA) occlusion guided by intracardiac echography (ICE) *versus* transoesophageal echocardiography (TEE).

METHODS AND RESULTS

METHODS: Single centre cohort analysis of 82 consecutive patients who underwent percutaneous LAA occlusion between 2010 and 2016. We created two groups – Group A, with ICE-guided procedure (N=22) and group B, TEE-guided procedure (N=60). We registered the main clinical variables in both groups and the events in both short (7 days) and long term follow-up.

RESULTS: Our population consisted of 82 patients with a mean age of 75±8 years (63% male). Mean CHA_2DS_2VASc and HAS-BLED scores were 4.3±1.4 and 3.0±1.1, respectively. Mean follow-up time was 12.7±14.0 months.

The two groups were comparable for all clinical variables but the CHA_2DS_2VASc score(A= 3.9±1.4 and B= 4.6±1.4, P=0.044) and serum creatinine (A= 2.1±2.2 and B= 1.0±5.6, P<0.01).

The procedure success rate was 96%, and was similar in the two groups. In 9 cases (11%) the first device was undersized or oversized and could not be used; it happened similarly in both groups.

The total number of early (7-days) complications was 7%, mainly due to vascular access complications (6 patients - 7%), with major bleeding happening in 4 patients (5%) and pericardial effusion in 3 patients (4%).

There were no differences between the two groups on the short term follow-up (including length of hospital stay, major bleeding, pericardial effusion/tamponade or vascular access complications).

During clinical follow-up, stroke occurred in 1 patient (1%) and major bleeding in 2 patients (2%); all-cause mortality was 6% (6 patients) and there were no cardiovascular deaths. In a preliminary analysis, there were no differences between groups, although follow-up needs to be extended to validate these results, since the follow-up time is significantly shorter in group A (2,8±2,3 vs 16,5±14,7 moths, p<0.01). In order to make a better comparison, we analysed mortality at 60 days, and there were no significant differences between groups.

Concerning the echocardiographic data, leaks >1mm were present in 3 patients (4%) and device thrombosis in 2 patients (2%). Once again, there were no differences between groups.

CONCLUSIONS

According to our data, ICE guided LAA occlusion is safe and outcomes are comparable to those of TEE guided procedures.

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Comparison of long-term clinical outcomes of balloon angioplasty vs. primary stenting for superficial femoral artery with long CTO lesions of trans-atlantic inter-society consensus C and D

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal, Other peripheral interventions

AIMS

We investigated the direct comparison of Balloon Angioplasty and Primary Stenting for SFA lesion with long CTO from three well-experienced hospitals.

METHODS AND RESULTS

Methods:

From January 2012 to December 2015, 190 lesions in 180 patients were received EVT for SFA long CTO lesions in 3 hospitals. Twenty-four lesions(26 patients) which underwent bailout stenting were excluded. Patients were divided into 2 groups: 57 lesions (57 patients) in the Balloon Angioplasty (BA) group and 99 lesions (107 patients) in the Primary Stenting (PST) group. Primary endpoint was clinically driven TLR at 24 months after EVT.

Results:

The mean age of patients was 72 years, 70% of them were males, 34% had on hemodialysis. Clinical presentations were 93 claudication and 87 critical limb ischemia (CLI), and the TASC D was 124 lesions. Number of stent implantation was 2.5±0.7, length of stent was 282±62mm, respectively. TLR rate at 24 months was significantly higher in BA group compared with PST group (43.9% vs. 32.7%, p = 0.035). However, among patients with CLI, hemodialysis or TASC D lesion, there were no different in TLR rate between both groups.

CONCLUSIONS

Conclusion:

Primary Stenting strategy was effective in SFA long CTO lesions. However, in patient with CLI, hemodialysis orTASC D lesion, the therapeutic efficacy of Primary Stenting diminished.

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Stent and leaflet stresses in different generations of balloon-expandable transcatheter aortic valves

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

AIMS

TAVR rapidly developed from 1st generation Sapien to S3, resulting in reduced profile. Durability depends upon valve design and decreases as leaflet stresses increase. Our objective was to compare stent and leaflet stresses across TAVR generations.

METHODS AND RESULTS

Edwards Sapien, Sapien XT, and Sapien 3 devices (26mm), Edwards Lifesciences, Inc, underwent micro-computed tomography scanning. Radiologic images were used to create precise computational models including stent, leaflets, Dacron, and suture connections. Finite element meshes were generated and simulations were performed using ABAQUS software. The stent and leaflet stresses of three generations were compared to determine differences at diastolic pressure.

For TAVR leaflets, maximum principal stresses on Sapien, Sapien XT and Sapien 3 were 1.79MPa, 2.32MPa and 5.87MPa, respectively at diastolic pressure under dynamic loading conditions (figure 1); while peak minimum principal stresses were -1.08MPa, -0.42MPa, and -0.65MPa, respectively. For TAVR stents, peak first principal stresses were 176.79MPa, 92.62MPa and 16.25MPa for Sapien, Sapien XT, and Sapien 3, respectively at diastolic pressure under dynamic loading conditions, while minimum principal stresses were -254.60MPa, -105.62MPa and -14.77MPa, respectively.

CONCLUSIONS

Our study demonstrated that the maximum stress appeared on the similar location of the leaflets across generations, primarily in the commissures where the leaflets attached to the stent. Maximum stress on TAVR leaflets increased while maximum stress on stents decreased during the evolution of TAVR devices. Our results suggest that the newer generation of TAVRs had increased stresses on leaflets which may impact durability in over the long-term. Comparison with similarly sized surgical bioprostheses may lead to further insight into relative TAVR durability.

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Agatston calcium score is not predictive of major events after TAVI performed with new generation prosthesis

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

AIMS

Agatston calcium score (CS) is associated with aortic regurgitation (AR) and major events after TAVI with first generation prosthesis. We aimed to determinate if CS remained a prognostic factor after TAVI with the new generation Sapien 3 device.

METHODS AND RESULTS

All consecutive patients implanted with Sapien 3 valve between September 2014 and November 2015 were included in this prospective monocentric study. Agatston CS was systematically evaluated on the pre-procedural multislice computed tomography in patients undergoing TAVI. Major adverse events were evaluated at 1-month.0ne-hundred forty-seven patients were included in this study. The mean age was 83.5 ± 6.9years, 49.6% (n=73) were female, mean logistic Euroscore was15.1%. Pre-procedural CS value was 4209 ± 2204. At follow–up, 8 patients (5.4%) had at least an adverse clinical event. A higher CS was not predictive of major events, 3496 ±876 in patients with a major event *vs* 4261 ±2225 in patients without a major event (p=0.4). CS was not associated with AR ≥ grade 2 (4663 ±3057 *vs* 4176 ±2149 respectively; p=0.9).

CONCLUSIONS

CS in not predictive of major events after TAVI performed with the new designed Sapien 3 valves. The performance of the device and increased operator’s experience may counterbalance effects of aortic annulus and valve calcifications.

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Incidence, clinical presentation, characteristics and analysis of predictors of restenosis in coronary BRS

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

AIMS

We set out to investigate the incidence, clinical presentation, angiographic and optical coherence tomography (OCT) characteristics as well as the predictors of in-BRS restenosis.

METHODS AND RESULTS

A total of 945 patients (age 63±12years, 739 (78%) males, 58 diabetics, 222 acute coronary syndromes) who underwent implantation of 1074 BRS for de novo native coronary artery lesions between May 2012 and October 2016 were included in this study. Predictors of in-BRS restenosis were investigated using cox regression and receiver operating characteristics analysis. During follow-up, 32 (3%) in-BRS restenoses (29 patients) were identified at 617±329 days after implantation. The binary angiographic rate of in-BRS restenosis was 0.8% at 1 year and 2,81% at three years (respectively, 0.7% and 2.7% of the lesions). The clinical presentation included incidental finding in 21%, stable angina in 55%, and acute coronary syndrome in 24% of the patients. The angiographic presentation according to the Mehran classification included type 1b in 22%, 1c in 31%, type 2 in 28%, type 3 in 17% of the restenotic lesions. Optical coherence tomography was available in 24 lesions. Characteristics of the restenotic neointima included mature neointima in 88% of the lesions, peri-strut low-intensity areas in 46%, microchannels in 29%, strut fractures in 71%. Multivariate analysis identified chronic total occlusion (HR: 7.56[1.80-31.81], P=0.006), minimum lumen diameter after implantation (HR: 0.21 [0.10-0.44], P<0,001), and diabetes (HR: 4.12[1.91-8.88], P<0.001) as independent predictors of binary restenosis. Receiver operating characteristic analysis identified a postprocedural minimum lumen diameter of 1.94mm as optimal cut-off value for predicting binary in-BRS restenosis (area under the ROC curve=0.81[0.70-0.89, P=0.0001, sensitivity 57%, specificity 93%).

CONCLUSIONS

In-BRS restenosis appears to be mostly clinically benign and mostly caused by proliferation of mature neointima, even though features potentially compatible with inflammatory reactions were not rare. Along with diabetes and chronic total occlusion, the most important predictor appear to be vessel size and incomplete scaffold expansion at the time of implantation.

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Contemporary real-life PCI practices: one-year clinical outcomes in patients treated with thin vs. thick strut DES - Data from two large, international registries

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

AIMS

To compare one year clinical outcomes of patients treated with thin strut cobalt chromium platform DES (Ultimaster), with thick strut stainless steel platform DES (Nobori) in two large all-comer registries representative of real life PCI practice.

METHODS AND RESULTS

We analysed data of unselected patients who received Ultimaster DES in a large prospective global multicentre e-ULTIMASTER registry, along with that of patients who received Nobori DES within the NOBORI-2 worldwide registry. Propensity score matching (PSM) was applied for this comparison. Continuous variables were compared using the Student's unpaired t-test and categorical variables using the chi squaretest or Fisher exact test as appropriate.

Of the 4597 patients enrolled since 2014 in e-ULTIMASTER registry and 3067 patients enrolled between 2008 and 2013 in NOBORI-2 registry, 4454 patients and 2938 patients were selected respectively using PSM. Baseline characteristics of the two study patient cohorts were comparable after PSM, except for a significantly higher representation of ST-elevation myocardial infarction (STEMI) patients in e-ULTIMASTER, most probably reflecting changes in real life practice over time. Mean patient age was 64.9 years in both registries, on average 77% were male patients and 66.2% had hypertension. 28.0% and 28.7% had diabetes mellitus, while 24.2% and 25.2% were current smokers in e-Ultimaster and NOBORI-2 respectively. In e-ULTIMASTER 21.4% and in NOBORI-2 8.3% ($p<0.001$) of patients presented with STEMI. In e-ULTIMASTER 81.6% and in NOBORI-2 38.5% of the patients had procedure via radial access. The number of treated lesions were similar in the two studies (1.4±0.7 vs 1.4±0.7, $p=0.70$), with 49.8% in e-ULTIMASTER and 50.1% of patients in NOBORI-2 presenting with multivessel disease. 69.3% and 70.3% of patients had complex lesions (type B2+C) in e-ULTIMASTER and NOBORI 2 respectively, with 10.5% vs 12.0% of ostial lesions ($p=0.05$), and 23.4% vs 25.5% of moderate to severely calcified lesions ($p=0.05$).

The 1-year clinical outcomes of e-ULTIMASTER and NOBORI-2 registries revealed cardiac death 0.82% vs 1.37% ($p=0.02$), any MI 1.2% vs 2.4% ($p<0.001$), target vessel MI 0.75% vs 2.1% ($p<0.001$), target lesion revascularisation 1.2% vs 2.6% ($p<0.001$), and target vessel revascularisation 1.7% vs 3.7% ($p<0.001$). The target lesion failure rate at 1 year was 2.1% in e-ULTIMASTER and 4.6% in NOBORI 2 ($p<0.001$), and the major adverse cardiac event rate at 1 year was 3.3% and 5.8% respectively ($p<0.001$).

CONCLUSIONS

This analysis of patient-level data from two large real life registries reflects the trends in contemporary PCI practices.

The 1-year clinical outcomes are favourable for patients treated with the thin strut Ultimaster DES in the e-ULTIMASTER registry, compared to patients treated with the Nobori DES with thicker struts.

These findings are likely reflective of advances in clinical practice of PCI as well as the potential benefits of the thin strut design of Ultimaster stent.

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Clinical outcomes of non-slip element scoring balloon for treating fibrocalcific coronary lesions in real-world patients

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

AIMS

Benefit of a scoring balloon for fibrocalcific lesions is still to be evaluated in modern drug-eluting stent (DES) era. We sought to evaluate Non Slip Element (NSE) scoring balloon for fibrocalcific lesions in a real-world population.

METHODS AND RESULTS

.We identified 92 patients with *de novo* fibrocalcific lesions, who underwent lesion modification using NSE scoring balloon prior to second generation drug-eluting stents from January 2014ã'to November 2015. We performed a quantitative coronary angiography (QCA) analysis. Major adverse cardiovascular event (MACE) was defined as cardiac death, recurrent heart failure, recurrentã'myocardial infarction, and ischemia-driven revascularization. We analyzed MACE as well as target vessel revascularization (TVR), and target lesion revascularization (TLR), and stent thrombosis atã'30 days, and 9 months.

Results: At baseline, 40.4% of cases were unstable angina, 20.2% of cases were acute myocardial infarction. Syntax score was 12.25 ± 3.86. Mean left ventricular ejection fraction was 58±12%. 90% of lesions were type B2/C. 63.6% of lesions were moderate/severe calcification. In QCA analysis, lesion length was 14.26 ± 7.81mm. Reference vessel dimeter was 2.9 ± 0.47mm. Minimal lumen dimeter was 0.86 ± 0.47mm. Acute gain was 1.64 ± 0.61mm. Late loss (in-stent) was 0.15 ± 0.48mm. Procedural success was 99.0%. MACE at 30 days, 9 months are 2.08%, and 6.2% respectively. TLR was 0% at 30days, 2.08% at 9 months. Neither definite stent thrombosis nor cardiac death was noted. DESs used in the case series were either everolimus-eluting stents (89.6%) or biolimus-eluting stents (10.4%). No complication related to a NSE balloon, such as coronary dissection (>Type D) or perforation was noted.

CONCLUSIONS

Use of NSE scoring balloon prior 2ndgeneration DES is safe and excellent procedural results and confers a benefit on acute and midterm clinical outcomes for fibrocalcific lesions. In spite of higher proportion of calcific and thrombotic lesions in this case series, no stent thrombosis was noted. This may be partially accounted for better stent expansion and apposition.

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Clinical and echocardiographic outcomes of patients undergoing TAVI at age 65 or less

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

AIMS

Young age is a known risk factor for structural valve degeneration (SVD) in patients undergoing surgical aortic valve replacement (SAVR). Whether the same is true for transcatheter valves is unknown.

METHODS AND RESULTS

As transcatheter aortic valve implantation (TAVI) moves towards younger, lower risk patients, this study aimed to assess long-term echocardiographic outcomes in 33 patients that underwent TAVI at the age of 65 years or less in our center, between January 2009 and December 2015. All patients were assessed by a Heart Team and deemed at prohibitive risk to undergo SAVR. Dedicated personnel prospectively collected clinical, procedural and echocardiographic outcomes reported herein as part of a national registry and local database. The key outcomes of this study were the occurrence of SVD, the change in mean gradient and the change in aortic regurgitation on the last available echocardiography, compared to the one performed at discharge.

Mean age was 58.7 ± 6.1 years (range: 42 to 65 years). Most patients were men (25/33, 75.8%) and in NYHA functional class 3 or 4 (20/33: 60.6%). Mean STS and logistic EuroScore were 2.29 ± 2.19 % and 6.75 ± 6.19 %, respectively. The aortic valve was bicuspid in 6 cases (18.2%).Reasons for selection of TAVI over SAVR included the following: active cancer or previous chest radiation for cancer (n=10), severe chronic obstructive pulmonary disease (n=10), severe pulmonary hypertension (n=8), LVEF ≤ 25% (n=4), patent mammary graft crossing the midline (n=2), porcelain aorta (n=2), dialysis (n=2) (some patients had more than one indication).

The Edwards devices (Sapien XT or Sapien 3) were used in 23 patients (69.7%), whereas the Medtronic devices (CoreValve or Evolut-R) were used in 7 patients. Other devices were selected for the remaining 3 patients. The transfemoral approach was selected for most patients (n=23, 69.7%), followed by the transapical approach (n=5, 15%) and other approaches in the remaining 5 patients.

Procedural complications occurred in the following rates: valve migration: n=2 (6%), tamponade: n=1 (3%), stroke: n=1 (3%), acute kidney injury: n=1 (3%), minor vascular complication requiring femoral angioplasty: n=3 (9%). Median hospital stay was 8 days (range: 2 - 25 days).

Mean aortic valve gradient at discharge was 11.2 ± 6.04 mmHg. One patient had a mean gradient above 20 mmHg at discharge. Five patients (15.2%) had aortic regurgitation (AR) greater than mild at discharge.

30-day mortality rate was 3/33 (9%). A fourth patient died between 30 days and 1 year.

In total, 18 patients had an echocardiographic exam available beyond one year. Median delay between procedure and last available echocardiogram was 3.1 years (range 1 - 7 years). SVD was not reported in any case. Mean gradient at last exam was 11.9 ± 5.4 mmHg (mean change in gradient: +1.18 ± 4.2 mmHg, paired t p-value: 0.24). The slope of a regression line plotting change in gradient by time was +0.1 mmHg per year after TAVI (p=NS). AR greater than mild was found in 3 cases. There was a reduction in AR grade in 2 patients, increase in AR grade in 1 patient, and no change in the remaining 15 patients. LVEF also remained stable between discharge and last follow-up (mean change: +3.5 ± 9.4%, p=0.15).

CONCLUSIONS

No signs of SVD or changes in echocardiographic parameters were found in TAVI patients younger than 65 years. These encouraging results should be validated in larger studies.

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Impact of well-developed coronary collateral circulation on prognostic in late presentation myocardial infarction

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

The aim of the study was to evaluate the relationship between well-developed coronary collateral circulation (CCC) and clinical outcomes in patients with late presentation (>24 hours) myocardial infarction (MI).

METHODS AND RESULTS

Ambispective multicenter longitudinal study on 107 patients with a late presentation MI and angiographic evidence of a thrombotic occlusion (TIMI 0) of a major coronary artery from 2009 to 2015.

The Rentrop and Werner score were used for the angiographic categorization of CCC. Two experienced cardiologists retrospectively evaluated the angiographies in a blinded manner to classify the CCC into grades.

Primary end point: Major adverse cardiac events (MACE) at 12 months defined as: Cardiovascular mortality (CVM), Non-fatal myocardial infarction (MI) and heart failure hospitalization. The secondary end point was CVM at 12 months.

Poor CCC was detected in 56% of the patients (mean age 57.9±20 years, 75% men) and 44% of them had a good CCC (mean age 60.3±12 years , 82% men) . The Kappa indices of agreement for variability for the classification of CC C was excellent (k = 0.88; 95% CI, 0.82-1.00).

Patients with good CCC more commonly had a right coronary (RC) occlusion but less often had a left anterior descending occlusion (p<0.05 for both) and had a non-significant trend for a longer time between symptom onset and catheterization (8.4±7.8 vs 5.6 ±7.2 days, p=0.1). There were no significant differences between both groups neither in baseline characteristics (Sex, age, cardiovascular risk factors, previous treatment and comorbidities) nor in medical treatment at discharge.

The median follow up was 3.4 years (interquartile range 1.2-5.7 years). 19 patients lost to follow up.

MACE at 12 months (26.1% vs 5%, p=0.008); CVM at 12 months (15.2% vs 2.5%, p=0.04) and cardiogenic shock (12.5% vs 0%, p=0.02) were significantly higher in poor CCC group compared to good CCC group.

Neither successful PCI of the culprit vessel (MACE: 8.7% vs 19%,p=0.2 and CVM: 8.7% vs 9.5,p=0.9) nor complete revascularization (MACE 17.2% vs 14.3%,p=0.7 and CVM:10.3% vs 7.1,p=0.4) showed an improvement in outcomes. However when myocardial viability of the culprit vessel territory had been proven both variables showed a significant and near-significant reduction of MACE and CVM respectively (23.1% vs 5.9%,p=0.03 and 22.2% vs 6.3%,p=0.052).

MACE at 12 months was associated to: Complete revascularization in proven viable myocardium (p=0.052); Poor CCC (p=0.008); proven viability (p=0.02); successful PCI of culprit vessel of viable territory (p=0.03); Time to cardiac catheterization (p=0.08); Killip classification (p<0.001); left ventricular ejection fraction (LVEF) (p<0.001); Rentrop (p=0.001) and Werner (p=0.52) CC classification. The significant independent variables in the multivariate analysis were LVEF (OR 0.89, 95%CI 0.82-0.96) and Rentrop (OR 0.4, 95%CI 0.13-0.99).

CVM at 12 month was also associated to CCC (Rentrop (p=0.006); Werner CC (p=0.09); and poor CC (p=0.06)) but the only significant independent variable in the multivariate analysis was LVEF (OR 0.85 95%CI 0.77-0.95);

On follow-up poor CCC patients were more often rated at NYHA ≥III (21% vs 0%, p=0.03) and
MACE (p=0.009) were higher compared to good CCC group according to log rank test.

CONCLUSIONS

The presence of a well-developed coronary collateral circulation in patients with late presentation MI is associated with lower major adverse cardiovascular event rates

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One-year clinical outcome of biodegradable polymer sirolimus-eluting stent in diabetes mellitus patients: insight from the ULISSE registry (ULtimaster Italian multicentre all-comerS Stent rEgistry)

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI, Stable CAD, Stents and scaffolds, Left main and multivessel disease, Bifurcation lesion, CTO

AIMS

Diabetes mellitus (DM) patients are affected by higher rate of adverse events after PCI with DES, mainly target lesion revascularization (TLR). Biodegradable polymer sirolimus-eluting stent (BP-SES) hasn't been extensively studied in DM patients.

METHODS AND RESULTS

776 consecutive patients (1134 lesions) treated with BP-SES between July 2014 and August 2016 were retrospectively enrolled in the ULISSE registry and divided in two groups: DM (218 patients, 335 lesions) and non-DM (558 patients, 799 lesions). Primary and secondary endpoints were TLR and target vessel failure (TVF) at 1-year, respectively.

Diabetic patients were more frequently affected by hypertension (p<0.001), dyslipidemia (p=0.012), chronic kidney disease (p<0.001) and more frequently dialyzed (p=0.010). At 1-year follow-up TLR occurred in 25 (3.2%) overall patients, and it was similar in DM and non-DM patients (3.6% vs 2.3%, respectively, p=0.360). The secondary endpoint (TVF) occurred in 47 (6.1%) overall patients and was higher in DM patients (9.6% vs 4.7%, respectively, p=0.009), due to more cardiac deaths (4.6% vs 1.3%, p=0.011). Furthermore, the primary endpoint was similar between insulin and non-insulin dependent DM patients (5.4% vs 1.3%, p=0.114), instead a higher rate of secondary endpoint affected the first group (17.9% vs 7.0%, p=0.033).

CONCLUSIONS

The results of this large, real-world, multicenter-independent registry show that BP-SES has similar efficacy profile in DM as well as in non-DM patients undergoing PCI. TVF was still higher in DM mainly due to more cardiac deaths.

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Third vs. second-generation stent graft for endovascular aneurysm repair: a device specific analysis

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THEME: Peripheral Interventions
TOPIC(S): AAA

AIMS

We aimed to analyze outcomes of different generations of Excluder endograft (*Gore*) used for endovascular repair of infrarenal aortic aneurysm, comparing 2nd generation featuring SIM-PULL delivery system (ExSP), and 3rd generation featuring C3 (ExC3).

METHODS AND RESULTS

This is a single-center, retrospective comparative study, analyzing 64 consecutive patients undergoing elective EVAR with Excluder for repair of intact infrarenal aortic aneurysm from May 2008 to December 2015, through totally percutaneous access. The population was divided according to the design of the endograft used and then a sub-analysis involving complex procedures (defined as Anatomic Severity Grading ≥ 14) was performed. We analyzed intra-procedural data (i.e. procedural and fluoroscopy time, radiation dose (DAP) and contrast medium amount) and long-term outcomes.

The study included 64 patients (24 ExSP and 40 ExC3). The high-score group (ASG ≥ 14) consisted of 26 patients (40.6 %), 9 (37.5%) belonging to the ExSP group whereas 17 (40.25%) to the ExC3 group.

Patients in ExC3 group had significantly more cardiovascular risk factors (history of smoking, p = 0.019) and comorbidities (chronic heart failure and chronic kidney disease, both p = 0.032).

EVARs performed in the ExC3 group had more complex anatomy: mean aneurysm neck angle was greater (156.60 ± 20.07 vs 166.40 ± 12.72, p = 0.035) and neck calcifications tended to be greater (23% ± 9.76% vs. 19% ± 18.5% p=0.09).Also in complex procedures, theExC3 group showed significantly greater neck diameter (27.46 ± 4.88 vs. 24.28 ± 3.18 mm, p = 0.029) and neck angle (142.00 ± 22.38 vs. 165.56 ± 13.79, p = 0.09).

With regards to intra-operative data, ExC3 group showed significantly shorter procedural time both in the overall population (120 ± 41.0vs. 151 ± 9.4 min, p = 0.002) and in complex cases (129 ± 33.4 vs. 173 ± 37.6 min, p = 0.004). In the overall population, a significant reduction in fluoroscopy time (18.35 vs. 26.35 min, p = 0.01) and radiation exposure (24084 vs. 32548 cGy/cm^2, p=0.020) was also found with ExC3. Also in complex cases fluoroscopy time (23 vs. 39 min, p = 0.025) and radiation exposure (26770 vs. 41104 cGy/cm^2,p = 0.003) were reduced in ExC3 group. No significant difference was found either in contrast volume or complication rates (including branch embolization, femoral artery rupture, hemorrhagic shock, anemia and acute kidney injury). No deaths were reported during in-hospital stay.

The mean follow-up was 31.6 ± 22.9 months. No differences were noted in survival between ExSP and ExC3 group. No type I or III endoleaks were reported, as well as no graft limb stenosis or kinking, nor graft migration. Eleven (45.8%) patients in ExSP group and ten (25%) patients in ExC3 group developed type II endoleak (p = 0.307), determining aneurysm sac enlargement and requiring reintervention in one case for each group. One patient in the ExSP group developed graft infection.

CONCLUSIONS

New C3 Excluder enables to reduce radiation exposure and procedural time compared to the previous device. C3 Excluder results are comparable to those of the previous device in spite of more complex anatomy.

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Comparison of Japanese and non-Japanese patients undergoing contemporary PCI practice - Long-term results from the CENTURY II trial

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

AIMS

In an effort to harmonize regulatory approval in Japan and Europe we conducted a multicentre, randomized CENTURYII trial to assess the performance of a new drug eluting stent with bioresorbable polymer-Ultimaster, designed and manufactured in Japan.

METHODS AND RESULTS

The CENTURY II trial enrolled 1119 patients in 58 centres located in Europe, Japan and Korea. The randomization was stratified for DES indications in Japan and in this cohort, 724 patients were enrolled. We compared Ultimaster with Xience DES while in this sub-study we aim to address the regional differences in percutaneous intervention practice. The principal difference from the total population was the exclusion of patients with acute ST-segment elevation myocardial infarction, left main disease, saphenous vein graft, in-stent restenosis and the use of 4mm diameter stent. Out of the 724 patients, 262 were enrolled in 15 centres in Japan. All data were 100% monitored and an independent clinical event committee adjudicated adverse events. Significant differences were observed in almost all baseline patient characteristics: age (69.1 vs. 63.5 years; p=<0.001), diabetes mellitus (40.8% vs. 31.2%; p=0.009), acute coronary syndrome (0.0% vs. 18.2%; p=<0.001) and multivessel disease (29.8% vs 45.9%; p=<0.001) in and out of Japan centres respectively. There were no significant differences in lesion characteristics except that more bifurcations (23% vs. 11%; p<0.001) and longer lesions (16.7 vs. 15.6 mm; p=0.02) were treated in Japan with 47% vs. 37% of treated lesions being longer than 20 mm. Additionally, radial access was more frequently used in than out of Japan (85.9% vs.69.7; p<0.002). Pre-dilatation was done in 96.2% of the lesions in Japan and in 73% outside Japan (p=0.003), while post dilatations was performed in 78.7% and 46.8% of patients (p<0.001) in the Japanese and non-Japanese cohort respectively.

At 3 years, the TLF rate was 6.1% vs. 6.9% (p=0.67), with an MI rate of 2.3% vs. 2.6% (p=0.80) and a clinically indicated TLR rate of 3.4% vs. 3.7% (p=0.87) in and out of Japan respectively. Furthermore, a cardiac death rate of 1.5% vs. 2.0% (p=0.68) and a stent thrombosis rate of 0.4% vs. 0.9% (p=0.45) was observed in the Japanese and non-Japanese cohorts respectively.

CONCLUSIONS

Despite the significant differences observed in several baseline patients' characteristics and procedural practice, 3 year results of this sub-study are promising and similar for both Japanese and non-Japanese patients. Follow-up of patients is ongoing and four-year data will be available at the time of presentation.

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Platelet function in resuscitated patients after myocardial infarction - Impact of target temperature management

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

AIMS

Aim of the study was to quantify platelet function under dual anti-platelet therapy (DAPT) in resuscitated patients after myocardial infarction (MI) during and after treatment with therapeutic hypothermia.

METHODS AND RESULTS

We hypothesized that hypothermia in combination with gastroparesis and impaired hemodynamics results in reduced platelet inhibition. We further tested for differences between the clopidogrel treatment and the treatment with newer P2Y12 inhibitors (ticagrelor and prasugrel) in this setting.
This observational single-centre study was done in 27 resuscitated patients (and 77 hemodynamically stable non-resuscitated patients with MI as control). Platelet function was monitored daily for 5 days in the resuscitated patients, covering the cooling period, the rewarming phase and steady-state post rewarming. Platelet function was measured with optical aggregometry and after stimulation with either collagen in combination with arachidonic acid to monitor ASS or ADP-to monitor P2Y receptor inhibition, respectively. The protocol was approved by the Local Ethics Committee and registered at clinicaltrials gov with the ID NCT02914795.
All P2Y12 inhibitors did show reduced inhibitory effects on platelet function in comparison with non-resuscitated patients; aggregation median (IQR) 23% (17-42%) vs. 17% (14-24%), $p<0.05$. Differences between the three P2Y12 inhibitors could not be detected. In contrast, aspirin was of comparable effect between the two group (IQR 11% (5-25%) vs. 16.5% (8-27%), n.s.. And the positive control using TRAP-6 (TRAP: thrombin receptor-activating peptide) did not show any difference, too (IQR) 61% (50-72%) vs. 62.5% (56-73%), n.s..

CONCLUSIONS

P2Y12-inhibitor mediated platelet function inhibition is impaired in resuscitated patients treated with TTM. This could be observed for all three oral inhibitors tested. Aspirin, however, administers intravenously was of comparable inhibitory effects in resuscitated and non-resuscitated patients. Therefore, resuscitation with consecutive hypothermia and/or gastroparesis impairs the pharmacological effect of oral P2Y12 inhibitors. Intravenous P2Y12 inhibitors might be able to overcome this problem.

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Observed vs. predicted mortality after MitraClip treatment in patients with symptomatic heart failure and significant functional mitral regurgitation

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

AIMS

No data are available regarding the observed mortality after MitraClip in patients with symptomatic heart failure (HF) and significant functional mitral regurgitation (FMR) compared to the mortality predicted by the available HF scores.

METHODS AND RESULTS

From 2008-2015, 171 patients with moderate-to-severe HF received MitraClip at two institutions. Patients were stratified according to aetiology in non-ischemic FMR (n=64) and ischemic FMR (n=107). The observed mortality was compared with that predicted by the Seattle Heart Failure Model (SHFM), the heart failure calculator of the meta-analysis global group in chronic heart failure (MAGGIC) and the Cardiac and Comorbid Conditions HF (3C-HF) Score after 1-year: 20% observed, 20% by SHFM (â'=0), 26% by MAGGIC (â'=-6%) and 45% by 3C-HF (â'=-25%). At 2-year: 32% observed vs. 34% by SHFM (â'=-2%). At 3-year: 44% observed vs. 52% by MAGGIC (â'=-8%). At 5-year: 63% observed vs. 60% by SHFM (â'=+3%). Patients with non-ischemic FMR had the lowest mortality rate after 1-year (12%) compared to that predicted by SHFM (17.5%, â'=-5.5%), MAGGIC (24%, â'=-12%) and 3C-HF (41%, â'=-29%).

CONCLUSIONS

In patients symptomatic for HF due to significant FMR the mortality rate after MitraClip procedure was consistent with that predicted by SHFM score and lower than those predicted by MAGGIC and 3C-HF scores at 1-, 2-, 3- and 5-years. Patients with non-ischemic FMR showed the greatest difference in mortality rates compared to the HF scores.

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DEB coronary angioplasty without stenting for de novo lesions in very small caliber vessels: a five-year experience

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

AIMS

The aim of our study was to determine whether the treatment of de novo lesions in very small coronary vessels (equal or inferior to 2.5mm) by drug-eluting balloon alone is feasible, safe and whether the long-term angiographic result is satisfactory.

METHODS AND RESULTS

Methods: 85 patients were enrolled in a prospective single center register between October 2011 and December 2016. The eligibility criteriawere all de novo lesions in very small caliber coronary vessels that wereplanned to receive paclitaxel-eluting balloon angioplasty alone without stenting, regardless of clinical context. Usually following pre-dilatation, the Medtronic coated balloon In-Pact Falcon was inflated for at least 60 seconds on the lesion. Implantation of a complementary stent was decided by the operator in case of dissection with TIMI flow under 3 or very poor angiographic result. Patients receiving drug-eluting balloon angioplasty for in-stent restenosis were excluded from the study. Our safety endpoints were the rate of immediate complications (coronary dissection) and the occurrence of angioplasty-related myocardial infarction. No systematic long term angiographic control was scheduled but for different reasons some inevitably occur during the follow up. We examined the rate of late lumen permeability and the restenosis rate of these specific cases.

Results: Medium size of the vessel and length of the lesion were respectively 2,04 mm and 12 mm. 95% of the lesions were located in distal or secondary branches of the coronary arteries. Pre-dilation was performed in 87% of the case. Medium size and length of the drug eluting balloon was respectively 2,07 mm and 19mm. Average percentage of lumen stenosis at diagnosis was 93% and average residual stenosis post drug-eluting balloon angioplasty was 29%. As immediate complications, there were 19 non-occlusive dissections and one occlusive coronary dissection requiring stenting. 59% of the patients were STEMI or NSTEMI of diagnosis. Consequently, a rise in troponin levels was frequently observed, but none could be solely attributed to the drug-eluting balloon angioplasty.

Long-term results, 20 coronary angiographies were performed during follow-up. They were performed in average 8 months from the initial procedure. The late lumen permeability was 100%, with no persisting dissection visible in any of the angiographic studies. Very good late angiographic results defined by residual stenosis under 30% were observed in 90% of the cases. During the follow up and for several reasons only 3 repeat revascularization of the target vessel were performed (1 PCA and 2 CBAG).

CONCLUSIONS

Our study shows that drug-eluting balloon angioplasty alone is a safe strategy in very small caliber coronary arteries and can give good immediate and long-term angiographic results. In addition, abstaining from systematic additional stenting seems to be a reasonable therapeutic strategy for the treatment of stenosis in these very tinny coronary vessels.

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Platelet distribution width as the prognostic marker in coronary bifurcation treatment with PCI

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Bifurcation lesion

AIMS

Platelet distribution width (PDW) is a more specific marker of platelet reactivity than mean platelet volume (MPV). The aim of study was to evaluate whether PDW can predict the outcome in patients undergoing PCI within coronary bifurcation lesion.

METHODS AND RESULTS

It was a two-center, retrospective, observational study, which included patients who underwent PCI within bifurcation lesions between January 2014 and December 2014. Thrombocytopenia below 100 000/µl and STEMI were the exclusion criteria. Analyzed data come entirely from in-hospital records and information obtained directly from the telephone follow-up at 1-year. Into the final analysis 269 patients were included. Mean PDW value was 13.4 ± 2.5 fL, whereas median was 13 with interquartile range (IQR) 11.6 – 14.8. Therefore, 4 quartiles were defined: Q1 < 11.6 fL, Q2 11.6 – 13 fL, Q3 > 13 – 14.8 fL and Q4 > 14.8 fL. We found strong correlation between PDW and MPV ($r = 0.96$, $p < 0.001$), but no correlation was revealed between red cell distribution width (RDW) and PDW ($r = 0.003$, $p = 0.95$) as well as RDW and MPV ($r = 0.0018$, $p = 0.98$). Receiver operating characteristics (ROC) analysis has shown, that PDW for cut-off 15.8% can predict major adverse cardiovascular event (MACE) rate with sensitivity of 79% and specificity of 47% (area under curve - AUC 0.654; $P = 0.01$). A ROC curve for PDW categorized by 1-year target lesion revascularization (TLR) rate is described by optimal cut off 16.3%, with sensitivity 69% and specificity 54% (AUC 0.697; $P = 0.0015$).

CONCLUSIONS

PDW is an affordable and reliable predictor of 1-year MACE and TLR rate after PCI within coronary bifurcation lesion. It is also more appropriate than MPV.

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Asymptomatic left ventricular dysfunction, coronariography and significant coronary artery disease

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

AIMS

We sought to determine the prevalence and predictors of clinically significant coronary artery disease in patients with left ventricle dysfunction of unknown aetiology referred for invasive diagnosis.

METHODS AND RESULTS

Single centre retrospective analysis including 599 patients with left ventricle dysfunction without angina or documented ischemia, who underwent coronary angiography, between 2005 and 2015. Clinically significant CAD was defined as left main stenosis >50%, left anterior descending artery (LAD) stenosis >70% or three vessel disease (proximal or middle LAD, circumflex and right coronary stenosis >70%). Predictors of clinically significant coronary artery disease were identified using binary logistic regression.

The mean age of the studied population was 66 (±12) years old and 69% of the patients were males. The prevalence of diabetes, hypertension, dyslipidaemia and tobacco consumption was 35.4%, 66.1%, 43.7% and 40.2%, respectively. The most common presentations were fatigue in 53% and dyspnoea in 35% of the patients. Mild, moderate and severe depression of the ejection fraction was present in 31%, 37% and 32%, respectively. Forty-nine percent of the patient presented some degreed of coronary atherosclerosis and 18,1% had at least one lesion > 50%. Seventy patients **(11,7%)** had significant CAD. In univariate analysis, CAD population were older, had more syncope and less fatigue and COPD. After correction for other variables, age (OR 1,034 95%CI 1,009-1,06, p=0.008) and tobacco use (OR 1,02 95%CI 1,009-3,1, p=0.044) were independent predictors of significant CAD, on the other hand patients who presented with fatigue (OR 0,473 95%CI 0,273-0,82 p=0.008) and with COPD (OR 0,22 95%CI 0,065-0,73 p=0.0138) had less CAD.

CONCLUSIONS

The prevalence of significant CAD among patients with left ventricle dysfunction referred for coronary angiography for coronary disease exclusion is high and probably supports the use of this invasive approach in this setting.

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Impact of an invasive strategy in the elderly with emphasis on the nonagerians presenting with ACS

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

AIMS

Published data about nonagenarians with ACS have been descriptive and limited by small sample sizes and unadjusted outcomes. We aim to describe the characteristics, management and the impact of an invasive strategy in this population.

METHODS AND RESULTS

We analysed data collected as part of the AMI-OPTIMA study, a cluster-randomized study of knowledge translation for discharge medications in patients admitted with ACS at 24 Quebec (Canada) hospitals. To determine whether an invasive strategy improved outcomes in the elderly and nonagenarians, we used inverse probability weighting to adjust for confounders between patients who underwent invasive vs. conservative strategies.Of 4,569 patients registered during two calendar years: 2395 (52%) were <70 years old, 1031 (23%) were septuagenarians, 941 (21%) were octogenarians, and 202 (4.4%) were nonagenarians.The majority of the nonagenarians were females with low or normal body mass index; one-third also had impaired kidney function. NSTEMI was the most common presentation. The use of an invasive strategy declined with increasing age, with most patients younger than 70 years undergoing a coronary angiogram (92%) but only 20% of nonagenarians.We compared the in-hospital outcomes in the nonagenarians to those from other age groups. Except for ventricular arrhythmia, the nonagenarians had increased rates of all in-hospital adverse events when compared to the younger patients. Their all-cause and cardiovascular (CV) mortality were 20-fold higher than those of patients younger than 70 years, and they had 10 times more strokes compared to patients less than 70 years of age.We contrasted the independent predictors of all-cause mortality and invasive strategy. Despite their associations with increases in all-cause mortality, advanced age and female sex were associated with reduced odds of invasive strategy. In-hospital coronary revascularization was associated with 80% reduction in in-hospital mortality for both PCI and CABG.We compared the in-hospital outcomes between the conservative and invasive strategies after inverse probability weighting. An invasive strategy was associated with lower all-cause and CV mortality in all age groups. With increasing age, there was a decrease in the relative risk reductions (RRR) of all-cause mortality: 1.1% vs. 4.1% in patients <70 years old (RRR: 73%, 95% confidence interval (CI): 59-83%), 2.6% vs. 8.8% in septuagenarians (RRR: 70%, 95% CI: 52-80%), 6.2% vs. 15.1% in octogenarians (RRR: 59%, 95% CI: 49-73%) and 16.9% vs 26.2% in nonagenarians (RRR: 37%, 95% CI: 7-65%) (Figure 2-3). However, the absolute risk reduction (ARR) of in-hospital all-cause mortality associated with an invasive strategy increased with age from 3.0% in patients < 70 years old (number needed to treat (NNT): 29) to 9.3% (NNT: 11) in octogenarians and nonagenarians (Figure 3). The invasive strategy was associated with similar magnitudes in reduction of CV mortality.There were more strokes in the nonagenarians who underwent an invasive strategy (3.1% compared to 1.5% with conservative strategy, albeit non-significantly). An invasive strategy was associated with increased TIMI major bleedings in nonagenarians (OR: 5.69, 95% CI: 1.91-16.97, NNH: 12). There was no significant increase in TIMI minor bleedings with advanced age.

CONCLUSIONS
In elderly with ACS, an invasive strategy was associated with lower in-hospital all-cause and CV mortality and these benefits remain in nonagenarians, albeit with higher bleeding risk.

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TAVR in dialysis patients: does approach matter?

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

AIMS

This study aimed to investigate the impact of procedural approach on short and mid-term outcomes in dialysis patients undergoing transcatheter aortic valve replacement(TAVR).

METHODS AND RESULTS

All end-stage renal disease patients undergoing dialysis who had TAVR at a single center were included. Patients were divided into two groups per TAVR approach (Trans femoral (TF) vs. Transapical (TA)). Baseline clinical characteristics, peri- and post-operative outcomes were compared between patient groups. Other outcomes that were evaluated included (1) Post-operative length of stay (PLOS) in the intensive care unit (ICU) and before discharge and (2) High resource utilization (HRU) (PLOS > 7 days, discharge to rehabilitation). A multivariable Cox proportional hazard model was used to identify predictors of 1-year all-cause mortality. Unadjusted mortality rates at 30-days and 1-year were calculated. Thirty-Seven dialysis patients who had TAVR via TF (n=25) or TA (n=12) approaches were investigated. Baseline demographics and risk factors were comparable in both TF and TA groups. Age: p=0.08, Sex: p=0.73, NYHA class: p=0.74, STS score: p=0.69, Frailty Score: p=0.18. Mean duration of stay (days) (TF vs. TA) was 3.5 vs. 5.4 (p=0.41) in the ICU and 6.2 vs. 7.8 (p=0.61) post-procedure. High resource utilization was 54% vs. 50%, p=0.813 for the TF and TA groups respectively. Except for new onset arrhythmia: TF: 8% vs TA: 33% p=0.05, there were no statistically significant differences between groups regarding other procedure-related adverse events (Stroke: p=1.0, permanent pacemaker requirement: p=0.97; moderate/severe paravalvular leak; p=0.25). After a mean follow up duration of 15 months, 30-day and 1-year all-cause mortality rates for TF vs. TA groups were 8% vs. 16%, p= 0.43 and 20% vs. 33%, p= 0.38 respectively. On univariable analysis, there were no predictors of 1-year all-cause mortality. Procedural approach did not predict 1-year all-cause mortality [TA]: HR: 0.97, p=0.93); [TF]: HR: 1.03, p=0.94).

