



Plaque modification using a cutting balloon is more effective for stenting of heavily calcified lesion than other scoring balloons

Ryuichi Matsukawa¹ · Toshiyuki Kozai¹ · Masaki Tokutome¹ · Ryouuske Nakashima¹ · Ryouhei Nishimura¹ · Sho Matsumoto¹ · Masato Katsuki¹ · Seigo Masuda¹ · Hiroshi Meno¹

Received: 18 October 2018 / Accepted: 8 February 2019 / Published online: 15 February 2019
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Abstract

Cutting balloons (CBs) and other scoring balloons are known to be useful for plaque modification in heavily calcified lesions. There have been some reports of the efficacy of these balloons compared to conventional balloons. However, there have been no reports exploring which balloon is most effective among these three types of balloons. We, therefore, compared these three balloons with respect to effectiveness in plaque modification of calcified lesions. We retrospectively investigated 201 cases using these three balloons from April 2015 to December 2017. Of these cases, 156 with severe calcified lesions that had undergone intravascular ultrasound (IVUS) or optical frequency domain imaging (OFDI) were enrolled. The ratio of severe calcified lesion was higher in the CB group than in the groups of other balloons ($p=0.001$), and IVUS and OFDI showed that a CB was more effective in plaque modification than the other balloons. The acute gain (minimum stent diameter minus minimum lumen diameter) and acute cross-sectional area (CSA) gain (minimum stent area minus minimum lumen area) were both larger in the CB group than in the others, and the stent symmetry index (minimum stent diameter/maximum stent diameter) showed that the CB group more closely approximated a perfect circle than the other groups ($p=0.0001$, 0.006 and 0.002 for the acute gain, acute CSA gain and the stent symmetry index). Similar results were obtained in cases without rotational atherectomy. These data suggest that CB is more effective for plaque modification in cases of severe calcified lesions than other scoring balloons.

Keywords Severe calcified lesion · Cutting balloon · Scoring balloon · IVUS · OFDI

Abbreviations

PCI	Percutaneous intervention
DES	Drug-eluting stent
BMS	Bare metal stent
CB	Cutting balloon
FDI	Optical frequency domain imaging
IVUS	Intravascular ultrasound
CSA	Cross-sectional area

Introduction

Percutaneous coronary intervention (PCI) for heavily calcified lesions is still challenging. PCI for heavily calcified lesions has been associated with lower success rates, greater

risk of acute complications and higher restenosis rates than PCI for simple lesions [1–6]. Drug-eluting stents (DESs) have achieved better clinical outcomes in calcified lesions than bare metal stents (BMSs) [7–10]. However, the stent delivery may be difficult, and inadequate stent expansion often occurs in heavily calcified lesions, resulting in insufficient acute gain compared to simple lesions [11]. It is, therefore, important to use rotational atherectomy and/or a cutting balloon (CB)/scoring balloon for plaque modification of heavily calcified lesions. Indeed, lesion modification using rotational atherectomy has provided better short- and long-term clinical outcomes [9, 12–15].

CB and scoring balloons have been used often in lesion modification of heavily calcified lesions. A number of studies have reported the efficacy of CBs and scoring balloons in calcified lesions for acute gain, stent expansion and target vascular revascularization (TVR) [12, 16–19]. These studies all investigated the efficacy of CBs and scoring balloons compared to conventional balloons, such as semi-compliant and non-compliant balloons. However, no report

✉ Ryuichi Matsukawa
matukawa@cardiol.med.kyushu-u.ac.jp

¹ Division of Cardiology, Fukuoka Red Cross Hospital, 3-1-1 Okusu, Minami-ku, Fukuoka 815-8555, Japan

has investigated which balloon is most effective in cases of heavily calcified lesions.

Therefore, in the present study, we compared CB, NSE and Scoreflex balloons for their effectiveness in plaque modification of calcified lesions.

Materials and methods

Study design

We retrospectively analyzed 201 cases using CB, NSE (Non slip element) and Scoreflex (balloons that are available at our hospital) from April 2015 to December 2017. The 156 cases that had severe calcified lesions and had undergone intravascular ultrasound (IVUS) or optical frequency domain imaging (OFDI) were enrolled. IVUS or OFDI was performed before dilatation, after dilatation and after stenting.

We then retrospectively measured reference vessel diameter, balloon to artery ratio, the minimum lumen diameter (MLD), minimum lumen area (MLA), acute gain (minimum stent diameter – minimum lumen diameter), minimum stent area (MSA), acute cross-sectional area (CSA) gain (minimum stent area – minimum lumen area) and stent symmetry index (minimum stent diameter/max stent diameter) for each case. We defined over 270° of calcification as severe calcification.

In addition, we also investigated the 123 cases without rotational atherectomy for the parameters mentioned above.

