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*Circulation*. 2006;114:2148-2153; originally published online October 23, 2006;

doi: 10.1161/CIRCULATIONAHA.106.666396

*Circulation* is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

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Print ISSN: 0009-7322. Online ISSN: 1524-4539

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## Sirolimus-Eluting Stent Versus Paclitaxel-Eluting Stent for Patients With Long Coronary Artery Disease

Young-Hak Kim, MD, PhD; Seong-Wook Park, MD, PhD; Seung-Whan Lee, MD, PhD; Duk-Woo Park, MD; Sung-Cheol Yun, PhD; Cheol Whan Lee, MD, PhD; Myeong-Ki Hong, MD, PhD; Hyun-Sook Kim, MD, PhD; Jae-Ki Ko, MD, PhD; Jae-Hyeong Park, MD, PhD; Jae-Hwan Lee, MD, PhD; Si Wan Choi, MD, PhD; In-Whan Seong, MD, PhD; Yoon Haeng Cho, MD; Nae-Hee Lee, MD; June Hong Kim, MD, PhD; Kook-Jin Chun, MD, PhD; Seung-Jung Park, MD, PhD; for the Long-DES-II Study Investigators

**Background**—Outcomes remain relatively unfavorable for stent-based coronary intervention of lesions with long diseased segments. This study compared sirolimus-eluting stents (SES) and paclitaxel-eluting stents (PES) for long coronary lesions.

**Methods and Results**—The present randomized, multicenter, prospective study compared the use of long ( $\geq 32$  mm) SES with PES in 500 patients with long ( $\geq 25$  mm) native coronary lesions. The primary end point of the trial was the rate of binary in-segment restenosis according to follow-up angiography at 6 months. The SES and PES groups had similar baseline characteristics. Lesion length was  $33.9 \pm 11.6$  mm in the SES group and  $34.5 \pm 12.6$  mm in the PES group ( $P=0.527$ ). The in-segment binary restenosis rate was significantly lower in the SES group than in the PES group (3.3% versus 14.6%; relative risk 0.23;  $P<0.001$ ). In-stent late loss of lumen diameter was  $0.09 \pm 0.37$  mm in the SES group and  $0.45 \pm 0.55$  mm in the PES group ( $P<0.001$ ). In patients with restenoses, a pattern of focal restenosis was more common in the SES group than in the PES group (100% versus 53.3%,  $P=0.031$ ). Consequently, SES patients had a lower rate of target-lesion revascularization at 9 months (2.4% versus 7.2%,  $P=0.012$ ). The incidence of death (0.8% in SES versus 0% in PES,  $P=0.499$ ) or myocardial infarction (8.8% in SES versus 10.8% in PES,  $P=0.452$ ) at 9 months of follow-up was not statistically different between the 2 groups.

**Conclusions**—For patients with long native coronary artery disease, SES implantation was associated with a reduced incidence of angiographic restenosis and a reduced need for target-lesion revascularization compared with PES implantation. (*Circulation*. 2006;114:2148-2153.)

**Key Words:** coronary disease ■ stents ■ restenosis

Use of drug-eluting stents (DES) has reduced the incidence of restenosis rate and the need for repeat revascularization compared with the use of bare-metal stents.<sup>1</sup> The sirolimus-eluting stent (SES; Cordis, Johnson & Johnson, Miami Lakes, Fla) and paclitaxel-eluting stent (PES, Boston Scientific Corp, Natick, Mass) are currently the most often used DES worldwide.<sup>2</sup> Therefore, the relative efficacies of SES and PES have been evaluated in several randomized and registry studies.<sup>3-15</sup> Although some studies of complex lesions and patient subsets found SES to have greater efficacy than PES,<sup>3-5,9-11</sup> not all studies reported such findings.<sup>6-8</sup>

risk of unfavorable outcomes after percutaneous coronary intervention.<sup>9,14-18</sup> In the Long-DES Registry Study, SES was associated with a lower angiographic restenosis rate than PES in patients with lesions  $>24$  mm in length.<sup>9</sup> That study, however, used a nonrandomized observational methodology.

The present study, the Long-DES-II Study, compared long-term angiographic and clinical outcomes in patients with long coronary lesions treated with SES or PES. The study used a randomized, multicenter, controlled design approach.

