



Original Article

# Clinical outcomes of percutaneous coronary intervention with rotablation in patients with acute or recent myocardial infarction

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Received September 16, 2016; accepted February 16, 2017

## Abstract

**Background:** Although rotational atherectomy (RA) has been an accepted and widely used medical procedure for more than 15 years, the clinical outcomes of RA in high-risk populations remain elusive. Therefore, the purpose of this study was to investigate the safety and efficacy of RA for patients with acute or recent myocardial infarction (MI), and report the short- and long-term clinical outcomes in this population.

**Methods:** We enrolled patients undergoing percutaneous coronary intervention (PCI) and RA at two medical centers in Taiwan between January 2004 and December 2013. Individuals who suffered an acute MI within 30 days before RA were assigned to the MI group; the remaining subjects were assigned to the non-MI group.

**Results:** A total of 154 subjects were enrolled in our study, among them: 47 (30.5%) had an acute MI within 30 days of RA (MI group), and the remaining 107 (69.5%) patients without MI comprised the non-MI group. PCI and RA procedures were performed successfully in 150 patients. The 30-day and 1-year total death, MI, and major adverse cardiac event (MACE included all-cause death, MI, and clinical-driven target lesion revascularization) rates were 6.5%, 12.3%, and 15.6%, and 9.7%, 15.2%, and 30.5%, at the 30-day and 1-year follow-ups, respectively. MI was identified as an independent predictor for both 30-day MACE and total death (MACE, OR: 3.95,  $P = 0.006$ ; total death, OR: 4.67,  $P = 0.043$ ), and remained an independent predictor for 1-year total death and MI (total death, HR: 4.47,  $P = 0.007$ ; MI, HR: 2.62,  $P = 0.016$ ).

**Conclusion:** Our study demonstrated the safety and efficacy of RA in patients with acute or recent MI, and identified MI as an independent predictor of both short- and long-term outcomes.

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**Keywords:** Acute myocardial infarction; Complex percutaneous coronary intervention; Rotational atherectomy

Conflicts of interest: The authors declare that they have no conflicts of interest related to the subject matter or materials discussed in this article.

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<http://dx.doi.org/10.1016/j.jcma.2017.02.009>

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## 1. Introduction

Heavily calcified or fibro-calcified stenotic lesions have remained challenging for interventional cardiologists, especially in an acute coronary syndrome setting. Rotational atherectomy (RA; Rotablator™ Boston Scientific, Maple Grove, MN, USA) is useful for debulking heavily calcified or fibrotic lesions, and leads to improved stent deliverability and procedural success rates.<sup>1–5</sup> However, RA has been associated with serious complications,<sup>6–9</sup> and previous studies have shown that the routine use of RA did not improve long-term clinical outcomes.<sup>10–12</sup> Furthermore, one large UK study involving 2152 patients undergoing RA showed that, compared with patients undergoing standard percutaneous coronary intervention (PCI), patients undergoing RA had poorer long-term survival.<sup>13</sup> However, RA is still necessary for some heavily calcified lesions in order to allow devices, such as stents, to pass the lesions. Regardless, RA for calcified culprit lesions of acute/recent myocardial infarction (MI) remains a high-risk procedure in the setting of jeopardized myocardium and may be associated with significantly higher risks of no-reflow and other angiographic complications due to unstable plaque and thrombus loads, even when performed by experienced surgeons. Therefore, RA is generally considered to be relatively contraindicated in this situation. Sometimes, PCI is not possible in patients with MI and heavily calcified lesions without RA, but the long-term clinical result in these patients undergoing RA has not been determined.<sup>14–16</sup> Therefore, this retrospective study aimed to investigate the safety profile and efficacy of RA for daily-practice patients (including patients with acute/recent MI), and report the short- and long-term clinical outcomes.

## 2. Methods

### 2.1. Design and study participants

We retrospectively analyzed all consecutive patients with coronary artery disease and heavily calcified lesions undergoing RA at Taipei Veterans General Hospital and Taichung Veterans General Hospital between January 2004 and December 2013. All subjects had been informed and agreed to participate in this research. Exclusion criteria included end-stage liver cirrhosis, acute or chronic infectious/inflammatory disease, malignancy with an expected lifespan of less than one year, and pre-procedural cardiogenic shock requiring inotropic agents or an intra-aortic balloon pump for hemodynamic support. Individuals with an acute MI within 30 days prior to RA were assigned to the MI group; the remaining subjects were assigned to the non-MI group.

