TCT-298
Six-month Intravascular Ultrasound Analysis of the DESolve FIM Trial with a Novel PLLA-based Fully Biodegradable Drug-eluting Scaffold

Jose Costa Jr1, John Ormiston1, Alexandre Abizaid2, James Stewart4, Daniel Chamie2, Mark Webster3, John Yan3, Vinayak Bahl3, Lynn Morrison3, Sara Toyloy6, Stefan Verheyec7
1Instituto Dante Pazzanese de Cardiologia, Sao Paulo, Brazil, 2Associate Professor, University of Auckland Medical School, Auckland, New Zealand, 3Visiting Professor Columbia University, Sao Paulo, Brazil, 4Auckland City Hospital, Auckland, New Zealand, 5Dante Pazzanese, Sao Paulo, Brazil, 6Elixir Medis Corp, Sunnyvale, CA, 7Anspear Cardiovascular Center, ZNA Middelheim, Antwerp, Belgium, Antwerp, Belgium

Background: The DESolve Bioresorbable Coronary Scaffold is a novel drug-eluting device combining a PLLA-based scaffold coated with a bioreabsorbable poly lactide-based polymer and the drug Myolimus. Myolimus, a macrocyclic lactone mTOR inhibitor, has demonstrated potent anti-proliferative properties in two First-in-Man (FIM) trials using Elixis metallic coronary stents. The drug is dose 3 mcg per mm of scaffold length. We aimed to present the IVUS results of the first-in-man evaluation of this novel scaffold.

Methods: The DESolve FIM trial enrolled 15 patients, treated with a single 3.0x14 mm DESolve at 3 centers. IVUS was performed at the end of the procedure and repeated at six-month interval follow-up. Complete and adequate IVUS images at baseline and follow-up were obtained for 11 cases. Serial changes in vessel volume, scaffold area and the degree of NIH formation were assessed. All analyses were performed by an independent core laboratory.

Results: From baseline to 6 months, IVUS showed a small increase in scaffold mean area (from 3.53 ± 0.78 mm² to 5.61 ± 0.81 mm²). Additionally, there was no significant change in vessel volume (from 148.0 ± 37.0 mm³ to 150.03 ± 35.38 mm³) or area, demonstrating the absence of constrictive or expansive remodeling. There was very low neointimal volume (5.6 ± 2.8 mm³) and % scaffold obstruction (7.18 ± 3.37%), and no cases of incomplete strut apposition.

Conclusions: The DESolve scaffold demonstrated a unique property of expansion and no chronic recoil from baseline to follow-up. Results at 6 months showed effective neointimal suppression and no late strut malapposition thus suggesting a very efficacious and novel bioresorbable scaffold.

TCT-299
Impact of Baseline Peri-Stent Plaque Volume on Positive Vessel Remodeling after Implantation of Patelixel Eluting Stents: A Pooled Volumetric Intravascular Ultrasound Analysis

Kenji Sakamoto1, Katsushia Waseda1, Hideki Kitahara1, Ryotaro Yamada2, Ching-Chang Huang3, Paul Yock1, Peter Fitzgerald1, Yasuhiro Honda1
1Stanford University Medical Center, Stanford, CA

Background: Positive vessel remodeling, caused by an increase in peri-stent plaque volume during follow-up, has frequently been demonstrated in clinical studies of paclitaxel-eluting stents (PES). Histopathologic studies have also shown an association of positive remodeling with vessel inflammation, possibly related to the occurrence of very late stent thrombosis. This study aimed to investigate the determinants of vessel remodeling in patients treated with PES as assessed by IVUS.

Methods: Serial (post-procedure and 8-9 months follow-up) volumetric IVUS data were analyzed in 227 de novo coronary lesions electively treated with PES. Volume index (VI) was defined as volume length (mm³/mm). Peri-stent plaque VI was standardized by stent VI (SPV). Vessel remodeling during follow-up was assessed as a change of peri-stent plaque VI per stent VI. Morphologic properties with a p-value<0.10 on univariate analysis were identified into multivariate models.

Results: Overall, the change of vessel VI during follow-up was 5.0±8.1% (range: -21.7% to +56.1%), resulted from a significant increase of %PVI (95.9±29.9% to 103.9±26.9%, p<0.0001). Among IVUS parameters at post-procedure, vessel VI and %PVI had significant inverse correlations with positive vessel remodeling (p=0.002, p=0.0002, respectively). In multivariate analysis, less %PVI at post-procedure was independently associated with positive vessel remodeling during follow-up (p=0.02).

