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Percutaneous Coronary Intervention

Advantages of Transradial Rotational Atherectomy versus Transfemoral Approach in Elderly Patients with Hard-Handling Calcified Coronary Lesions – A Single Center Experience

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Background: Balloons cannot pass through severely calcified coronary lesion (SCCL), and sometimes they cannot be opened at a high pressure even if they can pass through the lesion. There are limited data on rotational atherectomy (RA) via transradial access (TRA) in this setting. The aim of this study was to evaluate in-hospital and 1-year outcomes in elderly patients with SCCL who underwent RA via TRA.
Methods: Eighty-six consecutive elderly patients with de novo SCCL who underwent RA were enrolled and divided into TRA (n = 45) and transfemoral access (TFA, n = 41) groups in this retrospective analysis from 2008 to 2013. Baseline characteristics and in-hospital and 1-year endpoints were compared between both groups.
Results: Compared to TFA, 6Fr guide catheters were used significantly more in the radial approach (p < 0.001). In the TRA group, the rate of burr size (1.25 mm) was higher and the mean burr size was smaller (p = 0.021) than that in the TFA group. Vascular access site complications, bed rest time and hospital stay were significantly lower in the TRA group compared with the TFA group (p = 0.029, < 0.001, < 0.001, respectively). However, there was no significant difference in major adverse cardiac events during hospitalization and after 1 year follow-up between both groups (p = 0.338, 1.000, respectively).
Conclusions: TRA is a useful alternative to TFA in elderly patient with SCCL. The advantages of TRA over TFA include reduced time of bed rest and hospital stay and vascular complications at the puncture site.

Key Words: Calcification • Elderly • Radial artery

INTRODUCTION

Severely calcified coronary lesions (SCCL) are a challenge for interventional cardiologists. It is difficult to pass a stent or even a small balloon through SCCL, especially when accompanied by vessel geometry changes.[1] Even if the stent is successfully delivered to the target lesion, it cannot always fully expand, resulting in high rates of stent thrombus formation and in-stent restenosis.[2]

Rotational atherectomy (RA) or rotablation is used to remove calcified plaques by ablation with a high-speed rotating burr, and was first used in human coronary arteries as a standard angioplasty equipment in 1988.[3] RA can facilitate stent delivery by modifying plaque anatomy and smoothing inner vascular lumen in patients with SCCL.[4,5] Initially, the concept of RA was focused on complete debulking, with a suggested burr to artery ratio of 0.8. Thus, 7Fr and 8Fr sheaths were needed to accommodate 2.0- and 2.25-mm burrs by transfemoral rotational atherectomy (TFRA), respectively. Now-

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adays, plaque modification is performed instead of complete debulking in RA, and a burr to artery ratio of less than 0.7 is recommended to allow for the use of smaller sheaths and guide catheters.[4,6] Transradial interventions have been shown to be associated with a lower incidence of vascular access site complications compared to transfemoral interventions, particularly in elderly patients at high risk of vascular complications such as hematoma and bleeding at the puncture site.[7] Therefore, transradial rotational atherectomy (TRRA) can be used in RA for SCCL in elderly patients.

However, TRRA is not as popular as TFRA in elderly patients. The purpose of this retrospective study was to evaluate the in-hospital results and 1-year follow-up outcomes of elderly patients with SCCL who underwent RA prior to stent implantation via a transradial approach in our hospital.

MATERIALS AND METHODS

Patients

Eighty-six consecutive elderly patients (age > 65 years) with de novo SCCL who underwent RA from January 2008 to February 2013 in our hospital were enrolled into this retrospective analysis. We used transradial access (TRA) as the preferred route for RA and reserved transfemoral access (TFA) for the patients with a failed transradial approach before the procedure, and planned to use a ≥ 1.75-mm burr or a 7Fr guiding catheter. Eventually, the RA procedure was performed in 45 (52%) of 86 patients via radial access (TRRA group), and in 41 (48%) patients via the femoral approach (TFRA group). The Ethics Committee of our hospital approved this study protocol.

