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Comparison of rotational atherectomy and conventional angioplasty for calcified coronary stenosis with high calcium score detected by multi-slice CT coronary angiography.

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Abstract:

Objectives: comparing the clinical outcomes of rotational atherectomy (RA) and conventional PCI methods on heavily calcified lesions in patients with high calcium scores detected.

Methods: This was a clinical trial conducted on 30 patients aged above 18 years, their angiography proved coronary artery disease, having anginal symptoms and/or reproducible ischemia in the target area by ECG, functional stress testing, or fractional flow reserve, their calcium score more than 1000 on MS-CT coronary angiography. Patients were randomly assigned to 2 groups: Group A rotational atherectomy followed by DES implantation and Group B PCI through balloon predilatation using non-compliant balloons to facilitate device crossing followed by DES implantation. Angiographic assessment immediately after revascularization & 6 months later on was performed.

Results: Strategy success, the primary endpoint of the trial, was significantly more common in the RA group (46.6% in the conventional PCI group versus 100% in the RA group; $P=0.0447$). The main driving factor for strategy failure was the need to crossover to RA in the conventional PCI group (33.3% versus 0%; $P=0.042$). The reasons for crossing over in the conventional PCI group were, the lesion was not crossable by any balloon in 1 case, the lesion was not adequately dilatable in 3 cases and the stent was not deliverable despite adequate pre-dilatation in 1 case.

Conclusions: Lesion preparation with upfront RA before DES implantation is feasible in nearly all patients with complex calcified coronary lesions (as high as >1000 ca-score as detected by MS-CT) and is more commonly successful as a primary strategy compared with conventional PCI using non-compliant balloons.

Key words: Rotational atherectomy – calcified coronary stenosis – PCI – coronary angiography.

Introduction:

The outcome of coronary and endovascular revascularization depends on the interaction between biologic tissues and structures with tailored technology. While the development and application of devices and revascularization techniques for percutaneous coronary and vascular interventions have advanced rapidly in recent years, several challenges remain, most notably the presence of vascular calcification. This complex biocomponent is created by distinct pathologic–biologic mechanisms. Various types of calcifications are recognized, all of which can severely exert deleterious effects on the coronary and peripheral vasculature. ⁽¹⁾

Percutaneous coronary intervention (PCI) with calcified lesions is associated with poor clinical outcomes. It is essential to achieve optimal stent expansion in calcified lesions for improving clinical outcomes. ⁽²⁾ During percutaneous coronary intervention (PCI), coronary artery calcifications are an impediment to crossing the lesion with standard devices and to dilation with a standard balloon, which often results in stent under expansion, and procedural complications such as slow flow/no reflow, dissection, and perforation. ⁽³⁾

Numerous surgical techniques have been used to treat calcified coronary arteries, which includes non-compliant high-pressure balloons, excimer lasers, rotational atherectomy devices, and orbital cutting/scoring balloons. Lesion modification using rotational atherectomy (RA) has been proven to be associated with better clinical outcomes for severely calcified lesions. Rotational atherectomy (RA) is an alternative or adjunctive procedure to percutaneous balloon angioplasty; it mechanically ablates resistant or heavily calcified lesions by causing lumen enlargement by physical removal of atherosclerotic plaques and reduction in plaque rigidity, enabling dilation. ⁽⁴⁾

Our study aimed to compare the clinical outcomes of rotational atherectomy and conventional PCI methods on heavily calcified lesions in patients with high calcium scores detected by MS-CT coronary angiography.

Patients and methods:

This study was a controlled clinical trial conducted at the Cardiology department of Beni-Suef university hospital between July 2020 & January 2022. The study included 30 patients aged above 18 years, their angiography proved coronary artery disease, having anginal symptoms and/or reproducible ischemia in the target area by ECG, functional stress testing, or fractional flow

reserve, their calcium score more than 1000 on MS-CT coronary angiography. Their angiography revealed de-novo lesion in a native coronary artery, target reference vessel diameter between 2.25 and 4.0 mm by visual estimation, luminal diameter reduction of 50-100% by visual estimation and had severe calcification of the target lesion defined as radiopacities noted without cardiac motion before contrast injection generally compromising both sides of the arterial lumen. We excluded patients with myocardial infarction within 1-week, decompensated heart failure and limited long-term prognosis due to other conditions. Their angiography showed target lesion in a coronary artery bypass graft, the target lesion was an in-stent restenosis and patients with target vessel thrombus.

