

Drug REleasing Pantera LUX PTCA Balloon Catheter Registry (DELUX)

Prospective multi-center international registry

Conlusions

- Treatment with the Pantera Lux paclitaxel-coated balloon showed good 12-month outcomes in an international real-world setting in a predominantly difficult ISR population.
- Efficacy and safety are demonstrated by low revascularization, MI and cardiac death rates and confirm previous clinical results of this device using Butyryl tri-hexyl citrate (BTHC) as an inert excipient.
- Results are favorable both in the overall population and in the de novo lesion subgroup.



Major inclusion criteria

- Signed data release form
- Patients with restenotic lesion in a previously stented area of a coronary artery (irrelevant whether BMS or DES related)
- Target reference vessel diameter: 2 4.5 mm
- Target lesion length: 8 28 mm
- Target lesion stenosis: > 50 % < 100 %</p>

Major exclusion criteria

- Patient with allergy against appropriate anticoagulation/antiplatelet therapy
- Patients with allergy against paclitaxel or BTHC
- Patients with a target lesion that was previously treated by brachytherapy

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Baseline characteristics

Demographics	
Age (years)	66.5 ± 10.7
Male gender	74.6 %
Medical history/risk factors	
Hyperlipidemia	83.2 %
Hypertension	84.2 %
Prior MI	51.8 %
Smoking (current and previous)	60.6 %
Diabetes	34.1 %
Congestive heart failure	20.6 %

ISR distribution by stent type

Lesion dimension	
Length (mm)	15.7 ± 7.5
Diameter (mm)	3.0 ± 0.5

Mehran classification (ISR lesions only)		
Class I (focal)	31.6 %	
Class II (diffuse)	47.6 %	
Class III (proliferative)	13.6 %	
Class IV (total occlusion)	4.3 %	



Procedural results



Clinical device success¹: 98.2 %



12-month results

¹ Defined as successful deployment of device and < 50 % residual stenosis of target lesion by visual estimation ² Hierarchical MACE, composite of all death, non-fatal MI and clinically driven target vessel revascularization (TVR), adjudicated by clinical events committee

Source: Toelg R et al. EuroIntervention 2013 Dec 19. [Epub ahead of print]

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