e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2025; 17(1); 50-55

Original Research Article

# Evaluating Safety Outcomes of Rotablation-Guided PCI in Calcified Coronary Lesions: A Single Centre Study

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**Received: 25-10-2024 / Revised: 23-11-2024 / Accepted: 26-12-2024**
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**Conflict of interest: Nil**

**Abstract:**

**Background:** Management of severely calcified coronary artery disease (CAD) poses significant procedural challenges during percutaneous coronary intervention (PCI). Rotablation-guided PCI, which uses a high-speed rotational atherectomy device, has emerged as an important technique to facilitate stent deployment in these complex lesions. However, data regarding its safety outcomes, especially in resource-constrained settings, remain limited.

**Methods:** We conducted a mixed-design cohort study in the Department of Cardiology at MDM Hospital (Dr. S.N. Medical College, Jodhpur) from January 2023 to December 2024. Consecutive patients aged >18 years with significant (>70% stenosis) calcified coronary lesions were included. Procedural details—particularly comparing radial (RRA) and femoral (RFA) access routes—were recorded. Immediate and 3-month post-hospital complications were assessed. Statistical analyses were performed using chi-square and t-tests, with $p<0.05$ denoting significance.

**Results:** A total of 82 patients underwent rotablation-guided PCI. Baseline demographics and clinical characteristics were statistically comparable between RFA (60.98%) and RRA (39.02%) groups ($p>0.05$). The left anterior descending artery (LAD) was the most commonly treated vessel (78.05%). TIMI 3 flow was achieved in 100% of cases. Immediate complications included cardiac perforation (9.76%) and other minor complications (12.19%), with no statistically significant difference between access routes ($p=0.368$). All patients were free from post-hospital complications at the 3-month follow-up.

**Conclusion:** Rotablation-guided PCI in calcified coronary lesions demonstrated favorable safety outcomes in this single-centre study, with no significant differences between radial and femoral access routes. The technique appears to be a safe adjunctive therapy in managing complex calcified lesions, enabling successful stent deployment and excellent short-term outcomes.

**Keywords:** Rotablation, Coronary Artery Disease, Calcified Lesions, Percutaneous Coronary Intervention, Radial Access, Femoral Access.



## Introduction

Coronary artery disease (CAD) remains the leading cause of morbidity and mortality worldwide, posing a substantial burden on healthcare resources [1]. Advances in percutaneous coronary intervention (PCI) techniques, including the use of drug-eluting stents and improved antiplatelet regimens, have significantly improved patient outcomes [2]. However, heavily calcified coronary lesions continue to pose clinical and procedural challenges, contributing to suboptimal stent expansion, higher rates of in-stent restenosis, and potential periprocedural complications [3]. Rotational atherectomy (commonly referred to as rotablation) is a specialized technique designed to modify heavily calcified plaques. The high-speed rotational burr selectively ablates calcific and fibrous tissue, creating a smoother arterial lumen and facilitating stent delivery [4]. Although rotablation has been in use for several decades, the evidence base regarding its safety and long-term efficacy continues to evolve, particularly with the emergence of alternative plaque-modifying techniques such as orbital atherectomy and intravascular lithotripsy [5]. Furthermore, the choice of vascular access route—radial versus femoral—remains a point of debate. While radial

access is associated with fewer access-site complications and enhanced patient comfort, it can present technical difficulties in the setting of complex and calcified lesions [6]. On the other hand, femoral access may facilitate larger-bore catheters and device stability but carries a higher risk of bleeding complications [7].

In low- and middle-income countries, specialized devices like the rotational atherectomy system are less frequently used due to cost constraints and the perceived risk of complications, underscoring the importance of local data to validate the technique [8]. Hence, conducting focused single-centre studies can fill knowledge gaps regarding the procedural feasibility and clinical outcomes of rotablation-guided PCI under real-world conditions.

