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Original article

Five-year outcomes after first- and second-generation drug-eluting stent implantation in all patients undergoing percutaneous coronary intervention

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A B S T R A C T

Background: Use of the everolimus-eluting stent (EES) instead of the sirolimus-eluting stent (SES) has been shown to improve clinical outcomes in patients undergoing percutaneous coronary intervention (PCI) out to 3 years. However, it is not known whether the differences in efficacy and safety outcomes remain constant throughout 5 years.

Methods: This was a retrospective, non-randomized, observational study. We followed 1460 consecutive patients undergoing PCI in our institutions from April 2005 to March 2012. There were 718 cases in patients with SES (SES group) and 742 with EES (EES group). Ten-month angiographic follow-up results and 5-year clinical follow-up outcomes were compared between the EES and SES groups. The primary outcome of this study was major adverse cardiac events (MACE), defined as the composite of cardiac death, recurrent myocardial infarction (MI), target vessel revascularization (TVR), and stent thrombosis (ST).

Results: At 5 years, the rates of target lesion revascularization (TLR), TVR, recurrent MI and ST were significantly lower in the EES group compared to the SES group (TLR: 4.6% vs. 8.2%, $p < 0.05$; TVR: 5.0% vs. 9.0%, $p < 0.05$; recurrent MI: 1.5% vs. 4.4%, $p < 0.05$; ST: 1.2% vs. 3.9%, $p < 0.05$). Thus, MACE were significantly lesser in the EES group compared to the SES group (8.8% vs. 12.8%, $p = 0.006$).

Conclusions: EES improved clinical outcomes compared to SES, and specifically, was associated with reductions in TVR, ST, and recurrent MI out to 5 years.

Introduction

First-generation drug-eluting stents (DES), namely the sirolimus-eluting CYPHER stent (Cordis, Miami Lakes, FL, USA) and the paclitaxel-eluting TAXUS stent (Boston Scientific, Natick, MA, USA), led to dramatic reductions of in-stent restenosis [1–3]. However, late and very late stent thrombosis induced by delayed vascular healing due to hypersensitivity reactions to the coating/polymer [4,5] have emerged as a significant risk, and have resulted in recommendations for prolonged dual anti-platelet therapy (DAPT) [6,7]. These limitations led to the development of second-generation DES with superior designs incorporating biocompatible polymers, thinner struts, and new stent alloys [8–10]. These characteristics have led to the reduction of restenosis in coronary artery disease patients with complex lesions [11–13].

Recent meta-analyses have demonstrated the lower risk of stent thrombosis [14–16], target vessel revascularization (TVR) [14,15], and myocardial infarction (MI) [14] associated with everolimus-eluting stents (EES) compared with other DES. Event-free survival rates improved after EES implantation compared with paclitaxel-eluting stent (PES) implantation at 5 years [17], and improvement in clinical outcomes after EES implantation compared with SES implantation was demonstrated by the significantly lower cumulative incidence of target-lesion failure, but not late and very-late stent thrombosis (ST) throughout 3 years [18]. However, it was uncertain whether EES implantation could beneficially affect late adverse events beyond 3 years after SES implantation. Thus, we compared 5-year clinical outcomes between EES and SES implantations.

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Fig. 1. Enrollment period of the sirolimus-eluting stent and everolimus-eluting stent.

Methods

This study was conducted in two centers (Nasu Red Cross Hospital and Dokkyo Medical University Hospital). From June 2006 to January 2013, we recruited 1460 adult patients with chronic stable coronary artery disease or acute coronary syndrome including myocardial infarction with or without ST-segment-elevation. Enrollment period is shown in Fig. 1.

Procedures were performed following current clinical practice. After diagnostic angiography, oral aspirin (100 mg), and clopidogrel (75 mg) were administered in cases of elective PCI. In cases of emergent PCI, aspirin (loading dose 200 mg) and clopidogrel (loading dose of 300 mg) were administered just before PCI. During PCI, patients received unfractionated heparin that was used to maintain an activated clotting time of 250 s or longer. DAPT was continued for 1 year after DES implantation.

