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Comparison by Meta-Analysis of Drug-Eluting Stents and Bare Metal Stents for Saphenous Vein Graft Intervention

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This meta-analysis was undertaken to assess the efficacy and safety of drug-eluting stents (DESs) compared to bare metal stents (BMSs) in saphenous vein graft (SVG) interventions. DESs decrease the risk of target vessel revascularization in native coronary arteries compared to BMSs. The ideal treatment strategy in patients with SVG disease is unknown. A search of the published reports was conducted to identify studies that compared DESs and BMSs in SVG intervention with a minimum follow-up of 6 months. A total of 19 studies (2 randomized trials and 17 registries), including 3,420 patients who had undergone SVG intervention (DESs, n = 1,489 and BMS, n = 1,931), met the selection criteria. The mean length of follow-up was 20 ± 12 months. Using the fixed effect model, target vessel revascularization was less frequently performed in patients who had undergone SVG intervention with a DES than with a BMS (odds ratio [OR] 0.59, 95% confidence interval [CI] 0.49 to 0.72). The incidence of myocardial infarction was lower in patients with a DES than in those with a BMS (OR 0.69, 95% CI 0.49 to 0.99). No differences were found in the risk of death (OR 0.78, 95% CI 0.59 to 1.02) or stent thrombosis (OR 0.41, 95% CI 0.15 to 1.11) between the 2 groups. In conclusion, these findings support the use of DESs in SVG lesions. **(Am J Cardiol 2010;105:1076–1082)**

Although the advantage of drug-eluting stents (DESs) versus bare metal stents (BMSs) has been well documented for native coronary artery disease,[1–3] data are limited for the systematic evaluation of DESs and BMSs in saphenous vein graft (SVG) disease. The clinical studies undertaken to evaluate DESs in SVG were underpowered, and the results of these studies were inconsistent with respect to the rates of major adverse cardiac events, death, myocardial infarction (MI), and target vessel revascularization (TVR).[4–22] The results of the only 2 randomized clinical trials evaluating DESs and BMSs in SVG disease were also disparate, with one showing greater mortality with sirolimus-eluting stents at long-term follow-up.[15,19] Therefore, to determine the safety and efficacy of DESs in SVG intervention, we undertook the present meta-analysis of all published randomized controlled trials and observational studies comparing DESs and BMSs to treat SVG disease.

Methods

A data search of the MEDLINE, EMBASE, and Cochrane databases from January 2003 to February 2009 was conducted using the keywords "percutaneous coronary intervention," "saphenous vein graft," "drug-eluting stent," "sirolimus-eluting stent," and "paclitaxel-eluting stent."

The studies to be included in the analysis were reviewed for acceptability using predefined inclusion criteria. Randomized clinical trials and observational studies were included if they had been published in peer-reviewed journals, with the full text available in English; had compared sirolimus-eluting stents (Cypher, Cordis/Johnson & Johnson, Warren, New Jersey) and/or paclitaxel-eluting stents (Taxus Express, Boston Scientific, Natick, Massachusetts; and V-Flex Plus, Cook, West Lafayette, Indiana) with BMSs for SVG intervention; and had had a length of follow-up of ≥6 months after the index SVG intervention.

Two independent reviewers (MSL and TY) extracted the following data: the first author of the study, baseline demographic and procedural data, sample size, length of follow-up, and clinical events (death, MI, and TVR). The results of the Death and Events at Long-term follow-up AnalYsis: Extended Duration of the Reduction of restenosis in saphenous vein grafts with Cypher stent (DELAYED RRISC) trial[15] were used because the length of follow-up was longer than the follow-up in the Reduction of Restenosis In Saphenous vein grafts with Cypher sirolimus-eluting stent (RRISC) trial.[23]

The primary end point was TVR, which was defined as subsequent percutaneous or surgical revascularization of the

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Table 1
Baseline characteristics of clinical studies

