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Comparison of rotational atherectomy and modified balloons prior to drug-eluting stent implantation for the treatment of heavily calcified coronary lesions

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Abstract

The optimal strategy for lesion preparation in heavily calcified coronary lesions (HCCL) prior to drug-eluting stent (DES) implantation remains debatable. This study sought to compare the performance of rotational atherectomy (RA) and modified balloon (MB)-based strategy in patients with HCCL receiving current-generation DES.

This retrospective study comprised 564 consecutive patients who underwent RA (n = 229) or MB (n = 335) for HCCL at our hospital and were treated with DES. Baseline clinical and angiographic data was obtained from our database. Patients were clinically monitored for the occurrence of any adverse events during the hospitalization. One-year follow-up was conducted by either telephone contact or outpatient visits. 1:1 propensity score matching (PSM) was performed to balance the baseline covariates. After PSM, the clinical outcomes between the 2 groups were compared.

After PSM, except more target lesion in right coronary artery existing in the RA group ($P = .008$), no significant statistical differences were shown in regard of the other angiographic and procedural characteristics of the 2 groups. Strategy success rates were all 100% in both groups. In the unadjusted Cox proportional hazard analysis, participants with RA had a significantly lower risk of target lesion revascularization (TLR) (hazard ratio, HR 0.275, 95% confidence intervals, CI 0.119–0.635, $P = .003$) and major adverse cardiac event (MACE) (HR 0.488, 95% 0.277–0.859, $P = .013$). After adjusting for potential confounding variables, RA was significantly associated with TLR (HR 0.32, 95% 0.12–0.853, $P = .023$), but no longer significantly associated with MACE (HR 0.674, 95% 0.329–1.381, $P = .282$).

In patients with HCCL, lesion preparation with RA was safe and could improve strategy success rate. There was lower rate of TLR with RA, however, no significant difference was found in the MACE rate at 1-year follow-up between RA and MB-based strategy.

Abbreviations: CABG = coronary artery bypass grafting, DES = drug-eluting stent, HCCL = heavily calcified coronary lesions, IVUS = intravascular ultrasound, LDL = low density lipoprotein, MACE = major adverse cardiac event, MB = modified balloon, PCI = percutaneous coronary intervention, PMI = periprocedural myocardial infarction, PSM = propensity score matching, RA = rotational atherectomy, TLR = target lesion revascularization, TVR = target vessel revascularization.

Keywords: coronary calcification, drugeluting stents, modified balloons, rotational atherectomy

1. Introduction

Coronary artery calcification has long been known as a specific feature of coronary atherosclerosis[1] and the extent of calcium is thought to be correlated with the total coronary atherosclerotic burden. The presence of severe coronary artery calcification is also a risk predictor for adverse cardiovascular events.[2,3] In the last decades, many tools and techniques have been developed to facilitate treatment in patients with heavily calcified coronary lesions (HCCL). However, percutaneous coronary intervention (PCI) for HCCL is still challenging and associated with increased procedural risk, higher rate of revascularization, and poorer clinical outcomes.[4–6]

Currently, 2 standard strategies are adopted in lesion preparation for HCCL: rotational atherectomy (RA) and modified (scoring or cutting or lacrosseNSE) balloon (MB) based method. Although RA is recommended for plaque modification in HCCL, the ROTAXUS (Atherectomy Prior to Taxus Stent Treatment for Complex Native Coronary Artery Disease) trial failed to demonstrate the superiority of RA regarding to the restenosis and major adverse cardiac event (MACE) rate compared with standard balloon dilation.[7]

Another randomized clinical trial—PREPARE-CALC (Comparison of Strategies to Prepare Severely Calcified Coronary Lesions) also demonstrated no advantage in clinical outcome with RA[8] when compared with MB.

ROTAXUS trial was performed prior to the advent of new generation drug-eluting stents (DES) platforms and in the PREPARE-CALC trial, most cases in the MB group were performed using a scoring rather than a cutting balloon or lacrosseNSE. Thus, it is worthwhile to compare the performance of both strategies in patients with HCCL receiving current-generation DES in the real world.

