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ORIGINAL ARTICLE
Cardiovascular Intervention

Effect of Atherectomy on Lesion Preparation in Heavily Calcified Coronary Artery Disease

Hiroki Emori, MD, PhD; Yasutsugu Shiono, MD, PhD; Kosei Terada, MD, PhD; Daisuke Higashioka, MD; Masahiro Takahata, MD, PhD; Suwako Fujita, MD, PhD; Teruaki Wada, MD, PhD; Shingo Ota, MD, PhD; Keisuke Satogami, MD, PhD; Manabu Kashiwagi, MD, PhD; Akio Kuroi, MD, PhD; Takashi Yamano, MD, PhD; Takashi Tanimoto, MD, PhD; Atsushi Tanaka, MD, PhD

Background: Percutaneous coronary intervention (PCI) of heavily calcified lesions remains challenging. This study examined whether calcified lesion preparation is better with an ablation-based than balloon-based technique.

Methods and Results: Results of lesion preparations with and without atherectomy devices were compared in 121 patients undergoing optical coherence tomography (OCT)-guided PCI of heavily calcified lesions. Lesion preparation was performed with the ablation-based technique in 59 patients (atherectomy group) and with the balloon-based technique in 62 patients (balloon group). Lower grades of angiographic coronary dissections (National Heart, Lung, and Blood Institute [NHLBI] classification) occurred in the atherectomy than balloon group (atherectomy group: none, 33%; NHLBI A, 59%; B, 8%; C, 0%; D, 0%; balloon group: none, 1%; NHLBI A, 24%; B, 58%; C, 15%; D, 2%). On OCT, a large dissection was less common (49% vs. 90%; P<0.001) and calcium fractures were more frequent (75% vs. 18%; P<0.001) in the atherectomy than balloon group. In multivariable analyses, the ablation-based technique was associated with a lower grade of angiographic coronary dissection (adjusted odds ratio [aOR] 0.04; 95% confidence interval [CI] 0.01–0.12; P<0.001), a lower incidence of OCT-detected large dissection (aOR 0.09; 95% CI 0.03–0.30; P<0.001), and a higher incidence of OCT-detected calcium fracture (aOR 18.19; 95% CI 6.45–58.96; P<0.001).

Conclusions: The ablation-based technique outperformed the balloon-based technique in the lesion preparation of heavily calcified lesions.

Key Words: Atherectomy; Calcified lesions; Lesion preparation; Optical coherence tomography

Coronary artery calcification has been known to adversely affect procedural and clinical success in patients who undergo percutaneous coronary intervention (PCI). PCI of heavily calcified lesions is commonly associated with early complications (coronary dissection and perforation) and later adverse events (in-stent restenosis, stent thrombosis, and repeat revascularization).[1,2]

Lesion preparation is key to obtaining better clinical outcomes and preventing complications in PCI of heavily calcified lesions.[3] Reducing the volume of calcium and the development of fractures in calcium sheets facilitates more adequate stent expansion and allows sufficient enlargement of the vessel lumen. Moreover, calcified lesions may be treatable even without the need for coronary stents; drug-coated balloons (DCB) are a promising alternative when lesions are prepared well enough and if there are no large coronary dissections.[4,5] To prepare calcified lesions prior to stent implantation or DCB treatment, non-compliant or modified balloons (scoring or cutting balloons) are commonly used, and atherectomy devices are sometimes used, including rotational atherectomy (RA) or orbital atherectomy (OA). However, the most appropriate treatment methods for lesion preparation in heavily calcified lesions have not been established.

Optical coherence tomography (OCT) has advantages in the assessment of calcified lesions in that calcium plaque can be quantitatively measured and calcium fractures can be clearly visualized.[6–8] In addition, coronary dissections, which often occur in PCI of calcified lesions, can be accurately assessed.[9] Therefore, the aim of the present study was to compare the results of lesion preparations with and without the use of the atherectomy devices in patients undergoing OCT-guided PCI of heavily calcified coronary lesions.

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Department of Cardiovascular Medicine, Wakayama Medical University, Wakayama, Japan
Mailing address: Yasutsugu Shiono, MD, PhD, Department of Cardiovascular Medicine, Wakayama Medical University, 811-1 Kimiidera, Wakayama 641-8509, Japan. E-mail: yshiono@wakayama-med.ac.jp

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Methods

Study Population

In all, 1,185 PCIs were performed between January 2017 and July 2021 at Wakayama Medical University (Wakayama, Japan); of these, 145 patients presenting with de novo coronary lesions with moderate to severe calcifications were enrolled in this study. We excluded patients with calcified lesions in chronic coronary total occlusions, those with calcified ostial lesions, those with severely tortuous calcified lesions, and those with acute myocardial infarction (ST-segment elevation myocardial infarction or non-ST-segment elevation myocardial infarction) lesions within 30 days prior to the index procedure. All PCIs were performed using intravascular imaging (OCT in 133 cases, intravascular ultrasound [IVUS] in 12). We investigated only OCT-guided PCI cases, but excluded data from 12 patients for whom the OCT image quality was not sufficient for analysis. Thus, 121 cases were analyzed in the present study.

This study was approved by the Wakayama Medical University Hospital Institutional Review Board and complied with the Declaration of Helsinki for investigations in humans. Written informed consent was waived because of the retrospective nature of this study.