Operators decided which stent to use and performed stent implantation according to the standard techniques. In patients undergoing PCI with DES for multi-vessel disease, barring the presence of special clinical situations, operators selected the same brand of DES. Angiographic success was defined as less than 25% residual diameter stenosis after PCI. Follow-up included clinical visits at every 30 days continued to 5 years, and angiographic follow-up was conducted 10 months after PCI.

This study was approved by the Ethics Committees of Nasu Red Cross Hospital and Dokkyo Medical University Hospital, and informed consent for PCI was obtained from all participants.

Evaluation items

The primary outcome of this the study was major adverse cardiac events (MACE) defined as the composite of cardiac death, recurrent MI, TLR, TVR, and ST.

Follow-up angiographic results of the target lesions were also evaluated. ST was diagnosed according to the Academic Research Consortium definition using the definite or confirmed and probable categories [19]. TLR was defined as undergoing PCI or bypass surgery to treat restenosis of the target lesions that were associated with recurrent angina and/or evidence of myocardial ischemia. Quantitative coronary angiography (QCA) of target lesions was performed by a single operator who was blinded to the type of stent implanted. Reference diameter (RD), lesion length (LL), minimum lumen diameter (MLD), and percent diameter stenosis (%DS) were calculated by a QCA analyzer (QCA-CMS; Medis Medical Imaging Systems, Leiden, the Netherlands) pre-PCI, post-PCI, and at follow-up angiography.

Finally, we performed univariate and multivariate analyses to determine predictive risks for primary endpoint (MACE).

Statistical analysis

All calculated data are expressed as the mean ± SD. One-way analysis of variance, which was subsequently subjected to Scheffe's test for multiple comparisons, was used to determine the statistical significance of differences. The chi-square test was used for analyzing categorical variables with percentages. Multiple regression analysis was used to evaluate the association between clinical, procedural characteristics, and primary outcome. Statistical analysis was conducted with a commercially available statistical software (Statview Version 5.0; Abacus Concepts, Berkeley, CA, USA). Statistical significance was accepted at $p < 0.05$.

Results

One-thousand and three hundred seventy-four patients were enrolled to receive either EES (656 patients, 714 lesions) or SES (718 patients, 766 lesions). Baseline patient and angiographic characteristics of both groups are shown in Tables 1 and 2. The prevalence of diabetes and chronic kidney disease was higher in the EES group than in the SES group (p = 0.012, 0.002, respectively, Table 1). The lesions of restenosis, chronic total occlusion (CTO), diffuse long, bifurcation, presence of thrombus, STEMI, and left main trunk (LMT) were significantly greater in the EES group than in the SES group (p = 0.006, 0.028, 0.007, 0.030, <0.001, <0.001, <0.001, respectively, Table 2). Medication, procedural, and lesion characteristics were comparable between both groups (Tables 1, 3 and 4). However, lesion and stented lengths were longer in the

Table 1
Baseline patient characteristics.

	EES (N = 656)	SES (N = 718)	p-Value
Age, years	65.4 ± 7.0	66.8 ± 6.0	0.293
Male	397 (60.5%)	408 (56.8%)	0.354
Body mass index (kg/m^2)	24.0 ± 5.2	24.4 ± 6.2	0.832
Hypertension (%)	521 (79.4%)	552 (76.9%)	0.643
Hyperlipidemia (%)	393 (59.9%)	432 (60.2%)	0.788
Diabetes mellitus (%)	242 (36.9%)	216 (30.7%)	0.012
Estimated glomerular filtration rate <60 (%)	246 (37.5%)	211 (29.4%)	0.002
Current smoker (%)	250 (38.1%)	290 (40.4%)	0.389
The medications just before PCI			
ACEI/ARB (n)	446 (68.0%)	456 (63.5%)	0.169
Calcium channel blockers (n)	227 (34.6%)	265 (36.9%)	0.305
Beta blockers (n)	131 (20.0%)	165 (23.0%)	0.186
Statins (n)	282 (43.0%)	317 (44.2%)	0.449
Nicorandil (n)	70 (10.7%)	90 (12.5%)	0.306
DAPT (n)	656 (100%)	718 (100%)	1.000

Data are expressed as numbers (%) or mean ± SD.
EES, everolimus-eluting stent; SES, sirolimus-eluting stent; AP, angina pectoris; OMI, old myocardial infarction; ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; DAPT, dual antiplatelet therapy.

