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TAVI in low-risk patients, should we attend patient`s choice?

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

AIMS

TAVI is an established treatment for patients with severe aortic stenosis and intermediate to high surgical risk. However, there is scarce evidence about TAVI in low-risk patients that are already being treated with this therapy whitin these clinical scenarios.

METHODS AND RESULTS

Methods: A retrospective analysis of consecutive patients treated with transfemoral TAVI using Edwards Sapien prosthesis in one centre was performed, classifying the patients into three groups according to their surgical risk (high/intermediate/low risk for STS score > 8, 4-8 and

CONCLUSIONS

TAVI in low-risk patients is safe and associated with less complications and better outcome at mid and long-term follow-up compared to high- risk patients, with a significantly higher survival during follow-up. There are not significant differences in technical features of the intervention between patients in low or high risk. A tendency to treat patients with progressive lower risk during the study period is remarkable.

Waiting for the results of the on-going randomized clinical trials, TAVI in low risk patients seems feasible and safe.

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Determinants of early and mid-term outcomes in older women undergoing TAVR: results from the FRAILTY-AVR study

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

AIMS

Determinants of early and midterm outcomes in older women undergoing transcatheter aortic valve replacement: Results from the FRAILTY-AVR study

METHODS AND RESULTS

Data from a prospective cohort of older adults undergoing TAVR were collected at 14 centres in North America and Europe from 2012 to 2017. The cohort consisted of 327 (45%) women and 400 (55%) men. Women were older (84.3 vs 82.8 years, P

CONCLUSIONS

The present study has highlighted sex-specific differences in older adults undergoing for TAVR, with women exhibiting a greater burden of diastolic heart failure and physical frailty. While the prognostic impact of frailty was similar regardless of sex, other risk factors were differentially associated with outcomes. In particular, women with low body weight and those with pulmonary hypertension were at incrementally higher risk of 1-year mortality. Furthermore, women undergoing non-femoral procedures with large prosthesis sizes faced a significantly higher risk of adverse events.

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Comparison of tip and side placement of excision blades in atherectomy

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THEME: Peripheral Interventions
TOPIC(S): Below the knee, Iliac / Femoral / Popliteal

AIMS

The aim of the study was to compare long-term outcomes after PAD endovascular revascularization with two types of atherectomy with- tip(tAT) (Phoenix® Philips) and side(sAT) (SilverHawk® Medtronic) based excision blades.

METHODS AND RESULTS

This was a single center, retrospective registry of obstructive and symptomatic PAD patients who underwent revascularization with atherectomy. The endpoints were considered as target lesion revascularization (TLR), death, amputations and bailout stenting (BS).

In tAT group was 97 patients, whereas 85 was in sAT group. There were no significant differences between group in baseline characteristics except for increased CLI prevalence in tAT group. The mean follow up was 282.6± 147.4 and 255.7±186.1, sAT and tAT, respectively (p=0.44). The TLR was more frequent in sAT group than in tAT (sAT: 25 (29.0%) vs. tAT: 15 (15.9%) p=0.03). There were no significant differences in death (sAT: 1 (1.7%) vs. tAT: 5 (5.7%), p=0.54), amputations (sAT: 2 (2.3%) vs. tAT: 5 (5.7%), p=0.45) and bailout stenting (sAT: 2 (2.3%) vs. tAT: 3 (3.2%), p=0.74). Kaplan-Mayer analysis showed no significant differences between groups in time to TLR, amputation and death.

CONCLUSIONS

This study is hypothesis generating that plaque modification with tip based excision blades in directional atherectomy is more efficient than with blades placed on the side of the catheter.

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Characteristics of cardiac magnetic resonance imaging in spontaneous coronary artery dissection

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

AIMS

Spontaneous coronary artery dissection (SCAD) is an important cause of acute coronary syndrome (ACS) in women. Presently, coronary angiography is the gold-standard for establishing the diagnosis. However, angiographic abnormalities can be subtle and hence the diagnosis is often missed. We sought to examine the role of cardiac MRI (CMR) to characterize myocardial infarction (MI) patterns and establish differential diagnosis in SCAD patients.

METHODS AND RESULTS

Patients with non-atherosclerotic SCAD prospectively followed at Vancouver General Hospital and enrolled in our SCAD registries were reviewed. In this substudy, we included patients who underwent CMR to establish the cause of MI. Detailed baseline demographics, procedural results, hospital and long-term outcomes were recorded. CMR was performed as per the enrolling institution?s protocol and reviewed in detail. A total of 14 SCAD patients underwent CMR between 2009 to 2017. The mean age was 52.9±12.9yrs, and all were women. All patients presented with MI: 28.6% had ST- elevation, 71.4% had non?ST-elevation, and 28.6% had ventricular arrhythmias. Precipitating emotional stressors were reported in 50% and physical stressors in 42.9%. Fibromuscular dysplasia was present in 35.7% of this cohort. Ten patients presenting with the first SCAD event underwent early CMR testing at mean 6.8±6.0 days. Four patients presenting with second (recurrent SCAD) event underwent MRI at mean 263±164 days. Late gadolinium enhancement (LGE) in the left ventricular myocardium was noted in all 14 patients. LGE was transmural in 8 (57%) patients and subendocardial in 6 (43%) patients. All LGE distribution matched with culprit SCAD artery infarct territories.

CONCLUSIONS

LGE was present in all SCAD patients following their MI presentation. Segmental abnormalities on CMR can aid diagnosis of SCAD, differentiating from other causes of ACS such as myocarditis or Takotsubo syndrome.

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Intracoronary electrocardiogram to guide percutaneous interventions in coronary bifurcations: a proof of concept: the FIESTA (FFR vs. intracoronary electrocardiogram) study

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

The aim of this study was to determine the accuracy of the intracoronary electrocardiogram (icECG) to detect ischemia during bifurcation lesions percutaneous coronary intervention (PCI) with fractional flow reserve (FFR) as a reference.

METHODS AND RESULTS

Patients with significant bifurcation lesions defined as FFR?0.80 were included. FFR and icECG were performed in the main vessel (MV) and side branch (SB) before and after provisional stenting. icECG was recorded with a uninsulated proximal wire end connected to a unipolar lead. The diagnostic accuracy of icECG for the detection of ischemia in the SB after MV stenting was determined with FFR as a reference. Overall, 49 patients were included. Of all 24 bifurcations had SB FFR ?0.80 after MV stenting of those 22 patients had ST-segment elevation on the icECG. There was significant correlation between SB FFR and ST-segment elevation on icECG (r=-0.533,

CONCLUSIONS

Intracoronary ECG has a good ability to predict functionally significant stenosis at the SB after MV stenting during bifurcation PCI. This method provides a novel strategy to assess the significance of a SB lesion without the need of a pressure wire.

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Predictors of procedural and clinical outcome in patients with symptomatic tricuspid regurgitation undergoing transcatheter edge-to-edge repair

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

AIMS

Transcatheter tricuspid valve edge-to-edge repair with the MitraClipTM technique is a potential novel treatment option for symptomatic tricuspid regurgitation (TR) in patients at high surgical risk. Recent studies have suggested that TR reduction by edge-to-edge repair is safe and feasible, and improves functional status at short-term follow-up. The present study aimed to investigate predictors of clinical outcome at midterm follow-up in patients undergoing transcatheter edge-to-edge repair for TR. In addition, predictors of procedural success for TR edge-to-edge repair were investigated.

METHODS AND RESULTS

The analysis was carried out in 117 patients at increased risk for surgery (mean age 77.8 ± 8.1 years, EuroSCORE II 8.8 ± 7.8%, STS score 5.9 ± 5.3%) with symptomatic TR treated by interventional tricuspid valve edge-to-edge repair at two centers in Germany between March 2016 and November 2017. Seventy-four patients had concomitant severe mitral regurgitation and underwent combined transcatheter edge-to-edge repair of the mitral and tricuspid valve. Mean left ventricular ejection fraction was 48% and pre-procedural right ventricular function (tricuspid annular plane systolic excursion <17mm) was impaired in 58% of patients. Clip implantation failed in five patients due to insufficient echo view, excessive rete chiari or chordae entrapment. In the remaining patients, 107 clips were implanted at the anteroseptal commissure and 31 clips at the posteroseptal commissure. Procedural success (defined as successful clip implantation and TR reduction ?1) was achieved in 81% of patients. Tricuspid valve effective regurgitant orifice area (EROA) was reduced from 0.57 to 0.25 cm².

After a mean follow-up of 206 ± 126 days, 24 patients died and 21 patients were readmitted for heart failure. Procedural success independently predicted the time free of death and readmission for heart failure (HR 0.24 [0.12-0.47], p<0.01). The mortality rate was 64% in patients without procedural success and 23% in patients with procedural success (p<0.01). The rate of rehospitalization for heart failure was 50% in patients without procedural success and 11% in patients with procedural process (p<0.01).

While tricuspid EROA (OR 0.21 [0.06-0.73], p=0.01), tricuspid vena contracta (OR 0.87 [0.77-0.99], p=0.04), tenting area (OR 0.65 [0.45-0.94], p=0.02), TR coaptation gap (OR 0.74 [0.63-0.87], p<0.01) and a non-central or non-anteroseptal TR jet location (OR 0.22 [0.08-0.62], p<0.01) were predictive for procedural success, TR coaptation gap and a non-central or non-anteroseptal TR jet location independently predicted procedural success on multivariate analysis.

CONCLUSIONS

Among patients with symptomatic TR and increased surgical risk, successful transcatheter tricuspid valve edge-to-edge repair and post-procedural TR reduction are associated with lower mortality and rehospitalization for heart failure after a mean follow-up of 30 weeks. TR coaptation gap and a non-central or non-anteroseptal

TR jet are important predictors of procedural success, underlining the importance of echocardiographic imaging to guide patient selection for the procedure.

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Clinical and anatomical predictors of side branch problems in true bifurcation lesions treated by provisional strategy

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

One of the most common approach to manage coronarybifurcated-lesions (CBL) is the provisional stenting. Main drawbacks of provisional is the risk of side branch (SB) occlusion causing ischemia and technical troubles our aim is to elaborate the important anatomical and clinical factor that can predect risk of side branch impairment after provisional startegy

METHODS AND RESULTS

We retrospectively selected all patients who underwent PCI between January 2010 and December 2016 on a ? complex CBL? defined as Medina 1.1.1 or Medina 1.0.1 or Medina 0.1.1 class lesions. The primary procedural and angiographic end-points were: - ?SB trouble? defined as occurrence of at least one of: 1. SB TIMI flow <3 after MV stenting, 2. need of guidewire(s) different from the workhorse wire to
re-wire SB, 3. failure to re-wire the SB, 4. failure to dilate the SB after MV stenting, - ?angiographic success? defined as successful MV stenting with TIMI 3 in both MV and SB, - ?SB impairment?: SB TIMI flow <3 at the end of the procedure.

Out of 1420 consecutive patients underwent PCI on a bifurcated lesion, 538 patients underwent PCI with DES implantation on a complex bifurcated lesion. Angiographic success was achieved in 411 patients (76%), SB troubles occurred in 65 patients (12%) and SB impairment occurred in 47 patients (8%). At multivariable analysis to predict our study primary end points, interestingly we have a fixed variable that were able to predict our three end points. Smoking and hypercholesterolemia was a strong clinical predictors ($p = 0.009$, 0.02 respectively). Medina 1.1.1, extension of SB plaque more than 5 mm and SB TIMI flow before the procedures were the technical and anatomical predictors ($p = 0.002$, 0.02 and 0.001 respectively).

CONCLUSIONS

During provisional technique conduction the operator should be aware of the proper SB evaluation. In the present study, we introduce an easy five variables that from our experience affect the CBL procedure outcome (smoking, hypercholesterolemia, Medina 1.1.1, SB TIMI flow before intervention and the extent of the plaque more than 5 mm inside the SB) and may be considered as high risk factors for SB troubles and impairment.

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Thin-cap fibroatheroma is associated with higher rate of angiographic hidden plaque rupture in non-ischaemic vessels of diabetic patients - Insights from the COMBINE study

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

AIMS

The prevalence of thin-cap fibroatheroma (TCFA), plaque rupture (PR) and other thrombotic lesions in angiographic intermediate and fractional flow reserve (FFR) negative (>0.80) lesions in diabetes mellitus (DM) patients is unknown. Furthermore, whether the prevalence of PR, plaque erosion (PE) and calcified nodule (CN) associated thrombus in TCFA-containing vessels are also unknown.The aim of this study was to determine the prevalence of PR, PE and CN-associated thrombus in FFR negative vessels of DM patients with versus without TCFA defined by optical coherence tomography.

METHODS AND RESULTS

We performed the optical coherence tomography (OCT) analysis of the first 200 patients from the COMBINE study (NCT02989740), a multi-centre, prospective natural history study which combines OCT morphologic and FFR hemodynamic assessment of non-culprit lesions to better predict adverse event outcomes in DM patients. OCT analysis records the plaque types and the presence of plaque vulnerability features like thin-cap fibroatheroma, calcified nodule, neovascularization, cleft and, furthermore, the presence of plaque rupture, plaque erosion and intracoronary thrombus.

From 200 DM patients, 46 had TCFA and 154 had no TCFA in FFR negative vessels. The presence of risk factors and the clinical presentation including presentation for acute coronary syndromes, did not differ between the two groups. The mean angiographic diameter stenosis was 52.9±11.6%, the minimal lumen area stenosis was 61.0±12.6% in both groups (p=0.707, p=0.129, respectively). The baseline and the hyperaemic FFR value did not differ between the two groups: 94.9±4.7% vs. 94.6±9.0% (p=0.786) and 87.9±5.2% vs. 88.3±5.3% (p=0.628), respectively. The incidence of PR was significantly higher in TCFA positive group vs. TCFA negative group: 28.3% vs. 3.9%, respectively (

CONCLUSIONS

The major finding of this analysis is that in FFR negative vessels of DM patients containing TCFA had a significantly higher rate of angiographic hidden PR compared to vessels without TCFA. Furthermore, the total number of thrombotic lesions were more than three times higher in TCFA containing vessels which may predict a faster progression of the atherosclerotic disease and a possibly higher event rate in these patients.

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Polylactic-co-glycolic acid encapsulation of insulin-like growth factor 1 to promote stem cell survival following delivery to the heart

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

AIMS

Cardiac stem cells (CSCs) are a heterogenic group of cells and are concentrated in specific areas of the heart, such as the atria or pericardium. The overall aim of this study was to optimise a formulation providing an alternative option to activate in-situ intrinsic cardiac regenerative potential represented by the resident CSCs that would not require lengthy culture periods or patient specific culture preparations and methods.

METHODS AND RESULTS

Poly (lactic-co-glycolic acid) (PLGA) is a copolymer of poly (glycolic acid) (PGA) and poly (lactic acid) (PLA) and is a widely studied synthetic biodegradable polymer for encapsulating and delivering drugs/proteins to various target organs in the body. Because of its high biocompatibility and safety, it is approved by the United States Food and Drug Administration (FDA) and European Medicine Agency (EMA) to be used as a drug delivery vehicle in humans. We optimised the process parameters for fabrication of synthetic Insulin like growth factor (PIGF-1) loaded PLGA microparticles and nanoparticles using double emulsion solvent evaporation method or water-in-oil-in-water (W/O/W) method. The mean diameter of blank PLGA microparticles and PIGF-1 loaded microparticles were 1.63 +/- 0.62 µm and 2.09 +/- 0.47 µm respectively. The PLGA nanoparticle fabrication parameters resulted in blank nanoparticles and PIGF-1 loaded nanoparticles of 205.9 +/- 12.3 nm and 208.6 +/- 18.5 nm respectively. The size distribution was reported to be more consistent for PLGA nanoparticles. The polydispersity index (PdI) of blank and PIGF-1 loaded PLGA nanoparticles were 0.103 +/- 0.03 and 0.174 +/- 0.011 respectively. Scanning Electron microscopy (SEM) imaging revealed spherical morphology of both micro and nanoparticles.Encapsulation efficiency (EE) was significantly higher in microparticles (67 +/- 2%) than in nanoparticles (12 +/- 5%). Depending upon the feasibility of process parameters and good encapsulation efficiency of PIGF-1 loaded microparticles, we opted for the microparticles for our further experiments. PIGF-1 loaded PLGA microparticles were incorporated into cross linked hyaluronic acid-tyramide (HA-TA) hydrogel with the vision to increase the retention of PLGA microparticles in the noxious environment post MI. We tested various concentrations of PIGF-1 (10 and 25 ng/ml) released from PLGA microparticles itself and from PLGA microparticles in HA-TA gel (MP-HA) to induce a proliferative effect on treated rat cardiac stem cells (rCSCs). Cells exposed to PIGF-1 showed an increase in double stranded (dsDNA) compared to untreated control group, hence confirming the bioactivity of the released PIGF-1.

CONCLUSIONS

It is envisioned that the HA gel loaded with PIGF-1-PLGA microaprticles (MP-HA) will be delivered to the infarcted region of the heart via minimally invasive technique like transcatheter delivery method. This multimodal delivery of regenerative therapeutics by minimally invasive technique will be more feasible and economical in comparison to the stem cell transplant therapies.

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Angiographic late lumen loss revisited: impact on target lesion revascularisation

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

AIMS

To investigate the impact of late lumen loss (LLL) on target lesion revascularization (TLR) and device thrombosis in a patient- and study-level analysis of contemporary coronary devices.

METHODS AND RESULTS

We performed a patient-level meta-analysis of 7 randomized controlled trials including 2,426 patients treated with first- and second-generation drug-eluting stents and a study-level meta-analysis of 49 studies including 9,935 patients treated with contemporary devices (CE-marked after 2010). In the patient-level analysis, the probability regression curve showed an exponential relationship between the 2-year incidence of TLR and in-stent LLL only after having reached the highest quartile (in-stent LLL >0.435 mm). In the Cox proportional hazard model, LLL >0.435 mm was independently associated with an increased incidence of TLR up to 4 years after angiographic follow-up (adjusted HR 5.78 [95%CI: 3.44-9.73],

CONCLUSIONS

An angiographic LLL ?0.435 mm was not predictive of the incidence of TLR whereas a LLL >0.435 mm was. Low LLL in contemporary device trials may not be a sufficiently discriminating parameter for the comparative evaluation of devices.

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The clinical impact of psoas muscle cross-sectional area on medium-term mortality after TAVI

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

AIMS

Psoas muscle cross-sectional area is a proposed marker of frailty associated with mortality after TAVI. We aimed to assess the impact of psoas cross-sectional area on medium-term mortality in a large cohort of patients undergoing TAVI, adjusted for baseline variables including hypoalbuminaemia and anaemia.

METHODS AND RESULTS

This single centre registry-derived analysis assessed 1731 consecutive TAVI patients with available abdominal computed tomography between 2007 and 31st April 2015 at a high-volume centre. Gender-stratified, height-adjusted psoas cross-sectional area was measured at the mid-level of the 4th lumbar vertebral body. Kaplan? Meier survival distributions across psoas cross-sectional area quartiles were compared. Cox and logistic regression models were used to assess baseline variables associated with the five-year mortality primary outcome.

Median age was 81: 52.5% female. There were 555 deaths over 775 days mean follow up. Lower psoas cross-sectional area quartile patients were older, had a lower body mass index, lower creatinine clearance, with higher rates of anaemia, hypoalbuminaemia, and higher EuroSCORE. Unadjusted survival by psoas cross-sectional area quartile was significantly different in males (log rank p = 0.022) but not females (p = 0.251). In Bonferroni- adjusted multivariate analysis, psoas cross-sectional area quartiles were not significantly associated with mortality, hypoalbuminaemia (HR 2.10 [95% CI 1.53-2.87, p =

CONCLUSIONS

Psoas cross-sectional area was not significantly associated with mortality after adjusting for baseline variables. Hypoalbuminaemia and increasing age were significantly associated with increased risk of medium-term mortality after TAVI, whereas hypercholesterolaemia and female sex were associated with reduced risk.

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Thyroid disorders in spontaneous coronary artery dissection

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

AIMS

Spontaneous coronary dissection (SCAD) is an uncommon cause of acute coronary syndrome (ACS). Thyroid hormone affects the metabolism of all tissues in the body. The aim of this study was to analyze the prevalence and implications of thyroid disorders in a cohort of consecutive patients with SCAD.

METHODS AND RESULTS

This was a multicenter case (SCAD) and control (ACS without SCAD) study performed in 2 Spanish university tertiary hospitals. We evaluated 73 patients with SCAD and 73 controls who suffered an ACS matched by age, gender and clinical presentation. The prevalence of thyroid alterations in both groups was compared. In addition, among SCAD patients, findings of those with hypothyroidism were compared with patients with normal thyroid function.

Mean age was 55±12 years and 77% of patients were women. A statistically significant difference was observed in the prevalence of hypothyroidism between the two groups (26% vs 8%, p=0.004), being most of these patients on thyroid hormone replacement therapy with good metabolic control.

Among SCAD patients, those with hypothyroidism were more often female and had more distal dissections (74% vs 41%, p=0.03), located in curly vessels, and more often were managed conservatively (79% vs. 41%, p=0.007). During a mean follow-up of 4.1±3.8 years, the rate of adverse clinical events was 23% (n=17), with no differences according to the thyroid function status. Some patients with SCAD and abnormal thyroid function suffered iatrogenic dissections and this cohort tended to be associated with a higher recurrence rate (16% vs 7%, p=0.36) and lower rate of spontaneous resolution during follow-up.

CONCLUSIONS

There is a high prevalence of hypothyroidism in unselected consecutive patients with SCAD compared with a control group of ACS patients without SCAD. The group with hypothyroidism, with more distal dissections on curly vessels, is more frequently managed conservatively.

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Functional and structural coronary recovery following BRS at five-year follow-up: an OCT and quantitative flow ratio analysis

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

AIMS

Complete resorption of bioresorbable vascular scaffolds (BVS) with fully functional and structural recovery has not been demonstrated in real-world series. The objective of the study was to determine angiographic, quantitative flow ratio (QFR) and optical coherence tomography (OCT) findings 5-years after BVS implantation.

METHODS AND RESULTS

Lesions treated with BVS underwent prospective clinical, angiographic and OCT analysis from baseline to 5-year follow-up. Retrospective QFR analysis was performed. Mean lumen area (MLA) and QFR at follow-up were evaluated pre/post intracoronary nitroglycerine. Thirteen patients were treated with BVS in 2012. Nine of them presenting 11 lesions with one BVS per lesion enrolled. One single case presented severe restenosis at 6-months follow-up and was treated with metallic drug eluting stent. OCT analysis demonstrated fully resorption of all BVS at 5-years follow-up (?golden-tube? pattern). Neointimal thickness was 342.1±137.8µm. MLA decreased (8.84±1.6vs.6.64±2.19mm2,

CONCLUSIONS

Fully bioresorption of BVS and reduction of vulnerable plaques were found at 5-year follow-up. Despite normal flow and vessel morphology reduced vasomotion was found.

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Impact of chronic kidney disease on outcomes in TAVI

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

AIMS

Chronic kidney disease (CKD) in patients with aortic stenosis (AS) portends high morbidity and mortality. In the high-risk subset of AS patients undergoing transcatheter aortic valve implantation (TAVI), CKD is a common comorbidity. We aim to understand the impact of CKD on outcomes in AS patients treated TAVI.

METHODS AND RESULTS

Consecutive patients with severe AS who underwent TAVI at our institution were included. The patients were categorized by estimated glomerular filtration rate (eGFR) into CKD stage 1-2 (?60 mL/min/1.73 m2), stage 3 (30?59 mL/min/1.73 m2) and stage 4-5 (

CONCLUSIONS

AS patients with CKD undergoing TAVI represent a select high-risk group of patients at significantly greater risk of mortality and adverse outcomes. Care should be taken in the management of this challenging group of patients.

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New alternative in angiography: randomised comparison of digital subtraction angiography and kinetic imaging

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THEME: Peripheral Interventions
TOPIC(S): Below the knee, Iliac / Femoral / Popliteal

AIMS

To compare the performance of kinetic imaging in X-ray angiography and digital subtraction angiography (DSA)

METHODS AND RESULTS

We enrolled 42 patients undergoing lower limb X-ray angiography between February 2017 and June 2017. We compared the signal-to-noise ratio (SNR) of DSA and kinetic image pairs. Visual comparisons were performed using and inline questionnaire. Inter-evaluator agreement was determined using Fleiss? kappa test.
Kinetic images provided 3.3 times (median) and 2.3 times (median) higher SNR than raw and post-processed DSA images. Six specialists compared kinetic and DSA images. The LA was >73% (p 74% (

CONCLUSIONS

Kinetic imaging visualizes the same anatomical structures as DSA but offers better image quality. The improved SNR suggests that this approach could reduce the amount of contrast media and radiation exposure or improve the ability to effectively visualize smaller vessels.

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Percutaneous assessment and management of outflow graft obstruction in patients with continuous flow left ventricular assist devices

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

AIMS

Left ventricular assist device (LVAD) dysfunction is a major cause of morbidity and mortality among LVAD recipients. While much attention has focused on LVAD thrombosis, the management of outflow graft obstruction (OGO) is poorly defined. We report 4 cases of successfully treated LVAD OGO diagnosed using invasive haemodynamics in the cardiac catheterization laboratory.

METHODS AND RESULTS

We retrospectively reviewed all patients referred for right and left heart catheterization to evaluate LVAD obstruction in our institution from 2012-2017. OGO was identified in 4 patients by a stepwise approach in the catheterization laboratory. OGO was defined by high pull-back gradients across the outflow graft using fluid-filled manometers.

Out of 4 patients, 3 had received a HeartWare HVAD and 1 had a HeartMate II LVAD. The median time to OGO was 307 days after implantation (IQR 68-840). All patients presented with worsening heart failure requiring inotropes. Mean LVAD flow was 4.7+2.1 liters/minute. Mean peak LDH at admission was 409+99 U/L. Computed tomography angiography identified OGO in 1 out of 3 patients. Invasive haemodynamic assessment identified a high OGO gradient in all 4 patients. Successful percutaneous stenting of the OGO was performed in 3 cases with complete resolution of the OGO gradient. Surgical revision of the OGO was performed in 1 case. At 6 months, 75% of patients were alive without device exchange.

CONCLUSIONS

Outflow graft obstruction is an important and potentially reversible cause of LVAD dysfunction. We report the clinical utility of percutaneous treatment for OGO. Invasive LVAD interrogation is a highly sensitive measure of OGO and requires further study.

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Impact of different aortic stenosis pathophysiological subtypes on acute and late results after TAVI

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

AIMS

The aim of the present study was to compare acute and long-term clinical outcome after transcatheter aortic valve implantation (TAVI) in four different pathophysiological subtypes of severe aortic stenosis: high gradient, low flow-low gradient, paradoxical low flow-low gradient, normal flow-low gradient aortic stenosis.

METHODS AND RESULTS

This is an observational prospective study, that included 398 consecutive patients with severe aortic stenosis (aortic valve area < 1 cm2) referred for TAVI between January 1st 2008 and December 31st 2016. We excluded the valve in valve procedures for degenerate aortic bioprosthesis (n=23) and patients whose stroke volume could not be traced (n=32). The 343 patients who composed the study population were divided into four groups based on mean transvalvular aortic gradient, left ventricular ejection fraction (LVEF) and stroke volume index: 207 were classified high gradient [mean aortic gradient >40mmHg], 35 Low flow-low gradient [mean aortic gradient ?40mmHg, LVEF35ml/m2]. In hospital outcome was evaluated according to ? Valve Academic Research Consortium-2? definitions (myocardial infarction, stroke, bleeding, vascular complications, acute kidney injury, pacemaker implantation), while long-term follow up was performed by clinical outpatient evaluations at 1 month, 12 months and yearly thereafter and/or telephonic interviews.

Mean age was 82.9± 5.9 years. No significant differences were observed in the entire population in gender, diabetes mellitus, hypertension and clinical presentation at hospital admission. Conversly, low flow-low gradient patients had significantly higher incidence of previous myocardial infarction, previous coronary artery bypass grafting and rate of coronary artery disease. Logistic EuroSCORE and Euroscore II were also significantly higher in this group in comparison with high gradient, paradoxical low flow-low gradient and normal flow-low gradient groups. Transfemoral route (71.4%) and balloon expandable valves (58.3%) were used in the majority of cases. In hospital mortality was 5%. The 30-day mortality and procedural complications after TAVI was not different among the four groups. At long term follow-up, mean duration 26.6±25.8 months, the survival rate was significantly lower in the low flow-low gradient group. In the multivariate analysis low flow-low gradient aortic stenosis (hazard ratio [HR] 2.38, 95% confident interval [CI] 1.41-4.00 , p-value 0.001), age (HR 1.05, 95% CI 1.02-1.09, p-value 0.003) and creatinine at hospital admission (HR 1.15, 95% CI 1.02-1.31, p-value 0.024) were the only independent predictors of overall mortality.

CONCLUSIONS

In-hospital outcome after TAVI was similar in all aortic stenosis pathopysiologic subgroups, whereas patients with low flow-low gradient aortic stenosis had worse long term outcome.

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OCT surveillance of tissue coverage at six months after implantation of everolimus-eluting BRS vs. conventional everolimus-eluting stents in ISAR-Absorb MI trial

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

AIMS

Bioresorbable scaffolds (BRS) are novel devices designed to overcome the long-term limitations of permanent metallic stent implantation. Optical coherence tomography (OCT) surveillance can provide important insights on the process of vessel wall healing at follow-up. We sought to compare OCT-assessed healing at 6 months after implantation of everolimus eluting BRS and everolimus eluting metallic stents (EES) in patients treated for acute myocardial infarction (AMI).

METHODS AND RESULTS

ISAR-Absorb MI is a multicentre, assessor-blind randomized trial comparing outcomes of patients with AMI undergoing treatment with everolimus eluting BRS or conventional everolimus-eluting stents with angiographic surveillance planned for all patients at 6-8 months follow-up. Selected patients who had OCT surveillance (with commercially-available frequency domain OCT imaging systems) performed at the time of angiographic follow-up were included for the present analysis. Raw data of OCT image acquisitions were collected at four recruiting centres and analysed at a centralized core laboratory. Morphometric analysis of contiguous cross-sections was performed at 1 mm longitudinal intervals within the stented segment using QIvus 3.0.30.0 software. Data analysis was performed using IBM-SPSS, version 22.0.

OCT imaging data at post stenting follow-up on a total of 72 patients (83 stents) included in the BRS arm and 30 patients (36 stents) included in the EES arm at a median of 218 days was available for analysis. Morphometric analysis revealed mean stented length to be 21.35±8.78 and 21.60±7.35 mm in BRS and EES arm respectively. Mean minimum lumen area (5.35±2.04 vs. 5.26±2.00 mm2, respectively in BRS and EES) and minimum stent area (6.03±1.86 vs. 6.21±1.84 mm2 respectively in BRS and EES) were found to be comparable between the two stent arms. Similarly, average lumen area (6.99±2.27 vs. 6.87±2.12 mm2, respectively in BRS and EES), and average stent area (7.39±2.17 vs. 7.37±1.93 mm2, respectively in BRS and EES) were also found to be comparable.

Total number of frames assessed were 2,221 (1,569 in BRS, 652 in EES), with a total of 19,580 (13,022 in BRS, 6,558 in EES) visible struts. Overall strut coverage was better in the BRS group as compared to the EES group (97.5% vs. 91.4% respectively). Malapposed (1.1% vs. 0.4%) and uncovered struts (6.9% vs. 1.3%) were therefore more common in the EES group as compared to the BRS group. Mean percentage area stenosis was also higher in the EES group as compared to the BRS group (7.55±11.12 vs. 6.16±7.21 %

respectively).

Comparisons using generalised linear mixed model revealed significant differences in the two stent groups in terms of mean thickness of neointimal coverage (99.31±35.56 vs. 94.13±76.94 μm in BRS and EES respectively, p= 0.016) as well as mean neointimal area (0.39±0.47 vs. 0.50±0.79 mm2 in BRS and EES respectively, p= 0.001).

CONCLUSIONS

In selected patients undergoing OCT imaging at 6-8 months after implantation of everolimus eluting BRS and conventional EES stent systems for AMI, we observed generally favourable healing characteristics with high rates of strut coverage and low rates of strut malapposition in patients implanted with BRS in comparison to those implanted with EES.

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Incidence of long-term structural valve dysfunction and bioprosthetic valve failure after TAVR

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

AIMS

Long-term data on durability of currently available transcatheter heart valves are sparse. We sought to assess the incidence of long-term (8-year) structural valve dysfunction (SVD) and bioprosthetic valve failure (BVF) in a cohort of transcatheter aortic valve replacement (TAVR) patients who reached at least 5-year follow-up.

METHODS AND RESULTS

Consecutive patients with at least 5-year follow-up available undergoing TAVR from June 2007 to March 2012 were included. SVD and BVF were defined according to newly standardized EAPCI-ESC-EACTS criteria and reported as cumulative incidence function (CIF) to account for the competing risk of death. A total of 288 consecutive patients with a mean age of 80.7±5.3 years and with a mean STS-mortality score of 8.1±5.1% were analyzed. Survival rate at 8 years was 35.6%. Mean pressure gradients decreased from 53.3±15.9 mmHg (pre-TAVR) to 10.5±4.5 mmHg (in-hospital post-TAVR) (P

CONCLUSIONS

In an aged population of patients with symptomatic severe AS treated with first-generation bioprostheses, TAVR was associated with a survival rate of 35% but very low rates of bioprosthetic valve failure and structural valve dysfunction at 8 years.

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Safety of accelerated transfer to the ward and early discharge following minimalist TAVR in the cathlab setting

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

AIMS

We assessed the safety and efficacy of a clinical pathway with transfemoral (TF) TAVR performed in the catheterization laboratory setting and accelerated transfer to a general cardiology ward.

METHODS AND RESULTS

The Vancouver accelerated transfer to ward protocol is an initiative with aims to implement 1) heart team selection of patients with low TAVI procedural risk 2) peri-procedural minimalist approach under conscious sedation, 3) pre-specified criteria for accelerated transfer to a general cardiology ward, 4) rapid reconditioning post-procedural care, and 5) identification of patients suitable for early (

CONCLUSIONS

Use of a clinical pathway and rapid reconditioning protocol allows TAVR to be performed in the catheterization laboratory with accelerated transfer to the ward with minimal mortality, morbidity and a high proportion of patients achieving early discharge home. As TAVR continues to expand this has important implications for healthcare delivery.

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Preliminary exploration of supra-annular sizing for TAVR: the reasons behind

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

AIMS

We hypothesized that the greatest interference between the frame and aortic valvar complex occurs across the aortic valve leaflets. The aim of our study was to better understand the post-implant stent geometry of the Lotus valve and its potential implications for supra-annular sizing algorithms.

METHODS AND RESULTS

We retrospectively evaluated the multi-detector computed tomography (MDCT) of consecutive patients who received transcatheter aortic valve replacement (TAVR) with Lotus Valve System in our centre between November 2015 and January 2017 (N=32). Patient?s post-TAVR MDCT was first analyzed. Starting from the inflow, the maximal and minimal diameters, perimeter and area of prostheses were measured at every 3 mm along the prosthesis stent. The plane where the frame had the smallest area was defined as the waist. Compression was calculated as ([1 ? actual area/nominal area] × 100%) to represent interference between the implanted stent and anatomy. Pre-procedural MDCT was then blindly interpreted to predict where the maximal interference would be post-TAVR (i.e. the supra-annulus). The location of supra-annulus was often where bulky calcification and/or commissural fusion presented, around 4-8 mm above the annulus. The distances of the waist and predicted supra-annulus from the annulus were compared. The average age of this cohort was 71.97±6.10 years. The mean Society of Thoracic Surgeons predicted risk of mortality was 5.43% (interquartile range, 3.64-11.75%). Bicuspid morphology was confirmed on MDCT for 19 (59.4%) patients (type 0: n=15, type 1 left-right: n=4). The numbers of patients receiving a 23 mm, 25 mm and 27 mm valve were 15, 12 and 5 respectively. Measurements of the stent at various levels underwent a decrease from 3 mm above the inflow and an increase from the waist (areas from 3mm above the inflow to 18 mm above the inflow were 399.89±62.93 mm2, 363.71±60.06 mm2, 322.78±61.37 mm2, 314.30±64.62 mm2, 344.60±58.78 mm2 and 385.76±59.12 mm2), whereas the inflow edge of the stent adopted a variable depth along its circumference so the area measured was not very reliable. The waist was 5.75±1.65 mm higher than the native annulus on post-procedural MDCT. The waist had a nearly 2-fold larger compression rate than the stent at the native annulus level (36.27±10.36 vs. 18.90±9.55%, P<0.01). On the blindly interpreted pre-procedural MDCT, the predicted supra-annulus was only 0.18 mm higher than observed on the post-procedural MDCT scans (5.93±1.60 mm vs. 5.75±1.65 mm, P=0.55). The accuracy was consistent in different valve morphologies.

CONCLUSIONS

Major interference between the implanted prosthesis and anatomy occurred at a level above the annulus. Blinded interpretation of pre-procedural MDCT can reach a good accuracy of identifying the level of post-implant waisting. The concept of supra-annular sizing is reasonable and practical.

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Congestive profiles correlate with clinical outcomes among patients requiring acute mechanical circulatory support for cardiogenic shock

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

AIMS

The impact of congestive profile on clinical outcome in patients with cardiogenic shock (CS) supported by acute mechanical circulatory support (AMCS) is not well understood.

METHODS AND RESULTS

We retrospectively analyzed all patients (n=140) between 2012?2016 receiving VA-ECMO (n=59) or Impella (n=81) for CS at two institutions. Hemodynamic data were available for 106 patients and were used to categorize CS as euvolemic [right atrial pressure (RAP)<14 and pulmonary capillary wedge pressure (PCWP) <16], LV-dominant (PCWP>16 only), RV-dominant (RAP>14 only) or BiV congestion.

BiV congestion (56%) was more common than LV dominant (15%), RV-dominant (14%) or euvolemic shock (14%, p<0.01 for comparison). Compared to LV- or RV-dominant congestion, BiV congestion correlated with higher serum creatinine (1.94±1.12, 1.45±0.59, 1.64±1.15 mg/dl, p<0.01 for all comparisons), AST (1178±3281, 588±1774, 299±257 IU/L), ALT (541±1264, 358±1041, 161±196 IU/L) and lactate (5±4.1, 3.8±6.7, 4.3±2.6 mEq/L). Euvolemic shock was associated with similar serum creatinine, AST, ALT and lactate compared to LV- and RV-dominant congestion. Mortality was similar among patients with BiV congestion managed with left or right sided Impella (44%), BiPella (40%), VA-ECMO without (43%) and with a LV venting strategy (60%). Compared to VA-ECMO, in hospital mortality was lower among patients receiving Impella with LV-dominant congestion (0 vs 67%, p<0.01).

CONCLUSIONS

Biventricular congestion is common and associated with worse end organ function compared to univentricular dominant congestion among patients with CS supported by AMCS. Mortality was lower for patients with LV dominant congestion supported by Impella. Improved understanding of hemodynamics in CS may allow for congestive profile-device matching and potentially improve outcomes.

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Impact of device landing zone calcification on paravalvular regurgitation after TAVR with different next-generation devices

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

AIMS

Residual paravalvular regurgitation has been associated to impaired outcomes after TAVR. Aim of this study was to evaluate the impact of device landing zone (DLZ) calcification on residual PVR after TAVR with different next-generation transcatheter heart valves (THV).

METHODS AND RESULTS

560 patients underwent TAVR with the Edwards SAPIEN 3 THV (n=292), the Symetis ACURATE neo THV (n=166), the Lotus valve (n=52) or the Medtronic Evolut R THV (n=50). Calcification of the device landing zone was retrospectively assessed from routinely acquired preprocedural contrast-enhanced multidetector computed tomography data and correlated with echocardiographic data at discharge.

The occurrence and degree of PVR differed significantly between the different THV. PVR was ?moderate in 0.7% of SAPIEN 3 (S3) patients, 13.9% of ACURATE neo (NEO) patients, 0% of Lotus patients and 22.0% of Evolut R (ER) patients, respectively (

CONCLUSIONS

Device landing zone calcification predicted the degree of PVR after TAVR with 3 out of 4 devices. The susceptibility to PVR depending on the amount of calcium differed significantly with higher susceptibility in the self-expanding NEO compared to the balloon-expandable S3 or the Lotus valve. However, also permanent pacemaker implantation rates differed significantly between the implanted devices with higher rates in Lotus and ER treated patients. Thus, DLZ calcification is an import factor to be considered in prosthesis selection for each individual patient, keeping in mind the trade-off between PVR reduction and the occurrence of new-onset conduction disturbances requiring permanent pacemaker implantation.

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The feasibility of intracoronary electrocardiogram with provocative acetylcholine test in chest pain patients with non-obstructive coronary artery disease ? Results from AChPOL registry

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

A significant proportion of patients undergoing coronary angiography due to chest pain has normal or near normal coronary arteries. The aim of this study was to assess the changes detected with intracoronary electrocardiography (icECG) during provocative test with acetylcholine in mid-European patients population and its influence on further diagnosis and treatment.

METHODS AND RESULTS

Between January 2011 and December 2012 we selected patients with normal or insignificant changes in coronary arteries and a history suggesting Prinzmetal disease or microvasculature impairment. The full history of these patients included the nature of their chest pain (typical or atypical, exertional, at rest, nocturnal) and coronary risk factors. Nitrates and calcium channel blockers were stopped 48 hours before the test. Acetylcholine (ACh) was injected through the Judkin?s catheter after performing the angiographic procedure. Acetylcholine was injected in incremental doses of 25, 50 and 75 mg into the right coronary artery and 25, 50 and 100 mg into the left coronary artery. Test was defined as positive when asymptomatic > 70% coronary spasm was induced or when the reduction in lumen diameter was more than 50% together with present chest pain and/or changes in ECG. Unipolar intracoronary ECG (icECG) was recorded before, during and after ACh administration. The coronary wire was placed in all vessels at the border of mid and distal segments.

In the abovementioned period of time we performed 156 provocative tests with ACh, in which 54 were performed with the additional use of icECG. The spasm was observed in 35 patients (64.8%, Prinzmetal disease, group I), in 13 (24.1%) patients during ACh administration chest pain and ST depression in standard ECG appeared (microcirculation dysfunction, group II) and in 6 (11.1%) there were no signs and symptoms (group III).

When analyzing baseline icECG recordings we observed more pronounced ST depression in the group II (microcirculation dysfunction) than in the group I (Prinzmetal disease, $p = 0.003$) or the group III (negative ACh test, $p = 0.001$). During ACh administration there was no difference between the group I and the group II regarding ST-elevation in icECG. Moreover, after the procedure in the group II again ST depression was more pronounced comparing with two other groups ($p = 0.005$). There was difference between groups I and III.

When observing these patients during 3-year follow-up we disclosed that in group II there was the lowest rate of completely or nearly asymptomatic patients (after introduction of proper medical treatment). This rate was 62.9%, 23.1% and 83.3% in group I, group II and group III, respectively. At EuroPCR we will present the 5-year follow-up of these patients with special focus on cases of MINOCA.

CONCLUSIONS

icECG monitoring during provocative test with acetylcholine proved the presence of baseline ischemia in patients with microcirculation dysfunction. And this group proved to be the poorest responder to the given treatment.

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Feasibility and safety of pressure-regulated deployment of balloon-expandable transcatheter aortic valves

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

AIMS

Annular rupture is a devastating complication of transcatheter aortic valve implantation. The risk of rupture increases with prosthesis oversizing and subannular calcification. Conversely, valve undersizing leads to paravalvular regurgitation and poor long-term outcomes. Current deployment methods are volume-regulated and rely on an estimation of prosthesis cross sectional area based on the volume to which a deployment balloon is filled. We sought to determine if deploying valves in a pressure-limited manner would reduce risk of annular rupture without increasing paravalvular regurgitation.

METHODS AND RESULTS

99 consecutive patients undergoing TAVI with balloon-expandable transcatheter aortic valves were included in this study. Valves were deployed in a pressure-limited manner, between 4 and 5 atm, which invariably resulted in residual volumes remaining in the deployment syringe. Presence of aortic regurgitation was assessed for using aortography, echocardiography and hemodynamic measurements. A Chi-squared test was applied to assess for statistical significance with regards to the need for post-dilatation when deploying at 4 atm versus above 4 atm. Post-dilatation requirement was considered a surrogate for the presence of significant aortic regurgitation.

Of the 99 patients, 6 were excluded from analysis due to incomplete data. 52 patients received valves deployed at 4 atm. Of these 23 (44%) required post-dilatation balloon aortic valvuloplasty and 29 (56%) did not. 41 patients received valves deployed between 4.5-5 atm, of which 10 (24%) required post-dilatation and 31 (76%) did not. The chi-squared statistic was 3.94 ($p=0.047$) suggesting that deployment at 4.5 atm and above significantly reduces the need for post-dilatation.

Next, patients at high risk of annular rupture were identified based on prosthesis over-sizing and presence of subannular calcification. Prosthesis oversizing was determined using sizing charts provided by the device manufacturer with 20% taken as the cut-off point, above which patients would be considered to be at high risk of annular rupture. 30 patients were identified who received valves that would have been oversized by more than 20%, had they been deployed at nominal volume. TAVI CT images were then assessed for subannular calcification using pre-specified criteria. Patients with moderate-severe subannular calcification were considered to be at high risk of rupture and 17 patients were identified who fit this criterion. No patient undergoing deployment up to 5 atm experienced annular rupture. Thus, using pressure-limited technique, we demonstrated that safe deployment is possible despite prosthesis oversizing and presence of subannular

calcification.

CONCLUSIONS

At present, volume-regulated deployment techniques are used to minimize risk of annular rupture during TAVI procedures. However, this does not take into account the fact that arterial wall tension is determined by both inflation pressure as well as balloon diameter as demonstrated by Laplace?s Law where Hoop stress = Pressure x Diameter. We postulated that avoiding high pressures during valve deployment would reduce wall tension and risk of rupture. Our study has shown that pressure-regulated deployment is a safe and reproducible modification to current techniques of deploying balloon-expandable valves. In addition, our results suggest that deployment at 4.5 atm minimizes the risk of post-deployment paravalvular regurgitation without increasing the risk of annular rupture.

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PCI guided by enhanced stent visualisation system improves clinical outcomes

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

AIMS

Stent underexpansion and overlap are both significant risk factors for early and late stent thrombosis. Enhanced stent visualisation (e.g CLEARstent) provides comparable data with IVUS to improve underexpansion and reduce overlap. We aimed to strengthen data on its impact on outcomes, specifically using CLEARstent technology.

METHODS AND RESULTS

This was a cohort study based on this institution?s PCI registry. A total of 1293 patients who had PCI with overlapping DES in the same vessel between May 2015 and January 2017 were included in the analysis. Patients were divided into CLEARstent (n=528) and no CLEARstent guided intervention (n=765). Groups were comparable for patient characteristics (age, DM, ACS presentation) aside from the no CLEARstent guided group having a greater proportion of IVUS guidance (15% vs 9%). The primary end-points were MACE (target vessel revascularisation, myocardial infarction and all-cause mortality) recorded at a median follow up of 19.8 months. A significant difference in MACE was observed between patients who underwent CLEARstent-guided PCI (12.1%) compared with patients who underwent no CLEARstent guided PCI (19.2%, p=0.001). This difference was mainly driven by reduced rates of target vessel revascularisation and recurrent MI. Overall this difference persisted after multivariate Cox analysis (HR 0.64, 95% CI 0.46-0.90, p=0.0015) and propensity matching (HR=0.59, 95% CI: 0.41-0.88, p=0.0008).

CONCLUSIONS

The routine clinical use of CLEARstent technology during PCI can be useful, and appears to result in better medium-term angiographic and clinical outcomes. Further study is required to build on this promising signal.

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Propensity-adjusted subgroup analysis of outcomes in patients undergoing transcatheter and surgical aortic valve replacement in a nation-wide real-world cohort

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

AIMS

Transcatheter aortic valve replacement (TAVR) is recommended for patients suffering from aortic valve stenosis at increased operative risk or age over 75 years. Beyond that patients with different co-morbidities could profit from TAVR. The present study analyzes in-hospital outcomes of aortic valve replacement procedures in order to identify subgroups of patients in which TAVR might be preferable.

METHODS AND RESULTS

For all 33,789 isolated transfemoral TAVR and SAVR procedures performed in Germany in 2014 and 2015, co-morbidities and in-hospital outcomes were identified by ICD- and OPS-codes. Patients undergoing TAVR were older with more co-morbidities and at increased estimated risk (logistic EuroSCORE TAVR: 13.9±10.3%, SAVR: 5.3±4.7%, p<0.001). In order to allow comparison of outcomes after TAVR and SAVR, a covariate and propensity-adjusted analysis was performed in different subgroups. The risk of mortality is significantly lower in patients undergoing TAVR with an age over 80 years (TAVR vs. SAVR 80-84: OR 0.55, p=0.002, ? 85 OR 0.42, p=0.006) and at high operative risk (patients with EuroSCORE >9: OR 0.62, p=0.001). No significant difference in in-hospital mortality occurs between TAVR and SAVR in patients under 80 and intermediate or low risk (<75: OR 0.85, p=0.404, 75-79 OR 0.82, p=0.219, EuroSCORE <4: OR 1.44, p=0.308, EuroSCORE 4-9: OR 0.81, p=0.156). In contrast, patients with advanced renal failure and patients in NYHA-class III/IV had better outcomes after TAVR (GFR<30: OR 0.45, p=0.005, NYHA III/IV: OR 0.72, p=0.015). Female sex, previous CABG, peripheral arterial disease, COPD, pulmonary hypertension, and diabetes were not found to be factors which favor a treatment strategy. Patients undergoing TAVR suffered more often from strokes and acute kidney failure. After risk-adjustment TAVR was associated with a lower risk for acute kidney injuries (OR 0.62, p<0.001). Risk for stroke was similar (OR 1.07, p=0.558). Risk of bleeding (OR 0.17, p<0.001) and requiring prolonged mechanical ventilation (>48h, OR 0.21, p<0.001) was decreased in patients undergoing TAVR. As expected, the TAVR procedure is associated with an increased risk for pacemaker implantations (OR 4.61, p<0.001).

CONCLUSIONS

The present study analyzing over 33.000 real-world procedures confirms that TAVR is the safer procedure in clinical practice for patients with severe aortic valve stenosis at increased operative risk, over 80 years, in NYHA-class III/IV, and with renal failure.

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Coronary hemodynamics in patients with severe aortic stenosis and coronary artery disease undergoing TAVI: implications for clinical indices of coronary stenosis severity

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

A significant proportion of patients with severe aortic stenosis have concomitant coronary artery disease. There is no valid index of coronary stenosis severity in these patients. We undertake a systematic analysis of phasic intracoronary pressure and flow velocity in patients with severe aortic stenosis and coronary artery disease, undergoing TAVI, to determine the effect of the valve on coronary haemodynamics and implications for coronary stenosis assessment.

METHODS AND RESULTS

28 patients (30 lesions, 50.0% male, mean age 82.1±6.5 years) with severe aortic stenosis and coronary artery disease were included. Intracoronary pressure and flow assessments were made at rest and during hyperaemia immediately before and after TAVI.

Flow during the wave-free period of diastole (iFR-flow) does not change post-TAVI (29.78±14.9 cm/s versus 30.81±19.6 cm/s, p=0.64). Whole cycle hyperaemic flow (FFR-flow) increases significantly post-TAVI (33.44±13.4 cm/s pre-TAVI versus 40.33±17.4 cm/s post-TAVI, p=0.006), this is secondary to significant increases in systolic hyperaemic flow post-TAVI (27.67±12.1cm/s pre-TAVI versus 34.15±17.5cm/s post-TAVI, p=0.02). iFR values do no change post-TAVI (0.88±0.09 pre-TAVI versus 0.88±0.09 post-TAVI, p=0.73), whereas FFR decreases significantly post-TAVI (0.87±0.08 pre-TAVI versus 0.85±0.09 post-TAVI, p=0.001).

CONCLUSIONS

Systolic and hyperaemic coronary flow increase significantly post-TAVI, as a result, hyperaemic indices that include systole underestimate coronary stenosis severity in severe aortic stenosis. Flow during the wave-free period of diastole does not change post-TAVI, suggesting that coronary indices calculated during this period are not vulnerable to the confounding effect of the stenotic aortic valve.

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Patients dismissed from a programme of TAVI: clinical profile, reasons for the rejection and prognosis

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

AIMS

Since its beginning, TAVI has been the chance for those patients who are not suitable for surgical replacement of the aortic valve. But there still are some patients who cannot be beneficiated with this procedure, due to comorbidities or to technical or economic reasons. The aim of this study is to analyse the clinical profile and the prognosis of this group of patients.

METHODS AND RESULTS

Methods: Analytical and observational study developed in a University Hospital with a TAVI program since 2009. We analysed data of all consecutive patients who were evaluated by the interventional cardiologist as candidates for a TAVI procedure and in whom it was not performed. We used Chi-square test or Fisher?s exact to compare categorical variables. Time-to-event analyses, based on all available follow-up data, were performed with the use of Kaplan-Meier estimates and were compared between groups with the use of the log-rank test.

Results: Fifty patients (15.5%) out of the 322 who enter the screening were rejected for a TAVI procedure, 52.0% directly by the interventional team and 34.0% by the heart team. In the 14.0%, the patient rejected itself the procedure. Median age was 80,9±6.8 years-old, they had high charge of severe comorbidities (42.0% non-valvular cardiopathy, 34.0% respiratory, 26.0.0% renal, 14.0% neurologic and 8.0% oncologic). Four patients (8.0%) were in a critical situation at the moment of the evaluation. There were technical limitations for TAVI in 60.0% of the patients (48% had no auspicious vascular access, 10% had non-suitable annulus size and 2% both).

During the follow-up (median 15.8 months) 61.7% of patients died, 38.3% died for cardiovascular reasons. One patient finally underwent surgery and died immediately after it. Median survival was 25.7±5.0 months, with a p50 of 17.0 months (IC 95: 10.7-23.2months). Kaplan-Meier estimated first-year mortality to 40.0% and two years mortality was estimated at 63.0%.

Patients in which heart team was the responsible for the dismission showed a tendency to lower survival (11.8±2.5 vs 31.5±7.2, p 0.15).

Those who had respiratory comorbidities had lower cardiovascular mortality (11.8% vs 88.2%, p<0.01) and higher survival free of cardiovascular death (54.4±10.5 vs 26.6±7.4 months, p 0.01). Patients with neurological comorbidities had an almost-significant higher survival free of cardiovascular death (31.3±6.0 vs 80.0±0.0, p 0.05). Also, those who were evaluated on a critical situation had higher and earlier cardiovascular mortality (100 vs 0%, p 0.02, 6±5 vs 44.7±7.8 months, p<0.01).

CONCLUSIONS

In daily practice, 15,5% of the patients proposed for TAVI were rejected and they have a high mortality as is

known for the natural evolution of aortic stenosis. Nevertheless, those with severe respiratory comorbidities had lower and later cardiovascular mortality, a fact that will be probably seen in other comorbidities with a larger number of patients. Patients evaluated in a critical situation had a worse cardiovascular prognosis, which highlights the importance of an adequate timing indication. Further studies are necessary to give higher evidence which could help in the selection of the appropriated candidate for a TAVI.

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Could social media improve students? knowledge in cardiology?

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

AIMS

The recent expansion of e-learning in universities contributed to improve students', knowledge through new educational tools. Among the means used to these distance learnings, social networks, like Facebook, remain underused platforms. Our aim was to develop a new, easy-to-use, daily learning management system to improve students? knowledge in cardiology.

METHODS AND RESULTS

We developed a database of almost 300 multiple choice questions (MCQs) for medical students of Paris Descartes University. MCQs were sent daily through a dedicated group on Facebook network. A final evaluation was performed at 3 months, including 25 MCQs previously answered by students (part 1 on 25 points) and 25 unanswered new MCQs (part 2 on 25 points). The primary endpoint was this final evaluation score according to daily participation of each student.

A total of 255 medical students (64% female) participated in the MCQ program, with a daily participation rate of 71%. The majority of participants (61.6%) used their smartphone to answer the MCQs, with a mean time to answer of 50 seconds. Correct answers rate was globally noted in 26%. 190 students underwent the final evaluation at 3 months. Students with daily participation rate more than 90% had a better total score than students with participation rate inferior than 10% (26.3±7.1 points vs. 13.2±7.5 points, $p<0.0001$). Furthermore, there was a strong positive correlation between participation rate and total score to the evaluation ($R^2=0.28$, $p<0.001$), primarily due to part 1 score (including 25 previously answered MCQs). The surveyed participants rated their satisfaction with an average of 8.8 on 10

CONCLUSIONS

This study suggests that our learning management system, using Facebook network, has been well adopted by the medical students with a high rate of daily participation. Despite the short time spent on the formation (50 seconds per MQC), the program already showed its educational efficiency, especially for the most diligent students. Modernization of medical students? formation using social networks should be explored and considered.

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Can simulator-based teaching improve medical students? knowledge and competences? Results of a randomised trial using a coronary angiography simulator to teach the coronary anatomy

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

AIMS

Simulator-based teaching for coronary angiography (CA) is a seductive educational tool for medical students to improve knowledge and skills. Its pedagogical impact has not been fully evaluated yet. The aim of this study was to compare traditional face-to-face teaching with a simulator-based teaching.

METHODS AND RESULTS

118 students, in their 4th to 6th year of medical school, were prospectively randomized in two groups: a control teaching group (n=59, CONT group) and a simulator (Mentice AB, Sweden) group (n=59, SIM group). CONT group received a PowerPoint-based course whereas SIM group received a simulator-based course including exactly the same information in an interactive environment. After the course, students were evaluated by 40 multiple choice questions (maximum of 100 points (pts)), including questions on coronary anatomy (part1), angiographic projections (part2) and real case interpretations (part3).

Student characteristics were identical in both groups: 52.5% were female, age was 22.6±1.4 years. 35.6% were in their 4th year, 35.6% in 5th year and 28.8% in 6th year. SIM students scored higher than CONT students irrespective of age and year of medical school (59.5±10.8 vs. 43.7±11.3pts,

CONCLUSIONS

This trial suggests that simulator-based teaching in CA significantly improves students' knowledge in coronary anatomy and angiography projections, as well as clinical and decision-making competences. These results should encourage further evaluation of simulator-based teaching in other branches of medicine.

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Trancatheter repair for isolated tricuspid regurgitation - Morphological and functional implications - Insights from cardiac magnetic resonance

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

AIMS

Significant tricuspid regurgitation (TR) is a major determinant of morbidity and prognosis in advanced heart failure patients. Recently, percutaneous tricuspid valve repair has been proposed as a promising treatment option.

So far, data on the hemodynamic consequences of isolated catheter-based tricuspid valve intervention are scarce, partly due to the difficulty of imaging the right ventricle. We therefore sought to characterize the clinical outcomes and hemodynamic effects of interventional tricuspid valve repair one month after the intervention with the use of cardiac magnetic resonance.

METHODS AND RESULTS

Twenty patients (age 78.2 ± 2.3years) with severe TR and high surgical risk underwent interventional tricuspid valve repair using the MitraClip© system. Clinical Follow-UP including 6-minute-walk-test was realized 34 ± 16 days after the intervention. Fifteen patients underwent repeated CMR imaging with volumetric assessment and flow studies.

After the procedure patients experienced a significant improvement in symptoms with reduction of NYHA class (

CONCLUSIONS

Transcatheter tricuspid valve repair leads to significantly reduced TR, reverse remodeling of the RV and cardiac output augmentation in advanced heart failure patients with isolated right ventricular-atrial regurgitation. These hemodynamic changes translate into improvement in symptoms and clinical functionality at one month follow-up. Cardiac magnetic resonance is well suited to longitudinally study effects of percutaneous valve interventions.

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Impact of the table height and the operator?s height on the level of radiation delivered to interventional cardiologists

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

AIMS

We aimed to investigate the impact of the average table height on the level of radiation delivered to cardiologists performing coronary interventions.

METHODS AND RESULTS

The population for analysis included all invasive coronary procedures performed in a single catheterization laboratory (cathlab) in our centre from March to June 2017. The primary endpoint was operator radiation exposure, as assessed using personal electronic dosimeters located on the operator?s left arm. In total, 225 invasive coronary procedures were analyzed. When the average table height was 1126mm or more, the operators received a radiation dose that was, on average, 53% lower than when the table was lower than 1126mm ($p=0.02$). This reduction remained significant by multivariate analysis adjusted for the operator ($p<0.001$). The height of the operator was strongly related to the position of the table during the procedure, with the tallest operators (respectively 185 and 190 cm) routinely placing the table in a higher position (above 1126 mm) than the operators who were less tall (171 and 178 cm).

CONCLUSIONS

Our study shows that the position of the patient table at a height of 1126 mm or higher from the ground decreases the radiation exposure of the operator by 53%, regardless of the operator.

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Impact of cell therapy on cardiovascular outcomes in patients with refractory angina: a systematic review and meta-analysis

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

AIMS

The effect of stem/progenitor cells on cardiovascular outcomes (mortality, MACE) in patients with refractory angina (RFA) remains unclear because studies to date have been small phase I-II trials with one phase III trial stopped early due to futility (recruitment). We performed a meta-analysis of randomized controlled trials (RCTs) to evaluate the effect of stem cell therapy in patients with RFA who were ineligible for revascularization.

METHODS AND RESULTS

The Meta-analysis and systematic review was registered with the Prospero Database (CRD42018084257). MEDLINE, EMBASE, COCHRANE and ongoing trial databases were searched from inception till January 2018 for relevant randomized controlled trials, which yielded eight studies and a total of 452 patients. The outcomes pooled were MACE (myocardial infarction, cardiac-related hospitalization, and mortality), mortality and indices of angina (anginal episodes, Canadian Cardiovascular Society [CCS] angina class, exercise tolerance, anti-anginal medications). Our analysis showed a decreased risk of both MACE (OR 0.50,CI, 0.31?0.79) and mortality (OR 0.30, 95% CI, 0.12?0.75) in cell-treated patients compared with patients on maximal medical therapy. This was supported by improvements in surrogate endpoints of anginal episodes, use of anti-anginal medications, CCS class, and exercise tolerance.

CONCLUSIONS

The meta-analysis indicates that in addition to improvements in indices of angina, cell-based therapies improve cardiovascular outcomes (mortality/MACE) in patients with RFA. In view of the prior difficulties with a phase III study this supports the concept that cells could be used on compassionate grounds in patients with no further treatment options.

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Effect of adjunctive thrombus aspiration on in-hospital and three-year outcomes in patients with STEMI and large native coronary artery thrombus burden

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Although the long-term clinical benefit of adjunctive thrombus aspiration (TA) during primary percutaneous coronary intervention (PPCI) remains controversial, the impact of TA in patients with large thrombus has not been evaluated. The aim of the present study was to investigate the effect of adjunctive TA during PPCI on clinical outcomes in patients with ST-segment elevation myocardial infarction (STEMI) and a large thrombus.

METHODS AND RESULTS

We assessed the effect of adjunctive TA on in-hospital and 3-year clinical outcomes in 627 patients with STEMI and a large thrombus in the native coronary artery. The cumulative 3-year incidence of all-cause death was not significantly different between the 2 groups (91.5% vs 89.0%, log-rank test p?=?0.347). After adjusting for confounders, the risk of all-cause death in the TA group was not significantly lower than that in the non-TA group (hazard ratio 1.11, 95% confidence interval 0.60 to 3.54, p?=?0.674). The adjusted risks of target lesion revascularization, nonfatal acute myocardial infarction, and stent thrombosis were also not significantly different between the 2 groups.

CONCLUSIONS

Adjunctive TA during PPCI was not associated with better in-hospital and 3-year all-cause deaths in patients with STEMI and a large coronary artery thrombus.

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A new percutaneous technique (glue and suture) for effective vascular access site closure in patients undergoing transfemoral aortic valve implantation and thoraco-AAA repair

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

AIMS

In the absence of a simple yet effective vascular closure device for hemostatic control in large arteriotomy sites, there is a search for a percutaneous closure method which is proved to be safe and efficacious. A single ProGlide/Glubran technique involves a suture placement on vessel wall followed by tissue glue injection in tissue above the vessel wall and has not been studied previously for safety and efficacy. Aim- To study the feasibility, efficacy and safety of a new single-ProGlide/Glubran technique for vascular access site closure after transfemoral TAVI and TAAR.

METHODS AND RESULTS

We used this technique from 2011-2015 in 250 patients(218 TAVI, 32 TAAR). The primary end-point was success of technique defined as access site hemostasis without complications, not requiring any re-intervention within 30 days of index procedure. Complications were defined as vessel rupture, dissection, occlusion or stenosis > 50%, thrombosis, ischemic injury, blood loss requiring > 2 blood transfusion, arterio-venous fistula, pseudoaneurysm and neurological impairment. Mean sheath size was 18.09 +1.55 F. Patients had a mean age 82.4 +1.93 years, with a logistic Euro SCORE of 20.2. The overall success rate was 98.4%. VARC 2 minor bleed was seen in 1.6% with no major bleeding. Time of manual compression (mean+ SD) was 3.5 ±1.5 minutes. Thirty-day mortality was 0.4%(non-cardiovascular).

CONCLUSIONS

The single-ProGlide/Glubran technique is a safe and cost-effective method of closing the arterial access site after transfemoral TAVI and TAAR and results in favorable overall early outcomes.

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Contrast-zero TAVI for patients with severe renal dysfunction: a single-centre experience

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

AIMS

To assess the feasibility of a totally contrast-free TAVI procedure with no use of contrast dye both for pre-procedural assessment and during TAVI.

METHODS AND RESULTS

All consecutive patients with glomerular filtration rate (GFR) ? 30 ml/min and severe aortic stenosis treated with transfemoral TAVI at our Institution were included in the Registry. Patients underwent carbon dioxide angiography and no-contrast CT for assessment of vascular access suitability. Aortic annulus sizing was performed by intraprocedural TEE. Twenty patients (age 81.8±5.4, 60% males, GFR 27.4.±3.1 ml/min) were included in the study. All procedures were done in general anaesthesia. Three different devices were used (CoreValve Evolut R, Lotus, Acurate Neo). As a result, procedural success was obtained in 100% of cases. Paravalvular leak was not more than mild in all patients. Final gradient was ? 5 mmHg in all patients. No major vascular complications were reported. There were two deaths not related to TAVI procedures. No patients developed acute kidney injury during hospital stay.

CONCLUSIONS

We showed for the first time the feasibility of a totally contrast-free strategy, including planning and procedural standardized, for performing TAVI in patients with poor preoperative renal function at very high risk of acute kidney injury.

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Five-year clinical outcomes of PCI with DES in patients with left main equivalent coronary artery disease

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

AIMS

The aim of the present study is to assess the long-term clinical outcome of patients with left main equivalent coronary artery (LMECA) disease after PCI with DES.

METHODS AND RESULTS

Between September 2004 and December 2012, a total of 150 patients with LMECA disease were treated with PCI with a DES implantation. After PCI, all patients received dual antiplatelet therapy for at least 12 months.Thereafter, clinical follow-up was obtained for a mean period of 5 years for all patients and angiographic follow-up was performed for 92 (61.3%) patients. The primary endpoint was the cumulative rate of composite major adverse cardiac events (MACE), including the combined incidence of cardiac death, target lesion revascularization (TLR), target vessel revascularization (TVR) and new lesion, the second endpoint was the incidence of stent thrombosis. QCA was used to estimate the degree of plaque stenosis in the proximal parts of LAD and LCx.

Overall, 332 lesions were treated successfully with 354 DES. At 5-years, a total of 5 (3.3%) patients had suffered cardiac death. The incidence of TVR, TLR and new lesion was 4 (2.6%), 21 (14%) and 23 (15.3%) among the patients. Late stent thrombosis occurred in 1 (0.6%) patient. Predictors of MACE were age, diabetes mellitus and acute coronary syndromes (

CONCLUSIONS

To the best of our knowledge this is the first study to evaluate the long-term follow up of patients with LMECA disease treated with PCI and DES implantation. Treatment of LMECA disease with PCI results in a favorable acute clinical outcome and relatively low long-term MACE.

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Complete vs. culprit only lesion intervention in ACS patients with multivessel disease: incidence and outcomes from the London Heart Attack Group

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THEME: Coronary Interventions
TOPIC(S): NSTEMI

AIMS

A large proportion of patients presenting with non-ST-segment elevation myocardial infarction (NSTEMI) present with multi-vessel disease (MVD). We investigated the outcomes of complete revascularisation intervention compared to culprit vessel (CV) only intervention in a large contemporary cohort of patients undergoing percutaneous coronary intervention (PCI) for NSTEMI.

METHODS AND RESULTS

This was an observational cohort study of 37,491 NSTEMI patients treated at the 8 Heart Attack Centres in London, UK (between 2005-2015). Patients? details were recorded during the procedure into local databases using the British Cardiac Intervention Society PCI dataset. 21,857 patients (58.3%) presented with NSTEMI and MVD. Primary outcome was all-cause mortality at a median follow-up of 4.1 years (IQR: 2.2-5.8 years).

11,737 (53.7%) patients underwent complete revascularsation intervention during PCI for NSTEMI. Patients undergoing CV intervention were more likely to be male, diabetic, had previous MI and previous PCI compared to the complete revascularisation intervention group. In-hospital MACE rates were similar (52.0% vs 48.0%,p=0.462) between the two groups. Kaplan-Meier analysis demonstrated significant differences in mortality rates between the two groups during the follow-up period (22.5% in the CV intervention compared to 25.9% in the complete revascularisation interevention group, p=0.0005). After multivariate cox analysis (HR: 0.92 95%, CI: 0.87-0.98) and the use of propensity matching (HR: 0.85 95%, CI: 0.78-0.99) complete revascularisation intervention was associated with reduced mortality.

CONCLUSIONS

In NSTEMI patients with MVD, complete coronary revascularisation appears to be superior to culprit only vessel PCI in terms of long-term mortality rates.

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First clinical experience with the Magmaris magnesium BRS: a single-centre study

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

AIMS

Bioresorbable coronary scaffolds (BRS) with a magnesium backbone have been recently studied as an alternative to polymeric scaffolds, providing enhanced vessel support and a faster resorption rate. However, several recent case reports suggested early scaffold recoil resulting in adverse clinical events. We aimed to assess the performance of the commercially available Magmaris BRS with serial optical coherence tomography (OCT) at different time points.

METHODS AND RESULTS

The Magmaris BRS was implanted successfully in six patients with stable de-novo coronary artery lesions following recommendation for optimal implantation. Angiographic follow-up including OCT assessment was performed at a medium of 8 months (rang 4 ? 12 months) in all patients. Late lumen loss was 0.59 ± 0.39mm, percentage diameter stenosis of 39.65 ± 15.81% and binary restenosis rate was 33.3%. OCT showed a significant reduction in both minimal lumen area and scaffold area at the site of the minimal lumen area by 43.44 ± 28.62% and 38.20 ± 25.74% respectively, the percentage lumen area stenosis was 56.64% with a binary restenosis rate of 83.3%. A fast and heterogeneous scaffold degradation process was found with 62.8% of the struts reabsorbed at 4 months and 95.6% at 12 months post implantation. One patient presented 4 months post implantation with unstable angina, OCT revealed severe scaffold recoil with a minimal scaffold area of 1.19 mm2 (baseline 4.67 mm2) for which a target lesion revascularization using 2 drug-eluting stents was performed.

CONCLUSIONS

Our findings confirm premature dismantling of the latest magnesium BRS iteration with subsequent recoil and higher than expected decrease in minimal lumen area.

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Contemporary bifurcation lesion practice and outcome: insight from a global all comers registry

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS
The optimal management of bifurcation lesions remains a subject of considerable debate. Newer thin-strut drug eluting stent with improved design might offer better treatment option for this challenging lesion. The purpose of this study is to assess the contemporary bifurcation treatment practice using a thin-strut stent with bioresorbable polymer (Ultimaster).

METHODS AND RESULTS
e-ULTIMASTER is a large, prospective, multicentre registry that enrolled patients treated with Ultimaster DES worldwide. Among 8879 patients enrolled so far and reached 1-year follow up, 1168 patients were enrolled in pre-specified subset of bifurcation treatment.
Patients had a mean age of 65.6 years old, 79% were male, 24% had diabetes mellitus while 65% had hypertension. More than half of the patients (53%) presented with acute coronary syndrome with 15% ST elevated myocardial infarction (STEMI) patients. 80% of the procedure were performed using radial approach. On average, 1.6 lesions per patient were treated. More than half of the lesions were true bifurcation according to Medina classification with following frequencies: 1.1.1 (34%), 1.0.1 (8%), and 0.1.1 (10%). In total 559 patients (48%) were treated in both main and side branch, and among them 258 patients received stenting in both main and side branch. The distribution of two stent techniques was the following: T-stenting 22%, V-stenting 7%, Kissing stents 9%, Crush 14%, Culotte 17%, TAP 16% and others 14%. Kissing balloon post-stenting was performed in 35% of patients, while proximal optimisation technique (POT) was used in 31% of the patients. The number of stent implanted per patient was 1.7±1.0 and the total stent length per patient was 36.5±24.5 mm.
Clinical outcomes reported at 1 year for this subgroup of patients were: any death 2.8%, cardiac death 2.0%, target vessel MI 1.1%. Low rates of revascularisation were observed in this subgroup despite complex lesions with a clinically driven target lesion revascularisation (TLR) of 2.4% and target vessel revascularisation (TVR) of 3.8% at 1 year, respectively. The composite endpoint of target lesion failure and target vessel failure were 5.2% and 6.3%, respectively. The rate of stent thrombosis was 0.9% at 1 year.
At 1 year follow up, in 258 patients who were treated with a 2 stent strategy, the target vessel MI was higher (3.5% vs 0.8%, P=0.011) than in patients which received stenting only in main branches (n=266), while the cardiac death rates were similar between these two groups (2.3% vs 2.3%, p=0.99). The revascularization rates were also numerically higher in two stent group comparing with one stent group (4.3% vs 2.3% for clinically driven TLR and 6.2% vs 3.4% for clinically driven TVR) at 1 year respectively. The stent thrombosis rate was 1.6% in two stents group while no stent thrombosis occurred in main branch stenting only group.

CONCLUSIONS
Data from this large real-life registry reflect contemporary PCI practice in treating bifurcation lesions. The 1 year clinical outcome confirmed the good safety and efficacy profile of Ultimaster, a thin-strut drug eluting stent

with bioresorbable polymer, in the treatment of bifurcation lesions. Bifurcations treated with 2 stents tend to be more complex and have more adverse thrombotic events including MI and stent thrombosis.

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ConfidenHT system - Renal nerve mapping using electrical stimulation for a renal sympathetic denervation procedure

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

AIMS

As the exact location of renal nerves cannot be visualized, Renal Denervation procedure remains a so-called blind procedure. The aim of the present study is to assess the safety and feasibility of the ConfidenHTTM system, a renal nerve mapping system using electrical stimulation.

METHODS AND RESULTS

The Confiden(HT) study is a prospective first-in-man multicenter study designed to assess the safety and feasibility of renal nerve mapping using the ConfidenHT? system in 20 hypertensive patients with an indication for coronary angiography or with a planned renal sympathetic denervation. 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 and displays the stimulation outcome (BP and/or HR changes) during stimulation. 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.

The technology could help to improve RDN procedures by providing: (1)better patient selection of RDN responders and non-responders, and (2)intra-procedural guidance and feedback to optimize technical success rates. The primary performance endpoint was the change in blood pressure during stimulation.

20 patients (58 ± 11.5 years old, 156±23 office systolic BP, 9/11 male/female respectively, and GFR of 78 ± 13 mL/min/1.73 m2) have been included. Most of procedures were performed under local anesthesia with mild conscious sedation.

The system appeared safe in all 20 cases with no peri-procedural adverse events. Post stimulation there were no signs of angiographically visible spasms/thrombus or dissection in any of the treated arteries. A varying response to electrical stimulation was found among patients with a clear location dependent response along the artery (Hot and Cold spots). The increase in systolic BP and MAP ranged from 0 to 30 mmHg and 0 to 18 mmHg respectively.

CONCLUSIONS

Results suggest that renal nerve mapping using the ConfidenHTTM system technology is feasible and safe and offers promising diagnostic electrical renal nerve mapping opportunities in hypertensive patients which could help in optimizing the result of renal sympathetic denervation

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Is the microcirculation downstream non-culprit stenoses affected in the subacute phase of AMI? Implications for FFR-guided coronary revascularisation

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

AIMS

To investigate the status of the microcirculation remote to an infarcted territory in patients with AMI and non-culprit vessels (NCVs) suitable for fractional flow reserve (FFR)-guided coronary revascularization.

METHODS AND RESULTS

Methods: We enrolled patients with AMI (non-ST elevation [NSTEMI] and ST-elevation myocardial infarction [STEMI]) and multivessel disease. Within the subacute phase of AMI, NCVs were evaluated with FFR and the index of microcirculatory resistance (IMR). The microcirculation status subtended to NCVs was compared with that of vessels in a cohort of stable angina (SA) patients, using a propensity score matching (1:1 vessels). The propensity model was adjusted by age range, sex, previous myocardial infarction and target vessel to reduce differences in clinical predictors of high IMR. Patients presenting with unstable angina were excluded.

Results: From 309 patients (418 vessels) evaluated with FFR and IMR, 56 patients (70 NCVs) presented with AMI (NSTEMI: 26 patients, 33 NCVs, STEMI: 30 patients, 37 NCVs). Mean time between AMI to physiological interrogation of NCVs was 5.9±2.4 days. By applying the propensity model, a control group of 46 SA-patients (59 vessels) was generated and compared to 49 AMI-patients (59 NCVs). The matching model efficiently avoided significant differences in age (62.3±9.9 vs. 63.7±10.7, p=0.52), sex (male 89.8% vs. 89.1%, p=0.92), previous MI (20.4% vs. 19.6%, p=0.92) and target vessel (left anterior descending coronary artery 45.8% vs. 45.8%, p=1.00). Stenosis severity was similar in AMI and SA groups, either as judged by angiography (%DS 51±10.7 vs. 49±22.9, p=0.597) or FFR (0.79±0.11 vs. 0.81±0.13, p=0.345). Microcirculatory resistance subtended to NCVs was similar to that of target vessels of SA patients (AMI group: mean IMR 17.6±9.2, median 15.6 [10.4-21.2] vs. SA group: mean IMR 18.9±10.8, median 16.8 [11.9-23.8], p=0.496). Subtended microcirculatory resistance of NCVs was also similar between STEMI and NSTEMI patients (mean IMR 16.6±7.6, median 15.2 [10.2-18.9] vs. mean IMR 21.3±16.0, median 17.2 [11.2-24.8], respectively, p=0.125).

CONCLUSIONS

In the subacute phase of AMI, the microcirculation distal to non-culprit stenoses is not significantly affected, being similar to vessels in SA. This suggests that FFR-based physiological assessment of non-culprit stenoses is not affected by transient microcirculatory dysfunction in the subacute phase of AMI, as judged by IMR.

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Five-year clinical outcomes in the randomised SORT OUT VI non-inferiority trial comparing durable-polymer zotarolimus-eluting and biodegradable-polymer biolimus-eluting coronary stents

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

AIMS

Remnants of polymer materials on drug-eluting stents may trigger chronic inflammatory responses that can lead to impaired endothelialization of stent struts, positive vessel remodeling, and increased risk of stent thrombosis, or may serve as corrosive barriers and thus lessen the risk of stent thrombosis.

METHODS AND RESULTS

The SORT OUT VI is a randomized, multicenter, all-comer, non-inferiority trial comparing a highly biocompatible durable-polymer zotarolimus-eluting stent (Resolute Integrity, Medtronic CardioVascular, Inc., Santa Rosa, California) with a biodegradable-polymer biolimus-eluting stent (BioMatrix Flex, Biosensors Interventional Technologies Pte Ltd., Singapore) in unselected coronary patients. Eligible patients were aged 18 years or older with chronic stable coronary artery disease or acute coronary syndromes, and at least one coronary artery lesion (>50% diameter stenosis) requiring treatment with a drug-eluting stent. Endpoints included major adverse cardiac events (MACE), a composite of safety (cardiac death and myocardial infarction not clearly attributable to a non-target lesion) and efficacy (target-lesion revascularization), the individual endpoints of MACE, and definite stent thrombosis.

From March 2011, to August 2012, 2997 patients were randomly assigned (1:1) to receive either the durable-polymer zotarolimus-eluting stent (1502 patients) or the biodegradable-polymer biolimus-eluting stent (1497 patients). The zotarolimus-eluting stent was non-inferior to the biolimus-eluting stent at 12 months and 3 years. Results from the 5-year follow-up will be presented at EuroPCR 2018.

CONCLUSIONS

Conclusion will be presented at EuroPCR 2018.

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What we learned after first 122 CAS procedures using dual-layer micromesh Roadsaver stents

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

AIMS

In this study, we aimed to evaluate the 30-day clinical outcome after implantation of 5F mesh-covered ROADSAVER carotid stent in patients with symptomatic or high-risk carotid stenosis who had high or moderate risk of carotid endarterectomy and required revascularization.

METHODS AND RESULTS

This prospective study was carried out in high volume center in Poland. The primary endpoint was the 30-day rate of major adverse events (MAE), defined as the cumulative incidence of death, stroke and myocardial infarction. A total of 117 patients (122 carotid artery stenting (CAS) procedures) were recruited in the study, out of whom 83 (71%) were males. The mean age was 69.4±9.5 years and 37 (30.5%) of patients were symptomatic. During the procedure, the use of embolic protection devices was mandatory - proximal protection was used in 58 (47.5%) of cases and in 62 (51%) patients direct stenting was performed. Mean Internal Carotid Artery/Common Carotid Artery stenosis before stenting was 84.8±8.2%, whereas it was 17.8±7.4% after stent implantation (

CONCLUSIONS

The 30-day clinical outcome of 117 patients (122 procedures) treated with a new generation of dual-layer micromesh Roadsaver stent shows very good results. Our study suggests that the Roadsaver stent is safe and effective device for endovascular treatment in patients with symptomatic high-risk stenosis of carotid artery. Moreover, according to our experience implanting shorter Roadsaver stents during CAS procedure is feasible and should be considered in majority of cases.

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C-reactive protein and prognosis after PCI and bypass graft surgery for left main coronary artery disease: analysis from the EXCEL trial

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

AIMS

The prognostic impact of high-sensitivity C-reactive protein (CRP) levels in patients with left main coronary artery disease (LMCAD) treated with PCI or CABG is unknown. We sought to determine the effect of elevated CRP prior to LMCAD revascularization on 3-year outcomes.

METHODS AND RESULTS

In the EXCEL trial, patients with LMCAD were randomized to PCI with everolimus-eluting stents versus CABG. We used multivariable Cox proportional hazards regression to assess the associations between normal versus elevated baseline CRP, randomized treatment, and the 3-year risk of adverse events. The assigned revascularization was performed as the first procedure in 1882 of 1905 randomized patients with LMCAD, among whom 999 patients (53.1%) had available baseline CRP levels (509 and 490 randomized to PCI and CABG respectively). CRP was low (

CONCLUSIONS

In patients with LMCAD undergoing revascularization in the EXCEL trial, elevated baseline CRP levels were strongly associated with the occurrence of death, MI and stroke at 3 years, irrespective of the mode of revascularization. Further studies are warranted to determine whether anti-inflammatory therapies may improve the prognosis of high-risk patients with LMCAD.

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High-bleeding risk patients with ACS treated with contemporary DES and clopidogrel or ticagrelor: insights from change DAPT

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

AIMS

The prospective observational 'CHANGE DAPT' study compared clopidogrel versus ticagrelor-based dual antiplatelet (DAPT) regimens in consecutive patients with acute coronary syndrome (ACS), treated with percutaneous coronary intervention (PCI) with contemporary drug-eluting stents (DES). During the ticagrelor period (May 2014-August 2015) there were more major bleedings than during the clopidogrel period (December 2012-April 2014).

METHODS AND RESULTS

To evaluate whether the excess of major bleedings during the ticagrelor period may be limited to high bleeding risk patients, we performed an explorative analysis of all 2,062 'CHANGE DAPT' participants, of whom 547(26.5%) were classified as high bleeding risk (clopidogrel period, n = 245, ticagrelor period, n = 302). In high bleeding risk and non-high bleeding risk patients, we assessed the impact of the clopidogrel period versus the ticagrelor period on propensity score-adjusted rates of major bleeding and a pre-defined ischemic endpoint (composite of cardiac death, myocardial infarction, or stroke) at 1-year follow-up. Among high bleeding risk patients, the rate of major bleeding was significantly higher during the ticagrelor period (1.7% vs. 5.0%, adjusted hazard ratio 3.70 [95%CI 1.18-11.67], p=0.03), while there was no significant difference in the ischemic endpoint (6.6% vs. 8.0%, adjusted hazard ratio 1.23 [95%CI 0.63-2.42], p=0.54). In non-high bleeding risk patients, the rates of major bleeding (1.1% vs. 1.7%, adjusted hazard ratio 2.13 [95%CI 0.84-5.43], p=0.11) and the ischemic endpoint (2.8% vs. 3.4%, adjusted hazard ratio 1.38 [95%CI 0.74-2.57], p=0.32) were similar between both periods.

CONCLUSIONS

Among consecutive ACS patients, the increased risk of major bleeding during ticagrelor-based DAPT was limited to high bleeding risk patients. In both high bleeding risk and non-high bleeding risk patients, ticagrelor-based DAPT did not reduce ischemic outcomes following treatment with contemporary DES implantation.

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Comparison of short-term clinical outcomes between resolute onyx zotarolimus-eluting stents and everolimus-eluting stent in patients with AMI undergoing successful revascularisation

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

AIMS

Recently, percutaneous coronary intervention (PCI) with a second-generation drug-eluting stent (DES) is the standard treatment in patients with acute myocardial infarction (AMI). Although previous studies showed the comparable clinical outcomes between currently used second-generation stents, there is a lack of study to compare the efficacy and safety of the Resolute Onyx zotarolimus-eluting stent (O-ZES) and everolimus-eluting stent (EES) in patients with AMI. Therefore, the present study aimed to compare clinical outcomes of O-ZES and EES in patients with AMI undergoing successful PCI.

METHODS AND RESULTS

From January 2016 to December 2016, the Korea Acute Myocardial Infarction Registry (KAMIR) enrolled 3,364 consecutive patients. PCI with stent implantation was performed in 2,800 patients. Among of them, O-ZES was used in 402 patients and EES was used in 1,084 patients. The primary endpoint was the target lesion failure (TLF), defined as a composite of cardiac death, target vessel myocardial infarction (TV-MI), and ischemic driven-target lesion revascularization (ID-TLR) at six months clinical follow-up.

At six months, the incidence of TLF was not significantly different between O-ZES and EES group [4.0% vs. 3.9%, adjusted hazard ratio (HR) 1.36, 95% confidential interval (CI) 0.67 to 2.77, p = 0.930]. O-ZES also showed similar results of cardiac death (3.7% vs. 3.4%, adjusted HR 1.38, 95% CI 0.65 to 2.93, p = 0.771), TV-MI (0.2% vs. 0.6%, adjusted HR 0.86, 95% CI 0.09 to 7.90, p = 0.456), ID-TLR (0.0% vs. 0.3%, p = 0.524), and definite or probable stent thrombosis (0.2% vs. 0.3%, adjusted HR 1.71, 95% CI 0.06 to 46.09, p = 0.938) when compared with EES.

CONCLUSIONS

Our study shows that implantation of O-ZES or EES provided comparable clinical outcomes with similar risk of six-month TLF and definite/probable ST in patients with AMI undergoing successful PCI.

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Left ventricular reverse remodelling predicts long-term outcomes in patients with functional mitral regurgitation undergoing MitraClip therapy: results from a multicentre registry

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

AIMS

To explore whether left ventricular reverse remodelling (LVRR) is a predictor of outcomes in patients with functional mitral regurgitation (FMR) undergoing MitraClip.

METHODS AND RESULTS

We retrospectively analysed 184 consecutive subjects who underwent MitraClip for FMR between December 2009 and June 2016 at 3 Italian centres. LVRR was defined as a reduction in left ventricular end-systolic volume ?10% from baseline to 6-month and was observed in 79 (42.9%) patients. Compared with non-LVRR, LVRR patients were more likely to be females, less likely to have an ischemic aetiology of MR or a prior (<6 months) HF hospitalization and had smaller LV dimensions. NYHA class improved from baseline up to 1-year follow-up in both groups. Two-year survival free from all-cause and cardiovascular (CV) death, HF hospitalization and combined endpoint (CV mortality or HF hospitalization) was higher in LVRR vs. non-LVRR group (87.3% vs. 75.2%, p=0.039, 92.4% vs. 83.8%, p=0.070, 77.2% vs. 60%, p=0.020, and 74.7% vs. 55.2%, p=0.012 respectively). LVRR was associated to a significant reduction of the adjusted relative risk of mortality, HF hospitalization and combined endpoint (HR 0.44 95% CI [0.20-0.96], p=0.040, HR 0.55, 95% CI [0.32-0.97], p=0.038, and HR 0.54, 95% CI [0.32-0.92], p=0.023 respectively). Female gender and absence of HF hospitalizations 6-month before MitraClip were associated to an almost 3-fold increased relative risk to experience LVRR. Patients without diabetes mellitus, with non-ischaemic aetiology of MR and LVEDD <75 mm had a roughly 2-fold increased risk to develop LVRR.

CONCLUSIONS

LVRR is associated with better long-term outcomes in patients with FMR treated with MitraClip. Female gender, absence of diabetes, freedom from prior HF hospitalizations, non-ischaemic aetiology of MR and LVEDD<75mm are predictive of LVRR.

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Non-ischemic cardiomyopathy is associated with better outcomes in patients with functional mitral regurgitation undergoing MitraClip implantation

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

AIMS

Aim of the present study was to review the clinical and echocardiographic outcomes of a consecutive series of patients with functional mitral regurgitation undergoing Mitraclip therapy comparing ischemic versus non-ischemic etiology.

METHODS AND RESULTS

Among a consecutive series of 72 patients undergoing Mitraclip implantation between 2013 and 2016 at our Institution, 57 patients with functional mitral regurgitation [34 patients (mean age: 73±10 yrs) with ischemic cardiomyopathy and 23 patients (mean age: 72±9 yrs) with non-ischemic CMP] constituted the study population. Clinical and echocardiographic assessment was performed preoperatively, at discharge and at follow-up. A composite end-point (CE) of death and/or heart failure admission at follow-up was calculated. Finally, the ? variation for the main echocardiographic variables was calculated as the percentage difference between follow-up and baseline values.

As regard to preoperative data, all patients presented in advanced NYHA class (94% NYHA III-IV) with low EF (28±11%) and higher level of proBNP (8000±2107 ng/L). Patients with ischemic cardiomyopathy showed higher rate of male gender (p=.05), higher rate of CV risk factor and higher rate of previous cardiac surgery (71% vs 13%, p=.01) compared to non-ischemic cardiomyopathy.

Procedural success was similar in both group (92%), but ischemic patients had higher probability to be treated with two or more clips (56% vs 39%, p=.05), given the complexity of regurgitant jet. Postoperative complication (p=.43) as well as 30-days mortality (6% vs4%, p=.36) were similar in both group.

Mean follow-up was 20 months (range 4-49). FU mortality (33% vs 13%, p=.05) and heart failure admission (33% vs 18%, p=.04) were significantly higher in ischemic cardiomyopathy. Two-years Kaplan-meier freedom from CE was significantly lower in ischemic cardiomyopathy (47% vs 82%, p=.001). Mitraclip was effective in reducing mitral regurgitation in both group with nearly 80% of patients with mitral regurgitation less than 2+ and NYHA class I-II at follow-up.

Finally, in patients with ischemic cardiomyopathy, Mitraclip therapy was ineffective in preventing further left ventricular dilatation (?iEnd-Diastolic Volume=+25%, ?iEnd-Systolic Volume=+26%) and dysfunction (?EF= -7%). On the opposite, patients with non-ischemic CMP exhibited a significant increase in left ventricular function (?EF= +10%) and a significant reduction in pulmonary pressure (?PaPs=-18%).

CONCLUSIONS

In a cohort of high-risk heart failure patients, Mitraclip therapy showed satisfying results, with high success rate, low operative mortality and lower rate of complications, even if patients with ischemic cardiomyopathy exhibited worse clinical and echocardiographic results at medium term follow-up.

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Benefit of switching DAPT after ACS according to on-treatment platelet reactivity: the timing of platelet inhibition-vasodilator-stimulated phosphoprotein pre-specified analysis of the timing of platelet inhibition randomised study

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

AIMS

TOPIC trial suggested that switched dual antiplatelet therapy (DAPT) could improve net clinical benefit after acute coronary syndrome (ACS) by preventing bleeding. The Objective was to evaluate the impact of initial platelet reactivity on the benefit of switched strategy.

METHODS AND RESULTS

ACS patients, one month after coronary stenting and event-free, were randomly assigned to aspirin and clopidogrel (switched DAPT) or continuation of drug regimen (unchanged DAPT). All patients underwent platelet function testing at this time and were classified as low on-treatment platelet reactivity (PRI-VASP?20%) or no LTPR (PRI-VASP>20%). The primary endpoint aimed to evaluate the impact of platelet reactivity on clinical outcomes and benefit of switched DAPT strategy.

645 patients were included of whom 305 (47%) were classified as LTPR. LTPR patients were less often diabetic (p=0.01), had lower BMI (

CONCLUSIONS

Switched DAPT was superior regardless of initial platelet reactivity but benefit was greater in LTPR patients. Indeed, the switched strategy was highly effective in this group, who had impaired prognosis with unchanged DAPT but similar prognosis after switching.

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Long-term outcomes after treatment of bare-metal stent restenosis with paclitaxel-coated balloon catheters or everolimus-eluting stents. Three-year follow-up of the TIS randomised study

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

AIMS

In the previous TIS randomized study, the treatment of bare metal stent restenosis (BMS-ISR) using paclitaxel-eluting balloon catheters (PEB) led to significantly less 12-month late lumen loss (LLL) than the implantation of second generation everolimus-eluting stents (EES).
In this extended study, we aimed to compare the long-term ef?cacy of PEB or EES for BMS-ISR treatment.

METHODS AND RESULTS

We analyzed 3-year clinical follow-up data from patients included in the TIS study. A total of 136 patients with BMS-ISR were allocated to receive treatment with either PEB or EES (68 patients with 74 ISR lesions per group).
Clinical data were obtained for all patients at the 3-year follow-up. Time to follow-up did not significantly differ between the groups: 1210 days (±168, median 1270) in the PEB group, and 1172 days (±178, median 1270) in the EES group (P=0.289).
Despite the better 12-month angiographic results in the PEB group, at 3-year clinical follow up, the PEB and EES groups did not significantly differ in the incidence of major adverse cardiac events (MACE, 19.1% vs. 29.4%, P=0.230), including CV death (5.9% in both groups), myocardial infarction (4.4% vs. 5.9%, P=1.000) and target vessel revascularization (TVR, 8.8% vs. 17.6%, P=0.205). Both groups also did not differ with regards to death from all causes (8.8% in both groups), definite stent thrombosis (2.9% vs. 0%, P=0.496), or occurrence of a second MACE due to a need for repeated TVR (1.5% vs. 2.9%, P=1.000). The log-rank test revealed no significant difference in the event-free survival (time to MACE) between the PEB and EES groups (P=0.298), either.
In the PEB group, the MACE incidence was almost the same up to 12 months (10.3%) and after 12 months (8.8%, P=1.000). On the other hand, in the EES group, over 2/3 of MACE occurred earlier, during the first 12 months (19.1% vs. 8.8%, P=0.136).

CONCLUSIONS

Despite the better 12-month angiographic results after PEB treatment for BMS-ISR, the PEB and EES groups did not significantly differ with regards to 3-year MACE incidence.
Clinical Trial Registration: URL: http://www.clinicaltrials.gov. NCT01735825.

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The EVEREST II REALISM Continued Access study: five-year outcomes in high surgical risk patients

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

AIMS

The EVEREST II REALISM Continued Access study (REALISM) is a prospective, multi-center, continued access study to collect data on the real-world use of the MitraClip device in both high and non-high surgical risk patients. Enrollment in the high risk arm was initiated in January 2009 to provide continued access to the MitraClip therapy. We report outcomes through 5 years in the high risk arm.

METHODS AND RESULTS

REALISM high surgical risk patients had 3+ or 4+ MR and were deemed high risk for surgery predicted by STS risk calculator operative mortality of ?12%, or surgeon assessment based on pre-specified high surgical risk factors. Outcome measures included SF-36 quality of life and heart failure hospitalizations through the first year of follow-up, and NYHA functional class and echocardiographic measurements by an independent core laboratory through 5-year follow-up.

A total of 628 patients (FMR 69% (n=436), DMR 31% (n=192)) were treated with the MitraClip device in the high risk arm of REALISM between January 2009 and December 2013. Patients were elderly (mean age: 76.7±10.7 years) and symptomatic with 85.2% in NYHA functional class III or IV at baseline. Mean ejection fraction was 47.6±14.1% (60.7±9.4% DMR, 41.8±11.7% FMR). The mean predicted STS surgical mortality was 11.1±7.0%.

Freedom from mortality at 1, 3, and 5 years was 76.9%, 53.7%, and 34.0%, respectively. Through the first year of follow-up, SF-36 quality of life physical and mental component scores improved significantly from baseline by 4.9 ±9.8 and 6.2 ±13.1 points respectively, and annualized rate of HF hospitalizations decreased by 45.3%.

In patients surviving to 5 years (n=274), discharge and last known MR severity were ?2+ in 93.2% and 85.8% respectively. In patients who died within 5 years, discharge and last known MR severity were ?2+ in 87.7% and 75.6% respectively. Median time to last available transthoracic echocardiogram was 1,464 days for survivors versus 344 days for those who died within 5 years. Congestive heart failure was present in approximately 30% of deaths. At 5 years post MitraClip procedure, 90.9% of surviving patients (n=99 paired data) had MR severity ?2+, 47.5% had MR ?1+, and 82.2% were in NYHA functional class I or II. LV end-diastolic volumes decreased numerically from 150.4±60.3 ml at baseline to 146.8±71.6 ml at 5 years in the overall cohort (p=0.39, n=89 paired), decreased significantly from 124.0 ±33.6 ml at baseline to 109.9 ±26.3 ml at 5 years in the DMR cohort (p=0.016, n=26 paired) and were unchanged from 161.3 ±65.6 ml at baseline to 162.0 ±78.6 ml at 5 years in the FMR cohort (p=0.91, n=63 paired).

CONCLUSIONS

In the REALISM registry, five-years after treatment with the MitraClip System, surviving high risk patients with severe MR achieved significant reduction in MR, and symptomatic and functional improvement. Detailed final results including outcomes stratified by etiology and predictors of survival in this highly comorbid group will be presented.

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Effect of successful revascularisation on left ventricular diastolic dysfunction in patients with aortoiliac occlusive disease

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

AIMS
Aorto-iliac occlusive disease (AIOD) affect the systemic vascular resistance and increase the afterload, because the left ventricle (LV) must work harder to eject blood into a smaller vascular bed. We investigated whether successful revascularization of AIOD is associated with improvement of left ventricular diastolic dysfunction (LVDD).

METHODS AND RESULTS
A total of 37 patients with AIOD (34 men and 3 women, age 65.1 ± 7.2 years) were analyzed. The primary endpoint was defined as the change in mitral E/E? ratio. There were no significant changes in E velocity (from 0.7 ± 0.2 m/s to 0.7 ± 0.2 m/s, p-value=0.153), A velocity (from 0.8 ± 0.2 m/s to 0.9 ± 0.2 m/s, p-value=0.169), LAVI (from 36.1 ± 18.7 mL/m2 to 33.9 ± 15.7 mL/m2, p-value=0.176), E/A ratio (from 0.9 ± 0.4 to 0.8 ± 0.2, p-value=0.091), and E? velocity (from 6.5 ± 2.0 m/s to 6.9 ± 2.1 m/s, p-value=0.068). However, successful revascularization significantly reduced E/E? ratio (from 14.1 ± 5.7 to 11.7 ± 3.3, p-value=0.015). Additionally, a significant increase in A? velocity (from 9.1± 1.9 m/s to 10.0 ± 2.2 m/s, p-value=0.029) and a decrease of LA diameter (from 40.7 ± 6.4 mm to 38.6 ± 6.6 mm, p-value=0.014) were noted.

CONCLUSIONS
Our results showed that a successful revascularization of AIOD was associated with improvement of LVDD.

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IVUS-guided wiring re-entry technique for complex CTO

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

AIMS

The successful recanalization rate of chronic total occlusion (CTO) lesions without retrograde collaterals available is always low. Intravascular ultrasound (IVUS) may be useful to guide the subintimal guidewire to re-enter the true lumen. We evaluated the clinical feasibility and efficacy of the IVUS-guided wiring re-entry technique for these complex CTO lesions.

METHODS AND RESULTS

Twenty consecutive patients (19 male, mean age: 65.3±12.8 years) with both failed antegrade and retrograde approaches were enrolled. The IVUS catheter was introduced into the subintimal space to identify the entry point into the subintimal space, and guide another stiff wire to re-enter the true lumen with the adjacent side-branch or first wire as markers, or using IVUS-guided parallel wire technique.

The entry point into the subintimal space was identified by IVUS in all cases, and the IVUS-guided wiring re-entry technique succeeded in 17 cases (85%). No procedure-related complication was noted except 1 case of delayed cardiac tamponade due to the wire perforation. During the mean follow-up period of 1.9±1.3 years, there was no adverse cardiac event, except 1 patient died of the complication of cardiac transplantation.

CONCLUSIONS

The IVUS-guided wiring re-entry technique might be feasible and safe for the recanalization of complex CTO lesion

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Use of mechanical chest compression devices in the cathlab: nursing role and experience

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Chest compression devices are used mainly in pre-hospital cares, to perform continous, good quality CPR.
As scientific evidence are still weak, evidences may suggest the use of this device in particular setting like cath lab.
We aim to explore the use of mechanical devices in cath lab, to grant the patient high quality CPR and minimize staff exposion to ionizing radiation.

METHODS AND RESULTS

We implement the use of this device in every cardiac arrest that require prolonged CPR, to buy time for PTCA and/or ECMO.
We investigate the strategical role of nursing staff in managing this kind of emergency, cooperating with many other healtcare professionists, to ensure the best clinical outcome.
We had an initial training with mechanical chest compression devices and then we start to use extensively in our Cath Lab.
This device is kept in post-op cardiac ICU, and is checked routinely from ICU nursing staff, we used in every ward, cath lab and cardiac surgery OT.
Experience with mechanical chest compression devices in cath lab going from January 2016 to February 2017.
In this period chest compression device was used 11 times, allowing both angiography, PCI, IABP and ECMO positioning..
7 (63,6%) patients was supported with IABP and in 7 cases ECMO was implanted. 6 patients received both IABP and ECMO support.
Survival rate at 24 hr is 54.5%, and full recovery without significant vascular or neurological damages is 27.3%

CONCLUSIONS

Chest compression devices are helpful instruments to manage critical patient in particolar setting as cath lab, where well trained nurses, following shared guidelines with all the health professionels involved, could manage in a safe and efficacy way, this particolar clinical condition.
Ensure good quality CPR troughout the procedure allow the Phisician to decide the appropriate intervention (PCI or ECMO?) and operate in the safest possible condition.

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Procedural success and outcomes with increasing use of enabling strategies for CTO intervention: an analysis of 28,050 cases from the British Cardiovascular Intervention Society database

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

AIMS

Enabling strategies (ES) are increasingly used during percutaneous coronary intervention for chronic occlusive disease (CTO-PCI) to increase procedural success. On a national basis using the BCIS dataset, we examined changes in the use of ES and procedural/clinical outcomes for CTO-PCI.

METHODS AND RESULTS

ES were defined as intra-vascular ultrasound, rotational/laser atherectomy, dual arterial access, use of micro-catheters, penetration catheters or CrossBoss. Procedures categorised by ES use or not and also by the number of ESs used. Data were analysed on all stable angina CTO-PCI procedures performed in England and Wales between 2006 and 2014. The definition of procedural success was as used in a previous BCIS-derived CTO-PCI study i.e. less than a

CONCLUSIONS

Enabling strategy use during CTO-PCI was associated with significant improvements in success rates. Although increases in-hospital complications were associated with ES use, there were no differences in adjusted 30-day mortality.

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Zotarolimus-eluting stent in STEMI: a pre-specified prospective register from the DAPT-STEMI trial

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

AIMS

The Zotarolimus-Eluting Stent registry 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) was a prospective, randomized, multicenter, international open label trial testing the hypothesis that 6 months of dual antiplatelet therapy (DAPT) after second generation DES implantation in the setting of primary PCI for STEMI is not inferior to 12 months DAPT (non-inferiority hypothesis). Patients that underwent primary PCI with R-ZES in setting of STEMI were enrolled and if event-free at 6 months were randomized to 6 versus 12 months DAPT and followed for 18 months. The ZES-STEMI is a prespecified prospective registry that reports the outcomes of the primary endpoint (PE) at 6 months (before randomization) 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 1100 STEMI patients enrolled in the trial, 998 received a ZES. Mean age was 60.0 (Standard Deviation (SD) ±10.5) years, 760 (76%) patients were male, with an average Body-Mass index of 27.69 (SD ±4.4), 447 (45%) had hypertension, 273 (27%) dyslipidemia, 133 (13%) diabetes, 484 (49%) were smoker, 53 (5%) had previous MI and 26 (3%) a previous stroke. The culprit vessel was located in the LAD, RCA and LCX in 421 (42%), 398 (40%) and 179 (18%) of the patients respectively. The mean number and length of stents in the culprit lesion were respectively 1.28 (±0.60) and 26.1 (±12.8) mm. At 6 months follow-up the PE occurred in 42 (4.2%) patients. All-cause death, MI, revascularizations, stroke and TIMI major bleeding were respectively 8 (0.8%), 9 (0.9%), 34 (3.4%), 1 (0.1%), and 4 (0.4%). Of these revascularizations 11 (1.1%) involved target lesion revascularization (TLR), 5 (0.5%) target vessel revascularization, 18 (1.8%) non-target vessel revascularization and 15 (1.5%) were urgent. We detected 5 cases of definite and 2 cases of probable stent thrombosis, giving rates of definite and definite and probable stent thrombosis of 0.5% and 0.7% respectively. The number of hospitalizations was 17 (1.7%), with 10 (1.0%) because of chest pain.

CONCLUSIONS

This registry is the largest to date reporting outcomes with the second-generation ZES in setting of STEMI. At 6-months this registry confirms that the safety and the efficacy of the ZES is outstanding even in this high-risk category of patients.

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Influence of permanent pacemaker implantation after TAVI with the new generation devices on mortality and clinical outcome within one year

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

AIMS

Permanent pacemaker implantation (PPMI) after TAVI is the most common complication after the procedure. However, the impact of PPMI on mortality and clinical outcome is still a matter of debate. Data with new generation devices are scarce. Therefore, we sought to analyse the influence of PPMI after TAVI with the new generation devices on mortality as well as on clinical outcome in a large all-comers patient collective within a 12-month period.

METHODS AND RESULTS

683 consecutive patients undergoing transfemoral TAVI for treatment of symptomatic severe aortic stenosis were enrolled. Baseline characteristics of patients with (PPMI) or without (no-PPMI) after TAVI were compared as well as clinical outcome after hospital discharge at 30 days and one year, focusing on all-cause mortality, a combined endpoint of adverse events (cardiac and cerebral events, bleeding complications, valve function related events and heart failure) as well as rehospitalization due to valve-related symptoms and heart failure. Patients with preexisting permanent pacemakers were excluded from the analysis, leaving 607 patients for evaluation.

Implanted new generation TAVI devices were the balloon-expandable Edwards Sapien 3 valve (ES3) (58.5%), the mechanically expanded Boston Scientific Lotus/Lotus Edge valve (Lotus) (37.1%) and the self-expandable Medtronic CoreValve Evolut R (4.4%). PPMI became necessary in 165 patients (24.2% of the overall population). Baseline characteristics of patients were comparable between both groups.The rate of the Lotus valve was significantly higher in patients who had PPMI after TAVI (59.4% vs. 28.7%,p<0.01), whereas the rate of the ES 3 valve was significantly higher in patients without PPMI after TAVI (66.1% vs. 38.2%,p<0.01). There was no significant difference in 30-days and one-year outcome concerning all-cause mortality (PPMI vs. no-PPMI: 30-days: 0.6% vs. 0.9%, p=0.71, one-year: 10.4%vs.12.0%, p=0.61), rate of the combined endpoint of adverse events (30-days: 2.4% vs. 3.9%, p=0.39, one-year: 21.7% vs. 22.9%, p=0.76) or need for rehospitalization (30-days: 1.8% vs. 2.8%, p=0.51, one-year: 15.2% vs. 15.8%, p=0.87). In patients with reduced ejection fraction (<45%) there was no impact of PPMI on one-year all-cause mortality as well (11.1% vs. 15.7,%,p=0.56). Furthermore multivariate analysis did not reveal PPMI to be independently associated with one-year mortality (OR 0.79, 95% VI 0.41-1.54, p=0.49).

CONCLUSIONS

In our large cohort of TAVI patients treated with the new generation devices, PPMI after TAVI did not have an impact on all-cause mortality, rate of a combined endpoint of adverse events or hospitalization due to valve related symptoms or heart failure within a one-year follow-up.

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Predictors of rehospitalisation after percutaneous edge-to-edge mitral valve repair by MitraClip implantation

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

AIMS

In patients with prohibitive surgical risk due to concomitant comorbidities such as heart failure, transcatheter edge-to-edge mitral valve repair by MitraClip implantation (Abbott, Abbott Park, IL, USA) for severe, symptomatic mitral regurgitation has proven to relieve symptoms and improve quality of life. Rehospitalization for heart failure decompensation occurs frequently after MitraClip implantation, negatively impacting on quality of life. We aimed here to determine predictors of heart failure rehospitalization in a 1-year follow-up.

METHODS AND RESULTS

355 patients received implantation of MitraClip for severe mitral regurgitation at our centre. Within the 1-year follow-up period, 18.3% (n=65) were readmitted to hospital for heart failure decompensation at an average of 116 days (median 76 days, interquartile range 42-153 days) after MitraClip implantation. These patients had higher levels of Troponin T 106.8±321.1 vs. 43.1±51.7 ng/l, p= 0.006), high er levels of creatinine (145.5±51.0 vs. 127.3±71.1 ?mol/l, p=0.05), a higher logistic EuroSCORE (10.5±8.3vs. 8.3±7.9, p=0.046) and a reduced left ventricular ejection fraction (36.6±17.6% vs. 45.5±17.3%,

CONCLUSIONS

After percutaneous edge-to-edge mitral valve repair by MitraClip implantation, rate of rehospitalization due to heart failure decompensation was 18.3% during 1-year follow up. Patients readmitted for heart failure decompensation after MitraClip implantation had a 2.2-fold increased risk for mortality and 3.0-fold increased risk for cardiovascular mortality within 3 years after MitraClip procedure in comparison to patients not requiring rehospitalization. Baseline left ventricular ejection fraction, Troponin T and NYHA functional class are independent predictors for rehospitalization within 1 year after MitraClip implantation.

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Blood pressure reduction in the Global SYMPLICITY registry for patients with isolated systolic vs. combined systolic-diastolic hypertension

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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. The current analysis presents long-term safety data as well as a comparison of blood pressure (BP) reduction in isolated systolic hypertension (ISH) versus combined hypertension (CH) patients.

METHODS AND RESULTS

GSR is a prospective, multicentre, non-randomized international registry for renal denervation. Eligible patients for enrolment include all who are acceptable candidates for renal denervation. Initially patients were treated with the Symplicity FlexTM catheter (2237 patients) and more recently the multi-electrode Symplicity SpyralTM catheter (278 patients) with follow-up at 3, 6, 12, 24 and 36 months post-procedure. Data collected per routine care includes: clinical assessment, office blood pressure measurement, 24-hour ambulatory blood pressure measurement, blood tests, ECG, renal artery imaging, and EQ-5D quality of life questionnaire.

Since long-term follow up for patients treated with the Symplicity Spyral? catheter is limited, the focus of the current analysis is data from patients treated with the Symplicity Flex? catheter. Rates of safety events are low at 36 months (n=1199): cardiovascular death 2.4%, stroke 3.9% and myocardial infarction 2.8%. Rate of new artery stenosis >70% was 0.3% and 0.8% for renal artery reintervention at 36 months. Data from 24 months follow up for patients treated with the Symplicity Spyral? catheter demonstrate a similar safety profile.
Post-hoc analyses compared systolic BP (SBP) and diastolic BP (DBP) reduction in ISH versus CH patients. Matched populations of 256 ISH and 306 CH patients with office BP measurements at baseline and 6, 12, 24 and 36 months were analysed. Mean baseline office SBP/DBP measurements for the 2 groups were 175.2/101.9 (CH) and 162.3/78.4 (ISH). At 36 months, office SBP reduction was significantly greater for CH patients (-26.6 mmHg, 95% CI [-29.7, -23.6]) compared to ISH patients (-15.9 mmHg, 95% CI [-18.8, -13.1]),

CONCLUSIONS

Follow up data at 36 months in GSR support the long-term safety of renal denervation. BP reduction post-renal denervation was sustained at 36 months, with a greater SBP and DBP reduction for CH patients compared to ISH patients.

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Feasibility and safety of single vs. double use of a suture-based closure device for TAVR

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

AIMS

Reduced device profiles and the use of suture-based closure devices are important access related factors that have contributed to increased procedural success and safety of transfemoral transcatheter aortic valve implantation (TAVI). The most commonly used percutaneous closure device is the Proglide system (Abbott Vascular, CA, USA), that covers sheath sizes between 5 and 21 French.

Aim of the present study was to assess feasibility and safety of single versus double use of Proglide device in a selected population undergoing transfemoral TAVI.

METHODS AND RESULTS

Between March 2016 and December 2017, a total of 166 patients underwent transfemoral TAVI with implantation of the Edwards Sapien 3 device (23 mm, 26 mm) using the 14French E-Sheath, whereby 2 Proglides (Pro-2) were used until April 2017 (n=99), and thereafter only 1 Proglide (Pro-1) was inserted (n=67). We analyzed pre-procedural multidetector computed tomography (MDCT) to characterize femoral access including calculation of the sheath to femoral artery ratio (SFAR), visual estimation of tortuosity and of calcification at the puncture site (none/mild, moderate/severe), and position of the femoral bifurcation in relation to the lower edge of the femoral head (below, above). Primary outcomes of interest were access-related vascular and bleeding complications according to Valve Academic Research Consortium-2 criteria and the rate and type of bail-out measures performed for failure of the closure device.

The median age was 82.5 years [79.2-85.6], 56.6% were female, and the average STS score was 3.7% [2.7-5.4]. Baseline parameter, access site characteristics including the sheath-to-femoral artery ratio (1.33 [1.17-1.5] vs 1.33 [1.17-1.5], p=0.34), and procedural results were similar between the Pro-1 and Pro-2 group, particularly regarding bleeding events and vascular complications. Main access related major vascular complications accounted for 1.5% in the Pro-1 group and 2.0% in the Pro-2 group (p=0.80). The rate of bail-out measures for closure device failure was not different between the groups (Pro-1 vs. Pro-2: additional Angioseal 9.0% vs. 6.1%, p=0.48, interventional treatment: 0 vs. 2.0%, p=0.24, surgery: 4.5% vs. 3.0%, p=0.62).

CONCLUSIONS

Our data demonstrate feasibility, safety, and non-inferiority of single versus double use of the Proglide device for access site closure in a selected population undergoing transfemoral TAVI with the Sapien 3 prosthesis and the 14French E-sheath.

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Cardiac autonomic nerves stimulation improves hemodynamics: a pilot study in advanced heart failure patients

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

AIMS

Despite therapy advances in the management of heart failure, symptomatic congestion in acute heart failure is a leading cause of mortality and morbidity. An electrode catheter-based technology is being investigated to transvenously stimulate cardiac autonomic nerves to control left-ventricular contractility and heart rate (HR) in order to improve hemodynamics. The aim of this study was to investigate transvenous cardiac autonomic nerve stimulation (CANS) effects on in-hospital hemodynamics and signs and symptoms of congestion.

METHODS AND RESULTS

The present study was a single-center, observational, clinical investigation of CANS. Five (5) subjects with reduced left ventricular ejection fraction (LVEF < 40%), who presented with at least two signs and symptoms of congestion were consented and enrolled. A purpose-built electrical stimulation catheter was placed percutaneously, under fluoroscopic guidance, in the left brachiocephalic vein via left subclavian vein access. A purpose-built neurostimulator was then connected to the catheter and used to deliver CANS therapy bedside, for an allowed duration up to 24 hours. Hemodynamic effects and measures of signs and symptoms of congestion were observed over the stimulation period.

The majority of the subjects were male (3/5), had a mean age of 65 years, mean body mass index of 34, mean NT-proBNP of 3622 pg/mL and a mean Pulmonary Capillary Wedge Pressure (PCWP) of 30 mmHg. CANS was provided for a mean of 18 hours and was well tolerated. There were no safety concerns or adverse events reported. LVEF increased in all subjects (mean +8% from 27% to 35%) over the stimulation period. LVEF acutely decreased a mean of -5% (from a mean of 35% to 30%) in direct association with stimulation cessation. In three (3) subjects, CANS directly modulated arterial pulse pressure (12% average change) with a neutral heart rate effect (< 1% average change) over the stimulation period.

PCWP decreased in all subjects (mean reduction of 10 mmHg from 30 to 20 mmHg) over the stimulation period. PCWP improvements were accompanied by improvements in dyspnea and edema from pre-study to discharge. The hemodynamic and clinical improvements occurred in the presence of minimal changes to concomitant medical therapy.

CONCLUSIONS

Alongside concomitant medical therapy, CANS directly improved hemodynamics and was associated with improved signs and symptoms of congestion in advanced symptomatic heart failure patients. These

improvements, coupled with a positive safety profile, demonstrate that CANS holds promise as a tool to improve in-hospital hemodynamics and congestion. As the present study included stimulation of limited duration, in a specific patient phenotype, with a limited number of subjects, future study is warranted to investigate CANS Therapy for longer stimulation duration, in expanded patient phenotypes, in more subjects.

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Long-term mechanical unloading as a novel heart failure treatment option for inflammatory cardiomyopathy ? a mode of action study

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

AIMS

Short-term mechanical circulatory support is an appropriate method to stabilize patient in shock including those with an acute fulminant myocarditis (M) by unloading. Mechanical cues, involving integrins, are major drivers of cardiac fibroblast activation leading to increased production of extracellular matrix.
We aimed to investigate whether unloading via a temporarily percutaneously implanted left ventricle (LV) assist device (Impella-pump) over 4 weeks is a strategy to improve heart failure due to chronic inflammatory cardiomyopathy.

METHODS AND RESULTS

An Impella was implanted in a patient with severe M and pre-cardiogenic shock despite immunosuppression. Endomyocardial biopsies (EMB) were taken over time. Impella implantation resulted in an improvement in LV-EF (15 to 53%) and a reduction in NT-pro-BNP levels (8700 to 690 pg/ml). During presence of the Impella, cardiac immune cell presence decreased, paralleled by a drop in ?1, ?5, ?6, and ?10 integrins EMB mRNA expression by 2.0-, 2.0, 3.9-, and 6.6-fold, respectively, an effect which was abrogated after removal of the pump. Imaging mass spectrometry further revealed a drop in collagen ?-2VI and vimentin expression during unloading.

CONCLUSIONS

Prolonged unloading with an Impella device offers a circulatory support with additional disease modifying effects important for bridge of recovery in patients with fulminant myocarditis. The present findings further support the link between mechanical loading, fibrosis, and inflammation, which is of relevance in fields also beyond cardiology.

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Multivariate predictors of early and late stroke after TAVR implantation: insights from the randomised REPRISE III trial

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

AIMS

Stroke is a serious potential complication of transcatheter aortic valve implantation (TAVI). Identification of predictors for stroke will be important in the selection and treatment of TAVI patients. Thus, data from the REPRISE III randomized controlled trial was analyzed to determine predictors of early and late stroke.

METHODS AND RESULTS

REPRISE III compared 2 TAVI platforms: a mechanically-expanded, fully repositionable and retrievable aortic valve (MEV) and a commercially-available self-expanding valve (SEV). The trial 30-day primary safety endpoint was all-cause mortality, stroke, life-threatening/major bleeding events, stage 2/3 acute kidney injury, and major vascular complications. The primary effectiveness endpoint was all-cause mortality, disabling stroke, and moderate or greater paravalvular leak by echo at 1 year. The protocol required formal neurological exams by a neurology professional in all patients at baseline, discharge, 1 year, and following any suspected stroke. Multivariate models to assess predictors of stroke up to 30 days and between 30 days and 1 year were evaluated.

A total of 912 patients were randomised 2:1 (MEV:SEV). MEV was noninferior to SEV for the primary safety endpoint and superior for the primary effectiveness endpoint. There was no difference in overall stroke at 30 days (SEV 4.3% vs MEV 4.8%, P=0.72) or at 1 year (SEV 9.4% vs MEV 7.0%, P=0.20). Disabling stroke rates were similar at 30 days (SEV 3.3% vs MEV 2.0%, P=0.23) but occurred less often with MEV at 1 year (SEV 7.1% vs MEV 3.6%, P=0.02). The frequency of non-disabling stroke was 1.0% in SEV and 2.8% in MEV at 30 days (P=0.08), at 1 year the rates were 2.4% in SEV and 3.6% in MEV patients (P=0.33).

Multivariate predictors of overall stroke through 30 days included STS score (odds ratio [95% confidence interval]: 1.07 [1.01, 1.13]), serum creatinine (1.01[1.00, 1.01]), and procedure time (1.01[1.00, 1.01]). After 30 days (through 1 year), predictors of stroke included mild or greater paravalvular leak at discharge (4.40 [1.55, 12.47]) and the area of the sinus of valsalva (SOV area: 1.00 [1.00, 1.01]). Higher ejection fraction was associated with a reduced risk of stroke (0.96 [0.92, 0.99]).

CONCLUSIONS

While device selection did not impact overall stroke rate, the trial confirms that important clinical comorbid

conditions and procedural details predict stroke in TAVR patients who are at increased risk for surgical aortic valve replacement. These findings may help to appropriately direct therapies for stroke prevention.

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Who benefits from receiving ECMO therapy after collapse of hemodynamics?

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

AIMS

The value and role of Extracorporeal Membrane Oxygenation (ECMO) therapy after Cardiopulmonary Arrest (CPA) or collapse of hemodynamics is still unknown. Our aim is to reveal the risk factors of poor prognosis using our single facility data.

METHODS AND RESULTS

We have reviewed 48 patients who underwent ECMO therapy between January 2009 and December 2017. ECMO was placed mostly within 15 minutes for patients reaching the hospital with cardiopulmonary arrest (CPA) or patients facing hemodynamic collapse after reaching the hospital. Continuous bystandar cardiopulmonary resuscitation (CPR) with witness and total CPR time under 60 minutes were included in this study. Age mean was 62.0±16.8 and male was 75.0%. 28 patients were STEMI (11 LMT=left main trunk, 7 MV=multiple vessel, 10 SV=single vessel) and 20 were others (3 pulmonary embolism, 8 myocarditis, 3 valvular disease, 3 arrhythmia, 1 rupture, 1 sepsis and 1 anaphylaxis after PCI). Overall survival rate was at 35.4% and Cerebral Performance Categories (CPC) 1&2 was at 27.1%. PCI was attempted for all STEMI patient. We have compared the risk factors between survival (n=17) and non-survival (n=31) group. The risk factors we referred to were STEMI, hemodynamic collapse in or out of the hospital, ventricular tachycardia / ventricular fibrillation or pulseless electrical activity, age, gender, coronary risk factors and blood tests. Between survival and non-survival group, the number of STEMI were 6(35.3%) vs 22(71.0%) [p=0.02] and diabetes mellitus were 2(11.8%) vs 13(41.9%) [p=0.03]. But other factors, including hemodynamic collapse in or out of the hospital, were not statistically significant between groups. Survival rate for STEMI patient with LMT were only at 9.1% and LMT plus MV disease were at 11.1% respectively.

CONCLUSIONS

The value and role of ECMO therapy is higher for non-STEMI disease and patient without diabetes mellitus. Still STEMI with LMT and MV disease are the difficult survivors. Also very surprisingly, the timing of collapse in hemodynamics, out of the hospital or in the hospital, did not effect on the outcome of survival rate or CPC rate.

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MitraClip vs. Cardioband procedures for functional mitral regurgitation

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

AIMS

Interventional mitral repair techniques have evolved as safe and effective treatment options for patients with functional mitral regurgitation (MR) at high or prohibitive surgical risk.
Of the available techniques most experience exists for the MitraClip device and the Cardioband Mitral Repair system.
Both catheter-based approaches have been proven to bee effective with regard to MR reduction and improvement of clinical symptoms. However, a comparison of the two devices with regard to effectiveness ion reducing MR and improving patient´s symptoms has not yet been done.

METHODS AND RESULTS

We examined 27 consecutive patients with symptomatic FMR who had been treated with the Cardioband device and 27 patients who had been treated with the MitraClip system for functional MR. The MitraClip patients were matched for gender, age, MR grade, NYHA status, left ventricular (LV) ejection fraction (EF) and septo-lateral (SL) mitral annular diameter using propensity score matching.
All patients underwent standardized 2D transthoracic echocardiography with assessment and clinical follow up at baseline and at 12 months.
After propensity score matching, there were no significant differences regarding baseline demographic parameters, including EuroSCORE II values (p=0.3), 6 minutes walking distances (p=0.5) and NT-proBNP values (p=0.2).
Left ventricular ejection fraction (LVEF) was impaired in both groups (MitraClip: 31.6 ± 11.4%, Cardioband: 36.5 ± 7.3%). Systolic pulmonary arterial pressure was elevated (MitraClip: 38.3 ±12.5mmHg, Cardioband: 34.2 ±10.7mmHG, p=0.5) with no significant difference between the groups.
Of note, there were no statistically significant differences with regard to MR defining echocardiographic parameters (p>0.05).
Immediate success rate, defined as a reduction of MR to grade ? 2 at discharge, was high in both groups (MitraClip: 90%, Cardioband: 92%, p=0.5).
At 12 months follow-up there we found persisting significant MR reduction to MR ?II II in 89.1% of patients after MitraClip and in 94.9% of patients after Cardioband procedures with no difference between the patient groups (p=0.8).
With regards to functional outcomes, we found improvement in 6 minutes walking distance in both groups (MitraClip: 238 ± 113.6m, 330.1 ± 101.4m, p=0.04, Cardioband: 246.4 ± 93.7m, 354.4 ± 111.7m, p=0.04) again with no statistically significant difference between the groups (p=0.9).
Functional NYHA class improved significantly in both groups (MitraClip:

CONCLUSIONS

The MitraClip and the Cardioband procedure are effective alternatives for the treatment of patients with symptomatic functional MR at high surgical risk. Both procedures reduce symptoms and improve functional capacities.

However, the patients undergoing the Cardioband procedure showed a pronounced improvement with regard to functional NYHA class and NT-proBNP levels when compared to patients undergoing MitraClip.
Further, longterm studies including more, prospectively matched patients have to warrant our findings.

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Improvement in FFR predicts two-year outcome after PCI. A FAME 1 and FAME 2 subanalysis

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

After percutaneous coronary intervention (PCI), Fractional Flow Reserve (FFR) is often lower than 1. We aimed to investigate the prognostic value of the improvement in FFR (?FFR,post-PCI FFR ? pre-PCI) to predict clinical outcome

METHODS AND RESULTS

Lesions from patients included in the FAME 1 and FAME 2 trials who undergo PCI were classified into 3 tertiles of ?FFR. Primary endpoint was Vessel-Oriented Clinical Events (VOCE) at 2 years, a composite of cardiac death, target vessel-related myocardial infarction and target vessel revascularization (TVR). In 837 lesions (639 patients), pre-PCI and post-PCI FFR values were available. 277 lesions were classified into the lower tertile (?FFR?0.18), 282 into the middle tertile (0.190.31). VOCE were significantly more frequent in the lower tertile as compared to the upper tertile (n=25 [9%] versus n=13 [4.7%],Log-Rank

CONCLUSIONS

The present data indicate that the larger the improvement in FFR, the lower the event rate. This suggests that beyond the post-PCI FFR value itself, the reduction in potential ischemic burden is a predictor of clinical events.

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Six-year follow-up of FFR-guided vs. angiography-guided CABG surgery

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

To investigate the potential impact of Fractional Flow Reserve (FFR)-guided Coronary Artery Bypass Graft (CABG) surgery as compared to angiography-guided CABG surgery on long-term clinical follow-up.

METHODS AND RESULTS

Consecutive patients (n=627) treated by CABG between 2006 and 2010 were retrospectively included. In 198 patients, at least 1 stenosis was grafted according to FFR (FFR-guided group) while in 429 patients all stenoses were grafted based on angiography (angiography-guided group). The 2 co-primary end points were overall death or myocardial infarction and major adverse cardiovascular events (MACE: composite of overall death, myocardial infarction and target vessel revascularization) up to 6 years follow-up.
In the FFR-guided group, patients were significantly younger (66 [57,73] versus 70 [63,76], P

CONCLUSIONS

FFR-guided CABG is associated with a significant reduction in the rate of overall death or myocardial infarction at 6-year follow-up as compared with angiography-guided CABG.

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New fully absorbable patch based large hole vascular closure device

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

AIMS

Currently available large arteriotomy closure devices are complex to use, are associated with significant complications, and/or they rely on exogenous tissue and/or permanent sutures. Three clinical trials were designed to assess the safety and effectiveness of a new fully percutaneous patch based synthetic absorbable large arteriotomy vascular closure device.

METHODS AND RESULTS

A large arteriotomy closure device consisting of an absorbable implant and an easy-to use delivery system was developed. The implant comprises an intra-arterial patch, a supporting scaffold and an extra-arterial locator. All components of the implant are made of the same synthetic material, which in pre-clinical porcine models, is encapsulated and mostly endothelialised in ~ 30 days and completely absorbed in ~180 days post implantation, with no peri-vascular scaring. The device does not utilise sutures, collagen or metal components.

The safety and performance of the device iterations during its evolution was assessed in a series of three sequential multi-centre clinical trials. In total, 120 patients undergoing transfemoral TAVR, EVAR and TEVAR procedures were implanted, with arteriotomies in the range 18F-24F.

Post procedure follow-up assessments were at up to 6 hours immediately post implantation, discharge, 1, 3 and 12 months. The primary outcome was the incidence of (peri-procedure to 3 months post-procedure) major vascular complications as defined by the Valve Academic Research Consortium-2 (VARC-2) criteria.

Results: 58 patients (66 closures) were enrolled in the initial studies. There were no device-related major vascular complications and the technical success rate was 97%.

Geometric updates were made to the implant, following which a further 62 patients (70 closures) were enrolled. In this trial, there were no device related major vascular complications. There were no late device-related complications in any of the treated patients and the device technical success rate was 97% with a significant improvement in acute performance.

CONCLUSIONS

There were no major complications throughout the clinical experience with this closure technology. There were no post-discharge complications in any of the 120 patients treated representing a cumulative event-free device experience of 94 patient-years post discharge, demonstrating that this technology is safe and effective for percutaneous large arteriotomy closure.

In progress: delivery system updates have been implemented and this device is currently being investigated in a larger EU clinical trial designed to study the safety and performance of the device in a wider range of

arteriotomy sizes. Amongst other things, this study will investigate the incidence of major and minor access-site complications at 1 month post discharge, and the performance of the device as compared with the ? preclose? technique following EVAR and TAVR.

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Procedural details from the SPYRAL HTN OFF-MED trial of renal denervation for uncontrolled hypertension

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

AIMS

The prospective, multicentre, randomised, sham-controlled SPYRAL HTN-OFF MED trial demonstrated a clinically significant blood pressure (BP) reduction at 3 months post-renal denervation in hypertensive patients in the absence of anti-hypertensive medications. The goal of this analysis was to evaluate the technical details and safety of the procedure including the treatment of main, accessory and branch vessels.

METHODS AND RESULTS

The SPYRAL HTN-OFF MED trial enrolled resistant hypertensive patients with an office systolic BP (SBP) ? 150 and

CONCLUSIONS

Compared to previous renal denervation trials in uncontrolled hypertensive subjects, a substantially greater number of ablations were delivered per patient in the main renal arteries and ablations were applied to all eligible branch renal arteries. Despite a more aggressive treatment plan, no major angiographic or clinical safety events occurred.

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Long-term effectiveness and safety of transcatheter patent foramen ovale closure compared with antithrombotic therapy alone: a meta-analysis of randomised clinical trials complemented with multiple-outcome and trial-sequential analyses

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THEME: Interventions for Stroke
TOPIC(S): Ischaemic stroke, Other stroke interventions

AIMS

Available randomised trials comparing transcatheter patent foramen ovale (PFO) closure vs. antithrombotic therapy alone showed mixed results and have limited statistical power for individual endpoints. We aimed to define the net benefit of the interventional approach compared with medical therapy.

METHODS AND RESULTS

Major electronic databases were searched for randomised trials comparing transcatheter PFO closure with antithrombotic therapy alone. The primary endpoint was stroke at the longest available follow-up, the secondary endpoints were transient ischemic attack, atrial fibrillation, and major bleeding. Fixed- and random-effects models were used to pool trial-level effects. Sensitivity and subgroup analyses were applied to explore consistency of results. A multiple-outcome meta-analysis was performed to provide stroke and transient ischemic attack risk estimates taking into account the correlation between the outcomes and overcoming the heterogeneous reporting across original reports. A trial sequential analysis was used to verify type I error and assess meta-analysis statistical power. A total of 5 eligible trials (3,440 patients, 1,829 transcatheter PFO closure vs. 1,611 antithrombotic therapy alone) were identified. At a mean follow-up time of 5.9 ± 2.7 years, 111 events occurred (37 transcatheter PFO closure vs. 74 antithrombotic therapy alone). The risk of stroke was significantly lower after transcatheter PFO closure than antithrombotic therapy alone (HR 0.32, 95% CI 0.14-0.76, p<0.001). The annualised incidence of stroke was 0.49/100 person-years after transcatheter PFO closure and 1.20/100 person-years after antithrombotic therapy alone. The relative weight of trials was balanced overall, but a high degree of heterogeneity was observed (I2=67.8%) reflecting different magnitude of effects rather than directional differences. Regardless of the model applied, no single trial could significantly influence pooled estimates and heterogeneity remained high in any case. The benefit of transcatheter PFO closure seemed to be larger in patients <45 years old, males, with substantial shunt, but no significant interaction between subgroups was observed. At trial sequential analysis, the conventional significance threshold (z=1.96) was not reached by pooling the three earlier trials. The addition of the CLOSE trial produced spurious results (z curve=2.60, monitoring boundary=2.04) without pooling also the Gore REDUCE trial. Conversely, the Gore REDUCE trial alone produced a significant stroke risk reduction (z curve=2.28, monitoring boundary=2.04). Multiple-outcome meta-analysis showed that transcatheter PFO closure did not reduce transient ischemic attack compared with antithrombotic therapy alone (HR 0.80, 95% CI 0.35-1.81, p=0.591), without significant heterogeneity across trials (I2=21.8%). In addition, transcatheter PFO closure was

associated with more than 4-fold increase in the risk of atrial fibrillation (OR 4.48, 95% CI 1.99-10.10, p<0.001), though mostly early and transient. The risk of major bleeding was comparable between treatments (OR 0.98, 95% CI 0.42-2.29, p=0.954).

CONCLUSIONS

Compared with antithrombotic therapy alone, transcatheter PFO closure significantly reduces the risk of stroke at long-term follow-up, but no benefit is observed in terms of transient ischemic attack. Atrial fibrillation is higher after transcatheter PFO closure, though early and transient, while major bleeding is comparable between treatments.

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Novel percutaneous suture-mediated PFO closure technique. Early results of the NobleStitch EL Italian registry

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THEME: Interventions for Stroke
TOPIC(S): Other stroke interventions

AIMS

To assess the efficacy of a novel percutaneous ?deviceless? patent foramen ovale (PFO) closure system which may obviate the risk and limitations associated with umbrella-like closure devices such as embolization, erosion, thrombus, arrhythmias, hindered access to left atrial structures and death.

METHODS AND RESULTS

Between June 2016 and October 2017, a prospective registry aimed at assessing the safety and efficacy of the NobleStitch EL (HeartStitch, Fountain Valley, CA) suture-based PFO closure system was carried out at 12 sites in Italy. Among 200 consecutive evaluated patients, 192 were considered suitable for suture-mediated PFO closure (44±13 years, 114 women). Suture of the septum with the NobleStitch system was carried out successfully in 186 (96%) patients. Median fluoroscopy time was 16.1 minutes (13.0-22.5) and contrast volume 200 ml (150-270). Transesophageal echocardiography was used in 100 (53.8%) patients and 125 (67.2%) procedures were proctored. At 206±130 days follow-up, microbubbles transthoracic echocardiography with Valsalva maneuver revealed no RLS (grade 0) in 139 (75%) patients and RLS grade ?1 in 166 (89%) patients. Significant RLS was present in 20 (11%) patients (grade 2 and 3 in 11 and 9 patients, respectively). No variable was significantly associated with residual RLS at follow-up. There were no recorded device-related complications.

CONCLUSIONS

The early results of this first Italian Registry indicates that the suture mediated ?deviceless? closure of PFO is feasible in the majority of septal anatomies, provides an effective closure of PFO comparable to traditional devices with a superior safety profile at medium term follow-up.

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Long-term effectiveness of transcatheter patent foramen ovale closure compared with antithrombotic therapy alone: a reconstructed individual patient data time-to-event meta-analyses of randomised clinical trials

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THEME: Interventions for Stroke
TOPIC(S): Ischaemic stroke, Other stroke interventions

AIMS

Recently, the results of two randomised clinical trials leveraged transcatheter patent foramen ovale (PFO) closure by showing a significant reduction in stroke at long-term follow-up. However, none of the available randomised clinical trials has enough statistical power for stroke and previous findings suggested a possible association between transcatheter PFO closure effectiveness and length of follow-up. Against this background, we aimed to perform an updated time-to-event meta-analysis of reconstructed individual patient data.

METHODS AND RESULTS

Major electronic databases were searched from inception to December 1st, 2017 for randomised clinical trials comparing transcatheter PFO closure with antithrombotic therapy alone for the endpoint of stroke at the longest available follow-up. A total of 5 eligible trials (3,440 patients, 1,829 transcatheter PFO closure vs. 1,611 ATA alone) were identified. Original high-quality Kaplan-Meier curves were digitised at high-magnification. The retrieved spatial information was modelled for each time interval of 1 year along with occurred events and numbers at risk to obtain reconstructed individual patient data. Cumulative Kaplan-Meier analyses were performed and risk between treatments was estimated by mixed-effects Cox proportional hazards regression model accounting for the original clustering of patients across trials (?one-stage? meta-analysis). The survival free from stroke at very long-term follow-up (mean 5.9 ± 2.7 years) was 96.3% after transcatheter PFO closure and 88.2% after antithrombotic therapy alone (13,740 person-years, 7,586 transcatheter PFO closure vs. 6,154 antithrombotic therapy alone). The pooled risk of stroke showed a significant benefit of transcatheter PFO closure over antithrombotic therapy alone (hazard ratio 0.29, 95% CI 0.11-0.76, p=0.012). Approximately 12 patients needed to undergo transcatheter PFO closure to prevent 1 stroke compared with antithrombotic therapy alone (number needed to treat 12.2, 95% confidence interval 9.6-37.1). The landmark analysis showed that a significant difference between treatments emerged approximately after 1 year and survival free from stroke at 2-year follow-up was 98.5% in transcatheter PFO closure and 96.7% in antithrombotic therapy alone (hazard ratio 0.32, 95% confidence interval 0.18-0.77, p=0.008). The trend of events between treatments from 2 to 10 years showed distribution similar to the earlier time interval with an unchanged significant risk reduction associated with transcatheter PFO closure (hazard ratio 0.35, 95% confidence interval 0.17-0.70, p=0.003).

CONCLUSIONS

Compared with antithrombotic therapy alone, transcatheter PFO closure significantly reduces the risk of stroke

over time. The benefit of transcatheter PFO closure over antithrombotic therapy alone emerges approximately after 1 year and continues to diverge over time.

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Blood pressure changes with renal denervation in patients with refractory hypertension and end stage renal disease on maintenance hemodialysis (MHD)

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

AIMS

Increased sympathetic activity is a major factor which contributes to development and progression of hypertension and chronic kidney disease and is a predictor of cardiovascular outcomes. Reduction of sympathetic activity with renal denervation was initially seen in animal experiments and now has been seen to predict survival and cardiovascular events. Aim was to study the efficacy, safety and effect of bilateral renal artery denervation on ambulatory blood pressure in patients with end stage renal disease.

METHODS AND RESULTS

The study was conducted at Policlinico di Monza from Jan 2015 to Dec 2017. We included patients > 20 years age, on maintenance hemodialysis with ESRD > 2 years, Resistant hypertension and willing for procedure after informed consent. We excluded patients with renal artery stenosis, malignancy and life expectancy < 1 year. 6 patients were included in renal denervation group and 6 in medical group in this prospective study. They underwent ambulatory BP recording at basal, 1 month, 6 months and 12 months. Mean age of the RDT group was 56+ 16 years and 53+ 16 years in the medical group. There was no difference in the duration of dialysis, mean number of drugs used in both the groups. Mean number of ablations given was 29+ 5. 67 % underwent denervation with enlighten device (St Jude Medical®) and 33 % with simplicity spiral(Medtronic)®. No complications were noted during procedure. Patients were followed up with titration as per blood pressure recordings. There was a significant reduction in systolic BP, diastolic BP and mean BP from baseline in the renal denervation group at 6 months and 12 months(p value-0.001 and 0.003 respectively). Number of medications in the test group reduced however not statistically significant. Medical therapy group did not show any significant change till one year of study.

CONCLUSIONS

Renal denervation in end stage renal disease patients with refractory hypertension is safe and effective technique for control of blood pressure in addition to the drugs. Larger randomized studies are needed to test this procedure.

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Studying the modification of coronary atherosclerotic plaque post coronary stenting using OCT

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

AIMS

Introduction:

Coronary stent deployment leads to an alteration in the morphology of various plaque features. Optical Coherence Tomography (OCT) is a unique intravascular imaging modality with the ability to study detailed coronary plaque features with microscopic detail. However, plaque analysis is not routinely performed in stented segments due to stent artefact. Yet, various plaque features anecdotally remain visible in between stent struts post-stenting.

Aim:

To study the effect of coronary stenting on various plaque features using OCT.

METHODS AND RESULTS

Methods:

Patients were retrospectively identified from two centres, Royal Perth Hospital (WA, Australia) and Erasmus MC (Rotterdam, The Netherlands). OCT data from patients presenting for percutaneous coronary intervention(PCI) who received OCT imaging before and after PCI in the treated segment were included. Lipid arc (LA), calcium arc (CA), bright spots (BS), microchannels (MC), cholesterol crystals (CC) both before and after stenting were measured. Lipid index was calculated as LA X lipid length. Calcium index was calculated in the similar way as lipid index. Indexed BS (BS positive frames / total number of frames analysed X 100), indexed MC and indexed CC were also calculated.

Results:

A total of 7,729 OCT frames in 52 patients were analysed. The median lipid index was similar pre- vs post-PCI (1128 [463-2116] vs. 1107 [615-1643], difference 0 [-236 ? 416], p=NS). Calcium index was significantly underestimated post-PCI vs pre- PCI (369 [48-1171] vs. 380 [52-914], mean difference 42 [-38 ? 247], p=0.013). The indexed BS were significantly underestimated post-PCI vs pre-PCI (22 [5-55] vs. 14[3-37], difference 5 [0-19], p <0.001). Indexed MC were similar post-PCI vs Pre-PCI (0 [0-4] vs. 0 [0-5], difference 0 [0-3], P=NS). CC were not significantly different post- vs pre-PCI (0 [0-7] vs 0[0-5], difference 0[0-6], p=NS)

CONCLUSIONS

There was no significant difference in lipid content of plaque pre- and post-PCI. Calcium and bright spots were significantly underestimated post-PCI.Theses findings are contrary to previously reported significant reduction

in lipid content of plaque upon PCI by near infra-red spectroscopy.

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Clinical implications of distal vessel stenosis after successful coronary chronic total occlusion recanalization

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Coronary stenosis in the segment distal to chronic total occlusion (CTO) is a frequent finding after successful CTO percutaneous coronary intervention (PCI). Aim of this study is to investigate the angiographic outcome and clinical implications of these lesions.

METHODS AND RESULTS

The PRISON III and IV trials, which enrolled patients with successfully recanalized occlusions treated with DES implantation, were used as data source for this study. A total of 294 patients were suitable for this analysis and were divided according to the presence (n=121) or absence (n=173) of stenosis>50% in the segment distal to the CTO lesion after baseline revascularization. Baseline quantitative coronary analysis (QCA) disclosed significantly lower vessel diameters in the group with binary stenosis, with more severe diameter stenosis (61±8% vs 31±9%, p<0.001). At angiographic follow-up, broad improvements in lumen diameter were observed in both groups, which resulted clearly higher in the subgroup of patients with basal binary stenosis (mean lumen diameter: +31±22% vs +20±18%, p<0.001 and minimal lumen diameter +107±75% vs +30±31%, p<0.001). Of note, only 9 (7.4%) of the 121 binary stenosis observed at baseline were present at follow-up procedure. Clinical outcome at 1 year disclosed comparable incidence of death (0 vs 1.2%), myocardial infarction (0 vs 1.2%) and target vessel revascularizations (8.3% vs 7.5%) in the two subgroups (all p=ns).

CONCLUSIONS

Our results suggest that lesions in the segment downstream coronary total occlusions can be safely deferred from PCI and eventually re-assessed with follow-up angiography if judged untrustworthy.

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The optimal antiplatelet strategy after TAVI: a meta-analysis

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

AIMS

International guidelines recommend the use of dual antiplatelet therapy (DAPT) post transcatheter aortic valve implantation (TAVI). The recommended duration of DAPT varies between guidelines. In this two-part study we (1) performed a structured survey of 45 TAVI centres from around the world to determine if there is consensus amongst clinicians regarding antiplatelet therapy post TAVI, and then (2) performed a systematic review of all suitable studies (randomised control trials and registries) to determine if aspirin monotherapy can be used instead of DAPT.

METHODS AND RESULTS

A structured electronic survey regarding antiplatelet use post-TAVI was completed by 45 TAVI centres across Europe, Australasia and the United States. Following a structured search of Medline, Embase and Cochrane databases, a systematic review of all randomised controlled trials and registries of TAVI was performed comparing DAPT duration and incidence of stroke, bleeding and death. A variance weighted least squared meta-regression was then performed to determine the relationship of antiplatelet therapy and adverse events.

Of 45 TAVI centres who responded to our survey, 42.2% reported that their antiplatelet therapy policy was based on operator preference, 44.5% on local institutional policy, and 13.3% on national and international guidelines. Antiplatelet therapy post-TAVI was variable across centres, 82.2% reported using DAPT with 17.8% using monotherapy. Of the centres that routinely use DAPT following TAVI, 46.7% used 3 months, 22.2% used 6 months, 4.4% used 1 month, and 2.2% used 12 months.

11,781 patients (26 studies) were eligible for the meta regression. There was no benefit of DAPT over aspirin monotherapy for stroke (? = 0.04, 95% CI -0.08 to 0.17, p = 0.49, I2 = 64%, p for heterogeneity < 0.001), bleeding (? = -0.02, 95% CI -0.27 to 0.24, p = 0.91, I2 = 97%, p for heterogeneity < 0.001), or mortality (? = 0.02, 95% CI -0.09 to 0.14, p = 0.72, I2 = 96.7%, p for heterogeneity < 0.001).

CONCLUSIONS

There is large variance in the antiplatelet regimens used by different TAVI operators, with the majority of operators relying on personal or institutional policies rather than guideline recommendations. In this largest meta-analysis to date, aspirin monotherapy appears to be as safe and effective as DAPT following TAVI.

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Five-year clinical follow-up of the COBRA (complex coronary bifurcation lesions: randomised comparison of a strategy using a dedicated self-expanding biolimus A9-eluting stent vs. a culotte strategy using everolimus-eluting stents) study

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

Dedicated bifurcation stents have been proposed as an alternative treatment for coronary bifurcation lesions. The long-term performance of dedicated stents versus conventional dual-stent techniques for the treatment of complex coronary bifurcation lesions is unknown. We evaluated healing responses with OCT and clinical and angiographic outcome after treatment of complex coronary bifurcation lesions with a dedicated stent versus a conventional culotte technique.

METHODS AND RESULTS

Forty patients with true and complex coronary bifurcation lesions were randomly assigned to treatment with the dedicated Axxess bifurcation stent in the proximal main vessel (MV) and additional Biomatrix stents in the branches (both bioresorbable polymer biolimus-eluting stents [BP-BES]) versus a culotte technique using permanent polymer everolimus-eluting (PP-EES) Xience stents. Primary endpoint was the percentage of uncovered struts in each bifurcation segment at 9 months.The clinical endpoints included the rate of major adverse cardiac events (MACE) and their components, target lesion revascularisation (TLR), non-target lesion revascularisations (non-TLR) and stent thrombosis, MACE were defined as any of the following: all-cause death, myocardial infarction (MI) and ischaemia-driven target lesion revascularisation (TLR). The primary endpoint, the percentage of uncovered struts, was similar with BP-BES vs. PP-EES in all bifurcation segments. Five-year clinical follow-up was obtained in all patients (n=40). Based on the universal definition of MI, no peri-procedural MI occurred. At 5 years, in the culotte group, 1 patient had undergone TLR and another suffered a clinical MI, resulting in 10% MACE vs none (0%) in the Axxess group. TVR (5% vs 10%,p=0.54) and non-TVR (5% vs 20%,p=0.39) rates were similar between the Axxess and culotte groups, respectively. There was no stent thrombosis.

CONCLUSIONS

Compared with culotte stenting with Xience, complex coronary bifurcation stenting using a dedicated strategy combining the Axxess and Biomatrix stents results in similar stent strut coverage at 9 months, and excellent clinical outcomes at 5 years.

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Alone or with your relatives - in the acute phase of myocardial infarction and coronary angiogram

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

ST-elevation myocardial infarct (STEMI) may be a stressing situation for the patients. Patients are often supported by their family during life threatening events and the objective of the present study was to investigate the extent of wishes from the patients to have their relatives close by during an acute coronary angiogram at the catheterization room.

METHODS AND RESULTS

Data were collected through a questionnaire survey in the period from 25th of April to 10th of June 2017. The patients were given the questionnaire 1-2 days after their STEMI treated with primary percutaneous coronary intervention.

The questionnaire was given to 57 patients and 48 (82.4%) returned a completed questionnaire. The age of the respondents were 28-86 years, 38 (79.2%) were male and 10 (20.8%) were females.

Question 1: To the question if the patients wanted to bring their relatives along to the catheterization room when they had their acute angiogram, if they had been given the chance to choose, 33.3% wanted to bring relatives whereas 66.7% preferred not to bring them.

Question 2: When asked if including and involvement of the relatives in the catheterization room would improve the course during the hospital stay for the patient, 43.7% of the respondents would feel more secure during treatment and hospital stay if they had their relatives with them. About one third (37.6%) of the respondents could only see a few or no benefit and the rest felt neither strong benefits nor absolute no benefits. Another benefit for one third of the patients were that the relatives could help with different things (like remembering information and telling the patients history) both in the catheterization room and in the bed ward in the period after the primary PCI. Another 22.9% could not see any benefit and the rest of the patients answered in between the two other options.

Question 3: To the question if the patients had any concerns, bringing their relatives to the operation room 41.7% expected it to be too traumatic for their relatives to witness the acute angiogram and treatment whereas 20.9% did not see that as a concern.

Neither gender nor age influenced significantly on the wish or the opposite of having the relatives close to or in the surrounding area during the acute angiogram.

CONCLUSIONS

One third of the patients wanted a different practice than the current one during an acute coronary angiogram due to suspected STEMI. Because of that it will be relevant to focus on and discuss whether the presence of relatives should be allowed during an acute coronary angiogram either in the catheterization room or very close by ? and if needed change/adjust current practice.

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Early single-centre experience of new extra-large self- expanding TAVI valve: an analysis of procedural outcomes and pacing rate of largest TAVI prosthesis in clinical use

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

AIMS

Background: Transcatheter aortic valve implantation (TAVI) is an established mode of treatment in aortic stenosis. Although the different types of TAVI valves available (self-expanding, or balloon expandable) cover different annulus sizes upto 26mm, larger annulus sizes have proved a challenge until recently. We report our first experience of the new 34mm EvolutR valve, in a well-characterised cohort of patients with aortic stenosis. We analysed procedural outcomes and compared pacing rates between 34mm and 29mm EvolutR , valves.

METHODS AND RESULTS

Methods: TAVI procedures performed between January and October 2017 were analysed. Data on 135 consecutive patients treated with EvolutR valve was studied. Valve size was determined by gated contrast MSCT sizing of annulus.

Results: TAVI was performed in 135 patients (mean age=80.8yrs, male= 64.4%, EuroScore 19.1%). Transfemoral access was used in 90% of patients under LA. All EvoR sizes were implanted, including 23mm(6.7%), 26mm(10.4%), 29mm(52.6%) and 34mm(30.4%). In the 41 patients treated with 34mm valve, annulus range was 25-30mm (mean 26.8mm). The valve was successfully implanted in 100% of patients and there was zero mortality. Valve positioning was performed with fast pacing just prior to annular contact. Paravalvular leak was mild or none in 38 patients (93%), moderate in 3(7%). Post TAVI mean aortic gradient was 12.1mmHg, AVA=1.7cm2. Pacing rate for 34mm EvoR was significantly higher than with 29 EvoR (43.9%v 14.8%, p=0.003), one patient had vascular complication due to closure device failure with minor bleeding and one patient had slight valve migration into LVOT with consequent pacing.

CONCLUSIONS

Conclusion: The 34mm valve facilitated treatment of annulus up to 30mm using a controlled repositionable implantation, with very low PVL rate. The higher pacing rate of the 34mm valve might be partially explained by a higher radial force in a relatively low, mean annulus treated (26.8mm), with the 34mm valve. Evaluation of the valve positioning in a larger cohort may help in determining optimal position of valve to maintain a low PVL and lower ppm rate.

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Transcatheter mitral valve repair in patients with functional mitral regurgitation ? Up to two-year outcomes from the multicentre CE trial

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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 the feasibility, safety and outcomes of the Edwards Cardioband? Mitral Valve Reconstruction System in the treatment of patients with secondary mitral regurgitation (MR). We herein report outcomes up to 2 years of patients who underwent the Cardioband Mitral System procedure which led to the CE approval of the device.

METHODS AND RESULTS

Between February 2013 and June 2016, 61 patients at high risk for surgery with clinically significant secondary MR were enrolled at 11 European sites. All patients were screened by a heart team using echocardiography and cardiac CT. All echocardiography follow up assessments were performed by an independent core lab. Mean patient age was 72±7 years, 44 were males (72%). Mean EuroSCORE II was 7.1%. At baseline, 52 patients (85%) were in New York Heart Association (NYHA) Functional Classification III-IV, with a mean left ventricular ejection fraction of 33±11%. The implant success rate was 98% and the device success rate 78%. After implant size adjustment, an average 28% septolateral annular reduction was observed (from 37±4 mm to 26±4 mm, $p<0.01$). At one month follow-up, two patients died from non-device related causes, 87% of patients had MR ? 2+. At one year follow up, available for 39 patients, an average 31% annular reduction was observed (from 36±4 mm to 25±4 mm, $p<0.01$) and 95% of patients demonstrated MR? 2+. Two-year follow-up is currently available for 20 patients. An average 28% annular reduction was observed (from 36±4 mm to 26±4 mm, $p<0.0001$) and 95% of patients demonstrated MR ? 2+. Of the 20 patients, 89% were in NYHA class I/II. In addition, Minnesota Living with Heart Failure Questionnaire scores improved significantly by an average of 15 points ($p = 0.0019$).

CONCLUSIONS

Transcatheter mitral valve repair using the Cardioband Mitral System provides clinically significant annular reduction and MR grade reduction. The favorable clinical and hemodynamic results of this customized annular reduction procedure are maintained up to two years. This novel therapy demonstrates sustained effectiveness for patients with functional mitral regurgitation while leaving options open for future interventions.

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Predictors of the long-term antihypertensive effect of carotid artery stenting

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

AIMS

A sharp drop in blood pressure during carotid artery stenting occurs quite often. In a certain group of patients, the hypotensive effect can persist for a long time. In our study we evaluated the short-term and long-term effect of carotid artery stenting on blood pressure, and also revealed predictors for the development of a long-term hypotensive effect.

METHODS AND RESULTS

The results of treatment of 99 patients who underwent carotid artery stenting in our center between March 2014 and May 2016 were evaluated. Dynamics of blood pressure was assessed by 24-hour blood pressure monitoring (before and 12 months after the procedure), as well as office measurements of systolic and diastolic blood pressure (before, after procedure and 12 months after procedure). To determine the predisposing factors of the effect on the blood pressure, the following data were analyzed: anatomical and morfological data: degree of stenosis, presence of contralateral stenosis more than 50%, calcification of plaque, dilatation features (presence or absence of pre- post-dilation), residual restenosis, completeness of the Willis circle and clinical data: age, sex, body mass index, smoking, hypotension and bradycardia intra- or early postoperative in-stent restenosis.

Results:

According to the office BP measurement, the mean systolic/diastolic pressure was 107.1/60.7, 109.7/69.5, 134.7/80.2mmHg after 1 hour, 24 hours and 12 months after the intervention respectively. In comparison with the average BP figures before the intervention, 148.1/89.5mmHg a significant decrease in blood pressure after carotid stenting (

CONCLUSIONS

In our opinion, arterial hypertension in patients with an incomplete Willis circle, in combination with a significant carotid artery stenosis, may be due to the inclusion of a compensatory mechanism in chronic cerebral ischemia. Indirectly, this is confirmed by the fact that patients with severe carotid artery disease (stenosis 80% or more) had a significant decrease in BP (odds ratio = 2.27, 95% confidence interval, 1.01 to 5.11, p = 0.049). The results dictate the need for more careful conservative postoperative management of patients with a incomplete Willis circle, as well as an individualized correction of antihypertensive therapy to achieve target BP.

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Analysis of the efficacy of sympathetic renal denervation in patients with refractory arterial hypertension

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

AIMS

to evaluate the efficacy and safety of the sympatic renal denervation procedure in patients with refractory arterial hypertension.

METHODS AND RESULTS

the study included 70 patients with refractory arterial hypertension, who were randomized into 2 groups. The I group (n=35) included patients who underwent sympatic renal denervation (SRD) procedures. In the II (control) group (n=35) - patients who received multicomponent (4 or more drugs) antihypertensive therapy in accordance with current recommendations. In both groups, clinical blood pressure monitoring, 24-hour blood pressure monitoring, and laboratory evaluation of renal function before and after renal denervation were monitored. Inclusion criteria: refractory hypertension, age of patients 18-85 years, systolic blood pressure (SBP) ?140/90 mmHg and ?130/90 mmHg in patients with diabetes mellitus, functioning kidneys, renal arteries ?40 mm in diameter and the length of the site up to the first bifurcation of at least 20 mm, absence of stenoses in the renal arteries, GFR?40 ml/min/1.73m², suitable anatomy of the renal arteries for endovascular procedure.

Results: the mean age of patients in the main and control groups was 52.4 ± 0.4 and 56.1 ± 0.3 years, respectively. The average duration of the disease was 11.4 ± 0.3 years. During hospitalization, the mean daily value of office BP in the I group before intervention was: systolic 174.9 ± 1.6 mmHg and diastolic 99.7 ± 2.3 mmHg, and in the control group - 168.3 ± 3.4 mmHg and 98.7 ± 2.5 mmHg. art., respectively. The pronounced antihypertensive effect immediately after renal denervation was noted in 19 (54.2%) patients in the I group and made SBP 138.7 ± 1.6 mmHg and DBP 84.1 ± 2.4 mmHg, which was 36.2 and 15.6 mmHg lower from the initial (

CONCLUSIONS

sympatic renal denervation procedure can be considered as an effective method of treatment of refractory arterial hypertension, and allows achieving a steady decrease in blood pressure at the hospital stage of treatment in more than half of the patients observed.

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Dedicated bifurcation cobalt-chromium sirolimus-eluting stent in the treatment of distal left main stenosis ? OCT evaluation of the stent healing pattern

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THEME: Coronary Interventions

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

AIMS

Coronary artery disease of left main (LM) is a particular form of atherosclerosis, and the most optimal treatment is still debated. The aim of this study was to assess the effectiveness and safety profile of the distal LM stenosis treatment with the new cobalt-chromium sirolimus-eluting BiOSS LIM C stent (Balton, Poland).

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.

Between September 2016 and December 2017 in two centers in Poland patients with a final diagnosis of stable coronary artery disease (CAD) or NSTE-ACS who signed informed consent were enrolled. Patients with STEMI or Medina type 001 bifurcation lesions were excluded from the registry. Provisional T-stenting was the obligatory strategy. Double antiplatelet therapy is planned for 6 - 12 months. An angiographic control with IVUS or OCT is planned at 12 months. The primary end-point is the rate of cardiac death, myocardial infarction (MI), and target lesion revascularization at 12 months. Here are presented interim results.

Up to now 53 patients with stable CAD or NST-ACS (67.9% vs 32.1%, respectively) were enrolled. The mean age of enrolled patients (77.4% males) was 66.26 ± 8.57 years. There were 47 (88.7%) patients with hypertension, 23 (43.4%) with diabetes and 30 (56.6%) with prior MI. Additionally, 28 patients (52.8%) underwent prior PCI, while 11 (20.8%) patients had previous CABG. The mean SYNTAX score was 22.52 ± 7.58 and EuroScore II ? 1.62% ± 1.7%. True bifurcations were treated in 70.1% of cases.

According to Medina classification true bifurcations were present in 70%. All BiOSS stents were implanted successfully (avg. pressure 15 atm). The mean nominal stent parameters were as followed: 4.17 ± 0.36 mm x 3.42 ± 0.35 mm x 19.94 ± 3.16 mm. In 15 (28.3%) cases the second stent was implanted within the side branch, mainly in TAP technique. Proximal optimization technique was performed in 37 cases (69.8%). There were 92.5% of cases performed from radial access. In 3 cases (5.7%) periprocedural MI was diagnosed. At one (n = 51) and three (n = 47) months all patients were uneventful (out-of hospital MACE rate 0%). At EuroPCR we also present preliminary results of stent healing pattern assessed with OCT.

CONCLUSIONS

New dedicated bifurcation BiOSS LIM C® stents seem feasible devices with promising effectiveness and safety profile in distal LM stenosis. Complete BiOSS® LIM C angiographic and OCT data will answer the question if the used new stent platform with thin struts finds out to be bette

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Biolimus-A9 polymer-free coated stent in high bleeding risk patients undergoing complex PCI - Evidence from the Leaders Free randomised clinical trial

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

AIMS

Complex PCI is required in

METHODS AND RESULTS

Leaders Free included 2,432 patients undergoing PCI, who had at least one of 13 predefined criteria for an increased bleeding risk. Of these, 667 patients (BA9-DCS 346, BMS 321) underwent a complex PCI, defined by one or more of the following characteristics: total stent length > 60mm (n=289), >3 vessels treated (n=105), >3 lesions treated (n=315), >3 stents implanted (n=497), bifurcation lesion treated with > 2 stents (n=73), CTO (n=124), restenotic lesion (n=63), or lesion located in a SVG (n=41).

