

# Two-year Clinical Outcomes of Patients with Long Segments Drug-Eluting Stents: Comparison of Sirolimus-Eluting Stent with Paclitaxel-Eluting Stent

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## INTRODUCTION

Although drug-eluting stent (DES) use has remarkably reduced in-stent restenosis (ISR) and neointimal hyperplasia, percutaneous coronary intervention (PCI) of diffuse long coronary artery lesions remains challenging (1, 2); these lesions are commonly encountered in routine clinical practice and often lead to use long stented segments with stent overlap. Because stented segment length was a known independent predictor of ISR in the bare-metal stent (BMS) era and limited data are available on the long-term efficacy and safety of DES in diffuse long coronary artery lesions, we investigated the long-term efficacy and safety of DES in diffuse long lesions (3-5).

## MATERIALS AND METHODS

### Study population

From May 2006 to May 2007, a total of 335 consecutive patients

Limited data are available on the long-term clinical efficacy of drug-eluting stent (DES) in diffuse long lesions. From May 2006 to May 2007, a total of 335 consecutive patients (374 lesions) were underwent percutaneous coronary intervention with implantation of long DES ( $\geq 30$  mm) in real world practice. Eight-month angiographic outcomes and 2-yr clinical outcomes were compared between SES ( $n = 218$ ) and PES ( $n = 117$ ). Study endpoints were major adverse cardiac events including cardiac death, myocardial infarction, target-lesion revascularization, target-vessel revascularization and stent thrombosis. Baseline characteristics were similar in the two groups as were mean stent length ( $44.9 \pm 15.2$  mm in SES and  $47.4 \pm 15.9$  in PES,  $P = 0.121$ ). Late loss at 8 months follow-up was significantly lower in SES than in PES group ( $0.4 \pm 0.6$  mm in SES vs  $0.7 \pm 0.8$  mm in PES,  $P = 0.007$ ). Mean follow-up duration was  $849 \pm 256$  days, and 2-yr cumulative major adverse cardiac events were significantly lower in the SES than in the PES group (5.5% in SES vs 15.4% in PES,  $P = 0.003$ ). In conclusion, long-term DES use in diffuse long coronary lesions is associated with favorable results, with SES being more effective and safer than PES in this real-world clinical experience.

**Key Words:** Drug-Eluting Stents; Long Lesion; Long-Term, Outcomes

(374 lesions) underwent PCI with implantation of long DES ( $\geq 30$  mm) in de novo long coronary artery lesions at 3 cardiac centers (Inje University Busan Paik Hospital in Busan, Yeungnam University Medical Center in Daegu and Keimyung University Dongsan Hospital in Daegu) in Korea. Patients were divided into sirolimus-eluting stent (SES, Cypher, Cordis, Johnson & Johnson, Roden, The Netherlands,  $n = 218$ ) and paclitaxel-eluting stent (PES, Taxus, Boston Scientific Corp, Natick, MA, USA,  $n = 117$ ) recipient groups, and 8-month angiographic 2-yr clinical outcomes were compared.

### Procedures and medications

All interventions were performed using standard techniques. DES selection, Glycoprotein IIb/IIIa inhibitors and intravascular ultrasound (IVUS) were used at the discretion of the operator. All patients received a loading dose of 300 mg clopidogrel followed by a daily dosage of 75 mg for 12 months, in addition to life-long aspirin therapy.

### Follow-up

Angiographic follow-up was recommended for all living patients at 8 months after index procedure. Clinical follow-up was performed for all patients at 1, 3, 6, 9 and 12 months, and every 3 months thereafter either during out-patient department visits or by direct telephone calls to patients.

### Study outcomes and definitions

Study outcome was a composite of major adverse cardiac events (MACE) including cardiac death, myocardial infarction (MI), target-lesion revascularization (TLR), target-vessel revascularization (TVR) and stent thrombosis (ST).

