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 ± 9yr. At baseline, 73.5% of the patients presented in NYHA class II and 26.5% in NYHA class III. Mean LVEF was 32 ± 9% and mean estimated glomerular filtration rate (eGFR) was 71 ± 25 mL/min at baseline. Mean change in late HMR at 6months 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 6months (p <0.01) 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 ± 4mm (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 for heart failure occurred in 3 patients (1 in the RDN group, 2 in the OMT).

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

DRUG-COATED BALLOONS AND LOCAL DRUG DELIVERY FOR DENOVO LESIONS

Abstract nos: 208 - 212

TCT-208

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

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BACKGROUND 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 238 de novo lesions(90 lesions as LVD group with reference vessel diameter (RVD) ≥2.8 mm, the other 148 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± 0.36mm vs.1.52±0.30mm, P<0.05) , while in LVD group the MLD of follow-up had no statistical difference with that of post-procedure(2.35±0.48mm vs. 2.19±0.34mm, 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

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 Elutax SV registry (DCB RISE), comparing the performance of Elutax SV DCB (Aachen Resonance, Germany) for de novo lesions vs. ISR.

METHODS between 2012-2015 all patients treated with Elutax 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

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