Results: Mean age was 64 +/- 11.2 years, 84.4% males, 30.2% diabetics and 59.6% had unstable angina at inclusion. 54.3% with 3 vessels and ULM, 1.8 +/- 0.3 Firebird 2 per pt was implanted. Clinical success was accomplished in 100%. At discharge all pts received DAPT. Complete 6 months follow-up results are reported in Table. In pts with diabetes, Firebird-2 group also showed a benefit in MACCE compared to ERACI 3-DES p=0.02 and ERACI 3-CABG p=0.04.

6 months outcome

<table>
<thead>
<tr>
<th>ERACI 4</th>
<th>ERACI 3-DES</th>
<th>ERACI 3-CABG</th>
<th>ERACI 4 vs ERACI 3-DES</th>
<th>ERACI 4 vs ERACI 3-CABG</th>
</tr>
</thead>
<tbody>
<tr>
<td>N patients</td>
<td>225</td>
<td>225</td>
<td>225</td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>1 (0.4%)</td>
<td>6 (2.7%)</td>
<td>15 (6.7%)</td>
<td>0.05 &lt; 0.001</td>
</tr>
<tr>
<td>Myocardial Infarction (MI)</td>
<td>1 (0.4%)</td>
<td>5 (2.2%)</td>
<td>14 (6.2%)</td>
<td>0.1 0.001</td>
</tr>
<tr>
<td>Non-fatal Cerebrovascular accident (CVA)</td>
<td>0 (0%)</td>
<td>1 (0.4%)</td>
<td>2 (0.9%)</td>
<td>0.31 0.15</td>
</tr>
<tr>
<td>Death/MI/CVA</td>
<td>2 (0.9%)</td>
<td>9 (4.0%)</td>
<td>31 (13.8%)</td>
<td>0.03 &lt; 0.001</td>
</tr>
<tr>
<td>Target vessel revascularization (TVR)</td>
<td>2 (0.9%)</td>
<td>13 (5.8%)</td>
<td>5 (2.2%)</td>
<td>0.004 0.25</td>
</tr>
<tr>
<td>MACCE (Death/MI/CVA/TRV)</td>
<td>4 (1.8%)</td>
<td>17 (7.6%)</td>
<td>36 (16.0%)</td>
<td>0.004 &lt; 0.001</td>
</tr>
</tbody>
</table>

Conclusions: At 6 months this multicenter and prospective registry showed that Firebird 2 had a remarkable low incidence of MACCE and death/MI/CVA either compared to CABG or 1st DES arms. Firebird 2 also had lower TVR rate than 1st DES.

TCT-578

Two-Year “Real-World” Outcomes Following Implantation of the ION™ PtCr-EES: Results From the ION U.S. Post-Approval Registry

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Background: The ION Registry assessed clinical outcomes for the thin-strut, ION™ (TAXUS Element) Paclitaxel-Eluting Platinum Chromium Coronary Stent System (Boston Scientific, Natick, MA) in unselected patients at 40 sites in the United States. Two-year “real world” results with this stent have not been previously reported.

Methods: This prospective, open-label registry enrolled 1120 consenting all-comer patients treated with the ION stent for any indication at each site. Follow-up was at discharge, 30 and 180 days, and annually to 5 years. The primary endpoint was the 1-year rate of cardiac death or MI in PERSEUS-like patients (i.e., patients who met the enrollment criteria for the pivotal PERSEUS trial; JACC 2010;56:264-71). Per protocol, the primary endpoint result from the ION registry was also combined with the EU post-approval registry (TE-PROVE), which enrolled 306 PERSEUS-like patients, and the PERSEUS WH/SV populations (N=1166).

Results: Among 1111 patients who received a study stent, most (70.3%, 871/1111) were male, with a mean age of 64±11±110 years, and 316 were PERSEUS-like. At 1-year, clinical follow-up or death were recorded in 92.1% (1023/1111). The primary endpoint of cardiac death or MI at 1 year occurred in 2.1% (6/292) of PERSEUS-like patients in ION and 2.3% (40/1729) patients in the combined analysis. The upper 1-sided 95% CI for the combined analysis was 2.9%, which was significantly less than the prespecified performance goal of 7.6% (P< 0.001). Additional 1-year clinical endpoint rates were 9.4% (97/1028) MACCE (defined as cardiac death, MI, TVR), 2.0% (21/1028) cardiac death (0.4% related to ION stent), 3.0% (31/1028) MI (1.9% related to ION stent), 6.8% (70/1028) TVR (4.9% related to ION stent), and 2.1% (22/1028) ARC definite/probable ST (2.0% related to ION stent).

Conclusions: The 1-year results of the ION US Post-Approval Study confirm the safety and effectiveness of the ION stent for the treatment of coronary artery disease in everyday clinical practice. Two-year overall results and results from selected subsets of this real-world population (diabetes, small vessels, long lesions) will be available for the first time at TCT 2014.

