

Comparison of Bailout and Planned Rotational Atherectomy for Severe Coronary Calcified Lesions

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Abstract

Objective : To compare outcomes of bailout and planned rotational atherectomy (RA) in the treatment of severe calcified coronary lesions. **Methods:** Data of patients treated with RA from 2017 to 2018 at a single-center registry were retrospectively analyzed. All patients were divided into planned RA and bailout RA groups, data between two groups were compared. **Results:** A total of 190 patients were included in this study, 138 patients received planned RA and 52 patients received bailout RA. Baseline clinical characteristics had no significant differences between groups. The number of implanted stents and total stents length were similar. But the number of balloon (1.6 ± 0.8 vs. 2.7 ± 1.3 , $P < 0.001$), operation time (83.5 ± 26.2 vs. 100.8 ± 36.4 min, $P = 0.007$), fluoroscopy volume (941 ± 482 vs. 1227 ± 872 mGy, $P = 0.012$) and contrast amount (237 ± 62 vs. 275 ± 90 ml, $P = 0.003$) were all lower in planned RA group. Planned RA had a higher procedural success rate (99.3% vs. 92.3%, $P = 0.007$) and a lower complication incidence (4.3% vs. 17.3%, $P = 0.009$). But the cumulative 3-year incidences of MACE events (9.2% and 16.6%, log rank $p = 0.24$) had no difference between groups. **Conclusion:** For severe coronary artery calcification, although planned RA did not reduce MACE compared with bailout RA, but it can improve the immediate procedural success rate, reduce the incidence of complications, the operation time and the volume of contrast. **Keywords:** severe coronary calcified lesions, planned rotational atherectomy, bailout rotational atherectomy

Background

Calcified coronary lesions remain a challenge for percutaneous coronary intervention (PCI). Calcified lesions can lead to stent implantation failure or incomplete stent expansion, thus affecting the long-term efficacy of stents. It also increases the risk of perforation and coronary dissection during operation [1, 2]. Rotational atherectomy RA plays a key role in the therapy of severe calcified lesions [3, 4]. Although routine RA does not improve the clinical outcomes in the ROTAXUS trial, it can significantly improve the success rate of surgery [5]. However, it should be noted that more than 50% patients in ROTAXUS study were only moderately calcified lesions shown by coronary angiography, and 12.5% of the patients in the conventional balloon pre-expansion group received RA therapy. Therefore, it is of great clinical significance to explore when to start RA therapy for severe coronary artery calcification.

The aim of this study was to investigate the safety and procedural feasibility of a planned RA strategy for the treatment of severely calcified coronary lesions in comparison to a bailout RA approach following device failure.

Methods

Study Design and Population

This is a retrospective single-center study of all patients who underwent PCI using RA because of heavily calcified lesions at our hospital from January 2017 to December 2018. Severely calcified lesion was defined as: radiopacities noted without cardiac motion before contrast injection, generally compromising

both sides of the arterial lumen. All the patients were divided into 2 groups according to the indication for RA. Planned RA was defined as initial strategy without previous device failure. Bailout RA was defined as RA after incomplete expansion of balloon or failure delivery of any devices. Pre-intervention intravascular ultrasound (IVUS) or optical coherence tomography (OCT) was performed in partial patients, the patients will receive planned RA if the IVUS/OCT showed calcium angle $> 270^\circ$ and calcium length > 5 mm (Fig. 1) or the IVUS/OCT catheter cannot cross the lesions. When discharge from hospital, all the patients were followed-up regularly in clinic.

Data Collection

The demographic and clinical characteristics of all patients included age, gender, medical history, left ventricular function on admission, lipid profiles, serum creatinine, hemoglobin and procedural costs. The angiographic and procedural characteristics included number of diseased vessels, target vessel, the size of burr, total number of stents and total length of stents.

Major adverse cardiovascular events (all-cause death, target vessel revascularization, stent thrombosis) were collected during follow-up by telephone or electronic record system.

Procedural Details

Before procedural, all patients received an oral loading dose of 300 mg aspirin and 300 mg clopidogrel. During procedural, all patients received unfractionated heparin at a dose of 70–100 U/kg to maintain an activated clotting time (ACT) > 300 seconds. In both groups, the choice of vascular access, burr size, IVUS/OCT was left at the operators' discretion. The IVUS/OCT catheter was advanced beyond the target lesion using a commercially available IVUS/OCT system (40 MHz IVUS catheter; OptiCross, Boston Scientific. ILUMIEN C7-XR, Abbott). RA was performed by using the Rotablator (Boston Scientific Scimed, Inc., Maple Grove, MN, USA). The burr size was selected to reach a burr/vessel ratio of 0.5–0.6. RA speed ranged between 150,000 and 180,000 rotation per minute. Each RA time was 10–15 seconds. During RA, A continuous intracoronary infusion of a cocktail with unfractionated heparin and nitroglycerin was employed. Success of RA was defined as complete expansion of balloon of target lesion after RA.