Statistical analyses

All statistical analyses were performed with EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria). More precisely, it is a modified version of R commander designed to add statistical functions frequently used in biostatistics [20]. A multivariate analysis was performed using a multiple linear regression analysis about association with acute gain, acute CSA gain, and stent symmetry index. Dependent variables are as follows: age, balloon type, whether male or not, whether hypertension (HT) or not, whether dyslipidemia (DL) or not, whether diabetes mellitus (DM) or not, whether dialysis (HD) or not, whether smoker or not, whether complex lesion or not, whether severe calcification or not, whether performed rotational atherectomy or not and whether performed IVUS or OFDI. Continuous variables were compared using one-way ANOVA with Bonferroni's multiple comparison test. Categorical variables were compared using the Chi-squared test or Fisher's exact test, as appropriate. Unless otherwise specified, all data are expressed as the mean \pm standard deviation or median (95%

confidence interval). The probability was two tailed, with *p* values of <0.05 being regarded as statistically significant.

Ethical standards

All human and animal studies were approved by the appropriate ethics committee and were, therefore, performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. This study was approved by the ethics committee of Fukuoka Red Cross Hospital and was, therefore, performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

Results

Characteristics of all cases with calcified lesions

The characteristics of the 156 cases with calcified lesions are shown in Table 1. A CB was used in 30, an NSE was used in 39, and a Scoreflex was used in 87 cases (including six cases used the Scoreflex NC). The patients' background characteristics were similar. Larger numbers of complex cases were included in the CB and Scoreflex groups than in the NSE group. The ratio of severe calcified lesions was higher in the CB group than in the other groups. The balloon size, stent size, stent length and stent types were similar among groups. We then performed a multiple linear regression analysis about association with acute gain, MSA, acute CSA gain and stent symmetry index. Only balloon type was strongly associated with acute gain (estimated regression coefficient -0.161 , 95% confidence interval -0.263 to -0.006 , $p=0.0005$), acute CSA gain (estimated regression coefficient -0.556 , 95% confidence interval -1.034 to -0.078 , $p=0.02$) and stent symmetry index (estimated regression coefficient -0.027 , 95% confidence interval -0.044 to -0.009 , $p=0.002$). Male was only associated with MSA (estimated regression coefficient 1.114 , 95% confidence interval 0.198 – 2.030 , $p=0.01$). Then we compared these parameters among three balloons.

Comparisons of the acute gain, MSA, acute CSA gain, stent symmetry index and balloon dilatation pressure in all cases with calcified lesions

Although the ratio of severe calcified lesions was higher in the CB group than in the other groups ($p=0.001$), the acute gain [1.61 ± 0.52 (CB) vs. 1.18 ± 0.40 (NSE) vs. 1.23 ± 0.47 mm (Scoreflex); $p=0.0001$] and acute CSA gain [5.89 ± 2.51 (CB) vs. 4.38 ± 1.94 (NSE) vs. 4.60 ± 2.04 mm² (Scoreflex); $p=0.0006$] were larger in the CB group than in the other groups (Fig. 1a, b). The MSA tended to be larger

Table 1 The characteristics of all cases with calcified lesions

n	Cutting balloon 30	NSE 39	Scoreflex 87	p
Patient characteristics				
Age	68.4 ± 9.0	72.9 ± 8.1	69.2 ± 11.0	0.104
Male (%)	22 (73.3)	28 (71.8)	61 (70.1)	0.94
HT (%)	22 (73.3)	30 (76.9)	70 (80.5)	0.699
DL (%)	18 (60.0)	26 (66.7)	53 (60.9)	0.797
DM (%)	12 (40.0)	18 (46.2)	38 (43.7)	0.877
HD (%)	13 (43.3)	13 (33.3)	31 (35.6)	0.67
Smoking (%)	9 (30.0)	10 (25.6)	17 (19.5)	0.457
Complex case				
Total (%)	19 (63.3)	15 (38.5)	57 (65.5)	0.014
ACS (%)	1 (3.3)	6 (15.4)	12 (13.8)	0.249
CTO (%)	4 (13.3)	0 (0.0)	4 (4.6)	0.043
Ostium (%)	6 (20.0)	2 (5.1)	6 (6.9)	0.06
Bifurcation (%)	11 (36.7)	9 (23.1)	40 (46.0)	0.049
Lesion characteristics				
Target lesion				
LMT LAD (%)	16 (53.3)	23 (59.0)	55 (63.2)	0.809
LCX (%)	6 (20.0)	6 (15.4)	10 (11.5)	
RCA (%)	8 (26.7)	10 (25.6)	22 (25.3)	
Severe calcification (> 270°) (%)	25 (83.3)	23 (59.0)	39 (44.8)	0.001
Rota (%)	7 (23.3)	10 (25.6)	16 (18.4)	0.62
MLD (mm)	1.32 ± 0.23	1.45 ± 0.22	1.40 ± 0.27	0.111
MSD (mm)	2.93 ± 0.50	2.63 ± 0.39	2.63 ± 0.45	0.004
MLA (mm ²)	1.89 ± 0.70	2.25 ± 0.60	2.23 ± 0.75	0.051
MSA (mm ²)	7.78 ± 2.61	6.63 ± 2.15	6.83 ± 2.21	0.086
Reference vessel diameter (mm)	2.94 ± 0.41	2.82 ± 0.37	2.80 ± 0.48	0.348
Balloon to artery ratio	0.91 ± 0.07	0.94 ± 0.08	0.95 ± 0.09	0.261
Modality				
IVUS	21 (70.0)	33 (84.6)	60 (69.0)	0.171
OFDI	9 (30.0)	6 (15.4)	26 (29.9)	0.203
Device characteristics				
Balloon size	2.68 ± 0.38	2.65 ± 0.34	2.64 ± 0.42	0.846
Stent size	3.09 ± 0.37	2.97 ± 0.47	2.98 ± 0.47	0.466
Stent length	27.07 ± 8.21	29.49 ± 7.11	29.85 ± 7.34	0.208
Stent type				
EES	17 (56.7)	27 (69.2)	52 (59.8)	0.64
SES	10 (33.3)	10 (25.6)	30 (34.5)	
ZES	1 (3.3)	2 (5.1)	2 (2.3)	
BES	2 (6.7)	0 (0.0)	3 (3.4)	

