CONCLUSIONS The PROMUS Element stent demonstrated very low TLF and revascularization rates with favorable safety outcomes for the treatment of small vessels and long lesions through 5 years.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Clinical outcomes, Coronary artery disease, Drug-eluting stent, everolimus

TCT-562 Comparison of Neointimal Growth Pattern after Thin- or Thick-Strut Drug Eluting Stents Implanted in Coronary Bifurcation Lesions: an Optical Coherence Tomography Study

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BACKGROUND Recent study reported that arterial healing of drug eluting stents was impaired with greater delay at the flow divider (high shear stress region) as compared with the opposite side of side branch (SB) (low shear stress region). This study investigated the differences in neointimal growth on stent struts between thin- and thick-strut drug eluting stents (DES) implanted in coronary bifurcation lesions by using optical coherence tomography (OCT).

METHODS Sixty-two bifurcation lesions treated with second generation DES were evaluated with OCT in 51 patients (66.1 y.o) at 6 to 12 months follow-up angiography. The stent strut was divided as thin when less than 100μm and thick when more than 100μm. Each lesions were divided into thick-DES (n=20; Nobori biolimus-eluting stents) or thin-DES (n=42; Xience everolimus-eluting stents and Resolute Integrity zotarolimus-eluting stents). Neointimal coverage was assessed based on cross-sectional OCT images containing SB at 400μm interval, and separately evaluated according to three independent regions: SB ostium (SO), the 1/2 circumference of the vessel wall adjacent to SB (LS; low shear stress region), and the vessel wall adjacent to SB (HS; high shear stress region). Incidence of uncovered struts and neointimal thickness were measured on the cross sectional OCT images.

RESULTS Total of 2437 struts were analyzed in this study (thick-DES: 911 vs. thin-DES: 1526). The incidence of uncovered struts was significantly higher at HS region compared with LS regions in thick-DES (16.8% vs. 7.9%, p<0.01), while there was no significant difference in thin-DES at both HS and LS region (7.3% vs. 5.4%, p=0.1643). The incidence of uncovered struts was significantly higher in thick-DES compared with thin-DES at HS region (16.8% vs 7.3%, p<0.01), while there was no significant difference at both LS and SO region (7.9% vs. 5.4%, p=0.0846; 34.7% vs. 36.4%, p=0.7506, respectively). Neointimal thickness was significantly smaller in thick-DES compared with thin-DES at both HS and LS region (69.4±14.6μm vs. 99.9±70.8μm, p<0.01; 72.2±47.6μm vs. 98.5±69.5μm, p<0.01, respectively), while there was no significant difference at SO region (48.7±31.6μm vs. 48.7±36.1μm, p=0.9386).

CONCLUSIONS Thin strut DES was homogeneously endothelialized in bifurcation lesions and may have more favorable arterial healing response for bifurcation lesions compared with thick strut DES.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Bifurcation stenting, Drug-eluting stent, second generation, OCT

TCT-563 Results after recanalization of true coronary chronic total occlusions with the sirolimus eluting abluminal coated stent compared with the zotarolimus eluting stent

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BACKGROUND Chronic total occlusions (CTO), defined by TIMI 0 flow and duration of occlusion of more than 3 months, are associated with a higher risk of restenosis compared to other lesion types. We evaluated clinical and angiographic results after recanalization of CTOs with the Sirolimus eluting Orsiro hybrid stent with bioresorbable polymer coating. Orsiro is a cobalt chromium stent with an absorbable polymer and thin struts of 60 μm. We compared two consecutive patient series undergoing recanalization for CTO with either the Orsiro Sirolimus-eluting stent (O-SES) or a Zotarolimus-eluting stent (ZES)

METHODS 74 patients after successful recanalization of a true CTO in a native coronary artery were enrolled in our prospective registry (clinical.trials.gov NCT02162082) and compared with 57 patients treated with a Zotarolimus-eluting stent. In 68 % vs 50% CTO recanalization was performed by antegrade and in 32%/5% by retrograde approach. After pre-dilatation a mean of 2.7±1.3 (range 1-6) Orsiro stents and 2.7±1.2 (1-7) ZES were implanted (± 0.55mm, a mean length of 81.9±30.6mm. 32.4% (N= 24/74) of patients in the Orsiro group suffered from diabetes mellitus and 28.1%(N=16/57) in the Zotarolimus group. In 66.2% vs 61.4% CTO was located in LCA, 18.9%±15.8% in LCX and in 14.9%±22.8% in LAD. Reference diameter post PCI was 3.0±0.49mm (1.9±0.56mm), MLD 2.82±0.51mm (3.0±0.48mm) and percent diameter stenosis 7.6±10.0 (3.7±8.3). Dual antiplatelet therapy (DAPT) was recommended for 12 months with aspirin and clopidogrel. Control angiography was scheduled after 9 and clinical follow-up after 12 months. The primary angiographic outcome was in-stent late lumen loss. Secondary angiographic endpoints include minimal luminal diameter, percentage of diameter stenosis, binary restenosis. Primary clinical outcome measures were target lesion revascularization rate (TLR) and major adverse cardiac events (MACE) defined as composite of cardiac death, myocardial infarction related to the target vessel and vessel revascularization.

