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Sirolimus- Versus Paclitaxel-Eluting Stents for the Treatment of Coronary Bifurcations

Results From the COBIS (Coronary Bifurcation Stenting) Registry

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Objectives We aimed to compare the long-term clinical outcomes of patients treated with sirolimus-eluting stents (SES) or paclitaxel-eluting stents (PES) for coronary bifurcation lesions.

Background There are limited data regarding comparisons of SES and PES for the treatment of bifurcation lesions.

Methods Patients who received percutaneous coronary intervention for non-left main bifurcation lesions were enrolled from 16 centers in Korea between January 2004 and June 2006. We compared major adverse cardiac events (MACE [cardiac death, myocardial infarction, or target lesion revascularization]) between the SES and PES groups in patients overall and in 407 patient pairs generated by propensity-score matching.

Results We evaluated 1,033 patients with bifurcation lesions treated with SES and 562 patients treated with PES. The median follow-up duration was 22 months. Treatment with SES was associated with a lower incidence of MACE (hazard ratio [HR]: 0.53, 95% confidence interval [CI]: 0.32 to 0.89, $p < 0.01$) and target lesion revascularization (HR: 0.55, 95% CI: 0.31 to 0.97, $p = 0.02$), but not of cardiac death (HR: 2.77, 95% CI: 0.40 to 18.99, $p = 0.62$) and cardiac death or myocardial infarction (HR: 0.97, 95% CI: 0.38 to 2.49, $p = 0.94$). After propensity-score matching, patients with SES still had fewer MACE and target lesion revascularization incidences than did patients with PES (HR: 0.52, 95% CI: 0.30 to 0.91, $p = 0.02$, and HR: 0.48, 95% CI: 0.25 to 0.91, $p = 0.02$, respectively). There was no significant difference in the occurrences of stent thrombosis between the groups (0.7% vs. 0.7%, $p = 0.94$).

Conclusions In patients with bifurcation lesions, the use of SES resulted in better long-term outcomes than did the use of PES, primarily by decreasing the rate of repeat revascularization. (Coronary Bifurcation Stenting Registry in South Korea [COBIS]; NCT00851526) (J Am Coll Cardiol 2010;55:1743–50) © 2010 by the American College of Cardiology Foundation

Sirolimus-eluting stents (SES) and paclitaxel-eluting stents (PES) have been shown to markedly improve angiographic and clinical outcomes after percutaneous coronary intervention (PCI) when compared to bare-metal stents (1,2). A number of studies comparing the efficacy and safety of SES and PES have been performed in a variety of lesion subsets and clinical settings (3–7), but there are limited data comparing these 2 stents in the treatment of bifurcation lesions. Although 3 previous studies compared the clinical outcomes of patients treated with SES or PES for bifurcation lesions, these studies were small and underpowered, and the data from these studies are conflicting

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Abbreviations and Acronyms

DES = drug-eluting stent(s)
IQR = interquartile range
IVUS = intravascular ultrasound
MACE = major adverse cardiac events
MI = myocardial infarction
PCI = percutaneous coronary intervention
PES = paclitaxel-eluting stent(s)
SES = sirolimus-eluting stent(s)
ST = stent thrombosis
TLR = target lesion revascularization
TVR = target vessel revascularization

(8–10). Therefore, we sought to compare the long-term clinical outcomes after implantation of the 2 most widely available drug-eluting stent (DES) platforms for coronary bifurcation lesions using data from a dedicated, large, multicenter real-world registry.

Methods

Study population. The COBIS (Coronary Bifurcation Stent) registry was a retrospective multicenter registry dedicated to bifurcation lesion PCI with DES. It included data on consecutive patients from 16 major coronary intervention centers in Korea. Inclusion criteria were: 1) coronary bifurcation lesions treated solely with at least 1 DES between January 2004 and June 2006; and 2) main vessel diameter ≥2.5 mm and side branch diameter ≥2.0 mm. Exclusion criteria were the presence of cardiogenic shock, ST-segment elevation acute myocardial infarction (MI) within 48 h, life expectancy <1 year, or left main bifurcation. This registry was sponsored by the Korean Society of Interventional Cardiology. The local institutional review board at each hospital approved this study and waived the requirement for informed consent for access to the each institutional PCI registry.

