



# Clinical Outcomes of Rotational Atherectomy in Heavily Calcified Lesions: Evidence From the Largest Cardiac Center in Thailand

ORIGINAL RESEARCH

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## ABSTRACT

**Background:** Evidence regarding the clinical outcomes of rotational atherectomy (RA) in middle-income countries is limited. We analyzed the clinical outcomes of patients with heavily calcified coronary lesions who underwent RA-assisted percutaneous coronary intervention (PCI) and explored the risks for developing major adverse cardiovascular and cerebrovascular events (MACCE).

**Methods:** This is a single-center, retrospective cohort analysis that enrolled consecutive patients who underwent RA-assisted PCI at the largest tertiary hospital in Thailand. The primary endpoint is the incidence of MACCE during the first-year follow-up. MACCE consists of cardiac death, ischemic stroke, definite stent thrombosis, target lesion revascularization, and target vessel revascularization.

**Results:** From January 2015 to December 2018, 616 patients (663 lesions) were enrolled. The mean age was  $72.8 \pm 9.7$  years, 292 (47.4%) patients were female and 523 (84.9%) completed one-year follow-up. Drug-eluting stents were deployed in 606 (91.4%) lesions. The RA success rate – defined as when the operator successfully passed the burr across the target lesion – was 99.4% and the angiographic success rate was 94.8%. 130 (21.4%) procedures developed periprocedural complications. The cumulative MACCE rate at 30-days was 1.5% and at 1-year was 6.3%. The in-hospital mortality rate was 1.1% and the cardiac death rate was 1.6%. Independent risk factors for developing MACCE included the use of an intra-aortic balloon pump (hazard ratio [HR] 3.96, 95% confidence interval [CI] 1.54–10.21;  $P = 0.004$ ), a history coronary artery bypass graft (HR 2.30, 95% CI 1.01–5.25;  $P = 0.048$ ), and increased serum creatinine (HR 1.16, 95% CI 1.04–1.30;  $P = 0.008$ ).

**Conclusions:** RA is an effective revascularization technique for heavily calcified lesions. This study demonstrates a high success rate and good short- to intermediate-term results of RA-assisted PCI in middle-income countries which are similar to high-income countries. Nevertheless, the rate of periprocedural complications remains high.

## KEYWORDS:

Debulking the calcified lesion; percutaneous coronary intervention; major adverse cardiovascular and cerebrovascular events

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## INTRODUCTION

Approximately 20% of patients who undergo percutaneous coronary intervention (PCI) have severe calcified coronary artery disease (CAD) [1]. Heavy calcification causes PCI to be more challenging as the calcific plaque prevents the coronary balloon from fully dilating during lesion preparation and impedes stent delivery. As a result, calcified plaque leads to suboptimal PCI results such as stent underexpansion and stent mal-apposition [2, 3]. In addition, heavily calcified lesions are associated with long-term stent-related complications such as in-stent restenosis and stent thrombosis [4]. Consequently, coronary calcification adversely impacts clinical outcomes following PCI [5–7].

Rotational atherectomy (RA) is a technique that uses a dedicated diamond-coated burr to debulk the calcified lesions [8]. RA ablates the severely calcified plaque, enhancing optimal stent expansion and accommodating stent delivery [9, 10]. As a result, RA improves the immediate procedural success rate and long-term clinical outcomes in patients with heavily calcified lesions [11].

There is limited evidence regarding the clinical outcomes of RA in middle-income countries. Therefore, we conducted a single-center, retrospective cohort analysis to investigate the short- and mid-term clinical outcomes of patients who were undergoing RA-assisted PCI. We also explored potential independent risk factors for major adverse cardiovascular and cerebrovascular events (MACCE).

## METHODS

### STUDY DESIGNS AND POPULATIONS

We retrospectively enrolled all patients whom the operator decided to perform RA-assisted PCI, regardless of the RA outcome. The extent of coronary artery stenosis was assessed either by visual estimation, physiologic study, or intravascular imaging guidance. All RA procedures were performed at Her Majesty Cardiac Center, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand – a middle-income country in Southeast Asia – from January 2015 to December 2018. We divided the patients into a MACCE group and a MACCE-free group according to the occurrence of MACCE at the one-year follow-up. Two investigators manually extracted the relevant data from the electronic database into the dedicated case record form. The Siriraj Institutional Ethical Review Board of the Faculty of Medicine Siriraj Hospital, Mahidol University approved this cohort study (Protocol number 259/2562[EC2]).

