



Comparison of Short-term Outcomes between Planned and Bailout Rotational Atherectomy in Patients with Calcified Coronary Artery Lesions

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Abstract

Introduction: Percutaneous coronary intervention (PCI) of calcified coronary artery lesions remains challenging. Rotational atherectomy (RA) is useful device for plaque modification to facilitate balloon and stent delivery. Operators use either planned RA, defined as the initial strategy without previous device failure or bailout RA, defined as RA after device failure (lesions that cannot be crossed by a balloon or adequately dilated before stenting).

Objective: To compare short-term outcomes between planned and bailout RA in patients with calcified coronary artery lesions.

Methods: This Prospective observational study was conducted from April 2022 to September 2023 in the Department of Cardiology at National Institute of Cardiovascular Diseases (NICVD), Dhaka. A total of 60 patients who met the inclusion and exclusion criteria were enrolled in the study by consecutive sampling. Patients were divided into two groups: planned RA (n=30) and bailout RA (n=30). However, after 6 months of follow-up 4 respondents from bailout RA were lost to follow-up. The occurrence of major adverse cardiac events (MACE): death, myocardial infarction (MI), target vessel revascularizations (TVR) and stent thrombosis were recorded at 6 months of follow-up.

Results: Procedural time, fluoroscopy time and contrast amount used were significantly reduced in the planned RA group compared to bailout RA group. Coronary dissection >5mm as higher in bailout RA (0.0% vs. 23.1%, p=0.005). However, no significant difference in in-hospital MACE was found between the two groups (6.71% vs. 15.4%, p=0.401). After six-months follow-up, the incidence of Composite MACE in group I was lower than in group II (3.3% vs 15.3%, p=0.176) but it was not statistically significant (Kaplan-Meier estimates; hazard ratio [HR]: 3.265, 95% confidence interval: 0.866 to 12.317, p= 0.081).

Conclusion: Planned RA was associated with a reduction in procedural duration, fluoroscopy time, contrast amount and procedural complications. But planned RA was not significantly associated with reduced Six-month MACE compared with bailout RA.

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Introduction

Percutaneous coronary intervention (PCI) of calcified coronary artery lesions remains a challenge for decades [1]. The prevalence of coronary artery

calcification is higher over 70 years of age (>90% in men vs. 67% in women) [2]. Although the frequency of coronary calcification varies depending on the imaging method utilized, angiography has been shown that as much as one-third of coronary lesions may have moderate-to-severe calcification [3]. In the past, atherosclerotic plaque calcification was thought to be a quiescent, passive, degenerative process. But still, this idea has been changed, now it is an active process that represents a broader systemic inflammatory status supported by new research and this condition is commonly seen in individuals with chronic kidney disease, diabetes mellitus, and metabolic syndrome [4]. Coronary artery calcification (CAC) is influenced by calcium-regulating processes that impact bone growth and formation. Early calcium deposition depends on alkaline phosphatase, which has been suggested as a vascular calcification molecular marker. Compared to IVUS and CT to diagnose CAC, coronary angiography has low-to-moderate sensitivity and excellent specificity [5]. There are three categories into which angiographic CAC is commonly divided: none/mild, moderate, and severe. Severe calcification is characterized as radiopacities that are only detected during the cardiac cycle before contrast administration, typically impacting both sides of the artery lumen and being observed without cardiac motion. Moderate calcification as radiopacities is noted only during the cardiac cycle before contrast injection [6]. Intravascular ultrasonography has a sensitivity of 90% to 100% and a specificity of 99% to 100%, making it far more accurate than angiography for the identification of CAC [7]. The most popular method of revascularization for coronary artery disease is now percutaneous coronary intervention (PCI) [3]. Roughly 20% of patients undergoing PCI suffer from severe calcified coronary artery disease [8]. A year later, Fourrier et al. reported the first case of percutaneous coronary RA in humans, involving twelve patients, following promising results in animal models. Since then, the method has largely remained unchanged, and because of RA's special abilities to treat calcified lesions, it has withstood the advancement of balloons and stents over the past forty years. Furthermore, there are several explanations for why RA is becoming more and more important in the modern era of coronary intervention. First, a greater prevalence of several risk factors, including advanced age, diabetes mellitus, and renal failure, is contributing to an increase in the number of individuals with severely calcified coronary lesions. Second, a few technological advancements have made RA safer and easier to use. Third, the majority of high-volume centers agree that RA is necessary for the appropriate treatment of some complicated calcified coronary anatomies. Fourth, several observational studies and two randomized trials from the DES era the PREPARE-CALC (Comparison of Strategies to Prepare Severely Calcified Coronary Lesions) trial and the ROTAXUS (Rotational Atherectomy Prior to Taxus Stent Treatment for Complex Native Coronary Artery Disease)

