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Honorary Editor : **Dr. Vipul Kapoor**Interventional Cardiologist



Dear Friends,

Orbital atherectomy (OA) is an adjunctive therapy used for lesion preparation of calcified plaque with percutaneous coronary intervention (PCI) and peripheral percutaneous endovascular interventions. The goal of lesion preparation with OA is to modify calcified plaque, changing lesion compliance to allow adequate balloon and stent expansion in segments with heavily calcified lesions. This treatment modality help only recently been made available in india and not many people are aware of it. This article tries to make it easy to understand.



Orbital Atherectomy

Introduction

Coronary artery disease (CAD) has a significant impact on overall health and continues to grow in prevalence Data from the American Heart Association states that greater than 15.5 million people over age 20 have significant CAD. The deaths due to cardiovascular disease have also steadily increased since 1990. with nearly 650,000 deaths due to cardiovascular disease in 2019. In





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patients with advanced CAD, coronary artery calcification (CAC) is associated with increased atherosclerosis and potential future cardiac events. CAC is believed to be both gender and age-dependent. The prevalence of CAC in individuals over age 70 has been estimated to be greater than 90% in men and 67% in women. CAC is better detected using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) compared to coronary angiography.

A previous study in patients with known CAD demonstrated that coronary angiography could detect coronary calcium in 38% of lesions versus 73% utilizing IVUS. As intravascular imaging modalities are underutilized, CAC is likely underestimated in the general population.

As CAD prevalence increases, the incidence of CAC follows a similar trend. Previous studies have shown that those patients with severe CAC have more complex and worse outcomes when undergoing percutaneous intervention (PCI) than patients with low CAC.

Two different meta-analyses have revealed that severe coronary calcium is associated with less complete revascularization, increased mortality, increased rate of myocardial infarction (MI), and increased rate of coronary revascularization. The noted worse outcomes in patients with severe coronary calcium are multifactorial but are likely strongly associated with poor balloon expansion resulting in incomplete stent expansion and coronary calcium damaging stent polymer coating, decreasing efficacy.

To help decrease complication rates and improve stent deployment in patients with severe CAC, utilization of OA can be of significant benefit for vessel preparation and stent placement. In this manuscript, we provide a review of OA and the available devices, techniques, in dications, complications, contraindications, and clinical trial outcomes based on the most recent data.

Indications

For coronary arteries, orbital atherectomy (OA) is indicated to facilitate stent delivery in patients with known severely calcified coronary artery lesions who are candidates for percutaneous transluminal coronary angioplasty or stenting. The Orbital Atherectomy System has the Food and Drug Administration (FDA) approval to treat severely calcified coronary artery lesions. Situations in which to consider the use or OA is dependent on the thickness and severity of calcification.

Previous studies have suggested that lesions with calcium thickness < 0.24 mm are likely to fracture and can be treated with balloon angioplasty before stent placement. Similarly, lesions with a calcium score of 4 or more are at increased risk of the stent under expansion. In either case of increased calcium thickness or score, atherectomy before stent placement may be beneficial for successful stent placement.

Potential situations to utilize OA include severely calcified lesions in a patient with multi-vessel disease, lesion preparation for bioresorbable scaffold placement,



unprotected left main disease, ostial lesions, and chronic total occlusions.

Contraindications

Orbital atherectomy (OA) is contraindicated in the following conditions:

- 1. Unable to pass the guidewire across a lesion
- 2. The lesion is within a graft or stent
- 3. The patient is not a candidate for atherectomy, coronary angioplasty, or bypass surgery
- 4. The patient has evidence of thrombus on angiography
- 5. The patient has a multi-vessel disease with only one open coronary vessel
- 6. There is evidence of coronary dissection on the angiogram
- 7. The patient is pregnant
- 8. The patient is a child

Other warnings and precautions for consideration before utilizing OA include:

- 1. Very tortuous vessels which are at increased risk for vessel damage
- Treating lesions in the right coronary or left circumflex regions as there is an increased risk for heart block and need for temporary pacing
- 3. On-site and available cardiothoracic surgery staff if needed.
- Patients with heart failure and reduced ejection fraction less than 25%





Equipment

The orbital atherectomy system (OAS) comprises the following components: coronary orbital atherectomy device (OAD), orbital atherectomy system pump, coronary guidewire, and lubricant. The OAD consists of a sheath covered drive shaft, a 1.25/1.50 mm crown that slides over the VIPERWIRE coronary guidewire, a crown advancer knob, and a saline tubing connection to the OAS pump. A table side motor handle controls crown rotation speed, guides crown advancement, and contains the guidewire brake lever.

A minimum size 6 french guide or larger is needed for the use of the OAS. The lubricant combined with saline is attached to the pump and must always be utilized during OA to help reduce the risk of thermal injury and potential heart block. The saline flow rate is controlled by the pump and is approximately 18 ml/min, but can be increased throughout the procedure as needed. The device setup is efficient and can be assembled in minutes by an experienced operator.



Complications

Orbital atherectomy (OA) has been demonstrated to be a safe and effective device in both clinical studies and all comer real-world registries. Complications have been reported to be low in high-risk patient cohorts and lesion sub-types including females, diabetics, elderly, and patients with chronic kidney disease, low ejection fraction, previous coronary artery bypass grafts, subtotal occlusions, left main coronary artery lesions, aorto-ostial lesions, bifurcations, and small coronary vessels.

The most commonly reported complications associated with orbital atherectomy include dissections, slow or no-reflow, and perforations. In the ORBIT I trial involving 50 patients, there were six coronary dissections without clinical sequelae and only one perforation. There was no noted incidence of slow flow or distal emboli.

Similar results were noted in the much larger ORBIT II with 443 patients enrolled, with rates of dissection, perforation, and no flow being 3.4%, 1.8%, and 0%, respectively.

A transient heart block is uncommon with orbital atherectomy, but bradycardia has been observed. In a 2017 study by Lee et al. involving 50

patients, 4% experienced bradycardia, none of which required pacemaker implantation.

Rare complications have been reported and include pseudoaneurysm and dislodged microtip. A more recent review using the MAUDE database revealed 317 submitted cases in which there was device failure. The most common device malfunctions included detachment/separation of pieces and device structural damage. Structural damage was reported involving the following components: crown, body, and tip of guidewire tip, driveshaft tip, and driveshaft body.

Future Scope

Orbital Atherectomy is a very promising, safe and effective technique with a bright future. In properly selected patient subgroups it can deliver highly satisfactory and very gratifying immediate and long term results in these extremely high risk patients.





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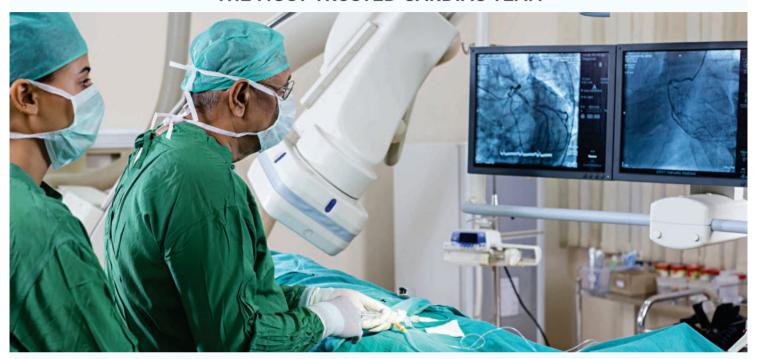




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