Table 2
Lesion characteristics.

	EES (*N* = 714)	SES (*N* = 766)	*p*-Value
Target lesion			
LMT	55 (7.7%)	7 (0.9%)	<0.001
LAD	287 (40.2%)	343 (44.8%)	0.220
LCX	115 (16.1%)	117 (15.2%)	0.485
RCA	257 (36.0%)	299 (39.0%)	0.172
ACC/AHA lesion types (*n*)			
A/B1	321 (45.0%)	428 (55.9%)	<0.001
B2/C	393 (55.0%)	338 (44.1%)	<0.001
Restenosis lesion	50 (7.4%)	19 (2.4%)	0.006
Ostial lesion	64 (8.9%)	47 (6.1%)	0.125
CTO lesion	59 (8.3%)	26 (3.4%)	0.028
LL >30 mm	93 (13.1%)	24 (3.1%)	0.007
Bifurcation lesion	162 (22.7%)	127 (16.5%)	0.030
Presence of thrombus	78 (10.9%)	7 (0.9%)	<0.001
STEMI	82 (11.5%)	10 (1.3%)	<0.001
LMT	57 (8.0%)	7 (0.9%)	<0.001

Data are expressed as numbers (%) or mean ± SD.
LMT, left main trunk; RCA, right coronary artery; LAD, left anterior descending artery; LCx, left circumflex artery; ACC/AHA, American College of Cardiology/ American Heart Association; CTO, chronic total occlusion; LL, lesion length; STEMI, ST elevation myocardial infarction.

Table 4
Quantitative coronary angiographic analysis before and after procedure.

	EES (*N* = 714)	SES (*N* = 766)	*p*-Value
Pre-procedure			
RVD (mm)	2.72 ± 0.28	2.70 ± 0.37	0.301
DS (%)	80.26 ± 7.88	76.38 ± 8.25	0.105
MLD (mm)	0.33 ± 0.11	0.37 ± 0.13	0.124
LL (mm)	21.56 ± 9.51	19.12 ± 8.54	0.013
Post procedure			
DS (%)	12.78 ± 7.64	14.07 ± 6.23	0.289
MLD (mm)	2.63 ± 0.23	2.61 ± 0.23	0.587

RVD, reference vessel diameter; DS, diameter stenosis; MLD, minimal lumen diameter; LL, lesion length.

EES group than in the SES group (21.56 ± 9.51 vs. 19.12 ± 8.54, $p = 0.013$, Table 4, 23.54 ± 7.76 vs. 20.03 ± 8.11 mm, $p = 0.008$, Table 3).

Angiographic restenosis 10 months after PCI and clinical outcomes at 5 years are shown in Table 5. The binary angiographic restenosis was lesser in the EES group than in SES group (7.3% vs. 11.3%; $p < 0.005$). The incidence of MACE was significantly lower in the EES group than in the SES group ($p = 0.006$). Rates of TLR and TVR were significantly lower in the EES group than in the SES group (4.6% vs. 8.2%; $p = 0.007$, and 5.0% vs. 9.0%; $p = 0.003$, respectively). Kaplan–Meier curves for cumulative TLR according to stent type for 5 years are shown in Fig. 2a. There was no difference in TLR rate between the 2 groups until 2 years. After 2 years, TLR was significantly lower in the EES group than in the SES group. The rate of definite or probable ST was significantly less in the EES group than in the SES group (1.2% vs. 3.9%, $p = 0.012$).

Cumulative incidences of definite or probable ST for 5 years in the EES and SES groups are shown in Fig. 2b. Early ST (from 0 to 30 days after PCI) was observed in 3 patients and 10 patients in the EES and SES groups, respectively. Late and very late ST (from 30 days to 5 years after PCI) was observed in 6 patients and 20 patients in the EES and SES groups, respectively. Thus, ST in the SES group was almost three times more frequent than in the EES group not only in the early period, but also in the late and very late periods.

