

Comparison of rotational atherectomy and modified balloons for calcified lesion preparation: a single-centre experience

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ABSTRACT

Aim To compare the efficacy and safety of rotational atherectomy (RA) and modified balloons (MB) for calcified coronary lesion preparation.

Methods This retrospective, single-centre study included 92 consecutive patients with angiographically significant coronary artery calcification (CAC) treated between September 2021 and December 2024. Patients were stratified according to lesion-preparation strategy: RA with the RotaPro system (Boston Scientific, Marlborough, MA, USA) (n = 42) or MB, including scoring or cutting balloons (n = 50). Patients treated with intravascular lithotripsy, super-high-pressure balloons, or non-compliant balloons alone were excluded. The primary endpoint was 1-year cardiovascular mortality, and the secondary endpoint was procedural success, defined as successful stent or drug-coated balloon implantation with <10% residual stenosis and final Thrombolysis in Myocardial Infarction grade 3 flow.

Results Baseline age and renal function were comparable between groups. Microcatheter use was more frequent in the RA group (p<0.001), whereas smoking was more prevalent in the MB group (p=0.043). Fluoroscopy time was longer in the RA group (p<0.001). Cardiovascular mortality and procedural success did not differ significantly between groups.

Conclusion In this real-world single-centre experience, RA and MB showed comparable feasibility and one-year clinical outcomes for the treatment of CAC. A lesion-specific approach integrating RA, MB and intravascular lithotripsy may optimise the management of calcified coronary lesions.

Keywords: coronary artery calcification, percutaneous coronary intervention, rotational atherectomy, treatment outcome

INTRODUCTION

Coronary artery calcification (CAC) is a major challenge in percutaneous coronary intervention (PCI), affecting more than 20% of treated patients (1). The ageing population and the increasing prevalence of arterial hypertension, type 2 diabetes and chronic kidney disease contribute to a growing burden of CAC (2). Calcified plaques may impair balloon and stent delivery and limit stent expansion, which adversely affects PCI outcomes (3). CAC is associated with higher rates of in-stent restenosis, stent thrombosis and mortality (4).

Several devices are available for CAC lesion preparation, including modified balloons (MB), atheroablative technologies and intravascular lithotripsy (IVL). Non-compliant (NC), super-

high-pressure, scoring and cutting balloons are commonly used to create intimal cracks or fractures. Laser atherectomy, rotational atherectomy (RA) and orbital atherectomy (OA) represent atheroablative strategies for calcified lesions.

RA was introduced into clinical practice in 1989 and remains one of the most widely used techniques for calcium plaque modification. Its fundamental principle is high-speed burr rotation, which ablates calcified plaque, while sparing the more elastic arterial wall (5). RA facilitates stent delivery and expansion (6) and is associated with high procedural and angiographic success rates (7). However, a recent meta-analysis reported higher long-term risks of major adverse cardiovascular events (MACE), mortality, target lesion revascularisation (TLR), bleeding, and longer fluoroscopy time (FT) with RA compared with other atheroablative strategies (8). These findings highlight the importance of careful patient selection and meticulous procedural performance to minimise complications.

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RA was introduced at General Hospital (GH) “Dr. Josip Benčević”, Slavonski Brod, in September 2021. More than 500 PCI procedures are performed annually at this high-volume centre. Before RA became available, severely calcified coronary lesions were prepared primarily with scoring and cutting balloons. The introduction of RA expanded local treatment options by enabling mechanical debulking of lesions that were resistant to balloon-based techniques.

The aim of this study was to retrospectively compare the efficacy and safety of RA with established MB-based practice for calcified lesion preparation.

MATERIAL AND METHODS

Patients and study design

This retrospective single-centre study included 92 consecutive patients treated for severely calcified coronary lesions at GH “Dr. Josip Benčević”, Slavonski Brod, between September 2021 and December 2024. Data were extracted from the local PCI registry. Patients were divided into two cohorts according to lesion-preparation strategy: the RA group (n=42), comprising patients treated with the RotaPro system (Boston Scientific, Marlborough, MA, USA), and the MB group (n=50), comprising patients treated with scoring or cutting balloons for operator-defined calcified stenosis. Patients treated with IVL, super-high-pressure balloons or NC balloons alone were excluded to maintain a focused comparison between RA and standard MB techniques.

