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**ORIGINAL ARTICLE**
**Cardiovascular Intervention**

# Use of a Cutting Balloon Reduces the Incidence of Distal Embolism in Acute Coronary Syndrome Requiring Predilatation Before Stenting

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***Background:*** Acute coronary syndrome (ACS) patients with solid lesions often require predilatation before stenting. Predilatation with high pressure may increase the risk of distal embolism, whereas direct stenting increases the risk of stent underexpansion. We recently reported that, in severely calcified lesions, using a cutting balloon (CB) can provide greater acute gain compared with other scoring balloons. Therefore, we hypothesized that predilatation with CB may reduce the incidence of distal embolism in ACS patients with solid lesions.

***Methods and Results:*** This study retrospectively analyzed data for 175 ACS patients who required predilatation, either with a conventional balloon (n=136) or CB (n=39). The occurrence of distal embolism was significantly lower in the CB than conventional balloon group (10.3% vs 32.4%, respectively; P=0.007). Multivariate analysis showed that the occurrence of distal embolism was positively associated with Thrombolysis in Myocardial Infarction (TIMI) grade and the presence of attenuated plaque, but negatively associated with the use of a CB. To support this clinical observation, we compared thrombus dispersal using a CB and non-compliant balloon in an ex vivo experimental model using a pseudo-thrombus. In this model, pseudo-thrombus dispersal was significantly smaller when a CB rather than non-compliant balloon was used (1.8±1.0% vs 2.6±1.2%, respectively; n=20, for each; P=0.002).

***Conclusions:*** In ACS patients with solid lesions that require predilatation, predilatation with a CB may reduce the incidence of distal embolism.

**Key Words:** Acute coronary syndrome; Cutting balloon; Distal embolism; Severe calcification

Suboptimal coronary reperfusion at the end of emergent percutaneous coronary intervention (PCI) in patients with acute coronary syndrome (ACS) is associated with worse outcomes.[1,2] No flow due to periprocedural distal embolism in primary PCI should be avoided as much as possible because it affects prognosis.[3–5]

Various devices have been developed and used to avoid no flow due to distal embolism. The efficacy of thrombus aspiration therapy is controversial.[6,7] In addition, the efficacy of distal protection using distal protection devices has not been good.[6,8] However, a recent prospective trial showed the possible effectiveness of a distal protective device in a selected population at high risk of distal embolism.[9]

Conversely, solid lesions, such as severely calcified and fibrous plaques mixed with thrombus or lipid-rich plaques, are often encountered in ACS. There is also a mechanism by which calcified nodules can lead to ACS, which has been widely reported in pathological investigations.[10,11]

In primary PCI, direct stenting is often chosen in cases in which there are many thrombi and lipid-rich plaques and is known to be useful in avoiding distal embolism. However, in cases in which there is a mixture of solid and soft lesions, direct stenting is not always possible, and predilatation is often required before stenting. In addition, severely calcified lesions have lower procedural success rates, a higher risk of acute complications, and higher restenosis rates than non-calcified lesions.[12–20] Furthermore, it is difficult to deliver a stent in a severely calcified lesion, making it difficult to obtain sufficient acute gain.[21]

Scoring balloons are widely used in the treatment of calcified lesions; of the different types of scoring balloons, cutting balloons (CB) have been reported to be effective in obtaining a greater acute gain.[22–26] We recently reported that CB can achieve a greater acute gain in severely calcified lesions compared with other scoring balloons and a stent symmetry index closer to a perfect circle, and that