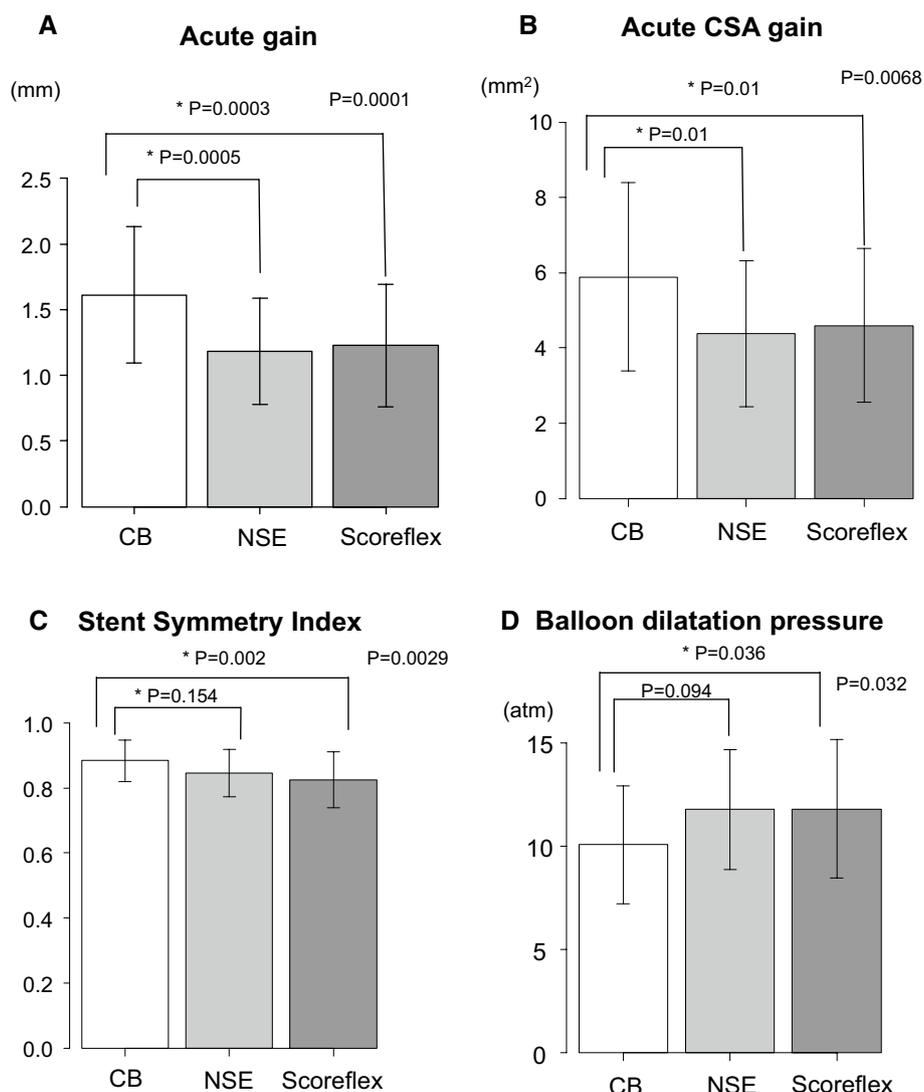
Data are given as n (%) or the mean ± SD

DM diabetes mellitus, HT hypertension, DL dyslipidemia, HD hemodialysis, ACS acute coronary syndrome, CTO chronic total obstruction, MLD minimum lumen diameter, MLA minimum lumen area, LMT left main trunk, LAD left anterior descending coronary artery, LCX left circumflex artery, RCA right coronary artery, IVUS intravascular ultrasound, OFDI optical frequency domain imaging, EES everolimus eluting stent, SES sirolimus eluting stent, ZES zotarolimus eluting stent, BES biolimus eluting stent

in the CB group than in the other groups [7.78 ± 2.61 (CB) vs. 6.63 ± 2.15 (NSE) vs. 6.83 ± 2.21 mm² (Scoreflex); p=0.08; Fig. 1c]. The stent symmetry index showed that the CB group more closely approximated a perfect circle than

the other groups [0.88 ± 0.06 (CB) vs. 0.85 ± 0.07 (NSE) vs. 0.83 ± 0.09 (Scoreflex); p=0.002; Fig. 1d]. Furthermore, the balloon dilation pressure was lower in the CB group than in the other groups [10.1 ± 2.9 (CB) vs. 11.7 ± 2.9 (NSE) vs.

