Journal of Cardiovascular Disease Research
ISSN: 0975-3583, 0976-2833 VOL15, ISSUE 11, 2024

"Comparative Outcomes of Rota Ablation in Calcific Coronary Lesions: Impact of SYNTAX Score, LV Dysfunction and Imaging vs. Non - Imaging-Guided PCI—A Single-Centre Experience from Central India"

1st Author:

- Name: Dr Ajinkya Mahorkar
- Designation: Consultant Cardiologist
- Degree: DM cardiology
- Department: Cadiology
- Institute/College (With Full Address): Avanti Institute of Cardiology, Abyankar road ,Nagpur,India

2nd Author:

- Name: Dr Virag Mahorkar
- Designation: Consultant Cardiologist
- Degree: DNB Cardiology
- Department: Cadiology
- Institute/College (With Full Address): Avanti Institute of Cardiology, Nagpur,India

3rd Author:

- Name: Dr Avanti Mahorkar
- Designation: Consultant Cardiologist
- Degree: DM Cardiology
- Department: Cadiology
- Institute/College (With Full Address): Avanti Institute of Cardiology, Nagpur,India

4rd Author:

- Name: Dr Uday Mahorkar
- Designation: Consultant Cardiologist
- Degree: DM,DNB Cardiology
- Department: Cadiology
- Institute/College (With Full Address): Avanti Institute of Cardiology, Nagpur,India

5rd Author:

- Name: Dr Tannu Namdeo
- Designation: Consultant Cardiologist
- Degree: DM Cardiology

- Department: Cadiology
- Institute/College (With Full Address): Avanti Institute of Cardiology, Nagpur,India

6th Author:

- Name: Dr Suresh Sarwale
- Designation: Consultant Cardiologist
- Degree: DM Cardiology
- Department: Cadiology
- Institute/College (With Full Address): Avanti Institute of Cardiology, Nagpur,India

7th Author:

- Name: Dr Amol Donkalwar
- Designation: Consultant Physician
- Degree: MD Medicine
- Department: Cadiology
- Institute/College (With Full Address): Avanti Institute of Cardiology, Nagpur,India

Corresponding Author

- Name: Dr Ajinkya Mahorkar
- Designation: Consultant Cardiologist
- Degree: DM Cardiology
- Department: Cardiology
- Institute/College (With Full Address): Avanti Institute of Cardiology, Nagpur,India
- Email ID: ajinkyamahorkar1@gmail.com
- Residential Address: Flat 102, Awing, Ujjwal Flats,Rahate colony,Nagpur, Maharashtra,India.

Abstract

Introduction: Severe calcified coronary artery disease (CAD) complicates percutaneous coronary intervention (PCI) by limiting stent expansion, leading to suboptimal outcomes. Rotational atherectomy (RA) has been instrumental in treating calcified lesions, enhancing procedural success. Despite its widespread use, the impact of SYNTAX score, left ventricular dysfunction (LVF), and imaging guidance on outcomes of RA-PCI remains understudied, especially in low-income settings. This study aims to assess these factors in patients undergoing RA-PCI in Central India.

Materials and Methods: This retrospective, observational study included 63 patients with calcific coronary lesions who underwent RA-PCI from 2018 to 2023. Patients were categorized based on SYNTAX score, LVEF (<40% vs ≥40%), and use of imaging. The primary outcome was major adverse cardiovascular events (MACE), including death, non-fatal myocardial infarction, and stroke. Statistical analyses were conducted using SPSS.

Results: The mean age of patients was 66.8 ± 8.9 years, with 74.6% male and 46% diabetic. Most patients had low SYNTAX scores (<22), and LAD was the most commonly treated vessel. IVUS was used in 23.8% of cases and OCT in 15.9%. The overall MACE rate was 15.9%, with cardiovascular mortality at 11.1%. Imaging-guided PCI showed better survival trends but was not statistically significant. Reduced LVEF (<40%) correlated with worse outcomes, though not statistically significant.

Conclusion: RA-PCI in calcified lesions shows favourable outcomes, with hypertension as a key predictor of MACE. Imaging guidance trends toward better survival but needs further investigation. Larger studies are needed to clarify the role of imaging and LVEF on outcomes.

Introduction –

Severe calcified coronary artery disease (CAD) affects approximately 20% of patients undergoing percutaneous coronary intervention (PCI)[1]. Severe calcified coronary artery disease (CAD) complicates percutaneous coronary intervention (PCI) by hindering stent delivery, leading to suboptimal outcomes such as stent under expansion, restenosis, and

thrombosis. Rotational atherectomy (RA), which uses a diamond-coated burr to debulk calcified plaque, enhances stent expansion and improves procedural success, making it a critical tool in treating heavily calcified lesions.

