Randomized Trial on the Treatment of In-stent Restenosis by a Paclitaxel-coated Balloon Catheter - PACCOCATH ISR I

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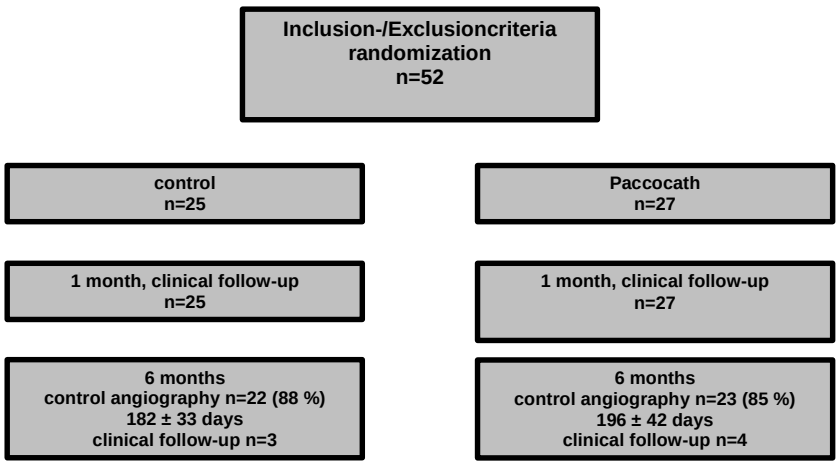
Background: Drug-eluting stents have shown promising anti-restenotic effects in clinical trials. It may be preferable, however, to avoid the stent-in-stent approach in treating in-stent restenosis (ISR). In prior preclinical trials, we demonstrated a highly significant reduction of neointimal formation by drug-eluting balloon catheters (DEB). The aim of the PACCOCATH ISR study was to investigate the novel DEB ("Paccocath") in the treatment of ISR.

Methods: The PACCOCATH ISR I study was a randomized, double-blinded German multicenter trial on the efficacy and tolerance of the DEB in coronary ISR. 52 patients (pts) were randomized to rePTCA of ISR either using the coated PTCA balloon (n=27; 3 µg paclitaxel / mm² balloon surface) or a non-coated balloon of the same type (n=25; control group). Balloon inflation time was 60 seconds in both cases. Major inclusion criteria were an ISR in a coronary artery with a diameter stenosis of at least 70 %, < 30 mm length, and a vessel diameter of 2.5 to 3.5 mm. The primary endpoint was late lumen loss after 6 months (independent angiographic core lab; U.D.). Secondary endpoints included binary restenosis rate and major adverse cardiac events. Study flow chart:



Mean age was 64 ± 11 years. Multivessel disease was present in 80% of pts in both groups. ISR pattern was predominantly Mehran class II and III.

Results No adverse events attributable to the investigational device occurred. Quantitative coronary angiography (QCA) revealed no differences in angiographic baseline parameters. However, after six months there was a highly significant reduction of the primary endpoint by the Paccocath. None of the patients in the Paccocath group underwent repeated revascularization after six months. QCA and clinical endpoints:

	control	**Paccocath**	**p**
Lesion length	18.2 ± 7.9 mm	17.9 ± 6.1 mm	0.868
Reference diameter	3.03 ± 0.37 mm	2.93 ± 0.47 mm	0.463
Minimal lumen diameter initial	0.69 ± 0.39 mm	0.72 ± 0.35 mm	0.811
Minimal lumen diameter post PTCA	2.52 ± 0.47 mm	2.44 ± 0.55 mm	0.603
Minimal lumen diameter 6 months	1.71 ± 0.91 mm	2.30 ± 0.74 mm	0.020
Late lumen loss (in segment)	**0.82 ± 0.86 mm**	**0.13 ± 0.51 mm**	**0.002**
Binary restenosis rate	40.9 %	8.7 %	0.017
Target lesion reintervention	24.0 %	0	0.009
Myocardial infarction	4.0 %	3.7 %	1.000
Death	0	0	1.000
TLR, infarction, or death	24.0 %	3.7 %	0.039

Conclusion: Treatment of coronary ISR with paclitaxel-coated balloon catheters is safe and effective. The reduction of late lumen loss and binary restenosis rate was more pronounced than recently reported with drug eluting stents in this indication.