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Original Research

Short-term and long-term outcomes of bailout versus planned coronary rotational atherectomy

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The goal of this study was to compare in-hospital and long-term events between bailout rotational atherectomy (RA) and planned RA. In this retrospective study, All patients who underwent percutaneous coronary intervention (PCI) using RA at Nanjing Drum Tower Hospital from November 2011 to December 2018 were enrolled in this study. Planned RA was defined as RA performed immediately before balloon pre-dilation, while bailout RA was defined as RA after failure to expand the balloon or perform any other procedure. In-hospital and long-term major adverse cardiac events (MACE, defined as cardiac mortality, myocardial infarction (MI), target vessel revascularization (TVR) and stroke) were compared between the two groups. After statistical analysis, a total of 211 patients underwent PCI with RA during the study period: 153 in the planned RA group, and 58 in the bailout group. The incidence of coronary dissection was significantly higher in the bailout RA group than in the planned RA group (22.4% vs. 6.5%, $P = 0.001$). However, no significant difference in in-hospital MACE was found between the two groups (12.1% vs. 13.7%, $P = 0.752$). There was no difference in all-cause mortality (9.1% vs. 12.5%, $P = 0.504$) or long-term MACE (13.8% vs. 17.1%, $P = 0.560$) between the groups. Bailout RA was associated with a significantly longer procedural time (139.86 ± 56.24 min vs. 105.56 ± 36.71 min, $P < 0.001$) than planned RA. Therefore, compared with bailout RA, planned RA is associated with shorter procedural time and reduced incidence of coronary dissection, with no difference in MACE or mortality.

Keywords

Rotational atherectomy; coronary artery disease; calcificatio

1. Introduction

As a result of the aging population in China, more patients with coronary heart disease (CHD) are undergoing percutaneous coronary intervention (PCI) than ever before. PCI is now being performed in patients with heavy calcified coronary lesions, which can change vascular wall compliance, add to the difficulty of stent placement, and increase the risk of postoperative complications and death (Arora et al., 2016). Coronary rotational atherectomy (RA) plays an important role in PCI of heavy calcified coronary lesions by using high-speed rotating burrs to reduce plaque volume and modify plaque morphology (Kuriyama et al., 2011). The American Heart Association 2011 guidelines for PCI recommend RA to process heavily calcified lesions (Levine et al., 2011). However, not all RA procedures are performed as a planned procedure directly after a coronary angiography (CAG) examination, and a considerable portion of RA procedures are performed after failed balloon expansion. The short- and long-term outcomes of planned RA versus bailout RA have not been previously studied. Therefore, we sought to compare in-hospital and long-term outcomes between planned RA and bailout RA performed at our institution.

2. Methods

2.1 Study population

A total of 211 patients who underwent PCI using RA in Nanjing Drum Tower Hospital between November 2011 and December 2018 were enrolled in this study. During the procedure, planned RA was defined as RA performed directly before balloon pre-dilatation, while bailout RA was defined as RA performed after failure to expand the balloon or perform any other procedure (such as intra-vascular ultrasound (IVUS) as an attempt to cross the target lesion). A total of 153 patients underwent planned RA and 58 patients underwent bailout RA. The study was conducted with the written informed consent of all participants, and the data collection procedure obtained permission from the local ethics committee.

2.2 Procedural details

Whether planned or bailout RA was performed was decided by the operators. All RA procedures were performed with the Rotablator system (Boston Scientific, Marlborough MA, USA) in accordance with manufacturer's indications for use (IFU). The burr size ranged from 1.25 to 2.0 mm, and the speed ranged between 130,000 and 220,000 rotations per minute. To reduce the occurrence of slow flow, RA irrigating fluid (normal saline, heparin) was continuously used. After RA, the operators performed bal-

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loon dilatation and implanted drug-eluting stents according to the characteristics of vascular lesions. Completion angiogram was then performed to evaluate the result of the procedure. The angiographic success of PCI was defined residual stenosis less than 30% by angiography and thrombolysis in myocardial infarction (TIMI) was grade III. If deemed necessary by the operators, IVUS was used to guide the procedure. All patients received dual antiplatelet therapy and secondary prevention of CHD after surgery.

