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Original Article

Optical coherence tomography-guided drug coated balloon in non-small de novo coronary artery lesions: a prospective clinical research

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Abstract: Purpose: The combined use of drug coated balloon (DCB) and optical coherence tomography (OCT) for the treatment of non-small coronary de novo lesion remains to be evaluated. We investigated the safety and efficacy of OCT-guided DCB in non-small coronary de novo lesion patients with predilation of cutting balloon. Methods: https://clinicaltrials.gov/, ClinicalTrials.gov Identifier: NCT04795144. This study was a prospective, and open-label study. We enrolled patients with non-small de novo lesions treated with OCT-guided DCB. The non-small de novo lesions indicated vessel lesions with a diameter ≥ 2.5 mm. The primary endpoints were the success rate of the procedure and the occurrence of target lesion revascularization. The secondary endpoints were myocardial infarction, cardiac death, and major adverse cardiac events (MACE) within 3 months after the procedure. Results: At the Second Hospital of Jilin University, we enrolled 54 patients (54 lesions) with non-small de novo lesions who were treated with OCT-guided DCB from October 2018 to June 2019. A total of 52 patients were successfully treated with DCB-only strategy, while 2 patients turned to bailout stenting. A total of 21 patients had undergone angiography 3 months after the procedure with the late lumen loss of 0.24±0.57 mm. There was no statistically significant difference in minimal lumen diameter (MLD) between post-DCB and at 3-month angiographic follow-up (2.25±0.40 mm vs 2.04±0.54 mm; P = 0.110). Only 1 patient developed restenosis with the incidence of MACE rate of only 1.92% (n = 1). There was no significant difference in the stenosis of the lumen diameter of the target lesion vessel between 3 months after operation and immediately after operation. Conclusions: Our study showed that OCT-guided DCB with cutting balloon under guidance may be a novel approach in non-small de novo coronary artery disease.

Keywords: Non-small Coronary de novo lesion, Drug coated balloon, cutting balloon, optical coherence tomography

Introduction

Drug-coated balloons were first introduced for the treatment of instent restenosis and are recommended (European Society of Cardiology [ESC] guidelines class IA recommendation) for instent restenosis following treatment with both baremetal and drugeluting stents [1]. The safety and efficacy of drug coated balloon (DCB) in de novo lesions such as small vessel disease and bifurcation lesion has been demonstrated [2]. Recently, a REVELATION randomized trial has confirmed that DCB strategy was noninferior to drug-eluting stent (DES) in primary percutaneous coronary intervention for ST-segment elevation myocardial infarction 9 months later [3]. But there are few studies on the feasibility of DCB in non-small de novo coronary artery disease. The primary concerns about the use of DCB in non-small de novo coronary artery disease are insufficient predilation of the lesion and dissection-associated acute occlusion. Cutting balloon, on the other hand, can mitigate the damage to the vascular wall, reduce postoperative elastic recoil and improve the success rate of predilation [4].

Coronary angiography (CAG) is a two-dimensional lumenogram that cannot depict coronary artery wall. DCB percutaneous transluminal coronary angioplasty (PTCA) is not effective in evaluating postoperative dissections or hema-

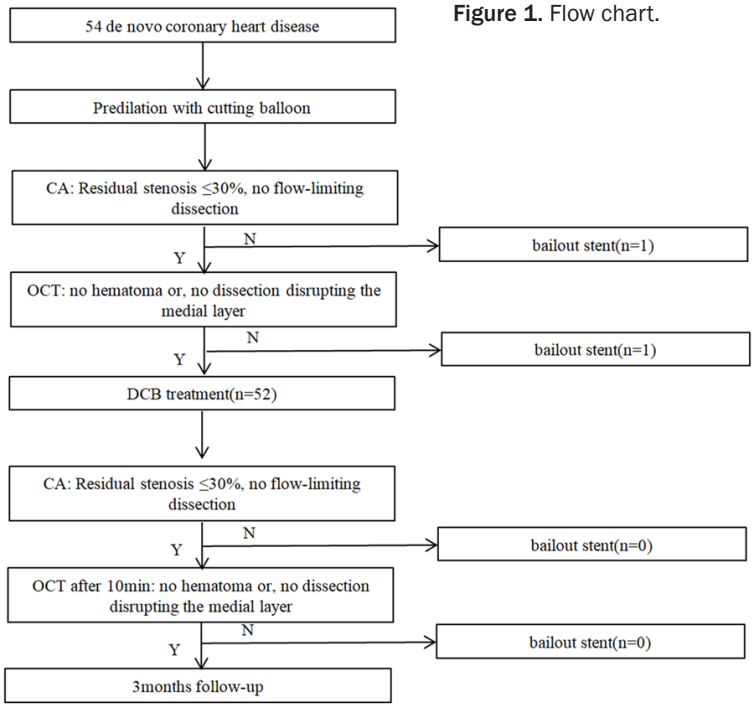

Figure 1. Flow chart.