Procedure and relevant medications

During hospitalization, all patients were given aspirin (100 mg per day) and clopidogrel (75 mg per day) routinely, and a loading dose of clopidogrel (300 mg) was prescribed 6-24 hours before coronary angiography (CAG) and percutaneous coronary intervention (PCI). During PCI, a bolus of unfractionated heparin (100-120 U/kg) was administered immediately after insertion of the arterial sheath to maintain an activated clotting time (ACT) > 300 seconds. After the PCI, all of the patients were advised to take aspirin (100 mg per day) for life and clopidogrel (75 mg per day) for at least 12 months according to current guidelines. CAG was performed in all patients, and angiographic measurements were analyzed by one experienced angiographer blinded to the data of the patients.

Three qualified and experienced operators performed RA at our institution. In all cases, RA was performed using a special rotablator device (Boston-Scientific, Natick MA, USA). A 0.009 inch (1 inch = 2.54 cm) RotaWire guidewire was passed through the target lesion directly or exchanged with a workhorse wire through a microcatheter. A smaller burr (usually 1.25 mm or 1.5 mm) was used first, followed by a larger burr (1.5 mm or 1.75 mm) according to the size of the distal reference vessel, reaching a burr to vessel ratio that did not exceed 0.7. During activation of the Rotablator device, a heparinized normal saline solution with verapamil and nitroglycerine was administered locally, with a view to prevent thrombus formation and vascular spasm and avoid the no-reflow phenomenon. In addition, a temporary pacemaker was inserted during a dominant right coronary artery or left circumflex artery rotablation. RA was performed using the pecking motion technique with an initial speed of 140000 rpm and at least 220000 rpm. We strictly confined the use of the rota burr to the predetermined atherectomy region. The duration of rota application was 15-20 s, with immediate cessation if the speed dropped by > 5000 rpm. After successful RA, a compliant balloon or a non-compliant balloon was used to predilate the target lesion which was sequentially stented with a drug-eluting stent (DES) and bare metal stent (BMS).

Endpoints and clinical follow-up

The primary endpoints included the success rate of the procedure (including RA and stenting), the rate of occurrence of in-hospital major adverse cardiac events (MACEs) and MACEs at follow-up after 1 year. Secondary endpoints included the incidence of vascular complications, RA-related complications and stenting-related complications during the procedure.

All of the patients were followed up after leaving hospital. Phone interviews were carried out every 3 months, while clinical and angiographic follow-up visits were performed at 1 year after the PCI unless clinically indicated earlier.

Definitions

Calcification was identified as readily apparent radiopacities within the vascular wall at the site of stenosis, and was classified as none, mild, moderate (radiopacities noted only during the cardiac cycle before contrast injection), and severe (radiopacities noted without cardiac motion before contrast injection generally compromising both sides of the arterial lumen). Intravascular ultrasound (IVUS) identification of tissue calcium (brighter than the reference adventitia and with shadowing of deeper arterial structures) was also performed.[8] Calcification was further classified as none, one-quadrant (≤ 90°), two-quadrant (91° to 180°), three-quadrant (181° to 270°), or four-quadrant (271° to 360°) calcification. If there was more than one calcific deposit in a given imaging slice, then the arcs of calcium were added. Severe calcium was defined as an arc of calcium ≥ 270°.[8,9] Procedural success was defined as an angiographic residual stenosis < 30% with thrombolysis in myocardial infarction (TIMI) flow of 3 in the target vessel without any in-hospital MACEs [including cardiac death, non-fatal myocardial infarction (MI), and repeat target vessel revascularization (TVR)].

Cardiac death was defined as death with a definite cardiac cause or without a non-cardiac cause that was established clinically. Non-fatal MI was defined as an increase in creatine kinase-MB (CK-MB) plasma level by more than 3 times the upper normal limit during hospitalization, or more than 2 times the upper normal limit during the follow-up period. Repeat TVR was defined as any repeat PCI or surgical bypass of any segment of the target vessel.[10] Vascular complications included severe vessel spasms needing a changed approach, access hematoma over 5 cm, pseudoaneurysm, arteriovenous fistula and needing a vascular closure device or surgery.[11] RA-related complications included target vessel dissection, intramural hematoma, slow flow or no reflow, side branch occlusion, distal embolization and perforation after RA.[12,13] Stenting-related complications included target vessel dissection, intramural hematoma, slow flow or no reflow, side branch occlusion, distal embolization and perforation after stenting.

