



Aggressive plaque modification with rotational atherectomy and cutting balloon for optimal stent expansion in calcified lesions

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Abstract

Objective To evaluate the factors affecting optimal stent expansion in calcified lesions treated by aggressive plaque modification with rotational atherectomy (RA) and a cutting balloon (CB). **Methods** From January 2014 to May 2015, 92 patients with moderate to severe coronary calcified lesions underwent rotational atherectomy and intravascular ultrasound imaging at Chinese PLA General Hospital (Beijing, China) were included in this study. They were divided into a rotational atherectomy combined with cutting balloon (RACB) group (46 patients treated with RA followed by CB angioplasty) and an RA group (46 patients treated with RA followed by plain balloon angioplasty). Another 40 patients with similar severity of their calcified lesions treated with plain old balloon angioplasty (POBA) were demographically matched to the other groups and defined as the POBA group. All patients received a drug-eluting stent after plaque preparation. Lumen diameter and lumen diameter stenosis (LDS) were measured by quantitative coronary angiography at baseline, after RA, after dilatation, and after stenting. Optimal stent expansion was defined as the final LDS < 10%. **Results** The initial and post-RA LDS values were similar among the three groups. However, after dilatation, the LDS significantly decreased in the RACB group (from 54.5% ± 8.9% to 36.1% ± 7.1%) but only moderately decreased (from 55.7% ± 7.8% to 46.9% ± 9.4%) in the RA group (time × group, $P < 0.001$). After stenting, there was a higher rate of optimal stent expansion in the RACB group (71.7% in the RACB group, 54.5% in the RA group, and 15% in the POBA group, $P < 0.001$), and the final LDS was significantly diminished in the RACB group compared to the other two groups (6.0% ± 2.3%, 10.8% ± 3.3%, 12.7% ± 2.1%, $P < 0.001$). Moreover, an LDS ≤ 40% after plaque preparation (OR = 2.994, 95% CI: 1.297–6.911) was associated with optimal stent expansion, which also had a positive correlation with the appearance of a calcified ring split ($r = 0.581$, $P < 0.001$). **Conclusions** Aggressive plaque modification with RA and CB achieve more optimal stent expansion. An LDS ≤ 40% after plaque modification was a predictive factor for optimal stent expansion in calcified lesions. This parameter was also associated with the presence of calcified ring split.

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1 Introduction

Suboptimal stent expansion, usually defined as a final lumen stent diameter stenosis ≥ 10% as measured by quantitative coronary angiography (QCA),^[1,2] is associated with an increased rate of adverse events.^[3] Highly calcified coronary lesions respond poorly to conventional percutaneous coronary intervention (PCI) and result in higher rates of

suboptimal stent expansion.^[4–6] Developing methods to optimize stent expansion in highly calcified lesions is challenging but important.

Although rotational atherectomy (RA) is recommended for plaque preparation in severely calcified lesions,^[7] the most recent ROTAXUS study showed that the degree of final stent diameter stenosis after RA and stent implantation was still high at 10.9%, and the restenosis rate and major adverse cardiac event (MACE) rate were not improved compared to patients treated with a stent and without RA.^[8] Some studies showed that the aggressive plaque modification of RA combined with a cutting balloon (CB) may act synergistically in plaque preparation in severely calcified lesions and can optimize stent expansion;^[9–12] however,

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there is limited evidence to support these claims. Moreover, factors associated with optimal stent expansion in aggressive plaque modification procedures for highly calcified lesions have not been fully explored. Therefore, in this study, we evaluated the efficacy of RA followed by CB for plaque preparation and stent deployment in highly calcified lesions and compared this treatment with RA followed by plain balloon angioplasty and plain balloon angioplasty alone. Then, we evaluated possible factors associated with optimal stent expansion during an aggressive plaque modification procedure.