tomas, which are predictors of acute coronary occlusion. While optical coherence tomography (OCT) is an emerging intracoronary imaging modality with a high-resolution (10-20 μm), which has been shown to be able to provide full evaluation of the dissection after DCB PTCA [5-8]. The aim of the present study was to investigate the safety and efficacy of OCT-guided DCB in the treatment of non-small de novo lesions with predilation of cutting balloon.

Materials and method

Patient selection

The study was a prospective single-center study, which included 54 consecutive patients scheduled to undergo elective percutaneous coronary intervention for de novo lesions between October 2018 and June 2019. Patients with lesion diameter stenosis ≥ 50% and reference diameter ≥ 2.5 mm, as well as documented ischemia were enrolled in this study. Exclusion criteria consisted of restenosis, left main disease, myocardial infarction with STsegment elevation, severe heart failure (left ventricular ejection fraction < 30%), life expectancy < 1 year, and severe renal failure (glomerular filtration rate [GFR] < 30 ml/min). This study strictly complies with the requirements of the ethics committee, and the ethics certificate number is 2017-11-15.

Interventional procedures

All patients were treated with the loading doses of 300 mg aspirin (SFDA approval number H32026317, Jianke Pharmaceutical) and 300 mg clopidogrel (SFDA approval number J20180029, Jianke Pharmaceutical), followed by aspirin 100 mg/day and clopidogrel 75 mg/day, until 3 months after the procedure. During the procedure, 100 U/Kg of unfractionated heparin (SFDA approval number H20053200, Kunming Jida Pharmaceutical Co., Ltd.) was injected intravenously to maintain the activated clotting time > 250 s. OCT (C7XR, LightLab Imaging, Inc.; Westford, Massachusetts, United States) was performed after predilation, post DCB application and at 3-month follow-up. In terms of lesion preparation, the lesion was first dilated with an optimal size cutting balloon with a diameter 0.5 mm smaller than the reference diameter (Flextome Cutting Balloon, Boston Scientific, Natick, MA, United States). If the cutting balloon cannot pass through the lesion, a small conventional balloon was then applied. Successful predilation was defined as residual stenosis ≤ 30%, no flow-limiting dissection displayed by CAG, and no hematoma or dissection disrupting the medial layer demonstrated by OCT. In the event of a successful predilation, the ratio of the DCB (SeQuent Please® B.Braun, Melsungen AG, Vascular Systems, Berlin, Germany) to the vessel should be 0.8-1.0, and the balloon should be inflated at nominal pressure for 30-60 seconds to avoid dissection, with the balloon exceeding the pre-dilated area by 2 mm on each side. A successful procedure was defined as residual stenosis ≤ 30%, no flow-limiting dissection displayed by CAG and no hematoma or dissection disrupting the medial layer demonstrated by OCT after DCB dilation (**Figure 1**). The stenosis degree of the lumen diameter of the target lesion vessel was calculated 3 months after operation (%): the degree of

Table 1. Baseline information and characteristics of the procedure

Characteristics	Values	Characteristics	Values
Age, y	56±11	Lesion type	
Male	40 (74.07%)	A	7 (12.96%)
Cardiovascular risk factors		B1	19 (35.19%)
Diabetes	8 (14.81%)	B2	22 (40.74%)
Hypertension	27 (50.00%)	C	6 (11.11%)
Current smoker	18 (33.33%)	Post-predilatation (n = 54)	
Hyperlipidemia	19 (35.19%)	Cutting balloon (% of all lesions)	51 (94.44%)
Body mass index, kg/m^2	26.17±4.07	Balloon diameter, mm	3.07±0.37
Family history of coronary artery disease	2 (3.7%)	Balloon length, mm	11.57±2.34
Previous PCI	11 (20.37%)	Maximal infation pressure, atm	9.41±2.60
Previous CABG	0 (0%)	Inflated time, s	19.44±7.63
Creatinine (mmol/L)	75.61±13.54	Dissection after predilatation	43 (79.63%)
Ejection fractions (%)	74.10±17.07	Type A	23 (42.59%)
No. of patients	54	Type B	15 (27.77%)
No. of lesions	54	Type C	4 (7.41%)
Location of lesion DCB treated		Type D-F	1 (1.85%)
LAD	31 (57.41%)	Bailout DES after predilatation	2
LCX	9 (16.67%)		
RCA	14 (25.93%)		

