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ORIGINAL ARTICLE

Long-term angiographic outcomes of sirolimus- and paclitaxel-eluting stent placement in diabetes, long lesions, and small vessels

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Abstract We conducted a lesion-based retrospective sub-analyses of diabetes mellitus (DM), diffuse long lesions (stented segment ≥40 mm; LLs), and small vessels (SVs; reference diameter ≤2.6 mm) in patients who received sirolimus- (SESs) or paclitaxel-eluting stents (PESs) for nonrandom treatment of de novo native coronary stenosis in a clinical practice setting. During the period from May 2007 to February 2009, 490 of 682 PES-treated and 293 of 386 SES-treated lesions were angiographically followed up within 1500 days of PCI, and the retrospective investigation was conducted in April 2013. The frequencies of target lesion revascularization (TLR; any recurrent PCI including both marginal stent restenosis) and binary in-stent restenosis (percentage diameter of in-stent stenosis >50 %) upon follow-up angiography, evaluated by adjusting 25 baseline variables using propensity score matching analysis, after placement of SESs and PESs were the following: DM ($n = 124$ per arm), 14.5 vs. 15.3 % ($p = 0.842$), and 14.5 vs. 16.1 % (0.856); LLs ($n = 81$), 16.0 vs. 21.0 % (0.433), and 12.3 vs. 22.2 % (0.117); SVs ($n = 107$), 11.2 vs. 29.9 % (<0.001), and 11.2 vs. 30.8 % (<0.001), respectively. The p values of log-rank tests for the cumulative TLR-free ratios after SES and PES placement were 0.504 in DM, 0.625 in LLs, and <0.001 in SVs group, respectively. Thus, compared to PES, SES showed the equivalent efficacy for DM, the tendency to be superior for LLs due to approximately 24–45 % reductions in TLR and binary restenosis rates, and the promising superiority for SVs on the angiographic outcomes during a long-term observational interval.

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Introduction

More than a decade has passed since the approval of the Cypher Bx Velocity sirolimus-eluting stent (SES; Cordis, Miami, FL, USA) for use in Japan. Although SES dramatically reduced the frequencies of target lesion revascularization (TLR) and binary in-stent restenosis (binary restenosis) compared to those of bare-metal stent (BMS) [1–3], a careful observation after SES placement needed to be continued over a long interval owing to the late adverse angiographic outcomes [1, 2]. The risk factors for late (≥1 year) TLR of SES were generally common to those for early (within the first year) TLR [4].

TAXUS Express paclitaxel-eluting stent (PES; Boston Scientific, Natick, MA, USA), the other major first-generation drug-eluting stents (DES), was also widely used in Japan. However, there were only a few reports comparing the mid- to long-term outcomes after SES and PES placements in Japan [5–7]. Therefore, the superiority of SES to PES with regard to the long-term angiographic outcomes including the frequencies of TLR and binary restenosis in a clinical setting should be further evaluated, particularly concerning about the known risk factors of late TLR of SES [4].

Therefore, we conducted 3 sub-analyses of a long-term angiographic follow-up data from the previous report [5], to determine which stent type produced better angiographic outcomes during a long-term observational interval in patients with (1) diabetes mellitus (DM), (2) diffuse long lesions (LLs; stented segment more than 40 mm long), and

(3) stenosis in small vessels (SVs; reference diameter ≤2.60 mm). Although debates about the superiority of PES to SES for DM had heated, there was none of the reports examining the long-term efficacy after PESs and SESs placement in Japanese patients with DM. In addition, LLs and SVs were highlighted, because those were the predictors of late adverse angiographic outcomes after SES placement [4]. It has been unclear whether the short-term angiographic outcomes after SESs placement were superior to those of PESs in LLs (stented segment lesions ≥40 mm long) [8–10]. Thus, the long-term angiographic outcomes after SESs and PESs placement should be examined in LLs. On the other hand, in SVs, the superiority of the short-term angiographic outcomes after SESs placement compared to PESs was consistent [11–14], needed to examine the SES's long-term superiority compared to PES. For these purposes, the frequencies with which TLR and binary restenosis in relation to the mean magnitude of late luminal loss observed on angiographic follow-up within 1500 days of stent placement were compared between SESs and PESs after baseline adjustment using propensity score matching analysis [15].

Methods

Study design and population

The present study was a sub-analysis of data from coronary stenosis patients who had DM, LLs, or SV stenosis who took part in our recent nonrandomized, lesion-based retrospective study [5] performed at Saitama Cardiovascular and Respiratory Center. The rationale was approved by the local ethics committee. The retrospective examination was performed in April 2013. As reported previously, patients were deemed eligible for inclusion if they had de novo stenosis in native coronary arteries successfully treated electively and exclusively with a Cypher Bx Velocity SES or TAXUS Express PES and had no history of coronary artery bypass grafting (CABG) or intra-aortic balloon pump therapy. Percutaneous coronary intervention (PCI) was considered successful when no periprocedural complications (e.g., death, Q-wave myocardial infarction, emergency CABG) occurred; further, patients were enrolled only if postprocedural antegrade coronary flow was grade 3 on the Thrombolysis in Myocardial Infarction (TIMI) scale and stent expansion considered acceptable on angiographic and intravascular ultrasound (IVUS) assessment. The composite exclusion criteria were bailout stenting, hybrid stenting, preprocedural reference diameter (RD) more than 5.0 mm, and postprocedural percentage diameter of stenosis (%DS) more than 33 % (see "Quantitative coronary angiography" below). The study was carried out from May 2007 (when the Express PES was approved in Japan) to February 2009 (before the second-generation Taxus Liberté PES was approved in Japan) and recorded data for 1134 lesions in 798 patients, all successfully treated: 682 with a PES, 386 with an SES, and 66 with a bare-metal stent [5]. Thus, a DES (PES or SES) was used in 94.2 % of lesions, and 63.9 % of the lesions treated with a DES were treated with a PES [2]. The angiographic outcome was determined by follow-up coronary angiography (CAG), which was planned for approximately a year after the procedure; this study includes data from all follow-up CAG examinations performed within 1500 days of the index procedure (SES: 293 lesions; PES: 490 lesions). Within this 1500-day period, severe clinical events such as cardiac death, nonfatal recurrent myocardial infarction, and definite stent thrombosis were observed in 12 patients (1.8 %) with 18 lesions (1.7 %) treated with an SES or PES, with a mean interval of 1397 ± 309 days between clinical observations. Since the frequency of severe clinical cardiac events in the cohort was very low, and most of the patients underwent their elective PCI without complications and were hemodynamically stable afterward, the present study focuses on the corresponding 1500-day angiographic outcomes at follow-up.

