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ORIGINAL CONTRIBUTION

Rotational Atherectomy Followed by Cutting-Balloon Plaque Modification for Drug-Eluting Stent Implantation in Calcified Coronary Lesions

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Abstract: Background. Drug-eluting stent (DES) underexpansion has been reported as an independent factor for restenosis and thrombosis; therefore, adequate plaque modification prior to DES implantation is the key of calcified lesion treatment. **Methods.** Consecutive patients with severely calcified lesions undergoing rotational atherectomy (RA) followed by balloon dilatation before DES implantation were analyzed. Patients were divided into two groups based on the balloon type before stent implantation: the cutting balloon (ROTACUT group) and the plain balloon (control group). **Results.** Twenty-five patients with 26 calcified lesions were identified: 10 patients (10 lesions) were included in the ROTACUT group and 15 patients (16 lesions) in the control group. There were statistically no differences in the final burr size (1.65 ± 0.21 mm vs 1.67 ± 0.22 mm; *P*=.803), the maximum (max) balloon diameter before stent implantation (2.85 ± 0.34 mm vs 2.72 ± 0.42 mm; *P*=.411), the max final balloon diameter (3.30 ± 0.33 mm vs 3.28 ± 0.44 mm; *P*=.908), and the max final balloon inflation pressure (15.3 ± 3.0 atm vs 16.4 ± 5.5 atm; *P*=.501). Final minimum stent cross-sectional area (CSA) was significantly larger in the ROTACUT group compared to the control group (6.80 ± 1.27 mm^2 vs 5.38 ± 1.89 mm^2; *P*=.048). **Conclusion.** RA followed by cutting balloon plaque modification for DES implantation in severely calcified lesions appears to be more efficacious including significantly larger final stent CSA.

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Key words: drug-eluting stent, rotational atherectomy

Coronary lesions with severe calcification have been classified as complex lesions and are known to carry lower success rates and higher complication rates following percutaneous coronary intervention (PCI).[1,2] In particular, lesion calcium imposes a rigid obstacle to optimal and symmetric stent expansion and results in smaller acute gain compared to non-calcified lesions.[2] DES underexpansion has been reported as an independent factor for restenosis and thrombosis;[3,4] therefore, adequate plaque modification prior to stent implantation is the key of calcified lesion treatment.

Rotational atherectomy (RA; Boston Scientific) can facilitate stent expansion through calcific burden reduction and plaque modification, and improve procedural success rates of PCI for calcified lesions.[2,5,6] Although the rates of target lesion revascularization (TLR) and/or restenosis were not satisfactory when bare-metal stents were used, a few recent studies have shown the encouraging outcomes of patients with calcified lesions undergoing RA followed by drug-eluting stent (DES) implantation.[7-9] In addition, Karvouni et al reported that the use of a cutting balloon (CB; Boston Scientific), without RA, for calcified lesions led to greater acute gain compared to a plain balloon.[10] Yet, little is available on the efficacy of calcified lesion modification with RA in conjunction with CB prior to stent implantation. The aim of this study was to evaluate postprocedural stent expansion in severely calcified coronary lesions requiring RA followed by CB predilatation (ROTACUT) for DES implantation. We hypothesised that aggressive lesion modification with ROTACUT can facilitate stent expansion.

Methods

Study population. From January 2010 to July 2011, a consecutive series of patients with severely calcified *de novo* lesions undergoing RA followed by balloon dilatation before DES implantation was retrospectively identified from our database. Severely calcified lesions were defined visually as ACC/AHA lesion type B or C due to the presence of calcium within the vascular wall at the site of the stenosis that was noted without cardiac motion before contrast injection, generally compromising both sides of the arterial lumen.[8] Patients with myocardial infarction (MI) within the last 72 hours were excluded from the analysis.

Patients were divided into two groups based on the predilatation balloon type prior to stent implantation: the CB (ROTACUT group) and the plain balloon (control group). The selection of the predilatation balloon type was left to the operator's discretion.

Procedure. PCI was performed after obtaining written informed consent. All patients were pretreated with aspirin and either ticlopidine or clopidogrel. A 300 mg loading dose of clopidogrel was administered before the procedure if patients were not pretreated. During interventions, patients received intravenous unfractionated heparin (100 IU/kg) to maintain activated clotting time >300 seconds.

