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Original Article

Left Main Coronary Artery Bifurcation Lesions: Two Stents vs One Stent Strategy-Comparison of Major Adverse Cardiac Events (MACE) at 2 years

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ABSTRACT

Objective: To evaluate the long-term clinical results for a one-stent (1S) strategy compared to a two-stent (2S) strategy in distal unprotected left main coronary artery (ULMCA) bifurcation disease.

Study Design: Comparative Cross-sectional study.

Place and Duration of Study: Armed Forces Institute of Cardiology, Rawalpindi Pakistan, from Jan 2019 to Apr 2020.

Methodology: 1-S approach was defined as stenting of the main vessel only and 2-S approach as stenting side branch and main vessel. Individual undergoing LMCA intervention were included via consecutive sampling in the study. Stent Crossover approach was used in 1-S technique; whereas, DK crush, culotte, and T-stenting approaches were employed in individuals who were treated with a 2-S approach. A composite of major adverse cardiovascular event (MACE) i.e., myocardial infarction, stroke or death and target lesion revascularization (TLR) were considered as primary end-point.

Results: A sum of 110 individuals were inducted, 74 of them had stenting of left main bifurcation using a 1-S approach; and 36 patients underwent a 2-S PCI. Average age of the patients included in the study was 63.9±10.8 years. In 1 stent subset, the success rate of procedure was 99% whereas 100% success rate was seen in 2-S group. During the 2-year duration of follow up, frequency of MACE in single stent subset was (5.4%) whereas it was (13.8%, p=0.253) in the 2-S subset.

Conclusion: When compared to 2-S approach of distal left main stenting, a 1-S strategy appears to demonstrate optimal clinical results and 2-year survival free of MACE. Choosing appropriate interventional strategy has proven prognostically significant; so, it demands mindful approach selection.

Keywords: Major adverse cardiovascular events, One-stent, Percutaneous coronary intervention, Two-stent, Unprotected left main coronary artery.

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INTRODUCTION

Left main coronary artery (LMCA) disease is considered very challenging and posing the highest risk primarily because around 70% of the myocardium is threatened and hence is linked to high mortality and morbidity and carries worst prognosis as compared to other forms of coronary artery disease.[1] Conventionally, CABG was considered as the gold standard method of revascularization in left main stem disease, given its proven mortality benefit and good long term results but with advancements in interventional cardiology and availability of advanced intracoronary imaging techniques, percutaneous intervention is being increasingly practiced.[2] Distal left main stem intervention is more difficult due to increased anatomical complexity with high chances of plaque shift.[3] Several randomized clinical trials have shown comparable clinical results with CABG as well as PCI for distal left main bifurcation lesions.[4-7] When it comes to PCI of unprotected distal left main stem, despite all advancements, it still represents a technical challenge and associated with relatively worse outcomes.[8] The question remains whether a single stent provisional strategy, which is usually considered the default strategy when it comes to bifurcation lesions, is better or a planned two stent strategy is linked to better clinical plus angiographic outcomes. Several studies have been done revealing the superiority of single stent strategy over 2 stent strategy in PCI of distal left main stem lesions as regards MACE and target lesion revascularization (TLR).[9] Various studies have shown comparable results in terms of MACE using both single and double stent strategies.[10] DKCRUSH-V randomized trial demonstrated that a planned double stent approach carries superiority over single stent technique in Medina 1,1,1 bifurcation lesions involving unprotected distal left main stem. Thus we see variable results when it comes to intervention of distal left main bifurcation and the optimal strategy chosen is usually

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based on operator preference. This study intends to compare MACE in patients with distal left main bifurcation disease intervened upon using a one or 2 stent technique.

METHODOLOGY

This comparative cross-sectional study was carried out at Department of Cardiology, Armed Forces Institute of Cardiology/ National Institute of Heart Disease (AFIC/NIHD), Rawalpindi Pakistan (IERB letter # 9/2/R&D/2022/167). using descriptive comparative method. Individuals planned for ULMCA PCI were inducted consecutively, from January 2019 to April 2019 and were followed up after 2 years. Distal left main disease was identified on angiogram.