Procedural success was defined as residual diameter stenosis  $\leq 30\%$  and the absence of any-in hospital MACE. MI was diagnosed when cardiac enzyme (creatin kinase MB fraction) levels were elevated more than threefold the normal level, with chest pain lasting  $\geq 30$  min, or with the appearance of new electrocardiographic changes, or with imaging evidence of new regional wall motion abnormality or loss of viable myocardium. TLR was defined as either surgical or percutaneous reintervention driven by significant ( $> 50\%$ ) luminal diameter narrowing within the stent or the 5 mm borders proximal and distal to the stent and undertaken in the presence of either anginal symptoms or objective evidence of ischemia. TVR was defined as revascularization within the target vessel encompassing the target lesion. Stent thrombosis (ST) was classified by the Academic Research Consortium definition as definite, probable, or possible and as acute (0 to 24 hr), subacute ( $> 24$  hr to 30 days), late ( $> 30$  days to 1 yr) or very late ( $> 1$  yr). ST was defined as 1) definite: an acute coronary syndrome with angiographic documentation of either vessel occlusion or thrombus within or adjacent to a previously successfully stented vessel or autopsy evidence of stent thrombosis, 2) probable: acute MI in the distribution of the treated vessel or unexplained death  $< 30$  days after the index PCI and 3) possible: unexplained death  $> 30$  days after the index PCI (6, 7).

Angiographic restenosis was defined as  $\geq 50\%$  of a diameter stenosis. Cumulative rates of event-free survival and MACE were analyzed over a two-year follow-up period.

### Quantitative coronary angiographic analysis

The percentage of diameter stenosis, minimal lumen diameter, lesion length and reference diameter were analyzed with an automated edge-detection system (CASS II, Pie Medical, Maastricht, The Netherlands) before the procedure, after the procedure, and at follow-up. Lesion morphology was defined according to the guidelines of the American College of Cardiology and the American Heart Association (8).

### Statistical analysis

Data are expressed as mean  $\pm$  SD for continuous variables, and as frequencies for categorical variables. A two tailed Student's t

test was used to assess differences between continuous variables. The chi-square ( $\chi^2$ ) test was used for comparison of categorical variables. Multivariate logistic regression analysis was carried out using the baseline clinical and angiographic characteristics to identify the independent predictors of MACEs. The following variables were tested; pre-lesion length, overlapping, number of stents in long lesion, multi-vessel disease and used stent type. Major adverse cardiac event-free survival distributions were estimated according to the Kaplan-Meier method. The log-rank test was used to compare MACE-free survival between two groups. Probability values  $< 0.05$  were considered significant. Data were analyzed with SAS 9.1.3. (SAS Institute Inc., Cary, NC, USA).

### Ethics statement

This study was reviewed and approved by the institutional review board (DCR-10-14) and is in accordance with the Declaration of Helsinki. Informed consent was obtained from all patients.

### RESULTS

Baseline characteristics of the patients are presented in Table 1 and there were no significant differences between groups. Angiographic and procedural data are shown in Table 2; most lesions were type C according to the American College of Cardiology and American Heart Association and guidelines (8). Mean lesion length ( $40.4 \pm 14.3$  mm in SES and  $43.6 \pm 15.2$  mm in PES,  $P = 0.063$ ) and mean stent length ( $44.9 \pm 15.2$  mm in SES and  $47.4 \pm 15.9$  mm in PES,  $P = 0.121$ ) did not differ significantly between groups. Post-procedural diameter stenosis was greater in the PES than that in SES group ( $6.1\% \pm 4.2\%$  in SES vs  $7.9\% \pm 5.0\%$  in PES,  $P = 0.001$ ). Angiographic follow-up at 8 months was performed in 47.3% and binary restenosis rate was 2.1% in the SES and 5.3% in the PES group ( $P = 0.094$ ). Late loss was signif-

**Table 1.** Baseline characteristics of the patients

Parameters	SES (n = 218)	PES (n = 117)	P value
Age (yr)	65 $\pm$ 10	63 $\pm$ 10	0.062
Gender (male)	139 (63.8%)	79 (67.5%)	0.491
Diabetes mellitus	72 (33.0%)	35 (29.9%)	0.560
Hypertension	117 (53.7%)	65 (55.6%)	0.741
Smoking	63 (28.9%)	37 (31.6%)	0.603
Pre-PCI	17 (7.8%)	10 (8.5%)	0.810
Pre-CABG	1 (0.5%)	2 (1.7%)	0.247
Clinical diagnosis			0.370
Stable angina	78 (35.8%)	43 (36.8%)	
Unstable angina	40 (18.3%)	17 (14.5%)	
STEMI	56 (25.7%)	40 (34.2%)	
NSTEMI	43 (19.7%)	17 (14.5%)	
Silent ischemia	1 (0.5%)	0	
LVEF (%)	54 $\pm$ 12	55 $\pm$ 11	0.366

