## Clinical Research

In-hospital Outcomes of Rotational Atherectomy in ST-Elevation Myocardial Infarction: Results From the Multicentre ROTA-STEMI Network

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Rotational Atherectomy in ST-elevation Myocardial Infarction
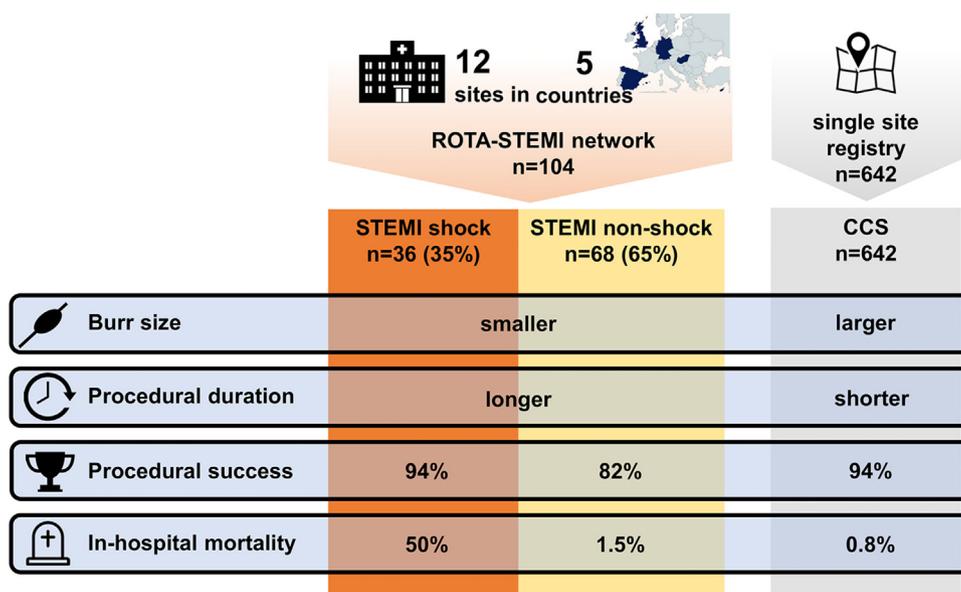
ABSTRACT

Background: Although the use of rotational atherectomy (RA) is off-label in the setting of ST-elevation myocardial infarction (STEMI), it can be the only option in severely calcified culprit lesions to achieve procedural success. We sought to investigate the safety and feasibility of RA during primary percutaneous coronary intervention (PPCI).

Methods: This was a retrospective observational study of patients who underwent RA during PPCI from 12 European centres. The main outcomes were procedural success (defined as successful stent implantation with final thrombolysis in myocardial infarction [TIMI] flow 3 and residual stenosis < 30%) and in-hospital mortality. A comparison of patients presenting with and without shock was performed.

Results: In 104 patients with RA during STEMI, the mean age was 72.8 ± 9.1 years, and 35% presented with cardiogenic shock. Bailout RA was performed in 76.9% of cases. Mean burr size was 1.42 ± 0.21 mm. Procedural success was achieved in 86.5% of cases, with no difference between shocked and nonshocked patients (94.4% vs 82.4%; $P = 0.13$). In-hospital stent thrombosis occurred in 0.96%, perforation in 1.9% and burr entrapment in 2.9% of cases. In spite of equally high procedural success, in-hospital mortality was higher in shocked (50%) compared with nonshocked patients (1.5%; $P < 0.0001$).

Conclusions: Patients presenting with STEMI requiring RA, represent a high-risk population, frequently presenting with cardiogenic shock. In this analysis of selected patients, RA was performed as a bailout strategy in the majority, and, as such, RA seems to be feasible with a high procedural success rate. In the absence of cardiogenic shock, RA-facilitated PCI seems to be associated with low in-hospital mortality.

RÉSUMÉ

Contexte : Bien que l'utilisation de l'athérectomie rotationnelle (AR) soit hors indication dans le contexte de l'infarctus du myocarde avec élévation du segment ST (STEMI), elle peut être la seule option pour les lésions calcifiées sévères pour obtenir un succès procédural. Nous avons cherché à étudier la sécurité et la faisabilité de l'AR pendant l'intervention coronaire percutanée primaire (ICPP).

Méthodes : Il s'agissait d'une étude observationnelle rétrospective de patients ayant subi une AR au cours d'une ICPP dans 12 centres européens. Les principaux critères d'évaluation étaient le succès procédural (défini comme l'implantation réussie d'une endoprothèse avec un flux final de thrombolyse dans l'infarctus du myocarde [TIMI] de grade 3 et une sténose résiduelle < 30 %), ainsi que la mortalité hospitalière. Une comparaison des patients présentant ou non un état de choc cardiogénique a été effectuée.

