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Immediate and Long Term Results of Percutaneous Coronary Intervention for Bifurcation Lesions in Diabetic Patients Using Two-Stents Technique Versus One Stent Technique

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Abstract

Background: Almost all previous trials on percutaneous coronary interventions in coronary bifurcation lesions concluded that the provisional approach is the standard approach for most true bifurcated lesions. The absence of diabetes subgroup analysis in these trials was an important limitation.

Aim: The present study aimed to assess a long term clinical outcome (at 1 year) of PCI to coronary bifurcation lesions in diabetic patients using two stents vs one stent techniques.

Methodology: Overall, 100 patients with true bifurcated coronary lesions were erratically allocated to undergo upfront 2-stent procedure (2-stent group) and provisional procedure (1-stent group).

Results: The TLF at the 12-month follow-up was the 1st endpoint, signified by a composite of target vessels myocardial infarctions (TVMI), clinically driven target lesions revascularization (TLR), and cardiac deaths. At the 12 months follow-up, TLF was present in 12 (24%) and 4 (8%) patients in the one and two-stent groups, respectively ($p = 0.029$) driven by increased TVMI in the one stent group.

Conclusion: In diabetic patients with bifurcated coronary lesions, the upfront two-stent plan was accompanied with better clinical results compared with the provisional approach.

Keywords: Coronary bifurcation lesions ; Provisional stenting ; Two-stent strategy ; Target lesion failure

1. Introduction

Occurrences of coronary bifurcation comprise 15–18 percent of all coronary interventions (PCI). Side branch (SB) occlusion is a significant procedural complication of bifurcation intervention that can result in critical adverse clinical outcomes, such as myocardial infarction.¹

For the majority of genuine bifurcated lesions, the provisional approach guided by the tenet "keep it simple and safe" has been determined to be the standard procedure in nearly all prior PCI trials for coronary bifurcation lesions.²

However, the absence of diabetes subgroup analysis in these trials was an important limitation.

There is a consensus of a higher rate of

restenosis and poorer outcomes of percutaneous revascularization in diabetic patients than in non-diabetics.^{3,4}

Randomized, controlled, or large observational trials have not yet reported the clinical outcomes of stenting for coronary bifurcated lesions in individuals with diabetes in the era of drug-eluting stents (DES) of the second generation.^{1,2}

Furthermore, the full clinical ramifications of employing second-generation DES to considerable bifurcated lesions in patients diagnosed with diabetes remain unclear.¹

Therefore, we attempted to detect benefits of 2-stents bifurcation lesions in diabetic patients and in the era of second generation DESs.

This study aimed to assess the clinical results of routine upfront dual stenting compared with one provisional stenting approach of bifurcated coronary lesions in patients with diabetes.

2. Patients and methods

This prospective randomized study was done on 100 bifurcated lesions of 100 diabetic patients of varying genders and ages. Patients were gathered from hospitals in Cairo, Egypt, including Al-Azhar university hospitals and National Heart Institute from May 2021 to May 2023.

Study Population

Patients with diabetes who needed PCI and were at least 18 years old with true bifurcation coronary artery disease (>50% narrowing of both the main vessel (MV) and the stenosis) were eligible to participate in the study. MV and SB reference diameters were both greater than 2.5 mm, and the length of SB ostial disease was greater than 5 mm. Therefore, these individuals qualified for intervention due to the SB's predominant ability to induce angina in them.

The main exclusion criteria were left main stem disease, chronic total occlusion (CTO), target lesion of In-stent restenosis, or bypass graft. Acute myocardial infarction, with a left ventricular ejection fraction not exceeding 30% and a platelet count not falling below $50 \times 10^9/\text{mm}^3$, and patient life expectation < one year, patients listed for surgery needed to stop taking antiplatelet medications within six months, required long-lasting oral anticoagulation could potentially impede adherence or require extended monitoring. Furthermore, pregnant women and patients with known relevant allergies were excluded. Participants who acceded to the study were randomized in a one to one ratio to each 1 stent or 2 stents group using a simple randomization technique by flipping a coin. All patients provided consent after being fully informed.

