Journal of Advances in Medicine and Medical Research

32(9): 83-93, 2020; Article no.JAMMR.58185
ISSN: 2456-8899
(Past name: British Journal of Medicine and Medical Research, Past ISSN: 2231-0614, NLM ID: 101570965)

A Short Term Clinical Outcome of Provisional versus Routine Kissing Balloon Technique after Main Vessel Crossover Stenting for Coronary Bifurcation Lesions

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Authors' contributions

This work was carried out in collaboration among all authors. Author MAK designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors FAE and MMA managed the analyses of the study. Authors SMSE and AME managed the literature searches. All authors read and approved the final manuscript.

Article Information

DOI: 10.9734/JAMMR/2020/v32i930488
Editor(s):
(1) Dr. Murali P. Vettath, Meitra Hospital, India.
Reviewers:
(1) Hamed Tavan, Ilam University of Medical Sciences, Iran.
(2) Stoia Mirela-Anca, University of Medicine and Pharmacy Iuliu Haţieganu, Romania.
Complete Peer review History: http://www.sdiarticle4.com/review-history/58185

Original Research Article

Received 18 April 2020
Accepted 21 June 2020
Published 30 June 2020

ABSTRACT

Background: Kissing Balloon Inflation (KBI) technique was the first technique for percutaneous intervention in bifurcation lesions. It's the standard strategy in the two-stent procedure. Its benefit in one-stent approach remains uncertain. Several trials comparing KBI strategy with the No-KBI strategy in one-stent technique did not show any advantages in the clinical outcome. Clinical outcome and the follow up of ischemic symptoms is a useful method to compare the effectiveness of both strategies.
Aims: To study the short-term clinical outcome (3and 6 months) of provisional versus routine kissing-balloon technique after main vessel stenting for coronary bifurcation lesions.
Patients and Methods: The study included sixty consecutive patients. They were randomized to receive different side branch (SB) intervention strategies: group I (provisional final kissing balloon

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inflation group - PFKBI) (FKBI only when SB Flow less than TIMI 3) and group II (routine final kissing balloon inflation group – RFKBI).
Results: 1- Dissection of side branch and conversion to two stent strategy was significantly higher in PFKBI group (14,3%) than in RFKBI group (0) 2-The amount of dye, total procedure time and time of admission was significantly higher in RFKBI group. 3-Chest pain immediately after the procedure was significantly higher in PFKBI group while at 3 and 6 months follow up no significant difference between both groups was noticed. 4- MACE, target lesion revascularization (TLR) and stent thrombosis were similar between both groups at 3 and 6 months.
Conclusions: Main vessel stenting with and without final kissing balloon dilatation was associated with favorable and similar 3 and 6-month clinical outcomes.

Keywords: Routine kissing balloon technique; main vessel crossover stenting; coronary bifurcation lesions.

1. INTRODUCTION

Bifurcation lesions are frequent among patients presenting with symptomatic coronary disease and undergoing percutaneous coronary intervention (PCI) accounting for 15% to 20% coronary lesions [1].

Treatment of these lesions is accompanied by increased peri-procedural myocardial infarction (MI), stent thrombosis, long-term restenosis and higher costs [2].

Dealing with bifurcation lesions also increases the risk of side branch (SB) damage, defined as worsening of degree of stenosis, or even SB occlusion due to plaque or carina shift, severe spasm, or ostial dissection [3].

Although many techniques have been developed, the conservative (provisional) approach, where the main branch (MB) is treated first and the side branch (SB) is only treated if needed, remain the current main strategy [4].

Kissing balloon inflation (KBI) technique was the first specific bifurcation technique that have been used for percutaneous bifurcation interventions and continues to play an important role [5].

One of its benefits is to optimize stent apposition, improve side branch entry and to correct stent deformation [6]. However, in complex anatomy, the procedure-time and contrast media are more increased than without kissing balloon [7,8].

KBI technique is the standard strategy in bifurcation lesions that are treated with the two-stent technique, unfortunately, the benefit of this procedure in the one-stent approach remains uncertain due to poor clinical data [9].