DM was defined as (1) previous clinical diagnosis with or current therapy for DM, (2) serum fasting plasma glucose level (FGP) ≥126 mg/dL, or (3) serum hemoglobin A1c level ≥6.5 % according to the report of the committee of Japan Diabetes Society (JDS) on the classification and diagnostic criteria of DM. Among patients with DM who underwent follow-up CAG within 1500 days of the index procedure, 41 % (with 135 lesions) received an SES (SES DM group) and 43 % (with 202 lesions) a PES (PES DM group).

Length of the stented segment was calculated by adding the lengths of each stent, regardless of any overlap; 84 SES-treated lesions and 147 PES-treated lesions in our analysis were LLs (SES LL and PES LL groups, respectively). SVs were defined by a preprocedural RD of less than 2.60 mm. In lesions with full occlusion, percentage diameter of stenosis (%DS) was defined as 100 % and minimal lumen diameter (MLD) as 0. For such lesions, postprocedural RD was substituted for preprocedural RD in the analysis (details of the analysis are described below). Among the SV lesions analyzed in this study, 116 were treated with an SES (SES SV group) and 185 with a PES (PES SV group).

Stenting and antiplatelet therapy

All patients were informed of the rationale for PCI and stenting, and consent to treatment was obtained. Whether

to use a device such as a rotablator to ensure successful stenting of the lesion was subject to the doctor's discretion. Stents were implanted, largely under IVUS guidance, to cover the entire baseline lesion as determined by visual angiography. When further stent dilation was needed, high-pressure balloon inflation was generally performed, using a noncompliant balloon.

Periprocedural antiplatelet therapy was conducted as previously reported [5]. Aspirin (81–100 mg) and ticlopidine (200 mg) were administered orally beginning approximately 10 days before the index procedure; aspirin was continued as long as possible. After the procedure, ticlopidine (200 mg/day) was prescribed for a minimum of 12 months; these prescriptions were not prospectively randomized.

Quantitative coronary angiography

Quantitative coronary angiographic (QCA) parameters were measured with a TCS cardiovascular imaging system (CAAS-2 or -5, Pie Medical, Maastricht, The Netherlands) as described previously [5] at 3 time points: before PCI (preprocedural), immediately after successful PCI (postprocedural), and long-term (follow-up). The in-stent MLD, %DS, and RD were measured, and the acute luminal gain (postprocedural MLD minus preprocedural MLD) and late luminal loss (postprocedural MLD minus follow-up MLD) were calculated.

Binary in-stent restenosis (ISR) was defined as %DS >50 % on follow-up CAG. Since the mean length of stent in our institute became long under the guidance of IVUS, binary restenosis of the present study was defined as binary in-stent restenosis, but not binary in-segment restenosis. Mehran et al. [16] divided ISR cases into focal (lesion length ≤10 mm at long-term follow-up; type 1) and diffuse (lesion length >10 mm; types 2–4). The prevalence of ISR types 2–4 among lesions with binary restenosis was compared between the SES and PES groups. The frequency with which target lesion revascularization (TLR) was performed after follow-up CAG because of in-stent stenosis (including definite stent thrombosis [17]) or edge restenosis was compared between the SES and PES groups. Thus, if several edge restenosis implicated in TLR, the frequency of TLR might exceed that of binary restenosis. The decision to perform TLR was made if binary restenosis on QCA or edge restenosis was observed and one of the following applied: (1) recurrent angina presumably related to the target vessel; (2) objective signs of ischemia at rest (e.g., electrocardiogram changes) or during exercise test (or equivalent) presumably related to the target vessel; (3) abnormal results on any invasive functional diagnostic test (e.g., fractional flow reserve); (4) %DS greater than 70 %. If criterion (4) was present, TLR was performed even in the absence of other signs and symptoms of ischemia.

Outcome measure

The outcome measure of primary efficacy was the percentage of TLR within 1500 days of PCI as described above. In addition, the presence or absence of binary restenosis (defined above) on follow-up CAG within 1500 days of PCI was also estimated as we have previously described [5].

Statistical analyses

Variables measured at baseline were expressed as mean ± standard deviation (SD). Baseline variables and outcomes in the SES group were compared with those in the PES group using the unpaired t test for continuous values and χ^2 or Fisher's test for categorical values. Because the study was retrospective and nonrandomized, propensity score matching was performed in both groups to adjust the baseline values for covariates [15]. Maximum pressure was excluded from adjustment because the rated burst pressure of the stents usually used in our institute differed between SESs (20 atm) and PESs (16 atm). After these adjustments, baseline variables and outcomes in the SES group were compared with those in the PES group using the signed-rank test for continuous values and McNemar's χ^2 test for categorical values. Cumulative TLR-free ratios after SES and PES placement were analyzed by constructing Kaplan–Meier curves and compared using the log-rank test in each sub-analysis. A p value of less than 0.05 was considered to represent statistical significance. The Stata for Windows software program (version 1; StataCorp, College Station, TX, USA) was used for the statistical analyses.