### 2.2. Procedure

Signed informed consent was obtained from all patients prior to intervention. Coronary intervention and ventriculography were performed by standard procedures. Unfractionated heparin (10,000 IU bolus) was administered before the

procedure to achieve an activated clotting time of >300 s. In most cases, over-the-wire balloon or micro-catheters were used to exchange the conventional guidewire for a RotaWire (Boston Scientific, Natick, MA, USA) before RA. A calcified lesion of the coronary artery was defined as radio-opacities within the vascular walls on the cine before contrast medium injection; a heavily calcified lesion was defined as a linear calcification compromising both sides of the arterial lumen or a 270-degree calcification in intravascular ultrasound (IVUS). RA was performed for lesions that were heavily calcified, could not be crossed by balloon catheter, or could not be dilated by balloon catheter. RA was initiated with a 1.25 or 1.5 mm burr at a burr speed of 150,000 to 200,000 rpm. A cocktail solution, consisting of unfractionated heparin (5000 IU), verapamil hydrochloride (2.5 mg), and isosorbide dinitrate (5 mg) in 500 ml of 5% glucose in water, was continuously infused during the debulking procedure. RA before balloon angioplasty was defined as planned RA, and RA after the failure of balloon angioplasty was defined as provisional RA. After the debulking procedure, balloon catheter dilatation was performed by either cutting, semi-compliant, or non-compliant balloon; dilation was followed by stenting for most lesions. Intravascular ultrasound and glycoprotein IIb/IIIa receptor antagonists were used at the discretion of the interventional surgeons. PCI was considered angiographically successful if a residual stenosis <30% and a coronary thrombolysis in MI (TIMI) grade 3 flow were obtained at the end of the procedure. Optimal views of the target lesions were analyzed off-line with the automated edge detection CASS II system (Pie Medical, Maastricht, the Netherlands). Calibration was performed with contrast-filled guiding catheters. Angiographic measurement of minimal lumen diameter and reference vessel diameter (average diameter of the proximal and distal non-involved segments) were obtained at end-diastole. TIMI flow and thrombus grade before RA were calculated according to angiographic finding.<sup>17</sup> Dual antiplatelets were started before the procedure. After the procedure, all patients received aspirin (100 mg/d) indefinitely and clopidogrel (300 mg loading dose and 75 mg/d maintenance dose) for at least one month with a bare metal stent (BMS), or one year with a drug-eluting stent (DES). Medications for the treatment of angina pectoris (calcium channel blockers, beta-blockers and nitrates) were continued. Operation records and medical charts were thoroughly reviewed, and all demographic and procedural variables were recorded.

### 2.3. Follow-up

Clinical follow-up data were collected from medical charts or by direct telephone contact, and included both 30-day and 1-year outcomes. Primary end-points included all-cause death, MI, and major adverse cardiovascular events [MACE, defined as all-cause death, MI, and clinical-driven target lesion revascularization (TLR)]. Post-procedural re-MI was defined as the presence of significant new Q waves in at least two electrocardiographic leads along with symptoms compatible

with MI (an increase in creatine kinase-MB fraction  $\geq 3$  times the upper limit of the reference range). Patients who suffered an MI within 30 days with stable cardiac enzyme status or who were under decrescendo before RA but were elevated again after the procedure were considered to have post-procedural re-MI. Patients with acute MI with persistent cardiac enzyme elevation before RA were excluded. TLR was defined as any repeated percutaneous intervention of the target lesion performed for  $>50\%$  angiographic re-narrowing of the treated lesion from 5 mm proximal to 5 mm distal to the stent, or repeat bypass surgery. Stent thrombosis occurrence was classified as definite, probable, or possible according to the Academic Research Consortium (ARC) criteria,<sup>18</sup> and was considered as acute (within 24 h), subacute (within 30 days), or late (after 30 days but within 12 months). No patients were lost to follow-up.

