


# The Drug Coated Balloon-Only Strategy for Treatment of de Novo Left Main Coronary Artery Bifurcation Lesion: Stentless Strategy

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## Abstract

The study aimed to evaluate the efficacy and safety of drug coated balloon-only strategy (DCB-only) in the treatment of de novo left main coronary artery (LM) bifurcation lesions. 85 patients were enrolled in this study and classified them into two groups: DCB-only group (n = 36) and DES group (n = 49). The MLD of target vessels was measured before and immediately after percutaneous coronary intervention (PCI) and late luminal loss (LLL) were also calculated. And the occurrence of major adverse cardiovascular events (MACE) was also evaluated. Compared with that before PCI, the MLD of target lesions significantly increased immediately after PCI ( $P < .05$ ) and no MACE was recorded during the perioperative period both in two groups. The MLD at follow-up was significantly higher than that before both DCB and DES treatment. Compared with the DES group, the MLD of the DCB group was smaller than immediately after PCI in the LM and LAD ( $P < .05$ ). The LLL of LAD in DCB group was smaller than that in DES group ( $P < .05$ ). There was no significant difference in the incidence of luminal restenosis at the target lesion between the two groups, and no significant difference in the incidence of MACE ( $P > .05$ ). The use of DCB-only to treat de novo LM bifurcation lesions is effective and relatively safe, which provides new ideas for the treatment of LM coronary artery bifurcation lesions in the future.

## Keywords

left main coronary artery bifurcation lesion, drug coated balloon-only, drug-eluting stent, percutaneous coronary intervention

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## Key Message

1. Though the new generation of drug-eluting stent (DES) remarkably reduces the rate of restenosis, the treatment of de novo left main (LM) coronary artery bifurcation lesions still has some unsolved problems.
2. The use of DCB-only to treat de novo LM bifurcation lesions is effective and relatively safe.

## Introduction

LM lesions, especially de novo LM bifurcation lesions, are one of the most difficult diseases to treat with coronary intervention, characterized by high risk, a poor prognosis, etc.<sup>1,2</sup> Recently, there are two primary intervention strategies in treating de novo LM bifurcation lesions, including single-stent strategy and two-stent strategy. Though the new generation of DES remarkably reduces the rate of restenosis,<sup>3</sup> there are still some unsolved problems,<sup>4,5</sup> such as a significantly increased risk of late stent thrombosis (ST) and very late ST, caused by chronic inflammation because of the permanent implantation of metal stents. Compared with DES, DCB is a coronary intervention without the implantation of stent made of polymer matrix and metallic foreign bodies, and has many unique advantages. For example, DCB can quickly and evenly distribute drugs that inhibits intimal proliferation on blood vessel walls, maintain the original structure of the blood vessel without damaging the vasomotor function, and reduce the treatment course of dual anti-platelet therapy (DAPT) which is especially important for patients at high bleeding risk.<sup>6,7</sup> So far, DCB has been increasingly used to treat in-stent restenosis (ISR) and in situ lesions of coronary small vessels and branch vessels that are not suitable for DES implantation.<sup>8-10</sup> The latest clinical studies also show that DCB-only can achieve better outcomes in the treatment of in situ lesions in coronary large arteries.<sup>11</sup> However, there are few studies on the treatment of LM bifurcation with DCB-only strategy. In this study, we retrospectively review clinical data on patients with LM bifurcation lesion who were treated with DCB-only strategy as an interventional therapy in the First Affiliated Hospital of Zhengzhou University. The aim of this study is to evaluate the efficacy and safety of the DCB-only strategy in LM bifurcation lesions.