Results

Baseline characteristics and angiographic outcomes in DM groups

Table 1 shows the baseline characteristics and angiographic outcomes of the lesions followed up angiographically in the SES DM ($n = 135$) and PES DM ($n = 202$) groups. The percentage of male patients, the percentage of lesions located in the right coronary artery (RCA), and the mean pressure differed significantly between the SES DM and PES DM groups (71.1 vs. 81.7 %, $p = 0.032$; 20.7 vs. 32.7 %, $p = 0.017$; and 19.1 ± 3.0 atm vs. 18.0 ± 3.1 atm, $p = 0.001$, respectively). The

Table 1 Thirty baseline variables related to the patients, lesions, procedure, and QCA parameters, and the angiographic outcomes are shown

	SES DM $n = 135$	PES DM $n = 202$	p values
Age (yr)	66.9 ± 8.6	66.1 ± 9.4	0.420
Male sex (%)	71.1	81.7	0.023
Insulin use (%)	11.9	9.9	0.570
Hemodialysis (%)	2.2	1.5	0.616
Previous MI (%)	55.6	50.5	0.362
Low EF (%)	4.4	2.0	0.191
LAD (%)	44.4	37.1	0.179
LCx (%)	31.1	28.7	0.637
LMT (%)	10.4	5.9	0.157
RCA (%)	20.7	32.7	0.017
Calcification (%)	9.6	11.9	0.517
LCx ostium (%)	5.9	4.5	0.546
RCA ostium (%)	1.5	2.0	0.734
CTO (%)	9.6	9.4	0.945
Number of stents	1.42 ± 0.72	1.36 ± 0.68	0.443
Diameter of stent (mm)	3.19 ± 0.47	3.07 ± 0.42	0.166
Length of stent (mm)	35.4 ± 21.8	32.7 ± 19.3	0.244
Pressure (atm)	19.1 ± 3.0	18.0 ± 3.1	0.001
Rotablator (%)	6.7	6.9	0.925
IVUS (%)	97.8	94.6	0.146
Main branch of 2-stent bifurcation (%)	9.6	7.9	0.584
Side branch of 2-stent bifurcation (%)	13.3	8.4	0.147
Preprocedural MLD (mm)	0.97 ± 0.58	0.97 ± 0.55	1.000
Preprocedural %DS	64.8 ± 19.4	64.0 ± 18.5	0.706
Preprocedural RD (mm)	2.76 ± 0.68	2.75 ± 0.56	0.887
Postprocedural MLD (mm)	2.53 ± 0.49	2.56 ± 0.48	0.579
Postprocedural %DS	12.6 ± 10.2	11.5 ± 8.7	0.304
Postprocedural RD (mm)	2.93 ± 0.61	2.91 ± 0.58	0.764
Acute luminal gain (mm)	1.57 ± 0.53	1.59 ± 0.66	0.759
Interval to follow-up CAG (days)	444 ± 254	458 ± 309	0.650
Follow-up MLD (mm)	2.18 ± 0.87	2.04 ± 0.73	0.123
Late luminal loss (mm)	0.35 ± 0.73	0.52 ± 0.70	0.033
Follow-up %DS	28.2 ± 22.4	28.5 ± 19.9	0.900
ISR types 2–4/binary restenosis (%)	35.0	50.0	0.295
Binary restenosis (%)	14.8	14.9	0.993
Target lesion revascularization (%)	14.8	13.4	0.707

The definitions of the variables defined are described as follows: age (age at the time of the procedure), male sex, diabetes (number of patients with diabetes mellitus), insulin use (number of patients who used insulin), hemodialysis, previous MI (prevalence of previous myocardial infarction), low EF (low ejection fraction of the left ventricle $\leq$40 as demonstrated by ultrasonography or left ventriculography), location of the targeted lesion located in the left anterior descending (LAD) artery, left circumflex artery (LCx), left main trunk (LMT), or right coronary artery (RCA), calcifications (visibly calcified lesions, estimated with an angiography and intravenous ultrasonography [IVUS]), LCx ostium (ostial lesion of the LCx), RCA ostium (ostial lesion of the RCA), bifurcation (bifurcated lesions requiring any treatment of the side branch), and CTO (chronic total occlusion for more than 3 months). These five variables were defined according to the American College of Cardiology/American Heart Association lesion classifications, as well as the number of stents (number of stents implanted stents per lesion), stent diameter (maximum diameter of the balloon used to dilate the stent), stent length (length of stented segment, calculated by adding the lengths of the each stents, regardless of any overlap), pressure (maximum pressure at the maximum balloon inflation diameter), direct stenting (stent placement without pre-dilation), rotablator (performing rotablator atherectomy prior to stenting), IVUS (IVUS available during percutaneous coronary intervention [PCI]), main branch and side branch of bifurcation 2-stent technique (main or side branches on which any bifurcation 2-stent technique was performed during the procedure), clinical observation interval [length of time after stenting (days)]. The definitions of QCA parameters and clinical endpoint-related variables were defined in the text and references [5]

mean late luminal loss was significantly less in the SES DM group (0.35 ± 0.73 mm) than in the PES DM group (0.52 ± 0.70 mm) ($p = 0.033$). The frequencies of binary restenosis and TLR did not differ significantly between the SES DM and PES DM groups.

