Patterns of Vessel Calcification and Clinical Relevance

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Conflicts of Interest

Consultant
- Abbott Vascular (non-compensated)
- AOPA
- Boston Scientific (non-compensated)
- Cardinal Health
- Cordis Corporation (non-compensated)
- Janacare, Inc
- Medtronic (non-compensated)
- Micell, Inc
- Novella (DSMB)
- Primacea
- Valiant
- Volcano

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  - www.vivapvd.com
  - Intersocietal Accreditation Commission
- CBSET

Equity
- Access Closure, Inc
- Embolitech
- I.C.Sciences, Inc
- Janacare, Inc
- MC10
- Northwind Medical, Inc.
- PQ Bypass, Inc
- Primacea
- Sano V, Inc.
- Vascular Therapies, Inc

January 2016
Vascular Calcium in PAD

- Difficult to manage with any revascularization strategy
- Acute and long-term endovascular outcomes inferior when severe calcium is present
- Grading the severity of vascular calcium in peripheral arteries is subjective with no uniform grading scale...an art.
IN.PACT Global Long Lesion Imaging Cohort: Lesion/Procedural Characteristics

<table>
<thead>
<tr>
<th>Lesions (N)</th>
<th>164</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lesion Type:</strong></td>
<td></td>
</tr>
<tr>
<td>de novo</td>
<td>83.2% (134/161)</td>
</tr>
<tr>
<td>restenotic (no ISR)</td>
<td>16.8% (27/161)</td>
</tr>
<tr>
<td>ISR</td>
<td>0.0% (0/161)</td>
</tr>
<tr>
<td><strong>Lesion Length</strong></td>
<td>26.40 ± 8.61 cm</td>
</tr>
<tr>
<td><strong>Total Occlusions</strong></td>
<td>60.4% (99/164)</td>
</tr>
<tr>
<td><strong>Calcification</strong></td>
<td>71.8% (117/163)</td>
</tr>
<tr>
<td>Severe</td>
<td>19.6% (32/163)</td>
</tr>
<tr>
<td><strong>RVD (mm)</strong></td>
<td>4.594 ± 0.819</td>
</tr>
<tr>
<td><strong>Diameter Stenosis (pre-treatment)</strong></td>
<td>90.9% ± 14.2</td>
</tr>
<tr>
<td><strong>Dissections:</strong></td>
<td>0</td>
</tr>
<tr>
<td>A-C</td>
<td>47.2% (76/161)</td>
</tr>
<tr>
<td>D-F</td>
<td>14.9% (24/161)</td>
</tr>
<tr>
<td><strong>Device Success</strong></td>
<td>99.5% (442/444)</td>
</tr>
<tr>
<td><strong>Procedure Success</strong></td>
<td>99.4% (155/156)</td>
</tr>
<tr>
<td><strong>Clinical Success</strong></td>
<td>99.4% (155/156)</td>
</tr>
<tr>
<td><strong>Pre-dilatation</strong></td>
<td>89.8% (141/157)</td>
</tr>
<tr>
<td><strong>Post-dilatation</strong></td>
<td>39.1% (61/156)</td>
</tr>
<tr>
<td><strong>Provisional Stent</strong></td>
<td></td>
</tr>
<tr>
<td>LL 15-25 cm:</td>
<td>40.4% (63/156)</td>
</tr>
<tr>
<td>LL &gt; 25 cm:</td>
<td>33.3% (33/99)</td>
</tr>
<tr>
<td>52.6% (30/57)</td>
<td></td>
</tr>
</tbody>
</table>

1. Device success: successful delivery, inflation, deflation and retrieval of the intact study balloon device without burst below the RBP
2. Procedure success: residual stenosis of ≤ 50% (non-stented subjects) or ≤ 30% (stented subjects) by core lab (if core lab was not available then the site reported estimate was used)
3. Clinical success: procedural success without procedural complications (death, major target limb amputation, thrombosis of the target lesion, or TVR) prior to discharge
How Should this Lesion Be Uniformly Graded?

