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Comparing Two Stents Technique Versus Provisional Stenting Technique in Bifurcation Coronary Artery Lesions in Beni-Suef University Hospital

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Abstract

Background: Percutaneous Coronary Intervention (PCI) of bifurcation disease remains a challenge in terms of procedural success rate as well as long term Major Adverse Cardiac Events (MACE), Target Lesion Revascularization (TLR), restenosis, and Stent Thrombosis (ST). Bifurcation interventions, when compared with non-bifurcation interventions, have a lower rate of procedural success and a higher rate of restenosis.

Aim: The purpose of this study was to assess the in hospital and mid-term outcome of two different techniques of stent deployment in bifurcation coronary artery lesions in Beni-Suef University Hospital: Two stent technique versus provisional stenting technique.

Patients and Methods: This study was a prospective non-randomized study performed on 50 patients referred to cardiology department at Beni-Suef University hospital. This study included two different techniques of stent deployment using DES for elective treatment of stable patients with *de novo* native bifurcation coronary artery lesions. Patients were divided according to the operator decision based on vessel and lesion characteristics and also operator experience into two groups: group I (provisional stenting technique) and group II (2 stent technique), each group included 25 patients. All our study patients were subjected to clinical follow-up by office visit at 1 month and 6 months after treatment for MACE (The mid-term MACE: at 6 months and the in-hospital MACE). Myocardial Perfusion Imaging (MPI) was scheduled 6 months post procedure for asymptomatic patients or those with atypical symptoms. Follow-up angiography was planned for all patients at six months (or earlier for symptomatic patients or patients with positive stress MPI for ischemia).

Results: Both groups were well matched regarding baseline characteristics. The procedural in-hospital success was 100% in all the patients in both groups (P=1). Typical angina (CCS class 2–4) occurred in 4 patients during the 6 months follow up period in the whole study:1 patient (4%) in group I and 3 patients (12%) in group II (P=0.29). MPI was done at 6 months post procedure for 46 asymptomatic patients: 2 patients had positive MPI in group II and no patients in group I (P=0.18). Follow up coronary angiography was done for all patients at 6 months or earlier: Stent thrombosis was detected in 1 patient in group I and 3 patients in group II (P=0.29). Clinically and angiographically driven TVR occurred in 1 patient in group II and no TVR occurred in group I (P=0.31). Death did not occur in any patient during the 6 months follow up period. Myocardial infarction during the 6 months follow up period occurred in 1 patient in group I and 3 patients in group II (P=0.29). Total composite MACE at 6 months occurred in 1 patient in group I (4%) and 3 patients in group II (P=0.29).

Conclusion: In developing countries with limited resources; the strategy of DES implantation in the main branch with provisional stenting of the side branch for the treatment of bifurcation lesions should be the preferred strategy.

Keywords: Provisional stenting; Bifurcation lesions; Two stents technique

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Introduction

Bifurcation lesions are one of the complex lesion subsets that are now being confronted more frequently. Percutaneous coronary intervention (PCI) of bifurcation disease remains a challenge in terms of procedural success rate as well as long term major adverse cardiac events (MACE), target lesion revascularization (TLR), restenosis, and stent thrombosis. Bifurcation interventions, when compared with non-bifurcation interventions, have a lower rate of procedural success and a higher rate of restenosis [1-3]. Bifurcation lesions carry a risk of side branch occlusion because of plaque redistribution or so-called "plaque shift" across the carina of the bifurcation. The risk is increased if there is an eccentric lesion at the bifurcation site and a stenosis in the ostium of the side branch [4]. To lower the risk of plaque shift, the "kissing" balloon technique was developed [5]. However, the results after balloon dilatation of bifurcation lesions are frequently suboptimal with a high incidence of complications and restenosis [4,6-8]. Stent implantation on both the parent vessel and the side branch, which is called "kissing stents," is a useful technique for maintaining maximum expansion of both vessels. The use of two stents minimizes lumen loss of one side during expansion of the other vessel [9]. Several studies [10 -12] have concluded that stenting the main vessel (MV) with provisional stenting (PS) of side branches (SB) is preferable in the great majority of bifurcation lesions. Various techniques with the use of one or two stents have been developed to optimize the treatment of this subset of lesions [1-3,13-19]. Paradoxically, although stenting of individual lesions has been shown to be superior to balloon angioplasty, stenting of both branches seems to offer no advantage over stenting of the main branch (MB) alone [3].