Several recent retrospective trials that compared the KBI strategy with the No-KBI strategy in patients undergoing the one-stent technique did not show any detectable advantages in the clinical outcome [10].

Clinical outcomes in the form of follow up for major adverse cardiac events (MACE), ischemic symptoms, and echocardiographic parameters that search for ischemia in the pretreated territory is a useful methods to compare the effectiveness of both strategies [11].

2. PATIENTS AND METHODS

This is a cohort prospective randomized study which was conducted at Tanta university hospital (TUH) in the period between (October, 2017 to October, 2018). The study included sixty consecutive patients. They were randomized to receive elective different side branch (SB) intervention strategies:

o Group I (Provisional final kissing balloon inflation group (PFKBI)):- FKI was done only when side branch flow was less than TIMI III after main vessel stenting).

o *Group* II (Routine final kissing balloon inflation group) (RFKBI, mandatory FKI was done after main vessel stenting until SB-residual stenosis less than 50%).

2.1 Inclusion Criteria

Patients: Patients who had angina or documented myocardial ischemia. Patients who were eligible for drug eluting stent (DES), aged more than 18 years.

Lesion: De-novo non-left main (non-LMT) culprit lesion (CBL) (main vessel > 2.5 mm, SB > 2.0 mm), except for Medina class (0,0,1), side branch lesion length <5mm visual estimate, MB

lesion length < 46 mm, TIMI flow III in main vessel and side branch.

2.2 Exclusion Criteria

Patient: patients with left ventricular ejection fraction less than 30%, patients with renal dysfunction (creatinine more than 2.3 mg/dl), patients with liver dysfunction, patients who were not agree with informed consent, patients with life expectancy less than 1 year, pregnant female patients, patients with contraindication for antiplatelet therapy.

Lesion: target lesion for acute myocardial infarction, left main disease, target lesion of in-stent restenosis, bypass graft, chronic total occlusion, main vessel reference diameter more than 4.5mm, bifurcation lesion that needed 2 stent strategy intention, highly tortious and calcified lesions.

2.3 Follow up was Done After

A-24 h after the procedure for chest pain, cardiac biomarkers (namely high sensitive serum troponin), access hematoma, cardiac death, stroke, signs of side branch occlusion and hospital admission time.

B-3 and 6 months: clinical signs including suggestive symptoms of cardiac ischemia, like chest pain and major adverse cardiac events (MACE) including cardiac death, myocardial infarction (MI), stent thrombosis, heart failure (HF) or target vessel revascularization (TVR) and stroke were monitored during the entire study period.

Echocardiographic evaluation was performed in order to assess left ventricular systolic function by Simpson method and diastolic dysfunction (by Measuring mitral inflow included the peak early filling (E-wave) and late diastolic filling (A-wave) velocities, the E/A ratio. Early diastolic mitral annular velocity (e′) in the apical 4-chamber view), left ventricular volumes (end systolic and end diastolic), regional wall motion abnormalities, global wall motion score index , valve dysfunction , global longitudinal strain.

2.4 Statistical Analysis

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) Qualitative data were described using number and percent. The Kolmogorov-Smirnov test was used to verify the normality of distribution Quantitative data were described using range (minimum and maximum), mean, standard deviation and median. Statistical significance was considered at p value<0.05.

3. RESULTS

3.1 Comparison between Both Groups as Regard Demographic Data

3.1.1 Sex distribution

PFKBI group: - 59.4% were male.

RFKBI group:-53.6 % were male.

There was no statistically significant difference in sex distribution between the studied groups

3.1.2 Age distribution

PFKBI group I mean age was 57.50 ± 6.55 ys
RFKBI group II mean age was 60.89 ± 7.97ys

There was no statistically significant difference between the studied groups regarding age.

3.2 Comparison of Outcome between the Two Studied Groups after 24 hrs

Chest pain: There was statistically significant difference between both groups as regards chest pain which occur more frequently in group I with P value =0.042*

Cardiac death: There was no statistically significant difference between both groups.

