Vascular Response after Directional Coronary Atherectomy for Left Main Bifurcation Lesion

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Research Article

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Abstract

Purpose: To evaluate the vascular response after directional coronary atherectomy (DCA) for left main (LM) bifurcation lesion.

Methods: This study was a retrospective, single-center study enrolling 31 patients who underwent stent-less therapy using DCA followed by drug-coated balloon angioplasty for LM bifurcation lesion. We compared the intravascular ultrasound (IVUS) findings pre- and post DCA.

Results: After DCA, the lumen and vessel areas significantly increased whereas the plaque area (PA) and %PA significantly decreased. When the lesions were divided into small and large vessel groups using the median vessel area value, the maximum balloon pressure of the DCA catheter was greater in the large than in the small vessel group. Changes in the lumen and vessel areas were also significantly greater in the large than in the small vessel group. Conversely, the PA and %PA changes were similar between the groups.

Conclusion: The main vascular responses associated with lumen enlargement after DCA were plaque reduction and vessel expansion. Contribution of vessel expansion to lumen enlargement was larger than the effect of plaque reduction in large than in small-vessel lesions.

Introduction

Percutaneous coronary intervention (PCI) is an established option for the treatment of left main (LM) coronary artery disease [1]. However, complex stenting is sometimes inevitable in cases of LM bifurcation lesions and its efficacy has not been proven compared with that of the simple stent strategy [2]. Previous studies have reported the efficacy of directional coronary atherectomy (DCA) to avoid complex stenting in bifurcated lesions and to reduce restenosis of the left circumflex artery (LCX) ostium after single stent implantation for LM bifurcation lesions [3, 4]. Once the DCA catheter became commercially unavailable, a novel, improved DCA catheter (ATHEROCUT, Nipro Corporation, Osaka, Japan) was developed and became commercially available in Japan in 2015. Recently, the efficacy of the stent-less strategy for LM bifurcation lesions using drug-coated balloon (DCB) angioplasty after DCA was reported [5]. Adequate lumen enlargement is important to achieve maximum efficacy of the stent-less strategy using DCA followed by DCB angioplasty. The percentage plaque area (%PA) is a popular indicator that used to determine the optimal DCA endpoint. Plaque reduction is the main lumen enlargement mechanism in DCA [6–8], and increasing the balloon pressure of the DCA catheter further enhances plaque reduction [9]. In contrast, balloon angioplasty can induce vessel expansion, which is also one of the lumen enlargement mechanisms [10, 11]. During DCA in LM bifurcation lesions, high balloon pressure of the DCA catheter is frequently required for large vessel lesions because the large plaque burden must be debulked. Therefore, the efficacy of vessel expansion and that of plaque reduction for large vessel lesions may increase. However, to date, little is known regarding the vessel response after DCA in LM bifurcation lesions. We

assessed intravascular ultrasound (IVUS) findings after performing DCA in cases of LM bifurcation lesions to evaluate the vascular response.

Materials And Methods

Patient population

Between April 2016 and October 2019, 58 patients who underwent PCI with DCA for LM bifurcation lesions were retrospectively identified. Of these, 27 patients were excluded because 18, two, and seven patients underwent implantation of drug-eluting stents after DCA, DCA alone, and DCA for proximal stent edge restenosis at the left anterior descending artery (LAD) ostium, respectively. Finally, 31 patients who underwent stent-less therapy with DCA followed by DCB angioplasty for *de-novo* LM bifurcation lesions were enrolled in this study. Among them, one patient underwent DCA followed by DCB angioplasty for the LAD and LCX ostium; therefore, in this study, we analyzed the IVUS findings after performing DCA in 32 lesions of 31 patients.

The indications of DCA for LM bifurcation lesions were as follows: 1) stable angina pectoris with LM bifurcation lesion involving the distal LM trunk, the LAD ostium, or the LCX ostium; 2) a reference diameter in the main branch of > 2.5 mm using visual estimation; and 3) IVUS findings suitable for DCA (no lipid-rich plaque, no thrombus, no severe superficial calcification, and plaque location to be debulked by DCA was accurately evaluated using IVUS). The exclusion criteria were as follows: 1) unstable angina pectoris and myocardial infarction; 2) poor patient's general condition and renal insufficiency (Cr > 1.5 mg/dL); 3) severe angle lesion; and 4) angiographic severe calcified lesions. This study was approved by the institutional review board of our hospital and complied with the Declaration of Helsinki. Written informed consent was obtained from all patients for the procedure and subsequent data collection.