To compare SES and PES, we selected patients in the COBIS registry database treated solely with SES or PES. Bifurcation lesions were classified according to the Medina classification, in which the proximal main vessel, distal main vessel, and side branch components of the bifurcation are each assigned a score of 1 or 0 depending on the presence or absence of >50% stenosis (11).

Percutaneous coronary intervention. All patients were administered loading doses of aspirin (300 mg) and clopidogrel (300 to 600 mg) or ticlopidine (500 mg) before the coronary intervention unless they had previously received these antiplatelet medications. Anticoagulation therapy during PCI was performed according to current practice guidelines by the Korean Society of Interventional Cardiology. The treatment strategy, stenting techniques, and selection of DES type were all left to the operator's discretion. Decisions to use glycoprotein IIb/IIIa receptor inhibitors or intravascular ultrasound (IVUS) were also made by the individual operators. Aspirin was continued indefinitely. The duration of thienopyridine treatment was also at the operator's discretion.

Follow-up and end points. Clinical, angiographic, procedural, and outcome data were collected with the use of a web-based reporting system. Additional information was obtained by further inquiry into medical records or telephone contact, if necessary. All baseline and procedural cine coronary angiograms were reviewed and qualitatively analyzed at the angiographic core laboratory in the Cardiac and Vascular Center, Samsung Medical Center, Seoul, Korea. Medina classification type 1.1.1, 1.0.1, and 0.1.1 lesions were defined as true bifurcation lesions.

The study end point was the occurrence of a major adverse cardiac event (MACE) during follow-up, defined as a composite of: 1) cardiac death; 2) MI; or 3) target lesion revascularization (TLR). All deaths were considered cardiac unless a definite noncardiac cause could be established. An MI was defined as elevated cardiac enzymes (troponin or myocardial band fraction of creatine kinase) more than the upper limit of the normal value with ischemic symptoms or electrocardiography findings indicative of ischemia that was not related to the index procedure. TLR was defined as repeat PCI of the lesion within 5 mm of stent deployment or bypass graft surgery of the target vessel. Target vessel revascularization (TVR) was repeat revascularization of the target vessel by PCI or bypass graft surgery. Periprocedural enzyme elevation was defined as a rise in creatine kinase-myocardial band ≥3 times the upper normal limit after the index procedure (12). The periprocedural period includes the first 48 h after PCI, and periprocedural enzyme elevation was not considered as MACE in our study. Stent thrombosis (ST) was assessed based on the definitions of the Academic Research Consortium as definite, probable, or possible stent thrombosis (12). The timing of ST was classified as early (within 1 month after index procedure), late (between 1 month and 1 year), or very late (after 1 year). All outcome data reported from the participating centers were reviewed by an independent clinical event adjudicating committee.

Statistical analyses. Differences between the groups of patients receiving SES and PES in baseline characteristics were compared using the *t* test or Wilcoxon rank-sum test for continuous variables, and the chi-square test or Fisher's exact test for categorical variables, as appropriate. Survival curves were constructed using Kaplan-Meier estimates and were compared with the log-rank test. Covariates statistically significant on univariate analysis and/or those clinically relevant were considered as candidate variables in the multivariate models. Adjusted hazard rates were compared by means of Cox regression with age, sex, acute coronary syndrome, diabetes mellitus, true bifurcation, stenting techniques, final kissing balloon inflation, use of IVUS, type of stent used, stent diameter, and total stent length. We also included use of clopidogrel as a time-dependent covariate (assessed at 1, 3, 6, and 12 months) in the model.

