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Clinical Outcomes of Rotational Atherectomy in Calcified Coronary Artery Lesions in Drug-Eluting Stent Era: A Single Centre Experience

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Abstract

Objective: Calcified coronary lesion poses formidable challenge to interventional cardiologist. This study was to evaluate safety and efficacy of Rotational Atherectomy (RA) as a lesion modifying tool for calcified lesions prior to DES implantation in 'real world' practice.

Methods: From April 2014 to March 2015, all consecutive patients who underwent RA in our hospital located in south India were enrolled. The relevant clinical and angiographic features at the time of index PCI with immediate and 6-month clinical follow-up data were analyzed.

Results: Total no. of cases were 39, mean age of 67.3 ± 6.4 years. 26 (66.7%) were male. Risk factor: HTN in 35 cases (89.7%), DM in 30 (76.9%), smoking in 4 (10.2%). 31 (79.5%) patients presented with acute coronary syndrome. 31 (79.5%) cases had SVD. The mean SYNTAX score was 24 ± 11. 25 cases (64.1%) had lesion in LAD. Mean lesion length was 23.9 ± 8 mm, mean% stenosis was 69 ± 7.3, and mean RD was 2.9 ± 1.1 mm. MLD before and after procedure was 1.1 mm and 2.8 mm respectively. 28 (71.8%) had severe calcification. 89.7% had Type-C lesions. 45 stents were used with a ratio of 1.15 stents/patient. 37 (97.4%) patients had DES with mean stent length of 26.22 ± 9.3 mm. Procedural success and clinical success were in 38 (97.4%) and 37 (94.9%) respectively. 36 cases (92.3%) cases were followed up clinically for 6 months. Out of 38 hospital survivors MACE was recorded in 3 (7.9%).

Conclusion: RA as a plaque modifying tool prior to stent implantation in DES era is safe with acceptable in-hospital and low out-of-hospital MACE.

Keywords: Coronary angioplasty; DES; Rotational atherectomy

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Introduction

Calcified coronary artery lesion remains a challenge to interventional cardiologist. By virtue of rigidity and hardness it requires multiple balloon dilatations at high pressure to eliminate the 'waist' of the balloon. Even highest balloon inflation pressure sometimes fails to yield the lesion or may cause rupture of the balloon at low inflation pressure. Vessel exposed to high pressure balloon dilatation has high incidence of dissection, mural thrombus and medial necrosis [1]. Furthermore, stent negotiation and deployment are difficult in highly calcified lesion resulting suboptimal stent expansion which may increase the risk of stent thrombosis and target lesion failure. In many occasions, even smallest available balloon fails to cross a tight calcified lesion. RA, which was developed as a debulking device in late 1980s, can favorably modify these heavily calcified lesions. However, long-term outcome is poor when it is used alone or even combined with bare-metal stents [2]. In the light of negative long-term benefit, the use of RA has dramatically been dropped and become a rare procedure practiced in limited centers by most experienced operators. But with the introduction of Drug-Eluting Stent (DES), revival of RA has been witnessed in parallel to the increased in number of interventions for complex calcified lesions. However, DES implantation in calcified lesion has multiple challenges. First, compared with bare-metal stent (BMS), DES has a twofold higher failure rate of successful deployment in calcified lesion [2], Second, vigorous manipulation of DES in a calcified lesion can damage and crack the stent polymer, which may increase vascular inflammatory reaction [3,4]. Third,

suboptimal deployment of DES in these lesions leads to stent thrombosis and increased major cardiac events [5]. At present, we have limited data on RA and use of drug-eluting stents in complex calcified coronary artery lesions. This prospective observational single centre study was carried out in Indian patients to evaluate safety and efficacy of RA in complex calcified lesions before implantation of drug eluting-stent.

Materials and Methods

From April 2014 to March 2015, all consecutive patients who underwent RA in our hospital located in south India were enrolled.