TCT-579

Two-Year Results Comparing Cobalt-Chromium XIENCE V and Platinum-Chromium PROMUS Element Everolimus-Eluting Stents

Jung-Min Ahn,1 Pil Hyung Lee,2 HEE SOON PARK,3 Min Su Kim,4 Jae Hyung Rohl,5 Sang Soo Cheon,3 Young-Hak Kim,3 Dak-Woo Park,3 Sang-Han Yoon,3 Hyun Woo Park,3 Muneok Chang,3 Jong Young Lee,3 Soo-Jin Kang,7 Cheol Whan Lee,7 Seung Whan Lee,7 Seong-Wook Park,7 Seung-Jung Park1 1Asan Medical Center, Seoul, Korea, Republic of, 2Asan medical center, Seoul, Korea, Republic of, 3University of Ulsan, Asan Medical Center, Seoul, Korea, Republic of, 4University of Ulsan College of Medicine, Asan Medical Center, Seoul, Korea, Republic of, 5Asan Medical Center, Seoul, Korea, Republic of, 6Centre Hospitalier Universitaire de Charleroi, Charleroi, Belgium, 7Krankenhaus der Barmherzigen Brüder Trier, Trier, Germany

Background: It remains unclear whether there are differences in the safety and efficacy outcomes between Cobalt Chromium (CoCr-EES) and Platinum Chromium everolimus-eluting stents (PtCr-EES).

Methods: From the Interventional Cardiology Research In-Cooperation Society-Drug-Eluting Stents Registry, we identified 6065 consecutive patients who received CoCr-EES (3080 patients) and PtCr-EES (2985 patients). We compared major adverse cardiac events (MACE) which was defined using a composite measure consisting of death, nonfatal myocardial infarction, or target vessel revascularization (TVR) with the use of propensity-score matching in the overall cohort according to type of stents.

Results: At 2-years of clinical follow-up, the 2 study groups (2510 patients for each propensity-score matched group) did not differ significantly in crude risk of the MACE (12.5% for CoCr-EES versus 11.6% for PtCr-EES; HR, 0.95; 95% CI, 0.81–1.13; p= 0.581). There was also no differences between the stent groups in the risks of the individual component of death (HR, 1.08; 95% CI, 0.78–1.492; p=0.624), MI (HR, 0.97; 95% CI, 0.770 – 1.228, p=0.812), and TVR (HR, 0.798; 95% CI, 0.598 – 1.065, p=0.125). The risk of a cerebrovascular event (HR, 0.914; 95% CI, 0.864 – 1.477, p=0.714) and definite stent thrombosis (HR, 1.000; 95% CI, 0.290 – 3.454, p=1.000) were also similar between the two groups.

Conclusions: The use of CoCr-EES and PtCr-EES showed similar rates of safety and efficacy outcomes with regard to death, MI, stent thrombosis and TVR.

TCT-580

Two-Year Real-World Outcomes in 1014 Patients Treated With the Thin-Strut, Platinum-Chromium, Paclitaxel-Eluting TAXUS Element™ Stent: Results From the TE-PROVE European Registry

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Background: The TE-PROVE post-market registry has enrolled 1014 patients at 37 sites in the EU to evaluate real-world clinical outcomes for patients receiving the paclitaxel-eluting, platinum chromium TAXUS Element™ stent (Boston Scientific, Natick, MA). This is the first report of 2-year outcomes with the TAXUS Element stent in everyday clinical practice.

Methods: The primary endpoint of overall and study-stent related target vessel failure (TVF, defined as cardiac death, and target vessel-related MI and reinervention [TVR]) at 1 year post-implantation was 6.0% (590/987), which compared to 3.7% (379/874) was considered related to the study stent (Tamburino et al, TCT 2013). Follow-up in the TE-PROVE will continue annually through 5 years. Secondary endpoints included the components of TVF, all-cause mortality, and ARC definite/probable stent thrombosis.

Results: At baseline, 75.0% (760/1014) of patients were male, mean age was 65.1±10.8 years, 25.5% (259/1014) had medically treated diabetes, mean lesion length was 19.8±12.0mm, and mean reference vessel diameter was 3.1±0.5 mm at 2
years, clinical follow-up or death occurred in 95.5% (966/1014) of patients. The 2-year rate of TVF was 10.4% (101/972), of which 6.4% (62/972) was considered related to the study stent. Cardiac death was 1.7% (7987), with 0.2% considered related to the study stent. Target vessel-related MI was 1.7% (17972) (1.5% study stent-related), and TVR was 8.3% (81792) (5.7% study stent-related). ARC definite/probable ST was 1.0% (10972), with 0.9% (9792) considered related to the study stent. Two-year outcomes for subsets, including small vessels, long lesions, and diabetes, will be available at the meeting.

Conclusions: At 2 years post-procedure, the thin-strut, platinum chromium, paclitaxel-eluting TAXUS Element stent continues to demonstrate good performance and safety in everyday clinical practice.

