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Effectiveness of Sirolimus-Eluting Stent Implantation for the Treatment of Ostial Left Anterior Descending Artery Stenosis With Intravascular Ultrasound Guidance

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OBJECTIVES This study was designed to evaluate the clinical and angiographic outcomes of sirolimus-eluting stent (SES) implantation for ostial left anterior descending (LAD) lesions compared with bare-metal stent (BMS) implantation.

BACKGROUND The effectiveness of SES implantation for ostial LAD lesions is currently unknown.

METHODS Sirolimus-eluting stents were implanted in 68 consecutive patients with ostial LAD stenoses. The control group was composed of 77 patients treated with BMS during the preceding two years. In the SES group, for complete lesion coverage, stent positioning was intentionally extended into the distal left main coronary artery (LMCA) in 23 patients (34%) with intermediate LMCA narrowing.

RESULTS Compared with the BMS group, the SES group had more multivessel involvement, received fewer debulking atherectomies, underwent more direct stenting, had a greater number of stents, and had more segments stented. The procedural success rate was 100% in both groups. The six-month angiographic restenosis rate was significantly lower in the SES group than in the BMS group (5.1% vs. 32.3%, $p < 0.001$). During the one-year follow-up period, neither death nor myocardial infarction occurred in either group, but target lesion revascularization was less frequent in the SES group than in the BMS group (0% vs. 17%, $p < 0.001$). In the SES group, there were no restenoses in cases with LMCA coverage, compared with three restenoses (7.9%) in cases with precise stent positioning ($p = NS$).

CONCLUSIONS Sirolimus-eluting stent implantation in ostial LAD lesions achieved excellent results regarding restenosis and clinical outcomes compared with BMS implantation. This finding may be associated with reduced neointimal hyperplasia and complete lesion coverage. (J Am Coll Cardiol 2005;46:787–92) © 2005 by the American College of Cardiology Foundation

Although previous studies have reported favorable outcomes of percutaneous intervention in ostial left anterior descending artery (LAD) stenosis, stenting at this lesion remains challenging because of the frequent involvement of the distal left main coronary artery (LMCA) and the potential for left circumflex artery (LCX) closure (1–3). Furthermore, repeat intervention for in-stent restenosis is not easy to perform because it is technically more complex than the index procedure.

Striking results of early trials using sirolimus-eluting stents (SES) have extended generalized use of SES for complex coronary lesions (4–7). Recently, the safety and efficacy of SES implantation in aorto-ostial lesions was reported (8). However, there have been no published data regarding the results of SES implantation for ostial LAD stenosis. The present study sought to evaluate the clinical and angiographic outcomes of SES implantation for ostial LAD lesions compared with bare-metal stent (BMS) implantation.

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METHODS

Study population and design. From March 2003 to January 2004, SES were implanted in 68 consecutive patients with de novo ostial LAD lesions in three cardiac centers (SES group). A control group was composed of 77 patients treated with BMS during the preceding two years (BMS group) who had been included in our previous randomized study (9). This study showed that debulking atherectomy before stenting for ostial LAD stenosis did not decrease angiographic restenosis (9). Ostial stenosis was defined as a narrowing located within 3 mm of the vessel origin on the view of least foreshortened angiographic projection. Patients had either angina or objective evidence of ischemia and lesions with a diameter stenosis ≥50% and a reference vessel diameter ≥2.5 mm. Although the BMS group included lesions with lengths ≤15 mm, lesion length in the SES group was not restricted. The following criteria were used for exclusion: contraindication to antiplatelet agents, acute myocardial infarction within 48 h, left ventricular dysfunction (ejection fraction <40%), previous bypass surgery, heavily calcified lesions, significant involvement (≥50% of diameter stenosis) of the LMCA or the LCX ostium, and chronic total occlusion. The institutional review board approved the study, and informed consents were obtained.

