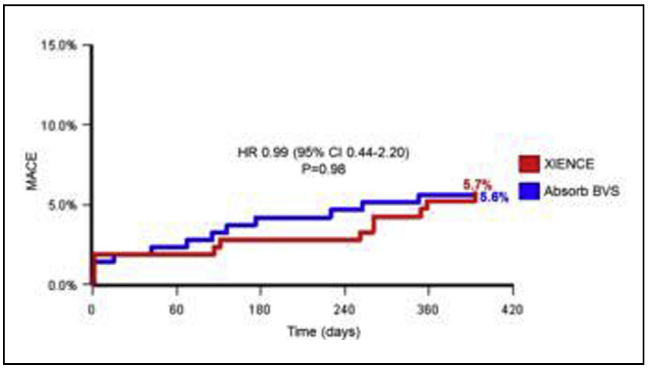
Short and Mid-Term Kaplan-Meier Estimates of MACE

| | Time After Index Procedure (days) | | | |
|---|---|---|---|---|
| | 0 | 37 | 194 | 393 |
| Absorb BVS | | | | |
| Patients at Risk | 215 | 211 | 206 | 202 |
| Number of Events | 0 | 4 | 9 | 12 |
| % of Events | 0.0% | 1.9% | 4.2% | 5.6% |
| XIENCE | | | | |
| Patients at Risk | 217 | 210 | 203 | 189 |
| Number of Events | 1 | 4 | 6 | 12 |
| % of Events | 0.5% | 1.8% | 2.8% | 5.7% |




**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 Abbot 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 lesion. The primary endpoint was the incidence of Academic Research Consortium (ARC) defined definite or probable stent thrombosis (ST). The co-primary endpoint was a composite of cardiac death and myocardial infarction (MI) at 1 year. The pre-specified secondary endpoints included a composite of all cause death, MI, repeat revascularization, target lesion failure (TLF) and major bleeding complications. Follow-up was obtained up to 1 year and all clinical endpoints were adjudicated by the Independent Clinical Events Committee.

**RESULTS** Patients who underwent PCI of UPLMCA were older (>70 years of age, p=0.0024), had more cardiovascular risk factors (diabetes mellitus 51.2% vs. 35.4%, p=0.0036), established atherosclerotic disease (multi-vessel coronary artery disease 53.0% vs. 24.0%, p=<0.0001) and renal insufficiency (20.7% vs. 9.9%, p=0.0043). The UPLMCA cohort also had a lower mean EF (51.7% vs. 55.0%, p=0.0478). There were no differences in rates of definite or probable stent thrombosis between UPLMCA cohort and non-UPLMCA cohort. One year death and MI occurred in 7.6% of patients in the UPLMCA cohort vs. 5.5% in the non-UPLMCA cohort (HR=1.35 [0.60, 3.04], p=0.4611). In addition, there were no statistical significant differences in MACE event rates between the two groups (UPLMCA: 11.5 vs. 7.4% non-UPLMCA, HR=1.54 [0.79, 2.97], p=0.1996). TLF was low at a rate of 10.2% in the UPLMCA cohort versus 6.8% in the non- UPLMCA cohort (HR=1.48 [0.72, 2.98], p=0.2721). Finally, TVR was performed in 6.6% of patients with a UPLMCA cohort vs. 3% in the non-UPLMCA cohort (HR=2.21 [0.91, 5.38], p=0.0738).

**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 underwent 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 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™ 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 11.37 (±11.13, range 0.88-70.23). The indication for SYNERGY™ stent use was as follows; frail or elderly (16%), concurrent anticoagulation (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-vessel disease (36%), bifurcation disease requiring side-branch stenting (9%), and 37% required CTO intervention. Mean Syntax score was 22.7 (±12.1, range 6-53). 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 (median follow up time per patient 341 days) follow up four patients died from non-cardiac causes (one from cancer, one sepsis and multi-organ failure, one ruptured abdominal aortic aneurysm and one vascular complication post-TAVI). There were two target vessel re-vascularizations (TVR) and one patient underwent CABG but no incidence of stent thrombosis by the same time-point.

**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