Benefit of Final Kissing Balloon Inflation Mandatory After Simple Crossover Stenting for Left Main Bifurcation Narrowing

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The role of final kissing balloon (FKB) inflation after simple crossover stenting in unprotected left main (LM) bifurcation stenosis remains unknown. From the Asan Medical Center-Left Main Revascularization (ASAN-MAIN) registry, 413 patients with LM bifurcation stenosis treated by simple crossover stenting with a drug-eluting stent were identified. After simple crossover stenting, FKB inflation was performed in 95 patients (FKB group) and 318 patients finished the procedure without FKB (no-FKB group). The primary end points of the 2-year incidence of major adverse cardiac events (death, myocardial infarction, and left main target lesion revascularization [LM-TLR]) were similar between the FKB and no-FKB groups (12.5% vs 8.5%, p = 0.24). After adjustment, the risk of major adverse cardiac event was not significantly different between the FKB and the no-FKB groups (hazard ratio [HR] 1.10, 95% confidence interval [CI] 0.49 to 2.49; p = 0.82). The risk of death (HR 1.03, 95% CI 0.28 to 3.82; p = 0.98), the composite of death or myocardial infarction (HR 0.95, 95% CI 0.26 to 3.51; p = 0.96), or LM-TLR (HR 1.32, 95% CI 0.46 to 3.75; p = 0.60) were not significantly different between groups. In conclusions, for the treatment for LM bifurcation stenosis, selective, not mandatory, FKB strategy after simple crossover stenting appears to be associated with a favorable outcome. © 2016 Published by Elsevier Inc. (Am J Cardiol 2016;■:■−■)

Percutaneous coronary intervention (PCI) for unprotected left main (LM) bifurcation stenosis is still challenging. Simple crossover stenting with provisional side branch intervention is preferred because this approach has lower event rates than the 2-stent strategy for the treatment of LM bifurcation stenosis.[1−3] However, the role of systematic final kissing balloon (FKB) inflation after simple crossover stenting has been unclear, particularly in cases of asymptomatic angiographic stenosis of the left circumflex coronary artery ostium. Therefore, we compared the long-term clinical outcomes of patients receiving FKB after simple crossover stenting for LM bifurcation stenosis with those of patients not receiving FKB in the Asan Medical Center-Left Main Revascularization (ASAN-MAIN) registry.

Methods

The study population was from the ASAN-MAIN registry, which was designed to investigate the "real-world" outcomes of treatment for patients with significant unprotected LM stenosis. The details of the design for the registry have been reported previously.[4,5] Briefly, significant unprotected LM stenosis was defined as a percentage diameter stenosis (DS) of >50%, based on a visual estimate. Patients who had undergone previous coronary artery bypass surgery, or concomitant valvular or aortic surgery, and those who had an acute myocardial infarction (MI) within 24 hours before revascularization or presented with cardiogenic shock were excluded.

From January 2003 to May 2012, 413 patients who had received simple crossover stenting using drug-eluting stent were enrolled in the present analysis. The institutional review board at our institute approved the use of clinical data for this study, and all patients provided written informed consent for enrollment in our registry.

Methods of stent implantation for patients with LM stenosis have been described previously.[6] All procedures were performed with standard interventional techniques. The use of FKB inflation, predilation, intra-aortic balloon pump, or intravascular ultrasound, and the choice of the specific type of stent were at the operator's discretion. Fractional flow reserve (FFR) was used to assess the functional severity of the jailed side branch after main vessel stenting at the discretion of the operator.[7] If the side branch showed decreased flow (thrombolysis in myocardial infarction <3), or serious dissection (the National Heart, Lung, and Blood Institute classification system types C through F[8]) before or after FKB, provisional stenting

Heart Institute, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea. Manuscript received June 11, 2016; revised manuscript received and accepted November 2, 2016.

Funding: This study was supported by funds from the Cardiovascular Research Foundation, Seoul, Korea.

See page 6 for disclosure information.

