

Original Article

One-stent versus two-stent techniques for distal unprotected left main coronary artery bifurcation lesions

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Abstract: Objective: To assess the clinical outcomes of percutaneous coronary intervention (PCI) with single-stent versus double-stents implantation in distal unprotected left main coronary artery (ULMCA) bifurcation lesions and evaluate their merits and demerits in this clinical setting. Methods: 88 patients with distal ULMCA bifurcation lesions and treated with PCI with single or double stents implantation (50 in the one-stent group and 38 in the two-stent group) was included. Results: No significant difference in the number of left main and multivessel disease, stenosis rate of left main, inner diameter of left main vessel, and distal bifurcation angle was noted. The procedural success rate was 100%. Single-stent group had significantly lower ostial residual stenosis of left anterior descending and higher ostial residual stenosis of left circumflex as compared to double-stent group. During the hospitalization period, no major adverse cardiovascular events were observed in the two groups. During the follow-up period, restenosis was observed in 1 case in single-stent group and in 2 cases in double-stent group, respectively. Recurrence of angina and target lesion revascularization was observed in 6 and 1 case in single-stent group, and 4 and 2 cases in double-stent group, respectively. There was no acute myocardial infarction, in-stent thrombosis and cardiac death in both of the groups. Conclusions: Both stenting strategies were feasible for distal ULMCA bifurcation lesions with a high operation success rate and safety. Single-stent technique had lower ostial residual stenosis of left anterior descending whereas double-stents technique had lower ostial residual stenosis of left circumflex.

Keywords: Unprotected left main coronary artery, bifurcation lesions, stent, percutaneous coronary intervention

Introduction

Coronary artery bypass surgery is considered as the gold standard treatment of unprotected left main coronary artery (ULMCA) disease according to current guidelines [1, 2]. With the extensive off-label use of drug-eluting stents (DES) for obstructive coronary artery disease, the interest in stenting unprotected left main coronary artery disease (ULMCA) has increased rapidly [3, 4]. Although the introduction of DES has significantly improved the outcome of patients with unprotected left main coronary artery (ULMCA) stenosis treated with percutaneous coronary intervention (PCI) [5-8], bifurcation lesions still represent a technical challenge [9]. Bifurcation lesions present a wide spectrum of anatomical complexity which varies from simple lesions, which may be treated with a single stent, to complex lesions that require more complex techniques. Preliminary studies showed that double kissing (DK) crush

and Culotte stenting were effective for coronary artery bifurcation lesions [10-13]. Whereas several other studies have suggested that the two-stent strategies may potentially be associated with adverse clinical outcomes [14-16]. To up now, it still has not been fully clarified which stenting strategy should be adopted in distal ULMCA bifurcation lesions. In the present study, we aimed to assess and compare the clinical outcomes of PCI with single-stent versus double-stent implantation for the treatment of distal ULMCA bifurcation lesions and evaluate their merits and demerits in this clinical setting.

Materials and methods

Patients

The study was approved by the local ethics committee and was conducted in accordance with the Declaration of Helsinki. Written

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informed consent was obtained from all subjects. Between May 2009 and May 2013, a total of 88 patients with distal ULMCA bifurcation lesions confirmed by coronary arteriography and treated with interventional therapy were included. The diagnosis of distal ULMCA bifurcation lesions was based on coronary arteriography. The inclusion criteria were: (1) patients diagnosed with distal ULMCA bifurcation lesions; (2) patients whose anatomical structure suitable for stent technique; (3) patients who denied or cannot tolerate coronary artery bypass surgery. The exclusion criteria were: (1) single left main trunk ostial or mid-shaft lesions; (2) patients who cannot tolerate antiplatelet drug therapy; and (3) patients who underwent acute left main occlusion.

The patients were divided into two groups (each with 50 and 38 cases, respectively), i.e., the single stent group comprising of 50 cases receiving PCI with one stent implantation, and the double-stent group consisting of 38 cases receiving double stent implantation.

