Evaluation of short-term outcome of different bifurcation stenting techniques at Assiut University Catheterization Laboratory

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Background
Coronary artery bifurcational lesions (BFLs) are a challenging branch in interventional cardiology, and their treatment is still debatable.

Objectives
To calculate the percentage of BFL intervention and evaluate the short-term outcome of various techniques used regarding major adverse cardiac events (MACEs) in Assiut University catheterization laboratory.

Patients and methods
This was an observational prospective study that was conducted from September 2017 till September 2018. Data from 60 BFL cases were reviewed and analyzed, and then the cases were divided into two groups: (a) one-stent group (provisional stenting) and (b) two-stent group; the type of technique to be used was left on the operator. The patients were scheduled for follow-up after 3 months to detect MACE.

Results
We had 31 patients in the provisional group and 29 patients in the two-stent group. Provisional stenting was the preferred strategy in ST-segment elevation myocardial infarction cases (22.6 vs. 10.3%).
More significant side branch (SB) stenosis (%) and lesion length (mm) were seen in the two-stent strategy group (77.9 ± 15.1 vs. 86 ± 13.2%, $P = 0.03$ and 9.2 ± 6.1 vs. 12.1 ± 5.8 mm, $P = 0.06$, respectively). Regarding MACE, death was seen in only one case in the provisional group (3.2 vs. 0%, $P = 0.52$).
Occurrence of acute coronary syndrome (unstable angina) was seen in 6.4 versus 3.4% in the provisional group and two-stent strategy group, respectively ($P = 0.52$), and the in-hospital procedural success was seen in 87.1 versus 96.6% in the provisional group and two-stent strategy group, respectively ($P = 0.4$), with no statistically significant difference between the two groups.

Conclusion
BFL stenting represented 6.5% of total percutaneous coronary intervention cases in Assiut University catheterization laboratory in 1 year, with the two-stent strategy at least as safe as provisional stenting regarding MACE during hospital stay and short-term follow-up.

Keywords:
Bifurcational lesions, major adverse cardiac event, percutaneous coronary intervention, side branch, ST segment elevation myocardial infarction

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Background

Percutaneous coronary intervention (PCI) in bifurcation is well known for being technically challenging. Indeed, there are various obstacles in percutaneous treatment of bifurcation lesions to be considered: (a) location, size, and angle in the coronary tree [e.g. left main (LM) vs. others]; (b) disease distension at bifurcation (true vs. pseudo-bifurcation lesions); (c) stenting technique; and (d) convenient device selection [1].

In each of these scenarios, several studies have been published, but therapy techniques remain largely dependent on the clinical setting and operator expertise [1].

Bifurcational lesions (BFLs) are defined as greater than 50% coronary artery stenosis adjacent to and/or involving the origin of a substantial side branch (SB), according to the American College of Cardiology/American Heart Association standards. A de novo BFL with a significant SB, defined as a vessel with a reference diameter larger or equal to 2.0 mm by visual assessment, was included in the BFL group [2].

BLF management choices range from main vessel (MV) single-stent technique alone to different double-stent techniques (one for the MV and one for the SB ostium), such as the crush, T-stenting, modified T-stenting, and culotte techniques. The procedure details (procedural time, contrast use, and radiation exposure) as well as potential long-term consequences can all be influenced by the choice of these PCI alternatives [3].

The provisional single-stent strategy is the recently recommended default technique for approaching bifurcation PCI [4,5]. The main postulates of the provisional single-stent strategy are optimal MB stenting and a possibility of subsequent SB stenting only in case of significant flow impairment and/or severe stenosis with hemodynamic relevance for a clinically important myocardial territory [6].

A two-stent strategy as intention to treat should be addressed in 'true' bifurcations (medina 1.1.1, 1.0.1, and 0.1.1), when a significant SB is implicated (>2 mm, large amount of myocardium subtended, and disease extending >5 mm from the ostium) [7].

