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ORIGINAL ARTICLE

Provisional Vs Dual Stenting of Left Main Coronary Artery Bifurcation Lesions

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ABSTRACT

Background: The primary LMCA stenting methods used nowadays consist of single stent (provisional), and two stent (T and protrusion, and double kissing crush {DK crush}, culotte, or classic crush). The optimal technique for bifurcation lesion treatment for the patients present with distal ULMCA disease is still unclear and not much is known about the best course of action and the clinical outcomes following various PCI techniques for ULMCA bifurcations in Pakistan.

Objective: To investigate the midterm (3-year) outcomes related to the provisional stenting compared to two-stenting technique for the bifurcations of ULMCA undergoing the percutaneous coronary intervention.

Methodology: A single-center retrospective, non-randomized cohort study was conducted during the period from March 2021 to August 2022 including all the consecutive LM bifurcation lesions. The patients attending Punjab Institute of Cardiology, Lahore were divided into two groups, depending upon the treatment received. One group underwent PCI with provisional stenting technique while the other underwent 2-stent PCI. The groups were compared for procedural success and 3-year clinical outcomes. Data was analyzed using SPSS.

Results: The success rate of left main bifurcation angiography was comparable between both the techniques (2-stent 93.6 % vs. Provisional 92.1 %, P = 0.62). MACE rates were comparable between groups at 1, 2, and 3 years (PS 3.0 % vs. Dual stent 2.4 %, p = 0.75 at 1-year, PS 4.8 % vs. Dual stent 8 %, p = 0.26 at 2-years, and PS 10.2 % vs. Dual stent 12 % at 3-years, p = 0.62).

Conclusion: Two stenting strategy was linked to same rates of MACEs at the 3-year duration in comparison to the single stenting technique (PS 10.2 % vs. 2-Stent 12 %, p=0.62) and both the dual and single provisional stent techniques have comparable angiographic success rate for LM bifurcation lesions.

INTRODUCTION

Prognosis is ominously affected by the unprotected left main coronary artery (ULMCA) significant stenosis.[1] The process of surgical revascularization (CABG) has remained treatment of choice for numerous years, recently collected evidence via randomized controlled trials (RCTs) indicates commensurable results between percutaneous coronary intervention (PCI) along with drug eluting stents (DES) and CABG with regards to stroke for duration of up to five years, death, and myocardial infarction.[2-4] Nevertheless, the larger number of stenosis involve distal bifurcations of ULMCA that are related to an increase of complexity in the procedure with comparison to midshaft lesions and ostial shaft lesions.[5] additionally, true bifurcations in distal ULMCA are linked to increased rates of revascularization of the target lesion (TLR).[6]

The primary LMCA stenting methods used nowadays consist of single stent (provisional), and two stent (T and protrusion, and double kissing crush {DK crush}, culotte, or classic crush).[7,8] Interventional cardiologist face the dire situation of choosing between 2-stent technique compared to the provisional stenting technique. Even though studies conducted previously[9] and a recent meta-analysis[10] have shown the edge that provincial stenting has compared to 2 stenting approaches, a multicenter randomized control trial compared provisional stenting and double kissing crush stenting for the left main distal bifurcation lesions and noted that target lesion failure (TLF) rates were increased in the provisional stenting along with occurrence of stent thrombosis.[11] Still another randomized study (European Bifurcation Coronary TWO), which made comparison of systematic culotte stenting with provisional stenting for the non-ULMCA true bifurcations and noted that outcomes were comparable at one year duration.[12] The optimal technique for bifurcation lesion treatment for the patients present with distal ULMCA disease is still unclear and not much is known about the best course of action and the clinical outcomes following various PCI techniques for ULMCA bifurcations in our setting and in Pakistan overall. Thus, this study aims to investigate the midterm (3-year) outcomes related to the provisional stenting compared to two-stenting technique for the bifurcations of ULMCA undergoing the percutaneous coronary intervention from registry of a single center.