Coronary Angiography

Coronary angiography was performed using a conventional technique via a transradial or transfemoral approach. Angiographic images were obtained from multiple projections. A target vessel was defined as a coronary artery with moderately to severely calcified lesions causing myocardial ischemia. A target lesion was defined as a coronary lesion revealing the maximum degree of diameter stenosis as assessed visually in the target vessel. Calcifications were graded based on angiographic findings; moderate calcification was defined as radiopacities only visible with cardiac motion, whereas severe calcification was defined as radiopacities visible even without cardiac motion.[10]

OCT-Guided PCI

PCI was performed using 6- to 8-Fr guiding catheters. OCT images were acquired before PCI by standard techniques using ILUMIEN OPTIS (Abbott Vascular, Santa Clara, CA, USA) or Lunawave (Terumo, Tokyo, Japan). In case an OCT catheter did not pass the target lesion, balloon dilatation with small balloons (diameter 1.5–2.0 mm) was performed prior to OCT image acquisition. After the pre-PCI OCT, lesion preparations were performed using modified or non-compliant balloons with or without the use of atherectomy devices (RA and/or OA). Device selection and the procedures (e.g., the types and sizes of the balloons, burr sizes for RA, and rotational speed of RA and OA) were at the operator's discretion, but when RA or OA were used, atherectomy always had precedence over balloon dilation.

After lesion preparations, the target lesion was assessed by angiography and OCT (post-lesion preparation angiography and OCT). Taking account of these angiographic and OCT findings, the target lesions were treated with either a second-generation drug-eluting stent (DES) or a DCB (SeQuent Please; B. Braun, Melsungen, Germany) at the operator's discretion. After DES or DCB treatment, angiography and OCT were performed (post-PCI angiography and OCT) to assess the PCI results.

Coronary Angiography Analysis

Pre- and post-PCI angiography were assessed by quantitative coronary angiography analysis using a validated automated edge detection algorithm (CAAS-5; Pie Medical Imaging, Maastricht, Netherlands). The reference vessel diameter, minimal luminal diameter, lesion length, and percent diameter stenosis were measured at the target lesions. In the post-lesion preparation angiography, coronary dissection was assessed and graded from A to F (with A the lowest grade and F the highest grade) according to the National Heart, Lung, and Blood Institute (NHLBI) classification.[11]

OCT Analysis

OCT images on 3 occasions (pre-PCI, post-lesion preparations, and post-PCI) were assessed using a dedicated offline review system with semi-automated contour detection software (Abbott Vascular or Terumo Corporation).

In the pre-PCI OCT analysis, we assessed maximum calcium thickness, maximum calcium length, maximum calcium angle, the presence of nodular calcification, and minimum lumen area. OCT-derived calcification was defined as signal-poor or heterogeneous regions with sharply delineated borders. Nodular calcification was defined as a calcified plaque protruding into the vessel lumen with fibrous cap disruption. For quantitative analysis, all the contiguous OCT frames were visually screened and a candidate frame was selected. Maximum calcium thickness, maximum calcium angle, and minimum lumen area were measured on each candidate OCT frame. Maximum calcium length was calculated from the number of contiguous OCT frames presenting with calcification. The calcium score was calculated based on the maximum angle, maximum thickness, and the length of the calcified plaque.[12]

In the post-lesion preparation OCT analysis, we assessed coronary dissection, intramural hematoma, and calcium fracture.[9] OCT-detected large coronary dissection was characterized as a dissection with an extensive lateral (>60°) and longitudinal (>2 mm) extension and involvement of deeper vessel layers (media or adventitia). Intramural hematoma was characterized as a double-lumen appearance with a glistening intimomedial membrane separating the false and true lumen. Calcium fracture was characterized by a gap created within calcifications. The thickness of the calcium fracture was measured at the location where the calcium fracture was created.

In post-PCI OCT analysis, minimum lumen area was measured in patients treated with a DCB, whereas minimum stent area was measured in those implanted with a DES, on each candidate OCT frame selected by visual screening of all the contiguous OCT frames as described in the pre-PCI OCT analysis.

Study Endpoints

The endpoints of this study were coronary dissections and calcium fractures detected by post-lesion preparation angiography or OCT. The clinical outcomes of major adverse cardiovascular events (MACE; composite occurrence of cardiac death, myocardial infarction, or target vessel revascularization), target lesion revascularization (TLR), and stent thrombosis were assessed at 30 days following the index procedure.[13]

