

Acute- and Long-term Outcomes of Rotational Atherectomy followed by Cutting Balloon versus Plain Balloon before Drug-Eluting Stent Implantation for Calcified Coronary Lesions

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Abstract

Background: Coronary calcification is a major determinant of stent underexpansion and subsequent adverse events. This study aimed to evaluate the acute- and long-term outcomes of rotational atherectomy (RA) followed by cutting balloon (CB) versus plain balloon before drug-eluting stent implantation for calcified coronary lesions.

Methods: From June April 2013 to March 2016, a total of 127 patients with moderately or severely calcified coronary lesions were treated with RA. Patients were divided into two groups according to the balloon type after RA: RA+CB group ($n = 75$) and RA+plain balloon group ($n = 52$). Minimal lumen diameter and acute lumen gain were analyzed by quantitative coronary angiography. In-hospital and long-term (>1 year) outcomes were recorded. Multivariate Cox regression analysis was performed to determine the independent predictors of in-stent restenosis.

Results: The mean age of the patients was 65.5 years, and 76.4% were men. Total lesion length and minimal lumen diameter at baseline were similar in the two groups. After RA and balloon dilation, the lumen diameter was significantly larger in the RA+CB group than in the RA+plain balloon group (1.57 ± 0.46 mm vs. 1.10 ± 0.40 mm, $t = 4.123$, $P < 0.001$). The final lumen diameter was also larger in the RA+CB group compared to that in the RA group (2.81 ± 0.41 mm vs. 2.60 ± 0.25 mm, $t = 2.111$, $P = 0.039$). Moreover, patients receiving RA and CB tended to have larger final lumen gain (2.15 ± 0.48 mm vs. 1.95 ± 0.47 mm, $t = 1.542$, $P = 0.132$). Multivariate Cox regression analysis indicated that the strategy of RA+CB was a significant protective factor against long-term (>1 year) in-stent restenosis (hazard ratio: 0.136, 95% confidence interval: 0.020–0.936, $P = 0.043$).

Conclusions: In patients with moderately or severely calcified lesions, a strategy of RA followed by CB before stent implantation can increase lumen diameter and acute lumen gain. This strategy is safe with lower risk of long-term in-stent restenosis.

Key words: Calcification; Cutting Balloon; Rotational Atherectomy

INTRODUCTION

Coronary calcification is a marker of atherosclerosis and is a major determinant of stent underexpansion, associated with adverse events including restenosis and stent thrombosis.^[1,2] Lesion preparation with rotational atherectomy (RA) has emerged as a strategy that allows mechanical ablation of inelastic calcified plaques, creating fractures in the calcified lesion and changing lesion compliance, and increasing the likelihood of maximal luminal gain and complete stent expansion.^[3] Several observational studies and registries have demonstrated favorable results of drug-eluting

stent (DES) implantation after RA in severely calcified lesions.^[4-6] By contrast, in the ROTAXUS randomized trial, there was greater short-term lumen gain with RA before

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Received: 21-03-2018 **Edited by:** Ning-Ning Wang
How to cite this article: Ai H, Wang X, Suo M, Liu JC, Wang CG, Zhen L, Nie SP. Acute- and Long-term Outcomes of Rotational Atherectomy followed by Cutting Balloon versus Plain Balloon before Drug-Eluting Stent Implantation for Calcified Coronary Lesions. Chin Med J 2018;131:2025-31.

Access this article online

Quick Response Code:



Website:
www.cmj.org

DOI:
10.4103/0366-6999.239299

paclitaxel-eluting stent implantation. However, routine angiographic follow-up at 9 months showed no difference in major adverse cardiovascular events (MACE) and greater late lumen loss with an RA strategy.^[7] However, this trial was limited by a preponderance of moderately calcified lesions, a higher crossover rate (8%) from balloon dilatation to RA, and a higher drop rate (about 20%) all of which may have offset the putative benefits of RA.^[3,8]

A few observational studies have shown that intensive plaque modification with RA combined with cutting balloon (CB) was efficient for the treatment of calcified lesions.^[9,10] Since RA ablates the calcium deposits and might reduce the thickness and volume of calcium, adding CB to RA might facilitate calcium fracture and stent expansion. One small pilot randomized trial allocated patients with intravascular ultrasound (IVUS) calcium arc $>180^\circ$ to receive RA+CB or RA+plain balloon. The results showed greater acute lumen gain in the RA+CB group.^[11] However, the long-term outcomes of RA followed by CB for calcified lesions remain less well determined. Thus, our goal in this study was to compare the acute procedural results and long-term cardiovascular events of RA with CB versus RA with plain balloon before DES implantation for moderately or severely calcified coronary lesions.