Résultats : Chez 104 patients ayant subi une AR au cours d'un STEMI, l'âge moyen était de 72,8 ± 9,1 ans, et 35 % d'entre eux présentaient un choc cardiogénique. Une AR palliative a été réalisée dans 76,9 % des cas. La taille moyenne de la fraise était de 1,42 ± 0,21 mm. Le succès procédural a été atteint dans 86,5 % des cas, sans différence entre les patients en choc et ceux exempt de choc (94,4 % contre 82,4 %; $p = 0,13$). Une thrombose de l'endoprothèse en milieu hospitalier s'est produite dans 0,96 % des cas, une perforation dans 1,9 % et un enrayement de la fraise dans 2,9 % des cas. Malgré un taux de succès procédural tout aussi élevé, la mortalité hospitalière était plus élevée chez les patients en choc (50 %) comparativement aux patients sans choc (1,5 %; $p < 0,0001$).

Conclusions : Les patients se présentant avec un STEMI nécessitant une AR représentent une population à haut risque, se présentant fréquemment avec un choc cardiogénique. Dans cette analyse de patients sélectionnés, l'AR a été réalisée comme stratégie de sauvegarde dans la majorité des cas, et, en tant que telle, l'AR semble être réalisable avec un taux de succès procédural élevé. En l'absence de choc cardiogénique, l'ICP assistée par l'AR semble être associée à une faible mortalité hospitalière.

Angiographically visible coronary lesion calcification is present in 16% to 20% of patients undergoing coronary angiography.[1,2] In patients presenting with an ST-segment elevation myocardial infarction (STEMI), one-third have angiographic evidence of coronary calcification,[3] with higher rates observed on intravascular imaging.[4] In some STEMI cases, calcified nodules are the underlying culprit lesion pathology.[5] Percutaneous coronary intervention (PCI) of the culprit lesion is the gold-standard treatment for STEMI.[6,7] However, PCI of the culprit lesion in STEMI is associated with no-reflow/slow-flow secondary to the thrombotic nature of the lesions and the risk of plaque embolization.

There is greater awareness of the impact of calcific coronary lesions on the acute and long-term success of PCI, and therefore adequate lesion preparation is essential. Rotational atherectomy (RA) is a well-accepted method to modify heavily calcific lesions,[8] but little is known about its safety and efficacy in patients with STEMI. Its use in STEMI is considered to be off-label. Nevertheless, RA may be the only option to achieve procedural success in some severely calcified culprit lesions. Several monocentric retrospective data demonstrated the feasibility of RA in the setting of an acute coronary syndrome (ACS), but none of them reported data on STEMI alone.[9-14] We therefore sought to investigate the safety and feasibility of RA during primary percutaneous coronary intervention (PPCI) for the treatment of the culprit vessel in patients with STEMI presenting with and without cardiogenic shock.

Methods

Study outlines

The ROTA-STEMI network involves 12 European centres with experienced RA operators. A list of the participating centers is provided in Supplemental Appendix S1. We identified 104 patients who presented with STEMI and required RA of the culprit vessel during primary PCI between 2002

and 2021. Each participating center provided anonymized data on baseline clinical, angiographic, and procedural characteristics as well as procedural and in-hospital outcomes. The data were merged in a single data sheet for analysis. Data collection and handling were conducted in compliance with the Declaration of Helsinki, and the study protocol was approved by the Ethics Committee of the Faculty of Medicine of Ruhr-University of Bochum, Germany (approval number: 22-7489, approval date February 18, 2022).

The study population was stratified according to hemodynamic status at presentation into patients with STEMI and shock vs without shock. The rationale of this stratification was 2-fold: First, the impaired hemodynamic state is associated with a higher rate of slow-flow/no-reflow during PPCI.[15] Second, patients with cardiogenic shock have a dismal prognosis, which may not be modified by the mode of coronary intervention.

Data of patients who underwent RA during PCI for stable coronary artery disease (CAD) from the Prospective Segeberg Registry for Rotational Atherectomy in Coronary Lesions (ClinicalTrials.gov Identifier: NCT04011527) served as a benchmark to which ROTA-STEMI data were contrasted, yet without statistical comparison.

Definitions and outcomes

STEMI was defined in accordance with the Fourth Universal Definition of Myocardial Infarction[16] as the presence of ischemic symptoms with new ST-segment elevation in at least 2 contiguous leads or new bundle branch block with ischemic repolarization patterns.

RA was performed according to operator discretion and in accordance with local institutional standards. Upfront RA was defined as RA performed without previous attempt to insert a balloon into the culprit coronary artery. Bailout RA was defined as RA after an attempt of balloon insertion into the culprit coronary artery. RA was performed using either the Rotablator or the Rotapro Rotational Atherectomy System (Boston Scientific, Natick, Massachusetts, USA).

The main outcomes were in-hospital death and procedural success, defined as a successful stent delivery and implantation with a residual stenosis < 30%, and the presence of thrombolysis in myocardial infarction (TIMI) flow 3.

Statistical methods

Continuous variables were summarized as mean ± standard deviation (SD) or median (25th-75th quartiles), according to normality of distribution. Categorical variables were summarized as frequencies and percentages. Continuous variables were compared using the 2-sided Student's t-test or the nonparametric Wilcoxon rank-sum test, whereas categorical data were compared using χ^2 or Fischer's exact test. A P value of less than 0.05 was considered as the level of statistical significance. The analysis was performed using SPSS version 23 (IBM Corp, Armonk, New York, USA). Given the retrospective nature of the work and the lack of penalty for multiple comparisons, all analyses should be viewed as exploratory.