2.3 Follow-up and endpoint

Endpoints included all-cause death and major adverse cardiovascular events (MACE). MACE was defined as cardiac mortality, myocardial infarction (MI), target vessel revascularization (TVR) or nonfatal stroke. Cardiac mortality was defined as death due to cardiac disease including MI, arrhythmia, heart failure or any death that was not clearly non-cardiac. MI was defined as meeting the 4th universal definition of ESC/AHA/ACCF (Goeddel et al., 2019). TVR was defined as a procedure for assisted-primary patency or secondary patency of the target vessel, including either PCI or coronary artery bypass grafting (CABG). Non-fatal stroke referred to cerebral ischemic or hemorrhagic lesions with new-onset focal neurological deficits that were not reversible within 24 hours.

2.4 Statistical methods

All data were analysed by the SPSS 22 system (IBM, Armonk, NY, USA). Continuous variables are represented as the mean $\pm$ SD and were compared with t-tests. Data that with non-normal distribution or uneven variances are presented as median and interquartile range (IQR) and were measured by Wilcoxon's rank sum test. Categorical variables are represented by numbers and percentages and compared by Chi-square and Fisher's exact test, the latter of which was used when the expected value was less than 5. In addition, Kaplan-Meier curve (KM curve) analysis was used to compare all-cause mortality and long-term MACE between the two groups. A Cox regression model was used to identify the risk factors for all-cause mortality and long-term MACE. All reported P-values are bilateral, and $P < 0.05$ was considered statistically significant.

3. Results

3.1 Baseline clinical characteristics

Both groups were similar in age, sex, and cardiac comorbidities such as hypertension, diabetes, hyperlipidemia, smoking history, or left ventricular ejection fraction (LVEF) (Table 1). The proportion of patients with renal failure was higher in the planned RA group than in the bailout RA group (6.9% vs. 18.3%, $P = 0.039$).

3.2 Angiographic and procedural details

Angiographic and procedural details are listed in Table 2. Degree of coronary artery stenosis (92.55 $\pm$ 6.90% vs. 89.37 $\pm$ 10.17%, $P = 0.030$) was higher in the bailout group than in the planned group. The minimum lumen diameter (0.20 $\pm$ 0.20mm vs. 0.31 $\pm$ 0.22mm, $P = 0.001$) in the bailout group was smaller than in the planned group. IVUS was used more commonly in the planned RA group than in the bailout RA group (12.1% vs. 57.5%, $P < 0.001$). The mean diameters of burrs (1.45 $\pm$ 0.14 vs. 1.51 $\pm$ 0.18, $P = 0.022$) and implanted stents were significantly larger in the planned RA group (2.88 $\pm$ 0.34 vs. 3.04 $\pm$ 0.44, $P = 0.011$)

Table 1. Baseline clinical characteristics of the population (211 patients) [$\bar{x} \pm$ s, n (%)]

Variable	bailout RA	planned RA	P-value
Age (years)	72.98 ± 9.54	73.20 ± 9.06	0.88
Male	37 (63.8%)	93 (60.8%)	0.688
Hypertension	44 (75.9%)	128 (83.7%)	0.193
Diabetes	25 (43.1%)	66 (43.1%)	0.996
Hyperlipidaemia	11 (19.0%)	28 (18.3%)	0.912
Renal failure	4 (6.9%)	28 (18.3%)	0.039
Smoke	21 (36.2%)	47 (30.7%)	0.446
Family history	3 (5.2%)	8 (5.2%)	1
MI history	13 (22.4%)	32 (20.9%)	0.812
LVEF	53.47 ± 9.51	53.11 ± 8.12	0.791

RA, rotational atherectomy; MI, myocardial infarction; LVEF, left ventricular ejection fraction; STEMI, ST-segment elevation myocardial infarction; NSTEMI, non-STEMI; UAP, Unstable Angina Pectoris.

than in the bailout RA group. Additionally, procedure time for planned RA was significantly shorter than bailout RA (139.86 $\pm$ 56.24 min vs. 105.56.32 $\pm$ 36.71 min, $P < 0.001$).