METHODS

Ethical approval

The study was conducted in accordance with the *Declaration of Helsinki* and was approved by the Institutional Review Board of Beijing Anzhen Hospital, Capital Medical University. Written informed consent was obtained from all patients.

Study design and population

This was a retrospective, single-center, and observational study to evaluate the acute- and long-term (>1 year) outcomes of RA combined with CB for the treatment of moderately or severely calcified coronary lesions. From April 2013 to March 2016, a total of 127 patients with moderately or severely calcified lesions were treated with rotational atherectomy at the Emergency and Critical Care Center of Beijing Anzhen Hospital, Capital Medical University. Moderate calcification was defined as radiopacities noted angiographically only during the cardiac cycle before contrast injection. Severe calcification was defined as radiopacities noted without cardiac motion before contrast injection generally compromising both sides of the arterial lumen. The exclusion criteria included lesions with in-stent restenosis or bypass graft failure, dissection or thrombus present in the target vessel (by visual estimate) before percutaneous coronary intervention (PCI), and patients with malignancy and less than 1-year life expectancy. Patients were divided into two groups according to the balloon type after RA and before DES implantation: RA+CB group and RA+plain balloon group. The selection of balloon type was left to the operator's discretion.

Procedures

All patients were pretreated with a loading dose of aspirin (300 mg) and clopidogrel (300 mg) or ticagrelor (180 mg) before PCI if patients were not pretreated. During the procedure, intravenous heparin (maintaining an activated clotting time >250 s) or bivalirudin (based on body weight) was administered.

RA was performed based on standard recommendations using a Rotablator system (Boston Scientific, Maple Grove, Minnesota). The burr size was selected to achieve a burr/vessel ratio of 0.5–0.6. The rotational speed was between 135,000 and 180,000 \times g. The burr catheter was prophylactically irrigated with a cocktail flush fluid to prevent slow flow occurring during or after RA. In the RA+CB group, the CB (Flextome, Boston Scientific) was used after RA and before stent implantation with a diameter/artery ratio of 0.8–1.0. For some tortuous or angulated lesions, a shorter balloon (6–10 mm) was chosen. The CB dilation pressure was increased step wise by 2 atmosphere (atm) every 2 s as recommended. In the control group, a plain conventional balloon was used after RA with a target balloon diameter/artery ratio of 0.8–1.0. All patients received a second-generation DES. Postdilation was performed at the operator's discretion. Final angiography of the vessel was performed in at least two orthogonal views that showed the target site to be free of either foreshortening or vessel overlap. At discharge, all patients were prescribed aspirin (100 mg/d) and clopidogrel (75 mg/d) or ticagrelor (90 mg twice a day) for at least one year unless there were contraindications.

Quantitative coronary angiographic analysis

Coronary angiograms were reviewed and analyzed independently by an experienced technician using a validated edge-detection system (CMS version 7.3, Medis Medical Imaging Systems, Leiden, The Netherlands) in the core laboratory of Beijing Anzhen Hospital, Capital Medical University. Measurements were done at baseline (before procedures), after RA, after balloon dilation (CB or plain balloon), and after stent implantation with or without postdilation. We only included angiograms with good quality and corresponding frames at each time-point. The minimal lumen diameter, lesion length, and reference lumen diameter were measured, and lumen diameter stenosis was defined as the following: $(1 - [\text{minimal lumen diameter}/\text{reference lumen diameter}]) \times 100\%$. Acute lumen gain was defined as the minimal lumen diameter after procedures (RA, CB or plain balloon, and stenting) minus the minimal lumen diameter at baseline.

