Percutaneous coronary intervention of severely/moderately calcified coronary lesions using single-burr rotational atherectomy: A retrospective study

Shuvanan Ray, Siddhartha Bandyopadhyay, Prithwiraj Bhattacharjee, Priyam Mukherjee, Suman Karmakar, Sabyasachi Mitra, Anirban Dalui, Ashok Dhar

Department of Cardiology, Fortis Hospital; Kolkata-*India*

Abstract

Objective: This study evaluates the safety and efficacy of percutaneous coronary intervention in moderately and severely calcified coronary lesions, which are either not crossed or dilated using a Scoreflex balloon at nominal pressure, using single-burr rotational atherectomy (burr–artery ratio, ≤0.6) followed by scoring balloon dilatation (balloon–artery ratio, 0.9).

Methods: We retrospectively identified 144 patients with severely and moderately calcified native coronary lesions, which were either not crossed or fully opened using an appropriately sized Scoreflex balloon at nominal pressure, from a tertiary care center in India. All patients underwent rotational atherectomy. The primary endpoint was angiographic and procedural success and in-hospital clinical outcomes. The secondary endpoint was the incidence of major adverse cardiac events (MACE) at one-year clinical follow-up.

Results: The mean age of the patients was 68.75±8.37 years, and 83.33% of them were over 60 years old. Moderate calcification was present in 21.53%, and the remaining 78.47% had severe calcification. Procedural success was achieved in 139 (96.52%) patients. In-hospital death was reported in four (2.77%) patients. Multiple regression analysis revealed that in severely calcified coronary lesions, burr rotation speed and heparin dose were significantly associated with in-hospital MACE occurrence (p=0.0337).

Conclusion: A modified small-burr rotational atherectomy technique with scoring balloon angioplasty pre-dilatation is a safe and effective surgical procedure with favorable clinical outcomes for moderately and severely calcified coronary lesions.

Key words: calcifications, complex coronary lesions, percutaneous coronary intervention, rotational atherectomy

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Introduction

The use of percutaneous coronary intervention (PCI) has expanded significantly over the years in unprecedented anatomical settings. Despite medical advances, successfully performing PCI on calcified coronary artery lesions remains a challenge (1, 2). More than 20% of patients with coronary artery disease (CAD) treated with PCI have severely calcified lesions (2, 3). Calcified lesions impede stent delivery, causing stent under-expansion or mal-apposition, and damage polymer/drug coating resulting in impaired drug delivery (1, 4, 5). PCI of such complex lesions may cause significant periprocedural complications, leading to stent thrombosis.

Severe coronary calcifications are difficult to dilate adequately and often require optimal lesion preparation before stent deployment, which has evolved considerably over the past four decades (1). Dilatation of calcified lesions using conventional plain old balloon angioplasty is not always satisfactory and may result in unsuccessful lesion preparation. Furthermore, it requires multiple balloons to be inflated at high pressures, which could fail to yield optimal expansion and produce intimal splits and medial dissections (1, 6). Modified balloons, that is, cutting and scoring balloons, are bulky and difficult to cross calcified lesions; however, they are superior to plain balloons in achieving luminal gain (1). However, cutting balloon angioplasty (CBA) results in a similar acute procedural success compared to plain balloon angioplasty (7).

Address for Correspondence: Shuvanan Ray, MD, Department of Cardiology,
Fortis Hospital; Anandapur, 700107, Kolkata-*India*
Phone: +91-9830024266 E-mail: shuvananray@gmail.com
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HIGHLIGHTS

- The study retrospectively included patients with moderately/severely calcified coronary lesions who underwent rotational atherectomy before stenting with procedural success of 96.52%.
- Multiple regression analysis stated that rota burr speed and dose of heparin have significant association with in-hospital events, especially in patients with severely calcified lesions (p=0.0337).
- A burr modified rotational atherectomy technique is a safe and effective procedure in moderately/severely calcified lesions with favorable clinical outcomes.

