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Long-Term Outcome of Simultaneous Kissing Stenting Technique With Sirolimus-Eluting Stent for Large Bifurcation Coronary Lesions

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Objectives: This study was conducted to evaluate the outcomes of simultaneous kissing stenting with sirolimus-eluting stent (SES). **Background:** Percutaneous intervention for bifurcation coronary lesions is still challenging. **Methods:** This study was designed to evaluate the long-term outcomes of 36 consecutive patients with large bifurcation coronary lesions who underwent simultaneous kissing stenting with SES. **Results:** Lesion location was unprotected left main in 29 patients (81%) and anterior descending artery in 7 (19%). The patients received a combination of aspirin and clopidogrel for 6 months and cilostazol for 1 month. Mean proximal reference diameter was 4.05 ± 0.68 mm. Compared with the side branch (SB), the main vessel (MV) involved longer lesions (25.8 ± 17.0 mm vs. 10.2 ± 10.8 mm, $P < 0.001$) and smaller preprocedural minimal lumen diameters (1.02 ± 0.53 mm vs. 1.46 ± 0.78 mm, $P = 0.006$) and was treated with larger stents (3.1 ± 0.3 mm vs. 3.0 ± 0.3 mm, $P = 0.006$). Angiographic success rate was 100%. Over the follow-up of 26.7 ± 8.6 months, no deaths, myocardial infarctions or stent thromboses occurred. Target lesion revascularization was performed in five patients (14%). Overall angiographic restenosis occurred in 5/30 patients (17%), consisting of 4 (13%) at MV and 3 (10%) at SB. At follow-up angiography, a membranous diaphragm at the carina was identified in 14 patients (47%), but only one of whom was associated with angiographic restenosis. **Conclusion:** Simultaneous kissing stenting with SES appears a feasible stenting technique in large bifurcation coronary lesions. However, a new angiographic structure of carinal membrane developed in a half of patients at follow-up and its influence needs to be further investigated.

Key words: bifurcation disease; stent; sirolimus; restenosis

INTRODUCTION

Percutaneous coronary intervention for bifurcation coronary lesions has been considered technically demanding and shown to be associated with high incidence of repeat revascularization rate than nonbifurcation lesions [1]. Although DES significantly decreased the need of repeat revascularization, a bifurcation lesion remains a predictor of worse prognosis in DES implantation [2–15].

Simultaneous kissing stenting technique is a revisited bifurcation stenting technique using DES [2–4,16]. We evaluated the long-term clinical and angiographic outcomes of simultaneous kissing stenting technique with sirolimus-eluting stents (SES, Cypher, Cordis) in the treatment of large bifurcation coronary lesions.

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MATERIALS AND METHODS

Patient Population

From March 2003 to September 2005, 36 consecutive patients with ischemic coronary artery disease at 36 bifurcation lesions who underwent simultaneous kissing stent placement with SES were enrolled in this study. All patients provided written informed consent before all procedures. Institutional review board approved this study.

Stenting Procedures

Simultaneous kissing stenting technique was selected at the operators' discretion when the bifurcation coronary lesions involved both the main vessel (MV) and the side branch (SB) and had a large proximal segment, which can accommodate two stents. Before the procedure, the degree of stenosis and morphological characteristics of MV and SB were carefully examined by angiography and intravascular ultrasound (IVUS). When the disease at distal left main coronary artery was extended to the major trifurcation with involvement of the ostial ramus intermedius branch as well as the ostial left anterior descending artery or left circumflex artery, this technique was not indicated.

The procedure was performed as previously described [1–4]. In patients with tight stenosis, predilation was performed prior to stent positioning to facilitate stent delivery and good visualization of stent location. After predilation, two stents were inserted into both branches. Stent size was selected at the operator's discretion on the basis of angiographic and IVUS findings of the proximal and distal references of both the MV and SB. In lesions at the left main coronary artery, left anterior descending artery and left circumflex artery were considered MV and SB, respectively. To make a short new carina, the proximal overlapping segment was kept as short as possible. However, stents were positioned to cover the lesion completely while keeping the proximal marker of both stents overlapped at the same site. After repeated confirmation of stent positions, they were sequentially dilated at high pressure (more than 12 atm) to achieve adequate stent expansion distal to the bifurcation, with the stent in the MV dilated first in most patients. Simultaneous kissing balloon inflation was performed before completing the procedure by dilating both stents with the balloon-to-artery ratio of $\sim$1.5 at the proximal segment. Inflation pressure of the two balloons was decided according to the vascular size of both branches. If the stent(s) appeared underdilated, additional balloon inflation was performed with more pressure. IVUS was used for guidance before and after the procedure. Debulking atherectomy was used in one patient (2.8%) to facilitate stent delivery to the target lesion. The use of glycoprotein IIb/IIIa inhibitors was left to the operators' discretion. Platelet function test was not routinely performed before the procedure. All patients received aspirin (200 mg/day) indefinitely and a loading dose of 300 mg clopidogrel followed by a single 75 mg dose daily for 6 months. In addition, 200 mg cilostazol was administered as a loading dose, followed by 100 mg twice daily for 1 month [17].