Rotational atherectomy-assisted PCI (RA-PCI) is frequently used for patients with complex coronary anatomy, yet important questions persist regarding its outcomes in specific subgroups, such as those with reduced left ventricular function (LVF). While intravascular imaging has shown potential in improving stent placement during RA procedures, direct comparisons between imaging-guided and non-imaging-guided RA-PCI remain limited. Furthermore, despite the increasing use of RA, robust data from middle- and low-income countries, including India, is notably lacking.

Our study seeks to fill this gap by providing a comparative analysis of short- and mid-term outcomes in patients undergoing RA-PCI at a tertiary care cardiology centre in Central India. The results could have implications for improving patient care in resource-constrained settings where coronary artery disease is becoming increasingly prevalent.

Materials and Methods:

This is a single-centre, retrospective, observational study conducted at a tertiary care cardiology centre in Central India. The study included all consecutive patients with heavily calcified coronary artery disease who underwent rotational atherectomy (RA)-assisted percutaneous coronary intervention (PCI) between January 2018 and June 2023. Patients with incomplete data or those lost to follow-up were excluded from the analysis.

Patients were categorized based on their left ventricular ejection fraction (LVEF) into two groups: those with reduced LV function (LVEF < 40%) v/s fair LV function (LVEF ≥40%), imaging-guided v/s non-imaging-guided RA-PCI and low, intermediate and high syntax score groups for comparative analysis.

The study aimed to compare the short- and mid-term clinical outcomes of these groups, focusing on the impact of above comparative groups. The primary outcomes of interest were the incidence of major adverse cardiovascular events (MACE), including all-cause mortality, Non-Fatal -myocardial infarction and stroke during the follow-up period.

Ethics approval for this study was obtained from the Institutional Ethics Committee, and the study adhered to the principles outlined in the Declaration of Helsinki, good clinical practice guidelines, and relevant local regulations.

Data collection included baseline demographic information, clinical characteristics, comorbidities, coronary angiography (CAG) findings, procedural details, and LVEF measurements. Follow-up data on MACE and other clinical outcomes were collected through electronic medical records and structured telephonic follow-ups with patients or their families. The follow-up period ranged from a minimum of 1 year to 5.5 years, with a median follow-up duration of 2.8 years.

Statistical analyses were performed using SPSS software. Categorical variables were expressed as frequencies and percentages, while continuous variables were presented as means and standard deviations or medians and interquartile ranges, depending on data distribution. The Chi-square test or Fisher's exact test was used to compare categorical variables, and continuous variables were analysed using the student t-test or Mann-Whitney U-test as appropriate. Kaplan-Meier survival analysis was performed to evaluate time to MACE, and a p-value of less than 0.05 was considered statistically significant.

Results –

Our study population consisted of 63 patients studied over approximately six years (Figure 1). The baseline characteristics of this cohort are shown in Table 1. The mean age was 66.8 ± 8.9 years, with the majority (74.6%) being over 60 years old. Most of the patients were male (74.6%), and common cardiovascular risk factors included hypertension (63.5%) and diabetes (46%). The mean left ventricular ejection fraction (LVEF) was relatively preserved at 51.2 ± 10.8%. In terms of presentation, 68.25% had unstable angina (UA) or chronic stable angina (CSA), 23.81% presented with STEMI, and 7.94% with NSTEMI.

