

Long-term results of transradial rotational atherectomy for heavily calcified coronary artery lesions

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ABSTRACT

Objective: Percutaneous coronary intervention (PCI) for the heavily calcified coronary lesions remains a challenge, and the periprocedural complication rates of the transfemoral approach are high. This study was conducted to investigate the feasibility and long-term results of the transradial approach for rotational atherectomy (RA) prior to stent implantation via the transradial approach in patients with heavily calcified coronary artery lesions.

Methods: RA followed by stent implantation via the transradial approach was performed in 47 patients with severely calcified coronary artery lesions in this retrospectively case-control study. The success rate of the procedure and the 3-year follow-up (36±7.5 months) results were analyzed.

Results: RA with subsequent stent implantation or balloon angioplasty procedures were successfully performed in all cases. 6F guiding catheters were used in 45 cases, and 7F catheters were used in 2 patients. Rotablation was performed with a 1.25-mm burr in 29 cases, a 1.25-mm burr followed by a 1.5-mm burr in 17 patients, and a 1.75-mm burr in 1 patient. Percutaneous transluminal coronary angioplasty after RA was performed, followed by stent implantation in all 47 patients. Restenosis was found in 7 cases (7/38) at 13 months (13±3.6) and in 13 cases (13/28) at 36 months (36±7.5) after the procedure; 3 patients died during the 3-year follow-up. The post-procedure cumulative 3-year event-free survival rate was 78%.

Conclusion: RA prior to stent implantation via the transradial approach is feasible and safe, the success rate is high, and long-term outcome is satisfactory in patients with heavily calcified lesions of the coronary artery. (*Anatol J Cardiol* 2016; 16: 696-700)

Keywords: stent, calcification, prognosis, angioplasty, coronary artery

Introduction

Heavily calcified coronary lesions remain a challenge for interventional cardiologists. High balloon inflation pressure is often used in these cases and sometimes may result in an increased risk of vessel injury and a high incidence of complications (1). Fitzgerald et al. (1) reported that the incidence of dissections was 53% for non-calcified lesions and 88% for calcified lesions after balloon angioplasty. Rotational atherectomy (RA) is a widely used invasive treatment modality for patients with symptomatic coronary artery disease (2), particularly for patients with complex, calcified, and long coronary lesions as well as coronary lesions in angulated segments. In some cases, even the smallest balloons cannot pass through the severely calcified lesion. RA has been proposed as a superior procedure

for patients with a heavily calcified plaque (3-5). An increasing number of patients, such as those with ostial lesion, bifurcation lesion, and long and severely calcified lesions, thus require a debulking strategy with RA.

Routinely, complicated percutaneous coronary intervention (PCI) is performed via the femoral approach, this lead bigger guiding to have a good support and bigger lumen for more instruments or bigger burrs. However, the femoral approach has a high complication rate, and the transradial approach is tested to be safer than the femoral approach with respect to major bleeding and death for elderly patients (6).

Although PCI via the transradial approach is established as a safe procedure with improved patient comfort and early ambulation, most of the cases of RA are still performed via the femoral approach (1, 3), which often prolongs the in-hospital stay and

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results in more complications after the procedure, such as hematoma and bleeding at the puncture site in some patients. To date, the transradial approach for RA is not as popular as the transfemoral approach. The aim of this retrospective study was to evaluate the short-term results and 3-year follow-up outcome in patients with severely calcified lesions of the coronary artery who underwent RA prior to stent implantation via the transradial approach in two hospitals.

Methods

This retrospective study recruited a total of 47 consecutive patients who underwent transradial RA prior to intracoronary stenting or Percutaneous transluminal coronary angioplasty (PTCA) from January 2009 to April 2013 from two hospitals. Coronary angiography was performed in all patients, and angiographic measurements were performed by two experienced angiographers blinded to the measurements. The inter- and intra-observer reproducibilities were good. Heavily calcified lesions were defined visually as the presence of calcium within the arterial wall at the site of the stenosis that was noted without cardiac motion before contrast injection, generally compromising all sides of the arterial lumen (5).

