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Randomized Comparison of Conservative Versus Aggressive Strategy for Provisional Side Branch Intervention in Coronary Bifurcation Lesions

Results From the SMART-STRATEGY (SMart Angioplasty Research Team–Optimal STRATEGY for Side Branch Intervention in Coronary Bifurcation Lesions) Randomized Trial

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Objectives The authors sought to compare conservative and aggressive strategies for provisional side branch (SB) intervention in coronary bifurcation lesions.

Background The optimal provisional approach for coronary bifurcation lesions has not been established.

Methods In this prospective randomized trial, 258 patients with a coronary bifurcation lesion treated with drug-eluting stents were randomized to a conservative (n = 128) or aggressive (n = 130) SB intervention strategy. The criteria for SB intervention after main vessel stenting differed between the conservative and aggressive groups; Thrombolysis In Myocardial Infarction flow grade <3 versus diameter stenosis >75% for non–left main bifurcations and diameter stenosis >75% versus diameter stenosis >50% for left main bifurcations. The primary endpoint was target vessel failure (cardiac death, myocardial infarction, or target vessel revascularization) at 12 months.

Results Left main bifurcation lesions were noted in 114 patients (44%) and true bifurcation lesions in 171 patients (66%). SB ballooning after main vessel stenting and SB stenting after SB ballooning were performed less frequently in the conservative group than in the aggressive group (25.8% vs. 68.5%, p < 0.001; and 7.0% vs. 30.0%, p < 0.001, respectively). The conservative strategy was associated with a lower incidence of procedure-related myocardial necrosis compared with the aggressive strategy (5.5% vs. 17.7%, p = 0.002). At 12 months, the incidence of target vessel failure was similar in both groups (9.4% in the conservative group vs. 9.2% in the aggressive group, p = 0.97).

Conclusions Compared with the aggressive strategy, the conservative strategy for provisional SB intervention was associated with similar long-term clinical outcomes and a lower incidence of procedure-related myocardial necrosis. (Optimal Strategy for Side Branch Stenting in Coronary Bifurcation Lesions [SMART-STRATEGY]; NCT00794014) (J Am Coll Cardiol Intv 2012;5:1133–40) © 2012 by the American College of Cardiology Foundation

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Some randomized trials have reported that the elective 2-stent technique is not superior to the provisional approach for coronary bifurcation lesions (1–3). As a result, selective side branch (SB) intervention after main vessel (MV) stenting is now regarded as the standard strategy for most bifurcation lesions (4,5). However, the optimal indications for SB ballooning or stenting during the provisional approach have not been established. Although previous studies reported that routine kissing ballooning after MV stenting did not improve clinical outcomes in the 1-stent technique (6,7), these studies still did not answer when the SB intervention should or should not be performed. Moreover, left main (LM) bifurcation lesions were not included in any previous studies. Therefore, to determine the optimal indications for SB ballooning and/or stenting in the provisional approach, we compared conservative and aggressive strategies in patients undergoing percutaneous coronary intervention (PCI) with drug-eluting stents (DES) for non-LM bifurcations and LM bifurcations.

Abbreviations and Acronyms

DES = drug-eluting stent(s)

LM = left main

MI = myocardial infarction

MV = main vessel

PCI = percutaneous coronary intervention

SB = side branch

TBR = target bifurcation revascularization

TIMI = Thrombolysis In Myocardial Infarction

TLR = target lesion revascularization

TVF = target vessel failure

TVR = target vessel revascularization

Methods

Study design and patients. The present study was a prospective, randomized, open-label, single-center study designed to compare conservative versus aggressive strategies for provisional SB intervention during coronary bifurcation PCI with DES. The local institutional review board approved this study, and all subjects gave their informed consent for participation. Patients with stable coronary artery disease or non–ST-segment elevation acute coronary syndrome were considered eligible for enrollment. The inclusion criteria were an elective coronary intervention for a de novo coronary bifurcation lesion, including unprotected LM, and MV diameter ≥2.5 mm and SB diameter ≥2.3 mm by visual estimation. We excluded patients with hemodynamic instability, left ventricular ejection fraction <25%, and those undergoing primary PCI.