### ROTATIONAL ATHERECTOMY

All RA procedures were performed using the Rotablator™ system (Boston Scientific, Marlborough, MA, USA) by experienced operators following the standard recommendations [9, 12]. The periprocedural medications and antithrombotic regimens were guided by standard clinical practice guidelines [13, 14]. The indication for PCI, vascular access route, PCI technique, PCI strategy, the options of coronary stents, the determination to perform RA, RA burr size and amount, the timing of each run of RA, RA speed, and the total number of RA runs were at the operators' discretion.

### STUDY OUTCOMES

The primary objective was to measure the cumulative incidence of MACCE at the one-year follow-up visit. The secondary objective was to identify the independent risk factors for developing MACCE. MACCE consists of cardiac death, ischemic stroke, definite stent thrombosis, target lesion revascularization (TLR), and target vessel revascularization (TVR) during the follow-up period.

### DEFINITIONS

Cardiac death is defined as death caused by acute coronary syndrome (ACS) or heart failure. Ischemic stroke is defined as the presence of new neurological deficits lasting longer than 24 hours with any evidence of ischemia from any imaging modality. Definite stent thrombosis is defined as described elsewhere [15]. TLR is defined as any repeat revascularization at the target lesion which includes the 5-mm margin from the stent edge [16]. TVR is defined as

any repeat revascularization of the target vessel [16]. Periprocedural myocardial infarction (MI) is defined as the absolute rise in serum creatinine kinase (CK-MB) of more than ten times the upper normal limit as described by the Society for Cardiovascular Angiography and Interventions [17]. No reflow phenomenon is defined as markedly limited coronary blood flow despite minimal residual stenosis, or no flow-limiting dissection at the target lesion. Contrast-induced nephropathy is defined as an absolute increase in serum creatinine (Cr) 0.5 mg/dl or more, or an increase in serum Cr at least 25% from baseline [18]. Angiographic success is defined as the achievement of residual stenosis not more than 20% after stent implantation. PCI procedural success is defined as angiographic success without major in-hospital adverse cardiac events [19]. RA procedural success is defined as when the operator could pass the burr across the target lesion. Intraprocedural complications consisted of flow-limiting coronary artery dissection after RA, coronary artery perforation, cardiac tamponade, no-reflow phenomenon required treatment, and burr entrapment. Periprocedural complications consisted of in-hospital death, in-hospital stroke, acute stent thrombosis, periprocedural MI, hemorrhage required blood transfusion, intracranial hemorrhage, fatal bleeding, vascular complications, and contrast-induced nephropathy.

## STATISTICAL ANALYSIS AND SAMPLE SIZE CALCULATION

Categorical data were presented as percentages and frequency. Quantitative variables with normal distribution were presented as mean  $\pm$  standard deviation (SD), while skewness variables were demonstrated as median, minimum, and maximum values. We used the Chi-squared or Fisher's exact test to compare categorical data and used the independent *t*-test or Mann-Whitney *U* test to compare the differences between continuous data. The cumulative MACCE was presented with a Kaplan-Meier curve and compared using Cox regression analysis. Cox's proportional hazards regression model was used to identify the independent risk factors for developing MACCE and presented as hazard ratio (HR) and 95% confidence interval (95% CI). A *p*-value less than 0.05 was considered statistically significant. We used SPSS version 18 (SPSS Inc., Chicago, IL) to analyze the data.

To estimate the sample size, we used the estimation proportion of the one-group method. First, we estimated the cumulative incidence of MACCE at the one-year follow-up visit to be 16.3% [20]. Then, we prescribed the standard error of measurement at 20% and the *Z*-value at 1.96 for the 95% CI. The calculated sample size was 482 patients.

## RESULTS

### BASELINE CLINICAL CHARACTERISTICS

We enrolled 616 patients (663 lesions). The mean age of the cohort was  $72.8 \pm 9.7$  years, 292 (47.4%) patients were female, 576 (93.5%) had hypertension, and 467 (75.8%) had dyslipidemia (Table 1). Most of the patients presented with stable CAD which had a non-significant difference in the incidence of MACCE compared to ACS patients ( $P = 0.254$ ) (Figure 1). Among 367 patients with left ventricular ejection fraction (LVEF) data, the median LVEF was 60.00% (Interquartile range 40–70%). The mean serum Cr was 1.9 mg/dl, indicating mildly impaired renal function. The Cr level was statistically significantly higher ( $P = 0.048$ ) and the hemoglobin level was statistically significantly lower ( $P < 0.001$ ) in the MACCE group.

