Feasibility and Safety of Drug-Coated Balloon-Only Angioplasty for *De Novo* Ostial Lesions of Left Anterior Descending Artery: Two Center's Retrospective Study

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Abstract

Background:

There is limited evidence of drug-coated balloon (DCB) only angioplasty in percutaneous treatment of complex *de novo* ostial coronary lesions. The major objective of our study is to explore the feasibility and test safety of this innovative approach in ostial lesions of left anterior descending artery (LAD).

Methods:

Patients treated with paclitaxel DCB or second-generation drug-eluting stent (DES) were retrospectively enrolled from two different large centers. The primary endpoints were defined as major adverse cardiovascular events (MACE) composed of cardiovascular death, target lesion revascularization (TLR), target vessel revascularization (TVR), and recurrent myocardial infarction related to target artery occlusion. Cox regression analysis were used to identify risk factors for MACE and propensity score matching is performed to minimize the selection bias.

Results:

A total of 53 patients were treated with paclitaxel DCB and 336 patients with DES in ostial lesions of LAD were recruited. In accordance with propensity score matching, 49 patients treated with DCB-only coordinated with 49 ones with the strategy of DES. After average follow-up time of 10 months, the rate of MACE trended to lower in DCB-only angioplasty treatment arm and triggered by post-procedure TLR (MACE: 6% vs. 4%, $p=0.65$; TLR: 2% vs. 4%, $p=0.56$). Cox regression analysis indicated that not DCB-only angioplasty was considered as an independent risk factor for adverse events after adjustment for cofound risk factors (HR: 1.748, $p=0.48$).

Conclusions:

Use of DCB-only approach in treatment of isolated ostial LAD disease could be an innovative and safe strategy without additional risk of aggressive progression of left circumflex artery.

Introduction

Isolated ostial lesion of left anterior descending artery (LAD) is an unusual symptom of coronary artery disease and it presents a challenge during interventions because of high elastic fiber content and calcium[1]. Due to specific location and potential involvement of distal left main (LM) artery displayed in intravascular ultrasound studies[2, 3], the LM cross-over technique is generally recommended for the treatment of LAD ostial lesion in the era of stenting. Although results from prior studies have suggested that a highly favorable clinical outcome is expected from cross-over LM stenting, almost fifty percentage of restenosis occurred in the location of LM segment adjacent to the stent[4]. Meanwhile, the cross-over stenting which inevitably covers the ostium of left circumflex (LCX) artery became a major contributor to

the flow limitation and risk of acute occlusion or late stenosis of health LCX ostium[5–7]. The optical strategy for isolated LAD ostial lesion remains no elaborated from the current clinical evidence.

Drug-coated balloon (DCB) is considered as an emerging angioplasty which combines mechanical expansion of the vessel and reduction of neo-intimal hyperplasia without implanting protruded struts; abolishing the risk of late or very late stent thrombosis and reducing the duration of dual antiplatelet treatment[8]. In a recently published by SPARTAN DCB study, it indicated that no evidence of higher long-term mortality associated with paclitaxel DCB for *de novo* coronary artery disease was observed compared with second-generation drug eluting stent (DES) [9]. However, DCB are generally recommended for the treatment of in-stent restenosis (ISR) and small-vessel disease (diameter of < 2.5mm) based on the evidence from numerous clinical studies[10, 11]. The study by Rosenberg et al has reported that DCB-only percutaneous coronary intervention (PCI) in large coronary arteries with *de novo* lesions are equally feasible and are effective as in small vessel disease[12]. To date, the available data does not provide any support to broad usage of DCB for large *de novo* lesions, especially for lesions involving ostium[13].

As previously outlined, the objective of this study was to explore safety and efficacy of the use of drug-coated balloon in lesions at the ostium of left anterior descending artery.