Study procedures and follow-up. All patients received dual oral antiplatelet therapy with 300-mg aspirin and either 300- or 600-mg clopidogrel before PCI if they had not previously received these drugs. Intravenous heparin was administered to maintain an activated clotting time >300 s. Intravenous administration of glycoprotein IIb/IIIa receptor antagonists was used at the operator's discretion. The selection of DES was also left to the operator's discretion, but the same type of DES was implanted in both branches. The myocardial band fraction of creatine kinase-MB (CK-MB) was measured at 6 h, and 18 to 24 h post PCI, and at discharge.

Patients were randomly assigned to undergo the conservative or the aggressive treatment strategy for provisional SB intervention (Fig. 1). Randomization was performed after MV stenting using a computer-based 1:1 randomization scheme, and patients were stratified by the presence or absence of LM bifurcation lesion. The triggers for SB ballooning and stenting happened only if the criteria were met. If the criteria were not met, no further intervention was performed. If SB ballooning after MV stenting was needed, kissing balloon inflation was mandatory. If SB stenting was indicated, the T-stenting and small protrusion technique, in which the SB stent was pulled back slightly into the MV to fully cover the ostium of the SB, was exclusively used (8). Final kissing balloon inflation was mandatory after SB stenting. All procedures were performed under intravascular ultrasound guidance whenever possible.

LEFT MAIN BIFURCATION LESION. In the conservative group, SB ballooning followed by kissing ballooning was performed only if there was diameter stenosis >75% in the SB after MV stenting. SB stenting was performed only if there was diameter stenosis >50% or Type B or greater dissection in the SB after ballooning. In the aggressive group, SB ballooning followed by kissing ballooning was performed only if there was diameter stenosis >50% in the SB after MV stenting. SB stenting was performed only if there was diameter stenosis >30% or Type B or greater dissection in the SB after ballooning.

NON–LEFT MAIN BIFURCATION LESION. In the conservative group, SB ballooning followed by kissing ballooning was performed only if there was Thrombolysis In Myocardial Infarction (TIMI) flow grade <3 in the SB after MV stenting. SB stenting was performed only if there was TIMI flow grade <3 in the SB after ballooning. In the aggressive group, SB ballooning followed by kissing ballooning was performed only if there was diameter stenosis >75% in the SB after MV stenting. SB stenting was performed only if there was diameter stenosis >50% in the SB after ballooning.

Follow-up. Clinical follow-up was performed with office visits or telephone contacts at 1, 3, 9, and 12 months after intervention. Adverse events were monitored throughout the study period. Follow-up coronary angiography and intravascular ultrasound were performed at 9 months unless clinically indicated earlier.

Study endpoints and definitions. The primary endpoint was the occurrence of target vessel failure (TVF), defined as a composite of cardiac death, spontaneous myocardial infarction (MI), or target vessel revascularization (TVR) during the 12-month period after randomization. Secondary endpoints included the individual components of the primary endpoint, target lesion revascularization (TLR), and target bifurcation revascularization (TBR) at 12 months;