Values are expressed as mean ± SD or n. CABG, Coronary artery bypass surgery; MI, myocardial infarction.

lumen diameter stenosis (%) = (1-minimum lumen diameter/reference vessel diameter) × 100%.

Statistical analysis

Continuous variables are described as mean ± standard deviation, and discrete variables are expressed as frequencies and percentages. SPSS version 19.0 (IBM, Munich, Germany) was used for statistical analyses. The Student's t-test was used for the comparison analysis. A *p*-value < 0.05 was considered statistically significant.

All data were analyzed by SPSS23.0 statistical software. Count data were represented by n (%), and comparison was performed by X^2 test; measurement data were represented by (x±s), and comparison between groups was conducted using independent sample *t* test; A *P*-value of < 0.05 was accepted as statistically significant; Kaplan-Meier was used to map the survival curve.

Results

Clinical characteristics of the patients

The characteristics of patients and lesions at baseline are shown in **Table 1**. The mean age of the patients was 56±11 years, and 40 of 54 patients were male. Procedure characteristics are shown in **Table 1**. 31 (57.41%) lesions were found in the left anterior descending artery (LAD), among which 19 (35.19%) were located in the ostium or proximal of LAD; 9 (16.67%) lesions were in the left circumfex artery (LCX) and 14 (25.93%) were in the right coronary artery (RCA). A cutting balloon was applied in 51 (94.44%) patients, but it failed in passing through the severe stenostic lesions in 3 patients due to poor flexibility. Post-predilation angiography revealed dissection in 43 (79.63%) patients. Type A, B and C dissection were found in 23 (42.59%), 15 (27.77%) and 4 (7.41%) patients respectively. Type C dissection was left alone because there was no hematoma detected by OCT. Two lesions (3.70%) required bailout stenting, one because of Type F dissection and the other because of OCT-confirmed hematoma after predilation. The remaining 52 lesions had residual stenosis < 75% and a final Thrombolysis in Myocardial Infarction (TIMI) 3 flow, which were successfully treated with DCB-only strategy. No acute obturation occurred in these 52 patients, **Table 2**.

Quantitative coronary arteriographis analysis and clinical outcomes

Quantitative coronary arteriographis analysis and clinical outcomes are presented in **Table 3**.

Table 2. Baseline characteristics of Post-DCB PTCA (n = 52)

Characteristics	Values
Reference diameter, mm	2.88±0.41
Minimal lumen diameter, mm	0.82±0.40
Lesion length, mm	10.47±5.09
Diameter stenosis,%	71.59±13.48
Minimal lumen diameter after DCB, mm	2.23±0.41
PCB diameter, mm	3.12±0.33
PCB length, mm	21.15±4.58
Maximal infation pressure, atm	8.79±2.23
Inflated time, s	57.40±7.64
Dissection after DCB	41 (78.84%)
Type A	22 (42.31%)
Type B	15 (28.85%)
Type C	4 (7.69%)
Type D-F	0 (0%)

Values are expressed as mean ± SD or n.

21 patients underwent angiographic follow-up. The reference vessel diameter was 2.86±0.46 mm. Late luminal loss was 0.24±0.57 mm. Minimal lumen diameter showed no difference between the post-DCB and at 3-month follow-up (2.25±0.40 mm vs 2.04±0.54 mm; P = 0.110). Among the 21 patients, 7 patients (33.33%) showed late lumen gain (0.12±0.13 mm). One patient developed binary angiographic restenosis, requiring revascularization.