2 Methods

2.1 Patients and study design

This was a single-center, retrospective study of 92 patients with moderate or severe calcified lesions who had RA and intravascular ultrasound (IVUS) performed at the Chinese PLA General Hospital (Beijing, China) from January 2014 to May 2015. The inclusion criteria were patients with ischemic coronary heart disease who had target lesions with more than 70% stenosis confirmed by QCA. Severe calcification was defined as radio-opacities observed without cardiac motion before contrast injection, whereas moderate calcification was defined as radio-opacities noted only during the cardiac cycle before contrast injection.^[13] Second-generation drug-eluting stents (DES) were implanted after plaque preparation. The exclusion criteria were myocardial infarction within 30 days, in-stent lesion, lesion with dissection before PCI, lesion within a vein graft, and unprotected left main disease; patients with malignancy and a less than 1-year life expectancy were also excluded. They were divided into either the RA group or the RACB group based on whether a CB angioplasty was performed after the RA. Forty patients with moderate or highly calcified lesions who received plain old balloon angioplasty (POBA) followed by DES implantation during the same study period were selected from our database as a control group and matched on severity of calcification, stenosis percentage, age, and sex.

The study protocol was approved by the ethics committee at the Chinese PLA General Hospital. Informed PCI consent was obtained from the patients prior to any procedures.

2.2 Operation procedure

All of the patients received an oral loading dose of 300 mg aspirin and clopidogrel 12 h prior to the intervention procedure. Immediately before intervention, intra-arterial or intravenous heparin (maintaining an activated clotting time ≥ 250 s) or bivalirudin (based on body weight) was admin-

istered as an anti-thrombotic.

Coronary angiography (CAG) was performed according to conventional standards.^[14] RA was performed based on standard recommendations^[15] using a Rotablator (Boston Scientific, Maple Grove, Minnesota). The burr size was selected to achieve a burr/vessel ratio of 0.5–0.7. Rotablation was between 140,000 to 180,000 r/min according to selection of the operator. To minimize slow flow occurring during or after rotablation, the burr catheter was irrigated during each run with a cocktail flush fluid. In the RACB group, the cutting balloon (Boston Scientific, Flextome) was used for further dilatation. According to the operator's decision, a plain balloon may also be used after the cutting balloon. We primarily used the recommended CB diameter/artery ratio of 0.7–1.0. For some tortuous or angulated lesions, a shorter balloon (6–10 mm) was chosen. The CB dilation pressure was increased step-wise by 2 atm every 2 s as recommended. In the RA group, a plain balloon was used for further dilatation, with a target balloon diameter/artery ratio of 0.8–1.0. In all patients who underwent RA and balloon dilatation, a second-generation DES was implanted. The appropriate stent length for the target lesions should be ≥ 4 mm longer than the lesion length to assure complete coverage of the lesion. Post-dilatation 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.

IVUS was performed when possible before PCI, after plaque preparation and stent implantation using a synthetic aperture array, 20 MHz, 3.2-F catheter (Eagle Eye, Volcano Corporation, Rancho Cordova, California) and S5 console (Volcano Corporation). The IVUS catheter was advanced distal to the lesion and pulled back at 0.5 mm/s (in some cases of resistance, the pullback was manumotive) to the aorto-ostial junction.

2.3 Follow-up

All patients received daily 100 mg aspirin indefinitely and daily 75 mg clopidogrel for at least 12 months. Strategy success was defined as successful stent delivery, residual stenosis $\leq 20\%$ and thrombolysis in myocardial infarction (TIMI) flow grade 3. A MACE was defined as death, myocardial infarction, or target vessel revascularization. Deaths included all causes of mortality.

Clinical follow-up for both groups was conducted by either telephone contact or office visits at one month and nine months.

2.4 Quantitative angiographic analysis

Procedural angiograms were digitally recorded and assessed off-line in the core laboratory with an automated edge-detection system (CMS version 7.1, Medis Medical Imaging Systems, Leiden, the Netherlands) by an independent experienced operator. Measurements were performed at the following four instances: baseline before procedures, after RA, after balloon dilation (CB and/or plain balloon), and after stent deployment. The external diameter of the contrast-filled catheter tip was used for calibration. The minimal lumen diameter, lesion length, and reference lumen diameter were measured, and lumen diameter stenosis (LDS) was defined as the following: (minimal lumen diameter/reference lumen diameter) \times 100%. Optimal stent expansion was defined as a final LDS of $<$ 10%.

