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Continued Benefit From Paclitaxel-Eluting Compared With Bare-Metal Stent Implantation in Saphenous Vein Graft Lesions During Long-Term Follow-Up of the SOS (Stenting of Saphenous Vein Grafts) Trial

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Objectives This study sought to report the long-term outcomes after drug-eluting stent (DES) implantation in saphenous vein graft (SVG) lesions in the SOS (Stenting of Saphenous Vein Grafts) trial.

Background The long-term outcomes after DES implantation in SVGs are poorly studied. Apart from the SOS trial, the only other randomized trial comparing DES with bare-metal stents (BMS) in SVGs reported higher mortality in the DES group at 32 months.

Methods In the SOS trial, 80 patients with 112 lesions in 88 SVGs were randomized to a BMS or paclitaxel-eluting stent (PES) and demonstrated improved short-term angiographic and clinical outcomes with PES. Extended clinical follow-up was subsequently obtained.

Results Mean age was 67 ± 9 years, and all patients were men. The indications for stenting included acute coronary syndrome in 60% and stable angina in 31% of patients. The mean SVG age was 12 ± 6 years. The baseline characteristics of the patients in the 2 study groups were similar. Procedural success was achieved in 77 patients (96%). During a median follow-up of 35 months, compared with patients randomized to BMS, those receiving PES had a lower incidence of myocardial infarction (hazard ratio [HR]: 0.32, p = 0.01), target lesion revascularization (HR: 0.20, p = 0.004), target vessel revascularization (HR: 0.41, p = 0.03), and target vessel failure (HR: 0.34, p = 0.001) as well as a trend toward less definite or probable stent thrombosis (HR: 0.15, p = 0.08). All-cause mortality (HR: 2.04, p = 0.19) and cardiac mortality (HR: 0.62, p = 0.51) did not differ between groups.

Conclusions During long-term follow-up, use of PES was associated with significantly better clinical outcomes than BMS in SVG lesions. (Stenting of Saphenous Vein Grafts Trial [SOS]; NCT00247208) (J Am Coll Cardiol Intv 2011;4:176–82) © 2011 by the American College of Cardiology Foundation

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Whether drug-eluting stents (DES) provide superior clinical outcomes compared with bare-metal stents (BMS) when used in saphenous vein graft (SVG) lesions remains controversial. Although 7 angiographic studies have all reported consistent reduction in in-stent late loss with DES than BMS in SVGs, the impact of DES on clinical outcomes has varied: approximately one-half of the published comparative studies suggested benefit with DES and one-half revealed no difference between DES and BMS (1). Only 2 randomized-controlled trials of DES versus BMS have been published to date. The RRISC (Reduction of Restenosis In Saphenous Vein Grafts With Cypher Sirolimus-Eluting Stent) trial compared a sirolimus-eluting stent (Cypher, Cordis, Warren, New Jersey) with a BMS of similar design (2,3). The SOS (Stenting of Saphenous Vein Grafts) trial compared a paclitaxel-eluting stent (PES) (Taxus, Boston Scientific, Natick, Massachusetts) to a similar BMS (4–6). In the RRISC trial, an initial benefit seen at 6 months (2) was no longer present at a median of 32 months of follow-up; moreover, the DES group had higher mortality (3). In the SOS trial, an angiographic and clinical benefit was seen with PES during a median follow-up of 18 months. Here, we report the long-term outcomes of patients enrolled in the SOS trial.

Methods

The primary results of the SOS trial have been published (4). The SOS trial was a randomized, controlled, single-blinded, multicenter trial designed to test the hypothesis that implantation of PES in SVG lesions would result in lower 12-month angiographic restenosis rate compared with the rates for a similar BMS (Express^2, Boston Scientific). Repeat angiography was performed in 83% of patients. Patients were asked to return for repeat coronary angiography 12 months after stent implantation and were contacted by phone until 24 months after enrollment to determine whether any late cardiovascular events had occurred. The SOS trial was approved by each participating site's Institutional Review Board, and all patients provided written informed consent. Due to concerns about the long-term outcomes after DES implantation in SVGs, Institutional Review Board approval was obtained to contact the patients to determine longer-term outcomes in 2010. Follow-up was available for all patients except 1.