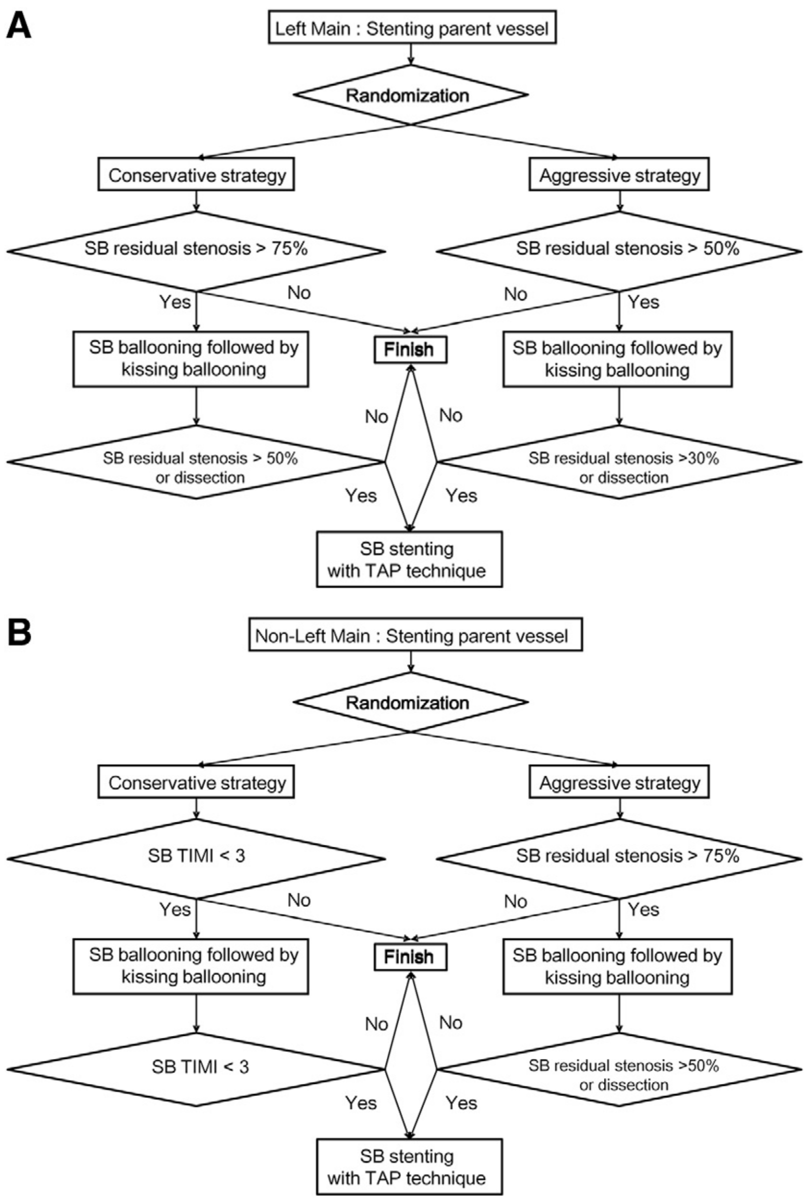


Figure 1. Trial Profile

Patients were randomized 1:1 to conservative or aggressive strategy for provisional side branch (SB) intervention after main vessel stenting. **(A)** Left main bifurcation lesion. **(B)** Non–left main bifurcation lesion. TAP = T-stenting and small protrusion; TIMI = Thrombolysis In Myocardial Infarction.

procedure-related myocardial necrosis; and binary angiographic (re)stenosis in the MV and SB as measured by quantitative coronary analysis at 9 months.

All deaths were considered cardiac in origin unless a definite noncardiac cause could be established. Spontaneous MI was defined as elevated cardiac enzymes (CK-MB or troponin I) above the upper limit of the normal range with ischemic symptoms or electrocardiography findings indicative of ischemia not related to the index procedure (6). TVR was defined as repeat revascularization of the target vessel by PCI or bypass graft surgery. TLR was defined as repeat revascularization of the lesion within 5 mm of stent deployment or bypass graft surgery in the target vessel. TBR was defined as repeat revascularization with stenosis ≥50% within 5 mm proximal or distal to the carina of bifurcation, onto the MV and/or SB (9). Procedure-related myocardial necrosis was defined as a rise in CK-MB ≥3 times the upper normal limit within the first 48 h after the index procedure. In patients with elevated baseline cardiac enzyme levels, procedure-related myocardial necrosis was defined as

Table 1. Baseline Characteristics

	Conservative (n = 128)	Aggressive (n = 130)	p Value
Age, yrs	61.8 ± 10.1	61.5 ± 10.2	0.83
Male	105 (82.0)	108 (83.1)	0.83
Clinical presentation			0.51
Silent ischemia	13 (10.2)	7 (5.4)	
Stable angina	80 (62.5)	82 (63.1)	
Unstable angina	26 (20.3)	31 (23.8)	
Myocardial infarction	9 (7.0)	10 (7.7)	
Hypertension	70 (54.7)	75 (57.7)	0.63
Diabetes mellitus	37 (28.9)	33 (25.4)	0.53
Dyslipidemia	16 (12.5)	17 (13.1)	0.89
Current smoker	33 (25.8)	23 (17.7)	0.12
Family history of coronary artery disease	17 (13.3)	19 (14.6)	0.76
Cerebrovascular accident	5 (3.9)	10 (7.7)	0.19
Chronic renal failure	2 (1.6)	4 (3.1)	0.68
Previous myocardial infarction	7 (5.5)	5 (3.8)	0.54
Previous percutaneous coronary intervention	14 (10.9)	9 (6.9)	0.26
Previous coronary bypass graft surgery	0	1 (0.8)	>0.99
Left ventricular ejection fraction, %	60.5 ± 7.3	59.3 ± 10.7	0.41

Values are mean ± SD or n (%).

a subsequent increase >2-fold from the baseline value (10). Stent thrombosis was assessed based on the definitions of the Academic Research Consortium as definite, probable, or possible stent thrombosis (11).

