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Rotablation in the Drug Eluting Syent Era

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1. Introduction

In the field of interventional cardiology, heavily calcified coronary lesions (HCCL) pose great technical challenges and are associated with a high frequency of restenosis and target lesion revascularization (TLR) (Moses et al, 2004). The prevalence of severe calcium, defined as superficial (calcium at the intimal-lumen interface or closer to the lumen than to the adventitia) with greater than 180° arc, is estimated to present itself in 12% of cases using angiographic imaging. When IVUS guidance is used, it is seen in approximately 26% of cases (Figure 1) (Mintz et al, 2005).

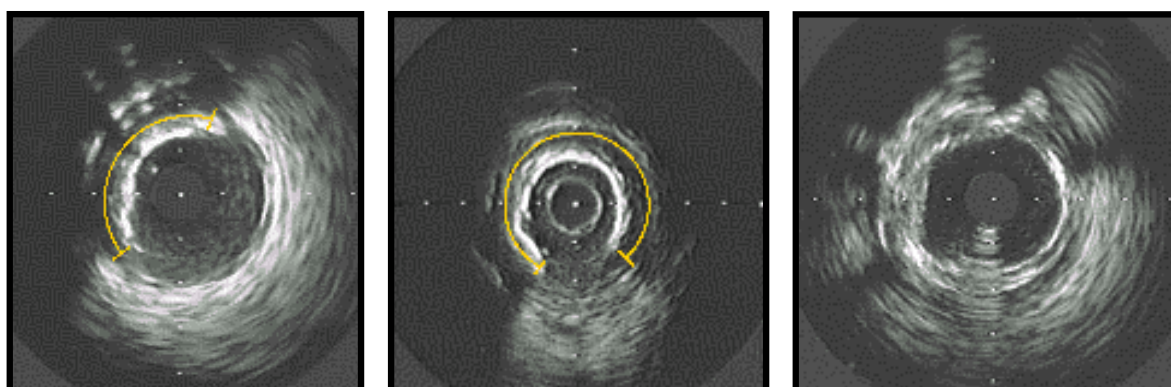


Fig. 1. Calcium distribution: Left: 180°, in the center: 270°, Right: superficial and deep

Occasionally, the degree of calcification and/or the geometry of the plaque prevent the crossing of the lesion with balloon or stent. Adequate lesion preparation before stent implantation remains an essential component of contemporary practice of coronary stent implantation in patients with complex lesions to improve both immediate and long-term outcomes. In heavily calcified lesions preparation with high-pressure balloon inflation may occasionally succeed but is often inadequate, or may create vessel wall rupture (undilatable lesion, figure 2) (Hoffmann et al, 1998).

In an attempt to overcome challenges posed by calcification, a number of devices and techniques have been developed. One such advance is rotational atherectomy, in which a rotating brass burr (figure 3) mounted on a flexible drive shaft and coated with diamond chips pulverizes a portion of the fibrous, calcified, inelastic plaque, modifies the

plaque compliance, and leaves a smooth, nonendothelialized surface with intact media (figure 4).

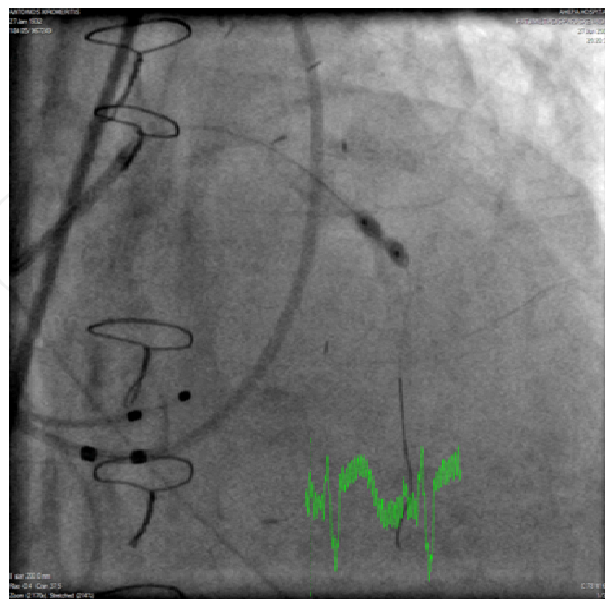


Fig. 2. Undilatable lesion
An undilatable lesion revealed by balloon inflation.

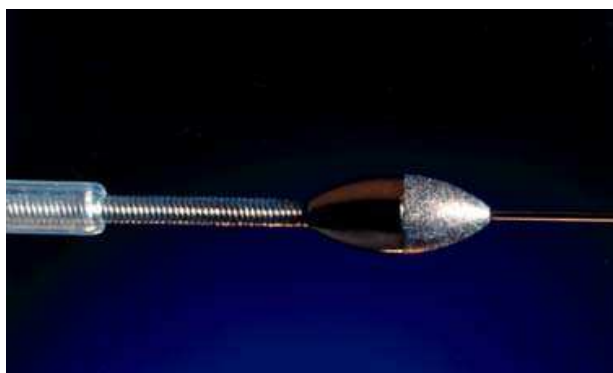


Fig. 3. Rotablator
The rotablator uses a rotating brass burr coated with diamond chips, mounted on to a flexible drive shaft.