## Materials and Methods

### Patients and Related Information

This retrospective study enrolled a total of 85 patients who were diagnosed with de novo LM bifurcation lesions of left main coronary artery by coronary angiography (CAG) and treated with drug-coated balloon only strategy (DCB-only) or DES between January 2018 and December 2019 at the First Affiliated Hospital of Zhengzhou University, Zhengzhou,

China. The inclusion criteria included: ① The presence of LM bifurcation lesions according to the Medina classification confirmed by CAG; ② At least one luminal stenosis of >50% diameter in the proximal or distal main coronary artery, or the circumflex coronary arteries, and was also involved with the orifices; and ③ 18-85 years of age. The exclusion criteria included: ① ISR lesions; ② chronic occlusive lesions; ③ severe calcified lesions; ④ acute myocardial infarction (AMI); ⑤ combined with primary cardiomyopathy; ⑥ left ventricular ejection fraction  $\leq 30\%$ ; and ⑦ severe renal insufficiency (GFR < 30 ml/min) or severe liver insufficiency. Characteristics of the patients were recorded, including gender, age, clinical diagnosis, history of hypertension, diabetes, hyperlipidemia, myocardial infarction, percutaneous coronary intervention (PCI), angina, smoking, left ventricular ejection fraction (LVEF), and so on. This study was approved by the Medical Ethics Committee of the First Affiliated Hospital of Zhengzhou University. All subjects signed their informed consent to participate in this study.

### PCI Procedure

All patients received dual antiplatelet therapy (DAPT) before and after DCB, including aspirin (Bayer, Germany, registration number H20130339; loading dose 300 mg) + clopidogrel (Sanofi, France, registration number J20180029; loading dose: 300 mg) or aspirin 300 mg + ticagrelor (AstraZeneca, UK, registration number J20130020; loading dose: 180 mg). Patients received maintenance treatment (maintenance dose: aspirin 100 mg·d<sup>-1</sup> + clopidogrel 75 mg·d<sup>-1</sup>, or aspirin 100 mg·d<sup>-1</sup> + ticagrelor 90 mg, twice daily). DCB group: The PCI operation was performed according to the procedure recommended by the Chinese medical experts' consensus statement on DCB treatment. All patients underwent DCB treatment via the radial artery approach. The balloon-vessel diameter ratio was 0.8-1.0, and the length of the balloon was at least 2-3 mm longer than the lesions at each end. The DCB was inflated at nominal pressure for about 60 s, and for patients who cannot tolerate myocardial ischemia, an inflation time of at least 30 s was recommended. Immediately after DCB treatment, the results were re-evaluated by CAG to determine if a post-dilation was needed based on the extent of residual stenosis at arterial cutdown sites. In general, the LM and left anterior descending coronary artery (LAD) were generally used as the main branch during PCI, and the left circumflex coronary artery (LCX) was used as the collateral branch. In this study, Bingo drug-coated balloons were purchased from Yinyi (Liaoning) Biotech Co., Ltd (No. 20173771535, Liaoning, China). The Flextome cutting balloons were purchased from produced Boston Scientific (No. 20173772071, Natick, MA, USA). The Lacrosse non-slip element (NSE) balloons were purchased from Goodman Co., Ltd, (No. 20163775067, Nagoya, Japan). DES group: specific PCI methods are selected by the surgeon. The specific ways of PCI were described before.<sup>12</sup>

## CAG Data Collection

Minimal lumen diameter (MLD) at the LM bifurcation before PCI, immediately after PCI, and at the time of follow-up. Diameter stenosis and late lumen loss (LLL) at target lesion sites were correspondingly calculated, and the LLL of other vessels without PCI treatment was also determined immediately after the PCI and at the time of follow-up.

## Follow up

Besides reviewing medical records, all patients were followed up at 1, 3, 6 and 12 months by outpatient visit or telephone contact after PCI. Coronary angiographic follow-up was scheduled or performed in case of staged revascularization or if clinically indicated according to the policy of each institution. The primary endpoints were re-examined by CAG, and the occurrence of major adverse cardiovascular events (MACE), including target lesion revascularization (TLR), non-fatal myocardial infarction (MI), angina pectoris, and cardiac death. Lumen restenosis at target lesion sites was defined as (1) an increase of at least 30% from the immediate post-operation stenosis to follow-up stenosis, (2) the follow-up stenosis of more than 70% from an immediate post-operation stenosis of less than 50%, or (3) a loss of at least 50% of the gain at the target lesion sites.