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Abbreviations and Acronyms

BMS = bare-metal stent
CSA = cross-sectional area
EEM = external elastic membrane
IVUS = intravascular ultrasound
LAD = left anterior descending coronary artery
LCX = left circumflex coronary artery
LMCA = left main coronary artery
MLD = minimal luminal diameter
SES = sirolimus-eluting stent

Stenting procedures. In the BMS group, stent placement for exact positioning was performed as previously described (1,9). In the SES group, two different strategies were applied to the stenting procedure according to the presence of intermediate narrowing at the distal LMCA. In cases with intermediate narrowing at the distal LMCA, the distal LMCA was intentionally covered with SES to achieve complete lesion coverage (SES-I group), whereas in lesions with a normal LMCA, SES was implanted in a way similar to the BMS group (SES-II group). Intermediate LMCA narrowing necessitating complete coverage was predetermined as a visually estimated diameter stenosis ≥30% by angiography or cross-sectional narrowing ≥40% by intravascular ultrasound (IVUS). The IVUS examination was strongly encouraged for accurate lesion assessment and optimal stenting in both groups.

During the intervention, patients received an 8,000 U heparin bolus with a repeat bolus to keep the activated clotting time ≥250 s. The use of glycoprotein IIb/IIIa inhibitors was left to the operator's discretion. After stenting, all patients received aspirin (200 mg/day) indefinitely. The SES group was treated with clopidogrel (75 mg/day) for six months. In the BMS group, either clopidogrel or ticlopidine (250 mg twice a day) was administered for at least one month.

Angiographic analysis. All coronary angiograms were forwarded to the Asan Medical Center (Seoul, Korea) and analyzed by two experienced angiographers not involved in the procedure. Using the guiding catheter for magnification calibration and an on-line quantitative coronary angiographic system (ANCOR V2.0, Siemens, Solna, Sweden), minimal luminal diameter (MLD), percent diameter stenosis, and reference vessel diameter were measured before and after the intervention and at follow-up from the single matched view showing the smallest luminal diameter. The acute gain was calculated as the difference between the MLD before and after procedure. The late loss was defined as the difference between in MLD after procedure and at follow-up.

IVUS imaging and analysis. All IVUS images were also forwarded to the Asan Medical Center and analyzed by two experienced sonographers not involved in the procedure. Intravascular ultrasound was performed after the administration of 0.2 mg intracoronary nitroglycerin via a motorized transducer pullback system (0.5 mm/s) and a commercial scanner (SCIMED, Boston Scientific, Natick, Massachusetts) that consisted of a 30-MHz transducer within a 3.2-F imaging sheath. Quantitative IVUS analysis was performed for 61 lesions (90%) in the SES group and 59 lesions (77%) in the BMS group. Validation of cross-sectional area (CSA) measurements of external elastic membrane (EEM), lumen, plaque, and media by IVUS has been previously described (10). The plaque burden (%) was measured as 100 × (EEM CSA − lumen CSA)/EEM CSA. In the SES group, quantitative IVUS measurements at the distal LMCA were also performed. The measurements were done with a commercially available program for computerized planimetry (TapeMeasure, Indec System, Mountain View, California).

Clinical definitions and follow-up. Procedural success was defined as a Thrombolysis In Myocardial Infarction (TIMI) flow grade 3 and <30% residual diameter stenosis without major procedural or in-hospital complications such as death, Q-wave myocardial infarction, or emergency bypass surgery. Deaths that could not be classified were considered cardiac related. Significant stent-jail of the LCX ostium was defined as stent coverage and >50% diameter stenosis at the LCX ostium after the procedure. Angiographic restenosis was defined as >50% diameter stenosis within a stented segment.

All patients were clinically evaluated by office visits or telephone interviews. Major adverse cardiac events, including cardiac death, non-fatal myocardial infarction, and target lesion revascularization, were obtained during the follow-up period. Repeat coronary angiography was routinely performed at six months after stenting, or earlier if clinically indicated by symptoms or documentation of myocardial ischemia.