Quantitative coronary angiographic analysis. All baseline, procedural, and follow-up coronary angiographies were analyzed by an independent blinded observer using an automated edge-detection system (Centricity CA1000, GE, Waukesha, Wisconsin). The minimum luminal diameter and reference diameter before, immediately after the procedure, and at follow-up were measured in matched views. Binary angiographic (re)stenosis was defined as a lumen diameter stenosis of ≥50% at any of the following sites: 1) inside the stent; 2) within 5 mm proximal or distal to the stent; 3) within the proximal 5 mm (SB ostium) of the un-intervened SB; or 4) at the site of balloon inflation in the SB. Late lumen loss was defined as the difference between minimum luminal diameter immediately after the procedure and at 9 months. Bifurcation lesions were classified according to the Medina classification, in which the proximal MV, distal MV, and SB components of the bifurcation are each assigned a score of 1 or 0 depending on the presence or absence of >50% stenosis (12). Medina classification type (1.1.1), (1.0.1), and (0.1.1) lesions were defined as true bifurcation lesions.

Statistical analysis. Power calculations were based on an expected 12-month TVF rate of 24% in the conservative group. With an alpha of 5% and power of 80%, 112 patients would be needed in each group to detect up to a 14% reduction (about 60% relative reduction) in 12-month TVF rate. Assuming a 10% loss to follow-up loss, 250 patients would be needed for both groups.

Continuous variables were expressed as the mean ± SD or the median and interquartile range and were compared using an independent *t* test or the Wilcoxon rank sum test. Categorical variables were compared with Pearson chi-square or Fisher exact tests. A p value <0.05 in the 2-tailed test was considered significant. The Statistical Analysis Software package (SAS version 9.1, SAS Institute, Cary, North Carolina) was used for all analyses.

Results

Baseline clinical characteristics. Between July 2007 and December 2010, a total of 258 patients with bifurcation lesions

Table 2. Procedural Characteristics

	Conservative (n = 128)	Aggressive (n = 130)	p Value
Target vessel			0.91
Left main bifurcation	57 (44.5)	57 (43.8)	
Non–left main bifurcation	71 (55.5)	73 (56.2)	
LAD/diagonal	52 (40.6)	66 (50.8)	
LCX/OM	10 (7.8)	3 (2.3)	
RCA bifurcation	9 (7.0)	4 (3.1)	
Medina classification			0.74
True bifurcation	82 (64.1)	89 (68.5)	0.46
1.1.1	68 (53.1)	76 (58.5)	
1.0.1	8 (6.3)	4 (3.1)	
0.1.1	6 (4.7)	9 (6.9)	
Non-true bifurcation	46 (35.9)	41 (31.5)	0.46
1.0.0	2 (1.6)	2 (1.5)	
0.1.0	26 (20.3)	19 (14.6)	
1.1.0	17 (13.3)	19 (14.6)	
0.0.1	1 (0.8)	1 (0.8)	
Remote site intervention	39 (30.5)	35 (26.9)	0.53
Treatment according to randomization	128 (100)	129 (99.2)	>0.99
Type of stent used			0.57
Sirolimus-eluting stent	60 (46.9)	62 (47.7)	
Everolimus-eluting stent	40 (31.3)	35 (26.9)	
Other drug-eluting stents	28 (21.9)	33 (25.4)	
Main vessel			
No. of stents per lesion	1.2 ± 0.4	1.2 ± 0.4	0.41
Total stent length, mm	24.9 ± 5.6	25.1 ± 5.3	0.76
Maximal stent diameter, mm	3.3 ± 0.4	3.3 ± 0.4	0.45
Maximal balloon pressure, atm	15.1 ± 3.4	14.7 ± 3.1	0.24
Side branch (n = 48)	n = 9	n = 39	
No. of stents per lesion	1.0 ± 0.0	1.0 ± 0.2	0.64
Total stent length, mm	18.4 ± 7.8	17.7 ± 5.6	0.73
Maximal stent diameter, mm	2.8 ± 0.2	2.9 ± 0.4	0.46
Maximal balloon pressure, atm	14.3 ± 3.0	15.7 ± 2.6	0.17

