parameters, functional class, quality of life and clinical endpoints including death, hospitalization and acute kidney injury.

RESULTS The results presented in this abstract are based on preliminary results of 34/70 patients who completed 6 months follow-up. A total of 6 females and 28 males were included, with a mean age of 60 ± 9 yr. At baseline, 73.5% of the patients presented in NYHA class II and 26.5% in NYHA class III. Mean LVEF was 52 ± 5% and mean estimated glomerular filtration rate (eGFR) was 71 ± 25 mL/min at baseline. Mean change in late HMR at 6 months was -0.06 ± 0.15 in the RDN group and -0.06 ± 0.25 in the OMT group (p=NS for both comparisons of the change from baseline). NYHA class significantly improved in the RDN group at 6 months (p <0.001) and remained unchanged in the OMT group. At 6 months blood pressure and eGFR remained unchanged in both cohorts. The mean (±SD) change in LVEF at 6 months was +2 ± 7% in the RDN group as compared with +0.5 ± 4% in the control group. Left ventricular end-diastolic diameter (LVEDD) significantly decreased in the RDN group -3 ± 4 mm (p<0.02) and remained unchanged in the OMT group (0.4 ± 3mm; p=0.52). During follow-up, 1 patient died in the OMT group, rehospitalization and remained unchanged in the OMT group (0.4 in the control group. Left ventricular end-diastolic diameter at 6 months was 3mm; p<0.52).

CONCLUSION The preliminary results of this randomized controlled study suggest that RDN in patients with HFREF was safe with a potential positive effect on signs and symptoms of heart failure. No significant change was observed in cardiac sympathetic nerve activity at 6 months in patients in both arms.

CATEGORIES STRUCTURAL: Heart Failure

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TCT-208

Therapeutic efficacy of Paclitaxel-coated balloon for coronary de novo coronary lesions- a single-institution experience from China

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ABSTRACT At present, percutaneous coronary intervention with DES implantation is still the mainstay of interventional therapy for symptomatic coronary heart disease. However, the complications following DES implantation, such as restenosis, late in-stent thrombosis, bleeding risk associated with long-term double anti-platelet therapy are still of great concern. Drug-coated balloon (DCB), which has been widely used to treat ISR has been recommended by ESC/ EACT Coronary Intervention Guideline 2014 with an IA level of evidence. In recent years, numerous trials reported that the effect of DCB to treat de novo lesions are non-inferior to those with DES. But most of these trials are limited to small vessel disease (SVD) involving coronary arteries with diameters of <2.8 mm. No specific report about DCB only strategy for de novo coronary lesions with diameters of >2.8mm(large vessel disease, LVD) is currently available. In this study, we prospectively observed patients receiving DCB alone for de novo coronary lesions at Beijing Hospital Heart Center and compared the clinical efficacy of DCB for coronary lesions both in LVD and SVD.

METHODS We performed a prospective study of 215 consecutive patients with de novo lesions (90 lesions in LVD group with reference vessel diameter [RVD] >2.8 mm, the other 125 lesions as SVD group with RVD <2.8 mm) received drug coated balloon (DCB) angioplasty in Beijing Hospital cardiac catheter lab. Clinical characteristic was recorded and coronary angiography was analyzed with Quantitative Coronary Angiography (QCA) software.

RESULTS Patients in LVD group are much younger than in small vessel group (60.1 ± 11.1 vs. 65.0 ± 10.6, P<0.001), less patients had diabetes (24.7% vs. 43.1%, P=0.01), three-vessel disease (35.5% vs. 53.6%, P<0.05) and complex lesions (34.4% vs. 50.0%, P<0.05) than in SVD group. During pre-dilation, 76.4% of lesions could be treated well only by plain old balloons in SVD group, while only 58.9% of lesions in LVD group (P<0.01) with additional use of non-compliant (NC) balloons. Each group had one failure case that was bailout stented with drug-eluting stents (DES). The success rate of DCB angioplasty were similar in LVD group and SVD group (98.9% vs. 99.3%, P>0.05). There was one acute myocardial infarction requiring emergent target lesion revascularization (TLR) in SVD group during hospitalization. No MACE was observed in LVD group during hospitalization. Forty-two patients with 53 lesions, including 27 LVD lesions underwent coronary angiography at average 9.4 months after DCB intervention. The QCA analysis showed follow-up MLD in SVD group increased significantly than that of post-procedure (1.71±0.30 mm vs. 1.52±0.30 mm, P=0.05), while in LVD group the MLD of follow-up had no statistical difference with that of post-procedural (2.35±0.47 mm vs. 2.19±0.34 mm, P=0.05). At average 9.1 months clinical follow-up, the MACE rate in LVD group was 0% and 2.3% in SVD group, with TLR rates was 0% and 1.5% respectively (P=0.05). No death was observed in either group.