• Assessment method should be widely available (i.e., fluoroscopy)
• Important features of vascular Ca++ should be assessed: intimal v. medial v. mixed (combination of fluoroscopy and DSA)
• Ratio of Ca++ grade length as a % of total lesion length should be assessed: SEVERE CA++ INDEX
No Consistent and Validated Calcium Scoring System has been established

<table>
<thead>
<tr>
<th>Physician reported based on arbitrary scale (biased and not specific)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DEFINITIVE Ca++ Trial</strong>¹</td>
</tr>
<tr>
<td><strong>DEFINITIVE AR</strong>²</td>
</tr>
<tr>
<td>Bard Lutonix DCB</td>
</tr>
<tr>
<td>MDT Admiral DCB³</td>
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# Published (Proposed) Ca++ Grading Scales

<table>
<thead>
<tr>
<th>Degree of Lesion Calcification – PARC</th>
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<tbody>
<tr>
<td><strong>Focal</strong></td>
<td>&lt;180° (one side of vessel) and less than half the total lesion length</td>
</tr>
<tr>
<td><strong>Mild</strong></td>
<td>&lt;180° and greater than half the total lesion length</td>
</tr>
<tr>
<td><strong>Moderate</strong></td>
<td>≥ 180° (both sides of vessel at same location) and less than half the total lesion length</td>
</tr>
<tr>
<td><strong>Severe</strong></td>
<td>&gt;180° (both sides of the vessel at the same location) and greater than half the total lesion length</td>
</tr>
</tbody>
</table>

This proposed scale does not account for intimal vs. medial calcification patterns

Proposed Vascular Ca++ Grading Scale: PACSS

PERIPHERAL VASCULAR DISEASE

Core Curriculum

Peripheral Arterial Calcification: Prevalence, Mechanism, Detection, and Clinical Implications

Krishna J. Rocha-Singh, MD, FACC, FAHA, Thomas Zeller, MD, and Michael R. Jaff, DO, FACC, FAHA
Proposed Fluroscopy/DSA based Peripheral Arterial Calcification Scoring Systems (PACSS): Intimal and medial vessel wall calcification at the target lesion site as assessed by high intensity fluoroscopy and digital subtraction angiography (DSA) assessed in the AP projection.

**Grade 0:** No visible calcium at the target lesion site

**Grade 1:** unilateral calcification < 5cm; a) intimal calcification; b) medical calcification; c) mixed type

**Grade 2:** unilateral calcification ≥ 5cm; a) intimal calcification; b) medical calcification; c) mixed type

**Grade 3:** bilateral calcification < 5cm; a) intimal calcification; b) medical calcification; c) mixed type

**Grade 4:** bilateral calcification ≥ 5cm; a) intimal calcification; b) medical calcification; c) mixed type
Tips to Assessing Peripheral Artery Calcium

- Assessment best performed at the time of diagnostic arteriography
- *Medial* calcification best assessed using fluoroscopy with a contrast-filled artery
- *Intimal* calcification best assessed using a dynamic DSA/cine run
- The majority of moderate/severely calcified SFA lesions have mixed components
**The REALITY Study**

- Multi-center, prospective assessment of the safety and effectiveness of combined “vessel preparation” with directional atherectomy (HawkOne® /TurboHawk®) + IN.PACT Admiral® DCB in LONG and SEVERELY calcified FP lesions in 250 patients with RC 2-4 claudication.

- Angiographic & Doppler core labs will independently adjudicate PP through 12 mos. and freedom from CD-TLR through 24 mos.

- IVUS, **peripheral Ca++ grading scale validation** sub-studies, WIQ, QoL and health economic assessments.
Vascular Calcification in PAD

• A uniform grading scale is needed
  ✓ PACSS is currently being prospectively evaluated

• A validated peripheral Ca++ scoring system will allow the comparison of technologies designed to manage vascular calcium:
  ✓ Atherectomy
  ✓ Atherectomy + DCB
  ✓ BMS
  ✓ DES
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