Preoperative preparation

Preoperatively, all patients were treated with oral aspirin (100 mg/d) and clopidogrel (75 mg/d) and continued for 3 days or administered with 300 mg aspirin combined with 300 mg clopidogrel at draught 12 to 24 hours before surgery. Preoperative routine test such as myocardial enzymogram, troponin, hepatorenal function supplemented with electrocardiogram, chest x-ray, and heart color ultrasound was performed to assess risk factors of coronary heart disease such as diabetes, hypertension, hyperlipidemia, and smoking.

One-stent or two-stents technique

PCI was performed via transradial approach or transfemoral approach. Pre-procedural intravascular ultrasound (IVUS) assessment and the use of intra-aortic balloon pump (IABP) were left to the physician's discretion. The stenting technique was chosen at the operator's discretion based on the coronary arteriography results combined with pathologic features of distal left main coronary artery bifurcation lesions. A one-stent technique was defined as a stent crossover technique (from LAD to left main) with or without a safety coronary wire jailed in the left circumflex coronary artery

(LCX), followed by kissing balloon dilatation if there was \leq grade II blood flow of the branch vessel after releasing the main stent \geq 75% diameter stenosis, by visual estimation, at the ostial LCX. An additional stent was required if there was obvious residual diameter stenosis, arteriography examination, at the branch lesions. Two-stent techniques used in the present study included mini-crush, culotte, T-stenting, and V-stenting. Stent release was obtained at high pressure in both groups. Non-compliant high-pressure balloon inflation was used according to the stent apposition condition. In double-stent group, final kissing balloon inflations were struggled.

Postoperative management

After the intervention, all patients received 300 mg/day aspirin for one month. Thereafter, they received 100 mg/day indefinitely for life. Clopidogrel (75 mg/d) was continued for at least 12 months, along with other medications such as β -blockers and angiotensin-converting enzyme inhibitors (ACEI) according to the judgment of the patient's condition.

Quantitative coronary angiographic measurements

Matched orthogonal views were used for quantitative coronary analysis (QCA) before, post-procedure, and at follow-up after intracoronary injection of nitroglycerin (100 to 200 μ g). Coronary angiograms were analyzed offline with a validated automated edge-detection coronary bifurcation system (CAAS II, Pie Medical Imaging, Maastricht, the Netherlands). Vessel segments involving bifurcation lesions were divided into proximal main vessel (MV), distal MV, and side branch (SB) segments within 5 mm proximal or distal to the stent, and polygon of confluence (POC). QCA variables included inner diameter of main vessel and side branch, stenosis rate of left main, distal bifurcation angle, ostial residual stenosis of anterior descending (LAD) and left circumflex (LCX). QCA analysis was performed by two independent experienced operators in an angiographic core laboratory (CCRF [China Cardiovascular Research Foundation], Beijing, China) unaware of the treatment allocation. True bifurcation lesions classified by Medina classification (1,1,1; 1,0,1; 0,1,1) [17].

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Table 1. Baseline characteristics of patients in two groups

	Single-stent group (n = 50)	Double-stent group (n = 38)	P values
Age (yrs)	56.8 ± 13.0	62.1 ± 12.7	0.09
Male, n (%)	34 (68.0)	28 (73.7)	0.56
Hypertension n (%)	32 (64.0)	30 (78.9)	0.88
Diabetes mellitus, n (%)	7 (14.0)	6 (15.8)	0.81
Hyperlipidemia, n (%)	10 (20.0)	11 (28.9)	0.33
Current smoker, n (%)	13 (26.0)	10 (26.3)	0.97
Prior MI, n (%)	5 (10.0)	4 (11.1)	1.00
LVEF (%)	54.5 ± 8.4	53.2 ± 8.1	0.15

LVEF, left ventricular ejection fraction; MI, myocardial infarction; Data are presented as means ± SD or percentages.