Study	Patients (n)	Age (years)	Men (%)	DM (%)	Hypercholesterolemia (%)	Previous PCI (%)	EF (%)	Graft in Place (years)	Stent Length (mm)	Stent Diameter (mm)	DEP (%)	Follow-up (mo)	Type of DES
Assali et al[4]	68/43	70/71	88/79	54/12	91/91	NR/NR	46/47	11/11	30.3/2020.7	3.3/3.6	38/48	24/24	Cypher/Taxus
van Twisk et al[5]	122/128	68/69	84/80	31/21	66/45	30/27	NR/NR	NR/NR	32/31.9	3.1/3.5	1.6/4.7	48/48	Cypher/Taxus
Okabe et al[6]	138/344	70/70	75/73	53/43	93/90	40/47	44/41	10/10	20.3/19.8	3.1/3.8	26/21	12/12	Cypher/Taxus
BASKET[7]	34/13	71/71	79/100	29/17	79/92	44/39	NR/NR	NR/NR	41/46	NR/NR	NR/NR	18/18	Cypher/Taxus
Kaplan et al[8]	37/33	72/71	92/91	16/24	60/42	65/61	48/52	NR/NR	18.9/15.6	3.4/3.7	27/33	12/12	Cypher/Taxus
Gioia et al[9]	106/119	71/70	80/81	45/37	75/65	40/35	44/47	12/12	21/24	3.3/3.9	NR/NR	24/24	Cypher/Taxus
Ramana et al[10]	141/170	70/69	81/88	52/42	94/89	61/51	47/45	12/13	28.3/2,029.3	3.3/4.2	NR/NR	31/36	Cypher
Vignali et al[11]	72/288	73/71	74/85	29/24	59/59	30/19	NR/NR	9/11	19.7/18.7	3/3.5	NR/NR	12/12	Cypher/Taxus
Bansal et al[12]	37/72	68/65	NR/NR	51/35	84/68	NR/NR	NR/NR	NR/NR	17.1/17.9	3/3.8	39/27	33/33	Cypher/Taxus
Minutello et al[13]	59/50	71/69	71/80	48/44	75/74	32/28	48/48	13/9	NR/NR	3.1/3.4	71.2/48	20/20	Cypher
Ellis et al[14]	175/175	70/69	76/79	39/39	91/89	NR/NR	NR/NR	NR/NR	20.6/2,021.6	NR/NR	35/25	12/12	Cypher
RRISC[15]	38/37	73/72	82/89	16/14	87/84	NR/NR	68/72	12/13	NR/NR	NR/NR	NR/NR	31/32	Cypher
Hoffman et al[16]	60/60	67/67	90/93	25/28	88/87	NR/NR	NR/NR	11/10	16.7/14.6	3.3/3.4	52/47	6/6	Paclitaxel-eluting stent
Lee et al[17]	139/84	69/69	81/74	23/24	78/77	NR/NR	45/42	8/8	NR/NR	2.9/3.0	15/19	9/9	Cypher/Taxus
Ge et al[18]	61/89	67/67	84/89	20/16	66/49	NR/NR	51/49	10/9	29.4/2,020.4	3.4/3.8	31/23	6/6	Cypher/Taxus
SOS[19]	41/39	66/67	100/100	44/44	98/95	NR/NR	NR/NR	11/12	18/18	3.1/3.2	51/56	18/18	Taxus
Lozano et al[20]	98/114	71/66	81/72	38/49	61/62	19/27	55/58	10/9	22/16	3/2.9	NR/NR	30/30	Cypher/Taxus
Wohrle et al[21]	13/26	71/70	92/96	23/31	77/92	NR/NR	NR/NR	11/9	12.1/12.4	2.71/1.84	NR/NR	12/12	Taxus
Guo et al[22]	50/47	74/71	56/55	24/30	80/68	34/40	51/49	NR/NR	22.1/18.8	2.76/3.03	4/0	12/12	Cypher/Taxus

Data are presented as DES/BMS.
DES = drug-eluting stent; DEP = distal embolic protection; DM = diabetes mellitus; EF = ejection fraction; GP = glycoprotein; NR = not reported; PCI = percutaneous coronary intervention.