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0002-9149/16/$ - see front matter © 2016 Published by Elsevier Inc.
http://dx.doi.org/10.1016/j.amjcard.2016.11.002

was selectively performed.[9] Antiplatelet therapy and periprocedural anticoagulation were used according to standard regimens. After the procedure, aspirin was continued indefinitely. Patients were prescribed clopidogrel (75 mg once/day) for at least 6 months, regardless of drug-eluting stent type. Treatment beyond this duration was at the discretion of the physician.

Clinical follow-up was performed at 1, 3, 6, 12, and 24 months. The primary end points of the study were major adverse cardiac outcomes (MACEs), including the composite of death from any cause, nonfatal MI, and LM target lesion revascularization (LM-TLR). Secondary clinical end points were the individual components of the primary end points: a composite of death and MI, MI, target vessel revascularization, and stent thrombosis.

Death was defined as death from any cause. MI was defined as follows: (1) within the first 48 hours after procedure: new Q waves and either an elevation of the creatinine kinase-MB fraction or troponin I concentration >3 times or (2) 48 hours after the procedure: any creatinine kinase-MB or troponin increase above the upper range limit with or without the development of Q waves on electrocardiogram. Target vessel revascularization was defined as any percutaneous or surgical revascularization procedure associated with the target vessel. LM-TLR was defined as any percutaneous or surgical revascularization procedure associated with LM stenosis. Stent thrombosis was defined according to the Academic Research Consortium definitions,[9] and the definite occurrence of a thrombotic event was regarded as a secondary end point.

Differences between groups were evaluated using the Student *t* test for continuous variables and the chi-square or Fisher's exact test for categorical variables. Cumulative event curves were constructed using Kaplan−Meier estimates and were compared using the log-rank test. Analyses of the clinical outcomes were truncated at 2 years of follow-up. To reduce the possible impact of potential confounding factors, we used the multivariate Cox proportional regression model to adjust potential confounding factors including age, diabetes mellitus, clinical presentation, stent number, preprocedural ostial diameter stenosis of left circumflex artery, and post-stenting ostial diameter stenosis of the left circumflex artery. The proportional hazards assumption was confirmed by examination of the log(-log[survival]) curves and the results of the partial Schoenfeld residuals tests. We could not detect any significant violations. SPSS was used for statistical analyses. All reported p values are 2 sided, and p values of <0.05 were considered statistically significant.

Results

As shown in Figure 1, after main vessel stenting, the procedure was finished without any side branch intervention in 318 patients (no-FKB group), whereas FKB inflation was performed in 95 patients (FKB group). Figure 2 showed representative cases requiring FKB or not. Baseline clinical and lesion characteristics of the 2 groups are provided in Table 1. There were no differences in clinical characteristics between the 2 groups. However, there were differences in lesion characteristics: the FKB group had a significantly higher incidence of left circumflex artery ostium stenosis with a DS >50% before (true bifurcation) and after main vessel stenting.

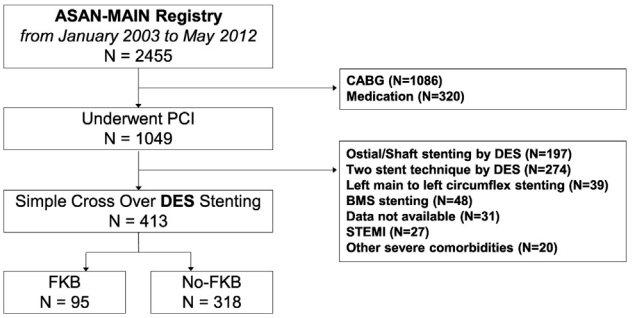


Figure 1. Study flow. CABG = coronary artery bypass grafting; DES = drug-eluting stent; STEMI = ST-segment elevated myocardial infarction.

