TCT-545
Coronary artery vessel healing pattern short term and long term after implantation of the Everolimus-Eluting Bioresorbable Vascular Scaffold
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BACKGROUND Although the ABSORB bioresorbable vascular scaffold (BVS) is increasingly being used in daily clinical practice for the treatment of coronary artery disease, the exact vascular healing pattern and the resorption process in humans remains unknown, since histological data are sparse and derived from animal studies.

METHODS Between August 2013 and January 2015, the pathology department of the Academic Medical Center had obtained four autopsy cases treated with five scaffolds, with duration of implantation ranging from 8 days until 501 days. All available clinical records were reviewed for patient history, duration of implantation and cause of death. All autopsies and histological assessments were performed by dedicated cardiovascular pathologists.

RESULTS One week after BVS implantation scaffold struts were covered with a fine layer of fibrin and platelets. Smooth Muscle Actin staining demonstrated at 113 days full coverage of the BVS struts with smooth muscle cells. Hyaline eosinophilic material infiltrating the scaffold struts, interpreted as resorption of the scaffold material, was observed at 501 days after implantation. At 8, 113 and 501 days after implantation we observed the presence of multinuclear foreign body giant cells adjacent to the struts.

CONCLUSIONS Resorption and healing process after BVS implantation in human patients mirrors observations made in porcine coronary artery models. The presence of multinucleated foreign body giant cells both at short term and long term follow up may be related to an inflammatory reaction to the bioresorbable polymer.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds
KEYWORDS Bioabsorbable scaffolds, Pathologic study

TCT-546
6-Month Angiographic Results of the Novel MIRAGE Microfiber Sirolimus-Eluting Bioresorbable Vascular Scaffold - A Quantitative Coronary Angiography Analysis from the Prospective, Randomized MIRAGE Clinical Trial
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BACKGROUND The MIRAGE bioresorbable vascular scaffold is a novel technology incorporating a microfiber (PLA based) helix coil design mounted on 3 backbones and a biodegradable PLA abluminal coating, which releases sirolimus as antiproliferative agent (Manli Cardiology Ltd., Singapore). It has high flexibility and radial strength with strut thickness ranging from 125 to 150µm (<3.0 mm: 125 µm; >3.0 mm: 150µm). Additional features of the MIRAGE microfiber sirolimus- eluting scaffold (MMSES) include: no time limitation for staying in artery before deployment, re-entering artery allowed, and no waiting time for balloon inflation during deployment. Our objective was to report the serial angiographic results at baseline/index procedure and 6-month follow-up.

METHODS The MIRAGE trial was a prospective, randomized, dual center (Indonesia and Malaysia), first-in-human evaluation of the MMSES for the treatment of diseased coronary vessels. A total of 60 patients with single or up to 2 de novo coronary target lesions located in native vessels were randomized in a 1:1 ratio for percutaneous coronary intervention with the MMSES versus the BVS (Abbott Vascular, Santa Clara, USA). All patients were assigned for 6-month angiographic re-evaluation, and all angiographic analyses were performed at an independent core laboratory (Cardiovascular Research Center, Sao Paulo, Brazil). The study’s primary efficacy endpoint was in-scaffold late lumen loss, as determined by quantitative coronary angiography (QCA) at 6 months.

RESULTS A total of 60 patients (31 patients in group A, 34 lesions; 29 patients in group B, 33 lesions) were randomized from October(2013) to August/2014. There were no significant differences in baseline clinical and angiographic characteristics comparing MMSES and BVS groups. Considering the overall patient population, LAD was the most prevalent target coronary vessel (59%) and type C lesions (according to the ACC/AHA lesion classification) were found in one third of cases. During procedure, pre dilatation was performed in all but one case, study scaffold was successfully attempted and implanted in all cases (100%), and post dilatation with an additional shorter balloon was performed in 61%. By QCA, baseline lesion length, reference diameter and % diameter stenosis were 17.27 ± 8.60mm, 2.85 ± 0.42mm, and 57.1 ± 9.8mm, respectively. All patients but 2 underwent angiographic re-evaluation at 6 months follow-up (QCA analysis ongoing).

CONCLUSIONS The MMSES is novel bioresorbable scaffold technology designed to provide optimal radial strength and temporary scaffold within the coronary vessel, while maintaining efficacy in inhibiting neointimal hyperplasia, as well as to address a few limitations of current fully bioabsorbable systems. The complete angiographic results at post procedure and 6-month angiographic follow-up comparing the MMSES versus the active control BVS will be presented at the meeting.

CATEGORIES CORONARY: Angiography and QCA