Original Article

Retrospective study of treatment with a drug-coated balloon alone is beneficial for ostial coronary lesions

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Background: The effects of ostial coronary lesion (OCL) treatment with a drug-coated balloon (DCB) alone remain controversial. This retrospective study assessed the effectiveness and safety with DCB only strategy for OCL and the factors associated with target lesion revascularization (TLR) in these patients.

Methods: The study retrospectively included patients whom had OCLs treated with a paclitaxel-eluting DCB only strategy from 1 May 2014 to 1 May 2017. Patients were divided into in-stent restenosis (ISR) and *de novo* (primary) groups. And all patients came back to hospital, and underwent clinical and also angiographic follow-up.

Results: Among the 44 patients with 55 OCLs, 12 (27.3%) were assigned to the ISR group and 32 (72.7%) to the *de novo* group. The outcomes included TLR, post-interventional lumen gain, and late lumen loss (LLL). Only 8 TLRs (7 ISR and 1 *de novo*) were observed after a mean follow-up of 16 months. The TLR rate in the *de novo* group was significantly lower than the ISR group (2.4% *vs.* 50%, P<0.001). The LLL was 0.07±0.63 mm. Logistic regression analysis showed that the TLR incidence was independently associated with the type of stenosis (ISR *vs. de novo*) after adjusting for sex [odds ratio (OR), 58.72; 95% confidence interval (CI): 4.42–779.94, P=0.002].

Conclusions: Treatment with DCB alone was beneficial to patients with OCLs, particularly those with *de novo* lesions.

Keywords: Drug-coated balloon (DCB); coronary artery disease (CAD); ostial coronary lesion (OCL); angioplasty

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Introduction

Atherosclerotic coronary artery disease (CAD) is a leading cause of global morbidity and mortality, with severe coronary ostial stenosis prevalence at 2.6% (1). The involvement of a large myocardial area can cause extensive myocardial ischemia, emphasizing the clinical significance of ostial coronary lesions (OCLs). Percutaneous coronary intervention (PCI) with drug-eluting stent (DES) implantation has become the leading non-pharmacological therapy for OCLs. However, the in-stent restenosis (ISR) incidence, particularly ostial restenosis, in OCLs is higher than in non-OCLs, and is associated with poor clinical outcomes (2-4). Hsieh *et al.* studied the prevalence of ISR in OCLs after treatment with DESs and bare-metal stents (BMSs) and observed restenosis prevalence rates of 6–8% and 33%, respectively (5).

Windecker *et al.* suggested that drug-coated balloons (DCBs) might be an alternative intervention strategy to DESs because they are simpler to implant. DCBs could

reduce the intraoperative use of contrast agents, the duration of postoperative dual-antiplatelet therapy (1–3 months), and residual metal or polymer (6). Moreover, DCBs were demonstrated to be a safe and effective alternative to DESs in patients with CAD (7). DCBs could improve the immediate and long-term outcomes for ISR and *de novo* lesions (8-12). However, only a few studies have reported DCB only treatment strategy for OCLs, especially for *de novo* OCLs.

This retrospective study assessed the effectiveness and safety with DCB only strategy for OCL and the factors associated with target lesion revascularization (TLR) in these patients. We present the following article in accordance with the STROBE reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-22-270/rc).

Methods

Patients

This study retrospectively included patients with stenotic lesions were treated at rBeijing hospital between 1 May 2014 and 1 May 2017, 50% of whom had OCLs. The OCLs were treated with a paclitaxel-eluting DCB (SeQuent Please; B. Braun Melsungen AG, Berlin, Germany) during angioplasty. An OCL was defined as a coronary ostial lesion if the lesion started <3 mm from the orifice of the left main coronary artery (LM) or right coronary artery (RCA), or as a branch ostial lesion if it started <3 mm from the left anterior descending artery (LAD), left circumflex artery (LCX), marginal arteries, posterior descending artery, or posterolateral artery. Based on stent implantation history, the patients were divided into previously stented and *de novo* groups. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the ethics committee of Beijing Hospital (No. 2016BJYYEC-067-01) and the requirement for informed consent was waived.