Statistical Analysis

Statistical analyses were performed with JMP 16.0 (SAS

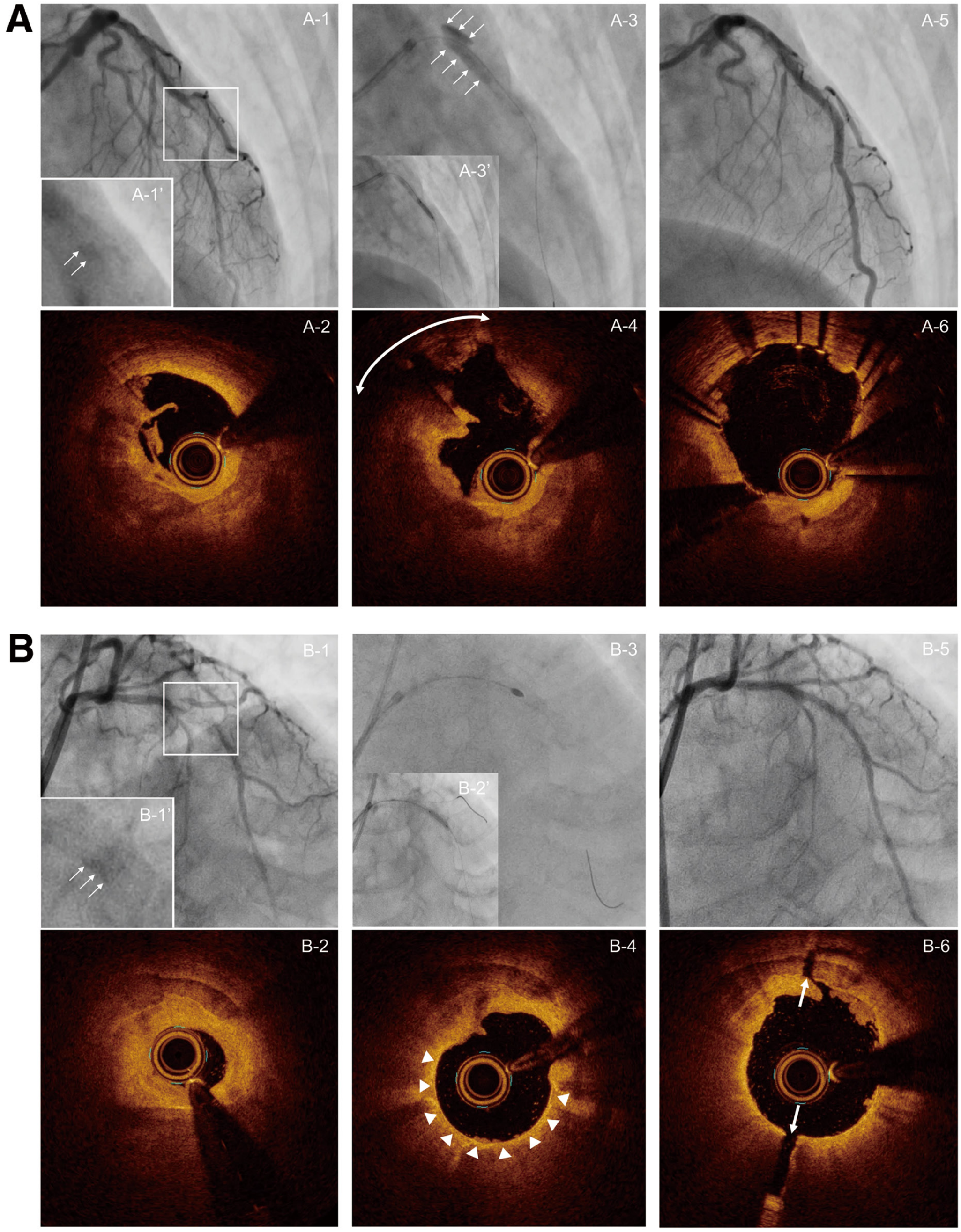

Figure 1. Representative images of lesion preparations with the (**A**) balloon- and (**B**) ablation-based techniques. (**A-1**) Angiography revealed stenosis with severe calcification (arrows in **A-1'**) in the mid left anterior descending artery (LAD). The boxed area in **A-1** is shown magnified in **A-1'** without contrast. (**A-2**) Pre-percutaneous coronary intervention (PCI) optical coherence tomography (OCT) cross-sectional image showing severe near-circumferential calcification in the target lesion. (**A-3**) After lesion preparation with a modified balloon (**A-3'**), retrograde Type C coronary dissection (arrows) with flow limitation occurred, originating from the balloon dilatation site to the proximal LAD. (**A-4**) Post-lesion preparation OCT cross-sectional image detected a large coronary dissection (double-headed arrow) involving the media, and the calcium plaque remained unscathed. (**A-5**) Coronary flow was restored with 2 drug-eluting stents sealing the entire dissected segment. (**A-6**) Post-PCI OCT cross-sectional image showing asymmetrical stent expansion in the direction opposite to the calcium plaque. (**B-1**) Angiography showed stenosis with severe calcification (arrows in **B-1'**) in the mid LAD. (**B-2**) Pre-lesion preparation OCT cross-sectional image showing severe near-circumferential calcification in the target lesion. The boxed area in **B-1** is shown magnified in **B-1'** without contrast. (**B-3**) Rotational atherectomy (RA) with a 2.0-mm burr was performed, followed by modified balloon dilatation (**B-3'**). (**B-4**) Post-lesion preparation OCT cross-sectional image showing a calcified plaque with a smooth concave surface ablated by RA (arrowheads). (**B-5**) Treatment of the target lesion was finished with a drug-coated balloon, and the lesion was opened wide without severe dissection. (**B-6**) Post-PCI OCT cross-sectional image showing multiple calcium fractures (arrows); the maximum thickness of the calcium fracture was 1,000 μm.