To reduce treatment-selection bias for stent type and potential confounding, we performed rigorous adjustment for baseline characteristics of patients using propensity score. The propensity scores were estimated using multiple logistic-regression analysis. A full nonparsimonious model was developed that included all variables listed in Tables 1 and 2. The discrimination and calibration abilities of the propensity-score model were assessed by means of the *c*-statistic and the Hosmer-Lemeshow statistic. Cox regression analysis using pairs matched by a greedy 5→1 matching algorithm was also performed. We assessed the balance in baseline covariates between the 2 groups in a propensity score–matched cohort. Continuous variables were compared with a paired *t* test or the Wilcoxon signed-rank test, as appropriate, and categorical variables were compared with the McNemar's or Bowker's test of symmetry, as appropriate. In the propensity score–matched population, a reduction in the risk of outcome was compared by use of a conditional Cox regression model (13). Cumulative incidence rates of individual clinical outcomes and composite outcomes were estimated by the Kaplan-Meier method and compared by the stratified Cox regression with clopidogrel use as a time-dependent variable. All p values are 2-tailed, and $p < 0.05$ was considered significant. All analyses were performed using a Statistical Analysis Software package (SAS version 9.1, SAS Institute, Cary, North Carolina).

Results

Baseline characteristics. OVERALL POPULATION. Among 1,919 patients registered, 251 patients did not fulfill the inclusion criteria by core laboratory cineangiographic analysis, and were excluded from the study. We also excluded other types of DES or mixed use of SES and PES (n = 73). A total of 1,595 patients was selected in the final analysis: 1,033 patients received SES and 562 patients received PES. Baseline demographic, clinical, angiographic, and procedural characteristics of the 2 groups are shown in Tables 1 and 2. The PES group had higher a prevalence of diabetes mellitus and acute coronary syndrome on admission. In the SES group, IVUS and final kissing balloon inflation were performed more frequently, and the diameter of side branch stents implanted was larger than that of the PES group. Other characteristics, including bifurcation site treated, Medina classification, and stenting technique, were similar in both groups. Main vessel stenting alone was primarily performed in both groups. There were no significant differences in procedural characteristics such as stent type, treatment strategy (1-stent vs. 2-stent), and use of glycoprotein IIb/IIIa inhibitors among centers. However, use of IVUS differed significantly according to the PCI volume of centers (data not shown).

PROPENSITY-MATCHED POPULATION. After performing propensity-score matching for the entire population, a total of 407 matched pairs of patients were created (Tables 1 and 2). The *c*-statistic for the propensity score model was 0.65, which indicates good discrimination (Hosmer-Lemeshow goodness of fit, p = 0.78). There were no significant differences in baseline clinical, angiographic, and procedural characteristics for the propensity-matched subjects.

Clinical outcomes. OVERALL POPULATION. Complete clinical follow-up data were obtained in 97.9% of all

Table 1 Baseline Clinical Characteristics

	Total Population			Propensity-Matched Population		
	PES (n = 562)	SES (n = 1,033)	p Value	PES (n = 407)	SES (n = 407)	p Value
Age, yrs	61.9 ± 10.9	62.1 ± 10.0	0.72	61.9 ± 11.2	62.2 ± 9.9	0.66
Age ≥65 yrs	246 (43.8)	432 (41.8)	0.45	183 (45.0)	171 (42.0)	0.40
Male	366 (65.1)	703 (68.1)	0.23	266 (65.4)	259 (63.6)	0.61
Clinical presentation			<0.01			0.87
Stable angina	205 (36.5)	463 (44.8)		159 (39.1)	155 (38.1)	
Unstable angina	245 (43.6)	398 (38.5)		164 (40.3)	162 (39.8)	
AMI	112 (19.9)	172 (16.7)		84 (20.6)	90 (22.1)	
Current smoker	144 (25.6)	242 (23.4)	0.33	101 (24.8)	101 (24.8)	>0.99
Diabetes mellitus	190 (33.8)	298 (28.8)	0.04	117 (28.7)	116 (28.5)	0.94
Hypertension	333 (59.3)	608 (58.9)	0.88	251 (61.7)	248 (60.9)	0.83
Dyslipidemia	180 (32.0)	316 (30.6)	0.55	118 (29.0)	123 (30.2)	0.70
Family history of CAD	21 (3.7)	41 (4.0)	0.82	18 (4.4)	13 (3.2)	0.36
Peripheral vascular disease	8 (1.4)	11 (1.1)	0.53	5 (1.2)	5 (1.2)	>0.99
Prior myocardial infarction	42 (7.5)	86 (8.3)	0.55	28 (6.9)	29 (7.1)	0.89
Prior cerebrovascular event	29 (5.2)	52 (5.0)	0.91	22 (5.4)	24 (5.9)	0.76
Chronic renal failure	18 (3.2)	34 (3.3)	0.92	13 (3.2)	7 (1.7)	0.17
LVEF, %*	59.3 ± 11.9	59.5 ± 11.4	0.80	58.7 ± 11.4	58.9 ± 11.4	0.88
LVEF <50%	68 (15.4)	126 (18.1)	0.24	50 (16.0)	54 (19.9)	0.21