Results

Baseline clinical characteristics of the 104 patients presenting with STEMI and requiring RA during primary PCI are presented in Table 1 and Supplemental Table S1. Age was 72.8 ± 9.1 years, and 37.5% of patients had diabetes. There was a high prevalence of life-threatening conditions, including out-of-hospital cardiac arrest in 11.5%, cardiogenic shock in 34.6%, and the use of hemodynamic support in 21.2% of cases.

Table 1. Baseline characteristics

	RA-STEMI Total population % (n = 104)	RA-STEMI shock % (n = 36)	RA-STEMI nonshock % (n = 68)	
Age	72.8 ± 9.1	72.7 ± 7.0	72.7 ± 10.1	0.929
Female gender	29.8 (31/104)	27.8 (10/36)	30.9 (21/68)	0.824
BMI	26.4 ± 4.3	26.2 ± 3.9	26.5 ± 4.5	0.975
Diabetes	37.5 (39/104)	36.1 (13/36)	38.2 (26/68)	1.0
Hypertension	89.4 (93/104)	88.9 (32/36)	89.7 (61/68)	1.0
Dyslipidemia	75.0 (78/104)	75.0 (27/36)	75.0 (51/68)	1.0
Active smoker	24.5 (25/102)	22.9 (8/35)	25.4 (17/67)	1.0
Family history	17.6 (18/102)	8.3 (3/36)	22.7 (15/66)	0.102
Vessel disease				
1-vessel disease	22.1 (23/104)	16.7 (6/36)	25.0 (17/68)	0.457
2-vessel disease	25.0 (26/104)	25.0 (9/36)	25.0 (17/68)	1.0
3-vessel disease	52.9 (55/104)	58.3 (21/36)	50.0 (34/68)	0.536
Previous myocardial infarction	14.4 (15/104)	27.8 (10/36)	7.4 (5/68)	0.008
Previous PCI	15.5 (16/103)	27.8 (10/36)	9.0 (6/67)	0.020
LVEF < 50%	67.0 (69/103)	82.9 (29/35)	58.8 (40/68)	0.016
Out-of-hospital cardiac arrest	11.5 (12/104)	25.0 (9/36)	4.4 (3/68)	0.003
Resuscitation	17.3 (18/104)	38.9 (14/36)	5.9 (4/68)	< 0.0001
Cardiogenic shock	34.6 (36/104)	100 (36/36)	0 (0/68)	-
Circulatory assist device	21.2 (22/104)	50.0 (18/36)	5.9 (4/68)	< 0.0001
Impella	11.5 (12/104)	25.0 (9/36)	4.4 (3/68)	
IABP	7.7 (8/104)	22.2 (8/36)	0.0 (0/68)	
ECMO	1.9 (2/104)	2.8 (1/36)	1.5 (1/68)	

BMI, body mass index; ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; LVEF, left ventricular ejection fraction; PCI, percutaneous coronary intervention; RA, rotational atherectomy; STEMI, ST-elevation myocardial infarction.

Table 2. Lesion characteristics

	RA-STEMI Total population % (n = 104)	RA-STEMI shock % (n = 36)	RA-STEMI nonshock % (n = 68)	P value shock vs nonshock
Culprit vessel				0.322
LM	12.5 (13/104)	19.4 (7/36)	8.8 (6/68)	
LAD	45.2 (47/104)	44.4 (16/36)	45.6 (31/68)	
LCx	6.7 (7/104)	2.8 (1/36)	8.8 (6/68)	
RCA	35.6 (37/104)	33.3 (12/36)	36.8 (25/68)	
Baseline TIMI flow				0.015
0	30.8 (32/104)	30.6 (11/36)	30.9 (21/68)	
1	15.4 (16/104)	30.6 (11/36)	7.4 (5/68)	
2	23.1 (24/104)	16.7 (6/36)	26.5 (18/68)	
3	30.8 (32/104)	22.2 (8/36)	35.3 (24/68)	
Diameter stenosis (%)	99 [95-99.5]	99 [97-99.5]	99 [95-99.5]	0.514
Lesion length (mm)	20.0 [14.5-40.0]	20.0 [15.0-30.0]	22.5 [13.5-42.5]	0.598
Thrombus	45.6 (47/103)	47.2 (17/36)	44.8 (30/67)	0.838
Bifurcation	32.7 (34/104)	44.4 (16/36)	26.5 (18/68)	0.080
Calcification				0.893
None/mild	2.0 (2/102)	2.9 (1/35)	1.5 (1/67)	
Moderate	14.7 (15/102)	14.3 (5/35)	14.9 (10/67)	
Severe	83.3 (85/102)	82.9 (29/35)	83.6 (56/67)	

LAD, left anterior descending artery; LCx, left circumflex artery; LM, left main artery; RA, rotational atherectomy; RCA, right coronary artery; STEMI, ST-elevation myocardial infarction; TIMI, thrombolysis in myocardial infarction.