In-hospital and long-term outcomes

Periprocedural complications included arterial perforation, abrupt coronary occlusion (including dissection and thrombosis), severe coronary dissection (NHLBI C-F), and no reflow. Follow-up was performed at 1 month, 3 months, 6 months, 1 year, and then, every 6 months

thereafter. The clinical events were collected through clinic visit, medical chart review, or telephone calls. Patients were recommended to receive angiography or computed tomography (CT) angiography during follow-up. Patients with recurrent ischemia symptoms underwent angiography or PCI during rehospitalization. In-stent restenosis was defined as >50% stenosis by angiography or CT angiography. MACE was defined as a composite of cardiovascular death, myocardial infarction, and ischemia-driven target lesion revascularization (TLR). All endpoints were defined in accordance with the proposed definitions of the standardized data collection for cardiovascular trials initiative.^[12] Stent thrombosis was defined according to the Academic Research Consortium (ARC) definition.^[13]

Statistical analyses

Categorical variables were presented as frequency and were compared using Chi-square statistics or Fisher exact test, as appropriate. Continuous variables were shown as mean \pm standard deviation (SD) or median (interquartile range) and compared using Student's *t*-test or the Mann-Whitney *U*-test. All tests were two-tailed with a 0.05 significance level. Time-to-event data were summarized as Kaplan-Meier estimates and were compared by the log-rank test. Multivariate Cox proportional hazard regression analysis was performed to determine the independent predictors of in-stent restenosis during follow-up, and the adjusted hazard ratio (*HR*) with 95% confidence interval (*CI*) was calculated. All statistical analyses were performed with SPSS 22.0 (IBM, Armonk, New York, USA).

RESULTS

Baseline characteristics

Of the 127 included patients, there were 75 (59.1%) in the RA+CB group and 52 (40.9%) in the RA group. Mean patient age was 65.5 years, and 76.4% were men. Most patients were diagnosed with unstable angina (87.4%). The baseline clinical characteristics were similar between RA+CB and RA groups, except current smokers, who were more frequent in the RA+CB group [Table 1].

Angiographic and procedural characteristics

The angiographic and procedural characteristics are shown in Table 2. Patients were balanced according to lesion location (mostly left anterior descending artery) and morphology. The maximum burr size was larger in the RA+CB group than in the RA group (1.66 \pm 0.20 mm vs. 1.53 \pm 0.22 mm, *t* = 3.257, *P* = 0.001) with most patients receiving a 1.75 mm burr (53.3%) in the RA+CB group and 1.50 mm burr (38.5%) in the RA group. All patients had successful stent implantation. The mean number of stents per lesions was similar between the two groups (1.9 \pm 0.7 vs. 1.9 \pm 0.9, *t* = -0.400, *P* = 0.690). The stent diameter and total stent length were similar in both groups. After stenting, balloon postdilation was performed more often in the RA+CB group than in the RA group (93.3% vs. 71.2%, χ^2 = 11.386, *P* = 0.001).

Quantitative coronary angiographic analysis

The results of baseline quantitative coronary angiographic analysis are shown in Table 3. A total of 67 angiograms with good quality were included in this study. Total lesion length