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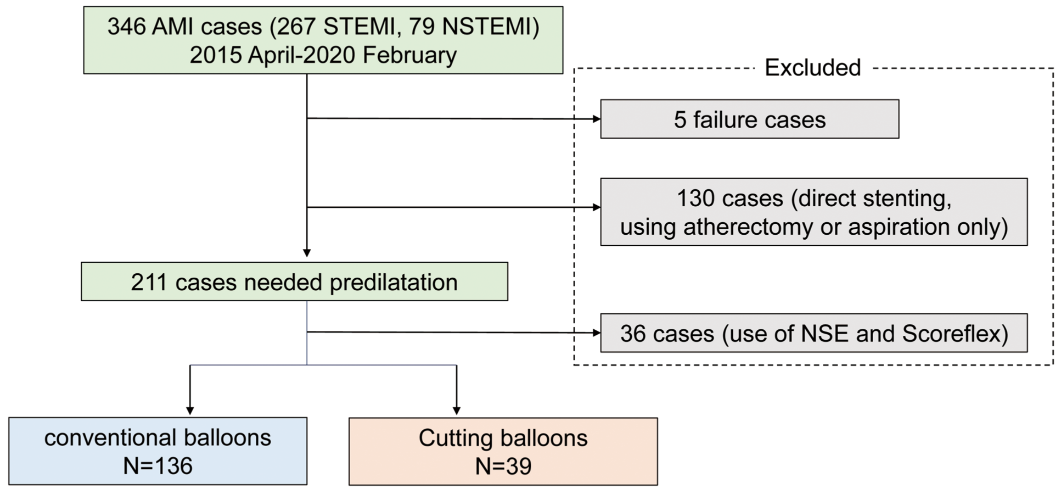


**Figure 1.** Study design. AMI, acute myocardial infarction; NSE, non-slip element balloon; NSTEMI, non-ST segment elevation myocardial infarction; STEMI, ST-elevation myocardial infarction.

these effects can be achieved with lower balloon dilatation pressure.[27]

The risk of distal embolism associated with predilatation should be carefully considered in patients with ACS when predilatation is required; however, no previous studies have reported an optimal strategy to assess the risk of distal embolism following predilatation. We hypothesized that the use of CBs, which provide greater acute gain with lower dilatation pressure, may reduce the risk of distal embolism in ACS patients requiring predilatation. Because this has not been investigated in previous studies, we evaluated the relationship between the use of a CB and the incidence of distal embolism in ACS patients with a mixture of solid and soft lesions requiring predilatation.

## Methods

### Patients and Study Design

We retrospectively analyzed data for 346 ACS patients (267 ST-elevation myocardial infarction [STEMI] and 79 non-STEMI) who underwent PCI at our institution between April 2015 and February 2020. After excluding 5 patients in whom predilatation failed and another 166 who underwent direct stenting, atherectomy, aspiration only, or predilatation using other scoring balloons, such as Scoreflex®, Scoreflex NC® and Lacrosse NSE®, 175 patients requiring predilatation were enrolled in the present study. Patients were divided into 2 groups for analysis, a CB group and a convention balloon group. The CB group contained 39 patients (36 treated with the Wolverine® CB and 3 treated with the Flextome® CB [Boston Scientific Japan, Tokyo, Japan]), whereas the conventional balloon group contained 136 patients (104 treated with semicompliant balloons and 32 treated with non-compliant [NC] balloons; **Figure 1**).

Data collected included patient characteristics, such as patient background and commonly known coronary risk factors,[28] target lesion details (including morphology and size),[29] devices, and the types of stents used. Predilatation is generally performed when the operator determines that direct stenting does not provide sufficient dilation in the presence of fluoroscopic calcification, as well as in the case of findings of severe calcification and/or firm fibrous plaques on intravascular ultrasound (IVUS), optical coherence tomography (OCT), and/or optical frequency domain imaging (OFDI).

The incidence of distal embolism was compared between the CB and conventional balloon groups. Distal embolism was defined as either angiographic no flow (Thrombolysis in Myocardial Infarction [TIMI] grade 0–1), slow flow (TIMI 2), and filter no flow (TIMI 0–1) with electrocardiographic changes during the procedure, regardless of postoperative increases in creatine kinase.

To compare post-procedural acute gain between the 2 groups, the ratio of final target lumen diameter or area to reference diameter or area was calculated from the final IVUS, OCT, and OFDI findings. The reference segment used for the calculation of the ratio was the proximal site of the target lesion.[30,31]

Severe calcification, attenuated plaque, and the balloon to artery ratio were determined on the basis of IVUS and OCT/OFDI findings. Severe calcification was defined as a calcified lesion >270° or calcified nodules. Calcified nodule lesions were present in only 4 of the severely calcified lesions. The definition of attenuated plaque was based on previous reports.[30,31] The balloon to artery ratio is presented as the balloon size relative to the proximal reference diameter.