Regarding cardiac death, it occurred in only one case of group II (3.6%) due to acute stent thrombosis of LAD stent while it was no case in group II.

Side branch occlusion: The rate of side branch occlusion immediately after the procedure was 9.4% in group I while it was not present in group II with no statistically significant difference between both groups.

Admission time: There was significant difference between both groups with prolonged admission time in group I.

Access hematoma: There was no statistically significant difference between both groups regarding access hematoma.

Troponin: There was no significant difference between both groups.

Table 1. Comparison between the two studied groups according to risk factors and previous cardiovascular disease

Risk Factors	Total (n = 60)		PFKBI group (n = 32)		RFKBI group 2 (n = 28)		χ^2	P
	No.	%	No.	%	No.	%		
DM	30	50.0	18	56.3	12	42.9	1.071	0.301
HTN	36	60.0	20	62.5	16	57.1	0.179	0.673
SMOKING	30	50.0	15	46.9	15	53.6	0.268	0.605
DYSLIPIDEMIA	36	60.0	18	56.3	18	64.3	0.402	0.526
Previous Cerebrovascular Accident (CVA)	3	5.0	1	3.1	2	7.1	0.508	^{FE}p=0.594
CABG	0	0.0	0	0.0	0	0.0		
BMI (kg/m^2)								
Min. – Max.	20.8 – 31.5		20.8 – 31.5		21.2 – 31.5		t =1.645	0.105
Mean ± SD.	25.7 ± 2.62		25.1 ± 2.75		26.29 ± 2.39			
Median	25.45		24.95		26.05			

χ^2: Chi square test, FE: Fisher exact; p: p value for comparing between the studied groups

Stroke: There was no significant difference between both groups regarding stroke incidence which occurred in one case (3.7%) of group II while did not occurred in group I.

3.3 Comparison of Outcome between the Two Studied Groups after 3 and 6 Months

Chest pain After 3 and respectively 6 months: there was no statistically significant difference between both groups.

Cardiac death After 3 months: Cardiac death occurred in only one case (3,3%) of group I while did not occurred in group II with no statistically significant difference between both groups. After 6 months: no cardiac death had detected in both groups.

Myocardial infarction after 3 months did not occurred in both groups. After 6 months: Occurred in one case of group II in the form of lateral STEMI while did not occurred in group I with no statistically significant difference between both groups.

Stent thrombosis after 3 months did not occurred in both groups. After 6 months occurred in one case of group II [in the form of sub-acute stent thrombosis (of the diagonal stent) and lateral STEMI which was treated by kissing balloon inflation with LAD stent] while did not occurred in group I with no statistically significant difference between both groups.

TLR after 3 months: There was no TLR in both groups. After 6 months: TLR occurred in one case of group II in the form of sub-acute stent thrombosis (of the diagonal stent) and lateral STEMI, solved by kissing balloon to LAD (left anterior descending coronary artery) and D (first diagonal coronary artery).

Stroke or TIA after 3 months occurred in one case in each group (3.4% and 3.8%) respectively with no statistically significant difference. After 6 months no stroke occurred in both groups.

Heart failure after 3 months: it was 6.9% in group I while it was 7.7 in group II with no statistically significant difference between both groups. After 6 months: There were no heart failure symptoms or admission refer rate in both groups.

4. DISCUSSION

The profile of age, gender and cardiovascular risk factors was similar in both study groups.

Regarding the immediate outcome (24 H post procedure), the present study showed that the mean admission time was significantly higher in PFKBI group than in RFKBI group. This difference might be–related with the chest pain after the procedure due to side branch occlusion or plaque shift leading to the ostium narrowing, situation that appeared in the result of the present study. The incidence of post PCI chest pain was higher (28.1%) in group I comparative with 7.4% in RFKBI group with statistical significant difference (P value =0.042*).

Koo et al. reported that diagonal branch occlusion could cause different symptoms like

chest pain, arrhythmia, but these symptoms are less present than in the left anterior descending artery (LAD) occlusion. Authors concluded that the aggressive procedure for side branches has not been translated into clinical benefit in coronary bifurcation lesions approach. However in the present study, these symptoms were the cause of prolonged admission time in PFKBI group [12].