Table 2. Lesion characteristics, angiographic and procedural characteristics in two groups

	Single-stent group (n = 50)	Double-stent group (n = 38)	P values
True bifurcation lesions, n	4 (8.0%)	29 (76.3%)	< 0.01
Medina classification, n			
1.1.1	2	21	
1.0.1	1	1	
0.1.1	1	7	
Left main and multivessel disease, n (%)	41 (82%)	33 (86.8%)	0.54
Left main stenosis area (%)	74.9 ± 12.5	76.4 ± 13.8	0.81
Left main vessel diameter (mm)	3.76 ± 0.55	3.82 ± 0.33	0.78
Distal bifurcation angle (°)	74 ± 15.21	75 ± 15.57	0.25
Intervention techniques			
Cross-over	50 (100%)	0	-
Mini-crush	0	19 (50.0%)	-
Culotte	0	14 (36.8%)	-
T-stent	0	3 (7.9%)	-
V-stent	0	2 (5.3%)	-
IVUS	3 (6.0%)	2 (5.2%)	1.00
IABP	0	0	-
Double wire protection	34 (68.0%)	38 (100%)	1.00
Maximum release pressure (atm)	16 ± 4.56	16 ± 3.88	0.86
Final kissing balloon inflations, n	6 (12%)	37 (97.4%)	< 0.01

Data are presented as means ± SD or percentages; IVUS, intravascular ultrasound; IABP, intra-aortic balloon pump.

Follow-up and clinical evaluation

Clinical follow-up was performed with office visits or telephone contact at 1, 3, 6, and 12 months. Adverse events such as death, myocardial infarction, target lesion revascularization (TLR), angina pectoris and acute in-stent thrombosis were monitored throughout the entire study period. A follow-up coronary angi-

ography was scheduled at 8 months to 12 months after discharge from the hospital. No patients were lost to follow-up.

Definition

Percutaneous coronary intervention procedural success was defined as Thrombosis In Myocardial Infarction (TIMI) flow grade 3 with a final residual stenosis of < 20% without death, myocardial infarction, or emergency CABG before hospital discharge. All deaths were considered as cardiac in origin unless non-cardiac reasons were indicated. Coronary restenosis was defined as vessel diameter stenosis > 50% measured by QCA. Myocardial infarction (MI) and In-stent thrombosis was defined according to the Academic Research Consortium (ARC) definition. Target lesion revascularization (TLR) and TVR were defined as any repeat revascularization for target lesions whose diameter stenosis > 50% within 5 mm proximal or distal to the stent.

Statistical analysis

SPSS 13.0 (SPSS Inc, Chicago, IL) was used for data analysis. Qualitative data were expressed as frequency and percentage. Chi-square test was used to examine the relation between qualitative variables. Normally distributed continuous data are presented as means ± standard deviation (SD) and were compared using *t* tests. Non-normally distributed continuous data are presented as the

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Table 3. Postoperative angiographic outcomes in two groups

	Single-stent group (n = 50)	Double-stent group (n = 38)	P values
Ostial residual stenosis of LAD (%)	4.32 ± 4.33	9.58 ± 6.21	0.02
Ostial residual stenosis of LCX	12.67 ± 10.85	5.61 ± 4.11	0.03
Angiographic success	50 (100%)	38 (100%)	

Data are presented as means ± SD or percentages; LAD, left anterior descending; LCX, left circumflex.

Table 4. Clinical events after hospital discharge

	Single-stent group (n = 50)	Double-stent group (n = 38)	P values
Recurrent angina	6 (12.0%)	4 (10.5%)	1.00
Restenosis	1 (16.7%)	2 (25.0%)	0.46
Total MACE	1 (2.0%)	2 (5.3%)	0.32
TVR	1 (2.0%)	2 (5.3%)	0.32
Cardiac death	0	0	
In-stent thrombosis	0	0	
Acute MI	0	0	

Data are presented as means ± SD or numbers of patients (percentages); MACE, major adverse cardiovascular events; TVR, target vessel revascularization; MI, myocardial infarction.

median and range, and were compared using rank sum tests. Independent risk factors were determined by multiple logistic regression models. Differences were considered statistically significant when $P < 0.05$.

