respectively (p < 0.001). Twenty +/- 4 months of follow-up results are reported in Table. In ERACI IV MACCE at 1 year was 2.2%, duplicating this number up to 5.8% at 20 months, although compared to ERACI III, ERACI IV has lower incidence of MACCE (p < 0.001), the same outcome was seen in diabetics (5.8% vs 25.5%), ERACI IV vs ERACI III respectively, p < 0.001 and non-diabetics (5.8% vs 12.4%, respectively p < 0.02).

### Table

<table>
<thead>
<tr>
<th>20 months outcome</th>
<th>ERACI III-DES</th>
<th>ERACI IV-FRB2</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N patients</td>
<td>225</td>
<td>225</td>
<td>NA</td>
</tr>
<tr>
<td>Death</td>
<td>7 (3.1%)</td>
<td>4 (1.8%)</td>
<td>0.54</td>
</tr>
<tr>
<td>Acute myocardial infarction (MI)</td>
<td>10 (4.4%)</td>
<td>2 (0.9%)</td>
<td>0.01</td>
</tr>
<tr>
<td>Non-fatal cerebrovascular event (CVA)</td>
<td>7 (3.1%)</td>
<td>0 (0.0%)</td>
<td>0.02</td>
</tr>
<tr>
<td>Death/MI/CVA</td>
<td>21 (9.3%)</td>
<td>6 (2.7%)</td>
<td>0.003</td>
</tr>
<tr>
<td>Unplanned revascularization</td>
<td>26 (11.6%)</td>
<td>8 (3.6%)</td>
<td>0.001</td>
</tr>
<tr>
<td>MACCE</td>
<td>38 (16.9%)</td>
<td>13 (5.8%)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Stent Thrombosis (ARC definition)</td>
<td>7 (3.1%)</td>
<td>2 (0.9%)</td>
<td>0.17</td>
</tr>
</tbody>
</table>

### CONCLUSIONS

At 20 +/- 4 months this multicenter prospective registry showed that Firebird 2 stent used in complex lesions has a remarkable low incidence of MACCE and other endpoints. Longer follow-up is guaranteed to assess if these numbers remains over time.

### CATEGORIES CORONARY

**KEYWORDS** Complete coronary revascularization, Drug-eluting stent, second generation

**TCT-599**


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**BACKGROUND**

The Svelte (New Providence, NJ) sirolimus-eluting coronary stent utilizing a bioresorbable amino acid-based (PEA) drug carrier is a novel stent-on-a-wire Integrated Delivery System (IDS) consisting of a low-compliant balloon with balloon control bands (BCBs) affixed to a 0.014” integrated steerable wire with shapeable tip. The IDS is low-profile and specifically designed for use with the transradial approach, ‘slender’ PCI and direct stenting. The DIRECT I first-in-human study was designed to evaluate the feasibility of the Svelte drug-eluting stent IDS.

**METHODS**

Thirty patients with symptomatic ischemic heart disease and a single de novo native coronary lesion suitable for percutaneous coronary intervention were prospectively enrolled at 4 New Zealand sites. Lesion length had to be <23 mm and the vessel reference diameter 2.5–3.5 mm. The primary safety endpoint was 6-month target vessel failure (TVF), defined as the composite of death, target vessel MI or clinically-driven target vessel revascularization (TLR). The primary efficacy endpoint was 6-month angiographic in-stent late lumen loss (LLL). All patients were scheduled to receive angiographic and IVUS follow-up at baseline and 6-months, with 15 patients additionally undergoing OCT analysis at the same time points. All angiographic and clinical data were reviewed and adjudicated by an independent core lab and DSMB at all reported time points.

**RESULTS**

Twenty-nine of 30 enrolled patients completed 6-month follow-up. Angiographic in-stent LLL was 0.22–0.27 mm at 6-months. Other 6-month follow-up included IVUS assessed neointimal volume of 3.3–4.4 mm³ and volume obstruction of 2.7–4.5%. OCT revealed 98.4% strut coverage at a depth of 0.12–0.06 mm. Through 36-month followup, no patient has experienced stent thrombosis, MACE or TVF.