Rotational atherectomy overcomes this obstacle through plaque modification of the calcified lesion; however, without adjunctive stenting, restenosis rates remain high (Warth, et al, 1994). Bare metal stents reduce restenosis rates in both calcified and noncalcified coronary lesions with and without atherectomy; however, restenosis and subsequent TLR rates continue to exceed 10-20% (Serruys et al, 1994; Fischman et al, 1994; Rankin et al, 1999; Cutlip et al, 2002). Drug eluting stents (DES) further reduce restenosis and TLR in both calcified and noncalcified lesions (Moses et al, 2003; Stone et al, 2004). Despite this benefit, the delivery of DES remains challenging in complex coronary anatomy, including eccentric, extensively calcified lesions. In order to obtain the desired long-term effectiveness of DES, successful initial implantation must be accomplished; therefore, aggressive lesion preparation becomes essential for these patient subsets.



Fig. 4. Histology
Histology cross-sections post balloon (left) and post Rota (right).

Whether the benefit of DES persists after the vessel injury caused by rotational atherectomy is unknown. Rotablation followed by DES implantation (Rota-DES) for complex severely calcified lesions is a rational combination that has not been thoroughly evaluated. The limited studies with rotablation and DES showed promising results with no long term safety concerns. In these studies, a subtle observation was made suggesting that rotablation prior to DES implantation in such lesions may have an add-on effect on long term outcome compared to DES alone (Clavijo et al, 2006; Rao et al, 2006; Khattab et al, 2007). Therefore, the goal of this chapter is to investigate the immediate and long term outcomes of patients who are treated with rotational atherectomy to facilitate the delivery of DES in heavily calcified lesions. In addition, a full overview of the technique, the pros and cons, the advantages and complications and its applications in various lesion subsets will be provided.

2. RotA- general concepts

The technique of RotA was invented at the start of the 1980s by David Auth and has been used during angioplasty for more than 20 years (Reisman et al, 1996). The method is most effective in the modification of calcified plaques, facilitating stent placement during angioplasty. The treatment of HCCL (as opposed to non-calcified lesions) with angioplasty has been associated with a lower success rate and a higher incidence of complications (Wilensky et al, 2002). The geometry and inflexibility of HCCL often does not permit successful approach and correct stent deployment (Hoffmann et al, 1998). In addition, balloon dilatation and stent deployment in HCCL carry a higher risk of dissection and rupture. RotA devices use a rotating brass burr that pulverizes a portion of the fibrous, calcified, inelastic plaque, modifies the plaque compliance, and leaves a smooth, nonendothelialized surface with intact media (Mintz et al, 1992; Kovach et al, 1993). RotA is based on the principle of differential atherectomy, namely selective atherectomy of the fibrous and calcified plaque (Reisman, 1996). (Figure 5) Successful RotA results in the creation of a smooth vessel lumen, suitable for the successful performance of balloon angioplasty and stenting at the site of the lesion (Ellis et al, 1994).

The findings of the various studies have created some general guiding rules for the optimized use of RotA (Brown et al, 1997; Reifart et al, 1997; Whitlow et al, 2001; Dill et al, 2000; Buchbinder et al, 2001; vom Dahl J et al, 2002; Goldberg et al, 2000):

1. It is essential to use specific guiding catheters with sufficient support and coaxial fitting.
2. The atherectomy speed must be approximately 140000 rpm, although there is no clear cut-off and some operators use 150,000 rpm.
3. The intermittent application of RotA within lesion is preferred; usually "pecking" technique is used, where the burr is moved forward and backward the lesion, without pushing the rotablator into the lesion
4. Starting with smaller burrs reduces the plaque burden to the distal bed and a patent lumen is achieved in a shorter period of time
5. A RotA technique with 2 burrs may be chosen in order to reduce the incidence of the no-reflow phenomenon. The smaller burr (usually 1.25 mm) is used first, followed by a larger burr based on the size of the vessel, aiming at a burr/vessel ratio that does not exceed 0.6-0.7. However sometimes a single small burr is sufficient
6. Bigger burrs may debulk more of the lesion but they also may damage/activate more blood cells
7. In cases of extensive rotablation and large amount of debulking, glycoprotein IIb/IIIa inhibitors is recommended.
8. The duration of RotA application should not exceed 15-20 sec, with immediate cessation if the revolutions drop by >5000 rpm
9. During RotA, 500 ml of heparinised (5000 units) normal saline solution with 5 mg verapamil and 1000 µg nitroglycerine is administered locally, with a view to preventing thrombus formation and vascular spasm, and avoiding the no-reflow phenomenon.