trial have established more reliable information regarding the indications and results of RA [9]. Results following PCI are measured using procedural success and complication rates. The achievement of successful angiographic results without any in-hospital MACE is referred to as procedural success. Death, myocardial infarction following a procedure, target vessel revascularization (TVR), and stent thrombosis are considered major adverse cardiac events (MACE), other adverse events include heart failure, cardiogenic shock, bleeding, significant arrhythmia, stroke, transient ischemic attacks, vascular complications, contrast-induced nephropathy, and angiographic complications [10]. At present, we have limited data on RA and the use of drug-eluting stents in moderate to severe calcified coronary artery lesions. This prospective observational single-center study was carried out in Bangladeshi patients to evaluate the safety and efficacy of RA in moderate to severely calcified lesions before implantation of drug eluting-stent and to assess and compare procedural outcomes, in-hospital events and clinical outcomes between planned and bailout RA.

Methodology of the Study

Study design: Prospective observational study.

Place of study: This study was carried out in the Department of Cardiology at National Institute of Cardiovascular Diseases (NICVD), Dhaka, Bangladesh.

Study period: This study was conducted from April 2022 to September 2023 for a period of one and half (1½) year.

Study population: Patients admitted into NICVD with calcified coronary artery lesions those who undergoing RA within the specified period of time were the study population.

Sample size calculation: The sample size for this study was calculated using the statistical formula as follows

$$\text{Formula- } n = \left[\frac{Z_{\alpha} \sqrt{2P(1-P)} + Z_{\beta} \sqrt{P_1(1-P_1) + P_2(1-P_2)}}{P_1 - P_2} \right]^2$$

So, calculated sample size was 61 in each group.

Sample size: A total of 60 patients were considered due to time constraints. Study subjects were divided into two groups.

Group I: 30 patients, planned rotational atherectomy in calcified coronary lesion

Group II: 30 patients, bailout rotational atherectomy in calcified coronary lesion

Selection Criteria:

A) Inclusion criteria:

Clinical:

- Age above 18 years.
- Angiographically proven coronary artery disease.

Angiographic:

- Significant coronary artery lesions with moderate to severe calcification.
- De-novo lesion in a native coronary artery.
- Target reference vessels diameter between 2- 4 mm by visual estimation.
- Superficial calcium $>270^\circ$ and calcium score 2-4 in IVUS.

B) Exclusion criteria:

Clinical:

- Myocardial Infarction within 1 month
- Cardiogenic shock
- Cardiomyopathy
- Active GIT bleeding and ulcer
- Recent history of cerebrovascular accident
- Valvular and congenital heart diseases
- Patients with bleeding disorder
- Patient unwilling to enroll in the study

Angiographic:

- Target lesion is in graft vessel.
- Target lesion is in stent restenosis
- Target vessel thrombus

Data collection Procedure:

- Patients admitted in the Department of Cardiology, NICVD, Dhaka, with indication for coronary intervention (PCI) who fulfilled the inclusion and exclusion criteria were considered for the study.
- Informed written consent was taken from each patient before enrollment.
- Meticulous history was taken and a detailed clinical examination was performed and recorded in a predesigned structured questionnaire.
- Demographic data such as age, sex, weight, height, and BMI were recorded.
- Risk factor profiles including smoking, hypertension, diabetes, dyslipidemia and family history of coronary artery disease were noted.
- Investigations findings of hemoglobin, serum creatinine, ECG, Troponin I, and Echocardiography will be recorded. Coronary angiography was performed through a trans-radial or distal trans-radial or transfemoral approach. Interventional cardiologist experts in PCI were involved in this research.
- PCI procedure was performed according to current standard international guidelines.
- During the procedure, intravenous heparin (70-100 units/Kg) was administered after sheath insertion to maintain an activated clotting time >300 seconds.

- Balloon crossable lesion was predilated & IVUS will be run through the calcified lesion and if superficial calcium $\text{arc}>270^\circ$ and IVUS calcium score 2-4 (calcium $>270^\circ$ in ≥ 5 mm length, 360° of calcium, calcium nodule, vessel diameter <3.5 mm, if yes=1, No=0 for each parameter) then we proceed as planned RA.

Data processing and analysis:

- After collection of all the required data, these were checked, verified for consistency and tabulated using the SPSS version 26 (IBM Corp., Armonk, NY).
- Frequencies and percentages were calculated as summary measures for the qualitative variables.
- Arithmetic mean and standard deviation were used to describe the quantitative variables.
- The student t-test was used to compare symmetrically distributed continuous variables.
- Chi-square test and Fisher's exact test was used to compare categorical variables.
- A 'p' value <0.05 was considered as statistically significant. After completion, the data were presented in the form of Tables, Figures and graphs as necessary.

Results

A total 60 patients admitted into NICVD with calcified coronary artery lesions those who undergoing RA within the specified period of time were included in this study as per

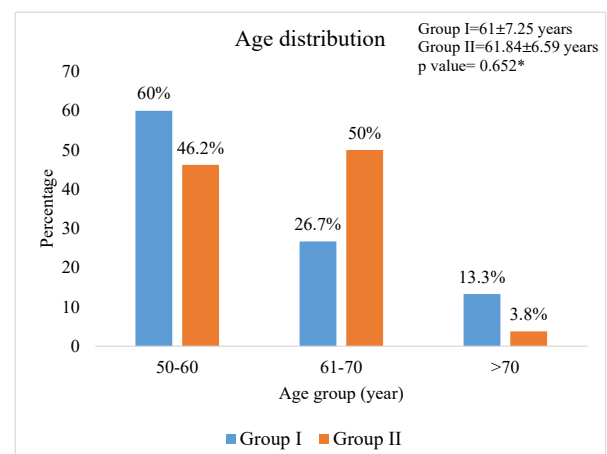


Figure 1: Age distribution of respondents among group I and group II (n=56).

*Student t test was done. Values were expressed as frequency with percentage over column

Group I= patients had planned rotational atherectomy in calcified coronary lesion

Group II= patients had bailout rotational atherectomy in calcified coronary lesion

The mean age of the respondents in group I and group II were quite similar 61 ± 7.25 years and 61.84 ± 6.59 years respectively and there was no statistically significant ($p > 0.05$) mean age difference between the two groups.

inclusion and exclusion criteria. Among them 30 patients had planned rotational atherectomy in calcified coronary lesions and another 30 patients had bailout rotational atherectomy in calcified coronary lesions which were considered as group I and group II respectively. However, after 6 months of follow-up 4 respondents from Group II were lost to follow-up, so final sample size was 56 in this study. The results of the study are arranged in Table 1-9 and Figure 1-3. Details of the study result are described below.

The mean age of the respondents in group I and group II were quite similar 61 ± 7.25 years and 61.84 ± 6.59 years respectively and there was no statistically significant ($p > 0.05$) mean age difference between the two groups.