Statistical analysis

All statistical analyses were performed using SPSS version 16.0 (SPSS Inc., Chicago, USA). Continuous variables were presented as mean ± standard deviation (SD) and were compared using the Student's *t*-test (Gaussian distribution) and non-parametric Mann-Whitney U test (non-Gaussian distribution). Categorical data were described as percentages and were analyzed using Fisher's exact test and the chi-square test. A p value < 0.05 was considered to be statistically significant.

RESULTS

Basic characteristics of the 86 study patients

The baseline demographic and clinical characteristics of the 86 study patients are shown in Table 1. The patients in the TRRA and TFRA groups were well matched for clinical characteristics. There were no obvious differences in gender, diabetes, hypertension, hyperlipidemia, tobacco use, previous MI, history of PCI or coronary artery bypass grafting (CABG) and renal insufficiency between the two groups (p = 0.111, 0.514, 0.188, 0.825, 0.278, 0.666, 1.000, 0.344, 0.613, respectively). There were also no significant differences in age and left ventricular ejection fraction (LVEF) between the TRRA and TFRA groups (p = 0.811, 0.612). In addition, there were also no significant differences in the use of medications [including aspirin, statins, beta-blockers, angiotensin converting enzyme inhibitors (ACEIs)/angiotensin receptor blockers (ARBs) and calcium antagonists between the two groups (p = 0.359, 0.267, 0.193, 0.522, 0.621, respectively)].

Angiographic demographics, procedural characteristics and quantitative coronary angiography analysis

CAG revealed that there were no significant differences in the number of diseased vessels, target vessels and American College of Cardiology (ACC)/American Heart Association (AHA) lesion type between both groups (p = 0.106, 0.511, 0.829, respectively). IVUS was used to identify the heavily calcified lesion in the patients with SCCL as IVUS can pass through narrow sites. If the balloon could not pass through the target calcified vessel or could not be dilated if it could pass also indicated that the calcified lesions were severe and heavy. This indicated that these heavily calcified lesions had to be handled by rotation. Furthermore, in the heavily calcified le-

Table 1. Basic clinical characteristics of the 86 study patients

Variables	TRRA group (n = 45)	TFRA group (n = 41)	p value
Age (years)	75.6 ± 5.8	76.2 ± 7.4	0.811
Male gender	34 (75.6%)	24 (58.5%)	0.111
Diabetes	20 (44.4%)	15 (36.6%)	0.514
Hypertension	30 (66.7%)	21 (51.2%)	0.188
Hyperlipidemia	16 (35.6%)	16 (39.0%)	0.825
Tobacco use	28 (62.2%)	20 (48.8%)	0.278
Previous MI	2 (4.4%)	3 (7.3%)	0.666
History of PCI	6 (13.3%)	5 (12.2%)	1.000
History of CABG	1 (2.2%)	3 (7.3%)	0.344
LVEF (%)	44.2 ± 5.6	43.5 ± 4.1	0.612
Renal insufficiency (eGFR < 30 mL/min)	2 (4.4%)	1 (2.4%)	0.613
Previousdrug medications			
Aspirin	12 (26.7%)	15 (36.6%)	0.359
Statins	14 (31.1%)	18 (43.9%)	0.267
Beta-blockers	7 (15.6%)	12 (29.3%)	0.193
ACEI/ARB	22 (48.9%)	17 (41.5%)	0.522
Calcium antagonists	13 (28.9%)	9 (22.0%)	0.621

ACEI, angiotensin converting enzyme inhibitor; ARB, angiotensin receptor blocker; CABG, coronary artery bypass grafting; eGFR, estimated glomerular filtration rate; LVEF, left ventricular eject fraction; MI, myocardial infarction; PCI, percutanous coronary intervention; TFRA, transfemoral rotation atherectomy; TRRA, transradial rotational atherectomy.

sions before rotation identified by IVUS, there were no significant differences in balloon passing and no balloon dilation rates between the two groups (p = 0.081, 0.222, 0.222, respectively) (Table 2).