Patients and methods

We reviewed all the 927 PCI procedures that were done in Assiut University Catheterization laboratory either primary or elective during the period from September 2017 to September 2018. From the flow chart illustrated in Fig 1, ten patients from 64 patients with BFLs were not included in the study because six patients had changed their contact information and could not be traced up and the other four patients were non-true BFLs (have SB <2 mm). The Committee of Medical Ethics of the Faculty of Medicine; Assiut University, approved this study. Written informed consent was obtained from all participants.

Figure 1

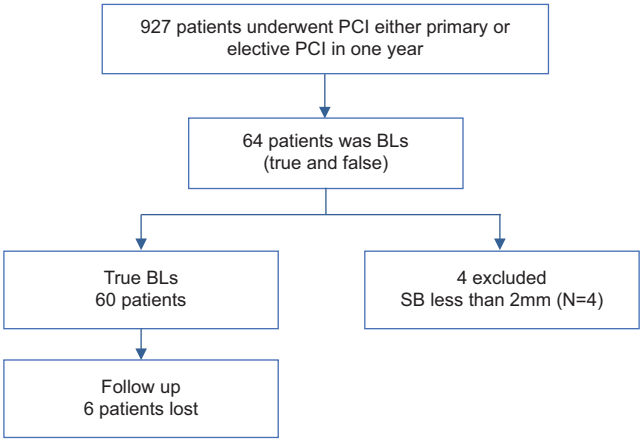


Figure 1 Flow chart of the included patients.

Patients in our study were subjected to the following:

(1) Full history taking: general and complete cardiac examination.
(2) 12-lead ECG and 2D-echocardiography.
(3) Coronary angiography findings: BFL location and angle, Medina classification, pre-procedural and post-procedural TIMI flow grade in MV and SB, quantitative angiographic measurements [reference diameter (mm), diameter stenosis (%), and lesion length (mm) of the three segments of the BFL], and the choice of treatment technique.

Follow-up

Patients were contacted during their hospital stay and 3 months following the procedure to detect any of the major adverse cardiac events (MACEs): cardiac death, myocardial infarction, target-vessel revascularization, or stent thrombosis and occurrence of unstable angina (UA) with ECG changes and echo findings in the same target vessel.

In addition, if patients were rehospitalized during the follow-up period, the medical records of admissions and treatments were reviewed and data was retrieved, confirmed, and recorded.

Statistical analysis

Statistical Package for the Social Sciences was used to collect and analyze the data (SPSS, version 20; IBM, Armonk, New York, USA). Continuous data were expressed as a mean, SD, or median (range), whereas nominal data were expressed as a frequency (percentage). The study was approved and monitored by the Medical Ethics Committee, Assiut Faculty of Medicine (IRB 17100301).

The χ^2 test was used to compare the nominal data of the study's separate groups, whereas the Student t test was used to compare the mean of the two groups. Because the level of confidence was preserved at 95%, a P value of 0.05 showed a significant relationship.

Results

Descriptive data of the study population

The mean age of the studied patients was 55.7 ± 9.2 years, 71.7% of them were males, and 53.3% of them were smokers. Overall, 40% of the patients were diabetics and 53.3% of these patients were hypertensive, as shown in Table 1.

The percentage of the patients who had chronic coronary syndrome (CCS) as the first presentation before PCI was 26.7%.

The most common Medina classification was 1,1,1, representing 55%, and the majority was between left anterior descending and diagonal branches, as shown in Table 2.

Many bifurcational techniques were used in our study, but the provisional technique was the most used (51.7% of the cases), and mini-crush was the most commonly used technique in the two-stent group, as seen in Fig. 2.

Sirolimus DESs were the most commonly used stents in our study (55.2%), followed by other types such as Ampilimus, Everolimus, and Biolimus.

Follow-up data of the studied patients

Follow-up was done for all of the patients included in the study by history, ECG, and echocardiography.

ECG follow-up showed that 73.4% of the patient had fixed ECG, and only 16.7% showed improvement in the ECG. Clinical follow-up showed improvement in 81.7% of the patients.