Follow-ups results

Follow-ups are shown in **Table 4** and **Figure 2**. At 3 months, all 52 patients treated with DCB-only strategy were followed up. No deaths or STEMI were reported. TLR occurred in only 1 patient (1.92%) in the right coronary artery. The incidence of MACE was only 1.92% (n = 1). At 12-month follow-up, however, MI occurred in 1 patient, TLR in 2 patients, cerebral hemorrhage in 2 patients, and death in 1 patient. The incidence of MACE was 11.54% (n = 6).

CAG and OCT findings of the culprit lesion at the time of percutaneous transluminal coronary intervention (PCI) and follow-up are shown in **Figure 3**. Pre-PCI CAG detected severe stenosis at the proximal of the LAD (white arrow; **Figure 3A**); **Figure 3B** shows predilation with the cutting balloon (3.5*10 mm) and dilation with the DCB (3.5*15 mm). CAG demonstrated the absence of dissection after PCI (minimal lumen diameter: 2.53 mm; **Figure 3C**). At the 3-month follow-up, late lumen gain (minimal lumen diameter: 2.68 mm; **Figure 3D**) was detected by CAG. OCT image after DCB revealed severe dissection after DCB dilation (location a; **Figure 3E**). OCT image after DCB showed no hematoma at the distal of the lesion (location b; **Figure 3F**). CAG at follow-up showed the healing of the dissection (location a; **Figure 3G**). CAG at follow-up revealed the healing of the dissection (location b; **Figure 3H**).

Discussion

The present study demonstrated that (1) there was significant difference between pre-procedure and post-procedure MLA in the quantitative coronary arteriography analysis, but no significant difference between post-procedure and at 3-month follow-up. (2) TLR is not higher than DES 3 months after DCB PTCA for non-small coronary artery disease. (3) Dissection after cutting balloon is not a risk factor for acute occlusion following PTCA. These findings suggest that DCB combined with cutting balloon is safe and effective in the treatment of non-small de novo coronary artery disease.

Successful predilation is the key to successful use of DCB. The primary concerns about the application of DCB in non-small de novo coronary artery disease are acute occlusion caused by elastic recoil, dissection and hematoma. According to the German Drug-eluting Balloon Consensus Group, DES should be implanted in case of flow-limiting dissection or severe residual stenosis [9]. Cutting balloon can reduce the damage to the vascular wall and elastic recoil after predilation. In order to achieve good angiographic results after predilation, we used cutting balloon and successful predilation using cutting balloon were achieved in 96.30% of the patients. None of the lesions had residual stenosis > 30% after predilation with cutting balloon (3 patients were treated with non-compliant balloon after predialtion with cutting balloon). Dissection occurred in 79.63% of the patients. Bailout stenting was performed on two patients: one with Type D dissection and TIMI < 3 flow, and the other with OCT-confirmed hematoma. Type A and B dissection were found in 21 (42%) and 14 (28%) of the cases respectively; Type C dissection occurred in 4 (8.00%) patients and were left alone because the TIMI

Table 3. Quantitative coronary angiography and functional measurements

	Pre-DCB (n = 21)	Post-DCB (n = 21)	At 3-month follow-up (n = 21)	P		
				Pre-DCB vs post-DCB	Post-DCB vs at 3-month follow-up	Pre-DCB vs at 3-month follow-up
Reference diameter, mm	2.86±0.46	2.79±0.37	2.78±0.34	0.16	0.793	0.241
Minimal lumen diameter, mm	0.81±0.44	2.25±0.40	2.04±0.54	0.000	0.110	0.000
Diameter stenosis, %	72.30±13.82	19.40±9.70	26.26±17.24	0.000	0.105	0.000
Lesion length, mm	11.08±4.99					
Acute gain, mm	1.44±0.50					
Late-luminal loss, mm	0.24±0.57					
Binary angiographic restenosis	1 (4.76%)					

Clinical follow-up at 3-months.