Notably, more 6Fr guide catheters were used in the radial approach compared with the femoral approach (p < 0.001). The number of burrs, burr size (1.5 mm or 1.75 mm), rotational speed and rotation-related complications were not significantly different between both groups (p = 0.056, 0.966, 0.723, 0.065, 0.862, respectively). However, the burr size (1.25 mm) in the TRRA group was obviously higher compared to the TFRA group, and the mean burr size in the TRRA group was smaller than that in the TFRA group (p = 0.021, 0.040, respectively) (Table 2).

There were no significant differences in implantable stent type (BMS and DES), successful stent implantation and stenting-related complications between the TRRA and TFRA groups (p = 0.337, 0.334, 0.187, 0.603, respectively). In addition, fluoroscopy time, contrast amount and total procedure time in the TRRA group were similar to the TFRA group (p = 0.910, 0.122, 0.782, respectively). However, vascular complications at the puncture site, bed rest time and hospital stay in the TRRA group were obviously lower compared to the TFRA group (p = 0.029, < 0.001, < 0.001, respectively). These results revealed that TRRA had some advantages over TFRA in decreasing vascular complications at the puncture site, bed rest time and hospital stay in the elderly patients with difficult to handle calcified coronary lesions (Table 2).

Nine SCCL were totally occluded in the TRRA group compared to seven in the TFRA group, and thus their reference vessel diameter (RVD) could not be measured. The results of quantitative coronary angiography (QCA) analysis are shown in Table 3. RVD, minimum lumen diameter (MLD) and diameter stenosis (DS) at baseline and post-procedure were similar between both groups (p = 0.635, 0.282, 0.423, 0.103, 0.079, 0.352, respectively). In addition, stent diameter (maximum and minimum), stent length and stent number in the TRRA group were also similar to those of the TFRA group (p = 0.163, 0.124, 0.792, 0.298, respectively). This indicated that TRRA had a similar effect on stent implantation as TFRA.

Clinical outcomes during hospitalization and after 1 year of follow-up

Table 4 lists the clinical outcomes during hospitalization and after 1 year of follow-up. There were no signifi-