SES, sirolimus-eluting stent; PES, paclitaxel-eluting stent; PCI, percutaneous coronary intervention; CABG, coronary artery bypass graft; STEMI, ST-segment elevation myocardial infarction; NSTEMI, non-ST-segment elevation myocardial infarction; LVEF, left ventricular ejection fraction.

icantly lower in the SES than in the PES ( $0.4 \pm 0.6$  mm in SES vs  $0.7 \pm 0.8$  mm in PES,  $P = 0.007$ , Table 3). Mean clinical follow-up duration was  $849 \pm 256$  days. In-hospital MACE rates were not statistically different between groups (1.8% in SES vs 2.6% in PES,  $P = 0.656$ , Table 4). During hospitalization, 4 patients in the SES group died; 2 with cardiogenic shock, 1 with cardiogenic shock and acute stent thrombosis, and one with cardiac tamponade, while two patients in the PES group died of cardiogenic shock after acute myocardial infarction (Table 4). At one-month follow-up, one additional patient died after subacute stent thrombosis in the SES group, and likewise in the PES group (Table 4). At one year follow-up, two additional deaths occurred in the PES group related to late stent thrombosis, while there were no deaths in the SES group. At two-year follow-up, two additional deaths were found in the PES group related to heart failure; however, there were no additional cases of stent thrombosis (Table 4). Cumulative total MACE showed SES yielded superior results than PES (5.5% in SES vs 15.4% in PES,  $P = 0.003$ ). MACE-free survival rates are presented in Figs. 1, 2 shows TVR-free survival and Fig.

**Table 2.** Angiographic and procedural findings

Procedures or variables	SES (n = 241)	PES (n = 133)	P value
Lesion type*			0.894
B2	12 (5.0%)	6 (4.5%)	
C	223 (92.5%)	124 (93.2%)	
Modified lesion type†			0.610
B2	109 (45.2%)	51 (38.3%)	
C	66 (27.4%)	42 (31.6%)	
Disease vessel number			0.078
1 vessel	101 (41.9%)	40 (30.1%)	
2 vessels	66 (27.4%)	44 (33.1%)	
3 vessels	74 (30.7%)	49 (36.8%)	
Target artery			0.106
LAD	126 (52.3%)	58 (43.6%)	
LCX	28 (11.6%)	25 (18.8%)	
RCA	87 (36.1%)	50 (37.6%)	
Bifurcation lesion	50 (20.7%)	30 (22.6%)	0.683
Infarct-related artery	87 (36.1%)	51 (38.3%)	0.666
Stent			
Size (mm)	$3.0 \pm 0.2$	$3.0 \pm 0.3$	0.157
Length (mm)	$44.9 \pm 15.2$	$47.4 \pm 15.9$	0.121
Maximal pressure (atm)	$15.9 \pm 2.0$	$15.8 \pm 2.0$	0.863
Post-dilatation	45 (18.7%)	34 (25.6%)	0.118
Overlapping stent	112 (46.5%)	74 (55.6%)	0.090
Stent number at target lesion	$1.7 \pm 0.5$	$1.8 \pm 0.6$	0.089
Lesion length (mm)	$40.4 \pm 14.3$	$43.6 \pm 15.2$	0.063
Pre-PCI			
RD (mm)	$2.8 \pm 0.4$	$2.8 \pm 0.4$	0.842
MLD (mm)	$0.3 \pm 0.2$	$0.3 \pm 0.2$	0.491
DS (%)	$88.6 \pm 9.1$	$87.8 \pm 10.3$	0.428
Post-PCI			
MLD (mm)	$2.7 \pm 0.3$	$2.7 \pm 0.3$	0.100
DS (%)	$6.1 \pm 4.2$	$7.9 \pm 5.0$	0.001
Acute gain	$2.4 \pm 0.3$	$2.4 \pm 0.4$	0.543

\*According to the ACC/AHA guidelines (8); †Modified lesion classification excluding lesion length. SES, sirolimus-eluting stent; PES, paclitaxel-eluting stent; LAD, left anterior descending artery; LCX, left circumflex artery; RCA, right coronary artery; PCI, percutaneous coronary intervention; RD, reference diameter; MLD, minimal lumen diameter; DS, diameter stenosis.