Data are presented as mean ± SD or n (%). *Left ventricular ejection fraction (LVEF) was available for 1,139 patients.
AMI = acute myocardial infarction; CAD = coronary artery disease; PES = paclitaxel-eluting stent(s); SES = sirolimus-eluting stent(s).

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Table 2 Angiographic and Procedural Characteristics

	Total Population			Propensity-Matched Population		
	PES (n = 562)	SES (n = 1,033)	p Value	PES (n = 407)	SES (n = 407)	p Value
Vessel involved			0.10			0.49
LAD/diagonal	414 (73.7)	809 (78.3)		303 (74.4)	305 (74.9)	
LCX/OM	113 (20.1)	175 (16.9)		79 (19.4)	70 (17.2)	
RCA bifurcation	35 (6.2)	49 (4.7)		25 (6.1)	32 (7.9)	
Medina classification			0.22			>0.99
True bifurcation	399 (71.0)	703 (68.1)		294 (72.2)	294 (72.2)	
1.1.1	298 (53.0)	509 (49.3)		223 (54.8)	210 (51.6)	
1.0.1	27 (4.8)	76 (7.4)		18 (4.4)	33 (8.1)	
0.1.1	74 (13.2)	118 (11.4)		53 (13.0)	51 (12.5)	
Non-true bifurcation	163 (29.0)	330 (31.9)		113 (27.8)	113 (27.8)	
1.0.0	36 (6.4)	80 (7.7)		25 (6.1)	26 (6.4)	
0.1.0	49 (8.7)	109 (10.6)		34 (8.4)	28 (6.9)	
1.1.0	71 (12.6)	124 (12.0)		48 (11.8)	54 (13.3)	
0.0.1	7 (1.2)	17 (1.6)		6 (1.5)	5 (1.2)	
Stenting technique			0.39			0.85
Main vessel stenting only	472 (84.0)	850 (82.3)		340 (83.5)	338 (83.0)	
Stent in both branches	90 (16.0)	183 (17.7)		67 (16.5)	69 (17.0)	
T-stenting	42 (46.7)	86 (47.0)		33 (49.3)	36 (52.2)	
Crush	22 (24.4)	72 (39.3)		19 (28.3)	18 (26.1)	
Kissing stenting	21 (23.3)	20 (10.9)		13 (19.4)	12 (17.4)	
Culottes	5 (5.6)	5 (2.7)		2 (3.0)	3 (4.3)	
Final kissing balloon inflation	192 (34.2)	475 (46.0)	<0.01	168 (41.3)	172 (42.3)	0.78
Guidance of intravascular ultrasound	148 (26.3)	370 (35.8)	<0.01	105 (25.8)	105 (25.8)	>0.99
Use of glycoprotein IIb/IIIa inhibitor	25 (4.4)	33 (3.2)	0.20	18 (4.4)	20 (4.9)	0.74
Remote site intervention	144 (25.6)	250 (24.2)	0.53	114 (28.0)	103 (25.3)	0.38
Main vessel						
Total stent length (mm)	31.1 ± 13.9	30.0 ± 12.1	0.12	30.0 ± 12.2	29.8 ± 12.7	0.76
Maximal stent diameter (mm)	3.14 ± 0.32	3.13 ± 0.31	0.92	3.14 ± 0.32	3.16 ± 0.31	0.53
Side branch	(n = 90)	(n = 183)		(n = 70)	(n = 72)	
Total stent length (mm)	20.8 ± 8.5	22.3 ± 8.9	0.18	21.1 ± 7.4	21.3 ± 8.8	0.90
Maximal stent diameter (mm)	2.69 ± 0.25	2.77 ± 0.29	0.02	2.70 ± 0.29	2.75 ± 0.31	0.39