### CONCLUSIONS

This first-in-human feasibility study demonstrated minimal in-stent proliferation by angiography and confirmed by IVUS, along with near complete strut coverage by OCT. The concordant excellent clinical outcomes, including no stent thrombosis, suggest that the Svelte drug-eluting coronary stent IDS warrants further evaluation. The novel approach to drug delivery may lessen the potential side effects of impaired endothelial recovery, fibrin deposition, burst drug release and luminal strut drug residue sometimes associated with durable polymer technologies, while direct stenting with the IDS also minimizes procedural time and adjunctive product use.

### CATEGORIES CORONARY

**KEYWORDS** Stents: Drug-Eluting

**TCT-600**

**Short and Mid-Term Outcomes of Diabetic Patients Treated with Everolimus-Eluting Bioresorbable Scaffolds Versus Second-Generation Drug Eluting Stents: a Propensity Score-Matched Analysis of ABSORB EXTEND and SPIRIT Clinical Trials**

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**BACKGROUND**

There are limited data on the clinical outcomes of diabetic patients treated with bioresorbable scaffolds (BRS). The aim of the present analysis is to compare the occurrence of clinical events in diabetics treated with the Absorb bioresorbable vascular scaffold (Absorb BVS; Abbott Vascular, Santa Clara, CA) versus everolimus-eluting metal stents (EES; XIENCE, Abbott Vascular, Santa Clara, CA).

**METHODS**

The present study included 812 patients in the ABSORB EXTEND study in which a total of 215 diabetic patients were treated with Absorb BVS. In addition, 882 diabetic patients treated with EES in pooled data from the SPIRIT clinical program (SPIRIT II [A Clinical Evaluation of the XIENCE V Everolimus Eluting Coronary Stent System], SPIRIT III [Clinical Trial of the XIENCE V Everolimus Eluting Coronary Stent System (EECSS1)], SPIRIT IV Clinical Trial [Clinical Evaluation of the XIENCE V Everolimus Eluting Coronary Stent System] and XIENCE V USA) were used for comparison by applying propensity score matching using 29 different variables (217 pairs). The primary endpoint was major adverse cardiac events (MACE), including cardiac death, myocardial infarction, and target lesion revascularization.

**RESULTS**

After propensity score matching, the baseline clinical characteristics were similar in Absorb BVS and EES groups. As shown in Figure 1 and Table 1, diabetic patients treated with the BRS had a similar incidence of MACE compared with diabetics treated with EES (5.7% vs. 5.6%, respectively; HR 0.99; 0.44–2.20; P = 0.98) after 393 days of follow-up.
CONCLUSIONS In this largest ever patient-level pooled analysis on treatment of diabetics patients with BRS, individuals treated with the Absorb BVS had similar rate of major cardiac events as compared with diabetics treated with EES.

CATEGORIES CORONARY: Diabetes
KEYWORDS Atherosclerosis, coronary, Bioresorbable scaffold, Diabetes mellitus

TCT-601 Outcomes After Unprotected Left Main Percutaneous Coronary Intervention: Evidence from the Xience V USA Registry

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BACKGROUND Percutaneous coronary intervention (PCI) for unprotected left main coronary artery (UPLMCA) using first generation drug eluting stents with ostial or mid-shaft lesions have favorable outcomes. The safety and efficacy of Xience V everolimus eluting stent (EES) for this lesion subset is unknown.

METHODS The Xience V USA is an observational registry of 8000 patients who underwent PCI from 2008-2014, designed as a single arm, non-randomized, post-approval study funded by Abbott Vascular. We identified 83 patients who had PCI of a UPLMCA and compared this to a matched cohort of 5275 patients who underwent PCI of a non-UPLMCA. Baseline and procedural characteristics were recorded. Center trails during the same time period are not included in this cohort. Baseline and procedural characteristics were recorded. Follow-up was by review of medical records or telephone contact for post-procedural complications or adverse events.