The aim of this work was to assess the in hospital and mid-term outcome of two different techniques of stent deployment in bifurcation coronary artery lesions in Beni-Suef University Hospital: Two stent technique versus provisional stenting technique.

Patients and Methods

Study population

This study was a prospective non-randomized study performed on 50 patients referred to Cardiology Department at Beni-Suef University hospital. The study was conducted from March 2014 to October 2015. The study protocol was approved by the committee of research and medical ethics of the cardiology department of Beni-Suef University in March 2014, and informed consent was obtained from all patients. This study included two different techniques of stent deployment (using DES: Drug eluting stents) for elective treatment of stable patients with *de novo* native bifurcation coronary artery lesions. Patients were divided according to the operator decision based on many factors as vessel and lesion characteristics and also operator experience into two groups: group I (Provisional stenting technique) and group II (2 stent technique), each group included 25 patients. Inclusion criteria: We electively selected all stable patients with *de novo* native coronary bifurcation lesions (when there is ≥ 50% lesion in both the main vessel and side branch) with main-vessel reference diameter was ≥ 2.5 mm and the side-branch reference diameter was ≥ 2.25 mm. Exclusion criteria were:

(1) Unprotected left main stenosis ≥ 50%, primary angioplasty for acute ST-elevation myocardial infarction, cardiogenic shock and left ventricular systolic dysfunction.

(2) Diameter of the side branch was <2.25 mm or diameter of the main branch was <2.5 mm.

(3) Contraindications for cardiac catheterization or contraindication of dual antiplatelet therapy.

(4) Undergoing a trans aortic valve implantation (TAVI) during the same hospital stay, as this is associated with a comparably large puncture site so that the relevant comparator would be vascular suture, rather than MC.

Assessment

Proper history taking, 12-lead ECG, echocardiography and coronary angiography were done for all patients. Two different techniques of stent deployment using DES were used for elective treatment of stable patients with *de novo* native bifurcation coronary artery lesions. Provisional stenting technique was used in group I while 2 stents technique was used in group II. The 1st strategy (provisional stenting technique): It included stenting the (MB). stenting of the (SB) was done only if there was SB deterioration resulting in less than TIMI grade 3 flow, ECG changes or persistent intraprocedural angina. The 2nd strategy (2 stent technique): routine side branch stenting. Coronary angiograms were obtained in at least two orthogonal projections. Visual estimation of the coronary anatomy and the lesions were done by two expert interventionists. The following parameters were calculated: location of bifurcation, medina classification, bifurcation angle, lesion length, reference vessel diameter and minimal lumen diameters (MLD) before and after stenting and the percent diameter stenosis (%DS) in the MB and SB before and after stent implantation (stenosis percentage is calculated as the difference between the minimal luminal diameters (MLD) from the reference vessel diameter (RVD) divided by the RVD

and multiplied by 100). The clinical follow-up was performed by office visit at 1 month and 6 months after treatment for MACE. Combined rest-stress myocardial scan was scheduled 6 months post procedure for asymptomatic patients or those with atypical symptoms, patients who are unable to exercise will be stressed pharmacologically with Dipyridamole or Dobutamine. Follow-up angiography was planned for patients at six months or earlier if there was angina during follow up period or for patients with positive stress Myocardial Perfusion Imaging (MPI) for ischemia.