#### 2.4. Statistical analysis

All continuous data are presented as mean  $\pm$  standard deviation or with 95% confidence interval (CI). Comparisons between groups were performed by the two-sample t-test. Categorical data between groups were compared by the Chi-square test or Fisher's exact test. Binary logistic regression analysis was used to identify potential predictors of 30-day MI, MACE, and total death; Cox-regression analysis was used to identify potential predictors of 1-year MI, MACE, and total death. Age, sex, diabetes, estimated glomerular filtration rate, provisional RA procedure, burr/artery ratio, use of DES, left ventricular ejection fraction, TIMI flow before RA, and MI within 30 days were adjusted in a forward stepwise method; variables with a P-value  $<0.1$  in univariate analysis were considered covariates for multivariate analysis. Kaplan–Meier survival curves were used to estimate cumulative MACE rates between the MI and non-MI group. Actuarial event-free survival curves between the MI group and the non-MI group were estimated using the Kaplan–Meier method and were compared using the log-rank test. A P-value of  $<0.05$  was considered to be statistically significant. The SPSS 17.0 (SPSS Inc., Chicago, IL, USA) software package was used for statistical analysis.

### 3. Results

#### 3.1. Patient baseline characteristics

A total of 154 patients underwent RA during the study period. Among them, 47 (30.5%) had experienced an MI within 30 days of the index procedure and constituted the study (MI) group; another 107 (69.5%) patients did not experience an MI in that period and constituted the control (non-MI) group. The baseline patient characteristics are summarized in Table 1. The mean population age was 75.07 years and most patients were male ( $n = 107$ , 69.5%). Ninety-eight patients (63.6%) had diabetes and fifteen patients (9.7%) had end-stage renal disease (estimated glomerular filtration rate  $<15$  ml/min/1.73 m<sup>2</sup> or dialysis patients). The majority of patients had triple vessel coronary artery disease (116, 75.3%)

Table 1  
Baseline characteristics between MI and non-MI group undergoing rotational atherectomy.

Baseline characteristics <sup>a</sup>	MI group N = 47	Non-MI group N = 107	P
Male, N (%)	28 (59.6)	79 (73.8)	0.077
Age, years (SD)	77.55 (10.25)	73.98 (9.98)	0.044
Smoker, N (%)	16 (27.6)	42 (39.3)	0.539
Comorbidity, N (%)			
Hypertension	39 (30.2)	90 (69.8)	0.861
Diabetes mellitus	33 (70.2)	65 (60.7)	0.261
End-stage renal disease	7 (14.9)	8 (7.5)	0.153
State of coronary artery disease, N (%)			
Previous myocardial infarction	11 (23.4)	19 (17.8)	0.415
NSTEMI	40 (85.1)	–	–
STEMI	7 (14.9)	–	–
Previous bypass surgery	6 (12.8)	16 (15.0)	0.721
LV systolic function <sup>b</sup>			
LVEF, % (SD)	45.15 (12.71)	48.53 (10.71)	0.101
LVEF $<40\%$ , N (%)	18 (38.3)	22 (20.6)	0.021
Laboratory data			
Creatinine, mg/dl (SD)	2.33 (2.02)	1.83 (2.07)	0.160
eGFR, ml/min/1.73 m <sup>2</sup> (SD)	42.00 (27.42)	55.70 (24.83)	0.003
eGFR $<30$ ml/min/1.72 m <sup>2</sup> N (%)	20 (42.6%)	16 (15.0%)	$<0.001$
Total cholesterol, mg/dl (SD)	155 (44.6)	164 (51.1)	0.347
Low-density lipoprotein, mg/dl (SD)	92.1 (34.03)	96.78 (41.73)	0.520
Triacylglyceride, mg/dl (SD)	126.91 (86.67)	147 (155.47)	0.479

RA, rotational atherectomy; NSTEMI, non-ST elevation myocardial infarction; STEMI, ST elevation myocardial infarction; eGFR, estimate glomerular filtration rate; LVEF, left ventricular ejection fraction.

<sup>a</sup> Baseline characteristics were collected within 48 h before RA procedure.

<sup>b</sup> Left ventricular systolic function measured with left ventriculography.

and 40 patients (26%) had left ventricular systolic dysfunction (left ventricular ejection fraction  $<40\%$ ). Taken together, these clinical features suggest that our cohort represented an extremely high-risk elderly population. In the MI group, the median duration between acute MI and the index procedure was four days (25%–75% CI: 1–9 days). Seven patients (4.5%) were diagnosed with ST segment elevation MI, but none received thrombolytic therapy before RA. Compared with the non-MI group, patients with MI were significantly older ( $P = 0.044$ ), had lower estimated glomerular filtration rate ( $P = 0.003$ ), and had more triple-vessel disease ( $P = 0.028$ ) and left ventricular systolic dysfunction (left ventricular ejection fraction  $<40\%$ ,  $P = 0.021$ ).