2.5 Statistical analysis

Data were reported as either the mean \pm SD or *n* (%) as appropriate, and group comparisons were made using one-way ANOVA (with post hoc Bonferroni's correction where appropriate) and the chi-square test when appropriate. Changes in the stenosis diameter between the RA and RACB groups were analyzed with one-way repeated-measures ANOVA. Univariate and multivariate logistic regression with the forward stepwise method was used to determine independent factors associated with the presence of optimal stent expansion; the included factors were basal lesion diameter stenosis, lesion length, RA, CB, calcified ring split, residual LDS after plaque preparation, stent length, and post dilation. Spearman's rank was used to evaluate the relationship between the calcified ring split and an LDS of \leq 40%. SPSS 16.0 was used for statistical analysis. All significance tests were 2-tailed, and $P < 0.05$ was considered to be statistically significant.

3 Results

3.1 Baseline clinical and angiographic characteristics

In this study, there were 46 patients (27 men, 66 ± 10 years old) in the RA group, 46 patients (26 men, 70 ± 7 years) in the RA followed by CB group, and 40 patients (16 men, 68 ± 9 years) in the POBA group. There were no differences among the groups with respect to clinical presentation (mostly unstable angina), cardiovascular risk factors, prevalence of chronic renal failure, or history of myocardial infarction (Table 1). Most of the patients presented with multi-vessel disease and had issues with more than one vessel at the time of admission. The patients were also evenly distributed based on lesion location (mostly the LAD) and morphology (Table 2).

Table 1. Baseline characteristics.

	RACB (<i>n</i> = 46)	RA (<i>n</i> = 46)	POBA (<i>n</i> = 40)	<i>P</i>
Age, yrs	66 \pm 10	70 \pm 7	68 \pm 9	0.331
BMI, kg/m ²	24 \pm 3	25 \pm 2	25 \pm 3	0.395
Men	27(58.7%)	26 (56.5%)	16 (40%)	0.173
Diabetes mellitus	16 (34.8%)	17 (37.0%)	19 (47.5%)	0.444
Hypertension	37 (80.4%)	39 (84.8%)	28 (70%)	0.233
Dyslipidemia	12 (26.1%)	8 (17.4%)	8 (20%)	0.580
Current smokers	11 (23.9%)	21 (45.7%)	11 (27.5%)	0.060
eGFR, %	65 \pm 28	77 \pm 23	65 \pm 24	0.192
Previous CABG	0	1 (2.2%)	0	0.396
Diagnosis				0.222
Unstable angina	33 (71.7%)	29 (63.0%)	32 (80.0%)	
Stable angina	13 (28.3%)	17 (37.0%)	8 (20.0%)	
Multivessel disease	38 (82.6%)	35 (76.1%)	28 (70%)	0.387
LV ejection fraction, %	62 \pm 8	59 \pm 7	60 \pm 9	0.090
Multilesion PCI	32 (69.6%)	24 (52.2%)	19 (47.5%)	0.088

Data were presented as mean \pm SD or *n* (%). BMI: body mass index; CABG: coronary artery bypass grafting; CB: cutting balloon; eGFR: estimated glomerular filtration rate; LV: left ventricular; PCI: percutaneous coronary intervention; POBA: plain old balloon angioplasty; RA: rotational atherectomy; RACB: rotational atherectomy combined with cutting balloon group.

3.2 Procedural details and outcomes

The procedural details are shown in Table 2. Most of the patients in the RACB (87%) and RA (78.3%) groups were accessed through the femoral artery with a 7-F guiding catheter, whereas most of the patients in the POBA group were accessed radially (90%) with a 6-F catheter. For rotablation, a single burr was used in most patients [37 (80.4%) from the RACB group and 36 (78.3%) from the RA group]. The number of patients in the RACB group (one case) requiring the maximum 1.75 size burr used was less than that in the RA group (eight cases). For the cutting balloon procedure, a single CB was used in most patients with a mean CB diameter of 2.4 ± 0.2 mm and a mean length of 9.1 ± 1.7 mm. Except for three patients in the RACB group, all of the patients underwent pre-dilation after RA and/or CB with a plain balloon and used a similar balloon diameter (2.5 ± 0.3 mm in the RACB group, 2.5 ± 0.3 mm in the RA group, and 2.4 ± 0.4 mm in POBA group). Stent implantation failed in only one patient in the RA group, while all others had successful stent implantation. The stent length was well beyond the lesion length, and the stent size was similar among the three groups. After stenting, balloon post-dilation was performed for almost two-thirds of the treated lesions in the RACB and RA groups and for nearly 90% of the patients in the standard group. The size of the non-complaint balloon was similar among the groups. In approximately 2/3 cases,