Statistical analysis. Data are expressed as mean ± 1 SD for continuous variables and as frequency (%) for categorical variables. Differences between groups were assessed by the Student *t* test for continuous variables and the chi-square test or Fisher exact test (if an expected frequency is <5) for categorical variables. A p value <0.05 was considered statistically significant. Statistical analysis was performed using commercially available software (SPSS 11 for Windows, SPSS Inc., Chicago, Illinois).

RESULTS

Baseline characteristics. The baseline clinical characteristics were similar between the two groups, except that the SES group had more multivessel involvement than the BMS group (Table 1). The baseline angiographic and IVUS data are shown in Table 2. Angiographically, the SES group had a smaller reference diameter and a longer lesion length than the BMS group.

Procedural results and in-hospital outcomes. The procedural success rate was 100% in both groups. Procedural characteristics are summarized in Table 3. The SES group,

Table 1. Baseline Clinical Characteristics

	SES	BMS	p Value
Patients	68	77	
Age, yrs	58.2 ± 9.0	57.8 ± 7.9	0.756
Male gender	48 (70.6)	62 (80.5)	0.163
Cardiac risk factors			
Hypertension	30 (44.1)	26 (33.8)	0.201
Diabetes mellitus	16 (23.5)	14 (18.2)	0.428
Hypercholesterolemia	12 (17.6)	21 (27.3)	0.168
Current smoking	24 (35.3)	37 (48.1)	0.120
Previous percutaneous coronary intervention*	6 (8.8)	4 (5.2)	0.389
Clinical manifestation*			0.145
Stable angina	23 (33.8)	15 (19.5)	
Unstable angina	41 (60.3)	56 (72.7)	
Myocardial infarction within 2 weeks	4 (5.9)	6 (7.8)	
Multi-vessel coronary disease (≥2 vessels)	33 (48.5)	7 (9.1)	<0.001
Left ventricular ejection fraction, %	61.3 ± 8.7	62.9 ± 9.9	0.318

*Analyzed by Fisher exact test. Values are given as numbers (%) or mean ± SD.
BMS = bare-metal stent; SES = sirolimus-eluting stent

compared with the BMS group, underwent more direct stenting and fewer debulking atherectomies and had more stents implanted per lesion and more segments stented. In addition, IVUS guidance and additional high-pressure balloons were used more frequently in the SES group than in the BMS group. The post-intervention MLD and lumen CSA were significantly larger in the BMS group due to greater acute gain than in the SES group (Table 2). However, post-procedural diameter stenosis was not different between the two groups due to the small reference diameter in the SES group. The SES group had a trend toward fewer significant stent-jail compared to the BMS group, without statistical significance (p = 0.067) (Table 3). Peri-procedural creatine kinase-MB elevation ≥3 times the upper normal value developed in five SES patients (7.4%) and in four BMS patients (5.2%) (p = 0.591). There were no cases of death, Q-wave myocardial infarction, emergency bypass surgery, or stent thrombosis during hospitalization in either group.

Follow-up angiographic and clinical outcomes. Six-month angiographic follow-up was performed on 59 SES patients (86.8%) and 62 BMS patients (80.5%). There was no significant difference in mean time to angiographic follow-up between the two groups (5.9 vs. 6.0 months, p =

Table 2. Quantitative Angiographic and Intravascular Ultrasound Characteristics

	SES	BMS	p value
Lesions	68	77	
Angiographic variables			
Distal reference vessel diameter, mm	2.86 ± 0.51	3.61 ± 0.54	<0.001
Lesion length, mm	24.6 ± 17.1	15.4 ± 5.2	<0.001
Minimal lumen diameter, mm			
Baseline	0.92 ± 0.53	1.04 ± 0.48	0.143
Final	2.97 ± 0.39	3.71 ± 0.56	<0.001
Follow-up	2.77 ± 0.56	2.13 ± 0.91	<0.001
Diameter stenosis, %			
Baseline	65.2 ± 15.7	71.1 ± 12.4	0.014
Final	−6.9 ± 12.0	−3.8 ± 13.8	0.147
Follow-up	−2.1 ± 19.0	40.9 ± 25.6	<0.001
Acute gain, mm	1.90 ± 0.62	2.67 ± 0.65	<0.001
Late loss, mm	0.22 ± 0.52	1.60 ± 0.81	<0.001
Restenosis*	3/59 (5.1)	20/62 (32.3)	<0.001
Intravascular ultrasound variables			
EEM CSA, mm^2			
Baseline	13.91 ± 3.98	14.33 ± 3.80	0.573
Final	15.89 ± 3.05	18.32 ± 3.49	<0.001
Lumen CSA, mm^2			
Baseline	2.35 ± 0.68	1.91 ± 0.34	<0.001
Final	7.39 ± 1.40	9.57 ± 2.04	<0.001
Plaque burden, %			
Baseline	82.3 ± 5.0	86.0 ± 3.4	<0.001
Final	53.0 ± 6.0	47.5 ± 6.7	<0.001