Procedure

Arterial catheterization was performed through the radial or femoral artery. The patients received 300 mg aspirin as a loading dose and 300 mg clopidogrel 1 day before the procedure. Heparin was administered as an initial bolus of 70–100 IU/kg body weight and then an additional dose of 1,000 IU every hour. The administration of glycoprotein IIb/IIIa antagonists was decided by the treating surgeons. Baseline angiography of the target vessel was performed after intracoronary injection of nitroglycerin (100–200 μg). At least 2 near-orthogonal views free of foreshortening and vessel overlap in the target lesion were acquired. Following the German Consensus Group recommendations on the use of DCBs (13), we performed predilatation with conventional balloons and dilation of non-compliant, cutting, or dual-wire balloons with a balloon-to-vessel diameter ratio of 0.8–1.0 to reduce the intimal dissection risk before using a paclitaxel-releasing balloon catheter. If the final predilatation outcome was satisfactory [with residual stenosis ≤30%, grade 3 flow according to Thrombolysis in Myocardial Infarction (TIMI) criteria, and no lesion or type A/B dissection based on the National Heart, Lung, and Blood Institute criteria (13), the patients were considered eligible for DCB therapy.

For DCB treatment, the balloon-to-vessel diameter ratio was maintained at 0.8–1.0, and the balloon ends extended 2–3 mm beyond the lesion margins under a pressure of 8–12 atm for ≥30 s. If re-dilatation was necessary after releasing the DCB, the balloon was used without drug coating to avoid drug overdose. Each DCB catheter was used only once. The procedure was considered successful if quantitative coronary angiography (QCA) exhibited residual stenosis of ≤30% and a grade 3 TIMI flow. The DCB treatment was considered to have failed if any of the following events occurred: an apparent dissection (NHLBI65 type C or above), TIMI flow below grade 3, or the need for "bailout" stenting.

Assessment of coronary lesions

The enrolled patients' targeted coronary lesions were analyzed using the built-in Quantitative Coronary Analysis software package of the Allura Xper FD20 Angiography System (Philips Healthcare, Amsterdam, the Netherlands). The minimal luminal diameter (MLD), lesion length, percent stenosis diameter, and percent stenosis area were measured or calculated and recorded as part of routine clinical workup by 2 individuals blinded to the study protocol. Measurements were performed in triplicate for each lesion, and the mean values were used for analysis.

Data collection and follow-up

The general demographic features, clinical status, associated risk factors, CAD characteristics, previous stent implantation,

and DCB characteristics were analyzed. Comprehensive inpatient and outpatient data were collected from the medical records, and interviews with patients and their coronary angiograms were analyzed.

The analyzed outcomes included target lesion revascularization (TLR), acute gain, and late lumen loss (LLL). TLR was defined as any repeated percutaneous intervention or surgical bypass performed for the target lesion because the treated segment showed >50% restenosis.

All patients came back to hospital and underwent clinical and also angiographic follow-up until 1 December 2019. The clinical data and coronary angiogram results of these patients were analyzed.

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics, version 21.0 (IBM Corp., Armonk, NY, USA). Quantitative data with normal distribution are expressed as mean ± standard deviation. Categorical variables were compared using the chi-squared test, whereas continuous variables were compared using analysis of variance (ANOVA). The 2 groups (with and without ISR) were compared for continuous variables using one-way ANOVA. Partial correlation analysis was performed to examine the relationship between the DCB and clinical parameters. An exact logistic regression analysis was performed to identify independent factors associated with TLR using Statistics Analysis System version 9.4 (University Edition). Significantly different variables were input into the exact logistic regression test. Differences with P<0.05 were considered statistically significant.

Results

Baseline patient characteristics

All 55 lesions of 44 patients were included in the study. Twelve (27.3%) patients were in the ISR group and 32 (72.7%) were in the *de novo* group. The mean age was 64.4±10.8 years, and 68.2% of patients were male. Of the 44 patients, 81.8% had hypertension, 56.8% had diabetes mellitus, 79.5% had hyperlipidemia, and 70.5% were current smokers. Additionally, 40% of the patients had triple-vessel CAD. The most prevalent clinical condition in our study cohort was unstable angina (81.8%). Eight (18.2%) patients had non-ST segment elevation myocardial infarction (NSTEMI). One patient with end-stage renal disease required hemodialysis. The mean estimated glomerular filtration rate (eGFR) was 75.8±20.6 mL/min. The lesion-related arteries were located in the LM (2 lesions), LAD (10 lesions), LCX (9 lesions), RCA (4 lesions), diagonal branch (17 lesions), marginal branch (4 lesions), posterior descending (7 lesions), and posterolateral (2 lesions). Most branches with OCLs (LAD, LCX, marginal, posterior descending, and posterolateral) were of Medina type 0.0.1 (43.6%; *Table 1*).

