

**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 Supraflex stent (length  $\geq 40$ mm) in view of long coronary lesions from 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). We also assessed stent thrombosis (ST) 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  $1.2 \pm 0.4$ . 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 cardiac event, 4 (1.69%) 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  $\geq 40$  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 entire 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 ( $64.2 \pm 10.8$  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 (77.4%). The 5-year incidence 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, XIENVE 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 and ST at 3 y after implantation of Biolimus A9™-eluting coronary stents (BioMatrix™, BioMatrix Flex™) 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 BioMatrix™ or BioMatrix Flex™ coronary stent, and were enrolled in e-BioMatrix, a prospective international multicenter 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  $64.6 \pm 10.2$  vs.  $62.8 \pm 11.1$  y;  $p < 0.001$ ) and had a higher Charlson comorbidity index ( $2.1 \pm 1.6$  vs.  $0.6 \pm 1.0$ ;  $p < 0.001$ ). A high percentage of 49.8% presented with acute coronary syndromes. Diabetic patients had more lesions ( $1.47 \pm 0.80$  vs.  $1.42 \pm 0.76$ ;  $p = 0.04$ ), more vessels treated ( $1.23 \pm 0.49$  vs.  $1.19 \pm 0.45$ ;  $p = 0.006$ ), and smaller stent diameters ( $2.95 \pm 0.36$  vs.  $3.0 \pm 0.36$ ;  $p < 0.001$ ), while the total stent length was similar. At 3y follow up (compliance 89.6%) 12.2% of DM patients and 8.0% of non-DM patients had a MACE event ( $p < 0.001$ ). Patients

with IDDM had the highest incidence of MACE (17.2%). MACE was similar for patients with NIDDM and non-diabetics. Clinically driven TVR was 5.97% for diabetics and 3.38% for non-diabetic patients. Definite or probable ST occurred in 0.9% for diabetic and non-diabetic patients, and in 1.0% of patients with IDDM.

**CONCLUSIONS** In this registry, diabetic patients receiving a Biolimus A9™-eluting DES had a significantly higher rate of MACE than non-diabetics, but similar and low rates of ARC definite or probable stent thrombosis at 3 y of follow up.

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

**KEYWORDS** Biodegradation polymer coating, Diabetes mellitus, Drug-eluting stent, second generation

#### TCT-574

##### The Impact of Comorbidities on Long-term PCI outcomes: Final Three year Results from the large, multi-center e-BioMatrix registry

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**BACKGROUND** The e-BioMatrix registry is a prospective, multi-center, observational registry investigating the long-term clinical events after treating a “real world, all-comers” patient population with either BioMatrix™ or BioMatrix Flex™ stents. This BA9™-eluting stent (BES) has an abuminal biodegradable polymer coating, which disappears within 9 months, and is intended to prevent the late events that may be associated with the existence of durable polymer. This work presents the influence of comorbidities on outcomes in this setting. We present the final result of our study on the impact of comorbidities (using the Charlson’s comorbidity index) on clinical outcomes.

**METHODS** We used the Charlson comorbidity index (CCI), a scoring system involving weighting factors on the basis of disease severity, including cardiovascular diseases, diabetes, renal failure, chronic infections and malignant tumors. Among 5472 patients in this registry, 2953 (54%) had at least one comorbidity, of which the most common comorbidities were prior myocardial infarction (24.9% of the population), diabetes mellitus (24.1%), peripheral vascular disease (6.8%), congestive heart failure (5.2%), chronic obstructive pulmonary disease (5.2%), cerebral vascular disease (5.7%) and renal failure (2.7%). Four patient subgroups with Charlson comorbidity indices equal to 0, 1, 2, and  $\geq 3$  are defined as follows: CCI-0 (no comorbidity; n=2517), CCI-1 (CCI=1; n=1709), CCI-2 (CCI=2; n=694), CCI $\geq 3$  (n=550). With increasing CCI, patients were older, had higher rates of hypertension, hypercholesterolemia, and obesity, but were less often current smokers. They had undergone increasingly often a prior PCI or CABG and had more often decreased LV ejection fraction. LVEF <40%: CCI-0: 4.78%, CCI-1: 6.5%, CCI-2: 14.19%, CCI $\geq 3$ : 28.1%; p<0.01. Compared to the other groups, patients with CCI $\geq 3$  underwent PCI less often for STEMI (CCI-0: 41.7%, CCI-1: 30.3%, CCI-2: 25.7%, CCI $\geq 3$ : 13.8%).