Adjusted baseline characteristics and angiographic outcomes in DM groups

Table 2 shows the adjusted baseline characteristics of the patients in the SES DM and PES DM groups ($n = 124$ in each arm). The mean late luminal loss remained significantly less in the SES DM group than in the PES DM group (0.34 ± 0.67 mm vs. 0.54 ± 0.72 mm, $p = 0.020$). The frequencies of binary restenosis and TLR did not differ significantly between the groups.

Cumulative TLR-free ratios after SES and PES placement in DM-specific sub-analysis

Cumulative primary endpoint-free ratio in the SES DM group was not significantly different from that in the PES DM group ($p = 0.504$) (Fig. 1).

Baseline characteristics and angiographic outcomes in LL groups

Table 3 shows the baseline characteristics and angiographic outcomes of the patients in the SES LL ($n = 84$) and PES LL ($n = 147$) groups. The mean length of stent in the SES LL group (60.8 ± 18.3 mm) was not significantly different from that in the PES LL group (60.9 ± 17.9 mm, $p = 0.968$). The percentage with low ejection fraction, the percentage of lesions located in the left anterior descending artery (LAD), the percentage of lesions located in the RCA, the mean pressure, the postprocedural MLD, and the postprocedural %DS differed significantly between the SES LL and PES LL groups (9.5 vs. 2.7 %, $p = 0.025$; 66.7 vs. 42.2 %, $p < 0.001$; 17.9 vs. 41.5 %, $p < 0.001$; 19.6 ± 2.8 atm vs. 18.5 ± 2.8 atm, $p = 0.004$; 2.44 ± 0.41 mm vs. 2.61 ± 0.47 mm, $p = 0.004$; 13.9 ± 9.4 vs. 11.2 ± 7.9, $p = 0.026$, respectively). The mean late luminal loss was significantly less in the SES LL group (0.35 ± 0.72 mm) than in the PES LL group (0.65 ± 0.75 mm, $p = 0.004$).

The frequency of binary restenosis in the SES LL group (11.9 %) was on a smaller trend compared to that of PES LL group (21.8 %) (45.4 % reduction, $p = 0.062$). The frequency of TLR in the SES LL group (15.5 %) was also on a smaller trend compared to that of PES LL group (21.8 %) (28.9 % reduction, $p = 0.245$). In the SES group, the number of lesion implicated in binary restenosis and TLR were 10 and 13, respectively. The frequency of TLR exceeded that of binary restenosis owing to 3 cases of stent edge restenosis in the SES LLs group.

Table 2 Adjusted baseline characteristics and angiographic outcomes in SES DM and PES DM groups

	SES DM $n = 124$	PES DM $n = 124$	p values
Age (yr)	67.0 ± 8.7	68.4 ± 7.9	0.083
Male sex (%)	75.0	81.5	0.194
Insulin use (%)	11.3	8.9	0.532
Hemodialysis (%)	2.4	0	0.083
Previous MI (%)	56.5	51.6	0.453
Low EF (%)	3.2	4.0	0.739
LAD (%)	44.4	50.0	0.336
LCx (%)	30.6	25.0	0.307
LMT (%)	9.7	8.9	0.317
RCA (%)	21.8	23.4	0.732
Calcification (%)	10.5	15.3	0.273
LCx ostium (%)	6.5	6.5	1.000
RCA ostium (%)	1.6	1.6	1.000
CTO (%)	8.9	8.1	0.827
Number of stents	1.38 ± 0.66	1.52 ± 0.91	0.396
Diameter of stent (mm)	3.17 ± 0.47	3.21 ± 0.44	0.357
Length of stent (mm)	34.1 ± 20.6	38.3 ± 24.9	0.254
Rotablator (%)	7.3	9.7	0.162
IVUS (%)	97.6	96.0	0.317
Main branch of 2-stent bifurcation (%)	9.7	11.3	0.695
Side branch of 2-stent bifurcation (%)	11.3	9.7	0.655
Preprocedural MLD (mm)	0.99 ± 0.57	1.05 ± 0.61	0.355
Preprocedural %DS	64.0 ± 19.2	62.1 ± 19.9	0.381
Preprocedural RD (mm)	2.77 ± 0.69	2.71 ± 0.57	0.475
Postprocedural MLD (mm)	2.54 ± 0.48	2.56 ± 0.53	0.498
Postprocedural %DS	12.5 ± 10.3	12.8 ± 9.5	0.834
Postprocedural RD (mm)	2.93 ± 0.59	2.96 ± 0.64	0.698
Acute luminal gain (mm)	1.55 ± 0.53	1.51 ± 0.77	0.707
Interval to follow-up CAG (days)	452 ± 262	436 ± 303	0.208
Follow-up MLD (mm)	2.20 ± 0.85	2.02 ± 0.72	0.063
Late luminal loss (mm)	0.34 ± 0.67	0.54 ± 0.72	0.020
Follow-up %DS	27.6 ± 21.3	29.3 ± 19.0	0.222
ISR types 2–4/binary restenosis (%)	27.8	52.2	0.116
Binary restenosis (%)	14.5	16.1	0.856
Target lesion revascularization (%)	14.5	15.3	0.842

The variables were defined as described in the text and in Table 1

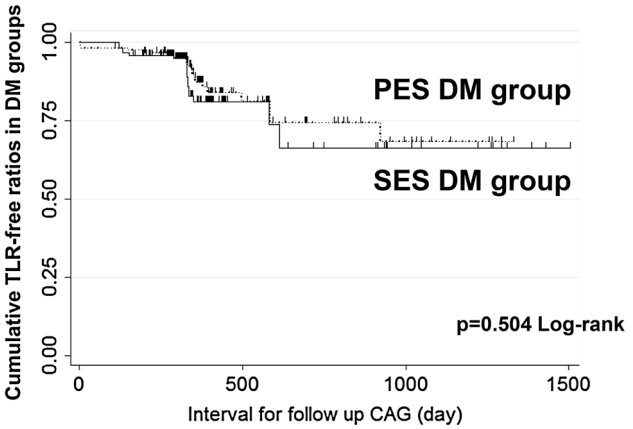

Fig. 1 Cumulative target lesion revascularization-free ratios after SES and PES placement in the DM groups. The cumulative target lesion revascularization (TLR)-free ratio in the SES DM group (*black solid line*) was not significantly different from that in the PES DM group (*black dot line*) by the log-rank test