CONCLUSIONS

Dialysis patients selected for TF or TA TAVR share similar and comparable outcomes in both short and mid-term post-procedure. TA-TAVR may be associated with a higher risk of conduction abnormalities. Approach has no significant impact on high-resource utilization and mortality in mid-term.

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Feasibility and safety of same-day discharge after PCI in stable coronary artery disease

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

AIMS

Aims: Percutaneous coronary intervention is frequent and getting safer. Same-day-discharge strategy has become an alternative to overnight hospitalisation. However, this practice remains limited.

METHODS AND RESULTS

Methods: A retrospective review of all the PCI performed in our ambulatory structure since its opening. Primary end points were complications including major cardiac events (MACE) and readmission within 24 hours after PCI. 30 days outcomes were also reported.
Results: from September 2012 to March 2015, 187 patients mainly male, 65 years old average, were admitted, with a stable coronary artery disease. Radial access was performed in 93% of the cases. 167 patients benefited from a same-day-discharged strategy. 20 patients needed a conventional overnight hospitalisation: 11 due to PCI minor complications and 9 due to physician's choice (comorbidities, complex procedures).
No MACE occurred in the first 24 hours reinforcing the same-day-discharge strategy. Only one patient was readmitted for chest pain without documented ischemia.
Within the first month, were observed 3 stent thrombosis but no death occurred.

CONCLUSIONS

Conclusions: Our study confirms that same-day-discharge PCI in stable coronary artery disease is feasible, safe and well-accepted by patients in our practice. This infrequent strategy must be developed, especially in the current context of care supply reorganization.

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One-year clinical outcomes of patients on oral anticoagulant therapy treated with second-generation DES

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

AIMS

We sought to further explore the safety and efficacy of Ultimaster sirolimus eluting stent in patients on oral anticoagulant therapy in the large eUltimaster registry.

METHODS AND RESULTS

eUltimaster is a prospective,single-arm, multi-centre registry. Out of 4597 patients that have reached 1-year follow-up, information on anticoagulation therapy was obtained on 2829 patients and out of these, 122 were on oral anticoagulant therapy. The primary endpoint of this registry is target lesion failure (TLF) defined as a composite of cardiac death, target vessel related myocardial infarction (MI) and clinicallydriven target lesion revascularization (TLR) at 1 year. All the serious adverse events related to the endpoints were independently adjudicated by the clinical events committee. The OAC patients were older than non-OAC patients (72 vs 65 years;p<0.001) and octogenarians were more often noted in the OAC group (16%vs. 10%; p=0.03). At baseline, rate of diabetes mellitus, hypertension, and previous coronary interventions was similar both groups, however, the OAC group had significantly lower left ventricular ejection fraction (47% vs. 55%; p=0.0052) and higher rates of renal impairment (20% vs. 7%; p<0.001). Rate of pre-procedural dual antiplatelet therapy (DAPT) was 49% in the OAC group and 82% in the non-OAC group (p<0.001) while the OAC group had significantly lower rates of ACS (40.5% vs. 56.5%; p<0.001). The lesion characteristics and complexity were similar in both groups except for higher rates of bifurcation in the non- OAC group (6% vs. 13%; p=0.005). Success rate of Ultimaster DES implantation was 99.5% in both groups. Overall, the OAC group showed significantly lower DAPT status compared to the non-OAC group; at discharge 70% vs. 99%; 3-month 68% vs. 98%; 1-year 28% vs. 71%; (p<0.001 for all). At 1 year, there was no significant difference in TLF between both groups (3.3% vs. 1.8%; p=0.29), clinically driven TLR (1.6% vs. 1.1%; p=0.65), all-cause death (2.5% vs. 0.8%; p=0.09) and cardiac death (0.8% vs. 0.4%; p=0.41) respectively. Additionally, no significant differences were observed intarget vessel related MI (1.6% vs. 0.6%; p=0.18) and stent thrombosis (1.6% vs. 0.4%; p=0.11) in both groups. Major bleeding according to the Bleeding Academic Research Consortium criteria was significantly higher in the OAC group (6.6% vs. 2.4%; p=0.01), however, there were no significant differences in cerebrovascular events and composite vascular complications in both groups (1.6% vs. 1.3%; p=NS, 1.6% vs. 2.1%; p=NS) respectively. In OAC patients with different DAPT duration, there was no significant differences at 1-year in cardiac death, target vessel related MI, ST nor TLR between the OAC group with DAPT<3 months and ≥3 months. Additionally, there were numerically higher, but not significantly different bleeding complications related to the duration of DAPT (4.8% vs. 10.3%; p=0.27) in DAPT<3 months vs. DAPT ≥3 months respectively.

CONCLUSIONS

The patients with OAC were older and had lower LV function. Duration of DAPT was shorter through 1 year follow-up. Although bleeding complications were higher in the OAC group, the DAPT duration did not have significant impact on adverse cardiac events at 1 year.

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Transradial access for balloon aortic valvuloplasty

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

AIMS

Balloon aortic valvuloplasty (BAV) can be useful in severe aortic valve stenosis however, the femoral access complication rate isn't negligible. The aim of our study was to establish the safety, technical and clinical success of transradial BAV.

METHODS AND RESULTS

8 patients with symptomatic severe aortic valve stenosis (AS) who were unsuitable for surgical (SAVR) or transcatheter aortic valve implantation (TAVI) were included in the study. All patients underwent both right and left radial and ulnar artery ultrasonography to define the safest access site. Transradial access was successfully obtained in all patients from the right radial artery. Contralateral radial access was used for the insertion of a pigtail catheter and a temporary pacemaker lead was implanted via the jugular vein. Valvuloplasty was performed during rapid pacing with an XXL Balloon (16-18 mm diameter) advanced across a 7 Fr sheath. During the procedure the efficacy of the procedure and the aortic valve insufficiency was measured both echocardiographycally and angiographycally.

In all patients aortic valvuloplasty was successfully performed. One patients underwent TAVI one month after BAV. Improved hemodynamic parameters were measured in all patients, mean AV gradient decreased from 48 to 38 (21%), and AVA increased from 0.7 to 1.0 (43% increase). Prior to BAV all patients had NYHA III-IV heart failure symptoms, nevertheless discharge functional status markedly improved (NYHA I-II). In total, no major adverse cardiac or cerebrovascular event or vascular complication (according to VARC 2 criteria) occured during the interventions.

CONCLUSIONS

Radial artery access is a safe and effective option for balloon aortic valvuloplasty in patients with sever aortic valve stenosis.

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Provisional stent technique in coronary bifurcation lesions: predictors and outcomes of side branch occlusion

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

AIMS

The occlusion of the side branch (SB) during PCI of a coronary bifurcation is a major complication of these procedures. To study the predictors of SB occlusion after treatment of coronary bifurcations with provisional stent technique.

METHODS AND RESULTS

From March 2014 to April 2015 1960 PCI performed in two centres were prospectively registered, of which 382 were PCI of bifurcation lesions with a side branch> 2 mm of diameter, performed in 353 patients (78.8% male, 65.8 ± 12.5 years).

We analysed those made by the provisional-stent technique (354 lesions) studying the predisposing factors of the SB occlusion defined as TIMI 0-1 flow during the procedure. Cardiovascular events related to it and the technique to recover the SB were also analysed.

33.2% of patients were diabetic, and mean left ventricle ejection fraction was 52.5 ± 12%. Clinical presentation was stable coronary artery disease in 44.4% and ACS in 55.6%. The location of the bifurcation was: left main: 13.9%, left anterior descending (LAD)-diagonal: 52.6%, Circumflex-obtuse marginal: 19.9%, right coronary artery-acute marginal: 4.3% and posterior descending-posterolateral: 7.7%. They were true bifurcations in 42.7%. SB was predilated in 9.9% and postdilated in 46.3% of cases. The main vessel (MV) was postdilated in 47.5% of cases finishing with kissing-balloon in 5.9% of them. SB occlusion during the procedure was observed in 22 cases (6.3%). The SB was recovered during the procedure in 90% of cases (5.3% spontaneously, 15.8% after recrossing with a wire, 68.4% after balloon dilatation and 5.3% needed a second stent in the SB). Occlusion of the SB during the procedure was associated with higher rates of cardiac death (13.6% vs 3.4%; p=0.02) and myocardial infarction (MI) (18.2% vs 2.9%; p<0.0001) but there was not a significant association with stent thrombosis (ST) or need of target lesion revascularization (TLR) after a mean follow up of 24.8 months.

Predictors of SB occlusion in univariate analysis were the existence of true bifurcation (10.7% vs 3% ; p =0.006), % of stenosis of the proximal MV (83.6 ± 21.9 vs 66.8 ± 32.2%; p=0.002), distal MV (83.3 ± 26.8 vs 66.3 ± 33.4 %; p= 0.009) and ostial SB (67.3 ± 36.6 ± 37.4 ± 36.8 %; p<0.0001), the SB lesion length (8.4 ± 7.1 mm vs 5.3 ± 7 mm; p= 0.048), ostial SB stenosis > 75% after MV stenting (14,2% vs 0,5%; p<0.0001) and presentation as ACS (8.2 % vs 2.7%; p = 0.035)

In multivariate analysis, the only independent predictor of SB occlusion during the procedure was ostial SB stenosis > 75% after MV stenting (OR: 22.9, 95 CI% 3.1-175; p = 0.02).

CONCLUSIONS

SB occlusion during PCI of bifurcation lesions with provisional stent technique is rare and recoverable during the procedure in most cases. It is associated with a higher rate of periprocedural MI and cardiac death but no with ST or TLR. The only independent predictor of SB occlusion during the procedure was ostial SB stenosis > 75% after MV stenting.

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Safety and efficacy of a novel sirolimus-eluting stent in diabetic patients: insights from the en-ABL study

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Diabetes remains a significant predictor of adverse clinical outcomes after PCI with DES. We thus sought to evaluate the comparative efficacy/safety profile of the ABLUMINUS DES+ siromus-eluting stent in diabetics versus non-diabetic patients.

METHODS AND RESULTS

In the en-ABL registry, 1951 “all-comer” patients underwent PCI with the ABLUMINUS DES+ (Envision Scientific Pvt. Ltd., Surat, India) and were prospectively followed.
The stent platform is a thin strut (73 microns) of L605cobalt chromium stent with open and closed cell (hybrid) design, with the polymer (PLLA)-drug combination applied solely to an abluminal configuration on stent and parts of balloon.
The primary endpoint was the rate of major adverse cardiac events (MACE) at one year and to evaluate the performance of the Sirolimus eluting coronary stent system against a performance goal which is pre-specified based on meta-analysis from published data of the studies: DIABETES, RAVEL DM, SIRIUS DM, TAXUS IV, SCORPIUS, ENDEAVOR DM . Secondary endpoints include Stent Thrombosis (ST) and MACE rates up to three years. Clinical follow-ups of this study are on going.
The clinical follow-up at one year was available in 80.25% (569/709) diabetic and 80.43% (999/1242) non-diabetic group. There were no statistically significant differences in the MACE rate between two groups: 2.99% in diabetic and 2.10% in the non-diabetic group (p=0.273). The 1-year MACE rate was 2.99% in diabetic patients, significantly lower than the performance goal of 14.5% (p= <0.001). Also, there were no statistically significant differences in ST between the diabetic and non-diabetic groups: 0.88% and 0.70% (p=0.697) respectively. To date, the 2-year clinical follow-up available for 57.55% in diabetic and 58.45% in the non-diabetic groups which include one additional event in diabetic patients only.

CONCLUSIONS

At 1 year, diabetic patients had a low rate of MACE, actually similar to non-diabetic patients and significantly lower than performance goal. These data support the safety and efficacy of the ABLUMINUS DES+ in the real world diabetic setting.

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Incidence and predictors of CTO reocclusion at long-term follow-up after successful PCI. Insight from the CLOSE study (Coronary chronic total occlusion Long-term Outcomes after Successful percutaneous rEvascularisation)

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

To assess the incidence and clinical and angiographic predictors of coronary chronic total occlusions (CTOs) occlusive restenosis after successful percutaneous recanalization at a long term follow-up.

METHODS AND RESULTS

This is a prospective cohort study. From April 1998 to December 2008 we recorded data regarding 744 patients referred to our clinic with at least one CTO on invasive coronary angiography and angina/proof of ischemia on non-invasive testing. Of these, 526 underwent successful percutaneous coronary intervention (PCI) with recanalization of the target lesion (success rate 70.7%) and were included in this analysis. Baseline clinical, angiographic and procedural data were collected. The endpoint was the angiographic evidence of occlusive restenosis of the target lesion.

Angiographic follow-up was done by means of invasive coronary angiography, follow-up was censored at the time of target lesion occlusive restenosis diagnosis and truncated at the last clinical follow-up available or at the patient's death, whichever came first.

At a mean follow-up duration of 5.4 years (IQR 4.9 years) the angiographic follow-up was 75%. A total of 37 occlusive restenosis occurred (reocclusion rate 9%). Recurrences presented more frequently as occlusive anatomical restenosis than as functional occlusion (18.9 vs 7.8%; p=0.043).

At the univariate analysis patients who experienced recurrence of CTO had more frequently a history of previous PCI (69.4 vs 47.5%; p=0.018) and prior attempt to CTO recanalization (21.6 vs 9.4%, p=0.038), experienced more angiographic complications at the time of the index procedure (10.8 vs 2.3%; p=0.012) showed a higher prevalence of procedural wire coronary dissection (5.4 vs 0.6%; p=0.044), presented more frequently with a blunt CTO lesion morphology (45.9 vs 26.4%; p=0.018) without coronary bridging collaterals (18.9 vs 38.9%; p=0.025), had a higher mean length of stent implanted (1.78 vs 1.45 mm; p=0.044).

At the stepwise backward Cox regression analysis, the only significant predictors of reocclusion of the target lesion at the long term follow-up were: the occurrence of angiographic complications, especially wire coronary dissection (RR 20.3; 95% CI 3.91-105.68; p<0.001), the absence of bridging collaterals at the time of the index angiography (RR 3.90; 95% CI 1.43-10.63;p=0.008), the blunt morphology of the lesion (RR 1.76; 95% CI 1.06-2.92; p=0.03), an higher mean length of implanted stents (HR 1.012; 95% CI 1.001-1.022; p=0.027) and a lower post-procedural TIMI flow score (HR 0.08; 95% CI 0.024-0.271; p<0.001). Notably, no differences were found between bare metal stent or drug eluting stent implantation (either first or second generation). The presence of diabetes mellitus, smoking habit, hypertension, dyslipidemia or chronic kidney disease did not add significance to the prediction model.

CONCLUSIONS

CTO revascularization is a safe procedure in experienced hands, with a high patency rate (91%) at long term follow-up. Procedural techniques and angiographic lesion characteristics are the most powerful predictors of occlusive restenosis after a successful PCI of CTO, while clinical variables show poor predictive value in terms of angiographic outcome.

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Relationship between OCT-derived fibrous plaque morphology and haemodynamic relevance as determined by FFR in intermediate coronary stenoses

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

AIMS

The aim of this study is to determine the relationship between fractional flow reserve (FFR) and optical coherence tomography (OCT)-derived measurements of coronary lesions in patients with intermediate grade stenoses by angiography.

METHODS AND RESULTS

In this single-centre, single-arm study consecutive patients with intermediate grade coronary stenoses by angiography were evaluated by both FFR and OCT. Stenoses were labelled hemodynamically relevant in case of the FFR ≤ 0.80. The minimal lumen area (MLA), reference lumen area(RLA), maximal angle of the calcium, mean and minimal fibrous cap thickness and the necrotic core angle within the lesion were evaluated. Of a total of 124 analyzed patients (124 lesions), 67 (54.0%) lesions were labeled as hemodynamically relevant by FFR. In the group with FFR ≤ 0.80 the MLA (3.74±1.43μm vs 5.07 ± 2.79μm; p = 0.003) as well as distal (4.89 ± 1.89 μm vs 6.73 ± 3.47μm; p < 0.001) and proximal RLA (7.23 ± 2.69 μm vs. 9.35 ± 5.04 μm; p = 0.004) were lower, compared to lesions with FFR > 0.80.

The maximal angle of the calcium (104.99 ± 52.92 vs. 67.69 ± 24.00; p = 0.095) proved to be numerically higher in the subset with relevant stenoses. No differences were found between the groups in terms of the mean fibrous cap thickness (0.09 ± 0.04 vs. 0.15 ± 0.09, p = 0.190), minimal fibrous cap thickness (0.09± 0.04 vs. 0.15 ± 0.09; p = 0.197) and the necrotic core angle (148.38 ± 72.18 vs. 94.35 ± 41.57; p = 0.010) as well as the cap thickness over the calcium (0.09 ± 0.06 vs. 0.14 ± 0.11; p = 0.168).

CONCLUSIONS

Although haemodynamic relevance of intermediate grade lesions correlated strongly with the luminal assessment, there were no differences in lesion morphology between the patients with severe and not severe coronary stenoses by FFR.

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Performance of a newer generation sirolimus-eluting stent to treat very small (≤2.25 mm) coronary artery disease. Insights from the en-ABL study

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

The results of PCI in very small coronary arteries is still suboptimal as compared to larger vessels. The aim of this study was to evaluate the performance of the ABLUMINUS DES+ sirolimus-eluting stent in very small (≤2.25 mm) vessels (VS).

METHODS AND RESULTS

Data from en-ABL study including patients with VS vessels were pooled for this analysis. The primary endpoint was the rate of major adverse cardiac events (MACE) at one year, defined as a composite of cardiac death, target vessel myocardial infarction (TV-MI), and target lesion/vessel revascularization (TLR/TVR). Secondary endpoints include stent thrombosis (ST) and MACE rates up to two years.

A total of 175 patients with 189 lesions were treated with the ABLUMINUS DES+ sirolimus-eluting stent (Envision Scientific Pvt. Ltd., Surat, India). Total Population of the study was pre-dominated by male patients (78.86 %). 49.71% patients presented with Diabetes and 45.71% patients presented with hypertension. Acute Myocardial Infarction accounted for 13.14 % of the patients. 1 year follow-up was available for 87.43 % patients and MACE rate was 3.92 % and MACE was only driven by TLR/TVR (3.92 %). There were no TV-MI, cardiac death and ST reported at 1 year. The 2-year clinical follow-up available in 72% of patients with no additional eve

CONCLUSIONS

Clinical outcomes among patients with VS vessels treated with the ABLUMINUS DES+ is favourable and supports the safety and efficacy of a novel newer generation sirolimus-eluting stent not only in patients with simple but also in those with complex coronary lesions.

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Plasma microRNA-126 and microRNA-155 are associated with vulnerable plaque characteristics assessed by iMAP-IVUS

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Altered expression of microRNAs (miR) are proven to have a significant role in atherosclerosis related processes. In this ongoing study we evaluated the correlation of plaque tissue characteristics by iMAP-IVUS with miR-126, -145, -155 expression.

METHODS AND RESULTS

Patients with stable coronary artery disease undergoing PCI were enrolled. During PCI lesions in the culprit artery were imaged by 40-MHz iMAP-IVUS. The data were stored for offline analysis with iMAP tissue characterization software. The proportion of plaque fibrotic, necrotic, lipidic and calcific tissue was determined. Patients fasting blood samples were obtained before cardiac catheterization procedure to evaluate miR-126, miR-145 and miR-155 expression and the correlation with plaque tissue characteristics assessed by iMAP-IVUS. Two weeks after PCI additional blood samples were obtained to analyze whether vascular injury caused by PCI changes the expression pattern of these miRs. iMAP-IVUS and miR expression analysis was done in the first 10 patients of whom seven were male. Mean patient age was 57.7 ± 7.71 years and weight 89.9 ± 9.53 kg. Arterial hypertension was present in nine patients. Half of patients reported smoking. Plasma miR-126 expression significantly correlated with plaque necrotic (r=0.68; p=0.045) and necrolipidic tissue content (r=0.73; p=0.027). MiR-155 negatively correlated with plaque fibrotic tissue content (r=-0.70; p=0.037) and positively with plaque lipidic (r=0.77; p=0.015) and necrolipidic tissue content (r=0.8; p=0.009). A tendency towards correlation with plaque volume not reaching statistical significance were observed both with miR-126 (r=0.62; p=0.073) and miR-155 (r=0.61; p=0.08). No correlations were found in the expression of miR-145 and plaque tissue characteristics. MiR expression at two week follow up did not show any significant changes from baseline (p=0.794; p=0.627 and p=0.746 for miR-126, miR-145 and miR-155, respectively). No significant correlations were found in miR expression with patient age, gender, weight, body mass index, smoking status, and lipid profile.

CONCLUSIONS

The preliminary results of this study indicate that miR-126 and miR-155 expression are associated with vulnerable plaque characteristics. MiR expression two weeks after coronary artery stenting did not change significantly compared to baseline.

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Angiographic restenosis after coronary stenting in patients with prior coronary bypass surgery

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

AIMS

Restenosis after PCI in patients with prior CABG is poorly studied. We investigated incidence and predictors of angiographic restenosis after PCI in patients with and without prior CABG.

METHODS AND RESULTS

Patients undergoing successful PCI of 1 or more *de novo* lesions at 2 centers with available surveillance angiography at 6-8 months after intervention were eligible for inclusion. Exclusion criteria were cardiogenic shock, ongoing renal replacement therapy and prior cardiac transplantation. Outcomes in patients without prior CABG were compared to those with prior CABG. Patients with prior CABG were then subclassified into patients who underwent bypass graft PCI versus native vessel PCI. The primary endpoint was binary restenosis at 6-8 months angiographic follow-up.10,004 patients with 14,999 lesions were included, 8,803 patients (88%) without prior CABG and 1,201 (12.0%) patients with prior CABG. Of patients with prior CABG, 379 (31.6%) patients had bypass graft PCI and 822 (68.4%) had native vessel PCI. Compared with patients without prior CABG, patients with prior CABG were older, had higher rates of diabetes and prior myocardial infarction, and lower left ventricular ejection fraction but larger reference vessel diameter (2.95 vs. 2.85 mm, p<0.001). At 6-8 month angiographic follow-up, the rate of binary restenosis was significantly higher in patients with prior CABG compared to those without (25.0% vs. 20.0%, respectively, p<0.001).Among patients with prior CABG, patients with bypass graft PCI as compared to patients with native vessel PCI had a lower incidence of diabetes, a higher rate of presentation with ACS, larger target vessel size (3.42 vs. 2.80 mm, p<0.001) and longer lesion length (16.0 vs. 13.9 mm, p=0.01) and BMS use was significantly higher (72.1% vs. 37.0%, p<0.001). At 6-8 month angiographic follow-up, there was no significant difference in binary restenosis rates among patients with bypass graft PCI compared with those with native vessel PCI (23.8% vs. 25.3%, p=0.56). Multivariate analysis showed an independent association between PCI to a native vessel in patients with prior CABG and restenosis compared with patients without prior CABG (OR 1.47, 95% CI 1.26-1.72, p<0.001). Bypass graft PCI was not independently associated with restenosis (OR 1.26, 95% CI 0.96-1.66, p=0.09).

CONCLUSIONS

Compared with patients without CABG, patients with prior CABG had overall higher rates of restenosis. In patients with prior CABG, restenosis rates were similar in patients undergoing bypass graft PCI and native vessel PCI. In multivariate analysis, native vessel PCI was independently associated with restenosis at 6-8 months.

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How long does it take? The learning curve in the field of the percutaneous treatment of coronary CTO - Single-centre experience

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

AIMS

We report the own experience after 402 procedures, accomplished by one dedicated operator and analyze procedural differences and lesion characteristics in four consecutive groups of patients.

METHODS AND RESULTS

Between January 2011 and December 2016, 402 PCI of CTO procedures in 378 patients were performed. Consecutive, unselected patients were divided into 4 groups and the groups were compared according to demographic and procedural data. These four groups did not differ in mean age and in percentage of women. There were no differences in diagnosis of hypertension, dyslipidaemia or diabetes between groups. Current smoking was found more often in first group (24%) than in the consecutive ones (22%, 13%, 14.7%, respectively, <0.05). It was observed differences in rate of the prior PCI (63% vs.71% vs. 83% vs.89.2%, <0.05). In the first group 50% of patients suffered from prior heart infract, 52% in the second group, 34% in the third and 51.9% in the fourth (<0.05). Characteristic of the occlusion differed in lesion length between groups (23.1±9.7 vs. 26.6±11.2 vs.30.9±15.5 vs.25.8±11.7, <0.05) but there were no changes in duration. J-CTO score was increasing in consecutive groups 1.5±0.9 vs. 1.9±0.8 vs. 2.1±0.9 vs. 2.5±1.1, <0.05, respectively). Contrast use (ml.) (329.1±159.9 vs. 362.1±162.4 vs. 355.1±149.9 vs. 299.2±149.0, <0.05, respectively), fluoroscopy time (min). (22.2±13.2 vs. 29.3±20.7 vs. 31.4±17.7 vs. 25.5±17.1, <0.05, respectively) and radiation dose (mGy) (2149±1554 vs.2444±1340 vs. 2541±1662 vs. 1654±1311, <0.05, respectively) differ beetwen groups. Retrograde technique was simmiliar in each group. It was observed increasing number of the used wires (1.8±0.8 vs. 2.2±1.3 vs. 2.7±1.7 vs. 2.6±1.6, <0.05, respectively). Succes rate remained high (79% vs. 89% vs. 87% vs. 85.1%, p=NS). Due to higher complexity of occlusions we observed in the third group the highest fluoroscopy and procedural time, radiation dose and number of stents and wires. In the fourth group, after 300 procedures, all of these parameters decreased. The overall success rate was 85.1% and remain high even in the most complicated cases.

CONCLUSIONS

In the treatment of complex CTO lesions learning curve is crucial. Within reasonable time it’s possible to keep high success rate and to improve some procedural data even in the most complicated cases.

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A three-and-a-half-year observational follow-up study of patients with critical limb ischaemia treated efficiently by endovascular approach

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal

AIMS

The aim of this study was to describe our experience with endovascular treatment in critical limb ischaemia and to bring new follow-up data about these patients with initial successfully revascularization.

METHODS AND RESULTS

A retrospective study of 115 patients with critical limb ischaemia, with successful endovascular treatment in our institution was performed. We followed death, reintervention and amputation rates during a mean period of 43,2 ±7,9 months. Follow up was made through referring physician, general practitioners or by phone call. The mean age of the patients was 65,4±11,6 years. Of these patients, 70,4% were males, 39,1% diabetics, 53% active smokers, 23,5% with chronic kidney disease, 34,8% with other peripheral artery disease. The final treatment was stenting in 20,8% of cases and ballon angioplasty alone in the rest of the cases. Treated arteries were in the femoral-popliteal segment – 55,4%, aorto-iliac segment – 30,2% and infrapopliteal segment – 14,4%. 23,7% of the patients underwent procedures on more than one arterial segment. More than 85% of lesions were type A and B (TASC II classification) in both aorto-iliac and femoral-popliteal segment. The most frequent arterial approaches used were antegrade femoral – 50,3%, left brachial artery – 20,1%, retrograde femoral – 9,3%. 6,9% patients required more than one access site. During follow up one death occurred (0,9%), 17 patients (14,8%) underwent reinterventions for revascularization (endovascular or surgical) and 18 patients (15,7%) suffered further amputations.

CONCLUSIONS

Despite a certain rate of death, amputation and reintervention, our results suggest that endovascular approach, can be considered an efficient and feasible treatment option for patients with critical limb ischaemia if successfully at the moment of implementation.

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Transfemoral implantation of a self-expanding valve for the treatment of aortic regurgitation: international experience

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

AIMS

The aim of this study was to report the international experience of transfemoral TAVI for the treatment of pure aortic regurgitation with the ACURATE neo transcatheter heart valve.

METHODS AND RESULTS

A total of 13 patients (10 women, 3 men, mean age 79 years) with severe aortic regurgitation underwent TAVI with the Symetis ACURATE neo at 8 centres in Europe and Israel. All patients were in NYHA class 3 (92%) or 2 (8%). The mechanism of regurgitation was leaflet degeneration in 10 (77%), prolapse in 2 (15%), and leaflet injury in 1 (8%). An ECG gated computed tomography was performed in all, and prosthesis size was selected based on the perimeter derived annular diameter with a tendency to oversize in case of borderline annuli. TAVI was successfully performed in all patients and residual aortic regurgitation was none in 8 (62%) and mild in 5 (38%, $p < 0.01$ compared to baseline). Left ventricular end-diastolic diameter decreased from 57 +/- 6 mm at baseline to 51 +/- 7 mm before discharge ($p<0.01$). Left ventricular ejection fraction remained unchanged. Patients were discharged after a median of 6 days. At 30 days follow-up, there was no mortality and no stroke, and one patient (8%) had received a permanent pacemaker. All patients were in NYHA class 1 or 2 ($p < 0.01$ compared to baseline).

CONCLUSIONS

In patients with aortic regurgitation and suitable anatomy, transfemoral TAVI with the ACURATE neo THV abolished aortic regurgitation, significantly reduced left-ventricular dimensions, and improved symptoms.

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Incidence and predictors of non-recovery of left ventricular longitudinal function after myocardial infarction treated with PCI

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

AIMS

Left ventricular (LV) remodeling may occur following myocardial infarction (MI). Increased pulse wave velocity (PWV) predicts cardiovascular event in different clinical conditions, but no study in patients with acute MI.

METHODS AND RESULTS

Methods: In 112 patients with acute MI and PCI (68% male, age 61.1±9.5 years (M±SD), 57.2% with ST-elevation MI (STEMI), smokers 35%, arterial hypertension 83%, diabetes 7%, blood pressure (BP) 128±8/82±87mmHg,LV ejection fraction (LVEF) 48.2±4.6%) arterial stiffness was assessed using applanation tonometry. Global longitudinal peak strain (GLPS) by speckle tracking echocardiography (STE) was calculated in a 16-segment LV model as the average segmental value on the basis of three apical imaging planes. Cardiac adverse remodeling was defined by ratio [follow up - initial LV end diastolic volume (LVEDV)]/ initial LVEDV) more than 20%. Mann-Whitney and Spearman tests were considered significant if $p<0.05$.

Results: Baseline GLPS >20% was not detected in any patient. GLPS increased from 14.4±2.4 to 17.4±3.5% in 4 weeks ($p<0.05$) and to 18.1±2.7 in 6 months after PCI ($p<0.05$). GLPS normalized (>20%) in 31 (28%) patients after 4 weeks and 6 months. After 6 months adverse cardiac remodeling was found in 81 (72%) patients (53% STEMI). Achieved GLPS differed significantly in patients with vs without adverse cardiac remodeling (16.7±1.9 vs 21.4±1.2%, $p<0.001$). Mean carotid-femoral PWV decreased from 11.1±2.1 to 8.7±1.8 m/s, $p<0.05$. Patients without vs with GLPS normalization in 6 months after PCI were older (62.5±8.5 vs 60.6±9.9 years, $p<0.05$), more frequent male (71 vs 66.2%, $\chi2=11.1$; $p<0.05$), smokers (36.2 vs 31.2%, $\chi2=3.4$; $p<0.04$), STEMI (58.7 vs 53%, $\chi2=7.7$; $p<0.05$), had higher systolic BP (134±10 vs 130±6 mmHg, $p<0.03$), baseline PWV (11.4±1.9 vs 10.4±2.6 m/s, $p<0.03$), lower baseline EF (47.6±4.9 vs 49.6±3.5%, $p<0.05$). A significant correlation was found between decreased Δ speckle tracking and higher PWV ($r=-0.31$, $p<0.05$) and speckle tracking and LVEDV after 6 months ($r=-0.75$, $p<0.05$).

CONCLUSIONS

65 % of patients with MI treated with PCI failed to normalize GLPS after 6 months. Adverse cardiac remodeling was revealed in 72% of patients and they more often had non-recovery of left ventricular longitudinal function.Higher baseline PWV is associated with less effective recovery of LV function.

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Myocardial viability in well-developed coronary collateral circulation in late presentation myocardial infarction

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

We hypothesized that good coronary collateral circulation (CCC) may be related to myocardial viability and left ventricular ejection fraction (LVEF) in late presenter myocardial infarction (MI) patients

METHODS AND RESULTS

Ambispective multicenter longitudinal study on 107 patients with a late presentation MI and angiographic evidence of a thrombotic occlusion(TIMI 0) of a major coronary artery from 2009 to 2015.

The Rentrop and Werner score were used for the angiographic categorization of CCC. Two experienced cardiologists retrospectively evaluated the angiographies in a blinded manner to classify the CCC into grades. Patients in Rentrop grades 0-1 were classified as poor CCC, and grades 2-3 were classified as good CCC

12 patients were prospectively followed upand left ventricular(LV) wall motion score(WMS) was assessed for each of the 17 segments of the LV with a visual scoring system in which 1=normal, 2=hypokinetic, 3=akinetic, and 4=dyskinetic. WMS was performed at baseline and at 2-4 months follow-up. Scoring was carried out by two experiences cardiologist with expertise in

The median follow up was 3.4 years (interquartile range 1.2-5.7 y). 19 patients lost to follow up.

Culprit vessel revascularization was attempted in 89% of the patients(78/88) and successfully recanalized in 75%(66/88). Successful PCI of culprit vessel was not associated neither with LVEF at baseline (48±13 vs 50±11 p=0.5) nor with increase in LVEF (p>0.05) nor with WMS at baseline and at follow up (p>0.5 for both).

The Kappa indices of agreement for the classification of CCCwas good (k = 0.88; 95% CI, 0.82-1.00) and the Pearson correlation coefficient of WMS at baseline and at follow up showed an excellent interobserver concordance (r=0.99, p=0.001 and r=0.98, p=0.0001) respectively.

The LVEF at baseline was 50.1±11 and at follow up (2-4 months after the angioplasty) was 50.8±12. LVEF was significantly higher in patients with good CCC at baseline (53±8 vs 46±12, p=0.006) and at follow-up (57±11vs 44±11, p=0.01).

Qualitative assessment of culprit vessel territory motion showed significant differences between patients with poor and good CCC(p=0.019): dyskinesia(15% vs 3%); akynesia(41% vs 12%), Hipokynesia(22% vs 59%) and normokynesia(22% vs 25%) respectively.

Myocardial viability in the culprit vessel territory was confirmed in 51% of the patients (45/88%), 9% of them had akinesia and viability was assessed by a stress echocardiogram. Viability was significantly higher in good CCC patients compare to poor CCC (73% vs 30%, p<0.001).

Rentrop and Werner classification were respectively correlated to: LVEF (r=0.38, p=0.001 and r=0.32, p=0.005); WMS at baseline (r=-0.605, p0.049 and r=-0.55, p=0.07) and WMS at follow up (r=-0.66 p=0.01 and r=-0.47, p=0.11) and both classificationswere significantly higher in patients with myocardial viability: 1.77±0.9 vs 0.9±0.9 p<0.001 for Rentrop and 1±0.6 vs 0.49±0.5, p<0.001 for Werner.

Rentrop and Werner were also correlated with some parameters analyzed on follow-up EKG: Number of leads with persistent ST segment elevation(>1mm) (r=-0.78, p=0.004 and r=-0.63, p=0.03), Number of leads with Q waves (r=-0.72, p=0.01 and r=-0.57, p=0.06) and with q(<3mm) waves (r=-0.61, p=0.046 and r=-0.56, p=0.07) respectively

CONCLUSIONS

Good CCC was related to myocardial viability and LVEF in late presenter MI patients. These patients could benefit from revascularization even late in the course of a MI. A randomized trial should be encouraged

to confirm these findings.

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Angiographic and haemodynamic modifications of myocardial bridge during supine bicycle exercise

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

AIMS

The aim of this study is to evaluate the hemodynamic effect of physiological exercise during coronary angiogram with Pd/Pa, end diastolic Pd/Pa and FFR measurements in symptomatics patients with Myocardial Bridge (MB).

METHODS AND RESULTS

Methods: In our prospective monocentric study, we included all consecutive patients between July 2014 and November 2016 with angina, positive stress test or syncopy during exercise and MB without significant coronary artery disease. Coronary angiogram was performed with right radial approach and supine bicycle set on the table. A pressure wire was placed downstream the MB. Systolic compression was assessed with quantitative coronary angiography (QCA). Hemodynamic was continuously recorded during the protocol with Pd/Pa and end diastolic Pd/Pa at rest and during exercise. The exercise protocol did not use nitrates prior to exercise, it started at 50 watts and increased of 15 watts every 2 minutes. Exercise was stop after reaching 70% of maximum heart rate, hypotension or symptoms. After exercise intracoronary nitrates was used and finally intracoronary adenosine administration for FFR measurement. The aim of this study is to evaluate the hemodynamic effect of physiological exercise on angiography, Pd/Pa, end diastolic Pd/Pa and FFR.**Results:**During the study period we included 9 symptomatic male patients non smoker, non diabetic with an isolated myocardial bridge. Mean age was 57±12 years, risk factors was 11% of hypertension, 11% past history of cardiovascular familly disease and 44% of dyslipidemia. Patients reached in average 73%±10% of maximum heart rate. One patient stopped for fatigue before reaching 70% of maximum heart rate. No complication occurs during this protocol. Compression during systole significantly increases in peak exercise compare to rest respectively 78% versus 37% (p=0.003)**.** However Pd/Pa and end diastolic Pd/Pa values did not significantly changed respectively 0.90 at rest versus 0.87 at peak exercise (p=0.21) and 0.85 versus 0.82 (p=0.35). During the protocol no significant difference was observe between rest, peak exercise Pd/Pa and after nitrates (p>0.05 for all). FFR was significatively lower compared to rest, peak exercise and after nitrates (p<0.05 for all). End diastolic Pd/Pa values did not differ significantely except after nitrates and when adding adenosine compared to rest, respectively 0.78±0.05,0.77±0.05 and 0.85±0.06,p=0.038 and p=0.017). Post exercise FFR was significantly lower compared to rest Pd/Pa. Lowest values were observed with FFR with a significant decrease flow (p=0.02) while it is not the case when using end diastolic Pd/Pa (p=0.20).

CONCLUSIONS

We reported invasive hemodynamic assessment of MB during physiological exercise conditions with suppine bycicle. Myocardial bridge increase systolic compression during exercise with a preserved hemodynamic indices. Invasive hemodynamic evaluation of MB might be better assessed with FFR at rest.

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The impact of routine post-dilatation on coronary blood flow in patients with STEMI undergoing PCI

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Postdilatation (PD) with noncompliant balloons has improved stent expansion and has been associated with less restenosis in elective PCI. This study aims to evaluate the coronary flow results of PD in patients who underwent primary PCI.

METHODS AND RESULTS

A total of 118 patients (mean age 61.1±12.8 years; 87 male) with STEMI who underwent primary PCI were evaluated prospectively. According to the postdilatation procedure, patients were divided into two groups: group I (n=62; PD) and group II (n=56, no-PD). The angiographic endâ' points were preprocedural and postprocedural correct TIMI frame count (cTFC) and TIMI flow by QCA (Quantitative Coronary Angiography). Basal clinical and angiographic parameters (age, MI localization, culprit artery, pain-to-balloon time, prepocedural TIMI flow, thrombus grade) were not significant differences among the groups. However final cTFC values were significantly higher in PD group than no-PD group (37.01±23.06 and 29.29±16.6, P=0.038). Additionally, cTFC increased from 31.1±18.6 frame to 37.01±23.06 frame after PD (p=0.004). The percent of final TIMI 0-2 flow (no-reflow) were higher in PD group than no-PD group (32.2% and 16.1%, p=0.041). In the multivariable regression analysis, the PD was a significant independent predictor of the no-reflow (OR=2.665, 95% CI: 1.034-6.869, p=0.042).

CONCLUSIONS

Our study revealed that PD yields adverse effects on final coronary flow parameters in patients with STEMI who underwent primary PCI.

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The outcome of intracranial thrombectomy for acute major artery occlusion in posterior circulation

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THEME: Interventions for Stroke
TOPIC(S): Ischaemic stroke

AIMS

The efficacy of mechanical thrombectomy (MT) for acute occlusion in posterior circulation (PC) had not been established. We investigated the outcome of acute-phase MT involving PC.

METHODS AND RESULTS

We enrolled consective patients who underwent MT for acute ischemic stroke involving PC in our institution from January 2011 to August 2016. We reviewed their medical records to investigate their outcome retrospectively.

A total of 20 patients were treated with MT for acute ischemic stroke involving PC. The median age was 79.5 years and 10 patients (50%) were male. The mean initial NIHSS was 24.3 and median PC-ASPECTS (posterior circulation Alberta Stroke Program Early CT) score was 8. The occlusion sites included the vertebral artery (VA) in 2 patients, basilar artery (BA) in 16, VA and BA in 1, and posterior cerebral artery in 1.

MT for acute occlusion in PC improved their symptom (NIHSS socre decreased from 24.3 to 16.9 pts at 24 hours). Although 2 patients died, four patients (20%) showed a favorable outcome (modified Rankin Scale: mRS 0-3) at 90 days. Compared to the poor outcome patients (mRS 4-6), the good outcome patients (mRS 0-3) were significantly lower initial NIHSS (6.0 vs 28.0, p = 0.047).

CONCLUSIONS

MT may contribute reduction of the mortality and relief of symptoms among the patients with acute vertebrobasilar occlusion.

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Role of brachial access for endovascular interventions

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THEME: Peripheral Interventions
TOPIC(S): Below the knee, AAA, Iliac / Femoral / Popliteal

AIMS

To evaluate the safety and efficiency of brachial artery catheterization for diagnostic and interventional purposes. The aim is to compare the usage of radial, brachial and femoral approaches in our clinic and complication rates

METHODS AND RESULTS

Between 01/2013 and 09/2016., our team performed 11274 endovascular procedures, 847 (7,5%) of them via brachial access. For diagnostic purposes in 26 % and for interventions including angioplasty, stenting, thrombolysis, renal denervation and as an adjunctive access in 74 %. In 53 patients (6,2%) this was the only possible access for interventional treatment.

While the radial access is the most used in our clinic (70%) and constant the rate of brachial access tends to increase (from 4% to 12%) causing the femoral to decrease (from 27% to 16%) . Brachial access site–related complications occurred in 25 patients (2.9 %) 19 patients required a surgical correction, mostly for brachial artery thrombosis or pseudoaneurysm. The rate is comparable with the reported data for vascular complications in the literature.

CONCLUSIONS

Brachial artery access is safe and efficient for a variety of endovascular procedures. It expands our capability to perform complex procedures by allowing us to reach arterial targets in all territories therefore is crucial in many cases.

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Endovascular treatment of acute pulmonary embolism and pulmonary hypertension

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

AIMS

To show the effectiveness of the endovascular treatment of acute pulmonary embolism and pulmonary hypertension.

METHODS AND RESULTS

We present the data for 62 patients, treated for the period 10.2013 - 06.2015: 34 men (55%) and 28 women (45%) with massive and submassive pulmonary embolism, with an average age- 61 years (24-82).
Procedure The purpose of the catheter intervention thromb-fragmentation is the destruction of the obstructive thrombus from the main pulmonary artery and to improve the early recovery of RV function, to stabilize the hemodynamic parameters and improve survival rates. These fragmented thrombus have considerably larger contact area, which increases the effect of fibrinolytic agents, leading to the restoration of blood flow in the pulmonary artery. The success of the therapy depends on the time factor, as the best results are achieved during the first days. After 14-21 days thrombus is in the phase of organization, making it difficult to make a mechanical impact on itDose of thrombolytic– alteplase 20mg (15-25)
During the procedure in 28patients (43%) pulmonary pressure decreased over 10% compared to the pressure measured at admission. Immediately after the procedure 52 patients (81%) showed clinical improvement (reduced shortness of breath, hemodynamic stability).
In9 patients (14%) with advanced age and comorbidities (cancer, coronary and cerebral vascular disease), there was a longer recovery period and persistence of respiratory failure during hospitalization.
Follow-up: At one month no complications or bleeding were observed in our grou

CONCLUSIONS

According to our initial experience endovascular techniques are an effective and feasible option for treatment of acute pulmonary embolism and pulmonary hypertension. They could become first line of treatment for acute pulmonary embolism in centers with experienced endovascular teams. The advantages are the usage of very low doses of adjunctive thrombolytic therapy (no bleeding complications) and rapid hemodynamic improvement in patients with an acute thrombotic event.

