Clinical Outcomes of Bifurcation Lesion Intervention: the Philippine Heart Center Experience

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Background **---** Successful percutaneous coronary intervention for coronary lesions is limited by lower procedural success, higher periprocedural complications, higher restenosis rates and need for repeat revascularization. Various techniques with the use of one or two stents have been developed to optimize the treatment of this type of lesion. The purpose of the study was to determine the intraprocedural, in-hospital, and 6-month outcomes of patients with bifurcation lesions who underwent intervention in terms of procedural success, major adverse cardiac events, and target vessel revascularization; and to correlate the type of bifurcation intervention done with the intraprocedural, in-hospital and 6-month outcome of patients.

Methods **---** Between January 2009 and April 2009, 23 patients with bifurcation lesions (who fulfilled the inclusion criteria) underwent percutaneous coronary intervention. Patients were grouped according to the type of stent strategy used : Group 1 (n = 20) underwent provisional 1-stent strategy; and Group 2 (n = 3) underwent 2-stent bifurcation stenting. In-hospital and 6-month outcomes were determined.

Results **---** Group 1 had lower angiographic and procedural success rates than Group2. In-hospital stay was similar. However, due to the small study population size and low event rate, 6 month outcome could not be compared or the type of bifurcation stenting correlated with outcome.

Conclusions **---** No two bifurcations are identical, and no single strategy exists that can be applied to every bifurcation. The important issue in bifurcation PCI is the selection of the most appropriate strategy for an individual bifurcation and optimizing the performance of the technique. ***Phil Heart Center J 2012; 16(2):19-26***

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Bifurcations of the coronary arteries are common sites for atherosclerotic plaque build-up due to differences in coronary flow, turbulence, and shear stress at the site of bifurcation. Based on anatomy and morphology of the vessel and the atheromatous plaque, many classifications of bifurcation lesions have been developed.[1] Some believe that a large plaque at the bifurcation site, even without significant stenosis at the ostium of the side branch, can cause a snow plough effect and occlusion of the side branch.[2] Bifurcation lesions comprise about 15-20% of coronary interventions.[3-5]

Percutaneous coronary intervention (PCI) of bifurcation lesions is complex and challenging. Various techniques with the use of one or two stents have been developed to optimize the treatment of this type of lesion.[6-16] However, coronary stenting in these cases continue to have a lower procedural success and a higher rate of restenosis. [6-8] The risk of side branch occlusion is a well-known complication of coronary intervention and has been reported to be about 12 to 41 percent.[1,17] Although occlusion of small side branches is well tolerated, occlusion of larger side branches may cause more serious complications.[2,18] Drug-eluting stents (DES) have shown better long term results for treatment of these lesions, but even with these stents the most effective technique for treating these lesions is unknown.[19]

This study aims to determine the intraprocedural, in-hospital, and 6-month outcomes of patients with bifurcation lesion who underwent

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intervention in the Philippine Heart Center, in terms of procedural success, major adverse cardiac events, and target vessel revascularization.

Methods

We conducted a prospective cohort study involving consecutive patients with true bifurcation lesions who underwent PCI of the bifurcation lesion from January 1 to April 30, 2009. True bifurcation lesions was defined as lesions in which there was >50% diameter stenosis in both the main branch (MB) vessel and the ostium of a side branch (SB) arising from the lesion, and both were >2.0 mm in diameter by visual estimation. Patients with two-vessel disease were also included if the non-bifurcated lesion is located in a different vessel and was successfully treated before the bifurcation procedure. Patients who have acute or recent myocardial infarction (MI) (defined as MI with in 72 hours of the procedure) or cardiogenic shock were excluded. This study was approved by the institutional review board and informed consent was obtained from all the subjects.

Stenting Procedure. All patients were treated before PCI with 325 mg aspirin and 75 mg clopidogrel. During the procedure, 80 units/kg heparin was given, and additional 2500-5000 units heparin were given to maintain activated clotting time of 300 seconds. GpIIbIIIa inhibitor was not given to any patient.

The type of stenting technique for the bifurcation lesion was left at the discretion of the attending interventional cardiologist.

The following were the possible approaches in the treatment of the bifurcation lesion:[6-15,20]

1) Stenting of MB only (provisional modified T-stenting technique)
2) V or simultaneous kissing stents technique
3) Crush technique
4) Reverse crush technique
5) Step crush technique
6) T technique
7) Culotte technique
8) Y and skirt technique

SUBGROUP ANALYSIS. Patients with comparable baseline characteristics of the bifurcation lesions were divided into two groups. Group 1 included patients who were treated with a stent in one branch and balloon angioplasty in the other branch. Group 2 consisted of patients who underwent stent implantation in both branches.

