early Vascular Restoration following treatment of single de-novo coronary artery lesions with the DESolve Nx Novolimus Eluting Bioresorbable Coronary Scaffold System (NEBCSS) at 6 months: Insights from the Serial IVUS analysis

Conclusions: Optimal distal cell recrossing of the guidewire is critical to ensure a successful stent optimization in bifurcation PCI.

TCT-596

Early Vascular Restoration following treatment of single de-novo coronary artery lesions with the DESolve Nx Novolimus Eluting Bioresorbable Coronary Scaffold System (NEBCSS) at 6 months: Insights from the Serial IVUS analysis of the pivotal, prospective, multicentre, DESolve Nx Trial

Jose D. Costa Jr1, Joaichim Schofer2, Stefan Verheyse3, Sara Tomas4, Daniel Chamie5, Vinayak Bhola5, Ricardo A. Costa6, Bernhard Witzenbichler7, Lynn Morrison8, John Wilder9, Amanda Souza10, J. Eduardo Sousa11, Alexandre Abizaid12

1 Instituto Dante Pazzaneze de Cardiologia, São Paulo, Brazil, 2Medicare center Prof Mathey, Prof Schofer, Hamburg University Cardiovascular Center, Hamburg, Germany, 3Antwerp Cardiovascular Center, ZNA Middelheim, Antwerp, Belgium, 4Elixir Medical Corporation, Sunnyvale, CA, 5Dante Pazzaneze, São Paulo, Brazil, 6Instituto Dante Pazzaneze De Cardiologia, Sao Paulo, Brazil, 7Charité Campus Benjamin Franklin, Berlin, Germany, 8Elixir Medical Corporation, Sunnyvale, CA, 9Instituto Dante Pazzaneze De Cardiologia, Sao Paulo, Brazil, 10Instituto Dante Pazzaneze de Cardiologia, São Paulo, Brazil

Background: The DESolve Bioresorbable Scaffold is a novel drug-eluting device combining a PLA-based scaffold coated with a bioresorbable polylactide-based polymer and a potent anti-proliferative sirolimus metabolite, Novolimus. The drug dose is 5 mcg per mm of scaffold length. An early benefit with regard to vessel restoration is a potential feature of this unique technology. The aim of this study is to assess the serial changes in the vessel treated with the DESolve scaffold using IVUS analysis.

Methods: The DESolve Nx is a pivotal, prospective and multicentre clinical trial, which enrolled 126 patients with de novo coronary lesions treated with a single scaffold available in three diameters (3.0, 3.25 and 3.5) and two lengths (14 and 18 mm). The first 46 patients enrolled in this trial were part of an IVUS sub-study, which consisted of a paired analysis of the automatic pullbacks performed at the end of the baseline procedure and at six-month follow-up (an additional 24 month follow up will also be performed). All analyses are being performed by an independent IVUS core lab.

Results: The mean age of the study population was 62 years, 68% of which were men and 21% had diabetes. The procedure reference vessel length and diameter were 11.2 ± 3.8mm and 3.06 ± 0.31, respectively. 40 of the 46 patients enrolled in the IVUS sub-study had serial analyses available at 6 months that demonstrated a significant increase in mean lumen (Δ 9.0%, p < 0.0001), scaffold (Δ 15.7%, p = 0.0001) and vessel (Δ 16.8%, p = < 0.0001) areas between baseline and 6 months and low % volume obstruction (5.05%) with no case of late acquired scaffold incomplete apposition or aneurysm formation.

Conclusions: The DESolve scaffold is the first scaffold to demonstrate lumen area expansion with no chronic recoil at 6 months follow up with no evidence of aneurysms. Serial IVUS results at 6 months showed effective neointimal suppression and low acute stent malapposition suggesting the natural ability of the scaffolded vessel to remodel at 6 months.

TCT-597

Predictors of Stent Expansion After Drug-eluting Stents: An ADAPT-DES IVUS substudy

Nobuaki Kobayashi1, Gary S. Mintz2, Bernhard Witzenbichler3, D. Christopher Metzger4, Michael Rinaldi5, Ernest L. Mazzaferri6, Peter L. Duffy7, John Wilder9, Amanda Souza10, J. Eduardo Sousa11, Alexandre Abizaid12

1Odense University Hospital, Odense, Denmark, 2Aarhus University Hospital, Skejby, Aarhus, Denmark, 3Elixir Medical Corporation, Sunnyvale, CA, 4Wellmont CVA Heart Institute, Kingsport, TN, 5Dante Pazzanese, São Paulo, Brazil, 6Ohio State University, Columbus, OH, 7Pinehurst Cardiology, Pinehurst, NC, 8Columbia University, New York, United States, 9Instituto Dante Pazzaneze de Cardiologia, Sao Paulo, Brazil, 10Instituto Dante Pazzaneze de Cardiologia, Sao Paulo, Brazil, 11Elixir Medical Corporation, Sunnyvale, CA, 12Columbia University, New York, United States

Background: While a smaller minimum stent cross-sectional area (MSA) predicts adverse events (stent restenosis and thrombosis), predictors of stent underexpansion have not been fully investigated.