the IVUS could not be flexibly advanced to the distal position of the lesion before PCI, and in 19 cases, the IVUS was could not be advanced to the distal edge of the stent even

Table 2. Angiographic and procedural characteristics.

	RACB (n = 46)	RA (n = 46)	POBA (n = 40)	P
Location				0.071
Left anterior descending	41 (89.1%)	35 (76.1%)	26 (65%)	
Left circumflex	3 (6.5%)	7 (15.2%)	6 (15%)	
Right coronary artery	2 (4.3%)	4 (8.7%)	8 (20%)	
Reference vessel diameter, mm	3.0 ± 0.3	3.0 ± 0.4	3.0 ± 0.4	0.987
Lesion length, mm	27.3 ± 7.1	23.8 ± 7.8	28.0 ± 7.8	0.061
Diameter stenosis by visual, %	80 ± 9	79 ± 7	78 ± 7	0.499
Bifurcation	5 (10.9%)	7 (15.2%)	6 (15.0%)	0.795
Severe tortuosity	5 (10.9%)	3 (6.5%)	6 (15.0%)	0.443
Severe calcification	31 (67.4%)	35 (76.1%)	30 (75.0%)	0.599
B2/C lesion	37 (80.4%)	42 (91.3%)	31 (77.5%)	0.186
Transradial	3 (6.5%)	5 (10.9%)	28 (70%)*#	< 0.001
7-F guiding catheter	40 (87%)	36 (78.3%)	4 (10%)*#	< 0.001
Plain balloon pre-dilation	43 (93.5%)	46 (100%)	40 (100%)	0.057
Pre-dilation balloon diameter, mm	2.5 ± 0.3	2.5 ± 0.3	2.4 ± 0.4	0.228
Pre-dilation pressure, atm	12 ± 3.1	14 ± 3.8	16 ± 4.2	0.042
Maximum burr size				< 0.001
1.25 mm burr	10 (21.7%)	22 (47.8%)	NA	
1.5 mm burr	35 (76.1%)	16 (34.8%)	NA	
1.75 mm burr	1 (2.2%)	8 (17.4%)	NA	
Use of > 1 burr	9 (19.6%)	10 (21.7%)	NA	0.797
CB diameter, mm	2.4 ± 0.2	NA	NA	NA
CB length, mm	9.1 ± 1.7	NA	NA	NA
CB pressure, atm	12 ± 4	NA	NA	NA
Stent diameter, mm	2.9 ± 0.3	2.9 ± 0.4	2.9 ± 0.4	0.794
Total stent length, mm	39 ± 15	37 ± 17	40 ± 18	0.800
Balloon post-dilation	29 (63.0%)	31 (67.4%)	36 (90%)*#	0.012
Post-dilation balloon size, mm	3.2 ± 0.3	3.1 ± 0.3	3.0 ± 0.4	0.225
Max. post dilation pressure, atm	18.8 ± 6.1	17.3 ± 5.6	21.3 ± 6.3	0.071
IVUS				
Calcified ring split	31 (67.4%)	11 (25.0%)*	8 (20.0%)*	< 0.001
Calcified arc, °	216.8 ± 21.7	226.7 ± 21.8	218.7 ± 22.9	0.708

*: compared with RACB group; #: compared with RA group. Data were presented as mean ± SD or n (%). CB: cutting balloon; IVUS: intravascular ultrasound; NA: not applicable; POBA: plain old balloon angioplasty; RA: rotational atherectomy; RACB: rotational artherectomy combined with cutting balloon group.

after stent implantation. Recording from the distal position of the IVUS imaging after plaque preparation, 67.4% of the lesions had visible calcified ring splits in the RACB group, 25% in the RA group, and 20% in the POBA group ($P < 0.001$).