Hemodialysis and the type of stent (SES implantation) were independent risk factors for the primary outcome after adjusting covariates, as shown in Table 6.

Discussion

This study assessed the impact of the EES implantations in an all-comers population through 5-year follow-up and revealed the safety and efficacy of EES implantations in routine clinical practice with a reduction in the TLR, TVR, and ST compared with SES implantations. The cumulative incidence of ST was consistently lower over 5 years in the EES implantations compared with SES implantations. In contrast, the rate of TLR was no different out to 2 years and was only significantly different between the EES and SES groups from 2 to 5 years after PCI.

Previously, the randomized evaluation of sirolimus-eluting versus everolimus-eluting stent (RESET) trial reported that the efficacy and safety outcomes after EES implantation remained comparable with those after SES implantation through 3-year follow-up, but there were significantly lower cumulative incidences of target lesion or vessel failure in the EES than in the SES implantations [18]. Interestingly, in our present study, the TLR rate was significantly lower in the EES implantations than in the SES implantations from 2 to 5 years but not for the first 2 years after PCI. In comparison, the cumulative incidences of TLR between 1 and 3 years by the 1-year landmark analysis showed no significant differences between the SES and EES implantations in the RESET trial. Furthermore, in our study, ST continuously occurred out to 5 years in the SES group, but no ST was observed in the EES group after 3.5 years.

Inconsistent results regarding ST in our study and the RESET trial may be explained by the low event rates of ST which makes it susceptible to be influenced by chance. In addition, RESET study indicated that the high rate of DAPT administration >1 year and that was maintained in almost two third of patients at 3 years might be related to the low very late ST rate in the SES group. Another explanation might be several differences in the patient and lesion characteristics between the RESET trial and our present study (current smoker: 21% vs. 39%, beta-blocker use: 37% vs. 22%, statin use: 77% vs. 44%, stent length: 26 mm vs. 22 mm, stent diameter: 2.97 mm vs. 2.79 mm, post-MLD: 2.46 mm vs. 2.62, post DS%: 10.6% vs. 13.5%, respectively). These different complexities of

Table 3
Procedural characteristics.

	EES (*N* = 714)	SES (*N* = 766)	*p*-Value
Direct stent (%)	249 (34.8%)	230 (30.0%)	0.207
IVUS utilization rate (%)	699 (97.9%)	727(94.9%)	0.554
Average number of stents per lesion	1.13 ± 0.33	1.15 ± 0.31	0.477
Average stent diameter (mm)	2.80 ± 0.33	2.77 ± 0.29	0.608
Average stent length per lesion (mm)	23.54 ± 7.76	20.03 ± 8.11	0.008
Maximum balloon pressure (atm)	15.7 ± 2.4	15.2 ± 3.1	0.622
Initial success rate (%)	99.6%	99.2%	0.963

Table 5
Incidence of angiographic restenosis 10 months after PCI and MACE for 5-year follow-up.

	EES 656 patients 714 lesions	SES 718 patients 766 lesions	*p*-Value
Angiographic restenosis	52 (7.3%)	90 (11.7%)	0.005
MACE	58 (8.8%)	92 (12.8%)	0.006
TLR	33 (4.6%)	63 (8.2%)	0.007
TVR	36 (5.0%)	69 (9.0%)	0.003
ST	9 (1.2%)	30 (3.9%)	0.012
MI	10 (1.4%)	32 (4.2%)	0.009
Cardiac death	22 (3.0%)	28 (3.6%)	0.582

Data are expressed as numbers (%).
Angiographic restenosis was defined as % diameter stenosis >50 by the QCA analysis in the coronary angiography 10 months after PCI.
MACE, major adverse cardiac event; TLR, target lesion revascularization; TVR, target vessel revascularization; ST, stent thrombosis; MI, myocardial infarction.

patients and lesions, and also the different follow-up period (3 years vs. 5 years) might explain the different outcomes (TLR: 7.3% vs. 6.4%, TVR: 10.4% vs. 7.0%, cardiac death: 2.7% vs. 3.3%, MI: 4.3% vs. 3.3%, definite or probable ST: 0.75% vs. 2.6%, respectively). However, it was undeniable that the difference in the drug therapy after PCI (drug type, drug ability, medication adaptation) between SES and EES implanted generations which had time lag affected our results.