Table 1. Patient and Lesion Characteristics

Variable	Balloon group (n=62)	Atherectomy group (n=59)	P value
Age (years)	75 [68–82]	76 [70–83]	0.95
Male sex	42 (68)	39 (66)	0.85
Hypertension	52 (84)	51 (86)	0.69
Dyslipidemia	42 (68)	41 (69)	0.84
Diabetes	33 (53)	37 (63)	0.30
CKD	29 (47)	33 (56)	0.31
Hemodialysis	6 (10)	12 (20)	0.10
Smoking	13 (21)	8 (14)	0.28
Previous MI	24 (39)	26 (44)	0.55
Previous PCI	26 (42)	27 (46)	0.67
Previous CABG	4 (6)	7 (12)	0.30
Multivessel disease	14 (23)	24 (41)	0.03
LVEF (%)	50 [40–60]	46 [38–54]	0.04
Presentation			0.92
Stable angina	54 (87)	52 (88)	
ACS	8 (13)	7 (12)	
Vessel			0.50
LMCA	0 (0)	1 (2)	
LAD	40 (65)	42 (71)	
LCX	10 (16)	9 (15)	
RCA	12 (19)	7 (12)	
ACC/AHA lesion classification			0.72
A	0 (0)	0 (0)	
B1	12 (19)	15 (25)	
B2	28 (45)	25 (42)	
C	22 (36)	19 (32)	
Reference vessel diameter (mm)	3.0 [2.8–3.0]	3.0 [2.8–3.1]	0.78
Minimum lumen diameter (mm)	1.4 [1.2–1.5]	1.4 [1.2–1.5]	0.69
Lesion length (mm)	15 [12–24]	16 [12–25]	0.60
Diameter stenosis (%)	75 [73–78]	75 [70–80]	0.49
Angiographic calcium severity			<0.001
Moderate	42 (68)	21 (36)	
Severe	20 (32)	38 (64)	
Moderate/severe tortuosity	9 (14)	10 (17)	0.32
Moderate/severe angulation	8 (13)	12 (20)	0.27
Bifurcation lesion	14 (23)	19 (32)	0.23
Pre-PCI OCT			
Maximum calcium thickness (μm)	1,165 [1,060–1,272]	1,300 [1,170–1,500]	<0.001
Maximum calcium length (mm)	13.9 [9.6–18.7]	15.0 [10.8–22.1]	0.15
Maximal calcium angle (degree)	190 [154–224]	200 [140–270]	0.40
Nodular calcification	15 (24)	20 (34)	0.24
MLA (mm^2)	1.7 [1.3–2.2]	1.7 [1.3–2.1]	0.73
Calcium score	4 [2–4]	4 [2–4]	0.98

Unless indicated otherwise, data are given as n (%) or the median [interquartile range]. ACS, acute coronary syndrome; CABG, coronary artery bypass graft; CKD, chronic kidney disease; LAD, left anterior descending artery; LCX, left circumflex artery; LMCA, left main coronary artery; LVEF, left ventricular ejection fraction; MI, myocardial infarction; MLA, minimum lumen area; OCT, optical coherence tomography; PCI, percutaneous coronary intervention; RCA, right coronary artery.

Institute, Cary, NC, USA). Continuous variables are expressed as the median and interquartile range (IQR) and were compared using the Mann-Whitney U test. Categorical variables are presented as numbers and percentages, and were compared by the Chi-squared test or Fisher's exact test as appropriate. Multivariable logistic regression analysis or ordered logistic regression analysis were used to assess the effects of the use of atherectomy devices on the occurrence of OCT-detected large coronary dissection, OCT-detected calcium fracture, and angiography-detected coronary dissection after adjusting for imbalances in baseline patient and lesion characteristics (variables with P<0.10). Two-sided P<0.05 was considered statistically significant.

Table 2. Procedural Characteristics

Variable	Balloon group (n=62)	Atherectomy group (n=59)	P value
Lesion preparation			
Atherectomy device			
RA		41 (69)	
OAS		13 (22)	
Combination of RA and OAS		5 (9)	
RA			
Maximum burr size		1.75 [1.5–2]	
Use of >1 burr		23 (50)	
Burr/artery ratio		0.6 [0.55–0.67]	
Rotational speed (r.p.m.)		180,000	
Total RA run time (s)		78 [52–94]	
OAS			
Low only		3 (17)	
Low and high		15 (83)	
High only		0 (0)	
Total OAS run time (s)		113 [90–180]	
Modified balloon	47 (76)	49 (83)	0.32
Maximum balloon diameter (mm)	2.5 [2.5–3.0]	2.75 [2.5–3.0]	0.30
Maximum balloon pressure (atm)	16 [14–20]	16 [12–20]	0.43
Post-lesion preparation			
Stent implanted	60 (97)	29 (50)	<0.001
No. stents	1 [1–1]	0.5 [0–1]	<0.001
Total stent length (mm)	30 [23–47]	30 [20–38]	0.33
Maximum stent diameter (mm)	3.0 [2.8–3.5]	3.0 [2.5–3.1]	0.09
Maximum balloon diameter (mm)	3.4 [3.0–3.5]	3.0 [2.8–3.5]	0.01

Unless indicated otherwise, data are given as n (%) or the median [interquartile range]. OAS, orbital atherectomy system; PCI, percutaneous coronary intervention; RA, rotational atherectomy.