In this study, the procedural endpoint of predilatation was defined as the loss of indentation of an inflated balloon on fluoroscopy. The loss of indentation was defined as the balloon not being firmly spread out rather than dumbbell-shaped on fluoroscopy.

### Ex Vivo Experimental Model

The dispersal of a pseudo-thrombus was evaluated using a 3-dimensional (3D) aorta model, as shown in **Supplementary Figure 1**. Tubes with an inner diameter (ID)

**Table 1. Patient Characteristics Before and After Propensity Score Matching**

| | Before propensity score matching | | | After propensity score matching | | |
|---|---|---|---|---|---|---|
| | Conventional balloon (n=136) | CB (n=39) | P value | Conventional balloon (n=38) | CB (n=38) | P value |
| **Patient background** | | | | | | |
| Age | 69.2±12.9 | 69.4±13.7 | 0.945 | 71.5±15.2 | 68.9±13.5 | 0.423 |
| Male sex | 107 (78.7) | 24 (61.5) | 0.037 | 24 (63.2) | 23 (60.5) | 1.000 |
| Hypertension | 103 (75.7) | 29 (74.4) | 0.836 | 31 (81.6) | 28 (73.7) | 0.583 |
| Dyslipidemia | 99 (72.8) | 25 (64.1) | 0.320 | 25 (65.8) | 25 (65.8) | 1.000 |
| Diabetes | 60 (44.1) | 17 (43.6) | 1.000 | 20 (52.6) | 17 (44.7) | 0.647 |
| Hemodialysis | 17 (12.5) | 7 (17.9) | 0.429 | 8 (21.1) | 7 (18.4) | 1.000 |
| Smoker | 27 (19.9) | 5 (12.8) | 0.359 | 6 (15.8) | 5 (13.2) | 1.000 |
| **Culprit lesion background** | | | | | | |
| LM/LAD (%) | 70 (51.5) | 23 (59.0) | 0.469 | 24 (63.2) | 23 (60.5) | 1.000 |
| RCA (%) | 41 (30.1) | 11 (28.2) | 1.000 | 10 (26.3) | 10 (26.3) | 1.000 |
| LCX (%) | 25 (18.4) | 4 (10.3) | 0.329 | 4 (10.5) | 4 (10.5) | 1.000 |
| SVG (%) | 0 (0.0) | 1 (2.6) | 0.223 | 0 (0.0) | 1 (2.6) | 1.000 |
| Target diameter (mm) | 2.99±0.59 | 2.99±0.49 | 0.944 | 2.86±0.61 | 2.97±0.49 | 0.377 |
| Target length (mm) | 25.4±8.1 | 26.8±8.9 | 0.346 | 23.8±7.8 | 26.8±9.1 | 0.129 |
| TIMI grade | 0.85±1.13 | 0.67±0.96 | 0.351 | 0.82±1.06 | 0.68±0.96 | 0.573 |
| Attenuated plaque | 23 (16.9) | 7 (17.9) | 1.000 | 6 (15.8) | 7 (18.4) | 1.000 |
| Severe calcification | 52 (38.2) | 16 (41.0) | 0.852 | 13 (34.2) | 16 (42.1) | 0.637 |
| **Devices** | | | | | | |
| Aspiration | 90 (66.2) | 28 (71.8) | 0.566 | 22 (57.9) | 27 (71.1) | 0.338 |
| Balloon size (mm) | 2.34±0.57 | 2.30±0.64 | 0.945 | 2.26±0.48 | 2.30±0.64 | 0.766 |
| Balloon : target ratio | 0.79±0.19 | 0.77±0.18 | 0.660 | 0.78±0.22 | 0.77±0.18 | 0.905 |
| Filter | 22 (16.2) | 6 (15.4) | 1.000 | 7 (18.4) | 6 (15.8) | 1.000 |
| DCB/balloon only | 16 (11.8) | 10 (26.3) | 0.038 | 7 (18.4) | 10 (26.3) | 0.583 |
| **Type of stent** | | | | | | |
| EES | 85 (62.5) | 14 (36.8) | 0.006 | 14 (36.8) | 14 (36.8) | 1.000 |
| SES | 24 (17.6) | 5 (12.8) | 0.627 | 7 (18.4) | 5 (13.2) | 0.754 |
| ZES | 11 (8.1) | 9 (23.0) | 0.017 | 10 (26.3) | 9 (23.7) | 1.000 |