Procedure and follow-up examinations

All PCIs were performed via the femoral artery using an 8Fr sheath introducer and an 8Fr guiding catheter. During the procedure, the activated coagulation time was maintained at > 300 s with heparin administration. We carefully evaluated plaque distribution and plaque characteristics using IVUS after crossing the lesion with a conventional guidewire. We decided to perform DCA after plaque distribution to be debulked was adequately evaluated using IVUS and after confirming that there were no lipid rich plaque, thrombus, and severe superficial calcification. ATHEROCUT (Nipro Corporation) was used for all lesions and size selection, and was dependent on the reference diameter of IVUS. DCA was initiated with low balloon pressure (0 or 1 atm) and gradually increased based on the IVUS findings. We repeated IVUS evaluation after several cuts of DCA, and again repeated to obtain residual %PA < 60% when possible [3]. The performance of the stent-less strategy was decided after careful evaluation of the IVUS and angiographic findings by experienced operators. DCB angioplasty using SeQuent Please (Nipro Corporation) was performed after DCA when the IVUS findings revealed that there was no large residual plaque burden, no huge dissection, and no hematoma formation. The DCB size was selected according to the reference lumen diameter by IVUS, and the balloon inflation time was 30 s with nominal pressure.

Dual antiplatelet therapy with 100 mg/day aspirin and either 75 mg/day clopidogrel or 3.75 mg/day prasugrel was administered before the procedure and continued for 3 months following the procedure. Complications during the procedure and procedure-related major events during hospitalization including death, emergent target lesion revascularization (TLR) and coronary artery graft bypass, myocardial infarction, and access site complications, were recorded. Myocardial infarction was defined as any postprocedural creatine kinase elevation more than two times than normal. All patients underwent a follow-up examination at 30 days after discharge and every 2–3 months subsequently. Follow-up coronary angiography was scheduled at 9–12 months after the procedure. TLR at 12 months and a major adverse cardiac event (MACE) defined as a composite of cardiac death, myocardial infarction, and any repeat revascularization at 12 months were investigated.

Quantitative coronary angiography analysis

Quantitative coronary angiography (QCA) analysis was performed using the computer-based software (Heart II ver 2.0.2.3, GADELIUS, Tokyo, Japan) before the procedure, after the procedure, and at follow-up examinations using a guiding catheter to calibrate the magnification. Optimal views of the lesions were obtained at baseline, and the same projection angle was used at follow-up examinations. Independent physicians who were blinded to all clinical information analyzed the minimal lumen diameter (MLD), reference diameter, lesion length, and percent diameter stenosis (%DS). The acute gain was defined as the increase in the MLD after PCI; late lumen loss was defined as the difference between the post-procedural MLD and MLD at follow-up.

Intravascular ultrasound analysis

All IVUSs were performed using commercially available IVUS catheters (OptiCross™, Boston Scientific, Marlborough, MA, USA; or ViewIT; Terumo, Tokyo, Japan) with automatic pull-back at a 0.5-mm/s rate. At the lumen site where the lumen area was the smallest, the lumen diameter, lumen area, vessel area, and %PA were analyzed. PA was defined as the vessel area minus the lumen area. %PA was defined as follows: %PA=(vessel area minus lumen area)×100/vessel area.

The changes in the vessel area, lumen area, PA, and %PA after DCA were defined as post-procedure minus pre-procedure values for the vessel area (Δ vessel area), lumen area (Δ lumen area), PA (Δ PA), and %PA (Δ %PA), respectively. These measurements were compared between the small and large vessel lesions, which were determined based on the median vessel area value. Incidences of hematoma, intimal dissection, and medial dissection were recorded. All images were analyzed using computerized planimetry software (echoPlaque; INDEC Medical Systems, Los Altos, CA, USA) by independent physicians who were blinded to all clinical data.

