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COMPARISON OF INTERMEDIATE TERM LATE LUMEN LOSS AFTER CORONARY IMPLANTATION OF BARE OR PACLITAXEL ELUTING ABSORBABLE METAL SCAFFOLDS: RESULTS FROM PROGRESS-AMS AND BIOSOLVE-1 TRIALS

i2 Poster Contributions
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Background: Absorbable metal scaffolds (AMS) are developed to overcome limitations of current permanent bare or drug-eluting coronary stents like stent thrombosis, despite prolonged dual antiplatelet therapy (DAPT), caged vessel segment not allowing vasomotion and remodelling or chronic vessel wall inflammation. Magnesium is an essential element of the human body, thus Magnesium is considered as a potential alloy for absorption. To overcome the limitations associated with the first generation of a bare AMS as demonstrated in the PROGRESS-AMS study a Drug (Paclitaxel) Eluting Absorbable Magnesium Scaffold was developed (DREAMS).

Methods: The first-in-man PROGRESS-AMS and BIOSOLVE-I study enrolled 63 and 46 subjects, respectively. Subjects from the BIOSOLVE-I study were assigned to two different cohorts with different follow-up schedules. Clinical follow-up in the PROGRESS-AMS study was conducted at 4, 6 and 12 months while clinical follow-up in the BIOSOLVE-I study are at 1, 6, 12, 24 and 36 months. Angiographic and IVUS follow-up was performed at 4-month in the PROGRESS-AMS study and at 6-month (Cohort 1) or 12-month (Cohort 2) in the BIOSOLVE-I study.

Results: No cardiac death, myocardial infarction or scaffold thrombosis was documented in either study. The target lesion revascularization rate (TLR) was reduced by 82% from 23.8% in PROGRESS-AMS (4-month) to 4.3% (6-month) in BIOSOLVE-I.The in-scaffold late luminal loss (LLL) of 0.64±0.50mm in the BIOSOLVE-I study showed a 41% reduction in comparison to the LLL of 1.08±0.49mm in the PROGRESS study. Based on the IVUS analysis the contribution of the 0.64 mm LLL was driven by 0.38 mm loss of scaffolding area and 0.26 mm of in-scaffold neointimal formation. Compared to the results of the PROGRESS study this demonstrates a reduction of the in-scaffolding diameter loss by 0.19mm (33% reduction) and of the in-scaffold neointimal hyperplasia by 0.26 mm (49% reduction).

Conclusions: Up to 6-month the DREAMS demonstrated an excellent clinical safety profile with no cardiac death, myocardial infarction or scaffold thrombosis and a significantly improved clinical and angiographic performance in comparison to the bare absorbable metal scaffold.