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Comparisons of the outcomes of two DES in small vessel lesion with diabetic patients abluminal biolimus-eluting biodegradable polymer stents and zotalimus-eluting permanent polymer stents

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

AIMS

Outcomes of treatment of small vessel lesion in diabetic patients were relatively not successful, however, with the second generation biodegradable polymer DES would offer potential for better results compared with permanent polymer DES.

METHODS AND RESULTS

Methods; We sought to compare the angiographic in-stent and in-segment late losses in patients with diabetes treated abluminal biolimus-eluting bioderadable polymer stents (BES) and zotalimus-eluting permanent polymer stents (ZES). 1200 patients were enrolled in prospective, double-randomized, open-label, multicenter trial. Among them, a total of 236 diabetic patients ((167 men, 64.8±9.6 years) who needed small vessel stenting were prospectively randomized into abluminal biolimus-eluting biodegradable polymer stent (Group I, n=117) or zotarolimus-eluting permanent polymer stent (Group II, n=119). Clinical outcomes of one year were investigated in both groups and all patients underwent follow up coronary angiography (CAG).
Results; There was no difference between abluminal biolimus-eluting biodegradable polymer stent group and zotarolimus –eluting permanent polymer stent group in demographic data and baseline QCA data. In follow up CAG data, late loss of group I tends to lower than that of group II, however there was no statistical significance (0.17 ± 0.33 mm vs. 0.28 ± 0.37mm, p=0.087). There was no in-stent restenosis and major adverse cardiac events (MACE) in both groups.

CONCLUSIONS

Both second generation DESs showed improved outcome in treating small vessel disease in diabetic patients. The safety and efficacy of abluminal biolimus-eluting biodegradable polymer stents were not inferior to those of zotarolimus-eluting permanent polymer stents. Although there was no statistical significance between the two groups, the late loss of abluminal biolimus-eluting biodegradable polymer stent tend to lower than that of zotarolimus-eluting permanent polymer stent in diabetic patients with stent diameter of less than 2.75 mm.

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Elevated lipoprotein(a) is associated with worse prognosis in diabetic patients with symptomatic coronary artery disease

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Along with type 2 diabetes, elevated Lipoprotein(a) is also known as a surrogate biomarker for cardiovascular disease. However, recent studies have demonstrated that Lp(a) level was lower in type 2 diabetic patients than in non-diabetic patients.

METHODS AND RESULTS

We sought to evaluate if elevated Lp(a) is associated with worse prognosis in diabetic patients with coronary artery disease (CAD).

Methods:1494 diabetic patients (62.3% male, mean age 63.5±10.3 years) with CAD were enrolled from 2002 to 2012 at Gangnam Severance Hospital. CAD was diagnosed by invasive coronary angiography. Laboratory values for lipid parameters including Lp(a) were obtained at the day of coronary angiography and analyses were done shortly after sampling. Patients were divided into tertile groups according to their Lp(a) levels. Baseline risk factors, coronary angiographic findings, length of follow-up, and major adverse cardiovascular event (MACE) including cardiac death and non-fatal myocardial infarction(MI) were recorded.

Results: Over a mean follow-up period of 4.4±2.6 years, there were 59 MACEs (35 cardiac death and 24 non-fatal MI) with an event rate of 3.9%. Elevated Lp(a) was a significant predictor of MACE on univariate and multivariate Cox proportional survival analysis [HR 3.869 (95% CI 1.855-8.067, $p<0.0001$) and HR 2.890 (95% CI 1.373-6.084, $p=0.005$)]. Kaplan-Meier survival analysis revealed that elevated Lp(a) was associated with worse prognosis ($p<0.0001$). Furthermore, survival probability plot according to Lp(a) tertiles after adjustment of age, gender, hypertension, hyperlipidemia, smoking habitus, and extent of CAD revealed that elevated Lp(a) was associated with worse prognosis ($p<0.0001$).

CONCLUSIONS

Conclusions: Elevated Lp(a) is associated with worse prognosis in diabetic patients with coronary artery disease.

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Impact of gender differences on the clinical outcomes of patients treated with bioresorbable polymer DES

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

AIMS

The influence of gender on clinical outcomes after percutaneous coronary intervention has been long debatable. Our aim was to assess gender-based outcomes in patients treated with the sirolimus eluting stent with biodegradable polymer.

METHODS AND RESULTS

eUltimaster is a prospective,single-arm, multi-centre registry. Among the 4597 patients enrolled at 244 sites in 37 countries that have reached 1-year follow-up, majority of patients were male (3483 patients; 75.8%). The primary endpoint is Target Lesion Failure (TLF) defined as a composite of cardiac death, target vessel related myocardial infarction (MI) and clinicallydriven target lesion revascularization (TLR) at 1 year. All serious adverse events related to the endpoints were independently adjudicated by the clinical events committee. The mean age of patients was higher in females (64.2 vs. 68.8 ; p< 0.00001), accounting for 18.0 % of the octogenarians with significant difference when compared to males. At baseline, female patients had significantly higher rates of diabetes mellitus (male vs. female, 25.8% vs. 29.6%; p= 0.01) and hypertension (60.6% vs. 69.7%; p <0.001). Lower rates of smoking (25.0% vs. 20.5%; p= 0.004) and history of previous coronary therapy (26.9% vs. 19.8%; p <0.001) were noted in females compared to males. Multi-vessel disease was more frequent in males (48.8% vs 43.4%; p=0.002), while small vessels (<=2.75mm) were more prevalent in female patients (43.5% and 48.5%; p=0.004). Lesion classification; CTO, bifurcation and left main tract lesions were similarly observed in both groups. The number of treated lesions was lower in female (1.5 male vs. 1.4 female; p=0.0001), however, the number of implanted stent was similar in both groups. (1.1 vs.1.1; p=1.0). There were no significant differences in access site between both groups.

At 1 year, there were no significant differences in TLF (2.3% vs 2.4%; p= 0.8) and likewise in clinically driven TLR (1.2% vs. 1.1%; p=0.9) in the male and female groups respectively. Both, male and female patients, respectively had similar rate of cardiac death (0.8% vs. 1.0%, p=0.6), target vessel related MI (0.8% vs. 0.9%; p=0.6), and stent thrombosis (0.9% vs. 0.6%; p=0.6). Furthermore, composite endpoint of cardiac death and MI, patient oriented endpoint defined as any cause of mortality, MI or any TVR showed no significant difference between males and females (2.0% vs.1.8%; p=0.8 and 4.1% vs. 4.0%; p=1.0, respectively).

However, females had statistically significant higher incidence of minor bleeding (0.1% vs. 0.5%; p=0.02) and composite vascular complications (0.9% vs. 3.1%; p<0.0001) at discharge. This difference in bleeding and vascular complications was maintained at 1 year (1.0 % vs. 3.2%; p<0.0001) despite the similar dual antiplatelet therapy (1 year DAPT, 68.3% vs. 64.7%; p=0.05).

CONCLUSIONS

Although there were gender differences in cardiovascular profiles and lesion characteristic, 1-year results of this sub-study are promising and rather similar between male and female patients. This indicates that the newer generation of drug eluting stents, such as Ultimaster, might be a good treatment option for both genders.

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Procedural impact of kissing-balloon technique before stenting in patients with complex bifurcations

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

AIMS

To assess the impact of kissing balloon technique performed before main vessel (MV) stenting in patients with complex bifurcation lesions undergoing percutaneous coronary intervention (PCI).

METHODS AND RESULTS

Consecutive patients underwent PCI on bifurcated lesions at our centre during 5 years were retrospectively identified. Clinical and procedural data have been prospectively recorded into a dedicated database. Provisional approach with eventual side-branch (SB) stenting according TAP was the routinely adopted.
A total of 483 patients underwent PCI on true bifurcation lesions (Medina 1.1.1, Medina 1.0.1, Medina 0.1.1) with the use of drug-eluting stent (DES) were included in the study. Bifurcation-management procedural aspects (like failure to rewire or dilate the SB) were systematically assessed.
Patients were stratified according to the modality of lesion preparation in two groups: 1. PRE-KISSING (predilation with kissing technique using undersized balloons) and 2. CONTROLS (predilation of MV and/or SB). To adjust for possible confounders, propensity-matched comparison was performed.
Primary study end-point was angiographic success (successful MV stenting and TIMI 3 in both MV and SB at the end of the procedure).
A total of 61 PRE-KISSING patients were compared with 122 (2:1) propensity-matched CONTROLS. Clinical and main angiographic variables were equally distributed. When assessing procedural data, PRE-KISSING patients had significantly better angiographic success (93.4 % vs. 83.6% in CONTROLS, P=0.047) and significantly lower failure to rewire the SB after the MV stenting (0% vs 7.3% in CONTROLS, P= 0.023).
After a mean follow-up of 19 months, target lesion failure occurred in 6% of the whole study population and did differed significantly between PRE-KISS and CONTROLS (P=0.3).

CONCLUSIONS

The kissing balloon technique before main vessel stenting is feasible and may facilitate bifurcation PCI interventions in patients with complex, true, bifurcated lesions undergoing provisional stenting strategy.

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Rotational atherectomy during TAVI. A single-centre experience

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

AIMS

No information is available regarding this specific use of rotation atherectomy (RA) during TAVI, and whether it should be performed before, during or after the valve implantation.To report about feasibility and safety of RA performed during TAVI.

METHODS AND RESULTS

RA was systematically performed in a consecutive series of TAVI patients after the implantation of the valve between 2010-2016. Immediate and long-term clinical outcome were monitored prospectively.Aconcomitant CAD (coronary stenosis visually >50%) was observed in 123/287 patients (43%). Mean Logistic EuroSCORE of these patients was 31±24%. Angioplasty was performed in 81 patients (28%) and 12 (4%) were treated with RA in 13 coronary arteries after TAVI, 6 after implantation of a balloon expandable trans-catheter valve, and 6 after a self-expandable valve. All procedures were successful and had no immediate complications. Troponin rise was observed in all cases, one patient had CK-MB rise 3 times uln, and 2 patients needed transient dialysis. At a mean follow-up of 29 months (range 4-48 months) all patients except one are alive and improved their renal function compared to baseline. The only death was due to neoplasia. One patient had recurrence of angina due to an occlusive intra-stent restenosis.

CONCLUSIONS

RA is feasible and safe when performed during the same TAVI procedure after the implantation of either, a self-expandable, or a balloon expandable trans-catheter valve.

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The long-term impact of acute kidney injury on renal function after coronary angiography and interventions. Data from 1,020 all-comer patients

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

AIMS

The aim of the study was to investigate the incidence of contrast-induced acute kidney injury in an unselected population of patients undergoing invasive coronary proceduresits predictors, and the impact on renal function at mid and long-term.

METHODS AND RESULTS

Complete clinical and biochemical data of 1020 all-comers patients were collected and analysed in hospital, at mid-term and at long-term. Logistic regression was used tofind variables associated with CI-AKI and with renal function impairment at follow up. ROC analysis was used to test the diagnostic accuracy of early serum creatinine (SCr) shift in predicting renal damage. CI-AKI occurred in 130/1020 patients (12.7%). At mid-term a “persistent” CI-renal damage occurred in 40 out of 130 (30.7%) patients who developed CI-AKI, and nearly half of them (18/40,45%) developed a permanent long-term renal function impairment (eGFR reduction≥25% at 14.4±7.8 months). The strongest independent predictor of CI-AKI was an early (12-24h) slight (5%) SCr Δ% compared to baseline (OR=1.05,CI:1.04-1.06, p<0.001). The SCr Δ%12-24h index predicted also the persistent (OR=1.03,CI:1.02-1.04, p<0.001) and the permanent renal damage(OR=1.02,CI:1.008-1.031, p=0.001).

CONCLUSIONS

CI-AKI may not be just a SCr elevation detected as laboratory finding, but the cause of severe and permanent renal damage at long-term. A Slight (5-10%) and early (12-24h) percentage increments of SCafter contrast administration, compared to baseline, might unmask a group of patients at risk for permanent renal damage that may benefit from new, specific, yet unknown, therapeutic measures.

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One-year clinical outcome of biodegradable polymer sirolimus-eluting stent in all-comer population of ULISSE registry (ULtimaster Italian multicentre all-comerS Stent rEgistry)

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI, Stable CAD, Stents and scaffolds, Left main and multivessel disease, Bifurcation lesion, CTO

AIMS

Delayed re-endothelialisation and inhibition of vascular repair after DES implantation, in part related to permanent polymers, are considered important part of target vessel failure (TVF) and stent thrombosis (ST) pathophysiology during follow-up.

METHODS AND RESULTS

The ULISSE study is a multicentre-independent, single-arm, all-comers, observational registry designed to assess safety and efficacy after biodegradable-polymer sirolimus-eluting stent (BP-SES) at 7 different centres in Italy. 918 consecutive patients (1310 lesions) treated with BP-SES between July 2014 and August 2016 were retrospectively enrolled. The primary and secondary endpoints were target vessel failure (TVF) and target lesion revascularization (TLR) at 1-year, respectively.

399 (43.5%) patients were treated for at least one complex lesion (chronic total occlusion 7.3%, bifurcation 23.5%, very long lesion (>35 mm) 23.6%, unprotected left-main 3.3%) and most of them (52.3%) presented a high-risk clinical profile (diabetes mellitus 30.4%, chronic kidney disease 9.25%, previous CABG 14.2%, low LVEF (<35%) 4.7%, STEMI as clinical presentation 10.2%). At 1-year follow-up, TVF occurred in 47 (6.0 %) patients: cardiac death 2.2%, target vessel–related myocardial infarction 1.0% and target vessel revascularization 4.07%. TLR occurred in 25 (3.2%) patients. Definite and definite/probable ST rates were 0.89% and 1.27%, respectively.

CONCLUSIONS

This study provides preliminary evidence for mid-term safety and efficacy of biodegradable-polymer sirolimus-eluting stent in all-comers daily practice cohort of Italian patients, including complex lesions.

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Radial artery access for primary PCI is associated with improved clinical outcomes compared to femoral artery access

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

To investigate the association of arterial access site with clinical outcomes following primary percutaneous coronary intervention (primary PCI) for ST-segment elevation myocardial infarction (STEMI) in a large consecutive patient-series.

METHODS AND RESULTS

Demographic, clinical, and 30-day follow-up data for all patients undergoing primary PCI for STEMI between 1-1-2009 and 31-12-2011, and 1-1-2013 and 31-12-2013 in a high-volume 24/7 UK PPCI centre, were collected prospectively. All arterial access sites were recorded. Cross-overs were analysed by initial arterial access site. Patients presenting with cardiogenic shock and/or cardiac arrest were excluded. Clinical endpoints were 30-day major adverse cardiovascular events (MACE – composite of total mortality, MI and repeat coronary revascularization), total mortality and major bleeding. Multivariable analysis was performed with Cox proportional hazards models adjusting for major confounding factors.4056 patients underwent primary PCI during this period (464 excluded due to cardiogenic shock and/or cardiac arrest). Data for 30-day bleeding and MACE were available for 3381 (94.2%) patients. 111 patients crossed over from radial to femoral access, and 102 patients crossed over from femoral to radial access. Transradial(n=2389; 70.7%) primary PCI was associated with reduced 30-day MACE (3.2% vs 9.5%; adjusted HR 0.53 (0.38-0.73)), mortality (1.8% vs 6.6%; adjusted HR 0.51 (0.34-0.77)) and major bleeding (2.5% vs 9.0%; adjusted HR 0.52 (0.36-0.75)) compared to transfemoral (n= 992; 29.3%) primary PCI.

CONCLUSIONS

In this large consecutive real-world series, transradial primary PCI was associated with lower probability of major bleeding, MACE and mortality at 30 days compared to transfemoral primary PCI after multivariable analysis.

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Improvement of quality of life following TAVI in the elderly: a multicentre study based on the Polish national TAVI registry

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

AIMS

The aim of the study was to evaluate short-term changes in elderly people's quality of life following TAVI, based on the POL-TAVI registry.

METHODS AND RESULTS

One hundred and eighty-four octogenarians' and nonagenarians' samples from the POL-TAVI database were included in the study. The quality of life status was assessed with EQ-5D-3L questionnaire at baseline and after one-month follow-up. The mean of patients' age was 84 (80–93) years. Logistic EuroSCORE mean was 19.83% (3.48–83.94%), and transaortic mean gradient was 54.99 (19.0–149.0) mm Hg. At baseline, up to 24.50% of patients declared severe problems in performing usual activities. 13.60% felt extreme pain or discomfort; 9.80% were unable to wash and dress by themselves; 8.20% were extremely anxious or depressed; and 7.10% of the patients in the study were confined to bed. After 30 days the percentage of patients declaring severe problems in each dimension did not exceed 4.00%. The comparison between quality of life data at baseline and after one-month follow-up showed a significant improvement in each of five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression ($p < 0.001$). Patients' quality of life was increasing regardless of gender (female vs. male), the type of anaesthesia (general vs. local), and the type of procedure (TA vs. TF).

CONCLUSIONS

Short-term quality of life in the elderly subjects was significantly improved after one-month follow-up following TAVI.

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Effect of renal function on clinical outcomes in patients undergoing TAVI

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

AIMS

To investigate the association between baseline renal function and clinical outcomes during early and late follow-up among patients undergoing transcatheter aortic valve implantation (TAVI).

METHODS AND RESULTS

Between August 2007 and April 2015, 927 consecutive patients were included into a prospective registry and classified on the basis of the baseline estimated glomerular filtration rate (eGFR) as no or mild (stage 1 and 2 - eGFR ≥ 60 mL/min/1.73m2) (n= 284, 30.6%); moderate (stage 3 - eGFR between 30 and 59 mL/min/1.73m2) (n= 535, 57.7%), and severe (stage 4 and 5 - eGFR <30 mL/min/1.73m2) (n= 108, 11.7%) renal dysfunction.
We observed an inverse relationship between increasing risk profile and stage of renal dysfunction with higher STS score, lower left ventricular ejection fraction, and higher rates of comorbidities among patients with eGFR<30 (all p<0.001 across groups). In patients with none or mild, moderate, and severe renal dysfunction the rate of all-cause mortality was 1.8%, 5.2% and 8.3%, respectively at 30-day follow-up and 11.0%, 15.0% and 19.5%, respectively at 1-year follow-up. After adjusting for relevant confounders, severe renal dysfunction (eGFR<30 mL/min/1.73m^2) was associated with an increased risk of cardiovascular death (adjusted hazard ratio, $HR_{adj,}$ 3.90, 95% Confidence Intervals, CI, 1.15-13.19, p= 0.02) and stage 3 acute kidney injury (HR_{adj} 5.15, 95% CI 1.72-15.48, p= 0.003) at 30-day follow-up, whereas no significant association was observed with clinical outcomes at 1-year.

CONCLUSIONS

Renal dysfunction at baseline was associated with a higher risk of cardiovascular mortality at 30 days but not at 1-year follow-up. These findings suggest that pre-procedural renal dysfunction affects early clinical outcomes, however the magnitude of this association is diminished over time by the overriding effect of the underlying patient risk and comorbidities.

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Impact of lesion length on clinical outcomes after implantation of a novel newer generation sirolimus-eluting stent in real-world patients

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

AIMS

We aim to understand the clinical safety and efficacy of ABLUMINUS DES+ sirolimus-eluting stent (Envision Scientific Pvt. Ltd., Surat, India) in the patients with lesions beyond 35 mm.

METHODS AND RESULTS

We compared the clinical outcomes of patients with lesion length ≥28 mm and ≤ 35mm (group A) and patients with lesion length >35 mm (group B) with one year clinical follow-up. In this Prospective, multicentre -registry, we studied 1097 patients with long lesion: 444 patients were with lesion length ≥28 mm and ≤ 35mm and 592 patients with lesion length >35 mm. The main outcomes were major adverse cardiovascular events (MACE) defined as a composite of cardiac death, target vessel myocardial infarction (TV-MI), and target lesion/vessel revascularization (TLR/TVR).

Total Population of the study was pre-dominated by male patients in both groups (79.28 % vs. 79.90 %, p=0.806). A high proportion of patients were diabetic in both groups (36.94 % vs. 38.51, p=0.605). Acute Coronary Syndrome also accounted for almost half of the population in both the groups (66.44 % vs. 60.81%, p=0.063). The mean lesion length for group A was 29.86 ± 1.99 mm. While in group B the mean lesion length was 43.91 ± 11.94 mm.

One year clinical follow-up was available for 77.70% and 81.25% patients in both groups respectively. At one year, the cumulative incidence of MACE were 1.74% in group A vs. 4.16% in group B, p=0.50. On the other hand, the one year rate of definite or probable ST increased with greater lesion complexity after ABLUMINUS DES+ implantation (group A 0.29% Vs. group B 1.46%; P=0.149).There were no significant differences in MACE and ST between the groups.

CONCLUSIONS

Clinical results among patients with Long lesion were not significantly different from those among patients with very long lesion which support the safety and efficacy of the ABLUMINUS DES+ in patients with complex coronary lesions.

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Appropriateness of CABG based on FFR lesions assessment

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Some studies reported that CABG on lesions with normal FFR arteries might result in early graft failure. Therefore, we aim to evaluate the appropriateness of CABG implantation by cardiac surgeons based on FFR evaluation of coronary lesions.

METHODS AND RESULTS

All patients having FFR evaluation of coronary lesion referred for CABG were screened between January 2013 and December 2014. Coronary lesions assessed by FFR were classified in two groups: Appropriate CABG or Inappropriate CABG. Inappropriateness was defined as negative FFR resulting in CABG or positive FFR without CABG.

FFR assessment was performed on 108 stenosis in 83 patients referred for CABG surgery. The mean age was 65 ±10 years. Patients were males in 74%, hypertensive 70% and diabetics in 44%. The clinical presentation was Non ST-Elevation Myocardial Infarction in 31% and stable angina in 34% of cases.Total number of CABG 78 (72%) and Inappropriate CABG was recorded in 16%. The inappropriate CABG was more frequent on lesions with negative FFR as compared to lesion with positive FFR (50% vs. 4% respectively; p<0,0001) and more frequent in LCx and RCA teritorries (40% and 50% respectively) as compred to the LAD territory (10% (p <0,01 for both)). Lesions with inappropriate CABG and negative FFR had a trend to be more severe as compared to ungrafted lesions (52% vs 47% respectively; p=0,08).

CONCLUSIONS

To our knowledge this is the first report addressing the integration of FFR results by cardiac surgeons in patients referred for CABG surgery. Inappropriate CABG occurred mainly in patients with negative FFR. The impact on adverse clinical events needs to be assessed in large clinical trials.

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Outomes following closure device usage in patients referred for transfemoral coronary angiogram in the real life

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI, Stable CAD, Left main and multivessel disease, Bifurcation lesion, CTO

AIMS

The impact of closure device (CD) to reduce vascular complications in patients referred for transfermoral coronary angiogram remains controversial. Our aim is to determine the incidence of CD usage and related vascular complication.

METHODS AND RESULTS

From January to December 2013, 362 patients had a transfemoral coronary angiogram. Data was retrospectively collected from medical files. Mean age was 68±11 years and mean body mass index was 28±6. Patients were women in 38% of cases, 291 had hypertension (80%), 161 had diabetes (44%), 99 had chronic renal failure (CRF) (27%), 86 had peripheral vascular disease (24%) and 121 had had a previous CABG (33%). The most common Indications were acute coronary syndrome in 175 patients (48%) and stable angina in 107 patients (30%). Femoral angiogram was performed in 267 patients (82%). Vascular CD was used in 286 patients (79%). Manual compression was more performed in patients wit peripheral vascular disease as compared to patients who had a CD (42% vs.19% respectively, p<0.001. The rate of vascular related complications was noted in 40 patients (11%). Local bleeding was the most common complication reported in 10 patients. However, TIMI major bleeding was noted in 12 patients (3%) during the index hospitalization. No significant difference was noted in the rate of vascular complications between the group of patients who had a CD or not 8% vs. 3% respectively, p=0.156). A multivariate analysis was performed and showed that vascular complication rate was higher in patients with CRF (OR=4.6; p=0.031) and patients who were referred for urgent coronary angiogram (OR=7.1; p=0.007).

CONCLUSIONS

In this real life cohort of patients referred for transfemoral coronary angiogram the rate of vascular complications was related to patients risk profile and was not reduced by the usage of CD as compared to manual compression.

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Indications and outcomes of new permanent pacing in patients with aortic stenosis treated with TAVI with a new-generation self-expanding valve

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

AIMS

In this study we aimed to explore the incidence and indications for permanent pacemaker implantation after a new generation self-expanding TAVI. Furthermore we explored whether new permanent pacemaker implantation impacts on survival.

METHODS AND RESULTS

From February 2013-November 2016 a total of 258 TAVI were performed using the Evolut R self-expanding valve. Mean age was 82.1±6.5 years and 145 (56.2%) were females. Mean logistic Euroscore was 13.9±7.8. Twenty three patients (8.9%) had pre-existing pacemaker, whereas 58 (22.5%) patients required a new permanent pacemaker. Complete heart block was the most frequent indication for pacing 39 (15.1%) followed by slow atrial fibrillation or sinus rhythm with significant pauses, 11 (4.3%). Only one case had Mobitz type II whereas 7 (2.7%) had LBBB with prolonging PR interval. The median time from TAVI procedure to permanent pacemaker implantation was 1 (1 to 5.2 days). In more than half of cases (55.2%), the permanent pacemaker was implanted within the first 48h post procedure. After age and gender adjustment, there was no significant difference in all cause mortality in patients with new permanent pacemaker compared to those without; hazard ratio 0.94; 95% confidence interval 0.56 to 1.60, p=0.824.

CONCLUSIONS

Despite advances in TAVI leading to reduction in vascular complications and paravalvular leak, post-procedural permanent pacemaker implantation rates remain high at ~20% when using a new generation self-expanding transcatheter valve. The main indication for permanent pacemaker was complete heart block followed by sinus pauses or slow atrial fibrillation. No survival disadvantage was observed in patients with new permanent pacemaker implants.

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Portico TAVI via distal axillary artery

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

AIMS

Retrograde trans-femoral approach should be considered the less invasive approach for trans-catheter aortic valve implantation (TAVI), however some patients are affected also by severe iliac-femoral arteriopathy.

METHODS AND RESULTS

Therefore, alternative access site for TAVI delivery have been developed, we describe our initial experience with the implantation of Portico™ TAVI system (St Jude Medical, St Paul, MN, USA) made through distal axillary artery. The Portico valve system consists of a nitinol self-expanding frame with a tricuspid bovine pericardium valve and a sealing cuff out of porcine pericardium. The delivery catheter has a soft tapered nose cone followed by a capsule, that contains the compressed valve, with an outer diameter of 18-F for 23 and 25mm valve and 19F for 27mm and 29mm prosthesis. Delivery system shaft is 12-F outer-diameter. Portico system is repositionable and recapturable. Seven consecutive patients (mean age 84 years) affected by severe symptomatic aortic stenosis (mean gradient 45 mmHg, mean Left ventricle EF 49%), and concomitant peripheral vasculopathy, underwent TAVI with a Portico valve via distal axillary artery, at our Hospital, between May and December 2016. All the patients underwent our standard screening process, including transthoracic echocardiography, coronary angiogram and ECG-gated multislice computer tomography (MSCT) for pre-procedural planning; all patients were considered high-risk for surgery candidates (mean STS mortality 14.5%) by our multidisciplinary heart team and gave informed consent to TAVI. All procedures were performed, under local anesthesia and conscious sedation, in a hybrid OR. Mean axillary diameter at MSCT was 6.5 mm. Three patients had prior permanent pace-maker implanted. Two patients were on chronic hemodialysis. Advancement of the Portico delivery system and valve delivery and deployment was successful in all cases. In two patients a combined percutaneous coronary intervention procedure was performed. Mean procedural time was 85 minutes (range 60-140 min), and mean contrast media used 90 cc. Device success was obtained in all patient, final hemodynamic evaluation revealed mean peak-to-peak gradient of 6 mmHg. Final aortography evidenced normal valve function, with none or trace para-valvular regurgitation in all patients. All patients had an uneventful hospital course, no major complications occurred. Four patients underwent blood transfusion but no bleeding complications were evident. Mean post-operative hospital stay was 9 days, all patients have been discharged with normal surgical wound. Pre-discharged echocardiography showed, in all patients, normal aortic valve function with mean gradient of 10 mmHg, and no para-valvular regurgitation in four patients and mild in three. Thirty-day survival was 100%, no stroke occurred; overall early safety outcome at 30 days was reached in all seven patients.

CONCLUSIONS

Our experience characterized by a heart team approach and multidisciplinary patient care demonstrated the safety and feasibility of Portico implantation through distal axillary artery. Distal axillary should represent a new attractive access site for TAVI.

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Treatment of SVG lesions with a thin strut design DES with bioresorbable polymer - One-year results from a large registry

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

AIMS

Treatment of the SVG remains a significant challenge in terms of maintaining long-term patency in patients with previous CABG. Our aim was to assess clinical outcomes of patients with disease in SVG treated with Ultimaster DES.

METHODS AND RESULTS

eUltimaster is a prospective,single-arm, multi-centre registry and 4597 of enrolled patients have reached 1-year follow-up. The primary outcome measure was Target Lesion Failure (TLF) defined as a composite of cardiacdeath, target vessel related myocardial infarction (MI) and clinicallydriven target lesion revascularization (TLR) at 1year. All the serious adverse events related to the endpoints were independently adjudicated by the clinical events committee. Among the 4597 patients, 63 patients (1.4%) underwent SVG PCI using Ultimaster DES and were included in a pre-specified subset. The patients in SVG group were older with more octogenarians compared to the non-SVG group (SVG vs. non-SVG, 71.8 vs. 65.2; p<0.00001, 19.1% vs. 10.5%; p=0.04, respectively) and the majority were male patients (90.5% vs. 75.6%; p=0.005).

When compared with the non-SVG group, the SVG group had significantly higher rates of diabetes (42.9% vs. 26.5%; p=0.006) and renal impairment (15.9% vs. 6.9%; p=0.01). Stable angina was treated more often in the SVG group (47.6% vs. 35.2%; p=0.046) while the incidence of ACS and STEMI at presentation was significantly higher in the non-SVG (46.0% vs. 59.3%; p=0.04, 9.5% vs. 23.1%; p=0.01) respectively.

Lesion complexity was similar between the two groups. However, ostial lesion and DES in-stent restenosis were treated more often in the SVG group (13.3% vs. 6.5%; p=0.02 and 11.1% vs. 3.3%; p=0.005) respectively.

At 1 year, there was no significant difference in TLF between the SVG group and the non-SVG (1.6 % vs 2.4%; p=1.0) and similarly in clinically driven TLR (1.6 % vs. 1.2 %; p= 0.5). Both groups showed similar rates of all-cause death (0% vs. 1.5%; p=1.0), cardiac death (0% vs. 0.9%; p=1.0), any MI (1.6% vs. 1.2%; p=0.5),target vessel related MI (0% vs. 0.8%; p=1.0), and ST (0% vs. 0.8%; p=1.0) in SVG and non-SVG groups, respectively.

Additionally, there were no differences in composite endpoint of cardiac death and MI, patient oriented endpoint defined as any cause of mortality, MI or any TVR between the SVG and the non-SVG patients at 1 year (1.6% vs. 1.9%; p=1.0 and 4.8% vs.4.1%; p=0.7) respectively.

At 1 year, target vessel failurerate (TVF), defined as target vessel revascularization, target vessel related Q-wave or nonQ- wave MI,or cardiac death that could not be clearly attributed to a vessel other than the target vessel, was similarly noted in both groups (3.2% vs. 2.7%;p=0.7).

CONCLUSIONS

Our data confirmed sustained clinical benefit in patients with SVG disease when treated with Ultimaster DES. Although number of patients is relatively small, absence of cardiac death, target vessel related MI and stent thrombosis in this complex patient subset is promising. The enrolment and follow-up of patients is currently ongoing and further data will be available at EuroPCR2017.

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Syntax score 2 in patients with coronary artery disease undergoing percutaneous mitral repair with the MitraClip

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair, Other valvular and structural interventions

AIMS

We sought to evaluate the prognostic value of the SYNTAX II score (SSII) in patients with concomitant coronary artery disease (CAD) undergoing a Mitraclip procedure.

METHODS AND RESULTS

In seventy-five consecutive patients who underwent PMVR at the University Heart Center Zürich and the Cardiocentro Ticino, the Syntax score II(SXSII) was calculated at baseline. Clinical endpoints comprised of all-cause mortality, mitral valve surgery due to failure of PMVR or reoperation, hospitalization for congestive heart failure, heart transplantation and the composite of all four endpoints.Patients were followed for a median of 271 days. and were divided in tertiles of SXSII: SXSII low ≤ 46.5 (n=25), SXSII mid 46.6 - 54.4 (n=25) and SXSII high ≥ 54.5 (n=25). Patients in the highest SXSII tertile had a lower left ventricular ejection fraction (33% vs. 40% vs. 53%) with a higher log-BNP (3.6 vs. 3.45 vs. 3.16) when compared to SXSII mid and SXSII low, respectively. However, the anatomical syntax score (SXS) did not differ significantly within the tertiles (9.1±6.3 (SXSII Low) vs 9.5±7.6 (SXSII Mid) vs 10.2±6.7(SXSII High), p=0.837). The primary endpoint occurred in 33% of patients (n=25). By multivariate analysis patients in the high SXSII tertile (OR=6.12, 95% confidence interval, [CI] 1.45-25.86, p=0.014) and patients with a history of MI (OR=3.57, 95% confidence interval, [CI] 1.17-10.88, p=0.025) were at significantly higher risk of experiencing adverse events. Furthermore, in a combined outcome ROC curve analysis, the SXSII showed good discrimination with an AUC of 0.73, p=0.001. A cutoff SSII >49 has been identified to have a sensitivity of 83% and specificity of 53% with approximately 45% of the patients experiencing an event during follow-up.

CONCLUSIONS

Using syntax score II in CAD patients undergoing PMVR is feasible and of prognostic significance hence widening its clinical utility in valvular heart disease.

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Invasive assessment of vascular stiffness as predictor for response to renal denervation in isolated systolic hypertension

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THEME: Interventions for Hypertension
TOPIC(S): Renal denervation

AIMS

To evaluate the additional predictive value of invasive pulse wave velocity (iPWV) for response to RD in patients with combined versus isolated systolic hypertension (ISH)

METHODS AND RESULTS

Patients scheduled for RDN underwent additional invasive measurement of iPWV and invasive pulse pressure (iPP) before denervation. Blood pressure (BP) was assessed via ambulatory measurement at baseline and after 3 months. One-hundred-nine patients (40 patients with ISH) were included into our analysis. After 3 months, BP reduction was more pronounced among patients with combined hypertension (CH) as compared to patients with ISH (systolic 24 h average 9.3±10.5 vs. 5.0±11.5 mmHg, p = 0.046). However, when stratifying patients with ISH by iPWV, patients in the lower tertile of iPWV had an even more pronounced BP reduction compared to the other tertiles (12.1±12.6 mmHg vs. -1.5±6.7 and -1.5±11.9 mmHg, p=0.006), despite a numerically higher iPP (95.9±18.4 vs. 87.6±21.6 mmHg, post-hoc$p$ = 0.20) and a lower systolic BP (141.2±8.1 vs. 154.8±12.5 mmHg, post hoc$p$ <0.001) than patients with combined hypertension. Responder rates (defined as daytime BP drop of ≥5 mmHg after 3 Months) were 75% for patients with CH and 50% in patients with ISH (p = 0.007). Among iPWV tertiles, rates were 77 vs. 50 vs. 23% (p = 0.001).

CONCLUSIONS

Among patients with ISH, low iPWV and therefore a lower degree of arterial stiffening indicates a subgroup of ISH patients which might benefit from RDN. Consequently, ISH might not generally be considered as an exclusion criterion for an interventional treatment of arterial hypertension.

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Pathophysiology and haemodynamics of iatrogenic arterial septal defect closure after MitraClip implantation - A pressure volume loop study

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair, Other valvular and structural interventions

AIMS

To assess the potential clinical and physiological consequences of iatrogenic atrial septal defects (iASD) following MitraClip™-implantation by aquisition of pressure-volume-loops during iASD balloon occlusion.

METHODS AND RESULTS

In 9 patients with relevant left-to-right shunting across the iASD (defined as Qp:Qs on echocardiography > 1.3), interventional iASD closure 42±9 days after MitraClip™-implantation was performed with concomitant recordings of pressure-volume loops (PVL) using conductance catheters during the intervention. PVL were recorded in the right (RV) and left ventricle (LV) before and after iASD balloon occlusion. We observed a shift from right ventricular (pre vs post: 109±29 vs 98±23 ml/$m^{2)}$, p=0.004) to left ventricular end-diastolic volume (pre vs post: 96±24 vs 104±23 ml/m^2, p=0.018) without significant changes in RV (pre vs post: 40±10 vs. 41±7 %, p=0.668) or LV ejection fraction (pre vs post: 35±16 vs 38±16 %, p=0.2). Importantly, increase in LV end-diastolic volume did not result in an increase in LV end-diastolic pressures (pre vs post: 25±11 vs. 27±8 mmHg, p=0.21) at maintained end-diastolic pressure-volume relationships (0.148±0.210 vs. 0.156±0.202 mmHg/ml; p=0.36). Likewise, iASD-closure did not increase wedge (17.0±8.0 vs 16.7±9.8 mmHg, p=0.89) or RV end-systolic pressures (42±14 vs. 45±12 mmHg; 0.09mmHg) significantly. iASD closure was associated with clinical improvement within days (NYHA class I-II pre 11% vs. post 44%, p=0.04).

CONCLUSIONS

Interventional closure of iASD after MitraClip™-implantation leads to a volume shift from the RV to the LV with no evidence for increased LV filling pressure or postcapillary pulmonary pressure rise. PVL assessment in such a setting could help to select those patients benefiting the most from iASD closure without the risk of increasing PA pressures.

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Ischaemic events after PCI in stable coronary artery disease according to high-platelet reactivity and inflammations factors

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

AIMS

to reveal factors associated with high platelet reactivity (HPR) and to determine the prognostic value of HPR and other factors in stable coronary artery disease (SCAD) patients undergoing percutaneous coronary intervention (PCI) with DES

METHODS AND RESULTS

Methods: In our single-centre prospective study 94 SCAD patients were included (mean age 59±9,67 year). All patients underwent elective PCI with DES implantation during dual antiplatelet therapy (DAPT) (aspirin and clopidogrel). The platelet reactivity were assessed using light transmission aggregometry with 5 μmol/L ADP (LTA 5ADP) and method VerifyNow® before PCI. All patients underwent genotyping to detect CYP2C19 polymorphism. In 74 patients were determined baseline levels of high-sensitivity C-reactive protein (hsCPR), sP-selectin, sCD40L, hs-IL-6, PAI-1 levels and von Willebrand factor activity. Mean follow-up was 28,2 ± 15,5 months.Results: Among study population the incidence of HPR according to LTA-5ADP was 16% and VerifyNow – 24,5%. According univariate regression analysis showed significant influence on HPR according to LTA-ADP had a body mass index (p=0.02), total cholesterol (p=0.01), LDL (p=0.004) level, sP-selectin level (p=0.009) and von Willebrand factor activity (p=0.04). It has also been found that CYP2C19*2 allele carriage is HPR risk factor (p=0.006). Multivariate regression analysis showed that body mass index and levels of soluble P-selectin were an independent predictors of HPR during DAPT. According to univariate regression analysis we found following MACE predictors after PCI: diabetes mellitus (p=0,049), PRU (p=0.01), number of stented arteries (p=0.01), number of implanted stents (p=0.01), baseline levels of PAI-1 (p=0.03) and von Willebrand activity (p=0.01). The presence of CYP2C19*2 carriers showed no significant impact on outcome after PCI. Using multivariate analysis we demonstrated that concomitant diabetes mellitus, PRU ≥202, PAI-1 level ≥75.95 ng/ml, von Willebrand factor activity ≥155.15% are independent predictors of adverse cardiac events after PCI in SCAD pts. Cut-off values were define using ROC-curve analysis. Based on our findings we developed predictive models for risk stratifying of patients undergoing elective PCI.

CONCLUSIONS

Present study shows that body mass index and sP-selectin level are an independent factors of HPR in SCAD patients. Independent predictors of adverse cardiac events after PCI were: concomitant diabetes mellitus, the value of PRU (≥202), the level of plasminogen activator inhibitor-1 (≥75.95 ng/ml) and von Willebrand factor activity (≥155.15%)

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Long-term quality of life benefits after successful PCI of CTO

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

To evaluate the long term relationship between successful coronary chronic total occlusion (CTO) percutaneous coronary intervention (PCI) and quality of life improvements within the full spectrum of the Seattle Angina Questionnaire.

METHODS AND RESULTS

From June 2010 to January 2015, 355 patients underwent CTO PCI. Seattle Angina Questionnaire was administered at baseline and 12 months after successful CTO PCI. 177 patients answered the baseline Seattle Angina Questionnaire and 120 answered both questionnaires. Seattle Angina Questionnaire responders were likely to be hypertensive, to have a higher proportion of right coronary artery as the target CTO vessel and more procedural technical success, and to receive more contrast, and less likely to have unstable angina and previous myocardial infarction than patients non approached. All five domains of the Seattle Angina Questionnaire improved in the 12-month follow-up ($p<0.0001$) compared to baseline. After conservative data imputation, the analyses of all 177 baseline responders also showed significant improvements. Absence of improvement in angina frequency ($p=0.0035$), physical limitation ($p=0.008$), treatment satisfaction ($p=0.02$) and disease perception ($p=0.03$) were associated to clinical event at 1year.

CONCLUSIONS

In patients who had undergone successful CTO PCI, there was significant improvement on patient's quality of life after 1 year compared to pre-procedural status. The presence of clinical events at 1-year follow-up was associated with worse quality of life.

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Pacemaker-related complications in patients undergoing TAVI: a single-centre experience

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

AIMS

Pacemaker (PMK) is not rarely required after TAVI but data are lacking about the rate of PMK-related complications in this population. The aim of our analysis was to describe the rate of complications secondary to PMK implantation after TAVI.

METHODS AND RESULTS

Methods: Consecutive patients were identified by retrospective review of a dedicated TAVI database of a single high volume center in Milan (Italy), between October 2007 and July 2015. Clinical and procedural data were collected to determine the main adverse events following this procedure, their incidence and severity.
Results: The overall population included 737 patients. 76 patients (10.3%) already had PMK and 538 patients (73%) did not require periprocedural PMK implantation. 123 patients (16.6%) underwent PMK implantation. Three of them were excluded from the final analysis because PMK was implanted after discharge in other hospitals. The final population consisted of 120 patients (16.3%). A high rate of major bleeding events (n=40; 33.3%) was observed in the population which received a PMK implantation. In 18 patients (15%) a pocket hematoma was found; in the other cases (n=22; 18.3%), the source of bleeding was not PMK-related and other sources of active bleeding were not found. Compared to patients not implanted with a PMK after TAVI, the rate of major bleeding events was higher in the group of patients receiving a PMK (33.3 vs 22.4%; p=0.01). The rate of major bleeding was significantly higher if the PMK was implanted within the first 24 hours after TAVI (43.6 vs 24.6%, p=0.02). In patients with major bleeding after PMK implantation, 5 patients (12.5%) did not take any antiplatelet/anticoagulant drugs the day of the procedure; 11 patients (27.5%) assumed only one antiplatelet drug, 20 patients (50%) were on dual antiplatelet therapy and one patient (2.5%) was taking an antiplatelet plus an anticoagulant. In 3 patients (7.5%) data were not available.
In 2 patients (1.6%) there was an infection of the pocket of the PMK. In 3 (2.5%) PMK implantation was complicated by cardiac tamponade: 2 (1.6%) required percutaneous drainage, while one (0.8%) required surgical drainage, with complete recovery. 3 patients (2.5%) had lead malfunction (2 patients had a lead replacement, in one case the problem was managed by reprogramming the PMK). One patient (0.8%) had a pneumothorax, 48 hours after PMK implantation, successfully treated with intercostal tube drainage. One patient (0.83%) had a thrombosis of the left brachiocephalic vein that required an anticoagulation therapy. One patient (0.83%) had a major vascular event - dissection of the left internal mammary artery - and haemothorax, which led to patient death.