Endpoints

The primary end-point: (The mid-term MACE at 6 months) defined as cardiac death, myocardial infarction and target vessel revascularization: TVR). Instent restenosis: defined as renarrowing to a diameter stenosis >50%, either within the stent or within 5 mm proximal or distal to the stent margin) [20]. Side branch affection: diagnosed if there is increase in the severity of side branch stenosis in comparison of the end result during the procedure). Definite stent thrombosis (ST): defined as the presence of a thrombus that originates in the stent or in the segment 5 mm proximal or distal to the stent and presence of at least 1 of the following criteria within a 48 hour time window: Acute ischemic symptoms or new ischemic ECG changes or typical rise and fall in cardiac biomarkers. The timing of (ST) was classified as acute if it occurred <24 h after stent implantation, as subacute if it occurred >2 h to 30 days after stent implantation, as late if it occurred >30 days to 1 year after stent implantation and as very late if it occurred >1 year after stent implantation [21].

The secondary end-point: (The in-hospital MACE: During the index hospitalization) includes device performance and periprocedural safety:

Angiographic success: Defined as the achievement of a residual diameter stenosis of <50% with PTCA or <20% with stenting with at least (TIMI) flow 3 in both the parent vessel and side branch [22].

Procedural success: Defined as the achievement of angiographic success in the absence of any in-hospital MACE.

In hospital MACE: Include death, myocardial infarction or emergency target vessel revascularization (TVR) during the index admission. Procedure duration: Time from initial infiltration of local anesthetic to removal of guiding catheter. Procedure fluoroscopy time: Duration of X-ray utilization.

Statistical analysis

Values were presented as means ± SD or as numbers and proportions, as appropriate. The relations between qualitative variables were evaluated by Chi-square test or Fisher's exact test, as indicated. Means were compared with unpaired Student's test. All tests were bilateral and a P value of 5% was the limit of statistical significance. Analysis was performed by statistical package software IBM- SPSS for MAC, version [23].

Results

Both groups were well matched regarding baseline characteristics: patients' demographics in **Table 1** and Lesion characteristics in **Table 2**.

As shown in **Table 3** the mean procedural time was 68 minutes ± 9.1 minutes in group I and 95 minutes ± 13.6 minutes in group

Table 1 Comparison of patients' demographics.

Variable	Provisional stenting (n=25)	Two-stent technique (n=25)	P value*
Age	58.6+7.1	58.6+8.6	1
Male sex	21 (84%)	21 (84%)	1
Diabetes mellitus	11 (44%)	11 (44%)	1
Hypertension	19 (76%)	15 (60%)	0.23
Dyslipidemia	0	2 (8%)	0.149
Smoking	15 (60%)	17(68%)	0.56
MI	14 (56%)	13 (52%)	0.78
ACS other than STEMI	10 (40%)	11 (44%)	0.77
PCI	8 (32%)	1 (4%)	0.713
CABG	2 (8%)	0	0.149
RWMA	17 (68%)	14 (56%)	0.382
EF%	58.9+7.3	61.7+4.4	0.11

Values are presented as numbers (%) or mean+SD. N=number of patients, *=Chi-square (or Fisher's exact test) or unpaired Student's test, as indicated, MI=Myocardial Infarction, ACS=Acute coronary syndrome, STEMI=ST elevation MI, PCI=Percutaneous Coronary Intervention, CABG=Coronary Artery Bypass Graft, RWMA=Regional Wall Motion Abnormalities, EF%=Ejection Fraction%.

Table 2 Lesion characteristics.