At 2 years, 16 deaths, 2 MIs, 20 LM-TLRs, and 37 MACEs occurred. Clinical outcomes are shown in Figure 3 and Table 2. There were no significant differences between the 2 groups' crude incidence rates of clinical outcomes. In multivariate analysis, the risk of MACE was not significantly different between the FKB and the no-FKB groups (hazard ratio [HR] 1.10, 95% confidence interval [CI] 0.49 to 2.49; p = 0.82). The risk of death (HR 1.03, 95% CI 0.28 to 3.82; p = 0.98), the composite of death or MI (HR 0.95, 95% CI 0.26 to 3.51; p = 0.96), or LM-TLR (HR 1.32, 95% CI 0.46 to 3.75; p = 0.60) were not significantly different between groups. In addition, there was no definite stent thrombosis in either group at 2-year follow-up. The locations of LM-TLR are shown in Figure 4. In both groups, the ostium of the left circumflex coronary artery was the most frequent site of restenosis. Figure 5 shows the clinical outcomes according to angiographic DS before and after main vessel stenting. Even after such stratification, both groups showed similar rates of clinical outcomes.

Among the study patients, 35 side branches (left circumflex coronary artery) were assessed by FFR after simple crossover stenting from the LM to the left anterior descending artery. The FFRs of only 2 side branches were ≤0.80 (0.76 and 0.77, respectively).

Discussion

For the treatment of LM bifurcation stenosis, we observed that the need for FKB is greater when the baseline lesion was critical at the ostium of the left circumflex artery. In addition, we showed that patients who underwent FKB strategy or did not had similar and favorable clinical outcomes even after adjustment of lesion complexity. Therefore, performing mandatory FKB

