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Feasibility Analysis of Planned Coronary Rotational Atherectomy Guided by Coronary Angiography for Severe Calcified Coronary Lesions in Grass-Roots Hospitals

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Abstract

Objective: To investigate the feasibility of planned percutaneous coronary Rotational Atherectomy (RA) under the guidance of coronary angiography in the treatment of severe coronary calcification in grass-roots hospitals.

Methods: The clinical data of 79 patients with coronary heart disease who underwent RA and PCI in Pinggu District Hospital from July 2019 to December 2021 were retrospectively analyzed.

Results: The 79 patients were all planned rotational atherectomy. Coronary interventions included 45 (55.5%) left anterior descending coronary artery, 8 (9.9%) left main truck-left anterior descending coronary artery, 23 (28.4%) right coronary artery, 5 (6.2%) circumflex artery. The angiographic success rate of PCI was 100.0%. Coronary dissection occurred in 4 patients (5.1%), slow flow/no-reflow occurred in 4 patients (5.1%), coronary perforation occurred in 3 patients (3.8%), and branch occlusion occurred in 5 patients (6.3%), while none of them occurred burr entrapment and wire fracture. The overall risk of complications was 20.3%. The above complications were properly handled without significant adverse consequences, and there were no major adverse cardiovascular events during hospitalization. There was no significant difference in platelet count, creatine kinase, creatine kinase isoenzyme, troponin I, and blood urea nitrogen before and after procedure ($P>0.05$), but there were statistically significant changes in hemoglobin, hematocrit, and creatinine ($P<0.05$).

Conclusions: The planned rotational atherectomy under the guidance of coronary angiography in grass-roots hospitals is safe and effective in the treatment of severe calcified coronary lesions.

Keywords: Grass-Roots hospitals; Coronary angiography; Severe calcified coronary lesions; Planned rotational atherectomy; Percutaneous coronary intervention.

Introduction

With the improvement of people's living standard and the progress of aging, the frequency of complex coronary artery lesions, including severe coronary artery calcification, is getting higher and higher. Epidemiological data show that coronary artery calcification occurs in 50% of the population aged 40-49 years and in 80% of the population aged 60-69 years [1]. Severe calcification is an independent predictor of Major adverse cardiovascular events [2] and is considered to be the "Toughest bulwark" in Percutaneous Coronary Intervention (PCI). It can lead to stent implantation failure or incomplete stent expansion, also increases the risk of complications and death [3].

Because of the expanding indications to percutaneous coronary angioplasty and an elevated number of coronary stenoses

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with heavy calcification, the use of debulking devices improved greatly in the last few years. Evidence-based medicine data suggests that adequate preparation of calcified lesions can significantly improve the success rate of PCI and reduce complications, and prevent stent thrombosis and restenosis [4]. Currently, two standard strategies are adopted in lesion preparation for severe calcified coronary lesions: Rotational Atherectomy (RA) and modified (scoring or cutting or lacrosse NSE) Balloon (MB) based method, and RA is one of the important methods to treat with coronary artery calcification lesions. It was invented in 1980s by David Auth et al, while Fourrier et al performed the first coronary RA in 1988, and in 1993, RA was approved for use in the United States. However, RA underwent a hot-cold-hot process. In the early era of Plain Old Balloon Angioplasty (POBA), RA was an irreplaceable"Plaque ablation" technique other than POBA. In the era of Bare-Metal Stent (BMS), RA had been neglected because it could not solve the problem of high in-stent restenosis. With the advent of Drug-Eluting Stents (DES), RA had been redefined as an important tool for"Plaque modification" and reentered the interventional physician's field of vision. In recent years, RA combined with DES has become one of the effective therapies for coronary calcification lesions. However, because of its relatively high risk of complications, it is not common for grass-roots hospitals to carry out RA in the treatment of coronary artery calcification lesions, the purpose of this study was to investigate the feasibility of the treatment of severe calcified coronary lesions with planned RA under the guidance of coronary angiography in grass-roots hospitals.