If the slow-flow phenomenon occurred after RA, 100–200 μ g of sodium nitroprusside was intracoronary administered to improve the coronary flow through a microcatheter. Clinical data were collected through hospital visits or telephone interviews at 6-month intervals. Angiographic follow-up was scheduled around 12 months after PCI. All patients were administered 300 mg of aspirin and 300 mg of clopidogrel more than 8 h prior to the procedure. After the procedure, aspirin was continued indefinitely, and clopidogrel was prescribed for at least 1 year for patients implanted with drug-eluting stents. Beta blockers were stopped prior to the procedure, and nitroglycerin was used intermittently during the procedure. Temporary pacing was used in patients who had a proximal lesion in the left anterior descending (LAD) artery or the ostial lesion in the right coronary artery (RCA).

EBU (Medtronic, Minneapolis, MN) guide catheters were used for the left coronary artery, and SAL (Medtronic, Minneapolis, MN) catheters were used for the RCA. In 45 cases (93%), 6F guiding catheters were used, and 7F guiding catheters were used in the remaining two patients. Heparin was used in all cases at a loading dose of 100 units/kg and 1000 units, of heparin was added if the operation time lasted more than 60 min to maintain the ACT at 250–350 s, and 25 patients were treated with IIb/IIIa antagonists (Tirofiban) during the procedure and 24 h after the procedure.

The range of burr size used was 1.25–1.5 mm, and all the procedures were started with a small burr. Rotablation was performed with 10–15 s rotation time each, and the rotating speed of the burrs was between 140.000 and 160.000 r/min.

Clinical follow-up

Outpatient visit was made at 4 weeks, 6 months, and then every 4 months up to 3 years (36 ± 7.5 months) after the procedure, and angiography follow-up was planned to be performed at 12 months after the procedure in all patients. The major adverse cardiac events, including death, nonfatal myocardial infarction, and repeat revascularization, were evaluated.

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) 16.0. Quantitative data were presented as mean \pm standard deviation. Comparisons between groups were performed using paired and unpaired Student's *t*-tests for continuous variables or factorial analysis of variance. The cumulative incidence of adverse events was calculated. A *p* value <0.05 was considered statistically significant.

Results

The patients' clinical and demographic characteristics are summarized in Table 1. The angiographic demographics and PCI procedures are summarized in Table 2. Fifty-two procedures were performed in 47 patients with a total of 60 lesions treated.

The distribution of the lesions was as follows: 45 (75%) were located in the LAD artery, 9 (15%) in the RCA, and 4 (6%) in the left circumflex artery. Two left main (4%) and 16 lesions (27%) were proximal, 35 (59%) mid, and 10 (16%) distal (Table 1).

The mean vessel diameter after RA was 1.30 ± 0.23 mm (1.16–1.45 mm), and the mean length of stents deployed was 23.5 ± 12.7 mm (17–31 mm). The 1.25-mm burr was used in 29 patients (62%), and one 1.25-mm burr plus one 1.5-mm burr in 17 patients (36%), and a 1.75-mm burr in 1 patient. All patients underwent PTCA with a high pressure balloon afterwards and DES implantation (Table 1).

All procedures were completed via the transradial approach with no major vascular complications. Five patients

Table 1. Baseline characteristics (n=47)

Age, years	63 \pm 12.6
Gender, male/female	35/12
Risk factors	
Smoking	31 (65%)
Diabetes mellitus	28 (59%)
Hypertension	39 (83%)
Hyperlipidemia	34 (72%)
Medications	
Nitrates	25 (52%)
ACEI/ARB inhibitors	32 (68%)
Beta-blockers	31 (65%)
Calcium antagonists	38 (81%)
Aspirin	47 (100%)
NYHA functional class >II	8 (17%)

Table 2. Angiographic demographics and procedure characteristics (n=47)

Numbers of vessels treated	52
Numbers of lesions treated	60
Lesion length, mm	19±12.5
RA segment	
LAD (%)	47/60 (79)
LCX (%)	4/60 (6)
RCA (%)	9/60 (15)
Mean lumen diameter, mm	
Before	0.11±0.12
After	1.30±0.23*
BMS or DES	
BMS	0 (0) (%)
DES	84 (100%)
Use of glycoprotein IIb/IIIa inhibitors	25 (53)
IVUS guided (%)	18 (38)
LAD - left anterior descending artery; mm - millimeter; RA - rotational atherectomy; RCA- right coronary artery. The statistical method to calculate the mean lumen diameter between "Before" and "After" is the t-test. *P<0.05	

had coronary spasm, while one patient had a severe chest compression, which was alleviated by intracoronary nitroglycerin infusion. Four patients developed the slow-flow phenomenon with chest discomfort, which disappeared after 100–300 µg (150±75) of sodium nitroprusside intracoronary infusion via a microcatheter. No perforation and death occurred, and no emergency bypass surgery was needed during the hospital stay. The post-procedural troponin I level was elevated in 21 patients (44%, >3 times the upper limit of normal), and the creatine kinase-MB level was elevated in 5 patients, with the creatine kinase-MB level more than 2 times the upper limit of the normal level found in 1 patient.