Methods

Study population

This retrospective study was conducted in two different cardiac centers: Beijing Chaoyang Hospital and Sinopharm Tongmei General Hospital during the period of January 2017 to December 2019. Patients with *de novo* lesions at ostium of LAD who underwent SeQuent Please DCB angioplasty or second-generation DES due to symptomatic coronary artery disease were selected. The excluded criteria include patients with acute myocardial infarction, left ventricular ejection rate (LVEF) < 35%, end-stage renal disease or in-stent restenosis. The study followed the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments and gained the approval from the local ethical review board at two hospitals.

Lesion Preparation And Interventional Procedure

Angiography analysis was performed by two independent physicians (Dr. Li and Pressor Xu). The distance between lesions and ostium of LAD was confine to 5 mm. Those ostial LAD lesions with concomitant significant LMCA distal bifurcation stenosis were regarded as LMCA lesions and excluded from the current analysis. Hence, the bifurcation lesions in this study only involved (0,1,0) and (0,1,1) lesions on the basis of the Medina classification system. Meanwhile, fluoroscopy time (FT) and dose-area product (DAP) were recorded. All angiograms were analyzed using quantitative coronary angiographic system (QCA, CASS system). Percent diameter stenosis, reference vessel diameter, and minimal luminal diameter (MLD) were gauged before and after intervention.

DCB angioplasty with bailout stenting strategy was conducted according to international guidelines and current consensus[14]. Target lesions were pretreated with standard balloon angioplasty, a non-compliant balloon, and/or cutting balloons. When minimal residual stenosis is achieved, DCB (the recommended diameter was 0.8-1.0:1 of nominal target vessel size) can be inflated for 30–90 seconds (Fig. 1). In cases of residual stenosis > 50% or type C coronary dissections, a stent was implanted only as a bailout for the treatment of suboptimal result after the DCB.

Stent implanting was conducted using standard procedure according to the type of lesions. Stenting approaches were performed at the operator's discretion: the cross-over stenting from the LM across the LAD ostium into the diseased branch or the stenting right at the ostium of the diseased branch. Regarding the cross-over strategy—the bifurcation technique with provisional side branch was implemented. Final kissing balloon was routinely used in patients treated with cross-over stenting. Intravascular ultrasound (IVUS) was not routinely conducted.

Study Endpoints And Follow-up

The primary endpoints were defined as major adverse cardiovascular events (MACE) composited of cardiovascular death, target lesion revascularization (TLR), target vessel revascularization (TVR) and recurrent myocardial infarction related to target vessel occlusion. All patients were followed up over telephone, outpatient visit or hospital records after discharge.

Statistical analysis

Statistical analysis was undertaken using STATA system (15.0 version). Categorical variables were reported as count (percentage) and continuous variables as mean $\pm$ standard deviation. Comparisons between groups were performed using the independent Student's t-test or Mann-Whitney test for continuous variables and the χ^2 test or Fisher's exact test for categorical variables. Kaplan-Meier survival curves was performed to compare the incidence of MACE among groups. Comparisons were performed by the log-rank test. Cox regression analysis were used to identify whether the intervention strategy is considered as an independent risk factors for MACE. A 1:1 nearest neighboring propensity score matching with a default caliper distance of 0.25 was also performed to minimize selection bias. Variables for matching included age, gender, the history of myocardial infarction, hypertension, diabetes mellitus, hyperlipidemia, PCI, ejection fraction, and target vessel diameter. All tests performed were two-tailed and p-values of < 0.05 were considered a statistically significant.

Result

Baseline clinical characteristics

A total of 52 consecutive patients treated with paclitaxel DCB and 336 patients with second generation DES in ostial lesions of LAD were finally recruited. Patients treated with DES had more frequent history of

myocardial infarction, higher value of SYNTAX score and SYNTAX score II compared with the ones with DCB. After propensity score matching, 49 cases treated by the strategy of DCB-only coordinated with 49 cases treated by the strategy of DES. The two treatment groups were well balanced in terms of baseline demographic and clinical characteristics of patients (Table 1). However, patients in DES arm seem to have higher values of SYNTAX score and longer follow-up duration ($p < 0.05$).