CONCLUSIONS

PMK-related complications are not uncommon in elderly patients after TAVI and some of these can be potentially lethal. Particular attention is required in the periprocedural management of these patients. Further studies are needed to confirm our findings.

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Re-angiogram and need for further revascularisation after PCI

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

AIMS

To investigate the number of clinically driven re-angiograms within 30 days and 1 year, respectively in patients treated with percutaneus coronary intervention (PCI), and the clinical consequences of the re-angiograms.

METHODS AND RESULTS

The Western Danish Heart Registry was used to identify patients who had a re-angiogram due to recurrent chest pain, other symptoms concerning for angina or acute coronary syndrome (ACS) within 12 months afterPCI in our hospital. Patients who had a re-angiogram due to other indications than stable angina (SAP) or acute coronary syndrome (ACS) where excluded from the data analysis. The index PCI was performed between January 2011 and April 2014. Logistic regression was used to test for association between risk factors and re-angiogram.

Among 6021 patients treated with PCI, 114 (1.9%) patients had a re-angiogram within 30 days and 539 (9.0%) patients had a re-angiogram within 1 year of the index PCI.

The indication for the re-angiogram differed between the two time periods, as the indication within 30 days was more often ACS (SAP in 20 (17.5%) patients and ACS in 94 (82.5%) patients) compared to ACS beyond 30 days and within 1 year (SAP in 268 (63.1%) patients and ACS in 157 (36.9%) patients), p<0.001.

Age (odds ratio (OR) 0.98 , 95% Confidence Interval (CI) 0.97-1.00) and previous PCI (before index PCI) (OR 2.70 ,95% CI 1.42-5.12) were independently associated with re-angiogram within 30 days. Age (OR) 0.99 ,95% CI 0.98-0.99), diabetes (OR 1.30 ,95% CI 1.02-1.65) and previous coronary artery bypass operation (CABG) before the index PCI (OR 1.45 ,95% CI 1.04-2.03) were independently associated with re-angiogram within 1 year.

Overall 324 (60.1%) out of the 539 patients who had re-angiogram within 1 year after PCI was treated with revascularization (5.4% of the total PCI treated population): within 30 days 48 (0.8 % of all PCI treated patients) with PCI and 5 (0.1%) with CABG and beyond 30 days to 1 year 236 (4.3%) with PCI and 35 (0.6%) with CABG.

CONCLUSIONS

Less than one out of ten PCI treated patients had a clinically driven re-angiogram within a year, which was followed by a new revascularization in half of these patients due to disease progression.

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Less paravalvular leak at the expense of higher pacing rates: a comparison of a new vs. an old generation self-expanding valve

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

AIMS

In the current study we aimed to compare complication rates (hospital mortality, paravalvular leak, major vascular access complications and permanent pacing) between the old CoreValve (CV) and the new generation Evolut R (ER) self-expanding valves.

METHODS AND RESULTS

From January 2010 to October 2016 a total of 329 self expanding valves were implanted; 71 CoreValve (CV) and 258 Evolut R (ER). Patients in both cohorts (CV vs ER) had similar age (80.7± 9.1 vs. 82.2±6.5 years, p=0.131), gender (females: 52.1% vs. 56.2%, p=0.539), logistic Euroscores (15.5±8.4 vs. 13.9±7.9, p=0.131), body mass index (28.4±6.6 vs. 27.8 ±5.1, p=0.534) and mean aortic annulus diameter as measured by computed tomography (22.0±2.1 vs. 22.1±2.9 mm, p=0.904). Major vascular complications were significantly lower in the ER group (7% vs. 2.3%, p<0.001) as was the rate of moderate/severe paravalvular regurgitation (21.1% vs. 5%, p<0.001). Amongst patients without pre-existing PPM, there was a borderline significant increase in the rates of new PPM implantations in the ER group (14.3% vs. 24.7%, p=0.049). In hospital mortality was increased in the CV group when compared to ER (12.7% vs. 3.1%, p=0.001). One year estimated mortality was increased in the CV group 15.6% vs 10.5%, $pl_{og\text{-}rank}$=0.17. This mortality benefit remained after adjustment for age, gender and baseline logistic Euroscore (Hazard Ratio 0.58 ; 95%CI: 0.34 to 0.99, p=0.44).

CONCLUSIONS

The new generation Evolut R valve was associated with significantly reduced rates of more than moderate paravalvular leak, major vascular complications, in-hospital and 1-year mortality. However the rates of new permanent pacemaker implantations were marginally higher compared to its predecessor CoreValve suggesting that the new features allowing for PVL reduction may potentially have an adverse impact on the conduction system.

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Ticagrelor effectively inhibits platelet aggregation in comatose survivors of cardiac arrest undergoing primary PCI treated with mild therapeutic hypothermia

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

AIMS

The aim of the study was to evaluate the impact of mild therapeutic hypothermia (MTH) on the antiplatelet effect of Ticagrelor in comatose survivors of cardiac arrest (CA) treated with primary percutaneous coronary intervention (pPCI).

METHODS AND RESULTS

We investigated platelet aggregation in 21 comatose survivors of out-of-hospital cardiac arrest (OHCA) with acute coronary syndrome (ACS) treated with MTH (Group MTH) and 7 consciousness patients with ACS (Group Control). All patient underwent immediate pPCI. MTH (32°C) was induced intravascularly, and maintained for 12-24 hours. A loading dose of 300 mg Aspirin and 180 mg Ticagrelor were administered via a nasogastric tube on admission, followed by Aspirin 75 mg once daily and Ticagrelor 90 mg twice daily. Platelet function was assessed using light optical aggregometry (LTA) after administration of adenosine diphosphate (ADP) and the VerifyNow-ADP test. Inhibition of platelet function was below 50% in LTA-ADP and below of 194 platelet reactivity units (PRU) in VerifyNow-ADP test. Analysis was performed: after admission (T_0), 12-24 hours after PCI (T_1) and 48-72 hours after PCI (T_2). There was no difference of antiplatelet effect of Ticagrelor between the group MTH vs. Control in period T_0, T_1 and T_2 in both methods (LTA and VerifyNow). During hypothermia, 95% patients received satisfactory effect of Ticagrelor using LTA-ADP (with mean 26±16[%]) compared with 85% patients obtained satisfactory effect using VerifyNow-ADP test (with mean 84±87[PRU]);p=0.5.

CONCLUSIONS

Enteral delivery of Ticagrelor in comatose survivors of cardiac arrest undergoing pPCI, is associated with adequate inhibition of platelet during mild therapeutic hypothermia, that does not differ with effect of Ticagrelor in conscious patients.

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Influence of gender on clinical outcomes following PCI with an everolimus-eluting stent

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

AIMS

There is a global concern regarding the lack of powered sex or gender-specific analyses in cardiology as clinical trial designs have not adequately capture data on women.

METHODS AND RESULTS

PLATINUM Diversity, using an enriched enrollment design, prospectively evaluated clinical outcomes in women and minorities treated with a contemporary everolimus-eluting stent. This subanalysis evaluates sex-related differences in outcomes.

PLATINUM Diversity enrolled US patients who received ≥1 Promus PREMIER stent and self-identified as having ≥1 of the following: female sex, Black (of African heritage), Hispanic/Latino, or American Indian/Alaskan Native. The primary endpoint of PLATINUM Diversity was the combined rate of 12-month death, myocardial infarction (MI), and target vessel revascularization (TVR). To enrich the patient population for women and minorities and allow comparison to white men, patients in PLATINUM Diversity (N=1,501) and PE Plus PAS (N=2,687) were combined (N=4,188); a total of 1,863 women were available for analysis. Outcomes in women were compared to white men from PE Plus PAS (N=1,635). A multivariate logistic regression analysis was used to adjust 12-month clinical outcomes for differences in baseline characteristics. Follow-up at 12 months was available in 94% and 95% of women and men, respectively.There were significant baseline clinical, angiographic, and procedural differences between men and women. Women were older (66 vs 63, *P*<0.01)The prevalence of diabetes was higher in women as compared to men (42% vs 34%, *P*<0.01) as was the history of treated hypertension (84% vs 76%, *P*<0.01), congestive heart failure (13% vs 9%, *P*<0.01) and renal disease (14% vs 9%,*P*<0.01). Acute coronary syndrome was less common in women than men (55% vs 59%, *P*<0.01), as were previous percutaneous coronary intervention (40% vs 45%,*P*<0.01), and coronary artery bypass graft surgery (19% vs 13%,*P*<0.01). Reference vessel diameter was smaller in women than men (2.9 mm vs 3.0 mm, *P*<0.01). Average lesion length and the number of study stents implanted per patient were similar between groups. Fewer women were taking dual antiplatelet therapy than men both at discharge (94% vs 96%, *P*<0.01) and at 12 months (85% vs 87%, *P*=0.03).The unadjusted and adjusted rates of death/MI/TVR at 12 months in women were not significantly different from men (adjusted odds ratio [OR] 1.1 [0.87, 1.47]). Both the unadjusted and adjusted risks of 12-month death/MI were increased in women compared to men (adjusted OR 1.6 [1.11, 0.39]). Though the individual adjusted rates of death and MI were higher in women than men, these differences did not reach statistical significance. The rate of TVR at 12 months was similar between women and men (OR 0.87 [0.63, 1.19]) at 12 months. Predictors of clinical outcomes in women compared to men will be available at the time of the presentation.

CONCLUSIONS

Significant differences were observed in baseline characteristics of women compared to white men. Even after adjustment for these differences, women had a higher risk of death and MI compared to white males at 12 months. The underlying mechanism of this increase is likely multifactorial and includes biological,

socioeconomic, and behavioral factors. Further study into sex/gender-related causes of these trends is warranted.

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Clinical performance of a dedicated self-expandable stent for the treatment of left main stem disease The MATISSE study.

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

AIMS

PCI of the left main coronary artery (LMCA) recently showed to be equivalent to CABG at long term, at least with one type of DES. The role of a dedicated, self-expandable DES has not been clinically proved yet.

METHODS AND RESULTS

a self-expandable stent offers an improved adaptation to the vessel wall, especially in case of tapered vessels, warranting adequate apposition. The MATISSE is a spontaneous registry, which enrolled 104 patients treated with a dedicated self-expanding DES in the LMCA at 9 european centers. Co-primary endpoints were procedural success, defined as angiographic success without the occurrence of adverse events during hospitalization, and device-oriented adverse cardiac events (DOCE), a composite endpoint of cardiac death, target lesion revascularization (TLR) and target-vessel myocardial infarction, with at least 6-month clinical follow-up. 62% of patients were males, 31.7% diabetics and average Syntax score was 22 (SD 8.6). 28.9% of patients underwent PCI for stable coronary artery disease, 19% for unstable angina, 40% for NSTEMI, 12.1% for STEMI. Lesions were located in distal LM bifurcation in 85.9% of patients. Stent sizes used were: 2.5-3.0 in 1.9%, 3.0-3.5 in 27.1%, and 3.5-4.5 in 71% of the patients. Immediate procedural success was achieved in 103 patients (99%), with no events during hospitalization. 73% of patients had a follow-up of at least 6 months (mean 13 ± 4.8 months). At follow up, DOCE occured in 6 patients (7.8%): 4 patients experienced cardiac death (5.3%), with one patient experiencing sudden death and 3 untreatable cardiogenic shock. TLR occurred in 2 patients (2.6%). In case of acceptance for presentation at EuroPCR, we expect to provide the complete 6-month follow up for the entire population of the MATISSE study.

CONCLUSIONS

in this study, a self-expandable stent implanted in LMCA showed preliminary promising results in terms of safety and efficacy in a high-risk population. In this setting, this device may overcome some drawbacks of balloon-expandable stents, namely the adaptability in tapered vessels and the risk of malapposition. Larger dedicated trials are needed to confirm its efficacy and safety in this setting.

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Everolimus-eluting BRS implantation to treat SVG disease

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

AIMS

Recent studies have demonstrated favorable clinical outcomes for the bioresorbable vascular scaffold (BVS) in patients with stable coronary artery disease. There are currently no data on its use in patients with saphenous vein graft disease.

METHODS AND RESULTS

We investigated the safety and efficacy of BVS implantation to treat SVG. This was an observational, retrospective, single-center study of consecutive patients treated with the Absorb BVS for SVG disease at our institution between May 2013 and June 2015.A total of 10 consecutive patients (13 lesions) underwent percutaneous coronary intervention for SVG disease with BVS implantation within this period at our institution and were included in the current analysis. Briefly, the median age was 75 (64-81) years, 90% of the patients were male, 60% had diabetes and 80% presented for acute coronary syndrome (either unstable angina, non-ST elevation acute coronary syndrome or ST-segment elevation myocardial infarction). Median time from SVG to BVS implantation was 11.9 (8.1-15.2) years.

Three of these patients had 2 distinct SVG lesions treated with a BVS during the same intervention. All procedures were performed through the femoral access. Median procedural time was 51 (45-73) minutes, and median fluoroscopic time was 15 (13-23) minutes. An embolic protection device was used in 4 (30.8%) patients. Pre-dilation was performed in 11 (84.6%) lesions. Procedural success was achieved in all patients. A total of 13 scaffolds were implanted with a mean diameter of 3.25±0.35mm and a mean length of 20.6±5.4mm. Mean deployment pressure was 13.1±2.6 atm and post-dilatation was performed in 10/13 lesions (76%). Mean post-dilatation pressure was 19.6±2.27atm. Procedural success was achieved for all patients, and no embolization, perforation, dissection, or no-reflow occurred. Likewise, no death, scaffold thrombosis, myocardial infarction, or repeat revascularization occurred during the index hospitalization.

Follow-up was completed in all patients. Mean follow-up period was 808.6±185.2 days. One patient had scaffold thrombosis (ScT) 15 months after stent implantation which was treated medically. Another patient had target lesion revascularization (TLR) in two different lesions. The composite endpoint of TLR, ScT, target vessel acute coronary syndrome and cardiac death, was reached in 3/13 lesions (23.1%).

CONCLUSIONS

In this first, real-world data on the use of the the ABSORB™ BVS in patients with SVG disease, its use was associated with high risk of target lesion revascularization, comparable to standard therapy with drug-eluting stents. Larger studies are required to better define the optimal use of BVS to treat SVG disease.

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Detailed serial analysis of vascular responses to everolimus-eluting cobalt-chromium stent for the treatment of stable coronary artery disease: The results of MECHANISM-Elective OCT follow-up study

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

AIMS

Several studies have indicated the advantage of everolimus-eluting cobalt chromium stents (EES) for the treatment of stable coronary artery disease (CAD). The aim of MECHANISM Elective was to explore early and mid-term vascular responses to EES.

METHODS AND RESULTS

MECHANISM Elective study (NCT02014818) was a multi-center registry using optical coherence tomography (OCT). Enrolled patients received OCT examination immediately after EES implantation (post EES) and were prospectively registered in either 1-month (1-mo, n=50) or 3-month (3-mo, n=50) scheduled OCT follow-up cohort who also received serial 12-month (12-mo) OCT. OCT images were independently analyzed at a core laboratory in a blinded fashion. In addition to standard OCT parameters, incidence of intra-stent thrombus (IS-Th), irregular protrusion (IRP) and intra-stent / edge dissections were assessed. A total of 104 patients were enrolled in MECHANISM-Elective study from 20 sites, 49 patients (51 EESs) in 1-mo cohort and 46 patients (51 EESs) in 3-mo cohort were available for complete serial OCT analysis. Patients and lesion demographics between 1-mo and 3-mo cohort were not different. Thickness of neointimal was 40±17 μm at 1-mo, 47±21 μm at 3-mo and 89±45 μm at 12-mo. In 1-mo cohort, %uncovered strut significantly decreased from post EES to 1-mo (87.0±8.7% to 6.4±10.3%, P<0.001), and further decreased at 12-mo (0.5±0.9%, P<0.001 vs. 1-mo). In 3-mo cohort, %uncovered strut also decreased from post EES to 3-mo (79.3±12.4 % to 2.0±2.5 %, P<0.001), and further decreased at 12-mo (0.5±1.5%, P<0.001 vs. 3-mo). The incidence of IS-Th was 66.7% at post EES, 32.7 % at 1-mo, 5.4% at 3-mo and 2.0% at 12-mo. The incidence of IRP was 21.8% at post EES, that were all disappeared at 1, 3, and 12-mo. Most of intra-stent and edge dissections were already restored at 1-mo and totally resolved at 12-mo. The frequency of target lesion revascularization at 12-mo was 3.0%.

CONCLUSIONS

MECHANISM Elective study revealed the early and mid-term vascular reactions following EES implantation in Stable CAD patients. Considering dynamic resolution of IS-Th, IRP and dissections as well as the rapid decrease in uncovered strut even at early phase, EES may have a potential to shorten the duration of dual-antiplatelet therapy up to 1 month in this patient subset.

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Incidence and consequences of non-cardiac incidentalomas on pre-procedural imaging in the work-up for TAVI, renal sympathetic denervation or MitraClip implantation

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

AIMS

To describe the incidence and consequences of non-cardiac incidental findings on computed tomography angiography or magnetic resonance angiography in the work-up for TAVI, renal sympathetic denervation (RDN) or mitraClip implantation.

METHODS AND RESULTS

Between January 2010 and November 2016 a total of 916 patients were referred for any of the above mentioned procedures with pre-procedural workup including CTA or MRA. Mean age of the population was 78 ±10 years, 53.8% of the patients were male and 18.4% had a history of neoplasms. The majority of the patients was screened for TAVI (85.6%) versus 11.8% screened for RDN and 2.6% screened for mitraClip. A total of 698 incidental findings were found in 395 (43.1%) patients. Classifying of the incidentalomas resulted in 155 patients (16.9%) with minor findings, 171 (18.7%) with moderate findings and 69 patients (7.5%) with major incidental findings. The 3 most frequent incidental findings were renal cysts, pulmonary nodules and pulmonary consolidation in 16.3%, 13.3% and 7.0% of the patients with incidentalomas, respectively.No significant differences in baseline characteristics were found in patients presenting with versus those without incidentalomas. Although only 11 patients out of the 395 patients (1.2%) presenting with incidentalomas were deferred for the intended procedure due to active malignancies, the presence of incidental findings at baseline significantly determined short and long-term outcome. One-year mortality rates were comparable in patients with versus those without incidentalomas (19.0% vs. 17.7%, p=0.60). One-year mortality rates were 11.9% in patients with minor findings, 22.2% in patients presenting with moderate findings and 27.0% in patients presenting with major incidental findings (log-rank p moderate or major findings vs. no incidentaloma, p=0.032).

CONCLUSIONS

Incidental findings were frequent in patients referred and screened for percutaneous cardiovascular interventions. The presence of moderate or major incidental findings significantly predicted one-year mortality rates.

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Can we rely on iFR to avoid FFR? Conclusions of a five-year experience

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

AIMS

Assess the concordance of FFR and iFR results, based on the 5-year experience of a single center; also analyse the effect of iFR in the operator's decision to proceed to FFR, and its impact on procedure duration and radiation time/dosage.

METHODS AND RESULTS

Single-center registry of all patients undergoing functional coronary lesion assessment during 5 years. FFR was used as a gold standard (with a cut-off point for intervention ≤ 0,80) for assessing the diagnostic accuracy of iFR in every patient who underwent measurements with both techniques.

For analysis purposes, an iFR value < 0,86 was considered positive (i.e. proceed to intervention), a value > 0,93 was considered negative (i.e. defer intervention). Values in between were deemed inconclusive. For statistical analysis we used the T student and Chi-Square tests.

Functional testing was undertaken in 326 patients (67±11 years, 65,6% male), encompassing 402 lesions. 154 lesions underwent assessment with both techniques, 222 by FFR only and 26 cases iFR only.

The average iFR was 0,9 ± 0,1. 60 lesions had an iFR > 0,93 and 21 an iFR < 0,86.

An iFR value between 0,86 and 0,93 was strongly associated with the decision to proceed to FFR (X^2 = 30,1; p < 0,001): the operators chose to perform FFR in 93 out of 94 cases. In the remaining cases, FFR was performed in 69,1% of cases, with no differences between values < 0,86 vs > 0,93 (71,4% vs 68%; p = 0,792).

In these cases, there was a statistically significant concordance of 87% between the iFR and FFR results (X^2 = 22,43; p < 0,001). Notwithstanding, there were 4 out of 13 cases (30,7%) of positive iFR with negative FFR and 3 out of 42 (7,1%) cases of negative iFR and positive FFR. This difference was statistically significant (p = 0,026).

Regarding procedural time, radiation time and radiation dose, there were no statistically significant differences between patients who only underwent iFR, FFR only, or both techniques.

CONCLUSIONS

The iFR results were inconclusive (i.e. between 0,86 and 0,93) in most cases. There was a high degree of concordance between the iFR and FFR values. However, a significant proportion of patients, particularly in cases of positive iFR (< 0,86), were classified as negative by FFR. The use of iFR had no impact on procedural time, radiation time and radiation dose.

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Subchronic pre-clinical biocompatibility evaluation of different drug elution rates in a novel drug-eluting magnesium stent

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

AIMS

Magnesium bioabsorbable stents (MBS) have been previously introduced as bioabsorbable options for intravascular devices. We aim to evaluate the coronary artery biocompatibility of a novel MBS platform versus its drug-elution version.

METHODS AND RESULTS

Seven MBS were implanted on the coronary arteries of three domestic swine. Under standard preclinical protocols all MBS were implanted under angiographic guidance in approximately 20% over stretch. Coronary arteries were randomize to the implantation of bare metal MBS (BMS; n=2), normal (ND; n=2) and low dose (LD; n=3) drug elution on the novel MBS platform. 28 days following implantation, all stents were harvested for histopathological evaluation under a semiquantitative scoring system (0=feature not present-4= severe, feature overwhelming feature). The histopathological evaluation demonstrated similar characteristics despite among all MBS despite drug elution or bare metal equivalent. In all cases, MBS presented complete strut apposition, endothelial cell lining covered by mature fibromuscular neointima without evidence of strut erosion but with similar evidence of strut bioresorption demonstrated by hyalinization (ND=2.4±0.5; LD=2.7±0.5; BMS=2.8±0.4) and initial strut fragmentation (ND=1.6±0.5; LD=1.3±0.8; BMS=1.8±0.4). The evaluation of the arterial wall revealed a low inflammatory response and distribution in the neointima (ND=1.1±0.0; LD=0.7±1; BMS=0.5±1); media (ND=0.3±1; LD=0.0±0.0; BMS=0.0±0.0) and adventitia layer (ND=0.2±0.0; LD=0.0±0.0; BMS=0.0±0.0). The peri-strut inflammatory response was also significantly low (ND=1.1±0.0; LD=0.7±1; BMS=0.5±1) composed principally of histiocytes. There was no evidence of vascular thrombosis or fibrin deposition.

CONCLUSIONS

In this preliminary preclinical study, the novel bare magnesium-based bioresorbable stent was associated proper vascular apposition and high vascular biocompatibility in its bare metal version as well as two dosage levels of drug elution.

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Age-dependent impact of baseline SYNTAX score on long-term mortality after DES implantation

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

AIMS

Limited data exist about the value of the SYNTAX Score among elderly patients, an increasing population of cardiovascular patients. We aimed to investigate whether age modifies the impact of baseline SYNTAX Score on 2-years mortality after PCI.

METHODS AND RESULTS

The baseline SYNTAX Score measures the complexity of coronary artery disease (CAD) and has been recommended for risk stratification and as decision tool to guide therapy in CAD patients. The baseline SYNTAX Score was calculated in 1331 patients who underwent PCI between 01/2013-03/2014 in our institution. Median age was 70,7 (IQR 61,6-77,4) years, 28% were female, 74% had multivessel disease and 55% presented with an ACS.The population was divided into two groups - older than 80 years (242 patients, 18%, median age 83,8 (IQR 81,8-86,0) years) and younger than 80 years (1089 patients, 82%, median age 67,8 (IQR 59,1-74,0) years). Octogenarians had a higher SYNTAX Score (median 17, IQR 10-28) compared to younger patients (median 15, IQR 7-24). At 2-years, cumulative incidence of all-cause mortality in the overall population was 15% (n=199), 32% among octogenarians and 11% among younger patients (p<0,001). Cumulative incidence of cardiac mortality was 9%, 22% among octogenarians and 7% among younger patients, p<0,001.In the uni- and multivariate analysis, baseline SYNTAX Score was a predictor for overall and cardiac mortality. There was a significant interaction of age with baseline SYNTAX Score regarding cardiac mortality (p interaction <0,001). There was also a significant interaction of age with baseline SYNTAX Score regarding overall mortality (ineraction p=0,0019). Mortality according to tertiles of baseline SYNTAX Score (<10, >=10-21, >21) was 24%, 37% and 33% in the octogenarians (p=0,249) and 8%, 9% and 17% in the younger patiens (p<0,001).

CONCLUSIONS

In this registry the impact of baseline SYNTAX Score on mortality is modified by age.

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Accuracy evaluation of MRI platform in preclinical radiofrequency denervation studies: high-resolution imaging as an adjunct to conventional histopathology

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THEME: Interventions for Hypertension
TOPIC(S): Renal denervation

AIMS

Magnetic resonance imaging (MRI) has demonstrated to be a useful tool as a non-invasive imaging modality in preclinical research. We aim to determine the accuracy of MRI in distinguishing the areas of ablation as confirmed by conventional histology.

METHODS AND RESULTS

Renal denervation was performed in porcine renal arteries (n=2) with a multielectrode catheter. Ablations (6W) were delivered along the renal artery.At 7 days arteries were extracted and imaged by MRI (Bruker BioSpec 70/20 USR) and processed for histology.MRI accurately identifies all anatomical structures. The non-treated areas exhibited compact, sharp edges with crisp definition of the surrounding structures. In contrast, the treated artery showed a thinning and blurry endoluminal edge with poor differentiation of the wall. This signal blends continuously with the surrounding anatomy. The adjacent tissue revealed an evident, delimited, and irregular area of haziness and attenuation projecting to variable lengths from the renal artery. Upon explant, histological preparations were evaluated to define the limits of ablation. These areas correlated faithfully to the areas of surrounding haziness in the MRI.

CONCLUSIONS

The evaluation of samples with MRI allows a comprehensive assessment of the circumferential and longitudinal delivery of the RF therapy. MRI evaluation demonstrated proper localization and an accurate 3D representation of the cross-sectional data provided by histology attesting to the fidelity of the method in outlining the ablated area. MRI serves as complementary technique to standard histopathology.

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Occlusion of secondary side branches predicts revascularisation rates at mid-term follow-up (up to 60-months) after stenting coronary bifurcation lesions from intracoronary electrocardiogram and myonecrosis after bifurcation stenting (COSIBRIA&CO)

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

To explore the value of angiographic parameters and changes on icECG, recorded from PCI wire from main and side branches and its relation to mid-term (up to 60 months) post coronary bifurcation PCIs restenosis rates.

METHODS AND RESULTS

Methods:We followed prospectively 115 patients with stable/unstable angina with complete angiographic records of every stage of the procedure and icECG record. Unipolar icECGs were recorded before, during and after stent placement and at the end of procedure in side branch (SB) and main branch (MB). The coronary wire was placed in all distal vessels with diameter >1.5mm, to “map” the distal zones of ischemia. Provisional T-stenting was default strategy.

Results:From the 115 patients included, 69% were males, mean age 68±6, diabetics 33%, 42% had previous myocardial infarction and 18% had multivessel disease. The main treated vessel was LAD (73%). True bifurcation lesions (Medina xx1) were 65%. Kissing balloon inflation was performed in 21% of the cases. On univariate analysis significantly associated with target lesion revascularization rates were occlusion of secondary, small size (<1.5 mm), side branches, diameters at proximal and distal stent edges, the final icECG main branch R-wave to S-wave ratio, side branch icECG R-wave final amplitude and final icECG side branch and main branch ST-segments elevations. On multivariate Cox proportional hazards analysis an independent predictors of TLR are occlusion of secondary branches at the end of bifurcation PCI (HR=8.849, CI 2.551 – 30.303, p=.001), final distal sent edge diameter (HR=14.925, CI 1.401-166.667, p=.025) and final side branch icECG R-wave amplitude (HR=1.101, CI 1.016-1.190, p=.018). The rates of TLR in groups with and without small branch occlusion differed highly significantly – 6/15 (40%) vs. 14/163 (8.6%), p<.001.

CONCLUSIONS

Periprocedural occlusion of small secondary branches predicts mid-term target lesion revascularization rates after stenting coronary bifurcation lesions. It is unrelated to periprocedural troponin rise, raising the possibility for alternative mechanism influencing in-stent restenosis process.

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Frequency, reasons and predictors of premature ticagrelor discontinuation in patients undergoing coronary revascularisation

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

AIMS

Ticagrelor was superior compared to clopidogrel for the treatment of ACS patients, however, its discontinuation within one-year was high (24%) in PLATO. We aimed to assess the frequency, predictors and reasons for preterm ticagrelor discontinuation.

METHODS AND RESULTS

Between November 2011 and June 2014, 4831 consecutive patients underwent PCI at a tertiary care center of whom 1278 patients (26.5%) were treated with ticagrelor and aspirin for the recommended duration of one year. Patients were prospectively followed throughout one year and cardiovascular events were collected. Compliance with and side effects related to ticagrelor treatment were assessed by a questionnaire and review of all medical reports obtained in the context of clinical events or changes in antiplatelet therapy. Ticagrelor discontinuation was defined as either change to a different P2Y12 inhibitor or a discontinuation without replacement prior to the prescribed duration of one year.

The indications for treatment with ticagrelor comprised NSTE-ACS in 52% (n=659), STEMI in 21% (n=273) and stable CAD in 14% (n=172), respectively. A total of 1073 patients (84%) continued ticagrelor treatment throughout one year. Out of 206 (16%) patients who prematurely discontinued ticagrelor, 10.8% (n=138) changed to another P2Y12 inhibitor (clopidogrel (n=106) or prasugrel (n=32)) and 5.2% of patients (n=82) stopped ticagrelor therapy without replacement. Reasons for ticagrelor discontinuation were in descending order: adverse effects (40%), initiation of oral anticoagulation (21%), preference of general practitioner (11%), bleeding events (8%), medical interventions (5%), ischemic events (2%) and financial reasons (2%). Independent predictors of ticagrelor discontinuation were female gender (Odds ratio [OR] 1.8, 95% CI 1.19-2.64, p=0.01), peripheral arterial disease (OR 2.0, 95% CI 1.02-3.90, p=0.04) and bleeding events (OR 3.92, 95% CI 1.68-9.13, p=<0.01). Adverse effects leading to discontinuation (n=82) included dyspnea (38%), nausea (22%), epistaxis (20%) and echymoses (7%). While 132 patients (10.3%) reported at least one episode of ticagrelor-related dyspnoe within one year, only 31 patients (2.4%) discontinued ticagrelor permanently due to dyspnea. After cessation of ticagrelor, 77% of patients reported immediate relief while 23% patients reported no amelioration of symptoms.

CONCLUSIONS

In this all-comers population, 16% of patients did not complete the recommended one-year treatment with ticagrelor. The principal reasons in descending order were adverse effects, initiation of oral anticoagulation, preference by general practitioner, and bleeding events. Dyspnea was the most frequent side effect and resulted in discontinuation of ticagrelor in 2.4% of patients. Independent predictors for premature ticagrelor discontinuation were female gender, peripheral arterial disease and bleeding.

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Restenotic lesions involving side branches predict future congestive heart failure and angina symptoms rates after stenting coronary bifurcation lesions - Insights from intracoronary electrocardiogram and myonecrosis after bifurcation stenting (COSIBRIA&CO)

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

AIMS

We explored the relation between restenotic lesion appearance in coronary bifurcation lesion subset and future recurrence of symptoms and major adverse cardiac events.

METHODS AND RESULTS

Methods: Complete angiographic analysis before, after stent placement and at the end or bifurcation percutaneous coronary intervention was performed. Unipolar icECGs were recorded before, during and after stent placement and at the end of procedure in side branch (SB) and main branch (MB). The coronary wire was placed in all distal vessels with diameter >1.5mm, to “map” the distal zones of ischemia. The patient population consisted of patients with stable/unstable angina. Provisional T-stenting was default strategy.

Results: A 167 patients were included into analysis; 71% were males, mean age 67±9, diabetics 35.2%; 42% had previous myocardial infarction and 18% had multivessel disease. The main treated vessel was LAD (78%). True bifurcation lesions (Medina xx1) were 55%. Kissing balloon inflation was performed in 23% of the cases. On univariate analysis significantly associated with angina or new-onset heart failure symptoms, requiring hospitalization (ANOCHF) were occlusion of secondary small (<1.5mm) side branches, previous anterior wall myocardial infarction, previous PCI on same vessel (restenotic lesion), statin use, left-ventricular ejection fraction, intracoronary ECG ST-segment elevation in side branch and/or main branch at the end of procedure. On multivariate Cox proportional hazards analysis independent predictors of future events were occlusion of secondary small branches (HR=3.236, CI 1.352-7.751, p=.008), previous anterior wall myocardial infarction, (HR=2.304, CI 1.029-5.155, p=.042), restenotic lesion (HR=2.689, CI 1.179-5.988, p=.018), final ST-segment elevation in side branch region (HR=5.291, CI 2.012-13.889, p=.001). The rates of ANOCHF significantly differed in restenotic and non-restenotic groups: 8/20 (40%) vs. 25/147 (17%), p=.004.

CONCLUSIONS

The restenotic lesions are important predictor of angina and heart failure symptoms recurrence after coronary bifurcation PCI.

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CT angiogram pre-TAVI, complications and pacemaker need: is it worth quantifying the calcium?

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

AIMS

We aimed to assess the ability of a calcium score and other CT parameters to predict the occurrence of leaks, complications and the need for pacemaker.

METHODS AND RESULTS

Prospective single center of all patients undergoing TAVI from 2012 to 2016. At baseline, all patients underwent clinical and imaging evaluation (CT angiogram). The latter included the assessment of vessel and aortic root size, valve calcium score, sheath/access size ratio and valve area/prosthesis size ratio. The valve calcium score was quantified in volume (mm^3) using the 3mensionValvesTM software with a calcium detection threshold of 500 HU, which was manually adjusted when needed. All patients underwent transoesophageal echocardiogram during the procedure, and the final result, including leak grade, was assessed. All complications and mortality were accounted for according to the VARC-2 criteria. For statistical analysis we used Cox multivariate regression.

225 patients underwent TAVI (mean age 81 ± 7 years, 54% male), with a success rate of 98,7%.

There were 62 (27,6%) procedure-related complications: 12 strokes (6 major), 24 bleeding events (10 major), 26 vascular complications (10 major). Definitive pacemaker was required in 38 patients. During a mean follow-up of 435 ± 385 days, there were 44 deaths 19,6%), 16 in the first 30 days.

None of the CT angiogram factors was a predictor of mortality. In particular, the calcium score had no impact on the need for pacemaker, peri-prosthesis leak, stroke or mortality. Likewise, the sheath/vessel ration was not a predictor of bleeding or vascular complications.

The only predictors of pacemaker need were complete left bundle branch block (LBBB) (p=0,003; HR 4,3 IC 95% 1,67 – 11,13), complete right bundle branch block (RBBB) (p=0,026; HR 3,71 IC 95% 1,17 – 11,79) and long-standing/permanent atrial fibrillation (AF) (p=0,002; HR 3,65 IC 95% 1,64 – 8,15). The association of LBBB and AF increased the need for pacemaker 13-fold (p<0,001; HR 13,36 IC 95% 2,57 – 69).

There was also a trend for increased stroke incidence with self-expandable valves (9,4% vs 3,5%; p = 0,086), particularly minor stroke (6,3% vs 1,4%; p = 0,057). Bleeding was more common in female sex (19,0% vs 4,3%, p = 0,002) and with self-expandable valves (20,0% vs 9,1%, p = 0,027). However, female sex was the only independent predictor of bleeding (p = 0,004, HR 5,15 IC 95% 1,71 – 15,54).

CONCLUSIONS

No CT angiogram parameter was a predictor of complications, mortality or pacemaker need. The only independent predictors of the latter were any bundle branch block or long-standing/permanent AF. These results suggest that CT angiogram pre-TAVI provides enough data to tailor the type and size of the prosthesis, as well as the access site, therefore minimizing adverse events. One cannot rule out the potential usefulness if assessing the amount of calcium in the remaining aorta regarding the impact on stroke and mortality.

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Variations in clinical outcomes of patients treated with second-generation DES within three European countries. One-year results of the large all-comer registry

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

AIMS

To compare local clinical practices within three European countries and assess differences in patient characteristics as well as 1-year clinical outcomes in a large all-comer registry population treated with Ultimaster, a bioresorbable polymer DES.

METHODS AND RESULTS

e-Ultimaster is a large, prospective, single-arm, multi-centre registry that is designed to further validate the safety and efficacy of the Ultimaster in unselected patients enrolled worldwide. Currently, 4597patients have been enrolled and have reached one-year follow-up. Among these, 3144 patients were included in this subset: 1564 in United Kingdom (UK), 793 the Netherlands (NL) and 787 in Spain (ES). The primary endpoint was target lesion failure (TLF) defined as a composite of cardiac death, target vessel related myocardial infarction (TV-MI) and clinically driven target lesion revascularization (TLR) at 1 year.Except for the average age of 65.5 years and 76.6% being male patients in UK, NL and ES, there were significant differences in baseline patient characteristics among these three countries. Patients enrolled from ES had higher comorbidities compared to UK and NL, with the rate of hypertension (58.1%, 47.8% and 67.1; p<0.001), diabetes (21.6%, 17.8% and 35.3%; p<0.001), renal impairment (6.3%, 5.7% and 9.5%; p=<0.001) and hypercholesterolemia (54.8%, 36.4% and 65.3%; p<0.001) in the UK, NL and ES groups respectively. Similarly, presence of NSTEMI and ACS differed in UK, NL and ES (23.5%, 26.7% and 34.3%; p<0.001 and 56.8%, 61.8% & 69.3%; p<0.001) respectively. Patients enrolled from ES had relatively more complex lesions, and the rate of multivessel diseased and treated were 46.1%, 45.5% and 51.2 % (p=0.03) and 9.5%, 19.4% and 28.0% (p<0.001) across UK, NL and ES respectively. Patients in ES had more bifurcation lesions with rates of 11.5%, 17.6% and 19.6% (p<0.001) in UK, NL and ES respectively. Procedural details showed further differences in direct stenting (31.4%, 31.0% and 43.7%; p<0.001), post-dilatation (59.7%, 41.3% and 30.1%; p<0.001), and total stent length implanted per patient (38.2±26.0mm, 30.3±19.7mm and 28.2±17.4mm; p<0.001) in UK, NL, and ES respectively. Majority of the procedures were performed via radial access in all three countries (87% in UK, 76% in NL and 82% in ES).At 1 year, the TLF rate across the three countries was similar: 2.8% in UK, 2.9% in NL and 2.0% in SP (p=0.49). The rates of any death and cardiac death were 2.0%, 1.0% and 1.8% (p=0.22) and 1.2%, 0.5% and 0.8% (p=0.26), any MI and TV-MI rates were 1.5%, 1.4% and 0.8% (p=0.33) and 0.9%, 0.8% and 0.6% (p=0.79) respectively, in UK, NL and ES. Furthermore the rates of TLR and TVR were 1.2%, 2.1% and 1.3% (p=0.18) and 1.8%, 2.8% and 1.9% (p=0.27). The stent thrombosis rate was 1.0% in UK, 0.8% in NL and 0.5% in SP (p=0.42).

CONCLUSIONS

Although there were significant differences observed in several baseline patients' characteristics and procedural practices, clinical outcomes at 1 year of the Ultimaster DES showed similar outcome in three European countries

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IFR diagnostic accuracy using FFR as gold standard: insights from a five-year experience

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI, Stable CAD, Stents and scaffolds, Left main and multivessel disease, Bifurcation lesion

AIMS

We aimed to analyse the diagnostic accuracy of iFR using FFR as gold standard.

METHODS AND RESULTS

Prospective registry of all patients undergoing functional coronary lesion assessment during 5 years. FFR was used as a gold standard for assessing the diagnostic accuracy of iFR in every patient who underwent measurements with both techniques. The decision was made on an individual patient basis according to the operator's decision. For statistical analysis we used Receiver Operating Characteristics (ROC) curve. The test was undertaken for 2 FFR cut-offs: ≤ 0,80 and <0,75.

Functional testing was undertaken in 326 patients (67±11 years, 65,6% male), encompassing 402 lesions. 154 lesions underwent assessment with both techniques, 222 by FFR only and 26 cases iFR only.

Using an FFR cut-off of ≤ 0,80, the area under the curve (AUC) was 0,73 (95% CI 0,65-0,81). The optimal iFR cut-off point was ≤0,91, with a sensitivity of 55%, specificity of 79%, positive predictive value (PPV) of 52% and negative predictive value (NPV) of 81%. The iFR interval with a sensitivity and specificity > 90% was 0,88-0,94.

Using an FFR cut-off of < 0,75, the AUC was 0,72 (95% CI 0,60-0,84). The optimal iFR cut-off point was also ≤0,91, with a sensitivity of 47%, specificity of 89%, positive predictive value (PPV) of 19% and negative predictive value (NPV) of 97%. The iFR interval with a sensitivity and specificity > 90% was 0,87-0,95.

CONCLUSIONS

Using FFR as a gold standard, iFR had a reasonable diagnostic accuracy, slightly inferior to other published results. The ideal cut-off points were slightly higher than those commonly employed. The use of a FFR cut-off point of < 0,75 mildly diminished the accuracy of iFR, but increased its specificity at the expense of sensitivity.

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OCT tissue coverage and characterisation with grey-scale signal intensity analysis after bifurcation stenting with new-generation bioabsorbable polymer everolimus-eluting stents

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

AIMS

We sought to evaluate optical coherence tomography (OCT)-assessed healing of a novel thin-strut bioresorbable polymer everolimus-eluting stent (SYNERGY EES) after 3-6 months post bifurcation stenting.

METHODS AND RESULTS

Bifurcation stenting is associated with higher rates of adverse clinical events in comparison with non-bifurcation stenting. OCT surveillance including grey-scale signal intensity (GSI) analysis can provide information on vessel wall healing after stenting and can differentiate mature from immature tissue coverage after stent implantation.

Patients receiving bifurcation stenting with a planned two-stent approach using a thin-strut bioresorbable polymer everolimus-eluting stent (SYNERGY EES) and having an OCT surveillance data collected at 3-6 months post stenting follow-up were included in this study. Following administration of intracoronary nitrates, OCT was performed using commercially-available frequency domain OCT imaging system C7XR system, LightLab Imaging, Westford, MA, USA- St. Jude Medical Inc.). Raw data of OCT image acquisitions were collected and sent to a centralized core laboratory (ISAR Center, Munich, Germany). Morphometric analysis of contiguous cross-sections was performed at 1 mm longitudinal intervals within the stented segment (QIvus 3.0.26.0 software). GSI analysis of tissue overlying stent struts was also performed. For each cross-section, the neointimal region of interest (ROI) above each covered stent strut was delineated and 256-level GSI was measured for every pixel within the ROI (Image J software).

Data on a total of 31 vessels from 17 treated patients was available at a mean of 5.1 months post stenting. The mean length of the stented segment was 27.68 mm. The mean minimum lumen and stent area were 5.97±2.97 and 6.67±2.63 mm² respectively. The total number of frames assessed was 869, with a total of 9,975 visible struts. Overall strut coverage was 96.93%, uncovered struts 2.73% and malapposed struts 0.34%. The mean thickness of neointimal coverage was 101±42 µm.

Overall 28 lesions and 7851 neo-intimal region of interests (ROIs) were assessed using GSI analysis. Tissue coverage was classified as mature or immature according to a cut-off value of 91.6. Final analysis of GSI scores will be available for presentation at euroPCR.

CONCLUSIONS

At 3-6 months after implantation of thin-strut bioresorbable polymer EES in bifurcation lesions using a planned two stent approach, antirestenotic efficacy was high and rates of uncovered and malapposed struts was low. GSI data evaluating maturity of tissue overlying stent struts will provide important additional characterisation of vessel healing.

