Original Article

Short and Long Term Outcome In Patients with Calcified Lesions Requiring Rotational Artherectomy

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Abstract:

Objective: Despite the evolution of interventional techniques and operator experience, percutaneous revascularization of complex coronary lesions especially calcified lesions remains challenging because of lower procedural success and higher restenosis rates. Limited data are available on the effect of rotational atherectomy (RA) plus stenting in the treatment of complex calcified lesions of coronary artery disease. This study was aimed to investigate the characteristics, short and long term outcomes in patients undergoing RA.

Material and Methods:A database search was performed from the year 2008 to 2013 in National Heart institute, Malaysia. A total of 16009 patients who underwent PCIs were enrolled in 2 groups, RA group (258 patients) and non RA group (15751 patients). The Chi square test and Kaplan - Meier analysis were used.

Results:Male patients (73.6%) and elderly population (63.2%) were predominant in this study.The RA group had more co-morbidities such as diabetic on insulin (34%) and chronic kidney disease (57%). The lesions in RA group were more complex with higher Type C lesion (68.8%) and longer lesion (20.6%) compared to non RA group. Despite higher patient risk profile, the success rate of revascularization remains high in RA group (99.3%) as in non RA group (97%) (p value 0.89%).

More importantly there were no significant difference in in-hospital mortality, myocardial infarction and stent thrombosis in both group (p value 0.1). In 1 year Kaplan - Meier survival graph, there were better survival noted in non RA group (97.7%) compare to RA (89.6%) (p value <0.005),

Conclusion: The use of RA allows debulking of a calcified lesion and possibly explains the higher acute procedural success rates. However, the lower 1-yearsurvival in the RA group highlights the higher associated baseline co-morbitidity in this group. Therefore, besides coronary intervention, this RA group requires aggressive medical therapy through a multi-disciplinary approach.

Keywords:

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Introduction:

Percutaneous coronary intervention is currently the most frequent form of revascularization for obstructive coronary artery disease. One challenge to successful revascularization is the calcified obstructed coronary

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vessel. Prevalence of calcified coronary lesion is high in elderly, diabetic and renal patients. Rotational atherectomy (RA) can be useful in the treatment of these lesions.

First used in 1989, rotational atherectomy is based on the differential removal of plaque by a rotating diamond covered burr (1). Since introduction of RA, data have not shown long-term benefit and target lesion revascularization rates remained unacceptably high, ranging from 15–36% at 6–9 months(2-9). However, it has found a niche in improving procedural success rates in complex, heavily calcified lesions in which balloon angioplasty and stenting alone often result in failure or suboptimal stent expansion(10-15). Once, RA was involved in up to 10% of percutaneous coronary interventions (PCI) (16). Currently, RA use has fallen to 3% to 5% in select high-volume centers and <1% in others (17) because it is technically demanding procedure reliant on operator experience.

Since the advent of drug-eluting stent (DES) technology, there has been a resurgence in rotational atherectomy(8-9). DES are associated with improved outcomes after RA. In patients treated with RA, rates of MACE are lower with DES compared with BMS in 3 recent series(8,18-19). Therefore, we sought to analyze patient characteristics, long and short clinical outcomes of patients who underwent RA between January 1, 2008 and December 31, 2013 in National Heart Institute, Malaysia .

Methods:

This was a retrospective analysis at National Heart Institute, Malaysia . The cardiac catheterization database was searched to identify all cases involving RA between the year 2008 to 2013. A total of 16009 patients who underwent PCIs were enrolled in 2 groups. RA group consist of 258 patients while in non RA group there were 15751 patients. The use of RA and all other clinical decisions were at the discretion of the interventionalist. DES were routinely implanted during coronary interventions. Patient demographics, medical history, procedural characteristics, short and long term outcomes were recorded through a comprehensive chart review. Procedural and lesion characteristics were further defined using quantitative coronary angiography.

All patients had objective evidence of myocardial ischemia and > 70% angiographic diameter stenosis by visual estimate. Informed written consent was obtained from each patient. Rotational atherectomy was performed using the standard femoral/radial approach and usually use of a single burr with burr-to-artery ratio of 0.7 to 0.8. But a step-up burr technique, generally beginning with 1.25 mm or 1.5 mm burrs also used if required. The rotational burr was slowly advanced with a high-speed rotation (> 160,000 rpm). Adjunctive balloon angioplasty was performed using balloons sized with balloon-to-artery ratios of 1.1:1. Stents were deployed by inflating the stent delivery balloon with a nominal pressure and, if necessary, adjunctive high-pressure balloon dilatation was performed to achieve angiographic optimization (residual diameter stenosis < 10% by visual estimate). During the procedure, patients received 100units/kg bolus heparin with repeated boluses to maintain the activated clotting time > 250 seconds.

