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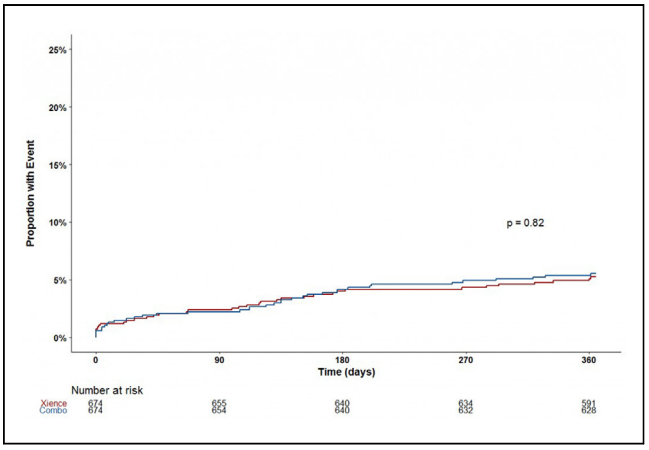
BACKGROUND The Xience stent (Abbott Vascular, USA) shows good clinical performance. The novel COMBO stent (OrbusNeich BV, The Netherlands) is a new device that combines a drug-eluting layer with an unique pro-healing layer. This device has not been compared to the well-established Xience stent in all-comers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

CONCLUSION There was a relationship between CPE levels and the appearance of Neointimal hyperplasia measured by OCT suggesting a role for these cells in vascular repair after vascular injury induced by the implantation of EES.

CATEGORIES CORONARY: Stents: Drug-Eluting

ECONOMIC ANALYSES

Abstract nos: 431 - 435

TCT-431

Socioeconomic disparities in access for Watchman device insertion in patients with atrial fibrillation and at elevated risk of bleeding.

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BACKGROUND Socioeconomic disparities exist in patient access to advanced cardiac therapies. We sought to investigate if there were any socioeconomic or racial disparities among patients with atrial fibrillation (AF), at elevated thromboembolic risk, and with contraindication to anticoagulation who were undergoing consideration for Watchman implantation at our institution.

METHODS June 2015 to December 2016, all patients with non-valvular AF requiring long term anticoagulation who underwent LAA exclusion with Watchman device were evaluated. Simultaneous control group was generated through electronic medical record query of patients with non-valvular atrial fibrillation, and criteria for LAA occlusion candidacy as deemed by WATCHMAN instructions for use, who were not referred for LAA closure within the predefined study time frame. The primary end point was disparities in socioeconomic status as defined by differences in median income between the control and study group. Mean household income was estimated utilizing Geocoding and 2016 US Census Data. Secondary endpoints included analysis for differences in patients receiving coverage for Medicaid, race, sex, and age.

RESULTS 201 patients with non-valvular AF were included (98 patients received Watchman device and 103 in the control arm). The mean estimated income was significantly higher in the Watchman insertion group compared to those who did not receive the device ($70,908.50 ± $25,847.20 vs. $56,569.90 ± $17,730.90; p <0.001). African-American patients were found to be less likely to receive Watchman insertion (5% vs. 27%; p<0.001). There was a higher percentage of patients in the control arm covered under Medicaid by both primary coverage (6% vs. 0; p=0.029) and with dual coverage of Medicare and Medicaid (13% vs. 4%; p=0.041). There was no significant difference between women referred for Watchman or women in the control arm (50% vs. 45%; p=0.428).

CONCLUSION Socioeconomic and racial disparities exist in patients with non-valvular AF at elevated risk of bleeding. African-American patients and those of lower incomes appear less likely to receive LAA exclusion. It remains essential to continually strive to improve access of cardiac procedures to patients of all races and socioeconomic classes.

CATEGORIES OTHER: Political, International and Societal Issues

TCT-432

Association of Primary Insurance Status with Use of Revascularization and In-hospital Outcomes in Patients with Non-ST-segment Elevation Myocardial Infarction in the United States

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BACKGROUND The issue of healthcare coverage has become a key focus of recent debate in the United States. We hypothesized that Medicaid or uninsured patients are less likely to receive revascularization and have worse outcomes after non-ST-segment elevation myocardial infarction (NSTEMI) compared with patients having private insurance.

METHODS We queried the 2003-2014 National Inpatient Sample databases to identify all patients aged ≥18 years with the principal diagnosis of NSTEMI. Patients who had Medicaid, private insurance, or were uninsured were included. Multivariable logistic or linear regression models were used to examine the association of primary insurance status with the use of revascularization (percutaneous coronary intervention [PCI] or coronary artery bypass grafting [CABG]) and in-hospital outcomes.

RESULTS There were 56,952 patients with Medicaid (mean age 55.8±11.4 years; 45.3% women), 238,497 with private insurance (mean age 58.2±11.1 years; 30.5% women), and 50,973 uninsured patients (mean age 53.5±10.3 years; 32.0% women) hospitalized with NSTEMI. Compared with patients with private insurance, Medicaid patients were less likely to receive PCI or CABG and uninsured patients were less likely to receive PCI. Patients in the Medicaid or uninsured groups had higher adjusted odds of not receiving revascularization compared with the private insurance group. Medicaid insurance status was associated with 25% higher and uninsured status with 40% higher adjusted odds of in-hospital mortality. Average length of stay (LOS) was longer in Medicaid and uninsured patients compared with those with private insurance (**Table**).

	Private Insurance	Medicaid	Uninsured
Treatment Strategy			
PCI Unadjusted OR (95% CI) Adjusted OR (95% CI)	44.9% Ref. Ref.	33.9% 0.63 (0.62-0.64) 0.82 (0.81-0.84)	43.2% 0.93 (0.91-0.95) 0.90 (0.88-0.92)
CABG Unadjusted OR (95% CI) Adjusted OR (95% CI)	11.6% Ref. Ref.	10.4% 0.88 (0.86-0.91) 0.89 (0.86-0.93)	11.6% 0.99 (0.97-1.02) 1.00 (0.97-1.04)
No Revascularization Unadjusted OR (95% CI) Adjusted OR (95% CI)	43.4% Ref. Ref.	55.6% 1.63 (1.60-1.66) 1.29 (1.26-1.32)	45.3% 1.08 (1.06-1.10) 1.13 (1.10-1.15)
In-hospital Mortality Unadjusted OR (95% CI) Adjusted OR (95% CI)	1.8% Ref. Ref.	2.8% 1.55 (1.47-1.65) 1.25 (1.17-1.33)	2.0% 1.10 (1.03-1.18) 1.40 (1.30-1.51)
Average Length of Stay Unadjusted Parameter Estimate (95% CI) Adjusted Parameter Estimate (95% CI)	4.1 days Ref. Ref.	5.5 days 1.21 (1.20-1.21) 1.08 (1.08-1.09)	4.2 days 1.03 (1.02-1.03) 1.04 (1.03-1.04)

CONCLUSION Compared with private insurance, Medicaid or uninsured payer status is associated with lower adjusted odds of receiving revascularization, higher odds of in-hospital mortality, and longer average LOS among patients with NSTEMI.

CATEGORIES CORONARY: Acute Coronary Syndromes

TCT-433

Death by Insurance: Insurance payer mix is tied to clinical outcomes in patients with acute myocardial infarction complicated by cardiogenic shock

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