The study was conducted in accordance with the Declaration of Helsinki. The protocol and data management were reviewed and approved by the Ethics Committee of GH “Dr. Josip Benčević” (approval code: 0801000/26-15; approval date: 30 April 2026). Because of the retrospective study design, the requirement for informed consent was waived.

Methods

Demographic, clinical, laboratory and procedural data were collected during hospitalisation. Heart failure with reduced ejection fraction (HFrEF) was defined as left ventricular ejection fraction (LVEF) <40%. Peripheral arterial disease (PAD) was defined as an ankle-brachial index (ABI) < 0.9, > 50% stenosis on imaging, or previous revascularisation. Estimated glomerular filtration rate (eGFR) was calculated using the 2021 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula. Procedural exposure was assessed using dose-area product (DAP), air kerma (AK) and FT. Lesion complexity was assessed according to long lesions, ostial lesions, bifurcation lesions and chronic total occlusion (CTO). Long lesions were defined as >20 mm by quantitative coronary analysis (Siemens Healthineers, Forchheim, Germany), and all types of bifurcation lesions according to the Medina classification were included. The primary clinical endpoint was cardiovascular death within 1 year. The secondary endpoint was procedural success, defined as successful stent or drug-coated balloon (DCB) implantation with <10% residual stenosis and final Thrombolysis in Myocardial Infarction grade 3 (TIMI 3) flow at the end of the index procedure.

RA procedures were performed using the RotaPro system (Boston Scientific, Marlborough, MA, USA). The first four RA cases were performed under proctor supervision, and an internal step-by-step procedural flowchart was subsequently developed. Two operators were present during each RA procedure, and 7 F guiding catheters were used. For femoral access, puncture

was performed under fluoroscopic or ultrasound guidance to facilitate subsequent vascular closure. Patients received unfractionated heparin (UFH) at 100 units/kg. Activated clotting time (ACT) was first checked 45 minutes after the intravenous UFH bolus, with a target ACT >250 s and further UFH administration as needed. The flush solution consisted of saline, heparin, nitroglycerin and verapamil. A workhorse wire and microcatheter were advanced into the target vessel, followed by RotaWire introduction through the microcatheter. The burr was advanced in DyneGlide mode and RA was performed at 160,000–170,000 rpm. Each run lasted ≤15 seconds, followed by ≥30 seconds of rest. After successful lesion crossing with a pecking motion, two or three polishing runs were performed. The RotaWire was then exchanged for an extra-support wire using the trapping-balloon technique. Additional use of NC, scoring or cutting balloons after RA was left to the operator’s discretion.

MB preparation was a routine method in the catheterisation laboratory and was performed according to an internal procedural flowchart. One operator was present during PCI. The choice of workhorse or extra-support wire, guiding catheter size (6 or 7 F), order of scoring or cutting balloon use, and number of inflations were left to the operator’s discretion. For femoral access, puncture was performed under fluoroscopic or ultrasound guidance to facilitate vascular closure. Patients received UFH at 100 units/kg. ACT was not routinely measured in the MB group. Balloon inflation lasted at least 15 seconds and was performed at nominal pressure.

Statistical analysis

Normality of distribution was assessed using the Shapiro-Wilk test. Data are presented as absolute frequencies, means with standard deviations (SDs), or medians with interquartile ranges (IQRs), as appropriate. Differences between independent groups were analysed using the Student’s t-test or the Brunner-Munzel test, as appropriate. Categorical variables were compared using the χ^2 test. Statistical significance was set at $p < 0.05$. Data were analysed using Jamovi (version 2.6.26, The jamovi project, Sydney, New South Wales, Australia).