Table 1: Baseline characteristics of patients in the RA+CB and RA groups

Variables	RA+CB (n = 75)	RA (n = 52)	t/ χ^2 /U	P
Age (years), mean \pm SD	66.1 \pm 8.8	64.7 \pm 8.4	0.891*	0.375
Male, n (%)	56 (74.7)	41 (78.8)	0.297 [†]	0.586
Diabetes, n (%)	47 (62.7)	29 (55.8)	0.608 [†]	0.608
Hypertension, n (%)	50 (66.7)	33 (63.5)	0.139 [†]	0.709
Hyperlipidemia, n (%)	26 (34.7)	20 (38.5)	0.191 [†]	0.662
Current smokers, n (%)	46 (61.3)	19 (36.5)	7.556 [†]	0.006
Chronic kidney disease, n (%)	3 (4.0)	3 (5.8)	0.214 [†]	0.405
Prior PCI, n (%)	9 (12.0)	7 (13.5)	0.060 [†]	0.807
Diagnosis, n (%)			1.556 [†]	0.459
Unstable angina	64 (85.3)	47 (90.4)		
NSTEMI	6 (8.0)	4 (7.7)		
STEMI	5 (6.7)	1 (1.9)		
Glucose (mmol/L), median (IQR)	6.5 (5.3–12.2)	6.0 (5.4–8.8)	1872 [‡]	0.493
Urea (mmol/L), mean \pm SD	6.1 \pm 2.8	6.3 \pm 3.1	-0.450*	0.654
Creatinine (μ mol/L), mean \pm SD	79.6 \pm 20.9	86.7 \pm 52.9	-0.925*	0.359
Uric acid (μ mol/L), mean \pm SD	344.2 \pm 87.3	352.7 \pm 103.4	-0.487*	0.627
Total cholesterol (mmol/L), mean \pm SD	3.8 \pm 0.9	4.0 \pm 1.0	-0.733*	0.466
Triglyceride (mmol/L), mean \pm SD	1.4 \pm 0.7	1.5 \pm 0.6	-0.443*	0.659
Low-density lipoprotein cholesterol (mmol/L), mean \pm SD	2.3 \pm 0.7	2.4 \pm 0.9	-0.634*	0.528
High-density lipoprotein cholesterol (mmol/L), mean \pm SD	1.0 \pm 0.2	1.0 \pm 0.2	-0.599*	0.550
High-sensitivity C-reactive protein (mg/L), median (IQR)	1.0 (0.4–4.0)	0.9 (0.3–3.1)	1714 [‡]	0.495

Data were presented as mean \pm SD, median (IQR), or n (%). **t* values; [†] χ^2 values; [‡]*U* values. CB: Cutting balloon; IQR: Interquartile range; NSTEMI; Non-ST-elevation myocardial infarction; PCI: Percutaneous coronary intervention; RA: Rotational atherectomy; STEMI: ST-elevation myocardial infarction; SD: Standard deviation.

Table 2: Angiographic and procedural characteristics of patients in the RA+CB and RA groups

Variables	RA+CB (n = 75)	RA (n = 52)	t/ χ^2	P
Target vessel, n (%)			0.878 [†]	0.645
Left anterior descending	51 (68.0)	39 (75.0)		
Left circumflex	7 (9.3)	3 (5.8)		
Right coronary artery	17 (22.7)	10 (19.2)		
Ostial lesion, n (%)	7 (9.3)	6 (11.5)	0.163 [†]	0.687
Bifurcation, n (%)	43 (57.3)	32 (61.5)	0.225 [†]	0.636
Severe tortuosity, n (%)	16 (21.3)	6 (11.5)	2.057 [†]	0.151
Severe calcification, n (%)	59 (78.7)	47 (90.4)	3.055 [†]	0.080
Maximum burr size (mm)	1.66 ± 0.20	1.53 ± 0.22	3.257 [*]	0.001
Maximum burr size (category), n (%)			11.369 [†]	0.023
1.00 mm burr	1 (1.3)	1 (1.9)		
1.25 mm burr	5 (6.7)	12 (23.1)		
1.50 mm burr	22 (29.3)	20 (38.5)		
1.75 mm burr	40 (53.3)	17 (32.7)		
2.00 mm burr	7 (9.3)	2 (3.8)		
Use of >1 burr	11 (14.7)	9 (17.3)	0.161 [†]	0.688
CB diameter (mm)	2.8 ± 0.4	NA	NA	NA
CB length (mm)	7.7 ± 3.3	NA	NA	NA
CB pressure (atm)	13 ± 2	NA	NA	NA
Number of stents/lesions	1.9 ± 0.7	1.9 ± 0.9	-0.400 [*]	0.690
Number of stents/lesions (category), n (%)			4.938 [†]	0.294
0	0	2 (3.8)		
1	24 (32.0)	13 (25.0)		
2	38 (50.7)	26 (50.0)		
3	12 (16.0)	9 (17.3)		
4	1 (1.3)	2 (3.8)		
Stent diameter (mm)	3.0 ± 0.5	2.9 ± 0.5	1.237 [*]	0.219
Total stent length (mm)	52.6 ± 20.3	48.9 ± 24.8	0.890 [*]	0.375
Balloon postdilation, n (%)	70 (93.3)	37 (71.2)	11.386 [†]	0.001
Postdilation balloon size (mm)	3.3 ± 0.5	3.2 ± 0.4	-1.061 [*]	0.291
Max. post dilation pressure (atm)	20 ± 3	18 ± 3	-2.082 [*]	0.040

Data were presented as mean ± SD or n (%). **t* values; [†] χ^2 values. CB: Cutting balloon; NA: Not applicable; RA: Rotational atherectomy; SD: Standard deviation.