Definitions and Follow-up

Angiographic success was defined as $<$50% diameter stenosis with **T**hrombolysis **I**n **M**yocardial **I**nfarction flow grade 3 in both the MV and the SB [5]. Q-wave myocardial infarction was defined by the postprocedural presence of new Q-waves of greater than 0.04 sec in two contiguous leads. Non-Q-wave myocardial infarction was defined as a creatine kinase-MB greater than three times the normal upper limit. Target lesion revascularization was performed in patients who had restenoses at target lesions and evidence of recurrent myocardial ischemia as assessed by symptoms or myocardial stress tests. All patients were evaluated clinically by office visits or telephone interviews at 1, 3, and 6 months after stenting, and then every 4 months. Repeat coronary angiography was routinely recommended 6 months after stenting or earlier if clinically indicated.

Angiographic Analysis

Coronary angiography was performed after administering 0.2 mg of intracoronary nitroglycerin, and the results were analyzed by two experienced angiographers. Using the guiding catheter for magnification calibration and an on-line QCA system (CASS II; Pie Medical, Maastricht, the Netherlands), minimal lumen diameter (MLD), percent diameter stenosis, and reference vessel diameter were measured before and after intervention and at follow-up. In calculating diameter stenosis, the mean and distal reference diameters were considered to be the reference diameters in the MV and SB, respectively. Acute gain was calculated as the difference between the MLD before and after the procedure, and late loss was defined as the difference between the MLD after the procedure and at follow-up. Bifurcation lesions were categorized by the Duke classification [1]. A type D bifurcation is a lesion involving the MV and the ostium of the SB. Angiographic restenosis was defined as a >50% diameter stenosis at the target site and was classified as focal ($<$10 mm in length) or diffuse ($\geq$10 mm in length).

Quantitative IVUS Analysis

Preintervention and postintervention IVUS images were obtained using a commercial IVUS system

TABLE I. Baseline Clinical and Lesion Characteristics

Variables	$N = 36$
Age (years)	61.2 ± 9.1
Men	25 (69%)
Hypertension	17 (47%)
Smoker	13 (36%)
Diabetes mellitus	9 (25%)
Total cholesterol ≥200 mg/dl	6 (17%)
Clinical manifestation	
Stable angina	16 (44%)
Unstable angina	18 (50%)
Acute myocardial infarction within 2 weeks	2 (6%)
Multivessel coronary disease except left main	25 (70%)
Previous percutaneous coronary intervention	8 (22%)
Previous coronary artery bypass surgery	0
Left ventricular ejection fraction (%)	62.7 ± 6.1
Lesion location	
Left main	29 (81%)
Left anterior descending artery	7 (19%)
Type of bifurcation	
Type A	0
Type B	2 (6%)
Type C	6 (17%)
Type D	26 (72%)
Type E	1 (3%)
Type F	1 (3%)

TABLE II. Quantitative Angiographic Measurements at Both Branches

Variables	Main vessel	Side branch	P value
Lesion length (mm)	25.8 ± 17.0	10.2 ± 10.8	<0.001
Proximal reference diameter (mm)	4.05 ± 0.68	–	–
Distal reference diameter (mm)	2.69 ± 0.46	2.77 ± 0.52	0.502
Minimal lumen diameter (mm)			
Baseline	1.02 ± 0.53	1.46 ± 0.78	0.006
After procedure	2.87 ± 0.41	2.66 ± 0.45	0.044
At follow-up	2.51 ± 0.63	2.20 ± 0.68	0.076
Diameter stenosis (%)			
Baseline	70.8 ± 14.2	48.4 ± 24.0	<0.001
After procedure	17.3 ± 10.7	−0.8 ± 16.2	<0.001
At follow-up	26.2 ± 15.8	18.7 ± 17.9	0.102
Acute gain (mm)	1.85 ± 0.51	1.20 ± 0.63	<0.001
Late loss (mm)	0.30 ± 0.54	0.49 ± 0.53	0.186
Angiographic restenosis	4/30 (13%)	3/30 (10%)	1.000
Cumulative angiographic restenosis	5/30 (17%)		

(SciMed/Boston Scientific, Natick, NA) and motorized pullback of the ultrasound catheter at 0.5 mm/sec. The external elastic membrane and lumen cross-sectional areas were measured using computerized planimetry, according to validated and published protocols [18]. The lesion sites, defined as the image slices within the analysis segment, and reference segments in the MV were analyzed.