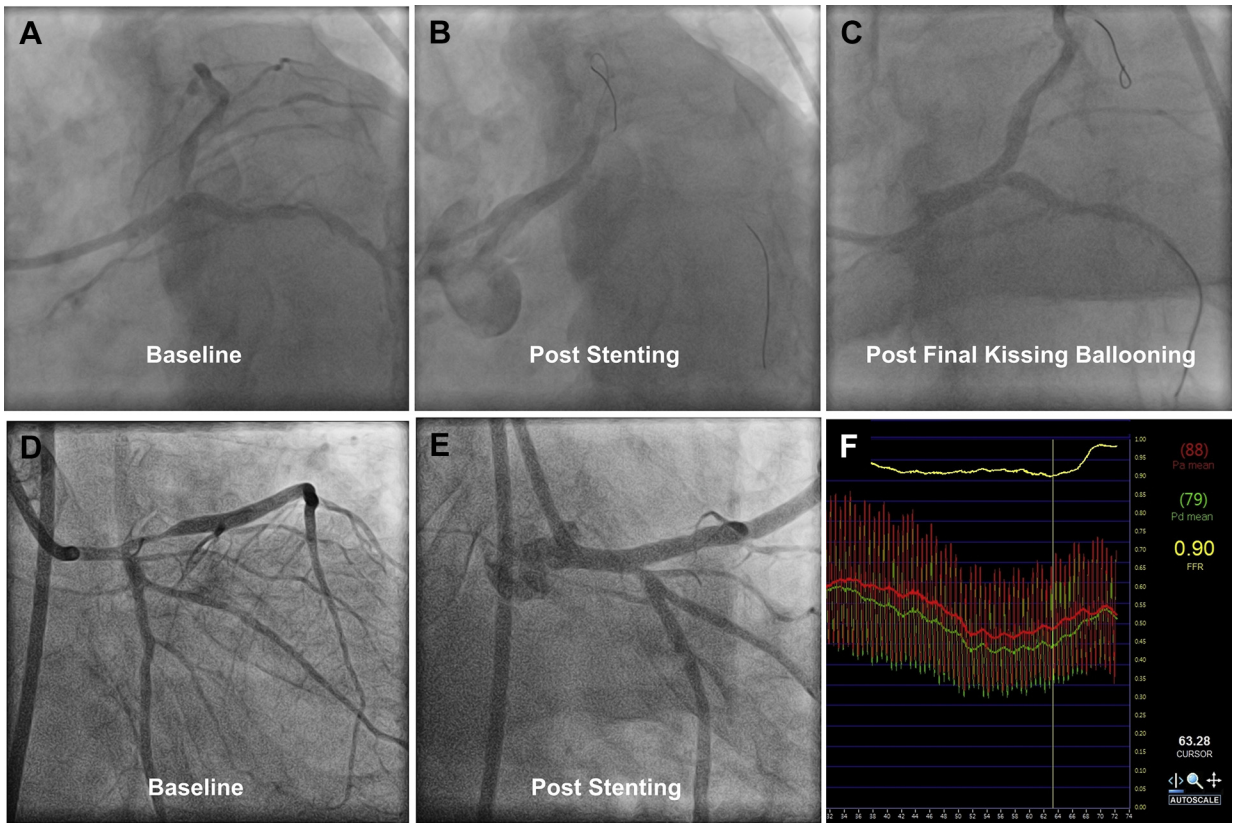


Figure 2. Representative cases. After simple crossover stenting for distal left main bifurcation narrowing, side branch flow was compromised *(A, B)*. After FKB, side branch flow was recovered *(C)*. After simple crossover stenting, left circumflex ostium became narrowed *(D, E)*. However, fractional flow reserve for left circumflex artery was 0.90 *(F)*. Furthermore, FKB was not necessary.

Table 1
Baseline patient and lesion characteristics

Variables	Final Kissing Ballooning		p value
	Yes (N=95)	No (N=318)	
Age (year)	62.6 ± 10.2	62.7± 10.9	0.96
Men	71 (75%)	236 (74%)	0.92
Hypertension	66 (63%)	201 (63%)	0.99
Diabetes mellitus	32 (34%)	126 (40%)	0.30
Current smoker	23 (24%)	80 (25%)	0.85
Dyslipidemia	44 (46%)	178 (56%)	0.10
Left ventricular ejection fraction (%)	61.4 ± 7.1	60.0 ± 7.8	0.13
Chronic renal failure	2 (2%)	15 (5%)	0.38
Acute coronary syndrome	34 (36%)	137 (43%)	0.21
Coronary disease extent			0.68
LM only	4 (4%)	19 (6%)	
LM plus 1vessel	30 (32%)	114 (36%)	
LM plus 2 vessel	32 (34%)	104 (33%)	
LM plus 3 vessel	29 (31%)	81 (26%)	
Left circumflex artery ostial diameter stenosis ≥ 75%			
Before Cross-over stenting	6 (6%)	6 (2%)	0.024
After Cross-over stenting	36 (38%)	15 (5%)	<0.001
TIMI <3 flow of left circumflex artery			
Before Cross-over stenting	0	0	>0.99
After Cross-over stenting	0	1 (0.2)*	>0.99
Intravascular ultrasound	93 (98%)	312 (98%)	>0.99
Total stent number in left main	1.59 ± 0.82	1.79 ± 0.82	0.36

FKB = final kissing balloon; TIMI = thrombolysis in myocardial infarction.
* TIMI 2 in only one patient after simple cross-over stenting.