Table 1
Baseline characteristics

	Before propensity matching			After propensity matching		
	DES	DCB	p-value	DES	DCB	p-value
N	336	52		49	49	
Age, year	61 (53, 71)	62 (54, 69)	0.66	61(55, 75)	62 (54, 68)	0.30
Sex, n (%)	268 (79.8%)	37 (71.2%)	0.20	35 (71%)	37 (76%)	0.82
Previous MI, n(%)	75 (22.3%)	1 (1.9%)	< 0.001	3 (6%)	1 (2%)	0.31
Previous PCI, n(%)	87 (25.9%)	8 (15.4%)	0.10	6 (12%)	8 (16%)	0.56
DM, n(%)	129 (38.4%)	13 (25.0%)	0.062	12 (24%)	12 (24%)	1.00
Hypertension, n(%)	183 (54.5%)	24 (46.2%)	0.26	21 (43%)	23 (47%)	0.68
Hyperlipemia, n(%)	180 (53.7%)	15 (28.8%)	< 0.001	17 (35%)	15 (31%)	0.67
Smoker, n(%)	240 (71.4%)	22 (42.3%)	< 0.001	30 (61%)	22 (45%)	0.16
Creatinine, mmol/L	83.47 (72.58)	70.72 (14.3)	0.21	66.2 (15.34)	71.1 (14.72)	0.11
EF, %	54.76 (12.38)	60.67 (9.83)	0.001	58.1 (12.2)	60.1 (9.84)	0.36
SYNTAX score	24.66 (8.67)	17.36 (6.92)	< 0.001	20.9 (8.17)	17.6 (7.00)	0.04
SYNTAX score II	30.56 (11.07)	25.02 (6.71)	< 0.001	26.1 (7.34)	24.8 (6.84)	0.39
Continuous variables were presented as mean (SD) or median (IQR) and categoric variables were shown as n (%). MI, myocardial infarction; PCI, percutaneous coronary intervention; DM, diabetes mellitus; EF, ejection fraction.						

Angiographic characteristics and quantitative coronary analysis

The characteristics of angiography and procedure and details of QCA were presented on Table 2. The groups were well balanced in accordance with significant lesions targeted with no difference in left main coronary artery, left anterior descending artery and left circumflex artery. According to the angiographic characteristics, the DCB group trend to lower frequent of multivessel disease and calcified lesions (61% vs. 41%, $p = 0.07$ and 10% vs. 2%, $p = 0.09$, respectively). Among all the procedures, the cross-over technique was conducted in 64% DES patients and 100% DCB patients ($p < 0.001$). On the other hand, both the total amount of fluoroscopy time and dose-area product significantly dwindled in DCB group, in contrast with the ones in DES group ($p < 0.001$). In the DCB treatment group, one case was received by the bailout stent due to the C-type dissection following predilatation and eleven patients complicated with blood pressure descent for duration of DCB dilatation. In terms of QCA data, it indicated that the DCB group had smaller post-procedural minimal lumen diameter ($2.78 \pm 0.38\text{mm}$ vs. $3.10 \pm 0.39\text{mm}$, $p < 0.001$) and higher diameter stenosis ($33.05 \pm 11.88\%$ vs. $19.78 \pm 10.75\%$, $p < 0.001$) while the DES group had significantly more aggressive targeted artery stenosis ($91.21 \pm 6.47\%$ vs. $87.94 \pm 7.55\%$, $p = 0.03$).

Table 2

The angiographic and procedural characteristic of quantitative coronary angiography analysis