#### 3.2. Procedural- and lesion-specific characteristics

In the entire population, nearly half of the lesions involved the bifurcation or ostia of major coronary arteries. The lesion- and procedural-specific characteristics are shown in Table 2. PCI and RA procedures were successfully performed in 150 patients (97.4%), with the rotablation burr able to cross the target lesion and the stent implantation completed, if needed. In the MI group, all patients received RA for infarcted-related artery; eight patients received RA for non-infarcted related artery in the same intervention.

Table 2

Procedural and angiographic characteristics between MI group and non-MI group undergoing rotational atherectomy.<sup>a</sup>

	MI group Lesions N = 55	Non-MI group Lesions N = 114	P
<b>Angiographic characteristics</b>			
Reference vessel diameter, mm (SD)	2.84 (0.37)	2.81 (0.43)	0.649
Minimal lumen diameter, mm (SD)	0.49 (0.21)	0.57 (0.36)	0.183
Percentage luminal stenosis, % (SD)	82 (8)	79 (12)	0.183
LAD, N (%)	37 (67.3)	67 (58.8)	0.287
LCX, N (%)	9 (16.4)	19 (16.7)	0.960
RCA, N (%)	9 (16.4)	25 (21.9)	0.398
Bifurcation lesion, N (%)	28 (50.9)	50 (43.9)	0.389
Ostial lesion, N (%)	26 (47.3)	38 (33.3)	0.080
CTO, N (%)	3 (12.5)	21 (18.4)	0.024
Instant restenosis, N (%)	1 (1.8)	5 (4.4)	0.398
TIMI thrombus grade $\geq 2$ , N (%)	3 (5.5)	2 (1.8)	0.398
TIMI flow $\leq 2$ before RA, N (%)	15 (27.3)	12 (10.5)	0.010
<b>Procedural characteristics</b>			
Provisional rotablation, N (%)	23 (41.8)	38 (33.3)	0.282
2nd rotablation vessel, N (%)	8 (14.5)	7 (6.1)	0.072
Drug-eluting stent, N (%)	43 (78.2)	97 (85.1)	0.265
Total stent number, N (SD)	1.78 (0.95)	1.68 (0.79)	0.484
Total stent length, mm (SD)	51.16 (30.3)	49.80 (25.7)	0.761
Final Burr size, mm (SD)	1.58 (0.18)	1.51 (0.20)	0.060
Minimal Burr, mm (SD)	1.47 (0.15)	1.41 (0.16)	0.031
Burr/arterial ratio, % (SD)	0.55 (0.07)	0.54 (0.08)	0.440
Two-burrs strategy, N (%)	19 (34.5)	37 (32.5)	0.787

RA, rotational atherectomy; LAD, left anterior descending coronary artery; LCX, left circumflex coronary artery; RCA, right coronary artery; CTO, chronic total occlusion.

<sup>a</sup> Fifteen patients received RA for two vessels in the procedure.

Major complications after PCI and RA are listed in Table 3. There were no significant differences in major complications between the MI group and non-MI group. RA procedures were unsuccessful in four patients. Two coronary perforations occurred after RA; one patient died and the other was treated with surgery. The no-reflow phenomenon occurred in another two cases and led to non-ST elevation MI. One rotawire fractured during the RA procedure in the non-MI group, and one burr entrapment occurred in the recent MI group. Fifteen (9.7%) patients underwent RA in two vessels in the same procedure. There were 21 (13.6%) patients who underwent RA for the left main coronary artery, and 53 (34.4%) patients underwent provisional RA. A two-burr strategy was used for 56 lesions (33.1%) in 52 patients (33.8%). The mean burr/arterial ratio of each lesion was 0.54. The majority of lesions received DES implantations (n = 140,

82.8%), while the remaining twenty lesions received BMS implantations. Overall, nine lesions did not receive stent implantations due to small reference vessel diameters. Compared with the non-MI group, lesions in the recent MI group had lower TIMI flow (P = 0.01), fewer chronic total occlusions (P = 0.024) and received larger initial burrs for ablation (P = 0.031). There were no significant differences in other lesion- and procedural-specific variables between the two groups.