Table 4. Follow-ups of all 52 patients

	MI	TLR	Cerebral Hemorrhage	Death	Total Mace Rate
At 3-month follow-up	0	1 (1.92)	0	0	1 (1.92)
At 12-month follow-up	1 (1.92)	2 (3.85)	2 (3.85)	1 (1.92)	6 (11.54)

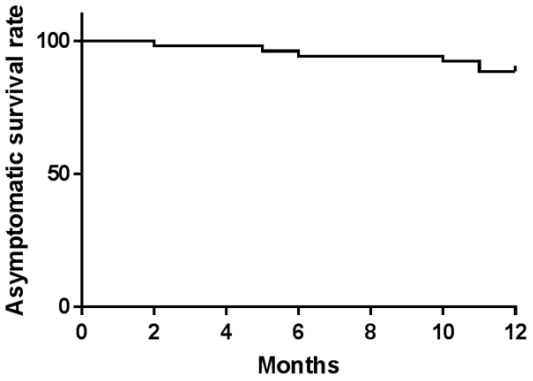

Figure 2. Asymptomatic survival curve of all 52 patients.

flow was normal without hematoma demonstrated by OCT, although the dissection flap was severe. This may be attribute to adequate antiplatelet and cutting balloon. Unlike plain balloon, the dissection of cutting balloon after predilation is regular and limited with less damage to the vascular wall [4]. OCT was used to assess vascular wall injury after predilation and DCB application. OCT is intracoronary imaging modality that allows visualization of detailed morphological characteristics after PTCA [10]. Acute vascular changes after PTCA such as dissection, thrombosis and hematoma can be described in detail by OCT [11-14], but not by CAG. Compared with dissection, hematoma is more prone to acute occlusion because of shear stress resulting from blood flow. In this study, none of the 52 patients treated by DCB-only strategy developed acute vessel occlusion, and complete vascular healing was observed in 20 patients (95.24%) by follow-up with angiography follow-up. Author Cortese revealed that the left dissection (Type A-C) was healed in 94% of patients [15], which is consistent with our research. It is speculated that dissection without flow-limiting after cutting balloon predilation is not a risk factor for acute occlusion following PTCA.

Among the 21 patients followed-up by angiography, the late lumen loss was only 0.24±0.57 mm, and 33.33% showed late lumen gain. The incidence of restenosis was 4.76%, which was comparable to DES. According to these results, DCB-only treatment is as effective as DES in selected patients.

During clinical follow-ups, only 1 patient developed ischemia driven TLR in the right coronary artery. Other DCB studies have shown that the incidence of TLR is 3.4% in patients with small-vessel disease treated by DCB [2], 0% in de novo lesions larger than 2.5 mm [1], and 3% in primary percutaneous coronary intervention for ST-segment elevation myocardial infarction [3]. All these studies suggest that DCB is safe and feasible in de novo lesions, no matter in small vessels or non-small vessels. In our study, predilation with cutting balloon yielded good angiographic results. The dissection caused by cutting balloon dilation facilitates the absorption of antiproliferative drugs delivered by DCB, thereby reducing restenosis.