Adjusted baseline characteristics and angiographic outcomes in LL groups

Table 4 shows the adjusted baseline characteristics of the patients in the SES LL and PES LL groups ($n = 81$ in each arm). The mean late luminal loss in the SES LL group was not significantly different from that in the PES LL group (0.34 ± 0.70 mm vs. 0.48 ± 0.76 mm, 29.2 % reduction, $p = 0.310$). The frequency of binary restenosis in the SES LL group (12.3 %) was also on a smaller trend compared to that of PES LL group (22.2 %) (44.6 % reduction, $p = 0.117$). In the SES LL group, the frequency of TLR (16.0 %) exceeded that of binary restenosis (12.3 %), and the frequency of TLR in the SES LL group was not significantly different from that of PES LL group (21.0 %) (24 % reduction, $p = 0.433$).

Cumulative TLR-free ratios after SES and PES placement in LL-specific sub-analysis

Cumulative primary endpoint-free ratio in the SES LL group was not significantly different from that in the PES LL group ($p = 0.625$) (Fig. 2).

Baseline characteristics and angiographic outcomes in SV groups

Table 5 shows the baseline characteristics and angiographic outcomes of the lesions followed up angiographically in the SES SV ($n = 116$) and PES SV ($n = 185$) groups. Percentage of male patients, mean pressure, preprocedural RD, postprocedural MLD, and postprocedural RD differed significantly between the SES SV and PES SV groups (71.6 vs. 82.7 %, $p = 0.022$; 18.7 ± 2.7 atm vs. 17.1 ± 3.3 atm, $p < 0.001$; 2.22 ± 0.41 mm vs. 2.35 ± 0.41 mm, $p = 0.007$; 2.57 ± 0.53 mm vs. 2.70 ± 0.46 mm, $p = 0.029$, respectively). The mean late luminal loss was significantly less in the SES SV group (0.28 ± 0.63 mm) than in the PES SV group

Table 3 Baseline characteristics and angiographic outcomes in SES LL and PES LL groups

	SES LL 84	PES LL 147	*p* values
Age (yr)	66.9 ± 9.1	66.8 ± 9.9	0.938
Male sex (%)	81	83.7	0.599
Diabetes (%)	48.8	38.8	0.138
Insulin (%)	3.6	5.4	0.521
Hemodialysis (%)	1.2	2.7	0.442
Previous MI (%)	51.2	53.7	0.709
Low EF (%)	9.5	2.7	0.025
LAD (%)	66.7	42.2	<0.001
LCx (%)	14.3	15.0	0.888
RCA (%)	17.9	41.5	<0.001
Calcification (%)	21.4	24.5	0.597
LCx ostium (%)	2.4	0.7	0.272
RCA ostium (%)	1.2	3.4	0.310
CTO (%)	21.4	21.8	0.952
Number of stents	2.29 ± 0.55	2.33 ± 0.58	0.602
Diameter of stent (mm)	3.27 ± 0.34	3.21 ± 0.34	0.197
Length of stent (mm)	60.8 ± 18.3	60.9 ± 17.9	0.968
Pressure (atm)	19.6 ± 2.8	18.5 ± 2.8	0.004
Rotablator (%)	13.1	14.3	0.801
IVUS (%)	96.4	98.0	0.482
Main branch of 2-stent bifurcation (%)	11.9	6.1	0.124
Side branch of 2-stent bifurcation (%)	6.0	1.4	0.050
Preprocedural MLD (mm)	0.76 ± 0.56	0.79 ± 0.57	0.707
Preprocedural %DS	71.2 ± 19.1	70.1 ± 19.8	0.679
Preprocedural RD (mm)	2.64 ± 0.67	2.81 ± 0.61	0.055
Postprocedural MLD (mm)	2.44 ± 0.41	2.61 ± 0.47	0.004
Postprocedural %DS	13.9 ± 9.4	11.2 ± 7.9	0.026
Postprocedural RD (mm)	2.86 ± 0.53	2.96 ± 0.58	0.183
Acute luminal gain (mm)	1.67 ± 0.55	1.82 ± 0.72	0.074
Interval to follow-up CAG (days)	486 ± 292	514 ± 348	0.514
Follow-up MLD (mm)	2.08 ± 0.72	1.97 ± 0.72	0.263
Follow-up %DS	29.8 ± 18.8	33.0 ± 20.6	0.232
Late luminal loss (mm)	0.35 ± 0.72	0.65 ± 0.75	0.004
ISR types 2–4/binary restenosis (%)	30.0	50.0	0.267
Binary restenosis (%)	11.9	21.8	0.062
Target lesion revascularization (%)	15.5	21.8	0.245

(0.53 ± 0.70 mm, $p = 0.001$). The frequencies of binary restenosis and TLR in the SES SV group were on smaller trends compared to those in the PES SV groups ($p = 0.059$ and 0.075, respectively).