Patients were randomly assigned to 2 groups (A total of 30 patients): Group A were submitted to rotational atherectomy followed by DES implantation and Group B underwent PCI through balloon pre- dilatation using non-compliant (NC) balloons to facilitate device crossing and followed by DES implantation.

Methods:

All patients were subjected to full history taking, baseline ECG & cardiac enzymes (cardiac troponins & CK-MB), baseline echocardiography calcium scoring by MS-CT coronary angiography and the standard pharmacological treatment as per the institutional guidelines for elective PCI.

Calcium scoring by MS-CT coronary angiography:

The extent of calcification was measured for each patient (total calcium score), vessel (per-vessel calcium score), and target lesion (per-lesion calcium score). Coronary calcium was defined as any plaque of least three contiguous pixels with a density >130 Hounsfield units (HU). ⁽⁵⁾ Per-lesion calcium scores were calculated by multiplying the target lesion area by a density factor derived from the maximal HU within this area, as described by Agatston. ⁽⁶⁾

Standard pharmacological treatment as per the institutional guidelines for elective PCI:

Intra-procedural anticoagulation using unfractionated heparin, if not pretreated, an aspirin loading dose of 300 mg is started, and will be encouraged to continue this regimen indefinitely. After a 600 mg clopidogrel or 180mg ticagrelor loading dose, additional antiplatelet therapy with a 75 mg clopidogrel or 90mg twice ticagrelor maintenance dose should be instituted in all patients, who

will then be advised to continue this regimen for 12 months. In all cases, adjunctive devices and pharmacotherapy will be at the discretion of the operating interventional cardiologist.

Group (A) was submitted to rotational atherectomy followed by DES implantation and Group (B) underwent PCI through balloon pre-dilatation using non-compliant (NC) balloons to facilitate device crossing and followed by DES implantation. The use of more than 1 balloon was allowed. The size of the final balloon used was chosen in a 1:1 ratio according to the vessel size. Crossover to RA was only allowed if the lesion was not crossable by any balloon, not crossable by any NC balloon even after standard balloon pre dilatation, not adequately dilatable (i.e., complete balloon expansion without a visible residual waist could not be achieved), or the stent could not be delivered to the lesion despite complete balloon expansion.

RA was performed by the Rotablator (Boston Scientific Scimed, Natick, MA). The burr size was selected to reach a burr/vessel ratio of 0.5 (maximum 0.7 if needed). Rotational speed ranged between 140 000–180 000 rotations per minute. The burr was parked immediately proximal to the lesion to avoid injury to the healthy vessel segment. Heparin, verapamil, and nitroglycerin were administered during RA as an intracoronary infusion. Stenting was performed using a new-generation sirolimus-eluting stent with a bioabsorbable polymer according to local resources.

More than 1 study stent was permitted for treatment of the target lesion(s). The appropriate stent length for the target lesion should have been ≥ 4 mm longer than the lesion length to allow for coverage between healthy vessel segments, with adequate stent overlapping. Post dilatation was performed at the operator's discretion. On procedure completion, intracoronary nitroglycerin was administered, and final angiography of the vessel was performed in at least 2 orthogonal views that showed the target site free of foreshortening or vessel overlap.

Detailed clinical and endpoint definitions

Access site complications: The presence of a hematoma at the procedural puncture site associated with or without pseudoaneurysm, before discharge and classified as 1 of 4 types: minor with no therapy used, moderate necessitating blood transfusion, moderate necessitating thrombin injection, or major for which an operation was performed. ⁽⁷⁾

Angiographic grading of coronary calcification: Coronary calcium was angiographically graded as follows; none/mild, moderate when radiopacities noted only during the cardiac cycle

before contrast injection and severe when radiopacities noted without cardiac motion before contrast injection generally compromising both sides of the arterial lumen. ⁽⁸⁾

Multivessel disease: Multivessel coronary artery disease (MVD) is defined as luminal stenosis of at least 70% in at least two major coronary arteries or in one coronary artery in addition to a 50% or greater stenosis of the left main trunk.

Cardiac death: Cardiac death was defined in accordance with the Academic Research Consortium (ARC) criteria as any death due to a proximate cardiac cause (e.g., myocardial infarction, low-output failure, fatal arrhythmia), unwitnessed death and death of unknown cause, and all procedure-related deaths, including those related to concomitant treatment, were classified as cardiac death.