Lesions were classified according to American College of Cardiology/American Heart Association criteria(20). Lesion length was measured as the distance from the proximal to the distal shoulder of the lesion in the least foreshortened projection. Complex lesions were defined as type B2 and type C lesions according to American Heart Association/American College of Cardiology classification(20). Long lesions were defined as e” 20 mm. A lesion was defined as bifurcating if a branch > 1.5 mm with ostial disease originated within the stenosis and the branch was completely surrounded by stenotic portions of the parent vesse(21). A lesion that originated within 3 mm of the vessel origin was defined as ostial (21). Lesion calcification was defined prior to contrast injection as: severe if radiopacities were readily apparent without cardiac motion; moderate if radiopacities were apparent only with cardiac motion; mild if faint radiopacities were seen only with cardiac motion; and none if no radiopacities were seen (21).

Clinical outcomes were determined during the index hospitalization, at six month and twelve month follow up. Complications were defined as death, periprocedural MI(new creatine kinase elevation above two times the upper limit of normal), stent thrombosis, perforation, worsening of renal function. Angiographic success was defined as < 20% residual stenosis and thrombolysis in myocardial infarction (TIMI) grade 3 flow at the conclusion of the procedure. Procedural success was defined as angiographic success in the absence of MACE. All patients were requested to visit the outpatient clinics at regular intervals (at 6month and one year after intervention). Follow-up information was obtained by hospital chart. One year survival was plotted in Kaplan – Meier graph.

Results are reported as median or percentages of the total. For statistical comparison, cases were devided into two groups based on whether or not undergone RA. Chi square test and Kaplan –Meier analysis were used. Statistical significance was considered a p-value < 0.05.

Results:

A total of 258 cases involving RA were identified between January 1, 2008 and December 31, 2013. RA was indicated for plaque modification in the setting of moderate to severe calcification in 1.6% of population. In 248 patients single vessel was rotablated while 16 patients required double vessel rotablation. There were no significant differences in the baseline clinical characteristics between the two groups (Table 1). Majority of the patients were male patients (73.6%) and elderly population (63.2%).

Although the patients in RA group had more comorbidities such as diabetic on insulin (34%) and chronic kidney disease(57%) in comparison to non RA group, the difference was not statistically significant (figure1).

Table-I

Baseline Characterstics

	RA Group		Non RA group		p-value	TOTAL
	TOTAL	%	TOTAL	%		
No of cases	258	1.6	15751	98.4		16009
Gender, N (%)						
Male	190	73.6%	12987	82.50%	0.473	
Female	68	26.4%	2764	17.50%	0.228	
Age, Median (IQR1,IQR3)	65.6 (58.1,71)	57.8 (51.1,64.9)				
Age range, N (%)						
Below than 40 yr	3	1.1%	640	4.1%	0.18	
40 – 50 yr	15	5.8%	2770	17.6%	0.014	
50 – 60 yr	59	22.9%	5691	36.1%	0.091	
60 – 70 yr	103	40.0%	4658	29.6%	0.232	
More than 70 yr	78	30.2%	1992	12.6%	0.01	
BMI, Median (IQR1,IQR3)	25.5 (23.3,28.8)	26.5 (24,29.4)				
BMI range, N (%)						
Below than 18.5	8	3.1%	192	1.2%	0.317	
18.5 – 24.9	93	36.0%	4743	30.1%	0.46	
25 -29.9	88	34.1%	6063	38.5%	0.558	
More than 30	43	16.7%	3037	19.3%	0.739	
Not available	26	10.1%	1716	10.9%	0.827	