Factor	DES group	DCB group	p-value
N	49	49	
Angiographic feature			
Multivessel disease, n (%)	30 (61%)	20 (41%)	0.07
Bifurcation angle > 90°, n (%)	40 (82%)	45 (92%)	0.23
Calcified lesion, n (%)	5 (10%)	1 (2%)	0.09
Medina classification, n (%)			0.81
(0, 1, 1)	12 (24%)	10 (20%)	
(0, 1, 0)	37 (76%)	38(78%)	
Procedural characteristic			
Cross-over, n (%)	30 (64%)	49 (100%)	< 0.001
IVUS, n (%)	-	5 (10.2%)	-
Type-C dissection, n (%)	-	1 (2.0%)	-
Blood pressure descent, n (%)	-	11 (22.4%)	-
DAP, Gy/cm ²	187 (140, 236)	94 (84.3, 105)	< 0.001
Intervention time, minutes	90 (75, 108)	65 (56, 78)	< 0.001
Previous intervention			
LMCA RVD, mm	4.30 (0.75)	4.16 (0.72)	0.35
LMCA MLD, mm	3.88 (0.65)	3.79 (0.79)	0.54
LMCA, %	16.75 (13.72)	16.33 (16.48)	0.89
LAD RVD, mm	3.52 (3.22, 3.63)	3.44 (3.04, 3.63)	0.33
LAD MLD, mm	0.96 (0.44)	1.11 (0.51)	0.13
LAD DS, %	91.21 (6.47)	87.94 (7.55)	0.03
TL length, mm	22.03 (10.26)	19.15 (5.69)	0.10
LCX RVD, mm	3.07 (0.60)	3.14 (0.71)	0.60
Continuous variables were presented as mean (SD) or median (IQR) and categoric variables were shown as n (%). DCB, Drug-coated balloon; DES, Drug-eluting stents; DAP, dose-area product; LMB, left main branch; LMCA, left main coronary artery; LAD, left anterior descending artery; LCX, left circumflex artery; RVD, reference vessel diameter; MLD, minimal lumen diameter; DS, diameter stenosis; IVUS, intravascular imaging.			

Factor	DES group	DCB group	p-value
LCX MLD, mm	2.73 (0.67)	2.80 (0.72)	0.62
LCX DS, %	20.74 (17.62)	20.53 (15.77)	0.95
Post intervention			
LM RVD, mm	4.35 (0.73)	4.14 (0.66)	0.17
LM MLD, mm	3.99 (0.70)	3.88 (0.65)	0.48
LM DS, %	14.73 (14.01)	11.06 (10.58)	0.18
LAD RVD, mm	3.50 (3.21, 3.65)	3.35 (3.03, 3.57)	0.12
LAD MLD, mm	3.10 (0.39)	2.78 (0.38)	< 0.001
LAD DS, %	19.78 (10.75)	33.05 (11.88)	< 0.001
LCX RVD, mm	3.05 (0.64)	3.08 (0.66)	0.81
LCX MLD, mm	2.68 (0.64)	2.78 (0.73)	0.53
LCX DS, %	25.01 (17.79)	19.01 (17.25)	0.12
Continuous variables were presented as mean (SD) or median (IQR) and categoric variables were shown as n (%). DCB, Drug-coated balloon; DES, Drug-eluting stents; DAP, dose-area product; LMB, left main branch; LMCA, left main coronary artery; LAD, left anterior descending artery; LCX, left circumflex artery; RVD, reference vessel diameter; MLD, minimal lumen diameter; DS, diameter stenosis; IVUS, intravascular imaging.			

Clinical Outcomes

The median follow-up duration for all eligible patients was 16 months and 10 months in DES group and DCB group, respectively (Table 3). Though some statistical difference of follow-up duration was observed ($p < 0.001$), the cumulative incidence of MACE and all-cause mortality was similar between two group (MACE: 11.3% vs. 3.8%, $p = 0.10$; all-cause mortality: 3.3% vs. 0.0%, $p = 0.19$). There was a recurrent myocardial infarction due to acute vessel closure and two target lesion revascularizations in DCB group.