Inclusion criteria

1. Significant coronary artery lesions with moderate to severe calcification.
2. Failed to dilate with plain balloon angioplasty before DES implantation.
3. Unable to cross calcified lesion with balloon.

Exclusion criteria

1. Unable to obtain consent.
2. Bleeding diathesis.
3. Active gastrointestinal ulcer or bleeding.
4. Allergic to anti-platelet drugs.
5. Recent (3-months) history of cerebrovascular accident.

The relevant clinical and angiographic characteristics were meticulously collected at the time of index PCI. Follow-up clinical data at the end of 6-months were collected at the time hospital visit.

Angiographic characteristics

The angiographic measurements were made on a viewing workstation with software for quantitative analysis of angiograms (Philips DICOM Viewer R3.0-SP10, Philip Medical Systems Netherland B V). Characteristics of target lesions in the index angiogram were analyzed by thorough review of cine angiographic pictures. Significant coronary artery disease was defined as diameter stenosis of ≥ 70% of any epicardial coronary artery. coronary calcification was defined as follows:

1. Severe: Readily apparent radio-opacities along the arterial course within the its walls in more than one angiographic projection before contrast medium injection.

2. Moderate: Linear radio-opacities seen in more than one angiographic projection after contrast medium injection.

3. Mild: As spotty radio-opacities within the vascular wall seen in more than one projection after contrast medium injection.

The diseased vessel numbers were defined as the number of the three major coronary vessels that had a ≥ 70% stenosis.

Procedure

All interventional procedures were carried out by experienced and qualified operators as per our standard institutional protocols. Informed consent was taken from all patients prior to the procedure. All patients received dual-antiplatelet drugs prior to the procedure according to the choice of primary consultant and loading dose if required. RA procedure was performed using Rotablator (Boston Scientific, Natick, Massachusetts), and started with 1.25 or 1.5 burr at the mean revolution of 1,56,000 rpm/min and supplemented by next size burr if required. Intravenous heparin was administered to keep activated clotting time (ACT) at ≥ 300 seconds and about 200 seconds if a GPIIbIIIa was used. Use of GPIIbIIIa was as per discretion of the primary consultant. The lesion was further prepared with balloon dilatation using non-compliant balloon using 1: 1 balloon to artery ratio at nominal pressure, followed by DES implantation of proper size and length to cover the entire lesion. Post dilatation was carried out in almost all cases using a non-compliant balloon of 1: 1 balloon to artery ratio at average final deploying pressure of 13.33 atm. Dual-antiplatelet drugs were continued for a period of at least one year after DES implantation.

Angiographic success was defined as post-procedural residual stenosis ≤ 20% by QCA analysis and TIMI (Thrombolysis in Myocardial Infarction Flow) III distal flow. Procedural success was defined as achieving successful angiographic results without any in-hospital Major Adverse Cardiac Events (MACEs). Target Lesion revascularization (TLR) was defined as a repeat revascularization for a restenosis ≥ 50% in the target segment.

Statistical analysis

Statistical method used in this study was descriptive analyses. Categorical variables are presented as frequencies with percentage. Continuous variables were reported as mean ± standard deviation.

Result

From April 2014 to March 2015, 39 cases were enrolled into the study. All clinical and procedural data were recorded and prospectively analyzed. Baseline clinical characteristics were presented in **Table 1**. There were 26 (66.7%) male, 13 (33.3%) were female with mean age of 67.3 ± 6.4 years. Risk factors analysis revealed: hypertension in 35 cases (89.7%), diabetes mellitus in 30 (76.9%), smoking in 4 (10.2%) and dyslipidemia in 2 (5.1%). Six (15.4%) cases had chronic kidney disease, 4 (10.2%) patients had previous CABG, 3 (7.7%) had prior PTCA, and one patient underwent permanent pacemaker implantation. 20 (51.0%) patients presented with unstable angina, 7 (17.9%) had stable angina, 9 (23%) with non-ST-elevation myocardial infarction (NSTEMI), 2 (5.1%) with ST-elevation myocardial infarction (STEMI), and one patient presented with cardiogenic shock. Majority of patients (79.5%) presented with acute coronary syndrome.

