**TCT-571**
Clinical Outcomes of Biodegradable-Polymer Coated Sirolimus-Eluting Stent in Unselected Patients with Long Coronary Lesions: LONG-FLEX Registry

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**BACKGROUND** Long lesions account for a significant proportion of percutaneous coronary intervention and it has been identified as one of the predictors which influence risk of angiographic and clinical restenosis. However, newer generation drug-eluting stents particularly of long length avoid incomplete coverage of the diseased segment of the long lesion and thereby minimize the occurrence of restenosis. Therefore, in this LONG-FLEX registry, we aimed to assess clinical outcomes of real-world patients who were successfully treated with long length Supraflex (Sahajanand Medical Technologies Pvt. Ltd., Surat, India), a novel biodegradable polymer coated sirolimus-eluting stent.

**METHODS** This retrospective, non-randomized and observational registry included 240 consecutive patients who were treated with long length Supraflex in nine different clinical sites of India. The primary endpoint of the study was 9-month incidence of major adverse cardiac events (MACE) defined as a composite of cardiac death, myocardial infarction (MI), target lesion revascularization (TLR) and target vessel revascularization (TVR). The data was analyzed according to the Academic Research Consortium definition at 9-month clinical follow-up.

**RESULTS** The study population consisted of 240 consecutive patients who were successfully treated with long study stents between July, 2012 and May, 2014. The study population predominantly included high risk patients with 120 (50.0%) hypertensive patients and 56 (23.3%) diabetic patients which reflected real-world scenario. A total of 248 lesions were intervened with a total of 287 study stents. The average number of implanted stents per lesion was 1.2±0.4. Clinical follow-up at 9-month was completed in 236 (98.33%) patients. At 9-month clinical follow-up, 1 (0.42%) died due to heart failure. 1 (0.42%) had MI and 2 (0.85%) underwent TLR. Thus, nine-month clinical follow-up demonstrated low rate of MACE (n=7; 2.97%). A total of 4 (1.69%) incidences of ST, 1 (0.42%) definite ST and 3 (1.27%) probable ST, were observed at 9-month clinical follow-up.

**CONCLUSIONS** The nine-month clinical outcomes of this “real-world” registry demonstrated safety and efficacy of Supraflex stent in patients receiving long study stents (stent length >40 mm) implanted over long length coronary lesions.

**CATEGORIES CORONARY:** Stents: Drug-Eluting

**KEYWORDS** Biodegradable polymer, Drug-eluting stent, Long lesion

**TCT-572**
Final 5-Year Outcome After Implantation of Zotarolimus-Eluting Resolute Stents Versus Everolimus-Eluting Xience V Stents in the Broad Patient Population of the Randomized TWENTE Trial

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**BACKGROUND** Only limited long-term safety and efficacy data from large randomized clinical trials are available on second-generation drug-eluting stents (DES). In a head-to-head comparison, we assessed the 5-year safety and efficacy of the zotarolimus eluting Resolute stent (Medtronic) versus the everolimus-eluting Xience V stent (Abbott Vascular).

**METHODS** The TWENTE trial is an investigator-initiated, patient-blinded, randomized, non-inferiority study with limited exclusion criteria (all coronary syndromes except for STEMI), performed in a broad patient population that reflects routine clinical practice. Patients (n=1,391; 81.4% of the eligible patient population) were randomly assigned to percutaneous coronary intervention (PCI) with Resolute (n=697) or Xience V stents (n=694). Similarity in one-year clinical outcome between trial participants and the non-enrolled patient population has previously been reported in detail. The primary endpoint is target vessel failure (TVF), a composite of cardiac death, target vessel-related myocardial infarction (MI), and target vessel revascularization (TVR). Secondary endpoints included the individual components of the primary endpoint and the incidence of stent thrombosis. An independent external research organization performed the clinical event adjudication.

**RESULTS** In the study population (64.2±10.8 years; 72.5% male) non-ST-elevation acute coronary syndromes were present in 52.6% of the patients and 21.6% of patients were diabetics. A large proportion of patients was treated for complex type B2 or C lesions (70.1%) and “off-label” indications for DES use (74.4%). The 5-year clinical outcomes of the primary endpoint TVF and various secondary endpoints will be presented for both DES groups. These include the components of TVF, stent thrombosis, and various composite clinical endpoints such as target lesion failure (TLF), major adverse cardiac events (MACE), and patient-oriented composite endpoint (POCE).

**CONCLUSIONS** We will report the final 5-year outcome of patients enrolled in the randomized TWENTE trial, which compared the Resolute zotarolimus-eluting stent versus the Xience V everolimus-eluting stent.

**CATEGORIES CORONARY:** Stents: Drug-Eluting

**KEYWORDS** Randomized clinical trial, Resolute, XIENCE V Everolimus-Eluting Stent

**TCT-573**
Following Biolimus-Eluting Stenting, No Excess in 3-Year MACE in Diabetic Patients not treated with Insulin

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**BACKGROUND** Patients with diabetes mellitus (DM) treated with first generation drug-eluting stents (DES) remain at higher risk of major adverse cardiac events (MACE) and stent thrombosis (ST) compared with non-diabetics. Long-term data on newer generation DES in diabetics are sparse. We assess and compare the incidence of MACE, ST and major adverse cardiac events (MACE) and stent thrombosis (ST) in diabetic and non-diabetic patients.

**METHODS** A total of 1315 diabetic patients (408 insulin dependent [IDDM], 907 non-insulin dependent[NIDDM]) and 4154 non-diabetic patients received a Biolimus™ or BioMatrix Flex™ coronary stent, and were enrolled in e-BioMatrix, a prospective international multi-center registry. The primary outcome measure of the present analysis was the 3-y incidence of MACE (composite of cardiac death, myocardial infarction [MI] or clinically driven target vessel revascularization [TVR]). ARC definite or probable ST were secondary outcome measures.

**RESULTS** Patients with DM were older than non-diabetics (mean age 64.6±10.2 vs. 62.8±11.1 y; p<0.001) and had a higher Charlson comorbidity index (2.1±1.6 vs 0.6±1.0; p<0.001). A high percentage of 49.8% presented with acute coronary syndromes. Diabetic patients had more lesions (1.47±0.76 vs. 1.23±0.49 vs. 1.19±0.44; p<0.001) and were enrolled in e-BioMatrix, a prospective international multi-center registry. The primary outcome measure of the present analysis was the 3-y incidence of MACE (composite of cardiac death, myocardial infarction [MI] or clinically driven target vessel revascularization [TVR]). ARC definite or probable ST were secondary outcome measures.

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