Procedural details of RA have been reviewed elsewhere.[11] Procedures began with 1.25, 1.5, or 1.75 mm burrs with speed of between 180,000 and 200,000 rpm. Care was taken to prevent any drop in rotational speed 5000 rpm using to-and-fro pecking motion of the burr, avoiding long passes. Intracoronary verapamil, heparin, nitroglycerin, and pauses of ablation runs were prophylactically used to control any slow-flow occurring during or after RA. All procedures were carried out with intravascular ultrasound (IVUS) guidance. The first IVUS was performed after RA in all lesions. When the guidewire bias was favorable (IVUS catheter contacted with superficial calcium) and the vessel was large enough, additional RA with a larger burr was performed. Subsequently, balloon dilatation was carried out. In general, the diameter of the balloon was between 0.5 mm smaller and equal to the planned stent size based on vessel media-to-media diameters evaluated by IVUS. When the vessel was diffusely diseased (ie, plaque burden at the reference segment >50%), the planned stent size would be 0.25 mm or 0.5 mm smaller than media-to-media diameters to avoid the stent edge dissection. The second IVUS was performed after the balloon predilatation to evaluate if the superficial calcium was cracked and the vessel was dissected, both signs of optimal stent expansion. In case no cracks of the superficial calcium or vessel dissection were documented by IVUS, additional larger balloon dilatation was carried out. Stents were deployed after confirmation of full balloon expansion. Non-compliant (NC) balloon postdilatation after stenting was considered when IVUS revealed the stent underexpansion based on the AVIO (Angiographic Versus IVUS Optimization Trial) criterion.[12]

Clinical definitions and follow-up. *Chronic kidney disease* was defined as the presence of previously documented renal failure and/or a baseline estimated glomerular filtration ratio (eGFR) <60 mL/min/1.73 m^2. *Chronic total occlusions* were defined as Thrombolysis In Myocardial Infarction (TIMI) grade 0 flow with a duration >3 months, estimated from clinical events or proven by previous angiography, or undetermined.[13] Procedural success was defined as a final residual stenosis <30% and TIMI 3 flow without in-hospital major adverse cardiovascular and cerebrovascular events (MACCE). *MACCE* were defined as death, stroke, MI, and repeat revascularization. *Periprocedural non-Q wave MI* was defined as an increase in CK-MB 3 times the normal range, Q-wave MI when a new Q-wave developed. *Stent thrombosis* was defined according to the Academic Research Consortium (ARC) definition.[14]

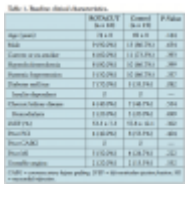
Clinical follow-up was conducted by telephone contact or office visit at 6 months for both groups.

Quantitative coronary angiographic analysis. Cineangiograms were analyzed with a validated edge-detection system (CMS, version 6.0; MEDIS). Analysis was performed inside the stent and within the 5 mm proximal and distal to the stented segment.

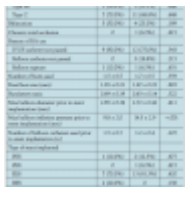
Intravascular ultrasonographic analysis. Off-line IVUS analyses were performed with the use of planimetry software (ECHOPLAQUE 3.0, Indec Systems). Quantitative IVUS measurements included the diameters and the cross-sectional areas (CSA) of the stent and the external elastic membrane.

Statistical analysis. Continuous variables are presented as mean ± standard deviation and categorical variables as frequencies and percentages. Data were statistically analyzed with SPSS version 19 (SPSS Inc.). Continuous variables were compared using independent sample t-test. Categorical variables were compared with chi-square statistics or Fisher's exact test. Fisher's exact test was used when any expected cell count was <5 (not resulting from missing rows or columns in a larger table).

Results

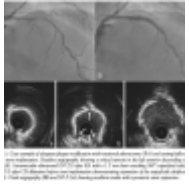


Baseline and procedural characteristics. A total of 25 patients with 26 *de novo* severely calcified coronary lesions were identified. Of those, 10 patients (with 10 lesions) were included in the ROTACUT group and 15 patients (with 16 lesions) in the control group. Baseline clinical, lesion, and procedural characteristics are shown in Tables 1 and 2. In particular, the full details of the procedural characteristics of the ROTACUT group are reported in Table 3. All CB were successfully delivered after RA and no crossovers between two groups



were recorded. Compared to the control group, the ROTACUT group had lower balloon inflation pressure before stent implantation (9.8 ± 2.0 atm vs 14.5 ± 2.9 atm; *P*<.001). There were statistically no differences between the final burr size (1.65 ± 0.21 mm vs 1.67 ± 0.22 mm; *P*=.803), the burr/artery ratio (0.69 ± 0.19 vs 0.63 ± 0.14; *P*=.322), the maximum (max) balloon diameter prior to stent implantation (2.85 ± 0.34 mm vs 2.72 ± 0.42 mm; *P*=.411), the max final balloon diameter (3.30 ±
0.33 mm vs 3.28 ± 0.44; *P*=.908), and the max final balloon inflation pressure (15.3 ± 3.0 atm vs 16.4 ± 5.5 atm; *P*=.501). The rate of NC balloon postdilatation was 70% in the ROTACUT group and 93.8% in the control

group (*P*=.142). The number of balloon catheters used per lesion was not significantly different but smaller in the ROTACUT group compared to the control group (2.3 ± 0.8 vs 2.6 ± 0.9; *P*=.460). Figure 1 illustrates the efficacy of RA followed by CB before stent implantation (Case 4, Table 3). Superficial calcium was separated after CB dilatation (Figure 1b) and the stent was symmetrically well expanded (Figure 1c).



