

## ORIGINAL ARTICLE

## CHARACTERISTICS AND OUTCOMES OF ROTATIONAL ATHERECTOMY IN A TERTIARY CARE CARDIOLOGY FACILITY IN PAKISTAN

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**Objectives:** To retrospectively review the short term outcomes of rotational atherectomy in a high CathPCI Risk and high Syntax Population.

**Methodology:** A total of 51 patients who underwent RA between 1<sup>st</sup> June 2017 and 31<sup>st</sup> April 2019 were retrospectively reviewed after approval from ethical review committee. Clinical follow up was obtained for procedural success and major adverse cardiovascular events (MACE) at 3 months.

**Results:** Patients who underwent RA were high risk with a mean Syntax score  $32.7 \pm 5.9$  and mean NCDR CathPCI risk score of  $51.1 \pm 13$ . The mean age of the patients were 70 years, majority were males (81%), type 2 diabetics (78%) with chronic kidney disease (52.7%), Non-ST elevated myocardial infarction (NSTEMI) (35%) and Syntax Score  $>32$  (64.8%). Out of 37 individuals, procedural success was reported in all subjects except one in the high risk syntax group. At three months, MACE was reported in 4 patients. Out of these four, one was intra-procedural death, three had repeat myocardial infarction. Out of these three, two declined repeat revascularization and were managed medically. One patient died during admission despite repeat revascularization. Almost all MACE reported, occurred in patients with Syntax  $>32$ .

**Conclusion:** Despite high risk Syntax and CathPCI scores, RA led to high immediate procedural success for PCI in calcified lesions at our hospital with infrequent MACE.

**Keywords:** Atherectomy, Directional/Rotational; Percutaneous Coronary Intervention (PCI), Coronary Artery Disease

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### INTRODUCTION

Coronary artery calcification (CAC) is a common finding on angiogram that increases the complexity of percutaneous coronary interventions (PCI).<sup>1</sup> Calcified lesions pose a higher risk of post-PCI complications due to stent under-expansion and mal-apposition as compared to lesions with minimal or no calcium.<sup>2</sup> CAC has a strong association with increasing age and male gender. Around 90% of males over the age of 70 years have CAC.<sup>3</sup> A recent retrospective analysis of a large multiethnic cohort undergoing PCI with drug eluting stents concluded that CAC remained an independent predictor of post PCI complications.<sup>4</sup> In this study major adverse cardiovascular events (MACE) among patients with none/mild, moderate, and severe calcification were 8.3, 14.6, and 17.8%, respectively.<sup>4</sup> Mechanical debulking of lesions with rotational atherectomy (RA) is essential in managing these calcified lesions.<sup>5,6</sup> RA involves differential sanding of calcified coronary plaques with the use of diamond tip rotator device (Boston Scientific, USA) that is advanced over a guide wire at 140,000 to 180,000 revolutions per minute.<sup>7</sup> Evidence of RA from the US and Europe is extensive, however, little has

been published from lower middle income countries (LMIC). Evidence from ROTAXUS (Rotational Atherectomy Prior to TAXUS Stent Treatment for Complex Native Coronary Artery Disease) study performed in mainly Caucasian patients showed that despite high immediate success (92%), there was no effect of rotational atherectomy on late lumen loss and recurrent cardiac events. At two years follow up there was no difference in outcomes between patients undergoing PCI with or without RA.<sup>8,9</sup> G Minocha et al. reported a procedural success rate of 99% in Indian patients with MACE reported in 8% patients whereas Baruah DK et al. concluded in Indian patients that the procedural success rates approached 97.8% and MACE was 8%. This is much lower than the MACE rate of 28% at 9 months and 29% at 2 years reported by ROTAXUS. A review of these South Asian studies also show that the predominant presentation was acute coronary syndrome (ACS) which is in contrast to ROTAXUS where the predominant presentation was stable angina. The mean burr size used was also smaller.<sup>10,11</sup> Data regarding RA from Pakistan is absent. Outcomes and characteristics of RA in our patients are expected to differ due to increased age, frailty, multiple co-morbidities, complex lesions,

genetics, environmental factors and resource limitation. Many of our patients presenting for rotablation have prohibitive surgical risk. We need to study if the difference in outcomes between ROTAXUS and Indian studies are reflected in our patients as well. This study is also an effort to put forward our experience of RA assisted PCI.