The incidence of overall procedural complications was higher in the bailout group than in the planned group (32.6% vs. 15.7%, $P = 0.001$). Twenty-three patients were found to have vessel dissection during the operation; this occurred after RA in 18 cases, and 5 patients had dissection after balloon pre-dilation and before RA. All patients with dissection underwent balloon dilation and stent placement after RA and successful treatment of the dissection was confirmed by CAG. The incidence of coronary dissection was significantly higher in the bailout group than in the planned group (22.4% vs. 6.5%, $P = 0.001$) (Table 3). Multivariate logistic regression was also confirmed that when compared with bailout RA, planned RA strategy significantly reduced the risk of dissection (OR = 0.24, 95% CI: 0.10-0.62, $P = 0.003$) (Table 4). No differences were observed in the incidence of other procedural complications, such as slow flow, perforation, Burr entrapment and wire fracture between the two groups, as shown in Table 3.

3.3 In-hospital events

In-hospital events are summarized in Table 5. No significant difference in in-hospital MACE was found between the two groups. One patient in the planned RA group died in the hospital due to an assumed subacute thrombosis in the coronary stent. The incidence rates of in-hospital MI, TVR and stroke were similar in both groups.

3.4 Long-term events

Through November 2019, 191 patients completed a median follow-up of 44 months, while 20 patients were lost to follow-up (91%, 191/211, interquartile range 22-65 months). No difference was observed in all-cause mortality (9.1% vs. 12.5%, $P = 0.504$) and long-term follow-up MACE (13.8% vs. 17.1%, $P = 0.560$) between the two groups. No differences in cardiac mortality (3.6% vs. 7.4%, $P = 0.529$), MI (7.3% vs. 5.1%, $P = 0.820$), TVR (7.3% vs. 9.6%, $P = 0.824$), or stroke (3.6% vs. 2.9%, $P = 1$) were found between the two groups (Table 6). Kaplan-Meier curves for the cumulative survival rate and the cumulative incidence of MACE

Table 2. Angiographic and Procedural Characteristics [$\bar{x} \pm$ s, n (%)]

Variable	Bailout RA	Planned RA	*P*-value
Target vessel			
LAD	39 (67.2%)	106 (69.3%)	
LCX	4 (6.9%)	2 (1.3%)	
RCA	6 (10.3%)	25 (16.3%)	0.152
LM-LAD and/or LM-LCX	9 (15.5%)	20 (13.1%)	
IVUS used	7 (12.1%)	88 (57.5%)	< 0.001
CAG success	55 (94.8%)	146 (95.4%)	1
Percent stenosis	92.55 ± 6.90	89.37 ± 10.17	0.03
Lesion length	60.82 ± 19.30	60.21 ± 20.74	0.846
Stent length/lesion length	0.89 ± 0.13	0.87 ± 0.17	0.504
Minimum lumen diameter	0.20 ± 0.20	0.31 ± 0.22	0.001
Reference vessel diameter	2.89 ± 0.32	3.07 ± 0.37	0.002
Severe (three vessels)	19 (32.8%)	69 (45.1%)	0.105
LM not protected	10 (17.2%)	22 (14.4%)	0.605
Stenosis	92.55 ± 6.90	89.37 ± 10.17	0.03
AMI culprit vessel	6 (10.3%)	12 (7.8%)	0.761
Long lesion	47 (81.0%)	125 (82.2%)	0.84
Tortuous	11 (19.0%)	21 (13.7%)	0.343
Number of burrs	1.10 ± 0.31	1.14 ± 0.35	0.443
Max diameter of burrs	1.45 ± 0.14	1.51 ± 0.18	0.022
Burr diameter / reference vessel diameter	0.51 ± 0.07	0.50 ± 0.07	0.414
Number of stent use	2.07 ± 0.62	1.94 ± 0.71	0.223
Stent mean diameter	2.88 ± 0.34	3.04 ± 0.44	0.011
DES use	57 (98.3)	149 (97.4)	1
New DES	30 (52.6)	61 (40.9)	0.158
Syntax	32.27 ± 10.49	31.82 ± 11.16	0.792
Contrast agent	182.67 ± 61.92	164.35 ± 66.72	0.203
Operation duration	139.86 ± 56.24	105.56 ± 36.71	< 0.001