### ANGIOGRAPHIC AND PROCEDURAL CHARACTERISTICS

Four hundred and forty-five (72.2%) of RA procedures were performed via the femoral approach (Table 2). Six hundred and fifty-two (98.3%) of the lesions were severely calcified and classified as type B2 or type C according to the American College of Cardiology and the American Heart Association system [21]. Forty-six (7.5%) lesions had chronic total occlusion lesions and 194 (31.5%) procedures involved bifurcation lesions. The two most common primary coronary de novo lesions involved the left anterior descending artery (372 lesions; 56.1%) and the right coronary artery (167 lesions; 25.2%). Sixty-four lesions (9.7%) involved the left main coronary artery. Balloon predilatation was performed in 126 (19%) of RA procedures, and balloon postdilatation was performed in 569 (85.8%) procedures. The operators used intravascular imaging guidance for PCI in 455 cases (73.9%), which was significantly higher in the MACCE-free group (75.4% versus 51.3%,  $P = 0.001$ ).

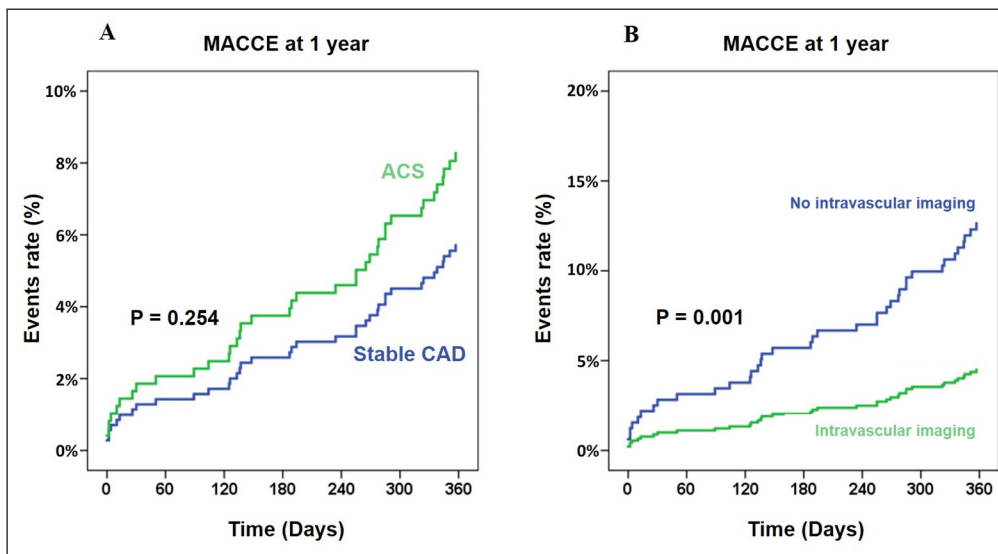
<b>BASILINE CLINICAL CHARACTERISTICS</b>	<b>ALL (n =616)</b>	<b>MACCE GROUP (n =39)</b>	<b>MACCE-FREE GROUP (n =577)</b>	<b>p-VALUE</b>
Age (year) – mean ± SD	72.81 ± 9.71	70.62 ± 9.48	72.96 ± 9.72	0.145
Sex (Female) – n (%)	292 (47.4%)	23 (59.0%)	269 (46.6%)	0.135
BMI (kg/m <sup>2</sup> ) – mean ± SD	24.5 ± 4.2	25.1 ± 4.0	24.4 ± 4.2	0.360
Hypertension – n (%)	576 (93.5%)	38 (97.6%)	535 (93.2%)	0.502
Cerebrovascular disease – n (%)	30 (4.9%)	3 (7.7%)	27 (4.7%)	0.428
Diabetes require insulin therapy – n (%)	7 (1.1%)	0 (0.0%)	7 (1.2%)	0.489
Current or ex-smoker – n (%)	68 (11.0%)	2 (5.1%)	66 (11.4%)	0.297
Dyslipidemia – n (%)	467 (75.8%)	29 (74.4%)	438 (75.9%)	0.827
CKD required hemodialysis – n (%)	74 (12.0%)	10 (25.6%)	64 (11.1%)	<b>0.018</b>
History of previous ACS – n (%)	118 (19.2%)	6 (15.4%)	112 (19.4%)	0.536
History of previous CABG – n (%)	49 (8.0%)	7 (17.9%)	42 (7.3%)	<b>0.028</b>
History of previous PCI – n (%)	252 (40.9%)	14 (35.9%)	238 (41.2%)	0.511
LVEF – mean ± SD <sup>1</sup>	55.59 ± 17.41	50.88 ± 16.18	55.94 ± 17.47	0.161
Hemoglobin level (g/dL) – mean ± SD <sup>2</sup>	11.72 ± 1.82	10.35 ± 2.25	11.82 ± 1.75	<b>&lt;0.001</b>
Creatinine level (mg/dL) – mean ± SD <sup>3</sup>	1.90 ± 2.05	2.76 ± 2.75	1.84 ± 1.97	<b>0.048</b>
Indication stable CAD – n (%)	412 (66.9%)	23 (59.0%)	389 (67.4%)	0.278
Indication NSTEMI-ACS – n (%)	187 (30.4%)	14 (35.9%)	173 (30.0%)	0.437
Indication STEMI – n (%)	16 (2.6%)	2 (5.1%)	14 (2.4%)	0.269
Total lesion per patient – mean ± SD	1.08 ± 0.27	1.07 ± 0.26	1.08 ± 0.27	0.763

