Original Article

Effect of Final Kissing Balloon Dilatation after One-stent Technique at Left-main Bifurcation: A Single Center Data

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Abstract

Background: Whether final kissing balloon (FKB) dilatation after one-stent implantation at left-main (LM) bifurcation site remains unclear. Therefore, this large sample and long-term follow-up study comparatively assessed the impact of FKB in patients with unprotected LM disease treated with one-stent strategy.

Methods: Total 1528 consecutive patients underwent LM percutaneous coronary intervention in one center from January 2004 to December 2010 were enrolled; among them, 790 patients treated with one drug-eluting stent crossover LM to left anterior descending (LAD) with FKB (n = 230) or no FKB (n = 560) were comparatively analyzed. Primary outcome was the rate of major adverse cardiovascular events, defined as a composite of death, myocardial infarction (MI) and target vessel revascularization (TVR).

Results: Overall, The prevalence of true bifurcation lesions, which included Medina classification (1,1,1), (1,0,1), or (0,1,1), was similar between-groups (non-FKB: 37.0% vs. FKB: 39.6%, P = 0.49). At mean 4 years follow-up, rates of major adverse cardiovascular events (non-FKB: 10.0% vs. FKB: 7.8%, P = 0.33), death, MI and TVR were not significantly different between-groups. In multivariate propensity-matched regression analysis, FKB was not an independent predictor of adverse outcomes.

Conclusions: For patients treated with one-stent crossover LM to LAD, clinical outcomes appear similar between FKB and non-FKB strategy.

Key words: Angioplasty, Balloon; Bifurcation; Percutaneous Coronary Angioplasty; Unprotected Left-main

INTRODUCTION

Randomized trials comparing simple and complex techniques for non-left-main (LM) coronary bifurcation disease demonstrated that provisional one-stent is easier and not inferior to two-stent technique.1-5 Although the provisional one-stent approach is now regarded as standard technique for most non-LM bifurcation lesions,6 three studies reached inconsistent conclusions on necessity of final kissing ballooning (non-FKB) after main vessel stenting.7,8 and there are no studies on FKB in LM bifurcation lesions.9-20 So, whether FKB dilatation after one-stent implantation at LM bifurcation site remains unclear currently. Therefore, we conduct this long-term follow-up study to comparatively assess FKB impact in patients with unprotected left-main (UPLM) disease treated with one-stent strategy.

METHODS

Study population

Data from 1528 consecutive patients from a single center (FuWai Hospital, National Center for Cardiovascular Diseases, Beijing, China) undergoing LM percutaneous coronary intervention (PCI) from January 2004 to December 2010 were prospectively collected. Among them, 790 patients treated with one drug-eluting stent (DES) crossover LM to left anterior descending (LAD) by FKB (n = 230) or no FKB (n = 560) were analyzed after exclusion of patients with acute myocardial infarction (MI) within 24 h and cardiac shock. UPLM disease was defined as documented myocardial ischemia with ≥50% UPLM stenosis and no patent bypass graft to the LAD or left circumflex (LCX) arteries. The decision for UPLM PCI was based on consultation with both patients and surgeons in instances of patient refusal for surgery or comorbidity that posed excessive surgical risk.

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Procedural details
At our center, it is common to perform provisional two-stent strategies if LCX ostium is severely jeopardized after one-stent crossover from LM to LAD that is, severe dissection or thrombosis in MI flow <3 grade or residual stenosis ≥80%. Otherwise, performing FKB was per treating physician’s discretion. FKB were performed with noncompliant balloons; main vessel balloons had similar diameter while side branch balloons were usually smaller than vessels. Final kissing pressure was comparatively low (6–10 atm) after the sequential high-pressure dilatation (16–20 atm). Proximal optimization technique[21] with larger noncompliant balloon was often performed. LCX ostium was assessed mainly by angiography, some by intravascular ultrasound (IVUS), and none by fractional flow reserve (FFR) because of its unavailability during the study period.

Before the procedure, all patients received aspirin, 300 mg daily, and a 300 mg loading dose of clopidogrel was given at least 1-day before the procedure. During the procedure, unfractionated heparin (100 U/kg) was administered to all patients, and use of glycoprotein IIb/IIIa inhibitors was per operator’s judgment. After the procedure, aspirin was prescribed at a dose of 300 mg daily for 3 months, followed by 100 mg daily indefinitely; clopidogrel 75 mg daily was prescribed for at least 1-year.