Statistical analyses

Data are presented as numbers with percentages or as means ± standard deviations. Comparisons of categorical variables were performed using Fisher's exact test. Comparisons of continuous variables were performed using Student's t-test or the Mann–Whitney U test. The Spearman rank correlation method was

applied to estimate correlations between continuous variables. All *P*-values were two-sided and *P*-values < 0.05 were considered statistically significant. All analyses were performed using SPSS software (version 19; IBM Corp., Armonk, NY, USA).

Results

Patient and lesion characteristics

The patient and lesion characteristics are summarized in Table 1. In total, 31 patients with LM bifurcation lesions (mean age: 70 ± 10 years; male: 94%; diabetes mellitus: 26%; hemodialysis: 3%) were enrolled. DCA was performed more frequently for the LAD ostium (68%), followed by distal left main trunk and the LAD ostium (17%). One patient (3%) with true bifurcation lesion (medina 1, 1, 1) underwent DCA for the distal LM trunk, LAD ostium, and LCX ostium.

Table 1
Baseline characteristics of the participants

Patient characteristics	**N = 31**
Age (years)	70 ± 10
Male (%)	29 (94)
Hypertension (%)	24 (77)
Diabetes mellitus (%)	8 (26)
Hyperlipidemia (%)	24 (77)
Hemodialysis (%)	1 (3)
Current smoker (%)	2 (6)
Previous percutaneous coronary intervention (%)	10 (32)
Previous coronary artery bypass graft (%)	0 (0)
Medication	
ACE/ARB (%)	21 (68)
β blocker (%)	22 (71)
Statin (%)	30 (97)
Aspirin (%)	31 (100)
Clopidogrel (%)	10 (32)
Prasugrel (%)	21 (68)
Medina classification	
(0, 1, 0) (%)	18 (58)
(0, 0, 1) (%)	4 (13)
(1, 0, 0) (%)	1 (3)
(1, 1, 0) (%)	7 (23)
(1, 1, 1) (%)	1 (3)
Main target of DCA	
LAD ostium (%)	21 (68)
LCX ostium (%)	2 (6)

DCA, directional coronary atherectomy; LAD, left anterior descending artery; LCX, left circumflex artery; ACE, angiotensin converting enzyme; ARB, angiotensin □ receptor blocker

Patient characteristics	N = 31
Distal left main trunk (%)	2 (6)
Distal left main trunk and LAD ostium (%)	5 (17)
Distal left main trunk, LAD ostium and LCX ostium (%)	1 (3)

DCA, directional coronary atherectomy; LAD, left anterior descending artery; LCX, left circumflex artery; ACE, angiotensin converting enzyme; ARB, angiotensin receptor blocker

Procedure results

The procedure results are presented in Table 2. ATHEROCUT type L was the most frequently used (91%). The total cuts were 28 ± 17, and the maximum balloon pressure of the DCA catheter was 3.5 ± 1.3 atm. When lesions were divided into the small and large vessel groups at the median vessel area value (14.9 mm^2), the maximum balloon pressure was significantly higher in the large than in the small vessel group (2.8 ± 0.9 vs. 4.1 ± 1.3 atm, $P = 0.014$). All lesions underwent DCB angioplasty after DCA with diameter (3.3 ± 0.4 mm) and balloon pressure (8.3 ± 2.9 atm). In the QCA analysis, MLD and %DS were significantly improved after the procedure (MLD: 1.3 ± 0.4 vs. 3.4 ± 0.9 mm, $P < 0.001$; %DS: 63.3 ± 10.6 vs. 12.2 ± 7.9 %, $P < 0.001$) (Table 3). There were no complications during the procedure and no procedure-related major events during hospitalization (Table 2).

