Calcium grading systems, which one is most accurate?

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Disclosures

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Boston Scientific, Surmodics, Cagent, CSI, Philips, Medtronic, Intervene, Limflow, Silk Road, Cagent, Devoro
Calcification

Challenging for both endo and open. Crossing and repair are compromised. Long-term results poor. Crosses TASC classification. No simple way to quantify.
Calcium Grading System

• Planning and approach
  • Open versus endovascular
  • Challenge to crossing, clamping

• Treatment
  • Atherectomy: directional, rotational, orbital
  • Lithoplasty
  • Serration angioplasty
  • Scoring angioplasty

• Understanding the results
Calcium Grading System

- Calcification is associated with acute and late device failure (e.g., PTA, nitinol stents, stand-alone atherectomy).
- Fluoroscopic quantification of calcification is imprecise but commonly used.
- What degree of calcification is predictive of acute and late procedural failure?
- How can the deleterious effects of calcification be mitigated to improve procedural results?
Calcium Grading Systems

<table>
<thead>
<tr>
<th>Fanelli et al. [1]</th>
<th>1a</th>
<th>1b</th>
<th>2a</th>
<th>2b</th>
<th>3a</th>
<th>3b</th>
<th>4a</th>
<th>4b</th>
</tr>
</thead>
<tbody>
<tr>
<td>Circumf.</td>
<td>0-90°</td>
<td>0-90°</td>
<td>90-180°</td>
<td>180-270°</td>
<td>180-270°</td>
<td>270-360°</td>
<td>270-360°</td>
<td></td>
</tr>
<tr>
<td>Length</td>
<td>&lt;3 cm</td>
<td>&gt;3 cm</td>
<td>&lt;3 cm</td>
<td>&gt;3 cm</td>
<td>&lt;3 cm</td>
<td>&lt;3 cm</td>
<td>&gt;3 cm</td>
<td>&gt;3 cm</td>
</tr>
<tr>
<td>Compliance 360° [2]</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Circumf.</td>
<td>NO calcium</td>
<td>&lt;180° (1 side of vessel)</td>
<td>&lt;180° (1 side of vessel)</td>
<td>≥180° (both sides of vessel)</td>
<td>≥180° (both sides of vessel)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length</td>
<td>NO calcium</td>
<td>&lt;50% of lesion length</td>
<td>≥50% of lesion length</td>
<td>&lt;50% of lesion length</td>
<td>≥50% of lesion length</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PACSS [3]</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Circumf.</td>
<td>NO calcium</td>
<td>unilateral</td>
<td>unilateral</td>
<td>bilateral</td>
<td>bilateral</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length</td>
<td>NO calcium</td>
<td>&lt;5 cm</td>
<td>≥5 cm</td>
<td>&lt;5 cm</td>
<td>≥5 cm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>location</td>
<td>a) intimal calcification; b) medial calcification; c) mixed type</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>PARC [4]</td>
<td>Focal</td>
<td>mild</td>
<td>moderate</td>
<td>severe</td>
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</tr>
<tr>
<td>Circumf.</td>
<td>&lt;180° (1 side of vessel)</td>
<td>&lt;180° (1 side of vessel)</td>
<td>≥180° (both sides of vessel)</td>
<td>&gt;180° (both sides of vessel)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Length</td>
<td>&lt;1/2 of lesion length</td>
<td>&gt;1/2 of lesion length</td>
<td>&lt;1/2 of lesion length</td>
<td>&gt;1/2 of lesion length</td>
<td></td>
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</tbody>
</table>

Fanelli LINC 2017
Calcification $\geq 180$ degrees

**Graphs and Tables**

- **Postprocedure MVA (mm²):**
  - No calcification (n=20): 17.7 [16.4, 19.0]
  - $<180°$ calcification (n=46): 15.4 [14.6, 16.3]
  - $\geq 180°$ calcification (n=45): 12.8 [11.9, 13.7]
  - P-values: $P = 0.006$, $P < 0.001$.

- **Restenosis Rate:**
  - P = 0.018* log-rank
  - Months: 0, 6, 12, 18, 24
  - Rates:
    | Months | 0 | 6 | 12 | 18 | 24 |
    |--------|---|---|----|----|----|
    | No Calc | 28 | 26 | 20 | 18 | 17 |
    | % | 0 | 8.0 | 24.0 | 24.0 | 26.0 |
    | Calc $<180°$ | 52 | 42 | 35 | 20 | 13 |
    | % | 0 | 12.5 | 27.8 | 33.3 | 41.8 |
    | Calc $\geq 180°$ | 50 | 37 | 25 | 16 | 12 |
    | % | 0 | 23.1 | 39.3 | 48.9 | 53.1 |

*Fujihara et al. JVE 2019;26:322*
PACSS Predictive of Patency

Okuno et al. JEVT 2016;23:731
Calcium and Drug Delivery

- DCB technologies enter into a new era of ‘data evolution’ to define their role in the management of complex FPA disease
- Beyond RCTs, robust adjudicated ‘real world’ multicenter registries are essential to that ‘data evolution’
- Importantly, a uniform definition of terms of what constitutes a ‘complex FPA lesions’, how ‘vessel preparation’ is used and assessed requires collaboration between physicians, industry and regulators
- One specific example is calcium, which has emerged as a possible ‘Achilles' Heel’ in DCB efficacy
Data in Context with Core Lab*

Adjudicated 12-Month Patency Rates

*VasCore (Boston, MA); PSVR: 2.5, KM estimates at day 365 (360 for IN.PACT SFA)
Example of “Severe” Calcium Definitions

IN.PACT SFA\textsuperscript{1}
DCB Arm: 8.1%
Severe calcification is defined as calcium visible along both sides of the arterial wall, covers 2cm or greater of the target lesion area, encompasses greater than 50% of the total target lesion treatment area by visual estimate and/or the calcium is circumferential (360\degree) in nature (i.e. on both sides of the vessel lumen extending 2cm or greater on a single AP view) or classified as exophytic calcification, significantly impedes blood flow in the vessel.\textsuperscript{2}

ILLUMENATE Pivotal\textsuperscript{3}
DCB Arm: 43.9%
Severe calcification defined as radiopacities noted on both sides of the arterial wall and extending more than one cm of length prior to contrast injection or digital subtraction.\textsuperscript{4}

Complex Lesions: Calcium and Lesion Length

Calcium limits full vessel expansion, promotes recoil and dissections

Calcium distribution evaluation by CTA (circumferential) and DSA (longitudinal)

Calcified plaque modification alters local drug delivery in the treatment of peripheral atherosclerosis

Abraham R. Tzafiri, Fernando Garcia-Polite, Brett Zan, James Stanley, Benny Murai, Jennifer Knutson, Robert Kohler, Peter Markham, Alexander Nikanorov, Elazer R. Edelman

Funded in part by CSI, Inc.

Tzafari J et al., Controlled Release Sept 2017
Calcium Grading Systems

Conclusion

- Standardized calcium definition will facilitate assessment of clinical efficacy of adjunct treatment strategies such as vessel preparation and drug eluting platforms.
- Severe calcium associated with decreased patency.
- Severe calcium appears to interfere with drug delivery.
- Circumference and length of calcium both outcomes.
- Fluoro-guided assessment-PACSS