Variable	Provisional stenting (n= 25)	Two-stent technique (n=25)	P value*
Location of bifurcation			
LAD/D[1]	20 (80%)	20 (80%)	1
LCX/OM[2]	4 (16%)	5 (20%)	0.713
RCA/PDA[3]	1 (4%)	0	0.312
Medina class			
Class 111	20 (80%)	19 (76%)	--
Class 101	3 (12%)	4 (16%)	--
Class 011	2 (8%)	2 (8%)	0.919
Angle of bifurcation			
<70°	16 (64%)	14 (56%)	--
>70°	9 (36%)	11 (44%)	0.564
MB reference diameter before (MM)	3+0.3	3+0.29	0.91
MB lesion length before (MM)	20.5+7.6	24.6+8.1	0.72
MB stenosis before (%)	93.3+4.7	92.2+3.7	0.36
SB reference diameter before (MM)	2.64+0.16	2.62+0.18	0.68
SB lesion length before (MM)	11.4+3.3	12.5+3.2	0.24
SB stenosis before (%)	72.9+18.9	71.8+18.5	0.84

Values are presented as numbers (%) or mean+SD. n=number of patients, MB =main branch, SB=side branch, *=Chi-square (or Fisher's exact test) or unpaired Student's test, as indicated, 1 left anterior descending/diagonal, 2 left circumflex/obtuse marginal, 3 right coronary artery/posterior descending artery.

II, with statistical significant difference (P=<0.001). The mean amount of contrast used in the procedure was 233.6 ml ± 33.5 ml in group I and was 288.4 ml ± 54.7 ml in group II, without statistical significant difference (P=0.91).

As shown in **Table 4**, The immediate angiographic success was 100% in all patients in both group, the procedural in-hospital success was 100% in all the patients in both groups, no documented ECG changes after intervention during the index hospitalization and no one from either group suffered in-hospital major complications (MACE); acute myocardial infarction, need for bypass surgery or repeat PCI, or death occurred (P=1).

As shown in **Table 5**, the patients were monitored clinically with follow up examination conducted at 1 month and 6 months after treatment for occurrence of anginal symptoms and for incidence of primary (MACE). Typical anginal symptoms (CCS class 2–4)

Table 3 Procedural characteristics.

Variable	Provisional stenting (n= 25)	Two-stent technique(n=25)	P value*
MB pre-dilatation	16(64%)	15(60%)	0.77
SB pre-dilatation	13(52%)	10(40%)	0.39
Both branches pre-dilatation	6(24%)	8(32%)	0.53
Stent diameter (mm)	3+0.3	3+0.29	0.91
Stent length (mm)	23.7+7.7	28.2+8.8	0.057
MB reference diameter after (mm)	3+0.3	3+0.29	0.91
MB stenosis after (%)	0	0	--
SB reference diameter after (mm)	2.64+0.16	2.62+0.18	0.681
SB stenosis after (%)	14+18.5	0	<0.001
SB post dilatation	17 (68%)	17 (68%)	1
SB stenting	5 (20%)	25 (100%)	<0.001
Kissing balloon inflation	10 (40%)	25 (100%)	<0.001
Time of procedure (min)	68+9.1	95+13.6	<0.001
Contrast volume (ml)	233.6+33.5	288.4+54.7	0.91

Values are presented as numbers (%) or mean+SD. n=number of patients, MB=main branch, SB=side branch, *=Chi-square (or Fisher's exact test) or unpaired Student's test, as indicated

Table 4 Comparison of in-hospital outcomes.

Variable	Provisional stenting (n=25)	Two-stent technique(n=25)	P value*
Procedural success	25 (100%)	25 (100%)	1
Angiographic success	25 (100%)	25 (100%)	1
Mortality	0	0	1
MI	0	0	1
TVR	0	0	1
MACE	0	0	1

Values are presented as numbers (%). n=number of patients, MI=myocardial infarction, TVR=target vessel revascularization, MACE=Major Adverse Cardiac Events, *=Chi-square or Fisher's exact test, as indicated

Table 5 Comparison of outcomes after 6 months.