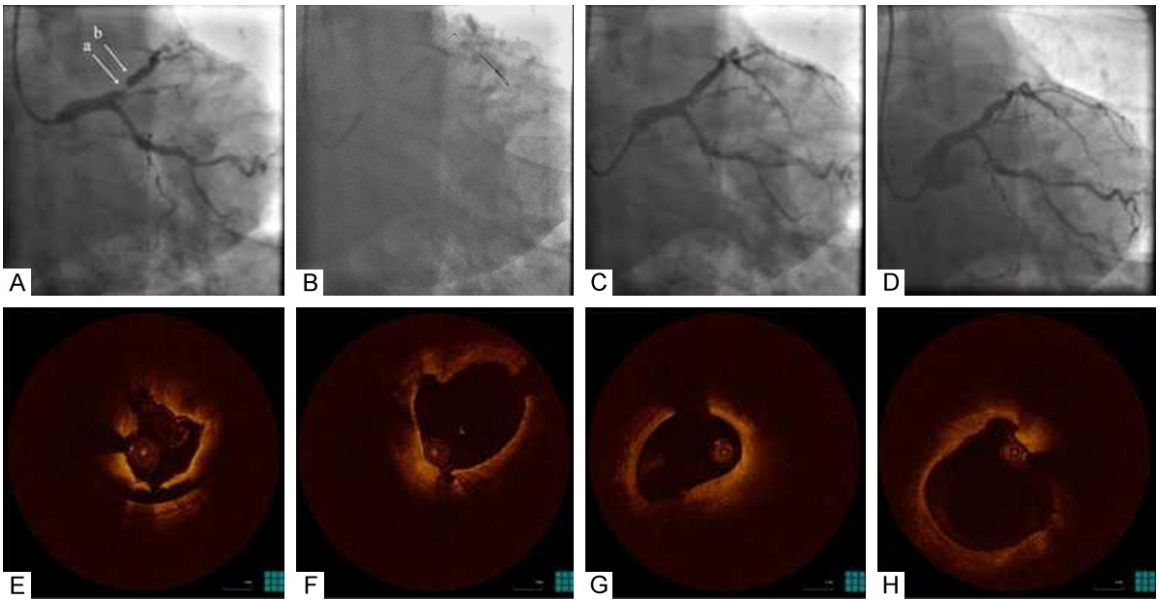

Figure 3. Coronary angiography and OCT findings of the culprit lesion at the time of PCI and follow-up. Note: Pre-PCI CAG detected severe stenosis at the proximal of the LAD [white arrow; (A) a = (2.53±0.06) mm; b = (3.51±0.12) mm]; (B) shows dilation with a DCB (3.5*15 mm) after predilation with a cutting balloon (3.5*10 mm). CAG demonstrated the absence of dissection after PCI (minimal lumen diameter: 2.53 mm; (C)). At the 3-month follow-up, late lumen gain (minimal lumen diameter: 2.68 mm; (D)) was detected by CAG. OCT image after DCB revealed severe dissection after DCB dilation (location a; (E)). OCT image after DCB showed no hematoma at the distal of the lesion (location b; (F)). CAG at follow-up showed the healing of the dissection (location a; (G)). CAG at follow-up revealed the healing of the dissection (location b; (H)).

At 3-month follow-up by angiography, some rare phenomena were observed under OCT. In one patient, the control angiography revealed an aneurysm at the place of DCB inflation. Aneurysm formation after DCB implantation is a rare event, which has only been reported in a few studies [16-19]. Franz X. Kleber found the probability of aneurysm formation after DCB implantation was approximately 0.8%, and that PCI with DCB does not cause an unexpectedly high incidence of coronary artery aneurysm [20]. Dissection, arterial wall injury, perforation and high-pressure inflation may contribute to the formation of aneurysms [21, 22]. Neointimal bridge caused by dissection is also a rare complication after DCB treatment [23]. In our research, neointimal bridge was found in one patient by OCT, but was left alone because it did't limit the blood flow. In addition, there was no statistically significant difference in stenosis degree of the lumen diameter of the target lesion vessel 3 months after operation.

Studies have confirmed that the cutting balloon has immediate good vascular parameters, which can significantly reduce the incidence of restenosis and the incidence of immediate and long-term cardiovascular adverse events. The microblade attached to the cutting balloon can cut the proliferated endometrial tissue longitudinally while expanding. It can firstly cut the plaque fiber, elastic fiber and smooth muscle; then push the plaque out of the stent. Compared with ordinary balloons, cutting balloons can reduce helical tears and loss of lumen geometry during expansion, and reduce the risk of treatment. Due to the large contour of the cutting balloon and the three blades attached to the surface, safety must be paid attention to during the operation, generally following the principle of expanding the distal end first and then the proximal end. The cutting balloon is not resistant to high pressure and should prevent the balloon from rupturing becase of excessive pressure. A catheter with good support should be selected to ensure the successful rate of cutting balloon. The results of this study show that the cutting balloon is safe and effective for small vessel disease, and can significantly reduce the rate of restenosis compared with ordinary balloons, and is worthy of clinical application. At present, technical examinations such as coronary angiography and intravascular ultrasound are commonly used

clinically to identify vulnerable plaques. However, due to the low resolution, these examinations cannot identify vulnerable plaques in advance to prevent the occurrence of acute coronary syndromes. The OCT has a very high resolution of 10×20 μm, which can clearly analyze the structure of organs and tissues, and is considered as the most excellent examination for identifying vulnerable plaques [24]. The limitation of the study is that the initial design of the trial did not prepare for a controlled study but only a single-center prospective study. In the future, traditional treatment methods in Non-small De Novo Coronary Artery Lesion will be included for comparison. The results obtained in this study are indicative of its values for further research.

In summary, to our knowledge, this is the first trial testing the safety and efficacy of DCB combined with cutting balloon in non-small de novo coronary artery lesions guide by OCT. Our study argues that DCB combined with cutting balloon is feasible, with low incidences of acute occlusion and TLR at 3-month follow-up, so DCB maybe a a novel approach for the treatment of non-small de novo coronary artery disease. However, this study also has some limitations. First, the number of patients included in this study is relatively small and our trail was a singe-center, single arm study. Second, DCB used in this study was only the SeQuent Please® DCB, and therefore, it might not be possible to generalize the results to other DCBs. Larger trials are warranted to confirm the equivalence or even superiority of the DCB-only strategy compared to a treatment with DES.