Methods

Study design and population

This was a retrospective single-center study of a total of 79 patients who underwent PCI using RA because of severe calcified coronary lesions with luminal diameter reduction of 70% to 100% in Pinggu District Hospital from July 2019 to December 2021. Pinggu District Hospital was a grass-roots hospital and responsible for the people's health and medical work in Pinggu District, Beijing. Severe calcified coronary lesion was defined as: radiopacities noted without cardiac motion before contrast injection [5]. Planned RA was defined as initial strategy before balloon pre-dilation. When discharge from hospital, all the patients were received standard pharmacological treatment (double antiplatelet therapy at least 1 year). The study was conducted with the written informed consent of all participants, and the data collection procedure obtained permission from the local ethics committee (NO.2022-006–01).

Procedural details

Before procedure, all patients began to take aspirin (100 mg, once a day), clopidogrel (75 mg, once a day) or ticagrelor (90 mg, twice a day) at least 5 days; If it was less than 5 days to the PCI date, they would received an oral loading dose of 300 mg aspirin and 300 mg clopidogrel (or 180 mg ticagrelor). During procedure, all patients received unfractionated heparin at a dose of 70–100 U/kg to maintain an activated clotting time (ACT) >250s. RA was performed with the Rotablator system (Boston Scientific, Marlborough MA, USA) in accordance with manufacturer's indications for use. The burr size was selected to achieve a burr/vessel ratio of 0.5–0.6, ranged from 1.25 to 2.15 mm, and the speed ranged between 140,000 and 180,000 rotations per minute, each RA time was 10–15s. To reduce the occurrence of slow flow, RA irrigating fluid (normal saline, heparin, nitroglycerin) was continuously used. After RA, the operators performed balloon 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. All patients received dual antiplatelet therapy and secondary prevention of CHD after procedure.

Data collection

The demographic and clinical characteristics of all patients included age, gender, medical history, left ventricular ejection fraction, hemoglobin and platelet, lipid profiles, serum creatinine. The angiographic and procedural characteristics included vascular approach, number of diseased vessels, target vessel, the size of burr, the number of burrs, the total time of RA, total number of stents, the total time of PCI, the complication of procedure, et al. Procedure complications included slow-no reflow, dissection, branch occlusion, perforation, burr entrapment and wire fracture.Dissection was defined as grades C to F according to National, Heart, Lung, and Blood Institute (NHLBI) criteria [6].

Statistical analysis

Statistical analysis was performed using SPSS 22.0. Continuous variables are represented as the mean±SD and were compared with t-tests. Categorical variables are represented by numbers and percentages. Difference was considered to be statistically significant at $P < 0.05$.

Results

Patients characteristics

All 79 patients (41 men and 38 women) and 81 lesions were treated with planned RA and implanted DES. Table 1 presented that the patients had a higher proportion of hypertension, Diabetes Mellitus (DM), dyslipidemia, smoking, while part of them combined with prior stroke. And still a minority had family history of CHD.

The age, Left Ventricular Ejection Fraction (LVEF), lipidemia, Blood Urea Nitrogen (BUN), Creatinine (Cr), Hemoglobin (HGB), Hematocrit (HCT), Platelet (PLT), Creatine Kinase (CK), isoenzyme of Creatine Kinase (CK-MB), Troponin I (TnI) of the patients were exhibited in Table 2, and most of the patients were old (70.3±0.92 years old).

Table 1: Baseline clinical characteristics.

	Percentage
Planned RA (%)	79(100%)
Family history of CHD (%)	5(6.3%)
Hypertension (%)	54(68.4%)
DM (%)	32(40.5%)
Prior myocardial infarction (%)	14(17.7%)
Prior CABG (%)	0(0%)
Prior stroke (%)	15(19.0%)
Dyslipidemia (%)	48(60.8%)
Smoking (%)	29(36.7%)

Table 2: Baseline clinical characteristics.

	x±s
Age (years)	70.22 ± 8.50
LVEF (%)	58.10 ± 12.21
Total Cholesterol (mmol/L)	4.11 ± 1.10
Triglyceride (mmol/L)	1.66 ± 0.80
High density lipoprotein cholesterol (mmol/L)	1.01 ± 0.23
Low density lipoprotein cholesterol (mmol/L)	2.27 ± 0.80
HGB (g/L)	125.43 ± 16.97
HCT (%)	38.08 ± 4.78
PLT (×10^9/L)	215.74 ± 56.43
CK (U/L)	144.64 ± 280.27
CK-MB (U/L)	5.44 ± 10.30
TnI (ng/ml)	0.75 ± 2.35
BUN (mmol/L)	6.10 ± 2.34
Cr (umol/L)	70.66 ± 26.33

Angiographic and procedural details

91.1% of the patients were transradial approach, and 5.1% patients were femoral artery approach, also 3.8% of them were distal transradial approach. Coronary interventions included 45 (55.5%) left anterior descending coronary artery, 8 (9.9%) left main truck -anterior descending coronary artery, 23 (28.4%) right coronary artery, 5 (6.2%) circumflex artery. The angiographic success rate of PCI was 100.0%.