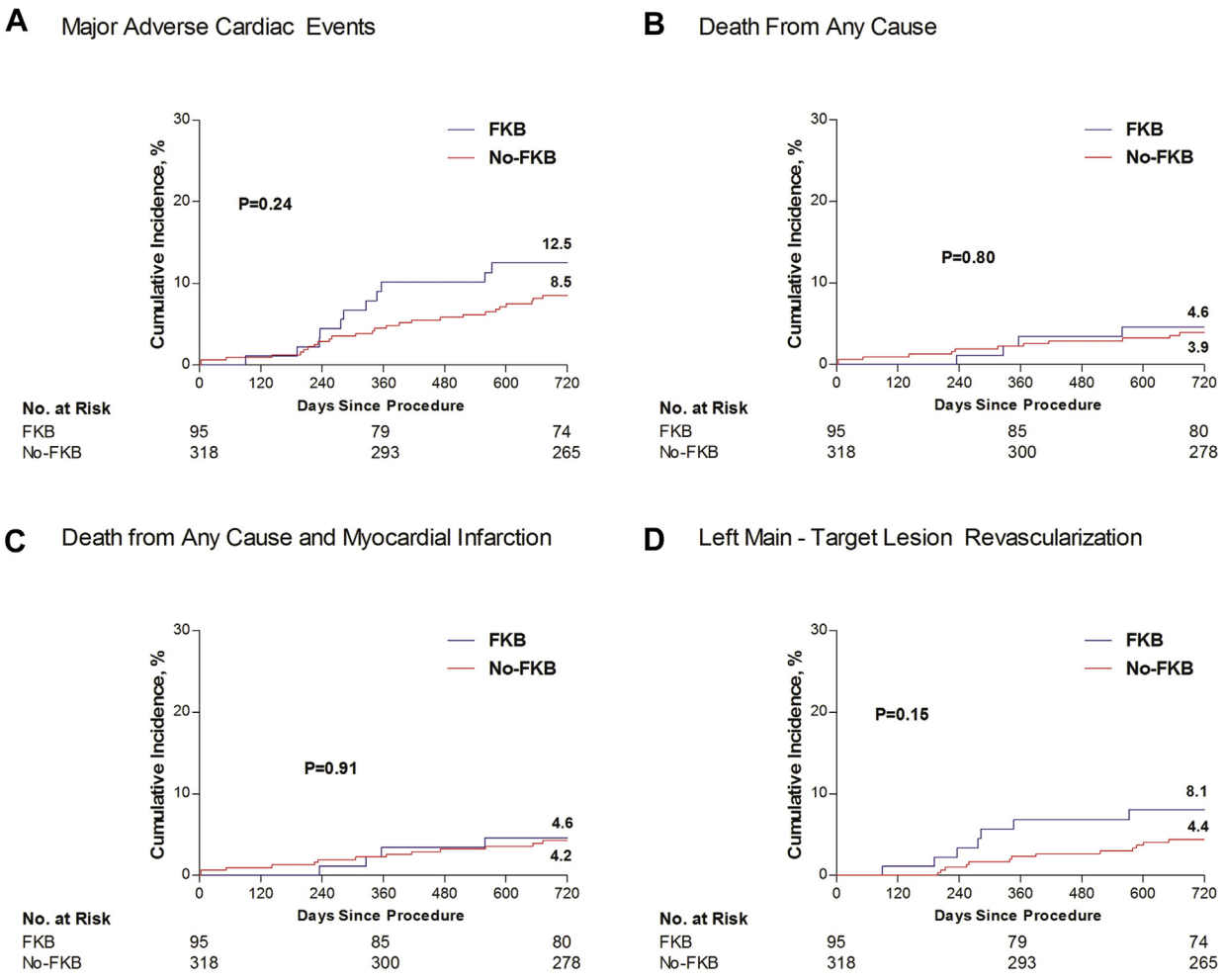


Figure 3. Kaplan–Meier curves for clinical outcomes.

Table 2
Adjusted hazard ratio for clinical outcomes at 2 years

	Final Kissing Ballooning		Adjusted Hazard Ratio (95% Confidence Interval)†	p value
	Yes (N=95)	No (N=318)		
Death	4 (4.6%)*	12 (3.9%)	1.03 (0.28–3.82)	0.97
Myocardial infarction	0	2 (0.7%)	infinite	0.96
Death or myocardial infarction	4 (4.6%)	13 (4.2%)	0.95 (0.26–3.51)	0.96
Any repeat revascularization	9 (10.5%)	20 (6.7%)	0.99 (0.41–2.38)	0.98
Target vessel revascularization	7 (8.1%)	14 (4.8%)	1.12 (0.40–3.11)	0.83
Left main-target lesion revascularization	7 (8.1%)	13 (4.4%)	1.32 (0.46–3.75)	0.60
Definite stent thrombosis	0	0	NA	NA
Death, myocardial infarction or left main-target lesion revascularization	11(12.5%)	26(8.5%)	1.10 (0.49–2.49)	0.82

FKB = final kissing balloon; NA = not available.
* Derived from a Kaplan-Meier estimate.
† Adjusted for age, diabetes mellitus, clinical presentation, stent number, preprocedural ostial diameter stenosis of the left circumflex artery, and post-stenting ostial diameter stenosis of the left circumflex artery.