During the follow-up, death as part of the major adverse cardiovascular events occurred in only one case as a sequela of frequent admission as heart failure during the period of follow-up, and no MACE were seen in 49 (81.7%) patients, as shown in Table 3.

Comparison between provisional technique and two-stent techniques

A total of 31 patients underwent provisional stenting, whereas 29 patients had two-stent techniques such as TAP, crush, mini-crush, V-stenting, and Culotte technique.

According to the clinical data, five (17.2%) patients were ischemic heart disease as CCS, compared with 24 (82.8%) patients as acute coronary syndrome (ACS) in the two-stent group, as shown in Table 4.

After 3 months, clinical follow-up showed that death occurred in one case in the provisional group, whereas clinical improvement was observed in 24 (77.4%) patients in the provisional group versus 25 (86.2%) cases in the other group according to clinical questionnaire about angina severity.

Angiographic data of both group showed that the SB stenosis was seen in 77.9 ± 15.1% in the provisional group, which is significantly lower ($P = 0.03$) compared with 86 ± 13.2% in the two-stent group.

SB lesion length was 9.2 ± 6.1 mm in the provisional group, whereas it was 12.1 ± 5.8 mm in the two-stent group, as shown in Table 5.

Table 1 Baseline demographic data

Variables	*n* (%) (*N*=60)
Age (years)	55.7±9.2
Sex	
Male	43 (71.7)
Female	17 (28.3)
DM	24 (40)
HTN	32 (53.3)
Smoking	32 (53.3)

DM, diabetes mellitus; HTN, hypertension.

Table 2 Baseline angiographic data

Variables	*n* (%) (*N*=60)
Medina classification	
0,1,1	15 (25)
1,0,1	11 (20)
1,1,1	33 (55)
BFLs	
LM-LAD-LCX	9 (15)
LAD-Diag.	35 (58.3)
LCX-OM	11 (18.3)
LCX-PDA	2 (3.3)
RCA-PL	3 (5)
TIMI flow after	
0	0
I	0
II	8 (13.3)
III	52 (86.7)

BFLs, bifurcational lesions; D, diagonal; LAD, left anterior descending; LCX, left circumflex; LM, left main; OM, obtuse marginal; OM2, obtuse marginal 2; PDA, posterior descending artery; PL, postero-lateral; RCA, right coronary artery; TIMI, thrombolysis in myocardial infarction.

Table 3 Follow-up major adverse cardiac event in the studied patients

Variables	*n* (%) (*N*=60)
MACE	
Missing patients	6 (10)
No	49 (81.7)
Death	1 (1.7)
TVR	0
MI	1 (1.7)
UA	3 (5)

MACE, major acute cardiovascular events; MI, myocardial infarction; TVR, target vessel revascularization; UA, unstable angina.

Regarding MACE during follow-up, death occurred in only one (3.2%) case in the provisional group with no deaths in the two-stent group. Majority of the patients experienced no MACE in the two-stent group, but occurrence of ACS (UA) was seen in two (6.4%) patients in the provisional group whereas one (3.4%) patient in the two-stent group, and a few patients were lost during the follow-up as seen in Table 6.

Procedural complications as plaque shift occurred in one case in each group, no statistical significance, as seen in Table 6.

Discussion

The current study investigated the short-term clinical outcomes after provisional stenting compared with the two-stent approach for the treatment of complex BFLs.

All patients with true bifurcational coronary artery lesions, defined as lesions in which there is more than 50% diameter stenosis in both the parent vessel and the ostium of the SB arising from the lesion, and both are more than 2.0 mm in diameter by visual estimation, were included in our study.

We also calculated the percentage of the BFL intervention cases in our catheterization laboratory, which represented 6.5% of total PCI cases during 1 year.

In conclusion, no significance difference was found between the two groups regarding MACE during the follow-up.