Table 3: Quantitative coronary angiography of patients in the RA+CB and RA groups

Variables	RA+CB (n = 47)	RA (n = 20)	t/U	P
Total lesion length (mm)	22.8 ± 12.8	23.3 ± 15.0	-0.110 [*]	0.913
Reference vessel diameter at baseline (mm)	2.50 ± 0.60	2.20 ± 0.52	2.054 [*]	0.046
Minimal lumen diameter (mm)				
Baseline	0.64 (0.40–1.04)	0.73 (0.46–0.82)	438 [†]	0.656
Post-RA	1.15 ± 0.34	1.11 ± 0.40	0.391 [*]	0.698
Postdilation	1.57 ± 0.46	1.10 ± 0.40	4.123 [*]	<0.001
Poststenting	2.81 ± 0.41	2.60 ± 0.25	2.111 [*]	0.039
Lumen diameter stenosis (%)				
Baseline	74.2 ± 14.1	69.8 ± 19.9	0.898 [*]	0.377
Post-RA	53.9 ± 13.6	49.6 ± 20.3	1.051 [*]	0.297
Postdilation	36.1 ± 17.3	49.5 ± 20.3	-2.564 [*]	0.015
Poststenting	3.0 (-0.8–7.9)	5.4 (-1.8–7.1)	470 [†]	0.995
Acute lumen gain (mm)				
Post-RA	0.47 (0.13–0.71)	0.39 (0.19–0.72)	451 [†]	0.795
Postdilation	0.87 (0.66–1.19)	0.39 (0.19–0.72)	195 [†]	<0.001
Poststenting	2.15 ± 0.48	1.95 ± 0.47	1.542 [*]	0.132

Data were presented as mean ± SD or median (IQR). **t* values; [†]*U* values. CB: Cutting balloon; IQR: Interquartile range; RA: Rotational atherectomy; SD: Standard deviation.

was similar between the two groups. The reference vessel diameter at baseline was slight higher in the RA+CB group

than in the RA group (2.50 ± 0.60 mm vs. 2.20 ± 0.52 mm, *t* = 2.054, *P* = 0.046). The baseline minimal lumen diameter

was comparable between the two groups. After RA, the lumen diameter became larger in both groups. However, after balloon dilation, the lumen diameter increased only in the RA+CB group and not in the RA group, and there was a significant difference (1.57 ± 0.46 mm vs. 1.10 ± 0.40 mm, $t = 4.123$, $P < 0.001$). In addition, after stent implantation (and postballoon dilation in some cases), the final lumen diameter was larger in the RA+CB group than in the RA group [2.81 ± 0.41 mm vs. 2.60 ± 0.25 mm, $t = 2.111$, $P = 0.039$; Table 3 and Figure 1a]. Similarly, the change in lumen diameter stenosis was only observed after RA+CB but not after RA+plain balloon, although there was no statistical difference of lumen diameter stenosis poststenting between the two groups [Table 3].

Moreover, the acute lumen post-RA was similar in the RA+CB group to that of the RA group. After dilation, the patients receiving CB had larger lumen gain compared to those receiving plain balloon (0.87 [0.66–1.19] mm vs. 0.39 [0.19–0.72] mm, $U = 195$, $P < 0.001$). The final lumen gain tended to be larger in the RA+CB group than in the RA group [2.15 ± 0.48 mm vs. 1.95 ± 0.47 mm, $t = 1.542$, $P = 0.132$; Table 3 and Figure 1b].