Several clinical presentation and baseline characteristics differed between patients with complex vs. non-complex PCI: age (76.5+8.8y vs. 75.3+9.5y,

CONCLUSIONS

27% of HBR patients enrolled in Leaders Free required a complex PCI procedure. This subset overall suffered higher event rates than patients with non-complex lesions. Both in absolute and relative terms, the safety and the efficacy benefits of a BA9-DCS over a BMS were markedly greater for patients with complex PCI.

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The importance of measuring FFR to improve the efficiency of endovascular treatment on left main bifurcation lesions

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

AIMS

to increase the effectiveness of endovascular treatment in patients with Left Main bifurcation lesions.

METHODS AND RESULTS

157 patients were enrolled in the study. Inclusion criteria: true bifurcation stenosis of the LMCA according to QSA and IVUS, total risk according SYNTAX score 0.05). Nonfatal MI was observed in 2 patients (2.9%) from group III (

CONCLUSIONS

measurement of FFR in the lateral branch of the left main bifurcation after performed PTS significantly improves the prognosis of patients with lesions of the LCA trunk and improves the efficacy and safety of PCI.

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Subclinical valve thrombosis after TAVI: a systematic review and meta-analysis on incidence, management, and potential neurological sequelae

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

AIMS

Transcatheter aortic valve implantation (TAVI) is an established intervention for patients with severe aortic stenosis and high or intermediate surgical risk, however some studies suggest that the rate of neurological events during follow-up remains higher than for surgical aortic valve replacement (SAVR). Subclinical valve thrombosis (SCVT) has been suggested to play a role and independant studies have shown increased incidence of SCVT after TAVI (2.0-40.0%) compared to SAVR (0.3-4.0%). This study aims to investigate the incidence, management, and sequelae of SCVT after TAVI.

METHODS AND RESULTS

A systematic review of postoperative valve dysfunction in TAVI patients with focus on incidence, predisposing factors, management, and potential sequelae was carried out on all published studies in three major electronic databases from their inception until January 2018. Studies with sufficient data were included in a follow-up meta-analysis comparing the risk of neurological events between patients with SCVT and those with normal valve function, as well as the protective effects of antiplatelet and anticoagulation on preventing SCVT in patients undergoing TAVI. A total of 2510 patients were identified from 10 patient series and included for systematic review with 1716 identified with sufficient data for meta-analysis. The most common valve inserted was the Sapien 3 (53.3%) followed by the Sapien XT (38.1%). Dual antiplatelet therapy (DAPT) was given in 38.9% of cases, single antiplatelet therapy (SAPT) in 42.8%, and oral anticoagulation (OAC) in 27.1%. 284 patients (11.3%) demonstrated evidence of SCVT during follow-up, and almost all (99.3%) were successfully treated with OAC with resolution of SCVT. Meta-analysis demonstrated that rates of stroke were three times higher in patients with SCVT compared to those without (RR 3.12, 95% CI 1.73-5.62). OAC was noted to be protective compared to DAPT or SAPT in the formation of RLM (RR 0.29, 95% CI 0.17-0.49), as was DAPT over SAPT (RR 0.83, 95% CI 0.55-1.26).

CONCLUSIONS

High rates of SCVT in patients who have undergone TAVI along with a correlated increase in stroke incidence suggest that new therapeutic protocols to mitigate thrombotic and embolic sequelae should be investigated. This is particularly relevant as TAVI becomes a viable procedural alternative to younger and lower risk surgical patients.

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Routine chest radiography after primary PCI for AMI: is it still clinically necessary?

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Aims: Chest radiographs (CXR) are a routine diagnostic modality widely used for the investigation of undiagnosed chest pain despite the known risks of radiation exposure. Based on historical data, in a large number of countries, CXRs are routinely performed in patients with acute myocardial infarction (AMI) treated with successful primary PCI, despite this confirmed diagnosis irrespective of the patients clinical well-being. We sought to determine CXR usage rates, diagnostic yields and prevalence of clinically significant abnormalities in AMI patients following primary PCI.

METHODS AND RESULTS

Method: Data was examined retrospectively on 728 STEMI patients treated with primary PCI at Barts Heart Centre between 2015-2016. Patient who were in cardiogenic shock, intubated or taken straight for CABG were excluded. We reviewed patients histories and request indications in concert with their CXR findings. The patients? state at the time of CXR was classified as being either ?well? or ?unwell?. ?Well? constitutes: no dyspnea, no tachypnea, no hypoxia, no cough, not intubated and no significant hypotension. Abnormal radiographs were stratified into significant and insignificant acute findings. Clinically significant findings included pneumothorax, pleural effusion, pneumonia, atelectasis and pulmonary oedema.

Results: After applying the exclusion criteria to our data we were left with 658 patients. In total 548 patients (83%) had a CXR after PCI with 27% (149) performed out of hours (8pm-8am). 98% (538) of the CXRs were performed anteroposterior (AP), with 95% (523) further labeled as portable radiographs. Of these 403 patients (74%) who had a CXR were classified as ?well? at the time of the examination with the remaining having a documented clinical indication for CXR. Of those clinically indicated 66% (63) had an abnormal CXR. Of the 403 ?well? patients, there were 12 (14%) abnormal CXRs that were significant findings and changed clinical management. Notably, two of these patients benefitted from having the CXR as it picked up asymptomatic TB and pulmonary fibrosis. However seven patients (1.6%) had false negative diagnoses: 4 of these patients had subsequent PA radiographs to investigate abnormalities seen on AP which returned normal diagnoses, 2 patients had a CT chest to rule out malignancies, both of which returned as normal, and 1 patient had a false negative diagnosis which lead to a right hemithyroidectomy, after which histology reported the lesion as benign.

CONCLUSIONS

Conclusion: Routine chest radiography after primary PCI for STEMI provides little diagnostic or therapeutic advantage over clinically indicated chest radiography or simple clinical assessment. Therefore there is the potential to limit post-primary PCI CXRs to when there is clinical indication thus giving cost savings, reducing radiation exposures on the ward, freeing up staff and limiting the incidence of false negative diagnoses arising from poor quality portable AP films. However, this would come at the expense of missing a small minority of

significant CXR abnormalities.

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Does large vessel size still justify the use of BMS for PCI? Insights from the EXAMINATION trial

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

AIMS

Drug eluting stents (DES) demonstrated improved efficacy and safety compared to bare-metal stents (BMS), and international guidelines advocate their use as first line treatment in patients undergoing percutaneous coronary intervention (PCI). Yet, BMS are still widely used in practice, especially among patients at high bleeding risk or with stenosis in large coronary vessels. The aim of this study was to explore the value of BMS, in spite of routine use of DES, in patients undergoing PCI with large coronary stent implantation.

METHODS AND RESULTS

We evaluated the impact of a treatment with large coronary stents (maximum stent size ?3.50mm) or smaller stents (

CONCLUSIONS

A treatment with drug eluting stents warrants a better efficacy and safety profile irrespective of the stent size among STEMI patients undergoing primary PCI. Our results support the thesis that the use of BMS may not be anymore justified in current practice for patients with large coronary vessels, in line with international guidelines recommendations.

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Results of programmed vs ad hoc PCI to CTO lesions

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Coronary chronic total occlusions (CTOs) are a common finding in coronary catheterization. Although percutaneous CTO revascularization has improved in recent years due to current technical developments, there is not consensus on indication or ideal timing for intervention. The objective of this study was to compare elective percutaneous revascularization vs. ad hoc percutaneous revascularization in patients with a CTO since the onset of a specific program in our Department.

METHODS AND RESULTS

We prospectively collected a total of 182 patients with CTOs treated percutaneously between September/2014 and September/2017, with 139 of them treated with elective angioplasty and 43 with ad hoc intervention. Follow up was available in all cases. Baseline characteristics of patients were similar, except for pre-treatment including dual antiplatelet therapy (40.0% in planned CTOs vs. 14.3%, p=0.014) and statins (69.0% vs. 46.2%, p=0.037). CTOs were more complex in elective procedures with J-Score ?3 (55.0% vs. 32.1%, p=0.029), with no differences in the location of CTO or Syntax score. Interventional cardiologists with specific training in CTOs performed most planned procedures (90.0% vs. 42.9% of ad hoc interventions, p<0.001), as well, contralateral angiography (70.0% vs. 3.6%, p<0.001), femoral artery as the main approach (73.0% vs. 7.1%, p<0.001), 7-French catheters instead of 6-Fr (84.0% vs. 7.1%, p<0.001), use of microcatheters (90.0% vs. 32.1%, p<0.001), and special interventional technics as ?anchoring? (44.0% vs. 14.3%, p=0.004) were more common in elective procedures. Planned procedures were more commonly successful than ad hoc ones (73.0% vs. 35.7%, p<0.001) but they presented higher rate of complications including ventricular fibrillation (1.0% vs. 0.0%, p=0.240) and cardiac tamponade (3.0 vs. 0.0%, p=0.240), that could be solved percutaneously in all cases. No procedural or in-hospital deaths occurred in none of the groups.

Independent predictors of successful revascularization included elective procedure (OR=0.254 [IC-95%:0.082-0.784], p=0.017) and use of microcatheters (OR=0.325 [IC-95%:0.108-0.980], p=0.046), with higher J-Score as a risk factor for failure (OR=1.556 [IC-95%:1.106-2.188], p=0.011)

CONCLUSIONS

An elective percutaneous revascularization made by trained interventional cardiologist in specific techniques and devices for CTO, translates into a 2-fold increase of success rate as compared to ad hoc interventions and may explain the variability in clinical benefits observed across different studies.

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Clinical performance of a dedicated self-expandable stent for the treatment of left main stem disease. Results of the left main angioplasty with a self-apposing stent - the MATISSE study

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THEME: Coronary Interventions

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

AIMS

In the recent years percutaneous treatment of the left main stem (LM) has gained a precise role as a result of consistent scientific evidence vs. coronary artery bypass. A self-expandable stent offers an improved adaptation to the vessel wall, especially in case of tapered vessels, aim of this study was to investigate the role of a novel self-expandable, sirolimus-eluting stent (Stentys, France) for the treatment of LM coronary artery disease

METHODS AND RESULTS

MATISSE is a retrospective, multicenter registry, which enrolled 151 patients treated with this device at 17 international centers. Co-primary endpoints were procedural success 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. Lesions were located in distal LM bifurcation in 84% of the patients. Procedural success was achieved in 150 patients. The average follow-up length was 348±52 days. DOCE occurred in 14 (9.3%) patients with 2 (1.3%) cardiac deaths. TLR occurred in 8 patients (5.3%). There were 2 cases of definite stent thrombosis, 1 acute and 1 very late. The multivariate analysis showed a not significant trend toward an increase in DOCE in patients that did not receive postdilatation after device delivery.

CONCLUSIONS

a self-expandable stent implanted for LM PCI in a real world, high risk population showed good immediate procedural results with low rates of adverse events at mid-term follow-up.

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DEB angioplasty for coronary bifurcation lesions, first UK experience

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THEME: Coronary Interventions

TOPIC(S): Stents and scaffolds, Bifurcation lesion

AIMS

We report clinical outcomes of drug coated balloon (DCB) angioplasty in coronary bifurcation lesions in a single centre from 01/01/2009 to 31/12/2015.

METHODS AND RESULTS

All patients who received DCB angioplasty during the above period were identified from the hospital data base. A lesion involving a side branch of 2mm or more (visual assessment) was considered a bifurcation lesion and is included in this analysis. The patient demographic details, risk factors, indication, lesion characteristics and procedural details were obtained retrospectively from the hospital data base and by reviewing angiograms. Their subsequent clinical events namely target lesion revascularisation (TLR), target vessel revascularisation (TVR) and myocardial infarction (MI) were ascertained using hospital data base/electronic records. Mortality data were obtained through the spine portal of NHS Digital for 100% of patients. 210 (68%) patients (223 lesions) have had 6 months documented follow up.

In total there were 327 lesions in 309 patients. Mean age was 66. 77% were males. 158 (48.3%) lesions were acute coronary syndrome of which 48 (14.7%) were due to ST elevation MI. 6 patients had out of hospital cardiac arrests. 11 lesions involved left main stem treatment and 207 (63.3%) had a left anterior descending/ diagonal bifurcation treated. 121 (37.0%) were complex bifurcation lesions (Medina 1.1.1 or 0.1.1). 49 lesions had coronary dissections (type A,B - 46, type C -3). 17 (5.2%) lesions had an additional stent/s implanted during the procedure whilst 94.8% had DCB-only angioplasty. 2 (0.6%) patients had to be taken back to the catheterisation lab on the same day for ongoing chest pain/ECG changes and had bail-out stents. There were 4 peri-procedural side branch occlusions, in all of which flow was regained without stenting. All cause death for 365 days was 8 (2.6%) for the whole group (309 patients). For patients who have had 6 months documented follow up (210 patients-223 lesions) all cause death was 6 (2.9%), MI was 5 (2.4%), TLR was 5 (2.2%), TVR (non TLR) was 1 (0.5%) and MACE (all cause death, MI and TVR per patient) was 16 (7.6%). We will be able to provide with clinical outcomes for 12 months for the whole group before the date of the conference once data from National Institute of Cardiac Outcomes Research are received which are pending.

CONCLUSIONS

DCB-only angioplasty in bifurcation coronary lesions appear to be safe and effective in acute to medium term follow up. We would recommend consideration of such an approach with the advantages of procedural simplification and shortened dual antiplatelet therapy.

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PFO closure is superior to medical therapy for cryptogenic stroke: a meta-analysis of randomised controlled trials

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THEME: Interventions for Stroke
TOPIC(S): Other stroke interventions

AIMS

The efficacy of patent foramen ovale (PFO) closure for cryptogenic stroke has been controversial. We undertook a meta-analysis of randomised controlled trials (RCTs) comparing device closure with medical therapy to prevent recurrent stroke for patients with PFO.

METHODS AND RESULTS

We systematically identified all RCTs comparing device closure to medical therapy for cryptogenic stroke in patients with PFO. The primary efficacy endpoint was recurrent stroke, analysed on an intention-to-treat basis. The primary safety endpoint was new onset atrial fibrillation (AF).

5 studies (3440 patients) were included. 1829 patients were randomised to device closure and 1611 to medical therapy. Across all patients, PFO closure was superior to medical therapy for prevention of stroke (HR 0.32, 95% CI 0.13 to 0.82, p=0.018, I2 = 73.4%). The risk of AF was significantly increased with device closure (RR 4.54, 95% CI 2.17 to 9.48, p<0.001, heterogeneity I2 = 22.9%). In patients with large shunts, PFO closure was associated with a significant reduction in stroke (HR 0.33, 95% CI 0.16 to 0.72, p=0.005), whilst there was no significant reduction in stroke in patients with a small shunt (HR 0.90, 95% CI 0.50 to 1.60, p=0.712). There was no effect from the presence or absence of an atrial septal aneurysm on outcomes (p=0.994).

CONCLUSIONS

In selected patients with cryptogenic stroke, PFO closure is superior to medical therapy for the prevention of further stroke: this is particularly true for patients with moderate-to-large shunts. Guidelines should be updated to reflect this.

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Influence of pre-treatment with aspirin or statins or both on clinical presentation as well as infarct size and inflammation in patients with de novo ACS: a propensity-matched analysis

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

AIMS

To investigate whether treatment with aspirin and/or statins prior to a first acute coronary syndrome (ACS) will affect the clinical presentation, inflammation and infarct size. To that end, we analyzed patients enrolled in the prospective Swiss Program University Medicine ACS cohort (SPUM-ACS, ClinicalTrials.gov number: NCT01075867).

METHODS AND RESULTS

1?639 eligible patients were categorized into 4 groups: (1) control group without antiplatelet drugs or statins prior to their first ACS (n=1?181), (2) only aspirin, no statins group (n=157), (3) only statins, no antiplatelets group (n=133) and (4) aspirin plus statin group (n=168). Their clinical as well as electrocardiographic (ECG) presentation, creatinine kinase (CK, U/l), troponin T (TNT, ?g/l), brain natriuretic peptide (NT-proBNP, ng/l), leucocytes (Lc, G/l), neutrophils (Nc, G/l), C-reactive protein (CRP, mg/l) and angiographic features were documented before and after propensity score matching.

: The incidence of ST-elevation myocardial infarction (STEMI) was 64% in the control group, 45% in the aspirin only group, 52% in the statin only group and 40% in the aspirin and statin group (

CONCLUSIONS

Pretreatment with either aspirin or statins but particularly with both ,favorably changes the clinical presentation, the degree of inflammation and infarct size in patients suffering their first acute coronary syndrome.

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The impact of plaque type on strut embedment/protrusion and shear stress distribution in BRS

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

AIMS

Scaffold parameters and plaque characteristics influence implantation outcomes and local flow dynamics in treated coronary segments. Our aim was to assess the strut embedment/protrusion of bioresorbable scaffold and yield up local shear stress distribution in different atherosclerotic plaque types.

METHODS AND RESULTS

Fifteen Absorb everolimus-eluting Bioresorbable Vascular Scaffolds were implanted in human epicardial coronary arteries. Optical coherence tomography(OCT) was performed post-scaffold implantation and strut embedment/protrusion were analyzed using a dedicated software. OCT data was fused with angiography to reconstruct three-dimensional coronary anatomy. Blood flow simulation was performed and wall shear stress (WSS) was estimated for each scaffold. Mixed-effects analysis was performed to identify the relationship between strut embedment/protrusion and WSS.There were 9083 struts analysed. Ninety-seven percent of the struts(n=8840) were apposed well to the vessel wall. There were 243 malapposed struts (3%) in all scaffolds. At cross-section level (n=1289), strut embedment was significantly increased in fibroatheromatous plaques (76±48 μm) and decreased in fibro-calcific plaques (35±52 μm). In the same direction with strut embedment, WSS was significantly higher in lipid-rich fibro-atheromatous plaques (1.50±0.81 Pa), whereas it was significantly decreased in fibro-calcified plaques (1.05±0.91 Pa). After categorization of WSS as low (

CONCLUSIONS

Scaffold design and the treated underlying plaque influence strut embedment which appears to impact on WSS. The struts of Absorb were embedded deeper in lipid-rich fibroatheromas resulting in higher WSS compared to other plaque types.

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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

AIMS

Permanent pacemaker (PPM) implantation is not uncommon after transcatheter aortic valve implantation (TAVI) but data are lacking about the rate of PPM-related complications in this population. The aim of this study was to describe the rate of complications secondary to PPM 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 June 2008 and October 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 PPM and 538 patients (73%) did not require periprocedural PPM implantation. 123 patients (16.6%) underwent PPM implantation. Three of them were excluded from the final analysis due to PPM implantation occurring in other institutions after discharge. The final population consisted of 120 patients (16.3%). A high rate of major bleeding events (n=29, 24.1%) was observed in the population who had PPM implantation. In 14 patients (11.7%) a pocket hematoma was found. Major bleedings occurred more frequently in those patients who received PPM implantation within the first 24 hours after TAVI than in the group of patients who required a PPM after 24 hours following after TAVI (n=21, 38.2% vs n=8, 12.3%, p= 0.001). Patients who experienced a major bleeding event following the PPM insertion were frequently on triple therapy compared to those who did not experienced bleeding complications (n=15, 51.7% vs n=9, 9.9%,

CONCLUSIONS

PPM-related complications are not uncommon in elderly patients after TAVI and some of these can be life-threatening. Particular attention is required in the periprocedural management of these patients. Further studies are needed to confirm our findings.

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Favourable vessel healing after ONYX stent implantation at 30-day follow-up

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

AIMS

A fast vessel healing after stent implantation is essential for patients and outcome after the coronary interventions. The present study assessed vessel healing after the implantation of a zotarolimus-eluting platinum-cobalt ONYX stent (strut thickness 81 ?m) at 30-day follow-up by optical coherence tomography (OCT) imaging.

METHODS AND RESULTS

Fifteen patients that underwent percutaneous coronary intervention (PCI) with implantation of 15 second-generation zotarolimus stents (ONYX, Medtronic Santa Rosa, CA, USA) and had an OCT assessment immediately after implantation and 1-month were included in this study. Mean patient age was 67±7 years (73% males). The clinical presentation consisted of acute coronary syndromes (n=13) and stable coronary disease (n=2). Four (26%) patients had diabetes, and one had a history of CABG (6%). All patients were treated with dual anti-platelet therapy during the entire duration of the study. The median stent diameter and length were 3.0mm (IQR2.5, 3.0) and 22mm (IQR 18, 26) respectively.

Optical coherence tomography (OCT) analysis was performed for all stents after implantation and at 1-month follow-up for a total of 378 cross-sections (stepwise for every 1mm) with 3582 struts assessed at baseline and 4118 at follow-up. The thickness of neointima was measured for every strut. In addition, a lumen area covered by the uncovered struts was estimated.

There were no differences in minimal lumen area (5.07±1.08 vs. 4.81±0.94, p=0.125) and minimal stent area (4.95±1.22 vs. 4.92±0.99) at baseline and at follow-up. There were no differences in the rate of stent strut malappositon (4.3% vs. 5.7%, p=0.417) and in malappositoin volume (mm3, 3.81±2.75 vs. 3.44±2.22, p=0.556) at baseline and at follow-up. At follow-up, 88% struts were covered by neointima with median thickness 37.91? m (IQR 22.32, 64.15). Maximal in-stent obstruction by neointima was 2.64% (IQR 1.70, 4.84). The percentage area stenosis based on reference was 17% (IQR 5, 17) at follow-up and three stents had >30% area stenosis. 44.54mm2 (7.68%) of total lumen surface area (579.42mm2) was covered by the uncovered stents strut. The endoluminal volume of neointima was 0.05 (IQR 0.01, 0,15) mm3 and abluminal volume of stent neointima was 1.81 (1.65, 2.00) mm3.

CONCLUSIONS

The second-generation durable polymer zotarolimus-eluting, ONYX stent presented a favorable vessel healing at 30-day OCT follow-up. Considering the observed favorable coverage rate, shorter dual-antiplateled regimens with this stent may be contemplated.

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Percutaneous mitral valve repair is associated with comparative symptomatic and echocardiographic improvement in patients with degenerative or functional mitral regurgitation, despite higher mortality in the functional cohort

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

AIMS

We present data from a large cohort of patients treated over a five year period at a single centre in the UK with the MitraClip percutaneous edge-to-edge mitral valve repair (PMVR) system. Patients with both Functional (FMR) and Degenerative (DMR) mitral regurgitation were treated. Recent international experience has suggested a potentially greater benefit from PMVR in patients with DMR. We hypothesized that our subgroup of DMR patients would demonstrate better outcomes than the FMR group in this retrospective analysis of consecutive cases.

METHODS AND RESULTS

We retrospectively analysed demographic, procedural and outcome data for 173 consecutive PMVR patients. Patients were categorized according to aetiology into predominantly DMR or FMR. We recorded baseline and 6 week (6w) MR grade, self-assessed quality of life scores (QOL), 6 minute walk distance (6MWT), New York Heart Association (NYHA) score, Brain Naturetic Peptide (BNP) and all-cause mortality.

Of the 173 patients, 76 (44%) were treated for DMR and 97(56%) for FMR. Data are presented as mean ± SD. Mean agewas 81 ± 8 in the DMR cohort and 71 ± 10 for FMR (

CONCLUSIONS

We have demonstrated in this real world UK series that MitraClip is an effective treatment for mitral regurgitation. Despite the lack of randomised outcome data for MitraClip in FMR, this series appears to demonstrate that the technique is equally effective in terms of symptom and MR improvement but is associated with higher mortality at 12 months compared to DMR. Although this group had a lower baseline LVEF, they were on average 10 years younger than the DMR cohort. These data support the need for randomized controlled trial outcome data for MitraClip, in particular for FMR patients. In the meantime, our study may encourage the continued use of MitraClip for symptom control in the high risk FMR population.

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Hemodynamic predictors of adverse outcome in patients with advanced heart failure awaiting heart transplantation: focus on the right ventricle

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

AIMS

The aim of this study is to examine the prognostic relevance of right ventricle function hemodynamic parameters, such as pulmonary artery compliance (PAC), elastance (PAE) and pulsatility index (PAPi) in patients awaiting HT.

METHODS AND RESULTS

104 patients underwent right heart catheterization during the evaluation for HT and were clinically followed until death or any censoring events. During a mean observation time of 15.6±23 months, 16.3% patients died, 23.1% underwent HT, 22.1% underwent VAD and 38.5% were alive without transplantation at follow-up contact. The composite adverse outcome (cardiovascular death, urgent cardiac transplantation and aborted sudden cardiac death) occurred in 24% of patients. At univariate analysis right atrial pressure (RAP), mean pulmonary arterial pressure (mPAP), pulmonary vascular resistance (PVR), PAE and PAC were significantly associated with the composite adverse outcome. The accuracy of PAC in predicting prognosis was superior to any other parameters except than for PAE. Into a multivariate Cox regression model only PAC resulted independently associated with worse event-free survival.

CONCLUSIONS

Impaired PAC yielded a strong and independent prognostic value in a selected cohort of patients with end-stage HFrEF enlisted for HT.

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Superficial femoral artery access for TAVI

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

AIMS

Trans-femoral transcatheter aortic valve implantation is an established therapy to treat elderly patients affected by severe aortic stenosis considered at high or extreme risk for surgical aortic valve replacement. The main route for TAVI is retrograde access from the femoral artery using large sheaths. We report the use of the superficial femoral artery (SFA) as the arterial site of puncture for new generation TAVI device.

METHODS AND RESULTS

Between January 2015 and December 2017, we performed 24 trans-femoral TAVI implantation through the superficial femoral artery. All the patients underwent our standard screening process, including transthoracic echocardiography, coronary angiogram and ECG-gated multislice computer tomography for pre-procedural planning. The indication to go via the SFA was mainly related to a high femoral bifurcation and/or severe patient obesity. In 17 patients, we implant a Medtronic Evolut R valve, all the other receive a St. Jude Portico prosthesis, sheathless. All patients were affected by severe aortic stenosis, mean age was 82-year-old. Four patients were treated with surgical SFA cut-down, all the percutaneous procedures were performed with 2 pre-closure Perclose ProGlide placement. Vascular access was successful in all the cases, before TAVI delivery system insertion a 14 Fr was advance. Successful TAVI procedure was achieved in all patients, with normal valve function. Successful vascular closure was obtained in all cases, two patients experience post-procedural pseudo-aneurysm, successfully treated with thrombin injection.

CONCLUSIONS

A superficial femoral artery approach should be considered in the setting of patients? obesity and when femoral bifurcation is high or above the inguinal ligament. In selected cases, the SFA may be suitable and easily approached percutaneously or by a small surgical incision. As for the common femoral artery approach, the main risks may be vascular complications that influence the outcome of all the transcatheter procedures.

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Distal axillary / brachial access for TAVI

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

AIMS

Trans-femoral transcatheter aortic valve implantation is an established therapy to treat elderly patients affected by severe aortic stenosis considered at high or extreme risk for surgical aortic valve replacement. Although significant technical improvements in last years, the trans-femoral approach is contraindicated in patients with severe peripheral artery disease, small vessel size diameter or severe tortuosity. In these patients, other vascular access routes may be considered, we describe our single center experience with the use of distal axillary and proximal brachial artery access

METHODS AND RESULTS

Between January 2015 and December 2017, we performed 15 distal axillary/brachial artery TAVI implantation. All the patients underwent our standard screening process, including transthoracic echocardiography, coronary angiogram and ECG-gated multislice computer tomography (MSCT) for pre-procedural planning. The indication to go via axillary or brachial artery was small femoral artery size or severe tortuosity of femoral-iliac access or abdominal aorta. The procedure was performed, under local anesthesia, in a hybrid OR by a team composed of ?hybrid? cardiac surgeon, interventional cardiologist, and cardiac anesthesiologist. In 6 patients, we implant a Medtronic Evolut R valve, all other patients received a St. Jude Portico prosthesis. All patients were affected by severe aortic stenosis, mean age was 79-year-old. In all cases except one, the artery was surgically exposed. Vascular access was successful in all the cases, before TAVI delivery system insertion a 14 Fr was advance. Successful TAVI procedure was achieved in all patients, with normal valve function. Successful vascular closure was obtained in all cases, two patients experience post-procedural minor vascular complication (ProGlide failure in one, and access site stenosis) successfully treated with normal left arm flow and function. Mean post-operative hospital stay was 9 days, all patients have been discharged with normal surgical wound and normal valve function at echocardiographic evaluation.

CONCLUSIONS

Our experience characterized by a heart team approach and multidisciplinary patient care demonstrated the safety and feasibility of trans-catheter aortic valve implantation through distal axillary / brachial artery, both should represent a new attractive access site for TAVI

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Clinical outcomes with the state-of-the-art PCI for the treatment of bifurcation lesions: a subanalysis of the SYNTAX II study

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

AIMS

To determine the impact of bifurcation treatment on clinical outcomes with state-of-the-art PCI (heart team decision-making using the SYNTAX score II, physiology guided coronary stenosis assessment, thin strut bioresorbable polymer drug-eluting stent and intravascular ultrasound ? IVUS ? guidance).

METHODS AND RESULTS

A sub-analysis of the SYNTAX II study stratified by the treatment of >1 bifurcation vs non-bifurcation lesions. The primary endpoint was the occurrence of target vessel failure (TVF) defined as cardiac death, target-vessel myocardial infarction (TVMI) and ischemia-driven target vessel revascularization (IDTVR). Four hundred and forty-seven subjects were included (bifurcation lesions n=159 and non-bifurcation n=288). True bifurcation were observed in 61.6%, and Medina 1,1,1 was observed in 34% of patients in the bifurcation group. Two-stent techniques were used in 23% patients, the most commons were: Culotte 27%, Minicrush 21.6%, Trouser legs and seats 18.9% and TAP 13.5%. In the bifurcation group, final kissing balloon was performed in 36.5%. At one year, the TVF occurred in 50 patients, with a trend towards higher rate in the bifurcation group (15.1% vs. 9.0%, hazard ratio [HR] of 1.70, CI 95% 0.98 to 2.97, p=0.059). Cardiac death (1.9% vs. 0.7%, HR 2.70, CI 95% 0.45 to 16.17, p=0.28), clinically-driven TVR (6.9% vs. 4.5%, HR 1.54, CI 95% 0.69 to 3.45, p=0.29), and TVMI (7.5% vs. 4.2%, HR 1.82, CI 95% 0.82 to 4.04, p=0.14) did not differ between the bifurcation and non-bifurcation groups. TVF occurred in 13.5% patients with 2-stent technique and in 15.5% subjects with 1-stent technique (p=0.50).

CONCLUSIONS

Bifurcation treatment in patients with 3VD undergoing state-of-the-art PCI was associated with a trend towards higher incidence of TVF compared with non-bifurcation lesions.

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Superior vena caval occlusion reduces cardiac filling pressures in patients with acute decompensated heart failure: first-in man experience

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THEME: Interventions for Heart Failure

TOPIC(S): Acute heart failure, Chronic heart failure

AIMS

Acutely decompensated heart failure remains a major clinical problem. Volume overload promotes cardiac and renal dysfunction. Reducing cardiac preload improves cardiac function in congestive heart failure. No current device based approach restricts cardiac preload. We hypothesize that occlusion of the superior vena cava (SVC) reduces cardiac filling pressures and improves cardiac output without reducing systemic blood pressure. We explored the safety and feasibility of SVC occlusion in patients with acutely decompensated heart failure with reduced ejection fraction.

METHODS AND RESULTS

Three consecutive patients with NYHA Class III-IV decompensated heart failure with reduced ejection fraction referred for right and left heart catherization were enrolled. Mean LV ejection fraction was 18±10%. Patients had baseline neurologic testing including quantification of Mini-Cog and NIH Stroke Scale (NIHSS) scores. A 30cc endovascular balloon was placed through the right internal jugular vein and inflated to occlude the SVC, as confirmed by venography, for a total of 5 minutes. Pulmonary artery catheter and pressure-volume loop data were measured at baseline, at 1-minute intervals during occlusion, and 5 minutes after release of occlusion. An SVC venogram was performed after release of occlusion to assess for vessel integrity. Repeat neurologic testing was performed within 10 minutes of balloon release, at 1, 4, and 24 hours.

SVC occlusion was successfully performed for five minutes in all three patients. No neurologic side effects were noted. Mini-Cog scores were unchanged from baseline and NIHSS remained 0 for all patients at all time points. Average mean arterial pressure (MAP) was unchanged throughout occlusion time. Right internal Jugular (IJ) venous pressure rose from 19 ± 1 to 44 ± 5 mmHg ($p = 0.014$) at 5 min and returned to baseline values after release of SVC occlusion. Compared to baseline, 5 minutes of SVC occlusion rsignificantly educed right atrial pressure (RA, 26 ± 5 vs. 10 ± 1 mmHg, $p< 0.05$), pulmonary artery systolic pressure (PASP, 57 ± 15 vs. 41 ± 18 mmHg, $p< 0.05$), pulmonary artery diastolic pressure (PADP, 32 ± 13 vs. 21 ± 14 mmHg, $p = 0.01$), mean pulmonary artery pressure (mean PA, 43 ± 13 to 29 ± 14 mmHg, $p = 0.02$) and pulmonary capillary wedge pressure (PCWP, 34 ± 17 vs. 19 ± 14 mmHg, $p = 0.01$). Cardiac index, peripheral vascular and systemic vascular resistance, and stroke volume were unchanged. Stroke work trended lower after 5 minutes of occlusion (2607 ± 1951 to 1522 ± 1443 mL-mmHg, $p = 0.06$) and returned to baseline after release. Compared to baseline, mean arterial pressure was unchanged after 5 minutes of SVC occlusion (99 ± 9 vs 99 ± 12 mmHg, p=NS).

CONCLUSIONS

We report the first-in-man experience with SVC occlusion as a novel intervention that reduces cardiac filling

pressures in patients with acutely decompensated heart failure and reduced ejection fraction. SVC occlusion was well tolerated with stable mean arterial pressures and without neurologic side effects. Future studies will determine the clinical utility of this approach to improve short and long-term outcomes for patients with congestive heart failure.

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Diagnostic performance of FFR and iFR in severe aortic valve disease

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Fractional flow reserve (FFR) is the gold standard of assessing functional stenosis in the catheterization laboratory, whereas the instantaneous wave-free ratio (iFR) is being introduced as a new non-pharmacologic-stress index of coronary stenosis severity. However, the diagnostic performance of FFR and iFR has not been explored in patients with severe aortic valve stenosis (AS). We aimed to investigate the diagnostic performance of FFR and iFR in AS patients.

METHODS AND RESULTS

We analyzed 95 consecutive AS patients (57 females) with intermediate coronary artery stenosis (116 vessels). We investigated the optimal cut-off values of FFR and iFR to indicate myocardial ischemia, as detected by adenosine-stress myocardial perfusion imaging. The median value and interquartile (Q1, first quartile, Q3, third quartile) of FFR was 0.84 (Q1 to Q3 range 0.76-0.91), and that of iFR was 0.86 (Q1 to Q3 range 0.76-0.93). The iFR values were well correlated with FFR values ($r = 0.854$, $p < 0.0001$). Receiver operating characteristic analysis demonstrated an optimal cut-off of 0.82 for iFR to indicate FFR ? 0.75, with an area under the curve (AUC) of 0.92. The optimal cut-off values of FFR and iFR for indicating myocardial ischemia on perfusion scintigraphy were 0.83 and 0.82, respectively (AUC = 0.93 and AUC = 0.84, respectively).

CONCLUSIONS

In patients with severe AS, there is a good correlation between FFR and iFR. FFR and iFR appear to have different optimal cut-off value to indicate myocardial ischemia, as detected by myocardial perfusion scintigraphy.

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Residual atrial septal defect after percutaneous LAA closure: does it matter?

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THEME: Interventions for Stroke

TOPIC(S): LAA closure, Ischaemic stroke

AIMS

Percutaneous LAA closure can lead to an acquired atrial septal defect. The data is scarce about its predisposing factors, prevalence and clinical impact.

The purpose of our work was to evaluate the prevalence and the variables associated with residual atrial septal defect after percutaneous LAA closure.

METHODS AND RESULTS

Methods: Retrospective study of 70 patients submitted to percutaneous LAA closure between May 2010 and August 2017 that performed TOE one month after the procedure. 46% (n=30) of the procedures were guided with intra-cardiac echocardiography and 54% (n=36) with TOE. The presence of residual atrial septal defect was identified by color Doppler study in a bi-caval plane. The shunt and the anatomical characteristics of the atrial septal defect were also evaluated. The sample was divided in two groups, A (n=26) - patients with residual atrial septal defect and B (n=44) - patients without residual atrial septal defect.

Results: The sample had a mean age of 75 years old and 67% were male. The prevalence of residual atrial septal defect was 37% (n=26). The mean diameter of the atrial septal defect was 4±1mm, ranging from 2 to 7 mm. The groups showed similar distribution of demographics, CHADs2Vasc2 or HAS-BLED risk scores. The heart rhythm (sinus rhythm versus atrial fibrillation) at the procedure time, was also equal for both groups. The use of intra-cardiac echocardiography showed to be statistically associated with the presence of residual atrial septal defect (A - 67 vs B - 33%, OR 2,4, P=0,009). None of the echocardiographic variables showed to be associated with the presence of atrial septal defect (examples: left ventricle interventricular diameter in diastole (A 51±7 vs B 52±8mm, P=0,557), left ventricle ejection fraction (A 54±8 vs B 56±12%, P=0,48) or left atrium volume index (A 45±16 vs B 50±21 ml/m2, P=0,278)). The groups didn?t show differences between in hospital mortality, 30 day mortality or readmission for heart failure.

CONCLUSIONS

The prevalence of residual atrial septal defect after percutaneous LAA closure was elevated, although the atrial septal defects were small. The use of intra-cardiac echocardiography showed to increase the risk of residual atrial septal defect. As future perspectives the authors underline the importance of evaluating the persistence of atrial septal defect on the long term as well as its prognostic significance.

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Safety and feasibility of percutaneous plug-based arteriotomy closure device in TAVI procedure. Initial experience

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

AIMS

A new vascular closure device, with collagen?based technology was developed to closure of large-bore ateriotomies.

The present study was conducted to evaluate safety and feasibility in term of vascular complications and bleedings of the Manta vascular closure device in patients undergoing to transfemoral transcatheter aortic valve replacement (TAVI)

METHODS AND RESULTS

Retrospective study, between April and December 2017 enrolling patients who underwent to transfemoral TAVI and planned percutaneous arteriotomy in a single tertiary centre. Femoral puncture was fluoroscopic either echo guided.

A total of 100 consecutive patients with a mean age of 79.3±7.6 years that underwent to transfemoral TAVI were included.

MANTA device was successfully deployed in all cases, using 14-F device in almost half of patients (45 of 100, 45%) and 18-F Manta device in the reminder.

One patient had a major vascular complication with major bleeding and requiring endovascular treatment with covered stent implantation.

13% (13 of 100) of patients presented minor vascular complications (2 pseudoaneurysms and 11 hematomas) resolved with manual compression except one pseudoaneurysm that needed embolization.

Angiography after artery closure with Manta device was performed in 66% (66 of 100) patients. It showed widely patent femoral vessels in all theses subjects, with the plug localized on the anterior wall in 78.8% (52 of 66) and with small extravasation in 10 patients (patients with minor vascular complications) and large extravasation in one case (patient with major vascular complication).

Minor bleeding was present in 15% (15 of 100), mostly related with presence of hematoma. A total of 6 patients needed 1 unit of packed red blood cells and 2 patients needed 2 units.

At 30 days, there were no late vascular complications related to the Manta device. All cause mortality at 30 days was 3% (n=3), none of the deaths were related to the Manta device or access site.

CONCLUSIONS

The MANTA device seems to be a safety and feasible option to vascular access closure in patients underwent to TAVI procedure. Small extravasation after procedure was related with minor hematoma whose treatment was conservative.

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Synchronous vs. staged carotid artery stenting and open heart surgery ? a propensity score matched comparison

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

AIMS

Significant carotid artery disease represents an important risk factor for stroke during cardiac surgery. The optimal management of the patients requiring cardiac surgery with concomitant severe carotid disease remains a controversy. The carotid angioplasty (CA) has evolved in the last decades and is now a valid alternative to endarterectomy, especially in patients with concomitant cardiac pathology candidates for urgent cardiac surgery (CS).

Objectives: The aim of this study was to evaluate the feasibility and compare the outcomes between synchronous or staged CA in patients undergoing CS

METHODS AND RESULTS

We retrospectively studied patients submitted to carotid angioplasty and cardiac surgery in our center from 2000 to 2017. The patients were divided in two groups: group 1 (synchronous procedures, n=40) and group 2 (staged procedures, n=113). Major adverse cardiovascular events (stroke, ACS or death) were evaluated peri-procedural, at 30 days and one year. 1: 1 propensity matched (PSM) analysis was performed with the covariables.

This study included 152 patients, 81% male, mean age of 71±10 years. A cerebral protection device was employed in 99% of the population. Mean age in group 1 was 71±9 years, 7.5 with previous stroke/TIA. Mean age in group 2 was 72±8 years, 5.3% with previous stroke/TIA. No significant differences were detected between basal characteristics. Despite the high baseline risk profile, our results were encouraging. Carotid stenting was successful in all patients. No neurologic complications occurred during the carotid stenting procedures. No peri-procedural myocardial infarction or death occurred in the synchronous group. There were no differences between groups regarding survival free of major events at 30 days (logrank, p=0.1) and one year (logrank, p=0.1). In the PSM cohort, there was a tendency for synchronous procedures to have a better survival for cardiovacular events at 1 year (logrank, p=0.08)

CONCLUSIONS

In our experience, carotid artery stenting followed immediately by cardiac surgery is safe and represents a reasonable option for selected patients presenting with severe carotid and coronary or valvular disease.

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The occlutech atrial flow regulator for the management of pulmonary hypertension: initial experience and mid-term follow-up from a single centre

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

AIMS

Pulmonary arterial hypertension (PAH) is a severe, progressive and fatal disease. The Occlutech Atrial Flow Regulator (AFR) have been reported to improve symptoms and hemodynamics in relatively younger patients with PAH and syncope. However, its performance in elderly patients with PAH and predominately right heart failure symptoms without syncope is unknown. AFR-PROPHET study is a prospective, pilot study to assess efficacy of the Occlutech AFR device in PAH. Our aim is to provide an initial assessment on efficacy of the Occlutech AFR device in the first case series of the AFR-PROPHET study.

METHODS AND RESULTS

The Occlutech AFR devices were implanted after informed consent in three patients (age 65±9, median) with severe PAH presenting with right heart failure and who showed increased mean right atrium pressure (mRAP>10 mmHg) and mRAP levels higher than mean left atrial pressure (mLAP). Two patients had a history of prior surgical atrial septal defect closure and one patient was diagnosed with idiopathic PAH. All the patients were receiving optimal doses of two oral pulmonary vasodilators of which one belonged to endothelin receptor antagonists and the other belonged to phosphodiesterase-5 inhibitors. Symptoms, early and mid-term hemodynamics, echocardiographic parameters, brain natriuretic peptide (BNP) levels, six-minute walk distance and device patency were documented. All devices were implanted successfully without any complications. In all patients, mRAP (15±6 to 9±3 mmHg, p=0.05), mean pulmonary artery pressure (mPAP 38±10 to 30±9 mmHg, p=0.04) and systemic oxygen saturation values (94±3% to 88±2%, p=0.07) declined, however cardiac index (2,37±0,6 to 3,19±0,9 ml/min/m2, p=0,1) increased immediately after the procedure. During the follow-up period, six-minute walking distance increased (126 to 176 meters, p=0,14) and functional status (NYHA class) improved in all patients. Echocardiographic parameters of right ventricular function, including right ventricular end-diastolic diameter and tricuspid annular planar systolic excursion also improved. Mid-term hemodynamic and echocardiographic parameters showed similar improvements. The device remained patent in all patients and there were no serious device-related adverse events.

CONCLUSIONS

These first case series of the AFR-PROPHET study suggest that the implantation of the novel Occlutech AFR is a safe and feasible treatment option to reduce symptoms, to decrease mRAP and mPAP levels, and to increase six-minute walking distance in elderly patients with severe PAH and right heart failure. The device remained patency at mid-term follow-up and the resultant systemic desaturation was well tolerated. Notably, the operator learning curve in this single-center experience was fast, paralleled by zero complication.

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Prevalence of thin-cap fibroatheroma and plaque rupture in non-ischaemic vessels in diabetic patients with or without ACS - Insights from the COMBINE study

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

AIMS

The prevalence of thin-cap fibroatheroma (TCFA), plaque rupture (PR) and other thrombotic intracoronary lesions in angiographic intermediate and fractional flow reserve (FFR) negative (>0.80) lesions in diabetes mellitus (DM) patients is unknown. Furthermore, whether the prevalence of TCFA, PR, plaque erosion (PE) and calcified nodule (CN) associated thrombus differs in acute coronary syndrome (ACS) vs. non-ACS patients is also unknown. The aim of this study was to determine the prevalence of TCFA, PR, PE and CN-associated thrombus in FFR negative lesions of DM patients with vs. without ACS.

METHODS AND RESULTS

We performed the optical coherence tomography (OCT) analysis of the first 200 patients from the COMBINE study (NCT02989740), a multi-centre, prospective natural history study which combines OCT morphologic and FFR hemodynamic assessment of non-culprit lesions to better predict adverse event outcomes in DM patients. From 200 patients, 55 had ACS and 145 had stable or silent angina. The clinical risk factors did not differ between the two groups. The mean angiographic diameter stenosis was 52.9±11.6% in both groups (p=0.979). No significant differences were observed between ACS vs. non-ACS group in the incidence of TCFA: 23.6% vs 22.8%, respectively (p=0.895). Importantly, the prevalence of angiographic hidden PR was similarly high in both groups and represented 9.5% of the total lesions (p=0.903). The PE and CN-associated thrombus did not differ between ACS and non-ACS subgroups (p=0.182 and p=0.429, respectively) The thrombotic lesions were in 52.8% associated with TCFA lesions in both groups (p=0.205).

CONCLUSIONS

The major finding of this analysis is that >9% of FFR negative lesions in DM patients had a PR, a condition for which FFR has not been validated. The total prevalence of thrombotic lesions were 18% in both groups. Furthermore, the prevalence of TCFA in DM patients was not impacted by clinical syndrome at presentation, proving again that ACS and stable/silent angina are just two different presentations of the same disease.

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Patency of the oval foramen: from closing by occlusive "device" to the "NobleStitch" technique. Experience of a centre

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THEME: Interventions for Stroke
TOPIC(S): Other stroke interventions

AIMS

Patency of the oval foramen (PFO) can be found in about 25% of the adult population and may be a potential source of ischemic stroke through the mechanism of paradoxical embolization. This relationship presents greater strength in young patients affected by cryptogenic stroke. The debate regarding the advantage offered by percutaneous closure in secondary prevention is still strong. Although the first studies did not show clear clinical benefits, new data and new techniques could change our clinical practice.

METHODS AND RESULTS

In our unit, from 2000 to today, we have been performed 371 procedures for closing the PFO, of which 355 through the implantation of an occlusive device (Amplatzer PFO Occluder, Abbott) and 16 by the Nobles Stitch technique (NobleStitch EL, Heartstich) in the last year. This is a percutaneous closure system that works suturing together secundum and primum septum. All patients were enrolled only in secondary prevention, when cryptogenic origin of TIA/stroke was strongly suspected and were first subjected to transcranial Doppler with microbubbles (P o l i g e l i n), than a transthoracic echocardiography with microbubbles for the detection of the right-left shunt at the level of the septum and finally a transesophageal study, to plan the best percutaneous treatment.

CONCLUSIONS

The RESPECT trial showed that after a mean follow-up of 5.9 years, there was a reduction of 54%, in the relative risk of cerebral ischemic recurrence in particular the greatest benefit was shown in patients with interatrial septal aneurysm (SIA) and with a large shunt2. In a recent meta-analysis, it was confirmed that in patients with a cryptogenic stroke, the closure of the patent foramen ovale reduced transient stroke/ischemic attack recurrence compared to medical therapy, although it was associated with a higher risk of atrial fibrillation/flutter of new onset.

The strengths of using Noblestitch EL in the treatment of PFO are the absence of implanted devices, no indication for antiplatelet therapy or other medical therapy, the lack of risk of thrombosis or dislocation of the device and absence of contraindication to future transeptal procedures. What is still important is the greater logistical ease of the procedure, in particular the absence of resuscitation assistance, related to oro-tracheal intubation and mechanical ventilation, and transesophageal echocardiography. To date, with the this new mini-invasive technique we have not had any periprocedural adverse events, confirming a simple, effective and safe method.

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The renal artery anatomy in patients with resistant hypertension qualified for renal denervation

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

AIMS

The aim of this study was to assess the anatomy of renal arteries in patients with resistant hypertension that were qualified for renal denervation.

METHODS AND RESULTS

Resistant hypertension was defined as blood pressure (BP) of > 140/90 mm Hg in adults despite the treatment with optimal doses of 3 or more antihypertensive agents, one of which is a diuretic. Blood pressure measurements were obtained by taking the average of 3 office-based measurements and twenty-four-hour ambulatory BP monitoring (ABPM). The biochemical and endocrine diagnostic procedures were carried out to rule out secondary hypertension.

The angioCT scans were taken using 64-row MSCT manufactured by Toshiba. Transthoracic echocardiography was performed using Vivid E9 ultrasound system equipped with M5S-D transducer (GE Healthcare). The acquired datasets were evaluated offline with EchoPAC Clinical Workstation Software (GE Healthcare). We analyzed the morphology, the diameters and the number of additional renal arteries.

A total of 72 patients (pts) were enroled in the study. There 31 pts with resistant hypertension (RHT) and 41 pts with non-resistant hypertension. There were no differences in diameter of renal arteries between the groups. In both groups, we found additional renal arteries. They were present more often on the left side (18 left side vs 7 right side). In comparison to main renal arteries the additional ones were longer - left side 41,7±12,1 mm vs 51,1±11,8 mm, right side 49,2±14,5 mm vs 60±8,6mm respectively ($p<0,05$). The diameters of ARN were similar in both groups. In the group of pts with resistant hypertension the number of additional renal arteries was significantly higher ($p<0,04$).

CONCLUSIONS

The additional renal arteries occur more often in patients with resistant hypertension. Also, the additional renal arteries have different anatomy than the main renal artery. Therefore it seems that there is no connection between the resistance of hypertension and the number and diameters of additional renal arteries.

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Impact of the SYNTAX score in uncertain DES candidates receiving zotarolimus-eluting or bare-metal stents: insights from the ZEUS trial

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

AIMS

It is unknown whether SYNTAX score may predict outcomes and zotarolimus-eluting stent (ZES) is superior to bare-metal stents (BMS) irrespective of coronary artery disease complexity in patients at high risk of bleeding or thrombosis or at low restenosis risk. Thus, we assessed the impact of SYNTAX score on outcomes after percutaneous coronary intervention (PCI) with implantation of a hydrophilic polymer-based, second-generation ZES versus BMS in these patients.

METHODS AND RESULTS

We performed a post-hoc analysis of the ZEUS trial. The impact of coronary anatomic complexity as measured by the SYNTAX score in the differences in outcomes following ZES and BMS was assessed at 1 year. Mean SYNTAX score was 16.3±13.1 with a median of 12 (interquartile range: 7 to 22). We stratified patients according to SYNTAX tertiles (0-8: n=563, 9-19 n=532, >19: n=511), and observed that the higher was the score, the higher was the rate of the primary endpoint of major adverse cardiovascular events (MACE) and other ischemic events. The superior efficacy of ZES versus BMS for MACE was consistent across SYNTAX teriles (tertile 1: HR 0.71, 95% CI 0.44-1.13, tertile 2: HR 0.71, 95% CI 0.46-1.09, tertile 3: HR 0.83, 95% CI 0.61-1.10) without significant heterogeneity (p for trend=0.55). This between-groups difference mainly reflected a reduction in MI and TVR but not mortality. There was no significant interaction between SYNTAX score and stent treatment for all ischemic and bleeding endpoints.

CONCLUSIONS

SYNTAX score was predictor of major adverse cardiovascular events and ZES was superior to BMS across the whole spectrum of CAD complexity.

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Five-year outcomes of percutaneous edge-to-edge mitral repair in the real-world according to mitral regurgitation aetiology

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

AIMS

To evaluate the 5-year outcomes of percutaneous edge-to-edge mitral repair according to mitral regurgitation (MR) aetiology in the real-world.

METHODS AND RESULTS

Out of 353 patients treated with MitraClip at our Department between October 2008 to December 2016, 242 (68.6%) were affected by functional (FMR) and 97 (27.5%) by degenerative (DMR).
At baseline, FMR patients had worse New York Heart Association class (³III in 79.4% vs 65.0%, P=0.01) as well as larger left ventricles (end diastolic diameter 69±9 vs 58±8 mm, P

CONCLUSIONS

In a real-world single centre experience, we observed an overall 5-year survival after MitraClip of roughly 55%, similar in FMR and DMR. In surviving patients, sustained symptoms benefit was observed in both groups. 5-year MR recurrence was observed in 1/3 of cases, not differently between FMR and DMR. Initial suboptimal MR reduction was associated with impaired 5-year outcomes.

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Jailed pressure wire for the evaluation of side branch result during provisional stenting for bifurcation lesions: the use of iFR as a new index

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

1.- To analyze the safety and usefulness of a jailed pressure wire in bifurcation lesions treated with provisional stenting strategy. 2.- To assess the side branch (SB) result using instantaneous wave free ratio (iFR).

METHODS AND RESULTS

Between June and December 2017, 21 patients who presented a bifurcation lesion considered appropriate for provisional stenting strategy were included in the study. The pressure wire was passed to side branch before treatment. Main vessel (MV) and side branch (SB) were pre-dilated at the operator criteria. Determination of instantaneous Wave Free Ratio (iFR) was obtained in the SB at baseline and after MV stenting (leaving the pressure wire jailed). Afterwards, the wire was removed up to the guide catheter to check the correct calibration. SB post-dilation was performed if iFR was £ 0,89, evaluating the result by a new iFR determination. The mean age was 63 ± 9 years and 17 patients (81%) were male. Seven patients (33,3%) had diabetes, 13 (61,9%) hypertension and 14 (66,7%) hypercholesterolemia. The clinical presentation was stable angina in 10 patients (47,6%), non-STEMI in 9 patients (42,8%) and STEMI (non culprit lesion) in 2 patients (9,5%). The bifurcation type according to the Medina classifications was: 1,1,1 in 3 patients (14,3%), 1,1,0 in 8 (38,1 %), 1,0,1 in 1 (4,8 %), 1,0,0 in 3 (14,3 %), 0,1,1 in 2 (9,5 %), and 0,1,0 in 4 patients (19 %).The MV and SB reference diameter was 2,89 ± 0,4 mm and 2,3 ± 0,5 mm respectively. Most of the bifurcations were located at the left anterior descending artery/diagonal branch (n=13, 62%). The mean time to SB wiring before treatment was 13,8 ± 8 seconds and the baseline iFR 0,79 ± 0,18. Under continuous monitoring of the guidewire pressure at the SB, the stent was deployed in the MV trapping the pressure wire. After MV stenting, the iFR in the SB changed to 0,88 ± 0,09. These values were confirmed by the correct calibration of the wire in 17 patients. In 4 patients (19%) a calibration failure was detected and this wrong iFR was not considered for taking decisions. Recalibration of the wire and SB rewiring was required.

According to post MV stenting iFR, 8 (38,1 %) patients required SB post-dilation. The final iFR after SB post-dilation was 0,92 ± 0,02. A second stent was not necessary in any patient. There were concordance between angiographic and physiologic results in 14 patients (66,7%): 7 (50%) with severe and 7 (50%) with mild SB ostial stenosis assessed by both methods. In the remaining 7 the decision of SB treatment was taken accordingly the iFR value.

There were no jailed wire fractures. According to the stereoscopic microscopy we observed mild or moderate damage in 13 wires (61,9 %), all of them proximally to the pressure sensor.

After a mean follow up time of 126 ± 70 days no major adverse events were registered.

CONCLUSIONS

The use of jailed pressure wire to monitoring the result of the SB in bifurcations treated by provisional stenting

is safe. The need for a new calibration during the procedure (19% of the patients) may be a limitation for this strategy. The iFR index seems to provide new physiological information about the clinical significance of the SB stenosis.

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The DIRECT II study: four-year follow-up

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

AIMS

Simplifying coronary stent delivery and reducing vascular access site size via ?Slender? PCI in appropriate subsets improves procedural outcomes and patient comfort. Direct stenting is associated with reduced procedure times, radiation exposure, contrast administration and costs compared with conventional stenting with pre-dilatation. The Svelte drug-eluting stent Integrated Delivery System (IDS) is designed to facilitate ? Slender? PCI and direct stenting. The DIRECT II study was undertaken to demonstrate the feasibility of the Svelte IDS in a randomized, controlled setting.

METHODS AND RESULTS

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

The transradial approach was used in 67% of interventions, approximately 40% of the invetigators were first-time users of Svelte IDS. At 6 months, in-stent LLL was 0.09 ± 0.31 mm with the Svelte IDS compared to 0.13 ± 0.27 with Resolute Integrity (

CONCLUSIONS

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

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The stenosis of common femoral artery after hemostasis with two Proglide for transfemoral TAVI - Two Proglide are too much?

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

AIMS

Percutaneous hemostasis for transfemoral TAVI is widely accepted.2 Proglide with ?pre-closure? technique is mainly used for percutaneous hemostasis in Europe. It gives easy and certain hemostasis after TAVI. However sometimes we encounter severe stenosis of common femoral artery (CFA) after this procedure. The predictor and mechanism of stenosis at CFA after percutaneous hemostasis with 2 Proglide are not well understood. Therefore we aimed to clarify the predictor and mechanism of CFA stenosis after percutaneous hemostasis with 2 Proglide in transfemoral TAVI patients.

METHODS AND RESULTS

We enrolled consecutive 744 transfemoral TAVI cases which were underwent femoral angiogram both pre and post procedure from August 2014 until August 2017 at our institution. The definition of ?CFA stenosis? is a case which had more than 90% stenosis at CFA or a case which had underwent ballooning or stenting to dilate CFA. CFA diameter and percent stenosis was calculated by OSIRIX. All patients underwent attempt to achieve full percutaneous hemostasis by using 2 ProGlide devices using the ?preclosure? technique. The ?Preclosure? technique is sequential insertion of the two Proglide devices rotated in opposite sides to create an interrupted X-figure closure as previously described. We divided cases into two groups, Stenosis(+) and Stenosis (-) and compared background and analyzed predictor.

There were 41 CFA stenosis cases (5.5%) in our cohort. Mean age (83±5 vs 83±6 p=0.79), Body Mass Index (27±7 vs 27±5, p=0.51) were similar but female proportion was significant higher (80% vs 50%,

CONCLUSIONS

Female, diameter of CFA

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TIMI flow grades in STEMI patients pre-loaded with Ticagrelor in the field in the Mid-West of Ireland

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

AIMS

Ticagrelor, a potent p2y12 receptor inhibitor, is recommended along with aspirin as a loading agent for ST Segment Elevation Myocardial Infarction (STEMI). Whether Ticagrelor can improve coronary patency before any intervention is not well known. Our aim was to find out the percentage of TIMI flow grades in STEMI patients on initial angiography, who were pre-loaded with Ticagrelor before presenting to our services between January Ist 2016 and November 30th 2017.

METHODS AND RESULTS

After retrospectively spotting STEMI patients (using hospital in patient enquiry and heart beat data bases) who were given pre procedure Ticagrelor, we reviewed their hospital notes and coronary angiograms. We used SPSS-22 for statistical analysis.

Results

A total of 308 patients with STEMI were enrolled, 243 were given Ticagrelor pre hospital and 65 in the Hospital. 57 (18.51%) were females and 251 (81.49%) males. Mean age was 62.79±11.94 years. TIMI flow grade 0 was 56.4%, TIMI I 8.2% , TIMI II 8.2% and TIMI III 27.2% in the pre hospital Ticagrelor group and TIMI 0 at 72.3%, TIMI I 7.7% , TIMI II 4.6% and TIMI III 15.4% in the In hospital Ticagrelor group. TIMI flow grades I-III were 43.6% and TIMI 0 56.4% in the pre hospital Ticagrelor group whereas TIMI flow I-III were 27.7% and TIMI flow 0 at 72.3% in the in hospital Ticagrelor group (

CONCLUSIONS

our findings of better TIMI flow grades in Ticagrelor pre-loaded STEMI patients , especially those given Ticagrelor in the field encourages its use in such patients. larger prospective studies will validate these findings.

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Economical cost of percutaneous vascular closure with ProGlide and Prostar XL following TAVR

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

AIMS

With new vascular closure devices for large bore femoral arteriotomies in development and soon commercially available, the aim of this study was to determine the average use of devices and cost per patient to obtain a successful percutaneous closure following transcatheter aortic valve replacement (TAVR).

METHODS AND RESULTS

Between August 2017 and December 2017, 137 patients underwent TAVR at our center and 131 (96%) of these were performed by percutaneous, transfemoral approach. In all cases, successful vascular closure ? without the need for vascular surgery ? was obtained by use of the commercially available ProGlideTM (n=98) or ProstarTM XL (n=33) vascular pre-closure devices. In case of use of ProGlideTM, typically two devices with an additional AngioSealTM were used. For ProstarTM XL, one device was routinely used. In case of incomplete vascular closure or vascular closure device failure, additional endovascular devices were used such as a TyshakTM balloon and/or a ViabahnTM covered stent. In those cases using ProGlideTM, the average devices used to obtain a successful vascular closure was 2.05 ProGlideTM, 0.93 AngioSealTM, 0.14 TyshakTM balloon, and 0.10 ViabahnTM ? resulting in an average cost of 808 Euro per patient. In case of use of ProstarTM XL, the large bore arteriotomy was successfully closed using 1.0 ProstarTM, 0.30 TyshakTM balloon, and 0.12 ViabahnTM in average per patient ? corresponding to an average cost of 811 Euro per patient. Vascular complications were only minor and statistically not different between both groups: small hematoma 29% vs. 39%, large hematoma 3% vs. 3%, and pseudoaneursym 1% vs. 0% in the ProGlideTM vs. ProstarTM XL group, respectively. In the total cohort of 131 patients, the total average cost was 809 Euro per closure of the TAVR arteriotomy.

CONCLUSIONS

Successful percutaneous closure following TAVR was obtained using either a ProGlideTM or ProstarTM XL vascular closure device and an additional balloon or covered stent in 15-30% and 10% of cases, respectively. The total average cost was 809 Euro per closure of a large bore arteriotomy ? this can be used as a reference when considering the use of new vascular closure devices in the future.

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Bioflow-III an all-comer registry with a sirolimus-eluting stent, presentation of five-year target lesion failure data

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

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

A total number of 1?356 patients were enrolled in this international, multicentre BIOFLOW-III all-comers registry using the Orsiro Sirolimus eluting stent. Clinical follow-ups were performed at 6, 12, 36 and 60 months post-procedure. All serious and device-related adverse events were adjudicated by an independent clinical event committee. Statistical analysis of primary (Target Lesion Failure [TLF] at 12 months) and secondary endpoints was performed for the entire patient cohort and for pre-specified subgroups: diabetes mellitus, small vessels, chronic total occlusion and acute myocardial infarction.

Nine hundred seventy one men (72%) and 385 women were enrolled at 43 sites in 14 countries. The mean age was 66.1±10.7 years. Seventy six percent of subjects had hypertension, 60% - hypercholesteremia, 30% - diabetes and 55% were smokers.

Number of treated lesions was 1?738, the mean lesion length 15.8±9.1 mm, the mean reference diameter 3.0±0.4 mm.

Orsiro device and procedural success were 99.2% and 98.3%, respectively. At 12 and at 60 months, 5.1% and 10.1% of the patients had TLF, respectively. Slightly higher TLF rates were observed in pre-defined small vessels (10.4%, total number of lesions - 828), acute myocardial infarction (11.5%, 551) and diabetes mellitus (14.0%, 517) study subgroups, but not in chronic total occlusion subgroup (1.8%, 83). Definite or Probable Stent Thrombosis occurred in 0.7% of patients within 60 months.

CONCLUSIONS

Five-year preliminary data for the BIOFLOW-III registry demonstrated an excellent device and procedural success with the Orsiro stent. Low TLF rate, observed already for the primary endpoint, was confirmed in this long-term follow up. Importantly, rates of definite and probable stent thrombosis remained low during 5 years, indicating safety of the Orsiro stent system.

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Immediate post-procedural 12-lead ECG as predictor of late conduction disorders after TAVI

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

AIMS

There are limited data on risk factors for the frequent development of late high-degree conduction disorders (HD-CD) and when to keep the temporary pacemaker (PM) in place after TAVI. The aim of this study was to identify predictors of HD-CD within 30 days after transcatheter aortic valve implantation (TAVI) based on ECGs taken pre- and immediate post-procedurally.

METHODS AND RESULTS

A total of 467 consecutive TAVI patients without pre-procedural PM were included. All patients had a 12-lead ECG taken before and immediately after TAVI. During the procedure HD-CD developed in 66 of patients (14%). Late HD-CD developed in 37 of patients (8%) up to 18 days after TAVI. None of 70 patients with sinus rhythm and a PR-interval < 200ms and a QRS-interval < 120ms on the immediate post-TAVI ECG developed late HD-CD, indicating a subset of patients with no need for temporary PM or telemetry after TAVI. Patients with atrial fibrillation (AF) and left bundle branch block (LBBB) with QRS-interval < 140ms (n = 4/49, 8%) and patients with sinus rhythm and a PR-interval < 240ms and LBBB with QRS-interval < 160ms, excluding those with normal PR- and QRS-interval (n = 6/139, 4%), had a low risk of late HD-CD and could leave catheterization laboratory without a temporary PM and continue telemetry. Conversely, patients with sinus rhythm had a high risk of late HD-CD in case of a PR-interval ? 240ms or LBBB with QRS-interval ? 160ms (n = 13/71, 18%), or right bundle branch block (RBBB) (n = 5/23, 22%) on the immediate post-TAVI ECG. Similar, the risk of late HD-CD was high for patients with atrial fibrillation and LBBB with QRS ? 140ms (n = 4/30, 13%) or RBBB (n = 3/15, 20%), or for patients with nodal rhythm (n = 2/4, 50%) on the immediate post-TAVI ECG. Keeping the temporary PM after in these patients seems reasonable.

CONCLUSIONS

A 12-lead ECG taken immediately after TAVI can predict the risk of late HD-CD, potentially aiding in the decision of when to safely remove or prophylactically keep the temporary PM before the patient leaves the catheterization laboratory.

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Elderly patients with coronary artery disease treated by PCI and one- or six-month DAPT: a SENIOR subanalysis

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

AIMS

In the SENIOR trial, among patients 75 years old and above who undergo percutaneous coronary intervention (PCI), a drug eluting stent (DES) and a short duration of dual antiplatelet therapy (DAPT) is superior to a bare metal stent (BMS) . DAPT was not randomised but selected prior to randomisation by the investigators, as being 1-month and 6-months in stable and unstable patients, respectively. Here, baseline characteristics and outcomes of patients treated with 1-vs. 6-months DAPT are reported.

METHODS AND RESULTS

Among the 1.200 patients, prior to angioplasty, 56.9% (n=683) and 43.1% (n=517) were planned to be treated with 1-month and 6-month DAPT, respectively. Patients were randomized by a central computer system to either a DES (1-mo, n=327, 6-mo, n=269) or a similar BMS (1-mo, n=356, 6-mo, n=248), in a single-blinded way. The objective was to compare baseline characteristics and outcomes of patients treated with 1-month vs 6-months DAPT. Primary endpoint was a composite of all-cause mortality, myocardial infarction, stroke or ischemia-driven target lesion revascularisation, and secondary endpoints include the rate of bleeding BARC 2-5 and stent thrombosis at one year.

Among the 1200 patients, 66.3% of the patients with planned 1 month DAPT received effectively 1 month DAPT. Similarly 45.1% of the patients with planned 6 months DAPT received effectively 6 month DAPT. The vast majority of patients planned for 1 month were stable patients, (n=592, 86.7%), while patients planned for 6 month were mainly unstable patients (n=453, 87.6%). The primary endpoint occurred in 90 patients (13.3%) in the 1-month group (n=683) and in 76 patients (15.0%) in the 6 months group (n=517) (relative risk [RR] 0.89, 95% confidence interval [CI], 0.67 to 1.88, P=0.41). Bleeding complications (4.5% vs 5.1%, RR 0.89, 95% CI, 0.52 to 1.57, P=0.67) and stent thrombosis (0.9% vs. 1.0%, RR 0.88, 95% CI, 0.17 to 7.23, P=0.84) rates were low in both groups.

CONCLUSIONS

The selected DAPT duration in SENIOR in general followed the type of presentation at baseline, 1-m when stable versus 6-m when unstable. Despite this difference in baseline risk and DAPT duration, the risk of ischemic as well as bleeding events appeared to be similar.

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Echocardiographic evaluation in patients with TAVI - What parameters should we monitor in the pre-implantation and its follow-up?

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

AIMS

To evaluate and compare the following echocardiographic parameters before and 6 months after TAVI: left ventricular mass (LVM), end-diastolic and end-systolic volume and ejection fraction (EF) of the left ventricle (LV), volume of the left atrium (VLA), severity of mitral regurgitation (MR).

METHODS AND RESULTS

Retrospective, comparative study in patients with symptomatic severe aortic stenosis with a high operative risk, who implanted TAVI between January 2015 and December 2017. All patients underwent echocardiographic study prior to implantation, on the day of the procedure and at 6 months follow up. The following parameters were evaluated: LVM (by the Devereux formula), EF (Simspon method), LV volumes, VLA, transvalvular and transprosthetic gradients, Vena contracta (VC) of mitral regurgitation, subjective assessment of periprosthetic leaks. Non-parametric tests (Wilcoxon and Chi-square) and the Spearman correlation test were performed. We studied 34 patients (79 ± 3.2 years, 58% female) with severe aortic stenosis (mean gradient of 57 ± 12 mmHg), concentric hypertrophy (MVE of 194 ± 12 g / m2 and relative wall thickness of 0.7 ± 0.05), EF ?55% and VLA biplane of 63 ± 5 ml / m2. In the comparative analysis between pre-implantation and follow-up, there were statistically significant differences in LVM in both genders, with a decrease in LVM from 194 ± 12 g / m 2 to 163 ± 9 g / m 2 (p = 0.005) .

The median value of VC at follow-up is significantly lower than pre-implantation (p = 0.03). EF showed an increase after TAVI, but this was non significant (p = 0.12). The LV end-diastolic and end-systolic volumes decreased in follow-up, with no statistically significant difference, and the same was observed for the VLA. In 22.3% of the patients there were observed significant leaks (moderate severity) assessed on the day of TAVI implantation, which decreased severity at follow-up.

CONCLUSIONS

In patients with symptomatic severe aortic stenosis who implanted TAVI there was a significant improvement in the hemodynamic status as well as a decrease in LVM and MR severity. These changes likely explain the symptomatic improvement observed in these group of patients at 6 months follow up. These results confirm the advantage of implanting TAVI in very high risk patients with severe aortic stenosis.

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Comparison of standard renal denervation procedure vs. novel distal and branch vessel procedure with brachial arterial access (y-pattern treatment)

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

AIMS

We assessed a novel approach to renal denervation for uncontrolled hypertension consisting of ablation beyond the proximal main renal artery, including the distal artery and primary branches, and compared this approach to the standard procedure. We also assessed the safety of brachial access approach to renal denervation.

METHODS AND RESULTS

Renal denervation was performed on 119 consecutive patients (60 ± 13 years) with resistant hypertension. In 68 of the patients, femoral approach was performed and in 51 subjects we used the less invasive brachial approach. In 80 patients treated with the standard ablation pattern, 12.0±3.0 total ablations (both sides) were applied while 20.4±3.9 total ablations were delivered for the group of 39 patients with Y-pattern denervation (P

CONCLUSIONS

Renal denervation using Y-pattern ablation strategy is safe and resulted in significantly greater decreases in mean 24-hour ambulatory systolic blood pressure compared to the conventional approach in this single-centre matched cohort study of resistant hypertensive patients. A novel brachial artery access denervation approach using a brachial approach was also shown to be feasible and safe.

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Direct oral anticoagulants vs. vitamin K antagonists after TAVI

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

AIMS

To compare direct oral anticoagulants (DOAC) and vitamin K antagonists (VKA) with regards to the incidence of ischemic and bleeding events, and mortality after transcatheter aortic valve implantation (TAVI).

METHODS AND RESULTS

OCEAN (Optimized transCathEter vAlvular interveNtion)-TAVI is a prospective, multicentre, observational cohort registry, comprising 1613 patients who underwent TAVI from October 2013 to July 2016 in Japan. We identified 322 patients (20.0%) with atrial fibrillation (AF) on anticoagulant therapy: 149 (46.3%) on DOAC and 173 (53.7%) on VKA at discharge. The composite endpoint of Net Adverse Clinical Events (NACE) endpoint consisted of stroke and myocardial infarction (MI) (12 patients), life-threatening or major bleeding events (4), and death (27) after discharge. The proportion of males (27.5% vs. 39.3%, p=0.026), chronic kidney disease (61.7% vs. 75.7%, p=0.007), and concomitant antiplatelet therapy (none, single antiplatelet, dual antiplatelet: 25.5% vs. 14.5%, 67.8% vs. 74.6%, and 6.7% vs. 11.0%, p=0.028) were significantly different between patients on DOAC and VKA. After propensity score matching, 86 patients were matched in each group. During the follow-up period, there were no statistically significant differences between both groups with regards to stroke and MI (1.2% vs. 5.8%, p=0.214), life-threatening or major bleeding (1.2% vs. 2.3%, p=1.0), death (5.8% vs. 8.1%, p=0.765), and NACE (8.1% vs. 16.3%, p=0.164). Kaplan-Meier analysis revealed that NACE were comparable between both groups (log-rank p=0.239).

CONCLUSIONS

Anticoagulant therapy with DOAC resulted in midterm outcomes similar to those with VKA. This study demonstrates that DOAC is as effective as VKA in patients with AF undergoing TAVI.

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Predictors of advanced conduction disturbances requiring a late (up to 48 hours) permanent pacemaker following TAVI

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

AIMS

To determine simple and reproducible clinical and electrocardiographic predictors of advanced conduction disturbances requiring late (?48 hours) permanent pacemaker implantation (PPM) after transcatheter aortic valve implantation (TAVI).

METHODS AND RESULTS

Methods: Clinical, procedural and electrocardiographic data of consecutive patients were identified by retrospective review of a dedicated TAVI database of a single high-volume centre in Milan, Italy between October 2007 and July 2015. We defined delta PR (DPR) and delta QRS (DQRS) as the difference between the last PR and QRS length available 48 hours after TAVI and the baseline PR and QRS length.
Results: The overall population included 740 patients. We excluded 78 patients who already had a PPM and 51 patients who received a PPM

CONCLUSIONS

This analysis showed that baseline right bundle branch block and the amount of increase of PR length after TAVI are independent predictors of late (?48 hours) advanced conduction disturbances requiring PPM implantation after TAVI in this cohort. This study suggests that a simple ECG analysis could help in detecting potentially lethal advanced conduction disturbances that could occur more than 48-hours after TAVI.

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Impact of vessel location on prognostic relevance of FFR after coronary stenting

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

AIMS

Fractional flow reserve (FFR) measured after percutaneous coronary intervention (PCI) has prognostic value. However, the influence of vessel location on the post PCI FFR has not been thoroughly investigated.

METHODS AND RESULTS

A total of 863 patients with available FFR after 2nd generation drug-eluting stent implantation were included in this study. The target vessels of 618 patients (71.6%) were located in left anterior descending artery (LAD) and those of 245 patients (28.4%) in non-LAD. The primary outcome was target-vessel failure (TVF) at 2 years, including cardiac death, target vessel related myocardial infarction and ischemia driven target vessel revascularization. In all vessels, the risk of TVF was significantly increased with the decrease of each 0.01 post PCI FFR (adjusted hazard ratio [HR] 1.06, 95% confidence interval [CI] 1.04-1.08, p<0.001). The distributions of post PCI FFR in LAD and non-LAD were significantly different (p<0.001) and optimal cut-off values of post PCI FFR for predicting TVF were 0.84, 0.83 and 0.90 in all vessels, LADs and non-LADs, respectively. Comparing clinical outcomes according to the optimal cut-off values, the cumulative incidences of TVF were significantly higher in patient with lower post PCI FFR than each cut-off value (9.5% vs. 2.9%, adjusted HR 3.28, 95% CI 2.23-4.84, p<0.001 in all vessels, 10.8% vs. 2.5%, adjusted HR 4.68, 95% CI 2.92-7.51, p<0.001 in LADs, 7.4% vs. 2.4%, adjusted HR 4.76, 95% CI 1.75-12.99, p=0.002 in non-LADs). Independent predictors of TVF were hypercholesterolemia, chronic kidney disease and low post PCI FFR.

CONCLUSIONS

Achieving adequate post PCI FFR was associated with better clinical outcomes, however, the optimal cut-off values of post PCI FFR for predicting clinical events should be treated different according to the vessels.

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Clinical outcomes of long lesion stenting in contemporary DES era: pooled analysis of the GRAND-DES registry

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

AIMS

Long length of stenting has been associated with poor clinical outcome after percutaneous coronary intervention. However, its clinical impact in contemporary drug-eluting stent (DES) era has not fully elucidated yet. Here we report the safety and efficacy of long lesion stenting using the second generation DES.

METHODS AND RESULTS

We analyzed 13,104 patients from the GRAND-DES registry, a patient-level pooled registry, including 5 Korean multicenter DES registries of EXCELLENT, RESOLUTE KOREA, HOST-PRIME, HOST-BIOLIMUS and HOST-RESOLINTE. To avoid confounding, we focused on the lesion-specific outcomes after long lesion stenting. To this end, we only included a total of 9,217 patients who underwent stenting to a single lesion in at least one of three coronary arteries. The primary endpoints were target lesion failure (TLF), clinically-driven target lesion revascularization (TLR), and definite or probable stent thrombosis (ST) at 2-year.

Maximally-selected rank statistics revealed that 40mm was the optimal cut-off value for TLF. Thus, we defined 40mm as ?long stenting? for a certain single lesion hereafter. A total of 8,035 patients was classified as short stenting group, and 1,182 as long stenting group. In baseline characteristics, age was older and the prevalence of male gender, diabetes, hypertension, chronic kidney disease, previous history of PCI or CABG, congestive heart failure and cerebrovascular attack were higher in long stenting group. However, there were no significant difference between 2 groups in terms of the prevalence of AMI, left ventricular (LV) dysfunction (EF < 40%), and the use of antiplatelet agents. Long stenting group had more complex lesion characteristics such as left main, type B2 or C, calcified and bifurcation disease. Total stent length was longer (56.2±13.7 mm vs. 23.3±6.7 mm, for long stenting vs. short stenting, respectively), and total number of stents was higher (2.2±0.4 vs. 1.0±0.2) in long stenting group. The incidence of TLF (8.6% vs. 4.6%, p < 0.001), TLR (4.4% vs. 2.1%, p < 0.001), and definite or probable ST (1.0% vs. 0.4%, p= 0.011) were significantly higher in a long stenting group. Long stenting (> 40mm) was a significant independent predictor of TLF (adjusted HR: 1.74, 95% CI: 1.38 to 2.18, p < 0.001), TLR (adjusted HR: 2.09, 95% CI: 1.53 to 2.85, p < 0.001) and definite or probable ST (adjusted HR: 2.22, 95% CI: 1.15 to 4.27, p = 0.017). Age (per 10 years), diabetes, peripheral vascular disease, chronic kidney disease, previous congestive heart failure, acute MI, left main disease, previous treated lesion, and LV dysfunction were other significant independent predictors for TLF. Left main disease, and previous treated lesion were significant independent predictors for TLR. And acute MI, LV dysfunction, and previous treated lesion for definite or probable ST. When clinical outcomes were analyzed according to the total stent length divided into 3 groups (<2ish0mm, 20-40mm, and > 40mm), only the group of >40mm showed significantly worse outcomes including TLF, target vessel MI, TLR, and definite or probable ST compared with other 2 groups.

CONCLUSIONS

This large scale patient level pooled registry data demonstrated that long lesion stenting is still associated with

worse clinical outcomes in the contemporary DES era. We should carefully weigh the risk and benefit of PCI when long stenting, especially longer than 40mm is needed.

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Treatment of extremely small de novo vessel coronary artery disease with DEB ? A single-centre experience

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

AIMS

To compare the outcomes of Paclitaxel-Drug-eluting Balloon (DEB) angioplasty in patients with ?2.25mm and >2.25mm denovo small vessel coronary artery lesions.

METHODS AND RESULTS

All patients underwent de novo coronary artery lesions angioplasty with DEB between January 2012 and December 2016 were included in the analysis. Patient baseline characteristics, angiographic data, post-procedural and follow-up outcomes, including cardiac death, myocardial infarction and major adverse coronary event (MACE) were compared between ?2.25mm and >2.25mm of vessel diameter.

A total of 626 patients with 678 de novo small coronary artery lesions were included in the study. Mean age was 58±10 years with a predominance of males (n= 530, 85%). Majority were hypertensive (n=452, 72%) and diabetes mellitus accounted for 335 (54%) of cases. Thirteen percent presented with acute coronary syndrome (ACS), 5% had STEMI, 5% had NSTEMI and 3% unstable angina. Diffuse vessel disease were present in 330 cases (49%). Majority of the stenotic lesions were in the left coronary artery, left anterior descending artery, n=270, (40%) and left circumflex artery, n=217 (32%). Hundred seventy nine (26%) lesions were in the right coronary artery and 12 were in the bypass grafts (2%). Majority of the lesions were type B2 and C lesions (n=446, 66%). Pre-dilatation of the lesions were performed in majority of cases (n=668, 99%) with a pressure of 11±4 atmospheres. The mean DEB diameter and dilatation pressure were 2.4±0.4 mm and 9±5 atmospheres, respectively. The mean inflation time was 60±16 seconds. Flow-limiting lesions post DEB that were bailed out with stents were 9 (1.3%). Five hundred and two (81%) patients received both Aspirin and Clopidogrel on discharge. Clinical follow-up were available in 605 (97%) patients with a median of 12 months. There were no complications of acute or subacute vessel thrombosis following treatment. Major adverse cardiac events (MACE) were observed in 17 (3%) cases with 5 (1%) cardiac death and TLR occurred in 10 (2%) cases. Out of 678 lesions, 251 (37%) cases treated with DEB had a diameter of ?2.25 mm. Dissection in vessels ?2.25 mm and >2.25 mm were in 17 (6.8%) and 23 (5.4%) cases respectively (p=0.459). Flow limiting dissection was not significant in vessels ?2.25 mm as compared to vessels >2.25 mm (p=0.107), which occurred in 9 (3.6%) and 7 (1.6%) cases respectively. TLR in vessels ?2.25 mm were 2 (0.9%) and 8 (2.1%) in vessels >2.25 mm, which was not significant. Freedom from MACE at 1 and 2 years in vessels ?2.25 mm was 98% and 92%, respectively and in vessels >2.25 mm was 98% and 95%, respectively (p=0.982).

CONCLUSIONS

Our experience demonstrates that using DEB in the treatment of extremely small de novo vessels in coronary artery disease was favourable and safe with a low MACE rate at mid-term follow-up and offers an alternative treatment to stenting in de novo small vessel coronary artery disease.

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Clinical outcomes of primary PCI for unprotected left main coronary artery culprit lesion in patients with ACS: an observation from the AOI-LMCA registry

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

AIMS

There are limited data available on clinical outcomes of percutaneous coronary intervention (PCI) for unprotected left main coronary artery (ULMCA) in patients with acute coronary syndrome (ACS).
The aim of this study is to investigate the prognosis of patients with ACS who have culprit lesion in ULMCA.

METHODS AND RESULTS

Among 1809 patients enrolled in the Assessing Optimal Percutaneous Coronary Intervention for LMCA (AOI-LMCA) registry, (which is a retrospective 6 centre registry of consecutive patients undergoing LMCA stenting in Japan,) 396 patients presented ACS due to LMCA culprit lesion [115 patient with shock (ACS+CS) and 281 patents without shock(ACS-CS)). The crude 180 days and 5 years mortality rates were 50% and 59% in ACS+CS, 9% and 18% in ACS-CS, and 3.3% and 16.0% in stable angina (SA), respectively. The risk of mortality within 180 days was greater for ACS+CS and ACS-CS than SA patients [adjusted hazard ratio(HR), 10 (4.5-22.5), P

CONCLUSIONS

In patients with left main disease, the risk of early mortality within 180 days was greater in ACS patients, however, long term mortality was comparable after 180 days. In left main ACS patients, survival correlates with baseline homodynamic deterioration and coronary flow status.

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PFO closure in patients with cryptogenic stroke: meta-analysis of randomised controlled trials

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THEME: Interventions for Stroke
TOPIC(S): Other stroke interventions

AIMS

Patent foramen ovale (PFO) with atrial septal aneurysm (ASA) is suggested as an important potential source for cryptogenic strokes. Percutaneous PFO closure to reduce the recurrence of stroke compared to medical therapy has been intensely debated. The aim of this study is to assess whether PFO closure in patients with cryptogenic stroke is safe and effective compared with medical therapy.

METHODS AND RESULTS

Among 282 studies, 5 were selected. Our analysis included 3,440 patients (mean age 45 years, 55% men, mean follow-up 2.9 years), 1,829 in the PFO closure group and 1,611 in the medical therapy group. The I^2 heterogeneity test was found to be 48%. A random effects model combining the results of the included studies demonstrated a statistically significant risk reduction in risk of recurrent stroke in the PFO closure group when compared with medical therapy (RR 0.42, 95% CI 0.20 to 0.91, P = 0.03). The occurrence of atrial fibrillation was reported in all studies. Atrial fibrillation had occurred in 77 patients (4.2%) in the PFO closure group compared with 12 (0.7%) patients in the medical therapy group [RR 4.63, 95% CI: 2.30, 9.30, I2= 16%, p < 0.0001] This effect represents an Absolute Risk Increase (ARI) of 0.03 [95% CI: 0.01, 0.06, p= 0.003] and a potential Number Needed to Harm (NNH) of 33.

CONCLUSIONS

Pooled data from 5 large RCTs showed that PFO closure in patients with cryptogenic stroke is safe and effective intervention for prevention of stroke recurrence compared with medical therapy. However, risk of post-closure atrial fibrillation is relatively high as demonstrated by this meta-analysis.

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Impact of the one-year angioscopic findings on long-term clinical events following the implantation of the second-generation XienceTM everolimus-eluting stent: the DESNOTE-X study

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

AIMS

The purpose of the present study was to test the hypothesis that the angioscopic findings of the stented segment, especially the presence of in-stent yellow plaque, at 1 year after stent implantation would be a risk of future very late stent failure (VLSF) of the second-generation cobalt chromium everolimus-eluting stent (CoCr-EES) like it was demonstrated in the first-generation drug-eluting stent (DES).

METHODS AND RESULTS

Study design was a single-center prospective cohort study: the DESNOTE-X study (Detect the Event of very late Stent failure from the angioscopic fiNdings Of everolimus-eluTing stEnt XienceTM: UMIN ID 000013515). All patients who received successful angioscopic examination at planned 1-year follow-up after the cobalt chromium everolimus-eluting stent (CoCr-EES) implantation without any event of earlier stent failure were enrolled and clinically followed up for the occurrence of VLSF. Primary endpoint was VLST defined as a composite of cardiac death, target vessel myocardial infarction, and target lesion revascularization.

A total of 255 patients (217 males, age 68±9 years) were assessed with a mean follow-up duration of 4.1±1.7 years. At 1-year follow-up of the CoCr-EES, the prevalence of the in-stent yellow plaque, thrombus, and uncovered struts was 31.0%, 22.4%, and 40.0%, respectively. VLSF occurred in 13 (5.1%) patients in whole population. The incidence of VLSF did not significantly differ between patients with in-stent yellow plaque and those without [2.5% (2/79) vs. 6.2% (11/176), p=0.189]. Statin use (p=0.554) and prolonged DAPT (p=0.583) were not significantly different between the groups.

CONCLUSIONS

In-stent atherosclerosis evaluated by yellow plaque at 1 year after implantation of the second-generation XienceTM CoCr-EES was, unlike the first-generation DES, not associated with the long-term adverse events. Further prospective large study would be warranted to investigate the underlying mechanisms of the adverse events following the second-generation DES implantation.

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The presence of a CTO in a non-infarct related artery during a STEMI treated with contemporary primary PCI is associated with increased rates of early and late cardiovascular morbidity and mortality: the CTO-TOTAL substudy

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

AIMS

The presence of a coronary chronic total occlusion (CTO) in ST elevation myocardial infarction (STEMI) has been associated with increased mortality. The TOTAL trial was a prospective, randomised, trial of routine manual thrombectomy versus percutaneous coronary intervention (PCI) alone. We sought to determine the prevalence and outcomes of a concurrent CTO in a non-infarct related artery compared with single-vessel disease (SVD) or residual multivessel disease without a CTO (MVD), in a large cohort of STEMI patients treated with primary-PCI.

METHODS AND RESULTS

Of 10,063 patients who underwent primary PCI, 658 (6.6%) had a CTO, whilst 5,162 (51.3%) had SVD and 4,243 (42.1%) had MVD. The presence of a CTO was associated with a significantly higher rate of cardiovascular death (10.8%) as compared with SVD (2.6%) or MVD (4%) (

CONCLUSIONS

The presence of a CTO in a non-infarct related artery following a STEMI is independently associated with a greater risk of mortality and overall prognosis. This persists after excluding events within the first month. These results suggest that the poorer prognosis is not a reflection of a greater burden of coronary disease, but may in fact confer independent prognostic risk.

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Pre- and peri-procedural factors associated with an increased risk of in-hospital stroke after TAVI ? Insights from the UK TAVI registry

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

AIMS

To determine whether there are pre- or peri-procedural factors that can predict the risk of in-hospital stroke after TAVI in a real world patient population.

METHODS AND RESULTS

The UK TAVI registry has recorded characteristics and clinical outcomes for every 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, providing a robust system for tracking all-cause mortality.

We performed a retrospective observational cohort analysis of all TAVI patients who suffered an in-hospital stroke post TAVI versus those who did not. Range checks were used during dataset cleaning to look for extreme values and assessments of internal consistency were applied. Missing data were not included in the analysis. After univariate analysis of in-hospital stroke versus no in-hospital stroke patients, ?promising? variables (

CONCLUSIONS

In-hospital stroke post TAVI significantly increases the risk of 30-day and 1-year mortality. Specific pre- and peri-procedural factors are independently predictive of stroke post TAVI and could be used as the basis of a stroke index risk score.

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Novel angiographic algorithm to grade calcification severity of carotid stenosis: development and performance in the CGuard PARADIGM trial involving highly-calcific lesions management

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

AIMS

Calcification severity evaluation is typically limited to the poorly reproducible flag of ?no/mild/moderate/severe?, limiting intra- and inter-study/device comparisons.

We aimed to (1) develop a reproducible algorithm to evaluate carotid stenosis calcification severity, and (2) evaluate feasibility, angiographic efficacy and clinical safety of ??Higly-calcific carotid stenoses (HCCS) endovascular management using a new generation carotid stent system that combines an open-cell high-radial-force stent frame conformability with MicroNet sealing properties.

METHODS AND RESULTS

HCCS are known to be associated with an increased risk of periprocedural complications and suboptimal angiographic outcomes in carotid artery stenting (CAS) using conventional stents.

HCCS was defined as calcific segment length to lesion length ratio exceeding 2/3 plus calcium severity grade of at least 3 on a novel 5-grade calcium scoring system (CSS) plus circularity of at least 3/4 of vascular circumference. The algorithm takes into consideration several quantitative, qualitative, semi-quantitative aspects of calcification severity such as calcium visibility on still frame/cine, calcium intensity and calcification pattern including calcium location (excentricity/circularity parameters). For calcification location and circularity, weighted kappa (95% CI) was 0.75 (0.57-0.92) for inter- and 0.79 (0.62-0.95 for intra-observer variability. For calcification severity, weighted kappa was 0.73 (0.58-0.88) for inter- and 0.83 (0.71-0.94) for intra-observer variability.

All-comer PARADIGM trial prospectively evaluated routine CGuard? use in CAS in symptomatic or increased-stroke risk asymptomatic patients. Consecutive, unselected patients were enrolled and CAS was routine except for allowing liberal post-dilations (larger balloon diameters and higher pressures) to optimize the angiographic outcome. CAS was performed in 106 lesions/101 patients (51-86 years, 55% symptomatic) whereas 8 others were treated surgically. 18/114 lesions were flagged HCCS, 16 (89%) were treated using the endovascular route whereas 2 (11%) were managed surgically due to either lack of appreciable channel or coexistence with severe aortic stenosis.

There was no difference in baseline diameter stenosis in HCCS vs. non-HCCS lesions [81.0 (66.0-97.4)% vs. 86.0 (61.3-99.0)%, p=0.556]. High-pressure HCCS CGuard CAS optimization was feasible and was free of extravasation. Despite higher postdilation pressures [(22 (18-24) in HCCS vs. 20 (10-24)atm in non-HCCS, p=0.005], residual DS (although below the conventionally accepted 30% DS threshold) was higher in HCCS [10.3 (0-46)% vs. 4.0 (0-20)%, p=0.005]. In one patient postdilatation optimisation was moved to a separate session due to severe bradycardia-asystole that required temporary pacing. By 30 days there were no adverse clinical events.

CONCLUSIONS

1. Novel algorithm to grade carotid stenosis calcification severity is reproducible and is applicable to clinical study data evaluation.
2. HCCS endovascular management using dual-layer CGuard? that combines a high radial force f the stent frame with sealing properties of the MicroNet was feasible and safe. Angiographic results were optimal in absence of perforation/extravasation and absence of stroke by 30 days.
3. Further work will expand the CCS algorithm to other vascular territories where calcification severity plays a fundamental role in procedure strategy, device choice and outcomes.

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Clinical impact of OCT-detected features of vulnerable plaque in intermediate grade coronary stenosis proven insignificant by FFR

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

AIMS

The aim of this study is to determine the relationship between the optical coherence tomography (OCT) detected features of vulnerable plaque morphology and the clinical outcomes at one year follow up among patients with angiography detected intermediate grade coronary lesions proven insignificant by fractional flow reserve (FFR) measurement. Some OCT findings, such as thin cap fibroatheroma (TCFA), have been reported to increase the rate of adverse events.

METHODS AND RESULTS

Patients were evaluated with OCT and FFR in this single-centre, single-arm study of consecutive patients with intermediate grade coronary stenoses by angiography. The features of vulnerable plaque, such as TCFA defined as minimal cap thickness below 65 μm, were traced. Stenoses were labelled hemodynamically relevant in case of the FFR < 0.80. All deaths were considered cardiac unless a non-cardiac cause was definitely confirmed. Myocardial infarction (MI) and stent thrombosis (ST) were reported according to the Academic Research Consortium definition. Target lesion revascularization (TLR) was defined as clinically-driven if at repeated angiography the diameter stenosis was > 70%, or if a diameter stenosis was > 50% together with clinical or electrocardiographic changes of myocardial ischaemia. MACE consisted of the composite of cardiac death, any re-infarction (Q- or non-Q-wave), emergent bypass surgery, or clinically driven TLR.

Of a total of 124 analyzed patients (124 lesions), 67 (54.0%) lesions were labeled as hemodynamically relevant by FFR. TCFA was reported in 12 (17.9%) patients with significant lesions and in 10 patients (17.5%) with insignificant lesions by FFR (p = 0.938). No differences were found between the groups in terms of the mean fibrous cap thickness (0.09 ± 0.04 mm vs. 0.15 ± 0.09 mm, p = 0.190), minimal fibrous cap thickness (0.09± 0.04 mm vs. 0.15 ± 0.09 mm, p = 0.197) and the necrotic core angle (148.4 ± 72.2? vs. 94.4 ± 41.6?, p = 0.010) as well as the cap thickness over the calcium (0.09 ± 0.06 mm vs. 0.14 ± 0.11 mm, p = 0.168). Clinical outcomes at one year will be reported at the EuroPCR 2018 Congress.

CONCLUSIONS

No significant differences in lesion morphology were observed between patients with haemodynamically relevant and non-relevant coronary stenosis by FFR. The one-year clinical outcomes categorized according to the presence of the OCT-determined vulnerable plaque morphology will be presented at the EuroPCR 2018 Congress.

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Accumulating two-year clinical and duplex ultrasound evidence from the CGuard PARADIGM-Extend prospective academic trial: durability of stroke prevention

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

AIMS

We aim to provide long-term clinical (including neurologic) and duplex ultrasound (DUS) evaluation of the CGuard embolic prevention stent system (EPS) routine use to perform CAS in all-comer (no exclusion criteria) patients with symptomatic or increased-stroke-risk asymptomatic carotid stenosis recommended for revascularization by the NeuroVascular Team (neurologist + angiologist + vascular surgeon + cardiologist) in a large cohort of consecutive CAS patients.

METHODS AND RESULTS

Routine diffusion-weighted cerebral imaging data indicated that CGuard? MicroNET-Covered EPS effectively minimizes cerebral embolization in carotid artery stenting (CAS) peri-procedurally and during device healing but long-term safety and efficacy has not been determined. PARADIGM-Extend is a non-industry-funded, prospective academic study in all-referrals-tracked symptomatic and asymptomatic carotid stenosis. In asymptomatic lesions, intervention is mandated only in case of increased-stroke-risk features. In all consecutive procedures there is first-line consideration to use the study device, with EPD choice according to tailored-CAS algorithm. Independent neurologist evaluation and DUS are performed before CAS, at 48h, 30 days, and then every 12 months. There is external source data verification, external angiographic corelab, and external statistical analysis.

Currently 251 patients (51-87 years, 57.1% symptomatic) with 263 arteries recommended for revascularization by the NeuroVascular Team (273 study procedures) crossed the trial first follow-up window. There has been 100% CGuardEPS use. Angiographic diameter stenosis was reduced from 83±9% to only 6.7±5% (

CONCLUSIONS

PARADIGM-Extend accumulating 24-month clinical and DUS evidence is consistent with unprecedented, sustained safety and cerebral embolism prevention efficacy of the CGuard? MicroNET-covered embolic prevention stent system used routinely for stroke prevention in symptomatic and increased-stroke-risk asymptomatic subjects with carotid stenosis.

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Total wrist access for carotid artery stenting

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

AIMS

Carotid artery stenting (CAS) is an alternative to carotid endarterectomy (CEA). CAS from the radial approach is gaining experience in high volume transradial centers. The purpose of this study was to evaluate the safety and efficacy of CAS using wirst (radial and ulnar) approach in all patients.

METHODS AND RESULTS

We did a prospective analysis including all consecutive patients who had undergone CAS in a single high volume transradial center. We analyzed procedural characteristics, carotid anatomy, procedural results and complications after procedure and at 30 days follow up.

From 2007-2017 CAS was performed in 986 patients (mean age 67, 72% male). Total wrist access was achieved in 961 (97%) and only 24 patients were swiched to TBA (transbrachial access, n=12) and TFA (transfemoral access, n=12). Right radial access was performed in 825 (83%) patients, transulnar (TUA) access in 124 (12,5%) and LRA (left radial access) in 12 (1,2%) patients.
464 (47%) patients were defined as high risk patients (?2 high-risk criteria according to SAPPHIRE classification). Procedural sussess was achieved in all patients.
CAS was performed in 507 (51%) right internal carotid artery (CA) and 479 (48%) left CA, with bovine left CA in 5.4%. Seven different carotid artery stents (34% Wallstent, 34% Xact, 5,5% Roadsaver) were used. Proximal protection device was used in 40 (4%) cases and distal protection device was used in the others. Total procedural time was 26 (10-120) minutes with filter time of 5 ± 2,5 minutes. Fluoroscopy time was 8 minutes (5 - 35 minutes) and contrast volume was 150 ml (150-350ml).
Adverse events included, 3 major strokes (0.3%), two deaths 0.2%, 6 minor strokes (0.6%), and 7 intraprocedural TIA?s (0,7%). There were no major bleeding complications. Minor bleeding access site complications were present in 45 (4,5%) of patients. Hospital stay was 1 ± 1 day in 97% of patients after the procedure. At 30 days follow up there were no additionally registered ischemic events.

CONCLUSIONS

Total wrist access (radial and ulnar) for CAS is safe and feasible with low rate of adverse events when done by experienced transradial CAS operators.

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Time of implantation of percutaneous mechanical support systems in infarct-related cardiogenic shock: does it influence short term survival?

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

AIMS

Aims: Use of percutaneous implantable left ventricular assist devices in patients with acute myocardial infarction complicated by cardiogenic shock (AMICS) is evolving. The current study presents real-world data of patients with AMICS undergoing hemodynamic support with the Impella CP® assist device. Purposes were to analyze the clinical outcome as a function of time of device implantation and to identify predictors of mortality.

METHODS AND RESULTS

Methods and Results: We performed a retrospective analysis of patients with cardiogenic shock (CS) supported by an Impella CP® assist device at our institution between January 2014 and December 2016.
100 consecutive patients with refractory CS were supported with an Impella CP® assist device. Of those, 73 were supported for AMICS and underwent percutaneous coronary intervention (PCI). Mean age was 68.9 ± 12.4 years. ST-elevation myocardial infarction (STEMI) was assessed in 48 patients (65.7%). The majority of the analysed patients (58.9%) sustained cardiac arrest before device implantation. Compared to these patients with support initiation after PCI (post-PCI group), patients who received early support before PCI (pre-PCI group) presented a higher survival rate at hospital discharge as well as 30 days after device implantation, respectively (50.0% vs. 23.1%, 48.5% vs. 23.1%, $p < 0.05$). Furthermore, Impella CP® implantation before PCI was identified as an independent predictor of survival in a multivariate regression analysis.

CONCLUSIONS

Conclusions: Early initiation of Impella CP® support prior to PCI is associated with significant survival benefit at discharge and up to 30 days in patients with AMICS.

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One-year clinical follow-up in patients treated with the bioabsorbable polymer-coated everolimus-eluting SYNERGY stent: insights from the SWEET registry (SWiss Evaluation of bioabsorbable polymer-coated Everolimus-eluting coronary sTents)

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

AIMS

We sought to assess 1-year clinical outcomes of all-comer patients treated with the thin strut bioabsorbable-polymer everolimus-eluting SYNERGY stent.

METHODS AND RESULTS

Consecutive patients treated with the SYNERGY stent for coronary artery disease at University and Hospital Fribourg, La Tour Hospital Geneva and the University Hospital Bern were enrolled in the SWEET registry (SWiss Evaluation of bioabsorbable polymer-coated Everolimus-eluting coronary Stent) starting in December 2012. Baseline and procedural characteristics were collected at baseline. Clinical follow-up at 1 year was performed by clinic visit or follow-up call. The primary end point was the ARC-defined device-oriented composite of cardiac death, target-vessel myocardial infarction and clinically indicated target lesion revascularization at 1 year.

This intermediate analysis includes a total of 1840 patients that had completed 1-year follow-up. Mean age was 68±12 years and 58% (n=1072) of patients were men. A history of previous myocardial infarction was found in 17% (n=304) of patients. Twenty-three percent (n=423) of patients were diabetic. Complex lesions were treated in 51% (n=940) of patients.

Follow-up information with regard to the primary end point was complete in 1601 patients. The primary end point occurred in 7% (n=111) of patients at 1 year. The rate of cardiac death was 3% (n=50). Target-vessel myocardial infarction occurred in 2% (n=28) of patients. Four percent (n=59) of patients underwent clinically indicated target lesion revascularization. Definite stent thrombosis occurred in 1.5% (n=25). Probable stent thrombosis occurred in 1.1% (n=15).

CONCLUSIONS

Device-oriented clinical outcome in real world patients treated with thin-strut bioabsorbable polymer everolimus-eluting stents is good.

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Antegrade fenestration and re-entry: a new controlled subintimal technique for CTO recanalisation

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

The widespread adoption of antegrade dissection/re-entry (ADR) for chronic total occlusion (CTO) percutaneous coronary intervention (PCI) is limited by several technical, logistic, and financial factors. Therefore, novel ADR techniques are needed. We aimed to describe and evaluate the efficacy of a novel ADR technique, called antegrade fenestration and reentry (AFR).

METHODS AND RESULTS

AFR consists in creating multiple fenestrations of the dissection flap separating the false and true lumen. This is achieved by advancing a balloon (sized 1:1 with the artery diameter) onto the antegrade wire into the subintimal space, and inflating it at the level of the distal cap. A soft polymer-jacketed guidewire is then advanced across the fenestrations created by balloon inflation from the subintimal space into the true lumen. Following its theoretical formulation, patients undergoing ADR-based CTO recanalisation at our institution were considered for AFR treatment. Between November 2015 and October 2017, 279 CTO PCIs were performed. Of those, ADR was utilized in 33 (12%) cases, of whom AFR was used in 6 (18%). In all but one cases, AFR was performed after failed true-totrue lumen crossing, while in the remainder it was utilized after extensive subintimal space disruption following alternative ADR techniques. AFR was successful in all 6 cases and no complications were observed.

CONCLUSIONS

We have developed a novel ADR technique which aims at complementing the CTO operator?s armamentarium. AFR does not preclude alternative bailout techniques, and is inexpensive and easy to perform. A dedicated study should confirm our findings in a large cohort.

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Predicting futility of emergency coronary angiography in out-of-hospital cardiac arrest patients

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

AIMS

Out-of-hospital cardiac arrest (OOHCA) is the leading mode of death in Europe and the USA. Emergency coronary angiography has a definite role in patients OOHCA patients with ST elevation, but outside of this group its role is unclear. The principal aim of this study was to create and validate a prediction model for 30 day mortality in OOHCA patients being considered for emergency coronary angiography. The principal aim of this study was to create and validate a simple prediction model for 30 day mortality in OOHCA patients being considered for emergency coronary angiography.

METHODS AND RESULTS

Methods

This study used recursive partitioning to generate a prediction model for 30 day mortality in the form of a classification tree. The predictive model was derived from a cohort of OOHCA patients who had emergency coronary angiography between October 2012 and May 2015. The predictive model was validated using a separate cohort of OOHCA patients who had emergency coronary angiography between January 2016 and July 2016.

Results

The predictive model identified 2 groups with extremely high mortality. Patients with pH of < 7.085 without both a ventricular arrhythmia and an ischaemic ECG had a 30 day mortality of 100%. Coronary angiography was therefore considered ?futile? in this group. Patients with a pH between 7.085 and 7.245 who were older than 69.5 years and who had a down-time of >24.5 minutes had a 30 day mortality of 94%. Coronary angiography was considered as ?approaching futility? in this group. When the classification of ?futile? and ?approaching futility? was applied to the validation cohort the specificities for death at 30 days were 100% and 97.4% respectively

CONCLUSIONS

This study offers a simple, accurate and validated model for identifying OOHCA patients being considered for emergency coronary angiography in whom the procedure is futile or approaching futility.

The predictive model presented here incorporates 6 variables , all of which have been shown to have independent associations with poor outcomes in previous studies using alternate statistical methodologies. The predictive model required a minimum of 2, and maximum of 3 variables to identify patients in whom emergency coronary angiography was ?futile? (pH, heart rhythm at the time of arrest, post ROSC ECG). The model could also identify patients in whom angiography was ?approaching futility? based on 3 variables (pH, age and downtime).

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Gender difference with the use of percutaneous left ventricular assist device in patients undergoing complex high-risk PCI: the cVAD registry

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THEME: Coronary Interventions

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

AIMS

The impact of gender on patient outcome who are undergoing high risk percutaneous coronary intervention (HRPCI) with percutaneous hemodynamic support is not well known. We sought to study the outcome of HRPCI in men compared with women.

METHODS AND RESULTS

We studied the sex differences in the cVAD Registry, the largest data set of patients undergoing HRPCI with hemodynamic support using Impella percutaneous assist devices. Patients without cardiogenic shock who underwent elective or urgent intervention were included. We excluded al patients who presented with shock..

A total of 1,053 patients were included in this analysis, 24.8% of which were women. Women were older (72 ±12 vs. 69±11,

CONCLUSIONS

This study demonstrates no gender difference in clinical outcomes when using percutaneous left ventricular assist device support for the treatment of complex HRPCI patients. Although presenting with higher comorbidities for HRPCI, women have similar favorable outcomes as men. This suggest that women continue to have barrier to highly specialized medical care.

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Prosthesis selection in the borderline range of aortic annulus size for self-expandable TAVI influences the rate of permanent pacemaker without affecting other clinical endpoints

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

AIMS

To investigate the impact of size selection of self-expanding transcatheter aortic valves on the clinical outcome in patients with a borderline range of the annulus.

METHODS AND RESULTS

From a total of 262 patients undergoing TAVI in our institution between August 2016 to July 2017, 161 patients underwent self-expanding TAVI for native severe tricuspid aortic stenosis and were retrospectively analyzed by an experienced CT corelab , 31 had a borderline annulus perimeter by pre-procedure CT images (the borderline range was defined as cut-off annulus perimeter value between two sizes of manufacturer?s sizing table ± 1 mm). Cases were correspondingly divided into larger prosthesis selection and smaller prosthesis selection groups respectively. The baseline data and the clinical end points were compared. There were 15 cases in the larger selection group and 16 cases in the smaller selection group. There were no significant differences between the two groups in the degree of valve and LVOT calcification, maximum velocity, mean gradient and LVEF at baseline. All the 31 patients were implanted with Evolut R or Evolut Pro prosthesis. The degree of oversizing at the annulus level was almost double in the larger selection group (21.2±2.4% vs12.5±1.2%,P

CONCLUSIONS

The selection of a larger prosthesis in a patient with annulus perimeter in the borderline range of self-expandable transcatheter aortic valve replacement was associated with an increased rate of new permanent pacemaker without affecting any other clinical end-points, including paravalvular leak.

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Mechanical circulatory support for acute right ventricular failure in the setting of pulmonary embolism

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

AIMS

?Right ventricular (RV) failure due to pulmonary embolism (PE) increases morbidity and mortality and contributes to prolonged hospital length of stay and higher costs of care. RV mechanical circulatory support (MCS) including Impella RP devices have been increasingly used in hemodynamically compromised PE patients who are refractory to intravascular volume expansion and inotropic therapy. However, effectiveness and safety of Impella RP, in hemodynamically unstable PE patients is unknown.

METHODS AND RESULTS

We included consecutive patients who presented to Detroit Medical Center between November 3, 2015 and October 2, 2017 with acute PE and had evidence of hemodynamic compromise indicating Impella RP. Total of 5 cases were identified. All patients met the shock definition due to massive or submassive PE and therefore received Impella RP on admission. Cardiac index was improved from mean of 1.69/min/m2, (0.88-2.15 l/min/m2), to 2.5 l/min/m2 (range 1.88-3.4), after 24 hours of treatment. Similarly, mean heart rate reduced to 92 beats per minute (79-105), and mean systolic blood pressure increased to 140 mmHg (115-179). No significant changes were found in renal function, hemoglobin and platelets level during device use. One patient experienced hemoglobin drop from 13.7 to 7.3 g/dl but didn?t require blood transfusion. All patients survived to discharge.

CONCLUSIONS

In patients with PE and RV shock, Impella RP device resulted in immediate hemodynamic benefit with reversal of shock and favorable survival to discharge. These findings support its probable benefit in this gravely ill patient population.

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Early specialist assessment in the emergency department: is there a role for the cardiology advanced nurse practitioner?

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

AIMS

In December 2014 the Care Quality Commission identified a number of issues with patients presenting to a United Kingdom inner city Emergency Department (ED): long waits in the ED, slow patient flow through the hospital and patients not always cared for on the most appropriate ward for their condition. Amongst other strategies, the Cardiology Advanced Nurse Practitioner (ANP) role was launched. The role focused on facilitating early specialist assessment of patients presenting with acute cardiological conditions in the ED, improving patient flow and facilitate direct admission to cardiology.

METHODS AND RESULTS

Methods:
Between March and September 2016 a Cardiology ANP assessed patients presenting to the ED with suspected Acute Coronary Syndromes (ACS), Dysrhythmias (Atrial Fibrillations, Atrial Flutter and Channelopathies) and symptoms suggestive of Heart Failure (HF). The post was piloted for two days a week (Monday and Friday) and a direct comparison with data from the previous year was completed.

Baseline Audit:
Baseline data demonstrated an overall admission rate of approximately 36%. On average 5.4% per week of patients presenting with cardiological conditions were directly admitted to a cardiology ward. On a Monday, 9% of patients were directly admitted to a cardiology ward, direct admissions rate dropped to 4.6% on a Friday.

Results:
After the implementation of the Cardiology ANP role a six month retrospective audit was completed. A total of 223 patients were assessed by the Cardiology ANP (two days a week). Of these, 64 (29%) were admitted to hospital. Of those admitted to hospital, 43 (67%) were admitted directly to a cardiology ward with one of the following conditions: ACS, Dysrhythmias, HF. The remaining 21 (33%) patients were admitted to a medical ward with Pneumonia, Chronic Airways Disease or Pulmonary Embolism. During the initial six months the average weekly admission rate directly to cardiology from ED rose from 5.4% (baseline data) to 10% per week (11.5% on Monday and Friday). Of the 223 patients assessed, 159 (71%) were discharged on the same day avoiding medical admission. Of these, 126 (79%) were discharged with a cardiological diagnosis following clinical assessment, face to face or telephone advice. The remaining 33 (21%) were discharged with a non-cardiological diagnosis. Total number of cardiological admissions avoided over six months was 126. The prospective bed days saving was 630 bed days per annum, based on an average bed day cost of £350, the cost saving can be estimated at £220,500 per annum.

CONCLUSIONS

Conclusions:

The implementation of the cardiology ANP in ED is effective at providing early specialist assessment, streamline direct admission to specialist care, decrease hospital admissions and facilitate early discharge. This improves the patient journey, facilitates early revascularisation for patients admitted with ACS (ESC 2016), thus improving patients? safety and outcome.

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Long-term outcome in patients treated with first-generation vs. second-generation DES for the treatment of unprotected left main coronary artery stenosis

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

AIMS

Treatment of unprotected left main coronary artery (ULMCA) stenosis by percutaneous coronary intervention (PCI) is now recognized as an alternative to coronary artery bypass grafting (CABG). Most trials however only studied 1st-gen drug-eluting stents (DES) and therefore long-term clinical outcome after PCI for ULMCA stenosis with 2nd-gen DES is largely unknown.The aim of this study was to assess the 5-year clinical outcome of 1st- vs 2nd-gen DES for the treatment of ULMCA stenosis.

METHODS AND RESULTS

From May 2002 to December 2014, a consecutive series of 656 all-comer patients underwent a PCI for ULMCA stenosis at our institution. A total of 235 patients were treated with 1st-gen DES, while a total of 421 patients were treated with 2nd-gen DES. Overall, the population consisted of 73% males and 58% presented with an acute coronary syndrome. Mean age was lower in the 1st-gen DES cohort as compared to the 2nd-gen DES cohort (66.5±11.7 vs. 68.4±11.5, p=0.04 respectively) and prior myocardial infarction and coronary artery bypass grafting (CABG) were more frequent in the 1st-gen DES cohort (40% vs. 21% p= 0.005 and 12% vs. 8% p=0.045 respectively). The use of intravascular imaging was less often performed in the 1st-gen DES cohort as compared to the 2nd-gen DES cohort (36% vs. 46% p=0.014 respectively).

Median follow-up time was 1361 days (range from 0 to 5031). At 5 years, the cumulative incidence of major adverse clinical events (the primary composite endpoint of all-cause death, any myocardial infarction or target vessel revascularization, MACE) did not differ between 1st- and 2nd-gen DES (45.1% vs 45.8% respectively, Log Rank p=0.67, adjusted hazard ratio (HR)= 1.05 [95% confidence interval (CI) 0.80 to 1.39]). No difference was observed in all-cause mortality between the 1st-gen DES and 2nd-gen DES cohorts (29.5% vs 29% respectively, p=0.88, adjusted HR=1.09 [95% CI, 0.77 to 1.54]), as were rates of myocardial infarction (MI) (8.5% vs 9,9% respectively , p=0.83, adjusted HR=0.99 [95% CI, 0.50 to 1.93]), target vessel revascularization (TVR) (17.5% vs 21.9% respectively, p=0.87, adjusted HR=1.17 [95% CI, 0.75 to 1.83]) and target lesion revascularization (TLR) (8.1% vs 9.8% respectively, p=0.94, adjusted HR=1.13 [95% CI, 0.58 to 2.21]).

CONCLUSIONS

In this large cohort of consecutive patients treated for ULMCA stenosis, no significant differences were found in the safety and efficacy of 1st vs. 2nd-gen DES at 5 years follow-up. Long-term adverse event rates following ULMCA stenting remain high.

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Clinical outcomes comparing the Tryton dedicated bifurcation stent system to provisional stenting for the treatment of true bifurcation coronary artery disease

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

AIMS

Bifurcation lesions are associated with lower procedural success and a higher risk of adverse cardiac events. Provisional stenting (PS) is currently the default approach for the treatment of bifurcation lesions. The Tryton stent is a dedicated bifurcation stent system for the treatment of true bifurcation lesions. We aimed to evaluate the safety and efficacy of the Tryton device for the treatment of true bifurcations involving large side branches (SB).

METHODS AND RESULTS

We performed an individual-patient-data pooled analysis of the Tryton randomized controlled trial and post-approval confirmatory study. Only patients with true bifurcations (>50% stenosis in both the main branch (MB) and side branch and either Medina 1,1,1, 1,0,1, or 0,1,1) involving a SB ?2.25 mm in diameter by QCA were included. The primary endpoint was non-inferiority of Tryton compared to PS for target lesion failure (TVF, cardiac death, target vessel myocardial infarction [SCAI definition of periprocedural MI], and target vessel revascularization) at 1 year. Secondary endpoints included 9 month angiographic outcomes. Of the 868 patients enrolled at 58 centers, 398 patients met the criteria for true bifurcation disease with SB ?2.25 mm. Of these, 275 patients were treated with the Tryton stent and 123 patients treated with PS. TVF at one year was 8.4% in the Tryton group and 9.8% in PS group, meeting the pre-specified criteria of non-inferiority (Pnon-inferiority=0.023). Major adverse cardiovascular events were also not different between the groups (Tryton stent 10.9% vs PS 9.7%, P=0.70). At 9 months angiographic follow up, SB diameter stenosis was significantly lower in the Tryton group (41±18 vs. 29±22, p=0.0008) consistent with lower incidence of binary restenosis (DS? 50%) (19% vs. 34%, p=0.05).

CONCLUSIONS

In the intended population for treatment with the Tryton device (true bifurcation, SB >2.5mm), treatment with the Tryton dedicated bifurcation stent system was non-inferior to PS for TVF and showed favorable 9-month angiographic outcomes

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Clinical outcomes after primary PCI using contemporary DES: evidence from a network meta-analysis comprising 12,639 patients

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

AIMS

To assess the safety and efficacy of contemporary drug-eluting stents (DES) in patients presenting with acute myocardial infarction (STEMI) undergoing primary PCI.

METHODS AND RESULTS

Randomized clinical trials comparing different types of metallic coronary stents in the setting of STEMI were selected. The primary outcome of interest was Major Adverse Cardiovascular Events (MACE, defined as a composite of all-cause death, reinfarction and target vessel or target lesion revascularization). Secondary outcomes of interests were the individual components of the primary outcome and definite or probable stent thrombosis. Patients with STEMI treated with everolimus-eluting stent (EES), zotarolimus-eluting stent (ZES), biolimus-eluting stent (BES), bare-metal stent (BMS), paclitaxel-eluting stent (PES) or sirolimus-eluting stent (SES) were included. Twenty-one studies, forty-five arms, and 12,639 patients were analysed. The mean age was 60.8 years (SD±1.65), 26.3% were female, and 16.7% were diabetics. Median follow-up was 24 months [Range 7 to 60 months]. For the network meta-analysis random effect models were used. BES and EES had comparable rate of MACE (OR 0.88, 95% CI 0.64 to 1.12, p value=0.44). However, compared to EES, ZES and BMS were associated with an increase in MACE (OR 1.51, 95% CI 1.04 to 2.19, p value=0.03 for ZES, and OR 1.66, 95% CI 1.35 to 2.05, p value

CONCLUSIONS

Everolimus-eluting stent and Biolimus-eluting stent had comparable clinical outcomes with respect to the MACE, all-cause death, reinfarction, TVR or TLR, and stent thrombosis in patients presenting with acute myocardial infarction. Patients treated with ZES had an increased MACE compared to EES and BES. The rate of stent thrombosis was similar between drug eluting stents, however, patients treated with BMS had an increased rate of stent thrombosis. In the STEMI setting, EES and BES appear to best safety and efficacy profile.

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Functional SYNTAX score in the assessment of patients with multivessel disease. A substudy of the SYNTAX II trial

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

To evaluate the repercussion of full evaluation with coronary physiology in patients with complex multivessel disease, included in the SYNTAX II trial. To assess the additional prognostic value of the functional SYNTAX score in the SYNTAX II population .

METHODS AND RESULTS

Of the 454 patients included in the SYNTAX II trial, 306 had all PCI targets assessed with physiology (excluding CTO?s and lesions with TIMI flow 23 identified patients with a significantly worse outcome at one year (MACE rate 25.6% vs. 11.2%, in FSS>23 and FSS?22 respectively, p=0.013), despite an equivalent degree of complete functional revascularisation. On the contrary, no difference in MACE at one year was noted when the SS was used to classify patients (13.0% vs. 14.7% in SS?22 and SS>23 respectively, p=0.258).

CONCLUSIONS

In this substudy of SYNTAX II, full evaluation with coronary physiology lead to a significant decrease in the anatomical PCI complexity, as shown by the significant reduction from SS to FSS. A FSS>23 was associated with a significantly higher MACE rate at 1-year follow up, which was not seen when the SS was used.

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Detection of vulnerable plaque with deep learning algorithm in IVUS imaging

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Near-infrared spectroscopy(NIRS) can detect coronary lipid-core plaque (LCP) leading to fatal future event. We are to reconstruct NIRS images from corresponding intravascular ultrasound (IVUS) images with deep learning method, which have shown high sensitivity and specificity for medical image diagnosis.

METHODS AND RESULTS

We used institutional image database of true vessel characterization (TVC, infraredx Inc, USA) and developed deep learning algorithms for segmenting lumen/adventitia and detecting LCP in coronary vessels. The TVC database of 199 arteries from 116 patients were used as training dataset and 17 arteries from 10 patients were used as validation dataset. First, we segmented lumen and adventitia of vessel as ROI of LCP by training U-net architecture integrated with residual block. After that, a specific type (VGG model) was used for classifying segmented vessel images as low(red) and high(yellow) probability LCP labeled by TVC images. The sensitivity and specificity of the algorithm for detecting high probability LCP were generated on Halogram and Chemogram. Training set consisted of 7,132 rectangles randomly chosen from 151,884 rectangles extracted from IVUS images. Test set was 176 rectangles, randomly chosen from 31,716 rectangles of 10 patients. Vessels? lumen and adventitia can be segmented with 0.95 and 0.9 IoU(Intersection over Union) respectively. For detecting LCP chemogram, IVUS frame images from validation dataset were classified with AUC 0.89 (95% CI, 0.88-0.90), with 85% sensitivity and 91% and specificity. For detecting LCP halogram, rectangular patches extracted from validation IVUS images are classified with AUC 0.88 (95% CI, 0.87-0.89) with 0.80 sensitivity and 0.92 specificity.

CONCLUSIONS

Deep learning method had high IoU for vessels? lumen and adventitia segmentation and high sensitivity and specificity for detecting LCP from IVUS images.

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Outcomes in patients with atrial fibrillation undergoing pressure wire-guided coronary revascularisation: results of the DEFINE-FLAIR trial

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Atrial Fibrillation (AF) is common in patients with coronary artery disease (CAD). The impact of AF on outcomes in whom coronary revascularisation is based on physiological guidance is unknown. It is also unclear if resting indices (iFR) are as safe as hyperaemic ones (FFR) in deciding revascularisation in patients with AF. We sought to determine whether AF in patients undergoing physiologically guided coronary revascularisation was associated with poorer prognosis compared with sinus rhythm (SR). We also sought to determine whether FFR and iFR could be used similar benefits to those in SR.

METHODS AND RESULTS

We reviewed the presenting ECG of 2,446 patients presenting for pressure wire assessment of an intermediate coronary lesion as part of the DEFINE-FLAIR trial. After excluding those with a paced rhythm, 2,311 (95.7%) patients were in sinus rhythm with 103 (4.3%) in either AF or atrial flutter. Patients with AF were older (74.8 vs 65.4,

CONCLUSIONS

In patients with CAD undergoing physiological interrogation the presence of atrial fibrillation is associated with a greater risk of all-cause and cardiovascular mortality in the mid-term, as compared to those in sinus rhythm. Mid-term clinical outcome of AF patients with stenoses interrogated with iFR and FFR was similar, supporting the use of both hyperaemic and resting indices.

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Is it possible to predict FFR in side branch after main vessel stenting in coronary bifurcation lesions by means of intracoronary electrocardiogram? A proof of concept FFR vs. intracoronary electrocardiogram in coronary bifurcations (FIESTA) study

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

The aim of this study is to explore and compare intracoronary electrocardiography (i.c.ECG) abilities to detect acute ischemia with FFR hemodynamic assessment during PCI of bifurcation lesions.

METHODS AND RESULTS

Methods: A total of 49 patients were selected based on occurrence of hemodynamically significant stenosis in main vessel. Provisional stenting was the default PCI procedure. We measured FFR and i.c. ECG values in main branch and side branch before and after stenting the main vessel, which guided our side branch treatment decision. Intracoronary ECG was recorded with uninsulated proximal wire ends connected to unipolar V leads. FFR was measured using Volcano PrimeWire/Prestige after i.c. adenosine bolus.
Results: Overall 24 (49%) patients had side branch FFR ? 0.80 after stenting the main vessel and 22 patients had ST-segment elevation on icECG. From the patients with FFR ? 0.80, only two did not have ST-segment elevation on icECG, but both patient had FFR > 0.75 (0.77 and 0.78). After performing a receiver operated curve analysis to define a cut-off value to SB FFR after stenting, we defined a new cut-off value of 0.77 for SB FFR after stenting with c-statistic of 0.921, sensitivity of 100%, and specificity of 77%.

There was a significant correlation between absolute measures of SB FFR after stenting and ST-segment elevation in millimeters on icECG ($r=-0.533$, $p < 0.001$). There was a significant difference of SB FFR values in groups with icECG STS elevation, without any overlap in variation ranges ($p < 0.001$). Neither STS elevation on icECG nor FFR in SB after stenting correlated significantly with ostial or minimal percentage diameter stenosis at SB, but there was significant correlation of both parameters with final SB ostial percentage diameter stenosis (SB icECG STSE: $r = -0.396$, $p = 0.025$, SB FFR: $r = 0.369$, $p = 0.038$). The only other parameter which correlated significantly with both FFR and icECG STSE was SB maximum ST-segment elevation during first balloon implantation or during stent implantation (SB icECG STSE: $r = 0.798$, $p < 0.001$, SB FFR: $r = -0.455$, $p = 0.020$).

CONCLUSIONS

Intracoronary ECG has excellent ability to predict hemodynamically significant stenosis (based on critical value of FRR) occurrence at SB ostium after MV stenting. This method provides a link between a direct measure of ischemia (icECG changes) and flow limiting capacity of stenosis (FFR).

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Long-term clinical outcomes of diabetic and nondiabetic patients after PCI for CTO lesions

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

We aimed to evaluate the long-term clinical outcomes of patients after percutaneous coronary intervention for chronic total occlusion lesions on the basis of the presence or absence of diabetes mellitus.

METHODS AND RESULTS

The study sample consisted of 527 consecutive patients with 593 chronic total occlusion lesions undergoing successful percutaneous coronary intervention with drug-eluting stents between January 2006 and December 2009. The 527 patients were classified into two groups on the basis of the presence or absence of diabetes mellitus: diabetic (n=204, 38.7%) and nondiabetic (n=323, 61.3%). Seven-year clinical outcomes were compared between the diabetic and nondiabetic groups. The median follow-up duration was 7.6 years. The 7-year cumulative rate of all-cause death was significantly higher in the diabetic group than in the nondiabetic group (20.3% vs. 13.9%, p = 0.039), whereas the 7-year cumulative rate of target vessel revascularisation was not significantly different between two groups (36.1% vs. 32.2%, p = 0.245).

CONCLUSIONS

In a 7-year follow-up of patients after percutaneous coronary intervention for chronic total occlusion lesions, diabetic patients had an increased risk of mortality in comparison with nondiabetic patients, but the cumulative rate of repeated revascuralisation was not significantly different between diabetic and nondiabetic patients.

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Speckle-tracking echocardiography detects improvements in regional left ventricular longitudinal deformation after CTO recanalisation

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

AIMS

LVEF improvement after successful PCI of CTO is controversial, specially in patients with baseline preserved LVEF in which global function is only marginally improved. However, echocardiographic speckle tracking allows for non-invasive, quantitative and regional longitudinal deformation evaluation. The purpose of this pilot study is to explore the ability of speckle tracking to detect regional function improvement in CTO-dependent segments.

METHODS AND RESULTS

Prospective study including 13 patients with baseline speckle tracking acquisition (3-layer Strain [S] and Strain Rate [SR]) and at least one successfully treated CTO. All patients had previously positive viability assessment and clinical indication for CTO recanalization. Follow up (FUP) echocardiograms were scheduled at 1, 3 and 12 months, although this abstract reports only 1 and 3 month results. Left ventricle was studied using a 16 segment model (total 208 segments studied), and for each patient segments were classified as CTO-dependent (n=62) or not (n=146). Comparison were made between baseline and FUP echocardiograms (?) and between dependent and non-dependent segments.

Mean age was 72±8 years, 85% male and mean baseline LV function 56.3±6%. CTO was located in LAD (5), LCX (2) and RCA (6). No changes in global LVEF, telediastolic diameter or E/E? were detected in 1 nor 3 months FUP (56±6% baseline vs. 59±6% 3 month FUP, p=0.20, telediastolic diameter 54.8±26 mm vs. 59.7±25 mm, p=0.6 and E/E 12.6±4.3 vs. 11.8±3.8). Deformation parameters from CTO dependent or non-dependent segments remained unchanged at 1 month FUP (p=ns). At 3 month FUP, strain of CTO dependent segments improved significantly at 3 months FUP: S-epicardial ? -2.6 ± 5.2,

CONCLUSIONS

This pilot study suggests that regional longitudinal strain improves in CTO-dependent segments after successful PCI, while global LVEF, E/E? and Strain Rate remain unchanged. Changes were not present after 1 month but became evident after 3 months. Further follow up will assess durability of these improvements and potential clinical implications.

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Real world prospective study assessing two ? year clinical outcomes after sirolimus coated balloon angioplasty in patients with coronary atherosclerosis

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

AIMS

Paclitaxel coated balloon is emerged as a novel modality to treat the coronary atherosclerosis. Sirolimus drug possesses potent antirestenotic properties and is less toxic than Paclitaxel. On DES platform, Sirolimus is proven drug to combat restenosis in coronary arteries. Hence, we sought to evaluate the performance of Magictouch Sirolimus coated balloon (SCB) (Concept Medical) incorporating a proprietary Nanolute technology in patients with de-novo and restenotic lesions in coronary arteries.

METHODS AND RESULTS

NANOLUTE was prospective, multicentre study enrolling real world patients from routine medical practice. There are total 447 patients with 475 de-novo/restenotic coronary lesions enrolled from July 2012 to December 2017 in this study. The study endpoints encompassed major adverse cardiac events (MACE) at 1 year of clinical follow-up and procedural success. MACE was defined as target lesion revascularization (TLR), target vessel myocardial infarction (TV-MI) and cardiac death. Procedural success is defined as technical and angiographic success in the absence of a MACE at hospital discharge. We also assessed MACE at extended clinical follow up of 2 years. Clinical follow-ups of this study are on-going.

Among 447 patients treated 45.19% had diabetes mellitus (DM). The study population was dominated by male patients (82.33%). The mean age of the patients in the study was 59.94 ± 10.50 years. Almost half of the patients were acutely presented (48.32%). Among 475 lesions treated, 46.96% were ISR while 53.05% were de-novo lesions. Of these 53.05% de-novo lesions, 42.95 % lesions were located in small coronary arteries (RVD ? 2.75 mm). Majority of lesions were successfully treated with SCB yielding the procedural success of 99.55% while vessel dissections occurred in only 2 patients. No acute segment thrombosis was observed. 1 year clinical follow up was available in 401(89.71%) patients and the MACE occurred in 4.24 % patients. MACE components were recorded as TLR (3.75%), TV-MI (0.25%) and cardiac death (0.25%). Long term follow up (2 years) was obtained in 339(75.84%) patients. 15 TLR, 1 TV-MI and 1 cardiac death were registered yielding the cumulative MACE of 5.01% at 2 years. MACE rates in complex cohorts were reported as Diabetics (N=202): 4.44%, de-novo small vessel (196): 3.33%, ISR (208): 6.07% and acute coronary syndrome (216): 5.36%.

CONCLUSIONS

In the present study demonstrated that SCB is valid revascularization strategy in all comers real world population of patients with coronary atherosclerotic disease with an acceptable rate of cardiac events up to 2 years follow up. The outcomes in complex cohorts were equally encouraging in NANOLUTE study.

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Clinical efficacy and safety of sirolimus-coated balloon in a real-world single-centre registry of Indian population

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

AIMS

During its 40-year journey, percutaneous coronary intervention (PCI) has witnessed enormous progress in procedural results and patient outcomes. Paclitaxel coated balloons have emerged as new treatment modality to treat coronary atherosclerosis. We sought to evaluate the safety and efficacy of Magictouch Sirolimus coated balloon (SCB) (Concept Medical) in patients with lesions located in native coronary vessels.

METHODS AND RESULTS

The present study is single centre, prospective study enrolling real world patients from routine clinical practice. From June 2013 to November 2017, 131 patients (83.20% male, 59.83±10.14 years) with a total of 139 lesions treated with 158 Magictouch SCB. The study endpoint comprised of major adverse cardiac event (MACE) at 12 months and procedural success. MACE is delineated as target lesion revascularization (TLR), target vessel myocardial infarction (TV-MI) and cardiac death. Procedural success is defined as technical and angiographic success in the absence of a MACE at hospital discharge. We also evaluated the performance of SCB in extended follow-up of 24 months.

Diabetes mellitus was present in 41 patients (31.30%) and 33.59% patients had history of prior stenting. Hypertension accounted for 40.46% of the patients while 18.32% patients had history of prior myocardial infarction. Acute coronary syndrome was present in almost half of the population (50.38%). Among 139 lesions treated, 23.02% lesions were in-stent restenotic lesions whereas majority of the lesions were de-novo type (76.98%). Among 107 de novo lesions, 85 lesions were located in small coronary vessels (reference vessel diameter ? 2.75 mm). Average of 1.20 SCB were used per patient. SCB alone therapy was the pre-dominant approach (92.37% of the patients) during PCI whereas SCB followed by additional stenting was performed for the remaining 7.63% patients. Procedural success was attained in 100% of the patients with no vessel dissection reported. 12 months follow up was available for 114(87.02%) of total patients and the incidence of MACE was reported among them was 4.39%. The MACE rate was only driven by TLR (4.39%) with no TV-MI and cardiac death reported at 12 months. 90 (68.7%) patients completed 24 months follow up with no increment in MACE. The present study is on-going so the follow up for the rest of the patients is yet to come.

CONCLUSIONS

The present study demonstrated that Magictouch Sirolimus coated balloon is a valid revascularization strategy in an all -comers real world population of patients with coronary ISR and de-novo lesions, with encouraging rate of clinical outcomes up to 24 months. The study also demonstrated excellent procedural success for the Magictouch SCB.

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A novel sirolimus-eluting stent with unique coating technology for the treatment of complex patients: two-year outcome from en-ABL e-registry

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

AIMS

Daily use of drug-eluting stent (DES) and real world settings data is still not extensive. It is thus of interest to determine the safety and long term performance of ABLUMINUS DES+ which has unique fusion coating technology (Sirolimus coating on stent as well as exposed parts of balloon), for the treatment of complex, high risk patient populations.

METHODS AND RESULTS

The en-ABL e-registry was a prospective, real-world, all-comers, multicenter registry with 31 centers which enrolled 2430 consecutive patients with 2888 lesion treated with 3191 ABLUMINUS DES+. The primary endpoint was major adverse cardiac events at 1 year [MACE: cardiac death, target vessel myocardial infarction (TV-MI), and target lesion/vessel revascularization (TLR/TVR)]. Secondary end-point was the Stent Thrombosis (ST) at 1-year. Clinical follow-ups of this study are ongoing.

The age of patients was 56.98 ± 12.73 years. Baseline clinical characteristics in this real-world complex population were acute coronary syndrome (64.28%), STEMI (42.30%), diabetes mellitus (33.70%.) and prior MI (12.10%). Furthermore, 16.79% of patients had multi vessels treated and average stents per patient was 1.31. They had significantly higher complexity of lesions (47.06% small vessel lesion & 54.81% long lesions). Mean stent diameter and stent length were 2.95 ± 0.44 mm and 26.72 ± 8.79 mm respectively.

1-year and 2-years Clinical follow-up available in 2078 (85.51%) and 1592 (65.51%) patients respectively. 1-year MACE was 2.60% (54 patients) represented by Cardiac death (0.67%), TV-MI (0.43%) and TLR/TVR (1.49%). 0.67% stent thrombosis was detected in overall population which includes 0.50% definite and 0.19% probable stent thrombosis. TLR reported additionally in one patient and there was no late stent thrombosis reported at two-year. The low MACE rate was confirmed for the pre-specified subgroups at the 1-year follow-up: Diabetes (834): 3.32%, acute myocardial infarction (N= 956): 2.77%, small vessels (N= 1217): 3.67% and long lesions (N= 1431): 3.36%.

CONCLUSIONS

The two-year data confirmed the safety and efficacy profile of the ABLUMINUS DES+ in a real-world complex patients. The low MACE rate, particularly in high risk subgroups, is a proof of concept for the technology behind ABLUMINUS DES+.

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Local, regional, and systemic factors in BRS thrombosis in small vessels: understanding the sub-2.5mm barrier

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

AIMS

Device thrombosis dominants bioresorbable vascular scaffolds (BRS) safety concerns, particularly in sub-2.5mm vessels. To better understand the mechanistic basis of this size threshold, we evaluated scaffold thrombogenicity (ST) in clinical- (thick, 157μm) and production-grade (thin, 99-119μm) BVS in computational and bench-top thrombosis models where vessel diameter and study conditions could be tuned precisely.

METHODS AND RESULTS

Thick and thin BRS designs (ABSORB and FALCON, respectively, Abbott Vascular) were considered across a range of small (2.125 - 2.5mm) and nominal (3.0, 3.5mm) dimensions. Bench experiments were performed using a standard flow loop model incorporating customized polyurethane segments of specified diameters. Since flow passing through segments of different diameters depends on local stenosis as well as downstream microvascular regulation, models were extended by imposing specific flow or pressure boundary conditions (BC) to allow differentiation of fractional and coronary flow reserve effects.

Following implantation of thick or thin devices, fresh porcine whole blood was perfused under prescribed pressure or flow BCs. In addition controlled scaffold design, vessel diameter, and BC, blood was considered in the absence of antithrombotic drug, or in the presence of DAPT (Aspirin, 50μM / Cangrelor 0.5μM) or anticoagulant (40nM, Rivaroxaban). Clotting responses were assessed visually and quantified using biochemical assays (hemoglobin, lactase dehydrogenase, LDH).

Clotting correlated inversely with vessel diameter, increasing sharply as diameter fell below 2.5mm, improving partly with thinner scaffolds. In absence of drug, thick-strut scaffolds favored red-cell rich clot, while thin favored platelet-rich clot (p=0.009). In presence of DAPT, the platelet enrichment observed with thin devices was blunted, with significantly fewer 2.5mm thin devices occluding fully compared with thick-strutted scaffolds (12.5% vs 75%, p=0.007). However as vessel diameter dropped to 2.25mm, occlusive ST rate increased sharply despite DAPT or scaffold design. Rivaroxiban had a greater effect in reducing small vessel occlusive thrombus with the strongest reduction in the thick-strut devices under pressure BCs ? conditions where microvascular auto-regulation was modeled as inadequate and where red cell rich clot was found to be highest.

Experimental findings aligned with theoretical considerations derived from 3D flow simulations (Star-CCM+, CD-Adapco). While thick struts were uniformly flow-shielding, inter-strut shear rates rose markedly for thin devices as vascular diameter diminished. In contrast, peak-strut associated shear was less dependent on

device design and driven by BC effects, approaching free-stream platelet activation levels of 10,000s-1 in small vessels irrespective of device.

CONCLUSIONS

Scaffold thrombosis becomes increasingly complex as vessel diameter drops below 2.5mm, and can be overcome in part by scaffold design. In small vessel cases, BC effects and blood state interact heavily with scaffold design to modify extent and type of local clot. In addition to optimizing scaffold design, knowledge of regional microvascular status and co-optimization of design with systemic drug regimens may help widen the therapeutic window of bioresorbable devices and more safely extend their use in small vessel disease.

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Clinical valve thrombosis after transcatheter aortic valve-in-valve implantation

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

AIMS

Limited data exist on clinical valve thrombosis (CVT) after transcatheter aortic valve-in-valve (ViV) implantation. Our objective was to determine the incidence, timing, clinical characteristics, and treatment outcomes of patients diagnosed with clinical ViV thrombosis.

METHODS AND RESULTS

Centers participating in the Valve-in-Valve International Data (VIVID) Registry were surveyed for thrombosis cases, and CVT was defined based on a combination of the presence of new valve dysfunction and an imaging evidence of leaflet thrombosis.

Three hundred ViV implantations were included. The surgical valve was stented in 86.3% and stentless in 13.7% of cases, and the transcatheter heart valve was self-expanding in 50%, balloon-expandable in 49% and mechanically-expanding in 1.0%. The incidence of CVT was 7.6% (n=23), diagnosed at a median time of 101 days (IQR, 21-226) after the procedure. Fifteen patients (65%) presented with worsening symptoms and 21 (91%) with transvalvular mean gradient elevation. The mean gradient at the time of diagnosis (35.9±14.3 mmHg) was significantly higher than immediately post-ViV (14.1±7.5 mmHg, $p<0.001$) and was significantly reduced after oral anticoagulation (OAC) therapy (16.5±6.3 mmHg, $p<0.001$). There were no deaths or strokes related to valve thrombosis. Valve thrombosis was less common in patients discharged after ViV on OAC (1.0% vs. 11.3% without OAC, $p=0.002$) and more common in patients with either Mosaic or Hancock II stented porcine bioprostheses (12.9% Mosaic/Hancock II vs. 5.2% all other valves, $p=0.02$).

CONCLUSIONS

Clinical valve thrombosis after transcatheter aortic ViV implantation is common, especially in patients not on OAC. Although aortic ViV is commonly associated with elevated gradients, valve thrombosis should be ruled out if gradients increase compared to early post-procedural values. A higher incidence was observed after treatment of certain stented porcine surgical valve types, suggesting a specific adjustment of the adjunctive antithrombotic therapy in this subset of ViV patients.

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Clinical outcomes among patients requiring acute mechanical circulatory support for cardiogenic shock supported by Impella or veno-arterial ECMO

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

AIMS

Clinical trials for acute mechanical circulatory support (AMCS) for cardiogenic shock (CS) have exclusively focused on patients with acute coronary syndrome (ACS). Outcomes for patients supported with AMCS for other indications have not been well described.

METHODS AND RESULTS

We retrospectively analyzed all patients (n=140) between 2012?2016 receiving VA-ECMO (n=59) or Impella (n=81) for CS at two institutions.

The indications for AMCS were acute coronary syndrome (46%: STEMI 30% and NSTEMI 70%), acute decompensated heart failure (ADHF) (39%), myocarditis (8%) and post-cardiotomy CS (7%). Compared to VA-ECMO, Impella patients were older (59±14 vs 54±12 years, all compariso

CONCLUSIONS

For patients with CS supported by AMCS, mortality is lower for patients supported with Impella, particularly for ADHF, although indices of CS severity are worse among VA-ECMO recipients. Investigation of outcome predictors for AMCS recipients is warranted.

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The role of urgent coronary angiography and PCI in comatose survivors of out-of-hospital cardiac arrest: single-centre experience

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

AIMS

Emergency coronary angiography, in the absence of ST elevation on a post-resuscitation ECG, is controversial. Our institution advocates early engagement of a specialist team at the front door. In the absence of non-cardiac aetiology, patients undergo emergency angiography irrespective of presenting ECG. We sought to evaluate our pathway, identify factors associated with improved survival and the association between ST elevation and the presence of acute coronary culprit lesion.

METHODS AND RESULTS

We retrospectively reviewed clinical data, ECG characteristics and angiograms of survivors of OHCA admitted to our institution between 1/10/2012 and 31/10/2015.

We obtained data for 217 patients (80 % male, average age 62 years). The prevalence of significant coronary artery disease (>70% stenosis in at least one coronary artery) was 77%. An acute culprit lesion (thrombotic occlusion or TIMI 1 flow) was found in 106 (49%) cases. Of these 37 (27%) did not have ST elevation. Survival to discharge rate was 58% and the 6-month survival was 54%. The majority of discharged patients (96%) had good neurological outcome (cerebral performance category 1 or 2). Survival to discharge and neurological outcome were similar among patients with ST elevation compared with those without (56% vs 54%) and (98% vs 95%).

In a univariate analysis basic life support (BLS), witnessed arrest, initial rhythm of VF/VT, downtime of < 30 min were associated with improved 6-month survival. There was a trend towards improved survival in patients who underwent successful PCI (P =0.075). Multi-variable analysis identified BLS, initial rhythm VF/VT and downtime of < 30 min to be associated with improved survival.

Furthermore, ST elevation was the only factor independently associated with the presence of a culprit lesion.

CONCLUSIONS

Early engagement of a specialist team leads to excellent outcomes in this unselected population of survivors of OHCA. Although ST elevation is strongly associated with a culprit lesion, a significant proportion of patients who would benefit from PCI didn?t have ST elevation on initial ECG. Moreover, PCI is associated with a trend towards improved survival.

Therefore, our results suggest that using ST elevation as a selection criterion for coronary angiography can neglect the existence of coronary occlusion in patients without ST elevation and supports an early invasive strategy in comatose survivors of cardiac arrest regardless of the presence of ST elevation on post arrest ECG.

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Impact of intravascular imaging methods for optimal scaffold implantation reducing thrombosis after Absorb BRS in a real-world setting at one-year follow-up: identification of factors related to stent failure

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

AIMS

Recently, bioresorbable vascular scaffolds (BRS) were related to an unexpected high incidence of thrombosis. The aim of this study was to analyze in a single center experience, the impact of intravascular imaging (intravascular ultrasound-IVUS, optical coherence tomography-OCT) identifying and treating mechanical factors related to stent failure that would act as possible predictors of thrombosis and MACE.

METHODS AND RESULTS

between 11/2014 and 10/2016, consecutive unselected patients (pts.) were treated with one or more Absorb BRS. Predilatation before stent deployment and post dilatation, IVUS and OCT were used in all cases. Identified mechanical factors possibly related with stent failure were: stent malapposition, wall hematoma, stent underexpansion, border dissection, device fracture, thrombus and/or plaque protrusion. Customized measures were taken for each case. All pts. are under clinical follow up.

100 pts (88% male, mean age 58,1 yo) were included in this analysis. Baseline characteristics show real world population (31% diabetics, 52% multivessel ds). A total of 141 lesions were treated (LAD 74%), being B/C class in 60%. Median SYNTAX score was 14,2±8.8. 190 Absorb BRS were implanted (1,9 stent/pt.). Further intervention following intravascular imaging with balloon optimization and/or new stent implantation was necessary in 16% of cases because of previously described mechanical factors, not seen by angiography. Mean procedure time including pre and post dilatation guided using intravascular imaging was 112 ± 47 minutes. After optimal result was obtained, oral anticoagulation in addition to double antiplatelet therapy was indicated during the first 45 days in those pts having thrombus and/or plaque protrusion in OCT analysis. With 100% procedure success, 100% completed 1 yr follow up. MACE shows definite/probable scaffold thrombosis in 0%, with 4% TLR and 3% TVR

CONCLUSIONS

The follow up analysis of this cohort of patients is showing no thrombosis so far, in a real world all comers setting. Detection of implantation defects by intravascular imaging and not seen by angiography, followed by customized treatment with balloon/stent and 45 days anticoagulation, seems to be responsible for the low adverse event rate, caused in these pts., by focal restenosis.

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TAVI-related thrombocytopenia and outcomes. Is there a prosthesis factor?

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

AIMS

To analyze the differences in drop platelet count (DPC) between Balloon-expandable valves (BEVs) and self-expanding (SEVs) and their prognostic implications in clinical outcomes after Transcatheter Aortic Valve Implantation (TAVI).

METHODS AND RESULTS

Consecutive patients undergoing transfemoral TAVI from 2008 to 2016 in a high-volume centre were included. BEVs included Sapien, Sapien XT and Sapien 3 and SEVs used were Corevalve and Evolut R. Patients with non-transfemoral approach, baseline platelet count 30% after TAVI (61.5% vs. 50.8%, OR 1.72, 95% CI, 1.23-2.42, p=0.002). At 30-days, the DPC>30% was associated with a higher rate of life-threatening/major bleeding (6.8 vs 2.1%, p=0.009) and mortality (3.5 vs 0.8%, p=0-036). At one-year, there were no statistically significant differences in the mortality rate between groups.

CONCLUSIONS

In this study, the use of BEV was independently associated with a higher risk of DPC after TAVI. A DPC >30% was associated with an increased risk of life-threatening/major bleeding and death at 30-days after TAVI.

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Novel numerical hemodynamic models for evaluating thromboresistance of BRS under clinically relevant scenarios

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

AIMS

The goal of BRS is to provide luminal support for coronary arteries similar to metallic DES with the additional progressive resorption over time. First-generation BRS implants have higher strut thickness and denser scaffold patterns than current generation DES due to material constraints. The purpose of the study was to assess the dependence on potential thrombogeneic effect on coronary vessel diameter, strut thickness, and BRS/DES implants using computational fluid dynamics (CFD) models.

METHODS AND RESULTS

Sixteen CFD models based on a Lagrangian model of flowing platelets were developed to evaluate the effect of vessel diameter (1.8-3.0 mm), strut thickness (81-157 mm), and stent design (Absorb BRS, Xience PRIME DES) on platelet stress history and the potential for platelet activation. Platelets stress accumulation (SA), a surrogate metric for the platelet activation potential, was calculated along platelet flow trajectories. A probability density function of SA was used to compare different scenarios.

The model results were consistent with clinical observations, indicating that devices deployed in very small vessels exhibited increased probability for platelets activity as compared to the same devices deployed in nominal sized vessels. Local narrowing of the vessel led to increased probability for platelets exposure to higher SA as compared to a straight vessel. Reduction of BRS strut thickness while keeping the same scaffold pattern led to its performance being closer to that of a lower footprint DES. However, it should be noted that BRS creates both areas of high shear stress over struts and areas of stagnation between rings, thus affecting platelet SA in two ways. DES only affects platelet SA via strut thickness, as stagnation areas in the immediate proximity to strut side-edges do not become a significant portion of platelet SA calculations. Thus, pattern thickness reduction without a change footprint can make BRS performance substantially closer to that of DES in vessels >2.5 mm and mitigate the effect of vessel diameter in much smaller vessels, but not eliminate it.

CONCLUSIONS

Results from this study, based on clinically relevant computational models, support clinical observations that indicate that thicker and denser patterns in BRS deployed in very small vessels have larger effects on platelet stress history than that occurring with similar nominal sized DES implants. Additionally, it was found that thicker struts and their pattern density play a role in the effect on the stress history experienced by the platelets, both by creating stagnation areas between rings and enhancing shear stress with thicker struts. These observations may provide guidance in scaffold design to enhance the utility of present BRS and to steward future design improvements, enhancing the intrinsic advantage of BRS.

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Bioabsorbable polymer everolimus-eluting stents in patients with AMI: a report from the Swedish coronary angiography and angioplasty registry

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

AIMS

The clinical performance of the Synergy (Boston Scientific Corporation, Marlborough, MA) drug-eluting stent (DES) in patients with acute myocardial infarction (AMI) has not been investigated in detail. Therefore, we sought to report on the outcomes after Synergy DES implantation in patients with AMI undergoing percutaneous revascularization (PCI).

METHODS AND RESULTS

We included all consecutive patients with AMI (ST-elevation and non-ST-elevation AMI) undergoing PCI with the Synergy DES and other newer generation DES (n-DES group) in Sweden. From March 2013 to April 2016, a total 46,466 n-DES and 7,044 Synergy stents were implanted. Patients in the Synergy group were older (p=0.002) and presented more often with left main or three-vessel disease involvement, as well as, with restenotic culprit lesions (

CONCLUSIONS

In a large and unselected cohort of patients with AMI undergoing percutaneous revascularization with the Synergy DES, stent performance and clinical outcomes did not differ compared with other newer generation DES up to one year.

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Visualising the tissue distribution and retention of sirolimus and analog delivered from polymer-free DES

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

AIMS

Biolimus A9 is a highly lipophilic Sirolimus analog (13-fold the lipophilicity of the parent drug) specifically designed for local-drug delivery. We developed immunofluorescence (IF) methods to contrast the arterial distribution of Sirolimus and Biolimus A9 after implantation of polymer-free drug-coated stents (PF DCS) in the pig coronary artery model.

METHODS AND RESULTS

Six PF DCS (Biosensors International) each of BioFreedom CoCr, BioFreedom? stainless steel (both coated with Biolimus A9) and Sirolimus PF DCS stainless steel were implanted in the coronary arteries of 6 Yucatan Mini Swine (stent-to-artery ratio of 1.05:1-1.15:1) for 7, 14 or 28 days (n=2/time point). All PF DCS had the same target drug load (15.6µg per mm of stent length) that was spray coated onto a textured ablumimal metallic stent surface. Explanted arteries were processed for H&E staining and immunofluorescent evaluation of drug distribution using an anti-Sirolimus antibody. Histopathologic evaluation revealed comparably favorable histopathological findings between stent types across time points with presence of minimal neointima.

IF distributions showed drug localization to struts with intensity levels that varied with strut, device and time. Peristrut IF distributions were quantified using image analysis routines. The area averaged intensity was evaluated within 15µm of the stent surface and compared at a group level using a paired two-tailed t-test. At 7d, the mean peristrut IF intensities of the Biolimus and Sirolimus were virtually the same (and P=ns), suggesting that Sirolimus and Biolimus display similar early release kinetics from the evaluated DCS. Over time, as retention becomes dominated by tissue binding, the ratio of peristrut Biolimus to Sirolimus IF intensities increased (14d: ratio=1.7, P=0.007, 28d: 2.5, P=0.001). Since the spray coating of the 3 tested DCS types was designed to be preferentially abluminal, we also evaluated the ratio of abluminally to luminally mean peristrut intensities. The abluminal to luminal intensity ratios for Biolimus DCS were 1.9 (P=0.006) at 7d and 2.1 (P

CONCLUSIONS

Polymer-free drug-coated stents (PF DCS) avoid the concern for inflammatory material responses, but pose challenges in providing controlled drug release and sustained tissue retention. Tissue retention of Sirolimus released from identically prepared PF DCS was less sustained than that of BA9 and less localized to the abluminal aspect. These data suggest that Sirolimus analog lipophilicity determines the rate of drug release from PF DCS and the corresponding tissue distribution and retention, providing a mechanistic underpinning for the sustained efficacy achieved with Biolimus A9 released from the BioFreedom DCS.

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Impact of the repositionable Evolut R CoreValve on the need for permanent pacemaker after TAVI in patients with severe aortic stenosis

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

AIMS

The depth of the valve implantation in the left ventricle has been related to the need for permanent pacemaker after transcatheter aortic valve implantation (TAVI). The Evolut R CoreValve can be recaptured and repositioned during deployment, allowing a more precise implantation. The aim of this study was to analyse the incidence of pacemaker with the latest generation of CoreValve in comparison with its predecessor.

METHODS AND RESULTS

From April 2008 to November 2017, 333 consecutive patients with symptomatic severe aortic stenosis undergoing TAVI with either CoreValve (n= 208) or CoreValve Evolut R (n= 125) have been analysed. Eleven patients were excluded due to pre-existing permanent pacemaker implantation. Procedures were performed under general anaesthesia and guided by transesophageal echocardiography according to local practice. The need for pre and postdilation was left to the discretion of the operator. Valve size was selected based on annular perimeter measurements obtained from multislice computed tomography. Depth of implantation was measured in all patients. Prothesis depth was defined as the maximal distance (mm) between the intraventricular end of the bioprosthesis and the aortic annulus at the level of the non coronary cusp and at the level of the left coronary cusp, obtained by angiography in the projection chosen after the deployment (annular perpendicular view). There were no differences in clinical characteristics between both groups, although CoreValve patients group were slightly younger (78±6 vs 79±5 years, p= 0.046). An important reduction in the need of permanent pacemaker was observed with the Evolut R in comparison to the old CoreValve (14/125, 11.2% vs 53/208, 25.5%, p= 0.002). Factors determining of need for permanent pacing were compared between CoreValve and Evolut R groups. Predilation was performed more frequently before CoreValve implantation (189/208, 90.9% vs 62/125, 49.6%, p< 0.01). However, postdilation rate was similar in both groups (91/208, 44% vs 54/125, 43%, p= 0.89). Abnormalities of conduction were present in 133 (39.9%) of the patients, without significant differences between the groups (85/208, 40.9% vs 48/125, 38.4%, p= 0.66): first-degree atrioventricular block in 41 (19.7%) vs 14 (11.2%) patients, p=0.47, left bundle branch block in 20 (9.7%) vs 15 (12%), p= 0.55, left anterior hemiblock in 35 (16.8%) vs 19 (15.2%), p= 0.70 and right bundle branch block (RBBB) in 25 (12.2%) vs 14 (11.2%), p= 0.82. With respect to the position, the prothesis was implanted more deeply in the CoreValve group in comparison with the Evolut R group. The mean depth measured at the level of the non coronary cusp was 10.9±4.2 mm in the patients treated with CoreValve while in the Evolut R was 5.9±3 mm,

CONCLUSIONS

The repositionable and recapturable capability of the CoreValve Evolut R system allowed a higher and precise valve implantation. This fact was associated with a significant reduction in the rate of permanent pacing in comparison with the previous CoreValve generation.

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Impact of staging PCI in patients with three-vessel coronary artery disease: insights from the SYNTAX-II study

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

AIMS

In the SYNTAX I trial, patients with multivessel coronary artery disease treated by staged PCI had a higher rate of major adverse cardiovascular and cerebrovascular events at five-year follow-up. However, whether staging PCI using the SYNTAX II strategy which comprises the selection of patients based on an equipoise risk between CABG and PCI according to the SYNTAX score II, physiology-guided PCI using thin struts biodegradable polymer everolimus-eluting stents optimized by intravascular ultrasound improves outcomes remains unknown.

METHODS AND RESULTS

Patients with three-vessel coronary artery disease (3VD) included in the SYNTAX II study were categorized according to the treatment strategy, i.e., staged PCI vs. single procedure. Rates of major adverse cardiac events (MACE, all-cause death, stroke, or myocardial infarction) and major adverse cardiac or cerebrovascular events (MACCE, MACE or ischemia-driven revascularization) were compared between groups at one-year follow-up. Staged procedures were performed in 138 patients (30%) whereas 312 patients underwent single-PCI. There were no differences in baseline clinical characteristics between patients in the staged and single PCI groups. However, the anatomic SYNTAX score was significantly higher in the staged procedure group (22.4±7.2 vs. 19.3±5.7, p=0.002). Patients in the staged procedure group had more stents implanted (4.6±2.1 vs. 3.5±1.8, p=0.023). At one year, MACE rates were similar between staged and single-PCI group (HR 0.96 [95% CI 0.34 to 2.70, p=0.94]). However, a significantly higher rate of MACCE was observed in the staged procedure group HR 2.16 (95% CI 1.15 to 4.05, p=0.0071) driven by a higher rate of any revascularization (HR 2.73 95% CI 1.37 to 5.6). No significant differences were found in the other components of MACCE. In the Cox proportional regression model gender and staged procedure were independent predictors of MACCE.

CONCLUSIONS

Despite higher anatomical and procedural complexity, staged procedures with state-of-the-art PCI with the SYNTAX II strategy was associated with comparable rates of MACE at one year. However, an increase in MACCE in the staged procedure group was observed driven by an increase in any revascularization.

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Clinical, angiographic and OCT characteristics of stent restenosis with neoatherosclerosis

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

AIMS

Optical coherence tomography (OCT) is a high resolution intracoronary imaging technique that allows the detection of neoatherosclerosis in stent restenosis (ISR). The study aims were i) to determine the differences in clinical and angiographic presentation between restenosis with and without neoatherosclerosis ii) to assess the OCT characteristics of restenosis with neoatherosclerosis

METHODS AND RESULTS

Methods: The present study included cases from the RIBS IV and RIBS V trials. These were 2 prospective multicenter, controlled, randomized clinical trials that compared drug eluting balloon (DEB) vs everolimus eluting stents (EES) in patients with DES-ISR (RIBS-IV) and BMS-ISR (RIBS-V). The trials included an OCT substudy at baseline. Neoatherosclerosis was defined in OCT as the presence of restenotic tissue with calcification (well-delineated, signal-poor region with sharp borders) or lipid content (signal-poor region with diffuse borders).

Results: Sixty-four patients were included in the OCT substudy at baseline. In 23 of them (36%) neoatherosclerosis was present in their restenotic tissue. Of those 7 (30%) were BMS and 16 (70%) were DES. Regarding baseline characteristics there were no differences in age, gender or risk factors between restenosis with and without neoatherosclerosis. Cases with neoatherosclerosis presented more frequently with unstable angina 15 (65%) vs 11 (27%) p=0.003 and had a longer time from stent implantation 1117 (270-2772) vs 270 (200-1075) days p=0.01. The proportion of DES in the group with neoatherosclerosis was numerically higher 16 (70%) vs 21 (51%) but the difference was not significant. ISR with neoatherosclerosis presented more frequently with a Mehran I angiographic pattern 18 (78%) vs 18 (44%) p=0.03. There was a non-significant tendency towards more edge restenosis in the neoatherosclerosis group 7 (30%) vs 7 (17%) p=0.22. There were no differences in other baseline angiographic parameters (minimum lumen diameter, % diameter stenosis, lesion length, reference diameter). Regarding optical properties cases with neoatherosclerosis showed more often a layered pattern 13 (57%) vs 8 (20%) p=0.007 and a low backscatter 14 (61%) vs 9 (22%) p=0.002. Neoatherosclerosis cases had more frequently an irregular lumen 13 (64%) vs 9 (22%) p=0.005 and visible intraluminal material 9 (41%) vs 7 (18%) p=0.04. No significant differences were found in microvessels but macrophages were significantly more frequent in ISR with neoatherosclerosis 21 (91%) vs 13 (33%) p<0.001. Peristrut low intensity areas were less often observed in neotherosclerosis 3(13%) vs 23(56%) p=0.001. No differences were observed in OCT measurements of lumen and stent areas, stent expansion and symmetry. There was a tendency towards a lower restenotic tissue burden in the neoatherosclerosis group 33±14% vs 40±14% p=0.08.

