sponsored insurance. Presence of DKA during admission for acute MI was associated with a significantly longer index and repeat hospitalization LOS, but not RR. These findings have significant implications in the era of value-based healthcare delivery. Increased focus on post-discharge care coordination and diabetic management for women and those with government health insurance may have a positive impact on the outcome of MI's in diabetic patients.

CATEGORIES CORONARY: Acute Myocardial Infarction

NEW BRS

Abstract nos: 328 - 332

TCT-328

Real World Performance Of The Novel MeRes100

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BACKGROUND Safety concerns with 1st generation of bioabsorbable vascular scaffolds(BRShave prompted the development of next generation of these devices, focused on thinner struts and faster resorption time. Recently developed, the MeRes100 (Meril Life Sciences) is a sirolimus-eluting (1.25 μg/mm2) BRS, which is built of a thin-strut (100μm) PLLA polymer with a hybrid cell design (closed cells on the edges and open cells on the center). There are couplets of tri-axial radiopaque markets at either end to facilitate scaffold positioning and post dilation. Bioresorption is expected to occur within 2 years.We sought to evaluate the performance of this device in the treatment of "real-world", less selected patients.

METHODS A propective, single center registry including patients treated between August 2016 and June 2017. Exclusion criteria were: cardiogenic shock, in stent restenosis and target lesions at left main/bypass graft. BRS were available in 2.5 to 3.5m and up to 40mm in length. All procedures were guided by OCT. Primary endpoints included procedure success and one-year MACE rate. Nine-month OCT assessment is part of the secondary endpoints.

RESULTS A total of 34 patients underwent PCI with 41 MeRes100. Most patients were male (87%), with mean age of 66yo and 45% of diabetes. Non ST elevation MI was the initial clinical presentation in 30% of the cases, while LAD was the most frequent target vessel (44%). Device success was achieved in 97% of the cases. In the hospital phase, MACE rate was 0%. During the clinical follow-up period, a single case of BRS thrombosis was observed, in a patient who discontinued DAPT in the 1st month after the procedure.

CONCLUSION Preliminary results of this experience showed a excellent acute performance of this novel thin-strut BRS. Late clinical follow up combined with 9-month OCT evaluation will add important information on this novel device.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds

TCT-329

Twelve-Month Follow-Up of a Novel Thin Strut (112 μm) Sirolimus-Eluting Absorbable Vascular Scaffold in Porcine Coronary Arteries

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BACKGROUND The first commercially available bioresorbable scaffold (BRS) Absorb has strut thickness of 157μm (scaffold material base of PLLA), far exceeding those of contemporary drug-eluting stents. As such, it has potential for delivery challenges and higher thrombogenicity. This study aimed to assess safety and biological efficacy of a novel thin strut (112-μm, scaffold base material blend of PLLA, PDLA and ε-Caprolactone) abluminally coated sirolimus-eluting BRS (ON-AVS, OrbusNeich Medical Inc., Fort Lauderdale, FL) in porcine coronary arteries.

METHODS A total of 16 coronary segments of 6 Yucatan miniswine were implanted with thin strut ON-AVS (n=12) or Absorb (n=4) at 110% overstretch. Angiography and optical coherence tomography (OCT) were performed at 1, 3, 6 and 12 months. Animals were euthanized at 6 (n=3) and 12 months (n=3) for histological evaluation.

RESULTS The animals in both groups were comparable with regard to weight, clinical status, baseline vessel size and procedural characteristics. OCT evaluation indicated no differences in percent late recoil rates (1 month: ON-AVS 7.2% [3.9, 11.2] vs. Absorb 10.7% [8.9,11.5], p=0.30; 3 month: ON-AVS 6.9% [3.0, 10.6] vs. Absorb 9.7% [8.3, 11.3], p=0.26; and 6 month: ON-AVS 4.5% [-5.9, 9.8] vs. Absorb 7.2% [5.5, 9.9], p=0.07) or area stenosis (1 month: 21 ± 6% vs. 22±9%, p=0.91; 3 month: 23 ± 8% vs. 31±17%, p=0.42; 6 month: 31±16% vs. 31±12%, p=0.95; 12 month: 29±8% vs. 32±0%, p=0.35) between the two devices. Histological analysis at 6 months revealed comparable results in neointimal proliferation and vascular healing (injury score 1.56±0.51 vs. 1.60±0.28, p=1.0) between the two devices. By the 12-month OCT, the early lumen area loss present at 1 to 6 month inverted into lumen gain that corresponded with the scaffold expansion as it degraded, in the group (ON-AVS scaffold area Day 0: 7.07±1.33 mm2 vs. 12-month: 9.26±2.20 mm2, p=0.01). Twelve-month histological results will be available by the time of the meeting.

CONCLUSION The novel thin strut sirolimus-eluting ON-AVS showed similar biomechanical behavior and vascular healing responses when compared to the benchmark Absorb BVS up to 12 months in normal porcine coronary arteries.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

TCT-330

Multi-Center Evaluation of a Novel 120 μm Novolimus-Eluting, Fully Bioresorbable Coronary Scaffold: First Report of 6-month Imaging and 12-Month Clinical Results

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BACKGROUND The DESolve Cx study is a prospective, multi-center evaluation of the safety and efficacy of the DESolve® Cx Novolimus-Eluting Bioresorbable Coronary Scaffold System (BCSS) using clinical endpoints and multiple imaging modalities.

METHODS The DESolve Cx BCSS is a novel, thin strut (120 μm) drug eluting bioresorbable vascular scaffold (BRS) that combines a poly-L-lactide-based (PLLA-based) scaffold coated with a biodegradable PLLA-based polymer and the drug Novolimus (5 μg per mm of scaffold length), a macrocyclic lactone mTOR inhibitor. The DESolve Cx scaffold differentiates itself from other BRS with thin struts minimizing areas of flow disturbance, and a shorter bioresorption time [>90% reduction in molecular weight within 6 months with near complete bioresorption by 1 year (~70% mass loss) in preclinical studies]. DESolve Cx scaffold also offers high expansion capacity without strut fracture. A total of 50 patients with single, de novo coronary artery lesions were enrolled in this prospective, multi-center, single-arm registry. Those patients receiving the study device are being analysed for multiple clinical endpoints including: Major Adverse Cardiac Events (MACE), a composite endpoint of cardiac death, target vessel MI, or clinically-indicated target lesion revascularization (CI-TLR); Device and Procedure Success; Clinically-indicated Target Lesion and Target Vessel Revascularization, (CI-TVR) and Stent Thrombosis assessed at 1, 6 and 12 months and annually to 3 years.

RESULTS Baseline subject characteristics included 68% male, 60.0 ± 10.3 years of age, 20% presented with diabetes mellitus, 26% were current smokers, 84% and 70% had hypercholesterolemia and hypertension respectively. There were no MACE events reported at