Study Endpoints And Definitions

Procedural success was defined as a final residual stenosis $< 30\%$ after stents and grade 3 TIMI flow. Procedural outcomes included total number of balloon and stents used, procedure time, fluoroscopy amount, and volume of contrast used in the two groups. Procedure time was defined as the interval from initial angiography by guiding catheter to final angiography of the target lesion. PCI-related myocardial infarction is defined following the third universal definition of myocardial infarction. Major adverse

cardiovascular events (MACE) were defined as the composite of all-cause death, target vessel revascularization and stent thrombosis.

Statistical analysis

Statistical analysis was performed using SPSS for Windows 18.0 (SPSS, Chicago, IL). Continuous variables are expressed as mean \pm SD, categorical variables are given as frequencies (%). Univariate comparisons between the two groups were performed using Pearson's chi-square test for categorical variables, and a Student t test for continuous variables. Kaplan-meier was used to analyze the cumulative incidence of clinical events during the follow-up. Difference was considered to be statistically significant at $P < 0.05$.

Results

Patients Characteristics

From January 2012 to December 2018, a total of 190 patients were treated with RA. In 138 patients, RA was performed as a planned procedure, while in other 52 patients, RA was as a bailout procedure. In both groups, patients were old, had a high proportion of hypertension, Diabetes Mellitus (DM), smoking. Most patients presented as stable coronary artery disease and multi-vessel disease. Baseline clinical characteristics had no significant differences between both groups. But the proportion of IVUS/OCT guided PCI was higher in planned RA group than that in bailout RA group (Table 1).

Table 1
Baseline Clinical Characteristics of the Study Population

	Planned RA(n = 138)	Bailout RA(n = 52)	P Value
Age (years)	70.2 ± 8.3	69.3 ± 10.1	0.224
Male (%)	86(62.3%)	36(69.2%)	0.376
BMI (kg/m ²)	25.0 ± 3.0	24.7 ± 2.6	0.352
Hypertension (%)	111(83.3%)	38(73.1%)	0.272
DM (%)	71(51.4%)	22(42.3%)	0.261
Dyslipidemia (%)	35(25.3%)	18(34.6%)	0.205
Smoking (%)	60(43.5%)	26(50.0%)	0.421
LVEF (%)	65.1 ± 8.2	63.4 ± 9.4	0.289
Prior PCI (%)	30(21.7%)	12(23.1%)	0.843
Prior CABG (%)	3(2.2%)	2(3.8%)	0.521
eGFR _{CKD} 60 ml/min/1.73 m ² (%)	16(11.6%)	9(17.3%)	0.299
Clinical presentation			0.812
SCAD	31 (22.5%)	11 (21.2%)	
ACS	107 (77.5%)	41 (78.8%)	
MVD (%)	103(74.6%)	41(78.8%)	0.740
IVUS/OCT-guided (%)	35(25.4%)	6(11.5%)	0.039
BMI: Body mass index, DM: Diabetes mellitus, LVEF: LV ejection fraction, SCAD: stable coronary artery disease, ACS: acute coronary syndrome, MVD: multi-vessel coronary disease.			

Lesion And Procedural Characteristics

The most common RA-target vessel was left anterior descending artery in both groups (58.4% and 59.2% respectively). The most commonly employed burr size was 1.25 mm (41.6%) and 1.5 mm (54.2%). And the use of more than 1 burr was necessary in 5.3% of all cases. The number of stents and the total stents length had no significant differences between both groups, but the number of balloons in bailout RA group was more than that in planned RA group. In addition, the operation time, fluoroscopy volume and contrast amount were all lower in planned RA group than bailout RA group (Table 2).