## Statistical Analysis

The data were analyzed using SPSS 25.0 (SPSS Inc., Chicago, IL, USA). Data were expressed as frequency and ratio (%). Non-normally distributed data were expressed as medians and interquartile ranges  $M (P_{25}, P_{75})$ , and the Wilcoxon rank-sum test was used for comparison between the two groups. Normally distributed data were expressed as means  $\pm$  standard deviation ( $\bar{x} \pm SD$ ) and the Student t-test was used for analyzing the mean difference of two independent samples. Categorical data were expressed as a percentage (%), and the chi-square test was used for comparison between categorical values. A two-sided test with a  $P < .05$  was considered statistically significant.

## Results

### Patient, Lesion and Procedural Characteristics

Between January 2018 and December 2019 in Zhengzhou University First Affiliated Hospital, a total of 85 consecutive patients who underwent PCI were enrolled in this study. Details regarding baseline patient characteristics are summarized in Table 1. In the "Drug coated balloon-only" group, there were 31 (86.11%) patients with LM and LAD stenosis and 17 (47.22%) patients with LCX stenosis. On the other hand, in the DES group, there were 39 (79.59%) patients with LM, 48 (97.96%) LAD stenosis and 49 (100%) patients with

**Table 1.** Baseline Characteristics of the Study Population.

Parameter	DES (n = 49)	DCB (n = 36)	P Value
Age, years	62.20 $\pm$ 10.41	57.86 $\pm$ 11.39	.981
Male	38 (77.55%)	29(80.56%)	.062
Clinical diagnosis			.654
Unstable angina	36 (73.47%)	28(77.78%)	
Stable angina	13 (26.53%)	8(22.22%)	
Hypertension	25 (51.02%)	18(50.00%)	.927
Diabetes	12 (24.49%)	10(27.78%)	.736
Hypercholesterolemia	1 (2.04%)	4(11.11%)	.118
Current smoker	11 (22.45%)	11(30.56%)	.405
Previous myocardial infarction	6 (12.24%)	7(19.44%)	.368
Previous percutaneous intervention	11 (22.45%)	9(25.00%)	.787
LVEF, %	62.0(59.5,63)	62(60.5,63.00)	.720

Abbreviations: DES, drug-eluting stent; DCB, drug coated balloon; LVEF, Left Ventricle ejection.

LCX stenosis. All target lesions were pre-dilated with cutting balloons/NSE balloons.

## Follow up

Among 36 patients in the DCB-only group, 31 patients were followed up. 17 (47.22%) patients returned to the hospital for CAG re-examination. The median follow-up time was 7.00 (6.00, 11.75) months. During follow-up, 1 patient (2.78%) had no obvious symptoms, but CAG re-examination showed the occurrence of restenosis at the target lesion site, so the patient received revascularization treatment. 14 patients who did not return to the hospital for CAG re-examination were followed up by telephone, 2 patients received revascularization treatment because of target vessel stenosis. In the DES group, 49(100%) returned to the hospital for CAG re-examination. During follow-up, 9 patients (18.37%) CAG re-examination showed the occurrence of restenosis at the target lesion site, and received revascularization treatment. And all the patients no MACE were recorded during follow up.

## The Results of CAG in Patients

We quantitatively analyzed the CAG data in patients before and after PCI treatment (Table 2). All the MLD at target lesion sites significantly increased immediately after PCI compared to that before PCI, and the degree of luminal stenosis also decreased significantly. CAG was examined immediately after PCI in both groups, compared with the DES group, the MLD of the DCB group was smaller immediately after PCI in the LM and LAD ( $P < .05$ ), but there was no statistical difference in the MLD in LCX ( $P = .912$ ) (Table 2). 17 patients received re-examination by CAG in the DCB group, and 49 patients received re-examination by CAG in the DES group. 1 (5.88%) patient had restenosis at the target lesion site in DCB group,

