Lesion Preparation Prior to DES

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The Impact and Pathophysiologic Consequences of Coronary Artery Calcium Deposition in Percutaneous Coronary Interventions

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**ABSTRACT:** The presence of coronary artery calcium is indicative of advanced coronary artery disease and is a predictor of clinical events including stroke, myocardial infarction, and cardiac arrest. Recognition of the risk factors and the clinical implications associated with coronary artery calcium is vital in identifying both preventative measures as well as treatment options. Non-invasive and invasive strategies can help quantify these calcified lesions and aid in appropriate patient selection for possible use of atheroablative devices. While mild to moderately calcified lesions can be predilated with balloon angioplasty, severely calcified vessels may be resistant to adequate predilatation and preclude stent delivery and optimal expansion, potentially increasing the risk of early and late complications. The use of atherectomy devices is an invaluable treatment option for these complex lesions, given the ability for plaque modification and changing the compliance of heavily calcified vessels, increasing procedural success rates.

**KEY WORDS:** atherectomy, coronary artery disease, calcium, percutaneous coronary intervention
Challenges with Calcified Lesions

- Difficult to treat
  - Prone to dissection during angioplasty
  - Difficult to dilate
  - Difficulty delivering stent
  - Prevent adequate stent expansion

- Poor clinical outcomes, including higher MACE
  - Most trials excluded calcified lesions
Impact of Coronary Artery Calcification in PCI with PES
**ARRIVE I and II Registries**

### TABLE III. Clinical Outcomes

<table>
<thead>
<tr>
<th>Variable</th>
<th>Calcification (nil/mild) (N = 3710/N = 2316)</th>
<th>Calcification (moderate/severe) (N = 1103/N = 363)</th>
<th>p-value (nil/mild vs moderate/severe)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1 year cardiac events</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major adverse cardiac events</td>
<td>502/5834 (8.6%)</td>
<td>189/1440 (13.1%)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Death</td>
<td>167/5834 (2.9%)</td>
<td>90/1440 (6.3%)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Cardiac death</td>
<td>103/5834 (1.8%)</td>
<td>56/1440 (3.9%)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Noncardiac death</td>
<td>64/5834 (1.1%)</td>
<td>34/1440 (2.4%)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>110/5834 (1.9%)</td>
<td>45/1440 (3.1%)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Q-Wave MI</td>
<td>33/5834 (0.6%)</td>
<td>13/1440 (0.9%)</td>
<td>0.15</td>
</tr>
<tr>
<td>Non-Q-Wave MI</td>
<td>81/5834 (1.4%)</td>
<td>32/1440 (2.2%)</td>
<td>0.02</td>
</tr>
<tr>
<td>TVR</td>
<td>370/5834 (6.3%)</td>
<td>122/1440 (8.5%)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Stent thrombosis</td>
<td>89/5834 (1.5%)</td>
<td>36/1440 (2.5%)</td>
<td>0.01</td>
</tr>
<tr>
<td><strong>2 Year cardiac events</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major adverse cardiac events</td>
<td>759/5629 (13.5%)</td>
<td>257/1406 (18.3%)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Death</td>
<td>316/5629 (5.6%)</td>
<td>145/1406 (10.3%)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Cardiac death</td>
<td>178/5629 (3.2%)</td>
<td>82/1406 (5.8%)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Noncardiac death</td>
<td>138/5629 (2.5%)</td>
<td>63/1406 (4.5%)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>169/5629 (3.0%)</td>
<td>60/1406 (4.3%)</td>
<td>0.02</td>
</tr>
<tr>
<td>Q-Wave MI</td>
<td>53/5629 (0.9%)</td>
<td>17/1406 (1.2%)</td>
<td>0.37</td>
</tr>
<tr>
<td>Non-Q-Wave MI</td>
<td>122/5629 (2.2%)</td>
<td>44/1406 (3.1%)</td>
<td>0.03</td>
</tr>
<tr>
<td>TVR</td>
<td>549/5629 (9.8%)</td>
<td>166/1406 (11.8%)</td>
<td>0.02</td>
</tr>
<tr>
<td>Stent thrombosis</td>
<td>130/5629 (2.3%)</td>
<td>44/1406 (3.1%)</td>
<td>0.08</td>
</tr>
</tbody>
</table>
80 year-old male with ACS
PMH: DM, HTN