Unless indicated otherwise, data are presented as the mean ± SD or n (%). CB, cutting balloon; DCB, drug-coated balloon; EES, everolimus-eluting stent; LAD, left anterior descending artery; LCX, left circumflex artery; LM, left main; RCA, right coronary artery; SES, sirolimus-eluting stent; SVG, saphenous vein graft; TIMI, Thrombolysis in Myocardial Infarction; ZES, zotarolimus-eluting stent.

of 5 or 10 mm were inserted into existing tubing in the 3D aorta model, and a pseudo-thrombus, consisting of agar : water (1 : 25), was injected into the 5- and 10-mm ID tubes. A roller pump (Just Medical) was used to irrigate the model at a slow perfusion rate. The pseudo-thrombus lesions were dilated with either a CB (Wolverine 3.0×10 mm, 6 atm) or a NC) balloon (control group; NC Emerge 3.0×12 mm, at 12 atm) for 10 s each (n=20 each for the CB and NC groups in both the 5- and 10-mm models). The weight of the pseudo-thrombus model was measured before and after dilatation. The difference in weight from before to after balloon dilatation was divided by the original weight to obtain the pseudo-thrombus dispersal rate.

## 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 (R Foundation for Statistical Computing, Vienna, Austria). More precisely, EZR is a modified version of R commander designed to add statistical functions frequently used in biostatistics.[32] Continuous variables were compared using unpaired t-tests. Categorical variables were compared using Fisher's exact test. Univariate and multivariate analyses were performed to investigate associations of clinical confounding factors, including the use of CB, with the development of distal embolism. A univariate analysis of factors associated with the incidence of distal embolism was performed using logistic regression analysis. Then, multivariate analysis using logistic regression analysis was performed. Independent variables which may affect the outcomes were selected in multivariate analysis. The following variables were included in the logistic regression model: absence/presence of dyslipidemia, target vessel diameter and length, TIMI grade, attenuated plaque, severe calcification, balloon-to-target ratio, use of a CB, the use of a drug-coated balloon (DCB) or balloon only, and stent type.

Unless specified otherwise, all data are expressed as the mean ± SD or median (interquartile range). Because the distribution of all continuous variables was confirmed as normal (F-test), the probability was 2-tailed, with $P<0.05$ considered statistically significant.

There were some differences in background between the 2 groups. Thus, propensity score matching analysis was performed. A propensity score indicating the predicted probability of CB use that was conditional on the observed covariates was calculated from the logistic equation for each patient. The following variables were included in the

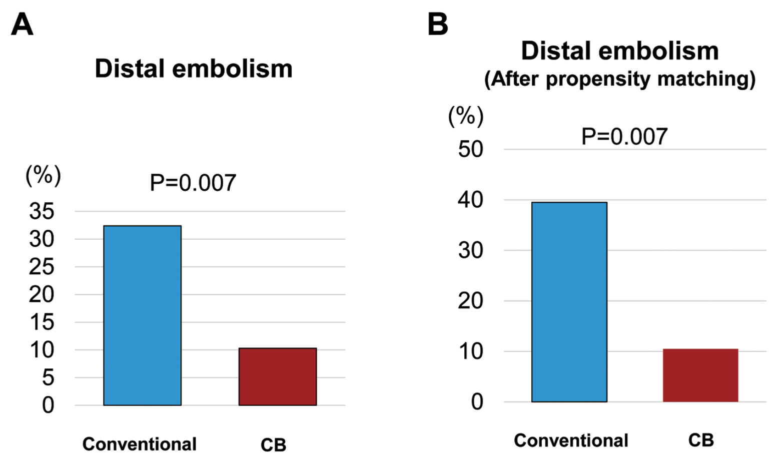


**Figure 2.** Incidence of distal embolism (**A**) before and (**B**) after propensity matching in the conventional balloon and cutting balloon (CB) groups.