**Table 1** Baseline clinical characteristics.

\*\* *Bold indicated statistically significant.*

1. 40% of LVEF data were missing 2. 18.3% of serum Hb were imputed. 3. 14.3% of serum Cr were imputed.

ACS – acute coronary syndrome; BMI – body mass index; CABG – coronary artery bypass graft; CKD – chronic kidney disease; LVEF – left ventricular ejection fraction; MACCE – major adverse cardiovascular and cerebrovascular events; NSTEMI-ACS- non-ST elevation acute coronary syndrome; PCI – percutaneous coronary intervention; SD – standard deviation; STEMI – ST-segment elevation myocardial infarction.



**Figure 1** Impact of the clinical presentation and the use of intravascular imaging on the occurrence of MACCE.

(A) The clinical presentation of the patients. ACS was the combination of non-ST elevation ACS and ST-segment elevation myocardial infarction. (B) Intravascular imaging consisted of intravascular ultrasound or optical coherence tomography.

ACS – acute coronary syndrome; CAD – coronary artery disease; MACCE – major adverse cardiovascular and cerebrovascular events.

<b>CHARACTERISTICS</b>	<b>ALL (n = 663)</b>	<b>MACCE GROUP (n = 43)</b>	<b>MACCE-FREE GROUP (n = 620)</b>	<b>p-VALUE</b>
<b>Angiographic characteristics</b>				
Thrombus (n) – n (%)	2 (0.3%)	0 (0.0%)	2 (0.3%)	0.713
Ostial lesion (n) – n (%)	113 (18.3%)	10 (25.6%)	103 (17.9%)	0.224
Chronic total occlusion (n) – n (%)	46 (7.5%)	2 (5.1%)	44 (7.6%)	0.759
Bifurcation (n) – n (%)	194 (31.5%)	11 (28.2%)	183 (31.7%)	0.648
Visible severe calcified coronary artery – n (%)	579 (94.0%)	37 (94.9%)	542 (93.9%)	0.811

**Table 2** Angiographic and procedural characteristics.

\*\* *Bold indicated statistically significant.*

ATM – atmospheric pressure; LAD – left anterior descending coronary artery; LCX – left circumflex coronary artery; LM – left main coronary artery; POBA – plain balloon angioplasty; RA – rotational atherectomy; RCA – right coronary artery; RPM – revolutions per minute.

