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

Prakash Chandwani,1 Puneet Verma,2 Sudheer Saxena,3 Atul Abhyankar,4 Manjinder Singh Sandhu,5 Nikhil Parikh,6 Jayesh Prajapati,7 Sharad Jain,8 Ashok N. Buphal,9 Padma Kumar Ramachandran,2 Arshi Sarang,1 Ashok Thakkar10 Heart and General Hospital, Jaipur, Rajasthan, India; 3ACE Heart and Vascular Institute, Mohali, Punjab, India; 5Max Superspeciality Hospital, Mohali, Punjab, India; 8Royal Sussex County Hospital, Brighton, United Kingdom; 9Kasturba Medical College and Hospital, Manipal, Karnataka, India; 10Sahajanand Medical Technologies Pvt. Ltd., Surat, Gujarat, India

**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 ≥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 will report the final 5-year outcome of patients 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 stent lengths 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 stent 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, 2 (0.80%) underwent TLR, 1 (0.42%) underwent TVR. Thus, nine-month clinical follow-up demonstrated low rate of MACE (98.33%) patients. At 9-month clinical follow-up, 1 (0.42%) died due to heart failure, 2 (0.80%) underwent TLR, 1 (0.42%) underwent TVR. Thus, nine-month clinical follow-up demonstrated low rate of MACE (98.33%) patients. At 9-month clinical follow-up, 6 (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 stent lengths (stent length ≥40 mm) implanted over long length coronary lesions.

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

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

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**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

Clemens von Birgelen,1 Liefke C. van der Heijden,1 Marlies M. Kok,2 Gert van Houwelingen,3 Martin G. Stool,4 Frits H. de Man,5 Hans W. Louwerenburg,5 Gerard C. Linssen,5 Kenneth Tandjung,5 Mounir W. Basalus,6 Job van der Palen,7 Marije M. Löwik7 1Thoraxcentrum Twente & University of Twente, Enschede, Netherlands; 2Thoraxcentrum Twente, Enschede, Netherlands; 3Ziekenhuisgroep Twente, Almelo, Netherlands

**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

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**TCT-573**
Following Biolimus-Eluting Stenting, No Excess in 5-Year MACE in Diabetic Patients not treated with Insulin

Marco Roffi,1 Franz Eberli,2 Mariano Valdes,3 Ian Menown,4 Imad A. Alhaddad,5 David Hildick-Smith,6 Keith G. Oldroyd,7 Eryfli Kallouli,8 Ashkan Yazdani,9 Philip Urban10 1Hopitaux Universitaires de Geneve (Hug), Geneva, Switzerland; 2Trieml Hospital Zurich, Zurich, Switzerland; 3Hospital Universitario Virgen de la Arrixaca, Murcia, Spain; 4Craigavon CardioCentre, Craigavon, United Kingdom; 5Jordan Hospital, Amman, Jordan; 6Royal Sussex County Hospital, Brighton, United Kingdom; 7University of Glasgow, Glasgow, United Kingdom; 8Biosensors International, Morges, Switzerland; 9Hopitalet de la Pate, Geneva, Switzerland

**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 years 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 multi-center registry. The primary outcome measure of the present analysis was the 3-year 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 morbidity 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±0.80 vs. 1.42±0.75; p=0.04), more vessels treated (2.3±0.49 vs. 1.99±0.06; p=0.001), smaller stent diameters (2.95±0.36 vs 3.2±0.36; p<0.001), while the total stent length was similar. At 3 year 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 5.9% 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

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**TCT-575**

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

Imad A. Alhaddad,1 Mohammad Jarrah,2 Ramiro Trillo,3 Andres Ilguez Romero,4 Ricardo A. Costa,5 Lynn Morrison,6 Sara Talty,5 Lynn Vandertie,5 Karl-Eugen Hauptmann7 Jordan Hospital, Amman, Jordan; 7King Abdullah University Hospital, Jeddah, Saudi Arabia; 5Hospital Clínico Universitario de Santiago de Compostela, Santiago de Compostela, Spain; 5Hospital Meixoeiro, Vigo, Spain; 3Instituto Dante Pazzanese de Cardiologia, Sao Paulo, Brazil; 7Elixir Medical Corporation, Sunnyvale, CA; 5Medical Device Consultancies, Christ Church, New Zealand; 6Krankenhaus der Barmherzigen Brüder Trier, Trier, Germany

**BACKGROUND**

A post marketing clinical follow-up study was conducted evaluating the completed 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 by 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 ± 0.45mm and lesion length of 17.27 ± 8.73mm. 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