In recent practical medicine, treatment using DES has become mainstream in patients with flow-limiting coronary stenosis [20,21]. First-generation DES revealed a substantial reduction in restenosis and subsequent repeat revascularization compared with bare metal stents [2,22]. However, they did not have significant benefits in long-term mortality [18], as higher incidences of late and/or very late ST were observed [23–28]. Second-generation DES, with novel stent design/material, improved polymer biocompatibility, and novel antiproliferative drugs were developed to improve acute performance and long-term outcomes [29,30].

Kolandaivelu et al. [31] reported that the drug/polymer-coated stent (XIENCE V, Abbott Vascular, Santa Clara, CA, USA) was consistently less thrombogenic than its corresponding bare-metal stent platform (Multilink Vision, Abbott Vascular, Santa Clara, CA, USA) in an ex-vivo model, and concluded that drug/polymer coatings do not inherently increase acute stent clotting—they may actually provide thromboresistance. Clinically, the EXAMINATION trial demonstrated significantly lower rates of stent thrombosis with EES (XIENCE V) than with bare-metal stent (Multilink Vision, Abbott Vascular, Santa Clara, CA, USA) which shared the same stent platform [32]. Furthermore, a comprehensive meta-analysis has also shown that EES is associated with the lowest rate of definite ST among other DES as well as bare-metal stents [33]. In addition, EES has shown significantly faster re-endothelialization at 14 days after stent implantation in a rabbit iliac artery model compared with SES [29].

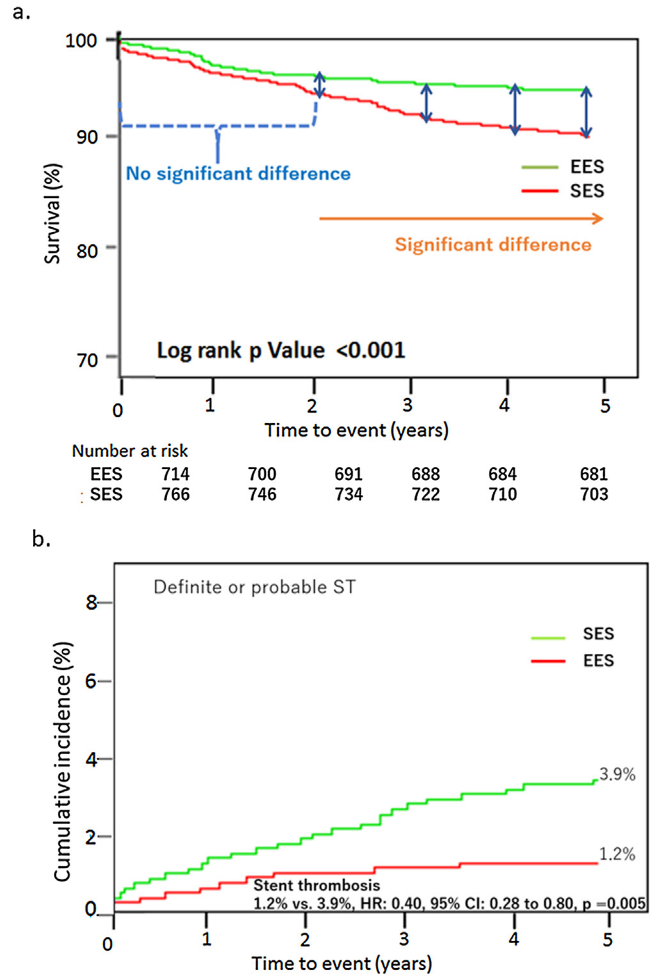

Fig. 2. (a) Kaplan–Meier curve for cumulative target lesion revascularization for SES and EES. (b) Cumulative incidences of definite or probable stent thrombosis through 5 years by the stent type. SES, sirolimus-eluting stent; EES, everolimus-eluting stent; ST, stent thrombosis.