Patient follow-up
All patients were evaluated by clinic visit or by phone at 1, 3, 6, and 12 months and annually thereafter. Patients were advised to return for coronary angiography if clinically indicated by symptoms or documentation of myocardial ischemia.

Study outcomes
Angiographic success was defined as residual stenosis of <30% by visual estimation in the presence of TIMI flow grade 3. MI was diagnosed by electrocardiographic changes and/or a rise and fall of the creatine kinase-myocardial band fraction in the presence of ischemic symptoms. New development of pathological Q-waves in two contiguous leads was defined as Q-wave MI; and in the absence of pathological Q-waves, an elevation in creatine kinase-myocardial band level >3 times the upper limit of normal was defined as non-Q-wave MI. Target vessel revascularization (TVR) was defined as repeated revascularization by PCI or surgery of the target vessel. The composite of major adverse cardiac events (MACE) was defined as the occurrence of death, MI, and TVR in-hospital and during follow-up. Stent thrombosis was defined on the basis of Academic Research Consortium definitions according to timing of presentation as early (0–30 days), late (31–360 days), or very late (>360 days) and to the level of certainty as definite, probable and possible.[22]

Statistical analysis
Continuous variables are described as mean (standard deviation) or median (Q1, Q3), and Student’s t-tests or Wilcoxon test were performed for between-group comparisons as appropriate. Categorical variables are shown as percentages and compared by Chi-square test.

Propensity score matching analysis was performed to minimize potential bias secondary to between-group imbalance. Propensity scores were calculated using a logistic model (C-statistics: 0.88) with inclusion of the following variables: Sex, age, body mass index, prior MI, prior PCI, previous coronary artery bypass grafting (CABG), diabetes mellitus, hypertension, unstable angina, hyperlipidemia, family history of coronary artery disease, prior stroke, left ventricular ejection fraction (LVEF), transradial approach, stent diameter, stent length, use of IVUS, and baseline SYNTAX score. Patients were matched 1:1 using the greedy 8-to-1 digit matching algorithm without replacement. Kaplan–Meier product limit methods were used to calculate survival curves for outcomes by group and log-rank tests were used to examine differences between-groups. Hazard ratios were estimated by the Cox proportional hazard regression model after controlling for the abovementioned confounders. All tests were two-sided and conducted at the 0.05 level.

Results
Baseline patient characteristics
The two groups were matched for all clinical characteristics except for a higher prevalence of prior CABG and a lower LVEF in the non-FKB group [Table 1]. Lesion and procedural characteristics are presented in Table 2. The patients enrolled in this study were at low-intermediate SYNTAX score (non-FKB: 25 ± 7 vs. FKB: 23 ± 5, P = 0.01), and clinical SYNTAX scores were similar between-groups (non-FKB: 31 ± 23 vs. FKB: 28 ± 20, P = 0.15). The prevalence of true bifurcation lesions, which included Medina classification (1,1,1), (1,0,1), or (0,1,1), was similar between-groups (non-FKB: 37.0% vs. FKB: 39.6%, P = 0.49). Compared with FKB patients, non-FKB patients more frequently were treated with transradial approach. Second-generation DESs including Xience V and Endeavor Sprint or Endeavor Resolute DES were commonly implanted in non-FKB than FKB patients (24.3% vs. 12.6%, P < 0.01). Procedure time was longer and more contrast was used in the FKB group. LM bifurcation angiographic success rate was significantly lower in non-FKB patients (68.9% vs. 83.0%, P < 0.01), mainly secondary to residual stenosis at LCX ostium.

In-hospital and long-term outcomes
During hospitalization, no differences were observed in the rates of death, MI and TVR between-groups; likewise for MACE rate (non-FKB: 2.7% vs. FKB: 0.9%, P = 0.17) [Table 3].