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Ventricular arterial uncoupling predicts adverse cardiac remodeling in patients with myocardial infarction treated with PCI

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

AIMS

The aim of the study was to determine the relationship of adverse remodeling with the left ventricular-arterial coupling (VAC) in patients with MI treated with percutaneous coronary intervention (PCI).

METHODS AND RESULTS

Methods: In 112 patients with MI (64 (57.2%) with STEMI) and PCI (68% male, age 61.1±9.5 years (M±SD), smokers 35%, diabetes 7%, arterial hypertension 83%)2-dimentional echocardiography was performed to assess arterial elastance (Ea) and end-systolic LV elastance (Ees) on admission and in 4 weeks and 6 months. VAC was assessed as the ratio Ea/Ees. Cardiac adverse remodeling was defined by ratio [follow up - initial LV end diastolic volume (LVEDV)] / initial LVEDV more than 20%.**Results:**Baseline LV ejection fraction (LVEF) was 48.2±4.6%, Ea 1.7±0.3 mmHg/ml/m^2, Ees 2.1±0.3 mmHg/ml/m^2, VAC 0.88±0.2. At baseline all patients had LVEF >40% and VAC in optimal (0.5-1.2) range. In 4 weeks after PCI VAC >1.2 was revealed in 24 (29%) patients (33% STEMI), adverse LV remodeling - in 12 (10%) patients, all of them with VAC >1.2. After 6 months VAC ≥1.2 was found in 67 (75%) patients (68.6% STEMI), adverse LV remodeling - in 81 (90%) patients (71.6% with VAC >1.2). Achieved VAC >1.2 was associated with adverse cardiac remodeling (odds ratio 6.16; 95% confidence interval 2.47-15.37; p <0.0005). In patients with achieved VAC >1.2 Ees significantly decreased (from 1.9±0.3 to 1.3 ±0.2 mmHg/ml/m^2, p <0.001) and Ea significantly increased (1.7±0.3 to 2.1 ±0.5 mmHg/ml/m^2, p <0.001).

CONCLUSIONS

In patients with MI treated with PCI impairment of functioning of cardio-vascular system assessed by increased value of VAC >1.2 was revealed 75% of patients in 6 months. Increase of VAC was associated with decrease of Ees and increase of Ea. Increased VAC index >1.2 indicating LV-arterial uncoupling may be considered as early marker of adverse LV remodeling.

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Long coronary lesions treated with overlapping stents: experience from CENTURY II study

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

AIMS

The aim of this study is to compare long term outcomes of patients with long lesion treated with overlap of drug eluting stents in the frame of a randomized controlled trial.

METHODS AND RESULTS

CENTURY II is a single-blind, randomized trial assessing safety and efficacy of new, bioresorbable polymer sirolimus-eluting stent (BP-SES) in comparison with permanent polymer everolimus-eluting stent (PP-EES). Among 1119 patients enrolled, 110 patients had long lesion (defined as ≥ 25mm) treated with overlapping stents, and assigned randomly to treatment with BP-SES (n=57) or PP-EES (n=53). Primary endpoint of the study was TLF at 9 months and 4th year follow-up is currently ongoing. There was no significant difference in baseline patient characteristics between BP-SES and PP-EES group. The mean age was 67.1 and 65.7 years, and 70.2% and 84.9% (p=0.07) were male patients in BP-SES and PP-EES groups, respectively. 19.3% of the patients in BP-SES and 13.2% of the patients in PP-EES presented with acute coronary syndrome. There was no difference in number of treated vessels (1.18±0.38 vs 1.26±0.45; p=0.26) and number of treated lesions (1.40±0.68 vs 1.51±0.80; p=0.45) per patient. At 3 years follow up, the total and cardiac death rates were 5.3% and 3.5% in BP-SES group, being numerically lower than in PP-EES (9.4% and 7.6%) but not reaching statistical significance (P=0.35). There was no difference in rate of any MI (5.3% vs 5.7%; p=0.93), target vessel MI (1.8% vs 5.7%; p=0.28), clinically driven target vessel revascularization (CD-TVR: 10.5% vs 9.4%; p=0.84) and target lesion revascularization (CD-TLR: 5.3% vs 5.7%; p=0.93), for BP-SES and PP-EES respectively. Composite endpoints such as target lesion failure (TLF: 10.5% vs 11.3%; p=0.89), target vessel failure (15.8% vs 15.1%; p=0.92) were following the same trend. There was no stent thrombosis (ST) in BP-SES group up to 3 years, with one case of subacute ST recorded in PP-EES group.

CONCLUSIONS

Patients with long coronary lesions treated with overlapped stents showed good and safe clinical outcomes in both BP-SES and PP-EES groups. Particularly no ST event was observed in BP-SES up to 3 years follow up. This might reflect potential advantages of bioresorbable polymer, as it promotes fast healing and endothelialization process even in the situation of overlap stenting. Follow-up of patients is ongoing and 4-year results will be available at the time of presentation.

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Intracardiac echocardiography enhances diagnostic accuracy in patient with suspected TAVI and other prosthetic valve endocarditis

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THEME: Interventions for Valvular Disease
TOPIC(S): TAVI, Tricuspid / Pulmonary valve, Other valvular and structural interventions

AIMS

Prosthetic valves with a stented design results in difficulties in echocardiography imaging due to shadowing of the stent frame. ICE gives the opportunity to image all valves in a way to overcome the shadowing

METHODS AND RESULTS

During the period ofJanuary 1st 2012 – December 31st 2016 patients with possible PVE and inconclusive TTE and TOE were further examined with ICE**.** Medical records were reviewed to assess clinical status, microbiological etiology, echocardiography, antibiotic treatment, and surgical procedures. Using the modified Duke criteria the ability of ICE to provide a *major (imaging)* criteria was examined.
A total of 37 patients were included of whom 17 patients had a TAVI, 2 had a Melody® valve and 18 had a surgical bioprosthetic or mechanical valve. 6 patients had grown-up congenital heart disease (67% with Tetralogy of Fallot. ICE changed the diagnosis from possible to definite PVE in 19 (51%) patients. Of the remaining patients with possible PVE, 14 (78%) patients were not treated as PVE with one case of relapse within 3 months and 4 (22%) patients were treated as PVE due to clinical considerations.Regarding procedural safety, 6 (16%) of the patients had minor hematoma which healed without sequelae. No pseudo aneurisms were observed.

CONCLUSIONS

In patients with possible PVE, ICE changed the diagnosis from possible PVE to definite PVE in half of the patients with a low frequency of relapse among patients not treated as PVE. ICE is a safe procedure which helps the clinician in the decision of duration of antibiotic treatment and surgical intervention to treat PVE.

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New processes in manufacturing, stent design and post-production control can improve clinically stent outcome

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal, Other peripheral interventions

AIMS

We wanted to investigate if the different steps in stent production and post production control can be optimised, so we receive indeed the"best" available stent for the patients treatment

METHODS AND RESULTS

Methods :
Due to a collaboration of our hospital and the Biomedical Department of a Technical Institute of Paris, France we created different in vitro tests to compare each production step of the most currently used self-expandable nitinol stentsÂ (Abbott Vascular; Bard Peripheral; Boston Scientific; Cordis Cardinal Health; IVascular;Â Medtronic; Terumo).Â
Each stent was examined on differentÂ topics of the production process : ingot & extrusion of the tube, presence of micro channels, effects of electro polish, corrosion,Â Nickel release, Titanium oxide layer, stent design etc.Â
Furthermore was every stent followed by a automoaticalyÂ post production control analysis done by Sensofars Qsix laser fasilitated microscopeResults :Based on these resultsÂ and the technical aspects we could make an overview of likelihood of fracture or device failure of every investigated device what will have a negative effectÂ on the result Â of the interventional procedure.
So balanced radial force and resistance to corrosion will have a positive effect of the restenosis rate
Stent design and quality of the used nitinol will lower the risk of stent fracture
Mimicking vessel anatomy and perfect electropolishing will limit thrombus formationFurthermore willÂ leave an "every"stent inspection and automised control no space left for "damaged" stents that can slip through human randomised control, as is done with the IVasculars Ivolution stent
So the less defects on microscopic Â level, the less influence the stent will have on the outcome.

CONCLUSIONS

We can conclude that the different steps in the production and control proces can have a clinical Â influence in stent outcomeBy optimising this, restenosis and fracture rates can be positively been influenced
Automatic post production control of every stent with the Sensofar Qsix system wil exclude "every damaged" stent

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Assessment of coronary disease comparing with four different images techniques

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Compare the feasibility of 4 different approaches in the angiographic evaluation of CAD.

METHODS AND RESULTS

For such purpose a total of 18 CAD patients and 36 coronary lesions were angiographically evaluated using: 1) nonionic contrast low iodine concentration (I-300) + intracoronary nitroglycerin placebo, 2) I-300 + nitroglycerin, 3) greater contrast iodine concentration (I-370) + nitroglycerin placebo and finally 4) I-370 + nitroglycerin. Results were expressed as mean of each variable and their correlations we also compared the effects of the amount of iodine and of nitroglycerin no difference among the techniques were observed when evaluating the severity of stenosis or the length of the coronary lesions.

Interestingly, the use of I-300 (groups 1 and 2) resulted in smaller values than those observed when using I-370 (groups 3 and 4) for RD and MLD (2.70 vs 2.84 mm, $p = 0.05$ and 1.46 mm vs 1.56mm, $p < 0.05$ respectively). Similarly the use of nitroglycerin (groups 2 and 4) resulted in significant differences when compared with the placebo (groups 1 and 3), for RD (2.84 vs 2.70 $p = 0.05$) and MLD (1.48 mm vs 1.56 mm, $p < 0.05$); the differences became even greater when comparing RD (2.61 mm vs 2.90 mm, $p = 0.05$) and MLD (1.44 mm vs 1.61 mm, $p < 0.05$) between groups 1 and 4.

CONCLUSIONS

non-ionic contrast medium + high iodine concentrations and intracoronary administration of nitroglycerin will result in the assessment of larger vessels leading to short and long term therapeutic implications.

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Coronary angiography, PCI and asymptomatic procedure-related myocardial cell injury

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

AIMS

We sought to explore the occurrence and context of asymptomatic procedure-related myocardial damage within the routine catheterization programme.

METHODS AND RESULTS

We included 220 consecutive patients with stable forms of coronary artery disease or NSTE-ACS with intermediate or low risk.
Cardiac high-sensitivity troponin I (cTnI) concentrations were measured before and after coronary angiography (CAG) with or without PCI. A correlation was performed with a number of clinical variables.
The cTnI elevation above the 99th percentile of the upper reference limit (URL), or above 20% of the initially positive already decreasing values â'â'occurred in 60 (37.2%) patients after CAG and in 45 (76.2%) patients after PCI. Statistical analysis in the subgroup of patients with initially negative cTnI (N = 157) reveals nearly identical conclusions: cTnI elevation above the 99th percentile URL occurred in 43 (36.1%) patients after CAG and 29 (76.3%) after PCI.
A significant relationship of cTnI elevation was find in several variables: volume of contrast ($p < 0.001$), fluorotime ($p < 0.001$), dose-area product ($p < 0.001$), the estimated amount of contrast agent applied directly into the coronary arteries ($p < 0.001$), the total time of balloon dilation ($p < 0.001$), the number of implanted stents ($p < 0.001$) and the total length of the implanted stents ($p < 0.001$).

CONCLUSIONS

An asymptomatic elevation of cTnI is a common finding after diagnostic CAG and especially after PCI. The asymptomatic procedure-related myocardial cell injury besides some presumed variables concerning PCI is surprisingly in context with the amount of contrast agent and X-ray dose.
Registration: clinicaltrials.gov - NCT02960321

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Preliminary results of real-life use of the latest generation of balloon expandable DES in below-the-knee treatment

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THEME: Peripheral Interventions
TOPIC(S): Below the knee

AIMS

We wanted to see if the use of the latest generation of drug eluting balloon expandable stents like the Angiolite could reduce the risk of major amputation and extend the primary patency rate

METHODS AND RESULTS

MethodsThis on going physician initiated, single center prospective follow-up study included all CLI patients of the last 6 months that were treated for limb threating arterial stenotic or occlusive lesions in the below the knee area with drug eluting stents.
We used the newer coronary Angiolite balloon expandable DES (IVascular, Barcelona Spain) for the treatment.ResultsOver more then 20 patients were treated with DES (80 % diabetic, 75 % cardiovascular comorbidity). Average stent amount was 1.2 per artery. Technical succes was100%. In case of ostial lesions and in case of heavy focal calcifications we preferred primary stenting with DES (70 %). We have a preliminary 6-months primary patency rate of 90 %? Compared with our balloonangioplasty group we saw an amelioration in wound healing and reduction in major amputation rate

CONCLUSIONS

The Angiolite balloon expandable DES can safely been used for below The Knee treatmentThe promising short term results needs to be consolidated by longer follow-upFurther investigation is needed to see if the long term results can be sustained in the same way

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Patient-specific 3D-printed cardiac model for percutaneous LAA closure

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

LAA occlusion (LAAO) is an alternative for patients with non valvular atrial fibrillation and contraindication for anticoagulation. We sought to assess the potential of patient-specific 3D-printed models of the LAA for optimizing percutaneous LAAO.

METHODS AND RESULTS

Ten patients with atrial fibrillation who undergoing LAAO were included in this study. To calculate the LAA landing zone (LZ) diameter by 2D-TEE (transesophageal echocardiography), the LAA was scanned from 0° to 135°, and the maximum and minimum diameters of the ostium and LZ were recorded. By fluoroscopy were used the RAO 30°/cranial 20° view. MSCT reconstruction provided images of high quality in either short-axis or long-axis views. We used the mean LAA LZ diameter derived by perimeter in the short-axis view. Multislice Computed tomography (MSCT) images of the heart were segmented, and 3D meshes were created by ITK-Snap (www.itksnap.org). A flexible translucent polyurethane polymer was used for printing the 3D replicas of the MSCT LAA images. Device sizes determined by traditional methods (TEE and fluoroscopy) were compared with device sizes based on data from multiple imaging modalities (TEE, fluoroscopy, and MSCT) plus 3D-printed models. Two specialists blinded to each study participant, used traditional methods (2D-TEE and fluoroscopy) to estimate the size of the device that should be used for each case.

The mean age was 77 ± 5 years, and 70% were male. The most common presentation of atrial fibrillation was permanent (60%). Most of patients had a history of previous stroke (30% hemorrhagic) or TIA (70%). The most common indication for LAAO was relative or absolute contraindication for oral anticoagulation. The mean CHA2DS2-VASc score was 4.5 ± 1.9, and mean HAS-BLED score was 3.3 ± 0.8. The success rate for implantation was 100%. The Amplatzer Amulet and the Watchman devices were used in 90% and 10% of the cases respectively. The sizes of implanted devices ranged from 22 to 34 mm. 3D-TEE presented a high correlation with fluoroscopy and MSCT diameters (r=0.92-0.98: p<0.0001 for all comparisons). In contrast, mean 2D-TEE (21.9 ± 3.8 mm) and fluoroscopy (22.2 ± 3.7 mm) diameter measurements were significantly smaller than those by MSCT (23.1 ± 3.8 mm), p<0.001 and p 0.02 respectively. Devices based on 2D-TEE and fluoroscopy measurements (imaging control-group) would have resulted in up to 30% of patients receiving a smaller device than they actually received during the intervention. On the other hand, all device sizes selected by the 3D printing model were fully consistent with those placed in the real intervention.

CONCLUSIONS

2D measurements of the LAA were smaller than those obtained by 3D-MSCT, and this could affect the size of the device used for LAAO. The 3D- model provided better understanding of the LAA anatomy and it might be used for accurate device sizing,planning of technical strategies with different devices to predict procedural difficulties and can be used to inform patients and colleagues about the aims and limitations of the procedure.

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Do all DEB have equal characteristics before their intraluminal therapeutic use: revealing the myths

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal

AIMS

We wanted to investigate if all drug coated balloons have the same matrix and drug characteristices before they reach their target lesion, we compared them with the new generation Legflow DCB

METHODS AND RESULTS

MethodsDue to a collaboration of our hospital and the Biomedical Department of the German Technical University of Rostock, we created different in vitro tests to compare the most currently used drug coated balloons (Cardionovum, Bard Peripheral; Boston Scientific; Spectranetics ; Medtronic; Biotronik). Each DCB was examined on different topics : dry inflation, introducer valve passage, wash off test, microsopic balloon coverage etcBased on these results and the technical aspects we can conclude that matrix characteristics (hydofilicity, lipofilicity etc) and nano christalyne coverage can have an important influence of the amount of Paclitaxel that reaches the target lesion .
So the less defects on microscopic level and the more stable the matrix , the less influence this will have on the outcome

CONCLUSIONS

The differences between matrix charachteristics will have an important role in the amount of Paclitaxel that will reach the target lesionLatest generation DCBs, like the Legflow DCB from Cardionovum, will bring the highest amounts of Paclitaxel to the lesion

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Rotational atherectomy through the radial artery: success and clinical outcomes

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Our goal was to assess if rotational atherectomy (RA) performed through the transradial approach (TR) is associated with the same rate of procedural success as the femoral access (TF) and evaluate long term clinical outcomes.

METHODS AND RESULTS

Methods: From January 2009 to October 2016, 225 consecutive patients (pts) underwent RA and were retrospectively analyzed (234 procedures). Choice of access was according to the target vessel, need for > 7 Fr guide catheters or bigger burrs and operator experience. TR was used in 149 proc (63%, TR group (gp)) and TF in 89 (37%, TF gp). Mean follow-up was 24±14 months. Procedural success and major adverse cardiovascular events (MACE) were evaluated.

Results: Procedural success was 96% in TR gp and 100% in TF gp (p=NS). Baseline characteristics were similar except for the presence of hypertension (75% in TR gp vs 89.6%, p=0.02), and prior coronary artery bypass graft (4.5% in TR gp vs 13%, p=0.01). In TR gp, smaller guide catheters were used (mean 6.2 vs 6.6 Fr, p<0.001 CI 0.4-0.6), with a mean maximum burr size of (1.4±0.17 vs 1.5±0.2mm, p=0.008, CI 0.02-0.13); DES were implanted in 85% pts vs 81% (p=NS). TF was preferred for the treatment of the right coronary artery (16.7 vs 20.8%, p=0.08) while TR was the choice for the left (83.3 vs 79.2%, p=0.08). In TR, mean maximum stent diameter was 3.2 vs 3.0mm (p=0.005) and mean total stent length was 35.2±16.6 vs 37.3±16.3mm (p=NS). Minor peri-procedural complications were similar in both gps. Crossover from TR to TF was observed in 10.6% of the overall group. In 2009, RA PCI through the TF was more frequent, with a TF/TR ratio of 1.4; since then the ratio was inverted, and in 2016 the TF/TR ratio was 0.25 showing an increasing confidence of the operators in TR. No differences were detected regarding in-hospital/long term all-cause mortality or MACE. It was observed that TR gp had lower target lesion revascularization (TLR) (5.4% vs 11.1%, p=0.001).

CONCLUSIONS

Our data suggest that despite the use of smaller guiding catheters and burrs in equally complex patients, TR was able to achieve a similar procedural success as TF, without increasing peri-procedural complications, and with less TLR. RA via the TR approach is feasible, safe and associated with good long term clinical outcome, with operator experience being decisive.

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Bailout strategies for failed percutaneous mitral valve repair with MitraClip

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

AIMS

We aim to identify the incidence of bail-out maneuvers for failed MitraClip procedures (per-procedural up to 1 month post MitraClip) and to describe different bail-out strategies.

METHODS AND RESULTS

This is a retrospective observational study from the complete MitraClip experience of two Dutch hospitals to identify the incidence of bail-out maneuvers for failed MitraClip procedures and to describe different bail-out strategies. Overall, 325 patients were treated with MitraClip. Seven out of 325 patients (2.2%) required a bail-out maneuver. Most common bail-out strategies were mitral valve surgery (43%) and occluder/plug implantation (43%) followed by placement of additional Clips (14%). Theoretically, bail-out with an direct or indirect annuloplasty could be considered however this wasn't performed in our cohort.

CONCLUSIONS

Bail-out maneuvers for a failed MitraClip implantation are relatively rare but constitute an essential component of a mature mitral valve program. These maneuvers require advanced surgical and catheter-based skill sets.

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Long-term clinical outcomes following TAVI using the CoreValve prosthesis

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

AIMS

The purpose of this analysis was to review the long term outcomes of patients that underwent TAVI using the CoreValve prosthesis as the long- term durability and clinical outcomes of these valves remains unanswered.

METHODS AND RESULTS

The first 94 patients undergoing TAVI (from February 2008 until August 2011) were included in this retrospective analysis to allow a minimum patient follow up of 5 years. Patient demographic, procedural and follow up data was obtained from the national TAVI database and the regional patient electronic care record. Outcomes were reported according to VARC-2 criteria where possible.

Mean transaortic gradients decreased from 46.8mmHg ± 15.1mmHg pre TAVI to 9.8mmHg ± 3.6mmHg at 30 days post TAVI and 9.9mmHg ± 4.6mmHg at 5 years post TAVI. There was one case (1%) of late severe prosthetic aortic regurgitation at 5 years which was not treated with a further invasive procedure due to the patient's comorbidity. One patient showed late moderate stenosis with a mean trans aortic gradient of 26.8mmHg. Four patients had echocardiographic follow up beyond 8 years with no evidence of valve degeneration. The average age at time of implant was 82 years (Range 67-94 years). The average logistic Euroscore was 17.6 (Range 4.3-60.0). All cause mortality rates at 1, 2, 3, 4 and 5 years were 16%, 20%, 30% 45% and 53% respectively. Cardiovascular mortality at 1, 2, 3, 4 and 5 years were 10%, 10%, 12%, 17% and 18% respectively. The most frequent cause of death was recorded as infection (36%, predominantly chest sepsis) followed by congestive cardiac failure (21%). Echocardiography was performed within 1 year of death in 70% of patients (47/67). During follow up, 89% (84/94) of patients had at least 1 unscheduled readmission. There were 112 readmissions for cardiovascular reasons in 54 patients (58%). The most common reason for admission was acute heart failure at 43%, followed by stroke (12.5%), arrhythmia (10%) and need for a permanent pacemaker (9%). There were 175 readmissions for non-cardiovascular reasons in 65 patients (69%). The most common reason was infection (49% of readmissions), followed by falls (21%). Just over a third of patients who had fallen had a fracture diagnosed, with 7 patients sustaining a neck of femur fracture. The overall neurological event rate at 5 years was 14.9% (13 ischaemic strokes and 1 subarachnoid haemorrhage in 12 patients). Five of these occurred within the first year and 1 within 30 days of the procedure. Sixty-six patients were treated with dual antiplatelet therapy for a minimum of 6 months, twenty four with warfarin +/- an antiplatelet and four were treated with a single antiplatelet only. The overall average NT-Pro BNP level pre TAVI was 5602ng/l ± 9140ng/l and 3766ng/l ± 3871ng/l in the group of patients who were still alive at 5 years. The average NT-Pro BNP level of the survivors was 2493ng/l ± 2708ng/l at 5 years.

CONCLUSIONS

In this group of patients, TAVI using the CoreValve has very acceptable 5 year outcomes with respect to prosthetic valve performance, with only 1 case of late prosthetic valve degeneration. Nevertheless, this cohort demonstrates the frailty of the early high risk patients who underwent TAVI, shown by the high number of readmissions and mortality from non-valve related causes.

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Cubital venous access - A new approach for catheter-directed treatment of acute pulmonary embolism

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

AIMS

Catheter-directed therapy of acute massive and submassive pulmonary embolism using cubital venous access offers valuable alternative reducing risk of systemic and local bleeding complications.

METHODS AND RESULTS

Twenty consecutive patients presenting with clinical diagnosis of acute massive (n=7) or submassive (n=13) pulmonary embolism confirmed by computed tomographic angiography were enrolled in the trial. Catheter-directed therapy involved mechanical catheter fragmentation and the application of adjuvant thrombolytic therapy (alteplase; 2.5 mg bolus dose in each main branch of pulmonary artery + 25 mg over 12 hours) through a pigtail catheter. Elevenwomen and nine man (average age 60.9±14.6 years [range, 21-87 years];boby mass index, 30.1±3.6 kg/m^2)participated in the study. Technical success (managing procedure *via* cubital vein) was achieved in all 20 patients. The systolic pulmonary artery pressure improved from 60.9 to 35.2 mmHg ($p<0.0001$). Pretreatment Miller angiographic obstruction score and index decreased from 26.1 and 0.77 to 12.2 and 0.36 post catheter-directed therapy ($p<0.0001$, respectively). There were no major periprocedural complications, major bleeding events, or hemorrhagic strokes.

CONCLUSIONS

Cubital, as once radial in left heart catheterization, offers interesting alternative to femoral or jugular approach in catheter-directed treatment of both acute massive and submassive PE minimizing the risk of access-related complications. Based on our relatively small sample it seems that catheter-directed therapy using cubital approach is technically simple, safe and feasible treatment option.

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The Real-life trial: "real-life" one-year results of the latest generation DEB for femoral and popliteal lesions

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal

AIMS

We wanted to investigate the effect of the latest generation of DCBs on real life lesions including long de novo, restenotic and instent stenosc superficial femoral and politeal artery stenotic disease

METHODS AND RESULTS

Methods
Single centre, follow-up study of popliteal/ superficial femoral artery balloon angioplasty, followed by the Legflow DCB (Cardionovum, Bonn, Germany) for the treatment of real life long, de-novo, restenotic and in-stent stenotic lesions Patient poplulation consist of 140 patients (76 de novo) with 41;4 % of Rutherford Becker 4-6 ând with a mean laesion length of all lesions of 11, 36 cm ResultsFollow-up was done by duplex ultrasound at 1,3, 6 and 12 months
Technical success wa achieved in 98 %,
Six months overall primary patency was 87.9 %, one year > 80 %

CONCLUSIONS

The Legflow DCB used for the treatment of real-life superficial femoral and popliteal lesions showed very good and comparable results to the more ideal randomized control trial lesions.Use of the Legflow DCB showed a sustained benefit for all types of lesions

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Myocardial injury after TAVR comparing self-expandable vs. balloon expandable vs. mechanical expandable valve

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

AIMS

We aim to evaluate the difference in change of high sensitive Troponine T (hsTnT) within 24 hours after TAVI between self-expanding (SEV), balloon expandable (BEV) and mechanically expandable (MEV) transcatheter heart valves.

METHODS AND RESULTS

Overall 1286 consecutive patients who underwent TAVI with a SEV (57%), BEV (32%) or MEV (11%) were included in this multi-center retrospective observational study. In all patients hsTnT (ng/L) was assessed pre-procedural and within 24h after TAVR. Significant myocardial injury was defined as a change in hsTnT of ≥ 20x upper limit of normal. Median hsTnT rise was 732 ng/L and was higher with SEV than with BEV or MEV (853 vs. 664 vs. 341 ng/L, p<0.001). Myocardial injury occurred in 901 patients (70%) and was more frequent with SEV (SEV 75%, BEV 68% and MEV 54%, p=0.001). There was no difference in the occurrence of myocardial injury after implantation of first vs. second generation SEV (75 vs. 77%, p=0.60) and BEV (71 vs. 66%, p=0.34). By multivariate analysis non-MEV (OR (95%CI) 1.716 (1.138-2.587), p=0.010), non-transfemoral access (OR (95%CI) 2.294 (1.118-4.704), p=0.023) higher mean aortic gradient (OR (95%CI) 1.016 (1.006-1.027), p=0.002), left ventricular ejection fraction (OR (95%CI) 1.028 (1.014-1.042), p<0.001), and logistic EuroScore (OR (95%CI) 1.028 (1.012-1.045), p<0.001) were associated with more myocardial injury whereas prior CABG (OR (95%CI) 0.573 (0.370-0.889), p=0.013), history of peripheral vascular disease (OR (95%CI) 0.614 (0.430-0.878), p=0.008), and ≥ moderate aortic regurgitation at baseline (OR (95%CI) 0.364 (0.272-0.486), p<0.001) were protective. The incidence of new left bundle branch block (LBBB) and pacemaker implantation was higher with MEV but was not associated with myocardial injury.

CONCLUSIONS

Transcatheter valve and access selection determine the occurrence of myocardial injury. Myocardial injury is more frequent with SEV than with BEV or MEV.

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Balloon pulmonary angioplasty for chronic thromboembolic pulmonary hypertension. Can we predict reperfusion pulmonary oedema and which patients will respond to this therapy?

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

AIMS

To evaluate safety and efficacy of balloon pulmonary angioplasty (BPA) in inoperable chronic thromboembolic pulmonary hypertension (CTEPH). To determine factors related to reperfusion pulmonary edema (RPE) and those linked to positive response to BPA

METHODS AND RESULTS

Methods: Since May 2013 we have performed BPA in inoperable patients with CTEPH. All patients had severe clinical signs and/or severe hemodynamics under medical therapy. We analyzed baseline characteristics of 45 patients and 149 procedures. We took into account 21 patients with ≥3 BPA procedures to determine BPA efficacy and factors related to good BPA response.

Results: Till January 2017 we have performed 149 BPA sessions in 45 CTEPH non-operable patients (42 distal-type CTEPH). Eight patients had triple pulmonary hypertension (PH) therapy including prostanoids, 19 double oral and 18 single oral therapy. Seven patients more began prostanoids to reduce BPA risk. Mean age was 59.9±15 (SD) years (22-84), 32 females. At baseline most patients were in functional class III (71.4%). We treated 1.2 lobes and 2.2 segmental branches/session. Mean contrast material was 305 mL/session, median X-Ray patient exposure/session 99 Gy/cm^2, mean fluoro time 36 minutes/session and mean session duration time 122 minutes. When we analyzed 21 patients with ≥3 BPA procedures, BPA did produce a significant clinical and hemodynamic improvement during follow-up. Baseline WHO-functional class I/II/III/IV was 0/0/61.5/38.5 % and changed to 15.4/61.5/27.1/0 % (p=0,02); the 6-minute walking test changed from 365±115 m to 429±130 m (p<0.01); mean pulmonary arterial pressure (PAP) 53.5±11.9 vs 38.8± 9.1mm Hg (p<0.01); pulmonary vascular resistance (PVR) 11.8±4 vs 5.7±2.1 W.U. (p<0.01) and cardiac index 2.2±0.5 vs 2.8±0.6 L/min/m^2 (p<0.01), baseline vs follow-up respectively. At the end of the procedures, patients had lower plasma leves of B-type natriuretic peptide, 2015±1711 pg/dl vs 545±803 pg/dl, p<0.01. RPE appeared in 9 out of 145 procedures (6%), one grade 4 and one grade 5. This last patient required mechanical ventilation and extracorporeal membrane oxygenation and finally died as a result of a brain hemorrage (periprocedural mortality 2.2%).

We analyzed factors related to the occurrence of RPE. Mean PAP, cardiac index and PVR before the procedure and, being the first BPA session, were significantly related to the occurrence of RPE according to univariate analysis. Multivariate analysis showed that mean PAP and mean pulmonary wedge pressure previous to BPA were related to the occurrence of RPE (OR 9.92, CI 1.98-49.7, p=0.005 and OR 2.81, CI 1.05-7.56, p=0.04 respectively). We determined also which factors were associated with good response to BPA therapy. By univariate analysis age, cardiac output, level of B-type natriuretic peptide and the number of PH specific drugs, were associated with good response to BPA. Multivariate analysis showed that a younger age and a being treated with a lower amount of PH specific drugs were related to good response to BPA (OR 0.07, CI 0.01-0.97, p=0.042 and OR 0.11, CI 0.02-1.2, p=0.07 respectively).

CONCLUSIONS

In our experience, BPA is an effective therapeutic approach for patients with CTEPH non-operable patients. It improves hemodynamics, functional capacity and biomarkers. Mean PAP and mean pulmonary wedge

pressure previous to BPA are factors related to the occurrence of RPE. A younger age and being on a lower amount of PH specific drugs were linked to good response to BPA therapy.

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Realistic trial: 24-month results and experiences with the latest generation nitinol stent for the treatment of femoropopliteal lesions

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal, Other peripheral interventions

AIMS

We wanted to see what the outcome is of distal superficial femoral and popliteal artery lesions is when they have been treated with the latest generation of selfexpandable nitinol stents

METHODS AND RESULTS

MethodsSingle centre, follow-up study of popliteal/ superficial femoral artery interventions/stenting with the new Smart Flex stent (Cordis, Cardinal Health, US.) 100 patients , with 24 months FU with direct post intervention flexion-angiogram in case of over the knee stenting,ResultsAll patient were had follow up with doppler duplex ultrasound on 1, 3, 6, 12, 18 and 24 months

We saw no fracture, investigated by random fluoroscopic control of aprroximately 50 %

One year primary patency was more then 90 % and even 24 months showed > 80 % with an average laesion length of > 15 cm

CONCLUSIONS

The 24 months results support the use of latest generation of selfexpanding nitinol stents like Cordis Smartflex stent for the treatment of extensive femoropopliteal occlusive disease

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Covered endovascular reconstruction of the aortic bifurcation as treatment of extensive aortoiliac occlusive disease: three-year results

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal, Other peripheral interventions

AIMS

We wanted to investigate if the Covered Endovascular Reconstruction of the Aortic Bifurcation or CERAB as treatment of extensive aortoiliac occlusive disease sustain its excellent 1-year results in the mid term

METHODS AND RESULTS

Methods /2 centre follow-up study (Belgium & The Netherlands) ; > 100 patients with 3 to > 72 months follow-up (mean > 36 months). CERAB made with 3 Atrium Maquet V12/ICast or LifeStream (Bard Peripheral) or Begraft and Begraft Aortic (Bentley) covered balloon expandable stents (through 7 and 9 Fr or as Hybrid procedure with endarteriectomy),ResultsPatients were followed by Duplex ultrasound at 1,3,56;12?18,24, 30, 36 and every half year, in case of doubt a CTangiogram was performed
5 patients died during follow up
we did not have any distal embolization
Primary patenty at 3 years was > 80 %

CONCLUSIONS

Covered endovascular reconstruction of the aortic bifurcation (CERAB) is safe and feasible and seems to be a valid alternative for surgery and/or kissing stents with very promissing and durable mid-term results

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Impact of implant techniques on pacemaker implantation rate using a fully repositionable and retrievable transcatheter aortic valve at a single centre: insights from REPRISE III and REPRISE III Continued Access studies

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

AIMS

To evaluate the impact of implant technique with the Lotus Valve on pacemaker rate at a single centre in the REPRISE III and REPRISE III Continued Access study

METHODS AND RESULTS

A total of 77 patients with severe aortic stenosis, at high or extreme-risk for surgery, were treated with a transfemoral Lotus Valve™ implant (Boston Scientific, Marlborough, MA, USA). There were 3 implant techniques utilised during the study. The first 22 patients were implanted using the traditional Lotus implant technique of deep initial entry and landing the radiopaque marker mid-pigtail. The second 22 patients were implanted using a deep initial entry but targeting implant depth of the bottom of the frame 3-4mm below the annulus. The final 33 patients were implanted by keeping the bottom of the frame at annular level while implanting and targeting a final depth of the bottom of the frame at 2mm below the annulus. Among 77 patients implanted with Lotus, the mean age was 77.9 years and 50.6% were female. The overall pacemaker rate was 16.8%, but there was a significant difference in pacemaker rate based on implant technique. The first 22 patients had a pacemaker rate of 31.8%, the second 22 patients had a pacemaker rate of 18.2% and the final 33 patients had a pacemaker rate of 6.1% (P=0.01 for the trend).

CONCLUSIONS

Adopting a modified implantation technique of the Lotus Valve, specifically, keeping the bottom of the frame at annular level and targeting an implant depth of 2mm below the annulus, may lead to significantly lower pacemaker rates.

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Incidence of conduction disturbances and new permanent pacemaker implantation following TAVR with a repositionable and resheathable self-expanding TAVI system: results from a prospective, multicentre trial

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

AIMS

To examine the incidence and timing of new-onset conduction disturbances and need for new permanent pacemaker implantation in patients undergoing TAVI using the fully resheathable and repositionable self-expanding Portico™ TAVI system.

METHODS AND RESULTS

As part of a prospective, single-arm, multicenter trial 222 high-risk TAVI patients (mean age 83.0 [SD:4.6] years, 74.3% female, mean STS score 5.8%) recruited from 12 sites in Europe and Australia were transfemorally implanted with the Portico™ transcatheter aortic heart valve (23mm, n=50; 25mm, n=52; 27mm, n=60; 29mm, n=60) (St Jude Medical, Minnesota, US). Twelve-lead electrocardiographic data was collected on-site prior to the procedure, during the implant procedure (prior to wire passing through the valve, prior to valvuloplasty, immediately post-valvuloplasty, prior to valve crossing the native annulus, post-valve deployment), post-procedure and at follow-up (discharge, 30 days and 1 year). Following the exclusion of 24 patients with preexisting pacemakers, 198 patients were included in the analyses.Pre-procedure rhythm and/or conduction disturbances were observed in 59 of the 198 patients including atrial fibrillation (20.0%), left bundle branch block (LBBB; 4.1%), right bundle branch block (2.1%) and sinus bradycardia (1.0%). In patients without a preexisting LBBB (n=190), 21 developed new-onset LBBB during the procedure, with the majority occurring immediately post-valvuloplasty (9 of 21; 42.9%). A further 26 patients developed new-onset LBBB between post-procedure and discharge (24.7%). At 30 days, LBBB had resolved in 38 patients, 1 patient developed new-onset LBBB and 4 patients required a new permanent pacemaker.Overall permanent pacemaker rates were 6.3% post-procedure, 13.1% at discharge, 13.5% at 30 days and 14.9% at 1 year follow-up. Of the 198 patients without a preexisting pacemaker who underwent TAVI, new permanent pacemaker implantation was required in 14 patients (7.1%) post-procedure and in an additional 15 patients at discharge (total of 29 of 198; 14.6%). During follow-up, the new permanent pacemaker rate increased marginally to 15.2% at 30 days (n=30) and 16.7% at 1 year (n=33). An acquired Third-degree AV block was the main CEC-adjudicated indication for a new permanent pacemaker (23 of 33; 69.7%). Patients with rhythm and/or conduction disturbances prior to the procedure reported a significantly higher rate of new permanent pacemaker than those with normal sinus rhythm (25.4% vs 12.9%; p=0.03). Implantation of the 25mm valve was associated with a significantly lower rate of new permanent pacemaker post-TAVI. Procedurally, valve implant depth (p=0.50), valve resheathed (p=0.96) and post-implant dilatation (p=0.75) were not associated with the need for new permanent pacemaker.

CONCLUSIONS

Compared to other self-expanding valves, the Portico™ TAVI system demonstrated a low rate of new permanent pacemaker implantation and induction of new-onset LBBB post-procedure. With the exception of pre-procedural rhythm and/or conduction disturbances and valve implant size (23,27 or 29mm), there does not appear to be any intra-operative factors associated with the need for a new permanent pacemaker post-TAVI. Further analysis is required to understand this phenomenon.

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Standardised minimalistic TAVI using the SAPIEN 3 device: stepwise description, feasibility and safety from a large consecutive single-centre single-operator cohort

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

AIMS

In the current study we aimed to describe our updated standardized minimlist approach (MA) for transfemoral (TF)-TAVI using the SAPIEN 3 device, its evolution, and associated safety and efficacy parameters from a large cohort of patients.

METHODS AND RESULTS

A stepwise description of the MA technique for TAVI used by our group for 300 consecutive patients was detailed. Safety and efficacy parameters were assessed using the VARC-2 criteria at the in-hospital and 30-days follow up.

300 consecutive patients (80 ± 7 years; median Logistic EuroSCORE of 11.4% [7.5-17.8]) between January 2014 and May 2016 were evaluated in this study. TF-TAVI was performed under conscious sedation in 247 (82%) patients. VARC-2 device success was achieved in 286 (95.6%) patients, and intended prosthesis performance in 289 (96.3%) patients. Significant paravalvular leak (PVL) graded more than mild was noted in 7 (2%) patients. No patient had severe PVL.

All-cause mortality was noted in one (0.3%) patient in-hospital and in 2 (0.7%) patients at the 30-days follow up. Major stroke occurred in 4 (1.3%) patients. 9 (3%) patients had major vascular complications at 30-days follow up. The VARC-2 composite early safety endpoint criteria were observed in 21 (7%) in-hospital and 25 (8.4%) at 30 days. A new permanent pacemaker implantation was required in 29 (10.7%) patients, and was reduced from 18% to 5.8% (p=0.002) in a subgroup analysis considering higher implantation position of the valve after the first year of experience.

CONCLUSIONS

MA of TF-TAVI, when simplified and standardized, is reproducible, safe and efficient, and should be encouraged to be accepted as the standard way of care.

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Implantation of DES over covered stents: a novel approach to treat coronary aneurysms

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

AIMS

Polytetrafluorethylen (PTFE)-covered stents have been successfully used to seal coronary aneurysms but the high rates of in-stent restenosis (ISR) and stent thrombosis (ST) are worrying.

METHODS AND RESULTS

Between October 2014 and June 2016 five patients with a coronary aneurysm were treated with the implantation of a modern drug eluting stent over a PTFE-covered stent at the Heart Centre Lucerne in Switzerland. After predilatation with a non-compliant balloon, a PTFE-covered stent was implanted to seal the aneurysm. This was followed by the implantation of a DES overlapping the edges of the covered stent. All patients were post-dilated with a non-compliant balloon. Planned angiographic and OCT follow-up was performed after 6 months to exclude ISR and assess vascular healing on OCT.All five patients were treated successfully and no adverse events occurred within 30 days. Planned angiographic and OCT follow-up was performed in all patients and demonstrated good result at 6 months without ISR. OCT demonstrated good vascular healing with a thin layer of neointima and without ISR. After a mean follow up of 376 days all patients are doing well and none had target lesion revascularization.

CONCLUSIONS

We describe a novel method to treat coronary aneurysms using a combination of covered stents and DES. The results are promising and our approach warrants assessment in a larger study/trial.

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Long-term outcomes post-CTO PCI - Is it only CTO success or completeness of revascularisation

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

AIMS

Long term outcomes post CTO intervention are uncertain. We aimed to determine long term outcomes post CTO-PCI and relate them to success of CTO intervention and/or completeness of revascularization in our study group.

METHODS AND RESULTS

Methods:

Consecutive patients taken up for CTO intervention with atleast one CTO vessel between Jan 2006 to Dec 2015 were enrolled from our institute. Clinical, procedural, and follow up details were obtained from a unique individualized data recording software where all patients details were recorded on a day to day basis as a part of routine departmental protocol and an additional attempt was made to complete any missing follow up information through a telephone call made after at least a 1 year gap after the last enrolled case i.e in Dec 2016 for purpose of study. Primary end point of analysis was event free survival (EFS) free of Major Adverse cardiac event (MACE) including death, MI, any repeat revascularization or surgery, or continued significant angina.

Results:

A total of 633 patients were available in the registry with follow up information available in 549 (86%) which constituted the study group. CTO success was obtained in 490 (89.2%) and complete revasularization was obtained in 411 (74.9%). Single, double or triple vessel disease was present in 176(32.1%), 243(44.4%) and 130 (23.7%) respectively. Mean age was 56.6 +/- 8.9 years and 86% were males. Follow up available was a median of 2.33 years with mean +/- SD of 2.94 +/- 2.14 years.

A total event free survival (EFS) was observed in 451(82.1%) patients. Based on success/ failure of CTO intervention EFS was 406 (82.3%) in patients with CTO success and 42 (71.1%) in patients with CTO failure (p=0.02). EFS in complete revascularization(CR)versus incomplete revascularization (IR) group was 84.1% versus 76% (p=0.039). Individual MACE events in CTO success versus failure were not significantly different between the two groups including death (3.4% vs 8.4% (p=NS)). MI (0.2% vs 1.6%, p= NS)), and any repeat revascularization (7.3% vs 8.4%)(p=NS). Continued significant angina was not significantly different in CTO success vs failure, 5.5% vs 8.4% (p= NS) but was significantly higher with incomplete vs complete revascularization, 4.3% vs 10.1 (p=00.02) respectively.