Sample Size: With reference to 9% prevalence of LMCA disease the sample size calculated was n=126 at 95% CI and 5% margin of error by using WHO calculator.

Inclusion Criteria: The criterion for inclusion was individuals having ULMCA bifurcation lesion on coronary angiogram; patients with optimal anatomy favorable for PCI described as less than moderate calcification, favorable angle, minimum discrepancy in diameters of main branch, side vessel and proximal artery, individuals refusing bypass even after detailed discussion and individuals having Euro Score >5%. **Exclusion Criteria:** Those having disease at ostium or shaft and those unable to tolerate aspirin/P2Y12 Inhibitor treatment were excluded.

Each recruited individual had his baseline tests done that included complete blood counts, liver and kidney profile along with troponins, an ECG, chest X-ray and 2D echocardiography. Assessment of co morbids hypertension, diabetes, dyslipidemias and tobacco use was carried out. Coronary Angiographies were seen and SYNTAX scoring was done. Individuals having higher SYNTAX got inducted only if surgery was denied or did not meet fitness criteria for CABG.

PCI was performed using mostly a 7 Fr sheath via either radial or femoral route. Intravascular Ultrasound (IVUS) was utilized in highly calcific lesions and cases where the angle was narrow between main vessel and side branch. (n=74 for 1S and n=36 for 2S). Either single stent or dual stent strategy was used, mainly based on operators preference keeping in view individual patients angiographic characteristics. Two stent techniques were chosen when LCX diameter was more than 2.5mm, angle between LCX and LAD was less than 60° with adjunctive diffuse disease in LCX. 1S approach was preferred when mild ostial lesion of LCX was observed, LCX diameter less than 2.5mm, angle of more than 60° between LAD and LCX. Medina Classification was used to categorize the bifurcation lesions. It describes true bifurcation lesions as 1,1,1; 1,0,1; 0,1,1. 11A 1S strategy or provisional stenting technique was demonstrated as a stent crossover method usually from LMCA to LAD with a second guide wire placed in left circumflex (LCX). Stent strut reopening followed by KBI was performed if after cross over, side branch developed slow flow or LCX ostium demonstrated stenosis of more than 75%.

The 2S approaches mainly used in this research were DK crush and culotte, and occasionally other approaches like, T stenting were employed. When there was a disparity in diameters of LAD and LCX, DK crush was given preference, otherwise Culotte technique was used.

Most stent placements were done at high pressures. Final serial KBI's were performed in 100% cases in 2S approach but in 1S technique it was performed only where stent struts were reopened (n=12). Moreover, POT was done in every patient managed via two stent technique, then REPOT was done. POT was performed in in 46 individuals treated via one stent technique.

After stenting, Dual antiplatelet therapy with aspirin and clopidogrel were prescribed for a standard period of 12 months and were switched to single antiplatelet after 12 months if indicated. Telephonic correspondence and hospital visits at one-and six-month post-PCI and later at 2 years were made to check upon patients and were asked about development of MACE.

The intervention was considered a success, if post procedure TIMI III flow with 50% reduction of the stenosis was seen on quantitative coronary analysis. Academic Research Consortium (ARC) definitions of MI and stent thrombosis were employed. TLR was described as a second intervention performed on reoccurrence of disease in stent.

Data analysis was done using SPSS 16.0 (SPSS Inc, Chicago, IL). Qualitative variables were demonstrated as Frequencies and percentages. Association between qualitative variables was checked via Chi-square/ Fisher Exact test. Means ± standard deviation (SD) was used to depict normally distributed continuous data and were compared employing independent sample t tests. The statistical significance was determined by a *p*-value of <0.05.