Myocardial infarction: The definition of myocardial infarction (MI) is based on the detection of high-sensitive cardiac troponin (hs-cTn) levels above the 99th percentile of upper reference limit (URL) value for a healthy reference population together with symptoms and/or ischemic electrocardiographic changes. ⁽⁹⁾

Stent failure: Defined as either stent loss (in the coronaries, the aorta, or other vessels), stent damage (e.g., damaged struts), or stent could not be implanted or had to be implanted in an unintended position. ⁽¹⁰⁾

Target lesion revascularization (TLR): TLR was defined as any repeat PCI of the target lesion or bypass surgery of the target vessel. ⁽¹¹⁾

Target vessel revascularization (TVR): TVR was defined as repeat PCI or bypass surgery of the target vessel. ⁽¹¹⁾ The target vessel consists of the target lesion(s) and any additional lesions in the main epicardial coronary artery or branches containing the target lesion. Clinically driven TVR was considered if any of the following criteria were met:

1. Diameter stenosis $\geq 50\%$ at follow-up angiography and the patient had a positive functional study corresponding to the area served by the target vessel, and ischemic symptoms and ECG changes at rest referable to the target lesion.
2. Diameter stenosis $< 50\%$ at follow-up angiography but a markedly positive functional study or ECG-changes corresponding to the territory supplied by the target vessel.

3. Diameter stenosis $\geq 70\%$ at follow-up angiography in absence of documented clinical or functional ischemia.

Target vessel failure (TVF) TVF was defined as a composite of cardiac death, target vessel-related myocardial infarction (Q- or non-Q-wave), and clinically driven target vessel revascularization during the follow-up period. ⁽¹¹⁾

Stent thrombosis (Academic Research Consortium definition). ⁽¹¹⁾ Acute coronary syndrome with angiographic or autopsy confirmation of stent thrombosis. The condition is said to be probable with unexplained death within 30 days of stent implantation without an autopsy and acute myocardial infarction in the territory of the target vessel where the stent was implanted but without angiographic confirmation. The condition may occur early during the procedure of stent implantation (PCI) or within 30 days outside PCI; late within 1-12 months after stent implantation (up to 1 year), and very late after one year of stent implantation.

Primary outcomes:

Angiographic assessment immediately after revascularization & 6 months later on. Angiographic success is defined as post-procedural stenosis $\leq 20\%$ and Thrombolysis in Myocardial Infarction (TIMI) flow grade III.

Secondary outcomes:

The secondary clinical endpoints included procedural duration, fluoroscopy time, contrast dye amount, access site complications, composite angiographic complications (severe dissection requiring stenting, sustained no-reflow, and perforation), and in-hospital (death, myocardial infarction, emergency coronary artery bypass grafting [CABG], bailout stent) and 6-month (death, myocardial infarction, or target lesion revascularization) major adverse cardiac events (MACE). Non-Q-wave myocardial infarction was defined as an elevation in total creatine kinase (CK) > 3 times normal, in the absence of pathologic Q-waves.

Statistical analysis

Values were presented as numbers and proportions or median and range. The distribution of qualitative variables among patient groups was compared by the Chi-square test or Fisher's exact test, as indicated. Quantitative variables were checked for normality by the Shapiro-Wilk test. Correlation between syntax score II, Ca score CT, fluoroscopy time and contrast amount was tested

using Spearman Correlation Coefficient. As data were not normally distributed, variables were compared between groups by the Mann-Whitney test. All tests were bilateral and a P-value of 5% is the limit of statistical significance. Analysis was performed by statistical package software IBM-SPSS version 24.

Results:

Baseline clinical and demographic data (Tables 1 and 2):

Thirty patients were enrolled in the study, 15 patients were randomized to lesion preparation with conventional balloon angioplasty (Conventional PCI group) and 15 patients to lesion preparation with rotational atherectomy (RA group). The mean age among the studied patients was 65 ± 6.93 years, about (70.0 %) of patients were males and (30.0%) were females. 60% were hypertensive, 60% were diabetic, 50% were smokers (all are males) and 53.3% were dyslipidemic. Other clinical risk factors included CA Ca-score by CT = 2080 ± 498 , Syntax II score 25.99 ± 5 , and Cr Cl (creatinine clearance ml/min) = 85 ± 11 . Baseline LV EF (Left ventricular ejection fraction) = 61 ± 7 % as measured by eyeballing & M-mode echocardiography. There were no significant differences between both groups as regards sex, age, Ca score CT, Syntax score II, CrCl (ml/min), baseline LV EF, or other risk factors including hypertension, diabetes mellitus, dyslipidemia, or history of smoking (Table 1).