Data are presented as mean ± SD or n (%).
LAD = left anterior descending artery; LCX = left circumflex artery; OM = obtuse marginal branch; RCA = right coronary artery; other abbreviations as in Table 1.

patients. The median follow-up was 20 months (interquartile range [IQR]: 14 to 29) in the PES group and 23 months (IQR: 15 to 34) in the SES group. There were a total of 101 events during the entire study period. The incidence of MACE was significantly lower in patients with SES than in those with PES (Table 3, Fig. 1A). Although both groups had comparable incidences of cardiac death or MI, the SES group had a significantly lower incidence of TLR and TVR (Table 3, Fig. 1B). Treatment strategy (single vs. double stent), use of glycoprotein IIb/IIIa receptor antagonists, and use of IVUS did not influence the MACE in overall patients. Multivariate analysis showed that the use of SES was associated with significantly lower MACE and TLR rates (Table 3). The incidence of periprocedural enzyme elevation was similar in the 2 groups (14.7% in the SES group vs. 17.3% in the PES group, p = 0.25).

Definite or probable ST was noted in 11 patients (0.7%) during the follow-up period; early ST in 6 patients (0.4%), late ST in 2 patients (0.1%), and very late ST in 3 patients (0.4%). The status of dual antiplatelet therapy was available in 97.0% of patients 1 year after the index procedure. The median duration of clopidogrel use was similar in the 2 groups (12 months [IQR: 7 to 20]) in the SES group vs. 12 months [IQR: 7 to 19]) in the PES group, p = 0.82). Four patients died of early ST, although no cardiac deaths occurred among patients who experienced late or very late ST. Of patients who had definite or probable thrombosis, the SES group had 6 on dual antiplatelet therapy and 1 on aspirin only, and the PES group had 3 patients on dual antiplatelet therapy and 1 on aspirin only. The incidence of definite or probable ST was not significantly different between the groups (0.7% vs. 0.7%, p = 0.99).

PROPENSITY-MATCHED POPULATION. There were 54 events with a median follow-up of 22 months in the matched patients. With respect to the primary composite outcome, SES was still associated with a significantly better outcome in the matched cohort of patients than was PES (Table 3, Fig. 2A). Although there were no differences

Table 3 Clinical Outcomes in Patients Receiving SES Compared With PES

	PES	SES	Unadjusted HR (95% CI)	p Value	Adjusted HR* (95% CI)	p Value
Total population (n = 1,595)	(n = 562)	(n = 1,033)				
Cardiac death	2 (0.4)	11 (1.1)	3.01 (0.67–13.64)	0.26	2.77 (0.40–18.99)	0.62
Cardiac death or MI	14 (2.5)	18 (1.7)	0.69 (0.34–1.41)	0.62	0.97 (0.38–2.49)	0.94
TLR	38 (6.8)	38 (3.7)	0.53 (0.33–0.84)	<0.01	0.55 (0.31–0.97)	0.02
TVR	47 (8.4)	50 (4.8)	0.56 (0.37–0.84)	<0.01	0.58 (0.38–0.90)	0.02
MACE	49 (8.7)	52 (5.0)	0.56 (0.37–0.83)	<0.01	0.53 (0.32–0.89)	<0.01
Propensity-matched population (n = 814)	(n = 407)	(n = 407)				
Cardiac death	2 (0.5)	6 (1.5)	3.03 (0.61–15.10)	0.29	2.32 (0.44–12.17)	0.32
Cardiac death or MI	8 (2.0)	8 (2.0)	1.00 (0.37–2.69)	>0.99	0.89 (0.33–2.41)	0.82
TLR	29 (7.1)	14 (3.4)	0.46 (0.24–0.89)	0.02	0.48 (0.25–0.91)	0.02
TVR	36 (8.8)	20 (4.9)	0.53 (0.30–0.94)	0.03	0.55 (0.32–0.95)	0.03
MACE	35 (8.6)	19 (4.7)	0.52 (0.29–0.93)	0.02	0.52 (0.30–0.91)	0.02