**Table 2. Association of Background Characteristics With Distal Embolism Based on Univariate and Multivariate Analysis**

| | Univariate analysis | | | Multivariate analysis | | |
|---|---|---|---|---|---|---|
| | OR | 95% CI | P value | OR | 95% CI | P value |
| **Background** | | | | | | |
| Age | 0.981 | 0.956–1.010 | 0.143 | | | |
| Male sex | 1.180 | 0.541–2.580 | 0.677 | | | |
| Hypertension | 1.130 | 0.518–2.480 | 0.755 | | | |
| Dyslipidemia | 0.998 | 0.481–2.070 | 0.997 | | | |
| Diabetes | 1.570 | 0.804–3.060 | 0.398 | | | |
| Dialysis | 0.886 | 0.321–2.330 | 0.774 | | | |
| Smoker | 1.780 | 0.794–4.010 | 0.161 | | | |
| **Culprit lesion** | | | | | | |
| LM/LAD | 1.060 | 0.644–2.060 | 0.867 | | | |
| RCA | 1.440 | 0.710–2.930 | 0.311 | | | |
| LCX | 0.499 | 0.179–1.390 | 0.185 | | | |
| Target diameter | 2.350 | 1.270–4.320 | 0.006 | | | |
| Target length | 1.010 | 0.971–1.050 | 0.601 | | | |
| TIMI grade | 0.640 | 0.445–0.921 | 0.016 | 0.608 | 0.411–0.899 | 0.012 |
| Attenuated plaque | 6.910 | 2.960–16.100 | <0.001 | 8.500 | 3.280–22.00 | <0.001 |
| Severe calcification | 0.721 | 0.359–1.450 | 0.358 | | | |
| **Device** | | | | | | |
| Balloon : target ratio | 0.844 | 0.143–4.980 | 0.851 | | | |
| Use of CB | 0.239 | 0.079–0.714 | 0.010 | 0.151 | 0.043–0.529 | 0.003 |
| DCB/balloon only | 0.581 | 0.206–1.640 | 0.306 | | | |
| **Type of stent** | | | | | | |
| EES | 1.560 | 0.782–3.090 | 0.208 | | | |
| SES | 0.640 | 0.243–1.680 | 0.366 | | | |
| ZES (%) | 1.140 | 0.412–3.170 | 0.797 | | | |

Results of univariate and multivariate analysis. CI, confidence interval; OR, odds ratio. Other abbreviations as in Table 1.

logistic regression model to calculate the propensity score: male sex, finished PCI with DCB/balloon only, everolimus-eluting stent (EES) use, and zotarolimus-eluting stent (ZES) use. Propensity score matching was used to adjust for the significant differences in baseline characteristics between 2 groups (n=38 each).

### Ethics Considerations

This study was approved by the Ethics Committee of Fukuoka Red Cross Hospital and was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. Informed consent for data handling was obtained before PCI was performed, and informed consent for the study was obtained opt out.

## Results

### Patient Characteristics

Characteristics of the CB and conventional balloon groups

**Table 3. Procedure Details Before and After Propensity Score Matching**

| | Before propensity score matching | | | After propensity score matching | | |
|---|---|---|---|---|---|---|
| | Conventional balloon | CB | P value | Conventional balloon | CB | P value |
| Pressure at predilatation (atm) | 13.9±4.0 | 10.0±3.7 | <0.001 | 13.4±4.3 | 10.1±3.7 | <0.001 |
| Post-dilatation (%) | 81 (59.6) | 18 (46.2) | 0.147 | 23 (60.5) | 18 (47.4) | 0.357 |
| Pressure at post-dilatation (atm) | 14.9±3.1 | 14.8±3.9 | 0.868 | 15.1±3.0 | 14.8±3.9 | 0.758 |
| Final target lumen diameter: reference diameter ratio | 0.76±0.09 | 0.80±0.09 | 0.041 | 0.74±0.09 | 0.80±0.09 | 0.021 |
| Final target lumen area: reference area ratio | 0.76±0.12 | 0.81±0.10 | 0.026 | 0.72±0.12 | 0.81±0.10 | 0.001 |

Unless indicated otherwise, data are presented as the mean±SD or n (%). CB, cutting balloon.

