drug-eluting stent (DES) compared with the second-generation durable polymer (DP) everolimus-eluting stent (EES).

METHODS Between November 2015 and October 2016, 57 lesions with DES (32 new BP-DES and 25 DP-EES) were evaluated by optical frequency domain imaging (OFDI) within 1 month after the procedure. Very early neointimal coverage was compared between BP-DES and DP-EES by OFDI.

RESULTS A total of 574 frames with 6195 struts of 32 stents in BP-DES and 494 frames with 5342 struts of 25 stents in DP-EES were analyzed. The average interval to follow-up OFDI was not significantly different between the groups (16.3 ± 7.7 days in BP-DES vs. 15.4 ± 7.4 days in DP-EES, P = 0.75). Neointimal coverage was significantly superior in BP-DES in both apposed and malapposed strut (apposed: 53.9% in BP-DES vs. 28.0% in DP-EES, P < 0.001; malapposed: 22.9% in BP-DES vs. 7.5% in DP-EES, P = 0.001). When the follow-up period was divided into < 2 weeks and > 2 weeks, neointimal coverage was also significantly superior in BP-DES (< 2 weeks: 47.7% in BP-DES vs. 19.2% in DP-EES, P < 0.001; > 2 weeks: 60.1% in BP-DES vs. 37.4% in DP-EES, P = 0.001).

CONCLUSION The new-generation BP-DES showed excellent early neointimal coverage compared with the second-generation DP-EES in both apposed and malapposed struts.

CATEGORIES IMAGING: Imaging: Intravascular

TCT-229

One-year clinical outcome of biodegradable polymer sirolimus-eluting stent in all-comer population of ULISSE registry (ULtimaster Italian multicentre all-comerS Stent rEgistry)

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BACKGROUND Delayed re-endothelialisation and inhibition of vascular repair after DES implantation, in part related to permanent polymers, are considered important determinants of target vessel failure (TVF) and stent thrombosis (ST) pathophysiology during follow-up.

METHODS The ULISSE study is a multicenter-independent, single-arm, all-comers, observational registry designed to assess safety and efficacy after biodegradable-polymer sirolimus-eluting stent (BP-SES) at 9 different centres in Italy. 1544 consecutive patients (2267 lesions) treated with BP-SES between July 2014 and August 2016 were retrospectively enrolled. The primary and secondary endpoints were target vessel failure (TVF) and target lesion revascularization (TLR) at 1-year, respectively.

RESULTS 655 (45%) patients were treated for at least one complex lesion (chronic total occlusion 9%, bifurcation 19%, very long lesion [>35 mm] 24%, unprotected left-main 4%) and most of them (51%) presented a high-risk clinical profile (diabetes mellitus 29%, chronic kidney disease 11%, previous CABG 13%, low LVEF [<35%] 5%, STEMI as clinical presentation 11%).1 year follow up was available for 1286 patients (83%) and TVF occurred in 81 (6.3 %) patients: cardiac death 24 (1.9%), myocardial infarction 24 (1.9%) and target vessel revascularization 58 (4.5%). TLR occurred in 44 (3.4%) patients. Definite ST rate was 12 (0.93%).

CONCLUSION This study provides preliminary evidence for mid-term safety and efficacy of biodegradable-polymer sirolimus-eluting stent in all-comers daily practice cohort of Italian patients, including complex lesions.

CATEGORIES CORONARY: Stents: Drug-Eluting

TCT-230

Vascular healing response to biodegradable-polymer sirolimus-eluting stent, UltimasterTM, in comparison with durable-polymer everolimus-eluting stent, XienceTM/PromusTM, assessed by optical coherence tomography and angioscopy at 10 months

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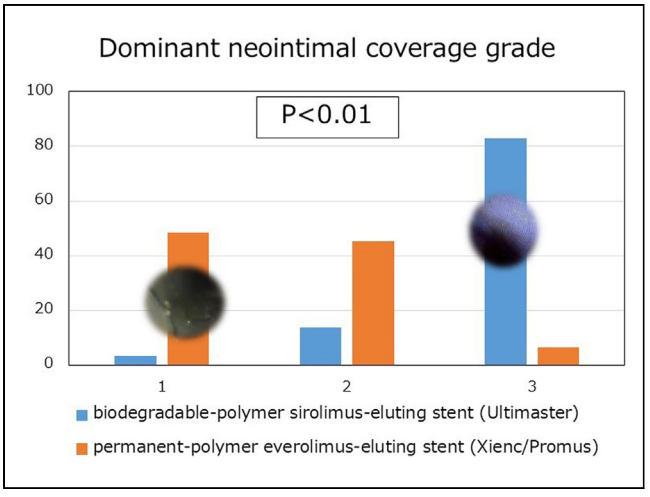
BACKGROUND Third generation biodegradable-polymer sirolimus-eluting stent (BP-SES, UltimasterTM stent) was expected to attain good arterial healing at chronic phase. We evaluated the arterial healing with angioscopy and optical coherence tomography (OCT).

METHODS In this multi-center prospective study, clinical outcome, follow-up angiography, angioscopy and OCT were evaluated at 10 months after implantation for 29 BP-SES in comparison with those for 31 permanent-polymer everolimus-eluting stent (PP-EES, XienceTM / PromusTM stent). By angioscopy, neointimal coverage (NIC) was graded into 4 groups (grade0: exposed, grade1: covered but bulging into lumen and visible, grade2: embedded but visible, grade3: invisible), and presence of intra-stent thrombus were also assessed. By OCT, the strut condition and thickness of neointima were evaluated.

RESULTS The rate of target lesion revascularization was similar between two groups (3.4% in BS-SES vs 3.2% in PP-EES, p>0.99). In angioscopy evaluation, the average dominant NIC grade was significantly higher in BP-SES compared with PP-EES (Fig). The Frequency of intra-stent thrombus was significantly smaller in BP-SES group (14% vs 39%, p<0.05). In OCT evaluation, percentage of covered struts was greater in BP-SES group (99.4% vs 97.2%, p<0.05), while average neointimal thickness was similar between two groups (132 ㎛ m vs 120 ㎛ m, p=0.37).



CONCLUSION BP-SES seemed to achieve better arterial healing at 10 months after implantation compared with PP-EES.

CATEGORIES IMAGING: Imaging: Intravascular

TCT-231

Abstract Withdrawn

TCT-232

Late clinical outcomes of diabetic patients treated with a novel third-generation drug-eluting stent: Highlights from Inspiron registry

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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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