### Clinical Perspective p 2153

Although the use of DES has decreased the effect of lesion length on restenosis, long coronary lesions remain at a higher

### Methods

#### Patient Selection

The present prospective, randomized, controlled, single-blinded study involved 500 patients  $\geq 18$  years of age who had angina

Received September 22, 2006; revision received October 6, 2006; accepted October 13, 2006.

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*Circulation* is available at <http://www.circulationaha.org>

DOI: 10.1161/CIRCULATIONAHA.106.666396

pectoris or a positive stress test and a native coronary lesion. The study involved 5 cardiac centers in Korea between August 2004 and August 2005. Angiographic eligibility for inclusion consisted of a target lesion with a diameter stenosis  $\geq 50\%$ , visual reference diameter  $\geq 2.5$  mm, and lesion length  $\geq 25$  mm. Inclusion required that the planned total stent length was  $\geq 32$  mm. Patients were excluded if they had (1) contraindication to aspirin, clopidogrel, or cilostazol; (2) left main disease (diameter stenosis  $\geq 50\%$  by visual estimate); (3) graft vessel disease; (4) left ventricular ejection fraction  $< 30\%$ ; (5) recent history of hematologic disease or leukocyte count  $< 3000/\text{mm}^3$  and/or platelet  $< 100\,000/\text{mm}^3$ ; (6) hepatic dysfunction with AST or ALT  $\geq 3$  times the upper normal reference limit; (7) history of renal dysfunction or a serum creatinine level  $\geq 2.0$  mg/dL; (8) serious noncardiac comorbid disease with a life expectancy  $< 1$  year; (9) planned bifurcation stenting in the side branch; (10) primary angioplasty for acute myocardial infarction (MI) within 24 hours; or (11) inability to follow the protocol. The institutional review board at each participating center approved the protocol. All patients provided written informed consent.

### Randomization and Procedures

Once the guidewire had crossed the target lesion, patients were randomly assigned to either SES or PES implantation on a 1:1 basis with sealed envelopes that contained a computer-generated randomization sequence. Stratified and block randomization was done according to participation sites. In patients with multiple lesions that fulfilled the inclusion and exclusion criteria, the operator determined the hierarchy of lesions and declared the target lesion for each patient before the procedure. The same type of allocated stent was used for all lesions in patients with multiple lesions.

Coronary stenting was performed according to the standard technique.<sup>9</sup> The decision of predilation or direct stenting was made by the operator. Beginning at least 24 hours before the procedure and continuing thereafter, all patients received aspirin (200 mg daily) and clopidogrel (a loading dose of 300 mg and then 75 mg daily for at least 6 months). To evaluate the effect of cilostazol on the reduction of in-stent late loss of lumen diameter after DES placement, cilostazol (a loading dose of 200 mg immediately after randomization and 100 mg twice a day for 6 months) was administered to 250 patients who were randomly allocated to receive this drug after the procedure on the basis of a 2-by-2 factorial design. The use of intravenous glycoprotein IIb/IIIa inhibitors was at the operator's discretion. A 12-lead ECG was obtained after the procedure and before discharge from the hospital. Serum levels of creatine kinase, its MB isoenzyme, and troponin I were assessed 8, 12, and 24 hours after the procedure and thereafter if considered necessary.

### Study End Point and Definitions

The primary end point of the trial was the rate of binary in-segment restenosis, defined as a diameter stenosis  $> 50\%$  with quantitative coronary angiography (QCA) at 6 months after the index procedure. The secondary end points included 9-month clinical and 6-month angiographic outcomes, such as rates of death; MI; target-lesion revascularization (TLR); target-vessel revascularization (TVR); composites of death, MI, and TLR/TVR; stent thrombosis; device success, defined as an in-segment final diameter stenosis  $< 50\%$  by QCA with the assigned device only; in-stent binary restenosis rate; and late loss, both in-stent and in-segment. Q-wave MI was defined by the postprocedural presence of new Q waves of  $> 0.04$  second in 2 contiguous leads. Non-Q-wave MI was defined as a creatine kinase-MB fraction or troponin I concentration  $> 3$  times the normal upper limit. TLR was considered clinically driven if prompted by symptoms or signs consistent with myocardial ischemia or if the lesion diameter stenosis was  $> 70\%$  at follow-up.<sup>7</sup> Stent thrombosis was defined as any of the following after the procedure<sup>19,20</sup>: angiographic documentation of stent occlusion with or without the presence of thrombus associated with an acute ischemic event, unexplained sudden death, or MI not clearly attributable to another coronary lesion.