CONCLUSIONS

ISR with neoatherosclerosis had more frequently an unstable clinical presentation. This correlated with the

more frequent presence of OCT findings suggestive of instability such as the presence of intraluminal material, irregular lumen and macrophages.

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Results of hybrid repair multilevel lesions of the brachiocephalic arteries

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

AIMS

The aim of our study was to evaluate the results of hybrid repairs for patients with multilevel and tandem stenosis of brachiocephalic arteries.

METHODS AND RESULTS

From December 2016 in our clinic were treated 21 patients with multilevel atherosclerotic lesions of carotid arteries. The patient?s age were from 49 to 82 years old. The distributions of lesions were: 10 patients with right internal carotid artery and brachiocephalic trunk hemodynamic stenosis, 9 - with left common and internal carotid arteries stenosis and 2 ? with tandem stenosis of bifurcation and distal part of internal carotid artery. 9 patients with combined cardiologic pathology requiring cardiosurgical treatment. In all cases were performed hybrid procedures which included carotid bifurcation endarterectomy and stenting affected artery. Follow-up consisted of clinical assessment, duplex ultrasound and MSCT-angiography during 3-6 months after treatment.

Technical success was 100% and there was no neurologic morbidity and mortality at 30 days. No intraoperative complications were encountered. The 3, 6-9 months results after operations are the absence of thrombosis, stroke and complications, including after aortocoronary bypass.

CONCLUSIONS

The use of hybrid surgical interventions in multilevel lesions of brachiocephalic arteries allows to reduce the risk of TIA and ischemic strokes in patients, and achieve immediate satisfactory results after the surgical treatment. It demonstrates an effective and safe correction of hemodynamically significant tandem stenosis of brachiocephalic arteries, avoiding neurological complications during surgical treatment of the patients with combined cardiologic pathology.

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Endothelial shear stress five years after implantation of a coronary BRS

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

AIMS

As a sine qua non for arterial wall physiology, local hemodynamic forces such as endothelial shear stress (ESS) may influence long-term vessel changes as bioabsorbable scaffolds dissolve. The aim of this study was to perform serial computational fluid dynamic (CFD) simulations to examine immediate and long-term haemodynamic and vascular changes following bioresorbable scaffold placement.

METHODS AND RESULTS

Coronary arterial models with long-term serial assessment (baseline and five years) were reconstructed through fusion of intravascular optical coherence tomography (OCT) and angiography. Pulsatile non-Newtonian computational fluid dynamic simulations were performed to calculate the ESS and relative blood viscosity. Time-averaged, systolic, and diastolic results were compared between follow-ups. Seven patients (seven lesions) were included in this analysis. A marked heterogeneity in ESS and localised regions of high blood viscosity were observed post-implantation. Percent vessel area exposed to low averaged ESS (

CONCLUSIONS

Immediately after scaffold implantation, coronary arteries demonstrate an alternans of extremely low and high ESS values and localized areas of high blood viscosity. These initial local haemodynamic disturbances may trigger fibrin deposition and thrombosis. Also, low ESS can promote neointimal hyperplasia, but may also contribute to appropriate scaffold healing with normalisation of ESS and reduction in peak blood viscosity by five years.

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Six-month outcome of provisional vs. double-stent strategy for true bifurcation lesion using transradial approach: single-centre, single-operator study in Bangladesh

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

Coronary bifurcation lesions are frequent in everyday practice and account for up to 20% of all PCIs. The question relating to a one or two stent strategy for bifurcation lesions has been a subject of many debates over recent years. Double stent technique is associated with a lower procedural success rates & a higher rate of long term adverse cardiac events such as stent restenosis and thrombosis.

METHODS AND RESULTS

80 patients with true bifurcation lesions according to Medina classification were included in this single-centre study and randomly assigned to one (n=40) or two (n=40) stent strategy group. The lesion type of 1,1,1 was the most common type seen in both groups (p=0.94). Both the groups were similar in terms of patient and lesion characteristics. PCIs were performed (90% via TAP technique & rest via DK crush or minicrush) according to standard routine through transradial approach using 6F guiding catheter. The most common site of treated bifurcation lesions in both groups was the junction of LAD/DG branches followed by LCX/OM branches. Cross over from one-stent to two stent strategy was none. The endpoints were cardiac death, MI, stent thrombosis & TLR during 6 months. For the bifurcation lesions, comparing routine two-stent strategy with a provisional strategy have shown comparable efficacy outcomes (TVR rates) between the two treatments strategies at 6 month follow up. The provisional strategy resulted in lower rates of periprocedural MI, less contrast use, lower X-ray doses & shorter procedural times.

CONCLUSIONS

Though limited due to low number of participants, this study gave results that in case of true bifurcation lesion, double stent strategy was non-inferior to provisional stent strategy.

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Prevalence and predictors of high-on treatment platelet reactivity during prasugrel treatment in patients with ACS undergoing stent implantation

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THEME: Coronary Interventions

TOPIC(S): NSTEMI, Stents and scaffolds

AIMS

Newly developed ADP-antagonists such as Prasugrel have reduced but yet not overcome the phenomenon of high-on treatment platelet reactivity (HRPR), that has been shown to increase the rate of major adverse cardiovascular events after an acute coronary syndrome (ACS) or PCI. However, the exact prevalence and the determinants of suboptimal platelet inhibition in patients treated with dual antiplatelet therapy (DAPT) with Prasugrel have not been completely cleared out, and was therefore the aim of the present study.

METHODS AND RESULTS

Patients with ACS (60 Kg) and treated with DAPT (ASA + Prasugrel) after PCI were enrolled. Platelet function tests evaluation was performed at 1-3 months from discharge. HRPR was assessed by Multiplate impedance aggregometry and defined for results above ULN (upper limit normal) after ADP stimulation.

We included 190 post-ACS patients. HRPR with Prasugrel was observed in 19 patients (10%). The prevalence of HRPR was quite stable in different high-risk subgroups of patients, (female gender, hypercholesterolemic and chronic kidney disease) whereas it was relevantly increased in diabetic patients (p=0.045), with a significant interaction between diabetic status and HRPR (p=0.04). However, at multivariate analysis, an impaired metabolic status, with higher levels of glycosylated haemoglobin and LDL cholesterol, but not diabetic status, emerged as independent predictors of HRPR with Prasugrel (OR[95%CI]= 2.1[1.32-3.33], p=0.002 and OR[95%CI]= 1.03[1.01-1.05], p=0.003, respectively.

CONCLUSIONS

In post-ACS patients treated with PCI and receiving DAPT with Prasugrel, high-on treatment platelet reactivity is observed in about 10% of patients. Impaired metabolic status, and especially elevated glycosylated haemoglobin, emerged as independent predictor of the suboptimal effectiveness of Prasugrel.

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Discordance between FFR and iFR in the real world

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Background: Invasive physiologic variables such as fractional flow reserve (FFR) and instantaneous wave-free ratio (iFR) are used in clinical practice to assess the functional significance of epicardial coronary stenosis and guide management. However, these two variables may show discrepancies when binary cut-offs are used to decide for revascularizationstrategy. We investigated the clinical characteristics of lesions with discordance between iFR and FFR.

METHODS AND RESULTS

Methods: 256 vessels (220 patients, age 61±12 years, mean±SD, 77% male) with available pre-intervention FFR and iFR values were included in the study. The vessels were classified according to FFR and iFR into concordant normal (Group 1[n=112], FFR>0.8 and iFR>0.89), discordant with abnormal FFR and normal iFR (Group 2 [n=12), FFR0.89),discordant with normal FFR and abnormal iFR (Group 3 [n=43], FFR>0.8 and iFR

CONCLUSIONS

Our study shows a high discordance rate between FFR and iFR with a female preponderance. The four groups classified according to FFR and iFR exhibit different clinical characteristics. The lesions with discordant FFR and iFR may have a different pathophysiology which warrants further investigation.

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Safety of early and late discharge in STEMI patients with Killip class I after primary PCI

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

AIMS

Primary percutaneous coronary intervention (PPCI) is currently highly vital in STEMI patients because it obviously reduces the rates of mortality, disability and disease complications compared to thrombolytic therapy. The present guidelines recommend primary percutaneous coronary intervention (PPCI) as the first line treatment for STEMI patients. According to the new ESC STEMI 2017 guidelines, early discharge is safe for low risk patients, however, the safety data of early discharge in STEMI patients with killip class I is limited.

METHODS AND RESULTS

This is a retrospective study. We collected consecutive 865 cases of STEMI patients with killip class I who underwent PPCI and were discharged from January 1999 to December 2015. The patients were divided into two groups, Group 1: early discharge within 3-day admission and Group 2: late discharge after 3-day admission.The mortality and readmission rates at 30-day and 1-year after discharge of Group 1 and Group 2 patients were compared using Cox regression analysis and Logistic regression analysis, respectively. Survivals of the early and late discharge groups were estimated using the Kaplan?Meier curves and compared using the log-rank test.

Of the 865 STEMI patients in killip class I, there were 544 (63%) patients classified as Group1 and 321(37%) patients as Group 2. Overall, median survival of all STEMI patients in killip class I was 3.7 years, survivals were 2.9 vs. 3.9 years for Group 1 and 2, respectively, p=0.173. All-cause mortality rate was 22.3/100 person-year for all patients, and were 24.5 vs. 21/100 person-year for Group1 vs. Group2, respectively. Patients in the late discharge group had a greater risk of 1-year mortality than those in the early discharge group, with hazard ratio (95% confidence interval) of 2.43 (1.25, 4.71), p=0.009, and 1-year mortality rate of 6.5% vs. 2.8%, p=0.007, respectively. However, there was no difference in 30-day mortality rate, i.e., 0.2% vs.1.3%, for Group 1 vs. 2, respectively, p=0.066. Group1 patients significantly had a lower 1-year readmission rate than group 2, i.e. 3.6% vs. 7.5%, p=0.02, but no difference in 30-day readmission, i.e. 1.1% vs. 1.6%, p=0.548. By multivariate analysis, predictive factors for early discharge in STEMI patients with killip class I were EF>40% (OR=2.25, p=0.004), CKD stage1 (OR=2.5, p=0.004) and CKD stage 2 (OR=1.99, p=0.029).

CONCLUSIONS

Early discharge in STEMI patients with killip class I within 3-day after PPCI is safe in terms of mortality and readmission. Especially, Killip class I patients with EF>40% and CKD stage1 and 2 could be safely discharged within 3-day after PPCI.

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Residual Syntax score as an in-hospital independent mortality predictor in multivessel disease STEMI patients

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

In multivessel disease(MVD) STEMI patients treated with primary angioplasty, complete versus incomplete coronary revascularization is still a controversial theme. Several studies have shown conflicting results and,in part, it is due to a lack of padronization on how to evaluate the degree of revascularization. The Residual SYNTAX Score(rSS) can evaluate coronary anatomy and its complexity after coronary intervention. The aim of the study was to describe the influence of the degree of revascularization after primary angioplasty, evaluated by rSS, on in-hospital mortality in MVD STEMI patients.

METHODS AND RESULTS

A cross-sectional and observational study using a hospitalar hemodinamic database of two public hospitals reference in cardiology. Between october 2013 and january 2015 database showed 431 consecutive STEMI patients treated with primary angioplasty. Only the 234 multivessel disease STEMI patients were included at the final analyses and divided in two groups according to the degree of revascularization: rSS < 8 e rSS ? 8. To identify the variables that would have an association with in-hospital mortality, initially a univariate Pearson chi-squared analyses was made, and Fisher exact test when necessary. A multivariate logistic regression model analised the set of variables that presented a p< 0.10 in the univariate analyses. The statistical analyses used the software SPSS, versão 21,0 and the significance level assumed was 0,05.

Results: 234 consecutive multivessel disease STEMI patients were selected. 124 (53%) had a rSS < 8 and 110 (47%) a rSS ? 8 after primary angioplasty. The median of the rSS in the study population was 7. The univariate analyses showed that the rSS ? 8 (OR 3,89, IC 95% 1.79-8.46, p < 0,01), diabetes mellitus (OR 2,32, IC 95% 1,14 - 4,74, p = 0,019) and the extension of coronary artery disease (OR 5,05, IC 95% 1,27 - 20,11, p = 0,022) were significant in-hospital mortality predictors, and the coronary flow TIMI=3 after primary angioplasty was a protector factor (OR 0,37, IC 95% 0,16 - 0,89, p = 0,032). Although, after multivariate analyses, only the rSS ? 8 was found as an independent in-hospital mortality predictor (OR 3,3, IC 95% 1,33 ? 8,21, p < 0,01).

CONCLUSIONS

The rSS was found as an independent predictor of in-hospital mortality, showing its important prognostic value on the evaluation of residual lesions in multivessel disease STEMI patients.

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The impact of first-generation vs. second-generation DES on long-term arterial healing and neointimal tissue formation in AMI assessed by OCT

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

AIMS

Little is known about coronary arterial response after stenting at very late phase in the clinical setting of acute myocardial infarction (AMI). We aimed to investigate the long-term arterial response to sirolimus- (SES) compared with zotarolimus- (ZES) and everolimus-eluting stents (EES) in patients with AMI assessed by optical coherence tomography (OCT).

METHODS AND RESULTS

This study examined 62 patients (SES group:16, ZES group:23, EES group:23) who underwent OCT assessment with an average follow-up of 6 years after stenting. At the OCT follow-up, we evaluated the OCT findings including the percentage of uncovered struts, the incidence of in-stent neoatherosclerosis, multiple intrastent hollow and the roughness of neointima (variability of neointimal thickness [NIT]). The variability of NIT was defined as a standard deviation of NIT computed from 360 equally-spaced radial sectors for every 1-mm cross-sectional OCT analysis. A total of 14,187 struts (SES: 3,271, ZES: 5,986, EES: 4,930) were analysed. In the strut-level analysis, the incidence of uncovered struts was significantly the highest in the SES group (SES: 4.5% vs. ZES: 0.8% vs. EES: 1.1%, ANOVA P = 0.003). The cross-sections level analysis showed that the variability of NIT was significantly the highest in the SES group (143 vs. 97 vs. 105, ANOVA P = 0.008, respectively), while mean NIT area in the ZES group was significantly the largest among the three groups. The cross-sectional qualitative analysis demonstrated that the frequency of in-stent thrombus was detected only in the SES group. The incidence of in-stent neoatherosclerosis in the SES group was the highest among three groups (75.0% vs. 17.4% vs. 13.0%, respectively). In addition, the SES group had more multiple interstrut hollow with uncovered struts (62.5% vs. 13.0% vs. 34.8%, respectively).

CONCLUSIONS

First-generation DES resulted in an unfavourable healing response after stenting in AMI patients compared with second-generation DESs, observed by long-term OCT follow-up.

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Outcomes in patients undergoing primary PCI according to average monthly temperature

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

AIMS

There are little published contemporary data assessing the association between average monthly temperature and outcomes in patients undergoing primary percutaneous coronary intervention (PPCI) for ST-segment elevation myocardial infarction (STEMI). We investigated this association in a large consecutive patient-series.

METHODS AND RESULTS

All patients undergoing PPCI in 2009, 2010, 2011, and 2013 in a high-volume UK surgical centre were included in this study. Baseline and clinical outcome data were obtained prospectively. The UK Met Office data were used to determine the coldest six months of the year in the region , based on average monthly temperature (November, December, January, February, March, and April). Cox-regression analyses were undertaken to assess the association between presentation in November-April and risk-adjusted 30-day mortality, adjusting for age at presentation, gender, out-of-hours PPCI, and call-to-balloon time. Patients presenting with cardiogenic shock and/or cardiac arrest ? ?high-risk patients?- were analysed separately.

During the study period, 4056 patient underwent PPCI, of whom 3703 (91.3%) were followed up to a minimum of 30 days. Overall, 1939 (52.4%) patients presented between November and April. In the non-?high-risk? patients (n= 3253), presentation in November-April (n=1697) was not associated with unadjusted (HR 0.99 (0.67-1.45)) or adjusted (HR 0.80 (0.54-1.20)) 30-day mortality. However, in the ?high-risk? cohort (n=450), presentation in November-April (n=242) was associated with higher unadjusted (HR 1.51 (1.03-2.23)) and adjusted (HR 1.65 (1.10-2.48)) 30-day mortality.

CONCLUSIONS

In patients undergoing PPCI for cardiogenic shock and/or cardiac arrest, presentation during the colder half of the year was associated with increased unadjusted and adjusted 30-day mortality. This association was not observed in patients presenting without cardiogenic shock and/or cardiac arrest.

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Long-term outcomes and predictors of morbi-mortality according to age in STEMI patients with multivessel disease

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Optimal management strategy for patients with STEMI and multivessel disease (MVD) remains unclear, especially in the elderly population. The aim of this study was to assess long-term outcomes and predictors of morbi-mortality according to age in patients with a STEMI and MVD.

METHODS AND RESULTS

This is a prospective observational single-centre study, where we included all consecutive patients admitted to our hospital, from January 2009 to June 2015, with a STEMI who underwent primary-PCI (p-PCI) and showed MVD on angiography. Patients were divided into two groups, according to age: younger than 75 years and more than or equal to 75 years. We differentiated 5 possible revascularization strategies: complete revascularization (CR) during p-PCI, CR during hospital index admission, outpatient CR, CABG and incomplete revascularization (IR), defined as p-PCI of only the culprit vessel and pharmacological treatment on the remaining diseased vessels.Co-primary outcomes were defined as the incidence of all-cause mortality and MACE (composite of cardiac death, myocardial infarction or re-admission for heart failure) during follow-up. The secondary outcome was to evaluate the impact in morbi-mortality of different clinical variables and revascularization strategies according to age.

A total of 377 consecutive patients with a STEMI who underwent p-PCI and showed MVD on angiography were analysed. 262 (69.5%) were

CONCLUSIONS

This study confirms the relevant prevalence of MVD in STEMI patients, even in elderly patients, as well as the difference in outcomes of an IR strategy between both age-groups, being only independently associated with MACE in younger patients.

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False lumen intervention to promote remodelling and thrombosis - the FLIRT concept in aortic dissection

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

AIMS

Thoracic endovascular aortic repair (TEVAR) has changed the management of aortic dissection by induced remodeling. Beyond reconstructing the true lumen, we describe the concept of False Lumen Intervention to promote Remodelling and Thrombosis (FLIRT) in both type A and B aortic dissection.

METHODS AND RESULTS

Methods

Between 2011 and 2017, 10 patients with aortic dissection (5 type A, 5 type B) underwent FLIRT using a combination of PFO or atrial septal defect (ASD) occluders, coils and glue. Patients were followed by CT angiography prior to, and 6 months following, discharge to evaluate false lumen (FL) thrombosis and aortic remodeling. Outcomes analyzed comprised successful device delivery, completeness of FL thrombosis and aortic remodeling, procedure-related complications and mortality.

Results

FLIRT induced aortic remodeling in all cases of proximal dissection, with aortic shrinkage from 63.8±7.5 pre-FLIRT, to 50.2±6.6 mm (p=0.057) and an increase in true lumen area from 5.8±3.6 to 11.4±2.5 cm2 (p=0.006). In distal dissection (after the previous TEVAR with residual FL flow), FLIRT successfully induced FL thrombosis in 4 of 5 cases at first attempt (1 case required additional coiling of the gutter between left subclavian artery and stent-graft for complete thrombosis). While maximal aortic diameter remained unchanged (55.6±9.1 pre-FLIRT and 54.4±13.7 mm at follow-up), true lumen area increased from 7.8±2.3 pre-procedure to 10.6±1.5 cm2 at follow-up (p=0.016), consistent with remodeling.

CONCLUSIONS

Interventional FL management, using the FLIRT concept, is feasible in selected cases of aortic dissection, promotes FL thrombosis and induces successful remodeling.

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Graft or native intervention in patients with prior CABG: insights from a large multicentre PCI registry.

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

AIMS

Percutaneous coronary intervention (PCI) of bypass grafts is associated with worse outcomes when compared to native coronary intervention due to the higher greater procedural risks, lower technical success rates and higher complication rates. Despite this, PCI is the most common revascularisation strategy in patients with prior coronary artery bypass graft surgery (CABG). We aimed to analyse the contemporary patterns of PCI in CABG patients, identify factors associated with PCI in native coronaries versus bypass grafts, and examine their procedural, in-hospital, and 12-month clinical outcomes.

METHODS AND RESULTS

Methods:

We analysed prospectively collected data from post-CABG patients who underwent PCI at 6 PCI centres in the Melbourne We analysed data from N=1459 patients with prior CABG who underwent PCI at 6 PCI centres in the Melbourne Interventional Group (MIG) registry from January 2005 through December 2015. Factors associated with native versus bypass graft PCI were examined and independent predictors of 12-month mortality were identified using logistic regression modelling.

Results:

During the study period, PCI was performed on 490 (33.6%) bypass grafts and 969 (66.4%) native coronary arteries in patients with prior CABG. The majority of grafts intervened were saphenous vein grafts (87.8%), and most bypass graft target lesions were located in the body of the graft. Patients who underwent bypass graft PCI were older, more likely to have had a prior MI and peripheral vascular disease. In addition, graft PCI patients were further along from their bypass surgery. Compared with patients who underwent native vessel PCI, graft PCI patients were more likely to undergo urgent or rescue PCI and receive glycoprotein IIb/IIIa inhibitors. As expected, more chronic total occlusions were intervened in native coronaries (5.0% vs. 0.4%, $p<0.01$). There were higher rates of perforation (0.9% vs. 0.2%, $p<0.01$) and no-reflow (8.4% vs. 1.8%, $p<0.01$) in patients undergoing bypass graft PCI, while dissection rates were higher in the native coronary artery PCI group (5.0% vs. 2.0%, $p<0.01$). There was no difference in the rate of periprocedural MI, in-hospital MACE or mortality. On multivariable analysis[u1] , older age, renal disease, cardiogenic shock, cerebrovascular disease and acute coronary syndromes were all associated with higher mortality at 1 year. Graft PCI was not (odds ratio: 1.14, 95% confidence interval: 0.68 to 1.91).

CONCLUSIONS

Most PCIs performed in prior CABG patients are done in native coronary artery lesions. However, compared with native coronary PCI, bypass graft PCI was not independently associated with higher 12-month mortality.

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Evaluation of in-vivo chemical stability of polymers of XIENCE everolimus-eluting coronary stents by pyrolysis-gas chromatography/mass spectrometry

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

AIMS

Due to the unique nature of the vascular environment, and the fact that coronary stents are permanent implants, the long-term chemical stability of the ?durable? polymers used for coating stents in contact with the blood is critical. The aim of the present study was to investigate the in-vivo chemical stability of the polymers poly(vinylidene fluoride-co-hexafluoropropylene) (PVDF-HFP) and poly(n-butyl methacrylate) (PBMA) employed in manufacturing XIENCE family of coronary stents.

METHODS AND RESULTS

For our investigation, XIENCE stents explanted from porcine coronary arteries (pCA) and from human coronary artery (hCA) specimens at autopsy were compared to freshly manufactured XIENCE stents (controls). Pyrolysis-gas chromatography/mass spectrometry, as one of the most sensitive techniques for the characterization of polymeric materials and understanding variations in their composition, was employed for the analysis. Sample size included in this analysis was n=10, five segments (samples) from explanted stents (two from pCA with XIENCE stent implants of a duration of 2 years [n=1] and 4 years [n=1] and three from hCA with XIENCE stents explanted at autopsy after the implant durations of 5 years [n=2] and 7 years [n=1]) and five segments (samples) from non-implanted stents (controls). All the explant segments/ controls were randomly selected, and the whole selected segment was tested to increase the concentration of the trace analytes.

The comparison of pyrograms of explanted stent samples and controls showed identical fragmentation fingerprints of polymers. Since the important features responsible for the polymer fragmentation fingerprints are the chemical linkages or bond strength, intra- and inter-molecular forces, structure of the polymer chain, crosslinking, and the impurities present, it can be concluded that no chemical change or polymer degradation occurred after multiple years of XIENCE coronary stent implantation. This conclusion is further supported by histological evaluation of these same samples from XIENCE-implanted arteries in which inflammation was not readily apparent in relation to either the stent or the stent coating.

CONCLUSIONS

Findings of the present study demonstrate the chemical stability of PVDF-HFP and PBMA polymers of the XIENCE family of coronary stents in the in-vivo environment, and constitute a further proof of the suitability of PVDF-HFP as a drug carrier for the DES applications. In addition, they provide clarity around the misconception that all durable polymers have the potential for being associated with an inflammatory response and late events due to the possible degradation products released over time.

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First-in-man experience of LAA occlusion with the steerable Fustar sheath

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

AIMS

Due the wide variability of left atrial appendage morphology left atrial appendage occlusion (LAAO) remains a challenging procedure. The steerable FuStar delivery sheath was designed to allow both, transseptal access and delivery of percutaneous devices. We here report the first-in-human experience of LAAO with the FuStar sheath.

METHODS AND RESULTS

20 patients (76.6 ± 8.4 years, 12 (60%) males, CHA2DS2-VASc score: 5.0 ± 2) with non-valvular fibrillation and contraindications to oral anticoagulation underwent LAAO with the LAmbre device using the FuStar steerable sheath (Lifetech Scientific Corp., Shenzhen, China) at two german centers. Successful device implantation was achieved in all patients (100%). No periprocedural complications were observed. Procedure time, fluoroscopy time, contrast media and radiation dose were 23.4 min ± 9.2, 11.9 min ± 4.1, 96.2 ml ± 45.7 and 2718.4 cG*cm² ± 3835.3, respectively.

CONCLUSIONS

This study demonstrates the feasibility and safety of the steerable FuStar sheath for LAAO.

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Long-term clinical outcomes of intermediate lesion in patients with coronary artery disease, a virtual histology-IVUS study

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

AIMS

There are little data about the relationship between long-term clinical outcomes and plaque composition of intermediate stenotic lesion. We sought to elucidate the virtual histology-intravascular ultrasound (IVUS) findings affecting the long-term clinical outcomes in coronary artery disease patients with intermediate lesion.

METHODS AND RESULTS

Eighty six consecutive patients who underwent coronary angiography and showed one or more non-culprit intermediate lesions were prospectively enrolled for 2 years. Total of 89 intermediate lesions underwent virtual histology-IVUS examination were included in the study. Patients had been followed-up for mean 50.7±5.7 months of duration.

Intermediate lesion was defined as 30% to 70% stenosis in coronary angiography. Primary outcome was major adverse cardiovascular events defined as all-cause death, target lesion revascularization, de novo lesion percutaneous coronary intervention (PCI), stroke and non-fatal acute myocardial infarction (AMI). Culprit lesion-related events were not counted. Time-to-event duration was defined as duration from enrollment to first event and subjects were divided into two groups according to the occurrence of major adverse cardiovascular events. Univariate and multivariable analyses were performed to see the predictor of major adverse cardiovascular events.

Total of 25 major adverse cardiovascular events were occurred and mean time-to-event duration was 14.4±11.7 months. There were 12 cases of target lesion revascularization, 3 cases of all-cause death, 10 cases of de novo lesion PCI, 1 case of stroke and 4 cases of non-fatal AMI, respectively. Two cases of target lesion revascularization and 2 cases of de novo lesion PCI were related with 4 cases of non-fatal AMI and 1 patient died the day after target lesion revascularization. These 5 cases were counted as 1 incidence.

There were no significant differences in baseline patient demographics between major adverse cardiovascular events group (n=25, 29.1%) and no major adverse cardiovascular events group (n=61, 70.9%). In the comparison of baseline lesion characteristics, diameter stenosis (47.6±8.1% vs. 42.2±1.2%, p=0.012), plaque burden (66.0±8.6% vs. 61.6±9.9%, p=0.045) and fibrofatty area (1.5±1.8mm2 vs. 0.8±0.8mm2, p=0.047) were higher or larger in major adverse cardiovascular events group (n=27, 30.3%) than no major adverse cardiovascular events group (n=62, 69.7%).

Univariate analysis showed that diameter stenosis (odds ratio 1.07, 95% confidence interval 1.01 ? 1.12, p=0.015), plaque burden (odds ratio 1.07, 95% confidence interval 1.00 ? 1.15, p=0.040), fibrofatty area (odds ratio 1.61, 95% confidence interval 1.10 ? 2.38, p=0.016), plaque burden ? 70% (odds ratio 3.93, 95% confidence interval 1.28 ? 12.07, p=0.018) and area stenosis ? 50% (odds ratio 2.94, 95% confidence interval 1.01 ? 8.56, p=0.042) were related with future cardiovascular events. In multivariable Cox-proportional hazard analysis, fibrofatty area was independently associated with major adverse cardiovascular events (hazards ratio 1.36, 95% confidence interval 1.05 ? 1.77, p=0.019).

CONCLUSIONS

In patients with coronary artery disease, plaque composition of intermediate lesion was related with clinical outcomes. Larger fibrofatty area of intermediate lesion was the only independent predictor of major adverse cardiovascular events in the study.

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Impact of predilation before TAVI with five leading new-generation devices: early results from the RISPEVA study

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

AIMS

Significant aortic stenosis can be safely and effectily treated with transcatheter aortic valve implantation (TAVI) in patients at high or intermediate surgical risk. Predilation is often performed to facilitate TAVI implantation, but its risk-benefit balance with new-generation devices is detabed. We aimed to appraise whether predilation is still needed with new-generation devices for TAVI.

METHODS AND RESULTS

We queried the data collected in the prospective multicenter RISPEVA Study, comparing patients with vs without predilation receiving Acurate, Evolut, Lotus, Portico, or Sapien3. Baseline, procedural features and early (within 1 month) clinical and echocardiographic results were compared with unadjusted bivariate analysis and adjusted inverse-probability-of-treatment weighting analysis obtained from propensity scores. A total of 1409 subjects were included, 1055 (74.9%) receiving predilation, and 354 (25.1%) undergoing direct TAVI. Several baseline and procedural differences were evident at undajusted analysis between the two groups, including device success, procedural success, contrast volume, procedural time, mean post-procedural gradient, and prevalence of aortic regurgitation 2+ (all

CONCLUSIONS

TAVI without predilation is not associated with adverse procedural, clinical or echocardiographic results when new-generation devices are used. Predilation may however reduce procedural time with Evolut and Portico devices.

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Ultrasound guidance for arterial access

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THEME: Peripheral Interventions
TOPIC(S): Below the knee, Iliac / Femoral / Popliteal

AIMS

Arterial access site complications during interventional procedures are associated with morbidity and prolonged hospitalisation. We report on the use of ultrasound (US) guidance and access site complication rates in a single centre.

METHODS AND RESULTS

Data were collected retrospectively from consecutive cases in 2016-2017 undergoing peripheral angiography (PA, N=200, mean age (SD) 65.3 (15.3)) or cardiac catheterisation (CC, N=225, mean age (SD) 65.8 (12.4)). Electronic procedure documentation and patient medical records were analysed for events up until 30 days post-procedure. All patients had a documented post-procedure access site assessment. Exclusion criteria: age <18 years. Complication was defined as: haemorrhage, haematoma, arterial dissection, distal arterial supply compromise, pseudoaneurysm, or arterio-venous fistula formation. Major complication was defined as any access site complication requiring transfusion, further invasive intervention or causing a functionally significant neurovascular compromise of the limb.

US guidance was used in 59% of cases undergoing PA, while in CC US was not used at all. All PA procedures were performed using femoral access, in contrast to 19% of coronary interventions (81% via radial artery). Baseline characteristics (age, gender, sheath size, periprocedural anticoagulation level, platelet counts) were not different between the patients undergoing peripheral or cardiac interventions, no significant differences were present between the subjects who had complications and those who did not. Femoral site complication rate for US-guided access was 0.85%, while no US guidance was associated with a complication rate of 11% (p=0.0007). Subgroup analysis for unguided femoral access demonstrated complication rates of 6.5% in peripheral interventions and 20% in coronary, however, the incidence of major complications was similar (1.2% and 4.9%, respectively, p=0.2719). There were no major complications in the US-guided femoral access group. Radial access had a 15% complication rate (no US guidance in this group), which was not significantly different from the overall complication rates using femoral access without US (p=0.3130). There were no procedure related deaths at 30 days.

CONCLUSIONS

US guidance for arterial access appears to be independently associated with significantly lower rates of vascular complications, however, the use of US remains low, particularly in interventional cardiology.

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Temporary rapid ventricular pacing through super-stiff wire for balloon aortic valvuloplasty

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

AIMS

Temporary rapid ventricular pacing is required during balloon aortic valvuloplasty (BAV), to reduce cardiac output and to facilitate the procedure. A temporary pacing wire is traditionally been placed via the internal jugular vein or femoral vein into the right ventricle. Complications such as cardiac tamponade may be catastrophic in frail patients, and its rate is increasing with patient age.

METHODS AND RESULTS

Between January 2015 and December 2017, we performed 55 balloon aortic valvuloplasty as bridge or alternative to transcatheter aortic valve implantation. In all patients, with the objective of reducing the complexity and enhancing the safety of the procedure, we performed pacing through the super-stiff wire, avoiding the need for a temporary pacing wire in the right ventricle and the associated complications. After aortic valve retrograde crossing a super-stiff wire Safari (Boston Scientific) or Confida (Medtronic) wire was advanced in the left ventricle (LV) over a pig-tail catheter. Rapid ventricular pacing (rate between 160 and 200 bpm) was provided via the super-stiff 0.035?? wire inserted into the left ventricle. The distal end of the super-stiff wire was inserted as cathode inside a sterile bridging cable while an anode was placed on a standard temporary pacing wire placed in the subcutaneous tissue at the site of the anesthetized groin. The bridging cable was than connected to the pulse generator. Left ventricular pacing was successfully implemented in all patients with one for one pacing obtained with a significant reduction in blood pressure achieved in all cases. In two patients, a complete atrio-ventricular block occurs during the procedure, immediate stimulation was delivered through the LV guidewire while a venous sheath was inserted for temporary pacing lead placement in the right ventricle. No complications related to pacing through the wire were reported in any patient.

CONCLUSIONS

Our experience demonstrated the safety and feasibility of the use of the left ventricular super-stiff guidewire for rapid pacing during balloon valvuloplasty. The technique is simple, shortens the procedure and may prevent the occurrence of all potential complications associated with right ventricle temporary leads and femoral venous puncture.?

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Efficacy of PCI for CTO assessed by stress myocardial perfusion imaging

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Percutaneous coronary intervention (PCI) for chronic total occlusion (CTO) are perceived to be technically challenging, and have limited data available on clinical outcomes of the procedures. The purpose of this study was to assess the quantitative therapeutic effect of PCI for CTO from the data acquired by stress myocardial perfusion imaging (MPI).

METHODS AND RESULTS

Methods: Consecutive 44 patients who successfully completed CTO-PCI and underwent stress MPI before and after PCI between 2013 and 2016 were examined. Severity of myocardial ischemia, cardiac function, and cardiovascular events including cardiac death and revascularization were assessed.

Results: SSS and SRS were significantly decreased after PCI (SSS, 17.6 plus minus 1.5 vs 11.3 plus minus 1.4,

CONCLUSIONS

Successful PCI for CTO lesions has contributed to improvement of ischemic severity and cardiac function. Our data suggests that the patients who had better effect by CTO PCI might be better outcomes.

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Assessment of individual responses to P2Y12 inhibitors: validation of a new point of care test and a novel rapid analysis

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

AIMS

There is potential value in testing individual response to P2Y12 inhibitors in order to predict ischaemic and bleeding risk in patients undergoing coronary stents implanatation. We aimed to: (a) validate the ability of a novel point of care (POC) assay using thrombelastography, TEG6s, to detect changes in ADP-induced whole blood clotting, using TEG5000 as a reference and (b) compare a novel, rapid test parameter, area under the curve at 15 minutes (AUC15), with the traditional maximum clot amplitude (MA).

METHODS AND RESULTS

This was a single centre, prospective, observational study conducted at a tertiary centre. The following study groups were recruited: a) group 1 - twelve healthy volunteers, who received clopidogrel 600 milligrams (mg) once and had blood sampling at baseline, 2 hours, 6 hours and 24 hours after clopidogrel ingestion, b) group 2 - twelve patients with suspected Non-ST Elevation Myocardial Infarction, who routinely received clopidogrel 600 mg and underwent blood sampling at baseline, 2 hours, 6-18 hours and 24 hours after clopidogrel ingestion, c) one healthy volunteer, who received clopidogrel 600 mg on five separate occasions, at least two weeks apart and undergo blood sampling at baseline and 6 hours after clopidogrel ingestion, in order to assess for intra-individual reproducibility.

The main aim of our study confirmed that the novel POC TEG6s is an accurate test of platelet-induced whole blood clotting. Specifically, we have described the following results:

1. TEG5000 and TEG6s detected changes in ADP-induced platelet activation.
2. TEG6s demonstrated a high level of intra-individual reproducibility.
3. Bland Altman analysis revealed a good level of agreement between the two devices in ADP channels with a mean difference of -3.9 and -7.2 in volunteers and patients respectively.
4. For TEG6S, correlation between MA and our novel AUC15 was strong for both thrombin and ADP channels ($R^2=0.867$, $R=0.936$, $p<0.001$)
5. The novel method of analysis allows to save on average 13.3 mins.

CONCLUSIONS

TEG6s is a rapid, easy to use and accurate test of ADP-induced clotting using TEG5000 as a reference. It has a satisfactory correlation and level of agreement with TEG5000 in ADP-induced whole blood clotting. A novel parameter, AUC15, is a viable and time saving option for this POC test. TEG6s shows promise as a truly POC assessment for individual response to P2Y12 inhibitors.

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Percutaneous treatment of multiruptured false aneurysm of the ascending aorta and valsalva sinus in the right ventricle

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

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Clinical outcomes in patients treated with glycoprotein IIb/IIIa inhibitors during primary PCI according to arterial access site.

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

There are little available contemporary real-world data in the era of third-generation P2Y12-receptor inhibitors, examining the association between glycoprotein IIb/IIIa inhibitors (GPI) and outcomes in patients undergoing primary percutaneous coronary intervention (PPCI) for ST-segment elevation myocardial infarction (STEMI), according to arterial access site. We sought to investigate this association in a contemporary cohort of real-world patients.

METHODS AND RESULTS

Clinical and follow-up data for all patients undergoing PPCI in a large surgical centre between 01-01-2009 and 31-12-2011, and 01-01-2013 and 31-12-2013 were collected prospectively. Patients included in this analysis had pre-procedural Thrombolysis in Myocardial Infarction (TIMI)-0 flow and post-procedural TIMI-3 flow in their infarct-related artery. Clinical endpoints were 30-day and 12-month mortality, and 30-day HORIZONS-major bleeding. Patients were analysed according to arterial access site with Cox-regression models, to assess the association between GPI use and outcomes in each group (transfemoral PPCI and transradial PPCI), adjusting for confounding variables.

A total of 2369 patients were included in this analysis, of whom 821 (34.7%) underwent transfemoral PPCI and 1548 (65.3%) underwent transradial PPCI. GPI was used in 169 (20.6%) patients undergoing transfemoral PPCI, and 179 (11.6%) patients undergoing transradial PPCI. In transfemoral PPCI, GPI use was independently associated with 30-day mortality (HR 2.04 (1.05-3.94), p=0.03) and 30-day bleeding (HR 2.05 (1.07-3.93), p=0.03), particularly arterial access site bleeding (HR 2.71 (1.00-7.37), p=0.05), with no significant difference in 12-month mortality (HR 1.48 (0.82-2.67), p=0.20). However, in transradial PPCI, GPI use was not associated with 30-day (HR 1.27 (0.39-4.16), p=0.69) or 12-month (HR 1.21 (0.58-2.51), p=s0.62) mortality, or 30-day bleeding (HR 1.93 (0.73-4.76), p=0.16).

CONCLUSIONS

In patients undergoing transfemoral PPCI, GPI use was independently associated with higher 30-day mortality and 30-day bleeding, particularly access-site bleeding. This association was not observed in patients undergoing transradial PPCI.

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Initial T-wave morphology in the chest leads in patients presenting with anterior STEMI as a predictor of spontaneous reperfusion of left anterior descending

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

This study aimed to assess whether the initial T wave morphology in the ECG at presentation can predict patency of the LAD in patients with Acute Anterior ST-segment elevation myocardial infarction (STEMI) undergoing primary percutaneous coronary interventions (PCI).

METHODS AND RESULTS

Methods: The study included 90 patients presented to the emergency department with acute anterior ST-elevation myocardial infarction.

The following patients were excluded from the study: Patients with left bundle branch or right bundle branch block, post CABG patients, patients with paced rhythm and patients who received thrombolytic therapy.

The T wave morphology in the 2 chest leads with maximal ST-segment elevation on the presenting ECG were identified according to the following definition:

Positive T waves: T?+, initial Positive deflection ? 0.5 mm above the isoelectric line. Biphasic T waves: T +?/- , initial positive deflection above the ST segment follows by negative deflection ? 0.5 mm below the isoelectric line. Negative T waves: T-, initial negative deflection? 0.5 mm below the isoelectric line without initial positive deflection.

Then according to the results of the initial angiography, patients were classified to spontaneous reperfusion (TIMI II or TIMI III) and non spontaneous reperfusion (TIMI flow 0 or TIMI I).

Then intervention was done with recording of all procedure data including procedure complications and after end of the procedure patient were kept and followed up in CCU with recording of in hospital MACE.

Results: Among the whole study group, 40 patients (44.4%) had positive T Waves (T+), 34 Patients (37.8%) had Negative T Waves (T-) and 16 patients (17.8%) had Biphasic T Waves (T+/-).

Initial angiogram showed that (18) patient had spontaneous reperfusion and (72) patients had no spontaneous reperfusion.

As regard T wave morphology, negative T wave were significantly present in spontaneous reperfusion group (66.7% versus 30.6%, p value 0.004), while positive T wave were predominantly present in non spontaneous reperfusion (50% versus 22.2%, p value 0.033).

CONCLUSIONS

T wave inversion in the chest leads in the presenting ECG of patients with acute anterior STEMI had a good sensitivity 66.7% and specificity 69.4% and with good negative predictive value 89.29% to detect the spontaneous reperfusion of LAD prior to revascularization by primary PCI.

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Assessment of the immediate and short-term cardioprotection effects of myocardial post-conditioning on patients undergoing primary PCI

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Ischaemic postconditioning is believed to be one of the mechanisms that can be used to enhance cardioprotection after myocardial revascularization.

We aimed to assess the effect of myocardial postconditioning on MBG (Myocardial Blush Grade), pattern of rise and fall of cardiac enzymes, and wall motion abnormality in STEMI patients undergoing primary PCI.

METHODS AND RESULTS

Methods: 110 STEMI patients treated with primary percutaneous coronary intervention (PPCI) were randomly assigned to either the postconditioning (n = 55) or the standard PCI group (control group, n = 55). Blood samples were obtained for creatine kinase - MB isoform (CK-MB) at 0,8 and 16 h. The angiographic myocardial blush grade (MBG) in the final angiogram after PPCI was done, and inpatient echocardiographic data were evaluated and compared between the 2 groups.

Results: The areas under the curve of CK-MB release to study the pattern of rise, peaking and fall of the CPK-MB showed that there was statistically significant reduction of the CPK-MB isoform value at 8 hours in the post conditioning group vs control group, (185±90 IU/L vs 130±70 IU/L, p=0.023), The number of patients who had MBG 3 was higher in the post conditioning group than in the control group (36 (65.5%) vs 29 (52.7%), respectively) but not strong enough to reach statistical significance (Median 45 vs 50, p=0.201), however there was significantly higher proportion of akinesia in the affected territory as assessed by transthoracic echocardiography among control group (n=22 vs n=43,

CONCLUSIONS

Myocardial post conditioning significantly had a better effect on post infarction pattern of rise and fall of CPK MB isoform, significantly reduced the akinesia detected by TTE in the affected territory and lead to a better - yet not significant- final MBG in the post-PPCI coronary angiogram.

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Thoracic outlet syndrome in a male patient presenting with distal phalangeal cyanosis

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

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Peri-procedural and clinical outcomes following TAVI for degenerative stentless vs. stented bioprostheses: insights from the global Valve-in-Valve International Data registry

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

AIMS

Valve-in-valve (ViV) transcatheter aortic replacement implantation (TAVI) is an alternative to redo open heart surgery for patients with a failing aortic bioprosthesis. We compared peri-procedural, echocardiographic, and clinical outcomes after ViV-TAVI for failing stentless bioprostheses versus failing stented bioprostheses using a large global registry.

METHODS AND RESULTS

1598 aortic ViV procedures from the Global International Data (VIVID) registry were investigated (291 stentless, 1307 stented bioprostheses). Bioprosthetic failure was secondary to aortic regurgitation in 56% stentless and 20% stented devices (

CONCLUSIONS

Stentless ViV-TAVI is associated with peri-procedural complications (initial device malposition, second transcatheter device, coronary obstruction, paravalvular leak), and a non-significant trend towards higher 30-day and 1-year mortality at 30-days and 1-year compared with stented ViV-TAVI. However, stentless ViV-TAVI offers better device haemodynamics on echocardiography at 30-days and 1-year.

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Acute degrees aortomitral angle is a predictor of left ventricular perforation in TAVR

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

AIMS

The arousal of TAVI allowed the high risk patients to be rescued. However, it´s still accompanied by intra and postoperative complications which must be thoroughly studied and interpreted. Left ventricular perforation is one of these rare but serious complications which may require rapid emergency sternotomy. Our study is trying to spot a light on the pathophysiology of this complication and its relation to the patient?s anatomy.

METHODS AND RESULTS

Methods: Out of 963 TAVI cases done in our hospital, we faced this complication among 11 of them (1.14%). 3 males and 8 females, with a mean age of 79 years. All of them were operated upon through a transfemoral approach. The 11 patients were complicated with left ventricular perforation during introduction of the wire in the left ventricle requiring emergency sternotomy and repairing the injury of the left ventricle. One patient died during the procedure and the others were rescued.

Results: Focus on the preoperative factors and intraoperative steps were established in favor to find possible predictors. Left ventricular cavity size was found to be less than 4.2 cm in 10 patients where the normal dimensions range from 4.2 to 5.9 cm. Only one patient had a dilated cardiomyopathic left ventricle with cavity size of 6.1cm. A hyper contractile state was common in the whole cohort group except for the same patient with end diastolic dimension of 6.1cm, he had an EF10%. These former 2 factors were previously studied but with no focus on the ventricular morphology which was our clue. Perforation was located in all of patients at the anterior free wall and our surgeons supposed from intraoperative observations that may be these patients have acute narrow aorto-mitral angle. This intraoperative Observation could be confirmed in the computer tomography measurements which revealed acute degrees aorto-mitral angle in all patients which obliged the wire to direct itself towards the anterior free wall of the left ventricle and induce its injury.

CONCLUSIONS

Small left ventricular cavity, hyper contractile state, thin muscular wall and acute aorto-mitral angle might be considered potential predictors of the occurrence of left ventricular perforation during TAVI.

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Short-term outcome of thoracic endovascular aortic repair in patients with thoracic aortic disease

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

AIMS

Open surgical repair for thoracic aortic diseases is associated with a high perioperative mortality and morbidity. Most of type B aortic dissections are uncomplicated and are medically treated which carries a high mortality rate. Thoracic endovascular aortic repair is the first-line therapy for isolated aneurysms of the descending aorta and complicated type B aortic dissection. The aim of this study is to test the safety of early thoracic endovascular aortic repair in patients with uncomplicated type B aortic dissection and patients with thoracic aortic aneurysms.

METHODS AND RESULTS

Methods: A total of 30 patients (24 men and 6 females, mean age 59±8 years) with uncomplicated type B aortic dissection and descending thoracic aortic aneurysm who underwent endovascular aortic repair in National Heart Institute and Cairo University hospitals were followed up. Clinical follow-up data was done at one, three and twelve months thereafter. Clinical follow-up events included death, neurological deficits, symptoms of chronic mal-perfusion syndrome and secondary intervention. Multi-slice computed tomography was performed at three and six months after intervention.

Results: Of the 30 patients, 24 patients had aortic dissection, and 6 patients had an aortic aneurysm. 7 patients underwent hybrid technique and the rest underwent the basic endovascular technique in whom success rate was 100%. Two patients developed complications, type Ia endoleak and type IIa endoleak, however both improved after short term follow up. The total mortality rate was 10% throughout the follow-up. Both death and endoleak occurred in subacute and chronic cases, while using TEVAR in acute AD and aneurysm showed no side effects. Early thoracic endovascular aortic repair showed better results and less complications.

CONCLUSIONS

Along with medical treatment, early thoracic endovascular aortic repair should be considered in uncomplicated type B aortic dissections and thoracic aortic aneurysms.

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Effect of access approach in cardiac catheterisation on operators? choice of revascularisation method in patients with ACS

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

AIMS

Study the influence of radial versus femoral access on the revascularization method in patients with acute coronary syndrome

METHODS AND RESULTS

This single tertiary center retrospective cohort studied 498 patients with acute coronary syndrome who underwent cardiac catheterization between Jan 2016 and July 2016 followed by revascularization of one or more vessels. We excluded patients with previous CABG (n=43) or those who were treated with optimal medical therapy (n=42). Included patients (n=413) were divided into two groups based on the access choice of either transfemoral access (TFA) (n=181) or transradial access (TRA) (n=232). The primary outcome was the revascularization modality.

In the TRA group, the mean age was lower and there were more males. Operators tended to prefer TRA in patients with a higher BMI. TFA was preferred over TRA in emergent procedures or when intraortic balloon pump support was needed. In the TFA group, the syntax score for PCI tended to be higher than the TRA group. TRA group had more referrals for CABG compared to the TFA group (22.4% vs 7.2%, p=<0.001). Patients in the TFA group were more likely to undergo PCI compared to the TRA group (92.8% vs 77.6% p=<0.001). The choice of access biasing the revascularization modality remained significant following a multivariate regression analysis of the confounding factors.

CONCLUSIONS

The revascularization modality was influenced by the access approach in cardiac catheterization where radial access was found to result in more referrals for CABG.

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Influence of low-density lipoprotein cholesterol level on the geometry of coronary bifurcation lesion

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

Low-density lipoprotein cholesterol (LDL-C) is well known as a potent risk factor of coronary atherosclerosis, however, it is not clear how the LDL-C contributes to the progress in the coronary bifurcation lesion. We sought to investigate the influence of LDL-C on the geometry of coronary bifurcation lesions.

METHODS AND RESULTS

A total of 300 non-left main bifurcation lesions in 298 patients treated with cross-over stenting under the guidance of intra-vascular ultra sound (IVUS) in a multi-center prospective registry were classified according to statin treatment status at admission (NT, non-treated, ST, statin-treated). They were further subdivided according to LDL-C levels with a cut-off of 100 mg/dL (NT-high, n=76 lesions, NT-low, n=46, ST-high, n=99 and ST-low, n=79). In addition, a group with strict control of LDL-C (<70 mg/dL) was defined (ST-SC, n=19). We analyzed bifurcation angle and diameter stenosis of side branch, proximal and distal main vessel in the quantitative coronary angiography as well as plaque and lumen volumes in the quantitative IVUS analysis.

The NT-high group had higher-angled bifurcations compared to that in the NT-low group (59.1±21.5° vs. 50.3±18.6°, p=0.02). In the multivariate analysis, LDL-C >100mg/dL was an independent factor contributing on generation of higher-angled (>80 degree) lesion (odds ratio 3.77, 95%CI 1.05-13.5, p= 0.04) in the NT group, whereas it was not significant in the ST group. The NT-low group had more men (95.6% vs. 81.6%, p=0.03), diabetic mellitus (56.5% vs. 38.2%, p=0.06), greater % diameter stenosis (58.1% vs. 50.0%, p=0.02), and greater plaque volume in the distal main vessel (7.1±3.2 mm3/mm vs. 5.7±2.7 mm3/mm, p=0.02), compared to those in the NT-high group. The ST-high group with uncontrolled LDL-C level occupied 33% of the whole cohort and had more younger patients (65.3±3.6 years vs. 68.6±8.4 years, p=0.02) and current smokers (36.7% vs. 16.9%, p=0.004) compared to the ST-low group. Although the ST-SC group had less unstable angina / acute coronary syndrome (5.6% vs. 22.4%, p=0.05) and involvement of left anterior descending artery (LAD, 42.1% vs. 69.7%, p=0.05) compared to those in the ST-high group, it limited luminal volume expansion (proximal: 6.7±1.4 mm3/mm vs. 7.7±2.3 mm3/mm, p=0.04, distal: 5.3±1.5 mm3/mm vs. 6.5±1.9 mm3/mm, p=0.04), regardless of similar plaque volumes.

CONCLUSIONS

Elevated LDL-C is likely to promote the generation of higher-angled bifurcation lesions and multiple risk factors lead to a more progressed bifurcation lesion even in patients with lower LDL-C levels. Strict-controlled statin treatment contributes on stabilization of coronary plaque and less involvement of LAD.

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Radial side, catheter size and clinical characteristics as factors of radiation exposure during transradial diagnostic coronary angiography

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

AIMS

Transradial approach during diagnostic cardiac catheterization is increasingly being adopted as the preferred vascular access, although it is associated with increased radiation exposure when compared with the use of femoral access. The aim of the present study was to evaluate the factors affecting radiation exposure using transradial approach including radial side, catheter size and clinical determinants.

METHODS AND RESULTS

Our population consisted of 1021 consecutive patients without previous history of CABG (673 males, aged 66 years) which underwent diagnostic coronary angiography at a tertiary cardiac center. Cardiac catheterizations performed via right or left radial approach using 5 or 6 French (Fr) diagnostic catheters. The primary end-points of the study were procedural success, fluoroscopy time (FT), dose-area product (DAP), air kerma (AK), number of catheters, and amount of contrast agent.

In the total population, FT was negatively related to height ($r = -0.100$, $p < 0.001$), while it was positively associated with age ($r = 0.111$, $p < 0.001$). Dose-area product was positively associated with weight ($r = 0.424$, $r < 0.001$), height ($r = 0.222$, $r < 0.001$), BMI ($r = 0.361$, $r < 0.001$), and BSA ($r = 0.418$, $r < 0.001$). Regarding the AK, the results were similar to DAP. Independent-samples t-test indicated that the male sex, compared to the female sex was characterized by increased DAP (30221±9543 versus 23208±5651 mGycm2, $p < 0.001$), increased AK (458±59 versus 352±53 mGy, $p < 0.001$), but decreased FT (2.88±1.00 versus 3.18±0.79 minutes, $p < 0.05$). The group of 6 Fr, compared to the group of 5 Fr was characterized by increased DAP (29072±9387 versus 25825±4861 mGycm2, $p < 0.001$) and AK (441±61 versus 392±49 mGy, $p < 0.001$). Finally, the group of left radial, compared to the group of right radial was characterized by increased FT (3.27±0.80 versus 2.86±0.73 minutes, $p < 0.01$). There were no significant differences in procedural success, number of catheters, and amount of contrast agent depending on radial side and catheter size.

CONCLUSIONS

Radial side, catheter size and clinical characteristics are factors of radiation exposure and FT in patients undergoing transradial diagnostic coronary angiography. These findings imply that these factors should be taken into account to help minimize radiation dose.

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Incidence of contrast-induced acute kidney injury in a large cohort of all-comers undergoing PCI: comparison of five contrast media

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

AIMS

There is controversy as to whether the risk of contrast-induced acute kidney injury (CI-AKI) is different with iso-osmolar (IOCM) vs. low-osmolar contrast media (LOCM). Most previous studies conducted have only compared two contrast media (CM) types at once. The aim of the present study was to perform a comparison across five different CM types in a large cohort of all-comers referred for PCI at our institution.

METHODS AND RESULTS

Between January 2012 and December 2016, 5788 PCIs were performed at our institution. Comparisons were performed across 5 CM types: 4 LOCM (ioversol, n=528, iopromide, n=1705, iomeprol, n=1346, iobitridol, n=1000) and 1 IOCM (iodixanol, n=1209). CI-AKI was defined as an increase in serum creatinine ?0.3 mg/dl or ?50% from baseline within 72 h. Multivariable logistic regression analysis was performed to identify independent predictors of CI-AKI, and included the following prespecified candidate variables: age, sex, diabetes, prior CABG, estimated glomerular filtration rate (eGFR), baseline haemoglobin, LVEF, heart failure on presentation, number of diseased vessels, hypotension during/before PCI, emergent PCI, ACS, complex PCI (total stent length >60 mm, ?3 stents implanted, 3 vessels treated, CTO, or rotational atherectomy/laser), vascular access, CM volume, and CM type.

Demographics and baseline clinical characteristics were well-balanced across groups. The overall prevalence of B2/C type lesions was 57.7%, CTO 10.8%, complex PCI 30.4%, and ACS 27.1%. Mean eGFR ranged between 79±26 (ioversol) and 85±27 (iobitridol) ml/min/1.73 m2 (p<0.001). The prevalence of an eGFR <60 ml/min/1.73 m2 ranged between 17.2% (iobitridol) and 22.1% (ioversol) (p=0.06). The overall prevalence of dialysis was 1.2% and was similar across groups (p=0.29). There was a higher incidence of hypotension during/before PCI (p<0.001) and emergent PCI (p<0.001) in patients receiving ioversol or iopromide. The prevalence of type C lesions (p<0.001), including CTO (p=0.005), was higher in subjects receiving ioversol. There were no differences in the prevalence of ACS (p=0.29) or complex PCI (p=0.26). The radial access was more frequently used in patients receiving ioversol or iobitridol (p<0.001). Contrast volume ranged between 207±101 (iodixanol) and 229±106 (ioversol) ml (p<0.001). CI-AKI occurred in 12.8% (ioversol 13.7%, iopromide 11.9%, iomeprol 12.6%, iobitridol 15.0%, iodixanol 11.8%, p=0.51), and in-hospital new need for dialysis was diagnosed in 0.2% overall (p=0.37). On multivariable analysis, independent predictors of CI-AKI were: age (OR 1.03, p<0.001), LVEF (OR 0.96, p<0.001), baseline haemoglobin (OR 0.89, p=0.008), hypotension during/before PCI (OR 2.50, p=0.002), ACS (OR 2.02, p<0.001), and CM volume (OR 1.00, p=0.02). CM type was not a predictor for CI-AKI (p=0.40).

CONCLUSIONS

In a large single-centre cohort of all-comers undergoing PCI, there were no differences in the incidence of CI-AKI across 5 CM types (4 LOCM and 1 IOCM), despite a high prevalence of complex procedures and high CM volumes.

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Outcomes of percutaneous revascularisation of chronic total occlusions in patients with vs. without chronic kidney disease: the impact of contrast-induced acute kidney injury

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

AIMS

To study the outcomes of chronic total occlusion (CTO) percutaneous coronary intervention (PCI) in patients with vs. without chronic kidney disease (CKD), and the impact of contrast-induced acute kidney injury (CI-AKI).

METHODS AND RESULTS

We compiled a multicentre registry of patients undergoing CTO PCI at 5 centers. CI-AKI was defined as an increase in serum creatinine ?0.3 mg/dl or ?50% from baseline within 48 h. Study endpoints were CI-AKI, and all-cause death and target-lesion failure (TLF: cardiac death, target-vessel myocardial infarction, or target-lesion revascularisation) on follow-up. Study population included 1092 patients (CKD n=214, no CKD n=878). CKD patients had more comorbidities and adverse angiographic features, compared to no CKD subjects. CKD patients experienced lower technical (79% vs 87%, p=0.001) and procedural (79% vs 86%, p=0.008) success rates. CI-AKI developed in 9.1% (CKD 15.0% vs. no CKD 7.8%, p=0.001). Rates of in-hospital need for dialysis were 0.5% vs. 0%, respectively (p=0.03). Patients with CKD had higher 24-month rates of all-cause death (11% vs. 3%, p<0.001) and new need for dialysis (1% vs. 0.1%, p=0.03), but similar TLF rates (12% vs. 11%, p=0.47). CI-AKI was not an independent predictor of all-cause death or TLF.

CONCLUSIONS

CTO PCI in CKD patients is associated with lower success rates and higher incidence of CI-AKI. The need for dialysis both in-hospital and on follow-up is infrequent. Although CKD patients suffer higher rates of all-cause death, TLF rates are similar regardless of CKD status.

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Outcomes of a novel thin-strut bioresorbable-polymer sirolimus-eluting stent in patients with CTOs: a multicentre registry

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

AIMS

We aimed to evaluate the mid-term outcomes of a novel thin-strut bioresorbable-polymer sirolimus-eluting stent (BP-SES) in chronic total occlusion (CTO) percutaneous coronary intervention (PCI), as compared with durable-polymer everolimus-eluting stents (EES).

METHODS AND RESULTS

We compiled a multicentre registry of patients undergoing CTO recanalisation followed by BP-SES or EES implantation. The primary endpoint was the incidence of target-lesion failure (TLF, a composite of cardiac death, target-vessel myocardial infarction, and target-lesion revascularisation) at one year. Propensity score matching (PSM) was used to adjust for case mix. Overall, 413 patients were included (BP-SES n=242, EES n=171). PSM resulted in 131 matched pairs, which represented the subject of the main analysis. Antegrade wire escalation was the most successful crossing technique (66% vs. 63%, p=0.98) in both the BP-SES and EES groups, respectively. Procedural success rates were similar between groups (BP-SES 96% vs. EES 93%, p=0.24). At one-year follow-up, there were no differences in the primary endpoint of TLF (5.7% vs. 8.3%, p=0.44), and in cardiac death (0.9% vs. 2.8%, p=0.32), target-vessel myocardial infarction (0.9% vs 1.9%, p=0.57), target-lesion revascularisation (3.7% vs 3.7%, p=0.99), or stent thrombosis (0.9% vs. 1.9%, p=0.57), in BP-SES vs. EES, respectively.

CONCLUSIONS

Patients undergoing CTO PCI with BP-SES suffer a low rate of TLF at one-year follow-up, which is similar to that of subjects treated with durable-polymer EES.

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Organised thrombus is one of the major causes of resistance to PCI in hemodialysis patients: from an intracoronary imaging study of in-stent restenosis

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

AIMS

Aims: Even in new DES era, PCI with stent in hemodialysis (HD) patients has a higher repeat revascularization rate than in non-HD patients. However, the mechanisms remain poorly understood. This study aimed to elucidate the characteristics of in-stent restenosis (ISR) in patients with HD by intra-coronary imagings.

METHODS AND RESULTS

Methods: We analyzed intra-coronary imaging of 93 in-stent restenosis (ISR) lesions (BMS-ISR: 18%, DES-ISR: 78%) in 61 HD patients with 1st target lesion revascularization (TLR) from April 2013 to December 2017.
Results: Intra-coronary imaging of 27 lesions in 18 cases showed a mass protruding into the lumen with an irregular surface, high backscattering signal and attenuation by OCT (18 lesions), and/or a protruding mass with a superficial hyperechoic signal that exhibit posterior acoustic shadowing by IVUS (19 lesions). Histopathological finding in two coronary atherectomy specimens revealed calcified thrombus containing micro-calcifications and fibrinous materials. The time from stent implantation to detection of organized thrombus was 183±89 days (32 to 313 days). Prevalence of organized thrombus was significantly more frequent in RCA (18/45,40.0%) and LCX (6/12,50.0%) than LAD (3/32,9.4%, $p<0.003$ respectively), and tended to be higher after DES implantation (25/73,34.2%) than BMS (2/17,11.8%, $p=0.07$). Re-TLR rate was significantly higher after DES implantation (7/8,88%) than in non-DES strategy (4/12,33%, $p=0.02$).

CONCLUSIONS

Organized thrombus including calcified thrombus was detected at ISR lesions in about 30% of HD patients. DES may be responsible to create these organized thrombus in some HD patients.

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The impact of successful revascularisation of coronary CTO on long-term clinical outcomes in patients with non-STEMI

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

AIMS

The purpose of this study was to assess the long-term clinical impact of revascularization of coronary concomitant coronary chronic total occlusion (CTO) in patients with Non-ST-segment elevation myocardial infarction (NSTEMI). CTO is associated with poorer prognosis in patients with NSTEMI. The evidence of revascularization of CTO in patients with NSTEMI is still conflicting.

METHODS AND RESULTS

Consecutive patients with NSTEMI and CTO who underwent percutaneous coronary intervention (PCI) within 72 hours of admission from 2006 to 2015 were retrospectively recruited and analyzed. A total of 967 patients underwent PCI for NSTEMI. Among them, 106 (11%) patients had concomitant CTO and were recruited for analysis. CTO lesions were revascularized successfully in 67(63.2%) patients (successful CTO PCI group), while the CTO in the remaining 39 patients were either not attempted or failed (No/failed CTO PCI group). The 30-day cardiac death and major adverse cardiac events (MACE) were significantly lower in the successful CTO PCI group (both cardiac death and MACE were 3% vs. 30%,

CONCLUSIONS

Successful revascularization of CTO was associated with reduced risk of long-term cardiac death in patients with NSTEMI and concomitant CTO.

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Impact of high-intensity statin therapy on clinical outcomes in AMI patients undergoing PCI

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

AIMS

The routine practice of statin prescription in Asians is to start patients with lower doses of statins in most clinical settings compared with Western counterparts. Impact of high-intensity statin therapy on clinical outcomes in Asian acute myocardial infarction (AMI) patients undergoing percutaneous coronary intervention (PCI) has not yet been investigated.

METHODS AND RESULTS

We consecutively enrolled 8,890 acute myocardial infarction patients who successfully underwent PCI with the exclusive use of drug-eluting stents from January 2004 to August 2014 in COREA-AMI II registry. Patients were categorized into two groups based on the intensity of statin therapy: high-intensity statin group (atorvastatin 40-80mg, rosuvastatin 20-40mg, n=2,098) and moderate-intensity statin group (atorvastatin 10-20mg, rosuvastatin 5-10mg, n=6,792). Baseline characteristics were similar between groups. Primary outcomes was all-cause mortality. After adjusting covariates with multiple Cox hazard regression model, high-intensity statin treatment was associated with greater all cuase morality than moderate-intensity statin group (HR=1.44,

CONCLUSIONS

High-intensity statin therapy was associated with worse outcome in Asian acute myocardial infarction patients undergoing PCI. However, a large randomized controlled trial is needed.

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Single long stent vs. overlapping multiple stents in the management of very long coronary lesions: comparison of success rates and one-year clinical outcomes

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

AIMS

Different percutaneous coronary intervention (PCI) strategies including using the single long stent (SLS) and overlapping multiple stents (OMS) have been introduced to treat very long coronary lesions (VLCL). However, which of these two strategies provides better clinical outcomes is yet unclear. The aim of this study was to compare procedural and long-term clinical outcomes of SLS versus OMS in patients with VLCL.

METHODS AND RESULTS

In this cohort study, 1709 patients who underwent PCI by new generation of drug eluting stent(s) with length ? 38mm were stratified into SLS [Promus-Resolute-Xience (PRX), (=38 mm), n=1121, 65.59%, BioMime, (? 40mm), n=124, 7.26%] and OMS [(59.4±10.8), n=464, 27.15%] groups and followed for 441±361 days. The study endpoints included both immediate post-PCI outcomes, and major adverse cardiovascular event (MACE), patient-oriented composite endpoint (POCE) and device-oriented composite endpoint (DOCE) at long-term follow-up. TIMI Flow 3 (p=0.296) and residual stenosis (p=0.533) were statistically similar among all groups. A lower level of troponin was observed in BioMime [14.4(11)ng/L,

CONCLUSIONS

In the treatment of VLCL, SLS and OMS had similar clinical outcomes. BioMime ultra-long stents showed comparable results to PRX coronary stents.

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Endovascular treatment of concomitant lesions: aneurysm and stenosis of right renal artery

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

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Post-dilation in primary PCI in STEMI patients: safe for short term and beneficial for long term

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

To evaluate immediate angiographic and long-term clinical outcomes after stent post-dilation during primary percutaneous coronary intervention (primary-PCI) in patients with ST-elevation myocardial infarction (STEMI). Achieving optimal apposition of coronary stents during PCI is not always feasible. Despite the established role of stent post-dilation in elective-PCI, the risks and benefits of post-dilation in primary-PCI has remained controversial.

METHODS AND RESULTS

We studied a cohort of patients (n=1224) with STEMI, who were treated with primary-PCI (n=500 post-dilated, n=724 controls). Post-PCI TIMI flow grade, myocardial blush grade (MBG), and corrected TIMI frame count (cTFC) were considered as immediate angiographic outcomes. The primary clinical outcome was defined as major adverse cardiovascular events (MACE), including cardiac death, non-fatal MI, or repeat revascularization. The secondary clinical outcome was defined as device oriented composite endpoint (DOCE), including cardiac death, target lesion revascularization (TLR), or target vessel revascularization (TVR). TIMI and MBG were not different between two groups, and cTFC was significantly lower in post-dilated group (15.7±8.4 vs. 17±10.4,

CONCLUSIONS

Post-dilation improved some angiographic and clinical outcomes and should not be discouraged in primary-PCI on patients with STEMI.

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Effect of conduction dynamics after TAVI with first- and second-generation self-expandable valves on need for permanent pacemaker implantation

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

AIMS

We aimed to compare conduction dynamics and need for permanent pacemaker implantation after transcatheter aortic valve implantation (TAVI) with 2 consecutive generations of self-expandable valves.

METHODS AND RESULTS

All patients who underwent transfemoral or transsubclavian TAVI for severe aortic valve stenosis between January 2012 and July 2017 in our center were entered in our prospective database. We included patients in whom a 1st or 2nd generation self-expanding valve was implanted. Patients with a pacemaker at baseline or who died within 72 hours post TAVI were excluded from the analysis. Daily electrocardiograms were reviewed for conduction abnormalities and correlated to permanent pacemaker implantation.

TAVI was performed with either Medtronic Corevalve (N=111) or Evolut R (N=101). Patients were divided into two cohorts, Cohort A included patients with normal baseline conduction and Cohort B with baseline conduction abnormalities. Three different QRS-patterns were described: stable QRS-duration (QRS-prolongation after TAVI ? 20ms OR more than 20ms but never exceeding a total QRS-duration of 120ms), transient QRS-prolongation (>20ms post-TAVI, but recovery within 20ms before discharge) and persistent QRS-prolongation (QRS-prolongation >20 ms after TAVI which persisted at least up to discharge). For the comparison of continuous and categorical variables between the defined conduction patterns the unpaired t-test/non-parametric Mann-Whitney U test or Pearson ?2 test was used, respectively. A two-sided value of

CONCLUSIONS

The newer generation Evolut R was associated with less permanent pacemaker implantations than Corevalve and was especially apparent in patients without conduction disorders at baseline. Our findings may help identify eligible patients for early discharge.

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Meta-analysis design and results in real life: problem solvers or detour to maze. A critical review of meta-analysis of DAPT randomised controlled trials

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Meta-analyses that include the same randomized clinical trials should produce similar results. Our aim in this study was to analyze the quality and to compare the results of meta-analyses focused on dual antiplatelet therapy after percutaneous coronary intervention.

METHODS AND RESULTS

We searched all published meta-analyses published in 2015, selecting those that included the same randomized clinical trials comparing patterns of briefer versus longer?term double antiplatelet therapy. Seventeen meta-analyses achieved our selection criteria. Of the seventeen analyzed, we identified seven (41.1%) based on the same ten randomized clinical trials (RCTs), yet their results varied. Many of them differed in only some minor aspect of the design (i.e. eligible studies, length of comparators and statistical methods used). Some authors differed in the number of patients participating in RCTs and even, despite reviewing the same underlying trials, only 2 over 7 meta-analyses included the same number of patients. The final conclusions of the meta-analyses around cardiovascular, all-cause or non-cardiovascular death differ frequently.

CONCLUSIONS

In the DAPT duration setting, several meta-analyses have been recently published based on the same data, presenting several issues making it difficult to determine clear recommendations on certain points.

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Neurological disability of stroke after percutaneous LAA occlusion compared with warfarin

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

AIMS

The stroke after left atrial appendage (LAA) occlusion in patients with non-valvular atrial fibrillation (AF) has been reported infrequent and non-disabling. This study sought to investigate a neurologic disability after ischemic stroke (IS) in patients treated with LAA occlusion compared to those with conventional warfarin treatment.

METHODS AND RESULTS

Among 1,189 patients in Korean LAA occlusion and European Amplazter Cardiac Plug multi-center registry, total of 24 patients who experienced a IS after LAAO were included and their neurologic outcomes were compared with 68 of total 429 patients who had IS on warfarin. Disabling strokes were defined as strokes with modified Rankin score (mRS) of 3-6. The mRS was assessed at discharge, 3 months and 12 months after discharge and compared between 2 groups. The mean age and CHA2DS2-VASc score in LAA occlusion and warfarin group were 73.4±10.9 vs. 74.1±9.5 (P=0.76) and 4.7±1.6 vs. 4.4±1.8 (P=0.49). The proportion of disabling stroke was 37.5% and 58.8% at discharge (P=0.07), 20.8% and 42.6% at 3 months (P=0.08), and 12.5% and 39.7% at 12 months (P=0.02) in LAA occlusion and warfarin group, respectively. The mRS was significantly lower in LAA occlusion group at discharge, 3 month (P

CONCLUSIONS

Ischemic stroke in patients who received the percutaneous LAA occlusion in non-valvular AF might be more favorable compared with stroke on warfarin treatment.

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Gender-specific differences in outcome of patients undergoing transcatheter or surgical aortic valve replacement

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

AIMS

Differences in baseline characteristics and anatomy between female and male patients with aortic valve stenosis may influence outcomes after surgical and transcatheter aortic valve replacement (TAVR). This study aims to evaluate the effect of patient sex on in-hospital outcomes after transfemoral (TF-TAVR), transapical (TA-TAVR) or surgical (SAVR) aortic valve replacement in a real-world nationwide cohort.

METHODS AND RESULTS

Patient baseline characteristics and outcomes from all isolated TAVR or SAVR procedures performed between 2011 and 2014 in German hospitals were analyzed (N=64,794). Female patients were generally older and had a higher EuroSCORE. Thus, they were preferentially treated with TF-TAVR, whereas the share of TF-TAVR and SAVR was similar in males. Women suffered from more relevant bleeding after TF-TAVR and SAVR (adjusted for baseline characteristics TF-TAVR: OR 1.16, p=0.018, TA-TAVR: OR 0.98, p= 0.799, SAVR OR 1.12, p=0.005). In contrast, prolonged postoperative ventilation was less frequently necessary in females (adjusted OR TF-TAVR: 0.69, p<0.001, TA-TAVR: 0.69, p<0.001, SAVR: 0.76, p<0.001). Strokes were slightly increased among female patients undergoing TAVR. However, after adjusting female sex was associated with a decreased stroke risk (TA-TAVR: OR 0.60, p=0.001, TF-TAVR: OR 0.74, p=0.001, SAVR: OR 0.61, p<0.001). In-hospital mortality was slightly decreased in women undergoing TF-AVR after adjustment (OR= 0.87, p=0.047), but did not differ between sexes after TA-AVR (OR 0.96, p= 0.640) or SAVR (OR= 1.02, p= 0.807).

CONCLUSIONS

Since outcomes were similar between the sexes, gender is no decisive point that should influence therapy selection in patients with severe aortic valve stenosis.

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Risk factors and outcome of post-operative delirium after TAVR

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

AIMS

Aims Postoperative Delirium (POD) is associated with a worse postoperative course in patients after cardiac surgery, but its incidence and effects after TAVR are not well understood. The Aim of the present study was to analyze incidence, risk factors, and consequences for in-hospital outcomes of postoperative delirium after transfemoral (TF-AVR) and transapical (TA-AVR) transcatheter aortic valve replacement (TAVR) in a nationwide cohort.

METHODS AND RESULTS

Administrative data from all patients undergoing isolated TAVR in Germany in 2014 were analyzed. 9,038 TF-AVR and 2,522 TA-AVR procedures were performed. POD?s incidence was 7% after
TF-AVR and 12% after TA-AVR. Atrial fibrillation (TF: OR 1.35,

CONCLUSIONS

Patients with POD after TAVR are at increased risk for in-hospital mortality. However, after adjusting for postoperative events and co-morbidities, stroke and bleeding, but not POD, are independent mortality predictors

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Outcomes of TAVR for left ventricular outflow tract calcification: new-generation device vs. old-generation device

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

AIMS

This study aimed to compare the clinical outcomes of patients undergoing transcatheter aortic valve replacement (TAVR) for left ventricular outflow tract (LVOT) calcification.

METHODS AND RESULTS

Between January 2014 and July 2016, 433 patients with severe aortic stenosis treated with TAVR for LVOT calcification at our institute. Propensity score has been developed using a logistic regression model according to a nonparsimonious approach, and all clinical variables (age, gender, body surface area, hypertension, diabetes mellitus, peripheral artery disease, chronic obstructive pulmonary disease, ischemic heart disease, old myocardial infarction, prior coronary bypass graft, New York Heart Association functional class III or IV, prior cerebrovascular accident, eGFR, right bundle branch block, left bundle branch block (LBBB), atrial fibrillation, prior permanent pacemaker, mean gradient, left ventricular ejection fraction, aortic valve area, pulmonary hypertension, aortic annulus size, leaflet calcium volume, valve morphology, and the severity of LVOT calcification) as well as procedural data (transfemoral access and device type were included in the analysis. After propensity matching, assembling 130 pairs of patients with similar baseline characteristics. TAVR endpoints and adverse events were considered according to the Valve Academic Research Consortium-2 definitions. Compared with patients with old-generation valve (Edwards-SAPIEN/ SAPIEN XT/ CoreValve), patients with new-generation valve (SAPIEN 3/ Evolut.R) had more frequent early safety at 30-days (91.5% vs. 83.8%, p = 0.059) and a significantly lower paravalvular leak by transesophageal echocardiography (mild 16.9% vs. 25.4%, p=0.095, mild to moderate 1.5% vs. 8.5%, p = 0.010, ?Moderate PVL 2.3% vs. 4.6%, p = 0.55, respectively). Both generation valve had similar device success rate (new 92.3% vs. old 90.0%, p = 0.51). For conduction disturbance after procedure, there was no difference permanent pacemaker implantation between new generation valve and old generation valve (new 20.5% vs. old 18.7%, p=0.73). However, patients who developed new onset LBBB post-TAVR were higher in the new generation valve group (23.5% vs. 9.0%, p = 0.0014).

CONCLUSIONS

In the setting LVOT calcification, compared with TAVR with old generation valve, TAVR with new generation valve was associated with a similar device success rate and had a trend towards higher early safety at 30-days. However, new generation valve had higher conduction disturbance post TAVR.

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Neutrophil-to-lymphocyte ratio and mean platelet volume in predicting outcomes after primary PCI in patients with STEMI: what is better?

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Elevated neutrophil-to-lymphocyte ratio is an indirect marker of inflammation, and is associated with adverse clinical outcomes in patients with ST-segment elevation myocardial infarction (STEMI). Mean platelet volume is another inflammatory marker that has been used as a prognostic marker in STEMI after primary percutaneous coronary intervention (PCI) The aim of the present study was to investigate which is better to predict adverse events after primary PCI.

METHODS AND RESULTS

We have included 593 consecutive patients with STEMI submitted to pPCI between March/2011 and December/2017. Receiver operating characteristic (ROC) curve analysis was performed to calculate the area under the curve for the occurrence of procedural complications, in-hospital mortality and major adverse cardiovascular events (MACE).

Mean age was 60.98(±12.10) years, 66.4% were male, and neutrophil-to-lymphocyte ratio median was 6.2 and mean platelet volume median was 10.7. The area under the ROC curve for in-hospital MACE was 0.6 for neutrophil-to-lymphocyte ratio (CI95% 0.56, 0.64, p = 0.01) and 0.56 for mean platelet volume (CI95% 0.52,0.6, p=0.12).

However, when AUC`s were compared two-by-two with DeLong test, there was no statistically significant difference (p=0.44). In multivariate analysis only neutrophil-to-lymphocyte ratio (p=0.01) remained independent predictors of MACE.

CONCLUSIONS

Only neutrophil-to-lymphocyte ratio remained independent in-hospital MACE predictor, but with no difference in the ROC curve comparison with mean platelet volume. A low neutrophil-to-lymphocyte ratio has an excellent negative predictive value for in-hospital MACE and this might be of clinical relevance in the management of low-risk patients, besides compared to other inflammatory markers, is a simple and less time consuming test.

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Is the goal avoidance of leg amputation? The factor of improved quality of life among patients with critical limb ischaemia

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

AIMS

The ratio of avoidance of leg amputation was improved by bypass surgery and angioplasty among patients with critical lib ischemia (CLI), but improvement of prognosis and quality of life (QOL) are inadequate.
In patients with CLI, and it can be said to be the end stage of arteriosclerosis, so the ratio of ischemic heart diseases (IHD) and cerebrovascular disorders is high (CVD), and many cases become bedridden due to hospitalization. Many of these patients couldn?t go home.
We evaluated not only factors of lib salvage and all cause death but also factors of discharge to home.

METHODS AND RESULTS

The 156 patients with CLI who were treated from June 2012 until June 2017 in our institute were included in this study. Mean age was 72±11 years, 62.6% were male gender and 55.6% were end stage renal failure. Rutherford class was V or more in 64% of these patients. The factors of lib salvage, discharge to home and one year mortality among these cases were evaluated.
These patients were divided into two groups. Failure of discharge to home (FDH) group, n=46. Success of discharge to home (SDH) group, n= 110.
The frailty score in FDH group was significantly higher than SDH group.(6.1±0.8 vs 4.7±1.0, P

CONCLUSIONS

Frailty score was an independent predictor of failure of discharge to home and procedure success was an independent predictor of limb salvage. Frailty score, discharge to home, BMI and albumin had an association with one year mortality. But limb salvage and procedure success didn?t have an association with one year mortality. In order to improve the quality of life and prognosis, it is necessary not only to revascularization, but also a collective treatment such as improving Frailty, nutritional status, and establishing a system that allows discharge to home.

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Percutaneous vs. surgical revascularisation for left main or multivessel coronary artery disease: a meta-analysis of seven randomised trials

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

AIMS

Whether percutaneous or surgical revascularization represent the best treatment options for complex coronary anatomies, as left main (LM) or multivessel coronary disease (MVD), is still a debated matter, and uncertainty still remains after that trials with newer generations of drug eluting stents (DES) have been conducted. Aim of present study was to perform a meta-analysis of randomized trials comparing percutaneous vs surgical revascularization for LM or MVD.

METHODS AND RESULTS

Literature archives (MEDLINE, Cochrane and EMBASE) and main scientific sessions were scanned. Primary efficacy endpoint was long-term overall mortality. Secondary endpoints were major adverse cardiovascular events, recurrent myocardial infarction, repeated revascularization or stroke at maximum follow-up available.

A total of 8 randomized trials were finally included, involving 8694 patients, 50% undergoing PCI. At a mean follow-up of 39.7 months, mortality rate was 8.2%, with no difference for PCI vs CABG (OR[95%CI]=1.18[0.90,1.55], p=0.24, phet=0.01). However, a significant interaction was observed between revascularization strategy and coronary anatomy, with results slightly favouring CABG for MVD (OR[95%CI]=1.54[1.12,2.13],p=0.008,phet=0.14), while resulting non-inferior in LM disease (OR[95%CI]= 0.88[0.60,1.29], p=0.50, phet=0.10, p interaction =0.03).

No impact on mortality was observed according to patients? risk profile, the rate of diabetic patients or the occurrence of cardiovascular or cerebrovascular complications. A similar benefit with bypass surgery was also observed in terms of repeated coronary revascularization. On the contrary, PCI was associated with a significant reduction in the rate of stroke (OR[95%CI]=0.64[0.48,0.85], p=0.002, phet=0.80).

CONCLUSIONS

Current meta-analysis shows that surgical coronary revascularization still offers advantages in survival and recurrent ischemic events as compared to PCI with drug-eluting stents in patients with multivessel disease, although being burdened by an increased risk of stroke. However, in trials on left main coronary disease, CABG did not provide benefits in mortality and major adverse cardiac events, but was associated with a higher risk of stroke as compared to percutaneous revascularization. Future additional large randomized trials are certainly needed with new generation DES.

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Reduction in exposure of interventional cardiologists to ionising radiation over a 10-year period

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

AIMS

The aim of this study was to compare the dose of radiation received by interventional cardiology operators at 11 years? interval (2006 vs 2017).

METHODS AND RESULTS

The study population comprised all interventional coronary procedures performed by a single operator in one catheterization laboratory (cathlab) of a large university hospital in north-eastern France. Exposure was compared between two periods, namely period 1 (from October 2005 to March 2006) and period 2 (from March 2017 to June 2017). The primary endpoint was the dose of radiation received by the operator, measured using an electronic dosimeter placed on the operator?s left arm.

In 2017, the dose of radiation received by the operators was, on average, 95% lower than the dose received in 2006 (

CONCLUSIONS

The dose of radiation received by interventional cardiology operators has decreased by 95% over the last ten years.

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Effect of modern dose-reduction technology on the exposure of interventional cardiologists to radiation in the cathlab

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

AIMS

To estimate the average percentage reduction in the operator?s exposure to radiation that could be achieved using ClarityIQ dose-reduction technology in interventional cardiology.

METHODS AND RESULTS

The study population comprised all patients undergoing invasive coronary procedures over a four month study period in a large referral centre equipped with two catheterization laboratories (cathlabs). Both cathlabs (A and B) were equipped with the AlluraXper FD10 imaging system (Philips Healthcare, The Netherlands), but only cathlab B was equipped with ClarityIQ technology. The endpoint was operator radiation exposure, assessed using a personal electronic dosimeters located on the operator?s left arm.

In total, 577 invasive coronary procedures were analysed. Operators working in Cathlab B received on average 71% less radiation than those working in Cathlab A (

CONCLUSIONS

In our study, the use of ClarityIQ dose-reduction technology reduced the radiation dose received by the operator by 71%.

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Long-term survival benefit of CTO revascularisation vs. conservative treatment in elderly patients

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

To compare long term survival of CTO revascularization (PCI or CABG) versus medical treatment (MT) in the old population.

METHODS AND RESULTS

From 2010 to 2014, 1.252 patients with at least one CTO were identified (26% ?75 years). The received treatment (PCI, CABG or MT) and clinical variables were analyzed according to age (? or < 75 years). Global and cardiovascular (CV) mortality and rates of MACE were assessed during a median follow-up of 3.5 years.
Older patients were more commonly treated with MT (71 vs 43 %, p < 0.001).
Among patients ?75 years, 29% underwent revascularization. These subjects were younger, had higher LVEF and lower ACEF scores compared to the MT group (p< 0.05). Global mortality was lower with CABG or PCI compared to MT (HR 0.35, IC 0.17-0.71 and HR 0.57, IC 0.33-0.98, respectively). No differences in mortality were observed according to type of procedure. The intervention group had lower rates of MACE (HR 0.39, IC 0.22-0.68 for CABG and HR 0.48, IC 0.26-0.91 for PCI). CV mortality was lower in the CABG group (HR 0.39, IC 0.18-0.81) compared to MT. A non-significant reduction of CV mortality was also observed in the PCI group (HR 0.59, IC 0.28-1.2).

CONCLUSIONS

CTO revascularization (PCI or surgery) confers a prognostic benefit to the elderly and should not be withheld because of age.

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Endovascular treatment of complete occlusion of the superior vena cava with a novel dedicated venous stent: initial and mid-term outcome

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

AIMS

We aimed to assess early and mid-term outcomes of a novel dedicated nitinol venous stent (Vici, Veniti Fremont, CA, USA) for the treatment of complete (Type III and IV) superior venous cava obstruction (SVCO). The stent has closed-cell segments designed to provide strength and flexibility in the venous anatomy.

METHODS AND RESULTS

We retrospectively analyzed 19 patients (9 men, mean age 59 +/- 14) with symptomatic SVCO who underwent endovenous revascularization using the Vici stent between May 2016 and August 2017 at a tertiary. Etiology of SVCO included prolonged indwelling central venous catheter (n=17, 89.5%) and malignant expansive mediastinal disease (n=2, 9%). 96% of lesions were complete SVCO with mean lesion length of 66.6±16.4mm. There were 7 (33%) cases of non-Vici in-stent re-occlusion. Procedural success with deployment of stents in the intended position was 90% without complications. Angioplasty failed in 2 cases due to failure of guidewire crossing. One stent was implanted in each case with average diameter and length of 14.8mm and 65.7mm, respectively. The median follow up period was 12.7 months (interquartile range, 4.4 to 19.2 month) and all patients had complete follow up. Good clinical response with resolution of SVCO symptoms was observed in all (100%) successful cases at 30-days. One death occurred at 30-days due to sepsis unrelated to the index procedure. There were 2 cases of repeat intervention to maintain patency during the follow-up period for recurrent symptoms. Mean time to first re-intervention was 10 months. The primary patency, primary assisted patency and secondary patency rate were 90%, 100%, and 100% at 12 months.

CONCLUSIONS

The Vici venous stent offered a safe, effective and durable stent platform for the treatment of complex superior vena cava obstruction.

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A combination strategy of quantitative flow ratio and FFR derived from coronary CT angiography for management of coronary artery disease patients

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

The aims of this study were to investigate the diagnostic performance of quantitative flow ratio and FFR derived from coronary CT angiography (FFRCT) for detecting ischemia-causing coronary artery disease (CAD), and to evaluate the potential benefit of a combination strategy of QFR and FFRCT for management of CAD patients.

METHODS AND RESULTS

We retrospectively analyzed a total of 136 vessels in 89 patients who had undergone FFRCT assessment, invasive coronary angiography (ICA), FFR measurement and QFR analysis between July 2015 and September 2017. The diagnostic performance of QFR and FFRCT were evaluated using wire-based FFR as reference standard. QFR had a better correlation with FFR than FFRCT (r=0.86, p<0.001 vs. r=0.68, p<0.001). Applying the FFR cutoff value of ?0.80 to both QFR and FFRCT, higher accuracy, specificity, and positive predictive value was observed for QFR than FFRCT, 85% (95%CI: 78-89) vs. 71% (95%CI: 63-76), 85% (95%CI: 79-89) vs. 63% (95%CI: 57-67), 77% (95%CI: 69-83) vs. 59% (95%CI: 52-64), respectively. The best cutoff value of QFR and FFRCT for FFR ?0.8 was 0.81 and 0.74. QFR had a higher area under the curve (0.90, 95%CI: 0.84-0.96) than FFRCT (0.80, 95%CI: 0.73-0.88), using FFR cutoff value of ?0.80.

A combination strategy was evaluated using the results of this study, (1) an FFRCT value of >0.80 could be used to defer ICA (NPV of 85%), whilst an FFRCT value of ?0.80 could be used to perform ICA, (2) a QFR value of ?0.85 could be used to defer revascularization (NPV of 84%), whilst a QFR value of ?0.70 could be used to confirm treatment (PPV of 94%), (3) wire-based FFR would be measured in the vessels of QFR value between 0.71 and 0.84. By this combination strategy, ICA could decrease by 45% and the need for FFR measurement decrease by 68%. The agreement with an FFR-only strategy was 93%.

CONCLUSIONS

QFR showed better diagnostic performance to detect ischemia-causing CAD than FFRCT using FFR as reference standard. A combination strategy of QFR and FFRCT could decrease ICA and FFR measurement in good agreement with FFR-only strategy for CAD patients. Both virtual FFR have the potential as an alternative and less invasive method for estimating functional myocardial ischemia.

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Magnesium vs. polymeric BRS: in vivo OCT comparison of mechanical performance

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

AIMS

to evaluate acute mechanical performance of Magmaris scaffold in comparison to Absorb BRS.

METHODS AND RESULTS

two groups of 10 coronary lesions treated with Magmaris and Absorb 1.1 (20584 vs 21016 struts) were compared. In all cases, OCT images were acquired after scaffold deployment. Baseline clinical, angiographical and procedural characteristics were compared, including OCT evaluations. No baseline clinical or angiographical significant differences were found. Most common indication for revascularization was effort angina (60% vs 70%, p =0.45) with no STEMI cases. Main target artery was left anterior descending, with a mean vessel diameter of 3.46±0.23mm in Absorb and 3.52±0.19mm in Magmaris groups (p=0.56) respectively. All cases underwent pre and postdilatation with a procedural success rate of 100%. OCT analyses showed larger scaffold and vessel diameters in Magmaris group: 3.11±0.38mm vs 3.07±0.36 mm, p=0.03 and 4.12±0.51mm vs 4.04±0.46mm, p=0.04. Despite the application of slightly higher postdilatation pressures to Magmaris devices (18.01±2.15 atm vs 17.20±3.80 atm, p=0.05), significantly lower percentages of disrupted and malapposed struts were identified within Magmaris scaffolds (0.15% vs 0.27 %, p=0.03 and 1.06 % vs 1.46% p=0.01). No cardiac death, target-vessel related myocardial infarction or clinically-driven target lesion revascularization were reported at 30-days.

CONCLUSIONS

mechanical properties of Magmaris scaffold allow to achieve larger vessel and scaffold diameters in a safe manner, with lower rates of malapposition and scaffold disruption

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TAVI in low surgical risk patients: outcomes from an Israeli multicentre registry

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

AIMS

Background: Transcatheter aortic valve implantation (TAVI) is currently recommended in European practice guidelines for patients with intermediate to high risk for surgical aortic valve replacement. Our aim was to compare the efficacy and safety of TAVI in patients with low versus intermediate and high surgical risk.

METHODS AND RESULTS

Methods: We performed a retrospective analysis on an Israeli multicenter registry comprised of four tertiary centers. We defined patients with low surgical risk (LSR) as patients with a Society of Thoracic Surgery (STS) score of under 4, and patients with intermediate and/or high surgical risk (I-HLR) as patients with STS score ? 4.

Results: The study population included 2,336 patients (LSR n=1198, I-HLR n=1138). As compared to LSR patients with I-HSR had significantly higher rates of baseline comorbidities including older age (85 vs. 81 years), renal failure (86% vs. 63%), ischemic heart disease (57% vs. 50%), prior stroke (17% vs. 13%), peripheral vascular disease (18% vs. 8%), diabetes mellitus (44% vs. 32%), chronic obstructive pulmonary disease (21% vs. 11%) and were more often considered frail (31% vs. 18%), respectively (all

CONCLUSIONS

Conclusion: In spite of a higher calculated surgical risk for 30-d mortality, and higher rates of baseline co-morbidities, comparable rates of procedural and post procedural complications were observed for TAVI patients at LSR versus I-HSR.

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Safety and feasibility of a same-day discharge programme after PCI in high-risk patients

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

AIMS

Same-day discharge (SDD) after elective PCI have been developed with satisfactory outcomes. However a significant number of patients are excluded considered not appropriate regarded increased risk.
Objetive: SDD safety and feasibility after elective PCI in high risk patients.

METHODS AND RESULTS

Prospective, single center study conducted between November 2015 and March 2017. High risk patients were defined according to SCAI length of stay consensus statement (SDD-HR). A historical cohort of elective patients intervened between January 2009 and October 2015 (pre-intervention period) was compared with SDD program (intervention period) to evaluate safety. In order to evaluate feasibility the population was divided into two groups: same-day discharge (SDD) or overnight hospitalization (ON).
Results: 661 high-risk patients were included, representing 77% of the total population. Form those, 345 (52.1%) were discharged the same day (SDD group). Mean hospital stay showed a significant reduction in the group SDD (ON 19.4 h, IQR 17.2 - 22.7 vs. SDD 7.27, IQR 5.80 - 9.1,

CONCLUSIONS

High risk patients represent a significant proportion in our potential SDD population nowadays. SDD-HR becomes feasible and safe within the program. There are still barriers that we should work to select appropriate population.

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Actual management of patients with severe aortic stenosis in the TAVR era - Why AVR is denied (IMPULSE registry)

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

AIMS

Contemporary data on the presentation and management of AS patients are scarce. Aim of the present analysis was to explore patient characteristics of those with an unusual management decision, e.g. 1) severe symptomatic patients denied intervention (TAVI or SAVR) and 2) asymptomatic patients getting an intervention.

METHODS AND RESULTS

We conducted a prospective, multicentre registry in 23 centres across 9 European countries. Hospitals with all treatment options (SAVR, TAVI) on site were asked to consecutively enrol, over a 1 year period, patients with severe AS that presented with or without symptoms and to document their treatment decisions.

A total of 2,171 pts were enrolled of which 1,743 pts were classified as symptomatic (based on the presence of chest pain, shortness of breath and/or dizziness on exertion / syncope) and 428 pts presenting without symptoms.

23.8% of the 1,743 patients with severe symptomatic aortic stenosis were denied intervention and assigned to ?watchful waiting?, medical management or were not further discussed. Patients were slightly older (79.8 vs. 77.7 years,

CONCLUSIONS

The results illustrate non guideline-conform treatment decisions in 23.8% of symptomatic patients with severe AS that may have been inappropriately denied an intervention and in 40% of patients without symptoms that underwent an intervention. Surprisingly, in this later group there was no clear decision pattern except a higher rate of reduced LVEF and TAVI was the preferred choice.

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The impact of comorbidity on the presentation and management of aortic stenosis patients across Europe (IMPULSE registry)

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

AIMS

Representative contemporary data of the presentation and management of AS patients are scarce. We aim to evaluate the prevalence of comorbidities and impact on presentation and management in a large multicenter prospective cohort of AS patients.

METHODS AND RESULTS

We conducted a prospective, multicentre registry in 23 centres across 9 European countries, investigating the efficacy of facilitated data transfer (FDT) intervention in improving time to intervention in severe AS. Hospitals with all treatment options (SAVR, TAVI) on site were asked to consecutively enrol patients with severe AS over a 1 year period that presented with or without symptoms. Management and outcome were recorded. Comorbidities investigated were selected based on their prevalence and potential impact.

The enrolled 2,171 pts (77.9 ± 10.0 years, 48.0% women) had a high comorbidity burden, 27.3% had a creatinine clearance of < 50 ml/min, 15.9% atrial fibrillation (AF) and 11.4% presented with chronic lung disease (COPD) which were subgroups of interest for this analysis. The mean log. Euroscore I (ES) was 15.6 ± 13.9%. Across comorbidities patients were older, more likely female, more frail and presented with more symptoms with slight differences between the type of comorbidity.

In patients with a high ES and those with renal impairment cardiac comorbidity was more prevalent with more cases of MR, TR and a lower EF being reported. Patients with AF had a lower indexed AVA (0.37 vs. 0.40, p<0.001) and a lower transvalvular gradient (44.1 vs. 48.0%, p<0.001). Patients with AF reported more symptoms such as shortness of breath (79.5 vs. 70.5%, p=0.001) / NYHA III/IV (47.3 vs. 38.5%, p=0.004) as did patients with COPD (SOB: 88.1 vs. 70.2%, NYHA III/IV: 58.7 vs. 37.8%, both p<0.05).

TAVI was more often considered the treatment of choice in patients with one of these comorbidities compared to patients without (high ES: 58.7 vs. 32.9%, p<0.001, renal impairment 55.0 vs. 40.6%, p<0.001, AF 54.8 vs. 44.4, p=0.001, COPD 52.1 vs. 44.1%, p=0.027) and the proportion of TAVI performed within 3 months was higher (high ES: 51.8 vs. 25.6%, p<0.001, renal impairment 49.0 vs. 33.5%, p<0.001, AF 47.4 vs. 37.6%, p=0.002, COPD 44.2 vs. 37.3%, p=0.049).

CONCLUSIONS

In a contemporary cohort of patients, selected comorbidities such as renal impairment, atrial fibrillation and

chronic lung disease as well as the resulting higher EuroSCORE were associated with more symptoms and more cardiac impairment. Patients with such comorbidities were assigned more frequently to TAVI than surgery and the intervention was performed with a shorter delay. On the other hand a third of patients was declined to get any intervention.

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Gender differences in the presentation and management of aortic stenosis patients in Europe countries (IMPULSE registry)

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

AIMS

Many patients with severe aortic stenosis (AS) continue to present late with advanced symptoms and too often intervention is delayed and may be denied. The aim of the present analysis of the IMPULSe registry was to explore gender differences in the presentation and management of severe AS.

METHODS AND RESULTS

A prospective, multicentre registry was performed in 23 centres across 9 European countries, investigating the efficacy of facilitated data transfer (FDT) intervention in improving time to intervention in patients diagnosed with severe AS. Centres were included that were able to deliver all treatment options (SAVR, TAVI) on site and were asked to record presentation and management of patients with severe AS diagnosed on echocardiography over a 1 year period.

A total of 2,171 pts (80.3% being symptomatic) were enrolled of which 45.0% were assigned to TAVI, 24.0% to SAVR and 31.1% were not intervened. 1,041 (48%) of the enrolled patients were female. Female patients were older (79.5±9.5 vs. 76.4±10.2,

CONCLUSIONS

Contemporary data from major treatment centres across Europe showed that female patients with severe AS have a distinct patient profile and are managed in a different way to males with the same condition. Women present later, are at higher risk and are more often treated with TAVI than their male counterparts.

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Healing score and morphological vascular changes after treatment with DEB in STEMI lesions: OCT substudy from the PEBSI trial

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Recently, paclitaxel-eluting balloon (PTX-B) has demonstrated clinical benefits for the treatment of the patient with in-stent restenosis. However, there is few data of the vascular healing and morphological characteristics after the treatment of PTX-B in the context of ST-segment elevation myocardial infarction (STEMI).

METHODS AND RESULTS

The PEBSI study was a prospective, multicentre, randomized controlled trial which compared the use of PTX-B after bare-metal stent (BMS) implantation with BMS-only implantation in STEMI patients. Optical coherence tomography (OCT) was performed at nine-month follow-up in the first 20% of the patients. A total of 44 patients (19 patients in the BMS group and 25 patients in the PTX-B group) with OCT images suitable for analysis were included in this substudy. We evaluated the frequency of malapposition, uncovered stent strut, and intraluminal defect and assessed the healing score for each group. In addition, we evaluated the peri-stent ulcer-like appearance (PSUA) by OCT which is observed as hollow shape in the vessel wall adjacent to the stent struts. There was no patient with uncovered and malapposed struts in either group. The frequency of the uncovered and apposed struts was 0% in BMS group and 0.45±1.08 % in PTX-B group (p= 0.03). The frequency of the covered and malapposed struts was 0.36±1.00% in BMS group and 1.35±3.03% in PTX-B group (p=0.32). Intraluminal defect was not found in BMS group and only one patient (4%) in PTX-B group had small intraluminal defect (p=1.00). As a result, mean healing score in PTX-B group was significantly higher than that of the BMS group (2.26 vs. 0.36, respectively, p=0.021). In the same way, PSUA was more frequently observed in PTX-B group than in BMS group (36% vs. 5.3%, respectively, p=0.027).

CONCLUSIONS

Treatment of STEMI patients with PTX-B and BMS demonstrated lower healing score and higher rate of PSUA compared with that using BMS alone. Clinical relevance of these findings needs to be defined in larger trials.

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Comparison of two different radiofrequency ablation systems for renal artery denervation: evaluation of short-term and long-term follow-up

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

AIMS

Several systems are available for radiofrequency renal artery denervation. Whether there is a difference in clinical efficacy amongst various systems remains unknown. We aimed to assess the short-term and long-term clinical efficacy of renal artery denervation in our centre and to compare the efficacy of two different radiofrequency systems.

METHODS AND RESULTS

Renal artery denervation was performed on 43 patients with resistant hypertension using either the single electrode Symplicity Flex (n=20) or the multi-electrode EnligHTN system (n=23). The median post-procedural follow-up was 32.93 months. Primary outcome was post-procedural change in office blood pressure within 1 year (short-term follow-up) from baseline. Secondary outcomes were change in office BP between 1-4 years (long-term follow-up) and the difference in blood pressure reduction between the two systems at each follow-up period. For the total cohort, mean change in blood pressure (systolic/diastolic) from baseline was -19.70/-11.86mmHg ($p<0.001$) and -21.90/-13.94mmHg ($p<0.001$) during the short-term and long-term follow-up periods, respectively. The difference in blood pressure reduction between Symplicity and EnligHTN groups was -8.96/-1.23mmHg ($p=0.42$ for systolic blood pressure, $p=0.83$ for diastolic blood pressure) and -9.56/-7.68mmHg ($p=0.14$ for systolic blood pressure, $p=0.07$ for diastolic blood pressure) for the short-term and long-term follow-up, respectively.

CONCLUSIONS

In our cohort, there was a clinically significant BP reduction after renal artery denervation, which persisted up to 4 years. No significant difference in blood pressure reduction between the two systems was found

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Impact of direct TAVI without predilatation on procedural and clinical outcomes: insights from France TAVI registry

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

AIMS

During Transcatheter Aortic Valve Implantation (TAVI), a systematic aortic valve predilatation before valve deployment has been a mandatory step from the early days .However, the necessity of systematic BAV has been debated over the last years and is now avoided by most of the teams (DIRECT TAVI). Therefore, based on the large FRANCE TAVI registry we planned to describe the current practices and compare outcomes according to predilatation performed during the TAVI procedure.

METHODS AND RESULTS

For the purposes of this analysis, all patients included from January 2, 2013, to December 31, 2015, in FRANCE TAVI database were screened. Patients with missing data on valve type or approach (n =353) were excluded from the analysis. Following this step, patients without informations regarding the predilatation were excluded (n=6634). Then, we excluded patients with previous surgical aortic valve replacement (n=291). We separated the patients in two cohorts according to predilatation performed (CONTROL n=3205 (55.4%)) or no predilatation (DIRECT TAVI n= 2579 (44.6%)). The primary endpoint of the study was device success comparison in the 2 cohorts.

We observed a progressive decline of the use of BAV over time, starting in 2013 with 78% of procedures to 49% in the last trimester of 2015.

We observed significant differences between the 2 groups. Patients with DIRECT TAVI were younger (83.1±7.6 vs. 84.0±6.6) and frailer with higher critical preoperative state before procedure (8.2% vs. 5.9%), COPD (19.8% vs. 16.9%) and peripheral arterial disease (28.1% vs. 19.0%). Patients having a DIRECT TAVI had lower EF (54.4±13.7 vs. 56.6±13.2) and less severe aortic stenosis with lower gradients (45.6±15.0 vs. 48.7±15.6) and higher area (0.72±0.31 vs. 0.68±0.19).

No differences in valve type (DIRECT TAVI 69.3% Sapiens and 30.2% core valve vs. CONTROL 67.9% sapiens and 30.8% core valve) was observed between the 2 groups (p=0.55). The transfemoral route was more often used in the CONTROL group (86.1% vs. 82.9%).

DIRECT TAVI was associated with procedural simplification. Fluoroscopy time (17.2± 9.1 min vs. 18.5 ± 8.8), radiation dose (608.9 ± 576.3 vs. 667.0 ±631.3) and contrast load (131.5 ± 61.6 vs. 141.6 ± 61.5) were lower in the DIRECT TAVI cohort.

After the TAVI, patients who underwent a DIRECT TAVI procedure had lower post-operative ejection fraction and similar aortic surface and mean gradient. However the rates of AR>2 was significantly increased in case of predilatation (8.3% vs. 12.2%, p<0.01 after adjustment).

Primary endpoint and clinical outcomes:
The primary endpoint did not differ between the 2 groups (device success: 97.3% DIRECT TAVI vs. 97.6% CONTROL p=0.40).
Stroke, permanent pacemaker implantation, acute kidney injury, annular rupture were not significantly different between the 2 groups. However, tamponade was more frequently noted in case of predilatation (1.5% vs. 2.3%, p=0.04). This interaction was not significant after multivariable adjustment (p=0.25)

CONCLUSIONS
In conclusion, a DIRECT TAVI procedure is commonly performed nowadays in FRANCE and proved to be safe. This procedure is associated with benefits in terms of procedural simplifications and may be associated with improved outcomes related to reduction in residual aortic regurgitation and tamponade rates. Therefore, this strategy should be validated in a dedicated randomized trial.

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Percutaneous coronary revascularisation of severe coronary lesions in side branches vs. conservative treatment

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

AIMS

To analyse the percutaneous revascularization strategy for severe lesions in the side branches (diameter ?2 mm) of major epicardial arteries compared to conservative treatment.

Side branches (SB) are the less developed, smaller calibre branches of main coronary arteries that supply blood to a smaller area of the myocardium. Studies published on side branch lesion procedures focus on analysing the treatment of bifurcation lesions, however, for other contexts there are no available studies about the prognostic value of SB lesions.

METHODS AND RESULTS

This retrospective cohort study analyses patients with severe SB lesions in main epicardial arteries who underwent percutaneous revascularization treatment compared to patients who received pharmacological treatment. The study examined the percentage of branch-related events (cardiovascular death, myocardial infarction attributable to SB, or the need for revascularization of the SB).

We analysed 679 SB lesions (662 patients). Percutaneous treatment was used in 430 lesions (63.3%), whereas 249 (36.6%) of the lesions received conservative treatment. The lesions selected for PCI presented a larger reference diameter (2.57±0.34 mm vs. 2.31±0.17 mm,

CONCLUSIONS

The percentage of SB-related events during follow-up is low, with no significant differences between the two treatment strategies. In the multivariate analysis, the presence of diabetes mellitus and greater lesion length are the variables associated with event occurrence.

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Compendium of cardiology

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

AIMS

METHODS AND RESULTS

CONCLUSIONS

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LAA occlusion using the Amplatzer device - a single-centre eight-year experience

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

AIMS

Aims
To assess patient outcomes who have had left atrial appendage occlusion using an Amplatzer device at a single center from January 2010 to December 2017.

METHODS AND RESULTS

Methods: A retrospective review of all cases where an Amplatzer Cardiac Plug or Amulet device was implanted. All patients or their families were contacted telephonically if they were not followed up at Vergelegen Medi-Clinic.
Results:
86 patients went to theatre. 80 were in permanent AF, 6 paroxysmal AF
6 procedures abandoned in theatre
Attempted implants = 82
Total implants = 80 (Successful implant 97.5%)
Follow up on 78 patients (97.5%). 2 lost to follow up

Mean age = 75y. Median age 75y. Age range 52-87years old
Indications for laa occlusion: Contra-indication for oral anti-coagulant therapy (OACT) 56 patients (65%), high bleeding risk (Hasbled>3 or perceived high bleeding risk due to frailty and falls) 25 patients (29%), Life style choice 5 patients (6%).
Chads-Vasc = 3.8 (Expected stroke rate 4%/year)
Hasbled 3.1
Average hospital stay 1.1 days

Complications at 7 days
3 minor groin bleeds.
Zero strokes/TIA
One pericardial effusion was seen on review 2 weeks post implantation. No treatment necessary
Zero cardiac tamponade
Zero device embolization

Long term follow up:
Mean Follow up 4.8 years. Median follow up 2.6 years
Actual strokes = 6 (7.5%) over mean 4.8 years follow up.
Observed stroke rate/ year = 1.6% (7.5/4.8). Stroke risk reduced by 60%
Strokes occurred ? 2 patients in 1st year follow up, 1 -2years, 2-3years,1 in 4 years

Major bleeds requiring discontinuation of anti-platelet therapy in 8 patients within first month post implantation ? 1 x epistaxis,1x Subdural after fall, 5 x gastro-intestinal bleeding mainly due to underlying angio-dysplasia of the colon

Mortality at 7years (Mean follow up of 4.8years) = 19 (24%)

Mean age at time of death 78.1 years (67-85 years) Median 81 years

CONCLUSIONS

This single centre long term follow up of laa occlusion using the ACP/Amulet shows findings similar to other published registries of this device. It shows a high implant success rate with a very low (zero) 7 day complication rate. The long-term outcomes show an acceptably high mortality for patients of this age with underlying AF and multiple other medical problems. The stroke risk is calculated to be approximately 60% below that expected for the Chads-Vasc score ? a figure similar to the risk reduction of warfarin, with a very low long-term bleeding risk.

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The impact of aortic pulsatility ratio and double product on physiological indices of coronary stenosis in patients undergoing cardiac catheterisation

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

AIMS

Invasive physiological indices such as fractional flow reserve (FFR) and instantaneous wave-free ratio (iFR) are used in clinical practice to identify ischemia-causing epicardial stenosis. Increased aortic pulsatility (AP), a measure of aortic stiffness, is associated with worse outcome in patients undergoing coronary intervention. Double product (DO), an index of myocardial oxygen demand, is associated with increased incidence of myocardial infarction. The aim of this study was to explore if these haemodynamic indices are related to iFR and FFR.

METHODS AND RESULTS

We explored prospectively collected data on 256 vessels (220 patients, mean age 61±12, 77% males) with available pre-intervention FFR, iFR and haemodynamic variables. AP was derived by dividing aortic pulse pressure by mean pressure. Double product (DP) was calculated by multiplying invasively-measured aortic systolic blood pressure by heart rate.

Haemodynamically significant lesions were found in 51.5% and 40% for FFR and iFR respectively. Compared with normal IFR, patients with low IFR values had higher AP (0.70 vs. 0.63,

CONCLUSIONS

Prevailing haemodynamic conditions and myocardial metabolic demand may affect iFR, a basal index of stenosis as well as stenosis severity, but not FFR. These observations may be important in patients with elevated blood pressure and tachycardia undergoing cardiac catheterization and need to be explored in larger prospective studies.

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Safety and performance of a bioresorbable polymer, sirolimus-eluting stent in high-risk patients with renal insufficiency

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

AIMS

The prevalence of chronic kidney disease (CKD) among patients requiring revascularization is relatively high and CKD is associated with a high risk of adverse cardiovascular outcomes. Moreover, patients with CKD at all stages are at higher risk of atherothrombotic disease, also impacting the complexity and calcification of the lesion. We aimed to investigate the safe and effective use of the thin strut, abluminal-coated Ulitmaster stent in this high-risk subgroup of patients with renal insufficiency.

METHODS AND RESULTS

The e-Ultimaster registry is currently enrolling all-comer patients at 336 sites in 48 countries world-wide. These patients are treated with the sirolimus-eluting Ultimaster, a thin strut cobalt chromium stent, abluminally coated with a bioresoarbable polymer. Follow-up is ongoing and more than 10,000 patients will have a 1-year follow-up at time of presentation.

Currently 693 (7.8%) patients with renal insufficiency, defined as an estimated glomerular filtration rate (eGFR) of less than 60ml/min/1.73m², were treated and completed the 1-year follow-up visit. Overall, these patients were older (70.9 vs 64.1 years,

CONCLUSIONS

This analysis shows that patients with renal insufficiency have higher co-morbidities and more complex lesions. Although higher rates of (cardiac) death and MI at 1 year follow-up were observed, low revascularization, and particularly low ST rates indicate the good performance of the Ultimaster stent in this challenging patient population.

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Clinical outcomes after PCI with a bioresorbable polymer-coated stent in hypertensive patients

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

AIMS

To compare clinical outcomes of patients with hypertension and those without, both suffering from coronary artery disease (CAD) requiring PCI treatment and performed with a thin strut bioresoarbable polymer-coated stent.

METHODS AND RESULTS

e-Ultimaster is a large registry enrolling world-wide patients with coronary artery disease requiring PCI and treated with a thin strut sirolimus-eluting stent with abluminal biodegradable polymer coating. By the time of presentation, 1-year follow-up data will be available in more than 10,000 patients. The primary endpoint of target lesion failure (TLF) is defined as a composite of cardiac death, target vessel (TV) related myocardial infarction (MI) and clinically driven (CD) target lesion revascularization (TLR).

At baseline, 5378 (66.2%) of patients reported history of hypertension. Mean age (66.1 vs 61.9 years,

CONCLUSIONS

These results from a large world-wide registry show that patients with hypertension, despite the higher cardiovascular risk profile show similar clinical outcomes to patients without hypertension when treated with Ultimaster DES.

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Differential clinical outcomes between angiographic complete vs. incomplete coronary revascularisation, according to the presence of chronic kidney disease in the DES era

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

AIMS

Chronic kidney disease (CKD) is a significant prognostic factor after percutaneous coronary intervention (PCI), even in the drug-eluting stent (DES) era. However, there have been limited data regarding the prognostic impact of angiographic complete revascularization (CR) using DES in this population. We sought to investigate the differential prognostic impact of angiographic CR over incomplete revascularization (IR) in patients with multivessel disease, according to the presence of CKD in the DES era.

METHODS AND RESULTS

Consecutive patients with multivessel disease receiving DES between 2003 and 2011 were enrolled from the prospective PCI registry in Samsung Medical Center. Patients were stratified by the presence of CKD (estimated glomerular filtration rate < 60 ml/min/1.73 m2) and classified according to angiographic CR (residual Synergy between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery (SYNTAX) score=0) or IR (residual SYNTAX score>0). Clinical outcomes were compared between angiographic CR and IR, stratified by the presence of CKD. Primary outcome was patient-oriented composite outcome (POCO, a composite of all death, any nonfatal myocardial infarction (MI), and any revascularization) at 3-years. Inverse probability of treatment weighting was performed to adjust for baseline differences between the CR and IR groups. A total of 3,224 patients were eligible for analysis: 2,295 without CKD (647 of CR and 1648 of IR), and 929 with CKD (193 of CR and 736 of IR). Among non-CKD patients, angiographic CR showed a significantly lower risk of POCO than IR (17.2% vs. 21.7%, adjusted hazard ratio (HR) 0.76, 95% confidence interval (CI) 0.62-0.95, p=0.014), mainly driven by a significantly lower risk of any revascularization. Among CKD patients, however, angiographic CR was associated with a significantly higher risk of POCO than IR (37.7% vs. 28.4%, adjusted HR 1.42, 95% CI 1.08-1.85, p=0.011), mainly driven by a significantly higher risk of nonfatal target vessel MI.

CONCLUSIONS

Angiographic CR was associated with the reduced risk of POCO than IR in patients without CKD, however, it was associated with a significantly higher risk of POCO and nonfatal MI in the CKD population.

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Renal function-based contrast dosing to define "prognostic" contrast media limits in patients undergoing PCI

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

AIMS

Renal function-based contrast dosing minimises renal injury following percutaneous coronary intervention (PCI). The ratio (R) of contrast volume:glomerular filtration rate (CV:GFR) has previously been studied but its prognostic relevance is unknown. The aim of this study is to firstly, establish the relationship between R and mortality, and secondly, define a ?prognostic? threshold (RT) for contrast dosing in PCI for stable disease, non ST-elevation ACS (NSTEACS) and ST-elevation ACS (STEACS).

METHODS AND RESULTS

We evaluated 44,082 non-dialysis patients between 2008-2014 in British Columbia, Canada. GFR was calculated using the Cockcroft-Gault (CG), Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) and Modification of Diet in Renal Disease (MDRD) equations. R was determined for each patient and its relationship with 1-, 2- and 3-year mortality was modelled mathematically and analysed using Cox regression and adjusted receiver operator curve (ROC) analyses. RT was defined as the value of R at and beyond which there was a significant association with mortality.

Results demonstrated that increasing R values were associated with greater adverse patient, clinical and procedural factors. There was an exponential relationship between R and adjusted mortality. With every unit increase in R, mortality increased by 14-15% across regardless of indication for PCI. Adjusted multivariable models indicated that RT was consistently higher for stable patients and lower for patients presenting with acute coronary syndromes (ACS), with RT = 7.7-8.3 (stable), RT = 5.3-5.7 (NSTEACS), and RT = 5.3-5.7 (STEACS). These were comparable to RT values derived from adjusted ROC curve analyses with RT = 7.0-7.6 (stable), RT = 5.2-5.4 (NSTEACS), and RT = 5.2-5.7 (STEACS).

CONCLUSIONS

These data highlight the importance of using lower contrast volumes for PCI in accordance with international guidance. However, when evaluating mortality to define ?prognostic? contrast limits for PCI, the RT was 7-8 for stable disease and 5-6 for either NSTEACS or STEACS. These limits are greater than those previously recommended in studies evaluating renal function-based contrast dosing. This data has important implications in the current PCI era where increasing burden and complexity of PCI may require a greater contrast dose.

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Clinical and CT angiographic predictors for the new development of coronary CTO

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Percutaneous coronary interventions for CTO lesions are increasing, however the risk of procedural complications and modest success rate still remain as obstacles. Identifying risk factors for development of CTO can help to treat susceptible patients and lesions earlier, with reduced complication risk and higher success rate. In this study, we investigated the patient-level and lesion-level risk factors of CTO development by coronary CT angiography (CCTA).

METHODS AND RESULTS

We performed a retrospective medical record and image review of patients with at least 1 vessel of diameter stenosis equal to or more than 70% in coronary angiography (CAG), and with a CCTA performed more than 12 months prior to the CAG.

A total of 216 patients with a previous CCTA were analyzed, 32 patients had a CTO lesion in CAG (CTO group) and 184 patients had at least one vessel with stenosis ?70% (non-CTO group). For patient-level risk factors, we compared clinical and CT-angiographic factors at the time of CCTA between the CTO group and non-CTO group. The two groups had no significant difference in baseline clinical factors, including age, sex, smoking, history of previous myocardial infarction. In baseline CCTA factors, however, CTO group had more severely stenotic (stenosis ?70%: 40.6% vs. 11.5% for CTO and non-CTO groups, p = 0.001) and longer lesion (diffuse lesions: 31.2% vs. 6.0% for CTO and non-CTO groups, p <0.001) with plaque characteristics of more non-calcified plaques (non-calcified plaque 50.0% vs. 19.2%, for CTO and non-CTO groups, p for trend <0.001) and more positive remodeling (75.0% vs. 9.2%, for CTO and non-CTO groups, p <0.001).

We also performed in-depth analysis of baseline CCTA characteristics of a future CTO lesion and a future most stenotic non-CTO lesion in each patient of the CTO group, resulting in 32 paired analyses. Future CTO lesions had a longer plaque length (16.2±11.3mm vs. 10.0±7.7mm, p=0.019), smaller minimal lumen diameter (1.06±0.71mm vs. 2.15±0.85mm, p<0.001), larger remodeling index (1.19±0.21 vs. 1.06±0.10, p=0.018), and a lower plaque Hounsfield unit (34.3±23.6 vs. 228.6±269.1, p=0.001). Also, plaque characteristics analysis revealed a more non-calcified plaques (non-calcified plaque: 51.6% vs. 9.4%, for CTO and non-CTO lesions, p for trend=0.007), and less multiple calcifications in the CTO group (multiple calcifications: 43.8% vs. 84.4%, p=0.029).

CONCLUSIONS

From our analysis, lesions which progressed to CTO showed distinct lesion characteristics compared to lesions which did not progress to CTO. Future CTO lesions were more stenotic, longer in length, less calcific with lower attenuation, leading to more unstable lesions.

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Impact of arterial stiffness on spasm occurrence in coronary angiography procedures performed via radial route

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Vasospasm is the major determinant of not only technical ease and success but also patient comfort in coronary angiography (CAG) performed via transradial route. Various factors like female gender, low body mass index, utilization of several catheters with broader luminal diameters had already been established as predictors for spasm occurence. Here we aimed to assess the relationship between radial spasm (RS) and arterial stiffness (AS) measured with oscillometric method.

METHODS AND RESULTS

123 consecutive patients scheduled for elective CAG in a single referral center were enrolled for the study. Once a written consent was obtained, baseline features were noted and by utilizing a validated oscillometric device (Mobil-O-Graph NG 24 hour PWA: IEM, Germany), parameters related with AS (augmentation pressure, AP, augmentation index, AIx, pulse wave velocity, PWV) were measured. Moreover, central arterial pressure recordings and some additional hemodynamic data like cardiac output (CO), peripheral resistance (PR) were calculated by integrated algorhythms. In the cath-lab following local anesthesia left radial access (which is the default access site in our clinic) was achieved with a 21 G needle and a 6F sheath was inserted thereafter. 100 mcg of nitroglycerin and 50 U/kg unfractional heparin was admistered through the sheath preprocedurally. Number of puncture attempts, total procedural time, largest catheter size were noted. If > 2 catheters were required to complete imaging, it was additionally specified. RS was accepted as positive, if 2 or more of predefined features had been met. Statistically significant relationship between all these baseline, procedure related and oscillometry derived parameters and RS was investigated.

RS was observed in 20 patients (16,3%). Patients were assembled in two distinct groups regarding to occurence of RS. In the RS(+) group, proportion of hypertensive individuals were significantly higher, whereas smokers were less. With respect to operational data, total elapsed time (TET) (mins, 24.3±9.8 vs 29.3±9.1, p=0.038) and procedures carried out with >1 arterial puncture attempts (%, 15 vs 40, p=0.012) were significantly higher in RS(+) group. Among all oscillometric parameters, AP, AIx and PR were ones those found to be higher in RS(+) group (mmHg, 11.91 ± 8.55 vs 17.75 ± 10.64, p=0.011, %, 26,65 ± 13.02 vs 35.4 ± 14.02, p=0.008, and, s*mmHg/ml, 1.27 ± 0.27 vs 1.39 ± 0.28, p=0.024, respectively). Presence of hypertension, smoking status, repetitive puncture attempts, TET, PR, AP and AIx were parameters which were involved in univariate analysis. P values of smoking status, TET, repetitive puncture attempts and AIx were significant and thus were involved in multivariate analysis. Eventually, TET (p=0.029) and AIx (OR: 1.044, 95% CI=0.977 ? 1.117, p=0.009) were designated as independent predictors of RS.

CONCLUSIONS

Along with conventional risk factors, AS assessment -as a practical, non-invasive method-, may help predicting RS in angiographic procedures.

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Percutaneous vs. surgical repair of paravalvular leak

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

AIMS

The aim of this study was to compare the safety and efficacy of percutaneous versus surgical correction of paravalvular leak (PVL).

METHODS AND RESULTS

Medical records and echocardiographic data of consecutive patients who undertook surgical and percutaneous PVL closure between 2008 and 2015 were retrospectively analysed. The primary indication was PVL causing symptomatic anaemia or dyspnoea. Patients who had PVL secondary to infective endocarditis were excluded from this study.

The severity of PVL was defined as mild (1/4), moderate (2/4), moderate to severe (3/4) or severe (4/4). Procedural success was defined as a reduction in paravalvular leak to less than or equal to moderate (? 2/4). Other outcomes assessed were length of stay, 30-day and 1-year mortality.

A total of 43 consecutive patients underwent PVL repair. The average age of the surgical group was 62±15 years and 67±12 years in the percutaneous group. In the surgical group PVL occurred in the aortic position in 12 patients (50%) and in the mitral position in the remaining 12 patients (50%). In the percutaneous group PVL occurred in the mitral position in 16 patients (89%) and in the aortic position in 2 patients (11%). 10 (42%) patients in the surgical group underwent valve replacement as treatment for PVL while 14 (58%) underwent valve repair.
Procedural success was achieved in 23 of 24 patients (96%) who underwent surgical treatment and 18 of 19 patients (89%) who underwent percutaneous repair.

There was no 30-day mortality in the surgical group compared to 1 (5.6%) in the percutaneous group. The death in the percutaneous group was due to acute aortic regurgitation post transcatheter aortic valve replacement with PVL repair as a salvage procedure. 1-year mortality was 3 (12%) and 2 (11%) in the surgical and percutaneous group respectively. Length of stay in the percutaneous group was 17±15 days and 28±23 days in the surgical group ($p = 0.085$).

CONCLUSIONS

Percutaneous and surgical PVL repair were both associated with high rates of procedural success with shorter length of stay in the percutaneous group.

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Autologous blood reinfusion during iatrogenic acute haemorrhagic cardiac tamponade: safety and feasibility in a cohort of 30 patients

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

AIMS

Background: A rare, lifethreating complication of percutaneous cardiac intervention, is hemopericardium with cardiogenic shock. In these cases, prompt pericardiocentensis is mandatory. The blood aspirated can be reinfused into a central vein, to support the circulation and avoid a rapid fall of the hematocrit. However interventionalists are reluctant to reinfuse unfiltered blood, for the risk of hemocoagulative disorders and septic complications.

Aim of the study: to verify the feasibility and safety of autotransfusion, in case of cardiac tamponade caused by an interventional procedure.

METHODS AND RESULTS

Methods: we reviewed all the cases of tamponade occurred in our cath lab from 2007 to 2017, treated with immediate re-infusion of whole blood, with a closed circuit in a femoral vein. Clinical and procedural data were obtained from the review of the medical records. Thirty days and one year follow-up have been collected.

Results: During 10 years, 30 cases of iatrogenic hemopericardium, have been treated, in our institute, with blood reinfusion through a pericardial-femoral circuit. Twenty-one (70%) coronary perforations during angioplasty, 6 cases of rupture during structural procedures (4 TAVI, 1 PFO closure, 1 mitral valvuloplasty), 2 perforations of the right ventricle during biopsy, 1 case of VT ablation. Cardiogenic shock occurred in all the patients. Intra-aortic counter-pulsation was used in 4 cases, homologous blood transfusion in 6 patients. In 4 cases cardiac surgery was necessary to seal the bleeding site. During hospitalization there were two thrombotic events (a post-infarction left ventricular apical thrombosis and a pulmonary embolism in a bedridden patient). Four patients (13%) died at 30 days (3 in the cath lab), and a non-cardiac death occurred during one year follow-up.

CONCLUSIONS

Conclusions: Autotransfusion of whole blood from the pericardium into a femoral vein, in case of iatrogenic tamponade complicating interventional procedures, is feasible and safe. In our experience, it contributes substantially to the restoration of acceptable hemodynamic conditions, limiting the use of homologous blood transfusions and mechanical circulatory support.

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Long-term evaluation of predilation-sizing-postdilation BRS implant in real-world settings: the REABSORBS registry

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

AIMS

Evaluating long term outcomes of Predilation-Sizing-Postdilation (PSP) technique-implanted everolimus-eluted BRS Absorb in a real world setting

METHODS AND RESULTS

This registry includes all consecutive patients (pt) treated with BRS in our cath lab between December 2012 and March 2017.

Registered endpoints are: cardiac death (CD), target vessel myocardial infarction (TV-MI), scaffold thrombosis (ScT), target vessel revascularization (TVR), target vessel failure (TVF), ischemia-driven target lesion revascularization (ID-TLR).

AS is defined as: successful BRS deployment, residual stenosis (RS) < 30%, final TIMI 3 flow.

220 pt (58.6±9.5 years, male 85.5%, diabetics 15.9%) were enrolled, 253 PCI were performed (90.5% radial) on 321 lesions and 376 BRS were implanted.

166 PCI (65.6%) were performed in STEMI, NSTEMI or UA.

Stenoses were mainly on LAD (168, 52.3%), 210 lesions (65.4%) were Ellis type B2-C.

152 pt (69.1%) were on DAPT with ticagrelor, 35 (15.9%) with prasugrel, 33 (15%) with clopidogrel.

Preprocedural QCA showed a 83.7±15.2% diameter and 21.6±11.3 mm lenght stenosis and a 2.89±0.41 mm reference vessel diameter.

Predilation with non-compliant balloon (NCB) at 19.6±3.8 atm was performed in 366 cases (97.3%) with balloon-artery ratio 1:1 in 282 (77%).

After careful sizing BRS was released at 12.9±2.7 atm, BRS length per vessel was 32.7±18 mm, marker-to-marker BRS overlap was present in 84 PCI (22.3%), a DES-BRS overlap in 47 (18.7%). 17 PCI (6.7%) were IVUS or OCT-guided.

Postdilation with NCB at 21.8±4.2 atm was performed in 376 cases (100%), NCB was 0.5 mm oversized in 156 (41.5%).

At QCA no RS was >30%, there were 3 final TIMI flow < 3 (all in STEMI pts) and 1 BRS implant failure, leading to a 98.9% AS.

At a median follow up (FU) of 790 days (interquartile range 565 - 1157) in the overall cohort we had 2 CD (1%, both for heart failure), 6 TV-MI (2.7%), 13 TVF (5.9%), 11 TVR (5%), 6 ID-TLR (2.7%), 5 restenosis (2.3%), 2 very late definite ScT (0.9%) causing NSTEMI.

One ScT of a 2.5x28 mm BRS occurred at 20 months FU (Reference Vessel Diameter RVD 2.4 mm, final Minimum Lumen Diameter, MLD 2.1 mm), the other ScT of a 2.5x23 mm BRS occurred at 15 months FU (RVD 2.3 mm, final MLD 2.2 mm), DAPT was interrupted respectively 4 months and 1 week before events.

CONCLUSIONS

In our experience, with the limitations of a single center registry, Absorb PSP implant 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 26 months.

Extra caution should be given when dealing with 2.5 mm diameter BRS implanted in small vessels.

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Bioprosthetic valve performance after TAVR with self-expanding vs. balloon-expandable valves in large vs. small aortic valve annulus: insights from the CHOICE trial and the CHOICE-Extend registry

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

AIMS

The degree of transcatheter heart valves (THV) oversizing varies according to the annulus size, and this could modify the hemodynamic performance of self-expanding and balloon-expandable transcatheter heart valves (SE- and BE-THVs). We sought to compare SE- and BE-THVs in large vs. small aortic valve annulus.

METHODS AND RESULTS

Patients undergoing transcatheter aortic valve replacement in the randomized CHOICE trial (CoreValve-CV, n=120 and Sapien XT-SXT, n=121) and the non-randomized CHOICE-Extend registry (Evolut R-ER, n=100 and Sapien 3-S3, n=334) were compared for THV performance by echocardiography and by cardiac magnetic resonance imaging-regurgitation fraction (MRI-RF). Patients were stratified according to aortic valve annulus mean diameter into large (>23 mm) or small annulus (?23 mm). Transvalvular mean pressure gradient was lower in CV and ER than in SXT and S3 in both large and small annulus groups. In the randomized CHOICE trial, moderate-severe prosthetic valve regurgitation (PVR) was more after CV than SXT in large (15.1% vs. 0.0%, p=0.002, MRI-RF: 10.5±10.2 vs. 4.4±4.5%, p=0.036) but not in small annulus (0.0% vs. 5.7%, p=0.50, MRI-RF: 4.0±4.1 vs. 4.0±3.4%, p=0.98). In the CHOICE-Extend registry, moderate-severe PVR occurred in 2 patients, and any PVR was not significantly different between ER and S3 in large (41.7% vs. 32.5%, p=0.24) or in small annulus (47.1% vs. 43.8%, p=0.84). MRI-RF was not different in large annulus (5.0±3.8 vs. 5.0±6.1%, p=0.99) but was significantly lower after ER than S3 in small annulus (2.9±2.3 vs. 4.8±3.7, p=0.023).

CONCLUSIONS

Older generation BE-THV was associated with less PVR than SE-THV in patients with a large but not in small annulus. The next generation SE-THV has an improved sealing in patients with a large annulus, and may have potential advantages in patients with a small annulus.

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Prevention of the radial artery occlusion during percutaneous coronary procedures: head-to-head comparison careful standard approach vs. Turned-TR Band technique

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

AIMS

The study sought to evaluate the real incidence of the radial artery occlusion (RAO) comparing our standard procedural approach with prophylactic ipsilateral ulnar artery compression after radial artery hemostasis using a simple, cheap and easily repeatable technique (named ?Turned-TR Band?).

METHODS AND RESULTS

From April to August 2017 131 patients undergoing cardiac catheterization using TRA were randomized to receive either standard hemostasis protocol [Control Group (CG)](69 patients) or prophylactic ipsilateral ulnar artery compression following standard hemostasis procedure [Turned TR-Band Group (TTR-B)](62 patients). Specifically, in the TTR-B group we performed a standard 2 hours mechanical radial artery pressure using the TR-BandTM (Terumo Corp. Tokyo, Japan) followed by simple turning of the same device to compress selectively ipsilateral ulnar artery for another 2 hours, with the intent to reach a reversal blood flow current through the radial vessel. In both groups we used a high puncture site (over 4 cm proximal to radial styloid process), twenty-five-centimeter-long 6-F hydrophilic introducer sheaths, correct anticoagulation with unfractionated heparin (70 u.i./kg), careful modes and times of compression (standard two hours from the sheath?s removal). Eco-Doppler analysis to evaluate radial artery patency, visual caliber assessment and Doppler spectrum with peak systolic velocity (PSV) was performed before TRA and the following day. The primary endpoint, incidence of RAO, was abolished in TTR-B group (0%) with only 1 case (1,4%) in the CG. The contingency table resulting in the RAO distribution has 50% of cells with values lower than 5, making the standard categorical test such as Chi-square and Fisher test hard to be applied. PSV value at Doppler analysis measured the day after the catheterization was: 93,6 cm/s in the CG, versus 90,1 cm/s in TTR-B group. A t-test on the fold change among the PSV values for PRE/POST treatment showed no statistical significance on the induction of PSV (p-value: 0.57), even the mean of fold change values were lower in the TTR-B group (0.91 vs 0.93), indicating a slightly stronger repression of PSV. Vessel caliber reduction, evaluated in the puncture site, was 12,7% in the CG, versus 6,3% in TTR-B group. A Fisher test on the contingency table for vessel caliber reduction (8 vs 61 in CG, 4 vs 58 in the TR group) resulted in 0.51 odds ratio (less likely in TTR-B group) but had p-value too high to be considered significant (0.37).

CONCLUSIONS

The TRA performed with our standard procedural protocol (high puncture site, 6-F hydrophilic introducer sheaths, correct anticoagulation with unfractionated heparin, careful modes and times of compression) resulted in a very low incidence of RAO (1,4%), as one of the lowest one among those described in the literature.

Therefore, a careful radial artery approach and a correct post-procedure management could minimize the RAO?s incidence. Due to this performance, prophylactic ipsilateral ulnar artery compression with ?Turned TR-Band technique? after TRA has not been able to show a statistically significant reduction of the RAO?s incidence. However, a slight trend towards lowering of PSV with a less likely vessel caliber reduction in puncture site in the TTR-B group (even if not statistically significant due to the narrowness of the sample), could impact on a better vessel preservation which may reduce the risk of RAO in everyday practice.

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Predictors of thrombus in patients with stable coronary artery disease: an OCT study

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

The pathophysiology of coronary atherosclerosis has undergone significant changes in paradigms during the past decades. In this context, the optical coherence tomography (OCT) played a crucial role in clarifying the mechanisms of coronary artery disease (CAD) and guiding the treatment. Furthermore, it represents the gold standard for intra-coronary thrombus detection.

In this OCT study, we aim at assessing the features of the coronary plaques and the presence of intra-coronary thrombus according to the stenosis degree, in a population of patients with stable CAD and 1 vessel disease.

METHODS AND RESULTS

We have prospectively enrolled 166 consecutive patients who met the following inclusion criteria: diagnosis of stable CAD, 1-vessel-disease at coronary-angiography and OCT evaluation of the lesion. The patients were divided in three groups according to the percentage of area stenosis (AS) degree: 23 patients (14%) with AS

CONCLUSIONS

In this study we demonstrated that, in a population of stable CAD: patients with AS>50% showed a higher frequency of lipid plaque and features of intra-coronary thrombus, compared to those with AS

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FFR post intraluminal vs. subintimal tracking in PCI for coronary CTO

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

In percutaneous coronary interventions (PCI) for chronic total occlusions (CTO), dissection re-entry techniques use the subintimal space for lesion crossing and subsequent re-entry into the true lumen, while wire escalation tries to follow an intraluminal course. The aim of this study was to compare the functional result of intraluminal versus subintimal tracking during CTO PCI as measured by fractional flow reserve (FFR).

METHODS AND RESULTS

This was a single centre prospective observational study. Patients who underwent CTO PCI of the right coronary artery (RCA) were included. FFR was performed immediately post successful PCI and at three months follow up.

24 patients (mean age: 61.4±9.9 years, males: 88%) with successful RCA CTO recanalization underwent FFR measurements both at the end of the index procedure and at 4-month follow up. Intra-luminal tracking (antegrade or retrograde wire escalation) was the successful technique in 62.5% of the cases and subintimal-tracking (antegrade or retrograde dissection re-entry) in 37.5%. There was no difference between the two groups regarding baseline demographics including age, sex, presence of diabetes mellitus and pre-procedure LV ejection fraction. Cases successfully recanalised with intraluminal-tracking had a significantly lower J-CTO score compared to cases recanalised with subintimal-tracking techniques (mean J-CTO score: 1.4 ± 1.2 vs. 2.9 ± 1.3, p= 0.01). There was no difference regarding the use of intracoronary imaging (60% vs. 66%, p=0.5) or the vessel size distal to stented segment as measured by QCA (1.99 ± 0.58 mm vs. 2.10 ± 0.47 mm, p=0.6) between the two groups. The subintimal-tracking group had significantly higher total stent length (87.9 ± 19.7 mm vs. 58.1 ± 32.1 mm, p=0.01). FFR in the intraluminal tracking group post PCI was 0.84 ± 0.08 and significantly increased to 0.90 ± 0.04 at 3-month follow up (p=0.01). In the subintimal group, FFR at the end of PCI was 0.82 ± 0.11 and 0.87 ± 0.10 (p=0.08) at follow-up. The final 4-month follow-up FFR was numerically higher in the intraluminal group, but this difference was not statistically significant (0.90 ± 0.04 vs. 0.87 ± 0.01, p=0.5).

CONCLUSIONS

Patients undergoing successful CTO PCI with subintimal techniques had higher J-CTO score and required longer length of stents. At 4 months follow-up, FFR increased significantly in the intraluminal group with an incremental trend in the subintimal group. Although, the intraluminal group had numerically higher FFR at both index procedure and 4-month follow up compared to the sub-intimal tracking group, this difference was not statistically significant.

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Distal vessel remodelling post PCI for CTO

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Percutaneous recanalization of a coronary chronic total occlusion (CTO) re-establishes antegrade blood flow, leading to restoration of impaired vasomotion function and positive vascular remodelling. The aim of this study was to evaluate the changes in vessel diameter distal to the stented segment post CTO PCI immediately after the index procedure and at four-month follow-up.

METHODS AND RESULTS

This was a single centre prospective observational study. Patients who underwent PCI for a CTO of the right coronary artery (RCA) were included. Mean lumen diameter (MLD) distal to the stent was calculated by quantitative coronary angiography (QCA) post index procedure and at follow-up. Measurements were performed up to 5mm from the distal end of the stent. Luminal gain (LG) in the distal reference segment, defined as an increase in lumen diameter from post-procedure to follow-up was assessed.

34 patients underwent successful recanalisation of an RCA CTO. Mean age was 62 ± 10 years old, 88% were male, 21% were smokers, 26% diabetic and 62% of the patients had a previous myocardial infarction. Viability in the RCA territory was confirmed by cardiac magnetic resonance imaging in all patients. Mean left ventricular ejection fraction was 51% ± 20. Antegrade wire escalation was the successful recanalization technique in 56% of the cases, antegrade dissection re-entry in 12% and retrograde techniques in 32%. Biodegradable-polymer Sirolimus-Eluting Stents were used in all cases. Mean diameter of stents used was 2.84mm ± 0.47 and mean length of stented segment 71.4mm ± 30. The mean lumen reference diameter distal to the stent increased significantly at follow-up from 2.01 ± 0.53 to 2.51 ± 0.43 mm ($p = 0.0002$) with a mean luminal gain of 0.5 mm ± 0.52. Luminal gain in the distal reference segment was observed in 86% of the patients

CONCLUSIONS

Post chronic total occlusion percutaneous coronary intervention, distal vessel diameter increased significantly at 4 months follow-up compared to measurements post index procedure. This has implications on vessel sizing during stent implantation and further stent optimisation.

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Efficacy of excimer laser coronary angioplasty in patients with ACS

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

AIMS

Previous studies demonstrated that excimer laser coronary angioplasty (ELCA) was useful procedure for patients with acute coronary syndrome (ACS). However, the efficacy and the safety of ELCA have not been fully elucidated. The purpose of this study was to evaluate the effectiveness and the safety of ELCA as a primary treatment strategy in patients with ACS.

METHODS AND RESULTS

From September 2016 to May 2017, a total of 71 consecutive patients with ACS (66+- 12years, 78.8% male) who underwent percutaneous coronary intervention (PCI) were included in this study. Among these patients, 31 patients were treated with ELCA (ELCA group) and 40 patients were treated with aspiration (non-ELCA group). We evaluated thrombolysis in myocardial infarction (TIMI) flow, myocardial blush grade (MBG) and procedural complications.

In ELCA group, onset-to-arrive time was significantly longer (7.0, 2.5-72 vs 2.3, 1.0-5.5, P=0.003) and the frequency of direct stenting was significantly higher (60.0% vs 20.0%, P=0.0005). Achievement of TIMI 3 flow was not statistically different between the 2 groups (ELCA group, 87.1% vs non-ELCA group, 77.5%, P=0.29). The rate of MBG 3 tended to be higher at the final angiogram in ELCA-group (64.5% vs 45.0%, P=0.10). There were no significant differences between 2 groups in procedural complications.

CONCLUSIONS

ELCA might be an effective and safe revascularization modality for patients with ACS.

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Aberrant right subclavian artery occlusion - Endovascular stenting in two cases

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

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Endovascular repair of subclavian artery aneurysm

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

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Impact of stenting strategy for ostial lesion of left anterior descending artery

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

Stent deployment in ostial lesion of left anterior descending artery (LAD) is challenging.
The preferable stenting strategy is not well known.
The aim of this study was to clarify the impact of stenting strategy for ostial lesions of LAD on clinical outcomes.

METHODS AND RESULTS

From January 2012 to December 2016, 229 consecutive patients who had ostial lesion of LAD had treated with second generation drug-eluting stents. Seventy nine patients had treated with left main trunk (LMT) crossover stenting, and 150 patients had treated with LAD just proximal stenting.
We defined the ostial lesion of LAD as the significant stenosis within 5mm from ostium of LAD. The cases which also had significant stenosis in LMT were excluded.
We compared the two year clinical outcomes between the LMT crossover stenting group and the LAD just proximal stenting group.
The 2-year survival rate showed no significant difference between two groups (96.1% vs 95.6%, p=0.96).
The cumulative target lesion revascularization rate was significantly lower in LMT crossover stenting group than in the LAD just proximal stenting group (0% vs 7.9%, p=0.03).
The cumulative revascularization rate for ostium of left circumflex artery was no significant difference between two groups (5.1% vs 1.2%, p=0.10)
Stent thrombosis was not observed in two groups.

CONCLUSIONS

Our data indicate that LMT crossover stenting may be more beneficial in treatment for ostial lesion of LAD.

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Treatment of bifurcation lesions with a thin-strut DES with bioresorbable polymer ? long-term clinical outcome of the century II trial

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

Our aim was to compare the long term 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 enrolled in a randomized trial.

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 (TV-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: 36.0±17.5 mm vs 34.11±23.4 mm (p=0.03), respectively. Clinical outcomes at 4 years for patients treated with BP-SES when comparing with PP-EES showed significantly lower rate of cardiac death (0% vs 5.1%, p=0.03). The rate of TLF and target vessel failure (TVF) was 7.4% vs 11.1% (p=0.37) and 8.4% vs 13.1% (p=0.29) 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 XX1 (so-called ?true bifurcation?) lesion, the TLF in BP-SES at 4 years was 2.5%, while in PP-EES groups it was 13.9% (p=0.07). Five years clinical outcome will be available at the time of EuroPCR2018.

CONCLUSIONS

Both stents showed good clinical outcomes up to 4 years with a trend favoring BP-SES in true bifurcation lesions, suggesting the potential benefit of Ultimaster stent in the treatment of complex bifurcation lesions.

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The impact of body mass index on clinical and limb outcome in patients with peripheral artery disease after endovascular treatment

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

AIMS

Obesity has been traditionally considered as risk factor of atherosclerotic disease. However, there are few data for the clinical impact of body mass index after peripheral artery angioplasty. We investigate the relationship between body mass index (BMI) and mid-term outcomes of patients with peripheral artery disease after endovascular treatment.

METHODS AND RESULTS

Among total 3073 patients in the Korean Vascular Intervention Society endovascular therapy in lower limb artery disease registry (K-VIS ELLA), 2910 patients were analyzed for this study. The patients were divided into groups based on BMI < 18.5kg/m2 (underweight, n=202), 18.5 to 24.9kg/m2 (normal weight, n=1813), and > 25.0kg/m2 (overweight, n=895). The endpoints were major cardiovascular event (MACE, a composite of all cause death, myocardial infarction and stroke) and major adverse limb events (MALE, a composite of major amputation and reintervention). The median follow up duration was 697 days (interquartile 300-964 days). 3 year MACE free survival rate were 76.5%, 83.6%, and 88.7% in underweight, normal and overweight patients, respectively (log rank p-value <0.001). 3 year MALE free survival rate were also significantly lower in underweight patients compared with normal and overweight patients (74.1%, 86.7% and 85.6%, log rank p-value =0.022). Older age, chronic kidney disease, diagnosis of critical limb ischemia and underweight are significantly associated with MACE. However, underweight was not a significant risk factor for MALE in multivariate cox-regression analysis.

CONCLUSIONS

Underweight was a significant independent predictor of MACE in patients with peripheral artery disease after endovascular treatment. However, BMI did not predict a prognosis of MALE.

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Effect of evolocumab therapy on fibrous cap thickness in coronary atherosclerotic plaque as assessed by OCT

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Fourier shows PCSK9 inhibition with evolocumab significantly & safely decreased outcomes at LDL-C levels of 30 mg/dL and major cardiovascular events when added to statin therapy.However, the effects of these drugs on coronary atherosclerosis have not been evaluated.

METHODS AND RESULTS

The aim of this study was to assess the effect of PCSK9-inhibitor(statin plus evoclomub,either 140mg every 2 weeks) versus standard statin monotherapy on fibrous cap thickness and plaque volume in coronary atherosclerotic plaques by using optical coherence tomography (OCT) at 4 weeks and 3 months after drug eluting stent implantation. 40 patients(with De-novo coronary artery disease) receiving elective PCI were enrolled from November 2016 to May 2017. Statin plus evolocumab and statin monotherapy group were implanted in 7 patients , and 33 patients, respectively. OCT was performed to assess intermediate nonculprit lesions at baseline ,4 and12 weeks follow-up. Serum LDL-c level was singnificantly lower during therapy with statin plus evolocumab compared with statin monotherapy(31mg/dl ,82mg/dl,P

CONCLUSIONS

Statin plus evolocumab provided a greater increase in fibrous cap thickness in coronary plaques compared with statin monotherapy. The increase of fibrous cap was associated with the decrese in serum LDL-c during evolocumab therapy.

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A patient with bilateral total occlusion of the subclavian and iliac arteries, abdominal aorta and left main coronary artery

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

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Impact of optimised procedure-related factors in DEB angioplasty for treatment of in-stent restenosis

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

AIMS

Although drug-eluting balloon (DEB) angioplasty is recommended as a reasonable option for in-stent restenosis (ISR), recurrent target lesion failure (TLF) still occurs in many patients after DEB angioplasty. We sought to investigate the impact of optimizing procedure-related factors during DEB angioplasty on clinical outcomes of ISR occurred in drug-eluting stent (DES).

METHODS AND RESULTS

Consecutive patients with DES-ISR treated with DEB (SeQuent® Please) were collected from four centres in South Korea. Primary outcome was 2-year TLF. Procedure-related modifiable independent predictors for TLF and their best cut-off values were determined.

In a total of 256 patients (309 lesions), TLF occurred in 52 patients (20.3%). Modifiable independent predictors of TLF among procedure-related factors were residual diameter stenosis after lesion preparation (residual %DS), DEB-to-stent ratio (BSR), and DEB inflation time (Tinflation), whose best cut-off values were 20%, 0.91, and 60 seconds, respectively. TLF rates were significantly higher in groups with residual %DS?20% (34.7% vs. 12.5%, adjusted hazard ratio [HRadjust] 2.15, 95% CI 1.86-2.48,

CONCLUSIONS

Residual %DS after lesion preparation, BSR, and Tinflation were only modifiable procedure-related factors in DEB angioplasty. The optimization of DEB angioplasty with perfect lesion preparation until residual %DS0.91 and prolonged inflation with Tinflation>60sec would reduce recurrent lesion failure and improve clinical outcomes in an unselected population with DES ISR.

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Cangrelor in ticagrelor-loaded STEMI patients undergoing primary PCI: a randomised, pharmacodynamic study

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

The intravenous P2Y12 receptor antagonist cangrelor provides rapid onset and offset of platelet inhibition. In clinical outcome studies cangrelor has been compared with clopidogrel but not prasugrel or ticagrelor. A randomized, pharmacodynamic comparison between a cangrelor involving strategy and an oral, fast-acting, P2Y12 receptor antagonist has not yet been reported.We aimed to compare the antiplatelet action of cangrelor plus ticagrelor with ticagrelor alone in ST-segment elevation myocardial infarction (STEMI) patients undergoing primary percutaneous coronary intervention (PCI)

METHODS AND RESULTS

In a prospective, 3-center, single-blind, parallel-design study, 30 patients loaded with ticagrelor 180 mg were randomized to either cangrelor (30 ?g/kg bolus + 4 ?g/kg/min infusion for 2 h) or no additional P2Y12 receptor antagonist. Platelet reactivity (VerifyNow P2Y12 function assay) was assessed at randomization (time 0), 15 min, 1 h, 2 h and 4 h.

The primary endpoint of platelet reactivity in P2Y12 reaction units (PRU) at 15 min was lower for cangrelor plus ticagrelor (104.6, 95% confidence interval [CI]: 70.8 to 138.5) versus ticagrelor alone (238.4, 95% CI: 204.5 to 272.2) with a least squares mean difference (95% CIs) of 133.8 (85.5 to 182.0),

CONCLUSIONS

In STEMI patients undergoing primary PCI a strategy involving cangrelor on top of ticagrelor provides peri-procedurally faster and stronger platelet inhibition than ticagrelor loading alone

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Status of percutaneous treatment of congenital and acquired ventricular septal defects in a congenital heart disease reference centre

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

AIMS

Ventricular septal defect (VSD) is the most common congenital heart disease accounting for approximately 20% of defects in isolation. Correction treatment is needed in case of synthomatic patients (heart failure) or asynthomatic patients with QP/QS > 1.5 so as to prevent further complications. Percutaneous closure is feasible in muscular defects (congenital or adquire defects) perimembranous defects and defects following cardiac surgery (aortic valve replacement). The purpose of this paper is to report on the current status of percutaneous closure of VSDs in our center.

METHODS AND RESULTS

Between February of 2000 and December of 2017 we have performed 20 procedures of percutaneous closure of VSD in a total of 9 pediatric (mean age 4.5) and 9 adults patients (Mean age 61,9). Among the pediatric population were 4 (44,4%) patients with muscular defect , 3 (33,3%) with perimembranous defect and 2 (22,2%) of them with postoperative residual defect. 4 patients had associated other congenital heart diseases including 2 arch aortic interruption, 1 Fallot Tetrallogy an 1 atrial septal defect).In adult population, 2 (22,2%) had perimembranous congenital defect, 2 (22,2%) postinfarct defect and 5 of them postoperative residual defect (3 following aortic valve replacement, 1 after Konno type surgery and 1 of them after ventricular wall repair secondary to myocardial infartion).

All the procedures were performed with double (arterial and venous) approach under echocardiographic monitoring .In the mayority of patients we used the traditional technique which consists in stablishing a wire arterio-venous loop . A guidewire is passed from the left ventricle (LV) through the VSD and advanced to the pulmonary artery, it is captured with a gooseneck loop and externalized into the right femoral vein to form an arteriovenous circuit. From the femoral vein through the externalized guidewire, a carrier catheter was advanced through the VSD to the LV to implant a device without interfering with the aortic or the tricuspid valve. Only in 1 of pediatric patients we used a perventricular access at the same time the Cardiac Surgeon was repairing the aortic arch. Device placement was successful in 16 of 18 patients (88,9%). 2 pediatric patients failed the attempt due to inability of achieve a good device position and other 2 adults patients needed their device to be retrieved surgically due to hemolysis. In all of the patients except one we used Amplatzer devices (10 Muscular Occluder, 3 Membranous Occluder, 4 Duct Occluder, 1 Cribiform), in the last patient we used a Nit Occludder device. Serious adverse events were encountered in 3 patients , 2 complete heart block (1 of them 24 hours after the procedure and the other 10 months later) and 1 retroperitoneal haemathoma. We followed up all the patients, with clinical improvemnent in the majority of them and only 1 death that was a patient refered to the procedure in cardiogenic shock after cardiac surgery.

CONCLUSIONS

In the current era and in experienced centres, percutaneous VSD closure provides a valuable alternative to surgery even in cases with complex morphology and in very young children. Finally, due to the late occurrence of cAVB, careful monitoring of rhythm and atrioventricular conduction is essential during follow-up, especially in the case of subjects treated for a perimembranous VSD.With new devices such as Nit Occludder the rate of heart block could be reduced but with a small increase of haemolysis.

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Silent coronary artery disease in patients with rheumatoid arthritis: a pilot study

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

AIMS

Objectives: To determine the silent coronary artery disease (CAD) in cohort of Iraqi Kurds patients diagnosed with rheumatoid arthritis (RA).

METHODS AND RESULTS

Methods and results:A total of 50 such patients without clinical evidence of CAD were evaluated appropriately, and had their coronary calcium and angiograms using multi slices computed tomography (MSCT) 64 slices. Coronary artery calcium (CAC) score > zero found in 31(62%) of cases. Coronary angiograms showed variable coronary lesions in 26 (52%). 17(34%) of them were obstructive (>50% luminal narrowing). Predictors including chronicity of disease, positive rheumatoid factor, anticyclic citrullinated peptide (anticcp), HTN, DM, dyslipidemia were significantly associated with CAD in these patients ($p<0.05$). After adjusting for above predictors the RA was independently related to CAD (3.11 (95% CI 1.26?5.43).

CONCLUSIONS

Conclusion: Patients with rheumatoid arthritis are at increased risk of silent CAD. This risk is independent of traditional cardiovascular risk factors. Follow up of such patients is warranted.

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Favourable effects of revascularisation on glucose, lipid metabolism, and muscle volume in peripheral artery disease by endovascular therapy

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

AIMS

Aims) Peripheral artery disease (PAD) is caused by atherosclerosis in lower extremities in patients with hypertension, dyslipidemia, and diabetes. PAD impairs quality of life and decreased activity predisposes patients to future cardiovascular events. The aim of this study was to explore the effect of endovascular therapy (EVT) on glucose and lipid metabolism as atherosclerotic properties, and muscle volume as mobility surrogate marker in PAD patients..

METHODS AND RESULTS

Methods) Symptomatic PAD patients with ilio-femoral lesions were enrolled. Ankle brachial index (ABI), 75g-oral glucose tolerance test (75gOGTT), and serum lipid profile were measured before EVT and 6 months after. Thigh muscle volume was measured by computed tomography.

Results) A total of 10 patients were enrolled. Seven patients were with ipsilateral and 3 were with bilateral stenosis. ABI significantly increased in the treated legs after EVT from 0.81±0.04 to 1.07±0.05. Blood glucose level at two-hour value significantly decreased (182.5±57.0 mg/dl vs 163.7±60.9 mg/dl, p=0.04). The level of high-density lipoprotein level significantly increased (42.4±5.2 mg/dl vs 47.0±7.4 mg/dl, p=0.04) whereas the level of low-density lipoprotein did not. Among apolipoproteins, apolipoprotein A-?as a representative anti-atherosclerotic marker significantly increased (119.0±18.2 mg/dl vs 127.8±16.8 mg/dl, p=0.00). The muscle volume of diseased leg was significantly smaller than of disease-free leg in ipsilateral PAD patients (663.80±171.76cm2) before EVT. The muscle volume of treated legs significantly increased than of the non-treated legs (270.05±183.32cm 2 vs -140.76±114.84cm 2, p=0.03) after EVT.

CONCLUSIONS

Conclusions) EVT improves glucose and lipid metabolism, and promotes increasing thigh muscle volume.

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Successful interventional therapy of acute upper limb ischaemia

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

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Impact of residual stenosis on the angiographic edge restenosis of second-generation DES (a quantitative coronary angiography from the post-marketing surveillance studies of cobalt-chromium everolims-eluting stent in Japan)

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

AIMS

Edge restenosis has gathered focus as a main cause for restenosis after 1st generation drug-eluting stents (DES) implantation. The aim of this study was to assess the incidence of edge restenosis and to detect predictors for edge restenosis after 2nd generation DES implantation in routine clinical practice.

METHODS AND RESULTS

1,977 lesions (72.0%) in 1,696 patients from several post marketing surveillances (PMS) of 2nd generation DES, cobalt-chromium everolimus-eluting etent (CoCr-EES [Xience V/PROMUS, Xience Prime, Xience Prime SV, or Xience Expedition SV]) at 58 centers in Japan were analysed in this study. In CoCr-EES PMS in Japan, quantitative coronary angiography (QCA) were conducted in an independent corelab, at pre- and post-procedure and 8-month follow-up with subsegmental analysis: in-stent region, proximal and distal edges. Restenosis rate of in-stent region, proximal and distal edges at follow-up were 4.1%, 3.2% and 1.4%, respectively. Late loss of in-stent region, proximal and distal edges were 0.23 ± 0.42 mm, 0.14 ± 0.43 mm and 0.03±0. 38mm, respectively. Probabilities of restenosis were compared between proximal and distal edges by multivariable adjusted logistic regression models including each lesion as a random effect. Risk of restenosis in distal edge was significantly lower than that in proximal edge (odds ratio [OR] 0.15 95% confidence interval [CI] 0.07 to 0.32 p=45°, stent overlap, hypertension, previous CABG, insulin treated diabetes, previous PCI, hemodialysis, moderate/severe calcification, age and male. Univariate and multivariable analysis of the 13 variables described above were performed in each subsegment. Multivariable analysis showed that post %DS (OR 1.05 95%CI 1.02 to 1.08 p=

CONCLUSIONS

Multivariable analysis of 8-month angiographic outcomes from the CoCr-EES PMS demonstrated higher restenosis risk in proximal edges than distal edges. Post %DS would be a main predictor for edge restenosis in the real-world setting. Edge restenosis might be attributed to angiographic results post-procedure rather than patient backgrounds.

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The prognostic role of coronary response to nitrate in patients with suspected vasospastic angina comparison with ergonovine provocation test

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

AIMS

Ergonovine provocation test has shown high sensitivity and specificity for the detection of vasospastic angina (VSA). However, the rate of undergoing ergonovine provocation test is quite low because it is time consuming with some risks. In real world clinical practice, VSA is assumed by coronary response to nitrate. In this study, we test the role of coronary response to nitrate in patients with suspected vasospastic angina and compare with ergonovine provocation test.

METHODS AND RESULTS

A total 438 consecutive patients underwent ergonovine provocation test for the diagnosis of VSA. Significant nitrate induced coronary vasodilation(NICV) was defined as >50% increase in luminal diameter after intracoronary nitrate compared with baseline diameter. The definition VSA was defined as coronary artery spasm (CAS, >70%) by intracoronary ergonovine injection with chest pain or ECG change.

Coronary response to ergonovine showed significant week inverse correlation with coronary response to nitrate (r=-0.318, p<0.001). Patients with VSA (n=51) had a significantly greater coronary response to ergonovine (-84.3±10.5 % vs -38.4±17.9 %, p<0.001) and nitrate (26.3±31.0 % vs 12.5±19.0 %, p<0.001) than in no VSA patients. In receiver operating characteristic curve analysis, coronary response to nitrate showed a weak accuracy for the diagnosis of VSA (AUC 0.64, p=0.001). During the mean follow-up period of 22.6±21.4 months, MACE (cardiac death, acute coronary syndrome, fatal arrhythmia and syncope) occurred more frequently in VSA group than non VSA group (n=5, 9.6% versus n=8, 2.2%, p=0.014). However, there were no significant difference between both groups according to nitrate induced coronary vasodilation group (n=1, 3.1% versus n=12, 3.0%, p=0.536).