Percutaneous transluminal rotational atherectomy (RA) was introduced by Ritchie et al. (8) primarily for mechanical debulking of the inelastic fibrocalcific tissues in the coronary arteries. Many modifications of this technique were attempted by different groups of operators to reduce complications and the restenosis rate. In the beginning of the century, the Study to Determine Rotablator System and Transluminal Angioplasty Strategy (9) and Coronary Angioplasty and Rotablator Atherectomy (10) trials compared more aggressive debulking with a less aggressive one by using burr–artery ratios of >0.7 and ≤0.7, respectively. The acute angiographic and six-month clinical results were identical; however, procedural complications (perforation, no reflow, and large dissection) were statistically higher in the more aggressive group. During almost the same time, Kiesz et al. (11) have reported that modifying the burr speed from 1,80,000 rpm to 1,40,000–1,60,000 rpm and modifying the burr movement to slow pecking one, procedural complications were significantly reduced without any difference in the restenosis rate. Depending on these findings, the American College of Cardiology/American Heart Association (ACC/AHA) guidelines for PCI in 2011 recommended percutaneous transluminal RA as an optional therapy for patients with severe calcified coronary artery lesions (12).

Li et al. (13) conducted a randomized controlled study (pilot study) in 2016 to evaluate the efficacy and safety of RA plus cutting balloon plaque modification before drug-eluting stent (DES) implantation relative to RA plus plain balloon angioplasty. They revealed that RA plus cutting balloon seemed to be safe and effective for severely calcified lesions. In addition, these findings conformed to those in the PREPARE-LC trial by Abdel-Wahab et al. (14) in 2018. They compared scoring balloons (AngioSculpt and Scoreflex) with cutting balloons after high-speed RA and showed similar results.

Thus, this study was designed to evaluate the safety and efficacy of PCI in moderately and severely calcified coronary lesions, which are either not crossed or not dilated by Scoreflex balloons at nominal pressure, using single-burr rotational atherectomy (burr–artery ratio, ≤0.6) followed by scoring balloon dilatation (balloon–artery ratio, 0.9) and implantation of a newer-generation DES.

Methods

Study design and patients selection

This was a single-center retrospective study conducted at a tertiary care center in India and included 144 patients diagnosed with myocardial ischemia and moderate to severe calcified native coronary artery lesions between July 2012 and June 2019. RA was the default strategy in all patients who were diagnosed with moderately and severely calcified lesions, which were either not crossed or not fully opened by an appropriately sized Scoreflex balloon (OrbusNeich, New Territories, Hong Kong) at nominal pressures. This study was approved by the Institutional Ethics Committee of the tertiary care center and strictly obeyed the standard guidelines. Written informed consent was obtained from either the patients or their family members.

The patients were eligible for the study if they met all inclusion criteria. The inclusion criteria included the presence of angiographically proven CAD along with typical angina symptoms or provocative ischemia in the target area confirmed using dobutamine stress echocardiogram (DSE), myoview scan on exercise, or fractional flow reserve. The patients with target reference vessel diameter of 2.5–4 mm and luminal diameter reduction of 70%–100% with the presence of moderate to severe calcification confirmed using cine angiography were included. Patients with an infarct-related artery in acute myocardial infarction within one week, left ventricular systolic dysfunction (ejection fraction of <30%), saphenous vein grafts, in-stent restenosis, and thrombotic lesions, and those intolerant to prolonged anti-platelet therapy were excluded from the study.

Severe calcification was defined as radio-opacities seen without cardiac motion before contrast injection, usually affecting both sides of the arterial lumen. Moderate calcification was defined as radio-opacities noted only during the cardiac cycle before contrast injection (15, 16).