### Follow-Up

Repeat coronary angiography was routinely recommended at 6 months after stenting or earlier if indicated by clinical symptoms or evidence of myocardial ischemia. Clinical follow-up visits were scheduled at 30, 90, 180, and 270 days. At every visit, physical examinations, ECGs, and laboratory examinations were conducted, and the occurrence of adverse cardiac events and the recurrence of angina were monitored. At each participating center, patient data were recorded prospectively on standard case report forms and gathered in the central data management center (Asan Medical Center, Seoul, Korea). All adverse clinical events were adjudicated by an independent events committee blinded to the treatment groups.

### QCA Analysis

Coronary angiograms were obtained before the procedure (baseline), after the procedure, and at follow-up and were submitted to the angiographic core analysis center (Asan Medical Center, Seoul, Korea) for analysis by independent angiographers. Digital angiograms were analyzed with an automated edge-detection system (CASS II, Pie Medical, Maastricht, the Netherlands). Angiographic variables included absolute lesion length, stent length, reference-vessel diameter, minimum lumen diameter, percent diameter stenosis, binary restenosis rate, immediate gain, late loss, and the patterns of recurrent restenosis. QCA measurements of target lesions were obtained for both the stented segment only (in-stent) and the region that included the stented segment and the margins 5 mm proximal and distal to the stent (in-segment). Lesion morphology was defined according to the guidelines of American College of Cardiology and American Heart Association.<sup>21</sup> Patterns of angiographic restenosis were quantitatively assessed with the Mehran classification.<sup>22</sup>

### Statistical Analysis

On the basis of the Long-DES Registry Study,<sup>9</sup> we assumed an in-segment angiographic restenosis rate of 9% in the SES group and 21% in the PES group. Using a 2-sided 5% significance level, we estimated that 201 patients per group were needed to detect this difference with a statistical power of 90%. Expecting that  $\approx 20\%$  of the patients would not return for angiographic follow-up, total sample size was estimated to be 500 patients (250 patients per group). Analyses of the 2 groups were performed according to the intention-to-treat principle. Because of a 2-by-2 factorial design, a possible interaction between types of DES and use of cilostazol was evaluated by logistic regression analysis. Continuous variables are presented as mean  $\pm$  SD or median (interquartile range), and compared with Student unpaired *t* or Mann-Whitney *U* tests and repeated-measures ANOVA with the Bonferroni correction for post hoc comparisons as appropriate. Categorical variables are presented as numbers or percentages and were compared with  $\chi^2$  or Fisher's exact tests. The relative risk and its 95% CI were computed for outcome measures. The Breslow-Day test was performed to assess treatment by participating center interaction.<sup>23</sup> The adjusted relative risk and CI after we controlled for the center interaction was computed by the Mantel-Haenszel method. A probability value  $< 0.05$  was considered to indicate a significant difference. Statistical analysis was performed with commercially available software (SPSS 11 for Windows, SPSS Inc, Chicago, Ill).

The authors had full access to the data and take full responsibility for the integrity of the data. All authors have read and agree to the manuscript as written.

## Results

### Baseline and Procedural Characteristics

A total of 500 patients were enrolled (250 SES and 250 PES subjects). Table 1 compares the baseline clinical and lesion characteristics between the 2 groups. The procedural characteristics are shown in Table 2. All stents were successfully implanted in all patients as randomly allocated. Device