In the present analysis, we examined the incidence of several clinical end points (death, target lesion revascularization, target and nontarget vessel revascularization, target vessel failure, device-oriented composite end point, major adverse cardiac events, and stent thrombosis) during the follow-up period. Myocardial infarctions (MIs) included in the present analysis were those occurring during follow-up, without including periprocedural cardiac biomarker increases. Target vessel failure was defined as the composite end point of cardiac death, MI, and target vessel revascularization. A composite end point of cardiac death, MI attributed to the target vessel, and target lesion revascularization was also evaluated (device-oriented composite end point, as suggested by Cutlip et al. [7]). For this analysis, if an adverse event could not unequivocally be attributed to a nontarget vessel, the event was considered to represent target-vessel failure. We also assessed the incidence of major adverse cardiac events defined as the composite of any death, any MI, or any coronary revascularization (similar to the patient-oriented composite end point suggested by Cutlip et al. [7]).

Abbreviations and Acronyms

BMS = bare-metal stent(s)
DES = drug-eluting stent(s)
MI = myocardial infarction
PES = paclitaxel-eluting stent(s)
SVG = saphenous vein graft

The incidence of these end points was calculated using the Kaplan-Meier method, and the differences between the 2 study groups were compared using the log-rank test. Cox proportional hazards methods were used to calculate the hazard ratios for the PES versus BMS groups for each of the end points. All analyses were performed on an intention-to-treat principle using JMP 8 (SAS Institute, Cary, North Carolina) and SPSS (SPSS Inc., Chicago, Illinois). A 2-sided p value <0.05 was considered statistically significant.

Results

Patient characteristics. Between 2005 and 2007, 80 patients were enrolled in the SOS trial and were randomized to a BMS (n = 39) or a PES (n = 41). Mean age was 67 ± 9 years and all patients were men. The 2 study groups had similar baseline clinical and procedural characteristics (Table 1). The

honoraria from St. Jude Medical; consulting fees from Medicure; his spouse is an employee of Medtronic. Dr. de Lemos has received speaker honoraria from Bristol-Myers Squibb/Sanofi-Aventis; and consulting income from Johnson & Johnson (<$10,000). Dr. Obel works predominantly with cardiac rhythm devices; and has speaker agreements with St. Jude Medical, Medtronic, and Boston Scientific. Dr. Addo has served on the Speakers' Bureau for Eli Lilly and Daiichi-Sankyo. Dr. Rossen participated in multicenter clinical studies supported by Boston Scientific. Dr. Berger has served as a consultant to AstraZeneca, Boehringer Ingelheim, Eli Lilly/Daiichi-Sankyo, Medicure, and Ortho McNeil (each for <$10,000) and has received research funding for Geisinger Clinic for studies on which he is the Principle Investigator from Thrombovision, Helena, Accumetrics, AstraZeneca, Haemoscope, The Medicines Company, and Corgenix/Aspirinworks (all for more than $10,000). He owns equity in Lumen, Inc. (a company that has an embolic protection device and aspiration catheter [greater than $10,000]). Dr. Banerjee is a consultant for Medtronic, Gilead, St. Jude Medical; and has received research grants from The Medicines Company and Boston Scientific; and Intellectual property: Mdcareglobal (spouse), Hygeiatel. All other authors have reported that they have no relationships to disclose.

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Table 1. Baseline Characteristics of the Study Population

	BMS (Patients = 39) (Grafts = 43) (Lesions = 55) (Stents = 62)	PES (Patients = 41) (Grafts = 45) (Lesions = 57) (Stents = 62)	p Value
Age, yrs*	67 ± 9	66 ± 9	0.71
Men	39 (100%)	41 (100%)	1.0
Years since coronary artery bypass surgery*	12 ± 6	11 ± 6	0.84
Indication for PCI			0.53
Stable angina	13 (33%)	12 (29%)	
Unstable angina	14 (36%)	16 (39%)	
Non–ST-segment elevation acute myocardial infarction	8 (21%)	10 (24%)	
Other	4 (10%)	3 (7%)	
Hypertension	37 (95%)	38 (93%)	0.69
Hyperlipidemia	37 (95%)	40 (98%)	0.53
Diabetes mellitus	17 (44%)	18 (44%)	0.98
Current smoking	9 (23%)	12 (29%)	0.53
Prior myocardial infarction	23 (59%)	23 (56%)	0.79
Number of lesions treated per patient*	1.41 ± 0.64	1.39 ± 0.70	0.89
1	26 (67%)	29 (71%)	0.71
2	10 (26%)	9 (22%)	
3	3 (8%)	2 (5%)	
4	0	1 (2%)	
Number of stents in each study SVG*	1.42 ± 0.63	1.40 ± 0.65	0.55
1	28 (65%)	31 (69%)	0.81
2	12 (28%)	10 (22%)	
3	3 (7%)	4 (9%)	
Number of stents per lesion*	1.13 ± 0.34	1.09 ± 0.29	0.50
1	48 (87%)	52 (91%)	0.50
2	7 (13%)	5 (9%)	
Embolic protection device use	31 (56%)	29 (51%)	0.56
Total stent length per patient, mm*	29 ± 16	28 ± 17	0.74
Total stent length per lesion, mm*	21 ± 9	20 ± 10	0.75
Range	8–60	8–56	
Post-PCI myocardial infarction	2/30 (7%)	2/35 (6%)	0.87

