PEPPER

12-month results

Conclusions

- Application of a paclitaxel coated balloon using Butyryl-tri-hexyl citrate (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 (LLL), revascularization and MACE rates
- Pantera Lux application is a valuable treatment option for In-Stent Restenosis (ISR) in either BMS or DES patients

Study design

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

81 patients enrolled in 9 clinical sites in Germany, Poland and Denmark

Lesions pre-dilated with an uncoated balloon and treated with one Pantera Lux. 3 month dual antiplatelet therapy recommended

1-month clinical follow-up

6-month clinical and angiographic follow-up

12-month clinical follow-up

Endpoints

Primary endpoint
- LLL at 6 months

Secondary endpoint
- MACE* at 6 and 12 months

Inclusion/exclusion criteria

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 (MI)
- Additional coronary lesions in the same vessel which requires treatment
- Totally occluded coronary artery

Patient characteristics

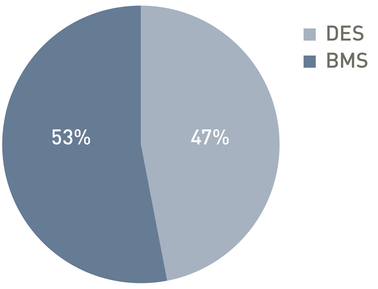
Demographics	
Age (years)**	66.1 ± 9.4
Male gender	77.8%
Medical history/risk factors	
Hyperlipidemia	87.7%
Hypertension	87.7%
Prior MI	63.0%
Diabetes	27.2%
Renal disease	13.6%

Lesion characteristics

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

* Composite of cardiac death, non-fatal Myocardial Infarction(MI), Clinically Driven Target Vessel Revascularization (CD-TVR)
** Data shown as mean ± SD

ISR distribution by stent type



Acute and 6-month angiographic results*	Pre-procedure	Post-procedure	6-month
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
LLL			0.07 ± 0.31 mm
Diameter stenosis	68.1 ± 13.8%	23.9 ± 9.8 %	25.9 ± 11.7 %
In-segment			
LLL			0.02 ± 0.32 mm

Primary endpoint

6-month clinical results	All	BMS	DES
MACE	5 (6.5%)	2	3
Cardiac death	-	-	-
Non-fatal MI	1 (1.3%)	1	-
CD-TVR	4 (5.2%)	1	3
CD-TLR	3 (3.9%)	-	2

12-month clinical results	All	BMS	DES
MACE	9 (11.8%)	2	7
Cardiac death	-	-	-
Non-fatal MI	1 (1.3%)	1	-
CD-TVR	8 (10.5%)	1	7
CD-TLR	7 (9.2%)	1	6

*Data shown as mean ±SD

Principal investigator

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Reference: Hehrlein C, et al. Twelve-month results of a paclitaxel releasing balloon in patients presenting with in-stent restenosis First-in-Man (PEPPER) trial. Cardiovasc Revasc Med. 2012 Sep; 13 (5): 260-264.

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