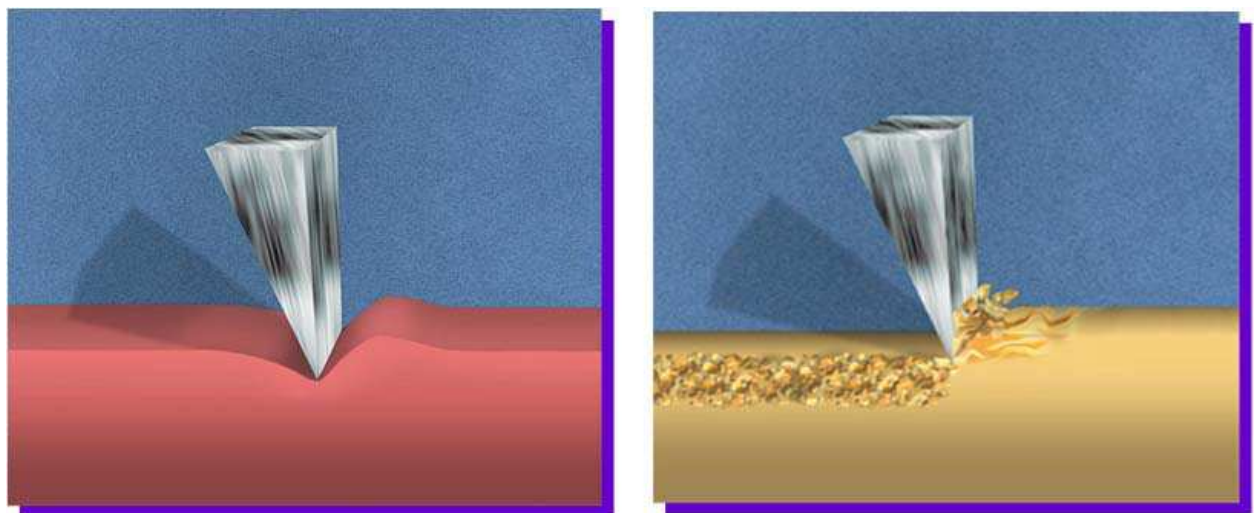


Fig. 5. Differential atherectomy

The concept of differential atherectomy: the rotablation preferentially ablates inelastic, calcified, atherosclerotic tissue.

3. RotA Indications and technique according to lesion specification

The absolute indication for RotA is the heavily calcified lesions (HCCL), localized or extended, and mainly the presence of a circumferential calcium ring where the lesion is undilatable by balloon angioplasty (Figures 6 and 7).

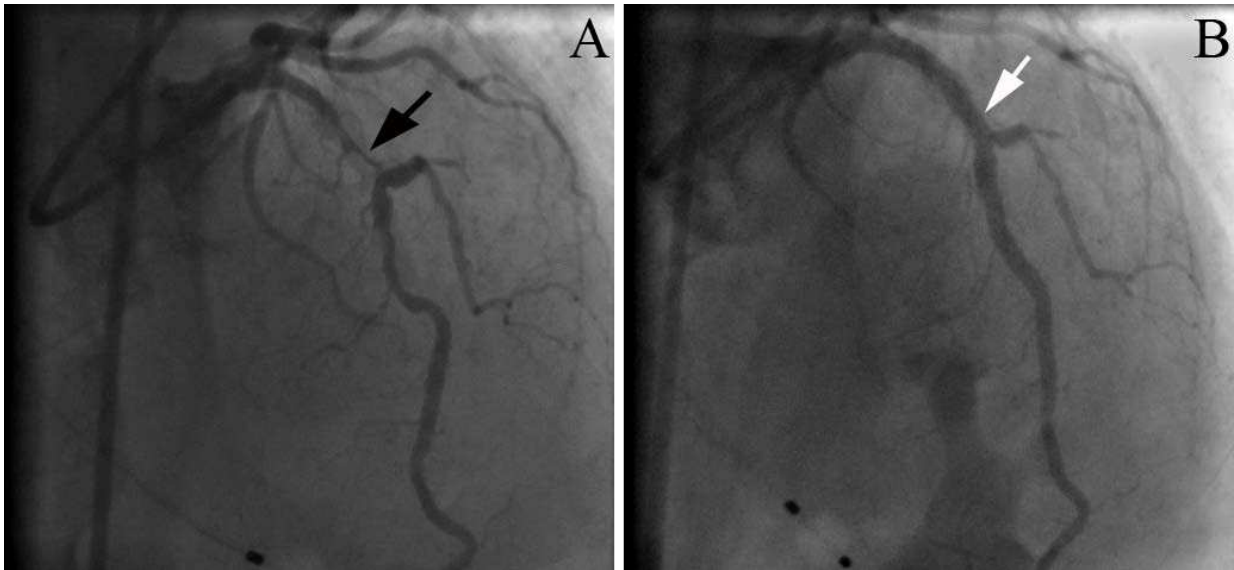


Fig. 6. Longitudinal calcified LAD lesion
A. Localised calcified longitudinal lesion of the left anterior descending artery before the origin of the first diagonal branch (black arrow).
B. Restoration of vessel patency with the combination of rotational atherectomy and drug-eluting stent (white arrow).