Values are n (%) or mean ± SD.
LAD = left anterior descending artery; LCX = left circumflex artery; OM = obtuse marginal coronary artery; RCA = right coronary artery.

were enrolled and randomly assigned to either the conservative (n = 128) or the aggressive group (n = 130). Baseline clinical characteristics were well matched between the 2 groups (Table 1).

Angiographic and procedural characteristics. There were no significant differences in the angiographic and procedural characteristics between the 2 groups (Table 2). An LM bifurcation lesion was noted in 114 patients (44%), and a true bifurcation lesion was detected in 171 patients (66%). No difference was found between the 2 groups in the distribution of true and non-true bifurcations based on the Medina classification (p = 0.74). Sirolimus-eluting and everolimus-eluting stents were used predominantly, with no difference between the study groups (p = 0.57). The number of stents, total stent length, and stent diameter implanted in the MV and SB, and the rate of treatment according to randomization were similar in the 2 groups. Figure 2 shows the rates of SB ballooning and stenting after stent implantation of the MV. SB balloon dilation after MV stenting was more frequently performed in the aggressive group than in the conservative group (68.5% vs. 25.8%, $p < 0.001$). SB stenting after SB dilation and kissing ballooning was also more frequently required in the aggressive group than in the conservative group (30.0% vs. 7.0%, $p < 0.001$). Only 1 patient randomized to the aggressive strategy failed to receive the assigned treatment due to rewiring failure.

Clinical outcomes. The aggressive strategy was associated with a significantly higher incidence of procedure-related myocardial necrosis compared with the conservative strategy (17.7% vs. 5.5%, p = 0.002). Clinical follow-up data at 12 months were available in all patients (Table 3). The cumulative incidence of TVF was similar in the 2 groups (9.2% in the aggressive group vs. 9.4% in the conservative group, p = 0.97) (Fig. 3). Similarly, both groups had comparable incidences of individual endpoints of cardiac death, spontaneous MI, TVR, and TLR. No significant difference was found in the rate of TBR between the groups (3.1% in the aggressive group vs. 4.7% in the conservative group, p = 0.50). Only 1 patient died of probable stent thrombosis during the follow-up period; this was a patient in the

Table 3. Clinical Outcomes at 12-Month Follow-Up

	Conservative (n = 128)	Aggressive (n = 130)	p Value
Total death	1 (0.8)	3 (2.3)	0.62
Cardiac death	0	1 (0.8)	>0.99
Stent thrombosis	0	1 (0.8)	>0.99
Spontaneous myocardial infarction	0	0	—
Procedure-related myocardial necrosis	7 (5.5)	23 (17.7)	0.002
Target bifurcation revascularization	6 (4.7)	4 (3.1)	0.50
Target lesion revascularization	10 (7.8)	7 (5.4)	0.43
Target lesion revascularization for MV	5 (3.9)	4 (3.1)	0.75
Target lesion revascularization for SB	5 (3.9)	4 (3.1)	0.98
Target vessel revascularization	12 (9.4)	11 (8.5)	0.80
Target vessel failure*	12 (9.4)	12 (9.2)	0.97

Values are n (%). *Defined as a composite of cardiac death, spontaneous myocardial infarction, or target vessel revascularization.
MV = main vessel; SB = side branch.