In-hospital and long-term outcomes

There were only one acute occlusion and one no flow in the RA+CB group and one no flow in the RA group. The incidence of severe dissections (NHLBI type C-F) was similar between RA+CB and RA groups ($P < 0.05$). There were no MACEs, cardiovascular deaths, myocardial

infarctions, ischemia-driven TLRs, or stent thromboses in either group during hospitalization.

During a median follow-up of 410 days (260–816 days), 6 (4.7%) had MACE: 3 (4.0%) in the RA+CB group, and 3 (5.8%) in the RA group. The crude rate of MACE was similar in the two groups. There was one death, two TLR in the RA+CB group, and three TLR in the RA group [Table 4]. One patient died during sleep due to cardiac arrest 2.2 years after index PCI. All five patients with TLR experienced recurrent unstable angina and were rehospitalized to undergo PCI. A total of 83 patients (65.4%) underwent follow-up angiography or CT angiography, in which the proportion were similar between RA+CB and RA groups ($P = 0.057$). Notably, the cumulative event-free survival rate of in-stent restenosis was significantly higher in the RA+CB group than in the RA group [log-rank $P = 0.006$, Figure 2]. Multivariate Cox regression analysis indicated that the strategy of RA+CB was a significant protective factor against long-term (>1 year) in-stent restenosis ($HR: 0.136$, 95% $CI: 0.020$ – 0.936 , $P = 0.043$), after adjustment of age, gender, diabetes, hyperlipidemia, ostial lesion, bifurcation lesion, severe tortuosity, and lesions with severe calcification [Table 5].

DISCUSSION

The present study showed that, in patients with moderately or severely calcified lesions, adding CB to RA was associated with a larger lumen diameter and lumen gain after PCI

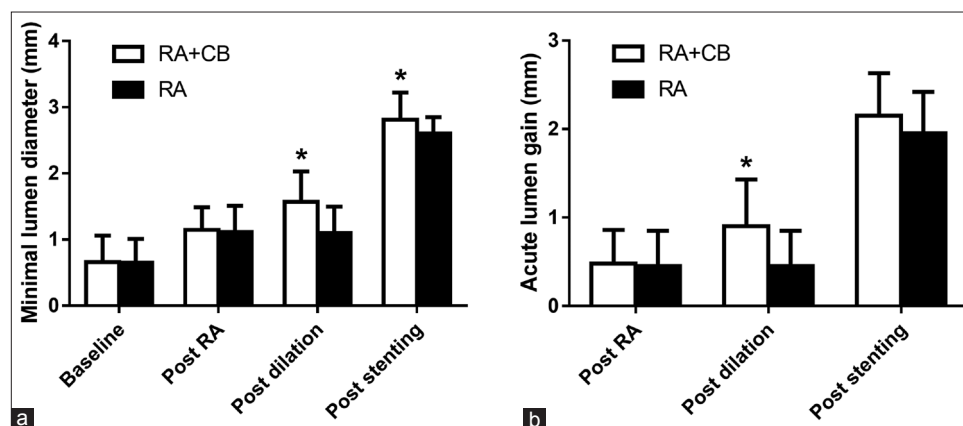


Figure 1: Serial analysis of minimal lumen diameter and acute lumen gain by quantitative coronary angiography between RA+CB group ($n = 47$) and RA group ($n = 20$). (a) Change of minimal lumen diameter at baseline, after RA, after CB or plain balloon dilation, and after stent implantation. (b) Change of acute lumen gain after RA, after CB or plain balloon dilation, and after stent implantation. * $P < 0.05$ versus RA group. CB: Cutting balloon; RA: Rotational atherectomy.

Table 4: Outcomes during the follow-up of patients in the RA+CB and RA groups

Variables	RA+CB ($n = 75$)	RA ($n = 52$)	χ^2	P
MACE*, n (%)	3 (4.0)	3 (5.8)	0.214	0.688
Cardiovascular death, n (%)	1 (1.3)	0	0.699	1.000
Myocardial infarction, n (%)	0	0	NA	NA
Target lesion revascularization, n (%)	2 (2.7)	3 (5.8)	0.782	0.399
In-stent restenosis [†] , n/N (%)	2/44 (4.5)	8/39 (20.5)	4.974	0.040

*MACE includes cardiovascular death, myocardial infarction, and target lesion revascularization; [†]In-stent restenosis was defined as >50% stenosis by angiography or CTA. CB: Cutting balloon; RA: Rotational atherectomy; NA: Not applicable; MACE: Major adverse cardiovascular events.