3.3 Procedural outcomes and follow-up at 9 months

Procedural outcomes are shown in Table 3. There was a higher rate of optimal stent expansion in the RACB group (71.7%) compared to the RA (54.5%) and POBA groups (15%) ($P < 0.001$). The procedural time was shorter in the POBA group compared to the RACB and RA groups. Strategy success was achieved in most patients except for two patients in the RA group in whom the stent was failed to delivery. The MACE rate was similar among the three groups. One patient in the RACB group experienced sudden death 21 days after PCI, which was suspected to be stent thrombosis.

3.4 Quantitative angiographic analysis

Details of the quantitative angiographic analysis are

Table 3. Procedural outcome and follow-up at 9 months.

	RACB (n = 46)	RA (v46)	POBA (n = 40)	P
Optimal expansion	33 (71.7%)	24 (54.5%)	6 (15%)*#	< 0.001
Procedural duration, min	67 ± 16	65 ± 22	50 ± 16*#	0.005
Perforations	0	0	0	NA
No/slow flow	1 (2.2%)	4 (8.7%)	0	0.084
Dissection				
A and B type	16 (34.8%)	9 (19.6%)	9 (22.5%)	0.212
C type	0	0	0	NA
Persistent advanced AV block	0	1 (2.2%)	0	0.390
Branch vessel jailed	2 (4.3%)	3 (6.5%)	5 (12.5%)	0.343
Stent delivery failure	0	2 (4.3%)	0	0.150
Strategy success	46 (100%)	44 (95.7%)	40 (100%)	0.150
At 9 months				
Death	1 (2.2%)	0	0	0.390
Myocardial infarction	0	0	0	NA
Target vessel re-PCI	1 (2.2%)	1 (2.2%)	2 (5%)	0.685
Target vessel CABG	0	0	0	NA
MACE	2 (4.3%)	1 (2.2%)	2 (5%)	0.767
Susceptive stent thrombosis	1 (2.2%)	0 (0)	0 (0)	0.390
Access site complications	4 (8.7%)	2 (4.3%)	0	0.155

*: compared with RACB group; #: compared with RA group. Data were presented as mean ± SD or n (%). CABG: coronary artery bypass grafting; MACE: major adverse cardiovascular events; NA: not applicable; PCI: percutaneous coronary intervention; POBA: plain old balloon angioplasty; RA: rotational atherectomy; RACB: rotational artherectomy combined with cutting balloon group.

listed in Table 4 and Figure 1. The baseline lumen diameter, reference lumen diameter, and LDS were similar among the groups. However, the lumen diameter and LDS appeared to undergo different changes among the groups during the procedure. After RA (post-RA), the lumen diameter was still similar between the RA and RACB groups, with the time \times group value producing a P value ≥ 0.05 . However, after balloon dilation (post-dilation) the lumen diameter significantly increased (from 1.37 ± 0.25 mm to 1.93 ± 0.17 mm) in the RACB group and only moderately increased in the RA group (1.36 ± 0.28 mm to 1.69 ± 0.31 mm), with the time \times group $P = 0.001$ (Figure 1A). Similarly, the LDS was significantly decreased in the RACB group (from $54.5\% \pm 8.9\%$ to $36.1\% \pm 7.1\%$) and moderately decreased ($55.7\% \pm 7.8\%$ to $46.9\% \pm 9.4\%$) in the RA group, with the time \times group value producing a P value < 0.001 (Figure 1B). After stent employment (post-stent), the final lumen diameter

trended larger in the RACB group compared to the RA and standard groups (2.87 ± 0.31 mm, 2.72 ± 0.35 mm, 2.65 ± 0.32 mm; $P = 0.01$). The final LDS was significantly reduced ($6.0\% \pm 2.3\%$, $10.8\% \pm 3.3\%$, and $12.7\% \pm 2.1\%$, $P < 0.001$) and acute lumen gain (2.26 ± 0.39 mm, 2.09 ± 0.37 mm, and 1.98 ± 0.32 mm, $P = 0.003$) was significantly higher in the RACB group compared to the other two groups.

