significant difference between the two groups. There was also no difference between the groups in regards to cardiovascular risk factors. The Single ISR group presented more often with MI (8% vs 4%, p=0.027) but there was no difference in angina. The Single ISR group was more often treated with DES (58% vs 23%, p<0.001) while brachytherapy was more often used to treat Multiple ISR (57% vs 17%, p<0.001). There was no difference in composite death, Q-wave MI, and target vessel revascularization (TVR) at one year between the groups, 17% vs 16% (HR 1.12 95% CI 0.77-1.62, p=0.560). However, after adjusting for MI presentation, composite death, Q-wave MI, and TVR was higher in the Multiple ISR group (HR 2.45, 95% CI 1.34-4.47, p = 0.004).

CONCLUSION There is no difference in clinical characteristics between patients with one episode of ISR and multiple episodes of ISR. ISR of DES remains a challenge with poor outcomes that are worse following recurrent ISR when adjusting for MI. Lesion-level characteristics are likely more predictive of DES ISR and efforts should focus on minimizing recurrent ISR.

CATEGORIES CORONARY: Stents: Drug-Eluting

TCT-737

BIOFLOW-III an all comers registry with a Sirolimus Eluting Stent, Presentation of Five Year Target Lesion Failure Data

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BACKGROUND BIOFLOW-III is a prospective, non-randomized, open-label registry evaluating clinical outcomes and safety of a new generation Sirolimus eluting stent system (Orsiro) in a large patient population in standard clinical care. Orsiro is a hybrid solution that combines passive and active components. PROBIO® passive coating encapsulates the stent and minimizes interaction between the metal stent and surrounding tissue. BIOlute® active coating contains a highly biocompatible and biodegradable polymer.

METHODS In total, 1356 patients were enrolled in this registry. Clinical follow-ups at 6, 12, 36 and 60 months were scheduled. All serious and device-related adverse events were adjudicated by an independent clinical event committee. Statistical analysis of primary (Target Lesion Failure at 12 months) and secondary endpoints was performed for the entire patient cohort and for pre-specified subgroups: diabetes, small vessels, chronic total occlusion and acute myocardial infarction.

RESULTS Nine hundred seventy one men (72%) and 385 women were enrolled at 43 sites in 14 countries. The mean age was 66.1±10.7 years. Seventy six percent of subjects had hypertension, 60% - hypercholesteremia, 30% - diabetes and 55% were smokers. Number of treated lesions was 1738; the mean lesion length 15.8±9.1 mm; the mean reference diameter 3.0±0.4 mm. Orsiro device and procedural success were 99.2% and 98.3%, respectively. At 12 months, 5.0% of the patients had target lesion failure (TLF). At 60 months, 9.2% of the patients had TLF. Slightly higher TLF rates were observed in predefined small vessels (9.4%; total number of lesions - 828), acute myocardial infarction (10.6%; 551) and diabetes (13.0%; 517) study subgroups, but not in chronic total occlusion subgroup (1.8%). Stent thrombosis occurred in 0.7% of patients within 60 months.

CONCLUSION Five-year preliminary data for the BIOFLOW-III registry demonstrated an excellent device and procedure success with the Orsiro stent. Low TLF rate, observed already for the primary endpoint, was confirmed in this long-term follow up. Importantly, rates of definite and probable stent thrombosis remained low during 5 years, indicating safety of the Orsiro stent system.

CATEGORIES CORONARY: Stents: Drug-Eluting

TCT-738

BIOTRONIK-Safety and Clinical Performance of the Drug Eluting Orsiro Stent in the Treatment of Subjects With Single De Novo Coronary Artery Lesions-II (BIOFLOW-II) – 5 Year Clinical Results

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BACKGROUND The aim of this study is to compare clinical outcomes and efficacy of the Orsiro Drug Eluting Stent with the Xience Prime™ Everolimus Eluting Stent in a prospective, randomized, controlled, non-inferiority setting in total patient cohort as well as in the diabetic and small vessel subgroups.

METHODS Totally, 452 patients across 24 sites in 8 European countries were enrolled in this study. All subjects were randomly assigned 2:1 to receive the Orsiro or the Xience Prime stent, respectively. The randomization was stratified for diabetes. The diabetic subgroup accounted for 28.3% (Orsiro N=84, Xience Prime N=44) of all subjects. The small vessel subgroup included all subjects with a reference vessel diameter ≤2.75mm, accounting for N=259 (57.3%) of the cohort (Orsiro N=168, Xience Prime N=91). Clinical follow up visits were performed at 1, 6, and 12 months and annually thereafter up to 5 years post index procedure. All angiographic images were analyzed by an independent Corelab. All clinical events were adjudicated by an independent clinical events committee. Statistical analysis was performed for total study population and for the pre-specified subgroups.

RESULTS All three study groups showed comparable populations in both randomization arms in terms of demographics, current risk factors, clinical history and lesion/vessel characteristics. The TLF rate at 60 months for the overall cohort of patients was 10.4% in Orsiro and 12.8% in Xience study groups (p = 0.4702). In diabetic subgroup TLF was detected in 15.9% of patients (Orsiro) vs 11.6% (Xience) (p = 0.5017). In small vessel subgroup 11.1% patients had TLF (Orsiro) vs 15.5% (Xience) (p = 0.3010). No definite or probable stent thrombosis occurred out to 60 months in the Orsiro group. In Xience group definite thrombosis was detected in 0.7% of patients at 5 years.

CONCLUSION The ultrathin Orsiro demonstrates an excellent long term safety and clinical performance in the overall cohort, as well as in the diabetic and small vessel subgroup and results are comparable to Xience.

CATEGORIES CORONARY: Stents: Drug-Eluting

TCT-739

Comparison of mid-term clinical outcomes after treatment of ostial right coronary artery lesions with early and new generation drug-eluting stents: insights from an international multicenter registry

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BACKGROUND The studies comparing clinical outcomes after early (E-) and new (N-) drug-eluting stents (DES) implantation for right coronary artery (RCA) aorto-ostial (AO) lesions are limited. The aim of