Table 5: Multivariate Cox regression analysis for in-stent restenosis

Variables	β	HR	95% CI	P
RA+CB versus RA	-1.996	0.136	0.020-0.936	0.043
Age	-0.013	0.987	0.912-1.067	0.737
Gender (male vs. female)	-1.341	0.262	0.015-4.453	0.354
Diabetes	0.420	1.521	0.305-7.587	0.609
Hyperlipidemia	0.520	1.682	0.304-9.323	0.552
Ostiallesion	2.363	NA	NA	0.187
Bifurcation lesion	-1.329	0.265	0.052-1.350	0.110
Severe tortuosity	-0.659	0.517	0.033-8.124	0.639
Severe calcification	11.090	NA	NA	0.979

CB: Cutting balloon; CI: Confidence interval; HR: Hazard ratio; RA: Rotational atherectomy.

than after RA with plain balloon. The strategy of combined RA and CB was safe, without increasing in-hospital and long-term (>1 year) cardiovascular events and was associated with lower risk of in-stent restenosis.

Coronary calcification may impair stent delivery and expansion and was associated with increased risk of subsequent cardiovascular events after PCI.^[14-16] In lesions with a maximum calcium >180°, a greater amount of calcium resulted in a smaller and more eccentrically shaped stent area.^[17] Vavuranakis *et al.*^[18] reported that the arc of calcium by IVUS was inversely related to stent expansion, even after high-pressure balloon inflations. In contrast to IVUS, optical coherence tomography (OCT) penetrated calcium to assess thickness, area, and volume of the calcium, thus reflecting true calcium severity.^[1,19] Some studies showed thinner calcium (<0.5 mm in thickness) was associated with calcium fracture irrespective of calcium angle, and calcium fracture was associated with greater stent expansion.^[20,21] In our study, lesions with a large angle of calcium that were thin (<0.5 mm in thickness) did not appear to inhibit stent expansion.^[22]

The 2014 European guidelines recommended RA for heavily calcified lesions that might not be crossed by a balloon catheter or adequately dilated before stent implantation; however, it should not be performed routinely.^[23] Tang *et al.*^[10] showed that RA combined with plain balloon did not increase acute lumen gain compared to plain balloon alone after the procedure. In the ROTAXUS trial, using RA before paclitaxel-eluting stent implantation showed greater late lumen loss at 9 months.^[7] Because RA could only ablate superficial calcium and moderately reduce calcium volume, the calcified ring remained, preventing stent expansion. CB was able to score calcified plaque and has been reported for the treatment of severe calcified lesions in a few observational studies.^[24,25] After ablation of calcium deposits by RA, adding CB to RA might facilitate calcium fracture and stent expansion. In the present study, we used a combination of RA and CB and found improved lumen diameter and lumen gain after the procedure that was consistent with previous studies.^[11] Moreover, the use of CB on the basis of RA might reduce tension during

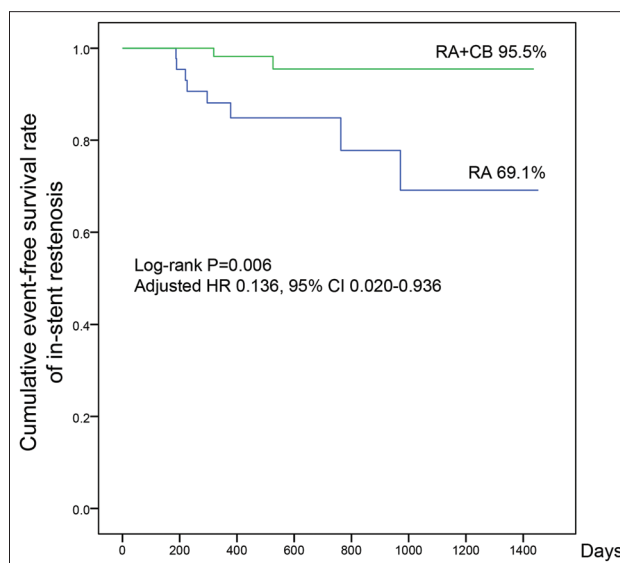


Figure 2: Cumulative event-free survival rate of in-stent restenosis in RA+CB group ($n = 75$) and RA group ($n = 52$). CB: Cutting balloon; CI: Confidence interval; HR: Hazard ratio; RA: Rotational atherectomy.

