Atherectomy Devices for the Treatment of Calcified Coronary Lesions

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KEYWORDS

• Atherectomy • Calcification • Coronary artery disease • Angioplasty • Coronary • Orbital atherectomy • Percutaneous coronary intervention • Stents

KEY POINTS

- An indicator of advanced coronary artery disease is the presence of coronary artery calcification (CAC).
- Advanced age, diabetes mellitus, and chronic kidney disease are important risks factors for CAC.
- Calcified coronary lesions are challenging to treat and have increased acute complications and worse long-term outcomes.
- Atherectomy can be used to modify the calcified plaque to facilitate percutaneous coronary intervention.

INTRODUCTION

Coronary artery disease (CAD) affects more than 16 million subjects in the United States, making it the most common form of heart disease. An indicator of advanced CAD is the presence of coronary artery calcification (CAC) and the extent of calcification strongly correlates with the degree of atherosclerosis and, therefore, with the rate of future cardiac events.[1–3] Percutaneous coronary intervention (PCI) in severely calcified lesions is associated with lower success rates, higher complication rates, and worse long-term outcomes compared with noncalcified lesions.[4–6]

PREVALENCE OF AND RISK FACTORS FOR CORONARY ARTERY CALCIFICATION

The prevalence of moderate/severe CAC in the PCI patient population is 32%, of which 5.9% is considered severe.[4] Several health behaviors and risk factors, as well as chronic inflammatory conditions, lead to calcium deposition in the coronary arteries.[1,6–8] Key factors include:

- Smoking and tobacco use;
- Physical inactivity;
- Obesity;
- Advanced age;
- Family history;
- Hyperlipidemia;
- Hypertension;
- Diabetes mellitus;
- The metabolic syndrome; and
- Chronic kidney disease.

These conditions cause endothelial injury and subsequent cell dysfunction, escalating an inflammatory response from leukocytes and vascular smooth muscle cells which leads to

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calcium deposition in the intimal and medial layers of arterial walls.[6,9,10] Many of these risks are increasing in the United States, including diabetes and obesity; therefore, CAC is becoming a greater issue for interventional cardiologists.[7]

IMPACT OF CALCIUM ON PERCUTANEOUS CORONARY INTERVENTION OUTCOMES

The presence of CAC may lead to:

- Unsuccessful PCI owing to undilatable lesions[11,12];
- Balloon ruptures[12,13];
- Coronary dissection[11];
- Coronary perforation or rupture[14,15];
- Asymmetric, malapposed, and underexpanded stents[13,16];
- Higher incidence of major adverse cardiac events (MACE)[17];
- Higher incidence of restenosis and target lesion revascularization[18];
- Higher incidence of periprocedural myocardial infarction (MI)[19]; and
- Higher incidence of stent thrombosis.[20]

Coronary perforation or rupture, albeit rare, remains one of the most serious complications in the catheterization laboratory, with multiple studies demonstrating very poor outcomes, particularly in relationship to cardiac tamponade, MI, and death.[15] In the general CAD population (all lesion types), coronary perforation has been reported in 0.1% to 3.0% of lesions treated with various interventional techniques.[15,21] Elderly, female patients and those with CAC are at greatest risk.[15]

The current standard of care for treating patients with severe and symptomatic CAD is PCI with a drug-eluting stent (DES). The use of DES in severely calcified coronary lesions results in worse outcomes compared with patients with noncalcified lesions.[4,22,23]

ATHERECTOMY TREATMENT OPTIONS FOR CALCIFIED CORONARY ARTERIES

Atherectomy devices have been used for vessel preparation before PCI in calcified coronary lesions. These devices can facilitate successful stent implantation that may otherwise not be possible. Commercially available coronary atherectomy devices currently include:

- Rotational atherectomy (RA; Rotablator, Boston Scientific, Marlborough, MA);
- Orbital atherectomy system (OAS; Diamondback 360, Cardiovascular Systems, Inc, St Paul, MN); and
- Laser atherectomy (Spectranetics, Colorado Springs, CO).

A comparison of these atherectomy devices in regards to mechanism of action, clinical indication, and technical features is shown in Table 1. We present the clinical data from a controlled literature search of the past 5 years of coronary atherectomy in de novo, severely calcified lesions.

Rotational Atherectomy

The clinical data from RA (studies with $\geq$150 patients) for the past 5 years are summarized in Table 2. One publication includes clinical data regarding RA from a prospective, randomized, multicenter clinical trial (Rotational Atherectomy prior to Taxus Stent Treatment for Complex Native Coronary Artery Disease [ROTAXUS]).[24] Acute gain was higher in the RA group. However, late lumen loss in the RA plus DES group was significantly higher than the DES alone group at 9 months follow-up (0.44 ± 0.58 vs 0.31 ± 0.52 mm; $P = .04$). The 12.5% crossover rate from the DES alone to RA indicates the need for atherectomy in certain complex calcified coronary lesions.

In RA studies reporting 12-month results, the MACE rates ranged from 12% to 23.5%.[25–27] One retrospective study not included in Table 2 reported on 221 consecutive patients at a single center who underwent RA and stenting to assess clinical outcomes stratifying by the age, creatinine, and ejection fraction (ACEF) and the clinical Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery (SYNTAX) score.[28] At 1 year, the MACE rate, defined as cardiac death, MI, and target vessel revascularization ranged from 9% to 24% by the ACEF score and 8% to 25% by the clinical SYNTAX score.

The current PCI guidelines state that RA is reasonable for fibrotic or heavily calcified lesions that might not be crossed by a balloon catheter or adequately dilated before stent implantation (class IIa level of evidence C).[14]

Orbital Atherectomy

Two clinical studies were performed with the coronary OAS in the past 5 years (Table 3). The pilot study to evaluate the safety and performance of the Orbital Atherectomy System in treating *de novo* calcified coronary lesions (ORBIT I) was a prospective, nonrandomized clinical trial that was conducted in 2 centers in India to evaluate the safety of using the OAS in de novo calcified coronary lesions in 50 subjects.[29] Device success ($\leq$50% residual stenosis after

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