Acta Cardiol Sin 2020;36:233–239
Original Article
doi: 10.6515/ACS.202005_36(3).20190922A

Percutaneous Coronary Intervention

The Use and Clinical Outcomes of Single-Burr Rotational Atherectomy: The Experience of a Local Hospital in Taiwan

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Background: Treating heavily calcified lesions is a challenge and is associated with high re-stenosis and target lesion revascularization (TLR). Before stent implantation, lesions must be adequately prepared using rotational atherectomy (RA), which has shown favorable results. The study aims to report our hospital's clinical outcomes when using rotational atherectomy on complex and heavily calcified coronary lesions with a single-burr strategy.
Methods: We retrospectively analyzed 58 patients who underwent percutaneous coronary interventions with RA at our center between December 2006 and April 2017. Data on immediate post-procedural events and major adverse cardiovascular events were collected during follow-up, including cardiovascular death, myocardial infarction, TLR, target vessel revascularization (TVR) and stroke.
Results: Of the 58 patients and 90 lesions treated over 10 years, 88 lesions (97.8%) used only one burr. The intervention procedure success rate was 100%. During a mean follow-up of 41.2 months, 6 patients experienced acute coronary syndrome, 12 required TLR, 2 needed TVR, and 6 died due to a cardiovascular event. We divided lesions into 5 categories. The prevalence of lesions and the burr size most commonly used were: category 1 (ostial lesion, 8.9%, 1.75 mm), category 2 (focal lesion, 20%, 1.75 mm), category 3 (intermediate lesion, 13.3%, 1.5 mm), category 4a (long, looser lesion, 26.7%, 1.5 mm), and category 4b (long, rigid lesion, 31.1%, 1.25 mm).
Conclusions: Rather than a routine step-by-step strategy for RA, this study shows convincing evidence supporting the use of this device to treat complex calcified coronary lesions using a single-burr strategy.

Key Words: Coronary artery disease • Calcified coronary lesions • Rotation atherectomy

INTRODUCTION

Heavily calcified coronary lesions often require numerous, high-pressure balloon inflations to eliminate the stenotic section. However, vessels exposed to high inflation pressure have a higher incidence of perforation and dissection,[1] poor expansion and incomplete stent apposition after angioplasty.[2,3] Calcified lesions often cannot be traversed even with the smallest balloons. Rigid, calcified lesions can also resist dilation, even at the highest balloon pressure, or can cause balloon rupture. Stent delivery to calcified lesions can also present problems, and stents can fail to expand fully due to high resistance from calcified plaques. Rotational atherectomy (RA) is particularly useful for these lesions,[4,5] especially those that are calcified, chronically totally occluded, complex, as well as for bifurcation and left main

Received: September 14, 2018 Accepted: September 22, 2019
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coronary artery lesions. The aim of this study was to evaluate the procedural and clinical outcomes of patients with highly complex, severely calcified coronary lesions treated with RA in our current percutaneous coronary intervention (PCI) practice.