2. Methods

This single-center, retrospective study comprised 564 consecutive patients who had received RA (229) or MB (335) for HCCL prior to DES implantation in Sir Run Run Shaw Hospital from January 2016 to December 2018. The inclusion criteria were as follows:

1. Patients with angiographically confirmed ischemic coronary heart disease and need revascularization;
2. Presence of target HCCL with luminal diameter reduction of 70% to 100%.

The exclusion criteria were myocardial infarction within 30 days, decompensated heart failure, in-stent restenosis, lesion in coronary artery bypass grafts, crossovers from one strategy to another, patients with malignancy and a less than 1-year life expectancy were also excluded.

The study complied with the Declaration of Helsinki for investigation in human beings and was approved by the ethics committee at the Sir Run Run Shaw Hospital (NO. 20200803–34). Informed consent was obtained from the patients prior to any procedures.

All patients received an oral loading dose of 300 mg aspirin and clopidogrel 12 hours prior to the intervention procedure and followed by maintenance dose of 100 mg aspirin and 75 mg clopidogrel once daily. After radial artery puncture (if failed, transfemoral approach was adopted), a 6F or 7F sheath was inserted. Heparin was given to maintain an activated clotting time ≥250 seconds or 200 to 250 seconds if a GP (glycoprotein) IIb/IIIa receptor blocker had been administered.

In all patients, the interventional strategy was left to the discretion of experienced operating interventional cardiologist. RA was performed based on standard recommendations using a Rotablator (Boston Scientific, Maple Grove, Minnesota). The burr size was selected to achieve a burr/vessel ratio of 0.5–0.7. Rotational speed ranged between 160,000 to 170,000 r/minute. the burr catheter was irrigated with a cocktail flush fluid to minimize slow flow occurrence. In the MB-based strategy group, predilatation with compliant or noncompliant balloons may be used before and after MB angioplasty to facilitate stent implantation. The MB size was selected to reach diameter/artery ratio of 0.7 to 1.0. Dilation pressure was increased step-wise by 2 atm every 2 s as recommended. In all cases, a second-generation DES was implanted. Postdilation was performed in each case and final angiography of the target vessel was performed in at least 2 orthogonal views.

During the hospitalization, patients were clinically monitored for the occurrence of any adverse events and any additional coronary intervention. 1-year follow-up for both groups was conducted by either telephone contact or outpatient visits.

HCCL were defined as radiopacities observed without cardiac motion before contrast injection.[9] Strategy success was defined as successful stent delivery, residual stenosis ≤20% and thrombolysis in myocardial infarction flow grade 3.[7] The diagnostic criteria of periprocedural myocardial infarction should accord with the 4rd universal definition of ESC.[10] Cardiac death was defined as the death due to cardiac diseases such as myocardial infarction, arrhythmia, and heart failure. TLR was defined as revascularization of in the stent or within 5 mm proximal or distal to the stent. target vessel revascularization. (TVR) was defined as a repeated intervention of the target vessel, either PCI or coronary artery bypass grafting (CABG). A MACE was defined as death, myocardial infarction, TVR or TLR, and non-fatal ischemic stroke.

Statistical analysis was carried out using the SPSS statistical package, version 18.0 (SPSS Inc, Chicago, Illinois). Data were reported as either the mean ± SD or n (%) as appropriate. Continuous variables were compared using a 2-sided unpaired t test or a Mann–Whitney U test. Categorical measures were compared using a $\chi 2$ test or Fisher exact test as required. 1:1 propensity score matching was used to match the age, hypertension, diabetes, low density lipoprotein (LDL) and left main disease to balance the covariates between 2 groups. The time to events was estimated using Kaplan–Meier analyses and the differences between 2 groups were compared using the log rank test. Multivariate Cox-proportional hazard analyses were undertaken to assess the association between RA and events. All tests were 2 sided, and $P < .05$ was considered statistically significant.

