Journal of Geriatric Cardiology (2013) 10: 213–216

Symposium: Rotational atherectomy updating

· Open Access ·

Guest Editor: Prof. Wei-HsianYin

Application of rotational atherectomy in the drug-eluting stent era

Chun-Chi Chen, I-Chang Hsieh

Department of Second Section of Cardiology, Chang Gung Memorial Hospital, Chang Gung University College of Medicine, Linkou, 5 Fuhsing St., Tao Yuan 333, Taiwan, China

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.

J Geriatr Cardiol 2013; 10: 213–216. doi: 10.3969/j.issn.1671-5411.2013.03.015

Keywords: Rotational atherectomy; Drug-eluting stents; Lesions

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)[1,2] and DES implantation.[3–5] 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.[6–10] However, the long-term efficacy and safety of DES combined with RA in patients with calcified coronary lesions is limited.

Correspondence to: I-Chang Hsieh, MD, Department of Second Section of Cardiology, Chang Gung Memorial Hospital, Chang Gung University College of Medicine, 5 Fuhsing St., Tao Yuan 333, Taiwan, China.
E-mail: hsiehic@gmail.com
Telephone: +886-3-3281200 **Fax:** +886-3-3289134
Received: March 25, 2013 **Revised:** June 19, 2013
Accepted: July 9, 2013 **Published online:** September 28, 2013

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.[11] 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.[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.[13] Furthermore, the RA causes less barotrauma 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.[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).[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.[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 lesons after POBA and stenting remain extremely high.[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.[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.[24–26]

6 Rotational atherectomy for heavily calcified & complicated lesions

Beatriz V, *et al*.[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.[27] Clavijo, *et al*.[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.[6] More recently, Shinichi F, *et al*.[28] 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 mm^2 *vs*. 5.38 ± 1.39 mm^2; $P = 0.048$).[28]

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 endotheliazation 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.[6,29,30] 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 ± 0.7 mm in the DES group and 1.11 ± 0.9 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 7.4% in the DES group and 38.2% in the BMS group; $P = 0.004$). DES continued to show more clinical benefit than BMS over two years of follow-ups.[31]

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.

References

1 Tan K, Sulke N, Taub N, *et al*. Clinical and lesion morphologic determinants of coronary angioplasty success and complications: current experience. *J Am Coll Cardiol* 1995; 25: 855–865.

2 Hoffmann R, Mintz GS, Popma JJ, *et al*. Treatment of calcified coronary lesions with Palmaz-Schatz stents. An intravascular ultrasound study. *Eur Heart J* 1998; 19: 1224–1231.

3 Moussa I, Ellis SG, Jones M, *et al*. Impact of coronary culprit lesion calcium in patients undergoing paclitaxel-eluting stent implantation (a TAXUS-IV substudy). *Am J Cardiol* 2005; 96: 1242–1247.

4 Berenguer A, Mainar V, Bordes P, *et al*. Incidence and predictors of restenosis after sirolimus-eluting stent implantation in high-risk patients. *Am Heart J* 2005; 150: 536–542.

5 Migliorini A, Shehu M, Carrabba N, *et al*. Predictors of outcome after sirolimus- eluting stent implantation for complex in-stent restenosis. *Am J Cardiol* 2005; 96: 1110-1112.

6 Clavijo LC, Steinberg DH, Torguson R, *et al*. Sirolimus-eluting stents and calcified coronary lesions: clinical outcomes of patients treated with and without rotational atherectomy. *Catheter Cardiovasc Interv* 2006; 68: 873–878.

7 Garciade LaraJ , Pinar E, Ramon Gimeno J, *et al*. Percutaneous coronary intervention in heavily calcified lesions using rotational atherectomy and paclitaxel-eluting stents: outcomes at one year. *Rev Esp Cardiol* 2010; 63: 107–110.

8 Furuichi S, Sangiorgi GM, Godino C, *et al*. Rotational atherectomy followed by drug- eluting stent implantation in calcified coronary lesions. *EuroIntervention* 2009; 5: 370–374.

9 Mezilis N, Dardas P, Ninios V, *et al*. Rotablation in the drug eluting era: immediate and long-term results from a single center experience. *J Interv Cardiol* 2010; 23: 249–253.

10 Benezet J, de la Llera LS Diaz, Cubero JM, *et al*. Drug-eluting stents following rotational atherectomy for heavily calcified coronary lesions: long-term clinical outcomes. *J Invasive Cardiol* 2011; 23: 28–32.

11 Reifart N, Vandormael M, Krajcar M, *et al*. Randomized comparison of angioplasty of complex coronary lesions at a single center. Excimer Laser, Rotational Atherectomy, and Balloon Angioplasty Comparison (ERBAC) Study. *Circulation* 1997; 96: 91–98.