Statistical Analysis

Continuous variables are presented as mean ± SD. Categorical variables are presented as counts or proportions (percentages). Differences were compared using χ^2 or Fisher exact tests for categorical variables, and Student's t test for continuous variables as appropriate. Target lesion revascularization-free survival distribution was estimated according to the Kaplan-Meier method. A P value < 0.05 was considered to indicate a significant difference. Statistical analysis was performed using commercially available software (SPSS 11 for windows, SPSS, Chicago, IL).

RESULTS

Baseline Demographics

Tables I and II show the baseline clinical and angiographic characteristics, respectively. Lesion location was unprotected left main in 29 patients (81%) and anterior descending artery in 7 patients (19%). Type D true bifurcation lesion was present in 26 patients (72%). Compared with the SB, the MV involved longer lesions and smaller preprocedural MLD. Table III showed the quantitative IVUS results of MV before and after the procedure. Target lumen in the MV was increased significantly at the proximal and distal to the bifurcation.

Procedural Results

Tables IV and V show the procedural findings. Sequential stent dilatation before kissing inflation was performed in 25 (69%) patients and multivessel intervention in 14 (39%). Compared with the SB, the MV was treated with more and larger stents, and dilated with a larger balloon-to-artery ratio at maximal stent inflation and kissing balloon inflation. Therefore, postprocedural MLD and acute gain were larger in MV than in SB (Table II). The angiographic success rate was 100%. After the procedure, all lesions which were evaluated by IVUS achieved optimal final lumen area, defined as ≥5.0 mm^2 [19] at the MV of target lesion. However, postprocedural IVUS evaluation at the SB was not routinely performed. Periprocedural creatine kinase-MB elevation >3 times normal occurred in four patients (11%). There were no incidents of death, Q-wave myocardial infarction, stent thrombosis, or emergent target lesion revascularization during hospitalization.

Follow-up Results

Clinical information was gathered in all patients at a mean follow-up of 26.7 ± 8.6 months (range, 7.9–37.6 months). No deaths, myocardial infarctions, or stent

TABLE III. Quantitative Analysis of Intravascular Ultrasound in Main Vessel

	Before procedure	After procedure	*P* value
Lesions	25	33	
Proximal reference			
EEM CSA (mm^2)	22.0 ± 3.2	23.9 ± 3.4	0.038
Lumen CSA (mm^2)	11.4 ± 2.8	14.4 ± 3.5	0.001
Minimal lumen diameter (mm)	3.47 ± 0.43	3.84 ± 0.38	0.001
Distal reference			
EEM CSA (mm^2)	12.2 ± 3.0	11.8 ± 3.3	0.669
Lumen CSA (mm^2)	7.4 ± 1.9	7.6 ± 2.2	0.673
Minimal lumen diameter (mm)	2.85 ± 0.41	2.86 ± 0.40	0.959
Target site at the proximal to bifurcation			
EEM CSA (mm^2)	21.3 ± 3.2	23.8 ± 4.0	0.012
Lumen CSA (mm^2)	4.5 ± 1.9	12.5 ± 2.9	<0.001
Minimal lumen diameter (mm)	2.13 ± 0.49	3.62 ± 0.45	<0.001
Target site at the distal to bifurcation			
EEM CSA (mm^2)	15.1 ± 3.0	17.3 ± 2.1	0.002
Lumen CSA (mm^2)	3.5 ± 1.5	6.7 ± 1.3	<0.001
Minimal lumen diameter (mm)	1.95 ± 0.33	2.85 ± 0.27	<0.001

CSA, cross sectional area; EEM, external elastic membrane.