Table 3. Angiographic and OCT Outcomes

Variable	Balloon group (n=62)	Atherectomy group (n=59)	P value
Post-lesion preparation			
Angiographic dissection (NHLBI classification)			<0.001
A	15 (24)	35 (59)	
B	36 (58)	5 (8)	
C	9 (15)	0 (0)	
D	1 (2)	0 (0)	
OCT-detected large dissection	56 (90)	29 (49)	<0.001
OCT-detected intramural hematoma	1 (2)	0 (0)	0.13
OCT-detected calcium fracture	11 (18)	44 (75)	<0.001
No. calcium fractures	0 [0–0]	1 [0–2]	<0.001
Calcium fracture thickness (mm)	470 [450–520]	705 [590–768]	<0.001
Post-PCI			
MLD (mm)	3.0 [2.8–3.0]	3.0 [2.6–3.0]	0.45
Residual stenosis (%)	0 [0–25]	0 [0–20]	0.44
MLA or MSA (mm^2)	5.0 [4.1–6.0]	4.9 [4.1–6.2]	0.82

Unless indicated otherwise, data are given as n (%) or the median [interquartile range]. MLD, minimum lumen diameter; MSA, minimum stent area; NHLBI, National Heart, Lung, and Blood Institute. Other abbreviations as in Table 1.

Results

Patient and Lesion Characteristics

Among the 121 patients who underwent OCT-guided PCI, lesion preparation was performed with the balloon-based technique in 62 (balloon group) and with the ablation-based technique in 59 (atherectomy group). Representative images of lesion preparations in the balloon and atherectomy groups are shown in **Figure 1**. Patient and angiographic lesion characteristics are presented in **Table 1**.

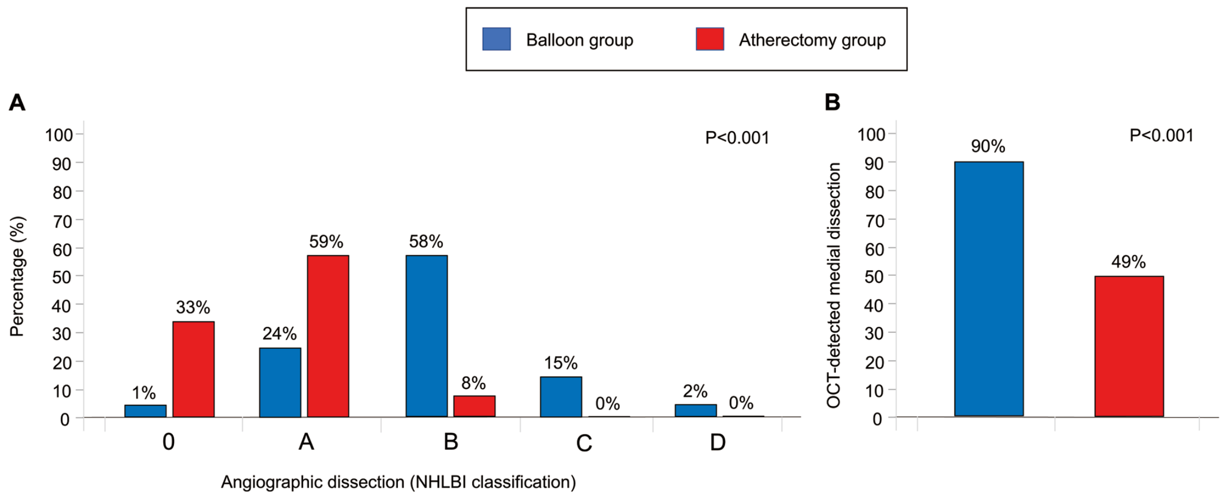

Figure 2. (**A**) Angiographic coronary dissection according to the National Heart, Lung, and Blood Institute (NHLBI) classification and (**B**) OCT-detected large dissection after lesion preparation in the balloon and atherectomy groups.

Patients in the atherectomy group more commonly had multivessel disease (41% vs. 23%; P=0.03) and a lower median left ventricular ejection fraction (46% vs. 50%; P=0.04) than those in the balloon group (**Table 1**). In addition, the atherectomy group presented with severe angiographic calcification more frequently than the balloon group (64% vs. 32%, respectively; P<0.001; **Table 1**).

Pre-PCI OCT Findings

Pre-PCI OCT findings are summarized in **Table 1**. OCT-measured maximum calcium thickness was significantly larger in the atherectomy than balloon group (1,300 μm, [IQR 1,170–1,500 μm] vs. 1,165 μm [IQR 1,060–1,272 μm], respectively; P<0.001). All other pre-PCI OCT findings, including calcium length, maximum calcium angle, calcium score, the presence of nodular calcification, and minimum lumen area, were comparable between the 2 groups.

Procedural Characteristics

Procedural details are presented in **Table 2**. For lesion preparation, RA with a median burr size of 1.75 mm (IQR 1.5–2 mm) was used in 41 (69%) patients in the atherectomy group, OA was used in 13 (22%) patients, and both types of atherectomy devices were used in 5 (9%) patients. There was no significant difference between the balloon and atherectomy groups in the use of modified balloons (76% vs. 83%, respectively; P=0.32), maximum balloon diameter (2.5 mm [IQR 2.5–3.0 mm] vs. 2.75 mm [IQR 2.5–3.0 mm], respectively; P=0.30), and maximum balloon pressure (16 atm [IQR 14–20 atm] vs. 16 atm [IQR 12–20 atm], respectively; P=0.43; **Table 2**).