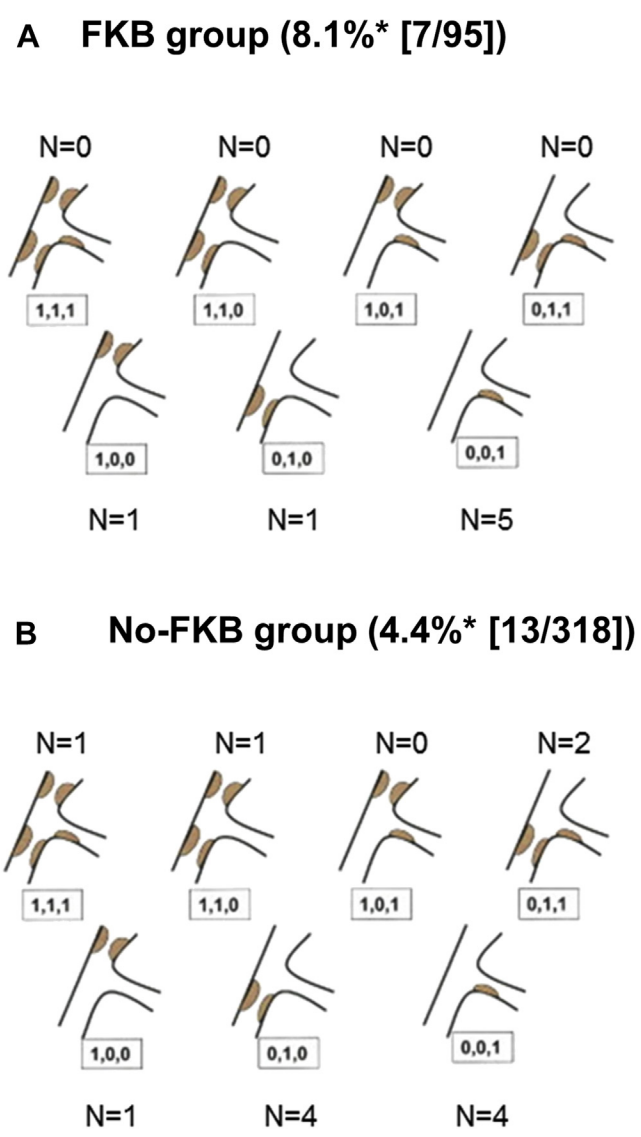


Figure 4. Location of left main target lesion revascularization. *Data derived from Kaplan−Meier estimates.

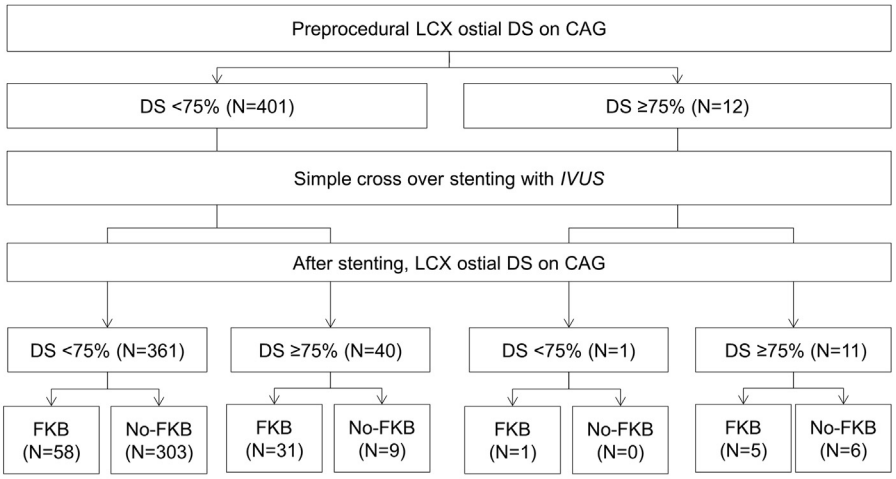
inflation may not be necessary, and selective FKB strategy appears to be more justified.

