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

METHODS We performed additional analysis using data from 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 both SES group, hemodialysis odds ratio [OR], 6.26; 95% confidence interval [CI], 3.77-12.61: 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, 2.70; 95% CI, 1.37-5.11: p=0.04), 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, 1.37-5.14: p=0.007). 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

Daisuke Ueshima,1 Takashi Ashikaga,1 Taro Sasaoka,1 Yu Hatano,1 Ken Kuniha,1 Shunji Yoshihara,1 Mitsuaki Isobe2 Tokyo Medical and Dental University, Tokyo, Japan

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 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 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, 19; Under-2-Year DAPT, 11, 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

Nicole Ferko,1 Giuseppe Ferrante,1 James T. Hasegawa,3 Nicole Edman,1 Paul Kennedy Research Computing, Burlington, Ontario, Canada; 2Italiano Clinico Humanitas, Humanitas Clinical and Research Center, IRCCS, Rozzano, Italy; 3Abbott Vascular, Santa Clara, CA; 4Thoraxcenter, Erasmus Medical Center, Rotterdam, Netherlands

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

Bo Xu,1 Changdong Guan,1 Yuejin Yang,1 Ma Changsheng,2 Yaling Han,3 Shao Liang Chen,4 Hui Li,5 Martin Leon,2 Run-Lin Gao3 Fu Wai Hospital, National Center for Cardiovascular Diseases, Beijing, China; 2Beijing Anzhen Hospital of Capital University of Medical Sciences, Beijing, China; 3General Hospital of Shenyang Military Region, Shenyang, China; 4Nanjing First Hospital, Nanjing Medical University, Jiangsu, China; 5Daqing Oil Field General Hospital, Daqing, China; 6Columbia University Medical Center, New York, United States

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, Shanghai, China) with a cobalt-chromium everolimus-eluting stent (CoCr-EES) XIENCE V for the treatment of single de novo
coronary outcomes. We for the first time report the 4-year clinical outcomes.

METHODS A total of 458 patients (vessel size between 2.25 – 4.0mm and lesion length ≤ 24mm) were enrolled in the TARGET I RCT. The primary non-inferiority endpoint was in-stent late lumen loss (LLL) at 9 months. Secondary endpoints were target lesion failure (TLF), a composite of cardiac death, target vessel myocardial infarction (TVMI), or ischemia-driven target lesion revascularization (ITLR), and patient-oriented composite endpoint (PoCE), a composite of all death, MI, or any repeat revascularization. Clinical follow-up (f/u) was scheduled at 1 month, 6 and 12 months, and annually up to 5 years for all enrolled patients. All adverse clinical events were adjudicated by an independent committee.

RESULTS Previous reports have demonstrated FIREHAWK stent was non-inferior to CoCr-EES for the primary endpoint of 9-month in-stent LLL (0.13±0.24 mm vs. 0.13±0.18 mm, p for non-inferiority <0.0001), and the two groups had similar clinical outcomes at 1 year. 445 (97.2%) patients completed 4-year clinical f/u. There were still no significant differences between groups up to 4 years in terms of any composite endpoints or individual components (Table). However, a landmark analysis at 1 year showed non-significant trends of lower incidences of MI (0% vs. 1.5%, log-rank p=0.08) and ITLR (1.8% vs. 3.5%, log-rank p=0.16) in favoring FIREHAWK group between 1 year and 4 years. Furthermore, the 4-year rate of PoCE was 9.2% in FIREHAWK group and 15.1% in CoCr-EES group, respectively, with a borderline difference (log-rank p=0.053). No definite/probable stent thrombosis (ST) was documented in FIREHAWK group through 4 years.

CONCLUSIONS In TARGET I RCT, the 4-year f/u results confirmed that the novel FIREHAWK stent had a durable safety and efficacy profile, which was comparable to the best-in-class CoCr-EES in single de novo coronary lesions. (ClinicalTrials.gov Identifier: NCT01968191)

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Drug-eluting stent, bioabsorbable, Long-term clinical outcomes, Randomized clinical trial

TCT-568 Multi-Center, Randomized Evaluation of the Elixir DESyne® Novolimus Eluting Coronary Stent System with Biodegradable Polymer compared to the control Endeavor Zotalorimus Eluting Coronary Stent System (ZECS) (Medtronic, Santa Rosa, CA).

METHODS 149 patients were randomized 3:1, either to the DESyne BD NECSS or to the Endeavor ZECS. Patients were analyzed for the primary endpoint (non-inferiority and superiority) of in-stent late lumen loss (LLL) assessed by qualitative coronary angiography (QCA) at 6 months. Secondary endpoints were evaluated at 1, 6, 9, and 12 months and annually through 5 years, and included a device-oriented composite endpoint (DoCE) defined as: cardiac death, target vessel MI, clinically-indicated target lesion revascularization (TLR); clinically-indicated target vessel revascularization (TVR); and stent thrombosis. Lesions were also evaluated for 6-month angiographic endpoints including: in-segment LLL, percent diameter stenosis, post-procedure minimal lumen diameter, and angiographic binary restenosis (ABR) (>50%). A subset of patients underwent 6-month intravascular ultrasound (IVUS) evaluation.

RESULTS The study met the primary endpoint demonstrating both non-inferiority and superiority of the DESyne BD NECSS compared to the control (0.12±0.15 vs 0.67±0.47, p<0.001). Six-month in-stent ABR was significantly lower for DESyne BD (0% vs 7.9%, p=0.003). Excellent clinical results were demonstrated for both devices with sustained low clinical event rates observed through 36 months (Table 1). Long-term clinical results through 48 months will be presented.

CONCLUSIONS The DESyne BD NECSS demonstrated both non-inferiority and superiority over Endeavor for in-stent late lumen loss at 6 months. Clinical events remained low through 36 months; clinical results through 48 months will be presented.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Biodegradable polymer, DES, Novolimus

| Table 1. Angiographic, IVUS and Clinical Results |
|-------------------|-------------------|-------------------|
|                  | DESyne BD | Endeavor | p-value |
| Anatomic Results   |             |          |         |
| Baseline IVUS (post-procedure) | 3.00±0.37 | 3.08±0.35 | 0.21 |
| 6 month angiographic/IVUS |          |          |         |
| In-stent Late Lumen Loss | 0.12±0.15 | 0.67±0.47 | <0.001 |
| % nonnal In volume  | 1.6±4.2    | 20±14.2  | <0.001 |
| Clinical Results   |             |          |         |
| 6-month DoCE (%)   | 2.7        | 3.2      | 1.00    |
| Clinically-indexed TLR | 1.8        | 3.2      | 0.52    |
| 12 month DoCE (%)  | 2.7        | 3.2      | 1.00    |
| Clinically-indexed TLR | 1.8        | 3.2      | 1.52    |
| 24 month DoCE (%)  | 2.7        | 3.2      | 1.00    |
| Clinically-indexed TLR | 1.8        | 3.2      | 1.52    |
| 36 month DoCE (%)  | 5.4        | 6.5      | 0.68    |
| Clinically-indexed TLR | 2.7        | 6.5      | 0.30    |

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Biodegradable polymer, DES, Novolimus

BACKGROUND A non-inferiority study evaluating the long-term safety and effectiveness of the Elixir DESyne® BD Novolimus Eluting Coronary Stent System (NECSS), a Co-Cr stent with a biodegradable