ANGIOGRAPHY. The severity of coronary artery disease was assessed visually by 3 observers using two orthogonal views. *Single-vessel coronary artery disease* was defined as luminal diameter stenosis of ≥70% one major epicardial artery. *Two- or three-vessel disease* was diagnosed if there was one or two additional major epicardial arteries with at least 70% luminal diameter stenosis.

FOLLOW-UP. The clinical follow-up data regarding patient symptoms, functional classification, death, and repeat PCI and CABG were obtained by patient visits to the hospital or by telephone interview. Follow-up angiography may be performed for clinical indications at the discretion of the attending physician, such as the recurrence of severe angina or for an early positive functional test.

END POINTS AND DEFINITIONS. The primary endpoint was *major adverse cardiac events (MACE)* intraprocedurally, in-hospital, or at 6 months, defined as cardiac death, Q-wave or non-Q-wave myocardial infarction (MI), and target lesion revascularization (TLR). All deaths were considered cardiac unless otherwise documented. *Non-Q-wave MI* was defined as creatinine kinase-MB enzyme elevation ≥3 times the upper limit of the normal value. *Q-wave MI* was defined as new pathological Q waves in two or more leads in addition to elevated enzymes. *Target lesion revascularization* was defined as repeat revascularization of the main-branch (MB) and/or side branch (SB) target site by PCI or coronary artery bypass grafting (CABG). Secondary endpoints were *angiographic success* (defined as ≥20% reduction in the stenosis of the lesions treated, resulting in <50% residual diameter stenosis in both branches); *procedural success* (angiographic success without in-hospital MACE); and target vessel failure at 6 months (composite of death, Q-wave or non-Q-wave MI, and TVR). *Target vessel revascularization (TVR)* was defined as any vessel revascularization. *Complete revascu-*

larization was defined as successful dilatation of all stenoses ≥70%. *Incomplete revascularization* was defined as a ≥70% diameter stenosis of one or more remaining arteries.

Sample size and Statistical analysis. At a confidence level of 95% ($\alpha = 0.05$), relative error of 20%, and assumed success rate of 34%,[4,5] the sample size was computed at $n \geq 87$.

Data was presented as mean (± SD). Discrete data was compared by Chi square analysis and continuous data with the Student's 2-tailed t-test. Correlation analysis was used to determine association of events with the bifurcation inter vention done. Logistic regression analysis was used to determine the factor with independent ef fect on the outcome. A p value ≤ 0.05 was considered significant.

Results

Of the 310 patients who underwent percutaneous coronary intervention (PCI) from January 1, 2009 to April 30, 2009, 31 patients had PCI of bifurcation lesions. Eight (8) patients were excluded because they had myocardial infarc tion within 72 hours or had cardiogenic shock. The remaining 23 patients constituted the study group. Twenty (20) patients belonged to Group 1, and had stenting of the main branch with or without balloon angioplasty of the side branch. Only three (3) patients had stenting in both the main and side branches, and belonged to Group 2. Two (2) patients had V stenting, and the other patient had culotte stenting.

Patient Characteristics. The baseline characteristics of patients from both groups are shown in Table 1. Due to the small population in Group 2, the characteristics of the two groups could not be compared. Majority of the patients had diabetes mellitus (56%) and hypertension (75%). Dyslipidemia was seen in three (3) patients; seven (7) were former smokers; three (3) had chronic kidney disease, and two (2) underwent angioplasty prior to their kidney transplants; one (1) had undergone CABG and two (2) had undergone coronary angioplasty. Ten (10) patients underwent angioplasty because of chronic stable angina despite medical management, while another 10 had a previous MI. Three (3) patients were asymptomatic. One (1) had hypotension during hemodialysis, but was otherwise well. The other two (2) had moderate to severe ischemia on non-invasive work-up.

Angiographic Characteristics. Majority of the bifurcation lesions were found in the LAD artery (87%). Most patients had multivessel coronary artery disease (78%). Lesion characteristics are shown in Table 2. Nineteen (19) out of twenty (20) patients in Group 1 and all three (3) patients in Group 2 had predilatation of the stenotic segments before implantation of stents. However, only two (2) patients in Group 1 had final kissing balloon (FKB) inflation. All three (3) patients in Group 2 had final kissing balloon inflation. Among the 20 patients in Group 1 who had stenting of the main branch, seven (7) patients had balloon angioplasty of the side branch and the rest of the 13 patients did not. Of the three (3) patients who underwent stent deployment in both branches, two (2) patients had V stenting and one (1) patient had culotte stenting.