Despite the immense progress and extensive investigation into LM stenting, the optimal strategy for LM bifurcation stenting has not yet been established. In particular, in cases in which decreased coronary blood flow or severe dissection does not occur in the side branch, it remains unknown whether FKB inflation provides a clinical advantage, although it is frequently performed in real-world practice because of the relatively large myocardial territory of the LM side branch during LM bifurcation stenting.[1,2,10] For non-LM bifurcation stenosis, several randomized and observational studies have already demonstrated that FKB inflation does not improve clinical outcomes. In fact, it is reported to be harmful in some studies.[11−16] For LM bifurcation stenosis, we first demonstrated that, as in the case of non-LM bifurcation stenosis, FKB inflation after simple crossover stenting did not provide a clinical benefit over a 2-year follow-up period.

Our findings can be explained by (1) the ineffectiveness of balloon dilatation for the prevention of side branch restenosis in the long-term, (2) the potential for harmful injury after balloon dilatation during main vessel stenting or side branch stenting,[11,15,16] and more importantly, and (3) the observation that most jailed side branches, even in the case of LM bifurcation, were not associated with functionally significant stenosis as seen in FFR study for non-LM bifurcation. Two small pilot studies demonstrated that, similar to non-LM bifurcation, only less than 1/3 of jailed ostial left circumflex arteries have functionally significant stenosis (FFR <0.80).[17,18] In our analysis, among jailed side branches evaluated by FFR measurements, only 2 jailed side (5.7%) branches had functionally significant stenosis (FFR ≤ 0.80). Therefore, further balloon inflation may not be associated with clinical benefits, although further large clinical study is necessary.

Because of the large jeopardized area of the left circumflex artery, side branch flow compromise after main vessel stenting should be avoided. In our study, symptomatic side branch flow compromise occurred in only 1 patient. This low rate could be due to the routine use of intravascular ultrasound (IVUS) to determine the bifurcation stenting strategy. As IVUS, particularly when it is used for direct imaging from the left circumflex artery, provides accurate information about the disease status of LM bifurcation, including a left circumflex artery ostium, preprocedural IVUS is very helpful for the selection of more appropriate and safer stenting strategies (1-stent or 2-stent strategies). In addition, its use may reduce the mandatory demand for FKB inflation after main vessel stenting. In fact, several IVUS findings, such as the presence of plaques on the carina side[19] and calcified plaques,[20] are associated with side branch compromise, and thus, the use of IVUS is reported to reduce the risk of side branch occlusion after main vessel stenting.[17,21]

There are several limitations to this study. First, this was a nonrandomized, retrospective, observational study. The decision to perform simple crossover stenting and FKB was at the operator's discretion. Therefore, despite statistical adjustment, this may represent an intractable limitation of the present study. Second, IVUS was used in almost all cases. Although IVUS is strongly recommended during LM stenting, IVUS is still underused in real-world practice. Therefore, our results, obtained by very experienced operators using mostly IVUS guidance, may not be generalizable to other hospitals. Third, as routine angiographic follow-up was not performed, the rate of angiographic restenosis may have been underestimated. However, current guidelines no longer recommend routine angiographic follow-up after LM stenting. Finally, a longer-term follow-up study is necessary to confirm the conclusions of the present study.



Death	3 (5.2%)	11 (3.6%)	1 (3.2%)	0	0	0	0	1 (16.7%)
MI	0	0 (0.7%)	0	0	0	0	0	0
LM-TLR	1 (1.7%)	12 (4.0%)	5 (16.1%)	1 (11.1%)	0	0	1 (20.0%)	0
MACE	4 (6.8%)	24 (7.9%)	6 (19.4%)	1 (11.1%)	0	0	1 (20.0%)	(16.7%)

Figure 5. Clinical outcomes according to the side branch-diameter stenosis. CAG = coronary artery angiogram; DS = diameter stenosis; FKB = final kissing balloon; IVUS = intravascular ultrasound; LCX = left circumflex artery; LM-TLR = left main target lesion revascularization.

Disclosures

The authors have no conflicts of interest to disclose.

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