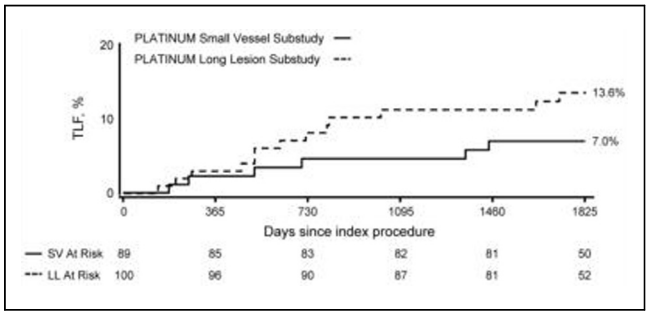

CONCLUSIONS The PROMUS Element stent demonstrated very low TLF and revascularization rates with favorable safety outcomes for the treatment of small vessels and long lesions through 5 years.

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 defined 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 opposite to SB (LS; low share 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%, $p=0.7606$, respectively). Neointimal thickness was significantly smaller in thick-DES compared with thin-DES at both HS and LS region (69.4±46.6μm 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±31.8μm vs. 48.7±36.1μm, $p=0.8386$).

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 month, 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 where 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%vs 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 with 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 RCA, 18.9%vs15.8% in LCX and in 14.9%vs 22.8% in LAD. Reference diameter post PCI was 3.04±0.49mm (3.19±0.56mm), MLD 2.82±0.51mm (3.06±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 month. 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 target 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

TCT-564

Clinical Predictors of Target Lesion Revascularization after SES or EES implantation

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BACKGROUND Several studies have performed the comparison of outcomes between 1st generation drug eluting stent Sirolimus-Eluting Stent (SES) and 2nd generation drug eluting stent Everolimus-Eluting

Stent (EES). However, the differences of clinical predictors between these stents have not been well evaluated.

METHODS We performed additional analysis using data of the Randomized Evaluation of Sirolimus-Eluting Stent Versus Everolimus-Eluting Stent Trial (RESET trial). In this all-comer prospective multicenter randomized open-label trial, 3196 patients were randomly assigned to implant either SES (1600 patients) or EES (1596 patients). Excluding the lesions where operators failed to implant assigned stents and which we could not follow for 3 years, we included in analysis 1666 lesions treated with SES and 1679 lesions with EES. Primary endpoint of this study was target lesion revascularization (TLR) within 3 years after index procedure. We detected the independent predictors of TLR for each stents using multivariate logistic regression model instead of Cox's proportional hazard model because log minus log curve of any predictor did not prove linearity of hazard during follow-up. We also analyzed angiographic data of some patients participating QCA substudy in RESET trial, stratifying important predictors.

RESULTS In RESET trial, there was no significant difference in target lesion revascularization between the SES and EES groups (7.9% versus 6.6%; P=0.16). After adjustment for the clinical factors of p<0.1 in univariate analyses, the following factors were independent predictors of TLR. In SES group, hemodialysis (odds ratio [OR], 6.36; 95% confidence interval [CI], 3.17-12.61: p<0.0001) and lowered ejection fraction <30% (OR, 2.94; 95% CI, 1.06-7.54: p=0.04) were an independent predictor of TLR. On the other hand, in EES group, although prior PCI (OR, 2.16; 95% CI, 1.37-3.45: p=0.001), number of stents more than 2 (OR, 2.14; 95% CI, 1.16-4.06: p=0.02), ostium lesion (OR, 0.40; 95% CI, 0.14-0.93: p=0.03), and direct stenting (OR, 0.56; 95% CI, 0.31-0.97: p=0.04) were also independent predictors of TLR, hemodialysis was a strong independent predictor of TLR (OR, 2.70; 95% CI, 1.37-5.11: p=0.005). In QCA data, late loss in 8 months follow-up coronary angiogram were similar after SES or EES implantation in both all cohort and stratified groups with hemodialysis or diabetes.

CONCLUSIONS In general, the clinical factors of TLR between SES and EES were similar. Hemodialysis was a strong clinical predictor of TLR in both stents.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Drug-eluting stent, everolimus, Drug-eluting stent, sirolimus

TCT-565

Continuing Dual Antiplatelet Therapy or Not Did Not Influence the Rate of Major Cardiac and Cerebral Adverse Events (MACCE) When Patients Were Free from MACCE during the First Two Years after Everolimus-eluting Stent Implantation

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BACKGROUND The duration of dual antiplatelet therapy (DAPT) after Everolimus-eluting stent (EES) implantation is controversial. Short term of DAPT was recommended, but long term of DAPT has been reported to be effective. We studied about major adverse cardiac and cerebral events (MACCE: combined end point of all cause of death, nonfatal myocardial infarction and cerebral arterial disorder) over the patients who were free from MACCE during the first two years after EES implantation.

METHODS A total of 1918 patients who underwent successful percutaneous coronary intervention (PCI) with EES at 22 centers in Japan from 2010 through 2011 were enrolled, and 742 patients were followed over 2 years free from MACCE. We divided these MACCE-free patients into two groups: those who were prescribed DAPT over 2 years (Over-2-Year DAPT: n=591) and those who were not (Under-2-Year DAPT: n=151). We compared these two groups about MACCE after 2-year follow-up with and without baseline adjustment by propensity score matching (n=145 in both group). And we studied about bleeding, stent thrombosis and restenosis.

RESULTS A total of 50 MACCE were observed in this study (Over-2-Year DAPT, 38; Under-2-Year DAPT, 12, respectively) without significant difference (Log-rank test, p=0.19). Even after baseline adjustment, there were no difference about MACCE (over-2-Year DAPT, 8; Under-2-Year DAPT, 11, respectively, p=0.19). In this study, 15 of major bleeding, 5 of restenosis and 2 of stent thrombosis were observed after 2-year follow-up, and there were no statistical difference, although the events numbers were not enough to compare.

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-566

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™ was more effective and less costly than BMS, resulting 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

TCT-567

Long-Term Outcomes With an Abluminal Groove-Filled Biodegradable Polymer Sirolimus-Eluting Stent Versus a Cobalt-Chromium Everolimus-Eluting Stent in Single De Novo Coronary Lesions: Four-Year Results of the TARGET I Randomized Controlled Trial

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BACKGROUND TARGET I randomized controlled trial (RCT) aimed to compare the safety and effectiveness of an abluminal groove-filled biodegradable polymer sirolimus-eluting stent (FIREHAWK, MicroPort Medical, Shanghai, China) with a cobalt-chromium everolimus-eluting stent (CoCr-EES) XIENCE V for the treatment of single de novo