Clinical follow-up was completed for all patients, and follow-up duration was longer for FKB patients (non-FKB: 4.1 ± 1.9 years vs. FKB: 4.8 ± 2.0 years, P < 0.01). Rates of death, MI and TVR were not significantly different between-groups; likewise for MACE rate (non-FKB: 10.0%
### Table 1: Baseline clinical characteristics

| Items                                | Total population | Propensity-matched population |
|--------------------------------------|------------------|-------------------------------|
|                                      | Non-FKB (n = 560) | FKB (n = 230)                | Non-FKB (n = 392) | FKB (n = 196) |
| Age, years                           | 59.7 ± 10.5      | 59.6 ± 10.8                  | 59.68 ± 10.39     | 59.80 ± 10.62 |
| Male gender, n (%)                   | 446 (79.6)       | 184 (80.0)                   | 308 (78.6)        | 157 (80.1)    |
| BMI, kg/m²                           | 25.9 ± 3.2       | 25.8 ± 2.9                   | 25.9 ± 3.1        | 25.7 ± 2.9    |
| Diabetes mellitus*, n (%)            | 124 (22.1)       | 52 (22.6)                    | 88 (22.4)         | 42 (21.4)     |
| Hypertension*, n (%)                 | 296 (52.9)       | 128 (55.7)                   | 214 (54.6)        | 104 (53.1)    |
| Hyperlipidemia*, n (%)               | 286 (51.1)       | 103 (44.8)                   | 204 (52.0)        | 94 (48.0)     |
| Prior MI, n (%)                      | 137 (24.5)       | 57 (24.8)                    | 93 (23.7)         | 48 (24.5)     |
| Prior PCI, n (%)                     | 109 (19.5)       | 58 (25.2)                    | 81 (20.7)         | 42 (21.4)     |
| Prior CABG, n (%)                    | 17 (3.0)         | 2 (0.9)                      | 3 (0.8)           | 2 (1.0)       |
| Current smoker, n (%)                | 159 (28.4)       | 67 (29.1)                    | 113 (28.8)        | 56 (28.6)     |
| Family history of CAD, n (%)         | 61 (10.9)        | 34 (14.8)                    | 43 (11.0)         | 21 (10.7)     |
| Prior stroke, n (%)                  | 35 (6.3)         | 16 (7.0)                     | 25 (6.4)          | 15 (7.7)      |
| Peripheral vascular disease, n (%)   | 32 (5.7)         | 7 (3.0)                      | 17 (4.3)          | 7 (3.6)       |
| Chronic lung disease, n (%)          | 4 (0.7)          | 4 (1.7)                      | 3 (0.8)           | 0 (0.0)       |
| Unstable angina, n (%)               | 345 (61.6)       | 145 (63.0)                   | 247 (63.0)        | 125 (63.8)    |
| LVEF, %                              | 62.6 ± 7.6       | 63.8 ± 7.0                   | 62.7 ± 7.2        | 63.0 ± 6.8    |
| Creatinine clearance rate, ml/min    | 81.1 ± 18.5      | 81.3 ± 20.8                  | 81.4 ± 19.7       | 81.3 ± 21.3   |

Data are presented as n (%) or mean ± SD. *Defined as requiring medical therapy. MI: Myocardial infarction; PCI: Percutaneous coronary intervention; CABG: Coronary artery bypass grafting; CAD: Coronary artery disease; LVEF: Left ventricular ejection fraction; SD: Standard deviation; FKB: Final kissing balloon; BMI: Body mass index.