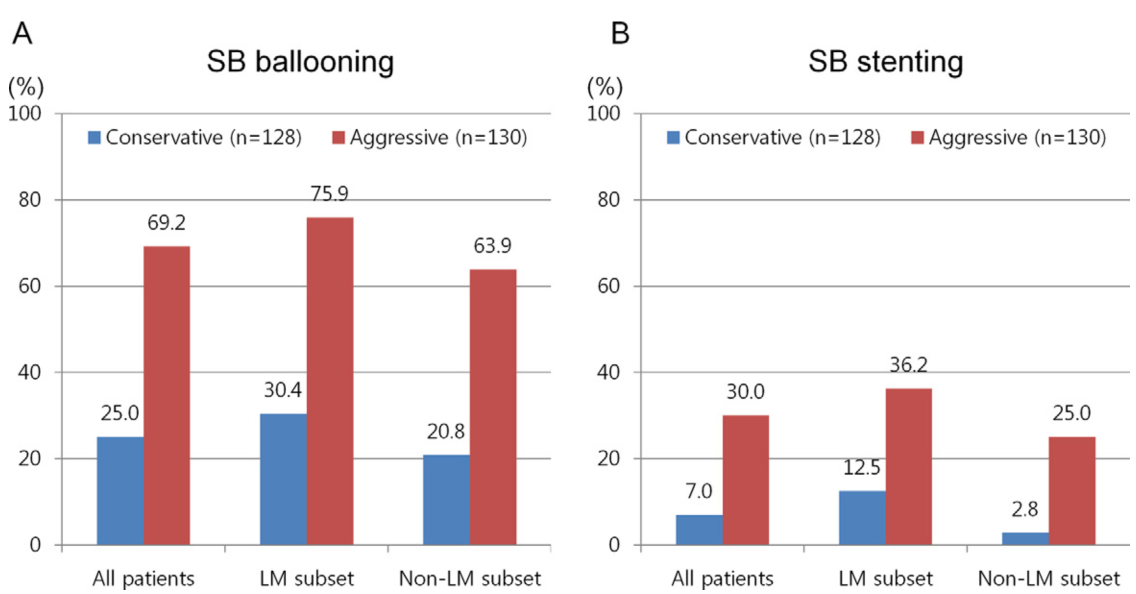
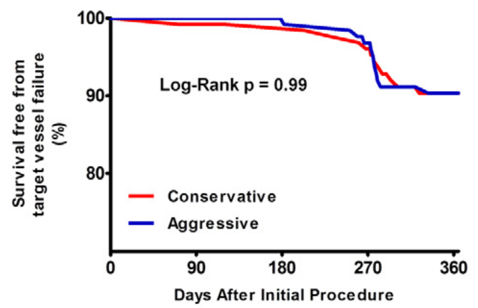


Figure 2. The Rates of SB Ballooning and Stenting

(A) Side branch (SB) ballooning after main vessel stenting according to treatment strategies. **(B)** SB stenting after side branch ballooning according to treatment strategies. LM = left main.



Numbers at Risk					
Conservative Group	128	128	127	122	102
Aggressive Group	130	129	127	122	103

Figure 3. Clinical Outcomes

Kaplan-Meier curves up to 12 months are shown for the composite outcome of cardiac death, myocardial infarction, and target vessel revascularization in the conservative versus aggressive group.

aggressive group who underwent stenting of both branches for a LM bifurcation lesion.

Quantitative coronary angiography analysis. Angiographic follow-up at 9 months was performed in 218 (84.5%) patients, 104 of whom were randomized to the conservative strategy and 114 to the aggressive strategy. Baseline quantitative coronary angiographic characteristics were well matched between the 2 groups (Table 4). There were significant differences in the SB between the 2 treatment strategies, with smaller minimal luminal diameters and increased diameter stenosis after the index procedure and at follow-up in the conservative group. The acute gain in the SB was significantly greater in the aggressive group than in the conservative group. Late lumen loss in the MV was not significantly different between the 2 groups, but that of the SB tended to be greater in the aggressive group. At follow-up, the binary restenosis rate of the MV was similar between the groups, but (re)stenosis of the SB was significantly higher in the conservative group than in the aggressive group ($p = 0.04$).