There were no significant differences between both groups with respect to clinical presentation (mostly stable angina), history of coronary interventions, MI, or presentation with unstable angina (Table 2).

Angiographic characteristics of the studied patients (Tables 3 and 4).

Multivessel disease was common and was present in the majority of patients in both groups (Table 3). The majority of lesions are located in the left anterior descending coronary artery. The target lesions were of high-grade stenosis (mean diameter stenosis by visual estimate $85.45 \pm 8.74\%$ in the conventional- PCI group and $84.02 \pm 10.57\%$ in the RA group (Table 4). Left main disease was involved in 5 cases (2 in the RA group & 3 in the conventional PCI group).

Angiographic procedural characteristics (Table 5).

Overall, 37 lesions were treated (1.2 lesions per patient): 18 in the conventional PCI group and 19 in the RA group. Patients were well balanced with respect to lesion location and morphology, with

the majority of lesions located in the left anterior descending coronary artery. The target lesions were of high-grade stenosis (mean diameter stenosis by visual estimate $88.26 \pm 6.04\%$ in the conventional PCI group and $88.33 \pm 5.56\%$ in the RA group) and had several criteria signifying lesion complexity in addition to severe calcification (20% located at bifurcations, and 23.3% ostial lesions). Lesion characteristics were well balanced between both study groups (Table 5).

All procedures ($n=30$) were performed through the femoral access route and were performed through a 7F guiding catheter. Unfractionated heparin was used in the majority of procedures, and the median dose was 7500 IU (range, 4000–20 000), with no significant differences between groups. Balloon pre-dilatation (before or after conventional PCI and after RA) was performed in the majority of lesions (86.7%) using mostly (96.0%) non-compliant balloons, with a similar mean balloon size but higher mean inflation pressure in the conventional PCI group (P value= 0.033) (Table 8). The use of more than 1 pre-dilatation balloon was significantly more common in the conventional PCI group (47.6% versus 36.3%; $P=0.033$) with the mean maximum pre-dilatation pressure slightly but not significantly higher in the conventional PCI group (16.4 ± 3.39 versus 14.54 ± 3.11 atm; $P= 0.25$).

In the conventional PCI group, the WOLVERINE cutting balloon was used once (6.6%), in the majority of cases NC balloons were used.

For the RA group, a single burr was used in most lesions (86.7%) with a mean burr size of 1.32 ± 0.146 mm. The mean stent length/lesion was well beyond the mean lesion length. After stenting, balloon post dilatation was performed for (46.6%) of treated lesions in both groups most of them in the conventional PCI group (57%), with the mean maximum post dilatation pressure slightly but not significantly higher in the conventional PCI group (20.75 ± 1.83 versus 19 ± 1.09 atm; $P=0.25$).

Procedural and in-hospital outcome (Tables 6).

Procedural complications and outcomes are shown in Table 6. Large coronary dissections, perforations, and no/slow-flow phenomena were rare and were not significantly different in both groups. There were no significant differences in fluoroscopy time, total procedural time, or the amount of contrast dye between both groups. Strategy success, the primary endpoint of the trial, was significantly more common in the RA group (46.6% in the conventional PCI group versus

100% in the RA group; $P=0.0447$). The main driving factor for strategy failure was the need to crossover to RA in the conventional PCI group (33.3% versus 0%; $P=0.042$). The reasons for crossing over in the conventional PCI group were, the lesion was not crossable by any balloon in 1 case, the lesion was not adequately dilatable in 3 cases and the stent was not deliverable despite adequate pre-dilatation in 1 case. There were no deaths, periprocedural MI or reinterventions during hospitalization. Three patients from the conventional PCI group were referred to CABG after strategy failure (20%).

Clinical and angiographic outcomes at 6 months:

Complete clinical & angiographic follow-up over 6 months (Table 7) was available for most of the patients (96.6%). At 6 months, overall mortality was 6.6% in both groups ($P=1.00$). Between discharge and 6 months, spontaneous myocardial infarction occurred in 1 patient in the conventional PCI group and none in the RA group. Clinically indicated target vessel revascularization was numerically higher in the conventional PCI group, but the event rates were low and statistically not significantly different between both groups ($P=0.330$).