Procedural and Clinical Outcome The average stenoses of the main branch in Groups 1 and 2 were 82.0 ± 7.9% and 78.0 ± 14.4%, respectively. The average ostial stenoses of the side branch in Groups 1 and 2 were 77.0 ± 9.3% and 80.0 10%, respectively. (Table 3)

After angioplasty, Group 1 had an average of 6.0 ± 7.0% residual stenosis in the main branch and 71.0 ± 21.8% residual stenosis in the side branch. All patients in Group 1 had <20% residual stenosis in the main branch. Only three (3) patients in Group 1 had angiographic success. All patients in Group 1 had TIMI 3 flow in the side branch despite persistent side branch stenosis, except for two (2) patients who had TIMI 2 flow of the side branch after stenting despite balloon angioplasty of side branch.

After angioplasty, Group 2 had an average of 32.0 ± 22.6% residual stenosis in the main branch and 2.0 ± 2.9% residual stenosis in the side branch. One of the three patients had 55% residual stenosis in the main branch. Side branches had angiographic success in all patients probably due to stenting and utilization of final simultaneous kissing balloon inflations in the three (3) patients. (*Table 4*)

None of the patients had intraprocedural complications or had in-hosptial MACE. On 6

Table 1. Baseline characteristics of patients who underwent bifurcation stenting included in the study. (PHC, 2010)

	Entire Cohort n=23 n(%)	Group 1* n=20 n(%)	Group 2 † n=3 n(%)
Age (mean ± SD)	62.3 ± 11.3	61.0 ± 10.0	70.7 ±18.3
Male gender	16 (70)	14 (70)	2(67)
Risk Factors			
Diabetes Mellitus	13 (56)	11 (55)	2(67)
Hypertension	17 (74)	15 (75)	2(67)
Dyslipidemia	3 (13)	3 (15)	0
Smoking History	7 (30)	7 (35)	0
Chronic Kidney Disease	3 (13)	3 (15)	0
Congestive Heart Failure	6 (26)	5 (25)	1 (33)
Previous MI	10 (44)	8 (40)	1 (33)
Previous CABG	1 (4)	1 (5)	0
Previous PTCA	2 (9)	1 (5)	1 (33)
Indications for intervention			
Stable Angina	10 (44)	9 (45)	1 (33)
Post-MI	10 (44)	9 (45)	1 (33)
Silent ischemia	3 (13)	2 (10)	1 (33)

*Group 1 included patients who were treated with a stent in one branch and balloon angioplasty in the other branch.
†Group 2 consisted of patients who underwent stent implantation in both branches.
CABG coronary artery bypass graft MI myocardial infarction PTCA Percutaneous transcatheter coronary angioplasty

month follow-up, two (2) patients in Group 1 had recurrence of angina, with one (1) patient requiring repeat angioplasty in another lesion. One (1) patient had periprocedural myocardial infarction following kidney transplantation. Group 2 patients were asymptomatic without evidence of MI or repeat intervention during the 6-month follow- up.

Discussion

PCI of bifurcation lesions continues to be a challenge to the interventional cardiologist. Despite recent literatures, there is still a lack of consensus on an array of important issues.[21] Bifurcation lesions vary not only in their anatomy (plaque burden, location of plaque, angle between branches, diameter of branches, and bifurcation site), but also in the dynamic changes in anatomy during treatment (plaque shift, spasm, and dissection).[22] One of the main technical issues when approaching a bifurcation lesion is whether to use provisional one-stent or two-stent approach. Most studies conducted in order to address this question are observational and non-randomized and do not provide definitive answers.

There are five randomized studies that compared the provisional approach of implanting 1-stent in the main branch only versus the 2-stent approach of implanting a stent on both main branch and side branch of the bifurcation.[23-27] They showed that routine stenting of both branches offered no clear advantage over a provisional strategy of stenting the main branch only with rescue PCI of the side branch (if necessary), with regard to restenosis rates in the main or side branches or in repeat bifurcation revascularization. In fact, a 2-stent approach was associated with longer procedure and fluoroscopy times, higher contrast volumes, and higher rates of cardiac enzyme elevation.[23]

There are bifurcations lesions that require one stent as a default treatment with a second stent implanted on the side branch if a suboptimal result has been obtained and an optimal result is needed. Most bifurcation lesions can be placed in this group. Likewise, there are bifurca-

Table 2. Angiographic characteristics of patients who underwent bifurcation stenting included in the study. (PHC, 2010)