LM and non-LM bifurcation subgroup analysis. In patients with LM bifurcation lesions (114 patients, 44%), the 12-month TVF rates were 10.5% and 10.5% ($p > 0.99$) and the TLR rates were 5.3% and 8.8% ($p = 0.46$) for the aggressive and conservative groups, respectively (Online Table 1). The conservative group had smaller minimal luminal diameters and increased diameter stenosis in the SB after the index procedure and at follow-up (Online Table 2). The binary (re)stenosis rates of the MV and SB on the 9-month follow-up angiogram were similar between the groups (Online Table 2). In patients with non-LM bifurcation lesions (144 patients, 56%), the 12-month TVF rates were 8.2% and 8.5% ($p > 0.99$) and the TLR rates were 5.5% and 7.0% ($p = 0.74$) in the aggressive and conservative groups, respectively (Online Table 3). At follow-up, the binary restenosis rate of the MV was similar between the groups (6.1% vs. 5.6%, $p > 0.99$), but (re)stenosis of the SB was significantly lower in the aggressive group than in the conservative group (18.2% vs. 42.6%, $p = 0.003$) (Online Table 4).

Discussion

This study is the first to our knowledge to compare different strategies for provisional SB intervention in patients undergoing coronary bifurcation PCI. The main findings of this study are as follows: 1) the conservative strategy for provisional SB ballooning or stenting yielded long-term clinical outcomes similar to those of the aggressive strategy; 2) the conservative strategy was associated with a lower incidence of procedure-related myocardial necrosis; 3) a provisional SB approach for LM bifurcation lesions was feasible and effective; and 4) the 9-month angiographic (re)stenosis rate

Table 4. Quantitative Coronary Angiographic Analysis

	Conservative (n = 128)	Aggressive (n = 130)	p Value
Bifurcation angle	64.7 ± 24.3	63.5 ± 22.7	0.68
Pre-intervention			
MV RD, mm	3.01 ± 0.45	3.07 ± 0.58	0.37
SB RD, mm	2.46 ± 0.55	2.49 ± 0.54	0.64
mm.	0.77 ± 0.48	0.82 ± 0.47	0.43
SB MLD, mm	1.29 ± 0.69	1.27 ± 0.71	0.83
MV DS,%	74.6 ± 15.2	73.4 ± 14.6	0.55
SB DS, %	48.8 ± 21.9	50.0 ± 22.9	0.66
MV lesion length, mm	13.2 ± 6.9	13.7 ± 8.1	0.66
SB lesion length, mm	4.4 ± 4.5	4.9 ± 4.0	0.40
Post-intervention			
MV RD, mm	3.20 ± 0.46	3.24 ± 0.60	0.51
SB RD, mm	2.44 ± 0.52	2.47 ± 0.53	0.61
MV MLD, mm	2.54 ± 0.41	2.58 ± 0.43	0.45
SB MLD, mm	1.48 ± 0.66	1.77 ± 0.64	<0.001
MV DS, %	20.5 ± 5.8	20.8 ± 6.1	0.70
SB DS, %	40.7 ± 20.3	29.3 ± 18.9	<0.001
MV acute gain, mm	1.77 ± 0.47	1.76 ± 0.50	0.91
SB acute gain, mm	0.19 ± 0.62	0.49 ± 0.67	<0.001
Follow-up at 9 months	n = 104	n = 114	
MV RD, mm	3.17 ± 0.45	3.21 ± 0.53	0.50
SB RD, mm	2.39 ± 0.50	2.48 ± 0.54	0.21
MV MLD, mm	2.28 ± 0.54	2.27 ± 0.51	0.92
SB MLD, mm	1.34 ± 0.58	1.57 ± 0.57	0.004
MV late lumen loss, mm	0.27 ± 0.30	0.29 ± 0.36	0.69
SB late lumen loss, mm	0.13 ± 0.36	0.23 ± 0.44	0.08
MV DS, %	28.2 ± 12.2	29.4 ± 10.5	0.46
SB DS, %	45.0 ± 18.9	37.0 ± 16.3	0.001
MV restenosis	5 (4.8)	6 (5.3)	0.88
SB restenosis	27 (26.0)	17 (14.9)	0.04

Values are mean ± SD or n (%).

DS = diameter stenosis; MLD = minimum luminal diameter; RD = reference diameter; other abbreviations as in Table 3.

was similar between the 2 groups for the MV, but was significantly higher in the conservative group for the SB.