## METHODOLOGY

A retrospective chart review was conducted at the Aga Khan University Hospital Karachi (AKUH, K), after approval from the hospital ethics review committee and conforms to national regulations. The Health Information Management Services at AKUH, K maintains comprehensive, updated hybrid patient medical records, integrating both paper and electronic records. After approval from the hospital ethics review committee, we retrospectively reviewed all PCI cases performed at AKUH, K between 1<sup>st</sup> June 2017 and 31<sup>st</sup> April 2019 from our cardiac catheterization lab records and identified patients who required atherectomy with rotablator device (Boston Scientific, USA) prior to PCI. We subsequently reviewed their medical records and angiograms. Through this review process we noted baseline, angiographic and procedural characteristics along with study outcomes. Angiographic complexity was recorded using Syntax score whereas clinical risk was calculated using NCDR CathPCI risk score.<sup>12,13</sup> The primary outcome of the study was immediate procedural success defined as residual stenosis less than 50 percent and TIMI (Thrombolysis in Myocardial Infarction) grade III flow after coronary intervention in target vessel. The secondary outcomes are MACE at 3 months defined as composite of (1) death from any cause, (2) myocardial infarction; defined as greater than 5-fold elevation of troponin I, new pathological Q-waves on ECG or angiographic findings of a flow-limiting coronary occlusion and (3) target lesion revascularization; defined as percutaneous intervention, or bypass surgery performed because of restenosis of the target lesion.<sup>14,15</sup> All adult patients aged 18 years of age or more, who underwent RA assisted PCI in the last 2 years at AKUH were retrospectively reviewed and clinical follow up obtained for procedural success and MACE at three months. For the purpose of study, patients who had undergone RA assisted PCI were identified. Information relevant to study objectives was collected using a predesigned proforma. The information regarding outcomes and MACE was collected from review of charts. The data was analyzed using SPSS V20.0 and results were expressed in terms of means and standard deviation for quantitative variables and percentages for qualitative variables.

## RESULTS

The mean age of the patients was  $70.1 \pm 9$  years. Out of 51 patients, 41 (82%) were males, 40 (78.4%) were diabetics and 45 (88.2%) were hypertensive. Out of 51 patients 21 (41.1%) had prior MI and 29 (56.8%) patients had left ventricular systolic dysfunction (left ventricular ejection fraction  $\leq 40\%$ ). The most common presentation was angina 28 (54.9%) followed by NSTEMI 18 (35.2%) and ST-elevation myocardial infarction (STEMI) 3 (5.8%). The baseline characteristics of patients are summarized in Table 1.

**Table 1: Baseline Characteristics**

Characteristics	N (%) / Mean $\pm$ SD
<b>Total Patients</b>	<b>N= 51</b>
Age in years	70.1 $\pm$ 9
Males	41 (82%)
Diabetes	40 (78.4%)
Hypertension	45 (88.2%)
Dyslipidemia	30 (58.8%)
Smoking	21 (41.1%)
Chronic Kidney Disease	19 (37.2%)
Hemodialysis	8 (15.6%)
Left ventricular Dysfunction	29 (56.8%)
STEMI	3 (5.8%)
NSTEMI	18 (35.2%)
Angina	28 (54.9%)
Cardiogenic Shock	2 (3.9%)
Prior MI	21 (41.1%)
Prior PCI	7 (13.7%)
Prior CABG	10 (19.6%)