CHARACTERISTICS	ALL (n = 663)	MACCE GROUP (n = 43)	MACCE-FREE GROUP (n = 620)	p-VALUE
<b>Procedural characteristics</b>				
Femoral access (n) – n (%)	445 (72.2%)	30 (76.9%)	415 (71.9%)	0.582
• Target vessel – n (%)				0.330
• LM to LAD or LM to LCX	64 (9.7%)	3 (7.0%)	61 (9.8%)	
• LAD	372 (56.1%)	19 (44.2%)	353 (56.9%)	
• LCX	59 (8.9%)	6 (14.0%)	53 (8.5%)	
• RCA	167 (25.2%)	15 (34.9%)	152 (24.5%)	
• Other	1 (0.2%)	0 (0.0%)	1 (0.2%)	
Target lesion B2 or C – n (%)	652 (98.3%)	43 (100%)	609 (98.2%)	0.378
Balloon dilate before RA – n (%)	126 (19.0%)	8 (18.6%)	118 (19.0%)	0.945
Post dilate after RA – n (%)	569 (85.8%)	38 (88.4%)	531 (85.6%)	0.620
Maximum diameter of postdilatation balloon (mm.) – mean ± SD	3.16 ± 0.56	3.18 ± 0.50	3.16 ± 0.56	0.803
Maximum pressure of postdilatation balloon (ATM.) – mean ± SD	20.22 ± 5.10	21.26 ± 6.00	20.14 ± 5.68	0.243
Maximum Burr size (mm.) – mean ± SD	1.55 ± 0.19	1.52 ± 0.19	1.55 ± 0.18	0.372
Use of laser – n (%)	2 (0.3%)	1 (2.3%)	1 (0.2%)	0.126
Successful RA – n (%)	659 (99.4%)	43 (100%)	616 (99.4%)	0.597
Number of burr(s) (n)				0.959
• 1 – n (%)	542 (81.8%)	36 (83.7%)	506 (81.7%)	
• 2 – n (%)	119 (17.9%)	7 (16.3%)	112 (18.1%)	
Maximum rotational speed x 10000 RPM – mean ± SD	184.88 ± 18.28	189.30 ± 11.36	184.57 ± 18.63	0.101
Intravenous pacemaker backup – n (%)	50 (7.5%)	5 (11.6%)	45 (7.3%)	0.362
Intra-aortic balloon pump – n (%)	26 (3.9%)	5 (11.6%)	21 (3.4%)	<b>0.021</b>
Stent deployment – n (%)	632 (95.3%)	41 (95.3%)	591 (95.3%)	0.994
POBA only – n (%)	23 (3.5%)	0 (0.0%)	23 (3.7%)	0.390
Drug-eluting stent – n (%)	606 (91.4%)	41 (95.3%)	565 (91.2%)	0.582
Diameter of the largest stent (mm.) – mean ± SD	3.18 ± 0.50	3.25 ± 0.52	3.17 ± 0.50	0.342
Number of stent(s) – n (%)				0.424
• 0	30 (4.5%)	2 (4.7%)	28 (4.5%)	
• 1	269 (40.6%)	16 (37.2%)	253 (40.8%)	
• 2	249 (37.6%)	13 (30.2%)	236 (38.1%)	
• 3	90 (13.6%)	9 (20.9%)	81 (13.1%)	
• 4	25 (3.8%)	3 (7.0%)	212 (3.5%)	
Maximum stent length (mm.) – mean ± SD	26.68 ± 7.71	25.54 ± 6.62	26.73 ± 7.77	0.327
Total stent length in target vessel – mean ± SD	41.51 ± 19.18	43.24 ± 21.24	41.39 ± 19.05	0.550

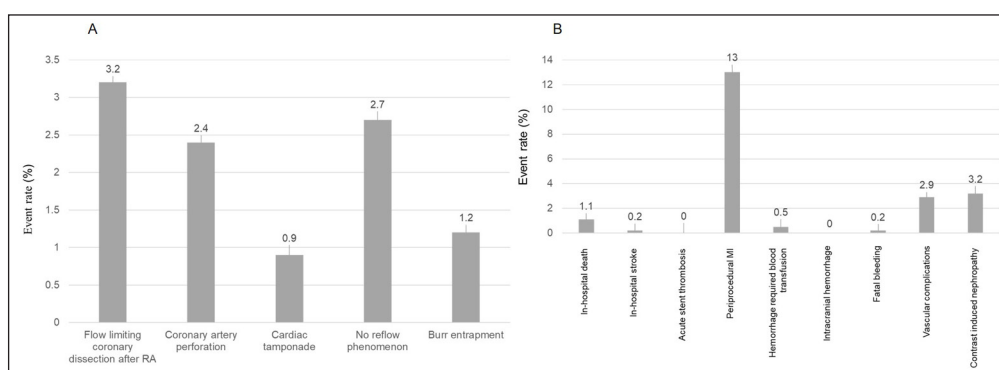
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CHARACTERISTICS	ALL (n = 663)	MACCE GROUP (n = 43)	MACCE-FREE GROUP (n = 620)	p-VALUE
Maximum burr size – n (%)				0.882
• 1.25	110 (17.9%)	23 (20.0%)	87 (17.4%)	
• 1.50	297 (48.4%)	56 (48.7%)	241 (48.3%)	
• 1.75	196 (31.9%)	35 (30.4%)	161 (32.3%)	
• 2.00	10 (1.6%)	1 (0.9%)	9 (1.8%)	
• 2.25	1 (0.2%)	0 (0.0%)	1 (0.2%)	
Intravascular imaging – n (%)	455 (73.9%)	20 (51.3%)	435 (75.4%)	<b>0.001</b>
Procedural success – n (%)	481 (78.1%)	20 (51.3%)	461 (79.9%)	<b>&lt;0.001</b>
Angiographic success – n (%)	584 (94.8%)	33 (92.3%)	548 (95.0%)	0.447
Total procedural time (min) – mean ± SD	91.43 ± 45.49	110.36 ± 55.10	90.15 ± 44.53	<b>0.007</b>
Total fluoroscopic time (min) – mean ± SD	35.16 ± 17.63	40.86 ± 16.31	34.78 ± 17.67	<b>0.037</b>
Total contrast volume (ml) – mean ± SD	177.24 ± 74.65	175.36 ± 77.68	177.37 ± 74.50	0.871