Table 4 Cardiac events and clinical follow-up comparison between the two groups

Variables	Provisional group (*N*=31) [*n* (%)]	Two-stent group (*N*=29) [*n* (%)]	*P*
Cardiac events			0.12
CCS	11 (35.5)	5 (17.2)	0.09
ACS	20 (64.5)	24 (82.8)	0.09
UA	9 (29)	14 (48.35)	0.10
NST-ACS	4 (12.9)	7 (24.1)	0.21
STEMI	7 (22.6)	3 (10.3)	0.17
Clinical follow-up			
Lost	3 (9.7)	3 (10.3)	0.55
Death	1 (3.2)	0	
Improvement	24 (77.4)	25 (86.2)	
No improvement	3 (9.7)	1 (3.4)	

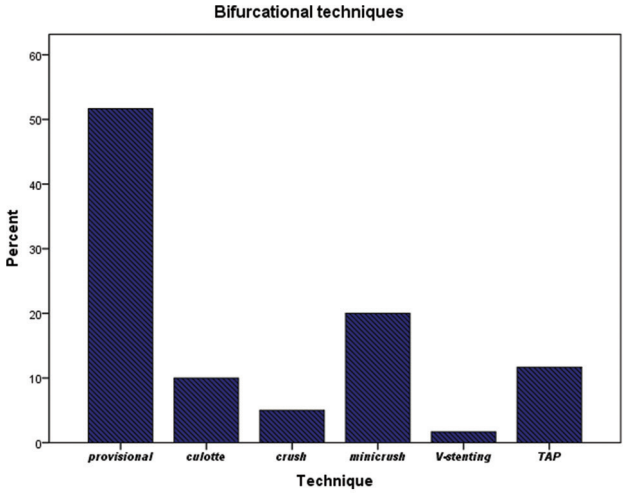
ACS, acute coronary syndrome; CCS, chronic coronary syndrome; NSTEMI, non-ST-segment elevation myocardial infarction; STEMI, non-ST-segment elevation myocardial infarction; UA, unstable angina.

Table 5 Baseline angiographic measurement in the studied groups

Variables	Provisional group (*N*=31)	Two-stent group (*N*=29)	*P*
MV stenosis (%)	83.5±12.4	83.1±10.3	0.90
SB stenosis (%)	77.9±15.1	86±13.2	0.03
MV lesion length (mm)	20.6±9.3	20±9.4	0.81
SB lesion length (mm)	9.2±6.1	12.1±5.8	0.06
BF angle (°)	55.5±19.8	62.9±18.5	0.14
MB stent length (mm)	28.9±7.2	29.6±7.2	0.71

Data were expressed in the form of mean±SD. MV, main vessel; SB, side branch.

Figure 2



Percentage of bifurcational techniques used.

Clinical presentation

Clinical presentation affects the decision of the operator regarding the technique, so it was a must to differentiate between ACS and CCS cases.

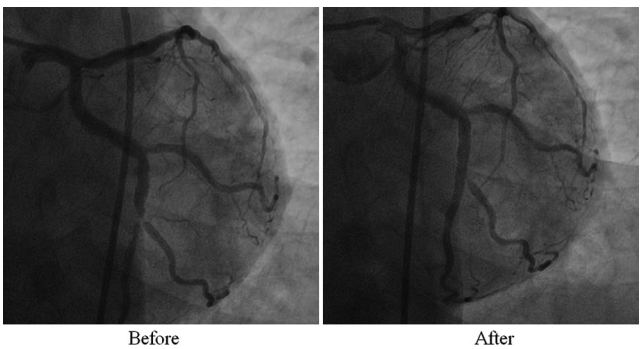
In our study, most of cases were ACS (73.3%), either UA, NST-ACS, or ST-segment elevation myocardial infarction (STEMI), but it did not show statistical significance between the two groups ($P = 0.09$).

This was concordant with the results of Kumsars *et al.* [8], as there was no statistically significant difference between the two groups regarding ACS ($P = 0.22$).

Provisional stenting was preferred in most of our STEMI cases, and it was used in 70% of the STEMI cases, as done in case no. 3, as illustrated in Fig. 3.

STEMI presentation is one of the most powerful predictors of stent thrombosis. The rate of stent thrombosis in patients with STEMI was 2.5 times higher than in patients without STEMI, according to the Swedish Coronary Angiography and Angioplasty Registry, which leads to widespread agreement that simple and quick techniques should be used in these circumstances [9].