3. Results

3.1. Baseline, angiographic, and procedural characteristics of the 2 groups

Before propensity score matching (PSM), there were 229 patients (137 men, 73.0±7.5 years old) in the RA group, 335 patients (225 men, 71.0±9.1 years old) in the MB group. In the RA group, there were higher proportion of hypertension, diabetes mellitus, left main disease, and lower LDL levels. There were more left main disease and the target lesions were more complex (72.9% at bifurcations and 98.7% type B2/C lesions) in the RA group. Almost all procedures were performed through the radial access route. Most procedures were performed through a 6-F guiding catheter, although more 7-F guiding catheters were used in the RA group. Predilation balloons were more used in the MB group. For (IVUS) intravascular ultrasound, almost 1/3 of all procedures were used, with no significant differences between 2 groups. More stents and longer average stent length were presented in the RA group. After stenting, balloon postdilation was performed for all treated lesions in both groups, with the mean maximum postdilatation pressure slightly higher in the RA group (21.3± 2.8 vs 20.1±0.7 atm, $P < .001$). After PSM, a total of 174 pairs were enrolled. Except more target lesion in right coronary artery existing in the RA group ($P = .008$), no significant statistical differences were shown in regard of the other angiographic and procedural characteristics of the 2 groups. Details are shown in Tables 1 and 2.

3.2. Procedural outcomes and in-hospital events

Procedural complications and outcomes are shown in Table 3. Compared to the MB group, the procedural time was longer

Table 1

Comparison of baseline characteristics before and after PSM.

	Before PSM			After PSM		
	MB (n=335)	RA (n=229)	P	MB (n=174)	RA (n=174)	P
Age, y	71.0±9.1	73.0±7.5	<.01	71.7±8.6	72.7±7.5	.227
male	225 (67.2%)	137 (59.8%)	.06	111 (63.8%)	106 (60.9%)	.580
BMI	23.9±3.7	23.9±3.3	.91	24.1±3.4	24.1±3.4	.840
Diabetes mellitus	105 (31.3%)	96 (41.9%)	.02	63 (36.2%)	70 (40.2%)	.508
Hypertension	246 (73.4%)	185 (80.8%)	.04	130 (74.7%)	141 (81.0%)	.196
Current smokers	115 (34.3%)	70 (30.6%)	.35	22 (12.6%)	14 (8.0%)	.217
Previous PCI	33 (9.9%)	27 (11.8%)	.46	27 (15.5%)	18 (10.3%)	.150
Previous MI	11 (3.3%)	13 (5.7%)	.17	6 (3.5%)	9 (5.2%)	.599
Previous CABG	0 (0%)	0 (0%)	NA	0 (0%)	0 (0%)	NA
eGFR, ml/min/1.73m2	77.6±23.4	73.8±21.6	.054	74.9±22	75.4±19.9	.815
LV ejection fraction, %	63.0±11.9	62.7±11.4	.78	63.2±11.9	62.3±12	.520
LDL	2.1±0.8	1.7±0.7	<.001	1.86±0.69	1.77±0.71	.199
Left main disease	43 (12.8%)	96 (41.9%)	<.001	38 (21.8%)	45 (25.9%)	.451
Multivessel disease	285 (85.1%)	189 (80.8%)	.42	151 (86.8%)	142 (81.6%)	.186
GP IIb/IIIa antagonists	1 (0.3%)	2 (0.9%)	.36	0 (0%)	0 (0%)	NA
Unfractionated heparin	335 (100%)	229 (100%)	NA	174 (100%)	174 (100%)	NA

Values are n (%) or mean ± SD.

BMI = body mass index, CABG = coronary artery bypass grafting, eGFR = estimated glomerular filtration rate, GP = glycoprotein, LDL = Low density lipoprotein, LV = left ventricular, MB = modified balloon, MI = myocardial infarction, NA = not applicable, PCI = percutaneous coronary intervention, PSM = propensity score matching, RA = rotational atherectomy.

(P=.025) and there was more contrast dye usage (P=.014) in the RA group. Strategy success rates were both 100%. Coronary perforations and dissections were rare and occurred equally in both groups, but no-/slow flow phenomena occurred less (P=.001) in the MB group. There were no deaths or target vessel re-PCI during hospitalization. The incidence of protocol defined periprocedural MI was high and significantly different between 2 study groups (25.3% in the MB group vs 52.3% in the RA group, P<.0001).