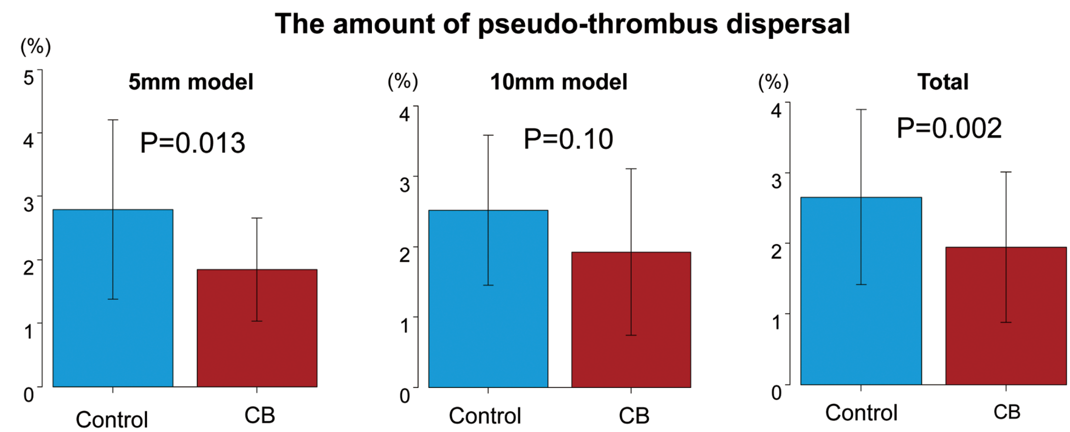


**Figure 3.** Pseudo-thrombus dispersal in an experimental model following the use of either a control (non-compliant) balloon or cutting balloon (CB). Data are presented as the mean±SD.

are presented in **Table 1**. A larger proportion of patients in the CB group was treated with a DCB or balloon alone, and a smaller proportion was treated with EES and ZES. The proportion of male patients was smaller in the CB group.

## Incidence of Distal Embolism

Distal embolisms occurred in 48 (27.4%) patients. No flow occurred in 10 (20.8%) patients (2 in the CB group, 8 in the conventional balloon group), slow flow occurred in 17 (35.5%) patients (0 in the CB group, 17 in the conventional balloon group), and filter no flow occurred in 21 (43.7%) patients (2 in the CB group, 19 in the conventional balloon group). Distal embolisms occurred at the time of predilatation in 12 of 48 patients (25.0%; 2 in the CB group, 10 in the conventional balloon group), at stenting in 26 (54.2%) patients (2 in the CB group, 24 in the conventional balloon group), and at post-dilatation 10 (20.8%) patients (all in the conventional balloon group).

The incidence of distal embolization was significantly lower in the CB than conventional balloon group (4/39 [10.3%] vs. 44/136 [32.4%]; P=0.007; **Figure 2A**). Univariate and multivariate analyses consistently showed that TIMI grade (odds ratio [OR] 0.608; 95% confidence interval [CI] 0.411–0.899; P=0.012), the presence of attenuated plaque (OR 8.500; 95% CI 3.280–22.00; P<0.001), and CB use (OR 0.151; 95% CI 0.043–0.529; P=0.003) were significantly associated with the occurrence of distal embolism (**Table 2**).

Propensity score matching was performed to align background factors that may affect the results, and the incidence of distal embolism was then compared between the 2 matched groups (**Table 2**). Following propensity score matching, the incidence of distal embolization remained significantly lower in the CB than conventional balloon group (4/38 [10.5%] vs. 15/38 [39.5%]; P=0.007; **Figure 2B**).

## Procedure Details

Procedure details, before and after propensity score matching, are summarized in **Table 3**. Before propensity score matching, balloon dilatation pressure at predilatation was significantly lower in the CB than conventional balloon group (10.0±3.7 vs. 13.9±4.0 atm, respectively; P<0.001). There was no significant difference in the percentage of patients requiring post-dilatation after stenting between the CB and conventional balloon groups (46.2% vs. 59.6%, respectively; P=0.147), and no significant difference in dilatation pressure at post-dilatation (14.8±3.9 vs. 14.9 ±3.1 atm, respectively; P=0.868).