RESULTS The primary endpoint in-stent late lumen loss was 0.24±0.53mm for the Orsiro stent compared with 0.59±0.72mm for the Zotarolimus stent (p=0.01), MLD was 1.99±0.63mm versus 1.87±0.80mm (p=0.86), percent diameter stenosis 24.7±19.2% vs. 27.7±28.7% (p=0.58), respectively. TLR was 9.7% for O-SES and 10.5% for ZES, resulting in a total MACE rate of 10.8% vs 12.3% (p=0.79). Of note, there was no definite or probable stent thrombosis according to ARC criteria in both groups within 12 months DAPT treatment.

CONCLUSIONS Treatment of true CTO lesions with the Sirolimus eluting abluminal coated Orsiro stent resulted in a significantly lower in-stent late lumen loss compared with Zotarolimus eluting stents and no occurrence of definite or probable stent thrombosis with a 12 months dual antiplatelet therapy. Clinical results were similar to Zotarolimus eluting stents.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Chronic total occlusion, Drug-eluting stent, sirolimus
CONCLUSIONS Continuing DAPT did not prevent MACCE in patients who were free from MACCE during the first two years after everolimus-eluting stent implantation.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS DES, Dual antiplatelet therapy

TCT-565
Cost-Effectiveness Of The Xience™ Cobalt Chromium Everolimus Eluting Stent Compared With Bare Metal Stents: A United States Payer Perspective
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BACKGROUND A patient-level meta-analysis of 5 randomized trials including 4,896 patients found that the XIENCE™ cobalt chromium everolimus drug-eluting stent (DES) significantly improved cardiovascular (CV) outcomes compared with bare metal stents (BMS) (Valgimigli et al., 2014). Using these results, a cost-effectiveness analysis (CEA) was conducted comparing XIENCE™ vs. BMS in percutaneous coronary intervention (PCI).

METHODS The CEA was conducted using a Markov state transition model with a 2-year time horizon from the U.S. payer perspective. The base case evaluated lesion-specific outcomes including CV-related mortality, target vessel revascularization (TVR), TVR-related myocardial infarction (MI), and stent thrombosis (ST). Patient-oriented outcomes were evaluated in a one-way sensitivity analysis with all-cause mortality, TVR, all-cause MI, and ST. Transition probabilities and risk of clinical events were taken from the Valgimigli 2014 meta-analysis. Resource use and unit costs (2015 USD) from the published literature were included for index PCI with XIENCE™ or BMS, TVR, MI, and dual antiplatelet therapy (DAPT). Quality of life impacts (i.e., health utilities) from the published literature were included for coronary artery disease (CAD), MI, and TVR.

RESULTS The lesion-specific base-case analysis found that XIENCE™ vs. BMS resulted in an additional 0.018 quality-adjusted life years (QALYs) and a cost savings of $236 per patient. The patient-oriented sensitivity analysis provided similar results that XIENCE™ was more effective and less costly than BMS, resulting in an additional 0.013 QALYs and a cost savings of $288 per patient. Results were robust to the majority of sensitivity analyses, only being sensitive to pricing for clopidogrel ($9,755 per QALY). The probabilistic sensitivity analysis predicted that XIENCE™ was associated with a 99.5% chance of being cost saving or cost-effective vs. BMS at a cost per QALY threshold of $50,000.

CONCLUSIONS Previous studies assessing cost-effectiveness of DES vs. BMS have shown mixed results which may be due to the clinical performance of earlier generation DES. Utilizing data from a high-quality, patient-level meta-analysis, our study clearly demonstrated that XIENCE™ is an economically attractive strategy compared to BMS for PCI.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Bare-metal stent, Cost-effectiveness, Drug-eluting stent