Figure 1: Distribution of cases over six years

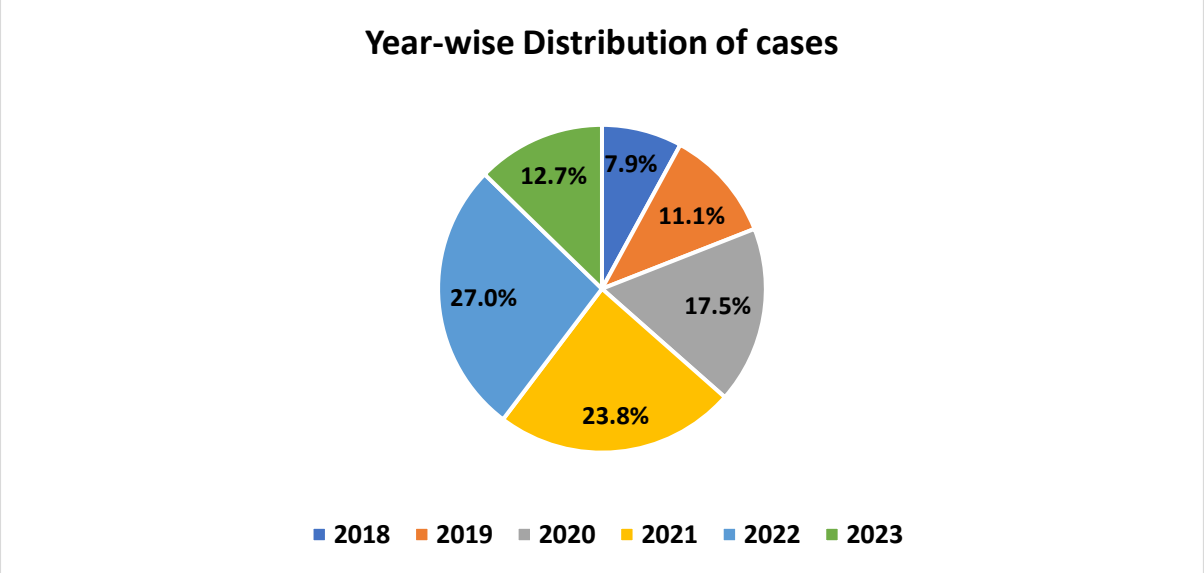


Table 1: Baseline Characteristics

Parameters	Total - 63 Subjects
Age, Mean±SD	66.8 ± 8.9
Age > 60 years	47 (74.6)
Gender, n (%)	
Male	47 (74.6)
Female	16 (25.4)

RISK FACTORS, n (%)	
HTN	40 (63.5)
Diabetes	29 (46)
LVEF, Mean±SD	51.2 ± 10.8
THROBOSUCTION, n (%)	2 (3.2)
Type of ACS, n (%)	
STEMI	15 (23.81)
NSTEMI	5 (7.94)
UA AND CSA	43 (68.25)

Angiographic and Procedural Characteristics

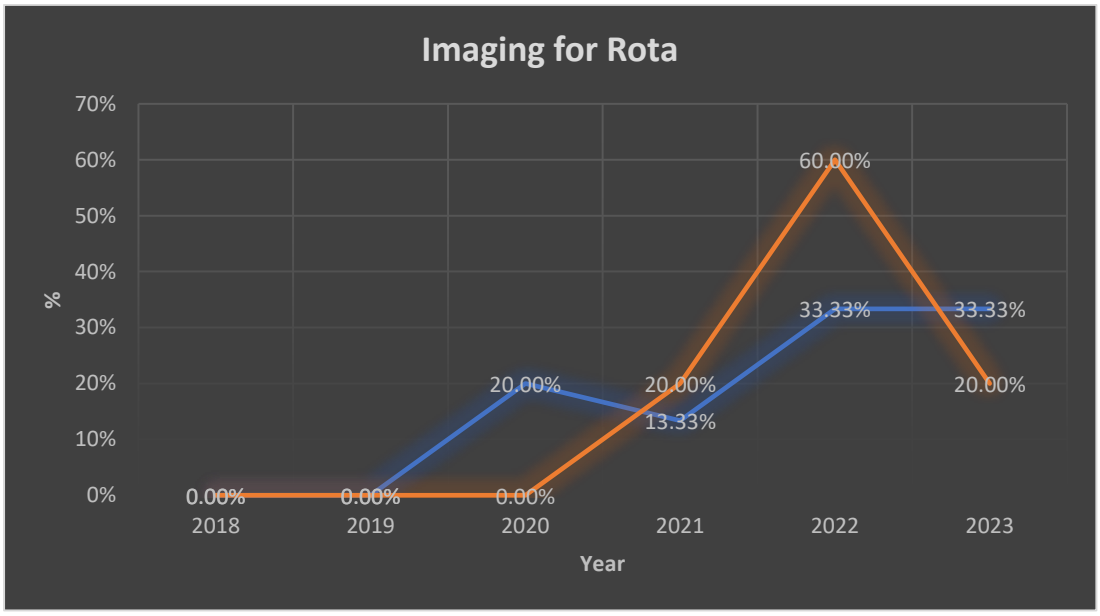
The angiographic and procedural details are presented in Table 2. Most patients (76.1%) had a SYNTAX score of less than 22, with a mean SYNTAX score of 16.15. The most commonly used burr size for rota ablation was 1.5 mm (79.3%), followed by 1.25 mm (11.1%) and 1.75 mm (9.5%). Rota ablation was performed primarily on the left anterior descending artery (LAD) in 60.31% of cases, with 17.4% involving the left main to LAD, and 15.8% in the right coronary artery (RCA). Only 3.2% of patients had undergone prior CABG. All cases required rota ablation for calcium modification, with one case (1.6%) utilizing both rota ablation and intravascular lithotripsy (IVL). In terms of imaging, IVUS was used in 23.8% of cases and OCT in 15.9%, with IVUS seeing more frequent use over time (Figure 2). The mean stent diameter was 3 ± 0.4 mm, and the average stent length was 29.9 ± 9.7 mm across 108 stents.

