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DE NOVO CORONARY LESIONS TREATED WITH THE NOVEL POLYMER-FREE BIOLIMUS-A9 COATED STENTS: 12-MONTH ANGIOGRAPHIC RESULTS FROM THE PROSPECTIVE, RANDOMIZED, MULTICENTER BIOFREEDOM CLINICAL TRIAL

i2 Oral Contributions
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Background: The BioFreedom (BF) Biolimus A9 (BA9) coated stent (Biosensors Int., Singapore) is a new generation polymer-free drug-eluting stent encompassing a 316L stainless steel platform modified with a proprietary surface treatment resulting in a selectively micro-structured abluminal surface. This technology allows adhesion of a potent antiproliferative agent (BA9) to the stent's abluminal surface and further controlled release of the drug without the use of a polymer or binder. We report the results of the first-in-man evaluation of the BF BA9-coated stents, which were available in 2 different formulations: standard dose (SD: 15.6µg/mm) and low dose (LD: 7.8µg/mm).

Methods: 182 pts w/ single lesion were included in the prospective, multicenter (4 sites in Germany), randomized (1:1:1 ratio) BIOFREEDOM trial. Pts were treated with the BF-SD (n=60), BF-LD (n=62) vs. Taxus paclitaxel-eluting stents (PES) (n=60). Lesion criteria were native vessels 2.25-3.0mm in diameter, and <14mm in length. Overall, pts were divided into 2 cohorts w/ same randomization ratio: 1st cohort (n=75), enrolled in Sep/08-Jan/09 (angiographic FU at 4-month); and 2nd cohort (n=107), enrolled in Jan-Jun/09 (angiographic FU at 12-month). Primary endpoint was in-stent late lumen loss (LLL) (non-inferiority, margin = 0.24mm) at 12-month FU (2nd cohort).

Results: Baseline characteristics were comparable among the 3 groups; 38% of lesions were located in LAD, and all pts achieved angiographic success. At 4-month FU (1st cohort), QCA results showed significant decrease in in-stent LLL w/ BF-SD and BF-LD vs. PES: 0.08 and 0.12 vs. 0.37mm ($p<0.0001$ for BF-SD vs. PES; $p=0.002$ for BF-LD vs. PES); at 12-month, similar results were found including in-stent LLL of 0.17 and 0.22 vs. 0.35mm for BF-SD and BF-LD vs. PES ($p=0.001$ for BF-SD vs. PES; $p=0.21$ for BF-LD vs. PES - non-inferiority).

Conclusions: The novel BF polymer-free BA9-coated stents showed excellent acute results, and sustained efficacy through 12-month FU. Specifically, the BF-SD met the primary endpoint of non-inferiority in LLL (a surrogate of neointimal proliferation) compared to polymeric PES. Larger trials with longer-term FU are warranted.