**RESULTS** At 1 year, the comparison of the subgroups by the Kaplan-Meier curves suggested a direct correlation between CCI and MACE, but not between CCI and bleeding or stent thrombosis. However, in a multivariate analysis CCI was shown to be no longer an independent predictor of MACE. The final 36-months data including the primary endpoint (MACE), Mortality, MI, stent thrombosis and bleeding, is in the process of being analyzed and will be reported at the time of presentation. Furthermore, the results of the multivariate analysis will be reported to identify the independent predictors of 36-month mortality, MACE, and major bleeding.

**CONCLUSIONS** This large international study demonstrates the impact of comorbidities on long-term safety and efficacy outcomes in patients undergoing PCI. The complete final 3-year follow-up analysis will be available at the time of the meeting.

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

**KEYWORDS** Biodegradable polymer, Complex lesion, Drug-eluting stent, second generation

#### TCT-575

##### Multi-Center, Post-marketing Evaluation of the Elixir DESyne® Novolimus Eluting Coronary Stent System: 1-Year Results from the EXCELLA PMCF Study

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**BACKGROUND** A post marketing clinical follow-up study was conducted evaluating the continued safety and effectiveness of the CE-mark approved DESyne® Novolimus Eluting Coronary Stent System (NECSS) (Elixir Medical, Sunnyvale, CA), a Co-Cr stent with a durable biocompatible polymer and Novolimus, a macrocyclic lactone mTOR inhibitor. The drug dose is 5 µg per mm of stent length.

**METHODS** A total of 57 patients were enrolled into the EXCELLA Post-marketing Clinical Follow-up (PMCF) study. All were treated with the DESyne NECSS for de novo lesions in native coronary arteries with a reference vessel diameter between 2.5 and 4.0mm treatable with stents between 14 and 38 mm in length. Patient data were analyzed for the clinical endpoints of major adverse cardiac events (MACE) defined as: cardiac death, target vessel MI, clinically-indicated target lesion revascularization (TLR); target vessel revascularization and stent thrombosis at 1, 9, 12 and 24 months. The study was approved the local Ethics Committees and all patients provided informed consent.

**RESULTS** Patients were enrolled between February 2014 and May 2014, in Germany, Jordan and Spain. After the index procedure, patients were contacted at 1, 9 and 12 months either via an office visit or telephonically. The mean age of patients was 62 years; 38.6% were diabetics and 72% presented with hypercholesterolemia and 72% with hypertension and 12.3% had unstable angina. Baseline lesion characteristics revealed 51% type C lesion with a mean reference vessel diameter of  $2.84 \pm 0.45$ mm and lesion length of  $17.27 \pm 8.73$ mm. Clinically, the DESyne NECSS demonstrates excellent safety with no clinical events reported through 30 days and continued low MACE rates through 12 months; with the full demographic, lesion and clinical data through 12 months to be presented.

**CONCLUSIONS** The DESyne NECSS continues to demonstrate excellent clinical safety similar to the clinical safety results seen in the pivotal EXCELLA II Randomized Study. Demographic and clinical results through 12 months will be presented.

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

**KEYWORDS** Biodegradation polymer coating, DES, Novolimus

#### TCT-576

##### Evaluation of Two-Year Outcomes Following Resolute Integrity Zotarolimus-eluting Stent Implantation

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**BACKGROUND** The Resolute Integrity™ zotarolimus-eluting stent (ZES; Medtronic, Inc.) is designed with a single continuous wire formed into a repeating sinusoidal pattern (as compared with discrete rings with the previous Resolute ZES) with the goal to enhance deliverability. The objective of RESOLUTE INTEGRITY US Zotarolimus-Eluting Coronary Stent System Clinical Study is to investigate outcomes with Resolute Integrity ZES.

**METHODS** The RESOLUTE INTEGRITY US study is a multi-center, single-arm, open label study in the United States that enrolled patients with de novo lesions with length  $\leq 30$  mm and vessel diameter of 2.25 to 4.2 mm. Clinical outcomes have not been previously reported. Patients will have been followed for two years by the time of TCT 2015.

**RESULTS** The RESOLUTE INTEGRITY US study enrolled 230 patients (251 lesions); 42% had diabetes mellitus, including 17% with insulin-dependent diabetes mellitus, 24% prior myocardial infarction, 83% of