RESULTS

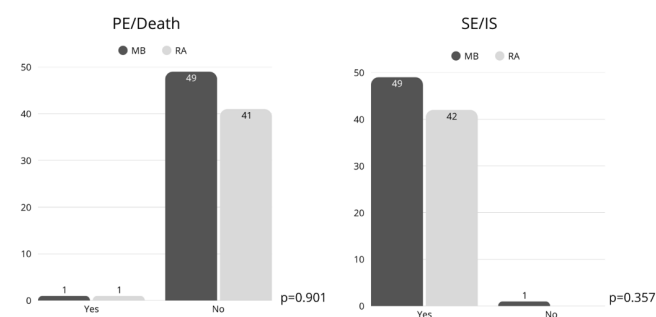


Figure 1. Cardiovascular death and procedural success in the rotational atherectomy (RA) and modified balloons (MB) groups PE, primary endpoint; SE, secondary endpoint; IS, intervention success

A total of 92 patients were included. Baseline characteristics were generally comparable between the RA and MB groups. The mean age was 69.5 ± 7.1 years, and age, creatinine and

Table 1. Baseline characteristics and procedural outcomes according to the lesion-preparation strategy

Variable	MB (N=50)	RA (N=42)	p
N (%)			
Indication			
CCS	25 (27.2)	28 (30.4)	0.182
NSTEMI	12 (13)	10 (10.9)	
STEMI	6 (6.5)	1 (1.1)	
UAP	7 (7.6)	3 (3.3)	
Sex			0.686
Female	15 (16.3)	11 (12)	
Male	35 (38)	31 (33.7)	
HFrEF	7 (7.6)	10 (10.9)	0.227
CAD	22 (23.9)	24 (26)	0.209
AH	48 (52.2)	40 (43.5)	0.858
DM II	18 (19.6)	15 (16.3)	0.977
AF	11 (11.95)	8 (8.7)	0.728
PAD	9 (9.8)	14 (15.2)	0.091
Smoking	22 (23.9)	10 (10.9)	0.043
PE/Death	1 (1.1)	1 (1.1)	0.901
SE/IS	49 (53.3)	42 (45.7)	0.357

MB, modified balloons; RA, rotational atherectomy; CCS, chronic coronary syndrome; NSTEMI, non-ST-elevation myocardial infarction; STEMI, ST-elevation myocardial infarction; UAP, unstable angina pectoris; HFrEF, heart failure with reduced ejection fraction; CAD, coronary artery disease; AH, arterial hypertension; DM II, diabetes mellitus type 2; AF, atrial fibrillation; PAD, peripheral arterial disease; PE, primary endpoint; SE, secondary endpoint; IS, intervention success.

eGFR did not differ significantly between groups. Smoking was more prevalent in the MB group ($p = 0.043$) (Tables 1 and 2).

Cardiovascular death within 1 year occurred in one patient in each group (MB 1/50, RA 1/42; $p = 0.901$), and procedural success was achieved in 49/50 patients in the MB group and 42/42 patients in the RA group ($p = 0.357$) (Figure 1, Table 1).

Microcatheter use was more frequent in the RA group ($p < 0.001$), reflecting the procedural requirement for wire exchange to the RotaWire (Boston Scientific, Marlborough, MA, USA). The distribution of lesion type and vascular access also differed between groups ($p = 0.026$ and $p = 0.017$, respectively) (Table 3).

Fluoroscopy time was longer in the RA group (24.3 min, IQR 20.1–30.6) than in the MB group (14.4 min, IQR 10.9–18.8) ($p < 0.001$). DAP and AK did not differ significantly between groups (Table 4).

DISCUSSION

This retrospective study of patients undergoing PCI for CAC showed that RA and MB were both associated with high procedural success and low 1-year cardiovascular mortality. Cardiovascular mortality and procedural success did not differ between groups, which is encouraging for a real-world regional centre.

The randomised PREPARE-CALC trial demonstrated higher procedural success with RA than with MB, and 5-year follow-up showed lower target lesion revascularisation rates with RA (9). As in our study, there was no difference in mortality between the 2 groups. A recent meta-analysis also reported that MB use after RA in severely calcified lesions was associated with lower major adverse cardiovascular events than plain balloon use, without additional procedural complications (10).