CONCLUSION Applying DCB for de novo coronary lesions was safe and effective both for SVD and LVD.

CATEGORIES CORONARY: Drug-Eluting Balloons and Local Drug Delivery

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TCT-209

Clinical outcome of a new generation drug-coated balloon for treatment of de novo coronary lesions and in-stent restenosis: an insight from the DCB-RISE registry

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BACKGROUND drug-coated balloons (DCB) have an acknowledged role for the treatment of in-stent restenosis (ISR), and there is some initial evidence of their efficacy for treatment of de novo lesions, especially in small coronary vessels. In the last years several new generation DCB have been developed, with improved trackability and drug deliverability to the vessel wall. We here report a sub-analysis of the Italian Elutas SV registry (DCB RISE), comparing the performance of Elutas SV DCB (Aachen Resonance, Germany) for de novo lesions vs. ISR.

METHODS between 2012-2015 all patients treated with Elutas S® at 9 italian centers were enrolled in this retrospective registry. Primary outcome was the occurrence of target-lesion revascularization (TLR) at the longest available follow up. Secondary endpoint was the occurrence of device-oriented adverse cardiovascular events (DOCE), a composite of cardiac death, target-vessel myocardial infarction (TV-MI) and TLR. A minimum of 6-month clinical follow up was required.

RESULTS We enrolled 544 consecutive patients, 282 with ISR and 262 with de novo lesions. Procedural success was obtained in 97.5% of the patients. At the longest available clinical follow up (average 12.9±6 months), we observed a TLR rate of 10% vs. 3.2% (P<0.006) in the ISR and de novo groups respectively. DOCE were significantly higher in the ISR group (12% vs 3.2%, P<0.001), while no significant statistical difference was observed in terms of cardiac death, TV-MI and stroke.

CONCLUSION this registry on the performance of a new generation DCB showed good procedural success in both ISR and de novo lesions, and a significantly lower rate of TLR in patients treated for de novo lesions at mid-term clinical follow up.

CATEGORIES CORONARY: Drug-Eluting Balloons and Local Drug Delivery

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TCT-210

Sirolimus coated balloon in the treatment of coronary artery disease in diabetic patients: Results from Nanolute Registry

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BACKGROUND Coronary artery disease is a major cause of complications and death among patients with diabetes. We sought to assess the clinical performance of MagicTouch Sirolimus coated balloon...
The Nano registry is prospective, multi-centre, non-randomized, all-comers registry to evaluate the safety and performance of Magictouch sirolimus coated balloon (SCB) in patients under real world conditions with treatment according to standard of care. The Major study endpoint encompassed MACCE (major adverse cardiac event) at 12 months. MACE is defined as composite of target lesion/vessel revascularization (TLR/TVR), target vessel myocardial infarction (TV-MI) and cardiac death.

RESULTS Overall, 185 diabetic patients underwent percutaneous transluminal angioplasty with Magictouch sirolimus coated balloon. Total 198 coronary lesions among 185 patients were treated with 225 study devices. The study population was dominated by male patients (81.08%). Hypertension was present in 65.95% patients. Most of the lesions were located in left anterior descending (46.97%) followed by right coronary artery (24.75%) and left circumflex (22.22%). SCB alone strategy was employed in majority of the patients (90.81%) while additional stenting was performed in 9.19% patients. 171/185 (92.43%) patients completed 12 months follow up and MACE was reported as 4.09%. The main results were derived by the product of MACE rate at 12 months follow-up with LDL, scarring and C6 group.

CONCLUSION The results observed in this “real world” population demonstrated a low MACE rate up to 12 months not only in the diabetic cohort but also in diabetic patients with complex lesions which have a higher risk of experiencing an adverse event.

CATEGORIES CORONARY: Drug-Eluting Balloons and Local Drug Delivery

TCT-211 Local intravascular delivery of low-density-lipoprotein cholesterol causes increased neointimal thickening in the healthy porcine coronary model. Insights into development of model of atherosclerosis

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BACKGROUND The preclinical studies of vascular response are limited due to lack of underlying disease. The available cholesterol diet based and genetic atherosclerotic models are not satisfactory due to long breeding, unpredictable lesion formation, low plaque burden and degree of stenosis. We aimed to evaluate the vascular response to local, intramural delivery of human, highly atherogenic lipids in the healthy domestic swine (DS) coronary arteries.