Figure 3



The bifurcational lesion from case number 3 and results after provisional stenting.

Table 6 Major adverse cardiac event and procedural complications in the studied groups

Variables	Provisional group (*N*=31) [*n* (%)]	Two stents group (*N*=29) [*n* (%)]	*P*
MACE			
Lost	3 (9.7)	3 (10.3)	0.52
No	24 (77.4)	25 (86.2)	
Death	1 (3.2)	0	
TVR	0	0	
MI	1 (3.2)	0	
UA	2 (6.4)	1 (3.4)	
Procedural complications			
No	27 (87.1)	28 (96.6)	0.40
SB occlusion	0	0	
ACS	2 (6.4)	0	
Bleeding	1 (3.2)	0	
Plaque shift	1 (3.2)	1 (3.4)	

ACS, acute coronary syndrome; MACE, major cardiovascular events; MI, myocardial infarction; SB, side branch; TVR, target vessel revascularization; UA, unstable angina.

This was mentioned in many studies with focus on the STEMI cases as in Choi *et al*. [10], which recorded that despite successful treatment of the SB lesion in patients with STEMI who underwent primary PCI, the two-stent technique was linked to a higher rate of MACE than the one-stent strategy.

As a result, in cases of primary PCI for STEMI, the one-stent strategy should be considered the preferred approach for the treatment of coronary bifurcation culprit lesions [10].

Angiographic data

As angiographic findings were the cornerstone in the operator planning and decision in choosing the proper technique, quantitative coronary angiographic measurements from our results showed that the main branch stenosis (%) had no statistical significance between the two groups.

SB stenosis was significantly higher in the two-stent group (86 ± 13.2%) than in the provisional group (77.9 ± 15.1%), with P = 0.03. This was discordant with the results of Zhang *et al*. [11], as there was no statistical difference between the two groups (P = 0.11).

This topic was mentioned by Hahn *et al*. [12] reviewing the predicators and results of SB occlusion after MV stenting in coronary bifurcation lesions. They reported that SB diameter stenosis (%) was one of the main predicators of SB occlusion, with P = 0.001.

SB lesion length (mm) in our study was longer in the two-stent technique than in the provisional technique, but did not reach statistically significant difference (P = 0.06).

The results of Ahmed Amin and colleagues and Zhang and colleagues, agreed with our results about the SB lesion length as both showed no statistical difference between the two groups (P = 0.24 and 0.28, respectively) [12,13].

However, the results of Kumsars *et al*. [8] showed that the SB lesion length was longer in the complex procedure than in the simple procedure, with statistically significant difference (P < 0.0001).

This controversy may be explained by the smaller number of the included patient in our study in comparison with the study by Kumsars and colleagues.

Bifurcation angle between the main branch and the SB was numerically larger in the two-stent technique than in the provisional technique, with no statistically significant difference (P = 0.14).

This was the same as the results of Kumsars *et al*. [8] and Zhang *et al*. [11], as there was no significant statistical difference in the bifurcation angle between the two groups (P = 0.93 and 0.56, respectively).

Although bifurcation angle is a major factor influencing coronary bifurcation hemodynamics, atherogenesis, intervention procedure, SB compromise, and clinical outcome, it is still debatable, so accurate and comprehensive measurement of bifurcation angle may aid in resolving this SB occlusion predictor [14].

Procedural complications such as SB occlusion, ACS, bleeding, or plaque shift have no significance difference between the two groups, with P = 0.4.

This was concordant with Leus *et al*. [15] and Zhang *et al*. [11], as both showed no significant difference in procedural complications (P = 0.27 and 0.23, respectively).

The risk of SB occlusion during the procedure is well known as the main cause of coronary bifurcation stenting's complexity. As a result, various maneuvers to get around this could be the cause of suboptimal MV stent expansion, which can lead to stent thrombosis and restenosis [16].