Discussion:

Severe coronary calcification is encountered in up to 20% of patients treated with PCI, with an even higher prevalence in certain patient subgroups, particularly the elderly and those with extensive atherosclerotic disease. Clinical practice guidelines emphasize the importance of lesion preparation before attempting stent implantation for a variety of reasons: calcium often impairs balloon advancement, prevents adequate balloon dilatation, impairs stent delivery, damages stent struts or polymeric coatings during vigorous stent advancement, and prevents adequate stent expansion and apposition. ^{(12) (13)}

Therefore, PCI of calcified coronary lesions is usually more complex and time consuming and may be associated with higher periprocedural and long-term complications if procedures are not adequately planned and executed. ^{(12) (14)}

The impact of regional calcified plaque score evaluated by multidetector computed tomography in predicting the addition of rotational atherectomy during percutaneous coronary intervention

was studied and showed that the extent of target lesion calcification in multidetector computed tomography (MDCT), a simple marker of calcified plaque, is useful for predicting the need for rotablation during PCI. ⁽¹⁵⁾

Our study objective was examining success of rotational atherectomy versus balloon-based strategy (non-compliant or modified balloons) as debulking methods for lesion preparation before drug-eluting stents implantation in patients with very high calcium score >1000 as measured by MDCT.

Strategy success is an outcome measure meant to characterize the success of lesion preparation and ultimately stent implantation with a certain PCI strategy and is thus an appropriate end point for the comparative evaluation of the feasibility of different tools and techniques. Theoretically, including crossovers from one group to the other in the composite primary end point may be considered a source of bias. However, assessing the success of a balloon-based strategy justifies the inclusion of crossovers as an important measure of strategic failure.

In our study, the strategy of pre-dilatation with balloon angioplasty failed in almost 46.6% (7 patients) of attempted procedures versus 100% (15 patients) in the RA arm. The majority of these failures were because of the inability of the balloon to reach the target lesion or to completely expand inside the calcified rigid plaque, and the procedures could only be successfully completed with bailout atherectomy. This can be partly explained by the difficulties associated with balloon delivery because of its higher crossing profile. On the contrary, virtually all patients (and lesions) were treatable with RA. Of the seven patients with failed strategy in the balloon-based arm, five patients were shifted to bailout RA and three patients were referred to surgery.

These findings were similar to results obtained from the COBRA study (A randomized comparison of balloon angioplasty Versus rotational atherectomy in complex coronary Lesions). ⁽¹⁶⁾ The rate of stenting for bailout or unsatisfactory results was significantly higher in the PTCA group compared with the rotablator group.

RA also appears to be feasible and effective, with a high rate of procedural success and favorable short- and long-term outcomes as stated in the ROTATE registry (ROTational ATHERectomy), a multicenter Italian registry developed to assess the short- and long-term outcome after RA in a large real-world population. ⁽¹⁷⁾

Similarly, in the ROTAXUS study Abdel-Wahab et al. results showed that the end point strategy success was significantly higher in lesions pretreated with RA compared with standard balloon pre-dilatation, particularly in severely calcified lesions (92.3% versus 71.3%; $P=0.001$). ⁽¹⁰⁾

PREPARE-CALC is a randomized clinical trial comparing different strategies for lesion preparation in patients with calcified coronary artery disease treated with DES and the first randomized trial to compare an MB-based strategy with a strategy of RA. In an elderly population with complex calcific atherosclerotic disease treated at 2 experienced PCI centers, the primary end point of strategy success was higher with RA, which was mainly attributed to a higher frequency of crossover and stent failure in the MB group. ⁽¹⁸⁾

This finding signifies the feasibility of RA in nearly every lesion in patient with more than 1000 calcium-score detected by MS-CT, although the feasibility in chronic total occlusions cannot be assessed from this study because of the low number of included patients.

Procedural duration and fluoroscopy time were slightly longer in RA group but weren't statistically significant.

Although RA seems to be successful in almost all calcified lesions, the procedure requires more fluoroscopy time and is usually longer than a balloon-based PCI procedure—a finding that was also observed in the ROTAXUS trial. ⁽¹⁰⁾ In addition, the technique is somewhat different to standard PCI and requires additional training and experience.

Contrast dye amount was larger in balloon-based strategy but wasn't statistically significant.