Procedural technique

Before the procedure, the patients who had been on clopidogrel and aspirin were loaded with 300-mg clopidogrel and 325-mg aspirin. However, those who were on ticagrelor or prasugrel continued the medications as such. The femoral route was the default access in most patients, except for few patients for whom the radial route was chosen. A temporary pacing lead was introduced only in patients for whom a right coronary artery, left circumflex artery, or left main coronary artery intervention was planned. In almost all cases, Floppy RotaWires were exchanged in microcatheters, except for those in the distal and ostial lesions where Extra-Support RotaWires were used. The Rota burr size was selected according to the size of the angiographic vessel distal to the lesion (burr–artery ratio, 0.4–0.6). Moreover, 100 units/kg of heparin was administered through the arterial sheath to maintain the activated clotting time of ≥250 seconds.

RA was performed using the ROTABLATOR system (Boston Scientific, Marlborough, Massachusetts, USA). Initially, the average burr speed used was 1,80,000 rpm with 10,000 units/L of heparin in Rota-Flush solution (17). However, from November 2015, the average burr speed was reduced to 1,50,000 rpm and the burr movement was modified with a lowered dose of heparin (3000 units/L) in Rota-Flush solution (18). Moreover, the Rota-Flush solution contained nicorandil (18 mg) and diltiazem (5 mg). After RA, Scoreflex balloons were used for bed preparation in all cases with balloon–artery ratios of 0.8–0.9. PCI was performed using a newer-generation DES, which included everolimus-eluting biostable polymer-coated stents (XIENCE; Abbott Vascular, Chicago, Illinois, USA, and Promus; Boston Scientific, Marlborough, Massachusetts, USA), zotarolimus-eluting stents (Endeavor Resolute and Onyx; Medtronic, Dublin, Ireland), and stents with biodegradable polymers (Synergy; Boston scientific, Marlborough, Massachusetts, USA, and Orsiro; Biotronik, Berlin, Germany). Stenting was performed only after appropriate sizing of the lesions. Post-dilatation was performed using a noncompliant balloon, which was at the operator's discretion, and intravascular ultrasonography was used in patients who underwent left main coronary artery intervention or in those where multiple overlapping stents were required.

After PCI, all patients were recommended dual anti-platelet therapy, that is, aspirin (75 mg) plus clopidogrel/prasugrel/ticagrelor in accordance with the dosage schedule in the guidelines, for at least one year. Electrocardiogram (ECG) was performed after the procedure and repeated after 12 hours in the coronary care unit. Quantitative troponin-I was measured 12 hours after the procedure, and if a significant elevation (≥5 times the normal value) was observed, additional tests were performed.

Study endpoints and follow-up

The primary endpoint was the angiographic and procedural success, defined as a final residual stenosis of <10%, after stent deployment in the target lesion in the presence of thrombolysis in myocardial infarction-3 flow (19), without any vessel perforation, significant coronary dissection, slow flow/no reflow, sustained bradycardia, burr entrapment, pericardial tamponade, death, myocardial infarction (MI), and target vessel revascularization (TVR) during hospitalization. The secondary endpoint was the incidence of major adverse cardiac events (MACE) at the one-year clinical follow-up. The standardized definitions by the Academic Research Consortium were used for MI, TVR, and stent thrombosis (20).

The patients were followed up clinically during their hospital stay for any adverse events (e.g., MI, cardiac tamponade, stent thrombosis, and death). After discharge, the patients were followed up one, six, 12, and 24 months after surgery or when symptoms were reported in the outpatient department. After 24 months, telephonic follow-ups were continued every six months. Coronary angiography was advised to patients who were symptomatic or had provocative ischemia (diagnosed using stress ECG/DSE) during follow-up.

Statistical analysis

Data were analyzed using R (version 3.5.1; The R Foundation, Vienna, Austria). All data were reported as either mean ± SD or frequency (percentage) as appropriate. Data were analyzed using multiple logistic regression analysis and nonparametric log-rank test. The event-free survival rate was estimated using the Kaplan–Meier estimator with 95% confidence interval (CI). *P* values of <0.05 were used to denote statistical significance.

