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Comparison between provisional Stenting and Two Stents Technique (DK-crush or Nano-crush) in Bifurcation Coronary Artery Lesions

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ORIGINAL ARTICLE

Comparison between provisional Stenting and Two Stents Technique (DK-crush or Nano-crush) in Bifurcation Coronary Artery Lesions

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Abstract

Background: ***A higher incidence of significant adverse cardiac events is linked to bifurcation lesions.***

Objectives: ***To evaluate the efficacy of provisional stents versus a planned 2-stent DK-crush or Nano-crush procedure in patients with distal LM bifurcation lesions. Compare the short- and long-term results of using two stent techniques with provisional stenting techniques in a hospital.***

Methods: ***150 patients were randomly assigned to two groups: group I (PS=75) and group II (2-stent DK=75) with lesions of the distal LM bifurcation. The first tactic, or provisional stenting procedure, involved stent placement in the (MB). The routine side branch stenting is the second (2 stent technique) strategy. Angiograms of the heart.***

Results: ***There were 18 females (24%) and 132 males (88%) in the study. Target lesion failure (TLF) was seen more frequently in group I compared to DK crush group II (5.3% vs. 0%; p=0.04), and stent thrombosis was observed at the 30-day follow-up. TLF occurred in 6 (8% of group one patients) in contrast to 2 (2.7%) of group two patients at the 6-month follow-up, with a significant difference between the two groups (p=0.028). Without a discernible difference, group I experienced higher rates of recurring anginal pain, stent thrombosis, target vessel MI, target lesion revascularization, and all-cause death.***

Conclusion: ***Regarding Target Lesion Failure (TLF) at the 6-month follow-up, the two-stent approach outperformed provisional stenting.***

Keywords: Bifurcation lesion; Provisional stenting; DK crush

1. Introduction

Lesions from coronary bifurcation might make up as much as 20% of total lesions with percutaneous coronary intervention (PCI).[1] Up to 70% of individuals who have been referred to bypass surgery, as well as other procedures, may have a distal left main artery.[2] Further consideration should be given due to the elevated frequency of unfavorable outcomes after therapy in this patient population.[3] A single-stent method and an upfront two-stent strategy have been examined in multiple trials. Asian data rekindle the argument about the best way to treat these lesions, favoring the double-kissing (DK) crush 2-stent approach over provisional stenting.[4]

2. Patients and methods

Study design: A prospective, non-randomized study conducted at Alazhar University Hospitals' Department of Cardiology. DES (drug-eluting stents) was used in two separate ways to implant stents in 150 patients who had real left main (LM) to electively manage stable individuals who have native bifurcation coronary artery lesions that occurred from scratch. Each patient gave written informed consent. The two groups (Group I, Provisional Stenting Technique) had half the patients. Inclusion criteria: The Medina categorization (type: 1, 1, 0) will be applied to stable patients aged <80 years or ˜18 years and who have de novo native coronary bifurcation lesions with main-vessel reference diameters of at least 2.5 mm and side-branch reference diameters of at least 2.25 mm.

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Exclusion criteria: 50% or more extraordinary occurrence of unguarded narrowing of the left ventricle, initial angioplasty for sudden blockage of blood flow in the heart due to ST-elevation myocardial infarction, heart failure caused by a weakened left ventricle, narrow diameters of side or main branches measuring less than 2.25 mm, conditions that make cardiac catheterization or just dual antiplatelet therapy unsuitable, moderate to severe kidney dysfunction with a creatinine clearance below 60 ml/min, liver disease, and severe heart valve disorders.

Patient population: The primary operators who participated in the study were mandated to have conducted at least 300 percutaneous coronary interventions (PCIs) annually for five years, with a minimum of 20 LM PCIs yearly. All patients had comprehensive history taking, 12-lead electrocardiography (ECG), and echocardiography. Two distinct methodologies for stent deployment utilizing drug-eluting stents (DES) were employed in the elective management of stable patients.

Coronary angiography: Group I utilized the provisional stenting approach, while Group II employed the two-stent procedure. The initial approach, known as the provisional stenting technique, entailed the insertion of a stent within the MB. The stenting of the SB was performed exclusively in cases where there was a decline in SB function, leading to a flow level below TIMI grade 3, electrocardiogram (ECG) alterations, or the presence of prolonged intraprocedural angina. The second strategy, known as the stent technique, involved the calculation of various parameters. These parameters included the location of the bifurcation, classification of the medina, angle of bifurcation, length of the lesion, The circumference of the reference vessel, as well as the minimal lumen diameters (MLD) prior to and during stenting, were measured. In addition, the calculated parameters included the percentage of diameter stenosis (%DS) in the MB and SB before and after the stent was implanted.

