TCT-16

Do overlapping scaffolds have an impact on clinical outcome? Analysis of the ABSORB-EXTEND single arm study

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BACKGROUND Pre-clinical data show that overlapping scaffold segments show delayed healing and strut coverage compared to non-overlapping scaffold segments. Little is known whether this may have an impact on clinical outcome.

METHODS Within the ABSORB-EXTEND study of 812 patients with 1 year follow-up complete, patients with overlapping scaffolds (n=115) were compared to patients with non-overlapping scaffolds (n=697).

RESULTS No differences in baseline patient and lesion characteristics between both patient groups were noted, apart from the significant longer lesion length in the overlapping scaffold group (16.7±7.3 versus 11.6±4.4 mm, [p<0.0001; 95% CI: 3.7-6.4]) and subsequently less lesion type B1 and more B2. Furthermore, more patients were treated for stable angina in the overlapping scaffold group (72% versus 54%, p=0.0003). In the overlapping scaffold group 41/125 (33%) lesions were > 20 mm long, compared to 33/734 (5%) lesions in the non-overlapping group, p<0.0001. The 1 year clinical outcome is summarized in the table below. Scaffold Thrombosis is reported according ARC and Myocardial Infarction according protocol definitions.

	Overlapping	Non-overlapping	P value
Cardiac death	0.9%	0.7%	0.6
Myocardial Infarction (MI)	8.7%	2.4%	0.002
- Q wave MI	1.7%	0.9%	0.3
- non-Q wave MI	7.0%	1.6%	0.003
Target Lesion Revascularization	0.9%	2.6%	0.5
Def/Prob Scaffold Thrombosis (ST)	1.8%	0.9%	0.3
- Early Def/Prob ST	1.7%	0.4%	0.1
- Late Def/Prob ST	0.0%	0.4%	1.0

CONCLUSIONS In the non to moderate complex lesion population of ABSORB-EXTEND, patients with overlapping scaffolds showed only significantly more non-Q wave myocardial infarctions compared to the non-overlapping scaffold group. This difference occurred mainly in-hospital and was procedure related.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds

KEYWORDS Bioabsorbable scaffolds, Long lesion treatment, PCI - Percutanoeus Coronary Intervention

TCT-17

Prospective, Multi-Center Evaluation of the DESolve Novolimus-Eluting Bioresorbable Coronary Scaffold: Imaging Outcomes and 3-Year Clinical and Imaging Results

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BACKGROUND The DESolve® Novolimus Eluting Bioresorbable Coronary Scaffold System (NEBCSS) is a drug-eluting bioresorbable scaffold combining a PLLA-based scaffold coated with Novolimus, a macrocyclic lactone mTOR inhibitor with potent anti-proliferative properties. The drug dose is 5 μg per mm of scaffold length; the device is available in multiple diameters (2.5 - 3.5 mm) and lengths (14, 18 and 28 mm). The DESolve Nx study is multi-center evaluation of the safety and efficacy of the DESolve NEBCSS in patients with single, de novo, native coronary artery lesions.

METHODS A total of 126 patients were enrolled in this prospective registry. Patients receiving the study device were analyzed for multiple clinical endpoints including: device and procedure success; Major Adverse Cardiac Events (MACE), a composite endpoint of cardiac death, target vessel MI, or clinically-indicated target lesion revascularization (CI-TLR); Target Vessel Revascularization, (CI-TVR) and stent thrombosis assessed at 1, 6 and annually to 5 years. All patients underwent angiographic assessment at 6 months and a subset of patients underwent IVUS and OCT assessment also at 6 months and imaging 12 months using multislice computed tomography (MSCT). Additionally, at single centers, multi-modality imaging was completed at 18 months and 3 years.

RESULTS Mean age at baseline was 62 years, 32% were females, and 21% diabetics. Lesion length was 11.2 mm, RVD was 3.06 mm, and 18.3% showed moderate-to-heavy calcification. Six-month QCA demonstrated low mean in-scaffold late lumen loss (0.20 mm), 18.3% DS and an MLD of 2.45 mm. Serial IVUS at baseline and 6 months demonstrated a significant increase in mean lumen (Δ 10.0%, p = < 0.001) and scaffold areas (Δ 15.7%, p = < 0.001) and low % volume obstruction (5.1%). Serial OCT demonstrated a significant increase in scaffold area (Δ 16.9 %, p = < 0.001) with 98.8% neointimal coverage of the scaffold at 6 months. Twelve-month MSCT results demonstrated lumen dimension maintenance from 6 to 12 months. QCA at 18 months shows minimal lumen change and 3 year OCT imaging reveals the "golden tube" indicating resorption of the scaffold. Clinical events remained low (MACE = 5.69% and 7.4% at 12 and 24 months respectively) with no reports of definite stent thrombosis.

CONCLUSIONS DESolve demonstrated safety and efficacy with low late lumen loss. Serial imaging assessments indicated early vessel restoration at 6 months with good luminal patency at 12 months by MSCT. At 12 and 24 months, the clinical event rates remain low. Imaging endpoints at 18 months and 3 years and 3-year clinical results will be presented.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds

KEYWORDS Bioabsorbable scaffolds, Drug-eluting stent, bioabsorbable, Novolimus

COMPLEX AND HIGHER-RISK INDICATED PATIENTS

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Abstract nos: 18 - 25

TCT-18

Impact of Incomplete Revascularization after Percutaneous Coronary Intervention as Assessed by the SYNTAX Revascularization Index in Complex Coronary Artery Disease: A SEEDS Substudy

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BACKGROUND The SYNTAX revascularization index (SRI), representing the percentage of revascularized myocardium, has been shown to be a strong independent predictor of adverse ischemic events after percutaneous coronary intervention (PCI); however, its predictive capability among patients with complex coronary artery disease (CAD) undergoing PCI with second-generation everolimus-eluting stents (EES) remains unexplored. We sought to evaluate the impact of incomplete revascularization as assessed by the SRI on 2-year adverse ischemic events in a population of patients with complex CAD undergoing EES-PCI.

METHODS Among 1900 patients enrolled in A Registry to Evaluate Safety and Effectiveness of Everolimus Drug Eluting Stent for Coronary Revascularization (SEEDS), SRI was available in 1851. Patients were stratified into three groups (SRI=100%, SRI 50 to 99%, and SRI <50%), according to the proportion of revascularized myocardium. Mortality and major adverse cardiac events (MACE) were compared between groups.