**TABLE 1. Baseline Clinical and Lesion Characteristics**

Variable	SES (n=250)	PES (n=250)
Age, y	61.4±9.0	60.7±9.0
Male sex	168 (67.2)	153 (61.2)
Hypertension	138 (55.2)	137 (54.8)
Diabetes mellitus	82 (32.8)	84 (33.6)
Total cholesterol ≥200 mg/dL	72 (28.8)	74 (29.6)
Current smoker	93 (37.2)	94 (37.6)
Previous percutaneous coronary intervention	21 (8.4)	29 (11.6)
Previous coronary artery bypass surgery	8 (3.2)	6 (2.4)
Stable angina pectoris	112 (44.8)	115 (46.0)
Acute coronary syndrome	138 (55.2)	135 (54.0)
Unstable angina	92 (36.8)	84 (33.6)
MI within 2 weeks	46 (18.4)	51 (20.4)
Left ventricular ejection fraction, %	58.8±9.6	58.7±10.0
Multivessel involvement (≥2 epicardial arteries)	149 (59.6)	167 (66.8)
Target-lesion location		
Left anterior descending artery	155 (62.0)	152 (60.8)
Left circumflex artery	26 (10.4)	26 (10.4)
Right coronary artery	69 (27.6)	72 (28.8)
TIMI flow grade=0 or 1	42 (16.8)	39 (15.6)
Ostial location	41 (16.4)	35 (14.0)
Thrombus	14 (5.6)	15 (6.0)
Severe tortuosity	8 (3.2)	4 (1.6)
Severe calcium	12 (4.8)	5 (2.0)
Bifurcation (side branch ≥1.5 mm)	104 (41.6)	84 (33.6)

TIMI indicates Thrombolysis In Myocardial Infarction.  
Values are n (%) or mean±SD.

success rate was 99.2% in both groups. The 2 groups were treated with similar stented lengths.

### Angiographic Outcomes

Baseline and postprocedural QCA outcomes for the 2 groups are shown in Table 3. Both groups had similar baseline and postprocedural QCA characteristics in terms of lesion length, reference diameter, minimum lumen diameter, diameter stenosis, and immediate gain. Follow-up angiography was performed in 210 SES patients (84.0%) and 205 PES patients (82.0%;  $P=0.552$ ). The median duration of angiographic

**TABLE 2. Procedural Results**

Variable	SES (n=250)	PES (n=250)	<i>P</i>
Maximal device diameter, mm	3.48±0.41	3.50±0.40	0.357
Maximal inflation pressure, atm	15.9±3.4	14.9±3.7	0.013
Use of intravascular ultrasound	105 (42.0)	99 (39.6)	0.585
Predilation before stenting	248 (99.2)	245 (98.0)	0.450
Use of glycoprotein IIb/IIIa inhibitor	2 (0.8)	6 (2.4)	0.177
Multivessel stenting	93 (37.2)	112 (44.8)	0.084
Treatment of side branch after stenting	51 (20.4)	47 (18.8)	0.652
No. of stents used at the target lesion	1.4±0.6	1.5±0.6	0.142

Values are n (%) or mean±SD.

**TABLE 3. QCA Measurements**

Variable	SES (n=250)	PES (n=250)	<i>P</i>
Patients at follow-up angiography	210 (84.0)	205 (82.0)	0.552
Primary end point (in-segment angiographic restenosis)	7 (3.3)	30 (14.6)	<0.001
Reference diameter, mm	2.84±0.48	2.82±0.46	0.711
Lesion length, mm	33.9±11.6	34.5±12.6	0.527
Stent length, mm	40.6±13.2	41.1±13.4	0.696
Minimum lumen diameter, mm			
In-segment			
Before procedure	0.70±0.50	0.70±0.46	0.999
After procedure	2.16±0.46	2.18±0.46	0.616
At follow-up	2.13±0.48	1.87±0.62	<0.001
In-stent			
After procedure	2.48±0.40	2.50±0.37	0.504
At follow-up	2.35±0.49	2.04±0.66	<0.001
Diameter stenosis, %			
In-segment			
Before procedure	73.5±16.8	73.5±15.7	0.953
After procedure	16.7±11.6	15.9±11.8	0.450
At follow-up	20.1±15.0	31.4±20.1	<0.001
In-stent			
After procedure	6.4±16.1	5.7±16.3	0.652
At follow-up	13.0±19.4	26.2±23.1	<0.001
Immediate gain, mm			
In-segment	1.46±0.61	1.48±0.60	0.701
In-stent	1.78±0.55	1.80±0.54	0.662
Late loss, mm			
In-segment	0.24±0.38	0.61±0.54	<0.001
In-stent	0.09±0.37	0.45±0.55	<0.001
In-stent angiographic restenosis	6 (2.9)	24 (11.7)	0.001

Values are n (%) or mean±SD.

follow-up was 188 (interquartile range 178 to 200) and 186 (interquartile range 177 to 205) days for the SES and PES groups, respectively ( $P=0.857$ ). Results of QCA measurements at follow-up are shown in Table 3.