Table 2
Procedural results

Directional coronary atherectomy	**32 lesions (31 patients)**
Size of catheter	
ATHEROCUT type M (%)	3 (9)
ATHEROCUT type L (%)	29 (91)
Total number of cuts (times)	28 ± 17
Maximum balloon pressure (atm)	3.5 ± 1.3
Drug-coated balloon	
Diameter (mm)	3.3 ± 0.4
Length (mm)	17.5 ± 3.4
Balloon pressure (atm)	8.3 ± 2.9
Procedure time (min)	126 ± 41
Amount of contrast media (mL)	196 ± 72
Complication during the procedure	
Vessel perforation (%)	0 (0)
Slow flow phenomenon (%)	0 (0)
Stuck of DCA catheter (%)	0 (0)
Procedure-related major events during the hospitalization	
Death (%)	0 (0)
Emergent TLR or CABG (%)	0 (0)
Myocardial infarction (Q or non-Q) (%)	0 (0)
Access site complictaions (%)	0 (0)

DCA, directional coronary atherectomy; TLR, target lesion revascularization; CABG, coronary artery bypass graft

Table 3
Quantitative coronary analysis results

Pre procedure	**32 lesions**
Minimum lumen diameter (mm)	1.3 ± 0.4
Reference lumen diameter (mm)	3.9 ± 1.1
% diameter stenosis (%)	63.3 ± 10.6
Lesion length (mm)	18.5 ± 6.7
Post procedure	
Minimum lumen diameter (mm)	3.4 ± 0.9
Acute gain (mm)	2.0 ± 1.0
Reference lumen diameter (mm)	3.8 ± 1.1
% diameter stenosis (%)	12.2 ± 7.9
Follow-up	
Minimum lumen diameter (mm)	3.3 ± 1.1
Late lumen loss (mm)	0.1 ± 0.5
% diameter stenosis (%)	15.4 ± 15.3

IVUS findings during DCA

The IVUS findings during DCA were summarized in Table 4. Both lumen and vessel areas became significantly larger after DCA (lumen area: 3.0 ± 0.9 vs. 8.9 ± 2.1 mm^2, $P < 0.001$; vessel area: 13.5 ± 3.6 vs. 16.1 ± 3.8 mm^2, $P = 0.004$). The plaque area and %PA significantly decreased after DCA (plaque area: 10.5 ± 3.3 vs. 7.2 ± 2.3 mm^2, $P < 0.001$; %PA: 77.5 ± 6.1 vs. 44.3 ± 6.7%, $P < 0.001$). There was a positive correlation between the lumen and vessel area after DCA (r = 0.90, $P < 0.001$). However, there was no correlation between %PA and the vessel area after DCA (r = 0.21, $P = 0.26$) (Fig. 1a, b). Δ lumen area and Δ vessel area were significantly larger in the large than in the small vessel group (Δ lumen area: 4.6 ± 1.4 vs. 7.3 ± 1.8 mm^2, $P < 0.001$; Δ vessel area: 1.6 ± 2.5 vs. 3.7 ± 3.0 mm^2, $P = 0.04$) (Fig. 2a, b). Conversely, Δ PA and Δ %PA were similar between the small and large vessel groups (Δ PA: -3.0 ± 1.6 vs. -3.6 ± 3.8 mm^2, $P = 0.59$; Δ %PA: -32.2 ± 7.9 vs. -34.1 ± 10.9 %, $P = 0.58$) (Fig. 2c, d). Intimal dissection was observed in five lesions (15.6%); however, there was no medial dissection and hematoma formation. Figure 3 shows the representative IVUS findings before and after DCA in small and large vessel lesions. In the small-vessel lesions, the Δ lumen area, Δ vessel area, Δ PA and Δ %PA were 5.6 mm^2, 2.3 mm^2, -3.3 mm^2, and − 34.0%, respectively (Fig. 3a). In the large-vessel lesions, the Δ lumen area, Δ vessel area, Δ PA and Δ %PA were 8.3 mm^2, 5.0 mm^2, -3.4 mm^2, and − 38.3%, respectively (Fig. 3b).