RESULTS

A sum of 110 patients underwent percutaneous coronary intervention for distal LMCA lesions. 74(67.3%) of individuals had 1S technique employed; while 36(32.7%) individuals were managed using a 2S technique. The clinical features of individuals of both categories are demonstrated in Table-I.

Table I: Clinical Features of patients in Single Stent and Double Stent Group (n=110)

Clinical Features		Single Stent Group, n=74	Double Stent Group, n=36	*p*-value
Age in years (Mean±SD)		67.3±10.8	32.7±10.0	0.289
Gender	Male	58(78.3)	32(88.8)	0.140
	Female	16(21.6)	4(11.1)	
Diabetes mellitus	Diabetics	36(48.6)	17(47.2)	0.525
	Non Diabetics	38(51.3)	19(52.7)	
Hypertension	Hypertensive	33(44.5)	16(44.4)	0.576
	Non hypertensive	41(55.4)	20 (55.5)	
Smoking	Active smokers	10(13.5)	8(22.2)	0.481
	Non smokers	34(45.9)	16(44.4)	
	Ex-smokers	30(40.5)	12(33.3)	
CKD	CrCl<30	2(2.7)	3(8.3)	0.318
	CrCl 30-50	17(22.9)	10(27.7)	
	CrCl >50	55(74.3)	23(63.8)	
LV ejection fraction	<35%	4(5.4)	5(13.8)	0.211
	35-45%	15(20.2)	11(30.5)	
	>45%	23(31.0)	9(25)	
Presentation	Acute coronary syndrome	30(40.5)	17(47.2)	0.322
	Stable Angina	44(59.4)	19(52.8)	

The procedural and angiographic features of the LMCA PCI subsets are shown in Table-II.

Cross over stenting was utilized in the 1S subset with 83.7% (n=62). Patients in 2S group were mostly treated Cross-over (50%, n=18), followed by cross-over with KBI (27.8%, n=10) and DK crush (11.1%, n=4). IVUS was used in 10.8% (n=8) of 1S subset and 27.8% (n=10) of 2S group. POT done in 62.1% (n=46) patients of 1S group and all 100% (n=36) cases of 2S group.

The clinical results after procedure covering the two year period revealed that mortality observed in the 1S subset was 4.0% (n=3) in comparison to 13.1% (n=5) in the 2S subset (p= 0.04), whereas total MACE that included mortality and TLR was 5.6%(n=2) in single stent group and none in double stent group . 1 (1.35%) case treated with 1S approach died during hospital stay. Patient had calcific vessel and suffered from vessel perforation Ellis type III though covered stent was put in and there was no tamponade, patient did not make it. 1 (2.8%) patient of 2S group experienced in hospital death, had concomitant end stage renal disease, severe left ventricular dysfunction and high SYNTAX. 2 (2.7%) cases managed with 1S approach developed angina recurrence compared to 3 (8.3%) cases where 2S technique was used. TLR was observed in none of the patients treated with 1S strategy and 2(5.6%) patients managed with 2S approach. No acute MI or stent thrombosis was seen in both subsets. Table-III summarizes the total MACE observed in two groups.

Table-II: Angiographic Features of patients in Single Stent and Double Stent Groups (n=110)

Angiographic Features		Single Stent Group n=74 (%)	Double Stent Group n=36 (%)	*p*-value
Extent of coronary artery disease	One vessel	10(13.5)	-	0.004
	Two vessel	31(41.8)	9(25)	
	Three vessel	33(44.5)	27(75)	
SYNTAX Score	<22	14(18.9)	-	0.01
	22-33	51(68.9)	18(50)	
	>33	9(12.1)	18(50)	
Medina classification	1,1,1	41(55.4)	36(100)	0.01
	1,1,0	29(39.1)	-	
	0,1,1	-	-	
	1,0,1	4(5.4)	-	
Intervention Strategy	Cross-over	62(83.7)	18(50)	-
	Cross-over with KBI	12(16.2)	10(27.8)	
	DK crush	-	4(11.1)	
	Culotte	-	-	
	Mini crush	-	-	
	SKS	-	-	
	T-stenting	-	-	
	Other two-stent modified techniques	-	-	
IVUS		8(10.8)	10(27.8)	0.024
Rotablator		1(1.3)	2(5.5)	0.249
POT		46(62.1)	36(100)	0.01