Six hundred and fifty-nine (99.4%) procedures were successfully performed, and four procedures failed as the burr was unable to cross the culprit lesion. Angiographic success was achieved in 584 (94.8%) procedures. The two most commonly used burr sizes were 1.5 mm. (48.4%) and 1.75 mm. (31.39%). The maximum burr size used (P = 0.372) and the maximum RA speed (P = 0.101) were similar between groups. Coronary stents were deployed after completing RA in 632 (95.3%) procedures, and drug-eluting stents were used in 606 (91.4%) procedures. The mean stent length was 41.51 ± 19.18 mm. In 269 (40.6%) cases, only one coronary stent was used. An intravenous pacemaker was used in 50 (7.5%) procedures. Twenty-six cases (3.9%) used the intra-aortic balloon pump (IABP) for hemodynamic support during RA. The fluoroscopic time (P = 0.037) and procedural time (P = 0.007) were significantly longer in the MACCE-group. The use of intravascular imaging guidance had a significantly lower rate of MACCE (P = 0.001) (Figure 1).

### INTRAPROCEDURAL AND PERIPROCEDURAL COMPLICATIONS

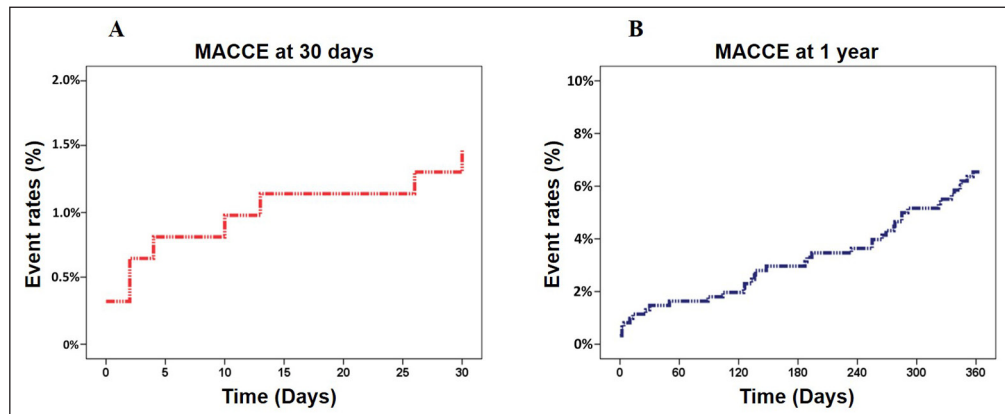
One hundred and thirty (19.6%) procedures developed periprocedural complications (Figure 2). The most common periprocedural complication was periprocedural MI (80 procedures; 13%). Coronary perforation occurred in 16 procedures (2.6%), and six (37.5%) of these developed cardiac tamponade. Seven cases of coronary perforation (43.8%) were treated with stent graft and two cases underwent emergency coronary artery bypass graft (CABG). Unfortunately, this catastrophic complication led to two in-hospital deaths. The incidence of burr entrapment occurred in eight (1.21%) cases. No acute stent thrombosis occurred.



**Figure 2** Intraprocedural and periprocedural complications. **(A)** intraprocedural complications that occurred during RA. **(B)** periprocedural complications post-RA. MI – myocardial infarction; RA – rotational atherectomy.

## CLINICAL OUTCOMES

Five hundred and twenty-three patients (84.9%) completed one-year follow-ups. The incidence of all-cause death at the one-year follow-up was 3.6% (22 patients). The cumulative MACCE rate was 1.5% at 30-days and 6.3% at one-year (Figure 3). The rate of cardiac death was 1.0% at 30-days and 1.6% at one-year. The incidence of definite stent thrombosis gradually increased from 0.5% at 30-days to 2.8% at one-year. The incidence of stent-related complications (TLR and TVR) markedly increased from 0.3% to 3.6% at 30-days to 0.5% to 4.7% at the one-year follow-up. No ischemic stroke occurred during the follow-up period (Table 3).



**Figure 3** Major adverse cardiovascular and cerebrovascular events (MACCE) during follow-up. (A) MACCE during 30-days follow-up. (B) MACCE during one-year follow-up.