*Values are mean ± SD or n (%).
BMS = bare-metal stent(s); PCI = percutaneous coronary intervention; PES = paclitaxel-eluting stent(s); SVG = saphenous vein graft.

indications for angiography and stenting included acute coronary syndrome in 60% and stable angina in 31%. The mean SVG age was 12 ± 6 years. The territory supplied by the target SVGs was the left anterior descending artery in 28%, circumflex in 38%, and right coronary artery in 34%. An embolic protection device was used in 54% of the lesions. Procedural success was achieved in 77 patients (96%).

Long-term outcomes. The clinical outcomes during a median follow-up of 35 months are presented in Figure 1 and Table 2.

Overall, 52 of 80 patients who participated in the SOS trial experienced at least 1 major adverse cardiac event during long-term follow-up: 30 of 39 BMS patients and 22 of 41 PES patients. The major adverse cardiac events were related to the target SVG in 77% of BMS versus 45% of PES patients and were not related to the target SVG in 7% of BMS versus 41% of PES patients; the relationship to the target SVG could not be determined in 17% of the BMS versus 14% of the PES patients (p = 0.01).

Five patients in the BMS and 10 in the PES group died during follow-up (log rank, p = 0.19) (Fig. 1). The cause of death in the BMS group was cardiac arrest in 1 patient, sudden in 2 patients, and unknown in 2 patients. In the PES group, death was due to MI in 1 patient, end-stage heart failure in 1 patient, unknown cause in 1 patient, and noncardiac causes in the remaining 7 patients (lung cancer in 4 patients, small bowel obstruction, multiple strokes and pneumonia, and chronic obstructive pulmonary disease, each in 1 patient).

A total of 25 patients (18 in the BMS and 7 in the PES group) experienced a MI during follow-up. In the BMS group, the MI was related to the target SVG in 9 of 18 patients (due to in-stent restenosis in 4 patients, stent thrombosis in 4 patients, and progression of intermediate