Revascularization Procedure

A 1:1 ratio of all patients were allocated randomly to receive either provisional stenting or an upfront 2-stent plan. In the one stent group, the side and main branches are wired. Although pre-dilation of the SB was discouraged, It was left to the discretion of the operator. whether to pre-dilate both branches. Following MV stenting in relation to the distal segments, the proximal optimization technique (POT) was performed using a stent ratio of 1:1 (>18 atm) to the non-compliant balloon. After that, if there is a severe compromise of the SB ostium, it has a dissection of type B/C or TIMI flow <3, and stenting or ballooning of the SB is performed. The SB is rewired distally over the main branch stent, and kissing ballooning inflation (KBI) is performed. As recommended, a final POT is conducted utilizing non-compliant balloons with an inflation pressure exceeding 18 atm. The bailout technique employed by the operator in the group utilizing a single stent was ascertained.

The initial plan for the two-stent group involved stenting of both the main and SB.

Alternative two-stent techniques such as TAP or traditional T, mini-crush or classical crush, and kissing stenting were not advised, while the double kissing crush technique was strongly recommended. Final kissing balloon inflation (FKBI) was mandatory. DK crush in brief, The SB stent protrudes minimally (2 mm) from the main vessel; complete crushing with a balloon is performed; initial kissing occurs while the MV is stented; post-dilation and POT follows; final kissing with or without POT. The SB stent underwent two rewirings (both times from proximal struts) during the DK crush. Prior to each kiss, both the MV and SB inflations are performed utilizing non-compliant balloons. The selection of the stent was at the operator's discretion. Revascularization of all remaining vessels was encouraged. Acute success in the procedure was achieved in the SB with a TIMI grade of flow three and less than 50% residual stenosis, and in the main branch with a TIMI grade of flow 3, less than 20% residual stenosis, and no SB loss.

Follow-up and primary endpoint

At 1, 6, and 12 months, Phone interviews or clinic visits were utilized for clinical follow-up. TLF at 12 months, which was the composite of target lesion revascularization (TLR), clinically driven target vessel myocardial infarction (TVMI), or cardiac death, was the primary endpoint. Death that was not attributed to a specific non-cardiac cause was classified as cardiac death. Peri-procedural MI was defined as a CK-MB of >10 URL or >5 URL plus either, occurring within 48 hours.: (i) Thrombosis in a newly identified severe lesion or coronary artery graft occlusion detected by angiography; (ii) Recent myocardium imaging has been deemed non-viable. (iii); new LBBB or new Q waves in at least two contiguous leads or (iv) Recently developed hypokinesia of wall motion. Classification of myocardial infarction (MI) as spontaneous occurred when the patient displayed cardiac markers (troponin or CK-MB >1 URL) in addition to newly observed ST-segment deviation or other previously noted findings. TVMIs were assigned to all MIs unless there was evidence that they were attributed to a vessel other than the intended target. (5) Chest pain or ischemia (confirmed by stress ECG or nuclear imaging) attributable to the target lesion that necessitates bypass grafting or repeat intervention was the definition of clinically driven TLR. (6)

Statistical analysis

The statistical analysis program SPSS v26 (IBM Inc., USA) was utilized. Mean and Standard deviation (SD) were employed to present quantitative data. Percentages and frequency (%) are utilized to represent qualitative variables. The Spearman correlation coefficient was utilized to determine the correlation degree between two

variables. In order to evaluate diagnostic performance, negative predictive value (NPV), positive predictive value (PPV), diagnostic specificity and sensitivity, and receiver operating characteristic curve (ROC curve) analyses are utilized. A p-value below 0.05 was considered to be indicative of statistical significance.

3. Results

From March 2021 to March 2023, total 113 consecutive diabetic patients with de novo true bifurcation lesions were randomized to receive different intervention strategies, 13 patients lost the follow up and were excluded to remain 100 patients

Demographic and baseline clinical data:

Insignificant difference observed in terms of age or gender between the two groups. Clinical features at baseline were well matched between the groups, unstable angina was found in 30% and 38% in both groups respectively. **Table 1. Baseline demographic and clinical characteristics; Group 1, one stent group; Group 2, two stents group**

Table 1. Baseline demographic and clinical characteristics; Group 1, one stent group; Group 2, two stents group