3.5 Determinants of optimal stent expansion

Determinants of optimal stent expansion were analyzed using a univariate logistic model and then a multivariate logistic model, as shown in Table 5. In the univariate analysis, the use of RA with a CB, the presence of a calcified split, and an LDS of $\leq 40\%$ after plaque preparation were associated with optimal stent expansion. After multivariate analysis, the use of RA (OR: 8.027; 95% CI: 2.896–22.250; $P < 0.001$) and an LDS of $\leq 40\%$ after plaque preparation (OR:

Table 4. Quantitative coronary angiography.

	Baseline	Post-RA	Post-dilation	Post-stent	In-subject P	Between-group P
Lumen diameter					< 0.001	0.001
RACB, mm	0.61 ± 0.26	1.37 ± 0.25	1.93 ± 0.17	2.87 ± 0.32		
RA, mm	0.65 ± 0.24	1.36 ± 0.28	$1.69 \pm 0.31^*$	2.72 ± 0.35		
POBA, mm	0.67 ± 0.23	NA	$1.64 \pm 0.32^*$	$2.65 \pm 0.32^*$		
P^1 Value	0.509	0.736	< 0.001	0.01		
Lumen stenosis					< 0.001	< 0.001
RACB, %	79.9 ± 8.8	54.5 ± 8.9	36.1 ± 7.1	6.0 ± 2.3		
RA, %	78.9 ± 6.8	55.7 ± 7.8	$46.9 \pm 9.4^*$	$10.8 \pm 3.3^*$		
POBA, %	77.9 ± 7.4	NA	$45.3 \pm 9.8^*$	$12.7 \pm 2.1^{*,\#}$		
P^1 Value	0.499	0.505	< 0.001	< 0.001		

*: compared with RACB group; #: compared with RA group; P^1 : compared by one way-ANOVA among three groups. Data were presented as mean \pm SD. NA: not applicable; POBA: plain old balloon angioplasty; RA: rotational atherectomy group; RACB: rotational atherectomy combined with cutting balloon group.

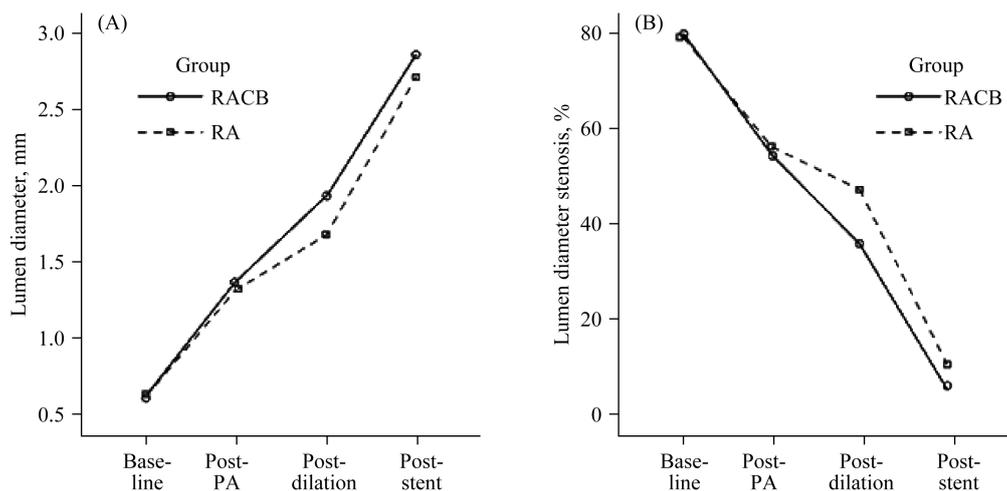


Figure 1. Change of lumen diameter and lumen diameter stenosis. (A): Change of lumen diameter at baseline, post-RA, post-dilation, and post stent deployment; (B): change of lumen diameter stenosis at baseline, post-RA, post-dilation, and post stent deployment. RA: rotational atherectomy; RACB: rotational atherectomy combined with cutting balloon group.

