Symposium: Rotational atherectomy updating

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Application of rotational atherectomy in the drug-eluting stent era

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Abstract

Rotational atherectomy (RA) was introduced in the interventional arena in 1988 as a dedicated device for calcified lesions. Due to the complexity of the technique, the development of alternative methods such as the cutting balloon procedure, and the high restenosis rate of subsequent bare metal stenting in long lesions, its use had later declined. However, with the increasing use of drug-eluting stents (DES) and the aggressive treatment of longer lesions, the number of procedure performed with RA has increased significantly again in recent years. In this article, we reviewed the application of RA in DES era.

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1 Introduction

Rotational atherectomy (RA) was introduced in the interventional arena in 1988 as a dedicated device for calcified lesions. Due to the complexity of the technique, the development of alternative methods such as the cutting balloon procedure, and the high restenosis rate of subsequent bare metal stenting in long lesions, its use had later declined. However, with the increasing use of drug-eluting stents (DES) and the aggressive treatment of longer lesions, the numbers of procedure performed with RA have increased significantly again in recent years.

Calcified coronary lesions are a well-known risk factors of short and long-term poor outcomes after both bare metal stent (BMS) and DES implantation. However, RA can facilitate the delivery of stents in severely calcified coronary lesions by modifying plaque anatomy and smoothing inner vascular lumen. Recent reports have suggested that the use of RA in combination with DES implantation to treat severely calcified lesions may achieve high procedural success and an acceptable restenosis rate. However, the long-term efficacy and safety of DES combined with RA in patients with calcified coronary lesions is limited.

2 Basics of rotational atherectomy

Rotational atherectomy (Rotablator, Boston Scientific, MA) usually begins with 1.25, 1.5, or 1.75 mm burrs with a speed between 180,000 and 200,000 r/min. Procedural success is defined as a residual stenosis below 30%. The corresponding anticoagulation therapy consists of weight-adjusted unfractionated heparin (100 U/kg) followed by supplemental boluses to maintain the activated clotting time for more than 300 s. All patients received dual antiplatelet therapy with aspirin and clopidogrel (300–600 mg per loading dose) before the procedure. Post-procedural antiplatelet therapy consisted of 100 mg/d of aspirin and 75 mg/d of clopidogrel, in accordance with procedure guidelines.

3 Rotational atherectomy for uncomplicated lesions

Registry and randomized control trials have failed to show RA can decrease rates of restenosis, or target lesion revascularization (TLR). Although the initial procedural success rate was highest in patients treated with RA (89% (RA) vs. 77% (Excimer Laser) vs. 80% (Balloon angioplasty)), TLR after one year was significantly increased compared to Excimer Laser and balloon angioplasty. Similar results were found in the Randomized Comparison of Balloon Angioplasty versus Rotational Atherectomy in Complex Coronary Lesions (COBRA). Procedural success rate was originally highest with RA (85% vs. 78%);
$P < 0.05$) but no differences were found regarding restenosis, TLR, or symptomatic outcome after six months.\textsuperscript{12} The routine use of RA for simple type A/B1 lesions is not recommended.

4 Rotational atherectomy for in-stent restenosis

Multiple treatment strategies are available for calcified lesions, including plain old balloon angioplasty (POBA), cutting balloons, brachytherapy, drug-eluting balloons and DES implantation. Neointimal hyperplasia is the primary mechanism for in-stent restenosis (ISR) and has been shown in animal models to be more effectively treated with RA than POBA.\textsuperscript{13} Furthermore, the RA causes less baro-trauma to the artery with a greater acute procedural minimum lumen diameter (MLD), which may further decrease the incidence of restenosis. Clinical comparisons of RA to several other methods for the treatment of ISR have shown mixed results. In the Angioplasty versus Rotational Atherectomy for Treatment of Diffuse In-Stent Restenosis Trial (ARTIST), 298 patients randomly received either POBA or RA with adjunctive POBA. This trial showed that there was no difference in acute procedural success. Furthermore, at 6 months, patients treated with POBA had less restenosis (51% vs. 65%; $P = 0.039$) and better event-free survival (91.3% vs. 79.6%; $P = 0.0052$) when compared with RA.\textsuperscript{14} In the Rotational Atherectomy versus Balloon Angioplasty for Diffuse In-Stent Restenosis trial (ROSTER), 200 patients were randomly selected to receive either RA with adjunctive POBA, or POBA alone. With an average follow-up of 12 months, patients treated with RA had lower TLR rates (32% vs. 45%; $P = 0.042$), lower repeat stent use, and less residual intimal hyperplasia by intravascular ultrasound (IVUS).\textsuperscript{15} The major difference between these two trials is that ROSTER was a single center randomized trial performed in the US, whereas the ARTIST trial was a multicenter randomized trial performed in Europe. In addition, patients with underexpanded stents were excluded from the ROSTER trial, whereas they were included in the ARTIST trial. Low pressure balloon angioplasty (< 6 atm) was applied in both trials, which may not adequately treat under deployed stents. Further studies are needed to properly answer this question.

