ISAR-DESIRE 4

12-month results

Conclusions

In patients presenting with DES restenosis:

- Paclitaxel-coated balloon based strategies confirmed a high clinical safety profile out to 12 months
- Neointimal modification with scoring-balloon significantly improves the angiographic antirestenotic efficacy of paclitaxel-coated balloon angioplasty

Study design

Prospective, randomized, active controlled multi-center clinical trial

Objective

To compare the anti-restenotic efficacy of scoring balloon (SCB) pre-dilatation before paclitaxel-coated balloon (DCB) therapy vs standard balloon pre-dilatation (POBA) before DCB therapy in patients with limus-eluting stent (LES) restenosis

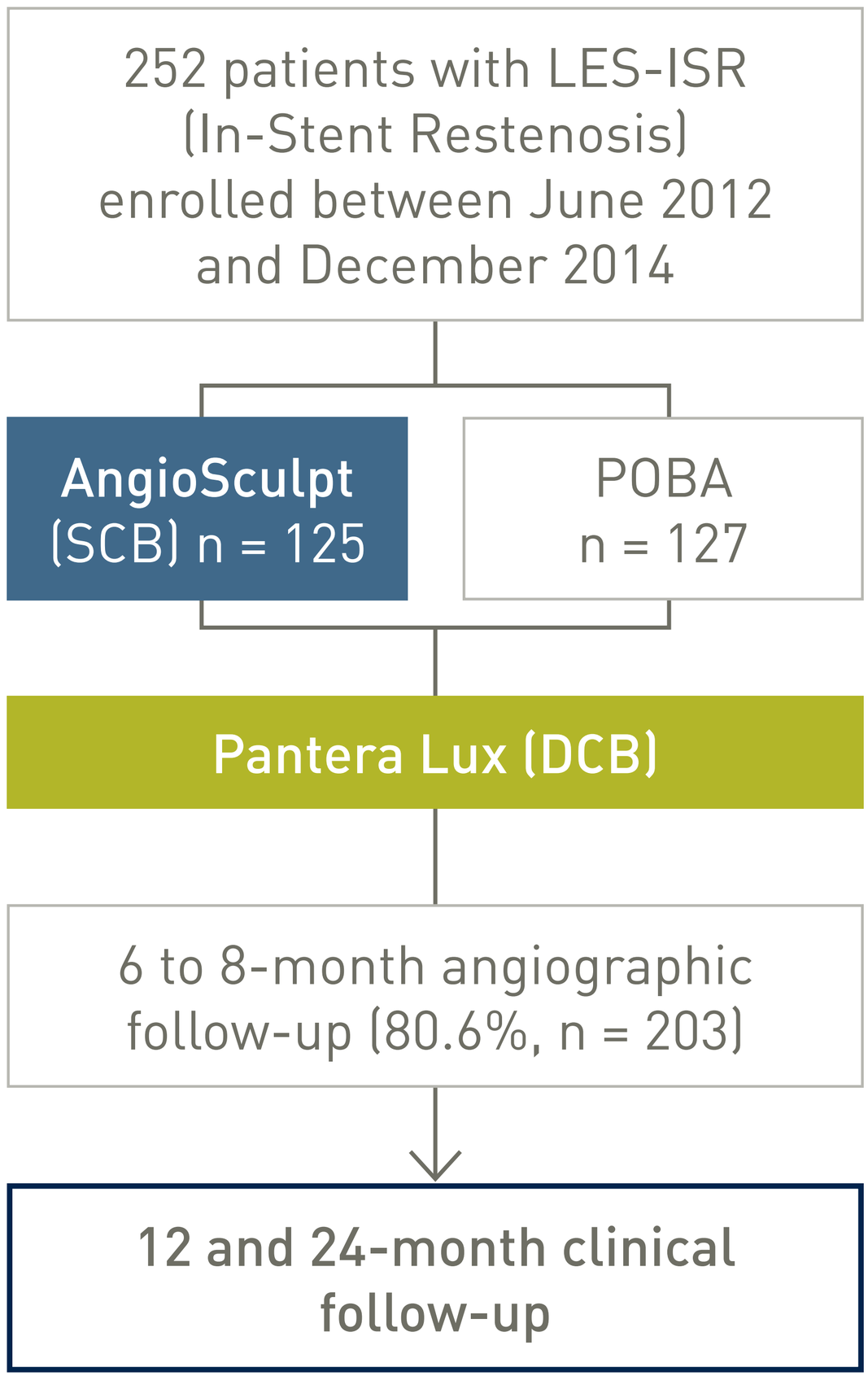
Endpoints

Primary endpoint

- Diameter stenosis at 6 to 8 months

Secondary endpoints

- Binary restenosis
- Target Lesion Revascularization (TLR)
- Death / Myocardial Infarction (MI)
- Target lesion thrombosis