The incidence of access hematoma was 3.1% in PFKBI group, while it was 14.8% in RFKBI group with no significant difference between both groups. This may be due to prolonged procedure time in RFKBI group Andersen et al. [13] studied the risk factors for femoral hematoma and found that the incidence of hematoma frequency would be higher in PCI patients when duration of the procedure is longer.

Dumont et al. [14] studied the predictors of vascular complications post cardiac diagnostic catheterization and percutaneous coronary interventions and found that the access hematoma frequency and confirmed the observations of Andersen study that the incidence of this complication is higher in PCI patients with a longer duration of the procedure.

The incidence of side branch occlusion in group I was 9.4% while it was 0% in RFKBI group with no significant difference between both groups.

Table 2. Comparison between the two studied groups according to baseline echocardiographic data

Parameter	Total (n= 60)	Group 1 (n= 32)	Group 2 (n= 28)	Test of sig.	p
EDD(Cm)					
Min. – Max.	4.30 – 5.80	4.30 – 5.80	4.40 – 5.80	t= 0.626	0.534
Mean ± SD.	5.14 ± 0.36	5.17 ± 0.35	5.11 ± 0.37		
Median	5.20	5.20	5.20		
ESD(Cm)					
Min. – Max.	2.30 – 4.50	2.50 – 4.30	2.30 – 4.50	U= 395.0	0.429
Mean ± SD.	3.20 ± 0.47	3.23 ± 0.41	3.16 ± 0.53		
Median	3.10	3.10	3.10		
WMSI					
Min. – Max.	1.0 – 1.30	1.0 – 1.23	1.0 – 1.30	U= 445.50	0.965
Mean ± SD.	1.07 ± 0.10	1.07 ± 0.10	1.07 ± 0.10		
Median	1.0	1.0	1.0		
EF (%)					
Min. – Max.	46.0 – 73.0	48.0 – 73.0	46.0 – 73.0	U= 384.50	0.341
Mean ± SD.	61.83 ± 6.77	62.88 ± 5.90	60.64 ± 7.57		
Median	64.50	65.0	63.0		
GLS (- %)					
Min. – Max.	-13.0 – 19.0	-13.0 – 19.0	-13.0 – 19.0	t= 0.593	0.556
Mean ± SD.	-16.28 ± 1.71	-16.41 ± 1.64	-16.14 ± 1.80		
Median	16.0	16.0	16.50		

t: Student t-test; U: Mann Whitney test; p: p value for comparing between the studied groups

Table 3. Comparison between the two studied groups according to chest pain and cardiac death (after 24 hr)

After 24 hr.	Total (n= 60)		PFKBI group (n = 32)		RFKBI group (n = 28)		χ^2	P
	No.	%	No.	%	No.	%		
Chest pain								
No	48	81.4	23	71.9	25	92.6	4.144*	0.042*
Yes	11	18.6	9	28.1	2	7.4		
Cardiac death								
No	59	98.3	32	100.0	27	96.4	1.162	^{FE}p =
Death	1	1.7	0	0.0	1	3.6		0.467

*χ^2: Chi square test, FE: Fisher exact, p: p value for comparing between the studied groups, *: Statistical significance at p ≤ 0.05*

Table 4. Comparison between the two studied groups according to different parameters after 24 hr

	Total		PFKBI group		RFKBI group		Statistical test	P
	No.	%	No.	%	No.	%		
SB occlusion	(n = 60)		(n = 32)		(n = 27)			
No	57	95.0	29	90.6	28	100.0	$\chi^2 = 2.763$	$^{FE}p = 0.241$
Yes	3	5.0	3	9.4	0	0.0		
Admission time(Hs)	(n = 60)		(n = 32)		(n = 27)			
Min. – Max.	24.0 – 48.0		24.0 – 48.0		24.0 – 48.0		U = 366.0*	
Mean ± SD.	27.2 ± 8.23		29.25 ± 10.08		24.86 ± 4.54			0.039*
Median	24.0		24.0		24.0			
Access hematoma	(n = 60)		(n = 32)		(n = 27)			
No	55	91.7	31	96.9	23	85.7	$\chi^2 = 2.435$	$^{FE}p = 0.175$
Yes	5	8.3	1	3.1	4	14.3		
Cardiac enzyme elevation(high sensitive troponin)	(n = 59)		(n = 32)		(n = 27)			
Negative	49	83	24	75	25	92.6	–	0.175
Positive	10	17	8	25	2	7.4		
Stroke or TIA	(n = 59)		(n = 32)		(n = 27)			
No	58	98.3	32	100.0	26	96.3	1.206	$^{FE}p = 0.458$
Yes	1	1.7	0	0.0	1	3.7		