Table 2: Angiographic and Procedural Characteristics

Syntax Score	
<22	48 (76.1)
22-32	13 (20.63)
>32	2 (3.17)
Mean Syntax score	16.15
Burr Size	
1.25 mm	7 (11.1)
1.5 mm	50 (79.3)
1.75 mm	6 (9.5)
Vessel Rotablated - n (%)	
LM to LAD	11 (17.4)
LM to LCX	1 (1.6)
LAD	38 (60.31)
LCX	3 (4.7)
RCA	10 (15.8)
PRIOR CABG, n (%)	**2 (3.2)**

CALCUM MODIFICATION, n (%)	
ROTA	63 (100)
ROTA + IVL	1 (1.6)
IMAGING, n (%)	
IVUS	15 (23.8)
OCT	10 (15.9)
STENT THROMBOSIS, n (%)	1 (1.6)
Stent Details	
Average diameter, Mean±SD	3 ± 0.4 (n=108)
Average length, Mean±SD	29.9 ± 9.7 (n=108)

Figure 2: Trends in Imaging for Rota Ablation



Clinical Outcomes

Table 3 and Figures 3(a) and 3(b) show the clinical outcomes. The overall composite major adverse cardiovascular events (MACE) rate was 15.9%, with cardiovascular death occurring

in 11.1% of patients. The Kaplan-Meier curve in Figure 3(b) illustrates the overall MACE-free survival in the cohort.

Table 3: Clinical Outcomes

Events, n (%)	Subject=63
NON-FATAL MI	2 (3.2)
NON-FATAL STROKE	1 (1.6)
CV DEATH	7 (11.1)
Composite MACE	**10 (15.9)**

Figure 3(a): 3D Bar Diagram of Clinical Outcomes

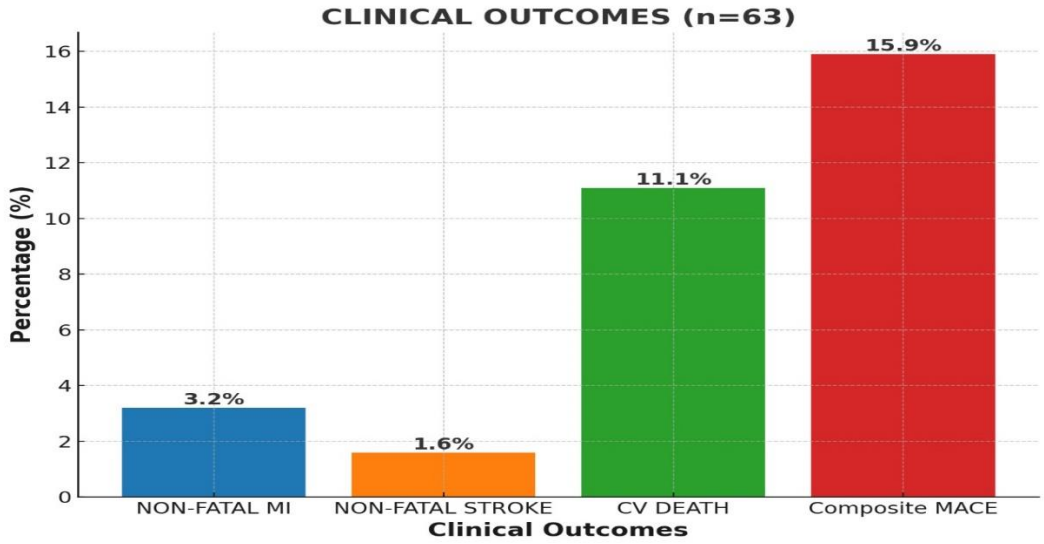
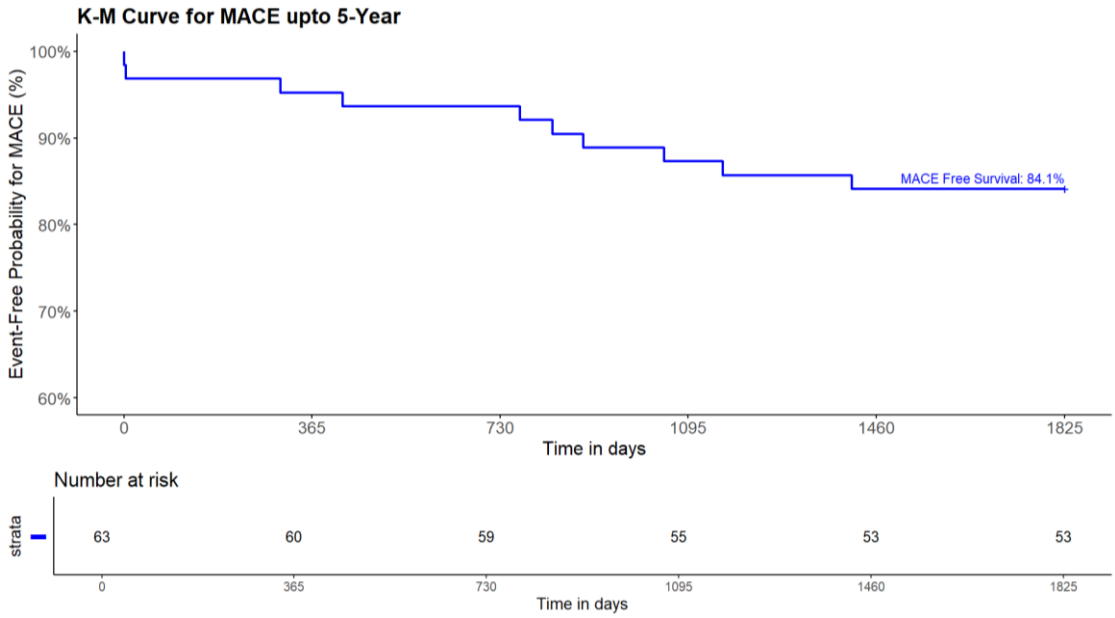