**Table 2.** Quantitative Analysis of CAG Data in 85 Patients Immediately After PCI Treatment.

Angiographic Characteristics	DES (n = 49)	DCB (n = 36)	P value
<b>LM</b>			
Reference vessel diameter, mm	3.81 (3.57,4.11)	3.62 (3.55,4.35)	.602
Preoperative MLD, mm	1.23 ± 0.52	1.59 ± 0.50	.024
Preoperative luminal stenosis, %	67.72 (54.92,75.95)	54.87 (51.55,58.72)	.004
MLD immediately after PCI, mm	3.43 ± 0.35	2.98 ± 0.51	.001
Luminal stenosis immediately after PCI, %	10.23 (7.89,12.86)	22.94 (13.73,29.61)	<.001
<b>LAD</b>			
Reference vessel diameter, mm	3.34 ± 0.32	3.48 ± 0.56	.233
Preoperative MLD, mm	0.84 ± 0.35	0.93 ± 0.40	.285
Preoperative luminal stenosis, %	75.00 ± 9.57	73.22 ± 10.54	.454
MLD immediately after PCI, mm	3.03 ± 0.31	2.68 ± 0.38	<.001
Luminal stenosis immediately after PCI, %	7.92 (6.48, 9.40)	21.94 (19.10,25.22)	<.001
<b>LCX</b>			
Reference vessel diameter, mm	2.81 ± 0.38	3.16 ± 0.42	.002
Preoperative MLD, mm	0.66 (0.46,0.99)	0.67 (0.48,0.91)	.832
Preoperative luminal stenosis, %	75.37 (66.62,83.53)	78.03 (71.47,83.86)	.359
MLD immediately after PCI, mm	2.23 (2.05,2.71)	2.27 (2.15,2.44)	.912
Luminal stenosis immediately after PCI, %	14.98 (10.13,23.86)	25.36 (21.80,31.13)	<.001

Abbreviations: CAG, coronary artery angiography; PCI, percutaneous coronary intervention; DES, drug-eluting stent; DCB, drug coated balloon; LM, left main coronary artery; MLD, minimal lumen diameter; LAD, left anterior descending coronary artery; LCX, left circumflex coronary artery.

and 9 (18.37%) patients had restenosis at the target lesion site in DES group. The LLL of LAD in DCB group was smaller than that in DES group ( $P < .05$ ), but there was no statistical difference between LM and LCX groups (Table 3). There was no significant difference in the incidence of luminal restenosis at the target lesion between the two groups, and no significant difference in the incidence of MACE ( $P > .05$ ) (Table 4).

## Discussion

The current study demonstrates that DCB-only strategy is an alternative treatment method for the management of LM coronary artery bifurcation lesions in terms of immediate outcome (acute gain), medium-term effect (LLL), and the safety.

**Table 3.** Quantitative Analysis of CAG Data in 66 Patients After PCI Treatment at Follow-up.

Angiographic Characteristics	DES (n = 49)	DCB (n = 17)	P value
<b>LM</b>			
Follow-up MLD, mm	3.24 (3.06,3.52)	2.83 (2.51, 3.14)	.03
Follow-up luminal stenosis, %	14.29(12.32,19.73)	29.43 (26.89,30.21)	.003
Follow-up LLL, mm	0.12(0.06,0.24)	0.16 (-0.04,0.47)	.881
<b>LAD</b>			
Follow-up MLD, mm	2.88 (2.61,3.01)	2.65 (2.37,3.12)	.223
Follow-up luminal stenosis, %	12.64(10.57,18.62)	24.09 (17.74,26.17)	<.001
Follow-up LLL, mm	0.16(0.06,0.28)	-0.05 (-0.09,0.16)	.001
<b>LCX</b>			
Follow-up MLD, mm	2.18 (1.58,2.53)	2.31 (2.25,2.65)	.240
Follow-up luminal stenosis, %	20.87(11.63,34.65)	24.04 (16.61,38.19)	.576
Follow-up LLL, mm	0.12(-0.19,0.56)	-0.07 (-0.29,0.21)	.169

Abbreviations: CAG, coronary artery angiography; PCI, percutaneous coronary intervention; DES, drug-eluting stent; DCB, drug coated balloon; LM, left main coronary artery; MLD, minimal lumen diameter; LAD, left anterior descending coronary artery; LCX, left circumflex coronary artery; LLL, late luminal loss.

