



## Original Article

# Evaluation of only heparin-based rota-flush solution against alternative rota-flush solution in patients with severe coronary artery calcification undergoing rotational atherectomy

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## ABSTRACT

**Objective:** There is limited evidence on feasibility and safety of only heparin rota-flush(OHRF)solution in rotational atherectomy (RA). We compared the safety and efficacy of OHRF solution with alternative rota-flush (ARF) solution in patients who underwent RA.

**Methods:** A total of 48 patients who underwent RA were enrolled in the study. In 25 patients OHRF solution and in 23 patients ARF solution was utilized. The study end points were procedural success rate and rota-related adverse cardiovascular event (RRAE) including slow flow, no reflow, bradycardia, and hemodynamic instability.

**Results:** Procedural success was achieved in all patients in both the OHRF and ARF groups. There was no statistically significant difference in RRAE between the two groups (32.0% vs. 34.7%,  $p = 0.83$ ).

**Conclusion:** OHRF solution appears a more simplistic solution while performing rotablation as compared to ARF solution. Side effects such as hypotension and bradycardia can be circumvented with OHRF solution during rotablation.

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## 1. Introduction

Since the introduction of percutaneous coronary intervention (PCI) in 1977 by Andreas Grüntzig,<sup>1</sup> this technique has evolved significantly through device innovation and greater operator expertise. However, severe coronary artery calcification (CAC) remains a challenge for successful PCI despite significant advancement over the past four decades.<sup>2</sup> Moderate to heavy calcification remains a strong predictor of failure to deliver a stent, higher rates of major adverse cardiovascular events (MACE), stent under-

expansion, and target lesion revascularization (TLR), with drug-eluting stents (DES) even in the contemporary era.<sup>3–5</sup>

Over the past three decades since the availability of rotational atherectomy (RA), PCI has matured as a tool for management of coronary calcified lesions with advancement in its design. However, its use varies widely from less than 1% to greater than 10% of PCI at select centres.<sup>6</sup>

RA is based on the principle of differential cutting which allows mechanical ablation of fibrocalcific plaque using a diamond-encrusted elliptical burr, rotated at high speed upto 180,000 rpm by a helical driveshaft. The best studied RA device, Rotablator Rotational Atherectomy System (Boston Scientific, MN, USA) approved for PCI, utilizes a pressurized flush solution to lubricate the drive shaft in order to reduce friction, heat generation, and sudden drops in revolutions per minute.<sup>7</sup> When performing RA, rota-flush solution is used, which is traditionally composed of heparinized saline, vasodilator, and Rotaglide lubricant. Rotaglide is a specially designed solution composed of olive oil, egg yolk, phospholipids, sodium deoxycholate, L-histidine, disodium ethylene diaminetetra acetic acid (EDTA), sodium hydroxide, and

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water. Its inclusion leads to less heat generation in comparison with heparinized saline alone.

The theoretical benefit of performing RA in absence of Rotaglide solution is multifactorial and includes benefits such as avoidance of allergic reaction in patients with egg allergy and decreased cost which is especially important in developing countries with poor health insurance coverage. The use of the preferred cocktail varies widely among RA experts. The efficacy and safety of alternative rota-flush (ARF) solutions without Rotaglide has not been thoroughly investigated. In a recent retrospective study by Hoyle L. Whiteside et al<sup>8</sup> an ARF solution containing heparin and vasodilator in absence of Rotaglide resulted in similar rates of procedural success with statistically non-significant increase of MACE. They concluded that alternative rota flush (ARF) solution can be effective alternatives to traditional solutions containing Rotaglide lubricant. Vasodilator drugs like nitroglycerin, verapamil, and nicorandil in different combinations have been traditionally included in the flush solution to reduce the risk of microvascular obstruction. Adverse reactions such as hypotension and bradycardia can develop and complicate the procedure with the use of these vasodilators. A recent retrospective non-randomized study by Lee et al<sup>9</sup> concluded that flush solution without vasodilator is a feasible and reasonable alternative to Rotaglide and vasodilator.