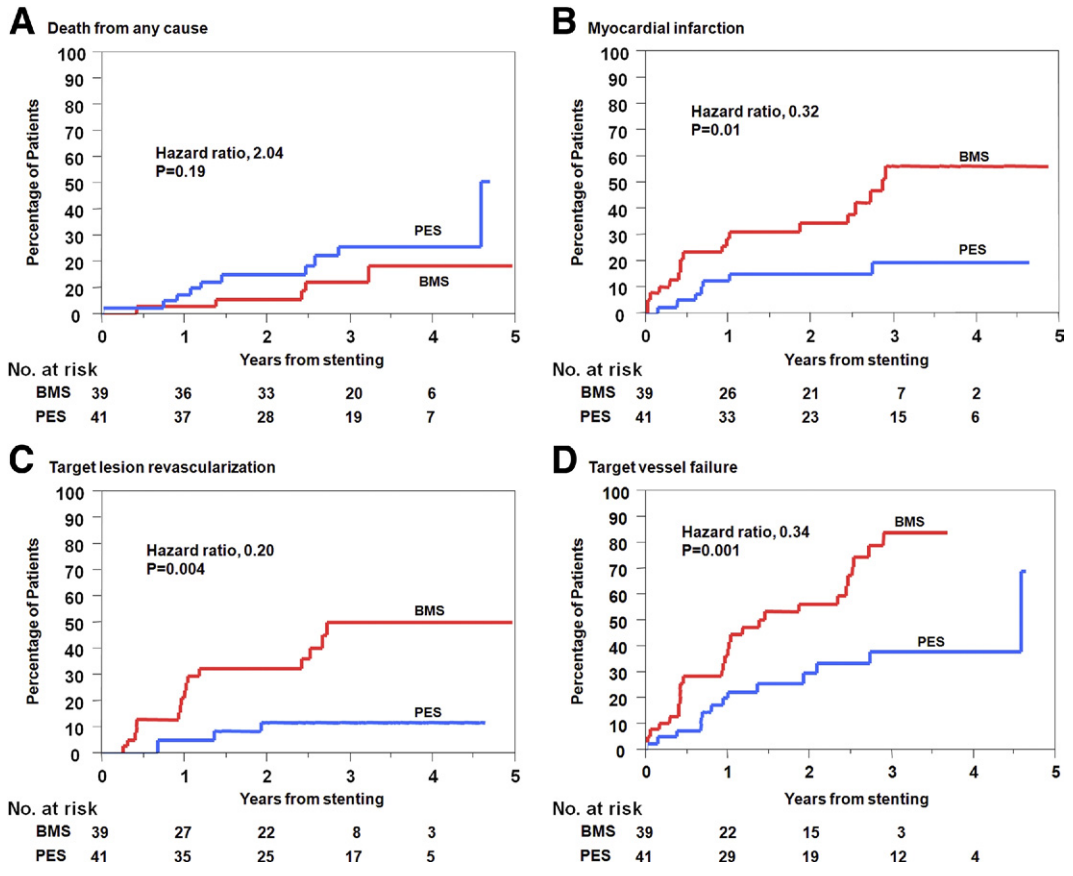

Figure 1. Kaplan-Meier Curves of the Study's Clinical End Points

There was no difference in all-cause mortality between the study groups **(A).** The incidence of myocardial infarction **(B),** target lesion revascularization **(C)**, and target vessel failure **(D)** (composite end point of cardiac death, myocardial infarction, and target vessel revascularization) was significantly lower in the paclitaxel-eluting stent (PES) group than the bare-metal stent (BMS) group.

Table 2. Long-Term Clinical Outcomes in the SOS Trial

Clinical Event	BMS (n = 39)	PES (n = 41)	Hazard Ratio (95% CI)	p Value
Death	5 (13%)	10 (24%)	2.04 (0.70–6.0)	0.19
Cardiac death	5 (13%)	3 (7%)	0.62 (0.15–2.60)	0.51
Myocardial infarction	18 (46%)	7 (17%)	0.32 (0.13–0.76)	0.01
Target lesion revascularization	16 (41%)	4 (10%)	0.20 (0.07–0.60)	0.004
Target vessel revascularization	19 (49%)	9 (22%)	0.41 (0.19–0.90)	0.03
Any revascularization	24 (62%)	10 (24%)	0.32 (0.15–0.67)	0.003
Death or myocardial infarction	20 (51%)	16 (39%)	0.64 (0.33–1.23)	0.18
Target vessel failure	28 (72%)	14 (34%)	0.34 (0.18–0.66)	0.001
Device-oriented composite end point	25 (64%)	11 (27%)	0.28 (0.13–0.59)	0.001
Overall major adverse cardiac events (patient-oriented composite end point)	30 (77%)	22 (54%)	0.82 (0.47–1.44)	0.49
Definite or probable stent thrombosis by ARC criteria	6 (15%)	1 (2%)	0.15 (0.02–1.26)	0.08

Values are n (%), unless otherwise specified.

ARC = Academic Research Consortium; CI = confidence interval; SOS = Stenting of Saphenous Vein Grafts; other abbreviations as in Table 1.

Table 3. Long-Term Outcomes in Published Studies of DES Versus BMS in SVG Lesions