The number of stents, the volume of contrast, procedure time were revealed in Table 3. In this study, 2 patients used 2.15 mm burrs (the diameter of the burr/vessel<0.6), which needed to be operated through the femoral artery under the support of the 8-F guiding catheter, A total of 7 patients were treated with 2.00 mm burrs, and the 7-F guiding catheters were guided by the no sheath technique through the radial artery; The rest were completed under the support of 6-F guiding catheters; The commonly type of guiding catheters were EBU or SAL (Launcher Guiding Catheter), which had strong passive support, good coaxiality and small bending.

Complications of procedure: Coronary dissection occurred in 4 patients (5.1%), slow flow/no-reflow occurred in 4 patients (5.1%), coronary perforation occurred in 3 patients (3.8%), and branch occlusion occurred in 5 patients (6.3%). While none of them occurred burr entrapment and wire fracture (Table 4). The overall risk of complications was 20.3%. There were no deaths, target vessel re-PCI during hospitalization, acute stent thrombosis or emergency CABG. The above complications were properly handled without significant adverse consequences, and there were no major adverse cardiovascular events during hospitalization occurs.

Table 3: Angiographic and procedural characteristics.

	x±s
Number of stents	2.12 ± 0.89
Contrast amount (ml)	192.04 ± 50.59
Procedure time (min)	135.32 ± 58.17

Table 4: Complications of procedure.

Complications	Num	Percentage
Dissection	4	5.1%
Slow flow/no-reflow	4	5.1%
Perforation	3	3.8%
Irreparable bradycardia	0	0%
Burr entrapment	0	0%
Wire fracture	0	0%
Branch occlusion	5	6.3%
Total		20.3%

There was no significant difference in platelet count, creatine kinase, creatine kinase isoenzyme, troponin I, and blood urea nitrogen before and after procedure (P>0.05), but there were statistically significant changes in hemoglobin, hematocrit, and creatinine (Table 5). Significance (P<0.05).

Table 5: Comparison of clinical characteristics before and after procedure.

	Before procedure	After procedure	P-value
HGB (g/L)	126.26 ± 14.75	120.79 ± 15.08	0.005
HCT (%)	38.20 ± 4.34	36.92 ± 4.38	0.024
PLT (×10^9/L)	208.23 ± 61.83	209.69 ± 69.18	0.810
CK (U/L)	154.42 ± 222.64	370.16 ± 486.32	0.105
CK-MB (U/L)	5.33 ± 10.36	8.59 ± 9.26	0.127
TnI (ng/ml)	0.76 ± 2.56	1.41 ± 1.86	0.085
BUN (mmol/L)	5.92 ± 2.36	6.41 ± 2.87	0.114
Cr (umol/L)	72.16 ± 28.70	75.81 ± 29.12	0.043

Discussion

With the increase of the number of coronary heart disease patients in China, more and more grass-roots hospitals developed Percutaneous Coronary Intervention (PCI). However, due to the limitations of economy and technology, they were often lack of intravascular imaging, included Intravascular Ultrasound (IVUS) and Optical Coherence Tomography (OCT), and these leaded to limitations in the diagnosis and analysis of calcified lesions.

In this study, we defined severe calcified coronary lesion as: Radiopacities noted without cardiac motion before contrast injection [7], so we could treat severe calcified coronary lesions guided by coronary angiography.As we all know, severe calcified coronary lesions were more frequently located in the left anterior descending coronary artery and/or left main trunk (65.4%) and the right coronary artery (28.4%), and less frequently in circumflex artery (6.2%). They were more often complex, multivessel, and >10 mm in length, more frequently eccentric, more often located in angulated segments than non-calcified lesions. Because of low success rate and high risk of complications, severe calcified coronary lesions were considered to be the greatest challenge for cardiac interventional physicians in PCI, also they were associated with high rate of revascularization compared with non-calcified lesions [8,9]. To address this challenge, modified balloons (cutting or scoring or lacrosse NSE), and RA were used to the lesion preparation of severe calcified coronary lesions [10]. And RA could effectively improve the success rate of PCI for such lesions.