TCT-581

Long-term Patient-related and Stent-related Outcomes of Second-Generation Everolimus-Eluting Xience V Stents versus Zotarolimus-Eluting Resolute Stents in Real-World Practice: Three Year Results From the Multicenter Prospective EXCELLENT and RESOLUTE-Korea Registries

Joo Myung Lee1, Kyung Woo Park1, Jung-Kyun Han1, Han-Mo Yang1, Hyun-Jae Kang1, Bon-Kwon Koo1, Hyeon Cheol Lee1, Sang-II Woo1, Jin Sik Park2, Dong-Seung Ju1, Dong Woon Jeon1, Seok-Kyu Oh1, Joon Seon Park3, Doo-Il Kim4, Min So Hyon1, Hui-Kyung Jeon2, Do-Sun Lim1, Taechoon Ahn1, Hyo-Soo Kim1
1Department of Internal Medicine and Cardiovascular Center, Seoul National University Hospital, Seoul, Korea, Republic of; 2Department of Internal Medicine and Cardiovascular Center, Seoul National University Hospital, Seoul, Seoul, 3Pusan National University Hospital, Busan, Korea, Republic of; 4Inha University hospital, incheon, Korea, Republic of; 5Sejong General Hospital, Bucheon, Korea; 6Chonnam University Hospital, Gwangju, Korea, Republic of; 7Inje University Ilsan hospital, Koyang, Korea, Republic of; 8Wonkwang University Hospital, Iksan, Korea, Republic of; 9Yonsei University Medical Center, Daegu, Korea, Republic of; 10Inje University Haemerdai Paik Hospital, Busan, Korea, Republic of; 11Soonchunhyang University Hospital, Seoul, Korea, Republic of; 12Uijeongbu St Mary’s Hospital, Uijeongbu, Korea, Republic of; 13Korea University Anam Hospital, Seoul, Korea, Republic of; 14Gachon University Gil Hospital, Incheon, South Korea

Background: Long-term outcomes are imperative to confirm safety of drug-eluting stents. Only two randomized controlled trials have reported 2-year comparisons of three stents and reported the 3-year long term clinical outcomes. This study was performed to compare the long-term clinical outcomes of Xience VPromus everolimus-eluting stents (EES) with Resolute zotarolimus-eluting stents (ZES-R) in “all-comer” cohorts.

Methods: The EXCELLENT and RESOLUTE-Korea registries prospectively enrolled 3,056 patients treated with EES and 1,998 with ZES-R, respectively, without exclusions. Stent-related composite outcomes (target lesion failure and patients-related composite events up to 3 years follow-up) were compared in crude and propensity score matched analyses.

Results: Of 5054 patients, 3830 patients (75.8%) had off label indication (2217 patients with R-ZES in very small diameter (<2.25 mm) compared with use in small vessels between 2.25 and 2.75 mm). Low rates of clinical events were observed through long-term follow-up in both groups. Submitted on behalf of the RESOLUTE Global Clinical Program.

TCT-582

Percutaneous Coronary Intervention of Very Small Vessels in the RESOLUTE Global Clinical Program

Antonio Serra1
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Background: Limited clinical data is available in patients who underwent percutaneous coronary intervention (PCI) with drug eluting stents in very small vessels (reference vessel diameter [RVD] ≤2.25 mm).

Methods: We examined the long-term outcomes of patients who underwent PCI using ResoluteTM zotarolimus-eluting stent (R-ZES) in the pooled RESOLUTE program in vessels with RVD ≤2.25 mm and compared them to those of patients with RVD >2.25 but ≤2.75 mm. The RESOLUTE global clinical program includes: RESOLUTE First-in-Human, RESOLUTE All Comers (R-AC), RESOLUTE International, RESOLUTE US, RESOLUTE Japan, RESOLUTE Japan Small Vessel, RESOLUTE Asia, RESOLUTE China, and Resolute China Registry. Target Lesion Failure (TLF) was the composite of death from cardiac causes, target vessel myocardial infarction (TV-MI), and target lesion revascularization (TLR). The incidence of clinical events was calculated using the Kaplan Meier. Differences in baseline characteristics, patients were matched by propensity scores based on 24 baseline variables and adjusted p-values are provided.

Results: A total of 1205 subjects with RVD ≤2.25 mm RVD and 2773 subjects with RVD >2.25 but ≤2.75 mm were treated with R-ZES. Compared with patients with RVD >2.25 but ≤2.75 mm, patients with RVD ≤2.25 mm had more complex baseline characteristics including prior PCI (33% vs. 26%, p < 0.001) and history of hypertension (78% vs. 72%, p < 0.001), respectively. However, there was no significant difference in TLF, TLR, CD/Tv-MI or ARC definite/probable ST at 3 years (Table).

Conclusions: No increased risk is associated with the use of R-ZES in very small vessels (RVD ≤2.25 mm) compared with use in small vessels between 2.25 and 2.75 mm.

SATURDAY, SEPTEMBER 13, 2014, 5:00 PM–7:30 PM