Baseline characteristics were generally comparable, whereas microcatheter use, lesion type, vascular access, smoking prevalence and FT differed between groups. These findings reflect the different technical requirements and lesion-selection patterns associated with the two lesion-preparation strategies. The higher use of microcatheters in the RA group reflects the technical requirements of this procedure. The RotaWire is a specialised 0.009-inch guidewire that tapers to 0.005 inches with a 0.014-inch spring tip, making it more delicate and prone to kinking than standard coronary guidewires (11). Routine microcatheter-assisted wire exchange is consistent with expert consensus and may reduce the risk of wire-related complications. Although this step increases procedural complexity and may contribute to longer FT, it provides a stable platform before ablation begins.

The higher prevalence of smoking in the MB group appears counterintuitive because smoking is associated with CAC development and progression (12). However, pooled trial data have described a smoker's paradox, in which smokers were more likely to have longer lesions and total occlusions but less likely to have moderate or severe calcification than non-smokers (13). This may partly explain the present distribution if lesions in smokers were more amenable to MB techniques.

In addition, long and ostial lesions were numerically more frequent in the RA group, whereas bifurcation lesions were more frequent in the MB group. In PREPARE-CALC, lesions treated with RA were on average approximately 30 mm long, highlighting the preference for RA in long calcified lesions (9). Bifurcation lesions requiring side-branch wiring may be less suitable for RA, which supports the observed pattern of treatment selection. In PREPARE-CALC trial, bifurcation lesions are often initially managed with MB because of technical considerations related to side-branch protection, although crossover to RA is reported in selected cases (9). More frequent femoral access in the RA group may also reflect greater lesion complexity and the need for mechanical circulatory support (MCS) or temporary pacing (10).

The longer FT in the RA group is consistent with the technical complexity of RA. This finding is consistent with the randomised PREPARE-CALC trial, in which rotational atherectomy was associated with significantly longer fluoroscopy time (23.9 vs. 19.6 minutes; $p = 0.03$) (9). Wire exchange through a microcatheter, temporary pacing during PCI of the right coronary artery, and careful monitoring of burr passages probably contributed to

Table 2. Continuous baseline characteristics according to the lesion-preparation strategy

Variable	MB (N=50)	RA (N=42)	Total (N=92)	p
Mean $\pm$ SD or median (IQR)				
Age	69.5 $\pm$ 8.15	69.6 $\pm$ 5.7	69.5 $\pm$ 7.1	0.973*
Creatinine ($\mu\text{mol/L}$)	81 (68–92.5)	83 (71–97.3)	82 (68.8–95)	0.447†
eGFR (mL/min/1.73 m^2)	85.3 (73–96.3)	84.3 (71.1–94.9)	85.3 (71.1–95.5)	0.708†

* Independent-samples t-test; † Brunner-Munzel test.

SD, standard deviation; MB, modified balloons; RA, rotational atherectomy; eGFR, estimated glomerular filtration rate.

Table 3. Procedural characteristics according to the lesion-preparation strategy

Variable		MB (N = 50)	RA (N = 42)	p
CA	CxA	4 (4.3)	5 (5.4)	0.780
	LAD	27 (29.3)	23 (25)	
	RCA	19 (20.7)	14 (15.2)	
Localization	Distal	3 (3.3)	2 (2.2)	0.924
	Middle	6 (6.5)	6 (6.5)	
	Proximal	41 (44.6)	34 (37)	
Scoring	No	0	3 (3.3)	0.055
	Yes	50 (54.34)	39 (42.4)	
Final	DCB	3 (3.2)	6 (6.5)	0.193
	DES	46 (50)	36 (39.1)	
	Caravel*	0	2 (2.2)	
	Corsair*	1 (1.1)	6 (6.5)	
Microcatheter	Finecross [†]	11 (11.96)	33 (35.9)	< 0.001
	SuperCross 120 [‡]	0	1 (1.1)	
IVUS	No	41 (44.6)	34 (36.96)	0.897
	Yes	9 (9.8)	8 (8.7)	
Extension	No	35 (38)	33 (35.9)	0.475
	Yes	15 (16.3)	9 (9.8)	
MCS	IVAC	1 (1.1)	2 (2.2)	0.565
	Impella	1 (1.1)	2 (2.2)	
	No	48 (52.2)	38 (41.3)	
Lesion type	BL	17 (18.5)	3 (3.3)	0.026
	CTO	3 (3.3)	3 (3.3)	
	LL	7 (7.6)	13 (14.1)	
	OL	9 (9.8)	10 (10.9)	
	Other	14 (15.2)	13 (14.1)	
VA	Femoral	9 (9.8)	17 (18.5)	0.017
	Radial	41 (44.6)	25 (27.2)	