Results

Baseline characteristics

Eighty-eight patients with distal ULMCA bifurcation lesions and treated with PCI were included. The patients consisted of 50 cases in single-stent group and 38 cases in double-stent group. The baseline clinical characteristics of the patients are summarized in **Table 1**. There was no statistically significant difference with respect to the baseline characteristics between the single-stent and double-stent groups.

Table 2 shows the lesion characteristics, angiographic and procedural characteristics of the distal ULMCA bifurcation lesion in the study groups. Patients in the double-stent group had more true bifurcation lesions compared to the single-stent group (29 (76.3%) vs 4 (8.0%)) ($P < 0.01$). This finding suggests that for distal ULMCA true bifurcation lesions double-stent implantation is the primary option. There was no statistically significant difference with

respect to the number and percentage of left main and multivessel disease, stenosis rate of left main, inner diameter of left main vessel, and distal bifurcation angle between the two groups. As for procedural characteristics, patients in single-stent group were all treated with stent crossover technique. Whereas patients in double-stent group in the present study were treated mainly with Mini-crush (19, 50%) and Culotte techniques (14, 36.8%) followed by T-stenting (3, 7.9%) and V-stenting techniques (2, 5.3%). Pre-procedural IVUS assessment was used in 3 of 50 cases (6%) in single-stent group and 2 of 38 cases (5.2%) in double-

stent group, respectively. No IABP was used preoperatively. Final kissing balloon inflations were obtained in 37 of 38 cases (97.4%) in double-stent group and 6 of 50 cases (12%) in single-stent group. Unsuccessful kissing balloon inflations was found in 1 case in double-stent group due to the guide wire failed to pass through the stent mesh after stent release.

Postoperative angiographic outcome

Table 3 shows postoperative angiographic outcomes in two groups. The procedural success rates were all 100% in both groups. Percutaneous coronary intervention procedural success in our study was obtained as Thrombosis In Myocardial Infarction (TIMI) flow grade 3 with a final residual stenosis of $< 20\%$ without death, myocardial infarction, or emergency CABG before hospital discharge. Immediately after the operation, ostial residual stenosis of LAD in single-stent group was significantly lower compared to double-stent group ($4.32\% \pm 4.33\%$ vs $9.58\% \pm 6.21\%$, $P < 0.05$) (**Table 3**). On the contrary, ostial residual stenosis of left circumflex (LCX) in single-stent group was significantly higher than that in double-stent group ($12.67\% \pm 10.85\%$ vs $5.61\% \pm 4.11\%$, $P < 0.05$) (**Table 3**). During the hospitalization period, no recurrent angina and MACE such as TVR, acute

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in-stent thrombosis, cardiac death, and MI was observed in the two groups. All the cases achieved the clinical success.

Postoperative follow-up outcome

The postoperative follow-up data was given in **Table 4**. During the 6-24 months of postoperative follow-up, restenosis was observed in 1 case in single-stent group and in 2 cases in double-stent group, respectively. The patient in single-stent group received TVR with PCI. One of The patient in double-stent group received TVR with PCI, while the remaining one received TVR with CABG. Recurrent angina, TLR was observed in 6 and 1 case in single-stent group, and 4 and 2 cases in double-stent group ($P > 0.05$), respectively. In addition, there was no acute MI, in-stent thrombosis and cardiac death in both of the two groups.