We observed a low rate of procedural complications, which supports the safety of both strategies considering the complexity of treated patients and anatomies.

Large dissections (>5mm) occurred in four patients in the balloon-based arm and two patients in the RA arm mostly due to compromise of side branches during high balloon inflation or due to excessive lacerations caused by the rotablator burr.

One case of perforation and hence pericardial effusion in the balloon-based strategy and was due to high inflation pressure at a distal LAD lesion where the artery caliber was small, prolonged balloon inflation at the site of perforation was done with successful ceiling and no pericardiocentesis was needed.

Despite procedural complexity, clinical events during the in-hospital period were rare, and periprocedural MI was uncommon.

Overall, the clinical event rates in this study at 6 months are low, particularly when compared with previous trials with similar patient and lesion complexity.^{(10) (19)} This may be explained by the profile of included patients (elderly with complex lesions but with stable coronary artery disease, preserved left ventricular function, and low incidence of atrial fibrillation) and by the success of performed interventions (aggressive lesion preparation, high rate of post dilatation, low residual stenosis, few periprocedural complications, and modern DES).

The numerically fewer target lesion revascularization and target vessel revascularization events in the RA group are encouraging and correspond to a lower angiographic binary restenosis rate.

Limitations and conclusions:

This study has some limitations. First, it includes a cohort almost exclusively treated through the femoral access route. Although complex procedures, such as RA, often require large sized catheters and optimal guide catheter support, advances in trans radial tools may allow the performance of these interventions via the radial access route as well.

Second, the majority of cases in the balloon-based group were performed using a noncompliant rather than modified balloons, and thus, the differential performance of the latter cannot be adequately determined from this study. However, our results are similar to those of the PREPARE-CALC clinical trial which investigated strategy success for lesion preparation in patients with calcified coronary artery disease treated with DES using an MB-based strategy compared with strategy of RA.

Third, the number of patients enrolled in this study was limited by the availability of rotablation devices and financial resources at this time.

Fourth, the limited use of IVUS based assessment of lesions and implanted stents for better judgment on acute gain and LLL after stent implantation.

Finally, the study included patients predominantly experiencing stable coronary artery disease, and, therefore, its findings cannot be applied to patients presenting with acute coronary syndrome.

In conclusion, lesion preparation with upfront RA before DES implantation is feasible in nearly all patients with complex calcified coronary lesions (as high as >1000 ca-score as detected by MS-CT) and is more commonly successful as a primary strategy compared with conventional PCI using non-compliant balloons.

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Tables

Table (1): Patients' characteristics.

Variable*		Rotational atherectomy group (n=15)	Conventional PCI group (n=15)	Total (n=30)	P-value
Age (years)		65	65	65±6.93	0.902
Sex	Male	11(73.3%)	10 (66.7%)	21 (70%)	1.000
	Female	4(26.7%)	5 (33.3%)	9 (30%)	
Ca-score CT		2077	1820	2080.66±498.55	0.081

Syntax score II	26	27	25.99 ± 5.58	0.967
CrCl (ml/min)	90.3	85.5	85.83 ± 11.40	0.486
LVEF %	63%	60%	60.93 ± 6.98	0.250
Hypertension	8	10	18	0.456
Diabetes	10	18	18	0.456
Dyslipidemia	8	8	16	1.000
Smoking	8	7	15	0.715

(N.) indicates the number of patients, LV EF, left ventricular ejection fraction & CrCl, creatinine clearance.

Table (2): Distribution of previous MI, PCI & unstable angina in both groups.

		Previous MI	Previous PCI	Unstable angina
Total	Count	2	13	7
	% within Groups	6.7%	43.3%	23.3%

Table (3): Distribution of multivessel disease in both groups.

			Multivessel disease		Total
			Yes	No	
Group	Rotational atherectomy	Count	6	9	15
		% within Group	40.0%	60.0%	100.0%
	Conventional PCI group	Count	5	10	15
		% within Group	33.3%	66.7%	100.0%
Total		Count	11	19	30

Table (4): Distribution of the target lesions in both groups.

Group		Target lesion			
		LAD	RCA	LCX	Lt main LAD
	Count	10	2	1	2

Rotational atherectomy	% within Group	66.7%	13.3%	6.7%	13.3
Conventional PCI group	Count	9	2	1	3
	% within Group	60.0%	13.3%	6.7%	20%
Total	Count	19	4	2	5

LAD= Left anterior descending artery, RCA= Right coronary artery & LCX= Left circumflex artery.