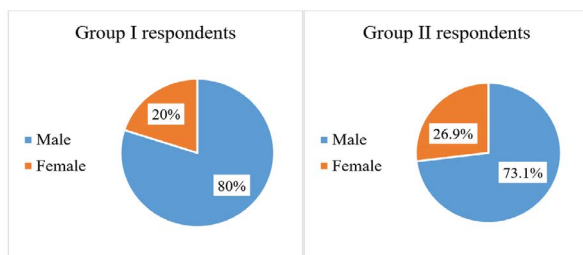


Figure 2: Gender distribution of respondents among group I and group II (n=56).

P value=0.541, *Chi-square test was done. Values were expressed as frequency with percentage over column

Group I= patients had planned rotational atherectomy in calcified coronary lesion

Group II= patients had bailout rotational atherectomy in calcified coronary lesion

Male patients were predominant in the study. Statistically no significant difference was seen in term of gender distribution among the study groups ($p=0.541$).

Table 1: Cardiac risk factor of respondents in group I and group II (n=56).

Variable	Group I n=30 n(%)	Group II n=26 n(%)	Total n=56 n(%)	p value*
Hypertension	16(53.3)	12(46.2)	28(50)	0.592*
Diabetes mellitus	20(66.7)	19(73.1)	39(69.6)	0.603*
Dyslipidemia	6(20)	4(15.4)	10(17.9)	0.0653**
Family history of premature CAD	11(36.7)	6(23.1)	17(30.4)	0.270*
Smoker	13(43.3)	16(61.5)	29(51.8)	0.174*

*Chi-square test and **Fisher's Exact test were done. Values were expressed as frequency with percentage over column

Group I= patients had planned rotational atherectomy in calcified coronary lesion

Group II= patients had bailout rotational atherectomy in calcified coronary lesion

There were no statistically significant differences between the two groups in terms of hypertension ($p=0.592$), diabetes mellitus ($p=0.603$), dyslipidemia ($p=0.0653$), or a family history of premature CAD ($p=0.174$).

Table 2: Investigation parameters of group I and group II respondents (n=56).

Variable	Group I n=30 Mean $\pm$ SD	Group II n=26 Mean $\pm$ SD	p value*
Hemoglobin(gm/dl)	11.63 $\pm$ 2.44	11.33 $\pm$ 3.57	0.705
S. creatinine (gm/dl)	0.96 $\pm$ 0.45	0.99 $\pm$ 0.47	0.844
Ejection fraction (%)	56.13 $\pm$ 9.39	52.46 $\pm$ 8.31	0.13

*Student t test was done

Group I= patients had planned rotational atherectomy in calcified coronary lesion

Group II= patients had bailout rotational atherectomy in calcified coronary lesion

There was no statistically significant difference of hemoglobin %, serum creatinine level and ejection fraction between group I and group II.

Table 3: Angiographic findings of respondents (n=56).

Variable	Group I n=30 n(%)	Group II n=26 n(%)	Total n=56 n(%)	p-value*
Target vessel				
LAD	18(60)	9(34.6)	27(48.2)	0.005
LMCA	4(13.3)	0	4(7.1)	
RCA	5(16.7)	15(57.7)	20(35.7)	
LCX	3(10)	2(7.7)	5(8.9)	
Access site				
Femoral	6(20)	6(23.1)	12(21.4)	0.403
Radial	22(73.3)	20(76.9)	42(75)	
Distal radial	2(6.7)	0	2(3.6)	
Coronary dominance				
Right	28(93.3)	22(84.6)	50(89.3)	0.442
Left	2(6.7)	2(7.7)	4(7.1)	
Codominant	0	2(7.7)	2(3.6)	

*Chi-square test was done. Values were expressed as frequency with percentage over column

Group I= patients had planned rotational atherectomy in calcified coronary lesion

Group II= patients had bailout rotational atherectomy in calcified coronary lesion

The majority of the respondents in group I had left anterior descending artery (60% vs. 34.6%) as target vessel while among group II most target vessels were right coronary artery (57.7% vs. 16.7%) which was statistically significant ($p=0.005$). However, in both groups common access site was radial artery (73.3% vs. 76.9%, $p=0.403$) which was not statistically significant. Also, right-sided coronary dominance was most commonly found in both groups ($p=0.442$) which was not statistically significant.

