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Second-generation versus first-generation drug-eluting stents in saphenous vein graftdisease: A meta-analysis of randomized controlled trials

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ABSTRACT

Background: Second-generation drug-eluting stents (DESs) have become increasingly popular devices for patients with saphenous vein graft (SVG) disease. Second-generation DESs were designed to have more safety and efficacy than first-generation DES, but clinical outcomes in SVG disease remain conflicting.
Methods and results: Randomized controlled trials (RCTs) were identified when comparing second- versus first-generation DESs in SVG disease. The main endpoint was all-cause death. The time of follow-up was at least 30 days. The secondary endpoints were major adverse cardiovascular events (MACEs), target vessel revascularization (TVR), target lesion revascularization (TLR), myocardial infarction (MI), and stent thrombosis. These endpoints were assessed at 30 days, 12 months and 24 months. Four RCTs with 1077 SVG patients undergoing the implantation of DES were collected in the current meta-analysis. As a result, second-generation DES-treated patients had the significantly lower MACE rates at 12 months ($P = 0.03$; OR: 0.69, 95% CI: 0.49,0.97). No differences in two groups were seen in all-cause death, MI, TVR, stent thrombosis and TLR.
Conclusions: Our limited evidence indicated that, second-generation DES in SVG patients, compared with first-generation DES, offered similar levels of safety, but were more effective than the former one.
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1. Introduction

It have been estimated that about 6% to 15% of patients with percutaneous coronary intervention (PCI) is related to saphenous venous graft (SVG) diseases [1–3]. Effective drug-eluting stent (DES) implantation has the obvious improvement in outcomes of SVG diseases treated with PCI [4,5]. Meta-analyses and many relevant randomized trials comparing bare-metal stents to DES in SVG patients treated with PCI have supported and encouraged application of DES for SVG lesions [6–11].

At beginning, first-generation DES was widely used to handle the diseases. In fact, despite the use of them, SVG patients undergoing PCI still had higher risk rates of clinical outcomes such as myocardial infarction and stent thrombosis than those undergoing native coronary artery PCI [12]. Stent technology has rapidly evolved and second generation DESs have been applied to the percutaneous treatment of SVG patients. Solving safety problems in the long term and using less toxic antiproliferative drugs and new biocompatible polymer coatings were the design goals of second-generation DES, which were extensively examined in clinical works and randomized clinical trials. A prospective study reported that, SVG patients using second-generation everolimus-eluting stent (EES) were linked with high stent strut coverage rates and high rates of malapposition at one year after PCI implantation [13]. On the other hand, three studies regarding second generation DES showed conflicting findings: one displayed relatively better results (lower target vessel revascularization risk) and two demonstrated similar clinical outcomes [14–16].

Therefore, to investigate efficacy and safety of second versus first-generation DESs in SVG PCI, the present meta-analysis of all published randomized controlled trials was carried out to compare DES between two generations for the treatment of SVG disease.

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2. Methods

2.1. Literature search

We searched for all randomized clinical trials (RCTs) involving the comparison between second and first-generation DESs in SVG interventions in PubMed and EMBASE (up to January 2016). The following keywords for literature search were used: "randomized trial", "percutaneous coronary intervention or PCI", "drug-eluting stent" and "saphenous vein graft or SVG". Citations in the identified articles were examined to collect other potentially eligible studies. For each RCT, the most updated or most detailed one was included. Studies in the meta-analysis should be met with the following criteria: (i) RCTs regarding human subjects; (ii) Patients undergoing DES implantation of SVG lesions; (iii) Studies regarding the efficacy and/or safety of second and first-generation DESs; (v) Sufficient data; (vi) Subjects were followed up for at least 30 days.

2.2. Data extraction

Data were independently reviewed and extracted by two authors and all discrepancies were resolved by consensus or a third author. The following information from each study was included: first author, publication year, sample size, follow-up time, all-cause death, major adverse cardiovascular events (MACEs), target vessel revascularization (TVR), myocardial infarction (MI), stent thrombosis and target lesion revascularization (TLR).

2.3. Statistical analysis

All data were analyzed with ReviewManager 5.0.25 and Stata 10.0 (Stata Corporation, College Station, Texas, USA). Odds ratios (ORs) and 95% confidence intervals (CIs) were adopted to assess the clinical outcomes. In our paper, the random-effects model was used to calculate the pooled estimates [17]. A Z-test was applied to test the significance of the pooled ORs, and a $P < 0.05$ was considered as the significance threshold. The heterogeneity among studies was estimated by X^2-based Q test and considered significant if $P < 0.10$ [18]. The inconsistency index I^2 was also calculated to assess the total variation that is caused by heterogeneity rather than chance. Higher value of I^2 represented the existence of heterogeneity [19]. In our meta-analysis, all-cause death was measured as the primary outcome. The secondary outcomes were MI, TVR, MACE, stent thrombosis and TLR. All outcomes were evaluated at 30 days, 12 months and 24 months. Each clinical outcome had at least two studies. We performed sensitivity analyses by removing one study each time and identified whether one single study would change the pooled ORs. Publication bias was investigated with a funnel plot using the outcomes of death [20]. An asymmetric plot indicated the potential bias. Egger's test was performed to evaluate funnel-plot asymmetry [21].