RESULTS In total 100 patients underwent PCI with a SYNERGY stent during the one-year study period. The mean age was 72.3 years (±10.0; range 41-92 years), 37% of the cohort was defined as elderly (age >75 years) and 8% defined as very elderly (age >85 years). Mean EuroSCORE was 11.57 (±11.15, range 0.88-702.23). The indication for SYNERGY stent use was as follows: elective (62%), unprotected (31%), concurrent anti-coagulation (28%) need for a non-cardiac procedure (10%), increased bleeding risk (31%), or other (15%). NSTEMI/STEMI was the presenting complaint in 32% of patients. The coronary disease was complex. Left main stem was involved in (13%), multi-vascular disease (36%), bifurcation disease requiring side-branch stenting (9%), and 37% required CTO intervention. Mean Syntax score was 22.7 (±12.1, range 5-63). The mean stent length/patient was 75.3mm (±41.5) with 1.44 (±0.64) lesions treated and 2.67 (±1.33) stents implanted per patient. DAPT discontinuation by 3 months has occurred in 77% to date. Despite the patient and lesion complexity, there were no thrombotic events after discontinuation of anti-platelets (acute, sub-acute or late stent thrombosis). Eleven patients were able to undergo non-cardiac surgery after three months DAPT. By a minimum of six months (mean duration), SYNERGY stents showed excellent safety and efficacy.

CONCLUSIONS When used in real world practice for UPLMCA PCI, the Xience V EES is safe and effective with similar rates of stent thrombosis and low MACE event rates compared to non-UPLMCA PCI at one year.

CATEGORIES CORONARY: Stents: Drug-Eluting
KEYWORDS Drug-eluting stent, everolimus, High-risk PCI, Left main coronary artery disease

TCT-602 Initial experience of bioabsorbable polymer Everolimus-eluting stents in high-risk patients

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BACKGROUND As progressively more elderly and comorbid patients are being considered for revascularization the need for one year of dual anti-platelets becomes of increasing concern. SYNERGY™ Everolimus-eluting platinum chromium coronary stents allow for early cessation of dual antiplatelet therapy (DAPT) due to complete polymer absorption and drug elution by three months. The aim of this study was to retrospectively assess those in our unit who have undergone PCI with a SYNERGY™ stent to look for adverse outcomes post discontinuation of DAPT.

METHODS All patients in our unit who underwent clinically indicated PCI with a SYNERGY™ stent from August 2013- December 2014 were retrospectively analyzed. Patients who have been enrolled in multi-center trials during the same time period are not included in this cohort. Baseline and procedural characteristics were recorded. Follow-up was by review of medical records or telephone contact for post-procedural complications or adverse events.

RESULTS In total 100 patients underwent PCI with a SYNERGY™ during the one-year study period. The mean age was 72.3 years (±10.0; range 41-92 years), 37% of the cohort was defined as elderly (age >75 years) and 8% defined as very elderly (age >85 years). Mean EuroSCORE was 11.57 (±11.15, range 0.88-702.23). The indication for SYNERGY stent use was as follows: elective (62%), unprotected (31%), concurrent anti-coagulation (28%) need for a non-cardiac procedure (10%), increased bleeding risk (31%), or other (15%). NSTEMI/STEMI was the presenting complaint in 32% of patients. The coronary disease was complex. Left main stem was involved in (13%), multi-vascular disease (36%), bifurcation disease requiring side-branch stenting (9%), and 37% required CTO intervention. Mean Syntax score was 22.7 (±12.1, range 5-63). The mean stent length/patient was 75.3mm (±41.5) with 1.44 (±0.64) lesions treated and 2.67 (±1.33) stents implanted per patient. DAPT discontinuation by 3 months has occurred in 77% to date. Despite the patient and lesion complexity, there were no thrombotic events after discontinuation of anti-platelets (acute, sub-acute or late stent thrombosis). Eleven patients were able to undergo non-cardiac surgery after three months DAPT. By a minimum of six months (mean duration), SYNERGY stents showed excellent safety and efficacy.

CONCLUSIONS The use of SYNERGY™ stents allows early discontinuation of DAPT, reducing the risk of bleeding complications and facilitating non-cardiac procedures, without an increase in the incidence of stent thrombosis. The results for TVR and clinical outcomes are excellent for a complex patient and disease group.

CATEGORIES CORONARY: Stents: Drug-Eluting
KEYWORDS Chronic total occlusion, Complex lesion, Stent thrombosis