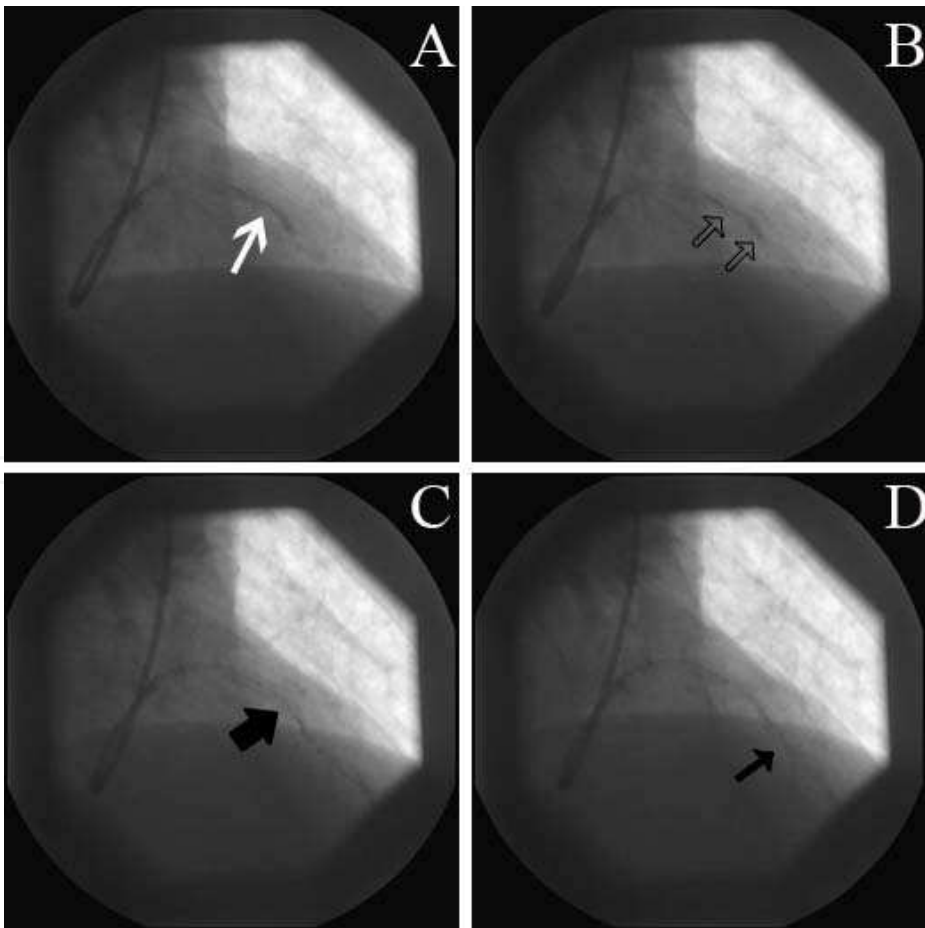


Fig. 7. Unsucessful treatment of calcified LAD lesion with POBA

The lesion in Figure 6 had previously been treated unsuccessfully using direct balloon dilatation without rotational atherectomy of the calcified plaque. A. Attempt to deploy the balloon (white arrow). B. Incomplete deployment of proximal end of the balloon (open arrows). C. Rupture of the angioplasty balloon (thick black arrow). D. The result of the rupture is the characteristic escape of contrast medium distal to the balloon (thin black arrow).

Other indications are ostial lesions with severe fibrosis with or without calcification, and balloon-inaccessible lesions, provided that the Rotawire can cross the lesion.

- In cases with multiple HCCL in the same vessel (tandem lesions) (Figure 8), segmental RotA is preferred. Because of the potential for a large quantity of plaque debris, a stepped burr approach is recommended. Interpolated low pressure balloon angioplasty may be helpful in improving flow, can also localize the areas of resistance and improve vasospasm.
- In ostial lesions (specifically in RCA) (figure 9) the frequent fibrocalcific characteristics of these lesions make them well suited for rotablation treatment. Coaxial placement of the guiding catheter is mandatory (assess in two projections-best RAO). Straight alignment of the guide catheter is essential in order to center the guidewire (extra support). The lie of the guidewire is essential and keeping the tip just beyond the lesion may improve the centering.
- In bifurcation lesions the mainstay of treatment is branch preservation and adequate lumen in both limbs. Rotablation should be started at the most difficult to wire branch first. Use low burr-artery ratios (<0.5) especially when there is angulation present.
- In coronary arteries with severe tortuosity the main issue is to avoid perforation. Keeping the tip of the guidewire just beyond the lesion is essential in order to reduce sidewall tension. A stepped-burr approach and the use of undersized burrs are recommended. The activated burr should be advanced at low speed ensuring that there is no wire tension. Ablation of normal tissue can occur if the tension on the wall exceeds the elasticity of the vessel (wire bias) (Figure 10).
- Failed PCI is either due to inability to cross the lesion or dilate. These lesions are frequently calcified. The decision to use rotablation should be made early, before large dissections appear.
- The inability to cross a CTO with a balloon catheter occurs in approximately 7% of all CTOs that are successfully crossed with a guidewire. RotA is a safe and effective technique to overcome this frustrating situation (Figure 11). Chronic total occlusions are well suited for rotational atherectomy and treatment is only limited by the ability to cross the lesion with the guidewire. Conventional guidewires should be used and exchange for the rota-wire with a OTW catheter. These lesions are frequently fibrocalcific. Initiating treatment with the smallest burrs (1.25 mm) is the safest approach.