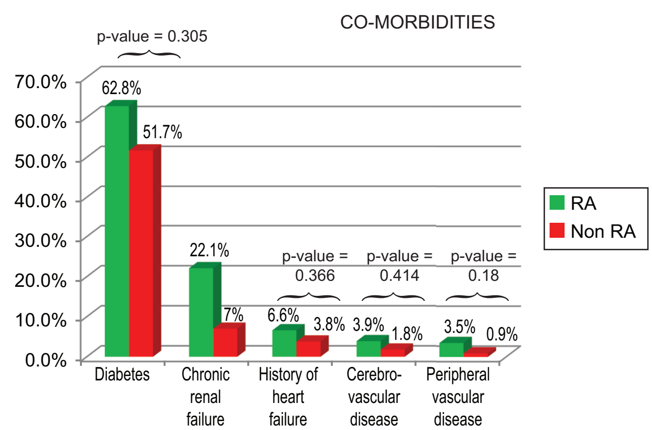

Fig.-1: *Patient's comorbidities*

Table-II
Lesion Characterstics

	RA Group		Non RA group		p-value	TOTAL
	Total	%	Total	%		
No of lesions treated	292	1.3	22400	98.7	22692	
Coronary lesion, N (%)						
De Novo	280	95.9	20989	93.7	0.885	
In Stent Restenosis	10	3.4	1273	5.7	0.317	
Stent thrombosis	1	0.3	72	0.3	NIL	
Lesion types, N (%)						
Type A	4	1.4	1863	8.3	0.02	
Type B1	25	8.6	5553	24.8	0.006	
Type B2	62	21.2	5773	25.8	0.466	
Type C	201	68.8	8894	39.7	0.005	
Not available			317	1.4	NIL	
Lesion description, N (%)						
Bifurcation	45	15.4	2391	10.7	0.433	
Total occlusion	9	3.1	1243	5.5	0.317	
CTO (>3 months)	27	9.2	1814	8.1	0.808	
Estimated lesion length, mm						
Mean (SD)	35.8 (20.6)	24.6 (14.6)	NIL			
Median (IQR1,IQR3)	30.2 (19.2,48.3)	20 (14.6,30.3)				
Cutting/scoring balloon, N (%)	11	3.8	463	2.1	0.414	
IVUS, N (%)	35	12	1196	5.3	0.09	

The baseline angiographic characteristics are shown in Table 2. Lesion length and morphology is defined by American Heart Association/American College of Cardiology classification. The lesions in RA group were more complex with higher Type C lesion (68.8% versus 37.9, p value 0.005) and longer lesion (20.6%vursus 14%) compared to non RA group. Utilization of intravascular ultrasound to clarify the lesion morphology and result outcome was low (17.3%).

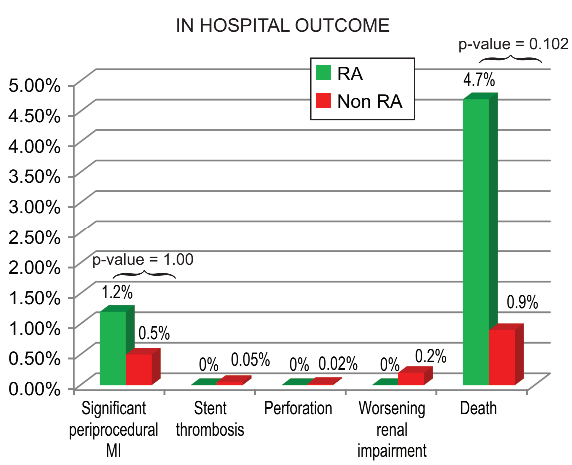

Fig.-2: *Periprocedural in hospital outcome.*

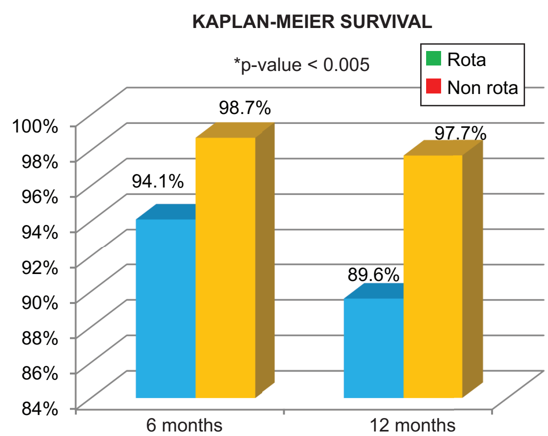

Fig.-3: *Kaplan-Meier survival*

Despite higher patient risk profile, the success rate of revascularization remains high in RA group (99.3%) as in non RA group (97%) (p value 0.89%). More importantly there were no significant difference in inhospital mortality, myocardial infarction and stent thrombosis in both group(p value 0.1).

Angiographic success was not achieved in 2 patients(0.7%) of RA group and 681patients(3%) in non RA group. Death occurred 4.7% patients in RA group in comparison to 0.9% in non RA group (0.102). In 1 year Kaplan –Meier survival graph, there were better survival noted in non RA group(97.7%) compare to RA (89.6%)(pvalue <0.005)(Figure3).

Discussion:

The commercially available Rotablator (Boston Scientific,Natick, Massachusetts), invented by Auth and described by Ritchie and colleagues (22) utilizes an over-the-wire, coaxially driven, diamond-tipped, high-speed speeds (140,000 to 180,000 rpm) rotating elliptical burr to pulverize the atherosclerotic plaque. It produces lumen enlargement by physical removal of plaque and reduction in plaque rigidity, facilitating dilation. The burr preferentially ablates hard, inelastic material, such as calcified plaque, that is less able to stretch away from the advancing burr than is healthy arterial wall (differential cutting). High rotational speeds facilitate longitudinal burr movement across calcific lesions by orthogonal displacement of friction. A guidewire helps to keep the burr's abrasive tip coaxial with the vessel lumen, although wire bias in highly tortuousor angulated segments may predispose to dissection or perforation(2). Unlike balloon angioplasty, which tends to produce intimal splits and medial dissections in calcified lesions, RA yields a relatively smooth luminal surface with cylindrical geometry and minimal tissue injury(2) .The cardinal indication for RA is the calcific lesion, which, in the absence of plaque modification, confers an increased likelihood of procedural failure, stent underdeployment, restenosis, and major complications (23).

