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BACKGROUND Percutaneous coronary intervention (PCI) treatment is closely related to worse clinical events in diabetic patients. This study aims to evaluate the safety and efficacy clinical performance of a new drug-eluting stent (DES) in this population.

METHODS Long-term evaluation of comparative results between insulin requirement (IRDM), non-insulin requirement (NIRDM) and non-diabetic (NDM) patients from a prospective all-comers design study which captured patients undergoing PCI with a novel DES with a thin-strut (75 μm) cobalt-chromium platform, abluminally coated with a biodegradable polymeric layer which releases sirolimus at low doses - Inspiron ™ (Scitech, Aparecida de Goiânia, Brazil). The primary endpoint was the occurrence of major adverse cardiac events [MACE: cardiac-death, non-procedure related myocardial infarction (MI), target vessel revascularization (TVR)].

RESULTS Patients' clinical profile (n=470) demonstrated a mean age of 63.5 years (=10.5 years), being the majority diabetic (233 individuals, 51.3% of total). Diabetic patients had higher cardiovascular risk factors in comparison to NDM, such as systemic arterial hypertension, chronic dialytic kidney disease and previous history of coronary artery disease. After 32 months of median follow-up, IRDM group had higher rates of MACE compared to NIRDM or NDM (25.3% vs. 14.3% vs. 14.1 %, p=0.05, respectively). The worst prognosis of IRDM occurred due a higher rate of cardiac mortality (10.9% vs. 6.4% vs. 4.4%; p=0.02) and a trend toward for MI (12.3% vs. 5.6% vs. 5.1%; p=0.09) and TVR (14.9% vs. 8.1% vs. 7.5%; p=0.10) in comparison to NIRDM and NDM respectively. There was also no difference between NDM and NIRDM groups for MACE (HR: 1.06; 95%CI; 0.64 - 1.77; p=0.79) composite by cardiac death (HR: 1.42; 95%CI; 0.63 - 3.23; p=0.39), MI (HR: 1.20; 95%CI; 0.53 - 2.73; p=0.65) and TVR (HR: 1.08; 95%CI; 0.53 - 2.21; p=0.81). Overall, stent thrombosis (definitive or probable) was low (0.9%).

CONCLUSION Patients with IRDM had worse clinical outcomes in long-term follow-up mainly caused by cardiac mortality. PCI treatment of NIRDM with this novel third-generation DES was not related with worse clinical events in comparison to NDM patients.

CATEGORIES CORONARY: Stents: Drug-Eluting

TCT-728

Polymer-free sirolimus eluting stents in a large scale all comers population

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BACKGROUND The purpose of this all-comers registry was to assess the safety and efficacy of a polymer-free sirolimus coated, ultrathin strut drug eluting stent (PF-SES) with a focus on acute coronary syndrome (ACS). Elective coronary artery disease (CAD) patients on short (≤ 6 months) and long (> 6 months) dual-anti platelet therapy (DAPT) were investigated as well.

METHODS Patients were treated with PF-SES in an unselected large-sale international, single-armed, multicenter, 'all comers' study. Target lesion revascularization (TLR) was the primary endpoint. Secondary endpoints were the 9-month MACE and procedural success rates. Moreover, patients with ACS, diabetes, lesion subsets and procedural characteristics relative to dual antiplatelet therapy (DAPT) were studied in subgroups.

RESULTS A total of 2877 patients of whom 1083 had ACS were treated with PF-SES (1.31±0.75 stents per patient). The 9-month TLR rate was 2.3% (58/2513) without differences between ACS and stable CAD patients (2.6% vs. 2.3%, p=0.389). The overall MACE rate was 4.3% (108/2513) with differences between ACS and elective patients a (6.1%, 58/947 vs. 3.2% 50/1566, p 6 months) DAPT.

CONCLUSION PF-SES are safe and effective in routine use with low rates of TLR and MACE in an all-comers population. Our data is in agreement with prior clinical findings that extended DAPT duration beyond 6 months do not improve clinical outcomes in patients with stable CAD (ClinicalTrials.gov Identifier NCT02629575).

CATEGORIES CORONARY: Stents: Drug-Eluting

LARGE BORE VASCULAR ACCESS AND CLOSURE

Abstract nos: 233 - 237

TCT-233

First in Man Experience with a Large Bore (≥14 FR) Bio-corrodable Vascular Closure Device

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BACKGROUND Femoral artery closure for large sheath (≥14 FR) procedures has been traditionally performed using either manual compression or suture based devices. We present the first in man (FIM) experience with the velox LB closure device which utilizes an intra-arterial footplate connected to an epi-vascular plug by an intervening mandrel constructed from a uniform biodegradable, non-inflammatory magnesium alloy. The intra-arterial and extravascular components resorb within 36 hr and 3 weeks respectively.

METHODS Patients with a common femoral artery(CFA) vessel diameter of ≥ 6.0 mm were treated with ≥14 FR sheaths. Velox LB was inserted over a wire after removal of the procedural sheath. Examination of the arterial closure site, pedal pulses and vascular ultrasound were all performed pre & post-procedure and at 24 hr. Definitions: Procedure success = no access site bleeding ≤10 min after sheath removal without complication. Device success = implant deployment + no access site bleeding ≤ 10 min without complication.

RESULTS Patient characteristics are displayed in table 1. Procedure success was (100%). Device success was achieved in 9 patients (90%). The device was not deployed in one patient due to operator error. Time to cessation of bleeding overall was 3.1 ± 3.1 min and fell to 2.4 ± 2.4 min with device success. Pedal pulses were unchanged following device deployment. Mean CFA diameter was unchanged at post procedure and 24 hr ultrasound. Patients with device success were out of bed 2.0 ± 0.3 hr post procedure. There significant findings on any access site exam or reported by patients.

Age (yr)	57 ± 14
BSA	1.88 ± 0.17
CF vessel diameter (mm)	7.9 ± 1.5 mm
Sytolic BP (mmHg)	124 ± 30 mmHg
ACT (sec)	233 ± 32
Diabetes (n/%)	1 (10%)

CONCLUSION This study demonstrated rapid and effective large bore arteriotomy closure with the velox LB without a change in the CFA lumen size. The implant was well tolerated. This is the first human experience with a large bore VCD constructed with a magnesium alloy. Further investigation is warranted.

CATEGORIES OTHER: Vascular Access

TCT-234

Trends Of Access And Operative Volume Of Transcatheter Aortic Valve Replacement In The Unites States- Descriptive Analysis

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