CONCLUSIONS

In suspected VSA patients, coronary response to nitrate is a potential predictor of a positive ergonovine provocation test. However, our findings indicate NICV cannot replace ergonovine provocation test in real practice and has limited clinical relevance in predicting MACE in suspected VSA patients.

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Comparison of transradial vs. femoral access in contemporary real-life PCI practices ? data from a large worldwide registry

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

AIMS

To compare the procedure and one year outcomes of patients treated using transradial vs femoral approach in a large all-comer registry representative of contemporary real-life PCI practice.

METHODS AND RESULTS

We analysed data of patients enrolled worldwide and received Ultimaster DES in the large multicentre e-ULTIMASTER registry. Ultimaster is a thin strut (80um) cobalt chromium stent coated with sirolimus-eluting bioresorbable polymer. In order to reduce baseline differences between patients treated using radial and femoral access, we applied weighted propensity score matching (PSM) method for this comparison.

Among patients who have been enrolled in e-Ultimaster registry and reached 1 year follow up, 1364 belong to femoral (FEM) group and 7324 belong to radial (RAD) group. Baseline characteristics in the two groups were comparable after weighted matching. The mean patient age was 65.1 years and 74.6% were male patients in both groups. In both groups, 31% were diabetic and 20% current smokers. At enrolment, 52% of patients presented with acute coronary syndrome, 20% in either group with ST segment elevation, while 28% had a history of previous PCI. The number of treated lesions was 1.42±0.70 per patient in both groups with 51% of patients having multi-vessel disease. Regarding lesion complexity, 60.3% of patients in FEM group and 61.6% of patients in RAD had complex lesions (type B2+C), 16.3% patients in FEM group and 14.6% in RAD group were treated for bifurcation, and 20% of patients in both groups had moderate to severely calcified lesions.

At the time of hospital discharge, more patients in FEM group had experienced bleeding (1.4% vs 0.4%,

CONCLUSIONS

These data from a large registry showed a high penetration of radial access in contemporary PCI practice. As expected, radial access showed favourable results over the femoral approach when considering in-patient bleeding and access site complications. One year clinical outcomes also showed a trend toward lower total death and revascularization rates in radial group. Our observations confirmed the benefits of the radial approach that is reported in literature.

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Effectiveness and safety of potent P2Y12 inhibitors among stable CAD patients undergoing PCI in routine clinical practice

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

While potent P2Y12 inhibitors reduce major cardiovascular events among patients with acute coronary syndromes, the safety and efficacy of these drugs among patients with stable CAD is not well established.

METHODS AND RESULTS

This study included all consecutive patients with stable CAD who were discharged on dual antiplatelet therapy (DAPT) enrolled into the BERN PCI Registry from August 2009 to September 2016. Bleeding risk was retrospectively assessed using the PRECISE DAPT score. Clinical outcomes were prospectively assessed including device oriented endpoint (DOCE) (cardiac death, target-vessel MI and target lesion revascularization) and BARC 2-5 bleeding.

A total of 4,257 stable CAD patients were discharged on DAPT of whom 20% (n=846) of patients received potent P2Y12 inhibitors (i.e. prasugrel or ticagrelor) and 80% (n=3411) received clopidogrel according to operator?s discretion. The duration of potent P2Y12 treatment was 1 year in 86.3% of patients (n=730) and less than one year in 13.7% of patients (n=116), whereby 67 patients thereof were de-escalated from potent P2Y12 inhibitor treatment to clopidogrel. Patients discharged on potent P2Y12 inhibitors were characterised by a higher stent-related recurrent ischemic risk (multivessel treatment: 40.9% vs. 28.0%, p<0.01, >=3 stents implanted: 43.1% vs. 23.3%, >=3 lesions treated: 25.3%% vs. 13.9%, p<0.01, bifurcation treatment with >=2 stents: 12.4% vs. 4.9%, p<0.01, total stent length >60mm: 35.5% vs. 14.2%, p<0.01, CTO treatment: 13.1% vs. 6.7%, p<0.01) and a lower bleeding risk (PRECISE DAPT Score: 16.9±10.9 vs. 20.3 ± 12.6, p<0.01).

DOCE at one-year was higher among patients treated with potent P2Y12 inhibitors (13.2% vs. 8.1%, HR: 1.7, 95% CI: 1.4-2.1, p<0.001), which was driven myocardial infarction (10.2% vs. 4.7% p<0.001) and TLR (5.9% vs. 2.7%, p<0.001). BARC 2-5 bleeding occurred at a similar frequency (3.1% vs. 3.4%, HR: 0.9, 95% CI: 0.6-1.4, p=0.65). The occurrence of definite stent thrombosis was largely confined to patients treated with potent P2Y12 inhibitors (2.0% vs. 0.4%, HR: 4.6 95%CI: 2.3-9.3, p<0.001).

CONCLUSIONS

Potent P2Y12 inhibitors were administered to one fifth of stable CAD patients undergoing elective PCI in this large scale registry. Patients allocated to DAPT with potent P2Y12 inhibitors were characterized by a higher risk of stent-related ischemic events and a lower bleeding risk. Although DOCE occurred more frequently among potent P2Y12 recipients, the risk of bleeding was similar. Against the background of similar safety, prospective randomized investigation of the efficacy of potent P2Y12 inhibitors compared with clopidogrel among patients with stable CAD seems warranted.

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Prognostic impact of beta-blocker dose after AMI

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

AIMS

The differential prognostic impact of beta-blocker dose after acute myocardial infarction (AMI) has been under debate. The current study sought to compare clinical outcome after AMI according to dose of beta-blockers using the Korea Acute Myocardial Infarction Registry-National Institutes of Health (KAMIR-NIH).

METHODS AND RESULTS

Among the total population of 13,104 consecutive AMI patients enrolled in the KAMIR-NIH, the current study analyzed 11,909 patients. These patients were classified into 3 groups (no beta-blocker, low dose [

CONCLUSIONS

The use of beta-blockers, regardless of administrative doses, in post-AMI patients showed significant survival benefit compared with the no use of beta-blockers. However, among patients taking beta-blockers, the high dose group showed higher mortality than the low dose group.

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Prognostic implication of thermodilution coronary flow reserve in patients with indeterminate pressure-bounded coronary flow reserve

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Recently, the concept of pressure-bounded coronary flow reserve (PB-CFR) has been introduced. However, using pressure-only data, a substantial proportion of patients could not be classified into high or low PB-CFR and remained as indeterminate PB-CFR. The current study evaluated the prognostic implication of thermodilution-based CFR (thermo-CFR) in patients with indeterminate PB-CFR.

METHODS AND RESULTS

Among 199 patients (211 lesions) who were classified into indeterminate PB-CFR, the rates of patient-oriented composite outcomes (POCO, a composite of all-cause mortality, any myocardial infarction, and any ischemia-driven revascularization) were compared according to thermo-CFR. All patients underwent fractional flow reserve (FFR) and thermo-CFR measurements. Thermo-CFR ?2.0 was classified as low thermo-CFR. The median follow-up duration was 1350.0 (Q1-Q3 1252.0-1468.0) days. Mean angiographic percent diameter stenosis, FFR, and thermo-CFR were 45.3± 15.4, 0.82 ± 0.08, and 2.99 ± 1.16, respectively. Among 199 patients, 48 patients (24.1%) showed low thermo-CFR. Patients with low thermo-CFR showed significantly higher rate of POCO compared to those with high thermo-CFR (27.1% vs. 6.0%, HR 5.121, 95% CI 2.188-11.986,

CONCLUSIONS

Patients with low thermo-CFR showed a significantly higher risk of POCO compared to those with high thermo-CFR among patients with indeterminate PB-CFR. Thermo-CFR showed additional prognostic implication, in addition to FFR, in patients with indeterminate PB-CFR.

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Prognostic impact of multivessel PCI in STEMI patients with cardiogenic shock

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Recent trials demonstrated benefit of multivessel percutaneous coronary intervention (PCI) for non-infarct-related artery (non-IRA) stenosis than IRA-only PCI in ST-segment elevation myocardial infarction (STEMI) multivessel disease patients. However, evidence is limited in patients with cardiogenic shock. We investigated the prognostic impact of multivessel PCI in STEMI multivessel disease patients presenting with cardiogenic shock, using a nationwide, multicenter, prospective Korea Acute Myocardial Infarction-National Institutes of Health (KAMIR-NIH) registry.

METHODS AND RESULTS

Among 13,104 consecutive patients enrolled in the KAMIR-NIH registry, we selected STEMI patients with multivessel disease presenting with cardiogenic shock and who underwent primary PCI. Primary outcome was 1-year all-cause death, and secondary outcomes included POCO (patient-oriented composite outcome, a composite of all-cause death, any myocardial infarction, and any repeat revascularization) and its individual components. A total of 659 patients were treated by multivessel PCI (n=260) or IRA-only PCI (n=399) strategy. The risk of all-cause death and non-IRA repeat revascularization was significantly lower in the multivessel PCI group than in the IRA-only PCI group (21.3% vs. 31.7%, hazard ratio [HR] 0.59, 95% confidence interval [CI] 0.43-0.82, p=0.001 and 6.7% vs. 8.2%, HR 0.39, 95% CI 0.17-0.90, p=0.028, respectively). Results were consistent after multivariable regression, propensity-score matching, and inverse probability weighting to adjust for baseline differences. In multivariable model, multivessel PCI was independently associated with reduced risk of 1-year all-cause death and POCO.

CONCLUSIONS

Of STEMI and multivessel disease patients with cardiogenic shock, multivessel PCI was associated with significantly lower risk of all-cause death and non-IRA repeat revascularization. Our data suggest that multivessel PCI for complete revascularization is a reasonable strategy to improve outcomes in STEMI patients with cardiogenic shock.

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Comparison of long-term clinical outcomes between revascularisation vs. medical treatment in patients with silent myocardial ischaemia

CHOI S. H. (1), LEE J. M. (1), RHEE T. M. (2), HWANG D. (2), PARK Y. H. (2), KOO B. K. (2), PARK Y. H. (1), YANG J. H. (1), SONG Y. B. (1), HAHN J. Y. (1), CHOI S. H. (1), GWON H. C. (1), PARK Y. H. (3)

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

There have been limited and conflicting results regarding the prognostic impact of revascularization treatment on the long-term clinical outcomes of asymptomatic patients with objective evidence of inducible myocardial ischemia in non-invasive stress test and significant angiographic stenosis. The current study aimed to determine whether revascularization treatment compared with medical treatment (MT) alone reduces long-term risk of cardiac death of asymptomatic patients with objective evidence of inducible myocardial ischemia in non-invasive stress test and significant angiographic stenosis.

METHODS AND RESULTS

Between October 2003 and December 2015, 1,473 consecutive asymptomatic patients with object evidence of inducible myocardial ischemia in non-invasive stress tests including exercise-stress electrocardiography, exercise or pharmacologic-stress echocardiography, or single-photon emission computed tomography, were selected from a prospective institutional registry in Samsung Medical Center. All patients showed at least 1 epicardial coronary stenosis with ?50% diameter stenosis in coronary angiography. Patients were classified according to their treatment strategies, i.e. revascularization treatment or MT alone group. The primary outcome was cardiac death during follow-up of 10 years. Multiple sensitivity analyses, including multivariable adjustment, propensity-score matching, and inverse-probability-weighted analysis, were performed.

Among the total population, 709 patients (48.1%) received revascularization treatment including percutaneous coronary intervention (PCI, n=558) or coronary artery bypass graft surgery (CABG, n=151), with the remaining patients (764 patients, 51.9%) receiving MT alone. During 10 years of follow-up, the revascularization treatment group showed a significantly lower risk of cardiac death compared with the MT alone group (25.4% vs. 33.7%, HR 0.624, 95% CI 0.498-0.781,

CONCLUSIONS

In patients with silent myocardial ischemia, revascularization treatment showed significantly lower long-term risk of cardiac death compared with the MT alone group. The current results support contemporary practice of ischemia-directed revascularization, even in patients with silent myocardial ischemia.

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Prognostic implication of thermodilution coronary flow reserve in patients undergoing FFR measurement

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Limited data are available regarding the long-term prognosis associated with thermodilution coronary flow reserve (CFR) in patients with coronary artery disease. The current study investigated the prognostic implication of CFR in patients who underwent fractional flow reserve (FFR) measurement.

METHODS AND RESULTS

A total of 519 patients (737 vessels) who did not undergo revascularization were classified according to FFR and CFR values. Low FFR and low CFR were defined with upper thresholds of 0.8 and 2.0, respectively. FFR and CFR were measured by a pressure/temperature-sensor wire. Clinical outcomes were assessed by the patient-oriented composite outcome (POCO, a composite of any death, any myocardial infarction, and any revascularization) during 5 years of follow-up. The correlation (r = 0.128,

CONCLUSIONS

Patients with low CFR had a significantly higher risk of clinical events during 5 years of follow-up, regardless of FFR levels. Low CFR was an independent predictor for POCO among patients with high FFR. These results support the value of CFR in patients who undergo FFR measurement.

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Unstable angina: where do we stand. A need to change??

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THEME: Coronary Interventions
TOPIC(S): NSTEMI

AIMS

A fast and accurate risk stratification in the initial approach of patients (pts) with suspected coronary syndrome is essential for prognosis. Due to widespread use of high sensitive cardiac troponin (hs-cTn) assays, the pts that were formerly included in the diagnosis of unstable angina (UA) group, were know classified as STEMI pts. With this paradigm shift, UA represents a new entity poorly characterized. The aim of this study was to identify the predictors of significative coronary artery disease and evaluate the prognosis in pts (pts) with unstable angina.

METHODS AND RESULTS

We performed a retrospective study including 229 pts (age 66±11 years, 68% men), admitted to emergency service between 01/01/2013 and 11/30/2017 with symptoms of unstable angina. All pts underwent coronary angiography and were divided into two groups: Group A (GpA), with significant coronary artery disease that underwent PCI (87 pts) and Group B (GpB), without significant coronary disease (136 pts). The remaining 6 pts were proposed for CABG. Demographic, clinical, electrocardiographic, echocardiographic and angiographic data were evaluated.

GpA pts were older (68 vs 65 years, P=0.028), had a higher prevalence of dyslipidemia (91 vs 80%, P=0.023), higher creatinine levels (93.3± 53 vs 80,5±28 µmol/L, P=0,021, and a higher prevalence of segmental abnormalities on echocardiography (41.3% vs 22.4%, P=0.004). At admission, there were no significant differences between the two groups regarding previous ACS, previous revascularization, hemodynamic variables at admission, hs-cTn assay, Killip class, NTproBNP levels and electrocardiographic changes. In the multivariate analysis, the only independent predictor of severity of disease was the presence of segmental abnormalities on echocardiography (OR 2.7: 95% CI 1.4-5.2, P=0.002) with an AUC of 0.59 by ROC analysis.

Regarding prognosis, the presence of major adverse cardiovascular events (AMI, stroke or death - MACE) during the follow-up period (747±525 days) in GpA was observed in 9 pts (10.3%). The mortality rate was 4.6% (2.3% of cardiovascular origin). In the univariate analysis, age (P=0.011), hemoglobin level (P=0.031), hs-cTn (P=0.002) and glomerular filtration rate (P=0.011) were the parameters associated with the occurrence MACE. Concerning the angiographic parameters, no risk factors associated with poor prognosis were identified. In the multivariate analysis, the only independent predictor of MACE was the hs-cTn concentration at admission (? =123, P=0.032), with a value higher than 0.013 ng/ml (and lower than the reference value: 0.034 ng/ml) as having a sensitivity of 89% and a specificity of 60% for the occurrence of major adverse cardiovascular events.

CONCLUSIONS

With the generalized use of hs-cTn a challenge emerged in the identification of pts with UA symptoms that really have severe disease coronary disease. In fact, in our study the only predictor of disease severity was segmental abnormalities in echocardiography. In this population with a low incidence of MACE, it is noteworthy that the angiographic characteristics were not related to the occurrence of adverse events and that hs-cTn in

this population, even below the limit of normality, was a strong predictor of long-term events. These findings suggest a need for a refinement of the severity criteria, to obtain a better risk stratification in an emergency context, allowing a better therapeutic planning and avoiding unnecessary burden on healthcare systems.

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Takotsubo syndrome (cardiomyopathy) complicating an LAA occluder implantation: an extremely rare complication

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

AIMS

METHODS AND RESULTS

CONCLUSIONS

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BRS alone vs. "hybrid" with metallic DES at two-year follow-up

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

AIMS

Due to known physical limitations of bioresorbable scaffolds (BRS) the intervention of long and complex lesions is challenging. However, these lesions contain segments suitable for BRS implantation. To avoid ?full-metal jackets? and provide further opportunities of revascularization therapy a ?Hybrid?-strategy with BRS and drug-eluting stents (DES) seems to be appropriate.

To evaluate the impact of ?Hybrid?-stenting with BRS and contemporary metallic DES on antirestenotic efficacy and clinical outcome at 2 years.

METHODS AND RESULTS

At two high volume centers in Munich we investigated patients between November 2011 and July 2015 who received ?Hybrid?-stenting with BRSs and DESs for complex lesions, not suitable for BRS only, compared to those who were treated with BRSs exclusively. ?Hybrid? stenting was defined as adjacent, superimposing or overlapping BRSs and DESs in a single coronary lesion. The primary outcome of interest was a device oriented composite endpoint (DOCE) consisting of cardiac death, target-vessel myocardial infarction (TV-MI) or target lesion revascularization (TLR) at 2-year follow-up. To identify independent predictors of DOCE multivariate analysis was performed.

Of 396 consecutive patients undergoing BRS implantation for symptomatic coronary artery disease at our institution 128 were treated with ?Hybrid-BRS-DES?-strategy. Patients treated with ?Hybrid?-stenting were more frequently men (79% vs. 70%, $p = 0.07$) or smokers (31% vs 20%, $p = 0.02$) and had extensive multi vessel disease (84% vs. 71%, $p < 0.01$) including more complex (78% vs. 44%, $p < 0.01$) and bifurcation (19% vs. 3.4%, $p < 0.01$) lesions compared to patients who received BRS only. Furthermore, they had longer lesions (27±18mm vs 16±11mm, $p < 0.01$) and consecutive longer stented segments (29±23mm vs 22±9.9mm, $p < 0.01$). Angiographic results also differed significantly postinterventional regarding minimal lumen diameter (MLD) (2.4±0.45mm vs 2.6±0.47mm, $p < 0.01$) and %-diameter stenosis (DS) (13±1.1mm vs 8.3±0.6mm, $p < 0.01$) between both groups. At 2 years, DOCE occurred in 7% of ?Hybrid? patients and 8.6% of Absorb patients ($p = 0.99$), TLR in 4.7% vs. 5.2% ($p = 0.88$). Independent predictors of 2-year DOCE were age, hazard ratio 1.04 (1.00-1.08), $p < 0.03$ and total stent length, 1.02 (1.00-1.05), $p = 0.04$.

CONCLUSIONS

At 2 years patients treated with ?Hybrid?-BRS-DES-strategy for complex coronary lesions showed similar antirestenotic efficacy and clinical outcomes compared to patients treated exclusively with BRS. Analyses of larger ?Hybrid?-BRS-DES collectives are required to better explore these findings.

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Impact of gender on long-term outcome after implantation of bioresorbable DES in routine clinical practise

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

AIMS

The cardio-vascular risk profile among women and men undergoing percutaneous coronary intervention (PCI) differs significantly. Men presenting more frequently with extensive coronary artery disease and women being older, having smaller arteries and more comorbidities. Whether these gender-related differences will translate in differences in long-term performance of bioresorbable scaffolds (BRS) has not been investigated. Aim of our study was to evaluate whether there are gender-related differences in clinical outcomes at long-term follow-up after BRS implantation in routine clinical practice.

METHODS AND RESULTS

We pooled the data of 2 institutional BRS registries in Munich, Germany, which prospectively collected the data of all consecutive patients undergoing BRS implantation. Combined incidence of death, target-vessel myocardial infarction (TV-MI) and target lesion revascularization (TLR) ? the device oriented composite endpoint (DOCE) ? at two-year follow-up was the primary outcome of interest. Secondary endpoints were the individual components of the primary endpoint as well as definite/probable BRS thrombosis rates.

Among 1032 enrolled patients 259 (25.1%) were women. Women were older (w 69.9±9.9 yrs vs. m 64.3±10.8 yrs, $p < 0.01$), smoked less frequently (w 17.4% vs. m 23.2%, $p = 0.05$), had less multivessel disease (w 72.2% vs. m 81.5%, $p < 0.01$), had shorter lesions (w 16.4±10.8 mm vs. m 18.0±12.1 mm, $p = 0.02$) and consequently shorter implanted BRS length (w 25.0±13.9 mm vs. 27.7±15.8 mm, $p < 0.01$) than men. At 2 years, DOCE occurred in 13.2% of women and 17.9% of men ($p = 0.12$), TLR in 7.5% vs. 12.4% ($p = 0.05$) and definite BRS thrombosis in 0.8% and 2.5% ($p = 0.13$) (Figure). Independent predictors of 2-year DOCE were age, hazard ratio 1.29 (1.10-1.52), $p < 0.01$, complex lesions, hazard ratio 1.84 (1.28-2.65), $p < 0.01$, bifurcation lesions, hazard ratio 1.69 (1.08-2.64), $p = 0.02$ and smaller vessel size, hazard ratio 1.25 (1.03-1.50), $p = 0.02$. Independent predictors of 2-year TLR were complex lesions, hazard ratio 2.46 (1.59-3.82), $p < 0.01$ and smaller vessel size, hazard ratio 1.29 (1.02-1.63), $p < 0.04$. Being women was in tendency associated with reduced adjusted risk for DOCE (HR 0.68 (0.45-1.02), $p = 0.06$) and TLR (HR 0.60 (0.35-1.01), $p = 0.05$).

CONCLUSIONS

At 2-years after BRS implantation, women experienced less frequently BRS thrombosis partially related to less extensive CAD. Additionally, they seem to be at lower risk for TLR. Analyses of larger BRS collectives are required to better explore these findings.

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Distal left main trifurcation treatment with dedicated bifurcation stents: five-year follow-up

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THEME: Coronary Interventions

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

AIMS

Left main (LM) trifurcations are encountered in about 10-20% of LM cases and may require specific treatment strategies. The aim of this retrospective analysis was to assess the effectiveness and safety of dedicated bifurcation BiOSS stents deployed in LM trifurcations in in patients with stable coronary artery disease (CAD) and NSTE-ACS.

METHODS AND RESULTS

BiOSS stents are a family of coronary dedicated bifurcation balloon expandable stents made of stainless steel. They are coated with a biodegradable polymer comprised of lactic and glycolic acids. The stent consists of two parts with different diameters connected with two struts. BiOSS Expert elutes paclitaxel and BiOSS LIM elutes sirolimus.

We retrospectively analyzed data from BiOSS Expert Registry, international randomized clinical trial POLBOS I with BiOSS Expert, BiOSS LIM Registry and international randomized clinical trial POLBOS I with BiOSS LIM. Patients were enrolled between 2010 and 2013 in centers in Poland, Spain and Bulgaria with a final diagnosis of stable CAD or NSTE-ACS who sign informed consent were enrolled. Patients with STEMI or Medina type 001 bifurcation lesions were excluded from the registry. Provisional T-stenting was the obligatory strategy. An angiographic control was planned at 12 months. The primary end-point was the rate of cardiac death, myocardial infarction (MI), and target lesion revascularization at 12 months.

The analyzed population counted of 345 patients, in whom 131 patients had BiOSS stent deployed in the distal LM. In this subgroup we identified 75 cases (72.8%) with distal LM bifurcation and 28 cases (27.2%) with distal LM trifurcation. Additionally, we differentiated three subgroups among trifurcations: treated with only BiOSS stent (group I: n = 5, 17.9%), treated with 2 or 3 stent technique (group II: n = 15, 53.6%) and pseudo-trifurcations with high take off of diagonal or marginal branches (group III: n = 8, 28.5%).

The mean age of enrolled patients (82.1% males) was 66.8 ± 9.77 years. Patients with trifurcation had more frequently hypertension ($p < 0.01$) and underwent prior PCI ($p < 0.01$) comparing with patients with bifurcations.

All BiOSS stents were implanted successfully (avg. pressure 12 atm). The mean nominal stent parameters were as followed: 4.09 ± 0.33 mm x 3.44 ± 0.38 mm x 16.99 ± 2.1 mm. In 19 (67.9%) cases the second stent was implanted within the side branch, mainly in TAP technique. Proximal optimization technique was performed in 23 cases (82.1%). There were 64.3% of cases performed from radial access, and 21.4% - using 7F guiding catheter. In 6 cases (21.4%) periprocedural MI was diagnosed. At 12 months there was no statistically significant differences between groups I, II and III in MACE rates, 0, 13.3% (n = 2), 12.5% (n = 1), respectively. At EuroPCR 2018 we will present data from the 5-year follow-up.

CONCLUSIONS
Distal left main trifurcations are challenging lesions. Dedicated bifurcation BiOSS stents seem feasible devices with promising safety profile and mid-term clinical effectiveness. Long-term data are pending.

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First-in-man study of the dedicated bifurcation cobalt-chromium sirolimus-eluting stent: six-month interim results

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THEME: Coronary Interventions
TOPIC(S): 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 1.7-2.3 mm length. BiOSS LIM C is mounted on a dedicated bifurcation balloon (Bottle, Balton, Poland). The stent delivery is a rapid exchange system.
Between September 2016 and December 2017 in three centers (PL, UZ) patients with a final diagnosis of stable CAD or NSTE-ACS who sign informed consent were enrolled. Patients with STEMI or Medina type 001 bifurcation lesions were excluded from the registry. Provisional T-stenting was 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 (MI), and target lesion revascularization at 12 months. Here are presented interim results.

Finally, 95 patients with stable CAD or NST-ACS (73.7% vs 22.3%, respectively) were included into this prospective, feasibility and safety assessment registry. The mean age of enrolled patients (82.1% males) was 66.8 ± 9.77 years. There were 86 (90.5%) patients with hypertension, 32 (33.7%) with diabetes and 51 (53.7%) with prior MI. Additionally, 44 patients (46.3%) underwent prior PCI, while 14 (14.7%) patients had previous CABG.
In 55.8% of cases the lesion was localized in the left main, followed by 27.4% in left anterior descending artery, 13.7% in circumflex artery and 3.2% in right coronary artery. According to Medina classification true bifurcations were present in 66.3%. All BiOSS stents were implanted successfully (avg. pressure 14 atm). The mean nominal stent parameters were as followed: 3.89 ± 0.45 mm x 3.18 ± 0.42 mm x 19.51 ± 3.29 mm. In 18 (18.9%) cases the second stent was implanted within the side branch, mainly in TAP technique. Proximal optimization technique was performed in 51 cases (53.7%). There were 93.7% of cases performed from radial access. In 5 cases (5.3%) periprocedural MI was diagnosed. At one (n = 90) and three (n = 75) months all patients were uneventful (out-of hospital MACE rate 0%).

CONCLUSIONS

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

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Prediction of future adverse cardiac events by stress myocardial perfusion imaging in the patients with procedural failure for CTOs

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

The success rate of CTO have been disappointing. Conversely, incomplete revascularization is often perceived as the best treatment strategy in selected patients because of its lower periprocedural risk of procedural failure in patients presenting with CTO. However, it's unclear if this prognostic benefit may apply to patients with residual CTO, where related myocardial ischemia might be prevented by well developed collateral circulation. The aim of this study was to evaluate prognostic value of adenosine stress myocardial scintigraphy in patients with residual CTO left by procedural failure.

METHODS AND RESULTS

Between April 2004 and December 2010, 102 consecutive patients with procedural failure in the recanalization of CTO by PCI in our institution were prospectively registered. This study focuses on patients with at least one CTO in a main coronary artery (vessel diameter> or =2.5mm) left after procedural failure in the recanalization of CTO. In all patients, adenosine stress technetium-99m-tetrofosmin single-photon emission computed tomography scintigraphy (MPS) was prospectively performed 4 to 6 months after procedural failure in the recanalization of CTO by PCI. A MPS with technetium-99m-tetrofosmin was carried out at rest and repeated after the adenosine infusion in the one-day protocol. The left ventricle was divided into 17 segments on three short axes and one vertical long axis slices, and each segment was graded according to perfusion using a semiquantitative 4-point system (0=normal, 1=slightly reduced, 2=mildly reduced, 3=severely reduced, 4=absent). Myocardial scintigrams were evaluated calculating the summed stress score (SSS), summed rest score, and summed difference score (SDS) indexes. MPS were evaluated calculating the summed stress score (SSS), summed rest score, and summed difference score (SDS) indexes (Less than SDS < 4 was considered minimal ischemia, between 4 and 8 was considered mild ischemia, and greater than 8 was considered severe ischemia). All patients were followed up for cardiac events. Hard events defined as cardiac death and myocardial infarction, soft events defined as incidence of unstable angina and revascularization procedures. Follow-up lasted more than 120 months.

Hard events were observed in 10 pts. None of them had minimal ischemia detected by MPS. Soft events occurred with in 0 (0%), 9 (15%), and 9 (16%) patients with minimal, mildly abnormal, and severely abnormal findings. During the follow-up period, patients with minimal ischemic nuclear findings were at low risk of hard cardiac events compared with patients with mildly and severely abnormal findings. A significant difference was observed in hard, soft, and composite event-free survival among patients with minimal, mildly abnormal, and severely abnormal findings. When multiple Cox regression analysis was implied, the factors that remained significant in the final model for soft events were SSS, SDS, and angina during stress testing. However, SDS was the only independent predictors for both hard and soft events.

CONCLUSIONS

MPS provides independent prognostic information for the risk stratification of patients with a residual chronic total occlusion left by procedural failure. The event rate is directly related to the scintigraphic extent of residual

ischemic area. Patients with normal perfusion have an excellent event-free survival rate.

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One-year outcome of single long 48mm DES vs. overlapping DES in the treatment of diffuse coronary artery disease

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

AIMS

Earlier studies suggested adverse outcomes with overlapping older generation drug eluting stents (DES). We aim to study the one-year clinical outcomes of patients implanted with new generation single long 48mm Everolimus DES versus overlapping DES.

METHODS AND RESULTS

This is a single-centre, all-comers registry from January 2012 to December 2016. We included all patients with 38-46mm lesion length treated with either single long 48mm DES (n=125) or overlapping DES (n=158, 149 had 2 overlapping DES, 9 had 3 overlapping DES). The primary outcome was the incidence of target lesion failure, defined as the combination of cardiac death, target vessel myocardial infarction and clinically driven target lesion revascularisation at one-year. Mean age was 60.9±10.4 years in single long DES and 63.6±12.5 years in overlapping DES, with more males in single long DES (89.6 vs.79.9%, p=0.033). Cardiovascular risk factors (diabetes, hypertension, hyperlipidemia, family history of premature coronary artery disease, chronic kidney disease and smoking history) were comparable except for higher prevalence of prior stroke (10.4% vs. 3.8%, p=0.025) and higher number of patients who had previous angioplasty (32.8% vs. 10.8%,

CONCLUSIONS

In treating diffuse lesions with new generation DES, the use of single long 48mm DES or overlapping DES perform similarly with low target vessel myocardial infarction and target lesion revascularisation rates at one-year. Overlapping DES was used more frequently to treat patients with myocardial infarction and cardiogenic shock, which resulted in higher target lesion failure which was driven by cardiac death at one-year.

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Impact of repeat CTO-PCI following previously failed attempt from the analysis of the Japanese CTO Expert registry

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

The experience of the operators strongly influences the success of CTO-PCIs. The aim of this study is to investigate the impact of repeat CTO-PCI by highly skilled operators following previously failed attempt

METHODS AND RESULTS

The Japanese Board of CTO Interventional Specialists has developed a prospective, nonrandomized registry of patients undergoing CTO-PCI performed by selected highly experienced Japanese specialists. From 2014 to 2016, the registry included 4177 consecutive CTO-PCI cases (mean age 66.8+10.8 years old, male 85.8%, mean J-CTO score 1.92+1.2). The overall procedure success rate of CTO-PCI was 88.9%. A prior failed attempt had been performed in 844 (20.2%) patients. As compared with patients without prior CTO-PCI failure, patients with prior CTO-PCI failure had higher Japanese CTO score (1.68+1.1 vs 2.86+1.0,

CONCLUSIONS

The repeat CTO-PCIs in our registry are associated with patient characteristic and angiographic complexity, longer procedure time and high contrast volume. The success rate of repeat CTO-PCI by highly skilled operators following previously failed attempt may be acceptable. However, the CTO lesion with severe calcification remains a difficult problem.

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Four-year predictive value of the modified Mehran restenosis classification adapted for coronary bifurcations: the results of subgroup analysis from the randomised POLBOS I and POLBOS II clinical trials

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

The wide variation in bifurcation anatomy has generated an ongoing search for stents designed specifically for coronary bifurcations. The aim of this study was to compare the restenosis profile between dedicated bifurcation BiOSS stents (Balton, Poland) and regular drug-eluting stents based on data from two clinical trials POLBOS I and POLBOS II.

METHODS AND RESULTS

In POLBOS trials dedicated bifurcation BiOSS® stents were compared with rDES in patients with stable CAD or NSTE-ACS (POLBOS I: paclitaxel eluting BiOSS® Expert vs rDES, POLBOS II: sirolimus eluting BiOSS® LIM vs rDES). Provisional T-stenting was the default strategy. The primary endpoint was the major adverse cardiovascular event (MACE) rate defined as the rate of cardiac death, myocardial infarction (MI) or target lesion revascularization (TLR). Quantitative coronary angiography (QCA) was done with dedicated bifurcation software (CAAS, Pie Medical).

In total 445 patients (222 patients in BiOSS group and 223 patients in rDES group) were analyzed. Control angiography was over 90%. In BiOSS group there were 24 cases of angiographic restenosis (10.8%) and in rDES group ? 17 cases (7.6%) at 12-month follow-up. In the BiOSS group most frequent Medina classification in restenotic cases was 0.0.1 (25%), whereas in rDES ? 0.0.1 and 0.1.1 (23.5% each). In QCA analysis in the BiOSS group minimal lumen diameter (MLD) was located in main vessel 2.43±2mm from the point of bifurcation (POB), and in main branch ? 4.17±3mm, whereas in the rDES group these values were: 2.88±1.92mm (NS) and 4.29±2mm (NS), respectively.

In multivariate regression analysis proximal optimization technique was associated with the lowest chance for restenosis (OR 0.15, 95% CI 0.06 ? 0.33), whereas diabetes on insulin was associated with the highest risk of restenosis (OR 4.21, 95% CI 1.48 ? 11.44). Interestingly, when we take into consideration only MV predilatation and POT it was shown that performing predilatation decreases the POT effectiveness (OR 0.545, 95% CI 0.134 ? 0.367, p < 0.001).

Also, we proposed a modified Mehran restenosis classification adapted for coronary bifurcations. In each main type we differentiated 3 or 4 subtypes depending on the location (MV - main vessel, MB - main branch, SB - side branch) as follows:

Type I (focal restenosis, < 10 mm in stent): IA (in MV-MB), IB (in SB) and IC (both),
Type II (> 10 mm within the stent): IIA (in MV-MB), IIB (in SB) and IIC (both),
Type III (> 10 mm + outside the stent): IIIA (in MV-MB), IIIB (in SB) and IIIC (both),

Type IV (total occlusion): IVA (in MV), IVB (in MB), IVC (in SB) and IVD (in MB and SB).

In both subgroups (BiOSS vs rDES) we observed similar restenosis profile independently on the specific type: type I (58.3% vs 52.9%), type II (20.8% vs 29.4%), type III (8.3% vs 11.8%) and type IV (12.5% vs 5.9%). Type IA was the most common type of restenosis in the BiOSS group (n = 6, 25%), whereas in the rDES group type IA, IB and IC were equally frequent (n = 3, 17.7% each). At EuroPCR we will be able to present modified Mehran classification predictive value at 4 year follow-up.

CONCLUSIONS

The restenosis profile is similar between BiOSS stents and rDES, which suggests that the middle zone with only two struts in the BiOSS stent might not be a weak point predisposing to restenosis.

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Safety and clinical performance of biodegradable polymer-coated ultrathin everolimus-eluting stents in "real-world" patients: a multicentre registry (PERFORM-EVER)

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

AIMS

To report 1-year clinical safety and efficacy outcomes for ultrathin-strut (60 ?m) biodegradable polymer coated Tetrilimus everolimus-eluting stent (EES) [Sahajanand Medical Technologies Pvt. Ltd., Surat, India] in patients with coronary artery disease in real-world clinical practice.

METHODS AND RESULTS

The PERFORM-EVER was an observational, multicenter, single-arm and investigator-initiated retrospective registry. All ?real-world? patients who had received Tetrilimus EES between July-2015 and October-2016 at our centers were analyzed. The data were collected retrospectively either by extraction from existing databases in consecutive fashion where index and follow-up data existed or the follow-up was obtained by telephonic contact. Primary endpoint was 1-year incidence of target lesion failure, which was defined as a composite endpoint of cardiac death, myocardial infarction, and target lesion revascularization by percutaneous or surgical methods. The Academic Research Consortium-defined stent thrombosis was assessed as additional safety endpoint.

During the study period, 815 Tetrilimus EES (1.4±0.5 stent/patient) were implanted to treat 735 coronary lesions (1.1±0.3 stent/lesion) in 594 patients (mean age: 55.6±12.1 years). Among them, 453 (76.3%) were males, 192 (32.3%) were hypertensives, 138 (23.2%) were diabetics, 205 (34.5%) were alcoholics, 141 (23.7%) were smokers, 106 (17.8%) were tobacco chewers, 46 (7.7%) had previous revascularization, and 225 (37.8%) displayed multi-vessel coronary disease. Of treated lesions, 577 (78.5%) were complex (i.e. Type B2/ C) and 103 (14.0%) had total occlusion. The average length and diameter of implanted Tetrilimus EES were 27.6±9.7 mm and 3.0±0.3 mm respectively. Post-implantation, events of target lesion failure were reported in 5 (0.8%) patients at 30-day follow-up and 13 (2.2%) patients at 6-month follow-up. The cumulative major adverse cardiac event rate at 1-year follow-up was 3.7%, which included 9 (1.5%) cardiac deaths, 8 (1.4%) myocardial infarctions, and 5 (0.8%) target lesion revascularizations. There were 5 (0.8%) cases of probable stent thrombosis and 4 (0.7%) cases of possible stent thrombosis at 1-year follow-up.

CONCLUSIONS

Low incidences of target lesion failure and stent thrombosis at 1-year follow-up indicates that Tetrilimus EES may have encouraging safety and efficacy in unselected real-world patients with coronary artery disease, including those with high-risk characteristics and complex lesions.

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Bivalirudin or unfractionated heparin with or without planned GP IIb/IIIa inhibitors in patients with ACS undergoing invasive management in the MATRIX trial

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

AIMS

Contrasting evidence exists on the comparative efficacy and safety of bivalirudin and unfractionated heparin (UFH) in relation to the planned use of glycoprotein IIb/IIIa inhibitors (GPI). Thus we assessed efficacy and safety of bivalirudin compared with UFH with or without GPI in patients with acute coronary syndrome (ACS) undergoing invasive management.

METHODS AND RESULTS

In the MATRIX program, 7213 patients were randomly assigned to receive either bivalirudin or UFH with or without GPI at operator?s discretion. The 30-day coprimary outcomes were major adverse cardiovascular events (MACE, composite of death, myocardial infarction, or stroke), and net adverse clinical events (NACE, composite of MACE or major bleeding). Among 3603 patients assigned to receive UFH, 781 (21.7%) underwent planned treatment with GPI prior to coronary intervention. Bailout use of GPI was similar between bivalirudin and UFH groups (4.5% and 5.4%, P=0.11). At 30-day, the two coprimary endpoints of MACE and NACE, as well as individual endpoints of mortality, MI, ST or stroke did not differ among the three groups after adjustment. Compared to UFH and UFH+GPI groups, bivalirudin reduced bleeding, mainly most severe ones, including fatal and non-access-site related events, as well as transfusion rates and need for surgical access-site repair. These findings were not influenced by intra-procedural dose of UFH administered, and were confirmed at multiple sensitivity analyses, including the randomly allocated access site.

CONCLUSIONS

In patients with ACS, the rates of MACE and NACE were not significantly lower with bivalirudin than with UFH, irrespective of planned GPI use. However, bivalirudin significantly reduced bleeding complications, mainly non-access site related, irrespective of planned use of GPI. (Minimizing Adverse Haemorrhagic Events by TRansradial Access Site and Systemic Implementation of angioX [MATRIX], NCT01433627)

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Gender differences in baseline cardiovascular risk profile and clinical outcomes one year after treatment with a bioresorbable polymer-coated DES

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

AIMS

Sex differences in clinical outcomes following PCI have been described, but there is limited data as to whether these persist in PCI undertaken with contemporary platforms in contemporary practice. Our aim is to assess differences between men and women in cardiovascular risk profile and clinical outcomes after treatment with a new generation DES.

METHODS AND RESULTS

The e-Ultimaster all-comer PCI registry is enrolling at 336 sites in 48 countries worldwide. Patients are treated with the sirolimus-eluting Ultimaster, a thin strut cobalt chromium stent, abluminally coated with a bioresoarbable polymer. More than 10,000 patients will have completed 1-year follow-up at time of presentation. The primary endpoint is target lesion failure (TLF), a composite of cardiac death, target vessel-related myocardial infarction (MI) and clinically driven target lesion revascularization (TLR) at 1 year. Serious adverse events related to the endpoints were independently adjudicated by a clinical event committee.
At baseline women (n=2073, 23%) compared to men (n=6806, 68%) were older (68.2 vs 63.6 years,

CONCLUSIONS

Despite differences in baseline risk factors and lesion characteristics, clinical outcomes after treatment with new generation DES were similar between men and women. Risk of having vascular complications, more specifically those related to access site, however, was higher in women, most probably driven by higher rate of femoral access. Differences in clinical outcomes between men and women mainly seem procedure-related.

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Comparison of different diastolic indices to iFR

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

The aim of this study was to compare different diastolic resting indexes to iFR as pressure measurement for the duration of the wave-free period (WFP) is considered essential for resting-state physiological assessment of coronary stenosis severity using the instantaneous wave-free ratio (iFR).

METHODS AND RESULTS

METHODS In the population of the VERIFY2 (Pd/Pa vs iFR in an Unselected Population Referred for Invasive Angiography) study, iFR calculated by proprietary software (Volcano Harvest, Volcano Corporation, Rancho Cordova, California) was compared with the ratio of resting distal coronary pressure and aortic pressure during the complete duration of diastole (dPR), 25% to 75% of diastole (dPR25?75), and midpoint of diastole (dPRmid), along with Matlab calculated iFR (iFRmatlab) and iFR-like indexes shortening the length of the WFP by 50 and 100 ms (iFR
-50ms and iFR-
100ms), respectively. Mutual differences, Spearman correlations, area under the curve values from receiver-operating characteristic analyses, and diagnostic performance with respect to iFR and fractional flow reserve (FFR) were calculated for all indexes.
RESULTS Median iFR in 197 patients with 257 vessels was 0.91 with an interquartile range of 0.87 to 0.95. The mutual differences (
±SD) with iFR were 0.006±0.011 (dPR), 0.001±0.007 (dPR25?75), 0.001±0.008 (dPRmid), 0.005±
0.009 (iFRmatlab), 0.003±0.008 (iFR-
50ms), and 0.001±0.009 (iFR
-100ms). Correlations for all indexes with iFR were >0.99 ($p < 0.001$ for all). Area under the curve values for predicting iFR were >0.99 for all indexes as well. Diagnostic accuracy compared with FFR was 76% to 77% for all indexes including iFR.

CONCLUSIONS

All diastolic resting indexes tested were identical to iFR, both numerically and with respect to their agreement with FFR. A numerically equal value to iFR can be determined without restriction to the WFP. Cutoff values, guidelines, and clinical recommendations for iFR can therefore be extended to these other indexes.

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Effect of thrombus and its composition on early re-endothelialisation in injured swine coronary arteries

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

AIMS

The aim of this study is to investigate the effect of thrombus and its composition on early re-endothelialization after stent placement in injured swine coronary arteries.

METHODS AND RESULTS

Twenty-four coronary arteries in a swine model (n=8) of coronary artery balloon injury (30% balloon oversizing) were implanted with either a bare metal stent (BMS) or a drug-eluting stent (DES) with 10% oversizing (stent-to-artery ratio). All animals received standard dual anti-platelet therapy. The study was approved by the local animal ethics committee. After three days follow-up, the proximal and distal sections of stented coronary arteries were prepared for light microscopy analysis, and the middle sections were processed for scanning electron microscopy (SEM) analysis. Spearman's correlation and multiple regression analyses were performed to determine the percentage of endothelium on the stent struts as assessed by quantitative light microscopy in relation to the balloon injury, stent malapposition, thrombus composition and thrombus dimension. The factors related to the percentage of endothelium evaluated by SEM were similarly analyzed using multiple regression. The Spearman's correlation revealed a positive correlation between thrombus thickness and percentage of endothelium ($p = 0.003$), as well as between percentage of erythrocytes within the thrombus and the percentage of endothelium ($p = 0.006$). In multiple regression analysis, positive correlations were again seen between thrombus thickness ($p = 0.03$), percentage of erythrocytes ($p = 0.04$) and percentage of endothelium, while a negative relationship between malapposition and percentage of endothelium ($p = 0.007$) was observed. Meanwhile, the animal, balloon-to-artery ratio, stent-to-artery ratio, stent types (DES, BMS) and other thrombus components (fibrin and platelets) did not correlate with the percentage of endothelium overlying the struts. Similarly, the percentage of endothelium evaluated by SEM was not related with animal, balloon-to-artery ratio, stent-to-artery ratio and stent type.

CONCLUSIONS

Thrombus thickness and erythrocytic composition of thrombus both highly correlated with early re-endothelialization after stenting in the coronary artery vascular injury model, while stent malapposition is reversely correlated with re-endothelialization. These findings could lead the way to optimization of future stent design and stent implantation techniques.

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Global use and implementation of the PRECISE-DAPT score in clinical practice in 2017. A website and mobile app based survey

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

AIMS

Guidelines recommend individualized dual antiplatelet treatment (DAPT) duration, and the use of dedicated risk scores. However, it is not clear what is the real penetration of these tools in everyday clinical practice. The PRECISE-DAPT score is a 5 item risk prediction tool used to inform DAPT duration decision-making, which is endorsed by international guidelines. The aim of this study was to evaluate the real-world use of the PRECISE-DAPT score in everyday clinical practice, focusing on the impact of the release of the European Society of Cardiology (ESC) DAPT update in August in 2017.

METHODS AND RESULTS

By using a web-based automated registry and collecting all the users? entries from the PRECISE-DAPT score website and mobile apps, we analyzed data from the launch of the service in January 2017 up to December 2017. Data for the PRECISE-DAPT score calculation, its components, and the users? IP address were collected. Each new calculation of the score represented a new session that was recorded in the database. Additional information such as the number and the type of stent implanted, the intended DAPT duration, the type of P2Y12 inhibitor, and the ability of the PRECISE-DAPT score to change the users? treatment strategy, were also optionally collected. A total of 50,101 sessions were registered from January 1st to December 31st 2017. The PRECISE-DAPT score was calculated in 122 countries and 10,973 different terminals. The score utilization increased from a total of 5.59 average daily uses during the first 3 months, to 109.83 uses immediately after the original article publication (+853%) and then up to 395.63 average daily uses 30 days after the European Society of Cardiology (ESC) guidelines presentation (+3075%). In 105 out of 122 countries, the peak usage of the score was registered during the third quadrimestre in 2017.

The median age of the included patient cohort was 68 years (IQR 57-76) and the median PRECISE-DAPT score was 25 (IQR 15-36). At baseline, 13.9% of patients were registered as having suffered a prior bleeding that required medical attention or intervention. In total 15.8% of patients were at very low risk (?10 points), 15.7% were at low risk (11-17 points), 17.3% were at moderate risk (17-24 points), and 51.2% were at high risk (?25 points). According to the PRECISE-DAPT score half of this patient cohort was deemed as high bleeding risk and as such were considered for a short course of DAPT. In a minority of patients that answered the optional survey, the intended DAPT duration among those at high bleeding risk was of 12 months respectively. Fifty percent of the users stated that the PRECISE-DAPT score calculation has changed their treatment duration strategy. Clopidogrel was the most commonly used P2Y12 inhibitor. Among patients at high bleeding risk 50.6 were on clopidogrel, 40% on ticagrelor and 4.7% on prasugrel. Patients treated with prasugrel were at low bleeding risk in 75% of cases.

CONCLUSIONS

During the first year since its introduction, the PRECISE-DAPT score has been widely implemented in everyday clinical practice on a global scale.

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Twelve-month comparative analysis of clinical outcomes using biodegradable polymer-coated everolimus-eluting stents vs. durable polymer-coated everolimus-eluting stents in all-comer patients

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

AIMS

The purpose of the present study was to examine whether clinical differences exist between the biodegradable polymer-coated Tetrilimus everolimus-eluting stent (EES) [Sahajanand Medical Technologies Pvt. Ltd., Surat, India] and the durable polymer-coated Xience Family of EES [Abbott Vascular, USA] and to compare major adverse cardiac event (MACE) rate at 12 months in all-comers patients.

METHODS AND RESULTS

This study was designed as a multicenter, observational, retrospective, investigator initiated study of 213 patients who underwent percutaneous coronary intervention (PCI) with the Tetrilimus EES compared to 204 patients who underwent PCI with the XIENCE Family of EES, irrespective of lesion complexity, co-morbidities, and acute presentation. All patients were identified retrospectively and included based on the PCI only with Tetrilimus EES or only with Xience Family of EES between January-2016 and October-2016. In this study, the primary end point was MACE defined as a composite of cardiac death, myocardial infarction (MI), and target lesion revascularization (TLR). Baseline clinical and lesion characteristics of the two groups were similar, although the Tetrilimus EES group had a significantly higher number of patients with diabetes mellitus (39.9% vs. 30.4%, p=0.042) and type C lesion (67.4% vs. 48.1%,

CONCLUSIONS

The present comparative analysis shows that the biodegradable polymer-coated Tetrilimus EES were as safe and effective as the durable polymer-coated Xience Family of EES during 12 months follow-up period despite of complex lesion characteristics.

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Comparison of neointimal coverage between ultrathin biodegradable polymer-coated sirolimus-eluting stents and durable polymer-coated everolimus-eluting stents: six-month OCT follow-up from the TAXCO study

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THEME: Coronary Interventions

TOPIC(S): Stents and scaffolds

AIMS

Assessment of uncovered struts, malapposed struts and neointimal thickness by optical coherence tomography (OCT) at follow-up is considered to be an important surrogate to help stratify the patient's future risk for thrombotic events. The TAXCO study was designed to compare the degree of neointimal coverage and the prevalence of malapposition at 6 months subsequent to implantation of ultrathin biodegradable polymer-coated sirolimus-eluting stents (SES) and durable polymer-coated everolimus-eluting stents (EES) using OCT.

METHODS AND RESULTS

The TAXCO study included total 37 patients who consented and underwent OCT examination between August 2017 and September 2017. Among them, 21 patients had been treated with Tetriflex SES (Sahajanand Medical Technologies Pvt. Ltd., Surat, India) and 16 with Xience V EES (Abbott Vascular, USA), 6 (±1) months earlier at our institution. The OCT was performed using a C7 Dragonfly? imaging catheter (St. Jude Medical Inc., USA). All OCT images were analysed at an independent core laboratory (Cardiovascular Research Center, São Paulo, Brazil) by analysts who were blinded to patient and procedural information. A total of 763 cross-sections (6908 struts) were analyzed in Xience V EES group, and 1134 cross-sections (9992 struts) in Tetriflex SES group. At 6 months, on per-lesion basis, no significant differences were observed between Xience V EES group and Tetriflex SES group in mean percentage of uncovered struts (1.87±3.86 vs. 2.42±3.45, p=0.137) and malapposed struts (0.05±0.20 vs. 0.21±0.69, p=0.302). Strut-level neointimal thickness also did not differ between Xience V EES group and Tetriflex SES group (0.18±0.12 vs. 0.14±0.07, p=0.370).

CONCLUSIONS

This OCT study found no significant difference in strut coverage and neointimal thickness at 6 months after implantation of biodegradable polymer-coated Tetriflex SES, when compared with durable polymer-coated Xience V EES.

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Continuous left atrial invasive hemodynamics as an adjunct to echocardiography predicts clinical improvement following MitraClip therapy

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

AIMS

Efficacy of MitraClip (MC) is assessed intraoperatively by transesophageal echocardiography (TEE). However, TEE measures are operator dependent and can be influenced by left ventricular (LV) function. The aim of this study is to assess the additional benefit of measuring left-sided heart pressures as a complement to echocardiographic assessment during MC therapy with particular focus on the assessment of left atrial (LA) hemodynamics and their prognostic impact on functional outcome at short-term follow-up.

METHODS AND RESULTS

Fifty consecutive patients undergoing MC therapy with continuous left-sided heart pressure measurements were enrolled and analyzed. LA v wave pressure (LAvP), mean pressure (LAmP), LV systolic pressure (LVSP) and end-diastolic pressure (LVEDP) were measured continuously. Left atrial pressures were indexed to LV pressures to allow a more constant comparison of hemodynamics in case of changes in afterload during the procedure.

Most patients (70%) had degenerative MR. LAvP ($p < 0.001$), LAmP ($p = 0.007$), LVEDP ($p = 0.001$), LAvP index ($p < 0.001$) and LAmP index ($p = 0.001$) decreased significantly, and LVSP ($p = 0.009$) significantly increased after MC therapy.

In multivariate logistic regression analysis, intraprocedural increase of LAmP index was significantly associated with re-hospitalization due to heart failure (odds ratio 1.027, 95% CI 1.002-1.054, $p = 0.036$) and with NYHA class III-IV (odds ratio 1.031, 95% CI 1.006-1.056, $p = 0.015$) at follow-up period.

CONCLUSIONS

This study documents an adjunctive value of real-time monitoring of left heart hemodynamics profile during MC therapy to predict clinical outcomes. The unfavorable change in LA mean pressure was a prognostic factor for worse clinical outcomes at short-term follow-up, independent from echocardiographic findings.

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Severity of stenosis and fractional myocardial mass, a vessel-specific myocardial mass, is associated with higher frequency of myocardial ischaemia and revascularisation

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Background Both the presence of and the extent of myocardial ischemia determine the clinical benefit of revascularization.

Objective To investigate the impact of myocardial ischemia defined by fractional flow reserve (FFR) ? 0.80 and ischemic extent defined by fractional myocardial mass (FMM), a vessel-specific myocardial mass, on the decision of percutaneous coronary intervention (PCI).

METHODS AND RESULTS

Methods In this multicenter prospective registry, (412) patients who underwent coronary computed tomography angiography (CCTA) were followed by invasive coronary angiography and FFR measurement. PCI was performed in (282) patients (__). %FMM subtended by diameter stenosis (DS)?70% or DS?50% were assessed.

Results PCI was increasingly performed according both to %FMM and FFR (

CONCLUSIONS

Conclusions %FMM correlated well with angiographic scores and had a potential to be used as an alternative to the angiographic scores in a noninvasive and quantitative manner. Both the severity of stenosis and the amount of subtended myocardium determined the functional significance of vessel.

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Seven-year clinical outcomes in patients undergoing PCI with biodegradable polymer-coated sirolimus-eluting stent: results from a single-centre real-world experience

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THEME: Coronary Interventions

TOPIC(S): Stents and scaffolds

AIMS

Sirolimus-eluting stents have been used in clinical practice due to their demonstrated ability to reduce restenosis. However, reports of late and very late stent thrombosis have raised questions about long-term outcome in patients treated with these stents. The aim of the present study was to assess seven-year clinical outcomes of biodegradable polymer coated sirolimus-eluting stent (Supralimus, Sahajanand Medical Technologies Pvt. Ltd., Surat, India) in real-world patients with coronary artery disease.

METHODS AND RESULTS

This observational, retrospective study was carried out in all 346 consecutive enrolled patients who underwent percutaneous coronary intervention (PCI) with the Supralimus sirolimus-eluting stent (SES), between April 2008 and December 2009, at a single centre. We analyzed major adverse cardiac events (MACE) [a composite of cardiac death, myocardial infarction (MI), target lesion revascularization (TLR) and target vessel revascularization (TVR)] as primary outcomes and estimated event-free survival by the Kaplan-Meier method at seven-year of follow-up. The seven-year follow-up was conducted by an independent clinical research organization and was supervised by an independent cardiologist from a remote institute. Out of 346 patients, seven-year follow-up was obtained in 327 (94.5%) patients and hence results were analysed for 327 patients. The mean age of patients was 56.0±11.4 years, and 40.1% (131/327), 34.9% (114/327) and 31.2% (102/327) had diabetes, hypertension and hypercholesterolaemia, respectively. A total of 386 target lesions were treated, including 11 (2.8%) unprotected left mains, 24 (6.2%) bifurcations, and 18 (4.7%) total occlusions. Among overall population most lesions (35.8%, 138/386) were located in the left anterior descending artery and 237 (61.4%) of 386 lesions were type B2/C, according to the American College of Cardiology/American Heart Association classification scheme. A total of 386 Supralimus SES were implanted at index procedure (1.18 stents per patient) with an average diameter and total stent length of 3.0±0.4 mm and 25.04±9.1 mm, respectively. At 7-year, MACE occurred in 41 (12.5%) patients, consisting of 23 (7.0%) cardiac deaths, 14 (4.3%) TLR, and 4 (1.2%) TVR. The incidence of late stent thrombosis was observed in 3 (0.9%) patients during 7-year follow-up with an annual thrombotic rate of 0.1% and 0.0004% stent thrombosis per patient-year. Non-cardiac deaths were reported in 6 (1.8%) patients. At seven-year follow-up, the cumulative event-free survival was found to be 84.7% by Kaplan-Meier method. A total of 259 (79.2%) patients were still on dual antiplatelet therapy at seven-year.

CONCLUSIONS

The results of the present study demonstrate satisfactory and sustained seven-year clinical outcomes for the biodegradable polymer coated Supralimus SES in treating patients in real-world settings, with low rates of MACE and stent thrombosis.

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Coronary angiography is related to improved clinical outcome of out-of-hospital cardiac arrest with initial non-shockable rhythm

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Coronary angiography (CAG) for survivors of out-of-hospital cardiac arrest (OHCA) enables early identification of coronary artery disease and revascularization, which might improve clinical outcome. However, little is known for the role of CAG in patients with initial non shockable cardiac rhythm.

METHODS AND RESULTS

We investigated clinical outcomes of successfully resuscitated 670 adult OHCA patients who were transferred to 27 hospitals in Cardiac Arrest Pursuit Trial with Unique Registration and Epidemiologic Surveillance (CAPTURES), a Korean nationwide multicenter registry. The primary outcome was 30-day survival with good neurological outcome. Propensity score matching and inverse probability of treatment weighting analyses were performed to account for indication bias.

A total of 401 (60%) patients showed initial non-shockable rhythm. CAG was performed only in 13% of patients with non-shockable rhythm (53 out of 401 patients), whereas more than half of patients with shockable rhythm (149 out of 269 patients, 55%). Clinical outcome of patients who underwent CAG was superior to patients without CAG in both non-shockable (hazard ratio (HR) = 3.6, 95% confidence interval (CI) = 2.5?5.2) and shockable rhythm (HR = 3.7, 95% CI = 2.5?5.4, $p < 0.001$, all). Further analysis after propensity score matching or inverse probability of treatment weighting showed consistent findings (HR ranged from 2.0 to 3.2, $p < 0.001$, all).

CONCLUSIONS

Performing CAG was related to better survival with good neurological outcome of OHCA patients with initial non-shockable rhythms as well as shockable rhythms..

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Thrombembolectomy with Fogarty through lumen catheter and guidewire for acute limb ischaemia patients

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THEME: Peripheral Interventions
TOPIC(S): Below the knee, Iliac / Femoral / Popliteal

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Impact of regional differences on long-term clinical outcomes in Japanese and non-Japanese patients treated with Ultimaster bioresorbable polymer sirolimus-eluting stent: a substudy of the CENTURY II trial

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

AIMS

Geographical differences and variations in clinical practice are possible influencing factors on clinical outcomes. However, the impact of regional differences on long-term clinical outcomes remains unclear in the contemporary drug-eluting stent (DES) era. We sought to assess whether regional differences affected long-term clinical outcomes in Japanese and non-Japanese patients enrolled in the CENTURY II trial.

METHODS AND RESULTS

The CENTURY II trial was a multicentre, randomized study whereby 1119 patients in 58 centres located in Europe, Japan and Korea were enrolled and designed to compare Ultimaster with Xience DES. Of 1119 patients, 722 patients met the eligible criteria of Japanese requirement (JR) matching for DES approval in Japan. Major exclusions for JR were as follows: acute myocardial infarction, left main truck disease, saphenous vein graft, and in-stent restenosis. Of 722 patients, 261 patients were enrolled at 15 sites in Japan and 461 patients were enrolled at 43 sites out of Japan. We assessed the cumulative 4-year incidence of patient oriented composite endpoints (POCE), defined as all-cause death, myocardial infarction (MI), and any revascularization, in the Japan and non-Japan groups. Notably, significant differences were observed in almost all baseline patient characteristics in and out of Japan as follows: age (69 vs. 64 years,

CONCLUSIONS

At 4 years, Ultimaster DES shows similar clinical outcomes in and out of Japan, regardless of the significant differences observed in baseline patient, lesion, and procedural characteristics.

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Novel prognostic value of PARIS score in patients after rotational atherectomy to the severely calcified coronary artery

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

AIMS

Rotational atherectomy (RA) is a promising strategic option for technical success of percutaneous coronary intervention (PCI) to severely calcified lesions. However, long-term clinical prognosis after RA has not been fully discussed in the drug-eluting stent (DES) era. PARIS score can separately predict embolic and bleeding events after PCI. We aimed to validate PARIS score in predicting clinical outcomes of patients who were treated with RA.

METHODS AND RESULTS

Total of 404 patients undergoing PCI with RA between 2004 and 2013 was enrolled. Median follow-up period was 1,521 days. The rate of coronary thrombotic events (CTEs: stent thrombosis and myocardial infarction) and major adverse cardiac events (MACE: CTEs, cardiovascular death, and target vascular revascularization) were compared among patients with PARIS-CTEs low (n=123), intermediate (n=109), and high (n=172) score group. Additionally, incidence of major bleeding (MB) was also compared among PARIS-MB low (n=35), intermediate (n=159), and high (n=210) score group.

As a result, Kaplan-Meier analysis revealed that both rates of CTEs and MB were comparable among the groups (4-year CTEs: 4.2%, 9.2%, 7.5%, p=0.11, MB: 7.2%, 5.5%, 10.0%, p=0.22). In contrast, MACE rate was significantly higher in the higher PARIS-CTEs score group (4-year MACE: 22.8%, 44.4%, 52.5%, p<0.001).

CONCLUSIONS

PARIS score may predict long-term MACE, but not each of CTEs or bleeding events in patients after RA in the DES era.

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Comparison of baseline clinical features between Japanese and non-Japanese patients treated with Ultimaster bioresorbable polymer sirolimus-eluting stent: observations from the e-ULTIMASTER registry

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

AIMS

Geographical differences and variations in clinical practice remain possible influencing factors on clinical outcomes. We sought to assess the differences in baseline clinical features between the Japan and non-Japan cohorts in the e-ULTIMASTER registry.

METHODS AND RESULTS

The e-ULTIMASTER registry is a large, prospective, single-arm, multi-centre registry that is designed to further validate the safety and efficacy of the Ultimaster drug-eluting stent (DES) (Terumo, Japan) in unselected patients enrolled worldwide. At present, a total of 21235 patients (Japan cohort, n=943, non-Japan cohort, n=20292) were enrolled in the e-ULTIMASTER registry. Compared with the non-Japan group, the Japan group had high risk clinical features such as advanced age, diabetes mellitus, renal failure, and prior percutaneous coronary intervention (70±10 vs. 64±11 years, 43.7% vs. 27.8%, 22.8% vs. 6.9%, 41.6% vs. 24.8%, p 25 mm (72.9% vs. 54.3%, 22.6% vs. 10.0%, 7.7% vs. 2.9%, 58.2% vs. 43.1%,

CONCLUSIONS

Even in the contemporary DES era, several differences in baseline clinical features between Japan and non-Japan cohorts were observed in the e-ULTIMASTER registry, which might reflect lots of differences in each country such as medical insurance system, clinical indication for PCI, and standard PCI technique. The clinical follow-up is currently ongoing and part of 1-year clinical follow-up data will be available at the presentation.

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Primary PCI: three-year experience

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Primary percutaneous coronary intervention (PCI) has emerged as the preferred treatment of acute MI if logistically feasible and has been proven to be a very effective method to obtain patency of the infarct-related artery. The purpose of this study was to discuss three years experience of primary PCI for STEMI patients in our hospital.

METHODS AND RESULTS

Methods: From November 2014 to October 2017(three years) primary PCI was performed on 450 patients and they were included in the study. They were studied for risk factors, clinical characteristics, angiographic profile, procedural characteristics and in-hospital outcome.

Results: The mean age of patients was 52.91±11.9 years (range, 25-104). Most patients were male (90.7% vs 9.3%). The most common risk factor was dyslipidaemia (92.4%), followed by smoking (58.4%), hypertension (50.7%), DM (43.8%), obesity (43.8%) and family history of ischemic heart disease (31.1%). The most common anatomical location for the MI was the anterior wall (49.8%). Single vessel disease (SVD) was seen in 54.4% patients, double-vessel disease (DVD) in 29.8% patients and triple-vessel disease (TVD) in 15.8% patients. Left anterior descending artery was the commonest vessel involved, with 230 lesions (51.1%) followed by right coronary artery (41.5%). Mean door to balloon time was 80.8± 33.36 min. Thrombus aspiration was done in 82.5% (371) patients. In-hospital mortality was 3.3%

CONCLUSIONS

Conclusion: Primary PCI is feasible in our hospital as acceptable door to balloon time with excellent procedural success and lower complications which are comparable with other good centre.

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Difficulties to enter into the left ventricle during balloon mitral valvotomy - Our experiences with 50 challenging cases

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

AIMS

Balloon mitral valvotomy (BMV) is the standard of treatment for symptomatic severe rheumatic mitral stenosis with long term follow up data equivalent to mitral valve replacement. BMV has the standard Inoue technique but we have to modify the procedure in many technically challenging cases among which crossing the mitral valve with balloon is the most common challenge.

METHODS AND RESULTS

We studied a total 50 cases of BMV where we had to modify the standard procedure to enter into LV. We used two over the wire strategies to enter the LV. The first one needs only the exchange of J shaped wire from the balloon and introduce the spring wire into the balloon and keeping the tip of the wire protruding though the tip of the balloon into the orifice of the mitral valve and push the wire during diastole into the LV. The second strategy needs removal of balloon keeping the spring wire into the LA and the Mullin sheath was introduced over the wire and the tip of the wire was directed towards the MV orifice and pushed during the diastole and the sheath was removed quickly and the balloon was introduced over the wire into LV.

We succeeded in all cases (100%) to enter into the LV. The first and second strategy were done in 20 and 30 cases, respectively. The first technique was applied to every patient and was successful in 40% of cases. Mean procedural time was 35±15 min and fluoroscopic time was 12±8 min which is higher than our daily practice. Strategy one required less time in comparison to the second one (procedure time 28±8 min vs 42±12 min and fluoroscopic time 10 ±2 min vs 14±3 min). Analyzing the causes of difficulties, critical mitral stenosis was the highest (18 cases, 36%) followed by low septal puncture (16 cases, 30%), critical MS and low septal puncture (10 cases, 20%), septal aneurysm (4 cases, 8%) and thickened interatrial septum preventing free movement of balloon (2 cases, 4%). Our procedures were free of any major complication. Ventricular ectopic developed in 100% of cases and non-sustained ventricular tachycardia developed in 92% cases and all were well tolerated needed no intervention.

CONCLUSIONS

Over the wire entry into LV was advised by few authors and Monjunath et al. published a report of 32 cases. Their technique is similar to our second strategy. But before taking the second one we tried with the first one which is very simple and has less fluoroscopic time and procedural time. Both strategies are cost effective requiring no other new equipment and are safe and can be used in difficult cases.

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Additional postdilatation with noncompliant balloons after everolimus-eluting stent implantation: results from the PRESS trial

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

There are limited data regarding the clinical value of routine postdilatation with noncompliant balloons for drug-eluting stent implantation. This study sought to evaluate the clinical impact of additional postdilatation with noncompliant balloons on clinical outcomes after everolimus-eluting stent implantation.

METHODS AND RESULTS

We planned to randomly assign 1,774 patients with coronary artery disease to additional high pressure postdilatation using noncompliant balloons and moderate pressure dilatation using stent balloons for everolimus-eluting stent implantation. The primary end point was a composite of death, myocardial infarction, stent thrombosis, or target vessel revascularization at 2 years since randomization. The study was stopped early due to slow enrollment. A total of 810 patients (406 patients in the high pressure group and 404 in the moderate pressure group) were finally enrolled. At 2 years, the primary end point had occurred in 3.6% of the patients in the high pressure group and in 4.4% of those in the low pressure group (p=0.537). In addition, no significant differences were observed between the two groups in the occurrence of an individual end point of death (0.8% in the high pressure group versus 1.5% in the moderate group, p=0.304), myocardial infarction (0.2% versus 0.5%, p=0.554), stent thrombosis (0% versus 0.2%, p=0.316), or target vessel revascularization (2.8% versus 2.6%, p=0.880).

CONCLUSIONS

A strategy of routine postdilatation with noncompliant balloons after everolimus-eluting stent implantation did not provide incremental clinical benefits.

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Effect of the introduction of a transcatheter aortic valve replacement programme on outcomes in severe aortic stenosis

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

AIMS

Transcatheter Aortic Valve Replacement (TAVR) has enabled intervention in elderly, comorbid patients with severe aortic stenosis (AS) previously thought inoperable. We reviewed the effect of the development of a TAVR programme and an Aortic Stenosis Heart Team on mortality in AS. It was hypothesised that a streamlined programme would provide a mortality benefit independent of the effect of intervention.

METHODS AND RESULTS

A large echocardiography database was reviewed including consecutive patients from Jan 1, 2006 to Dec 31, 2016. Patients were identified with severe AS using the following criteria, Aortic Valve (AV) mean gradient >= 40mmHg, AV peak velocity >= 4.0m/s, AV Area <= 1.0 cm2, or Dimensionless Performance Index <= 0.25. The effect of the introduction of a TAVR programme in January 2010 was estimated using Cox multivariable regression analyses as well as propensity-matched analyses. The primary outcome of interest was overall mortality. Interactions between AV intervention and comorbidities were assessed using interaction terms in the models.

In total 3,399 patients were available for analysis. Observed mortality in our population was high, with 210 (6.18%) deaths by 30 days, and a total of 722 deaths (21.24%) by 1 year. We compared the populations before and after the introduction of the TAVR programme. No significant differences were seen with age, Body Mass Index (BMI) or overall Ejection Fraction (EF), but patients were significantly more likely to be female, with a higher glomerular filtration rate (GFR), a higher rate of moderate left ventricular (LV) dysfunction and a lower rate of severe LV dysfunction in the post TAVR era. A previous diagnosis of heart failure, COPD or dementia was less likely, but a higher proportion had a history of AMI or stroke. There was no difference in prior CABG, diabetes or cancer. In all patients who had undergone any AV intervention, patients treated after the TAVR programme were older, had a lower EF, a lower GFR and a higher likelihood of a previous cancer diagnosis.

After adjusting for age and comorbidities, the TAVR programme was associated with a significant reduction in overall mortality (HR=0.82, 95% CI 0.72-0.93, p=0.003). After adding Aortic Valve (AV) intervention by any modality into the multivariable model, the effect estimates of this survival benefit were diminished, but remained statistically significant (HR=0.86, 95% CI 0.75-0.98, p=0.021). Propensity-matched analyses showed a similar trend, but the survival benefit of having a TAVR programme was no longer significant after adjusting for AV intervention (HR 0.88, 95% CI 0.76-1.02, p=0.083). Whilst the TAVR programme was associated with a reduction in overall mortality, in our interaction analysis, the absolute survival benefit attributed to the intervention itself in the post TAVR era appeared to be less compared to the pre-TAVR programme era (interaction p=0.018).

CONCLUSIONS

The development of the TAVR programme expanded the treatment population, allowing treatment of older patients with more comorbidities. Even when matching for the presence of AV intervention, there was a reduction in overall mortality. We propose that improved outcomes may be the result of both expanded treatment modalities and, independently, a streamlined multidisciplinary approach. The diminished benefit of AV intervention in the post TAVR era could be the result of enabling intervention strategies in an older, more comorbid population.

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ACS in patients receiving long-term oral anticoagulation: from the procedure to long-term management

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

AIMS

Patients on long-term oral anticoagulation (OAC), that are hospitalized for an acute coronary syndrome (ACS) represents a substantial challenge to the physician who must balance the risks of periprocedural haemorrhage and thrombotic complications. We sought to describe the management patterns in a real-life setting for those patients and to document clinical outcomes.

METHODS AND RESULTS

Analysis of 5545 consecutive ACS patients, enrolled in a Portuguese, multicenter, observational, longitudinal cohort study with 1 year follow-up. Patients who were on OAC before ACS (n=326, 5.9%) were older (70±11 vs 66±13 years,

CONCLUSIONS

Despite evidence-based guidelines for the management of ACS, the real-world setting in Portugal shows discrepancies in clinical practice, particularly in those who need long-term OAC. Patients with ACS previously treated, for several reasons, with OAC are facing a dramatic increase on the risk of death and/or rehospitalization.

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Ambulatory transradial coronary angioplasty: is there any limit nowadays?

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

AIMS

The ambulatory PCI has been developed as a form of improvement in the care of coronary intervention. Its safety and feasibility has been demonstrated in selected patients with "simple" lesions but it is not well known if this practice could be applied to more "complex" lesions and patients.

METHODS AND RESULTS

Prospective multicentre registry of 1047 consecutive patients planned for same-day discharge transradial PCI. Patients were divided in two groups according to ?simple PCI? (group A: 734, 70%) or complex PCI (group B: 313 (30%), Include CTO, Left Main PCI, Grafts, True bifurcations, rotational atherectomy and multivessel PCI). Feasibility (% of patients finally discharged) and safety (MACE at 24 h and at 1 month: combined end-point of death, AMI, new revascularization, stroke, admission, stent thrombosis and BARC 2-3 bleeding) were compared between groups. We also analyze visits to emergency departament and vascular complications. The only diference in baseline was for peripheral artery disease (3.4% in A vs. 8.6% B p: 0.001). Feasibility was higher in group A (81% vs 64%, RR 1.89, 95% CI 1.52-2.35, p <0.001). Ambulatory PCI was very safe in both groups. Two MACE (admission due to low digestive hemorrhage and atypical chest pain) occured at 24 h in group A (0.3%) vs. none in group B (p: NS). At 30 days, 1% (6) of patients in group A, had a MACE (3 admissions due to chest pain, one revascularization of another vessel, one subacute stent thrombosis and one minor stroke) compared to 1.5% of the group B (3 admissions for chest pain), p: NS. There were also no differences in visits to the emergency department or vascular complications (a non significative tendency to higher rate of radial occlusion at 1 month in group B, 2.5 vs 0.9, p: 0.07).

CONCLUSIONS

Feasibility of ambulatory PCI in selected patients with complex lesions is less probable than in simple lesions, however when it is possible, it is as safe as in selected patients with simple lesions.

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Endovascular repair of coarctation of the aorta in a bodybuilder

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

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Health-related quality of life following TAVI using transfemoral and transaortic approaches - single-centre study

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

AIMS

Medical literature provides a massive amount of studies assessing quality of life following transcatheter aortic valve implantation (TAVI). However, there is still lack of evidence describing this variable in transaortic TAVI approach (TAVI TAo). The aim of the study was to evaluate short- and long-term changes in quality of life status in patients undergoing transaortic TAVI procedure, in comparison to transfemoral TAVI and aortic valve replacement (AVR) patients.

METHODS AND RESULTS

Ninety-seven patients? samples were included in the study. Thirty-two patients underwent transaortic TAVI procedure, thirty-one transfemoral TAVI procedure and thirty-four patients underwent AVR procedure. The quality of life status was assessed with EQ-5D-3L questionnaire at baseline, after one-month and one-year follow-up. The overall mean of patients', age was 80 (61 - 92) years and logistic EuroSCORE mean was 12.45% (1.39 - 78.98%). The analysis of baseline values compared to follow-up data, showed a significant improvement of declared quality of life in all three groups ($p < .001$). At baseline, up to 23.7% patients reported extreme problems in EQ-5D-3L questionnaire, mainly in pain and discomfort dimension, and up to 76.3% patients declared moderate problems before the procedure. Declared health state at baseline was significantly lower in transfemoral patients (TAVI TF), (ps < .001) and after one month there were no differences between the three groups ($p = .987$). After one year, the AVR patients results of EQ-5D-3L index value were lower in comparison to TAVI patients (ps < .05). The analysis also showed significant differences between results of EQ-5D-3L index value for the period of time (TAVI TAo - $p < .001$, TAVI TF $p < 0.05$, AVR - $p < 0.05$). In all groups, the values were significantly increasing after one-month and one-year follow-up, in comparison to baseline value. Significant differences were also found between Visual Analogue Scale values (VAS) for TAVI TAo and AVR group ($p < 0.001$) and TAVI TF and AVR group ($p < .001$) after one month and one year. AVR patients reported lower values of VAS, the two TAVI groups presented no differences among them.

CONCLUSIONS

In summary, a great improvement of quality of life status was presented in the following study for all three groups. Regardless of the TAVI approach, EQ-5D-3L index value and Visual Analogue Scale values were significantly rising after one-month and one-year follow up, the AVR patients however, reported lower health status in comparison.

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Ambulatory transradial anterograde CTO, safety and feasibility

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

PCI of a CTO has been classically considered a high-risk intervention and it is not usually contemplated to perform it in an ambulatory way. The increasingly experience and more atraumatic cath-lab tools may be feasible to perform it in an ambulatory way as other simple lesions.

METHODS AND RESULTS

Prospective multicentre registry of 1047 consecutive patients planned for same-day discharge transradial PCI (group A: simple PCI (734), group B: CTO (50), group C: Complex PCI (263)). Feasibility (% of patients finally discharged) and safety (MACE at 24 h and at month: combined end-point of death, AMI, new revascularization, stroke, admission, stent thrombosis and BARC 2-3 bleeding) were compared between groups. We also analyze visits to emergency department and vascular complications at discharge, at 24 hours and at 1 month. Procedures were more frequent scheduled than ad hoc in group B (26% vs 48%, p: 0.002). CTO procedures were also longer (88 min vs 57 min, p: 0.001), with larger-sized sheaths (7 Fr: 63% vs. 4.2%, p: 0.001), and more stents (1.77 vs. 1.32, p: 0.001). CTO were 100% anterograde with contralateral injections in 70%. Feasibility was lower in group B (81% vs 57%,

CONCLUSIONS

It is possible to safely perform ambulatory transradial anterograde PCI of CTO in selected patients, although its feasibility is lower than in patients with simpler lesions.

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Efficacy and safety of snuffbox approach for coronary angiography and PCI

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

AIMS

Distal radial artery approach, called snuffbox approach, has several advantages regarding vascular complications and hemostasis. However, there is few data on the snuffbox approach. This study is to investigate the efficacy and safety of snuffbox approach for coronary angiography (CAG) and PCI

METHODS AND RESULTS

From November to December 2017, a total of 81 consecutive patients (59 male, 65 ± 13 years) were included who underwent left snuffbox access. The snuffbox approach was performed in 50 patients for investigation for ischemic heart disease, 27 due to NSTE-ACS, and 4 due to STEMI. Success rate of snuffbox puncture was 94.4% (n=74). Among 22 patients who underwent PCI, only 1 patient failed to PCI via snuffbox approach. We also compared with distal radial artery and conventional left radial artery regarding diameter of artery by quantitative coronary analysis (QCA). QCA of 60 patients showed the difference of diameter between left snuffbox puncture site and conventional left radial artery (Snuffbox: 2.60 ± 0.54 mm, Conventional: 2.72 ± 0.51, $p = 0.004$). Nevertheless, 6 French sheath was successfully engaged into distal radial artery in all patients. Moreover, there was significant correlation between the distal and conventional radial artery diameter ($r = 0.836$, $p < 0.001$). There were no cases which were failed to CAG due to tortuosity of artery and no puncture site complications including major bleeding, hematoma, pseudoaneurysm, and arteriovenous fistula.

CONCLUSIONS

Snuffbox approach was feasible and safe for CAG and PCI when compared conventional radial artery approach

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Lack of exercise induced hand ischaemia in patients with chronic radial artery occlusion

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

To evaluate the existence of exercise induced hand ischemia in patients with radial artery occlusion after transradial access.

METHODS AND RESULTS

After a transradial coronary procedure, patients with suspicion of radial artery occlusion were asked for study participation. After informed consent radial ultrasound was performed to confirm radial artery occlusion in 18 patients. Rest perfusion of the digits was analyzed by laser Doppler digital imaging followed by an exercise test. Ischemia was assessed with transcutaneous oxygen pressure (TcPO2) and thumb capillary lactate. In the same patient the results of the radial artery occlusion side were compared to the contralateral side.

Although there were differences in compensatory ulnar perfusion of the RAO side compared to the open side, we found that after 5 minutes of exercise there were no significant differences in TcPO2 (51.4 mmHg (±17.2) vs 43.9 mmHg (±15.5), p = 0.18) or lactate (2.0 mmol/L (±0.7) vs 2.1 mmol/L (±0.7), p = 0.80). Differences in mean TcPO2 were found to be stable during exercise and not different from baseline differences with mean TcPO2 higher in the RAO hand (mean difference: 7.05, 95% CI: [3.96, 10.1], p < 0.001) when all measurements were considered in a mixed model analysis.

CONCLUSIONS

Chronic radial artery occlusion does not lead to exercise induced hand ischemia.

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Direct oral anticoagulant in addition to antiplatelet therapy after ACS according to revascularisation strategy: a systematic review and meta-analysis

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

AIMS

Aim: Therapeutic advances have dramatically improved survival of patients with acute coronary syndromes (ACS). However, this population remains at high risk for recurrent adverse cardiovascular events. Despite concerns regarding an increased bleeding risk, oral anticoagulation represents an attractive option for secondary prevention after ACS.

Our aim was to investigate safety and efficacy of direct oral anticoagulants (DOACs) in addition to antiplatelet therapy after ACS, focusing on clinical outcomes according to the revascularization strategy.

METHODS AND RESULTS

Methods and Results: PubMed, EMBASE and Google scholar database were searched to perform a meta-analysis of randomized controlled trials (RCTs) investigating the impact of DOACs on top of antiplatelet therapy after ACS. Only studies in which patients had access to percutaneous coronary intervention (PCI) for the index event were considered. Primary efficacy endpoint was the composite of cardiovascular death, myocardial infarction or urgent revascularization, and stroke. Primary safety endpoint was the rate of major bleedings.

A total of 29,667 patients from six RCTs were included in the present meta-analysis. A significant lower risk of the primary efficacy endpoint was observed in patients treated with DOACs as compared to the control group (odds ratio [OR]: OR 0.85, 95% CI 0.77-0.93,

CONCLUSIONS

Conclusions: Findings from this meta-analysis suggest that clinical benefits of DOACs on top of background antiplatelet therapy might depend of revascularization strategy. Indeed, DOACs might improve ischemic outcomes in patients not undergoing PCI after ACS besides an acceptable higher risk of major bleedings. Conversely, the risk-benefit profile of DOACs strategy appears unfavorable in patients undergoing PCI after ACS.

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The degree of aortic calcification influences outcome following balloon aortic valvuloplasty for severe aortic stenosis

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

AIMS

Balloon aortic valvuloplasty has a role in a select group of patients with severe aortic stenosis and identifying appropriate patients is key. Histologically, it has been shown that the intervention involves physically disrupting the leaflet calcification. We therefore hypothesized that the degree of calcification will impact on the success of the procedure and could aid in patient selection.

METHODS AND RESULTS

We retrospectively analyzed all patients who had undergone balloon valvuloplasty and multi-slice CT in our centre between July 2011 and April 2014. All patients underwent echocardiography pre- and post-procedure. For those patients managed medically following BAV, a clinical assessment was performed at 3 months and an echocardiogram at 6 months. A potential predictive aortic valve calcification value for mortality was calculated using Youden?s index. Death was recorded from the office of national statistics.

A total of 240 BAV procedures were performed in 206 patients (male=124). Mean age was 82.3±9.6 years and mean logistic Euroscore 19.0±11.8. BAV caused a significant (pre: 0.63±0.21 vs post: 0.77±0.27 cm2, p<0.01, n=240), but temporary (post: 0.80±0.27 vs 6 months: 0.64±0.18 cm2, p<0.01, n=88) increase in aortic valve area. At 6 months those patients with a reduced ejection fraction (<50%) demonstrated a significant improvement in ejection fraction (33.2±9.3 vs 37.8±13.4%, p=0.01, n=52).

Those patients with a non-severely calcified aortic valve (<1853.5 AU) had a larger increase in aortic valve area following valvuloplasty compared to those with severe calcification (0.22±0.21 vs 0.11±0.24 cm2, p=0.01). Multivariate analysis revealed severe aortic valve calcification (HR 2.79, 95% CI: 1.18-6.63, p=0.02) along with pulmonary artery pressure post-BAV (HR 1.02, 95% CI: 1.00-1.03, p=0.03) to be predictive of survival.

CONCLUSIONS

In patients with severe aortic stenosis the degree of aortic calcification impacts on the success of balloon aortic valvuloplasty both echocardiographically and clinically. This is important to consider when treatment-stratifying patients and when undertaking this intervention. In particular, patients with a heavily calcified valve are unlikely to gain much benefit from BAV and should be considered directly for TAVI, even in an emergency setting. Alternatively, in those in whom TAVI is not appropriate more aggressive dilatation protocols should be considered in patients with heavily calcified valves undergoing BAV.

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TAVI with the 34mm self-expanding CoreValve Evolut R: initial experience in 101 patients from a multicentre registry

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

AIMS

The recently released Medtronic CoreValve Evolut R® 34 mm is the largest ever developed self-expanding transcatheter heart valve. Clinical data of this device size are scarce.

METHODS AND RESULTS

We report on the first 101 consecutive patients treated with transfemoral transcatheter aortic valve implantation (TAVI) using the 34 mm Evolut R® device in a multicenter registry. Clinical parameters were determined before the procedure and echocardiography was performed at baseline and discharge. VARC-2 criteria were assessed at 30 days.

Mean age was 80.7 years (±6.6), mean logistic EuroSCORE was 19.8%. At baseline, 47.5% suffered from atrial flutter or fibrillation and 66.3% from significant coronary artery disease. 18.8% of the patients had undergone cardiac surgery before TAVI. Before treatment, 83.2% of the patients suffered from dyspnea NYHA class III or IV. The majority (76.2%) had a normal or mildly reduced left ventricular ejection fraction according to echocardiography. The mean pressure gradient (MPG) averaged 41.7 mmHg.

Procedural duration was 71.6 min. Balloon valvuloplasty was carried out in 55.4% before TAVI. After the initial valve deployment moderate or severe aortic regurgitation was evident in 35.6% of the cases (36 patients) and post-TAVI balloon valvuloplasty was performed in 47 patients (46.5%). Three patients received a second valve as a bailout TAVI procedure. Echocardiography at discharge revealed a mean AVA of 2.0 cm2, moderate aortic regurgitation (AR) in 4.0% and severe AR in 1.0%. VARC-2 device success was achieved in 92.1%, the early safety endpoint occurred in 11 patients (10.9%). New permanent pacemakers were implanted in 17 patients (16.8%). 30-day-mortality was 2.0%, a stroke occurred in 3.0% with a disabling stroke in one patient. The incidence of major vascular complications and bleeding was 1.0 % and 5.0 %.

CONCLUSIONS

This consecutive registry of the first 101 patients treated at five high volume centers with the new Medtronic CoreValve Evolut R 34 mm TAVI device confirms the encouraging efficacy and safety results of the established smaller CoreValve Evolut R valves. Initial experience with the new self-expanding CoreValve Evolut R® 34 mm valve is characterized by high procedural success, excellent hemodynamic performance and a low early complication rate.

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A comparison of renal outcome, periprocedural complications and long-term mortality of kidney transplanted patients vs. patients with native kidneys undergoing TAVI ? Data from an international multicentre registry

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

AIMS

To describe the clinical course of kidney transplanted patients with severe aortic stenosis undergoing TAVI in terms of renal outcomes and overall mortality, and compare these to matched patients with native kidneys, matched according to renal function and major clinical and procedural characteristics.

METHODS AND RESULTS

A retrosprctive case control study based on data from 13 TAVI centres in Europe, North America and Israel (total sample size of 11,753 patients). The study cohort included 186 patients (62 kidney transplanted and 124 control patients). The mean fraction of transplanted patients out of the overall sample size was 0.52% and the median fraction by centre was 0.53% (range 0.16-1.6%). The mean eGFR for the transplanted patients was 37.6 ±21.9 ml/min and distribution of CKD stages was: I/II- 16%, III-43.5%, IV-19.3%, V-21.2%. The control cases were similar to the transplanted patients in all aspects apart from age (72.9±9.5 vs 81.7±10.7 years,

CONCLUSIONS

Kidney transplanted patients constituted around 0.5% of TAVI cases in our registry. These patients are younger and have larger valve area compared to the general TAVI population. Overall, TAVI seems to be safe in these patients, with short term complications and long term mortality rates that are equivalent to those of similar patients with native kidneys. However, transplanted patients are at considerably increased risk for deterioration in eGFR, CKD stage, and need for initiation of haemodialysis for up to one year follow up.

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Differences in patients, lesion and procedure characteristics depending on the age of the CTO

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

AIMS

Despite the growth of the number of performed procedures and introduction of new techniques and equipment, angioplasty of chronic total occlusion (CTO) remains one of the most demanding procedures in interventional cardiology. So far, there are only few reports describing how CTO duration may influence lesion and procedural characteristics. Thus, our aim was to see if the duration of a CTO may affect lesion characteristics and revascularization success by percutaneous coronary intervention (PCI) procedure.

METHODS AND RESULTS

Altogether 4044 patients from the EuroCTO registry undergoing a CTO PCI procedure between January 2015 and April 2017 have been included and divided into 6 subgroups depending on the occlusion age: 1) 3-4 months, 2) ?4 and

CONCLUSIONS

Older CTOs are associated with greater prevalence of calcification, longer lesions length, better developed collateral circulation and lower procedural success rate.

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Aortic dissection with renal malperfusion

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

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Safety and efficacy of a sirolimus-eluting stent in an all-comer French patient population: presentation of one-year target lesion failure data

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

AIMS

The aim of this registry is to evaluate the safety and clinical performance of the Orsiro ultrathin bioresorbable polymer sirolimus eluting stent in an all-comers French patient population in standard clinical care.

METHODS AND RESULTS

BIOFLOW-III French Satellite is a prospective, national, multicentre all-comers registry that enrolled 1000 patients between November 2014 and July 2016 in 50 French national sites and overseas. Primary composite endpoint is Target Lesion Failure (TLF) including cardiac death, target vessel Q-wave or non-Q-wave myocardial infarction (MI), emergent coronary artery bypass graft (CABG) and clinically driven target lesion revascularisation (CD-TLR) at 12-months follow-up. Secondary endpoints included definite stent thrombosis.

757 men (75.7%) and 243 women (24.3%) were enrolled. Mean age was 66.7 ± 11.1 years ranging from 33-94 years. Major cardiovascular risk factors were: hypertension (65.8%), hypercholesterolemia (60.3%), current or previous smoker (57.7%), and diabetes (31.4%). 31.6% of patients had previous coronary surgeries or intervention and 35.6% of patients presented with acute MI.

1326 lesions were treated with the sirolimus eluting stent. Of all stented vessels, 50.5% were B2/C lesions with a mean vessel diameter of 2.9 ± 0.5 mm and 18.6 ± 8.6 mm mean length. Pre-dilatation was performed in 58.3% of lesions. Percutaneous Coronary Intervention (PCI) procedures were successful for 97.6 % of patients.

At 12 months, TLF rate was 3.5% for the overall population with 2.2% cardiac deaths, 2.8% TV-MI, 0.2% emergent CABG and 2.0% CD-TLR. Definite stent thrombosis was observed in 6 patients (0.6%). In the pre-defined subgroup of patients with MI at baseline, diabetics and small vessels (?2.75 mm), the TLF rate was 2.6%, 5.6% and 4.2% respectively.

In a previous study, BIOFLOW-III with inclusion completed 3 years ago, TLF rate was 5.1%. Post-dilatation was performed in 25.3% of lesions vs 33.9% in the BIOFLOW-III French Satellite ($p<0.0001$). Moreover, at discharge, association of aspirin and ticagrelor was prescribed for 8.0% of patients in the historical cohort vs

29.3% (p <0.0001).

CONCLUSIONS

BIOFLOW-III French Satellite confirms the low TLF rate (3.5%) and the safety of Orsiro sirolimus eluting stent in an all comers population, even in high risk subgroups of patients. The 1.6% difference in TLF could be explained by the evolution of the practices, in particular, more systematic post dilatation as well as the use of newer drugs.

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Evaluation of microvascular dysfunction in patients with Takotsubo syndrome

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Aims of this study was the evaluation of microvascular function in patients with Tako-tsubo cardiomyopathy using two quantitative angiographic parameters: TIMI frame count and myocardial blush grade.

METHODS AND RESULTS

67 patients with Tako-tsubo cardiomyopathy, showing typical left ventricular apical dysfunction, was retrospectively analyzed. A control group of patients with anterior STEMI, matching age, LVEF and the main cardiovascular risk factors, was selected. This group was also subdivided into two subgroups based on myocardial reperfusion (a group of 35 patients with myocardial reperfusion and a group pf 32 patients with persistent microvascular obstruction). Epicardial flow was studied with TIMI frame count using Gibson method. Myocardial perfusion was evaluated using QuBE software (Quantitative Blush Evaluator). The Tako-tsubo cardiomyopathy group showed , a significantly higher corrected TIMI frame count on the LAD compared to STEMI underwent to PCI (p=0,0018), while it was not significantly different compared to STEMI with persistent microvascular obstruction (p=0,58). QuBE score in patients with Takotsubo cardiomyopathy was significantly lower compared to patients with STEMI underwent to PCI (p=0,008) and significantly higher compared to STEMI with persistent microvascular obstruction (p=0,00046). Moreover in patients with Tako-tsubo cardiomyopathy, both TIMI frame count and QuBE score, were pathological in an myocardial area more extended than the area perfused by a single epicardial vessel (LAD).

CONCLUSIONS

Our data shows that in Tako-tsubo cardiomyopathy epicardial flow and myocardial perfusion are impaired, suggesting that microvascular dysfunction could be one of the pathophysiological driver of the disease. Furthermore the microvascular dysfunction is widespread, extending over the area perfused by a single epicardial vessel.

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Mid-term angiographic performance of a self-expanding sirolimus-eluting stent for left main PCI. A substudy of the MATISSE registry

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

AIMS

recently percutaneous treatment of left main (LM) coronary artery disease obtained a stronger scientific evidence. This lesion setting shares several anatomical characteristics (plaque distribution, tapered vessel, resistance to dilatation) that make a self-expandable stent theoretically favorable, in order to reduce the risk of stent malapposition or underexpansion. We here report the results of the angiographic sub-analysis of the MATISSE study.

METHODS AND RESULTS

The MATISSE study analyzed the immediate technical performance and the mid-term efficacy of the self-expanding sirolimus-eluting Stentys stent (STENTYS S.A., France) for LM PCI in a real world, high risk population. We analyzed a subgroup of 33 patients with complete angiographic follow-up and centralized quantitative coronary angiographic analysis (QCA). Primary study end-point was late lumen loss (LLL). Secondary endpoint was binary restenosis. Lesions were located at distal LM bifurcation site in all patients, and 31 patients received a LM-left anterior descending artery (LAD) stent. In the LM reference vessel diameter (RVD) was 4.1±0.5 mm and percent diameter stenosis 69±15%. RVD of lef anterior descending (LAD) and left circumflex (LCX) were respectively 3.2±0.4 and 3±0.5 mm, with a MLD of 1.6±0.7 and 2.2±1 mm. After device deployment and postdilatation, final MLD in LM, LAD and LCX was respectively 3.8±0.6, 3±0.5 and 2.8±0.5mm. Procedural success was achieved in all patients. Angiographic follow up was scheduled at an average time of 7.8±3.7 months. MLD of the LM was increased determining a negative LLL of -0.1±0.9 mm. LLL of LAD and LCX was respectively 0.3±0.3 and 0.3±0.4 mm. One case of binary restenosis of the LM occurred and was treated with drug-coated balloon angioplasty. Zero were the cases of binary restenosis for the LAD, and 6 for the LCX (3 cases were treated with stenting during index procedure, one of which was the study device).

CONCLUSIONS

The use of a self-expanding stent for distal LM angioplasty showed good angiographic performance at mid-term follow-up.

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Impact of blood pressure variability and heart rate variability on one-year clinical outcomes in patient with AMI from KAMIR-NIH registry

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

AIMS

Blood pressure (BP) variability and heart rate (HR) variability are known risk factors for cardiovascular and cerebrovascular events. But, the evidence is still lack in patients with acute myocardial infarction (AMI). Therefore, we assessed the impact of BP variability and HR variability on long-term clinical outcomes in patients with acute myocardial infarction.

METHODS AND RESULTS

From Nov. 2011 to Dec. 2012, total 7657 AMI patients from KAMIR-NIH registry were analyzed. Patients not received percutaneous coronary intervention, missing values for follow-up BP, patients lost follow-up at 12 months were excluded. Chronic kidney disease (CKD) was defined as eGFR

CONCLUSIONS

In this KAMIR-NIH registry, MACCE group showed higher BP variability and HR variability. Moreover, HR variability (CV of HR) was a significant prognostic factor for predicting MACCE in patients with AMI at 1-year clinical follow-up.

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Reproducibility of quantitative flow ratio: an inter-core laboratory variability study

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Quantitative flow ratio (QFR) is a novel approach to derive FFR from diagnostic coronary angiography. The FAVOR II China Study demonstrated excellent accuracy of online QFR in identifying hemodynamically significant coronary stenosis in the catheterization laboratory. This study sought to evaluate the reproducibility of QFR when analyzed offline in two independent core laboratories.

METHODS AND RESULTS

All the interrogated vessels in the FAVOR II China Study were separately analyzed using the AngioPlus system by two independent core laboratories following the same standard operation procedures. The analysts were blinded to the FFR values and the online QFR values. For each interrogated vessel, the same angiographic image runs were used by the two core laboratories for QFR computation. In both core laboratories QFR was successfully obtained in 330 of 332 interrogated vessels, in which FFR was available in 328 vessels. Thus, a total of 328 vessels ended in the final statistical analysis. The mean difference in QFR between the two core laboratories analyses was 0.00±0.03(p=0.0397), which was slightly smaller than that between the online (in procedure) analysis and the two core laboratories analyses (0.01±0.05, p=0.0003 and 0.01±0.05, p=0.0379, respectively). The systematic and random errors of QFR with respect to FFR were comparable between the two core laboratories (0.00±0.06, p=0.6087, and 0.00±0.06, p=0.5310). Receiver operating characteristic curve analysis showed that diagnostic accuracies of QFR analyzed by the two core laboratories were both excellent (AUC = 0.97 versus 0.96, p=0.1424), when using FFR as the reference standard.

CONCLUSIONS

Our study showed excellent diagnostic accuracy of QFR in assessing the physiological significance of coronary stenosis. The low variability in inter-core laboratory QFR analyses suggests that QFR analyses can be carried out in different core laboratories if and only if highly standardized conditions are maintained.

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Clinical and procedural benefits of a very low profile DES: the OPTIMIZE trial

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

AIMS

OPTIMIZE is a prospective, single-blind, randomized, active-control, multi-center clinical study comparing the safety and efficacy of the Svelte sirolimus-eluting coronary stent Integrated Delivery System (Svelte IDS) and Svelte sirolimus-eluting coronary stent Rapid Exchange delivery system (Svelte RX) to the commercially available Abbott Vascular XIENCE or Boston Scientific Promus Drug-Eluting Coronary Stents (control DES) for the primary treatment of symptomatic ischemic heart disease.

METHODS AND RESULTS

The Svelte IDS utilizes an 81?m thick cobalt-chromium stent with bioresorbable amino acid-based (PEA) drug carrier eluting sirolimus mounted on a low-compliant balloon affixed to a 0.014? integrated Asahi wire. The resulting profile is low enough to enable delivery through a 5F diagnostic catheter (0.047? inner diameter). The Svelte RX utilizes the same stent, drug coating and delivery balloon technology as the Svelte IDS on a standard rapid-exchange platform. Prior controlled and post-market clinical studies have demonstrated the safety and efficacy of the Svelte IDS as well as its ability to reduce the steps, time and cost of coronary stenting procedures.

OPTIMIZE will enroll 1,630 subjects (1:1 randomization to Svelte IDS or Svelte RX and control DES) at up to 120 institutions in the US, Europe and Japan with symptomatic ischemic heart disease due to ? three de novo stenotic lesions contained within ? two native coronary arteries with RVD ? 2.50 mm and ? 4.00 mm and lesion length ? 24 mm amenable to revascularization with percutaneous coronary intervention and stent deployment. Patients will be stratified based on the ability to utilize a direct stenting approach.

The study primary endpoint is non-inferiority of target lesion failure at 1 year post-procedure, defined as cardiac death, target vessel myocardial infarction (Q wave and non-Q wave) or clinically-driven target lesion revascularization. Secondary endpoints include target vessel failure, target lesion revascularization, target vessel revascularization, target vessel myocardial infarction, major adverse cardiac event, death and stent thrombosis at 30 days, 6 months 1 year and annually through 5 years. Angiographic evaluation will be performed at the index procedure and at 1 year follow-up in 150 subjects, equally randomized between the treatment and control groups. The first 60 of these 150 subjects will also have IVUS performed at the index procedure and 1 year follow-up. An indepent assessment will be conducted to evaluate the health economic benefit of the Svelte IDS.

The first patient in OPTIMIZE was enrolled in January 2018.

CONCLUSIONS

This is the first report of the multinational, randomized, controlled OPTIMIZE study. Review of the study

design, enrolment progress and case examples will be provided. The study will evaluate, in controlled fashion, the potential clinical and economic benefits associated with this novel fixed-wire DES technology with a new class of bioresorbable drug coating technology as well as transradial intervention, direct stenting and the health economic benefits of streamlining PCI.

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Long-term clinical outcomes of patients with multivessel coronary artery disease after treatment with thin strut DES with bioresorbable polymer: long-term results from CENTURY II trial

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

AIMS

Our purpose was to assess the safety and efficacy of a bioresorbable polymer sirolimus-eluting stent (BP-SES), in patients with MVD and compare the long-term outcomes of these patients to those treated with a permanent polymer everolimus-eluting stent (PP-EES).

METHODS AND RESULTS

CENTURY II is a randomised, multicentre study where a total of 1119 patients were enrolled. Out of these, 546 patients were diagnosed with MVD and stratified to treatment with BP-SES Ultimaster (275) or PP-EES Xience (271). The primary endpoint was target lesion failure (TLF) defined as a composite of cardiac death, target vessel related MI and clinically driven revascularization at 9 months. The data was 100% monitored and an independent clinical event committee adjudicated adverse events. Four year data is herein presented and five-year data will be available at the time of presentation.

There were no significant differences noted in the baseline patient characteristics: age 66±10 vs 66±11, p=0.38, male patients 77.8% vs 81.9%, P=0.23, DM 35.3% vs 31.0%, p=0.29, smokers 19.6% vs 23.0%, p=0.4 and a previous MI rate of 33.8% vs 34.3%, p=0.90 in the BP-SES and PP-EES groups respectively. 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 the BP-SES and PP-EES groups respectively. There was no significant difference noted in 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 1.1±0.5, p=0.5). The left anterior descending vessel was the most commonly treated vessel in both groups 49.8% and 50.9% (p=0.8) in the BP-SES and PP=EES groups respectively.

At 4 years, there was no significant difference noted in the patients? clinical outcomes in both groups. Angina was present in 6.9% of the in the BP-SES and 6.8% of the P-EES group (p=0.98). The rates of cardiac death (2.9% vs 3.7%, p=0.61), target vessel-MI rate (1.8% vs 3.0%, p=0.39), clinically driven target lesion revascularisation rate (6.2% vs 8.9%, p=0.24) and clinically driven target vessel revascularisation (8.4% vs 8.9%, p=0.83) did not differ significantly in the BP-SES and PP-EES groups respectively. Composite endpoints such as TLF (9.8% vs 11.0% p=0.63) and target vessel failure (12.4% vs 13.3%, p=0.75) in the BP-SES and PP-EES groups respectively, were also similar. Patient oriented composite endpoint defined as a composite of all MI, all death and all coronary revascularization rate was 23.6% vs 31.0%, p=0.05 in BP-SES and PP-EES groups respectively. The rate of stent thrombosis followed a similar trend 1.5% in BP-SES vs 2.6% in PP-EES (p=0.35), while the DAPT rate at 4 years was 18.1% vs 13.6, p=0.18) in the BP-SES vs PP-EES groups respectively.

CONCLUSIONS

Coronary stenting in patients with complexities such as multivessel disease using BP-SES and PP-EES, showed similar long-term clinical outcomes of up to 4 years with the trend favouring outcomes in both safety and efficacy of the bioresorbable polymer sirolimus-eluting stent.

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Treatment of left main coronary artery disease with a DES with bioresorbable polymer: one-year patient outcomes

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THEME: Coronary Interventions

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

AIMS

To assess the performance of a thin-strut sirolimus-eluting stent with bioresorbable polymer in a subgroup of patients with left main coronary artery (LMCA) disease, which is recognized as the highest-risk lesion subset of ischemic heart disease and where PCI interventions showed comparable outcome compared to CABG in low to intermediate anatomic complexity.

METHODS AND RESULTS

e-Ultimaster is a prospective, multicentre registry, designed to further validate the safety and efficacy of the Ultimaster in unselected patients enrolled worldwide. Of the 8879 patients enrolled and reached 1-year follow-up, 263 patients were treated in LMCA, among which 110 patients were treated for isolated LM disease (LM only), while 153 patients were treated in LM plus one or more vessels (LM+MV). Most of the patient characteristics were similar between these two groups, with a mean age of 68.5±10.0years, body mass index of 27.8kg/m2, 73.4% had hypertension and 68.1% had hypercholesterolemia. In the LM only group, there were numerically fewer male patients (67.3% vs 75.8%, p=0.16) compared to LM+MV group. In the isolated LM group, there are more patients with history of CABG (26.4% vs 16.0%, p=0.04). Patients presented with acute coronary syndrome at enrolment were 49.1% in isolated LM and 43.1% in LM+MV group.

Regarding lesion characteristics, 34.6% of patients in the LM only group had lesions longer than 25mm, while more than half the patients (55.9%) in LM+MV group had long lesions (P<0.01). In the LM only and LM+MV groups, 29.7% and 30.9% lesions had moderate or severe calcifications, 50% and 55.6% of patients had bifurcation lesions, while 0% and 7.2% of patients were treated for CTO lesions. The number of lesion treated were on average 1.0 in LM only group and 2.6 in LM+MV group, respectively. Regarding the procedure, 74.6% in LM only and 65.4% in LM+MV group were performed via transradial approach, while imaging (OFDI or IVUS) were used to assist 33% of the procedures in both group. In LM only and LM+MV groups, direct stenting was performed in 33.3% and 37.5% of the lesions, while post dilatation was performed in 65.8% and 50.1% of the lesions respectively. The number of Ultimaster stents implanted per patient was 1.3±0.7 in LM only group and 2.3±1.2 in LM+MV group, and the total length of successfully implanted Ultimaster stent was 27.0±18.8mm and 48.4±28.3mm.

At one year, the clinical event rates were comparable in LM only and LM+MV groups as the following: cardiac death (3.6% vs 3.9%, p=0.99), target vessel myocardial infarction (MI) (0.9% vs 1.3%, p=0.99), clinically driven target lesion revascularization (3.6% vs 2.6%, p=0.72), and clinically driven target vessel revascularization (4.6% vs 3.9%, p=0.99). The composite endpoint of target lesion failure rate was 7.3% vs 7.2% (p=0.99) and target vessel failure was 8.2% vs 7.8% (p=0.99) respectively. There was only 1 probable stent thrombosis in both LM only and LM+MV 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 excellent clinical outcomes at 1 year, with low rates of target vessel MI and stent thrombosis. These results indicate that thin strut sirolimus-eluting Ultimaster stent with bioresorbable polymer offers a good option for treating high risk LMCA patients.

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Bifurcation lesions: three-year experience

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

Bifurcation is recognized as a common site for atherosclerotic plaque buildup due to the differences in coronary flow, turbulence, and shear stress at the site of the bifurcation. Bifurcation lesions remain a challenge for interventional cardiologist. The aim of this study was to identify preferred treatment option and long term follow-up of patients with bifurcating lesion.

METHODS AND RESULTS

Methods: This prospective observational study was done fromNovember-2014 to October-2017 in the department of cardiology at NHFH & RI. Total 1254 patients who underwent percutaneous coronary intervention (PCI) for bifurcation lesion during this period were included in the study. They were studied for clinical characteristics and management strategy.

Result: PCI for bifurcation lesion included 17.29% of total PCI. Most patients were male (83.9% vs 16.1%). Mean age of the patients was 55.26± 10.52 years. Hypertension (69.9%) was the most common risk factor followed by family history of IHD (63.3%), dyslipidemia (53.1%), smoking (52.8%) and diabetes (50.5%). Most common diagnosis was chronic stable angina. Single stent strategy was the most common (86.1% vs 13.9%) treatment option. Mortality rate was 1.2%.

CONCLUSIONS

Provisional stenting of main branch is the preferred first-line treatment for most of the bifurcation lesions.

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Multivessel coronary disease assessed with FFR angio compared to invasive FFR: a pilot study

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

AIMS

To assess the diagnostic performance of FFRangio, a non-invasive method to measure FFR directly from angiography films, in patients with multivessel coronary artery disease. FFRangio was compared to invasive FFR (invFFR), the current gold standard for functional assessment of coronary lesions.

METHODS AND RESULTS

This study is a single centre, prospective clinical trial. Patients undergoing coronary angiography (excluding urgent procedures for STEMI) at Gifu Heart Centre (Gifu, Japan), who were found to have multivessel disease and in whom invFFR was assessed, were included in the study. Following the procedure, offline FFRangio measurement was performed. The primary outcome is per lesion sensitivity and specificity of the FFRangio regarding the functional significance of the lesion (with a threshold of 0.8 for definition of a functionally significant lesion). Secondary outcomes include per lesion accuracy, as well as the correlation between invFFR and FFRangio.

The trial will enrol a total of 50 patients, presented herein are the preliminary results of the first 17 patients (42 lesions) that were enrolled between August 29 and December 13, 2017. Mean age was 70.6±9.4 years. 94.1% (16/17) were male, 58.8% (10/17) had triple vessel disease and 52.9% (9/17) presented with UAP/NSTEMI. The distribution of lesions was: LAD/Diagonal 54.9% (22/42), Cx/OM 28.1% (14/42) RCA 17.0% (6/42). Mean % stenosis by QCA was 49.1±12.2%.

Mean invFFR was 0.8 ±0.12 (range 0.46-0.99) with 23.8% (10/42) of lesions having invFFR in the ?grey zone? (0.75-0.85). 19 lesions were invFFR positive (?0.8) and 23 lesions were invFFR negative (>0.8). iFFR-FFRangio were in agreement regarding functional significance in 88% (37/42) of lesions. Compared to invFFR as reference, FFRangio had a sensitivity of 84.2%, sensitivity of 91.3% and accuracy of 88.1%. In 2 patients with two vessel disease, invFFR-FFRangio were discordant on 1 out of the 2 lesions and in 3 patients with triple vessel disease, invFFR-FFRangio were discordant on 1 out of the 3 lesions (in all cases FFRangio determined a false positive). Pearson?s r for correlation between invFFR-FFRangio was 0.85 (

CONCLUSIONS

In patients with multivessel coronary artery disease, FFRangio shows a high level of agreement, is closely correlated with invFFR and has high diagnostic accuracy. The use of FFRangio has the potential to improve and simplify the integration of physiology and anatomy for aiding in the decision-making process regarding revascularization in multivessel disease patients. These results need further validation from larger studies.

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Severe left ventricular outflow tract calcification is associated with poor outcome in patients undergoing TAVR with balloon-expandable valves

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

AIMS

The impact of severe LVOT calcification on patient?s outcome after transcatheter aortic valve implantation (TAVI) is poorly understood. The aim of this study was to investigate the impact of left ventricular outflow tract (LVOT) calcification on outcome in patients with native calcified aortic valve stenosis (AS) undergoing TAVI with balloon-expandable valves (BEV).

METHODS AND RESULTS

Of 587 consecutive patients undergoing transfemoral TAVI with second and third generation BEVs from January 2013 to December 2015, 509 presented with non-severe (NSCALVOT) and 78 (13.3%) with severe (SCALVOT) LVOT calcification. SCALVOT was defined as a calcium volume of ?609 mm3 revealed by receiver-operating curve statistics (ROC). Calcium quantification was performed utilizing a new individualized technique allowing for accurate calcium measurement in contrast-enhanced scans. Primary outcome of interest was a composite of death from any cause, any stroke, prosthesis dislocation, annulus rupture or significant para-valvular leakage within 30 days. Secondary outcome of interest was all-cause mortality at 30-days, one year and two year after TAVI and incidence of device success. Clinical events were defined according to VARC-2 criteria. Compared to patients with NSCALVOT, patients with SCALVOT more frequently experienced the 30-day composite endpoint (7.1% vs. 15.4%, p=0.012) and were at higher risk of all-cause mortality at 30 days (2.4% vs. 9.0%, p=0.001), one year (13.2% vs. 20.5%, p=0.082) and two years (23.0% vs. 34.9%, p=0.019) after TAVI. In addition, patients with SCALVOT showed lower device success rates compared to those with NSCALVOT (96.9 vs. 93.6%, p=0.14). In multivariate analysis SCALVOT was identified as independent predictor of the 30-day composite endpoint (hazard ratio 2.44, 95% CI 1.26 to 4.73, p=0.007) and two-year all-cause mortality (hazard ratio 1.86, 95% CI 1.17 to 2.93, p=0.007).

CONCLUSIONS

Severe LVOT calcification is associated with poor peri-procedural outcome and increased risk of 30-day as well as midterm mortality in patients undergoing transfemoral TAVI with balloon expandable valves.

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Radial vs. femoral access in octogenarian patients with ACS undergoing PCI

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

AIMS

Transradial approach (TRA) is associated with lower complications rate in vascular access site and improved clinical outcomes compared with transfemoral approach (TFA). However at present data examining transradial access in the very elderly is limited. Therefore this study aims to compare in-hospital 1-year outcomes between TRA and TFA in this group.

METHODS AND RESULTS

Our group included patients had under gone percutaneous coronary interventions (PCI) from January 2014 to September 2016. The primary end point was defined as major adverse cardio- vascular events (MACE) during hospitalization and follow-up at average follow-up of 14 months, this included all-cause death, myocardial infarction (MI) and target vessel revascularization (TVR). The secondary end point was defined as any of the component of the primary end point as well as major bleeding. BARC 3 grade (Bleeding Academic Research Consortium) bleeding was considered as major bleeding. Total 285 patients older than 80 years were enrolled in this prospective registry. These patients were on average 85 year-old, predominantly female (64%) and having the following risk factors: hypertension (81%), diabetes mellitus (32%), chronic renal failure (18%). More than half of the patients (71%) having with ST-Elevation Myocardial Infarction. We divided our group into two, according to the angiographic approach: transradial (n. 89) (TR) or transfemoral (n. 196) (TF). Both groups of patients were not statistically different from the baseline characteristics. There were 5 cases of conversion radial access to the femoral access and 2 cases of conversion transfemoral to transradial. The time of the procedure and radiation exposures in both groups were comparable.
MACE illness rates during hospitalization (5% vs 12%,

CONCLUSIONS

Transradial approach significantly reduces vascular complications reducing in-hospital 1-year major adverse cardio-vascular events. Therefore transradial approach should be considered as the preferred vascular access method with the elderly.

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No difference in outcomes between immediate and delayed complete revascularisation in patients with multivessel disease following primary angioplasty

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

AIMS

About 50% of patients presenting with STEMI undergoing primary PCI have multivessel coronary artery disease which is associated with poorer outcomes compared to single vessel disease. Whilst there is general consensus on the above, currently neither guidelines nor evidence exist regarding the optimal time for complete revascularisation (inpatients or outpatients staged). The aim of the study is to compare clinical outcomes in STEMI patients with multivessel coronary artery disease who underwent complete revascularisation as inpatients respect to patients who had staged PCI within six weeks.

METHODS AND RESULTS

This was an observational cohort study of 497 patients with multivessel disease who underwent primary PCI from 2012 to 2017. Patients with previous CABG and cardiogenic shock were excluded. Patients were divided into 2 groups according to whether they underwent complete inpatient or outpatient staged PCI. The primary outcome was major adverse cardiac events (all cause mortality, myocardial infarction, target vessel revascularisation). 317 (68.76%) patients underwent complete inpatient revascularisation and 144 patients (31,23%) had outpatient PCI (at a mean of 53 days post discharge). Of the inpatients complete revascularisation group, 248 patients (53,79%) underwent complete revascularisation during the index procedure whilst 69 (14,96%) patients underwent inpatient bystander PCI in a 2nd separate procedure. There was no significant difference between the groups in terms of baseline (age, sex, smoking history, diabetes, hypertension or hypercholesterolemia) or procedural characteristics. On Kaplan-Meier analysis there was no significant difference in major adverse cardiac events between the inpatient and outpatient cohorts (p-value 0.62). Age-adjusted Cox analysis demonstrated no difference in outcomes between inpatient and outpatient procedures (HR 1.40 [95% CI 0.87-1.92]), which persisted after multivariate adjustment (HR 1.21 [95% CI 0.72-1.96]).

CONCLUSIONS

According to the literature, improved prognosis has been shown in randomized controlled trials when bystander disease is treated at time of the primary PCI compared to culprit only treatment. In this study we observed that the timing of bystander PCI after STEMI did not appear to have an effect on cardiovascular outcomes. Our results suggest that patients with multivessel disease could be promptly discharged and have bystander PCI as an outpatient which could have a significant impact on hospital length of stay and reduce costs.

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Brain MRI following TAVI in transfemoral and transcarotid approach. The question of neurological injury. A preliminary study

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

AIMS

As the TAVI experience has developed in the last few years, so have the options for vascular approaches. A large number of patients with severe peripheral atherosclerosis or physiological abnormalities of the vasculature are often considered for the alternative approach. Transcarotid access was recently suggested as one of these alternatives, however, the manipulation of carotid arteries can potentially increase the risk of neurological injury. The aim of the study was to compare brain MRI scans in patients undergoing TAVI procedure in transfemoral and transcarotid approach.

METHODS AND RESULTS

The preliminary study included six patients, who underwent TAVI procedure. Half of the patients underwent the procedure in transfemoral approach, and the other half, in transcarotid approach. The process of qualification included computed tomography angiography and an interview with the patient and his relatives. Carotid Doppler was performed on all of the patients disqualified from transfemoral approach, in order to assess an alternative access. The mean patients? age in both groups was 83 years, all of the patients had comparable comorbidities. Transfemoral procedures were performed using local anaesthesia, and transcarotid procedures ? using general anaesthesia. All of the patients underwent non-contrast magnetic resonance brain imaging (MRI) before and several days after the procedure, in order to evaluate the number of potential, recent ischaemic lesions. The procedures were performed without any complications and the mean hospital stay for both groups was approximately five days. Echocardiographic parameters were also improving in comparison to baseline values. In the transfemoral group, two patients? MRI scans showed several minor, recent, ischaemic lesions, up to 7 mm, in both hemispheres and cerebellum ? approximately 30 for each patient. There were no recent lesions in the third patient?s scan. In the transcarotid group, there were no recent lesions found after the procedure, except for one patient with a single, recent, 4mm, ischaemic lesion in the precentral gyrus, which was not significant clinically. Two patients, with lesions from the transfemoral group, presented mild post-operative delirium symptoms, approximately three days after surgery.

CONCLUSIONS

The presented study compared brain MRI scans of two groups of patients that underwent TAVI procedure in transfemoral and transcarotid approach. All of the recent, ischaemic lesions did not have any significant clinical consequences on the patients? wellbeing. The preliminary data suggest that patients undergoing TAVI procedure are not exposed to severe neurological injury ? including transcarotid access.

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Procedural success of transarterial retrograde closure approach in VSD types

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

AIMS

The transcatheter closure of VSD has become a widespread procedure. Generally, the procedure is performed using antegrade method and transvenous approach by creating an arteriovenous guidewire loop. Retrograde approach, using arterial route is less frequently used. The purpose of this study is to assess procedural success of transcatheter retrograde closure for whether membranous or muscular type.

METHODS AND RESULTS

20 consecutive patients undergoing catheter based VSD closure were included in this study. (Twelve with perimembranous, seven with muscular and one with postoperative residual VSD). The mean age was 28,2 (Range 18-58). 13(65%) of the participants were female and 7(35%) were male. Maximum and minimum defect sizes were 12 and 5 mm and the mean defect size was 7.04 mm. The procedural success was achieved in 19 of the patients (95%). 17 of 19 procedures were performed with a retrograde technique using arterial route (89,4%). The remaining two procedures were initially started with retrograde technique but for the lack of supply for one case and the shortness of the sheath to reach the VSD for the other, the methods were switched and the patients were treated with anterograde method (11,6%). One muscular (5%) procedure was unsuccessful. Two stiff guidewires were used to provide enough support for postoperative residual VSD. We did not encounter any valvular and conductional complications. The average fluoroscopy time was 24,4 minutes, total radiation exposure was 118,1 mGy and Dose Area Product was 10,6 Gycm2 respectively. The radiation exposures were significantly less than antegrade approach. Retrograde approach had to be switched to antegrade in 4 muscular VSD (total 7).

CONCLUSIONS

Retrograde VSD closure, using trans arterial route, shortens the procedure time, decreases the radiation exposures both for the patient and the operator. As the length or the arterial route is longer when compared to venous route, VSD occluder devices should be redesigned to provide sufficient length and supply. Retrograde approach seems more reliable for especially membranous type VSD in terms of success rate, duration of procedure and radiation exposure.

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Very long-term impact of thrombosuction and glycoprotein IIb IIIa inhibitor administration in STEMI patients with a large thrombus burden

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

The use of thrombosuction during percutaneous coronary interventions remains debated. The aim of this study was to investigate the very long term impact of thrombosuction and glycoprotein IIb IIIa inhibitor (GPI) administration during drug-eluting stent (DES) implantation in ST-segment elevation myocardial infarction (STEMI) patients with a large thrombus burden (LTB).

METHODS AND RESULTS

We retrospectively analyzed 806 consecutive patients treated with DES implantation for STEMI. Thrombus burden was angiographically estimated and defined as large when thrombus burden ? 2 vessel diameters (N=226). Major adverse cardiac events (MACE) were defined as death, repeat myocardial infarction, and IRA reintervention. Completeness of follow-up at 10 years was 95.4% for mortality and 96.3% for MACE. In patients with a LTB, the positive effect of thrombosuction was still present a decade after PCI (mortality 29.3% versus 22.2%, Log Rank p=0.04, MACE 46.1% versus 34.1%, Log Rank p=0.02). GPI administration resulted in comparable results that were still present a decade after PCI (mortality 39.1% versus 21.7%, Log Rank p=0.0008, MACE 53.3% versus 37.7%, Log Rank p=0.03). When combining thrombosuction and GPI administration, mortality and MACE appear even lower when compared to one or none of these treatments (mortality 29.9% versus 16.9%, Log Rank p=0.01, MACE 48.2% versus 28.8%, Log Rank p=0.02).

CONCLUSIONS

In STEMI patients with a large thrombus burden, thrombosuction or GPI administration is associated with lower mortality and MACE. This effect is still present a decade after initial treatment and appears to be stronger when combining thrombosuction and GPI administration.

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Application of ultra-low dose radiation settings in coronary CTO intervention and comparison of radiation exposure

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

One of the main limitations for coronary CTO (Chronic Total Occlusion) is high radiation exposure. It has been well established that total radiation exposure mainly depends on the frame rate. In addition to that extensive radiation reducing set-up can be applied over it to reduce exposure more efficiently. The purpose of this study is to measure the cumulative doses and dose-area products exposed in chronic totally occluded coronary interventions performed under ultra-low dose radiation procedure.

METHODS AND RESULTS

Total fluoroscopy time, number of cinegraphic runs, Cumulative dose(CD, mGy), the dose area product (DAP, Gy cm2) were reviewed for each procedure (Siemens Artis Zee VC14H). Three operators were performing these procedures, one of whom was working with ALARA principles (Operator Group 1), the remaining operators were working in standard cine mode (Operator Group 2). 31(66%) of the interventions were performed by Operator 1 and the remaining 16 (34%) by the other operators. 40(85,1%) of the patients were male. The mean age of the study group was 62,4±12. Duration of CTOs were between 1,5-10 years. All possible radiation reducing modifications were used by Operator 1, such as pulse width (5.0 ms) and exposure dose (0.10 mGyf-1), setting for copper filter protection, a longer line for Y connector, pedaling two seconds after contrast injection techniques as well as low frame rate (7.5 f s-1 for cine and ?uoroscopy). Comparison of total fluoroscopy time and the number of cinegraphic runs were not significant. But, on the other hand, cumulative doses and dose area products were significantly lower for the Operator Group 1 ($p<0,001$ for both parameters). Mean dose area product of CTO procedures (44,3±34,9 Gy cm2) were lower than reference levels in the literature (252±234 Gycm2) in operator Group 1.

CONCLUSIONS

Besides frame rate and fluoroscopy time, above mentioned protective techniques like special exposure settings, adaptive copper filter, longer line and pedaling techniques have been shown to be seriously effective on radiation protection. Because of both deterministic and stochastic effects of radiation exposures, better standardization for radiation exposure lowering techniques should be routine in cath lab.

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Impact of stent optimisation with non-compliant balloons on coronary microcirculation in patients undergoing primary PCI for STEMI

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

The aim of this study was to assess the impact of stent optimisation by post-dilatation with non-compliant (NC) balloons on coronary microcirculation in patients undergoing primary percutaneous coronary intervention (PPCI) for ST elevation myocardial infarction (STEMI).

METHODS AND RESULTS

This was a single centre observational prospective study (POSTDIL-STEMI, ClinicalTrials.gov: NCT02788396). 32 patients undergoing PPCI for STEMI were recruited. After stent implantation, all patients had post-dilatation (PD) with non-compliant balloons at high pressures. The index of microvascular resistance (IMR) was measured pre and immediately post PD. Wedge pressure was calculated during balloon inflation in order to allow corrected IMR (IMRc) calculation.

Mean age was 66 ± 11 years, 78% of the patients were male, 12.5% diabetic and 21.8% current smokers. Mean symptoms-to-device time was 4.2 ± 2.9 hours and LAD was the culprit vessel in 43.7% of the cases. 80% of the patients had TIMI flow 0 on presentation. All patients received everolimus eluting stents. 1.2 ± 0.5 stents were placed with a mean diameter of 3.1 ± 0.5 mm. The mean length of the stented segment was 29.9 ± 10.7 mm. Post stent deployment, in 94% of the cases there was TIMI flow 3. 1 patient (3%) had TIMI flow 2 and 1 (3%) TIMI flow 1.

NC balloons were used for post-dilatation in all cases with a mean diameter of 3.6 ± 0.6 mm and 15.8 ± 3.4 mm of length. Mean max inflation pressure was 19 ± 2 Atm and number of inflations was 2 ± 0.6. 88% of the patients had TIMI flow 3 at the end of procedure, 9% had TIMI flow 2 and 3% TIMI flow 1.

Mean IMR after stent placement and pre post-dilatation was 44 ± 26. Post post-dilatation the IMR was 48 ± 34, an increase that was not found to be statistically significant (p=0.287). When IMR was corrected for wedge pressure results remained similar: IMRc pre post-dilatation was 42 ± 27 and 46 ± 34 post post-dilatation (p=0.230).

CONCLUSIONS

In STEMI patients undergoing PPCI, post dilatation with NC balloons at high pressures did not have an impact on coronary microcirculation as assessed by the index of microvasular resistance.

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Percutaneous device closure of aortic sinus pseudoaneurysm

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

AIMS

METHODS AND RESULTS

CONCLUSIONS

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The impact of different characteristics of coronary artery disease patients on the cardiac autonomic modulation

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

To study the impact of different clinical and angiographic characteristics of coronary artery disease (CAD) patients on the cardiac autonomic modulation assessed by heart rate variability (HRV) measurement.

METHODS AND RESULTS

A prospective study which included 100 patients undergoing elective coronary angiography when clinically indicated either by patient?s ischemic symptoms or if there is an evidence of ischemia either by a stress test or post-acute coronary syndromes (ACS) excluding patients with contraindication to contrast or dual antiplatelet therapy, patients with atrial fibrillation or multiple premature beats, patients receiving anti-arrhythmic drugs except class II, IV and patients who underwent previous Percutaneous Coronary Intervention (PCI) or Coronary Artery Bypass Grafting (CABG). Detailed clinical history and examination, electrocardiographic, echocardiographic and angiographic assessment with SYNTAX score (SX) calculation using SYNTAX score calculator software were done. A short-term HRV measurement was performed using CheckMyheart ? handheld HRV device from DailyCare BioMedical Inc, Taiwan. HRV data were interpreted by CheckMyheart ? 5-min HRV analysis software using the standard methods for HRV measurement as discussed in the Task Force of the European Society of Cardiology and The North American Society of Pacing and Electrophysiology.

Results: Baseline patient?s characteristics included 85 males (85%) and 15 females (15%). Their age ranged from 27 to 80 years with mean age of 56.89 ± 10.75 years, 41 patients (41%) were diabetics, 47 patients (47%) were hypertensive, 54 (54%) were smokers, 11 patients (11%) had a family history of CAD, 8 patients (8%) had dyslipidemia and 4 patients (4%) had other miscellaneous diseases (peripheral arterial disease, cerebrovascular stroke and end-stage renal disease). 6 patients (6%) had typical ischemic symptoms (CSA-CCS II, III), 8 patients (8%) had an evidence of ischemia (positive stress test), while 86 patients (86%) had a history of ACS, 18 of them (20.9%) had a history of unstable angina (UA) while 68 (79.1%) had a post MI angina, 45 of them (66.2%) had a history ST-elevation Myocardial Infarction (STEMI), while 23 patients (33.8%) had a history of Non-ST Elevation Myocardial Infarction (NSTEMI). The mean heart rate was 77.95 ± 11.79 beats/minute and the mean left ventricular ejection fraction was 54.03 ± 11.08%. The mean SYNTAX score (SX) of the studied cases was 13.11 ± 8.52 with 87 patients (87%) had a low SX, 9 patients (9%) had intermediate SX while 4 patients (4%) had a high SX. 42 patients (42%) had multi-vessel CAD while 58 patients (58%) had a single vessel CAD. Distal TIMI flow of the target vessel for revascularization was zero in 24 patients (24%), TIMI I distal flow in 3 patients (3%), TIMI II distal flow in 8 patients (8%) and TIMI III distal flow in 65 patients (65%). Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). Multivariate linear analysis logistic regression of different patient characteristics that affect HRV parameters revealed that the type of CAD whether single or multi-vessel CAD and SYNTAX score are the strongest independent factors that affect HRV parameters in patients with CAD.

CONCLUSIONS

The complexity of CAD quantified by SYNTAX score is by far the strongest independent factor in patients with CAD affecting the cardiac autonomic modulation assessed by HRV measurement.

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Impact of completeness of percutaneous coronary revascularisation on TAVI outcomes

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

AIMS

Background and aims:
Coronary artery disease (CAD) is common in patients undergoing transcatheter aortic valve implantation (TAVI). In spite of numerous studies, the impact of pre-TAVI coronary revascularization on early and longer-term outcomes are not yet fully understood. Moreover, it is not known whether a complete revascularization is warranted before TAVI. We sought to investigate the impact of the completeness of percutaneous coronary revascularization on TAVI outcomes.

METHODS AND RESULTS

Methods and results:
From September 2007 to December 2016, 875 patients underwent TAVI at our institution. Before TAVI, coronary angiography was performed in all patients and significant CAD (at least one stenosis ?50% in a vessel ?1.5 mm) was documented in 572 (65.4%) and involved 1 vessel in 169 (29.9%), 2 vessels in 168 (29.7%), and 3 vessels in 229 patients (40.5%). In 300 patients (52.5% of those with CAD), percutaneous coronary intervention (PCI) was scheduled pre-TAVI (within 90 days before the procedure). The SYNTAX (Synergy Between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery) score was calculated in all patients with no previous bypass grafting (n=206) - before and after PCI - to assess the SYNTAX Revascularization Index (SRI= % reduction of the SYNTAX score from before to after PCI). PCI that led to an SRI of 100% was considered complete revascularization.
Percutaneous revascularization was complete in 129 patients (62.6%) and incomplete in 77 (37.4%). Compared to patients with incomplete revascularization, those who had a complete revascularization had a lower 30-day all-cause mortality (0.0% vs. 5.2%, p=0.019), cardiovascular mortality (0.0% vs. 3.9%, p=0.050), and major vascular complications (4.7% vs. 14.5%, p=0.018). The rates of 30-day stroke, major and life-threatening bleeding, and acute kidney injury were not different between the two groups. The SRI was higher in patients who survived beyond 30 days post-TAVI than in those who died in the peri-procedural period (82.2±28.1% vs. 44.4±16.1%, p=0.005, OR, 0.968 [95%CI, 0.940-0.996] /1% increment in SRI, p=0.024).
At one year post-TAVI, all-cause mortality was significantly lower in patients who had a complete percutaneous coronary revascularization (14.1%) than in patients with incomplete revascularization (25.3%, log rank p=0.028, HR, 0.492 [95% CI, 0.258-0.940], p=0.032). Similarly, cardiovascular mortality was higher in the former than in the latter group (7.8% vs. 16.5%, log rank p=0.030, HR, 0.403 [95% CI, 0.172-0.943], p=0.036). The SRI was significantly higher in patients who survived (83.8±26.8%) than in patients who died within 1 year after the procedure (71.9±32.0, p=0.024, HR, 0.989[0.979-0.998] /1% increment of SRI, p=0.017). Cardiovascular mortality was similarly associated with a lower SRI (68.7±35.3% vs. 83,2±26,8% p=0.036, HR, 0.985 [95% CI, 0.974-0.997]/1% increment of SRI, p=0.014).

CONCLUSIONS

Conclusions:

The completeness of percutaneous revascularization of significant CAD is a determinant of early and mid-term mortality after TAVI. A higher SRI should be targeted in patients undergoing PCI before TAVI.

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A comparison between thin- and thick DES implantation in patients with coronary artery disease: one-year clinical outcomes of two international registries

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

AIMS

Assessment of safety and efficacy of percutaneous coronary intervention (PCI) with a thin strut cobalt chromium sirolimus-eluting stent (Ultimaster) in comparison with a thick strut stainless steel biolimus-eluting stent (Nobori), both abluminally coated with biodegradable polymer.

METHODS AND RESULTS

The one year clinical outcomes of two large registries, representative of real-life PCI practice, are analysed. The e-Ultimaster registry included 8879 patients treated with the Ultimaster drug-eluting stent (DES) at 336 sites in 48 countries world-wide. This on-going registry started in 2014, so more than 10,000 patients will have a one year follow-up visit at time of presentation. The Nobori-2 registry included 3067 patients treated with the Nobori DES at 125 sites. Patients were enrolled between 2008 and 2013. To overcome differences in baseline characteristics, propensity score matching (PSM is performed between the two registries.

After PSM, 8137 patients from e-Ultimaster and 2738 patients from Nobori-2 were selected to obtain a similar distribution of baseline patient- and lesion characteristics in both registries. Mean patient age was 64.6 years in both registries, on average 76.9% were male patients and 67.9% had hypertension. Lesion characteristics were similar between two registries, but radial access was used more in e-Ultimaster compared to Nobori-2 (82.8 vs 38.8%,

CONCLUSIONS

The one year clinical outcomes of the two registries indicates that overall and cardiac mortality associated with thin strut cobalt chromium sirolimus-eluting stent in comparison with a thick strut stainless steel biolimus-eluting stent are similar. However, significantly lower rates of MI, TLR, TVR and POCE at one year were observed after treatment with Ultimaster DES compared with Nobori DES. These findings show that the Ultimaster DES is clinically safer and efficient than Nobori DES.

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One-year clinical outcomes of contemporary PCI in patients with stable angina: experience from large scale e-ULTIMASTER registry

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

AIMS

We aimed to compare one-year outcomes of stable angina patients with different risks undergoing percutaneous revascularisation in the real world population.

METHODS AND RESULTS

Among a total of 8879 all-comer patients enrolled in the large single-arm, multicentre, e-Ultimaster registry and who reached 1-year follow up, 3097 patients presented with stable angina. These stable patients were most frequently treated in the UK (19.1%) and Nederland (14.6%) followed by Ireland (3.9%). Out of 3097 stable patients, 2490 patients (80.4%) had non-LM single vessel disease (SV), 490 patients (15.8%) non-LM multivessel disease (MV), and 117 patients (3.8%) LMT disease (LM). The primary endpoint of the study was Target Lesion Failure (TLF) at 1 year. All the endpoint related serious adverse events were adjudicated by the clinical events committee. LM group were elder (SV vs. MV vs. LM, 65.9 vs. 66.0 vs. 68.6 years, p=0.021) and had the higher rates of renal impairment defined as GFR

CONCLUSIONS

In the e-ULTIMASTER registry, LM group with stable angina had significantly higher cardiac adverse events rates at one year. Angina symptoms were improved in all groups, which was improved more effectively in MV group.

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CTO PCI is not associated with a higher risk for contrast-induced acute kidney injury compared to revascularisation of non-occlusive stenoses

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

AIMS

Contrast volume is strongly associated with the incidence of CI-AKI, and the risk of CI-AKI thus appears to be particularly high in CTO PCI (which is associated with higher contrast volumes) as opposed to non-CTO PCI. The aim of the present study was to evaluate the incidence of CI-AKI in patients undergoing CTO vs. non-CTO PCI.

METHODS AND RESULTS

A total of 2580 PCIs, performed at our institution between January 2012 and December 2016, represented the study population. CTO was defined as a 100% stenosis with TIMI 0 flow for ?3 months. CI-AKI was defined as an increase in serum creatinine ?0.3 mg/dl or ?50% from baseline within 72 h. Multivariable logistic regression analysis was performed to identify independent predictors of CI-AKI, and included the following variables: CTO vs. non-CTO PCI, age, sex, diabetes, prior CABG, baseline estimated glomerular filtration rate (eGFR), LVEF, number of diseased vessels, hypotension during/before PCI, heart failure on presentation, ACS, emergency PCI, vascular access, and contrast volume.

From the 2580 patients, 309 had CTO PCI and 2271 had non-CTO PCI. Patient in CTO PCI group were younger, 65.4±11.0 vs 68.6±11.2 years old (

CONCLUSIONS

In a large single-centre cohort of patients undergoing percutaneous revascularization, CTO PCI, was not associated with a higher incidence of CI-AKI, compared with non-CTO PCI. This lack of association persisted after adjusted analysis. Our findings question the commonly-held belief of a higher risk of CI-AKI in patients undergoing CTO PCI, and should be confirmed by larger, multicentre studies.

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Unprotected left main coronary artery stenting with a self-expandable DES

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

AIMS

To look at the end results of efficacy of PCI with the self-expandable drug eluting stent- Xposition S in significantly stenosed left main coronary artery disease.

METHODS AND RESULTS

This is a single center, retrospective pilot study looking into the acute procedural success and 1 year outcome of stenting significantly stenosed left main coronary artery disease with a self- expandable drug-eluting stent. We included all-comers and our inclusion criteria were significantly stenosed lesions in the ostial, mid and distal left main stem. Maximum size of the vessel had to be 6.0mm while the length of the lesion had to be less than 37mm. We also included patients with significant side branch disease that we treated in the same setting as well as patients with high SYNTAX scores who were not suitable for coronary artery bypass grafting (CABG) after a prerequisite heart team meeting.

The primary endpoints were device success, acute procedural success as well as in-hospital, 6 months and 1 year major adverse cardiac and cerebrovascular events (MACCE). A total of 32 patients were enrolled and they were followed up for at least 1 year post PCI. Their median age was 58.2 years. Majority of patients had STEMI on admission (34.4%), followed by NSTEMI (28.1%), unstable angina (25.0%) and the remainder had stable coronary artery disease (12.5%).
The median SYNTAX score was 24.0 (23.0-31.0) points. Majority of the left main lesions treated were in the distal left main (84.0%) followed by the ostial (9.0%) and mid segment (7.0%). Two stent sizes were used: 3.0-3.5 mm in 12 cases (37.5%) and 3.5-4.5 mm in 20 cases (62.5%). In terms of length, all 4 lengths were used. In order of increasing length: 17mm in 5 cases (15.6%), 22mm in 15 cases (46.9), 27 mm in 9 cases (28.1%), and 37 mm in 3 cases (9.4%).

Device success and acute procedural success were achieved in all 32 patients (100%), with no edge dissection in any patient. There was no incidence of geographical miss. Side branch access was uncomplicated. There was no difficulty in re-crossing the stent struts, dilating a balloon or deploying a second stent when needed. In this small study, 2 critically ill patients who presented with cardiogenic shock died despite successful revascularisation. Another 2 patients died within 6 months from a subsequent episode of ACS with cardiogenic shock. For the 6 months and 1 year follow up at our outpatient clinic, the remainder 28 patients (87.5%) had no major adverse cardiac and cerebrovascular events.

CONCLUSIONS

This study evaluated the safety and efficacy of the Xposition S DES self-expanding coronary stent in treating ostial, middle and distal LMCA stenosis. The data compiled from this small, single-centre pilot study suggest that the Xposition S DES self-expanding coronary stent is a valid approach to treating ostial, middle and distal

LMCA lesions.

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The effect of hydrostatic pressure on FFR

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

The aim of this study was to assess height differences between all major coronary arteries and the hydrostatic effect on FFR.

Coronary arteries are at different anatomical heights when supine. Hydrostatic pressure exerts an effect based on height of the coronary artery. This has clinical relevance, as fractional flow reserve (FFR), uses pressure to assess stenosis severity. Distal pressure (Pd) is seldom measured at the same vertical height as proximal pressure (Pa). Hydrostatic pressure will have an effect on FFR due to height variations within the artery, independent of stenosis severity.

METHODS AND RESULTS

CT coronary angiography was used to measure height differences between coronary ostia, and the highest or lowest points in the left anterior descending artery (LAD), circumflex (Cx), and right coronary artery (RCA). The RCA was divided into posterior descending artery (PDA) and posterior left ventricular artery (PLV) due to the difference in their course. Measurements were taken using an electronic reporting system and in-built measuring calliper. The mean heights were then used to calculate the hydrostatic force in each artery and its effect on FFR value, using a correction factor for hydrostatic pressure change of 0.8mmHg / cm. The theoretical clinical effect of hydrostatic pressure was then tested in a simulation of intermediate coronary stenosis. 200 random FFR values between 0.75 and 0.85 were corrected for hydrostatic pressure to give the corrected FFR (cFFR). Finally, the % of FFR values crossing the clinical treatment cut-off of 0.8 was calculated for each coronary artery.

100 CT coronary angiograms (giving 100 measurements for each artery) were carried out in patients with low to intermediate risk chest pain attending the chest pain clinic. The mean age was 55.9 years with 68% being female. The mean height measurement from coronary ostium to distal LAD was +5.26cm (i.e above the coronary ostium), Cx -3.35cm (i.e below the coronary ostium), RCA-PLV -4.29cm and RCA-PDA +1.53cm.

For the LAD, the mean change in FFR was +0.042, -0.027 in the Cx, -0.034 in the PLV and +0.012 in the PDA. Using 200 random FFR values between 0.75 and 0.85, the resulting cFFR crossed the clinical treatment cut-off of 0.8 in 45% of LAD, 27% of Cx, 34% of PLV and 9% of PDA cases.

CONCLUSIONS

There are clear differences in anatomical height between coronary arteries as shown on coronary CT. These differences result in potentially important hydrostatic pressure changes in all 3 coronary arteries. When tested in the simulated model of intermediate coronary stenosis, there was a change across the treatment cut-off in a high proportion of cases, particularly in the LAD. Our data has important clinical implications especially when assessing the functional significance of borderline coronary stenosis with an FFR around the clinical cut-off. An

in-vivo study needs to be conducted to validate the clinical significance of cFFR.

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Impact of postdilation on procedural and clinical outcomes in complex lesions treated with BRS - a prospective registry study

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

AIMS

There is limited data on the impact of postdilation (PostDil) on acute procedural and late clinical outcomes in patients with complex lesions treated with bioresorbable vascular scaffolds (BRS). We sought to evaluate the effect of Postdil on procedural and clinical outcomes.

METHODS AND RESULTS

Methods:

We performed an analysis of patients who underwent BRS implantation. The effect of PostDil on quantitative coronary angiographic (QCA) outcomes immediately after BVS implantation, after postdilation and major adverse cardiovascular events (MACE) were investigated.

Results:

294 patients treated with BRS (387 lesion, postdilation 54%) were studied. Baseline clinical characteristics were similar between both groups, with more complex lesion characteristics in the PostDil group. PostDil resulted in 6% increase in minimal lumen diameter (MLD, after BRS implantation 2.18±0.43mm vs Final 2.32±0.35mm, ? 0.14 ± 0.32mm, p<0.001) and an increase in proportion of final MLD > 2.4mm (28.2% vs 41.9%, p<0.001). Still acute lumen gain (ALG) was significantly less in PostDil compared to non-PostDil (1.33±0.59 vs 1.53±0.63mm, p=0.002). ALG was significantly affected by postdilation high inflation pressure (>16mmHg) and the vessel size (pre RVD >2.25mm) but not size of PostDil balloon. At 2 years, there was no difference in MACE (9.9 vs 6.9% respectively, p=0. 402).

CONCLUSIONS

PostDil of BRS resulted in a slight increase in minimal lumen diameter, not yet achieving similar acute gain and final MLD as in patient where PostDil was deemed not indicated by the operator. Yet PostDil importantly increased the rate of acceptable final MLD in these complex lesions although 2 year clinical outcomes were not affected by PostDil.

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Real world experience of DEB use

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

AIMS
The aim of this retrospective analysis was to understand the clinical indication, context, quantity and success rate of drug eluting balloon (DEB) PCI use over a 1 year period at our institution, in order to better understand our clinical decision making and the short term impact on our patients.

METHODS AND RESULTS
All patients who had DEB PCI between January 2016 and January 2017 were included in the analysis. Data was collected retrospectively from electronic databases from ten operators and one institution. Data included patient demographic, clinical syndrome and indication for DEB use, artery treated and size of DEB. Death at 1 year and repeat revascularisation were also recorded.

72 patients had DEB PCI (3% of total PCI at our institution) treating 72 vessels all with paclitaxel covered balloons (Restore DEB 54% (39) Sequent Please 46% (33). 76% (55 patients) of patients were male, 70% (50 patients) were hypertensive and 67% (48 patients) hypercholesterolaemic. 28% (20 patients) were diabetic and 11% (8 patients) current smokers. In 74% of cases (53 patients) access was gained radially, with 6F guiding catheters being used in every patient.

54% (39) of clinical presentations were in stable elective patients. The remaining 46% (33) patients suffered an acute coronary syndrome (ACS), of which 85% (28) were non-ST segment elevation myocardial infarction (NSTEMI). In the ACS group, all DEB PCI was in the culprit vessel.

The most common indication for DEB use was in-stent restenosis, which occurred in 47% of patients (34). This was followed by small vessel size, which accounted for 35% (25) of DEB use. Operator choice with no other documented reason made up 7% (5) of the total, with bifurcation lesions accounting for a further 6% (5). The remaining 5% was made up of multiple other reasons, including inability to advance the stent, bypass graft PCI and aspirin allergy.

The left anterior descending artery was the most commonly treated artery accounting for 35% of DEB's used (25). The remaining target vessels comprised of 28% (20) right coronary artery, 20% circumflex (14) and 13% diagonal (9). The remaining 4% included left main stem, intermediate and bypass graft target vessels.

2.0mm and 2.5mm balloons made up 56% all sized of DEB use. Mean balloon size used was 2.74mm. In the in-stent restenosis group, mean balloon size was 3.1mm. In the small vessel group, mean balloon size was 2.3mm.

At 1 year follow-up, 1 patient died from non-cardiac causes with no other reported deaths. Two patients needed revascularisation after presenting with stable angina (both initially treated for in-stent re-stenosis) and

patients were treated with drug eluting stents. One patient re-presented with stable angina, with the originally treated vessel (obtuse marginal) progressing into a chronic total occlusion (CTO). This was managed medically with resolution of angina. Therefore the overall target vessel revascularisation rate was 3% with a target vessel failure rate of 4%.

CONCLUSIONS

In this single centre registry, paclitaxel drug eluting balloon PCI was used in a small proportion of patients, the majority of whom had in-stent restenosis or small calibre target vessels. Stable disease accounted for half of the patients. Target vessel revascularisation and failure rates were low. It therefore appears in our cohort of patients, DEB use at 1 year has similar outcomes to conventional drug eluting stent PCI [1].

1. Bonaa et al. N Engl J Med. 2016 Sep 29,375(13):1242-52

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Carotid arteriovenous malformation - Identify the feeder vessels

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

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Impact of aortic valve calcium score on balloon-expandable transcatheter heart valve morphology

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

AIMS

Flared morphology of SAPIEN 3 transcatheter heart valve (THV) has been reported to contribute to a lesser degree of paravalvular leak. We evaluated the impact of aortic valve calcium score (AVCS) on balloon-expandable THV morphology after TAVI by comparing SAPIEN 3 with SAPIEN XT.

METHODS AND RESULTS

We performed TAVI with balloon-expandable THV in 135 patients between January 2013 and December 2017. In 108 of the 135 patients who were evaluated by multidetector CT pre- and post-TAVI (SAPIEN XT, 68 patients, SAPIEN 3, 40 patients), the ratios of the areas of the inflow edge, middle position, outflow edge of THV to the nominal commercial valve area and the % constriction rate defined as {1-2×mid-THV area / (inflow area + outflow area)}×100 were investigated. The correlation of the % constriction rate with filling volumes was evaluated on the basis of the severity of calcification by the cutoff point of AVCS >3000 AU, whose predictive efficacy for paravalvular leak after TAVI has been reported by previous studies. The rate of transfemoral access was significantly different between the SAPIEN XT and SAPIEN 3 groups (49% [33/68 patients] vs. 100% [40/40 patients], p<0.01), but other patient characteristics such as age, sex, body mass index, hypertension, diabetes mellitus, dyslipidaemia, and STS score were almost similar. Preprocedural laboratory findings showed no significant differences in CT annulus area, AVCS, aortic valve area, peak aortic valve flow, and left ventricular ejection fraction between the SAPIEN XT and SAPIEN 3 groups. Postprocedural laboratory findings showed that the peak aortic valve flow was significantly higher in the SAPIEN 3 group than in the SAPIEN XT group (2.1±0.5 m/s vs. 2.3±0.4 m/s, p=0.03), and the aortic valve area was significantly smaller in the SAPIEN 3 group than in the SAPIEN XT group (2.0±0.5 cm2 vs. 1.8±0.4 cm2, p=0.02). While the ratio of the middle position area of THV to the nominal valve commercial area was not significantly different between the SAPIEN XT and SAPIEN 3 groups (80±6% vs. 80±7%, p=0.5), the ratios of the inflow edge area and outflow edge area of THV to the nominal commercial valve area were higher in the SAPIEN 3 group than in the SAPIEN XT group (88±7% vs. 81±7%, p<0.01, 89±7% vs. 83±7%, p<0.01, respectively). The average % constriction rate was significantly higher in the SAPIEN 3 group than in the SAPIEN XT group (9.2±3.7% vs. 2.7±2.0%, p<0.01). In the SAPIEN XT group, there was no correlation between the % constriction rate and balloon filling volumes, irrespective of AVCS (r=?0.06, p=0.71 in the low AVCS group, r=?0.02, p=0.92 in the high AVCS group). In the SAPIEN 3 group, there was a significantly negative correlation between the % constriction rate and balloon filling volumes in the low AVCS group (r=?0.46, p<0.01), while there tended to be a positive correlation in the high AVCS group (r=0.54, p=0.16).

CONCLUSIONS

In patients treated with SAPIEN 3, the correlation of the % constriction rate with filling volumes was significantly negative in patients with low AVCS, but tended to be positive in those with high AVCS. No correlation between the % constriction rate and balloon filling volumes was seen in patients treated with

SAPIEN XT.

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First report of the use of long-tapered sirolimus-eluting coronary stent for the treatment of CTO with the hybrid algorithm

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Coronary chronic total occlusions (CTO) usually coexist with diffusely diseased coronary segments proximal and/or distal to the CTO segment. During percutaneous treatment of CTO, multiple overlapping stents are often needed to treat these long lesions. Aim of this study is to report the first use of long, tapered coronary sirolimus-eluting stents (SES) in this setting.

METHODS AND RESULTS

This is a retrospective analysis of 100 consecutive patients undergoing CTO recanalization following the hybrid algorithm. Procedural success rate was 89% (11 failures). Among the successful cases, ?conventional? drug-eluting stents(DES) were used in 40(44.9%) patients, while in 49(55%) patients long-tapered SES were attempted with a success rate of 98% (1 cross-over to regular stents). Total stent length in the long-tapered DES group was higher compared to the ?conventional? stenting group (76±28mm vs 46±22mm, p<0.001), with a similar total number of stent (1.6±0.8 vs 1.9±0.8). At QCA, proximal and distal segment involvement was more extended in patients undergoing long-tapered stenting, with longer overall lesion length. No differences in periprocedural complications and clinical outcomes at a mean follow-up of 303±179 days were observed.

CONCLUSIONS

The use of long tapered coronary DES is technically feasible and safe for the percutaneous treatment of CTOs, especially for patients presenting with long lesions. Although this effect was not directly observed in our registry, the use of these devices has indeed the potential to reduce the number of stents necessary to effectively treat long lesions as frequently observed in the settings of CTO revascularization.

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Long-term follow-up of polymeric BRS in complex coronary bifurcation interventions, an imaging and histological assessment

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

AIMS

The polymeric Absorb Bioresorbable Vascular Scaffold (BVS) has yet to be evaluated in true bifurcation lesions because of inherent limitations such as bulky profile and limited expansion capacity, and concerns regarding prolonged reabsorption time. Here we report on long-term imaging and histopathological outcomes after using the BVS for both simple and complex bifurcation techniques in non-diseased rabbit aorto-iliac bifurcations.

METHODS AND RESULTS

Fifteen New Zeeland white rabbits were anaesthetized and a 6 French arterial sheath was placed in the carotid artery extending to the distal aorta. Bifurcation stenting procedures of the aorta-iliac bifurcation were performed with 3.0x28 mm BVS using the following stenting techniques: main-vessel stenting with ballooning of side branch (SB, Provisional stenting, n=2), modified T (mini-crush of BVS in SB first , n=6) and culotte (n=7) stenting. Proximal optimization was performed with 3.5 mm non-compliant balloons at 16 atm followed by mini-kissing balloon inflation in the bifurcation. To limit contrast exposure only angiography was performed after stenting. The rabbits were treated daily with aspirin 40 mg. At 18 months, angiography, optical coherence tomography (OCT) and histology were performed. All index procedures were performed without complication with excellent angiographic result. In the first 5 days post stenting 3 rabbits succumbed to renal failure and anaesthetic complications. One further rabbit was anaesthetized after 4 months due to a severe skin infection. At 18 months a total of 11 rabbits (provisional (2), Mod-T (4) and culotte (5)) underwent follow-up angiography, OCT and histology. Overall there were no episodes of scaffold thrombosis. In all 11 rabbits the non-bifurcation segments revealed complete endothelialisation with excellent healing characteristics. In all bifurcations treated with a 2-stent technique there were uncovered and malapposed ?black box? struts present at the level of the neocarina. In more than half of cases there was a significant burden of chronic thrombus on the uncovered neocarinal struts. In 2 cases there was evidence of intraluminal scaffold dismantling at the level of the bifurcation with single BVS struts protruding intraluminal. histological data will be available upon presentation

CONCLUSIONS

This is the first in vivo study examining long-term outcomes after complex bifurcation treatment with current generation polymeric BVS. At final follow up, chronic thrombus was found to be present and adherent to the uncovered neocarinal struts in the majority of the complex 2-stent bifurcation procedures. Furthermore, in two bifurcations treated with 2-stent techniques, scaffold dismantling with intraluminal strut protrusion was noted at 18 months post PCI. These findings caution further against the use of current generation polymeric bioresorbable vascular scaffolds in complex bifurcation interventions.

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Utilising metabolic risk factors to predict the functional significance of intermediate coronary artery lesions in patients with and without diabetes mellitus

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Fractional Flow Reserve (FFR) is the gold standard invasive assessment of intermediate coronary lesions. Whether metabolic risk factors may be used to predict the functional significance of lesions being assessed by FFR is as yet unknown, and with this study we aimed to determine if this was possible.

METHODS AND RESULTS

We included all patients who underwent FFR assessment of intermediate coronary lesions in whom fasting metabolic risk factors were assessed from 1/7/15 to 1/7/17. FFR measurements were performed using a standard pressure wire at maximum hyperaemia following intracoronary nitrate and adenosine. FFR hyperaemic results were compared against fasting risks including Total Cholesterol (TC), High Density Lipoprotein Cholesterol (HDLc), Triglycerides (TG), calculated Low Density Lipoprotein Cholesterol (LDLc), fasting glucose and HbA1c. Statistical analysis was performed to determine correlation between these metabolic risks and FFR hyperaemic values using Pearson?s R Coefficient.

156 patients (130 non-diabetic and 26 diabetic) who underwent FFR assessment of 237 intermediate coronary lesions and also had fasting metabolic risk factors were included. Interestingly, despite similar angiographic appearances of lesions, amongst the diabetic patients higher values of LDLc (r=-0.6072, p = 0.001939) and TG (r = -0.476, p =0.019) were predictive of lower FFR values, however this was not seen in the non-diabetic group. Moreover, amongst the diabetic patients worsening glycaemic control as assessed by HbA1c (r = -0.276 p = 0.046) were associated with lower values of FFR. Finally, higher HDL levels were found not to be protective in either group.

CONCLUSIONS

This study is the first to assess the predictive effect of metabolic risk factors on the functional significance of intermediate coronary lesions, showing that despite similar angiographic lesion appearance, worsening metabolic derangement as assessed by LDL, TG, and HbA1c levels are predictive of lower FFR values in diabetic patients. This same pattern was not observed in non-diabetic patients. Whether more stringent risk factor modification may improve outcomes in the DM group remains unknown.

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Incidence and clinical course of iatrogenic aortic dissection during coronary catheterisation

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

AIMS

Iatrogenic coronary artery dissection due to guiding catheter during coronary catheterization is a rare but feared complication. Furthermore, it extended to the ascending aorta in some cases. Acute type A aortic dissection is a fatal disease and generally requires surgical therapy. However, the prognostic data on iatrogenic aortic dissection are scare. We aimed to describe the incidence and clinical course of iatrogenic aortic dissection.

METHODS AND RESULTS

The study sample consisted of 59707 patients undergoing diagnostic coronary angiography (CAG, 41782 patients) and percutaneous coronary intervention (PCI, 17925 patients) between January 2005 and December 2017, in whom the incidence and clinical course of iatrogenic aortic dissection were investigated. Iatrogenic coronary artery dissection due to guiding catheter occurred in 86 patients (during CAG, 8 patients, during PCI, 78 patients), and dissection extending to the aortic root was angiographically detected in 20 patients. Thus, the incidence of iatrogenic aortic dissection was 0.03%. All the 20 patients underwent bailout stent implantation in aorto-ostial lesion. Dissection was confirmed by immediate post-procedure computed tomography (CT) in 13 of the 20 patients, and it was confined to the sinus of Valsalva in 7 of the 13 patients, however, it extended to the ascending aorta beyond the sinotubular junction in the remaining 6 patients. Furthermore, dissection extended to aortic arch in 2 of the 6 patients. All the 13 patients underwent follow-up CT, in all of whom dissection improved, and no complications due to dissection were observed.

CONCLUSIONS

Iatrogenic aortic dissection did not extend any further in this study. It may be because the stent covered the entry point of dissection. Although iatrogenic aortic dissection is a feared complication, these results suggest that dissection can be managed conservatively without surgery by taking an appropriate procedure.

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Trends of in-hospital outcomes after transfemoral TAVI: a single-centre 10-year experience

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

AIMS

Transcatheter aortic valve implantation (TAVI) is a safe alternative to surgical aortic valve replacement (AVR) for the treatment of symptomatic severe aortic valve stenosis in patients at increased surgical risk. We analyzed temporal changes in the occurrence of in-hospital complications during a 10-year experience.

METHODS AND RESULTS

Observational study including 383 consecutive patients with severe aortic stenosis undergoing transfemoral TAVI at our institution between 2008 and 2017. Procedural volume increased through the years thus patients were grouped into quartiles in order to have numerically equivalent groups. Hence, the first quartile (Q1) enrolled patients treated between 2008 and January 2012, the second quartile (Q2) between February 2012 and March 2015, the third quartile (Q3) between April 2015 and December 2016, the fourth quartile (Q4) between January and September 2017. In hospital outcome was evaluated according to the Valve Academy Research Consortium 2 definitions (myocardial infarction, stroke, bleeding, vascular complications, device success, acute kidney injury and pacemaker implantation).

Mean age was 83.1±6.7 years, 54.6% were female. STS score and logistic EuroSCORE were significantly lower in Q3-Q4 than in Q1-Q2 (STS Q1-Q4: 7.9±3.9 ? 5.0±3.2, logEuroSCORE Q1-Q4: 21.3±12.1 ? 12.6±8.1, p<0.001 for both). No significant differences were observed between quartiles in baseline left ventricle ejection fraction. Balloon-expandable valves were used in 54.3% of cases. Overall, device success was 89.6% and in Q4 was significantly higher than in other quartiles (95.8%, p=0.009). No significant differences were observed for valve malposition, need for a second valve or conversion to open surgery but all of these events had numerically lower incidence in Q4. 30-day mortality maintained stable in Q1-Q2-Q3 (3.1% - 3.2% - 3.1%) but was lower in Q4 (1%). Occurrence of disabling stroke was low (0-1%) in all quartiles. Incidence of major vascular complications and bleedings was significantly lower in Q4 (p=0.001). Overall rate of new permanent pacemaker was 11.3% and decreased from Q1 (17.7%) to Q4 (9.4%).

