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;118:3010-4812; fax: (+82) 2-475-6898.

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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 F8) before or after FKB, provisional stenting...
was selectively performed.\(^7\) Antiplatelet therapy and peri-procedural 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.

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...
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