Fig. 1 Comparisons of acute gain (a), acute cross-sectional area gain (b), stent symmetry index (c), and balloon dilatation pressure (d) among cutting balloon (CB), NSE and Scoreflex in all calcified cases. The data are given as the mean \pm SD



11.8 \pm 3.4 atm (Scoreflex); $p=0.032$; Fig. 3a]. These data suggested that a CB achieved larger acute gain and better stent expansion with a lower dilatation pressure regardless of the larger ratio of severe calcified lesions.

Characteristics of patients with calcified lesions without rotational atherectomy

PCI was performed without rotational atherectomy in 123 of 156 cases with calcified lesions. The characteristics of these patients are shown in Table 2. A CB was used in 23, an NSE in 29, and a Scoreflex in 71 cases (including 5 cases using Scoreflex NC). The patients' background characteristics were similar among the groups, as was the ratio of complex cases. The ratio of severe calcified lesions was also higher in the CB group than in the other groups. The MLD was smaller in the CB group than in the other groups, but

the balloon size, stent size, stent length and stent types were similar among the groups.

Comparisons of acute gain, MSA, acute CSA, stent symmetry index and balloon dilatation pressure in cases with calcified lesions without rotational atherectomy

Although the ratio of severe calcified lesions was higher in the CB group than in the other groups ($p < 0.001$), acute gain [1.68 \pm 0.46 (CB) vs. 1.14 \pm 0.33 (NSE) vs. 1.18 \pm 0.45 mm (Scoreflex); $p < 0.0001$], acute CSA gain [6.14 \pm 2.52 (CB) vs. 4.50 \pm 1.95 (NSE) vs. 4.50 \pm 1.99 mm² (Scoreflex); $p = 0.002$] and MSA [8.09 \pm 2.61 (CB) vs. 6.71 \pm 2.17 (NSE) vs. 6.77 \pm 2.07 mm² (Scoreflex); $p = 0.032$] were larger in the CB group than in the other groups (Fig. 2a–c). The stent symmetry index showed that the CB group also more

Table 2 The characteristics of cases not performed rotational atherectomy

<i>n</i>	Cutting balloon 23	NSE 29	Scoreflex 71	<i>p</i>
Patient characteristics				
Age	67.7 ± 9.3	71.4 ± 7.5	68.9 ± 11.6	0.397
Male (%)	17 (73.9)	25 (86.2)	50 (70.4)	0.255
HT (%)	18 (78.3)	21 (72.4)	55 (77.5)	0.842
DL (%)	14 (60.9)	20 (69.0)	44 (62.0)	0.774
DM (%)	10 (43.5)	16 (55.2)	29 (40.8)	0.422
HD (%)	10 (43.5)	16 (55.2)	22 (31.0)	0.519
Smoking (%)	6 (26.1)	10 (34.5)	14 (19.7)	0.29
Complex case				
Total (%)	16 (69.6)	14 (48.3)	49 (69.0)	0.122
ACS (%)	1 (4.3)	5 (17.2)	12 (16.9)	0.301
CTO (%)	3 (13.0)	0 (0.0)	3 (4.2)	0.088
Ostium (%)	4 (17.4)	2 (6.9)	4 (5.6)	0.193
Bifurcation (%)	10 (43.5)	9 (31.0)	34 (47.9)	0.303
Lesion characteristics				
Target lesion				
LMT•LAD (%)	13 (56.5)	16 (55.2)	44 (62.0)	0.674
LCX (%)	4 (17.4)	6 (20.7)	7 (9.9)	
RCA (%)	6 (26.1)	7 (24.1)	20 (28.2)	
Severe calcification (> 270°) (%)	19 (82.6)	14 (48.3)	23 (32.4)	< 0.001
MLD (mm)	1.33 ± 0.23	1.51 ± 0.18	1.43 ± 0.27	0.033
MSD (mm)	3.01 ± 0.46	2.65 ± 0.39	2.61 ± 0.42	0.0004
MLA (mm ²)	1.96 ± 0.75	2.37 ± 0.57	2.27 ± 0.74	0.091
MSA (mm ²)	8.09 ± 2.62	6.71 ± 2.17	6.77 ± 2.07	0.033
Reference vessel diameter (mm)	2.98 ± 0.39	2.88 ± 0.32	2.81 ± 0.46	0.247
Balloon to artery ratio	0.92 ± 0.07	0.94 ± 0.08	0.95 ± 0.09	0.2
Modality				
IVUS	18 (78.3)	28 (96.6)	54 (76.1)	0.053
OFDI	5 (21.7)	1 (3.4)	16 (22.5)	0.067
Device characteristics				
Balloon size	2.74 ± 0.39	2.70 ± 0.32	2.67 ± 0.40	0.761
Stent size	3.10 ± 0.40	3.00 ± 0.45	2.97 ± 0.46	0.506
Stent length	27.30 ± 7.68	29.14 ± 7.54	30.21 ± 7.07	0.249
Stent type				
EES	11 (47.8)	19 (65.5)	45 (63.4)	0.234
SES	9 (39.1)	8 (27.6)	24 (33.8)	
ZES	1 (4.3)	2 (6.9)	1 (1.4)	
BES	2 (8.7)	0 (0.0)	1 (1.4)	

