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One-Stent Versus Two-Stent Techniques for Unprotected Distal Left Main Bifurcational Lesions: Early and Late Outcomes

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Abstract

Background and aim: Left main disease account for 3–5% of the coronary lesions. PCI on coronary bifurcation lesions is considered a challenge for any cardiologist. These lesions include a wide spectrum of anatomic complexity varying from simple lesions, which can be managed with a single stent, to complex lesions necessitating more complex procedures. The goal of the present study was to compare the clinical outcomes of PCI with single-stent vs. double-stent implantation for the management of ULMCA distal bifurcation lesions.

Patients and methods: A total of 60 cases with ULMCA distal bifurcation lesions eligible for PCI were included in the current study. Cases were divided into 2 main groups: one-stent group (20 cases) and two-stents group (40 cases). All patients underwent follow up during hospitalization and post-discharge at 1 and 6 months.

Results: Comparison between the study groups as regards the lesional and angiographic characteristics demonstrated that cases in the one-stent group had significantly lower SYNTAX score (21.70 ± 5.58 versus 24.88 ± 4.93 , P = 0.028) and lower frequency of true bifurcation lesion (65.0% versus 100.0%, P < 0.001) and higher frequency of 1,1.0 Median class (55.0% versus 7.5\%, P < 0.001). Besides, both groups had similar early post-interventional outcomes including hematoma and used target vessel revascularization techniques. Also, no significant differences were reported between both groups as regards the 6-month outcome parameters, including cardiac death, TV MI, TVR, and TL failure.

Conclusions: Both single-stent and two-stents techniques are technically feasible and safe techniques for management of ULMCA with comparable outcomes.

Keywords: Left main disease, PCI, ULMCA

1. Introduction

L eft main disease account for 3–5% of the coronary lesions. Affected patients are prone to develop fatal cardiovascular events such as ventricular fibrillation, cardiac arrest and cardiac shock. Among the different anatomical types of coronary artery disease (CAD), severe ULMCA lesion is the greatest-risk type which is linked to worse outcome in comparison to non-LMCA CAD.¹

Three anatomical regions are often involved in ULMCA: the LMCA's origin from the aorta, a mid-

segment, and distal bifurcation segment. In comparison to nonbifurcation lesions, ULMCA bifurcation lesions are challenging for any cardiologist, being of wide lumen and plaque burden, local higher blood flow and lower stress, greater distal bifurcation angles and local anatomical complexity.²

Coronary artery bypass grafting (CABG) has been considered as the standard of care for revascularization of severe LMCA lesion for a long time.³ During this era, PCI was carried out mainly in surgically-unfit individuals. Since the LMCA is the initial portion of coronary tree with a relatively wide

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https://doi.org/10.58675/2682-339X.1695 2682-339X/© 2023 The author. Published by Al-Azhar University, Faculty of Medicine. This is an open access article under the CC BY-SA 4.0 license (https:// creativecommons.org/licenses/by-sa/4.0/). diameter and a short length, its stenosis is considered as an attractive target, even during the early PCI period.⁴

However, as technical evolving continued, the recommendations of last guidelines in 2014 European Society of Cardiology/European Association for Cardio-Thoracic Surgery and 2014 ACC/AHA/American Association for Thoracic Surgery/SCAI/Society of Thoracic Surgeons guidelines provided Class II and Class III indications of PCI among those having low to intermediate anatomical complexity and those having highly complex lesions, respectively.^{5,6}

PCI on a lesion at the coronary bifurcation has been considered a challenging task for interventionists.⁷ Preliminary studies demonstrated that double kissing crush and Culotte stenting effectively treated bifurcation lesions.^{8–11} Whereas many other studies suggested that the two-stent approaches might be linked to poor outcome.^{12,13}

The goal of this work was to compare the clinical outcomes of PCI with single-stent vs. double-stent implantation as a treatment of ULMCA distal bifurcation lesions.

2. Patients and methods

The current prospective study was carried out at Al-Azhar University Hospitals, Cairo, Egypt and Almokkatam insurance hospital in the period from January 2018 to December 2021. Approval was obtained from the ethical committee of Al-Azhar Faculty of Medicine. Each of the participants provided an informed consent before participation.

Sixty cases complaining of ULMCA distal bifurcation lesions eligible for PCI were enrolled in our study. Patients were excluded if they had single left main trunk lesion (ostial or mid shaft), left main trifurcation anatomy, protected left main disease (Post-CABG), depressed LV systolic function (below 30%), intolerance to dual antiplatelets therapy or renal impairment.

Each patient was submitted to detailed history taking, clinical assessment, 2D transthoracic echocardiographic imaging and standard laboratory investigations (serum creatinine, creatinine clearance, complete blood count and international normalized ratio). Obtained angiographic data included LM anatomy (Medina classification), location and length of the lesion and dominance of the left system.