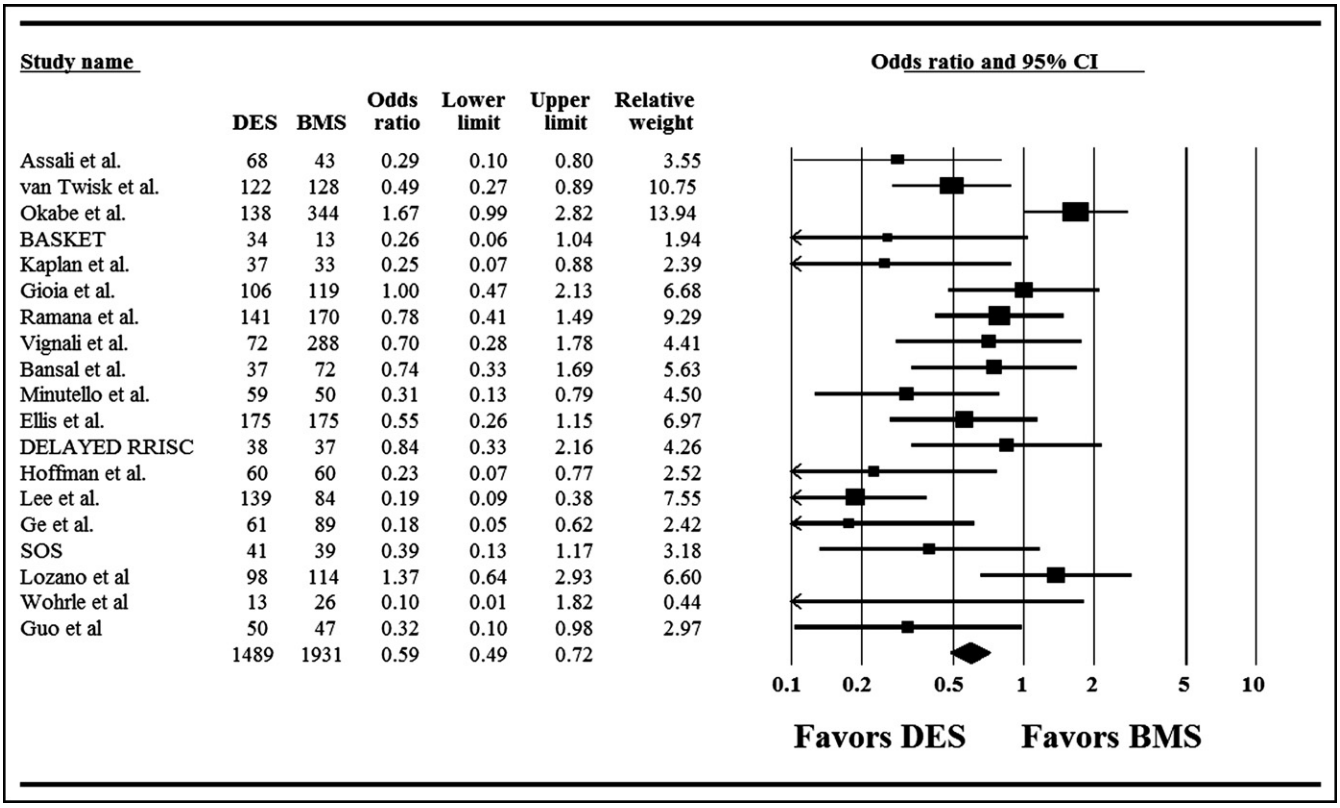

Figure 1. OR and summary plot of TVR associated with DESs versus BMSs.