Disclosure of conflict of interest

None.

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References

[1] Rissanen TT, Uskela S, Eränen J, Mäntylä P, Olli A, Romppanen H, Siljander A, Pietilä M, Minkkinen MJ, Tervo J and Kärkkäinen JM; DEBUT trial investigators. Drug-coated balloon for treatment of de-novo coronary artery lesions in patients with high bleeding risk (DEBUT): a single-blind, randomised, non-inferiority trial. Lancet 2019; 394: 230-239.

[2] Jeger RV, Farah A, Ohlow MA, Mangner N, Möbius-Winkler S, Leibundgut G, Weilenmann D, Wöhrle J, Richter S, Schreiber M, Mahfoud F, Linke A, Stephan FP, Mueller C, Rickenbacher P, Coslovsky M, Gilgen N, Osswald S, Kaiser C and Scheller B; BASKET-SMALL 2 Investigators. Drug-coated balloons for small coronary artery disease (BASKET-SMALL 2): an open-label randomised non-inferiority trial. Lancet 2018; 392: 849-856.

[3] Vos NS, Fagel ND, Amoroso G, Herrman JR, Patterson MS, Piers LH, van der Schaaf RJ, Slagboom T and Vink MA. Paclitaxel-coated balloon angioplasty versus drug-eluting stent in acute myocardial infarction: the REVELATION randomized trial. JACC Cardiovasc Interv 2019; 12: 1691-1699.

[4] Zhang XY, Tang Z, Zeng YP and Nie SP. Comparison of lacrosse non-slip elements and cutting balloons in treating calcified coronary lesions: a retrospective, single-blind randomized controlled study. Adv Ther 2019; 36: 3147-3153.

[5] Suter MJ, Nadkarni SK, Weisz G, Tanaka A, Jaffer FA, Bouma BE and Tearney GJ. Intravascular optical imaging technology for investigating the coronary artery. JACC Cardiovasc Imaging 2011; 4: 1022-1039.

[6] Prati F, Guagliumi G, Mintz GS, Costa M, Regar E, Akasaka T, Barlis P, Tearney GJ, Jang IK, Arbustini E, Bezerra HG, Ozaki Y, Bruining N, Dudek D, Radu M, Erglis A, Motreff P, Alfonso F, Toutouzas K, Gonzalo N, Tamburino C, Adriaenssens T, Pinto F, Serruys PW and Di Mario C; Expert's OCT Review Document. Expert review document part 2: methodology, terminology and clinical applications of optical coherence tomography for the assessment of interventional procedures. Eur Heart J 2012; 33: 2513-2520.

[7] Jia H, Abtahian F, Aguirre AD, Lee S, Chia S, Lowe H, Kato K, Yonetsu T, Vergallo R, Hu S, Tian J, Lee H, Park SJ, Jang YS, Raffel OC, Mizuno K, Uemura S, Itoh T, Kakuta T, Choi SY, Dauerman HL, Prasad A, Toma C, McNulty I, Zhang S, Yu B, Fuster V, Narula J, Virmani R and Jang IK. In vivo diagnosis of plaque erosion and calcified nodule in patients with acute coronary syndrome by intravascular optical coherence tomography. J Am Coll Cardiol 2013; 62: 1748-1758.

[8] Iftikhar A, Bond RR, McGilligan V, Leslie SJ, McShane A, Knoery C, Rjoob K and Peace A. Computational time series analysis of patient referrals to a primary percutaneous coronary intervention service. Health Informatics J 2020; 26: 2222-2236.

[9] Kleber FX, Mathey DG, Rittger H and Scheller B; German Drug-eluting Balloon Consensus Group. How to use the drug-eluting balloon: recommendations by the German consensus group. EuroIntervention 2011; 7 Suppl K: K125-128.

[10] Di Vito L, Yoon JH, Kato K, Yonetsu T, Vergallo R, Costa M, Bezerra HG, Arbustini E, Narula J, Crea F, Prati F and Jang IK; COICO group (Consortium of Investigators for Coronary OCT). Comprehensive overview of definitions for optical coherence tomography-based plaque and stent analyses. Coron Artery Dis 2014; 25: 172-185.