There is paucity of published literature comparing feasibility and safety of alternative rota-flush solution without Rotaglide and with vasodilator (ARF solution) and without vasodilator (OHRF solution). We sought to evaluate the procedural success rate and safety of an OHRF solution containing heparinized saline only without vasodilator.

## 2. Materials and methods

### 2.1. Study population

We enrolled patients who underwent after obtaining institutional ethical clearance. Data was analysed from 48 patients who fulfilled the inclusion criteria in accordance with the study protocol.

### 2.2. Procedural technique

PCI was performed according to standard techniques. The vascular access route was femoral route in all except one patient. In this one patient, the procedure was initially attempted through the radial route which was unsuccessful after which the femoral route was accessed. The procedure was completed successfully in all patients. Dual-antiplatelet therapy in the form of aspirin and P2Y12 inhibitors was administered prior to RA in all patients. To achieve activated clotting time (ACT) > 250 seconds unfractionated heparin (UFH) was administered intravenously throughout the procedure. The selection of arterial access sheath and burr size was at the discretion of the operating physician. As per institutional policy DES were implanted in all cases.

Typically, a 6 or 7 Fr guiding catheter was used depending on the maximum burr size. A 0.014" work-horse wire was used to cross the target lesion followed by wire exchange for 0.009" Rota-floppy wire (Boston Scientific, MN, USA) via microcatheter. The use of either ARF or OHRF solution was based on operator preference. The ARF solution contained 5000 Units UFH, and vasodilator (2000 mcg nitroglycerin and 4 mg diltiazem) in 500 ml normal saline without Rotaglide. The OHRF solution contained only 5000 Units UFH in 500 ml normal saline without vasodilator and Rotaglide. Rota-flush solution was administered through pressure bag infusion and the burr was advanced through the lesion using pecking motion (quick push-forward/pull-back movement of the burr). The duration of

each pass with the burr was restricted to less than 20 s. The decision to proceed with coronary angioplasty and/or stent placement was routinely guided by angiography.

All patients were treated with dual antiplatelet and statin therapy for a minimum period of one year. Beta-blocker, and angiotensin-converting enzyme inhibitor or angiotensin II receptor blocker were adhered to unless clinically contraindicated.

### 2.3. Data collection

All data for demographic characteristics (such as cardiovascular risk factors), procedural characteristics, echocardiographic findings, peri-procedural complications, and RRAE was collected for all patients. Physician notes were reviewed up until the time of discharge from which both subjective and objective data such as the development of anginal symptoms or hematoma at arterial access site were extracted.

### 2.4. Study endpoints

The study end points were procedural success and RRAE. Procedural success was defined as thrombolysis in myocardial infarction (TIMI) flow grade 3 and residual stenosis  $\leq 30\%$  after final percutaneous transluminal coronary angioplasty (PTCA) and/or stent placement without emergency coronary artery bypass graft surgery (CABG) and/or PCI, stent loss or death. The procedure was considered a failure if stent loss, death, or an indication for emergent PCI and/or CABG developed during the first 24 h. RRAE was defined as bradycardia requiring transvenous pacing, hypotension requiring vasopressors, or placement of mechanical hemodynamic support (intravenous aortic balloon pump), sustained ventricular arrhythmia, need for TLR, non-fatal myocardial infarction (MI), stroke, and cardiac death.

### 2.5. Study definitions

TLR was defined as the development of ischemia due to a stenosis of  $\geq 50\%$  of the luminal diameter either within the stent or within 5 mm of its borders which required surgical or percutaneous revascularization. Acute and subacute stent thrombosis was defined according to the Academic Research Consortium definition.<sup>10</sup> MI was defined as the development of new ST-segment elevation or an increase in cardiac biomarkers either  $\geq 2$  times the upper limit of normal or above the previously documented value in addition to the development of ischemic symptoms, unless a non-cardiac origin was documented in the electronic medical record it was to be considered cardiac in origin. Minor peri-procedural complications were defined as development of hematoma or pseudoaneurysm at the vascular access site or reported systemic blood loss from any source.