The radial artery pulse was present in 44 (94%) patients at the 6-month follow-up and it was absent in 6 out of 31 patients with 2 times puncture. Two patients died of gastric bleeding at 9 months and 15 months after the procedure, 1 patient died of heart failure 16 months after the procedure; 31 patients underwent second angiography (66%) at 13-month (13±3.6) follow-up, and in-stent restenosis was detected in 7 patients at this time point. Another 13 patients developed restenosis at the 3-year follow-up. Event-free survival during the 3 years after the procedure was 78% in this patient cohort; MACE rate (death, chest pain because of target lesion, heart failure) was 22%.

Discussion

Our present study provides a 3-year clinical outcome of RA via the transradial approach in 47 consecutive patients. The main findings of this study were as follows: 1) most RA can be performed via the radial approach with a 6F guiding catheter

without severe complications and 2) the 3-year follow-up of RA results were satisfactory.

Stent implantation delivered into calcified lesions is sometimes difficult, and stent expansion is often inadequate because of the resistance of the calcified plaque in some cases (7). RA is becoming a widely used procedure with relatively good instant results, but most of the cases were performed via the transfemoral approach, which often leads to a longer hospital stay and more procedure-related complications (8). Heavily calcified coronary lesions often lead to the failure of routine PCI. Sometimes, the balloon cannot even pass through the calcified area, and the balloon cannot be opened even at high balloon inflation pressure or could be ruptured by the sharp calcified edge of the calcified plaque (9). We found that after RA with 1.25-mm burrs, PTCA could be easily and successfully performed in 62% of cases, and the stent could then be delivered to the lesions. Although the use of small burr sizes (1.25 mm and 1.5 mm) did not produce complete debulking, it allowed for the use of a balloon to successfully pass through the lesion for the dilation. In most cases, the plaque is not uniformly calcified (7, 10) and when the hardest part of the calcified cap is rotablated, the overall characteristic could be changed, and the balloon can then pass through the calcified area and open the calcified vessel successfully. In majority of the patients, the 1.25-mm burrs are effective for partial debulking and can lead to alteration of plaque compliance, which facilitates further ballooning and stenting. In our experience, the change to 1.5 mm occurred in 17 patients, and only 1 patient changed to a 1.75-mm burr.

The transradial approach is now widely used for coronary intervention (6, 9). Most coronary interventional diagnoses were performed via the transradial approach since 2003 in our center. We mostly use this approach, apart from the puncture complication such as bleeding and hepatoma, because the patients' compliance is high. Although we have not analyzed the patients' data who were treated via the femoral approach before 2003, the bleeding complications was a huge problem in our mind. Besides, the 6F catheter can be used in most patients, including LM bifurcation (9) for Chinese people. For patients treated with RA, these patients often have a higher pre-procedural risk (11).

RA procedures via the transradial approach are the routine standard procedure in our center since 2004. The major advantage of this procedure is the shorter hospital stay, and there is no need to keep the patient in bed after the procedure. The patients will have to stay for 24 h after the transfemoral approach (we use manual compression), and this will prolong the time for the procedure. The bleeding, particularly periprocedural hematoma, is often found in the procedures via the transfemoral approach, while no major bleeding or hematoma is found at the radial artery access site in our center.

The majority of the procedures were successfully performed with a 6F guiding catheter and a 1.5-mm burr. Thus, a smaller burr size would be good enough for plaque compliance altera-

tion and for partial debulking via the radial artery approach, and the cutting balloon strategy was used in most cases of this patient cohort. Our experience is that the use of a cutting balloon will facilitate the opening of the lumen.

The long-term clinical outcome of RA varies followed by drug-eluting stent implantation in complex calcified coronary lesions (11). In our cohort, 3 patients died in 3 years, and the total MACE was 22%. The mortality rate was not as higher as that found in the study of Édes (12) reported recently. In their single-center study, the postprocedural death was 37.2% in a mean follow-up of 36 months. Compared with their study, our patients were elder and have more complications, thereby leading to a worse prognosis.