### 3.3. Clinical outcomes

Within 30 days after PCI with RA, 10 patients (6.5%) died, 19 patients (12.3%) suffered from post-procedural MI, and 24 patients (15.6%) suffered from MACE (Table 4). Significantly

Table 3

Major complications after rotational atherectomy.

Major complications	MI group (n = 47)	Non-MI group (n = 107)	P
Slow/no flow (TIMI flow $\leq 2$ after RA)	1	1	0.52
Definite/probable stent thrombosis	2	2	0.59
Coronary perforation	1	1	0.52
Rotawire broken	0	1	1.00
Burr trapping	1	0	0.31

RA, rotational atherectomy.

Table 4

30 days and 1-year adverse events (total death, MI and MACE) after rotational atherectomy.

	MI group	Non-MI group	P
<b>Thirty days outcomes</b>			
MACE, N(%)	12 (25.5)	12 (11.2)	0.024
Myocardial infarction, N(%)	9 (19.1)	10 (9.3)	0.088
Mortality, N(%)	6 (12.8)	4 (3.7)	0.036
<b>Accumulated outcomes (12 months)</b>			
MACE, N(%)	19 (40.4)	28 (26.2)	0.077
Myocardial infarction, N(%)	13 (27.7)	12 (11.2)	0.011
Mortality, N(%)	10 (21.3)	5 (4.7)	0.001

MI, myocardial infarction; MACE, major cardiac events.

more patients in the MI group experienced MACE ( $P = 0.024$ ) and total death ( $P = 0.036$ ) within 30 days. There were four cases (2.6%) of definite/probable stent thrombosis, with two in each group (2 in 47 and 2 in 107 in MI and non-MI, respectively,  $P = 0.059$ ) (Table 3). Two patients presented with acute stent thrombosis and two presented with subacute stent thromboses. Among these patients, three (two MI and one non-MI) died and one presented with non-ST-segment elevation MI. Multivariate logistic regression analysis for 30-day total death, MI, and MACE are shown in Table 5. MI (acute MI within 30 days) was identified as an independent predictor of both MACE and total mortality within 30 days (MACE, OR: 3.14, 95% CI: 1.24–7.90,  $P = 0.015$ ; total death, OR: 4.67, 95% CI: 1.05–20.74,  $P = 0.043$ ) and was also a marginal predictor for 30-day MI (OR: 2.30; 95% CI: 0.87–6.09,  $P = 0.095$ ).

When the 12-month outcomes after PCI with RA were assessed, there were a total of 15 deaths (9.7%), 25 patients (15.2%) with post-procedural MIs, and 47 patients (30.5%) with MACE (Table 3). The one-year Kaplan–Meier survival curves (free from total death, re-MI, and MACE) are shown in Fig. 1. Outcomes were significantly poorer in patients with AMI within 30 days ( $P = 0.001$ , 0.01, and 0.05 for total death, re-MI, and MACE, respectively). Multivariate Cox-regression analyses for 1-year total death, re-MI, and MACE are shown in Table 6. MI within 30 days remained an independent predictor for 1-year total death (HR: 4.47, 95% CI: 1.47–13.37,  $P = 0.007$ ) and re-MI (HR: 2.62, 95% CI: 1.20–5.76,  $P = 0.016$ ); while left ventricular ejection fraction was identified as the only independent protective risk factor for 1-year MACE (HR: 0.74, 95% CI: 0.550–0.995,  $P = 0.046$ ).

Table 5  
Multivariate regression analysis for 30 days all-cause death, MI and MACE.<sup>a</sup>

	All-cause death		MI		MACE	
	OR (95% CI)	P	OR (95% CI)	P	OR (95% CI)	P
AMI within 30 days	4.67 (1.05–20.74)	0.043	2.30 (0.87–6.09)	0.095	3.14 (1.24–7.90)	0.015
DM	0.13 (0.28–0.65)	0.012	–	–	0.36 (0.14–0.90)	0.029
LVEF	0.38 (0.16–0.91)	0.030	–	–	–	–
Burr/artery ratio	0.48 (0.21–1.08)	0.077	–	–	–	–

AMI, acute myocardial infarction; DM, diabetes mellitus; LVEF, left ventricular ejection fraction; MACE, major cardiac events.