First Author (Ref. #) (Year)	Mean Follow-Up (Months)	BMS (n)	DES (n)	DES Type	Death (%)			MI (%)			TVR (%)		
					BMS	DES	p Value	BMS	DES	p Value	BMS	DES	p Value
Retrospective studies													
Minutello (14) (2007)	20	50	59	SES	12	6.8	0.51	2.0	6.8	0.37	36	15.3	0.01
Bansal (15) (2008)	33	72	37	95% SES	22	19	0.68	NR	NR	NR	42	35	0.47
Gioia (16) (2008)	24	119	106	45% SES, 46% PES, 8% tacrolimus-eluting	6	6	0.9	1	2	0.8	14	14	0.9
Ramana (17) (2008)	34	170	141	SES	12	6	0.05	9	5	0.19	16	13	0.52
Applegate (18) (2008)	24	74	74	91% SES, 9% PES	5	6	0.79	15	11	0.40	17	10	0.18
Assali (19) (2008)	24	43	68	SES, PES	4.7	2.9	0.6	7	8.8	0.9	27.9	10.3	0.02
van Twisk (20) (2008)	48	128	122	SES, PES	27	22.5	NS	11.1	7.6	NS	31	18.4	NS
Guo (21) (2008)	12	47	50	SES, PES	0	2.0	0.32	4.2	0	0.30	25.5	10	0.05
Lozano (22) (2009)	30 median	114	98	NR	NR	NR	NR	NR	NR	NR	13	17	0.49
Shishehbor (23) (2009)	35 median	349	217	NR	16	13	NS	6	7	NS	6	13	NS
Goswami (24) (2009)	36	95	284	84% SES, 16% PES	14.6	18.6	NS	3.4	9.6	NS	10.6	10.6	NS
Brodie (25) (2009)	24	343	785	59% SES, 38% PES, 3% both	14.7	8.2	0.005	11.3	11.9	0.06	16.9	18.3	0.86
Latib (26) (2010)	24	131	127	SES, PES	7.8	8.7	0.99	9.4	6.3	0.50	24.2	19.7	0.47
Baldwin (27) (2010)	36	192	203	63% SES, 30% PES, 7% both	18.1	16.8	0.73	18.6	16.1	0.39	22.2	23.0	0.88
Prospective studies													
Jeger (28) (2008)	18	13	34	65% SES, 35% PES	NR	NR	NR	0	6	1.0	46	18	0.045
RRISC (2,3) (2006, 2007)	32 median	37	38	SES	0	29	<0.001	5	18	0.15	38	34	0.74
SOS (4) (present)	35 median	39	41	PES	13	24	0.19	46	17	0.01	49	22	0.03

DES = drug-eluting stent(s); MI = myocardial infarction; NR = not reported; NS = not significant; SES = sirolimus-eluting stent(s); TVR = target vessel revascularization; other abbreviations as in Tables 1 and 2.

lesion in 1 patient), was not related to the target SVG in 4 patients, or its relationship to the target SVG could not be determined in 5 patients. In the PES group, the MI was related to the target SVG in 3 of 7 patients (due to in-stent restenosis in 2 patients, and progression of an intermediate lesion in 1 patient), was not related to the target SVG in 3 patients, or its relationship to the target SVG could not be determined in 1 patient. The type of MI was non–ST-segment elevation in 21 patients (15 in the BMS and 6 in the PES group), ST-segment evaluation in 1 patient (in the BMS group), or unknown in 3 patients.

The incidence of target lesion and target vessel revascularization was significantly lower in the PES group (Table 1). Stroke occurred in 1 patient (in the PES group) who subsequently died. Use of clopidogrel was similar in the BMS and PES groups at 1 year (73% vs. 84%), 2 years (67% vs. 50%), and 3 years (55% vs. 58%) after enrollment.

Discussion

This extended analysis of the SOS trial suggests that placement of a PES in SVG lesions continued to provide benefit during a median follow-up period of 35 months compared with BMS.

The role of DES in SVG remains controversial. Five meta-analyses (8–12) and 1 systematic review (1) comparing DES with BMS in SVG lesions have recently been published. All showed reduction in target vessel revascularization with DES. One meta-analysis also revealed reduction in MI with DES (8), and 2 suggested reduction in mortality (10,11) with DES. However, the results of these meta-analyses and systematic reviews were driven by the retrospective, uncontrolled studies that provided most of the analyzed data. As a result, the long-term outcomes presented in this analysis of the randomized SOS trial provide an important addition to the literature. Long-term follow-up is particularly important because of the high risk of intermediate SVG lesion progression (13) that could cancel out some of the early reduction in target vessel revascularization provided by DES.

Whether DES implantation in SVGs provides long-term benefit has also been controversial. The results of 17 published studies reporting ≥12-month clinical outcomes after DES versus BMS implantation in SVGs are summarized in Table 3 (2–4,14–28). Only 5 of 14 retrospective studies (14,19,21,26,28) reported a reduction in target vessel revascularization with DES implantation. However, similar to the meta-analyses, a major limitation is the retrospective nature of most long-term outcome studies. The prospective and randomized RRISC trial provides the best quality long-term comparative analysis to date (3,29), in which mortality at a median follow-up of 32 months, was higher in the sirolimus-eluting stent group (29%