3.3. 1-Year clinical outcome

Complete clinical follow-up over 1 year was available for all patients (Table 4). At 1-year, cardiac death was 1.2% vs 1.8% in the MB and RA group, respectively (P=.001). Stroke/ transient ischemic attacks occurrence was lower in the RA group (P<.001). TLR/TVR rate was also lower compared to the MB group (P=.001, P=.013, respectively). The total MACE was significantly lower in the RA group (P=.011).

Table 2

Comparison of angiographic and procedural characteristics before and after PSM.

	Before PSM			After PSM		
	MB (n=335)	RA (n=229)	P	MB (n=174)	RA (n=174)	P
Location of target lesion						
Left anterior descending	294 (87.7%)	197 (86.0%)	.55	156 (89.7%)	144 (82.8%)	.086
Left circumflex	18 (5.4%)	8 (3.5%)	.30	9 (5.2%)	7 (4.0%)	.799
Right coronary artery	23 (6.9%)	24 (10.5%)	.13	9 (5.2%)	23 (13.2%)	.008
Target lesion length, mm	25.8±11.3	26.5±9.2	.24	25.4±11.1	26.2±9.5	.264
Bifurcation	192 (57.3%)	167 (72.9%)	<.001	109 (62.6%)	122 (70.1%)	.173
B2/C lesion	295 (88.1%)	226 (98.7%)	<.001	168 (96.6%)	171 (98.3%)	.502
Transradial intervention	329 (98.2%)	221 (96.5%)	.20	174 (100%)	174 (100%)	NA
7-F guiding catheter	32 (9.6%)	70 (30.6%)	<.001	0 (0%)	0 (0%)	NA
IVUS	91 (27.2%)	75 (32.8%)	.15	44 (25.3%)	56 (32.3%)	.192
IABP	1 (0.3%)	1 (0.44%)	.79	1 (0.6%)	0 (0%)	NA
ECMO	0 (0%)	3 ((1.31%)	.04	0 (0%)	3 (1.7%)	.248
No. of predilatation balloons	1.6±0.5	1.1±0.2	<.001	1.7±0.5	1.8±0.3	.076
Use of >1 scoring, cutting or lacrosseNSE	78 (23.3%)	NA	NA	43 (24.7%)	NA	NA
Use of >1 burr	NA	55 (24.0%)	NA	NA	40 (22.9%)	NA
Rotational speed, RPM	NA	169345±1687	NA	NA	169195±1842	NA
Maximum burr size, mm	NA	1.5±0.13	NA	NA	1.46±0.12	NA
No. of stents/TV	2.0±0.8	2.2±0.7	.02	2±0.8	2.1±0.7	.196
Total stent length/TV, mm	53.6±25.0	59.1±18.8	.003	52.8±25.5	56.1±19.4	.094
Maximum postdilation balloon pressure, atm	20.1±0.7	21.3±2.8	<.001	20.1±0.7	20.6±0.8	.072

Values are n (%) or mean ± SD.

ECMO = extracorporeal membrane oxygenation, IABP = intra-aortic balloon pump, IVUS = intravascular ultrasound, MB = modified balloon, MI = myocardial infarction, NA = not applicable, PSM = propensity score matching, RA = rotational atherectomy, RPM = rotations per minute, TV = target vessel.

Table 3

Procedural and inhospital outcome.

	MB (n = 174)	RA (n = 174)	*P*
Procedural duration, min	92.4 ± 27.6	104.6 ± 30.2	.025
Contrast amount, ml	151.4 ± 52.7	179.6 ± 93.9	.014
Strategy success	174 (100%)	174 (100%)	NA
Dissections	3 (1.72%)	9 ((5.17%)	.078
Perforations	1 (0.57%)	3 (1.72%)	.315
No/slow flow	0	10 (5.75%)	.001
Cardiac tamponade	0	0	NA
Target vessel re-PCI	0	0	NA
Stent thrombosis	0	0	NA
Periprocedural MI	44 (25.3%)	91 (52.3%)	<.0001
Emergency CABG	0	0	NA
Death	0	0	NA

Values are n (%) or mean ± SD.
CABG = coronary artery bypass grafting, MB = modified balloon, MI = myocardial infarction, NA = not applicable, PCI = percutaneous coronary intervention, RA = rotational atherectomy.