This study was sought to describe the short and long term outcome of RA. RA was used primarily in 292 complex lesions (1.3%) with moderate to severe calcification where the operators felt balloon angioplasty and stenting alone would not be sufficient. At one time, RA was involved in up to 10% of percutaneous coronary interventions (PCI)(16)but in the recent series, RA use has fallen to 3% to 5% in select high-volume centers and <1% in others (17).

Lesion characterstics analysis revealed that RA group had higher Type C lesion (68.8% versus 37.9, p value 0.005) and longer lesion (20.6% versus 14%) compared to non RA group. Among these lesions 9.2% were CTO in RA group.

The major findings of this study is despite higher patient risk profile, rotational atherectomy, followed by stenting, is associated with favorable short-term outcomes. Angiographic and procedural success rate remains high in RA group (99.3%) as in non RA group (97%) (p value 0.89%) and complications in terms of inhospital mortality, myocardial infarction and stent thrombosis was similar in both group(p value 0.1). Retrospective series of RA describe high rates of short-term procedural success (range 93.4% to 98.6%), superior to rates reported separately in the absence of preceding plaque modification (6,7,15). The literature describes the use of RA in heavily calcified lesions improve stent expansion(3-6,13) and enable DES deployment in nondilatable, calcified lesions(26,27). Other studies showed RA facilitates procedural success in PCI of complex(American College of Cardiology/American Heart Association types B2 and C) lesions (28,29), including chronic total occlusions (30,31), ostial lesions (32-34), and bifurcation lesions, which may be associated with both bulky plaque and vessel geometry unfavorable for stent deployment.

Several nonrandomized trials have reported that rotational atherectomy shows no obvious difference in the acute success rate or restenosis rate in noncomplex coronary lesions compared with other techniques(35,36). Two previous studies by Kishi and Teirstein reported a disappointing restenosis rate of 57.5and 59.0% after rotational atherectomy in patients with diffuse coronary artery disease, which suggested that debulking of excess tissue with rotational atherectomy was not effective therapy for diffuse coronary artery disease(37,38). In other studies, heavily calcified lesions, RA and DES deployment results in target lesion revascularization rates ranging from 2–10.6% at 6 months to 3 years, which is significantly better than RA and BMS(8-9,24-26). Furthermore, several techniques using rotational atherectomy, such as use of a single burr with burr-to-artery ratio of 0.5 to 0.6-rotational speed of 140,000 to 150,000 rpm, gradual burr advancement using a pecking motion, short ablation runs of 15 to 20 s, and avoidance of decelerations >5,000 rpm. Combined with meticulous technique, optimal antiplatelet therapy, vasodilators, flush solution, and provisional use of atropine, temporary pacing, vasopressors, and mechanical support may prevent slow-flow/no-reflow, which in contemporary series is reported in 0.0%to 2.6% of cases(2).

Beyond immediate procedural success, however, data have not shown a consistent long-term benefit of lesion modification by RA for restenosis and major adverse cardiovascular events (MACE)(2). In this study in 1 year Kaplan –Meier survival graph, better survival was noted in non RA group(97.7%) compare to RA (89.6%)(p value <0.005). Long-term benefit was again absent in the recent ROTAXUS (Rotational Atherectomy Prior to Taxus Stent Treatment for Complex Native Coronary Artery Disease) study, the first randomized trial to directly test the impact of RA on long-term outcomes of DES placement (39). In a series of 240 patients with moderately or severely calcified obstructive lesions treated with or without RA before paclitaxel-eluting stent implantation, there was greater strategy success and short-term lumen gain with RA. However, routine angiographic follow-up at 9 months showed no difference in MACE and greater late lumen loss (40) with an RA strategy.

Conclusion:

The cardinal indication for RA is the calcific lesion, which, in the absence of plaque modification, confers an increased likelihood of procedural failure, stent underdeployment, restenosis, and major complications.

The present study indicates that calcified coronary artery lesions can be successfully treated by high speed rotational atherectomy and the success rate of rotational atherectomy was not reduced by calcification despite the more frequent complex nature of the calcified lesions. Though higher mortality and lower rate of survival were noted in rotational atherectomy group in this study, it should be attributed to the fact that they come from high risk group of patients who have multiple comorbidities.

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