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=657).

RESULTS No differences in baseline patient and lesion characteristics were observed, 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%, \( p<0.0001 \)). The overlapping scaffold group demonstrated a mean late loss of 0.16 mm at 1 year and 0.27 mm at 2 years compared to 0.13 mm at 1 year and 0.2 mm at 2 years in the non-overlapping scaffold group, \( p<0.0001 \). The 1 year clinical outcome is summarized in the table below. Scaffold Thrombosis is reported according to ARC and Myocardial Infarction according protocol definition.

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

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 - Percutaneous 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 (2.3 - 3.5 mm) and lengths (14, 18 and 28 mm). The DESolveNx 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 thereafter. 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%, \( p<0.0001 \)) and scaffold areas (Δ 15.7%, \( p<0.0001 \)) with 98.8% neo-intimal 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

Tuesday, October, 13, 2015, 2:00 PM-4:00 PM

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 non-stentially to 5 years. All explored. 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 1831. Patients were stratified into three groups (SRI<100%, SRI 30 to 99%, and SRI<50%), according to the proportion of revascularized myocardium. Mortality and major adverse cardiac events (MACE) were compared between groups.