*STEMI=ST- elevation myocardial infarction, NSTEMI=Non ST elevated myocardial infarction, MI=myocardial infarction, PCI=percutaneous coronary intervention, CABG=coronary artery bypass grafting*

In the majority of patients, target lesion for RA was located in the left anterior descending artery (LAD) 36 (70.5%), followed by the left main coronary artery (LMCA); 12 (23.5%). The mean length of the lesions rotablated was  $36.41 \pm 14.5$  mm. Of all the lesions rotablated, 16 (31.3%) were bifurcation lesions. All patients with left main disease or three vessel disease with Syntax score  $>22$ , consulted a cardiothoracic surgeon prior to procedure. The mean Syntax score was  $32.7 \pm 5$ . A total of 34 (66.6%) patients had a Syntax score  $> 32$  at the time of presentation. Our patients had a significantly high mortality risk and complex coronary lesions as depicted by a mean NCDR CathPCI risk score of  $51.1 \pm 13$  and a mean Syntax score  $32.7 \pm 5.9$  respectively. The angiographic characteristics of patients are presented in Table 2.

A pre-procedure temporary pacemaker was placed in 44 (86.2%) patients but only 11 (21.6%) needed to be retained post-procedure. The mean burr size used was  $1.5 \text{ mm} \pm 0.2$ . A single burr was used in 50 (98.0%)

patients and the mean number of vessels rotablated per patient was  $1.27 \pm 0.45$ . No reflow was noted in 3 (5.9%) patients and inotropes were required in 21 (56.7%). The mean volume of contrast used was  $246.62 \pm 112.3$ . Intravascular ultrasound was performed in 7 (13.7%) and all 51 patients received drug eluting stents (DES).

**Table 2: Angiographic and Procedural Characteristics of Patients Undergoing Rotational Atherectomy**

Characteristics	N (%) / Mean $\pm$ SD
<b>Total Patients</b>	<b>N= 51</b>
Target lesion location (Vessel)	
Left Main	12 (23.5%)
LAD	36 (70.5%)
LCX	11 (21.5%)
RCA	8 (15.6%)
Target lesion length	$36.41 \pm 14.5$ mm
Bifurcation Lesions n (%)	16 (31.3%)
Syntax score	
<22	5 (9.8%)
22-32	12 (23.5%)
>32	34 (66.6%)
Mean Syntax Score	$32.7 \pm 5.9$
Mean CathPCI Score	$51.1 \pm 13$
TPM placed	44 (86.2%)
TPM retained	11 (21.6%)
Burr size in mm	$1.5 \pm 0.2$
Number of burrs	
1 burr	50 (98.0%)
2 burr	1 (1.9%)
No reflow	3 (5.9%)
Intra-aortic balloon pump	1 (2.7%)
Inotropes	21 (41.2%)
Total vessels rotablated	$1.27 \pm 0.45$
Contrast used in ml	$246.62 \pm 112.3$
Intravascular Ultrasound	7 (13.7%)

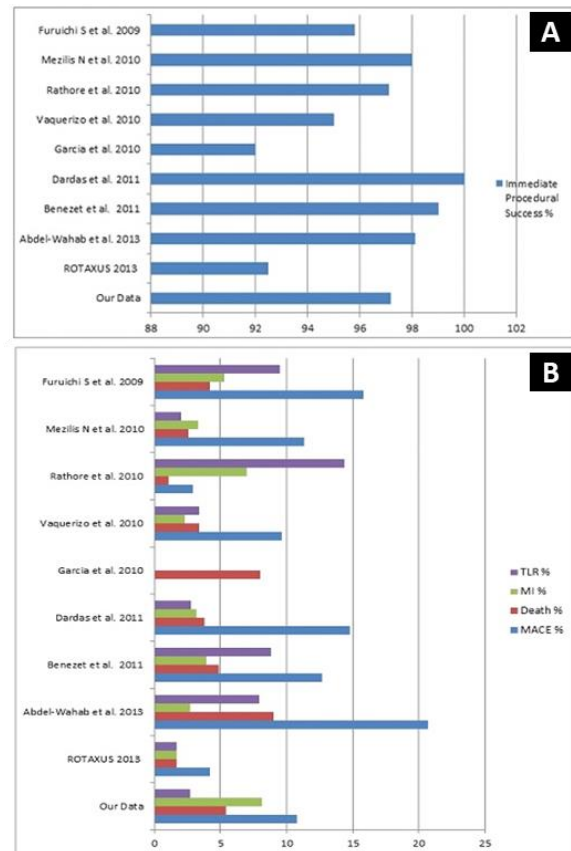
STEMI=ST- elevation myocardial infarction, NSTEMI=Non ST elevated myocardial infarction, MI=myocardial infarction, PCI=percutaneous coronary intervention, CABG=coronary artery bypass grafting