* Caravel and Corsair: Asahi Intecc Co., Ltd., Aichi, Japan; [†] Finecross: Terumo Corporation, Tokyo, Japan; [‡] SuperCross 120: Teleflex, Wayne, PA, USA.

MB, modified balloons; RA, rotational atherectomy; PCI, percutaneous coronary intervention; CA, culprit artery; CxA, circumflex artery; LAD, left anterior descending artery; RCA, right coronary artery; DCB, drug-coated balloon; DES, drug-eluting stent; IVUS, intravascular ultrasound; MCS, mechanical circulatory support; BL, bifurcation lesion; CTO, chronic total occlusion; LL, long lesion; OL, ostial lesion; VA, vascular access.

Table 4. Procedural exposure according to the lesion-preparation strategy

Variable	MB (N=50)	RA (N=42)	Total (N=92)	p
FT (min)	14.4 (10.9–18.8)	24.3 (20.1–30.6)	18.8 (12.2–24.6)	< 0.001 [†]
DAP (Gy·cm ²)	146 (107–204)	172 (132–191)	165 (114–193)	0.396 [†]
AK (Gy)	3.14 (2–4.16)	3.26 (2.65–4.12)	3.15 (2.18–4.15)	0.642 [†]

* Independent-samples t-test; [†] Brunner-Munzel test. FT, fluoroscopy time; DAP, dose-area product; AK, air kerma.

longer radiation exposure. As procedural experience increases, FT may decrease, as reported in other high-volume centres.

Several limitations should be acknowledged. The retrospective single-centre design, modest sample size and operator-selected treatment strategy may have introduced selection bias and may limit generalisability. The study was not sufficiently powered for multivariable regression or propensity-score analyses; therefore, adjustment for potential confounding was not possible and the findings should be interpreted as unadjusted associations. Intravascular ultrasound (IVUS) or optical coherence tomography (OCT) was used infrequently, precluding detailed assessment of calcification morphology, stent expansion, minimal stent area and calcium fracture. Moreover, treatment-era effects and local procedural experience may have influenced outcomes, particularly because RA was introduced during the study period.

CONCLUSION

In this single-centre experience, RA and MB were feasible strategies for lesion preparation in severely calcified coronary lesions, with similar procedural success and 1-year cardiovascular mortality. These techniques should be considered complementary rather than mutually exclusive. A lesion-specific calcium-modification algorithm that includes RA, MB and IVL may help optimise procedural planning in contemporary catheterisation laboratories.

FUNDING

No specific funding was received for this study.

CONFLICTS OF INTEREST

None to declare.

ETHICS STATEMENT

The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of GH “Dr. Josip Benčević” (approval code: 0801000/26-15; approval date: 30 April 2026). Because of the retrospective design, the requirement for informed consent was waived.

DATA AVAILABILITY STATEMENT

The data presented in this study are available from the corresponding author upon reasonable request due to privacy and Ethics Committee restrictions.

AUTHOR CONTRIBUTIONS (CRediT)

Conceptualization: I.H.; **Data curation:** K.G.; **Formal analysis:** K.C.L., M.K.P.; **Funding acquisition:** K.C.L.; **Investigation:** K.G., J.S.; **Methodology:** J.J., A.Đ.H., J.M.; **Supervision:** K.C.L., M.K.P., I.H.; **Writing – original draft:** J.J.; **Writing – review & editing:** J.S., J.J., K.C.L., I.H. All authors have read and agreed to the published version of the manuscript.

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