This study aims to evaluate the safety outcomes of rotablation-guided PCI in patients with calcified coronary lesions and compare procedural success, immediate complications, and short-term follow-up between radial (RRA) and femoral (RFA) approaches. By systematically documenting demographic information, comorbid risk factors, procedural details, and outcomes up to 3 months post-discharge, this study seeks to contribute evidence toward optimizing care for this high-risk subset of patients. In doing so, we hope to guide cardiologists and interventionalists in selecting the most appropriate strategy to manage heavily calcified coronary lesions, thereby improving both procedural and long-term clinical success.

## Materials and Methods

**Study Design and Setting:** This mixed-design cohort study is being conducted in the Department of Cardiology at MDM Hospital, affiliated with Dr. S.N. Medical College, Jodhpur. Enrollment extends from January 2023 to December 2024, following institutional ethical committee approval.

### Inclusion Criteria

1. Patients aged >18 years.
2. Patients with significant coronary artery stenosis (>70% on coronary angiography) and calcified coronary lesions.

### Exclusion Criteria

1. Patients with chronic kidney disease (eGFR <60 mL/min/1.73 m^2).
2. Patients with anemia (hemoglobin <10 g/dL).
3. Patients presenting in cardiogenic shock (systolic BP <90 mmHg and cardiac index <1.8 L/m^2).

**Patient Enrollment and Data Collection:** All eligible patients admitted for coronary angiography and PCI during the study period were screened. Those fulfilling the inclusion criteria and providing written informed consent were enrolled. Calcification on angiography was further evaluated using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) whenever feasible, to determine the extent and precise location of the calcified lesion.

For each patient, demographic data, comorbidities (e.g., diabetes mellitus, hypertension, history of stroke, poor left ventricular function), and baseline clinical characteristics were recorded. Procedural details—access route (radial vs. femoral), lesion location (index artery), burr size and rotational speed, stent deployment, and adjunctive pharmacotherapy—were documented. Immediate post-procedural events were monitored, and patients received standard in-hospital care.

**Follow-up:** Patients were followed up for 3 months post-discharge. Follow-up data were obtained during outpatient visits or via telephone calls, focusing on the occurrence of any adverse events such as re-infarction, re-hospitalization, or other complications. Notably, serious procedural complications—cardiac perforation and cardiac tamponade—were carefully documented.

**Sample Size:** Because this descriptive, observational study focuses on an uncommon but important intervention (rotablation) in a limited timeframe, all eligible patients presenting from January 2023 to December 2024 were included.

**Statistical Analysis:** Categorical variables were expressed as counts and percentages and compared using chi-square or Fisher's exact tests as appropriate. Continuous variables were reported as mean ± standard deviation (SD) and analyzed using t-tests for two-group comparisons or ANOVA for more than two groups. A p-value <0.05 was considered statistically significant.

## Results

**Baseline Demographics and Clinical Characteristics:** A total of 82 patients presenting with significant calcified coronary lesions were included in this interim analysis. As shown in Table 1, the mean age was 64.78±8.95 years, with a male predominance (65.85%) over females (34.15%).

The majority of patients had normal to mildly reduced left ventricular ejection fraction (LVEF=0. 47±0.13). Regarding clinical presentation, 41.46% of patients had acute coronary syndrome (ACS), while 58.54% had non-ACS presentations. Crucially, no statistically significant differences were observed when comparing the baseline demographic and clinical characteristics across different procedural routes (RRA vs. RFA; p>0.05). This suggests that both groups were reasonably well matched, allowing for a meaningful comparison of procedural outcomes.

**Table 1: Demographic and Baseline Clinical Characteristics**

| Variable | Mean (SD) | Frequency (%) | p-value (Route) |
|---|---|---|---|
| Age | 64.78 (8.95) | | 0.986 |
| Gender - Female | | 34.15% | 0.980 |
| Gender - Male | | 65.85% | 0.980 |
| Diagnosis - ACS | | 41.46% | 0.461 |
| Diagnosis - NACS | | 58.54% | 0.461 |
| LVEF | 0.47 (0.13) | | 0.216 |

### Procedural Details

Table 2 illustrates the key procedural details. Of the total procedures, 60.98% were performed via femoral access (RFA), while 39.02% employed radial access (RRA).