*Analyzed by Fisher exact test. Values are given as numbers (%) or mean ± SD.
CSA = cross-sectional area; EEM = external elastic membrane; other abbreviations as in Table 1.

Table 3. Procedural Characteristics

	SES	BMS	p Value
Patients	68	77	
Intervention of other coronary lesions	19 (27.9)	7 (9.1)	0.003
Direct stenting*	24 (35.3)	0 (0)	<0.001
Debulking coronary atherectomy*	1 (1.5)	38 (49.4)	<0.001
Cutting balloon angioplasty*	2 (2.9)	0 (0)	0.218
Guidance of intravascular ultrasound*	61 (89.7)	59 (76.6)	0.037
Use of glycoprotein IIb/IIIa inhibitors*	1 (1.5)	2 (2.6)	1.000
Use of additional high-pressure balloons	39 (57.4)	11 (14.7)	<0.001
Stents per lesion	1.4 ± 0.6	1.0 ± 0.2	<0.001
Contiguous stent length, mm	31.2 ± 19.3	16.6 ± 5.2	<0.001
Maximal device size, mm	3.77 ± 0.39	3.94 ± 0.56	0.037
Maximal inflation pressure, atm	17.6 ± 3.1	14.9 ± 2.6	<0.001
Kissing balloon inflation after stenting*	12 (17.6)	4 (5.2)	0.031
Stent-jail*	1 (1.5)	7 (9.1)	0.067

*Analyzed by Fisher exact test. Values are given as numbers (%) or mean ± SD.
Abbreviations as in Table 1.

0.76). Late lumen loss (0.22 ± 0.52 mm vs. 1.60 ± 0.81 mm, $p < 0.001$) and binary restenosis rate (5.1% vs. 32.3%, $p < 0.001$) was significantly lower in the SES group than in the BMS group (Table 2). Cumulative frequency curves of the MLD before and after the procedure and at follow-up are shown in Figure 1. Clinical follow-up at one year was available for all patients in the two groups. At one year, there were no deaths or Q-wave myocardial infarction in either group, but target lesion revascularization was significantly lower in the SES group than in the BMS group (0% vs. 16.9%, $p < 0.001$). Three restenotic lesions occurred in the SES group, all of which were focally involved and did not require repeat revascularization because they had angiographic diameter stenosis ≤70% without symptoms or objective evidence of ischemia.

Results of two SES implantation techniques. Comparison of the quantitative angiographic and IVUS data between the SES-I group and the SES-II group is summarized in Tables 4 and 5. The SES-I group had smaller MLD and more plaque burden at the distal LMCA than the SES-II group. There were no statistically significant differences regarding target lesion characteristics. The reference diameter and MLD of the LCX ostium in the SES-I group was significantly smaller than that in the SES-II group, but the diameter stenosis was not different between two groups at baseline. Final kissing balloon dilation was more frequently used in the SES-I group (39.1%) than in the SES-II group (6.7%) ($p = 0.001$). Immediately after intervention, there were no significant differences in quantitative angiographic and IVUS results concerning target lesions between the two groups, and this trend continued in the follow-up angiography. Additionally, the LCX ostial diameters after stenting and at follow-up did not differ significantly between the two groups.