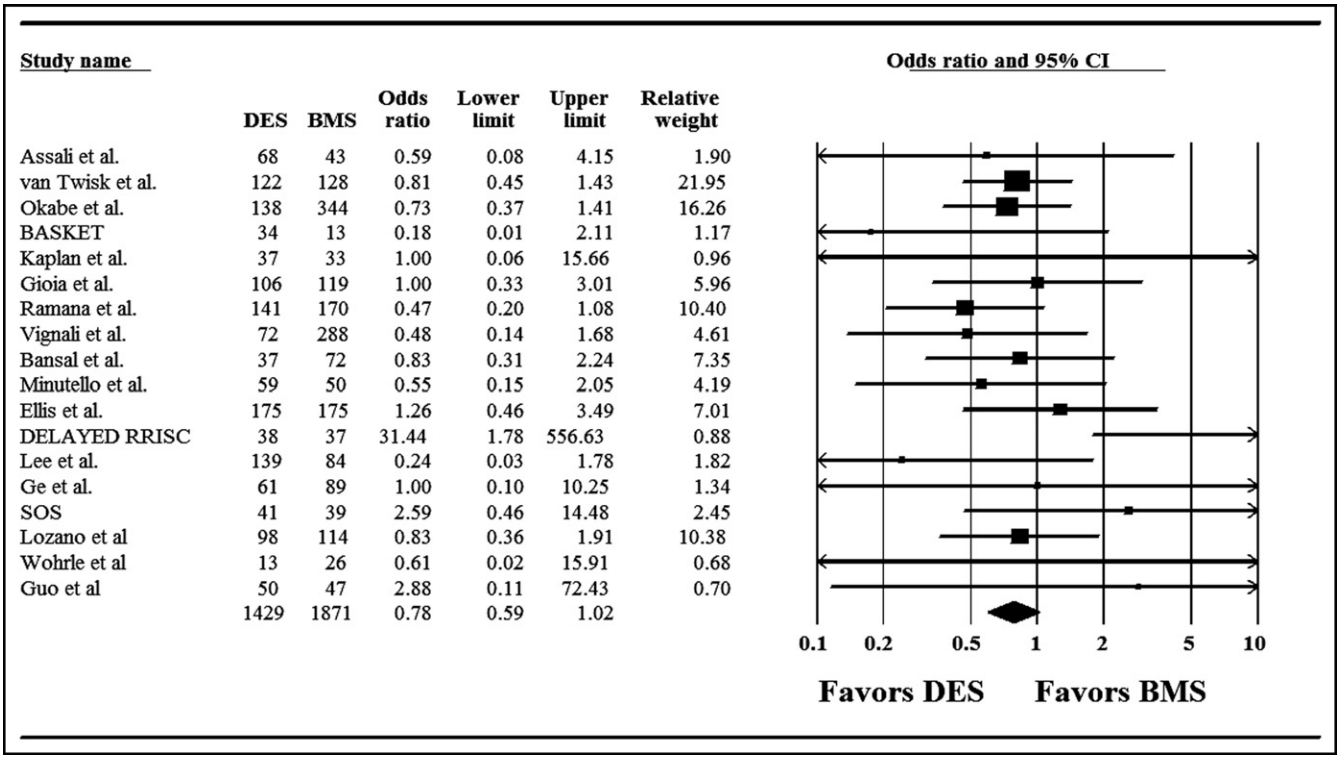

Figure 2. OR and summary plot of death associated with DESs versus BMSs.

