The Reality of PAD: Treatment Strategies for Improved Outcomes

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Agenda

The Reality of PAD: Treatment Strategies for Improved Outcomes

Panel: Thomas Zeller, MD, Giovanni Torsello, MD, Ralf Langhoff, MD, Ravish Sachar, MD

Introduction
Dierk Scheinert, MD
Universitätsklinikum Leipzig, Leipzig, Germany

Live Case: Use of Directional Atherectomy and IN.PACT™ Admiral™ DCB for Long, Calcified Lesion
Andrej Schmidt, MD
Universitätsklinikum Leipzig, Leipzig, Germany

Redefining the Management of PAD: A Critical Look at Calcium
Ralf Langhoff, MD
Sankt Gertrauden Krankenhaus, Berlin, Germany

Clinical Evidence for Vessel Preparation Followed by DCB in the Most Challenging Lesions
Ravish Sachar, MD
North Carolina Heart & Vascular, UNC-Rex Healthcare, Raleigh, NC

What is the Clinical Evidence for Long-term Effectiveness of DCB to Reduce Reinterventions?
Giovanni Torsello, MD
St. Franziskus-Hospital, Münster, Germany

Additional Strategies, Tools & Techniques for Peripheral Vascular Therapies: A Pre-Recorded Case
Thomas Zeller, MD
Universitäts Herzzentrum Freiburg-Bad Krozingen, Bad Krozingen, Germany

Discussion
Panel

Closing
Dierk Scheinert, MD
Redefining the Management of PAD: A Critical Look at Calcium

Ralf Langhoff, MD
Sankt Gertrauden Hospital
Berlin, Germany
Challenges Associated with Severe Calcium in Practice

**Procedural Obstacles**
- Endovascular strategies are challenged in the presence of calcification
- High lesion complexity
- Difficult lesion crossing
- Highly resistive plaque
- Extended intervention time

**Outcome Limitations**
- Dissection
- Provisional stenting
- Stent fractures
- Residual stenosis / re-stenosis
- Drug-coated balloon effectiveness (decreased absorption)

References:
Limitations of Calcium for Endovascular Therapy

- Calcium is a potential barrier to optimal drug absorption
- Calcium distribution and severity may affect late lumen loss (LLL) and primary patency

- Primary patency defined as freedom from restenosis by duplex based on PSVR<2.4 and TLR
How is Calcification Addressed in DCB Clinical Trials?
## Clinical Trial Angiography Core Labs

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<thead>
<tr>
<th>Beth Israel</th>
<th>SynvaCor</th>
<th>Genae Associates, Belgium</th>
<th>No Core Lab</th>
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<tr>
<td>ILLUMENATE US</td>
<td>ILLUMENATE Global</td>
<td>ILLUMENATE FIH</td>
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## Core Lab Definitions of Severe Calcium Vary Bilateral Calcification

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<thead>
<tr>
<th>Beth Israel&lt;sup&gt;1-3&lt;/sup&gt;</th>
<th>SynvaCor&lt;sup&gt;4-11&lt;/sup&gt;</th>
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<tr>
<td><strong>Severe calcification:</strong></td>
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<td>▪ Radiopacities noted on both sides of the arterial wall and extending more than 1 cm of length prior to contrast injection or digital subtraction.</td>
<td>▪ Calcium visible along both sides of the arterial wall</td>
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<td>▪ Covers 2 cm or greater of the target lesion area</td>
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<td>▪ Encompasses greater than 50% of the total target lesion treatment area by visual estimate and/or the calcium is circumferential (360°) in nature</td>
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<td>▪ on both sides of the vessel lumen extending 2 cm or greater on a single AP view</td>
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<td>▪ Classified as exophytic calcification, significantly impedes blood flow in the vessel.</td>
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## Calcium Grading System
### Bilateral Calcification

<table>
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<tr>
<th>Beth Israel¹-³</th>
<th>SynvaCor⁴-¹¹</th>
<th>PACSS¹²</th>
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<tr>
<td><strong>Severe calcification:</strong></td>
<td><strong>Severe calcification:</strong></td>
<td><strong>Grading System: Severe Calcification</strong></td>
</tr>
<tr>
<td>▪ Radiopacities noted on both sides of the arterial wall and extending more than 1 cm of length prior to contrast injection or digital subtraction.</td>
<td>▪ Calcium visible along both sides of the arterial wall</td>
<td>Grade 3: bilateral calcification &lt; 5 cm; a) intimal calcification; b) medical calcification; c) mixed type</td>
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<td>▪ Covers 2 cm or greater of the target lesion area</td>
<td>Grade 4: bilateral calcification ≥ 5 cm; a) intimal calcification; b) medical calcification; c) mixed type</td>
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<td>▪ Encompasses greater than 50% of the total target lesion treatment area by visual estimate and/or the calcium is circumferential (360°) in nature</td>
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Summary

- Presence of calcium in the peripheral vasculature poses a significant challenge to current endovascular device strategies.
- Results from contemporary DCB studies show promising outcomes when treating calcified lesions, however comparisons of calcium across these trials are futile given differences in calcium definitions and differences in adjudication.
- Need for consensus on how calcium is defined.

Is calcium the Achilles of endovascular treatment strategies or is there an option?

Current strategies to remove calcium before application of antiproliferative therapy.
Thank You