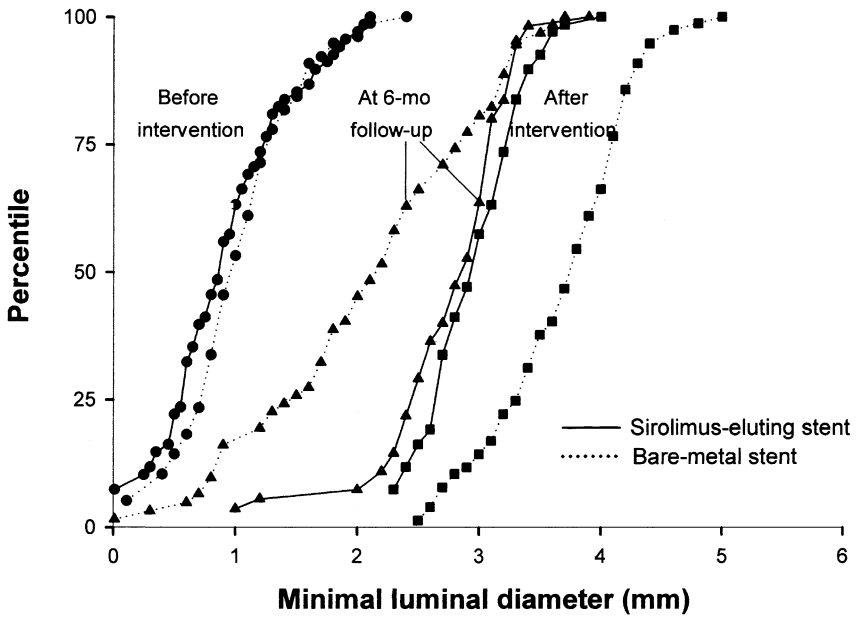

Figure 1. Comparison of the cumulative distribution curves for minimal luminal diameter between the patients who received sirolimus-eluting stents and bare-metal stents before and immediately after the intervention and at six months' follow-up.

Table 4. Comparisons of Quantitative Angiographic Analysis

	SES-I	SES-II	p Value
Patients	23	45	
Distal left main before procedure			
Reference, mm	3.78 ± 0.66	4.00 ± 0.54	0.157
Minimal lumen diameter, mm	2.38 ± 1.01	3.67 ± 0.62	<0.001
Diameter stenosis, %	33.8 ± 25.8	7.7 ± 13.7	<0.001
Left circumflex ostium			
Reference diameter, mm	2.63 ± 0.63	3.09 ± 0.59	0.004
Minimal lumen diameter, mm			
Baseline	2.17 ± 0.59	2.78 ± 0.66	<0.001
Final	2.08 ± 0.69	2.73 ± 0.58	0.936
Follow-up	1.99 ± 0.69	2.63 ± 0.57	0.254
Diameter stenosis, %			
Baseline	16.4 ± 18.7	10.0 ± 14.3	0.120
Final	21.7 ± 22.8	13.5 ± 15.0	0.513
Follow-up	24.1 ± 21.8	13.3 ± 14.4	0.320
Stent-jail after procedure*	1 (4.3)	0 (0)	0.338
Target lesion			
Lesion length, mm	21.7 ± 12.9	26.1 ± 18.8	0.321
Distal reference diameter, mm	2.87 ± 0.48	2.85 ± 0.53	0.873
Minimal lumen diameter, mm			
Baseline	1.00 ± 0.54	0.88 ± 0.52	0.400
Final	2.97 ± 0.35	2.97 ± 0.42	0.936
Follow-up	2.88 ± 0.32	2.71 ± 0.65	0.270
Diameter stenosis, %			
Baseline	64.8 ± 19.4	65.4 ± 13.4	0.902
Final	−5.6 ± 10.94	−7.6 ± 12.6	0.513
Follow-up	−6.2 ± 11.89	0.3 ± 21.9	0.224
Restenosis*	0/21 (0)	3/38 (7.9)	0.546

*Analyzed by Fisher exact test. Values are given as numbers (%) or mean ± SD.
SES-I = covering distal main coronary artery; SES-II = precise location.