The Rotablator catheter consists of an elliptic, diamond-coated burr connected to a helium-driven turbine. This burr rotates at up to 180,000 rpm, abrading calcified lesions into particles generally less than 5 um in diameter, and these particles are engulfed by macrophages finally. The Rotablator burr selectively removes rigid atherosclerotic lesions, leaving a smooth lumen, especially in severe calcified coronary lesions, so RA is unique and apparently particularly well suited to severe calcified coronary lesions. Based on the principle of moderate cutting, the burr size is selected to achieve a burr/vessel ratio of 0.5–0.6. In our study, the burr size ranged from 1.25 to 2.15 mm, in which 2 patients used 2.15 mm burrs, 7 patients used 2.00 mm burrs, the rest patients (88.6%) were completed by the burr size ranged from 1.25 to 1.75 mm. In terms of vascular approach, most of the patients (91.1%) were transradial approach, and 5.1% patients were femoral artery approach, also 3.8% of them were distal transradial approach. The radial artery approach is the first recommended approach in PCI at present [11], on the other hand, the distal transradial approach has been developed as a new approach for PCI in recent years [12]. Because the transradial approach (including the distal transradial approach) have the limitations of small diameter, the sheathless technique guided by Balloon Assisted Tracking (BAT) is a better method [13].

In our study, all the procedures were performing RA before balloon pre-dilation, which was named planned RA. In the Rotate multicenter registry, planned RA appeared to be safe, and it could shorten procedural and fluoroscopy time, reduce contrast volume and the number of pre-dilation balloon catheters used [14], compared with bailout RA, which was designated as RA after incomplete expansion of balloon or failure delivery of any devices, planned RA was also associated with a reduction incidence of coronary dissection, and had no difference in MACE or mortality [15].

There are some details in the procedure that need your attention, such as RA should be operated under continuous vasodilating heparinized infusion, there should be enough leeway for the forward and backward motion of the burr, the burr must be kept spinning all the time and must never stop distal to the target lesion, the lesion is addressed by short repetitive movements (‘pecking’) to limit engagement with the lesion to a minimum (less than 15 seconds), et al. And these means can prevent most complications. In our study, coronary dissection occurred in 4 patients (5.1%), slow flow/no-reflow occurred in 4 patients (5.1%), coronary perforation occurred in 3 patients (3.8%), and branch occlusion occurred in 5 patients (6.3%).while none of them occurred burr entrapment and wire fracture (Table 4). The overall risk of complications was 20.3%, this result was similar to that of previous studies [16-19]. And the above complications were properly handled without significant adverse consequences, and there were no major adverse cardiovascular events during hospitalization occurs.

The changes of hemoglobin and hematocrit before and after RA were considered to be related to the rupture of red blood cells by the high-speed spinning burr, but these changes did not cause serious consequences. In addition, patients with elevated creatinine levels were considered to be associated with a larger dose of contrast, and for patients who were expected to require RA, enhanced hydration might reduce contrast-induced kidney damage to some extent. There were no significant differences in platelet count, creatine kinase, creatine kinase isoenzyme, troponin I and blood urea nitrogen between pre-operation and post-operation, these results suggested that RA did not cause severe myocardial injury and thrombocytopenia.

In our study, we observed a low rate of severe procedural complications, confirming the safety of the strategy. So we got the conclusion that the planned rotational atherectomy under the guidance of coronary angiography in grass-roots hospitals is safe and effective in the treatment of severe coronary calcification lesions.

Limitations

First, this was a retrospective study presenting with single center experience. Secondly, severe coronary calcification lesions was judged by angiography rather than IVUS, whether intimal calcification is involved is hard to be confirmed in some cases. Finally, differences in PCI process, such as the use of different DES types may impact the results.

Conflicts of interest: The authors have no conflicts of interest to declare.

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