The left anterior descending artery (LAD) was the most commonly treated vessel (78.05%), followed by the right coronary artery (17.07%), and other vessels (4.88%). Only 2.44% of cases required the use of an additional burr, emphasizing that minimal device escalation was needed. The mean rotational speed of the burr was approximately 158,537±3,578 rpm. There were no statistically significant differences in these procedural parameters across the access routes, suggesting that operator preference or clinical scenario rather than route choice dictated specific device utilization.

**Table 2: Procedural Details**

| Variable | Frequency (%) | Mean (SD) | p-value (ROUTE) |
|---|---|---|---|
| Route | RFA: 60.98%, RRA: 39.02% | | |
| Index Artery | LAD: 78.05%, RCA: 17.07%, Other: 4.88% | | 0.231 |
| Burr Used | No: 97.56%, Yes: 2.44% | | 0.820 |
| Average Speed of RA | | 158,537 (±3,578) | |

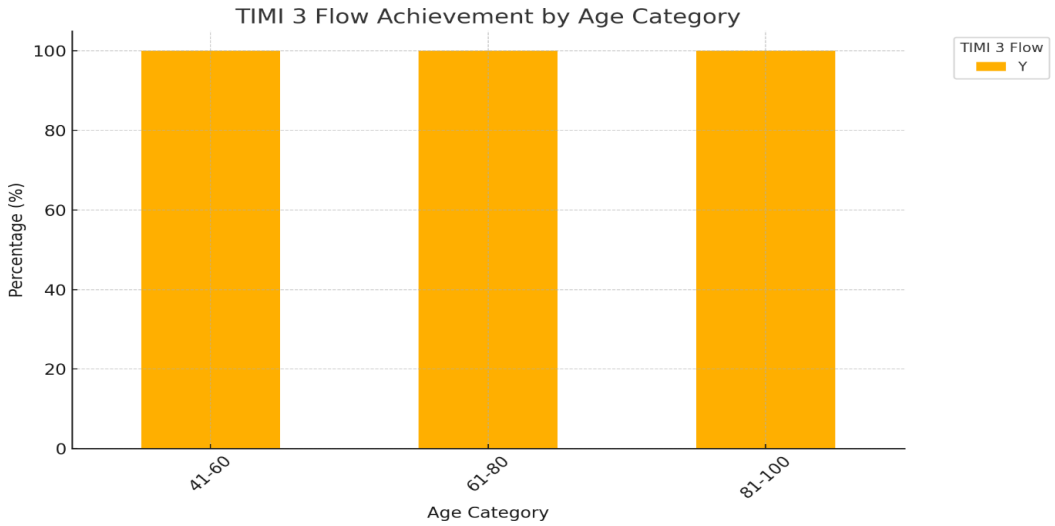


**Figure 1: TIMI 3 Flow Achievement by Age Category**

### Immediate Procedural Outcomes

As noted in Table 3, TIMI 3 flow was successfully achieved in all cases (100%). Immediate complications were relatively rare: 78.05% of patients had no complications, 9.76% experienced cardiac perforation, and 12.19% encountered other minor events (e.g., transient arrhythmias). There was no statistically significant difference in immediate complication rates between RRA and RFA (p=0.368).

This uniformity underscores the overall safety of the procedure across different access routes.

**Table 3: Immediate Procedural Outcomes with Statistical Significance**

| Variable | Frequency (%) | p-value (ROUTE) |
|---|---|---|
| TIMI 3 Flow Achieved | Yes: 100% | 1.000 |
| Immediate Complications | None: 78.05%, Cardiac Perforation: 9.76%, Others: 12.19% | 0.368 |