12 Dill T, Dietz U, Hamm CW, *et al*. A randomized comparison of balloon angioplasty versus rotational atherectomy in complex coronary lesions (COBRA study). *Eur Heart J* 2000; 21: 1759–1766.

13 McKenna CJ, Wilson SH, Camrud AR, *et al*. Neointimal response following rotational atherectomy compared to balloon angioplasty in a porcine model of coronary in-stent restenosis. *Cathet Cardiovasc Diagn* 1998; 45: 332–336.

14 vom Dahl J, Dietz U, Haager PK, *et al*. Rotational atherectomy does not reduce recurrent in-stent restenosis: Results of the angioplasty versus rotational atherectomy for treatment of diffuse in-stent restenosis trial (ARTIST). *Circulation* 2002; 105: 583–588.
15 Sharma SK, Kini A, Mehran R, *et al*. Randomized trial of Rotational Atherectomy Versus Balloon Angioplasty for Diffuse In-stent Restenosis (ROSTER). *Am Heart J* 2004; 147: 16–22.
16 Stone GW, Ellis SG, Cox DA, *et al*. A polymer-based, paclitaxel-eluting stent in patients with coronary artery disease. *N Engl J Med* 2004; 350: 221–231.
17 Sousa JE, Costa MA, Abizaid A, *et al*. Lack of neointimal proliferation after implantation of sirolimus-coated stents in human coronary arteries: A quantitative coronary angiography and three-dimensional intravascular ultrasound study. *Circulation* 2001; 103: 192–195.
18 Morice MC, Serruys PW, Sousa JE, *et al*. A randomized comparison of a sirolimus-eluting stent with a standard stent for coronary revascularization. *N Engl J Med* 2002; 346: 1773–1780.
19 Moses JW, Leon MB, Popma JJ, *et al*. Sirolimus-eluting stents versus standard stents in patients with stenosis in a native coronary artery. *N Engl J Med* 2003; 349: 1315–1323.
20 Ivanhoe RJ, Weintraub WS, Douglas JS, Jr., *et al*. Percutaneous transluminal coronary angioplasty of chronic total occlusions. Primary success, restenosis, and long-term clinical follow-up. [comment]. *Circulation* 1992; 85: 106–115.
21 Sirnes PA, Golf S, Myreng Y, *et al*. Stenting in Chronic Coronary Occlusion (SICCO): A randomized, controlled trial of adding stent implantation after successful angioplasty. *J Am Coll Cardiol* 1996; 28: 1444–1451.
22 Hancock J, Thomas MR, Holmberg S, *et al*. Randomised trial of elective stenting after successful percutaneous transluminal coronary angioplasty of occluded coronary arteries. *Heart* 1998; 79: 18–23.
23 Gruberg L, Mehran R, Dangas G, *et al*. Effect of plaque debulking and stenting on short- and long-term outcomes after revascularization of chronic total occlusions. *J Am Coll Cardiol* 2000; 35: 151–156.
24 Nageh T, Kulkarni NM, Thomas MR. High-speed rotational atherectomy in the treatment of bifurcation-type coronary lesions. *Cardiology* 2001; 95: 198–205.
25 Cho GY, Lee CW, Hong MK, *et al*. Side-branch occlusion after rotational atherectomy of in-stent restenosis: incidence, predictors, and clinical significance. *Catheter Cardiovasc Interv* 2000; 50: 406–410.
26 Dauerman HL, Higgins PJ, Sparano AM, *et al*. Mechanical debulking versus balloon angioplasty for the treatment of true bifurcation lesions. *J Am Coll Cardiol* 1998; 32: 1845–1852.
27 Beatriz V, Antonio S, Faustino M, *et al*. Aggressive plaque modification with rotational atherectomy and/or cutting balloon before drug-eluting stent implantation for the treatment of calcified coronary lesions. *J Interven Cardiol* 2010; 23: 240–248.
28 Shinichi F, Tetsuya T, Ryuta A, *et al*. Rotational atherectomy followed by cutting-balloon plaque modification for drug-eluting stent implantation in calcified coronary lesions. *J Invasive Cardiol* 2012; 24: 191–195.
29 Minocha G, Chugh S, Agarwal P, *et al*. Rotational atherectomy with sirolimus-eluting stents in calcific lesions: Acute results and long-term outcomes. *Indian Heart J* 2005; 57: 207.
30 Schluter M, Cosgrave J, Tubler T, *et al*. Rotational atherectomy to enable sirolimus-eluting stent implantation in calcified, nondilatable de novo coronary artery lesions: Mid-term clinical and angiographic outcomes. *Vasc Dis Manag* 2007; 4: 63–69.
31 Khattab AA, Otto A, Hochadel M, *et al*. Drug-eluting stents versus bare metal stents following rotational atherectomy for heavily calcified coronary lesions: Late angiographic and clinical follow-up results. *J Interv Cardiol* 2007; 20: 100–106.