Procedure was carried out from femoral route in 34 (87.2%) cases and from radial approach in 5 (12.8%). 6 F radial sheath and guide catheter was used in all radial cases with maximum burr size of 1.25 mm. Lesion characteristics analysis revealed type-C in 35 cases (89.7%), type-B2 in 6 (15.4%), and one case had type-B1 lesion. Severe coronary calcification was recorded in 28 cases (71.8%), moderate in 8 (20.5%), and mild in one (2.5%). Lesion with mild focal calcification was very much resistant to balloon dilatation and optic coherence tomography (OCT) revealed eccentric calcification of RCA which finally required RA. There were four cases (10.2%), which had significant tortuosity of the coronary arteries. 3 cases (7.7%) had bifurcation lesions and were treated by provisional stent technique. 31 (79.5%) cases had SVD, 7 (17.9%) had DVD and one (2.5%) had TVD (**Table 2**). The mean SYNTAX score was 24 ± 11. 25 cases (64.1%) had lesion in LAD, 11(28.2%) had RCA, and 8 (20.5%) cases in Lcx. 31 cases (79.5%) had good left ventricular function and 8 (20.5%) had left

Table 1 Baseline clinical characteristics (No. of patients-n =39).

Age, n (%)	67.3 ± 6.4
Male, n (%)	26 (66.7%)
Female, n (%)	13 (33.3%)
Tobacco user/smoker, n (%)	4 (10.2%)
Systemic hypertension, n (%)	35 (89.7%)
Diabetes mellitus, n (%)	30 (76.9%)
Dyslipidemia, n (%)	2 (5.1%)
Chronic renal failure, n (%)	6 (15.4%)
Prior PCI, n (%)	4 (10.2%)
Prior CABG, n (%)	3 (7.7%)
Prior PPI, n (%)	1 (2.5%)
Clinical presentation, n (%)	
• Stable angina	7 (17.9%)
• Unstable angina	20 (51.3%)
• NSTEMI	9 (23.07%)
• STEMI	2 (5.1%)
• Cardiogenic shock	1 (2.5%)
Total cholesterol (mg/dL)	160.3 ± 36.2
LDL-cholesterol (mg/dL)	96.3 28.1
HDL - cholesterol (mg/dl)	38.2 ± 13.3
VLDL-cholesterol (mg/dl)	27.2 ± 11.4
Triglyceride (mg/dl)	129 ± 32.4

PCI: Percutaneous Coronary Intervention; CABG: Coronary Artery Bypass Graft Surgery; PPI: Permanent Pacemaker Implantation; NSTEMI: Non-ST-Elevation MI; STEMI: ST-elevation MI; LDL: Low-DensityLipoprotein; HDL: High-DensityLipoprotein; VLDL:Very Low- Densitycholesterol

Table 2 Angiographic and procedural characteristics (n=39).

CAD vessel numbers, n (%)	
· SVD	31 (79.5%)
· DVD	07 (17.9%)
· TVD	01 (2.5%)
Target vessel, n (%)	
Left main	0
Left anterior descending artery	25 (64.1%)
Left circumflex artery	08 (20.5%)
Right coronary artery	11(28.2%)
Calcification, n (%)	
Mild	01 (2.5%)
Moderate	08 (20.5%)
Severe	28 (71.8%)
Type of lesion	
· Type A	0
· Type B1	01 (2.5%)
· Type B2	06 (15.4%)
· Type C	35 (89.7%)
Reference vessel diameter (mm)	2.9 ± 1.1
Lesion length (mm)	23.9 ± 08
Baseline minimal lumen diameter (mm)	1.1 ± 09
Baseline percent diameter stenosis (%)	69 + 7.3
Mean burr size	1.37 ± 04
Total no DES implantation, n	45
No of DES used/patient	1.15
Multiple stenting, n (%)	09 (23%)
Mean stent diameter (mm)	2.73 ± 07
Mean stent length (mm)	26.22 ± 9.3
Non compliant balloon post dilatation, n (%)	38 (97.4%)
Average inflation pressure (atm)	13.3
Final minimal lumen diameter (mm)	2.8 ± 0.5

