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Incidence of adverse cardiac events after endothelial progenitor cell capturing stent implantation compared to paclitaxel-eluting stents

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Background: A "pro-healing" approach for prevention of in-stent restenosis is theoretically favorable over the use of cytotoxic/cytostatic drugs released from drug eluting stents to treat coronary artery disease. Promoting accelerated endothelialization of the stent, endothelial progenitor cell capturing stents (ECS) have shown promising results in studies with patients carrying non-complex lesions. The purpose of this study was to evaluate the Genous™ stents versus the Taxus Liberte® paclitaxel-eluting stent (PES) in patients with coronary lesions.

ECS versus the Taxus Liberte® paclitaxel-eluting stent (PES) in patients with coronary lesions.

Methods: During the study period (2010–2012) all consecutive patients receiving ECS were retrospectively compared to age, sex and lesion location matched controls receiving PES. 6-months angiographic and long term clinical outcomes were analyzed. The primary endpoint was the cumulative long-term major adverse cardiac events (MACE).

Results: Out of 908 patients analyzed (454 ECS and 454 PES), 811 (89.3%) were available for up to 60 months follow-up (FU) (mean 34.5 ± 16.8 months). The primary end point occurred in 33.5% (ECS) versus 14.8% (PES) resulting in a hazard ratio of 3.4 (95% CI: 2.29–4.04; $p < 0.0001$) and included cardiac death (7.3% versus 4.4%; $p = 0.09$), myocardial infarction (2.2% versus 5.3%; $p = 0.02$), and target vessel revascularisation (TVR) (24.0% versus 10.4%; $p < 0.0001$). The incidence of definitive/probable stent thrombosis (ST) was 0.4% versus 0.9% ($p = 0.69$); very late (>1 year) ST occurred in one patient in each group (0.2%).

A total of 513 patients (58.7%) underwent 6-months angiographic follow-up. Target lesion revascularisation, TVR, and MACE were significantly more frequent in the ECS group (13.8% versus 4.5%; 15.9% versus 4.5%; and 16.7% versus 6.2%, respectively; $p < 0.0001$ for all).

	ECS-Stent; n=454	PES-Stent; n=454	p-Value
Baseline characteristics			
Age [years] mean \pm SD	73 \pm 8.5	73 \pm 9.0	matching characteristics
Male gender	304 (67.0%)	304 (67.0%)	0.40
Prior coronary artery bypass grafting	95 (20.5%)	94 (21.5%)	0.29
Prior percutaneous coronary intervention	224 (49.3%)	241 (53.1%)	<0.0001
History of myocardial infarction	156 (34.4%)	260 (57.3%)	<0.0001
Hypertension	420 (92.5%)	340 (75.9%)	0.006
Diabetes	203 (44.7%)	161 (35.5%)	0.009
Insulin treated	48 (10.4%)	58 (12.7%)	0.006
Hyperlipidemia	301 (66.7%)	262 (57.7%)	0.006
Angiographic characteristics			
ACC/AHA lesion type B2/C	384 (73.0%)	259 (56.6%)	0.22
Lesion location			
LAD	108 (37.6%)	198 (37.6%)	matching characteristics
RCA	165 (51.4%)	185 (31.4%)	
LCX	125 (21.8%)	125 (23.8%)	
Bifurcation lesion			
	19 (3.6%)	34 (7.3%)	0.02
Mean stent diameter [mm]	3.0 \pm 0.48	2.7 \pm 0.47	<0.0001
Mean stent length per lesion [mm]	24 \pm 15	24.6 \pm 5.2	0.38

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Table 1

Conclusions: Within 3 years FU implantation of the ECS in patients with de-novo coronary lesions resulted in a significant higher rate of the primary endpoint compared to PES. This was mainly driven by repeat revascularizations, the number of stent thromboses was low in both groups.

Topic: paclitaxel, stent, endothelial progenitor cells, cardiac event

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