Table 4: Procedural characteristics of PCI and RA among respondents (n=56).

Variable	Group I n=30 n(%)	Group II n=26 n(%)	p-value*
Number of burr	1.4±0.49	1.6±0.49	0.112*
Maximum burr size(mm)	1.54±0.15	1.56±0.15	0.525*
Rotational speed (rpm)	165666.7±14064.7	171538.4±12551.4	0.107*
Burr to artery ratio	0.57±0.07	0.57±0.07	0.694*
Pre-dilationballoon diameter(mm)	2.12±0.32	2.25±0.33	0.125*
Pre-dilationballoon length (mm)	12.97±3.13	12.31±2.85	0.414*
Diameter of DES (mm)	2.97±0.45	2.84±0.21	0.210*
Length of DES (mm)	31.9±9.81	34.08±6.59	0.348*
Number of DES	1.47±0.57	1.54±0.71	0.676*
IVUS calcium score	2.5±0.68	2.6±0.79	0.445*
IVUS	27(90)	4(15.4)	<0.001**
TPM done	1(3.3)	4(15.4)	0.115**

**Fisher's Exact test and *student t test were done. Values were expressed as frequency with percentage over column

Group I= patients had planned rotational atherectomy in calcified coronary lesion

Group II= patients had bailout rotational atherectomy in calcified coronary lesion, Intravenous ultrasound = IVUS, Temporary pacemaker =TPM

IVUS was commonly done in group I than group II. However, number of burr, maximum burr size, rotational speed, burr to artery ratio, pre-dilation balloon diameter, number of stent, length and diameter of stent had no statistically significantbetween two groups (p>.05).

Table 5: Procedural outcome of group I and group II (n=56).

Variable	Group I n=30 n(%)	Group II n=26 n(%)	p-value*
Procedural duration(min)	71.67±16.15	115.38±17.25	<0.001**
Contrast amount(ml)	131.67±33.43	186.54±26.67	<0.001**
Fluoroscopy time(min)	22.59±3.31	35.35±4.34	<0.001**
Large dissection >5mm	0	6(23.1)	0.005*
Perforation	0	0	
Pericardial effusion	0	2(7.7)	0.122*

No/slow flow	0	5(19.2)	0.012*
Final TIMI 3 flow	30(100)	22(84.6)	0.026*
Residual stenosis <20%	30(100)	20(76.9)	0.005*
Stent failure	0	0	
Strategy success	30(100)	21(80.8)	0.012*

*Fisher's Exact test and **student t test were done. Values were expressed as frequency with percentage over column

Group I= patients had planned rotational atherectomy in calcified coronary lesion

Group II= patients had bailout rotational atherectomy in calcified coronary lesion

Procedural duration, contrast amount and fluoroscopy time were significantly higher in group II compared to group I. Group II had large dissection (>5mm), had no/slow flow(p=0.005 and p=0.012) which was statistically significant but pericardial effusion(p=0.122) was not statistically significant.While in group I had no large dissection, pericardial effusion, and no/slow flow. Furthermore, both group had final TIMI3 flow,residual stenosis <20% and strategy success which was significantly higher in group I (p=0.026, 0.005, 0.012). There were no perforation or stent failure in both group.

Table 6: In hospital outcome of respondents in group I and group II (n=56).