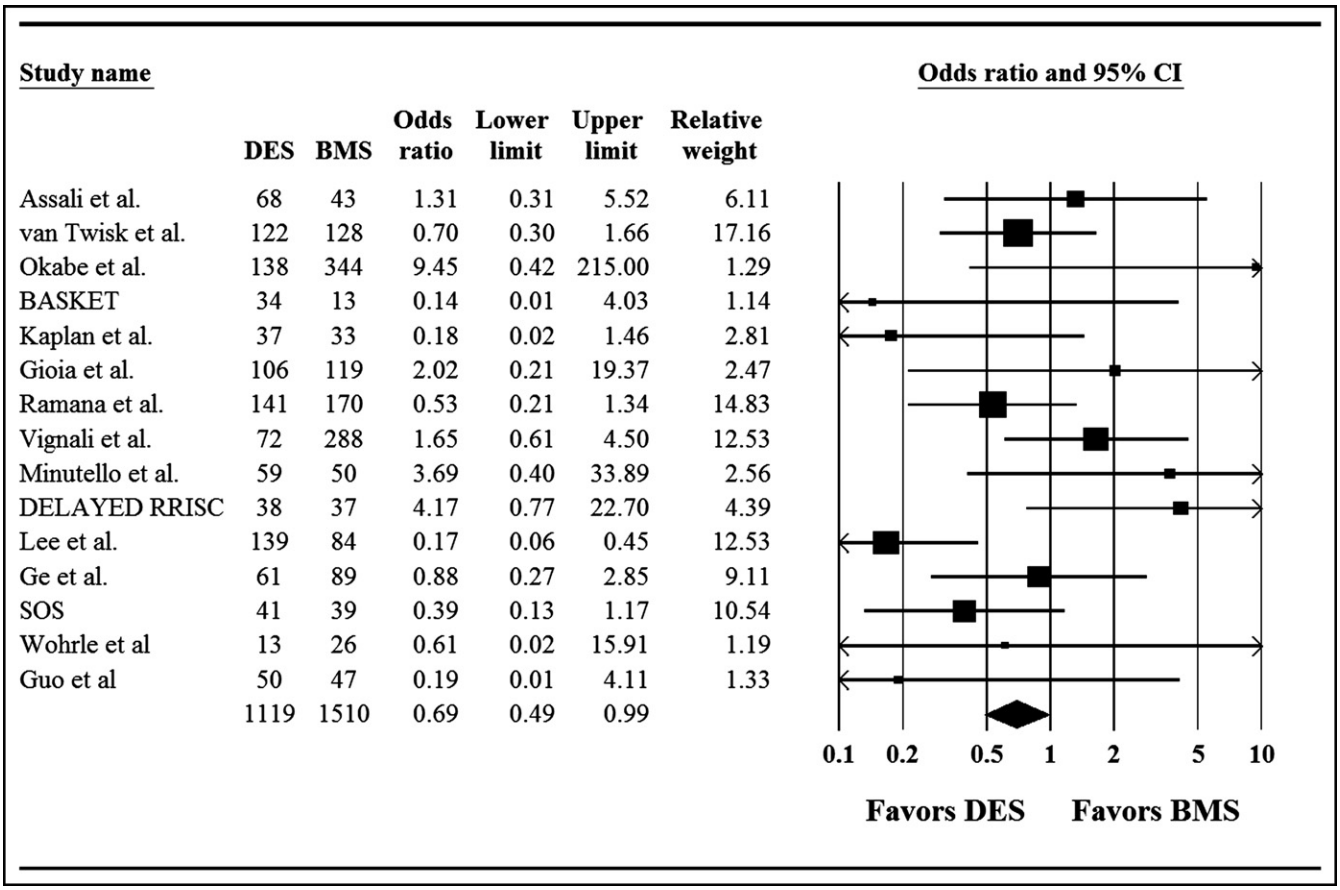

Figure 3. OR and summary plot of MI associated with DESs versus BMSs.

target vessel. The secondary end points were death, MI, and stent thrombosis.

All meta-analyses were done using the Comprehensive Meta-Analysis system, version 2.2 (Biostat, Inc., Englewood, New Jersey). A fixed effect model of meta-analysis was used to aggregate the study level data. In addition, a random effects model was used for reference. Forest plots were generated for the graphic presentations, and Q-statistics were computed for test of heterogeneity across the different studies. For each study and all studies overall, the odds ratios (ORs) and their associated confidence intervals (CIs) were calculated according to the event rates for comparing DES and BMS patients.

The aggregate baseline characteristics were computed using weighted means and standard deviations for continuous variables and the weighted proportions for the binary variables according to the availability of the data in each study arm. The p values for the 2-group comparisons of baseline covariates were calculated using a 2-sample *t* test for continuous data and the chi-square test for categorical data in Microsoft Excel (Microsoft, Redmond, Washington) as ancillary software.

Results

The 19 studies that met the selection criteria included 2 randomized controlled trials (Stenting of Saphenous Vein Grafts [SOS] and RRISC trials) and 17 registries.[4–22] A total of 1,489 patients underwent SVG intervention with DESs and 1,931 patients with BMSs.

The clinical characteristics are listed in Table 1. Several differences were present in the baseline characteristics owing to the limitation of observational studies and the increase in the power of the test by the aggregate sample size. The DES group was older (70.0 vs 69.3 years, $p = 0.02$), had fewer patients who were smoking (31% vs 35%, $p = 0.03$), more diabetic patients (37% vs 33%, $p = 0.001$), more patients with hypercholesterolemia (80% vs 74%, $p < 0.0001$), and had a greater mean ejection fraction (48% vs 47%, $p = 0.02$), longer mean stent length (24 ± 11 vs 21 ± 9 mm, $p < 0.001$), smaller mean stent diameter (3.1 ± 0.1 vs 3.6 ± 1.3 mm, $p < 0.001$), more frequent use of distal embolic protection device (28% vs 23%, $p = 0.01$), and less frequent use of glycoprotein IIb/IIIa antagonists (24% vs 42%, $p < 0.001$) than the BMS group. The mean length of follow-up was 20 ± 12 months (range 6 to 48). Of the 19 studies comparing DESs and BMSs, 12 included a combination of sirolimus-eluting and paclitaxel-eluting stents, 4 studies were exclusively of sirolimus-eluting stents, and 3 studies were exclusively of paclitaxel-eluting stents. Finally, Gioia et al[9] reported ST-segment elevation MI only.