### Table 2: Lesion and procedural characteristics and outcomes

| Items                                | Total population | Propensity-matched population |
|--------------------------------------|------------------|-------------------------------|
|                                      | Non-FKB (n = 560) | FKB (n = 230)                | Non-FKB (n = 392) | FKB (n = 196) |
| Baseline SYNTAX score                | 24.6 ± 6.5       | 23.4 ± 5.3                   | 23.9 ± 5.9        | 23.8 ± 5.4    |
| Clinical SYNTAX score               | 30.6 ± 22.5      | 28.3 ± 19.6                  | 30.5 ± 22.9       | 29.3 ± 19.7   |
| Medina classification, n (%)         |                 |                               |                  |
| 1,1,1                                | 140 (25.0)       | 59 (25.7)                    | 77 (21.9)         | 52 (28.3)     |
| 1,0,1                                | 34 (6.1)         | 17 (7.4)                     | 19 (5.4)          | 15 (8.2)      |
| 0,1,1                                | 33 (5.9)         | 15 (6.5)                     | 4 (1.1)           | 2 (1.1)       |
| 1,0,0                                | 51 (9.1)         | 11 (4.8)                     | 12 (3.4)          | 6 (3.3)       |
| 1,1,0                                | 222 (39.6)       | 81 (35.2)                    | 165 (42.4)        | 73 (37.2)     |
| 0,1,0                                | 66 (11.8)        | 41 (17.8)                    | 45 (11.5)         | 37 (18.9)     |
| 0,0,1                                | 14 (2.50)        | 6 (2.61)                     | 6 (1.5)           | 3 (1.5)       |
| True bifurcation*, n (%)             | 207 (37.0)       | 91 (39.6)                    | 142 (36.2)        | 75 (38.3)     |
| Restenotic lesion, n (%)             | 13 (2.3)         | 8 (3.5)                      | 8 (2.0)           | 6 (3.1)       |
| Transradial approach, n (%)          | 351 (62.7)       | 121 (52.6)                   | 153 (39.0)        | 79 (40.3)     |
| Stent/patient                        | 2.1 ± 1.1        | 1.9 ± 1.1                    | 2.0 ± 1.1         | 2.0 ± 1.2     |
| Stent diameter, mm                   | 3.35 ± 0.39      | 3.39 ± 0.39                  | 3.36 ± 0.39       | 3.39 ± 0.39   |
| Stent length, mm                     | 33 ± 19          | 30 ± 17                      | 33 ± 19           | 30 ± 16       |
| DES type, n (%)                      |                 |                               |                  |
| Sirolimus-eluting                    | 347 (62.0)       | 160 (69.6)                   | 237 (60.5)        | 141 (71.9)    |
| Paclitaxel-eluting                   | 77 (13.8)        | 41 (17.8)                    | 62 (15.8)         | 31 (15.8)     |
| Second-generation DES                | 136 (24.3)       | 29 (12.6)                    | 93 (23.7)         | 24 (12.2)     |
| IVUS, n (%)                          | 177 (31.6)       | 79 (34.3)                    | 126 (32.1)        | 63 (32.1)     |
| Hemodynamic support with IABP, n (%) | 27 (4.8)         | 12 (5.2)                     | 19 (4.9)          | 11 (5.6)      |
| Procedure time, min                  | 46 ± 32          | 61 ± 36                      | 45 ± 31           | 63 ± 37      |
| Contrast volume, ml                  | 232 ± 83         | 266 ± 82                     | 234 ± 79          | 265 ± 78     |
| LM bifurcation angiographic success, n (%) | 386 (68.9)   | 191 (83.0)                   | 263 (67.1)        | 158 (81.1) |

Data are presented as n (%) or mean ± SD. *True bifurcation included Medina classification (1,1,1; 1,0,1; 0,1,1); †Second-generation DES included: Xience V and Endeavor Sprint or Endeavor Resolute DES. DES: Drug-eluting stent; IVUS: Intravascular ultrasound; IABP: Intra-aortic balloon pump; LM: Left-main; FKB: Final kissing balloon; SD: Standard deviation.

vs. FKB: 7.8%, P = 0.33) [Table 3]. Definite and probable stent thrombosis rates were also similar overall and at different time intervals (early, late, very late) between-groups (overall, non-FKB: 2.1% vs. FKB: 3.5%, P = 0.29). There were no
Propensity score: Matched analysis

After performing propensity score matching, a total of 196 matched pairs (392 patients from the non-FKB group and 196 patients from the FKB group) were generated. There were no significant differences in baseline clinical, lesion and procedural characteristics for the propensity-matched subjects except for the rate of second-generation DES [Tables 1 and 2]. In this adjusted model, MACE and its individual components did not differ significantly between-groups [Table 3 and Figure 1b], and FKB was not predictive of MACEs in multivariate regression analysis [Figure 2].

**DISCUSSION**

The major finding of this relatively large study evaluating FKB impact on long-term outcomes after one-stent at LM bifurcation site was that one-stent crossover LM to LAD without FKB was associated with similar in-hospital and long-term clinical outcomes to that with FKB.