In-segment restenosis, the prespecified primary end point of the present study, was identified in 7 SES patients (3.3%) and 30 PES patients (14.6%; relative risk, 0.23; 95% confidence interval [CI], 0.10 to 0.51;  $P<0.001$ ). The in-stent restenosis rate was also lower in the SES group than in the PES group (2.9% versus 11.7%; relative risk, 0.24; 95% CI, 0.10 to 0.58;  $P=0.001$ ). After we controlled for the center interaction, almost identical relative risks for in-segment (Breslow-Day test,  $P=0.054$ ; relative risk, 0.25; 95% CI, 0.12 to 0.56) and in-stent restenosis (Breslow-Day test,  $P=0.139$ ; relative risk, 0.27; 95% CI, 0.12 to 0.64) were found between the 2 groups. The interaction between types of DES and use of cilostazol was not significant ( $P=0.219$  for in-segment restenosis and  $P=0.191$  for in-stent restenosis). Patterns of in-stent restenosis are shown in Table 4. In patients with restenoses, a pattern of focal restenosis (type I) was more common in the SES group than in the PES group

**TABLE 4. Angiographic Patterns of Restenosis\***

Variable	SES (n=7)	PES (n=30)	P
Focal, n (%)	7 (100)	16 (53.3)	0.031
IA (articulation or gap)	0	0	1.000
IB (margin)	0	6 (20.0)	0.571
IC (focal body)	6 (85.7)	8 (26.7)	0.007
ID (multifocal)	1 (14.3)	2 (6.7)	0.477
Diffuse, n (%)	0	14 (46.7)	0.031
II (intra-stent)	0	9 (30.0)	0.160
III (proliferative)	0	0	1.000
IV (total occlusion)	0	5 (16.7)	0.560
Length of in-stent restenosis, mm, mean±SD	5.5±3.1	11.6±7.1	0.016

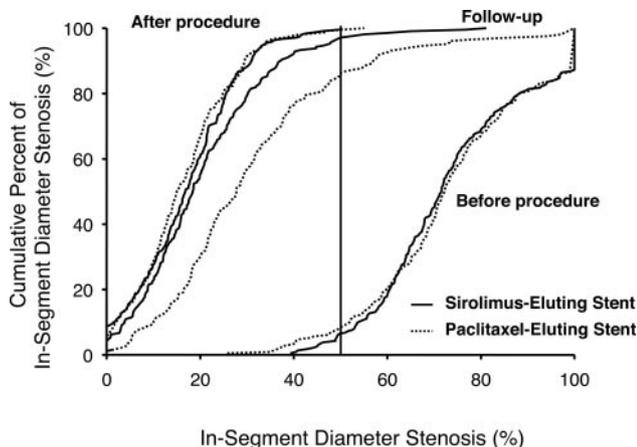
\*Classified with the Mehran criteria.<sup>22</sup>

(100% versus 53.3%,  $P=0.031$ ). Similarly, length of in-stent restenosis was shorter in the SES group than in the PES group.

Late loss of in-stent and in-segment lumen diameter was lower for the SES group than for the PES group. Consequently, minimum lumen diameter at follow-up was significantly larger in the SES group than in the PES group. The Figure shows the cumulative percent of in-segment diameter stenosis before and after the procedure and at follow-up angiography. Serial angiographic changes of in-segment minimum lumen diameter ( $P<0.001$ ) and percent diameter stenosis ( $P<0.001$ ) were significant over time, before and after the procedure and at follow-up in each group. Serial changes were also significantly different between the 2 groups with regard to in-segment minimum lumen diameter ( $P=0.021$ ) and diameter stenosis ( $P=0.001$ ).

### Clinical Outcomes

A minimum 9-month clinical follow-up was performed in 249 SES patients (99.6%) and 245 PES patients (98.0%;



Cumulative percent of in-segment percent diameter stenosis before and after the procedure and at follow-up angiography. In-segment percent diameter stenosis by QCA analysis in each group showed significant changes over time ( $P<0.001$ ), and these serial changes were significantly different between the 2 groups ( $P=0.001$ ).