Coronary angiography after DCB

Angiography after PCI revealed that the stenosis diameter was 73.13±17.60 mm. While the pre-procedure MLD was 0.76±0.54 mm, the post-procedure MLD was 1.93±0.62 mm. All OCLs were predilated, and a cutting balloon was used in 9 lesions (21.9%). The mean length of the DCB was 17.56±3.97 mm, the mean diameter was 2.67±0.53 mm, and the mean dilation pressure was 8.65±2.09 atm. No immediate complications related to PCI were recorded (*Table 2*).

Outcomes after DCB treatment and factors related to TLR incidence

No mortality was observed, and the immediate procedure success rate was 100%. The TLR rate differed between the ISR and *de novo* groups (50% *vs.* 2.4%, P<0.001). Of the 8 TLRs, 7 were due to ISR of the OCL (3 in the LCX, 2 in the RCA, and 2 in a diagonal branch), and 1 was due to a *de novo* OCL in a posterolateral branch (*Table 3*).

We observed 7 TLRs in 14 OCLs in the ISR group and only 1 TLR in 41 OCLs in the *de novo* group. Angiography showed no difference between the groups in the postoperative and follow-up MLD (1.76±1.31 *vs.* 1.88±0.64 mm; P=0.187). The acute gain in MLD in the ISR group OCLs was significantly higher than in the *de novo* group. However, the LLL at follow-up in the *de novo* group was significantly larger than in the ISR group (0.61±0.85 *vs.* –0.1±0.41 mm, P<0.001; *Table 3*).

Exact logistic regression analysis showing that age, sex and ISR lesion independently associated with TLR (*Table 4*).

OCL comparison between the ISR and de novo groups

The groups were similar in age, sex, risk factors, body mass index, lesion location, and Medina classification (P>0.05 for all; *Table 3*). More cutting balloons were used during the PCIs in the *de novo* group than in the ISR group (9 *vs.* 0). The predilatation diameter and length of the balloon

Table 1 Demographic and clinical characteristics of patients with ISR and *de novo* OCLs

Clinical characteristics	Total (n=44)	ISR (n=12)	*De novo* (n=32)	P
Age, years, mean ± SD	64.4±10.8	61.1±12.2	65.5±10.2	0.348
Males, n (%)	30 (68.2)	8 (66.6)	22 (68.7)	0.432
Risk factors				
DM, n (%)	25 (56.8)	9 (75.0)	16 (50.0)	0.092
Hypertension, n (%)	36 (81.8)	12 (100.0)	24 (75.0)	0.055
Dyslipidemia, n (%)	35 (79.5)	10 (83.3)	25 (78.1)	0.153
Current smoker, n (%)	31 (70.5)	7 (58.3)	24 (75.0)	0.420
Renal impairment (eGFR, mL/min)	75.8±20.6	78.68±27.49	74.81±17.98	0.549
BMI, kg/m^2	25.38±2.68	24.59±2.17	25.54±2.79	0.252
PCI, n (%)	27 (61.3)	12 (100.0)	25 (78.1)	NA
Clinical presentation				0.217
UAP, n (%)	36 (81.8)	8 (66.6)	28 (87.5)	
NSTEMI, n (%)	8 (18.2)	4 (33.3)	4 (12.5)	
Three-vessel disease, n (%)	22 (40.0)	3 (21.4)	19 (46.3)	0.249
LVEF, mean ± SD	61.8±8.4	61.42±4.63	61.31±9.46	0.967
Lesions	(n=55 lesions)	(n=14 lesions)	(n=41 lesions)	
Lesion location, n (%)				0.520
LM	2 (3.6)	1 (7.1)	1 (2.4)	
LAD	10 (18.2)	3 (21.4)	7 (17.1)	
LCX	9 (16.4)	4 (28.6)	5 (12.2)	
RCA	4 (7.3)	2 (14.3)	2 (4.9)	
D	17 (30.9)	3 (21.4)	14 (34.1)	
OM	4 (7.3)	0 (0)	4 (9.8)	
PDA	7 (12.7)	1 (7.1)	6 (14.6)	
PL	2 (3.6)	0 (0)	2 (4.9)	
Medina type, n (%)				0.313
0.0.1	24 (43.6)	4 (28.6)	20 (48.8)	
0.1.1	8 (14.5)	2 (14.3)	6 (14.6)	
1.1.1	14 (25.5)	4 (28.6)	10 (24.4)	
0.1.0	9 (14.4)	4 (28.6)	5 (12.2)	