Values are presented as numbers (%) or mean ± standard deviation; CAD: Coronary Artery Disease; DES: Drug-Eluting Stent; SVD: Single Vessel Disease; DVD: Double Vessel Disease; TVD: Triple Vessel Disease

ventricular dysfunction. 1.25 mm burr was used in 24 (61.5%), 1.5 mm in 15 (38.5%) and 1.75 mm in one (2.5%). Mean burr size was 1.37 ± 07 mm, and mean revolution was 1,56,338.9 rpm. GPIIbIIIa inhibitor was used as adjunctive therapy in 5 (12.8%) cases who presented with acute coronary syndrome. 45 stents were used with a ratio of 1.15 stents/patient with a mean stent length of 26.22 ± 9.3 mm. 37 (97.4%) patients had DES implantation, one had bioabsorbable scaffold (BVS), and in one patient stent was not used considering good post rotablation result and diffuse disease of entire RCA. Intra-aortic balloon pump (IABP) was used in one case who presented with cardiogenic shock. Intracoronary imaging was used in 5 cases (12.8%). 3 cases had intravascular ultrasound (IVUS), and 2 cases underwent optic coherence tomography (OCT). 38 (97.4%) cases had TIMI III coronary blood flow after stent implantation, and one patient had TIMI II flow.

Procedural outcome

Procedural success was achieved in 38 cases (97.4%). A 1.25 mm burr could not be negotiated in a patient with tight, tortuous, and severely calcified lesion and maintained on optimal medical therapy. At 6-month follow up, the patient was asymptomatic with preservation of left ventricular function. Clinical success could be achieved in 37 cases (94.9%). One patient died during hospitalization. This 77-year-old man presented with acute anterior wall myocardial infarction with cardiogenic shock and was taken for primary PCI with ventilator and IABP support. LAD had proximal to mid long segment, heavily calcified lesion, which was successfully treated with rota-stenting to achieve TIMI II distal flow. The patient had sudden cardiac arrest on 4th day and died. Another patient developed groin hematoma with significant drop of hemoglobin and treated with two units of pack-cell transfusion. His serum creatinine was marginally rose which recovered after conservative treatment. 36 cases (92.3%) cases were followed up clinically for 6 months. 8 cases (23.07%) underwent angiographic study. Angiography was performed based on positive stress test. Out of 38 hospital survivors MACE was recorded in 3 (7.9%), 2 patients died, and one required TLR (**Table 3**).

Discussion

Atherosclerotic calcification is an organized, regulated active process like bone formation that occurs only when other aspects of atherosclerosis are also present [6]. Calcification makes arterial wall rigid, hard, and irregular which poses a great challenge to interventional cardiologist during PCI. Most of the heavily calcified coronary lesions are resistant to plain balloon dilatation and need additional device. RA is one of the most efficient and useful tools in this situation [7]. RA was developed in the late 1980s as a debulking device and used to facilitate the removal of plaque. Since than it has been passing through ups and down in its entire

Table 3 In hospital and follow-up result.

In-hospital MACE, n (%)	01 (2.5%)
Death, n (%)	01 (2.5%)
Q wave MI, n (%)	0
TLR, n (%)	0
TVR, n (%)	0
Out-of-hospital MACE, n (%)	03 (7.9%)
Death, n (%)	02 (5.1%)
Q wave MI, n (%)	0
TLR, n (%)	01 (2.5%)
TVR, n (%)	0
Stent thrombosis, n (%)	0

MACE: Major Adverse Cardiac Event; MI: Myocardial Infarction; TLR: Target Lesion Revascularization; TVR: Target Vessel Revascularization

course. In the BMS era, the combination of RA and BMS was reported to be most likely associated with optimal final lumen dimensions [8], but its long-term outcome was not satisfactory. The debulking prior to stenting (SPORT) study revealed a better procedural success rate and post treatment minimal luminal diameter in the rota-stenting group; however, no differences were observed in the rates of in-hospital MACE, binary restenosis, or TLR rates at the 6-month follow-up [9].