Table 2. Angiographic demographics and procedural characteristics

Variables	TRRA group (n = 45)	TFRA group (n = 41)	p value
Diseased vessel number			0.106
Single-vessle	15 (33.3%)	8 (19.5%)	
Double-vessle	22 (48.9%)	18 (43.9%)	
Triple-vessle	8 (17.8%)	15 (36.6%)	
Target vessel			0.511
LAD	30 (66.7%)	31 (75.6%)	
LCx	5 (11.1%)	2 (4.9%)	
RCA	10 (22.2%)	8 (19.5%)	
ACC/AHA lesion type			0.829
B	20 (44.4%)	20 (48.8%)	
C	25 (55.6%)	21 (51.2%)	
Guide catheter diameter			< 0.001
6F	22 (48.9%)	0 (0%)	
7F	23 (51.1%)	41 (100%)	
Heavily calcified lesion before rotation			
IVUS guidance	19 (42.2%)	10 (24.4%)	0.081
No balloon passing	32 (71.1%)	24 (58.5%)	0.222
No balloon dilation	13 (28.9%)	17 (41.5%)	0.222
Burr number			0.056
1 burr	43 (95.6%)	34 (82.9%)	
2 burrs	2 (4.4%)	7 (17.1%)	
Burr size			
1.25 mm	30 (73.2%)	23 (51.1%)	0.021
1.5 mm	15 (36.6%)	22 (48.9%)	0.966
1.75 mm	2 (4.9%)	3 (6.7%)	0.723
Mean burr size (mm)	1.41 ± 0.32	1.63 ± 0.63	0.040
Rotational speed	16.80 ± 1.84	16.10 ± 1.68	0.065
Rotation related complications	6 (13.3%)	6 (14.6%)	0.862
Perforation	2 (4.4%)	3 (7.3%)	0.570
Dissection	4 (8.9%)	3 (7.3%)	0.790
Implantable stent type			
BMS	1 (2.2%)	0 (0.0%)	0.337
DES	43 (95.6%)	37 (90.2%)	0.334
Successful stent implantation	44 (97.8%)	37 (90.2%)	0.187
Stenting related complications	1 (2.2%)	2 (4.9%)	0.603
Dissection	0 (0.0%)	1 (2.4%)	0.292
Slow blood flow	1 (2.2%)	1 (2.4%)	0.947
Fluoroscopy time (min)	25.3 ± 15.6	26.5 ± 18.7	0.910
Contrast amount (ml)	146.3 ± 46.5	163.3 ± 66.5	0.122
Total procedure time (min)	87.7 ± 43.1	90.0 ± 42.7	0.782
Vascular complications	2 (4.4%)	8 (19.5%)	0.029
Pseudoaneurysm	0 (0.0%)	3 (7.3%)	0.065
Arteriovenous fistula	1 (2.2%)	2 (4.9%)	0.503
Subcutaneous hematoma	1 (2.2%)	3 (7.3%)	0.262
Bed rest time (h)	9.1 ± 18.0	38.4 ± 25.8	< 0.001
Hospital day (d)	3.8 ± 1.5	5.3 ± 1.7	< 0.001

ACC, American College of Cardiology; AHA, American Heart Association; BMS, bare metal stent; DES, drug-eluting stent; IVUS, intra vascular ultrasound; LAD, left anterior descending artery; LCx, left circumflex artery; RCA, right coronary artery; TFRA, transfemoral rotation atherectomy; TRRA, transradial rotational atherectomy.

Table 3. QCA analysis between TRRA and TFRA groups

Variables	n	TRRA group	n	TFRA group	p value
Baseline QCA					
RVD (mm)	36	2.37 ± 0.50	34	2.31 ± 0.53	0.635
MLD (mm)	45	0.83 ± 0.49	41	0.70 ± 0.56	0.282
DS (%)	45	65.06 ± 0.49	41	69.73 ± 55.71	0.423
Post-procedural QCA					
RVD (mm)	36	3.10 ± 0.77	34	2.83 ± 0.46	0.103
MLD (mm)	45	2.85 ± 0.80	41	2.55 ± 0.47	0.079
DS (%)	45	8.09 ± 9.01	41	9.96 ± 6.43	0.352
Stent diameter (mm)					
Max	44	3.02 ± 0.37	37	2.90 ± 0.39	0.163
Min	44	2.63 ± 0.32	37	2.53 ± 0.24	0.124
Stent length (mm)	44	62.80 ± 24.03	37	64.50 ± 33.22	0.792
Stent number	44	2.17 ± 0.80	37	2.40 ± 1.14	0.298

DS, diameter stenosis; MLD, minimum lumen diameter; QCA, quantitative coronary angiography; RVD, reference vessel diameter; TFRA, transfemoral rotation atherectomy; TRRA, transradial rotational atherectomy.

Table 4. Clinical outcome during hospitalization and after one year follow-up

Variables	TRRA group (n = 45)	TFRA group (n = 41)	p value
MACE during hospitalization	4 (8.9%)	7 (17.1%)	0.338
Myocardial infarction	1 (2.2%)	1 (2.4%)	1.000
Cardiac death	0 (0.0%)	1 (2.4%)	0.477
TVR	3 (6.7%)	5 (12.2%)	0.470
MACE at 1 year follow-up	4 (8.9%)	3 (7.3%)	1.000
Myocardial infarction	0 (0.0%)	0 (0.0%)	NS
Cardiac death	1 (2.2%)	0 (0.0%)	1.000
TVR	3 (6.7%)	3 (7.3%)	1.000

MACE, major adverse cardiac events; NS, not significance; TVR, target vessel revascularization; TFRA, transfemoral rotation atherectomy; TRRA, transradial rotational atherectomy.

cant differences in MACEs during hospitalization including MI, cardiac death and TVR between the two groups (p = 0.338, 1.000, 0.477, 0.470, respectively). After 1 year of follow-up, there was no significant difference in MACEs between the two group (p = 1.000). This revealed that in-hospital and 1-year clinical outcomes through TRRA were comparable with the TFRA approach.

