Aorto-Ostial Disease and Geographic Miss

A Single Center Experience With The “FLASH®” Ostial Balloon

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Disclosures

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• Abbott: Investigator
• The Medicines Company: Investigator
• OstialCorp: Investigator, Scientific Advisory Board, Stock Holder
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Aorto-Ostial Disease
Current Landscape

- >300,000 aorto-ostial endovascular stenting procedures performed annually world wide (1-4)
- Majority are non-coronary; >90% mesenteric and renal (1-4)
- Aorto-ostial disease in 7 to 8% of coronary interventions (1-4)
- CTA demonstrates that angle of ostial vessel anatomy is typically NOT 90 degrees (4)
- Angiographic paralax preclusdes precise positioning

Ostial Treatments

- POBA
- Rotational atherectomy
- Eximer laser atherectomy
- Stenting
Ostial Stenting & Geographic Miss

- 54% of ostial stenting results in geographic miss (1)
- 48% of cases with geographic miss result in stent being placed too distally requiring a 2nd stent (1)
- Distal miss results in increased risk of restenosis (1,2)
- Proximal miss results in difficulty with future engagement of the vessel
- 50% of cases with distal miss and placement of a 2nd stent result in 2nd stent being too proximal – a so called “double miss” (1)
- Higher complication rates and increased contrast usage

(1) Dishmon et al: J Invasive Cardiol. 2011; 23:322-326
Proximal Miss

Difficult target
Difficult Engagement of Prior Ostial Stent

Guide behind Stent

Left Renal Stent
Previously Reported Stenting Techniques

• Multiple Orthogonal Views “eye-balling”
• Szabo Technique (1,2)
  • Ostial-Pro ® device (Merit Medical, South Jordan, UT) (3)

(1) Szabo et al: Am J Cardiol. 2005;96:212(H)
Szabo Technique

1) Second wire is inserted through last (proximal) stent coil
2) Second wire resides outside of the ostium
3) Stent is advanced over both wires; second wire acts as a stop to prevent stent from moving past the ostium
4) Stent is deployed, second wire removed, and then post dilated

!! May result in stent deformation or wire entrapment !!
!! Stent may protrude into Aorta and is not flared flush to wall !!
1) Gold tipped struts are pushed up against the wall of the aorta
2) Guide is kept from entering vessel os
3) Camera is adjusted to align markers and remove paralax
4) Stent is deployed after aligning proximal stent marker with device markers

* Device still requires significant angiographic guidance (1)

(1) Kwan et al, J Invasive Cardiol 2011;23(8): 327
“FLASH”™ Ostial Balloon
(Ostial Corporation, Mountain View, CA)

- 6F compatible; sizes 3.5, 4, 4.5, 5.0, 6.0 mm; 8 and 14 mm lengths.
- Rapid exchange
- Dual balloon system
- High pressure anchoring balloon
- Low pressure/compliant flaring balloon
- Coronary and peripheral sizes
Three Markers

Central/Transition Marker

Proximal Marker

Tip Marker

Flash Balloon

Anchoring Balloon

Guide wire

Transition zone
“FLASH” Balloon
Procedural Steps

• Intentional stent placement slightly into the aorta
• Post-dilate stent with non-compliant balloon
• (care not to lose wire position)
• Exchange for “FLASH” balloon
• Position central marker approximately flush with vessel ostium
• Inflate (size matched) distal/anchoring balloon
• Inflate proximal compliant balloon
• Deflate balloons in reverse order and remove
Step 1: Stent placed beyond os
Step 2: FLASH balloon inflated
Step 3: Vessel re-engaged
Advantages

• Intentional stent placement into aorta insures that entirety of ostial lesion is covered/treated which in turn may decrease chance of restenosis.

• Aortic wall apposition of exposed stent allows for easier recanulation of vessel at subsequent procedures.