vs. 0%, p = 0.001) and there was no reduction with DES in the incidence of target vessel revascularization. Several explanations for the different results observed in the SOS and RRISC trials could be proposed. First, different DES were used: a sirolimus-eluting stent was used in RRISC versus a PES in SOS. Sirolimus-eluting stent did not show benefit in a large prospective cohort study (30), whereas PES have shown excellent results in SVGs in the ARRIVE (TAXUS Peri-Approved Registry: A Multicenter Safety Surveillance) 1 and 2 registries (31) and in the VELETI (Treatment of Moderate Vein Graft Lesions With Paclitaxel Drug Eluting Stents) trial, in which stenting of intermediate (30% to 60%) SVG lesions, compared with medically treated lesions, was associated with significant reduction in disease progression (13). A recent comparison between patients who underwent SVG stenting with either a sirolimus-eluting stent or PES in the Southern California Registry, showed a trend for higher target vessel revascularization with sirolimus-eluting stents (hazard ratio: 2.54, p = 0.09) (32), although 2 small and underpowered prior studies (33,34) did not show any difference between the 2 stents. Whether various DES have different efficacy and safety in SVGs, and whether such differences are due to the drug eluted or the elution rate, remains to be determined (35). Second, patients in the DES arm of RRISC had excessive mortality compared with what would be expected based on previous SVG stenting studies (36,37) (11% per year in RRISC compared with 5% to 7% in other studies, including SOS); moreover, the BMS arm of RRISC surprisingly had no deaths during 2.7 years. However, most deaths in the DES arm of RRISC were not related to the study SVG: 3 of 11 deaths were noncardiac, 3 of 11 were cardiac but proven to not be related to the study SVG, 3 were sudden deaths and only 2 were confirmed to be related to the study SVG (1 in-stent restenosis requiring redo coronary arterial bypass graft surgery in 1 patient and 1 perioperative stent thrombosis 14.5 months after implantation after antiplatelet therapy was discontinued before knee surgery) (3). Similarly, in the SOS trial, 7 of 10 deaths in the PES arm were noncardiac, highlighting the high overall risk and multiple comorbidities of patients who need SVG stenting. Third, there were significant differences between the 2 study populations: patients enrolled in RRISC were older (mean age 73 years vs. 67 years in SOS), less likely to have diabetes mellitus (15% vs. 44% in SOS), and received shorter duration of mandatory antiplatelet therapy (12 months in SOS vs. 2 months in RRISC). Moreover, in the SOS trial, more major adverse cardiac events were related to the target SVG in the BMS than the PES group (77% vs. 45%), suggesting that the benefit observed with PES was likely related to improved outcomes in the target SVG.

Although DES are used in most SVG interventions in the U.S. (38), there remains an unmet need for large, prospective, randomized-controlled trials to better delineate both the short- and long-term outcomes after DES implantation. Three such trials are ongoing: 1) the ISAR-CABG (Prospective, Randomized Trial of Drug-Eluting Stents versus Bare Metal Stents for the Reduction of Restenosis in Bypass Grafts) trial; 2) the BASKETSAVAGE (Basel Stent Kosten Effektivitäts Trial—Saphenous Venous Graft Angioplasty Using Glycoprotein IIb/IIIa Receptor Inhibitors and Drug-Eluting Stents) trial; and 3) the DIVA (VA Cooperative Study #571, Drug Eluting Stents in Saphenous Vein Graft Angioplasty) trial (1). These studies, once completed, will provide a significantly improved understanding of the role of DES in SVGs.

Study limitations. First, this was a non-pre-specified, post hoc analysis of the SOS trial, and the results should be viewed as hypothesis-generating. Second, all study patients were men, and even though sex differences are unlikely to contribute to the findings of this study, extrapolation of the results to women should be done with caution. Third, due to the relatively small sample size, it is subject to both type I and type II statistical error, although the study findings were consistent between the early and long-term follow-up periods.

Conclusions

In the prospective, randomized SOS trial, implantation of PES, when compared with BMS, was associated with improved long-term clinical outcomes, suggesting that PES may provide significant benefit in this high-risk patient population.