MATERIAL AND METHODS

Study Population: This is a single-center retrospective, non-randomized cohort study which includes all of the patients present with distal unprotected LMCA we have been treated using the DES in Punjab Institute of Cardiology Lahore. Consecutive patients who were present with ULM, treated from the duration of March 2021 to August 2022 were made part of the study. Patients present with 50% stenosis in the left main that involves both the left main along with the origin of one of arteries which stems from left main artery were made part of the study and their division was done into two study groups: patients who are treated by the provisional stenting (PS) and patients who were treated by the two-stenting technique. For this study, the exclusion criteria consisted of percutaneous coronary intervention for the ostial lesions or the body lesions, non-true bifurcations of unprotected left main coronary artery, cardiogenic shock, and acute myocardial infarction.

Procedural Details: The decision regarding the unprotected left main percutaneous coronary intervention was taken on the basis of consultation of surgeons as well as patients in situations arising due to refusal of patient for the surgery or in situations where comorbidity existed presenting elevated surgical risk. The decision regarding choosing either two stenting technique or provisional stenting technique was completely under the discretion of operators. Provisional stenting technique means crossover stent technique either with side branch balloon angioplasty or without it. Dual stenting techniques include the classical crush or double kissing crush, culotte, T stenting, and simultaneous kissing stent (SKS) or V stenting (VS). In cases where angiography or intravascular ultrasound (IVUS) revealed suboptimal expansion of stent, a noncompliant balloon was used to carry out post dilation.

Prior to the procedure, every patient was provided with 300 milligram of aspirin regularly along with 300 milligram of clopidogrel as a loading dose one day prior to procedure. Intraprocedural unfractionated heparin 100 unit per every kg of the patient was administrated to every patient, and glycoprotein IIIa and

glycoprotein IIb usage was subjected to operators discretion. Prescription of 300 milligram of aspirin regularly for the duration of three months was done postoperatively followed by 100 milligram of aspirin on the regular basis for a lifetime; 75 milligram of clopidogrel was prescribed for a minimum of one year.

Study Definitions: Classification of the ULMCA lesions was done visually at every center as per Medina classification [16]. True bifurcation lesions were demonstrated as the Medina class 1-0-1, 0-1-1, or 1-1-1.[13] major adverse cardiovascular events (MACEs) consisted of overall revascularization of target lesion, all resulted deaths, and myocardial infarction. General TLR was defined as repeating CABG or PCI for the lesion of ULMCA which was previously stented including segments of distal or proximal edges of stent, or at side branches (SBs) ostium. Moreover, evaluation of the TLR of the LCX (LCX-TLR), left main stem (LM-TLR), and LAD (LAD-TLR) was done separately. Occurring deaths were contributed to cardiac origins unless otherwise obviously identified as occurring due to non-cardiac reasons. Myocardial infarction was identified as per Third Universal Definition of Myocardial Infarction.[14] Classification of stent thrombosis (ST) was done as per the definitions of Academic Research Consortium (ARC).[15]

Data Collection: All the procedural or clinical data was extracted from hospital registry. Clinical data for the follow up duration was collected via telephonic contacts or patient visits to the hospital.

Collection of the angiographic data was done following the examination of the coronary angiographies via minimum of 2 physicians, and angiographic laboratory calculated the SYNTAX score of every patient independently. As per the recommendations, determination of total score for every patient was done by addition of score for every individual segment of disease which is defined as segments where there is ≥ 50% stenosis occurrence in the vessels that are ≥ 1.5 mm in diameter.[16]

Study endpoints and follow-up: Angiographic success was the primary endpoint for the current study whereas MACE rate at the duration of three years and every component of it including probable or definite ST, cardiac death, TLR, and MI were secondary endpoints.

Angiographic success was defined as residual stenosis of <30% and the presence of TIMI flow grade 3.

Occurrence of MI, target vessel revascularization, death, stent thrombosis, and MI were confirmed during hospitalization of the patients, at the duration of 6 months and the 1-year interval following the procedure and then at an annual rate for the duration of 3 years.

Statistical Analysis: Mean ± standard deviation (SD) are used to present the continuous variables. Student T test was used to calculate the difference in the continuous variables among groups. Fisher's exact test or the chi-square test was used for the comparison of the categorical data. Analysis for the outcome were done with intention of treating the population, with no regards to the received treatment. Every statistical test was a 2-sided test and the p value of <0.05 was taken as statistically significant. SPSS v 24.0 was used for performing all the analysis.