The overall analysis under the fixed effect model revealed a 41% reduction in TVR in patients who underwent SVG intervention with DESs compared to BMSs (OR 0.59, 95% CI 0.49 to 0.72; Figure 1). The chi-square test with

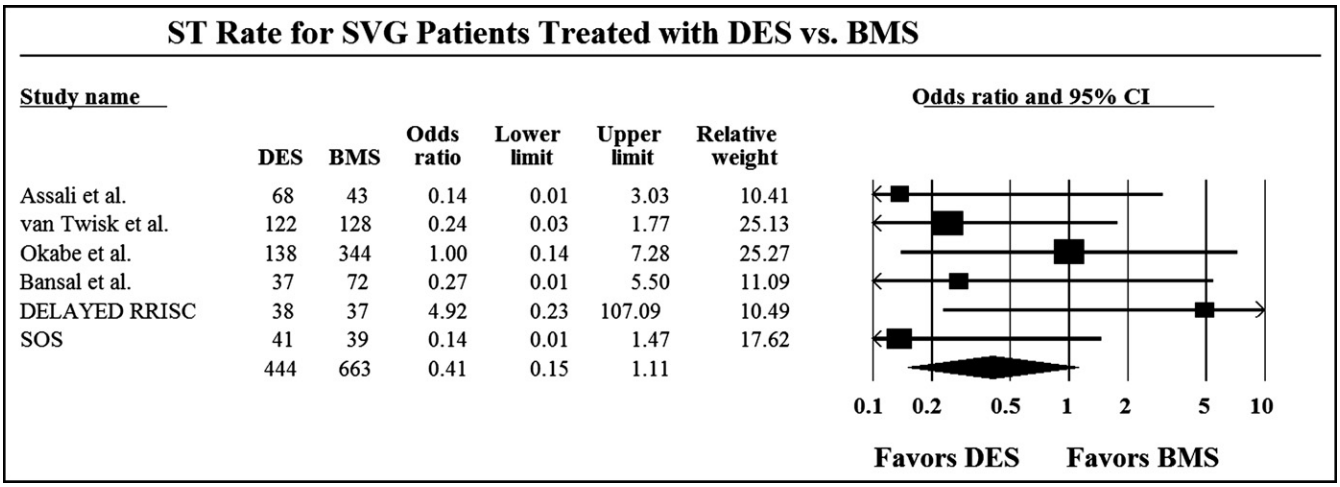

Figure 4. OR and summary plot of stent thrombosis associated with DESs versus BMSs.

18 degrees of freedom for the Q statistic was 49.85 ($p = 0.0001$), indicating that significant heterogeneity was present among the studies. The random effects model was therefore used to analyze the heterogeneity, and the result was consistent (OR 0.50, 95% CI 0.36 to 0.71). Hence, the result for the overall analysis was robust.

The present analysis revealed that patients who underwent SVG intervention with DESs had lower mortality by 22% compared to the mortality rate of the patients with BMSs (OR 0.78, 95% CI 0.59 to 1.02; Figure 2). The chi-square test with 17 degrees of freedom for the Q statistic was 15.17 ($p = 0.58$), indicating no significant heterogeneity among the studies.

The overall analysis under the fixed effect model revealed that patients who underwent SVG intervention with DESs had a lower risk of MI by 31% compared to BMS use (OR 0.69, 95% CI 0.49 to 0.99). The chi-square test with 14 degrees of freedom for the Q statistic was 26.11 ($p = 0.03$), indicating significant heterogeneity among the studies. The random effects model was therefore used to analyze the heterogeneity (OR 0.76, 95% CI 0.44 to 1.29; Figure 3).

Only 6 studies were included in the analysis, because 9 studies did not report stent thrombosis and 4 studies had no reported cases of stent thrombosis. No significant difference was found in the risk of stent thrombosis (OR 0.41, 95% CI 0.15 to 1.11; Figure 4). The wide CIs can be explained by the low frequency of stent thrombosis reported and the limited sample size. The chi-square test with 5 degrees of freedom for the Q statistic was 4.91 ($p = 0.43$). Because no significant heterogeneity was present, the observed effect size was identical for both the fixed effect model and the random effects model.

