BACKGROUND Cerebral embolization remains a major concern after transcatheter aortic valve replacement (TAVR). This patient-level meta-analysis pools data from three randomized, controlled trials (CLEAN-TAVI, MISTRAL-C and SENTINEL) to evaluate the impact of the dual filter cerebral embolic protection (CEP) system (Montage™ or Sentinel®, Claret Medical) on the occurrence of TAVR-related new brain lesions.

METHODS Patients (pts) of CLEAN-TAVI and MISTRAL-C (n=165) were randomized 1:1 to TAVR with or without CEP. The SENTINEL study randomized 363pts with 121 in the test imaging and 119 in the control imaging arm. Pts underwent brain imaging by MRI at baseline and at 2-7days after TAVR. A single stage approach was employed for the meta-analysis that resulted in total of available imaging for 320pts (Treatment group n=162; Control group n=158). The primary outcome measure was the volume of new DW-MRI positive brain lesions at 2-7days relative to baseline in the protected areas.

RESULTS Combining the three trials, evidence of preexisting brain damage was observed in 316pts. No difference in median [interquartile change] volume in pre-existing brain damage was observed between the Treatment and Control group, 6559.8[2056.6;18704.4] vs 6259.8[3012.5;15573.6]mm^3, respectively. Total median [IQR] new lesion volume in protected areas was 118.4[36.9;345.5] for the Treatment, and 214.9[50.6;551.0]mm^3 for the Control group, resulting in a 38% reduction (p=0.02) in mean new lesion volume in favor of CEP in the mixed effects model using transformed data. In the protected areas, total median new lesion volume was greater for subjects treated with a self-expandable (SE) vs balloon-expandable (BE) valves in both the Treatment and Control groups, and as expected, protected area total median new lesion volume was higher in the Control group than the Treatment group for both BE (152.9 [31.6;319.0] vs 71.2[31.6;274.2]), and SE (359.3[172.9;930.3] and 173.5 [58.4;414.0]) valves.

CONCLUSION This patient-level pooled analysis demonstrated that the use of CEP resulted in significant reduction (p=0.02) in total new lesion volume in protected territories post TAVR independent of valve type selection and pre-existing lesion burden.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

TCT-426

CT predictor of periprocedural stroke related to transcatheter aortic valve replacement.

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BACKGROUND Ischemic stroke related to transcatheter aortic valve replacement (TAVR) remains an important concern. There is limited data regarding imaging predictors of periprocedural stroke. The aim of this study was to determine whether anatomic features on MDCT might predict periprocedural stroke after TAVR.

METHODS 1005 consecutive patients undergoing TAVR for severe aortic valve stenosis via transfemoral approach at Cedars-Sinai Medical Center, Los Angeles between April 2012 and May 2016 were analyzed. We excluded patients with non-contrast computed tomography (CT) (n=93), insufficient cardiac phases (n=67), incomplete CT data (n=88) and inadeqaute slice thickness (n=7). One patient with a hemorrhagic stroke was excluded. Of the remaining 837 patients, we identified 26 patients with periprocedural ischemic stroke and matched 104 patients without stroke after conducting 1:4 propensity score matching. In addition to conventional pre TAVR MDCT measurements we measured the thickness of aortic valve leaflet edges, calcium volume of aortic valve leaflets, calcium volume of the aortic valve complex (leaflets, annulus and LVOT) and plaque thickness in the aortic wall (ascending aorta, aortic arch and descending thoracic aorta).

RESULTS There were no significant differences between the two groups in terms of preoperative clinical and echocardiographic variables. The patients with stroke had a higher incidence of second valve implantation (15.38% vs. 1.92%, P=0.003) and longer fluoroscopic time (19.6±11.7 min vs. 14.3±11.2, p=0.03). The summed thickness of aortic valve leaflet edges (STAL) was significantly greater among the stroke group (5.47±2.30 mm vs. 3.62±1.25 mm; p<0.0001). Multivariate analysis identified STAL as an independent predictor of stroke (OR 2.38; 95% CI 1.43-3.98; P<0.0001). Neither calcium volume of aortic valve complex nor plaque thickness in the aorta was associated with stroke.

CONCLUSION Leaflet edge thickness of aortic valve as assessed by contrast-enhanced MDCT pre procedure is an independent predictor of stroke after TAVR. This may serve as a predictive parameter to identify patients at increased risk for stroke following TAVR.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

COMBO STENT STUDIES

Abstract nos: 427 - 430, 755

TCT-427

Three Year Clinical Performance of the Dual-therapy COMBO stent: Insights from the REMEDEE Registry

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BACKGROUND The bio-engineered COMBO stent (OrbusNeich, The Netherlands) is a dual-therapy stent. This device combines an abluminal sirolimus eluting layer with a novel circumferential anti-CD34+ antibody layer. The antibody coating captures circulating endothelial progenitor cells, that can differentiate into normal endothelium on the stent surface. This technology may allow a shorter duration of dual antiplatelet therapy after percutaneous coronary intervention. There is, however, no long term clinical follow-up of this new device. We present the first results of all-comers patients treated with COMBO stent with a follow-up of 3 years.

METHODS The prospective, multicentre, investigator-initiated, REMEDEE Registry evaluates clinical outcomes after COMBO stent treatment in a 1000 all-comers patient population. Patients were enrolled between June 2013 and March 2014. Patients had a mean of 65yrs ±11, 26% are females and 18% of patients have diabetes mellitus (DM). In 30% of patients there was an urgent indication for PCI, 60% of lesions were AHA/ACC lesion type B2 or C. Target lesion failure (a composite of cardiac death, target vessel myocardial infarction and target lesion revascularization) at 3 year follow-up is the primary focus of this analysis. Subgroup analysis will be done for the predefined subgroups: sex, age, DM and acute coronary syndrome.

RESULTS Three year clinical results are currently being adjudicated by the independent clinical event committee. The results will be available at the TCT Congress 2017 in Denver.

CONCLUSION The dual-therapy COMBO stent has shown good clinical results up to two year follow-up. We will present the first three year clinical performance of this new stent technology. ClinicalTrials.gov Identifier: NCT01874002

CATEGORIES CORONARY: Stents: Drug-Eluting

TCT-428

Abstract Withdrawn

TCT-429

Comparison of the clinical performance between COMBO and Xience stent at one year follow-up in all-comers patients

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