### 2.6. Statistical analysis

Data was statistically analysed with IBM SPSS version 16.0 (Statistical Package for Social Services, Chicago, IL, USA). Continuous variables were presented as mean  $\pm$  SD and categorical variables as frequencies and percentages. The difference between means for continuous variables was tested by two-tailed *t*-test. Categorical variables were compared with chi-square statistics or Fishers exact test in testing the significance of dependent variables on independent variables. Descriptive statistics was used to analyse procedural characteristics. All *p*-values < 0.05 were considered statistically significant.

### 3. Results

#### 3.1. Demographic characteristics

Baseline demographic characteristics including cardiovascular risk factors are documented in Table 1. Mean age of the study population was 62.81 years (range 48–77 years). Majority of the patients in both groups were male (79.2% overall). Diabetes mellitus was the most common risk factor with incidence of 68.75%. History of MI was present in 52.2% patients of both ARF and OHRF solution groups (p = 0.99). Out of a total of 48 lesions which were targeted for intervention, left anterior descending artery (LAD) was the most common targeted vessel in both groups (73.9% in ARF vs. 72.0% in OHRF solution group) as illustrated in Fig. 1. Unprotected left main disease was targeted in two patients one in the ARF group and one patient in the OHRF group. Details of procedural characteristics are provided in Table 2.

#### 3.2. Clinical outcomes

The study endpoint of procedural success was achieved in all patients of both groups with acceptable rates of severe hypotension, bradycardia, slowflow, and coronary spasm. Burr was delivered successfully in all target lesions in both groups and subsequently removed successfully after the procedure. RRAE occurred in eight patients in each group (34.7% vs. 32.0%, p = 0.83) in the ARF and OHRF group, respectively. TLR and stroke did not occur in any patient. Four(17.4%) patients developed hypotension requiring vasopressor in the ARF group vs. three (12.0%) patients in the OHRF group. One patient from each group developed intra-operative complete heart block (CHB) which required temporary pacing support. Five patients developed transient bradycardia during RA, out of these two patients (8.7%) were in the OHRF group and three patients (12.0%) were in the ARF group (p = 0.56). Total number of patients who developed slow flow during the procedure was four out of which one (4.3%) was from the ARF group and three (12.0%) patients were from the OHRF group. Clinical outcomes according to type of rota-flush used during the procedures detailed in Table 3 and incidence of each minor peri-procedural complication is displayed in Fig. 2.

### 4. Discussion

Procedural success was achieved for RA performed with both the predefined ARF and OHRF solutions. In all cases, the burr was successfully delivered to the target lesion. The procedural success rate of ARF solution without standard Rotaglide and vasodilator in our study is comparable to a previous study by Lee et al<sup>9</sup> which evaluated the safety and feasibility of a OHRF solution in the absence of vasodilators in a retrospective case series of 67 patients

and concluded that it is a reasonable alternative to standard flush solutions containing Rotaglide lubricant. Similarly procedural success rate of 98.0% (98/100) of cases utilizing the ARF solution without standard Rotaglide compared to a 100.0% (50/50) success rate in the Rotaglide group (p = 0.553) was reported by HoyleL. Whiteside et al<sup>8</sup> This study provides further evidence for use of the predefined rota-flush solution without Rotaglide in RA. The above two studies were single centre studies from western populations. This data provides additional evidence to validate the efficacy of predefined ARF and OHRF solutions in RA in an Asian population.