Figure 3(b): Kaplan-Meier Curve for Overall MACE-Free Survival



Comparative Survival Analysis

Figure 4 compares MACE-free survival between the STEMI/NSTEMI group versus the UA/CSA group. The p-value of 0.948 indicates no significant difference between these groups, with the NSTEMI + STEMI group showing a slightly higher MACE-free survival rate (85.0% vs. 83.7%), though not statistically significant.

Figure 4: Kaplan-Meier Analysis Between STEMI/NSTEMI and UA/CSA Groups

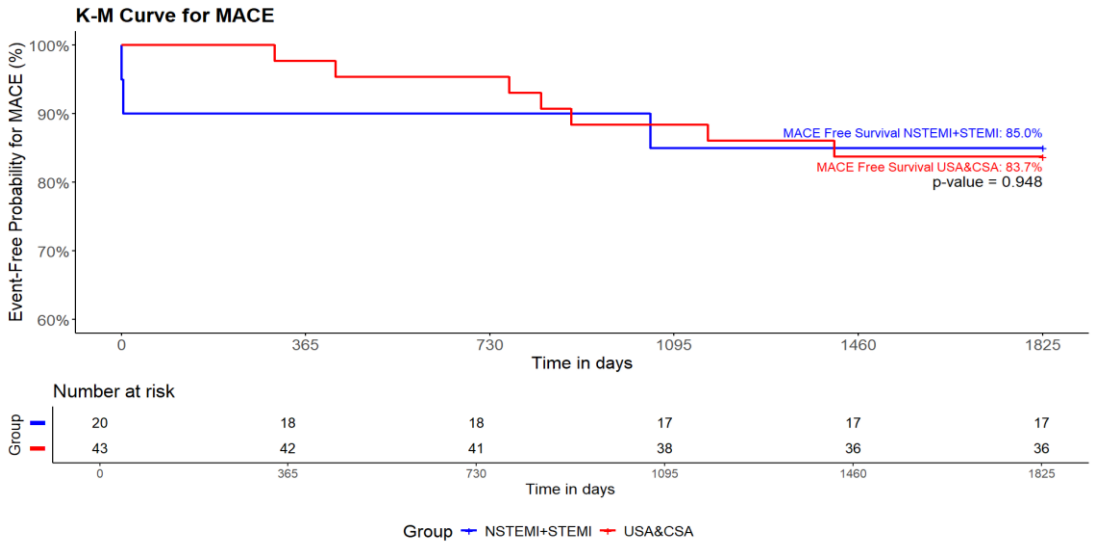


Figure 5 shows the Kaplan-Meier curve comparing MACE-free survival between imaging-guided and non-imaging-guided PCI. At 5 years, the imaging group had an event-free survival rate of 88.0%, compared to 81.6% in the non-imaging group, though the difference was not statistically significant (p-value = 0.518).