Although several clinical studies have shown that RA is associated with higher rates (6%–15%) of the no-reflow/slow-flow phenomenon than other coronary revascularization procedures and this phenomenon can lead to serious ischemic complications, such as conduction disturbances, myocardial infarction, cardiogenic shock, or even death, the results are generally good (13–14). It has been reported that high-speed rotablation may cause platelet aggregation/activation of platelet-rich plasma and distal flow disturbance during RA procedures, and the ablated particles may be a cause of the slow-flow phenomenon during RA procedures (15). During ablation of the plaque, microparticles are produced by the advancing burr, and experimental studies suggested that these particles pass harmlessly through the distal microcirculation. In our study, 5 patients suffered severe coronary spasm, with 1 patient having significant chest pain and 4 patients having the slow-flow phenomenon after the procedure, which were successfully alleviated by 100–300 µg intracoronary sodium nitroprusside infusion via a microcatheter without inducing low blood pressure. Although for ACS or RA, microembolism resulted in thrombus or small plaques; therefore, sufficient antiplatelet therapy, particularly before the procedure, is pivotal (16). In our experience, distal use of a small dose of nitroprusside by a microcatheter is the most useful method. Although the TIMI flow regained after nitroprusside injection from a microcatheter, the post-procedural troponin I level elevation is still high (44%).

Study limitations

There were several limitations in this study. First, this was a two-center experience with RA for calcified lesions. Second, no control group was used to compare the long-term efficacy of RA with other procedures. Third, the rate of follow-up angiography was limited to 80% of the total 47 patients at 1 year and 60% of 47 patients at 3 years. Fourth, this was only a retrospective study; therefore, a prospective study should be performed to address the unanswered questions. Finally, the IVUS-guided evaluation of the calcified vessels was performed only in a small proportion of the included patients (18.38%), and these may cause a bias for the overall study.

Conclusion

Our study showed that the transradial approach for RA with a small burr is feasible and safe for heavily calcified coronary lesions in most cases, and this procedure is associated with a high success rate and a satisfactory long-term outcome.

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Conflict of interest: None declared.

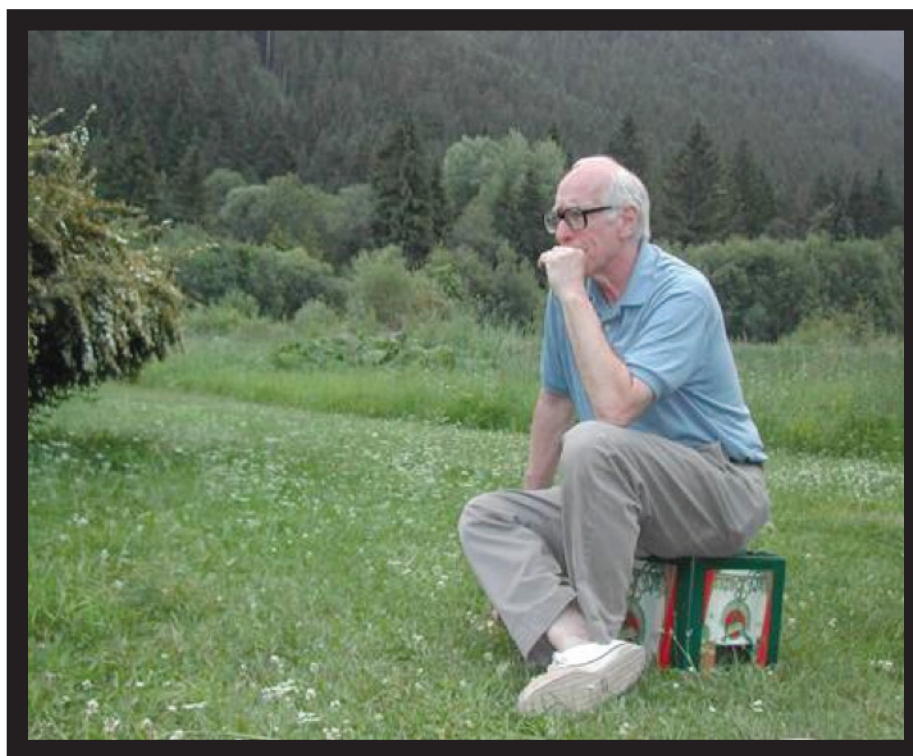
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