TABLE IV. Procedural Characteristics

Variables	$N = 36$
Multivessel intervention	14 (39%)
Number of used stents per patient	3.0 ± 1.2
Number of used stents per target lesion	2.7 ± 1.0
Total stent length (mm)	44.5 ± 10.3
Sum of nominal stent sizes used at both branches/ proximal reference diameter	1.44 ± 0.20
Sum of balloon sizes at kissing inflation/ proximal reference diameter	1.47 ± 0.21
Direct stenting	7 (19%)
Administration of glycoprotein IIb/IIIa inhibitor	8 (22%)
Use of intravascular ultrasound	32 (89%)
Sequential balloon inflation before kissing balloon inflation	25 (69%)
Debulking atherectomy	1 (3%)
Length of new carina (mm)	8.9 ± 2.5
Use of intra-aortic balloon pump	0

thromboses occurred after discharge. Target lesion revascularization was performed in five patients (14%). Coronary artery bypass surgery was performed in three patients with diffuse restenosis at the MV, in whom two had concomitant restenosis at the SV and two had lesions at the left main. Repeat percutaneous coronary intervention was performed in two patients, one treated with repeat kissing stenting with SES for proximal edge restenosis at the left main and one with cutting balloon angioplasty for focal restenosis at the ostial circumflex artery. Target lesion revascularization-free survival rate at 2 years was (85.9 ± 5.8)%.

Angiographic follow-up at 6 months was performed in 30 patients (83%). Angiographic restenosis occurred in five patients (17%), two of whom had restenosis at both the MV and SB (Table VI). Single branch restenosis at the MV or SB alone occurred in two and one patients, respectively. Late loss was 0.30 ± 0.54 mm in the MV and 0.49 ± 0.53 mm in the SB (P = NS).

TABLE V. Stenting Techniques at Both Branches

Variables	Main vessel	Side branch	*P* value
Stent number	1.5 ± 0.7	1.2 ± 0.5	0.045
Stent length (mm)	23.0 ± 6.2	21.5 ± 5.5	0.271
Stent size used (mm)	3.1 ± 0.3	3.0 ± 0.3	0.006
Nominal stent size used/distal reference diameter	1.20 ± 0.22	1.10 ± 0.18	0.039
Maximal balloon size (mm)	3.47 ± 0.35	3.21 ± 0.36	0.004
Maximal balloon size/distal reference diameter	1.33 ± 0.27	1.19 ± 0.19	0.017
Balloon size at final kissing inflation (mm)	3.29 ± 0.34	2.95 ± 0.28	<0.001
Balloon size at final kissing inflation/distal reference diameter	1.25 ± 0.27	1.09 ± 0.19	0.006
Maximal pressure (atm)	17.6 ± 3.2	17.4 ± 3.2	0.769
Pressure at kissing inflation (atm)	13.0 ± 3.8	10.9 ± 3.4	0.016

Diaphragmatic Carinal Membrane

Follow-up angiography showed a diaphragmatic linear line at the new carina, which was not found after the procedure, in 14 patients (47%) (Fig. 1). The incidence of angiographic restenosis in lesions with the diaphragm (two lesions, 14%) did not differ significantly from that in lesions without the diaphragm (three lesions, 19%; P = 1.0). The carinal diaphragm was associated with occurrence of restenosis in only one patient (Fig. 2).

DISCUSSION

The major finding of the present study is that the simultaneous kissing stenting with SES appears a feasible bifurcation stenting strategy for lesions with a large proximal reference. There were no incidents of death, myocardial infarction, or stent thrombosis during the long-term period. In addition, the incidence of angiographic restenosis and target lesion revascularization were acceptably low. A membranous diaphragm at the new carina was frequently observed during follow-up angiography, but this was not significantly related to the occurrence of angiographic restenosis.

Drug-eluting stent has been shown to be effective in reducing the incidence of restenosis and the need for target lesion revascularization for bifurcation coronary lesions when compared with bare metal stents [1]. However, using drug-eluting stent for bifurcation stenting remains challenging because of its technical complexity and the relatively high restenosis rate when

TABLE VI. Lesion Characteristics and Clinical Outcome of Patients with Restenoses

	Site	Used stents (mm)	Restenosis	Carinal diaphragm	Treatment
Male, 62 years	LM	Two 3.0 × 18	Focal at proximal edge	No	Repeat kissing stenting with SES
Female, 65 years	LM	3.0 × 23, 2.5 × 33	Diffuse at MV and focal at ostial SB	Yes	Bypass surgery
Male, 67 years	LM	2.75 × 23, 2.75 × 28, 2.5 × 33	Focal at distal SB	Yes	Cutting balloon angioplasty
Male, 68 years	LM	2.5 × 33, 2.75 × 28, 3.0 × 28, 3.0 × 33	Focal at ostiums of MV and SB	No	Bypass surgery
Female, 54 years	LAD	Two 3.0 × 18	Diffuse at MV	No	Bypass surgery

LM, left main; LAD, left anterior descending artery.