METHODS

The study was conducted according to the Declaration of Helsinki and was approved by the Institutional Review Board of MacKay Memorial Hospital, Taiwan. The study patients' cardiac catheterization reports over the past 10 years were stored in the information system of Taitung MacKay Memorial Hospital. From December 2006 to April 2017, all consecutive patients who required RA treatment for heavily calcified and angiographically significant lesions (≥ 70% stenosis) were selected from the database for evaluation. Patients were excluded if they did not attend a follow-up visit for more than 6 months and did not have a major adverse cardiovascular event (MACE). Sixty-seven patients were enrolled in this study, of whom 9 were excluded (2 cases without complete medical data and 7 cases because they did not attend a follow-up visit for more than 6 months and did not have a MACE). The follow-up rate was 86.6%. The relevant clinical and angiographic data at the time of the PCI were retrieved from the database and completed by fully reviewing the medical records. The angiographic measurements were performed using quantitative analysis software for angiography. The angiographic characteristics of the target coronary lesions were obtained by thoroughly reviewing the cine coronary angiography sessions. Lesions that needed treatment were defined as those with 70% or greater diameter stenosis. EuroSCORE (European System for Cardiac Operative Risk Evaluation) II was calculated during the admission for PCI. The Synergy between PCI with TAXUS^{TM} and Cardiac Surgery (SYNTAX) score for coronary artery diseases was calculated using cine-fluoroscopy at the time the patient underwent diagnostic coronary angiography. All PCIs were performed by a single operator following standard practice in our catheter laboratory room. Patients were pretreated with aspirin, clopidogrel or ticagrelor, along with one or two antiplatelet agents. Heparin was administered to maintain an activated clotting time of > 300 seconds. The burr was inserted via a catheter using a flush solution of verapamil, nitrates, and heparin (5 mg, 5 mg, and 5000 U, respectively, in 500 mL of saline) to prevent friction and placed immediately proximal to the stenosis to avoid damaging the normal vessel segment. Plaque ablation was performed using a "pecking" technique at a mean rotational speed of 140,000-220,000 rpm. Each application lasted 15-20 s and was interrupted immediately if a reduction of more than 5000 rpm was observed (which indicated increased vessel resistance and overheating). The PCI then proceeded with balloon dilation and drug-eluting stent (DES) or bare-metal stent (BMS) implantation to achieve minimal residual stenosis. Dual antiplatelet therapy, with aspirin and clopidogrel, was continued for at least 12 months after the DES implantation and 3 months after the BMS implantation. The procedure was deemed to be successful if stent placement in the lesion was achieved with an angiographic confirmation of < 20% residual stenosis and a thrombolysis in myocardial infarction (TIMI) 3 flow. We analyzed the MACEs, all-cause mortality, myocardial infarction (MI), and repeat revascularization. MI was defined according to current guidelines, and target lesion revascularization (TLR) was defined as a repeat revascularization for restenosis > 50% in the target segment. Target vessel revascularization (TVR) was defined as any repeat revascularization within the treated vessel.

We used descriptive analysis in this study. Continuous variables are presented as mean (standard deviation), and categorical variables as frequencies and percentages.

RESULTS

During the study period, 58 patients with 90 severely calcified coronary lesions, that were successfully treated with RA plus DES or BMS implantation, were recruited into this study and retrospectively analyzed. The study population's clinical and demographic characteristics are shown in Table 1. The mean age of the successfully treated patients was 74.3 ± 9.7 years; 31 patients were male (53.4%), 34 patients (58.9%) had diabetes mellitus, and 53 patients (91.4%) had hypertension. Three patients (5.2%) had undergone prior coronary artery bypass graft surgery (CABG), and 6 patients (10.3%)

had a prior MI. Thirty-seven patients (63.8%) presented with unstable angina, 12 patients presented (20.7%) with non-ST-elevation MI (NSTEMI), and 2 patients (3.4%) presented with ST-elevation MI (STEMI). The mean serum creatinine level was 2.0 ± 2.3 mg/dL.

The angiographic success rate was 100% for the lesions in which the rotablation burr could be delivered to the target lesion and the DES/BMS could be implanted, and those complicated by one coronary perforation but no other major procedural complications. Only 1 coronary artery perforation was wire-related and was improved by prolonged balloon occlusion at the proximal segment. The overall angiographic and procedural characteristics of the patients are presented in Tables 2 and 3. Fifteen patients (25.9%) had double-vessel disease

Table 1. Study patients' clinical characteristics

No. of patients	N = 58	%
Mean age (years)	74.3 ± 9.7	
No. of men, n (%)	31	53.4
Dyslipidemia, n (%)	39	67.2
DM, n (%)	34	58.6
CKD		
Stage 1, n (%)	29	50
Stage 2, n (%)	3	5.2
Stage 3, n (%)	13	22.4
Stage 4, n (%)	5	8.6
Stage 5/hemodialysis, n (%)	8	13.8
HTN	53	91.4
BUN, mg/dL	24.7 ± 16.6	
Cr, mg/dL	2.0 ± 2.3	
Total cholesterol, mg/dL	164.7 ± 37.7	
Triglycerides, mg/dL	156.0 ± 147.5	
Current smokers, n (%)	7	12.1
Ex-smokers, n (%)	15	25.9
Previous CABG, n (%)	3	5.2
Previous PCI, n (%)	20	34.5
Previous AMI, n (%)	6	10.3
EuroSCORE II, %	3.3 ± 4.3	
SYNTAX score, n (%)		
≤ 22	26	44.8
22-33	19	32.8
≥ 33	13	22.4
Clinical presentation, n (%)		
Stable angina	2	3.4
Unstable angina	37	63.8
NSTEMI	12	20.7
STEMI	2	3.4
CHF	5	8.6
Coronary disease, n (%)		
Single-vessel	6	10.3
Double-vessel	15	25.9
Triple-vessel	28	48.3
Left main	10	17

AMI, acute myocardial infarction; BUN, blood urea nitrogen; CABG, coronary artery bypass graft surgery; CHF, chronic heart failure; CKD, chronic kidney disease; Cr, creatinine; DM, diabetes mellitus; HTN, hypertension; NSTEMI, non-ST-elevation myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction.