3.4. Association between RA and TLR and MACE

Kaplan–Meier survival analyses assessing the cumulative incidence of TLR and MACE are illustrated in Figures 1 and 2. In the PSM cohort, a greater cumulative proportion of patients with RA experienced a TLR (Fig. 1; log-rank test $P = .001$) and MACE (Fig. 2; log-rank test $P = .011$). In the unadjusted Cox proportional hazard analysis, participants with RA had a significantly lower risk of TLR (hazard ratio, HR 0.275, 95% confidence intervals, CI 0.119–0.635, $P = .003$) and MACE (HR 0.488, 95% 0.277–0.859, $P = .013$). After adjusting for potential confounding variables, RA was significantly associated with TLR (HR 0.32, 95% 0.12–0.853, $P = .023$), but no longer significantly associated with MACE (HR 0.674, 95% 0.329–1.381, $P = .282$) (Table 5).

4. Discussion

The principal finding of the study was that the use of RA was safe and could achieve similar strategy success and lower rate of TLR compared to the MB-based strategy, but there was no significant difference in the MACE rate at 1-year follow-up.

PCI of HCCL is associated with significantly increased periprocedural complications, high incidence of failure in deploying DES and high rate of revascularization compared with non-calcified lesions.[4–6,11] To address these challenges, several strategies are used in lesion preparation for HCCL,

Table 4

Clinical outcome at 1 year.

	MB (n = 174)	RA (n = 174)	*P*
All-cause death	3 (1.8%)	3 (1.8%)	NA
Cardiac death	2 (1.2%)	3 (1.8%)	.001
Non-cardiac death	1 (0.06%)	0 (0%)	NA
MI	4 (2.3%)	4 (2.3%)	NA
Stroke/TIA	5 (2.9%)	2 (1.2%)	<.001
TLR	25 (14.4%)	7 (4.0%)	.001
TVR	29 (16.7%)	13 (7.5%)	.013
Total MACE	36 (20.7%)	18 (10.3%)	.011

Values are n (%).
MACE = major adverse cardiovascular events, MB = modified balloon, MI = myocardial infarction, NA = not applicable, RA = rotational atherectomy, TIA = transient ischemic attacks, TLR = target lesion revascularization, TVR = target vessel revascularization.
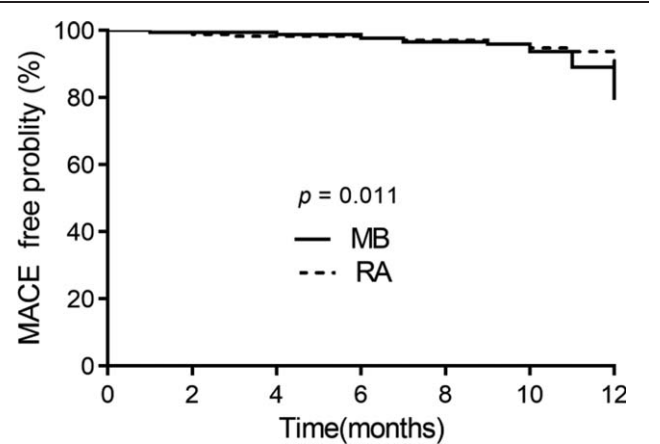

Figure 1. Kaplan–Meier curves illustrating the freedom from having a MACE. Differences between both groups compared using the log-rank test.

including standard balloons (compliant or noncompliant), MB (cutting or scoring or lacrosseNSE), and RA.[12–14] However, the optimal technique prior to DES implantation remains debatable.

In the randomized ROTAXUS trial, lesion preparation of calcified lesions with RA before first-generation DES implantation was not superior to standard balloon predilatation in regard of in-stent late lumen loss (0.44 ± 0.58 vs 0.31 ± 0.52, $P = .04$), restenosis rate (11.4% vs 10.6%, $P = .71$), and target lesion revascularization (TLR) (11.7% vs 12.5%, $P = .84$).[7] In another retrospective study, Tian et al compared the clinical outcomes of lesion preparation with RA, plain old balloon angioplasty (POBA), or cutting-balloon angioplasty (CBA) in patients with HCCL who were treated with DES, discovering that the 3 strategies may be associated with similar clinical outcomes and the RA group had a trend toward greater MACE, death, and TLR.[15] PREPARE-CALC is a small sample randomized trial to compare the MB-based strategy with the strategy of RA, demonstrating increased strategy success rate but no superiority in TLR (7% vs 2%; $P = .17$) in the RA group.[8] In this setting, reassessing the different techniques in the new-generation DES era in different center is of great interest.

