TCT-500
Comparative Study With Optical Coherence Tomography At 6 And 12 Months Between Drug-eluting Stents Of Resorbable Polymer And Drug-eluting Scaffolds With Full Biodegradable Platform Implanted In Different Lesions Of The Same Patient.

BACKGROUND Biodegradable everolimus-eluting scaffolds (BVS) and metallic drug-eluting stents with bioabsorbable polymers (MBP-DES) have shown positive clinical results in studies. Direct comparative evaluation between both for the process of endothelialization is lacking and could be relevant to define the heterogeneity profile and subsequently estimate the appropriate duration of dual antiplatelet therapy. In this study we sought to evaluate endothelialization of BVS and MBP-DES, implanted both in the same patient, with OCT performed at 6 and 12 months.

METHODS Multicenter (16 centers) prospective study. Patients were recruited when requiring stent implantation (without overlapping) in at least two separate lesions of similar morphologic characteristics. Each lesion was randomized to be treated with a BVS or a MBP-DES (Synergy TM, Orsiro TM or Biomatrix TM). After the procedure patients were scheduled alternatively for 6 or 12 months evaluation with optical coherence tomography. Co-primary endpoints are % of uncovered struts at 6 and 12 months.

RESULTS Up to date 100 patients have been included all treated in at least one lesion with a BVS and in at least other lesion with a MBP-DES (50% Synergy TM, 25% Orsiro TM and 25% Biomatrix TM). Among these, 20 patients have been so far examined with OCT at 6 months. The proportion of uncovered struts was 2.8 ± 2.4 % with MBP-DES and 3.2 ± 3.8 % with BVS (p=0.4) and the proportion of malapposed struts was 2.2 ± 2.8 % and 2 ± 3.7% respectively (p=0.7). Maximal malapposition area was 1 ± 3 mm2 with MBP-DES and 1.8 ± 2.4 mm2 with BVS (p=0.1). Evaginations or protrusion of covered struts were more common with BVS.

CONCLUSIONS Pending of final follow up and analysis of the whole cohort, at 6 months the proportion of uncovered struts is very low and comparable between biodegradable everolimus-eluting scaffolds and metallic drug-eluting stents with bioabsorbable polymers. Differences in evagination and malapposition magnitude could be observed.

CATEGORIES CORONARY: Biodegradable Vascular Scaffolds