Figure 5: Kaplan-Meier Curve for Imaging-Guided vs. Non-Imaging-Guided PCI

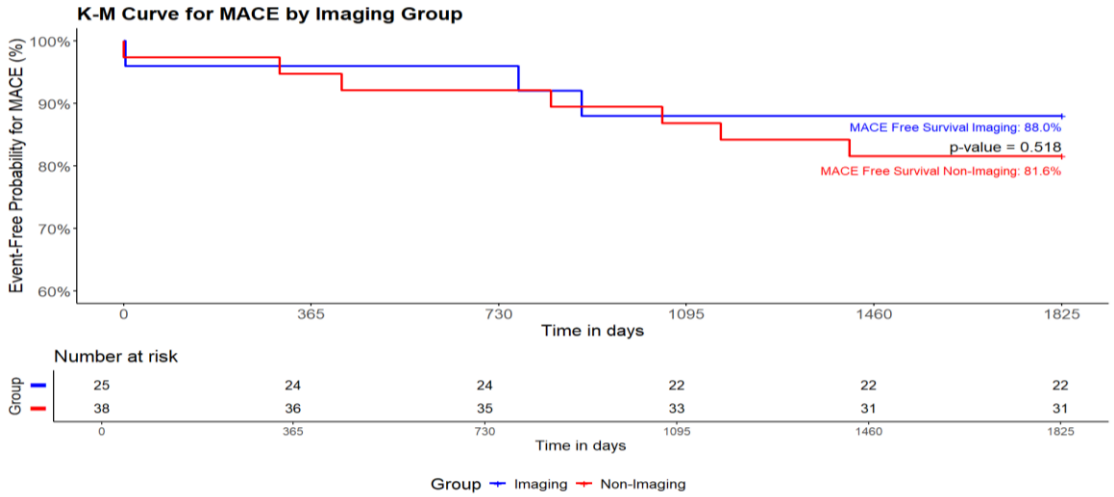
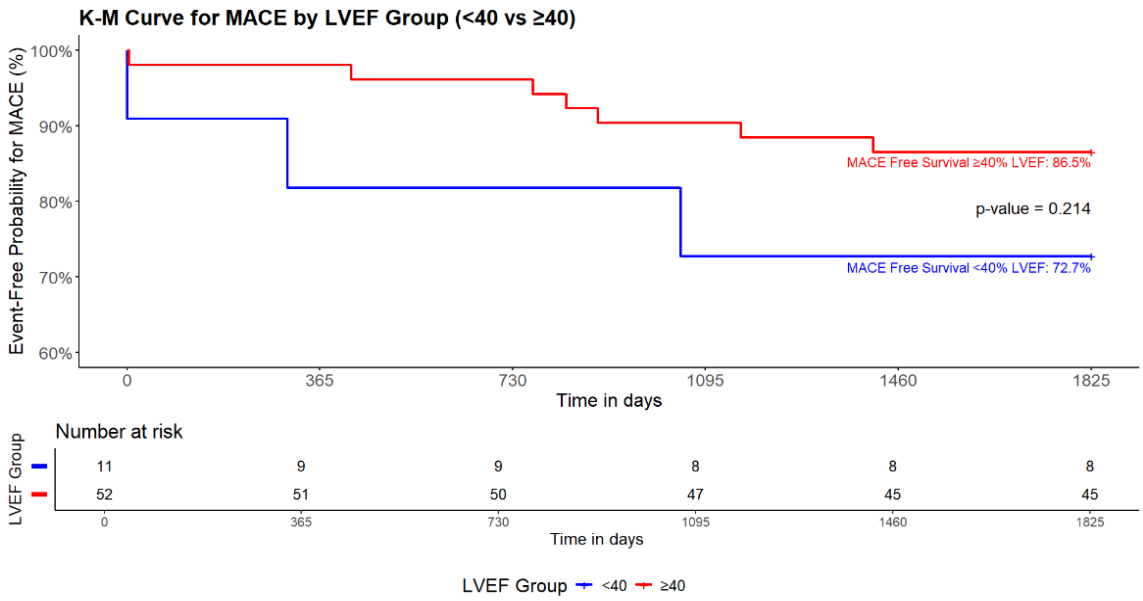


Figure 6 compares MACE-free survival between low LVEF (<40%) and fair LVEF (≥40%) groups. While there is a trend toward worse outcomes for the low LVEF group, the p-value (0.214) indicates no significant difference, likely due to sample size limitations.