Left main coronary artery was the culprit vessel in 12.5%, and the culprit lesion involved a bifurcation in 32.7% of cases. TIMI flow at baseline was 0 in 30.8% of cases, and thrombus was detected on angiography in 45.6% of cases. Of them, thrombus caused total occlusion in 55.3% of cases. RA was used for stent ablation in 2 cases, and, in the rest of cases, culprit lesions showed moderate-to-severe calcification.

Further culprit lesion characteristics are summarized in Table 2 and Supplemental Table S2, and detailed procedural characteristics are presented in Table 3 and Supplemental Table S3. In the majority of cases, bailout RA was performed (76.9%), as in 43.9% the lesion was uncrossable, and in 52.2% of cases the lesion was undilatable. In 4.3%, the stent could not reach the target lesion as a reason for RA. Upfront RA was performed in 23.1% of cases. The mean burr size was 1.42 ± 0.21 mm. Burr-to-artery-ratio was 0.43 (0.40-0.50). Predilatation was performed before RA in 50.5% of cases. In most cases, ≥ 4 predilatation balloons were used. Special balloons (cutting, scoring, ultra-high pressure OPN, and lithotripsy) were used in 17% of cases. Data on

Table 3. Procedural characteristics

	RA-STEMI Total population % (n = 104)	RA-STEMI shock % (n = 36)	RA-STEMI nonshock % (n = 68)	P value shock vs nonshock
Number of burrs				0.257
1 burr	92.3 (96/104)	97.2 (35/36)	89.7 (61/68)	
2 burrs	7.7 (8/104)	2.8 (1/36)	10.3 (7/68)	
Max burr diameter	1.42 ± 0.21	1.40 ± 0.19	1.44 ± 0.21	0.292
Burr-to-artery ratio	0.43 [0.40-0.50]	0.42 [0.38-0.44]	0.50 [0.42-0.50]	0.005
Rotational speed (rpm)	170,000 [160,000-180,000]	170,000 [160,000-180,000]	170,000 [160,000-180,000]	0.590
Indication of RA				0.089
Upfront RA	23.1 (24/104)	33.3 (12/36)	17.6 (12/68)	
Bailout RA	76.9 (80/104)	66.7 (24/36)	82.4 (56/68)	
Balloon uncrossable	43.9 (43/98)	48.5 (16/33)	41.5 (27/65)	0.527
Balloon undilatable	52.2 (48/92)	37.5 (12/32)	60.0 (36/60)	0.050
Stent not able to reach target	4.3 (4/92)	6.3 (2/32)	3.3 (2/60)	0.608
Predilatation before RA	50.5 (52/103)	44.4 (16/36)	53.7 (36/67)	0.413
Special balloons	17.0 (17/100)	11.8 (4/34)	19.7 (13/66)	0.406
Cutting/scoring	52.9 (9/17)	75.0 (3/4)	46.2 (6/13)	
OPN	52.9 (9/17)	25.0 (1/4)	61.5 (8/13)	
IVL	5.9 (1/17)	0 (0/4)	7.7 (1/13)	
Total stent length (mm)	53.1 ± 27.9	57.4 ± 30.7	50.6 ± 26.1	0.317
Postdilatation	68.4 (65/104)	73.5 (25/34)	65.6 (40/61)	0.494
Final TIMI flow 0	1.0 (1/104)	0 (0/36)	1.5 (1/68)	0.685
1	1.0 (1/104)	0 (0/36)	1.5 (1/68)	
2	7.7 (8/104)	5.6 (2/36)	8.8 (6/68)	
3	90.4 (94/104)	94.4 (34/36)	88.2 (60/68)	

IVL, intravascular lithotripsy; RA, rotational atherectomy; rpm, revolutions per minute; STEMI, ST-elevation myocardial infarction; TIMI, thrombolysis in myocardial infarction.