Following the discouraging results of RA there had been significant drop in its use and remained confined to limited high volume centres. DES has significantly eliminated the problem of restenosis resulting lower MACE rate after percutaneous coronary intervention [10]. Over the past decade, the incidence of DES failure, defined as instant restenosis (ISR), requiring target vessel revascularization (TVR), has been approximately 5-10%. This has opened the avenue for more complex interventional procedures, like complex bifurcation angioplasty [11], CTO [12], left main stenting [13], even in a high-risk clinical environment. However, complex, calcified lesion still poses a challenge to interventional cardiologists. More ever, implantation of DES in heavily calcified lesions has certain challenges [3-5]. Proper lesion preparation prior to DES implantation is of paramount importance to reduce incidence of stent thrombosis, injury to DES polymer and failure rate of stent delivery [14]. RA is an indispensable tool in lesion preparation of heavily calcified lesions [15,16]. It helps in easy delivery and proper deployment of even long DES in a complex, tortuous calcified lesion [17]. This in turn helps in reduction of instant restenosis and MACE [18]. Although excimer laser is a reasonable alternative it is expensive and not available in most of the centres [19]. Orbital atherectomy is another evolving technique in calcified coronary artery lesions, but it requires proper evaluation [20]. Cutting balloon angioplasty is also another alternative for lesion preparation in calcified coronary lesions [21]. However, because of the bulky nature, and its stiffness makes it difficult to negotiate in heavily calcified diffuse and tortuous lesions. In smaller coronaries with diffuse calcified lesions mostly seen in Indians cutting balloon many a times fails to cross lesion.

Conclusion

In our study, majority of patients (79.5%) presented with acute coronary syndrome and most of the patients had severe coronary calcification. Despite complex coronary lesion, in a highly thrombogenic clinical environment we could achieve procedural success rate of 97.4%. All our patients were followed up very meticulously with proper recording of symptomatic status, stress test evaluation, and ischemia guided coronary angiography. 23% of our cases had angiographic study. Out of 38 hospital survivors MACE was recorded in 3 (7.9%), 2 patients died, and one required TLR. This result is comparable to most of the previous studies of rotational atherectomy and DES implantation [22].

There are some limitations of our study. This single centre prospective observational study was carried out in a small number of patients with only 23% angiographic follow-up. Majority of our cases were followed up clinically, which was also adopted in most of the previous DES studies. We feel rotational atherectomy still has significant role in lesion preparation of calcified coronary artery disease before DES implantation and a larger prospective randomized study is required to establish its efficacy.

References

1 Tomey MI, Kini AS, Sharma SK (2014) Current status of rotational atherectomy. JACC Cardiovasc Interv 7: 345-353.

2 Gruberg L, Mehran R, Dangas G, Hong MK, Mintz GS, et al. (2000) Effect of plaque debulking and stenting on short-and long-term outcomes after revascularization of chronic total occlusions. JAm Coll Cardiol 35: 151-156.

3 Moussa I, Ellis SG, Jones M, Kereiakes DJ, Stone GW, et al. (2005) Impact of coronary culprit lesion calcium in patients undergoing paclitaxel-eluting stent implantation (A TAXUS-IV sub study). Am J Cardiol 96: 1242-1247.

4 Wiemer M, Butz T, Schmidt W, Langer C, Horstkotte D, et al. (2010) Scanning electron microscopic analysis of different drug eluting stents after failed implantation: From nearly undamaged to major damaged polymers. Catheter Cardiovasc Interv 75: 905-911.