Figure 6: Kaplan-Meier Curve for LVEF <40% vs. ≥40%

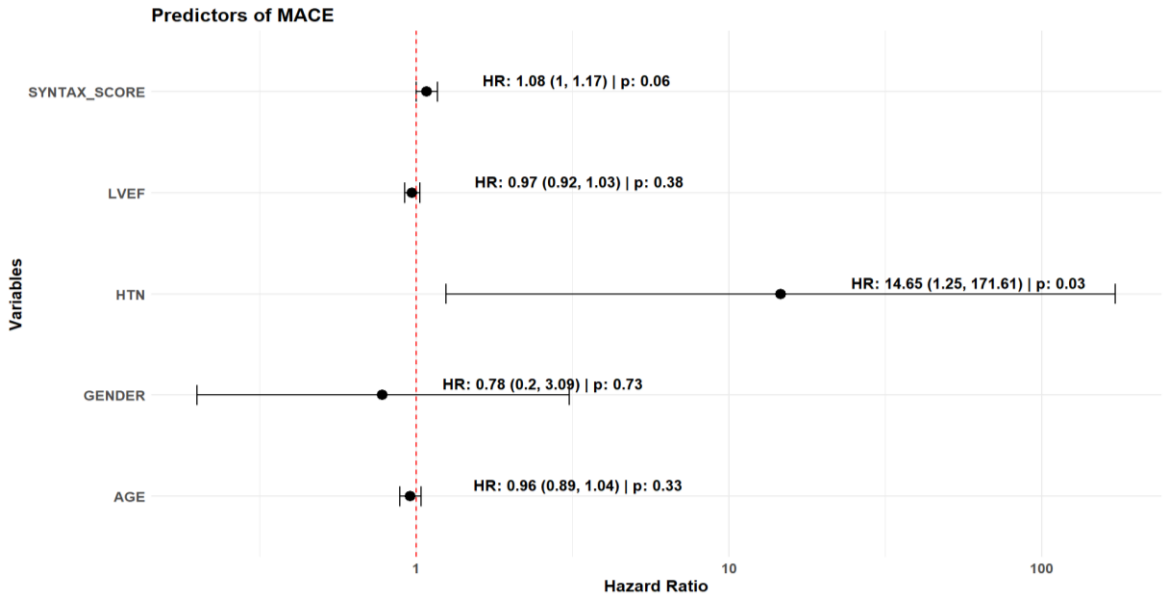


Predictors of MACE

Figure 7 summarizes the predictors of MACE in the cohort via a forest plot. Key findings include:

- **SYNTAX Score**: The SYNTAX score shows a trend toward predicting MACE (HR >1), indicating increased risk as the score rises, but the borderline p-value (0.06) suggests limited statistical significance.
- **LVEF**: LVEF is not a significant predictor of MACE (HR ≈1), with a wide CI and a high p-value (0.38), indicating no meaningful association with MACE in this cohort.
- **Hypertension (HTN)**: Hypertension is a strong predictor of MACE (HR 14.65, p=0.03), showing a significantly increased risk in hypertensive patients, despite variability in the CI.
- **Gender**: Gender is not a significant predictor of MACE (HR ≈1, p=0.73), indicating no association between gender and MACE.
- **Age**: Age is not a significant predictor of MACE (HR ≈1, p=0.33), suggesting no strong relationship between age and MACE within this cohort.

Figure 7: Forest Plot of MACE Predictors in Patients Undergoing Rota Ablation



Discussion: Comparative Analysis of Rota Ablation in Calcific Vessels

In our study of 63 patients undergoing Rota ablation over six years, the patient demographics and procedural outcomes show several similarities and distinctions when compared with larger registries and large single centre studies.

Our cohort had a mean age of 66.8 ± 8.9 years, with 74.6% of patients being male. The cardiovascular risk factors, notably hypertension (63.5%) and diabetes (46%), were prevalent. These characteristics align with those seen in the Euro 4C Registry[2], which also reported older patients (mean age of 72.4 years) and a predominance of male patients (77%). However, the incidence of diabetes in our study (46%) was slightly higher compared to the Euro 4C Registry (36%).

Similarly, the Korea ROCK Registry[3] reported comparable demographics with a mean age of 68 years and a male predominance of 79%. In contrast, a large single centre study from Thailand reported a slightly younger population (mean age 64.6 years) but had a similarly high percentage of hypertensive and diabetic patients, closely mirroring our study's profile[4].

In our study, 76.1% of patients had a SYNTAX score below 22, with a mean score of 16.15, indicating moderate complexity in calcific coronary disease. These findings are consistent with the Korea ROCK Registry, where the majority of patients also presented with lower SYNTAX scores (mean 20.2).

The use of Rota ablation primarily in the LAD (60.31%) and left main to LAD (17.4%) in our study also mirrors findings from the case Series from North India[5], where rotablation in the left main artery and LAD was the most common vessels involved . Our choice of burr sizes (1.5 mm in 79.3% of cases) is similar to those seen in other registries, such as the Euro 4C, where 1.5 mm burrs were predominantly used.

The composite MACE rate in our study was 15.9%, with cardiovascular death in 11.1% of patients, comparable to the Euro 4C Registry, where MACE occurred in 16.9% of patients. Both studies underscore the risk profile of patients undergoing Rota ablation for heavily calcified vessels. In terms of non-fatal MI, our cohort experienced a rate of 3.2%, slightly lower than the 4.1% reported in the Korea ROCK Registry.

Interestingly, the Thailand Registry reported a slightly lower MACE rate (13%), although their study had a larger cohort, which may explain the difference. Additionally, the Rota-REF Study[6] (focusing on patients with reduced EF) reported higher MACE rates, reflecting the higher risk in patients with more compromised cardiac function. Our study's MACE rate of 15.9% compares favourably given that only a subset (23.8%) of our patients had reduced LVEF (<40%).