Table 2
Angiographic and Procedural Characteristics

	Planned RA(n = 138)	Bailout RA(n = 52)	P Value
Target vessel			0.031
LM	2	1	
LAD	111	31	
LCX	4	3	
RCA	21	17	
Chronic total occlusion (%)	5(3.6%)	4(7.7%)	0.135
ACC/AHA type B2/C (%)	110(79.7%)	43(82.7%)	0.569
Predilatation (%)	136(98.6%)	50(96.2%)	0.897
Burr size			0.678
1.25	59	20	
1.5	73	30	
1.75	6	2	
More than 1 burr	7(5.1%)	3(5.8%)	0.848
Number of balloons	1.6 ± 0.8	2.7 ± 1.3	0.001
Number of stents	2.0 ± 0.8	2.2 ± 0.8	0.224
Total stents length (mm)	60.7 ± 24.1	62.1 ± 26.0	0.307
Postdilation(%)	137(99.3%)	50 (96.2%)	0.923
Operation time (min)	83.5 ± 26.2	100.8 ± 36.4	0.007
Operation cost (Yuan)	85090 ± 22171	93801 ± 25923	0.342
Fluoroscopy Volume (mGy)	941 ± 482	1227 ± 872	0.012
Contrast amount (ml)	237 ± 62	275 ± 90	0.003
LM: left main, LAD: Left anterior descending artery, LCX: left circumflex artery, RCA: right coronary artery.			

Procedural Complication Characteristics

The procedural success was achieved in the majority of cases (97.4%), but was lower in the bailout RA group (92.3% vs. 99.3%, P = 0.007). The incidence of complications was higher in bailout RA group

(17.3% vs. 4.3%). The most common complications were bradycardia, slow flow/ no reflow and dissection (Table 3).

Table 3
Complications between groups

	Planned RA(n = 138)	Bailout RA(n = 52)	P Value
Procedural Success	137(99.3%)	48(92.3%)	0.007
PCI-related MI	7(5.1%)	4(7.7%)	0.688
Complications	6(4.3%)	9(17.3%)	0.009
Bradycardia	2	4	
Slow flow/no reflow	2	1	
Dissection	2	3	
Burr entrapment	0	1	

Long Time Outcomes

All patients were followed up for a long period, with a median follow-up time of 36 months (1–84 months). The cumulative 3-year incidences of MACE events were 9.2% and 16.6% (log rank p 0.24), and the cumulative 3-year incidences of all-cause death were 6.4% and 12.0% (log rank p 0.34), the 3-year cumulative rates of target vessel revascularization were 3.0% and 5.1% (log rank p 0.49), and the 3-year cumulative rates of stent thrombosis were 0.9% and 2.9% (log rank p 0.46) in planned RA and bailout out RA group respectively. There was no significant difference between groups (p > 0.05) (Fig. 2).

Discussion

The low success rate and high incidence of complications of severe calcification lesions have always been the difficulty during PCI. RA can significantly improve the success rate. Studies showed that the success rate of RA was 95%-96.4% [6,7]. In our study, the success rate of RA was 97.4%. Especially, the success rate in planned RA group was 99.3%, which was significantly higher than that in bailout RA group (92.3%), confirming that planned RA can significantly improve the success rate for severe coronary artery calcification, but there were no difference of MACE between groups.

The complications during RA cannot be ignored. Previous studies [8–10] have shown that common complications and the incidence during RA were coronary dissection (10.5%), severe coronary spasm (1.6–6.6%), acute vascular occlusion (3.1%), slow/no-reflow flow (1.2–7.6%) and coronary artery perforation (0–2%). The most common complications in our study were slow heart rate (3.2%), coronary dissection (2.6%), slow/no-reflow flow (1.6%) and burr entrapment (0.5%). The incidence of complication

is high in bailout RA group than that in planned RA group (17.3% vs. 4.3%), which shows that planned RA is more safe than bailout RA.

RA is a complicated and time-consuming operation in the treatment of severe calcified lesions, which may lead to the increase of operation cost, contrast volume, operation time and fluoroscopy amount, and thus increase the economic burden of patients and the risk of contrast-induced nephropathy after operation. However, there are few studies on this issue. Our study showed that compared with bailout RA, planned RA could significantly reduce the operation time, the volume of contrast used and the fluoroscopy volume during the operation, which is important for both the interventional cardiologist and the patients. It is consistent with the results of ALLALI et al [11].

The ROTATE study showed that compared with bailout RA, planned RA did not reduce the adjusted 1-year MACE [12]. The results of ALLALI showed that although planned RA could improve the success rate of immediate surgery, but the incidence of 2-years MACE did not decrease compared with bailout RA (25.2% vs 28.7%, log rank P = 0.52) [11].It is a pity that our study is lack of long-time follow-up data.

The major limitation of this study is its non randomized design in which operator bias and unmeasured confounders may prohibit definitive conclusions. This study is also retrospective and has been performed at a single center.