Table-III: MACE observed in single(1S) and double stent(2S) groups

MACE	Single Stent Group n=74 (%)	Double Stent Group n=36 (%)	*p*-value
Death	3(4.0%)	5(13.1%)	0.04
TLR	-	2(5.6%)	
Myocardial Infarction	-	-	
Stroke	-	-	

**TLR=target lesion revascularization*

Table-IV demonstrates the association of clinical and angiographic features of patients with number of stents.

Table-IV: Association of Clinical and Angiographic Features of patients with number of Stents

Characteristics of Patients		Single Stent Group n=74 (%)	Double Stent Group n=36 (%)	*p*-value
Syntax scoring	<22	1(20)	-	0.027
	22-33	3(60)	-	
	>33	1(20)	4(100)	
Age (years)	<40	-	-	0.595
	40-50	-	-	
	51-60	3(60)	3(75)	
	61-70	-	-	
	≥71	2(40)	1(25)	
Medina classification	1,1,1	3(60)	4(100)	0.278
	1,1,0	2(40)	-	
	1,0,1	-	-	
	0,1,1	-	-	
Extent of CAD	One vessel	0(0)	-	0.119
	Two vessel	3(60)	-	
	Three vessel	2(40)	4(100)	
LV ejection fraction	<35%	3(60)	-	0.056
	35-45%	1(20)	4(100)	
	46-55%	1(20)	-	
	>55%	0(0)	-	
Diabetes Mellitus	Diabetics	3(60)	3(75)	0.595
	Non-diabetics	2(40)	1(25)	
HTN	Hypertensive	3(60)	1(25)	0.357
	Non-hypertensive	2(40)	3(75)	
Smoking status	Active smoking	2(40)	2(50)	0.892
	Quitters	1(20)	1 (25)	
	Non-smokers	2(40)	1(25)	
		-	-	
Chronic kidney disease	CrCl <30	2(40)	-	0.347
	CrCl 30-50	1(20)	1(25)	
	CrCl >50	2(40)	3(75)	

**CrCl=creatinine clearence*

DISCUSSION

Left main stem disease signifies a greater prognostic risk as a due to significant area of myocardium at risk of jeopardy i.e. more than 75% in case of a right dominant system and nearly 100% if the system is left dominant. The incidence of left main disease is as high as 9% and has more chances of leading to worse outcomes if not revascularized. Bifurcation PCI is linked to a greater risk of procedural complications, restenosis and lower angiographic success rates.[12] It is technically difficult to go about due to angulation of the bifurcation, higher plaque burden with greater shear stress and more blood flow and greater luminal area, proximal and distal vessel mismatch. Also sometimes there is a large ramus intermedius vessel having disease in its ostio proximal course.[13] Accumulated evidence that demonstrated similar outcomes for intervention and CABG and progress in interventional cardiology practice has resulted in an increased volume of left main bifurcation intervention being performed worldwide.[14] The outcomes of EXCEL, PRECOMBAT and SYNTAX trials evidenced PCI is not inferior to CABG for left main disease.[15] However, still there exists substantial debate about the favorable interventional approach for ULMCA disease.[16] Bifurcation lesions, whether treated with CABG or PCI have a rather grim prognosis when compared to non bifurcation lesions.