CONCLUSIONS

During ten years of experience with transfemoral TAVI progressively lower-risk patients were treated, procedural success significantly increased and incidence of adverse events decreased.

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Paris score utility for risk prediction after PCI with DES in Japanese clinical practice

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

AIMS

The aim of this study was to validate the utility of Paris thrombotic and bleeding scores in Japanese patients after PCI with DES.

METHODS AND RESULTS

The study subjects were 1747 Japanese patients who underwent PCI with DES between January 2010 and December 2015. We retrospectively validated Paris thrombotic and bleeding score to predict long-term thrombotic events (defined as the composite of myocardial infarction, stent thrombosis and cerebral infarction), major bleeding (defined as the occurrence of a Bleeding Academic Research Consortium type 2, 3 or 5 bleeding), and net clinical outcomes (defined as the composite of all-caused death, thrombotic events, and major bleeding). The patients with in-hospital events were excluded. The patient characteristics were 71.9 years, 72% male, 37% diabetes mellitus, 74% hypertension, 45% chronic kidney disease, 25% current smoking, 16% anemia, 6% taking anticoagulant, and 11% ACS. Both Paris thrombotic scores (3.08 ± 1.84) and Paris bleeding scores (6.01 ± 2.66) were relatively high compared with those in PARIS (Patterns of Non-Adherence to Anti-Platelet Regimen in Stented Patients) registry. During median follow-up of 4.1 years (IQR: 2.4-5.0), 11 patients developed thrombotic events, 19 patients developed major bleeding, and 57 patients developed net clinical outcomes. High bleeding score (>8) was significant associated with major bleeding (HR: 4.65, 95% CI: 1.87-12.49, p=.001) and net clinical outcomes (HR: 4.29, 95% CI: 2.54-7.42, p<.0001), whereas high thrombotic score (>5) was not associated with thrombotic events or net clinical outcomes. Especially, the factors of age, chronic kidney disease and anemia in Paris bleeding score were significantly increased risks for major bleeding (HR: 1.83, 95%CI: 1.11-3.28, p=0.016, HR: 2.31, 95%CI: 1.25-4.28, p=0.002, and HR: 1.75, 95%CI: 1.27-2.36, p=.001, respectively) and net clinical outcomes (HR: 1.90, 95%CI: 1.40-2.62, p<.0001, HR: 1.93, 95%CI: 1.43-2.71, p<.0001, and HR: 1.83, 95%CI: 1.53-2.17, p<.0001, respectively) in univariate analysis.

CONCLUSIONS

This study indicates that both Paris thrombotic and bleeding score are relatively high compared with those in PARIS registry, and especially Paris bleeding score is useful for risk prediction after PCI with DES in Japanese clinical practice.

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Percutaneous closure of the LAA for stroke prevention in patients with atrial fibrillation: the Asia-Pacific experience in Taiwan

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

AIMS

In patients with non-valvular atrial fibrillation (NVAF), percutaneous implantation of left atrial appendage occluder (LAAO) has become an efficacious and safe alternative treatment for stroke prevention. Most of the data were collected from Caucasian populations. Our study reports the initial safety, feasibility, and clinical outcomes following LAAO implantation in Taiwan.

METHODS AND RESULTS

Methods: This is a multi-center registry study in Taiwan. One hundred and ten patients with NVAF (72 males, age 70.3±12.8 years) with CHA2DS2-VASc scores 3.5±1.8 and contraindications to oral anticoagulants or ischemic stroke/transient ischemic attack despite use of oral anticoagulants underwent percutaneous LAAO implantation (71 Watchman and 39 ACP/Amulet) from Aug. 2013 to Dec. 2017. One hundred and six patients received general anesthesia and the procedures were guided by fluoroscopy and transesophageal echocardiography (TEE), and 4 only local anesthesia and fluoroscopic guidance. The patients received either aspirin pus warfarin or aspirin plus clopidogrel or single anti-platelet if having severe bleeding and were followed up at 45 days and then every 3 months after implantation. A follow-up TEE was scheduled at 45 to 60 days after implantation to detect peri-device lead and device-related thrombus.

Results: The LAA occluder was successfully implanted in 109 of these 110 patients (99%). The mean size of implant was 26.4±4.5 mm. There were 3 patients with peri-procedural pericardial effusion and cardiac tamponade (2.7%). Two of them received pigtail drainage and one surgical pericardiotomy (this is the failure case). Follow-up TEE showed 2 patients with peri-device leak more than 5 mm (1.8%), and one of them received additional vascular plaque to occlude the leak. Three patients had device-related thrombus formation (2.7%) and were kept on long-term oral anti-coagulants after the procedure. During a mean follow-up of 23.1±15.8 months, one patient developed ischemic stroke (0.48% per patient year) and one developed clinically significant gastrointestinal bleeding (0.44% per patient year). There was no device embolization and mortality during procedure or follow-up.

CONCLUSIONS

Our multi-center LAAO registry data show that percutaneous LAA closure is a safe and technically feasible procedure with satisfactory clinical outcomes and an efficacious alternative treatment for stroke prevention for patients with NVAF in Taiwan.

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A new predictive model using inflammatory biomarkers, cardiac enzyme, and white blood cell in combination can differentiate ruptured plaque from non-ruptured plaque in ACS: verification by OCT

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Soluble lectin-like oxidized LDL receptor-1 (sLOX-1), neutrophil gelatinase-assoicated lipocalin (NGAL), and matrix metallopeptidase-9 (MMP-9) are well known inflammatory biomarkers involved in the progression and destabilization of atherosclerotic plaque leading to acute coronary syndrome (ACS). The aim of study is to investigate diagnostic value of the biomarkers to discriminate between ruptured plaque and non-ruptured plaque in ACS.

METHODS AND RESULTS

Methods: ACS patients (n=120) who underwent the coronary angiography with OCT evaluation were prospectively enrolled. Their serum levels of sLOX-1, MMP-9, and NGAL were measured. Total 85 patients with the appropriate OCT images were finally analyzed and categorized into two groups, ACS with plaque rupture (ruptured ACS, R-ACS, n=42) and ACS without plaque rupture (non-ruptured ACS, N-ACS, n=43) verified by optical coherence tomography.

Results: Baseline clinical characteristics showed that R-ACS had more men (88.1% vs. 69.8%, p=0.039) and higher white blood cell (WBC) count (6820/μL vs. 8370/μL, p=0.0098) and peak CK-MB level (2.69 ng/mL vs. 13.39 ng/mL, p=0.0016) than N-ACS. Levels of sLOX-1 (227.9 vs. 51.7 pg/mL,

CONCLUSIONS

The new predictive model containing sLOX-1, MMP-9, peak CK-MB and WBC in combination can predict R-ACS in ACS without imaging tools.

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Percutaneous closure of the LAA vs. novel oral anticoagulants for stroke prevention in patients with non-valvular atrial fibrillation: a propensity score matched study in Taiwan

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

AIMS

In patients with non-valvular atrial fibrillation (NVAF), both implantation of left atrial appendage occluder (LAAO) and novel oral anti-coagulants (NOAC) are emerging novel treatments for stroke prevention. So far there has been no clinical trial directly comparing the efficacy and safety of these two treatments. We conducted the first propensity score matched study to address this issue in the Asia-Pacific region.

METHODS AND RESULTS

Methods: This is a multi-center registry study in Taiwan. A total of 110 NVAF patients (72 males, age 70.3±12.8 years) undergoing LAAO implantation (71 Watchman and 39 ACP/Amulet) with mean CHA2DS2-VASc scores 3.5±1.8 were consecutively registered, enrolled and followed up from Aug. 2013 to Dec. 2017. The clinical outcomes of these patients were compared to 220 propensity score matched NVAF patients who took NOACs (83 patients taking dabigartran, 79 rivaroxaban and 58 apixaban). The primary outcomes were systemic embolization and stroke of all types, and the secondary outcomes were major bleeding, cardiovascular hospitalization and mortality and total mortality.

Results: There was no significant difference of baseline characteristics between these two study groups. During a mean follow-up of 23.1±15.8 months, one patient developed ischemic stroke in the LAAO arm and 7 patients developed systemic embolization or stroke in the NOAC arm (0.48% per patient year vs. 1.58%, P<0.001). Patients undergoing LAAO were less likely to develop stroke or systemic embolization (hazard ratio 0.28 [0.03-0.24], P=0.035 in the Cox model). One patient had major bleeding in the LAAO arm and 8 patients had major bleeding or cardiovascular hospitalization in the NOAC arm (0.44% per patient year vs. 1.81%, P<0.001). Patients taking NOACs were more likely to have major bleeding or cardiovascular hospitalization (hazard ratio 4.00 [0.45-32.25], P=0.032 in the Cox model). There was no patient developing intracranial hemorrhage in the LAAO arm, but 3 in the NOAC arm. There was no mortality in all of the study groups. The event rates of our NOAC group were comparable to those of major NOAC trials.

CONCLUSIONS

Our multi-center propensity score matched study shows that percutaneous LAA closure is comparable or even superior to NOACs for stroke prevention in patients with NVAF in Taiwan.

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Impact of comorbidity burden following transcatheter aortic valve implantation

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

AIMS

The comorbid burden of patients undergoing transcatheter aortic valve implantation (TAVI) is expected to be high, but evidence around the impact of comorbidity on clinical outcomes is limited. The aim of this study was to investigate the clinical impact of the Charlson Comorbidity Index (CCI) on clinical outcomes following TAVI.

METHODS AND RESULTS

Data from 1887 patients from the UK, Canada, Spain, Switzerland and Italy were collected between 2007 and 2016. The effect of CCI on 30-day mortality, long-term survival and length of stay (LOS) was explored through logistic regression and Cox proportional hazard models, at both, a whole cohort, and at a country-level through a two-stage individual participant data (IPD) random-effect meta-analysis.

Most patients had a CCI=3+ (60.1%)-with this ranging from 56% (UK) to 72% (Switzerland). Total CCI was not associated with increased odds of 30-day mortality (OR 1.09, 95% CI: 0.95-1.23), but was associated with increased hazard of long-term mortality (HR 1.10, 95% CI: 1.04-1.15). The pooled result from the two-stage IPD meta-analysis indicated that LOS did not significantly differ with increases in CCI (HR 0.97, 95% CI: 0.92-1.02). A very-weak to weak Spearman?s rank correlation coefficient was found between the total CCI and 4 different predicted preoperative risks scores (?=0.16 to 0.29) and, even those patients classed as low preoperative risk presented with a CCI=3+ in about 50% of the patients.

CONCLUSIONS

IIn this multi-centre international study, patients undergoing TAVI had significant comorbid burden, with most having at 3 or more comorbid conditions as assessed by the CCI. We found a very-weak to weak correlation between the CCI and well-established preoperative risks scores. CCI was not associated with 30-day mortality, but was associated with increased hazard of mortality up-to 5-years post TAVI.

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Mid-term efficacy and safety of LAA occlusion vs. standard medical care with direct oral anticoagulants in patients with atrial fibrillation

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

AIMS

We sought to evaluate at a mid-term follow-up the efficacy and safety of left atrial appendage occlusion in prevention of thromboembolism as compared to standard medical therapy with direct oral anticoagulants in patients with atrial fibrillation at high bleeding risk or ineligible for oral anticoagulants due to previous major bleeding.

METHODS AND RESULTS

All consecutive patients with non-valvular atrial fibrillation who underwent a successful left atrial appendage occlusion (between July 2009 and October 2016) or started a direct oral anticoagulant (between June 2011 and December 2015) at our center were enrolled. The primary combined efficacy and safety endpoint was a composite endpoint of systemic thromboembolism (including ischaemic stroke and transient ischaemic attack) and TIMI major bleedings. The efficacy endpoint (ischaemic stroke and transient ischaemic attack) and the safety endpoint (TIMI major bleedings) were also analyzed separately as secondary endpoints.

A total of 935 patients were included (left atrial appendage occlusion group n=274, direct oral anticoagulant group n=661). Patients in left atrial appendage occlusion group had higher prevalence of diabetes (27.7% vs 18.2%, p=0.001), chronic kidney disease (9.7% vs 0.7 %,

CONCLUSIONS

Although patients in the left atrial appendage occlusion group were at higher risk of both thromboembolic and bleeding events, the primary combined efficacy and safety endpoint was comparable to that of the direct oral anticoagulant group. Left atrial appendage occlusion can be considered a safe and effective alternative indication in this high risk setting of patients with atrial fibrillation.

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Angiographic derived endothelial shear stress: a new predictor of atherosclerotic disease progression

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

AIMS

To examine the efficacy of angiography derived endothelial shear stress (ESS) in predicting atherosclerotic plaque progression.

METHODS AND RESULTS

Thirty five patients admitted with ST-elevation myocardial infarction that had 3-vessel intravascular ultrasound (IVUS) imaging at baseline, immediately after successful revascularization and at 13 months follow-up were included in the study. Three dimensional (3D) reconstruction of the non-culprit vessels was performed using the quantitative coronary angiographic (QCA) data and using an established methodology that relies on the fusion of IVUS and biplane angiography. In the models obtained by the two approaches blood flow simulation was performed and the minimum predominant ESS was estimated in 3mm segments. The baseline plaque characteristics and ESS were used to identify predictors of atherosclerotic disease progression that was defined as lumen reduction and an increase in plaque area at follow-up. Fifty four vessels were included in the final analysis. A moderate correlation was noted between the minimum predominant ESS estimated in 3D QCA and in IVUS-derived models (r=0.603, P<0.001), 3D QCA modelling was able to identify with a high accuracy segments exposed to low (<1Pa) ESS in the IVUS-based reconstructions (AUC: 0.789, P<0.001). Low 3D QCA-derived ESS was associated with lumen area reduction, plaque area, plaque burden and necrotic core increase at follow up. In multivariate analysis low ESS estimated either in 3D QCA (OR: 1.87, 95%CI: 1.07-4.35, P=0.028) or in IVUS (OR: 2.40, 95%CI: 1.32-4.35, P=0.004) models and plaque burden were the only independent predictors of atherosclerotic disease progression. There was no difference in the accuracy of the model that included the ESS estimated in the 3D QCA and of the model that included the ESS derived from the IVUS-based reconstructions in predicting disease progression (AUC: 0.824 vs. 0.828, P=0.718).

CONCLUSIONS

3D QCA-derived ESS has a similar prognostic value to IVUS-derived ESS in predicting disease progression. Further research is required to examine the prognostic value of the ESS estimated in 3D QCA models in detecting vulnerable high-risk plaques.

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Safety and efficacy of low dose prasugrel as part of triple antithrombotic therapy with aspirin and oral anticoagulation in patients with atrial fibrillation undergoing PCI

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

AIMS

The use of standard dose prasugrel (10mg/day) as part of triple antithrombotic therapy with aspirin and oral anticoagulation (OAC) is not recommended in current guidelines because it increase the risk of bleeding compared with clopidogrel. However, whether low dose prasugrel also increase the risk of bleeding is unclear. The aim of this study was to evaluate the safety and efficacy of Japanese domestic dose of prasugrel (3.75mg/day) combined with aspirin and OAC in atrial fibrillation (AF) patients undergoing percutaneous coronary intervention (PCI).

METHODS AND RESULTS

Consecutive 816 AF patients undergoing PCI from January 2011 to June 2016 were registered at 8 hospitals in Japan. We examined clinical outcomes of patients who took aspirin and OAC with either prasugrel (n=57) or clopidogrel (n=451) after PCI. The incidence of bleeding (TIMI criteria major and minor bleeding) and major adverse cerebro-cardiovascular events (MACCE, all cause death, non-fatal myocardial infarction, non-fatal stroke and unplanned revascularization) within one-year after PCI were evaluated. The mean age of whole population was 73.3±8.4 years old, 81% of them were male, 42% were diabetes, and 45% were CKD ? stage3. In terms of OAC, 77% of whole population were prescribed vitamin K antagonist and the others were non-vitamin-K oral anticoagulant (NOAC). The mean duration of triple antithrombotic therapy was 287±157 days. The mean CHADS2 score, CHA2DS2-VASc score and modified HAS-BLED score (omitting labile INR) were 2.4±1.2, 4.5±1.5 and 2.3±0.8, respectively. These baseline characteristics were not significantly different between prasgurel group and clopidogrel group. The cumulative incidence of MACCE was not significantly different (prasugrel group 11.5% vs. clopidogrel group 12.3%, Log-rank p=0.87). Moreover, the cumulative incidence of bleeding was not significantly different either (prasugrel group 5.6% vs. clopidogrel group 8.1%, Log-rank p=0.56).

CONCLUSIONS

Low dose prasugrel as part of thriple antithrombotic therpy with aspirin and OAC did not increase the risk of bleeding compared with clopidogrel. It might be an alternative to clopidogrel for the patients with AF undergoing PCI. Further studies are warranted to determine the potential benefit of prasugrel.

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Mid-term outcomes after second-generation DES implantation for non-left main trunk bifurcation lesions by culotte stenting: a comparison between three-link and less than three-link design DES

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

AIMS

Midterm outcomes after second-generation DES implantation for non-left main trunk bifurcation lesions by culotte stenting: a comparison between 3-link and less than 3-link design DES

METHODS AND RESULTS

Methods and results: Between 2010 and 2017, 254 patients (508 lesions) underwent second-generation DES (zotarolimus-, sirolimus-, or everolimus-eluting stents) implantation for non-left main trunk bifurcation lesions by culotte stenting, of whom 200 patients (400 lesions) underwent midterm follow-up within 1 year after the procedure. The 200 patients were classified into two groups on the basis of the stent designs: 3-link design DES group (55 patients, [27.5%]) and less than 3-link design DES group (145 patients, [72.5%]). Less than 3-link design DES consisted of Promus Element? (everolimus-eluting, Boston Scientific, Natick, MA, USA), Resolute? (zotarolimus-eluting, Medtronic, Santa Rosa, CA, USA), and Ultimaster? (sirolimus-eluting, Terumo, Tokyo, Japan) stents and 3-link design DES consisted of only Xience® (everolimus-eluting, Abbot Vascular, Santa Clara, CA, USA). Multiple lesions in one patient treated by one culotte stenting procedure were considered one lesion for statistical analysis. The midterm outcomes were compared between the two groups using the chi-square test on a per-lesion basis. The definition of bifurcation lesions was the main branch ranging from the proximal stem to the distal main branch with boundaries defined by 5 mm proximal and distal to the stent-implanted area and the side branch ranging from the bifurcation carina to the distal side branch with boundaries defined by the carina and 5 mm distal to the stent-implanted area. The midterm outcomes of the 3-link and less than 3-link design DES groups were as follows: in-stent restenosis rate, 23.6% (13/55 lesions) vs. 11.7% (17/145 lesions), p=0.035, bifurcation restenosis rate, 18.2% (10/55 lesions) vs. 9.0% (13/145 lesions), p=0.048), target lesion revascularisation rate, 3.6% (2/55 lesions) vs. 3.4% (5/145 lesions), p=1.000, main branch late lumen loss, 0.354±0.707 vs. 0.325±0.497 mm, p=0.225, and side branch late lumen loss, 0.394±0.514 vs. 0.270±0.413 mm, p=0.074).

CONCLUSIONS

After second-generation DES implantation for non-left main trunk bifurcation lesions by culotte stenting, less than 3-link design DES were superior to 3-link design DES in the rates of in-stent restenosis and bifurcation restenosis. However, no difference in the rate of target lesion revascularisation was observed between the two groups. The stent designs may be associated with angiographic restenosis, but are not likely to affect the patients? clinical events.

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Nine-month clinical outcomes in dialysis patients following polymer-free sirolimus-eluting stent implantations

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

AIMS

In the treatment of acute coronary syndrome (ACS) or stable coronary disease, drug-eluting stents are the standard of care. Unfortunately, patients with chronic kidney disease who are affected by high morbidity from cardiovascular diseases are frequently excluded from coronary artery disease trials. The aim of this study was to study the safety and efficacy of polymer-free sirolimus-eluting stents (PF-SES) in dialyzed patients.

METHODS AND RESULTS

Methods: A previously published unselected large-scale, international, single-armed, multicenter, ?all comers? observational study (ClinicalTrials.gov Identifier NCT02629575) was used for this subgroup analysis to study the clinical outcomes in patients with normal renal function (NRF), with chronic renal insufficiency (CRI) and dialysis dependent (DD) patients. The 9-month target lesion revascularization (TLR) rate was the primary endpoint whereas the 9-month major adverse cardiac events (MACE) and procedural success rates were part of the secondary endpoints.

Results: The primary endpoint TLR at 9 months was not significantly different between NRF, CRI and DD patients (2.2% vs. 4.3% vs. 2.2%, p=0.969). As compared to patients with NRF, the 9-month MACE rate in the CRI group was significantly higher (10.3% vs. 3.9%, p=0.001) whereas the 9-month MACE rate in the DD group was only numerically higher (3.9% vs. 6.7%, p=0.348), However, the accumulated stent thrombosis (ST) rates were significantly higher in the DD group (4.4%) as compared to the NRF (0.6%) and the CRI groups (0.9%, p<0.001).

CONCLUSIONS

Percutaneous coronary interventions with a polymer free, ultra-thin strut sirolimus-eluting stent are safe and effective in dialysis patients. The TLR rate in dialyzed patients is not higher as compared to patients who are not dialyzed. Randomized controlled trials or propensity score matched cohorts would be highly desirable to confirm this result.

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Incidence, predictors, and clinical impact on long-term outcomes of distal vessel expansion by IVUS after recanalisation of CTO

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

After opening the chronic total occlusions (CTO), the morphologic changes of shrunken distal vessels to CTO segments and its clinical implications were not well evaluated.

METHODS AND RESULTS

From the CTO-IVUS (Chronic Total Occlusion InterVention with drUg-eluting Stents) randomized trial, 69 patients (1) with IVUS examinations both at percutaneous coronary intervention (PCI) and 1-year follow-up, and (2) without any adverse events within 1 year were finally analyzed. Distal reference lumen areas were measured after PCI and at 1-year follow-up. Cardiac death, stent thrombosis, and target-vessel revascularization were compared between the patients with distal vessel expansion and those without distal vessel expansion. The mean distal reference lumen area was expanded from 5.42±1.81 mm2 to 6.16±2.00 mm2 (P

CONCLUSIONS

After opening the segment of the chronic total occlusion (CTO), two-thirds of patients underwent distal vessel expansions by IVUS at 1-year. The proximal CTO segment with smaller lumen area at PCI was associated with distal vessel expansion, but the presence of distal vessel expansion at 1-year follow-up IVUS was not associated with long-term clinical outcomes.

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Determinants and long-term outcomes of PCI vs. surgery for multivessel disease according to clinical presentation

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

AIMS

The long-term outcome of percutaneous coronary intervention (PCI) versus coronary artery bypass graft (CABG) particularly for patients with non-ST elevation acute coronary syndrome (NSTE-ACS) remains controversial.

METHODS AND RESULTS

We retrospectively analyzed 2827 patients (stable coronary artery disease [SCAD], n=1601, NSTE-ACS, n=1226) who underwent either PCI (n=1732) or CABG (n=1095). Eight-year composite of cardiac death and myocardial infarction (MI) was compared between PCI and CABG before and after propensity matching. For patients with NSTE-ACS, PCI was performed more frequently for those with higher Thrombolysis in Myocardial Infarction risk score and three-vessel disease. For patients with NSTE-ACS, PCI led to significantly higher 8-year composite of cardiac death and MI than CABG (14.1% versus 5.9%, hazard ratio [HR]=2.22, 95% confidence interval [CI]=1.37?3.58, P=0.001), mainly driven by higher MI (12.3% versus 3.9%, HR=3.45, 95% CI=1.85?6.42, P

CONCLUSIONS

Although the determinants of PCI versus CABG for multivessel coronary disease were different between patients with SCAD and those with NSTE-ACS in real-world clinical practice, a significant interaction between clinical presentation and revascularization strategy was not noted. The revascularization strategies among patients with NSTE-ACS may be decided based on the criteria applied in patients with SCAD.

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Impact of sex on comparative outcomes of bivalirudin vs. unfractionated heparin in patients with ACS undergoing invasive management: a pre-specified analysis of the MATRIX trial

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

AIMS

Over the past decade, antithrombotic therapies after acute coronary syndrome (ACS) have improved outcomes more in men than in women, raising the question of whether there are sex-specific differences in treatment patterns and response to such therapy. However, there is contrasting evidence on the impact of sex on clinical outcomes. Thus, we assessed whether bivalirudin compared with unfractionated heparin (UFH) is associated with consistent outcomes in male and female patients with acute coronary syndrome (ACS) undergoing invasive management.

METHODS AND RESULTS

In the MATRIX program, 7213 patients were randomized to bivalirudin or UFH. Patients in the bivalirudin group were subsequently randomly assigned to receive or not to receive a post-PCI bivalirudin infusion. The 30-day coprimary outcomes were major adverse cardiovascular and cerebrovascular events (MACE), defined as death, myocardial infarction, or stroke, and net adverse clinical events (NACE), defined as MACE or major bleeding. The primary outcome for the comparison of a post-PCI bivalirudin infusion with no post-PCI infusion was a composite of urgent target-vessel revascularization (TVR), definite stent thrombosis (ST), or NACE. The rate of MACE was not significantly lower with bivalirudin than with heparin in male (rate ratio, 0.90, 95% confidence interval [CI], 0.75-1.07, P=0.22) and female patients (rate ratio, 1.06, 95% CI, 0.80-1.40, P=0.67) without significant interaction (Pint=0.31), nor was the rate of NACE (males: rate ratio, 0.85, 95% CI, 0.72-1.01, P=0.07, females: rate ratio, 0.98, 95% CI, 0.76-1.28, P=0.91, Pint=0.38). Post-PCI bivalirudin infusion, as compared with no infusion, did not significantly decrease the rate of urgent TVR, definite ST, or NACE (males: rate ratio, 0.84, 95% CI, 0.66-1.07, P=0.15, females: rate ratio, 1.06, 95% CI, 0.74-1.53, P=0.74, Pint=0.28).

CONCLUSIONS

In ACS patients, the rates of MACE and NACE were not significantly lower with bivalirudin than with UFH in both sexes. The rate of the composite of urgent TVR, definite ST, or NACE was not significantly lower with a post-PCI bivalirudin infusion than with no post-PCI infusion in both sexes. (Minimizing Adverse Haemorrhagic Events by TRansradial Access Site and Systemic Implementation of angioX [MATRIX], NCT01433627)

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Polymer-free sirolimus-eluting stents in an elderly and octogenarian all-comer population

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

AIMS

The purpose of this report was to evaluate the 9-month safety and efficacy of polymer-free sirolimus eluting drug eluting stents in octogenarians and the elderly treated.

METHODS AND RESULTS

Methods: An ?all comers?, worldwide single armed trial (ClinicalTrials.gov Identifier NCT02629575) was conducted to demonstrate the safety and efficacy of an ultra-thin strut, polymer-free sirolimus eluting stent (PF-SES). The primary endpoint was the all cause 9-month target revascularization rate (TLR). Secondary endpoints included the rates of major adverse cardiac events (MACE) as the ensemble of TLR, in-hospital cardiac death, overall death, and myocardial infarction (MI). We investigated the clinical outcomes and in particular the stent thrombosis (ST) and bleeding (BARC) rates in the elderly (?70 years,

CONCLUSIONS

In octogenarians treated with PF-SES, the rates for MACE, overall mortality and bleeding are higher as compared to the younger age groups. However, the rates for TLR and ST were not significantly different across the investigated age groups. PF-SES are safe and effective in octogenarians.

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Improved exercise tolerance after successful CTO-PCI in stable CAD - A single-centre study

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Observational studies have shown a benefit in cardiovascular outcome and less residual angina after successful CTO-recanalization. Other studies have demonstrated no beneficial effect of CTO-PCI on cardiac death vs. optimal medical therapy. A recent study demonstrated benefits in ischemic burden, exercise tolerance and quality of life after successful CTO-recanalization. This single centre study aims to evaluate excercise tolerance after CTO-PCI in stable CAD by 6-MWT and cardiac function by stress perfusion imaging with cardiac MRI.

METHODS AND RESULTS

Patients with a CTO, symptoms of SCAD, viable and ischemic myocardium in cardiac MRI were eligible for enrollment. 6-MWT was performed prior to PCI and 6 months after PCI. Ejection fraction (EF) and ischemia in the 16-segment model was evaluated in cardiac MRI. Continuous data was shown as mean with standard deviation (SD). Comparisons of 6-MWT-total-distance (6-MWT TD), reference-distance (6-MWT RD) and CMR studies before and after PCI were performed by paired, two-sided t-test,

CONCLUSIONS

6 months after successful CTO-PCI patients showed a significant overall improvement of ischemia. Exercise tolerance has been improved significantly only in the group from 50-59 years. This might be due to a better coronary flow reserve and less diastolic dysfunction in younger patients and a higher co-morbidity and reduced mobility in elder patients. We conclude that especially younger patients might benefit from CTO-recanalization.
In this single centre study, exercise tolerance and myocardial ischemia were evaluated by 6-MWT and cardiac MRI 6 months after successful CTO-PCI. The results clearly demonstrate a benefit in exercise tolerance in mid aged patients and an improvement of ischemic area in the 16-segment model.

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Impact of age on delta iFR in patients with coronary artery disease

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Instantaneous wave free ration (iFR) is a method which is used to identify the angiographically intermediate lesions requiring revascularization. However, discordance between iFR and FFR is occasionally observed. It might be attributed to individual differences in the drug effect of maximal hyperemia. The aim of this study investigated the patient background in which the discordance occurs by measure of delta iFR (the decrease in hyperemia iFR after adenosine administration from iFR value).

METHODS AND RESULTS

A total of 71 CAD patients with intermediate stenotic lesions were investigated. We underwent FFR, iFR and hyperemia iFR against the intermediate lesion in our hospital from March 2016 to July 2017 December. Delta iFR was significantly correlated with age (r=-0.327, P

CONCLUSIONS

Age was significantly negative impact on delta iFR. Young patients tended to have a higher maximum hyperemic effect. This phenomenon might be associated with endothelial and microvascular dysfunction. And our findings suggested that young patients might be took particular care to evaluate myocardial ischemia by iFR.

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Anatomic and procedural predictors of transcatheter heart valve dislodgement following self-expandable valve

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

AIMS

This study aimed to predict the dislodgement of self-expanding (SE) transcatheter heart valve (THV) in order to quantify possible operator-dependent device movements during transcatheter aortic valve implantation (TAVI).

METHODS AND RESULTS

At our institution, 103 patients who underwent transfemoral TAVI with Evolut R were retrospectively identified. Multiple linear regression models were created, and a predictor equation was built to quantify how the factors affect THV behavior. Multiple linear regression analysis for THV dislodgement on the left coronary cusp (LCC), angle of misalignment between THV and the ascending aorta (ATA), pre-dilation, and less operator experience were independent predictors of upward dislodgement, whereas estimated glomerular filtration rate (eGFR) was inversely related with THV behavior (95% confidence interval: 0.219 to 0.340, 0.447 to 2.092, 0.165 to 1.757, and -0.053 to -0.011, respectively). Since the strongest predictor of THV dislodgement on the LCC side was ATA, after controlling for other variables, the predictor equation was modified as below:
THV dislodgement distance on the LCC side [mm] = -3.248 + 0.280 × ATA [°]
Predictors of THV dislodgement on the non-coronary cusp (NCC) side could not be identified using this model.

CONCLUSIONS

ATA immediately before deployment, pre-dilation, and less operator experience were independent predictors of upward dislodgement of THV on the LCC side. eGFR was an independent predictor of THV downward dislodgement on the LCC side. Of them, ATA was the strongest predictor. Predictors of THV dislodgement on the NCC side were not identified.

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Predictor factors of revascularisation and long-term prognosis in patients with borderline FFR values

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

AIMS

To analyse factors that can influence decision-making strategy in coronary revascularization (PCI or CABG) for lesions with borderline FFR values and evaluate clinical outcomes

METHODS AND RESULTS

A retrospective and unicentric study including 54 patients with 57 intermediate lesions, in which a so called borderline value (0,78 ? 0,82) was assessed by FFR. The population was divided in deferal (N=21) and revascularization (N=33) groups, based on the therapeutic decision, and correlated to clinical and angiographic data of each subject. We observed higher presentation of Unstable angina (29% x 4,7%, p = 0,039) in the revascularization group and higher incidence of distal lesions (17% x 0%, p=0,024) in the deferal group. Although non-significant, long lesions, proximal coronary segments and multiarterial patients were also more frequente in the revascularization group. The 29 month incidence of MACE were low and non-significant between groups.

CONCLUSIONS

In patients with borderline FFR values, coronary revascularization was more frequent in patients presenting unstable angina and deferal was higher in distal lesions, with low incidence of MACE in this population.

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Clinical outcome of FFR-deferred lesions in patients with stable angina and ACS

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

AIMS

We compared clinical outcome between acute coronary syndrome (ACS) and stable angina (SA) patients who have deferred lesions with FFR > 0.8.

METHODS AND RESULTS

In 534 patients (mean age 64 ± 10 years, male 62%), 613 deferred lesions with FFR measurement > 0.80 (mean 0.89 ± 0.05) were enrolled in this study retrospectively. The rate of target lesion revascularization (TLR) and major adverse cardiac events (MACE, TLR, myocardial infarction, and cardiac death) were evaluated up to 5 years follow up. 143 lesions were included in the ACS group and 470 lesions were included in the SA group. During a median follow-up of 2.3 years, 14 TLRs, 5 myocardial infarctions, 6 cardiac deaths, and 24 MACEs happened. There was no difference in FFR between the ACS and the SA group (0.89 ± 0.05 vs. 0.89 ± 0.05, p = 0.175). However, the rate of TLR and MACE was significantly higher in the ACS group than in the SA group (4.9% vs. 1.5%, p = 0.025, 7.7% vs. 2.8%, p = 0.013, respectively). Using Kaplan-Meier survival analysis, the SA group showed better TLR (p=0.018) and MACE (p=0.009) compared to the ACS group.

CONCLUSIONS

Among the deferred lesions with FFR > 0.8, the clinical outcome was different according to clinical diagnosis. The SA group showed the better lesion-related events and clinical outcome compared to the ACS group.

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Multicentre clinical outcomes of hybrid tapered sirolimus-eluting coronary stent system with biodegradable polymer in long diffuse de novo coronary artery lesions

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

AIMS

Tapering of coronary arteries is a major challenge observed with long coronary lesions. This study was conducted to investigate the safety and performance of BioMime? Morph tapered sirolimus-eluting coronary stent system (Meril Life Sciences, Pvt. Ltd., Vapi, India) with an ultra-thin cobalt-chromium platform and a biodegradable polymer in real-world long de novo coronary artery lesions.

METHODS AND RESULTS

This was a retrospective, non-randomised, multi-centre study conducted in 362 patients with long diffuse coronary artery lesions who were implanted with BioMime Morph. The major clinical end-point was major adverse cardiac events (MACE), which is a composite of cardiac death, myocardial infarction (MI), ischemia driven-target lesion revascularization (ID-TLR) at 30-day, and 6-month follow-up period.

The mean age of patients was 61.09 ± 9.04 years with signs and symptoms of stable angina, unstable angina, STEMI or NSTEMI. Out of 362 patients, 170 (46.9%) were diabetics and 159 (43.9%) had hypertension. A total of 627 lesions were intervened successfully with 402 stents (1.11 stent per patient). The incidence of MACE was 1 (0.29%) and 4 (1.19%) at 30-day and 6-month follow-up respectively. There was 1 (0.30%) case of MI and ID-TLR, and 2 (0.59%) cases of cardiac death were reported at 6-month follow-up. In addition, 1 (0.30%) patients presented acute stent thrombosis.

CONCLUSIONS

The BioMime Morph tapered coronary stent system demonstrated the safety and performance in real-world patients with long diffuse de novo coronary artery lesions.

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Effect of diabetes mellitus on outcomes after TAVI

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

AIMS

Aims: We aimed to investigate the effect of diabetes on the feasibility of the procedure of transcatheter aortic valve implantation.

METHODS AND RESULTS

Methods and results: From an overall population of 2000 patients who underwent TAVI, we compared 663 patients with diabetes with a control group of 1337 patients. 387 of the patients with diabetes were orally treated and 276 were insulin treated. The patients underwent TAVI between 2008 and 2015. The patients with diabetes were younger, had lower ejection fraction and a higher prevalence of comorbidities at the baseline, such as pulmonary hypertension, coronary artery disease and renal failure as well as a higher Euro-Score.

Device success and VARC-2 complications were not different between the two groups of patients, except a higher incidence for minor strokes and kidney injury. The incidence of severe kidney injury (RIFLE 2/3) was though not different between the two groups. The two factors remained statistically significant after adjusting the odds ratios through invert probability treatment weighting for the factors that were different at the baseline (p-values 0.023 and

CONCLUSIONS

Conclusions: TAVI is feasible in patients with diabetes without a higher risk for periprocedural complications

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DEB utility in 2018: indications and three-year follow-up results from a tertiary centre

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

AIMS

Drug eluting balloon (DEB) angioplasty provides non-stent-based local drug delivery that maintains the antiproliferative properties of DES, but without the limitations of drug eluting stents (DES)- mainly vessel recoil and in-stent thrombosis. We investigate the utility and outcome of DEB in clinical practice.

METHODS AND RESULTS

Patients who underwent PCI using drug eluting balloons between January 2012 and June 2014 from a single tertiary centre were retrospectively analysed. The indication for PCI was documented as well as patient demographics, vessel characteristics and size of drug eluting balloon. Patients were followed up till Dec 2016. Primary outcomes were target vessel revascualrisation and whether in the context of ACS or stable disease. Patients were followed up by reviewing the hospital computer system for follow up data and any further intervention. Patients who were not reviewed in hospital under any disciple were contacted personally. Statistical analysis were performed by Graph Prism 2016. Normally distributed are described as mean +/- standard deviation.

Results: In total 86 patients were included in the study (male 68%, mean age 67 +/- 12yrs). Drug eluting balloons were used in the context of ACS in 65% of patients with the remaining patients undergoing elective procedures. Indications for utilising DEB included: instent restenosis in previously stented patients in native vessels or previous grafts (46% of cases, mean vessel diameter treated 3.0mm+/-1.5mm), to treat de novo disease (41% of patients, mean vessel diameter: 2.75 +/- 0.5mm), as part of bifurcation treatment (13%, mean vessel diameter: 2.5+/-0.75mm).

Patients were followed up for 32+/-14 months. Primary outcome occurred in 9 patients (10%), with instent restenosis in previously stented vessels due to neointimal hyperplasia remained to be the predominant cause for recurrent target vessel revascularisation, occurring in 8 out of 9 patients. Only one patient with originally de novo disease treated with drug elution had a primary outcome. There was no primary outcome in those who had drug elution as part of bifurcation PCI strategy.

CONCLUSIONS

Drug eluting balloons are traditionally used in treating in-stent restenosis. However this study indicate that the outcome of drug elution in de novo disease even in the context of bifurcation PCI equates to outcomes from published data in third generation drug eluting stents and with the advent of bioabsorbable scaffold. They are a safe and affordable option in patients requiring shorter dual antiplatelet therapy.

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Coronary angioplasty of very small vessels with DEB: immediate and long-term results

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

AIMS

The aim of this work was to study the feasibility and the safety of treatment of de novo lesions in very small coronary vessels (equal or inferior to 2.5mm) by drug-eluting balloon alone and to determine whether the long-term angiographic results are satisfactory or not.

METHODS AND RESULTS

Methods: Ninety eight patients were enrolled in a prospective single center register between October 2011 and June 2017. The eligibility criteria were all de novo lesions in very small caliber coronary vessels that were planned to be treated by 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 in case of dissection with TIMI flow under 3 or 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 and the occurrence of angioplasty-related myocardial infarction. On Follow-up, no systematic long term angiographic control was scheduled but some patients got angiographic control(s) for different reasons. We examined the rate of late lumen patency and the restenosis rate of these specific cases.

Results: Mean vessel size and length were 2,09 mm and 13 mm, respectively. Ninety eight percent of the treated lesions were located in secondary branches of the coronary tree and 38% of them had an ostial location. Pre-dilation was performed in 91% of procedures. Mean size and length of the drug eluting balloon were 2,10 mm and 19 mm, respectively. The mean lumen stenosis at diagnosis was 93% and mean residual stenosis post drug-eluting balloon angioplasty was 30%. As immediate complications, there were 21 non-occlusive dissections, one occlusive coronary dissection requiring stenting, and one case of coronary perforation by the guide wire. Sixty eight percent of patients had an acute coronary syndrome. Consequently, a rise in troponin level was frequently observed, but none could be solely attributed to the drug-eluting balloon angioplasty. On Follow-up, 25 patients had coronary angiograms, performed after a mean period of 13.6 months of the index procedure. Late lumen patency was maintained in 92% of cases, with no dissection visible in any of the angiographic studies. Late lumen patency was well correlated to TIMI flow at the end of the index procedure (

CONCLUSIONS

Conclusion: Our study shows that drug-eluting balloon angioplasty alone is a safe strategy in very small sized coronary arteries and can give good immediate and long-term angiographic results. Consequently, abstaining from systematic additional stenting seems to be a reasonable strategy for the treatment of such stenosis.

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Relationship between distal embolisation and reduction of lipid core burden index in near-infrared spectroscopy after PCI: Korean TVC registry

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

We sought to determine whether reduction of lipid core burden index (LCBI) using near-infrared spectroscopy (NIRS) after percutaneous coronary intervention (PCI) was associated with distal embolization of plaque or lipid migration outward to stent platform.

METHODS AND RESULTS

From January 2015 to August 2016, Korean TVC? registry which consisted of 6 tertiary hospitals enrolled 214 patients who performed NIRS during coronary angiography. To evaluate the association between reduction of LCBI and distal embolization, the patients with stable angina were selected (78/214, 36.4%). Culprit segments were analyzed for the maximum lipid core burden index in a 4-mm length of artery (max LCBI4mm). Distal embolization was assessed with post-procedural increase in creatine kinase-myocardial band (CK-MB). The delta LCBI was defined as max LCBI4mm minus post-stenting LCBI4mm at same culprit lesion.

Male was 70.5%, hypertension 42.3%, diabetes mellitus 32.1%, and dyslipidemia 43.6%. Mean age was 64.64 ± 10.68. The target lesion was left main (LM) (7.7%), left anterior descending artery (LAD) (73.1%), left circumflex artery (LCX) (17.9%), and right coronary artery (RCA) (1.3%). Max LCBI4mm at LM was median [interquartile range (IQR)]: 435 [103 to 577], LAD 388 [226 to 556], LCX 264 [34 to 427], and RCA 251 [86 to 633]. Max LCBI4mm of culprit lesion was 393 [207 to 550], and post-stenting LCBI4mm decreased significantly to 143 [14 to 302] (p 1 time, 3 times, or 5 times upper limit of normal did not show significant relationships with max LCBI4mm of > 400 or 600. There was no in-hospital cerebral infarction, stent thrombosis, no reflow, or mortality.

CONCLUSIONS

The present study has demonstrated that LCBI was significantly decreased after stent implantation. However, distal embolization accessed by elevation of CK-MB was not associated with reduction of LCBI at culprit lesion. Consequently, decrease in LCBI after stent implantation more likely reflected lipid migration outward to stent platform rather than distal embolization, and diminished absorbance of near-infrared light.

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A systematic review of amputation-free survival in patients with no-option critical limb ischaemia

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

AIMS

A subset of patients with chronic, critical limb ischaemia have no options available for revascularization. Patients are either poor surgical candidates or have unfavorable vascular anatomy. Mortality and amputation rates in no-option patients vary widely due to differences in baseline disease state and on time periods of study enrollment. To that end, we sought to assess the natural history of patients with no-option critical limb ischaemia.

METHODS AND RESULTS

Using OVID (Wolters Kluwer, New York, NY) we searched publications and abstracts in MEDLINE, the Cochrane Library, and Embase. Briefly, examples of search terms included ?no-optical critical limb ischemia?, ?amputation-free survival?, ?death (and/or) major amputation?, ?Rutherford?, and ?Fontaine?. The titles and abstracts were appraised by two reviewers, MIG and DT. Randomized controlled trials, controlled trials, case-control studies, longitudinal series, and case studies were selected if they met the PICOT (Population(s)/ disease(s) or condition(s), Intervention(s), Comparator group(s)/control(s), Outcome(s)/endpoint(s), Time) eligibility criteria. Population(s): The target population consisted of Rutherford Category 4, 5, or 6 or any symptomatic equivalent including Fontaine III and IV. Intervention(s): No surgical, endovascular, or experimental intervention. Comparator group(s)/control(s): None. Outcome(s)/endpoint(s): mortality, major (above the ankle amputation), amputation-free survival (AFS), and/or wound healing. Time: Clinical outcomes reported at a minimum follow-up duration of 6 months, 12-months also collected. A total of 1142 abstracts and titles were appraised. Twenty-three studies reported amputation-free survival at 6 months, 19 studies reported amputation-free survival at 12 months.

Statistical analysis showed an increasing trend of the 6-month amputation-free survival based on time period of enrollment. Weighted averages for pre-2003, post-2003, and cumulative 6-month amputation-free survival were 57.2%, 71.3%, and 62.7% ($p < 0.0001$), respectively. Weighted averages for pre-2003, post-2003, and cumulative 12-month amputation-free survival were 46.4%, 62.2%, and 55.9% (

CONCLUSIONS

Our systematic review highlights that patients with Rutherford 5/6 no-option critical limb ischaemia have an especially poor prognosis. Despite advances in cardiovascular disease management, there exists an opportunity to improve outcomes for patients with no-option critical limb ischemia.

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Cardiovascular risk profile and clinical outcomes of patients from three continents treated with a thin-strut DES

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

AIMS

To compare clinical practices in a large all-comer registry population treated with Ultimaster, a thin strut sirolimus-eluting stent with abluminal biodegradable polymer coating, within 3 continents and assess differences in patient characteristics, routine practice and 1-year clinical outcomes.

METHODS AND RESULTS

e-Ultimaster is a registry enrolling world-wide patients with coronary artery disease requiring PCI and treated with Ultimaster DES. By time of presentation, 1-year follow-up data will be available in more than 10,000 patients. The primary endpoint of target lesion failure (TLF) is defined as a composite of cardiac death, target vessel (TV) related myocardial infarction (MI) and clinically driven (CD) target lesion revascularization (TLR).

Currently 7462 patients have reached 1 year follow-up in Europe (86.1%), 798 in Asia (9.2%) and 404 in South America (4.7%). European patients were older compared to Asian and South American patients (65.4 vs 59.7 vs 61.6 years, p<0.001), but were less likely to have hypertension (61.9 vs 76.5 vs 73.8%, p<0.001) or diabetes (24.0 vs 29.1 vs 40.8%, p<0.001). Asian patients included less smokers (18.5%) compared to Europe (24.0%) and South America (26.5%). Previous PCI was similar in the 3 groups, while proportion of patients with previous CABG was 14.3% in South America, 6.1% in Europe and 3.4% in Asia (p<0.001). Compared to Asia (64.2%) and South America (62.9%), ACS was present less in European patients (59.1%, p<0.001). A lower percentage of European patients was on DAPT at 1 year follow-up (63.4 vs 71.7 vs 78.7%, p<0.001). Presence of multivessel disease was 59.0% in Asia, 45.1% in Europe and 42.8% in South America. Number of lesions treated was higher in Europeans (1.4 vs 1.2 in Asia vs 1.3 in South America). Radial access was used less in Asia (72.8%) compared to Europe (85.6%) and South America (94.1%). More bifurcation lesions were treated in Europe (11.5 vs 7.3 vs 6.2%, p<0.001) compared to the other 2 regions, while left main, long lesions (?25 mm) and small vessel (?2.75 mm) lesions were similar across the 3 groups. Balloon pre- and post-dilatation was used most in Asia (68.9 and 52.8%) compared to Europe (60.1 and 39.8%) and South America (60.9 and 30.8%, p<0.001). Average number of days from procedure to discharge was 6.3 days in South America, and 5.1 and 2.7 days in Asia and Europe (p<0.001).

At 1 year follow-up, higher cardiac death rates were observed in South American patients (3.7 vs 1.3 vs 1.3%, p=0.001) compared to Europe and Asia. Target vessel related MI and target lesion revascularizations were significantly higher in Europeans (1.3% and 1.6%) compared to the Asia (0.1% and 0.8%) and South Americans (0.3% and 0.5%). Target lesion failure did not differ significantly between the 3 groups (3.4% Europe vs 2.1% Asia vs 4.2% South America, p=0.10), but target vessel failure (4.0 vs 2.1 vs 4.2%, p=0.03) and patient-oriented composite endpoint of all death, MI and any revascularization were lower in Asian patients (2.9% vs 6.5% in Europeans vs 5.7% in South Americans, p<0.001). No definite or probable stent thrombosis was observed in Asian patients, compared to 0.8 and 0.7% in Europe and South America.

CONCLUSIONS

Differences in risk factors at baseline as well as procedural and lesion characteristics were observed between

patients recruited in Europe, Asia and South America. Clinical outcomes at 1 year showed good safety and efficacy of the Ultimaster DES in all populations, with especially low rates in Asia.

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Transradial vs. transfemoral intervention in NSTEMI-ACS patients undergoing PCI: from the Korean transradial intervention registry of 1,285 patients

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THEME: Coronary Interventions
TOPIC(S): NSTEMI

AIMS

Although the adoption of TRI has been increasing over the past few years, there are limited data on the impact of TRI on efficacy and safety in patients with NSTE-ACS. We sought to compare the 1-year clinical outcomes and bleeding complications of transradial intervention (TRI) with transfemoral intervention (TFI) in patients with non-ST-segment elevation-acute coronary syndrome (NSTE-ACS).

METHODS AND RESULTS

The Korean TRI registry was a cohort of 20 centers from 2012 to 2015. The primary efficacy endpoint was major adverse cardiovascular events defined as a composite of cardiac death, nonfatal myocardial infarction, and repeat revascularization. Among the 1,319 patients with NSTE-ACS, 1,285 patients were finally analyzed after excluding 34 patients due to loss to follow-up and were divided into TRI group and TFI group according to the final access site. At 1 year follow-up, TRI group showed a significantly lower rate of major adverse cardiovascular events and a lower rate of cardiac death with marginal significance than TFI group in the crude population. However, in propensity-score matched analysis, the rate of major adverse cardiovascular events did not differ between TRI and TFI group. Regarding to bleeding complications, TRI group was associated with significantly lower rate of major bleeding in both the crude and matched population. Independent predictors of major adverse cardiovascular events were chronic kidney disease and multi-vessel disease.

CONCLUSIONS

In patients with NSTE-ACS, TRI was associated with favorable 1 year clinical outcomes and lower bleeding complications compared to TFI. Independent predictors of major adverse cardiovascular events were clinical and angiographic profiles (chronic kidney disease, multi-vessel disease), not vascular access sites.

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Long-term outcomes after PCI in patients with insulin-treated vs. non-insulin-treated diabetes mellitus

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Patients with diabetes mellitus have been shown to have worse outcomes after percutaneous coronary intervention (PCI) compared to non-diabetics. There is however conflicting data on whether insulin-treated diabetics (ITDM) have worse outcomes compared to non-insulin treated diabetics (non-ITDM) and it has been postulated that insulin may have direct effects that promote worsening of coronary artery disease. In this study, we sought to compare clinical outcomes following PCI in patients with insulin-treated vs. non-insulin treated diabetes mellitus in a contemporary multi-centre PCI registry.

METHODS AND RESULTS

This study included 4,579 consecutive patients with diabetes undergoing PCI from 1 January 2005 to 31 December 2014 enrolled prospectively in the multi-centre Melbourne Interventional Group registry, of which 1,111 patients were in the ITDM group and 3,468 were in the non-ITDM group. The primary endpoint was a composite endpoint of major adverse cardiovascular and cerebrovascular events (including all-cause mortality, myocardial infarction, target vessel revascularisation and stroke, MACCE) at 12 months. Logistic multivariate regression analysis was used to identify independent predictors of 12-month MACCE. Long-term survival was compared using Kaplan-Meier survival curve analysis. Further subgroup analyses were also performed comparing 12-month outcomes in patients treated with diet-control only (diet-DM), oral hypoglycaemic agents only (OHG-DM) and insulin. ITDM patients tended be slightly younger, and were more likely to be female and obese, as well as have comorbidities like stage 4-5 chronic kidney disease, peripheral vascular disease and severe left ventricular systolic dysfunction (all

CONCLUSIONS

Among diabetic patients undergoing PCI in our study, those treated with insulin at the time of PCI had a significantly higher prevalence of comorbid cardiovascular risk factors, and also worse 12-month outcomes compared with patients not treated with insulin, including increased MACCE, mortality and repeat myocardial infarction. ITDM was found to be an independent predictor of 12-month MACCE. There appears to be a gradient of risk with a significant increase in 12-month MACCE with escalation of therapy for diabetes from diet control only to insulin. Further studies to ascertain whether this is caused by insulin itself or is due to associated comorbidities in the ITDM group, are required.

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Was OCT guidance necessary during all BRS implantation?

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THEME: Coronary Interventions

TOPIC(S): Stents and scaffolds

AIMS

We aimed to assess the impact of OCT guided implantation on clinical outcomes in patients who received either ABSORB BRS or Everolimus DES.

METHODS AND RESULTS

The study included 176 patients with OCT guided implantation of either ABSORB BRS (124 patients, 70% males , mean age 53 ± 20 years) or Everolimus DES (52 patients, 75% males, mean age 51 ± 20 years). We have analyzed by OCT intraprocedural complications including edge dissection, struts fracture and malapposition, and scaffold/stent underexpansion after angiographically successful implantation of Absorb BRS or DES. MACE including cardiovascular mortality, myocardial infarction (MI), target lesion revascularization (TLR), and scaffold/stent thrombosis were also evaluated at 6 months, 1and 2 years.

We studied 160 lesions from 124 patients in the ABSORB BRS arm, and 60 lesions from 52 patients in the DES arm. Post successful angiographic results, further postdilatation for OCT detected underexpansion and malapposition were observed in 37.0% in BRS group and 28.0% in DES group , and dissection stenting were required in 10.5% in BRS and 6.6% in DES . Strut fracture was observed in 3 lesions in the BRS arm, and none in the DES arm. The total rate of required further intervention after OCT review was 52.0% in BRS and 35.0% in DES group (

CONCLUSIONS

Compared to DES, BRS implantation was associated with a significant higher rate of intraprocedural complications as detected by OCT, necessitating more scaffold optimisation and stenting. There was no significant difference in the rate of MACE between Absorb BRS and Everolimus DES in the mid to long term follow-up.

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Procedural and in-hospital outcomes of CTO interventions. Single-centre experience

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Chronic total occlusions represents one of the most significant problems in the endovascular treatment of patients with coronary artery desease. We investigated procedural and clinical outcomes of patients who underwent CTO recanalization in a consecutive series of patients.

METHODS AND RESULTS

We retrospectively analyzed 628 patients who underwent 656 CTO PCI procedures during 2014 ? 2017 in a multi-operator single center, which is the largest volume PCI center in Russia. Median age of patients was 59.9 ± 9.1, females 14.3%. The 41.6% of patients were presented with severe stable angina (Canadian Classification System class III or IV). Previous failed CTO PCI attempt had been undertaken in 14.6% of patients. The CTO target vessel was the right coronary artery (61.1%), followed by the left anterior descending (23.3%) and left circumflex (15.4%) arteries. In one case CTO was located in Left Main. According to the J-CTO score, 22.4% of lesions were classified as easy (J-CTO score = 0), 33.7% intermediate (J-CTO score = 1), 24.2% difficult (J-CTO score = 2) and 19.7% very difficult (J-CTO score ? 3).

Overall procedural success was achieved in 497 lesions (75.8%). A retrograde approach was undertaken in 139 lesions (21.2%), in 41 lesions as a primary strategy. Septal collaterals were used in the most cases ? 91.3%. approach as primary strategy was used in 27 (5.7%) cases. The most frequent arterial access was the radial artery (93.7%) and dual injection was used in 256 cases (31.5%). There were no cases of in-hospital death and stroke in our study. Periprocedural myocardial infarction occurred in 1.4% patients, repeat revascularization in 2%. Coronary artery perforation was observed in 26 patients (4%). However most of these perforations (24 patients) were benign. In 2 patients perforation was eliminated during the same procedure: in 1 case 40 min balloon inflation was used, in the other patient we used Histoacryl glue for embolization. Only in 2 case coronary perforation caused cardiac tamponade. The median number of stents per case was 1,7 ± 0,94.?Mean fluoroscopy time was 37,2 ± 22 min.

CONCLUSIONS

The success rate in our study is comparable with those reported in most studies. The rate of procedural adverse events was low and similar to the non-CTO PCI series. However, further work is needed to increase rates of procedural results in this group of patients.The use of algorithms developed by North American and Japanese colleagues or development of the own algorithm could likely increase the technical success rate.

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Ultrasound-guided vs. palpation-guided radial artery catheterisation: meta-analysis of randomised controlled trials

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

AIMS

Cannulation of the radial artery is often undertaken through manual palpation, however, ultrasound (US) guided access has been advocated as a mean to increase access success and lower RA complication rates. We sought to evaluate the impact of US-guided RA access compared with palpation alone on RA access related complications.

METHODS AND RESULTS

We used the items ?radial?, ?trans-radial?, ?ultrasound?, ?ultrasound-guided?, ?access?, and ? catheterization? during literature review in this meta-analysis. Literature review was undertaken using Pubmed, Medline, Embase and Cochrane Central Registry from January 2000 until November 2017 for randomized controlled trials (RCT?s) comparing the use of US-guided access to blind access for radial artery catheterization. Data was pooled for the primary and secondary outcome measures using the random effect model as pooled odds ratio (OR). The primary outcome was successful first attempt at obtaining radial access. The secondary outcomes were failure rate in obtaining access, and risk of hematoma. Among 121 potentially eligible studies, 6 were selected that included 1,295 patients with a mean age of 66.6 and 53% females. 648 underwent radial artery access using US-guidance compared with 647 patients where palpation was used. A random effects model combining the results of the included studies demonstrated a statistically significant greater odd of first attempt success in the US group compared with the palpation group (OR=2.58, 95% CI 1.54 to 4.33, p 0.0003). There was no difference in failure rate or in the risk of hematoma between both groups (OR 0.55, 95% CI 0.26 to 1.16, p 0.12 and OR 0.49, 95% CI 0.16 to 1.48, p 0.21, respectively)

CONCLUSIONS

Ultrasound-guided technique for radial artery access has higher success first attempt rate compared with palpation. Ultrasound guidance does not appear to affect complication rates. We recommend using ultrasound in certain cases when radial artery pulse is weak or hard to palpate.

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Impaired blood flow in the acute marginal artery during an inferior STEMI is associated with worse in hospital clinical outcomes

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Impaired blood flow in the acute marginal artery (AMA) following percutaneous coronary intervention (PCI) to the right coronary artery (RCA) during ST elevation myocardial infarction (STEMI) is often observed. In particular, stenting across the ostium of the AMA, may result in plaque shift as well as direct limitation to coronary flow. The clinical implications of this are unknown.

METHODS AND RESULTS

We sought to determine whether impaired flow in the AMA, following primary PCI to an RCA during STEMI affects in-hospital clinical outcomes. We reviewed coronary angiograms and medical records in all patients presenting with inferior STEMI and an occluded RCA on angiography between February 2011 and December 2017 at our institution to determine AMA flow at the end of each case and in-hospital clinical outcomes.

A total of 547 patients with inferior STEMI were identified. Of these, 281 had RCA occlusion at or proximal to the AMA and required stent insertion across the ostium of the AMA. Mean age was 62.5 years with 26.3% females. Impaired blood flow in the AMA, defined as TIMI flow

CONCLUSIONS

Impaired blood flow in the AMA during inferior STEMI treated with primary PCI to the RCA is associated with greater risk of right ventricular dysfunction, amount of myocardial necrosis and poorer clinical outcomes. Whether these patients would improve with percutaneous coronary intervention to the AMA should be further investigated.

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Characteristics of national and major regional PCI registries: a systematic review

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

AIMS

Clinical registries are a powerful tool to assess healthcare effectiveness and safety, as well as to inform on the real-world impact of new interventions or medications. It is unclear however, how many countries have major registries, to measure quality of care and outcomes of patients undergoing percutaneous coronary intervention (PCI). The aim of this structured review was to provide an overview of the characteristics of active PCI registries from around the world, and their approach to clinical outcome measurement, risk adjustment and public reporting of outcomes.

METHODS AND RESULTS

A systematic search of the published literature was undertaken to identify currently active national PCI registries. A registry was considered to be ?national? if it was reported as the accepted country-wide system for data collection on PCI and had published reports or publications. In countries where there was no national PCI registry, up to three of the largest regional registries were included. A further search of the online literature was performed using Google to identify registries meeting the inclusion criteria and more information on their characteristics. The search yielded 2160 potential papers, of which 293 papers were included. With an additional 9 registries identified based on the online search, a total of 30 registries from 26 countries were identified. Of these, 24 are national registries while 6 are major regional registries. Most of the registries are located in Europe while there are no major PCI registries in Africa. Although the earliest registry was established in 1990, 22 out of the 30 registries (73%) were established in or after the year 2000. Overall, 12 registries (40%) collect data on PCI procedures only, while 18 registries (60%) also collect data on patients undergoing diagnostic coronary angiography without PCI. Estimated case coverage is variable but more complete where participation is mandated by government. Just under half of all registries collect mortality rates at 30 days post PCI while only 30% collect mortality rates at 12 months. Less than a third of all registries (30%) provide risk-adjusted mortality rates and only half report bleeding outcomes, with a variety of bleeding definitions used. Twelve registries (40%) provide publicly available reports of their data at hospital or operator level.

CONCLUSIONS

Our review demonstrates that the global distribution of PCI registries is patchy, with the highest concentration of registries in Europe. Clinical PCI registries have a key role to play in improving the quality of local cardiac care, but comparison across regions and countries is challenging due to varying registry definitions and data collection timepoints. While public reporting of key quality metrics may help to improve processes and outcomes, registries must consider how to avoid risk-averse behaviour with use of appropriate and sophisticated risk adjustment models.

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Long-term outcomes after TAVR using the Portico valve: favourable hemodynamics and importance of oversizing

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

AIMS

Long-term outcome data of the second-generation Portico THV are lacking to date.
We report our large single center short- and long-term outcomes using the self-expandable, repositionable second generation Portico transcatheter heart valve (THV).

METHODS AND RESULTS

One hundred sixteen consecutive patients who had undergone TAVR with Portico THV were enrolled. Evaluation of paravalvular leak (PVL) and mean transaortic gradient by transthoracic echocardiography (TTE) as well as clinical follow-up was performed before discharge, at 30-days and at 1-year follow-up.
Sixteen patients died within the first year (14%). At discharge and 30-days, no patient had severe PVL, and moderate PVL was found in 3% and 1% of patients, respectively. At 1-year, significant PVL were found in 6% of patients. The mean transaortic gradient was reduced from baseline (42mm Hg (IQR 31?51)) to discharge (6mmHg (IQR 4?8), $p < 0.001$). The low transaortic gradients were maintained throughout 30 days and 1 year (7mmHg (IQR 5.0 ? 9.0) and 8mmHg (IQR 6.0 ? 11.0), respectively. At one year, 95% of the patients were in NYHA class ?2+.
On Multivariate Cox Regression analysis, 1-year mortality was independently associated with a lower rate of valve oversizing (HR 0.90, 95% CI 0.81 ? 0.99, $p = 0.043$).

CONCLUSIONS

The Portico THV system was associated with low rates of PVL, as well as low mean transaortic gradients at 1-year. One-year mortality was independently associated with a lower rate of valve oversizing.

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Safety and efficacy of the treatment of in-stent restenosis and small vessels with the novel paclitaxel-coated Scoring Balloon (AngiosculptX): A preliminary multicentre real-world registry

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

AIMS

To assess the safety and efficacy of real-world patients with in-stent restenosis (ISR) or small vessel (<2.5 mm) treated with the novel paclitaxel-coated Scoring Balloon

METHODS AND RESULTS

A multi-center, "real-world", prospective registry was performed including consecutive patients presenting with ISR or small vessel and treated with AngiosculptX. 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.

Overall, 17 real-world patients and 18 lesions (76% male, 66±8 years, 30% smoker, 71% hypertensive, 53% diabetic, 71% hyperlipidemic, 42% LVEF impairment) were enrolled in the study. Clinical presentation was stable angina in 35% and NSTEMI in 65%. Radial access account 88%. Fluoroscopy time was 12±5.7 min. De novo small vessels were treated in 20% (n=3) while ISR in 80% (n=15), (Prior BMS 20%, Sirolimus DES 13%, Everolimus DES 13%, Biolimus/Anfilimus DES 40%, Zotarolimus DES 13%) with a median time to ISR of 5.3 (IQ range 1.1-13.5) years. Total stent length was 23±18 mm, with an overlap spot affected in 13%, and 20% had >1 treatment for ISR. The most frequent artery treated was left anterior descending (56%) followed by right coronary and Circumflex artery (22% each one).

QCA reference diameter of lesions was 2.6±0.5 mm and length 11.2±5.4 mm, with a % stenosis of 64±17. Predilatation/postdilatation was performed in 61/17% respectively. Device diameter was 3±0.3 mm and length 13±4.4 mm, deployed at 15±3 atm, with an inflation time of 30±4.1 sec. The balloon/artery ratio was 0.99±0,02. Crossover was decided on 1 case (5.6%) due to remaining intimal flap, but the success rate (residual stenosis <30%) was 100%. Intracoronary imaging technique was performed in 22% (n=4), all of them OCT. Patients were on DAPT for 3 months. At 3±4 month follow-up, there were no MACES.

CONCLUSIONS

Paclitaxel-coated Scoring Balloon offers a safe and valuable treatment option for ISR and de novo small vessels lesions.

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Increased specialisation of CTO PCI improves success rates but increases procedural complexity: a single-centre experience

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Outcomes for chronic total occlusion (CTO) PCI have improved significantly. Putative reasons for this include improved strategies, devices and expertise. In this observational study we compared the outcomes of CTO PCI conducted in a large non-surgical cardiac centre before and after the establishment of a specialist CTO programme.

METHODS AND RESULTS

The CTO programme was established at Birmingham City Hospital between 2015-2016 with the following key changes to clinical practice: 1) centralisation of CTO procedures into the hands of two specialist operators (Except where JCTO score ? 1), 2) dedicated/ protected CTO lists, 3) avoidance of Ad-Hoc CTO PCI where JCTO score > 1, 4) mandated primary PCI cover during CTO lists, 5) bilateral injections where applicable. Proctoring for CrossBoss and Stingray was completed in April 2016.

The British Cardiovascular Interventional Society (BCIS) database was used and outcomes in patients undergoing CTO PCI evaluated for calendar years of 2014 (n = 32) and 2017 (n = 66). Independent review of procedural angiograms was performed by two experienced operators for JCTO score (evaluated on bilateral injection angiograms where available), technique used (antegrade wire escalation (AWE), antegrade dissection re-entry (ADR) or retrograde dissection re-entry (RDR)), and procedural success (per patient-vessel). Chi-Squared test or Spearman?s Rho (for JCTO) were used to test for statistical significance. Data is expressed as mean or percentage ± Standard Error.

There was very little variation in CTO vessel targeted (right coronary artery: left anterior descending: circumflex) between 2014 and 2017, 53%:25%:12% versus 59%:27%:14% respectively. Lesion complexity as measured by the JCTO score increased between 2014 and 2017 (2.4 ± 0.1 vs. 3.0 ± 0.1, p = 0.01). ADR was used significantly more frequently in 2017 than in 2014 (

CONCLUSIONS

The implementation of a specialist CTO programme with a defined protocol in our centre has led to better success rates in CTO PCI despite increasing lesion complexity. Use of bilateral injections and the spectrum of CTO techniques (e.g. ADR) have concurrently increased. We demonstrate that a paradigm shift from ?all-operators? to more specialised delivery of CTO PCI could be desirable and increase the scope of lesions undertaken with improved procedural success.

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Long-term follow-up after BRS implantation ? Focus on a young real-world population

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

AIMS

To assess the safety and feasibility of bioresorbable scaffold implantation and to identify target vessel failure in a young real-world population at long term follow-up.

METHODS AND RESULTS

From December 2012 to September 2017, 175 patients underwent clinically-driven percutaneous revascularization with one or more bioresorbable scaffold on 259 critical coronary stenosis and entered our prospective monocentric bioresorbable scaffolds registry. Our population (154 males) presented with an average age of 54±11 years, was treated with the placement of 313 bioresorbable scaffolds. Previous myocardial revascularization was performed in 4% of cases. 81% of the patients presented with acute coronary syndrome, specifically with ST-elevation myocardial infarction (39%), non-ST elevation myocardial infarction (31%) and unstable angina (10%). 12 patients with cardiac allograft vasculopathy were enrolled. Intravascular ultrasound and optical coherence tomography were obtained in 36% of patients, according to the cardiologist judgment. Around 42% of the population had multi-vessel disease with complex lesions (80% B2-C according to Ellis classification). At least 50% of lesions were localized on proximal and mid-left anterior descending artery. The majority of the procedures were performed with strict predilation, postdilation and gradual scaffold expansion. Mean number of scaffold implanted for lesion was 1,2±0,5. Mean scaffold diameter was 3,1±0,4 mm and mean total scaffolds length was 26,2 ± 13,8 mm. Device success was achieved in 99,6% of the treated lesions. Systematic clinical follow-up to evaluate clinical target vessel failure was performed. Follow up was obtained in 168 patients (96%) with an average follow-up length of 20,8 ± 12,2 months. Follow-up > 24 months was obtained in 63 patients. Target vessel failure occurred in 15 patients (8,5%). Two in-hospital cardiac death occurred, the first-one in an out of hospital cardiac arrest with prolonged resuscitation maneuvers, the second-one was due to a mechanical complication of acute myocardial infarction. A cardiac death due to heart failure in a patient with CAV was detected during the second month of follow-up. Two non-cardiac deaths, consequent to a major bleeding, were detected at 10 and 13 months follow-up, in patients with dual antiplatelet therapy dismission. Peri-procedural myocardial infarction occurred in two patients (the first-one in a HIV positive patient presenting with non-ST elevation myocardial infarction, while the second-one due to a coronary dissection at the distal edge of the scaffold). 6 cases of target vessel myocardial infarction were reported at 2, 4, 10, 14 and 26 months of follow-up. 5 cases of ischemia driven-target lesion revascularization (no-myocardial infarction-related) were reported at 7, 12, 14, 21 and 31 months-follow-up (two in patients with CAV). In addition, one case of hyper-acute, a very late definite scaffold thrombosis and a probable very late scaffold thrombosis occurred in the total population cohort (1,7% of cases).

CONCLUSIONS

Overall, our data show a low rate of target vessel failure at long-term follow-up in an extremely heterogeneous population of young patients. Bioresorbable vascular scaffold could be considered in selected patients, especially with diffuse coronary artery disease, to avoid full metal jacket and to restore late surgical myocardial

revascularization option.

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Vascular access site and outcomes in 58,870 patients undergoing PCI with a previous history of coronary bypass surgery: results from the British Cardiovascular Interventions Society National database

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

AIMS

Radial access in unselected patients undergoing PCI is associated with lower major bleeding and vascular complications. Patients with previous CABG undergoing subsequent PCI (PCI-CABG) present an access site challenge and therefore use and outcomes of radial access (TRA) in PCI-CABG warrants further investigation.

METHODS AND RESULTS

Using the British Cardiovascular Intervention Society PCI database, access site choice and outcomes of patients undergoing PCI-CABG. Data were analysed from 58,870 PCI-CABG procedures performed in England and Wales between 2005 and 2014. Multivariate logistic regression was used to identify predictors of access site choice. In order to take into account baseline characteristics that might influence outcomes, we performed a propensity score analysis using the inverse probability of treatment weights. Femoral artery (TFA) utilisation fell from 90.8% in 2005 to 57.6% in 2014 ($p<0.001$ for trend) with no differences in the rate of change for left vs. right radial use. During the study period, there was a temporal change in the vessel treated with a significant relative reduction in graft PCI compared to native vessel PCI ($p=0.0125$), and although TFA use for PCI in graft vs. native vessel PCI fell in a parallel fashion, TFA rates for native vessel PCI were consistently lower. In contemporary study years (2012-14), independent predictors of TFA were CTO intervention (OR 4.68 [95% CI 3.35-6.01, $p<0.001$], chronic renal failure (OR 1.46 [1.24-1.71], $p<0.001$), previous PCI attempt (OR 1.22 [1.15-1.39], $p<0.001$), ACS presentation (OR 1.45 [1.32-1.51], $p<0.001$) and female sex (OR 1.18 [1.08-1.39], $p<0.001$. TFA was less common with higher operator volume (OR 0.68 for 3rd tertile vs. 1st tertile [0.56-0.82], $p<0.001$) and in patients treated with chronic anticoagulation (OR 0.57 [0.46-0.67], $p<0.001$). The number of successful lesions and immediate coronary complications rates were similar between groups. Unadjusted outcomes including an access site complication (1.1 vs. 0.3%, $p<0.001$), blood transfusion (0.2% vs. 0.04%, $p<0.001$), major bleeding (1.3 vs. 0.4%, $p<0.001$) and in-hospital death (1.1 vs. 0,6%, $p=0.001$) were more common in the TFA group. After adjustment for baseline differences, whilst arterial complications (OR 3.70 [2.13-6.67], $p<0.001$), transfusion (OR 3.44 [1.01-12.5], $p=0.049$) and major bleeding (OR 3.57 [2.13-5.88], $p<0.001$) remained more common with TFA use, 30-day mortality (OR 0.93 [0.65-1.35], $p=0.709$) and 12-month mortality (OR 1.04 [0.85-1.26], $p=0.711$) were similar. Adjusted length of stay was significantly longer in the TFA cohort compared to the TRA cohort (2.4±11.1 vs. 1.7±104 days, $p<0.001$) with same-day discharge also less likely (24.6 vs. 37.8%, $p<0.001$). These differences were mainly driven by greater reductions in LOS with the elective cohort compared to the ACS cohort.

CONCLUSIONS

In contemporary practice, TFA access remains predominant during PCI-CABG with patient and procedural complexity associated with it use. TFA use was associated with longer length of stay, and higher rates of vascular complications, major bleeding and transfusion compared to TRA. There were no differences in adjusted mortality between access sites.

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Functional evolution of non-culprit lesions in AMI. A quantitative flow ratio study

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Complete revascularization in patients with acute myocardial infarction is recommended. Whether treating non-culprit lesions during primary-PCI improves prognosis or not is unknown. Evolution of functional severity of non-culprit lesions is unsettled. QFR (Quantitative flow ratio) is a novel tool to evaluate the significance stenosis using computational fluids dynamics that has shown a high concordance with FFR.

Aims: to evaluate the evolution of functional significance of non-culprit lesions initially after primary-PCI by QFR.

METHODS AND RESULTS

Consecutive patients admitted for STEMI and with stenosis greater than 50% in non-culprit vessels were included. After PCI of a culprit lesion a second intervention to treat the non-culprit lesions was scheduled during the same admission. In both interventions, projections for the subsequent analysis by QFR were acquired. Two independent observers, certified in the use the software, performed off-line QFR analysis. Good agreement between FFR and QFR was shown in a sample of 10 patients.

A total of 131 lesions in 88 patients were analysed. 86.4% were male. 64.8% were admitted for primary PCI, 25% for routine PCI after fibrinolysis and 10.2% for rescue PCI. The most frequent location of the STEMI was inferior (57.9%) followed by anterior (37.5%). 44.3% of patients presented TIMI flow 0 in the culprit artery and 4.5% shock. The left anterior descending artery was the most frequent non-culprit artery affected (50%). Diameter and area stenosis were significantly different in both procedures (DS%: 58.92±12.03% vs 51.15±10.64,

CONCLUSIONS

Functional assessment by using QFR in non-culprit lesions after an acute myocardial infarction demonstrated a reduction in severity after the acute phase. About half of the stenosis is no longer significant. These results suggest that a two-procedure strategy could prevent from non-culprit vessel revascularization procedures of uncertain benefit. A QFR value over 0.82 at primary-PCI identifies non-culprit lesions which revascularization could be unnecessary. Further studies are needed to test this hypothesis.

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Long-term follow-up (>3.8 years) after stent graft placement for access-site and access-related vascular injury during TAVI ? The Bonn-Copenhagen experience

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal

AIMS

Stent graft placement is a safe and effective treatment option for vascular complications in the context of transcatheter aortic valve implantation (TAVI). We aimed to provide long-term angiographic follow-up of stent grafts used for this indication.

METHODS AND RESULTS

In this analysis, we included 71 patients (64.8% female, log. EuroScore of 14.7 ± 6.8 %) who had undergone TAVI for severe symptomatic aortic stenosis at our two centers between March 2010 and October 2015 in whom Viabahn or Fluency stent grafts had been implanted for an access-site or access-related vascular injury (ASARVI). Hereby, stent grafts were implanted due to access-site bleeding complications (83.1%) into the common femoral artery (97.1%) in the majority of patients. Duplex sonography was available in all patients and was performed 3.8 ± 1.3 years after TAVI. Ultrasound revealed tri- or biphasic flow patterns in 16.9% and 77.6% respectively and excellent stent graft patency without signs of relevant stent graft stenosis in any patient (mean peak velocity ratio 1.0 ± 0.2). In 5.6% of patients, pseudo-aneurysms or endoleaks were diagnosed. Additional imaging including fluoroscopy and/or CT was available in 36.6% and revealed stent fractures in 2.8%.

CONCLUSIONS

Both the Viabahn and the Fluency stent graft provide excellent long-term function when implanted in the context of TAVI-associated access-site and access-related vascular injury.

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Twelve-month outcomes of patients unsuitable for prolonged DAPT presenting with an ACS and treated with polymer-free biolimus A9 DES

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

AIMS

Prolonged DAPT is undesirable in certain patients. The biolimus-A9 drug-coated stent (BA9-DCS) has a rapid drug-elution profile allowing shortened DAPT. The study aim was to define the 12-month outcomes of patients deemed unsuitable for prolonged DAPT presenting with an ACS and treated with a polymer-free Biolimus A9 drug-coated stent (PCI-DCS).

METHODS AND RESULTS

The demographics, procedural data and clinical outcomes for 505 patients presenting with an ACS to three UK centres between January 2015 and March 2016 and treated with a BA9-DCS stent (PCI-DCS) were collected. Implantation was at the discretion of the treating interventional cardiologist and was most frequently for high bleeding risk associated with prolonged DAPT. PCI-DCS patients were compared to consecutive unselected ACS patients treated in the same period with drug-eluting stents (PCI-DES, 71.1% everolimus-eluting, 26.8% biolimus-eluting and 2.1% zotaralimus-eluting). We performed propensity score analysis in order to balance for baseline differences. The PCI-DCS cohort had a mean Mehran bleed risk score of 21.5±7.7 vs. 15.9±7.7 for the PCI-DES group (

CONCLUSIONS

The outcomes of patients treated with polymer-free BA9 drug-coated stent who present with an ACS and who were deemed unsuitable for prolonged DAPT are encouraging. Further studies are warranted.

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Activity tracking devices as novel and robust monitoring strategy for assessing improvements in heart failure patients after percutaneous valve repair

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

AIMS

Percutaneous repair of tricuspid and mitral regurgitation is an interventional strategy to improve the quality of life in patients with chronic heart failure. However, an objective assessment of the parameters representing heart failure such as daily physical activity and quality of life is currently challenging. In this study, we aim to assess novel monitoring strategies with the innovative utility of activity tracking devices (ATDs).

METHODS AND RESULTS

We prospectively analyzed 35 patients with percutaneous repair of the tricuspid and/or mitral valve. Prior intervention, all patients suffered from severe tricuspid or mitral regurgitation (grade 3 or 4). The physical activity reflecting the quality of life was monitored using the Minnesota Living With Heart Failure Questionnaire (MLHFQ) and the 6-minute walk test (6MWT). Innovatively, we utilized ATDs (Fitbit, San Francisco, USA) and tracked the physical activity at baseline and follow-up (after a mean of 2.6 months). ATDs proved to have a good adherence to the monitored patients and recorded the steps per day over a mean of 6.3 (baseline) and 6.9 days (follow-up). After percutaneous valve repair we recorded a mean improvement of 1 NYHA category, 644 pg/ml in pro-BNP level, 12 points in MLHFQ, 65 meters in 6MWT and 1043 steps per day monitored by ATDs. Overall improvements were categorized in moderate (+1 NYHA category) and good (+2 NYHA category) improvement from baseline to follow-up. ATDs represented higher relative improvements compared to the 6MWT in both categories. An improvement of 2 NYHA categories was connected to a relative increase of 46% steps per day recorded by ATDs and only 22% meters in 6MWT. Interestingly, the change of MLHFQ and 6MWT between baseline and follow-up showed a low correlation to the change of pro-BNP (pearsons correlation coefficient of 0.07 for MLHFQ and 0.19 for 6MWT). In contrast, ATDs demonstrated a more precise correlation to pro-BNP (pearsons correlation coefficient of 0.77).

CONCLUSIONS

ATD monitoring of one-week physical activity appears to be more representative and less influenced by co-factors for the measurement of clinical improvement after percutaneous repair of tricuspid or mitral valve repair in heart failure patients compared to MLHFQ or snapshot evaluation by 6MWT. In summary, we introduce ATDs as novel and robust monitoring strategy for the assessment of physical activity in patients with chronic heart failure.

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In vitro comparison of stability, sealing and re-sheathing induced deformation of two LAA occlusion systems

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

AIMS

The aim of this study was to introduce in-vitro bench tests of LAA occlusion (LAAo) devices regarding stability and sealing capacity.

METHODS AND RESULTS

Two LAA occlusion devices, namely the WATCHMAN? and the Occlutech® occluder, of three different sizes underwent testing for tug force and sealing capacity in a novel dedicated in-vitro setup. At baseline, tug force of the WATCHMAN? devices was significantly higher when compared to Occlutech® occluders across the entire sizing range of all devices (maximum tug force: 2.6 ± 0.1 N for WATCHMAN? vs. 1.8 ± 0.1 N for the Occlutech®, p

CONCLUSIONS

In-vitro, the WATCHMAN? LAA occluder series showed progressive deformation and increased peridevice leakage after resheathing presumably as a result of diameter reduction. Most likely due to its anchoring mechanism, the stability of the WATCHMAN was not impaired by resheathing and was significantly higher than that of the Occlutech® device.

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Coronary calcium score in negative myocardial perfusion imaging - Does it matter? A single-centre experience

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

AIMS

Coronary calcium score (CCS) and Single-Photon Emission Computed Tomography Myocardial Perfusion Imaging (SPECT MPI) provide independent and complementary prognostic information in patients at risk of cardiac events. We aimed to establish the relationship between CCS and severity of Coronary Artery Disease (CAD) on invasive coronary angiography (ICA) in patients with a negative MPI.

METHODS AND RESULTS

We retrospectively analysed symptomatic patients who underwent an adenosine stress 99mTc Tetrofosmin MPI and CCS in our centre between January 2012 and January 2017. Receiver Operating Curve (ROC) was computed to discriminate the effect of the CCS on the severity of visualised CAD on ICA. In addition, correlation between CCS quartiles and CAD severity was assessed by Spearman?s rho.

596 patients had a negative (339 AU had a sensitivity of 65.12% and a specificity of 62.86% (Youden Index J=0.2797) in predicting moderate/severe CAD. Spearman?s rho demonstrated statistically significant relationship between calcium quartiles and CAD severity (rs [78] =0.344, p=0.002).

CONCLUSIONS

We have demonstrated a significant relationship between CCS and severity in symptomatic patients with a negative MPI. The addition of CCS in this cohort of patients can lead to identification of high risk cases, guiding decisions regarding invasive investigation and facilitating early intervention.

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Clinical outcomes of bioresorbable vs. durable polymer-coated everolimus eluting stents in ACS

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

AIMS

Objectives: to evaluate the performance of new-generation, SYNERGY everolimus-eluting stents (S-EES) as compared to XIENCE everolimus-eluting stents (X-EES) with a durable polymer coating in acute coronary syndrome (ACS).

METHODS AND RESULTS

Methods: A retrospective, case-control 1:1 registry including patients with ACS treated with S-EES (group 1) or X-EES (group 2). The primary outcome was major adverse cardiac events (MACE), defined as the composite of all-cause death, myocardial infarction (MI), and target lesion revascularisation (TLR), at one year.

Results: The study included 100 patients in each group. The baseline patient and lesion characteristics were similar in the 2 groups apart from the age that was higher in the S-EES than in the X-EES group, (Age 68 vs 64 , p=0,01 and female gender 25% in each group). The most frequent artery treated was Left Anterior Descending (50%), followed by Right Coronary Artery 5 (30%). There were no differences in the procedural parameters. Bifurcation lesions account 18%, calcified 33% and 27% were CTO.

Predilatation was performed in 69%, Debulking was performed in 36%. Mean stent length was 25,9 +/-11,4 mm . The number of stents per lesion was 1.4±0.3, with overlapped stents in 59%.

At 12-months follow-up, MACE rates did not differ between the S-EES and X-EES groups (13% vs. 9%, p=0.24, HR 1.04, CI: 0.72-1.48) this trend toward more events in the S-EES could be explained in part by presenting greater age, death for any cause did not differ between the S-EES and X-EES groups (8% vs 8%, p=0,59), cardiovascular death did not differ between the S-EES and X-EES groups (5% vs 7%, p=0,28). There were 2 stent thrombosis (ST) one in each group.

CONCLUSIONS

Conclusions: New-generation S-EES with a bioresorbable polymer coating appear to be safe and effective as compared to X-EES in ACS.

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Does the routine use of an iso-osmolar contrast medium reduce the occurrence of acute kidney injury following PCI for STEMI?

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Temporal changes in baseline risk and subsequent contrast-induced acute kidney injury (CI-AKI) incidence following primary percutaneous coronary intervention (PPCI) are poorly defined. Additionally, the benefits of iso-osmolar contrast media (IOCM)compared to low osmolar CM (LOCM) are uncertain.

METHODS AND RESULTS

Using data from a United Kingdom regional PPCI service, temporal changes between 2012 and 2015 in Mehran CIN risk score and annual incidence of CI-AKI were studied. In late 2013 the PPCI cath lab CM protocol changed allowing a comparison of the incidence of CI-AKI between routine LOCM use (2012-13) and routine IOCM use (2013-15). The conventional definitions were used to define CI-AKI i.e. ?25% or absolute ? 44µmol/l increase in serum creatinine from baseline value within the first 48-72 hours following PPCI. We performed multivariate logistic regression to identify the predictors of CI-AKI. We also performed a propensity score analysis using the inverse probability of treatment weights to adjust CI-AKI outcomes for baseline differences between the two CM cohorts. During the study period, 208/1,310 patients experienced CI-AKI (15.9%). Only the trends for diabetes mellitus (p=0.015 for the increase in incidence) and contrast volume (p<0.001 for the decrease in annual volume) changed significantly during the study period. However, the overall Mehran score did not change during the study period but despite this there was a significant increase in the incidence of CI-AKI in later study years (p<0.001 for trend) when IOCM was used. Factors independently associated with CI-AKI were IOCM use (OR 1.96, [1.39-2.75]), age/year (OR 1.02, [1.01-1.04]), baseline creatinine/unit increase (OR 1.006, [1.003-1.01]) and contrast volume/ml (OR 1.002, [1.001-1.004]). The baseline characteristics of patients treated using IOCM (n=783) vs. LOCM (n=527) were well matched with only diabetes being more frequent in the IOCM group (16.6% vs. 12.0%, p=0.020). Baseline renal function was similar (creatinine 85.9µmol/L for IOCM vs. 84.9µmol/L for LCOM p=0.336), as was baseline Mehran score (6.6 vs. 6.9 respectively, p=0.173). CI-AKI occurred in 19.2% of patients receiving ICOM and in 11.2% of patients receiving LOCM (p<0.001). Although the overall rates of CI-AKI using the KDIGO criteria were lower, the relative increase in patients treated with Iodixanol remained similar. After adjustment for minor baseline differences between CM cohorts, use of IOCM remained independently associated with the development CI-AKI (OR 1.98 [1.339-2.774], p<0.001) with consistency across all sub-groups including age, gender, shock, contrast volume, baseline renal function and diabetes. The adjusted in-hospital mortality was significantly increased with IOCM compared to LOCM (OR 3.03, [1.313-6.994], p=0.009). In patients without CI-AKI, there was no significant difference in the rate of in-hospital mortality between the two CM groups (2.1 vs. 1.6% respectively, p=0.505).

CONCLUSIONS

Although baseline Mehran risk was stable during the study period, CI-AKI occurred more frequently with protocolised IOCM use. IOCM use was independently associated with increased incidence of CI-AKI and in-

hospital mortality.

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Impact of left ventricular outflow tract calcification on pacemaker implantation after TAVR with second-generation devices

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

AIMS

Left ventricular outflow tract calcification (LVOT-CA) has been reported in 30% to 40% of patients undergoing TAVR and has been associated to the risk of annular rupture and significant paravalvular leak with first generation devices, furthermore, it has been showed that LVOT-CA has a predictive role in permanent pacemaker implantation (PPI) in patients receiving Edwards Sapien 3 device. The aim of this study is to evaluate the impact of LVOT-CA localization and extension on PPI risk after TAVR with second generation devices.

METHODS AND RESULTS

This is a single center retrospective study including all consecutive patients which underwent transfemoral TAVR with current generation devices (Edwards Sapien 3, Boston Scientific Lotus, Medtronic Corevalve Evolut R, St Jude Portico, Accurate Neo Symetis) at San Raffaele Hospital, Milan, from January 2014 to June 2017. Patients with any kind of previous surgery involving the LVOT, the aortic valve complex and the ascending aorta (except for CABG) or a previous TAVR were excluded from the study, as well as patients without pre-operative CT scan and patients with bicuspid aortic stenosis. The localization and extension of LVOT-CA were evaluated at CT scan: LVOT regions were named accordingly to the overlying coronary cusps (left-coronary cusp, right-coronary cusp and non-coronary cusp). The final analysis included 377 patients: 94 patients (25%) were treated with Sapien 3, 81 (21.5%) were treated with Lotus, 127 (33.7%) were treated with EvolutR, 44 (11.7%) were treated with Portico and 30 (7.9%) were treated with Symetis.

LVOT-CA was present in 133 patients (35.3% of the total population), mostly isolated in the Non-Coronary Cusp (NCC) and Left Coronary Cusp (LCC).

Among the overall population included in our study, 31 patients already had a permanent pacemaker, thus they have not been included in the analysis of PPI predictors. Patients with LVOT-CA presented significantly higher rate of PPI after the procedure (32.0% vs.19.2%, p=0.009).

Patients with PPI were more likely to have received a Lotus prosthesis. The incidence of pre-operative right bundle branch block (RBBB) and first degree atrio-ventricular (AV) block was significantly higher in patient requiring PPI. Furthermore, patients who received PPI presented significantly higher incidence of LVOT-CA (47.6% vs. 31.5%, p=0.007), interestingly LVOT-CA of the NCC was significantly higher in the same group (31.0% vs. 15.2%, p=0.001). After multivariable analysis, the strongest independent predictor of PPI was pre-operative RBBB (OR 4.7, CI 2.07?10.69,

CONCLUSIONS

The prevalence of LVOT-CA in a TAVR cohort treated with current generation devices was 35.3%. LVOT-CA in the NCC appears to be an independent predictor of new PPI after TAVR. This finding suggests a strong correlation between NCC LVOT-CA and PPI: this should be explained by the proximity of the NCC with the conductive system of the heart, particularly the AV node and the left bundle branch.

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Intra-aortic balloon counterpulsation pump in heart failure patients during MitraClip implantation - a patient series

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

AIMS

MitraClip implantation emerged as a favourable treatment option especially for patients with prohibitive surgical risk due to severe reduction of left ventricular function. The use of intra-aortic balloon counterpulsation pump extended the spectrum of percutaneous coronary interventions, to complex high-risk procedures with acceptable outcome. We analyse immediate and 30-day results after percutaneous mitral valve repair using an IABP as circulatory support during MitraClip implantation

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METHODS AND RESULTS

Since 2012 17 patients of 557 patients (3%) at our centre received an IABP during MitraClip implantation procedure. The indication for prophylactic IABP implantation was a severely reduced left ventricular function (22.8±8.3%) and haemodynamic impairment (cardiac index 1.9±0.4l/min/m²). The mean age of the predominantly male population was 66.8±12.1 years, mean Logistic EuroSCORE was 6.8±5.6 and mean ASA Score was 3.8±0.4. The mean NT-pro BNP at baseline was 6616.1±4748 pg/ml, and the mean New York Heart Association (NYHA) functional class was 3.5±0.5. Grade of MR before Clip procedure was 3.4±0.5. All procedures were carried out successfully, with 1.2±0.4 implanted clips and achieving a sufficient MR reduction (grade of MR after Clip 1.5±0.5). Length of in-hospital stay was 11.7±14 (3-48) days. No peri- or postprocedural death and no periprocedural resuscitation were observed. All 17 patients had an event-free 30-day follow-up. One patient remained hospitalized due to refractory heart failure until the end of follow-up and died after 48 days.

CONCLUSIONS

Implantation of an IABP during MitraClip procedure may provide additional safety and improve procedural outcomes in the setting of high-risk percutaneous mitral valve repair.

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The relationship between endothelial dysfunction assessed by digital pletysmography and discrepancies between FFR and iFR measurements

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

We aimed to test the hypothesis that one of the reasons for discrepancies between FFR and iFR could be an endothelial dysfunction causing a low response to adenosine.

METHODS AND RESULTS

We investigated patients who underwent a clinically indicated assessment of hemodynamic significance of coronary arteries, with stenosis in a range of 40-70% (by visual estimation of angiography), together with both FFR and iFR for stable angina in our institution. We included all consecutive patients with both FFR and iFR in one native coronary artery without any previous intervention only. We included 116 patients. Out of those, 17 patients (14.7%) had FFR negative (>0.8) and iFR positive (<0.9) ? (group A), and 20 patients (17.2%) had FFR positive (? 0.8) and iFR negative (?0.9) ? (group B). The rest of the patients had concordant FFR/iFR results ? (group C). We did not find any significant difference in RHI among these three groups. RHI indexes were 1.59 ± 0.57 (A), 1.67 ± 0.76 (B) and 1.51 ± 0.44 (C). Active smoking was the most significant difference between both types of disagreement (A or B), and patients in group C (p=0.04 and p=0.002 resp.). Females more frequently tended to have type A disagreement compared to males (p=0.05). Patients with a lower level of hemoglobin (p=0.02) and a higher level of creatinine (p=0.04) more frequently had type A discrepancy compared to group C.

CONCLUSIONS

The presence of endothelial dysfunction assessed by digital pletysmography cannot explain discrepancies between FFR and iFR. A predictor of both A and B disagreements is active smoking.

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Primary angioplasty in catastrophic acute left main coronary occlusion: a multicentre registry

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

AIMS

This study aim to determine the incidence, clinical features, and outcome in totally occluded left main coronary artery (LMCA) patients referred to primary angioplasty.

METHODS AND RESULTS

Since April 2003 to December 2017 emergent primary angioplasty was performed in 1701 patients at the 3 participating centers and 17 of those patients had an acute totally occlusion in the LMCA(0.01%)

The mean age was 61.4±10, 76.5%(13/17) were males, 29.5%(5/16) had documented hyperlipidemia, 59%(10/16) prior tobacco abuse and 12%(2/17) diabetes.

The predominant symptom at presentation was dyspnea in 65% of cases(11/17), chest pain in 17.5% and cardiac arrest in 17.5%. Twelve patients(70.5%) presented in cardiogenic shock, 3 patients(17.5 %) had a Killip score 3, and 2 patients(12%) a Killip score 2. Six patients(35%) required orotracheal intubation, intra-aortic balloon pump was deployed in 5 patients(29.5%) and ECMO in one patient.

Eight patients(47%) developed malignant ventricular tachyarrhythmias and required cardioversion/defibrillation. Twelve patients(70.5%) suffered a cardiac arrest and required cardiopulmonary resuscitation.

GP IIb/IIIa inhibitors were used in 70.5%(12/17) and intravenous vasoactive drugs in 88% of procedures(15/17), in 2 case intracoronary route was used.

Cardiac catheterization was performed by femoral approach in 76.5%(13/17), the rest were by radial approach(23.5%). Collateral circulation (CC) by right coronary artery was not angiographically assessed before LMCA PCI in 53%(9/17), 23.5%(4/17) had a RENTROP score of 0, one patient, with a Killip score of two, had a RENTROP 3 and in the rest (3/17) the information about CC was lost. All the patients had right coronary dominance.

A stent was deployed in 59%(10/17) of procedures, the mean stent diameter was 3.6±0.2 mm. In 70% of cases (7/10) a drug eluting stents was deployed, a bare metal stents in 2 cases(20%) and in the well-collateralized patient, a bioabsorbible stent was implanted.

LMCA angioplasty success rate was 70.5%(12/17) and a final TIMI flow of 3 was achieved in 47% of procedures(8/17). Mean contrast volume was 251±223 ml. An intracoronary technique was performed in 3 cases(17.5%).

Mean peak creatine kinase value was 11379±1242.

Five patients(29.5%) died in the catheterization laboratory during the procedure and 2(12%) died in the following 24 hours due to pump failure. Two patients died in the hospital on the ninth and sixteenth days due to cardiogenic shock and nosocomial sepsis. Total in hospital mortality rate was 53%. Another patient died suddenly on the day 19th after discharge. Therefore 7 patients (41%) survived at 30 days follow-up.

One of the survivors was admitted to hospital due to heart failure on the day 21st after discharge.

The well-collateralized patient (RENTROP 3) was asymptomatic and free of event at 38 month follow up

CONCLUSIONS

Clinical presentation of LMCA occlusion patients referred to primary angioplasty is catastrophic, most of them presented in cardiogenic shock and required CPR maneuvers.

All of our patients had a right coronary dominance, suggesting that complete total occlusion and left dominance could be incompatible with life.

Although early developed CC was confirmed just in one patient, clinical presentation and follow-up compare to the rest of patients, suggests that CC may play an important role. Despite the high in-hospital mortality we found that primary LMCA occlusion angioplasty is feasible and it may save lives in this clinical setting

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Atrial fibrillation predicts long-term outcome after transcatheter edge-to-edge mitral valve repair by MitraClip implantation

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

AIMS

Atrial fibrillation is common in patients with mitral regurgitation and negatively impacts on clinical outcome of patients with valvular heart disease. We aimed to evaluate the impact of pre-procedural atrial fibrillation on long-term clinical outcomes of patients with mitral regurgitationundergoing transcatheter edge-to-edge mitral valve repair by MitraClip implantation.

METHODS AND RESULTS

We analysed 355 consecutive patients with and without atrial fibrillation with symptomatic, severe mitral regurgitation and inoperability or high surgical risk undergoing MitraClip implantation in a 3-year follow-up. In patients with pre-procedural atrial fibrillation undergoing MitraClip implantation, we found advanced age, higher baseline NT-pro-BNP levels, increased left atrial diameter, and higher rate of severe tricuspid regurgitation, compared to patients with sinus rhythm. In the 3-year follow-up after MitraClip implantation, mortality and major adverse cardiovascular and cerebral events (MACCE) occur significantly more often in patients with atrial fibrillation, compared to patients without atrial fibrillation. Multivariate regression analysis confirmed atrial fibrillation (hazard ratio 1.66, 95% confidence interval 1.03 - 2.68, p =0.036) as independent predictor for 3-year-mortality after MitraClip implantation.

CONCLUSIONS

Atrial fibrillation is an independent predictor for long-term mortality after MitraClip implantation. We demonstrate association of atrial fibrillation with mortality and MACCE in the long-term follow-up of patients undergoing MitraClip implantation.

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Procedural and clinical results of the new MitraClip NT after percutaneous edge-to-edge repair of mitral valve regurgitation

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

AIMS

The MitraClip® NT as an updated version aim to facilitate improved maneuvering of the guide catheter and more efficient leaflet capture due to technical improvements of the delivery system and clip material. We evaluate procedural results and 12 -month clinical outcomes of the new MitraClip® NT device and compare them with the previous MitraClip®.

METHODS AND RESULTS

We analyzed a total population of 231 patients from our Ulm - Transcatheter Mitral Valve Repair registry. To adjust for differences of baseline characteristics a propensity-score matching was performed (N=142). 30-day endpoints were analyzed in accordance with the Mitral Valve Academic Research Consortium (MVARC). For both devices 12-month clinical results (MACCE, mortality, and heart failure rehospitalization) were evaluated. Acute technical success was achieved in 100% with both device groups. Device, procedure and fluoroscopy time were comparable in both treatment groups. In-hospital mortality was 2.8% in the MitraClip® NT group and 4.2% in the MitraClip® group (p=0.65). After 30 days single-leaflet clip detachment was observed in 2.8% in the MitraClip® NT group compared to 1.4% in the MitraClip® group (p=0.56). Mitral regurgitation was reduced to the same extent in both treatment groups (1.6±0.6 in MitraClip® vs. 1.6±0.5 in MitraClip® NT group, p=0.57) with comparable rates of recurrent moderate to severe mitral regurgitation after 30 days and during 12-month follow-up. Clinical results up to 12 months and improvement of New York Heart Association functional class were comparable in both device groups (3.1±0.7 to 2.1±0.9 vs. 3.2±0.6 to 2.1±0.9, p=0.75).

CONCLUSIONS

The new MitraClip® NT presents itself as efficacious and safe deivce, but failed to prove superiority compared to the original MitraClip® in terms of procedural and clinical results.

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Procedural and clinical benefits of selective thrombus aspiration in AMI treated with primary PCI. Insights from the TAPER registry

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

After the results of some randomised studies, routine thrombus aspiration (TA) has been left in the background for not improving the prognosis of patients with STEMI and even supposedly increasing their complications (especially the rate of stroke). However, this technique can facilitate primary PCI (pPCI) by improving its results. Aim: to assess the advantages of TA during pPCI, its safety and benefits after one year of follow-up.

METHODS AND RESULTS

The TAPER registry (efficacy and safety of selective Thrombus Aspiration in Real clinical Practice) retrospectively included patients with STEMI treated with pPCI in four high volume centres of different countries (Spain, The Netherlands, France and Chile). A total of 298 patients (78% males, 63.7 ± 12.3 years) treated during 2016 were analysed. Procedures were performed by 18 interventional cardiologists using TA at their discretion. 17% were diabetic, 43% presented hypertension and 29% dyslipidaemia. Mean body mass index was 27.6 ± 4.7 Kg/m2 and mean LVEF of 48 ± 2%. Radial approach was performed in 55% of cases. The culprit artery was the left main in 2% of cases, left anterior descending in 48%, left circumflex in 14%, right coronary artery in 35% and saphenous vein graft in 0.3%. The rate of multivessel disease was 48%. During the procedure, unfractionated heparin was used in 99% of the cases and a glycoprotein IIb/IIIa inhibitor in 26%. Initial TIMI flow grade was 0-1 in 74%. TIMI thrombus grade was ?3 in 61% of cases. TA was attempted in 43% of the cases, 90% as an initial strategy and 10% as rescue therapy, and was successfully performed in 94% cases. TA was not associated with a higher rate of procedural complications (no-TA group: 10.8% vs TA group: 12.5%, p=0.64). When TA was performed, a significant improvement of the TIMI flow grade of 2.1 points [CI 95% (1.9-2.3),

CONCLUSIONS

TA is frequently used in current clinical practice with high success rate and low associated complications. The technique reduces significantly the angiographic thrombus grade and improves coronary TIMI flow, allowing direct stenting more frequently. At one-year follow up, similar rate of adverse events was observed in patients with or without TA.

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Crusade score as a predictor of one-year major bleeding events in North African patients with NSTE-ACS

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

AIMS

To examine the value of CRUSADE bleeding score in predicting bleeding events in our local patients with NSTE-ACS in an Algerian population.

METHODS AND RESULTS

Our study included 296 patients with NSTE-ACS. They underwent history and clinical examination, 12-lead electrocardiography, echocardiography, coronarography, troponin T us, hematocrit value, estimated glomerular filtration rate (eGFR), application of CRUSADE score, and a one year follow-up with documentations of events. Patients were classified into two groups: Group I: patients with major bleeding, and Group II: patients without major bleeding.

Sixteen (5.4%) patients had a major bleeding events, seven (2.4%) during the initial in-hospital period and nine (3%) during the follow-up after discharge.

Patients with major bleeding events were significantly older (69±12 vs.61±12 years, p=0.024), with more diabetic (9.3% vs. 1.9%, p=0.008), lower hematocrit (34.1±5.3 % vs.40.2±5.2 %, p<0.0001), lower eGFR (65.6±32.4 ml/min vs.85.2±36.4 ml/min, p=0.036), and higher CRUSADE risk score.

Crusade score measurement in patients with major bleeding was significantly higher than in those without coronary artery disease (36.9 ± 14.1 vs. 27.1 ± 13.1, p =0.004).CRUSADE bleeding score was the strongest predictor of major bleeding. Sensitivity of CRUSADE score ?38 in prediction of major bleeding in the whole study group was 62.5%, specificity was 79.6%, and overall accuracy was 70.0%.

CONCLUSIONS

CRUSADE score is a good predictor for one-year major bleeding events in Algerian patients with NSTE-ACS.

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Transcatheter aortic valve-in-valve treatment of degenerative mitroflow bioprosthesis: a single-centre experience

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

AIMS

The aim of this study was to evaluate outcomes of valve in valve (ViV) TAVI for degenerative mitroflow bioprosthesis.

METHODS AND RESULTS

Between July 2012 to September 2017, 41 patients with the mitroflow bioprosthesis underwent ViV TAVI. Surgical valve size ranged between 19mm to 25 mm (19 mm ? 9.8%, 21 mm ? 43.9%, 22 mm ? 2.4%, 23 mm ? 34.1% and 25 mm 9.8%). Mean age of patients was 79.8+/-6.5, and 58.5% were males. 3 patients had critical preoperative status requiring urgent ViV intervention. The procedure was performed transfemorally in 95.1% patients and 37.5% were done under general anaesthesia. Successful TAVI was performed in 40 (97.6%) patients (Corevalve/Evolut 23 mm in 35 patients, and 26 mm in 5 patients). Coronary protection was used in 2 (5%) patients. 1 patient had transient coronary obstruction during balloon valvuloplasty due to which the valve was not deployed. TAVI resulted in a significant reduction in mean aortic valve gradient (41.3+/-19.3 vs. 19.0+/-11.6, p< 0.0001) with symptomatic improvement. As per the VARC2 criteria, 2 patients had a major bleed requiring transfusion, 1 patient developed acute kidney injury requiring hemodialysis and 1 patient died of hospital acquired pneumonia 28 days post procedure. 30 days survival was 97.6% and 6 month survival 92.7%.

CONCLUSIONS

ViV TAVI in degenerated mitroflow bioprosthesis can be safely performed. Significant improvement in trans-valvular haemodynamics is seen in all the valve sizes treated.

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Development of a dried blood spot based measurement of antihypertensive drug levels to assess treatment adherence

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

AIMS

Resistant hypertension is a common health issue leading to suboptimal cardiovascular prevention. A major part of these patients have a problem with adherence to their medication, explaining their assumed resistance to therapy. Proving and improving adherence is of major importance to reduce disease burden and costs. We aimed to develop a method using UPLC-MS/MS to measure drug levels of antihypertensive drugs in a dried blood spot (DBS).

METHODS AND RESULTS

A single center, cross-sectional observational study that will assess drug levels of antihypertensive drugs using UPLC-MS/MS in DBS, which will be obtained by a finger prick. The following antihypertensive drugs and [active metabolites] were measured: enalapril [enalaprilate], perindopril [perindoprilate], losartan [losartan carboxylic acid], valsartan, hydrochlorothiazide, spironolactone [canrenon], amlodipine and nifedipine. For clinical validation, we measured peak and trough levels in both DBS and plasma from patients assumed to be adherent (based on blood pressure below target value).

Samples were collected between October 2016 and March 2017, a total of 52 patients were included. Peak and trough levels for all drugs varied considerably between patients. For instance trough levels of valsartan when dosed 320 mg qd were in a range of 283-1138 µg/l. Trough levels in plasma were below LLOQ (lower limit of quantification) for spironolactone, enalapril, perindopril and hydrochlorothiazide but for the first three the levels of the active metabolites were above LLOQ. LLOQs were on average 10 times higher for the DBS methods than for plasma measurement. However, using DBS, drug levels or an active metabolite could be detected at least 24 hours (hydrochlorothiazide: six hours, amlodipine and nifedipine additional studies ongoing) after intake above the lower limit of detection (LLOD) which is most important for assessing (non-) adherence at a random time point.

CONCLUSIONS

Therapeutic drug monitoring (TDM) using DBS can be a convenient method to monitor drug adherence. The advantage of DBS above plasma measurements is that sampling can take place at the exact moment the increased blood pressure is measured. This diminishes the risk of white coat adherence as seen in case of an additional visit to the blood sampling unit. When more exact analyses of drug levels are desired plasma measurement is more accurate at lower concentrations.

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Feasibility and safety of sheathless radial access for coronary interventions

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

AIMS

The coronary intervention by radial access, with multiple benefits with respect to the femoral, is hampered in patients with decreased arterial caliber and requirement of sheath / catheters of greater diameter. The objective of this work was to evaluate the feasibility and safety of performing coronary interventions by radial access without sheath and using standard catheters, decreasing the required diameter of the artery to achieve a successful vascular access.

METHODS AND RESULTS

A total of 82 coronary procedures were performed in 82 patients from January 2016 to October 2017. The patients were chosen at random at discretion of the physician and the indications for the procedure were heart valve disease, NSTEMI and stable coronary artery disease. Patients with STEMI, cardiogenic shock and negative Allen test were excluded.

The feasibility of the method was evaluated through the possibility of successfully performing the diagnostic procedure (3 French) and / or therapeutic (4 and 5 French) by a sheathless system. The safety of the method was determined according to the appearance of complications related to access: severe vasospasm, radial artery occlusion, hematoma greater than 5 centimeters. In the cases of PCI, it was performed with a telescoped guide catheter technique (5 French diagnostic Multipurpose catheter inside the 6 or 7 French guide catheter).

In 33 (40.2%) patients coronary angiography alone was performed, in 18 patients (21.9%) scheduled PCI and in the remaining 31 coronary angiography and PCI in the same procedure. Mean age was 65±10.5 years, 64.6% were men, and mean body mass index was 26.9±5.1. 70% of the patientes were hypertensive, 58.5% had dyslipidemia, 36.5% diabetes and 34% were current smoker. Among patients, 42.6% had previous history of PCI, 13.4% of CABG and 10% of heart valve disease. Right radial access was used in 85.3% of patients. 82.9% of the procedures were scheduled and the remaining were emergencies.

Of the total diagnostic procedures, 96.9% were successful. A 90% of them were performed with a Tiger catheter. In 1 patient, the sheath had to be placed due to difficulty in advancing the catheter. There were two episodes of severe vasospasm (6%).

Of the patients in whom coronary angiography and PCI was performed (n = 31), in only one case sheath should be placed. The success of the PCI was 96.8% and only one patient presented vasospasm.

In those who underwent delayed PCI (n = 18) the success was 100%, without complications. Two patients had hematoma less than 5 centimeters.

Of the total PCI, 74% was performed with a 6 French catheter telescope on a multipurpose catheter 5 French (insertion size 4 French). Drug eluting stents were used in all cases, achieving complete revascularization in 60%.

Follow-up was performed at 7 and 30 days by pulse palpation / plethysmography curve to all patients and was confirmed by arterial Doppler ultrasound to 50 patients (60%) with no evidence of radial artery occlusion.

CONCLUSIONS

The coronary intervention by radial access without sheath is a feasible procedure to perform and is associated with a low rate of major complications. The use of this technique could be considered in patients who carry a high risk of vasospasm or a history of complications of this access in previous procedures.

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Renal sympathetic denervation as a potential treatment strategy in patients with vasospastic angina

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

AIMS

Although sympathetic hyperactivity has been linked to the disease, the exact pathophysiology of vasospastic angina (VSA) is still poorly understood. The purpose of the present study was to assess if renal sympathetic denervation (RDN) reduces cardiac sympathetic activity with a subsequent beneficial effect on angina relief in patients with refractory VSA.

METHODS AND RESULTS

A total of 10 patients with refractory VSA underwent RDN using a dedicated circumferential ultrasound balloon catheter. Cardiac sympathetic nerve activity was assessed at baseline and 6 months using iodine-123 metaiodobezylguanidine (MIBG) imaging heart to mediastinum ratio (HMR) and washout rates. The Seattle Angina questionnaire (SAQ) was used to assess physical limitations caused by angina, frequency of angina and the degree to which the disease impacts quality of life at baseline, 1, 3, 6 months and 12 months.

Mean age was 57 ± 11 years, 90% were male and 80% were in CCS class III or IV. Average 24h ambulatory blood pressure and heart rate at baseline were 121 ± 16mmHg and 62 ± 7,5 bpm, respectively. Most patients (80%) had a history of prior coronary revascularization. At 6 months CCS class improved significantly (3,00 ± 0,47 at baseline vs. 1,80 ± 0,92 at 6 months, p=0.01). No significant change was observed in both early HMR (baseline: 2.68 ± 0.71 vs. 6 months: 2.60 ± 0.60, p=0.43) and late HMR (baseline: 2.58 ± 0.75 vs. 6 months: 2.46 ± 0.77, p=0.23). No significant change was observed in washout rates at baseline versus 6 months (p=0.15). SAQ results revealed significant improvements in perceived physical limitation, angina frequency and quality of life at both 3 and 6 months. Finally, no significant change in both office/ambulatory blood pressure and heart rate was observed at baseline vs. 6 months.

CONCLUSIONS

RDN resulted in significant improvements in angina class and quality of life at 6 months in patients with refractory VSA. RDN did not result in significant changes in cardiac sympathetic nerve activity.

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Early clinical impact of cerebral embolic protection with TAVI

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

AIMS

We aimed to compare the rates of neurological events and all-cause mortality at 72 hours and 30 days after transcatheter aortic valve implantation (TAVI) in patients with or without cerebral embolic protection (CEP).

METHODS AND RESULTS

All patients who underwent transfemoral TAVI with or without Sentinel CEP (Claret Medical Inc., CA, USA) at our center were included in the analysis. Data on all-cause mortality and neurological events up to 30 days post TAVI was prospectively collected in all patients. For the comparison of continuous and categorical variables the unpaired t-test/non-parametric Mann-Whitney U test and the Pearson ?2 test was used, respectively. A two-sided value of $p<0.05$ was considered statistically significant.

A total of 747 consecutive patients underwent TAVI at our center with 294 of them receiving cerebral embolic protection. Patients without CEP were more likely to be older (median 80 vs. 81 years), have a higher logEuroScore (median 12 vs. 14 %), longer procedure times (median 155 vs. 164 minutes) and to undergo TAVI with Medtronic CoreValve (20 vs. 56 %) and less likely with Evolut R (18 vs. 10%) and Lotus valve (35 vs. 12%).

Patients who received protection by the Sentinel CEP device had less immediate peri-procedural neurological events (1% vs. 5%, $p<0.01$), but no statistically significant difference in all-cause mortality (1% vs. 2%, $p=0.52$). The composite of all-cause mortality and neurological events at 72 hours post TAVI favored the CEP group (2% vs. 7%, $p<0.01$). Also at 30 days post-TAVI protected patients suffered less neurological events (3% vs. 8%, $P<0.01$) and similar all-cause mortality (3% vs. 4%, $P=0.69$). Unprotected patients suffered more disabling strokes (1% vs. 5%, $p<0.01$). The composite of all-cause mortality and neurological events was significantly different between both groups and favored the patients with embolic protection during TAVI (6% vs. 10%, $P=0.04$). We found no difference in the occurrence of the 30 day Valve Academic Research Consortium-2 composite endpoint Early Safety between both groups (89% vs. 85%, $P=0.14$).

CONCLUSIONS

The use of CEP during TAVI was associated with improved clinical outcome at 72 hours and 30 days, driven by less neurological events, notably disabling strokes.

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Serum cystatin C predicts acute kidney injury according to the KDIGO criteria and long-term outcome in myocardial infarction patients undergoing PCI

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

AIMS

Data on the association between serum cystatin C and acute kidney injury (AKI) according to the KDIGO criteria and outcome in patients with myocardial infarction (MI) undergoing coronary intervention (PCI) are scarce. Our aim was to evaluate the association between serum cystatin C and AKI in these patients and its possible association with the outcome.

METHODS AND RESULTS

Data on 2239 MI patients were analyzed using descriptive statistics. The prevalence of AKI according to the serum cystatin C quartiles and all-cause long-term mortality were documented. Patients were divided into AKI stage 1 and AKI stage 2/3 according to the KDIGO criteria. Median follow-up time was 5 years (25th,75th percentile: 4, 7).

According to the KDIGO criteria, 173 (7.7%) patients suffered AKI. AKI stage 1 comprised 120 (69.4%) patients and 53 (30.6%) were in AKI stage 2/3. Serum cystatin C independently predicted AKI. When serum cystatin C was analyzed as a continuous variable, higher serum cystatin C concentrations were associated with the development of AKI (OR, 2.69, 95%CI 1.70 to 4.26, p70 years, bleeding, diabetes, and contrast volume-to-glomerular filtration rate ratio were other predictors of AKI. For predicting AKI, the area under the receiver operating characteristic curve (AUC) of serum cystatin C for all participants in this study was 0.714. A cut-off of 1.315 mg/L yielded low sensitivity (30.1%) but excellent specificity (99.9%).

Higher serum cystatin C predicted long-term mortality (adjusted HR 1.79, 95 CI 1.48 to 2.16,

CONCLUSIONS

Serum cystatin C is a strong predictor of both AKI and long-term outcome in patients with myocardial infarction undergoing PCI. Early nephroprotective strategies for contrast-induced renal injury, such as a low volume of contrast, crystalloid infusions, a radial access to prevent bleeding and other complications, measures for optimal hemodynamics, and discontinuation of nephrotoxic drugs should be implemented in patients with higher serum cystatin C concentrations.

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Paclitaxel-eluting angioplasty balloon in the real-world trial interim results of six-month follow-up

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

AIMS

In patients with coronary stenosis in which metal scaffolding is undesirable a drug-eluting balloon (DEB) has become an alternative treatment option. Studies on the use of DEB for various indications are still lacking. Recently a paclitaxel-eluting low-profile balloon (Protégé, Blue Medical) was developed using a novel folding technique for enhanced drug exposure to the vessel wall and allowing three effective consecutive inflations. The aim of the current study is to investigate the safety and efficacy of the Protégé DEB in real-world indications.

METHODS AND RESULTS

This is a multicenter, prospective one-arm observational study. Patients with coronary stenosis unsuitable for stent implantation but suitable for DEB are included. The primary endpoint is the incidence at 6 months of a composite endpoint of major adverse cardiac events (MACE) including: cardiac death, target vessel myocardial infarction and target lesion revascularization (TLR).
200 patients (144 male) were included in the study. Medical history revealed that 127(64%) patients had a previous myocardial infarct, 177(89%) patients had previous PCI and 41(21%) patients had previous CABG. In total 225 lesions were treated with the Protégé DEB. Most of the lesions that were treated were complex lesions: 33% of the lesions were type B2 and 43% were type C. Indications for DEB were instent restenosis 61%, operator preference 16%, stent implantation more demanding 10%, small vessel 9% and long diffusely diseased lesion 5%. In 89% patients with stable angina pectoris the Canadian Cardiovascular Society Score was decreased at 6 months compared to baseline (P

CONCLUSIONS

The present data show that the new Protégé paclitaxel-eluting balloon is associated with low risk on MACE even when performed in a high-risk patient population with mostly complex coronary lesions. Although patients in the current study had a more complex coronary anatomy MACE rate seems to be similar to two recent paclitaxel-eluting balloon studies involving the SeQuent Please and Pantera lux(1).

References:

1. Assadi-Schmidt A, Mohring A, Liebsch E, Dannenberg L, Achilles A, Pöhl M, et al. SeQuent Please vs. Pantera Lux drug coated balloon angioplasty in real life: Results from the Düsseldorf DCB registry. Int J Cardiol. 2017,231:68?72

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One-year clinical outcomes of patients on oral anticoagulant therapy treated with second-generation DES: a propensity score-matched analysis from a worldwide registry

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

AIMS

We sought to further validate the safety and efficacy of Ultimaster DES in patients on oral anticoagulant therapy in the large eUltimaster registry.

METHODS AND RESULTS

eUltimaster is a prospective, single-arm, multi-centre registry. Of 8879 patients that have reached 1-year follow-up, information on anticoagulation therapy was obtained on 5776 patients. Of these, 239 were on oral anticoagulant therapy (OAC). The weighted matching propensity score matching (PSM) was applied to reduce baseline differences between OAC and non-OAC population.
OAC patients were older than non-OAC (70.5 vs 64.5 years,

CONCLUSIONS

OAC patients were older and had more severe comorbidities than non-OAC. Duration of DAPT was shorter in OAC than in non-OAC through 1 year follow-up. After PSM, mortality rates remain higher in OAC, associated with higher composite endpoints at 1 year, however, in OAC, DAPT duration did not have significant impact on adverse cardiac events.

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PtCr everolimus-eluting stent with bioabsorbable polymer in the treatment of patients with ACS

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

AIMS

Trial evidence supports the overall efficacy and safety of the Synergy coronary stent (a PtCr everolimus-eluting stent with bioabsorbable polymer). However, a recent trial (TIDES-ACS) exploring the use of titanium-nitride-oxide coated bio-active-stent (Optimax) in the context of acute coronary syndromes (ACS) reported worrying figures of infarction and definite/probable stent thrombosis in the Synergy control arm. On these grounds, we investigated the safety of Synergy in patients with ACS in a real-world study population.

METHODS AND RESULTS

Multicenter registry (10 centers) in which consecutive patients with ACS treated only with Synergy stent were included, applying the same inclusion and exclusion criteria as used in the TIDES-ACS trial. All cases had a completed 12 months follow up. Primary endpoint was the composite of cardiac death, myocardial infarction and ischemia-driven TLR at 12 months. Secondary endpoints were cardiac death, myocardial infarction, TLR and definite/probable stent thrombosis at 12 months. A total of 1,008 patients have been included, age 65±15 years, 76.3% males, 24.5% diabetics, 41.8% STEMI, 33% NSTEMI and 25.2% UA. The number of lesions treated was 1.37±0.69, stent diameter 3±0.48 mm and stent length 20 ±5.2 mm. DAPT was on for 11.7±3 months, in 48.5% with Clopidogrel and in 51.5% with Prasugrel or Ticagrelor. Primary outcome was 3% (7% in Synergy TIDES-ACS,

CONCLUSIONS

Despite a higher risk profile of ACS patients treated in the real world with Synergy, compared with the TIDES-ACS trial population, we found a significantly better long-term outcome than patients included in both the Synergy and Optimax arms of that trial.

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LAA closure with a novel device: initial experience and mid-term follow-up from a single centre

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

AIMS

Left atrial appendage (LAA) closure is considered an effective option in patients with non-valvular atrial fibrillation (NVAF) and contraindications to long-term oral anticoagulant (OAC) therapy. However, there are some concerns about safety of currently available devices. Our aim is to provide an initial assessment on safety and efficacy of the novel LAA closure Ultraseal device in patients with NVAF and contraindications to long-term OAC therapy.

METHODS AND RESULTS

Thirteen consecutive patients with NVAF undergoing Ultraseal device implantation between July 2016 and April 2017 were included. All patients performed transesophageal echocardiography and computed tomography angiography prior to LAA closure.

Procedural success was achieved in all patients except one who experienced incorrect device deployment but with complete LAA closure. Procedure duration halved from first to last procedure performed. No adverse events, including pericardial effusion, were observed during index hospitalization. At mean follow-up (166±80 days) all patients were alive and free from major bleedings and ischaemic strokes.

CONCLUSIONS

Our results suggest that the Ultraseal device is a safe and feasible option for LAA occlusion. Notably, the learning curve in this single-center experience was fast, paralleled by extremely low complication rates. These results should be considered hypothesis generating and larger studies are mandatory.

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Relevance of type and dose of beta-blockers in prognosis among patients with stable angina and myocardial infarction undergoing coronary revascularisation

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

AIMS

We investigated the clinical significance of type and dose of beta-blockers on prognosis among patients with stable angina and myocardial infarction after percutaneous coronary intervention (PCI).

METHODS AND RESULTS

Total 6,184 patients with stable angina and 5,166 patients with myocardial infarction (MI) who had undergone PCI were screened for inclusion from Korean multicenter drug-eluting stent registry. Prescription records of types and total dose of the beta-blockers were retrieved from discharge through 3 years follow up period. After excluding patients without available records of beta-blockers prescription at discharge, total 2,796 patients with stable angina and 2,673 with MI were included for analysis. Patients were categorized based on the types of beta-blockers for subgroup analysis in whom those with carvedilol or nebivolol were defined as vasodilating beta-blockers group and those with bisoprolol or metoprolol were defined as conventional beta-blockers group. Also, patients were stratified based on the mean dose of beta-blockers during the follow up period for analysis, which over 50% of maximal dose was defined as high, 25% to 50% as middle-range and lower than 25% as low dose beta-blockers. Primary end points were cardiac death, target vessel MI (TVMI), and a composite of cardiac death and TVMI at 3 years. Risk factors including age, sex, diabetes mellitus, hypertension, dyslipidemia, smoking history and previous medial history such as congestive heart failure and chronic kidney disease were adjusted for analysis. Total 1,378 (49.3%) and 2,162 (80.9%) patients had prescribed beta-blockers at discharge in those with stable angina and MI, respectively. In with stable angina group, 60.0% were on vasodilating and 20% were on high dose beta-blockers whereas 59.4% and 9.2% of MI patients were on vasodilating and high dose beta-blockers, respectively. Among MI patients, prescription of beta-blockers was independently associated with lower risk of cardiac death (Adjusted hazard ratio (HR) 0.26 (0.18-0.36), $p < 0.001$), TVMI (Adjusted HR 0.40 (0.17-0.92), $p = 0.031$) and composite endpoint (Adjusted HR 0.28 (0.20-0.39), $p < 0.001$) whereas no significant benefit had shown among those with stable angina. Regarding types of the beta-blockers, patients with vasodilating beta-blockers showed no significant benefit in both stable angina and MI patients compared to conventional beta-blockers. Regarding dose of the beta-blockers, dose dependent trends of risk reduction were shown among patients with stable angina in cardiac death (Adjusted HR 0.62 (0.30-1.29), $p = 0.202$ for middle-range dose, HR 0.46 (0.17-1.28), $p = 0.138$ for high dose), and composite endpoint (Adjusted HR 0.52 (0.26-1.04), $p = 0.063$ for middle-range dose, HR 0.36 (0.13-0.98), $p = 0.046$ for high dose). Interestingly, among MI patients, those with middle-range dose of beta-blockers showed significantly lower risk of cardiac death (Adjusted HR 0.43 (0.22-0.83), $p = 0.012$) and composite endpoint (Adjusted HR 0.50 (0.28-0.91), $p = 0.023$) compared to those with low dose beta-blockers, however, patients with high dose beta-blockers were related to similar risk compared to low dose groups.

CONCLUSIONS

Beta-blocker therapy was associated with better outcomes in patients with MI after coronary revascularization.

In particular, those patients got best benefit from middle-range dose. In contrast, high dose beta-blockers may have positive impact on prognosis among patients with stable angina.

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DuraGraft, an endothelial damage inhibitor mitigates negative remodelling in SVG after CABG: results from a within-in patient, randomised multicentre trial using multidetector CT angiography

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(1) ,

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

AIMS

Saphenous vein grafts (SVGs) are the most often used conduits in coronary bypass grafting (CABG), but are known to be associated with impaired long-term patency rates due to the occurrence vein graft disease and failure (VGD/F) which may compromise clinical outcomes. This trial aims to determine if DuraGraft, an endothelial damage inhibitor has the potential to reduce the occurrence of wall thickness/intima hyperplasia (early marker of VGD/F) and graft stenosis/occlusion (late marker) utilizing longitudinal multi-detector CT angiography in patients undergoing CABG.

METHODS AND RESULTS

In this prospective randomized, double-blinded multicenter trial (NCT02272582 and NCT02774824), a total of 125 CABG patients requiring at least two SVGs were enrolled. Using an in-patient randomization, one graft was treated with DuraGraft (treatment group), while the other graft was treated with standard of care (saline, control group). Patients were followed up clinically for safety and for the occurrence of cardiac adverse events and with CT angiography of paired grafts (cm intervals of both grafts within each patient) at 4-6 weeks (baseline), 3months and 12months. CT angiography analysis included several graft parameters such as the magnitude of change in wall thickness, lumen diameter, degree of stenosis and other remodeling variables to determine the protective effect of Duragraft on the SVG. Enrollment of patients was completed at seven investigational sites with well-matched subject and graft perioperative and conduit characteristics (>20, i.e. SVG harvest location quality, target-territory, quality and target territory of anastomosis, etc.) indicating sufficient within-patient randomization. CT angiography protocol efficacy was confirmed with ?95% assessable coronary segments (n=8030). DuraGraft treatment was safe and no adverse events such as myocardial infarction (MI), need for repeat revascularization (RR), death or MACE occurred. SVGs exposed to saline solution showed statistically significant increases towards negative remodeling, as measured by significant increases in mean wall thickness, compared to DuraGraft at 12 months post CABG in both whole graft (p= 0.02) and proximal graft (p= 0.01) analyses. Saline also showed statistically significant increases in maximum focal luminal narrowing compared to DuraGraft treated grafts over time (1 to 12 months) in proximal graft analysis (p= 0.01).

CONCLUSIONS

In this comparative trial, significant increases in negative remodeling, as measured by wall thickness and maximum stenosis, as seen with saline solution support the potential for DuraGraft to mitigate intimal hyperplasia and luminal narrowing, early and late markers of graft failure, respectively. Preserving SVG endothelial function with DuraGraft has the potential to reduce vein graft failure.

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Novel diagnostic system for functional assessment of the severity of cardiac shunts in patients with severe pulmonary hypertension

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

AIMS

Intracardiac shunts with severe pulmonary hypertension are complicated in terms of correct indication for shunt closure. Noninvasive procedures are inaccurate. Current approach with temporary occlusion of the shunt has several limitations. We present results of clinical outcome of the newly designed system (Inntherm®, Innova Medical, Czech Republic) that allows accurate functional assessment of the cardiac shunts. The system has been previously evaluated for general population. However specific cohort of patients with severe pulmonary hypertension has never been studied.

METHODS AND RESULTS

Cardiac output (CO = systemic blood flow), pulmonary blood flow (PBF), pulmonary vascular resistance (PVR) and volume of shunt has been measured in a group of seven patients (1 man, 6 women) with intracardiac shunts (5 atrial septal defect, 1 persistent ductus arteriosus, 1 PFO) and concomitant severe pulmonary hypertension (systolic pulmonary pressure 73±17,2 and mean pulmonary pressure 46±10,0 mmHg). Left-right (L-R) shunt was found in 4 patients and right-left shunt (R-L) in 4 cases. Mean cardiac output was 4,5±2,00 l/min, cardiac index 2,4±0,68 l/min/m2, mean pulmonary blood flow reached 7,5±4,11 l/min, mean pulmonary vascular resistance 5,5±4,63 Wj. In subgroup of L-R shunt mean Qp:Qs was 2,4±0,54:1 eg. in volume 5,33±1,538 l/min. In group of R-L shunt mean shunt volume was 0,65±0,338 l/min. 6 patients were treated with Amplatzer type of occlusion device, one patient has been refused due to dominant R-L shunt. We did not record any adverse event during the procedure.

CONCLUSIONS

The novel diagnostic system Inntherm® is safe and effective in patients with intracardiac shunts with severe pulmonary hypertension. It can measure not only shunt severity and shunt volumes, but also other hemodynamic parameters of pulmonary and systemic circulation. Inntherm® measurements are useful for proper selection patients for treatment of the intracardiac shunts.

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Role of vascular damage to neointima formation and progenitor cell mobilisation in stable patients treated with everolimus-eluting stent

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Previous studies established that bare metal stents cause neointimal proliferation proportional to vascular injury. We sought to assess the contributions of vascular injury measured by optical coherence tomography (OCT) to the neointimal formation and in the number of circulating immature progenitors cells: CD133KDRCD45lo (i-CPC) in stable patients who underwent everolimus stent implantation (EES).

METHODS AND RESULTS

Consecutive patients with stable coronary artery disease and one or more severe lesions amenable to stent implantation and OCT evaluation were included. We excluded any factor that may influence in the mobilization of i-CPC (statins, troponin elevations). Blood samples were collected to analyze i-CPC before the procedure, 1 weeK, 1 month and 9-months.OCT studies were performed after stent implantation and 9-month follow-up. Injury score was calculated as follow: (0/absence of dissection, 1/minor [b300 ?m in depth] and 2/major dissections [?300 ?m in depth]), at the 4 quadrants of each image (total injury score by frame from 0 to 8). Subsequently, stent level neointimal injury (IS) score was calculated as a mean of the injury score of individual frames (also from 0 to 8). We also analyzed other parameters of vascular damage (VD): the presence of tissue prolapse, intra-stent dissections, dissection at the edges of the stent and thrombi. All parameters were calculated at 1mm intervals throughout the total stent length and included both edges (5 mm). Twenty patients (21 lesions) were included. Mean age was 66+9 years and 80% were male. IS was associated with a significant increase in i-CPC at 1 week (? 0.28 (95IC 0.15,0.41:p< 0.001) and associated with the maximum neointimal thickness at 9 months follow-up (? 0.008 (95IC -0.0004, 0.002:p=0.04). i-CPC was also significantly associated with the increase in the number of dissections (? 0.17 (95IC 0.079,0.27:p< 0.001) and the number of quadrants with dissection (? 0.17 (95IC 0.001,0.27:p< 0.001) at 1 week. The number of prolapses was associated with the absolute number of i-CPC at 1-week (? 0.33 (95IC 0.21,0.45:p< 0.001) and also with the maximum neointimal thickness (? 0.005 (95IC 0.0008,0.002:p< 0.001) at 9-months follow-up.

CONCLUSIONS

These data suggest that vascular damage after EES implantation contributes to intimal hyperplasia and is associated with the increase of i-CPC at 1 week.

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Safety and performance of the Portico transcatheter valve in patients with severe aortic stenosis and high surgical risk: 30-day results from the Portico I study

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

AIMS

TAVI is established as an effective treatment of patients with symptomatic severe aortic stenosis and high surgical risk. The Portico I study aims to investigate the longer-term performance and safety profile of the PorticoTM Transcatheter aortic valve in this population. This is the first report on 30-day results for the complete cohort of 1032 Portico I patients.

METHODS AND RESULTS

Portico I is an on-going prospective, international, multi-center, dual cohort, longer-term follow-up study of patients with symptomatic, severe aortic stenosis. Patients were assessed by the center?s local Heart Team and referred for implant of a self-expanding, repositionable PorticoTM Transcatheter Aortic Valve (23, 25, 27 or 29mm) via a Transfemoral access.

The primary endpoint is all-cause mortality at 1 year post implant. Secondary endpoints include device performance, improvement in functional capacity and adverse event rates at 30 days, 1 year and annually thereafter for 5 years. Adverse events are defined according to VARC-2 criteria and adjudicated by an independent Clinical Events Committee. Echocardiography at 30 days and 1 year is evaluated by an independent Core Lab.

Between April 2013 and June 2017, a total of 1032 patients were enrolled. The study had two pre-specified patient cohorts: Cohort A included de novo implants (n=973), whereas Cohort B included patients rolled over at 1 year from previous Portico valve pre-CE Mark trials for ongoing prospective follow-up through 5 years (n=59). Of these patients, 1005 underwent an implant attempt at 61 sites across 14 countries worldwide. Of the 61 sites, 44 were located in Europe, 9 were in Australia and 8 were in Canada.

At baseline, the mean age was 82.3±5.9 years, 35.0% was male and mean STS score for mortality was 5.8±4.7%. Balloon pre-dilatation was performed in 89.3% patients. Implantation of the Portico valve was successful in 996 out of 1005 patients (99.1%). Procedurally, re-sheathing and repositioning of the valve was performed in 41.1% of implant attempts and was successful in 99.5% of instances.

At 30 days, all cause and cardiovascular mortality were 2.5% and 2.3% respectively. Disabling stroke was observed in 1.6% of patients, AKI (stage 3) was 1.0%, major vascular complications were 6.0% and life threatening bleeding was 2.9%, while 18.4% of patients at risk required new pacemaker implantation.

Paravalvular leak was absent/trace in 31.5%, mild in 64.5%, moderate in 4.0% and severe in 0%. The mean aortic valve area increased from 0.7±0.4cm2 to 1.8±0.5cm2 and the mean gradient decreased from 49.4±15.2mmHg to 8.5.1±4.0mmHg at 30 days. At baseline, 32.6% of patients were NYHA class II and 64.5% were NYHA Class III/IV compared to 51.0% of patients classified as NYHA class II and 13.0% classified as NYHA Class III/IV at 30-day follow-up. Similar, mean 6 min walk distance significantly improved from 250±116 meters to 274±117 meters.

CONCLUSIONS

The Portico? valve shows excellent short-term clinical outcomes with low rates of mortality, stroke and major adverse events. Hemodynamic results at 30 days reveal very low rates of paravalvular leak and low transvalvular gradients. In conclusion, the Portico? valve continues to exhibit safe and effective performance in use at expanded sites and geographies with performance comparable to that seen in pre-CE Mark trials trial patients.

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Patient-specific computer simulation of TAVI in bicuspid aortic valve morphology

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

AIMS

Transcatheter aortic valve implantation continues to expand into younger, lower-risk patients, the majority of whom have bicuspid aortic valve morphology. Paravalvular regurgitation remains an important complication of TAVI in bicuspid aortic valve morphology. Computer modelling may help identify patients at risk for paravalvular regurgitation.

METHODS AND RESULTS

A retrospective multi-centre study was performed on all patients with bicuspid aortic valve morphology who had undergone TAVI and had both pre- and post-procedural CT imaging. Bicuspid aortic valve morphology was classified using the Sievers system. Finite element computer modelling and computational fluid dynamics analysis was performed using TAVIguide technology (Feops, Ghent, Belgium). The primary hypothesis was that a finite element computer model could predict the final transcatheter heart valve frame morphology, as measured at the inflow, annular, leaflet and outflow segments of the transcatheter heart valve. This was assessed using a two-way mixed intraclass coefficient (ICC) with values 0.90 indicative of excellent reliability. The secondary hypothesis was that a computational fluid dynamics model could predict the occurrence of more than mild paravalvular regurgitation. This was assessed using the area under the curve (AUC) of a receiver operator characteristic curve with a value 0.9 considered outstanding.

A total of 24 patients were included in the study, of whom 6 patients had Sievers Type 0 morphology and 18 patients had Sievers Type 1 morphology. Transcatheter heart valve prostheses implanted included CoreValve (n=5), Evolut R (n=9), Evolut PRO (n=1) and Lotus (n=9). More than mild paravalvular regurgitation occurred in 9 patients (38%). The finite element model demonstrated good-to-excellent reliability at predicting the final transcatheter heart valve frame morphology (maximum frame diameter ICC 0.91, minimum frame diameter ICC 0.87, frame area ICC 0.93, frame perimeter ICC 0.93). The computation fluid dynamics model demonstrated an excellent discriminative power to predict the occurrence of more than mild regurgitation (AUC 0.87). A predicted paravalvular regurgitation rate of 13mL/sec was 89% sensitive and 80% specific for the occurrence of more than mild paravalvular regurgitation, representing a 73% positive predictive value and a 92% negative predictive value.

CONCLUSIONS

For patients with bicuspid aortic valve morphology who had undergone TAVI, computer modelling was able to predict the final transcatheter heart valve frame morphology and the occurrence of more than mild paravalvular regurgitation. Patient-specific computer simulation may help risk stratify patients with bicuspid aortic valve

morphology who are being considered for TAVI.

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Quantitative evaluation and comparison of coronary artery characteristics by three-dimensional coronary volume reconstruction

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

The aim of this study was to evaluate and compare coronary artery characteristics of diabetic, normal and aneurysmal or ectatic coronary arteries 3-dimensional (3D) quantitative coronary angiography (QCA).

METHODS AND RESULTS

We selected 131 individuals (43 ± 5.3 years, 76% male) from patients under 50 years-of-age who had undergone coronary angiography for suspected myocardial ischaemia between 1st January 2011 and 31st December 2015, at the Bristol Heart Institute, Bristol, UK. This included 42 healthy patients, 36 diabetic patients, and 53 patients with abnormal coronary dilatation (aneurysm and ectasia). A total of 1,099 segments were analysed using QAngio XA 3D (Research Edition, Medis medical imaging systems, Leiden, The Netherlands). The combined volume of the major coronary arteries was significantly different between each group (1,240 ± 476 mm3 diabetic, 1,646 ± 390 mm3 normal, and 2,072 ± 687 mm3 abnormal, $p < 0.001$). Moreover, the combined coronary artery volumes correlated with patient body surface area (BSA) ($r = 0.476$, $p < 0.001$). A subset of 30 patients with 208 segment were randomly reanalyzed by a second observer. The Intraclass correlation coefficient of these measurements demonstrated an excellent inter-observer variability of 3D QCA ($r = 0.985$, $p < 0.001$)

CONCLUSIONS

This is the first study reporting the quantitative assessment of coronary volumes and comparison of coronary artery characteristics using 3D QCA. We demonstrated the differences of coronary artery volumes in diabetic, normal, aneurysmal or ectatic groups and that coronary artery volumes is correlated with BSA. Furthermore, 3D QCA has good reproducibility, and is therefore a useful tool for measuring coronary artery volume.

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Relevance of anatomic, plaque and hemodynamic characteristics of non-obstructive lesions in the prediction of ACS

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

AIMS

We explored the clinical importance of anatomic, plaque and hemodynamic characteristics of the lesions in identifying high risk plaques causing acute coronary syndrome (ACS) among those with non-obstructive stenosis.

METHODS AND RESULTS

From the EMERALD study subjects with ACS and available coronary CT angiography (cCTA) before ACS, 132 lesions without significant stenosis (Percent diameter stenosis (%DS) less than 50%, 24 culprit and 108 non-culprit lesions) were included. Anatomic characteristics (%DS, minimal luminal diameter, lesion length, plaque volume and plaque burden of the target lesion) and plaque characteristics (Low-attenuation plaque (average density ?30 HU) and positive remodeling (lesion diameter/reference diameter ?1.1) were analyzed using cCTA. Hemodynamic characteristics (per-vessel FFR derived from cCTA (FFRCT) and change in FFRCT across the lesion (delta-FFRCT)) of the target lesions were analyzed using computational fluid dynamics. Relative importance of each lesion characteristics on ACS was compared by C-statistics using 10,000 bootstrap resampling methods. Based on the relative significance of lesions characteristics, prediction models for subsequent ACS were constructed by step-wise multiple combination of the lesion characteristics. The prediction ability of the models was compared by C-statistics using 10,000 bootstrap resampling methods.

Despite no significant difference in anatomic and plaque characteristics between culprit and non-culprit lesions, culprit lesions showed higher delta-FFRCT (0.08 ± 0.07 vs. 0.05 ± 0.05, p=0.033). Among the lesions characteristics, delta-FFRCT showed highest relative importance (C-statistics 0.67, 95% CI 0.56-0.74) and was significantly related to higher risk of subsequent ACS (HR 3.25, 95% CI 1.31-8.04, Log rank p=0.010). Based on multiple combination of anatomical characteristics (Combination step1), prediction model including plaque volume showed highest performance (C-statistics 0.64, 95% CI 0.40-0.73). After combining plaque characteristics (Combination step2) and hemodynamic parameters (Combination step3), the final prediction model including plaque volume, low density plaque, FFRCT and delta-FFRCT showed highest performance in ACS prediction (C-statistics 0.76, 95% CI 0.59-0.81).

CONCLUSIONS

Non-invasive assessment of hemodynamic parameters can identify high risk plaques for subsequent ACS among non-obstructive lesions.

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Outcomes in elderly patients planned for one-month DAPT after PCI: subanalysis of the SENIOR trial

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

AIMS

In the SENIOR trial, among patients 75 years old and older who undergo percutaneous coronary intervention (PCI), a bioresorbable polymer drug eluting stent (DES) and a short duration of dual antiplatelet therapy (DAPT) is superior to bare metal stent (BMS) with respect to the occurrence of all-cause mortality, myocardial infarction, stroke and ischemia-driven target lesion revascularisation. DAPT was tailored to the patient?s clinical presentation to be one and six months in stable and unstable patients, respectively. One-month DAPT patients baseline characteristics and outcomes are reported.

METHODS AND RESULTS

A one month DAPT duration was planned by investigators in n=683 (56.9%) PCI patients aged 75 years and above before randomisation by a central computer system to either a DES (n=327, 54.9%) or a similar BMS (n=356, 58.9%), in a single-blinded way. The objective was to compare a composite primary endpoint of all-cause mortality, myocardial infarction, stroke or ischemia-driven target lesion revascularisation, and secondary endpoints including the rate of bleeding and stent thrombosis between DES and BMS-treated patients at one year.

Results

Among the patients planned to receive one-month DAPT, 86.7% had a stable presentation and 13.3% an unstable presentation. The primary endpoint occurred in 34 patients (10.5%) in the DES group and in 56 patients (15.9%) in the BMS group (relative risk [RR] 0.66, 95% confidence interval [CI], 0.43 to 0.97, P=0.0358). Ischemia driven target-lesion revascularisation was reported in 2 patients (0.6%) in the DES group versus in 23 patients (6.5%) in the BMS group (RR 0.09, 95% CI, 0 to 0.26, P

CONCLUSIONS

Among elderly PCI patients planned for one-month DAPT by the investigator, a DES is superior to BMS with respect to the occurrence of all-cause mortality, myocardial infarction, stroke and ischemia-driven target lesion revascularisation.

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The impact of completeness of revascularisation by PCI in patients with coronary artery disease on the autonomic modulation of the heart

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

To evaluate the impact of completeness of revascularization assessed by Residual SYNTAX Score (RSS) in coronary artery disease (CAD) patients undergoing elective PCI on the cardiac autonomic modulation assessed by heart rate variability (HRV).

METHODS AND RESULTS

A prospective study included 100 patients undergoing elective PCI when clinically indicated either by patient's symptoms or if there is an evidence of ischemia either by a stress test or post-acute coronary syndromes (ACS) excluding patients with contraindication to contrast or dual antiplatelet therapy, patients with atrial fibrillation or multiple premature beats or pacemaker programmed in non-tracking mood, patients receiving anti-arrhythmic drugs except class II, IV and patients who underwent previous Percutaneous Coronary Intervention (PCI) or Coronary Artery Bypass Grafting (CABG). SYNTAX score (SX) and RSS were calculated before and after PCI to determine the completeness of revascularization using SYNTAX score calculator software. Complete revascularization (CR) was defined as RSS <8 while incomplete revascularization (IR) was defined as RSS ?8. A short-term HRV measurement was performed before PCI, 24 hours and 6 months after PCI at the same time of the day using CheckMyheart™ handheld HRV device from DailyCare BioMedical Inc, Taiwan. HRV data were interpreted by CheckMyheart ™ 5-min HRV analysis software using the standard methods for HRV measurement as discussed in the Task Force of the European Society of Cardiology and The North American Society of Pacing and Electrophysiology. Results: Baseline characteristics included 85 males and 15 females, age ranged from 27 to 80 years with a mean of 56.89±10.7, 41 patients were diabetics, 47 hypertensives, 54 smokers, 11 had a family history of CAD, 8 dyslipidemic and 4 had miscellaneous diseases.6 patients had typical ischemic symptoms, 8 had a positive stress test, while 86 had a history of ACS, mean heart rate was 77.95±11.79 beats/minute, mean ejection fraction was 54.03±11.08%. The mean SX score was 13.11±8.52. 42 had multi-vessel CAD while 58 had a single vessel CAD. Among the studied cases, TVR was a single vessel in 69 patients, 31 was multi-vessel. The mean RSS was 2.0±5.77. 90 patients had CR, while 10 had IR. There was a statistically significant difference between time and frequency domain HRV parameters 24 hours after PCI in patients who had CR with those who had IR. Time domain parameters included mean time, SDNN, RMSSD which were lower in patients with RSS?8 and statistically higher in patients with RSS<8 (p-value<0.001). Frequency domain parameters included LF, HF which was lower in patients with RSS?8 and statistically higher in patients with RSS<8 (p-value<0.001) and LF/HF ratio was higher in patients with RSS ?8 and statistically lower in patients with RSS<8 (p-value<0.001). Also, there was a statistically significant difference between HRV parameters 6 months after PCI in patients who had CR with those who had IR. Mean time, SDNN, RMSSD of time domain which was lower in patients with RSS?8 and statistically higher in patients with RSS<8 (p-value<0.001). Frequency domain parameters included LF, HF which was lower in patients with RSS?8 and statistically higher in patients with RSS<8 (p-value<0.001) and LF/HF ratio was higher in patients with RSS ?8 and statistically lower in patients with RSS<8 (p-value<0.001).

CONCLUSIONS

CR whenever feasible is recommended in patients with CAD for an improved autonomic modulation and overall survival.

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DEB angioplasty for coronary in-stent restenosis, a UK single-centre experience

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THEME: Coronary Interventions

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

AIMS

PCI with drug coated balloons for in-stent restenosis is well recognised but with widely differing published outcomes. We report clinical outcomes of drug coated balloon (DCB) angioplasty in coronary in-stent restenosis in a single centre from 01/01/2009 to 31/12/2015.

METHODS AND RESULTS

All patients who received DCB angioplasty for in-stent restenosis were identified from the hospital data base. Demographic and procedural details were obtained retrospectively from the hospital data base and by angiographic review. Subsequent clinical events (target lesion revascularisation (TLR), target vessel revascularisation (TVR) and myocardial infarction (MI)) were retrieved from hospital data base/electronic records. Mortality data were obtained through the spine portal of NHS Digital for 100% of patients. 207 (68%) patients (224 lesions) have had 6 months documented hospital follow up.

In total there were 327 lesions in 300 patients. Mean age 66, 76% were males, 89 (30%) had diabetes mellitus,185 (62%) previous MIs.167 (51%) lesions were acute coronary syndrome of which 57 (17%) were due to ST elevation MI. 6 lesions involved left main stem and 150 left anterior descending (46%) artery. 76 (23%) were bifurcation lesions. Of those known, 71% were DES and 29% were BMS restenosis. Pre dilatation was done with non-compliant balloons in 183/56% lesions and cutting or scoring balloons in 69(21%). Inflations were carried out at high pressures aiming for 1:1 balloon-to-artery ratio. IVUS/OCT was used in 149 lesions (46%), with a trend for less imaging over time (63%, 52%, 44% and 28% of procedures in 2012, 13, 14 and 15). Mean (SD) DCB diameter was 3 (0.6) mm and mean (SD) treated length was 26 (14) mms. There were 17 coronary dissections and 5 were left uncovered. 20 lesions had bail-out stenting during the procedure and in another 41 lesions stents were used electively. Hence 266 lesions (81%) were treated with DCB-only PCI. One patient was taken back to the catheterisation lab for ongoing chest pain and had a bail-out stent during the same admission due to a distal stent edge dissection. All cause death at 365 days for the whole group was 10 (3.3%). Of 207 (68%) patients/224 lesions with documented 6 months follow up, all cause death was 6 (2.9%), MI 8 (3.9%), TLR 6 (2.7%) and TVR (non TLR) 3 (1.3%). MACE (death, MI and all TVR per patient) was 17 (8.2%). For those with 6 months documented follow up with intra coronary imaging (101 patients) the MACE rate was 7 (6.9%) and with non-imaging MACE rate was 8.4% for 107 patients. Unadjusted comparison using chi squared test revealed the difference was non-significant (diff 1.5%, 95% CI -6.2462 to 9.1612, p 0.69). At conference we will provide 12 month clinical outcomes for the whole ISR group upon receipt of National Institute of Cardiac Outcomes Research data (due imminently).

CONCLUSIONS

ISR patients are a high risk group and remain susceptible to further clinical events. The clinical outcomes of this all comer ISR cohort treated with DCB-angioplasty are satisfactory in short to medium term follow up. Aggressive lesion preparation with 1:1 balloon-to-artery sizing and high pressure inflations aiming for a near

normal angiographic appearance prior to delivery of the DCB might have played a role in low TLR rate observed. Our declining rate of intravascular imaging with maintained low subsequent event rates would support a simplified approach to the management of all ISR patient groups.

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Endovascular treatment of acute aortic dissection in childhood ? first-in-man experience

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THEME: Peripheral Interventions
TOPIC(S): AAA

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Normal reference values of transcatheter valves leaflet thickness: a pilot study of a small CT case series

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

AIMS

Subclinical leaflet thrombosis - described as hypoattenuated leaflet thickening and restricted leaflet motion- has recently emerged as a new computed tomography (CT) evidence in transcatheter heart valves (THV). However, data regarding CT reference values of leaflet thickness are still missing.

METHODS AND RESULTS

We analyzed data from 13 patients out of a prospective registry on CT valve follow-up, who successfully received in our center transcatheter aortic valve implantation (TAVI) with self-expandable, balloon-expandable or mechanically-expandable prostheses. We collected data from serial echocardiograms (baseline, discharge and 1-12-24 months follow-up) and post-procedural CT scan. Clinical events and antithrombotic regimen were also obtained. In all patients hemodynamic valve performance was normal at discharge and follow-up, with an effective aortic valve area (AVA) of 1.5±0.5 cm2 and a mean indexed AVA of 0.9±0.3 cm2/m2. Peak instantaneous velocity was 2.2±0.5 m/s, with a peak aortic gradient of 20±9 mmHg and a mean aortic gradient of 12±5 mmHg. Median time between TAVI and CT was 552 days (interquartile range [IQR] 62-885). Mean and median leaflet thickness were 1.2±0.2 mm and 1.2 mm (IQR 1.0-1.3) respectively. Median leaflet thickness was smaller in self-expandable porcine pericardial valves than in balloon-expandable and mechanically-expandable bovine pericardial valves, respectively 1.03 mm (IQR 0.9-1.1) versus 1.3 mm (IQR 1.1-1.4), p=0.02. No neurological events occurred during a median follow-up of 357 days (IQR 91-787). Most patients (11/1, 84.6%) received single antiplatelet therapy at the time of the CT scan.

CONCLUSIONS

In patients with normal prosthesis performance leaflet thickness ranges from 1.0 to 1.3 mm at CT scan, with the known difference between porcine and bovine pericardium. This case series represents, to our best knowledge, the first reporting data about normal values of THV leaflet thickness evaluated by CT. Further investigations are needed in order to confirm our results.

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World-wide everyday practice registry assessing the Xposition S self-apposing stent in challenging lesions with vessel diameter variance (Sizing registry)

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

AIMS

While performing a PCI, difficulties are encountered in vessels with very large diameter, significant diameter variance, or diameter difficult to estimate (e.g. STEMI). In this setting, optimization steps are required, which may be aggressive for the vessel or the stent structure, without ensuring stent apposition. There is scarce data in the use of any coronary stent in this lesions set. Self-apposing stents may provide a solution in this lesions set. We investigate the sirolimus eluting stent Xposition S (STENTYS, Paris, France) in these specific lesions in a everyday practice registry.

METHODS AND RESULTS

The SIZING international registry is designed to provide safety and clinical outcome data on STENTYS stents, from routine clinical practice, in lesions subsets with significant vessel diameter variance, e.g. left main coronary, ectatic/aneurysmatic vessels, bifurcations, vessels with high thrombus load, significantly tapered vessels, vein grafts, ? 3000 patients from approx. 100 sites are expected to be enrolled. The primary endpoint is Major Adverse Cardiac Events (MACE) evaluated at the 12 months follow-up, defined as cardiac death, target vessel related myocardial infarction (MI), clinically-indicated target lesion revascularization (TLR) or emergent CABG. MACE events are independently adjudicated.

In this registry, 1650 patients with the different generations of the STENTYS self-apposing stents were enrolled. This is the largest self-apposing coronary stent registry available to date. An interim analysis was performed on all patients with Xposition S, with a median follow-up of 1 year (mean: 294 days). 588 patients have been enrolled. Mean age was 65.1 ± 12.7 year. 66% of patients presented with acute coronary syndrome, 32% with STEMI. 36% of patients were treated for lesions in vessels with diameter variance, 17% for thrombus containing lesion, 16% for lesions in left main coronary or bifurcation, 7.5% for saphenous vein graft, 5% in chronic total occlusion patients. MACE rate (Kaplan-Meier estimate) is 5.1%, including 1.6% of death from cardiac or unknown cause, 2.1% of target vessel related MI and 3.1% of clinically-indicated TLR. Stent thrombosis rate (definite/probable) is 0.75%. Regarding subgroups, the MACE rate was 4.4% in vessel diameter variance subgroup, 2.8% in large vessel subgroup (?4.5mm diameter) and 1.7% in high thrombus load subgroup. An updated analysis will be presented (555 patients are expected to have 1-year follow-up completed).

CONCLUSIONS

It is the largest data analysis reported on Xposition S. A broad set of challenging lesions are treated in this registry. In this set of lesions, and in all the subgroups investigated, the observed clinical events rates are low.

The SIZING registry confirms the interest of the Xposition S stent in the challenging anatomies where vessel diameter varies.

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Dousing the fire dragon

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Safety and efficacy of novel sirolimus-eluting stent in management of patients with AMI: a substudy from the en-abl e-registry

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

AIMS

The objective of this study was to investigate clinical outcomes of the last generation DES which has unique fusion coating technology, merging the properties of a sirolimus coated balloon with those of a bioresorbable polymer drug eluting stent in patients with acute myocardial infarction (AMI).

METHODS AND RESULTS

The en-ABL e-registry was a prospective, real-world, all-comers, multicenter registry that enrolled 956 patients with AMI and 1474 patients without AMI. The primary endpoint was major adverse cardiac events at 1 year [MACE: cardiac death, target vessel myocardial infarction (TV-MI), and target lesion/vessel revascularization (TLR/TVR)]. Secondary end-point was the Stent Thrombosis (ST) at 1-year.

The all-comer nature of the AMI sub study was illustrated by a mean age of 56.42 ±12.09 years, 81.80% male, diabetes in 29.18%, and hypertension in 32.32%. The average number of stents per patient 1.27. The culprit lesion was most often located in LAD (52.50).36.19 % of patients had direct stenting and thrombus aspiration was performed in 4.50%.

1-year clinical outcome was available for 758 (79.29%) AMI patients and 1320 (89.55%) non-AMI patients. The MACE rate was 2.77% at 1-year and which was driven by cardiac death (0.92%), TV-MI (0.92%), and TLR (0.92%). 1.32% stent thrombosis was detected in AMI patients which includes 0.40% acute ST and 0.92% sub-acute ST. The present study is on-going so the follow up for the rest of the patients is yet to come. The rate of MACE at one year was not significantly different among patients with AMI (2.77%) and non-AMI (2.5%) groups (p= 0.709). Stent thrombosis occurred more frequently in the AMI group (1.32% vs. 0.30% in the non-AMI group, p= 0.006).

CONCLUSIONS

The present study demonstrated safety and effectiveness of this stent, in a high risk cohort of AMI patients from real-world clinical settings which support the concept of technology behind this kind of stent.

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Prognostic implication of door-to-balloon time and onset-to-door time on mortality in patients with STEMI treated with primary PCI

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

In patients with ST-segment elevation myocardial infarction (STEMI), timely reperfusion therapy with door-to-balloon time (D2B time) less than 90 minutes is recommended by the current guidelines. We asked whether the survival benefit of shortening D2B time would be continuously observed at D2B time shorter than 90 minutes.

METHODS AND RESULTS

We analyzed a nationwide multicenter prospective registry for consecutive patients with acute myocardial infarction including STEMI. In 20 tertiary hospitals capable of primary PCI in Korea, 5,243 patients with STEMI were treated with primary PCI from November 2011 to December 2015. Patients who underwent primary PCI within 24 hours of symptom onset and 6 hours after admission were included for the analysis. Primary outcome was all-cause mortality at 1-year after index procedure. The median O2D time was 2.0 hours [Q1-Q3: 1.0-4.2] and the median D2B time was 59 minutes [Q1-Q3: 46-72]. 92.2% of total population showed D2B time ? 90 minutes and 55.3% were with D2B time ? 60 minutes. In a univariable analysis, 1-hour delay of door-to-balloon time was associated with 55% increased 1-year mortality (HR 1.55, 95% CI 1.40-1.72,

CONCLUSIONS

Shortening D2B time was significantly associated with survival benefit, however, the benefit of shortening O2D time was not evident. The survival benefit of shortening D2B time was consistently observed below 90 minutes. Further development of strategies to keep D2B time at minimum are warranted to reduce mortality in STEMI patients.

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Changes in renal function and occurrence of contrast-induced nephropathy after PCI in patients with atrial fibrillation treated with non-vitamin K oral anticoagulants or warfarin

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Patients with atrial fibrillation (AF) receiving non-vitamin K oral anticoagulants (NOAC) have a slower decline in renal function than those taking warfarin. Moreover, a warfarin-related nephropathy has been described. In our study, we aimed at assessing variation of estimated glomerular filtration rate (eGFR) and the occurrence of contrast-induced nephropathy (CIN) after percutaneous coronary intervention (PCI) in patients with AF taking warfarin compared with NOAC.

METHODS AND RESULTS

We retrospectively enrolled consecutive patients taking oral anticoagulation for AF and undergoing PCI in three Italian centres from January 2015 to September 2017. Baseline and post-procedural (after 48-72h) eGFR was calculated using the Modification of Diet in Renal Disease (MDRD) equation. CIN was defined as a ?25% relative increase, or a ?0.5 mg/dL absolute increase, in serum creatinine levels within 48-72h of contrast exposure.

We enrolled 420 patients [mean age 76.3±8.7 years, 272 (64.7%) male], 124 (29.5%) treated with NOAC and 296 (70.5%) with warfarin. Patients in the NOAC group showed a reduced decline in renal function after PCI compared with warfarin (eGFR change -2.8±5.9 ml/min/1.73 m2 vs. -4.6±8.4 ml/min/1.73m2, respectively, p=0.03). In the multivariate linear regression model independent predictors of eGFR changes were diabetes, baseline eGFR?60 ml/min/1.73m2 and warfarin use. Occurrence of CIN did not differ between NOAC and warfarin patients [13 (10.5%) vs. 46 (15.5%), p=0.22, respectively]. However, among patients with eGFR?60 ml/min/1.73 m2, the occurrence of CIN tended to be higher among warfarin patients compared with NOAC patients [3 (7.7%) vs. 19 (20.4%), p=0.08, respectively].

CONCLUSIONS

Our study shows for the first time that patients with AF taking warfarin have a significant greater decline in renal function after PCI compared with patients taking NOAC, suggesting that NOAC may be a reasonable option for patients with a high-risk of developing CIN.

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Individual participant data meta-analysis comparing various doses of intracoronary bolus injection of adenosine with intravenous administration of adenosine for FFR assessment

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Maximal hyperemia is essential for stenosis evaluation by FFR and/or coronary flow reserve. Intravenous infusion of 140mcg/kg/min (IV) adenosine is considered standard practice, but is associated with adverse side effects and is time-consuming. Intracoronary bolus injection of (IC) adenosine is better tolerated by patients, cheaper and less time-consuming. Nevertheless, the optimal dosage of IC adenosine remains a topic of debate. We performed a individual participant data meta-analysis to compare low-dose, intermediate-dose and high-dose IC adenosine with IV adenosine for FFR assessment.