Angiographic and OCT Outcomes

Post-lesion preparation angiographic and OCT outcomes are presented in **Table 3**. After lesion preparation, a higher grade of angiographic coronary dissection occurred in the balloon than atherectomy group (balloon group: none, 1%; NHLBI A, 24%; B, 58%; C, 15%; D 2%; atherectomy group: none, 33%; NHLBI A, 59%; B, 8%; C, 0%; D, 0%; P<0.001; **Figure 2A**). On OCT, a large dissection was less common (49% vs. 90%; P<0.001; **Figure 2B**) and calcium fractures were more common (75% vs. 18%; P<0.001; **Figure 3A**) in the atherectomy than balloon group. These findings were confirmed after adjusting for baseline patient and lesion characteristics (**Table 4**). The use of atherectomy was associated with a lower degree of angiographic coronary dissection (odds ratio [OR] 0.04; 95% confidence interval [CI] 0.01–0.12; P<0.001), a lower incidence of OCT-detected large dissection (OR 0.09; 95% CI 0.03–0.30; P<0.001), and a greater occurrence of OCT-detected calcium fracture (OR 18.19; 95% CI 6.45–58.96; P<0.001). In addition to the use of atherectomy devices, maximum calcium thickness was negatively associated with the occurrence of OCT-detected calcium fracture (OR 0.79; 95% CI 0.63–0.99; P=0.043; **Table 4**). However, even thicker calcium was fractured in the atherectomy compared with balloon group (705 μm [IQR 590–768 μm] vs. 470 μm [IQR 450–520 μm]; P<0.001; **Figure 3B**).

After lesion preparation, more stent implantations (97% vs. 50%; P<0.001) and a larger size of post-stent balloons (3.4 mm [IQR 3.0–3.5 mm] vs. 3.0 mm IQR [2.8–3.5 mm]; P=0.01) were required in the balloon group (**Table 3**). At the end of procedures, the OCT-derived minimum stent/lumen area was comparable between the balloon and atherectomy groups (5.0 mm^2 [IQR: 4.1–6.0 mm^2] vs. 4.9 mm^2 [IQR: 4.1–6.2 mm^2], respectively; P=0.82), despite there being less stent implantation and a smaller maximum balloon size in the atherectomy group (**Table 3**).

Clinical Outcomes at 30 Days

In all patients, 30-day clinical follow-up was achieved. The rates of MACE were comparable between the balloon and atherectomy groups (2% vs. 2%; P=0.97). The frequency of TLR (2% vs. 2%; P=0.97) and stent thrombosis (2% vs. 2%; P=0.97) also did not differ significantly between the 2 groups (**Supplementary Table**).

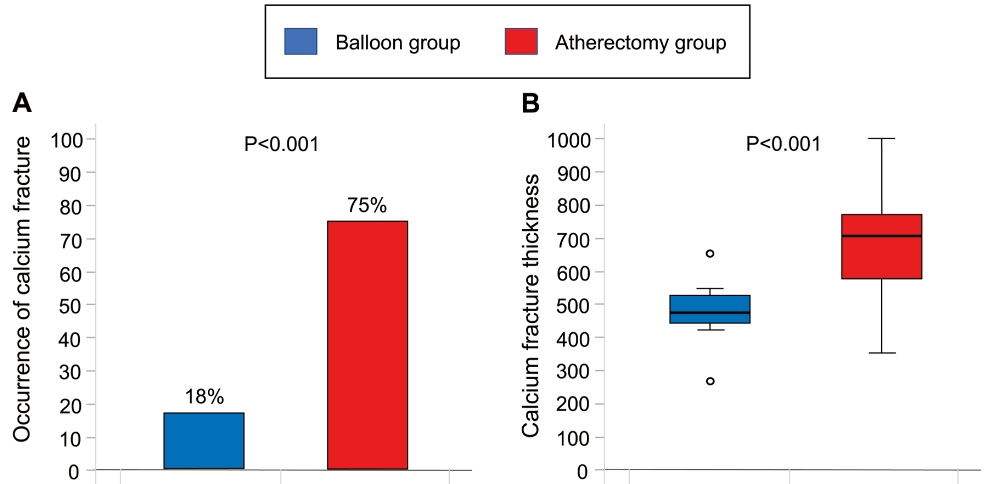

Figure 3. (**A**) Occurrence and thickness of calcium fracture after lesion preparation in the balloon and atherectomy groups. (**B**) Thickness of calcium fractures in the balloon and atherectomy groups. The boxes show the interquartile range, with the median value indicated by the horizontal line; whiskers show the range. Open circles indicate outliers. The median (interquartile range) thickness of the calcium fractures in the balloon and atherectomy groups was 470 (450–520) and 705 (590–768) μm, respectively. The range of calcium fracture thickness in the balloon and atherectomy groups was 280–650 and 350–1,000 μm, respectively.