Overall, amongst 37 individuals, procedural success was reported in 50 (98.0%) subjects; 33(97.0%) in Syntax >32 and 17(100%) in Syntax<32 (Table 3). At three months, MACE was reported in 5 (9.8%) patients. Two patients (5.4%) died. All these events were reported in patients with Syntax>32 group. Out of these one was intra-procedural death whereas one patient died in the coronary care unit despite repeat revascularization after being readmitted for NSTEMI. In all, three patients (8.1%) experienced another MI in 3 months; two of these declined repeat revascularization and were managed medically. Only one patient (2.7%) underwent repeat revascularization with unfavorable final outcome as mentioned above. Almost all the events occurred in Syntax >32 subgroup where the proportion of MACE was 5 (9.8%), death 2 (3.9%), myocardial Infarction 3 (5.8%) and target

lesion revascularization 1 (1.9%). In the Syntax <32 subgroup only one myocardial infarction was reported MACE (7.6%) (Figure 1).

**Table 3: Outcomes of Rotational Atherectomy**

	Overall	Syntax Score	
	Outcomes	>32	<32
Immediate Procedural Success	50 (98.0%)	33(97.0%)	17(100%)
Major Adverse Cardiovascular Events At 3 months			
Total Major Adverse Cardiovascular Events	5 (9.8%)	5 (9.8%)	0(0%)
Death	2 (3.9%)	2 (3.9%)	0(0%)
Myocardial Infarction	3 (5.8%)	2 (3.9%)	1 (1.9%)
Target Lesion Revascularization	1 (1.9%)	1 (1.9%)	0(0%)



**Figure 1: Comparison of procedural success (A) comparison of major adverse cardiovascular outcomes (B)**

**DISCUSSION**

The European expert consensus document concludes that in the hands of experienced operators; rotablation is both safe and effective in the treatment of calcified lesions.<sup>16</sup> Our procedural success was high and

comparable to international data; despite significantly high risk clinical parameters, angiographic features. In contrast to previous South Asian data, majority of the patients had non-ACS presentation. Resource limitations led to the adoption of a predominant single burr strategy and limited use of intravascular imaging. We reported the highest mean Syntax score for any RA study so far. In our review of literature, we could not find any study on RA that examined the NCDR CathPCI risk scores of participants. Compared to ROTAXUS, our MACE rates were higher, however our patient population had more comorbidities and were at higher risk (Figure 1).<sup>8</sup>