PARAMETER	GROUP 1 (N = 50)		GROUP 2 (N = 50)		P VALUE
	N	%	N	%	
AGE	53.40 ± 9.39		52.12 ± 8.78		0.076
MALE SEX	41	82%	36	72%	0.251
HYPERTENSION	40	80%	38	76%	0.822
SMOKING	32	64%	34	68%	0.673
DYSLIPIDEMIA	43	86	41	82	0.43
INSULIN DEPENDENT DM	14	28%	10	20%	0.594
HISTORY OF CABG	0	0.0	0	0.0	–
FAMILY HISTORY OF IHD	13	26	17	34	0.388
UNSTABLE ANGINA	15	30	19	38	0.566
CHRONIC STABLE ANGINA	35	70	31	62	0.76
BMI	25.1 ± 2.75		26.29 ± 2.39		0.105

Baseline angiographic characteristics:

The incidence of multivessel disease is 45% among the patients. 63% of the total lesions were localized in the LAD. Medina 1,1,1 was predominant. insignificant difference among both groups was found concerning lesion length or reference vessel diameter

Table 2. Comparison between the two studied groups according to baseline angiographic characteristics; RVD, reference vessel diameter; MB, main branch; SB, side branch; SD, standard deviation

Table 2. Comparison between the two studied groups according to baseline angiographic characteristics; RVD, reference vessel diameter; MB, main branch; SB, side branch; SD, standard deviation

		Group 1 (n = 50)		Group 2 (n = 50)		P value
		N	%	N	%	
Access	Femoral	45	90	40	80	0.657
	Radial	5	10	10	20	
Target Vessel	LAD/D	33	66	30	60	0.715
	RCA	10	20	11	22	
	LCX/OM	7	14	9	18	
No. of Vessel Disease	1 Vessel	26	52	29	58	0.927
	2 vessel	17	34	15	30	
Medina classification	3 vessel	7	14	6	12	0.43
	Medina 1,1,1	43	86	41	82	
	Medina 0,1,1	7	14	9	18	
Lesion length of main branch		20.5 +/- 7.6		24. +/- 8.		0.72
Lesion length of side branch		11.4 +/- 3.3		12. +/- 3.		0.24
RVD of MB		3.0 +/- 0.3		2.96 +/- 0.28		0.91
RVD of SB		2.64 +/- 0.44		2.62 +/- 0.48		0.68

Procedural characteristics

A total of 4 (8%) participants in the one stent group needed an SB stent. 42 (84%) patients in the 2-stent group had DK crush, 3 (6%) patients had Culotte technique and other 2-stent strategies were used in 5 (10%). Final kissing inflation was mandatory in the 2-stent group in contrast to the one stent group, although POT following last kissing was done similarly in both groups. The 2-stent plan was associated with larger contrast volume and more procedural time compared with the provisional (1 stent) plan **Table 3. Comparison between the two studied groups according to procedural characteristics; MB, main branch; SB; side branch SD, standard deviation; POT, proximal optimization technique.**

Table 3. Comparison between the two studied groups according to procedural characteristics; MB, main branch; SB; side branch SD, standard deviation; POT, proximal optimization technique.

	Group 1 (n = 50)		Group 2 (n = 50)		P value
	N	%	N	%	
Pre-dilation of MB	40	80	44	88	0.216
Pre-dilation of SB	2	4	45	90	<0.001
DK CRUSH	0	0	42	84	<0.001
Culotte	0	0	3	6	1
T and protrusion / others	4	8	5	10	
Final kissing balloon	4	8	48	96	<0.001
Final POT	50	100	45	90	0.23
SDstenting	4	8	50	100	<0.001
Procedural time	41.52 +/- 11.30		60.90 +/- 4.13		<0.001
Contrast volume	155.9 ± 25		237.5 ± 49.71		<0.001

(ml)			
Mean+/-SD			
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(ml)			
Mean+/-SD			

Immediate outcomes

In main branch, 100% of all patients in both groups had while in SD, 96% of group I and 98% of group II had acute procedural success with no significant difference.

Clinical outcomes

The one-year clinical follow-up of one hundred patients (13 lost) was completed. At 12 months, 12 (24%) participants in the 1-stent group and 24 (8%) patients in the 2-stent group achieved the primary endpoint of TLF (p value 0.029). This variation was caused by decreased TVMI rates (p = 0.046) with the 2-stent upfront plan, without significant differences in cardiac death and clinically driven TLR. Additionally, There were no observed differences in ST between the two groups.