*χ^2: Chi square test, FE: Fisher exact, U: Mann Whitney test, p: p value for comparing between the studied groups, *: Statistical significance at p ≤ 0.05*

Table 5. Comparison between the two studied groups according to chest pain and cardiac death

		Total		PFKBI group		RFKBI group		χ^2	P
		No.	%	No.	%	No.	%		
Chest pain	After 3 months	(n = 55)		(n = 29)		(n = 26)			
	No	46	83.6	22	75.9	24	92.3	2.709	$^{FE}p = 0.149$
	Yes	9	16.4	7	24.1	2	7.7		
	After 6 months	(n = 55)		(n = 29)		(n = 26)			
	No	52	94.5	26	89.7	26	100.0	2.845	$^{FE}p = 0.238$
	Yes	3	5.5	3	10.3	0	0.0		
Cardiac death	After 3 months	(n = 56)		(n = 30)		(n = 26)			
	No	55	98.2	29	96.7	26	100.0	0.882	1.000
	Death	1	1.8	1	3.3	0	0.0		
	After 6 months	(n = 55)		(n = 29)		(n = 26)			
	No	55	100.0	29	100.0	26	100.0	-	-
	Death	0	0.0	0	0.0	0	0.0		

*χ^2: Chi square test, FE: Fisher exact, p: p value for comparing between the studied groups, *: Statistically significance at p ≤ 0.05*

Watanabe et al. [15] studied 49 patients who underwent elective coronary stenting with the provisional stenting technique, 52 bifurcation lesions without baseline SB stenosis. SB complication was defined as angiographic worsening of SB stenosis (>75%). They found that SB complication was noticed in 22 lesions (42%), but this high rate of side branch occlusion could be related to the extreme criteria used to define side branch occlusion (more than 75% occlusion reported).

The Nordic-3 and CROSS trials [16] compared FKI and non-FKI cases, randomization was performed after crossover MV stenting. The rate of SB-flow deterioration was significantly higher in the PFKBI group before the procedure. Nevertheless, the rates of peri-procedure MI were identical between those groups.

Despite the fact that incidence of post-PCI chest pain was higher in PFKBI group, at 3 and 6 months follow up there were no significant

Table 6. Comparison of non-fatal events between the two studied groups

		Total (n = 55)		PFKBI group (n = 29)		RFKBI group (n = 26)		χ^2	P
		No.	%	No.	%	No.	%		
MI	After 3 months								
	No	55	100.0	29	100.0	26	100.0	-	-
	Yes	0	0.0	0	0.0	0	0.0		
	After 6 months								
	No	54	98.2	29	100.0	25	96.2	1.136	$^{FE}p = 0.473$
	Yes	1	1.8	0	0.0	1	3.8		
ST thrombosis	After 3 months								
	No	55	100.0	29	100.0	26	100.0		-
	Yes	0	0.0	0	0.0	0	0.0		
	After 6 months								
	No	54	98.2	29	100.0	25	96.2	1.136	$^{FE}p = 0.473$
	Yes	1	1.8	0	0.0	1	3.8		
TLR	After 3 months								
	No	55	100.0	29	100.0	26	100.0		
	Yes	0	0.0	0	0.0	0	0.0		
	After 6 months								
	No	54	98.2	29	100.0	25	96.2	1.136	$^{FE}p = 0.473$
	Yes	1	1.8	0	0.0	1	3.8		
Stroke	After 3 months								
	No	53	96.4	28	96.6	25	96.1	0.006	$^{FE}p = 1.000$
	Yes	2	3.6	1	3.4	1	3.8		
	After 6 months								
	No	55	100.0	29	100.0	26	100.0		
	Yes	0	0.0	0	0.0	0	0.0		
Heart Failure	After 3 months								
	No	51	92.7	27	93.1	24	92.3	0.013	$^{FE}p = 1.000$
	Yes	4	7.3	2	6.9	2	7.7		
	After 6 months								
	No	55	100.0	29	100.0	26	100.0		
	Yes	0	0.0	0	0.0	0	0.0		