**TABLE 5. Clinical Outcomes of Follow-Up**

Variable	SES (n=250)	PES (n=250)	P
Follow-up at 30 days			
Death	0	0	1.000
MI	21 (8.4)	27 (10.8)	0.362
Non-Q-wave	21 (8.4)	27 (10.8)	0.362
Q-wave MI	0	0	1.000
TLR	1 (0.4)	0	1.000
TVR	1 (0.4)	0	1.000
Stent thrombosis	1 (0.4)	0	1.000
Composite of death, MI, and TLR	21 (8.4)	27 (10.8)	0.362
Composite of death, MI, and TVR	21 (8.4)	27 (10.8)	0.362
Follow-up at 9 months			
Death	2 (0.8)	0	0.499
Cardiac	1 (0.4)	0	1.000
Noncardiac	1 (0.4)	0	1.000
MI	22 (8.8)	27 (10.8)	0.452
Non-Q-wave	21 (8.4)	27 (10.8)	0.362
Q-wave MI	1 (0.4)	0	1.000
TLR	6 (2.4)	18 (7.2)	0.012
TVR	8 (3.2)	19 (7.6)	0.030
Stent thrombosis	2 (0.8)	0	0.499
Composite of death, MI, and TLR	28 (11.2)	42 (16.8)	0.071
Composite of death, MI, and TVR	30 (12.0)	43 (17.2)	0.100

Values are n (%).

$P=0.216$ ). Clinical outcomes at 30 days and 9 months are shown in Table 5. Two SES patients (0.8%) and no PES patients died during the study period ( $P=0.499$ ). MI occurred in 22 SES patients (8.8%) and 27 PES patients (10.8%;  $P=0.452$ ). Forty-seven patients with MI (9.4%) were observed during hospitalization as having non-Q-wave infarctions related to the procedure. Stent thrombosis occurred in 2 SES patients and in no PES patients ( $P=0.499$ ). Of the 2 cases of stent thrombosis, 1 was angiographically documented. Consequently, the rates of TLR (2.4% versus 7.2%; relative risk, 0.33; 95% CI, 0.13 to 0.83;  $P=0.012$ ) and TVR (3.2% versus 7.6%; relative risk, 0.42; 95% CI, 0.19 to 0.94;  $P=0.030$ ) were lower in the SES group than in the PES group. Clinically driven TLR (1.6% versus 5.6%,  $P=0.028$ ) and TVR (2.4% versus 7.2%,  $P=0.012$ ) rates were also lower in the SES group than in the PES group.

### Discussion

Use of DES has been shown to improve both angiographic and clinical outcomes compared with the use of bare-metal stents.<sup>1</sup> Recent reports evaluating follow-up outcomes across various clinical and angiographic subgroups, however, showed that several factors conferred a higher risk of restenosis even after DES use.<sup>14,15</sup> A long diseased segment is a key predictor of worse prognostic outcome in terms of restenosis.<sup>14,15</sup> Therefore, an investigation to identify a differential outcome between the 2 leading DES in the treatment of long coronary lesions is clinically important to the physi-

cian's choice of stent during percutaneous coronary intervention. The previous Long-DES Registry Study showed that SES might be more effective in reducing angiographic restenosis than PES for treatment of long native coronary artery disease.<sup>9</sup> The present study further investigated the efficacy of these 2 leading DES using a randomized, controlled study design.

Several previous reports of randomized studies, registry data, and a meta-analysis showed that SES were more effective than PES in reducing the restenosis rate.<sup>3-5,8-11</sup> Those studies assumed that the lower late loss associated with SES might contribute to lower incidences of angiographic restenosis and repeat revascularization than PES.<sup>3-5,8-11,24,25</sup> Not all studies, however, found SES to be superior.<sup>6,7,12,13</sup> Some studies challenged the expected relationship between late loss and clinical outcome.<sup>12,13,26</sup> The present study supported the formal predictive model that late loss is closely related to long-term angiographic and clinical outcomes.<sup>2,24,25</sup> In the present study, SES consistently reduced late loss, the incidence of angiographic restenosis, and the need for TLR compared with PES in patients with long coronary lesions. In addition, the fact that a focal restenosis pattern was more common in SES patients may be an additional benefit, because the focal pattern is a predictor of benign clinical prognosis compared with the diffuse pattern.<sup>27</sup>