5 Fujii K, Carlier SG, Mintz GS, Moses JW, Leon MB, et al. (2005) Stent under-expansion and residual reference segment stenosis are related to stent thrombosis after sirolimus-eluting stent implantation: An intravascular ultrasound study. J Am Coll Cardiol 45: 995-998.

6 Wexler L, Brundage B, Crouse J, White R, Taubert K, et al. (1996) Coronary artery calcification: Pathophysiology, epidemiology, imaging methods, and clinical implications. Circulation 94: 1175-1192.

7 Hansen DD, Auth DC, Vracko R, Ritchie JL (1988) Rotational atherectomy in atherosclerotic rabbit iliac arteries. Am Heart J 115: 160-165.

8 Cavusoglu E, Kini AS, Marmur JD, Sharma SK (2004) Current status of rotational atherectomy. Catheter Cardiovasc Interv 62: 485-498.

9 Buchbinder M, Fortuna R, Sharma SK, Bass T, Kipperman R, et al. (2000) Debulking prior to stenting improves acute outcomes: Early results from the SPORT trial. J Am Coll Cardiol 35: 8A.

10 Ramsdale DR, Rao A, Asghar O, Ramsdale KA, McKay E (2008) Late outcomes after drug-eluting stent implantation in "real-world" clinical practice. J Invasive Cardiol 20: 493-500.

11 Movahed MR (2008) Coronary artery bifurcation lesion classifications, interventional techniques and clinical outcome. Expert Rev Cardiovasc Ther 6: 261-274.

12 Kandzari DE (2009) Import and export of interventional technique: Something to declare at the border. J Am Coll Cardiol Intv 2: 843-845.

13 Lopez JJ, HO KK, Stoler RC, Baim DS, Cohen DJ, et al. (1996) Percutaneous treatment of protected and unprotected left main coronary stenoses

with new devices: Immediate angiographic results and intermediate-term follow-up. J Am Coll Cardiol 29: 345-352.

14 Kuriyama N, Kobayashi Y, Yamaguchi M, Shibata Y (2011) Usefulness of rotational atherectomy in preventing polymer damage of everolimus-eluting stent in calcified coronary artery. JACC Cardiovasc Interv 4: 588-589.

15 Sharma SK (2006) Update in management of coronary bifurcation lesions in the drug-eluting stent era. Indian Heart J 58: 108-119.

16 Furuichi S, Sangiorgi GM, Godino C, Carlino M, Colombo A, et al. (2009) Rotational atherectomy followed by drug-eluting stent implantation in calcified coronary lesions. Euro Intervention 5: 370-374.

17 Khattab AA, Richardt G (2008) Rotational atherectomy followed by drug-eluting stent implantation (Rota-DES): A rational approach for complex calcified coronary lesions. Minerva Cardioangiol 56: 107-115.

18 Moussa I, Di Mario C, Moses J, Reimers B, Di Francesco L, et al. (1997) Coronary stenting after rotational atherectomy in calcified and complex lesions. Angiographic and clinical follow-up results. Circulation 96: 128-136.

19 Bilodeau L, Fretz EB, Taeymans Y, Taylor K, Hilton DJ, et al. (2004) Novel use of a high-energy excimer laser catheter for calcified and complex coronary artery lesions. Catheter Cardiovasc Interv 62: 155-161.

20 Lee MS, Shlofmitz E, Kaplan B, Alexandru D, Meraj P, et al. (2016) Real-world multicenter registry of patients with severe coronary artery calcification undergoing orbital atherectomy. J Interv Cardiol 29: 357-362.

21 Karvouni E, Stankovic G, Albiero R, Takagi T, Corvaja N, et al. (2001) Cutting balloon angioplasty for treatment of calcified coronary lesions. Cathet Cardiovasc Interv 54: 473-481.

22 Chiang MH, Lee WL, Tsao CR, Chang WC, Su CS, et al. (2013) The use and clinical outcomes of rotablation in challenging cases in the drug-eluting stent era. J Chin Med Assoc 76: 71-77.