Table 4. Comparison between the two studied groups according clinical outcomes at the 1-year follow-up. TLR: Target lesion revascularization

		Group I		Group II		P value
		N	%	N	%	
Target vessel MI (TVMI) at 1 year	yes	8	16.0%	2	4.0%	0.046
	no	42	84.0%	48	96.0%	
TLR at 1 year	yes	9	18.0%	4	8.0%	0.14
	no	41	82.0%	46	92.0%	
stent thrombosis at 1 year	yes	4	8.0%	2	4.0%	0.678
	no	46	92.0%	48	96.0%	
Heart failure at 1 year	yes	2	4.0%	1	2.0%	1
	no	48	96.0%	49	98.0%	
Stroke at 1 year	yes	0	0.0%	0	0.0%	----
	no	50	100.0%	50	100.0%	
Death at 1 year	yes	3	6.0%	2	4.0%	1
	no	47	94.0%	49	96.0%	
Target lesion failure (TLF)	yes	12	24.0%	4	8.0%	0.029
	no	38	76.0%	46	92.0%	

4. Discussion

The present randomized trial investigated clinical results in diabetic patients after an upfront 2-stent plan (mostly DK crush) in comparison with a 1-stenting provisional plan for the management of the true bifurcated lesions. The primary findings are as follows: in Figure 1, a two-stent strategy significantly reduced the incidence of TLF within a whole year compared to a provisional one-stent strategy, owing to the reduced occurrence of TVMIs.

Coronary bifurcation lesions constitute 15-20% of all coronary interventions. SB occlusion, a serious side effect of bifurcation intervention, may be associated with major complications, including myocardial infarction and adverse clinical results.¹

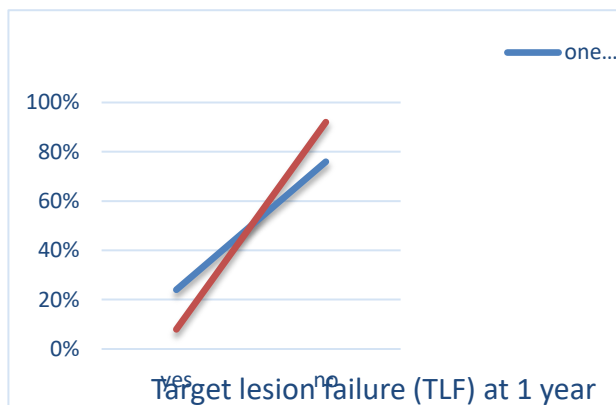


Figure 1. Comparison between the two studied groups according to TLF at 12 months

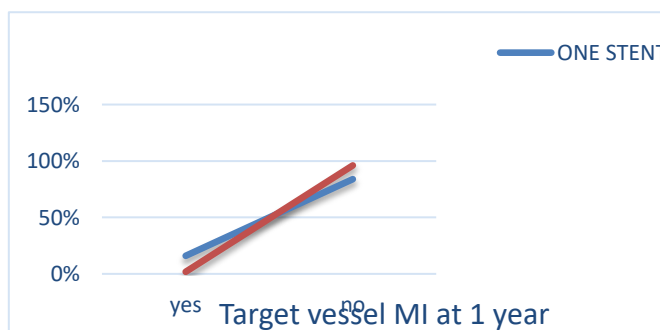


Figure 2. Comparison between the two studied groups according to target vessel MI at 12 months.



Figure 3. Comparison between the two studied groups according to TLR at 12 months

There is a consensus of a higher rate of restenosis and poorer outcomes of percutaneous revascularization in diabetic patients than in non-diabetics. Additionally, the clinical consequences of stenting techniques for coronary bifurcation lesions in diabetic patients using 2nd-generation DES are not fully clarified.⁶

Additionally, DM was a more reliable independent predictor of all-cause mortality than lesion calcification one year after PCI.⁷

Therefore, in our study we investigated the efficacy of 2-stents versus 1-stent approach for bifurcation lesions in diabetic patients and in the era of second generation DESs.