LM, left main coronary artery; LAD, left anterior descending artery; LCX, left circumflex artery; RCA, right coronary artery; IVUS, intravascular ultrasound; CAG, coronary angiography; AMI, acute myocardial infarction

Table 3. Operative complications [n (%)]

Variable	Bailout RA	Planned RA	*P*-value
Overall complications	21 (36.2%)	24 (15.7%)	0.001
Slow flow	9 (15.5)	14 (9.2)	0.185
Dissection	13 (22.4%)	10 (6.5%)	0.001
Perforation	1 (1.7%)	1 (0.7%)	0.475
Burr entrapment	1 (1.7%)	2 (1.3%)	1
Wire Fracture	0	1 (0.7%)	1

also showed no significant difference between the two groups (*P* = 0.543, *P* = 0.628, Figure 1).

Cox regression analysis (Table 7-8), which included age, diabetes, an eGFR < 60, LVEF, IVUS and syntax score, demonstrated that the RA strategy (HR = 1.12, 95% CI: 0.49-2.56, P = 0.784) was not a predictor of long-term MACE and that a low LVEF (HR = 0.96, 95% CI: 0.92-0.99, *P* = 0.015) and high syntax score (HR = 1.05, 95% CI: 1.02-1.09, *P* = 0.004) were the main risk factors for long-term MACE.

4. Discussion

Coronary RA has emerged as an important adjunct to PCI, with the benefit of decreasing disease burden in heavily calcified coronary vessels. Compared with coronary balloon dilation alone, RA can be used to form a smooth endovascular lumen in a calcified vessel, thereby improving the success rate of stent implantation and reducing the incidence of thrombosis and restenosis when combined with drug-eluting stents (Tian et al., 2015). Januszek et al. (2017) noted that RA was associated with reduced periprocedural complications and lower rate of in-hospital complications. In this study, the incidence of coronary dissection was lower in the planned RA group than in the bailout RA group, a finding that has been previously described in other studies (Allali et al., 2016). A possible explanation for this finding is the increased shear force associated with balloon inflation at the border of a heavily calcified vessel next to relatively normal artery, as is done with bailout RA. Dissection may increase procedural difficulty. Therefore, many experts believe that planned RA is a more appropriate treatment strategy than bailout RA.

However, in a study by Abdel-Wahab et al. (2013), RA did not improve the prognosis of patients with complex calcified coronary stenosis. Some studies have reported that in patients with unsuccessful PTCA, bailout RA is safe and improves the success of the

Table 4. Logistic regression analyses of dissection

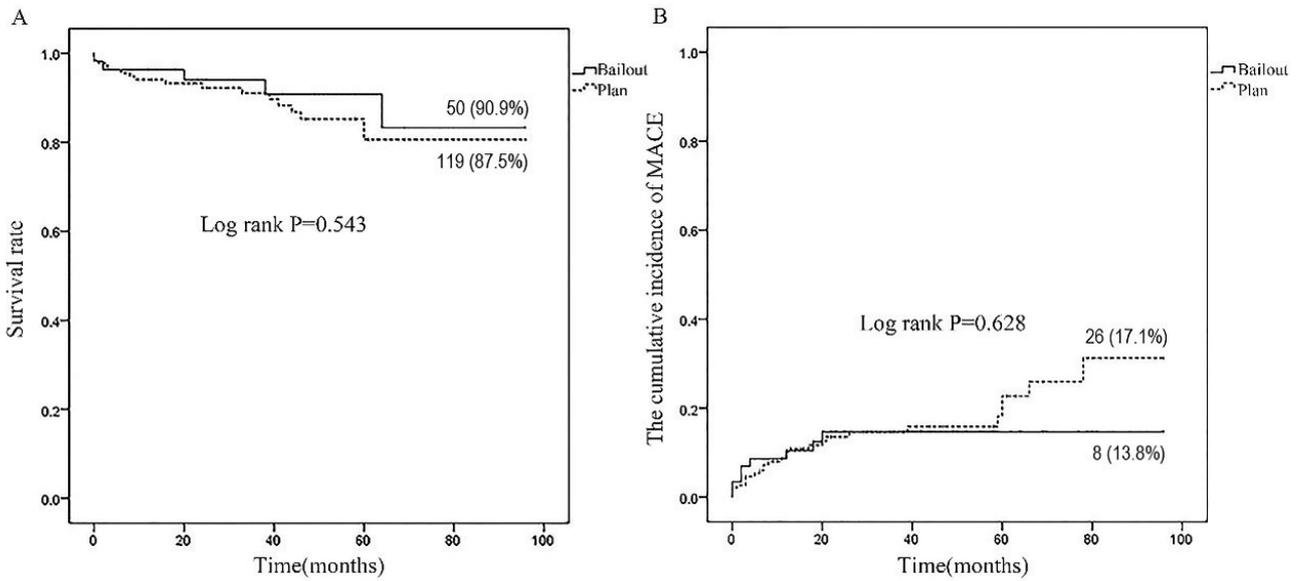| Variable	P-value	OR	Univariate logistic regression analyses 95% CI	P-value	OR	Multivariate logistic regression analyses 95% CI
Planned RA	0.003	0.23	0.08-0.61	0.003	0.24	0.10-0.62
Smoke	0.003	4.62	1.67-12.79	0.001	4.85	1.86-12.60
Tortuous	0.072	2.7	0.92-7.94	0.067	2.71	0.93-7.86
Age	0.487	0.98	0.93-1.03			
Minimum Lumen diameter	0.28	3.42	0.37-31.79			
Max diameter of burrs	0.327	0.17	0.01-6.05			