**Table 4.** The Incidence of MACE in Two Groups After PCI.

Variable	DES (n = 49)	DCB (n = 31)	P value
TLR, %	9(18.0)	3(9.68)	.351
MI, %	1(4.08)	0(0.0)	-
Cardiac death, %	0(0.0)	0(0.0)	-

Abbreviations: MACE, major adverse cardiovascular events; PCI, percutaneous coronary intervention; DES, drug-eluting stent; DCB, drug coated balloon; TLR, target lesion revascularization; MI, myocardial infarction.

In 36 patients who underwent DCB treatment in this study, CAG showed MLD at the target lesion sites significantly increased immediately after DCB compared to that before DCB, which was accompanied by a significant reduction in the degree of luminal stenosis, suggesting that the DCB-only strategy could effectively treat LM bifurcation lesions. Besides, compared with the DES group, the MLD of the DCB group was smaller immediately after PCI in the LM and LAD ( $P < .05$ ), but there was no statistical difference in the MLD immediately after PCI ( $P > .05$ ) in LCX. This is because DCB, as an antiproliferative drug carrier, does not have the function of expanding and supporting the lumen, and the lumen of side branch, usually left circumflex branch, may be less due to plaque displacement or compression of main branch stent.<sup>12</sup> Though there was still a certain degree of residual luminal stenosis at each target lesion site after

DCB, which is relatively higher than that reported in previous studies<sup>13</sup> on DCB treatment of common de novo lesions in large coronary arteries. It might be explained as follows: The vascular wall at LM bifurcation lesion sites had more smooth muscle tissues and elastic fibers than other sites, and the DCB-only treatment lacked the support of metal stents, therefore, elastic recoil of coronary arteries was more obvious after pre-dilation. At the same time, DCB itself is only used as a medium for drug delivery without an ability to dilate coronary stenosis, and its acute lumen gain often depends on the degree of pre-dilation using cutting balloons/NSE balloons. To avoid the occurrence of severe dissection, however, the surgeon usually does not use the balloons with an excessively large diameter to pre-dilate the lesions, so the extent of lumen expansion might be limited. Nevertheless, in this study, CAG immediately after DCB showed that the DCB-only strategy could still achieve relatively satisfactory immediate outcome in the treatment of LM bifurcation lesions. Besides, the majority of patients did not undergo conventional kissing balloon inflation after DCB treatment. Because without the support of metal intents, unnecessary kissing balloon inflation could cause damage to the proximal region of main branch, thereby affecting the long-term prognosis. Only when the orifices of side branch were severely blocked by plaque or carina displacement, the kissing balloon dilation at low pressure (usually  $\leq 6$  atm) is considered to be an option.