Conclusions: This pooled IVUS analysis identified thinner peri-stent plaque surrounding PES at baseline as a predictor of larger positive vessel remodeling during follow-up. This may reflect the differential mechanical compliance and/or increased drug infiltration into the deep vessel wall structure in the setting of less underlying plaque behind the stent.

TCT-300
Differential Prognostic Impact of Intravascular Ultrasound Utilization According to Implanted Stent Length

Jung-Min Ahn1, Shin-Eui Yoon1, Seung Mo Kang1, Hyun Woo Park1, Ik Jo1, Young-Rak Choi1, Gyung-Min Park1, Won-Jang Kim1, Jong-Young Lee1, Duk-Woo Park2, Soo-Jin Kang1, Seung-Whan Lee1, Young-Hak Kim1, Cheol Whan Lee2, Seong-Wook Park1, Seung-Jung Park1
1Heart Institute, University of Ulsan College of Medicine, Asan Medical Center, Seoul, Korea, Republic of

Background: It is unknown whether IVUS utilization during percutaneous coronary intervention (PCI) may modify the stent length effect on clinical outcomes. We sought to find differential prognostic impact of intravascular ultrasound (IVUS) utilization according to the implanted stent length.

Methods: Between April 2008 and June 2010, we enrolled 3244 consecutive patients undergoing PCI with at least one consecutive stent implantation at 46 academic or community hospitals in Korea. The primary endpoint was a composite of death, myocardial infarction, or target vessel revascularization (MACE). Study population was divided by the tertiles of implanted stent length and IVUS utilization.

Results: After adjustment for significant covariants, implanted stent length was not significantly associated with the risk of MACE in IVUS group (hazard ratio [HR] 1.08, 95% confidence interval [CI] 0.97-1.20, p=0.042). In addition, in patients with implanted stent length of ≤22mm (N=988), the risk of MACE was not significantly different between IVUS group and no IVUS group (HR 1.06, 95% CI 0.56-2.08, p=0.88). By contrast, in patients with longer implanted stent length, the risk of MACE was significantly lower in IVUS group than in no IVUS group (HR 0.47, 95% CI 0.24-0.92, p=0.027 for ≥22-32mm [N=1109], HR 0.57, 95% CI 0.33-0.98, p=0.042 for ≥32-40mm [N=1137]).

Conclusions: IVUS utilization may attenuate the detrimental effect of the increase of implanted stent length, supporting the favor of IVUS utilization, particularly during PCI with the long stent implantation.

TCT-301
Feasibility and Results of Novel Side Branch Evaluation by Reconstructed 3-Dimensional Optical Coherence Tomography. Matched Analysis of Baseline and 12-month follow-up in Native, Jailed and Opened Side Branches

Niels Holm1, Shengxian Tu2, Rasmus Christensen3, Trine Ørhøj1, Evald Høj Christiansen1, Michael Maeng1, Niels Holm1, Shengxian Tu2, Rasmus Christensen3, Trine Ørhøj 1, Michael Maeng1, Niels Holm1, Shengxian Tu2, Rasmus Christensen3, Trine Ørhøj 1, Michael Maeng1, Niels Holm1, Shengxian Tu2, Rasmus Christensen3, Trine Ørhøj 1, Michael Maeng1, Niels Holm1, Shengxian Tu2, Rasmus Christensen3, Trine Ørhøj 1, Michael Maeng1
1Heart Institute, University of Ulsan College of Medicine, Asan Medical Center, Seoul, Korea, Republic of
2Leiden University Medical Center, Leiden, Netherlands, 3Aarhus University Hospital, Aarhus, Denmark

Background: Assessment of the side branch (SB) ostium by angiography and 2D optical coherence tomography (OCT) is challenging. This is the first presentation of ostial SB assessment by centerline guided 3D OCT.

Methods: The study was a substudy to the SORT-OUT V OCT study comparing a sirolimus eluting durable polymer stent (Cypher Select +, Cordis, US) and a biolimus eluting biodegradable polymer stent (Nobori, Terumo, JP). The SB ostium was evaluated in all SBs visible on both baseline and 12-month follow-up OCT. Each SB ostium was reconstructed in 3D by the main vessel OCT acquisition using VantageOCT prototype (Medis medical imaging systems, NL). The minimal luminal area (MLA) was assessed up to one millimeter into the SB. The measurement plane (the cut plane), was reconstructed perpendicular to the SB centerline. In case of nonintimal bridging over the SB ostium, the areas of the individual ostia of the same SB were summed.

Results: Matched baseline and FU OCT was available in 96 patients. At baseline 208 SBs were detected and of these were 107(51%) in-stent SBs. SBs were not analyzable due to wire shadow in 49 (23%) SBs and due to impaired image quality in 26 (12.5%) of SBs.