ISR, in-stent restenosis; OCL, ostial coronary lesion; SD, standard deviation; DM, diabetes mellitus; eGFR, estimated glomerular filtration rate; BMI, body mass index; PCI, percutaneous coronary intervention; UAP, unstable angina pectoris; NSTEMI, non-ST segment elevation myocardial infarction; LVEF, left ventricular ejection fraction; LM, left main coronary artery; LAD, left anterior descending artery; LCX, left circumflex artery; RCA, right coronary artery; D, diagonal branches; OM, obtuse marginal; PDA, posterior descending artery; PL, posterolateral; NA, not applicable.

Table 2 Coronary angiography data and follow-up after DCB

Item	Total (n=55 lesions)	ISR (n=14 lesions)	*De novo* (n=41 lesions)	P
Cutting balloon predilatation, n (%)	9	0	9 (21.9)	0.055
Predilatation balloon diameter, mm	3.50±2.60	2.82±0.61	2.52±0.43	0.052
Predilatation balloon length, mm	13.16±2.71	14.14±2.41	12.8±2.75	0.119
Predilatation balloon pressure, atm	12.21±3.7	14.0±3.59	11.6±3.63	0.038
Balloon angioplasty (SeQuent Please®)				
Balloon diameter, mm	2.67±0.53	3.01±0.46	2.55±0.50	0.481
Balloon length, mm	17.56±3.97	19.28±4.25	16.97±3.74	0.573
Balloon pressure, mmHg	8.65±2.09	9.28±2.49	8.43±1.92	0.193
Balloon inflation time, s	41.83±9.26	43.92±8.80	41.12±9.41	0.499
Reference diameter, mm	2.73±0.56	3.16±0.51	2.58±0.51	0.776
Diameter stenosis (visual), mm	84.00±10.55	88.92±10.41	82.31±10.19	0.144
Diameter stenosis (QCA), mm	73.13±17.60	82.29±17.28	67.57±19.67	0.293
Area stenosis (QCA), mm^3	87.59±12.02	93.80±10.65	85.46±11.83	0.161
Follow-up (months)	15.60±8.7	21.29±11.7	13.66±6.54	0.005

DCB, drug-coated balloon; ISR, in-stent restenosis; QCA, quantitative coronary angiography.

Table 3 Comparison of the MLD in the 55 lesions at follow-up

Item	Total (n=44)	ISR (n=14)	*De novo* (n=41)	P
TLR, n (%)	8 (18.2)	7 (50.0)	1 (2.4)	<0.001*
Pre-procedure MLD, mm	0.76±0.54	0.59±0.59	0.81±0.52	0.414
Post-procedure MLD, mm	1.93±0.62	2.37±0.70	1.77±0.51	0.062
Acute gain, mm	1.16±0.72	1.77±0.81	0.95±0.55	<0.001#
Follow-up MLD, mm	1.85±0.85#	1.76±1.31	1.88±0.64	0.187
LLL	0.074±0.63	0.61±0.85	−0.1±0.41	<0.001#

#, follow-up MLD *vs.* post-procedure MLD, P<0.001; *, TLR in *de novo* OCLs *vs.* TLR in OCLs with ISR. MLD, minimal luminal diameter; ISR, in-stent restenosis; TLR, target lesion revascularization; LLL, late lumen loss; OCL, ostial coronary lesion.

Table 4 Exact logistic regression analysis showing factors independently associated with TLR

Item	OR	95% CI	P
Age	1.02	0.924–1.147	0.6975
Sex (female)	10.11	0.35–987.2	0.2727
Lesion type (ISR)	67.82	3.258–999.99	0.0007

Variables included in the original model (backward stepwise) were age, sex, the presence of diabetes mellitus, hypertension, lipid disorder, coronary artery disease, LVEF <50%, pre-minimal luminal diameter, and the lesion type. TLR, target lesion revascularization; OR, odds ratio; CI, confidence interval; ISR, in-stent restenosis; LVEF, left ventricular ejection fraction.