	Entire Cohort n=23 n (%)	Group 1 * n=20 n (%)	Group 2 † n=3 n (%)
Location	62.3 ± 11.3	61.0 ± 10.0	70.7 ±18.3
LAD/Diagonal	20 (87)	17 (85)	3 (100%)
Circumflex/Obtuse marginal	2(9)	2 (10)	0
RCA/PDA/PLA	1(4)	1 (5)	0
Extent of Disease			
1VD	5 (22)	5 (25)	0
2VD	9(39)	7 (35)	2(67)
3VD	9(39)	8 (40)	1(33)
Type of Bifurcation ≠			
0,1,1	7 (31)	5 (25)	2 (67)
1,0,1	4(17)	4 (20)	0
1,1,1	12(52)	11 (55)	1 (33)
Lesion Characteristics**			
Thrombus	0	0	0
Moderate /Severe Calcifications	7 (30)	5(25)	2 (67)
TIMI Flow Grade 3 Pre procedure	23 (100)	20 (100)	3 (100)
Tortuosity	4 (17)	3 (15)	1 (33)
Eccentricity	3 (13)	2 (10)	1 (33)
Angle of Origin of Side Branch (Degrees)	63.3 ± 20.1	62.5 ± 20.6	68.3 ± 20.2
Lesion Length (mm)	17.7 ± 11.1	17.8 ± 11.6	17.3 ± 8.3
Predilation	22 (96)	19 (95)	3 (100)
Final Kissing Balloon Technique	5 (22)	2 (10)	3 (100)
Complete Revascularization	15 (65)	14 (70)	1 (33)

*Group 1 included patients who were treated with a stent in one branch and balloon angioplasty in the other branch.
†Group 2 consisted of patients who underwent stent implantation in both branches.
‡ According to the Medina Classification **ACC/AHA, American College of Cardiology/American Heart Association
QCA, quantitative coronary angiography TIMI Thrombolysis in Myocardial Infarction

tion lesions that require a 2-stent approach as intention-to-treat because of the characteristics of the lesion and the distribution of the side branch. The distinction between these strategies is that in the 1-stent approach, the operator may be willing to accept a suboptimal result in the side branch provided that the Thrombolysis In Myocardial Infarction (TIMI) flow is normal and the SB has limited clinical relevance regarding territory of distribution.[22] Among the five randomized trials, the definition of suboptimal result has a major impact on both the crossover rate from a 1-stent to 2-stent strategy and the restenosis rate in side branches treated with a provisional strategy. In the Sirius bifurcation study, a residual stenosis of >50% in the side branch was considered unacceptable, which explains the very high crossover rate of 51.2%;[24] in contrast, in the Nordic study,[23] the residual side branch stenosis was irrelevant and the side branch just had to remain open with TIMI flow >0. This clarifies why the greatest (19.2%) side branch restenosis rate with a 1-stent approach was observed in this study. There appears to be increasing evidence that attempting to get an optimal angiographic result with minimal residual stenosis in the side branch may not be physiologically important. Koo and his co-workers performed fractional flow reserve (FFR) measurement on 94 jailed side branch lesions after stent implantation on the main branch. No lesion with ≥50% and <75% had FFR of <0.75. Among 73 lesions with >75% stenosis, only 20 lesions were functionally significant.[28] Smaller

Table 3. Coronary angiographic analysis of patients who underwent bifurcation stenting included in the study. (PHC, 2010)

	Entire Cohort n=23	Group 1 * n=20	Group 2 † n=3
Main Branch			
Baseline			
Reference Vessel diameter (mm)	3.02 ± 0.45	2.98 ± 0.43	3.33 ±0.58
Minimal Lumen Diameter (mm)	0.55 ± 0.25	0.54 ± 0.22	0.67 ± 0.40
Diameter Stenosis (%)	82.0 ± 7.9	82.0 ± 7.0	78.0 ± 14.4
Lesion Length (mm)	17.70 ± 11.08	17.75 ±11.61	17.33 ± 8.33
Post-procedure			
Minimal Lumen Diameter (mm)	2.70 ± 0.43	2.78 ± 0.38	2.20 ± 0.46
Diameter stenosis (%	10.0 ± 13.0	6.0 ± 7.0	32.0 ± 22.6
Side Branch			
Baseline			
Reference Vessel diameter (mm)	2.38 ± 0.51	2.75 ± 0.38	3.08 ± 0.80
Minimal Lumen Diameter (mm)	0.54 ± 0.22	0.54 ± 0.23	0.57 ± 0.18
Diameter Stenosis (%)	77.0 ± 9.3	77.0 ± 21.8	80.0 ± 10.0
Post-procedure			
Minimal Lumen Diameter (mm)	1.01 ± 1.04	0.70 ± 0.66	3.04 ± 0.84
Diameter stenosis (%)	62.0 ± 31.4	71.0 ± 21.8	2.0 ± 2.9