Table 3
The cumulative incidence of MACE

	Before propensity matching			After propensity matching		
	DES	DCB	p-value	DES	DCB	p-value
N	336	52		49	49	
Time, month	16 (11, 21)	10 (9, 12)	< 0.001	12 (10, 13)	10 (9, 12)	0.16
MACE Total, n(%)	38 (11.3%)	2 (3.8%)	0.10	3 (6%)	2 (4%)	0.65
cardiovascular mortality, n(%)	11 (3.3%)	0 (0.0%)	0.19	1 (2%)	0 (0%)	0.31
MI related to target vessel occlusion, n(%)	9 (2.7%)	1 (1.9%)	0.75	0 (0%)	1 (2%)	0.31
TVR, n(%)	25 (7.4%)	0 (0.0%)	0.04	2 (4%)	0 (0%)	0.15
TLR, n(%)	5 (1.5%)	2 (3.8%)	0.23	1 (2%)	2 (4%)	0.56
Abbreviation: MACE, major adverse cardiovascular events; MI, myocardial infarction; TVR, target vessel revascularization; TLR, target lesion revascularization.						

In the propensity score analysis (49 patients in each group), overall event's rates in both groups were too low to find any significant differences regarding adverse outcomes among two groups (MACE: 6% vs. 4%, $p = 0.65$). MACE rate is relative lower in DCB-only angioplasty treatment arm and mainly triggered by post-procedure TLR.

Cox Hazard Regression And Kaplan-meier Survival Curves

There was no evidence of increased adverse events related to paclitaxel DCB for ostial de novo coronary artery lesion. The Kaplan-Meier survival curves indicated that the cumulative incidence of MACE was similar between two groups after propensity score analysis (log-rank test, $p = 0.78$; Fig. 2). Meanwhile, Cox regression analysis demonstrated that not the strategy of angioplasty but prior PCI was considered as an independent risk factor for adverse events following the treatment of ostial LAD lesions (HR = 1.748, 95% CI = 0.371–8.240, $p = 0.48$; HR = 3.081, 95% CI = 1.234–7.694, $p = 0.02$, respectively) (Table 4).

Table 4
Cox proportional hazard regression analyses for major adverse cardiovascular events

	Univariate analysis		Multivariable analysis	
	HR (95%CI)	P	HR (95%CI)	P
DCB strategy	1.224 (0.280, 5.344)	0.78	1.748 (0.371, 8.240)	0.48
Age	1.019 (0.991, 1.048)	0.18	1.017 (0.988, 1.01)	0.24
Male	1.086 (0.458, 2.573)	0.85	0.981 (0.391, 2.458)	0.97
History of PCI	2.334 (1.131, 4.816)	0.02	3.081 (1.234, 7.694)	0.02
History of MI	1.981(0.925, 4.245)	0.08	0.948 (0.231, 3.928)	0.95
Diabetes mellitus	1.251 (0.606, 2.583)	0.54	0.904 (0.413, 1.978)	0.80
Hypertension	0.941 (0.459, 1.926)	0.87	0.773 (0.354, 1.688)	0.52
Hyperlipemia	1.22 (0.591, 2.517)	0.59	1.107 (0.483, 2.543)	0.81
Current smoking	1.170 (0.757, 1.807)	0.48	0.916 (0.547, 1.532)	0.74
EF	0.987 (0.957, 1.017)	0.40	0.982 (0.950, 1.016)	0.30
Creatinine	1.007 (0.997, 1.017)	0.17	1.009 (0.998, 1.020)	0.08
SYNTAX	1.013 (0.977, 1.052)	0.48	1.019 (0.979, 1.062)	0.35
Abbreviation: DCB, drug coated balloon; PCI, percutaneous coronary intervention; MI, myocardial infarction; EF, ejection fraction.				

Discussion

DCB only-strategy is recommended by guidelines for the treatment of an ISR while there is also favorable evidence of feasibility and safety for the use of DCB-only angioplasty on both small and large *de novo* coronary artery disease[9, 12, 15]. In this retrospectively two-center study, our main finding suggested that similar results between the treatment of DCB-only and DES strategy on ostial lesion of LAD were observed during the average median of 10 months. Hence, this study could throw light on the feasibility and safety of the use of DCB in special LAD ostial lesions.