Table 4. Indicators of Dissection and Calcium Fracture on Multivariable Analysis

Variable	Multiple regression		
	OR	95% CI	P value
Angiographic dissection after balloon dilatation			
Atherectomy device use	0.04	0.01–0.12	<0.001
Multivessel disease	0.81	0.35–1.84	0.608
LVEF	1.03	0.99–1.07	0.106
Angiographic calcium severity	0.94	0.43–2.05	0.881
Maximum calcium thickness (per +100 μm)	0.83	0.69–1.00	0.055
OCT-detected large dissection			
Atherectomy device use	0.09	0.03–0.30	<0.001
Multivessel disease	0.91	0.35–2.41	0.860
LVEF	0.99	0.95–1.03	0.816
Angiographic calcium severity	0.87	0.34–2.41	0.860
Maximum calcium thickness (per +100 μm)	0.99	0.81–1.21	0.939
Occurrence of calcium fracture			
Atherectomy device use	18.19	6.45–58.96	<0.001
Multivessel disease	0.61	0.21–1.71	0.596
LVEF	0.98	0.94–1.03	0.810
Angiographic calcium severity	2.18	0.84–5.65	0.881
Maximum calcium thickness (per +100 μm)	0.79	0.63–0.99	0.043

CI, confidence interval; OR, odds ratio. Other abbreviations as in Table 1.

Discussion

The main findings of the present study were as follows. First, after lesion preparation, a higher grade of coronary dissection occurred when heavily calcified lesions were treated by the balloon-based technique than by the ablation-based technique. Second, calcium fractures were more frequently found on OCT in the atherectomy than balloon group. Although maximum calcium thickness was negatively associated with the occurrence of calcium fracture, the median thickness of calcium fracture was significantly greater in the atherectomy than balloon group. At the end of procedures, the OCT-derived minimum stent/lumen area was comparable between the 2 groups despite there being less stent implantation and a smaller maximum balloon size in the atherectomy group. Finally, 30-day clinical

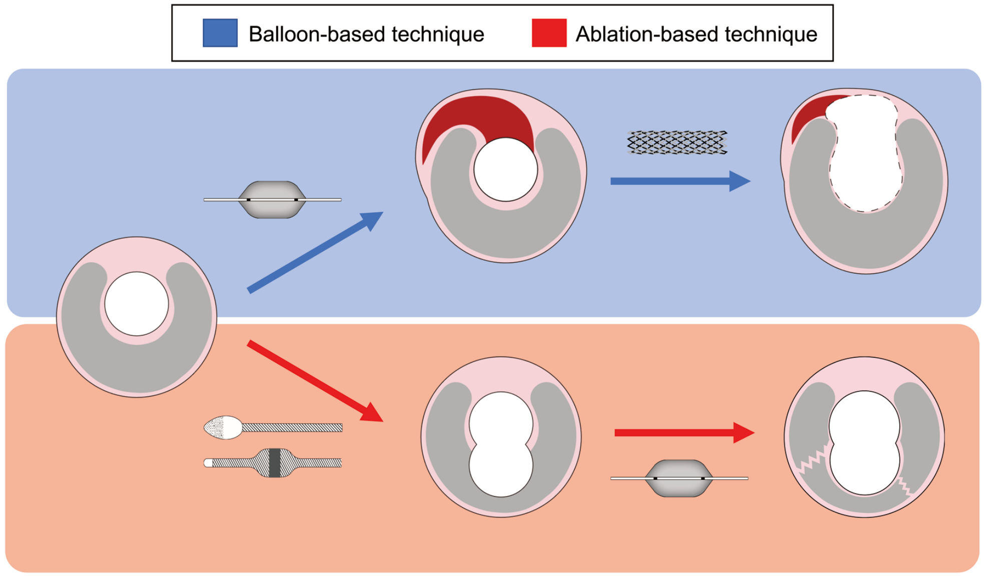

Figure 4. Diagram showing lesion preparation of heavily calcified lesions with the balloon- and ablation-based techniques. Pink areas show a coronary vessel walls, gray areas represent calcified plaques, and white circles are vessel lumen. The balloon-based technique in heavily calcified lesions (blue) is more likely to cause large coronary dissections (red) without calcification itself being cracked, and more frequently requires bailout stent implantation. Conversely, the ablation-based technique (orange) modifies calcification and makes the occurrence of calcium fractures more likely after subsequent balloon dilatation with a lower risk of large coronary dissection. Devices above the diagonal blue arrow and below the horizontal red arrow are balloons. Devices below the diagonal red arrow are rotational atherectomy and orbital atherectomy. A device above the horizontal blue arrow is coronary stent.

outcomes were comparable between the 2 groups.