No cardiac death, peri-procedural MI, TLR, or stroke was observed in our study. Although the incidence of RRAE was numerically increased in the rota-flush with vasodilator group, the disparity between the two groups did not meet statistical significance. Most common adverse events observed were hypotension, bradycardia, and slow flow with no statistically significant difference between the two groups. Although statistically non-significant (p = 0.59), a numerically higher number of patients developed hypotension requiring vasopressor in the ARF group compared to the OHRF group (17.4% vs. 12.0%). Significant hypotension occurred in 6.0% in the study by Lee et al<sup>9</sup> while it was found to be 8.0% and 4.0% in ARF and Rotaglide group respectively in a study by L. Whiteside et al.<sup>8</sup> Out of the four patients from the ARF group who developed hypotension, two patients had associated episodes of bradycardia in the setting of right coronary artery (RCA) intervention, the other two developed hypotension in the setting of LAD intervention, which was likely attributable to use of vasodilator in rota-flush and underlying cardiac pathology. Of the three patients from the OHRF group who developed hypotension in the setting of LAD intervention, one had accompanying bradycardia and slow flow, while another patient had hypotension accompanied with slow flow likely due to long lesion >30 mm and absence of vasodilator. No patient had hypotension based on hemodynamic instability prior to intervention.

In comparison to ROTAXUS trial<sup>11</sup> where no patient developed slowflow/no reflow, one patient (4.3%) from the ARF group and three (12.0%) patients from the OHRF group developed slowflow in our study. The rate of slow flow in our study is comparable to those by Lee et al.<sup>9</sup> This statistical non-significant but numerically higher rate of no slowflow in OHRF group is likely due to two factors, absence of vasodilator and long lesion length (>30 mm). There is a lack of evidence supporting higher risk for adverse event in patients with a lesion length (>25 mm).<sup>9</sup>

All patients who developed slow flow during the procedure were reverted by intracoronary nitroglycerin, adenosine, tirofiban or eptifibatide, and angiography demonstrated TIMI 3 flow prior to departure from the catheterization laboratory.

One patient from the ARF group developed intra-operative CHB in the setting of RCA intervention and reverted to normal sinus

**Table 1**  
Baseline demographics according to type of rota-flush used during the procedure.

Variable	Type of rota-flush		p-value
	Alternative rota-flush (n = 23)	Heparin rota-flush (n=25)	
Tobacco chewing	9 (39.1%)	11 (44.0%)	.73
Smoking	6 (26.1%)	6 (24.0%)	.86
Diabetes mellitus	13 (56.5%)	20 (80.0%)	.07
Hypertension	12 (52.2%)	13 (52.0%)	.99
Hyperlipidemia	10 (43.5%)	6 (24.0%)	.15
History of cerebrovascular accident	0 (0%)	1 (4.0%)	NA
History of myocardial infarction	12 (52.2%)	13 (52.0%)	.99
History of percutaneous coronary intervention	5 (21.7%)	6 (24.0%)	.85
History of coronary artery bypass graft	0 (0%)	0 (0%)	NA

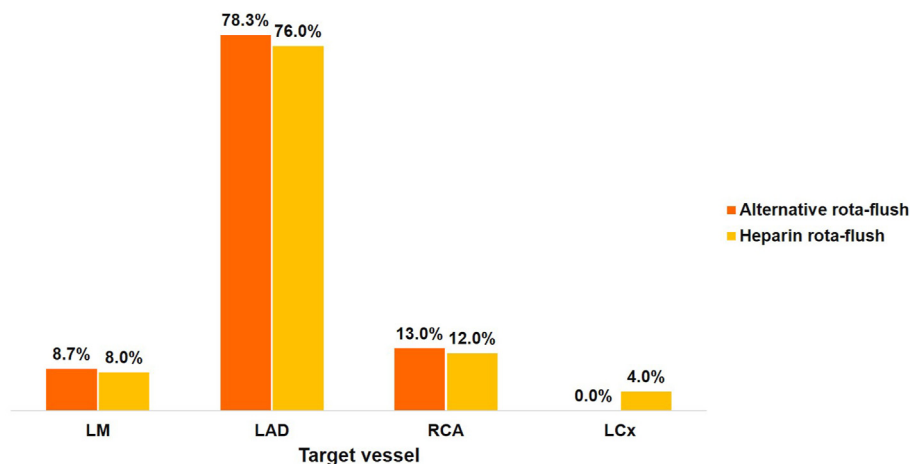


Fig. 1. Details of procedural characteristics.

