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Angiographic patterns after drug-coated balloon angioplasty for *de novo* coronary lesions

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KEYWORDS

- drug-coated balloon
- drug-eluting stent
- QCA

Abstract

Background: Drug-coated balloon (DCB) angioplasty has emerged as an effective treatment option for *de novo* coronary artery lesions; however, the chronic-phase angiographic patterns after DCB angioplasty for *de novo* lesions have not yet been described.

Aims: The aim of the present study was to evaluate chronic-phase angiographic classification after DCB angioplasty.

Methods: This was a single-centre, retrospective, observational study. From June 2016 to August 2022, 708 lesions (670 patients) underwent DCB angioplasty for *de novo* coronary lesions. Successful DCB angioplasty was defined as a non-flow-limiting dissection, with residual stenosis ≤30% and absence of a bailout stent. A total of 337 lesions (318 patients) were enrolled in this study.

Results: Of the 337 lesions analysed, 91.1% (n=307) were in the non-restenosis group, and 8.9% (n=30) were in the restenosis group. The non-restenosis group was classified into non-restenosis (45.1%; n=152) and lumen enlargement (46.0%; n=155). The restenosis group was classified into focal restenosis (5.0%; n=17), diffuse restenosis (3.6%; n=12), and occlusive restenosis (0.3%; n=1). There were no aneurysms, and plaque cavities were often observed (8.0%). During the chronic phase, residual dissection was seen in only one case (0.3%).

Conclusions: This report demonstrates for the first time the angiographic classification after DCB angioplasty for *de novo* coronary lesions. Restenosis patterns were seen in 8.9% of lesions, and half of the restenosis patterns presented a focal restenosis pattern. Late lumen enlargement was observed in 46% of the treated lesions.

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Abbreviations

DCB drug-coated balloon
DES drug-eluting stent
LLE late lumen enlargement

Introduction

Drug-coated balloon (DCB) angioplasty has emerged as an effective treatment option for *de novo* coronary artery lesions. The clinical outcomes following treatment with DCB angioplasty are not inferior to those with drug-eluting stents (DES)[1]. Previous studies have reported that the angiographic classification of stent restenosis is prognostically important[2,3,4], although the chronic-phase angiographic patterns after DCB angioplasty for *de novo* lesions have not yet been described. Furthermore, the distribution of these patterns is unclear. Therefore, the aim of the present study was to evaluate chronic-phase angiographic classification after DCB angioplasty.

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Materials and methods

This study was a retrospective, observational study conducted at a single centre. Between June 2016 and August 2022, a total of 670 patients with 708 *de novo* coronary lesions underwent DCB angioplasty. A successful DCB angioplasty was defined as a non-flow-limiting dissection, with a residual stenosis ≤30% and absence of a bailout stent. A drug-coated balloon (SeQuent Please [B. Braun]) was used for the procedure. Patients with suboptimal results (residual stenosis >30%), acute target lesion thrombosis, and those without follow-up coronary angiography (CAG) after DCB angioplasty were excluded from the study. All patients were consulted about having angiographic follow-up, and those who consented underwent a planned angiogram 6 to 12 months later. Alternatively, CAG was performed on patients if they complained of symptoms suggestive of angina pectoris within 12 months after DCB angioplasty. Consequently, only 318 patients with 337 lesions were included in this study **(Figure 1)**. In total, 312 lesions (92.6%) were evaluated by a planned angiography. Meanwhile, a symptom-driven angiography was performed for 25 lesions (7.4%). There were two emergent angiograms. The baseline clinical, lesion, and procedural characteristics of the patients are presented in **Table 1** and **Table 2**. **Table 2** shows the final balloon used. If sufficient lumen was not obtained after dilatation with the initially used balloon, an additional dilatation was performed using a larger and/or scoring balloon. Several balloons were used in 102 lesions (30.2%). The most common final balloon used was a scoring balloon or cutting balloon (84.6%). An intracoronary imaging device was used in 311 lesions (92.3%). Bailout stent criteria recommended by the Japanese Association of Cardiovascular Intervention and Therapeutics (CVIT) expert consensus document were enforced. Medial dissection, intramural haematoma, or extra-medial injury was fixed with bailout stenting to avoid acute coronary closure in this institution. The Ethics Committee of Hokkaido Cardiovascular Hospital approved this study, which was carried out according to the 1975 Declaration of Helsinki guidelines. Before participation, informed consent was obtained from all eligible patients.