Conclusions

Overall, our study showed that, for severe coronary artery calcification, although planned RA did not reduce the MACE than bailout RA, but it can improve the immediate procedural success rate, reduce the incidence of complications, the operation time and the volume of contrast compared with bailout RA.

List Of Abbreviations

abbreviation	
PCI	percutaneous coronary interventions
RA	rotational atherectomy
IVUS	intravascular ultrasound
OCT	optical coherence tomography
ACT	activated clotting time
MACE	major adverse cardiovascular events
DM	Diabetes Mellitus

Declarations

Ethics approval and consent to participate

This study was approved by the ethics at Peking University People's Hospital, all patients provided written informed consent before participation.

Consent for publication

Not applicable

Availability of data and materials

The datasets used during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests

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Authors' contributions

CAO CF and LI Q were major contributors in writing the manuscript. MA YL analyzed and interpreted the patient data, LIU J, ZHAO H and LU MY collected patients data, WANG WM was the corresponding author. All authors read and approved the final manuscript

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Figures

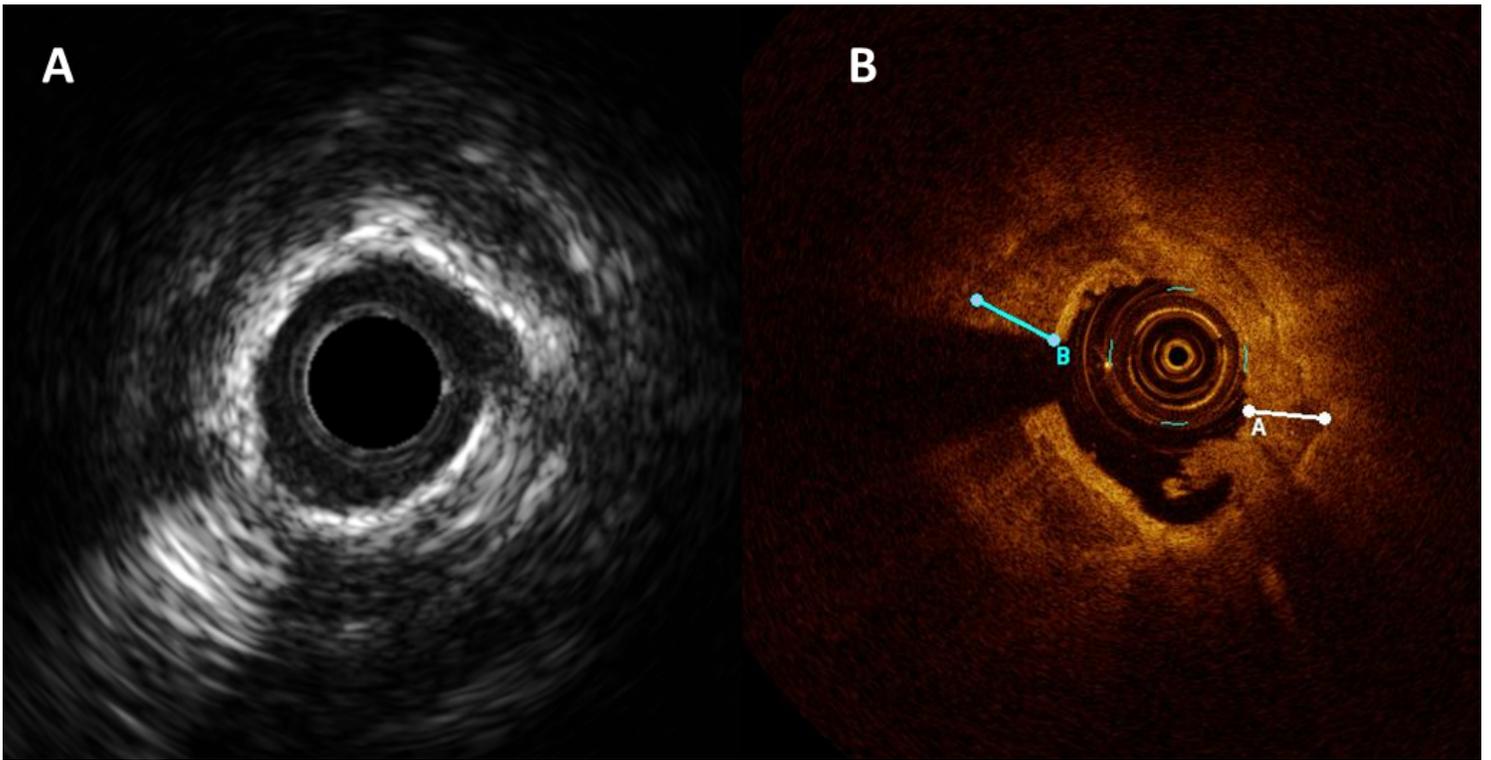


Figure 1

A representative calcification lesion images of IVUS/OCT A shows 360° calcium with a minimum lumen area 2.1 mm² B shows 360° calcium with maximum calcium thickness 0.58mm and minimum lumen area 1.8 mm²