RAO caudal view

RAO cranial view
Unable to fully dilate balloon

Contrast staining
CPR

Impella insertion
**Orbital Atherectomy**

*Mechanism of Action*

**Differential Sanding:**
- 30 micron diamond coating
- Bi-directional sanding, eccentric mounted crown
- Healthy elastic tissue flexes away minimizing damage to the vessel

**Centrifugal Force:**
- 360° crown contact designed to create a smooth, concentric lumen
- Allows constant blood flow and particulate flushing during orbit
- Increasing speed increases orbital diameter
- Ability to treat multiple vessel diameters with one crown
- Treat large vessels through small sheaths

*Before OAS*
- Crown will only sand the hard components of plaque

*After OAS*
- Soft components (plaque/tissue) flex away from crown
Technique

- 6F guiding catheter
- Wire technique
- Intracoronary IC NTG
- Tortuous vessel
  - Consider Guideliner if difficulty advancing crown
  - Brief activation to advance distally
Technique

• Start on low-speed
  – 3 mm: consider high speed
  – ≥3.25 mm: high speed
• Continuous flush of NS
• Wait 30 seconds in between runs
Single-Operator Technique

76 y.o. male with angina
PMH: smoking, HTN

Unable to dilate calcified lesion
Angiography at 1 week

Difficulty wiring
• Advance 1 mm/second. Max 25 seconds
• Continue low-speed until change in cadence
• Slow, pecking. Never push

Look, Listen, and Feel
Treatment Algorithm

Coronary Angiography

- Mild CAC
  - PCI
  - CAC $0-180^\circ$ (PCI Alone)
- Moderate CAC
  - IVUS
  - CAC $180-270^\circ$ ($\pm$ Atherectomy)
- Severe CAC
  - PCI with atherectomy
  - CAC $>270^\circ$ (Atherectomy)

Unable to dilate

Repeat angiography
Orbital atherectomy

Full stent expansion
Final angiography
Real-World Multicenter Experience on Patients with Severe Coronary Artery Calcification Undergoing Orbital Atherectomy

Participating Sites

- Retrospective study
- 458 consecutive patients with severe CAC who underwent orbital atherectomy followed by stenting
- October 2013 to December 2015

Angiographic Complications

Values are n (%)

<table>
<thead>
<tr>
<th>Complication</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perforation</td>
<td>3</td>
<td>0.7%</td>
</tr>
<tr>
<td>Dissection</td>
<td>4</td>
<td>0.9%</td>
</tr>
<tr>
<td>No reflow</td>
<td>3</td>
<td>0.7%</td>
</tr>
</tbody>
</table>

## 30-day Clinical Event Rates

<table>
<thead>
<tr>
<th>Event</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACE</td>
<td>8 (1.7%)</td>
</tr>
<tr>
<td>Death</td>
<td>6 (1.3%)</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>4 (1.1%)</td>
</tr>
<tr>
<td>Target vessel revascularization</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Stroke</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>Stent thrombosis</td>
<td>4 (0.9%)</td>
</tr>
<tr>
<td>Emergent CABG</td>
<td>1 (0.2%)</td>
</tr>
</tbody>
</table>

Values are n (%)

Outcomes After Orbital Atherectomy of Severely Calcified Left Main Lesions: Analysis of the ORBIT II Study

Michael S. Lee, MD1; Evan Shlomfritz, DO2; Richard Shlomfritz, MD3; Sheila Sahni, MD1; Brad Martinson, MD4; Jeffrey Chambers, MD3

ABSTRACT: Objectives. The ORBIT II trial reported excellent outcomes in patients with severely calcified coronary lesions treated with orbital atherectomy. Severe calcification of the left main (LM) artery represents a complex coronary lesion subset. This study evaluated the safety and efficacy of orbital atherectomy to prepare severely calcified protected LM artery lesions for stent placement. Methods. The ORBIT II trial was a prospective, multicenter clinical trial that enrolled 443 patients with severely calcified coronary lesions in the United States. The major adverse cardiac event (MACE) rate through 2 years post procedure, defined by cardiac death, myocardial infarction (MI) or target-lesion revascularization (TLR), was compared in the LM and non-LM (NLM) groups. Results. Among the 443 patients, a total of 10 underwent orbital atherectomy of protected LM artery lesions. At 2 years, there was no significant difference in the 2-year MACE rate in the LM and NLM groups (30.0% vs 19.7%, respectively; P = .36). Cardiac death was low in both groups (0% vs 4.4%, respectively; P = .99). Myocardial infarction occurred within 30 days in both groups (5.0% vs 9.7%, respectively; P = .99). Severe dissection, perforation, persistent slow flow, and no reflow did not occur in the LM group. Arial closure occurred in 1 patient in the LM group. Conclusions. Orbital atherectomy for patients with heavily calcified LM coronary artery lesions is safe and feasible. Further studies are needed to assess the safety and efficacy of orbital atherectomy in patients with severely calcified LM artery lesions.