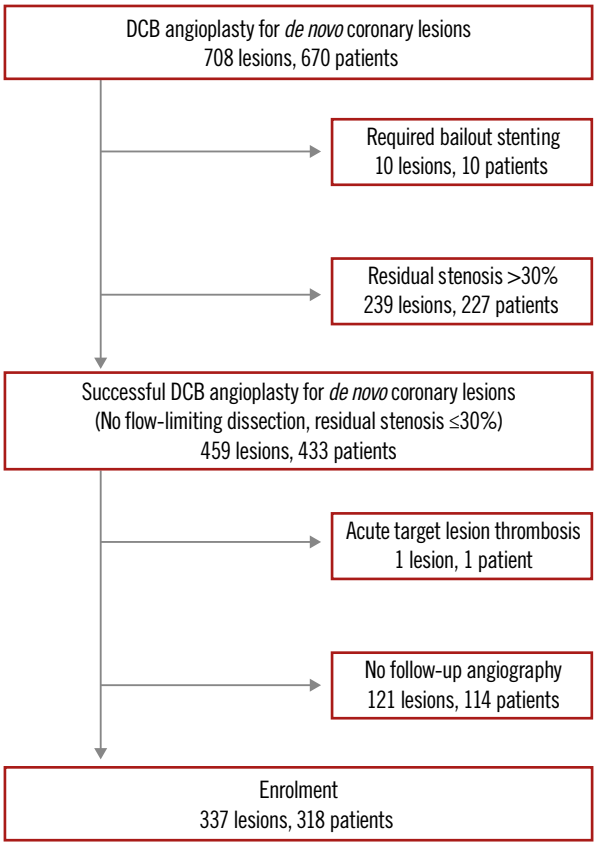

Figure 1. *Study schema. DCB: drug-coated balloon*

Table 1. Baseline clinical characteristics.

	Overall (n=318)
Age, years	68.2±11.1
Male	246 (77.4)
Hypertension	245 (77.0)
Diabetes mellitus	132 (41.5)
Dyslipidaemia	246 (77.4)
Smoking history	190 (59.7)
HD	28 (8.8)
CKD	55 (17.3)
Index presentation	
Stable angina	221 (69.5)
ACS	97 (30.5)
Prior PCI	98 (30.8)
Prior CABG	10 (3.1)
Prior MI	60 (18.9)

Values are mean±standard deviation or n (%). ACS: acute coronary syndrome; CABG: cardiac artery bypass graft; CKD: chronic kidney disease; HD: haemodialysis; MI: myocardial infarction; PCI: percutaneous coronary intervention

Table 2. Lesion and procedural characteristics.

	Overall (n=337)
Target vessels	
LAD	149 (44.2)
LCx	82 (24.3)
RCA	104 (30.9)
LMCA	2 (0.6)
AHA type B2/C	193 (57.3)
Angiographic calcification	69 (20.5)
Ostial lesion	38 (11.3)
CTO	12 (3.6)
Bifurcation	58 (17.2)
Before procedure	
Lesion length, mm	14.3±7.5
RVD, mm	2.34±0.55
MLD, mm	0.69±0.48
%DS, %	70.8±18.8
After procedure	
RVD, mm	2.41±0.51
MLD, mm	1.90±0.42
%DS, %	20.8±7.4
Dissection (No/A/B/C)	279 (82.8) / 14 (4.2) / 39 (11.6) / 5 (1.5)
Follow-up	
Follow-up duration, days	215±119
RVD, mm	2.47±0.51
MLD, mm	1.82±0.51
%DS, %	26.1±15.4
LLL, mm	0.09±0.41
Dissection (No/A/B/C)	336 (99.7) / 0 (0) / 1 (0.3) / 0 (0)
DCB size	
DCB diameter, mm	2.70±0.45
DCB length, mm	19.7±7.4
Maximum inflation pressure, atm	7.6±2.4
Duration of inflation, s	54.7±11.5
Predilatation performed	337 (100)
Conventional balloon	44 (13.1)
Scoring/cutting balloon	285 (84.6)
High pressure balloon	8 (2.4)
Balloon diameter, mm	2.61±0.47
Balloon length, mm	12.8±2.1
Maximum inflation pressure, atm	11.7±4.5
Rotablator	5 (1.5)
DCA	1 (0.3)
Excimer laser	14 (4.2)
Intracoronary imaging-guided PCI	311 (92.3)