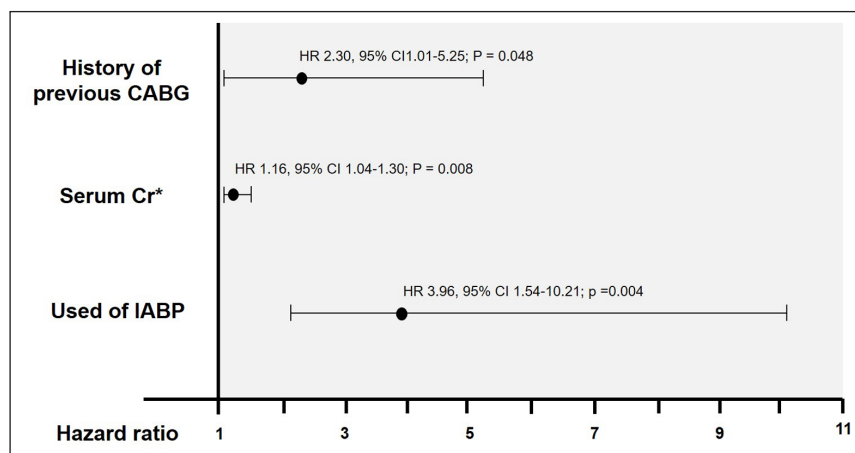
ADVERSE OUTCOMES	TOTAL, n (%)
<b>30-day MACCE – n (%)</b>	9 (1.5%)
• Cardiac death	6 (1.0%)
• Ischemic stroke	0 (0.0%)
• Definite stent thrombosis	(0.5%)
• TLR	2 (0.3%)
• TVR	3 (0.5%)
<b>1-year MACCE – n (%)</b>	39 (6.3%)
• Cardiac death	10 (1.6%)
• Ischemic stroke	0 (0.0%)
• Definite stent thrombosis	17 (2.8%)
• TLR	22 (3.6%)
• TVR	29 (4.7%)

**Table 3** Primary adverse outcomes during the follow-up period.

MACCE – major adverse cardiovascular and cerebrovascular events; TLR – target lesion revascularization; TVR – target vessel revascularization.

## PREDICTORS OF MACCE

A history of previous CABG (HR 2.30, 95% CI 1.01–5.25;  $P = 0.048$ ), the use of IABP (HR 3.96, 95% CI 1.54–10.21;  $P = 0.048$ ), and increased serum Cr from the reference value at 1 mg/dl (HR 1.16, 95% CI 1.04–1.30;  $P = 0.008$ ) were associated with MACCE at the one-year follow-up. (Figure 4).



**Figure 4** Multivariate analysis adjusted for the independent risk of developing MACCE.

CABG – coronary artery bypass graft; 95% CI – 95% confidence interval; HR – hazard ratio. \* 14.3% of serum Cr values were imputed.

Our results support that RA is a feasible revascularization technique for heavily calcified lesions that provides satisfactory immediate PCI results and good, short- to mid-term clinical outcomes. However, periprocedural complications were high. Intravascular imaging guidance for RA-assisted PCI may reduce the occurrence of MACCE. Impaired renal function is associated with adverse clinical outcomes in patients undergoing RA-assisted PCI. We observed high RA and angiographic success rates (99.4% and 94.8%, respectively) that were similar to other published registries investigated in high-income countries [22–25]. Together, our analysis suggests that RA-assisted PCI is an effective strategy for heavily calcified lesions in daily practice.

The majority (66.9%) of our participants had stable CAD. We found that ACS patients who underwent RA had rates of MACCE comparable with those with RA with stable CAD ( $P = 0.254$ ) (Figure 1). This is in contrast to a multi-center registry from Italy that reported higher adverse cardiac events in ACS patients who underwent RA compared to RA in stable CAD [26]. The Euro4C registry also reported that ACS is an independent predictor for developing MACCE post-RA [27]. The most common vascular access site in our study was the femoral route (72.2%). This is similar to the ROTATE registry in Japan that enrolled subjects between 2002 to 2013 and reported that the femoral route was used in 71.6% of cases [28]. This is in contrast to other published registries [23, 27] that reported preferential vascular access via the radial approach. We observed a vascular complications rate of 2.9%, similar to the 2.5% rate reported in a registry of 103,070 PCI patients (98.9% femoral approach) [29].

Interestingly, our rate of intravascular imaging-guided PCI was markedly higher (73.9%) than the Euro4C registry (6.9%) [27]. This finding may explain the relatively low rate of cardiac death and stent-related complications (TLR and TVR) we observed compared to other published registries [22–24] (Table 4). In a meta-analysis that included 4,724 patients from nine randomized controlled trials, intravascular imaging-guided PCI significantly reduced the rate of cardiac death and coronary revascularization [30]. Our findings, therefore, support the use of intravascular imaging guidance during RA-assisted PCI. However, further randomized control trials are needed to conduct to confirm this hypothesis.

**Table 4** Comparison of recently published rotational atherectomy registries that were conducted in Asia.

ACS – acute coronary syndrome; TLR – target lesion revascularization; TVR – target vessel revascularization.