Although strategy success rate is 100% in both groups, the procedure of RA requires more contrast amount and procedural
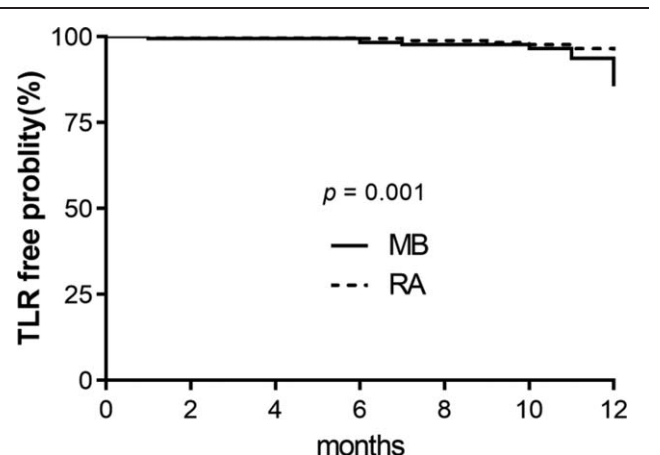

Figure 2. Kaplan–Meier curves illustrating the freedom from having a TLR. Differences between both groups compared using the log-rank test.

Table 5

Cox proportional hazard analyses for the association between RA and TLR and MACE.

	Unadjusted analysis			Adjusted analysis		
	Hazard ratio	95% CI	*P* value	Hazard ratio	95% CI	*P* value
TLR						
MB	(reference)					
RA	0.275	0.119–0.635	.003	0.32	0.12–0.853	.023[*]
MACE						
MB	(reference)					
RA	0.484	0.277–0.859	.013	0.674	0.329–1.381	.282[#]

CI = confidence intervals, MACE = major adverse cardiovascular events, MB = modified balloon, RA = rotational atherectomy, TLR = target lesion revascularization.

[*] Results are adjusted for age, BMI, LM, No. of predilatation balloons.

[#] Results are adjusted for age, BMI, LM, No. of predilatation balloons, No. of stents/TV.

duration is usually longer than the MB-based PCI procedure, which was also observed in the ROTAXUS and PREPARE-CALC trial. We observed a low rate of severe procedural complications, confirming the safety of both strategies. RA seems to be associated with higher periprocedural myocardial infarction (PMI) incidence compared with the above researches, however, the definition of PMI was not clearly defined in those studies. Idris et al reported that the incidence of PMI could reach to 23.2% (by 2007 universal myocardial infarction definition) in a single group of PCI patients.[15] Thus, the high PMI incidence in HCCL may be explained by the procedural complexity (both plaque laceration and removal may cause dissection, slow flow, or small side-branch loss).

Overall, the clinical event incidence was low and similar to previous trials.[7,16,17] The rate of TVR/TLR after RA was 4.9% to 11.8%,[18–21] which seems lower in our study. The lower TVR/TLR rate in the RA group may be explained by the effective lesion preparation, which can facilitate stent delivery and expansion.

5. Limitations

Our study has limitations. First, this was a retrospective study presenting with single center experience and the long-term outcome of RA and MB group was not evaluated due to loss to follow -up. Secondly, HCCL was judged by angiography rather than IVUS, whether intimal calcification is involved is hard to be confirmed in some cases. Thirdly, use of RA or which type of MB was decided by the operator's experience and discretion. Finally, Differences in PCI process, such as the use of different DES types and IVUS in some patients but not in others may impact the results.

6. Conclusion

In patients with HCCL, lesion preparation with RA was safe and could improve strategy success rate. There was lower rate of TLR with RA but without significant difference in the MACE rate at 1-year follow-up between RA and MB-based strategy.

Author contributions

Conceptualization: Binquan Zhou, Guosheng Fu, Wenbin Zhang.
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Validation: Binquan Zhou, Wenbin Zhang.
Writing – original draft: Xulin Hong.

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