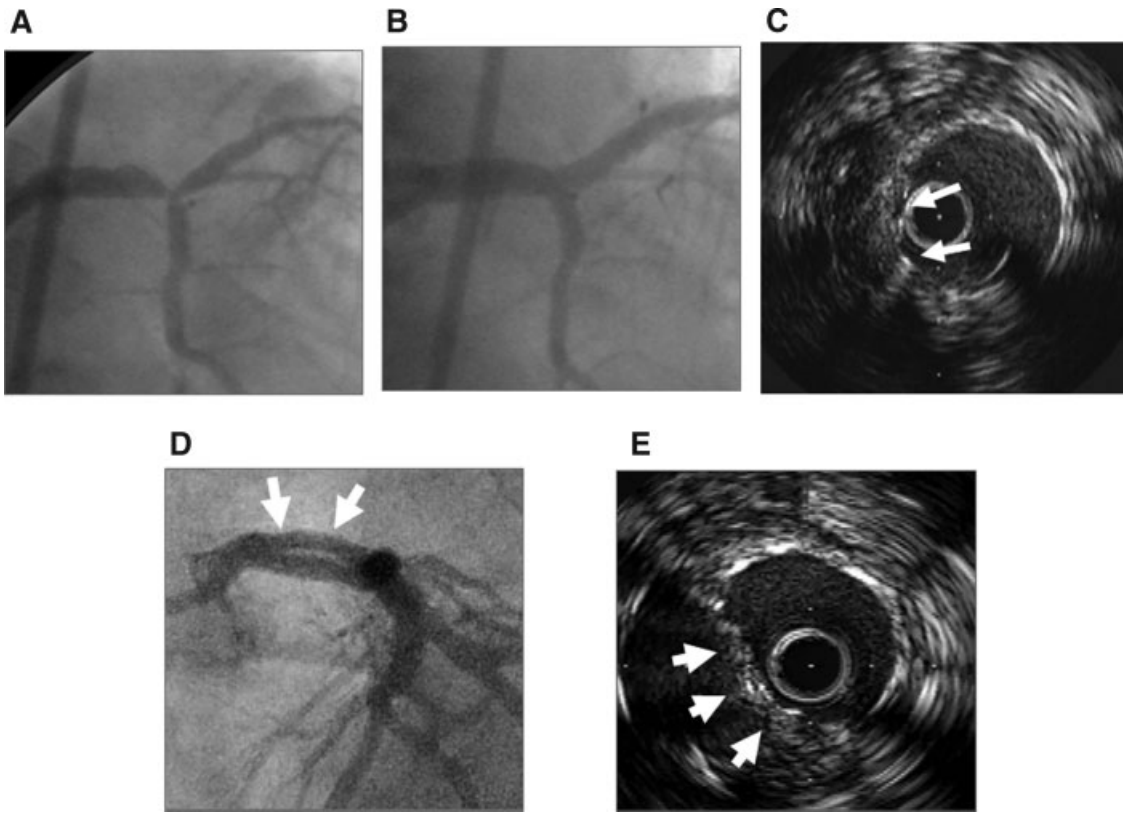

Fig. 1. A 49-year-old man who received three SESs (3.0 × 18 mm^2, 3.0 × 23 mm^2, and 3.0 × 28 mm^2) with simultaneous kissing stenting for the treatment of an unprotected left main bifurcation stenosis. A: Angiogram at baseline. B: Angiogram after 6-months. C: Postprocedural IVUS showing a new carina with overlapped stents (arrow). D: Six month angiogram showing a linear diaphragm at the new carina (arrows), which was not observed after the procedure and was not associated with angiographic restenosis. E: IVUS showing a linear membranous structure (arrows) on overlapped stents strut.

compared with nonbifurcation lesions [1]. Traditional T stenting may leave a gap at the SB ostium, which may be associated with a high incidence of restenosis [7]. The crush technique, a new bifurcation technique with drug-eluting stent, was thought to assure high procedural success and complete lesion coverage. However, it has been reported that the crush technique may not completely resolve the potential problem of bifurcation stenting; i.e. stent underexpansion and incomplete apposition of the SB ostium [6,13]. IVUS analysis showed that, although final kissing inflation was performed in 90% of patients, incomplete apposition of the SB or MV was found in 60% of nonleft main lesions [13]. In addition, the crush technique may increase the procedural time and cost with utilization of final kissing balloon inflation.