Lesion Preparation of Heavily Calcified Lesions Using Atherectomy Devices

Heavy calcification remains one of the most challenging entities for PCI. In general, there are 2 approaches for severely calcified lesions: the balloon-based technique and the ablation-based technique.[14,15] In the balloon-based technique, high-pressure balloon dilation is almost always required, but the high-pressure dilation is unlikely to expand lesions successfully. To make matters worse, high-pressure balloon dilation poses a risk of complications, such as large coronary dissection and vessel rupture. Conversely, ablation-based techniques ablate calcification and introduce plaque modification. Complications such as coronary dissections and perforation are concerns in the ablation-based technique, but these risks can be mitigated with a modest approach. Even a simple passage of atherectomy devices increases the chance of subsequent balloon dilatation breaking calcium components and promoting stent expansion.[7,16] In the present study, calcium fractures happened more often and thicker calcium was cracked in the atherectomy than balloon group, even though the ablations performed were not necessarily extensive by either RA (maximum burr size 1.75mm [IQR 1.5–2mm]) or OA (low-speed rotation was used in all cases). Furthermore, angiographic coronary dissections observed in the atherectomy group were all benign types (Types A or B) and the incidence of large coronary dissection was lower than in the balloon group. Calcium was perhaps likely to be fractured by the ablation-based technique, whereas with the balloon-based techniques it was not calcium itself that was fractured, but rather soft tissues adjacent or opposite to the calcium were overstretched and torn. To the best of our knowledge, this is the first study that has shown that the ablation-based technique is more effective and safer than the balloon-based technique in lesion preparation of heavily calcified lesions. Based on these findings, the ablation-based technique could be said to be better suited to this end (**Figure 4**).

OCT-Guided PCI of Heavily Calcified Lesions

The high spatial resolution and capability of penetrating through calcium gives OCT an unrivaled position in the guidance of PCI for heavily calcified lesions.[6–8] OCT not only allows accurate identification of calcium plaque, but it also enables quantitative assessments, such as of the angle, area, thickness, length, and even 3-dimensional volume of calcium.[17] Each of these parameters is reportedly associated with the response to balloon dilatation and stent expansion. Furthermore, a calcium scoring system developed using these quantitative parameters has been shown to be useful in predicting which calcified lesions would benefit from plaque modification.[12] In line with these previous studies, the present study showed that maximum calcium thickness was a predictor of the occurrence of calcium fracture. In addition, the balloon and atherectomy groups both had a median calcium score of 4, indicating poor response to balloon dilation, and the balloon group had undesirable results of fewer calcium cracks but more large dissections than the atherectomy group, as predicted. Our results have corroborated the utility of

OCT in predicting PCI results in heavily calcified lesions.

Another advantage of OCT in the PCI of calcified lesions is that trajectories along which RA or OA will proceed inside target vessels may be predictable. The position of a guidewire and an imaging catheter relative to calcified plaques recognized during image acquisition will help predict the impact of ablation and improve the safety of the ablation-based technique by avoiding unintended ablation of tissues other than calcium.

DES or DCB in Heavily Calcified Lesions

Even with the latest types of DES, the results in calcified lesions are disappointing compared with those in non-calcified lesions.[18,19] Stent underexpansion probably contributes to the unfavorable outcomes.[6] Once DESs have been placed in heavily calcified vessels, they cannot be redone; the stents are hardly retrievable, unlikely to expand symmetrically to their full size with post-stent dilation, and stent ablation risks serious complications. Caution therefore needs to be exercised before stent implantation, or rather stenting in heavily calcified lesions should be avoided. DCB is an alternative to DES in treating not only in-stent restenosis, but also de novo coronary lesions. Randomized studies have proven non-inferiority of DCB to the second-generation DES in terms of angiographic and clinical endpoints.[20,21] In calcified lesions, TLR rates of DCB following RA have been shown to be similar to those of DES (6–16% vs. 6.8–11.7%).[22–24] In the present study, half the cases in the atherectomy group were successfully treated with DCB and no clinical events arose thereafter. Given these findings, DCB may be a viable option for heavily calcified lesions, as long as optimal lesion preparation has been achieved by the ablation-based technique. The effectiveness and safety of this strategy needs to be tested in a randomized trial.

Clinical Implications

The ablation-based technique using RA or OA is safer (less severe angiographic and OCT-detected coronary dissections) and more effective (more calcium fracture formations) for lesion preparation of heavily calcified lesions than the balloon-based technique. Calcified lesions can be well prepared for stenting, or even for treatments with DCB instead of stenting, by the ablation-based technique.

Study Limitations

This study has some limitations. First, this was an observational study performed at a single center and the selection of ablation- or balloon-based techniques was at the operator's discretion, so there may be selection bias. In addition, there must have been unmeasured factors, such as the operators' skills and experience, that influenced the study findings despite the adjustment of baseline characteristics. Second, dilatation with small balloons (diameter 1.5–2.0 mm) was performed prior to OCT image acquisition in some cases when an OCT catheter did not pass or when it was anticipated that the catheter would not be able to be passed. However, none of the PCI complications (coronary dissection and perforation) occurred due to these procedures, and alterations of the lesions were unlikely considering the heavily calcification. Third, other treatment options, such as an excimer laser and lithotripsy balloons, were not used in our study population because they were not available. Fourth, the number of patients studied was modest and the follow-up period was short. Our study findings need to be re-evaluated in a future study with a more adequate number of patients and a longer follow-up period. Finally, further studies are required to elucidate the mechanisms underlying the differences in calcium fracture formation between using and not using atherectomy devices in heavily calcified lesions.

Conclusions

In heavily calcified lesions, the ablation-based technique resulted in less severe coronary dissections and more calcium fracture formation than the balloon-based technique. The ablation-based technique can better prepare heavily calcified lesions for stenting, or even for treatments without stenting.

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IRB Information

This study was approved by the Wakayama Medical University Ethics Committee (Reference no. 3296).

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Supplementary Files

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