

# Impact of Side-Branch Flow in Coronary Bifurcation Intervention

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## Abstract

**Background:** The optimal strategy in percutaneous coronary intervention (PCI) for coronary artery bifurcation lesions has yet to be agreed upon. We compared a strategy for stenting the main vessel to provide a complete perfusion flow in the side branch, namely thrombolysis in myocardial infarction (TIMI) - III, with a strategy for intervention in both the main vessel and the side branch (MV + SB).

**Methods:** This retrospective study utilized data on 258 consecutive patients with bifurcation lesions scheduled for PCI at Tehran Heart Center between March 2003 and March 2008. The patients were followed up for 12 months, and the primary end point was a major adverse cardiac event (MACE), i.e. cardiac death, myocardial infarction, target-vessel revascularization, and target-lesion revascularization during the 12-month follow-up period.

**Results:** A total of 52.7% of the patients underwent PCI on the main vessel of the bifurcation lesions (MV group) and 47.3% with a similar lesion type received a percutaneous intervention on both the main vessel and the side branch (MV + SB group). The total rate of MACE during the follow-up was 4.3% (11 patients); the rate was not significantly different between the MV and MV + SB groups (3.7% vs. 4.9%, respectively;  $p$  value = 0.622).

**Conclusion:** There was no association between MACE in performing a simple or complex interventional strategy to treat coronary bifurcation lesions when drawing the TIMI- III flow as a goal in a simple technique.

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## Introduction

Percutaneous coronary intervention (PCI) has gained increasing favor in the past three decades as a treatment option for coronary artery lesions. In comparison with medical therapy, PCI reduces the symptoms and enhances the quality of life in patients with coronary artery disease and is thus sometimes an appropriate option for revascularization in suitable patients. However, an informed choice amongst a series of other treatment options on the part of the physician and patient requires a thorough assessment of the potential benefits and harms of this treatment modality.<sup>1-3</sup>

Coronary bifurcation lesions (CBL), which account for 15-18% of percutaneous coronary angioplasty procedures,<sup>4, 5</sup> pose a challenge for the interventional cardiologist and remain a difficult lesion subset to treat. Balloon angioplasty was amongst the first techniques to emerge for the treatment of CBL, but it came to be associated with poor outcomes.<sup>6</sup> More recent years have seen the advent of different techniques using multiple bare metal stents.<sup>7</sup> Non-randomized studies on bare metal stents have suggested improved long-term results with a strategy for stenting the main vessel only with the balloon dilatation of the side branch in comparison to more complex approaches with stenting of both branches.<sup>8-13</sup> The introduction of drug-eluting stents into the medical practitioner's armamentarium has even further improved the outcome in CBL.<sup>14</sup> Despite all the improvements in facilities and techniques in PCI, restenosis in the ostium of the side branch, thrombosis, and major adverse cardiac events (MACE) are the concerns that still exist.<sup>8, 14-20</sup>

The optimal way for the treatment of CBL has been a matter of debate in recent years.<sup>21</sup> The majority of trials have thus far sought answer to the question which of the simple or complex strategy is superior and which technique (T stenting, Crush, and Collute) is preferable.<sup>22-26</sup>

The thrombolysis in myocardial infarction (TIMI) flow in the side branch could be a determinant for decision-making with respect to CBL. There is a dearth of data in the existing literature on a comparison between PCI on CBL by stenting only the main vessel and terminating the procedure through the creation of a good flow in the side branch and a method of intervention in both the main vessel and the side branch in terms of their long-term adverse outcomes. In an attempt to characterize patients undergoing CBL intervention at our institution, we used the Tehran Heart Center Registry of Interventional Cardiology (THCR-IC) and Follow-up Registry to investigate the data on the demographics, risk factors, procedural details, in-hospital outcomes, and long-term follow-ups in the outpatient and/or inpatient settings. Meanwhile, we reviewed the films of the procedures to complete our data.

## Methods

Our study population comprised 258 patients with CBL, who underwent PCI between March 2003 and March 2008. Data were obtained from the THCR-IC, and the films of the procedures were reviewed by two interventionists, who filled in the study questionnaire in light of the data on the TIMI flow as well as the diameters and lengths of the lesions. The study protocol was approved by the Institutional Review Board, overseeing the participation of human subjects in research at Tehran University of Medical Sciences.