From the previously mentioned data in our study, we concluded that the clinical presentation (patients with STEMI), bifurcational angle, and SB lesion (stenosis and lesion length) were the major determinants that influence the operator decision in the chosen technique.

This is what has been concluded from the data of COBIS II registry, as proximal MV stenosis, pre-procedural stenosis and lesion length of the SB, and clinical

presentation were determined to be predictors of SB occlusion after MV stenting [12].

The European Club of Bifurcation (EBC) recommended that the optimization of the technical steps in the provisional pathway, which allows for treatment of the majority of complex BFLs with a single stent, is seen as a remarkable achievement [17].

Complex BFLs, particularly when including the LM, provide significant technical obstacles, as well as an increased risk of adverse outcomes. Potential objectives for improving outcomes include intracoronary imaging, bifurcation simulation, and treatment with drug-eluting balloon technologies, as well as personalized antiplatelet therapy [17].

Follow-up

MACE showed no significant difference between provisional stenting and two-stent groups, with $P = 0.52$.

These findings matched those of Leus *et al.* [15], Ahmed Amin and colleagues, and Kumsars *et al.* [8], who found no statistically significant differences between the two groups (P = 1.0, 0.11, and 0.07, respectively) [10].

The provisional group had a numerically higher MACE rate than the two-stent group (12.8 vs. 3.4%), with statistically insignificant difference.

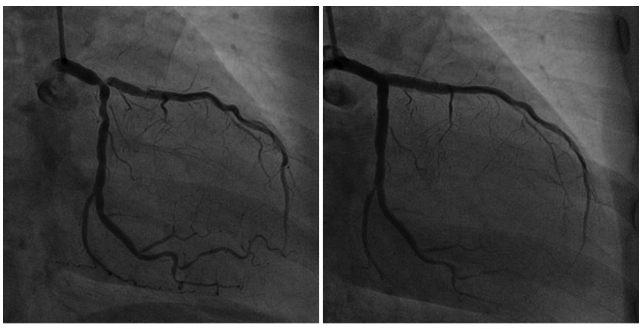
Although we did not find a significant benefit in using complex two-stent techniques, the numerically lower MACE rate suggests that two-stent procedures such as the culotte technique, which was used in case no. 20 in Fig. 4, were at least safe in the treatment of patients with significant SB disease.

This agreed with Wang *et al.* [18], who discussed complex LM BFL stenting, that two-stent technique resulted in numerically lower 3-year cardiac death rate among patients with true LM bifurcations lesion.

As a result, most guidelines have highlighted the effect of the bifurcation's complexity on clinical results, recommending that when the SB lesion length is more than 5 mm and the SB diameter is more than or equal to 2.75 mm, the two-stent approach may be better [19].

This what was mentioned recently by Raphael and O'kane [20] that although provisional stenting approach may be appropriate in many cases, the two-stent technique should be of choice in patients with complex anatomy or a large myocardial area supplied by the SB.

Figure 4



The bifurcational lesion from case number 20 and results after culotte stenting.

Limitations

The following were the limitations of the study:

(1) Single-center study.
(2) Sample size was relatively small.
(3) Short duration of follow-up.
(4) Data about fluoroscopy time and contrast volume used for cases.
(5) No IVUS used owing to high financial cost.
(6) No coronary angiography follow-up owing to financial cost.
(7) No SB assessment with IFR or FFR owing to financial issues.
(8) Nonrandomized trial, so may be subject to selection bias.

Conclusion

BFL stenting represents 6.5% of total PCI cases in Assiut University catheterization laboratory in 1 year, with the two-stent strategy at least as safe as provisional stenting regarding MACE during hospital stay and short-term follow-up.

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Mohamed A. El-Naser Abd El-Raheem analyzed and interpreted the patient data regarding the clinical presentation and follow-up.

Mohamed A. Abdelhafez analyzed the angiographic data of the patients and was a major contributor in writing the manuscript.

Amr A.A. Youssef reviewed the results and contributed in writing of the manuscript.

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Conflicts of interest
There are no conflicts of interest.

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