3 shows myocardial infarction, death and stent thrombosis free survival.

From test variables with pre-lesion length, overlapping, number of stents in long lesion, multi-vessel disease and used stent type, the independent risk factors of MACE for diffuse long coronary artery lesions were used stent ( $P = 0.003$ , odds ratio 3.181, C.I. 1.492-6.779) and overlapping stent ( $P = 0.025$ , odds ratio 1.790, C.I. 0.814-3.937).

**Table 3.** Follow-up angiographic results

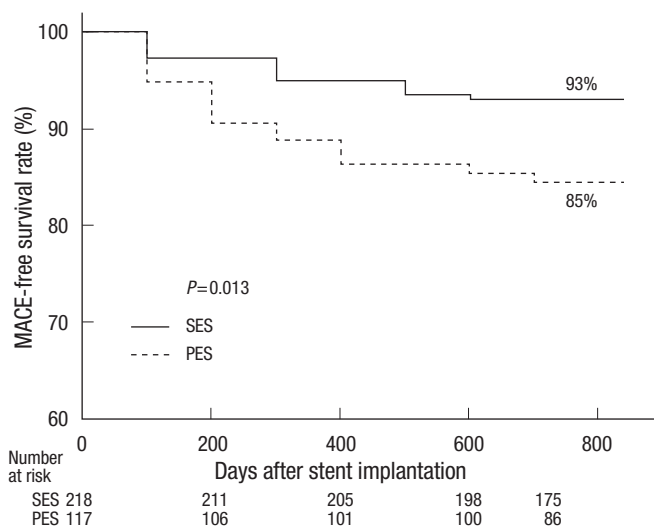
Parameters	SES (n = 241)	PES (n = 133)	P value
Follow-up CAG	109 (45.2%)	68 (51.1%)	0.274
Restenosis	5 (2.1%)	7 (5.3%)	0.094
Restenosis type			0.110
Body	1 (0.4%)	0	
Edge	1 (0.4%)	5 (3.8%)	
Diffuse	1 (0.4%)	0	
Total	2 (0.8%)	2 (1.5%)	
RD (mm)	$2.9 \pm 0.4$	$3.0 \pm 0.4$	0.178
MLD (mm)	$2.3 \pm 0.7$	$2.0 \pm 0.8$	0.034
DS (%)	$21.6 \pm 21.5$	$31.4 \pm 22.5$	0.007
Late loss (mm)	$0.4 \pm 0.6$	$0.7 \pm 0.8$	0.007

SES, sirolimus-eluting stent; PES, paclitaxel-eluting stent; CAG, coronary angiography; RD, reference diameter; MLD, minimal lumen diameter; DS, diameter stenosis.

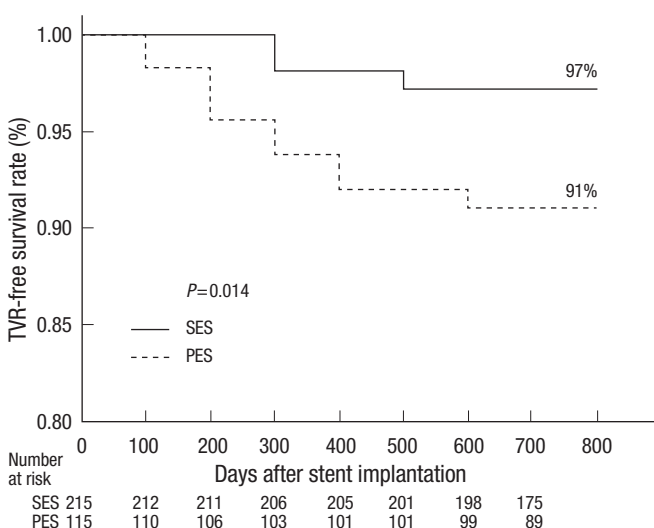
**Table 4.** Major adverse cardiac events (MACE) at 2 yr