Results

Baseline clinical characteristics

The baseline clinical characteristics of all patients are summarized in Table 1. The mean age of the patients was 68.75±8.37 years, and 83.33% of the patients were over 60 years old. The prevalence of diabetes mellitus was 51.39% (n=74). Forty-five (31.25%) patients presented with acute coronary syndrome. The left ventricular function was preserved with a mean ejection fraction of 54.9%±13.2%.

Lesion and procedure characteristics

The lesion and procedural characteristics are outlined in Table 2. In 80.22% (n=116) of the patients, RA was performed using a 7-Fr guiding catheter. The target lesions were primarily located in the left anterior descending artery (73%). Chronic total occlusion was observed in 4.16% of the lesions. The reference vessel diameter was 3.01±0.41 mm, and the proportion of lesions with angulations of ≥45° or more than two angulations was 7.64%. Long lesions (>30 mm) were present in 22.92% of the patients. Moderate calcification was present in 21.53% of the patients, and the remaining 78.47% had severe calcification. The most common burr size used

Table 1. Baseline clinical characteristics

Characteristics		n=144
Age	Mean ± SD	68.75±8.37
	>70 years	64 (44.44%)
	≤70 years	80 (55.56%)
Gender, n (%)	Male	118 (81.94%)
	Female	26 (18.06%)
Comorbidities, n (%)	Hypertension	105 (72.92%)
	Diabetes mellitus	74 (51.39%)
	Chronic kidney disease on hemodialysis	9 (6.25%)
Clinical presentation, n (%)	Acute coronary syndrome	45 (31.25%)
LVEF	Mean ± SD	54.9±13.2
Vessel involved, n (%)	LMCA	19 (13.19%)
	LAD	106 (73.61%)
	LCx	22 (15.28%)
	RCA	23 (15.9%)
	Ramus intermedius	1 (0.69%)

LVEF - left ventricular ejection fraction; LMCA - left main coronary artery; LAD - left anterior descending artery; LCx - left circumflex artery; RCA - right coronary artery; SD – standard deviation

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Table 2. Lesion and procedural characteristics

Parameter		n (%) or mean ±SD
Route	Femoral	114 (79.16%)
	Radial	30 (20.84%)
Guide catheter	6F	28 (19.78%)
	7F	116 (80.22%)
Target lesion calcification	Moderate	31 (21.53%)
	Severe	113 (78.47%)
Lesion length >30 mm (long)		33 (22.92%)
Long and tortuous artery (≥ 45˚ bend)		11 (7.46%)
Burr size	1.25 mm	13 (9.03%)
	1.5 mm	112 (77.78%)
	1.75 mm	19 (13.19%)
Average burr speed	1,80,000 rpm	41 (28.4%)
	1,50,000 rpm	103 (71.5%)
Heparin in Rotaflush	10000 units/L	41 (28.4%)
	3000 units/L	103 (71.5%)
Scoring balloon	2 mm	20 (13.88%)
	2.5 mm	73 (50.69%)
	3 mm	33 (22.91%)
	3.5 mm	18 (12.5%)
Number of stents	1 stent	99 (68.75%)
	2 stents	40 (27.78%)
	≥3 stents	5 (3.47%)
2 stent bifurcation		16 (11.1%)
Average stent diameter (mm)		3.09±0.40
Average stent length (mm)		43.92±18.10
Intra-aortic balloon pump used		5 (3.47%)

was 1.5 mm (77.78%). Initially, approximately 28.4% of the patients were ablated using a burr speed of 1,80,000 rpm (heparin dose: 10,000 units/L), which was reduced to 1,50,000 rpm (heparin dose: 3,000 units/L) in 71.5% patients.

Scoreflex balloons were used for pre-dilatation after RA. The most common balloon size used was 2.5 mm (50.69%). Single stents were used in 64.58% of the patients. Complex bifurcation (two-stent strategy and the left main coronary artery) was performed in 11.1% of the patients, and overlapping stents were used in 24.3%. The mean stent diameter and length were 3.09±0.40 mm and 43.92±18.10 mm, respectively.