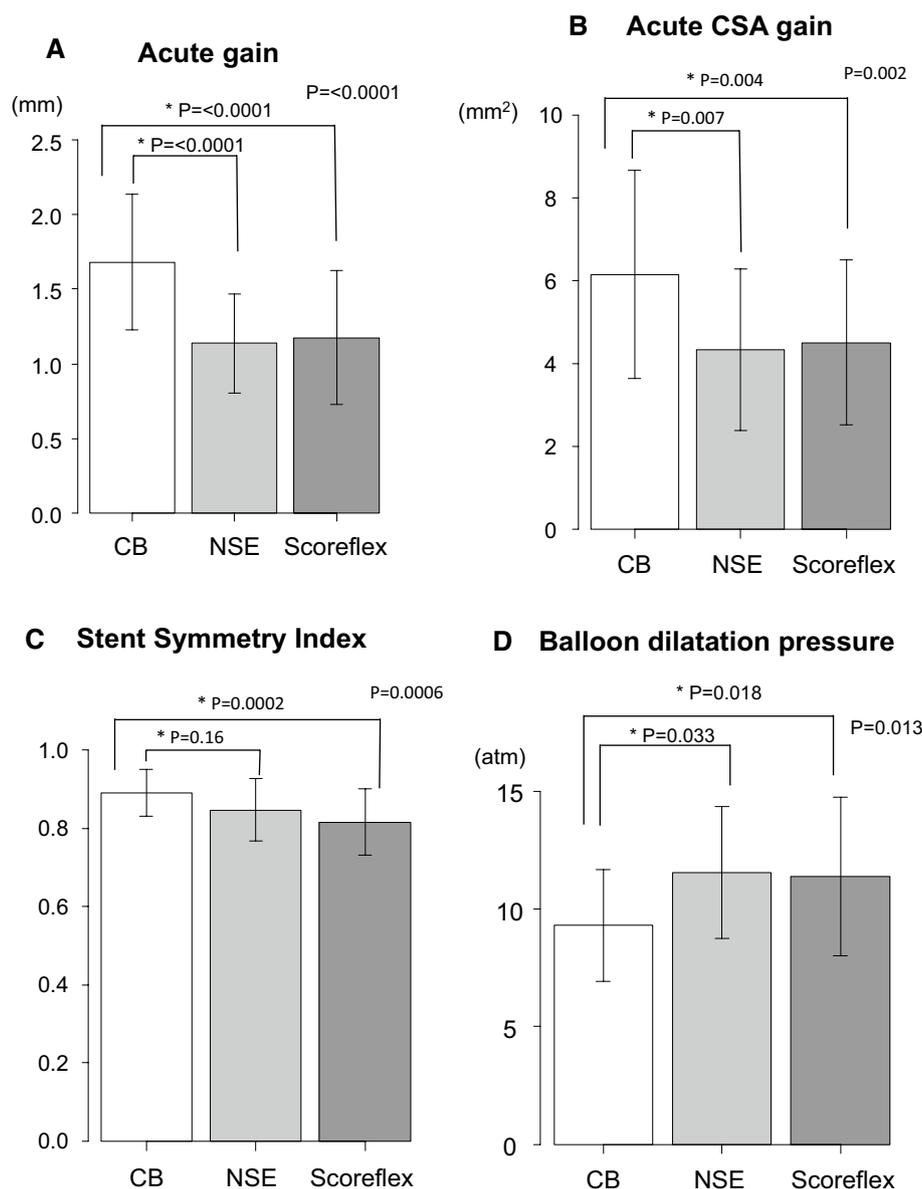
Data are given as *n* (%) or the mean ± SD

DM diabetes mellitus, *HT* hypertension, *DL* dyslipidemia, *HD* hemodialysis, *ACS* acute coronary syndrome, *CTO* chronic total obstruction, *MLD* minimum lumen diameter, *MLA* minimum lumen area, *LMT* left main trunk, *LAD* left anterior descending coronary artery, *LCX* left circumflex artery, *RCA* right coronary artery, *IVUS* intravascular ultrasound, *OFDI* optical frequency domain imaging, *EES* everolimus eluting stent, *SES* sirolimus eluting stent, *ZES* zotarolimus eluting stent, *BES* biolimus eluting stent

closely approximated a perfect circle than the other groups [0.89 ± 0.06 (CB) vs. 0.85 ± 0.07 (NSE) vs. 0.82 ± 0.08 (Scoreflex); *p* = 0.0006; Fig. 2d]. Furthermore, the balloon dilation pressure was lower in the CB group than in the other groups [9.3 ± 2.4 (CB) vs. 11.6 ± 2.8 (NSE) vs.