To date, there have been only three studies assessing FKB impact in patients with bifurcation lesions treated with one-stent strategy. The randomized Nordic III study which recruited 477 patients, indicated that there was neither advantage nor disadvantage to kissing balloon inflations within 6 months follow-up. The study conducted by Gwon et al. enrolled a total of 1065 consecutive patients in the COBIS registry, one-third of whom underwent FKB dilatation. During a mean follow-up of 22 months, the main vessel re-intervention rate was significantly higher in the kissing balloon group (9.1%) than the nonkissing balloon group (3.4%). The study, therefore, concluded that in patients treated with one-stent technique for bifurcation lesions, FKB after main vessel stenting may be harmful due to increased TLR. Another study conducted by Yamawaki et al. was a sub-analysis of the TAXUS Japan Postmarket Surveillance Study, comparing 132 FKB patients versus 121 non-FKB patients with 3 years follow-up. The study concluded that in a one-stent approach, FKB was associated with worse angiographic outcomes in the main vessel and did not demonstrate any clinical benefit over the long-term follow-up period. It was noted that these studies focused on non-LM bifurcation studies, and the sample size of Yamawaki et al.’s study was too small, which could not evaluate low incidence clinical events of different approaches. Although Gwon et al.’s and the current analysis are based on registry studies reflecting real world practice, obvious higher prevalence of true bifurcation lesions was found in the former study (65.9% vs. 37.7%). This may reflect operators’ preference of two-over one-stent techniques for LM than non-LM true bifurcation lesions to avoid the dire consequences of losing a large side branch such as LCX or LAD.

Theoretically, there are several advantages for FKB after one-stent crossover LM to LAD. This technique scaffolds the origin of the LCX, retains access to LCX, and optimizes expansion of the proximal part of the stent. This study showed higher angiographic success rate for FKB group (83.0% vs. 68.9%; \( P < 0.01 \)), mainly secondary to
Figure 2: Multivariable analysis of major adverse events multivariable matched propensity analysis demonstrates no significant difference in incidence rates of individual and composite clinical outcomes between final kissing balloon (FKB) and non-FKB strategies. MACE: Major adverse cardiac events; MI: Myocardial infarction; TVR: Target vessel revascularization. propensity score matched analysis that is, the immediate better angiographic result did not translate into better

less stenosis of LCX after FKB. However, in-hospital and long-term outcomes were similar between-groups even after
long-term clinical outcomes. However, because this study only enrolled patients with mild to intermediate stenosis at LCX ostium (<80% in diameter) without functional assessment by FFR, it remains undefined if FKB would result in better clinical outcomes in patients with severe stenosis at LCX ostium (≥80% in diameter). Nordic III study showed similar results to those of this study,[7] however 6 months’ follow-up in Nordic III was not long enough particularly because the first-generation DES used exhibits a restenotic catch-up phenomenon.[24]

FKB potentially may be associated with complications including main vessel stent deformation, DES polymer disruption caused by side branch ballooning and main vessel proximal part injury secondary to over-dilatation. In Gwon et al.’s study, FKB increased TLR rate,[8] perhaps secondary to harmful effects of FKB; however, no information was provided on balloons and FKB pressure. Presumably, bigger than vessel size and semi-compliant balloons and higher pressure FKB would increase the severity of all those harmful effects. In this study, however, FKB were noncompliant and main vessels balloons were similar in diameter to the vessels while side branch balloons were usually smaller than vessel size; final kissing pressure also was comparatively low (6–10 atm) after sequential high pressure dilatation (16–20 atm), and proximal optimization technique[21] with bigger noncompliant balloon was often performed. All the latter features might minimize damage and deformation of the main vessel proximal part. Moreover, higher TLR rate in FKB group in Gwon et al.’s study might be secondary to higher prevalence of true bifurcations (74.8% vs. 62.0%, P < 0.001), in contrast to this study, in which the prevalence of true bifurcation lesions was similar between-groups (non-FKB: 37.0% vs. FKB: 39.6%, P = 0.49).

Although patients with FKB had similar clinical outcomes as those without FKB, this study also showed that FKB more often required higher volume of contrast, longer procedure time and more balloons, indicating that FKB cases were technically more challenging and required more resources than non-FKB ones.

The major limitation of this study is its nonrandomized design in which operator bias and unmeasured confounders may preclude any definitive conclusion. Because patients with bail-out side branch stenting were excluded from this analysis, study conclusions do not apply to all LM bifurcation lesions. In addition, the study did not include qualitative comparative analysis data although it would have provided more detailed information, we did not think it would affect result interpretation.

In conclusion, for patients treated with one-stent crossover LM to LAD, clinical outcomes appear similar between FKB and non-FKB strategy.

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