Technical analysis of DK-crush, Nano-crush, and other similar products: The DK-crush, which was first launched, has been further developed into the Nano- and DK-Crush by Colombo et al.[5] Afterwards, one kind of kissing balloon was used in both methods: Classical in Nano-Crush with a cuddle arrangement for the DK. TAP or traditional T usually causes the SB stent strut to float into the MB; this non-physiologic flow can result in turbulent flow and decreased wall shear stress, which may encourage thrombosis and restenosis inside the catheter.[6] The patient was monitored during their hospital stay and again one month and six months after their MACE treatment. Include mortality, heart attack, or emergent target vessel revascularization (TVR) falling under the hospital MACE classification during the hospitalization of the index patient. After six months, an additional angiography was planned, or earlier if angina continued throughout the monitoring period. At six months, myocardial infarction, cardiac death, and targeted vessel revascularization (TVR) were the primary endpoints or the mid-term MACE. Re-narrowing to a more than 50% diameter stenosis is known as instent restenosis. A thrombus that originates in the stent or the segment 5 mm proximal or distal to the stent, along with the presence of at least one of the following criteria during 48 hours, are considered definitive stent thrombosis (ST)—symptoms of acute ischemia, fresh ECG alterations, or periodic fluctuations in cardiac biomarkers. Acute cases occurred less than 24 hours after stent implantation, subacute cases occurred more than two hours to thirty days after stent implantation, and late cases occurred more than thirty days after stent implantation. Preprocedural aspirin medication and, if not receiving chronic dual antiplatelet therapy, a 300 mg loading dose of clopidogrel were administered to seven patients. Current guidelines were adhered to for the prescription of other medications, such as statins, B-blockers, and angiotensin-converting enzyme inhibitors.

Statistical analysis: The baseline attributes are presented either as the mean value plus or minus the standard deviation (SD) or in percentages and numbers. The methods were compared to the unpaired Student's t-test. A p-value below 0.05 signifies the threshold for statistical significance in all two-sided statistical tests. The analysis was conducted using IBM SPSS for MAC, namely version 23, a statistical package program.

3. Results

The study included 150 patients, 132 males (88%) and 18 females (24%). Patients with left main disease were diabetics 69(46%). Baseline demographic, clinical, laboratory, and echocardiographic features are displayed in Table 1

Table 1. Baseline Characteristics.

BASELINE CHARACTERISTICS OF STUDY PATIENTS	PROVISIONAL STENT N=75	2-STENT DK-CRUSH N=75	*P*-VALUE
AGE (YEARS) MEAN±SD	55.4267±10.05	55.68±11.70	0.8
(BMI) MEAN±SD	28.8±4.6	29.6± 3.20	0.21
MALE N	64(85.3%)	68(90.70%)	0.45
SMOKING N	47(62.7%)	44(58.7%)	0.45
DYSLIPIDEMIA N	37(49.3%)	34(45.3%)	0.71
DM N	33(44.0%)	36(48.0%)	0.81
HYPERTENSION N	36(48.0%)	40(53.3%)	0.62
PRIOR STROKE OR PVD	6(8.0%)	4(5.3%)	0.74
HEMOGLOBIN (G/DL)	14.1±2.7	13.8±3.4	0.29
TOTAL CHOLESTEROL (MG/DL)	196.3±46.2	191.15 ±66.5	0.61
TG (MG/DL)	183.56±69.2	181.72 ±49.3	0.43
CREATININE (MG/DL)	0.93±0.24	0.89 ±0.10	0.17
ECHOCARDIOGRAPHIC FINDINGS			
LVEDV	98.40±17.2	95.61±19.82	0.35
LVESV	42.50±9.67	41.72±8.46	0.62
EF	64.2±12.6	62.61±11.36	0.40
WMA SCORE INDEX	1.18±0.22	1.12±0.13	0.47

SD: BMI: Body Mass Index, Standard Deviation Mellitus diabetes (DM), peripheral vascular diseases (PVD), TG: Triglycerides, EF stands for Ejection Fraction, WMA for Wall Motion Score Index, LVEDV for Left Ventricular End Diastolic Volume, LVESV for Left Ventricular End Systolic Volume.