Adjusted baseline characteristics and angiographic outcomes in SV groups

Table 6 shows the adjusted baseline characteristics of the patients in the SES DM and PES SV groups (n = 107 in each arm). The mean MLD and late luminal loss on follow-up in the SES SV group significantly differed from those in the PES SV group (1.95 ± 0.63 mm vs. 1.75 ± 0.74 mm, $p = 0.033$; 0.29 ± 0.63 mm vs. 0.49 ± 0.75 mm, $p = 0.024$). The frequencies of binary restenosis and TLR in the SES SV group were significantly smaller than those in the PES SV group (11.2 vs. 30.8 %, $p < 0.001$; 11.2 vs. 29.9 %, $p < 0.001$).

Cumulative TLR-free ratios after SES and PES placement in SV-specific sub-analysis

Cumulative primary endpoint-free ratio in the SES SV group was significantly higher than that in the PES SV group ($p < 0.001$) (Fig. 3).

Discussion

Long-term angiographic outcomes of SES and PES placement in DM

The present DM-specific sub-analysis was conducted for the following several reasons: (1) long-term angiographic outcomes after placement of SESs and PESs in Japanese patients with DM were not fully understood, although the J-DEsERT study [18] reported that SESs and PESs had equivalent efficacy at 1 year; (2) a laboratory study in which paclitaxel exerted different effects from sirolimus (referred to as rapamycin in the study) in experimental models of hyperglycemia and insulin resistance [19] needed to be confirmed by long-term angiographic follow-up; (3) a study in which the TAXUS Liberté (the second-generation TAXUS PES) showed a statistically equivalent frequencies of binary restenosis and TLR with significantly greater late luminal loss compared with SESs [20] needed to be confirmed by SES and Express PES by long-term follow-up.

The present study, analyzing 337 angiographically followed up de novo coronary stenosis lesions treated in a clinical practice setting, provides the first evidence that PESs and SESs have equivalent mid- to long-term efficacy in Japanese patients with DM, as measured by the frequencies of binary restenosis and TLR (Table 2). Mean in-stent late luminal loss was consistently greater after PES placement than after SES placement (Tables 1, 2), as in previous reports comparing short-term in-stent late luminal loss between these devices (routine angiographic follow-up approximately 8–12 months after index procedure) [21]. However, because the threshold value at which mean late luminal loss is associated with a significantly increased incidence of TLR is 0.65 mm [22], the greater late luminal loss after PES placement did not translate into higher rates

Table 4 Adjusted baseline characteristics and angiographic outcomes in SES LL and PES LL groups

	SES LL 81	PES LL 81	*p* values
Age (yr)	67.0 ± 9.2	66.9 ± 8.3	0.974
Male sex (%)	81.5	81.5	1.000
Diabetes (%)	46.9	46.9	1.000
Insulin (%)	3.7	4.9	0.706
Hemodialysis (%)	1.2	2.5	0.564
Previous MI (%)	51.9	54.3	0.758
Low EF (%)	7.4	6.2	0.763
LAD (%)	65.4	63.0	0.724
LCx (%)	14.8	19.8	0.394
RCA (%)	18.5	17.3	0.808
Calcification (%)	22.2	18.5	0.564
CTO (%)	21	24.7	0.578
Number of stents	2.28 ± 0.55	2.30 ± 0.54	0.969
Diameter of stent (mm)	3.27 ± 0.34	3.28 ± 0.31	0.237
Length of stent (mm)	60.8 ± 18.4	61.2 ± 16.1	0.834
Rotablator (%)	13.6	8.6	0.317
IVUS (%)	96.3	91.4	0.206
Main branch of 2-stent bifurcation (%)	12.3	12.3	1.000
Side branch of 2-stent bifurcation (%)	6.2	1.2	0.103
Preprocedural MLD (mm)	0.78 ± 0.56	0.70 ± 0.57	0.191
Preprocedural %DS	70.6 ± 18.8	73.3 ± 18.5	0.492
Preprocedural RD (mm)	2.66 ± 0.67	2.65 ± 0.58	0.873
Postprocedural MLD (mm)	2.45 ± 0.41	2.45 ± 0.45	0.591
Postprocedural %DS	14.1 ± 9.2	13.0 ± 8.8	0.505
Postprocedural RD (mm)	2.88 ± 0.53	2.85 ± 0.59	0.639
Acute luminal gain (mm)	1.67 ± 0.55	1.75 ± 0.59	0.934
Interval to follow-up CAG (days)	491 ± 296	587 ± 392	0.227
Follow-up MLD (mm)	2.08 ± 0.71	1.98 ± 0.71	0.308
Follow-up %DS	29.8 ± 19.0	31.8 ± 20.4	0.609
Late luminal loss (mm)	0.37 ± 0.70	0.48 ± 0.76	0.310
ISR types 2–4/binary restenosis (%)	30.0	44.0	0.453
Binary restenosis (%)	12.3	22.2	0.117
Target lesion revascularization (%)	16.0	21.0	0.433

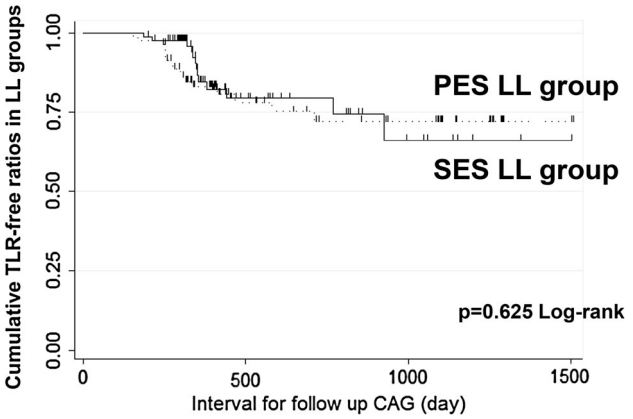

Fig. 2 Cumulative target lesion revascularization-free ratios after SES and PES placement in the LL groups. The cumulative target TLR-free ratio in the SES LL group (*black solid line*) was not significantly different from that in the PES group (*black dot line*) by the log-rank test