METHODS AND RESULTS

A systematic search in MEDLINE/Pubmed and Cochrane library was performed for literature that compared IC adenosine with IV adenosine at a rate of 140 mcg/kg/min for FFR assessment on a vessel-level basis. The search was restricted to peer-reviewed papers only, and reference lists of all-retrieved studies were screened. Vessel-level data was obtained by digitization of scatterplots using custom-made semiautomatic bitmap-to-digital software (MatLab®, Mathworks Inc, Natick, MA) or by contacting the respective authors for vessel-level data. Low-dose IC adenosine was defined as adenosine bolus injection of

CONCLUSIONS

The present individual participant data meta-analysis demonstrates that IC adenosine confers a practical and patient-friendly alternative for IV adenosine for contemporary FFR assessment. We documented no clinically relevant differences in FFR outcome between the various doses of IC adenosine and IV adenosine.

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Hospital academic status and outcomes in patients with AMI complicated by cardiogenic shock in the United States of America: insights from the National Readmission Database

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

AIMS

Cardiogenic shock (CS) following acute myocardial infarction (AMI) places an important burden on healthcare utilization. Previous studies have shown an advantage in outcomes for individuals admitted to teaching hospitals with certain medical conditions. We sought to evaluate the relationship between hospital teaching status and outcomes in patients with CS after AMI.

METHODS AND RESULTS

We derived the study cohort of patients with AMI and CS from the 2013-14 HCUP?s National Readmission Database, sponsored by the Agency for Healthcare Research and Quality in the United States of America. Teaching hospitals were defined as those with an approved residency program, members of the Council of Teaching Hospital or those with a ratio of full-time equivalent interns and residents to beds of 0.25 or higher. Outcomes measures included in-hospital mortality and 30-day readmissions. Descriptive statistics was used to assess the relationship between hospital teaching status and outcomes.

We identified a total of 25,937 index admissions for AMI with CS, out of which 16,624 (64 %) survived to discharge. Mean age and length of stay were 69 years and 11 days respectively. Total of 16,475 (63.5%) patients were admitted to teaching hospitals, whereas 9,453 (36.4%) patients went to a non-teaching hospital during index hospitalization. In-hospital mortality was significantly lower in patients admitted to teaching hospitals when compared to non-teaching hospitals (35.14 % vs. 37.16 % p 0.0011 FET) no significant difference in length of stay was noted (10.8 vs. 9 days p 0.1 T-test)

CONCLUSIONS

Patients presenting with CS secondary to AMI to a teaching hospital had significantly lower all-cause mortality rates compared with non-teaching hospitals in this unadjusted analysis. The underlying factors causing these variations are unclear. These findings may support the emerging concept of Cardiogenic Shock networks within healthcare regions where prompt referral to teaching hospitals may impact outcomes of this challenging patient population.

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SYNTAX II score vs. SYNTAX score to predict long-term patient outcome after left main stenting with second-generation DES: insight from the FAIL-II multicentre registry

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

AIMS

The aim of this study was to evaluate the capacity of the SYNTAX Score-II (SS-II) to predict long-term mortality in patients undergoing left main percutaneous coronary intervention (LM-PCI) treated with second-generation drug-eluting stents (DES).

METHODS AND RESULTS

SYNTAX score (SS) and SYNTAX score II (SS-II) were calculated in 854 patients with de novo left main coronary artery disease undergoing PCI included in FAILS-2 multicenter registry (Failure in Left Main Study With 2nd Generation Stents-Cardiogroup III Study), followed up to 10 years. Patients were divided into tertiles according to the SS-II: low SS-II (SS-II ? 33 n=288), intermediate SS-II (SS-II between 33 and 44, n=291), and high SS-II (SS-II ? 44, n=275). The survival curves were estimated by the Kaplan-Meier method. Cox proportional hazard regression analyses were performed to evaluate associations between the SS-II and long-term mortality or Major Adverse Cardiovascular Events (MACE). Area Under the receiver operator Curve (AUC) and Net Reclassi?cation Improvement (NRI) were assessed comparing SS with SS-II.

Mean SS-II was 39.2 ± 5.5. At a mean follow-up of 5.2 ± 3.6 years mortality rates were 4%, 7.4%, and 17.4%, respectively among patients in the 3 groups ($p < 0.001$). SS-II score showed a more accurate prediction of mortality than SS score (AUC = 0.73, 95%CI: 0.67-0.79 vs. AUC = 0.55, 95%CI: 0.48-0.63, $p < 0.001$). For all-cause mortality, the NRI was 71% (

CONCLUSIONS

In real-world high risk patients with LM-PCI treated with a second-generation DES, the SS-II demonstrated a superior predictability compared with the SS. Besides, other factors not included in the SS-II like ACS at presentation and T2DM has to be considered as an additive marker of poor outcome.

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

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

AIMS

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

METHODS AND RESULTS

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

The primary endpoint was target vessel failure (TVF) rate at 12 months. Clinical follow up visits were/are performed at 1, 6, 12 and 24 months and annually thereafter up to 5 years post index procedure. All angiographic index images were analyzed by an independent Corelab. All clinical events were adjudicated by an independent clinical events committee.

The primary endpoint TVF (Universal Definition) rate at 12 months (including a time window of 14 days) was 5.1% in the Orsiro group vs 6.6% in the Xience group. Non-inferiority between the two treatment groups was confirmed with p=0.0001.

At 24 months (including a time window of 30 days), the TVF failure estimates were 8.9% (Orsiro) vs 9.1% (Xience) (p= 0.7182) for the overall cohort. Definite or probable stent thrombosis failure estimates were 0.8% in the Orsiro group vs 0.0% in the Xience group (p=0.5544).

CONCLUSIONS

The ultrathin Orsiro SES with biodegradable polymer was non inferior to the Xience EES with durable polymer at 12 months for TVF and there were no statistically significant differences in other clinical endpoints at 12 and 24 months between the two treatment groups in a mixed population of Japanese and Caucasian subjects.

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Real-world comparison of the new 34mm self-expandable transcatheter aortic bioprosthesis to its 31mm predecessor

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

AIMS

The self-expanding and partially recapturable 34mm bioprosthesis recently became available in Europe replacing its 31mm non-recapturable predecessor. Apart from the wider annulus diameter coverage, the latest device is designed to lower paravalvular aortic regurgitation rates and optimize deliverability in challenging large anatomies. In the present study we report the incidence of periprocedural complications and short-term outcomes comparing the new 34mm device with its 31mm predecessor.

METHODS AND RESULTS

Consecutive patients, who had undergone transcatheter aortic valve implantation (TAVI) with a self-expandable device (Medtronic, Minneapolis, Minnesota), in two centers were retrospectively studied. In-hospital, procedural characteristics and in-hospital outcomes, such as death, paravalvular regurgitation, need for permanent pacemaker (PPM) implantation, stroke and major vascular complications were recorded and compared among the two groups.

In total, 106 patients (35pts treated with a 34mm and 71pts treated with a 31mm device) were included in the current study. Baseline demographics (age, gender, LVEF and coronary artery disease risk factors) were similar between the two groups with the exception of logistic Euroscore, which was significantly higher in patients treated with the 31mm valve (12.1 vs. 19.6 for 34mm and 31mm respectively, p=0.001). Patients treated with the 34mm valve had significantly larger annulus perimeter (86.7mm vs. 84.5mm for 34mm and 31mm respectively, p=0.044). There was a trend for lower in-hospital mortality using the 34mm device (8.5% vs. 0%, p=0.077). The 34mm device demonstrated significantly lower rates of new PPM implantation (5.7% vs 26.8% for 34 and 31mm respectively, p=0.037), as well as, significantly lower rates of bail-out valve-in-valve implantation (0% vs 11.9% respectively, p=0.036). No significant difference was detected with regards to residual mean transvalvular gradients (11.6 mmHg vs 8.7mmHg, p=0.207), moderate+ paravalvular regurgitation (3.2% vs. 4.5%, p=0.125), stroke (0% vs. 2.0%, p=0.431) or major vascular access complications (4.2% vs. 0%, p=0.218) for the 34 and 31mm valves respectively.

CONCLUSIONS

The recently introduced 34mm self-expandable device, apart from the wider annulus coverage range, seems to demonstrate reduced rates for new PPM and need for bail-out valve-in-valve implantation, compared to its 31mm predecessor. Larger registries are needed to confirm these findings and compare long-term outcomes.

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Effects of statin intensity on clinical outcomes in AMI patients

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

AIMS

There has been debate regarding the incremental benefit of high intensity statins compared with low to moderate intensity statins, especially in patients with acute myocardial infarction (AMI). Therefore, we sought to investigate the prognostic effects of statin intensity in post-AMI patients in contemporary practice.

METHODS AND RESULTS

The Korea Acute Myocardial Infarction Registry-National Institutes of Health consecutively enrolled 13,104 AMI patients. Among these, a total of 12,182 patients, who completed 1-year follow-up, were included in this study, and all patients were classified into 3 groups (no statin, low to moderate intensity and high intensity statin groups). The primary outcome was major adverse cardiac event (MACE) including cardiac death, non-fatal MI, and repeat revascularization at 1-year. Both low to moderate intensity and high intensity statin significantly reduced LDL cholesterol levels (all p-value

CONCLUSIONS

By achieving adequate LDL cholesterol levels, patients on a low to moderate intensity statin dose demonstrated comparable cardiovascular outcomes with patients in the high intensity statin group.

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Vascular healing in plaque ruptures and non-ruptured plaques after primary PCI: an OCT study

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

AIMS

Vascular healing and strut coverage are important factors in reducing the risk of stent thrombosis after percutaneous coronary intervention (PCI). Differences in healing response between plaque ruptures (PR) and non-ruptured plaques (NRP) are not known. We sought to compare the early vascular healing of PR and NRP one month after primary PCI in patients with ST-segment elevation myocardial infarction (STEMI), using optical coherence tomography (OCT).

METHODS AND RESULTS

Twenty-six STEMI patients underwent PCI with implantation of the polymer-free drug-coated Biofreedom stent. OCT of the culprit lesion was performed pre-PCI, post-PCI and at 1-month follow-up. Based on the pre-PCI OCT, patients were divided into patients with PR=15 and NRP=11. Vascular healing index based on the presence of uncovered and/or malapposed stent struts, and intraluminal filling defects was assessed by OCT at follow-up.

The vascular healing index one month after BioFreedom stent implantation did not differ between PR (median 11.5 [interquartile (IQR) [9.5-14.5]) and NRP (median 11.5 [IQR 5.5-12.5]) (p=0.68). Neither did the percentage of uncovered struts: PR 26.5% [IQR 15.0-49.0] versus NRP 28.1% [IQR 15.5-38.8], (p=0.78). At 1-month follow-up, PR showed an increased percentage of late acquired malapposed struts (1.4% [IQR 0.8-2.4] vs. 0.0% [IQR 0.0-1.4], p=0.03) and a larger total malapposition area (1.3mm2 [IQR 0.4-2.5] vs. 0.0mm2 [IQR 0.0-0.9], p=0.01), compared to NRP.

CONCLUSIONS

The vascular healing index one month after primary PCI with BioFreedom stent implantation was comparable in PR and NPR, and three out of four stents struts were covered. However, PR lesions had more late acquired malapposition and larger total malapposition areas than NRP.

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The Bioflow-III Satellite Italy registry: eighteen-month results of the ultrathin-strut biodegradable-polymer Orsiro DES in an all-comer high-risk population

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

AIMS

Thin-strut biodegradable-polymer drug-eluting stents have been developed to improve clinical outcomes in patients undergoing PCI. We aimed to corroborate clinical evidence on safety and efficacy of the ultrathin-strut biodegradable-polymer Orsiro DES in an all-comer population including high-risk subgroups.

METHODS AND RESULTS

The Bioflow-III Satellite Italy was a nationwide, prospective, all-comer registry conducted at 18 centers. The study cohort was treated with the Orsiro DES according to standard practice and followed up for 18 months. High-risk subgroups were pre-specified. The study primary endpoint was the 12-month cumulative rate of target lesion failure (TLF), a composite of cardiac death, target vessel MI, emergent CABG and clinically driven target lesion revascularization (TLR). We report the 18-month follow-up results in a total of 601 enrolled patients (31.9% diabetics, 34.6% AMIs) with 736 lesions (26.2% small vessels [

CONCLUSIONS

The study results confirmed excellent clinical performance of the Orsiro DES at 18 months in the whole all-comer population and in the pre-specified high-risk subgroups.

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Improving use of ambulance 12-lead electrocardiography telemetry system in Taiwan: an eight-year experience

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Previous studies showed the multiple benefits of ambulance 12-lead electrocardiogram (ECG) in patients with ST-elevation myocardial infarction (STEMI), including to shorten ischemia to balloon time, to avoid patients to transfer to non percutaneous coronary intervention (PCI) hospital and further to improve the outcomes of these STEMI patients. However, it is still difficult to set up ambulance 12-lead electrocardiogram system. Therefore, the aim of this study is to investigate the improving use of ambulance 12-lead electrocardiogram in Taiwan.

METHODS AND RESULTS

METHODS: There were 20 cities or counties in Taiwan. The establishment of ambulance ECG system is complicated in Taiwan, because it requests the cooperation among multiple hospitals, fire bureau and department of health in different city councils. This study collected data from 2011 to 2018. The percentage of ambulance ECG system establishment in Taiwanese cities or counties was analyzed. There were 3 different ambulance ECG system in Taiwan, including simplified telemetry ECG system, multi-function telemetry ECG system and freeware app transmitted ECG system.

RESULTS: Since 2012, Kaohsiung City is first city to set up ambulance ECG system in Taiwan.There were 2, 4, 7, 9, 13, and 16 cities or counties to set up ambulance ECG system in 2013, 2014, 2015,2016, 2017 and 2018. In Taiwan, 12 cities or counties used simplified telemetry ECG system (75%). Two cities (12.5%) used multi-function telemetry ECG system and other 2 cities (12.5%) used freeware app transmitted ECG system. In total, the percentage of ambulance ECG system establishment in Taiwanese cities or counties is 5%, 10%, 20%, 35%, 45%, 65% and 80% in 2012, 2013, 2014, 2015, 2016, 2017 and 2018.

CONCLUSIONS

This study showed, from 2011 to 2018, the percentage of ambulance ECG system establishment in Taiwanese cities or counties increase from 0% to 80%, However, there were still limited fire bridges to have this saving system in most of cities or counties, which might be due to lack of government regulations and finicial support.

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Impact of jailed struts in the treatment of left main coronary bifurcation lesions: a comparison between single stenting and culotte stenting

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

Jailed struts after DES implantation for the treatment of left main coronary bifurcation lesions have become an important concern because of its potential association with restenosis. We conducted this study to evaluate the impact of jailed struts in the treatment of left main coronary bifurcation lesions by comparing jailed struts after single stenting and those after culotte stenting.

METHODS AND RESULTS

We analysed 307 patients with 307 left main coronary bifurcation lesions treated by IVUS-guided left main bifurcation stenting between January 2011 and May 2014. Routine angiographic follow-up was performed 8 months after the procedure. Postprocedural IVUS data and clinical outcomes within 1 year after the procedure were compared between lesions with and without jailed struts (jailed and non-jailed struts groups). The primary endpoint was defined as target lesion revascularisation (TLR) within one year after the procedure. Jailed struts were defined as two or more residual stent struts. Non-jailed struts were defined as complete removal of struts or one residual strut visualized with IVUS. Among the 307 lesions, 247 lesions were treated by single stenting and 60 lesions by culotte stenting. The mean age of the 307 patients was 72±10 years. The number of patients with diabetes mellitus was 128 (42%) and that with haemodialysis was 24 (8%). The proximal optimization technique was performed in 135 (44%) of the 307 lesions. The rate of jailed struts in the lesions treated by single stenting was 17% (41/247 lesions) and that in the lesions treated by culotte stenting was 20% (12/60 lesions) (P=0.57). In the lesions treated by single stenting, the TLR rate within 1 year after the procedure was not significantly different between the jailed and non-jailed struts groups (2.4% vs. 2.4%, P=1.00). In the lesions treated by culotte stenting, however, it was significantly higher in the jailed struts group (41.7% vs. 4.2%, P=0.002).

CONCLUSIONS

Jailed struts in left main coronary bifurcation lesions after culotte stenting may be related to the risk of restenosis and subsequent TLR, but those after single stenting may be not.

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Procedural volume and outcome with radial or femoral access for PCI in patients with STEMI

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

AIMS

Radial and femoral arteries are usual routes for PCI. Radial access for PCI can reduce vascular bleeding compared with femoral access, and this results in lowering major adverse cardiovascular and cerebrovascular events in patients with AMI. However, in the previous studies, femoral access in high volume radial PCI centers showed increased trend of major adverse cardiovascular and cerebrovascular events. Therefore, we aimed to investigate the associations between procedural volume and outcome with radial or femoral access for PCI in patients with STEMI in real world practice.

METHODS AND RESULTS

We examined 5,921 STEMI patients who underwent primary PCI through radial or femoral access from the Korean Acute Myocardial Infarction Registry (KAMIR) ? National Institute of Health (NIH) database. Major adverse cardiovascular and cerebrovascular events were defined as in-hospital death, major bleeding, and cerebrovascular accidents. Radial dedicated center was defined as over 50% of radial access when PCI was performed for with and without STEMI.

Femoral access has worse outcome than radial access. Compared with femoral dedicated center, radial dedicated center increased in-hospital major adverse cardiovascular and cerebrovascular events (10.9% versus 7.6%, p=0.032) when femoral access was used, therefore femoral access has worse outcome because of radial dedicated center. The difference was mainly driven by in-hospital death (10.0% versus 5.0%,

CONCLUSIONS

In patients with STEMI, femoral access in a radial dedicated center increased In-hospital event. However, radial access showed no significant difference in terms of major adverse cardiovascular and cerebrovascular events between radial and femoral centers.

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Impact of insulin-dependent and non-insulin-dependent diabetes mellitus on long-term clinical outcomes after everolimus-eluting stent implantation in patients with and without hemodialysis

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

It was reported that insulin-dependent diabetes mellitus (IDDM) and hemodialysis (HD) were risk factors of adverse event after drug-eluting stent implantation. However, IDDM and HD were also reported as the confounding factors of each other. We aimed to investigate the impact of IDDM and non-IDDM on long-term (6 years) clinical outcomes after everolimus-eluting stent (EES) implantation in patients with and without HD.

METHODS AND RESULTS

The study population comprised 2170 lesions treated with EES for the first time between January 2010 and December 2011: Non-DM group, 1255: IDDM group, 256: non-IDDM group, 659. The mean follow-up period was 2140 ± 397 days. Clinical outcomes were compared between 3 group.

Proportion of HD was significantly higher in IDDM group among 3 groups (4.9% vs 5.2% vs 10.9%, P < 0.001). In lesion without HD, cumulative rate of target lesion revascularization (TLR) at 6 years was significantly higher in IDDM group than non-DM group and non-IDDM group (10.2% vs 17.4%, P = 0.003, 11.3% vs 17.4%, P = 0.02). In contrast, cumulative rate of TLR in non-IDDM and non-DM group was not significantly different (10.2% vs 11.3%, P = 0.56). In lesion with HD, cumulative rate of TLR up to 6 years was not significantly different between IDDM and non-DM groups (28.1% vs 29.0%, P = 0.76), and non-IDDM and non-DM groups (38.2% vs 29.0%, P = 0.74).

CONCLUSIONS

IDDM is the risk factor of TLR up to 6 years in patients without HD. However, non-IDDM was not in patients with and without HD.

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Impact of emergency coronary intervention in a super-aging population: report from Japanese AMI registry

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Cardiovascular diseases, including acute myocardial infarction (AMI), are leading causes of deaths in Japan. Comprehensive information from Japan, with its rapidly aging population, will be crucial for developing future perspectives in other countries. The Japan Acute Myocardial Infarction Registry (JAMIR) was established by integrating 10 regional registries. The present study analyzing the nationwide database was designed to explore medical practices and emergency care for AMI in the aging Japanese society.

METHODS AND RESULTS

JAMIR conducted retrospective analysis of 20,462 AMI patients (mean age, 68.8±13.3 years, 15,281 men [74.7%]) hospitalized between January 2011 and December 2013. In the JAMIR study, 23.6% of patients were aged ?80 years (n=4,837 [2,543 men and 2,294 women]). We then compared patients in their 80s (n=4,074) with patients in their 90s (n=763). The proportion who underwent emergency PCI was lower (90s, 62.4% vs. 80s, 82.9%, P

CONCLUSIONS

The large JAMIR database, with 24% of AMI patients aged ?80 years, could provide useful information about medical care in an aging society. The reasonable in-hospital outcomes observed may justify consideration of PCI for patients with AMI aged ?90 years.

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Association of serum calcium levels with clinical events after second-generation DES implantation in patients on maintenance hemodialysis

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

AIMS

Maintenance hemodialysis (HD) remains to be a risk of clinical events even after second generation drug-eluting stents (2nd-gen DES) implantation. Previous study showed that calcification is frequently observed in restenotic tissue especially in patients undergoing HD. Elevation in serum calcium, phosphorus, and parathyroid hormone (PTH) levels are associated with increased cardiovascular calcification which can lead to clinical events. We sought to evaluate the association of serum calcium, phosphorus, and PTH levels with clinical events after 2nd-gen DES implantation in patients on HD.

METHODS AND RESULTS

This study enrolled 89 HD patients (110 lesions) who underwent 2nd-gen DES (everolimus, zotarolimus or biolimus A9) implantation for the first time. Blood samples were obtained just prior to hemodialysis. Clinical events were followed up to 66 months. MACCE (major adverse cerebrocardiac events: death, myocardial infarction, stroke, target lesion revascularization) group (N=42, 47.2%) showed significantly higher serum calcium levels (9.28 ± 0.88 mg/dL vs. 8.70 ± 0.90 mg/dL, p=0.003). On the other hand, there were no significant difference in serum phosphorus (4.76 ± 1.38 mg/dL vs. 4.71 ± 1.57 mg/dL, p=0.86) and PTH (167.58 ± 101.68 pg/mL vs. 184.83 ± 174.24 pg/mL, p=0.64) levels between two groups. Target lesion revascularization group (N=42, 24.7%) showed significantly higher serum calcium levels (9.35 ± 0.84 mg/dL vs. 8.85 ± 0.93 mg/dL, p=0.022). However, there were no significant difference in serum phosphorus (4.86 ± 1.46 mg/dL vs. 4.69 ± 1.45 mg/dL, p=0.64) and PTH (152.50 ± 91.36 pg/mL vs. 183.93 ± 157.29 pg/mL, p=0.30) levels between two groups.

CONCLUSIONS

High serum calcium level is a predictor of MACCE and target lesion revascularization after 2nd-gen DES implantation for HD patients. Further investigations should be warranted to explorer if the hyperparathyroidism of patients on HD impacts on restenosis after 2nd-gen DES implantation.

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Validation of the "multivalvular score" for the assessment of patients with concomitant mitral and aortic valve disease: updating strategies to the "fully percutaneous" era

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

AIMS

The impact of concomitant mitral regurgitation (MR) on clinical outcomes has not been evaluated formally across the main TAVI trials given that severe MR has been frequently considered an exclusion criterion. We previously evaluated factors associated to an improvement in its degree following TAVI which was associated to a reduction in cardiac mortality. We elaborated the "Multivalvular Score" to predict its persistence following TAVI and developed an online electronic tool (also available for smartphones) to help cardiologists in the decission-making process.

METHODS AND RESULTS

Prospective analysis across 4 insitutions where patients with moderate of severe mitral regurgitation who underwent TAVI were evaluated with the "multivalvular score" to determine the risk of persistence of the mitral regurgitation through a receiver operator characteristic curve analysis. The characteristic included in the "multivalvular score" and prospectively evaluated in the validation cohort were those included in the former multivariable analysis (performed with 1110 patients across 8 institutions and already published), including: Presence of mitral calcification in the annulus and in the leaflets, functional MR according to echocardiographic assessment, atrial fibrillation at any time, persistent left bundle branch block, pulmonary pressure as estimated by echocardiography, and mitral annular diameter.

A total of 144 patients with moderate or severe MR were included in this validation study. Of them, 51% presented an improvement in the degree of mitral regurgitation at 6 month of follow up that persisted at 1 year of follow up in 48%. Sensitivity and specificity for the model were 0.821 and 0.752, respectively, with an area under the curve of 0.930 (95%confidence interval: 0.891-0.969),

CONCLUSIONS

In conclusion, we confirmed a constant improvement in the degree of MR in patients undergoing TAVI with moderate or severe concomitant MR. The multivalvular score demonstrated an excelent external validity to predict the persistance of MR after TAVI which was associated to higher mortality. Hence, this tool might be useful to determine when alternatives to isolated TAVI (as combined mitral percutaneous treatment or surgery) ought to be considered.

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High common femoral artery bifurcation has a risk of vascular complication in transfemoral TAVI

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

AIMS

Vascular complications of transfemoral TAVI following femoral artery cannulation are common when puncture site is not in the optimal common femoral artery (CFA) segment. But sometimes it is difficult to obtain optimal CFA segment in case of CFA bifurcation is high. The aim of this study is to clarify the impact of high CFA bifurcation to vascular complication in transfemoral TAVI.

METHODS AND RESULTS

We enrolled consecutive 744 transfemoral TAVI cases which were underwent femoral angiogram both pre and post procedure from August 2014 until August 2017 at our institution. We divided cases into 3 groups depend on the position of CFA bifurcation (Type1, bifurcation level is inferior to the lower edge line of femoral bonehead, Type2, bifurcation level is between lower edge line and midpoint line of femoral bonehead, Type3, bifurcation level is superior to midpoint line of femoral bonehead). Hemostasis was achieved by percutaneously in all the case. All endpoints were defined according to the VARC-2 criteria for event definition.
The prevalence of femoral bifurcations was Type1, 73%, Type2, 24%, Type3, 3% respectively. Mean age (83±6.6 vs 84±6.6 vs 83±4.3 p=0.13), body mass index (27±5 vs 27±6 vs 27±5, p=0.78) were similar but female proportion was significantly different (48% vs 63% vs 65%, p=0.001). The baseline STS score did not differ significantly between groups (5.2±3.9 vs. 5.4±3.7 vs 5.4±4.6 p=0.36), the baseline logistic Euroscore was also similar (17±12% vs. 17±10% vs 13±6.9 p=0.34). Other baseline co-morbidities were similar between 3 groups. Type and size of implant valve were not different in each group. CFA diameter was similar (8.0±1.0mm vs 7.8±0.97mm vs 7.8±0.83mm, p=0.15)and ?sheath to femoral artery ratio? was also similar (0.80±0.12 vs 0.81±0.12 vs 0.83±0.11, p=0.52). However the distance from bifurcation and puncture point was significantly different (28±8.1mm vs 17±8.2mm vs 12±6.7mm p<0.0001).In-hospital mortality was not different in each group (1.3% vs 3.3% vs 0%, p=0.21). But there were statistically significant difference in vascular complication between each group (Type1, 7.8 %, 2, 16%, 3, 22% respectively P<0.01).On univariate analysis, we found that the distance between bifurcation and puncture point less than 20mm is strong predictor to vascular complication(odds ratio: 2.7, 95% confidence interval 1.66 to 4.39, p<0.0001)

CONCLUSIONS

High CFA bifurcation had a risk of vascular complication in transfemoral TAVI because the distance from bifurcation to puncture point was narrow.

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Comparison of survival after subclavian vs. direct aortic access for TAVI ? Insights from the UK TAVI registry

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

AIMS

To compare 30-day and 1-year survival after subclavian (SC) versus direct aortic (DA) vascular access for TAVI.

METHODS AND RESULTS

The UK TAVI registry has recorded characteristics and clinical outcomes for every 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, hence providing a robust system for tracking all-cause mortality.

We performed a retrospective observational cohort analysis of those patients in whom TAVI was performed via DA or SC access and for whom validated life status was available. 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 reported by the TAVI centre. Death after hospital discharge was taken from national census data. Missing data were not included in the analysis.

From January 2007 to July 2015, all-cause mortality data were available for 7691 TAVI patients. From this cohort we identified 224 cases (SC 82 [37%] vs. DA 142 [63%]) performed from January 2013 to July 2015, to ensure a contemporaneous comparison with respect to both approaches. Median follow-up among survivors was 545 days.

Mean (± standard deviation) age at operation was similar (SC 78 ± 6.8 vs. DA 80 ± 8.9, p=0.14). Significantly more men had TAVI performed via the SC route (SC 65.9% vs. DA 48.6%, p=0.02). Those undergoing SC TAVI also had balloon aortic valvuloplasty immediately before TAVI significantly more often (SC 78.0% vs. DA 50.7%,

CONCLUSIONS

Thirty-day and 1-year survival are similar after subclavian versus direct aortic vascular access in the UK TAVI registry. There are, however, significant differences in other determinants of post-procedural outcome, which could potentially have important cost and safety implications.

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Impact of IVUS in the results of percutaneous recanalisation of coronary CTO: results from the multicentre Iberian registry

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Current controversy regarding the benefits of percutaneous recanalization (PCI) of coronary chronic total occlusions (CTOs) could be partially related to mixed results across different institutions. We summarize the global results of the Iberian Registry from more than 20 Spanish centers

METHODS AND RESULTS

Methods

Prospective registry with specific online database of all patients undergoing PCI of CTOs across 24 centers along 2 years. Follow up was available for 99% of the patients.

Results

A total of 1001 PCIs of a CTO were performed in 952 pacients along 2 years. Most patients were symptomatic (81.5%), with chronic ischemic cardiomyopathy (56.3%) and previous attempts of desobstruction of the CTO in 15%. Mean anatomic Syntax score was 22.4±9.9 (including left main disease in 3.9% and more than one CTO in 13.1%) and J-score?3 in 17.3%. Right coronary artery was the most commonly affected (49.7%).

Retrograde procedure was performed in 107 pacients (10.7%), in 75% as initial approach. Success rate was 74.9% being higher in those without previous attempts (82.2 vs. 75.2%, p=0.001), a J-Score?2 (80.5 vs. 69.5%, p=0.002), and when IVUS was used (89.9% vs. 76.2%, p=0.001). Indeed, use of IVUS was an independent predictor of success (OR=2.165, IC95%(1.074-4.365), P=0.031). On the contrary, severe calcification (OR=0.455, IC95%(0.267-0.773), P=0.004), length >20 mm (OR=0.424, IC95%(0.273-0.657), P

CONCLUSIONS

As compared to other national registries, pacients from the Iberian Registry undergoing PCI of CTOs presented similar complexity, success rate, and complications. A higher use of IVUS and further training in retrograde approach or alternative strategies may be helpful to improve outcomes

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Could aortic infective endocarditis be treated with TAVI?

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

AIMS

Only few cases of aortic infective endocarditis (IE) treated with transfemoral aortic valve implantation (TAVI) have been reported. Although TAVI resolves the functional problem of a damaged valve, the device might be at risk of a reinfection, which would carry a particular awful prognosis. However, antibiotic treatment in IE is very useful, and many times the main reason for cardiac surgery is a symptomatic severe valvular dysfunction. In order to know which IE patients could benefit from TAVI we investigatigated the predictors of local valve infection at the time of cardiac surgery.

METHODS AND RESULTS

Methods: We defined local infection at the time of intervention as the presence of either periannular complication or concordant positive cultures from the cardiac tissue removed during surgery. Concordant positive valve cultures mean the presence of the same microorganism in the blood and the valve cultures. From a total of 732 episodes of left-sided IE consecutively diagnosed in two tertiary centres between 1996 and 2015, 432 underwent cardiac surgery and 224 of them have affected either native or biological prosthetic aortic valves. Only patients in which the removed cardiac tissue was cultured (n=182) were included. Also, patients with discordant positive valve culture (n=14) were excluded since culture contamination could not be ruled out. In order to determine predictors of local infection, we build up a predictive model using a logistic regression model with the maximum likelihood method and backward stepwise selection, which included the variables that were clinically relevant and statistically significant in the univariable analysis avoiding overfitting. For the final model, we calculated the odds ratios (OR) adjusted for each of the variables included, along with their 95% confidence intervals (95% CI). Goodness of fit for each model was determined with the Hosmer?Lemershow test.

Results: Main independent predictors of local infection were diabetes mellitus (OR 3, 95%CI: 1.1-7.7), Staphylococcus aureus (OR 4.3, 95%CI: 1.4-13.6) and concomitant mitral affection (OR 2.6, 95%CI: 1.1-5.9). On the contrary, a time between diagnosis and intervention ? 10 days was a predictive actor of healed infection (OR 0.3, 95%CI: 0.1-0.6). The model had an area under receiver operating characteristic curve of 0.782 (95%CI: 0.712-0.851) and a p-value of 0.799. In the absence of fever, patients without diabetes mellitus, Staphylococcus aureus or concomitant mitral affection, and beyond 10 days from appropriate antibiotic treatment presented a risk of local infection at the time or intervention of <1%.

CONCLUSIONS

In conclusion, our findings suggest that, under the assessment of a multidisciplinary experienced IE team, TAVI could be considered as an alternative therapeutic option in selected cases of IE with low risk of local infection at the time of the planned intervention.

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Low-function type of polymorphism in gene for endothelial nitric oxide synthase can cause discrepancy between FFR and iFR measurements

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

We aimed to test the hypothesis that decreased production on nitric oxide (NO) - as a result of low-function type of polymorphism in gene for endothelial NO synthase (ENOS) - can cause non-maximal hyperemia after adenosine administration and thereby discrepancy between fractional flow reserve (FFR) and instantaneous wave free ratio (iFR).

METHODS AND RESULTS

We examined patients with stable angina who underwent assessment of hemodynamic significance of coronary arteries with stenosis in a range of 40-70% (by visual estimation of angiography) with both FFR and iFR (system Philips-Volcano) analyses from two institutions. We included all consecutive patients with both FFR and iFR in one native coronary artery without any previous intervention. We analyzed 894 G/T (Glu298Asp) polymorphism in ENOS gene. In this polymorphism, guanine (G) is replaced by thymidine (T) at position 894 resulting in a substitution of glutamic acid (Glu) for aspartic acid (Asp). This substitution leads to blunted endothelial-dependent vasodilation. The GG variant was classified as being protective, whereas the GT and TT variants were classified as conferring risk.

Total 280 patients (85 females) were included to the study. FFR negative and iFR positive (FFRn/iFRp) type of discrepancy was found in 23 patients (8.2%). Genetic analysis was performed in 147 patients: all patients fro one institution and patients with discrepancy only from a second institution. Risk type of polymorphism was found in 30.8% of patients with FFRn/iFRp type of discrepancy and in 13.7% patients with concordant measurements, p=0.037.

CONCLUSIONS

Risk type of 894 G/T polymorphism in ENOS gene can caused a higher rate of FFRn/iFRp discrepancy, probably for impaired endothelial-depend vasodilatation. These patients could potentially profit more from iFR examinations.

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Impact of final minimal stent area by IVUS on one-year outcome after PCI in the SYNTAX II trial

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

AIMS

To investigate the impact of final minimal stent area (MSA) evaluated by post-procedural IVUS on clinical outcomes after contemporary PCI in patients with multi-vessel coronary artery disease.

METHODS AND RESULTS

The SYNTAX II study is a multicentre, all-comers, open-label, single arm study that investigated the impact of a state-of-the-art PCI strategy on clinical outcomes in patients with three-vessel disease. (454 patients with 1,559 lesions)

Post-implantation IVUS was performed in 84.1% of the patients (76.4% of the lesions, n=876/1146) leading to a further optimization (i.e. balloon post-dilatation) of the stented lesion in 30.2%. The mean minimum stent area post-procedure was 6.17 ± 2.31 mm2.

The final minimum stent area per patient was divided into terciles (smaller tercile: 1.9- 4.3 mm2, intermediate tercile: 4.4 ? 5.7 mm2, and largest tercile 5.8 ? 12.3 mm2). TVF was observed in 14/125 (11.2%), 17/122 (13.9%), and 7/120 (5.8%), respectively (p=0.115). Cardiac death was observed in 1/125 (0.8%), 2/122 (1.6%), and 2/120 (1.7%), respectively (p=0.792). Target-vessel myocardial infarction was observed in 3/125 (2.4%), 3/122 (2.5%), and 0/120 (0.0%), respectively (p=0.238). Clinically-driven TVR was observed in 7/125 (5.6%), 7/122 (5.7%), and 2/120 (1.7%), respectively (p=0.228).

For a lesion level analysis, the final minimum stent area per lesion was divided into terciles (smaller tercile: 1.9 ? 5.0 mm2, intermediate tercile: 5.1 - 6.7 mm2, and largest tercile: 6.8 ? 19.6 mm2). All TVR was observed in 14/288 (4.9%), 9/265 (3.4%), and 2/267 (0.7%), respectively (p=0.019). Clinically driven TVR was observed in 11/288 (3.8%), 8/265 (3.0%), and 2/267 (0.7%), respectively (p=0.067). All TLR was observed in 12/288 (4.2%), 9/265 (3.4%), and 2/267 (0.7%), respectively (p=0.043). Clinically driven TLR was observed in 9/288 (3.1%), 8/265 (3.0%), and 2/267 (0.7%), respectively (p=0.123). Definite/Probable stent thrombosis was observed in 0/288 (0.0%), 3/265 (1.1%), and 2/267 (0.7%), respectively (p=0.219).

CONCLUSIONS

In the SYNTAX II trial, the final MSA measured by IVUS after PCI correlates with adverse events at 1 year in a lesion level.

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Long-term natural history of CABG depending on the initial haemodynamic significance of the native stenotic coronary arteries

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

AIMS

Patency of coronary artery bypass grafts (CABG) is known to be higher in arterial than in venous conduits. However, long-term graft patency rate based on the hemodynamic significance of the native stenotic coronary arteries remains poorly investigated.

METHODS AND RESULTS

All consecutive patients treated with CABG between 2006 and 2010 who underwent a coronary angiogram during follow-up were retrospectively included. All grafts were classified into 2 groups according to whether implantation was guided by haemodynamic assessment of the native coronary artery stenosis by fractional flow reserve (FFR) (FFR-guided group) or not (angiography-guided group).

An angiographic follow-up was available in 512 grafts from 171 patients: 384 (75%) grafts were angiography-guided, while 128 (25%) were FFR-guided. At 6 years, 72/512 (14%) grafts were occluded: the proportion of occluded venous grafts was higher than that of arterial grafts (24% versus 10%, respectively, p< 0.001). Overall, the occlusion rate was higher in the angiography-guided group than in the FFR-guided group (17% versus 9%, respectively, p=0.022). However, when looking at the type of grafts, the difference in term of patency according to guidance was only significant among the arterial grafts (17% versus 9%, respectively, p=0.028). When comparing the baseline characteristics of occluded arterial grafts with patent arterial grafts, FFR-guidance was the only factor statistically significantly different between the 2 groups (HR = 2.99 [1.15 , 7.78] , p=0.028).

CONCLUSIONS

FFR-guidance is associated with higher graft patency rate at 6 years. Long-term patency of arterial grafts is higher when implanted on coronary arteries evaluated by FFR.

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Acute and long-term relocation of minimal lumen area after Absorb BRS or Xience metallic stent implantation

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

AIMS

Although late luminal loss (LLL) is commonly used for device evaluation, it is often overlooked that LLL is assessed irrespective of the axial location of minimal lumen diameter (MLD) in the treated area. Relocation of MLD and minimal lumen area (MLA) after bioresorbable scaffold (BRS) implantation has not been investigated.

METHODS AND RESULTS

In the ABSORB II randomized trial [BRS vs. everolimus-eluting stent (EES)], lesions were investigated by serial intravascular ultrasound pre-procedure, post-procedure, and at 3-year. Taking into account the motion of the epicardial vessel around the catheter, relocation was defined whenever longitudinal MLA position changes by more than 2.4 mm, either proximally or distally. Acute relocation was defined as relocation from pre-procedure to post-procedure, and late relocation was defined as relocation from post-procedure to follow-up. Serial and matched changes of the MLA pre-, post-procedure, and at follow-up were investigated in the two cohorts.

In lesions with complete set of IVUS pre-, post-procedure, and at 3-year (n=366), acute and late relocations were observed in 200 (54.6%) and 238 (65.0%) lesions, respectively. Late MLA relocation was observed in 163/237 (68.8%) and 75/129 (58.1%) of lesions treated by BRS and EES, respectively (p=0.041). When matching pre-procedural MLA site with the same topographical sites post-procedure and at 3-year, BRS showed significant late lumen enlargement and expansive remodelling compensating for significant plaque increase, whereas EES showed significant late lumen narrowing with significant plaque growth not compensated by expansive remodelling from post-procedure to 3-year. In multivariate analysis, female gender (Odds ratio (OR) 2.05 [95% CI: 1.16, 3.63], p=0.014), previous PCI (OR 1.71 [95% CI: 1.05, 2.79], p=0.031), BRS implantation (OR 1.68 [95% CI: 1.02, 2.78], p=0.043), total device length (OR 1.04 [95% CI: 1.01, 1.07], p=0.006), maximal pressure either at device implantation or post-dilatation (OR 1.08 [95% CI: 1.00, 1.16], p=0.042) were independent predictors of MLA relocation.

CONCLUSIONS

Late MLA relocation was more frequent in lesions treated with BRS than EES. Late lumen enlargement and expansive vessel remodelling at the pre-procedural MLA site was observed in BRS, but not in EES.

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Relation between BRS sizing using QCA-Dmax and long-term clinical outcomes in 1,232 patients from three study cohorts (ABSORB Cohort B, ABSORB EXTEND, and ABSORB II)

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

AIMS

Scaffold oversizing, defined as a larger scaffold implantation as compared to both proximal and distal Dmax, is associated with higher rate of major adverse cardiac event (MACE) up to 1 year. This study sought to investigate the long-term clinical outcomes related to appropriate lumen sizing based on quantitative coronary angiography during implantation of bioresorbable scaffold.

METHODS AND RESULTS

A total of 1,248 patients who received Absorb bioresorbable scaffolds (BRS) in the ABSORB Cohort B, ABSORB EXTEND, ABSORB II trials were included in the analysis. The incidence of MACE (a composite of cardiac death, any myocardial infarction [MI], and ischemia-driven target lesion revascularization [ID-TLR]) was analyzed according to the Dmax subclassification of oversized scaffold group versus non-oversized scaffold group.

The analysis was performed comparing oversized scaffold group (n=649) and non-oversized group (any scaffold undersize. n=583). At 3 years, event rates were similar in both groups in MACE (9.4% vs. 9.8%, p=0.847), target vessel MI (5.2% vs. 4.8%, p=0.795), and ID-TLR (4.8% vs. 5.8%, p=0.445). Landmark analysis after 1 year showed that non-oversized scaffold group had higher rates of MACE (3.2% vs. 6.8%, log rank p=0.004), target-vessel MI (0.7% vs. 2.7%, log rank p=0.007), ID-TLR (2.4% vs. 4.6%, log rank p=0.041).

CONCLUSIONS

Implantation of an undersized Absorb scaffold in a relatively large vessel was associated with a higher risk of MACE between 1 and 3 years, while an oversized Absorb scaffold in a relatively small vessel was associated with a higher risk of MACE at 1 year.

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TAVI leads to improvement in cognition in several domains using a well-validated, computer-based method of cognitive assessment

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

AIMS

Cognitive decline is a well-recognised complication of open heart surgery. The same may be true of Transcatheter aortic valve implantation (TAVI), particularly given the known risks of embolization and stroke. Traditional cognitive function tests require trained neuropsychologists, are expensive to perform and hard to replicate across centres. Our aim was to trial a well-validated, computer-based cognitive battery of tests (CANTAB Eclipse). This requires minimal training and can be replicated in multiple centres. However, there is no data using these tests in the TAVI population.

METHODS AND RESULTS

Thirty-one patients due to undergo transfemoral aortic valve implantation were recruited to the study. Each underwent a standardised battery of 7 cognitive tests, designed to assess those domains tested in traditional cognitive function batteries. All but one of these tests had built-in methods for practice prior to the main test. The tests were carried out on a dedicated tablet PC, took between 50 and 60 minutes to administer each time and were carried out by one of three individuals using the standard script provided with the tests to reduce bias. These were performed pre-procedure, at 6 weeks and 6 months. A sub-set of 17 patients underwent two sets of tests pre-procedure at intervals of 1 to 6 weeks, with no significant differences found, implying no learning effect of the tests. A total of 4 patients did not complete follow-up due to not wanting to perform the tests, 2 patients felt too unwell at follow-up to complete the tests and 1 patient died between the 6 week and 6 month follow-ups.

Between baseline and 6 weeks there were improvements in two tests of reaction time (Motor Test, MOT p=0.04 and Stop Signal Test, SST p=0.03), one related to shape-based learning and known to be sensitive to age-related changes and Alzheimer?s (Paired Associate Learning, PAL p=0.03) and one related to written-word recall (Verbal Recognition Memory, VRM p=0.02). None of the remaining three tests showed a significant improvement or decline. Between baseline and 6 months, there were similar improvements in the MOT (p=0.01), SST (p=0.03) and PAL (p=0.01), although the improvement in VRM was not significant (p=0.11), again with none of the tests showing a significant decline.

CONCLUSIONS

The CANTAB Eclipse system can be successfully used for cognitive assessments in TAVI patients, providing an ideal tool for multi-centre studies due to it being operator-independent. Cognitive function in several domains shows improvement post-TAVI and there was no suggestion of cognitive decline in any domain. This pilot has identified those tests where changes are seen. This will help to rationalise the test battery for further studies, given that some patients found the whole battery difficult to complete.

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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

AIMS

After surgical or endovascular treatment of acute aortic dissection the complication rate 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 20 patients (18 men and 2 women), mean age 50 ± 16 years (15-69 y). We divide the patients in three groups. First group consists of 9 surgically treated patients (45%) with resection and prosthesis interposition of the ascending aorta in the context of acute type A AD and late bare aortic stent implantation. Second group consists of five patients (25%), one with type A, four with type B AD, who had combined treatment- endovascular stent graft implantation (TEVAR) and implantation of non covered stent due to residual compression. Third group includes six patients (30%) who underwent endovascular approach with only non-covered stents implantation. Two of them had type A AD- an implantation of stent from ascending to descending aorta was performed. The other four patients were with type B AD, with endovascular treatment of the descending and/or abdominal aorta. All patients presented with severe symptoms and evidence of end organ ischemia. In all patients CT aortography was performed with analyses of intimal tears localization, compression zone and measurement of true and false lumen diameter before and after decompression.Immediate symptom relief was achieved in all patients with restoration of flow in aortic branches and 0% mortality during the 1 year follow-up period. We performed urgent decompression in all patients, using different stent types- with the same immediate result: progressive true lumen expansion and false lumen decrease/thrombosis was proven. True lumen diameter increased from 7.46 ± 6.01mm before to 23.94 ± 7.27mm in the 6 month follow-up, $p < 0.001$, while false lumen diameter decreased from 27.97 ± 11.04 mm to 13.85 ± 12.21mm, $p = 0.001$.

CONCLUSIONS

Centralization of flow and decompression of the false 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. In our small series it proved to be a safe and effective way of restoring the flow in the aortic true lumen and its side branches, leading to positive aortic remodeling, relieve of end-organ ischemia and excellent survival.

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Fifteen-year follow-up of a patient with rescue endovascular treatment of complicated type A aortic dissection

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THEME: Peripheral Interventions
TOPIC(S): AAA

AIMS

METHODS AND RESULTS

CONCLUSIONS

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The long-term impact of post-procedural asymmetry and eccentricity of bioresorbable everolimus-eluting scaffold and metallic everolimus-eluting stent on clinical outcomes in the ABSORB II trial

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

AIMS

Previously, bioresorbable scaffold (BRS) was reported to exhibit more lumen eccentricity and asymmetry than metallic everolimus-eluting stent (EES) as assessed by intravascular ultrasound (IVUS) post-implantation and that lesion asymmetry was an independent predictor of device-oriented composite endpoint (DOCE) after 1 year following percutaneous coronary intervention. The aim of this study is to elucidate the impact of lumen asymmetry and eccentricity on clinical outcomes at 3 years.

METHODS AND RESULTS

The ABSORB II trial including 501 patients with de novo coronary lesions, randomized in a 2:1 ratio to receive either treatment with an everolimus-eluting BRS or with a metallic EES. IVUS pre, post-procedure, and at 3-year were mandated.

Among patients with post-procedural IVUS available (n=308 in BRS, n=162 in EES), DOCE (cardiac death, target-vessel myocardial infarction, or ischemia-driven target lesion revascularization) was observed 16 (5.2%) and 5 (3.1%) patients up to 1 year, 18 (5.8%) and 3 (1.9%) patients between 1 to 3 years, 34 (11.0%) and 8 (4.9%) patients through 3 years in the BRS arm and the EES arm, respectively. During the first year of follow-up, DOCE was observed significantly more in the asymmetric group than in the symmetric group (6.9% vs. 1.8%, p=0.007) or in the eccentric group than in the concentric group (8.2% vs. 3.5%, p=0.043). However, from 1 to 3 years, DOCE occurred in 10 of 246 patients (4.1%) in the asymmetry group and 11 of 224 patients (4.9%) in symmetry group (p=0.658), 4 of 97 patients (4.1%) in the eccentric group and 17 of 373 patients (4.6%) in the concentric group (p=0.854).

Changes in lumen asymmetry and eccentricity were analyzed in lesions with paired post-procedure and 3-year IVUS (247 and 136 lesions in the BRS and EES arm, respectively). In BRS, lumen became more asymmetric and eccentric in 3 years with asymmetry index (AI) increased from 0.34±0.08 to 0.42±0.09 (

CONCLUSIONS

At 1 year, clustering of DOCE in asymmetric and eccentric lesions was observed, however, at 3 years, cases with DOCE became scattered. In 3 years, lesions treated with the BRS became more asymmetric and eccentric. The different clustering of event cases in the scatter plot of asymmetry and eccentricity at 1 and 3 years suggests that the mechanical causes of long-term events are at variance with those of early events.

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Outcomes of elderly patients with ACS: a subanalysis of the SENIOR trial

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

AIMS

In the SENIOR trial, among patients 75 years old and above who undergo percutaneous coronary intervention (PCI), a bioresorbable polymer drug eluting stent (DES) and a short duration of dual antiplatelet therapy (DAPT) is superior to bare metal stent (BMS) with respect to the occurrence of all-cause mortality, myocardial infarction, stroke and ischemia-driven target lesion revascularisation. Outcomes of patients with and without acute coronary syndrome (ACS) at presentation are compared.

METHODS AND RESULTS

Among the 1200 patients, 45.3% (n=544) had an ACS at presentation (unstable angina, n=109, ST elevation MI, n=127, NSTEMI, n=308). Patients were randomized by a central computer system to either a DES (n=274, 50.4%) or a similar BMS (n=270, 49.6%), in a single-blinded way. The objective was to compare a composite primary endpoint of all-cause mortality, myocardial infarction, stroke or ischemia-driven target lesion revascularisation, and secondary endpoints including the rate of bleeding and stent thrombosis between DES and BMS-treated ACS patients at one year.

Compared to stable patients, patients with ACS were at higher risk of the primary ischemic endpoint (16.7% vs. 13.5%) but similar bleeding complication rates (3.8% vs 4.8%, RR 0.8 95% CI, 0.3 to 1.7, P=0.499). Among patients with ACS, the primary endpoint occurred in 38 patients (14.1%) in the DES group and in 46 patients (17.3%) in the BMS group (relative risk [RR] 0.80, 95% confidence interval [CI], 0.5 to 1.2 , P=0.312). Ischemia driven target-lesion revascularisation was reported in 7 patients (2.6%) in the DES group and in 14 patients (5.3%) in the BMS group (RR 0.5, 95% CI, 0.1 to 1.2, P=0.116). Bleeding complications (BARC 2-5) (5.2% vs. 4.9%, RR 1.1, 95% CI, 0.5 to 2.5, P=0.881) and stent thrombosis (0.7% vs. 1.1%, RR 0.7, 95% CI, 0.0 to 1.8, P=0.646) rates were low in both groups.

CONCLUSIONS

Among elderly ACS patients undergoing PCI, a DES was numerically superior to BMS with respect to the occurrence of all-cause mortality, myocardial infarction, stroke and ischemia-driven target lesion revascularisation up to one year.

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PCI in STEMI patients with multivessel disease: complete vs. incomplete revascularisation

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

The revascularisation strategy in ST-segment elevation MI (STEMI) patients presented with multivessel diseases (MVD) remains a topic of debate. While complete revascularisation in STEMI patients was not recommended in 2012?s guideline, latest ESC guideline state that complete revascularization should be considered. In this study, we compared one year clinical outcome of patients who underwent complete versus incomplete revascularisation.

METHODS AND RESULTS

In a large, multicentre, worldwide registry (e-Ultimaster), we identified 249 STEMI patients with MVD who underwent complete revascularisation at baseline procedure (COMP), and 416 STEMI patients with MVD who had incomplete revascularisation (INCOMP) at baseline procedure. COMP and INCOMP patients had similar age (63.5 and 63.7years) and 80% were male in both groups. Most of the baseline characteristics of these two groups were similar including rates of hypertension (59.4% vs 58.0%, p=0.74), current smokers (35.8% vs 31.9%, p=0.34) and previous PCI (8.2% vs 9.0%, p=0.78). The COMP patients tended to have lower incidence of renal impairment (4.4% vs 8.9%, p=0.03), and were more often already on dual antiplatelet therapy (83.1% vs 75.7%, p=0.025).

In COMP group 80% and in INCOM 88% of the procedures were performed via radial access. At index procedure, number of lesions treated were 1.7±0.8 vs 1.2±0.5,

CONCLUSIONS

In patients treated with thin-strut bioresorbable DES, a complete revascularisation strategy showed similar events rates as an incomplete revascularisation approach, with tendency towards lower patient oriented composite endpoint rate at 1 year. Our study provided some insights from a real life practice scenario and more evidence for this unresolved question.

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Clinical outcomes of amphilimus DES in an all-comer South-East Asian registry

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

AIMS

Amphilimus-eluting stent (AES) is a novel polymer-free drug eluting stent (DES) that combines sirolimus with fatty acid as antiproliferative drug and has shown promising results in percutaneous coronary intervention (PCI). There is limited data on the safety and efficacy of AES in Asian patients in contemporary clinical registries.

We evaluated the clinical safety and efficacy of AES in an all-comers South-East Asian registry and report on the 9-month clinical outcomes.

METHODS AND RESULTS

Between May 2014 to January 2017, 171 patients (88% male, mean age 59.3 ± 10.8 years) with a total of 182 coronary lesions were treated with AES. The primary endpoint was major adverse cardiac events (MACE) ie a composite of all-cause mortality, target vessel related myocardial infarction (MI), target lesion revascularization (TLR) and stent thrombosis at 9 months follow-up.

The majority of patients presented with acute coronary syndrome (71%) with 76% found to have multi-vessel disease on angiography. Diabetes mellitus was present in 74 patients (43%). 23% of patients had prior PCI and 25% had prior MI. Transradial access was used in 90% of cases. The most common target vessel for PCI was left anterior descending artery (48%) followed by right coronary artery (35%), left circumflex (9%) and left main (5%).

The majority of lesions were type B-C (88%) by ACC/AHA lesion classification with chronic total occlusion accounting for 5.3% of cases. Intravascular imaging was utilised in 8% of PCI. Glycoprotein 2b/3a inhibitor was used in 28% of PCI. An average of 1.23 + 0.5 AES were used per patient, with mean AES diameter of 3.1 ± 0.4 mm and average total length of 33.8 ± 16.7 mm.

At 9 months follow-up, 3.6% of patients developed MACE. MACE was mainly driven by all-cause mortality (2%), target vessel related myocardial infarction (2%) and TLR (2%). The rate of stent thrombosis (2 cases of subacute) was 1.2%.

CONCLUSIONS

In a real world all-comers South-East Asian registry, AES was found to be safe and effective with a low

incidence of MACE observed at 9 months follow-up.Larger studies with longer follow-up are required to confirm our initial observation.

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Treatment strategies and outcomes in elderly patients with atrial fibrillation undergoing PCI with planned short DAPT: a SENIOR subanalysis

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

AIMS

In the SENIOR trial, in patients 75 years and older who underwent a percutaneous coronary intervention (PCI) followed by a prespecified planned short duration of dual antiplatelet therapy (DAPT, 1-m or 6m), a bioresorbable-polymer drug eluting stent (DES) proved to be superior to a bare metal stent (BMS) at one year follow-up. This benefit was consistent across all subgroups except of a significant treatment interaction in patients with atrial fibrillation (AF).

METHODS AND RESULTS

Of the 1200 patients, 211 had AF at baseline (17.6%). AF patients were older (82±4.3 vs 81±4.2 years, p=0.005), less often female (34% vs 39%, p=0.17), and less likely to have an ACS at presentation (36% vs 48%, p=0.002), more likely to have a previous stroke (11% vs 6%, p=0.02) and previous CABG (9% vs 6%, p=0.06) than non-AF patients. A 1-m or 6m DAPT duration was prespecified by investigators in 77% and 23% AF patients, vs 52% and 48% in non-AF patients, and an oral anticoagulant was prescribed at discharge in 68% and 5% of AF and non-AF patients, respectively. The median DAPT duration was 32 days with AF vs 54 without. 9% AF patients had stopped DAPT before day 14, vs 8% of non-AF patients.

The composite primary endpoint of all-cause mortality, myocardial infarction, stroke or ischemia-driven target lesion revascularisation at one year occurred in 45 AF patients (21.6%) and in 121 (12.4%) non-AF patients (p=0.003). Among AF patients, the primary endpoint occurred in 23.8% patients randomized to DES versus 19.5% in the BMS group (RR 1.2, 95% CI, 0.7 to 2.1, P=0.452), while among non-AF patients, the primary endpoint occurred in 9.1% patients randomized to DES versus 15.8% in the BMS group (RR 0.6, 95% CI, 0.4 to 0.8, P=0.001). Bleeding complications BARC 2-5 rates were higher in AF than non-AF patients(13.2% vs. 3.1%, RR 4.3, 95% CI, 2.5 to 7.4, P

CONCLUSIONS

Compared to elderly patients without AF, elderly AF patients undergoing PCI have a higher risk profile and are treated with shorter DAPT durations. They are at increased risk for ischemic events irrespective of the stent type, and experience significantly more bleeding complications in the year following the procedure.

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Radial vs. femoral approach for SVG angiography and interventions

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

AIMS

Coronary angiography and intervention to saphenous venous grafts (SVGs) remains challenging due to technical aspects and thus, might preclude a wider adoption of the radial approach in this subset of patients. The aim of this study was to investigate the feasibility and safety of the radial approach compared to femoral access in a large cohort of patients undergoing SVG angiography and intervention.

METHODS AND RESULTS

Data from 1481 patients from Canada, US and Spain were collected between 2010 and 2016. Patients must have undergone diagnostic and/or interventional procedures and present with at least one SVG. Demographics, procedural data and in-hospital complications were collected.

A total of 863 and 618 procedures were undertaken by the radial and femoral approach, respectively. The mean number of SVGs per-patient was comparable between groups (radial: 2.3±0.7 versus femoral 2.6±1.1, P=0.610) but the radial group used fewer number of diagnostic catheters (2.3±1.5 versus 3.6±1.2, P

CONCLUSIONS

Transradial access for SVG angiography and intervention appears safe and feasible, without increasing fluoroscopy time. Radial access was associated with a statistically significant fewer catheters and lower contract volume, and numerically fewer bleeding and vascular access-site complications. Outpatients undergoing radial SVG-PCI had a higher likelihood for a same-day discharge home.

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Novel ultra-long (48 mm) everolimus-eluting stent for diffusely disease coronary vessels

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

AIMS

The best management of coronary artery disease patients with diffusely diseased vessels is an unresolved issue. When PCI is selected in diffusely diseased coronary vessels, complex procedures are often faced and full coverage strategy with DES of diseased vessel may be selected. Yet, long stenting (full metal jacket) is associated with higher risk of stent failure. Of note, DES overlaps represent critical areas for stent healing. A novel ultra-long DES became recently available and it theoretically may facilitate the treatment of long coronary lesions by reducing stent number and overlaps.

METHODS AND RESULTS

We retrospectively selected all patients who underwent PCI with ultra-long (48 mm) everolimus-eluting stent (EES) (Xience Pro®) between June 2015 and April 2017 in our centre. Clinical, angiographic and procedural characteristics were prospectively recorded in a validated database. Only exclusion criteria was cardiogenic shock before PCI. Target vessels were divided according to their angiographic presentation in ?diffuse disease? (diseased coronary segment ?38 mm) and ?multiple focal disease? (two or more significant stenosis separated by coronary segments >10 mm without significant disease). Clinical follow-up was performed to evaluate the occurrence of device-oriented composite endpoint (DOCE) (primary end-point), major adverse cardiac events (MACE) and target vessel revascularization (TVR) (secondary end-points).

A total of 216 patients (treated on 230 vessels) with acute coronary syndrome (n=104) or stable coronary artery disease (n=112) were identified. Mean age was 70.6 ± 11 years and 29% were diabetics. The target vessel appearance was ?diffuse disease? in 44.8% of cases and ?multiple focal disease? in 55.2%, a chronic total occlusion (CTO) was present in 10 lesions (4.3%).

PCI procedures were usually performed through the radial approach (95.7%). A ventricular assist support was adopted in 5.2%. To enhance support in order to facilitate stent/balloon delivery, Guideliner was used in 7% of cases. Multiple overlapping stents were implanted in 101 cases (43.9%), while a 48 mm EES in 129 (56.1%). Total stent length was 64.9 ± 24.0 mm and number of stents was 1.6 ± 0.7 per lesion.

Clinical follow-up was obtained in 95% of patients and median follow up time was of 363 (251?444) days.

The incidence of MACE was 10.1% (total mortality 3.9%, 4 patients with non-fatal myocardial infarction). All TVR were repeat PCI. No definite or probable stent thrombosis was noticed. The primary endpoint, DOCE, occurred in 5.5% of patients.

At multivariate analysis, ?diffuse disease? (p=0.03) and diabetes (p=0.02) were the independent predictors of DOCE.

CONCLUSIONS

The present single-centre experience reports the first real-world experience with the novel ultra-long (48 mm) EES. The low rate of DOCE observed in the study shows promising clinical results and calls for further

evaluations of the benefit of selecting longer DES in the case of full metal jacket PCI.

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Impact of advanced New York Heart Association functional class on early and long term outcome after TAVI: results from a multicentre analysis

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

AIMS

We sought to investigate the impact of an advanced functional New York Heart Association class (IV) at the admission on clinical outcomes after TAVI.

METHODS AND RESULTS

The population included 2,467 patients who underwent TAVI from June 2007 to September 2017 at 14 Italian centres of the Italian ClinicalService® Project. A severe impairment of functional status (New York Heart Association class IV) at the baseline was observed in 271 subjects (11%). Compared to patients presenting a functional New York Heart Association class ?IV, those with New York Heart Association class IV at the admission were more likely to have chronic kidney disease (36.4% vs. 20.3%,

CONCLUSIONS

An advanced New York Heart Association functional class at the admission was associated to an 80% increased risk of death within 3 months after TAVI. However, after this time-point, the mortality risk was comparable between patients with New York Heart Association class IV and those with New York Heart Association ?IV at the admission.

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Does the variable response to adenosine explain the disagreement between quantitative flow ratio and FFR?

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

QFR is a novel fluid dynamic-based method developed to estimate the hyperemic invasive translesional gradient, FFR. Overall, the agreement between QFR and FFR is very good. We investigated whether inter-individual variability in the hyperemic response to adenosine accounts for discrepant results between both techniques.

METHODS AND RESULTS

Methods: We enrolled patients who underwent FFR-guided coronary revascularization as part of a multicenter international registry. QFR was analyzed in a blinded manner at a core laboratory. The degree of hyperemic response during FFR measurement was defined as the difference (delta-Pa) between aortic pressure (Pa) at baseline and during hyperemia, achieved by intravenous adenosine infusion (140 mcg/kg/min). The type of hyperemic response was defined as hypotensive (HYPO) if delta-Pa was positive (+), or hypertensive (HYPER) if delta-Pa was negative (-). Diagnostic performance of QFR was compared between each tertile of delta-Pa in the HYPO group, and also between overall HYPO and overall HYPER groups. The efficiency of QFR was determined as the area under the receiver-characteristics curve (AUC), and accuracy as the binary concordant classification agreement by using the cutoff 0.80 for both QFR and FFR. The diagnostic performance of QFR was tested using FFR as reference on per-vessel analysis.

Results: 299 vessels from 247 patients were enrolled. Mean age, percent diameter stenoses (%DS) and FFR were 64.2±10.3 years (male 76%), 51.9±12.1% and 0.80±0.11, respectively. Mean Pa at rest and during hyperemia were 94.2±15.5 and 85.9±22.8 mmHg. In the HYPO group (214 patients, 253 vessels) mean delta-Pa was 12.4±10.4 mmHg (tertile 1:

CONCLUSIONS

Inter-individual variations in the degree of hyperemic response to adenosine infusion do not seem to influence the diagnostic efficiency of QFR, as judged by FFR, nor the occurrence of disagreement between both techniques.

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Hybrid procedure in lower limbs salvage

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THEME: Peripheral Interventions
TOPIC(S): AAA, Iliac / Femoral / Popliteal

AIMS

To improve the surgical treatment of patients with multilevel lesions of arteries of lower extremities.

METHODS AND RESULTS

Material and Methods: From March 2013 to June 2017 58 patients with multilevel lower extremity arterial occlusive disease underwent hybrid procedure . The mean age was 66 years (range: 39-82) Most patients were male (31 males, 55%). According to the Fontaine grading, 26 patients (43%) were treated for severe intermittent claudication , 25 patients (39%) had persistent rest pain and 97 patients (24%) had minor tissue loss . And 1 patient with acute ischemia. Iliac lesions were defined according to the TASC II Type A 5 patients type B 3 patients type D 12 patients. The most commonly associated cardiovascular risk factors were hypertension (100%), smoking (59%), dyslipidaemia (73.6%), coronary artery disease (76.3%). Totally 60 hybrid interventions were performed (2 patients underwent procedures on both extremities).

Techniqu?: The most common open procedure was endarterectomy of the External iliac artery and stenting 41 , SFA remote endarterectomy folowed by PTA of BTK vessels 12 cases, Iliac stenting with SFA endarterectomy in 9 cases Iliac stenting Femoro-popliteal bypass 8.Technical success was achieved in all patients (100%). Mean ABPI increase was 0.40. Mean length of hospital stay (6.1 days). The median follow-up period was 10.5 months (range, 1-18 months), Primary patency rates at 12 months 86.7%. Limb salvage rates 95%.

CONCLUSIONS

Hybrid procedures provide an effective treatment of multilevel lower extremity in critical limm ischemia . Our data suggest that the immediate results, expressed as technical and haemodynamic success and the mid-term outcomes, represented by the patency and limb-salvage rates, are satisfacto

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Ultrasound-guided distal transradial (snuff box area) access for coronary angiography and angioplasty using 5Fr guiding or 6Fr sheathless guiding system

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

AIMS

To demonstrate the feasibility and safety of the distal transradial approach (snuff box) for coronary angiography and interventions.

METHODS AND RESULTS

Methods: The clinical, angiographic and ultrasonography data of 106 consecutive patients with symptomatic coronary artery stenosis between 2017.01 and 2017.12 were evaluated in a pilot study. The distal radial artery was investigated with a Doppler ultrasound and the puncture was made by ultrasound guidance. At the first postoperative day, all radial arteries were examined by vascular ultrasound. We have used 5F Terumo sheath for coronary angiography and after diagnostic angiography we have used 5F or 6.5 sheathless guiding for the intervention. Sheathless guiding was used for rotational atherectomy, left main and complex bifurcation intervention and for CTO recanalisation). We have investigated the technical success of the procedure, the rate of MACEs and the rate of access site complications.

Results: The ultrasound guided radial artery puncture and the procedure were successful in all cases (106/106). The cross-over rate to alternative access site was 0%. The procedure was finished with good angiographic result in all cases (100%). PCI was performed in 80 cases with a 6.5F sheathless guiding in 16 cases and through a 5F guiding in 64 cases. Mean contrast consumption was 115 [86-14.3] ml, DAP was 34.8 [18.7-51.5] Gycm2, fluoroscopy time 7.1 [4.5-9-8] minutes. The size of the radial artery in the snuff box and conventional punture area was 2.14 ± 0.5 vs. 2.27 ± 0.7 mm (

CONCLUSIONS

Ultrasound guided distal transradial access from the snuff box area is safe and effective and the rate of radial artery occlusion is extremely low.

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Absolute coronary blood flow and microvascular resistance: correlation with instrumented coronary artery blood flow ring measurements and coronary histology analysis in swine

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

AIMS

Measurement of absolute coronary blood flow (ABF) and microvascular resistance, assessed by coronary thermodilution using a dedicated infusion catheter (RayFlow, HexaCath, Paris, France) is available in clinical practice. We sought to compare ABF and resistance values obtained at different infusion rates, to coronary artery blood flow ring measurements and histological analysis of the infused vessel in animals.

METHODS AND RESULTS

Domestic swine were instrumented with coronary artery blood flow (CBF) rings on the left anterior descending (LAD) and circumflex (LCx) coronary arteries. We performed ABF using saline infusion at room temperature, at flow rates of 5, 10, 15 and 20 mL/min. After measurement, histological analysis of the infused vessel was performed, at the level of the infusion and at least 60 mm distal to the infusion area (control).

In 13 swines, we compared 72 pairs of measurements in the LAD and the LCx. The correlation between ABF and CBF at flow rates of 5 and 10 mL/min were R= 0.67 (0.45-0.82) (n= 40 pairs). The correlation between ABF and CBF at flow rates of 15 and 20 mL/min were R= 0.84 (0.69-0.92) (n= 32 pairs). The correlation between resistances assessed with ABF and CBF at flow rates of 5 and 10mL/min were R= 0.63 (0.34-0.80) (n= 32 pairs). The correlation between resistances assessed with ABF and CBF at flow rates of 15 and 20mL/min were R= 0.76 (0.56-0.88). Maximal hyperaemia, comparable to 45 seconds of coronary occlusion, was observed with saline infusion rates of 15 and 20 mL/min (n= 32 pairs). Histological analysis was performed in 14 coronary arteries (28 samples), and showed no coronary dissections after ABF measurement. Some endothelial injury was observed in both infusion and control samples: 62 ± 39 % and 53 ± 38% (p=0.53), respectively. Endothelial injury in the control sample parts might be due to trauma caused by the pressure wire.

CONCLUSIONS

ABF and microvascular resistance correlate well with CBF in animals at flow rates ?15 mL/min. Measurement using coronary thermodilution with Rayflow infusion catheter is accurate in vivo and, in clinical practice, at flow rates of 15 to 20mL/min, induce maximal hyperemia and may be as safe as FFR measurement.

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Mechanism of hyperaemia induced by saline infusion during coronary thermodilution: animal experimentation

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

AIMS

Absolute coronary blood flow and resistance can be measured by thermodilution with a dedicated catheter (RayFlow, HexaCath, Paris, France). The infusion of saline (15-20 mL/min) through the RayFlow Catheter induces maximal hyperaemia. We aimed to explore the mechanisms of this hyperemic response.

METHODS AND RESULTS

In 19 domestic swines, instrumented with quantitative Doppler coronary blood flow (CBF) rings on the left artery descending (LAD) and circumflex (LCx) coronary arteries, saline was infused through a RayFlow catheter in the proximal part of the artery to induce hyperemia. The latter was compared to the hyperemic response to a 45 s coronary occlusion. The possible mechanisms of saline-induced hyperemia were explored under various experimental conditions: (1) at different infusion rates, (2) infusion through an end-hole rather than to the side-holes, (3) infusion at body temperature, (4) infusion after inhibition of the endothelial function by (L-arginine methyl ester) L-NAME, by endothelial destruction, or by the placement of a (covered) stent, and (5) vibrations as induced by the use of a Rotablator at different speeds.

Compared to hyperaemia induced after 45 seconds of coronary occlusion we confirmed that that maximal hyperaemia was elicited by saline at room temperature infused through the side holes at a rate ?15 mL/min without any signs of myocardial ischemia. This response persisted with saline at body-temperature and with the infusion of glucose but could not be obtained when saline was infused through an end-hole. A maximal hyperaemic response also occurred after L-NAME (n=10), after balloon de-endothelialisation (n = 8), after stent (n = 3) and covered stent implantation (n = 2). High-speed (160000rpm) but not low-speed (40000 rpm) Rotablation also induces maximal hyperaemia (n = 4).

CONCLUSIONS

These data confirm that maximal hyperemia is induced by the infusion of saline at room temperature (?15 mL/min) through the 4 side-holes of the RayFlow catheter. This phenomenon is not induced by ischemia and does not depend on the endothelial integrity but might relate to vibrations of the epicardial wall and its neurogenic transmission to the resistive vessels.

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A novel approach to assess cerebral perfusion and hemodynamic changes after cardiac arrest with absolute blood flow and microvascular resistance measurements in a porcine model

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THEME: Interventions for Stroke
TOPIC(S): Other stroke interventions

AIMS

Several indices exist to assess cerebral perfusion after cardiac arrest (CA). We aimed to investigate a new approach allowing absolute flow and microvascular resistance measurement based on selective arterial continuous thermodilution before and after CA resuscitation in an animal model.

METHODS AND RESULTS

In anaesthetised pigs, intravascular absolute cerebral blood flow (CBF) and coronary blood flow (ABF) with corresponding microvascular resistances were measured. CA was induced with 3 and 5 minutes of no-flow time in group 1 and 2, respectively. CBF was obtained at baseline, at 15 minutes (T15) and 30 minutes (T30) after resuscitation. Thereafter, CBF in the contralateral cerebral artery and ABF were measured.

Thirteen pigs were included in this protocol: five in group 1 and eight in group 2. The protocol could not be completed in three pigs from group 2 due to haemodynamic instability. Compared to baseline, significantly lower CBF (0.040 ± 0.03 vs. 0.026 ± 0.02 L/min, p=0.03) and significantly higher cerebral microvascular resistances (2014 ± 1015 vs. 3202 ± 1838 Woods Units, p=0.04) were observed at T30. ABF and resistances remained stable at baseline, as compared to T30 (0.122 ± 0.05 vs. 0.143 ± 0.06 L/min, p=0.15 and 563 ± 203 vs. 478 ± 181 Woods Units, p=0.36, respectively) with similar haemodynamic parameters. The same trend was observed in both groups according to no-flow time.

CONCLUSIONS

ABF and CBF measurement after CA resuscitation is feasible with thermodilution technique, allowing accurate monitoring and measurements. This novel approach allows simultaneous measurements of flow and microvascular resistances. This animal model simplifies experimentations to evaluate cerebral perfusion and test therapies.

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One-year results of the e-Cobra registry: 1,027 all-comer, consecutive, prospective, high-risk patients treated with the Cobra PzF NanoCoated Coronary Stent (NCS)

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(1) ,

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

AIMS

The CeloNova COBRA PzF? NanoCoated Coronary Stent is a new stent design, balloon expandable cobalt chromium alloy coronary stent with 71um thin struts. The alloy stent is surface coated with a nano-layer of Polyzene-F (PzF) [Poly-bis(trifluoroethoxy) phosphazene]. Polyzene-F is an inorganic polymer with a high molecular weight. Polyzene-F is a thrombo-resistant and has anti-inflammation and rapid healing properties that help prevent tissue reaction. e-Cobra Registry is a large real world evalaution of the device in high risk parients with short DAPT.

METHODS AND RESULTS

1 027 all comers, consecutive patients, non-eligible for prolonged DAPT, have been included from 17 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

1 027 patients have been enrolled and One year results of the whole population will be presented

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Endovascular approach in treatment of critical lower limb ischaemia

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(1) ,

THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal

AIMS

To show effectiveness of endovascular procedures in patients with critical lower limb ischemia.

METHODS AND RESULTS

From March 2013 to June 2017 68 patients with arterial occlusive disease underwent 81 endovascular procedures.. The mean age was 68 years. Most patients were male (88,2%). 26 patients had persistent rest pain and 42 patients had minor tissue loss. Iliac lesions were defined according to the TASC II Type A 7 patients, type B 4 patients, type? 2 patients type D 12 patients. PTA/stent procedure . Selective angiography was performed with the patient under local anesthesia through a contralateral, retrograde, or ipsilateral antegrade common femoral artery approach using 6F or 7F sheaths. Lesionswere crossed with platinum-tipped (0.018, 0.014) or hydrophilic wires (0.035, 0.018, 0.014) and balloon angioplasty was performed under systemic anticoagulation. Subintimal angioplasty was used to traverse occluded SFA lesions in 5 cases. Balloon catheter diameter was chosen to match the nondiseased artery adjacent to the lesion. A selective approach to the use of Nitinol self-expanding stents was used for flow-limiting dissections or when angioplasty alone did not produce a satisfactory result, for SFA. For Illiac lesions always used stents. Postprocedure, all patients were given a loading dose of clopidogrel (300 mg) and maintained on 75 mg per day for 12 weeks. Patients also received 325 mg of aspirin on the day of the procedure. Results: primary technical success in group with A, B, C TASC II aortoiliac lesions was 100%, with D TASC II aortoiliac lesions was 91,7%. In group with infrainguinal lesions overall primary technical success was 91,9%. Regression of ischemia was marked in all patients. During one year follow-up period 3 major amputations were performed (5,8% of follow-up patients), all in cases of above knee interventions with one recanalized tibial artery. Limb salvage rate was 94,2% .

CONCLUSIONS

Endovascular procedures are effective in patients with critical lower limb ischemia

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The modified natural history of mitral regurgitation in patients undergoing TAVI

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

AIMS

Previous studies highlighted the importance of mitral regurgitation (MR) in patients undergoing transcatheter aortic valve implantation (TAVI). We sought to investigate whether baseline or post-procedural MR is more prognostic, what MR severity threshold is more clinically-relevant, and whether the likelihood of MR regression/ persistence can be estimated.

METHODS AND RESULTS

MR was assessed by transthoracic echocardiography and classified into none-trace, mild, moderate, moderately-severe, and severe at baseline (before TAVI) and 30 days post-TAVI. Greater than moderate MR (moderately-severe and severe) were collectively labeled severe MR. A total of 875 patients underwent TAVI (age, 80.6±6.6 years, male, 45.8%, STS-PROM, 5.8±4.9). At baseline, MR was none-trace in 87 patients (10.2%), mild in 502 (58.9%), moderate in 217 (25.4%), and severe in 47 (5.5%). Severe, but not moderate, MR at baseline was associated with increased rates of 1-year all-cause mortality (13.4%, 15.4%, and 28.3% for patients with ?mild, moderate, and severe MR, log rank p: mild vs. moderate, 0.521, moderate vs. severe, 0.037, mild vs. severe, 0.006) and cardiovascular mortality (7.1%, 11.3%, and 17.2% , log rank p: mild vs. moderate, 0.077, moderate vs. severe, 0.369, mild vs. severe, 0.038).

Severe MR at baseline improved to mild or less in 6 patients (13.6%). Moderate MR at baseline improved to mild or less in 110 patients (55.0%). None-trace or mild MR at baseline deteriorated to ?moderate MR post-TAVI in 85 patients (15.5%). Eventually, on 30-day echocardiography, ?moderate residual MR was present in 215 patients (26.7%) and was associated with increased mortality as compared to patients with residual ?mild MR (all-cause mortality: 16.3% vs. 10.4%, log rank p=0.033, cardiovascular mortality: 10.4% vs. 4.8%, p=0.007). On the other hand, mortality did not differ between moderate and severe residual MR (p=0.704). Therefore, patients with residual MR ?moderate were combined in one group (significant MR group), in which the risk of all-cause (HR: 1.65 [1.08-2.52], p=0.020) and cardiovascular mortality (HR: 2.17 [1.21-3.88], p=0.009) was increased. Among survivors at 1 year, residual impairment of functional capacity (i.e. NYHA? II) was more likely in patients with significant (43.3%) than in patients with non-significant residual MR (34.0%, p=0.038).

After accounting for the severity of MR at baseline, the following 5 factors were associated with significant residual MR on multivariable regression analysis: atrial fibrillation (OR: 1.60 [1.01-2.52], p=0.046), reduced LVEF (OR: 2.14 [1.53-2.98], p2 risk factors.

CONCLUSIONS

Severe baseline MR and moderate post-TAVI MR are associated with impaired outcomes after TAVI. Significant residual MR after TAVI can be predicted based on the combination of baseline MR severity and a set of baseline and procedural risk factors.

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Long-term outcomes of the LifeTech LAmbre device for LAA occlusion: the German LAmbre registry

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

AIMS

We here report first European experience with the novel LAmbreTM left atrial appendage occlusion (LAAO) system, a self-expanding device consisting of an umbrella and a cover connected by a central waist.

METHODS AND RESULTS

A total of 60 consecutive patients with atrial fibrillation and contraindication to oral anticoagulation underwent LAAO with the LAmbreTM device at two German centers between November 2013 and September 2015. Procedural success rates, along with transesophageal echocardiographic and clinical follow-up at 1, 6, and 12 months, are reported.

Mean age of the patients was 74.4±9.0 years (66.7% men). Implantation success with stable device placement was high (100%). In 3 (5.0%) patients, exchange of the device for a different size was necessary. Procedure-related complications included 2 (3.3%) pericardial effusions requiring pericardiocentesis.

Nearly complete sealing of the LAA orifice (residual jet flow of

CONCLUSIONS

This study demonstrates the safety, efficacy, and advantages of the LAmbreTM LAAO device for stroke prevention in patients with contraindications to oral anticoagulation.

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Performance of a new automated resting pressure-derived index during PCI compared to FFR - the PREDICT multicentre prospective study

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

AIMS

Non-hyperemic pressure-derived indices have emerged as an alternative to fractional flow reserve (FFR) for the hemodynamic evaluation of coronary stenoses. Recently, the instantaneous wave-free ratio (iFR) has been shown to be non-inferior to FFR with respect to major cardiovascular outcomes at 1 year. We have developed a novel resting pressure index that automatically determines the lowest distal coronary (Pd) to aortic (Pa) pressure ratio as a measure for stenosis severity and tested its relationship with FFR.

METHODS AND RESULTS

In a multicenter study, patients with coronary artery disease and an indication for FFR were prospectively enrolled. Pd/Pamin was defined as the lowest Pd/Pa ratio during the cardiac cycle, representing the maximal translesional pressure gradient occurring at peak coronary blood flow (under resting conditions), and calculated automatically using dedicated software. To test for reproducibility, two measurements of Pd/Pamin were performed one minute apart at baseline and a third, 3 minutes after completion of the FFR measurement, FFR was determined using IV adenosine, according to standard practice. A central core laboratory reviewed all pressure tracings for significant artifact or pressure drift.

In 108 patients, 124 lesions were evaluated (69% in the 30-70% intermediate range by visual estimation and 51% located in the LAD). After core lab validation, 116 lesions were available for analysis. Mean FFR was 0.82±0.09 (

CONCLUSIONS

The novel index Pd/Pamin was reproducible and performed similarly to other resting indices in prior reports against core lab validated FFR in a clinical population of intermediate stenosis. Although further testing and validation is warranted, this simple measure may provide an alternative for non-hyperemic physiological assessment in the future. (ClinicalTrials.gov ID: NCT03237169)

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Regional differences in one-year clinical outcomes following PCI with the dual-therapy COMBO stent: results from the global COMBO collaboration

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

AIMS

The novel COMBO stent is a dual-therapy stainless steel stent with 100µm strut thickness combining sirolimus-elution with an anti-CD34+ antibody layer. This anti-CD34+ layer can promote early endothelialization. The clinical outcomes with this pro-healing stent have been evaluated in the MASCOT and REMEDEE registries. In this analysis we investigated the influence of regional factors on 1-year clinical outcomes from the COMBO collaboration.

METHODS AND RESULTS

The COMBO Collaboration is a pooled patient level analysis of the MASCOT and REMEDEE registries. The REMEDEE registry was a European registry (n=1000, 9 sites in 5 countries). The MASCOT registry was a global registry conducted in Asia, Europe and Egypt, Tunis and Venezuela (n=2614, 61 sites in 19 countries). All-comer patients undergoing percutaneous coronary intervention (PCI) were enrolled with follow up at 30 days, 6 months and 1 year. All endpoint adverse events were adjudicated by independent clinical event committees. The primary outcome for this analysis was 1-year target lesion failure (TLF), defined as a composite of cardiac death, target vessel myocardial infarction (TV-MI) or target lesion revascularization (TLR). The COMBO collaboration included 3614 patients, including 2775 European patients (76.8%), 604 Asian patients (16.7%) and 235 (6.5%) patients from other regions. For this analysis we compared Europe vs. Asia and excluded other region patients due to the small numbers. European patients were older than Asian patients (65.1± 10.8 years vs. 58.7± 11.2years), and included more females (25.3% vs. 17.1%). Although more than half the patients presented with cute coronary syndrome, the prevalence was lower in Europe vs. Asia (54.8% vs. 60.0%). At one year, TLF occurred in 4.1% European patients (n=113) vs. 4.0% Asian patients (n=24), p=0.932. The incidence of cardiac death was lower (0.3% vs. 2.8%, p=0.007), whereas the incidence of TLR was higher (2.5% vs. 1.0%, p=0.025) in European vs. Asian patients, without differences in the rate of TV-MI (1.2% vs. 1.5%, p=0.536).

CONCLUSIONS

The COMBO collaboration is the first study to examine regional effects in the occurrence of 1-year TLF among patients treated with the COMBO stent. Significant differences were noted in baseline characteristics of patients undergoing PCI in Europe compared to Asia. Although 1-year TLF was similar, significant differences were noted in the individual components of TLF with lower cardiac death but higher TLR in European patients.

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Clinical outcomes in patients with and without diabetes mellitus after treatment with dual-therapy COMBO stent

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

AIMS

The novel bio-engineered COMBO stent has been shown to allow safe shorter duration of dual-antiplatelet therapy by combining sirolimus-elution with an anti-CD34+ antibody layer. This layer can attract circulating endothelial progenitor cells that can form endothelial cells on the stent surface. The aim of this analysis is to evaluate the impact of the insulin treated diabetes mellitus (ITDM) and non-ITDM compared to non-DM on clinical outcomes after treatment with the new COMBO stent.

METHODS AND RESULTS

This patient level pooled analysis consists of all patients enrolled in the MASCOT (n=2614) and REMEDEE registries (n=1000). These large, prospective, all-comer registries evaluated target lesion failure (TLF) at one year follow-up as primary endpoint, defined as a composite of cardiac death, target-vessel myocardial infarction (TV-MI) or clinically driven target lesion revascularization (TLR). Clinical follow-up was obtained at 30 days, 6 months and 12 months post-procedure. All events were adjudicated by independent clinical event committees. Clinical outcomes were analyzed in a time-to event manner using Kaplan-Meier methods and groups were compared using the log-rank test. Of the 3614 patients in the pooled COMBO dataset, 9 patients (0.2%) did not have information on diabetic status and were excluded from the analysis. Of the total 3605 patients 2546 (70.6%) were non-DM patients.

In DM patients the mean age was 64.3± 10.2years and 26.9% of patients were female. In non-DM patients mean age was 63.2± 11.6 with 22.5% females. In 49.9% of DM patient presentation was acute coronary syndrome and 56.1% in non-DM patients. TLF at 1-year follow-up occurred in 4.6% of DM-patients (N=49) and 3.5% of non-DM patients (n=90), p=0.114. From the diabetic patients 272 (7.5%) had ITDM and 787 (21.8%) were non-ITDM. When non-DM patients are compared with non-insulin treated DM (nITDM) patients and insulin treated DM patient (ITDM) event rates are 3.5% in non-DM, nITDM 3.7% and 7.4% in ITDM, p = 0.007.

CONCLUSIONS

In the largest pooled patient level analysis of patients treated with COMBO stent we found overall low one-year clinical event rates. A numerically higher, but not significant difference between patients with and without DM at one year follow-up is observed. ITDM patients have a significantly higher TLF rate compared to nITDM and non-DM patients.

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Peri-procedural, in-hospital and long-term clinical outcome of patients with reduced left ventricular ejection fraction undergoing rotational atherectomy

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

AIMS

This study aims to analyze the feasibility and outcome of rotational atherectomy (RA) in high-risk patients with reduced left ventricular ejection fraction (EF) presenting with severely calcified coronary lesions.

METHODS AND RESULTS

This is a retrospective analysis of prospectively collected data in a single center registry. Between November 2002 and July 2015, a total of 588 patients were treated with RA at a single high volume center. Of these, 177 patients treated for 194 lesions presented with a left ventricular EF lower than 50% as evaluated by echocardiography or angiography and constituted the population of the current study.

Overall, the mean age of the study population was 72.6 ± 10 years and 74.6% were male. The mean ejection fraction was 36 ± 9 % and in 88 patients (49.7%) the EF was ? 35%. Diabetes mellitus was present in one third of the study population (37.3%) and a history of myocardial infarction in 25 patients (14.1%).

RA was performed in the left main coronary artery in 34 patients (17.5%) and 9.3% of treated lesions were chronic total occlusions. The 1.5mm burr size was used in 43.3% of cases with a mean burr to artery ration of 0.51 ± 0.08. Hemodynamic support with an intra-aortic balloon pump was used in 14 patients (7.9%). Procedural outcome was characterized by high rate of procedural success (183 lesions, 94.3%). Slow- / low-flow phenomenon was documented in 10 patients (5.1%) and coronary perforation in 4 patients (2.1%).

The rate of in-hospital major adverse cardiac events (MACE) defined as the composite of all cause mortality, target vessel revascularization and myocardial infarction was 13.6%. In hospital mortality occurred in 8 patients (4.5%) and periprocedural myocardial infarction in 16 patients (9%). Long term follow-up was available for 93% of the study population. The Kaplan-Meier estimated rate of MACE at two years was 36.6%. Mortality at two years was 22.7%.

CONCLUSIONS

In a population of very high risk patients with reduced left ventricular EF having severely calcified coronary lesions, the use of RA is safe with a relatively low risk of peri-procedural complications. However, in-hospital and long-term mortality remain high.

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Ultrasound-assisted, catheter-directed thrombolysis in patients with pulmonary embolism at high-risk and intermediate-high-risk: short-term and long-term efficacy and safety outcomes from a large single-centre study

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

AIMS

Ultrasound asssisted thrombolysis (USAT) is a novel technology which provides a high efficacy with a reduced bleeding risk in patients (pts) with acute pulmonary embolism (PE). In this study, we aimed to evaluate the correlates of short-term and long-term efficacy and safety outcomes after USAT treatment in patients with PE at intermediate-high and high risk status (IHR, HR).

METHODS AND RESULTS

Our single-centre study is based on retrospective evaluation of 141 pts (age 61,8 (20 - 93) with PE who underwent USAT treatment after diagnostic and prognostic work-up including computed tomography (CT), echocardiography, biomarkers, PE severity indexes and cardiac catheterization.

Baseline risk status were HR and IHR is 17 and 124 pts, respectively. The median time delay from symptoms to USAT was 5 days, and bilateral device placement was needed in 113 of the pts. The mean tissue-type plasminogen activator (t-PA) dosage was 36,1±15,3 mg, and infusion duration was 24,5±8,1 hours. The USAT resulted in significant improvements in tricuspid annular planary systolic excursion and systolic tissue velocity, Qanadli score of pulmonary arterial (PA) obstructive burden, right to left ventricle diameter ratio (RV/LV ratio) and right to left atrial diameter ratio, PA diameters and invasively assessed PA pressures, irrespective of the risk status ($p < 0.0001$ for all). In-hospital death, and major and minor bleeding rates were 5,7%, 7,8% and 11,3%, respectively. Post-discharge follow-up (median 752 days ,8 ? 1803 days) data were available in all of the pts. Although the absolute and % changes in RV/LV ratio (p=0.032 and 0.009) and % change in PA mean pressure (p=0.026) were significantly higher in pts younger than 65 years compared with older pts, overall bleeding, 30-day and long-term mortality rates were similar. The HR compared with IHR status was only associated with a higher 30-day mortality (unadjusted hazard ratio 4.74 (1.13-20), log-rank p=0.018). Bleeding risk and mortality were not associated with lytic dosage or infusion duration.

CONCLUSIONS

Our study has confirmed that USAT improved the lysis of PA clot, stabilization of right heart functions and hemodynamics with acceptable risks of complications in pts with PE regardless of the risk status. The HR compared with IHR status, but not age, related to a higher short-term mortality risk. Moreover, data seem to be consistent with novel low-dose and shorter-duration t-PA infusion hypothesis in USAT treatments.

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Short-term, mid-term and long-term clinical outcome in diabetic patients with different stent length and diameter

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Is to evaluate the effect of vessel size (diameter and length of lesions) in clinical outcome of diabetic patients after PCI in the setting of DES, tight control of DM, long-term use of antiplatelet therapy, and statin therapy.

METHODS AND RESULTS

1630 patients underwent PCI in Shiraz hospitals between 2006 till February 2017 entered this retrospective cohort study. 485 diabetic and 1145 non-diabetic patients had a long mean follow up period of 74.0±46.6 months and for all diabetic patients and most of non-diabetic patients we used DES, dual anti platelet-therapy, Statin therapy and hypertension control, and in diabetic patient',s blood sugar was tightly controlled. The entire patients evaluated according to lesion length (less or more than 27 mm), diameter of lesion (less or more than 3 mm), sex (Male or female) and age (above and below 55) at the time of procedure.This study showed that in the era of DES with long term use of dual anti-platelet therapy, using DES stents with different diameter and length in diabetic patients has no influence in major adverse cardiac event rate of male and female diabetics with comparison to non-diabetics in short-term, mid-term and long-term term follow up. Also time to clinical end point was not statistically different in male and female diabetics and non-diabetics above and below 55 years old.

CONCLUSIONS

It seems that in the era of DES, tight control of DM, hypertension and use of long-term (more than 2 years) Dual anti platelet-therapy, the impact of DM doesn',t influence the major adverse cardiac event rate with different lesion length & diameter in different age & sex group.

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Five-year prognostic value of cumulative FFR measurements in patients with diffuse, but hemodynamically not significant, coronary artery disease

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

To investigate whether the sum of the FFR values correlates with clinical outcome in patients with diffuse 3-vessel disease but no FFR value ?0.80.

METHODS AND RESULTS

A total of 1,122 patients without any significant lesion (n=275) or with at least one lesion treated with PCI (n=847, and with measured post-PCI FFR) were included in this study. None of the FFR values were below the ischemic threshold. The patients were classified into high, mid or low total FFR according to the the 3 tertiles of total FFR (<2ish.80 , 2.80-2.88 , >2.88). The primary endpoint was major adverse cardiac events (MACE, composite of death, myocardial infarction and any revascularization) at 5 years. The patients in low total FFR group showed a higher risk of 5-year MACE than those in the mid and high group (28.7% vs. 22.0 and 20.4%, respectively, P = 0.020). The higher 5-year MACE rate was mainly driven by a higher rate of revascularization in the low total FFR group (17.0% vs. 11.5 and 11.6%, respectively, P = 0.043). In a multivariable model adjusted for baseline differences, cumulative FFR was an independent predictor of MACE (HR 0.305 [0.109 , 0.853] , P=0.024).

CONCLUSIONS

Even in the non-ischemic range, a lower hemodynamic impact of diffuse epicardial atherosclerosis (high total FFR value) translates into better clinical outcome in patients with diffuse 3 vessel disease.

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Impact of new permanent pacemaker implantation on long-term survival after TAVR

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

AIMS

Transcatheter aortic valve implantation (TAVI) is an alternative treatment to surgical aortic valve replacement in intermediate-to-high risk patients with symptomatic severe aortic stenosis. One of the most common complications after TAVI is the appearance of conduction disturbances that may require permanent pacemaker implantation. The aim of this study was to investigate the impact of permanent pacemaker implantation on patients? survival after one-year follow up.

METHODS AND RESULTS

This observational study included 383 consecutive patients with severe aortic stenosis who received TAVI at our institution by transfemoral approach from January 2008 to September 2017. 39 patients (10.2%) already had a permanent pacemaker at baseline (previous- permanent pacemaker implantation group), 42 (12.2%) received permanent pacemaker for rhythm disturbances related to the procedure (new- permanent pacemaker implantation group) and 303 patients (79.1%) did not need permanent pacemaker implantation (no- permanent pacemaker implantation group). Follow-up visits were planned for all patients at 3 months and 1 year. Survival was assessed using Kaplan-Meier analysis and differences between groups were compared by log-rank test.
Mean age of patients was 83.1±6.7 years, 54.6% were female. Balloon-expandable valves were used in 54.3% of cases. Permanent pacemaker implantation frequency (calculated excluding patients with permanent pacemaker before TAVI procedure) decreased through the years (from 21.4% in 2008 to 10.6% in 2017) while the number of procedures definitely increased (17 procedures in 2008 versus 96 in 2017), a lower incidence of permanent pacemaker implantation was observed after TAVI with balloon-expandable valves compared to self-expandable (8.0% versus 17.3%, p=0.094). After one-year follow up, survival was 91.6% in the no- permanent pacemaker implantation group, 86.0% in the new- permanent pacemaker implantation group and 82.5% in the previous- permanent pacemaker implantation group, although the difference between groups was not statisticallty significant (p=0.295).

CONCLUSIONS

Implantation of new permanent pacemaker after TAVI does not affect 1-year survival. Patients with previous permanent pacemaker implantation showed a numerically higher incidence of mortality at 1 year follow-up in comparison with either patients without permanent pacemaker and those with new- permanent pacemaker.

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AMI: role of percutaneous revascularisation strategy in cardiogenic shock

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Most patients with acute myocardial infarction that are admitted in cardiogenic shock have multivessel significant coronary disease. It´s well known that the sooner the revascularization, the better the prognosis, but in these patients, it?s still a matter of debate whether PCI should be performed immediately for significant stenosis in non-culprit arteries.

The aim of this study was to evaluate the effects of revascularization strategy (PCI of the culprit lesion versus immediate multivessel PCI) in patients with acute myocardial infarction in cardiogenic shock.

METHODS AND RESULTS

We performed a retrospective study including 16820 patients, from the Portuguese Registry on Acute Coronary Syndromes (RNSCA) with the diagnosis of acute myocardial infarction in cardiogenic shock (n=95, age 72±12years, 62% men) with multivessel coronary disease, admitted between 01/10/2010 and 03/01/2018. The population was divided into two groups according to the revascularization strategy: Group A (A), PCI only of the culprit lesion (n=74), and Group B (B), immediate multivessel PCI (n=21). The primary outcome was intra-hospital death. Demographic, clinical, electrocardiographic, echocardiographic and angiographic data were evaluated. Multivariate analysis was conducted by logistic regression.

Significant differences were observed between groups regarding age (A 74±12 vs B 66±12 years, P=0,031). No differences between groups were observed regarding gender, cardiovascular risk factors, symptoms, previous and in-hospital therapy, sub-type of acute myocardial infarction, echocardiographic and electrocardiographic parameters with exception of ST-depression in EKG, more prevalent in Group B patients (A 5,5 vs B 24%, P=0,024).In respect to the primary outcome, the overall in-hospital mortality observed was 38%. No differences were obtained in this outcome in respect to the revascularization strategy (A 37,8 vs B 38,1%, OR:1,01 P=0,98). This finding was also observed after adjusting for age and gender. There were also no differences between groups regarding occurrence of mechanical complications, need for intra-aortic balloon or invasive ventilation, sustained ventricular arrhythmias or cardiorespiratory arrest.

CONCLUSIONS

Despite the low incidence of cardiogenic shock (0,6%) in patients with acute myocardial infarction, in-hospital mortality rate remains high (38%). In the new STEMI guidelines from the European Society of Cardiology (2017), the recommendation is to perform a multivessel PCI in these patients, but this is a subject of debate. In this study no differences were observed in in-hospital mortality among those who initially underwent PCI of the culprit lesion only and those who underwent immediate multivessel PCI. Given the specific in-hospital setting of our study, further studies are needed to evaluate the long-term prognosis of both revascularization strategies.

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The role of transradial approach in TAVR

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

AIMS

This study sought to assess the potential benefits of the transradial (TRA) approach as an alternative vascular access instead of contralateral femoral approach for transcatheter aortic valve replacement (TAVR).

METHODS AND RESULTS

We compared the outcomes after TAVR of a prospective cohort of 217 consecutive patients undergoing right or left TRA as the second vascular access (TRA-TAVR) and a retrospective cohort of 194 patients undergoing transfemoral (TF) approach as a second vascular access (TF- TAVR).

In the TRA-TAVR group, the radial artery was catheterized using a 25 cm 6F hydrophilic sheath. A 4 or 5 F 125 cm multipurpose catheter was navigated into the common iliac artery to guide the main common fermoral puncture. Subsequently, the MP catheter was exchanged for a Pigtaill being used again at the end of the procedure to assess ilio-femoral artery axis integrity after femoral closing. In cases of an iliac or femoral access complications, the radial sheath was exchanged for a 120 cm long 5F OptiMed sheath and introduced at the level of the iliac bifurcation. An 0.018??/400 cm nitinol guidewire was inserted beyond the lesion and a compatible long shaft (180 cm) 5F non-compliant balloon or nitinol expandable stent was introduced and used accordingly. In case of haemostasis failure after the use of a closure device, 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.

Baseline clinical characteristics and the mortality risk calculated by Logistic Euroscore and Society of Thoracic Surgeons (STS) were well matched. Regarding the parameters of the procedure, fluoro time was significantly lower in the TF-TAVI group (19.1 ± 7.8 vs. 16.9 ± 7.2, p= 0.003), however, there was no significant difference in the amount of contrast use, x-ray exposure or procedure time.

There was a lower rate of VARC-2 vascular complications in the TRA-TAVR group (8.7% vs. 19.6%, p=0.001) and a lower need for percutaneous vascular treatment in this group (5.1% vs. 10.8%, p= 0.048). The vascular injury in primary and secondary access was also lower in the TRA-TAVR group (2.3% vs. 8.2%, p= 0.006). There were no complications related to the TRA access. In the TRA-TAVR group, TF vascular access site complications occurred in 12 cases (5.5 %). Four complications were successfully managed using self-expanding stents from the transradial access.

Thirty-day mortality from all causes and cardiac causes was similar in both groups. There were no statistically significant differences between groups with respect to peri-procedural myocardial infarction (MI), spontaneous

MI, life-threatening or disabling bleeding, major or minor bleeding, acute kidney injury (AKI), major or minor vascular primary access complications and percutaneous closure device failure. The rate of major stroke was higher in TF-TAVR group (4.6% vs. 0.5%, p=0.008). Logistic regression model showed the non-inferiority of radial to femoral access in terms of 30-day mortality, OR =0.71 (IC 95%, 0.21-2.32) with a p value of 0.005 and superiority in terms of VARC-2 vascular complications.

CONCLUSIONS

Secondary TRA access approach in TAVR is feasibility and safety with a 50% reduction of VARC-2 vascular complications and need for percutaneous vascular intervention. These promising results were not associated with an increase in x-ray exposure, procedural time or the amount of contrast employed.

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Acute and mid-term follow-up results of treatment of old degenerated SVGs with self-apposing coronary stents

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THEME: Coronary Interventions

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

AIMS

PCI of SVG, although an attractive treatment option, remains challenging, due to patient comorbidities and thrombotic-prone lesions, increasing the risk for acute (eg distal embolization, graft rupture) and long term events (restenosis, re-occlusion). Moreover, old degenerated SVGs, with large, aneurysmatic/varying vessel diameters, make stent sizing difficult. Embolic Protection Device (EPD) reduces the acute risk for acute events in SVG. The self-expanding STENTYS stent may reduce these risks and the need for EPD. We report on this stent to treat these lesions in every-day patients.

METHODS AND RESULTS

Data on all SVG lesions treated with self-apposing STENTYS stents from two clinical centers have been collected. Primary analysis focuses on major adverse cardiac events at 1 year. Unknown cause death is considered as cardiac death. Data on 90 lesions (72 patients) have been analysed. Mean age was 74.1+/_10.2 years and 82% of patients were male. 33% of patients were smoking, and 37% of them presented diabetes, 92% hypercholesteremia and 82% hypertension. ACS was observed in 51% of patients. Mean age of graft was 16.1+/-5.9 years. The mean vessel diameter was 3.8+/-0.8mm, and mean lesion length 24.8+/-17.1mm. Ostial and anastomotic lesions were found respectively in 16% and 14% of cases. Significant thrombus was present in 37% of cases. Pre-dilatation was performed in a majority of cases (81%). In all cases except one, a drug eluting stent was implanted. In 60% of the cases, a sirolimus eluting Xposition S was implanted. An average of 1.6 stent was implanted per lesion. Complications were observed in 4 procedures (all with STENTYS older generation stents) leading to a procedural success rate of 96%. EPD was used only in 9% of cases. Post-dilatation was performed in 66% of cases without any dissection. Persistent no reflow was observed in 4% of cases. Follow-up was available for 71% of the patients with a mean follow-up of 1.0 +/-0.9 year. Cardiac death was observed in 6% of patients. The observed rate of target vessel related MI was 1%, and 10% for the TLR rate. Stent thrombosis events were observed in 2%. The TLR rate for the Xposition S subgroup was particularly low (4%) (mean follow-up of 9 months).

CONCLUSIONS

PCI of large degenerated SVGs with self-expanding stents can be done safely and easily, even for patients with ACS. High cardiac death rates are observed, related to patient significant comorbidities. Target vessel related MI rate is particularly low. EPD was used only in a few cases. TLR rate compares favorably to literature. This is the first report presenting results of the Xposition S to treat SVG lesions. Data on a larger population is planned to be presented at PCR.

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DES with an absorbable platform for primary lower extremity arterial revascularisation ? DESappear study initial results

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal

AIMS

The DESappear Study is a multicenter, prospective, single-arm, safety and performance evaluation of the Prava Sirolimus Eluting Bioresorbable Peripheral Scaffold System for the treatment of de novo SFA lesions through clinical and imaging endpoints

METHODS AND RESULTS

Bioresorbable scaffolds may address limitations of drug-eluting balloons and stents for superficial femoral artery (SFA) atherosclerotic disease by: preventing acute recoil, reducing restenosis, and allowing area retreatment made difficult with stents.

The Prava scaffold is a balloon expandable poly L-lactide-based polymer scaffold incorporating approximately 17µg of sirolimus per mm of scaffold length and is available in 5mm and 6mm diameters and 18 and 57mm lengths. Approximately 30% of the drug is eluted over 4 weeks and the scaffold has a short bioresorption time [>90% reduction in molecular weight within 6 months with near complete bioresorption by 1 year (~70% mass loss) in preclinical studies].

The study conducted in Europe and New Zealand, is enrolling patients with symptomatic claudication (Rutherford 2-4), vessel diameter ? 5.0 mm to ? 6.0mm, lesion length ? 53 mm and target lesion ? 50% DS. Subjects are scheduled to undergo clinical and duplex ultrasound (DUS) follow-up assessments at 1, 6 and 12 months and annually up to 3 years.

The primary safety endpoint is the composite of freedom from perioperative death through 30 days and freedom from major adverse limb events, or major open surgical revascularization through 6 months. The primary effectiveness endpoint is primary patency defined as freedom from restenosis using DUS or clinically-driven target lesion revascularization through 6 months. An imaging cohort at a single center is undergoing angiographic and optical coherence tomography (OCT) imaging following scaffold deployment and repeat angiography with OCT at 6 months.

A total of 16 patients have been enrolled. Clinical and duplex ultrasound data will be presented

CONCLUSIONS

The DESappear study will evaluate the safety and performance of the Prava scaffold. Acute and long-term data will be presented for enrolled patients.

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Single-centre experience of valve-in-valve TAVR using the Portico system

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

AIMS

Valve-in-valve (VIV) transcatheter aortic valve replacement (TAVR) has recently emerged as a less invasive treatment for patients presenting with failed surgical aortic bioprostheses. We sought to evaluate the safety and efficacy profile of the Portico System in patients undergoing VIV.

METHODS AND RESULTS

From January 2016 to November 2017, TAVR were performed in symptomatic patients with a failed aortic bioprosthesis at increased risk for surgical re-do (mean STS score: 6.8 + 4.5%). All patients were evaluated for TAVR by the ?Heart team?. Follow-up was scheduled at 1, 6 and 12 months.

A VIV procedure was performed in 22 patients who have been analysed according to the type of bioprosthesis dysfunction: group A (mainly stenotic, 14 patients) and group B (mainly regurgitant, 8 patients). Mean age was 77.5 + 13.9 years, 9 patients were male (40.9%). At baseline, all patients suffered from dyspnea on exertion and most were in NYHA class III (54.5%) and IV (27.3%). Degenerated aortic bioprostheses were stented in 19 patients (86.4%) and mean time from previous surgery was 8.5 + 3.5 years.

All patients underwent TAVR via the transfemoral approach, procedural success rate was 100%. General anesthesia was chosen in 4 cases (18.3%). The most used Portico valve size was 23mm (72.7%) and balloon post-dilation performed in 15/22 patients (68.2%).

At 30 days, all-cause mortality, cerebrovascular events, major vascular complications and conversion to surgery were 0%, new pacemaker insertion occurred in one case (4.5%). Patients in group A had a significant reduction in mean and peak aortic valve gradient (76.7 mmHg vs 31.5 mmHg, p = 0.001 and 47 mmHg vs 19.5 mmHg, p = 0.001). In group B, residual aortic regurgitation was none in 37.5% and mild in 50%, one patient showed a moderate paravalvular leak. In both groups, echocardiographic follow-up showed no significant difference of left ventricular ejection fraction and a slight reduction in estimated systolic pulmonary artery pressure.

At a mean follow-up of 8.1 months, one patient died for a cardiac cause. No other major cardiovascular events occurred (cerebrovascular events, arrhythmia, myocardial infarction, heart failure hospitalizations). NYHA class III was observed in 2 patients (9%), > 90% of patients were in NYHA class I and II.

CONCLUSIONS

In this cohort of patients with failed surgical aortic bioprostheses, the Portico System for VIV TAVR was associated with a low rate of mortality and complications, improved hemodynamic parameters and NYHA class at short-term follow-up. Further studies with a larger sample size and long-term follow-up are needed to confirm its efficacy in this setting.

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Efficacy and safety of amphilimus polymer-free DES in diabetic patients: 12-month follow-up. An all-comer multicentre Spanish registry (Control-8 registry)

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

AIMS

Patients with diabetes mellitus (DM) remain at high risk of in-stent restenosis and adverse cardiovascular events. The Cre8 stent is a third generation DES characterized by a permanent biocompatible i-Carbofilm strut coating and abluminal reservoirs, loaded with a polymer-free sirolimus formulation (Amphilimus), in order to obtain a more efficient targeted elution towards the vessel wall. Preclinical and clinical data have shown interesting and promising results in DM patients.

METHODS AND RESULTS

Methods

The aim of the study is to assess the clinical performance of Cre8-stent in a ?real-world? cohort of diabetic patients. An all-comer Spanish multicentre registry of diabetic patients undergoing PCI with Cre8 stent was designed. The main objectives were to evaluate the incidence of MACE (cardiovascular death, Target lesion revascularization [TLR], myocardial infarction [MI] and stent thrombosis [ST]) at a 12-month follow-up.

Results

390 lesions in 306 patients were included in 7 Spanish hospitals. The mean age was 65±9 years. 64.7% were male. 94.4 % were Type 2 Diabetes mellitus and 5.6 % Type 1, 25.1 % were insulin-dependent. 83.6% and 86.6% had hypertension and hyperlipidaemia respectively. LDL mean value of the population was 105.2±40 mg/dl and the HbA1c 7.3±1.3 %. The main indication for the angiogram was NSTEMI (56.2 %) followed by stable angina (24.1%). 39.5% had two or three vessel disease, 90% had type B/C lesions and 32.7% were bifurcations. The vessels more frequently affected were left anterior descending (39,2%) and right coronary artery (30%). 26.4% and 7.8% were on Ticagrelor or Prasugrel respectively and the rest of them on Clopidogrel. The mean length and diameter of the lesion was 20.8±7.2 mm and 3.11±0.65 mm respectively. 1.51 stents/patient were implanted and 63.4% were predilated. OCT or IVUS was used in 3.9% of the cases. The incidence of MACE at 12 months follow-up was 18 p (5.8%) (cardiac death 2p [0.6%], MI 7p [2.2 %], TLR was 9 p [2,9 %] respectively). Only 6 p (1.9 %) had in-stent restenosis, two of them asymptomatic. The incidence of ST was 3 p (0.9%) and all of them were acute or subacute ST.

CONCLUSIONS

The results of this real-world multicentre registry, show that Cre8 has a very positive safety and efficacy profile in DM patients, with a low incidence of MACE in a high-risk population at a 12 month follow-up.

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"Burying" covered stents with DES might prevent in-stent restenosis and stent thrombosis

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

AIMS

The implantation of a polytetrafluoroethylene (PTFE) covered stent, which are used to seal coronary perforations or aneurysms, is associated with a high risk of in-stent-restenosis (ISR) and stent thrombosis (ST). We hypothesized that "burying" the covered coronary stent with a third-generation drug eluting stent (DES) might reduce target lesion failure (TLF).

METHODS AND RESULTS

We report the results of a novel approach applied in 8 patients (mean age 65±6) requiring treatment with covered stents. In 5/8 patients, coronary aneurysms were excluded with covered stents, and in 3/8 patients, covered stents were used to seal coronary perforations after aggressive post-dilatation of underexpanded stents. After deployment, all covered stents were initially post-dilated using non-compliant balloons and then completely unroofed using a third-generation DES overhanging the proximal- and distal edges. Finally, all lesions were post-dilated using non-compliant balloons. All covered stents were successfully deployed and no peri-procedural complications occurred. No ISR, ST or myocardial infarction occurred during the observational period of 28±8 months. Repeat angiography was performed in 6/8 patients after a mean follow-up of 7±5months and in 5/8 patients additionally optical coherence tomography (OCT) was performed. None of the patients had angiographically relevant ISR and OCT exams demonstrated good stent apposition, expansion and endothelialization.

CONCLUSIONS

Burying? covered stents with contemporary DES might represent a promising strategy to mitigate the well-known mid- and long-term complications associated with the use of those devices. Those possible benefits might be attributable to the following aspects: (1) usage of DES ameliorate the covered stent´s lack of radial strength and improves stent expansion, (2) The presence of the anti-proliferative drug allows a more controlled endothelialization and therefore reduces early ISR.

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Expansion of a balloon-expandable TAVI valve: an analysis of the filling volume of the implantation balloon and valve recoil in 296 patients of the TAVIK registry

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

AIMS

Expansion of balloon-expandable Sapien 3(S3) valve is dependent on the filling volume of the implantation balloon. Underfilling is utilized in annular/LVOT calcifications to avoid ruptures, additional filling in paravalvular insufficiencies(PVL) to minimize the regurgitation. Angiographic determination of the valve expansion may help to adjust the maximum filling volume in an attempt to minimize the risk of annular rupture and PVL.

METHODS AND RESULTS

Analysis of expansion of 296 S3 implantations(valve size:66x23mm,139x26mm,91x29mm) in 2016/2017 using angiography during/after implantation. Inflow area(IF), the tightest narrowing at the height of the annulus(middle) and the outflow area(OF) were determined. It was calibrated against the inner diameter of the marker at maximum filling of the implantation balloon with a perpendicular orientation using X-ray.
Recoil of S3 valve after implantation was 0.4±0.4mm in IF, 0.7±0.5mm in the middle and 0.7±0.5mm in OF(

CONCLUSIONS

Expansion of S3 valve is highly dependent on the filling volume of the implantation balloon. At nominal filling, the difference to the normal size is 7.3-7.8%. Only when the implantation balloon is overfilled with 2cc, S3 almost reaches nominal size. The recoil of the valve is between 0.4 and 0.7mm.

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Timing of new conduction disorders leading to permanent pacemaker implantation after TAVI

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

AIMS

Transcatheter aortic valve implantation (TAVI) is frequently complicated by high-grade atrioventricular block (AVB), requiring post-procedural permanent pacemaker implantation (PPI). There is no consensus on the required observation period after TAVI to evaluate new conduction disturbances (CD) and the timing for PPI. This study aimed to investigate the minimum required admission time to discharge patients post TAVI safely regarding the need for PPI.

METHODS AND RESULTS

Methods:
A national, multi-centre, and retrospective analysis was conducted on 300 TAVI patients that received a PPI after the TAVI procedure. We evaluated electrocardiograms (ECGs) at baseline, and ECGs and clinical records of telemetry post-TAVI to identify CD.

Results:
Results of a retrospective subanalysis of one centre, show that most PPI indications (91%) are observed within 72 hours after TAVI. Patients treated with a balloon-expandable valve with pre-existing right bundle branch block (RBBB) and/or first-degree AVB, did not developed a new CD requiring PPI after 48 hours. Therefore, these patients might be safely discharged if no CD are observed within the first 48 hours. Full study results will be presented at EuroPCR.

CONCLUSIONS

The vast majority of CD leading to PPI are observed within 72 hours after TAVI. Patients with a balloon-expandable valve implantation and pre-existing RBBB and/or first-degree AVB, might be safely discharged 48 hours post-procedural, if no CD have been observed.

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The performance of conical stents, chromium-cobalt platform L605, sirolimus ? Experience on CHLN

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

AIMS

The coronary arteries naturally have a proximal diameter greater than the distal diameters. In treatments of long lesions, the miss match of diameter becomes more evident, which may make it difficult to choose the stent (s) to be used. Conical stents are recent on the market and an option to avoid stent overlap. The present study has as main purpose to evaluate the performance of conical stents (chromium-cobalt platform, 65 ?m mesh thickness and coated with sirolimus conical stents), implanted in segments of coronary arteries with long lesions and the miss match.

METHODS AND RESULTS

This study included 59 patients (68.05 ± 10.6 years-old , 79.7 % males), of which 55 had a conical stent from 01/01/2016 to 14/11/2017. Demographic, clinical data procedures, novo intervention and clinical follow-up (minimum 180 days) were evaluated. The most frequent risk factors in these patients are arterial hypertension (67.8%), dyslipidemia (37.3%) and diabetes mellitus (27.1%).

The success of implantation the conical stent was 93.2% (55/59). The results obtained in the analysis of pre-dilatation of the lesion, inflation pressure and qualitative variables didn?t demonstrate influence, significantly, in success.

Patients were submitted to the novo intervention, on a period of less than 3 months, represent 20.0% (11/55). On a majority, there were programmed PCI (54.4%) where there was moderate to sever lesions on other vessels, and the operator decided to treat them ahead, on a posterior date.

In 44 patients, the follow-up had a mean of 340.6 ± 119.9 days, maximum was of 644 days and minimum of the 188 days. Regarding to major adverse events, on patients with follow-up higher than 180 days and successful implantation, there was an occurrence of cardiac causes death in an individual due to acute stent thrombosis, probably, due to the suspension of the anti-platelet therapy. The remaining 3 deaths (7.4%) were of non-cardiac causes.

CONCLUSIONS

Conical stent (chromium-cobalt platform, 65 ?m mesh thickness and coated with the drug sirolimus) has been shown to be a good treatment option in segments of coronary arteries with long lesions with miss match.

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Outcomes after use of covered stents to treat coronary artery perforations. Comparison of old and new-generation covered stents

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

AIMS

To compare outcomes in patients receiving polytetrafluoroethylene (PTFE) and the newer polyurethane (PL) covered stents (CSs) after coronary artery perforation (CAP) during percutaneous coronary intervention (PCI).

METHODS AND RESULTS

We included 61 patients requiring implantation of CSs in a high-volume PCI Institution over a 5-year period (June 2012 to June 2017). Patients requiring CS for no-perforation indications were excluded. Procedural and clinical data were retrospectively collected. Patients included in the PTFE-CS group were treated with the Jostent Graftmaster stent graft (Abbott Vascular, Santa Clara, CA, USA). In the PL-CS group, PK Papyrus stent (BIOTRONIK, Berlin, Germany) was used. CAPs were defined as extravasation of contrast from the coronary artery and were reported according to Ellis classification. Procedural success was defined as the successful implantation of CS at the lesion level (TIMI3 flow and a residual stenosis of less than 30%) and absence of residual extravasation of blood needing emergent surgical intervention. The primary endpoints were: procedural success, all-cause death and Major adverse cardiac events (MACE) defined as the composite of death, myocardial infarction, target vessel revascularization, target lesion revascularization and need for surgical repair (including coronary artery bypass grafting. Secondary endpoints were the rate of in-stent restenosis and stent thrombosis, defined according to the Academic Research Consortium definitions.
The mean age was 77±8 and 75% were males. Twenty-two (36%) received PL-CSs and 39 (65%) PTFE-CSs. The PL-CS group had higher rate of procedural success than the PTFE group (86 vs 69%, p=0.216). In-hospital death (9 vs 23%, p=0.370), need for surgical repair (9 vs 13%, p=1.000) and MACE (23 vs 36%, p=0.391) were lower in the PL-CS arm. At 1-year follow-up, the rates of MACE were similar among both arms (58 vs 56%, p=1.000) mainly driven by a higher rate of TVR in the PL-CS arm (21 vs 5%, p=0.083). Mortality remained lower in the PL-CS arm (26 vs 41%, p=0.385). Each group had 1 stent thrombosis and in-stent restenosis was higher in the PL-CS group (12% vs 3%, p=0.223).

CONCLUSIONS

The PL-CSs showed better acute performance in comparison to the PTFE-CSs. One-year follow-up revealed similar rates of MACE in both groups. Larger and prospective studies are needed to confirm these findings.

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TAVI vs. surgery for severe symptomatic aortic stenosis: a reconstructed individual patient data meta-analysis

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

AIMS

TAVI and surgery are both well-established methods for treating elderly patients with severe symptomatic aortic stenosis. We wished to undertake a reconstructed individual patient data meta-analysis of randomised trials comparing these two treatment modalities.

METHODS AND RESULTS

We searched the US National Library of Medicine ClinicalTrials.gov database for all randomised trials comparing TAVI and surgery. Abstracts, manuscripts and conference presentations were reviewed and individual patient data was then reconstructed from Kaplan-Meier curves. The primary hypothesis was that at 2 years, TAVI and surgery would have a similar rate of all-cause mortality. The secondary hypothesis was that in patients suitable for transfemoral access, TAVI would be associated with a lower rate of all-cause mortality, disabling stroke and the composite endpoint of all-cause mortality or disabling stroke, when compared with surgery. The primary and secondary hypotheses were assessed using a hazard ratio with a p value

CONCLUSIONS

TAVI and surgery have differing risk profiles. At 2 years, TAVI and surgery have a similar rate of all-cause mortality. In patients suitable for transfemoral access, TAVI is associated with a lower rate of all-cause mortality, disabling stroke and the composite endpoint of all-cause mortality or disabling stroke, when compared with surgery.

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Hemodynamic changes in patients with isolated systolic hypertension following renal sympathetic denervation ? Pathophysiologic insights

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

AIMS

Response to renal sympathetic denervation (RDN) seems to be blunted in patients with isolated systolic hypertension (ISH). Recently, we identified a subgroup of patients with ISH characterized by lower invasive pulse wave velocity (IPWV), showing excellent response to RDN therapy. In these patients, elevated ISH might be caused by increased vascular tone, leading to pulse wave augmentation or elevated cardiac output, both suggestive of elevated sympathetic activity. As effects of RDN on central hemodynamics are only sparsely understood, we aimed to investigate these changes using repeated CMR.

METHODS AND RESULTS

Thirty-four patients with ISH underwent renal sympathetic denervation. CMR was performed before and 3 to 6 months after catheter-based RDN. Ascending aortic forward flow and simultaneous blood pressure measurements were used to calculate cardiac index (CI), stroke volume index (SVI), systemic vascular resistance index (SVRI) and total arterial compliance (TAC). Additional volumetry from short axis stacks was available in a subgroup of 20 patients to assess left-ventricular ejection fraction (EF) and end-systolic/end-diastolic volume indices (ESVI and EDVI). Additionally, PWV was assessed invasively before RDN. Patients were stratified by tertiles of IPWV.

Patients in the lower tertile of IPWV as compared to the higher tertiles presented with lower daytime systolic BP (143.8 ±5.4 vs. 150.8 ±12.4, p = 0.029), had a higher SVRI (1010 ±428 vs. 769 ±262 dyn×s×cm-5, p = 0.049) and tended to be younger (p = 0.080). At follow up, CI, SVI and EF were unchanged in this group, while SVRI and EDVI were significantly reduced (-184 ±263 dyn×s×cm-5 and -15.6 ±12.3 ml, p = 0.043 and 0.009 respectively) and TAC increased by 0.18 ±0.25 ml/mmHg (p = 0.036). ESVI tended to be reduced without reaching statistical significance (-6.2 ±9.8 ml, p = 0.11). 24h blood pressure was reduced by -10.9 ±5.8 mmHg (

CONCLUSIONS

In a subgroup of patients with ISH characterized by lower arterial stiffness and high systemic vascular resistance, RDN results in significant reduction of resistance and compliance and improves ventricular diastolic loading. This suggests that ISH in these patients is caused by sympathetic rather than structural hypertension, which seems to be a favorable target for RDN despite the clinical phenotype of ISH. Application of CMR should enhance our understanding of the pathophysiological implications of RSD in these patients and could serve as a selection tool in the future.

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Successful endovascular repair of giant thoraco-abdominal aneurysm in patient with coronary artery disease: a case report

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

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Influenza vaccination and prevalence of myocardial infarction: an analysis of the 2014 U.S. national inpatient sample

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

AIMS

Some initial studies have suggested that patients receiving influenza vaccination have fewer instance of myocardial infarction (MI). We utilized the 2014 United States? National Inpatient Sample (NIS) database to study the relationship between influenza vaccination and prevalence of MI.

METHODS AND RESULTS

This was a retrospective cohort study of all adult patients in the 2014 NIS database. The patients were divided into two groups: those who received influenza vaccination in 2014 (defined by the appearance of the corresponding ICD-9-CM diagnosis code) and those who did not. The primary outcome was MI, including both ST- and non-ST-segment elevation MI as well as unstable angina. A multivariate regression analysis was performed to compute the adjusted odds ratio (AOR) for MI, controlling for age, gender, ethnicity, socioeconomic status, insurance category, as well as hospital size, location, and type. The study included 29,763,704 adult patients. The raw data showed a lower prevalence of MI in vaccinated patients (3.4% vs. 4.4%). Adjusting for the confounding variables listed above, the AOR for MI was computed to be 0.91 (95% confidence interval 0.87-0.96) in vaccinated patients compared to non-vaccinated ones.

CONCLUSIONS

In the 2014 NIS database, adult patients with influenza vaccination were associated with a statistically significantly lower prevalence of MI compared to non-vaccinated patients. This is consistent with other initial studies and suggests that influenza vaccination may be useful as a preventative measure for MI.

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Clinical outcomes in patients with equipoise four-year mortality risk based on the SYNTAX score II with different anatomic complexity: insights from the SYNTAX II study

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

AIMS

The SYNTAX score II combines clinical characteristics and comorbidities with angiographic complexity to provide a treatment recommendation based on 4-year all-cause mortality. The aim of this study was to compare clinical outcomes in patients selected on the basis on an equipoise 4-year mortality risk according to the SYNTAX score II with different anatomic SYNTAX score (SS) risk tertiles.

METHODS AND RESULTS

Patients with three-vessel coronary artery disease (3VD) included in the SYNTAX II study were categorized according to the anatomic SYNTAX score tertile (i.e. SS >22 and ?22). The rate of major adverse cardiac or cerebrovascular events (MACCE: combined clinical outcome of all-cause death, stroke, any myocardial infarction and any revascularization) were compared between groups at one-year follow-up. In 298 patients, an anatomical SYNTAX score of ?22 (Mean 16.7 95% CI 16.3 to 17.1) was calculated whereas SYNTAX score >22 (Mean 27.2 95% CI 16.4 to 27.9) was obtained in 152 patients. Patients in the low SS tertile were younger (65.9±10.1 vs. 67.9±8.8, p=0.05), There were no differences in baseline clinical characteristics between groups. The SYNTAX score II for PCI was comparable between group (25±3.1 vs 25±2.9, p=0.13). Patients with anatomic SYNTAX score II >22 had more stents implanted (4.5±2.1 SS >22 vs. 3.4±1.8 ?22,

CONCLUSIONS

Clinical outcomes in patients with three-vessel coronary artery disease with low or intermediate/high anatomic SYNTAX score selected on the basis of the SYNTAX score II were comparable at one-year follow-up.

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Impact of diabetes mellitus on clinical outcomes in patients with three-vessel coronary artery disease undergoing state-of-the-art PCI using the SYNTAX II strategy

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THEME: Coronary Interventions
TOPIC(S): Stable CAD, Bifurcation lesion

AIMS

To assess the impact of diabetes mellitus on clinical outcomes in patients with three-vessel coronary artery disease undergoing physiology-guided using thin struts biodegradable polymer everolimus-eluting stents optimized by intravascular ultrasound selected on the basis of the SYNTAX score II.

METHODS AND RESULTS

Patients with three-vessel coronary artery disease (3VD) included in the SYNTAX II study were stratified according to the presence of diabetes mellitus. The rate of major adverse cardiac or cerebrovascular events (MACCE: combined clinical outcome of all-cause death, stroke, any myocardial infarction and any revascularization) were compared between groups at one-year follow-up. Diabetes mellitus was present in 136 patients (30%) and were compared to 311 non-diabetic patients. Diabetic patients were older (68.1±9.4 vs. 66.0±9.7, p=0.038) without other differences in baseline clinical characteristics. The anatomic was comparable between group (19.8±37.3 DM vs. 20.4±5.9 non-DM, p=0.37). The number of stents implanted was similar between groups (3.8±1.9 vs. 3.8±1.9, p=0.82). At one-year MACCE rates were similar between staged and single-PCI group (HR 1.1 [95% CI 0.60 to 2.4, p=0.746]). No significant differences were found in the other components of MACCE.

CONCLUSIONS

Diabetic patients undergoing state-of-the-art PCI using the SYNTAX II strategy had comparable major adverse cardiac or cerebrovascular events rate compared to non-diabetic patients.

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Chronic kidney disease is not associated with more frequent acute kidney injury in patients undergoing angiography for ACS

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

AIMS

The treatment of choice in acute coronary syndrome (ACS) is early revascularization. Contrast-induced nephropathy is a common problem in invasive cardiology. An invasive approach is often delayed or even avoided in patients with chronic kidney disease (CKD) to protect renal function. The aim of this study was to evaluate the potential acute loss in kidney function in ACS patients with preserved renal function and compare it with that of CKD patients undergoing coronary angiography.

METHODS AND RESULTS

Two independent cohorts were evaluated. The first cohort, defined as the evaluation cohort, consisted of 198 patients (29% female) presenting with acute myocardial infarction (AMI) enrolled between 2012 and 2014 in a prospective biomarker registry. The second cohort, an application cohort, comprised 943 ACS patients (30% female) who were enrolled in a prospective registry between 2003 and 2005. Here, a 6-month follow-up (median 200 days) was obtained with all-cause mortality as the outcome measure. All patients in both cohorts underwent coronary angiography. The estimated glomerular filtration rate (eGFR) was obtained at admission (before coronary angiography) and before discharge. Patients were classified based on the admission eGFR as having preserved kidney function (?non-CKD?) with eGFR ?60 ml/min/1.73m2 or as having CKD with eGFR

CONCLUSIONS

After coronary angiography, patients with CKD have no more frequent AKI than patients with initially preserved kidney function. The use of iodine contrast media might not be as harmful in CKD patients with ACS as commonly suspected.

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Image-based computation of coronary rest hemodynamics from routine coronary angiography: evaluation of rest diastolic Pd/Pa in a hybrid decision-making strategy with FFR

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Resting state pressure-derived indices have been validated in large outcome-based trials for the functional assessment of coronary artery stenosis.

We introduce a method for computing coronary rest hemodynamics from routine coronary angiography, and evaluate the diagnostic performance of diastolic rest Pd/Pa against FFR.

METHODS AND RESULTS

A single-centre, observational study was carried out, enrolling 84 consecutive patients with suspected coronary artery disease (CAD), with no exclusion criteria related to type / location of lesions, prior myocardial infarction, prior PCI or prior CABG. Routine coronary angiograms were acquired and invasive FFR was measured for a total of 161 lesions. Coronary angiograms from two views at least 30° apart were selected and two corresponding end-diastolic frames were chosen. On each frame, the lumen segment of interest was identified manually by selecting at least two points. Next, the lumen boundary was automatically determined by the software and manually corrected if deemed necessary. Subsequently, the three-dimensional anatomical model was automatically generated.

A computational fluid dynamics based reduced-order model of the coronary circulation (this feature is based on research, and is not commercially available. Due to regulatory reasons its future availability cannot be guaranteed) was employed to compute personalized rest-state time-varying pressures in the reconstructed 3D model. The resting total coronary blood flow was estimated from the anatomical model using allometric scaling laws, following the relationship between form and function. Blood was modeled as an incompressible Newtonian fluid and, to account for coronary autoregulation, the boundary conditions were personalized using a fully automatic parameter estimation framework. The rest diastolic Pd/Pa index (rest dPd/Paangio) was computed as the ratio of average distal to the average aortic computed pressure during diastole. A hybrid strategy based on rest dPd/Paangio and invasive FFR was further evaluated.

From the 161 lesions, 61 were hemodynamically significant (FFR ? 0.80). The discriminatory power of rest dPd/Paangio versus invasive FFR was evaluated with the following metrics: the AUC of the receiver-operator characteristic curve was 0.906, and the optimal cut-off point was 0.90, leading to a per-lesion accuracy of 85.1%, sensitivity of 75.4%, specificity of 91.0%, positive predictive value (PPV) of 83.6%, and negative predictive value (NPV) of 85.8%. Rest dPd/Paangio demonstrated superior discriminatory performance compared to 3D-QCA?derived % diameter stenosis (AUC: 0.728, accuracy 74%). A hybrid rest dPd/Paangio ? FFR strategy (hybrid window 0.87 ? 0.93) resulted in a per-lesion accuracy of 95.0%, sensitivity of 95.1%, specificity of 95.0%, PPV of 92.1%, and NPV of 96.9% when compared to an FFR-only strategy, while requiring invasive FFR assessment in only 30% (48) of the lesions.

CONCLUSIONS

We evaluated a simple and fast method for virtual functional assessment of coronary artery stenoses, demonstrating good diagnostic agreement with invasive FFR. The hybrid rest dPd/Paangio ? FFR strategy could potentially obviate the need for invasive pressure measurements in 70% of the lesions of this cohort, whilst maintaining a high diagnostic accuracy with respect to the FFR-only strategy. Future research activities will focus on model refinement and further validation of the method.

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Anomalous connection of the right coronary artery with interarterial course: preliminary prospective experience of stenting in a selected adult population

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

AIMS

Anomalous connections of the coronary arteries (ANOCOR) with interarterial course raise therapeutic problems. Current guidelines recommend a surgical repair for right ANOCOR with evidence of ischemia. The lack of controlled studies and the scarcity of long-term data may explain an underutilization of surgical treatment. A percutaneous approach may provide an interesting alternative in a selected adult population. The purpose of our study was to assess the feasibility and safety of preaortic segment stenting in right ANOCOR with interarterial course.

METHODS AND RESULTS

A percutaneous treatment by stenting was proposed according to predefined criteria (age >30 years, symptoms or documented ischemia, no history of aborted sudden death, ostial ovoid shape) for patients referred to an expert group. All patients underwent selective coronary angiography and coronary computed tomography (CT). Evaluation by intravascular ultrasound (IVUS) or optical coherence tomography (OCT) was recommended. Clinical follow-up was scheduled at 6, 12 and 60 months. A systematic coronary CT was proposed between 6 and 12 months.

Eleven patients were prospectively included between 2014 and 2017, mean age 54 years (35-81). Two patients had acute coronary syndrome, six had stable angina, two were asymptomatic with positive stress test and one had syncope. All patients had right ANOCOR connected to the contralateral aortic sinus with an interarterial course and an intramural segment was identified in more than half of the patients. Stenting was successful with residual angiographic stenosis < 50% in all procedures, 45% radial access, > 90% of drug-eluting stents, mean stent diameter 3.4 mm, mean stent length 26 mm, mean fluoroscopic time of 18 min, > 70% of IVUS or OCT guidance, mean troponin at 24 hours of 0.53 µg/L and no periprocedural complication.

Follow-up at 6 months was uneventful in all but one patient requiring a new hospitalization at 5 months for persistent angina reported to a vasospastic angina.

CONCLUSIONS

Preaortic segment stenting of right ANOCOR with interarterial course appears feasible and safe in this preliminary experience. A longer follow-up and a more important population are needed to know whether this technique is suitable for a next therapeutic algorithm.

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Percutaneous retreatment of patients with stented aortic coarctation at early age

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

AIMS

Stenting has become the treatment of first choice in adult patients with coarctation of the aorta. Since there are few information regarding stent re-dilation in patients with aortic coarctation, stenting has not been recommended in growing children or young adults without a definitive aortic size.
The aim of our paper is to assess the efficacy and safety of the re-treatment in patients with stented aortic coarctation at early age, several years after the stent implantation, when the aorta reached a near definitive size.

METHODS AND RESULTS

We analyzed our series of patient with aortic coarctation treated with stent, who needed balloon re-dilation or re-stenting because of their somatic growth. From 1993 to 2017, 183 patients with coarctation of aorta were treated in our center by stent implantation. For our study, we selected those patients who were treated by stent implantation younger than 12 years and required re-treatment because of their rate of growth (n=30). The age at the first procedure was 5±3 years and at the second procedure 18±6 years. So, the time between stenting of the aorta and re-treatment was 13 ± 4 years. In this time interval, the aorta grew from 8±3 mm to 12±4 mm at the level of isthmus below the subclavian artery and from 11±4 mm to 17±4 mm at the level of the diaphragm. At the second procedure, 14 (46 %) patients were treated with balloon re-expansion. In patients with a suboptimal result after balloon dilation or those with poor integrity of the first stent, a second stent was implanted. Stent fracture was a frequent finding after 13 years follow-up (n=10, 33%) however it was not associated to restenosis or aneurysm and could facilitate the expansion of the second stent. We could not identify factors responsible for stent fractures. Thus, the time interval between the 2 procedures were similar between patients with and without fractures (14 ± 5 vs 14 ± 4 years, p:ns). The age at the stent implantation was also similar between patients with and without fractures (6 ± 4 vs 6 ± 4 years, p:ns). Primary success was obtained in 29 patients (97%). An immediate reduction of the peak gradient across the coarctation was obtained in all of them. The final residual gradient was 6±6 mmHg. In the patient without primary success the stent remained unexpanded despite repeat dilations. There were no major complications. After the coarctation re-treatment, the minimal lumen diameter at the level of the coarctation changed from 10±5 to 16±3 mm (

CONCLUSIONS

Patients with aortic coarctation treated with stent at early age, can be successfully re-treated by balloon dilation or re-stenting after the completion their somatic growth.

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Implantation of the Allegra transcatheter heart valve for the treatment of degenerated transcatheter aortic valves: initial experience

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

AIMS

Report the initial experience with the novel Allegra transcatheter aortic valve for the treatment of degenerated transcatheter valves.

METHODS AND RESULTS

The Allegra transcatheter aortic valve has a barrel-like shape and may be well suited for the treatment of degenerated transcatheter aortic valves. In particular, minimal interference between the frames of the transcatheter valves can be expected, and the frame height may be sufficient for the treatment of degenerated supraannular valves. Here, we report outcomes of the first three patients presenting with severe regurgitation of a CoreValve 29 mm 8 years after TAVI, severe stenosis of a CoreValve 26 mm 8 years after TAVI, and severe stenosis of a Sapien XT 23 mm 6 years after TAVI. Standardized computed tomographyîes were performed to assess the annular dimensions and the coronary ostia. It was evident that all degenerated valves were initially underexpanded. Patients were successfully treated via transfemoral access by implantation of an Allegra 27 mm, 23 mm, and 23 mm, respectively. Mean postprocedural transvalvular gradients were 18, 18, and 5 mmHg, respectively and calculated aortic valve areas were 1.6, 1.4, and 1.8 cm2, respectively. There was no severe patient prosthesis mismatch, but moderate mismatch occurred in 2/3. None of the patients had more than mild paravalvular leak. Patients were discharged home 6-8 days after the procedure.

CONCLUSIONS

Due to its unique shape, the Allegra transcatheter aortic valve may be well suited for the treatment of both degenerated intra- and supraannular transcatheter heart valves, a scenario that we may encounter more frequently in future.

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Short-term outcome of patients with out-of-hospital cardiac arrest presenting without ST-elevation as compared to ST-elevation on ECG? experience from the Hannover Cooling registry

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

AIMS

To establish whether coronary angiography should be a part of standardized diagnostic work-up in patients following out-of-hospital cardiac arrest (OHCA) and return of spontaneous circulation (ROSC) without obvious ST-segment elevation (STE).

METHODS AND RESULTS

Consecutive data of all patients with OHCA admitted to our institution between 2010 and 2016 were collected in a database. Patient received standard intensive care with additional therapeutic hypothermia. All patients received a coronary angiogram prior to ICU admission.

Mean age of overall patient population (n=243) was 65±14 years with a male predominance (78%). Cardiac arrest was witnessed in 82% and bystander cardiopulmonal resuscitation (CPR) was performed in 65%. Initial rhythm was ventricular fibrillation in 71%. ROSC had been achieved after 23±16 minutes. At hospital hypothermia was applied in all patients after percutaneous coronary angiography and intervention (98% and 78%, respectively). After ROSC, STEMI was present in 47%. Critical coronary stenosis requiring PCI was present in 67% in STEMI as compared to 52% in NSTEMI (p=0.24). Mechanical support was required in 20% of STE and 19% of NSTE population (p=0.89). 30 day mortality was 39% in the total cohort, 32% in STE and 53% in NSTE OHCA (

CONCLUSIONS

Standardised procedures in OHCA patients with a strict protocol incorporating ECG, coronary catheterisation and intervention, use of mechanical haemodynamic support and mandatory therapeutic hypothermia is mandatory for these high-risk patients. Diagnostic work-up revealed a high rate of culprit lesions on coronary angiography irrespective of STE or NSTE, which underlines the need for invasive diagnostics after excluding non-cardiac causes in OHCA.

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Early strut protrusion and late neointimal thickness in Absorb BRS: a serial shear stress analysis up to five years

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

AIMS

To evaluate the effect of strut protrusion on wall shear stress(WSS) and neointimal growth one and five-years after implantation of the Absorb bioresorbable vascular scaffold.

METHODS AND RESULTS

Eight patients were selected from the first-in-man study population. Following three-dimensional(3D) reconstruction of the coronary arteries, WSS was quantified using Newtonian steady flow simulation in each cross-section in 5-degree subunit(sector) of the circumferential luminal surface. At 1-year follow-up, neointimal thickness was measured by optical coherence tomography(OCT) and correlated to WSS and strut protrusion post-procedure. Median strut protrusion was 112.9(90.8, 133.1) μm post-implantation. Post-procedure, a logarithmic inverse relationship between strut protrusion and post-implantation WSS(r=-0.425,

CONCLUSIONS

Strut protrusion disturbs laminar flow, creates region of low-WSS(

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Endovascular treatment of acute pulmonary embolism with thrombus aspiration in a patient with recent intracranial haemorrhage

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THEME: Interventions for Stroke
TOPIC(S): Other stroke interventions

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Sex-based outcomes in patients at high bleeding risk: results from the LEADERS FREE randomised controlled trial

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THEME: Coronary Interventions

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

AIMS

Women undergoing percutaneous coronary intervention (PCI) are traditionally at high bleeding risk (HBR), and consequently may be undertreated with drug eluting stents (DES). We conducted a pre-specified analysis for 2-year outcomes by sex from the LEADERS FREE randomized controlled trial and examined for treatment interaction by stent type.

METHODS AND RESULTS

The LEADERS FREE trial randomized 2432 HBR patients to either the Gazelle bare metal stent (BMS) or polymer free Biolimus-A9 eluting BioFreedom stent followed by one month of dual antiplatelet therapy (DAPT). The primary safety endpoint was a composite of cardiac death, myocardial infarction (MI) or stent thrombosis (ST). The primary efficacy endpoint was clinically driven target lesion revascularization (TLR). A total of 1694 (67.7%) men and 738 (30.3%) women were enrolled. Women were older with higher prevalence of acute coronary syndrome (31.4% vs. 25.2%) but lower prevalence of prior MI or revascularization and smoking. With respect to eligibility criteria, more women were >75yrs of age, with higher prevalence of renal failure (24.1% vs. 16.9%) but men more often had an indication for oral anticoagulation (32.4% vs. 37.8%) and higher prevalence of malignancy, anticipated poor DAPT compliance or history of bleeding within the previous year. Angiographically, women had less multivessel disease, less severe stenosis, shorter lesion length and smaller reference vessel diameter. More than half of the patients underwent radial access PCI in both groups. At 2-years HBR women had similar incidence of the primary safety (14.7% vs. 13.6%, p=0.37) and efficacy (9.2% vs. 9.6%, p=0.70) endpoints as well as MI (7.2% vs. 7.2%, p=0.95) and ST (2.5% vs. 2.1%, p=0.47) with numerical differences in major bleeding (10.2% vs. 8.6%, p=0.14) compared to men. The BioFreedom stent was superior to Gazelle BMS in both women and men with lower TLR (6.3% vs. 12.1% in women, 7.0% vs. 12.0% in men, p-int=0.70) and similar incidence of ST (1.7% vs. 3.3% in women, 2.3% vs. 1.8% in men, p-int=0.13). Women were observed to have a greater absolute reduction in the primary safety endpoint (in women: 12.4% vs. 17.0%, ARR 4.6%, in men 12.6% vs. 14.5%, ARR 1.9%) however there was no evidence of treatment interaction (p-int =0.40).

CONCLUSIONS

HBR women are more often older, present with renal failure and undergo PCI for ACS, whereas HBR men present with higher prevalence of malignancy, indication for oral anticoagulation and anticipated poor DAPT compliance within 12 months of PCI. Women had similar 2-year outcomes to men, suggesting that HBR women should not be denied benefits of PCI. In both groups polymer free DES performed better than BMS with respect to TLR and should be favored regardless of sex.

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Endovascular treatment of CTO of the persistent sciatic artery and acute thrombosis of the popliteal artery

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Lg G4-related aneurysm - new pathological unit

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THEME: Peripheral Interventions
TOPIC(S): AAA

AIMS

We perform a case study of 20 patients with aneurysm of the abdominal part of aorta. All of them we examined on availability of Ig G4-related disease by aortic biopsy.

METHODS AND RESULTS

During aorto-bifemoral bypass interoperative biopsy of aortic wall were done for 20 patients with aneurysm of the abdominal part of aorta. Morphological and immunohistochemical analysis was performed. The number of IgG4-positive plasma cells was semiquantitatively scored.

Histological findings performed on the surgical specimen disclosed Ig G4-related disease. In the study group 8 (40%) patients had an increased Ig G4-positive plasma cells, so it confirms a probability of autoimmune etiology of the aortic disease. Another 12 patients had atherosclerotic etiology of aneurysm.

CONCLUSIONS

The well-timed diagnostics of Ig G4-related aneurysm will significantly change the tactic of postoperative management and the long-term results of patients with this pathology.

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Long-term results of infrarenal aortic aneurysm correction

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THEME: Peripheral Interventions
TOPIC(S): AAA

AIMS

Compare the long-term results of endovascular and open surgical treatment of patients with infrarenal aortic aneurysms.

METHODS AND RESULTS

For the period from 2009 to 2016 in the medical center 135 patients with abdominal aorta aneurysms were operated . A retrospective multivariate analysis of the abdominal aorta aneurysm open and endovascular treatment results has been performed. The endovascular repair of aneurysms with the implantation of self-expanding nitinol stent-grafts was performed in 40 patients (Group 2) and the open surgical correction with aorto-femoral-bifurcation bypass in 95 patients (Group 1). All operations were exucuted under general anaesthetsia. Surgical approach for endovascular repair of the aneurysm in all cases has been achieved through the femoral arteries. For open surgeries the Rob access has been performed in 85 (89%) and the midline laparotomy in 10 (11%) cases. Patients in the groups were compared on age (67 ± 6 years vs. 68 ± 6 years, p> 0.05), both groups were dominated by male patients (76% vs. 87%, p> 0.05). The groups under study were prevailed by a fusiform aneurysm (in Group 1: 71% vs. 29%, p = 0.001 and in Group 2: 80% vs. 20%, p=0.001). In both groups, the aneurysm diameter in most patients was 5.5 to 6.5 cm (in Group 1: 62 % vs. 38%, p = 0.001 and in Group 2: 68% vs. 32%, ?=0.001).

In the long-term postoperative period (12 months) after surgical correction, the patients have shown complications, e.g. a postoperative ventral hernia in 2 patients (2.1%) with a surgical treatment followed, in one patient (1.05%) the aorto-femoral-bifurcation bypass has complicated by the prosthesis jaw thrombosis. In the long-term post-endovascular treatment period, a right renal artery stenosis has been observed in 3 patients (7.5%) with no need for a correction. Endoleaks have also been shown: type I in 1 patient (2.5%) - eliminated by an additional aortic stent, type II in 2 patients (5%) - on outpatient follow-up observation.

CONCLUSIONS

Considering an early recovery in the postoperative period, a short admission period and a lower occurrence of postoperative complications, it can be noted that the endovascular treatment of the infrarenal aortic aneurysms is the operation of choice in high-risk factor patients.

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Direct transcatheter valve-in-valve implantation in mechanical valve prostheses during left ventricular assist device implantation

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

AIMS

Left ventricular assist device (LVAD) implantation is a reasonable and at the latest practible treatment option for endstage heart failure. However, the presence of a mechanical valve is a relative contraindication for LVAD implantation due to thrombembolic events. We therefor evaluated the Valve-in-Valve concept, by removal of mechanical leaflets and consecutive implantation of a balloonexpandable transcatheter valve.

METHODS AND RESULTS

Between april 2016 to date, four patients, mean age of 52.9±11.3 years (3 male, 75%), were elected for LVAD implantation due to dilated cardiomyopathy (Ejection fraction: 13.75±2.6%). Three (75%) patients were in a critical preoperative state with NYHA classification IV. Medical history of all patients revealed at least one previous cardiac operation, but all with mechanical aortic valve implantation (2 Bentall procedure). After standard LVAD implantation with HeartMate III (St. Jude Medical, USA), aortic crossclamping and cardioplegic arrest was delivered. After removal of the mechanical leaflets, Sapien 3 (Edwards Lifesciences, USA) valves were placed within the mechanical ring, additionally secured with two prolene sutures.
Procedural success, 30 day mortality, echocardiographic and longterm follow up was analyzed.
Intraoperative course was successful in 100 % of the cases. One patient required additional RVAD implantation due to right heart failure. Cross clamp time was 28.3±9.4min. One patient (25%, LVAD/RVAD) died after 25 days, due to multi-organ failure. Echocardiographic findings revealed no (n=3, 75%) and trace (n=1, 25%) aortic regurgitation of the transcatheter valves over time. All patients were discharged (n=3, 75%) and doing well with a maximum follow-up of more than 300 days.

CONCLUSIONS

Transaortic transcatheter valve implantation in mechanical aortic valve during LVAD implantation is a feasable and safe procedure. It reduces thrombembolic events and safes crossclamp time, by avoiding Re-Root-or Re-aortic valve replacement in the presence of excessive scar tissue.

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Effectiveness and safety of TAVI in patients with pure aortic regurgitation and advanced heart failure

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

AIMS

Results of trans-catheter aortic valve implantation (TAVI) for treatment of severe non-calcific isolated aortic regurgitation (AR) complicated by advanced heart failure or cardiogenic shock has been previously reported only in isolated case reports. The aim of this study is to assess the feasibility and the effectiveness of TAVI in this challenging context.

METHODS AND RESULTS

Current self-expanding trans-catheter aortic valves are designed to treat aortic valve stenosis (AS), and have also been implanted in cases of severe AR due to degenerated bioprosthesis, and in very few cases of native aortic valves. We report thirteen consecutive inoperable patients with non-calcific, pure AR, and advanced heart failure treated with emergency percutaneous trans-femoral implantation with self-expandable Core-Valves at our institution between July 2012 and September 2017. The immediate and long-term clinical outcome was prospectively assessed according to the VARC-2 criteria for device success and safety. All but 3 patients had a previous surgery of the aortic root, including three implants of Heart Mate-II left ventricle assist device (LVAD), none had a surgical aortic bio-prosthesis at the time of the TAVI. Valve implantation was successful in 12/13 patients (92%) and one patient required a second unplanned valve procedure within 18 hours. Oversizing the prosthesis by approximately 15% yielded better results with one valve. Two patients with LVAD died within 30 days of TAVI. All patients who survived to hospital discharge had none or just mild residual AR, improved their cardiac function and survived at long-term without recurrence of clinical events.

CONCLUSIONS

The implantation of self-expandable trans-catheter valves in patients with pure AR in this small study was safe and effective, and represented an important option for inoperable patients with non-calcific severe AR.

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Clinical outcomes of ultrathin strut biodegradable polymer-coated everolimus-eluting coronary stent system in treatment of patient with de novo coronary artery lesions

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

AIMS

Evermine 50? everolimus-eluting coronary stent (EES) is a novel ultrathin strut (50 μm) cobalt-chromium coronary drug-eluting stent platform coated with biodegradable polymer. The purpose of Evermine 50 EES-KLES study was to evaluate clinical safety and performance of Evermine 50 EES in patients with de novo coronary artery lesions.

METHODS AND RESULTS

This was single-arm, single-centre, non-randomized study, and carried-out in 171 patients in which 246 lesions were treated with Evermine 50 EES. The major endpoint was major adverse cardiac events (MACE) which is a composite of cardiac death, any myocardial infarction (MI) and ischemia-driven target lesion revascularization (ID-TLR) at 6 and 12-month follow-up.

The study population included higher number of male 139 (81.29%) and average mean age was 57.85 ± 10.05 years. Diabetes was present in 70 (40.94%) patients and 69 (40.35%) had hypertension. The rate of MACE was 1 (0.66%) and 3 (2.04%) which represented similar percentage of cardiac death at 6 and 12-month follow-up, respectively. There were no ID-TLR and MI reported, and no any stent thrombosis during the follow-up period. CTRI Number: CTRI/2017/09/009939.

CONCLUSIONS

This study revealed favourable clinical safety and performance of Evermine 50 everolimus-eluting coronary stent in de novo coronary artery lesions patients.

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Is it safe to defer myocardial revascularisation according to a negative FFR in patients with severe aortic stenosis undergoing TAVI?

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

AIMS

Little is known about the best management of coronary artery disease (CAD) in patients undergoing TAVI. Fractional flow reserve (FFR) has never been validated in severe aortic stenosis (AS) and some concerns have been raised on the actual safety of deferring coronary lesions with negative FFR. The aim of this study was to evaluate the safety of FFR-guided revascularization in TAVI patients, with a particular focus on clinical outcome of deferred patients with FFR>0.80.

METHODS AND RESULTS

410 patients with severe AS underwent coronary angiography during the workup for TAVI between March 2010 and December 2017. Significant CAD, defined as the presence of a coronary narrowing >50% in the proximal segment of the main coronary branches was found in 211 (51%) patients, that were included in this retrospective analysis. Since the very first TAVI patients (treated in 2010), had a significantly higher risk profile, those with a STS score >15% or a Logistic EuroSCORE >50% were excluded from the analysis (20/211). Patients were divided in two groups according to revascularization strategy: angio-guided (108/191, 57%) vs FFR-guided (83/191, 43%). Among the physiology-guided group, the majority of lesions (99 out of 137, 72%) resulted FFR negative (>0.8) and were deferred. No complication related to the pressure-wire assessment was recorded. Less PCIs were performed in the FFR-guided group (23% vs 32%, p=0,15) with an evident trend towards better MACCE-free survival at 24-months follow up compared with the angio-guided group (96% vs 88%, p=0.08). A similar trend was observed in patients with deferred FFR-negative against those who underwent angio-guided treatment (97% vs 88%, p=0.07). When the clinical outcome of patients with FFR values between 0.75-0.85 was compared with those with FFR>0.85, no significant difference was observed between the 2 subgroups (91% vs 95% p=0,56), confirming the safety of deferring PCI after FFR-evaluation even in borderline lesions of patients with severe AS.

CONCLUSIONS

FFR-guided revascularization in patients undergoing TAVI is safe, with a 96% MACCE-free survival at 24-months follow up. Further prospective randomized clinical trials are needed to confirm the long-term benefit of FFR-guided revascularization against angiographic guidance alone in patients with severe AS.

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A comparative analysis of real-life one-year clinical outcomes in patients with coronary CTO vs. patients with non-CTO coronary artery disease treated with new generation DES - Data from E-Ultimaster registry

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

AIMS

Therapeutic approach for chronic total occlusions patients and the long term clinical outcomes in real life still remain unclear. We sought to compare one-year clinical outcomes between CTO patients and non-CTO patients treated with Ultimaster DES in a large prospective cohort.

METHODS AND RESULTS

Among atotal of 8879 patients enrolled in the large single-arm, multicentre, e-Ultimaster registry and who reached 1-year follow up, 430patients underwent percutaneous angioplasty for at least one CTO lesion (CTO), while 8383 patients had no CTO lesions (Non-CTO). The primary endpoint of the study was Target Lesion Failure (TLF) at 1 year.

CTO group had the higher rates of male than Non-CTO (CTO vs. Non-CTO, 82.3% vs. 76.3%, p=0.0041), while the mean ages were similar in both groups (64.2 vs 64.7 year, p=0.37). CTO group had significantly more cardiovascular risk factors: diabetes mellitus (32.6% vs. 25.6%, p=0.0019), lower LV ejection fraction (51.9% vs. 54.6%, p=0.005), previous MI (35.4% vs. 21.5%,

CONCLUSIONS

Despite the differences in patient and lesion characteristics, and the high complexities of the procedures, CTO group treated with Ultimaster DES yielded similar 1-year safety and efficacy outcomes to Non-CTO group. At the time of presentation complete data on more than 10.000 patients will be available along with propensity score matched analysis.

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New modified jailed balloon technique: small side branch balloon protrusion and three times inflations

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

Coronary bifurcation lesions are involved in approximately 15% of all PCI. Drug-eluting-stents are actually hired to treat most of bifurcated lesions. A major complication of this technique is the risk of side-branch (SB) occlusion after main vessel (MV) stenting. The SB occlusion may cause peri-procedural myonecrosis or hemodynamic compromise, even if in small branch. In case of small SB less than 2.5 mm diameter, two-stent strategy is not discouraged. Therefore, strategies are desirable to reduce the SB occlusion requiring to rewire of SB and stent strut dilatation during MV stenting.

METHODS AND RESULTS

Methods: Recently modified jailed balloon technique (MJBT) has gotten known for one of strategies to reduce the SB occlusion during MV stenting. In traditional MJBT, main vessel is dilated by stent and SB balloon at the same time, so proximal stent edge dissection tends to occur. Furthermore, many of cases need POT because stent under expansion due to jailed balloon is often found. Therefore, we developed evolved MJBT. Our technique is different in two points. First, the proximal markers of the SB balloon and MV stent balloon are aligned in conventional MJBT. In our institution, we set SB balloon only a little protruded into MV, and so proximal marker is distal to MV stent proximal marker. This prevents MV stent deformation and over expansion. Second, to achieve better stent expansion, stent is inflated three times. First two stent inflations are simultaneous with those of SB balloon. Then, SB balloon is removed and SB patency is confirmed by test shot, stent balloon is inflated alone. This inflation is an alternative for POT in a measure.

Results: Between March 2016 and December 2017, we picked out 55 patients (34 male, mean age 72.8±10.4 years) with 59 consecutive coronary bifurcation lesions underwent PCI using evolved MJBT. All patients PCI and clinical data were followed during hospitalization. All PCI procedures were complete. The majority of the patients had stable angina (72.7%) and Medina 1.1.1. bifurcation lesions (64.4%). LAD is the most common target (74.6%). Distal left main (LM) coronary artery disease were contained in 8 patients (14.5%). Stent diameter and length were 2.92±0.37 mm and 22.9±7.4 mm, SB balloon diameter and length were 1.84±0.33 mm and 12.8±2.2 mm, respectively. After the MV stenting, all jailed SB balloons were removed easily. TIMI3 flow was achieved in 94.9% of SB. Permanent SB occlusions were occurred in 2 lesions (3.4%). In these cases, side branches were very small and diffuse plaques were to be found, and so distal side branches were occluded. Provisional SB stenting was required only in one case (1.7%). Imaging device uses were 100%. Proximal and distal edge dissections were observed in 2 cases (3.4%) respectively by IVUS or OCT, but they were not critical. There was no major adverse cardiac event during in-hospital stay.

CONCLUSIONS

MJBT is a relatively novel technique aimed at improving SB protection during provisional stenting of bifurcated lesions considered at high risk of SB compromise after MV stenting. Our new evolved MJBT could reduce stent deformation, proximal stent edge dissection and POT demand.

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Ethnic differences in ischaemia/bleeding risk trade-off during antiplatelet therapy after DES implantation: individual patient level meta-analysis from seven randomised controlled trials

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

AIMS

Dual antiplatelet therapy (DAPT) is standard therapy in patients with ischemic heart disease undergoing drug-eluting stent (DES) implantation. Prolonged dual antiplatelet therapy (DAPT) is intended to reduce risk of ischemic events at the cost of slightly increased risk of bleeding in patients undergoing drug-eluting stent (DES) implantation. However, whether ethnicity influences this tradeoff remains unclear.

METHODS AND RESULTS

We searched for randomized clinical trials (RCT) comparing DAPT duration after DES implantation. Individual patient data meta-analysis was performed to compare outcomes between prolonged DAPT and short duration DAPT, and whether the benefit or harm of prolonged DAPT is different in Asians and non-Asians (review protocol registered at clinicaltrials.gov: NCT03338335). The primary ischemic endpoint was major adverse cardiac events (MACE) defined as the composite of cardiac death, myocardial infarction, or definite/probable stent thrombosis. The primary bleeding endpoint was major bleeding events. Analyses were performed from the time of DAPT discontinuation in the short duration DAPT group in each RCT.

Seven RCTs including 16,518 patients (8,605 Asian patients and 7,913 non-Asian patients) were pooled. MACE occurred more frequently in non-Asians (0.8% vs 1.8%,

CONCLUSIONS

Our results suggest that the ischemia/bleeding tradeoff and thus the optimal therapeutic range of antiplatelet effect differ between Asians and non-Asians. Prolonged DAPT may have no significant effects in reducing ischemia, while significantly increasing the risk of bleeding in Asians. Considering the clinical implications of bleeding events after DES implantation, we need future large-scale studies in Asian patients to test our findings before we can apply current guidelines to Asians.

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Prosthetic valve endocarditis in patients receiving a transcatheter or surgical aortic valve prosthesis - results from the NOTION (Nordic aortic valve intervention) trial

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

AIMS

Patients with severe aortic stenosis (AS) in either high or intermediant risk can be treated equally effective with surgical aortic valve replacement (AVR) or transcatheter aortic valve insertion (TAVI). Currently the longterm durability of TAVI is being investigated in order to safely include patients at lower risk and longer expected lifespan. Prosthetic valve endocarditis (PVE) is a feared complication with high mortality. Due to the difference in valve design as well as nature of the surgical and the transcatheter procedure comparison of PVE incidence and outcome is important.