In terms of the prespecified primary end point, the present study found a 77.2% relative risk reduction (11.3% of absolute) in the in-segment restenosis rate in SES compared with PES patients. This relative reduction is greater than that reported in previous randomized studies that showed a 7% to 42% relative reduction,<sup>8</sup> possibly because the present study involved very complex coronary lesions with a long diseased segment, which may make differences between the performances of the 2 stents more pronounced. The previous studies with bare-metal stents suggested that the potential risk of restenosis in stent trials may be strongly dependent on the inclusion of patients with complex lesions.<sup>28,29</sup> Similarly, randomized trials involving more complex patients/lesions, such as the ISAR-DIABETES (Intracoronary Stenting and Angiographic Results: Do Diabetic Patients Derive Similar Benefit from Paclitaxel-Eluting and Sirolimus-Eluting Stents?) and the ISAR-DESIRE (ISAR: Drug-Eluting Stents for In-Stent Restenosis) study, showed a more significant benefit of SES over PES than trials that involved relatively simple lesions, such as the REALITY (Randomized multicenter head-to-head comparison of the sirolimus-eluting stent and the paclitaxel-eluting stent) and TAXi (A prospective randomized comparison between paclitaxel and sirolimus stents in the real world of interventional cardiology) trials.<sup>4-7</sup>

In the present study, the incidence of serious adverse clinical outcomes, such as death, MI, or stent thrombosis, was low for both groups. Although angiographic and clinical stent thrombosis occurred in 2 SES patients, the incidence of these events was not found to differ significantly between the 2 groups. This finding is consistent with previous randomized studies that showed that both types of DES were safe in terms of an acceptably low incidence of cardiac mortality and stent thrombosis.<sup>8</sup> The relatively high incidence of periprocedural non-Q-wave MI was related to the inclusion of patients with

complex lesions and a high prevalence of acute coronary syndrome.<sup>16-18</sup>

The late loss and restenosis rates for both stents were relatively low in the present study compared with the previous Long-DES Registry Study.<sup>9</sup> In the Long-DES Registry Study, in-stent late loss was 0.26 mm for SES and 0.78 mm for PES. In contrast, in the present study, in-stent late loss was 0.10 mm for SES and 0.43 mm for PES. Consequently, the in-stent angiographic restenosis rate was lower in the present study for both SES (2.9% versus 7.6%) and PES (11.7% versus 16.0%) implantations. The different outcomes in the 2 studies might be in part a result of differences in study design, enrolled patient/lesion characteristics, and stenting procedures. A significant interaction by 2-by-2 factorial design was not introduced into the primary outcome, however.

The present study has some limitations. First, the routine 6-month angiography performed in the study might have resulted in an underestimation of the rates of restenosis and TLR compared with a study with a longer angiographic follow-up period. The present median duration of angiographic follow-up of 187 days, however, was similar to that of previous studies.<sup>4,5</sup> Second, the present study was underpowered to detect differences in serious adverse clinical outcomes between the 2 groups. A large number of patients with longer follow-up may be required.

In conclusion, the present study showed that use of an SES resulted in a reduced incidence of angiographic restenosis and a reduced need for TLR compared with use of a PES.

## Sources of Funding

This study was supported by the Cardiovascular Research Foundation (Korea), a grant from the Korean Ministry of Health & Welfare as part of the Korea Health 21 Research & Development Project (0412-CR02-0704-0001), and a grant from Cordis, a Johnson & Johnson company (Miami, Fla).

## Disclosures

Young-Hak Kim and Seung-Jung Park have received research grants from Cordis.

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### CLINICAL PERSPECTIVE

Although drug-eluting stents improve the prognosis of percutaneous coronary intervention, long coronary lesions remain at a relatively higher risk of restenosis. The present randomized, controlled study comparing the efficacy of sirolimus-eluting stents (SES) with paclitaxel-eluting stents (PES) showed that the in-segment binary restenosis rate was significantly lower in the SES group than in the PES group (3.3% versus 14.6%; relative risk 0.23;  $P < 0.001$ ). In patients with restenoses, a pattern of focal restenosis, which has been considered more benign than a diffuse pattern, was more common in the SES group than in the PES group (100% versus 53.3%,  $P = 0.031$ ). Consequently, SES patients had lower target-lesion revascularization rates at 9 months (2.4% versus 7.2%,  $P = 0.012$ ). This result revealed that SES had better efficacy than PES in the treatment of long coronary lesions. In contrast to clinical trials that included simple coronary lesions, the present study involved very complex coronary lesions with a long diseased segment, which may make differences between the performances of the 2 stents more pronounced. Because SES and PES are the 2 leading drug-eluting stents, the present investigation may help physicians decide which treatment to use during percutaneous coronary intervention for long coronary lesions.