CBL was defined as a significant division of a coronary artery into two branches, each of them being > 1.5 mm or greater in diameter.<sup>27</sup> The PCI procedures and stent applications were performed via standard techniques using the femoral approach.<sup>28</sup>

The inclusion criteria were PCI on a CBL, presence of TIMI III flow in the side branch after stenting the main vessel, and a minimum of a 12-month follow-up period. Patients with a history of coronary artery bypass grafting (CABG), myocardial infarction (MI) during the previous 48 hours, and high levels of CKMB at the time of admission, or allergy to either aspirin or clopidogrel were excluded from the study. Patients with TIMI flow less than III in the side branch after stenting the main vessel were excluded as well. Follow-up was clinical, and the primary end point was any MACE (cardiac death, MI, and target-vessel revascularization either by CABG or by PCI). The subjects were categorized into two groups: those undergoing intervention only on the main vessel, with the procedure being terminated after the provision of TIMI-III in the side branch (MV group, n = 136), and those undergoing PCI on their side branch, depending on the diameter and/or severity of stenosis at the side-branch ostium (MV + SB group, n = 122). The selection of each strategy was at the discretion of the operators.

All the patients were pre-medicated with 325 mg of aspirin, followed by the same dose for one month before it was tapered to 80 mg daily for life, and 600 mg of clopidogrel prior to the procedure and followed up for at least one to twelve months based on the stent type. Bolus intravenous (IV) heparin, 100 IU/kg, was given after sheath insertion. The use of glycoprotein IIb/IIIa inhibitors was at the operators' discretion. Beta blockers, angiotensin-converting enzyme inhibitors, and statin drugs were administered as appropriate in the absence of a specific contraindication. The patients were visited at one, six, and twelve months after their procedure in the clinics. Follow-up information was obtained either by direct clinical visits or by telephone calls. The patients were not subjected to further coronary angiography, unless clinically indicated. The two procedure-based groups were compared with respect to MACE during the in-hospital period and within the 12-month follow-up period. MACE was defined as the presence of cardiac death, non-fatal MI, target-vessel revascularization, or target-lesion

revascularization during the follow-up. MI was defined as the elevation of cardiac enzymes  $\geq 3$  times the upper normal limit, either asymptomatic or with recurrent ischemic chest pain associated with new electrocardiographic changes. Target-vessel revascularization was defined as ischemia-driven repeat PCI or bypass surgery of the target vessel, and target-lesion revascularization was defined as ischemia-driven repeat revascularization of the target lesion by PCI or CABG.

The numerical variables are presented as mean  $\pm$  standard deviation, while the categorical variables are summarized by absolute frequencies and percentages. The continuous variables were compared using the student t-test or nonparametric Mann-Whitney U test whenever the data did not appear to be normally distributed, and the categorical variables were compared using the chi-square or Fisher exact test, as appropriate, between the two groups (MV versus MV + SB).

A multivariable Cox proportional hazards model was established to compare MACE during the 12-month follow-up period between the two groups, with the confounding effects of the lesion length and vessel diameter of the side branch being adjusted.

For the statistical analyses, the statistical software SPSS version 13.0 for Windows (SPSS Inc., Chicago, IL) and the statistical package SAS version 9.1 for Windows (SAS Institute Inc., Cary, N.C., U.S.A.) were used. All the p values were two-tailed, with statistical significance defined by a p value  $\leq 0.05$ .

## Results

Of the 258 patients with a mean age of  $55.76 \pm 10.98$  years old (range: 27 to 81 years), 188 (72.9%) were male. The demographic and clinical characteristics of the patients

are listed in Table 1. Patients in the two groups were similar in most of their baseline characteristics. The frequencies of atherosclerotic risk factors, demographic and clinical characteristics, and presentations for the patients constituted no significant difference between the two groups. The procedural characteristics and the results of the twelve-month follow-up are depicted in Table 2 and Table 3, respectively. The distribution of the target vessels was as follows: left anterior descending (LAD)-diagonal: 74%; left circumflex-optus marginal (LCX-OM): 19%; and right coronary artery-posterior descending (RCA- PD) or posterolateral (PL): 7%. The rate of final kissing balloon inflation in the MV + SB group was 63.1%. The left ventricular ejection fraction (LVEF) varied from 20% to 70% with a mean of  $52.91 \pm 9.26\%$ . The average number of stents used for each lesion was not significantly different between the two groups ( $1.03 \pm 0.21$  vs.  $1.05 \pm 0.25$ , respectively; p value = 0.492). The characteristics of the main vessels and side branches were compared between the groups. There was no significant difference in terms of the length and diameter of the target vessels and the stents utilized in the main vessels, but the lesions in the side branches were significantly longer ( $10.19 \pm 5.99$  mm vs.  $6.71 \pm 3.36$  mm, respectively; p value  $< 0.001$ ) and larger ( $2.55 \pm 0.29$  mm vs.  $2.13 \pm 0.39$  mm, respectively; p value  $< 0.001$ ) in the patients who received a kind of intervention for their side branches. The types of the procedures performed on the main vessels and side branches were compared between the two groups (Table 2), and the results showed that the frequency of plain old balloon angioplasty (POBA) on the main vessels was higher in the MV + SB group (3.3%), whereas the use of bare metal stents on the main vessels was significantly higher in the MV group (0 vs. 3.3, p value = 0.049 and  $57.9$  vs.  $45.3$ , p value = 0.039, respectively). The most common procedure was POBA, which was carried out on the side branches (78.7%), followed by bare metal stents (57.9%) on the main vessels in