Values are mean±standard deviation or n (%). %DS: percentage diameter stenosis; AHA: American Heart Association; CTO: chronic total occlusion; DCA: directional coronary atherectomy; DCB: drug-coated balloon; LAD: left anterior descending artery; LCx: left circumflex artery; LLL: late lumen loss; LMCA: left main coronary artery; MLD: minimal lumen diameter; PCI: percutaneous coronary intervention; RCA: right coronary artery; RVD: reference vessel diameter

ANGIOGRAPHIC CLASSIFICATION AT FOLLOW-UP AFTER DCB ANGIOPLASTY

Angiographic patterns at follow-up were classified as follows **(Figure 2)**:

Non-restenosis patterns

- Class I: non-restenosis. Stenosis is ≤50%.
- Class II: lumen enlargement. The minimal lumen diameter (MLD) on chronic-phase angiography was greater than the MLD immediately after DCB angioplasty.

Restenosis patterns

- Class III: focal restenosis. Stenosis is >50%. The lesions were approximately 10 mm in length.
- Class IV: diffuse restenosis. Stenosis is >50%. The lesions were >10 mm long.
- Class V: occlusive restenosis.

Additional findings

- Type A: aneurysm. This was defined as an abnormal coronary dilatation exceeding the diameter of the normal segment by at least 50%.
- Type B: balloon-edge restenosis. Stenosis was defined as stenosis within 5 mm of the border of the DCB-treated lesion, both distally and proximally.
- Type C: plaque cavity. This was defined as contrast staining outside the surface of the vascular lumen <50% of the diameter of the normal segment.
- Type D: residual dissection.

ANGIOGRAPHIC ANALYSIS

We performed preprocedural, postprocedural, and follow-up serial coronary angiography. Angiographic follow-up was not mandatory; it was performed for recurrent symptoms or as part of the routine angiographic follow-up if patients consented. We performed a quantitative coronary analysis (QCA) of the coronary angiographic data using the CAAS II Research System (Pie Medical Imaging) for each angiogram. Lesion length, reference vessel diameter (RVD), MLD, and percentage diameter stenosis (%DS) were measured. We calculated late lumen loss (LLL) as the postprocedural MLD minus the follow-up MLD. Angiographic calcification was identified as a readily apparent radiopacity within the vascular wall at the stenosis site. Angiographic restenosis was defined as a diameter stenosis of >50% of the treated lesion at follow-up. QCA was performed by experts at Hokkaido Cardiovascular Hospital who were blinded to the patient data.

Results

The mean follow-up period was 215±125 days. Of the 337 lesions analysed, 91.1% (n=307) were in the non-restenosis group, and 8.9% (n=30) were in the restenosis group. The non-restenosis group was classified as having non-restenosis (class I, 45.1%; n=152) or lumen enlargement (class II, 46.0%; n=155). The restenosis group was classified into focal restenosis (class III, 5.0%; n=17), diffuse restenosis (class IV, 3.6%; n=12), and occlusive restenosis (class V, 0.3%; n=1) **(Table 3)**. In the additional findings, there were