CONCLUSIONS

Successful CTO-PCI confers long term event free survival and the same is better with complete revascularization vs incomplete revascularization.

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Incidence and characteristics of in-stent and in-scaffold fractures: a novel OCT pattern-based classification

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

AIMS

To describe the prevalence of strut fractures within metallic stents and bioresorbable vascular scaffolds according to different optical-coherence tomography (OCT)-patterns.

METHODS AND RESULTS

The reported prevalence of strut fractures in coronary stents and scaffolds varies between 1% and 17%, depending on the definition of strut fracture and the methods used for its identification. We report on the prevalence of each OCT pattern in a multicenter cohort study.

OCT pullback sequences (5 or 10 frames/mm) of 306 patients with previously implanted stents or scaffolds were analyzed. 2D-Qualitative analysis was performed on a frame-by-frame basis, quantitative analysis in 1-mm increments. Fractures were identified based on the presence of one of the following patterns used in previously published papers for the diagnosis of fracture: Pattern 1: one stackedstrut diverging from the normal circular pattern of the stent/scaffold; Pattern 2: 2 or more stacked struts without deformation; Pattern 3: multiple strut fractures in one frame with transection; Pattern 4: gap. Clinical, angiographic and intracoronary imaging data were collected and predictors of strut fracture were investigated.

257 scaffolds and 130 stents of 306 patients (age 62±12 years) were included in the database at 146±337 days after implantation. A total of 40518 frames with 233525 struts were analyzed. 22% of the scaffolds and 27% of the stents presented pattern 1 fractures (p=0.680); 10% and 12% presented pattern 2 fractures (p=0.586); grade 3 and 4 fractures were observed less than 4% of both scaffolds and stents, without difference between groups (p=0.943 and =0.587) and without significant increase beyond 180 days of follow up in the scaffold group (p=0.728). Peri-strut low intensity areas, suggestive of inflammation, showed an association only with pattern 1 (p=0.044). Malapposed and uncovered struts were observed in 59% and 12% without difference between stents and scaffolds (p=0.223 and p=0.112). Fractures were not associated with the presence of microvessels (p=0.558) or malapposed struts (p=0.396).

CONCLUSIONS

The prevalence of strut fractures varies substantially based on the definition used for its diagnosis but not according to the type of device. Only mild associations were observed with signs of inflammation but not with signs of incomplete vascular healing.

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The measurement of FFR with catheter-based equipment results in more PCIs

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

To compare the rates of consequent percutaneous coronary intervention after fractional flow measurement by catheter based equipment (ACIST Navvus® MicroCatheter) and pressure wire based measurement (PrimeWire, Volcano).

METHODS AND RESULTS

For a year 2016, 304 consecutive patients with intermediate angiographic stenosis were examined for functional significance the lesions. In total 448 lesions were interrogated. A 177 patients with 290 lesions were examined with pressure wire and 127 patients with 158 lesions were examined with catheter based FFR. The choice of the method was left to a chance depending on in which angiographic room patient was placed for examination. The two groups were well balanced regarding the baseline risk factors, as well as angiographic characteristics. The rate of consecutive PCI was 7% in pressure wire group and 17% in catheter based group. On univariate analysis significant associates were: diabetes, carotid artery disease, CPK prePCI, number vessel disease, %DS prePCI, SYNTAX score and type of FFR measurement. On multivariate analysis the only independent predictors were SYNTAX score (OR=1.168, CI 1.012-1.384, p=.034) and %DS prePCI (OR=1.062, CI 1.004-1.125, p=.037).

CONCLUSIONS

The type of FFR measurements possibly could influence measured FFR value. A large randomized study is needed to explore this problem.

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Coronary artery calcium scoring as a predictor of peri-procedural myocardial infarction in patients with stable angina

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

AIMS

Severe coronary artery calcification have potential to myocardial damage causing worse clinical outcomes even if successful PCI.

METHODS AND RESULTS

Patients with stable angina undergoing computed tomography coronary angiography (CTCA) before PCI were included retrospectively (n=197, from January 2011 to December 2015). We evaluated relationship between the levels of coronary artery calcium score (CACS) by Agatston scoring system and prevalence of periprocedural myocardial infarction (PPMI) defined by elevation troponin I, above 5 times ULN.The prevalence of PPMI was 18.7% (37 patients). CACS of patients with PPMI exhibited a trend toward a higher CACS (721± 779 vs. 498±842, p=0.142). Prevalence of PPMI showed a good correlation with CACS distribution (10.8%, 1st IQR; 18.9%, 2nd IQR; 29.7%, 3rd IQR; 40.5%, 4th IQR, p=0.026, respectively). The CACS cutoff-value for PPMI was CACS>113, AUC: 0.670; 95% CI: 0.600 - 0.736; p=0.001). Patients with CACS>113 before PCI showed the higher prevalence of PPMI (23.7% vs. 5.6%, OR 5.944; p=0.001). Patient with PPMI was associated with major adverse cardio-cerebrovascular events (21.6% vs. 7.5%, OR 3.402, p=0.010; mean duration 18± 20 months). In present study multivariate analysis demonstrated CACS>113 was main predictor for PPMI (OR 2.370, 95% CI: 1.041 - 5.396, p=0.040).

CONCLUSIONS

This study suggests higher levels of CACS by CTCA is main predictor for PPMI and is associated with worse long term clinical outcomes in patients with stable angina.

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Chronic heart failure: efficacy of renal denervation

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

AIMS

The purpose of this study is to assess the effect of renal denervation (RD) in NYHA class II-IV heart failure (HF) patients treated with optimal drug therapy to increase the distance reached in the six-minute walk test, to decrease BNP values and to diminish cardiovascular death.

METHODS AND RESULTS

Methods: Prospective, multicenter, longitudinal and comparative study. Patients diagnosed with NYHA class II-IV heart failure receiving optimal drug treatment were randomly assigned to RD or continued medical treatment in two tertiary care centers in Venezuela. The six-minute walk test and BNP values were used to evaluated improvement with either treatment modality and cardiovascular mortality was evaluated at the first and third month after randomization.
Sample size was calculated beforehand with a power of 80%, alfa error of 0.05 to detect a difference on 42m in the six-minute walk test as significant. Each group had to be composed at least of 42 subjects. Continuous variables were expressed as mean±SD and compared using the t-test, categorical variables were expressed as percentages and compared with Pearson's chi-squared and Fischer exact test as indicated. A $p<0.05$ was considered as statistically significant.**Results:** Eighty-six patients were included in the study (43 per group). The mean age in the control group was 64±9 years and 57±10 years in the RD group (p=0.231). Fifty-three percent of patients in the RD group and 48.8% in the control group were males (p=0.66). The basal six-minute walk distance in the control group was 302.51±78 m and 296.49± 80 m in the intervention group (p=0.73). In the control group the difference in the distance reached during walking at month 1 and 3 compared with basal was +1m (p=0.721) and -6 m (p=0.059) respectively, while it was +21 m (p=0.76) and +43 m (p=0.001) in the RD group.The basal BNP value was 300±38.81 pg/ml in the control group and 316 ± 63.52 pg ml in the interventional group (p= 0.181). The reduce in BNP in the control group between basal and the first month was 0.06 pg/ml, (p= 0.129) and 0,001 pg/ml at month 3 (p = 1,000), while in the interventional group was 0,30 pg/ml at moth 1 with an additional decrease of 0.17 pg/ml at month 3 (p=0.001).There were 8 hospitalizations (18.6%) in the control group and 2 (4.65%) in the RD group (p=0.047). Two deaths were registered in the control group and none in the RD group (p=0.120). No complication was recorded during the procedure.

CONCLUSIONS

The RD increases the six-minute walk distance and reduce the BNP values and hospitalizations in patients with NYHA II-IV optimally treated.

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A risk model for the prediction of mortality in patients undergoing percutaneous edge-to-edge mitral valve repair: derivation and internal validation of the GRASP nomogram

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THEME: Interventions for Valvular Disease
TOPIC(S): Mitral valve replacement and repair, Other valvular and structural interventions

AIMS

We aimed at combining pre-procedural variables with prognostic impact into a specific risk model for the prediction of 1-year mortality in patients undergoing MitraClip implantation.

METHODS AND RESULTS

A total of 311 consecutive patients undergoing MitraClip implantation were included. A lasso-penalized Cox-proportional hazard regression model was used to identify independent predictors of 1-year all cause mortality. A nomogram (GRASP nomogram) was obtained from the Cox model. Validation was performed using internal bootstrap resampling. Forty-two deaths occurred at 1-year follow-up. The Kaplan-Meier estimate of 1-year survival was 0.845 (95% confidence interval, 0.802-0.895). Four independent predictors of mortality (mean arterial blood pressure, hemoglobin and log-transformed pro-brain natriuretic peptide levels, NYHA class IV at presentation) were identified. At internal bootstrap resampling validation, the GRASP nomogram had good discrimination (area under ROC curve of 0.78, Somers' Dxy statistic of 0.53) and calibration (le Cessie-van Houwelingen-Copas-Hosmer p-value of 0.780). Conversely, the discriminative ability of the euroSCORE II and the STS-PROM was fairly modest with AUC values of 0.61 and 0.55, respectively.

CONCLUSIONS

A treatment-specific risk model in patients undergoing MitraClip implantation may be useful for the stratification of mortality at 1 year. Further studies are needed to provide external validation and support the generalizability of the GRASP nomogram.

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Peri-procedural reductions in left atrial pressure after percutaneous mitral valve repair do not correlate with improvements in symptomatic outcome

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

AIMS

Mitraclip reduces left atrial (LA) pressure but the relationship between this and clinical outcome remains unknown. We evaluated the nature and scope of changes in LA pressures following Mitraclip and their relationship with quality of life measures.

METHODS AND RESULTS

Invasive LA pressures were directly measured pre- and post-Mitraclip in 78 patients at a single UK Tertiary centre. Quality of Life (QOL) scores were evaluated at baseline and 6 weeks after procedure using the EuroQol visual analogue scale. LA pressure was classified as normal if V wave was <20mmHg (**Group 1**), mild-moderately raised if 20-30mmhg (**Group 2**) and severely raised if ≥30mmHg (**Group 3**).

88 patients (median age 77 (range 37 - 93 years, 30 females) at high surgical risk were referred for Mitraclip after Heart Team discussion. MR was significantly reduced across the whole cohort from Grade 3.8 to 1.9 (**P<0.05**) and by >2 Grades in 65 patients, requiring 1.4 clips per patient. Patients with incomplete haemodynamic data were excluded from the analysis.

The median V wave pressure of the entire cohort improved after Mitraclip (28mmHg before vs. 23mmHg after Mitraclip; **p<0.01**) as did mean LA pressure (18mmHg before vs. 14mmHg after; **p<0.01**). However, patients in Group 3 (severely raised LA baseline pressure) were the only group which showed a marked significant improvement in LA pressure after Mitraclip (**Group 3** - median v wave pressure 44mmHg pre-Mitraclip vs. 25.5mmHg following Mitraclip (**p<0.05**). There was no significant change in LA pressure in patients with normal or moderately raised LA pressures (**Group 1** - 15mmhg before vs. 16mmHg after;(p=0.18); **Group 2** - 25mmHg before vs. 23mmHg after;(p=0.19)).

MR grade improved equally and significantly in all 3 groups (**Group 1** – MR grade before 3.9 vs. 2.3 after; **p=0.008**; **Group 2** – MR grade before 3.7 vs. 1.7 after **p<0.05**; **Group 3** – MR grade before 3.8 vs. 1.8 after; **p<0.05**). Despite a significant improvement in LA pressure occurring only in those with severely raised pressures at baseline (**Group 3**), there was an equal and significant improvement of QOL in all groups (**Group 1** - EuroQoL score 50 before vs 67.5 after (**p=0.014**); **Group 2** - 50 before vs. 60 after Mitraclip (**p<0.01**); **Group 3** - 50 before vs. 65 after; (**p=0.004**).

CONCLUSIONS

Mitraclip significantly improves LA pressure in patients with severely raised pressures at baseline. However, reductions in LA pressure do not correlate with reductions in MR grade or improvements in symptomatic outcome. Intra-procedural reductions in LA pressure may be a useful adjunct in guiding the Mitraclip procedure but do not predict early functional outcome.

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Percutaneous ECMO implantation in patients with STEMI complicated with refractory cardiogenic shock

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

AIMS

Optimal management of STEMI patiens complicated with refractory cardiogenic shock is under discussion. Veno-Arterial ExtraCorporeal Membrane Oxygenation (VA-ECMO) is an alternative for these patients in the catheterization laboratory.

METHODS AND RESULTS

We prospectively analyzed patients treated with a percutaneous VA-ECMO from July 2013 (the beginning of the program) to Dec 2016 in our institution.In this period, sixteen consecutive patients with STEMI and cardiogenic shock were supported with a percutaneous VA-ECMO using a Cardiohelp device (Maquet Cardiopulmonary, AG. Germany). The cannulation procedure was exclusively performed, through the femoral vein and artery, by the interventional cardiologist during the primary angioplasty. Mean age was 53±6.1 years and eleven (69%) were men. Mean left ventricular ejection fraction prior to VA-ECMO implantation was 16.7±10%, eight patients had previously suffered cardiac arrest (two patients were cannulated under resuscitation maneuvers) and mean lactic acid levels were 6.1±3.2 mmol/L. The femoral cannula sizes varied between the vein (n=8 21F; n=8 23F) and the artery (n=11 15F; n=2 17F; n=3 19F), and a distal perfusion sheath could be inserted in nine patients. Since the decision to undergo VA-ECMO treatment was made, mean time to beginning of the therapy was 26.5±11 minutes.During the therapy period, five patients developed significant acute bleeding complications. Two subjects, one if them without a distal perfusion sheath, had an acute arterial ischemia (one successfully treated with an upgrade to a central VA-ECMO). Moreover, only 2 patients had renal failure, with no need of dialysis, and pulmonary infections related to intubation status were present in five subjects.Mean patient circulatory support duration was 5.4±3.4 days. During in-hospital stay, two patients died due to refractory ventricular arrhythmias (one after VA-ECMO decannulation, both after an unsuccessful ventricular substrate catheter ablation procedure), one died after development of severe lower limbs ischemia and the fourth patient died after a severe post-anoxic cerebral damage was confirmed (allowing multiple organ donation under VA-ECMO therapy). The other twelve patients survived VA-ECMO support: VA-ECMO weaning was successfully performed in eight and a heart transplantation was conducted in the other four (one under VA-ECMO-therapy, two under a Berlin Heart Excor ventricular assist device and one with a Levitronix® assist device). No neurological significant damage was observed in all survivors, and the twelve patients are still alive after a mean follow-up of 6.2±8.8 months.

CONCLUSIONS

Our initial results support the use of a percutaneous VA-ECMO in the setting of STEMI complicated with refractory cardiogenic shock. This procedure seems to be safely performed by the interventional cardiologist, with a prompt initiation of the therapy and good late results.

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Identification of coronary artery side branch supplying myocardial mass which may benefit from revascularisation

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

AIMS

The amount of subtending myocardium and physiological stenosis is frequently different between MV and SB. To identify coronary side branch (SB) supplying myocardial mass which may benefit from revascularization.

METHODS AND RESULTS

Methods In this multicenter registry, 482 patients who underwent coronary CT angiography and fractional flow reserve (FFR) measurement were enrolled. % fractional myocardial mass (FMM), a fraction of vessel-specific myocardial mass to whole myocardium, was assessed in 5,860 MV or SB consisting 2,930 bifurcations. Physiological stenosis was defined by fractional flow reserve (FFR) <0.80. Myocardial mass which may benefit from revascularization was defined by %FMM ≥10%.

Results In per-bifurcation analysis, MV supplied 1.5- to 9-fold larger myocardial mass compared with SB. Unlike left main bifurcation (N=482), only one out of every five non-left main SB (N=2,448) supplied %FMM ≥10% (97% versus 21%, p<0.001). SB length≥73 mm could estimate %FMM ≥10% (c-statistics=0.85, p<0.001). In 604 vessels interrogated by FFR, diameter stenosis was similar (p=NS) but %FMM≥10%, FMM/minimal luminal diameter, and frequency of FFR<0.80 was higher in MV compared with SB (p<0.001, all). Generalized estimating equations modeling demonstrate that vessel diameter, left myocardial mass, and FFR were not (p=NS) but SB length≥73 mm and left main bifurcation were significant predictors for %FMM ≥10% (p<0.001).

CONCLUSIONS

Compared with MV, SB supplies smaller myocardial mass and showed less physiological severity despite similar stenosis severity. SB supplying myocardial mass of %FMM≥10% which may benefit revascularization could be identified by vessel length≥73mm. Pre-procedural recognition of these findings may guide optimal revascularization strategy for bifurcation.

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Real-time IVUS-guided penetration in stumpless CTO - Outcome analysis

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

CTO with blunt stump and side branch has been identified as a negative predictor for success of PCI. IVUS guided CTO recanalization placed at side branch may be useful to identify the proximal stump and improve the success rate.

METHODS AND RESULTS

The IVUS-guided wiring technique is useful in identifying the entry point of occlusion when the occlusion site is angiographically unrecognizable because of its smooth entrance into the adjacent side branch. 20 consecutive patients (18 males; mean age 56.6 $\pm$ 9.9 years) of CTO with ambiguous stump undergoing PCI from January 2013 to December 2016 were enrolled. Diabetes was present in 6(30%), hypertension in 13(65%), previous MI in 9(45%) with mean left ventricle ejection fraction of 50.9 $\pm$ 7.6%. Left anterior descending artery was most common artery involved in 18(90%) cases and left circumflex artery and right coronary artery involved in 1(5%) case each. Mean J-CTO score was 2.6 $\pm$ 0.9. Bridging collaterals were present in 2(10%), calcification in 8(40%), Rentrop grade 1 collaterals in 4(20%), grade $\geq$2 in 16(80%) cases. All procedures were performed through radial route with 7Fr guide catheter. A 40-MHz IVUS catheter (Atlantis SR Pro®, Boston Scientific, CA, USA) was advanced into the side branch to identify the CTO entry point and the stiffer guidewire was advanced towards the occlusion entry point. With the help of real-time IVUS images the CTO proximal cap was penetrated with stiffer wire. IVUS was placed in diagonal branch in 16 cases, septal branch in 2 cases, conus branch in 1 case and in obtuse marginalis in 1 case. The technical success was achieved in 17(85%) cases. In 3 CTO-PCI failure cases proximal stump was not identified due to calcification at site of occlusion in 1 case, in 1 case there was difficulty in IVUS advancement due to ostial disease and in 1 case distal wire went sub-intimal. Bilateral angiography was done in 11(55%) cases and rest of cases had ipsilateral collaterals. Conquest Pro was the most successful wire for proximal stump penetration in 13(65%) cases followed by Gaia series wires in 3(15%) cases and Fielder XT in 1(5%) case. In 5 cases distal wire went sub-intimal after IVUS guided proximal stump penetration. Parallel wire technique was used in these cases for re-entry into true lumen 5(25%). Mean number of stent deployed was 1.2 with mean stent diameter and length of 3.09 $\pm$ 0.34 mm and 41.8 $\pm$ 11.3 mm respectively. Bifurcation stenting was done in 6(35%) cases. Mean contrast volume used was 309 $\pm$ 110 ml, mean fluoroscopy time was 42.5 $\pm$ 20.8 minutes and mean procedure time of 82.4 $\pm$ 34.8 minutes. PCI related complication occurred in 1 patient (coronary dissection). There was no in hospital mortality or emergent CABG.

CONCLUSIONS

The IVUS guided wire penetration is safe and effective in recanalization of CTO's with ambiguous stump having side branch with good success rate despite having high J-CTO score.

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"Minimalist" cardiac catheter laboratory-based TAVI reduces intensive care and in-hospital length of stay and is as safe as TAVI conventionally performed in theatre under general anaesthetic and with transoesophageal echocardiography. A single-centre experience

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

AIMS
TAVI is conventionally performed in theatre under general anaesthetic (GA). We assessed the impact on safety and length of hospital stay of our move to minimalist TAVI performed in the catheter lab under local anaesthetic (LA) and TTE in our centre.
METHODS AND RESULTS
Methods:
We compared all transfemoral (TF) procedures performed in our centre from 2008 to date. 126 procedures were performed in theatre under GA until September 2015. 119 procedures were performed under LA in the catheter laboratory from October 2015 to November 2016. Median age in the LA group was 83 and in the GA group 86 (*p*=0.001). No statistical difference was seen in female gender (55.5% LA vs 53.2% GA), body mass index (27 LA vs 26.7 GA), previous CABG (24.4% LA vs 24.6% GA), diabetes (16% LA vs 24.6% GA, *p*=0.09), previous stroke (6.7% LA vs 13.5% GA, *p*=0.08), respiratory disease, peripheral vascular disease or severe left ventricular systolic dysfunction (11.8% LA vs 10.3% GA, *p*=0.72). 22 patients (18.5%) underwent TAVI under LA on an urgent or emergency basis compared to 17 (13.5%) in the GA group (*p*=0.29). Median logistic Euroscore was 15.8% in the LA group compared to 16.7% in the GA group (*p*=0.21).

Results:
In-hospital mortality was 1.7% in the LA group vs 2.4% in the GA group (*p*=>0.99). Stroke rate was 0.8% in the LA group vs 2.4% in the GA group (*p*=0.62). No post operative MI was seen in either group. Pacemaker rate was higher in the LA group (11.8% vs 6.4%, *p*=0.14).

None of the patients who underwent TF TAVI in the cath lab under LA spent time in intensive care. Median length of stay for patients who underwent TF TAVI in theatre was 2 days. (0 days LA vs 2 days GA, *p*=<0..001). Similarly, median length of stay in hospital for the LA group was 4 days (*iqr* 3-6) vs 6 days (*iqr* 4-10) for the GA group (p=<0.001).

CONCLUSIONS
In our single centre study, performing TF TAVI in the cardiac catheter laboratory under local anaesthesia and analgesia with TTE reduced length of in-hospital stay. Significantly, none of these patients needed an intensive care bed.
Performing TF TAVI in the catheter laboratory under local anaesthesia is also at least as safe as TF procedures performed conventionally in theatre with TOE and general anaesthesia. The reduced length of in hospital stay, may also have important implications on the overall cost of the procedure per patient.

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Influence of calcification shape around aortic valve annulus on paravalvular leak after TAVI: investigation using patient specific pulsatile circulation model

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

AIMS

We preliminary investigated factors associated with paravalvular leakage (PVL) in six patients after TAVI using pulsatile flow and pressure circulation system with patient-specific calcified aortic valve model.

METHODS AND RESULTS

Based on pre-procedural CT data of six patients who had PVL after TAVI with 23-mm Sapien XT (Edwards Lifesciences), anatomically-equivalent aortic valve model with designed tri-leaflets were developed. The shape and distribution of patients' calcification were reproduced in the model and its mechanical property (maximum elastic modulus) was adjusted to those of referenced human data. In order to duplicate procedural conditions in transfemoral access, elastic patient-specific thoracic, abdominal, and iliofemoral artery models were developed using 3D printing technique.

The valves were deployed in each aortic valve model with the same balloon inflation volume as in the clinical situations. The areas of aortic valve annulus before TAVI and valve stent-frame after TAVI in the models were adjusted to those in the patients by regulating distensibility of the valve models. Each aortic valve model after TAVI was tested in pulsatile flow and pressure circulation. Forward flow and heart rate of each patient in two days after operation were duplicated, and mean aortic pressure was adjusted to 80 mmHg in the circulation. Then, PVL and transvaluvular regurgitation were measured using electromagnetic flow sensor. Moreover, 3D incompletely apposed gap between transcatheter valves and aortic valve were examined using a micro-CT. The PVL volume in each six patient-specific model in the pulsatile flow test was consistent with each PVL grade by echocardiography in the patients. The micro-CT analysis revealed presence of 3D incompletely apposed tracts from aortic to left ventricle side. The minimal cross-sectional gap of the incompletely-apposed tracts had a positive correlation with the PVL volumes (R=0.94).In 5 cases, the plane of the minimal cross-sectional area were present at 2.5±0.2 mm distal from the valve annulus, whereas in one case with small left ventricular outflow tract, the plane was present at 1.7 mm proximal. In 4 cases, the minimal cross-sectional gaps were present in the vicinity of the maximally protruded calcification. In the other 2 cases which had extended calcification from aortic valve to the base of left ventricle outflow tract, the minimal cross-sectional gaps were present around the long axis of oval valve annulus. Pearson's correlation analysis between calcification shape in the patient-specific models and PVL in the pulsatile flow tests showed that the correlation coefficients R were 0.90, 0.68, -0.26, and 0.36 for protrusion height, length in flow direction, width in annular direction, and volume of calcification, respectively. These data suggested that protrusion height of calcification was a significant factor for PVL.

CONCLUSIONS

This study revealed that the minimal cross-sectional gap of the incompletely-apposed tract between the transcatheter valve and aortic valve was associated with PVL volume. The gaps were present in the vicinity of maximally protruded calcification and extended calcification from aortic valve to the base of left ventricle outflow tract. The in vitro pulsatile flow study using patient aortic valve replicas and micro CT analysis suggested that protrusion height of calcification was a significant factor for PVL.

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Detect FFR of epicardial stenosis with guiding catheter disengagement: DISENGAGE study

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

AIMS

During FFR measurement, the simple presence of the guiding catheter might impede the hyperemic flow. We investigated the impact of the selective guiding catheter engagement on serial FFR measurements and related clinical decision-making.

METHODS AND RESULTS

Between October 2015 and December 2016, FFR was prospectively measured in 202 intermediate isolated stenosis (DS 46±10%; MLD 1.6±0.4 mm; RVD 3.0±1.6 mm; LL 15±8 mm) of 173 patients with stable angina (93%), silent ischemia (5%), and ACS (2%, in non-culprit lesion). Stenoses were located on left anterior descending artery (n=124), diagonal branch (n=3), left circumflex artery (n=28), obtuse marginal branch (n=14), intermediate branch (n=5) and right coronary artery (n=28). Patients with diffuse disease, tandem lesions, left main and aorto-ostial stenosis, and culprit lesions of STEMI and NSTEMI were excluded. FFR were measured with a 0.014-inch pressure guidewire (Pressure Wire Certus, St. Jude Medical, St. Paul, MN, US) with intra-coronary adenosine at the dose of 100 µg for the RCA and 200 µg for the LCA. For each stenosis, FFR was measured twice: with the guiding catheter engaged (FFR_{eng}) and with the guiding catheter disengaged (FFR_{diseng}). To assure the quality of the measurements, the equalization was checked with both guiding catheter engaged and disengaged, likewise the position of the wire was filmed to document the stability of the pressure sensor during the manipulation of the guiding catheter.

Overall FFR did not significantly change when re-measured after disengaging the guiding catheter: FFR_{eng}0.84±0.08 vs. FFR_{diseng}0.80±0.08, p=0.92. In 102 stenoses (50%), ΔFFR (FFR_{eng}–FFR_{diseng}) was ≥ 0.04 (twice the value of the test-retest repeatability of FFR). Of interest, in 38 stenoses (22%) whose FFR values were mostly located in the 0.81-0.85 stratum, guiding catheter disengagement was associated with a shift from above to below the clinical-decision making threshold of 0.80.

CONCLUSIONS

Guiding catheter disengagement is associated with a slight albeit non-significant decrease in FFR values overall. Yet, guiding catheter disengagement resulted into a shift of FFR values from above to below the clinical-decision making threshold of 0.80 in 1 out of 5 measurements. Therefore it might be advisable to reassess FFR after disengaging the guiding catheter in case of FFR values close to 0.80.

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Evaluation of the everolimus-eluting BRS in an all-comer cohort with high prevalence of ACS: up to four years of follow-up. First report of a Canadian registry

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

AIMS

Limited data are available on very-long term follow-up (4 years) of patients treated with bioresorbable vascular scaffolds (BVS) in the real-life setting.

METHODS AND RESULTS

Up to150 patients treated with BVS were enrolled in a prospective Canadian registry. Preliminary results of eighty-nine patients are presented for a median follow-up of 1024 days [365-1540]. Patients were 59±11 years old and males in 69%. They had hypertension in 57%, dyslipidemia in 55%, diabetes in 28% and smokers in 55% of cases. Coronary artery disease was already known in 21% with previous myocardial infarction in 14% and previous percutaneous coronary intervention in 16%. Clinical presentation was acute coronary syndrome in 64% of patients. Patients had a single vessel disease in 64% and the left ventricular ejection fraction (LVEF) was 58±8%. Treated lesions (n=112) were type A in 31%, type B1/2 in 63% and type C in 7%. The BVS/ patient ratio was 1.3±0.6. Mean BVS diameter and length were 3.1±0.4 mm and 21.8±5.4 mm respectively. Pre and post dilatation were performed in 96% and 82% respectively. OCT-guided PCI was performed in 19% of cases. Procedural success and device success were 100% and 98%. At one-year follow-up, clinical outcome was favorable with 5.6% target lesion failure. Cardiac death, target vessel myocardial infarction and ischemia-driven target lesion revascularisation occurred in 0%, 1.1% and 4.5% respectively). TLF was significantly lower in the ACS group compared to stable angina group 0% vs. 8%; $p<0.05$). BVS thrombosis rate was 1.1% (one early definite). MACE-free survival using Kaplan-Meier methods shows a high rate of 93.3% up to 4 years of clinical follow-up.

CONCLUSIONS

BVS use in this cohort was associated with high acute procedural success and favorable long term clinical outcomes. Further long term results from randomized trials are warranted to support the conclusion of this study.

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Treatment of left main coronary artery disease with a bioresorbable polymer DES: one-year patient outcomes

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

AIMS

The purpose of this study is to assess the performance of a thin-strut sirolimus-eluting stent with bioresorbable polymer (Ultimaster™) in a subgroup of patients with left main disease.

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 4597 patients enrolled and reached 1-year follow-up, 151 patients were treated in left main (LM) artery, among which 58 patients were treated for isolated LM disease (LM only), 57 patients were treated in LM plus one more vessel (LM+1V), while 36 patients underwent treatment in both LM and two or more vessels (LM+2V). Most of the patient characteristics were similar between these three groups, with a mean age of 69±11years, body mass index of 27.8kg/m^2, 72% had hypertension and 63% had hypercholesterolemia. In the LM only group, there were fewer male patients (57% vs 81% vs 81%, p=0.007) compared to the other two groups, and also less frequently reported family history of heart disease (9.3% vs 30% vs 31%, p=0.03).
Regarding lesion characteristics, 28.1% of patients in the LM only group had lesions longer than 25mm, while more than half the patients in LM+1V (55.4%) and LM+2V (47.2%) had long lesions. In the LM only, LM+1V and LM+2V groups, 75.9%, 74.8% and 70.5% were B2+C lesions respectively, 33.9%, 31.8% and 27.6% had moderate or severe calcified lesion, 0%, 5.3% and 2.8% CTO rate respectively. In the three groups, direct stenting was performed in 35.6%, 34.5% and 44.0% of the lesions, while post dilatation was performed in 55.9%, 47.9% and 38.5% of the lesions. The number of stents implanted per patient was 1.24±0.63, 2.09±1.05, and 2.25±1.57 (P<0.01), and the total length of successfully implanted stent was 23.9±13.6, 45.5±29.0, and 45.7±34.4mm respectively.
By 3 months, one patient died of cardiac cause and one had target vessel myocardial infarction (MI) in the LM+1V group, while no cardiac death or target vessel MI occured in the LM only and LM+2V groups. Only 1 patient in the LM only group had clinically driven target lesion revascularization (TLR) at 3 months, while 1 patient in the LM only group and 1 in LM+2V group underwent target vessel revascularization (TVR) within 3 months. One year clinical outcomes in the three groups (LM only, LV+1V, and LM+2V) are as follows: cardiac death (0% vs 3.5% vs 0%; p=0.19), target vessel myocardial infarction (MI) (0% vs 1.8% vs 0%; p=0.44), clinically driven target lesion revascularization (1.7% vs 1.7% vs 0%; p=0.73), and clinically driven target vessel revascularization (3.5% vs 1.8% vs 2.8%; p=0.85). The composite endpoint of target lesion failure rate was 1.7% vs 7.0% vs 0% (p=0.13) and target vessel failure was 3.5% vs 7.0% vs 2.8% (p=0.55) respectively.
There was no stent thrombosis reported in any of the three LM treated groups at 1 year.

CONCLUSIONS

In complex patients treated for left main artery disease, with or without additional diseased and treated vessels, the Ultimaster™DES showed good clinical outcomes at both 3 months and 1 year, with low rates of cardiac death, target vessel MI and no stent thrombosis. 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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Effects of transendocardial delivery of bone marrow-derived CD133+ cells on quality of life in patients with refractory angina. Randomised, double-blinded, placebo-controlled REGENT-VSEL trial

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

AIMS

Assessment of effects of transendocardial delivery by NOGA of autologous bone marrow-derived CD133+ cells on quality of life parameters in patients with refractory angina.

METHODS AND RESULTS

Methods: Randomized, double-blinded, placebo-controlled trial enrolled 31 patients with recurrent CCS II-IV angina despite optimal medical therapy, ≥ one myocardial segment with inducible ischemia in Tc-99m SPECT who underwent bone marrow biopsy and were allocated to intramyocardial injection of $CD133^+$ cells (n=16) or placebo (n=15). The primary endpoint was the absolute change in myocardial ischemia by SPECT.
Results: There were no significant improvement of cell therapy on extent of inducible ischemia between active and placebo arms but a significant reduction of left ventricle volumes in the cell group vs. placebo. Clinical follow-up was done after 1, 4, 6 and 12 months. There was no difference in number patients showing improvement of at least one CCS class and nitrate use after 1, 4, 6, 12.

CONCLUSIONS

Trans-endocardial CD133+ cell therapy was safe and feasible. The study was limited by low number of patients, however it did not show a significant improvement of quality of life in patients receiving cell therapy.

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Pd/Pa and FFR - Two is better than one

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

AIMS

Recent data suggests that baseline distal-to-aortic pressure ratio (Pd/Pa) may complement or even replace FFR.

This study sought to explore the relation between FFR and Pd/Pa to assess potential clinical implications of combining the two parameters.

METHODS AND RESULTS

A total of 167 vessels with a single stenotic lesion from 130 consecutive patients submitted to FFR assessment in a single center were studied. Only patients with stable angina (54%) or non-culprit vessels in acute coronary syndrome were considered. Baseline Pd/Pa, FFR, clinical and angiographic data were prospectively collected. Angiographic stenosis severity was defined by blinded QCA analysis. Vessels were classified according to Pd/Pa (cutoff 0.92) and FFR (cutoff 0.80) values.

In general Pd/Pa correlated only modestly with FFR (r=0.565; 95% CI: 0.435 to 0.672). Moreover categorical discordancewas observed in 28.7% cases (11.4% vessels with Pd/Pa>0.92/FFR≤0.80 and 17.4% vessels with Pd/Pa≤0.92/FFR>0.80). Discordance was associated with smoking habits ($p<0.05$) and left anterior descending or right coronary artery ($p<0.05$). Consequently no single exploratory Pd/Pa cutoff could predict subsequent FFR <0.8. However, from stenosis with Pd/Pa <0.82 (88.2%, n=17) only 2 (12.8%) developed FFR >0.8. Moreover, combination of Pd/Pa <0.92 and >70% stenosis (9.6% of the overall population) had 87.5% accuracy to predict FFR<0.8. On the opposite end, from 57 vessels (34.1%) with baseline Pd/Pa≥0.96 only 9 (15.8%) progressed to FFR <0.8.

CONCLUSIONS

Currently used Pd/Pa index alone cannot replace FFR. However, in selected cases (such as baseline Pd/Pa ≥0.96 or Pd/Pa<0.92 in combination with stenosis >70%) may obviate the need for FFR in more than one-third of cases. Prospective studies using validation cohorts are needed to confirm these findings.

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Percutaneous closure of LAA in complex anatomies

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

Morphological variability of LAA has been recently described, with some anatomies related to greater emboligen ability.
Percutaneous closure of LAA in complex anatomies performed with Amplatzer devices in one center is described.

METHODS AND RESULTS

54 LAA closures were analyzed, 9 with ACP device and 45 with Amulet.
LAA anatomy was classified into 4 groups (chicken win, cactus, cauliflower and cone).A complex anatomy was defined if one of the following was present: wide mouth of the LAA (landing zone>25 mm), scarce depth (<15 mm), more than one premature lobes, or membrane presence.24 patients presented an unfavorable anatomy; in all of them the closure was succesfully achieved. The mean age was 78 years, with a CHA2DS2VASc score of 2.9 and a HASBLED of 4.1. 35% of patients were under new anticoagulants therapy and 77% had a previous major bleeding.
The mean device size was 24.8 mm and was repositioned in 18 patients (in 11 of them with several tries).One patient presented an echocardiographic image suggesting a thrombus sticked on the Amulet screw at the end of the procedure that was treated with oral anticoagulation during 2 weeks.Complete closure of the LAA was achieved in 96% of cases. There were no complications related to the procedure.

CONCLUSIONS

Percutaneous closure with Amplatzer devices seems to be feasible and sure, with a good adjustment to the more unfavorable anatomies and a good repositioning ability.

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NOAC in patients with atrial fibrillation who are undergoing PCI: a prospective observational study

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

AIMS

In atrial fibrillation (AF) patients with PCI real-word data on novel oral anticoagulants (NOACs) are scarce. We performed a long term follow-up with initial dual therapy (DT; NOAC plus $P2Y_{12}$ inhibitors) and a consecutive NOAC monotherapy.

METHODS AND RESULTS

This is a retrospective analysis of prospectively collected data from 220 AF patients, who underwent PCI at two german centers. After the procedure patients were treated with DT including low-dose NOAC (rivaroxaban n=186, dabigatran n=17, apixaban n=16, or edoxaban n=1) in combination with a P2Y12 inhibitor (clopidogrel n=218 or prasugrel n=2) for 6 months followed by NOAC monotherapy at recommended dose.

Efficacy endpoints included cardiac death, myocardial infarction (MI), stent thrombosis (ST) and stroke at follow-up, while safety was assessed by bleeding events, defined by Bleeding Academic Consortium (BARC).

The mean age of the study population was 74.8 years, 79.1% were males. The comorbidity index was high with 29.5% of the patients being diabetics, 13.1% had previous MI and 10% a previous ischemic event, which resulted in a mean CHA_2DS_2-Vasc Score of 4.3. Indication for PCI was an ACS in nearly 10% of the patients. PCI was complex in most of the patients with a mean of 2.0 stents per patient.

Follow-up was available in 98.2% (n=216/220) of the study population. At a mean follow-up duration of 17.5 months the mean duration of DT was 6.7 months and 11.6 months of NOAC monotherapy. Bleeding complications occurred in 33 of the patients (15.3%). Fatal bleeding (BARC 5) was observed in one patient (0.5%) during DT and did not occur during NOAC monotherapy. Moderate and severe bleeding (BARC 3a, 3b, 3c) occurred in nine patients (4.3%) during DT and in only one patient (0.5%) during NOAC monotherapy.

Efficacy events occurred in 15 of the patients (6.9%). We observed six cardiac deaths (2.8%), two MIs (0.9%) and only one definite ST (0.5%). Stroke occurred in six patients (2.8%), all were ischemic. Ten efficacy events (4.6%) occurred during NOAC monotherapy (five cardiac deaths (2.3%), one MI (0.5%) and four strokes (1.8%)), while five events (2.3%) occurred during DT (one cardiac death (0.5%), one MI (0.5%), one ST (0.5%) and two strokes (0.9%).

CONCLUSIONS

In all-comer AF patients treated with PCI the administration of low dose NOAC plus$P2Y_{12}$ inhibitor followed by normal dose monotherapy with NOAC appears to be safe and effective at long-time follow-up. Bleeding risk dropped after DT, while ischemic events increased during NOAC monotherapy, which might argue for an individualized duration of DT after PCI.

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Uninterrupted reduced dose chronic oral anticoagulation is safe and effective compared to heparin bridging therapy during TAVR

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

AIMS

The optimal peri-procedural antithrombotic strategy for those undergoing TAVI with a prior indication for chronic anticoagulation is unknown and currently guided by consensus. A strategy of uninterrupted reduced dose anticoagulation was evaluated.

METHODS AND RESULTS

A prospective non-randomized consecutive observational analysis from a single center of patients undergoing TAVI with a prior indication for chronic anticoagulation. Uninterrupted therapy with half dose anticoagulation starting 96 hours pre-procedure was compared to conventional discontinuation of anticoagulation with heparin bridging therapy with low molecular weight heparin. Additional antiplatelet therapies were used at the discretion of the attending physicians.

Vascular access was percutaneous bilateral femoral arterial access in all patients. Vascular closure devices were used in all: double Prostar XL for large calibre (14F-20F) arterial access and AngioSeal for the small calibre (6F) arterial access. intra-procedural anticoagulation with unfractionated heparin (aiming for an ACT>250 seconds) was used in all; protamine at the end of the procedure was not used.

A non-adjudicated endpoint consisting of a composite outcome of in-hospital VARC-2 defined bleeding, vascular and stroke complications was used. All-cause mortality at 90 days was evaluated using linkage to a national register.

In a cohort of 302 patients, 107 were taking chronic anticoagulation. Consecutive uninterrupted antithrombotic therapy (n=57) was compared to conventional therapy (n=50). There was no significant difference in the composite endpoint between the uninterrupted and conventional therapy. The non-hierarchical composite endpoint occurred in 12.3% and 23% (p=0.333) respectively, with an adjusted OR 0.74 (0.32-1.75 p=0.50). There was no difference in short-term all-cause mortality at 90 days (HR 0.66 95% CI 0.32-1.35 p=0.271).

CONCLUSIONS

An uninterrupted oral anticoagulation strategy at a reduced dose with intra-procedural heparin during TAVR, appears to be safe and is associated with a similar short-term survival outcome and frequency of in-hospital complications compared to conventional temporary discontinuation of anticoagulation and bridging heparin therapy.

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Final OCT results from the COBRA PzF SHIELD trial: long-term arterial response to a novel coronary stent system with nanothin surface coating for pro-endothelialisation

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

AIMS

This study aimed to assess clinical performance of the COBRA PzF thin-strut (71 µm) cobalt-chromium alloy stent system with novel nano-layer Polyzene-F surface coating which has shown reduced thrombogenicity and inflammation in preclinical studies.

METHODS AND RESULTS

The PzF SHIELD study was the first multicenter, prospective, single-arm, non-randomized trial. To provide mechanistic and biological insights, this trial included an optical coherence tomography (OCT) cohort with prescheduled enrollment of 75 patients. Overall, baseline OCT revealed well-expanded stents with incomplete strut apposition (ISA) only at 3.4% (table). At 9-month follow-up, neointimal coverage was nearly completed, and the majority of post-stent edge tears were resolved. No late-acquired ISA, strut fracture, nor intra-stent thrombus was detected. During the follow-up period, target vessel revascularization (TVR) occurred only in 8.1% of patients. Patients with TVR showed a significantly higher stent over-expansion index (defined as average stent area / smaller reference lumen area) and more frequent edge tears at baseline, compared with no TVR patients (Figure).

CONCLUSIONS

The final OCT results of PzF SHIELD demonstrated excellent device performance with no adverse arterial response, achieving clinical outcomes comparable to current drug-eluting stents with antiproliferative agents. Optimization of procedures to avoid arterial injury at deployment may further improve the long-term clinical outcomes.

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Coronary calcium scoring in patients with Takotsubo syndrome - Is Takotsubo protective against coronary atherosclerosis?

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

AIMS
The aim of this study was to evaluate coronary artery calcium (CAC) score CAC score in patients with takotsubo syndrome.