Variable	Provisional stenting (n=25)	Two-stent technique (n=25)	P value*
MPI			
Negative	24 (96%)	20 (80%)	-
Positive	0	2 (8%)	-
Not done	1 (4%)	3 (12%)	0.186
Typical angina	0	3(12%)	0.149
Smoking	15 (60%)	0	0.56
ISR	14 (56%)	3 (12%)	0.78
Stent thrombosis	10 (40%)	3 (12%)	0.77
MI	8 (32%)	1 (4%)	0.713
TVR	2 (8%)	0	0.149
Death	17 (68%)	3 (12%)	0.382
MACE	58.9+7.3	3 (12%)	0.11

Values are presented as numbers (%). n=number of patients, MPI=myocardial perfusion imaging, ISR=in stent restenosis, MI=myocardial infarction, TVR=target vessel revascularization, *=Chi-square or Fisher's exact test, as indicated.

occurred in 4 patients during the 6 months follow up period in the whole study (so MPI not done): 1 patient (4%) in group I vs. 3 patients (12%) in group II, without statistical significant difference between both groups (P=0.29). Myocardial perfusion imaging for 46 asymptomatic patients (or with atypical symptoms) in the whole study. 2 patients had positive MPI: 2 patients (8%) in group II vs. no patients (0%) in group I. 44 patients had negative MPI: 24 patients (96%) in group I and 20 patients (80%) in group II, without statistical significant difference between both groups (P=0.186). No in stent restenosis (0%) was detected in both groups. Stent thrombosis was detected in 4 patients in the whole study: 1 patient (4%) in group I and 3 patients (12%) in group II, without statistical significant difference between both groups (P=0.29). Clinically and angiographically driven target vessel revascularization occurred in 1 patient (4%) in group II (no TVR occurred in group I), without statistical significant difference between both groups (P=0.31).

Death during the 6 months follow up period did not occur in any patient in the whole study. Myocardial infarction during the 6 months follow up period occurred in 4 patients in the whole study: 1 patient (4%) in group I and 3 patients (12%) in group II, without statistical significant difference between both groups (P=0.29). Total composite MACE at 6 months occurred in 4 patients in the whole study: 1 patient in group I (4%) and 3 patients in group II (12%), without statistical significant difference between both groups (P=0.29).

Discussion

In our study, provisional stenting had superior safety. Compared with provisional strategy, the Two stents' strategy was associated with increased risk of total composite MACE at 6 months (1 patient in group I (4%) vs. 3 patients in group II (12%)) without statistical significant difference between both group (P=0. 29). This was mainly contributed to by myocardial infarction (1 patient (4%) in group I vs. 3 patients (12%) in group I, P=0.29) rather than death (no deaths in whole study) or TVR (1 patient

(4%) in group II vs. no TVR in group I, P=0.31). The increased risk of myocardial infarction in group II was mainly contributed to by increased incidence of stent thrombosis (1 patient (4%) in group I and 3 patients (12%) in group II, P=0.29), most probably due to much more stent metal used, longer procedure times and higher contrast volumes.

Results of our study were in agreement with that reported in the Nordic study (10,23): 413 patients with significant bifurcation lesion were randomized to a simple or complex stenting strategy, using sirolimus-eluting stents (SESs). In the simple stenting strategy, the main vessel was stented with provisional side branch stenting (MV). In the complex stenting strategy; both main vessel and side branch were stented (MVSB). The occurrence of (MACE): Cardiac death, myocardial infarction, target-vessel revascularization, or stent thrombosis at 6 months were the primary end point. In this study, there was no significant differences in major adverse cardiac events rates between both groups (2.9% in the provisional group vs. 3.4% in the complex group; P=NS). Thus, the use of sirolimus-eluting stents for treatment of *de novo* coronary bifurcation lesions was safe regardless the technique of stenting.

