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INTERNATIONAL FIRST IN MAN TRIAL WITH A NOVEL DRUG ELUTING BALLOON IN PATIENTS PRESENTING WITH IN-STENT RESTENOSIS (PEPPER)

i2 Oral Contributions
Ernest N. Morial Convention Center, Room 353
Sunday, April 03, 2011, 5:27 p.m.-5:41 p.m.

Session Title: Restenosis and In-stent Restenosis
Abstract Category: 22. Restenosis/Instent Restenosis - Prevention and Mgt.
Presentation Number: 2904-8

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Background: In-stent restenosis continues to be a therapeutic challenge. The present study aimed to evaluate the safety and efficacy of a new drug eluting balloon Pantera Lux Paclitaxel Releasing Balloon in patients with a single in-stent restenotic lesion in coronary arteries.

Methods: Between August 17, 2009 and April 27 2010, 81 patients presenting with in-stent restenosis were treated with the Pantera Lux at 9 European sites. Patients with a single restenotic lesion in a previously stented area, irrelevant whether bare metal or drug eluting stent presenting with a vessel diameter of 2 - 4 mm, and a lesion length of 8 - 28 mm were enrolled in this first in man trial. The primary endpoint was angiographic in-stent LLL at 6-month FUP evaluated by an independent core laboratory.

Results: Sixty-three men (77.2%) and 18 women (22.2%) with a mean age of 67 ± 9.0 yrs presented with in-stent restenosis from 44 (54.3%) bare metal and 37 (45.7%) drug eluting stents.

Following results are from the first 45 German patients.

	Pre-Procedure N= 45 Mean + SD	Post-Procedure N= 45 Mean + SD	6-Month FUP N= 34 Mean + SD
Reference Vessel Diameter in mm	2.81 + 0.41	2.84 + 0.40	2.75 + 0.38
Minimum Lumen Diameter in mm	0.92 + 0.40	2.15 + 0.43	2.05 + 0.38
Diameter Stenosis in %	67.5	24.0	25.1
In-Stent Late Lumen Loss in mm			0.03 + 0.35

Major Adverse Cardiac Events at 6-month clinical follow-up is 7.7% (3/39).

Final results of the full study population will be presented during ACC.

Conclusions: Treatment of in-stent restenosis form a bare-metal or drug-eluting stent in coronary arteries with the Pantera Lux Paclitaxel Releasing Balloon showed excellent acute and 6-month follow-up results. However the results are based on the first 45 German patients and final results of the full 81 international patients will be presented at ACC.