Table 2. Features of the Lesion.

	PROVISIONAL STENT N=75	2-STENT DK-CRUSH N=75	*P*-VALUE
MULTIVESSEL	65(86.7%)	68(90.7%)	0.32
DISEASE N%	43(57.30%)	46(61.30%)	0.49
LAD LESION N%	31(41.30%)	35(46.70%)	0.37
LCX LESION N%	40(53.30%)	38(50.70%)	0.61
RCA LESION N%			
SYNTAX SCORE	29.8±9.2	30.10±8.4	0.39
LM LESION			
LOCATION	2(2.70%)	3(4.0%)	0.74
OSTIAL	9(12.0%)	6(8.60%)	0.49
SHAFT	75(100%)	75(100%)	1.0
DISTAL LM	61(81.30%)	58(77.30%)	0.35
MEDINA 1,1,1	10(13.30%)	12(16.0%)	0.81
BIFURCATION	4(5.30%)	5(6.70%)	0.76
MEDINA 1,0 ,1			
BIFURCATION			
MEDINA 0,1 ,1			
BIFURCATION			
CALCIFICATION			
MAIN VESSEL	19(25.30%)	23(30.7%)	0.13
SIDE BRANCH	10(13.30%)	15(20.0%)	0.10
TIMI FLOW GRADE			
<3	17(22.70%)	15(20.0%)	0.61
MAIN VESSEL	7(9.30%)	5(6.70%)	0.54
SIDE BRANCH			
COMPLEX	21(28.0%)	27(36.0%)	0.13
BIFURCATION			

LCx stands for left circumflex artery; RCA stands for right coronary artery; LM stands for left main; DK stands for double kissing. Percutaneous Coronary Intervention With Taxus and Cardiac Surgery Working Together, or SYNTAX; Myocardial Infarction Thrombolysis (TIMI).

Table 3. procedural attributes.

	PROVISIONAL STENT N=75	2-STENT DK-CRUSH N=75	*P*-VALUE
TRANSFEMORAL	70(93.30%)	72(96.0%)	0.53
APPROACH N%	5(6.70%)	3(4.0%)	0.72
TRANSRADIAL	69(92.0%)	72(96.0%)	0.39
APPROACH N%			
7-F GUIDING	72(96.0%)	67(89.30%)	0.04
CATHETER USED N%	43(57.30%)	58(77.30%)	0.001
PRE-DILATION			
PERFORMED			
MAIN VESSEL N%			
SIDE BRANCH N%			
MAIN VESSEL STENT	1.54±0.42	1.48±0.51	0.58
TOTAL STENTS IN	112	118	0.76
MAIN VESSEL N	25.6±6.5	27.1±8.2	0.27
LM SEGMENT	45.9±15.3	47.1±14.8	0.49
LENGTH, MM	27(36.0%)	29(38.70%)	0.38
TOTAL MAIN VESSEL			
LENGTH, MM			
COVERED OSTIAL LM			
SIDE BRANCH STENT			
1 OR MORE STENTS	23(30.70%)	75(100%)	<0.001
IMPLANTED	22.6±7.4	23.6±9.2	0.73
LM SEGMENT	29.5±8.7	33.7±10.2	0.09
LENGTH, MM			
TOTAL SIDE BRANCH			
LENGTH, MM			
POT PERFORMED	73(97.3%)	75(100%)	0.12
FINAL KISSING	57(76.0%)	75(100%)	<0.001
INFLATION			
MAIN VESSEL	3.49±0.72	3.51±0.63	0.23
BALLOON DIAMETER,	13.8±4.5	14.3±4.3	0.59
MM			
INFLATION	2.6±0.40	3.1±0.53	0.01
PRESSURE, ATM	11.2±3.4	13.8±2.9	0.03
SIDE BRANCH			
BALLOON DIAMETER,			
MM			
INFLATION			
PRESSURE, ATM			
FINAL TIMI FLOW			
GRADE 3	75(100%)	75(100%)	1.0
MAIN VESSEL	73(97.30%)	75(100%)	0.47
SIDE BRANCH			
COMPLETE	57(76.0%)	55(73.30%)	0.51
REVASCULARIZATION			
PROCEDURAL TIME,	52.5±21.3	68.30±24.6	<0.001
MIN	150±55.8	175±61.4	<0.001
CONTRAST VOLUME,			
ML			

DK: double kissing; LAD: left anterior descending coronary, artery; LM: left main; SYNTAX: Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery; TIMI: Thrombolysis in Myocardial Infarction.