Variable	Group I n=30 n(%)	Group II n=26 n(%)	p-value*
MACE	2(6.7)	4(15.4)	0.401
Cardiac death	0(0.0%)	1(3.8)	0.464
Myocardial infarction(MI)	1(3.3)	2(7.7)	0.592
Target vessel revascularization (TVR)	1(3.3)	1(3.8)	>0.999
Stent thrombosis	0(0.0)	0(0.0)	

*Fisher's Exact test was done. Values were expressed as frequency with percentage over column

Group I= patients had planned rotational atherectomy in calcified coronary lesion

Group II= patients had bailout rotational atherectomy in calcified coronary lesion

In-hospital clinical outcomes were listed in Table 6. The occurrence of composite MACE in group I (6.7%) was lower than group II (15.4%) but there was no significant difference between the two groups (p=0.401).). There was no statistical significance between the two groups with respect to the risk of death (group I vs. group II: 0% vs. 3.8%, p=0.592), MI (group I vs. group II: 3.3% vs. 7.7%, p=0.592) and TVR (group I vs.group II: 3.3% vs.3.8%,p>0.992). No stent thrombosis was found in both groups.

Table 7: Other in hospital complications of group I and group II respondents (n=56).

Variable	Group I n=30 n(%)	Group II n=26 n(%)	p value*
Cardiogenic shock	1(3.3)	3(11.5)	0.328
Left ventricular failure(LVF)	1(3.3)	4(15.4)	0.172
Bleeding	1(3.3)	1(3.8)	>0.999
Stroke	0	0	
Arrhythmia (AF/VT/ VF/Others)	2(6.7)	4(15.4)	0.293

*Fisher's Exact test was done. Values were expressed as frequency with percentage over column

Group I= patients had planned rotational atherectomy in calcified coronary lesion

Group II= patients had bailout rotational atherectomy in calcified coronary lesion

There was no statistical significance between the two groups with respect to the risk of cardiogenic shock (group I vs. group II: 3.3% vs. 11.5%, $p=0.328$), LVF (group I vs. group II: 3.3% vs. 15.4%, $p=0.172$), Bleeding (group I vs. group II: 3.3% vs. 3.8%, $p>0.999$), arrhythmia (group I vs. group II: 6.7% vs. 15.4%, $p=0.293$) and no stroke was seen in both groups.

Table 8: After 6 months outcome of group I and group II respondents (n=56).

Variable	Group I n=30 n(%)	Group II n=26 n(%)	p value*
MACE	1(3.3)	4(15.3)	0.176
Death	0(0.0)	1(3.8)	0.464
Myocardial infarction	1(3.3)	2(7.7)	0.219
Target vessel revascularization (TVR)	0(0.0)	1(4)	0.455
Stent thrombosis	0(0.0)	0(0.0)	

*Fisher's Exact test was done. Values were expressed as frequency with percentage over column

Group I= patients had planned rotational atherectomy in calcified coronary lesion

Group II= patients had bailout rotational atherectomy in calcified coronary lesion

The 6-months clinical outcomes were listed in Table 7. After 6-months follow-up, the incidence of composite MACE in the group I (3.3%) lower than group II (15.3%) was not statistically significant ($p=0.176$). The risk of death (group I vs. group II: 0.0 % vs. 3.8 %, $p=0.464$), MI (group I vs. group II: 3.3 % vs. 7.7%, $p=0.219$), TVR (group I vs. group II: 0.0% vs. 4.0%, $p=0.455$) did not differ significantly among the groups. No stent thrombosis was found in both groups.

Table 9: Binary logistic regression analysis of MACE outcome after 6 months of follow-up with confounding variables.

Variable	P value	OR	95%CI
Male	0.105	0.233	0.04-1.354
Hypertension	0.592	0.717	0.213-2.420
Diabetes mellitus	0.379	1.876	0.462-7.621
Dyslipidemia	0.986	0.986	0.200-4.854
Smoking	0.124	3.339	0.720-15.490
Family history of CAD	0.43	0.576	0.146-2.270

Statistical test: binary logistic regression; OR= Odds ratio; CI= Confidence interval; 95% CI and p- value were calculated.

Binary logistic regression was performed to assess the impact of several factors on the likelihood six months composite MACE.

Among the variables did not exhibit significant associations ($P> 0.05$).