Table 4
Intravascular ultrasound findings

Pre directional coronary atherectomy	**32 lesions**
Minimum lumen diameter (mm)	1.6 ± 0.3
Lumen area (mm^2)	3.0 ± 0.9
Vessel area (mm^2)	13.5 ± 3.6
Plaque area (mm^2)	10.5 ± 3.3
% plaque area (%)	77.5 ± 6.1
Post directional coronary atherectomy	
Minimum lumen diameter (mm)	2.8 ± 0.3
Lumen area (mm^2)	8.9 ± 2.1
Vessel area (mm^2)	16.1 ± 3.8
Plaque area (mm^2)	7.2 ± 2.3
% plaque area (%)	44.3 ± 6.7
Intimal dissection (%)	5 (15.6)
Medial dissection (%)	0 (0)
Hematoma (%)	0 (0)

Follow-up results

Angiographic follow-up examinations were performed for 28 patients (angiographic follow-up rate: 90.3%). At follow-up coronary angiography examination, MLD and %DS were similar to those after the procedure (MLD: 3.3 ± 1.1 vs. 3.4 ± 0.9 mm, P = 0.78; %DS: 15.4 ± 15.3 vs. 12.2 ± 7.9%, *P* = 0.32) (Table 3). TLR at 12 months occurred in one patient (3.2%) and no MACE except for TLR was observed at 12 months.

Discussion

The main findings of our study were as follows: 1) the mean %PA after DCA was 44.3% and the incidence of TLR at 12 months was 3.2% for *de-novo* LM bifurcation lesions after the stent-less strategy by DCA followed by DCB angioplasty; 2) the IVUS findings revealed that the lumen and vessel areas increased, while the PA and %PA decreased after DCA; 3) the lumen area was well correlated with the vessel area after DCA; however, %PA after DCA was not correlated with the vessel area after DCA; 4) the Δ lumen and

Δ vessel areas after DCA were larger in large vessel lesions compared with those in small-vessel lesions. However, Δ PA and Δ%PA after DCA were similar between the small and large vessel lesions.

A previous study reported that lumen enlargement is the result of a combination of vessel expansion, plaque dissection, and plaque redistribution after balloon angioplasty [11]. In contrast, plaque removal was the specific mechanism in DCA that is associated with lumen enlargement [6–8], and the effect of plaque removal is controlled by increasing the balloon pressure of the DCA catheter [9]. Generally, large vessel lesions have a large amount of plaque to be debulked; therefore, high balloon pressure of the DCA catheter is required to achieve a lower %PA. Actually, the maximum balloon pressure was greater in large than in small-vessel lesions in this study. Our results revealed that increasing the maximum balloon pressure of the DCA catheter in large vessel lesions was associated with greater vessel expansion but did not increase the effect in plaque reduction compared with that in small-vessel lesions. Previous studies have also reported that vessel expansion is a significant contributor to lumen enlargement after DCA [12, 13]. Nakamura et al. demonstrated that lumen cross-sectional area improved from 2.9 ± 1.5 to 7.0 ± 1.5 mm^2 ($P < 0.0001$), while the vessel cross-sectional area increased from 17.1 ± 5.9 to 18.7 ± 5.5 mm^2 ($P < 0.001$), as observed by IVUS after DCA [12]. The largest size (L) of the DCA catheter was frequently used (91%) in the current study; therefore, a larger DCA catheter size may be necessary for further plaque reduction in large vessel lesions. However, the %PA obtained was sufficiently low even in large vessel lesions and the incidence of TLR at 12 months was acceptable. Therefore, we consider that the current size (L) of the DCA catheter will be adequate for DCA of large vessel LM bifurcation lesions. High balloon pressure of the DCA catheter will strengthen the contribution of vessel expansion in large vessel lesions. However, the DCA catheter is a bulky device and, thus, a vessel injury may occur. Operators should consider the occurrence of dissection, hematoma, and vessel perforation particularly for large vessel lesions with eccentric plaque or mild calcified plaque when the balloon pressure of the DCA catheter is increased.