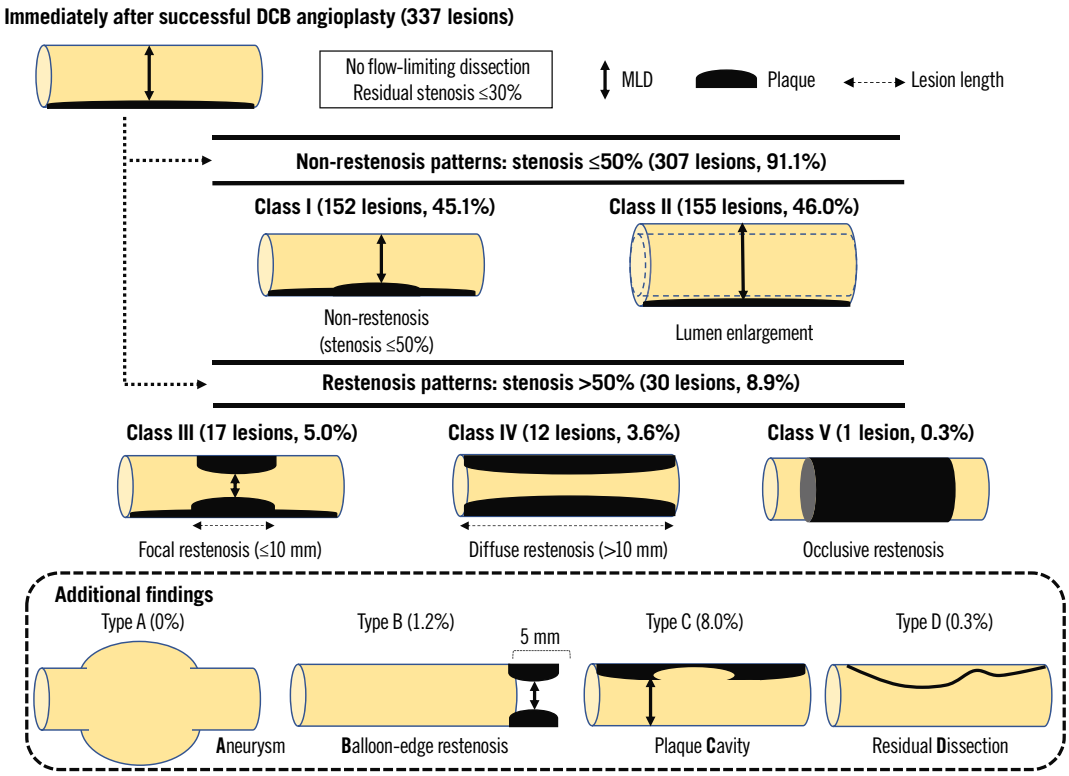

Figure 2. *Schematic images of angiographic classification at follow-up after DCB angioplasty for de novo coronary lesions. DCB: drug-coated balloon; MLD: minimal lumen diameter*

Table 3. Angiographic classification.

Angiographic classification (n=337)				
Non-restenosis: 307 (91.1)		Restenosis: 30 (8.9)		
Class I	Class II	Class III	Class IV	Class V
152 (45.1)	155 (46.0)	17 (5.0)	12 (3.6)	1 (0.3)
Additional findings (type A/B/C/D) in each class				
Class I	Class II	Restenosis (Class III, IV, V)		
0/1/7/1	0/2/15/0	0/1/5/0		
Additional findings (type A/B/C/D) in all cases				
Type A: 0 (0)	Type B: 4 (1.2)	Type C: 27 (8.0)	Type D: 1 (0.3)	
Values are n (%).				

no aneurysms, and plaque cavities were often observed (8.0%). The rate of balloon-edge restenosis was 1.2%. Residual dissection in the chronic phase was only observed in one case (0.3%). The baseline clinical, lesion, and procedural characteristics are presented in **Table 4** and **Table 5**.

Discussion

This is the first report on the classification of chronic-phase angiographic patterns after DCB angioplasty for *de novo* lesions. The main findings of our study were as follows: (1) 46.0% of lesions presented late lumen enlargement (LLE), (2) half of the lesions with restenosis patterns presented a focal pattern of restenosis, and (3) plaque cavities were the most frequently observed additional finding.

LUMEN ENLARGEMENT

Luminal increase during the chronic phase is a specific feature of DCB angioplasty, referred to as LLE. Previous studies have shown that the rate of LLE ranges from 50-70%[5,6]. Similarly, in this study, 46.0% of the lesions presented with late lumen enlargement. We have previously reported that the mechanisms of LLE include positive vessel remodelling and plaque regression[7]. Some previous reports have shown that dissection without flow limitation after DCB angioplasty might be a predictor of LLE[8].

RESTENOSIS

This study showed that the binary restenosis rate after DCB angioplasty for *de novo* lesions was 8.9%. Previous studies reported similar binary restenosis rates (10.5%[9], 11.0%[10]). In this study, 56.7% of patients with restenosis patterns presented with a focal restenosis pattern. A residual %DS ≥20% after lesion preparation, DCB-to-stent ratio ≥0.91, and DCB inflation time ≥60 seconds serve as predictors of restenosis after DCB angioplasty for in-stent restenosis of DES[11]. Although severe dissection and imaging device use have been reported as predictors of restenosis after DCB angioplasty for *de novo* coronary lesions[12], the causes for this remain unclear.

