METHODS Patients receiving two different BVS, Absorb (Abbott Vascular) and DESolve (Elixir Medical) in a single Center, have been followed-up (mean 18 months) with clinical examination, coronary CT-scan and eventually coronary angiography. Quantitative Coronary Angiography (QCA), performed before and after BVS implantation, measured: Minimal Lumen Diameter and Area (MLD; MLA) and % Stenosis. CT images have been post-processed by experienced operators, to get similar measurements.

RESULTS Within 2 years, 50 patients (M/F= 4/1; mean age 54±8 years) have been treated with BVS (26 Absorb; 24 DESolve) for: stable angina (30%), UA/NSTEMI (52%), STEMI (18%). Mean diameter of implanted scaffolds was higher in the Absorb group (3.25±0.4 vs 2.97±0.39; p=0.016), but postdilation diameters were similar (3.44±0.5 vs 3.24±0.54; p=0.2) due to the higher confidence to overdilate the DESolve scaffold. CT highlighted 4 cases of restenosis (Absorb), only 2 confirmed by angiography. Comparison among QCA after-BVS and CT follow-up showed "positive" differences, at 18 months, only in the DESolve group, where significant late Lumen Gain resulted: MLD (2.13±0.5 vs 2.33±0.5; p=0.03); MLA (3.73±1.6 vs 4.45±2; p=0.03). Measures from different techniques (QCA and CT) showed significant correlation. Direct comparison Absorb vs DESolve showed no differences at the follow-up.

CONCLUSION Our experience with two generations BVS showed no acute recoil or mid-term clinical events, with two cases of Absorb failure (TLF). CT resulted a useful tool for qualitative and quantitative BVS assessment, showing good correlation with QCA measures. BVSs kept similar diameters at 18m follow-up. DESolve scaffold showed greater lumen gain compared to the other BVS, due to innovative features.

CRT-600.05

Intravascular Ultrasound Findings of the Fantom Bioresorbable Scaffold at 6 and 9 Months Follow-up: Results from the Multicenter FANTOM II Study

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BACKGROUND FANTOM II is a prospective multicenter study designed to assess the safety and efficacy of the FANTOM Sirolimus-Eluting Bioresorbable Coronary Scaffold (BRS) in patients with stable coronary artery disease. The present substudy focuses on the performance of the device as assessed by IVUS.

METHODS A total of 240 patients with de novo coronary artery lesions presenting with stable or unstable disease were included in 2 cohorts. In cohort A (n=117), angiographic follow-up was performed at 6 months. IVUS data was available in 35 paired cases. In cohort B 23, angiographic follow-up was performed at 9 months, with IVUS available in 26 paired cases. IVUS was performed at 40MHz with a pullback speed of 0.5mm/sec. Analyses were performed by an independent corelab (Cardialysis BV, Rotterdam, the Netherlands). The region of interest beginning 5 mm distal to and extending 5 mm proximal to the treated segment was examined and analyzed.

RESULTS Mean age was 62.7 years, 70.4% were male. Diabetes was present in 23.8% of the patients. Post procedure mean scaffold area was 6.09±1.08mm in cohort A and 6.46±1.11mm in cohort B. diameter was 2.94±0.16 mm. Average scaffold length was 18.59±1.80 mm. Post dilatation was performed in 80.4% of the cases (77.9% in cohort A and 86.1% in cohort B). In cohort A, mean and minimum scaffold area (SA) slightly decreased at 6 months (from 6.09±1.08mm^2 to 5.88±1.07mm^2, p=0.009 and 5.27±0.99mm^2 to 5.05±0.99mm^2, p=0.01 respectively). Neointimal hyperplasia area at 6 months was 0.11±0.12 and in-scaffold obstruction volume was 1.94±2.25%. In cohort B, the struts were still visually recognizable on IVUS as high echogenic structures. No significant change in mean scaffold and minimum scaffold area was observed at 9 months (6.46±1.11mm^2 to 6.38±0.96mm^2; p=0.35 and 5.45±1.00mm^2 to 5.36±0.86mm^2; p=0.32 respectively). Neointimal hyperplasia area at 9 months was 0.20±0.21 and in-scaffold obstruction volume was 3.40±4.11%.

CONCLUSIONS The use of the FANTOM BRS in stable coronary artery disease was safe and effective with low rates of neointimal hyperplasia volume and in-scaffold volume obstruction at both 6 and 9 months.

CRT-600.06

Implantation Technique in Magmaris Second-generation Drug-eluting Absorbable Metal Scaffold in Patients with Denovo Coronary Artery Lesions: Optical Coherence Tomography Analysis

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BACKGROUND Second-generation drug-eluting absorbable metal scaffold (Magmaris) is an alternative novel device for treating coronary lesions. However, the relationship between in-scaffold geometry after implantation of Magmaris and late lumen loss (LLL) is unknown. The aim of this study is, therefore, to investigate the effect of implantation technique, using optical coherence tomography (OCT), on Magmaris and LLL.

METHODS The present study population comprises of a total 67 patients with 67 lesions who were enrolled in the prospective, multicenter BIOSOLVE-II trial between October 2013 and May 2015. We assessed apposition, dissection, intraluminal mass, side branch relationship, and expansion of Magmaris after implantation evaluating frame by frame using OCT. % device expansion was defined as a ratio of mean device area to mean reference lumen area at post procedure and expansion group was defined as either patients who have in-scaffold MLA > 90% of the average reference lumen area or ≥ 100% of lumen area of the reference segment with the lowest lumen area. In addition, lumen volume loss was also assessed by OCT. Using quantitative coronary angiography (QCA), LLL at 6 months was also assessed.

RESULTS By OCT, a total of 8726 frames were assessed. The total number of incomplete scaffold strut apposition (r = 0.25, p = 0.04) and the sum of maximum distance from strut to lumen surface (r = 0.23, p = 0.06) correlated with in-scaffold LLL (QCA). The other OCT findings including presence of dissection, malapposition, intraluminal mass and presence of a side branch after implantation of Magmaris had no statistically significant correlations with in-scaffold LLL (QCA) at 6 months follow-up. However, in-scaffold lumen volume loss evaluated by OCT was significantly greater in patients with expansion group compared to those without (p = 0.03). Furthermore, % device expansion at post procedure tended to be inversely correlated with in-scaffold lumen volume loss (r = 0.23, p = 0.06).

CONCLUSIONS We found that high expansion indexes are associated with high late luminal loss assessed by OCT. Excessive scaffold expansion (i.e. "the bigger, the better") might not be needed to reduce in-scaffold late luminal loss assessed by OCT in Magmaris implantation. These findings should be considered hypothesis generation and need to be confirmed in future studies.

CRT-600.07

Comparison of Clinical Outcomes Between Magmaris (DREAMS 2G) and Orsiro Drug Eluting Stents: Pooled Patient Level Analysis From Biosolve II-III and Bioflow II Trials

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