Study limitations

This study had some limitations. First, the sample size of the current study was small and highly selected patients were enrolled. Thus, selection bias must be considered. Second, this study was retrospective; therefore, the protocol of the DCA procedure had not been strictly decided. We aimed to obtain %PA < 60% by DCA; however, the number of cuts and maximum balloon pressure were decided by the operator for each case. The DCA procedure itself extremely influenced the vessel response and, thus, our findings should be validated in other prospective studies. Third, we could not evaluate the effect of plaque distal embolization, which was considered as another possible mechanism of lumen enlargement after balloon angioplasty and stent implantation [14, 15]. Minor plaque distal embolization might occur after DCA, but there was no slow-flow phenomenon during the procedure and no myocardial infarction after the procedure; lesions with lipid plaque were excluded in this study. We believe that plaque distal embolization might be associated with lumen enlargement after DCA. However, it is quite difficult to evaluate the effect of distal embolization with lumen enlargement using IVUS. Finally, specific techniques

are required for interpretation of the IVUS findings and for precise control of the DCA catheter during the DCA procedure; therefore our results may not be generalized.

Conclusions

Plaque reduction and vessel expansion are the main mechanisms of DCA associated with lumen enlargement. High balloon pressure of the DCA catheter was frequently employed to increase the efficacy of plaque reduction particularly in large-vessel lesions. However, the effect of plaque reduction did not increase, whereas the contribution to vessel expansion became larger in large-vessel lesions after DCA. We should pay careful attention to avoid vessel injury when increasing the maximum balloon pressure of the DCA catheter in large-vessel lesions.

Declarations

Funding:

Not applicable.

Conflicts of interest:

The authors declare that they have no conflict of interest.

Availability of data and material:

The data used to support the findings of this study are restricted by the Ethics Committee of Saiseikai Yokohama-city Eastern Hospital to protect patient privacy and are available from the corresponding author upon request.

Code availability:

Not applicable.

Ethics approval:

This study was approved by the institutional review board of our hospital and complied with the Declaration of Helsinki.

Consent to participate:

Informed consent was obtained from all individual participants included in the study.

Consent for publication:

Patients signed informed consent regarding publishing their data and photographs.

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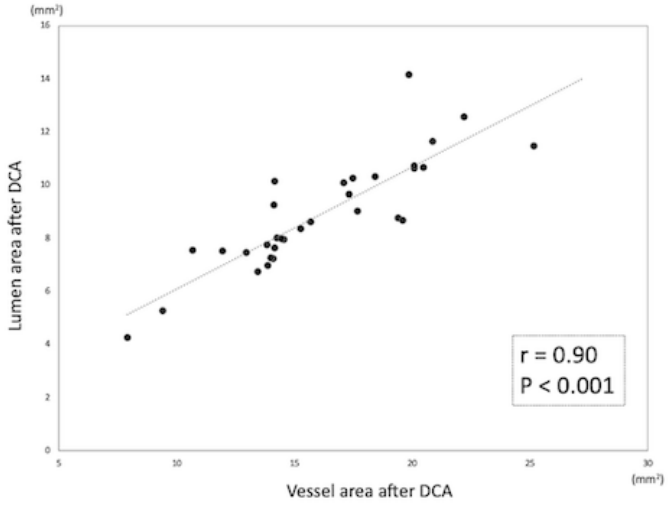
Figures



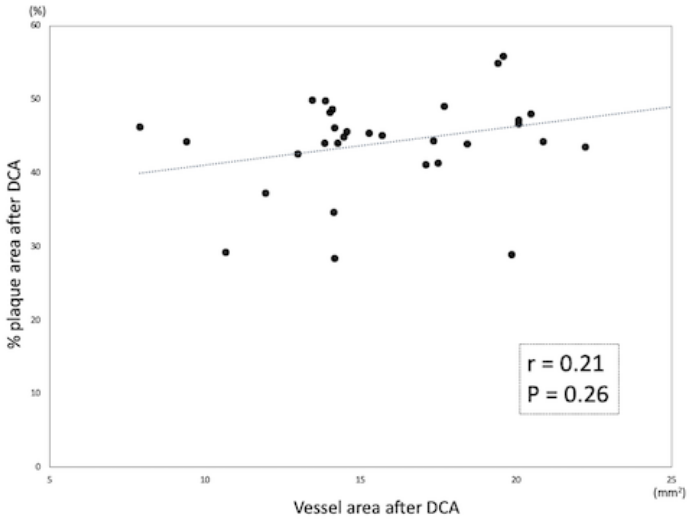


Figure 1

(a) Correlation between the lumen and vessel area after DCA (b) Correlation between %PA and the vessel area after DCA DCA, directional coronary atherectomy; PA, plaque area

