Paclitaxel-Eluting vs. Bare Metal Stent Implantation in Saphenous Vein Graft Lesions: Very Long-Term Follow-Up of the SOS (Stenting Of Saphenous vein grafts) Trial

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Background

- The very long-term (>3 year) outcomes after implantation of drug-eluting as compared with bare metal stents (BMS) in saphenous vein grafts (SVGs) have received limited study.
- The Stenting Of Saphenous vein grafts (SOS) trial demonstrated better outcomes with DES vs BMS during a median follow-up of 35 months.
- In the present study we examined the very long-term (>3 years) outcomes of the SOS trial.

Methods

In the SOS trial (NCT00247208) 80 patients were randomized to BMS or paclitaxel-eluting stents (PES). During a median follow-up of 35 months use of PES was associated with better clinical outcomes. We report very-long term outcomes on 62 patients enrolled at the highest enrolling institution.

Table 1. Baseline clinical and angiographic characteristics

	BMS (patient = 31) (grafts = 35) (lesions = 46) (stents = 51)	PES (patients = 31) (grafts = 34) (lesions = 45) (stents = 48)	P value
Age (years)*	66 ± 9	66 ± 10	0.95
Men, n (%)	31 (100%)	31 (100%)	1.0
Years since coronary artery bypass surgery*	12 ± 6	11 ± 6	0.58
Indication for PCI, n(%)			0.48
Stable Angina	9 (29%)	10 (32%)	
Unstable Angina	12 (39%)	11 (35%)	
Non-ST-segment elevation acute myocardial infarction	6 (19%)	9 (29%)	
Other	4 (13%)	1 (3%)	
Hypertension, n(%)	30 (97%)	29 (94%)	1.0
Hyperlipidemia, n(%)	30 (97%)	30 (97%)	1.0
Diabetes mellitus, n(%)	12 (39%)	12 (39%)	1.0
Current Smoking, n(%)	9 (29%)	8 (26%)	0.65
Prior myocardial infarction, n(%)	18 (58%)	19 (61%)	0.80
Number of lesions treated per patient*	1.48 ± 0.68	1.45 ± 0.72	0.86
1, n(%)	19 (61%)	20 (65%)	0.57
2, n(%)	9 (29%)	9 (29%)	
3, n(%)	3 (10%)	1 (3%)	
4, n(%)	0	1 (3%)	
Number of stents in each study SVG*	1.45 ± 0.68	1.42 ± 0.67	0.85
1, n(%)	20 (65%)	21 (68%)	0.96
2, n(%)	8 (26%)	7 (23%)	
3, n(%)	3 (10%)	3 (10%)	
Number of stents per lesion*	1.11 ± 0.31	1.07 ± 0.25	0.48
1, n(%)	41 (89%)	42 (93%)	0.48
2, n(%)	5 (11%)	3 (7%)	
Embolic protection device use, n(%)	29 (63%)	26 (58%)	0.61
Total stent length per patient (mm)*	30 ± 16	30 ± 18	0.96
Total stent length per lesion (mm)*	20 ± 7	20 ± 8	0.71
Range	8-44	8-44	
Post PCI myocardial infarction, n(%)	1/23 (4%)	1/27 (4%)	0.91

* mean ± standard deviation

Results

- Of the 62 studied patients 31 received a BMS and 31 a PES.
- Both study groups had similar baseline characteristics.
- During a median follow-up of 6.9 years the study patients experienced 116 major adverse cardiovascular events (MACE), 73 in the BMS and 43 in the PES group. Ten pts did not experience any MACE, eight of whom were randomized to PES.
- A non-fatal initial event was experienced by 26 pts in the BMS group and 14 pts in the DES group.
- A recurrent MACE occurred in 31 patients: 22 (85%) in the BMS group and 9 (64%) in the PES group (p = 0.008).