Before intervention, all patients received dual anti platelets therapy; according to revascularization guidelines. Coronary angioplasty and stent implantation were done through the femoral approach. Stenting procedure were chosen at the operator's preference based on the coronary arteriography results combined with pathologic features of LMCA distal bifurcation lesions. A onestent approach is defined as a stent crossover procedure (from LAD to left main) with or without a safety coronary wire placed in the left circumflex coronary artery (LCX), to be succeeded by kissing balloon dilatation after releasing the main stent. An additional stent was used if there is obvious residual diameter stenosis at the ostial left circumflex coronary artery. Two-stent techniques utilized in the present study included: crush technique with its variants, and T-stenting or TAP aiming at full coverage of the diseased portion.

Each of the patients was followed during hospitalization and following discharged at 1 and 6 months. Adverse outcomes which include myocardial infarction, target lesion revascularization (TLR), angina pectoris, death as well as acute in-stent thrombosis were monitored. Coronary angiogram was scheduled at 6 months post-discharge from the hospital, or earlier whenever indicated.

In the present study, the main outcomes were successful PCI, coronary restenosis, TLR, total vessel revascularization (TVR) and mortality. Successful PCI is defined as Thrombosis In Myocardial Infarction (TIMI) flow grade 3 with a residual stenosis <20% with no mortality, MI, or emergency CABG prior to discharging patients. All mortalities were considered of cardiac origin except if non-cardiac causes were reported. Coronary restenosis is defined as stenosis >50% measured via visual evaluation. TLR and TVR are defined as any repeat revascularization for target lesions whose diameter stenosis >50% within 5 mm proximal or distal to stent.

Data were presented as numbers and precents or means and standard deviations. Cartological data underwent comparison by Fisher's exact test or chisquare test whereas numerical data underwent comparison by *t*-test. All statistical calculations were computed utilizing SPSS 25 with *P* value is < 0.05was considered statistically significant.

3. Results

In our study, sixty cases with ULMCA distal bifurcation lesions were divided into two main groups: one-stent group (n = 20) and two-stents group (n = 40). Comparison between the studied groups as regards the baseline data showed non-statistically significant differences (Table 1). Comparison between both groups regarding the lesional and angiographic characteristics revealed that cases in the one-stent group had a significantly lower SYNTAX score (21.70 ± 5.58 versus 24.88 ± 4.93,

	Single-sten $N = 20t$	Two-stent $N = 40$	P value
Age (years) mean \pm SD	63.30 ± 5.04	66.23 ± 5.78	0.059
Male/female n	17/3	30/10	0.38
Body weight (kg) mean \pm SD	87.80 ± 6.42	91.73 ± 8.94	0.463
Associated risk factors <i>n</i> (%)			
Dyslipidemia	18 (90.0)	37 (92.5)	0.741
Diabetes	11 (55.0)	28 (70.0)	0.251
HTN	16 (80.0)	34 (85.0)	0.624
Current smoker	11 (55.0)	19 (47.5)	0.584
Peripheral vascular Disease	2 (10.0)	2 (5.0)	0.464
Previous stroke or TIA	_	_	NA
Previous MI	7 (35.0)	13 (32.5)	0.846
Previous PCI	4 (20.0)	12 (30.0)	0.409
Positive Family history	4 (20.0)	10 (25.0)	0.666
LVEF <i>n</i> (%)			
Good LVEF (>55%)	17 (85.0)	35 (87.5)	0.788
Fair LVEF (40-55%)	3 (15.0)	5 (12.5)	
CHA2D2 Vasc Score mean \pm SD	2.50 ± 1.10	3.03 ± 0.53	0.086

Table 1. Baseline characteristics in the studied groups.

Table 2. Lesion and angiographic characteristics in the studied groups.

	Single-stent $N = 20$	Two-stent $N = 40$	P value	
Dominant RCA n (%)	15 (75.0)	36 (90.0)	0.125	
Multi-vessel disease n (%)	11 (55.0)	22 (55.0)	NA	
SYNTAX score mean \pm SD	21.70 ± 5.58	24.88 ± 4.93	0.028	
True bifurcation lesion n (%)	13 (65.0)	40 (100.0)	< 0.001	
Bifurcation angle	84.75 ± 14.73	84.00 ± 15.82	0.860	
Medina class n (%)				
1,1.0	11 (55.0)	3 (7.5)		
1,1,1	0 (0.0)	25 (62.5)	< 0.001	
0.1.1	2 (10.0)	12 (30.0)		
0.1.0	6 (30.0)	_		
0.0.1	1 (5.0)	_		

P = 0.028) and lower frequency of true bifurcation lesion (65.0% versus 100.0%, P < 0.001) and higher frequency of 1,1.0 Median class (55.0% versus 7.5%, P < 0.001) (Table 2). procedural (95.0 versus 97.5%, P = 0.611) success. Other procedural specifications are listed in Table 3.

The studied groups showed comparable results as regards technical (75.0 versus 85.0%, P = 0.345) and

In addition, both groups had similar early postinterventional outcomes including hematoma and used target vessel revascularization techniques. Also, nonsignificant differences were reported

Table 3. Procedural characteristics in the studied groups.