RESULTS

Baseline characteristics: Amongst a total of 970 patients in this registry, ostial/body lesions (n = 150), non-true ULMCA bifurcations (n = 446), and acute myocardial infarction or cardiogenic shock (n = 83) for ULMCA bifurcations were excluded. 291 patients (30 %) were included in the final analysis (166 patients in the PS, and 125 patients in the dual stent group). The mean follow-up period was 927 ± 33. Between the two groups, patient baseline characteristics were equivalent (Table 1).

Table 1: Baseline and clinical features of the patients

Baseline features	Provisional stent (n = 166)	Dual stent (n = 125)	p-value
Age	56.8 ± 9.9	57.4 ± 10.4	0.61
Gender			0.75
Male	129 (77.7 %)	99 (79.2 %)	
Female	37 (22.3 %)	26 (20.8 %)	
Comorbidities			
Diabetes	76 (45.7 %)	48 (38.4 %)	0.21
Hypertension	139 (83.7 %)	98 (78.4 %)	0.25
Smoking	53 (31.9 %)	37 (29.6 %)	0.67
Dyslipidemia	116 (69.9 %)	83 (66.4 %)	0.52
Previous MI	62 (37.3 %)	35 (28 %)	0.09
Family history of CAD	22 (13.3 %)	16 (12.8 %)	0.90
Previous stroke	10 (6.02 %)	10 (8 %)	0.50
Chronic pulmonary disease	5 (3 %)	4 (3.2 %)	0.92
Chronic kidney disease (eGFR < 60 ml/min/1.73 m^2)	81 (48.8 %)	59 (47.2 %)	0.78
Clinical presentation			0.85
Stable angina	126 (75.9 %)	96 (76.8 %)	
Unstable angina	40 (24.1 %)	29 (23.2 %)	
LVEF (%)	56.0 ± 11.9	55.9 ± 10.9	0.94

Lesion and procedural characteristics are given in table 2. SYNTAX score higher in dual stent group (26 ± 5.4 vs 23 ± 7.2, p = 0.0001). A true Medina 1,1,1 bifurcation made up the majority of distal ULM lesions. (Medina 1,1,1; PS 73.5 % vs. 2-stent 72.8 %, p = 0.41).

Table 2: Lesion and procedural characteristics of the patients

Characteristics	Provisional stent (n = 166)	Dual stent (n = 125)	p-value
Vessel involved			
LAD	146 (87.9 %)	105 (84 %)	0.34
LCX	144 (86.7 %)	106 (84.8 %)	0.64
RCA	127 (76.5 %)	103 (82.4 %)	0.22
Triple vessel disease	104 (62.6 %)	83 (66.4 %)	0.50
SYNTAX score	23 ± 7.2	26 ± 5.4	0.0001
Two-stent technique			
Crush	-	59 (47.2 %)	-
Culotte	-	41 (32.8 %)	-
T	-	18 (14.4 %)	-
V	-	7 (5.6 %)	-
Medina classification			0.41
0,1,1	18 (10.8 %)	19 (15.2 %)	
1,0,1	26 (15.6 %)	15 (12 %)	
1,1,1	122 (73.5 %)	91 (72.8%)	

Study outcomes are enlisted in table 3. The success rate of left main bifurcation angiography was comparable between both the techniques (2-stent 93.6 % vs. Provisional 92.1 %, P = 0.62). MACE rates were comparable between groups at 1, 2, and 3 years (PS 3.0 % vs. Dual stent 2.4 %, p = 0.75 at 1-year, PS 4.8 % vs. Dual stent 8 %, p = 0.26 at 2-years, and PS 10.2 % vs. Dual stent 12 % at 3-years, p = 0.62). None of the other clinical outcomes showed a significant difference, either.