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REFERENCES

1. Brilakis ES, Saeed B, Banerjee S. Drug-eluting stents in saphenous vein graft interventions: a systematic review. EuroIntervention 2010;5:722–30.
2. Vermeersch P, Agostoni P, Verheye S, et al. Randomized double-blind comparison of sirolimus-eluting stent versus bare-metal stent implantation in diseased saphenous vein grafts: six-month angiographic, intravascular ultrasound, and clinical follow-up of the RRISC trial. J Am Coll Cardiol 2006;48:2423–31.
3. Vermeersch P, Agostoni P, Verheye S, et al., for the DELAYED RRISC Investigators. Increased late mortality after sirolimus-eluting stents versus bare-metal stents in diseased saphenous vein grafts: results from the randomized DELAYED RRISC trial. J Am Coll Cardiol 2007;50:261–7.
4. Brilakis ES, Lichtenwalter C, de Lemos JA, et al. A randomized controlled trial of a paclitaxel-eluting stent versus a similar bare-metal stent in saphenous vein graft lesions the SOS (Stenting of Saphenous Vein Grafts) trial. J Am Coll Cardiol 2009;53:919–28.
5. Lichtenwalter C, de Lemos JA, Roesle M, et al. Clinical presentation and angiographic characteristics of saphenous vein graft failure after stenting: insights from the SOS (Stenting of Saphenous Vein Grafts) trial. J Am Coll Cardiol Intv 2009;2:855–60.
6. Badhey N, Lichtenwalter C, de Lemos JA, et al. Contemporary use of embolic protection devices in saphenous vein graft interventions: insights from the Stenting of Saphenous Vein Grafts trial. Catheter Cardiovasc Interv 2010;76:263–9.
7. Cutlip DE, Windecker S, Mehran R, et al., for the Academic Research Consortium. Clinical end points in coronary stent trials: a case for standardized definitions. Circulation 2007;115:2344–51.