*Adjusted covariates included age, sex, acute coronary syndrome, diabetes mellitus, true bifurcation, stenting techniques, final kissing ballooning, use of intravascular ultrasound, type of stent used, stent diameter, total stent length, and clopidogrel use.

CI = confidence interval; HR = hazard ratio; MACE = major adverse cardiac events; MI = myocardial infarction; TLR = target lesion revascularization; TVR = target vessel revascularization; other abbreviations as in Table 1.

between the 2 groups in the incidence of death or MI, patients with SES had a significantly lower rate of TLR and TVR compared with patients who had PES (Table 3, Fig. 2B). In multivariate analysis, SES was associated with significant reductions in the primary composite outcome and TLR (Table 3). The incidence of periprocedural enzyme elevation and definite or probable ST was similar in the 2 groups (17.4% in the SES group vs. 16.5% in the PES group, p = 0.71; and 1.0% in the SES group vs. 0.5% in the PES group, p = 0.41, respectively).

Subgroup analysis. To determine whether the superior outcomes for SES observed in the overall population were consistent, we calculated the unadjusted hazard ratio for MACE in various complex subgroups (Fig. 3). The rate of MACE was numerically lower in the SES group than in the PES group in all subgroups, although statistical significance was not found in patients with diabetes, non-true bifurcation, or those treated with 2-stent techniques. As shown in Figure 3, there were no significant interactions between the type of stent and MACE among the 5 subgroups.

Discussion

In the present study, we compared long-term clinical outcomes after implantation of SES or PES for the treatment of coronary bifurcation lesions in the largest dedicated bifurcation registry data to date. The main findings of this study were: 1) SES implantation was associated with a lower incidence of MACE than was PES implantation, driven mainly by the lower incidence of TLR; and 2) there was no difference in the rates of cardiac death, MI, or ST between the 2 groups.

Coronary bifurcation lesions are 1 of the most challenging lesion subsets and are known to have lower angiographic success rates and a higher risk of procedural complications with a greater restenosis rate than are nonbifurcation le-

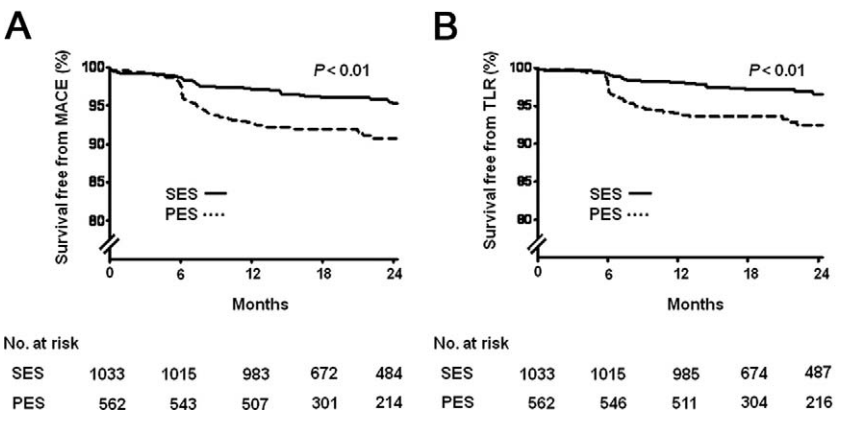

Figure 1 Kaplan-Meier Curves in Patients Receiving SES Versus PES

(A) Kaplan-Meier curves for major adverse cardiac events (MACE) in the overall population receiving sirolimus-eluting stents (SES) **(solid line)** versus paclitaxel-eluting stents (PES) **(dashed line)**. **(B)** Kaplan-Meier curves for target lesion revascularization (TLR) in the overall population receiving SES versus PES.