Our analysis showed that imaging-guided PCI (IVUS or OCT) was used in 39.7% of cases. Although this is lower than the rates reported in recent studies, such as the Euro 4C Registry (48%) and a large centre study from Thailand (73.9%), the Kaplan-Meier analysis (Figure 5) did not show a statistically significant survival advantage for imaging-guided PCI over non-imaging-guided PCI. This lack of significance is consistent with findings from the Euro 4C

Registry, where imaging did not significantly alter the long-term MACE-free survival rate. However, a large centre study from Thailand showed imaging significant reduction in mace in the Imaging guided RA-PCI group.

Hypertension emerged as a significant predictor of MACE in our study (HR 14.65, p=0.03), which aligns with findings from the Korea ROCK Registry and the Rota-REF Study, where hypertension was also highlighted as a key determinant of poor outcomes. In contrast, gender and age were not significant predictors in our cohort, similar to the findings in the Euro 4C Registry.

The borderline significance of the SYNTAX score (p=0.06) in predicting MACE in our cohort suggests that anatomical complexity, while important, may be influenced by other factors such as procedural strategy and patient comorbidities.

Conclusion:

Our study provides valuable insights into the real-world outcomes of Rota ablation in patients with calcific coronary artery disease over a six-year period. Despite a smaller sample size, the clinical outcomes, particularly the MACE rate of 15.9% and cardiovascular death at 11.1%, are consistent with larger registries such as the Euro 4C and Korea ROCK. While imaging-guided PCI showed no statistically significant impact on outcomes, hypertension emerged as a key predictor of MACE, highlighting the importance of aggressive risk factor control. These findings reinforce the efficacy of Rota ablation in managing heavily calcified lesions, especially in resource-limited settings, but larger studies are needed to further clarify the role of procedural variables like imaging in improving long-term outcomes.

Limitations:

This study is limited by its relatively small sample size, which may reduce the statistical power to detect significant differences, especially in subgroup analyses. The retrospective, single-centre design may also limit the generalizability of the findings. Additionally, the use of imaging techniques was not uniform throughout the study period, potentially impacting the comparability of outcomes between imaging-guided and non-imaging-guided PCI. Longer follow-up and larger multicentre studies are needed to validate these results.

References –

1. F. B. Shukurov, R. P. Myasnikov, O. V. Kulikova, D. A. Nefedova, D. A. Feshchenko, D. K. Vasiliev, Endovascular rotational atherectomy for multivessel coronary calcification involving the main trunk of left coronary artery and the left anterior descending artery, Cardiovascular Therapy and Prevention, 10.15829/1728-8800-2024-3890, **23**, 2, (3890), (2024)

2. Meyer-Gessner M, Bressollette E, Cayla G, Lhermusier T, Zajdel W, Palazuelos Molinero J, Ferenc M, Ribichini FL, Carrié D. Clinical outcomes of PCI with rotational atherectomy: the European multicentre Euro4C registry. EuroIntervention. 2020 Jul 17;16(4):e305-e312. doi: 10.4244/EIJ-D-19-01129. PMID: 32250249.

3. Lee K, Jung JH, Lee M, Kim DW, Park MW, Choi IJ, Lee JH, Lee JH, Lee SR, Lee PH, Lee SW, Yoo KD, Yun KH, Lee HJ, Her SH. Clinical Outcome of Rotational Atherectomy in Calcified Lesions in Korea-ROCK Registry. Medicina (Kaunas). 2021 Jul 7;57(7):694. doi: 10.3390/medicina57070694. PMID: 34356975; PMCID: PMC8303478.

4. Towashiraporn K, Krittayaphong R, Tresukosol D, Phankingthongkum R, Tungsubutra W, Wongpraparut N, Chunhamaneewat N, Phichaphop A, Panchavinnin P, Reanthong T, Chotinaiwattarakul C. Clinical Outcomes of Rotational Atherectomy in Heavily Calcified Lesions: Evidence From the Largest Cardiac Center in Thailand. Glob Heart. 2022 Oct 25;17(1):77. doi: 10.5334/gh.1162. PMID: 36382162; PMCID: PMC9615607.

5. Himanshu Gupta, Samman Verma, Yash Paul Sharma, Navjyot Kaur, Kunwer Abhishek Ary, Left Main Rotablation: Case Series From a Tertiary Care Centre in North India, *Journal of Asian Pacific Society of Cardiology 2023;2:e45.*

6. Ayoub M, Tajti P, Akin I, Behnes M, Schupp T, Forner J, Omran H, Westermann D, Rudolph V, Mashayekhi K. Safety and Long-Term Outcomes of Rotablation in Patients with Reduced (<50%) Left Ventricular Ejection Fraction (rEF) (The Rota-REF Study). J Clin Med. 2023 Aug 30;12(17):5640. doi: 10.3390/jcm12175640. PMID: 37685706; PMCID: PMC10488397