Table 1. Baseline clinical characteristics\*

Variable	Total (n=258)	MV (n=136)	MV+SB (n=122)	P value
Age (y)	55.7 $\pm$ 10.9	56.9 $\pm$ 11.1	54.4 $\pm$ 10.6	0.062
Male	188 (72.9)	93 (68.4)	95 (77.9)	0.087
Smoking	50 (19.7)	29 (21.8)	21 (17.4)	0.373
DM	47 (18.5)	28 (21.1)	19 (15.7)	0.273
HTN	89 (35.0)	51 (38.3)	38 (31.4)	0.247
HLP	165 (64.4)	87 (64.4)	78 (64.5)	0.998
FHx	67 (26.5)	31 (23.3)	36 (30.0)	0.228
Prior PCI	12 (4.7)	5 (3.7)	7 (5.7)	0.432
UA	79 (30.9)	39 (29.1)	40 (32.8)	0.524
SA	103 (40.2)	56 (41.8)	47 (38.5)	0.595
TCP FC II-IV	156 (60.5)	86 (63.2)	70 (57.4)	0.337

\*Data are presented as mean $\pm$ SD or n (%)

MV, Main vessel; MV+SB, Main vessel + side branch; DM, Diabetes mellitus; HTN, Hypertension; HLP, Hyperlipidemia; FHx, Family history; PCI, Percutaneous coronary intervention; UA, Unstable angina; SA, Stable angina; TCP, Typical chest pain; FC, Functional class



Table 2. Procedural characteristics\*

Variable	MV (n=136)		MV+SB (n=122)		P value	
	MV	SB	MV	SB	MV	SB
LVEF (%)	52.8±9.4		53.0±9.0		0.870	
Target Vessels						
LAD/D	107 (78.7)		97 (79.5)		0.870	
LCX/OM	23 (16.9)		20 (16.4)		0.911	
RCA/PD or PL	6 (4.4)		5 (4.1)		0.901	
Number of Stent per Patient	0.9±0.1		1.2±0.4		< 0.001	
Number of Stent per Lesion	1.0±0.2		1.0±0.2		0.492	
Lesion Length (mm)	19.4±8.6	6.7±3.3	21.5±9.8	10.1±5.9	0.069	< 0.001
RVD (mm)	3.0±0.4	2.1±0.3	3.0±0.3	2.5±0.2	0.745	< 0.001
Stent Length (mm)	21.8±8.8	-	24.0±9.5	17.8±7.9	0.057	-
Stent Diameter (mm)	3.0±0.3	-	2.9±0.3	2.8±0.3	0.648	-
Procedural Type						
POBA	0	-	4 (3.3)	96 (78.7)	0.049	-
DES	59 (42.1)	-	66 (51.6)	15 (12.3)	0.119	-
BMS	81 (57.9)	-	58 (45.3)	11 (9.0)	0.039	-
Final Kissing Balloon	-		77 (63.1)		-	

\*Data are presented as mean±SD or n (%)

MV, Main vessel; SB, Side branch; LVEF, Left ventricular ejection fraction; LAD, Left anterior descending artery; D, Diagonal artery; LCX, Left circumflex artery; OM, Optus marginal artery; RCA, Right coronary artery; PD, Posterior descending artery; PL, Posterior left artery; RVD, Reference vessel diameter; POBA, Plain old balloon angioplasty; DES, Drug-eluting stent; BMS, Bare metal stent

Table 3. Major adverse cardiac events (MACE) during a 12-month follow-up period\*

Outcome	Total (n=258)	MV (n=136)	MV+SB (n=122)	P value
MACE	11 (4.3)	5 (3.7)	6 (4.9)	0.622
TVR	9 (3.5)	3 (2.2)	6 (4.9)	0.315
TLR	4 (1.6)	0	4 (3.3)	0.049
CABG	4 (1.6)	2 (1.5)	2 (1.6)	0.999
Cardiac Death	1 (0.4)	1 (0.7)	0	0.999
Non-fatal MI	4 (1.6)	2 (1.5)	2 (1.6)	0.999

\*Data are presented as or n (%)

MV, Main vessel; MV+SB, Main vessel + side branch; TVR, Target-vessel revascularization; TLR, Target-lesion revascularization; CABG, Coronary artery bypass grafting; MI, Myocardial infarction

the MV group and drug-eluting stents on the main vessels in the MV + SB group (51.6%).