**Table 2**  
Procedural characteristics according to type of rota-flush used during the procedure.

Variable	Type of rota-flush		p-value
	Heparin with vasodilator (n = 23)	Heparin without vasodilator (n=25)	
<b>Sheath size</b>			
6 Fr	4 (17.4%)	3 (12.0%)	.59
7 Fr	19 (82.6%)	22 (88.0%)	.59
<b>Vascular access</b>			
Radial	0 (0%)	0 (0%)	NA
Femoral	23 (100%)	24 (96.0%)	
Radial + femoral	0 (0%)	1 (4.0%)	
<b>Target vessels</b>			
Left anterior descending artery	17 (73.9%)	18 (72.0%)	.88
Left anterior descending artery/First diagonal	1 (4.3%)	0 (0%)	NA
Left anterior descending artery/Left circumflex artery	0 (0%)	1 (4.0%)	
Left circumflex artery	0 (0%)	1 (4.0%)	
Left main artery	1 (4.3%)	0 (0%)	
Left main artery bifurcation	1 (4.3%)	0 (0%)	
Left main artery/Left anterior descending artery	0 (0%)	2 (8.0%)	
Right coronary artery	3 (13.0%)	3 (12.0%)	.91
<b>Adjunct tools</b>			
Microcatheter	5 (21.7%)	8 (32.0%)	.42
<b>Maximum burr size</b>			
1.25 mm	12 (52.17%)	10 (40.00%)	.57
1.50 mm	10 (43.47%)	15 (60.00%)	.25
1.75 mm	1 (4.3%)	0 (0%)	NA
Ejection fraction, (%)	56.13 ± 7.71	52.72 ± 8.14	.14
Rotations per min	162,608 ± 10,098	157,800 ± 13,850	.17
Passes/case	4.61 ± 1.31	3.96 ± 1.67	.14
Stent diameter, mm	2.90 ± 0.33	2.73 ± 0.32	.07
Stent length, mm	37.04 ± 8.91	37.84 ± 7.58	.74
Final TIMI flow	3.00 ± 0.00	3.00 ± 0.00	NA

TIMI = Thrombolysis in Myocardial Infarction.

rhythm three days post procedure, while the other patient in the setting of RCA intervention developed CHB during the procedure and reverted to sinus rhythm spontaneously during procedure. One patient in the OHRF group, in the setting of LAD intervention developed CHB. Permanent pacemaker implantation was done after 48 h for persistent CHB.

Recent consensus document on RA by Sakakura K. et al<sup>12</sup> concluded that as long as the option of intra-coronary injection of

vasodilators is available in the catheterization laboratory, either combination of drugs is acceptable and ACT should be checked before RA to prevent possible thrombus formation, if only saline is used. Important factors which favour use of rota-flush solution without Rotaglide are its cost effectiveness and avoidance of allergic reaction in patients known allergic to egg.

As evidence of successful RA with acceptable adverse event rates without using Rotaglide solution are gradually increasing, it may

**Table 3**  
Clinical outcomes according to type of rota-flush used during the procedure.

Variable	Type of rota-flush		p-value
	Alternative rota-flush (n = 23)	Heparin rota-flush (n=25)	
RRAE	8 (34.7%)	8 (32.0%)	.83
Hypotension	4 (17.4%)	3 (12.0%)	.59
Bradycardia	3 (13.0%)	2 (8.0%)	.56
Ventricular arrhythmia	0 (0%)	0 (0%)	NA
Slow flow	1 (4.3%)	3 (12.0%)	.33
No reflow	0 (0%)	0 (0%)	NA
Tamponade	0 (0%)	0 (0%)	NA
Dissection	0 (0%)	0 (0%)	NA
Recurrent angina	0 (0%)	0 (0%)	NA
Blood loss	0 (0%)	0 (0%)	NA
Pseudoaneurysm	0 (0%)	0 (0%)	NA
Hematoma	3 (13.0%)	2 (8.0%)	.56
Guidewire entrapments	0 (0%)	0 (0%)	NA