Table 3: Clinical outcome of the patients

Outcome	Provisional stent (n = 166)	Dual stent (n = 125)	p-value
1-year follow up			
MACE	5 (3.0 %)	3 (2.4 %)	0.75
Death	1 (0.6 %)	1 (0.8 %)	0.83
MI	3 (1.8 %)	2 (1.6 %)	0.89
TLR	0 (0 %)	1 (0.8 %)	0.24
Definite or probable ST	1 (0.6 %)	0 (0 %)	0.38
2-year follow up			
MACE	8 (4.8 %)	10 (8 %)	0.26
Death	2 (1.2 %)	3 (2.4 %)	0.43
MI	5 (3.0 %)	4 (3.2 %)	0.92
TLR	2 (1.2 %)	4 (3.2 %)	0.23
Definite or probable ST	1 (0.6 %)	2 (1.6 %)	0.40
3-year follow up			
MACE	17 (10.2 %)	15 (12 %)	0.62
Death	5 (3.0 %)	6 (4.8 %)	0.42
MI	7 (4.2 %)	5 (4 %)	0.93
TLR	8 (4.8 %)	7 (5.6 %)	0.76
Definite or probable ST	4 (2.41 %)	3 (2.4 %)	0.99

DISCUSSION

In the current study, we noted both systematic two stenting approaches and the stepwise provisional approach as potent stent treatment options for bifurcation lesion of true left stem with low

rates of adverse events in a 3-year period. The principal findings of the current study are: (1) provisional stent technique and two stent technique both were similar in terms of success rate of the procedure for the distal UPLM lesions; and (2) in comparison with the provisional stent technique, implantation of two stent showed similarity in the late outcomes.

Distal unprotected left main CA lesions are linked to poor prognosis as two primary ostial lesions are involved in such lesions in the descending left anterior arteries and the left circumflex artery, [17,18] presenting CABG the choice of treatment. With DES being introduced along with latest adjuvant medications such as antiplatelet agents, glycoprotein IIIa inhibitors and glycoprotein IIb inhibitors, statins, and clopidogrel and the latest devices particularly IVUS guidance, DES stenting has been performed increasingly via interventional cardiologists with appropriate experience for patients suffering from ULMCA disease. PCI has been demonstrated as a safe option for the patients suffering form ULMCA, presenting only low-intermediate risk.[19]

In spite of the new treatment modalities being developed, most suitable stenting technique for distal unprotected left main CA disease is yet under debate,[10] and studies which compare one-stent technique with the two-stent technique for the UPLM bifurcation disease in Pakistan are lacking. The baseline characteristics of present study patients did not differ significantly between the groups and were find consistent with the findings of Kawamoto et al.[20] with older age patients predominantly being males. Hypertension was found to be the most common comorbidity in both the groups.

Previously conducted observational studies which compare the aforementioned strategies for the treatment of distal UPLM provided conflicting results, most of them favored the provisional stenting technique owing to the superior clinical outcomes in the long term and ease in performing.[21-23] Nonetheless, as these are RCTs, using two stent technique might indicate high disease severity and subsequently a difficult treatment and thus consequently related to worse outcomes. Furthermore, these studies had shorter sample size and shorter follow-up periods. As far as our knowledge is concerned, the current study demonstrates biggest survey of the percutaneous coronary intervention for the distal UPLM disease and compares provisional stent technique and the two stenting technique from Pakistan, with results comparable to the findings of recently done large-scale studies.[20,24] The results acquired by the current study are in accordance with the results of FAILS-2 sub-study[20] which revealed that two stenting technique is linked to the same MACE rate at the duration of 3 years upon comparison with single stenting technique (PS 28.1% vs. E2S 28.9%, p = 0.99). Similarly, Gao et al.[24] also concluded that patients suffering from distal UPLM disease and those whose SYNTAX score was low to intermediate treated with the DES strategy had similar clinical outcomes among the optimal dual stent strategy and single stent implantation. Contrarily, the recently conducted DKCRUSH-V trial[11] establishes that by using a planned DKCRUSH dual stenting technique, both ST and TLF saw a reduction in a 3 year duration follow up in comparison to the provisional stenting technique in the patients suffering from true distal left main bifurcation lesions. There is need of more single centre and multi-centre randomized studies to verify the findings of the current study as well as for the assessment of the MACE patterns in the population of Pakistan who underwent PCI with provisional stenting in comparison to two stenting for treatment of left main bifurcation lesions.

CONCLUSION

Two stenting strategy was linked to same rates of MACEs at the 3-year duration in comparison to the single stenting technique (PS 10.2 % vs. 2-Stent 12 %, p = 0.62) and both the dual and single provisional stent techniques have comparable angiographic success rate for LM bifurcation lesions.

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