Table 4. Procedural and in-hospital clinical outcomes

|	RA-STEMI population total % (n = 104)	RA-STEMI shock % (n = 36)	RA-STEMI nonshock % (n = 68)	P value shock vs nonshock	RA-stable CAD % (n = 642)
Procedural duration (min)	101.6 [74.3-137.6]	133.0 [93.0-160.0]	94.5 [66.5-127.5]	0.009	92.2 ± 49.1
Fluoroscopic time (min)	24.5 [17.5-38.5]	22.0 [18.0-37.5]	28.5 [17.5-38.5]	0.279	30.6 ± 23.1
Contrast amount (mL)	200 [150-280]	220 [170-280]	200 [140-290]	0.540	236 ± 120
Procedural Success	86.5 (90/104)	94.4 (34/36)	82.4 (56/68)	0.130	93.8 (602/642)
Final TIMI flow 3	90.4 (94/104)	94.4 (34/36)	88.2 (60/68)	0.488	96.7 (621/642)
Residual stenosis < 30%	94.2 (98/104)	94.4 (34/36)	94.1 (64/68)	1.000	96.6 (620/642)
Stent implanted	95.2 (99/104)	97.2 (35/36)	94.1 (64/68)	0.657	97.4 (625/642)
Residual stenosis (%)	0 [0-10]	0 [0-10]	0 [0-10]	0.432	
Dissection (beyond lesion)	13.5 (14/104)	11.1 (4/36)	14.7 (10/68)	0.766	6.1 (39/642)
Perforation	2.9 (3/104)	0 (0/36)	4.4 (3/68)	0.550	2.0 (13/642)
Burr entrapment	1.9 (2/104)	0 (0/36)	2.9 (2/68)	0.543	0.8 (5/642)
Pericardial effusion	1.9 (2/104)	0 (0/36)	2.9 (2/68)	0.543	2.5 (16/642)
Stent thrombosis	1.0 (1/104)	0 (0/36)	1.5 (1/68)	1.0	
In-hospital death	18.3 (19/104)	50.0 (18/36)	1.5 (1/68)	< 0.0001	0.8 (5/642)
In-hospital TLR	1.9 (2/104)	0 (0/36)	2.9 (2/68)	0.543	0.6 (4/642)
In-hospital TVR	1.9 (2/104)	0 (0/36)	2.9 (2/68)	0.543	0.9 (6/642)
In-hospital CABG	1.0 (1/104)	0 (0/36)	1.5 (1/68)	1.0	0.6 (4/642)
In-hospital bleeding (BARC type 3 or 5)	4.8 (5/104)	11.1 (4/36)	1.5 (1/68)	0.030	
In-hospital stroke	1.9 (2/104)	5.6 (2/36)	0 (0/68)	0.118	2.0 (13/642)

BARC, Bleeding Academic Research Consortium; CABG: coronary artery bypass graft; CAD, coronary artery disease; RA, rotational atherectomy; STEMI, ST-elevation myocardial infarction; TIMI, thrombolysis in myocardial infarction; TLR, target lesion revascularization; TVR, target vessel revascularization.

antithrombotic therapy are summarized in Supplemental Table S4. The temporal trend in RA use over the study time-period is depicted in Supplemental Figure S1.

Procedural and in-hospital outcomes are summarized in Table 4. Procedural duration was 101.6 (74.3-137.6) minutes, and the amount of contrast material was 200 (150-280) mL. Procedural success was achieved in 86.5% of patients (Fig. 1). A final TIMI flow 3 was achieved in 90.4% of cases, residual stenosis was < 30% in 94.2%, and a stent could be implanted in the target lesion in 95.2% of cases. Complications such as perforation (2.9%), burr entrapment (1.9%), and pericardial effusion (1.9%) were infrequent.

Overall in-hospital death occurred in 18.3% of patients. When excluding patients with cardiogenic shock, in-hospital mortality was low (1.5%). Conversely, one-half of patients with cardiogenic shock died in hospital (50.0%) (Fig. 2). In-hospital target lesion revascularization rate was 1.9%. One case of definite stent thrombosis was reported 11 days after the

Procedural Success
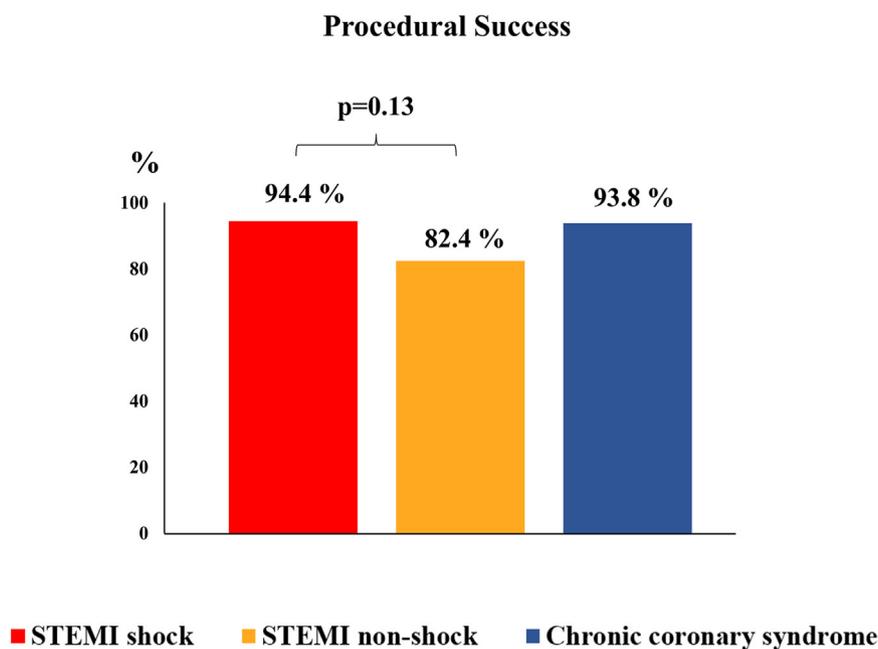
Figure 1. Procedural success in patients presenting with ST-segment elevation myocardial infarction (shock and nonshock) and chronic coronary syndrome.