Although the 1-stent technique with provisional SB intervention is simple and is now regarded as the standard technique for most bifurcation lesions (1,3,13), SB ballooning or stenting is still required in a substantial portion of patients. However, the appropriate criteria for SB ballooning or stenting have not been established. In previous studies, the rate of crossover to SB stenting during provisional SB intervention was highly variable, mainly due to different criteria for the SB stenting. Several randomized studies, including the CACTUS (Coronary Bifurcations: Application of the Crushing Technique Using Sirolimus-Eluting Stents) study, in which residual stenosis >50% was considered 1 of the criteria for SB stenting, found that approximately one-third of patients in the provisional group crossed over to the 2-stent group (2,14). This crossover rate was similar to that of the aggressive strategy (30%) in the present study. By contrast, the Nordic Bifurcation Study and BBC ONE (British Bifurcation Coronary Study: Old, New, and Evolving Strategies) used very strict criteria for SB stenting, such as impaired flow or severe residual stenosis (1,3,15). In those studies, the crossover rate to the 2-stent technique was only 2% to 4%; this is slightly lower than that of the conservative strategy (7%) in the present study, partly because we included LM bifurcation.

To date, there has been no study comparing aggressive and conservative strategies of provisional SB intervention after MV stenting. The present study found that the aggressive strategy for SB ballooning or stenting did not provide better clinical outcomes than the conservative strategy. There was no significant difference between the 2 treatment groups in the binary restenosis rate of the MV at the 9-month angiographic follow-up. Although the rate of SB (re)stenosis was higher in the conservative group, this did not translate into increased clinically driven revascularization rates.

The feasibility and usefulness of a provisional approach in patients with LM bifurcation lesions have not been fully assessed in previous trials comparing provisional SB stenting to a systematic 2-stent approach because these studies excluded LM bifurcation lesions or included a limited number of cases (2,3,13,14). By contrast, the present study included a substantial number of cases with LM bifurcation lesions. Although the approach to keep SB just patent seems reasonable in the treatment of non-LM bifurcation or a relatively small branch from previous reports and ours (16), this approach might be limited in a large SB with a large amount of subtended myocardium, such as a LM bifurcation. Therefore, we adopted different criteria for provisional SB intervention according to the involvement of LM bifurcation. In the treatment of LM bifurcation lesions, the criterion of conservative strategy for the initiation of SB intervention was diameter stenosis >75% in SB after MV stenting. This criterion was based on a previous report that the vast majority of lesions with SB stenosis <75% after MV stenting are not associated with ischemia, and thus do not need further treatment (17). When applying this criterion, we showed that LM bifurcation lesions can be treated safely and effectively by a provisional SB approach. Although both strategies for provisional SB ballooning or stenting provided favorable and comparable clinical outcomes in the treatment of LM bifurcation lesions, there was a higher incidence of procedure-related myocardial necrosis in patients who underwent the aggressive strategy than in those who underwent the conservative one. In addition, patients treated with the aggressive strategy were 3 times more likely to need SB stenting than the conservative group. Previous studies showed that, compared with the 2-stent technique, use of the 1-stent technique for the treatment of LM bifurcation lesions with DES was associated with a significant reduction in major adverse cardiac events (18,19). Considering the significance of periprocedural myocardial necrosis together with this finding, the conservative strategy could initially be considered as the preferred approach for the treatment of LM bifurcation lesions. It is also conceivable that the conservative strategy would be simpler and more cost effective, and could be performed with less contrast and a shorter procedural time.

Study limitations. First, the sample size was relatively small. Although we calculated the sample size based on previous data, the clinical event rate in the conservative group was lower than expected. With an event rate of 9% in the conservative group, the power was only about 42%. In addition, different properties of the LM and non-LM lesion subsets were not considered in the sample size calculation. Second, the present study was an inevitably open design, and both patients and operators were aware of the strategy used, which might have introduced bias in the assessment of symptoms at follow-up. No specific functional testing was systematically performed during the follow-up period.

Conclusions

In patients undergoing coronary bifurcation stenting with the provisional approach, the conservative strategy for provisional SB intervention was associated with similar clinical outcomes and a lower incidence of procedure-related myocardial necrosis compared with the aggressive strategy. However, these are hypothesis-generating findings due to the small sample size, and warrant a large randomized study.

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Key Words: bifurcation ■ coronary artery disease ■ side branch ■ treatment strategy.

APPENDIX

For supplementary tables, please see the online version of this paper.