DISCUSSION

In this retrospective study, SCCL in elderly patients were identified by CAG analysis and IVUS. Increasing evidence has shown that a balloon cannot pass through calcified lesions and cannot always be opened even at high balloon inflation pressure.[14] We also tried using a balloon to pass through or (and) dilate the SCCL before RA, and if the balloon did not work we used RA to handle the SCCL via a transfemoral or transradial approach. To date, there are limited data on RA using a transradial approach in this setting. The main learning points of this study were as follows: 1) radial access was a useful alternative method to perform RA to treat SCCL in elderly patients; 2) a transradial approach can reduce bed rest time, hospital stay and vascular complications at the puncture site compared to a transfemoral approach; 3) the MACE rate associated with TRRA in the elderly patients with SCCL during hospitalization and after 1 year of follow-up was satisfactory.

RA is becoming a widely used procedure with relatively good results in patients with SCCL, however most of these patients undergo a TFRA approach, which often results in longer bed rest and hospital stay and a higher rate of vascular complications at the puncture site.[15] TRA has significant advantages compared to TFA. TRA can decrease access site-related complications such as bleeding, pseudoaneurysm and retroperitoneal hemorrhage compared with TFA in elderly patients.[7] In this investigation, we also found that TRRA had some advantages over TFRA in reducing vascular-related complications at the puncture site, bed rest time and hospital day in the elderly patients with SCCL.

Currently, the focus of RA is on plaque modification rather than complete debulking, and this can be successfully carried out using smaller burr-to-artery ratios.[16] In the present study, we found that RA could be performed through TRA using 6Fr and 7Fr guiding catheters, and that 7Fr guiding catheters were only used in TFA. Egred reported that a 7Fr transradial complex PCI was feasible and safe in suitable male or female patients.[17] Anatomical variations and severe spasms are the two main reasons for an extraordinarily small radial artery, which can lead to failure of 7Fr sheath insertion.[17,18] Because larger guides were used in the TFRA group, the transradial approach was associated with the use of slightly smaller burr sizes than the TF approach. Our results are similar to those of a study published by Oldroyd.[19] The similar rate of successful stent implantation after RA between the TRRA and TFRA groups further indicated that smaller burr-to-artery ratios were sufficient for plaque compliance alteration and for partial debulking via TRA.

Young and colleges reported that the incidence of in-hospital death or MI was low between both TRRA and TFRA groups, and that there was no statistical significance in adverse event rate (21% vs. 27%, p = 0.135) in SCCL patients.[20] Kotowycz et al. reported that the rate of MACEs (death, MI, or urgent CABG) was much higher in their TFRA group, but that this difference was not statistically significant between the TRRA and TFRA groups in patients with SCCL (14.9 vs. 7.7%, p = 0.26).[21] In this study, the MACE rate during hospitalization and after 1 year of follow-up was also low between the two groups, and there was no obvious difference, revealing that in-hospital and 1-year follow-up MACE rate with TRRA were acceptable in elderly patients with SCCL as compared to a TFRA approach.

Limitations

The main limitations of this study is its retrospective design, and that the sample of the enrolled patients was relatively small and drawn from one center.

CONCLUSIONS

In summary, we demonstrated that TRA was a useful alternative to TFA in elderly patients with SCCL. This approach was associated with a successful procedure, reduced bed rest time and hospital stay, a lower rate of vascular access complications and comparable in-hospital and 1-year clinical outcomes compared to a transfemoral approach.

CONLICTS OF INTEREST

There are no conflicts of interest.

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