Figure 1. Kaplan-Meier curves for the cumulative survival rate (A) and the cumulative incidence of MACE (B)

Table 5. In-hospital events [n (%)]

Variable	Bailout RA	Planned RA	P-value
MACE	7 (12.1%)	21 (13.7%)	0.752
Death	0	1 (0.7%)	1
MI	7 (12.1%)	21 (13.7%)	0.752
TVR	1 (1.7%)	2 (1.3%)	1
Stroke	0	0	1

HF, heart failure; MI, myocardial infarction; TVR, target vascular reconstruction; MACE, main adverse cardiovascular events

Table 6. Follow-up events [n (%)]

Variable	Bailout RA	Planned RA	P-value
All-cause death	5 (9.1%)	17 (12.5%)	0.504
MACE	8 (13.8%)	26 (17.1%)	0.56
Cardiac mortality	2 (3.6%)	10 (7.4%)	0.529
MI	4 (7.3%)	7 (5.1%)	0.82
TVR	4 (7.3%)	13 (9.6%)	0.824
Stroke	2 (3.6%)	4 (2.9%)	1

operation (Eftychiou et al., 2016).

Unlike previous studies (Allali et al., 2016; Kawamoto et al., 2016), we found no significant differences in in-hospital and long-term events were between the two groups. A study by Allali et al. (2016) showed the incidence of in-hospital MACE was higher in the bailout RA group than in the planned group (bailout 10.3% vs. planned 5.5%, P = 0.04), and the authors proposed that this result may be related to the baseline lesion morphology or represent a consequence of intraprocedural crossover with the hazards of higher interventional effort. A study by Kawamoto et al. (2016) reported no differences in in-hospital events and one-year MACE after adjustment by regression analysis, but the incidence of one-year TVR remained significant; they suggested that this result may be related to the lesion and patient characteristics in their study population. Our study showed no difference between the two groups in terms of TVR, and stent restenosis was related to the post-procedure angiographic minimal lumen diameter (Saito et al., 2019). However, no significant difference in stent diameters was found between the two groups in our study.