of binary restenosis or TLR relative to SES placement (Table 2), a result consistent with previous reports [5, 20, 21]. The frequency of diffuse ISR among lesions with binary restenosis after DES placement did not differ significantly between the PES DM and SES DM groups (Tables 1, 2). This is attributable to the adjustment of the data using propensity score matching, as discussed above, which was reflected in greater in-stent late luminal loss (>0.30 mm) after SES placement (Tables 1, 2, 3, 4) than observed in previous reports, where it was in the range of 0.19 mm [21]. On the other hand, the mean in-stent late luminal loss in the PES group after baseline adjustment ranging from 0.48 to 0.54 mm was similar to that (1) in a DM cohort (0.46 mm) [14], (2) in a all-comer study of patients with de novo coronary stenosis (0.50 mm) [5], and (3) of lesions with complex lesions defined as the consistent predictors of TLR after SES placement (0.48 mm) [6]. Over all three sub-analyses in the present study, the percentage change after adjustment in mean late luminal loss in the SES group was 27.6 % (from 0.29 to 0.37 mm) and that in the PES group was 12.5 % (from 0.48 to 0.54 mm); this difference may result from the different anti-restenotic properties of SESs and PESs. Therefore, although differences between SESs and PESs with regard to the impact of late restenosis could not be clearly determined in the present group of DM patients, this study can report statistically equivalent long-term angiographic outcomes (mean follow-up intervals of approximately 430 to 450 days) after SES and PES placement for treatment of de novo native coronary lesions in a clinical practice setting in Japanese patients with DM (Table 2; Fig. 1).

Long-term angiographic outcomes of SES and PES placement in LL

The present LL-specific sub-analysis needed to be evaluated in the long-term interval because LL was the predictor of late adverse angiographic outcome after SES placement [4] and the short- to mid-term superiority of SES to PES on the angiographic outcomes was inconsistent [8–10]. Target lesions in the RCA usually treated using a PES (Table 3), as the type of SES used was prone to fracture when placed in that location [23], were adjusted. The present mean total length of stented segments was more than 60 mm, with a mean late luminal loss not more than 0.37 mm in the SES LL group after adjustment, expressing the great complexity of the LL cohorts. Whereas the mean late luminal loss in the PES LL group after adjustment did not significantly differ from that of SES (Table 4), closing to 0.50 mm as discussed above. The smaller trends in the magnitudes of late luminal loss and of the mean type 2–4 ISR per binary restenosis ratios in the SES LL group did not translate into the significant change in the frequency of binary restenosis compared to PES LL group. However, according to the tendency of the smaller binary restenosis rate in the SES LL group, we could not deny the superiority of SES, or there might be the possibility of SES's superiority for LL compared to PES. This was the limitation of the present very small cohort. Similarly, 24 % reduction in the frequency of TLR in the SES LL group compared to PES LL group should be evaluated in a larger cohort. Thus, from the present small number of LL-specific sub-analysis, according to the tendency of better outcomes, particularly, in the binary restenosis rate in the SES LL group, there remained the possibility of the SES's superiority to PES for LLs.

Long-term angiographic outcomes of SES and PES placement in SV

Since SV is the predictor of late adverse angiographic outcome after SES placement [4], the consistent short-term superiority of SES to PES on the angiographic outcomes in SV [11–14] needed to be evaluated in the long-term interval. In the SV-specific sub-analysis, the greater late luminal loss in the PES SV group consistently translated into significantly higher frequencies of binary restenosis and TLR compared with the SES SV group during a long-term observational interval (Table 6; Fig. 3). The present study first confirmed the superiority of SES treatment for SVs, in terms of all of the late luminal loss, binary restenosis, and TLR after adjustment of baseline variables, over PES treatment in Japanese patients.

Table 5 Baseline characteristics and angiographic outcomes in SES SV and PES SV groups

	SES SV 116	PES SV 185	*p* values
Age (yr)	67.9 ± 8.7	66.0 ± 9.0	0.069
Male sex (%)	71.6	82.7	0.022
Diabetes (%)	45.7	47.0	0.821
Insulin (%)	7.8	4.9	0.303
LAD (%)	50.0	43.2	0.252
LCx (%)	33.6	35.7	0.716
RCA (%)	15.5	18.9	0.451
Calcification (%)	12.1	14.6	0.534
LCx ostium (%)	3.4	4.9	0.556
Number of stents	1.42 ± 0.69	1.37 ± 0.61	0.523
Diameter of stent (mm)	2.91 ± 0.39	2.89 ± 0.33	0.646
Length of stent (mm)	35.9 ± 21.6	32.7 ± 17.1	0.176
Pressure (atm)	18.7 ± 2.7	17.1 ± 3.3	< 0.001
Rotablator (%)	6.0	9.7	0.258
IVUS (%)	95.7	96.8	0.317
Main branch of 2-stent bifurcation (%)	8.6	4.9	0.192
Side branch of 2-stent bifurcation (%)	12.9	7.6	0.125
Preprocedural MLD (mm)	0.86 ± 0.28	0.91 ± 0.28	0.132
Preprocedural %DS	59.8 ± 13.0	59.6 ± 12.0	0.894
Preprocedural RD (mm)	2.15 ± 0.32	2.27 ± 0.26	< 0.001
Postprocedural MLD (mm)	2.22 ± 0.41	2.35 ± 0.41	0.007
Postprocedural %DS	12.5 ± 9.6	12.2 ± 8.8	0.785
Postprocedural RD (mm)	2.57 ± 0.53	2.70 ± 0.46	0.029
Acute luminal gain (mm)	1.36 ± 0.44	1.44 ± 0.40	0.112
Interval to follow-up CAG (days)	470 ± 322	532 ± 375	0.127
Follow-up MLD (mm)	1.94 ± 0.61	1.82 ± 0.66	0.108
Late luminal loss (mm)	0.28 ± 0.63	0.53 ± 0.70	0.001
Follow-up %DS	26.3 ± 19.9	30.9 ± 20.8	0.055
ISR types 2–4/binary restenosis (%)	38.5	33.3	0.739
Binary restenosis (%)	11.2	19.5	0.059
Target lesion revascularization (%)	11.2	18.9	0.075