4. RotA complications

Possible but rare complications include myocardial infarction, emergency CABG, coronary artery dissection, no reflow phenomenon, due to peripheral embolization, perforation or severe coronary artery spasm (Cavusoglu et al, 2004). The strict application of the general rules for the optimal use of RotA mentioned above, eliminates the possibility of any complication.

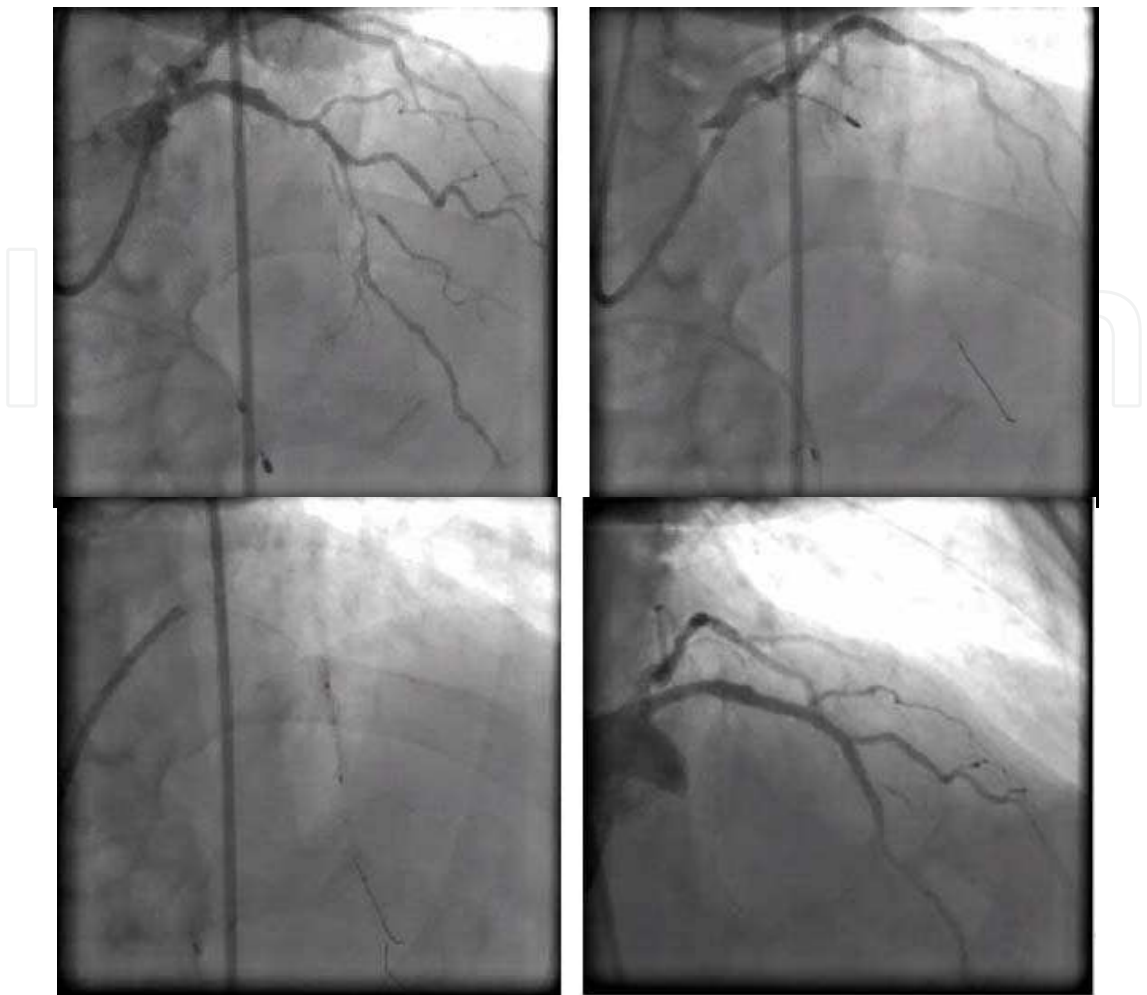


Fig. 8. Tandem calcified LAD lesion
Tandem LAD lesions before, after Rota (segmental approach) and final result after DES.