Table 2. Pre-intervention angiographic characteristics

No. of lesions	N = 90	%
Treated vessel, n (%)		
Anterior descending	64	71.1
Circumflex	10	11.1
Right coronary	14	15.6
Left main	10	11.1
Ostial lesion	22	24.4
Bifurcation	26	28.9
Chronic total occlusion	1	1.1
Lesion classification, n (%)*		
Type B1	0	0
Type B2	15	17.7
Type C	75	83.3

* According to American College of Cardiology/American Heart Association classification.

Table 3. Peri-intervention rotablation characteristics

No. of lesions	N = 90
Other devices	
IABP, n	6
TPM, n	39
IVUS, n	25
Cutting balloons, n	7
Supporting catheter, n	14
Rotational atherectomy	
Mean no. of burrs per vessel	1.02
Mean burr size, mm	1.5 ± 0.2
Minimum burr size, mm	1.25
Maximum burr size, mm	2
Burr-to-vessel ratio	0.5 ± 0.0
Highest speed (rpm)	174132.1 ± 16918.4
Stent	
Total stents implanted, n	90
Bare metal stents, n	24
Drug eluting stents, n	66
No. of stents per vessel (mean)	1.5 ± 0.1
Stent diameter, mm (mean)	3.0 ± 0.4
Total stent length, mm (mean)	27.5 ± 7.4
Angiographic success, n	90
Final TIMI flow, n	90

IABP, intra-aortic balloon pump; IVUS, intravascular ultrasound; TIMI, thrombolysis in myocardial infarction; TPM, temporary pacemaker.

and 28 patients (48.3%) had triple-vessel diseases. Most lesions were located in the left anterior descending artery (71.1%). Approximately 15% of the lesions were located in the right coronary artery, and 11.1% were involved in the left main coronary artery. There was 1 chronic total occlusion (1.1%) and 26 bifurcation lesions (28.9%). The average number of burrs used in each vessel was 1.02, and only 2 lesions (2.2%) needed a second burr in 90 lesions. In the two lesions requiring two burrs, a 1.25-mm burr was used initially. However, the lesions could not be opened fully by non-compliant balloons with a balloon/artery size ratio 1:1 maximal pressure dilatation, and the cutting balloon could not pass through the tight lesion after first burr rotational atherectomy. We then used a 1.5-mm burr for one lesion and a 1.75-mm burr for the other lesion, and the final angiographic results were successful. The mean burr size was 1.5 ± 0.2 mm, and the burr/artery ratio was 0.5. A DES was implanted in 66 lesions (73.3%), and a BMS was implanted in 24 lesions. An intravascular ultrasonography-guided procedure was performed for 25 lesions (27.8%), and temporary pacemakers were employed for a backup heart rate for 39 lesions (43.3%). Six patients underwent intra-aortic balloon pump-assisted procedures due to the risk of cardiogenic shock. The number of stents implanted per lesion was 1.5 ± 0.1, and the total stent length per lesion was 27.5 ± 7.4 mm.

The in-hospital and follow-up clinical outcomes are shown in Table 4. The intervention procedure success rate was 100%, and 21 patients (36.2%) had a MACE including cardiovascular death, MI, TLR, TVR and stroke during a mean follow-up of 41.2 months. The Kaplan-Meier curve of MACE-free survival is presented in Figure 1. TLR and TVR were needed for 12 (20.7%) and 2 (3.4%) patients, respectively, all of whom were successfully reopened by PCI without the need for CABG.

Table 4. Procedural complications and major adverse cardiac events during follow-up

No. of lesions	N = 90	%
Procedural complications, n (%)		
Side branch occlusion	0	0
Coronary perforation/extravasation	1	1
No. of patients	N = 58	%
Non-CV deaths	7	12.1
CV deaths	6	10.3
TVR	2	3.4
TLR	12	20.7
ACS	6	10.3
Stroke	3	5.2
MACE	21	36.2

ACS, acute coronary syndrome; CV, cardiovascular; MACE, major adverse cardiovascular events; TLR, target lesion revascularization; TVR, target vessel revascularization.