*Group 1 included patients who were treated with a stent in one branch and balloon angioplasty in the other branch.
†Group 2 consisted of patients who underwent stent implantation in both branches.

side branches are also less likely to result in angina if a residual stenosis is left untreated or if restenosis occurs.[29,30] However, this should not diminish the importance of protecting side branches with guidewires to prevent their closure, because it has also been shown that side branch compromise is not inconsequential. Occlusion of side branches >1 mm can be associated with 14% incidence of MI,[31] and compromise of side branches ≥2 mm can be associated with a large periprocedural myocardial infarct.[32]

Niemela et al have performed the only randomized study comparing two (2) different 2-stent techniques (culotte vs. crush). The study showed no difference in clinical outcomes at 6 months, but was limited by short follow-up period, lack of angiographic follow-up, and less final kissing balloon inflation in the crush group. There was insufficient data to recommend one technique over another based on the low event rates. The decision was based instead on the anatomy of the bifurcation and the familiarity and competence of the operator with a specific technique.[33] However, it was apparent that optimal performance of the 2-stent techniques was mportant and improved outcome. This included ihe importance of the final kissing balloon postdilatation in reducing late loss and restenosis, especially at the side branch. This has been repeatedly demonstrated and has become the standard in the performance of all 2-stent techniques.[34,35] There are other important technical factors that may contribute to optimizing outcomes when performing 2-stent techniques, such as high-pressure sidebranch inflation, the use of noncompliant balloons, selection of correct balloon size for the final kissing balloon inflation, and the use of intravascular ultrasound (IVUS).

It is a question whether final kissing balloon is also mandatory in the provisional 1-stent approach. Bench testing has observed that the final kissing balloon may have several advantages: it opens the stent cells to the side branch, it allows the side branch ostium to be less covered by stent struts, and its prevents the main branch stent from becoming deformed by side branch dilatation. However, the clinical impact of final kissing balloon in the provisional 1-stent is still to be established in future trials.[21]

In this study, it appears that 2-stent approach has a higher angiographic and procedural

Table 4. Clinical outcomes of patients who underwent bifurcation stenting included in the study. (PHC, 2010)

	Entire Cohort n = 23	Group 1 * n = 20	Group 2 + n = 3
Angiographic success (%)	6 (26)	3(15)	2 (67)
Procedural success (%)	6 (26)	3 (15)	2 (67)
In-hospital MACE (%)			
Cardiac Death	0	0	0
Q-wave MI	0	0	0
Non-Q-wave MI	0	0	0
TLR	0	0	0
TVR	0	0	0
6-month MACE (%)			
Cardiac Death	0	0	0
Q-wave MI	0	0	0
Non-Q-wave MI	1	1	0
TLR	0	0	0
TVR	1	1	0

*Group 1 included patients who were treated with a stent in one branch and balloon angioplasty in the other branch.
†Group 2 consisted of patients who underwent stent implantation in both branches.
MACE, major adverse cardiac events MI, myocardial infarction TLR, target lesion revascularization TVR, target vessel revascularization

success rates than the provisional 1-stent approach. However, we are limited by the small size of the study population. Other studies have a larger population, but was collected over a longer period of time. The definitions of success and suboptimal results in this study resulted in a low success rate of Group 1, but may still vary if referenced to definitions from other studies. The low event rate may be due to the small popula-tion size and short study period.

Variability in anatomy, morphology, technique, and learning curve makes it almost mpossible to have reproducible and reliable trials that can detect the preferred strategy. Even when the same strategy is performed by the same opera tor, it may still be hard to draw definitive conclusions perhaps due to bias in case selection. In the Nordic bifurcation study, provisional stenting was superior to 2-stent strategy, but in the Nordic bifurcation stent technique study, either of the 2-stent techniques – crush or culotte – demontrated excellent results when compared with the historical provisional group.

Conclusion

According to the definition of success in this study, Group 1 had lower angiographic and procedural success compared to Group 2. However, this is limited by the smallness of the study population size and short study period. Likewise, a definite conclusion cannot be drawn regarding the 6-month outcome of patients with bifurcation lesions who underwent PCI in the Philippine Heart Center, in terms of major adverse cardiac events and target vessel revascularization. A correlation between type of bifurcation intervention done with the intraprocedural, in-hospital and 6-month outcome is also not possible. It is recommended that an hospital registry be established in order to follow-up a larger population of patients for a longer period of time. No two bifurcations are identical, and no single strategy exists that can be applied to every bifurcation. The important issue in bifurcation PCI is the selection of the most appropriate strategy for an individual bifurcation and optimizing the performance of the technique.

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