<sup>a</sup> Age, sex, diabetes, estimated glomerular filtration rate, provisional RA procedure, burr/artery ratio, use of DES, left ventricular ejection fraction, and recent MI within 30 days were adjusted in a forward stepwise method; variables with a p value <0.1 in univariate analysis were considered covariates for multivariate analysis.

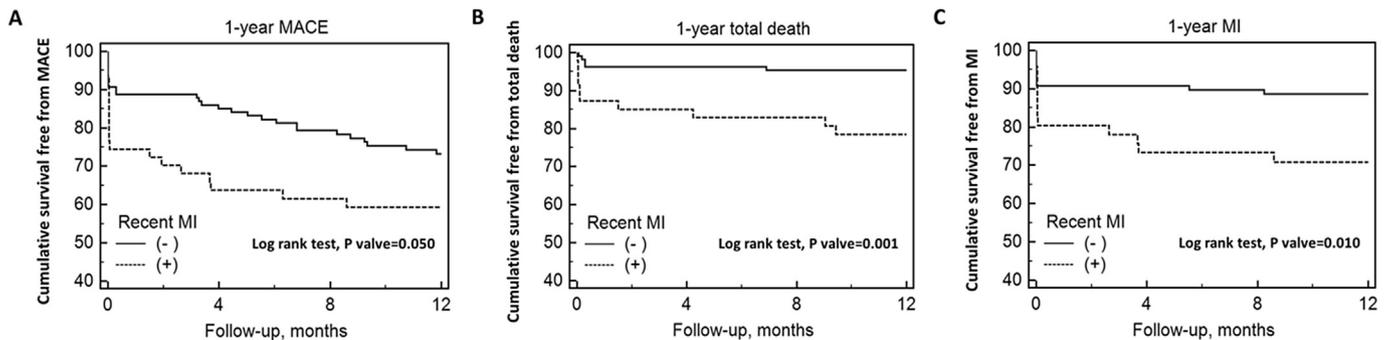


Fig. 1. Kaplan–Meier survival analyses for 1-year MACE (A), 1-year total death (B), and 1-year MI (C), according to recent MI within 30 days or not. P values by log-rank test are shown. MACE: major cardiac events; MI: myocardial infarction.

Table 6  
Multivariate regression analysis for 1-year all-cause death, MI and MACE.<sup>a</sup>

	All-cause death		MI		MACE	
	HR (95% CI)	P	HR (95% CI)	P	HR (95% CI)	P
AMI within 30 days	4.47 (1.50–13.36)	0.007	2.62 (1.20–5.76)	0.016	–	–
DM	0.25 (0.09–0.72)	0.011	–	–	–	–
LVEF	0.39 (0.21–0.72)	0.003	–	–	0.74 (0.55–0.995)	0.046

AMI, acute myocardial infarction; DM, diabetes mellitus; LVEF, left ventricular ejection fraction.

<sup>a</sup> Age, sex, diabetes, estimated glomerular filtration rate, provisional RA procedure, burr/artery ratio, use of DES, left ventricular ejection fraction, and recent MI within 30 days were adjusted in a forward stepwise method; variables with a p value <0.1 in univariate analysis were considered covariates for multivariate analysis.

## 4. Discussion

### 4.1. Main findings

The results of this study showed that RA was feasible, was associated with a high success rate, and had acceptable 30-day and 1-year outcomes despite high patient and angiographic risk profiles. Furthermore, RA in patients with MI within 30 days was associated with higher risk of adverse cardiovascular events, and MI within 30 days was identified as one of the independent predictors of both short-term and long-term outcomes.