In-hospital Mortality
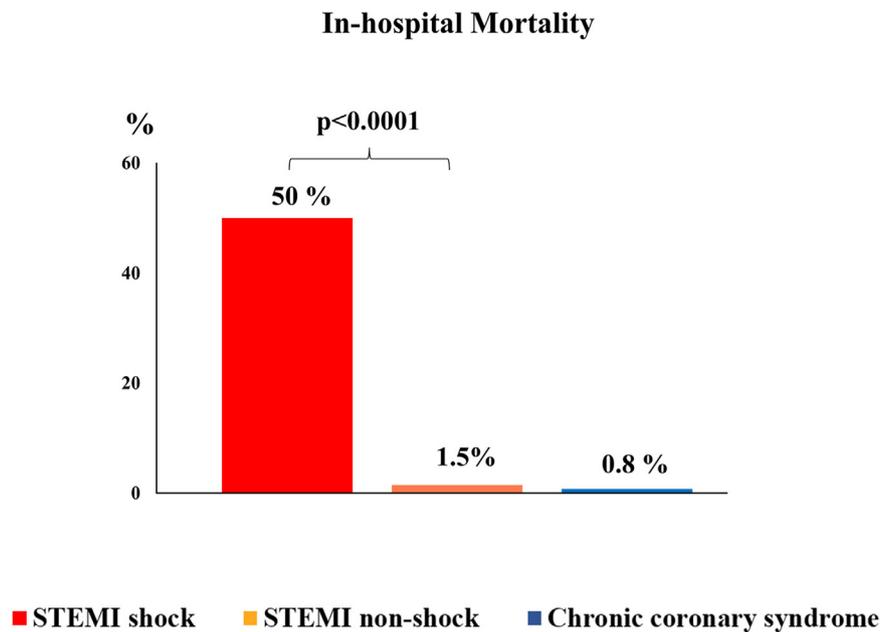
Figure 2. In-hospital mortality in patients presenting with ST-segment elevation myocardial infarction (shock and nonshock) and chronic coronary syndrome.

index procedure (0.96%). Bleeding Academic Research Consortium (BARC) type 3 or 5 bleeding occurred in 4.8% of cases. Of these, 1 patient died from access-site–related bleeding associated with large-bore access of an Impella device (Abiomed, Inc, Danvers, Massachusetts, USA). One patient was referred to bypass surgery after unsuccessful PCI.

Cardiogenic shock

The baseline clinical characteristics of patients with vs without cardiogenic shock are presented in Table 1 and Supplemental Table S1. There was a trend toward a higher rate of upfront use of RA in shocked patients compared with nonshocked patients (33.3% vs 17.6%, 0.089). The burr-to-artery ratio was smaller in shocked patients compared with nonshocked patients (0.42 [0.38-0.44] vs 0.50 [0.42-0.5], $P = 0.005$). Procedural success did not significantly differ between the 2 groups (Table 4).

Data of RA-STEMI patients (n = 104) and RA in patients with stable CAD (n = 642) are summarized in Table 4 and Supplemental Table S5. RA was bailout in 77% of RA-STEMI vs 40% of RA-stable CAD. Procedural success was achieved in 87% vs 94% of the 2 groups, respectively (Fig. 1).

Discussion

The main findings of this analysis can be summarized as follows: RA for the treatment of culprit lesion during STEMI is feasible with a high procedural success and a low rate of serious—especially thrombotic—complications. In most cases, RA was performed as a bailout strategy. However, in approximately one-quarter of cases, upfront RA was performed. Patients were multicomorbid with a high rate of cardiogenic shock, which was associated with a high in-hospital mortality, even though procedural success was

achieved in most cases. Excluding patients with cardiogenic shock, in-hospital mortality was low (1.5%).

Culprit lesions in ACS are typically soft, with a thin-cap fibroatheroma.[17] However, among patients with STEMI, 46% have moderate-severely calcified coronary lesions on angiography,[3] with even higher frequency of calcification when assessed by intracoronary imaging.[4] However, in patients with ACS and calcified culprit lesions undergoing PCI, RA is adopted in a small minority of cases (0.7%).[3]

Given the low rate of RA in patients with ACS undergoing urgent/emergent PCI, data on RA in STEMI are scarce. Several reports demonstrated the safety and feasibility of RA in ACS, but most included a very small number of patients with STEMI and none provided detailed insights on this special subgroup.[9-14]

RA is relatively contraindicated in the presence of target lesion thrombus as the burr rotation as such leads to platelet activation and ablation debris as such can lead to thrombotic/embolic impairment of coronary flow. Thus, no flow or slow flow is expected, posing a great challenge to the application of RA in this clinical and angiographic setting. Nevertheless, with the aging population and the increasing frequency of anatomic complexity, RA is sometimes mandatory to achieve procedural success, and primary PCI is not an exception to this rule.

In our analysis, procedural success was achieved in 86.5% of cases, and procedural failure was mainly driven by a no flow or slow flow (9.6%). In an analysis by Généreux et al.[3] no/slow flow occurred in 14.1% of patients with STEMI and severely calcified coronary lesions. In large all-comer STEMI registries, the rate of no/slow flow varies from 5.3% to 13%,[18-20] which compares favourably to those observed with RA-STEMI. A possible contributing factor to this relatively low rate of no/slow flow in our series is the frequent use of the smallest burr size (1.25 mm) in 50% of cases and the relatively low burr-to-artery ratio (0.43).