DISCUSSION

Heavily calcified lesions present significant challenges for PCI, even with the numerous helpful techniques and devices currently available. These lesions can be treated with RA, reducing vessel difficulty and facilitating subsequent procedures.[6] Although the use of an excimer laser and cutting balloon is a reasonable alternative, the technique is expensive or not available in most catheter rooms.[7] Moreover, excimer lasers are also ineffective for extremely calcified lesions.[8] Although RA is an effective and less expensive de-bulking modality and is readily available in most catheter rooms, the technique is more cumbersome to set up, more difficult to use (especially for distal lesions), and more prone to complications if not adequately prepared or performed.[9,10] The lack of insurance reimbursement for rotablation is,

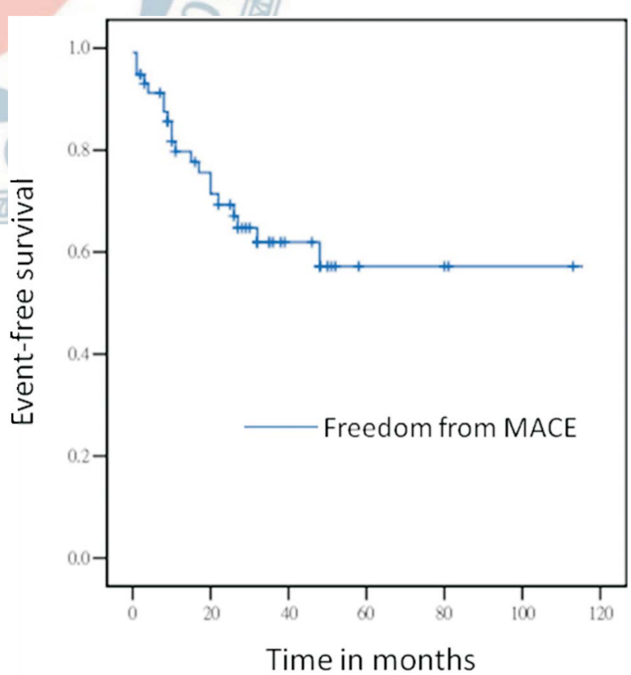

Figure 1. *The Kaplan-Meier curve of the event-free survival.*

however, the most likely reason this device is underused in Taiwan and numerous other countries. Underuse, less familiarity with the device and incorrect use in heavily calcified, complex lesions in high-risk patients can increase the complication rate and worsen the angiographic and clinical outcomes. A European expert consensus suggested that a step-up approach starting with a 1.25-mm burr may be a safer approach. A single 1.5-mm burr is a good compromise for different lesion characteristics, achieving good plaque modification (burr-to-artery ratio of 0.6) and taking into account budgetary constraints.[11] Based on our clinical practice in recent years, we divided lesions into different categories, and our rotablation strategy recommendations are as follows:

1. For ostial lesions, the burr size will almost always need to be greater than 1.5 mm.
2. For focal lesions (lesion length < 10 mm), choose larger burrs with a burr-to-artery ratio of 0.5-0.7.
3. For intermediate lesions (lesion length 10-20 mm), choose a burr with a size to fit a burr-to-artery ratio of ≤ 0.5.
4. For long (lesion length > 20 mm) diffuse or tortuous lesions, two conditions need to be considered:
   a. For looser lesions, select a burr size with a burr-to-artery ratio of approximately 0.5; a 1.5-mm burr is the best choice.
   b. For rigid lesions (≥ 90% stenosis), select a burr size with a burr-to-artery ratio < 0.5. Based on our observations, a 1.25-mm burr is the best option.
5. For other lesions, such as bifurcation lesions, the burr size will depend on the main branch situation and the size should be chosen according to the above recommendations.

According to these recommendations, we classified the lesions as listed in Table 5. The size distribution of the burrs in the 5 categories of lesions is listed in Table 6. The prevalence of category 1 lesions (ostial lesion) was 8.9%, category 2 (focal lesion) was 20%, category 3 (intermediate lesion) was 13.3%, category 4a (long, looser lesion) was 26.7%, and category 4b (long, rigid lesion) was 31.1%. The burr size most commonly used in category 1 was 1.75 mm, compared to 1.75 mm in category 2, 1.5 mm in category 3, 1.5 mm in category 4a, and 1.25 mm in category 4b.