### 4.2. Clinical outcome of rotational atherectomy

Although RA has been associated with acceptable immediate and long-term outcomes,<sup>7,19</sup> few patients with acute/recent MI have been studied. In fact, RA is relatively contraindicated in the presence of coronary thrombosis, such as acute/recent MI, because of the risk of potential platelet activation by the procedure. The manufacturer advises waiting 2–4 weeks after the use of thrombolytics in ST segment elevation MI before performing RA. However, several case reports indicate RA has been performed successfully in acute ST segment elevation MI.<sup>20–22</sup> Sakakura et al. reported that off-label use of RA was associated with higher incidence rates of no-reflow and peri-procedural MI compared with rates from on-label use of device.<sup>8</sup> However, only 10 patients with MI (4%) were included in the off-label group. In the current study, we included 47 patients with recent MI and found that, although the RA procedure was four days later, recent MI remained an independent predictor of short- and long-term adverse cardiovascular events. However, the optimal timing of PCI with RA for recent MI patients with heavily calcified lesions remains to be elucidated in a larger study.

Although the overall angiographic success rate of PCI with RA was 97.4%, the 30-day risk of adverse events remained high, with 12.3%, 6.5%, and 15.6% rates of MI, total death, and MACE, respectively, within 30 days. In a recent study assessing the clinical outcomes following RA in a high-risk population, the peri-procedural MACE rate was extremely low (2.3%).<sup>23</sup> The poorer outcomes observed in our study may be related to the higher risk profile of our patient population, which was older and had more cases of diabetes (63.6%), end-stage kidney disease (9.7%), triple-vessel disease (75.3%) and recent MI (30.5%), though we excluded patients with cardiogenic shock.

Previous studies have shown that though large (>0.8) or small (<0.6) burr/artery ratios may be associated with better acute luminal results, the optimal burr/artery ratio (0.6–0.8) may be associated with lower long-term repeat revascularization rates. Interestingly, a larger burr/artery ratio was marginally associated with better survival at 30 days ( $P = 0.077$ ) but was not associated with long-term outcomes. As the burr/artery ratio in our population was smaller relative to previous studies and the two-burr strategy was used in only 52 patients (34%), the relationships between burr/artery ratio and short- and long-term outcomes warrant further study.<sup>24</sup>

Kawamoto et al. recently reported that planned RA may be associated with reduced procedural and fluoroscopy times, contrast volume, and the number of balloon catheters used compared to those with provisional RA. Furthermore, the in-hospital and one-year MACE rates were better in the planned RA group.<sup>25</sup> However, there were no significant differences in 30-day or one-year clinical outcomes between the planned RA group ( $n = 101$ ) and the provisional RA group ( $n = 53$ ) in our study. Although the poorer clinical outcomes after RA with recent MI were more marked in the provisional RA subgroup, this association was not significant in our multivariate analyses. As the heavily calcified lesions in the provisional RA subgroup were un-crossable or un-dilatable, some dissections might have been present at those lesions before RA. Therefore, RA might be particularly associated with a potential risk of complications, such as perforation or no-reflow, in the unstable plaques of culprit lesions of MI. Although RA was indispensable for the success of PCI in these patients, planned RA might decrease the risk of adverse events.

### 4.3. Limitations

There were several limitations to this study. First, this was a retrospective observational study conducted in two centers. The sample size was limited and the follow-up period was relatively short. Second, a significant heterogeneity in treatment/stenting strategy may exist due to the long enrollment period. For example, patients treated with both BMS and DES were included. However, the use of DES was not identified as an independent predictor for 1-year adverse cardiovascular events in the multivariate analysis. Third, our patients received follow-up coronary angiography based on clinical indications. However, a potential bias related to the incomplete angiographic follow-up may have substantially impacted the final results.

In conclusion, our results showed that the RA procedure was feasible and effective, and had a high success rate with acceptable 30-day and 1-year outcomes, even in high-risk patients. RA performed in patients with MI within 30 days was associated with a higher risk of adverse cardiovascular events compared with those without recent MI. However, calcified lesions could be found in 8% of patients with AMI,<sup>26</sup> and one-quarter of them were balloon un-dilatable or un-crossable.<sup>27</sup> In this study, balloon un-dilatable or un-crossable lesions could be found in 23 (41.8%) patients in MI group, and revascularization in these cases couldn't be completed without RA. Therefore, RA could be considered as an alternative or rescue treatment for infarcted-related arteries with balloon un-dilatable/crossable lesions, especially for patients with high EuroSCORE.<sup>28</sup>

## Acknowledgments

The materials of this study were supported by the Division of Cardiology, Department of Medicine, Taipei Veterans General Hospital and Division of Interventional Cardiology, Cardiovascular Center, Taichung Veterans General Hospital.

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