Paclitaxel REleasing Balloon in Patients PresEnting with In-Stent Restenosis – FIM Trial

Prospective multi-center European trial

PEPPER

Conclusion

- Application of a paclitaxel coated balloon using BTHC as excipient is feasible and safe in a mixed population of patients with predominantly type I BMS or DES-ISR lesion.
- A short exposure of the vessel wall to paclitaxel results in very low late lumen loss, revascularization and MACE rates.
- Pantera Lux application is a valuable treatment option for ISR in either BMS or DES patients.

Study design

Prospective, multi-center, non-randomized, European clinical trial of the Pantera Lux Paclitaxel Releasing Balloon

Major inclusion criteria

- Patients with a single restenotic lesion
- Target reference vessel diameter 2 - 4 mm
- Target lesion length 8 – 28 mm
- Target lesion stenosis ≥ 50 % - < 100 %

Major exclusion criteria

- Myocardial infarction
- Additional coronary lesions in the same vessel which requires treatment
- Totally occluded coronary artery

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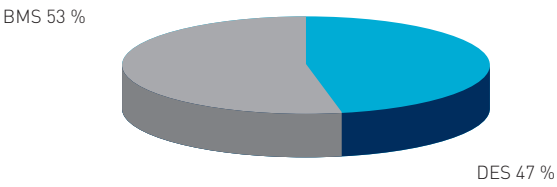
Baseline characteristics

Demographics	
Age (years)	66.1 ± 9.4
Male gender	77.8 %

Medical history/risk factors	
Hyperlipidemia	87.7 %
Hypertension	87.7 %
Prior MI	63.0 %
Diabetes	27.2 %
Renal disease	13.6 %

ISR distribution by stent type



Mehran classification	
Focal (Type I)	71.6 %
Diffuse (Type II)	19.8 %
Proliferative (Type III)	7.4 %
Occlusive (Type IV)	1.2 %

Acute and 6-months angiographic results

	Pre-procedure	Post-procedure	6-months
In-stent			
Reference vessel diameter	2.84 ± 0.39 mm	2.86 ± 0.39 mm	2.82 ± 0.38 mm
Minimum lumen diameter	0.91 ± 0.43 mm	2.18 ± 0.39 mm	2.08 ± 0.41 mm
Late lumen loss			**0.07 ± 0.31 mm**
Diameter stenosis	68.1 ± 13.8 %	23.9 ± 9.8 %	25.9 ± 11.7 %
In-segment			
Late lumen loss			0.02 ± 0.32 mm

■ Primary endpoint

6- and 12-months clinical results

	6-months			12-months		
	All	BMS	DES	All	BMS	DES
Major adverse cardiac events	5 (6.5 %)	2	3	9 (11.8 %)	2	7
Cardiac death	-	-	-	-	-	-
Non-fatal MI	1 (1.3 %)	1	-	1 (1.3 %)	1	-
TVR (clinically driven)	4 (5.2 %)	1	3	8 (10.5 %)	1	7
TLR (clinically driven)	3 (3.9 %)	-	2	7 (9.2 %)	1	6

Source: Hehrlein C et al. Cardiovasc Revasc Med. 2012 Sep; 13(5):260-4.

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