Several techniques involving the use of two stents have been in practice like DK crush, culotte, simultaneous kissing stent (SKS) technique, mini- crush and T-stenting.[17] There are varied results in different studies and trials some favoring a single stent strategy and others demonstrating satisfactory outcomes with planned 2 stent approach. The DKCRUSH-V randomized trial showed that the DK crush 2S technique largely improved 1-year target lesion vs 1S cross over technique in true bifurcation disease. In comparison, a sub study of the EXCEL trial demonstrated that a planned 2S approach was linked to grim results than a one-stent technique, and this was limited to cases where there was no significant disease involving the side vessels.[18] The current research aims to review the long term results for 2S compared to 1S approach for distal unprotected left main bifurcation disease. 1S approach caused 5.4% MACE at 2 years whereas MACE is 13.8% for 2 stent strategy at 2-years though no statistical significance was demonstrated (p=0.253). Hence, the current study demonstrated that 1S approach results in better outcomes in distal left main, quite in similarity with non left main stem bifurcations.

Several reasons could be given as to 2S approach is linked to undesirable outcomes in comparison to 1S approach. The 2S approaches are rather complicated and challenging, that prolongs procedural and radiation time, contrast usage and increased incidence of myocardial damage . In addition, overlapping of stents results in layering of metal and excess deposition at disease location. There is increased chance of strut fracturing that ultimately results in worse outcome.[19] Whereas if there is sizable side vessel disease and it is not intervened upon, it can lead to higher MACE. Mostly side vessel disease where ostium is involved, are pseudo lesions.[20] suggested by fractional flow reserve study by Koo *et al*. that shows if side vessel lesion is visible as >75%, 30% of it proves to be significant via FFR.[21]

Apart from the angiographic factors, clinical characteristics also have an impact in establishing

outcomes in both subsets. In the current research, it was demonstrated that cases which suffered from MACE at 2 years were above age of 50 years, had Medina 1,1,1 disease (55.4% in 1S and 100% in 2S subset). Mostly individuals who developed MACE at 2 years had significantly high SYNTAX scores (p=0.028) with reduced EF on 2D echo. There was higher MACE in those who had diabetes, hypertension, those who smoked and those with CKD.

In the current study, the calculation of SYNTAX scores was done and Medina classification was used for lesion classification. The selection of interventional approach was done by primary interventionist depending upon anatomy of the lesion and individual choice. The 2S strategy mostly used DK crush (50%) then culotte (27.8%). POT was performed succeeded by REPOT in 100% cases of 2S subset and in 62.1% of cases of 1S subset. Intravascular ultrasound was employed in 10.8% cases of 1S subset and 27.8% individuals of 2S group. 5.4% of individuals in the 1S category developed MACE at 2 years in comparison to 13.8% of cases in the 2S category. Despite the difference in percentages, no statistical significance could be demonstrated in comparison to a similar study comparing the MACE at 6 months.[22] Apart from MACE, 2 of the patients underwent TLR both belonging to the two stent group. This demonstrated that both approaches efficiently treated distal left main bifurcation disease with higher success rates of the procedures. Although, it was deduced that one stent approach were easier technically and also showed favorable outcomes, specifically in individuals having insignificant disease at the lcx ostium.

LIMITATIONS OF STUDY

As the study was conducted in single center and sample size was small, so the results cannot be generalized.A study with survival analysis will be conducted in future.

CONCLUSION

One stent approach is linked to lesser incidence of MACE at 2 years in contrast to two-stent approach in distal left main bifurcation disease. More literature from randomised control trials shall be required to consolidate these results.

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Author's Contribution

Following authors have made substantial contributions to the manuscript as under:

HMS: Manuscript writing, concept and final approval

MN: Study design, drafting the manuscript and critical review

NAS: Intellectual contribution, concept and final approval

AF: Data management, data collection & manuscript writing

MNT: Data collection, data analysis and review of article

IA: Drafting the manuscript, proof reading and critical review

SS: Data collection, manuscript writing and proof reading

JK: Analysis, manuscript writing and proof reading

AK: Analysis, manuscript writing and proof reading

NA: Data analysis, proof reading and critical review

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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