Inclusion/exclusion criteria

Inclusion criteria

- Stenosis >50% in LES
- Symptoms/signs of ischemia

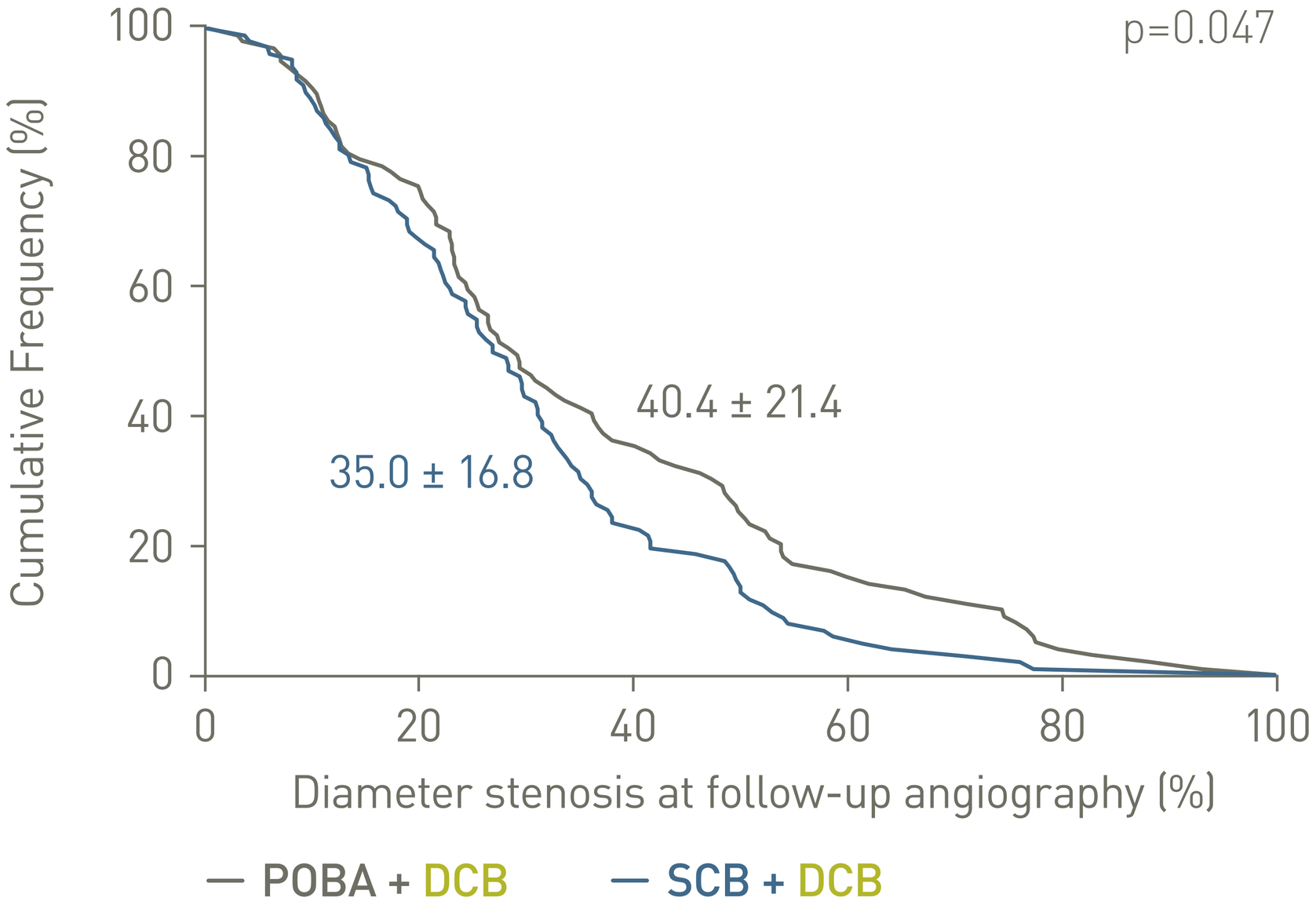
Exclusion criteria

- Lesion in left main stem
- Acute STEMI
- Cardiogenic shock

Baseline characteristics were not significantly different in the two groups

Primary endpoint result

Diameter stenosis at 6 to 8-month follow-up angiography



Secondary endpoint results

6 to 8-month angiographic follow-up

	SCB+DCB	POBA+DCB	p-value
Binary restenosis	18.5%	32.0%	0.026

12-month clinical follow-up

	SCB+DCB	POBA+DCB	p-value
Target lesion revascularization	16.2%	21.8%	0.26
Death or MI	4.0%	3.4%	0.73
TLR	0%	0%	-

Principal investigator

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Reference: Kufner S, et al. Neointimal Modification With Scoring Balloon and Efficacy of Drug-Coated Balloon Therapy in Patients With Restenosis in Drug-Eluting Coronary Stents JACC: Cardiovascular Interventions. 2017; 10 (13): 1332-1340.

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