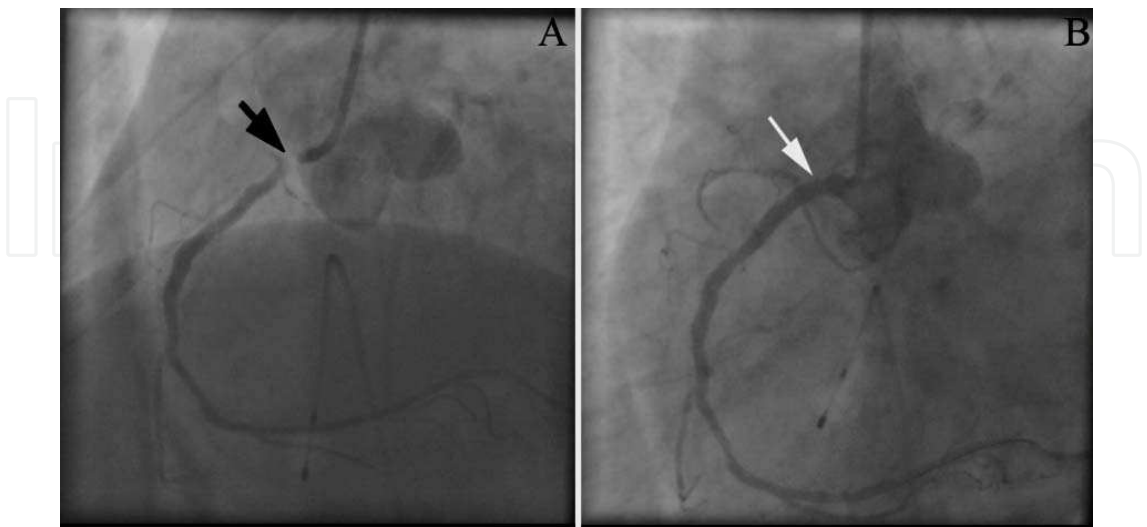


Fig. 9. Calcified ostial RCA lesion
A. Calcified ostial lesion in the right coronary artery (black arrow). B. Restoration of vessel patency with the combination of rotational atherectomy and drug-eluting stent (white arrow).

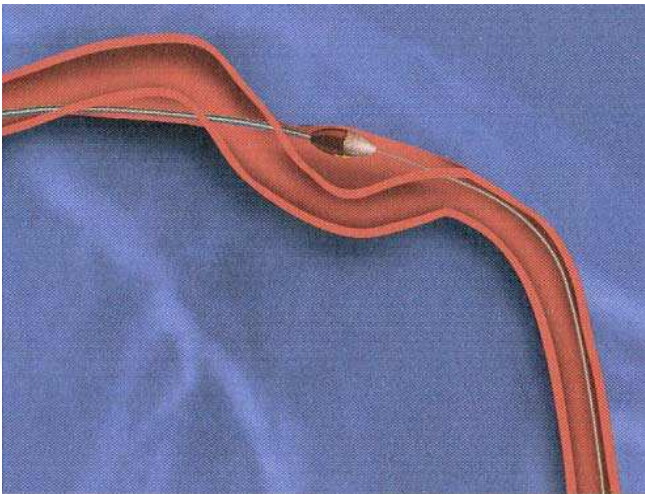


Fig. 10. Wire bias

Wire bias can occur in tortuous vessels, increasing the risk of perforation.

5. RotA contradictions

Coronary dissection, severe thrombosis and severe tortuosity are general contradictions of the method. Also RotA is relatively contraindicated in vein grafts due to the increased risk of dissection and distal embolization.