METHODS AND RESULTS
We included 73 patients diagnosed with takotsubo syndrome at Sahlgrenska university hospital (Gothenburg, Sweden) between 2005 and 2013. All patients underwent CT examination on a multi-slice CT scanner (Siemens Definition Flash). In addition to calcium scoring, we also performed contrast CT angiography (Omnipaque 350 mg/ml, 325 mg iodine/kg) in 43 patients without contraindications. The CT scans were performed during a breath hold and with ECG-gating. Each coronary vessel was identified with a multiplanar reconstruction technique. Calculation of total CAC score was done according to the standard scoring system. The area (mm2) of each calcified lesion was multiplied by a density factor depending on the maximum computed number Hounsfield units (HU) in the lesion; 1= 130-199 HU, 2= 200-299 HU, 3= 300-399 HU and 4= ≥ 400 HU. The total CAC score was determined by calculating the sum of all calcifications in each patient.The mean age was 65.7 years and 9 (12%) were male. The distribution of traditional risk factors for coronary artery disease was similar to age and gender matched population. Successful CT examination was achieved in 72 (99%) patients. Of these, 35 patients (49%) had no calcifications in coronary arteries. The median total calcium score was 1.5. This value is lower than median calcium score (~8) reported previously in healthy volunteers in Sweden. Only 5 patients (7%) had a total CAC score of >400. We found significant stenosis (>50%) in two (4.6%) patients.

CONCLUSIONS
Patients with takotsubo syndrome have low total CAC score. The takotsubo phenotype may confer protection against progression of atherosclerosis in coronary arteries.

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Drop in Pd/Pa after contrast injection during intravenous adenosine-induced hyperemia: effect on FFR classification

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

AIMS

We aimed to investigate if administration of a contrast bolus induced additional drops in the distal pressure/ proximal pressure (Pd/Pa) ratio during intravenous adenosine administration.

METHODS AND RESULTS

Methods: This study was a post-hoc analysis of the Dan-NICAD population (NCT02264717). Consecutive patients (n=362) with positive CT-scans were referred for CAG. FFR was measured during intravenous adenosine infusion at 140 ug/min/kg in all lesions with a 30-90 % diameter stenosis. Increase in adenosine infusion rate was allowed at operator's discretion. An intra coronary contrast bolus was administrated during maximum hyperaemia as determined by the PCI operator with doses per normal clinical practice. All pressure wave-forms were analyzed in a core-lab setting for FFR values and effect of contrast on FFR.

Results: FFR was measured in 292 lesions from 191 patients. Thirteen lesions were excluded due to predefined FFR core-lab criteria. A contrast bolus was administrated during hyperemia in 266 lesions (95 %) with a mean diameter stenosis of 46 ± 11 %. In 93 (35 %) lesions, the contrast injection induced a drop in Pd/Pa. The mean±SD Pd/Pa-drop was 0.03±0.3, thus within the limits for normal variation in FFR measurements based on test/retest data for FFR. Compared to nondiabetic patients, lesions with an additional drop in Pd/Pa more often occurred in diabetic patients (56% vs. 33%, p=0.03) and drops tended to occur more in RCA (46% RCA, 36 % LAD, 23 % LCx, 26 % LM, p=0.07); a predictor of a higher index of microvascular resistance that may attenuate adenosine's vasodilation of the microvasculature. In cases with effect of contrast injection during intravenous adenosine administration, the binary FFR classification (cut off ≤0.80) changed in 9 % of the lesions (3 % of the total lesions with FFR measurement).

CONCLUSIONS

Administration of a contrast bolus during intravenous adenosine administration induced minor additional drops in Pd/Pa in more than 1/3 of the lesions there by changing the FFR classification in a considerable fraction.

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Durability of stroke prevention using routinely the CGuard MicroNET-covered embolic prevention stent system to perform carotid revascularisation in symptomatic and increased-stroke-risk asymptomatic patients: 12-month prospective evidence from the PARADIGM study

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THEME: Interventions for Stroke
TOPIC(S): Carotid stenting

AIMS

CGuard™ MicroNET-Covered stent effectively minimizes cerebral embolization in CAS peri-procedurally and up to 30 days. We aimed to provide prospective 12-month evaluation of CGuard routine use to perform CAS in increased stroke risk patients.

METHODS AND RESULTS

PARADIGM (**P**rospective evaluation of **A**ll-comer pe**R**cutaneous c**A**roti**D** revascularization in symptomatic and **I**ncreased-stroke-risk asymptomatic carotid artery stenosis using C**G**uard™ **M**icronet-covered embolic prevention stent) is a non-industry-funded, prospective academic study in all-referrals-tracked carotid stenosis (CS) revascularization. Independent neurologist evaluation occurred per-protocol before CAS, at 48h, 30 days, and 12 months. Duplex ultrasound (DUS) was at baseline, 30 days and 12 months. There was external source data verification, external angiographic corelab, and external statistical analysis.

Over 11 months,108 referrals were NeuroVascular Team (neurologist+interventional angiologist+vascular surgeon+cardiologist)-recommended for optimal medical treatment (OMT) plus revascularization whereas 31 were labeled for supervised OMT-only (intervention deferral mostly due to absence of increased-stroke-risk features). Carotid endarterectomy (CEA) was performed in 8/114 arteries (7%) while 101 patients (51-86 years, 70% male, 54.5% neurologically symptomatic, 41% diabetics, concomitant CAD in 63%, stroke-in-evolution in 8.9%) underwent 106 neuroprotected (46% - proximal protection by transient flow reversal, 54% - filters) CAS. CGuard use was 100% with no other stents utilized during the study period. In this high-risk patient cohort, in 18% subjects CAS was preceded by simultaneous percutaneous coronary revascularization (one-stage PCI+CAS) or by first-stage PCI as a bridge to CAS at second admission. Baseline CS velocities were 3.7±1.2 (PSV) and 1.2±0.5m/s (EDV). Angiographic diameter stenosis was reduced from 83±9% to only 6.7±5% ($p<0.001$, 'CEA-like' effect of CGuard CAS). Peri-procedural death/major stroke/MI rate was 0%. One event (asymptomatic extension of prior cerebral infarct in a subject with transient haemodynamic compromise, with no change in NIH-SS or Rankin scale at discharge and no clinical sequel) was Clinical Events Committee - adjudicated as minor stroke (0.9%). By 30 days there were no new adverse events (0%). The clinical, neurological and DUS follow-up by 12 months was executed in 100% patients and lesions. Between 30 days and 12 months, there were no stroke deaths or strokes (0%) and no MIs (0%); there was 1 cardiac death due to heart failure exacerbation and 3 non-cardiac deaths (urosepsis, cancer, pulmonary embolism). One asymptomatic in-stent restenosis occurred at 12 months (0.9%); this was treated uneventfully by neuroprotected drug-eluting balloon angioplasty. Six external carotid arteries (ECA) were occluded prior to CAS; 3 severely stenosed ECAs occluded at CAS. CAS-related ECA patency rate was 97% post CAS and at 30 days, and 97% at 12 months. At 12 months, CGuard in-stent velocities were normal (PSV 0.81±0.3; EDV 0.21±0.3m/s).

CONCLUSIONS

The PARADIGM study 12-month clinical and DUS data indicate normal healing and provide evidence for sustained safety and sustained cerebral embolism prevention efficacy of the CGuard™ dual-layer stent used routinely for stroke prevention in unselected symptomatic and increased-stroke-risk asymptomatic subjects with carotid stenosis. This indicates a paradigm shift in carotid revascularization for primary and secondary stroke prevention.

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The impact of coronary CTO on clinical outcome of patients undergoing PCI for unprotected left main disease

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

AIMS

Our aim was to assess whether CTOs have prognostic implications in patients undergoing percutaneous coronary intervention (PCI) for unprotected left main disease (ULMD).

METHODS AND RESULTS

Retrospective multicenter longitudinal study on 235 consecutive patients who underwent ULMD PCI between 2006 and 2010.

The primary endpoint was Major adverse cardiac events (MACE) at 5 years defined as composite cardiovascular mortality (CVM), nonfatal myocardial infarction (MI), target lesion revascularization (TLR) or cerebrovascular accident (CVA) at 5years.The Secondary endpoint was 5 years total mortality.

The study protocol was approved by the local ethics committee.317 patients with LM disease underwent cardiac catheterization and 235 (74%) were treated percutaneous and were included in our study. CTO prevalence was higher in the surgery group (49%vs24%, p=0.001).

The median follow up was 6.3 years (interquartile range 4.5-8.3 years). 38 patients lost to follow up.

No differences in baseline clinical/angiographic characteristics neither in the procedure were observed between CTO group (n=47) and Non-CTO group (n=150) *except* for a higher percentage of males in CTO group(85%vs67%, p=0.017) and, as expected, CTO patients had a lower LVEF (51±15 vs 59±10, p=0.02) and complete revascularization was less frequent achieved (74%vs6%, p<0.001).

The main clinical outcomes were more prevalent in the CTO-group: 5 years CVM (31% vs 7.2%,p<0.001);5 years total mortality (34%vs10%, p<0.001); MACE at 5 years (58%vs29%,p<0.001) and CVA at 5 years (1.4% vs 6.8% p=0.09) but not TLR (14.9% vs 23.9%,p>0.05) nor non-fatal MI (6.7% vs 8.6% p>0.05) at 5 years follow-up. Probable or confirmed stent thrombosis at follow-up was also similar in both groups (4.3%vs2%, p>0.05)

MACE at 5 years was associated to: Presence of a CTO (58.7% vs29.8% p<0.001); Incomplete revascularization (p=0.04); Femoral approach(p=0.005); Bare metal stent (BMS) in left main (LM) (p<0.001); Previous coronary PCI (p=0.058); Diabetes (p=0.01); Age (70.8 ±8.4 vs 67±9.7 p=0.01); Killip at presentation(p=0.02) and EUROSCORE (3.5±0.6vs1.99±1.3 ,p=0.01). The significant independent variables in the multivariate analysis were the presence of a CTO (OR 0.26 95%CI 0.1-0.7); Age (OR 1.06 95%CI 1.009-1.1) and Killip (OR 3.6 95%CI 0.8-16).

Total mortality at 5 years was associated to: Presence of a CTO (31.1% vs 10.1% p<0.001); Incomplete revascularization (p=0.001); Multivessel disease (p=0.06); RCA disease (p=0.007); Femoral approach (p=0.016); No final kissing balloon in bifurcation (p=0.08);No IVUS in LM (p=0.038); BMS in LM(p<0.001); Diabetes (p=0.07); LVEF (47.5±17vs58.4 ± 10, p=0.002); Age (74 ±7.7 vs67.4 ±9.4, p<0.001); Killip at presentation (p<0.001) and EUROSCORE (3.1±0.8 vs 1.99±1.3 , p=0.02) .The significant independent variables in the multivariate analysis were the presence of a CTO (OR 0.09; 95% CI 0.02-0.38); Age (OR 1.1; 95% CI 1.04-1.23) and Killip (OR 3.6; 95% CI 1.04-12.4)

At long term follow-up Kaplan meier curves showed a significant worse prognosis in CTO patients. Total mortality (p=0.004), MACE (p<0.001) and cardiovascular mortality (p<0.001) rates were significantly higher in the CTO-group according to log rank test.

CONCLUSIONS

Coronary CTO is a significant predictor of mortality and MACE in patients with ULMD undergoing PCI

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Abnormal coronary vasomotor reactivity is frequent and associated with altered outcomes in patients with symptoms compatible with myocardial ischaemia at rest

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

AIMS

Abnormal coronary vasoreactivity (ACV) in patients with chest pain at rest remains illknown. We conducted a retrospective study in patients who underwent methylergonovine-based provocative test (PT) to define ACV incidence and its clinical outcomes.

METHODS AND RESULTS

In our center, all patients with chest pain at rest and without significant coronary stenosis (<50%), systematically undergo PT)during conventional coronary angiography. During a 10 year period, ACV was documented in 294 (12.4%) of the 2,379 patients with PT,out of the 13,654 patients undergoing coronary angiography. Compared to the overall population, patients with ACV were more often female (43.9% vs. 30%; p<0.0001), younger (median [IQR], 55 [48-64] years vs. 61 [53-70] years; p<0.0001), and current smokers (37.4% vs. 8.7%; p<0.0001). At admittance, patients with ACV had more frequently a suspected acute coronary syndrome (36.7% vs. 29.0%, p=0.005) or an atypical chest pain (46.3% vs. 21.7%, p<0.0001), compared to patients with normal PT. PTs were mostly well-tolerated (99·6%). Complications (death, non-fatal myocardial infarction (MI), non-fatal stroke, severe ventricular arrhythmias, transient atrioventricular block and delayed coronary spasm) were more frequent in patients with abnormal compared to normal PT (1.7% vs. 0.017%, p=0.009). During clinical follow up (6.4 y, IQR : 3.9 - 9.0y), MACCE (death, MI, stroke, revascularization) occurred more frequently in patients with compared to those without ACV (9.8 vs 3.7%; p<0.0001) despite medical treatment in the former including calcium channel blocking agents (79.8%), antiplatelet therapy (67.3%) and statins (60.5%). Patients with ACV had more frequent MI (4.0 vs. 0.4%; p<0.0001), myocardial revascularization (6.1% vs. 1.11%; p<0.0001) and another occurrence of coronary spasm (9.5% vs. 0.1%; p<0.00001) compared to patients with normal PT at baseline. In addition, cardiovascular mortality tended to be higher among patients with ACV (2.2% vs 1.3%, p=0.061.

CONCLUSIONS

ACV is frequent in patients with myocardial ischemia symptoms at rest and no significant coronary artery disease. PT is a safe strategy to identify a high-risk population for recurrent ischemic events. Optimal management of patients with ACVR deserves further investigations.

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Bioresorbable coronary devices in clinical practice: one-year results of the prospective REPARA registry

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THEME: Coronary Interventions
TOPIC(S): STEMI, Stents and scaffolds, Bifurcation lesion

AIMS

Use of bioresorbable coronary devices in daily clinical practice is still a matter of controversy. There are some concerns about clinical outcomes in specific lesions or clinical scenarios.

METHODS AND RESULTS

REPARA is a multicentre, prospective registry, designed to evaluate the efficacy and safety of the bioresorbable coronary device Absorb® in native coronary arteries in daily clinical practice. Primary objective is MACE at 12 months, including cardiac death, myocardial infarction, target lesion revascularization and stent thrombosis. 2448 patients were included (81% male, mean age 57±11 years), 24% diabetics, whose clinical indication for PCI was ACS in 59.1%, unstable angina in 15.4% and stable angina/silent ischemia in 25.5%. A total of 3370 lesions were treated (1.38±0.7 per patient, 53% in LAD, 21% in Cx and 26% in RCA), mean length of 18.3±9.4 mm. Bifurcations were involved in 18.4% and overlapping devices were required in 16.5%. Predilatation was performed in 78% of lesions, and 1.2±0.5 devices per lesion were implanted (mean length 23.8±13 mm, mean diameter 3±0.4 mm). Postdilatation was performed in 46% of the lesions and intracoronary imaging was used in 11.1% of cases (IVUS in 2.5%, OCT in 8.6%). Procedural success was obtained in 98.9% of the lesions. At 1 year follow-up events were: cardiac death 0.7%, myocardial infarction 2.3%, need for revascularization 3.5% and device thrombosis 1.6%. Univariant analysis found that overlapping devices had significantly higher rates of cardiac death (1.7% vs 0.5%, p=0.015), need for revascularization (6.1% vs 3%, p=0.002) and device thrombosis (3.6% vs 1.2%, p<0.001). Cardiac death was higher in diabetic patients (1.7% vs 0.4%, p<0.001). There were no other significant differences regarding revascularization or thrombosis in patients treated for STEMI, diabetics or in bifurcation lesions.

CONCLUSIONS

Bioresorbable coronary devices in daily clinical practice show a high procedural success rate and a low incidence of MACE at 1-year follow-up. The need for overlapping devices increases significantly the rate of MACE during follow-up.

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Should short-term DAPT be indicated for post-TAVR patients?

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

AIMS

Dual antiplatelet therapy (DAPT) could add benefit of reducing ischemic complication and valve thrombosis in pts who had TAVR. There is a lack of data if those benefits outweigh the risks. We evaluated clinical data comparing DAPT to MAPT

METHODS AND RESULTS

Pub Med, Cochrane databases were systematically searched for clinical studies comparing short-term outcomes of DAPT and MAPT for pts who had TAVR. Primary endpoint was bleeding at 30 days post-procedure. Secondary endpoints included AMI, stroke and all-cause death.We used fixed (I^2 < 55%) and random effect analysis. Total of 5 studies provided 1180 patients (579 in the DAPT and 601 MAPT group). Overall, there was a significant less bleeding events in the MAPT group compared to DAPT (14% vs. 27%, p < 001). There was no significant difference in regards stroke between DAPT and MAPT (2% vs. 2%, p>0.05), AMI (0.5% vs. 0.6%, p>0.05) and all-cause death (4% vs. 4%, P>0.05).

CONCLUSIONS

Our analysis suggests DAPT is not associated with any significant better clinical outcome if not with increased bleeding risks. In- dept analysis with further RTC's should be pursued in order to investigate the long-term outcomes

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Bioresorbable polymer-coated thin strut sirolimus-eluting stent vs. durable polymer-coated everolimus-eluting stent in daily clinical practice: propensity matched one-year results from interventional cardiology network registry

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

AIMS

We sought to determine the 1-year clinical follow-up in patients treated with the thin strut (71um) bioabsorbable polymer-coated sirolimus-eluting stent versus durable coating everolimus eluting stent in daily clinical routine.

METHODS AND RESULTS

Interventional Cardiology Network Registry is a multicenter, all-comers registry of 21 400 consecutive patients treated with primary PCI between 2010 and 2016. We analyzed 7968 patients treated with either a biodegradable polymer coated ALEX™(Balton, Poland) or durable polymer coated XIENCE™ (Abbott, USA) with available one year clinical follow up using propensity-score matching. After propensity score matching 1649 patients treated with ALEX and 1649 patients treated with XIENCE were selected. We evaluated the incidence of overall mortality at 12 month follow-up and composite endpoint of death or myocardial infarction after discharge. Procedural and clinical characteristics were similar between the 2 groups. There was no significant differences between tested groups in procedure related complications and in-hospital mortality (ALEX 2.2% vs. XIENCE 1.9% p=0.17). 30 days mortality was similar in both studied groups (ALEX 0.81% vs. XIENCE 0.31% p=0.06). One year follow up demonstrated comparable mortality (ALEX 3.91% vs. XIENCE 3.53% p=0.57), as well as comparable incidence of composite endpoint after discharge in ALEX group when compared to XIENCE (respectively: 8.62% vs. 7.85%, p=0.43).

CONCLUSIONS

In this multicenter registry, the ALEX thin strut biodegradable polymer coated sirolimus-eluting stent demonstrated comparable clinical outcomes at 1 year after implantation to the Xience everolimus-eluting stent. These data support the relative safety and efficacy of ALEX in a broad range of patients undergoing percutaneous coronary intervention.

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Atrial fibrillation and contraindication for antithrombotic therapy - Will the closure of the LAA be a safe and effective strategy in patients at high hemorrhagic risk?

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

To evaluate the safety and efficacy of percutaneous closure of the left atrial appendage (LAA) for prevention of stroke in patients (P) with non-valvular atrial fibrilhation (AF) and with failure or contraindication for oral anticoagulation (OAC).

METHODS AND RESULTS

Observational, longitudinal and prospective study of 82 consecutive P, submitted to percutaneous closure of the LAA between May 2010 and September 2016. A clinical and imaging evaluation was performed before and after the procedure. The clinical results were evaluated with a mean follow-up time of 21±1.0 months.The sample included 82 P (mean age 74±8 years, 63% male) with a history of AF (permanent in 65%, paroxistic in 30% and persistent in 5%). History of ischemic stroke and severe hemorrhage were observed in 42% and 60% of the P, respectively. The contraindications for OAC were: severe hemorrhage or anemia (65%), high hemorrhagic risk (14%), labile INR (16%) and recurrent embolic events despite therapeutic INR (5%). The mean size of the implanted device was 23.4±3.0mm, with a success rate of 96%. In two P it wasn't possible to close the LAA because of its small size.

There was a major complication during the procedure (cardiac tamponade). In the peri-procedure, there were 8 bruises (9.8%) at the site of venous puncture and one femoral pseudoaneurysm (1.2%). In 7 P minor leaks were detected (8.5%). No device offset or migration or incomplete closure of LAA was verified. There were 4 deaths (3 colon cancer and one of unknown cause). The CHA2DS2VASC embolic risk score was 4.7±1.4 and the HASBLED haemorrhagic score was 3.3±1.0. During clinical follow-up, one P had ischemic stroke at 12 months and two P bleeding complications. We found a reduction of 76% in the rate of cardioembolic events and 54% in predicted hemorrhagic complications in P with AF, compared to the risk estimated by the CHAD2S2VASc and HASBLED scores.

Most of the P with implanted device stayed without antithrombotic therapeutic (96%) or simple antiplatelet therapy (40%) one month after the closure.

CONCLUSIONS

According to our data, in a sample of high-risk ischemic patients with non-valvular AF, percutaneous closure of LAA was considered safe and effective.

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Zotarolimus-Eluting Stent in STEMI (ZES-STEMI): a prespecified prospective register from the DAPT-STEMI trial

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

AIMS

The ZES-STEMI aims to evaluate the clinical outcomes after primary percutaneous coronary intervention (PCI) for STEMI with second-generation zotarolimus-eluting stent (ZES) (Resolute™ and Resolute Integrity, Medtronic, Santa Rosa Ca, USA).

METHODS AND RESULTS

The DAPT-STEMI trial (NCT01459627) is a prospective, randomized, multicentre, international open label trial assessing non-inferiority of a 6 vs. 12 months dual antiplatelet therapy (DAPT) regimen in ST-elevation myocardial infarction (STEMI) patients.

Patients that underwent primary PCI with ZES in setting of MI were enrolled and if event-free at 6 months were randomised to 6 vs 12 months DAPT and followed for 18 months. The ZES-STEMI is a prespecified prospective register that reports the outcomes of the primary endpoint (PE) at 6 months (before randomisation) in the entire study population. The PE is a patient oriented composite endpoint of all-cause mortality, any myocardial infarction (MI), any (unscheduled) revascularization, stroke and TIMI major bleeding (net MACCE) at 6 months. From a total of 1110 STEMI patients enrolled in the trial, 997 received a ZES. Mean age was 60 (SD±10.6) years, male 76%, hypertension 44.5%, hypercholesterolemia 27.3%, diabetes 13%, renal impairment 1.6%, smoking 48.3%, previous MI 5.2% and previous stroke 2.6%. The mean number and length of stents in the culprit lesion was respectively 1.28 (range 1 to 5) and 26 mm. At 6 months the PE occurred in 47 (4.7%) patients. All-cause death, MI, revascularization, stroke and TIMI major bleeding wasrespectively 6 (0.6%), 8 (0.8%), 30 (3%), 0 (0%), and 3 (0.3%). The rate of target lesion revascularizations involving culprit lesion was 1%. The rate of definite stent thrombosis was 0.5%. The rate of both definite or probable stent thrombosis was 0.7% (definitive and more detailed results will be available at Euro-PCR).

CONCLUSIONS

The present analysis is the largest to date reporting outcomes with the ZES stent in setting of STEMI. At 6-months ZES-STEMI Prospective Registry confirms that the safety and the efficacy of this device is outstanding even in this high-risk category of patients.

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The discrepancy between iFR and FFR: associated factors

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

To investigate factors that are associated with discordant measurements between fractional flow reserve (FFR) and instantaneous wave-free ratio (iFR).

METHODS AND RESULTS

Both iFR and FFR were performed in 223 intermediate (40-70%) lesions in 183 patients (159 with stable symptoms, 24 presented with unstable angina or non-ST elevation MI).
The overall correlation between iFR and FFR was strong (r=0,77, p<0,001), yielding a diagnostic agreement of 85,7% for cutoff point of iFR<0,9, FFR 0,8. The weakest correlation was in lesions with iFR between 0,83-0,93. Using hybrid iFR-FFR approach - measuring FFR only in those lesions - would generate diagnostic match of 95,7%. Diagnostic discordance was found in 32 measurements (14,3%), nineteen of which were iFR-positive and FFR-negative, while the remaing thirteen were iFR-negative and FFR-positive. Discordant measurements were significantly higher in post-MI patients (62,5% vs. 26,9%, p=0,002) and in patients taking beta-blockers (75,0% vs. 56,7%, p=0,05). The mean age of patients in the discordant group was significantly lower (63,2±10,6 vs. 68,1±10,2, p=0,02).

CONCLUSIONS

Subgroups of patients with higher discordance between iFR and FFR were identified. More attention is needed to understand possible patophysiological explanations for discordant measurements.

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Outcomes of BRS use for the treatment of bifurcating lesions: global study analysis

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

AIMS

Bioresorbable vascular scaffold (BVS) is demonstrated to be clinical equivalent to drug eluting stents (DES) for treatment of de-novo CAD. We aimed to evaluate the global experience of bifurcating lesion with BVS

METHODS AND RESULTS

We searched Pub Med, Cochrane, Embase for all clinical data reporting outcomes of bifurcating lesions treated with BVS. We reported number of patients, lesions, sex, type per Medina classification and location. Clinical outcomes included 30 days mortality, long-term mortality, stroke, AMI, TLR, scaffold thrombosis and stenting technique. 6 studies provided a total of 415 patients and 466 lesions. 76% of these patients were men. LAD and diagonal were the most common site (> 50%). 51% were true bifurcation. There was 0.5% mortality at 30 days and 1.2 % at long-term follow up (1 year). There was no stroke and 1.4% of AMI. TLR rate was 7.4% and Thrombosis 1.4%. Stenting techniques included V shaped in 1.8% of the cases, T shape in 6.6%, and culotte in <1%

CONCLUSIONS

Our analysis suggests that BVS can safely be used for bifurcating lesions with good clinical outcomes. Its unique characteristics of absorption can prevent the side branched jailing as it occurs with DES

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ICARO trial: Invasive Coronary Angioplasty with bioRresorvable scaffold in saphenOus vein and arterial grafts

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

AIMS

We aim to evaluate long term results of SVG lesions treated with BRS. The SVG PCI is an unresolved scenario. BRS open a new tool with potential benefits: they might reduce distal embolization and they might confer a better long term healing

METHODS AND RESULTS

We present the initial results of a prospective non randomized, all-comers, independent obstervational study, aimed, for a 5 year follow up.

Since march 2014 we have included 23 patients with 24 lesions. Patients were selected only if the size and lesion characteristics were acceptable for BRS implantation; severely and ectasic grafts were excluded. Only 1 (4.2%) was an arterial conduit, a radial graft, the rest were SVG (95,8%). 50% of grats were anastomosed to obtuse marginals, 33.3% to the right coronary artery and 12.5% to diagonal branches. The mean age was 76.25 (65 to 91), 83.2% were male, 37.5% diabetic, 29.2% had intermittent claudication and 12.5 % chronic renal failure. 2 of these lesions were restenotic lesions (8.3%).

All the procedures were succesfull; direct stenting was done in 37.5% and postdilatation in 56.5%; of note, in 25% of cases neither predilatation nor postdilatation were performed. The total rate of complications was 16,7%: 2 no-reflow (8.3%) and 1 slow-flow (4.2%), all of whom recovered to TIMI 3 with adenosine, and 1 distal dissection. The distal protection device was inserted in 60.9% of patients (1 failure); no significant debris was found in any of them.

The mean follow up was 423,21±53,8 days (31 to 916). 18 patients completed 1 year of follow up; among these, there have been 2 MACE (11.2%), with TLR in 1 case (5.6%): one patient presented exertional angina with a severe restenosis of the scaffold and the second was admitted for a suspected unstable angina, but the cardiac catheterizations didn't show any coronary lesion. During the 2nd year of follow up we have observed 3 additional MACE: 2 severe restenosis, one of whom required admission for NSTEMI and one cardiac death, due to an acute pulmonary oedema in a 92 year old patient, who died the day before to invasive coronariography. Only 9 patients have completed the 2nd year of follow up.

CONCLUSIONS

The present data are the initial results of a limited cohort of patients with an aortocoronary graft lesion, mostly SVGs, treated with a BRS. To our knowledge this is the largest series in this scenario. There might be concerns about the need for such exploration, but there are some features that might be seen as an advantage: the capacity to trap the plaque material and reduce periprocedural MIs and a possible more favourable very long term healing of the graft. In this report, we present the follow up data up to 1 year with favourable results compared to historical series. It is evident that such a comparison cannot be assumed, but the first year results, with clinical restenosis and TLR rate of 5.6% seem acceptable.

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BRS expansion impact on acute and one-year clinical outcomes in ACS. A pooled analysis from BVS STEMI First and BVS EXPAND studies

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THEME: Coronary Interventions
TOPIC(S): STEMI, Stents and scaffolds, Bifurcation lesion, Other Coronary Interventions

AIMS

The aim of the study was to assess the impact of bioresorbable vascular scaffold (BVS) underexpansion on acute and one year clinical outcomes in patients with acute coronary syndromes (ACS) treated with bioresorbable devices.

METHODS AND RESULTS

Patient data were pooled from the BVS STEMI First and BVS Expand studies. Device underexpansion was evaluated assessing the final minimal lumen diameter (MLD), the % scaled residual diameter stenosis (%scDS) and the scaffold maximal footprint (MFP). The rates of unsatisfactory final MLD, defined as final MLD below 70% of BVS nominal diameter, were reported. The one-year clinical outcomes were presented.

A total of 285 ACS patients treated with BVS implantation were analyzed. The unsatisfactory final MLD, overall revealed in 95 patients (112 lesions), was associated with a higher rate of myocardial infarction (8.4% vs. 2.6%, p = 0.026) and a numerically higher rate of MACE (8.4% vs. 3.7%, p = 0.087), compared with patients with a satisfactory final MLD. Patients with MACE (n=15) presented with a numerically lower final MLD (2.16±0.50 mm vs. 2.36±0.43 mm, p = 0.098), accompanied by a higher %scDS (32.57±12.96% vs. 24.73±10.75%, p=0.007) and a numerically higher MFP (42.45±10.22% vs.37.82±6.05%, p = 0.103), compared to persons with no adverse clinical events.

CONCLUSIONS

Despite relatively soft lesion morphology, implantation of bioresorbable scaffold in acute coronary syndromes might be associated with device underexpansion. Achievement of satisfactory final minimal lumen diameter is relevant for BVS performance in the acute setting.

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Could the combination of cilostazol with aspirin decrease restenosis rate in patients who received endovascular treatment of femoropopliteal disease?

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THEME: Peripheral Interventions
TOPIC(S): Below the knee, Iliac / Femoral / Popliteal

AIMS

Cilostazol is indicated for the treatment of PAD. Adding cilostazol to the antiplatelet regimen in pts post endovascular therapy might add some benefit but can increase risk of bleeding. We investigated the outcome of combined use

METHODS AND RESULTS

We searched Pub Med and Cochrane for all studies that compared pts post femopopliteal angioplasty who received cilostazol in addition to aspirin. Primary outcome was binary restenosis. Secondary outcomes included amputation, freedom from TLR and all-cause death. We used fixed or random effect analysis. A total of 792 patients (395 cilostazol, 397 non-cilostazol gp). Pts had either/both angiographic or doppler investigation for at 12 months. They were all treated with balloon angioplasty with provisional stenting and kept on aspirin plus a thienopiridine class drug for at least 4 weeks. Primary outcomes analysis disclosed significant less binary restenosis in the cilostazol gp (50% vs. 70%, $p < 0.01$). Secondary outcomes analysis disclosed significantly less freedom from TLR in the cilostazol gp (63% vs. 84%, $p < 0.01$). There was no difference in amputation and all-cause death

CONCLUSIONS

Our analysis suggests that adding cilostazol for 12 months after endovascular treatment of femoropopliteal disease can reduce binary restenosis and TLR

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Percutaneous treatment strategies of femoropopliteal arterial disease: evidence from a network meta-analysis

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal

AIMS

We aimed to compare different percutaneous treatment in pts with femoropopliteal arterial disease.

METHODS AND RESULTS

Method: We included all RCTs comparing different percutaneous strategies through a broad search of published articles. Primary outcomes were TLR and BR. A pairwise meta-analysis was performed by using random effects model, followed by a network meta-analysis (NMA) synthesizing direct and indirect evidence.
Results: A total of 33 relevant RCTs (n = 4851) were included in the analyses. BNS and DCB had significantly lower rate of TLR while CNS and DCB had significantly lower rate of BR compared with PTA. However, no significant differences in TLR were apparent between PTA and CNS, BMS, SES and PES. Similarly, no significant differences in BR were apparent between PTA and BNS, BMS, SES and PES. The use of DCB was significantly associated with lower TLR rates than BNS, PTA and BMS and lower BR rates than BNS, PTA and BMS. There were no significant differences between treatment strategies regarding all cause mortality and major/minor amputation rates.

CONCLUSIONS

In this network meta-analysis, we showed that drug eluting technologies (balloon and stent) were superior to non-drug eluting technologies (balloon, bare stent, covered stent).

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Value of PCI in octagenarians, a prospective study in a large tertiary cardiothoracic centre

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

AIMS

To identify predictors of outcome in octogenarians presenting with STEMI, with the particular aim of identifying patients in whom death was inevitable who might thus be spared a potentially difficult and uncomfortable procedure.

METHODS AND RESULTS

Retrospective cohort analysis of patients over the age of 80 years who underwent PPCI for STEMI in a large tertiary cardiothoracic centre in Hull, UK. Data relating to all patients aged 80 years or over presenting to our institution over a 7 year period (January 2008 to December 2014) was reviewed.Primary outcome measure was all-cause mortality.We identified factors that we thought might be predictors of outcome; we were only interested in factors that might be apparent to the treating physicians at the time of presentation.Following variables: age, sex, blood pressure, heart rate, comorbidities, left ventricular systolic function, site of myocardial infarction, pulmonary oedema, and cardiogenic shock.195 patients aged 80 years old or above who underwent PPCI. Ninety one (46.7%) were women and 104 (53.3%) were men.Mortality was 17.4% at one month, 27.3% at 12 months and 37.2% at 36 months.

CONCLUSIONS

Older age at presentation with STEMI is an independent predictor of long-term mortality in patients with ST-elevation myocardial infarction treated with primary percutaneous coronary intervention. Although primary PCI in the setting of acute STEMI is of proven benefit, the apparent increased mortality in Octagenarians has to be taken into account. We suggest that the care of elderly people presenting with STEMI should be formulated after case review on individual basis rather than putting them through a difficult procedure that can potentially cause more harm than good.

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Acute and late side branch findings after treatment of coronary artery lesions with a novel sirolimus-eluting BRS. A Fantom II substudy

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

AIMS

Bioresorbable stents (BRS) was shown to cause small side branch occlusions due to a large footprint.This study aimed to evaluate the fate of small side branches six months after implantation of the sirolimus eluting Fantom BRS (Reva Medical, USA).

METHODS AND RESULTS

The Fantom BRS was evaluated in the Fantom II study enrolling 240 patients in two cohorts. Angiographic follow-up with optional optical coherence tomography (OCT) was performed at 6 months (Cohort A) or 9 months (Cohort B). The present study was a post-hoc analysis of Cohort A. Number of in-stent side branches of any size were visually evaluated by coronary angiography (CAG) at baseline and follow-up and side branches with pinched ostium was indicated. Baseline and six-months follow-up were matched and compared with a maximum deviation in angiographic projection angle of 10 degrees. All major side branches ≥1.5 mm by visual estimate, were evaluated by 3D-OCT using cutplane analysis to obtain ostial side branch area, ostial side branch flow area and ostial side branch obstruction. Ostial stent footprint was measured using cutplane analysis, bench-modelling and micro-CT scan.

A total of 117 patients were enrolled in cohort A, 100 patients returned for angiographic follow-up and 73 patients had matched OCT-recordings. Preliminary results from the first 66 analysed patients with matched angiograms have shown a mean number of 1.8±1.4 in-stent side branches at baseline and 2.0±1.5 at follow-up (p=0.0003). Further a reduction in number of pinched side branches from a mean of 0.7±0.8 to 0.5±0.6 was observed (p=0.0003). In patients with matched OCT scans 13 patients had an in-stent, jailed side branch ≥ 1.5mm and 8 patients had sufficient image quality both at baseline and follow-up for cutplane 3D-analysis. Maximum ostial diameter was 2.5±0.9 mm at baseline and 2.3±0.8 mm (p=0.18) at follow-up. Ostial area was decreased by 0.6±0.4 mm^2 (p=0.18), and the ostial flow-area was decreased from 4.0±3.7mm^2 to 2.8±3.2 mm^2 (p=0.03) at six months. The ostial stent footprint was 34[28;45]% in vivo and 46% in vitro using a bench model with a proximal main vessel diameter of 2.9 mm and a SB diameter of 2.5mm.

CONCLUSIONS

Despite the larger footprint of BRS it seems that some recruitment of occluded small side branches occurs during follow-up. In side branches ≥1.5 mm we found a reduction in flow area at follow-up due to tissue added at the edges, and on struts in front of the SB ostium. Finalized results are to be presented at EuroPCR 2017.

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Venoarterial ECMO for refractory cardiogenic shock. Immediate and six-month results in 22 consecutive patients

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

AIMS

We report results in a consecutive series of patients with refractory cardiogenic shock undergoing Veno-Arterial ExtraCorporeal Membrane Oxygenation.Particularly we analyzed clinical features,in-hospital and 6-month survival rate,neurological outcome

METHODS AND RESULTS

Out of 50 patients treated with peripheral VA-ECMO between 2010 and 2016, we selected the 22 consecutive patients (56.5% males, 52.0 years median age) with refractory cardiogenic shock. We excluded the remaining 28 patients implanted because of refractory cardiac arrest, and other patients with post-cardiotomic shock in which ECMO was implanted surgically.Shock was caused by acute STEMI/NSTEMI (54.5%), dilated cardiomyopathy (9.1%), myocarditis (9.1%),Tako-tsubo syndrome (4.5%), pulmonary embolism (4.5%), arrhythmic storm (4.5%). In all the 22 cardiogenic shock patients peripheral VA-ECMO was implanted percutaneously with cannulation of femoral vein and artery with Seldinger technique, using 19-23 F arterial cannulas and 23-25 F venous cannulas. A distal reperfusion cannula in the femoral artery was inserted in all patients to avoid leg ischaemia. In most cases ECMO was implanted by interventional cardiologists in the catheterization laboratory, in 12 cases preceding or following primary angioplasty. Nine patients were directly admitted to our hospital, 13 patients were transferred from peripheral hospitals (median distance 32.8 Km). In 6 of these 13 patients ECMO was implanted in the peripheral hospitals by the ECMO team and then patients were transferred with a dedicated ambulance continuing extracorporeal life support with no adverse events. In the twelve patients with coronary artery disease STEMI was the most frequent clinical presentation (75%), with 6 patients (50%) showing critical three vessel disease undergoing multivessel primary PCI, in 10 patients culprit lesion were localized in left main and left anterior descending artery. Twenty patients (90.9%) were also supported also with intra-aortic balloon pump and 11 patients (50%) received continuous renal replacement therapy. At admission mean arterial pressure was 63.0±13.7 mmHg, heart rate 102.7±23.4 bpm, median lactate 6.5 mmol/l, mean SAVE score (Survival After Veno-arterial ECMO) -4.3, median vaso-inotropic score 30. The median duration of ECMO support was 4 days and median intensive cardiac care unit length of stay was 18 days. In hospital survival rate was 72.7%, with one patient dying of intestinal ischaemia and five of irreversible multi-organ failure. In survivors ECMO was used as a “bridge to recovery” in 14 cases (87.5%), as a “bridge to transplantation” in 2 cases (12.5%). Leg ischaemia, treated with Fogarty catheter embolectomy, occurred in 2 patients (9%), intestinal ischaemia occurred in 3 patients (13.6%). Six-month survival rate was 63.6%, with two patients dying of cerebral hemorrhage waiting for cardiac transplantation. Survivors showed a good neurological outcome, assessed as cerebral performance category scale 1-2 at 6 months, 12 patients (75%) showed a good functional status (New York Heart Association class I-II) at 6 months.

CONCLUSIONS

Pharmacological support is often not sufficient to assure a valid haemodinamic support in refractory cardiogenic shock. Rapid percutaneous implantation of ECMO should be considered in these patients, with treatment possible also in centers with no cardiac surgery dispatching a dedicated ECMO team

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Impact of implantation depth on haemodynamics after transcatheter aortic valve-in-valve replacement using self-expanding device: a single-centre experience

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

AIMS

Valve-in-valve TAVI is an interesting therapeutic option for high-risk surgical patients with degenerated bioprosthesis. We aimed to evaluate the effect of implantation height of self-expanding prosthesis on hemodynamics in aortic valve-in-valve.

METHODS AND RESULTS

Cases from a single center experience with self-expanding prosthesis for valve-in-valve TAVI were retrospectively analyzed. Early postimplantation hemodynamic data were obtained with intraprocedural transesophageal echocardiography. Elevated postprocedural gradients were defined as mean ≥20 mmHg. Implantation depth values were obtained from fluoroscopic images of each case after the prosthesis was implanted in its final position. Optimal implantation depth has been defined in the range of 0- to 5-mm deep for self-expanding prosthesis.

Between October 2015 and November 2016, a total of 6 patients with failing stented aortic bioprosthesis underwent transcatheter valve in valve implantation via femoral approach, (aged 82,83 ± 6,7 years; Society of Thoracic Surgeons score 7,36 ± 3,42). Bioprosthesis mode of failure was stenosis for 5 (83%) patients, and severe regurgitation combined with moderate stenosis in 1 (17%) patient. Surgical valves were small (label size ≤21 mm) in 2 (33%) cases. No one presented prosthesis-patient mismatch of the surgical valves. At baseline 5 (83%) patients had a preserved left ventricle ejection fraction (≥60%) and it was reduced (40%) in one of them. All patients were highly symptomatic before TAVI; 4 patients (66%) were in New York Heart Association functional class III/IV. All underwent valve-in-valve TAVI procedure with self-expanding device: 29 mm (n=1), 26 mm (n=1) and 23 mm (n=4). The mean implantation depth of the prosthesis was of 4,92±1.37 mm and mean postprocedural gradient was of 17,17±3.76. 2 patients (33%) presented postprocedural mild stenosis with mean gradient ≥20 mmHg (respectively 20 and 22 mmHg). At baseline, one of them had reduced left ventricle ejection fraction and the other presented severe bioprosthetic valve regurgitation. After the procedure, paravalvular aortic regurgitation was absent or mild in all patients. None of the patients required implantation of the pacemaker before discharge. The 30-day mortality was 0%; 5 (83%) patients were at New York Heart Association functional class I/II and 1 (17%) was readmitted at the hospital in NYHA class IV. One-year follow-up was obtained in 4 (66%) patients, with 100% survival; mean aortic valve gradient was unchanged and paravalvular aortic regurgitation was reduced

CONCLUSIONS

The highdevice position for valve-in-valve TAVI might help in achieving optimal hemodynamics postprocedure, and in reducing the likelihood of valve underexpansion, which impair device durability. Therefore, baseline mechanism of surgical valve failure and the type of transcatheter aortic device may also influence valve-in-valve hemodynamics.

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Comparison of endovascular aneurysm repair and open surgery for elective and ruptured AAA: meta-analysis of randomised clinical trials

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THEME: Peripheral Interventions
TOPIC(S): AAA

AIMS

Endovascular Aneurysm Repair (EVAR) is a newer treatment option for patients with abdominal aortic aneurysm (AAA) with suitable anatomy. We evaluated the clinical outcomes of EVAR and open surgery for elective and emergent treatment of AAA.

METHODS AND RESULTS

Pub Med and Cochrane databases were systematically searched for all randomized clinical trials (RCT's) comparing the outcomes of EVAR and surgery for elective and emergent (ruptured aneurysm) treatment of AAA. We combined overall results of these two sub-analysis. Primary endpoint was mortality at 30 day. Secondary endpoints included cardiac complication, stroke and mean hospital stay.We used fixed ($I^2 < 50\%$) or random effect analysis. Total of 9 RCT's were included. 5 RCT's for elective AAA repairprovided 2,912 pts (1,533 EVAR; 1,379 surgery), 4 RCT's on emergent repairincluded a total of 868 pts (444 EVAR; 424 surgical). There was significant less mortality in the EVAR group compared to open surgery for elective AAA repair (1.1% vs. 3.3%, $p<0.01$). Among pts treated for ruptured aneurysm, there was no mortality difference (32% vs. 36%, $p=0.2$). There was no difference in cardiac complications and stroke. Hospital stay was significant less in EVAR grou

CONCLUSIONS

Our analysis suggest that use of EVAR for pts with AAA can lead to good outcomes not only for elective repair but also for ruptured aneurysms. Ruptured aneurysm patients carry higher mortality rate therefore survival benefit from EVAR might not be achieved.

