

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

Franz X. Kleber,¹ Franz Eberli,² Mariano Valdes,³ Ian Menown,⁴ Imad A. Alhaddad,⁵ David Hildick-Smith,⁶ Keith G. Oldroyd,⁷ Eriflyi Kalloudi,⁸ Ashkan Yazdani,⁸ Philip Urban⁹
¹Cardio Centrum Berlin, Berlin, Germany; ²Triemli Hospital Zurich, Zürich, Switzerland; ³Hospital Universitario Virgen de la Arrixaca, Murcia, Spain; ⁴Craigavon Cardiac Centre, Craigavon, United Kingdom; ⁵Jordan Hospital, Amman, Jordan; ⁶Royal Sussex County Hospital, Brighton, United Kingdom; ⁷University of Glasgow, Glasgow, United Kingdom; ⁸Biosensors International, Morges, Switzerland; ⁹Hôpital de la Tour, Geneva, Switzerland

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 ≥ 3 are defined as follows: CCI-0 (no comorbidity; n= 2517), CCI-1 (CCI=1; n=1709), CCI-2 (CCI=2; n=694), CCI ≥ 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 ≥ 3 : 28.1%; p<0.01. Compared to the other groups, patients with CCI ≥ 3 underwent PCI less often for STEMI (CCI-0: 41.7%, CCI-1: 30.3%, CCI-2: 25.7%, CCI ≥ 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

Imad A. Alhaddad,¹ Mohammad Jarrah,² Ramiro Trillo,³ Andres Iñiguez Romo,⁴ Ricardo A. Costa,⁵ Lynn Morrison,⁶ Sara Toyloy,⁶ Lynn Vandertie,⁷ Karl-Eugen Hauptmann⁸
¹Jordan Hospital, Amman, Jordan; ²King Abdullah University Hospital, Irbid, Jordan; ³Hospital Clínico Universitario de Santiago de Compostela, Santiago de Compostela, Spain; ⁴Hospital Meixoeiro, Vigo, Spain; ⁵Instituto Dante Pazzanese de Cardiologia, Sao Paulo, Brazil; ⁶Elixir Medical Corporation, Sunnyvale, CA; ⁷Medical Device Consultancies, Christ Church, New Zealand; ⁸Krankenhaus der Barmherzigen Brüder Trier, Trier, Germany

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 ± 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

TCT-576

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

Ronald Caputo¹
¹St Josephs Hospital Cardiology, Syracuse, NY, United States

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 ≤ 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