	Single-stent $N = 20$	Two-stent $N = 40$	P value
Sheath Size <i>n</i> (%)			
6F	16 (80.0)	14 (35.0)	0.001
7F	4 (20.0)	26 (65.0)	
Double wire protection <i>n</i> (%)	12 (60.0)	40 (100.0)	< 0.001
Preparation of main vessel <i>n</i> (%)	10 (50.0)	26 (65.0)	0.264
Preparation of side branch <i>n</i> (%)	2 (10.0)	29 (72.5)	< 0.001
Crushing Balloon parked in MV before SB stent delivery n (%)	_	13 (32.5)	< 0.001
Diameter of main vessel stent (mm) mean \pm SD	3.44 ± 0.36	3.30 ± 0.31	0.128
Length of main vessel stent (mm) mean \pm SD	29.40 ± 8.38	27.45 ± 9.77	0.449
POT after first stent n (%)	12 (60.0)	31 (77.5)	0.156
Rewiring second vessel <i>n</i> (%)	7 (35.0)	29 (72.5)	0.005
Kissing balloon after main vessel stent n (%)	7 (35.0)	18 (45.0)	0.459
MV lesion length >25 mm n (%)	17 (85.0)	28 (70.0)	0.206
Procedure duration (min.) mean \pm SD	36.80 ± 9.73	73.78 ± 13.33	< 0.001
Technical success n (%)	15 (75.0)	34 (85.0)	0.345
Procedural success n (%)	19 (95.0)	39 (97.5)	0.611

Table 4. Early and late treatment outcome in the studied groups.

	Single-stent $N = 20$	Two-stent $N = 40$	P value		
In-hospital complications n (%)					
Hematoma	2 (10.0)	4 (10.0)	1.0		
Target vessel revascularization n (%)					
TVR total	2 (10.0)	5 (12.5)	0.776		
CABG	1 (5.0)	1 (2.5)	0.611		
Balloon PTCA	_	3 (7.5)	0.209		
PCI	1 (5.0)	1 (2.5)	0.611		
Target vessel MI n (%)	2 (10.0)	3 (7.5)	0.741		
Total stent thrombosis n (%)	1 (5.0)	2 (5.0)	1.0		
6-months outcome n (%)					
Cardiac Death	1 (5.0)	2 (5.0)	1.0		
TV MI	2 (10.0)	4 (10.0)	1.0		
TVR	2 (10.0)	5 (12.5)	0.775		
TL Failure	5 (25.0)	11 (27.5)	0.836		

between both groups as regards the 6-month outcome parameters including cardiac death, TV MI, TVR, and TL failure (Table 4).

4. Discussion

The present study showed comparable early and late outcome parameters between patients' groups submitted to single-stent or two-stents PCI interventions. Our findings are in consistence with findings by Gao *et al.*¹⁴ In a large single-center investigating including 1528 consecutive cases who had left main PCI, they comparatively evaluated stenting approach in individuals who had distal left main disease. At a mean of 4 years follow-up, rates of MACE (9.2% and 11.6% for one stent and two stents, respectively, P = 0.23), mortality, MI, and TVR were comparable among groups. Besides, two-stent strategy was not a predictor for MACE.

In another study, Zhang et al.,¹⁵ included 88 patients having distal ULMCA bifurcation lesions and underwent PCI with single or double stents implantation (50 cases and 38 cases in the one-stent group and two-stent group, respectively). There were no significant differences regarding the number of left main and multivessel disease, stenosis rate of left main, inner diameter of left main vessel, and distal bifurcation angle. The success rate was 100%. During hospitalization, no major adverse cardiovascular outcomes were observed among the 2 groups. During follow-up, restenosis was observed in 1 and 2 cases in single-stent group and double-stent group, respectively. Recurrence of angina and TLR was observed in 6 and 1 case in single-stent group, and 4 and 2 cases in double-stent group, respectively. There was no AMI, in-stent thrombosis and cardiac death in the 2 groups. The authors concluded that both stenting techniques were effective for distal ULMCA bifurcation lesions with a significant success rate and safety.

In contrast, another study found that as compared with two-stent approach of ULMCA bifurcation intervention, a single-stent technique seemed to have better outcome and six-month MACE-free survival.¹⁶ Likewise, the prospective study of Chen et al.¹⁷ on 633 cases that had ULMCA bifurcation lesions (232 underwent one-stent strategy vs. 401 underwent two-stent strategy) found that with distal left main bifurcations, two-stent approach independently predicted the long-term MACE. DK crush was linked to a better long-term outcome.

4.1. Conclusions

As a conclusion, our study found that both singlestent and two-stents techniques are technically feasible and safe techniques for management of ULMCA with comparable outcomes.

Ethical approval

The study was approved by the ethical committee of Al-Azhar Faculty of Medicine and informed consent was obtained from all participants and all patients provided written informed consent before enrollment in the study.

Author contributions

All authors equally shared in formulating the idea, conception, and data collection statistics, writing and drafting the manuscript.

Data availability statement

Data of this research will be available upon reasonable request.

Conflict of interest

None.

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