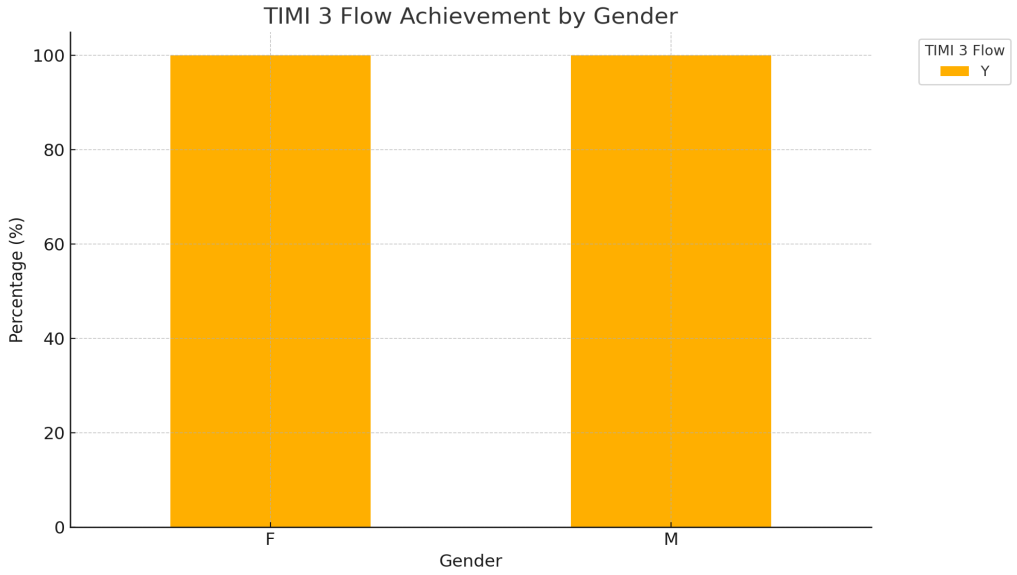


**Figure 2: TIMI 3 Flow Achievement by Gender**

**Post-Hospital Complications and Follow-up**

In terms of longer-term safety, Table 4 shows that none of the patients reported complications during the post-hospital stay up to 3 months. This finding indicates that rotablation-guided PCI in calcified lesions can yield favorable short-term outcomes with minimal morbidity.

Ongoing follow-up beyond 3 months will be necessary to assess longer-term event rates such as target lesion revascularization or stent thrombosis.

**Table 4: Post-Hospital Stay Complications**

| Variable | Frequency (%) | Notes |
|---|---|---|
| Post-Hospital Stay Complications | None: 100% | No complications reported |

In summary, the interim results highlight the safety and procedural feasibility of rotablation in a single-centre setting. Complete achievement of TIMI 3 flow, low immediate complication rates, and an absence of post-hospital adverse events all suggest that rotablation-guided PCI may be a valuable technique for challenging calcified lesions in real-world practice.