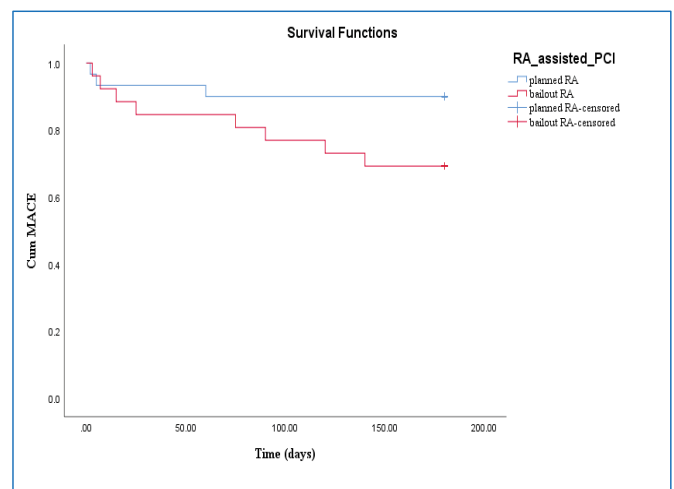


Figure 3: Kaplan-Meier Curves of 6-months composite MACE study.

Cox regression analysis showed the incidence of 6 months composite MACE in bailout RA group was statistically not significantly higher compared to planned RA group (hazard ratio 3.265, 95% CI 0.866-12.317, p value=0.081).

Discussion

In this prospective observational study, the main objective was to compare the short- term outcomes between planned and bailout RA in patients with calcified coronary artery lesions. According to this study, the mean age of the study populations in planned rotational atherectomy and bailed rotational atherectomy were comparable which was 61 ± 7.25 years and 61.84 ± 6.59 years respectively. However, there were notable differences found in the age distribution, while Planned RA predominantly includes aged 50-60 years while bailout RA comprises a higher proportion of individuals aged 61-70 years in this study. This age distribution was dissimilar to Allali et al. [11] where the mean age was 71.5 ± 8.9 vs 71.2 ± 9.5 which was higher than this study. As calcified coronary artery

lesions are more common above 70 years age but in this study family history of premature CAD might be the cause of increase prevalence of calcified coronary artery lesions in young age. Male gender was predominant in both group (80% vs 73.1%). The male-female ratio was approximately 5:1. Apart from male gender is the risk factors for coronary artery disease; social and financial constraints might be the contributor for lower participation of women in intervention procedure. This findings were also similar to Kawamoto et al [12] where male gender was predominant 76.1% (n= 271) vs 79.3% (n=245). The study found cardiac risk factors such as hypertension, diabetes mellitus, dyslipidemia, a family history of premature coronary artery disease (CAD), and smoking history do not differ significantly between the groups, Kawamoto et al. [12] observed that patients with bailout RA had a higher proportion of smokers (24.3% vs. 15.9%), had a family history of CAD (29.4% vs. 19.0%) but had less insulin dependent diabetes (10.7% vs. 16.2%). Interestingly in this study, both planned and bailout RA procedures have similar angiographic characteristics, including a preference for radial artery access and a prevalence of right-sided coronary dominance. However, there were considerable changes in the selection of target vessels, with planned RA largely involving the left anterior descending (LAD) artery (60%) and bailed RA favoring the right coronary artery (RCA) (57.7%) following this study. Similar study showed LAD and RCA were most common target vessel among bailed RA group while the majority had LAD in planned RA patients [11]. Another study also found the RCA was the most common target for RA (40.8%) and radial artery the commonest access site for RA [13]. Comparison to bailout RA, Intravenous ultrasonography (IVUS) was commonly done among planned RA group in this study. However, number of burr, maximum burr size, rotational speed, burr to artery ratio, pre-dilation balloon diameter, number of stent, length and diameter of stent were quite similar in both groups. Kawamoto et al. [12] also, revealed number of IVUS, maximum, burr size, number of stent, length and diameter of stent were significantly higher among bailout RA though, the number of pre-dilation balloon catheters was significantly lower in the planned RA group. Nevertheless, procedural parameters and outcomes demonstrated significant differences between the two approaches. While there are no notable differences in parameters such as hemoglobin levels, serum creatinine levels, or ejection fraction, bailout RA exhibits longer procedural durations, higher contrast volumes, and increased fluoroscopy times compared to planned rotational atherectomy. In this study large dissection (>5mm), no/slow flow and pericardial effusion as a procedural complications were higher in bailout RA. Furthermore, both groups had final TIMI3 flow, residual stenosis <20% and strategy success but higher rate in planned RA. Also, none of the groups had perforation or stent failure in this study. Allali et al [11] found in their study that angiographic success was achieved in the