balloon dilation because RA could first ablate calcium and make it thinner. In addition, we showed RA with CB was not associated with increased periprocedural complications and in-hospital events. By contrast, in the ROTAXUS randomized trial, routine angiographic follow-up at 9 months showed no difference in MACE and greater late lumen loss with an RA strategy.^[7] In our study, although there was no significant difference in MACE in the RA+CB group compared to the RA group, patients using combined strategy had increased event-free survival rate for in-stent restenosis. These results indicated RA combined with CB might be a more reasonable strategy for plaque modification of moderately or severely calcified lesions.

This was a retrospective observational study. The sample size was relatively small and may have reflected inclusion bias. Even though we performed multivariable analyses, the potential residual confounding remains a threat to the validity of results. The follow-up rate of angiography or CT angiography of this study was relatively low. However, the follow-up rates in the RA+CB and RA groups were similar. The role of OCT or IVUS in guiding plaque modification needs further evaluation.

In patients with moderately or severely calcified lesions, a strategy of RA followed by CB before DES implantation was associated with an increased lumen diameter and lumen gain after PCI. This strategy was safe with lower risk of long-term in-stent restenosis.

Financial support and sponsorship

This study was supported by grants from National Natural Science Foundation of China (No. 81670222 and No. 81600209), Beijing Municipal Science and Technology Commission (No. Z181100001718060), Beijing Municipal Administration of Hospitals Clinical Medicine Development of Special Funding Support

(No. ZYLX201710), Beijing Municipal Administration of Hospitals' Youth Program (No. QML20160605), Beijing Municipal Administration of Hospitals Incubating Program (No. PX2016048), and Beijing Municipal Organization Department (No. 2016000021469G194).

Conflicts of interest

There are no conflicts of interest.

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冠状动脉钙化病变药物洗脱支架植入前采用旋磨联合切割球囊对比普通球囊的急性期和远期结局

摘要

背景：冠状动脉钙化是支架膨胀不良和不良事件的主要决定因素。本研究旨在评估冠状动脉钙化病变药物洗脱支架植入前采用旋磨联合切割球囊对比普通球囊的急性期和远期结局。

方法：从2013年4月到2016年3月，共127例中重度钙化病变患者接受旋磨术。根据旋磨后球囊类型分为旋磨+切割球囊组（n=75）和旋磨+普通球囊组（n=52）。采用定量冠状动脉造影分析最小管腔直径和急性管腔获得，并记录院内和长期（>1年）结局。采用多因素Cox回归分析支架内再狭窄的独立预测因素。

结果：患者平均年龄65.5岁，76.4%是男性。两组基线总病变长度和最小管腔直径相当。旋磨和球囊扩张后，旋磨+切割球囊组管腔直径明显大于旋磨+普通球囊组（ 1.57 ± 0.46 mm vs. 1.10 ± 0.40 mm, $t = 4.123$, $P < 0.001$ ）。旋磨+切割球囊组最终管腔直径明显大于旋磨+普通球囊组（ 2.81 ± 0.41 mm vs. 2.60 ± 0.25 mm, $t = 2.111$, $P = 0.039$ ）。此外，旋磨+切割球囊组患者最终管腔获得有增大趋势（ 2.15 ± 0.48 mm vs. 1.95 ± 0.47 mm, $t = 1.542$, $P = 0.132$ ）。多因素Cox回归分析提示，旋磨+切割球囊策略是远期（>1年）支架内再狭窄的保护因素（风险比：0.136，95%置信区间：0.020–0.936， $P = 0.043$ ）。

结论：对于中重度钙化病变患者，支架植入前采用旋磨联合切割球囊策略增加管腔直径和急性管腔获得。该策略是安全的，且远期支架内再狭窄风险较低。