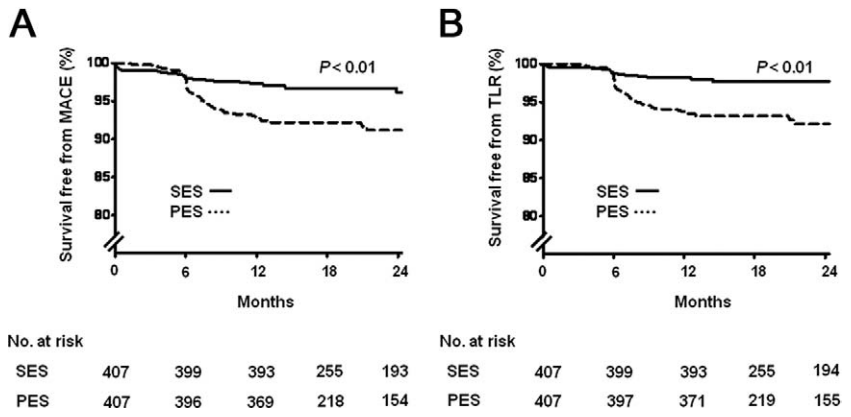

Figure 2 **Kaplan-Meier Curves in Propensity-Matched Patients Receiving SES Versus PES**

(A) Kaplan-Meier curves for major adverse cardiac events (MACE) in propensity-matched patients receiving sirolimus-eluting stents (SES) **(solid line)** versus paclitaxel-eluting stents (PES) **(dashed line)**. **(B)** Kaplan-Meier curves for target lesion revascularization (TLR) in propensity-matched patients receiving SES versus PES.

sions, even in the DES era (14,15). Considering that bifurcation lesions are frequent in real-world practice (16), it is very important to investigate which DES is most effective in treating bifurcation lesions. However, there are limited data regarding comparisons among DES in bifurcation lesions. Although 3 previous studies were performed comparing the clinical outcomes of patients treated with SES versus PES for bifurcation lesions, all of these studies were actually underpowered for the determination of clinical end points. Moreover, the data from these studies were conflicting, with 2 studies demonstrating significantly lower TLR rates for SES compared with PES (8,9) and the other showing no differences between the 2 stents (10). Therefore, we compared the long-term clinical outcomes after PCI with the 2 most widely available DES, SES, and PES, using the COBIS registry. This nationwide multicenter registry is solely dedicated to bifurcation lesions treated with DES; it is the largest registry for coronary bifurcation lesions to date. Broad indication may make it possible to reflect real-world practice and outcomes regarding PCI on bifurcation lesions. All baseline and procedural cine coronary angiograms were reviewed at the angiographic core laboratory and patients were thoroughly monitored.

In this study, we demonstrated that SES was more effective in improving long-term outcomes than was PES, primarily by decreasing repeat revascularization. Patients with PES have shown comparable clinical outcomes to those with SES in several studies (5–7), but the latter DES may be superior to the former in complex lesion subsets (17–19). Considering the complexity of bifurcation lesions,