• Potentially fewer stents used due to distal geographic miss
DHLC Experience

• 229 patients between 12/11 and 5/14 treated for aorto-ostial disease

• 136/140 patient with attempted use of the FLASH balloon were treated successfully

• 2 RCA, 1 LMCA, 1 Renal: FLASH used unsuccessfully
Complications:

• 1 perforation (ostial RCA)
• 1 Distal edge dissection
• 1 transient hemodynamic instability (LMCA)
• 1 deformity of the contralateral renal stent (successfully resolved with another FLASH balloon)

• Except in the 3 stent complications listed above, no other case using the FLASH balloon required a second ostial stent
<table>
<thead>
<tr>
<th>Target Lesion</th>
<th>LM</th>
<th>RCA</th>
<th>SVG</th>
<th>Renal</th>
<th>Subclavian</th>
</tr>
</thead>
<tbody>
<tr>
<td>OF Attempted</td>
<td>49</td>
<td>66</td>
<td>5</td>
<td>19</td>
<td>1</td>
</tr>
<tr>
<td>OF successfully used</td>
<td>47 (95.91%)</td>
<td>64 (96.96%)</td>
<td>4 (80%)</td>
<td>19 (100%)</td>
<td>1 (100%)</td>
</tr>
<tr>
<td>Fluoroscopy time (mean ± SD)</td>
<td>33.10 ± 20.42</td>
<td>31.50 ± 17.53</td>
<td>53.62 ± 50.65</td>
<td>32.26 ± 27.39</td>
<td>39</td>
</tr>
<tr>
<td>Contrast (ml)</td>
<td>289.28 ± 138.36</td>
<td>245.50 ± 81.40</td>
<td>310 ± 78.79</td>
<td>150 ± 52.71</td>
<td>220</td>
</tr>
<tr>
<td>Procedure Time</td>
<td>2:10 ± 1:08</td>
<td>1:56 ± 0:45</td>
<td>2:57 ± 1:17</td>
<td>2.13 ± 0:55</td>
<td>1.45</td>
</tr>
<tr>
<td>&gt;1 stent for ostial target lesion</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Ostial Flash Size (mean)</td>
<td>4.0mm</td>
<td>3.5 mm</td>
<td>4.0 mm</td>
<td>5.00 mm</td>
<td>5.0 mm</td>
</tr>
<tr>
<td>Time to use ostial Flash balloon (minutes)</td>
<td>5 ± 2</td>
<td>5 ± 2</td>
<td>5 ± 3</td>
<td>4 ± 2</td>
<td>8</td>
</tr>
<tr>
<td>Access: Radial/ Femoral/ Brachial</td>
<td>7/41/1</td>
<td>22/44/0</td>
<td>1/4/0</td>
<td>6/11/02</td>
<td>0/1/0</td>
</tr>
<tr>
<td>Complication (Attributed to Ostial Flash)</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>6 months Followup completed</td>
<td>48(1 Death)</td>
<td>66</td>
<td>4(1 Death)</td>
<td>17(Lost to f/up 2)</td>
<td>1</td>
</tr>
<tr>
<td>Successful cath placement in Target vessel</td>
<td>7</td>
<td>5</td>
<td>1</td>
<td>1</td>
<td>NA</td>
</tr>
<tr>
<td>&gt;50% or FFR positive ISR @ 6 Months</td>
<td>2(4.09%)</td>
<td>3(4.54%)</td>
<td>0</td>
<td>1(5.6%)</td>
<td>NA</td>
</tr>
</tbody>
</table>
Case Example
Steps for Deployment

Stent (deliberately) beyond ostium into aorta

(Left Renal)

Aortic Wall
Balloon Positioning

- Proximal Marker
- Stent Edge
- Transition (center) Marker
- Distal Marker
“FLASH” Inflated

Compliant Balloon

Anchoring Balloon (sized to native vessel)
Flashed Stent With Easy Re-engagement
Conclusions:

• Ostial stenting remains problematic, primarily in terms of accuracy, risk for geographic miss, and therefore incomplete treatment or possible higher risk for restenosis.

• The Ostial FLASH balloon catheter appears to reduce the technical challenges of aorto-ostial stenting and is associated with a high technical success rate, low complication rate, and low restenosis rate.
Conclusions (cont)

- Previous reports have suggested a low technical success rate for aorto-ostial interventions (some <50%)
- We demonstrated a 97.14% technical success rate from both the femoral and radial approaches, a very low complication rate, and excellent patency rates at 6 months.
Thank You
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