CLINICAL TRIAL	POPULATION	NUMBER OF LESIONS	ACS (%)	CENTER(S)	COUNTRY	AN-GIOGRAPHIC SUCCESS (%)	FOLLOW UP DURATION	CARDIAC DEATH (%)	STENT THROM-BOSIS (%)	TLR (%)	TVR (%)	STROKE (%)
Lee K et al. [22]	540	583	60.5%	Multi-center	Korea	96.4	1.5 years	6.9	1.2	8.2	9.8	2.0
Gao W et al. [23]	540	540	14.6%	Single-center	China	96.8	In-hospital	1.1	0	–	–	0
Okai I et al. [24]	1090	–	15%	Multi-center	Japan	96.2	3.8 years	10.9	1.4	17.7	23	5.1
Ray S et al. [25]	144	–	31.25%	Single-center	India	96.5	1 year	0.7	–	–	2.1	–
Our registry	616	663	33.1%	Single-center	Thailand	94.8	1 year	1.6	2.8	3.6	4.7	0

The high rates of periprocedural complications we observed were mainly driven by the rate of periprocedural MI (13%). Nevertheless, the incidence of intraprocedural complications was acceptable. Our rate of periprocedural MI was higher than the Korea-ROCK registry which reported the rate of periprocedural MI at 7.9% [22] and Park DW, et al. that enrolled 23,604 patients from 11 clinical studies (7%) [31]. This may be explained by the high number of complex lesions, (98.3% were type B2 or C) in our study, and the criteria to diagnose periprocedural MI using the elevation of serum CK-MB that may overdiagnose [22]. In addition, calcified lesions and RA procedures enhance the risk of rising postprocedural serum CK-MB levels [32]. We observed that burr entrapment occurred in 1.2% of RA, which is higher than the 0.4% rate reported in a study by Nobuyoshi M, et al. [33]. The absolute amounts of contrast media used in our study were numerically lower than the ROCK registry (Mean contrast media 177 ml. versus 210 ml.). Nevertheless, the rate of contrast-induced nephropathy was similar (3.2% versus 3.3%) [22].



Our results demonstrate the impact of the serum Cr level on the occurrence of MACCE. We found that for each 1 mg/dl of serum Cr increase, the incidence of MACCE increased 1.16 times (HR 1.16, 95% CI 1.04–1.30;  $P = 0.008$ ). The mean serum Cr in our study was relatively high (Cr 1.9 mg/dl.), which suggests that RA should be performed cautiously in the presence of renal insufficiency, as these patients are at high risk for developing MACCE. Patients who used IABP during RA and patients with a history of prior CABG were also at increased risk of MACCE. However, our finding was in contrast to evidence from the Euro4C registry that demonstrated a protective effect of prior CABG against the occurrence of adverse clinical outcomes [27].

Our non-randomized, retrospective study has limitations. The design leaves open the possibility that confounding factors and sources of bias [34], known and unknown, may have influenced our analysis. In this present study, several data are missing, for example, 40% of LVEF data are missing. We also impute 18.3% of serum Hb and 14.3% of serum Cr. Nevertheless, our findings reflect real-world data regarding the RA procedure in middle-income countries. Second, stent-related complications may have been underdiagnosed because controlled coronary angiography was not routinely performed. Third, our study does not have access to information regarding patients' medication at discharge, specific lesion characteristics, and details of the coronary stents used. Finally, because this was a tertiary-referral center cohort, our findings may not be generalizable to other settings. In addition, our data were collected between 2015–2018, in the era that the shockwave intravascular lithotripsy, which was recently approved by the U.S. Food and Drug Administration for treating coronary calcification, was scantily used. However, this device is not currently available worldwide, especially in low- to middle-income countries.

## CONCLUSIONS

We conclude that RA in the DES-era is useful for treating heavily calcified coronary artery disease. This procedure in middle-income countries still provides a high procedural success rate and good short- to mid-term results similar to the results from high-income countries. Nevertheless, periprocedural complications – especially MI – were high. The use of an IABP during RA, a history of CABG, and increased serum Cr are strongly associated with MACCE. On the other hand, the use of intravascular imaging guidance for PCI potentially reduces the rates of adverse events.

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## COMPETING INTERESTS

The authors have no competing interests to declare.

## AUTHOR CONTRIBUTIONS

- Substantial contributions to the conception or design of the work (KT, RK); or the acquisition, analysis, or interpretation of data for the work (KT, RK, CC).
- Contributed to drafting the work, or revising it critically for important intellectual content. (KT, RK, DT, RP, WT, NW, NC, AP, PP, TR, CC).
- Provided final approval of the version to be published. (KT, RK, DT, RP, WT, NW, NC, AP, PP, TR, CC).
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. (KT, RK, CC).
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