Table 5. Predictors for sub-optimal stent expansion.

	Univariate analysis		Multivariate analysis		
	Beta	P	OR	95% CI	P
Lesion length	-0.062	0.726	NA	NA	NA
Lesion LDS	-0.036	0.330	NA	NA	NA
RA	2.281	<0.001	8.027	2.896–22.250	<0.001
CB	1.519	<0.001	NA	NA	NA
Calcified split	1.318	0.001	NA	NA	NA
Stent length	-0.028	0.014	0.969	0.944–0.995	0.019
LDS after plaque preparation	1.447	<0.001	2.994	1.297–6.911	0.010
Post dilation	-1.255	0.004	NA	NA	NA

CB: cutting balloon; LDS: Lumen diameter stenosis; NA: not applicable; RA: rotational atherectomy.

2.994; 95% CI: 1.297–6.911; $P = 0.010$) were the primary impact factors for optimal stent expansion, with stent length being another influential factor. Moreover, the presence of a calcified ring split had a positive correlation with an LDS of $\leq 40\%$ after plaque preparation ($r = 0.581$, $P < 0.001$).

4 Discussion

This study compared RA combined with a CB, RA combined with a plain balloon, and traditional plain balloon angioplasty for the treatment of highly calcified lesions. We observed that the use of RA with a CB could optimize stent expansion and achieve a larger acute lumen gain compared to the other two methods without any significant differences in the MACE rate at nine months. Notably, this study measured the lumen diameter and LDS change at four time points and observed that the benefit of RA combined with a CB manifested after plaque preparation, as shown in Figure 1. Additionally, a lumen diameter stenosis of $\leq 40\%$ after plaque preparation was associated with optimal stent expansion. Furthermore, IVUS imaging showed that this decreased LDS was associated with the calcified ring split.

There was a higher optimal stent expansion rate in the RACB group compared to the RA and standard groups. Severely calcified lesions are highly resistant to treatment; thus, optimizing stent expansion is a challenge. The 2013 AHA/ACC PCI guidelines recommend RA for the preparation of calcified lesions to facilitate stent delivery and expansion.^[7] In the balloon angioplasty and bare metal stent era, complete plaque debulking was emphasized to facilitate stent deployment and expansion as well as to decrease stent thrombosis and in-stent restenosis.^[16] For adequate plaque removal, a larger RA burr and higher speed were recommended by experts. However, these recommendations led to a higher rate of PCI-related complications, including slow

flow, no reflow, vessel perforation, and MACE.^[4,17–19] In the DES era, because of next-generation anti-thrombotic drugs and a lower rate of in-stent restenosis due to inhibition of neointimal formation, plaque modification became more prevalent over plaque debulking, and a smaller burr size and lower burr speed were recommended to avoid complications.^[15] In our study, the RA burr/vessel ratio was 0.5–0.7. Although the vessel diameter was similar between groups, the further dilatation in RACB group could be treated by a cutting balloon. Therefore, in our study, the 1.75 burr was only used in one case in RACB group, but the RA group had eight cases that required the 1.75 burr. Of these nine instances, three experienced slow flow and one had no reflow.

However, a small burr may not completely split a calcified ring, and the resistance due to this ring still limits stent expansion.^[20–22] Final LDS values after treatment by RA followed with stent implantation have ranged from 8.2% to 10.8% in different studies.^[8,23–25] In our study, the final LDS was approximately 10.87%, which was similar to that observed in the ROTAXUS study. Usually, optimal stent expansion is defined as a final diameter stenosis $< 10\%$ guided by angiogram, and optimal stent expansion is a crucial factor for lowering the risk of recurrence and improving long-term outcomes after PCI.^[26–30]

CB angioplasty followed by RA could help split calcified rings by CB microblades creating discrete incision in the dilated vessel segment.^[31,32] There were only 11 cases that appeared to show calcified breakage under IVUS in the RA group compared to 31 cases in the RACB group. After dispersing the resistance of the calcified ring by combining RA and a CB, the LDS was optimized (Figure 2). Previous studies have shown that RA combined with a CB may facilitate stent delivery and expansion.^[11,12] However, there is controversy regarding whether such a combined method is necessary for the treatment of calcified lesions.^[10–12] In this study, we explored the standard of an adequate plaque preparation for optimal stent expansion in calcified lesions, and our results suggest that the following factors should be considered: (1) the appearance of a calcified ring split and (2) a residual LDS of less than 40% after plaque morphology.