METHODS AND RESULTS

The NOTION trial was a randomized-controlled trial including all-comer patients with severe AS above 75-years of age. Patients are followed continuously and cases with endocarditis including information about microbiology and imaging as well as mortality are reported.

The follow up time (median, IQR) was 4.1 (3.7,5.1) years. Sixteen cases of definite IE was recorded 9 in the TAVI group and 7 in the AVR group (NS p=0.6). The time from procedure to PVE ranged from 14 to 1920 days, (median, IQR) 626 (244,909) days. The most prevalent bacteria was Enterococci (50%) followed by Streptococci (29%) and Staphylococci (21%). Mortality was significantly increased in the PVE group, but was not different between treatment groups (AVR vs TAVI p=0.1 log rank). The only predictor of PVE in logistic regression analysis was male gender (p=0.03), whereas aortic regurgitation, pacemaker implantation, STS-score and age did not predict PVE.

CONCLUSIONS

During intermediate term follow-up PVE was equally presented among patients receiving either AVR or TAVI. The PVE diagnosis was related to increased mortality. The most prevalent bacteria were Enterococci. PVE does not seem to be a complication that should stop the current exploration of TAVI treatment in lower risk populations.

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Comparison of neointimal hyperplasia between the thin strut MiStent with microcrystalline sirolimus and the durable polymer coated everolimus-eluting Xience stent: six- and 24-month results of the DESSOLVE III OCT substudy

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

AIMS

To compare neointimal hyperplasia volume obstruction (%VO) and neointimal tissue characteristics between the thin strut MiStent with early polymer elimination and 9-month sustained drug release from microcrystalline sirolimus and the durable polymer coated everolimus-eluting Xience stent 6 and 24 months after implantation.

METHODS AND RESULTS

Optical coherence tomography (OCT) was performed in a subgroup of 53 patients (MiStent 25 lesions, Xience 30 lesions) enrolled in the all-comers randomized DESSOLVE III trial. In this sub-study, all patients required treatment of a single, de novo coronary artery lesion and had an anatomy appropriate for OCT imaging. The 6-month analysis revealed that mean abluminal %VO was significantly lower in the MiStent group (15.0±4.1% vs 18.9±6.2%,

CONCLUSIONS

The OCT analysis performed at 6-month follow-up revealed that MiStent showed favourable effects in terms of neointimal formation (efficacy endpoint) compared to Xience stents. Strut coverage and malapposition (safety profile) were comparable between the two groups. The OCT results 24 months after implantation will be reported at the time of presentation.

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Functional comparison between BuMA Supreme biodegradable polymer sirolimus-eluting and durable polymer zotarolimus-eluting coronary stents using quantitative flow ratio: PIONEER QFR substudy

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

AIMS

Quantitative Flow Ratio (QFR) based on 3-dimensional quantitative coronary angiography (3D-QCA) is a novel method to assess the physiological functionality after treatment with stents. The current study aimed to evaluate the difference in physiological functionality 9 months after implantation of a bioresorbable polymer-based sirolimus-eluting stent with an electrografting base layer (BuMA Supreme: B-SES) versus a durable polymer-based zotarolimus-eluting stent (Resolute: R-ZES).

METHODS AND RESULTS

The current post-hoc analysis was performed in the PIONEER randomized trial (1:1 randomization to B-SES and R-ZES). QFR was measured in stented vessels in both arms at pre-procedural, post-procedural and 9-month angiography without pharmacologically induced hyperemia (contrast QFR). At 9 months, both the values of QFR distal to the stent (B-SES: 0.89±0.10 vs. R-ZES: 0.89±0.11, p=0.97) and the number of the vessels with QFR

CONCLUSIONS

Quantitative flow assessment 9 months after stenting did not differ between B-SES and R-ZES, despite a significant difference in in-stent late lumen loss

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A machine-learning approach for enhancing resting state measurements for the functional assessment of coronary lesions - Initial validation on a real-world single-centre population

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Resting state pressure-derived indices have been validated in large outcome-based trials for the functional assessment of coronary artery stenosis.

This study evaluates a machine learning (ML) algorithm for inferring the hyperemic cycle-averaged pressure ratio (Pd/Pahyperemia)computed from resting state pressures and imaging measurements.

METHODS AND RESULTS

A single-centre, observational study was carried out, enrolling 84 consecutive patients with suspected coronary artery disease (CAD), with no exclusion criteria related to type / location of lesions, prior myocardial infarction, prior PCI or prior CABG. Routine coronary angiograms were acquired and invasive FFR and Pd/Parest were measured for a total of 158 lesions. Coronary angiograms from two views at least 30° apart were selected and two corresponding end-diastolic frames were chosen. On each frame, the lumen segment of interest was identified manually by selecting at least two points. Next, the lumen boundary was automatically determined by the software, manually corrected if deemed necessary, and, subsequently, the three-dimensional anatomical model was automatically generated. The coronary stenosis severity was automatically assessed quantitatively from the reconstructed anatomical model (3D QCA) and three experienced observers independently visually assessed the stenosis severity (stenosis degree: mild (

CONCLUSIONS

(Pd/Pahyperemia)computed determined from coronary angiography and invasively measured Pd/Parest has a high diagnostic accuracy and correlates closely with invasively determined FFR, thus potentially obviating the need for hyperemia.

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The correlation between quantitative flow ratio and iFR in the patients with three-vessel coronary artery disease: post-hoc quantitative flow ratio analysis of the SYNTAX II trial

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

AIMS

To assess the correlation between angiography-derived fractional flow reserve: quantitative flow ratio (QFR) and instantaneous wave-free ratio (iFR) in the patients with three-vessel coronary artery disease.

METHODS AND RESULTS

Post-hoc QFR analysis including 1,150 pre-intervened lesions evaluated by iFR in the SYNTAX II trial (NCT02015832). Out of the 1,150 lesions, 78.5% of lesions were analysable for QFR. Mean iFR of analysable lesions was 0.78±0.22 while mean QFR was 0.74±0.18. When cut-off values were set on 0.89 for iFR and 0.80 for QFR, the accuracy of QFR was 69.8 % while the accuracy of QFR among the lesions out of gray zone (0.76

CONCLUSIONS

In the patients with three-vessel coronary artery disease, QFR demonstrated good capability to predict ischemia diagnosed by using iFR as reference.

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The prevalence of heterogeneous tissue in native coronary lesions ? insight from the COMBINE study

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

AIMS

Heterogeneous tissue, described by optical coherence tomography (OCT), was associated with the increased risk of late drug eluting stent failure exclusively. Such tissue pattern was not previously described in native coronary lesions. This report for the first time presents the prevalence of heterogeneous tissue in non-ischemic native coronary lesions in diabetic patients enrolled to COMBINE trial. The single case study of a patient from COMBINE trial suggests that the heterogenous intima is the healed plaque rupture (OCT figures will be demonstrated during the report presentation).

METHODS AND RESULTS

COMBINE (OCT-FFR, NCT02989740) study is a multi-center, prospective natural history study which assesses non-culprit lesions to better predict adverse events in diabetes. OCT analysis records the presence of typical plaque vulnerability traits like thin fibrous cap atheroma, plaque rupture, plaque erosion, calcification nodules, thrombi, and neovascularization. Along the OCT analysis, a heterogeneous tissue was also found in intermediate lesions. Heterogenous tissue was defined as a well-bordered honey-like structure.

OCT analysis was performed in 236 lesions for first 200 patients of COMBINE study. Heterogeneous tissue was detected in 38 (16%) lesions of 34 (17%) patients. There were no differences in minimal lumen area (mm2, 2.6 IQR 1.6-3.3 vs. 2.4 IQR1.8-3.3, p=0.911), lesion length (mm, 25.10 IQR17.10-43.20 vs. 21.10 IQR 13.10-32.10, p=0.145), FFR values (0.88 IQR0.83-0.93 vs. 0.89 IQR0.85-0.93, p=0.174], presence of lipids [29 (76%) vs. 139 (70%), p=0.446], calcifications [33 (86%) vs. 169 (85%), p=0.811], thin fibrous cap atheromas [11 (29%) vs. 40 (20%), p=0.230], rupture plaques [5 (13%) vs. 15 (8%), p=0.258] and dissections [1(3)% vs. 10(5%), p=0.510] between lesions with or without heterogeneous tissue. Interestingly, heterogeneous tissue occurred less frequently in smoking patients [2(6%) vs. 37 (23%), p =0.062], but with the same frequency in patients with acute coronary syndromes [6 (18%) vs. 26 (16%), p =0.774] and insulin intake [12 (35%) vs. 65 (39%), p=0.673].

CONCLUSIONS

The presence of heterogeneous tissue occurred in non-culprit lesions more often in non-smoking diabetic patients. Any traits of plaque morphology do not have an impact on heterogeneous tissue presence. The patients? follow-up will answer whether heterogenous tissue has any prognostic value on diabetic patients? adverse events.

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Screening of systemic arteriopathy in patients with spontaneous coronary artery dissection

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

AIMS

Systematic investigation of extracoronary arterial territories in North American patients with spontaneous coronary artery dissection (SCAD) has revealed a high prevalence (near two thirds) of systemic arteriopathy, namely fibromuscular dysplasia (FMD). The purpose of this study was to prospectively investigate the presence of systemic arteriopathy in a large Spanish cohort of SCAD patients using magnetic resonance angiography (MRA).

METHODS AND RESULTS

Patients recently diagnosed with SCAD in our centre were invited to participate in a non-invasive screening protocol based on contrast-enhanced MRA to assess the cephalic and abdominal-pelvic arterial territories. The procedure was performed in a two-in-one acquisition using a 1.5 Tesla magnetic resonance with the administration of intravenous gadolinium. Two vascular radiologists supervised the acquisitions and analysed the results. FMD was diagnosed with the finding of an arterial beading appearance in at least 1 vascular territory.

A total of 40 patients completed the MRA protocol. Mean age was 51±8.6 years, 90% (n=36) were women, 50% (n=20) smokers, 35% (n=14) had hypertension, 40% (n=16) had dyslipidemia and only 1 patient was diabetic. STEMI was the clinical presentation in 55% (n=22) of the patients and NSTEMI in the remainder. A total of 16 patients (40%) had at least one pathological finding: 6 patients (15%) were diagnosed with FMD, 5 patients (12.5%) showed arterial elongations, 3 (7.5%) had focal stenoses, and only 2 (5%) patients were found to have aneurysms, at the celiac trunk and splenic artery respectively. Patients with detected FMD were all women. No significant differences were observed between patients with and without FMD regarding clinical characteristics or presentation. However, the small number of patients with FMD precludes detecting relevant differences. Regarding outcomes, 3/6 (50%) and 5/34 (15%) received PCI in the FMD and non-FMD groups respectively (p=0.08). At a mean follow-up duration of 4±3 years, there was 1 SCAD recurrence episode in each group. No deaths or strokes occurred.

CONCLUSIONS

In this single-centre SCAD cohort systematically studied with MRA of the cephalic and abdominal-pelvic arterial beds, systemic arteriopathy including FMD showed a much lower prevalence than previously reported. This association might not be as strong as presumed, yet a larger study is needed to provide more accurate data in this population.

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Feasibility and safety of intracoronary imaging in spontaneous coronary artery dissection

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

AIMS

Intracoronary imaging (ICI), especially OCT, provides unique findings in spontaneous coronary artery dissection (SCAD). On the other hand, spontaneously dissected arteries have a propensity to suffer iatrogenic damage from vessel manipulation. The present study aims to provide real-world data regarding the use of ICI in SCAD, describing feasibility and safety of these techniques.

METHODS AND RESULTS

From a single centre experience, we scrutinised procedures where ICI was used for diagnosis or surveillance of SCAD. The main objectives were: (1) to describe the cases were ICI was unfeasible (fail to assess target lesion) and/or where ICI potentially caused iatrogenic damage (worsening in TIMI flow from baseline or new/ propagated dissection to a different vessel), (2) to analyse differences between complicated and uncomplicated cases, (3) to describe the number of true SCAD diagnoses and non-SCAD aetiologies found with ICI.

Regarding feasibility, ICI was intended for ascertaining SCAD diagnosis in 38 patients and was used for surveillance after SCAD (> 1 month) in 10 patients. In the 10 surveillance cases, ICI was successfully acquired. In the 38 diagnostic cases, ICI was unfeasible in 4 (incomplete advancement of the imaging catheter or vessel trauma) and successful in 34. Of these latter, 26 were confirmed as SCAD and 8 were attributed a different aetiology i.e. eroded/ulcered plaque, adhered thrombus or false angiographic image. Of the 4 failed cases, 3 were confirmed to be SCAD by the finding of spontaneous vessel restoration on repeat angiography. Overall, ICI successfully diagnosed 90% (26/29) of the attempted SCAD lesions and was able to assess 100% (10/10) of the follow-up SCAD vessels.

Regarding safety, in 6 out of 39 SCAD cases (29 diagnosis + 10 follow-up) ICI produced some degree of iatrogenic damage. All cases occurred in women (6/30 vs 0/9, p=0.3) during ad hoc ICI at the time of initial diagnostic angiography (n=17). In contrast, there were no complications when diagnostic ICI was staged (n=12, mean deferral time 3.8 days) nor when it was performed at follow-up (n=10, mean follow-up time 6 months). Iatrogenic damage was attributed to wiring (4), guiding catheter (1) or to the imaging catheter (1). Half of the cases presented initially with impaired TIMI flow. Half of the cases occurred in the LAD and the other half in the RCA. No relevant differences were found in vessel size or in other variables. One case was managed conservatively whereas the other 5 required PCI, with no further complications during admission nor hard clinical events during a minimum follow-up of 1-year.

CONCLUSIONS

Intracoronary imaging employed for diagnosis or surveillance of SCAD was feasible in the majority of cases. ICI related complications were infrequent and happened invariably in the acute setting.

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Left main stenting in patients with a high SYNTAX score. The results of the first 12 months

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

AIMS

According to current European Guidelines patients with left main stenosis and high SYNTAX Score should be transferred to bypass surgery. However left main stenting may be the only method of radical treatment if the surgery is impossible. Our study aims to assess effectiveness and safety of endovascular intervention in the patients with left main stenosis and high SYNTAX score

METHODS AND RESULTS

The prospective single-center study of left main stenting in the patients with medium and high SYNTAX Score included 112 consecutive patients with combination of left main stenosis with multi-vessel coronary lesions and concomitant diseases, who were denied for surgery by Heart Team. The patients were divided into two groups. The first group included 66 patients with the SYNTAX Score 23 - 32 and the second group consisted of 46 patients with Syntax Score >32. The rate of myocardial infarction, stent thrombosis, strokes, deaths for 12 months were assessed. The basic data such as age, comorbidities, previous myocardial infarction and stroke was similar. The group 1 included more patients who were previously treated with PCI. 30 - day rate of cardiac deaths (3.03% vs. 4.35%. p=0.36) and non-fatal myocardial infarction (0% vs. 2.17%, p = 0.16) were similar for the both groups. In 12 months the combination of fatal and non-fatal myocardial infarction rate (8.47%, vs. 11.11%. p=0.33) and cardiac death rate (6.78%, vs. 6.67%. p=0.5) were the same. There were no strokes and noncardiac deaths in both groups. 12 month probable stent thrombosis rate was statistically same (3.39% vs. 6.67%. p=0.23) although there was some trend to higher absolute values in the second grou

CONCLUSIONS

The first results of our study showed that left main stenting to the patients with medium and high SYNTAX Score is possible and comparable for 12 months. Further assessment is necessary for this complex cohort of patients

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Non-uniform temporal evolution of FFR in intermediate coronary lesions: what matters?

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

To explore if FFR evolves uniformly over time in coronary lesions according to their location and their baseline hemodynamic status.

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

CONCLUSIONS

Faster functional atherosclerosis progression (lower FFR values) is observed with LAD stenoses. From a practical standpoint, our data suggest to systemically re-assess with FFR intermediate LAD lesions at the occasion of a repeat angiogram. Similarly, progression (or regression) rate of FFR also differs according to baseline values, lesions that have the higher FFR baseline (in the range of 0.9-1.00) deteriorate faster.

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Outcomes from the OPTALYSE-PE trial of ultrasound-facilitated, catheter-direct thrombolysis in intermediate-risk pulmonary embolism

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

AIMS

Patients presenting with intermediate-risk pulmonary embolism (IR-PE) have a variable outcome, with published mortality rates of 3-15%. Optimal management of this group remains uncertain. Systemic tPA causes an excess of bleeding and therefore low-dose, catheter-directed thrombolysis may be a better option for IR-PE, though the optimal regimen for this treatment remains uncertain.

Ultrasound-facilitated, catheter-directed thrombolysis (USCDT) has been shown to rapidly offload the dilated right ventricle in IR-PE. We report results from a randomised trial of USCDT using very-low doses of tPA.

METHODS AND RESULTS

We conducted a multinational, multicenter, prospective randomised trial of differing doses and durations of treatment using USCDT to compare safety and efficacy of four prospective protocols designed to reduce duration of treatment and/or dose of tPA administered.

OPTALYSE PE randomized 101 patients in 17 centers in the USA and the UK to one of four treatment protocols using the Ekos system. One patient did not undergo the procedure and therefore results from 100 patients are reported. Each patient was categorized as having an intermediate-risk PE, with proximal PE and right ventricular dilatation (RV/LV diameter ratio ?0.9) on CT pulmonary angiography

Arm 1 received 2 hours of USCDT using 4mg of tPA in total per lung.

Arm 2 received 4 hours of USCDT using 4mg of tPA in total per lung.

Arm 3 received 6 hours of USCDT using 6mg of tPA in total per lung.

Arm 4 received 6 hours of USCDT using 12mg of tPA in total per lung.

Arm 4 was stopped prematurely after 18 patients had been randomised to treatment due to an adverse bleeding event. We therefore report results for Arms 1-4 on 27, 27, 28 and 18 patients, respectively.

Repeat CT scans performed at 48+/-6 hours showed similar reductions in RV/LV ratio between all four arms (Arms 1-4: reduction in RV/LV ratio of 24%, 23%, 26%, and 26% respectively). A dose dependent reduction in CT clot burden, as demonstrated by Modified Miller Score, was seen across the four groups (Arms 1-4 clot burden reduction: 4%, 10%, 14% and 39% respectively).

At 30 days, there were two episodes of intracranial hemorrhage, one following conversion to systemic thrombolysis and one in a patient who received the 24mg dose (this event led to the termination of Arm 4). Pre-specified criteria for major bleeding (ISTH) were met in 4% of patients, two of whom had received additional tPA at investigator discretion. One year outcomes show an all-cause mortality rate of 2%, only one of whom died in the first 30 days.

CONCLUSIONS

One year safety outcomes were excellent in this prospectively studied group of 101 patients randomized to

four different regimens of ultrasound-facilitated, catheter-directed thrombolysis for intermediate-risk pulmonary embolism using the Ekos catheter. The degree of RV unloading observed by repeat CT at 48 hours suggests a flat dose-response curve, with the lowest dose/duration of tPA as effective as the highest dose/duration.

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Use of quantitative flow ratio to perform functional assessment of non-culprit lesions at the time of STEMI in patients with multivessel disease

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

AIMS

Quantitative Flow Ratio (QFR) is a novel diagnostic tool that estimates FFR from 3D-quantitative coronary angiography and TIMI frame count. The aim of this study was to evaluate the reliability of QFR in estimating Fractional Flow Reserve (FFR) of non-culprit (NC) stenoses in the context of STEMI with multivessel disease (MVD), taking as a reference the FFR value measured at staged interval.

METHODS AND RESULTS

The study included patients with STEMI and one or more NC stenoses in a coronary artery different than the culprit vessel, investigated in two centres in Spain and the United Kingdom. FFR was measured in a staged procedure in the subacute phase of the infarction. Exclusion criteria was left main stem stenosis, previous CABG, and coronary angiogram during primary PCI not suitable for analysis. QFR measurements were performed at a central core laboratory, by analysts blinded to FFR data and decision to revascularise the NC vessel. The contrast QFR modality (TIMI frame count included in the computation) was used to adjust as much as possible for flow conditions during primary PCI. The agreement and diagnostic efficiency of QFR in assessing functional NC stenosis relevance was established using 0.80 as a cut-off value for both FFR and QFR.

41 NC stenoses (35 patients) were included in the study. The NC was located in the left or right coronary 37 (90.2%) and 4 (9.8%) respectively. FFR was measured 24.7 ± 37.7 days after STEMI. Adenosine was administrated intravenously in all cases. Mean patient age was 61±10.5 years, 81% were men and 22% were diabetics. Mean diameter stenosis (DS), FFR and QFR were 53.5±8.4%, 0.80±0.09 and 0.79±0.10 respectively. QFR Pearson coefficient of 0.63 indicated a moderate positive correlation. The diagnostic accuracy, sensitivity and specificity of QFR were 78, 76 and 80% respectively. ROC analysis showed area under the curve for QFR and DS of 0.87 (CI 95% 0.76-0.97) and 0.68 (CI 95% 0.51-0.85) respectively (p=0.007).

CONCLUSIONS

In patients with STEMI and MVD, quantitative flow ratio showed good diagnostic performance in assessing the functional relevance of non-culprit stenoses, providing a strong incremental value over conventional angiographic indices. These findings open a new avenue to a faster risk stratification of patients with STEMI and MVD.

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Stent - Save a Life Initiative in Argentina: STEMI treatment in 37 model centres

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Reperfusion therapy is the treatment of choice in STEMI patients,however,many patients don´t benefit from it because of the lack of access to well-organized health care system.A highly fragmented health system,lack of culture of reperfusion in cardiology community,absence of coordinated care between the emergency medical system and 24/7 primary PCI centers with a few STEMI networks developed were the more common barriers found in our country.The aim of the present work is to know how are we treated STEMI patients at model centers participating in the Stent Save a Life Initiative in Argentina.

METHODS AND RESULTS

From March 2016 to December 2017 we prospectively included all patients with suspected STEMI within 48 hours of the onset of pain in 37 models center with primary PCI 24/7 capacity participating in the Stent Save a Life Initiative in Argentina. A total of 2636 patients were included, of which 149 (5.6%) were false activations.
The average age of the population was 61 ± 11 years with 80% of male patients.
20.5% of the patients called the EMS, while 40.5% and 39% went directly to the emergency department of the pPCI and non-pPCI centers respectively.
Of the patients who contacted the EMS, 17.3% were transferred directly to centers without pPCI capacity, and only 22.5% of the patients who were transfered to pPCI center pre-activated the cath lab.
Regarding reperfusion strategy: 2278 patients (91.5%) were treated with PCI (88.5% pPCI

CONCLUSIONS

This data is the first step to understand the reality of the management of patients with STEMI in our country. The suboptimal FMC to device time reflect the lack of a coordinated work between the different actors involved in the treatment of our STEMI patients.The active and continue participation will allow to develop strategies for create STEMI networks adapted to local reality of each center.

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Creation of a Catheter Laboratory Emergency Medical Simulation training programme: the "CLEMS" course

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

AIMS

Cardiac catheterisation laboratories (cath labs) deal with increasingly fragile populations presenting in the acute setting. Dedicated staff resuscitation training is not always guaranteed in some hospitals. We devised a focused training programme for cath lab medical and allied healthcare professionals (AHPs). Our aim was to develop confidence, team building & the use of advanced life support algorithms. We used human factors training to aid independent recognition, assessment & management of unstable cath lab patients, allowing medical staff to complete interventions in critical scenarios.

METHODS AND RESULTS

Methods: We utilised a computerised high-fidelity and physiologically realistic mannequin within the University of Manchester's dedicated simulation facilities to deliver multi-disciplinary training to cath lab medical and allied healthcare professionals. We adapted Guarmard software, with a dedicated interface to a mannequin that offers real-time alteration of haemodynamic and cardiopulmonary data in response to evolving clinical scenarios. Delegates attended in teams that normally work together, to simulate real-world interactions in their own hospitals. All delegates received two days of didactic lectures, workshops and simulation scenario training. Clinical vignettes included evolving emergency situations seen commonly in the cardiac cath lab, following internationally recognised Advanced Life Support (ALS) algorithms. Expert teaching input was provided by a large faculty of dedicated teaching staff drawn from nursing, radiography and cardiac physiology, as well as cardiology and anaesthesia backgrounds. Delegates were observed by their peer groups, and underwent a structured debriefing process. Emphasis was made on the role of team working with clinical human factors and WHO checklisting methods being a key facet of the programme.

Results: Over a three year period, feedback from delegates has been positive. 100% of attendees felt they had received significant benefit. 100% of delegates felt the knowledge and skills gained on the course would be used in future clinical practice. Enhanced familiarity with resuscitation protocols has led to local uptake of similar programmes, and the authors have been asked to train other units. Further feedback from delegates has been apparent with one group forming a similar scheme in their own hospital and presenting this project at a national (UK) resuscitation meeting.

CONCLUSIONS

We have successfully created a dedicated and highly realistic simulation programme for cath lab staff working with critically sick patients. Our aim was to allow AHPs and more junior medical staff to manage unstable patients whilst more senior cardiologists completed interventional procedures during life-threatening emergencies. We are now introducing in-house training during routine lists in our own laboratories. Additional roll-out of our programme and a specific training algorithm is to be introduced this year. Further work will increase professional independence of AHPs during critical incidents enabling physicians to safely complete

technical tasks.

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Circumflex artery movement at dynamic cardiac CT: implications for transcatheter direct mitral annuloplasty

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

AIMS

Catheter-based mitral valve direct annuloplasty is an emerging treatment for patients with severe mitral regurgitation (MR) deemed too high-risk for surgery. This study aims to evaluate the motion and spatial relationship of the circumflex coronary artery (Cx) with respect to the mitral valve annulus (MVA) during the cardiac cycle, using dynamic cardiac computed tomography (DCCT).

METHODS AND RESULTS

A total of 20 patients with severe MR (mean age 78 ± 7 years, 62% men) who underwent DCCT prior to Cardioband transcatheter annuloplasty were evaluated. In all patients, a distance of 4 mm from LV endocardium to device anchor and a 45° angle of anchor?s penetration were set. The minimum distance from the 6 mm-long projected anchor to Cx was measured in the systolic and diastolic phase, along fixed regions of the posterior MVA, from anterolateral to posteromedial trigone.

In 18 out of 20 patients non dominant Cx artery was present. At multiplanar reconstruction CT analyses, at the level of the anterolateral trigone a distance of 6.1 mm (IQR 4.9-7.8) from Cx to projected anchor was measured, with a Cx excursion of 0.7 mm (IQR 0.4-1.3). The narrowest points anchor-Cx were found in end-diastolic phase, at the first and middle portion of P1, with a median distance of 4.1 mm (IQR 2.2-5.3) and 3.5 mm (IQR 2.5-5.1), respectively. The movement of the Cx between systole and diastole in these regions revealed a median excursion of 1.9 mm (IQR 1.1-2.3) and 1.4 mm (IQR 0.6-2.8), respectively. In the 2 patients presenting left dominance, the Cx maintained stable distance [median 4.5 mm (IQR 3.7-5.5)] and significant systolic-diastolic excursion [median 3.3 mm (IQR 2.6-4.0)] in P2 and P3 segments.

CONCLUSIONS

This is the first systematic dynamic CT analysis reporting the excursion of the Cx during the cardiac cycle, with respect to the mitral annulus. The range of movement of the Cx is high in the P1 region, in which the artery is closer to the annulus. The independent movement of the Cx with respect to the mitral annulus supports the fact that static CT measurements can overestimate the risk of circumflex coronary impingement during direct mitral annuloplasty.

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The use of thrombectomy and glycoprotein IIb/IIIa inhibitors in primary PCI for STEMI is not associated with increased mortality

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

The treatment of STEMI with thrombectomy, and routine use of GPIIB/IIIA inhibitors, have been questioned in the setting of primary PCI (pPCI). Furthermore the socioeconomic status of patients is thought to be an important determinant of cardiovascular outcomes following MI. We investigate whether these treatment options, or a patient?s deprivation index, are independent predictors of mortality in pPCI for STEMI at a high-volume tertiary referral centre.

METHODS AND RESULTS

We retrospectively collated 6,468 cases from 2007 ? 2017 who presented to a tertiary service with ST elevation myocardial infarction and went on to receive pPCI. Patients undergoing thrombectomy and receiving a glycoprotein IIB / IIIA inhibitor (GPIIb/IIIa) were identified. We recorded their comorbidities, procedural details. and derived their index of deprivation from their home postcode and its nationally ascribed UK Carstairs index, expressed as a continuous variable.

Logistic regression was carried out to determine whether any of the comorbidities (gender, previous MI, previous CABG, previous PCI, diabetes mellitus, use of insulin, smoking status, family history, hypertension, prior renal impairment and age at the time of procedure), or index of deprivation, were determinants of the dependent variable of surviving to discharge. This demonstrated that age (

CONCLUSIONS

Thrombectomy or GPIIb/IIIa during pPCI for STEMI were not significant independent predictors of mortality. Also patients? index of deprivation was not seen to be a significant independent predictor of mortality in our cohort. The factors that did affect mortality were all pre-existant or demographic.

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Early and mid-term outcomes of TAVI using the new-generation self-expanding Evolut R compared with the previous generation CoreValve

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

AIMS

To assess early and mid-term outcomes of transcatheter aortic valve implantation (TAVI) using the new-generation self-expanding Evolut R (Medtronic Inc., Galway, Ireland) compared with the previous generation CoreValve (Medtronic Inc., Galway, Ireland).

METHODS AND RESULTS

This is a prospective, single-center study including 734 consecutive patients undergoing transfemoral TAVI either CoreValve (n=436) or Evolut R (n=298). For the purpose of our analysis 290 patients treated with the Evolut R were matched using the propensity score method to 290 patients treated with the CoreValve.

Mean age was 81.5 ± 4.8 years and mean STS score was 5.0 ±3.4%. No differences between groups were reported in any of the baseline characteristics.

In-hospital all-cause and cardiovascular death were 5.9% vs. 3.4% (p=0.168) and 3.8% vs. 1.4% (p=0.067) among CoreValve and Evolut R patients, respectively. Patients treated with Evolut R experienced higher significantly lower incidence of moderate or severe paravalvular regurgitation (14.4% vs. 1.3%,

CONCLUSIONS

In this matched comparison of high surgical risk patients undergoing TAVI, the use of Evolut R was associated with a significant lower incidence of moderate or severe paravalvular leak, pacemaker implantation and minor vascular complications

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Evaluation of the efficacy of OCT processed with the attenuation-compensated technique in assessing plaque and neointima morphology in atherosclerotic and neoatherosclerotic lesions

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

AIMS

To evaluate the efficacy of optical coherence tomography (OCT) processed by the attenuation-compensated technique in assessing plaque pathology in native and stented segments.

METHODS AND RESULTS

We analysed data from 37 patients who underwent OCT imaging for clinical purposes, 400 frames (200 portraying native and 200 portraying stented segments) were randomly selected and processed using the attenuation-compensated technique as well as the conventional technique. The processed and the conventional images were segmented by two analysts who identified the internal elastic membrane (IEM), lipid pools, calcium, plaque micro-characteristics and thrombus burden. The analysis was performed twice and the inter- and intra-observer variability in the attenuated-compensated and conventional images were reported.

In the native vessels, the intra-observer variability was lower in the conventional OCT images compared to the attenuation-compensated OCT images for the presence of lipid pools (k=0.751 vs k=0.683) and calcific tissue (k=0.967 vs k=0.880). Similar findings were reported in the neoatherosclerotic analysis where there was an excellent agreement for lipid pools (k=0.905) and calcium (k=0.979) in the conventional method and a moderate agreement (k=0.704 for lipid pools and k=0.638 for calcium) in the attenuation-compensated method where artefacts from the stent struts inhibited the accurate evaluation of neointima characteristics.

The inter-observer agreement was similar in native segments for the lipid pools (k=0.789 vs 0.765) and calcific tissue (k=0.911 vs 0.913) for the conventional and the attenuation-compensated method. In the neoatherosclerotic segments similar agreement was noted for the lipid pools (k=0.789 vs k=0.770). However, the increased artefacts seen in the neointima in the attenuated-compensated images resulted in an underestimation of the incidence of the lipid component in this group (6% vs 29%). On the other hand, the inter-observer agreement for the calcific tissue was higher in the conventional method (k=0.911 vs k=0.767).

Another limitation of the attenuation-compensated algorithm was the increased noise that prevented visualisation of vessel wall micro-characteristics (i.e. macrophages, cholesterol streaks, neovessels) and quantification of the fibrous cap thickness. There was no difference between the two visualisation techniques for the detection of the IEM and thrombus.

CONCLUSIONS

The attenuation-compensated method does not appear to increase the efficacy of OCT in detecting plaque morphology in native segments and underperforms compared to conventional method in stented segments. Further research using histology data in needed to examine whether combined conventional and attenuated-compensated OCT imaging enables more accurate detection of plaque pathology than standard OCT.

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Post-conditioning reduces the extent of microvascular obstruction in early presenters with acute STEMI

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Postconditiong (postcon) has been reported to reduce infarct size in ST-segment myocardial infarction (STEMI). However recently few other studies did not show any effect of postcon or suggested that it may be even harmful.

We sought to assess whether postcon could reduce infarct size (IS) and microvascular obstruction (MVO) zone in early presenters with high-risk STEMI.

METHODS AND RESULTS

74 STEMI patients treated with primary coronary intervention (PCI) were randomly assigned to postcon group (n=37) or standard PCI group (n=37). Postcon was performed immediately after obtained reperfusion with 4 balloon occlusions, each lasting 30 seconds, followed by 30 seconds of reperfusion. Cardiac magnetic resonance was performed in all subjects within 48 to 96 hours after the admission. Morphology and function of myocardium was estimated by a steady-state free precession (SSFP) sequence. To evaluate the infarct size and MVO, a late gadolinium enhancement (LGE) technique was performed. Infarct size was defined as an area greater than 50% of the maximal signal intensity within LGE. MVO was defined as an area of the absence or hypoenhancement of contrast surrounded by LGE. Infarct size and MVO were determined by planimetry and a summation of discs method. Postcon was associated with significantly smaller IS (16.58±9.6 vs 31.2±22.9 g, p=0.007) and higher ejection fraction (59.8±9.2% vs 52.3±10.2%) as well as in lower creatinine kinase and troponin I peak serum level (2297±1391 vs 3268±1163,

CONCLUSIONS

In early presenters with STEMI postcon could significantly reduce infarct size and limit reperfusion injury.

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Standardised outcomes and cumulative sum of failure analysis according to clinical risk in transfemoral TAVI patients

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

AIMS

Multiple registries and clinical trials report early and long-term outcomes after Transcatheter Aortic Valve Implantation (TAVI). However, the low rate of standardized events adoption, especially for composite endpoints, limits the comparability of different experiences. We report the VARC-2 composite outcomes of a monocentric transfemoral TAVI-program, stratified by clinical risk as assessed by STS-SCORE. Furthermore, we analysed the performance of the TAVI intervention for each risk group by means of the Cumulative Sum of Failure (CUSUM) method.

METHODS AND RESULTS

Between April 2010 and December 2017, 335 consecutive patients (43% males), aged 81.5 ± 7.6 years, underwent transfemoral TAVI in our center. Mean STS-SCORE varied broadly but averaged 7.7% (median 5.6%). In 225 patients (67.2%) STS-SCORE was >8% for mortality (high-risk), while in 110 patients (32.8%) STS-SCORE wa

CONCLUSIONS

The comparability of transfemoral TAVI outcomes in literature is limited by the limited adoption of standardized outcome reporting. In our monocentric experience of 335 consecutive transfemoral TAVI procedures all-cause death was 2.4% at 30 days and 11% at 2-years. Myocardial infarction and stroke were 0.6% at 30 days, while 1.1 and 1.7% at 2 years, respectively. As expected, VARC-2 composite endpoints were more frequent in higher risk subjects. Nevertheless, at CUSUM analysis, TF procedure remained under control in each subgroup with the exception of ES in higher risk group, being stably under the upper limit after 18 cases. Reporting clinical events using shared parameters, such as VARC-2 endpoints, is crucial to enhance the analysis of outcomes for different TAVI studies.

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Acute response to low flow ischaemia in mechanically assisted high-risk PCI

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

AIMS

Obstructive coronary artery disease affects Left Ventricular performance. Coronary ischemia results in increased left ventricular (LV) volumes, diastolic stiffness and end-diastolic pressure with reduced contractility. These effects ensue within 60s after the onset of ischemia but may be reversible with revascularization. This study aims to evaluate the immediate effects of multi-vessel PCI on left ventricular dynamics by interrogating real-time pressure-volume relations.

METHODS AND RESULTS

Left ventricular pressure-volume relationships were evaluated with a dedicated conductance catheter, inserted into the left ventricle before PCI. Single-beat estimation algorithms were used in systole and diastole. For each patient, pre-PCI measurements were matched with post-PCI sets. A total of 5 patients underwent multi-vessel PCI with concomitant pressure-volume loop assessment. Mean age was 74.8±8.8 years, SYNTAX II 4-year mortality risk was 28±21.3%, and LVEF was 51±11%. Revascularization decreased the end systolic pressure volume relationship (ESPVR) end-systolic elastance (Emax: 2.4 IQR: 1.04 to 3.76 vs 1.7 IQR: 1.15 to 2.26 mmHg/mL). The systolic Ejection Time and LV compliance increased. The coefficients ? for chamber stiffness (5.24, IQR: 2.98 to 7.51 vs 3.06, IQR: 2.69 to 3.42) and ? (43.2, IQR: 34.3 to 52.1 vs 41.4, IQR: 29.9 to 52.9 ms) both decreased, demonstrating a reduction in stiffness with improvement of ventricular relaxation and filling. The End-systolic Pressure (141, IQR: 133.65 to 148.35 vs 121.9, IQR: 113.6 to 130.2 mmHg) and End-diastolic Pressure (21.71, IQR: 15.19 to 28.23 vs 13.26, IQR: 12.05 to 14.47 mmHg) decreased. The End-diastolic volume (125.31, IQR: 94.31 to 156.3 vs 124.96, IQR: 95.07 to 154.85 mL) and LVEF remained stable (52.99, IQR: 45.22 to 60.76 vs 50.63, IQR: 46.31 to 54.95 %). Stroke volume increased (70.31, IQR: 48.26 to 92.37 vs 72.15, IQR: 65.87 to 78.43mL) with concomitant reduction in heart rate (68.66, IQR: 60.62 to 76.7 vs 62.29, IQR: 52.81 to 71.77 bpm) leading to an overall reduction in the cardiac output post procedurally (5.57, IQR: 4.99 to 6.14 vs 4.39, IQR: 3.26 to 5.52 L/min).

CONCLUSIONS

PCI has immediate effects on LV dynamics, with reduced LV stiffness and lower filling pressures.

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First-in-man experience of a novel transradial device for embolic deflection during TAVI

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

AIMS

Periprocedural embolic stroke is a major cause of morbidity in cardiovascular interventions. Clinical cerebrovascular event rates as high as 10% have been reported at 30 days following transcatheter aortic valve implantation (TAVI). Although cerebral embolic protection devices that provide partial protection of the brain during TAVI have been developed, a low profile adjunctive transradial device for complete protection of the brain is desirable.

METHODS AND RESULTS

The ProtEmbo Cerebral Protection System (Protembis GmbH, Germany) is an intra-aortic filter device that deflects embolic material arising during cardiovascular intervention away from the cerebral circulation. The device consists of an implantable filter introduced via a 6F transradial access, which prevents the migration of embolic particles through the three great branch vessels into the cerebral vasculature. The safety and feasibility of the device will be tested in a prospective, observational, multi-center, intention-to-treat study in subjects with severe symptomatic native aortic valve stenosis indicated for TAVI (up to 10 patients). The primary safety endpoint of the study is defined as in-hospital procedural safety defined as occurrence of all Major Adverse Cardiac and Cerebrovascular Events (MACCEs) defined by the Valve Academic Research Consortium (VARC-2) criteria, including device-related safety outcomes. Stroke severity will be quantified according to the National Institutes of Health Stroke Scale (NIHSS). The primary feasibility endpoint is defined as technical success. The secondary efficacy endpoint is defined as frequency, number and volume of new cerebral lesions assessed on diffusion weighted magnetic resonance imaging (DW-MRI) prior to discharge at day 3 compared to baseline and historical control group, and same MRI outcomes evaluated on DW- and fluid-attenuated inversion recovery (FLAIR) MR images at 30 days. Neurocognitive function will be compared using MoCA at baseline, post-op and 30 days post-procedure.

CONCLUSIONS

Ongoing patient recruitment and prospectively collected core-lab adjudicated neurological assessment and serial MRI studies will be available for presentation for the first time at EuroPCR 2018.

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Comparative registry of everolimus-eluting stent and zotarolimus-eluting stent in diffuse long coronary artery lesion (EXLONG registry): three-year clinical outcomes

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

AIMS

Everolimus eluting stent and zotarolimus eluting stent is popular stent. But there is insufficient data to compare clinical outcomes of everolimus eluting stent (EES) versus zotarolimus eluting stent (ZES) in long lesion of coronary artery. In this study, clinical outcome and safety of EES and ZES were evaluated in diffuse long coronary lesion.

METHODS AND RESULTS

300 patients treated with ZES or EES in long coronary lesion (total stent length ? 25mm) were enrolled respectively (Total 600 patient). Clinical outcomes and safety were compared between two groups. Primary end point is target lesion failure (Composite of Cardiac death, Target vessel MI and Clinically driven target lesion revascularization) at 1 year. All cause mortality, other MI, target vessel revascularization, target lesion revascularization, stent thrombosis and readmission rate for 3 years were included in secondary endpoints.

From September 2011 to December 2016, out of a total of 600 patients enrolled prospectively and followed for 3 years at 7 centers in Korea, a total of 528 patients, excluding 72 patients for valid reasons, were analyzed (255 patients in EES group and 273 patients in ZES group). Baseline characteristics of two groups were not shown significant difference except current smoking (36.7% in ZES vs. 26% in EES, p=0.007). Complex lesions were more common in the ZES group and lesions previously treated were more in EES group. Both stents showed proper result (TLF at 1 year 2.9% in ZES vs. 1.9% in EES, p=0.472). There was no significant difference in target lesion failure at 1 year follow up. Major adverse cardiac events during the three years follow-up also showed no significant difference between the two groups.

CONCLUSIONS

Both EES and ZES showed excellent clinical results in patients with long coronary lesion. The results showed that there was no statistical difference in target lesion failure at 1 year and clinical event during the 3-year follow-up.

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Outcomes in patients with three-vessel coronary artery disease undergoing state-of-the-art PCI treated with different DAPT regimens: insights from the SYNTAX-II study

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

AIMS

Ticagrelor and prasugrel are recommended in patients presenting with acute coronary syndromes, however, data on patients with stable coronary artery disease are scarce. The aim of this study was to compare the outcomes between patients with three-vessel coronary artery disease undergoing state-of-the-art PCI with the SYNTAX-II strategy treated with ticagrelor/prasugrel or clopidogrel.

METHODS AND RESULTS

Patients with de novo three-vessel coronary artery disease without left main involvement included in the SYNTAX-II study were analyzed. Patients treated with clopidogrel were compared with patients treated with more potent antiplatelet therapy (i.e., ticagrelor or prasugrel [non-clopidogrel group]). Primary endpoint was major adverse cardiac and cerebrovascular events (MACCE) at 1 year. Secondary endpoints were the individual component of the primary endpoint and definite or probable stent thrombosis. Event rates are reported using Kaplan-Meier estimates and compared with the log-rank test. Cox proportional hazard model was used to adjust baseline characteristics between groups. In 446 patients who received oral P2Y12 inhibitors at discharge, 298 received clopidogrel (66.8%) whereas 148 patients received ticagrelor or prasugrel (33.2%). Mean age was higher in the clopidogrel group when compared to non-clopidogrel group (mean difference 3.2 years, standard error ± 0.97, p value=0.001). There was no significant difference in comorbidities between groups except for a higher percentage of chronic kidney disease (Creatinine clearance

CONCLUSIONS

In patients with de novo three-vessel coronary artery disease undergoing state-of-the-art PCI with the SYNTAX-II strategy, treatment with clopidrogrel or more potent antiplatelet therapy was associated with comparable MACCE rate at one year. However, a trend towards increase all-cause death in the non-clopidogrel group was observed.

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Safety and efficacy of new-generation balloon-expandable TAVI in bicuspid vs. tricuspid aortic valve stenosis: a propensity score adjusted analysis

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

AIMS

Aims: As transcatheter aortic valve implantation (TAVI) expands into younger and lower risk cohorts, bicuspid aortic valve anatomy is increasingly encountered, posing new challenges in this field.
Data on TAVI in bicuspid aortic valves are limited, since this anatomic subgroup was excluded from the major randomised trials and is still in favour of surgical replacement in the current guidelines.
We aimed to evaluate safety and efficacy of TAVI with new-generation balloon-expandable transcatheter heart valve in bicuspid compared with tricuspid aortic valve stenosis.

METHODS AND RESULTS

Methods and Results: Consecutive TAVI patients treated by new-generation balloon-expandable transcatheter heart valve at our institute were analysed. After careful review of computed tomography scans, patients were grouped according to aortic valve anatomy, either bicuspid or tricuspid. Crude analysis was performed and key clinical outcomes were assessed at discharge, after 30 days from procedure and at 1-year follow-up. Long-term outcomes were assessed by Kaplan-Meier method and Cox proportional hazards regression. All the results were adjusted by propensity score for key baseline and procedural characteristics.

Out of 563 patients undergoing TAVI with new-generation balloon-expandable transcatheter heart valve, 39 (6.9%) had bicuspid anatomy of which 3 (7.7%) comprised of non-raphe and 36 (92.3%) raphe types. Bicuspid aortic valve patients were younger (75.4±7.0 vs. 80.5±5.7,

CONCLUSIONS

Conclusions: TAVI for bicuspid aortic valve stenosis by using new-generation balloon-expandable aortic valves appears safe and effective when compared with the tricuspid anatomy.

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Preliminary results of two-centre initial experience on a dedicated sirolimus-eluting stent in patients with de novo coronary bifurcation lesions including distal left main subgroup

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THEME: Coronary Interventions

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

AIMS

To assess the safety and efficacy of the Nile Sir bifurcated sirolimus-eluting stent in the treatment of coronary bifurcation lesions including the distal left main artery.

METHODS AND RESULTS

In this two centers initial experience study, 68 patients with bifurcation lesions (including 42 lesions in the distal left main) were treated with the Nile Sir dedicated sirolimus-eluting stent. The in-hospital and 6 months clinical events after stent implantation were evaluated. Clinical and angiographic results on a subgroup of patients treated in the distal left main were also analysed.

Clinical presentation: with stable angina were 52.94%, with ACS 47.06% of the cases (one STEMI). The target coronary bifurcations were 29.41% of LAD/Dg, 7.35% of LCx/OM and 61.76% of LM/LAD or LCx. The true bifurcation lesions (Medina classification) comprised 33.82% of type 1,1,1, 20.59% of type 1,0,1 and 11.76% of type 0,1,1 lesions. There were 6 minor procedure complications with a procedure success of 97.06% and 1.47% adverse cardiac events at discharge.

Analysis was obtained for 85.29% of patient who reached the 6 months follow-up. There were 5.88% of major adverse cardiovascular event (MACE, defined as a composite of myocardial infarction, target lesion revascularization and cardiac death), which was the study primary endpoint.

At 6 months post-procedure, in the 42 patients with distal left main lesion, there was only a single repeat revascularization at the level of the side branch. No other clinical event was reported. The measures of the late lumen loss were 0.22±0.38mm, 0.29±0.34mm and 0.18±0.31mm for the main branch proximal, distal and side branch respectively.

CONCLUSIONS

These results with the Nile Sir bifurcated sirolimus-eluting stent demonstrated promising results in the treatment of bifurcation coronary artery lesions including the distal left main artery.

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Gender differences in FFR after PCI

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

AIMS

Recent studies have shown that mean pre-procedural fractional flow reserve (FFR) values of intermediate coronary stenoses are higher in women as compared to men. The latter has been hypothesized to be due to a higher frequency of microvascular dysfunction in women. Conversely, there is at present a lack of knowledge about gender specific differences in FFR values after PCI. Therefore, the aim of the current study was to investigate whether differences exist in FFR after successful PCI in men vs. women.

METHODS AND RESULTS

The FFR SEARCH study is a prospective registry in which a consecutive series of all-comer patients underwent FFR evaluation after successful PCI. Both Pd/Pa and FFR measurements using intravenous adenosine were performed with a dedicated microcatheter advanced ±20mm distal of the most distal stent edge.

A total of 1000 patients (725 men and 275 women) were included. In 959 patients at least one lesion was measured with a total of 1165 successfully treated and measured lesions. Men were significantly younger as compared to women (63.2±11.4 vs. 68.0±12.3,

CONCLUSIONS

Mean post PCI FFR values were slightly higher in women as compared to men, a difference which was driven by dissimilarities in baseline and procedural characteristics.

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Outcomes with everolimus- vs. zotarolimus-eluting stents in percutaneous coronary CTO intervention

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Several studies have demonstrated comparable efficacy and safety profiles of everolimus and zotarolimus-eluting stents for a broad spectrum of coronary artery diseases. But, there is a paucity of data concerning their safety and efficacy for coronary chronic total occlusions (CTO). This study compared the clinical performance of Everolimus-eluting stent and Zotarolimus-eluting stent following successful percutaneous coronary intervention for CTO.

METHODS AND RESULTS

Among the 362 patients who underwent coronary CTO-PCI between 2009 and 2017, 270 were successfully treated with second-generation of drug-eluting stent. In total, 210 patients were successfully treated with Everolimus-eluting stent (n = 100) and Zotarolimus-eluting stent (n = 110).

The primary outcome was defined as the composite of death, myocardial infarction, target vessel revascularization, target lesion revascularization and coronary artery bypass grafting at a median follow-up of 549 days (interquartile range 180.5 -1133 days).

Overall, the primary outcome occurred in 7.5 % of patients. By Kaplan-Meier analysis the follow-up analysis was censored at the end of follow-up or at five years, which came first.

There were no differences in the primary outcome according to the stent type (Everolimus-eluting stent 9.1% vs. Zotarolimus-eluting stent 5.4%, p log-rank 0.701) through the follow-up.

After multivariable adjustment with Cox regression analysis, no significant difference were observed between the two groups in the risk of primary outcome [hazard ratio (HR) 1.04, 95% confidence interval (CI) 0.34?3.19, P = 0.93 for Everolimus-eluting stent compared with Zotarolimus-eluting stent].

In the same way, there were no significant differences in the non-adjusted rate of death (Everolimus-eluting stent 3% vs Zotarolimus-eluting stent 0.9%, P = 0.94), myocardial infarction (Everolimus-eluting stent 2% vs. Zotarolimus-eluting stent 1.8%, P = 0.924) and target and lesion vessel revascularization (Everolimus-eluting stent 6% vs Zotarolimus-eluting stent 2.7%, P = 0.23). The incidence of definite/probable stent thrombosis was relatively low (Everolimus-eluting stent 0% vs. Zotarolimus-eluting stent 0.9%, P = 0.33).

CONCLUSIONS

No significant differences were observed between Everolimus-eluting stent and Zotarolimus-eluting stent in terms of clinical outcomes for coronary CTO at the follow-up.

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Percutaneous occlusion of paravalvular leaks ? A single-centre experience

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

AIMS

To characterize the population referred for percutaneous paravalvular leak (PVL) occlusion and to assess the outcomes after the procedure.

METHODS AND RESULTS

Cohort analysis of 26 consecutive percutaneous PVL occlusion (successful or not) in a single centre between January 2012 and October 2017. The main clinical and anatomic characteristics were noted for each patient. We assessed the short term outcomes through a composite endpoint of death, myocardial infarction and stroke (MACE) at 30 days. We also assessed mortality and re-admittance due to heart failure in the long term (mean follow-up time 19±18 moths).

Our sample consisted mostly of women (77%) and had a mean age of 66±8 years. The median New York Association class was 2,9 (2,0-3,0), 92% of the patients presented with anaemia and left ventricle systolic dysfunction was present in 35%. Mean mortality risk was 6,8% ± 4,0%, according to the Euroscore II, and 4,8% ± 3,7% according to the society of Thoracic surgeons score.

Mitral PVL occlusion was attempted in 62% of the cases and aortic PVL in 38%. The prostheses were more often mechanical (75% of mitral prostheses and 90% of the aortic prosthesis). In 58% of the cases more than one PVL were present and in 65% there were other significant valvulopathies. Seventy-three per cent of the PVL were considered severe, while the remaining were considered to be moderate.

Procedural success was defined as successful release of at least one PVL occlusion device and was achieved in 65% of the cases. Intraprocedural complications were present in 8% (2 cases ? one device embolization to the LVV and one prosthesis obstruction due to guide-wire entrapment) and vascular access site complications were present in 8% of the cases. In-hospital mortality was 4% (1 patient).

The occurrence of MACE at 30-days was 8%. Mortality during follow-up was 31% and re-admission due to heart-failure was 32%.

Reduction of regurgitant jet through the PVL was achieved in 62% of all attempts and 88% of all successful procedures, although effective clinical reduction of NYHA class was achieved only in 38% of all attempts and 50% of all successful procedures.

CONCLUSIONS

Percutaneous PVL occlusion is a complex procedure often reserved for high risk patients with multiple comorbidities and advanced heart failure. As expected, there is a high percentage of adverse events in this population during follow-up. Raising awareness for early PL diagnosis and referral for procedure earlier in the course of the disease could potentially improve outcomes.

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The use of antiplatelet agents after an ACS in a large community Italian setting of more than 12 million subjects

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

AIMS

Antiplatelet agents are the cornerstone of medical treatment in acute coronary syndromes (ACS). Aim of this study was to evaluate the clinical epidemiology of patients after an ACS treated with different antiplatelet agents regimens in a large real community setting.

METHODS AND RESULTS

The ARCO database, including more than 12 million inhabitants, was evaluated. Antiplatelet agents prescriptions were analyzed as follows: aspirin, clopidogrel, other antiplatelet agents used alone, the free and fixed combination of clopidogrel and aspirin, the free combination of aspirin with other antiplatelet agents. Healthcare costs included drug prescriptions (prices reimbursed by the Italian National Health System), outpatient specialist services and hospitalizations (Italian national tariffs).

From January 1 to December 31, 2014, 26,834 patients were discharged after an ACS. Of these, 19,333 (77%) were prescribed with an antiplatelet agents. Among patients treated invasively (47% of the total population), antiplatelet agents were prescribed in 90% of the cases. Dual antiplatelet therapy (DAPT) was prescribed in 49.6% of the total population and in 68.5% of those treated invasively.

Prescription continuity was observed just in 75% of patients. The highest adherence was observed for the fixed combination of aspirin/clopidogrel (81.5%). Throughout 1-year follow-up: re-hospitalization occurred in 47.9% of the patients and the direct cost per patient treated with an antiplatelet agents was ? 13,297 vs ? 16,647 in patients not treated with antiplatelet agents.

CONCLUSIONS

This study highlights that the rate of antiplatelet agent prescriptions, specifically DAPT, is at least suboptimal. A treatment with at least one antiplatelet agent as well as prescription of DAPT after ACS is strongly driven by interventional procedures. More than 25% of the patients does not show prescription continuity at 1 year follow-up.

Re-hospitalizations are frequent, being a new ACS the most frequent cause of re-hospitalization. The costs for the National Health Service are really consistent, and higher in patients not treated with an antiplatelet agent at discharge. The major reason for the high costs for the Italian National Health System are related to the re-hospitalizations.

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Cardiac allograft vasculopathy predictors in a single-centre cohort

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

AIMS

Cardiac allograft vasculopathy (CAV) remains the most important long-term survival limitation after heart transplantation (HT). We aimed to investigate CAV incidence and risk factors in a large cohort of HT patients.

METHODS AND RESULTS

We conducted a retrospective analysis on a prospective cohort of 233 patients who underwent HT at our institution from November 2003 to May 2014. HT recipients younger than 18 years (n=3) and those who died less than a year after HT were excluded (n=28). Baseline data was extracted from a main database, we analysed all invasive coronary angiograms (ICA) (n=712) performed as part of the structured follow up program of HT patients. CAV was defined by at least one coronary angiogram with visible coronary lesions. The International Society for Heart & Lung Transplantation classification for coronary angiograms was used considering CAV0 (not detectable angiographic lesion), CAV1 (Mild with angiographic left main (LM) lesio

CONCLUSIONS

In a retrospective analysis of a single centre HT cohort, only a prior history of IHD and donor?s age were independently associated with CAV. This may suggest that a prior history of IHD might influence post-transplant outcomes and may elicit a specific follow-up program, focused on the progression of the systemic vascular disease.

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Transcatheter treatment of major vascular complications after transradial catheterisation

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Transradial access is associated with extreme low rate of symptomatic vascular access complications. The aim of this study was to investigate the pathology of the symptomatic hand ischemia and to assess the feasibility, safety and outcomes of percutaneous transluminal angioplasty.

METHODS AND RESULTS

Methods: 32 patients (age 60.3 ± 15 years) were treated with symptomatic hand ischemia between 2012 and 2017 in three cardiovascular centers. Those patients which were asymptomatic after conservative treatment were excluded from the study. Anatomically the upper arm was divided in three segments (Segment 1- Brachiocephalic, Segment 2- Axillo-brachial, Segment 3- Below-the-elbow). We have examined technical and clinical success, the rate of major adverse events (myocardial infarction, stroke, death, reintervention or bypass operation, major amputation), target lesion revascularization (TLR) and vascular access site complications at one year.

Results: 18 patients were enrolled in the study. 15 patients were treated with chronic (83.3%) and 3 patients (16.7%) with acute symptoms. Clinical symptoms were: isolated rest pain in 16 patients (88.9%), digital ulcer or gangrene in 2 (11.1%) patients. The cause of hand ischemia was subclavian-brachial dissection in one patient (5.5%), extreme spasm in one patient (5.5%), external radial compression in 2 patients (11.1%) and radial artery occlusion in 14 patients (77.8%). Patients with radial artery occlusion (14 patients) were symptomatic due to embolism in 3 (21.4%), Raynaud syndrome in 2 (14.3%), incomplete palmar arch in 8 (57.2%) and ulnar artery stenosis in 4 patients (28.6%). Technical and clinical success rate of the intervention was 100% and 94.4%, respectively. Angioplasty was performed in segment I in 1 patient (5.5%), in segment II in 2 patients (11.1%) and in segment III in 15 patients (83.3%). Stent implantation was necessary in 6 cases (33.3%). The rate of vascular access site complication was 0%. One year MAEs occurred in 3 patients (16.6%) and the target lesion revascularization rate was 11.1 %, respectively.

CONCLUSIONS

Angioplasty of the hand vessels for symptomatic hand ischemia is a feasible and safe procedure with acceptable rates of technical success and hand healing. Major adverse events are not frequent in this population, despite the high rate of severe comorbidities.

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Intrapatient randomised study with polymer? Free DES vs. abluminal biodegradable polymer DES with early OCT follow-up

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

AIMS

We sought to compare early strut coverage process after sirolimus coronary stent implantation between an ultrathin strut polymer-free stent (PF) and a thin strut abluminal biodegradable polymer stent (BP). The early healing process of strut coverage seen by Optical Coherence Tomography (OCT) at 1 to 3 months can be different depending on stent characteristics such as strut thickness, drug dose release and polymer technology.

METHODS AND RESULTS

A prospective, randomized and multicenter study including consecutive patients admitted to the cathlab with at least two similar angiographic lesions amenable to be treated with DES was performed. All patients gave informed consent and randomized to either treatment with PF stent or BP stent for the first treated lesion. At operator?s discretion, the second lesion was treated either during the same procedure or after one month at a second stage procedure. All patients were scheduled for an angiographic follow up 3 months after the first procedure with an OCT analysis of both treated lesions. Clinical follow up was conducted at 1, 3, 6 and 12 months. The primary endpoint was percentage of strut coverage (defined as struts showing ?20 microns of tissue coverage) comparing PF and BP stent at first with 3 month OCT.

Results: Between June 2016 and December 2017 a total of 70 consecutive patients were included. These patients were 75% hypertense, 62% dyslipidemic, 30% diabetic, 17% with previous MI and 21% with previous PPF. Indication for PPF was unstable angina or NSTEMI in 38 patients and stable angina in 32. No significant angiographic differences were observed between the target lesions. The mean visually estimated reference vessel diameters were 2.86 (±0.51) vs 2.92 (±0.5) mm for the PF and BP stents. The rates of predilatation, stent length and diameter, deployment pressure, postdilatation and the need for side branch dilatation were similar for both stents. Remarkably, in 2 patients bailout rotational atherectomy was needed and in 2 cases severe complications occurred. In 4 patients the treatment of the second lesion was deferred for a staged procedure for clinical reasons, so they were not included in this comparative analysis. In 2 additional patients control OCT acquisition could not be obtained for technical reasons. We present the results of the first 51 patients who completed the 3-month follow up OCT in both lesions. None of the treated lesions showed angiographic restenosis.

A total of 20.152 struts were analyzed, showing strut coverage thickness of 45,6±6 mm for BP vs 57,8±6 mm for PF,

CONCLUSIONS

In patients with comparable angiographic lesions, those treated with ultrathin strut polymer-free stent show a higher proportion of covered struts and a thicker tissue coverage than patients treated with abluminal

biodegradable polymer stent.

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Impact of gender in long-term clinical outcomes after PCI of CTO

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Some studies report an increased morbidity and mortality in women after percutaneous coronary intervention (PCI). Little is known about the impact of gender in the long-term outcomes in patients undergoing PCI for chronic total occlusions (CTO). We aim to determine whether gender difference has any significant impact in the long-term outcomes after PCI for CTO lesions.

METHODS AND RESULTS

A total of 362 patients underwent PCI between 2009 and 2017. Of them 307 patients were men (85%) and 55 (15%) were women.

The primary outcome was defined as the composite of death and coronary artery bypass grafting at a median follow-up of 545 days (interquartile range 179 -1236 days). The cohort was stratified according sex and successful PCI. Overall, the primary outcome occurred in 9.4% of patients. By Kaplan-Meier analysis the follow-up analysis was censored at the end of follow-up or at five years, which came first.

There were no differences in the primary outcome according to the gender (men 9.8% vs. women 7.3%, p log-rank 0.652). According to the PCI success stratification there were no differences between gender in the primary outcome when the PCI was successful (men 3.8% vs. women 0%, p log-rank 0.25) neither when it was failed (men 28.8% vs. women 21.1%, p log-rank 0.621) through the follow-up.

After multivariate adjustment with Cox regression analysis, successful CTO-PCI was associated with reduced risk of primary outcome (HR 0.11, 95% confidence interval 0.05 - 0.26, p < 0.0001) and no significant differences were observed between the two groups (Men vs. Women= HR 1.88, 95%CI 0.63 - 5.61, p 0.253). There was not significant interaction between gender and procedural success in terms of MACE (P 0.98).

CONCLUSIONS

Our study suggests a similar impact of successful CTO intervention in both genders, and a successful PCI was a strong protective factor reducing the primary outcome.

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Angiographic predictors of coronary hemodynamics: the FFR is not affected by lesion length, location or presence of side branches

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

AIMS

The use of intracoronary physiological measurements to guide revascularization for coronary artery disease (CAD) has been shown to reduce major adverse outcomes compared to coronary angiography only. Previous studies show modest correlation between angiographic stenosis and physiological assessment. We sought to determine if fractional flow reserve (FFR) value correlated with diameter stenosis. We also sought to determine if other angiographic factors, including vessel location (proximal, mid or distal), the presence of diffuse coronary disease and lesion length, correlated with FFR values.

METHODS AND RESULTS

We reviewed 388 lesions with stable CAD, which underwent FFR measurements in patients presenting to a single high volume center between January 2015 and July 2017. The mean age of patients was 68.2, with 77.6% being males. 72.3% of the patients had a history of hypertension, 72% had hypercholesterolaemia, 29.1% had diabetes mellitus and 60% had a smoking history and 32% had relevant family history. The left anterior descending artery (LAD) was the most commonly interrogated vessel (65.8%) followed by the left circumflex (18.6%) and the right coronary artery (15.6%). The median diameter stenosis, as determined by quantitative coronary angiography, was 56%, whilst median lesion length was 10mm. 22.2% of patients had evidence of diffuse disease in the interrogated vessel. 38.1% of lesions were in the proximal vessel, 48.2% in the mid vessel and 13.7% in the distal vessel. 39.5% had no proximal side branches, whilst 37.2% had one side branch proximal to the lesion, 19.3% had 2 proximal side branches and 2.9% had 3 proximal side branches. The median FFR was 0.85, with 70% of lesions being deferred to medical management. A greater diameter stenosis was significantly associated with a lower FFR (

CONCLUSIONS

Whilst there is a modest correlation between FFR value and diameter stenosis along with the presence of a diffusely disease artery, haemodynamic assessment of CAD is not related to lesion length lesion location, or number of proximal side branches. Intracoronary physiological measurements should remain routine regardless of angiographic appearance to ensure appropriate management.

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Funding challenges and outcomes in a resource-constrained economy, and the role of local data

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

AIMS

The SHARE - TAVI registry is a prospective multi-centre registry, designed to capture data for all patients undergoing TAVI across South Africa, to compare outcomes to international data and to delineate and address the unique challenges faced in a dichotomously funded and resource-constrained healthcare economy.

METHODS AND RESULTS

All 11 TAVI centres (3 State, 8 Private) actively capture data into the dedicated web-based registry, patients are followed up postoperatively at 30d and annually for 5 years. From Sept 2014 to Dec 2017, a total of 589 patients were entered after an evaluation for TAVI suitability, 422 received implants. 10 had anatomy unsuitable for TAVI, 85 still await response from funders (average wait for decision 103d). 11 exited for other reasons (choice or deteriorated health). 40 patients declined funding had 1-year mortality of 48% (n=19) and a further 21 died during the funding application process.

Outcomes are reported as defined by the VARC-2 criteria. The population (mean age 80.4±7.3 years, 52.9% male, mean risk predictions 6.3±5.8% [STSPROM] and 22.2±14.5 [logEuroSCORE] and 6.4±4.8% [EuroSCORE 2]) is comparable to the US Corevalve Pivotal trial population, German Aortic Valve registry [GARY] and SOURCE 3 registry.

30d follow-up entered in 416 patients, transfemoral access predominates (89.7%), procedural success is 92.5% and mortality is 4.8%, Peri-operative strokes 0.48%, MI 0.72%, and peri-operative mortality of 0% in the newer generation valves (combined SapienS3, Corevalve EvolutR), and vascular complications (7.0%) twice as frequent in females (n=20, males n=9), bleeding 6.25%.

Outcomes at 1 year n=251: Mortality 35/251 (13.94%) [compared to 14,2% in US Corevalve, 12.6% in SOURCE 3, and 20% for GARY], cardiovascular deaths (n=19/35, 54%). Non-cardiac events 46% (n=16/35) mostly caused by cancer or renal failure (2/3 pre-existing). Combined Sapien S3 and Corevalve EvolutR valves account for 19% of implants but only 1 mortality, which was of non-cardiac cause. At 1 year NYHA Class (III,IV) in only 6.9% patients represents significant functional improvement from 68% at baseline. Pacemaker implantation remains lower (7.9%) than comparable registries. Mean ICU stay was similar in both the State (1.73±1.95 days) and the Private sector (2.46±1.86 days) as was total length of stay (State 4.48±3.40, Private 5.07±4.20 days).

CONCLUSIONS

Resistance to acceptance of TAVI by private healthcare funders in South Africa constrains availability of TAVI even within appropriately selected target high-risk patient groups, and a comparatively high percentage (>15%) of TAVIs in South Africa are performed in State centres, despite the private sector accounting for 52% of all national healthcare spend and 80% of all specialists. Newer generation valves show improved mortality at 1 year. Funding process delays and resistance lead to unnecessary deaths in appropriately selected patients

who could benefit from TAVI procedures which are offered in State and Private centres at standards which compare favourably to international best practice. Local data from independent registries such as SHARE-TAVI may support access to TAVI by a wider range of patients in resource-constrained economies.

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Balloon push-out method as a last resort for refractory venous thrombosis

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

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Massive uptake of the transradial approach for STEMI and favourable outcomes following ultimaster stent implantation: insights from a contemporary world-wide registry

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

For the first time in 2015, ESC guidelines recommended with a class I indication the transradial access (TRA) over the transfemoral access (TFA) in patients with acute coronary syndromes. The purpose of the present study is to assess the uptake of TRA and to compare one year clinical outcomes of patients presented with ST-elevation myocardial infarction (STEMI) treated with TRA vs. TFA in a worldwide all-comer registry representative of contemporary real-life PCI practice.

METHODS AND RESULTS

We analysed data from a total of 1907 STEMI patients enrolled in the multicentre prospective e-ULTIMASTER registry who underwent and Ultimaster drug-eluting stent (DES) implantation. Ultimaster is a thin strut (80um) cobalt chromium stent coated with sirolimus-eluting bioresorbable polymer. We applied weighted propensity score matching (PSM) method for the comparison transradial approach (TRA) vs. transfemoral approach (TFA), in order to minimize imbalances in baseline characteristics. Continuous variables were compared using the Student?s t-test and categorical variables using the ?2 test or Fisher exact test as appropriate.

Among enrolled STEMI patients, 1641 (86.1%) were treated by TRA and 266 (13.9%) via TFA. The proportion of transradial use was 86.8% in Europe, 76.8% in Asia, 95.3% in South America and 52.0% in Africa.

Baseline characteristics in the two groups were similar after weighted matching. The mean age was 61.8 years with 77.5% male patients. About 10.8% of patients had previous PCI and 12.1% reported history of myocardial infarction.

The number of lesions identified was 1.9±1.1 in both TRA and TFA groups, and the number of lesions treated was also similar in both groups (1.3±0.6). The treated lesion complexity were comparable between two groups: complex lesions (type B2+C), 60.3% in TFA and 65.6% in TRA, Bifurcation: 12.1% in TFA and 9.8% in TRA, moderate to severe calcification: 11.8% in both groups. Regarding the procedure, 69.3% had predilatation and 46.9% underwent postdilatation in both groups.

Patients had low and comparable in-hospital major bleeding rates (0.6% TRA vs 1.2% TFA , P=0.25) and vascular complication related to access site (0.4% vs 1.1%, respectively p=0.14) . At 1 year, bleeding rate remained low and comparable among the groups (2.5% vs 2.3%, respectively, p=0.85).

The clinical outcomes at 1 year showed death rate of 2.9% in the TFA group and 2.7% in the TRA group (p=0.88), the corresponding cardiac death rate were 2.1% and 1.7% respectively (p=0.65). In the TFA group, any myocardial infarction rate (1.1%) was higher (p=0.02) than in the TRA group (0.2%). The clinically driven target lesion revascularization (2.7% vs 1.1%, p=0.04) and target vessel revascularization rates (4.0% vs 1.8%, p=0.02) were higher in the TFA group than in the TRA group. Target lesion failure (TLF) rate was 4.8% vs 3.0% in TFA and TRA group (p=0.13) while the target vessel failure (TVF) rate was 6.0% vs 3.6% (p=0.06).

Stent thrombosis (definite+probable) occurred in 3.0% and 0.9% of TFA and TRA patients, respectively (p=0.003).

CONCLUSIONS

Data from this worldwide registry show a massive uptake of TRA for STEMI, with some differences among the continents. After propensity matching, outcomes of STEMI patients undergoing Ultimaster stent implantation were favourable, independent of the vascular access strategy.

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Effect of pioglitazone in combination with moderate intensity atorvastatin on atherosclerotic inflammation: randomised controlled clinical trial using serial FDG-PET/CT

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

AIMS

Non-statin therapy in combination with lower intensity statin might be an alternative in patients experiencing unacceptable adverse effects when taking the recommended intensity of statin. Although pioglitazone is an intriguing inflammatory-modulating agent that may improve the cardiovascular outcome, limited data exist on whether pioglitazone on top of statins further attenuates plaque inflammation.

METHODS AND RESULTS

This randomized controlled study included statin-naïve patients with coronary artery disease and carotid plaques of ?3 mm on the carotid ultrasound. Patients were randomly prescribed moderate intensity atorvastatin (20 mg/day), or moderate intensity atorvastatin plus pioglitazone (30mg/day) for 3 months. The primary endpoint was the change in the arterial inflammation of the carotid artery measured by the initial and follow-up 18F-fluorodeoxyglucose positron emission tomography/computed tomography (FDG-PET/CT). Of the 41 randomized patients, 33 underwent an evaluation by FDG-PET/CT (17 atorvastatin plus pioglitazone and 16 atorvastatin patients). The addition of pioglitazone significantly improved the insulin sensitivity and increased the high-density lipoprotein cholesterol after 3 months. Although a reduction in the FDG uptake by pioglitazone on top of atorvastatin in carotid arteries with plaque was nearly statistically significant in the entire patient group (atorvastatin plus pioglitazone, -0.10±0.07 and atorvastatin -0.06±0.04, p=0.058), pioglitazone showed a further reduction of the FDG uptake among patients who had a baseline FDG uptake above the median (atorvastatin plus pioglitazone, -0.14±0.04 and atorvastatin -0.03±0.03,

CONCLUSIONS

Pioglitazone demonstrated marginally significant anti-inflammatory effects on serial FDG-PET/CT in addition to a moderate intensity statin.

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Multimodality imaging-guided femoral access combined with transradial secondary access to reduce overall vascular complications in patients undergoing transfemoral TAVI

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

AIMS

Major vascular complications are associated with increased morbidity and mortality in patients undergoing trans-catheter aortic valve implantation (TAVI). This study aims to compare the rates of vascular complications in two groups employing two different approaches towards primary and secondary arterial access: the ? traditional? fluoroscopy or angiography guided bi-femoral access (group-A) and the ?novel? strategy of combined multimodality imaging-guided, single femoral access and trans-radial secondary access (group-B), in patients undergoing trans-femoral TAVI.

METHODS AND RESULTS

This retrospective, single-center study evaluated all the trans-femoral TAVI cases done between Nov 2009 (start of the program) to October 2017. Patients with planned surgical vascular access were excluded. Group A comprised of cases done with the traditional method of landmark and angiography-guided, standard needle puncture for primary and secondary, bi-lateral femoral access. The cases performed with a hybrid of the old and new strategies during the transition phase, up until routine incorporation of all the components of the of the new strategy (as explained below), were also included in group A. Group B comprised of the cases performed using the ? multimodality approach? involving all of the following steps for vascular access: 1) CT based selection of preferred side of access, 2) ultrasound-guided micro-puncture and micro-sheath angiography before upsizing, 3) mandatory presence of luminal protective wire if use of > 2 suture closure devices deemed necessary for haemostasis, and 4) routine use of trans-radial secondary access. Vascular complications were prospectively recorded or retrospectively verified in accordance with Valve Academic research Consortium-II (VARC-II) criteria.

A total of 435 trans-femoral cases were performed in the study period. Of these, 38 underwent planned surgical access and were excluded. A total of 397 cases were included in the final analysis (group A: 319, group B: 78).

There were no significant differences in baseline characteristics in both groups. The median age of the patients in the entire study was 84 years (IQR 80 to 88 years), with 44.2% and 47.4% being females in A and B respectively (p=0.60). Approximately one fifth of the subjects had diabetes in either group (A: 75/319 (23.5%) B: 15/78 (16.7%) p=0.5). The prevalence of peripheral vascular disease was also similar (A: n=44 (13.8%), B: n=17 (21.8%), p=0.44).

Overall rate of access related complications was low. The rates of major vascular complications (A: n=8/319 (2.5%), B: n=0/78 (0 %) p = 0.15), and composite of major and minor vascular complications (A: n=24/319 (7.5%), B: n= 2/78 (2.6%), p = 0.38) were lower in group B but did not reach statistical significance. 14 cases (4.4%) in group A, and none (n=0) in B required surgical bail out for access closure (p = 0.14). There was no intra-procedural mortality in either group.

CONCLUSIONS

A multi-step approach of ultrasound guidance and micro-puncture for primary vascular access together with wire protection for extra suture-closure, combined with routine trans-radial secondary access in the trans-femoral TAVI cases offers potentially superior safety over the conventional angiography-guided bi-femoral approach. Since the routine adaptation of this approach at our center, rates of major vascular complications and surgical bail out for vessel closure have dropped to zero. A larger scale study is required to explore the true difference.

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New generation DES for left main coronary artery disease according to the EXCEL trial inclusion criteria: insights from the all-comer, international, multicentre DELTA-2 registry

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

AIMS

The DELTA 2 registry is an international, all-comers, multicenter registry that evaluated clinical outcomes of unprotected left main coronary artery PCI with new-generation drug-eluting stents. Recently, the EXCEL randomized trial demonstrated the non-inferiority of PCI with the new-generation everolimus-eluting stent compared with CABG in patients with low or intermediate SYNTAX score. The aim of this study was to evaluate the outcomes of PCI versus CABG in a real-world population according to the inclusion and exclusion criteria of the EXCEL trial.

METHODS AND RESULTS

We compared the outcomes of PCI with new-generation DES in the DELTA-2 registry with the historical CABG cohort enrolled in the DELTA-1 registry according to the EXCEL inclusion or exclusion criteria. The primary endpoint was the composite of death, myocardial infarction, or stroke at the median time of follow-up of 501 days. The interaction between revascularization strategies (DELTA-2 PCI versus DELTA-1 CABG) and the EXCEL inclusion and exclusion criteria was evaluated using propensity score-adjusted Cox regression models that included the interaction term.

Out of 3986 patients enrolled in the DELTA-2 PCI registry, 2417 were EXCEL candidates and 1569 were not EXCEL candidates. The occurrence of the primary endpoint was lower among EXCEL candidates compared with non-EXCEL candidates (6.9% vs 15.4%, hazard ratio: 0.40, 95% confidence interval: 0.32-0.50,

CONCLUSIONS

In a real-world population, PCI seems to be a more favorable option among patients meeting the inclusion of the EXCEL trial.

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Incidence, predictors and prognostic value of acute kidney injury among patients undergoing LAA closure

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

AIMS

No data exist on the occurrence of acute kidney injury (AKI) after left atrial appendage closure (LAAC). The aims of this registry were to determine the incidence, predictors and prognostic value of periprocedural AKI after LAAC.

METHODS AND RESULTS

A total of 355 patients undergoing LAAC were included in the study. Acute kidney injury was defined as an absolute or a relative increase in serum creatinine of >0.3mg/dl or ?50%, respectively, after the procedure or the need for haemodialysis during index hospitalization.

The incidence of AKI was 9% and patients with worse baseline renal function were at higher risk of developing AKI (OR: 1.32, 95% CI 1.09-1.61, p=0.004 for each 10ml/min decrease in the glomerular filtration rate). In-hospital bleeding events occurred more frequently in the AKI group (5.3% versus 15.6%, p=0.037). After a median follow-up of 18 months, patients in the AKI group had a higher mortality (HR 2.59, 95% CI 1.36-4.92, p=0.004), more embolic events (HR 6.14, 95% CI 2.23-16.92, p=0.001) and major bleeding events (HR 2.36, 95% CI 0.89-6.24, p=0.083). The occurrence of AKI was an independent predictor of mid-term mortality (HR 2.00, 95% CI 1.02-3.91, p=0.044).

CONCLUSIONS

The occurrence of AKI was relatively frequent in this population undergoing LAAC, and patients with lower renal glomerular filtration rate were at high risk of developing this complication. Acute kidney injury was correlated with worse mid-term outcomes, highlighting the importance of further preventive strategies in this population.

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Five-year outcomes of patients with atrial fibrillation undergoing rotational atherectomy: from the J2T multicentre registry

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

AIMS

Atrial fibrillation (AF) and severely calcified coronary lesions requiring rotational atherectomy (RA) are considered as one of the worst subset of percutaneous coronary intervention (PCI). However, there are few available data of AF patients who undergone PCI using RA.

METHODS AND RESULTS

Among 1090 consecutive patients undergoing PCI with RA between 2004 and 2015, 167 (14.7%) patients were diagnosed with AF. We compared clinical outcomes between patients with and those without AF throughout 5-year. In-hospital death was similar between AF group (5, 3.1%) and non-AF group (28, 3.0%, p=1.0). Kaplan-Meier curves show all-cause death (38.5% vs 23.8%, p=0.001), cardiac death (20.6% vs 10.7%, p=0.008) and stoke (9.8% vs 4.3%, p=0.001) at 5-year were significantly higher in AF group than in non-AF group, respectively. Non-fatal myocardial infarction was similar for both group (7.7% vs 7.0%, p=0.948). Bleeding death occurred in 5 AF patients (6.0%) all of whom was taking triple therapy (dual antiplatelet therapy and oral anticoagulant) and 9 non-AF patients (1.4%, p=0.012). Multivariable Cox hazard analysis revealed chronic kidney disease (hazard ratio (HR) 2.82, 95% confidence interval (CI) 1.07-8.38, p=0.037), low ejection fraction (

CONCLUSIONS

Although similar in-hospital outcome, AF patient has poor prognosis compare with non-AF patient in 5-year follow-up. Optimization of medical therapy is important to improve AF patient prognosis.

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Elliptical stretch as a cause of side branch ostial compromise after main vessel stenting in coronary bifurcations ? new insights from numerical analysis

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

To explore a mechanism for SB compromise, which can operate in conjunction with carina displacement and plaque shifting. We explore the theoretical effects and correlation of these possible deformational effects with fractional flow reserve.

METHODS AND RESULTS

A total of 49 patients with stable or unstable angina were included. The inclusion criterion were angiographic bifurcation lesions in a native coronary artery with diameter ? 2.5 mm and ? 4.5 mm and SB diameter ? 2.0 mm. We excluded patients with ST-segment elevation myocardial infarction and those with non-cardiac co-morbidity conditions with a life expectancy of less than one year. PCI was performed according to the current guidelines. Provisional stenting was the default strategy in all patients. Initial FFR was performed using the PrimeWire or PrimeWire Prestige (Volcano Corp., USA). After stenting the MB we used FFR in SB to access the ostial stenosis.

Based on angiographic measurements and using formulas from theoretical analysis, we calculated 3 different SB ostial areas which were compared with FFR values after MV stenting.

First group - we assumed a circular ostial shape at SB ostium after stenting. Circular area stenosis ? ASc

Second group we assumed elliptical ostial shape of SB ostium after MV stenting. ASds is ostial elliptic area stenosis of the SB

For the third group, for calculation of SB ostial area after stenting, we used the same assumptions and formulas as in second, but as a reference diameter instead of SB reference diameter we used the SB ostial minimal lumen diameter before stenting. ASmld is ostial area stenosis.

Results:

The correlation coefficients for entire group with FFR values after stent implantation were: r=-0.326, p=.025 for ASc (I group), r=-.416, p=.004 for ASds(II Group), r=-.511, p<.001 for ASmld (III Group).

When compared in groups with (n=24, 49%) and without SB FFR?.80, there was no significant difference in calculated circular shape ostial areas stenosis, ASc (FFR?.80 vs. FFR>.80 - 94%±8% vs. 82%±25%, p=.098), but both calculated elliptical area stenoses were significantly different - ASmld (FFR?.80 vs. FFR>.80: 88% ±9% vs. 76%±13%, p=.008) and ASds (FFR?.80 vs. FFR>.80: 68%±20% vs. 52%±23%, p=.033).

On ROC ?analysis a cut-off values for identification of FFR?.80 were found ? for ASmld>83%, ASds>62%, ASc>93%.

On multivariate regression analysis ASmld > 83%, but neither circular area stenosis values nor continuous parameter was independently associated with FFR ?0.80 (OR=7.143, CI: 1.006-50.000, Negelkerke R square 0.477, p=.002, Hosmer & Lemeshov p=.427). On stepwise analysis, no other independent predictor was identified.

CONCLUSIONS

The elliptical ostial transformation of side branches after MV stenting of coronary bifurcation is a possible mechanism for SB compromise. The ostial area stenosis, calculated based on this assumption correlates better with physiological parameter of lesion severity, i.e. FFR, compared to area stenosis calculated based on traditional circular formula.

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Long-term impact of diabetes in patients with STEMI treated with everolimus-eluting stents or bare-metal stents

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Long-term outcomes of diabetic patients suffering from ST-segment elevation myocardial infarction (STEMI) and treated with second-generation drug-eluting stent have been scarcely evaluated. The aim of this substudy was to compare 5-year outcomes according to the presence of diabetes in patients included in the EXAMINATION trial. ?

METHODS AND RESULTS

Out of a total of 1497 patients included, 258 were diabetics (n=137 received EES and n=121 BMS) whereas 1:239 were non-diabetics (n=613 treated with EES and n=626 with BMS). Patient-oriented endpoint (POCE), device-oriented endpoint (DOCE) and other clinical parameters were collected up to 5 years.

At 5-years, rates of POCE and DOCE were similar between diabetics treated with EES and those treated with BMS (32.8%vs.32.2%, p=0.65 for POCE, 20.4%vs.17:3%, p=0.65 for DOCE). However, rates of TLR were significantly lower in the EES group (4.4%vs.9.9% in the BMS arm, p=0.04,). In non-diabetics, the use of EES was associated with a significant improvement in all-clinical parameters except MI rate. Overall, diabetic patients showed a higher rate of POCE at 5-years (32.6%vs.21.5% in non-diabetics: p=0.03) driven by an increased rate of MI and revascularization remote from target lesions.

CONCLUSIONS

Diabetic patients had worse clinical outcomes than non-diabetics after STEMI. EES implantation in diabetics reduced the need for revascularization compared with BMS at 5-years.

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Stent re-occlusion in a patient with May-Thurner syndrome

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

AIMS

METHODS AND RESULTS

CONCLUSIONS

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The influence of diabetes mellitus on clinical outcomes following sirolimus coated balloon angioplasty in patients with coronary in-stent restenosis: insights from Nanolute study

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

AIMS

Diabetic patients have an elevated risk of restenosis after stent implantation, resulting in increased morbidity and mortality compared with non-diabetic patients. Paclitaxel coated balloons have proven their safety and efficacy for treating in-stent restenosis (ISR). We sought to assess the performance of Magictouch Sirolimus coated balloon (SCB) (Concept Medical) in diabetic patients with ISR in coronary arteries.

METHODS AND RESULTS

NANOLUTE study was multicentre and prospective study. The patient cohort includes a consecutive series of 208 patients (221 lesions) treated with 252 Magictouch SCB between July 2012 to December 2017. Patients were divided into two groups according to their diabetic status. There were 97 (46.63%) patients without diabetes mellitus and 111(53.36%) patients had documented history of diabetes mellitus. The principal study endpoint was occurrence of major adverse cardiac event (MACE) at 1 year. MACE comprised of target lesion revascularization (TLR), target vessel myocardial infarction (TV-MI) and cardiac death. We also assessed the Procedural success which is defined as technical and angiographic success in the absence of a MACE at hospital discharge.

The prevalence of hypertension in diabetic group was bit higher than the non-diabetic group (67.57% vs. 31.96%,

CONCLUSIONS

The present analysis demonstrated that diabetes mellitus does not appear to have a negative impact on the performance of Magictouch SCB in in-stent restenosis which is associated with promising clinical outcomes at 1 year in this complex group.

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One-year outcomes after sirolimus-coated balloon angioplasty for DES associated restenosis: subanalysis from prospective, multicentre Nanolute registry

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

AIMS

Drug coated balloon is emerged as potential treatment modality for drug eluting stent associated in-stent restenosis by delivering the antirestenotic drug without leaving behind any additional metal layer. We aimed to investigate the clinical outcomes of Magictouch Sirolimus coated balloon (SCB) (Concept Medical) in this setting.

METHODS AND RESULTS

NANOLUTE was multicentre, prospective study enrolling patients from real world. 208 patients presenting with coronary in-stent restenosis (ISR) were enrolled in NANOLUTE. Among those, 167 patients presented with drug eluting stent associated in ?stent restenosis (DES ISR). We conducted the subgroup analysis of patients with DES ISR. The study endpoint comprised of major adverse cardiac event at 6 months and procedural success. MACE was defined as composite of target lesion revascularization (TLR), target vessel myocardial infarction (TV-MI) and cardiac death. Procedural success is defined as technical and angiographic success in the absence of a MACE at hospital discharge.

Of the 167 patients, 53.9% patients presented diabetes mellitus, while 51.50% patients had hypertension. Almost half of the patients presented with acute coronary syndrome (46.11%). Among 179 DES-ISR lesions treated majority of the lesions were located in left anterior descending artery (49.10%). DES-ISR lesions were classified according to Mehran?s classification: Focal (61.45%) diffuse intra-stent (18.44%), diffuse proliferative (9.50%) and diffuse total occlusion (7.82%). SCB alone therapy was employed in 92.81% patients where as additional stenting was performed in 7.19% patients. Procedural success was achieved in 99.4% patients with only one vessel dissection reported. One year clinical follow-up was obtained in 142 patients (85.03%). The MACE was reported as 6.34% at 12 months mainly driven by TLR (5.63%) followed by TV-MI (0.70%). There was no cardiac death reported in this group at 1 year. The present study is on-going so the follow up for the rest of the patients is yet to come.

CONCLUSIONS

In patients with drug eluting stent associated in-stent restenosis, Magictouch Sirolimus coated balloon demonstrated promising clinical outcomes at 1 year clinical follow-up. The study also demonstrated excellent procedural success for the Magictouch SCB.

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Comparative analysis of the inflammatory response of the vascular wall after angioplasty of BRS and everolimus-coated stents in patients with stable coronary heart disease

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

AIMS

Carry out a comparative analysis of the dynamics of markers of vascular wall inflammatory response in patients with stable coronary artery disease (CAD) after angioplasty of bioresorbable scaffolds and stents coated with everolimus.

METHODS AND RESULTS

Twenty patients with stable CAD and single-vessel coronary lesion were examined according to coronary angiography and indications for percutaneous coronary intervention (PCI). The study did not include patients who underwent PCI or coronary artery bypass grafting in the previous year, with the presence of restenosis in the stent. Group 1 included 9 patients with an implanted stent coated with everolimus (Xince Prime), group 2 included 11 people with an implanted bioresorbable scaffold (Absorb). Randomization was carried out by the random number method. All patients received optimal medical treatment that included statins and dual antiplatelet therapy. Lipid profile parameters, inflammatory markers (hs-CRP, TNF-alpha, homocysteine, interleukine 1?, 6, 8, 16, sCD40 L, MMP-9, TIMP-1), endothelial dysfunction markers (endothelin-1, nitrites) were measured. The parameters were evaluated at baseline, 1, 4 day and 1 months after PCI.

Results: Initially, the groups did not differ in biochemical parameters before PCI. In both groups, 1 day after PCI, the increase in cytokines, including IL-6, was registered as a response to damage to the vascular wall, followed by a decrease in 4 days to the baseline level. An increase in MMP-9 was observed on the day after PCI in both groups, in the dynamics, the decrease without reaching the baseline level after 1 month was recorded only in group 2. In both groups, an increase in sCD40 L with maximal values ??after 4 days was maintained after 1 month. Both groups maintained a high level of hs-CRP.

CONCLUSIONS

Patients with stable CAD after implantation of bioresorbable scaffolds and stents coated with everolimus did not show any differences in the dynamics of the mediators of the acute phase of inflammation. The remaining high levels of the remodeling marker of the extracellular matrix structures of MMP-9, the pro-inflammatory factor of atherosclerotic plaques sCD40L instability, and the increased concentrations of hs-CRP suggest a high risk of restenosis in 1 month, more pronounced after angioplasty of the everolimus-covered stents.

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Hemodynamic impact of different forms of anomalous coronary connection using CT-derived FFR

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

AIMS

Computed Tomography derived Fractional Flow Reserve (FFRCT) is a non-invasive functional test providing anatomical and functional evaluation of the overall coronary tree. These unique features could help to tackle difficult decisions in patients presenting anomalous coronary connection (ANOCOR). We aimed to evaluate the hemodynamic impact of different types of ANOCOR using FFRCT in a large cohort of patients.

METHODS AND RESULTS

Adult patients with ANOCOR detected during coronary angiogram or computed tomography (CT) were included in the multi-centric ANOCOR registry and followed clinically during 5 years. Among 476 patients included, 106 patients were evaluated between 2009 and 2012 with a coronary CT at the time of inclusion. Patients with coronary artery connection from the pulmonary arterial trunk were excluded from the analysis. FFRCT values could be calculated in 60 patients. Mean age of patients was 58 ± 14 years, 47 (78%) were male. Preaortic, retroaortic, subpulmonar and prepulmonar courses were observed respectively in 34 (53%), 16 (27%), 6 (8%) and 4 (8%) patients. Mean FFR values were 0.82 ± 0.11 in preaortic, 0.85 ± 0.08 in retroaortic, 0.81 ± 0.16 in subpulmonar, and 0.83 ± 0.12 in prepulmonar courses. No statistical difference was observed between courses (P > 0.05). The ANOCOR involved the left main/left anterior descending (LM/LAD) in 10 patients (17%), the left circumflex (LCx) in 11 patients (18%) and the right coronary artery (RCA) in 39 patients (65%). In ANOCOR vessels, mean FFR values in LM/LAD, LCx and RCA were respectively 0.81 ± 0.13, 0.81 ± 0.12 and 0.83 ± 0.11 (p>0.5 for all). Overall, FFRCT analysis showed mean FFR value downstream the ANOCOR was 0.90 ± 0.09. In the distal part of ANOCOR vessels mean FFR value was significantly lower compared to non ANOCOR vessel respectively 0.83 ± 0.10 versus 0.87 ± 0.09 (P=0.0003).

CONCLUSIONS

The hemodynamic impact of different forms of ANOCOR measured with FFRCT showed majority of values above 0.80 in ANOCOR and non ANOCOR vessels. FFR value was significantly lower in the distal part of ANOCOR compared to non ANOCOR vessels. Five years clinical follow up is waited to confirm the utility of FFRCT evaluation in patients with ANOCOR.

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Features of immuno-inflammatory parameters of blood serum in patients with stable angina and obstructive coronary artery stenosis with and without type 2 diabetes mellitus. Results of prospective follow-up after angioplasty

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

To perform comparative analysis of lipid profile and markers of vascular immuno-inflammatory reaction in patients with coronary artery disease (CAD), stable angina, obstructive coronary artery stenosis with and without type 2 diabetes mellitus (DM) and to estimate biochemical parameters of blood serum prospectively after angioplasty in subgroups of patients with obstructive coronary artery stenosis.

METHODS AND RESULTS

97 patients (mean age 60.3±9.8 years) with CAD and stable effort angina were studied. Patients were divided into two groups: patients with CAD in group 1 (n=64) and CAD patients with DM in group 2 (n=33). According to selective coronary angiography patients in both groups had obstructive stenosis (?75%) of one of the coronary arteries. Patients with obstructive coronary artery stenosis in both groups underwent coronary angioplasty with one-type drug-eluting stents. Study of blood plasma laboratory parameters was conducted in the groups of patients initially at the admission before coronary angiography and at the control points 3, 6 and 12 months after angioplasty and stenting. Duration of patients follow-up was 12±1.2 years after angioplasty.
Results: In both groups of patients elevation of the reference values of the lipid profile atherogenic parameters (Total cholesterol, LDL cholesterol, VLDL cholesterol, triglycerides) was detected. Significant increase of the level of vascular immuno-inflammatory markers (C-reactive protein (hs-CRP), tumor necrosis factor - alpha (TNF??), homocysteine, interleukin-1?) was registered along with the increase of normal values of metalloproteinase- 9 (MMP-9) and endothelin-1 in patients with CAD and DM that could indicate more significant vascular inflammation in this group. Prospective follow-up showed the maximum increased level of immuno-inflammatory markers at the control point "3 months" after angioplasty in both groups. In general, within the positive dynamics of the studied parameters, the target levels of lipid profile parameters (Total cholesterol, HDL cholesterol, triglycerides) and markers of inflammation (hs-CRP, MMP-9) were not achieved at the endpoint of follow-up "12 months" that could indicate the persistence of systemic slow vascular immuno-inflammatory response.

CONCLUSIONS

Maximum level of vascular inflammation parameters activation at the point "3 months" after angioplasty and persistence of systemic slow vascular inflammatory response to the follow-up endpoint determine that patients of both groups are at a high cardiovascular risk. We suggest that they have equivalent potential in the development of both early restenosis and late atherothrombotic complications.

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Resting heart rate at 30 days and prognosis following TAVR, analysis from the PARTNER 2 trial

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

AIMS

Resting heart rate is associated with adverse cardiovascular outcomes in patients with aortic valve stenosis. However, the impact of resting heart rate after transcatheter aortic valve replacement (TAVR) for severe aortic stenosis on cardiovascular outcomes is unknown. We sought to determine the effect of resting heart rate at 30 days after TAVR on 2-year cardiovascular outcomes in patients with symptomatic severe aortic stenosis.

METHODS AND RESULTS

Among 3,997 patients who underwent TAVR in the PARTNER 2 randomized cohorts and nested registries, excluding the valve-in-valve registry, 2,480 patients who had available 12-lead electrocardiograms demonstrating sinus rhythm at 30 days post-TAVR were identified, comprising the study cohort. Outcomes at 2 years were analyzed according to resting heart rate in groups defined as high resting heart rate (>= 75 beats per minute, bpm) and low resting heart rate (< 75 bpm) groups. Baseline clinical characteristics did not differ significantly between patients with high versus low resting heart rate except for age (81.0 versus 82.4 years,

CONCLUSIONS

In patients with severe aortic stenosis treated with TAVR, elevated resting heart rate at 30 days post procedure was associated with the composite outcome of all-cause mortality, rehospitalization or stroke and with aortic valve related rehospitalization at 2 years follow up. Elevated resting heart rate at 30 days may be a marker of aortic valve-related complications and should prompt further evaluation.

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Multicentre, post-marketing evaluation of the Elixir DESolve novolimus-eluting bioresorbable coronary stent system: 24-month results from the DESolve PMCF study

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

AIMS

Bioresorbable scaffolds are an equivalent alternative to DES for the treatment of coronary artery lesions, but experience with other than Everolimus-eluting PLLA-based scaffolds is limited. A post marketing clinical follow-up study was conducted evaluating the continued safety and effectiveness of the CE-mark approved DESolve® Novolimus Eluting Bioresorbable Coronary Scaffold System (Elixir Medical, Sunnyvale, CA), a drug-eluting bioresorbable scaffold combining a PLLA-based backbone coated with a biodegradable polylactide-based polymer and Novolimus, a macrocyclic lactone mTOR inhibitor.

METHODS AND RESULTS

A total of 100 patients with stable coronary artery disease were treated with a DESolve scaffold in de novo coronary artery lesions with a reference vessel diameter between 2.25 and 3.5 mm and treatable with a single scaffold between 14 and 28 mm in length. Patient data was analyzed for the occurrence of clinical endpoints including major adverse cardiac events (MACE) defined as cardiac death, target vessel MI, clinically-indicated target lesion revascularization, and stent thrombosis at 24 months.

A total of 102 DESolve scaffolds were analyzed. The mean age of the patients was 62.0±12.9 years, 77.5% were male. Hypertension was present in 86.3%, 25.5% were diabetics. The lesion morphology according to the AHA/ACC lesion class B2/C was present in 50.5%. Predilation was performed in 89.9%, and postdilation in 81.7%, respectively. The MACE rate at 24 months was 4.2%. Target lesion revascularization and definite/ probable scaffold thrombosis occurred in 3.1% and 1.0%, respectively. Clinical results at 3 years will be presented.

CONCLUSIONS

The DESolve post-marketing clinical follow-up study shows efficacy of the DESolve scaffold after 24 months with a very low event rate, final 36-month clinical data will be presented. The DESolve scaffold can be considered a reasonable alternative for an effective treatment of coronary artery lesions. However, this has to be confirmed by larger randomized trials and long-term data is needed.

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Aspiration of the blood from the left ventricular cavity to treat refractory ventricular arrhythmias during complex coronary interventions

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

AIMS

Ventricular fibrillation (VF) may happen during complex coronary intervention due to wire or catheter manipulation, balloon inflation or reaction to the contrast. This can be treated easily with prompt cardioversion, however some of VF may become refractory especially in the cases of severe ischemic burden, elevated left ventricular filling pressure (LVEDP) or reduced left ventricular function.

METHODS AND RESULTS

We report a new simple quick method to reduce LVEDP by inserting a catheter (e.g a pigtail or JR) inside the left ventricle (LV) and doing quick manual aspiration of 80-100cc of blood from the LV cavity. This will quickly reduce the LVEDP and make refractory VF easily responsive to cardio version. It can also provide a simple decompression of the overfilled LV after prolonged circulatory arrest.

Results: This method was used in 5 cases of refractory VF. Three of them failed 3 attempts of DC cardio version despite recanulization of the diseased artery. After doing this maneuver, those three cases responded immediately to the next attempt of cardioversion. 2 other cases of VF responded to cardioversion with electrical sinus rhythm however the 2 patients remained pulseless in electromechanical dissociation (EMD), no arterial pressure and no cardiac movement on fluoroscopy. Despite ruling out tamponade and mechanically treating cardiac ischemia the two patients remained in EMD After doing the pigtail maneuver EMD resolved and active cardiac movement were seen on fluoroscopy with acceptable arterial pressure recovery. All of these 5 patients survived till hospital discharge.

CONCLUSIONS

Quick insertion of a catheter in the LV with quick blood aspiration facilitates response to cardioverion and may relief EMD not related to tamponade during coronary intervention. It looks that the interventional cardiologists need this simple way of LV venting in the cath lab.

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Determinants and pathways of rehabilitation after surgical aortic valve replacement: a population-based, retrospective study with administrative data

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

AIMS

Rehabilitation after surgical aortic valve replacement (SAVR) improves patients functional capacity and quality of life (Ribeiro et al, 2017). No published studies ever investigated the factors influencing the decision to undergo rehabilitation and its pathway.
We conducted a population-based, retrospective study to determine the factors influencing the probability to start rehabilitation and to identify the factors affecting index hospitalization and rehabilitation length of stay (LOS). The study aims at providing a comprehensive overview of care process for SAVR patients.

METHODS AND RESULTS

We analysed all SAVR performed in Italy in 2009-2015 as reported in the National Hospital Discharges database. We performed linear and logistic regression analyses to explore the determinants of LOS and of probability of rehabilitation respectively.
Our sample consists of 113,849 patients who underwent AVR, of which 97,571 SAVR patients. On average 64.3% patients started a rehabilitation program after SAVR and 5.5% after Transcatheter Aortic Valve Replacement (TAVI). At the patient level, the probability of starting rehabilitation was significantly ($p<.05$) higher in older and female patients, living in Northern Italy and hospitalised in their residence region. The probability was lower when index hospitalisation occurred in private teaching or public non-teaching hospitals and higher in public teaching hospitals. Patients who underwent SAVR in hospitals with a long-term care facility showed higher odds of undergoing rehabilitation.
The average index hospitalization and rehabilitation LOS in the sample was 15.7 (SD=12.4) and 18.9 days (SD=11.0) respectively, with a decreasing trend over time. At the individual level, index hospitalization LOS significantly increased with age, patient severity (proxied by Charlson Comorbidity Index) and extra-regional residence (i.e., SAVR performed out of residence region), and when hospitalisation occured in public hospitals - both teaching and non-teaching. Northern regions hospitals tended to discharge patients earlier.
The rehabilitation LOS was significantly higher in older and female patients, and negatively influenced by extra-regional residence. The LOS was longer in teaching hospitals and in case the index hospitalization occurred in a hospital with long-term care facilities. The latter might be due to rehabilitation pathway starting during the index hospitalization.

CONCLUSIONS

Rehabilitation is a key factor that facilitates patients? recovery. The knowledge of the factors, both at the patient and at the institutional level, that impact on the decision to start a rehabilitative program after SAVR are relevant to inform evidence-based policies aimed at encouraging the most appropriate clinical pathway, reducing uneven access to care across different areas.

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Long-term clinical outcomes in diabetic patients after PCI of CTO

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

AIMS

There has been recent concern about prognostic of percutaneous coronary intervention (PCI) for chronic total occlusions (CTO) in diabetic patients.

Therefore, we aim to determine whether diabetes has any significant impact in the long-term outcomes after PCI for CTO lesions.

METHODS AND RESULTS

We analyzed data from 362 patients who underwent CTO PCI between 2009 and 2017 in a single high-volume center of Argentina, 78 of whom had diabetes (21,55%).

The primary outcome was defined as the composite of death, stroke, acute myocardial infraction (AMI), target lesion revascularization (TLR) and coronary artery bypass grafting (CABG) at a median follow-up of 545 days (interquartile range 179 -1236 days). The cohort was stratified according presence of diabetes and successful PCI. Follow-up analysis was censored at the end of follow-up or at five years, which came first.

Overall, the primary outcome occurred in 12.6% of patients. There were no differences in age (67 vs. 66 years), J-CTO score (2,08 vs. 2,11), successful PCI (74,65% vs. 74,36%) or primary outcome at follow up (21,79% vs. 14,4%, OR 1,65 [0,88-3,11], p=ns) between diabetic and no-diabetic patients. According to PCI success, there were no differences in the primary outcome when PCI failed (35% vs. 34,72%, p=ns). But we found a significant increase in diabetic patients when PCI was successful (17,24% vs. 7,55%, OR 2,55 [1,09-5,98],

CONCLUSIONS

Our study reaffirms diabetes as a strong predictor of negative outcomes at follow up in patients who underwent CTO PCI. The best approach to these patients must be individualized until concluding randomized evidence is available.

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Impact of access site on bleeding complications and in-hospital ischemic events in ACS patients undergoing PCI: data from a real-world cohort

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Although randomized controlled trials have established the superiority of transradial access (RAD) over transfemoral access (FEM) in acute coronary syndrome (ACS) patients undergoing percutaneous coronary intervention (PCI), the impact of RAD in Switzerland is unknown.

METHODS AND RESULTS

We retrospectively analyzed data from the prospective nationwide Acute Myocardial Infarction in Switzerland (AMIS) Plus registry with respect to the impact of vascular access site on bleeding complications, and in-hospital ischemic outcomes after matching for age, gender, STEMI/NSTEMI, Killip>2, Charlson comorbidity index >2 and resuscitation prior to admission.

Among 10841 patients enrolled in the AMIS Plus registry between January 2013 and August 2017, 8904 (82.1%) underwent a PCI, with data on the access site available in 8651 (97.2%) patients. FEM was used in 60.2% and RAD in 39.8%. 2017 was the first year to show more RAD (54.7%) than FEM (45.3%), whereas in 2013 the distribution between RAD and FEM was 33% versus 66%, respectively. The matched population included 3437 patients in each group. Baseline characteristics were well matched, except that RAD patients less frequently had diabetes (17.6% vs 20.4%, p=0.004), hypertension, dyslipidemia (64.0% vs 66.4%, p=0.044), previous coronary bypass surgery (2.2% vs 6.5%, p<0.001) or prior acute myocardial infarction (13.2% vs 15.4%, p=0.01). Concerning regular medication, there was no difference for anticoagulation (RAD:4.2%, FEM: 4.1%, p=0.833), but less frequent chronic use of aspirin (33.8% vs 40.6%, p<0.001) and P2Y12 inhibitor in the RAD group (7.1% vs 8.9%, p=0.018).The in-hospital rate of cerebrovascular events (RAD:0.6%, FEM:0.6%, p=1) and reinfarction (RAD:0.6%, FEM:0.9%, p=0.155) were similar between both groups, but in the RAD group there was less cardiogenic shock (1.9% vs 3.2%, p=0.001), bleeding according to the BARC definition (3.5% vs 4,5%, p=0.032) major adverse cardiac and cerebrovascular events (reinfarction, stroke and/or death)(2.8% vs 4.3%, p=0.001) and in-hospital mortality (1.9% vs 3.3%, p<0.001).

CONCLUSIONS

RAD has steadily increased during the last 5 years in Switzerland to become dominant in AMI PCI. Current analysis shows that in a real-world cohort RAD reduces bleeding complications as well as MACCE and in-hospital mortality.

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Bioactive or DES in patients older than 75 years: preliminary data from the bioactive group of the BIODES-75 registry

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

AIMS

Elderly patients are at higher risk of bleeding and PCI is often performed with BMS in order to shorten the duration of dual antiplatelet therapy. Recently, some trials comparing specific third-generation DES with BMS in these patients have demonstrated lower rate of ischemic events without increasing rate of bleeding with DES. The OPTIMAX® stent is a bioactive stent with some properties different respect other BMS, and it results would be comparable with DES in elderly patients.

METHODS AND RESULTS

Prospective multicentre registry of consecutive patients older than 75 years old undergoing PCI for stable coronary artery disease or acute coronary syndrome from 2015-2017 and treated with the OPTIMAX® stent are compared with a control group of patients older than 75 years old treated with second or third generation DES. Follow-up at 30 days, 6 month and 1 year. Major adverse events are recorded: Death, myocardial infarction, stent-thrombosis, target lesion revascularization (TLR), target vessel revascularization (TVR) and stroke. Data from the OPTIMAX group with 30 days follow-up are presented. Overall 443 patients (69.5% Male, 82.8±6 years old, 11.5% nonagenarians, 34% Diabetes Mellitus, 24% Chronic Kidney Disease) were included in this group. Atrial fibrillation were recorded in 27% of patients and 18% were under chronic oral anticoagulation, mainly with warfarin. The main reason for PCI was N-STEMI (47%) and primary PCI for STEMI was performed in 31% of cases. The majority of patients received aspirin and clopidogrel, 83% were transradial procedures and a median of 1.3 lesions were treated with 1.2 stents. PCI was successful in 99% of cases. At 30 days, 87% were on dual antiplatelet therapy and 20% were orally anticoagulated (34% with direct oral anticoagulants). Five patients (1.1%) presented stroke, 5(1.1%) TLR, 3(0.67%) TVR, 4 (0.9%) revascularizations of other vessel and 5 stent-thrombosis (1.1%). Fourteen patients (3.1%) presented bleeding (mainly BARC 1 or 2, only 3 with BARC 3) and 13 (2.9%) died, 12 due to cardiovascular causes.

CONCLUSIONS

Patients included in OPTIMAX subgroup of the BIODES-75 registry are very high-risk profile patients with low rate of adverse events at 30 days.

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The complete arterial revascularisation of lower-extremities: the successful opening of the CTO of right superficial femoral, right external iliac and osteal common iliac arteries

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

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Platelet-monocyte aggregates formation is increased among patients undergoing PCI identified with poor response to clopidogrel ? a preliminary report

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

The present investigation aimed to determine the pattern of platelet-leukocyte aggregates (PLA) formation among patients among patients undergoing percutaneous coronary interventions (PCI) with identified inadequate and adequate response to clopidogrel. Clopidogrel has been reported to impact the interaction between platelets and leukocytes via P2Y12 receptor present on the leukocyte surface.

METHODS AND RESULTS

This is a subanalysis from the randomized controlled ONSIDE TEST Study - Optimal antiplatelet pharmacotherapy guided by bedside clopidogrel resistance testing in elective PCI patients (NCT01930773). Analysis of CYP2C19 gene polymorphism and platelet function testing was conducted among stable coronary artery disease (SCAD) patients undergoing elective PCI after initiation of dual antiplatelet therapy (DAPT) with aspirin and clopidogrel. Formation of PLA (defined as CD45+ / CD42b+), platelet-monocyte aggregates (PMA, CD14+ / CD42b+) and platelet-neutrophil aggregates (PNA, CD66b+ / CD42b) among patients with inadequate response to clopidogrel was assessed by flow cytometry. The results were compared with an age- and gender-matched control group of SCAD patients on DAPT after PCI with a documented adequate response to clopidogrel. Inadequate response to clopidogrel was understood as the presence of at least one CYP2C19 LOF*2 allele or platelet reactivity units (PRU) > 208.

A total of sixty patients were included in the present analysis. Of them, sixteen subjects were identified as inadequate responders to clopidogrel. The concentration of PMA (21,96 ± 11,66 vs 12,12 ± 10,21, p = 0,034) was signicantly higher among patients identified with inadequate response to clopidogrel, as compared to the control group (n = 10 patients). No differences were observed in PLA (11,15 ± 10,39 vs 13,24 ± 10,82, p = 0,632) and PNA (21,39 ± 12,42 vs 19,25 ± 9,85, p = 0,631) formation between the groups.

CONCLUSIONS

Some circulating PLA may potentially constitute a novel biomarker for the monitoring of antiplatelet therapy among patients undergoing PCI.

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Role of non-invasive CT coronary angiogram in PCI for CTO: a single-centre experience in UK

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Percutaneous coronary intervention (PCI) for chronic total occlusion (CTO) is a challenging procedure in intervention cardiology. One of the major limiting factors for successful CTO recanalization is unsatisfactory visualization of the occluded CTO segment. The use of non-invasive CT coronary angiography (CTCA) can help define the morphological features of the occluded CTO segment including shape of proximal cap, length of occluded segment and any calcification or tortuosity in its course. We evaluated the role of CTCA on procedural success rate in selected patients undergoing CTO PCI.

METHODS AND RESULTS

Between January and December 2017, all patients awaiting PCI procedure for CTO were discussed in multi-disciplinary team (MDT) meeting. The CTO segments were classified using J-CTO scoring tool. Patients with J-CTO score ?2 were further assessed to select those with potential challenges including unsatisfactory visualisation of occluded CTO segment, selected patients underwent CTCA prior to CTO procedure. The procedural outcomes in this selected group were compared to all patients with J-CTO ?2 who underwent CTO PCI between January and December 2016 without the use of CTCA prior to procedure.

21 patients (mean age 68.6 years, 71% males, mean J-CTO score 2.77) underwent non-invasive CTCA in 2017 prior to revascularization of CTO, target vessels included 18 RCA, 2 LAD and 2 LCX. In comparison, 61 patients (mean age 67.9 years, 72% males, mean J-CTO score 2.54) underwent PCI for CTO in 2016 without the use of CTCA, target vessels included 42 RCA, 14 LAD and 5 LCX.

The procedural success rate in patients who had CTCA prior to CTO procedure was 90.4% compared to 70.4% for those who had PCI without the use of CTCA prior to PCI (p = 0.0677, 95% CI 1.82 to 34.18). The comparison of procedure and screening times for CTCA vs no CTCA groups were 157.7 ± 63.2 min vs 153.3 ± 55.9 min (p = 0.76) and 52.9 ± 30.9 min vs 50.9 ± 23.9 min (p = 0.76) respectively, the contrast volumes were 251.7 ± 96.9 mL vs 266.9 ± 90.7 mL (p = 0.52) respectively, and mean radiation doses were 26224 cGycm2 vs 21153 cGycm2 (p = 0.11) respectively. There were no major adverse cardiac events in both groups. Procedural complications included pericardial effusion (n=1) and arterial access related haematoma (n=1) in group who had CTCA, whereas in the group without CTCA the complications included pericardial effusion (n=2), contrast nephropathy (n=1) and arterial access site haematoma (n=2).

CONCLUSIONS

The use of non-invasive CTCA in selected patients with CTO improves procedural success compared to those in whom CTCA is not used prior to PCI (90% vs 76%). This improvement is achieved due to better understanding of morphological features of the occluded CTO segment. A formal multi-disciplinary team (MDT) meeting has valuable role in strategic planning by identification of patients requiring further investigations prior to PCI. There was no significant difference in procedure time, screening time, radiation exposure and contrast

volume between both groups.

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Peri-strut low intensity areas and vascular healing response after everolimus-eluting BRS implantation in STEMI. Preliminary insights from an OCT analysis

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

AIMS

To determine the association between peri-strut low intensity areas (PLIA) surrounding bioresorbable scaffold (BRS) struts by optical coherence tomography (OCT) and the vascular healing response after BRS implantation in the setting of acute myocardial infarction. In autopsy studies, PLIA have been linked with delayed vessel healing, inflammation, and neointimal growth after PCI with metallic stents.

METHODS AND RESULTS

This is a single-centre, longitudinal study with a serial (baseline, 12 month, 24 month) OCT evaluation of neointimal response after BRS implantation in patients presenting with ST-segment elevation myocardial infarction (STEMI).

Mean and minimal neointimal thickness and area were evaluated. A PLIA was understood as a region surrounding scaffold struts characterized with a homogenous low intensity appearance by OCT without significant signal attenuation. The analyzed cross sections were scored: 0 - no PLIA, 1 if PLIA i

CONCLUSIONS

In STEMI population treated with BRS implantation, the presence and extent of PLIA by OCT may be associated with the pattern of neointimal formation. Nevertheless, further larger studies on inflammatory response after BRS implantation in acute myocardial infarction are warranted.

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TAVI in patients with concomitant mitral stenosis

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

AIMS

The objective of the present analysis was to investigate the impact of concomitant mitral stenosis (MS) on clinical outcome in patients undergoing transcatheter aortic valve implantation (TAVI) for aortic stenosis (AS).

METHODS AND RESULTS

Among 1,339 patients undergoing TAVI between August 2007 and December 2015 at a single institution, adequate echocardiographic data for the assessment of severity and etiology of MS was available in 971 (72.5%) patients. Patients were stratified according to the degree and the etiology of concomitant MS. The primary endpoint of the study was cardiovascular mortality at 1 year. Mild MS was present in 149 (15.3%) patients (mitral valve area: 2.1 ± 0.3 cm2), and moderate/severe MS in 28 (2.9%) patients (mitral valve area: 1.2 ± 0.2 cm2). The etiology of MS was degenerative in 110 (62.1%) and rheumatic in 67 (37.9%) patients, respectively. Baseline characteristics were comparable between patients with versus without MS. Cardiovascular mortality at one year was significantly increased in patients with mild MS (20.3%, HR 3.49, 95% CI 1.98-6.16), and moderate/severe MS (26.7%, HR 3.19, 95% CI 1.62-6.27) as compared to TAVI patients without concomitant MS (12.4%). As compared to patients with isolated AS (12.4%), patients with concomitant rheumatic (30.2%, HR 4.73, 95% CI 2.32-9.63) and degenerative MS (27.6%, HR 1.89, 95% CI 1.43-2.49) had an increased risk of cardiovascular death. Rates of stroke were higher in patients with concomitant degenerative (6.6%, HR 1.77, 95% CI 1.01-3.08) and rheumatic (7.9%, HR 4.70, 95% CI 1.14-19.5) MS as compared to patient with isolated AS.

CONCLUSIONS

TAVI patients with concomitant MS were found to have a mora than three-fold increased risk of cardiovascular death at one year as compared to patients with isolated AS. Both patients with concomitant degenerative and rheumatic MS had an increased risk of cardiovascular death and stroke at one year, respectively.

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Impact of valvular resistance on aortic regurgitation after TAVI according to the type of valve

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

AIMS

With the refinement of transcatheter heart valve, the incidence of moderate or greater aortic regurgitation (AR) after transcatheter aortic valve implantation (TAVI) is decreasing. However, since it has not reached complete control owing to the underlying physical properties of the valve prosthesis, novel predictor of post-TAVI AR should be studied. The aim of the present study is to seek the relationship between aortic valvular resistance (VR) at baseline and post-TAVI AR.

METHODS AND RESULTS

Between August 2007 and December 2015, 708 patients who underwent TAVI and had sufficient right heart catheterization to calculate VR before the intervention were considered eligible for this analysis. The association between VR and post-TAVI AR was assessed according to the type of valve. Among the candidate of our study, 176 (24.9%) had low VR (LVR,

CONCLUSIONS

HVR is associated with moderate or greater post-TAVI AR and identified as a novel independent predictor of post-TAVI AR in patients treated with a SE, but not with a BE.

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Reductions in peri-procedural left atrial pressures seen in patients with degenerative but not functional mitral regurgitation following percutaneous mitral valve repair

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

AIMS

Degenerative mitral regurgitation (DMR) and functional mitral regurgitation (FMR) represent two distinct pathophysiological entities, but are often treated similarly. We sought to evaluate and compare the peri-procedural haemodynamic changes in left atrial (LA) pressure following percutaneous edge-to-edge mitral valve repair (Mitraclip) in these two groups.

METHODS AND RESULTS

114 patients (Median age 78 years (Range 38 to 94), 64% male) with FMR (n=70, 61%) and DMR (n=44, 39%) deemed inoperable or high-surgical risk following Heart Team discussion underwent the Mitraclip procedure at a single UK tertiary center between December 2014 - December 2017. LA mean and V-wave pressures were invasively recorded directly during the procedure. Measurements were taken immediately before and after delivery of the Mitraclip (or after the final Mitraclip, if more than one clip was required) and mitral regurgitation (MR) grade calculated on transoesophageal echo. Data presented as mean ± SD or median ± IQR.

MR grade fell significantly in DMR (pre-Mitraclip, 3.9 ± 0.3, post-Mitraclip 2.0 ± 0.9,

CONCLUSIONS

MR reduction was similarly significant across the entire cohort independent of aetiology. Baseline LA mean and V-wave pressures were similar in patients with DMR and FMR. However, the MitraClip procedure reduced these pressures only in the DMR group, not in the FMR group.

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Indications and eligibility for percutaneous LAA occlusion in patients with atrial fibrillation admitted in a tertiary cardiology department

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

AIMS

Percutaneous left atrial appendage occlusion (LAAO) is an alternative non-pharmacological therapeutic option for stroke prevention in patients with non-valvular atrial fibrillation (AF), who have contraindications to oral anticoagulation therapy (OAC). However, relative and/or absolute contraindications to OAC are not well defined so the actual indication for LAAO is commonly underdetermined. The purpose of this study was to identify the clinical characteristics of patients with non-valvular AF who are admitted to a cardiology department and have a potential indication for LAAO.

METHODS AND RESULTS

We evaluated 817 consecutive patients with AF as a primary or secondary diagnosis, who were admitted in the cardiology department of our university hospital between December 2015 and December 2017. Common criteria for contraindication to OAC like previous major or minor bleeding or HASBLED score ?3 were identified and analyzed as single or combined variables.

A total of 744 patients fulfilled the study enrolment criteria [73 (8.9%) were excluded due to valvular AF]. Mean age was 74±11 years and 410 (55.1%) were male. The mean CHA2DS2-VASc score was 4.4±1.9. A CHA2DS2-VASc score ?4 was present in 523 patients (70.3%). A total of 129 patients (17.3%) had a history of prior stroke [ischemic 69 (9.3%), hemorrhagic 5 (0.7%), transient ischemic attack 31 (4.2%), not-categorized 24 (3.2%). A total of 49 patients (6.6%) had a history of stroke while treated by OAC. A history of bleeding was present in 236 patients (31.7%). Previous upper gastrointestinal bleeding was present in 52 patients (6.9%) of and 58 patients (7.8%) had previous lower gastrointestinal bleeding. Nose bleeding had occurred in 147 patients (19.8%), intracranial bleeding in 8 patients (1.1%), and bleeding of other source in 34 patients (4.6%). A total of 53 patients (7.0%) had a bleeding from >1 one origin. The mean HASBLED score was 1.9±1.1. A HASBLED score ?3 was present in 208 patients (28.1%). The high HASBLED score (?3) correlated well with the history of gastrointestinal (

CONCLUSIONS

One third of patients with non-valvular AF who are admitted to a tertiary cardiology department for any reason have a high risk for bleeding as defined by their HASBLED score and a history of previous bleeding and may be considered for percutaneous LAAO.

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Lesion preparation using high-pressure non-compliant balloons achieves better stent-expansion compared to semi-compliant balloons ? an OCT-guided, randomised controlled study

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THEME: Coronary Interventions

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

AIMS

Stent underexpansion is a strong predictor of in-stent-restenosis and stent thrombosis. Traditionally semi-compliant balloons (SCB) have been used for lesion preparation before stent implantation but early non-randomized studies indicate that non-compliant balloons (NCB) have demonstrated better stent expansion.
We present the pooled results of two randomized controlled trials (Pre-NC and OPRENBIS), which compared NCB vs. SCB for lesion preparation.

METHODS AND RESULTS

In the Pre-NC study the Beo NC and in the OPRENBIS the OPN NC (both SIS Medical, Switzerland) were compared to standard SCB for lesion preparation in all-comers with stable angina or non-ST-elevation myocardial infarction. By protocol high-pressure balloon inflation (> 24 atm) was recommended for NCB. Stent expansion was assessed using the stent expansion index (SEI: minimal luminal area/mean luminal area) on optical coherence tomography (OCT). Post-dilatation using NCB was left at the discretion of the operator and BEO NC or OPN NC were used for post-dilatation in both groups if necessary. A total of 99 patients with a mean age of 63+10 years were included in both studies. 48 patients were randomized to NCB and 51 patients to SCB group. Baseline clinical and angiographic characteristics were similar between both groups. The mean balloon inflation pressure was 24+7 vs. 14+3 for pre-dilatation (

CONCLUSIONS

Lesion preparation using NCB at high-pressures was safe and was associated with better stent expansion compared to SCB. Post-dilatation using NCB at high pressures only slightly increased SEI in the SCB group. In order to achieve optimal stent expansion pre- and post-dilatation using NCB at high pressures is needed.

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Optimal antiplatelet therapy in out-hospital cardiac arrest patients treated by primary PCI and therapeutic hypothermia

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Out-of-Hospital Cardiac Arrest (OHCA) and Mild therapeutic hypothermia (MTH) has been linked to an increased risk of Stent Thrombosis (ST) in comatose survivors who underwent percutaneous coronary intervention (PCI). There is no formal recommendation about which antiplatelet regimen should be used in patients with Acute Coronary Syndrome (ACS) after OHCA. We compared antiplatelet efficacy of clopidogrel and ticagrelor with a point of care system (VerifyNow®) at different time points after primary PCI in OHCA patients underwent MTH.

METHODS AND RESULTS

In a cohort of 25 consecutive OHCA patients included in our hospital, we compared antiplatelet efficacy of clopidogrel and ticagrelor with a point of care system (VerifyNow®) at different time points after primary PCI and MTH. We confirmed that residual platelet activity was higher with clopidogrel than with ticagrelor, expressed as platelet reaction units, 2h after loading dose (229± 56 vs. 180 ± 30, p: 0,014), 6h after loading dose during MTH (203 ± 45 vs. 135 ± 51, p: 0,004), 24h after loading dice during MTH (188 ± 52 vs. 58 ± 64, p:0,0001), after warming (200 ± 55 vs. 27 ± 24, p: 0.0001), and 24 hs after warming (201 ± 57 vs. 31 ± 24, p: 0.0001)

CONCLUSIONS

In this study, we observed a lower antiplatelet efficacy of clopidogrel compared with ticagrelor in patients with OHCA after PCI with MHT. This decrease in antiplatelet efficacy persists after the warming. Similarly to other settings, ticagrelor might be a valid alternative to clopidogrel in those patients.

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Post-implantation shear stress assessment: an emerging tool for differentiation in BRS

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

AIMS

Optical coherence tomography based computational flow dynamic (CFD) model provides detail information about the local flow environment in stented/scaffolded vessel segments. Our aim was to investigate the in-vivo effect of strut thickness and protrusion on wall shear stress (WSS) distribution in similar strut designs of Arteriosorb Absorbable Drug-Eluting Scaffold (ArterioSorb) and Absorb everolimus-eluting Bioresorbable Vascular Scaffold (Absorb).

METHODS AND RESULTS

In ArterioSorb group, six coronary arteries were implanted with a single ArterioSorb in three animals. In Absorb group, six coronary arteries were implanted with a single Absorb in six animals. Following three-dimensional(3D) reconstruction of the coronary arteries, WSS was quantified using Newtonian steady flow simulation in each cross-section in 5-degree subunit(sector) of the circumferential luminal surface in CFD models. Mixed effects models have been implemented for statistical analysis. There were 4591 struts in 477 cross-sections from Absorb (strut thickness=157μm) and 3105 struts in 429 cross-sections from ArterioSorb (strut thickness=95μm) for the embedment/protrusion analysis. In cross-section level analysis, there was significant difference between the scaffolds in the protrusion (153±137μm for Absorb, 84±12 μm for ArterioSorb,

CONCLUSIONS

The thinner struts of ArterioSorb provide more favorable shear stress compared to the Absorb. In comparable strut profiles, strut thickness drives the local hemodynamic microenvironment. Strut protrusion -which is obviously related with strut thickness- has significant effect on shear stress distribution.

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Impact of ascending aorta dilatation on outcome after TAVI

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

AIMS

Ascending Aorta Dilatation (AAD) is often associated to aortic valve stenosis. In case of surgical aortic valve replacement, combined correction of the aortic aneurysm is often performed, in order to reduce the risk of rupture. The aim of this is study is to evaluate the impact of AAD on acute and midterm outcome of patients receiving just aortic stenosis treatment through TAVI procedure.

METHODS AND RESULTS

This is a single center retrospective study including all patients who underwent transfemoral TAVI at San Raffaele Hospital, Milan, from January 2008 to December 2016. Patients with any kind of previous surgery involving the LVOT, the aortic valve complex and the ascending aorta (except for CABG) or a previous TAVI were excluded from the study as well as patients without a pre-operative CT scan or patients with congenital aortic defects.

Five hundred and eighty-three patients were ultimately included in the analysis. Patients with cross section diameter of the ascending aorta equal to or greater than 40 mm were defined as having AAD. All cause-mortality and cardiovascular-related mortality at 2 years were then compared between the two groups by using Kaplan-Meyer analysis.

Among the included patients, 220 (37.7%) were implanted with a balloon-expandable valve (9 Edwards Sapien, 132 Edwards Sapien XT, 79 Edwards Sapien 3), 213 (36.6%) were implanted with a self-expanding valve (110 Medtronic Corevalve, 79 Medtronic Corevalve Evolut R, 23 St Jude Portico), 74 (12.7%) patients were implanted with a mechanical expanding valve (Boston Scientific Lotus) and 76 (13%) patients received prosthesis which are no available any more (Direct Flow valve).

Sixty patients (10.3%) presented AAD. Of note, only 8 patients (1.3%) presented an ascending aorta diameter > 45 mm. Baseline clinical characteristics were the same in the two groups. AAD does not appear to impact on periprocedural outcome (moderate-to-severe paravalvular leak, procedural success, peri-procedural death, permanent pace-maker implantation).

According to Kaplan Meier analysis, there were no difference in freedom from cardiovascular mortality rate at 2 years between patients with and without AAD (95.0% vs 91.6%, p = 0.42).

CONCLUSIONS

The incidence of AAD in our population was 10.3%. Ascending aorta dilatation does not appear to impact on acute and midterm outcome after TAVI. However, caution must be paid: there were few patients presenting moderate (diameter > 45 mm) or severe (diameter > 50 mm) AAD, a theoretical increased risk of aortic rupture after TAVI in this setting should not be excluded. Further studies are needed to assess the safety of TAVI in case of severe AAD.

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The CHADS-MI score: a simple CHA2DS2-VASc derived score for assessing long term prognosis in STEMI patients

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

There are multiple clinical score for assessing the prognosis of STEMI patients, GRACE score is recommended by current guidelines. Nevertheless, most of these clinical scores are complex and time consuming. The CHA?DS?-VASc score is a simple score developed for predicting thromboembolic event in patients with atrial fibrillation, recently this score has been associated with a worse prognosis in STEMI patients.

Our aim was to develop a user friendly score, derived from the CHA?DS?-VASc, for assessing the long term prognosis of STEMI patients, and compare it to the GRACE score.

METHODS AND RESULTS

A cohort study was conducted with 1723 consecutive patients diagnosed with ST elevation myocardial infarction (STEMI) who underwent primary angioplasty between January 2008 and December 2016.

The CHADS-MI score was calculated using variables from the CHA?DS?-VASc score who where positive correlated with death in the follow up in both the univariate or multivariate analysis. Killip class was added to the score due to its powerful association with events and its ease implementation to the clinical practice. Previous stroke, transient ischemic attack or thrombo-embolism were excluded as they shown no association with death. The CHADS-MI score, included the following variables: heart failure (previous or Killip >1 at admission), hypertension, age > 75 years, diabetes mellitus, female sex and previous myocardial infarction. Female sex, hypertension and previous myocardial infarction scored 1 point, the rest of variables 2 points. Patients where classified as high risk if they had a CHAD-MI score ? 2 points and in low risk (0-1 point).

Mean age was 63,9 years, 23% of the patients were female, 22% had diabetes mellitus, 49% had hypertension and 7,8% had Killip 4 at admission. Low risk patients were younger, more frequently on smoking, had a higher GRACE score and lower extension of coronary artery disease. 49.5 %of the population were classified as high risk by the CHAD-MI score.

The CHADS-MI score risk was positive correlated with all cause death and MACE during follow-up (median follow up 859 days). Patients classified as high risk had a higher mortality (20% vs 2% in with low risk CHADS-MI patients, HR 8.274 [5.308 ? 12.896], p < 0,001) and more MACE events (30% vs 14% in low risk CHADS-MI patients, HR 2.398 [1.932 ? 2.976],

CONCLUSIONS

The CHADS-MI score may be a useful test for predicting long term prognosis of STEMI patients, showing with a similar performance to the GRACE score in our registry.

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Initial experience with the novel BioMime Morph 40-60 mm long sirolimus-eluting tapered stent in long coronary lesions

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

AIMS

Aims: Long lesions treated with overlapping stents has been reported to be associated with healing problems and/or adverse events [1-2]. The novel BioMime Morph (Meril Life Sciences, India) is a 40, 50 and 60 mm long sirolimus-eluting cobalt chromium stent (65 µm strut thickness, biodegradable polymer) with a tapered design (0.5 mm taper from proximal to distal end) and is available in the following proximal and distal diameters (2.75-2.2 5mm, 3-2.5 mm and 3.5-3 mm). It can be a novel alternative for treatment of long coronary lesions, overcoming the limitations of overlapping stents.

METHODS AND RESULTS

Methods: Data was evaluated from our centre?s prospective BioMime Morph database from August 2016 - September 2017. Primary endpoint was device oriented composite endpoint (DOCE: cardiac death, TV-MI, TLR and TVR). Secondary endpoints were technical (successful Morph implantation) and procedural success (successful procedure with Morph without in-hospital MACE).

Results: 55 patients had BioMime Morph stents implanted, with mean follow up of 200(+/-50) days. Mean age was 67(+/-11) years, 70% were men. Co-morbidities included hypertension (57%), hypercholesterolemia (34%), diabetes mellitus (30%), PVD (2%), CVD (5%), CKD (13%), previous MI (22%), smoking (38%) and positive family history (15%). There was history of previous PCI in 15% and CABG in 6%. Indication for PCI was predominantly ACS (82% including 16% STEMI), 12% were CTOs. 89% of the procedures were performed via radial access using 5-6F sheath. Vessels treated included LAD (46%), Cx (10%) and RCA (44%). Pre-dilatation was performed in 95% including use of non-complaint balloons in 43%, scoring balloons in 15% and rotablation in 4%. Post-dilatation was performed in 100%. Buddy wire was used in 37% while a guideliner used in 10%. Technical and procedural success (secondary endpoint) were achieved in 100%. Cumulative DOCE (primary endpoint) was 3.6% (cardiac death 1.8%, TV-MI 1.8%, definitive ST 0%, possible ST 1.8%, TLR 1.8% and TVR 0%).

CONCLUSIONS

Conclusions: Our initial experience of the use of the novel BioMime Morph tapered DES for treatment of long coronary lesions exhibit promising results in short to medium follow-up. BioMime Morph stents can potentially be an alternative to overlapping conventional stents for treating long coronary lesions.

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Very long (>40 mm) DES performance comparison between CTO and non-CTO coronary lesions: multicentre registry

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

AIMS

The aim of this study was to evaluate the effectiveness of very long (>40 mm) DES between patients with CTO and non-CTO lesions.

METHODS AND RESULTS

A multi-centre, ?real-world?, prospective registry was performed including consecutive patients treated by percutaneous coronary intervention with at least one implanted >40 mm DES and divided into two groups according to CTO (Group 1) or non-CTO lesions (Group 2: control). 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.

Overall, 37 real-world patients with CTO lesions were compared to 128 non-CTO patients treated with long DES. The baseline patient characteristics were similar in the 2 groups (77% vs 78% male, age 62.4±15 vs 62.7±14 years, 40% vs 35% smoker, 74% vs 75% hypertensive, 40 vs 44% diabetic, 66% vs 55% hyperlipidemic), apart from (previous ischemic heart disease 57% vs 30%

CONCLUSIONS

The safety profile, long-term angiographic and clinical outcomes were similar between patients with CTO and Non-CTO lesions treated with very long DES (>40 mm).

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One-year outcome of multivessel PCI vs. staged PCI in STEMI: a single-centre experience

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

The aim of this study was to review patients presenting with STEMI and multivessel disease and compare one-year outcomes of those undergoing multivessel PCI (MVPCI) at the time of PPCI to those undergoing staged PCI after initial acute culprit artery intervention.

METHODS AND RESULTS

Methods

St. James?s Hospital is Dublin?s largest PCI centre. We identified all patients undergoing PPCI for STEMI between January and December 2015 using the Code STEMI database. Electronic health records, chart review and HIPE data were used to further characterize patients. The number of patients undergoing MVPCI during index procedure was recorded, as was the number undergoing staged intervention. Those referred for CABG were excluded from further analysis Average patient length of stay and need for re- intervention and mortality at one year were noted.

Results

There were 417 patients with a confirmed diagnosis of STEMI, either clinically or angiographically, out of this 364 (87.2%) underwent PPCI. 153 patients (36.6%) presenting with STEMI had multi-vessel coronary artery disease, 136 (88.8%) had PCI and 17 (11.2%) had CABG. Of the 136 undergoing PCI for multi-vessel disease, 59 (43.4%) underwent MVPCI during PPCI, the average age of this group was 61years and 12 (21%) were female. 77 (56.6%) patients underwent staged PCI, the average age was 62years and 13 (17%) were female. Of those undergoing staged PCI 21 (27%) occurred during the index patient admission and 56 (73%) occurred as an outpatient. Within one-year of follow-up 4 (6.7%) in the MVPCI group and 6 (7.8%) in the staged PCI group had represented with recurrent MI requiring further revascularization, thus the relative risk of MVPCI patients presenting with recurrent MI was 0.8701, though the p value was non-significant at 0.82. 4 patients (6.7%) in MVPCI and 10 patients (12.9%) in staged PCI represented with angina, this represents a relative risk of 0.522, again with a non-significant p-value of 0.25. 1 patient died in MVPCI group, though this was due to non-cardiac causes, there were no deaths in the staged PCI group. Median hospital stay was 8.4 days (range 4.4-17.7) in the MVPCI group and 6.3days (range 3.3-26.2) in the staged intervention group.

CONCLUSIONS

In the largest Irish Primary PCI center, we found there no significant difference in patients representing with recurrent MI requiring repeat revascularization in multivessel PCI as compared to staged PCI. There was a trend for those undergoing staged PCI to represent with more angina than those undergoing MVPCI, though this did not reach statistical significance. There was no difference in length of stay between cohorts.

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Impact and prognosis of grade 3 coronary artery perforations during CTO PCI

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THEME: Coronary Interventions
TOPIC(S): CTO

AIMS

Grade 3 coronary perforation (G3CP) represents one of the life-threatening complications of Chronic Total Occlusion (CTO) percutaneous coronary intervention (PCI), however, few data exists regarding its impact on acute and long-term outcomes.

METHODS AND RESULTS

Data were analysed from 7,473 CTO PCI and 90,306 Non-CTO PCI performed in 9 European institutions among patients enrolled in the Grade 3 Coronary Artery Perforation (G3-CAP) Registry from 1998 to 2015. We identified 58 G3CP in the CTO PCI group and 154 G3CP in the Non-CTO PCI group, with a growing trend for incidence of G3CP in the last years: from 0.23% vs 0.10% in the years 1998-2000 to 1.09% vs 0.23% in the years 2013-2015, respectively for CTO PCI group and Non-CTO PCI group. In the CTO-PCI group, mean J-CTO score was 2.3±0.8. G3CP were more frequently related to non-compliant balloons (27.3% vs 6.9%, p=0.001) and coronary stents implantation (19.8% vs 3.4%, p=0.003) in the Non-CTO PCI, while guidewires caused G3CP in the 56.9% of CTO PCI vs 29.8% of Non-CTO PCI (

CONCLUSIONS

Despite contemporary trends for higher incidence of grade 3 coronary perforations in the setting of CTO PCI, in our registry this harmful complication did not seem to be associated with addictive worse acute and long-term clinical outcomes.

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Residual in-stent stenosis treated by deploying second stent

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Coronary lesion structure features in patients undergoing CABG after PCI

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THEME: Coronary Interventions

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

AIMS

The aim of study was to research the coronary lesion characteristics and distinctions in surgical techniques used for CABG patients with prior history of percutaneous coronary intervention (PCI).

METHODS AND RESULTS

Materials and methods. The results of coronary artery bypass grafting (CABG) procedures during the period from 2012 to 2015 were analyzed. The patients were divided into three groups. Patients undergone PCI (group I - 112 after single PCI, group II - 46 after multiple PCI sessions) were compared with 160 cases of primary CABG (group III). In all cases on-pump CABG were performed. Surgical procedure intraoperative tactics and one year result of CABG were assessed

In all patients left anterior descending artery was bypassed by internal mammary artery while autovenous grafts were used in bypass the rest of the diseased arteries. Each coronary anastomosis was formed under the surgical microscope with 8-0 prolene continuous suture. The groups were equal in age, gender, functional class angina, SYNTAX score, comorbidities and number of bypassed arteries (mean 3,7). Interestingly, diffuse coronary artery lesion was determined more often in group I and II in comparison with primary CABG patients while intraoperatively coronary artery assessment (

CONCLUSIONS

Patients with a history of PCI more frequently have diffuse coronary lesion and need of CE during CABG.

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Five-year durability of clinical and hemodynamics outcomes - Long-term Israel TAVI durability (LIABILITY study)

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

AIMS

There are little ?real life? data on the long-term durable functionality of the transcatheter heart valves.
We intended to assess the 5-year outcomes of transcatheter aortic valve implantation (TAVI) using the current available prosthesis (Sapien/XT or CoreValve devices).

METHODS AND RESULTS

Methods: We performed a joined multicenter Israeli registry for the data of the long term echocardiographic follow up of post TAVI patients (Sapien/XT, CoreValve) in 3 Israeli sites. We collected the 5 year follow up echocardiographic and clinical outcomes for all TAVI survival who underwent TAVI procedure from 9/2008 till 12/2011 the 3 participating centers (Rabin, Sheba & Hadassah Medical Centers). Prosthetic valve dysfunction was defined according to ESC 2017 guidelines definitions for prosthetic valve failure. Only consecutive patients with 5-year follow-up data available were included in our study.

Results: Among 162 patients (84.9±6.1 years,36.2% men), CoreValve/SAPIEN valves were used in 65.6/34.6% cases. On echocardiography, mean trans-aortic valve gradient 5 years post TAVI was 9.6±6.4 mm Hg. Late structural valve deterioration was observed in 13 (8%) patients: 7 cases due to new significant peri-valvular leak (PVL) and 6 due to mild stenosis with a mean trans-aortic valve gradient ranging from 20 to 40 mmHg. Late prosthesis failure occurred in 2 cases (1.2%) who presenting with symptomatic prosthesis restenosis with augmented gradients and required redo-TAVI. Death caused by bioprosthetic valve dysfunction were not reported. Valve dysfunction occurred equally with SAPIEN and CoreValve devices.

CONCLUSIONS

TAVI using the Sapien/XT or CoreValve devices was associated with relatively low rate (1.2%) of significant prosthetic valve degeneration. Thus, TAVI appears to be a durable therapeutic solution for aortic stenosis in selected high-risk patients at least up to 5 years.

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Large single-centre experience of TAVI for severe symptomatic aortic stenosis using a novel resheathable self-expanding device with advanced sealing

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

AIMS

To evaluate the hemodynamic and clinical performance of the self-expanding CoreValve Evolut Pro transcatheter aortic valve implantation (TAVI) system in patients with severe symptomatic aortic stenosis.

METHODS AND RESULTS

The study population is constituted of consecutive patients who underwent transfemoral TAVI for native severe aortic valve stenosis with the self-expanding CoreValve Evolut Pro device between August 2016 and July 2017 at a single US center. Patients with bicuspid aortic valve were excluded. The primary endpoints were device success per the VARC-2 (Valve Academic Research Consortium-2) definition, mild-or-more aortic regurgitation as assessed by echocardiography, and conduction disturbances requiring permanent pacemaker insertion during hospitalization. The other clinical endpoints, including major bleeding, major vascular complication, any stroke and death at 30 days were also recorded and compared with a group of patients who underwent TAVI with the Evolut R system.

During the study period, 262 TAVI procedures were performed at our institution. Data of 54 and 107 patients who underwent TAVI with the Evolut Pro and Evolut R system, respectively, were analysed. Patients in the Evolut Pro group were more frequently women (64.9% vs 47.1%, P = 0.030) with lower body surface area (BSA: 1.8 ± 0.2 m2 vs 1.9 ± 0.3 m2, P = 0.026). A second transcatheter valve was required in none of the patients of the Evolut Pro group and in 2 (1.9%) patients of the Evolut R group (P = 0.540). There was no moderate or severe residual aortic regurgitation in either group. The incidence of residual mild aortic regurgitation was numerically lower in the Evolut Pro group than in the Evolut R group (28.6% vs 37.5%, P = 0.257). Permanent pacemaker implantation was required in 7.0% and 7.7% of patients in the Evolut Pro and Evolut R group, respectively. There was no inter-group difference in the incidence of major bleeding, major vascular complication, any stroke or all-cause death at 30 days.

CONCLUSIONS

The novel repositionable Evolut Pro TAVI system featured of the advanced sealing technology is safe and effective for the treatment of symptomatic aortic stenosis patients. Compared with its predecessor (Evolut R), the Evolut Pro was associated with a trend toward less residual aortic regurgitation without increasing the risk of heart block requiring permanent pacemaker insertion or vascular complication.

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Prognostic evaluation of cardiac biomarkers and late gadolinium enhancement following revascularisation in stable coronary disease: MASS V trial long-term follow-up

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

AIMS

There is lack of evidence correlating post-procedural release of biomarkers and new late gadolinium enhancement (LGE) with long-term prognosis. The aim of this study is to evaluate the prognostic value of myocardial necrosis biomarkers elevation and new late gadolinium enhancement in long-term follow-up.

METHODS AND RESULTS

Methods: Patients with stable coronary disease who underwent revascularization were included. Biomarkers and magnetic resonance imaging were done before and after procedures. Primary outcome was the composite of death, nonfatal myocardial infarction, new revascularization and hospitalization for cardiac causes.

Results: In a median follow-up of 3.9 years, 202 patients were included, 136 in surgery (CABG) and 66 in angioplasty (PCI) group. Mean peak CK-MB was 26.35ng/ml and 5.67ng/ml for high sensitive troponin (Tn). Primary outcome was observed in 16 patients (7.9%). Event-free survival were 93.8% and 87.9% in patients below and above mean peak CK-MB, 93.5% and 87.2% below and above mean peak Tn, 92.7% and 89.2% in absence and presence of LGE (p=0.21, p=0.13 and p=0.46, respectively). Survival was 98.8% and 91.9% for LGE absent and present respectively (p=0.004). In CABG group, event-free survival was 97.5% and 87.3% for those with elevation of CK-MB below and above 26.35 ng/ml, respectively (p=0.02). Otherwise, in PCI group, event-free survival was 91.7% and 66.7% for those with Tn below and above 5.67 ng/ml, respectively (p=0.02).

CONCLUSIONS

Post-procedural LGE was associated to higher mortality in a long-term follow-up. Besides, elevation of CK-MB and Tn after CABG and PCI, respectively, are related to higher rates of clinical events.

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Ticagrelor in the elderly - Real-world data

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THEME: Coronary Interventions
TOPIC(S): NSTEMI

AIMS

Ticagrelor is a reversible and direct-acting oral antagonist of the adenosine diphosphate receptor P2Y12 licensed for use in the treatment of acute coronary syndromes. Elderly patients with acute coronary syndrome are at high risk of recurrent ischemic events and death, and for both antithrombotic therapy and catheter-based complications. This study was designed to assess the safety and efficacy of 12 months of ticagrelor therapy in elderly patients presenting with acute coronary syndromes.

METHODS AND RESULTS

We retrospectively looked at the outcomes of all patients >75yrs of age admitted to our cardiac centre with an acute coronary syndrome(ACS)and subsequently discharged. Our institutional protocol ensures all elderly patients with ACS are treated with 12 months of ticagrelor and aspirin from admission. All patients are also treated with a proton-pump inhibitor where tolerated. Only patients with concomitant warfarin therapy are given clopidogrel. The data was collected from local databases.

Over the 35month time period 235 patients were discharged with a diagnosis of ACS and taking ticagrelor. The mean age was 84 (range 76-103) with 63% male. Of the cohort 9% were also taking oral anticoagulants. Of the 235 patients, 117 (50%) underwent PCI and 112(48%) were managed medically with 6 patients having CABG. The rate of death during the 12 months of ticagrelor therapy was 39 (16.6%). Over the 12months of therapy 112 (47.7%) discontinued ticagrelor prematurely. Of the 112 who discontinued prematurely, 39 (34%) died, 26 (23%) patients stopped for bleeding complications, including 6 patients with a life-threatening bleed, 26 (23%) were changed to clopidogrel, 13(11.6%) due to breathlessness and 11(9.8%) due to commencing oral anticoagulation and 2 patients due to a CVA. Of the medical management group, 7 patients were readmitted with a further ACS whereas from the PCI group 4 patients were readmitted with an ACS.

CONCLUSIONS

Compared to the PLATO study, our cohort had an increased mortality, MACE rate, non-CABG major bleeding rate and an increased rate of medical management. This would be consistent with a higher risk group. The mean age of the over 75 group in PLATO was not published so it is difficult to compare. Complications of ticagrelor therapy in the real world are higher than in randomised studies although we found a lower MI and CVA rate over 12 months.

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The influence of gender in STEMI patients treated in the "Codi IAM network" from 2010-2015

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

STEMI networks were initiated in order to increase reperfusion rates and reduce ischaemic times. Female gender is associated with worse prognosis after STEMI. Gender factors influencing STEMI are still being debated. The aim of the present work is to analyse the differences between genders in first STEMI treated patients in the STEMI network (Codi IAM) in the autonomous region of Catalunya, Spain, during the 2011-2015 period and evaluate factors influencing prognosis.

METHODS AND RESULTS

Methods: The ?Codi IAM? registry analysis of all data from code activation for first STEMI in Catalunya from 1/1/2010 to 31/12/2015. The registry contains data of first assistance (onset of symptoms, time to first EKG), clinical risk factors, reperfusion time, 30-day mortality and one-year mortality. Variables are presented with mean and standard deviation, median and ICR and were studied with mean-SD and Student-t test, rates with Chi-Square test and logistic and Cox regression to obtain factors associated with reperfusion and mortality at 1 month and at one year. Statistical analysis was performed with SPSS software (SPSS Inc., Chicago, Il, USA).

Results: During the study period, 12743 cases of first STEMI were recognised: 24% in females and 76% in males. Clinical risk factors and timings in women and men: age (70±13 vs 60.5±12, 0.0001), High Blood Pressure (40% vs 26%, p=0.0005), Dyslipidaemia (28% vs 23%, p=0.01), Diabetes Mellitus (24% vs 16%, p=0.001), Killip I at presentation (78% vs 86%, p=0.001), Onset of symptoms to first assistance time (90(42-194) vs 69(33-157), p=0.005), ischaemic time 240 (163-380) vs 205 (144-324), p=0.005) . Effective reperfusion rates (rate of TIMI 2-3) were lower in women than in men (91% vs 93%, p=0.004). Final diagnosis of STEMI differed between genders (anterior STEMI 43% vs 41%, inferior STEMI 45 vs 49%, p=0.001). Total ischaemic time was longer in women than in men (339±335 vs 315±472, p=0.03), mortality was also superior at 30 days in women (9.8% vs 5.1%, p=0.0001) and mortality at 1 year was also higher in women (15% vs 8%, p=0.0001). Mortality was associated to gender (HR 1.1, CI 1-1.2, p=0.049), dyslipidaemia (HR 1.4, CI 1.1-1.8, p=0.005), diabetes mellitus (HR 1.3, CI 1.2-1.46, p=0.001), older age (HR 1.06, CI 1.06-1.07, p=0.001), presence of heart failure at presentation (HR 3.4, CI 3.1-3.8, p=0.001 but not to smoking (p=0.8), hypertension (p=0.5) or total ischaemic time (p=0.1).

CONCLUSIONS

Females with first treated STEMI were older, more diabetic and more frequently presented with heart failure. Longer ischaemic times and longer treatment delays are still observed in female gender compared to male. Mortality is higher in females than in males and is basically associated to the presence of heart failure, older

ages, diabetes mellitus, dyslipidaemia and female gender.

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Impact of post-dilatation on stent edge deformation in second- and third-generation DES: an experimental study using OCT

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

AIMS

To avoid stent edge injury, post-dilatation (PD) is often performed using a short noncompliant balloon (NCB), few millimetres inside the stent edge (stent edge protect method). Using this method, we evaluated the impact of PD on stent edge strut deformations of second- or third-generation drug-eluting stents (DES) using optical coherence tomography (OCT) in bench tests.

METHODS AND RESULTS

Of 30 new-generation DESs, 18 were second-generation DESs [everolimus-eluting cobalt chromium stents (CoCr-EES), everolimus-eluting platinum chromium stents (PtCr-EES), and zotarolimus-eluting cobalt chromium stents (CoCr-ZES), n = 6 for each], and 12 were third-generation DESs [PtCr-EES, and sirolimus-eluting cobalt chromium stents (CoCr-SES), n = 6 for each]. OCT was performed on those DESs (3.0-mm diameter) after stent delivery and PD in a silicone mock vessel. After deploying nominal-pressure using a stent delivery balloon, PD was performed using a NCB (3.5 mm, 12 and 20 atm), 2 mm inside the stent edge. Mean stent area (SA), minimum SA (MSA), and incomplete stent apposition (ISA) were evaluated using OCT images with 0.2-mm intervals in the edge section (ES, 0?2 mm from stent edge) and body section (BS, 2?4 mm from stent edge). After stent deployment using original delivery systems, no differences were observed in mean SA, MSA, and ISA between the ES and BS (6.5 ± 0.3 vs. 6.5 ± 0.3 mm2, p = 0.55, 6.3 ± 0.4 vs. 6.4 ± 0.3 mm2, p = 0.47, and 9.8% ± 11.0% vs. 7.6% ± 7.5%, p = 0.37, respectively). While using the stent edge protect method for PD, BS showed increased MSA with decreased ISA (6.4 ± 0.3 to 8.0 ± 0.6 mm2, p < 0.01 and 7.6% ± 7.5% to 0.7% ± 2.2%, p < 0.01, respectively). Contrarily, the ES showed a significant increase in ISA without increased MSA (9.8% ± 11.0% to 13.3% ± 11.0%, p < 0.01 and 6.3 ± 0.4 to 6.3 ± 0.4 mm2, p = 0.29, respectively). In material-based analysis, ISA prevalence in the ES was more frequent in CoCr than in PtCr DESs during PD (12.7% ± 12.8% to 16.2% ± 11.9% vs. 5.5% ± 5.6% to 8.8% ± 7.9%, p = 0.04). In generation-based analysis, third-generation DESs showed a tendency toward less ISA compared to second-generation DESs (5.2% ± 6.5% to 9.0% ± 9.1% vs. 12.9% ± 12.4% to 16.1% ± 11.4%, p = 0.07) during PD in ES.

CONCLUSIONS

ISA has been identified as an important risk factor for poor outcomes after DES implantation. Additionally, ISA in the stent ES can be a hindrance to the wire or device passing through the stent during percutaneous coronary intervention procedures. In the present study, despite some differences observed depending on materials or designs, all second- and third-generation DESs showed increased ISA in ES after PD. Although PD using a short NCB with the stent edge protect method could achieve optimal stent body expansion without overexpansion of the stent edge, ISA due to stent strut deformations in the ES adjacent to the dilated BS appeared to increase in exchange for the stent edge protection.

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Micro-CT analysis of DK crush stenting vs. culotte stenting for left main distal bifurcation lesions: using three dimensional left main elastic bifurcated coronary artery models

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

Both double kissing crush (DK-crush) stenting and Culotte stenting are considered efficacious treatment options when a planned 2-stent strategy is deemed necessary for unprotected left main coronary artery disease. However, there are limited data available with regard to the long-term clinical outcomes of each strategy in this setting. This study aimed to investigate the influence of stent implantation technique on the reduction of incomplete stent apposition volume (ISA-volume) between DK-crush and Culotte, using a three-dimensional elastic left main coronary artery bifurcated model.

METHODS AND RESULTS

The referenced left main bifurcation angle data of 209 patients were stratified by tertiles focusing on the angle between the left main trunk and left anterior descending artery. Then, a modified-angled bifurcation model with angles of 141°, 122°, and 71° for left main trunk?left anterior descending, left main trunk?left circumflex, and left anterior descending?left circumflex, respectively, was fabricated, with diameters of 4.3mm, 3.3mm, and 3.0 mm for left main trunk, left anterior descending, and left circumflex, respectively, these diameters fulfill Murray? s law. A 60% and 50% stenosis was included along the left main trunk?left anterior descending and left main trunk?left circumflex. All in vitro experiments were performed under fluoroscopy in the catheterization laboratory. Six DK crush stenting and six Culotte stenting were performed using SYNRGY stent. In the DK crush group, side branch stent was crushed using 4.0mm non-compliant balloon with 16atm. The final kissing balloon inflation was performed using 3.5mm semi-compliant +3.0mm non-compliant balloon with 6atm+12atm. In the Culotte group, stent implantation was performed 6 or 8atm. The final kissing balloon inflation was performed using 3.5mm semi-compliant +3.0mm non-compliant balloon with 6atm+8atm. The main branch ISA-volume, carina ISA-volume and total ISA-volume were quantified using micro-CT. Each case was successfully performed and completed. On the frontal plane, There was no place where the strut was not covered. In addition, extreme strut jailing at the both bifurcation ostium was not observed. Micro-CT analysis showed a higher proportion of ISA-volume into the main branch, carina and total with DK-Crush compared to Culotte, respectively (2.72 ± 1.50 mm3 vs. 0.24 ± 0.15 mm3, p=0.01 with main branch, 1.30 ± 0.40 mm3 vs. 0.42 ± 0.26 mm3, p=0.001 with carina and 4.02 ± 1.37 mm3 vs. 0.66 ± 0.28 mm3, p=0.002 with total).

CONCLUSIONS

Culotte stenting reduces the proportion of ISA-volume into the three strut overlapping portions in the main branch and the carina compare to DK crush stenting. In DK crush stenting, it is considered necessary to devise

crush at more higher pressure or reduce stent overlap. In Culotte stenting, we can achieve good apposition with low pressure KBI.

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Does out-of-hours primary PCI portend worse outcomes? Insights from an Australian multicentre registry

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Systems of care both outside and within the hospital system have been established to allow for timely access to primary percutaneous coronary intervention (PPCI) for patients with ST-elevation myocardial infarction (STEMI). It however remains unclear whether, in contemporary practice, patients presenting out-of-hours with STEMI have equivalent outcomes to those presenting in-hours. The aim of our study was therefore to compare procedural characteristics, time to reperfusion and clinical outcomes in patients undergoing PPCI in-hours vs. out-of-hours.

METHODS AND RESULTS

This observational study of patients included consecutive patients with STEMI undergoing PPCI from 1 January 2005 to 31 December 2016, enrolled prospectively in the multi-centre Melbourne Interventional Group registry. Patients were divided by whether PPCI was performed in-hours (i.e. 8 a.m. to p.m. on weekdays, excluding public holidays) or out-of-hours (6 p.m. to 8 a.m. on weekdays and all day on weekends and public holidays) and the 2 groups were compared. Patients having PCI following thrombolytic therapy and those transferred from other hospitals with STEMI for PPCI were excluded. The primary endpoint was 30-day mortality. Secondary endpoints include major adverse cardiovascular events (MACE, a composite of all-cause mortality, myocardial infarction and target vessel revascularisation) at 30 day and 12-month follow-up. Logistic multivariate regression analysis was used to calculate odds ratio for 30-day mortality for out-of-hours presentation relative to in-hours presentation. Of the 4,590 patients included in this study, 1,865 patients (40.6%) were treated in-hours while 2,727 patients (59.4%) were treated out-of-hours. Patients in the out-of-hours group were likely to be slightly younger (62.1±12.6 vs. 64.6±12.6 years,

CONCLUSIONS

This large multi-centre observational study demonstrates that despite a slight increase in DTBT, out-of-hours presentation with STEMI is not associated with worse clinical outcomes in patients undergoing PPCI. Our study reassuringly demonstrates consistent procedural and clinical quality across multiple PPCI centres in Australia, regardless of time of presentation. While hospitals should continue to improve processes to minimize delays to PPCI, the small inherent delays in treatment that occur for out-of-hours cases are not long enough to adversely affect outcomes in these patients.

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Off-hour presentation and outcomes in patients with STEMI: insights from the Catalonian codi infart network

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

To determine the impact of the off-hour presentation on clinical outcomes of patient with STEMI treated with primary PCI in the Catalan Codi Infart Network.

METHODS AND RESULTS

This was an observational, multicenter study based on prospectively collected data from consecutive patients treated within the Catalonian STEMI Network (Codi Infart) from January 2010 through December 2015. Clinical and angiographic characteristics, in-hospital complications and all-cause mortality data were analyzed. On-hour presentation was defined as patient attended between 8:00h and 19:59h on business days and off-hour as attended between 20:00h to 7:59h on business days, weekends (Saturdays and Sundays) and holidays. Population was divided according to on-hour vs. off-hour presentation. The primary endpoint was 1-year all-cause mortality. The secondary endpoints were 30-day all-cause mortality and in-hospital complications. A logistic regression model along with a Wald test was used to compare the outcomes of 30-day and 1-year all-cause mortality between groups. The model was adjusted for the following baseline characteristics: age, first-aid care provider, fibrinolytic therapy at first-aid assistance, Killip class, left-main coronary artery disease, multivessel disease and total ischemic time. A total of 8608 patients were included in the analysis, 44.1% were attend at on-hour presentation and 55.9% at off-hour. There was a significant difference between on-hour vs. off-hour group in the use of fibrinolytic therapy at first-aid assistance (1.3% vs. 3.3%,

CONCLUSIONS

In this large and contemporary registry, the off-hour presentation was not related to an increase in 1-year all-cause mortality when compared to on-hour. Off-hour presentation was associated with a lower patient delay time and higher system delay, without an increase in total ischemic time. There was a significant higher use of fibrinolytic therapy use in the off-hour presentation group, which was related to a 2-fold increase in all-cause mortality.

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Clinical results of endovascular treatment in Buerger?s disease with critical limb ischaemia

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

AIMS
Despite recent progress made in endovascular techniques and devices tailored for complicated below-the-knee (BTK) disease, there are few publications describing the use of catheter-based intervention in Buerger?s disease. We report our experience in endovascular treatment for Buerger?s disease with critical limb ischemia.

METHODS AND RESULTS
Between January 2011 and December 2016, endovascular treatment was performed in 24 limbs of 22 consecutive patients (mean age: 43.5) with critical limb ischemia (Rutherford class 4: 7 patients, class 5: 15 patients) associated with Buerger?s disease. In terms of technical outcome, complete success was defined as revascularization of at least one straight-line flow to the foot and partial success as revascularization of at least one arterial segment. Involvement of BTK arteries were found in all cases (from superficial femoral artery to BTK in 11 and from popliteal artery to BTK in one case).
Technical success was achieved in 18 (75%) limbs (complete success in 14 and partial success in 4). Complete success rate was 33% (4/12) in the first half of the study period while it increased to 83.3 % (10/12) in the latter half. Re-intervention free rates were 90.0 % at 6 months and 75.5% at 12 months. During a mean follow up period of 25 ±16 months, limb salvage rate was 95.4% with no mortality. Sustained clinical improvement was achieved in 16 of 18 limbs (88.9%) that were successfully treated.