Upfront RA was performed in 23% of cases. In the rest of the cases, lesions were resistant to balloon delivery or inflation, and aggressive predilatation was required in most cases (frequently using several balloons or special balloons). This pattern of lesions and the "aggressive" therapy required to modify them is reflected by a dissection rate of 13.5%.

As expected for patients with heavily calcific culprit coronary lesions, our population is relatively older and more morbid compared with a general STEMI population (eg, in comparison with data from **H**armonizing **O**utcomes With **R**evascular**iza**t**ion** and Stents in **A**cute **M**yocardial **I**nfarction [HORIZONS-AMI] and **A**cute **C**atheterization and **U**rgent Intervention **T**riage Strategy [ACUITY] trials).[3] As such, and as expected, mortality was high in our cohort, but this was mainly driven by the most-sick patients subset presenting with cardiogenic shock. Excluding this subgroup, in-hospital mortality was reasonably low with 1.5%. The US National Cardiovascular Data Registry shows rates of 4.9%.[21]

Mechanistically, our analysis emphasizes the feasibility and the relative safety of RA in the setting of STEMI, basically as a bailout option. Nevertheless, some experienced RA operators have a relatively low threshold for upfront RA or an early conversion to RA, knowing that a "delayed" bailout RA after exhaustive balloon dilatation attempts is associated with adverse outcomes and marked prolongation of the procedure.[22-24] This should be avoided in general: more so in a primary PCI setting. Another alternative to ablative techniques is the use of the expanding arsenal of special balloons such as cutting or lithotripsy balloons or even the combination of those balloons with RA (as seen in 17% of our series).

In our analysis, 35% of patients presented with cardiogenic shock. This is a high rate compared with large Spanish and German STEMI registries,[18,19] in which cardiogenic shock affected 7.5% of patients with STEMI. This high rate reflects the very high-risk profile of RA-STEMI candidates. In one-half of cases, a circulatory assist device was used, further prolonging the procedure and contributing to its complexity and to the risk of complications. Although procedural success was achieved in 94% of cases, in-hospital mortality remained very high in patients with cardiogenic shock, further supporting a minimalistic PCI approach to these patients.

Contrasting RA-STEMI data to RA-stable CAD data, several important—yet only hypothesis-generating—observations are worth mentioning: Operators tend to use a smaller burr in patients with STEMI. A final TIMI 3 flow was achieved in 87% vs 97%, and overall procedural success was achieved in 86.5% vs 93.8% of RA-STEMI vs RA-stable CAD cohorts. In-hospital mortality was low in patients with STEMI without cardiogenic shock (1.5%) and in patients with stable CAD (0.8%). Taken together, RA-STEMI candidates represent a special high-risk STEMI patient category, but mechanistic outcomes of the procedure compare favourably with RA applied in other settings.

Study limitations

First, this is a retrospective analysis of collected cases from several centres over a relatively long period of time. Therefore, the results should be considered hypothesis generating. However, as the use of RA in primary PCI is rather uncommon, a randomized study comparing different calcium modifying devices in this setting may not be feasible. Second, this study describes in-hospital clinical outcomes without longer-term follow-up. Third, the total number of patients and the rate of in-hospital events make the comparison of shock vs nonshock patients underpowered. Fourth, lesion characteristics and outcomes were reported by the participating centres without independent adjudication, and some more objective angiographic data (such as quantitative coronary angiography and TIMI thrombus score) were not systemically collected. Fifth, although our study documents the feasibility and the acceptable short-term outcome of RA in patients with STEMI, a comparison vs patients with STEMI who have severely calcific culprit lesions treated without RA would shed more light on the relative safety and efficacy of RA-STEMI.

Conclusions

Patients presenting with STEMI and requiring RA during primary PCI represent a high-risk population: basically because of frequent hemodynamic instability. In this analysis of selected patients, RA was performed as a bailout strategy in the majority of cases, and, as such, RA seems to be feasible with a high procedural success rate. In the absence of cardiogenic shock, RA-facilitated PCI seems to be associated with low in-hospital mortality.

Ethics Statement

The research reported adheres to the ethical guidelines.

Patient Consent

The authors confirm that patient consent is not applicable to this article. This is a retrospective analysis using deidentified data; therefore, the institutional review board did not require consent from the patients.

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References

1. Sharma SK, Tomey MI, Teirstein PS, et al. North American expert review of rotational atherectomy. Circ Cardiovasc Interv 2019;12:e007448.

2. Hemetsberger R, Abdelghani M, Toelg R, et al. Impact of coronary calcification on clinical outcomes after implantation of newer-generation drug-eluting stents. J Am Heart Assoc 2021;10:e019815.

3. Genereux P, Madhavan MV, Mintz GS, et al. Ischemic outcomes after coronary intervention of calcified vessels in acute coronary syndromes: pooled analysis from the HORIZONS-AMI (Harmonizing Outcomes With Revascularization and Stents in Acute Myocardial Infarction) and ACUITY (Acute Catheterization and Urgent Intervention Triage Strategy) trials. J Am Coll Cardiol 2014;63:1845-54.