In era of stent implanting, percutaneous procedures of ostial lesion remained challenge due to their complex geographic feature and skilled technical warrant. In case of inaccurate stent localization at the LAD focal ostium, it could undoubtedly contribute to the potential risk for plaque shift into the LM and/or the LCX and for distal LM damages related to balloon dilatation, which in turn may predispose the LM segment adjacent to the stent to stimulate a progressive restenosis lesion[16]. On the other hand, deploying a cross-over stent in ostium of LAD could increase risk of recurrent restenosis or stent thrombosis in setting of normal left main coronary artery. Occasionally, there is the possibility of bail-out

two sent technology which is susceptible to higher risk of in-stent stenosis. Prior results from series of studies demonstrated that the lesions and procedural involvement of left main bifurcation have been shown to be an independent risk factor of in-stent restenosis[17, 18]. In the contrast, no progression of LCX stenosis and minimal lumen diameter was observed in DCB arm, similarity to other register studies[19, 20]. On the other hand, the absolute increase in DAP values for patients

receiving DCB-only approach instead of DES was 93 Gy/cm². This significant difference indicated that DCB-only strategy has an advantage of lowering exposure time and dose of ionizing radiation. As the result presented above, the DCB-only angioplasty not only has an advantage of protection of ostium LCX, but also simplifies the complex of crossover stent technique, involving guidewire or jailed balloon side branch protection, post-procedural rewiring, kissing balloon angioplasty and proximal optimization technique, and further diminishes ionizing radiation exposure time and the amount of radiation dose which is likely to impair cardiologist and patients' lens and take higher risk of tumors[21, 22] .

Previously, interventional strategy with coronary stenting remained prevalence in part due to elimination of lesion recoil and the reocclusion of the infarct artery related to balloon angioplasty. However, in recent published study of *Brodie et al* which recruited 2195 consecutive STEMI patients treated with drug-eluting or bare metal stents or balloon angioplasty from 1994 to 2010, patients treated by balloon-only angioplasty had similar trend for one-year cardiovascular mortality and reinfarction rates compared with the ones treated with BMS or DES[23], similarity to results as our paper presented. The efficacy and safety of DCB with SeQuent Please in the treatment of native-vessel coronary artery disease have been extensively reported[13]. As the largest randomized clinical study to date, BASKET-SMALL 2 compared Sequent Please DCB-only approach with everolimus or Taxus DES in the treatment of small de novo coronary artery(< 3mm). It indicated that DCB is non-inferior to DES regarding MACE (7.5% vs. 7.3%) while patients in the DCB arm faced higher risk of cardiac death (3.1% vs. 1.3%) than DES arm without statistically significant during 12 months follow-up[24]. Furthermore, series of clinical studies demonstrated that Sequent Please DCB-only strategy is also safe and as efficient in de novo lesions of large coronary vessels[12, 25, 26]. Regardless of coronary lumen and lesion location, DCB angioplasty presented the similar rates of adverse clinical outcomes from previous results to our data as this study presented. Meanwhile, the recent published study of Kook *et al*[27] reported the comparable long-term clinical outcomes of DES and Sequent Please DEB in patients with in-stent restenosis involving left main bifurcation. According to incidence of target vessel revascularization from our study, it indicated that the treatment of a drug-coated balloon-only approach to de novo angioplasty could avoid late and very late in-stent thrombosis, reduce early restenosis and neo-atheroma formation, and simplify the procedure.

Despite of the confirmed advantage of DCB on *de novo* lesions, the limitation of DCB restricted by acute vessel closure due to elastic recoil and flow-limiting dissections should not be underestimated. Signiant notable feature of BASKET-SMALL 2[24] were 14% failed cases due to dissection or residual stenosis following predilatation. This scarce but fatal immediate side effect of DCB-only approach seems to be taken consideration by the majority of inventors. In this present study, only one patient (2%) in DCB arm suffered the acute occlusion and received the bailout stent in ostial LAD. These favorable results partly