In table 3: Provisional Stent patients more than 2-stent DK-crush group with significant difference between both groups. But for Pre-dilation performed in the side branch vessel was done more in 2-stent DK-crush patients with significant difference between both groups. Side branch stent with one or more stent implantation in group two was more frequent than in group one with highly significant statistical difference. Mean procedural time and contrast volume (52.5±21.3 and 150±55.8 versus 68.30±24.6 and 175±61.4 respectively) were more in group II than group I with highly significant statistical difference ($p<0.001$).

Table 4. 6-months follow-up.

	PROVISIONAL STENT N=75	2-STENT DK-CRUSH N=75	*P*-VALUE
TLF N%	4(5.3%)	0(0 %)	0.043
STENT THROMBOSIS	1(1.3%)	2(2.7%)	0.29
DEFINITE N%	1(1.3%)	1(1.30%)	1.0
PROBABLE N%	0(0%)	1(1.30%)	0.45
TARGET VESSEL MI	1(1.30%)	0(0%)	0.31
PERIPROCEDURAL N%	1(1.30%)	0(0%)	0.31
NON-	0(0%)	0(0%)	1.0
PERIPROCEDURAL N%	1(1.30%)	0(0%)	0.45
TARGET LESION			
REVASCULARIZATION			
6 MONTHS FOLLOW-			
UP	8(10.7%)	6(8.0%)	0.32
RECURRENT ANGINAL	6(8.0%)	2(2.7%)	0.028
PAIN	2(2.70%)	3(4.0%)	0.63
TARGET LESION	2(2.70%)	1(1.30%)	0.27
FAILURE N%	3(4.0%)	2(2.70%)	0.65
STENT THROMBOSIS	2(2.70%)	1	0.29
N%		(1.30%)	
TARGET VESSEL MI			
TARGET LESION			
REVASCULARIZATION			

ALL-CAUSE DEATH |

TLF: Target lesion failure; MI: myocardial infarction

In Table 4 : At six months, all patients had completed their clinical follow-up. TLF had happened in group one more often than in DK crush group two at the 30-day follow-up (5.3% vs. 0%; p=0.04). TLF occurred in 6 (8% of group one patients) compared to 2 (2.7%) of group two patients at the 6-month follow-up, with a significant difference between the two groups (p=0.028). Group one experienced higher rates of recurrent anginal pain, stent thrombosis, target vessel MI, target lesion revascularization, and all-cause death, However, there was no discernible difference that reached statistical significance.