A similar finding can be found in a recent meta-analysis conducted by Fujisaki et al.⁸ which incorporated 4041 patients who were undergoing coronary bifurcation stenting interventions and reported that For a bifurcation lesion, a two-stent strategy, particularly DK crush is significantly more effective than provisional stenting, as demonstrated by the a noteworthy decrease in MACE.

Thirteen randomized controlled trials were incorporated in this meta-analysis, eleven of them compared the 2-stent technique to the provisional technique.

In this meta-analysis, The detection rate for true bifurcation lesions was 3954% (3954 patients). 2392 patients (59%) underwent a 2-stent approach, and more than 99 percent of patients received DES of the recent generation. Moreover, there was insignificant difference between trials and non significant publication bias for any of the outcomes evaluated.⁸

Also in agreement with this study, the definition II trial, in which 35% of patients were diabetic.

In the Definition II trial, where a multicenter randomized trial with some criteria for complexity added to the lesion defined as definition criteria, Consistent with our research, it demonstrated that a planned 2-stent strategy reduced TLF at one year in patients with true bifurcated lesions whose increase in TVMI was the primary driver of TLF reduction compared to a provisional strategy.⁷

Also come in agreement with The DKCRUSH II trial, where DM was present in 20 % of patients.

The DKCRUSH II trial was the first to present enhanced clinical outcomes in true bifurcation lesions when provisional stenting was compared to the DK crush technique (two stents), as evidenced by a decreased TLR rate after a five-year follow-up period. In both the Definition II and The DKCRUSH II trials, the majority of patients were treated with the DK crush technique; thus, the majority of the evidence originates from trials in which patients were treated with the DK crush technique.⁹

In our study, 84% of patients in the two-stent group underwent DK crush, which is consistent with the findings of Zhang et al.⁷ and Chen et al.⁶

Previous trials showed that the DK-Crush technique improved the quality of the final KBI and resulted in a larger post-procedural mean luminal area of the SB, as compared to other dedicated techniques, including culotte and other crush techniques.¹⁰ It is hypothesized that the provisional stenting group experienced a higher rate of plaque shifting recoiling while the rate of restenosis in the SB is low. These differences may account for the DK crush technique's association with enhanced acute

gain and late loss of SB fractional flow reserve in comparison to provisional stenting.¹¹

Moreover, the current trial can be agreed by Zhizhong et al.¹² who studied diabetic patients with true bifurcation lesions and aimed to compare late angiographic results of one vs. two-stent implantation for coronary bifurcation lesions and did coronary angiography as a follow up after one year for detection of silent restenosis and found that 2-stent implantation was superior to 1-stent in the treatment of coronary bifurcation in diabetic patients, with silent restenosis occurring in 19.7% in the one-stent group and 4.9% in the two-stent group ($p = 0.003$).

Furthermore, Our findings are supported by Cha et al.⁶ who investigated the impact of bifurcation strategies utilizing second-generation DES on the long-term clinical results of individuals with diabetes. Their research revealed that DM was an independent predictor of TLF in non-LM lesions.

In the combined trial of BBC ONE and NORDIC, 75% of patients in the kissing balloon group achieved a successful procedure, compared to 94% in the two stent groups.^{13, 14}

Higher success rate of KBI in our study may explains higher rate of acute procedural success. Earlier studies have demonstrated that successful KBI is independently associated with better outcomes.¹⁵

This is consistent with Zhang et al.^{7,16} who found that acute procedural success in SB was more than 95% of cases in two groups (98.8% in the provisional group and 98.2% in the two stent group, patients with two stents had a FKBI of 99.3%).

Also, our finding agrees with Chen et al.⁹ in the DKCRUSH-II study, where procedural success (provisional >96%, DK crush 100%) and kissing balloon inflation (100% in two stents patients) were high.

In accordance with the findings of The European Bifurcation Coronary II (EBC II) Study compared provisional T-stenting with the 2-stent culotte technique in cases involving true bifurcation lesions using randomized comparisons, the results demonstrated that both approaches had a high rate of success (provisional 97%, culotte 94%, kissing balloon inflation 98%).^{16,17}

4. Conclusion

Our study discovered that a planned routine two-stent technique enhanced the clinical outcomes in diabetic patients with coronary bifurcation lesions after one year compared to a one-stent method.

Disclosure

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Authorship

All authors have a substantial contribution to the article

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Conflicts of interest

There are no conflicts of interest.

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