Adverse events	SES (n = 218)	PES (n = 117)	P value
In-hospital MACE	4 (1.8%)	3 (2.6%)	0.656
Myocardial infarction	0	2 (1.7%)	0.053
TLR/TVR/CABG	0	0	
Death	4 (1.8%)	1 (0.9%)	0.481
Stent thrombosis	0	1 (0.9%)	0.172
1-month MACE	2 (0.9%)	3 (2.6%)	0.236
Myocardial infarction	2 (0.9%)	2 (1.7%)	0.525
TLR/TVR/CABG	0	0	
Death	1 (0.5%)	2 (1.7%)	0.247
Stent thrombosis	1 (0.5%)	1 (0.9%)	0.654
1-yr MACE	4 (1.8%)	8 (6.8%)	0.019
Myocardial infarction	0	3 (2.6%)	0.018
TLR	3 (1.4%)	6 (5.1%)	0.043
TVR	5 (2.3%)	6 (5.1%)	0.165
CABG	0	0	
Death	0	2 (1.7%)	0.053
Stent thrombosis	0	2 (1.7%)	0.053
2-yr MACE	2 (0.9%)	6 (5.1%)	0.016
Myocardial infarction	0	5 (4.3%)	0.002
TLR	2 (0.9%)	2 (1.7%)	0.525
TVR	2 (0.9%)	2 (1.7%)	0.525
CABG	0	0	
Death	0	2 (1.7%)	0.053
Stent thrombosis	0	0	
Cumulative total MACE	12 (5.5%)	7 (15.4%)	0.003
Myocardial infarction	4 (1.8%)	10 (8.5%)	0.003
TLR	5 (2.3%)	9 (7.7%)	0.019
TVR	6 (2.8%)	10 (8.5%)	0.018
CABG	0	0	-
Death	5 (2.3%)	7 (6.0%)	0.165
Stent thrombosis	1 (0.5%)	4 (3.4%)	0.033

SES, sirolimus-eluting stent; PES, paclitaxel-eluting stent; MACE, major adverse cardiac events; TLR, target-lesion revascularization; TVR, target-vessel revascularization; CABG, coronary artery bypass graft.



**Fig. 1.** Cumulative major adverse cardiac event (MACE) free survival is represented. Follow-up duration was  $849 \pm 256$  days. The outcomes associated with sirolimus-eluting stent (SES) use were better than those of paclitaxel-eluting stent (PES) use (93% in SES vs 85% in PES,  $P = 0.013$ ).



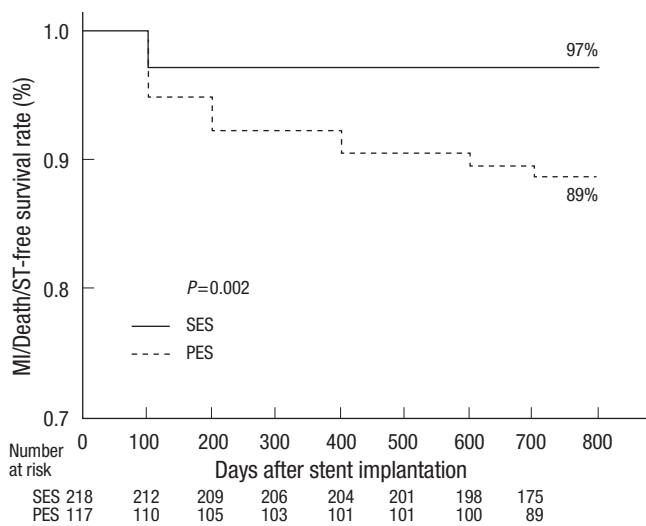
**Fig. 2.** Target vessel revascularization-free survival rate is represented. The outcomes of sirolimus-eluting stent were better than those of paclitaxel-eluting stent (97% in SES vs 91% in PES,  $P = 0.014$ ).