ANEURYSM

Coronary artery aneurysms following DCB angioplasty are rare. No aneurysms were observed in the present study. Kleber et al reported that they found aneurysms after DCB intervention with an incidence of 0.8%[13]. The mechanism of this phenomenon

Table 4. Baseline clinical characteristics.

	Non-restenosis		Restenosis	*p*-value	
	Class I (n=152)	Class II (n=155)	Class III, IV, V (n=30)	Class I vs Class II vs restenosis	Non-restenosis vs restenosis
Age, years	68.7±10.7	67.3±11.5	69.2±11.6	0.460	0.556
Male	113 (74.3)	122 (78.7)	27 (90.0)	0.157	0.091
Hypertension	118 (77.6)	121 (78.0)	21 (70.0)	0.618	0.328
Diabetes mellitus	63 (41.4)	64 (41.3)	15 (50.0)	0.658	0.361
Dyslipidaemia	112 (73.6)	130 (85.5)	20 (66.7)	0.031	0.126
Smoking history	88 (57.9)	99 (63.9)	18 (60.0)	0.560	0.922
HD	16 (10.5)	10 (6.5)	2 (3.3)	0.409	0.733
CKD	27 (17.8)	24 (15.5)	7 (23.3)	0.564	0.352
Index presentation				0.231	0.122
Stable angina	110 (72.4)	107 (69.0)	17 (56.7)		
ACS	42 (27.6)	48 (31.0)	13 (43.3)		
Prior PCI	50 (32.9)	45 (29.0)	9 (30.0)	0.760	0.915
Prior CABG	3 (2.0)	7 (4.5)	1 (3.3)	0.456	0.982
Prior MI	28 (18.4)	31 (20.0)	7 (23.3)	0.812	0.588
DAPT	149 (98.0)	152 (98.1)	30 (100)	0.742	0.440

Values are mean±standard deviation or n (%). ACS: acute coronary syndrome; CABG: cardiac artery bypass graft; CKD: chronic kidney disease; DAPT: dual antiplatelet therapy; HD: haemodialysis; MI: myocardial infarction; PCI: percutaneous coronary intervention

after paclitaxel-coated balloon angioplasty without stenting was suspected to be vessel enlargement due to the toxic effects of the drug and the influence of any dissection.

BALLOON-EDGE RESTENOSIS

Previous studies have reported that the predictors of stent edge restenosis are a large hinge angle, residual plaque burden, lipidic plaque, and minimal lumen area in the stent-edge segment[14,15]. Although stent-edge struts may cause mechanical stimulation of the vessel wall, leading to continuous injury and/or inflammation, DCB angioplasty can avoid the need for an implantation of a permanent metallic scaffold. The mechanism of balloon-edge restenosis after DCB angioplasty is suspected to be a predictor of geographical miss. The longitudinal geographic miss, in which the DCB does not fully cover the injured lesions by predilatation, could lead to insufficient drug delivery and failure to prevent neointimal proliferation.

PLAQUE CAVITY

Plaque cavities were the most frequently observed additional finding in the present study. On angiography, the plaque cavity appeared as an ulcer with overhanging margins **(Figure 3)**. Although an ulcer might result from the rupture of atherosclerotic plaques in most cases, the present study showed that the plaque cavity was found not only in patients with acute coronary syndrome but also in those with stable angina. In this study, 8.0% of patients had plaque cavities on follow-up angiography. We previously reported that drug-induced plaque regression may contribute to chronic luminal enlargement[7]. It was suspected that the "cast-off shell" of plaque is one of the mechanisms of the plaque cavity **(Figure 3C')**. In this case, the normal vascular structure was maintained, and the plaque volume was reduced. Most of the abnormal dilatated findings on the follow-up angiogram after DCB angioplasty might be due to plaque cavities rather than true aneurysms.

RESIDUAL DISSECTION

The international DCB consensus group recommended that the absence of flow-limiting dissection is a factor for acceptable angiographic results after lesion preparation. A previous study reported that more than 90% of dissections after DCB angioplasty healed completely despite the initial severity, and there were no new or worse dissections[16]. The present study demonstrated a residual dissection rate of 0.3%.