[11] Yonetsu T, Kakuta T, Lee T, Takayama K, Kakita K, Iwamoto T, Kawaguchi N, Takahashi K, Yamamoto G, Iesaka Y, Fujiwara H and Isobe M. Assessment of acute injuries and chronic intimal thickening of the radial artery after transradial coronary intervention by optical coherence tomography. Eur Heart J 2010; 31: 1608-1615.

[12] Uemura S, Ishigami K, Soeda T, Okayama S, Sung JH, Nakagawa H, Somekawa S, Takeda Y, Kawata H, Horii M and Saito Y. Thin-cap fibroatheroma and microchannel findings in optical coherence tomography correlate with subsequent progression of coronary atheromatous plaques. Eur Heart J 2012; 33: 78-85.

[13] Gonzalo N, Serruys PW, Okamura T, Shen ZJ, Onuma Y, Garcia-Garcia HM, Sarno G, Schultz C, van Geuns RJ, Ligthart J and Regar E. Optical coherence tomography assessment of the acute effects of stent implantation on the vessel wall: a systematic quantitative approach. Heart 2009; 95: 1913-1919.

[14] Kume T, Akasaka T, Kawamoto T, Ogasawara Y, Watanabe N, Toyota E, Neishi Y, Sukmawan R, Sadahira Y and Yoshida K. Assessment of coronary arterial thrombus by optical coherence tomography. Am J Cardiol 2006; 97: 1713-1717.

[15] Cortese B, Silva Orrego P, Agostoni P, Buccheri D, Piraino D, Andolina G and Seregni RG. Effect of drug-coated balloons in native coronary artery disease left with a dissection. JACC Cardiovasc Interv 2015; 8: 2003-2009.

[16] Vassilev D, Hazan M and Dean L. Aneurysm formation after drug-eluting balloon treatment of drug-eluting in-stent restenosis: first case report. Catheter Cardiovasc Interv 2012; 80: 1223-1226.

[17] Solomonica A, Musallam A and Roguin A. Coronary artery aneurysm following drug-coated balloon treatment. Cardiovasc Revasc Med 2015; 16: 505-507.

[18] Zhang HP, Yu X, Ji FS and Sun FC. Coronary artery aneurysm formation after drug-coated balloon treatment of de novo lesions: two case reports. Medicine (Baltimore) 2018; 97: e13208.

[19] Huang J, Zhang JY, Wei M, Yuan MJ and Lu ZG. Coronary artery aneurysm formation after drug-coated balloon treatment. Chin Med J (Engl) 2018; 131: 2249-2251.

[20] Kleber FX, Schulz A, Bonaventura K and Fengler A. No indication for an unexpected high rate of coronary artery aneurysms after angioplasty with drug-coated balloons. EuroIntervention 2013; 9: 608-612.

[21] Hawkins BM and Meier IC. Drug-coated balloon, limb ischemia, and the elephant in the room. JACC Cardiovasc Interv 2020; 13: 2300-2302.

[22] Giacoppo D, Alfonso F, Xu B, Claessen B, Adriaenssens T, Jensen C, Pérez-Vizcayno MJ, Kang DY, Degenhardt R, Pleva L, Baan J, Cuesta J, Park DW, Schunkert H, Colleran R, Kukla P, Jiménez-Quevedo P, Unverdorben M, Gao R, Naber CK, Park SJ, Henriques JPS, Kastrati A and Byrne RA. Paclitaxel-coated balloon angioplasty vs. drug-eluting stenting for the treatment of coronary in-stent restenosis: a comprehensive, collaborative, individual patient data meta-analysis of 10 randomized clinical trials (DAEDALUS study). Eur Heart J 2020; 41: 3715-3728.

[23] Koszegi Z, Szuk T, Vajda G, Marty F and Jenei C. Optical coherence tomography imaging of intrastent neointimal bridge caused by semicircumferencial dissection after drug eluting balloon dilatation of instent restenosis of sapheneous venous graft. Anadolu Kardiyol Derg 2014; 14: E5.

[24] Safi M, Mehrabi MA, Alipour Parsa S, Khaheshi I and Naderian M. The role of FFR in clinical decision making in patients with moderate coronary lesions: a pilot study. Acta Biomed 2018; 89: 378-381.