Clinical outcomes

The in-hospital outcomes (n=144) and overall clinical outcomes during follow-up (n=140) are tabulated in Table 3.

Calcification and other variables, including gender, age, comorbidities, burr size, and long lesions, were not associated

Table 3. In-hospital and follow-up clinical outcomes

Outcome	n (%) or mean ± SD
Procedural success	139 (96.52%)
In hospital outcomes (n=144)	
Total death	4 (2.77%)
Access site bleeding	2 (1.38%)
Resistant slow flow	1 (0.69%)
Perforation	1 (0.69%)
Pericardial tamponade	1 (0.69%)
Clinical follow-up (n=140)	
Mean follow-up (days)	1228.80±701.15
Overall MACE	6 (4.28%)
Target vessel revascularization	3 (2.14%)
Sudden cardiac death	1 (0.71%)

MACE - major adverse cardiac event

with in-hospital events ($p>0.05$) (Table 4). However, multiple regression analysis (Table 5) of in-hospital events on rotablation speed and heparin gave a minimum Akaike information criterion of 42.496 as the best fitted model. It stated that in severely calcified coronary lesions, the rota burr speed and heparin dose were significantly associated with in-hospital events ($p=0.034$) meaning that burr speeds of 1,50,000 rpm plus a heparin dose of 3000 units/L in Rota-Flush solution were associated with significantly lower in-hospital event rates [odds ratio (OR), 0.133; 95% CI, 0.017–0.858) than burr speeds of 1,80,000 rpm plus a heparin dose of 10,000 units/L.

Survival without MACE did not vary significantly with respect to rota burr speed and heparin dose (1,80,000 rpm plus a heparin dose of 10,000 unit/L vs. 1,50,000 rpm plus a heparin dose of 3000 unit/L), rota burr size (1.25 mm vs. 1.5–1.75 mm), calcification (moderate vs. severe), long lesion, long and tortuous lesion, gender (male vs. female), and age (≤65 years vs. >65 years) (log-rank score test; $p>0.05$) (Fig. 1).

Discussion

This retrospective study presents the results of treating moderately and severely calcified coronary lesions, which were not crossed or dilated using scoring balloon (Scoreflex) dilatation at nominal pressures using RA. This study demonstrated that: i) the RA procedure using a single burr with a burr–artery ratio of <0.6 was safe for severely long and tortuous lesions and moderately calcified lesions, which were unamenable to dilatation using modified balloons alone (Scoreflex); ii) routine application of scoring balloon angioplasty after RA might be advantageous in patients with severely calcified complex lesions, especially after using a small burr; and iii) newer-generation DES implantation after intensive plaque modification leads to acceptable occurrence of MACE at least in mid-term follow-up (1228.80±701.15 days).

Table 4. Simple logistic regression analysis

Variables		No. (%)	Odd ratio (95% confidence interval)	*P* value	AIC
Gender	Female (n=26)	1 (3.85%)	0.877 (0.123-17.552)	0.908	47.415
	Male (n=118)	4 (3.39%)			
Age, years	≤70 (n=80)	1 (1.25%)	5.267 (0.755-104.45)	0.142	44.677
	>70 (n=64)	4 (6.25%)			
Comorbidities (HTN, CKD, and DM)	Yes (n=120)	3 (2.50%)	0.282 (0.044-2.233)	0.179	45.826
	No (n=24)	2 (8.33%)			
Calcification	Moderate (n=31)	0 (0.10%)	1.45e+07 (1.78 e-85-NA)	0.993	44.955
	Severe (n=113)	5 (4.42%)			
Rota burr speed	1,80,000 rpm + heparin dose of 10,000 units/L (n=41)	3 (7.32%)	0.251 (0.032-1.569)	0.138	45.192
	1,50,000 rpm + heparin dose of 3000 units/L (n=103)	2 (1.94%)			
Rota burr size	1.25 mm (n=12)	1 (8.33%)	0.344 (0.046-7.032)	0.358	46.734
	1.5–1.75 mm (n=132)	4 (3.03%)			
Long lesion	Present (n=33)	2 (6.06%)	2.323 (0.296-14.618)	0.368	46.673
	Absent (n=111)	3 (2.70%)			