The baseline characteristics (Table 1) of our patients were comparable with European data. A review of published literature shows that the mean age varies from 67-70.5 years and proportion of males were 68-86%. The most common co-morbidities reported are hypertension, diabetes followed by dyslipidemia. In almost all studies, patients presented mainly with angina followed by NSTEMI. In comparison with previous studies, our patients had significantly high risk clinical parameters like LV dysfunction, current MI, high Syntax Score, LMCA interventions and acute coronary syndrome (ACS) presentation. The proportion of LV dysfunction (defined as LV ejection fraction  $\leq 40\%$ ) in previous literature was 25-32% and current MI (4-14%).<sup>17-26</sup> In our review of literature we did not come across a single study that looked into CathPCI risk scores of RA patients. Syntax Score, on the other hand has been extensively studied and is an important determinant of outcomes following RA. In one study, Syntax Score cut-off value of 15 had 73% sensitivity and 62% specificity for predicting in-hospital adverse outcomes.<sup>25</sup> Our mean Syntax score ( $32.7 \pm 5$ ) was higher than reported by previous authors (Table 1). The reason for this dissimilarity in patient population is that most of our RA patients had been either turned down for CABG by the surgical team or had refused surgery. The angiographic /procedural characteristics and procedural outcomes (Table 2) reflect this high mean Syntax score of participants. LMCA was the target vessel in 2.1-16.3% in published literature whereas LAD is consistently; the most common vessel rotablated (50-70%). The average length of the coronary lesions reported are 20.6-39 mm. No-reflow or slow flow in our patients was higher than reported by Abdel-Wahab et Al. (1.9%).<sup>17</sup> This can be explained by the greater lesion length and larger proportion of ACS patients encountered; both of which are important risk factors for no reflow during RA. Previous investigators have reported a mean burr size of  $1.5 \pm 0.2$  mm. Although in most cases we rotablated only a single vessel whereas Garcia et al. had reported a mean of  $2.36 \pm 0.8$  vessels rotablated.

Contrast volume used is essential consideration during complex PCI. However, it has been seldom reported in rotational atherectomy studies. Only ROTAXUS had reported a mean volume of contrast at  $201.0 \pm 113.6$  ml. This is less than our study but can be explained by the higher risk and complex lesions encountered in our patients.<sup>8</sup> IVUS is critical in ensuring stent expansion and apposition post rotablation. Our use of IVUS was limited by financial constraints to LMCA interventions only. Studies have reported a wide variation in IVUS use; from none in ROTAXUS to 96.5% by Rathore et al.<sup>8,22</sup> Patients also significantly differed in the type of drug eluting stents deployed. We mainly used everolimus eluting stents whereas in previous studies, sirolimus and paclitaxel eluting stents were predominantly used. This simply reflects advancement in stent design and drug delivery, since sirolimus and paclitaxel eluting stents are now obsolete.<sup>8,17-24</sup> Immediate procedural success after RA is usually high (Figure 1). Our procedural success rate was comparable to the success rates reported by multiple studies (92-95%).<sup>17-24</sup> In our review of literature we found only one paper by MH Chiang et.al that had reported rotablation outcomes in high Syntax scores and had reported nearly similar procedural success rate of 91.2% and MACE of 16.1%.<sup>25</sup> MACE after RA varies from study to study (Figure 1). The reason for this is that some studies like ROTAXUS had excluded certain high risk patient groups (ACS and LV dysfunction).<sup>8</sup> Our MACE rates were comparable to Mezilis et al. (11.3%), where a significant proportion of patients underwent LMCA rotablation.<sup>21</sup> Our MACE rates were also comparable to Benezet et al. (12.7%) where a large number of patients had ACS presentation.<sup>16</sup>

This study showed that RA assisted PCI at our institute had a high success rate despite the high risk substrate and limited resources. However, it has limitations due to its retrospective design, short follow up and limited sample size. To ascertain whether these results can be generalized to the entire population would require a multi-center prospective study.

## CONCLUSION

Despite high risk Syntax and CathPCI scores, RA led to high immediate procedural success for percutaneous coronary intervention in calcified lesions with infrequent major adverse cardiovascular events. However, larger prospective studies are required to study the outcomes of RA in a LMIC with a high risk patient population.

## AUTHORS' CONTRIBUTION

BKK: Concept and design, data acquisition, interpretation, drafting, final approval, and agree to be accountable for all aspects of the work. OF and MNR:

Data acquisition, interpretation, drafting, final approval and agree to be accountable for all aspects of the work.

**Conflict of interest:** Authors declared no conflict of interest.

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