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Rate and type of complications after LAA occluder implantation

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THEME: Interventions for Stroke
TOPIC(S): LAA closure

AIMS

To establish mid-term and long-term results after left atrial appendage (LAA) occluder implantation: thromboembolic incidence and rate of any LAA occluder related complication.

METHODS AND RESULTS

Study included 11 consecutive patients with atrial fibrillation with contraindication to or impossibility of oral coagulation. Average age 63,27±8,82 years old, CHADS-VASc 3,18±0,98. All patients underwent Amplatzer Plug LAA occluder implantation. Follow up was set for 3 and 12 month. All patients were controlled by transesophageal echo. All 11 patients had successful acute implantation results with optimum fluoroscopic position of LAA occluder without leaks at transesophageal echo. No complication registered at the in-hospital stay of the patients. At 3 month follow up 2 patients had dislodgements of LAAO (18.18%). 1 patient has LAA occluder lobe dislodgement in proximal direction with formation of 3 mm leak. Disk was still covering entrance to the appendage at original position. 2-nd patient has dislodgement of a Disk-part in to distal direction of appendage, when the upper part of a disk slept under the ridge. Above the Disk was registered pannus formation, which is recalling previous Disk position, when it was covering the main part of the ridge. We could describe triangle formation, with is build by Pannus, Disk surface and the ridge. At the end of observation none of the patients had thromboembolic complication. 10 patients were taking acetylsalicylic acid, 1 patient with pannus formation was taking rivaroxaban.

CONCLUSIONS

LAA occluder implantation is procedure with low perioperative complication rate. But some LAA occluder position alternations were mentioned in a follow up period with rate of 18% in this patients group setting. Pannus formation needed continued anticoagulation in our opinion.

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Functional difference of left circumflex artery ostial lesion between jailed and non-jailed status assessed with FFR

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

AIMS

Although left circumflex artery (LCX) ostium is Achilles heel of PCI, functional significance of ostial lesion after left main crossover stenting is unclear. The aim of this study is to clarify functional difference between jailed and non-jailed LCX.

METHODS AND RESULTS

Consecutive patients with the lesion in LCX ostium evaluated with fractional flow reserve (FFR) between 2010 and 2016 were included in this study. Ostial lesion was defined as the localized lesion <5mm from the bifurcation carina. Eighty-five patients with jailed side branch (51 single stent and 34 two stent technique) and 25 patients with non-jailed side branch (*i.e.* de-novo lesion) ware assessed because of angiographic diameter stenosis >50%. the patients characteristics and demographics were not different between two groups. FFR was significantly lower in jailed group; 0.87±0.11 vs 0.92±0.05 ($p = 0.039$). Positive FFR defined as <0.80 was observed in 18/85 (21.2%) patients in jailed group and 1/25 (4%) patients in non-jailed group ($p < 0.01$). There was no significant difference between single and two stent technique regarding FFR value and frequency of posotive FFR (0.86±0.12 vs 0.87±0.12, $p = 0.88$, 11/51 vs 7/34. $p = 0.91$).

CONCLUSIONS

The functional significance of LCX ostial lesion after left main coronary artery bifurcation stenting with cross-over technique was much greater than de-novo LCX ostial lesion. Physiological assessment with FFR is reliable guidance to perform or not the additional treatment for the jailed LCX ostial lesion.

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Severe mitral regurgitation: impact of edge-to-edge repair in symptoms, quality of life and prognosis

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

AIMS

We aim to assess the impact of this technique in symptoms, quality of life and prognosis.

METHODS AND RESULTS

Single center prospective registry of consecutive patients undergoing percutaneous mitral valve repair with the MitraClip system from 2013 to 2016. All patients underwent a standardized clinical follow-up including symptom assessment with the NYHA class, and quality of life assessment with the Minnesota Living with Heart Failure Questionnaire (MLHFQ). For assessing the impact on prognosis, we estimated mortality at baseline with the Cardiac and Comorbid Conditions Heart Failure (3C-HF) score. We used a primary composite endpoint of death of any cause or hospital admission due to heart failure. Individual components of this endpoint were used as secondary endpoints. For statistical analysis we used the T student test, Chi-Square test, Kaplan-Meier survival analysis and Receiver Operator Characteristics (ROC) Curve.33 patients (mean age 71 ± 13 years, 18 male) underwent MitraClip implantation. All had severe MR (III or IV out of IV). 16 (48,5%) patients had primary MR, 4 (12%) secondary MR and the remaining mixed MR. The mean ejection fraction (EF) was 39 ± 17%. The success rate of the procedure was 97%, with a complication rate of 3% (1 case of chordal rupture).

During a mean follow-up of 354 ± 201 days, there was a significant improvement of the NYHA class after the procedure, both short-term (3,2 ± 0,6 vs 2,1 ± 1,0, p < 0,001) and also between the immediate follow-up and 6 months (2,1 ± 1,0 vs 1,7 ± 0,8 p = 0,003). There was also a significant improvement in quality of life, as the MLHFQ score more than halved (56 ± 18 vs 24 ± 17, p < 0,001).

Regarding prognosis, there were 7 deaths (21,2%) and 7 admissions due to heart failure (21,2%). 30,3% of patients reached the primary endpoint. Patients who reached the primary endpoint had a higher NYHA class (2,5 ± 0,6 vs 1,5 ± 0,6, p = 0,035) and lower ejection fraction (30 ± 11% vs 43 ± 17%, p = 0,037). ROC curve analysis identified an ejection fraction < 30% as the cut-off point with the highest accuracy for the primary endpoint occurrence (area under the curve = 0,72; sensitivity 80,0%; specificity 64,0%, positive predictive value 50%, negative predictive value 88%). Kaplan-Meier analysis confirmed that an ejection fraction < 30% was strongly associated with the occurrence of the primary endpoint (LogRank = 4,175; p = 0,041).

The predicted mortality at 1-year with the 3C-HF score was 48,1%. As a result, there was a statistically significant reduction of 9 deaths at 1-year overall (p = 0,015).

CONCLUSIONS

In a real world, single centre cohort, percutaneous mitral valve edge-to-edge repair yielded a significant and sustained symptomatic improvement. In addition, as based on the mortality risk of this particular population, the 1-year prognosis also improved. This major survival benefit should be properly confirmed in randomized controlled trials.

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A novel technique for the effective local application of micro-RNA inhibitors prevents neointima formation while enhancing endothelial regeneration

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

AIMS

Here, we propose that targeting micro-RNA-146a might be an attractive approach to enhance endothelial healing, while effectively preventing smooth muscle cell proliferation, thereby limiting angioplasty-related complications.

METHODS AND RESULTS

Micoarray analysis revealed a significant and robust upregulation of miR-146a at 10 days and 21 days following wire-induced injury in C57BL6/N mice. The inhibition of miR-146a *in vitro* led to opposing effects in endothelial (EC) and vascular smooth muscle cells (VSMC): EC proliferation and migration was enhanced (100 % vs 141.90 % vs. 100 %; $p<0.05$ and 153 % vs. 100 %; $p<0.05$) whereas VSMC proliferation and migration was reduced (63 % vs. 100 %; $p<0.05$ and 70 % vs. 100 %; $p<0.001$), respectively. Vasorin, a transmembrane protein, mainly expressed in VSMC, was verified as a direct target mRNA of miR-146a as shown by qRT-PCR, Western Blot analysis and luciferase assays. Concordantly,

vasorin mRNA was shown to be downregulated upon wire-induced injury _in vivo_ (21 % vs. 100 %; p<0.001). In a subsequent _in vivo_ study, a miR-146a inhibitor was applied locally in a self-degrading pluronic gel after wire-induced injury. Inhibition of miR-146a led to a significant reduction of neointimal hyperplasia in mice 21 days after injury (Neointima/Media Ratio 1.74 in treated vs. 2.84 in control animals p<0.01). In this context also VSMC proliferation was reduced as assessed by Ki67 immunofluorescence (10% vs. 22 %; p<0.05). In contrast, reendothelialization was significantly improved compared to control animals as assessed by Evan's Blue incorporation (63 % vs. 37.64 %; p<0.01). A further translational approach using a rat carotid artery injury model, we utilized a clinically approved drug-application balloon catheter to apply a selective miR-146a-inhibitor (LNA-146a) in a temporarily and locally restricted manner (5 min, 2-4 Atm). Using this approach, miR-146a-expression could be selectively suppressed in the treated vessel segment and neointimal hyperplasia was significantly reduced (Neointima/Media Ratio 0.22 vs. 1.41; p<0.001). Consistently, VSMC proliferation was reduced 14 days after injury (Ki67 positive cells, 1.92 % vs. 8.95 %; p<0.01).

CONCLUSIONS

This study reports an essential and conserved role of miR-146a during vascular remodeling and healing following an acute injury. Furthermore, a single, short and locally restricted application of a miR-146a inhibitor using a clinically approved drug-delivery catheter is sufficient to improve vascular healing while effectively preventing neointima formation.

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Mortality differences for elective and acute SVG PCI - A 10-year single-centre real-world experience

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

AIMS

The outcome of patients undergoing SVG PCI is poorer compared to native coronary artery PCI. Little is known about the outcome in SVG PCI between elective and ACS cases. We compared the outcome of SVG PCI between these two groups.

METHODS AND RESULTS

Detailed demographic, procedural and mortality data were obtained over a 10-year period for 9253 consecutive patients undergoing PCI in our centre - 314 (3.4%) were SVG PCI cases.The SVG PCI cases were categorised as Elective (116 cases – 36.9%) or ACS (198 cases – 63.1%). The Elective SVG PCI group were younger (mean age - ACS 71.5 ± 10.9 years and Elective 67.5 ± 12.2 years [p <0.05]), with a higher proportion of male patients (ACS 77.8% and Elective 87.5% [p < 0.05). There were no other differences in the baseline characteristics between the two groups – Caucasian ethnicity (p = 0.43), hypertension (p = 0.16), dyslipidaemia (p = 0.59), smoking history (p = 0.78), diabetes (p = 0.64), chronic kidney disease (p = 0.69) and family history of ischaemic heart disease (p = 0.87).In the ACS group, 14 patients (6.6%) were in cardiogenic shock and 9 patients (4.6%) were ventilated. There were no shocked or ventilated patients in the Elective group.There were no differences in the number of stents used (ACS 1.3 ± 0.8 stents and Elective 1.4 ± 1.0 stents [p = 0.84]) or the largest stent/balloon diameter used (ACS 3.8mm ± 1.8mm and Elective 3.4mm ± 1.3mm [p = 0.18]). The length of stented segment was longer in the ACS group (ACS 22.8mm ± 12.5mm and Elective 19.2mm ± 7.6mm [p < 0.05]). Use of drug eluting stents (ACS 78.8% and Elective 78.4% [p = 0.94]), embolic protection devices (ACS 15.7% and Elective 17.2% [p = 0.71]) and GPIIb/IIIa inhibitors (ACS 47.5% and Elective 44.8% [p = 0.65]) was similar between both groups.At 30-days there were differences in unadjusted all-cause mortality between the 2 groups (ACS 8 [5.2%] deaths and Elective 1 [1.0%] death [p = 0.07]).For patients who survived beyond 30-days (median follow up 466 days [range 41-3364 days] – no follow up on 20 patients beyond 30 days), unadjusted all cause mortality was higher in the ACS group (ACS 28 [15.6%] deaths and Elective 7 [6.7%] deaths [p < 0.05]). However, when adjusted for verified demographic, clinical and procedural factors which adversely influence the outcome of PCI (using a multivariate regression model with backward stepwise elimination), there was no association between the indication of SVG PCI (ACS or Elective) and mortality (p = 0.99).

CONCLUSIONS

Our data show no difference in early or late mortality in SVG PCI cases between Elective and ACS cases, despite several of the ACS patients being critically unwell (cardiogenic shock and/or ventilated) at presentation. Additionally, our use of embolic protection devices and GPIIb/IIIa inhibitors was lower than expected for SVG PCI, but this did not adversely influence outcome - both of these methods are thought to improve procedural outcome in SVG PCI, especially for ACS where thrombus burden may be significant.Whilst the overall outcome of SVG PCI in our study is worse than seen in registries of native coronary artery PCI, our data suggests the outcome of SVG PCI in ACS is no worse than in elective SVG PCI.

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Accuracy of length measurements using IVUS/angiography co-registration system with manual pullback

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

AIMS

To investigate the accuracy of length measurements and the interobserver variability using an IVUS Angiography co-registration system which uses manual pullback and to compare the results to reported data using motorized pullback systems.

METHODS AND RESULTS

Intravascular ultrasound studies performed using the Volcano Sync Vision IVUS-Coregistration system with the Eagle eye platinum, 40Mhz Electronic short tip catheter at our center were enrolled. Studies with overlapping stents, previously deployed stent or studies in which co-registered IVUS was not performed following stent deployment were excluded. 4 operators measured stent length using the co-registration system on three different occasions. Categorical data were presented as values and percentages. Continuous variables were presented as mean +/-SD. Bland-Altann plots were generated for the differences between mean IVUS measurement for each operator and the known stent length. Interobserver differences were estimated by calculating the intraclass correlation coefficient between the mean of each operators measurements (and 95% confidence interval (CI)). Statistical analysis was performed using SPSS v.21.After reviewing 53 IVUS cases with co-registration, 13 cases were found to meet the inclusion criteria. Known stent lengths ranged from 12 to 38mm. All were located in native coronary arteries (30% LAD, %30 LCX, %25 RCA, %5 LM). The absolute deviation of mean measurements from the known stent length varied from -3.28mm to 5.27mm. Using Pearson's correlation the correlation between known stent length and the mean stent length measured by each operator using the IVUS co-registration system varied from 0.892-0.947 ($p<0.001$) and the correlation of the mean of all the operators measurements and the known stent length was 0.943 ($p<0.001$). 67% of measurements were within 90% of the known stent length. 100% of measurements were within 80% of the known stent length. Bland Altman plots showed no proportional bias in the measurements. The interobserver correlation coefficient was 0.962 (95% CI, 0.901-0.988).

CONCLUSIONS

Co-registered IVUS with manual pullback length measurements show a high accuracy with low interobserver variability. Results for accuracy and interobserver variability are superior to those reported for motorized IVUS pullback length measurements.

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Prevention of contrast-induced acute kidney injury with intravenous fluid administration matched to urine ouput

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THEME: Coronary Interventions
TOPIC(S): STEMI, NSTEMI, Stable CAD, Stents and scaffolds, Left main and multivessel disease, Bifurcation lesion, CTO

AIMS

The administration of intravenous fluid remains the primary treatment for the prevention of contrast induced acute kidney injury (CI AKI).We aimed to evaluate our fluid protocol to prevent CI AKI among our patients with chronic kidney disease.

METHODS AND RESULTS

We studied prospectively 557 patients who underwent coronary angiography or angioplasty and with pre-existing renal impairment defined by creatinine clearance<60ml/min. Before the procedure patients receive bicarbonate solution (152 meq/l) at the rate of 1ml/kg/h and a solution of 102 meq/l of sodium chloride matched with urine output. After the procedure they receive on top of this regimen a continuous infusion of furosemide in order to obtain an urine flow rate of 1.5ml to 1.75ml/kg/h. the primary endpoint of our study is the occurrence of CI AKI definedas an absolute increase of 5mg/L or a relative increase of >25% in creatinine levels 24–48 hours after the procedure.Between January 2012 and January 2014, 575 patients were included. Mean age was 75+/-10y. 54% were male and 199 (34.6%) underwent coronary angioplasty. CI AKI occurred in 9% of the patients. Predictive factors for the occurrence of CI AKI were pre-procedure creatinine (13.6 vs 21.3), pre-procedure creatinine clearance (42.5 vs 26.5) and contrast media volume/creatinine clearance ratio (4 vs 6).
Our results are comparable to other studies using a specific device for administering intravenous fluid matched to the diuresis.

CONCLUSIONS

Our hydration protocol allows us to limit the occurrence of contrast induced acute kidney injury to 9% of high-risk patients with chronic kidney disease. This is in addition to other strategies to lower the contrast media volume/creatinine clearance ratio especially among angioplasty patients.

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Efficacy of DEB in unsuitable coronary artery disease for DES implantation

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

AIMS

Aim: The aim of this study was to investigate whetherdrug-coated balloonwas effective inunsuitable de-novo coronary lesions for drug-eluting stent implantation.

METHODS AND RESULTS

Methods and results: The study included 78 de-novo lesions which were not suitable for stent implantation. Optimal lesion preparation was defined as the acquisition of TIMI 3, minor coronary dissection, and residual stenosis <25%. Endpoints were the rate of achieved optimal lesion preparation before drug-coated balloon and 3-month outcomes, and further to identify the factor related with suboptimal lesion preparation. Of lesions, 41% of lesions was treated due to very small vessel disease. Patients with planned non-cardiac surgery and at high bleeding risk were 8% and 14%, respectively. Lesions which were easy to develop of stent fracture was 31%. Twelve lesions (15.4%) failed to achieve optimal lesion preparation previously defined 3 criteria. Patients treated with drug-coated balloon after achieved optimal lesion preparation were not observed any cardiac events within 3 months. The eccentric lesion was an independent predictor for suboptimal lesion preparation (odds 11.9; 95%CI,2.5-76.2; p=0.002).

CONCLUSIONS

Conclusions: Lesions not suitable metal stent should be initiatively chosen stent-less intervention with drug-coated balloon. The present study also highlighted that optimal lesion preparation is key to success drug-coated balloon strategy.

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Implications of the local haemodynamic forces on the formation and destabilisation of neoatherosclerotic lesions

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

AIMS

To investigate the implications of the local hemodynamic forces on the formation and destabilization of high-risk neoatherosclerotic lesions.

METHODS AND RESULTS

Thirty-six consecutive patients who had neoatherosclerotic lesions indentified on optical coherence tomography (OCT) were included in this study. The OCT examinations were performed for suspected stent failure, 7.6±4.8 years after the stent implantation, and the acquired images were used to reconstruct coronary anatomy along with biplanar angiograms. Blood flow simulation was performed in the model reconstructed from the stent borders which it was assumed that represented the lumen surface at baseline – immediate after stent implantation. The estimated baseline endothelial shear stress (ESS) were associated with the neointima burden, neoatherosclerotic burden and neointima characteristics. In segments with neointima rupture blood flow simulation was also performed in the model representing the lumen surface before rupture and the ESS was estimated at the ruptured site.

An inverse association was noted between baseline ESS and the incidence and the burden of neoatherosclerotic (β=-0.91, P<0.001, and β=-5.33, P<0.001 respectively) and lipid-rich neoatherosclerotic tissue (β=-0.87, P<0.001, and β=-5.00, P<0.001 respectively). There was no associationbetween ESS and the incidence and burden of calcific tissue in the neointima. Segments exposed to low ESS (<1Pa) were more likely to exhibit macrophage accumulation (25.9% *vs* 12.6%, P<0.001), thrombus (11.0% *vs* 2.3%, P<0.001) and evidence of neointima discontinuities (7.4% *vs* 1.3%, P<0.001) comparing to those exposed to normal or high ESS. In segments with neointima rupture high ESS was noted at the rupture site comparing to the average ESS over the culprit lesion (4.00±3.65Pa, *vs* 3.14±2.90Pa, P<0.001).

CONCLUSIONS

Local EES appear to regulate neoatherosclerotic, lipid-rich lesion formation and contribute to the destabilization of high-risk vulnerable plaques in stented segments.

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Long-term safety and efficacy of consecutive patients treated with biodegradable-polymer biolimus-eluting stent or durable-polymer everolimus-eluting stents in routine clinical practice

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

AIMS

Although randomised trials comparing biolimus- vs. everolimus-eluting stent are available, there is a paucity of comparative data in large unselected cohorts. We assessed long-term outcomes after biolimus- vs. everolimus-eluting stent implantation.

METHODS AND RESULTS

Consecutive patients undergoing either biolimus- or everolimus-eluting stent implantation for de novo coronary artery disease at two tertiary-referral centres were entered into a dedicated database. Quantitative coronary angiography analysis was performed offline in a core lab. Clinical follow up was assessed at 3 years. The primary efficacy endpoint of interest was target lesion revascularisation, while the primary safety endpoints of interest were all-cause death or myocardial infarction and definite/probable stent thrombosis. A total of 800 patients were treated with biolimus-eluting stent (1,120 lesions) and 3,035 patients with everolimus-eluting stent (4,411 lesions). Clinical characteristics were well balanced between groups with the exception of a slightly higher baseline left ventricular ejection fraction (58 [48-62] vs. 56 [46-61], p= 0.034) in biolimus-eluting stent group. Angiographic characteristics were also well matched with the exception of reference vessel which was higher in the biolimus-eluting stent group diameter (2.96 [2.59-3.35] vs. 2.81 [2.51-3.12], p<0.001). Target lesion revascularisation at 3-year follow up was significantly lower in the biolimus-eluting stent group as compared with everolimus-eluting stent group (11.3% vs. 14.5%, HR 0.76, 95% CI 0.59-0.98, p=0.035). All-cause death or myocardial infarction was comparable between groups (10.9% vs. 13.0%, HR 0.90, 95% CI 0.70-1.15, p=407). Similarly, risk of definite/probable stent thrombosis was very low and comparable between biolimus-eluting stent and everolimus-eluting stent (0.4% vs. 0.4%, HR 1.14, 0.31-4.14, p=0.843). After adjustment using multivariable regression differences in rates of target lesion revascularisation between biolimus-eluting stent and everolimus eluting stent were no longer significant (adjusted HR 1.14, 95% CI HR 0.66-1.13, p=0.290).

CONCLUSIONS

In consecutive patients treated in routine practice, implantation of biolimus-eluting stent and everolimus-eluting stent has similar efficacy and safety at 3 years. Rates of definite/probable stent thrombosis were very low and comparable with both stents.

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Inter-hospital delays in transfer of STEMI patients to primary PCI centre: should we re-introduce 30-min target in district general hospitals?

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

AIMS

To study the delays in inter-hospital transfer of STEMI patients from district general hospital (DGH) to PCI centre. We evaluated various segments of trabsfer time delay; and resulting impact on call-to-balloon (CTB) time and in-hospital mortality.

METHODS AND RESULTS

All STEMI transfers from 5 DGH to our tertiary centre for primary PCI (PPCI) from January to June 2016 were assessed. Times were noted from patient notes, and ambulance and AE records. Compliance with 120min and 150min CTB targets, as recommended by ESC and NICE resppectively, were assessed. Following sequential time delays were calculated: time of AE arrival to ECG time (A), ECG time to time PPCI-ambulance called (B), time PPCI-ambulance called to time left DGH (C), and ambulance transit time from DGH to PCI centre (D). Times A, B and C were classified as 'modifiable' delays weheras D was classified as 'non-modifiable' delay as far as hospital health professionals were concerned. Total of 84 STEMI patients were transferred from DGH to PPCI centre in 6 months (20% of all STEMI; 74% male; mean age 67 years); 50% sel-presented to DGH; 73% eventually underwent PCI. The median 'modifiable' time delays (A, B and C) were 35min, 41min and 35min respectively. The median 'non-modifiable' delay (D) was 29min (range 19-39min due to variable distance from DGH). The overall median CTB was 139min; however door-to-balloon was 30min in those undergoing PCI. The 120min and 150min CTB targets were met in 36% and 54% cases respectively (compared to 86% of direct admissions achieving CTB<150min). The median door-in-door-out (DIDO) time was 108min; the median time from first medical call (FMC) to time PPCI-ambulance called was 61min (hypothetically comparable to historical door-to-needle time used for fibrinolysis). Factors contributing to 'modifiable' delays included: delay in obtaining ECG in patients self-presenting to AE, limited experience and relatively slow response when dealing with STEMI patients in AE compared to old fibrinolysis era, and unnecessary use of fax machine to transfer ECG to PCI centre prior to activation of PPCI pathway. The in-hospital mortality was 3.9% for inter-hospital STEMI transfers (compared to 2.7% for direct admissions and 3% for all STEMI during this time period).

CONCLUSIONS

There are significant delays in transferring STEMI patients from DGH to PPCI centre, adversely affecting CTB time and in-hospital mortality. Following measures could minimise 'modifiable' time delays: immediate ECG for patients presenting to AE with chest pain, prompt recognition and management of STEMI patients in AE, and direct activation of PPCI pathway by AE staff prior to ECG being faxed to PCI centre where possible. A collaborative effort is required to reduce delays, aiming for FMC to PPCI-ambulance call time of 30min (equivalent to door-to-needle time previously used for fibrinolysis).

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Relationship between NT-pro-BNP and change in symptomatic status following TAVI for aortic stenosis

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

AIMS

Analyses of baseline brain-natriuretic peptide (BNP) level and TAVI outcomes have assumed a linear relationship; yielding conflicting results. We re-examined the ability of baseline NT-pro-BNP level to predict futility of symptom relief from TAVI.

METHODS AND RESULTS

Symptom status (New York Heart Association (NYHA) class, Canadian Cardiovascular Society (CCS) class, syncope) at baseline and 12-month follow-up, clinical characteristics, baseline NT-pro-BNP levels and echocardiographic measures of valvular and left ventricular function were analysed from a prospectively maintained database of consecutive patients undergoing TAVI at two high volume institutions over a two-year period (01/01/2013-01/06/2015).Complete datasets were available for 161 of 212 patients (82 ± 7 years) with severe aortic stenosis (AVA 0.71±0.24 cm2, peak velocity 4.26±0.76 m/s, LVEF 50±13 %) undergoing TAVI. Mean baseline NT-pro-BNP was 5026±8495 ng/L. Mean NYHA functional class was 2.58±0.76 and 1.72±0.96 pre- and post-procedure, respectively. NT-pro-BNP values were positively skewed and were normalised with a logarithmic transformation. There was a non-linear, inverted-U, relationship between baseline NT-pro-BNP and post-TAVI change in NYHA functional class. Received operator characteristic (ROC) curves identified clinically relevant cut-off values of baseline NT-pro-BNP of <800 and >10,000 ng/L; which predicted no improvement in NYHA functional class at 12 months with a high degree of diagnostic accuracy (area under the curve (AUC) 0.917 (0.840-0.994, p<0.001) and 0.817 (0.796-0.929, p<0.001).

CONCLUSIONS

NT-pro-BNP may be a useful prognostic marker in predicting futility of symptom relief following TAVI. Patients with baseline values <800 ng/L or >10000 ng/L derive no functional improvement post-procedure; suggesting an alternative cause for symptoms in the former and an irrevocably diseased ventricle in the latter. Further evaluation of this relationship is warranted on a prospective basis with more sensitive objective metrics of functional status.

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CT angiography as a method of exclusion of coronary artery disease in candidates for TAVI

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

AIMS

To evaluate the diagnostic value of CT angiography (CTA) for coronary artery disease (CAD) in patients with severe Aortic Stenosis (AS), and determine the number of cases in which patients do not have to undergo invasive coronary angiography (ICA).

METHODS AND RESULTS

Single-center retrospective study where the results of coronary evaluation were compared between CTA and ICA, in patients with severe symptomatic AS, during a one-year period. The CTA exams were conducted using a 64-slice double source equipment, with a median interval of 30 days to ICA (IQI 11-93). In both exams, obstructive CAD was defined as a ≥50% stenosis in an epicardial vessel ≥2 mm diameter. A per-patient and per-vessel analysis was conducted, excluding and including non-evaluable segments by CTA. In the latter, non-evaluable segments were considered as obstructive CAD.
The study included 133 patients (61 male patients, 82±6 years of age). The prevalence of obstructive CAD in ICA was 50% (n=67). The median coronary calcium score was 679 (IQI 177 - 1799). Only 26% of the patients (n=35) had all the coronary segments evaluable by CTA. The results of the per-patient and per-vessel analysis, including and excluding non-evaluable segments, showed sensibility and negative predictive values of >90%. Of the 35 patients all with evaluable coronary segments, 22 (17% of the total sample) had no obstructive CAD on CTA and none of them had obstructive disease on ICA.

CONCLUSIONS

About 83% of the patients, eligible to TAVI, had non-evaluable or obstructive CAD on CTA. The sensibility and negative predictive values remain elevated in this context, allowing the safe exclusion of obstructive CAD in the cases in which the CTA exam is normal, sparing the need for ICA to one in every six cases.

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Clinical outcomes of intermediate stenosis in CT coronary angiography

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Several comparative studies showed that computed tomography coronary angiography (CTA) has a higher diagnostic accuracy. The aims of this study access to clinical outcomes of intermediate stenosis in CTA.

METHODS AND RESULTS

The study was a retrospective analysis of the findings in patients with atypical or typical angina and no history of CAD. Patients underwent CTA. For each segment, the severity of luminal stenosis was visually scored. Intermediate stenosis in CTA was defined as 30%≤luminal stenosis <70%. Of all patients, 420 patients enrolled within intermediate stenosis in CTA. The severity of intermediate stenosis was divided as follows: low-grade intermediate stenosis (30%≤luminal stenosis <50%, n=350, 79.5%) and high-grade intermediate stenosis (50%≤luminal stenosis <70%, n=70, 20.5%). The clinical outcomes were all cardiac events, defined as cardiac death, nonfatal myocardial infarction (MI), and revascularization (revascularization defined as elective revascularization 60 days after CTA).

The patients were followed for 5 year. (mean duration: 4.7±1.1 years). The patients were 226 men and 214 women (51:49%) with mean age of 65.5 years and mean body mass index of 24.4kg/m^2. All cardiac events were nonfatal myocardial infarction and revascularization without cardiac death. The incidence of all cardiac events was 11.1% (n=49). The incidences of nonfatal MI and revascularization were 1.6% (n=7) and 9.5% (n=42), respectively. The odds ratio of high high-grade intermediate stenosis for low-grade intermediate stenosis was 2.314 (95%CI: 1.219-4.393, p=0.009). In multivariate analysis after adjustment of age, sex, diabetes, hypertension and ejection fraction, high-grade intermediate stenosis for low-grade intermediate stenosis is the only independent predictor of cardiac events (HR: 2.357, 95% CI: 1.032-5.381, p=0.042).

CONCLUSIONS

Severity of luminal stenosis in intermediate stenosis could be associated with higher rate of cardiac events.

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Impact of the longitudinal straightening effect of DES on restenosis (a 3D reconstruction analysis)

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

AIMS

After our previous BMS study we wanted to examine the correlations between spatial curvature of the target vessel segment and restenosis in DES cases.

METHODS AND RESULTS

A homogeneous patient group regarding to the implanted DESs were investigated retrospectively. Among the 35 patients 12 exhibited angiographic restenosis, while 23 showed widely patent stents 12±6 months after the index procedure. 3D coronary reconstruction was performed before and after the stent implantation from appropriate projections by QAngio®XA 3D software. Arch/chord (A/C) ratio of the target vessel segment, the proximal and the distal edge bending angle, and the changes of these parameters by stenting were calculated. Age, diabetes and hyperlipidaemia as established risk factors were taken into account for the statistical evaluation.Based on descriptive analysis of the data, the prestent value (p=0.042) and the change by stenting (p=0.018) of A/C ratio were significantly different between the two groups. Logistic stepwise regression analysis was carried out to identify effects predicting the in-stent restenosis. Bigger changes of A/C ratio (p=0.016) and diabetes (p=0.046) were found to be independent predictors of the increased risk of restenosis.

CONCLUSIONS

In our opinion A/C ratio sets out on three-dimensional reconstruction characterize well the spatial curve of coronary artery. The change of this value results such a chronic stress in the vessel wall that can lead to the pathological intimal proliferation. In contrast with the case of BMS where the initial curvature before the intervention proved to be more important, after DES implantation the long-term effect of the longitudinal straightening can predispose for the restenosis.

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The cerebral embolic protection during TAVI: efficacy and safety of a dual filter cerebral embolic protection device

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

AIMS

Cerebral embolization of debris is common in transcatheter aortic valve implantation (TAVI) with ischemic brain lesions. Balloon valvuloplasty (BAV) and actual valve positioning and deployment are primary causes of cerebral embolization during TAVI.

METHODS AND RESULTS

Between February 2014 and December 2016, 100 patients (pts) - age 82.3±10 years, 55 female - with severe symptomatic aortic stenosis and inoperable or high-surgical risk underwent TAVI with or without prior BAV at our institution. Balloon-expandable transcatheter heart valves (THVs) were used in 90% of patients and self-expanding THVs in 10%. After aortic arch angiography, a dual filter–based cerebral embolic protection device (Sentinel System, Claret Medical, Santa Rosa, CA,USA) was placed via the right radial artery in the last 32 consecutive pts (32%) who underwent TAVI, prior BAV, 28 pts with transfemoral access, 4 with transaortic. 6 pts were in atrial fibrillation, 1 with mechanical mitral valve prosthesis.The larger proximal filter was deployed in the brachiocephalic trunk, and the smaller distal filter in the left common carotid artery. No additional contrast agent was used during the actual deployment of the double filter. Self-expanding THVs underwent in 4 pts, Balloon-expandable THVs in 28. Balloon post-dilation for significant paravalvular aortic regurgitation was needed in 7 pts (21%) after TAVI. Filters were retrieved after TAVI. Technical success rate with delivery of the proximal and distal filter was 93.7%. In two cases the device was not placed due to excessive tortuosity of the brachiocephalic artery. No peri or post procedural transient ischemic attacks, minor or major strokes occurred. Macroscopic material liberated during the TAVI procedure was captured in the device filter baskets in 26 pts (81%). The visible material captured was found in 1 or both filters, different sizes, maximum of 3 mm.

CONCLUSIONS

In our experience the use of dual filter–based cerebral embolic protection device system is feasible and safe. Embolic debris traveling to the brain and potentially conducive to cerebrovascular events was captured in 81% of TAVI procedures where a filter-based embolic protection device was used.

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Final three-year clinical outcomes of patients treated with everolimus-eluting BRS vs. everolimus-eluting metallic stents: a propensity score comparison of patients enrolled in the ABSORB EXTEND and SPIRIT trials

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

AIMS

We souhgt to determine the long term (3 years) safety and efficacy of ABSORB BVS in comparison to mettalic DES in low to moderate scenarios of the daily practice.

METHODS AND RESULTS

The ABSORB EXTEND Trial was initiated as a global, continued access, international study to expand the clinical experience with the Absorb BVS to different geographies with broader inclusion criteria to include the treatment of longer lesions and multiple vessels. This final 3-year report provides data on the largest cohort of patients with long term follow-up who have received the device.
ABSORB EXTEND is a prospective, single-arm, open-label clinical study in which 812 patients were enrolled at 56 sites.Included were patients with lesions ≤ 28 mm in length and reference vessel diameter of 2.0 - 3.8 mm (as assessed by on-line QCA or IVUS). Treatment of a maximum of two *de novo* native coronary artery lesions was permitted with each lesion located in a different epicardial vessel. An independent Clinical Events Committee adjudicated all endpoint-related events.
Propensity score analysis was performed to compare the entire population of the Extend Registry to patients treated with the Xience V metallic DES from the SPIRIT trials with similar inclusion / exclusion criteria.
At 2 years of clinical follow-up, we reported no statistical difference between Absorb and the EES with regards to MACE (7.2% vs 7.7% p = 0.72), TLF (8.4% vs 9.3% p =0.55), ID-TLR (4.2% vs 4.6% p = 0.73) and ST (1.5% vs 0.7% p = 0.13).

CONCLUSIONS

Twenty four-month clinical results from the full study cohort demonstrated that the treatment of relatively non-complex patients with the Absorb BVS is safe and results in low rates of MACE and scaffold thrombosis.In addition, propensity score matched analysis demonstrated that the clinical safety and effectiveness of Absorb remains comparable to XIENCE V among this population. An update with the final 3- year results for the same 812 patient cohort will be presented.

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Independent predictors of MACE at different time points after the treatment of non-selected patients with DES: an analysis of the Desire registry

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

AIMS

We sought to determine the independent predictors of MACE at short, mid and long-term clinical follow-up among unselected patients (pts) treated solely with drug-eluting stents (DES).

METHODS AND RESULTS

The DESIRE registry is a prospective, single-center registry encompassing all consecutive pts treated solely with DES between May/2002 and Jun/2015. There are virtually no exclusion criteria, aiming to reflect our daily practice. A regression model was built to determine in-hospital MACE predictors while a multivariate model (Cox model simplified by Akaike criteria) was built to determine independent predictors of MACE at two other time points: 1) between hospital discharge and 1 year, and; 2) long-term (>1 year) clinical follow-up. MACE was defined by the composite of cardiac death, non-fatal MI and TLR.

A total of 6,361 pts were enrolled. The mean age was 64 ± 11 years. DM was detected in 31.5% and 16.8% presented with STEMI. Follow-up was obtained in 98% of the patients (median 5.4 years). Currently, 66.7% of the population is free of any MACE. Predictors of MACE in the in-hospital phase were: age (OR 1.025, p=0.04), treatment of SVG (OR 1.8, p<0.01), stent length (1.02, p<0.01) and residual stenosis (1.03, p<0.01). Predictors of MACE between hospital discharge and 1 year FU were: age (HR 1.02, p=0.04), smoking (HR 1.98, p<0.01), renal insufficiency (HR 1.7, p=0.05), treatment of SVG (HR 3.0, p <0.01), stent length (HR 1.8, p <0.01), and residual stenosis (1.03, p<0.01). After the first year of PCI, predictors of MACE were: age (HR 1.01, p=0.04), smoking (HR 1.5, p <0.01), presence of peripheral vascular disease (HR 2.0, p =0.01), renal insufficiency (HR 1.7, p<0.01), treatment of SVG (HR 1.8, p <0.01) and treatment of patients with ACS (HR 1.7, p<0.01). Use of 2nd generation DES had a protective effect (HR 0.7, p=0.04)

CONCLUSIONS

In this large, real-world registry, advanced age, treatment of SVG and long lesions were predictors of MACE at all time points. The type of stent used (1st generation DES) and the initial clinical presentation (ACS) only impacted the occurrence of long-term negative events (>1 year).

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Late thrombotic events after BRS implantation: a systematic review and meta-analysis of randomised clinical trials

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

AIMS

To compare the long-term safety and efficacy of bioresorbable vascular scaffolds (BVS) with everolimus-eluting stent (EES) after percutaneous coronary interventions.

METHODS AND RESULTS

A systematic review and meta-analysis of randomized clinical trials comparing clinical outcomes of patients treated with BVS and EES with at least 24-month follow-up was performed. Random-effect model adjusted by the Knapp-Hartung method was used to compute odds ratios (OR) and 95% confidence intervals (CI). The primary safety outcome of interest was the risk of definite/probable device thrombosis (DT). The primary efficacy outcome of interest was the risk of target lesion failure (TLF). Five randomized clinical trials (n=1,730) were included. Patients treated with Absorb BVS had a higher risk of definite/probable DT compared to patients treated with EES (OR 2.93, 95%CI 1.37-6.26, p=0.01). Very late DT (VLDT) occurred in 13 patients (12/996 [1.4%, 95%CI: 0.08-2.5] Absorb BVS vs. 1/701 [0.5%, 95%CI: 0.2-1.6] EES; OR 3.04; 95%CI 1.2-7.68, p=0.03), 92% of the VLDT in the BVS group occurred in the absence of dual antiplatelet therapy (DAPT). Patients treated with Absorb BVS had a trend towards higher risk of TLF (OR 1.48, 95%CI 0.90-2.42, p=0.09) driven by a higher risk of target-vessel myocardial infarction and ischemia-driven target lesion revascularization. No differences were found in the risk of cardiac death.

CONCLUSIONS

Compared to EES, the use of Absorb BVS was associated with a higher rate of DT and ischemia-driven target lesion revascularization. VLDT occurred in 1.4% of the patients, the majority of these events occurred in the absence of DAPT.

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"Less invasive" FFR measurement from three-dimensional quantitative coronary angiography and classic fluid dynamic equations

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Aims: To develop a simplified model of FFR calculation (FFR_{sim}) deriving from 3-dimensional (3D) coronary angiographic data and classic fluid dynamic equations without using finite element analysis and the Navier-Stoke equations.

METHODS AND RESULTS

Methods: A total of 68 de novo coronary artery lesions of 64 patients from four centers were enrolled. Intracoronary pressure measurements were performed by pressure wire sensors.
Lumens of the interrogated vessel segments starting from the coronary orifice to the level of the pressure wire sensor were reconstructed in 3D, using a dedicated 3D–QCA software package. The coronary artery volumetric flow was calculated based on the velocity of the contrast material in the 3D reconstructed coronary segments. Pressure gradients were computed by classic fluid dynamic equations using the morphological data derived from 3D coronary angiography and the contrast medium velocities. The diagnostic power of the simplified computation of the FFR (FFR_{sim}) was assessed by comparing the results with standard invasive FFR measurements (FFR_{meas}).
Results:111 FFR_{sim}assessments were performed in 68 vessels of 64 patients. We found a strong correlation between the $FFR_{sim}$and the FFR_{meas}($r=0.85$, $p<0.0001$). Based on receiver operating characteristic (ROC) curve analysis, the sensitivity and specificity were 89.58% and 87.3%, respectively for predicting the abnormal FFR of ≤0.80 associating to hemodynamically significant stenosis. The area under the curve (AUC) was 0.95 . The Bland-Altman analysis revealed a good agreement between the two methods determining FFR with a mean difference of –0.02±0.14. To achieve 100% negative and positive predictive value we could define the $FFR_{sim} > 0.96$ and the $FFR_{sim} \leq 0.79$ ranges. In our patient population these ranges were found in the 41% of the cases.

CONCLUSIONS

Conclusions: We developed a simplified and quick model to assess the functional significance of intermediate coronary artery lesions using the hyperemic coronary angiography data with the 3D anatomical data. In pre-specified ranges of the calculated $FFR_{sim}$the invasive FFR measurement can be omitted without misclassification.

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Very late scaffold thrombosis of BRS: systematic review and an updated meta-analysis

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

AIMS

We sought to compare the long-term outcomes between BVS and everolimus-eluting metallic drug-eluting stent (EES).

METHODS AND RESULTS

We conducted a meta-analysis of 24 studies (BVS: 2567 patients, and EES: 19806 patients) reporting the 2-year outcomes of BVS and/or EES to compare the risk of BVS versus EES for stent/scaffold thrombosis (ST) and target-lesion failure (TLF) in 7 comparative studies (3 randomized and 4 observational), and to estimate the pooled incidence rates of ST and TLF including additional 17 single arm studies. (UMIN-CTR ID: UMIN000023801) In the 7 comparative studies, the risk for VLST between 1- and 2-year was numerically higher in BVS than in EES (odds ratio [OR] 2.03, 95% confidence interval [CI] 0.62-6.71). The excess risk of BVS relative to EES for ST through 2-year was significant (OR 2.08, 95%CI 1.02-4.26). The risk for TLF was neutral between BVS and EES. In the entire 24 studies, the pooled estimated incidence rates of VLST, and ST through 2-year were higher in BVS than in EES (0.240 [95%CI: 0.022-0.608]%, versus 0.003 [95%CI: 0.000-0.028]%, and 1.43 [95%CI: 0.67-2.41]%, versus 0.56 [95%CI: 0.43-0.70]%, respectively). The corresponding rates for TLF were comparable between BVS and EES (1.88 [95%CI: 1.30-2.55]%, and 1.78 [95%CI: 1.17-2.49]%, and 7.90 [95%CI: 6.26-9.69]%, and 7.49 [95%CI: 5.86-9.29]%, respectively). We will present updated data at the presentation.

CONCLUSIONS

In this meta-analysis, BVS as compared with EES was associated with higher risk for VLST between 1- and 2-year and ST through 2-year.

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		Group A (121 pts)	Group B (112 pts)	p value
Baseline	sCr	1,42±0,59	1,64±1,07	t test ns
	eGFR (ml/min/1.73 m^2) (Cockroft-Gault)	37,87±9.68	34,51±10,08	t test ns

V/CrCl ratio		4,36±1,9	9,1±3,68	t test ns
24 hour	sCr	1,37±0,8	1,6±0,97	t test ns
48 hour	sCr	1,46±1,15	1,75±1,2	t test ns
5 days	sCr	1,42±0,54	1,85±1,69	t test ns
CI-AKI	%	9,1	10,7	X^2 ns