11.4 ± 3.4 atm (Scoreflex); *p* = 0.013; Fig. 3b]. These data suggested that, even without rotational atherectomy, a CB achieved a larger acute gain and better stent expansion with a lower dilatation pressure than the other balloons.

Fig. 2 Comparisons of acute gain (a), acute cross-sectional area gain (b), stent symmetry index (c), and balloon dilatation pressure (d) among cutting balloon (CB), NSE and Scoreflex in cases not performed rotational atherectomy. The data are given as the mean \pm SD



Comparisons of acute gain, MSA, acute CSA, stent symmetry index and balloon dilatation pressure in cases with calcified lesions with rotational atherectomy

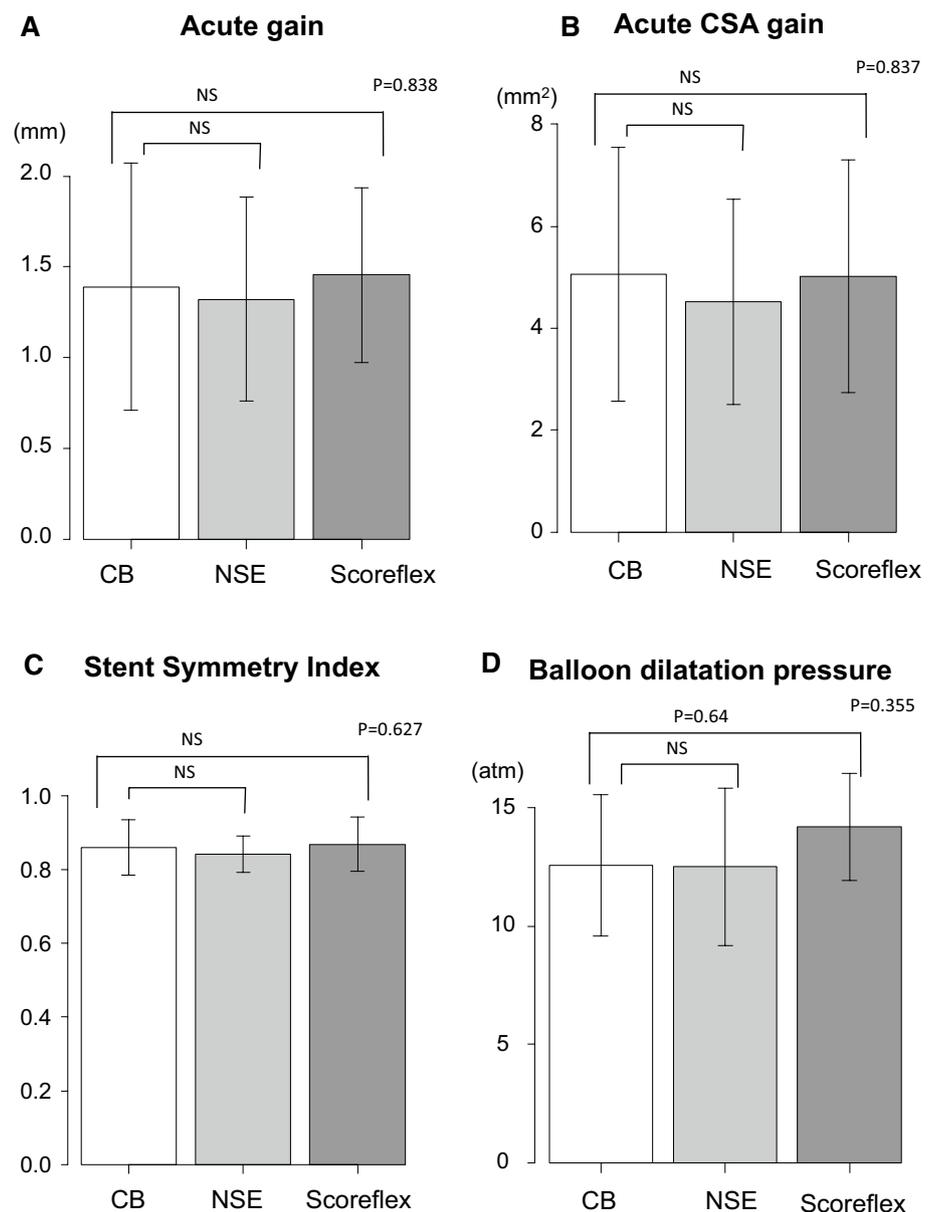
PCI was performed with rotational atherectomy in 33 of 156 cases with calcified lesions. Backgrounds were similar among three balloons (Table 3). The effects of CB were denied in rotational atherectomy group; acute gain: 1.39 ± 0.68 (CB) vs. 1.32 ± 0.56 (NSE) vs. 1.45 ± 0.48 mm (Scoreflex), $p = 0.838$; acute CSA gain: 5.06 ± 2.49 (CB) vs. 4.52 ± 2.02 (NSE) vs. 5.01 ± 2.28 mm² (Scoreflex), $p = 0.837$; MSA: 6.72 ± 2.48 (CB) vs. 6.41 ± 2.19 (NSE) vs. 7.09 ± 2.81 mm² (Scoreflex), $p = 0.807$; stent symmetry index: 0.86 ± 0.07 (CB) vs. 0.84 ± 0.05 (NSE) vs. 0.86 ± 0.74