The ratio of final target lumen diameter to reference lumen diameter was higher in the CB than conventional balloon group (0.80±0.10 vs. 0.76±0.09, respectively;

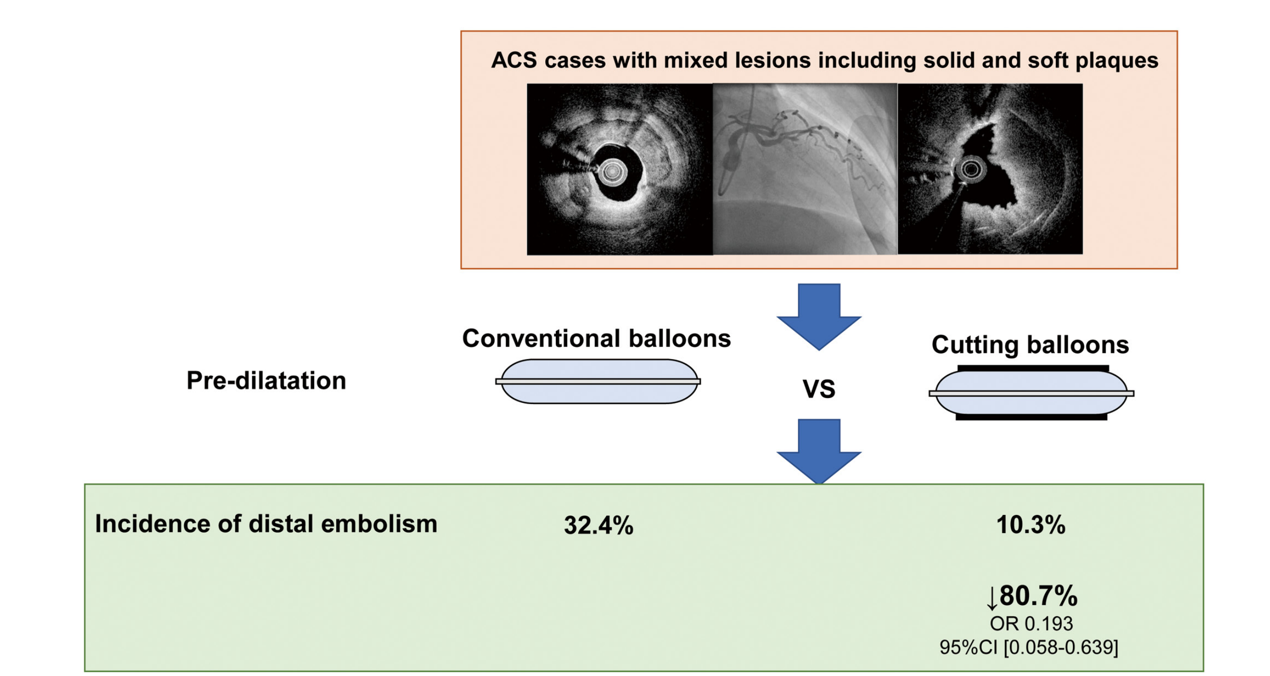


**Figure 4.** Central findings of this study. ACS, acute coronary syndrome; OR, odds ratio.

P=0.041), as was the ratio of final target lumen area to reference lumen area (0.81±0.10 vs. 0.76±0.12, respectively; P=0.026). Similar results were obtained after propensity score matching (**Table 3**).

### Comparison of Pseudo-Thrombus Dispersal in an Experimental Model

The incidence of distal embolism using a pseudo-thrombus in an experimental system was compared between the CB and conventional balloon groups (**Figure 3**; **Supplementary Figure 2**; **Supplementary Movies 1,2**). Pseudo-thrombi, consisting of agar, 5 and 10 mm in length models were created. Pseudo-thrombus dispersal, regarded as an index of distal emboli, was significantly lower in the CB than control group in the 5-mm model (1.64±0.81% vs. 2.79±1.41%, respectively; P=0.013) and tended to be lower in the CB than control group in the 10-mm model (1.92±1.18% vs. 2.51±0.64%, respectively; P=0.1). When the 5- and 10-mm models were combined, pseudo-thrombus dispersal was significantly lower in the CB than control group (1.88±1.00% vs. 2.65±1.24%, respectively; P=0.002).