The somewhat controversial data regarding the efficacy of RA in ISR has become less important since the introduction of DES. Now, the best way to treat ISR is to prevent it in the first place. In multiple studies involving the use of DES for the treatment of simple and complex coronary lesions, TLR rates have consistently been below 10% with reduced major adverse cardiac events (MACE) when compared to BMS.\textsuperscript{16–19} These results are far superior in comparison to the historical controls for RA as a stand-alone procedure, or with adjunctive POBA, even in simple coronary lesions.

5 Rotational atherectomy for chronic total occlusions (CTO) & bifurcation lesions

A primary concern in the treatment of CTO is the ability to completely expand the lesion for the optimal deployment of stents, once the lesion has been crossed with a guide wire. Failure to fully expand stents may increase the risk of both stent thrombosis and ISR. Furthermore, restenosis rates of CTO lesions after POBA and stenting remain extremely high.\textsuperscript{20–22} The modification of vessel compliance with RA has been utilized to address these issues. Similar to its use in ISR and native vessels, RA has failed to show a benefit over conventional therapies regarding decreasing long-term restenosis rates, or acute complications.\textsuperscript{23} Mechanical debulking prior to the stenting of bifurcated lesions has also been proposed in order to prevent less plaque shifting (“snow plowing”) while increasing the preservation of side branches. Although no randomized trials have yet been performed to see if RA decreases the rate of restenosis or side branch occlusion, clinical studies have shown mixed benefits.\textsuperscript{24–26}

6 Rotational atherectomy for heavily calcified & complicated lesions

Beatriz V, et al.\textsuperscript{27} performed a study with a series of 164 calcified coronary lesions in 145 consecutive patients who underwent aggressive plaque modification (PM) with either RA and/or the cutting balloon (CB) technique before DES implantation. CB was used in moderate calcified lesions and RA alone, or followed by CB in severe calcified lesions. PM was achieved by using CB in 57% and by RA alone, or followed by CB in 43%. All patients received their DES implantations successfully. At follow-ups at 15 ± 11 months, the overall MACE rate was 9.6% (3.4% cardiac death, 2.3% myocardial infarction, and 3.4% TLR). The only independent predictor of MACE was left ventricular ejection fraction (LVEF) ≤ 50% (odds ratio (OR) 3.88; 95% confidence interval (CI): 1.15–13.1; $P = 0.03$). The incidence of stent thrombosis (ST) was 2.1%. There were no significant differences in MACE and TLR based on the type of PM used.\textsuperscript{27} Clavijo, et al.\textsuperscript{6} reported a death rate of 6.8% at a 6-month median follow-up without in-hospital deaths using sirolimus-eluting stents with RA. The average age in the series was 71.5 ± 9.6 years, 44.4% of patients were diabetic.
and 83.6% had type C lesions. More recently, Shinichi F, et al. reported on a series regarding the use of RA followed by DES only in calcified coronary lesions. The incidence of cumulative MACE, defined as death, myocardial infarction (MI) and target vessel revascularization, was 15.8% at an average follow-up period of 14.7 months. Death occurred in four patients (4.2%), non Q-wave MI occurred in 3 patients (3.2%), and Q wave MI occurred in 2 patients (2.1%). Their study also reported on another series that used RA followed by CB plaque modification for DES implantation in severely calcified lesions that appeared to be more efficacious than the control group, including significantly larger final stent cross-sectional area by measurement of intravascular ultrasound (6.80 ± 1.27 mm² vs. 5.38 ± 1.39 mm²; P = 0.048).

7 Rotational atherectomy and the use of drug-eluting stents

Several unique concerns are involved with the use of DES in severely tortuous and calcified lesions: (1) the vigorous manipulation of DES through calcified lesions can result in the disruption of the polymer coating and decrease its effectiveness in preventing restenosis; (2) suboptimal deployment of DES in such complex lesions may further increase the risk of stent thrombosis already posed by the delayed endothelialization in patients with DES; and (3) local delivery of drugs through a calcified lesion can be greatly impaired. Three studies have specifically investigated the use of DES following RA. In these studies, there was a 98% to 100% procedural success rate, no major adverse cardiac events and less than 10% TLR at follow-up examinations. When DES was compared directly to BMS in patients with heavily calcified lesions that required RA, there was a significant difference in the late lumen loss (0.11 ± 0.2 mm in the DES group and 0.27 ± 0.4 mm in the BMS group, P = 0.001) at nine month follow-ups. This difference was manifest in the clinical event rates at late follow-up (combined endpoint of all cause mortality, MI, and TLR was 15.2% in the DES group and 46.2% in the BMS group; P = 0.004). DES continued to show more clinical benefit than BMS over two years of follow-ups.

8 Conclusions

A strategy combining the RA technique and DES implantation is a safe and effective treatment option for patients with complex lesions. We believe that RA with DES should be considered as an essential technique in certain lesions, especially the calcified lesions visible by fluoroscopy, more than 180 degree of calcification under IVUS study, or the IVUS catheter cannot pass the lesions, and thus, be available in all catheterization laboratories.

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