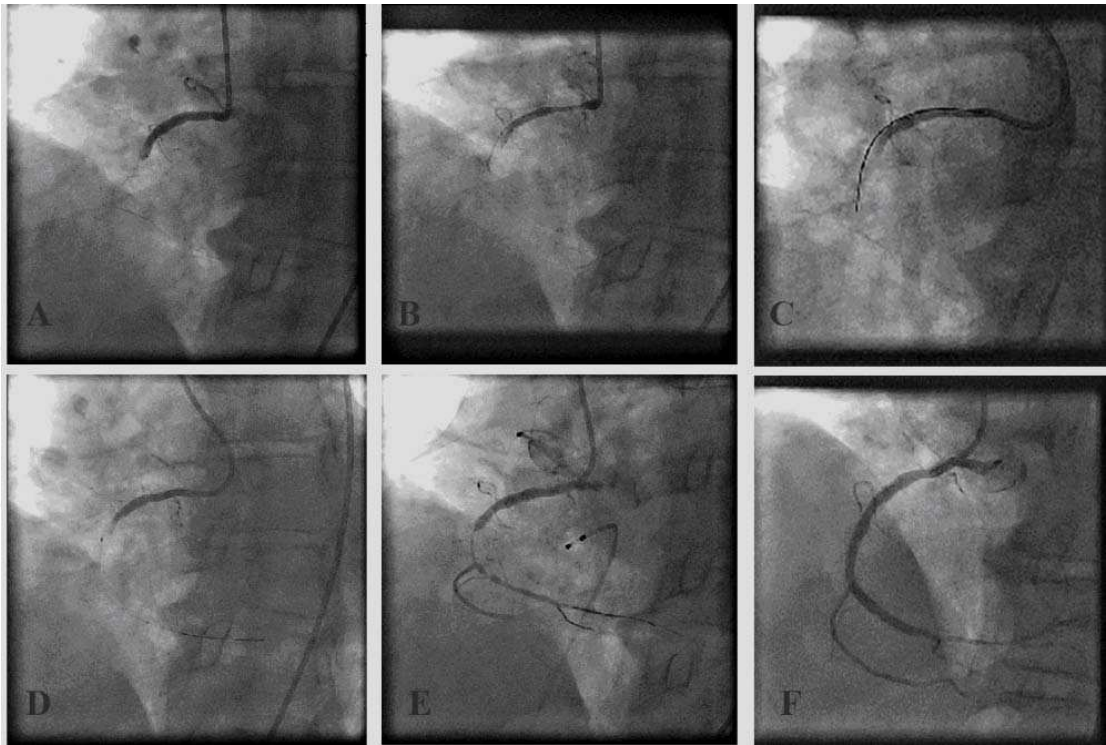


Fig. 11. Calcified chronic total occlusion of a RCA
A. Guide Wire insertion. B. Three different catheters: JR4, AL1, H-STICK. C. Inability to cross CTO with eight different balloons (diameters from 1,5 - 0,85 mm). D. Rotawire crosses the lesion. E. Rotational atherectomy with 1.25 mm burr. F. DES deployment

6. RotA in DES era

RotA followed by balloon angioplasty does not improve the rates of restenosis compared to direct balloon angioplasty, leading to high rates of restenosis and need for TLR—in up to 40% of cases (Reifart et al, 1997). RotA + balloon angioplasty strategy is better for the prevention of restenosis in small coronary vessels compared to balloon angioplasty alone (Mauri et al, 2003). BMS implantation after RotA has a high success rate, with an acceptable incidence of complications and a clearly lower incidence of angiographic restenosis compared to plain angioplasty, but the restenosis rate and need for TLR remain high, at 22.5% according to one previous study (Moussa et al, 1997).