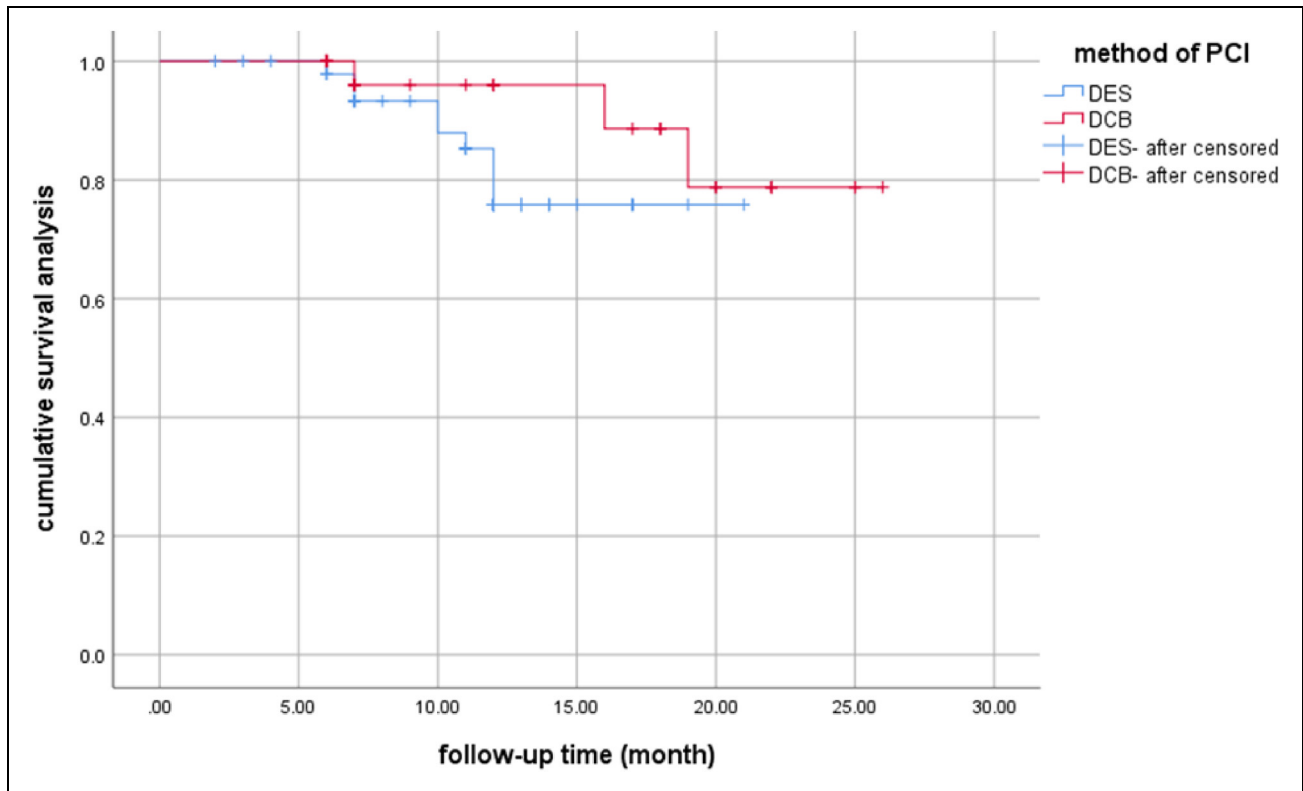
In this study, 31 (86.1%) patients were followed up in the DCB group. 17 patients of them returned to the hospital for CAG re-examination, and 14 patients were followed up by telephone or outpatient. 49 (100%) patients received re-examined by CAG in DES group, the other people who did not received re-examined by CAG were followed up by outpatient visit or telephone contact. 3 (9.68%) patient and 9 (18.37%) patients had restenosis at the target lesion site in DCB and DES groups, the other patients showed relatively low LLL and the degree of stenosis at lesion sites. At follow-up, the MLD of the DCB group was smaller in the LM compared with the DES group ( $P < .05$ ), and there was no significant difference about the MLD of LAD and LCX. In addition, the LLL of LAD in the DCB group was smaller than that in DES group ( $P < .05$ ), but there was no significant difference about LLL of LM and LCX, suggesting that the DCB-only strategy might have a better medium-term effect in the treatment of LM bifurcation lesions. The LLL at follow-up was: DES group: LM 0.12(0.06,0.24) mm, LAD 0.16(0.06,0.28) mm, LCX 0.12(-0.19,0.56) mm; DCB group: LM 0.16(-0.04,0.47) mm, LAD -0.05(-0.09,0.16) mm, LCX -0.07(-0.29,0.21) mm. On the one hand, all lesions in this study were sufficiently pre-dilated using cutting balloons or NSE balloons. Compared with common pre-dilation balloons, cutting balloons/NSE balloons dilate the lumen mainly through the compression and displacement of plaques, without excessive expansion of blood vessels, which causes less damage to blood vessels and thereby reduces the proliferation of the arterial intima after PCI.<sup>14</sup> On the other hand, drugs carried on the surface of DCB can