CONCLUSIONS
Endovascular treatment may be feasible and effective for management of critical limb ischemia in patients with Buerger?s disease. Improved technical success may derive from recent advances in endovascular techniques and devices.

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Transcatheter or surgical aortic valve replacement in intermediate-risk patients with previous CABG surgery: a subanalysis from the SURTAVI trial

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

AIMS

The risk associated with surgical aortic valve replacement (SAVR) is higher for aortic stenosis patients with a history of coronary artery bypass graft (CABG) surgery, mainly due to the technical complexity of a redo operation and because these patients present with more comorbidity. Transcatheter aortic valve replacement (TAVR) may be a preferred treatment approach. The aim of this analysis was to compare the clinical outcomes in prior CABG patients treated with SAVR or TAVR in the SURTAVI trial.

METHODS AND RESULTS

The Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI) trial randomized 1,746 patients with severe, symptomatic aortic stenosis at intermediate surgical risk 1:1 to TAVR using a self-expanding device or SAVR. Of them, 1,660 patients underwent an attempted procedure. Patients with a prior CABG comprised 16.6% of this population (N=138 TAVR, N=137 SAVR). There were no significant differences in the baseline characteristics of the TAVR and SAVR groups. Within 30 days, SAVR patients experienced higher rates of stage 2 or 3 acute kidney injury (2.9% vs. 0.0% in TAVR, p=0.04), and atrial fibrillation (37.5% vs. 10.1% in TAVR,

CONCLUSIONS

This randomized comparison of surgical and transcatheter aortic valve replacement in intermediate-risk patients with a history of CABG demonstrates that treatment modality influences the post-operative course, with TAVR facilitating a more rapid and robust improvement in physical condition and quality of life. The risk for certain serious complications such as atrial fibrillation or permanent pacemaker implantation also depends on treatment approach, however all-cause mortality and stroke rates are similar for TAVR and SAVR.

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Clinical outcomes of surgical or TAVR in intermediate-risk patients according to sex: results from the SURTAVI trial

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

AIMS

In studies randomizing high-risk elderly patients to transcatheter aortic valve replacement (TAVR) or surgical aortic valve replacement (SAVR), women had improved survival with TAVR compared to SAVR. Also, women undergoing TAVR have shown better survival than men undergoing TAVR. The aim of this analysis was to determine whether sex-specific differences in outcome, quality of life by Kansas City Cardiomyopathy Questionnaire (KCCQ) and functional capacity by 6-minute walk test (6MWT) exist among patients at intermediate surgical risk undergoing TAVR or SAVR.

METHODS AND RESULTS

The Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI) trial randomized 1,746 patients with severe, symptomatic aortic stenosis deemed intermediate risk for surgical mortality 1:1 to TAVR using a self-expanding device or SAVR. Of them, 1,660 patients underwent an attempted TAVR or surgical procedure. For this analysis, the population was separated by sex and treatment modality (female TAVR, N=366, male TAVR, N=498, female SAVR, N=358, male SAVR, N=438), and clinical outcomes were compared. Males treated by either TAVR or SAVR had a lower STS score (TAVR: males, 4.2% vs. females, 4.6%,

CONCLUSIONS

Aortic valve replacement, either by surgical or transcatheter approach, is equally safe up to 1 year for males and females at intermediate surgical risk. Early complications due to TAVR were more common in females than males. TAVR facilitated a more robust improvement in physical condition than SAVR, especially in females.

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Outcomes of patients with severe aortic stenosis treated with balloon aortic valvuloplasty prior to surgical aortic valve replacement, TAVR or conservative management

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

AIMS

Balloon Aortic Valvuloplasty (BAV) usage for patients with severe aortic stenosis (AS) has increased with the development of TAVR, but its role is not clearly defined. We reviewed the characteristics and outcomes of patients treated with BAV followed by medical therapy or definitive intervention compared with those treatments alone.

METHODS AND RESULTS

A large echocardiography database was reviewed including consecutive patients from Jan 1, 2006 to Dec 31, 2016. Patients were identified with severe AS using the following criteria, Aortic Valve (AV) mean gradient >= 40mmHg, AV peak velocity >= 4.0m/s, AV Area

CONCLUSIONS

Patients who underwent BAV were older, and had more comorbidities, but BAV still provided a mortality benefit over medical management up to 280 days, and did not worsen outcomes in patients who had subsequent S/TAVR. BAV is likely underused in current clinical practice.

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Dynamic absolute microvascular function assessment: resistance and compliance in real time by controlled flow infusion

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

AIMS

Myocardial microvascular resistance MVR is difficult to measure directly due to inaccuracies in microvascular flow determination. Absolute MVR determination (mmHg-min/ml) is difficult because it requires coronary flow (Q, ml/min) in its calculation. Real-time continuous measurement during invasive procedures could prove very useful for understanding pathologies such as microvascular obstruction in STEMI, no-reflow, and other microvasculopathies as diabetes and transplant disease. This study evaluated a novel method for real-time absolute MVR measurement in a preclinical STEMI model.

METHODS AND RESULTS

Microvasculature integrity and compliance was assessed in 7 normal domestic pigs. MVR was determined in real time using a novel infusion catheter with a proximal balloon to completely block antegrade flow and distal infusion ports for precise, pump-driven flow distal to the occlusion balloon, and a commercial coronary pressure wire placed distal to the infusion ports. By varying pump infusion flow and measuring resulting counter-pressure. Absolute real time MVR is the simple time dependent function P(t)/Q(t), and additional measures across multiple controlled flow rates additionally yields global microvascular bed compliance across lumen pressure, DMVR/DP. MVR was measured in normal pigs with no coronary intervention and MVR determined at infusion flows 5, 25, 50 ml/min.

Coronary pressure waveforms at each flow showed both tonic and phasic components, due respectively from basal tonic microvascular state and cyclic intramyocardial compression. Mean resistances at each flow showed a direct linear relationship for pressure and flow. Total microvascular resistance varied strongly and linearly and inversely to infusion flow and derived pressure. Total change between 50 ml/min (MVR=1.12 mmHg/ml) and 5 ml/min (MVR=4.19 mmHg/ml) was a factor of 3.75. The pressure-resistance relationship showed a slope of .07 mmHg-min, a parameter measuring microvascular compliance

CONCLUSIONS

Real time absolute microvascular resistance is readily measured with controlled flow infusion. MVR is highly dependent on pressure, and shows a tight linear pressure-flow relationship. The observed inverse MVR-flow infusion relationship permits assessing microvascular compliance an entity likely to show strong dependence on pathologic conditions such as acute coronary syndromes, microvascular obstruction, and micro vasculopathies such as transplant micro arteriopathy. Microvascular dynamics in the cath lab may have application detecting microvascular obstruction and have clinical relevance to late prognosis. The method should be practical, efficient, and readily implemented in the cardiac catheterization laboratory.

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Effectiveness of over-the-wire balloon catheter for below-the-knee-CTO endovascular therapy - Single-centre experience and bench testing

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

AIMS

In penetrating BTK-CTO lesions with a 0.014 inch guidewire (GW), microcatheter support is generally utilized for obtaining backup force and GW controllability. In our hospital, we substitute a long over-the-wire (OTW) balloon catheter for a microcatheter. The tibial and peroneal artery are relatively straight, and the OTW balloon catheter provides further backup support compared to the microcatheter. The paper reported our result of ? long OTW balloon catheter supported GW crossing? for BTK-CTO and the bench testing of the GW tip load for phantom models.

METHODS AND RESULTS

1) From January 2013 to December 2015 (36 months), consecutive 204 de novo BTK-CTO vessels underwent EVT with our OTW balloon catheter strategy were assessed. The initial success was defined as the successful guidewire crossing antegradely. All patients had critical limb ischemia. The initial success rate was 79% and 85.8 % of the crossing GW was a floppy GW. This result might be adequate success rate as the antegrade approach.
2) As the bench testing, we investigated the tip load of the floppy and intermediate GW mounted in the microcatheter?prominent? or the long OTW balloon catheter?SHIDEN OTW 2.0/200?. The tip load of Chevalier floppy through the microcatheter and the OTW balloon catheter were 2.74 gf and 5.19 gf, respectively. The tip load of Athelete Rubby Hard through the microcathter and the OTW balloon catheter were 2.95 gf and 12.37 gf, respectively.

CONCLUSIONS

From the bench testing, the GW mounted in the long OTW balloon catheter provided a stronger buckup support and penetrating force compared to the microcatheter. Increased static friction with the long OTW balloon contributed to the feature. In our routine EVT, ?long OTW balloon catheter supported GW crossing? might be useful for BTK-CTO lesions.
The long OTW balloon catheter might be useful for guidewire crossing as a backup tool in the BTK-CTO lesions.

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Morbidity and mortality in a Brazilian cohort of subjects undergoing rotational atherectomy for extremely calcified lesions

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

AIMS

This study aims to evaluate the early and late incidence of complications of rotational atherectomy for complex and extremely calcified lesions with DES implantation.

METHODS AND RESULTS

A cohort of 138 subjects (71±10y, 63%male, BMI:26.9±4.6, creatinine clearance: 69.6±38.0mg/dl, LVEF: 59±14%), were followed after rotational atherectomy between 2012 - 2016. The most frequent risk factors observed were hypertension (87%), dyslipidemia (69%), diabetes (44%) and sedentary lifestyle (72%). 244 vessels were treated, of which 179 vessels with the aid of rotational atherectomy (burr size 1.75mm in 46% of the procedures, Relation burr size/vessel was 0.6:1). In all, 308 Everolimus eluting stents were implanted (2.28±2.0 stents/patient). Vessels stenosis: 86±11%, 42.6±23.8mm in extension, 63% presented multivessel disease, Average Syntax score data: 22.4±11.5, with 18% of individuals classified as high risk, 24% as intermediate risk and 58% as low risk, Arterial access: Femoral in 76.8% of cases, radial in 22.5% and ulnar in 0.7% of cases. 70% of the subjects performed rotational atherectomy in 1 vessel, 28% in 2 and 2% in 3 vessels. Lesion transposition was achieved in 99% of the cases, Angiographic success with stent implantation in 98% of vessels. The most common approach was performed in the left anterior descending artery (58% of cases). The hospital length of stay was 2.6±3.7days, and the late follow-up was performed by phone calls within four years of the procedure. In-hospital events were observed in 20 (14.4%) of the individuals. In-hospital major adverse cardiovascular events (MACE) were observed in 10 subjects (7.2%), with 6 deaths (in-hospital mortality: 4.3%). Minor events occurred in 10 subjects (7.2%). The following events were observed: Myocardial infarction 3 (2.1%), Large dissections 6/179 (3.4%) in vessels submitted to rotational atherectomy and adequately treated with stents, Arterial perforations (3/244), Peri-procedure stroke (1/138), Pneumonia (1/138), Rotawire fracture with buried tip between stent and vessel (1/138), Hematoma at the access site (3/138), Renal failure exacerbation (2/138), Burr entrapment (2/138). Regarding phone contact, 60% (83/138) of individuals or their families were successfully contacted. The late mortality rate within 4 years observed through phone was 14.5% (12/83 individuals), being renal failure the major cause of death 4/12 patients (33.3%). 97% of patients maintained regular use of DAPT. Only 42% reported regular exercise. Disconfort/ chest pain were reported by 13% of the individuals. The total mortality rate found in 4 years was 13% (18/138), including in-hospital and out-of-hospital late events.

CONCLUSIONS

Rotational atherectomy and DES in heavy calcified and long lesions presented a low occurrence of MACE in immediate and late follow up, leading to a high success rate of appropriate stent implantation (98%) in lesions that otherwise might not be feasible.

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TAVI in patients with elliptic aortic annulus: single-centre experience with two self-expandable aortic valves

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

AIMS

To assess the prevalence and the clinical correlates of an elliptic aortic annulus in patients undergoing transcatheter aortic valve implantation (TAVI) as well as to compare the performance of two self-expandable aortic valves (Portico and Evolut-R) with respect to significant paravalvular leak (PVL).

METHODS AND RESULTS

This retrospective study included 248 patients submitted to TAVI with Portico (64 patients) and Evolut-R (184 patients) aortic valves at Policlinico San Donato. At pre-procedural computed tomography (CT) angiography, the aortic annulus was defined elliptic if the index of eccentricity (IE) calculated as (1 - aortic annulus minimum diameter / maximum diameter) was >0.25. PVL was defined significant if > mild to moderate at post-procedural echocardiography.

Overall, an elliptic aortic annulus was found in 75 (30.2%) of 248 patients, predominantly in women (69.3% vs. 55.4%, P=0.038). Patients with an elliptic aortic annulus had a smaller perimeter (72.1±6.4 mm), area (383.6±96.0 mm2), and sinus of Valsalva (30.2±3.0 mm), compared to the non-elliptic group (respectively 74.6±6.5 mm, 432.1±92.9 mm2 and 31.3±3.6 mm, P=0.017, P

CONCLUSIONS

At CT-angiography, an elliptic aortic annulus was found in 30.2% of patients undergoing TAVI, it was frequently observed in women and was characterized by a small perimeter, area, and sinus of Valsalva. In these patients, implantation of a Portico aortic valve may be associated with fewer significant PVL, as compared to Evolut-R.

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Long-term clinical data and multimodality imaging analysis of the Biosolve-II study with the drug-eluting absorbable metal scaffold in the treatment of subjects with de novo lesions in native coronary arteries - Biosolve-II

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

AIMS

In order to assess the long term safety, clinical performance and bioabsorption process of the Sirolimus-Eluting Bioabsorbable Magnesium Scaffold (DREAMS 2G) 3-year clinical data and multi-modality imaging outcomes up to 3-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 Intravascular ultrasound and optical coherence tomography assessments 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, 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

Multi-modality imaging and clinical outcomes of the second-generation device DREAMS 2G until 12 months have been presented in previously published papers. The late lumen loss remained stable between 6 and 12-month (paired data on 42 subjects) with an in-segment late lumen loss of 0.20±0.21 mm versus 0.25±0.22 mm, p=0.117 and in-scaffold late lumen loss of 0.37±0.25 mm versus 0.39±0.27 mm, p=0.446, respectively. Intravascular ultrasound (IVUS) and optical coherence tomography (OCT) findings corroborated the quantitative coronary angiography results. Paired IVUS parameters did not differ significantly between 6 and 12-month with a median minimum lumen area of 4.0mm2 vs 4.69mm2, p = 0.700. Neointimal hyperplasia area remained low with 0.05 mm2 vs 0.13 mm2, p=0.240 respectively. No intraluminal masses were observed by OCT until 12-month follow-up.
A vasomotion of ? 3% change in mean lumen diameter (after administration of acetylcholine or nitroglycerine) for 80% (20/25) of the subjects at 6-month with no further change at the 12-month follow-up.

The target lesion failure (TLF) rate at 36-month remained low with 7.0% and is comparable to second

generation DES. The TLF rate includes 5 clinically driven target lesion revascularizations (TLR), 1 peri-procedural MI and 2 cardiac deaths. Only 1 TLR occurred after the 12 months follow-up. This is a patient where the DREAMS 2G was implanted overlapping a previously implanted DES. The restenosis occurred at the distal edge of the implanted scaffold, in the overlapping area. No definite or probable scaffold thrombosis was observed up to 36-month. All clinical events are adjudicated by an independent clinical event committee.

CONCLUSIONS

The 36-months safety and clinical performance results of the DREAMS 2G are encouraging and remain without any definite or probable scaffold thrombosis. The long term multi-modality imaging data will be available upon presentation

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Sex-related differences in clinical presentation and outcome after transcatheter aortic valve implantation for severe aortic stenosis: insights from the randomised REPRISE III trial

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

AIMS

We sought to examine sex differences in clinical presentation and 1-year outcomes in patients treated with a retrievable and repositionable mechanically-expandable valve (MEV) as part of a randomised trial comparing 2 different valves.

METHODS AND RESULTS

REPRISE III was a randomised, multicentre trial comparing MEV to a self-expanding valve (SEV) in patients with severe aortic stenosis at high or extreme risk for surgery. A total of 912 patients were randomised 2:1 (607 MEV: 305 SEV). Enrolled patients were required to have a Society of Thoracic Surgeons (STS) risk of mortality score ?8% or another indicator of high or extreme risk (based on Heart Team assessment), 51% were female. Men were 82 years of age, on average, with an STS score of 5.7±3.4, women were 83 years of age with an STS score of 7.9±4.4 (age P=0.39, STS score P<0.01).

In the MEV arm, compared to men, women were significantly more likely to have a slower gait speed and be classified as New York Heart Association (NYHA) class III or IV. In contrast, women in the MEV arm were less likely to have a history of hyperlipidaemia, coronary artery disease, myocardial infarction, PCI, or CABG. Aortic valve annulus and left ventricular outflow tract size were smaller in women than men, the mean aortic valve gradient was higher in women than men. Women received significantly more small valves (56.9% women vs 5.1% men, 23 mm MEV) and men received significantly more large valves (10.3% women vs 57.1% men, 27 mm MEV).

At 1 year, there were no significant differences in all-cause mortality (men 10.8% vs women 12.2%, P=0.58), stroke (6.6% vs 8.3%, P=0.45), new permanent pacemaker implantation (35.4% vs 34.9%, P=90) or myocardial infarction (3.8% vs 3.2%, P=0.71). Life-threatening or disabling bleeding occurred significantly more often in women than men (6.6% vs 12.2%, P=0.02). Other Valve Academic Research Consortium (VARC) endpoints in the MEV cohort were not significantly different between the sexes. The rates of moderate or greater paravalvular leak at 1 year were not significantly different between men and women (0.4% vs 0.9%, P=0.60). Effective orifice area was smaller in women (1.37±0.40) than men at 1 year (1.60±0.46, P<0.01), mean aortic valve gradient remained higher at 1 year in women compared to men (11.18±4.47 vs 13.58±6.84,

P<0.01). At 1 year, 9.9% of men and 9.4% of women were in the NYHA class III or IV classification (P=0.12).

Similar baseline differences were found between men and women treated with SEV, although aortic valve area and mean pressure gradient were not significantly different at baseline. No significant differences in 1-year VARC endpoints were found in men and women treated with SEV, however, moderate or greater PVL was significantly lower in women at 1 year (men 11.3% vs women 2.7%, P=0.01). More women (38%) than men (24%) had an improvement of ?2 NYHA classes from baseline to 1 year (P=0.03).

CONCLUSIONS

Despite significant differences in baseline characteristics, valve size/hemodynamics and higher predicted risk of mortality in women, the 1-year rates of death and stroke were not significantly different between men and women treated with MEV, however, life-threatening/disabling bleeding was higher in women. Both women and men treated with MEV had substantial improvements in symptoms. No differences in VARC endpoints were observed in the SEV cohort though moderate or greater PVL was less common in women treated with SEV compared to men.

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Validation of novel three-dimensional quantitative coronary angiography based software to calculate vessel FFR: the FAST study

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

AIMS

FFR assessment requires the use of a costly pressure wire in combination with the administration of a hyperemic agent, which may contribute to the low adoption rate of FFR in clinical practice. The aim of our study was to validate novel software to calculate FFR based on 3D-QCA (vessel FFR) and to assess inter-observer variability in patients who underwent routine pre procedural FFR assessment for intermediate coronary artery stenosis.

METHODS AND RESULTS

Observational, prospective, single-center cohort study. One hundred patients presenting with stable angina or non ST segment elevation acute coronary syndrome, referred for coronary angiography with or without percutaneous coronary intervention (PCI) and an indication to perform FFR between Oct 2016 and June 2017 were included. FFR measurements were performed using the pressure wire based system (St. Jude Aeris, Abbott Vasuclar, St Paul, MA). Two orthogonal angiographic projections were acquired to create a 3-D coronary artery reconstruction of the coronary artery using the CAAS workstation software (Version 8.0, Pie Medical Imaging, Maastricht, The Netherlands). vFFR was subsequently calculated using the aortic root pressure.

Mean age was 64±11 years and 67% were males. Mean FFR and vFFR were 0.82±0.08 and 0.84±0.07 respectively. A good linear correlation was found between FFR and vFFR (r = 0.89,

CONCLUSIONS

vFFR based on 3D-QCA as determined using novel software has a high linear correlation to invasively measured FFR, a high diagnostic accuracy to detect FFR

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Initial experience of a self-expanding transcatheter heart valve with an external tissue wrap: the UK and Ireland Implanters? registry

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

AIMS

The UK and Ireland Implanters? registry is a multicentre registry which reports on real-world experience with new transcatheter heart valves. The Medtronic Evolut PRO valve is a self-expanding, repositionable and fully-recapturable transcatheter heart valve with an external pericardial tissue wrap, designed to reduce rates of paravalvular regurgitation. Real-world clinical, procedural and outcome data have not been reported with this transcatheter heart valve.

METHODS AND RESULTS

Clinical, procedural and outcome data for the Evolut PRO valve was prospectively collected from multiple implanting centres. A total of 44 consecutive Evolut PRO implantations were performed across four centres. Mean age was 81.0 ± 6.4 years. Mean logistic EuroSCORE was 21.6 ± 14.9%. Aortic stenosis was the dominant aortic valvular pathology in 98% and aortic regurgitation in 2%. Two valve-in-valve procedures were performed for a failed surgical and transcatheter heart valve. Mean aortic annulus diameter ranged from 20.1 to 25.8mm. Conscious sedation or local anaesthesia was used in 82% of cases. Femoral access route was used in 98% and subclavian access in the remainder. The mean minimum iliofemoral diameter on the TAVI access side was 6.6 ± 1.2mm. In 98% of transfemoral cases the system was inserted using the 16F EnVeo R InLine sheath, without the need for an outer delivery sheath. Balloon pre-dilatation was performed in 39%. The valve was at least partially recaptured in 27% and fully recaptured in 21%. Mean implant depth was 4.6 ± 2.2mm. Balloon post-dilatation was performed in 27%. The valve was successfully deployed in all cases with no requirement for a second transcatheter heart valve. Post-procedure mean valve gradient was 6.7 ± 4.2 mmHg and effective orifice area 2.1 ± 0.4cm2. Moderate paravalvular regurgitation occurred in 2% but there were no cases of severe paravalvular regurgitation. Permanent pacemaker insertion was performed in 14% of patients. Thirty-day mortality was 0%, stroke 9% and major vascular complication 2%.

CONCLUSIONS

This registry presents a large real-world experience of the Evolut PRO valve. Paravalvular regurgitation rates are lower when compared with previous studies of the Evolut R valve.

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Leaflet sealing with self-expanding transcatheter heart valve prostheses

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

AIMS

Despite advances with current-generation transcatheter heart valves, paravalvular regurgitation remains an important complication of TAVI. The role that the native aortic valve leaflets play in sealing the transcatheter heart valve prosthesis has not been previously described. We hypothesised that the relationship between the sinotubular junction and the transcatheter heart valve prosthesis would be a strong predictor for the occurrence of paravalvular regurgitation.

METHODS AND RESULTS

All patients who had undergone TAVI with a self-expanding transcatheter heart valve prosthesis and had received pre-procedural CT scanning were included in this single-centre retrospective study. CT scans were analysed and the dimensions of the aortic annulus were used to calculate the cover index [100 x (prosthesis diameter ? aortic annulus diameter) / prosthesis diameter]. Values <0% indicate that the prosthesis diameter is smaller than the aortic annulus diameter. The dimensions of the sinotubular junction were used to calculate a new metric, the sealing index [100 x (prosthesis diameter - sinotubular junction diameter) / prosthesis diameter)]. Values <0% indicate that the prosthesis diameter is smaller than the sinotubular junction diameter. Calcium volume was recorded. The primary outcome was the occurrence of more than mild paravalvular regurgitation on either procedural angiography, transoesophageal or transthoracic echocardiography. The primary outcome was assessed using the area under the curve (AUC) of a receiver operator characteristic curve with a value <0.7 indicating no discriminative power, 0.7-0.8 considered acceptable, 0.8-0.9 considered excellent and >0.9 considered outstanding.

A total of 212 patients were included in the study, including 16 patients (8%) with bicuspid aortic valve morphology. A CoreValve prosthesis was implanted in 67 patients (32%) and an Evolut R prosthesis in 145 patients (68%). The primary outcome occurred in 22 patients (10%). A low sealing index was an excellent predictor for the occurrence of paravalvular regurgitation (AUC 0.87) and was a stronger predictor for the occurrence of paravalvular regurgitation than a low cover index (AUC 0.72) or a high calcium volume (AUC 0.76). A sealing index of <0% was 86% sensitive and 72% specific for predicting the occurrence of paravalvular regurgitation, representing a 26% positive predictive value and a 98% negative predictive value. The sealing index was an excellent predictor for the occurrence of paravalvular regurgitation in both patients with bicuspid (AUC 0.87) and tricuspid (AUC 0.85) aortic valve morphology. The sealing index was an excellent predictor for the occurrence of paravalvular regurgitation with both CoreValve (AUC 0.83) and Evolut R (AUC 0.88) prostheses.

CONCLUSIONS

In patients undergoing TAVI with self-expanding transcatheter heart valve prostheses, a low sealing index is an excellent predictor for the occurrence of paravalvular regurgitation. For patients in the borderline zone of transcatheter heart valve sizing algorithms, the sinotubular junction diameter could be used as an additional

metric to guide valve sizing.

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Prognostic factors for one-month mortality of AMI complicated by cardiogenic shock or cardiac arrest treated with ECMO therapy

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

AIMS

The purpose of this study was to identify the prognostic factors for patients given extracorporeal membrane oxygenation (ECMO) therapy for acute myocardial infarction (AMI) combined with cardiogenic shock or cardiac arrest.

METHODS AND RESULTS

Between January 2006 and December 2016, 3047 patients received coronary angiography for AMI, and 108 of these patients received ECMO therapy for AMI with cardiogenic shock or cardiac arrest. Comparison of survivors and non-survivors indicated the older age (60.5 ± 10.3 vs. 69.4 ± 11.9 years, P

CONCLUSIONS

Early initiation of ECMO before cardiac arrest was an independently associated with improved 1-month mortality and complete revascularization in multivessel disease were also provided better clinical outcome. Elevated levels of biomarkers which reflecting organ ischemia were significantly associated with poor clinical outcomes in patients who received ECMO therapy for AMI with cardiogenic shock.

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The index of microcirculatory resistance as a tool to characterise microvascular obstruction and to predict infarct size regression in patients with STEMI undergoing primary PCI

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

The index of microcirculatory resistance (IMR) can identify patients with microvascular dysfunction acutely after primary percutaneous coronary intervention (pPCI) and a threshold of >40 has been shown to be associated with an adverse outcome. Even though IMR and microvascular obstruction (MVO) on cardiac magnetic resonance (cMRI) reflect coronary microvascular status, the interaction between these two parameters is uncertain.

We aimed to compare the value of IMR and MVO in patients treated and recovering from ST elevation myocardial infarction (STEMI).

METHODS AND RESULTS

One hundred and ten patients treated with pPCI were included and IMR was measured immediately at completion of pPCI. Infarct size (IS) as a percentage of left ventricle mass was quantified at 48 hours (38.4±12.0hours) and 6 months (194.0 ± 20.0 days) using cMRI. MVO was identified and quantified at 48 hours by cMRI.

Overall, a discordance between IMR and MVO was observed in 36.7% of cases, with 31 patients having MVO and IMR?40.In patients with both MVO and IMR>40 there was a 11.9 fold risk of final IS>25% at six months (p= 0.001). Compared with patients with MVO and IMR>40, patients with MVO and IMR?40 had a significantly smaller IS at six months (p= 0.001) with significant regression in IS over time (34.4% (27.3 ? 41.0) vs 22.3% (16.0 ? 30.0), p= 0.001).

CONCLUSIONS

Discordant prognostic information was obtained from IMR and MVO in nearly one third of cases. However, IMR can be helpful in grading the degree and severity of MVO, with IMR ?40 being a potential marker of myocardial viability and ultimate myocardial recovery even in the presence of MVO.

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A comparison of the stent crossability: An in vitro performance test using diffuse calcified vessel models.

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

AIMS

The crossability of stents is one of the important factors for successful coronary interventions in the case of diffuse calcified lesions, especially with bending calcified lesions. However, there are few reports evaluated the crossability of stents.

METHODS AND RESULTS

METHODS

We made a diffuse calcified vessel model consisting of silicon tube with a combination of hard glass rings and silicon rings inside. We examined the maximum crossing forces of the 4 different commercially available drug-eluting stents (DES, all n = 6, XIENCE Alpine, Resolute Onyx, Orsiro, and SYNERGY) by using the vessel model with 3 conditions: straight and two different bending angles (45 and 90 degrees). All stents were 3.0 mm diameter with a length of 15 or 16 mm.

RESULTS

In all types of bending conditions, XIENCE Alpine needed the highest maximum crossing forces among the 4 types of DES. In the straight and 45 degrees conditions, there were no differences of maximum crossing forces in the 4 types of DES except for XIENCE Alpine. In the 90 degrees condition, SYNERGY needed the lowest maximum crossing force (2.89 N), followed by Orsiro (3.61 N), Resolute Onyx (5.02 N) and XIENCE Alpine (7.43 N). Significant differences were evident between SYNERGY vs. Orsiro, Resolute Onyx and XIENCE Alpine ($p = 0.0079$, $p < 0.0001$, $p < 0.0001$, respectively).

CONCLUSIONS

This experimental study shows that there are differences of the stent crossability among contemporary DESs. SYNERGY may be the most appropriate for calcified lesions. The selection of an appropriate stent is important to obtain a satisfactory result especially in diffuse calcified lesions.

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Long-term durability and hemodynamic performance of a self-expanding transcatheter heart valve beyond five years after implantation: a prospective observational study applying the standardised definitions of structural deterioration and valve failure

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

AIMS

Long-term results of transcatheter aortic valve implantation (TAVI), in particular the incidence of bioprosthetic valve failure (BVF), are uncertain. Using data from a prospective registry with a structured follow-up after TAVR, we assessed the long-term performance and the incidence of BVF of the self-expanding CoreValve? beyond 5 years after implantation.

METHODS AND RESULTS

The study prospectively included all 152 patients who had undergone TAVI with the self-expanding CoreValve? up to December 2011 at the Heart Center, Bad Segeberg, Germany. Late BVF (>30 days) was defined as either: 1) Severe structural valve deterioration (trans-prosthetic mean pressure gradient ?40?mmHg and/or ? 20?mmHg rise from baseline OR severe intra-prosthetic aortic regurgitation), OR 2) Bioprosthetic valve dysfunction leading to death or re-intervention. Echocardiographic follow up at 6.3±1.0 years (range: 5.0 ? 8.9 years) was 88% complete (60 out of 68 survivors beyond 5 years) and all echocardiograms were analyzed by an independent core laboratory.

All-cause mortality rate at 1, 2, 5, 6, 7 and 8 years was 14%, 20%, 50%, 60%, 65%, and 73%, respectively. Among survivors beyond 5 years, effective orifice area was 1.60±0.46 cm2, and transvalvular mean pressure gradient was 6.7±3.1 mmHg, and no cases showed evidence of structural valve deterioration. Five patients (3.3%) had undergone redo TAVI (n=4) or surgery (n=1) 0.6 to 5.2 years after the index procedure, all due to paravalvular leakage. The estimated rate of BVF at 8 years was 7.9% for the actuarial and 4.5% for the actual analysis.

CONCLUSIONS

Long-term follow-up up to 8.9 years after TAVI documents favorable performance of the self-expanding CoreValve? with low rates of BVF.

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Prosthesis-patient mismatch after TAVI with self-expanding and balloon-expandable prostheses: impact of the change in prosthesis iteration and sizing practice

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

AIMS

The vast majority of data on prosthesis-patient mismatch (PPM) after transcatheter aortic valve implantation (TAVI) is derived from studies of the first and second generation transcatheter heart valves (THVs). We sought to investigate: 1) the impact of the introduction of the next generation self-expanding (SE) and balloon-expendable (BE) THVs on the incidence of PPM, and 2) the predictors of PPM after TAVI with the next generation THVs.

METHODS AND RESULTS

The study included all patients who received TAVR for native aortic valve stenosis in 1) the randomized CHOICE trial, in which patients were randomized to receive the second generation SE-THV (CoreValve, Medtronic, Minneapolis, Minnesota, n=120) or the second generation BE-THV (Sapien XT, Edwards Lifesciences, Irvine, California, n=121) between March 2012 and December 2013, and 2) the prospective CHOICE-Extend registry including patients treated with the third generation SE-THV (Medtronic Evolut R, n= 100) or the third generation BE-THV (Edwards Sapien 3, n=334) between March 2014 and November 2017. Based on 30-day effective orifice area of the THV indexed to the body surface area (EOAi), PPM was classified into clinically non-significant (EOAi >0.85 cm2/m2), moderate (0.66 - 0.85 cm2/m2), or severe (?0.65 cm2/m2).

The % THV diameter oversizing was 15.2±7.7% with the second generation THVs (CoreValve vs. Sapien-XT: 19.1±6.4 vs. 11.4±7.0, p<0.001), and 7.2±8.3% with the third generation THVs (Evolut R vs. Sapien 3: 18.8±4.8 vs. 3.7±5.5, p<0.001).

The incidence of any (moderate or severe) and severe PPM was 15.1% and 0.0% after TAVR with the second generation THVs (CoreValve and Sapien XT), and 43.1% and 11.5% with the third generation THVs (Evolut R and Sapien 3).

Comparing Sapien 3 vs. Evolut R, the EOAi was 0.85±0.22 cm2/m2 vs. 1.06±0.31 cm2/m2 (p<0.001) and the incidence of any and severe PPM was 47.2% vs. 26.9% (p=0.001) and 15.4% vs. 2.6% (p=0.001), respectively. In Sapien 3, severe PPM was less in patients in whom the THV was oversized (10.4%) than in patients in whom the THV diameter was equal to or smaller than the annulus diameter (22.1%, p=0.015).

Predictors of any PPM after TAVR with the third generation THVs were previous myocardial infarction, lower left ventricular ejection fraction, small aortic valve annulus (?23 mm), and THV %oversizing, irrespective of the THV type. The only independent predictor of severe PPM was THV %oversizing (OR=0.942 [95% CI: 0.915 ? 0.969], p<0.001).

CONCLUSIONS

We observed a considerable increase in the incidence of PPM in contemporary TAVI with the next generation THVs, especially with the Sapien 3 prosthesis. Among other factors, less THV oversizing appears to be an important ?and avoidable? risk factor for PPM.

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Quantitative flow ratio identifies non-culprit coronary lesions requiring revascularisation in patients with STEMI and multivessel disease

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

The non-culprit lesion (NCL) management in ST-segment elevation myocardial infarction (STEMI) patients with multivessel disease is debated. We sought to assess if quantitative flow ratio (QFR), a non-invasive tool to identify potentially flow limiting lesions, may be reliable in this scenario.

METHODS AND RESULTS

The present proof-of-concept study is based on a 3-step process: i) identification of the QFR reproducibility in NCLs assessment (cohort A, n=31), ii) prospective validation of QFR diagnostic accuracy in respect to fractional flow reserve (FFR) (cohort B, n=45), iii) investigation of long-term clinical outcomes of NCLs stratified according to QFR (cohort C, n=110). A blinded core-lab computed QFR values for all NCLs. Cohort A showed a good correlation and agreement between QFR values at index (acute) and at staged (subacute, 3-4 days later) procedures (r=0.98, 95%CI 0.96-0.99, mean difference 0.004 [-0.027-0.34]). The inter-rater agreement was k=0.9. In cohort B, FFR and QFR identified 16 (33%) and 17 (35%) NCLs potentially flow limiting. Sensitivity, specificity, negative and positive predictive values were 88%, 97%, 94% and 94%. The area under the ROC curve was 0.96 (95% CI 0.89-0.99). Finally, in cohort C we identified 110 STEMI patients where at least one NCL was left untreated. Patients with NCLs showing a QFR value ?0.80 were at higher risk of adverse events (HR 2.3, 95%CI 1.2-4.5, p=0.01).

CONCLUSIONS

In a limited and selected study population, our study showed that QFR computation may be a safe and reliable tool to guide coronary revascularization of NCLs in STEMI patients.

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Which DES is the most appropriate for calcified lesion? Insights from experimental study

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

AIMS

Stent luminal conformability is important for sufficiently crimping of the stent on the vessel wall with calcification. There were no reports of the luminal conformability of contemporary drug-eluting stent (DES) for calcified lesion. Our purpose of this study was to evaluate the luminal conformability of DES with specific mechanical bench test using metal pipe as a calcified lesion of the vessel wall.

METHODS AND RESULTS

We studied 4 different DES platforms: Synergy, Ultimaster, Xience Alpine and Resolute integrity. We examined 5 pieces in each kind of DES at nominal pressure and at rated burst pressure in a metal pipe with a hole in the center. We measured the height and the cross-sectional area of the stent protruding from hole in the metal pipe and compared them between each stent. At nominal pressure, there was no significant difference between each stent for the protrusion length and the cross-sectional area. At rated burst pressure, both the protrusion length and the cross-sectional area were the highest and largest in Resolute integrity, followed by Synergy, Ultimaster, Xience Alpine. Resolute integrity was significantly higher in the protrusion length (0.26±0.02mm vs 0.17±0.02 mm, P=0.0051) and was larger in the cross-sectional area (0.39±0.06 mm2 vs 0.21±0.06 mm2, P=0.0104) than Xience Alpine.

CONCLUSIONS

This experimental study shows that there is the difference in stent luminal conformability at high pressure between contemporary DESs. Resolute may be the most appropriate for calcified lesions.

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Correlation of FFR and Pd/Pa with resting diastolic pressure ratio calculated by a novel algorithm: the dPR-study

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

AIMS

Instantaneous wave free ratio (iFR) offers a reliable non-hyperemic assessment of coronary physiology but requires dedicated specialized software with a fully automated algorithm. We hypothesized that a diastolic pressure ratio (dPR) calculated using different software, applicable to any type of pressure wire or catheter, might have similar diagnostic accuracy as compared to FFR and resting Pd/Pa as iFR.

METHODS AND RESULTS

An observational, prospective, single-center cohort study including patients who underwent FFR using either a pressure wire (FFRPW) or microcatheter (FFRMC). Dedicated software was used to calculate the dPR from DICOM pressure waveforms. The ?flat? period on the Dp/Dt signal was used to detect the dPR in 5 consecutive heartbeats. Measurements were performed by 3 independent operators to assess inter-observer variability.

One hundred patients who underwent either FFRPW (n=50) or FFRMC (n=50) were included. Mean age was 66±11 years and 80% was male. No significant differences were found in baseline characteristics between the FFRPW and FFRMC groups. Mean FFR, resting Pd/Pa and dPR were 0.85±0.09, 0.94±0.05 and 0.93±0.07 respectively. There was a significant linear correlation between dPR and FFR and between dPR and resting Pd/Pa (R = 0.78,

CONCLUSIONS

dPR, calculated by a novel software tool, correlated well with Pd/Pa and FFR with a better diagnostic accuracy as compared to Pd/Pa and a low inter-observer variability.

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Laser doppler assessment of the limb before and after below-the-knee angioplasty in critical limb ischaemia

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

AIMS

Laser Doppler (LD) measurement is a non-invasive, direct tool to assess microcirculation providing data regarding flow reserve capacity, viability of the assessed tissue and wound healing potential. The measurement is completed by the transcutaneous oximetry (tcpO2) method which gives information about local oxygenisation.

The aim of the study was to investigate microcirculation (LD and tcpO2) in critical limb ischemic (CLI) patients before and after below-the-knee (BTK) angioplasty and to follow up outcome regarding wound healing, amputation and death.

METHODS AND RESULTS

We enrolled 39 CLI patients in a prospective study referred for BTK intervention. We used a commercially available laser Doppler system (PeriFlux system 5000, Perimed, Stockholm). LD perfusion and tcpO2 were measured at rest and during stress (heat and 100% O2 challenge). We analysed the percentage change between rest and stress conditions. The measurements were performed prior and within four days after BTK angioplasty and at 3 and 12 months follow up.

The male/female ratio was 30/9, the average age was 68.3 years. 11 patients suffered from rest pain and 28 patients had ulcer/gangrene. By the 12 months follow up 10 patients had a major event (amputation and/or death), wound healing was complete in 11 patients and 7 patients had permanent wounds. Patients with rest pain (n=11) became all symptomless after BTK intervention.

Patients suffering a major event compared to patients with ulcer had significantly lower LD% change prior and after intervention and baseline tcpO2 results prior to intervention. Regarding patients with proper wound healing LD% change was significantly higher after intervention than prior to intervention compared to patients with no melioration. When compared the cases with convalescence to the rest part of the cohort the LD% change was significantly higher prior to intervention, after intervention and during 3 and 12 months follow up.

By the 36 months follow up 15 patients suffered a major adverse event (9 deaths, 3 major amputations, 1 stroke, 2 myocardial infarctions) and 12 patients were symptomatic again (2 gangrene, 10 rest pain).

CONCLUSIONS

LD and tcpO2 measurements are important methods to investigate microcirculation in patients with CLI and could be useful tools to predict the individual prognosis of patients with CLI. As CLI enrolles patients in the very high cardiovascular risk category of its own, accurate follow up is mandatory in order to save more limbs and lives.

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Incidence and predictors of micro-dislodgement during TAVI and its impact on peri-interventional results

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

AIMS

Aims

Precise positioning of the prosthesis is a crucial step of the transcatheter aortic valve implantation (TAVI) procedures. During the final release of self-expanding prosthesis, micro-dislodgement is observed in some cases. We aimed to quantify the incidence of micro-dislodgement with the Medtronic CoreValve Evolut R prosthesis and to evaluate its impact on peri-procedural outcome. Furthermore, we aimed to identify risk factors for the occurrence of micro-dislodgement.

METHODS AND RESULTS

Methods and Results

We retrospectively analyzed 304 consecutive patients who underwent transfemoral TAVI with the Medtronic CoreValve Evolut R prosthesis. Micro-dislodgement was defined as movement of the prosthesis of at least 1.5 mm from its position directly before the final release in comparison to the final position after release. Patients were grouped according to the occurrence (+MD) or absence (-MD) of micro-dislodgement. Pre-procedural data concerning demographic characteristics, imaging data and peri-procedural parameters according Valve Academic Research Consortium (VARC) II were analyzed.

Micro-dislodgement was observed in 28.9% of the patients (n=88). Mean implantation depth projected towards the non-coronary cusp was 6.4±3.5mm in the +MD group and 5.2±2.5mm in the -MD group (p=0.005). Mean implantation depth projected towards the left-coronary cusp was 7.2±3.3 mm in the +MD group and 6.4±3.4mm in the -MD group (p=0.025).

Concerning patient characteristics there were no significant differences between both groups. We looked at 31 pre-procedural imaging parameters. An asymmetric aortic valve calcification was found in 59.6% of the +MD group and 47.6% in the ?MD group (p=0.2). (In patients with micro-dislodgement, the right coronary cusp was more often heavily calcified (25.5% vs. 10.5%, p=0.02).

Looking at peri-procedural parameters, none ore ?trace? paravalvular leackage occurred in 89.1% of the patients in the +MD group and 92.3% of the patients without micro-movement (p=0.437). A mild paravalvular leackage was found in 9.4% in de +MD group and 7.7% in the ?MD group (p=0.8). There were no differences between the groups with regard to need for permanent pacemaker (18.2% in the +MD group vs. 11.2% in ?MD group, p=0.1), vascular complications (34.1% in the +MD group vs. 27.6% in -MD group, p=0.259), bleeding complications (25% in the +MD group vs. 21% in the ?MD group, p=0.450) or incidence of acute kidney injury (3.4% in the +MD group vs. 0.5% in the ?MD group, p=0.08).

CONCLUSIONS

Conclusion

Micro-dislodgement occurs in nearly one third of the patients undergoing transfemoral TAVI with the Medtronic CoreValve Evolut R prosthesis. A heavily calcified right coronary cusp seems to be an anatomical risk factor. Micro-dislodgement does not negatively affect the peri-procedural outcome.

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Predictors of irreversible reduction of left ventricular ejection fraction after STEMI: a cardiac magnetic resonance substudy from DANAMI-3 programme

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Irreversible reduction of LVEF is an important prognostic factor after STEMI and has implications regarding prophylactic ICD implantation. However, decision of ICD implantation is taken only after approximately 90 days at which time the infarct is considered fully developed. Since low LVEF patients may suffer ventricular fibrilation during this period, it would be desirable to predict which patients will have irreversible reduction in LVEF.

METHODS AND RESULTS

This is a sub-study from DANAMI-3 program, which enrolled 2300 patients admitted with STEMI. In this post-hoc sub-study 649 patients were included in whom TTE and cardiac MRI were performed during admission and cardiac MRI after 3 months.

Patients were divided into 2 groups: group 1 with LVEF?35% after 3 months using MRI (15 patients (2.3%)), and group 2 with LVEF>35% (634 patients).

Using univariate analysis, the following factors were predictors of LVEF?35% after 3 months: Killip class >1 on admission, anterior ST-elevation on the ECG, TIMI flow 0 before PCI, CKMB level increase, LVEF?35% on TTE during admission, and all the tested parameters on MRI during admission including LVEF and infarct size percent.

On multi-variate analysis, Killip class >1 (OR 7.39, CI:1.47-36.21, P 0.01), symptoms to intervention > 6 hours (OR 7.19, CI 1.07-50.91, P 0.04), LVEF ?35% on TTE (OR 7.11, CI: 1.27-47.43, P 0.03), and infarct size ?40% of left ventricle on index MRI (OR 42.62, CI:7.83-328.29, P 1+ LVEF?35% on TTE+ infarct size ?40% of LV.

CONCLUSIONS

Irreversible damage to the myocardium and reduction in LVEF can be predicted in a subgroup of STEMI patients, where implantation of prophylactic ICD should be considered already during the admission.

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Comparison of stent apposition after kissing balloon inflation between left main and non-left main bifurcation in the 3D-OCT bifurcation registry

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THEME: Coronary Interventions

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

AIMS

To achieve the distal rewiring and favorable stent positioning against side branch (SB) ostium by three-dimensional reconstruction of optical coherence tomography (3D-OCT) lead to a reduction of incomplete stent apposition (ISA) at the bifurcation segment after main-vessel stenting with kissing balloon inflation (KBI). However, it is unclear that the optimal rewiring provides the same results in left main (LM) bifurcation lesions in compare with non-LM bifurcation lesions. We aimed to investigate the difference of ISA after main-vessel stenting with KBI using 3D-OCT between LM and non-LM.

METHODS AND RESULTS

The 3D-OCT bifurcation registry is a multicenter prospective registry that enrolled patients who underwent percutaneous coronary intervention (PCI) for de-novo bifurcation lesions with SB having a diameter of at least 2 mm under OCT guidance in 10 participating centers in Japan. From this registry, 105 bifurcation lesions treated with main-vessel stenting with kissing balloon inflation were analyzed. Stent-link location and rewiring position were assessed by 3D-OCT in the OCT pullback obtained after stent deployment crossing over SB. The optimal rewiring was defined as following, guide wire passed through the distal large cell without stent-link. The optimal rewiring was achieved in 55 cases (52.3%). These cases were divided into 2 groups by LM bifurcation group (n=21) and non-LM bifurcation group (n=34). We compared the incidence of ISA between the two groups. Separation of even one stent strut from the vessel wall was considered incomplete strut apposition (ISA), defined as a distance between the strut marker and the lumen contour greater than the specific strut thickness plus the axial resolution of the OCT (14 μm). In this study, all non-apposed SB struts were considered ISA. Strut apposition was assessed at four segments: the proximal main vessel segment (extending 5 mm proximal to the first cross-section where the side branch was visible), two sides of the bifurcation (divided into two 180° halves toward or opposite the origin of the side branch), and the distal main vessel segment (extending 5-mm from the last cross-section in which the side branch was visible).

There was no significant difference in procedural and lesion characteristics between 2 groups, except with stent size (p=0.023), vessel size (p=0.008), and bifurcation angle between distal main vessel and side branch (p=0.016). The incidence [%, median and inter quartile range (IQR)] of ISA in LM bifurcation group was significantly higher than that of non-LM bifurcation group [9.6 (2.2-14.1) vs 3.9 (1.2-8.1), p=0.032]. There was no significant difference in the incidence of ISA at toward the origin of the SB [5.2 (1.7-11.6) vs 3.0 (0.8-7.1), p=0.170]. However, the incidence of ISA at opposite the origin of the SB was significant higher than that of non-LM bifurcation group [1.1 (0.0-3.4) vs 0.0 (0.0-0.0), p=0.001].

CONCLUSIONS

Even with the achieving the optimal distal rewiring by 3D-OCT, stent malapposition and residual jailed struts at the bifurcation segment remained at LM bifurcation. Morphological differences (large vessel size and bifurcation angle) between LM and non-LM might potentially affect the stent apposition at the bifurcation segment after KBI.

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EUROTA registry: preliminary results of the first 523 patients treated by rotational atherectomy in eight European countries

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

AIMS

To evaluate clinical and safety endpoints with use of rotational atherectomy (RA) in a large patient population with moderate to severely calcified lesions undergoing percutaneous coronary intervention (PCI).
Coronary artery calcification (CAC) has been recognized as a risk factor for adverse outcomes in coronary artery disease and represents a very challenging scenario PCI. Interventional cardiologists have learned how best to apply RA through better patient and lesion selection. Analysis of clinical and safety endpoints forms the basis of our European multicenter registry.

METHODS AND RESULTS

From January to November 2017, we studied the first consecutive 523 patients with severe calcifications treated with RA. We assessed clinical outcomes including death, myocardial infarction (MI), and target lesion revascularization (TLR) at 30 days and one year in addition to post-procedural complications. The mean age was 71.8 ± 9.9 years. The majority of patients presented with stable angina and silent ischemia (62.4%).
The procedural success rate for lesions treated by RA was 97.8 % and the per-procedure complications observed were as follows : mortality (0.7 %), MI (1.3 %) and coronary artery dissection (5 %). In-hospital complications included cardiac death (1.3 %), MI (2.8 %) and stroke (0.4 %).
One-month clinical follow-up was performed in 407 patients with global cardiac death of 3.3%, MI of 3.3% and stroke of 0.5%.

CONCLUSIONS

RA is a safe and effective strategy to treat patients with severe CAC. The EUROTA registry is ongoing and the procedural and clinical follow-up data of more than 1000 patients will be presented at EuroPCR in May 2018.

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3D bifurcation aspect of side branch angle related to the unopposed struts after kissing balloon dilatation ? insights from 3D OCT bifurcation registry

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

Bifurcation angle (BA) relates to the incidence of unopposed struts at bifurcation after kissing balloon dilatation (KBD). However, measurements of BA in quantitative coronary angiography (QCA) require the dedicated software. Recently, on-line 3D optical coherence tomography (OCT) can visualize 3D aspect of bifurcation during coronary intervention. We aimed to investigate whether 3D bifurcation aspect relate to the incidence of unopposed struts at bifurcation after KBD.

METHODS AND RESULTS

The 3D OCT bifurcation registry is a multicenter prospective registry that enrolled patients who underwent PCI for de-novo bifurcation lesions with side branch (SB) having a diameter of at least 2 mm under OCT guidance in 10 participating centers in Japan. From this registry, 105 bifurcation lesions treated with single stent crossing over SB and subsequent KBD were analyzed. We assessed the 3D bifurcation aspect and guidewire recrossing position in the 3D OCT after stent deployment crossing over SB and counted the incidence of unopposed struts at SB orifice in the OCT pullback after KBD. The 3D bifurcation aspect was defined as follows: the perpendicular type is the bifurcation in which the SB opening is visible as an elliptical shape and not concealed by the carina when viewed perpendicular to the vessel wall, in contrast, the parallel type is as the bifurcation in which proximal course of SB is concealed behind the carina. Regarding the guidewire recrossing point, if the guidewire located in the larger area enclosed by both the carina and the stent strut, with at least one distal top of the stent hoop located on the SB ostium, the distal recrossing is accomplished. Furthermore, the BA measurement was performed using the QAngioXA version 7.3 (Medis Specials, Leiden, The Netherlands) before the procedure. A bifurcation-dedicated tool was used for the analysis. Cases were compared between the perpendicular type and the parallel type. There were 80 parallel types and 25 perpendicular types. Mean BA between distal MV and SB measured by QCA were 54±18° in the parallel type and 77±23° in the perpendicular type ($p<0.01$). The best cut-off angle between distal main vessel and SB predicting the perpendicular type was 66 degree (AUC 0.802, sensitivity 76%, specificity 79%). Left main was more frequent in the perpendicular type than in the parallel type (64.0% vs 31.3%, $p<0.01$). The incidence of the unopposed struts at SB orifice in the perpendicular type was more frequent than that in the parallel type (14.7[9.0-22.2]% vs 6.4[2.1-12.2]%, $p<0.01$). There was no significant difference in the distal recrossing rate between two types (81.3% in the parallel type vs 88.0% in the perpendicular type, $p=0.43$) Although the distal recrossing reduced the unopposed struts at the SB orifice in the parallel type (5.2[1.9-8.5]% vs 14.9[8.6-25.6]%, $p<0.01$), the distal recrossing did not reduce the unopposed struts in the perpendicular type

(16.3[7.6-22.9]% vs 14.0[12.6-14.7]%, p=0.56).

CONCLUSIONS

Assessment of 3D bifurcation aspect, which is easy-to-use approach, divided the BA between distal main vessel and SB into ?parallel type? and ?perpendicular type?, adequately. 3D bifurcation type might expect how stent struts in front of SB orifice dilate by KBD. In particular the distal recrossing should be accomplished in the parallel type while in the perpendicular type a case-by-case selection of the recrossing point under 3D-OCT guidance may be needed to achieve better SB dilatation.

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Completion of inter-technique comparison of intra-procedural assessment of aortic regurgitation after TAVI

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

AIMS

To complete the inter-technique comparison of aortic regurgitation (AR) after TAVI, we assessed post-TAVI AR on aortic root angiogram, echocardiogram, and hemodynamics. To our knowledge this study is a first report of the intra-procedural comparison among 3 techniques.

METHODS AND RESULTS

Consecutive nineteen patients with symptomatic severe aortic stenosis underwent TAVI in our hospital from Mar 2017 to Dec 2017.

We assessed post-TAVI AR using the pre-defined protocol for post TAVI AR assessment. First, for the hemodynamic assessment, both systemic blood pressure and left ventricle (LV) pressure were simultaneously measured to calculate the AR index at least 10 minutes either after prosthetic valve implantation or final post-dilatation. Second, after removal of the pig-tail catheter from LV to avoid the influence of the pig-tail catheter on the prosthetic valve competence, the echocardiographic circumferential extent (CE) of paravalvular regurgitant jet was measured. 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 based on the Valve Academic Research Consortium (VARC)-2 cut-points with minor modification: none-trace 0?CE

CONCLUSIONS

Although there was a strong correlation between angiographic and echocardiographic post-TAVI AR severities, AR index did not correlate with both angiographic and echocardiographic AR severities. Despite small population study, this study revealed that AR index seemed to be a prognostic tool rather than AR diagnostic tool. To clarify these relationship, we should collect more cases with 3 technique results.

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Pulmonary Embolism: PERTinent information for cathlab personnel

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

AIMS

Pulmonary embolism (PE) is the fourth leading cause of cardiovascular death (CV) and a leading cause of CV morbidity worldwide. Identification and prompt treatment is necessary, although the choice and implementation of treatments is often a clinical challenge among facilities and experts in the field. As more cath labs are becoming involved in the treatment of these patients, pulmonary embolus response teams (PERT) teams are being created- (much like code STEMI and code Stroke teams). Goal is to review the roles and multi disciplinary specialities who align in the care of these PE patients.

METHODS AND RESULTS

Review of published data evaluating:

outcomes as a result of best practices,
quality improvement and data collection processes, and
published algorithms created to maximize a team based approach to PE care.
Review of PERT program: tools, resources & data of established program

CONCLUSIONS

In the past few years there have been several advances in the treatment of PE. It is important for the cath lab professional to be familiar with the diagnosis and advanced therapeutic techniques to treat acute PE. While it is important to realize that not all PE's present the same way (often divided into low, medium and high risk categories), detection of PE is often a challenge as the signs and symptoms are subtle and often mimic other disease states. Furthermore, there has been minimal guidance regarding treatment options as no universal accepted algorithm exists regarding treatment modalities. Addtionally, there is also a paucity of historical data regarding outcomes, and evaluation and long term effects of PE are still poorly understood.
Therefore, this is a perfect opportunity to address this complex disease and discuss treatment options to maximize optimal care for patients presenting in the cath lab setting.

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Co-registered photoacoustic and duplex ultrasound imaging for the evaluation and management of carotid artery atherosclerosis: first-in-man clinical study

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

AIMS

In this study a combined photoacoustic (PA) and duplex ultrasound (DUS) imaging system suitable for co-registered imaging was optimised and evaluated for clinical carotid imaging.

METHODS AND RESULTS

A combined PA and DUS imaging system was optimised for clinical imaging of carotid artery. An experimental framework for multi-spectral PA imaging was developed. Monte Carlo simulations and tissue mimicking phantoms were used to better assess optical propagation/absorption in neck tissue and plaque rupture mechanism. In vivo pre-clinical translational studies were carried out to see the feasibility, appropriateness and performance of combined PA and DUS for human carotid imaging. The first-in-human (FIH) clinical study is in progress. The main aims of this FIH study are to determine: a correlation between PA and DUS measurements, the diagnostic efficiency of PA imaging in identifying degree of carotid stenosis as determined by DUS and vulnerable plaque.

CONCLUSIONS

The combination of PA and DUS imaging can be used to visualise both stenosis and plaque composition which plays an important role in plaque rupture and relates to the evaluation treatment protocols and/or postprocedural follow up.

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Relationship between debulking area of rotational atherectomy and platform revolution speed - frequency domain optical coherence tomography analysis

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

AIMS

Patients with severe calcified coronary artery disease are increasing, and calcified lesion modification, including rotational atherectomy (RA) has been recommended. However, there is actually little evidence available to focus on debulking effectiveness of RA. The aim of this study was to investigate the safety and efficacy of frequency-domain optical coherence tomography (FD-OCT) guided RA procedure, with interest on platform revolution speed of RA.

METHODS AND RESULTS

We enrolled 30 consecutive lesions of 29 patients who underwent RA. The median age was 74 years (quartile 65-78), and there were 24 male patients (80.0%). The median burr-size was 1.5 mm (1.5-1.75), and the total ablation time was 120 seconds (100-180). FD-OCT revealed that the median minimum lumen area (MLA) was significantly increased by RA (from 1.64mm2 (1.40-2.09) to 2.45 mm2 (2.11-2.98), P value

CONCLUSIONS

FD-OCT guided RA with lower revolution speed around 150,000 rpm might have the potential to improve calcium debulking effect in patients with severe calcified coronary lesion, without increasing complications.

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Impella, HeartMate PHP and PulseCath for protected PCI

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

AIMS

Patients with complex left main and/or 3-vessel disease with a poor left ventricular systolic function are at high risk for life threatening complications during PCI. Preventive use of ?low-support? assist devices such as IABP in high-risk patients failed to reduce MACCE rate in previous RCT?s. The aim of the present study was to investigate safety and efficacy of ?high-flow? assist devices such as heartmate PHP, Pulsecath, and Impella during protected PCI

METHODS AND RESULTS

Methods: retrospective analysis of the database of Erasmus MC Rotterdam
Results: Between 2013 and 2017, 60 patients (mean age 72 ± 10 years) underwent a high risk PCI (mean LVEF 28 ± 11%, eGFR 55 ± 22 ml/min, syntax I score 25 ± 7, syntax II score 53 ± 12, 55% unprotected LM, 6% on inotropes/IABP, 75% rejected for CABG after heart-team discussion) supported with a ?high-flow? assist device (21 pulsecath (35%), 26 heartmate PHP (43%), 13 Impella (21%)). Indication for PCI was (un)stable angina in 28 patients (46%), ACS in 27 patients (45%) and heart failure in 4 patients (7%). Assist devices were introduced by one of both femoral arteries with ultrasound-guided punctures using 15 ± 2F sheats that were closed after the procedure with dedicated closure devices (68% proglide, 13% prostar, 13% manta). Mean procedural time was 2.46 ± 1.30 hours and on average 3.7 ± 1.7 stents were placed. Rotablation was used in 6 patients (10%). Complete revascularization was achieved in 61% of the patients. In the remaining 39% of the patients, a complex or non-viable CTO lesion was left untreated. Major procedural cardiac events included perforation (n=2) and tamponade (n=1). None of the patients experienced circulatory arrest requiring chest compressions during the procedure. Titrated adrenaline had to be administrated in 3 patients (5%) and endotracheal intubation was performed in 1 patient (2%). Vascular complications requiring surgery occurred in 2 patients (1 access bleeding and 1 limb ischemia).

CONCLUSIONS

In this high-risk PCI cohort, the use of ?high-flow? percutaneous left ventricular assist devices such as pulsecath, heartmate PHP and impella was safe and associated with few per procedural adverse events.

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Impact of guideline-recommended medical therapy in patients undergoing endovascular therapy for femoropopliteal lesions

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal

AIMS

Current guidelines recommend several medical therapies for patients with peripheral artery disease. However, there is a paucity of data about the comprehensive impact of guideline-recommended medical therapy (GRMT) in patients undergoing endovascular therapy (EVT) for femoropopliteal (FP) lesions.

METHODS AND RESULTS

This study was an observational study examining consecutive patients performing EVT for de novo FP lesion from July 2004 to March 2016. Study population included 1524 patients. Excluded due to lack of data about medical therapy (n=2), less than 3 years follow-up (n=97) or not de novo FP lesion (n=1), subjects were 1424 patients with (n=371) or without (n=1053) GRMT. GRMT was defined as the combination of at least 1 antiplatelet drug, statin and angiotensin-converting enzyme inhibitor/angiotensin receptor blocker. Outcome measures were major adverse cardiovascular event (MACE) (all-cause death, non-fatal myocardial infarction or stroke) and major adverse limb event (MALE) (re-intervention, revision or major amputation) at 3 year.

The incidence of MACE at 3 year was significantly higher in patients without GRMT than those with GRMT (28.6% versus 19.7%, p=.01). In MALE, although there was a tendency that its incidence without GRMT was higher than GRMT group, it was not statistically significant (36.7% versus 30.7%, p=.075). After adjustment for confounders, the risks for MACE and MALE in patients without GRMT were not significantly higher than those with GRMT in all subjects (hazard ratio (HR), 0.99, 95% confidential interval [CI], 0.71-1.35, HR, 0.90, 95% CI, 0.69-1.16, respectively). For the subgroup analysis, HR for MACE in ambulatory status (HR, 0.70, 95% CI, 0.48-0.98), claudication (HR, 0.67, 95% CI, 0.43-1.00), or without atrial fibrillation (HR, 0.63, 95% CI, 0.45-0.87) and HR for MALE in patients under 70-year-old (HR, 0.63, 95% CI, 0.40-0.96), ambulatory status (HR, 0.78, 95% CI, 0.60-1.00), or cilostazol (HR, 0.42, 95% CI, 0.19-0.78) showed the superiority of GRMT.

CONCLUSIONS

Our study suggests that GRMT was associated with better outcomes in some specific subgroups in patients undergoing EVT for femoropopliteal lesions.

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Impact of percutaneous endoatherectomy of heavily calcified lesion in non-stent zone with sheathless guiding catheter and bioptome (BRAVO)

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THEME: Peripheral Interventions
TOPIC(S): Iliac / Femoral / Popliteal

AIMS

In endovascular treatment (EVT) for heavily calcified lesion in common femoral artery, stent should be avoided because of the mobile joint area. We introduced ?BRAVO? technique (Bioptome assisted by RAMBO Via OPTIMO), which is the percutaneous endoatherectomy using 7Fr sheathless guiding catheter with protection balloon on its tip (OPTIMO), and bioptome.

METHODS AND RESULTS

"BRAVO" procedure is consisted with 2 parts.

Double vended hard guidewire and Crosser was introduced to peel off calcified plaque from the vessel wall (? RAMBO? technique).
calcified plaque was scraped off by bioptome under OPTIMO protection introduced from frontal superficial femoral artery (SFA) puncture.

We underwent angioplasty for 10 cases of heavily calcified total occlusion in common femoral artery with BRAVO technique. All the cases were done successfully. After procedure, angiogram showed no residual stenosis, and IVUS showed residual stenosis less than 20%. Hemostasis of OPTIMO was done safely by hemostasis device with assistance of long balloon inflation from inside via contra-lateral femoral and outer compression device from outside.
All the cases were assessed by both angiogram and IVUS, and Duplex in some cases.

CONCLUSIONS

This procedure may represent one of the promising option for revascularization of calcified non-stenting zone occlusion including joint position via EVT alone, without surgical endoatherectomy.

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TAVI with or without predilatation: analysis from the forward study

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

AIMS

The role of predilatation during transcatheter aortic valve implantation (TAVI) for aortic stenosis is not well defined. We compared clinical and echocardiographic outcomes in patients without pre-implant balloon aortic valvuloplasty (no pre-BAV) vs patients with pre-BAV following TAVI with a repositionable, self-expandable valve in routine practice.

METHODS AND RESULTS

The Evolut R FORWARD Study is a multicentre, prospective, single-arm, observational post-market study to document safety and performance of the Evolut R system (23 mm, 26 mm or 29 mm, Medtronic, Minneapolis, MN, USA) in a routine hospital setting at 53 centres in 20 countries. Eligible patients had symptomatic native AV or surgical bioprosthesis stenosis and were considered at high or greater risk of surgical mortality/morbidity based on Heart Team assessment. Evolut R is a self-expanding, repositionable, supra-annular valve in a conformable Nitinol frame. An independent echocardiographic core laboratory centrally analysed all studies. A total of 1038 patients with symptomatic aortic stenosis underwent attempted implant of which, 566 (54.5%) were without predilatation (no pre-BAV).

Compared with pre-BAV patients, the no pre-BAV patients had a lower STS score (5.3±4.0% vs 5.8±5.0%, p=0.048) and were less likely to have a severely calcified aorta (9.2% vs 13.6%, p=0.026), or moderate or severe LVOT calcification (12.2% vs 22.2%,

CONCLUSIONS

The results of this study show that Evolut R valve implantation can be performed with equally good results with or without predilatation. Waiving of pre-implant dilatation can simplify the TAVI procedure, however pre-BAV may still be useful in selected patients.

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Effect of non-compliant balloon post-dilatation on magnesium-based BRS

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

AIMS

For percutaneous coronary intervention (PCI) with bioresorbable vascular scaffolds (BRS), post-dilatation with non-compliant (NC) balloons is usually mandated under the assumption that it achieves optimal scaffold apposition and minimizes event rates. We evaluated the mechanical effect of non-compliant (NC) balloon post-dilatation on magnesium-based BRS.

METHODS AND RESULTS

In 35 patients (mean age 66±12years), 40 magnesium-based BRS were implanted to treat 37 de novo coronary artery stenoses. Following appropriately sized NC Balloon pre-dilatation (1:1:1 vessel:balloon:scaffold ratio), magnesium-based BRS were implanted with a pressure of 10 atm, followed by NC balloon post-dilatation at nominal BRS size (standardized at 16 atm). OCT was performed before and after post-dilatation and images were analyzed at a spacing of 0.2 mm to measure BRS dimensions and determine apposition as well as to detect strut fractures. Incomplete scaffold apposition area was defined as difference between lumen area and abluminal scaffold area.

PCI with magnesium-based BRS (mean diameter: 3.2±0.3mm, mean length: 20±4mm) was successful in all cases, in one case a non flow-limiting distal edge dissection occurred after implantation and before post-dilatation. NC balloon post-dilatation resulted in a significant increase of mean scaffold diameter (3.2±0.3 vs. 2.8±0.3mm, $p < 0.001$), scaffold area (6.9±1.3mm² vs. 6.2±1.2mm², $p< 0.001$) and lumen area (7.0±1.3mm² vs. 6.4±1.4mm²,

CONCLUSIONS

High-pressure NC balloon post-dilatation of magnesium-based BRS is required to achieve optimal expansion. It significantly reduces malapposition and can safely be performed without relevant rates of strut fractures.

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Determinants of success and hemodynamic impact of balloon post-dilatation of self-expanding transcatheter aortic valves

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

AIMS

Balloon post-dilatation (BPD) is commonly used to optimize valve expansion and reduce paravalvular leakage (PVL) after transcatheter aortic valve implantation without clearly knowing its hemodynamic benefits. We sought to explore the rate, the determinants of success, and the hemodynamic impact of balloon BPD of self-expanding transcatheter heart valves (SE-THVs)

METHODS AND RESULTS

Patients (n=307) who received a SE-THV were stratified according to the severity of PVL at discharge and whether a BPD was performed, into three groups: ?mild PVL + no BPD (no PVL + no BPD), ?mild PVL + BPD (Successful BPD), and moderate-severe PVL + BPD (Failed BPD). BPD was performed in 121 patients (39.4%) and was successful in 106 patients (87.6% of attempts). Independent predictors of BPD failure were: atrial fibrillation (OR, 12.29 [2.26-66.98], p=0.004), and a ratio of the post-dilatation balloon diameter to the annulus diameter ?0.95 (OR: 10.72 [2.02-56.76], p=0.005). Peak transvalvular pressure gradient (PG) was lower in the Successful BPD group (14[12-22] mmHg) than in the Failed BPD group (18[16-23] mmHg, p=0.029), and did not rise in either group during follow-up (median [IQR], 364[161-739] days).

CONCLUSIONS

BPD was performed in 39% of patients who received a SE-THV, and was successful in the majority of attempts. BPD failure was more likely in patients with atrial fibrillation and in those with a small post-dilatation balloon-to-annulus diameter ratio. Effective BPD improved THV hemodynamic performance, and this was maintained in the intermediate-term post-TAVI.

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TAVI in the cathlab vs. hybrid operating room: insights from the FRANCE-TAVI registry

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

AIMS

To compare short- and long-term outcomes of patients undergoing TAVI in the catheterization laboratory (CL) to those undergoing TAVI in a hybrid operating room (HOR).

METHODS AND RESULTS

All TAVIs performed in 48 centres across France between January 2013 to December 2015 were prospectively included in the FRANCE TAVI registry. Procedure location (CL or HOR) and clinical outcomes were site-reported. Mortality data was obtained through a national database query. The primary endpoint of this study was all-cause mortality at 1 year. Mortality rates were also analyzed up to 3 years. Secondary endpoints consisted in 30-day complications including stroke, vascular complications, bleeding, new pacemaker implantation, acute kidney injury and infections. All analyses were adjusted for baseline and procedural characteristics.

A total of 12 121 patients were included in this study, 62% of which underwent TAVI in a CL vs. 38% in a HOR. Several baseline characteristics differed significantly between the cath lab and hybrid OR groups: patients undergoing TAVI in a CL were significantly older (83.2 vs. 82.5 years), had higher logistic EuroScore (18.4 vs. 17.0), more chronic kidney disease, more coronary artery disease, and more chronic obstructive pulmonary disease, among others. In contrast, patients undergoing TAVI in the hybrid OR had more peripheral vascular disease and more previous cardiac surgeries (all p-value

CONCLUSIONS

Long-term mortality after TAVI was similar between the catheterization laboratory and the hybrid operating room. Patients done in the hybrid operating room were more likely to have major bleeding and infections.

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Retrograde transpedal access for revascularisation of isolated below-the-knee arteries in critical limb ischaemia

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

AIMS

Background: Traditional access for the treatment of below-the-knee (BTK) lesions is the femoral approach, but in failed anterograde cases transpedal access can be utilized. The aim of the study was to evaluate the safety and technical and clinical success of endovascular (BTK) artery revascularization by a primarly retrograde transpedal access.

METHODS AND RESULTS

Methods: The clinical and angiographic data of 36 consecutive patients treated via transpedal access with symptomatic BTK stenosis were evaluated. We have selected patiens with good distal run-off and non-infected distal puncture zone. The distal pedal artery was punctured by ultrasound guidance, and the angiography was done from radial artery access to guide the intervention. Distal pressure at the end of the pedal sheath was also measured before and after the intervention. The primary endpoint was a composite of procedural success, major adverse events. Secondary endpoints were: rate of access site complications, angiographic result of BTK intervention, procedural factors, cross over rate to another puncture site and duration of hospitalization.
Results: The indication of the intervention was critical limb ischemia in all patiens. Technical success was achieved in all patients (36/36) and there was no need for femoral cross over. Right radial access was applied in all patients for diagnostic angiography. Anterior tibial artery access was utilized in 14 (56%) and posterior tibial artery (44%) was used in 11 patients. Pre-interventional diameter stenosis was 89.5 ± 13 %, lesion length 82.7 ± 51.8 mm, and reference vessel diameter 2.75 ± 0.5 mm. Post-interventional diameter stenosis was 21 ± 12 %. Balloon angioplasty was done in 25 cases (100%), but in 6 cases additional drug eluting stent implantation was applied (24%). Major adverse event was detected in one patient at two months follow up (4%). Radial and pedal artery access site complications were not encountered by ultrasound (0%).

CONCLUSIONS

Below-the-knee artery angioplasty can be safely and effectively performed using radial and transpedal access in selective patient population.

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Temporal, nine-month vascular response to novel, long, thin strut BRS in the porcine coronary restenosis model

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

AIMS

Treatment of long coronary lesions with bioresorbable scaffolds is currently limited to overlapping implantations only due to the lack of long devices. Additionally, vascular response to long versus regular scaffolds is unknown. Therefore, we compare long vs. regular scaffolds with 100 micrometer struts (MeRes100) in the porcine coronary restenosis model.

METHODS AND RESULTS

In total 44 scaffolds, including 29 regular (3.0 x 16 mm) and 15 long (3.0 x 33 mm), were implanted with 120% overstretch with optical coherence tomography (OCT) guidance in 15 domestic animals for 1, 7, 28, 90, 180 and 270 days. At terminal follow-up, terminal imaging with OCT was performed and long scaffolds evaluated in pathology. Stent areas and the neointimal hyperplasia as expressed as % Area Stenosis were comparable at all time points between long and regular scaffold, achieving the value of respectively 5,63 vs 5,38 (long vs short, mm^2) in stent area and 20,84 vs 24,15% in % area stenosis at 270 days follow-up. Healing and endothelialisation were already complete at 28 days in the long scaffold group.

CONCLUSIONS

Implantation of long bioresorbable scaffolds was feasible. At long-term their integrity remained intact and neointimal response comparable to regular size scaffolds, which is contrary to historical data with metallic stents.

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Critical technical aspects of the proximal optimisation technique during bifurcation stenting

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THEME: Coronary Interventions
TOPIC(S): Bifurcation lesion

AIMS

Postdilatation of the proximal main vessel segment after stenting across a coronary bifurcation is known as the proximal optimization technique (POT) and bears several advantages including improved stent expansion and apposition, better side branch access, and less risk of accidental abluminal rewiring. A POT performed after kissing balloon inflation designated ?final POT? has been widely advocated despite almost no clinical evidence. We aim to show that a proximal balloon position during final POT is crucial to avoid severe distortion of the bifurcation.

METHODS AND RESULTS

In coronary bifurcation phantoms with a narrow angle between distal branches we implant newer generation drug eluting stents in two series by 1) stenting the main vessel only, and 2) by the culotte two-stent technique with stenting of the side branch first. In both series, to mimic an unintended proximal rewiring, a proximal rewiring of the side branch ostium is performed with subsequent kissing balloon inflation to produce a long ? metallic carina? of struts extending from the flow divider and proximal. A non-compliant balloon sized according to the reference size of the proximal main vessel segment is then positioned a) across the ostium with the distal balloon marker at the carina level, or b) with the marker proximal to the proximal off-spring of the side branch. The balloon is inflated to 20 atm, deflated and positioned with the proximal marker at the proximal stent edge and inflated again to 20 atm. The configuration of the stent is documented by micro-CT before and after final POT. The position of the metal carina is characterized and the area difference of the side branch ostium is measured and compared for the proximal and distal POT balloon positions.

CONCLUSIONS

Balloon position during final POT may be of critical importance in avoiding severe distortion of the bifurcation anatomy established by kissing balloon inflation. This bench study is ongoing and these important results with immediate clinical relevance can be presented at EuroPCR 2018.

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First report of two-year healing patterns after implantation of the fantom BRS

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

AIMS

The Fantom bioresorbable scaffold (BRS) has a strut thickness of 125µm, is radiopaque and was shown to have almost complete tissue coverage of struts, effectively reduction of malapposition, and no recoil at six- or nine months follow-up. Here we present the scaffold properties and healing patterns after 24 months assessed by optical coherence tomography (OCT).

METHODS AND RESULTS

The Fantom II study evaluated safety of the Fantom BRS (REVA Medical, USA) in simple coronary lesions. 240 patients were included in two arms with angiographic follow-up at six- or nine months. A subgroup of patients in the cohort with six-month OCT follow-up was scheduled at baseline for 24 months follow-up. Matched cross-sectional OCT analysis at frame level was performed over all three time points with dedicated software. Twenty-nine patients were included in the 24-month cohort. Five patients were excluded from the matched analysis due to missing OCT pullback at one of the three specific time-points leaving 24 patients in analysis. Mean age was 61±10 years and 72% were males. Mean BMI was 28±4kg/m2, 28% had diabetes, 76% had hypertension, and 28% had previous myocardial infarction. Pre-procedural diameter stenosis was 78±11% with a lesion length of 14±3mm. Mean nominal device diameter was 2.9±0.2mm with a length of 18±1mm. Implantation was per protocol successful in all cases. Quantitative OCT analysis showed a decrease in mean lumen area from 7.1±1.4mm2 at baseline to 6.0±1.4 mm2 at six months (

CONCLUSIONS

After 24 months, the Fantom BRS had scaffold enlargement and excellent healing patterns with complete apposition in almost all cases and very few uncovered struts. The mean and minimal lumen areas were stable between 6 and 24 month indicating a favourable neointimal response.

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Acute and short-term performance of Magmaris BRS implantation in complex lesions: a multicentre experience

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

AIMS

Although recent discouraging data on poly-L-lactic bioresorbable scaffolds (BrS), there is still a strong rationale in scaffold employment for coronary stenosis treatment. New magnesium-made BrS Magmaris showed promising results in clinical trials in terms of efficacy and safety, nevertheless few data regarding its implantation in real world and complex lesions are available.

METHODS AND RESULTS

All consecutive patients undergoing PCI with implantation of at least one Bioresorbable (BrS) Magmaris Scaffolds (BIOTRONIK, Buelach, Switzerland) in 10 Italian Institutions with high volume PCI were included. Device acute success defined as 1) successful BrS delivery and implantation 2) post-procedural residual diameter stenosi

CONCLUSIONS

Magmaris BrS implantation is feasible with a high intraprocedural success also in complex lesions. Longer follow-up data and larger samples are required.

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Prevalence of mitral regurgitation following acutely revascularised STEMI and its impact on mid-term outcome

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

AIMS

Ischemic mitral regurgitation (MR) is a known complication of ST elevation myocardial infarction(STEMI). There is a paucity of evidence on the impact of revascularised STEMI on the mitral valve. The current ESC and ACC STEMI guidelines do not specifically advise a management strategy in this cohort. The aim of this study is to delineate the effect of revascularised STEMI on the mitral valve, identify predictors of MR and compare mortality between these groups.

METHODS AND RESULTS

In this observational registry study, we analysed 1,122(mean age 64+/-13yrs, and 76% male) consecutive patients presenting with STEMI who underwent primary PCI (April 2014 and April 2016). Demographic data, relevant past medical history, cardiovascular risk factors, biochemical markers, PCI details and all-cause mortality were documented for each patient. We looked at the predictors of significant MR (moderate or severe) and compared the mortality risk in MR group vs no MR group. Statistical analysis was done on SPSS.
94 were excluded due to missing echocardiogram data. 62 patients (6%) were found to have significant MR at baseline. Patients? with significant MR were on average 10 years older than patients with no MR (95% CI = 6.75-13.13, P

CONCLUSIONS

Acute MR was associated with poor outcome following acutely revascularised STEMI. Age, LV ejection fraction, renal impairment and non-smoker status were all shown to be significant predictors for ischaemic MR. Prospective multicenter trials are warranted to identify potential transcatheter treatment for this cohort.

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Feasibility of overlapped magnesium-made BRS implantation in long lesions: results from a multicentre Italian registry

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

AIMS

Prospective registries on new magnesium- made bioresorbable scaffolds (BrS) Magmaris enrolled patients with simple coronary lesions. The present report was sought to give preliminary findings about feasibility and safety of implantation of overlapped scaffolds in long coronary lesions.

METHODS AND RESULTS

From July 2016 and September 2017, we collected data encompassing patients treated with at least two overlapped BrS Magmaris Scaffolds (BIOTRONIK, Buelach, Switzerland) in 10 italian participating institutions. Endpoints of interest were successful overlap implantation according to edge-to-edge technique and 30 days device-oriented endpoint (DOCE), including cardiac death, target vessel myocardial infarction and target lesion revascularization.

Fifty-eight lesions in 37 patients accounting for an overall number of 83 BrS overlaps were included in this analysis. The majority of patients presented with ACS/NSTE (64.8%). Left Anterior Descending was target for revascularization in 70.2% of cases. Mean lesion length was 47.8± 15.2 mm treated with a mean of 2.49 ± 0.69 MAGMARIS scaffolds. Scaffold predilatation and postdilatation were performed in 100% and 97% of patients, respectively. Edge-to-edge implantation technique was attempted in all cases. Almost two-third of cases (64.9%) underwent intravascular imaging guided procedure (OCT 21, IVUS 3). Successful overlap was performed in 96.5% of attempts with 3 failures due to geographical missing, resolved with bailout BrS implantation. Device acute success was achieved in all cases without any in-hospital event. At 3-month follow-up (available in 73% of patients) no DOCE occurred.

CONCLUSIONS

Multiple Magmaris implantation using an edge-to-edge technique is feasible with acceptable risk of geographical missing, probably due to the low radiopacity of nitinol markers. Clinical outcomes need to be confirmed in trials with longer follow-up.

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Early clinical outcomes of three different second-generation transcatheter aortic valve prostheses

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

AIMS

Different devices for transcatheter aortic valve implantation (TAVI) are available on market. A detailed characterization of the aortic valve anatomy by computerized tomography (CT) may guide the selection of a suitable aortic valve prosthesis. The aim of this study is to compare early outcomes of three second generation transcatheter heart valves (THVs) currently available for TAVI.

METHODS AND RESULTS

This is a single center, prospective, observational study. All consecutive patients undergoing transfemoral transcatheter aortic valve implantation (TAVI) for native severe tricuspid aortic stenosis with second generation prostheses (Edwards SAPIEN 3, Medtronic Evolut R and Symetis Acurate NEO TF) were included in the study. We accounted for differences in baseline clinical characteristics between groups using propensity score weighting.

From September 2014 to December 2017, a total of 540 patients performed transfemoral TAVI with a second generation device. Among these, 174 didn?t performed a pre-TAVI MDCT assessment due to severe renal failure and were excluded from this study. 366 patients were evaluated with MDCT scans prior TAVI and received a Edwards SAPIEN 3 (n=147), Medtronic Evolut R (n=123) or Symetis Acurate NEO TF (n=96) prosthesis, according to cardiovascular imaging assessment and Heart Team evaluation.

The mean age for the entire study cohort was 81.3 ± 5.2years while the STS predicted risk of mortality was 3.9 ± 2.7%. Rates of complications in the study were low at 30 days (all-cause mortality 1.8%, cardiovascular mortality 1.2%, major stroke 0.9%, permanent pacemaker implantation 9.7%, VARC-2 defined composite safety endpoint 15.4%). In propensity score weighted analyses, second generation TAVI prostheses did not differently impact on 30-day all-cause (p=0.644 and p=0.693 for SAPIEN 3 and Symetis vs. EvolutR, respectively), and cardiovascular mortality (p=0.861 and p=0.907 for SAPIEN 3 and Symetis vs. EvolutR, respectively). The VARC-2 defined composite safety endpoint was more frequently encountered in patients treated with the Evolut R prosthesis as compared to the SAPIEN 3 valve (

CONCLUSIONS

TAVI using second generation prostheses was associated with high success and low complications rates. In adjusted head-to-head comparisons between different devices, the EvolutR valve yielded a numerical increase in permanent pacemaker implantation and increased rates of VARC-2 defined composite safety endpoint. SAPIEN 3 THV showed an higher 30-days mean transvalvular gradient respect to Evolut R THV but a longer comparison is needed to establish the clinical relevance of this finding.

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Long-term outcomes from the all-comer Nordic Aortic Valve Intervention (NOTION) randomised clinical trial in patients with severe aortic valve stenosis

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

AIMS

In patients with severe symptomatic aortic valve stenosis, transcatheter aortic valve implantation (TAVI) is the preferred treatment in extreme surgical risk patients and a reasonable alternative to surgical aortic valve replacement (SAVR) in high- and intermediate risk patients. Longer term outcome data are needed for TAVI in lower risk patients

METHODS AND RESULTS

The multicenter Nordic Aortic Valve Intervention (NOTION) trial randomized operable patients 1:1 to TAVI using the CoreValve self-expandable device (n=145) or SAVR (n=135). The primary outcome was the composite rate of all-cause mortality, stroke, or myocardial infarction at 1 year defined according to Valve Academic Research Consortium-2 definitions. Up to eight-year results will be presented at EuroPCR 2018 the meeting.

Baseline characteristics were similar. The mean STS-PROM was 3.0±1.7. After 4 years, there were no differences between TAVI and SAVR in composite rate of all-cause mortality, stroke or myocardial infarction (29.1% and 30.2%, respectively (p=0.76). TAVI patients had larger aortic valve area (1.67 cm2 vs. 1.29 cm2, p<0.001) with a lower mean gradient (7.9 vs. 13.5 mm Hg, p<0.001). These values have been unchanged over time. However, more TAVI patients had moderate/severe paravalvular leakage (6.0% vs. 1.0%, p<0.001) and required a pacemaker (43.7% vs. 9.0%, p<0.001).

CONCLUSIONS

TAVI with a self-expandable prosthesis in lower risk patients provides a sustained haemodynamic benefit compared with SAVR after 4 years with similar rate of major clinical outcomes. Long-term data will be presented at EuroPCR 2018.

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Early and mid-term outcomes of TAVI using the new-generation self-expanding Symetis Acurate neo valve

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

AIMS

To assess early and mid-term outcomes of transcatheter aortic valve implantation (TAVI) using the new-generation ACURATE neo transfemoral (TF) Device (Boston Scientific).

METHODS AND RESULTS

This is a prospective, single-center study. All consecutive patients undergoing TAVI with S, M, L ACURATE neo/TF Device valve were included. From July 2015 to December 2017, a total of 98 patients with a median age of 81.4 ± 4.4 years and mean STS score of 3.6 ± 2.6% were treated. Device success was obtained in 91 patients (92.9%). Implantation of a second prosthesis was required in 3 cases (3.1%). In 2 cases an Edwards SAPIEN 3 (Edwards Lifesciences) was implanted to treat the ventricular dislocation of the prostheses, in 1 case a second ACURATE was implanted subsequently to the aortic embolization of the first prosthesis. Postdilatation for suboptimal expansion of the prosthesis was performed in 25 cases (25.5%). Post-TAVI transthoracic echocardiogram showed a reduction in mean gradient from 50.1±15.9 mmHg to 8.6±3.9 mmHg (

CONCLUSIONS

In this prospective, single-center study, TAVI using the new-generation ACURATE neo/TF device was associated with high device success rate, excellent hemodynamics and low early complications rates

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Basic physiology of the new parameter ECOStif: animal validation of an invasive measurement of coronary pulse wave velocity

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

Epicardial COronary STIFfness (ECOStif:) represents a new paradigm for caring patients in the cathlab, it can be assessed by measuring coronary pulse wave velocity (PWV) with a regular pressure wire. In humans, it seems associated with plaque instability (Harbaoui et al. JAHA 2017), Yet, the basic physiology of ECOStif: is mostly unknown while it should be critical for its interpretation. This study aimed at determining the impact on ECOStif:of 1) mean blood pressure (MBP) and heart rate (HR) variations and of, 2) various degrees of luminal stenosis (St).

METHODS AND RESULTS

10 female pigs weighting 48 ± 3 kg were included. Coronary angiography was performed under general anesthesia via the right carotid artery (6F). ECOStif:was measured in the left anterior artery with 2 pressure wires (Abbott) positioned at the proximal and at the distal part of the artery. This allows for calculating the transit time of the pressure wave across the artery and for calculating the corresponding PWV after determining the travel distance (assumed to be equal to the elongation of the wire after pull-back from distal to proximal). ECOStif:was measured in 3 MBP conditions (60, 80, 100 mmHg) produced by i.v norepinephrine (up to 1.8 mg/h) or isosorbide dinitrate (up to 32 mg/h) and in 3 HR conditions (90, 110, 130 bpm) induced by atrial pacing. One condition was repeated for assessing repeatability using the coefficient of variation. At 80 mmHg and 110 bpm, 2 different stenosis were produced by inflating balloons of increasing size (St1, St2) and assessed by measuring fractional flow reserve (FFR).

In basal conditions ECOStif was 8.1 ± 1.1 m/s. ECOStif: increased significantly with increasing MBP and HR (2-way-ANOVA repeated measurements,

CONCLUSIONS

ECOStif: has a reasonable repeatability. As expected from basic physiology, it is influenced by large MBP variations and at a lesser extent by HR changes. It is also slightly influenced by coronary stenosis. This is rather reassuring with respect to the conditions of ECOStif measurement in routine with mostly stable hemodynamic conditions and moderate coronary stenosis. The present study is critical to better understand this new parameter and to address its robustness in the prospect of its clinical use.

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Periprocedural variations of platelet and endothelium function biomarkers during rotational atherectomy

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

AIMS

Rotational atherecotomy is a complex and aggressive coronary intervention which may be associated with significant platelet activation and endothelium damage.
The aim of this study was to assess the impact of rotational atherectomy on different platelet and endothelium function biomarkers, and determine which procedural aspects of rotational atherectomy have the biggest influence on them.

METHODS AND RESULTS

We prospectively evaluated data of 22 patients who underwent elective RA procedures.
Blood samples were collected before procedure, directly after sheath insertion but before administration of heparin, and immediately after the procedure.
Levels of soluble E selectin, soluble intercellular adhesion molecule 1 (ICAM-1) , platelet factor 4 (PF 4), P Selectine, and cluster of differentiation (CD 40) ligand were measured in both blood samples with commercially available immunoassay kits.
Most of the patients were male (68%), the mean age of the study population was 73 ± 8,5 years and mean ejection fraction was 51 ± 11%. Prevalence of traditional risk factors presented as follow: hypertension 91%, diabetes mellitus 64%, prior stroke 27%, hyperlipidemia 36%, atrial fibrillation 9%.
Radial access site was used in 95% of patients, procedure was successful in 91% of patients. Mean maximal burr size was 1,4 ± 0,21 mm, mean burr speed was 146 000 ± 5 000 revolutions per minute. During the procedure operators performed 7,3 ± 4,4 burr runs for total 204 ± 104 seconds with 1,23 ± 0,43 burrs.
We observed significant decrease in E-selectine (29,54 ±15,5 ng/ml -> 22,55 ± 11,9 ng/ml, p=0,006), intercellular adhesion molecule 1 (215,23 ± 65,2 ng/ml -> 189,73 ± 70,1 ng/ml, p=0,05) and platelet factor 4 (7729,2 [2126,4-12835,8] ng/ml -> 0 [0-1079,1] ng/ml, p=0,001) levels.
There were no signifficant differences in P-selectine and cluster of differentiation 40 levels during the procedure.
Periprocedural variations in E-selectine levels significantly correlated with total time of burr use (r=-0,45, p=0,03) and maximal burr diameter (r=0,44, p=0,04). We also observed a trend in correlation between periprocedural variation of E-selectine levels and number of burr runs (r=-0,4, p=0,06).

CONCLUSIONS

Rotational atherectomy has a significant impact on platelet and endothelium function. Change in E Selectine levels was proportional to duration of burr runs and maximal burr diameter. Reducing the time of burr runs during rotational atherectomy may decrease the endothelial dysfunction and platelet activation. This may effect in reduction of thrombotic periprocedural complications.

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A systematic literature review and meta-analysis of Impella devices used in cardiogenic shock and high-risk PCI

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

AIMS

To perform a meta-analysis on pooled survival and complications rates of Impella® heart pumps (Abiomed Inc., Danvers, USA) use in cardiogenic shock and high-risk coronary percutaneous coronary intervention (PCI).

METHODS AND RESULTS

Data sources: Articles were searched in Medline, Medline In-Process, EMBASE and the CENTRAL bibliographic databases on the 30th April, 2017. Study Inclusion: Prospective and retrospective studies with ? 10 patients supported with Impella. Survival and complication rates were pooled. Data extraction and synthesis: The literature review identified 33 articles. Data on patient characteristics, indication of support, type of Impella device and outcomes were extracted. A random effect was used to pool the various outcomes. Low heterogeneity (I2 ?0.25) results are presented.

A total of 2,827 patients (40.5% cardiogenic shock, 59.5% high-risk PCI) were included (mean age 64.9±11.4, male 74.6%). In the cardiogenic shock indication, survival rate to 90 and 180 days was 62.6% and 58.3%, respectively, the rates of hemolysis and device malfunction were 8.8% and 2.5%, respectively. In the high-risk PCI indication, the 30 day major adverse cardiac and cerebrovascular event (MACCE) rate was 15.3% with a 30 day survival, stroke, myocardial infarction and repeat revascularization rates of 92.2%, 0.3%, 13.5% and 1.6%, respectively. Hemolysis and device malfunction affected respectively 0.7% and 1.4% of the high-risk PCI patients.

CONCLUSIONS

This is the largest meta-analysis summarizing the literature outcome data of Impella heart pumps. The present study demonstrates very encouraging survival in cardiogenic shock patients and very good 30 day outcomes in patients undergoing prophylactic support for high-risk PCI

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Endovascular treatment with catheter-directed thrombolysis in patients with acute pulmonary embolism and evaluation of deep vein thrombosis recanalisation rate

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

AIMS

To test the safety and efficacy of endovascular treatment of acute pulmonary embolism via Pigtail Catheter-Directed Therapy and local thrombolysis. To observe the relationship between deep vein thrombosis recanalization rate in patients treated for acute pulmonary embolism with local fibrinolysis and anticoagulant compared to anticoagulant alone.

METHODS AND RESULTS

For the time period from January 2013 to December 2017 a total of 185 patients (mean age 62+/- 15 years, 56% female and 44% male) with acute pulmonary embolism were treated in our center. Endovascular treatment with thrombus defragmentation and local thrombolysis with Pigtail Catheter-Directed Thrombolysis was used in 47 patients with massive and 89 with submassive pulmonary embolism. A group of 49 patients was treated with anticoagulant alone due to hemodynamic stability and no major echocardiography and laboratory signs of right ventricle overload. In the endovascular group the mean invasively measured systolic pulmonary artery pressure (PAP) before the procedure was 68 +/- 24 mmHg and 47 +/- 21 mmHg after the procedure with a calculated mean drop of 21 +/- 3 mmHg. An average dose or 39 +/- 17 mg tissue plasminogen activator (tPA) was used. In the endovascularly treated group two patients died due to refractory cardiogenic shock and on a couple of occasions a hematoma at puncture site was observed. No other procedure-related complications or bleeding events were registered. Being highly associated with pulmonary embolism, deep vein thrombosis was to be found in 112 of 185 (60%) of the patients ? 85 of 112 (75%) in the endovascularly treated group and 27 of 112 (25%) in the conservatively treated one. Deep vein recanalization was evaluated with ultrasound Doppler sonography. A group of 77 of 112 (69%) patients were followed-up for 1 month and 61 of 112 (54%) for a period of 6 months. A recanalization rate over 50% at one month was observed in 1 of 77 (1.3%) patient in the anticoagulant alone treated group and 39 of 77 (51%) in the endovascularly treated group. At six months the follow-up of a total of 61 of 112 (55%) patients showed a recanalization rate over 50% in 9 of 61 (14%) patients in the conservatively treated group and 39 of 61 (50%) in the endovascularly treated group.

CONCLUSIONS

Endovascular treatment with catheter-directed local thrombolysis and thrombus defragmentation proves to be a safe and efficient way of treating acute pulmonary embolism, with low mortality and complications rate and excellent safety profile. In our experience, treatment of pulmonary embolism with local thrombolysis and anticoagulant leads to improvement of deep vein thrombosis recanalization rate, although additional investigation of the topic should be made. Our hypothesis is that this kind of treatment may lead to reduction of the highly disabling post-thrombotic syndrome.

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Prevalence and outcome of infective endocarditis after TAVR

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

AIMS

Aims:

Trans-catheter Aortic Valve Replacement (TAVR) is increasingly being used as an alternative to conventional surgical valve replacement. Up to date there has been only limited research on the prevalence ant outcome of infective endocarditis developing after TAVR. This research was performed to gain insight in the prevalence and outcome of IE after TAVR.

METHODS AND RESULTS

Material and methods:

A multi-centre study was performed using the in hospital TAVR registration which is used in all TAVR implanting centres in the Netherlands. Patients who underwent TAVR were screened for IE by using the insurance database. Patients were analysed for age, gender, valve type and size, approach of implantation, date of IE diagnoses, organism, concomitant IE of a non TAVR valve, presence of a Cardiac Implantable Electronic Device (CIED), concomitant IE of a CIED, Intensive Care Unit (ICU) admission, re-intervention mortality and complications.

Results:

A total of 3968 patients who underwent TAVR were screened for IE. A total of 16/3698 (0.4%) developed IE. The majority of patients was male ((9/16 (56.3%)) with a median age of 81 (60-91) years. None of the patients who presented with IE after TAVR were known to have suffered from IE prior to TAVR and 31% (5/16) had a CIED. The effected prosthetic valves were a Corvalve CRS® in 25% (4/16), Sapien XT® in 44% (7/16), Evolute R® in 13% (2/16) and a Direct Flow® in 19% (3/16). The implantation was trans-femoral in 81% (13/16), via the subclavian artery in 13% (2/16) and one patient received a trans-apical approach. All patients had positive cultures. A possible bacterial entry point into the bloodstream was found in 9 patients consisting of a gastro-intestinal (GI) entry point in 5/9 patients (4 GI tract and one patient who had an oral entry point), an infected knee prosthesis which developed after knee prosthesis implantation, a femoral TAVR catheter access site, a subclavian TAVR catheter access site and an inguinal abscess which developed one month after TAVR implantation of the TAVR catheter puncture site of the femoral artery.

In the follow up period of 15 months (1-42months) mortality was 31% (5/16) with 25% dying during hospital admission. Concomitant mitral valve endocarditis was present in 25% (4/16). All patients were treated

conservatively with intravenous antibiotics alone. Complications of IE occurred in 31% (5/16) and consisted of cerebral infarction due to a dislodged vegetation in one patient, aortic root abscess formation in 2/16 patients and decompensated heart failure in 2/16 patients. The mean time for IE to develop from the moment of valve implantation was 451 days (21-2837 days) with 9/16 (56%) patients developing IE within a year after TAVR. None of the patients went for re-intervention of the TAVR. Aortic valve regurgitation developed in 50% (8/16) of the patients all in the form of grade 2/4 aortic regurgitation. The mean length of hospitalisation was 31.8 days (7-49 days).

CONCLUSIONS

Conclusion:

In this multi-centre study infective endocarditis in patients receiving trans-catheter aortic valve implantation is a rare complication with a low prevalence and outcome is relatively good even when treated conservatively.

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Pressure-controlled intermittent coronary sinus occlusion reduces infarct size after primary PCI: a propensity-controlled matched study

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Pressure controlled intermittent coronary sinus occlusions (PiCSO) has been shown to decrease ischemic damage during coronary occlusions in pre-clinical studies. The study presented here explores the effect of PiCSO therapy provided during primary PCI on infarct size

METHODS AND RESULTS

In the parallel-arm non-randomized UK PiCSO in adjunct to PCI study, patients with a first anterior infarct underwent PiCSO treatment after TIMI 3 flow was established in the infarct related artery. Infarct size was assessed by cardiac MRI on day 5, and was compared to control patients without PiCSO from the INFUSE-AMI with day 5 cardiac MRI. A statistician, blinded to infarct size, balanced the PiCSO and INFUSE-AMI cohorts on sex, age, pre-PCI TIMI flow (0/1 vs 2/3), post-PCI TIMI flow (2 vs 3), diabetes mellitus, culprit lesion location (proximal vs mid LAD), and symptom to balloon time with a propensity score adjusted ~1:3 match. A second statistician compared the infarct size between PiCSO and INFUSE-AMI patients.

Twenty-six patients enrolled in the PiCSO study and 80 control patients from INFUSE-AMI were available. After propensity score matching, 22 PiCSO patients and 56 INFUSE-AMI remained. Baseline variables were well matched between the groups. Mean infarct size (% total left ventricular mass) in PiCSO treated patients was 14.29% with 95% (9.22%, 19.35%), which was less than that in the INFUSE-AMI control group (21.20% with 95% CI (18.03%, 24.38%)), mean difference -6.92%, 95% CI equal to (-12.89%, -0.94%), p-value = 0.023.

CONCLUSIONS

In the present propensity matched analysis, initiation of PiCSO in patients with acute anterior MI immediately after flow restoration but before stenting was associated with a 32% relative reduction in 5-day infarct size. These findings have formed the basis for an upcoming randomized trial to determine the safety and efficacy of PiCSO in patients with anterior STEMI undergoing primary PCI.

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Direct stenting vs. pre-stent balloon dilatation in patients treated with orbital atherectomy: an ORBIT II subanalysis

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

AIMS

Direct stenting (DS) offers many potential advantages in appropriately selected lesions. Coronary artery calcification increases the complexity and risk of adverse events associated with percutaneous coronary intervention. This study aimed to examine the impact of DS after treatment with the Diamondback 360° Coronary Orbital Atherectomy System (CSI, St. Paul, MN).

METHODS AND RESULTS

ORBIT II was a single-arm trial enrolling 443 subjects at 49 US sites with de novo severely calcified coronary lesions. Of subjects with the orbital atherectomy (OA) device inserted (N=432), DS was utilized in 59.0% of cases. In this post-hoc sub-analysis procedural outcomes and 3-year major adverse cardiac event (MACE) rates were compared in subjects treated with pre-stent balloon dilatation versus DS after orbital atherectomy.
There were no differences in terms of gender, history of diabetes, renal function, or lesion location in the DS and pre-stent balloon dilatation groups, however, ACC/AHA lesion classification distribution was different, with more Type C lesions in the pre-stent balloon dilatation group. Procedural success was significantly worse in subjects with pre-stent balloon dilatation compared to those treated with DS (84.2% vs. 93.3%, p= 0.004), driven primarily by increased in-hospital myocardial infarction (MI, CK-MB > 3X ULN) (14.7% vs. 5.9%, p=0.003). Angiographic success was worse in the pre-stent balloon dilatation cohort (88.7% vs. 95.3%, p=0.01) as a result of increased incidence of the composite of severe angiographic complications (10.2% vs. 4.3%, p=0.02). However, no specific complication was determined to be significantly different between the two groups. At 3-year follow-up, MACE occurred more frequently in patients treated with pre-stent balloon dilatation (29.9% vs. 19.1%, p=0.006), driven by MI (17.1% vs. 7.1%, p=0.002) and TLR (11.5% vs. 5.1%, p=0.02).

CONCLUSIONS

The use of OA facilitates DS and is associated with a high procedural success rate with low procedural complications in select patients. The favorable outcome of DS after OA is sustainable at 3-year follow-up. Comparative randomized studies are needed to assess the optimal strategy after OA.

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Clinical utility of a luminal diameter correction factor for approximation of external elastic lamina based stent sizing with OCT: an ILUMIEN III substudy

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

AIMS

Controversy exists regarding the optimal measurement parameter to use for stent sizing by optical coherence tomography (OCT). In patients undergoing PCI with OCT guidance, stent diameter may be selected based on reference segment measurements of the external elastic lamina (EEL) or mean lumen diameter (MLD). MLD measurements afford the advantage of automated measurements and hence ease of use, while EEL-based measurements lead to larger stents yielding a minimal stent area similar to IVUS-guidance. An automated method of approximating EEL-based stent sizing would thus be desirable.

METHODS AND RESULTS

We sought to determine whether an MLD correction factor (MLDCorr) applied to automated lumen measurements could be used to choose similar stent diameters to EEL-based sizing, obviating the need to identify and measure the EEL. A correction factor for stent sizing was derived by subtracting the reference segment MLD from the EEL in OCT acquisitions from the ILUMIEN III study (n=140). In a separate validation cohort (n=100), stent diameter was determined by measuring reference mean EEL diameter (if ?180 degrees was visible) and compared to MLDCorr (MLD multiplied by the correction factor). The smaller of the proximal or distal reference diameters rounded down to the nearest 0.25mm was used to determine stent diameter for both direct EEL measurement and MLDCorr.

Baseline characteristics were well matched between the derivation and validation groups. Although EEL and MLD measurements were well correlated, at both the proximal (4.08±0.66mm vs. 3.14± 0.61mm,

CONCLUSIONS

EEL-based stent-sizing leads to selection of a significantly larger diameter stent compared to MLD-based stent sizing. While a correction factor may be applied to approximate MLD to EEL measurements, this leads to significant discordance in choice of stent sizing, including a potentially hazardous choice of larger stent. A universal MLD correction factor cannot be recommended to replace OCT-based EEL measurement for stent sizing.

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TAVR for the treatment of pure native aortic valve regurgitation

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

AIMS

Patients with NAVR and increased surgical risk are often denied heart valve surgery, there is an unmet need for a less invasive approach. Our objective was to evaluate the ?off-label? use of transcatheter heart valves (THV) for the treatment of pure native aortic valve regurgitation (NAVR).

METHODS AND RESULTS

In a retrospective cohort study of consecutive non-surgical candidates undergoing transcatheter aortic valve replacement (TAVR) for NAVR, we investigated device and clinical outcomes according to the Valve Academic Research Consortium-2 definitions. Between 2007 and 2017, a total of 254 patients (age 74±12 years, STS score 6.6±6.2%) with NAVR underwent TAVR with early (43%) or newer generation (57%) devices at 46 different sites. Device success was significantly higher in patients treated with newer as compared to early generation THV (82% vs.47%, p 8% (HR 3.6, [1.2-9.5]) and residual AR ? moderate (HR 2.8, [1.0-7.9]) were identified as independent predictors of 1-year mortality.

CONCLUSIONS

TAVR is a feasible treatment strategy in selected patients with NAVR that is associated with a considerable risk of THV malpositioning and residual AR. Although newer-generation devices were associated with better device and clinical outcomes, novel devices for the treatment of NAVR are warranted.

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Acute outcomes of a novel self-expanding transcatheter heart valve for valve-in-valve treatment (a pilot study)

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

AIMS

The Allegra Transcatheter Heart Valve (THV) is a novel, supra-annular, self-expanding nitinol valve, made from bovine pericardial tissue that is 18F compatible. Procedural results of safety, effectiveness and haemodynamic performance are reported and intermediate results at the time of PCR2018 will be presented.

METHODS AND RESULTS

The study is a preliminary pilot study to investigate the performance of the Allegra THV (New Valve Technology GmbH, Hechingen, Germany) for treatment of degenerated small surgical bioprostheses (internal diameter: < 22mm) at a single center in Germany. Follow-up visits? evaluations encompass the primary endpoint of all-cause mortality, safety endpoints, echocardiographic results, paravalvular leak and functional assessments.
Transvascular THV implantation was conducted in 18 patients with a degenerated bioprostheses and increased surgical risk (log EuroSCORE 23.2±9.3%) and successfully completed in 18 patients (acute device success 94.4%). The mean age was 78.9±4.9 years, 61% were female, and 83.3% were in NYHA class III/IV, the implanted THV size was 23 mm in all patients. Inner bioprosthesis diameter by MSCT was 19.5±1.5 (Perimeter: 61.5±4.8mm) and a low take off (< 8mm) of coronaries was found in 61% of the cases. Echocardiographic haemodynamic performance revealed an increase in mean aortic valve area from 0.8±0.2 cm2 at baseline to 1.4±0.3 cm2 at conclusion of the procedure ($p < 0.01$). Accordingly, the mean transaortic gradient decreased from 34.5±20.1 mmHg to 11.7±4.3 mmHg (

CONCLUSIONS

This novel self-expanding transcatheter valve with a supraannular valve function demonstrates to be effective with significant haemodynamic improvements after treatment of degenerated small surgical valves with favorable transvalvular haemodynamics. More data including 30 day results will be presented at PCR2018.

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Haemodynamic support during PCI with Impella percutaneous ventricular assist device: a single-centre experience

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

AIMS

Short-term support with percutaneous left ventricular assist devices (pLVAD) is emerging as an effective strategy to maintain haemodynamic stability and protect end-organ function during high-risk PCI. Our study aim was to analyse the outcomes of patients undergoing PCI with the Impella pLVAD (Abiomed, Danvers, MA) at our institution.

METHODS AND RESULTS

All patients undergoing PCI with Impella support at our hospital between October 2013 and December 2017 were included. Baseline, procedural, hospitalisation, and follow-up data were reviewed. The primary outcome was all-cause death during index admission and on follow-up. A total of 45 patients undergoing 47 procedures were identified. Mean age was 65.5±11.0 years, 81% of patients were male. The prevalence of diabetes was 44%. The indications for Impella insertion were: ACS with cardiogenic shock in 91%, and elective implantation for high-risk PCI (protected PCI) in 9%. Mean LVEF was 24.0±9.5%. In 30% of cases, concomitant support with ECMO (15%) and IABP (15%) was initiated prior to Impella insertion. Impella 2.5 was the most frequently used device (83%), followed by Impella CP (14%), and Impella RP (2%). In 38% of patients Impella was inserted before PCI, and in 62% during or after PCI. Mean number of diseased vessels was 1.9±0.8, and number of treated vessels was 1.3±0.5. Technical success was achieved in 85%. Mean duration of Impella support was 3.7±3.2 days. After Impella insertion, escalation to ECMO was required in 16%, and 9% of patients received a surgical ventricular assist device during hospital stay. Impella-related complications were as follows: access-site bleeding 7%, acute limb ischaemia requiring intervention 19%, haemolysis 21%. Other in-hospital complications were as follows: contrast-induced nephropathy 53%, renal replacement therapy 19%, stroke 7%, red blood cell transfusion 64%. The incidence of all these latter complications was higher in patients who also received ECMO. In-hospital mortality was 33%. LVEF at discharge was 34.4±13.2%. At a median follow-up duration of 69 days, the incidence of all-cause death was 47%.

CONCLUSIONS

Mechanical support with Impella pLVAD during cardiogenic shock and high-risk PCI is feasible and associated with good outcomes and reasonable rates of complications, considered the severity of clinical presentation of the study population.

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Diagnostic performance of angiography-derived FFR: a systematic review and Bayesian meta-analysis

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THEME: Coronary Interventions
TOPIC(S): Stable CAD

AIMS

The present systematic review and meta-analysis aimed to determine the diagnostic performance of angiography-derived FFR for the diagnosis of hemodynamically significant coronary artery disease.

METHODS AND RESULTS

A systematic review and meta-analysis of studies assessing the diagnostic performance of angiography-derived FFR systems were performed. The primary outcome of interest was pooled sensitivity and specificity. Fourteen studies comprising 1971 vessels were included in the final analysis. A Bayesian bivariate meta-analysis yielded a pooled sensitivity of 89% (95% credible interval 84% to 93%), specificity of 90% (95% credible interval 88% to 92%), positive likelihood ratio (+LR) of 9.1 (95% credible interval 7.2 to 11.4) and negative likelihood ratio (-LR) of 0.1 (95% credible interval 0.1 to 0.2). The summary area under the receiver-operating curve (SROC) was 0.84 (95% credible interval 0.66 to 0.94). Meta-regression analysis did not find differences between the methods for pressure-drop calculation (computational fluid dynamics vs mathematical formula), type of analysis (online vs offline) or software packages.

CONCLUSIONS

The accuracy of angiography-derived FFR was excellent to detect hemodynamically significant lesions with pressure-wire measured FFR as a reference. Computational approaches and software packages did not influence the diagnostic accuracy of angiography-derived FFR. A diagnostic strategy trial with angiography-derived FFR evaluating clinical endpoints is warranted.

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Incidence and predictors of poor in-hospital clinical success of rotational atherectomy

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

AIMS

Indications to percutaneous coronary intervention (PCI) expand to more and more complex lesions and that results in growing usage of rotational atherectomy (RA). Predictors of poor outcome including periprocedural and in-hospital complications after RA in the current era are still to be extensively determinated. The aim of the study was to assess predictors of poor in-hospital clinical success after PCI with the use of RA in all-comers population.

METHODS AND RESULTS

The primary endpoint of the study was the lack of clinical success. Clinical success was defined as composite angiographic success, no procedure related complications and no procedure related adverse events during hospitalization.

A total of 310 consecutive patients after 341 RA procedures were included in an all-comers observational study. The composite outcome was observed in 90 (26%) procedures, including the lack of angiographic success in 36 (11%), periprocedural complications in 33 (9,8%) and in-hospital adverse events in 73 (21,4%) procedures. Periprocedural complications included no/slow flow in 7 (2,1%), side branch occlusion in 7 (2,1%), dissection in 13 (3,8%) and permanent pacing in 6 (1,8%) procedures. In-hospital adverse events included death in 6 (1,8%), peri-procedural myocardial infarction in 38 (11,1%), target vessel revascularization in 4 (1,2%), contrast induced nephropathy in 9 (2,6%) and access site bleeding in 16 (4,7%) procedures.

The clinical variables associated with the lack of clinical success in multivariate analysis were lesion length (HR 0.97, 95% CI 0.95-0.99, p<0.001), low Syntax Revascularization Index (HR 1.03, 95% CI 1.02-1.04, p<0.001), female sex (HR 2.09, 95% CI 1.16-3.79, p=0.01), the use of Gp2b3b inhibitor (HR 0.08, 95% CI 0.01-0.58, p=0.01) and procedure time (HR 0.99, 95% CI 0.98-1.00, p=0.04).

CONCLUSIONS

Incidence of overall poor outcome including periprocedural and in-hospital complications reached 26%. Independent predictors of poor clinical outcome were lesion length, low Syntax Revascularization Index and female sex, that can help in preprocedural risk stratification of patients undergoing complex coronary intervention with RA.

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Mortality in patients with cardiogenic shock treated with the Impella CP microaxial pump for isolated left ventricular failure

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

AIMS

Cardiogenic shock (CS) is still associated with high mortality rates of around 50%. Intra-aortic counterpulsation had been frequently used in CS, but was previously found to provide no mortality benefit. We investigated the effect of an interdisciplinary and multiprofessional routine strategy of early invasive hemodynamic support in combination with complete revascularization in patients with CS before admission to our intensive care unit.

METHODS AND RESULTS

We analyzed all CS patients (mean age 62±13 years) presenting at our institution between 2013 and mid 2016, who received an ImpellaCP microaxial pump for isolated LV support (n=61). 61% (n=37) had been resuscitated before Impella insertion.

Overall mortality was 48% (n=29/61) at 30 days. 30-day mortality was higher in resuscitated patients (resuscitated: 65% (n=24/37), non-resuscitated: 21% (n=5/24)). When applying the inclusion/exclusion criteria of the SHOCK-II trial, eligible patients (n=25) had a markedly lower mortality (24% (n=6/25) at 30 days) compared to the published trial (~40% in both arms). The observed mortality of SHOCK-II-like patients in the registry was also lower compared to their predicted mortality using IABP shock II-score (49%) and CardShock-score (36%).

CONCLUSIONS

The results of this registry suggest that using a standardised protocol including early active hemodynamic support with ImpellaCP in CS in patients with isolated LV failure may be associated with improved outcomes and lower than previously reported or predicted mortality rates. Pre-implantation cardiac arrest critically influences observed mortality. The results support the case for a randomised trial.

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Veno-arterial-ECMO for the treatment of cardiogenic shock in primary PCI for STEMI, a multicentre experience

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

AIMS

Primary PCI (pPCI) is the cornerstone in the treatment of STEMI. STEMI can cause great haemodynamic instability through a mechanism of cardiac failure. Veno-Arterial(VA)-ECMO can provide haemodynamic support in patient suffering STEMI with cardiac failure but data on outcome and complications are lacking to prove the efficacy and safety of this new technique.

METHODS AND RESULTS

Methods:

An in-hospital registry was kept at two centres involving all patients who received VA-ECMO treatment for haemodynamic support during pPCI for STEMI. All patients were analysed for age, sex, previous medical history, coronary vessels involved, Synergy between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery (SYNTAX)-score Survival after Veno Arterial-ECMO (SAVE) score, left ventricular function prior to admission, survival, complications, length of ECMO treatment and length of stay.

Results:

Between 2009 and 2016 16 patients underwent veno-arterial ECMO support for the treatment of cardiogenic shock in pPCI for STEMI. The majority of patients was male 81% (13/16) with a median age of 61 (47-75) years and 4/16 patients had a history of coronary artery disease in the form of a previous PCI. None of the patients had impaired left ventricular function prior to admission.A cardiac arrest was witnessed in 82% (13/16) of the patients. The culprit lesion was a left main in 32% (5/16), a left anterior descending artery in 43% (7/16) and a right coronary artery in 25% (4/16). Concomitant coronary artery disease was present in 56% (9/16) of which 25% (4/16) was a CTO. Complete revascularisation of the culprit lesion was achieved in 81% (13/16) and 38% (6/16) of the patients received combined IABP support as well.

The median SYNTAX score was 26.5 (4-48.5) and the median SAVE-score was -6 (-2?11) which represents an estimated survival of 25-35%.

Survival to discharge was 75% (12/16) and one-year survival was 38% (6/16), 5/16 (32%) patients have not yet reach the one-year survival point but are still alive and one patient died of an aspiration pneumonia due to neurological impairment caused by prolonged resuscitation. Good neurological outcome was achieved in 69% (11/16) of the patients. Patient related complications occurred in 43% (7/16), 32% (5/16) patients suffered a haemorrhage at the cannula site and 13% (2/16) developed limb ischaemia. There were no ECMO hardware related complications.

The mean time on ECMO was 5 (1-10) days, the mean time in intensive care was 20 (1-68) days and the mean time in hospital was 30 (1-82) days.

CONCLUSIONS

VA-ECMO for the treatment of cardiogenic shock has a higher than predicted survival rate and a relatively low complication rate. Three quarter of the patients survived even when admitted with a cardiac arrest.

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The prevalence of plaque erosions and calcium nodule associated thrombus in non- culprit FFR-negative lesions of diabetic patients ? data from the COMBINE study

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

AIMS

Plaque erosion (PE) and calcium nodule associated thrombus (CNtr) has already been related to new onset of acute coronary syndromes, however its prevalence in non-culprit lesions in high-risk diabetes mellitus patients is unknown

METHODS AND RESULTS

The optical coherence tomography (OCT) analysis was performed in patients enrolled to the COMBINE (OCT-FFR, NCT02989740) study, a multi-center, prospective natural history study which assesses non-culprit lesions to better predict adverse events in diabetes. OCT scrutinized every lesion to assess its length, minimal lumen area (MLA), and its morphology. If calcification occupied more than 270 degrees of the lumen circumference in OCT, calcium ring was detected. PE was defined as surface irregularity, and as any thrombus visible in underlying intact plaque or as thrombus without superficial lipids and calcium. CNtr was defined as calcium protruding to the lumen superimposed with thrombus. During the analyses, the thickness of the fibrous cap covering lipid plaque was also measured.

236 FFR negative lesions in 200 patients were imaged by OCT. Fourteen (6%) PE and eleven (4%) CNtr was found in 26 (11%) lesions in 24 (12%) of patients. There was no difference in MLA (mm2, 2.5 IQR2.0-3.3 vs. 2.4 IQR1.8-3.2, p=0.449) and FFR values (0.88 IQR0.83-0.92 vs. 0.88 IQR0.84-0.92, p=0.553) between lesions with or without PE/CNtr lesions. No clinical factors like smoking (HR 1.613, 95% CI0.167-2.062, p=0.406) or acute coronary syndrome (HR 0.975 95%CI 0.316-3.014, p=0.965) were found to increase the risk of PE/CNtr occurrence. Although, patients with PE tend to be elder as compared to those without PE (72.00±2.13 vs. 67.57±0.66, p=0.084). PE/CNtr were found in longer lesions vs. PE/CNtr negative lesions [mm, 30.65 (IQR 17.60, 40.60) vs. 21.1 (IQR 14.1, 30.10), p=0.020). CNtr occurred more often in lesions with calcium ring (HR 1.735 CI 0.165-1.925, p=0.024). There was no distinctive plaque morphology which increases the risk of plaque erosion in terms of fibrous cap thickness (HR 20.439 95%CI 0.137-3038,134 p=0.237), calcium (HR 2.025 95%CI 0.253-16.215, p=506) or lipid (HR1.518 95%CI 0.410-5.620, p=0.532) presence.

CONCLUSIONS

PE and CNtr occurred at non-culprit lesions of diabetic patients, especially in long lesions. Heavy calcified lesions increased the risk of CNtr presence. In non-culprit lesions, PE tended to occur in elder diabetic patients.

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Balloon-expandable transcatheter valve positioning during aortic valve-in-valve procedures and clinical outcomes

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

AIMS

Aortic valve-in-valve (ViV) is associated with elevated post-procedural gradients. Our objective was to evaluate whether there is an association between positioning of SAPIEN 3 (S3) using different strategies and clinical outcomes.

METHODS AND RESULTS

S3 aortic ViV procedures in stented bioprostheses were evaluated utilizing the VIVID Registry. Positioning strategy 1 evaluated the relation between the surgical valve ring and the central marker. Positioning strategy 2 evaluated the relationship between the top of the crimped S3 in relation to the top of surgical valve stent posts. Coaxiality was also measured. The incidence of a combined endpoint of final mean gradient ? 30 mmHg or permanent pacemaker use between groups with high positioning (strategy 1: central marker above the surgical valve ring, strategy 2: top of crimped S3 above the top of stent post) and low positioning was compared.

A total of 112 patients were included (65% male, 76.5 ± 9.7 years, STS 8% ± 7.6). Baseline characteristics did not differ between high or low implantation groups. High positioning with both methods was associated with a decreased incidence of the combined endpoint (strategy 1: high positioning 8.9% vs. low positioning 33.3%, p = 0.001, strategy 2: high positioning 11.5% vs. low positioning 30%, p = 0.05). Strategy 1 demonstrated greater correlation to final implantation depth than strategy 2 (R-squared 0.5 and 0.08, p < 0.001 and p = 0.02, respectively). We found no association between coaxiality (median: 8 degrees, IQR: 4.3 ? 13 degrees) and clinical outcomes.

CONCLUSIONS

High positioning is associated with improved clinical outcomes with S3 aortic ViV procedures using different positioning strategies. Positioning using central marker method correlated better with post implantation depth.

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Rotation speed drop during rotational atherectomy is associated with troponin I elevation during PCI

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

AIMS

Only few data is available for myocardial injury by rotational atherectomy (RA). The aim of this study is to investigate procedural factors that affected troponin I (TnI) elevation during percutaneous coronary intervention (PCI) with RA.

METHODS AND RESULTS

This is a retrospective single-center analysis of consecutive 134 patients treated by RA between January 2010 and December 2016. Out of these, patients whose TnI level pre-procedure was >1.0ng/ml were excluded in the study. Difference of TnI levels between pre-procedure and 6-12 hours after procedure were analyzed. Patients were divided into two groups according to the difference of TnI level: Elevation group vs. Non-elevation group. The cutoff value was arbitrarily defined as 1.0ng/ml in the study. Patient background and procedural factors were evaluated.

Elevation group was 49 cases (38%) and Non-elevation group was 79 cases (62%) in the cohort. There were no differences between the groups in patient characteristics. In procedural factors, maximum burr size (Elevation group vs. Non-elevation group: 1.60±0.24 mm vs. 1.56±0.22 mm, P=0.56), total ablation time (Elevation group vs. Non-elevation group: 97±65 sec. vs. 92±53 sec., P=0.62), longest ablation time (Elevation group vs. Non-elevation group: 13±5 sec. vs. 13±4 sec., P=0.81), and Burr/Stent ratio (Elevation group vs. Non-elevation group: 0.53±0.09 vs. 0.55±0.09, P=0.23) were similar between the groups, whereas maximum rotation speed down was higher (9020±2602 rpm vs. 7813±2395 rpm, P=0.01), total implanted stent length was longer (47±21 mm vs. 37±20 mm, P=0.03), and maximum implanted stent diameter was larger (3.0±0.4 mm vs. 2.9±0.4mm, P=0.03) in Elevation group than in Non-elevation group.

CONCLUSIONS

Maximum rotation speed down as well as total implanted stent length and maximum stent diamter is associated with TnI elevation during PCI with RA.

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Selective CRP apheresis as a new treatment option in AMI: first results of the CAMI1 study

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Background: High serum levels of C-reactive protein (CRP) are associated with a poor prognosis in STEMI. CRP may contribute to myocardial damage in STEMI by activating the complement system. In animal experiments, CRP removal after STEMI reduces infarct size and results in a significantly better left ventricular ejection fraction (LVEF). The CRP adsorber (PentraSorb® CRP) allows selective lowering of CRP serum levels in humans. Here, we present preliminary data of the ongoing human multi-center matched-control pilot study CRP-apheresis in Acute Myocardial Infarction (CAMI1).

METHODS AND RESULTS

Methods: After complete coronary revascularization, 23 Patients with STEMI received CRP apheresis, whereas 23 patients treated by standard protocols served as controls. CRP apheresis was performed 24(±12) hrs and 48(±12) hrs after onset of symptoms. In case of a rapid increase in CRP serum levels following the second session, a third treatment was carried out 24(±12) hrs later. In each apheresis session, 6000 ml plasma were treated via peripheral venous access. Primary study endpoint was myocardial infarction size as determined by Cardiac Magnetic Resonance Imaging (MRI) 5±3 days and 12±2 weeks after STEMI.

Results: Apheresis sessions were well tolerated with no relevant side effects. CRP baseline levels were 25 mg/l (median) (range 12-279 mg/l). CRP apheresis resulted in an average 64% reduction in CRP plasma levels. Myocardial infarct size in the CRP apheresis-treated STEMI patients was 51% smaller (p=0.0035) compared to controls, and circumferential strain was 12% (p=5x10-10) better while the longitudinal strain was 17% (p=9x10-11) better already 5±3 days after STEMI. In the follow-up period (? 12 months), 3 major adverse cardiac events (MACE) occurred in the control group and none in the CRP apheresis group.

CONCLUSIONS

Conclusion: CRP apheresis following STEMI seems feasible and safe. First results show a significant beneficial effect on myocardial infarction size and wall motion. Selective CRP apheresis may emerge as a new therapeutic approach in the treatment of acute myocardial infarction.

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Mechanistic effects of coronary intravascular lithotripsy in severe coronary artery calcification by OCT: disrupt coronary artery disease OCT

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

AIMS

Coronary artery calcification (CAC) adversely affects procedural and clinical success. Lithoplasty is a technique based on lithotripsy, in which multiple emitters mounted on a traditional balloon catheter platform create diffusive circumferential pulsatile mechanical energy to disrupt calcified plaque and prepare the vessel for stent implantation. This study sought to determine the mechanistic effects of lithoplasty on severe CAC and subsequent stent placement using optical coherence tomography (OCT).

METHODS AND RESULTS

The lithoplasty balloon, sized 1:1 to the reference artery, was inflated to 4atm and 10 pulses delivered followed by dilatation to nominal pressures, repeated as necessary. OCT was performed pre-lithoplasty, post-lithoplasty and following stent implantation. Calcific plaque was defined as low-attenuation signal with sharply delineated borders. The degree of calcification was stratified into tertiles according to calcium volume. To determine the number of fractures per lesion, the fracture lines were traced for continuity frame by frame throughout the lesion. Results. 31 patients in 5 countries were treated with lithoplasty and underwent serial OCT imaging. Lithoplasty was performed using 2.0 [IQR 1,2] catheters, delivering 4.0 [IQR 2,7] treatments totaling 94±75 pulses at an inflation pressure of 6.0 [IQR 6,6] atm for 107±56 seconds. Using lithoplasty for vessel preparation stent delivery was facilitated in all cases followed by stent implantation where the percent diameter stenosis decreased from 65.1±14.4% to 13.9±12.5%. Prior to lithoplasty, calcification length on OCT was 20.6±9.9mm, calcification arc was 130±51.6°, and calcium volume index 2753±1794mm·°. Following lithoplasty, intraplaque calcium fracture was identified in 43% of lesions, with circumferential multiple fractures noted in more than 25%. The frequency of calcium fractures per lesion increased in the most severely calcified plaques (highest tertile vs lowest tertile, P=0.009), with a trend towards greater incidence of calcium fracture (77.8% vs 22.2%, P=0.057). Post-lithoplasty, mean acute area gain was 2.1 mm2, which further increased with stent implantation, achieving a minimal stent area of 5.94±1.98mm2 and mean stent expansion of 112±37.2%. Deep dissections, as part of the angioplasty effect, occurred in 13% of cases and were successfully treated with stent implantation without incidence of acute closure, slow flow/no reflow, or perforation.

CONCLUSIONS

High-resolution imaging by OCT delineated calcium modification with fracture as a major mechanism of action of lithoplasty in vivo, demonstrating efficacy in achieving significant acute area gain and favorable stent expansion.

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Acute mechanical unloading prior to reperfusion is cardioprotective and limits the development of heart failure after myocardial infarction

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Ischemic heart failure after acute myocardial infarction is a major cause of morbidity and mortality. We recently reported that activation of a trans-valvular axial-flow pump in the left ventricle and delaying myocardial reperfusion, known as Primary Unloading, limits infarct size. Whether this acute decrease in infarct size results in a sustained improvement in cardiac function remains unknown. We explored the cardioprotective mechanisms and the late-term impact on myocardial function associated with Primary Unloading in a preclinical model of acute myocardial infarction.

METHODS AND RESULTS

Adult male swine were subjected to Primary Reperfusion or Primary Unloading after 90 minutes of left anterior descending artery occlusion. Compared to Primary Reperfusion, 30 minutes of Primary Unloading was necessary and sufficient prior to reperfusion to limit infarct size 28 days after acute myocardial infarction. Whole transcriptome gene-expression analysis identified that compared to Primary Reperfusion, Primary Unloading was associated with a global shift in gene expression within the infarct zone favoring preservation of genes associated with mitochondrial integrity and cellular respiration. Compared to Primary Reperfusion, Primary Unloading for 30 minutes preserved myocardial expression of the cardioprotective cytokine, stromal derived factor 1 alpha (SDF1a) protein levels within the infarct zone and promoted a shift towards anti-apoptotic signaling within the infarct zone. Primary Unloading reduced activity levels of proteases known to degrade SDF1a. Blocking the cognate SDF1a receptor, CXCR4, attenuated the cardioprotective effect of Primary Unloading supporting a role for SDF1a in the mechanism of cardioprotection. Finally, Primary Unloading reduced LV scar size, improved cardiac function, and limited cardiac expression of markers associated with heart failure and maladaptive remodeling 28 days after acute myocardial infarction.

CONCLUSIONS

This is the first report to identify that Primary Unloading of the left ventricle for 30 minutes before, not after, reperfusion prevents the adverse consequences of acute myocardial infarction by triggering a global shift in gene expression within the infarct zone and by limiting degradation of the cardioprotectvive cytokine SDF1a. Primary Unloading promoted a durable reduction in LV scar with improved systolic function 28 days after acute myocardial infarction. These findings identify a novel approach to limit the onset of ischemic heart failure after acute myocardial infarction.

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Drug-eluting resorbable magnesium scaffold implantation in STEMI: a pilot study

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

AIMS

Magnesium-based BRS have demonstrated favorable clinical outcomes in stable coronary artery disease patients. However, to date data are lacking regarding use of this novel type of BRS in the setting of STEMI. Therefore we sought to assess feasibility and short-term clinical outcomes associated with magnesium-based BRS implantation in the setting of primary percutaneous coronary intervention for STEMI.

METHODS AND RESULTS

Single-center prospective non-randomized pilot study. Patients admitted for STEMI were enrolled according to pre-specified inclusion and exclusion criteria. Primary endpoint was device-oriented composite endpoint (DOCE) including cardiac death, target vessel myocardial infarction and target lesion revascularization (TLR) within 30 days of the index procedure. Secondary endpoints were procedural success, any probable/definite scaffold thrombosis and DOCE at subsequent follow-up.

From 1st December 2016 to 30th October 2017, 18 patients were included. Follow-up data were available for 17 patients (94%). There was no primary endpoint event. Procedural success was 100%. Over the extended follow-up period (147 ± 75 days), one case of TLR occurred 102 days after the index procedure, and there was no case of definite or probable scaffold thrombosis.

CONCLUSIONS

The results of this pilot study, the first assessing feasibility and clinical outcomes associated with magnesium-based BRS implantation in selected STEMI patients seem reassuring with favorable short-term clinical outcomes, and absence of definite/probable scaffold thrombosis. These results should prompt further research including randomized controlled trials evaluating magnesium-based BRS implantation in the setting of STEMI.

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Veno-arterial ECMO therapy in patients with cardiac arrest - Insight from the first German retrospective multicentre analysis: the Lazarus register

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

AIMS

The use of mechanic circulatory support with VA-ECMO therapy is an emerging therapeutic adjunct in patients with refractory cardiac arrest (ECPR), however, there is only limited evidence regarding patient selection and benefit. This first German multicenter register study (Lazarus register) analyzed the results of ECPR therapy as a rescue approach in patients with out-of-hospital-(OHCA) and in-hospital cardiac arrest (IHCA)

METHODS AND RESULTS

This retrospective multicenter study included 206 patients with cardiac arrest and ongoing CPR or return of spontaneous circulation (ROSC) with refractory cardiogenic shock, who were treated with V-A-ECMO therapy between January 2009 and June 2016 at the Asklepios Klinik St Georg and the Kerckhoff Klinik Bad Nauheim. The study cohort consisted of 153 (75%) male and 53 (25%) female patients. In total 106 (51%) patients suffered from IHCA, mostly within the first week of stay (median 1d, Mean 5±18d, 90%-percentile 9.3). In 100 (49%) patients the CA occurred as an OHCA, mostly witnessed (81%). The mean conventional cardiopulmonary resuscitation (CCPR) time was 54±43 minutes. The mean initial pH-value was 7.0±0.2. The interval between the beginning of CCPR and ECPR (CCPR-ECPR-interval) was significantly longer in the OHCA cohort (67±32 min vs. 42±49 min,

CONCLUSIONS

The use of ECPR might be a valuable therapeutic adjunct in patients with refractory CA and a reversible genesis. The identification of patients who might benefit of this approach needs quickly detectable and reliable markers. The Lazarus-Register is the first German multicenter register study in this context. Our results suggest patients with an CCPR

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Effect of intra-coronary tirofiban following aspiration thrombectomy on infarct size, in patients with large anterior STEMI undergoing primary PCI

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

To evaluate effect of intra-coronary delivery of bolus Tirofiban following aspiration thrombectomy on reduction of infarct size using cardiac magnetic resonance imaging (cMRI) in patients with large anterior STEMI undergoing primary PCI.

METHODS AND RESULTS

A Prospective single-blind randomized controlled trial was conducted between August, 2015 and November, 2016. 50 patients with large anterior STEMI were screened at 2 sites in one country (Egypt). Aspiration thrombectomy was performed in all patients using a 6 F aspiration catheter. Patients were randomized to IC Tirofiban (Study group) and no IC Tirofiban (control group). To ensure high intra-thrombus drug concentrations, a 25 mcg/kg bolus of Tirofiban was administered locally at the site of the infarct lesion via the aspiration catheter after flushing of the aspiration catheter well.

Primary end point: Infarct Size at 30 Days measured by cMRI. Secondary end point: Myocardial blush grade at the end of the PCI procedure. Major Adverse Cardiac and Cerebrovascular events (MACCE) at 30 days defined as re-infarction, stroke, severe heart failure and death.

Evaluable MRI results at 30 days where present in only 40 of 50 patients (80%), with the most common reasons for missing data being patient re-infarction prior to 30 days and inability to tolerate the procedure. Patients randomized to IC Tirofiban compared with no IC Tirofiban had a significant reduction at 30 days infarct size (median, 15451 mm3 - IQR, 17404 mm3 - n=20) vs (median, 43828 mm3 - IQR, 49599 mm3 - n=20) P value= 0.002. Myocardial blush grade results at the end of the PCI where present in 50 patients, randomized to IC Tirofiban compared with no IC Tirofiban had no significant difference (P value= 0.67). There is no significant difference in MACCE at 30 days between patients received bolus IC Tirofiban and patients who did not receive (P value= 0.723).

CONCLUSIONS

In patients with large anterior STEMI presenting early after symptoms onset and undergoing primary PCI, infarct size at 30 days was significantly reduced by bolus IC Tirofiban delivered to the infarct lesion site following manual Aspiration thrombectomy via aspiration catheter. There is no significant difference in MACCE at 30 days between patients received bolus IC Tirofiban and patients who did not receive.

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In vitro flow and OCT comparison of two bailout techniques after failed after provisional T-stenting for bifurcation PCI

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

AIMS

To evaluate, in vitro, two bailout side branch stenting techniques after failed provisional T-stenting. Provisional T-stenting with bailout side branch (SB) stenting is used to treat most coronary bifurcation stenoses. We aimed to compare flows and stent strut apposition of T And Protrusion (TAP) versus Reversed String (RS) bailout techniques using a flow simulator, optical coherence tomography (OCT), in silicon bifurcation phantoms with different angulations between branches.

METHODS AND RESULTS

Ten 30°-angle and ten 60°-angle silicon bifurcation phantoms were used. After performing provisional T-stenting, TAP and RS techniques were compared in 5 phantoms with 30° and 60° angles. Flow measurement was performed using absolute coronary flow and particle image velocimetry techniques. Strut apposition was evaluated using OCT.

Each case was successfully performed and completed. Longer fluoroscopy time in the RS group compared to the TAP group (404 ± 137 vs. 267 ± 47 seconds, p=0.043) was observed. Flow analyses showed that disturbed flow regions were observed in the vicinity of floating struts protruded into the lumen both regardless of TAP and RS techniques. OCT analysis showed a higher proportion of floating struts protruding into the main branch with TAP compared to RS, respectively (12% vs. 3%, p=0.009) in both angles (11 % vs. 1% with 60°, p= 0.006 and 13% vs. 6% with 30°, p=0.15).

CONCLUSIONS

RS reduces the proportion of floating struts protruding into the main branch compared to TAP, at comparable flow rates. Clinical studies are needed to evaluate feasibility and potential clinical benefit of this technique.

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Insights in neurological events with a self-expanding repositionable transcatheter heart valve ? a forward substudy

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

AIMS

In comparison to the first generation CoreValve transcatheter bioprosthesis, the Evolut R self-expanding transcatheter aortic valve is associated with lower adverse event rates. Yet, stroke after TAVI is still associated with poor prognosis. We sought to determine the predictors of early stroke following TAVI with a self-expanding repositionable valve in real-world practice.

METHODS AND RESULTS

The Evolut R FORWARD Study is a multicentre, prospective, single-arm, observational post-market study to document safety and performance of the Evolut R system (23 mm, 26 mm or 29 mm valve sizes, Medtronic, Minneapolis, MN, USA) in a routine hospital setting at 53 centres in 20 countries. Eligible patients had symptomatic native aortic valve or surgical bioprosthesis stenosis and were deemed at least at high risk of surgical mortality/morbidity based on Heart Team assessment. The Evolut R is a self-expanding, supra-annular valve within a conformable nitinol frame that can be partially or fully repositioning during implant to assist with accurate placement. Use of embolic protection devices was left to the operator?s discretion. The diagnosis of stroke events was based on Valve Academic Research Consortium-2 and adjudicated by an independent clinical event committee. A neurological event included any stroke or transient ischemia attack (TIA). Antithrombotic medication was based on standard clinical practice at each investigational site. The presence of atrial fibrillation was based on site-reported EKGs.

A total of 1038 patients underwent attempted implant of the Evolut R valve. Overall, the mean age was 81.8±6.2 years, 64.9% were women, the mean Society of Thoracic Surgeons score was 5.5±4.5%, the mean EuroSCORE II was 5.7±5.0%, 72.0% had New York Heart Association class III/IV symptoms and 33.9% were considered frail. A neurological event up to 30 days occurred in 32 patients (3.1%). Age and frailty were associated with a higher risk for a neurological event at 48 hours (OR: 1.11 [1.01-1.22] and 2.99 [1.21 ? 7.38], respectively) and 30 days (OR: 1.08 [1.01-1.15] and 2.58 [1.27-5.26], respectively). A filter-based embolic protection device was used in 43 patients (4.1%). Patients treated with an embolic protection device were younger (79.0 ± 8.5 vs. 81.9 ± 6.1, p = 0.03) but had more peripheral arterial disease (51.2% vs. 21.6%, p < 0.001) including severely atherosclerotic aorta (21.4% vs. 10.8%, p = 0.03). Retrospective, post-hoc analysis of the incidence of stroke events at 48 hours and 30 days in patients with vs without use of embolic protection devices were 0% (0/43) vs. 2.0% (20/995), p = 0.43, and 2.3% (1/43) vs. 3.1% (31/995), p = 0.36, respectively.

CONCLUSIONS

Implantation of an Evolut R transcatheter heart valve was associated with a low neurological event rate. Older

age and frailty were associated with a higher risk for stroke.

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Multicentre evaluation of a novel 120µm novolimus-eluting, fully BRS: 12-month clinical and six-month 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 ± 10 years of age, 20% presented with diabetes mellitus, 26% were current smokers, 84% and 70% had hypercholesterolemia and hypertension respectively. Complex Type C lesions were present in 34% of patients. All patients underwent clinical and angiographic follow-up, approximately 50% of patients underwent IVUS and OCT assessment at 6 months. Clinical MACE results were excellent with no events reported. Late lumen loss was 0.19 ± 0.25mm with no scaffold thrombosis. Clinical results through 12 months and full 6-month multimodality imaging results will be presented.

CONCLUSIONS

The 120 µm DESolve® Cx Novolimus-Eluting BCSS offers unique characteristics and has demonstrated excellent safety and efficacy in this study through 6 months, 12-month and full 6-month imaging results will reported.

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Impact of prosthetic valve regurgitation quantified by cardiac magnetic resonance imaging on long-term mortality after TAVI

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

AIMS

Prosthetic valve regurgitation (PVR) is more common after transcatheter aortic valve implantation (TAVI) than after surgical aortic valve replacement, and has been linked to increased mortality. Cardiac magnetic resonance-derived regurgitant fraction (CMR-RF) outperforms echocardiography in terms of reproducibility of PVR quantification, as well as in terms of mid-term prognostication. We sought to investigate the impact on long-term mortality and to define the optimal cut-off value of CMR-RF from a large single-center TAVI database.

METHODS AND RESULTS

In 444 patients undergoing TAVI, CMR-RF of PVR was measured at a median of 12 (IQR, 8-19) days after the procedure. Clinical follow-up (up to 1095 days) was complete in 426 patients (96%). All-cause mortality at 3 years was the primary end-point and was met in 58 patients (13.6%).

The median CMR-RF for the entire population was 3.7% (IQR, 1.6-7.1%) and averaged 7.5±9.8% in patients who died and 5.2±5.4% in those who survived beyond 3 years after TAVI. On ROC curve analysis, a cut-off value of 18-20% yielded the highest sum of sensitivity and specificity for the prediction of 3-year mortality. Patients were accordingly stratified according to CMR-RF into two groups, non-significant PVR (CMR-RF< 20%) and significant PVR (CMR-RF?20%). Mortality at 3 years post-TAVI was significantly higher in patients with CMR-RF?20% (41.2%) than in patients with CMR-RF<2ish0% (12.4%, log rank p=0.040, HR, 2.24 [95% CI, 1.02-4.95], p=0.046).

CONCLUSIONS

CMR-RF assessed early after TAVI can predict long-term mortality. A lower than previously thought cut-off value of CMR-RF could be more clinically relevant in the post-TAVI setting.

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Self-expandable valve for the treatment of bicuspid aortic valve stenosis: a multicentre registry

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

AIMS

Transcatheter aortic valve implantation (TAVI) has shown promising results in the treatment of symptomatic severe aortic stenosis of tricuspid aortic valves. However, few data are currently available on bicuspid aortic valves treatment.

METHODS AND RESULTS

Methods: All patients with severe symptomatic aortic stenosis in bicuspid aortic valves treated with TAVI with Symetis ACURATE in 6 European centres were included in this analysis.

Results: The Symetis Acurate implantation in bicuspid valve registry included consecutive 54 patients with a proven diagnosis of bicuspid aortic stenosis. The mean age of the patients was 80 ± 5.3 years and the mean STS score was 4.7 ± 2.7. A high proportion of the patients was in New York Heart Association class III-IV (n=46, 85.1%). In most of the patients (n=45, 83.3%) the transfemoral route was preferred over the transapical approach. The computed tomography scan identified 49 patients (90.7%) with a type 1 bicuspid valve, 2 patients (3.7%) with a type 0 bicuspid valve and in 1 case (1.8%) with a type 2 bicuspid valve. CT scan revealed in most of the cases a moderate (n=25, 46.2%) or severe (33.3%) burden of calcifications on the aortic valve.

Predilation of the native valve was performed in most of the cases (n=51, 94.4%) and the Acurate M was the mostly used size (n=14, 48.1%). The rate of post dilatation was 57.4% and was especially required among patients with severe calcifications of the aortic valve. The overall rate of device success was 90.7%: in 4 cases (7.4%) a residual moderate perivalvulr leak was accepted, in one case the initial implant of Symetis was characterized by malposition with significant perivalvular regurgitation that required the implant of a second Sapien 3 29 mm with optimal final result. Other complications were one cardiac tamponade secondary to wire perforation successfully managed with pericardial drainage and one coronary occlusion. At 30-days clinical follow-up, 2 (3.7%) deaths (one patient died as consequence of a ventricular septal defect which lead to refractory heart failure, the other patient died of mesenteric ischemia) and 5 (9.2%) neurological events [one transient ischemic attach (1.8%), one disabling stroke (1.8%) and 3 non disabling strokes (5.5%)] were reported. The rate of moderate perivalvular leak was 7% (n=4). The rate for pacemaker insertion was 9.2% (n=5) and one case was secondary to an advanced conduction disturbance that occurred after discharge. After the procedure patients experienced an improvement in their NYHA functional class with significant reduction in the mean transvalvular gradient (9.8±4.2 mmHg).

CONCLUSIONS

This preliminary analysis shows that the use of Symetis ACURATE in bicuspid aortic valves is feasible and has acceptable 30-days outcome. Larger studies are needed to confirm our preliminary findings.

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Evaluation of stent and side-branch opening after single-stent technique with and without kissing balloon after deployment of new coronary stents

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

AIMS

Bifurcation lesions account for approximately 15% of all percutaneous coronary interventions. Provisional single stenting remains the recommended treatment. Novel stents are available but mechanical and clinical comparisons are lacking. The aim of this study is to evaluate stent characteristics and side-branch (SB) opening after single stent technique with currently available coronary stents with and without kissing balloon (KB) strategy.

METHODS AND RESULTS

Four new devices are evaluated: Xience (Abbott Vascular, USA), COMBO (OrbusNeich, The Netherlands), Supraflex (SMT, India) and Stentys (STENTYS, France). All devices are deployed with single stent technique in identical silicon bifurcation models (diameter: main branch 4.0mm, SB 3.5mm). After deployment 2 strategies were evaluated: A. Balloon dilatation SB and main branch post-dilatation B. Balloon dilatation SB and final KB. Micro-Computed Tomography (micro-CT) was used to visualize the dimensions of the SB opening, and to evaluate any stent deformation. Micro-CT assessed SB opening and stent deformation adequately. 2D and 3D pictures are available for presentation. SB opening with main branch post-dilatation resulted in no deformation of the stent, but limits opening of the SB in all stents. Stenting with KB resulted in larger SB opening (although limited with Stentys) but at the cost of stent deformation, most evident in Supraflex.

CONCLUSIONS

With new coronary stents, KB resulted in a larger SB opening for all stents in bifurcation models. However, stent deformation seems frequent after KB strategy.

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TAVR with the self-expanding Portico valve system: results from the Copenhagen TAVR registry

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

AIMS

This study aimed to investigate the safety and clinical efficacy of the PorticoTM transcatheter aortic valve system as used in a real-world, all-comers patient population with severe aortic valve stenosis

METHODS AND RESULTS

This single centre registry study evaluated the PorticoTM TAVR system (St. Jude Medical, Minnesota, USA) in an all-comers population including 216 patients with severe, symptomatic aortic stenosis with a low-intermediate risk profile (mean STS risk score: 4.3% ± 3.0%). Implantations were performed using transfemoral (91.2%), transsubclavian (5.6%) and transcaval (3.2%) access. Valve Academic Research Consortium (VARC)-defined device success was achieved in 94%. At 30 days post-TAVR, mortality and stroke rates were 2.3% and 0.5%, respectively. Early safety was achieved in 91.7%. Compared to baseline, there was an improvement in valve hemodynamics at 30 days, with increased aortic valve are (AVA) from 0.7 ± 0.1 cm2 to 1.8 ± 0.3 cm2 ($p< 0.01$) and reduced mean transvalvular gradient from 48.1 ± 14.0 mmHg to 7.0 ± 3.0 mmHg (

CONCLUSIONS

The PorticoTM TAVR system was safe to implant and achieved a high device success rate. With learning curve effects, the device achieves very low rates of PVL and pacemaker implantation as well as provides excellent clinical and hemodynamic outcomes through one year.

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Long-term results of endovascular AAA repair with short/absent neck: single-centre experience

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THEME: Peripheral Interventions
TOPIC(S): AAA

AIMS

To analyse clinical and long-term results and used techniques of endovascular abdominal aneurism repair (EVAR) in patients with short necks

METHODS AND RESULTS

69 patients with AAA, who underwent endovascular procedure, were retrospectively analysed. We performed 11 emergent interventions and 48 planned procedures. In 10 patients combined procedures were done: visceral EVAR+coronary stenting, EVAR+visceral stenting, EVAR+TAVR, EVAR+thoracic aneurism repair. In general 32 cases were considered as ?complex anatomy? (26% - neck of aneurism was less then 10 mm, in 21.7% neck was angulated >900, 5.8% - need for chimney technique).

Technical success was achieved in all 69 cases (100%). Total complication rate was slightly higher in the group of complex anatomy (15.5% vs 13.5%, p>0.05). Migration of stent-graft with type I endoleak formation was observed in 1 case in each group (abdominal extensor was used to treat complication). To perform successful implantation in short (angulated) neck as first step we pay particular attention for main body access side to achieve maximum possible alignment. Opening proximal part of main body on the soft part of hard wire didn?t prove efficacy in our practice. As the most effective ?tip and trick? we use opening main body higher then renal arteries level until contralateral gate opening, with further precise positioning in infrarenal segment by simple controlled pulling. In follow-up period (2.5+1.4 y.) we observed 1 complication ? renal stent graft thrombosis (due to aspirin cancelling) in chimney patient, resolved by recanalization with angiographic succe

CONCLUSIONS

Knowledge of different technical manipulations with instruments allows to perform successful interventions in complex anatomy, including short and/or angulated neck. ?Chimney technique? was safe and effective in our 4 patients

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Left ventricular remodelling and one-year clinical outcome after immediate vs. deferred stent implantation in primary PCI

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

Impact of Immediate Stent Implantation Versus Deferred Stent Implantation on Infarct Size and Microvascular Perfusion in Patients With ST segment?Elevation Myocardial Infarction (STEMI) (INNOVATION) study reported routine deferred stenting (DS) did not reduce infarct size and microvascular dysfunction. We aimed to evaluate the impact of DS on left ventricular (LV) remodeling and 1-year clinical outcome after STEMI.

METHODS AND RESULTS

A total of 114 patients were randomly assigned to the immediate stenting (IS) or DS group in a 1:1 ratio. Stent implantation was performed mean 72.8 hours after primary reperfusion of infarct- related artery in the DS group. The primary endpoint was the rate of LV remodeling and secondary endpoint was major adverse cardiac event (MACE) defined as a composite of death, MI, unplanned target vessel revascularization (uTVR) or hospitalization due to heart failure (HoHF) at one year. Serial quantitative echocardiographic analyses and 1-year clinical follow-up were completed in 89 (78%) and 108 (95%) patients, respectively. At mean 8.9 months after primary reperfusion, The incidence of LV remodeling was not different between two groups (21.7% in IS group vs 20.9% in DS group, p=0.999). MACE occurred 5 patients (9.1%, 1 death, 2 uTVR, and 2 HoHF) in IS group vs 2 patients (3.8%, 1 non-fatal MI, 1 uTVR, and 1 HoHF) in DS group at 1 year (hazard ratio 0.43, 95% confidence interval 0.08-2.23, p=0.317).

CONCLUSIONS

Routine DS does not seem to improve on adverse LV remodeling and 1-year clinical outcomes in patient with STEMI.

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Prevalence and clinical correlates of extended haemodynamic support in high-risk PCI: insights from the CVAD registry

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

AIMS

Acute mechanical circulatory support devices (AMCS) may be used during high-risk percutaneous coronary interventions (HRPCI) for haemodynamic support. We sought to describe the prevalence and clinical correlates of continuous circulatory support post-HRPCI in patients enrolled in the cVAD registry.

METHODS AND RESULTS

Patients enrolled in the cVAD Registry, an international database documenting outcomes with temporary Impella support who underwent elective or urgent HRPCI were included. Patients with cardiogenic shock, STEMI, on vasopressors/inotropes pre-procedure were excluded. 507 patients were identified who were supported either with Impella 2.5 or Impella CP. In 464 (91.5%) patients (group A) Impella was immediately removed and in 43 (8.5%) patients (group B) Impella support was continued post HRPCI. Baseline characteristics including patient demographics, ejection fraction (EF), STS score, procedural characteristics, were analyzed. Multivariate logistic regression analysis was used to describe the predictors of need for continuous Impella circulatory support.

Mean age was 70 ± 11 years. The prevalence of comorbidities was similar in both groups. Death and vascular complication were higher in group B (11.6% in group B vs 1.9% in group A, p=0.004). Patients with documented chronic total occlusion of coronary arteries were more than 3 times likely to receive continuous Impella support [OR: 3.2 (1.2-8.5), p=0.01]. Patients with high STS score were also associated with a higher likelihood for continuous Impella circulatory support post HRPCI [OR: 1.06 (1.0-1.12), p=0.03]. Lesion location, left ventricular ejection fraction, mean arterial blood pressure and use of rotational atherectomy did not predict continuous Impella support post PCI in this analysis. Bleeding requiring transfusion was higher in group B (13.95% in group B vs 9.3% in group A, p=0.03)

CONCLUSIONS

Chronic total occlusion of coronary vessels and high STS mortality score were associated with continuous Impella circulatory support post HRPCI. Hence, in patients where need for continuous left ventricle support is likely, consideration for alternative access should be entertained.

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Predictors of long-term mortality after TAVI: insights from the FRANCE-TAVI registry

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

AIMS

To describe predictors of long-term mortality in patients undergoing TAVI.

METHODS AND RESULTS

All TAVIs performed in 48 centres across France between January 2013 to December 2015 were prospectively included in the FRANCE TAVI registry. Clinical outcomes were site-reported and mortality data was obtained through a national database query. The primary endpoint of this study was all-cause mortality at 3 years. Secondary endpoints consisted in 30-day complications including stroke, vascular complications, bleeding, new pacemaker implantation and acute kidney injury. Independent predictors of 3-year mortality were identified by means of Cox regression.

A total of 12 121 patients were included in this study. Mean age was 82.9 years, and mean logistic Euroscore and STS score were 17.9 and 10.2%, respectively. Transfemoral access was used in 85.1%, local anesthesia in 49.9%, and TEE guidance in 27.3%. Balloon expandable devices were used in 63.8% and self-expanding devices in 35.4%. Procedural complications (annulus rupture, device embolization, tamponade, coronary obstruction, conversion to surgery) rates were all below 2%. Mortality at 30 days was 4.8% and stroke was 2.0%. Mortality at 1 and 3 years were 16.0 and 37.8%, respectively. Independent predictors of mortality at 3 years included the following: Logistic EuroScore (HR=1.10 per 10% increment), pulmonary artery pressure (HR=1.10 per 10 mmHg increment), GFR (HR=1.10 per 10ml/min decrement), Male sex (HR=1.28), NYHA class 3 or 4 (HR=1.23), non-TF access (HR=1.38), COPD (HR=1.21) and atrial fibrillation (HR=1.26) (all p-value

CONCLUSIONS

Pre-procedural characteristics and procedural events independently predict long-term mortality in patients undergoing TAVI.

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A novel approach for cardioprotection in patients with STEMI

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THEME: Coronary Interventions
TOPIC(S): STEMI

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Facilitating the delivery of the self-expanding coronary stent

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

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Computational angiography software (C angio)

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

AIMS

METHODS AND RESULTS

CONCLUSIONS

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Codelivery of ribonucleic and nitric oxide as new strategy to treat coronary restenosis

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

AIMS

Use of conventional drugs such as paclitaxel, siroliums and analogues have allowed a first revolution in treatment of restenosis in combination with intravascular medical devices. The use of therapeutic RNA molecules may open a whole new area of treatment, making it possible to target new patient sectors where current therapies have failed. In our approach we developed a new therapy combining delivery of nitric oxide and RNAs. We expect to exploit the powerful effects of NO in vascular biology and the specific use of siRNA, mRNA to express or suppress specific genes.

METHODS AND RESULTS

A library of polymers backbones able to delivery NO and RNAs have been developed modyfing hidrophobicity and kinetics of nitric oxide release. Stability of the polymers comprising the NO and the RNA have been tested within coatings and nanoparticles and used within stents and DEBs (drug eluting balloons). Toxicity and biological activity of RNA and NO have been tested and used in vitro and in vivo in combination with a medical device. It has been shown that polymer backbones are non-toxic and able to tune the kinetics of NO and a whole set of RNA.

CONCLUSIONS

New set of polymers being able to co-deliver nitric oxide and RNA simultaneously have been developed and tested both in vitro and ex vivo in combination with medical devices. Opening a new set of opportunities to improve current therapies.

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Pathology and advanced imaging, two views of one heart ? characterisation of rare congenital cardiac defect in a pig

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

AIMS

Phase-Contrast or 4D-Flow MRI is an increasingly important imaging modality in human cardiovascular medicine, however with high risk patients its application is challenging, and correlation with pathological findings is difficult in the majority of cases. We describe the pathological findings and their manifestation in cardiac blood flow pattern in a porcine case of complex congenital cardiac defect.

METHODS AND RESULTS

A female pig (30kg, Edelschwein) underwent functional and phase-contrast MRI as a preliminary to being part of a study group. Owing to abnormal findings, the animal was euthanised and the heart submitted to pathology where macroscopical and histological examination was carried out including immunohistology and special staining.

Magnetic resonance examination revealed elevated ratio of pulmonary to systemic flow (Qp/Qs = 1.8) supporting the find of an atrial-septal defect (area 182 mm2) with an diastolic left-to-right shunt (1.4 l/min) as well as mitral and severe tricuspid valve insufficiency, indicated by regurgitant jets, and disturbed diastolic intra-cardiac blood flow patterns.

Post mortem examination of the heart revealed an ostium primum atrial septal defect (ASD), also known as incomplete atrioventricular SD (AVSD) with a tri-leaflet left AV valve, together with a serous valvular cyst partially occluding the defec

CONCLUSIONS

Pathology examination confirmed the septal defect observed in 4D-Flow MR imaging as well as the suspected AV valve malformation and identified a valvular cyst. The correlation of pathology findings with those of advanced MR imaging modalities brings a greater understanding of the in vivo lesion significance to all parties. AVSDs account for ~3% of human congenital cardiac defects, and are additionally highly associated with both Noonan and Down syndrome, making them of interest from a comparative pathology sense.

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Comparison study on endothelial cells adhesion and their qualities on the surface of various PCI-DES in vitro

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

AIMS

Though the biocompatibility of DES in current stage improved a lot, late thrombosis, etc. are still problem. In this situation, various type of the DES products are in market. To achieve the long term biocompatibility of stent, endothelialization is one of key factors. In this study, we aim to compare the endothelial cells adhesion and their qualities on the surface of various PCI-DES in vitro.

METHODS AND RESULTS

Seven different stents were evaluated. A and B are conformal durable hydrophobic PVDF-HFP polymer coating with Everolimus. C is conformal durable hydrophilic polymer(BioLinx) coating with Zotarolimus. D is conformal bioresorbable Poly(l lactide)(PLLA) coating with Sirolimus. E is made by SUS-316 stainless steel with abluminal Biolimus coating without any polymer. F is Co-Cr alloy strut with abluminal Poly(d-l lactide-co-caprolactone)(PLCL) coating with Sirolimus. G is Pt-Cr alloy strut with abluminal Poly(l lactide-co-glycolide) (PLGA) coating with Everolimus. Samples were immersed into 100% fetal bovine serum and incubated at 37 degree centigrade for 0-6 months. Scanning electron microscopic observation and energy dispersive X-ray spectrometry were carried out. After the 6 months immersion, the surfaces were changed with the different degrees. Even A and B and C(durable polymers), unexpected polymer deterioration and denaturation of adsorbed protein were observed. About the bioresorbable polymer coating, PLLA coating on the D did not change so much, PLCL coating on the F and PLGA coating on the G were almost disappeared by their degradation. Coated drug on the E was completely disappeared and rough SUS316 surface was appeared just after one month.

Human umbilical cord vein endothelial cell(HUVEC) adhesion and proliferation assay were carried out using 5000 cells/ml suspension. After 1-21 days, samples were stained with fluorescent anti-F-actin and DAPI. Adhered cell numbers were counted from the pictures that were randomly taken the five different places on the strut by image J 1.51j8 software. The adhered-cell numbers were normalized by the strut area.

On the non aged samples, HUVEVC adhesion and growth on the E showed big difference from other samples. On the E, HUVEC attached well initially but dramatically decreased after 4 days culture. E is polymer-free system. In this case, rapid drug release would happened and cause the endothelial cell damage during the culture. This hypothesis was supported the results for 6 months(did not show any HUVEC growth inhibition because the drug release was completed). This result suggested that polymer carrier is important to control the drug eluting speed.

VE-Cadherin and Connexin37 appearance were observed by using immunohistostaining technique. Condition of the adhered cells were very much different on the different stent surfaces. VE-cadherin expression and localization of the cell junctions were fully observed on the HUVEC adhered on G(Pt-Cr) and were partially observed on B(PVDF-HFP). Connexin37 expression were much clearly observed on F(Co-Cr) and G(Pt-

Cr). Bear metal surface, especially Pt-Cr alloy surface, seems to be much better substrate for endothelial cells adhesion in initial stage.

CONCLUSIONS

Bear metal surface, especially Pt-Cr alloy, showed much better affinities toward vascular endothelium in initial stage of implantation to compare to the polymer coated surfaces. Polymer seems to control the drug eluent speed.