Limitations

This study had some limitations. First, this was a retrospective study, and a selection bias may have occurred. Second, because this was a single-centre study, the number of patients was small. Third, angiogram at follow-up was not mandatory; therefore, the rate of angiographic follow-up was approximately 50%. These data might be insufficient, and silent ischaemia could have been underestimated. Fourth, the association between the findings of intracoronary imaging devices and angiographic classification was not assessed in this study. The sample size of the restenosis group was small. Further study involving follow-up intracoronary evaluation is needed to reveal any association.

Conclusions

This report demonstrates for the first time the angiographic classification after DCB angioplasty for *de novo* coronary lesions. Restenosis patterns were seen in 8.9% of lesions, and half of the restenosis patterns presented a focal restenosis pattern. Late lumen enlargement was observed in 46% of the treated lesions; however, it is still unclear whether angiographic classification after DCB angioplasty has an impact on clinical events. We expect the impact of this classification on clinical outcomes to be revealed in the future.

Table 5. Lesion and procedural characteristics.

	Non-restenosis		Restenosis	*p*-value	
	Class I (n=152)	Class II (n=155)	Class III, IV, V (n=30)	Class I vs Class II vs restenosis	Non-restenosis vs restenosis
Target vessels				0.322	0.734
LAD	58 (38.2)	77 (49.7)	14 (46.7)		
LCx	36 (23.7)	37 (23.9)	9 (30.0)		
RCA	57 (37.5)	40 (25.8)	7 (23.3)		
LMCA	1 (0.6)	1 (0.6)	0 (0)		
AHA type B2/C	86 (56.6)	87 (56.1)	20 (66.7)	0.550	0.276
Angiographic calcification	29 (19.1)	33 (21.2)	7 (23.3)	0.820	0.684
Ostial lesion	13 (8.6)	19 (12.2)	6 (20.0)	0.169	0.113
CTO	5 (3.3)	5 (3.2)	2 (6.7)	0.629	0.336
Bifurcation	26 (17.1)	28 (18.1)	4 (13.3)	0.820	0.556
Before procedure					
Lesion length, mm	14.5±7.8	14.1±7.6	14.6±5.5	0.866	0.844
RVD, mm	2.32±0.52	2.32±0.55	2.49±0.61	0.261	0.101
MLD, mm	0.70±0.46	0.70±0.51	0.54±0.40	0.234	0.088
%DS, %	69.7±17.9	70.6±20.1	77.5±15.2	0.047	0.039
After procedure					
RVD, mm	2.43±0.48	2.37±0.50	2.53±0.63	0.175	0.165
MLD, mm	1.96±0.43	1.84±0.39	1.94±0.51	0.032	0.536
%DS, %	19.5±8.07	21.7±6.9	23.0±6.6	0.009	0.088
Dissection (No/A/B/C)	120/7/21/4	131/6/17/1	28/1/1/0	0.437	0.405
Follow-up					
Follow-up duration, days	215±125	214±115	220±116	0.956	0.776
RVD, mm	2.38±0.50	2.53±0.47	2.56±0.68	0.014	0.271
MLD, mm	1.71±0.43	2.07±0.41	1.05±0.37	<0.001	<0.001
%DS, %	27.6±11.2	18.0±9.7	59.6±7.5	<0.001	<0.001
LLL	0.25±0.22	–0.24±0.20	0.90±0.25	<0.001	<0.001
Dissection (No/A/B/C)	151/0/1/0	155/0/0/0	30/0/0/0	0.543	0.754
DCB size					
DCB diameter, mm	2.70±0.47	2.67±0.42	2.84±0.50	0.165	0.074
Balloon-to-artery ratio	1.19±0.21	1.22±0.64	1.17±0.19	0.572	0.636
DCB length, mm	19.4±5.3	20.1±9.3	19.8±5.3	0.762	0.949
Maximum inflation pressure, atm	7.42±2.13	7.72±2.45	7.53±3.00	0.536	0.930
Duration of inflation, s	53.2±12.6	55.9±9.1	55.5±16.0	0.121	0.686
Predilatation balloon				0.434	0.154
Conventional balloon	22 (14.5)	21 (13.5)	1 (3.3)		
Scoring/cutting balloon	126 (82.9)	130 (83.9)	29 (96.7)		
High pressure balloon	4 (2.6)	4 (2.6)	0 (0)		
Balloon diameter, mm	2.59±0.48	2.61±0.45	2.80±0.53	0.084	0.027
Balloon-to-artery ratio	1.15±0.23	1.19±0.63	1.15±0.17	0.690	0.808
Balloon length, mm	12.8±2.0	12.8±2.2	12.8±2.6	0.991	0.947
Maximum inflation pressure, atm	11.9±4.7	11.6±4.3	11.3±4.6	0.751	0.608
Rotablator	3 (2.0)	1 (0.6)	1 (3.3)	0.428	0.380
DCA	1 (0.7)	0 (0)	0 (0)	0.543	0.754
Excimer laser	3 (2.0)	9 (5.8)	2 (6.7)	0.187	0.470
Intracoronary imaging-guided PCI	141 (92.8)	142 (91.6)	28 (93.3)	0.908	0.822