Methods: ADAPT-DES was a prospective, multicenter, registry of 8,583 consecutive patients undergoing PCI with DES. Among 2064 pts enrolled in a pre-specified intravascular ultrasound (IVUS) sub-study, 769 pts with 889 lesions were examined by both pre and post-PCI IVUS. Stent expansion (ST-Exp) was calculated as MSA divided by average of proximal and distal stent edge lumen area; %ST-Exp was divided into (1) >70% (adequate expansion), (2) 60-70% (moderate underexpansion), and (3) <60% (severe underexpansion). ROC curve analysis revealed that cut-off values of lesion length and maximum arc of superical calcium that best predicted stent expansion <60% (severe underexpansion) were 42.0 mm and 127°. Conversely, plaque burden was unrelated to stent expansion.

TCT-598

Mechanisms of Incomplete Stent Apposition After Implantation of Drug-eluting Stents in patients with ST-segment Elevation Myocardial Infarction

Liselbeth Antonson1, Eivald H. Christiansen2, Michael Maeng3, Anne Kaltoft4, Per Thaysen1, Hans-Henrik Tilsted5, Leif Thuesen1, Jan Ravkilde1, Lars Krusell1, Mikkel Hougaard1, Jens F. Lassen6, Lisette Okkels Jensen7, Odense University Hospital, Odense, Denmark, Aarhus University Hospital, Skejby, Aarhus, Denmark, Aalborg University Hospital, Aalborg, Denmark

Background: Incomplete stent apposition (ISA) is a potential factor in the subsequent development of later adverse events, including stent thrombosis, in patients treated with drug-eluting stents (DES). We assessed the incidence and mechanisms of ISA in patients with ST-segment Elevation Myocardial Infarction (STEMI) treated with a biolimus-eluting Nobori stent (BES) or a sirolimus-eluting Cypher stent (SES).

Methods: In the Randomized Comparison of Biolimus-Eluting Biodegradable Polymer Coated Stent and Durable Polymer Sirolimus-Eluting Stent in Unselected Patients (SORT OUT V) trial, a pre-specified intravascular ultrasound (IVUS) substudy enrolled 116 STEMI patients (57 BESs and 59 SESs) treated with PCI where post-procedure and 12-month follow-up imaging data were available. The vascular response and influence of remodeling (changes in external elastic membrane (EEM) cross sectional area (CSA) in “acute”, “resolved”, and “late acquired” ISA was evaluated.

Results: Post-intervention ISA occurred in 22 (19.0%) stented lesions (15.8% BES and 22.0% SES, p=ns). Of these, 7 (31.8%) resolved at follow-up without significant remodeling (post-intervention EEM CSA 19.7 mm2 (interquartile range (IQR) 17.0 to 23.5 mm2) vs. follow-up EEM CSA 20.9 mm2 (IQR 17.8 to 23.5 mm2), p=ns). Plaque CSA increased from post-intervention 6.7 mm2 (IQR 5.5 to 8.9 mm2) to follow-up plaque CSA 10.0 mm2 (IQR 9.2 to 12.4 mm2), p=0.018. At follow-up late acquired ISA was seen in 19 (16.4%) stented lesions (14.0% BES and 18.6% SES, p=ns). In patients with late acquired ISA, the mechanism was positive remodeling in 73.7% of the stented lesions (post-intervention EEM CSA 21.0 mm2 (IQR 13.5 to 26.9 mm2) vs. follow-up EEM CSA 27.4 mm2 (IQR 18.6 to 31.3 mm2), p<0.0001, and maximum ISA CSA was 3.5 mm2 (IQR 1.3 to 5.8 mm2). In 26.3% of the patients with late acquired ISA, negative remodeling and plaque/thrombus resolution was seen.

Conclusions: In STEMI patients “acute” ISA resolved in one third of the stented lesions, mainly due to plaque progression. “Late acquired” ISA was predominantly due to positive remodeling.