Procedural complications. No-flow subsequent to RA was recorded in 2 lesions: 1 each in both groups (10.0% vs 6.3%; *P*=.631), which recovered to TIMI 3 flow after intracoronary nitroprusside injection. No coronary perforations or severe spasms were recorded.

There was only one CB-related complication: rupture of the CB (Case 4, Table 3). The 2.5 mm CB was not fully dilated due to the hard calcium of the lesion and multiple dilatations at 10 atm (the rated burst pressure of 12 atm) with rotation of the CB to change the position of the blades were performed before the rupture. The ruptured CB was not directly retrieved because of the undilated calcified segment. Subsequently, the CB was distally placed and another guidewire was inserted to bring an NC balloon into the undilated segment. A 2.5 mm NC balloon was fully dilated at 16 atm and the ruptured CB was successfully retrieved. Additional 3.25 mm CB dilatation was performed prior to stent implantation.

Quantitative angiographic and intravascular ultrasonographic results. The quantitative angiographic and IVUS results are reported in Table 4. Final lesion minimum (min) stent diameter and stent CSA were significantly larger in the ROTACUT group compared to the control group (2.65 ± 0.25 mm vs 2.28 ± 0.44 mm *P*=.025; 6.80 ± 1.27 mm^2 vs 5.38 ± 1.89 mm^2; *P*=.048).

In-hospital and clinical outcomes. Procedural success rate was 100% in both groups. No stent thromboses were recorded during hospitalization and all patients discharged in stable condition. No MACCE or stent thromboses were recorded at 6-month clinical follow-up in both groups.

Discussion

The main finding of this study was that the min stent CSA in the ROTACUT group was significantly larger than the control group, although the max final balloon diameter and balloon inflation pressure were not different. This supports the hypothesis that aggressive lesion modification with ROTACUT before DES implantation in severely calcified lesions can facilitate stent expansion. On the other hand, DES underexpansion is associated with stent restenosis and thrombosis.[3,4] Thus, ROTACUT prior to DES implantation in calcified lesions can hypothetically reduce both stent restenosis and thrombosis. Furthermore, this is, to the best of our knowledge, the first study comparing the ROTACUT approach to the conventional approach with RA followed by plain balloon dilatation before stent implantation in calcified lesions. Palmer et al reported a successful case with a calcified lesion undergoing ROTACUT prior to stent implantation.[15] Vaquerizo et al reported that calcified plaque modification by RA and/or CB before DES implantation in 145 consecutive patients with 164 lesions provided the low rates of TLR of 3.4% and stent thrombosis of 2.1% at 15 ± 11 months follow-up.[16] Of those, ROTACUT was performed in 45 lesions; however, no specific data on ROTACUT were available.

Previous studies demonstrated that the use of RA prior to stent implantation in calcified lesions resulted in greater acute stent diameter and CSA gain, compared to pretreatment with a plain balloon.[2] However, calcified plaque modification only with RA may be insufficient, especially for large proximal vessels because of the limitation of the burr size. CB is a unique device consisting of a balloon catheter with 3 (<3.5 mm) or 4 (3.5-4.0 mm) blades that create longitudinal incisions in the atherosclerotic lesion during balloon inflation. As shown in Figure 1, CB can separate the superficial calcium and lead to better stent expansion. In addition, CB is useful to better control the vessel dissection and avoid further distal extension of the dissection or intramural hematoma, which requires longer stenting. There has been great concern on delivery failure of CB into severely calcified lesions because of its larger profile and rigidity compared to a plain balloon. RA can facilitate delivery of CB into such lesions. Furthermore, IVUS guidance is mandatory for the ROTACUT approach to select the optimal size of CB, stents, and postdilatation NC balloons (if needed). Precise IVUS-guided procedure is quite important not only to avoid vessel rupture but also to evaluate if the plaque modification is enough for stenting when dealing with severely calcified lesions.

Study limitations. The present study has some limitations. It is a retrospective study reflecting the experience of a single institution. The selection of the predilatation balloon type prior to stent implantation was at the operator's discretion. In addition, the sample size is too small to draw any definitive conclusions. However, we feel that ROTACUT lesion preparation prior to stent implantation for severely calcified lesions may be superior to the conventional approach with RA and a plain balloon in terms of optimal stent expansion. Further studies are needed to fully clarify our hypothesis.

Conclusions

The ROTACUT approach for DES implantation in severely calcified lesions is feasible and more efficacious compared to the conventional approach with RA followed by a plain balloon dilatation. It yields a significantly larger final stent CSA. The next step is a randomized clinical trial of ROTAtional atherectomy followed by

CUTting balloon plaque modification for drug-eluting stent implantation in calcified coronary lesions (ROTACUT).

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