## 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

**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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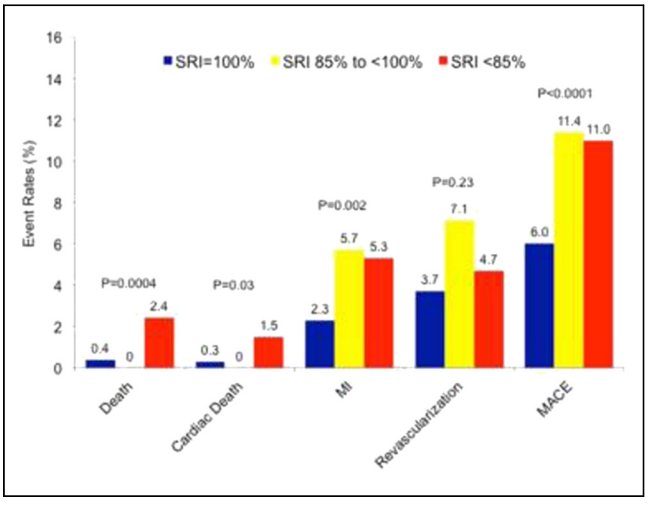
**BACKGROUND** The SYNTAX revascularization index (SRI), representing the percentage of revascularized myocardium, has been shown to be a strong independent predictor of adverse ischemic events after percutaneous coronary intervention (PCI); however, its predictive capability among patients with complex coronary artery disease (CAD) undergoing PCI with second-generation everolimus-eluting stents (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.

**RESULTS** Among the 1851 patients, the mean SRI was 85.4% ± 23.4%, ranging from 4% to 100%. Complete revascularization (SRI=100%) was achieved in 64.3% of patients, SRI= 50-99% in 472 patients (25.5%), and SRI <50% in 189 patients (10.2%). The 2-year rates of mortality (0.4%, 1.9%, and 2.7%, p=0.001) and MACE (6.0%, 11.4%, and 10.1%, p<0.001) were higher in patients with lower SRI. By ROC analysis, an SRI cut-off of 85% showed the best prognostic accuracy for 2-year mortality. A SRI of ≥85% had similar low all-cause death and cardiac death rates when compared to complete (SRI=100%) revascularization (Figure). By multivariable analysis, SRI was a strong predictor of 2-year mortality (HR: 4.20, 95% CI: 1.46-12.08, p=0.008) and 2-year MACE (HR: 1.59, 95% CI: 1.14-2.23, p=0.007).




**CONCLUSIONS** In patients with complex CAD undergoing EES-PCI, the SRI was identified as a strong predictor of 2-years mortality and MACE. Given its correlation with mortality, the SRI may be useful in assessing the degree of revascularization after PCI, with SRI ≥85% as a reasonable goal.

**CATEGORIES CORONARY:** Complex and Higher Risk Procedures for Indicated Patients (CHIP)

**KEYWORDS** Complex lesion, Everolimus-eluting stents, Syntax score

## TCT-19

### Two-Year Clinical Outcome and Chest Pain in 1,811 All-Comer Patients, Treated for Bifurcated Versus Non-Bifurcated Lesions With Highly Deliverable Drug-Eluting Coronary Stents

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**BACKGROUND** Recurrent chest pain after successful percutaneous coronary intervention (PCI) is the main trigger of repeat assessment and resource utilization. PCI of bifurcated target lesions are often complex and bear a higher risk of adverse events and chest pain.

**METHODS** To compare 2-year clinical outcome and patient-reported chest pain of patients with bifurcated vs. non-bifurcated lesions, we assessed data of the DUTCH PEERS randomized trial (clinicaltrials.gov NCT01331707), in which 1,811 all-comers were treated with zotarolimus-eluting Resolute Integrity (Medtronic) or everolimus-eluting Promus Element (Boston Scientific) stents. Among 465 patients with bifurcated lesions, we also compared the outcome of patients with true bifurcation lesions (i.e. lesions with side-branch involvement) vs. non-true bifurcation lesion. The primary endpoint target lesion failure (TLF) is a composite of cardiac death, target vessel myocardial infarction (MI), and target lesion revascularization.

**RESULTS** Clinical follow-up was available in 1,810 patients (99.9%). TLF was similar in patients with and without bifurcated lesions (8.2% vs. 6.9%, p=0.37). Target vessel MI was more common in patients with bifurcated lesions, however, after multivariate analysis with use of a propensity score, this relation turned out to be not statistically significant (HR 1.40, 95%CI 0.71-2.76, p=0.34). There was no difference in TLF between patients treated for true vs. non-true bifurcation lesions (8.9% vs. 7.8%, p=0.70). At 1 and 2-year follow-up, 88.0% and 88.1% of patients with bifurcated lesions and 87.7% and 87.8% of patients with non-bifurcated lesions were free from clinically relevant chest pain (p=0.89 and 0.87, respectively). Between patients with true vs. non-true bifurcation lesions, no difference in patient-reported chest pain at 1 and 2-year follow-up was observed (86.5% vs. 88.5%, p=0.54, and 90.2% vs. 86.7%, p=0.30, respectively).

**CONCLUSIONS** The rates of chest pain were low and similar in patients with bifurcated versus non-bifurcated target lesions, who showed favorable clinical outcomes at 1 and 2-year follow-up after treatment with contemporary flexible drug-eluting stents.

**CATEGORIES CORONARY:** Complex and Higher Risk Procedures for Indicated Patients (CHIP)

**KEYWORDS** Bifurcation lesion, Drug-eluting stent, PCI - Percutaneous Coronary Intervention

## TCT-20

### Use of a Percutaneous Left Ventricular Assist Device for High Risk Percutaneous Coronary Interventions. Clinical Trial versus Real World Experience

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**BACKGROUND** High-risk percutaneous coronary intervention (PCI) supported by percutaneous left ventricular assist devices offers a treatment option for patients with severe symptoms, complex and extensive coronary artery disease (CAD), and multiple comorbidities. The extrapolation from clinical trial to real-world practice has inherent uncertainties. We compared the characteristics, procedures, and outcomes of high-risk PCI supported by a microaxial pump (Impella 2.5) in a multicenter registry versus the randomized PROTECT II trial (NCT00562016).

**METHODS** The USpella registry is an observational multicenter voluntary registry of lmpella technology in 47 sites in the United States and 2 sites in Canada. A total of 637 patients undergoing high-risk PCI supported by Impella 2.5 between 6/2007 and 9/2013 were included in this analysis. Of them, 339 patients would have met enrollment criteria for the PROTECT II trial. Baseline variables, procedural characteristics, and in-hospital outcomes of these registry patients were compared with 216 patients treated in the Impella arm of the PROTECT II trial. All events were centrally adjudicated by an independent clinical events committee.

**RESULTS** Compared to the clinical trial, registry patients were older (70±11.5 vs. 67.5±11.0 years), more likely to have chronic kidney disease (30% vs. 22.7%), prior myocardial infarction (69.3% vs. 56.5%), prior by-pass surgery (39.4% vs. 30.2%), and had similar prevalence of diabetes, peripheral vascular disease, and prior stroke. Registry patients had more extensive CAD (2.2 vs. 1.8 diseased vessels), and had a similar STS predicted risk of mortality (6.0±6.0 vs. 5.8±6.0, p=0.64). Left ventricular ejection fraction was 23.4±6.3% and 21.6±7.7%, in the registry and clinical trial, respectively (p=0.004). Use of rotational atherectomy was similar (16.4% vs. 14.8%, p=0.63), but the number of passes per lesion was significantly