Table 5 Patient characteristics and clinical parameters based on the TLR status

Clinical characteristic	No TLR (n=47)	With TLR (n=8)	P
Age (year)	65.2±10.2	59.4±13.7	0.163
Female, n (%)	9 (19.1)	4 (50.0)	0.079
BMI (kg/m^2)	25.3±2.7	26.0±2.5	0.491
Risk factors, n (%)			
DM	20 (42.6)	5 (62.5)	0.445
Hypertension	38 (80.9)	8 (100.0)	0.327
Current smoker	27 (57.4)	4 (50.0)	0.718
Lipid disorder	29 (61.7)	6 (75.0)	0.696
PCI	42 (89.4)	7 (87.5)	0.258
Clinical presentation, n (%)			
UAP	40 (85.1)	5 (62.5)	0.149
NSTEMI	7 (14.9)	3 (37.5)	
LVEF <50%	2 (4.3)	0 (0)	1.00
Stage lesion, n (%)			
Single	18 (38.3)	5 (62.5)	0.442
Double	9 (19.1)	1 (12.5)	
Triple	20 (42.6)	2 (25.0)	
Lesion type, n (%)			
ISR	7 (14.9)	7 (87.5)	<0.001
De novo	40 (85.1)	1 (12.5)	
Acute gain (mm)	1.0 (0.6–1.4)	1.5 (1.2–1.8)	0.141
Pre-MLD (mm)	0.9 (0.4–1.2)	0.4 (0–0.8)	0.071
Post-MLD (mm)	1.8 (1.4–2.3)	1.9 (1.6–2.2)	0.892
Follow-up (months)	12 [9–18]	19 [16–28]	0.065

Values are expressed as mean ± standard deviation, median with interquartile range, or n (%). TLR, target lesion revascularization; BMI, body mass index; DM, diabetes mellitus; PCI, percutaneous coronary intervention; UAP, unstable angina pectoris; NSTEMI, non-ST segment elevation myocardial infarction; LVEF, left ventricular ejection fraction; ISR, in-stent restenosis; pre-MLD, before PCI minimal luminal diameter; post-MLD, post PCI minimal luminal diameter.

were similar in both groups (P>0.05); however, the mean predilatation balloon pressure was higher in the ISR group than in the *de novo* group. The mean length, diameter, dilation pressure, inflation time, and pre- and post-PCI MLD of DCBs were all similar in the 2 groups (P>0.05 for all; *Table 5*).

Discussion

The present study demonstrated the efficacy and safety of treating OCLs with DCB alone. Recurrent TLR after treating OCLs with DCB occurred more often in the ISR group than in the *de novo* group.

Ostial stenosis is a unique situation that challenges cardiovascular surgeons (14). The treatment of ostial stenosis cases involves technically difficult interventions in both *de novo* and restenosis lesions. They are also prone to a high rate of complications such as ISR. In our study, all OCLs exhibited high acute gains (1.16±0.72 mm) without complications. After a mean follow-up of 16 months, only

8 TLRs (7 in the ISR group and 1 in the *de novo* group) were observed. Furthermore, the LLL at follow-up was very good (0.07±0.63 mm).

This is the first study to report using DCB in *de novo* OCLs of the LM (1 lesion), RCA (2 lesions), and LAD (7 lesions). *De novo* lesions of the LM and RCA are aorto-ostial lesions, composed of fibrotic or calcified tissue, and have a complicated three-dimensional anatomy (15). Aorto-ostial lesions have poor initial outcomes and higher procedure-related complications and restenosis rates than non-aorto-ostial *de novo* lesions because of their anatomical characteristics (16). All large-vessel OCLs in the present study exhibited superior predilatation (mostly with cutting balloons) and were treated successfully with DCBs. No TLR or adverse clinical events were observed in these patients after a follow-up of >1 year. Our study suggested that a treatment strategy with DCB alone might be the optimal one.

PCI of OCLs in side branches is a technically difficult procedure as it is associated with greater recoil, low acute gain, high rate of inaccurate stent placement, and high rates of acute and long-term complications (15,17). An optimal strategy for treating OCLs is required as it was reported that 6–28% of patients with OCLs treated with stents required target vessel revascularization (TVR) within 10 months (18).