(Scoreflex), $p = 0.627$; balloon dilatation pressure: 12.5 ± 2.9 (CB) vs. 12.5 ± 3.3 (NSE) vs. 14.2 ± 2.2 atm (Scoreflex); $p = 0.355$ (Fig. 3).

Discussion

This study was the first to compare the efficacy of a CB with those of other scoring balloons in plaque modification of heavily calcified lesions. Adequately modifying plaque in heavily calcified lesions remains difficult in the era of DESs. Rotational atherectomy and angioplasty using a CB or scoring balloon are known to be useful for comfortable plaque modification in heavily calcified lesions. Reducing calcified plaque using rotational atherectomy is ideal. However, this

Fig. 3 Comparisons of acute gain (a), acute cross-sectional area gain (b), stent symmetry index (c), and balloon dilatation pressure (d) among cutting balloon (CB), NSE and Scoreflex in cases performed rotational atherectomy. The data are given as the mean \pm SD



technique is not available at many hospitals in Japan. CBs and scoring balloons are, therefore, indispensable for PCI in cases of heavily calcified lesions in such hospitals.

CBs and scoring balloons do not remove calcification but improve the vessel compliance by making discrete incisions in the atherosclerotic plaque, thereby enabling greater lesion expansion and a reduction in uncontrolled malignant dissections [21]. Ozaki et al. showed that pre-dilatation by CB achieved better lesion preparation, resulting in a significantly lower ratio of restenosis and TVR than pre-dilatation with a conventional balloon in BMS patients [18]. Li et al. showed that intensive plaque modification with rotational atherectomy and CB achieved a significantly larger acute CSA gain and reduced the ratio

of TVR and major adverse cardiovascular events (MACEs) compared with rotational atherectomy and conventional balloon in DES patients [14]. These studies suggest that greater stent expansion requires better lesion preparation regardless of stent type.

The scoring effects of CB and scoring balloons, such as the NSE and Scoreflex, for severe calcified lesions are well advertised. CB has three metallic blades, NSE has three nylon elements, and Scoreflex has one nitinol integral wire. Theoretically, the concept of CB seems to be most effective for making discrete incisions. Some studies have reported on the efficacy of CB compared to conventional balloons; however, there have been few studies evaluating CB in comparison to other scoring balloons. We, therefore, compared

Table 3 The characteristics of cases performed rotational atherectomy

<i>n</i>	Cutting balloon	NSE	Scoreflex	<i>p</i>
	7	10	16	
Patient characteristics				
Age	70.7 ± 8.5	77.3 ± 8.7	70.8 ± 7.9	0.134
Male (%)	5 (71.4)	3 (30.0)	11 (68.8)	0.106
HT (%)	4 (57.1)	9 (90.0)	15 (93.8)	0.068
DL (%)	4 (57.1)	6 (60.0)	9 (56.2)	0.982
DM (%)	2 (28.6)	2 (20.0)	9 (56.2)	0.148
HD (%)	3 (42.9)	4 (40.0)	9 (56.2)	0.683
Smoking (%)	3 (42.9)	0 (0.0)	3 (18.8)	0.078
Complex case				
Total (%)	3 (42.9)	1 (10.0)	8 (50.0)	0.11
ACS (%)	0 (0.0)	1 (10.0)	0 (0.0)	0.305
CTO (%)	3 (42.9)	0 (0.0)	1 (6.2)	0.478
Ostium (%)	2 (28.6)	0 (0.0)	2 (12.5)	0.206
Bifurcation (%)	1 (14.3)	0 (0.0)	6 (37.5)	0.066
Lesion characteristics				
Target lesion				
LMT•LAD (%)	3 (42.9)	7 (70.0)	11 (68.8)	0.379
LCX (%)	2 (28.6)	0 (0.0)	3 (18.8)	
RCA (%)	2 (28.6)	3 (30.0)	2 (12.5)	
Severe calcification (> 270°) (%)	6 (85.7)	9 (90.0)	16 (100.0)	0.344
MLD (mm)	1.27 ± 0.22	1.26 ± 0.22	1.28 ± 0.28	0.984
MSD (mm)	2.66 ± 0.58	2.58 ± 0.44	2.73 ± 0.55	0.778
MLA (mm ²)	1.66 ± 0.44	1.89 ± 0.57	2.07 ± 0.76	0.393
MSA (mm ²)	6.72 ± 2.48	6.41 ± 2.19	7.09 ± 2.81	0.807
Reference vessel diameter (mm)	2.79 ± 0.45	2.66 ± 0.46	2.76 ± 0.58	0.868
Balloon to artery ratio	0.90 ± 0.10	0.94 ± 0.08	0.90 ± 0.09	0.481
Modality				
IVUS	3 (42.9)	5 (50.0)	6 (37.5)	0.821
OFDI	4 (57.1)	5 (50.0)	10 (62.5)	0.821
Device characteristics				
Balloon size	2.50 ± 0.29	2.50 ± 0.35	2.47 ± 0.50	0.978
Stent size	3.07 ± 0.24	2.90 ± 0.56	3.02 ± 0.50	0.744
Stent length	26.29 ± 10.42	30.50 ± 5.89	28.25 ± 8.50	0.249
Stent type				
EES	6 (85.7)	8 (80.0)	7 (43.8)	0.382
SES	1 (14.3)	2 (20.0)	6 (37.5)	
ZES	0 (0.0)	0 (0.0)	1 (6.2)	
BES	0 (0.0)	0 (0.0)	2 (12.5)	