Compared with the bailout RA group, the planned RA group was associated with significantly shorter procedure time. Because bailout RA is performed after other devices fail, a longer procedure time is not surprising. Shorter operation times usually correspond to shorter-term exposure to radiation, and it may thereby

Table 7. Cox regression analyses of the incidence of MACE

Variable	P-value	HR	Univariate cox regression analyses 95% CI	P-value	HR	Multivariate cox regression analyses 95% CI
LVEF	0.077	0.96	0.93-1.00	0.015	0.96	0.92-0.99
Syntax score	0.017	1.04	1.01-1.08	0.004	1.05	1.02-1.09
Planned RA	0.784	1.12	0.49-2.56			
Age	0.855	1	0.96-1.04			
Diabetes	0.342	1.41	0.69-2.87			
eGFR<60	0.348	1.56	0.62-3.91			
IVUS	0.302	0.662	0.30-1.45			

Table 8. Cox regression analyses of all-cause mortality

Variable	P-value	HR	Univariate cox regression analyses 95% CI	P-value	HR	Multivariate cox regression analyses 95% CI
Age	0.039	1.07	1.00-1.14	0.015	1.08	1.01-1.14
LVEF	0.038	0.94	0.89-1.00	0.003	0.93	0.89-0.98
Planned RA	0.192	2.11	0.69-6.49			
Syntax score	0.333	1.02	0.98-1.07			
Diabetes	0.426	0.67	0.25-1.80			
eGFR < 60	0.416	1.61	0.51-5.11			
IVUS	0.032	0.32	0.11-0.91			

improve patient and operator safety. In this regard, previous studies have produced similar results (Allali et al., 2016; Gorol et al., 2018; Kawamoto et al., 2016)

In our study, the proportion of procedures in which IVUS was used was significantly higher in the planned RA group than in the bailout RA group. IVUS plays an important role in the detection of coronary calcification lesions due to its exceedingly high sensitivity and specificity (Sonoda et al., 2019) and can provide clear details of vascular calcification before atherectomy to guide the selection of the RA strategy (Casella et al., 2003). Shavadia et al. (2018) reported that with coronary calcification > 270°, balloon dilatation often fails to pre-expand the plaque, which will affect subsequent stent placement. Under these conditions, RA is recommended. In this study, the usage of IVUS was determined by the operators, and in patients not treated with IVUS, the operators might have underestimated the severity of calcification lesions, causing balloon dilatation failure and thus leading to the need for bailout RA. This may explain why the frequency of IVUS use was higher in the planned RA group than in the bailout RA group. Moreover, in our study, the mean diameters of the burrs and implanted stents were significantly larger in the planned group than in the bailout group; this finding is thought to be related to the fact that IVUS provides an accurate measurement of target vessel diameter, while angiography may underestimate lumen diameter (Chieffo et al., 2013).

The planned RA group had more patients with poor renal dysfunction. Cai et al. (2013) reported that chronic kidney disease (CKD) can lead to coronary calcification acceleration and result in more severe and extensive lesions , which is thought to be related to disturbed calcium and phosphate metabolism (He et al., 2012). This may be one of the reasons that operators select planned RA in patients with CKD. Allali et al. (2016) reported that the mean contrast dose was significantly lower in planned RA than in bailout RA. In our study, planned RA also was also associated with lower contrast dose than in bailout RA.

When a COX regression model was used including age, renal function, diabetes, smoking, LVEF, IVUS and syntax score which may affect the prognosis (Édes et al., 2015; Eftychiou et al., 2016; Okai et al., 2018), we found no significant differences in all-cause mortality and long-term MACE between the two groups. Additionally we found that a low LVEF was an independent risk factor for all-cause mortality and long-term MACE after coronary RA. Syntax score was also found to be predictive of long-term MACE, which has also been reported by Eftychiou et al. (2016).

This study has some limitations, including retrospective data collection and small sample size. Prospective studies with larger sample sizes are needed to further assess the effects of the RA strategy on patient outcomes.

Compared with bailout RA, planned RA is associated with shorter procedure time and lower rate of arterial dissection. However, with regard to in-hospital events and long-term follow-up events, planned RA provided no benefit. Further studies are needed to determine the long-term differences in outcomes of rotational atherectomy approach.

Ethics approval and consent to participate

Authors' contributions

All authors have contributed significantly. ZRQ, HYZ and JMZ designed and conducted the trial. ZHW, QD, JX, LW, JMZ and JS were all involved in the operation and contributed to data collection. ZRQ and HYZ collected date, analyzed the data, in-

terpreted the data and wrote the manuscript. ZHW, QD and JS discussed the data and revised the manuscript.

Conflicts of interest

The authors declare no conflicts of interest statement.

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