derived from less calcified lesion selected by experienced operators. In the pathogenesis of ACS, the calcified plaque is the least frequent etiology, but associated with aggressive lesion preparation which entails predilatation with a high-pressure post-balloon, a large-sized balloon, or a cutting balloon [28, 29]. Accordingly, the potential risk of coronary dissection inevitably ramp up due to this approach to achieve sufficient lumen area. In the study of Sugiyama et al[1], superficial calcific sheet, one type of calcified plaque, prefers to dominate in area of LAD and needs debulking or plaque modification such as rotational and orbital atherectomy. Alternatively, similarly to the other registers[12, 30–32], the middle-term TLR rates was as low as 4% in spite of up to 30% residual stenosis of target coronary artery. The uncompact predilatation completed prior to the treatment of DCB-only approach could contribute to subsequent addition stenting implantation and increased TLR rates[12, 33]. Hence, it's worth noting that rigorous lesion preparation to achieve an acceptable angiographic result before use of DCB was mandatory to avoid complications.

Limitations

There are some limitations with regards to this study. First, this retrospective feature of our data is the major limitation as it can introduce unavoidable referral bias. However, the practitioners from those two centers located in different districts could provide more than a thousand cardiac interventions annually and minimized the selection bias. Second, the accuracy of lumen measures and further comparisons in all details confined to a relative low proportion of IUVS conducted in our study and the absence of follow-up angiography. Nevertheless, the advantage of this study is, it presents the real-world data and the propensity score matching could alleviate the credibility of data analysis. Finally, this current analysis didn't involve moderate or severe calcified cases and had lower proportion of complicate bifurcation lesion. This selection bias could give rise to subsequent favorable outcomes and the limitation of widespread applications.

Conclusions

Despite of deficiency of evidence, the use of DCB-only approach in treatment of *de novo* lesions at the ostium of LAD could be an innovative, feasible and safe strategy without additional risk of progression of the disease with LCX.

Abbreviations

DCB

drug-coated balloon; DES:drug-eluting stent; MACE:Major adverse cardiovascular events; TLR:target lesion revascularization; TVR:target vessel revascularization; LAD:left anterior descending artery; LCX:left circumflex artery; PCI:percutaneous coronary intervention; IVUS:Intravascular ultrasound; MLD:minimal luminal diameter; LVEF:Left ventricular ejection fraction; QCA:quantitative coronary angiographic system; FT:fluoroscopy time; DAP:dose-area product

Declarations

Availability of data and materials

The datasets generated and analyzed during the current study are not publicly available because of the restrictions by the Beijing Chaoyang Hospital and Sinopharm Tongmei General Hospital who are the data owners. This dataset is only available for the authors under an agreement with both two hospitals for the current study.

Ethics approval and consent to participate

This study was approved by the institutional review board of Beijing Chaoyang Hospital and performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. Written informed consent was obtained from all patients or their legal relatives.

Consent to publication

Not applicable.

Competing interests

All authors declare no conflict of interest.

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Authors' contributions

Dr. CL and Professor LX conceived the present study, participated in the design, conducted data analysis and drafted the manuscript. Dr. XBD collected and assembled all data. Dr. LPL and Dr. CL commented on the manuscript drafts. Dr. LFW and Professor LX provided material and technical support and commented on the manuscript drafts. Dr. KBL and Professor XCY aided interpretation of data, commented on this study design and provided critical review. All authors have read and approved the manuscript.

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Disclosure and conflicts of interest

All of authors declare no potential conflicts of interests.

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Figures

Figure 1

(a). Angiography showing 80% ostial stenosis of LAD and normal LMB and LCX from two different angles. (b) Pre-procedural IUVS confirmed the minimal lumen area of LAD ostial lesions. (c). The 2.0mm×15mm balloon was pre-dilated at LAD ostial lesions; (d). The 3.0mm×10mm cutting balloon was repeatedly predilated at LAD ostial lesions; (e). The 3.5mm ×20mm DCB was dilated with 7 atm ×60 seconds; (f).

The post-procedural angiology showing significant stenosis decreasing; (g). Post-procedural IUVS confirmed the minimal lumen area and the extent of dissection following DCB-only.

Figure 2

(a) The Kaplan-Meier survival estimates between DES group and DCB group before neighboring propensity score matching; (b) The Kaplan-Meier survival estimates between DES group and DCB group after neighboring propensity score matching.