Percutaneous Coronary Intervention in Severely Calcified Unprotected Left Main Coronary Artery Disease: Initial Experience With Orbital Atherectomy

Michael S. Lee, MD1; Evan Shlomfritz, DO2; Barry Kaplan, MD3; Richard Shlomfritz, MD3

ABSTRACT: Objective. We report the clinical outcomes of patients who underwent percutaneous coronary intervention (PCI) with orbital atherectomy for severely calcified unprotected left main coronary artery (ULMCA) disease. Background. Although surgical revascularization is the gold standard for patients with ULMCA disease, not all patients are candidates for PCI. This study is designed and used to treat complex coronary artery disease, including ULMCA disease. The presence of severely calcified lesions increases the complexity of PCI. Orbital atherectomy can be used to facilitate stent delivery and expansion in severely calcified lesions. The clinical outcomes of patients treated with orbital atherectomy for severely calcified ULMCA disease have not been reported. Methods. From May 2014 to July 2015, a total of 14 patients who underwent PCI with orbital atherectomy for ULMCA disease were retrospectively evaluated. The primary endpoint was major coronary and cerebrovascular event (cardiac death, myocardial infarction, stroke, and target-lesion revascularization) at 30 days. Results. The mean age was 78.4 ± 6.6 years. The mean anatomic score was 1.8 ± 1.0, whereas 23 (87%) had anatomic score ≤2.6. The procedural success was achieved in 11 of 14 patients. The 30-day major adverse cardiac and cerebrovascular event rate was 0%. One patient had cardiac dissection that was successfully treated with stenting. No patient had perforation, slow flow, or thrombosis. Conclusions. Orbital atherectomy in patients with severely calcified ULMCA disease is feasible, even in high-risk patients who were considered poor surgical candidates. Randomized trials are needed to determine the role of orbital atherectomy in ULMCA disease.

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KEYWORDS: calcification, percutaneous coronary intervention, atherectomy, left main

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KEYWORDS: atherectomy, calcified lesions, ULMCA
Table 6. Clinical outcomes.

<table>
<thead>
<tr>
<th></th>
<th>Left Main</th>
<th>Non-Left Main</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-day MACE</td>
<td>10.0%</td>
<td>10.4%</td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Cardiac death</td>
<td>0.0%</td>
<td>0.2%</td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>10.0%</td>
<td>9.7%</td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Target-vessel revascularization</td>
<td>0.0%</td>
<td>1.4%</td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Severe angiographic complications</td>
<td>1/10 [10.0%]</td>
<td>31/433 [7.2%]</td>
<td>.53</td>
</tr>
<tr>
<td>Severe dissection [type C-F]</td>
<td>0/10 [0.0%]</td>
<td>15/433 [3.5%]</td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Perforation</td>
<td>0/10 [0.0%]</td>
<td>8/433 [1.8%]</td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Persistent slow flow</td>
<td>0/10 [0.0%]</td>
<td>4/433 [0.9%]</td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Persistent no reflow</td>
<td>0/10 [0.0%]</td>
<td>0/433 [0.0%]</td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Abrupt closure</td>
<td>1/10 [10.0%]</td>
<td>7/433 [1.6%]</td>
<td>.17</td>
</tr>
</tbody>
</table>

Data given as number [%]. MACE = major adverse cardiac events.
Coronary Angiography

68 y.o. male pre-lung transplant

Calcified LM and LAD
Orbital Atherectomy
Left Main Artery

Unique MOA treats 360° of the vessel. The diamond coated crown sands away calcium and allows healthy elastic tissue to flex away minimizing injury to the vessel.
Final Angiographic
Conclusion

- CAC may prevent stent delivery and optimal stent expansion
- CAC is associated with increased risk of complications, including death, MI, TVR, and stent thrombosis
- Orbital atherectomy is a safe and effective treatment strategy for patients with CAC
- Low angiographic complications
- Low rates of TVR
John Wooden

“Failing to prepare is preparing to fail.”