## Discussion

This study is the first to report that a CB is useful in reducing distal embolism in ACS patients with a mixture of solid and soft lesions that require predilatation (**Figure 4**). It is well known that the use of atherectomy and scoring balloons is very important for optimal lesion modification in severely calcified lesions, and this is also true in the case of ACS. However, in the setting of ACS, hemodynamic instability often makes it difficult to use a rotablator, and plaque modification using only a balloon is often necessary. Conversely, predilatation with a high-pressure balloon without a debulking device may increase the risk of distal embolism. We previously reported that a CB can provide greater acute gain than other scoring balloons at a lower dilatation pressure and is useful for optimal lesion modification in severely calcified lesions.[25] We also reported that plaque modification with a CB was more useful in patients treated without atherectomy devices.[25] Therefore, in the present study we tested our hypothesis that the CB would be useful in ACS patients requiring predilatation. Although this study was a retrospective study, we demonstrated that using a CB could achieve lesion modification without increasing distal embolism in ACS patients with a mixture of solid and soft lesions requiring predilatation. In addition, the CB group in the present study was treated at a lower dilatation pressure than the conventional balloon group (10.0±3.7 vs 14.0±3.9 atm, respectively; P<0.001), which may have contributed to the lower number of distal embolisms in the CB group.

Evaluation of the timing of distal embolism showed that approximately 80% of emboli occurred before stenting in the present study. The percentage of patients requiring post-dilatation was similar between the 2 groups, and the balloon dilatation pressure required for post-dilatation was also similar. Subsequently, the post-procedural acute gain of the target lesions was comparable between the 2 groups, suggesting adequate predilatation of the target lesions in the CB group. Together, these findings suggest that the CB can be used to provide effective and safe lesion modification before stenting, and may even reduce distal embolism during stenting.

We performed ex vivo bench experiments to further support the clinical results. We compared pseudo-thrombus dispersal using a pseudo-thrombus model and confirmed that dispersal was lower in the CB than control group. In this experimental system, NC balloons were used as the control group, and each balloon was dilated to the same diameter at nominal pressure to simulate the clinical situation. If we make an inference from the structural aspect of the CB, because the CB has 3 or 4 blades the pressure is not applied as a plane, but rather as an evenly distributed point of force. These structural characteristics allow the CB to achieve acute luminal gain at lower dilatation pressures. As a result, less ubiquitous force is applied to the thrombus, which may reduce its dispersion. Lower thrombus dispersal with CB dilatation may be one of the mechanisms leading to the lower incidence of distal embolism. However, the results of ex vivo experiments are for reference only, and do not directly explain the mechanism underlying the clinical results in this study.

### Study Limitations

This study has several limitations. First, this study is a single-center retrospective cohort study. We therefore performed an additional bench experiment, and obtained consistent results. Further investigations, such as prospective studies, are needed to confirm the results of the present study. Second, it was up to each operator to decide whether to choose a CB or another type of balloon, leading to selection bias. Thus, we performed additional analysis using propensity score matching to align the background characteristics of patients. Third, detailed morphology of all lesions was not available in the studied groups. Thus, there may have been differences in thrombus volume and other factors, depending on the lesion.

## Conclusions

The present study demonstrated the possibility of reducing distal embolism by using a CB in ACS patients requiring predilatation. The use of a CB could be an effective and safe strategy, and is thus recommended in ACS patients with a mixture of solid and soft lesions requiring predilatation during primary PCI.

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### Disclosures

R.M. has received honoraria for lectures from Abbott Japan LCC, Boston Scientific, and TERUMO. The remaining authors have no conflicts of interest to declare.

### IRB Information

The study protocol was approved by the Institutional Review Board of Fukuoka Red Cross Hospital (Approval no. 594), informed consent for data handling was obtained before PCI was performed, and informed consent for the study was obtained opt out.

### Data Availability

The deidentified participant data will not be shared.

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## Supplementary Files

**Supplementary Movies.** Movies of pseudo thrombus dispersal. The file named 'Control MP4' shows the control balloon case. The file named 'Cutting balloon MP4' shows the control balloon case.

Please find supplementary file(s);
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