DISCUSSION

The major finding of this study is that SES implantation for ostial LAD lesions was safe without procedural complications or stent thrombosis and effective in decreasing in-stent restenosis and target lesion revascularization as compared to BMS implantation. In addition, in cases with intermediate distal LMCA involvement, stenting covering the distal LMCA across the LCX ostium with IVUS guidance achieved complete lesion coverage and led to favorable clinical outcomes that were comparable with precise location.

This study has been designed so that the results of SES implantation were compared with those of BMS implantation that was conducted during a different period. Therefore, there are significant differences between the two groups in terms of the clinical and procedural characteristics. The BMS group had shorter and larger vessels and more debulking atherectomy, assuring greater acute gain. On the other hand, a less restrictive approach applied to the SES group, which had more complex lesion characteristics implying a higher risk of suboptimal procedure and restenosis. Nevertheless, the SES group achieved similar post-procedural diameter stenosis and remarkably lower incidence of angiographic restenosis compared with the BMS group. These findings indicate that SES appear effective in obtaining favorable procedural results and improving long-term outcomes, even in complex ostial lesions.

Importantly, in this study, we performed a stenting strategy for complete lesion coverage in cases with intermediate distal LMCA narrowing. The previous report suggested that the relatively high restenosis rate (14.7%) in ostial lesions might be associated with incomplete lesion coverage due to the technical difficulties encountered in

Table 5. Comparisons of Quantitative Intravascular Ultrasound Analysis

	SES-I	SES-II	p Value
Patients	20	41	
Distal left main			
Before procedure			
EEM CSA, mm^2	19.64 ± 6.33	20.57 ± 5.38	0.574
Lumen CSA, mm^2	9.86 ± 2.83	12.39 ± 3.71	0.014
Plaque burden, %	48.01 ± 11.47	39.75 ± 8.22	0.004
Target lesion			
Before procedure			
EEM CSA, mm^2	13.68 ± 4.34	14.03 ± 3.85	0.770
Lumen CSA, mm^2	2.26 ± 0.50	2.39 ± 0.76	0.532
Plaque burden, %	82.28 ± 5.06	82.30 ± 5.06	0.993
After procedure			
EEM CSA, mm^2	15.41 ± 3.11	16.11 ± 3.03	0.420
Lumen CSA, mm^2	7.35 ± 1.69	7.42 ± 1.25	0.866
Plaque burden, %	52.16 ± 6.37	53.44 ± 5.84	0.451

Values are given as mean ± SD.
CSA = cross-sectional area; EEM = external elastic membrane; SES-I = covering distal main coronary artery; SES-II = precise location.

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stent positioning (7,11). More specifically, our study showed that mean late loss was similar to the results of the SES implantation in aorto-ostial lesions, but the binary restenosis rate was approximately half of the previous value (8). These more favorable results, compared with recent data of SES implantation for ostial lesions (7,8,11), may be explained by the different stenting strategy. Also, complete lesion coverage with provisional kissing balloon dilation in cases with normal LCX showed the feasibility of this technique in preserving the LCX ostial patency after procedure and at follow-up. This favorable result was experienced in our recent study on the efficacy of SES for unprotected LMCA (12).

Study limitations. Our study has several limitations, including the fact that it was conducted in a non-randomized basis and included a small study population. Furthermore, the study period for the SES group was not extended long enough to compare long-term clinical outcomes with the BMS group. Therefore, our findings cannot be directly extrapolated to the entire population with ostial LAD lesions. However, our study indicates that SES implantation with a modified stenting technique may achieve excellent outcomes in ostial LAD lesions, similar to the outcomes seen in relatively simple coronary lesions (4,5).

Conclusions. Sirolimus-eluting stent implantation in ostial LAD lesions achieves excellent results regarding angiographic restenosis and clinical outcomes compared with BMS implantation. These results may be explained by reduced neointimal hyperplasia and the complete lesion coverage strategy.

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