4.1 Limitations

This is a retrospective study, not a randomized study. Calcified lesions are all highly resistant, so the IVUS probe was unable to pass through the lesion in most cases to evaluate the initial lumen area and plaque morphology. In 19 cases, the IVUS could not pass even after stent implantation. Therefore, we could not obtain all of the IVUS data

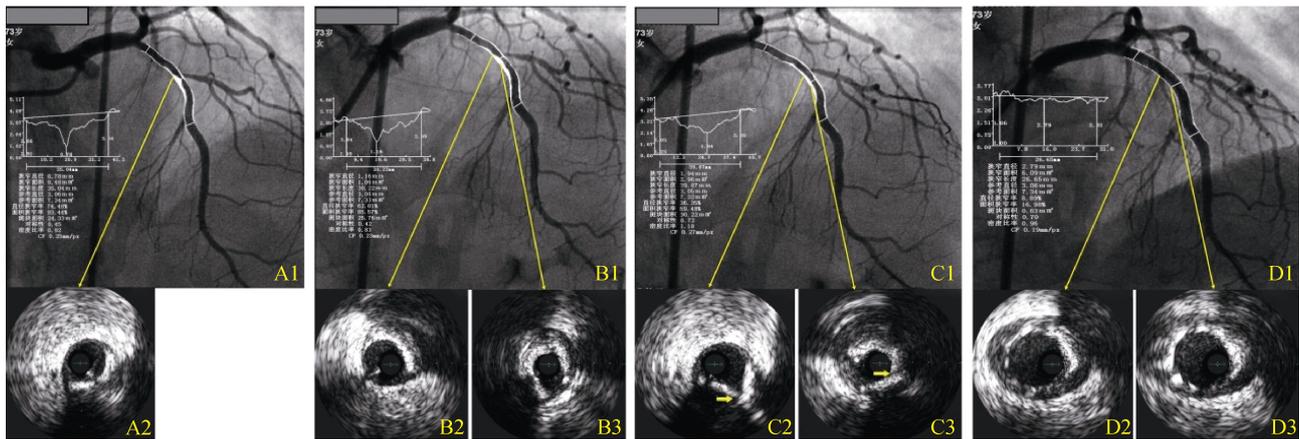


Figure 2. A case of severely calcified lesion treated by RA combined with CB. (A1): the lesion lumen diameter and stenosis measured by QCA pre-PCI; (A2): IVUS probe cannot pass the serious stenosis and was stunned at the proximal segment. There was a 180° calcified ring; (B1): the lumen diameter increased and stenosis was decreased after RA, and IVUS could pass the lesion; (B2 and B3): superficial calcified rings; (C1): the lumen stenosis was further decreased after CB; (C2 and C3): the calcified ring was broken as the arrow shown; (D1, D2 and D3): the final result after stent implantation, without stent underexpansion or malposition. CB: cutting balloon; IVUS: intravascular ultrasound; PCI: percutaneous coronary intervention; QCA: quantitative coronary angiography; RA: rotational atherectomy.

needed to perform a fully accurate analysis. Moreover, some patients did not undergo angiography at the 9-month follow up visit. Therefore, late lumen loss and stent restenosis rate were not evaluated in this study. Although the immediate stent expansion was better in RACB group, the clinical outcome was not different among groups. Thus, the cost-effectiveness of RA combined with CB need to be future evaluated.

4.2 Conclusions

This study suggests that before DES implantation in moderately or highly calcified lesions, RA followed by CB is more effective than RA followed by plain angioplasty or plain angioplasty alone to achieve optimal stent expansion. Optimal stent expansion in highly calcified lesions is associated with the appearance of a calcified ring split and a decreased LDS after aggressive plaque preparation.

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