In this study, the EES group included more complex lesions such as diffuse long lesions, chronic total occlusion, bifurcated lesions, and STEMI lesions, and had a higher prevalence rate of diabetes mellitus and chronic kidney disease than the SES group. It has been reported that EES is more appropriate for the treatment of diffuse long lesions [34], chronic totally occluded lesions using long stents [35], bifurcated lesions [36], STEMI lesions [37] in patients with diabetes mellitus [38], and/or chronic kidney disease [39] compared with non-EES DES.

ST rates at 1 year in EES patients have been reported ranging from 0.3 to 0.7 [40,41]. The Bern–Rotterdam cohort study was a

Table 6
Predictive risk of primary endpoint after drug-eluting stent implantations by univariate and multivariate analyses.

Variable	Univariate		Multivariate	
	HR (95% CI)	*p*-Value	HR (95% CI)	*p*-Value
EES vs. SES	4.08 (1.68–7.77)	0.010	2.46 (1.23–5.77)	0.015
Diabetes mellitus	1.08 (0.60–2.12)	0.506		
Chronic renal insufficiency	3.60 (1.10–5.77)	0.093		
Hemodialysis	5.20 (2.80–11.67)	0.007	3.60 (1.81–6.58)	0.009
Diffuse long lesion ≥30 mm	1.63 (0.60–2.70)	0.084		
Severe calcified lesion	3.53 (1.23–9.02)	0.023	1.88 (0.70–3.66)	0.108
STEMI case	1.13 (0.79–1.38)	0.384		
Type C lesion	1.55 (0.77–2.88)	0.456		
CTO case	1.08 (0.49–2.50)	0.204		

large European registry of 12,339 unselected patients designed to evaluate the long-term safety of unrestricted use of EES by comparing the ST rates among patients with EES versus sirolimus- or paclitaxel-eluting stents [42]. The primary endpoint of definite ST at 4 years was significantly lower in the EES implantations (1.4%) than in the SES (2.9%) or PES (4.4%) implantations without improvement in mortality. The present study demonstrated similar low ST rates (1.4%/5-year) in patients with XIENCE stent who were recommended for 1 year with DAPT. Another noteworthy point, multivariate analysis demonstrated an independent association between the type of stent and MACE, but not cardiac death. A recent meta-analysis of 13 randomized trials with >17,000 patients demonstrated that ST was reduced by half by using EES compared with other DES (0.7% vs. 1.5%). Moreover, this benefit was not affected by the duration of the DAPT [14].

Reduction of the composite end points may include factors not only related to stent performance itself, whereas the reduction of ST with EES may be highly dependent on the sophisticated design with thinner stent struts, an open cell design, and the unique fluoropolymer of the XIENCE stent, which has been shown to have high resistance to platelet and thrombus deposition [43].

In Japan, although the duration of DAPT after DES implantation become controversial, the questionnaire showed that it tended to become shorter with the use of the second-generation DES [44].

Study limitations

There are several potential limitations to our data. First, only two centers participated, and patients were non-randomly and retrospectively selected, so selection bias may have influenced our results. Second, the sample size in this study was still too small to evaluate low-frequency events, such as ST, which may have induced type II error. Although our data are consistent with other reports on the use of EES, only larger trials will provide a definitive conclusion. Third, as the understanding of EES performance in clinical practice has increased, the temporal difference in the use of EES and SES during the several years of enrolment may have affected our results. In terms of differences in procedural characteristics, the stent length in lesions treated by EES was relatively longer compared to SES.

Conclusion

The 5-year follow-up of this study confirms the safety and efficacy of EES implantations compared with SES implantations. The rate of ST including late and very late ST was substantially reduced in recipients of EES compared to SES. Thus, EES offers a safe and effective treatment throughout 5 years in patients with coronary artery stenosis.

Conflicts of interest

The authors indicate no potential conflicts of interest.

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