Values are mean±standard deviation or n (%). %DS: percentage diameter stenosis; AHA: American Heart Association; CTO: chronic total occlusion; DCA: directional coronary atherectomy; DCB: drug-coated balloon; LAD: left anterior descending artery; LCx: left circumflex artery; LLL: late lumen loss; LMCA: left main coronary artery; MLD: minimal lumen diameter; PCI: percutaneous coronary intervention; RCA: right coronary artery; RVD: reference vessel diameter

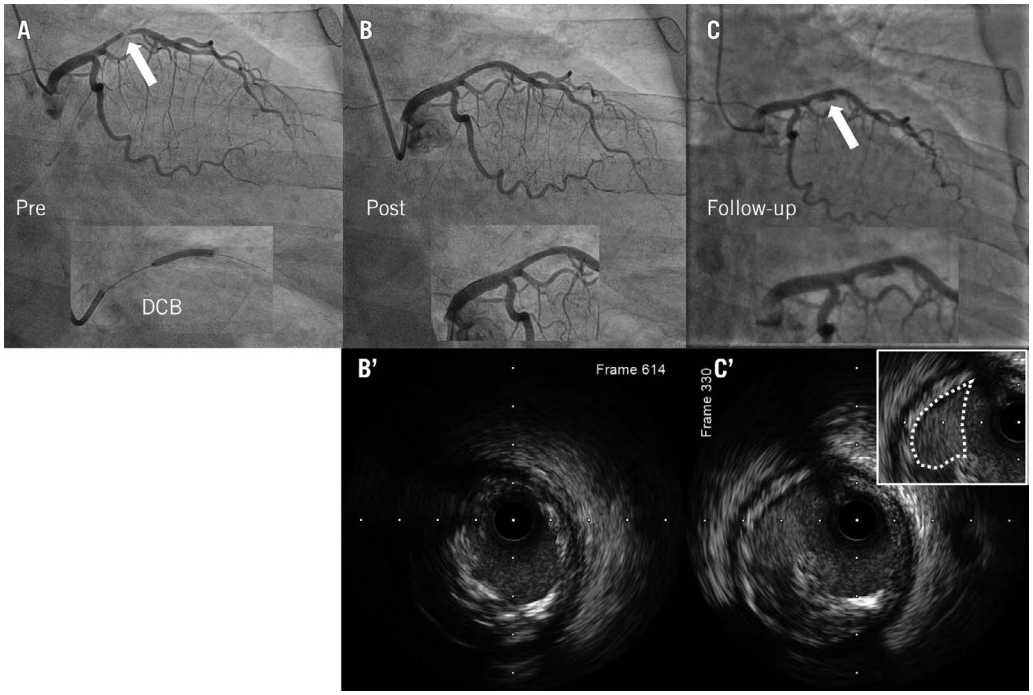

Figure 3. *A representative case with a class I (non-restenosis) and type C (plaque cavity) lesion. A) Preprocedure; (B) post-DCB treatment; (C) follow-up angiographic images showing the plaque cavity (arrow); (B') IVUS image post-DCB treatment; (C') IVUS image at follow-up showing the plaque cavity (dotted line). DCB: drug-coated balloon; IVUS: intravascular ultrasound*

Impact on daily practice

This report demonstrates for the first time the angiographic classification after DCB angioplasty for *de novo* coronary lesions. Late lumen enlargement was observed in 46% of the treated lesions. Half of the restenosis patterns presented a focal restenosis pattern. In the future, it is expected that the impact of this classification on clinical outcomes will be demonstrated.

Conflict of interest statement

The authors have no conflicts of interest to declare.

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