majority of cases, but was lower in the bailout RA group. Procedural duration were longer in that group (32min vs. 18 min, $P < 0.001$), mean contrast amount was higher (279mL vs. 202mL, $P < 0.001$), and fluoroscopy time and (93.7% vs. 97.6%, $P = 0.02$). Similar to this study Cao et al. [14] also showed the number of balloon (1.6 ± 0.8 vs. 2.7 ± 1.3 , $P < 0.001$), procedure time (83.5 ± 26.2 vs. 100.8 ± 36.4 min, $P = 0.007$), fluoroscopy volume (941 ± 482 vs. 1227 ± 872 mGy, $P = 0.012$) and contrast amount (237 ± 62 vs. 275 ± 90 ml, $P = 0.003$) were all lower in planned RA group which was similar to our study. In-hospital complications were found in both planned and bail out RA in this study. Among these two groups in- hospital MACE was lower in planned RA compared to bailout RA but it was not statistically significant (6.7% vs. 15.4%, $p = 0.401$). Some other complications like left ventricular failure, arrhythmia, cardiogenic shock, access site complications and major bleeding were found relatively less in planned RA procedure comparison to bailout RA in this study. Bacmeister et al. [15] also, showed the in hospital complications including slow-flow, coronary dissection, and MI occurred in 4.8% after planned, and in 5.7% after unplanned RA, but TVR occurred in 18.5% after planned, and in 14.7% after bailout RA. However, in a meta-analysis study found no difference in major adverse cardiovascular events on follow-up, death, MI, target vessel re-vascularization, stroke or stent thrombosis in the comparison of planned vs. bailout RA procedures [16]. After six months follow up, the incidence of composite MACE in group-I was lower than group-II (3.3% vs. 15.3%, $p = 0.176$) but it was not statistically significant. Gorol et al. [17] revealed the rate of in-hospital complications did not significantly differ between bailout RA and planned RA and also no difference in the 12-month survival rate (86.1% vs. 92.0% in group 2; $p = 0.27$) or MACE (16.3% vs. 15.0%; $p = 0.8$). The study of Qi et al. [18] reported that there was no difference in all-cause mortality (9.1% vs. 12.5%, $P = 0.504$) or long-term MACE (13.8% vs. 17.1%, $P = 0.560$) between bailout versus planned RA. All these findings above indicated there was no significant difference in in-hospital and six-month MACE between the two groups.

Conclusion

PCI of calcified coronary artery lesions with planned RA were not significantly associated with reduced six- months MACE compared to bailout RA. Although statistically non-significant, PCI of calcified coronary artery lesions with planned RA numerically lowered MACE than bailout RA which may be advantageous in planned RA in term of short-term outcomes.

Limitations

- It was a single center study.
- Sample size was small.

- Sampling was done by non-randomized (consecutive) sampling method.
- Long-term follow-up after RA was not done. Extended follow-up may be critical to assess the long-term clinical benefit of planned RA over bailout RA.

Recommendations

- Further randomized multicenter studies with larger sample size and longer follow-up are recommended.
- Planned RA can be considered as a better alternative to bailout RA in calcified coronary artery lesions in Bangladeshi population.

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