3. Results

3.1. Identification and characteristic of studies

After a comprehensive review, 219 potentially papers were found in the initial analysis. 212 articles were excluded due to abstract, reviews and not SVG disease or comparison of two generation DES. Three studies were eliminated due to lack of the available data [22–24]. Finally, four trials with a total of 1077 patients (465 cases vs. 612 controls) met with our inclusion criteria and entered the current meta-analysis [14–16,25].

For these studies, they were from Italy [16], Switzerland [15] and USA [14,25], respectively. Sample size ranged from 211 to 331. All trails were followed up for at least 18 months. The average age was 68.3 ± 8.0 and 67.7 ± 9.5 years in second-and first-generation DESs, respectively. Male in these RCTs accounted for the majority of the patients and only 11.8% and 14.9% of them in two groups were female. Three studies used one second-generation DES (EES) and two first-generation DES (paclitaxel-eluting stent (PES) and sirolimus-eluting stent (SES)) [14,15,25]. The remaining one used two second-generation DES (zotarolimus-eluting stent (ZZS) and EES) [16]. The most common comorbid disorders were hypercholesterolemia (87.1% vs. 82.4%), hypertension (85.6% vs. 78.4%), diabetes mellitus (47.1% vs. 37.9%), and smokers (28.6% vs. 29.7%) in the two groups, respectively. The mean stent lengths for the two groups were 27.4 ± 16.3 and 27.1 ± 19.1 mm, respectively. Among all the four studies, one [15] only provided available data at 12 months and the rest ones [14,16,25] had enough information at 30 days, 12 months and 24 months. The detailed characteristics of all the trials were described in Table 1 and the data of clinical events was shown in Table 2.

3.2. The primary outcome

The results for all-cause death from the random-effects model were shown in Table 3. In this analysis, 787, 1048 and 515 patients were investigated at 30 days, 12 months, and 24 months, respectively. Accordingly, no significant difference between second and first-generation DESs was observed in the primary outcome (all-cause death) at 30 days ($P = 0.48$; OR: 0.58, 95% CI: 0.12,2.68), 12 months ($P = 0.81$; OR: 1.08, 95% CI: 0.59,1.95), and 24 months ($P = 0.81$; OR:

Table 1
Characteristics of the included RCT in the meta-analysis.

First author, y	Costopoulos C, 2013		Pokala NR, 2015		Kitabata H, 2013		Taniwaki M, 2014	
Stent type	Second	First	Second	First	Second	First	Second	First
Sample size, n	84	127	166	81	88	243	127	161
Age, y	69.4 ± 9.6	67.6 ± 8.3	66.1 ± 0.6	65.8 ± 0.9	70.1 ± 10.1	68.3 ± 11.2	69.2 ± 9.6	67.8 ± 9.9
Male, n	78	113	162	79	66	190	104	139
Stent name	EES/ZZS	PES/SES	EES	PES/SES	EES	PES/SES	EES	PES/SES
Follow up, m	18	18	36	36	24	24	48	48
Hypercholesterolemia, n	66	99	160	80	78	217	101	108
Hypertension, n	66	85	158	77	85	223	89	95
Diabetes mellitus, n	27	42	99	43	47	118	46	29
Smokers, n	43	58	36	26	11	27	43	71
LVEF(%)	48.6 ± 10.7	49.0 ± 9.1	13(<30%)	9(<30%)	45 ± 14	44 ± 14	3(<30%)	9(<30%)
Graft age, y	14.3 ± 6.0	11.6 ± 5.3	11.2 ± 0.5	10.8 ± 0.7	132.4 ± 90.8 (m)	128.1 ± 77.5 (m)	NR	NR
EPD use, n	72	79	156	57	22	109	NR	NR
Mean stent length, mm	30.5 ± 19.4	34.1 ± 25.1	26.3 ± 1.5	23.2 ± 2.0	19.1 ± 13.1	20.6 ± 6.8	32.4 ± 23	36.0 ± 25.2

Abbreviations: y, year; n, number; EPD, embolic protection device; LVEF, left ventricular ejection fraction; Second, second-generation drug-eluting stents (DESs); First, first-generation drug-eluting stents (DESs); EES, everolimus-eluting stent; ZZS, zotarolimus-eluting stent; SES, sirolimus-eluting stent; PES, paclitaxel-eluting stent; NR, not reported.

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