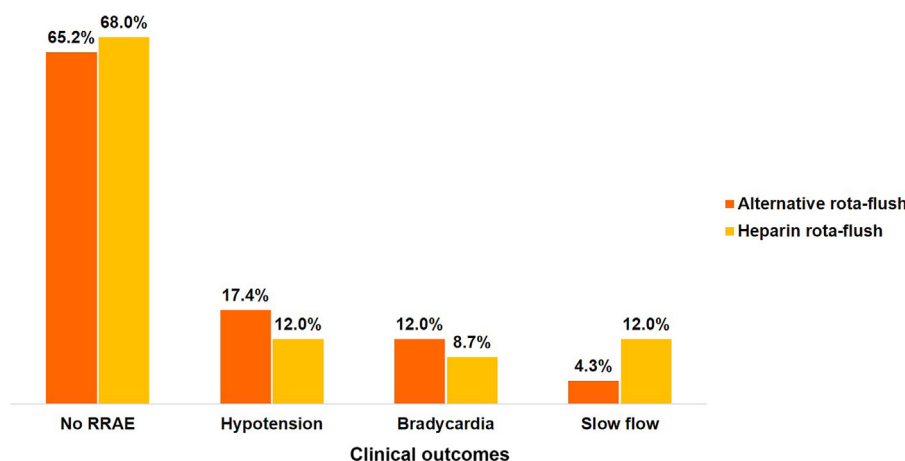


Fig. 2. Incidence of minor peri-procedural complications.

lead to future formulation of guidelines or guidance regarding use of the rota-flush solution with or without vasodilator without Rotaglide. In view of paucity of published literature, this data provides new evidence in favour of using relatively inexpensive OHRF solution without vasodilator. The decision to use vasodilator may be taken on individual basis depending on clinical status like hypotension or severe left ventricular dysfunction or bradycardia at baseline of the patients and lesion characteristics.

**5. Limitations**

This was a non-randomized study conducted at a single centre. The study is also limited by its small sample size. The number of patients that had underwent RA was hugely affected by the unprecedented COVID-19 pandemic. Comparison of patients who underwent RA with the conventional rota-flush solution was not performed with patients who underwent RA with the standard rota-flush solution with Rotaglide. Validation of our findings in a larger group and a longer follow up period would be of benefit.

**6. Conclusion**

Both OHRF solution containing 5000 Units UFH, in 500 ml of normal saline without vasodilator or Rotaglide, and ARF solution containing 5000 Units UFH, and vasodilator (2000 mcg nitroglycerin, and 4 mg diltiazem) in 500 ml normal saline without Rotaglide can be a reasonable and effective alternative to standard rota-flush solution containing Rotaglide lubricant and vasodilators like nitroglycerin, verapamil, or nicorandil in different combination particularly in patients with known allergies to olive oil, egg yolk phospholipids, glycerin, sodium deoxycholate, L-histidine, disodium EDTA, or sodium hydroxide. RA performed with the pre-defined OHRF solution without vasodilator resulted in similar rates of procedural success as in alternative Rota-Flush solution(ARF) with vasodilator. There was no statistically significant difference in RRAE observed between these two groups.

**What is Already Known?**

- There is limited evidence on feasibility and safety of only heparin rota-flush(OHRF) solution in rotational atherectomy (RA).

**What this Study Adds?**

- The OHRF solution is particularly attractive in a patients with hypotension, severe left ventricular dysfunction, or bradycardia at baseline. Validation of our findings in a larger group and for a longer follow up period are needed to determine safety and efficacy of this treatment strategy compared with the standard rota-flush solution.

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**Declaration of competing interest**

There is no direct or indirect financial interest of author in the subject matter of the submitted manuscript. The authors declare no other potential conflict of interest.

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