4. Wang X, Matsumura M, Mintz GS, et al. In vivo calcium detection by comparing optical coherence tomography, intravascular ultrasound, and angiography. JACC Cardiovasc Imaging 2017;10:869-79.

5. Ali ZA, Karimi Galougahi K, Maehara A, et al. Intracoronary optical coherence tomography 2018: current status and future directions. JACC Cardiovasc Interv 2017;10:2473-87.

6. Ibanez B, James S, Agewall S, et al. 2017 ESC guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation: the task force for the management of acute myocardial infarction in patients presenting with ST-segment elevation of the European Society of Cardiology (ESC). Eur Heart J 2018;39:119-77.

7. Writing Committee M, Gulati M, Levy PD, et al. 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR guideline for the evaluation and diagnosis of chest pain: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol 2021;78:e187-285.

8. Picard F, Pighi M, Marquis-Gravel G, Labinaz M, Cohen EA, Tanguay JF. The ongoing saga of the evolution of percutaneous coronary intervention: from balloon angioplasty to recent innovations to future prospects. Can J Cardiol 2022;38:S30-41.

9. Allali A, Abdelghani M, Mankerious N, Abdel-Wahab M, Richardt G, Toelg R. Feasibility and clinical outcome of rotational atherectomy in patients presenting with an acute coronary syndrome. Catheter Cardiovasc Interv 2019;93:382-9.

10. Iannaccone M, Piazza F, Boccuzzi GG, et al. ROTational AThErectomy in acute coronary syndrome: early and midterm outcomes from a multicentre registry. EuroIntervention 2016;12:1457-64.

11. Januszek R, Siudak Z, Dziewierz A, et al. Bailout rotational atherectomy in patients with myocardial infarction is not associated with an increased periprocedural complication rate or poorer angiographic outcomes in comparison to elective procedures (from the ORPKI Polish National Registry 2015-2016). Postepy Kardiol Interwencyjnej 2018;14:135-43.

12. Kubler P, Zimoch W, Kosowski M, Tomasiewicz B, Telichowski A, Reczuch K. Acute coronary syndrome: still a valid contraindication to perform rotational atherectomy? Early and one-year outcomes. J Cardiol 2018;71:382-8.

13. Chen YW, Lai CH, Su CS, et al. The procedural and clinical outcomes of rotational atherectomy in patients presenting with acute myocardial infarction. Front Cardiovasc Med 2022;9:846564.

14. Qaqish O, Sharma S, Kumar A, et al. Rotational atherectomy in acute coronary syndrome: a meta-analysis. Cardiovasc Revasc Med 2022;42:143-53.

15. Wang Q, Shen H, Mao H, Yu F, Wang H, Zheng J. Shock index on admission is associated with coronary slow/no reflow in patients with acute myocardial infarction undergoing emergent percutaneous coronary intervention. J Interv Cardiol 2019;2019:7873468.

16. Thygesen K, Alpert JS, Jaffe AS, et al. Fourth universal definition of myocardial infarction (2018). Circulation 2018;138:e618-51.

17. Stone GW, Maehara A, Lansky AJ, et al. A prospective natural-history study of coronary atherosclerosis. N Engl J Med 2011;364:226-35.

18. Rodriguez-Leor O, Cid-Alvarez AB, Perez de Prado A, et al. Analysis of the management of ST-segment elevation myocardial infarction in Spain: results from the ACI-SEC Infarction Code Registry. Rev Esp Cardiol (Engl Ed) 2022;75:669-80.

19. Harle T, Zeymer U, Hochadel M, et al. Use and impact of thrombectomy in primary percutaneous coronary intervention for acute myocardial infarction with persistent ST-segment elevation: results of the prospective ALKK PCI-registry. Clin Res Cardiol 2015;104:803-11.

20. Huang X, Zheng W, Zhao XD, Nie SP. CHA2DS2-VASc score predicts the slow flow/no-reflow phenomenon in ST-segment elevation myocardial infarction patients with multivessel disease undergoing primary percutaneous coronary intervention. Medicine (Baltimore) 2021;100:e26162.

21. Hillerson D, Li S, Misumida N, et al. Characteristics, process metrics, and outcomes among patients with st-elevation myocardial infarction in rural vs urban areas in the US: a report from the US National Cardiovascular Data Registry. JAMA Cardiol 2022;7:1016-24.

22. Allali A, Abdel-Wahab M, Sulimov DS, et al. Comparison of bailout and planned rotational atherectomy for heavily calcified coronary lesions: a single-center experience. J Interv Cardiol 2017;30:124-33.

23. Allali A, Abdel-Wahab M, Elbasha K, et al. Rotational atherectomy of calcified coronary lesions: current practice and insights from two randomized trials. Clin Res Cardiol 2022;112:1143-63.

24. Kawamoto H, Latib A, Ruparelia N, et al. Planned versus provisional rotational atherectomy for severe calcified coronary lesions: insights from the ROTATE multi-center registry. Catheter Cardiovasc Interv 2016;88:881-9.

Supplementary Material

To access the supplementary material accompanying this article, visit the online version of the *Canadian Journal of Cardiology* at www.onlinecjc.ca and at https://doi.org/10.1016/j.cjca.2023.12.018.