Discussion

The results of the present meta-analysis of 19 studies comparing DESs and BMSs in SVG intervention have indicated that the use of DESs in these patients provides superior clinical outcomes compared to BMS use. SVG intervention with DESs was associated with a lower risk of TVR compared to BMSs, without an increase in the risk of death, MI, or stent thrombosis using DESs in SVG intervention.

The data on the use of BMSs versus DESs for SVG disease have been conflicting, without a consensus regarding the superior approach to decreasing the restenosis rates, in part because of the variability in trial design and sample size. The only 2 randomized trials provided very different results. The SOS trial reported that the quantitative in-segment, in-stent, and binary angiographic restenosis rates at 12 months were significantly superior in the paclitaxel-eluting stent group ($p < 0.0001$).[19] This was accompanied by a lower rate of TVR in the paclitaxel-eluting stent group compared to the BMS group (15% vs 31%, $p = 0.08$). However, in the DELAYED RRISC trial, no difference in TVR (sirolimus-eluting stent group vs BMS group, 34% vs 38%, respectively; $p = 0.74$) was observed.[15] The present meta-analysis of 3,420 patients has demonstrated a significant reduction in the likelihood of future TVR when SVG disease was treated with a DES instead of a BMS.

In the RRISC trial, no mortality difference was found at 6 months of follow-up with sirolimus-eluting stents versus BMSs in SVG disease.[23] However, late follow-up data from the same trial at 48 months, reported in the DELAYED RRISC trial, demonstrated an increase in mortality for patients who underwent SVG intervention with sirolimus-eluting stents compared to BMSs (29% vs 0%, respectively; $p < 0.001$).[15] Although this appears to be a concerning finding from this small randomized trial ($n = 75$), no other study has suggested increased mortality with DESs in SVG disease at long-term follow-up. Also, the present meta-analysis showed a mortality advantage with DESs in this group.

The lack of long-term SVG stent data has raised concern for the benefit of DESs during the course of a patient's life. The DELAYED-RRISC trial had a mean follow-up of 32 months, long enough to detect late stenosis in DES patients, and the results were favorable for BMSs. Because not all the trials included in the present analysis were designed with follow-up long enough to detect "late catch-up" in DESs, these results might not reflect the true clinical event rates. In addition, the risk of late angiographic stent thrombosis with DESs has been reported for native coronary arteries, and, if

this occurs in SVG stents, it could negatively affect the benefits seen in the present study.[24–26] However, 1/2 of the clinical events after stenting occur within 6 to 12 months after PCI and 65% of major adverse clinical events occur within 200 days.[27,28] In the overall cohort, no increase in MI or stent thrombosis was observed with DES use in SVG disease. Although large-scale randomized trials with long-term data are not available, the present meta-analysis included studies with a mean follow-up of 33 and 34 months, both with favorable results for the DES group. The length of follow-up obtained in most studies included in the present analysis might help in alleviating the safety concerns of DES use in SVG lesions.

Meta-analyses have inherent limitations, including the interpretation of data from summary estimates. The present study-level meta-analysis included predominantly observational registry studies and only 2 randomized trials. Observational studies are limited owing to publication bias, patient selection, confounders, and the tendency to overestimate the treatment effects. Owing to the incompleteness of the baseline information, the aggregate data showed statistically significant differences between the DES and BMS groups for several baseline covariates. Adjusting methods for baseline imbalance with propensity score analysis is almost unfeasible owing to a lack of patient-level data.

Most studies had small sample sizes, and larger population studies would be more accurate in detecting a true benefit. The length of follow-up varied among the different studies, ranging from 6 to 48 months. Longer term follow-up might be needed to determine whether the benefits of DES use are sustained. However, studies with long-term follow-up such as the DELAYED RRISC trial might not provide an accurate description of benefit or harm of SVG intervention with DESs, because the patients might have a high incidence of subsequent clinical events unrelated to the stented SVG lesion. This could introduce "noise" in determining the true efficacy of DESs. Only the 2 randomized trials, RRISC and SOS, had included protocol-driven angiography at 6 and 12 months, respectively. Therefore, the rate of angiographic restenosis is unknown. However, clinically driven TVR, instead of protocol-driven angiographic follow-up, would provide a more accurate assessment of clinical restenosis. The duration of optimal dual antiplatelet therapy after SVG stenting could also not be determined from the studies included in the present analysis.

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