P values of <0.05 are considered statistically significant.
AIC - Akaike information criterion; CKD - chronic kidney disease; DM - diabetes mellitus; HTN - hypertension

Table 5. Multiple logistic regression analysis

Factors	Odd Ratio (95% confidence interval)	*P* value	AIC
Rota burr speed (1,80,000 rpm + heparin dose of 10,000 units/L vs. 1,50,000 rpm + heparin dose of 3000 units/L)	0.133 (0.017-0.858)	0.034	42.496
Calcification (Moderate vs. severe)	9.08e+07 (2.8e+137-NA)	0.995	

P values of <0.05 are considered statistically significant. AIC - Akaike information criterion

Severe coronary calcification is encountered in up to 20% of the patients treated with PCI, and complex calcified lesions (e.g., long, tortuous, bifurcation, and left main stem disease) were more frequently found in elderly patients. These lesions demand more aggressive plaque modification due to the suboptimal stent expansion, usually defined as the final lumen stent diameter stenosis of ≥10% measured using quantitative coronary angiography, and have been associated with an increased rate of adverse events (21-23). The 2013 ACC/AHA guidelines for PCI recommended the performance of RA to prepare calcified lesions to facilitate stent delivery and expansion (24). Plaque debulking requiring a larger burr and higher speed were recommended in balloon angioplasty, and bare metal stents should be used to decrease stent thrombosis and in-stent restenosis (25). However, these recommendations led to a higher rate of PCI-related complications, including slow flow, no reflow, vessel perforation, and MACE. In the DES era, because of powerful anti-thrombotic drugs and a lower restenosis rate, plaque modification became more prevalent over plaque debulking, and smaller burr sizes and lower burr speeds were recommended to avoid complications (6, 26).

In the patients in this study, we used a smaller burr size (burr–artery ratio of <0.6) as a strategy from the beginning of the study. Initially, we used a higher burr speed (1,80,000 rpm) along with a higher dose of heparin in Rota-Flush solution (10,000 units/L) in the first 41 patients. Later, from November 2015, we used a lower burr speed (1,50,000 rpm) and slow pecking movement of burr during ablation was performed, and we used a lower dose of heparin (3000 units/L) in Rota-Flush solution. In this study, multiple regression analysis showed that the combination of high-speed burr movements and higher heparin doses was related to a significantly higher occurrence rate of in-hospital MACE ($p<0.05$), especially in patients with severely calcified coronary lesions. One patient had resistant slow flow, and two patients experienced severe access site bleeding in the higher burr speed group. There was one episode of perforation, and one case of pericardial tamponade in the lower burr speed group. The pericardial tamponade was due to the use of a temporary pacemaker. The use of a temporary pacemaker was stopped in the lower burr speed group where the incidence of bradycardia or heart block was only transient and managed with intravenous atropine.

