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

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

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™ Paclitaxel-Eluting Platinum Chromium Coronary Stent in Routine Clinical Practice: 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 (ie, 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%, 781/1111) were male, with a mean age of 64.1±11.0 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) MACE (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

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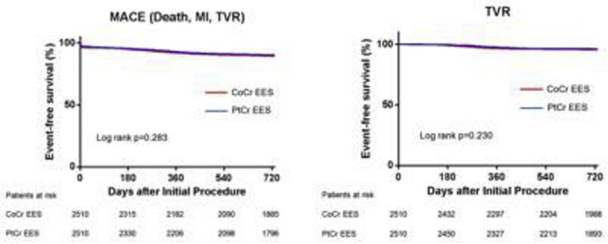
Background: It remains unclear whether there are differences in the safety and efficacy outcomes between Cobalt Chronium (CoCr-EES) and Platinum Chronium everolimus-eluting stents (PtCr-EES).
Methods: From the Interventional Cardiology Research In-Cooperation Society-Drug-Eluting Stents Registry, we 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 (12.0% for CoCr-EES versus 11.6% for PtCr-EES; HR, 0.954; 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, 1.083; 95% CI, 0.786 – 1.492, p=0.624), MI (HR, 0.972; 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 cerebrovascular event (HR, 0.914; 95% CI, 0.566 – 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 reintervention [TVR]) at 1 year post-implantation was 6.0% (59/987), of which 3.7% (37/9874) was considered related to the study stent (Tamburino et al, TCT 2013). Follow-up in TE-PROVE will continue annually through 5 years. Secondary endpoints included the components of TVF, all-cause mortality, and ARC definite/probable stent thrombosis. An independent Clinical Events Committee adjudicated all events for relatedness to the study stent.
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% (968/1014) 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% (7/987), with 0.2% considered related to the study stent. Target vessel-related MI was 1.7% (17/972) (1.5% study stent-related), and TVR was 8.3% (81/972) (5.7% study stent-related). ARC definite/probable ST was 1.0% (10/972), with 0.9% (9/972) 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

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Background: Long term outcomes are imperative to confirm safety of drug-eluting stents. Only two randomized controlled trials have reported 2-year comparisons of these stents, and no study has reported the 3-year long term clinical outcomes. This study was performed to compare the long-term clinical outcomes of Xience V/Promus 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 treated with EES and 1613 treated with ZES-R). The stent-related outcome (189 [6.2%] vs. 127 [6.4%], p=0.812) and the patient-related outcome (420 [13.7%] vs. 250 [12.5%], p=0.581) did not differ between EES and ZES-R respectively at 3 year, which was corroborated by similar results from the propensity score-matched cohort (HR 0.92, 95% CI 0.70-1.20, p=0.523 and 0.85, 95% CI 0.70-1.02, p=0.081, for stent and patient related outcomes, respectively) . The rate of definite or probable stent thrombosis up to 3 years (22 [0.7%] vs. 10 [0.5%], p=0.370) was also similar. The rate of very late definite or probable stent thrombosis was very low and comparable between the two stents (3 [0.1%] vs. 1 [0.1%], p=0.657). In multivariate analysis, chronic renal failure (adjusted HR 3.615, 95% CI 2.440-5.354, p< 0.001) and off label indication (adjusted HR 1.782, 95% CI 1.169-2.718, p=0.007) were the strongest predictors of target lesion failure at 3-year.
Conclusions: In this robust real world registry with unrestricted use of EES and ZES-R, both stents showed comparable safety and efficacy at 3-year follow-up. Overall incidences of target lesion failure and definite stent thrombosis, including very late stent thrombosis, were low, even in the patients with off label indications, suggesting excellent long term safety and sustained efficacy of both types of second generation DES.

TCT-582

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

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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 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. Given 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 1203 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. Low rates of clinical events were observed through long-term follow-up in both groups. Submitted on behalf of the RESOLUTE Global Clinical Program

	≤ 2.25 mm reference vessel diameter	>2.25 but ≤2.75 mm reference vessel diameter	Adjusted p-value
Target Lesion Failure, %	11.2%	10.0%	0.59
Target Lesion Revascularization, %	6.2%	4.5%	0.12
Cardiac Death / Target Vessel Myocardial Infarction, %	6.0%	6.3%	0.57
ARC definite/probable stent thrombosis, %	1.2%	0.8%	0.26

TCT-583

Longest available clinical follow-up of a cohort of "real-world" patients treated exclusively with drug-eluting stents: Results of 12 years of the DESIRE (Drug-Eluting Stents In the REal world) Registry

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Background: There is still uncertainty about the durability of the results of drug-eluting stents (DES) in real-world complex patients. We sought to provide the longest clinical follow-up data on outcomes of unselected patients treated solely with DES.
Methods: The DESIRE registry is a prospective, single-center registry encompassing all consecutive patients treated solely with DES since May 2002. The primary goal is the very long-term occurrence of MACE and stent thrombosis (ST). Patients were clinically followed at 1, 6 and 12 months and then annually. A multivariate model was built to determine independent predictors of MACE, TLR and ST.
Results: A total of 5,500 patients were included. The mean age was 64 ± 11 years. DM was detected in 29.7% and 44.8% presented with acute coronary syndrome. SVG lesions and STEMI represented 6% and 12% of the cohort, respectively. Follow-up was obtained in 98.2% of the patients (median 5.6 years). Currently, 79.6% of the population is free of any MACE. TVR was performed in 5.3% of the patients. Q-wave MI rate was only 1.7% while total ST rate was 1.9%. The majority of definite ST cases occurred between the 1st and 3rd years. Independent predictors of MACE were treatment of SVG (HR 1,63; 95% CI, 1.22 to 2.18, p= 0.001), multivessel disease (HR 1.39; 95% CI, 1.03 to 1.87, p< 0.001), residual stenosis (HR 1.3; 95% CI, 1.1 to 1.5, p= 0.034), DM (HR 1.6; 95% CI, 1.1 to 2.2, p= 0.006) and renal insufficiency (HR 1.5; 95% CI, 1.34 to 1.81, p= 0.004). Independent predictors of ST were PCI for STEMI (HR 3.5; 95% CI, 1.3 to 9.4, p= 0.013), stent length (HR 1.8; 95% CI, 1.09 to 3.02, p=0.023), moderate/severe calcification at lesion site (HR 2.38; 95% CI, 1.34 to 4.23, p=0.003), and in-stent residual stenosis (HR 1.04; 95% CI, 1.01 to 1.06, p=0.003).
Conclusions: In our single center experience, the use of DES was associated with very long-term safety and effectiveness with acceptable low rates of adverse clinical events, including ST.