DCBs have been successfully used to treat ISR after treating OCLs in side branches by BMS implantation (19). Stent ISR is recommended by the European Society of Cardiology and the European Association for Cardio-Thoracic Surgery (ESC/EACTS) Coronary Intervention Guideline 2014 with an IA level of evidence (6). A pooled analysis of 4 randomized controlled trials found that DCB utilization was associated with a lower LLL (20). Additionally, one study on DCB in clinical practice investigated the TLR rate at 12 months as its primary outcome, showing that the use of DCB was associated with low TVR and TLR rates in *de novo* and ISR lesions (21). However, DCBs cannot overcome ISR in all OCLs. Cassese *et al.* investigated patients treated with DCB angioplasty, analyzing ISR incidence as the primary outcome. They reported that the risk of recurrent ISR was significantly lower after DCB angioplasty than plain balloon angioplasty (12.2% *vs.* 47.1%, respectively), as was the risk of TLR (22). The present study found that 7 TLRs were required within 2 years in OCLs after ISR (50% of the total). Of these, the 2 cases with ISR in the RCA were treated with one more stent. The TLRs of the 3 LCX and 2 First diagonal branch ISR lesions were previously treated in the main vessels and side branches (LCX and D1) with double stents. ISR occurs in approximately one-fifth of OCLs treated by DCB. Additionally, the outcome of cases with ISR treated with DESs was worse than those treated with DCBs, regardless of whether it was ostial or non-ostial ISR (23).

However, our study showed that treatment of side-branch *de novo* OCLs with DCB alone (especially Medina 0.0.1 lesions) exhibited high efficacy and safety. All procedures in the present study were completed without serious dissection or requirement of bailout stents. Only one case with a *de novo* OCL had TLR during follow-up of >1 year, with no adverse events. Additionally, we observed that the severity of dissection decreased with the fit of the cutting balloon used.

Recurrent TLR occurred more often in OCLs following ISR than in *de novo* OCLs. This phenomenon may be due to 3 main reasons. First, the drug coating on the balloon might have difficulty penetrating the endothelial cells because of the stent. Second, the main and side branches were treated by a double-stent procedure. Therefore, it was difficult to have full contact with the vessel wall to allow drug penetration when the DCB was expanded (e.g., OCLs in the LCX). Third, the metal materials in the stent might act as allergens, leading to ISR (24). We also found an independent association between ISR and TLR.

The present study had some limitations. The relatively small sample size and homogenous population (middle-aged and elderly) presenting at a single health institute prevent the generalization of our findings. Furthermore, only one brand of DCB was used at our hospital, which might result in a certain bias. Finally, intravascular ultrasonography or optical coherence tomography were not used in our study. Multicenter studies with larger sample sizes, using multiple brands of DCB, will help further strengthen our findings.

The present study demonstrated the efficacy and safety of treating OCLs with DCB alone. Treatment of *de novo* OCLs with DCBs has better angiographic outcomes than ISR OCLs. The DCB-only strategy for OCLs might be safe and effective, especially for *de novo* OCLs. The present study provides preliminary data for future multicenter randomized controlled trials.

Contribution to the field statement

The factors associated with the prognosis of patients with OCLs treated with DCBs remain controversial. The TLR rate differed between the ISR and *de novo* groups (50% *vs.* 2.4%, P<0.001). The acute gain in the ISR group was higher than the *de novo* group (1.77±0.81 *vs.* 0.95±0.55 mm,

P<0.001). The LLL also significantly differed between the ISR and *de novo* groups (0.61±0.85 *vs.* −0.1±0.41, P<0.001). ISR was independently associated with TLR [odds ratio (OR), 58.72; 95% confidence interval (CI): 4.42–779.94, P=0.002] after adjusting for sex. Treatment of *de novo* OCLs with DCBs has a better angiographic outcome than ISR OCLs. The present study provides preliminary data for future multicenter randomized controlled trials.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://jtd.amegroups.com/article/view/10.21037/jtd-22-270/rc

Data Sharing Statement: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-22-270/dss

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jtd.amegroups.com/article/view/10.21037/jtd-22-270/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are 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. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the ethics committee of Beijing Hospital (No. 2016BJYYEC-067-01) and the requirement for informed consent was waived.

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