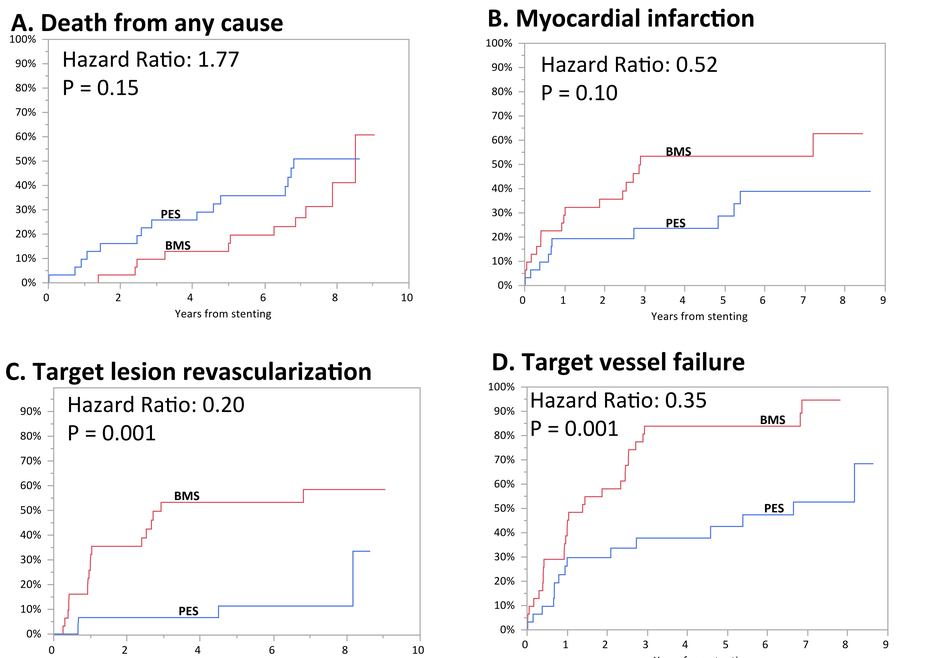

Figure 1. Kaplan-Meier Curves of the Clinical End Points

Table 2. Very long-term clinical outcomes of the study patients

Clinical event	BMS (N=31)	PES (N=31)	Hazard ratio (95% CI)	P Value
Death, n (%)	11 (35%)	15 (48%)	1.77 (0.81, 3.96)	0.15
Cardiac death, n (%)	11 (35%)	9 (29%)	0.88 (0.36, 2.19)	0.78
Myocardial infarction, n (%)	17 (55%)	10 (32%)	0.52 (0.23, 1.12)	0.10
Target lesion revascularization, n (%)	17 (55%)	4 (13%)	0.20 (0.06, 0.54)	0.001
Target vessel revascularization, n (%)	20 (65%)	9 (29%)	0.41 (0.18, 0.88)	0.02
Any revascularization, n (%)	24 (77%)	13 (42%)	0.38 (0.18, 0.74)	0.004
Death or myocardial infarction, n (%)	22 (71%)	19 (61%)	0.75 (0.40, 1.39)	0.36
Target vessel failure, n (%)	28 (90%)	15 (48%)	0.35 (0.18, 0.66)	0.001
Device-oriented composite endpoint, n (%)	26 (84%)	12 (39%)	0.29 (0.13, 0.57)	0.0003
Overall major adverse cardiac events (patient-oriented composite endpoint), n (%)	29 (94%)	23 (74%)	0.56 (0.31, 0.99)	0.04
Definite or probable stent thrombosis by ARC criteria, n (%)	7 (23%)	1 (3%)	0.14 (0.01, 0.78)	0.03

ARC, academic research consortium; CI=confidence intervals.

Limitations

- Non-prespecified, post hoc analysis that included subjects from only one of the participating sites
- The SOS study used first generation DES
- Small sample size
- SOS was not blinded and included planned angiographic follow-up, that may increase the follow-up revascularization rates

Conclusions

The early benefit observed with use of PES vs BMS in SVGs persisted during very-long term follow-up.

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