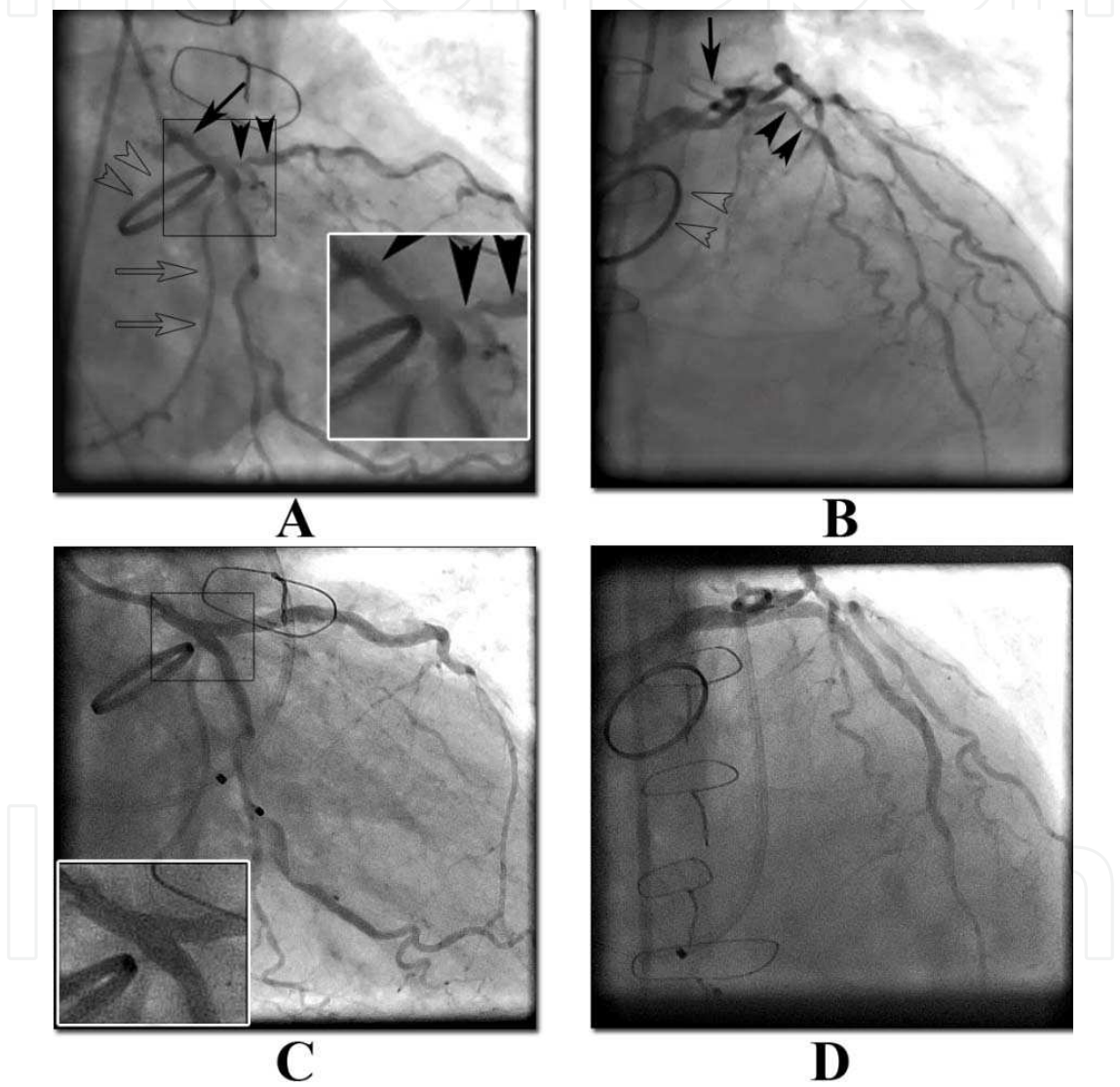


Fig. 12. Complex LMS-LAD Rotablation with ECMO support (A- B) heavily calcified ostial LMS stenosis (black arrow), elongated 95% LAD stenosis (black head arrows)- (in magnification on the right-down corner), metallic aortic valve (white head arrows) and a collateral artery from the LAD to the occluded RCA (white arrows), in a patient with poor LV and EF 20%. (C-D) Final angiographic result after rotablation and stent implantation (in magnification on the left- down corner) with the hemodynamic support of ECMO machine.

DES reduce neointimal hyperplasia and are safer and more effective than BMS in the treatment of stable coronary lesions (Stone et al, 2007; Mauri et al, 2007). However, DES in HCCL presents a technical difficulty of stent implantation and deployment. Calcification of the lesion is already known to have a negative impact on stent deployment (MacIsaac et al, 1995). Disruption of the stent's polymer coating during forceful deployment and unsatisfactory drug elution because of extreme calcification of the lesion are the main reasons for the unsuccessful deployment and implantation of stents in HCCL. Indeed, the rates of MACE and the need for TLR were significantly higher in patients with calcified as opposed to non-calcified lesions that were treated with DES implantation (Kawaguchi et al, 2008). RotA + DES approach had better clinical and angiographic results over a 9-month follow up compared to RotA + BMS in the treatment of patients with HCCL (Khattab et al, 2007). The results from patients treated with RotA + BMS with those from a group treated with RotA + DES and another group treated with DES without RotA shows that the use of DES reduced the incidence of MACE in patients who underwent RotA, mainly because of a significant reduction in the need for TLR (Rao et al, 2006). A study compared two groups of patients with HCCL who were treated with DES, where RotA was necessary in the first group but not in the second. There was no significant difference between the groups as regards in-hospital complications or clinical outcomes (Clavijo et al, 2006). A previous study of ours showed that the therapeutic strategy of RotA + DES was effective in treating HCCL as regards both the clinical outcome and the angiographic result (Mezilis et al, 2010). The mortality and MACE rates were very low (3.3% and 11.3%, respectively) over a mean follow up of >36 months. No immediate complications related to the angioplasty were recorded, while in previous studies the incidence of such complications was from 4% to 7%. A 2-burr technique was used with a view to limiting the occurrence of the no-reflow phenomenon. Initially, a small burr was used (1.25 mm), followed by a larger burr depending on the size of the vessel. Whether this gradual approach contributed to limiting the immediate complications and to the low rate of stent thrombosis will need further investigation. Another study (Schwartz et al, 2011) reported a slightly higher rate of MACE (15.8%) and mortality (4.2%). However, in this study the authors did not describe the technique they used (i.e. burrs at one or more stages).

A recent study (Benezet et al, 2011) compared the angiographic and procedural success rates of three therapeutic strategies in patients with HCCL: RotA + only balloon angioplasty, RotA + BMS and RotA + DES. In unadjusted analysis, procedural success appears high with subsequent stent placement (DES or BMS) versus RA alone (96.4% for DES versus 95% for BMS versus 63% for no stent). However, 1 in 4 cases were not candidates for stent placement, due to reference vessel diameter < 2.25, inability to deliver DES, or desire to avert clopidogrel therapy, and the lower procedural success rate in this population should be considered prior to embarking on Rota. This rate of unsuccessful stent placement is much higher than in previous studies. Another recent study (Pagnotta et al, 2010) confirms the safety and effectiveness of Rota + DES strategy to tackle HCCL with good long-term clinical outcomes. Although the radial approach was used in 37.3% of cases, the procedure was successful in 97% of cases; this rate of success is similar to previous studies. Rotablation, when used in very high risk subsets combined with the use of short term LVADs was also proved to be efficient (Figure 12) (Dardas et al, 2011).

7. Conclusion

The combination of RotA + DES is an integrated, effective and safe method of treating HCCL. The wide use of DES may cause a renaissance of RotA and its return to daily use in the catheterization laboratory, after its decline a decade ago when it failed to show better long-term results after angioplasty. In the future, randomised studies will be needed to confirm the above results.

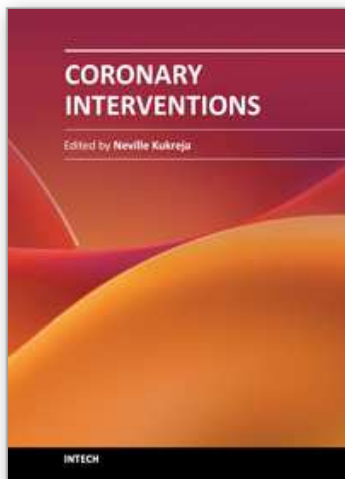
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