Discussion

Left main disease account for 3% to 5% of the coronary lesions and are prone to develop fatal cardiovascular events such as ventricular fibrillation, cardiac arrest and cardiac shock due to interrupted blood flow. ULMCA is generally divided into three anatomic regions: the ostium or origin of the left main coronary artery from the aorta, a mid-portion, and the distal bifurcation portion [18]. Compared with non-bifurcation lesions, ULMCA bifurcation lesions nevertheless represent a technical challenge for the interventional cardiologist due to ULMCA bifurcation has unique features including: (1) larger lumen diameter and plaque burden; (2) local greater blood flow and lower stress; (3) greater distal bifurcation angles; (4) local anatomical complexity (eg., trifurcation); (5) left main disease mismatch the branch vessel; (5) disastrous consequence occur once branch vessel was injured.

PCI on lesions located on coronary bifurcations have been considered a challenging task for interventionists. Before drug-eluting stents became available, the restenosis rate was unacceptably high on both branches regardless of the technique used. The availability of drug-eluting stents (DES), associated with single-digit angiographic restenosis, prompted renewed interest in the percutaneous treatment of ULMCA lesions. Several reports have shown that PCI with single stent was better for

ULMCA distal bifurcation lesions than double stents [19, 20], with a 5% lower rate of TVR [21]. While others reported that the two-stent techniques for distal ULMCA bifurcation lesions do not provide any additional advantages compared to the one-stent technique, and may even be detrimental [22]. In our study, we compared the efficacy of single-stent versus double-stent techniques for the treatment of distal ULMCA bifurcation lesions. We found that all the cases achieved the instant success after PCI. There was no MACE in the present study including TVR, acute in-stent thrombosis, cardiac death, and MI during the operation and the hospitalization period in the two groups. Furthermore, during the 6-24 months of postoperative follow-up, no significant differences with respect to the restenosis rate and MACE between the two groups was observed. These findings suggested that the two different stenting strategies were both feasible and safe for distal ULMCA bifurcation lesions with a high operation success rate and safety. Our findings were consistent to some of the previous studies [20, 23] which reported that have suggested that the two-stent techniques for distal ULMCA bifurcation lesions do not provide any additional advantages compared to the one-stent technique. These might be related to the use of double wire protection, high-pressure post dilatation, kissing balloon inflation, and/or limited number of patients in the present study. Further studies with a larger sample size, a longer follow-up or randomized prospected controlled trial are still needed to confirm our findings.

According to the results of coronary arteriography, the ostial residual stenosis of left anterior descending in single-stent group was significantly lower compared to double-stent group. On the contrary, ostial residual stenosis of left circumflex in single-stent group was significantly higher than that in double-stent group. These findings showed that single-stent technique had a better ability of attaching stent to vessel wall of LAD and a lower residual stenosis rate while double-stent technique had a better ability of attaching stent to vessel wall of LCX compared to that of LAD. Although the clinical outcomes in the two-stent techniques during the hospitalization period and postoperative follow-up period were comparable to the one-stent technique, they still had their own advan-

tages and disadvantages. Our findings was consistent with a previous study [24]. Therefore, we recommend that the optimal stenting strategy for distal ULMCA bifurcation lesions should be according to the patient condition and operator's experience. In clinical practice, the accuracy of the classification of the bifurcation lesions is important for clinical physicians to choose an optimal treatment strategy. In this study, bifurcation lesions were classified according to the Medina classification [25]. The double-stent technique mainly including crush technique (50.0%) followed by culotte technique (36.8%) was used mainly in true bifurcation lesions to ensure the complete coverage of the lesions. The single-stent technique was technically easier and appeared to be more effective in improving clinical outcomes in non-true ULMCA patients with normal LCX.

In conclusion, both stenting strategies were feasible for distal ULMCA bifurcation lesions with a high operation success rate and safety. Single-stent technique had lower ostial residual stenosis of left anterior descending whereas double-stents technique had lower ostial residual stenosis of left circumflex. Further studies with larger number of patients and longer follow up are still needed to confirm these findings.

Disclosure of conflict of interest

None.

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