χ^2: Chi square test, FE: Fisher exact, MC: Monte Carlo, p: p value for comparing between the studied groups.

differences between both groups regarding the occurrence of angina pain.

Niemelä et al. [17] showed that the majority of patients had severe angina pectoris after main vessel stenting in the provisional group. At the 6-month follow up, symptom relief was substantial and similar in both groups.

The present study showed no significant differences between both groups regarding MACE (cardiac death, stroke, MI, HF) at 3 and 6 months. Also the present study showed no significant differences between both groups regarding chest pain, stent thrombosis, target lesion revascularization (TLR) at 3 and 6 months.

These observations are in concordance with the conclusions from a meta-analysis done by Zhong et al. [18] who compared the KBI strategy and the No-KBI strategy of treating coronary bifurcation lesions in patients undergoing PCI by 5 RCTs (1264 patients) and showed no overall difference in clinical outcome.

Interesting, the uncommon finding of this meta-analysis is that the KBI strategy tends to increase the incidence of main vessel restenosis compared to the No-KBI technique, aspect that was not noticed in the present study.

Multiple factors could be involved. First, main vessel restenosis was higher in the KBI group due to the elliptical deformation of the main vessel stent. Balloons that overlapped together during KBI can cause oversizing of the proximal stent segment and may lead to increased risk of main vessel restenosis. Then, the differential of

the diameter between the proximal and distal sites may induce an increased incidence of strut malposition in the main vessel. Furthermore, kissing balloon-induced vessel dissection and injury at the proximal edge of the implanted stent may be associated with main branch restenosis. In addition, over-dilatation of the main vessel proximal segment associated with KBI could cause abnormal local hemodynamic conditions. Finally, decreased main vessel stent area associated with side branch intervention may lead to increased restenosis in the main vessel.

In THUEBIS pilot trial [19], the SB intervention was randomly assigned to routine versus provisional groups, depending on the SB flow deterioration. The MACE rate was similar in both study groups (17.9% vs. 14.8%) despite the higher performance of KBI.

A long-term clinical outcome in the recently published patient level pooled analysis of the COBIS II and TAXUS PMS studies reported no difference in cardiac death, MI and stent thrombosis between both groups for 3 years follow-up.

However, COBIS II study [18] showed that rates of TLR were higher in the No-KBI group than in the KBI, while the present study did not identify different rates of TLR in the two groups. However, as the short-term study does not allow for a safe conclusion to be drawn, more evidence is needed to shed light on this ongoing debate.

A meta-analysis conducted by Liu et al. [20], which combined the results of 7364 patients with coronary bifurcation lesions treated with provisional stent strategy from ten eligible studies, found that there were no statistically significant benefits for the FKB group compared with the non FKB group in MACE, including cardiac death, MI, and TLR.

Peng et al. [21] compare the clinical outcome of different strategies for bifurcations with or without percutaneous coronary intervention (PCI) of small side branch after they have been compromised, and concluded that not treating the side branch will not increase the risk of MACE and will not get worse the CCS and NYHA classification when small side branch are compromised during intervention.