Table (5): Angiographic procedural characteristics (N. 37 lesions).

	Conventional PCI (n=15)	RA (n=15)	P-Value
Reference vessel diameter, mm	2.93±0.40	2.96±0.38	0.25
Lesion length, mm	37.13± 8.44	33.93±9.88	0.285
Diameter stenosis, %	88.26±6.04	88.33±5.56	0.967
Ostial location	3 (20%)	4 (26.6%)	0.261
Bifurcation	2 (13.3%)	4 (26.6%)	0.361
Moderate/severe tortuosity	0 (0%)	0 (0%)	...
Chronic total occlusion	1 (6.6%)	3 (20%)	0.3
7F guiding catheter	15 (100%)	15 (100%)	...
Use of NC balloon	14(93.3%)	6(40%)	0.02
Use of MB (Modified balloon-cutting)	1 (6.6%)	...	...
MB-to-artery ratio	1.0	...	...
Starting burr size, mm	...	1.28±0.08	...
Maximum burr size, mm	...	1.75	...
Use of >1 burr	...	2 (13.3%)	...

Rotational speed (RPM)	...	160000	...
Balloon predilatation	15 (100%)	11 (73.3%)	0.182
No. of pre-dilatation balloons*	2.4±1.9	1.45±0.68	0.033
Maximum pre dilatation balloon diameter, mm	2.26±0.34	2.29±0.36	0.267
Maximum pre dilatation balloon pressure, atm	16.4±3.39	14.54±3.11	0.250
No. of stents per lesion	0.93±0.798	1.4±0.736	0.161
Total stent length per lesion, mm	28.2±22.37	37.42±9.04	0.505
Maximum stent diameter, mm	2.75±0.75	2.875±0.25	0.158
Maximum stent implantation pressure, atm	13.86±10.35	16.57±1.82	0.270
Balloon post dilatation	8(53.3%)	6 (40%)	0.464
Maximum post dilatation balloon diameter, mm	3.34±0.39	3.33±0.37	0.567
Maximum post dilatation balloon pressure, atm	20.75±1.83	19±1.09	0.250

Values are n (%) or mean ±SD. MB indicates modified balloon; RA, rotational atherectomy; and RPM, rotations per minute.

Table (6): Procedural and in hospital outcomes (N. 30 patients).

	Conventional PCI (n=15)	RA (n=15)	P-Value
Procedural duration, min	83.73±18.32	90±32.26	0.624
Fluoroscopy time, min	16.71±13.4	17.83±3.73	0.461
Contrast amount, mL	197.33±61.49	194.66±49.51	0.870
Large dissection, >5 mm	4 (26.6%)	2 (13.3%)	0.651
Perforation	1 (6.6%)	0 (0%)	1.000
Pericardial effusion	1 (6.6%)	0 (0%)	1.000
No/slow flow	0 (0%)	0 (0%)	1.000
Final TIMI flow <III	0 (0%)	0 (0%)	1.000

Residual stenosis >20%	1 (6.6%)	0 (0%)	1.000
Stent failure	3 (20%)	0 (0%)	0.1856
Crossover*	5 (33.3%)	0 (0%)	0.042
Strategy success*	7 (46.6%)	15 (100%)	0.0447
Death	0 (0%)	0 (0%)	1.000
MI	0 (6.6%)	0 (0%)	1.000
Target vessel re-PCI	0 (0%)	0 (0%)	1.000
CABG	3 (20%)	0 (0%)	0.1856
Stent thrombosis	0 (0%)	0 (0%)	1.000
Access site complications	0 (0%)	0 (0%)	1.000

Table (7): Clinical outcome at 6 months (N. 30 patients).

	Conventional PCI (n=15)	RA (n=15)	P-Value
Cardiac death	0 (0%)	1 (6.6%)	1.000
Non-cardiac death	0 (0%)	0 (0%)	1.000
MI	1 (6.6%)	0 (0%)	1.000
Stent thrombosis	0 (0%)	0 (0%)	1.000
TLR	1 (6.6%)	0 (0%)	1.000
TVR	4 (33.3%)	1 (6.6%)	0.330
Any revascularization	3 (20%)	2 (13.3%)	1.000

MI indicates myocardial infarction; TLR, target vessel revascularization; and TVR, target vessel revascularization.