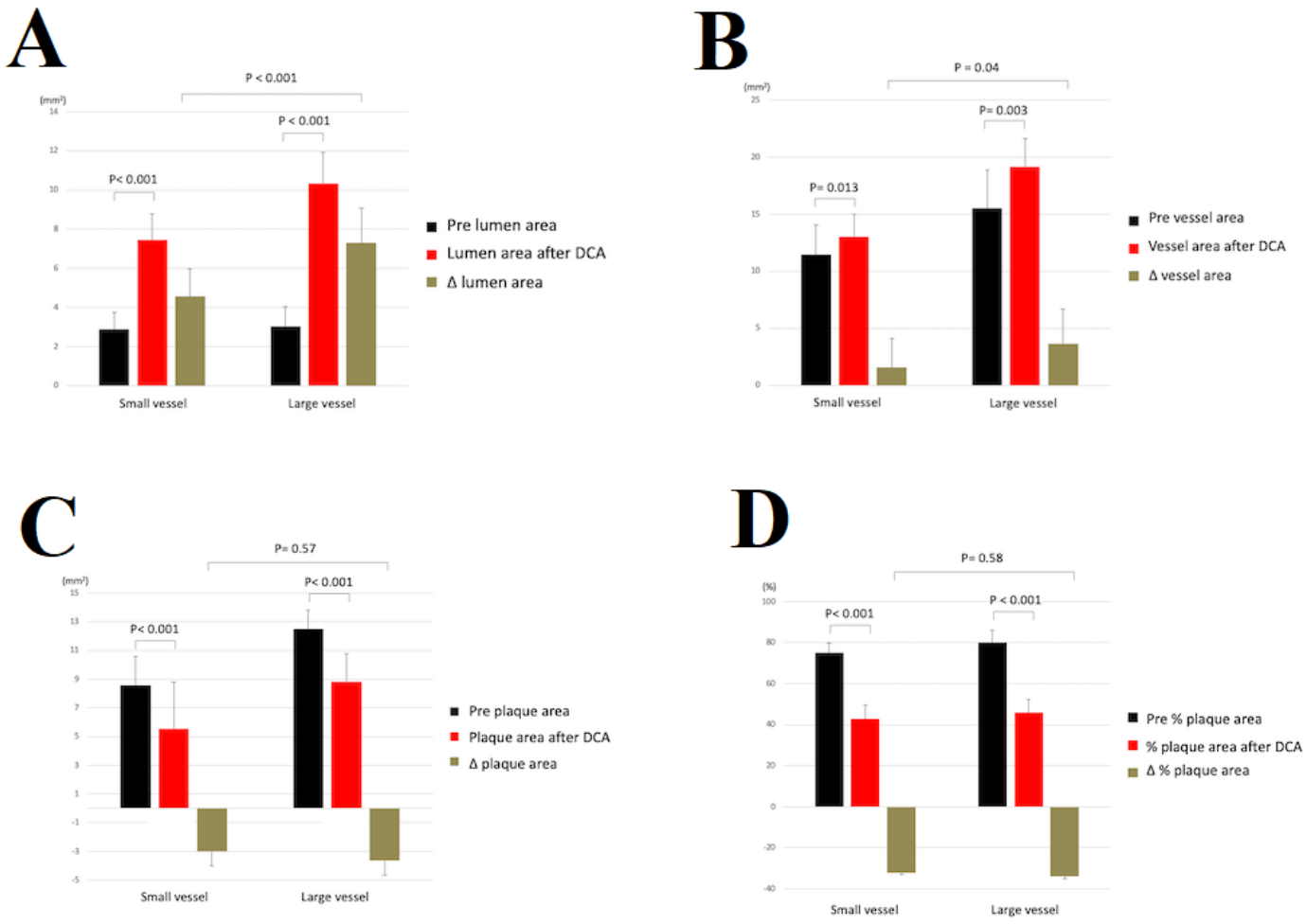


Figure 2

(a) Comparison of the pre-lumen area, lumen area after DCA, and change of the lumen area between the small and large vessel groups (b) Comparison of the pre-vessel area, vessel area after DCA, and change of the vessel area between the small and large vessel groups (c) Comparison of pre-PA, PA after DCA, and change of PA between the small and large vessel groups (D) Comparison of pre %PA, %PA after DCA and change of %PA between the small and large vessel groups DCA, directional coronary atherectomy; PA, plaque area