Niemelä et al. [17] demonstrated that a provisional MV stenting technique without FKBD provides satisfactory clinical results that are similar to those of the more complex strategy of MV stenting with FKBD in patients with coronary bifurcation lesions. Both study groups had excellent clinical results. Mortality and incidence of MI were low. The rate of definite stent thrombosis was 0.4% in the 2 groups. Thus, according to their study MV stenting without FKBD do not increase the risk of stent thrombosis in the observation period. They found that the need for TLR was 2% after 6 months, therefore the need for subsequent SB access was low. An important observation of this study is related to the favorable results regarding the occurrence of angina pectoris. The majority of patients had severe angina pectoris at baseline. At the 6-month follow up, symptom relief was the same in both groups. They strengthened their study by an 8-month quantitative coronary analysis that showed excellent results in the MV segment and improved angiographic results in the SB in the FKBI group. The follow-up percent diameter stenosis and the incidence of (re)stenosis in the SB were higher in the no-FKBD group compared with patients of FKBI group. This difference was not linked to a greater late lumen loss, which was similar in both treatment arms. Significant residual SB stenosis causes significant angina pectoris and subsequent TLR. However, CCS class 2 or higher angina occurred with similar rate during follow-up in both treatment arms.

Furthermore, the need for clinical driven TLR in the patients included in the angiographic sub-study was only 0.6% and 1.9% in the FKBI and no FKBI groups, respectively. Thus, the clinical occurrence of angiographic SB (re)stenosis, although assessed 2 months later, was negligible in the study. Accordingly, the assessment of SB stenosis with fractional flow reserve found that this functional assessment was weakly correlated with angiography findings.

In contrary to the present study Kim et al. [22] studied the effect of FKBI after simple stent deployment for the treatment of non-left main true coronary bifurcation lesions in ACS patients. The main findings in this study are the following: 1) FKBI after simple stent implantation for the treatment of non-left main true coronary bifurcation lesions had favorable outcome in ACS Patients with regard to the prognosis; 2) In ACS patients, performing FKBI after simple stent deployment for the treatment of non-left main true coronary bifurcation lesions was a significant factor in MACE prediction, especially important events consisting of non-fatal MI and cardiac death. They concluded that FKBI after simple

stent implantation for the treatment of non-left main true bifurcation lesions was associated with favorable outcome compared to the non-FKBI group. Thus, the data reveal that performing FKBI after simple stent implantation in ACS patients had its merits with regard to the prediction of MACE.

This different result may be related to the fact that the present study did not included patients with myocardial infarction presentation, which were included in Kim et al. study.

The COBIS II registry, which included LMCA lesions in 26% of cases, demonstrated that a single-stent technique with FKBI for any bifurcation lesions was associated with better long-term clinical outcomes, whereas a one-stent strategy with FKBI for LMCA was not associated with favorable MACE outcomes compared with a one-stent strategy without FKBI.

Also Lefevre et al. [23] concluded that there is a decrease in the incidence of target vessel revascularization rate after kissing balloon inflation within 7 months.

5. CONCLUSION

Dissection of side branch and conversion to two stent strategy was significantly higher in provisional final kissing balloon inflation group (PFKBI) than in routine final kissing balloon inflation group (RFKBI). The amount of dye contrast, total procedure time and time of admission was significantly higher in routine final kissing balloon inflation group. Chest pain immediately after the procedure was significantly higher in provisional final kissing balloon inflation group, while at 3 and 6 months follow up no significant difference between both groups was noticed. MACE, target lesion revascularization (TLR) and stent thrombosis were similar between both groups at 3 and 6 months.

6. STUDY LIMITATION

The number of patients was relatively small for significant clinical endpoint analyses

Coronary bifurcation lesions with SB diameter >2.0 mm were included based on visual estimation, which can widely vary and is not precise for the selection of clinically relevant SB.

Future studies will have to focus on imaging or fractional flow reserve end points and possibly longer-term follow-up.

Recruitments of more cases and angiographic follow up was not possible due to patient factors and financial issues.

Because the clinical follow-up was restricted to 6 months, no conclusions can be drawn about the long-term safety profile of either treatment strategy.

CONSENT

An informed and written consent was taken from all participants.

ETHICAL APPROVAL

As per international standard written ethical permission has been collected and preserved by the author(s).

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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Peer-review history:
The peer review history for this paper can be accessed here:
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