Results of our study were in agreement with that reported in The CACTUS trial [12], (Coronary bifurcations: application of the crushing technique Using Sirolimus-eluting stents): 350 patients with true bifurcation lesion were randomized to simple or complex stenting strategy, with mandatory final kissing-balloon inflation. In the simple stenting strategy, the main branch was stented with provisional side branch stenting (using T stenting technique). In the complex stenting strategy group, both main branch and side branch were electively stented using "crush technique". Rates of (MACE) at 6 months were the primary clinical end point. In this study, there was no significant differences in rates of major adverse cardiac events between both groups (15% in the simple group vs. 15.8% in the complex group, P=NS). Thus, the complex stenting strategy was not less safe than the simple stenting strategy at 6 months. Results of our study were in agreement with that reported in the British Bifurcation Coronary (BBC) trial (11): 500 patients with significant coronary bifurcation lesions were randomized to a simple or complex stenting strategy, using drug-eluting stents. 82% of lesions were true bifurcations (>50% narrowing in both vessels). In the simple stenting strategy, the main branch was stented, with provisional side branch kissing balloon dilatation/T-stent. In the complex strategy, both main branch and side branch were stented (using culotte or crush techniques) with mandatory kissing balloon dilatation. In the simple group (no.=250), 66 patients (26%) had kissing balloons in addition to main-vessel stenting, and 7 patients (3%) had T stenting. In the complex group (no.=250), 89% of culotte (no.=75) and 72% of crush (no.=169) cases were completed successfully with final kissing balloon inflations. In this study, there was a significant difference in rates of composite major adverse cardiac events between both groups (8.0% in the simple group vs. 15.2% in the complex group, P=0.009) (hazard ratio 2.02, 95% confidence interval 1.17 to 3.47). There was a significant difference in rates of myocardial infarction between both groups (3.6% in the simple group vs. 11.2% in the complex group, P=0.001). Thus, the provisional stenting strategy was safer than the complex strategy that was associated with higher incidence of in-hospital and 9-month major adverse cardiovascular events, mainly contributed to by periprocedural myocardial infarction. Results of our study were in agreement with that reported in Gao et al. [24]: 566 patients with significant coronary bifurcation lesions were randomized to a simple or complex stenting strategy, using drug-eluting stents. In the simple stenting strategy, the main branch was stented, with mandatory side branch kissing balloon dilatation (i.e., single-stent strategy). In the complex strategy, both main branch and side branch were stented (using crush, culotte, Y-, V-, and kissing-stent techniques) (i.e., two-stent strategy). MACE rates were higher in the complex group than in the simple group (5.5% vs. 2.0%; p=0.032), which were mainly contributed to by acute myocardial infarction (4.5% vs. 1.4%; p=0.032) rather than death MBand TLR (0% vs. 0.5%, p=0.389; 1.4 vs. 2.7%, p=0.352). Stent thrombosis rates were higher in the complex group than in the simple group (0.6% vs. 2.7%; p=0.042). Results of our study were in agreement with that reported in Yamashita et al. [25], 92 patients with bifurcation lesions were treated with a simple or complex stenting strategy, using Bare-metal stents (BMS). In the simple stenting strategy, the main branch was stented, with balloon angioplasty of the side branch (i.e., single-stent strategy). In the complex strategy, both main branch and side branch were stented (i.e., Two-stent strategy). In this study, there was no significant difference in the incidence of 6-month total MACE between both groups (38% in the simple group vs. 51% in the complex group).

Results of our study were in agreement with that reported in Brar et al. [26], who published a meta-analysis of 6 randomized controlled trials (RCTs) comparing 2 different techniques for treatment of coronary bifurcation lesions, using drug-eluting stents: Provisional (simple) stenting strategy vs. two-stent (complex) strategy. The endpoints were death, myocardial infarction, target vessel revascularization (TVR) and DES thrombosis after 7 months ± 2 months. Compared with the simple strategy, the complex strategy had similar mid-term mortality (0.82 in the complex group vs. 0.82% in the simple group, P=NS) and similar TVR (5.45% vs. 5.22%, P=NS), but showed a trend toward an increased occurrence of stent thrombosis (1.36% in the complex group vs. 0.69% in the simple group, P=0.17) and a significant increase in the risk of myocardial infarction (6.81% in the complex strategy vs. 3.43% in the simple strategy, P=0.005). The higher rate of myocardial infarction with the two-stent strategy was consistent with the results of individual trials.

