A192.E1801
JACC March 9, 2010
Volume 55, issue 10A

i2 SUMMIT

PRELIMINARY ANGIOGRAPHIC RESULTS OF THE NOVEL POLYMER-FREE BIOLIMUS-A9 COATED STENTS FOR THE TREATMENT OF CORONARY ARTERY LESIONS - FOUR-MONTH ANGIOGRAPHIC FOLLOW-UP OF THE PROSPECTIVE, RANDOMIZED, MULTICENTER BIOFREEDOM TRIAL

i2 Poster Contributions
Georgia World Congress Center, Hall B5
Sunday, March 14, 2010, 3:30 p.m.-4:30 p.m.

Session Title: DES II, Restenosis, Left Main and Outcomes
Abstract Category: PCI - DES
Presentation Number: 2502-421

Authors: *Ricardo A. Costa, Alexandre Abizaid, Roxana Mehran, Alexandra J. Lansky, Marco A. Magalhaes, Louise Gambone, Helen Parise, Gerhard Schuler, Karl E. Hauptmann, Joachim Schofer, Eberhard Grube, Cardiovascular Research Center / Cardiovascular Research Foundation, Sao Paulo, NY, Brazil, Helios Heart Center, Siegburg, Germany*

Background: The BioFreedom (BF) biolimus A9 (BA9) coated stent (Biosensors SA, Switzerland) is a new drug-eluting stent (DES) with a 316L stainless steel platform which has been 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 first-in-man angiographic outcomes of the BF DES w/ 2 different formulations: standard dose (SD) and low dose (LD).

Methods: From Sep/08-Jan/09, 75 pts w/ single coronary lesion were prospectively randomized at 4 sites in Germany in a 1:1:1 ratio for treatment with: BF-SD (15.6μg/mm) vs. BF-LD (7.8μg/mm) vs. Taxus paclitaxel-eluting stents (PES). Lesion criteria were native vessels 2.25-3.0mm in diameter, and length<14mm.

Results: Baseline characteristics were comparable among the 3 groups; 38% of lesions were located in LAD, and all pts achieved angiographic success. QCA data (in-stent meausres) are shown in the Table. At follow-up (FU), there was no in-stent restenosis or aneurysm formation in all groups.

Conclusions: The novel BF polymer-free BA9-coated stents showed excellent acute results, and efficacy at 4-month FU including significant reductions in late lumen loss (a surrogate of neointimal proliferation) with both BF-SD and BF-LD compared to the Taxus PES. Longer-term FU is warranted. (ns=non-significant).

QCA	BF-SD N=25	BF-LD N=26	Taxus PES N=24	P value (BF-SD vs. Taxus PES)	P value (BF-LD vs. Taxus PES)
Lesion length, mm	9.4	10.7	10.9	ns	ns
Reference diameter, mm	2.7	2.8	2.7	ns	ns
MLD, mm	0.7	0.6	0.7	ns	ns
% DS	72.8	78.1	75	ns	ns
Final MLD, mm	2.5	2.6	2.6	ns	ns
Final % DS	6.3	8.7	6.3	ns	ns
Final acute gain, mm	1.7	1.8	1.9	ns	ns
Follow-up MLD, mm	2.5	2.5	2.2	ns	ns
Follow-up % DS	7.6	10.1	18	0.002	0.02
Follow-up late lumen loss, mm	0.08	0.12	0.37	<0.0001	0.002