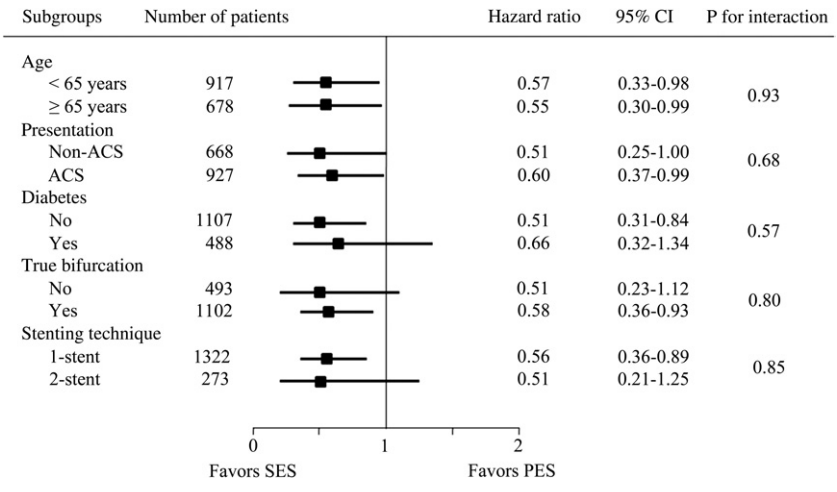

Figure 3 **Comparative Unadjusted Hazard Ratios of MACE for Subgroups**

ACS = acute coronary syndrome; CI= confidence interval; MACE = major adverse cardiac events; PES = paclitaxel-eluting stent(s); SES = sirolimus-eluting stent(s).

our results that SES decrease adverse outcomes seem to be relevant. However, the rates of cardiac death or MI were not significantly different between patients with SES and patients with PES. More potent inhibition of neointimal growth with SES than with PES may be translated into reduction of TLR in bifurcation lesions (4), but not into death or MI. In the present study, some baseline clinical and procedural characteristics were unfavorable in the PES group compared with those in the SES group: a higher prevalence of diabetes mellitus and acute coronary syndrome on admission; smaller stents in the side branch; and less frequent use of IVUS and final kissing balloon inflation. These factors may contribute to differences in adverse outcomes between SES and PES. However, we performed various adjustments including propensity score-matching to adjust for the differences in baseline characteristics between the groups, and the result was consistent in all patients and propensity-matched populations.

Across various subgroups, SES consistently showed better outcomes compared with those of PES. However, the superiority of SES was not statistically significant in patients with diabetes. There is some controversy regarding the efficacies of SES and PES in diabetic patients. Although SES had better outcomes than did PES in terms of late loss and angiographic restenosis in a randomized study (3), some registries have reported conflicting results on clinical outcomes (7,20), and a recent meta-analysis showed no differences in clinical outcomes between SES and PES in diabetic patients (21). Among diabetic patients, PES may be comparable to SES in bifurcation lesions, in contrast to patients without diabetes. However, no interaction was found between the type of DES and diabetes. Statistical significance was not found in patients treated with 2 stents, either. However, there was no interaction between the type of DES and stent technique. Our results may be simply attributable to a relatively small numbers of patients with diabetes or those treated with the 2-stent technique. Numerical differences were similar, and the tendency toward SES was consistent across all subgroups.

Study limitations. Our study had several limitations, including the fact that it was a nonrandomized, observational design, which may have significantly affected the results because of confounding factors. The selection of treatment strategies and stent types were at the discretion of the operators. Although we performed various risk-adjusted and propensity score-matched analyses to adjust for these potential confounding factors, we were not able to correct for the unmeasured variables and adjustment by propensity score resulted in a reduction of the original population with subsequent loss of statistical power. Moreover, we used many variables to reduce treatment selection bias for potential confounding in observational study, and the overfitting problems that this would increase are the limitations of this study. Our findings should be confirmed by adequately powered, randomized trials. Another limitation is that systemic angiographic follow-up was not performed, and coronary angiography was analyzed qualitatively, not quantitatively. Detailed quantitative coronary analysis may be helpful in further interpreting our findings.

Conclusions

The present study showed that SES implantation for the treatment of coronary bifurcation lesions resulted in a significantly reduced risk of MACE mainly driven by decreased TLR without a significant difference in cardiac death or MI compared with PES implantation.

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Key Words: angioplasty ■ bifurcation lesions ■ paclitaxel-eluting stent ■ sirolimus-eluting stent.