Following the introduction of drug-eluting stent, the simultaneous kissing stenting technique has been used

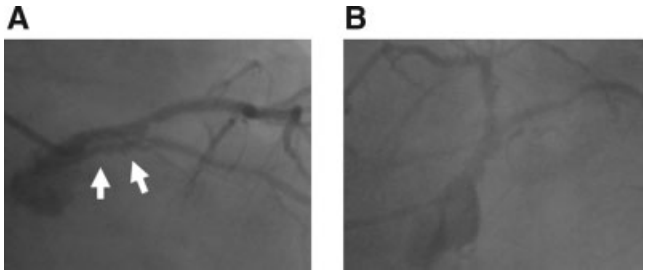

Fig. 2. A 65-year-old female who received three SESs (2.5 × 33 mm^2, 3.0 × 18 mm^2, and 3.0 × 23 mm^2) with simultaneous kissing stenting technique for the treatment of unprotected left main bifurcation stenosis. A and B: Diffuse angiographic restenosis involving both branches; the arrows in A point to the carinal diaphragm, which was associated with angiographic restenosis.

by the some advantages over other bifurcation stenting techniques [1,2]. Because kissing stenting does not require rewiring into the SB or reopening through the side of stent strut, it is technically very simple and did not distort stent structure. In addition, overstretch of the proximal stent strut, which is often required for complete stent apposition in large bifurcations such as left main lesions, is not needed. A recent study showed a technical feasibility of simultaneous kissing stenting with SES that the target lesion revascularization rate was 4% [3]. That study, however, had a limitation that angiographic follow-up rate was very low. The present study was designed to assess the long-term outcomes of the simultaneous kissing stenting technique using SES by more complete angiographic follow-up in more than 80% of patients and longer follow-up duration. Our findings of an overall restenosis rate of 16.7% and a target lesion revascularization rate of 13.9% were comparable to those observed using the crush technique [5,9–12]. Notably, a low restenosis rate of 10% at the SB in the present study was similar to that of the crush technique with final kissing inflation [10–12]. In contrast, restenosis at the SB using the crush technique without final kissing inflation was as high as 40% [10–12]. A similar tendency was also shown when comparing late luminal loss after the crush technique and kissing stenting.

Interestingly, we found that none of our patients presented clinical or angiographic features of stent thrombosis after greater than 2 years of mean follow-up. In previous studies, bifurcation stenting has been considered a significant predictor of stent thrombosis [15,16]. The stent thrombosis rate after the crush technique with drug-eluting stent was reported to be 1.7–4.3%, which might be higher than the rates obtained using nonbifurcation stenting [10–12]. Our approach of an additional use of cilostazol for 1 month might have contributed to the no incidence of stent thrombosis [17]. However, given the growing concern about the late occurrence of stent thrombosis, rigorous use of the standard antiplatelet combination with aspirin and clopidogrel for more than 1 year may be currently recommended after DES placement with such a complex procedure [20].

At follow-up angiography, we observed a thin diaphragmatic membranous structure at the new carina in a half of patients. This unique finding is in agreement with that observed in kissing stenting with paclitaxel-eluting stent [21]. Fortunately, the clinical influence of this structure was benign in our study, in that only one patient had to undergo angiographic restenosis. However, long-term outcome should be meticulously followed because the characteristics and prognosis of this structure were not clearly ascertained by pathologic and clinical studies. Before these studies are performed, this procedure needs to be reserved for cases in which an alternative technique is deemed to be infeasible.

This study had several limitations. First, the kissing stenting technique can be utilized in selected bifurcation lesions with a relatively large proximal reference. The majority of patients had lesion at the left main bifurcation. Therefore, caution should be taken when determining an optimal stenting strategy for an individual patient. Second, the sample size is relatively small so that the safety of this technique needs to be further investigated in studies with larger population and longer follow-up. Third, IVUS evaluation was not routinely performed in the SB after the procedure. Forth, we have not sufficiently tested a potential problem in recatheterization though the stented segment. However, in two restenoses treated with repeat percutaneous coronary intervention, we did not experience any serious difficulty in performing the procedure. Fifth, the results of this study cannot be directly compared with other bifurcation stenting techniques because this was an observational study in a single center without a control group.

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