## DISCUSSION

The major finding of this study is that long-term follow-up of DES implantation in diffuse long coronary lesions showed acceptable low rates of clinical events, with SES being more effective and safer than PES in this real-world clinical experience.

Restenosis remains a major problem in treating with DES use, particularly in off-label usage such as in diffuse long lesions. Stent type can affect the risk of restenosis and SES is superior in terms of late loss and restenosis (9, 10).

Lee et al. (11) reported that the full metal jacket DES method was safe and effective in the treatment of diffuse long coronary artery disease with restenosis rates of 11.1% and 22.2% for SES



**Fig. 3.** Myocardial infarction, death and stent thrombosis free survival rate is represented. The outcomes of sirolimus-eluting stent were better than those of paclitaxel-eluting stent (97% in SES vs 89% in PES,  $P = 0.002$ ).

and PES, respectively, suggesting that the risk of restenosis is influenced by the type of DES used. Kim et al. (12) also reported that for patients with long coronary artery disease, SES implantation was associated with a reduced incidence of angiographic restenosis and a reduced need for TLR compared with PES implantation, although incidence of death or myocardial infarction at 9-month follow-up was not significantly different. Our study yielded similar results with SES use being associated with better outcomes than PES use, which might be due to significantly lower late loss ( $0.4 \pm 0.6$  mm in SES vs  $0.7 \pm 0.8$  mm in PES,  $P = 0.007$ ) and TVR rates (2.8% in SES vs 8.5% in PES,  $P = 0.018$ ). The outcome rates in this study were more favorable than those in the study by Lee et al. (11), which may be secondary to differences in lesion length (mean stent length  $71.9 \pm 13.7$  mm in Lee et al. report (11) vs  $45.8 \pm 15.5$  mm in the present study), because ISR occurrence increases with increased stented length. However, this study was not focused on full lesion coverage such as with full metal jackets, but on the treatment of long lesions more commonly seen in the real-world clinical practice.

Our study showed that MACE of patients with SES had better results in not only efficacy (TLR/TVR) but also myocardial infarction and cardiac death. Compared with the previous reports, our study represented different results in hard endpoints because our data reflected real world clinical practice and long term follow-up for 2 yr in diffuse long coronary artery lesion (13).

From our study, small differences already uncovered before one year follow-up, however the results came to clearer towards two years. This represents short-term follow-up is necessary but also long-term follow-up is important in patients treated with DES, especially PES, in diffuse long lesions.

Stent thrombosis is another important complication in patients treated with DES, especially in diffuse long lesions. One

study reported a 9-month late stent thrombosis rate of 1.25% (4/318) for a mean stent length  $\geq 55$  mm (14). In the present study, 4 stent thrombosis (one acute, two sub-acute and one late) events developed in the PES group (3.4%), while only one subacute stent thrombosis occurred in the SES group (0.5%,  $P = 0.033$ ). The reasons for this significant difference are unknown and might include multiple factors such as different environmental or individual factors.

There are several limitations in this study. First, angiographic follow-up was performed only in 47.3% of patients, which might underestimate restenosis rates. This could be another major source of selection bias. So we compared between the patients with and without angiographic follow-up. However, there were no differences in baseline characteristics and angiographic, procedural findings. Second, the total number of patients was relatively small to fully assess the safety and efficacy of DES. Third, this study is a retrospective analysis and stent selection was not randomized and could be biased. So we used multivariate regression analysis. From this analysis, used stent and overlapping proved independent risk factors for MACE in patients with diffuse long coronary artery disease as described early. Fourth, another type DES like zotarolimus-eluting stent and second generation DES such as everolimus-eluting stent were not included in this study and further investigation will be warranted.

In conclusion, long-term DES use in diffuse long coronary lesions is associated with favorable results, with SES being more effective and safer than PES in this real-world clinical experience.

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**AUTHOR SUMMARY****Two-year Clinical Outcomes of Patients with Long Segments Drug-Eluting Stents: Comparison of Sirolimus-Eluting Stent with Paclitaxel-Eluting Stent**

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