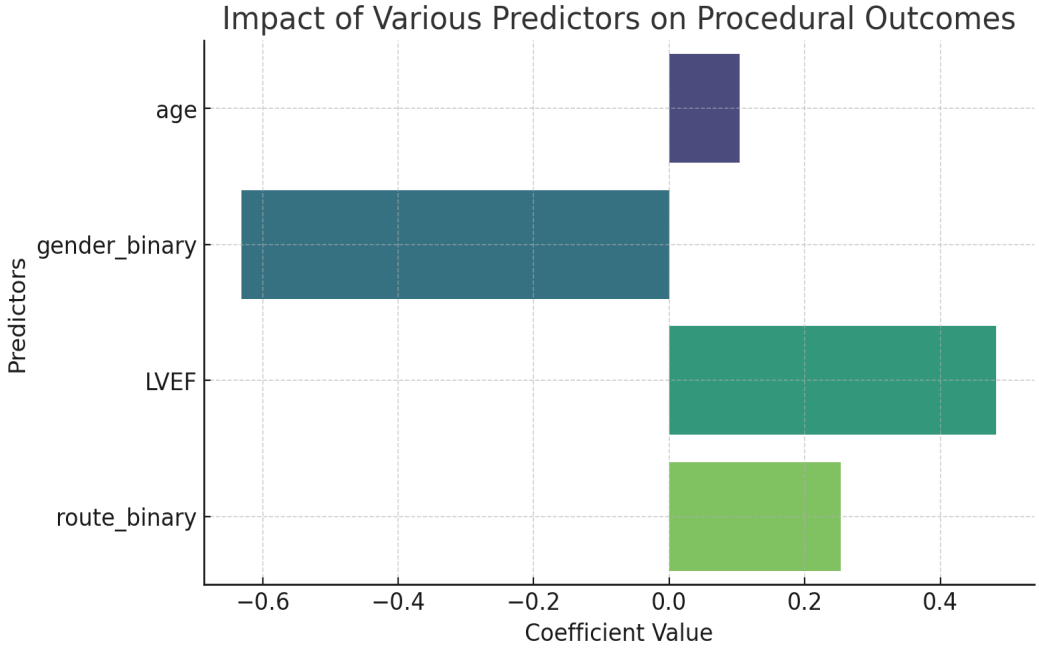


**Figure 3: Impact of Various Predictors on Procedural Outcomes**

## Discussion

Heavily calcified coronary lesions present a unique challenge in PCI, often leading to suboptimal stent expansion and higher complication rates if not adequately treated [9]. Rotational atherectomy modifies the calcified plaque, thereby facilitating optimal stent placement. In this single-centre study, we observed that rotablation-guided PCI led to 100% achievement of TIMI 3 flow, underscoring its ability to achieve effective lesion debulking [10]. Although cardiac perforation occurred in approximately 10% of cases, this rate aligns with previously documented ranges in rotablation-specific registries, which report rates from 5% to 15% depending on lesion complexity [11]. Timely recognition and management of perforations—along with meticulous burr size selection—can significantly mitigate adverse outcomes [12].

The choice between radial and femoral access routes for high-risk procedures like rotational atherectomy continues to be debated [13]. Our data show no statistically significant difference in immediate complications or success rates between RRA and RFA, suggesting that operator expertise and patient anatomy may be more important determinants of successful outcomes than the choice of access route. Previous larger registries and randomized trials have similarly found that radial access is both safe and feasible in many cases, provided that operators are experienced and smaller-bore devices are adequate for lesion complexity [14]. In contrast, femoral access may be preferred for complex interventions requiring larger equipment or higher support.

Importantly, no patients in our cohort experienced major adverse events or re-hospitalization within 3 months after discharge, pointing to the potential durability of rotablation outcomes in the early phase [15]. Nevertheless, the real challenge lies in ensuring long-term lesion patency, as calcified lesions are prone to restenosis if stent expansion is inadequate. While our data confirm excellent early results, long-term follow-up is needed to ascertain the clinical impact of rotablation on freedom from target lesion revascularization.

Rotablation may incur increased procedural time, contrast use, and cost, which can be limiting factors, especially in resource-limited settings [16]. However, this study's findings suggest that with appropriate patient selection and operator proficiency, rotablation can safely expand treatment options for severe calcified CAD. Future research efforts could incorporate intravascular imaging to optimize burr selection and confirm adequate plaque modification, potentially further reducing complication rates. Additionally, prospective multi-centre registries or randomized trials would be valuable for robustly comparing rotablation with newer plaque-modification technologies such as orbital atherectomy and intravascular lithotripsy. Taken together, these interim results highlight that rotablation-guided PCI provides a safe and effective approach for addressing severely calcified lesions, with minimal immediate and short-term complications. As the study continues, additional patient enrollment and extended follow-up should yield greater insight into the long-term efficacy and safety of this crucial interventional strategy.

## Conclusion

In this single-centre study, rotablation-guided PCI proved to be a safe and effective modality for managing severely calcified coronary lesions, achieving TIMI 3 flow in all cases. Neither the choice of vascular access route nor the procedural complexity significantly influenced immediate or short-term complication rates. The absence of post-hospital complications up to 3 months further underscores the potential of rotablation as an essential tool in complex coronary interventions. Larger multi-centre studies with extended follow-up will be instrumental in validating these findings and providing more robust guidance for clinical practice.

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