4. Discussion

The most significant results in our study, Mean procedural time and contrast volume (52.5±21.3 and 150±55.8 versus 68.30±24.6 and 175±61.4 respectively), were more in group II than group I with highly statistically significant difference observed (p<0.001).[7] The results of the provisional stenting technique suggest that it offers enhanced safety benefits, including reduced operation and fluoroscopy durations and lower contrast volumes. The findings of our investigation were consistent with the results published in the reported literature on the Nordic trial.[8] Unlike the simple method, the complex stenting group in this trial had considerably longer procedure and fluoroscopy times, larger contrast volumes, and a higher rate of process-related elevations in myocardial damage biomarker levels. Following up with all patients for six months, the study's outcome was complete. TLF had been more common in group I at the 30-day follow-up than in group II (DK crush, 5.3% vs. 0%; p=0.04). At the 6-month follow-up, there was a significant difference between the two groups (p=0.028), with TLF occurring in 6 (8%) of group I patients against 2 (2.7%) of group II. Compared to a PS approach, Chen et al. found that the DK crush stenting technique produced better angiographic and clinical follow-up outcomes due to its complexity and increased upfront procedural time and contrast. This difference was statistically significant.[9] Similarly, patients with complex bifurcation lesions were randomized in the DEFINITION II trial to a systematic two-stent approach (n = 328) or provisional stenting (n = 325). The results showed that the two-stent approach was associated with a lower TLF (11.4% vs. 6.1%, p = 0.019), primarily because of target vessel MI and clinically driven target lesion repair.[10] The results of our analysis were consistent with the CACTUS trial[11], It involved randomly assigning 350 patients with actual bifurcation lesions to receive either a simple or sophisticated stenting procedure, requiring the last kissing-balloon inflation. The principal clinical result in the straightforward stenting approach was rates of (MACE) at six months. The incidence of serious adverse cardiac events did not significantly differ between the two groups (15.8% in the complex group vs. 15.8% in the simple group, P=NS). Our results corroborated those of the Nordic study.[12] major adverse cardiac event rates at 6-month follow-up did not significantly differ between the two groups (2.9% in the provisional group vs. 3.4% in the complex group; P=NS). Our study's findings were consistent with those published in Yamashita et al.,[13]. The primary branch was stented using the straightforward approach, whereas the side branch underwent balloon angioplasty. The sophisticated method involved the stenting of both the main branch and the side branch. No statistically significant disparity was observed in the occurrence of 6-month total MACE between the two groups, with the simple group reporting a rate of 38% and the complex group reporting a rate of 51%. Our study's findings were consistent with those published in Brar et al.,[14] They released the following meta-analysis of six RCTs evaluating two distinct approaches to the use of drug-eluting stents in the treatment of coronary bifurcation lesions: When comparing the complex strategy to the simple strategy, the complex group had mid-term mortality (0.82 vs. 0.82% in the simple group, P=NS) and TVR (5.45% vs. 5.22%, P=NS), but the simple group had a significantly higher risk of myocardial infarction and an increased incidence of stent thrombosis (P=0.17). In the study of Gao et al., The major branches and side branches were both stented using a two-stent technique. MACE rates went higher in the complicated group compared to the simple one, with acute myocardial infarction accounting for the majority of the rise (4.5% vs. 1.4%; p=0.032) as opposed to mortality MB and TLR (0% vs. 0.5%, p=0.389; 1.4 vs. 2.7%, p=0.352). The complex group had a greater rate of stent thrombosis than the basic group (p=0.042).[15] The results of our investigation regarding mortality, MI, and TLR can be attributed to the small patient population and brief duration of follow-up. The results of long-term follow-up vary, as indicated by Ford et al. The long-term results (> one year) are assessed based on the treatment approach for coronary bifurcation lesions. Their findings indicate that performing Coronary bifurcation percutaneous coronary intervention with a provisional single stent method is linked to a decrease in overall death rates over the long-term follow-up period.[16] A comprehensive meta-analysis of randomized controlled trials (RCTs)

revealed a notable rise in overall mortality among patients who were randomly assigned to extended DAPT (odds ratio: 1.30; 95% CI, 1.02–1.66; P=0.03).[17] Park et al. According to experts, it is recommended to use a 2-stent strategy for treating lesions in the left main coronary artery (LMCA) that involve the left circumflex artery (LCx) and have a Medina classification of 1,1,1 or 1,0,1 or 0,1,1. This strategy is particularly suitable for cases where the LCx has a large diameter of 2.5 mm, the patient has a diseased left dominant coronary system, there is a narrow-angle between the left anterior descending artery (LAD) and LCx, and there is also diffuse disease occurring in the LCx.[18] The DK crush technique was found to have a better clinical outcome compared to a provisional stent in the previously reported DKCRUSH-V trial, specifically in situations where there are actual bifurcation lesions that fall within the Medina diagnostic categories of 1,1,1 and 0,1,1.[19] Overall data indicated that while a 2-stent technique performed better in severe instances of pre-intervention SB DS, a 1-stent strategy had an improved clinical outcome overall. This was revealed by Rab et al. More details on the best course of action for treating LMCA bifurcation lesions will be provided by the ongoing EBC MAIN trial (European Bifurcation Club Left Main trial) RCT, which compares one against two stents (DK crush or culotte).[20]

Limitations: The limited number of patients, the single-center study, and short-term follow-up could limit the incidence of MACE over a longer period.

4. Conclusion

Regarding Target Lesion Failure, the two-stent approach demonstrated superiority over provisional stenting. Implementing the double kissing crush, the 2-stent technique resulted in a 7-month reduction in Target Lesion Failure. The DK crush technique demonstrates superiority over the PS in complex bifurcation lesions. Despite MACE, revascularization rates were more frequent in the provisional stenting group but without any significant statistical difference. So, the two techniques used were equal in terms of clinical outcome. Although new studies propose a 2-stent approach for treating coronary bifurcation lesions, it is essential to note that there is no universally applicable solution.

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