Data are given as *n* (%) or the mean ± SD

DM diabetes mellitus, *HT* hypertension, *DL* dyslipidemia, *HD* hemodialysis, *ACS* acute coronary syndrome, *CTO* chronic total obstruction, *MLD* minimum lumen diameter, *MSD* minimum stent diameter, *MLA* minimum lumen area, *MSA* minimum stent area, *LMT* left main trunk, *LAD* left anterior descending coronary artery, *LCX* left circumflex artery, *RCA* right coronary artery, *IVUS* intravascular ultrasound, *OFDI* optical frequency domain imaging, *EES* everolimus eluting stent, *SES* sirolimus eluting stent, *ZES* zotarolimus eluting stent, *BES* biolimus eluting stent

CB and other scoring balloons (NSE and Scoreflex) in the present study.

We showed in the present study that CB achieved a larger acute gain and acute CSA gain than the NSE and Scoreflex

balloons. Furthermore, the MSA tended to be larger in the CB group than in the other groups. The stent symmetry index showed that the CB group more closely approximated a perfect circle than the other groups. In addition, CB did not

require a high dilatation pressure. These data suggest that a CB was more useful and achieved safe adequate plaque modification in heavily calcified lesions than the NSE and Scoreflex despite the CB group including a greater proportion of severe calcified lesions than the other groups. These data also suggest that our initial impression was true.

In addition, we investigated the scoring effects in cases without rotational atherectomy. In these cases, CB also achieved a larger acute gain, acute CSA gain and MSA than the NSE and Scoreflex groups, and the stent symmetry index showed that the CB group more closely approximated a perfect circle with a lower dilation pressure than the other groups. However, these data were denied in rotational atherectomy group. These data suggest that rotational atherectomy was effective for heavily calcified lesion as already known and the CB was more useful and achieved safer adequate plaque modification in heavily calcified lesions than the NSE and Scoreflex in cases of heavily calcified lesions if rotational atherectomy could not be performed. Given that many hospitals cannot perform rotational atherectomy in Japan, these data may prove particularly useful.

Each balloon (CB, NSE and Scoreflex) is used for different purposes, and we must additionally consider their deliverability into heavily calcified lesions in an actual clinical setting. In fact, the share of CB was only less than one-third in the present study. The biggest reason for this low showing was its relatively poor deliverability to lesions once operator bias was excluded. We were unable to compare the deliverability of the three balloons in the present study due to a lack of data.

Unfortunately, CB has the worst deliverability among the three balloons for structural and technical reasons, so despite its good performance in cases of severe calcified lesions, this balloon has largely been avoided. However, a next-generation CB was recently developed, and this balloon is said to have an improved deliverability compared to previous generations thanks to improvements in the balloon profile. If the CB can be delivered to severe calcified lesions as easily as other scoring balloons, its use may increase.

Several limitations associated with the present study warrant mention. First, this was a retrospective and single-center study. We, therefore, cannot exclude the possibility of operator bias. Second, the present study only included cases in which balloons were able to be delivered to the lesion and dilatation was achieved. As such, severely calcified lesions aside from those evaluated by modalities such as IVUS/OFDI may not have been included in the present study. Third, each operator chose balloon according to his own criteria in this study. Unfortunately, we cannot determine each criterion of each case because of the retrospective nature of this study. It may affect selection bias. We should

perform another prospective study using the next-generation CB in the future.

In conclusion, a CB was more effective for plaque modification in severe calcified lesions than other scoring balloons. The scoring effect of this balloon for plaque modification will likely be improved in the next generation of CBs with an improved deliverability.

Funding This research received no grant from any funding agency in the public, commercial or not-for-profit sectors.

Compliance with ethical standards

Conflict of interest The author's declare that they have no conflict of interest.

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