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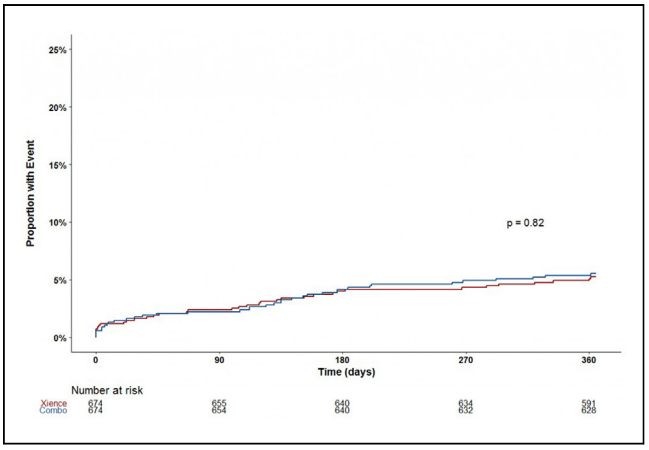
BACKGROUND The Xience stent (Abbott Vascular, USA) shows good clinical performance. The novel COMBO stent (OrbusNeich BV, The Netherlands) is a new device that combines a drug-eluting layer with an unique pro-healing layer. This device has not been compared to the well-established Xience stent in all-comers patients.

METHODS The REMEDEE Registry is a 1000 patient registry, evaluating patients treated with COMBO. The randomized AIDA trial compares Xience and Absorb BVS. Both trials are investigator-initiated, prospective, multicentre all-comers studies. A propensity-matched analysis is performed for COMBO versus Xience, using 13 baseline variables: age, gender, insulin treated-Diabetes Mellitus, hypertension, previous MI/PCI/bypass, acute coronary syndrome (ACS), number of treated lesions, target vessel location, stent length and diameter and ACC/AHA classification. Target lesion failure (TLF, a composite of cardiac death, target vessel myocardial infarction and any target lesion revascularization) is the primary focus of this analysis. Definite and probable stent thrombosis (ST) is evaluated.

RESULTS The analysis yields 674 true all-comers patients-pairs, with a high number of ACS and B2/C lesions. All baseline characteristics are well-balanced between both groups. TLF was observed in 5.5% of COMBO and 5.3% in Xience, HR 1.05, p=0.82. Definite and probable ST occurred in 0.7% of patients treated with both Xience and Combo, HR 1.00, p=1.00.



CONCLUSION This is the first study to compare clinical performance between COMBO and Xience stent in all-comers patients. No significant differences were found.

CATEGORIES CORONARY: Stents: Drug-Eluting

TCT-430

Nine-Month Angiographic and 1-Year Clinical Outcomes of the RECOVERY Study: A Randomized Trial Evaluating the Safety and Efficacy of the Combo Bio-Engineered Sirolimus-Eluting Stent Versus the Nano Polymer-Free Sirolimus-Eluting Stent in Patients with Coronary Artery Disease

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BACKGROUND We sought to evaluate the angiographic efficacy and clinical safety and effectiveness of the combined sirolimus-eluting CD34 antibody coated Combo stent (OrbusNeich Medical, Ft. Lauderdale, Florida) in a randomized trial designed to enable its approval by the China Food and Drug Administration.

METHODS RECOVERY is a multicenter randomized controlled trial comparing the Combo bio-engineered stent with the polymer-free sirolimus-eluting Nano stent (PF-SES) (Lepu Medical Technology, Beijing, China) in the treatment of patients with de novo native coronary artery lesions [NCT02542007]. The primary endpoint is 9-month angiographic in-segment late loss, powered for non-inferiority testing. Secondary endpoints include the 1-year rates of target lesion failure (TLF), a composite of cardiac death, target-vessel myocardial infarction, or ischemia-driven target lesion revascularization, TLF components, and ARC defined definite/probable stent thrombosis.

RESULTS A total of 433 patients were randomly assigned in a 1:1 ratio to the treatment with Combo stent or the treatment with PF-SES between May, 2015 and May, 2016 at 16 centers in China. Compliance rates for clinical follow-ups were 100% at 30 days, 99.8% at 6 months, and 100% at 1 year, and 88% for angiographic follow-up at 9 months. The baseline clinical, angiographic, and procedural characteristics were well balanced. The primary and secondary endpoint data will be presented at TCT2017.

CONCLUSION RECOVERY is the first randomized trial to evaluate the safety and efficacy of Combo bio-engineered stent vs. the PF-SES, both based on 316L stainless steel platforms and abluminally coated with sirolimus. Combo features a unique bio-engineered double coating consisting of an abluminal biodegradable polymer for the delivery of sirolimus, combined with a circumferentially immobilized EPC capturing antibody, whereas the SES comparator is polymer-free.

CATEGORIES CORONARY: Stents: Drug-Eluting

TCT-755

Role Of Circulating Progenitor Cells in the Appearance of Neointimal Hyperplasia After Everolimus Eluting Stent Implantation

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BACKGROUND Previous studies have shown a relationship between the change in thenumber of circulating progenitor cells (CPC) and the presence of restenosis after the implantation of bare metal stent. However, no data are available on the behavior of CPCs after implantation of everolimus-eluting stent (EES). The objective of this study was to evaluate the relationship of CPC with the degree of neointimal hyperplasia measured by optical coherence tomography (OCT) at 9 months in patients undergoing elective angioplasty (PCI) after EES implantation.

METHODS Consecutive patients with stable coronary disease treated with EESwere included. All patients were on statin therapy at least 2 months prior toinclusion in the study. Patients with elevated myocardial damage markers were excluded. CPC were identified using a flow cytometry technique. CPCs were defined as those Cells expressing the markers: CD34 + CD45dim. The analyses were performed before Implantation of the SRE (baseline determination), at the week, at 1 month and at 9 months after the PTCA.Studies with optical coherence tomography (OCT) were performed after stent implantation and 9 months follow up. All OCT analyses were performed at an independent corelab.

RESULTS Twenty patients were included in the study. The mean age was 66 ± 9 years and the 80% were male. A significant relationship between the basal and 1-week levels of CPC with mean neointima area was observed : [beta coefficient (CB) 0.29; 95% confidence interval (CI) 0.15Up to 0.42; P <0.001)] and [(CB: 0.15, 95% CI (0.04-0.26), p = 0.007, respectively] Similarly, a significant correlation between baseline, and at 1 week levels of CPC and the percentage of in-stent obstruction area (CB 2,17; IC95% (1,0 a 3,34; p < 0,001)] y [(CB: 2,04; IC95% (1,11 a 2,98); p < 0,001], respectively.