have a long-term anti-proliferative effect after being distributed to vascular intima.<sup>15</sup> At the same time, the locally released drug could rapidly interact with the lesions, and residual drug could also be quickly diluted and eliminated. In this case, endothelial cells and their precursor cells that migrate from a remote area to the damaged vascular segments will not be affected by the residual drug and can repair the damaged vascular endothelium to achieve rapid endothelialization.<sup>16</sup> In addition, most of the target vascular lesions (16/28) in this study showed late lumen enlargement during follow-up in the DCB group, which is similar to the results of Kleber *et al.*<sup>17</sup> Although the specific mechanism is not clear, this suggests that DCB may have a good long-term effect in the treatment of LM bifurcation lesions and other large vessel diseases. And the survival analysis curve was drawn according to the follow-up time of patients and the occurrence of MACE, as shown in Figure 1, there was no statistical difference in the occurrence of MACE, suggesting that the treatment of DCB-only strategy in LM bifurcation lesions is relative safety.

Among 36 patients in the DCB group, only 3 (7.69%) patients developed TLR, which is consistent with the result obtained the first single-blind, randomized controlled trial (DEBUT) done in the Finland.<sup>18</sup> At the same time, the quantitative analysis of CAG showed patients had low LLL in other branches without DCB treatment immediately after operation and at the time of follow-up, suggesting that DCB had little effect on other branches when treating LM bifurcation lesions. The result demonstrated the safety of DCB in the treatment of LM bifurcation lesions. In this study, there was a lack of data on the occurrence of dissection in the treatment of LM bifurcation lesions with DCB-only strategy. But it is reported that the incidence of acute myocardial infarction after DCB treatment is less than 0.5%,<sup>19</sup> and mild coronary side branch dissections of type B and below were spontaneously healed without treatment during mid-term follow-up and did not cause an increase in LLL.<sup>20</sup>

## Study Limitations

First of all, as a retrospective study, this study included a relatively small number of cases and lacked of a comparison with current intervention strategies for treating LM bifurcation lesions. Secondly, intravascular ultrasound (IVUS) is a high-resolution imaging method and can accurately identify the size and nature of the lesions. Using IVUS to guide interventional treatment of left main diseases can optimize PCI results and improve prognosis. However, in clinical practice, many patients refused to accept the IVUS imaging due to cost reasons, resulting in a low proportion of patients receiving precise PCI, which might have a certain impact on the surgical results. Last, the follow-up time is short, so the long-term effects after PCI could not be obtained. Therefore, the results need to be confirmed by large-scale randomized controlled studies in a longer follow-up period.



**Figure 1.** The survival analysis curve of occurrence of MACE in two groups after PCI.

Log Rank (Mantel -Cox) :  $P = .155$

MACE: major adverse cardiovascular events, PCI: percutaneous coronary intervention, DES: drug-eluting stent, DCB: drug coated balloon.

## Conclusion

In summary, this study demonstrated that the DCB-only strategy could achieve relatively satisfactory immediate and mid-term outcome in the treatment of LM bifurcation lesions, and it was also relatively safe. Compared to stent implantation, the DCB-only strategy has some unique advantages, such as simple surgical procedure and no residual metal stent, and it has the great potential to become a first-line treatment for LM bifurcation lesions in the future.

## Author Contributions

Conception and design of the research: Hengdao Liu, Hailong Tao and Heping Gu; acquisition of data: Shilong Zhou, Yanyan Zhao, Yang Lu, Ruihan Feng, Yubin Zhang, Junhui Xing, XiaoFei Xue, Junwei Zhao and Huilin Yang; analysis and interpretation of data: Hengdao Liu, Heping Gu, Shilong Zhou, Yanyan Zhao, Yang Lu; statistical analysis: Yang Lu, Yanyan Zhao and Junwei Zhao; drafting the manuscript: Hengdao Liu and Shilong Zhou; revision of manuscript for important intellectual content: Ruipeng Song and Heping Gu. All authors read and approved the final manuscript.

## Data Availability

The authors confirm that the data supporting the findings of this study are available within the article.

## Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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## Ethical Approval

This study was approved by the Medical Ethics Committee of the First Affiliated Hospital of Zhengzhou University.

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