DELUX Registry

DELUX

12-month results

Conclusions

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

Study design

Prospective multi-center international all comers registry

1,064 patients enrolled in 62 sites in 12 countries

1,137 lesions treated with **Pantera Lux**. Pre-dilation recommended with an uncoated balloon.

6-month clinical follow-up n = 1,033

12-month clinical follow-up n = 1,008

Endpoints

Primary endpoint

- Major Adverse Cardiac Events (MACE) at 6 months

Secondary endpoints (selected)

- MACE at 1, 6 and 12 months
- Clinically-Driven Target Vessel Revascularization (CD-TVR) at 1, 6 and 12 months
- Acute success:
  - Clinical procedural success
  - Clinical device success

Inclusion/exclusion criteria

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%

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

Patient 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%

Lesion characteristics

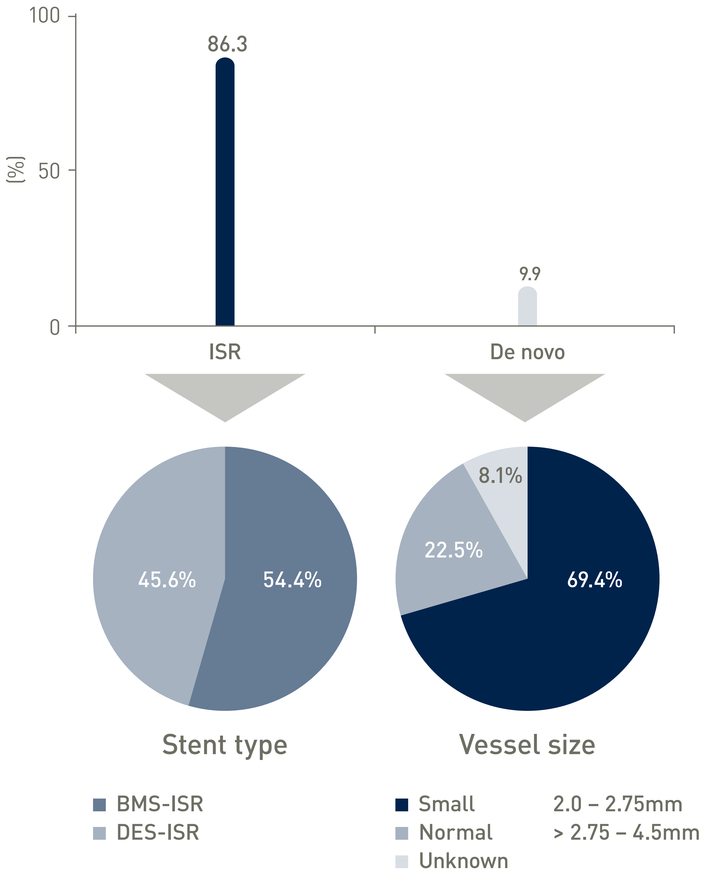
	n = 1,137**
Lesion dimension	
Length (mm)*	15.7 ± 7.5
Diameter (mm)*	3.0 ± 0.5
Mehran classification (ISR lesions only)	
Class I (focal)	31.6%
Class II (diffuse)	47.6%
Class III (proliferative)	13.6%
Class IV (total occlusion)	4.3%

* Data shown as mean ± SD
**Number of Lesions

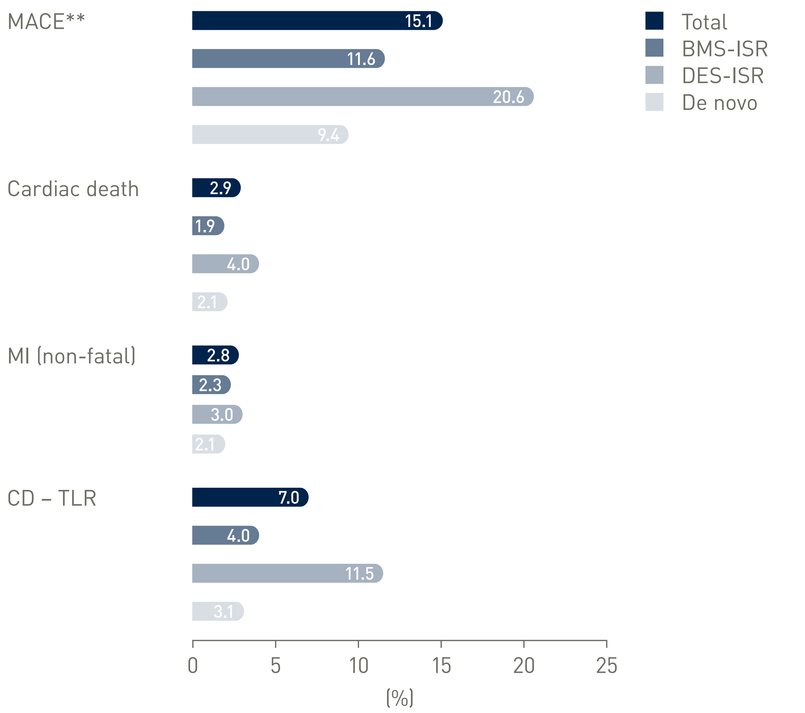
Procedural results

	Pantera Lux
Clinical device success*	98.2%

Indications



12-month results



* Defined as successful deployment of device and < 50% residual stenosis of target lesion by visual estimation

**Hierarchical MACE: Composite of all death, non-fatal Myocardial infarction (MI) and clinically driven target vessel revascularization (TVR), adjudicated by clinical events committee.

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Reference: Toelg R, et al. Coronary artery treatment with paclitaxel-coated balloon using a BTHC excipient: clinical results of the international real-world DELUX registry. EuroIntervention. 2013;10(5):591-599.ClinicalTrials.gov: NCT01081366.

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