## Discussion

There was no relationship between MACE and the clinical and procedural characteristics in our study. Having adjusted the confounding effects of the lesion length and vessel diameter of the side branch vessels in the Cox multivariable regression analysis, we found no statistically significant difference in the 12-month MACE between the two groups (Table 3). Although the introduction of drug-eluting stents has consistently lowered the rate of needing a repeat revascularization both in simple and complex lesion subsets,<sup>27, 28</sup> CBL still remains a subset of lesions with increased in-stent restenosis.<sup>29</sup> Various approaches to stenting CBL have been described so far, each with specific advantages and disadvantages.<sup>30</sup> The heterogeneity of the

techniques and the lack of information on the individual outcomes might have diluted the potential advantages associated with the universal use of a unique technique in the complex strategy, precluding the identification of the best complex technique for bifurcation stenting.<sup>24</sup>

For all the evidence in favor of stenting the main branch with provisional stenting of the side branch as the optimal approach to CBL,<sup>31</sup> the best technique of PCI on CBL still seems to be obscure in CAD patients. Hubertus et al.<sup>3</sup> showed that the simple strategy of intervention for CBL, including stenting the main vessel with a drug-eluting stent and terminating the procedure whenever obtaining a good TIMI in the side branch, had no inferiority to the complex strategy. These findings chime in with those of our study. Furthermore, Giampaolo et al.<sup>29</sup> reported that there was no detectable advantage in the clinical outcome at follow-up between a complex strategy and a simple strategy in the treatment of CBL. And similarly in our study, we detected no significant difference in the rate of MACE between the

two groups (5, 3.7% vs. 6, 4.9%;  $p$  value = 0.622 in group 1 and group 2, respectively) (Table 3). A recent review of five major clinical trials comparing simple versus complex strategy in CBL showed an increased rate of early and late MI in the complex strategy; there was no difference in the rate of stent thrombosis, cardiac death, and restenosis in either the main vessel or the side branch between the two groups.<sup>21, 23-27</sup> Considering the higher procedural time<sup>24</sup> radiation dose, and radiographic contrast media used for the complex strategy<sup>24</sup> and similar rate of MACE between simple and complex strategies in the present study, it can be concluded that the simple strategy is preferred if after stenting the main vessel, the side branch TIMI flow is III. Different methods have been employed to evaluate the significance of side-branch stenosis after stenting the main vessel. Angiographic criteria have been used traditionally for the assessment of the side branch after stenting the main vessel. It has been demonstrated that these criteria are of low diagnostic accuracy for this purpose.<sup>32</sup> The definition of a suboptimal result in the side branch has been a major difference between randomized trials comparing the simple versus complex strategy. Residual stenosis of more than 50% in the side branch was an indication for stenting the side branch in the CIRIUS study,<sup>22</sup> with a cross-over rate of 51.2%.<sup>22</sup> In the Nordic study,<sup>24</sup> the TIMI III flow in the side branch was more important than residual stenosis. A physiological assessment of the side branch stenosis after the stenting of the main vessel could be another field of interest. A Fractional Flow Reserve (FFR) study in the side branch is a valuable tool in the assessment of the functional severity of jailed side-branch lesions,<sup>33</sup> and it has been shown that it can predict the outcome.<sup>33</sup> Our study deals with the importance of the TIMI flow in the side branch for decision-making in CBL, showing that in the presence of the TIMI III flow in the side branch, we could be less aggressive about performing intervention on it. The anatomical location of the bifurcation (for example distal left main), severity of stenosis, diameter of the side branch, and physiological significance of the stenosis are complementary to the TIMI flow in the side branch.

It can, therefore, be said that a simple PCI strategy, consisting of PCI on the main vessel and providing TIMI-III in the side branch, may be regarded as an acceptable strategy for the treatment of CBL.

That our study was a retrospective analysis of a single-center registry of collected data renders it somewhat inherently limited. The small rate of MACE and the selection of POBA, which did necessitate the use of stents, precluded an analysis of the data on the basis of the different types of stents. We had a relatively short follow-up duration; a longer follow-up period might have yielded different results. Moreover, our study was not a randomized controlled one, so the treatment strategy was planned during the procedure. Another shortcoming was that we did not obtain routine

angiographic follow-up, not permitting the detection of all probable target-vessel or in-stent restenoses.

Future studies with larger patient populations and longer follow-up durations should be undertaken to shed sufficient light on this issue.

## Conclusion

The simple strategy is preferred to the complex strategy in treating a bifurcation lesion if after stenting the main vessel, the TIMI flow in the side branch remains III. Gaining TIMI-III flow in a side branch could be a reliable indicator for terminating the procedure. A physiological assessment of the side-branch stenosis using the FFR is another helpful indication in opting for the most suitable treatment modality.

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