Table 6 Adjusted baseline characteristics and angiographic outcomes in SES SV and PES SV groups

	SES SV 107	PES SV 107	*p* values
Age (yr)	67.2 ± 8.6	67.4 ± 8.6	0.802
Male sex (%)	73.8	68.2	0.343
Diabetes (%)	47.7	50.5	0.668
Insulin (%)	7.5	5.6	0.593
LAD (%)	48.6	53.3	0.484
LCx (%)	33.6	29.9	0.547
RCA (%)	16.8	16.8	1.000
Calcification (%)	11.2	15.0	0.414
LCx ostium (%)	3.7	8.4	0.132
Number of stents	1.40 ± 0.69	1.38 ± 0.61	0.752
Diameter of stent (mm)	2.88 ± 0.37	2.92 ± 0.33	0.480
Length of stent (mm)	34.9 ± 21.5	33.8 ± 18.5	0.969
Rotablator (%)	6.5	6.5	1.000
IVUS (%)	96.3	100.0	0.125
Main branch of 2-stent bifurcation (%)	7.5	1.9	0.058
Side branch of 2-stent bifurcation (%)	14.0	13.1	0.842
Preprocedural MLD (mm)	0.87 ± 0.28	0.88 ± 0.33	0.864
Preprocedural %DS	59.5 ± 13.1	60.2 ± 14.7	0.503
Preprocedural RD (mm)	2.16 ± 0.31	2.21 ± 0.26	0.226
Postprocedural MLD (mm)	2.24 ± 0.40	2.25 ± 0.37	0.869
Postprocedural %DS	12.3 ± 9.4	10.7 ± 9.3	0.276
Postprocedural RD (mm)	2.58 ± 0.52	2.53 ± 0.42	0.534
Acute luminal gain (mm)	1.37 ± 0.43	1.37 ± 0.36	0.853
Interval to follow-up CAG (days)	468 ± 311	519 ± 374	0.180
Follow-up MLD (mm)	1.95 ± 0.63	1.75 ± 0.74	0.033
Late luminal loss (mm)	0.29 ± 0.63	0.49 ± 0.75	0.024
Follow-up %DS	26.7 ± 20.3	33.0 ± 24.1	0.054
ISR types 2–4/binary restenosis (%)	41.7	33.3	0.606
Binary restenosis (%)	11.2	30.8	<0.001
Target lesion revascularization (%)	11.2	29.9	<0.001

Limitations

Several limitations of this study must be recognized. First, the study was a retrospective, nonrandomized single-center analysis. However, the population was consecutively enrolled from a cohort in which DES was used at a very high rate. Although propensity score matching analysis was used to adjust baseline variables for covariates [15], the underlying confounders, such as the stent selection bias against the characteristics of target lesion for RCA (Tables 1, 3) and vessel size (preprocedural RD) (Table 5), could not completely adjusted. Second, the study examined angiographic outcomes at only one long-term follow-up interval, so the occurrence of late restenosis [1, 2] could not be determined. Third, the impact of stent fracture (which may be related to stent thrombosis and binary restenosis) on clinical and angiographic outcomes could not be fully defined. It was difficult to determine whether a Bx Velocity SES was fractured by visual estimation alone, particularly after the use of the 2-stent bifurcation technique [24], and the Express PES was radiopaque, with similar effects.

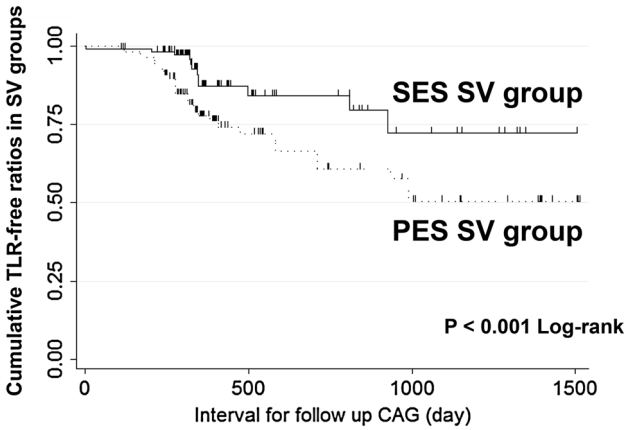

Fig. 3 Cumulative target lesion revascularization-free ratios after SES and PES placement in the SV groups. The cumulative target TLR-free ratio in the SES SV group (*black solid line*) was significantly higher than that in the PES SV group (*black dot line*) by the log-rank test

Finally, although minimum stent area predicts the outcome of PCI, IVUS assessment of this parameter was not available.

Conclusions

SESs and PESs showed various angiographic outcomes in DMs, LLs, and SVs in terms of TLR, binary restenosis, and late luminal loss within 1500 days of placement for de novo native coronary lesions in a Japanese clinical practice setting. SES showed the equivalent efficacy for DM, the tendency to be superior for LLs, and the promising superiority for SVs on the angiographic outcomes compared to PES during a long-term observational interval.

Conflict of interest None to declare.

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