METHODS A total of 24 coronary artery segments of 10 DS were enrolled. Following triple, 130% balloon overstretch injury (POBA), segments were assigned to local delivery of 2 mL of oxidized human LDL from apheresis (400 mg/dL, n=9), 0.9% NaCl (control, n=7) or to POBA alone. The solutions were infused with the modified, circumferential micro-needle catheter (Peregrine, ASI) into the vessel wall. Following 28 days, optical coherence tomography (OCT), virtual histology IVUS (VH-IVUS) and NIRS spectroscopy were performed. The vessel segments were harvested for pathological analysis.

RESULTS The balloon injuries expressed as balloon to artery ratios were comparable among groups and the delivery of solutions was feasible in all cases. At 28 days the plaque burden in IVUS was not different between LDL, control and POBA groups respectively (23.4±12% vs. 16.7±9.7%, 16.7±9%; p=0.45) and the %Area Stenosis in OCT was highest in the LDL group (23.6±13 vs. 10.8±7 vs. 8.1±7%; p<0.02). The presence of necrotic core (LDL: 55.5%, Control: 37.5% and POBA: 42.8%; p=0.77) and dense calcium (LDL: 33.3%, Control: 28.5%, POBA: 37.5%; p=0.94) in VH-IVUS were comparable between groups. The Lipid Core Burden index in NIRS was negative in all cases. In histopathology, the injury was comparable between groups (LDL:1.6±0.4, Control: 1.7±0.8, POBA:1.7; p<0.0). In pathology the specimens showed no signs of necrotic core, cholesterol or calcium. The lesion consisted of fibrointimal hyperplasia and proteoglycan-rich matrix in all groups.

CONCLUSION Local delivery of saturated human LDL into the coronary wall was feasible, resulted into higher degree of stenosis caused by pathological neointimal thickening. The discrepancy between histopathological findings and VH-IVUS was also noted.

CATEGORIES OTHER: Pre-Clinical/First In-Human Studies

TCT-212 Statistical Comparison of the DANCE Trial 12-Month Outcomes of Adventitial Dexamethasone versus Comparator Drug-Coated Balloon Studies

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BACKGROUND Drug-coated balloons (DCB) and drug eluting stents (DES) improve patency of endovascular interventions by the passive diffusion of drugs that target down-stream responses to vessel injury, like cellular proliferation. Direct adveniitial drug delivery may be a potent anti-restenotic strategy by instead targeting the initial triggers of the inflammatory reaction to injury. This study was designed to evaluate the outcomes of direct adveniitial delivery of dexamethasone as an adjunct to mechanical revascularization in femoropopliteal obstructive atherosclerotic disease.

METHODS The DANCE trial enrolled 283 limbs in subjects with symptomatic PAD and Rutherford scores of 2-4 at baseline who had received primary angioplasty (PTA, N=124) or athrectomy (ATX, N=159) in femoropopliteal lesions up to 15 cm in length. A mix of dexamethasone (80%) and contrast medium (20%) were delivered to the adventitia and perivascular tissue around target lesions at a target dosage of 1.6 mg dexamethasone (0.5 mL) per centimeter of lesion length in all enrolled subjects. The 30-day assessments included major adverse limb events and post-operative death (MAE-POD), and 12-month assessments included primary patency, freedom from clinically driven target lesion revascularization (CD-TLR), Rutherford scoring and a walking impairment questionnaire. Primary statistical analysis compared the primary patency rates to historical PTA and DCB treatments from pivotal IDE trials, with similar eligibility criteria to the DANCE study.

RESULTS At 12 months, primary patency in DANCE-ATX and -PTA subjects were 74.8% (78.4% per protocol, PP) and 74.3% (75.5% PP), respectively. Rates of CD-TLR in DANCE-ATX and -PTA subjects were 13.1% (10.0% PP) and 13.7% (11.0% PP), respectively. There were no 30-day MAE-POD events nor device- or drug-related deaths or major adverse limb events through one year in either group. DANCE patency rates were superior to historical PTA patency rates of 52.5% (p<0.001 for ATX and PTA groups) and non-inferior to DCB patency rates of 72.3% (p<0.001 for ATX and p<0.004 for PTA).

CONCLUSION Direct adventitial delivery of dexamethasone is an effective and safe therapy to prevent restenosis, demonstrating patency rates similar to paclitaxel-coated balloons and superior to historical PTA treatment.

CATEGORIES CORONARY: Drug-Eluting Balloons and Local Drug Delivery