In our study, no in stent restenosis (0%) was detected in both groups at 6 months follow up, without statistical significant difference between both groups (P=1). Results of our study were in agreement with that reported by Brar et al. [26].

Meta-analysis: Compared with the simple stenting strategy, the complex stenting strategy had similar angiographic restenosis in both main vessels (4.46% vs. 6.02%, P=NS) and the side branch (12.38% vs. 15.04%, P=NS).

In our study, compared to the routine two-stent strategy, provisional stenting strategy had similar efficacy. The immediate angiographic success was 100% in all patients in both groups, the procedural in-hospital success was 100% in all the patients in both groups, no documented ECG changes after intervention during the index hospitalization and no one from either group suffered in-hospital major complications. Results of our study were in agreement with that reported in the BBC trial [11]. Study. In this study, there was a significant difference as regard the in-hospital major adverse cardiovascular events between the simple stenting group (2.0%) and complex stenting group (8.0%) (P=0.002).

In our study, provisional stenting strategy had superior safety due to shorter procedure and fluoroscopy times and lower contrast volumes. The mean procedural time was 68 minutes ± 9.1 minutes in group I and 95 minutes ± 13.6 minutes in group II, with statistical significant difference (P=<0.001). The mean amount of contrast used in the procedure was 233.6 ml ± 33.5 ml in group I and was 288.4 ml ± 54.7 ml in group II, without statistical significant difference (P=0.91). Results of our study were in agreement with that reported in the Nordic trial [10, 23]. In this study, the complex stenting group (when compared with simple strategy) was associated with significantly longer procedure and fluoroscopy times, higher contrast volumes, and higher rates of procedure-related increases in biomarkers of myocardial injury. So, the simple stenting strategy can be recommended as the routine bifurcation stenting technique.

Conclusion and Future Research

In treatment of bifurcation lesions, strategy of DES implantation in the main branch tl (MB) with provisional stenting of the side branch (SB) should be the preferred strategy as the strategy of DES deployment in both branches is associated with increased mid-term risk of MI (mostly due to stent thrombosis) due to much more stent metal used, longer procedure and fluoroscopy times and higher contrast volumes.

The low cost needed to treat patients with bifurcation coronary lesions using one stent is of utmost importance in developing countries, where hospitals have limited financial resources.

In the developing countries with limited financial resources; we can cut the cost by using one stent for many bifurcation coronary artery lesions without sacrificing the best outcome.

Limitations of the Study

1) It is non-randomized trial

That is like majority of studies in literature as RCT are the small number.

The aim of randomization is to create 2 comparable groups and this aim was nearly fulfilled without randomization (as shown in baseline demographic data table of comparison). This will mean that any difference after the methods used will be due to the methods themselves and not because patients were initially different.

2) Small number of patients included in the study (50 patients)

Our results showed that provisional technique was better, as previously shown by all major studies and meta-analysis. The only remark is that-like many randomized prospective studies that were done on a much larger number of patients-those better results were not significant, because our sample size was small like those studies. So, we need larger studies to put into statistical evidence this difference. If we considered meta-analysis as an appropriate start (for a difference of 6.81% and 3.43%), we need a sample size of 670 patients per group for the usual primary risk of error of 5% and a study power of 80%.

Conflict of Interest

None

Authors' Contributions

Nader Galal Hussein–patient screening, follow up, echocardiorapic assessment, myocardial perfusion imaging and manuscript editing; Hesham Boshra Mahmoud–coronary interventions and manuscript editing; Yasser Ahmed Abdel Hady–echocradiographic assessment, coronary interventions; Osama Ahmed Amin–patient screening, coronary interventions, statistical analysis and manuscript editing.

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