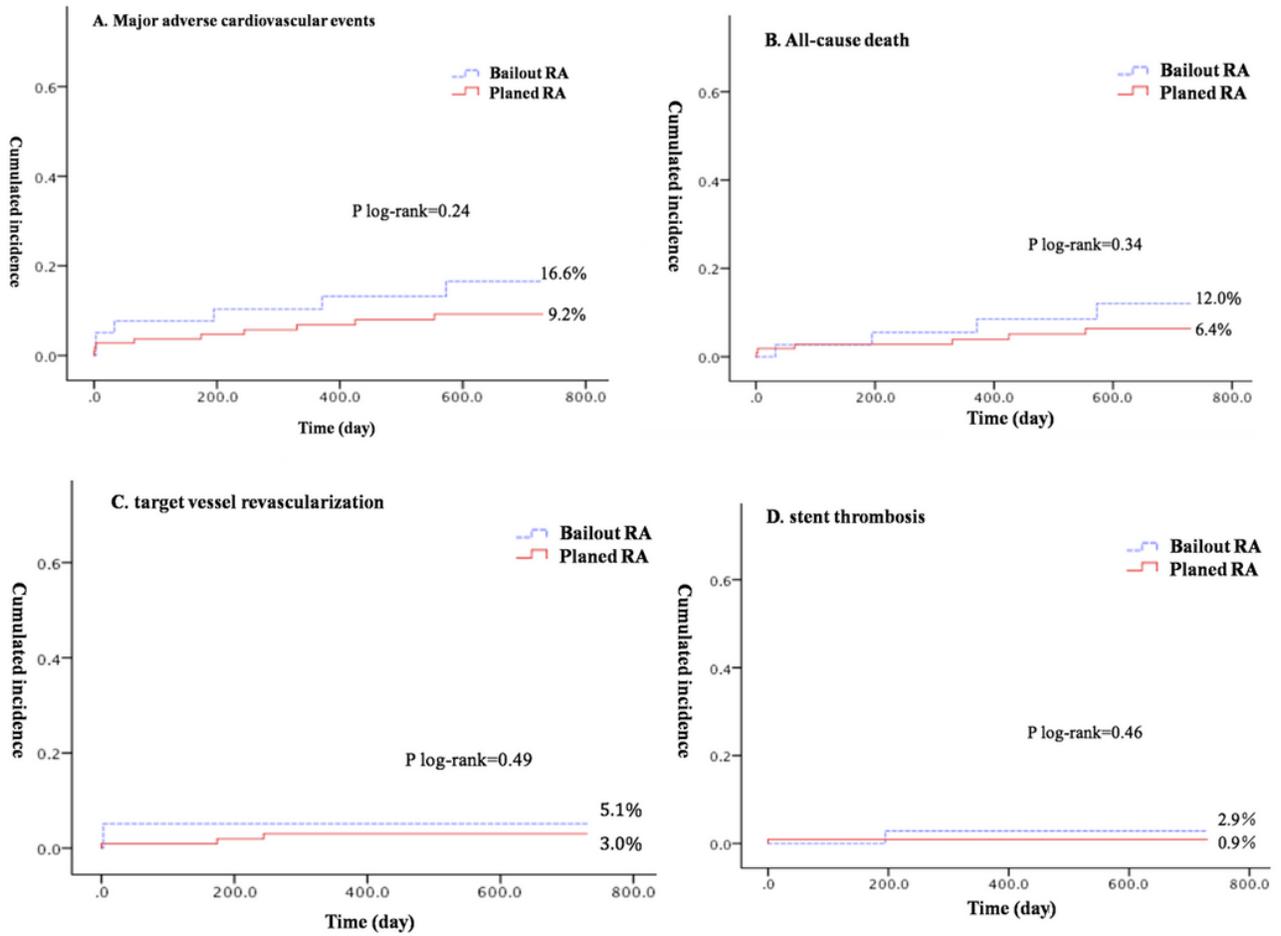


Figure 2

Major adverse cardiovascular events between groups