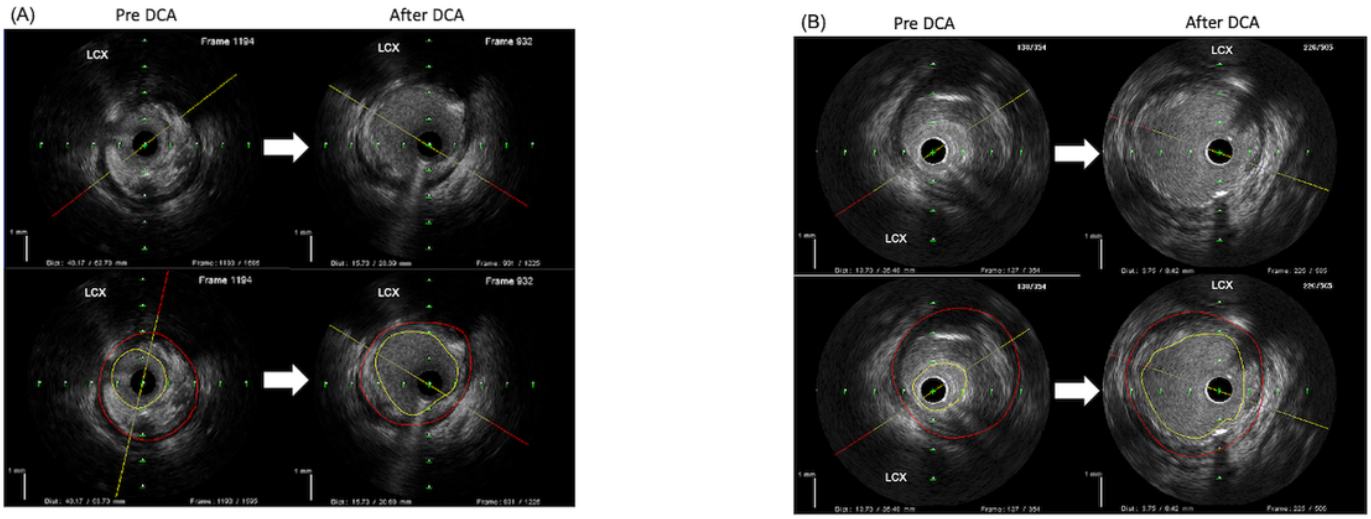


Figure 3

(a) IVUS findings before and after DCA in small-vessel lesions The red and yellow lines represent the vessel and lumen areas, respectively. The lumen area, vessel area, PA, and %PA before DCA were 2.7 mm2, 12.6 mm2, 9.9 mm2, and 78.5%, respectively. The lumen area, vessel area, PA, and %PA after DCA were 8.3 mm2, 14.9 mm2, 6.6 mm2, and 44.5%, respectively. The Δ lumen area, Δ vessel area, Δ PA, and Δ %PA were 5.6 mm2, 2.3 mm2, -3.3 mm2, and -34.0%, respectively. (b) IVUS findings before and after DCA in large vessel lesions The red and yellow lines represent the vessel and lumen areas, respectively. The lumen area, vessel area, PA, and %PA before DCA were 2.3 mm2, 14.8 mm2, 12.6 mm2, and 84.8%, respectively. The lumen area, vessel area, PA, and %PA of after DCA were 10.6 mm2, 19.8 mm2, 9.2 mm2, and 46.5%, respectively. The Δ lumen area, Δ vessel area, Δ PA, and Δ %PA were 8.3 mm2, 5.0 mm2, -3.4 mm2, and -38.3%, respectively. DCA, directional coronary atherectomy; PA, plaque area; IVUS, intravascular ultrasound