RA should be stopped when the plaque has been sufficiently modified to allow for optimal balloon dilation and stent implantation. Residual dog boning of an inflated balloon with low pressure indicates insufficient plaque modification, meriting further rotablation with a larger burr. A cutting balloon is an excellent assistant for the rotablator. The ratio of the cutting balloon size to vessel should be ≥ 1, however, the size should not exceed 0.5 mm. Assessing the lesion plaque is the key to a successful procedure. The guidelines even suggest increasing the burr size step by step. However, we used a single-burr strategy based on the following advantages: it is more economical, reduces the procedure time, decreases complications, and produces the same result. Following the single-burr strategy, only 2 lesions (2.2%) needed the second burr in 90 lesions. Both of these lesions were treated in the early stage of our case series and all started with 1.25-mm burr with second burrs of 1.5 mm and 1.75 mm. We then reviewed why we needed the second burr. The first case met our strategy recommendation 4a (long, looser lesion), and a 1.5-mm burr was more suitable. The other lesion met strategy recommendation 1 (ostial lesion), and we could have avoided using the second burr if we had chosen a burr > 1.5 mm according to the strategy recommendation. You et al. (2018) reported a single-burr rate of 82.9% in patients with transfemoral rotation atherectomy, compared to 97.8% in our group with a single-burr strategy.[12] The fi-

Table 5. The categories of lesions according by our strategy recommendations

Lesion type of recommendations	N = 90	%
1 (ostial lesion)	8	8.9
2 (focal lesion)	18	20
3 (intermediate lesion)	12	13.3
4a (long, looser lesion)	24	26.7
4b (long, rigid lesion)	28	31.1

Table 6. The size distribution of the burrs in 5 categories of lesions

Lesion type of recommendations	Burr size			
	1.25 mm	1.5 mm	1.75 mm	2 mm
1 (ostial lesion)	1	0	6	2
2 (focal lesion)	0	3	13	2
3 (intermediate lesion)	0	9	3	0
4a (long, looser lesion)	2	23	0	0
4b (long, rigid lesion)	28	0	0	0

nal angiographic stenosis after stenting in all 5 classes of lesions was < 20%.

The coronary artery SYNTAX score in our study was very high. Of all the study lesions, 32.8% had a score of 22-33, and 22.4% scored more than 34 points. The study patients were all at high-risk: 87.9% of the patients presented with acute coronary syndrome (unstable angina + NSTEMI + STEMI), 44.8% presented with more than chronic kidney disease stage II, 58.6% presented with diabetes, and 74.1% had multiple-vessel disease. The final mean stent length was 27.5 ± 7.4 mm. The rates of DES implantation in our study were 73.3% and 62.9% in the acute coronary syndrome registry of Taiwan during 2012-2015.[13] Despite these factors, the angiographic success rate was 100%, and our study results were comparable with those from other studies in the literature.[14-21]

There are several limitations to this study . Due to the lack of national health insurance support in Taiwan, our observational study had a relatively small sample size. In addition, this is a retrospective, medical chart review study, so we excluded the patients who did not attend a follow-up visit for more than 6 months and did not have a MACE to decrease the possibility of underestimating the MACE rate. Furthermore, there was no routine angiographic follow-up of these patients; however, clinically driven follow-up has also been used in most previous studies. Our results showed that the overall MACE rate was relatively low and comparable to studies in real-world practice.

CONCLUSIONS

RA remains an integral tool for enabling optimal angiographic outcomes when treating complex coronary disease involving moderately to severely calcified lesions. RA also ensures stent delivery and appropriate stent deployment in these complex lesions and can be safely performed with low complication and extra-hospital MACE rates, even in high-risk patients. Despite the lack of insurance reimbursements limiting its use, RA using a single-burr strategy has a high procedural success rate and low TLR and cumulative MACE rates, which supports maintaining and even broadening the use of this device in the PCI era.

ACKNOWLEDGMENT

We are grateful to the staff of the cardiac catheterization room at the Taitung MacKay Memorial Hospital for their assistance with the rotational atherectomy and the data recording.

CONFLICT OF INTEREST

All the authors declare no conflict of interest.

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