8. Lee MS, Yang T, Kandzari DE, Tobis JM, Liao H, Mahmud E. Comparison by meta-analysis of drug-eluting stents and bare metal stents for saphenous vein graft intervention. Am J Cardiol 2010;105:1076–82.
9. Meier P, Brilakis ES, Conti R, Knapp G, Shishehbor MH, Gurm HS. Drug-eluting versus bare-metal stent for treatment of saphenous vein grafts: a meta-analysis. PloS One 2010;5:e11040.
10. Joyal D, Filion KB, Eisenberg MJ. Effectiveness and safety of drug-eluting stents in vein grafts: a meta-analysis. Am Heart J. 2010;159:159–69e4.
11. Sanchez-Recalde A, Valero SJ, Moreno R, et al. Safety and efficacy of drug-eluting stents versus bare-metal stents in saphenous vein grafts lesions: a meta-analysis. EuroIntervention 2010;6:149–60.
12. Testa L, Agostoni P, Vermeersch P, et al. Drug eluting stent versus bare metal stent in the treatment of saphenous vein graft disease. a systematic review and meta-analysis. EuroIntervention 2010;6:527–36.
13. Rodes-Cabau J, Bertrand OF, Larose E, et al. Comparison of plaque sealing with paclitaxel-eluting stents versus medical therapy for the treatment of moderate nonsignificant saphenous vein graft lesions: the moderate vein graft lesion stenting with the Taxus stent and intravascular ultrasound (VELETI) pilot trial. Circulation 2009;120:1978–86.
14. Minutello RM, Bhagan S, Sharma A, et al. Long-term clinical benefit of sirolimus-eluting stents compared to bare metal stents in the treatment of saphenous vein graft disease. J Interv Cardiol 2007;20:458–65.
15. Bansal D, Muppidi R, Singla S, et al. Percutaneous intervention on the saphenous vein bypass grafts: long-term outcomes. Catheter Cardiovasc Interv 2008;71:58–61.
16. Gioia G, Benassi A, Mohendra R, Chowdhury K, Masood I, Matthai W. Lack of clinical long-term benefit with the use of a drug eluting stent compared to use of a bare metal stent in saphenous vein grafts. Catheter Cardiovasc Interv 2008;72:13–20.
17. Ramana RK, Ronan A, Cohoon K, et al. Long-term clinical outcomes of real-world experience using sirolimus-eluting stents in saphenous vein graft disease. Catheter Cardiovasc Interv 2008;71:886–93.
18. Applegate RJ, Sacrinty M, Kutcher M, Santos R, Gandhi S, Little W. Late outcomes of drug-eluting versus bare metal stents in saphenous vein grafts: propensity score analysis. Catheter Cardiovasc Interv 2008;72:7–12.
19. Assali A, Raz Y, Vaknin-Assa H, et al. Beneficial 2-years results of drug-eluting stents in saphenous vein graft lesions. EuroIntervention 2008;4:108–14.
20. van Twisk PH, Daemen J, Kukreja N, van Domburg RT, Serruys PW. Four-year safety and efficacy of the unrestricted use of sirolimus- and paclitaxel-eluting stents in coronary artery bypass grafts. EuroIntervention 2008;4:311–7.
21. Guo JC, Xu M, Wang GZ, Ma CS. Late lumen loss of drug eluting stents versus bare mental stents for saphenous vein graft intervention. J Clin Rehabilitative Tissues Eng Res 2008;12:6971–5.
22. Lozano I, Garcia-Camarero T, Carrillo P, et al. [Comparison of drug-eluting and bare metal stents in saphenous vein grafts. Immediate and long-term results]. Rev Esp Cardiol 2009;62:39–47.
23. Shishehbor MH, Hawi R, Singh IM, et al. Drug-eluting versus bare-metal stents for treating saphenous vein grafts. Am Heart J 2009;158:637–43.
24. Goswami NJ, Gaffigan M, Berrio G, et al. Long-term outcomes of drug-eluting stents versus bare-metal stents in saphenous vein graft disease: results from the Prairie "Real World" Stent Registry. Catheter Cardiovasc Interv 2009;75:93–100.
25. Brodie BR, Wilson H, Stuckey T, et al., for the STENT Group. Outcomes with drug-eluting versus bare-metal stents in saphenous vein graft intervention: results from the STENT (Strategic Transcatheter Evaluation of New Therapies) Group. J Am Coll Cardiol Intv 2009;2:1105–12.
26. Latib A, Ferri L, Ielasi A, et al. Comparison of the long-term safety and efficacy of drug-eluting and bare-metal stent implantation in saphenous vein grafts. Circ Cardiovasc Interv 2010;3:249–56.
27. Baldwin DE, Abbott JD, Trost JC, et al. Comparison of drug-eluting and bare metal stents for saphenous vein graft lesions (from the National Heart, Lung, and Blood Institute Dynamic Registry). Am J Cardiol 2010;106:946–51.
28. Jeger RV, Schneiter S, Kaiser C, et al., for the BASKET Investigators. Drug-eluting stents compared with bare metal stents improve late outcome after saphenous vein graft but not after large native vessel interventions. Cardiology 2008;112:49–55.
29. Ellis SG. "Crying fire in a theater" or a "confirmatory sighting?" J Am Coll Cardiol 2007;50:268–9.
30. Ellis SG, Kandzari D, Kereiakes DJ, et al. Utility of sirolimus-eluting Cypher stents to reduce 12-month target vessel revascularization in saphenous vein graft stenoses: results of a multicenter 350-patient case-control study. J Invasive Cardiol 2007;19:404–9.
31. Brilakis ES, Lasala JM, Cox DA, et al. Outcomes after implantation of the Taxus paclitaxel-eluting stent in saphenous vein graft lesions: results from the ARRIVE (TAXUS Peri-Approval Registry: A Multicenter Safety Surveillance) program. J Am Coll Cardiol Intv 2010;3:742–50.
32. Lee MS, Hu PP, Aragon J, et al. Comparison of sirolimus-eluting stents with paclitaxel-eluting stents in saphenous vein graft intervention (from a Multicenter Southern California Registry). Am J Cardiol 2010;106:337–41.
33. Chu WW, Kuchulakanti PK, Wang B, et al. Efficacy of sirolimus-eluting stents as compared to paclitaxel-eluting stents for saphenous vein graft intervention. J Interv Cardiol 2006;19:121–5.
34. Gormez S, Erdim R, Erdogmus O, et al. Treatment of saphenous vein graft lesions with paclitaxel- and sirolimus-eluting stents: comparison of short- and long-term clinical outcomes. Anadolu Kardiyol Derg 2008;8:431–6.
35. Brilakis ES, Banerjee S. Could paclitaxel-eluting stents be superior to sirolimus-eluting stents for the treatment of saphenous vein graft lesions? Am J Cardiol 2010;106:1367–8.
36. Mehta RH, Honeycutt E, Peterson ED, et al. Impact of internal mammary artery conduit on long-term outcomes after percutaneous intervention of saphenous vein graft. Circulation 2006;114:I396–401.
37. Varghese I, Samuel J, Banerjee S, Brilakis ES. Comparison of percutaneous coronary intervention in native coronary arteries vs. bypass grafts in patients with prior coronary artery bypass graft surgery. Cardiovasc Revasc Med 2009;10:103–9.
38. Brilakis ES, Wang TY, Rao SV, et al. Frequency and predictors of drug-eluting stent use in saphenous vein bypass graft percutaneous coronary interventions: a report from the American College of Cardiology National Cardiovascular Data CathPCI registry. J Am Coll Cardiol Intv 2010;3:1068–73.

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