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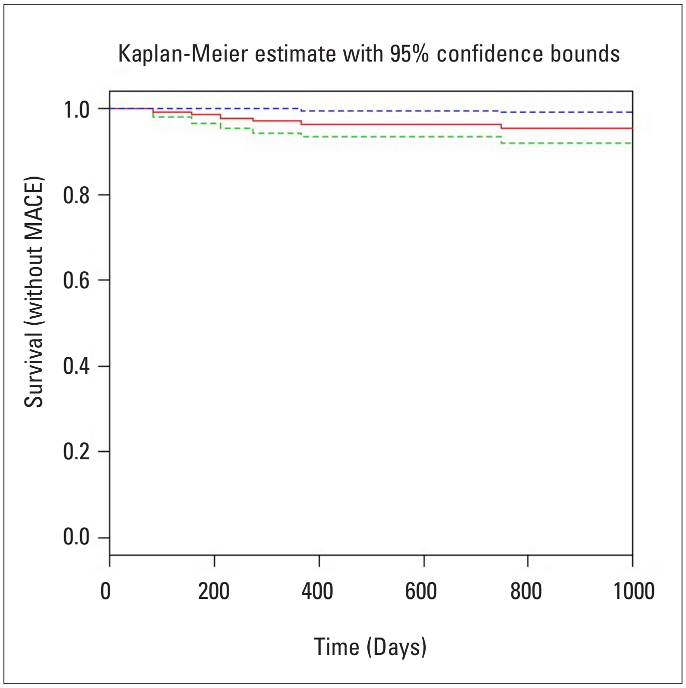

Figure 1. The Kaplan–Meier estimate of survival without major adverse cardiac events

Sakakura et al. (27) in a randomized controlled trial of 100 cases have shown similar slow flow incidences between high–speed (≥1,90,000 rpm) and low–speed (1,40,000 rpm) RA. In addition, they have reported similar incidences of MI in both groups; however, other investigators (1, 28, 29) have recommended modified burr movements with slower speeds and slow pecking motions to reduce complications.

Though the heparin dose of 10,000 units/L in Rota-Flush solution was recommended in traditional RA (17, 25), we lowered the heparin dose in Rota-Flush to 3000 units/L due to two episodes of severe access site bleeding in the high heparin dose (and high-speed burr) group. Dong et al. (30) have shown that lower heparin doses were safe in a large number of elderly patients treated with RA, and using a low heparin dose in Rota-Flush solution and using a modified (low-speed) burr movement in the patients in this study, bleeding and in-hospital MACE were reduced ($p<0.05$).

However, a small burr may not be adequate to crack a calcified ring, and resistance due to this ring can prevent optimal stent expansion. Conventionally, in this condition, burr step-up was advised; however, a recent study has reported that burr step-up was a multivariant indicator of MACE, even though a small burr was used initially (31). People have attempted using (13, 32, 33) both plain balloons (semi-compliant and noncompliant) and modified balloons (cutting and scoring) in this situation. Modified balloons perform better than plain balloons for optimal bed preparation, possibly due to the reduction of traumatic vessel wall injury and dissection found in plain balloon dilatation. Mechanically, modified balloons with blades (cutting balloon) or wires (scoring balloon) prevent balloon slippage and reduce vessel injury. In this study, we used scoring balloons (Scoreflex) in every case with a balloon–artery ratio of 0.8–0.9. Thus, after pre-dilatation and DES implantation, we found acceptable occurrence rates of MACE at follow-up. We used DES with both biostable and biodegradable polymers containing everolimus, zotarolimus, and sirolimus drugs; however, no stent was better than the other regarding MACE-free survival in the multiple regression analysis.

Study limitations

The study design was its main limitation, that is, single-center and retrospective study with a very small sample size. Furthermore, the lack of quantitative coronary angiography analysis made the proper determination of the diameters and lengths of the target lesions difficult. Angiography analysis would not use any core laboratory facility. Moreover, the heparin dose in Rota-Flush solution and burr speed were conjointly changed making them variables, whereas making three separate ones would have provided better information.

Conclusions

A small-burr modified RA technique with scoring balloon angioplasty pre-dilatation and implantation of a newer-generation DES is a safe and effective procedure for moderately and severely calcified coronary lesions with acceptable in-hospital and follow-up clinical outcomes. In addition, this study revealed that rota burr speed and heparin dose are significantly associated with the occurrence of in-hospital MACE in patients with severely calcified coronary lesions.

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Statement of Ethics: The study protocol was approved by the Institutional Ethics Committee and written informed consent was obtained from each patient before the start of the study.

Conflict of interest: None declared.

Peer-review: Externally peer-reviewed.

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