

The Reality of PAD: Treatment Strategies for Improved Outcomes

January 26, 2021

15:05 pm – 16:35 pm CET



Footer and page numbers
don't line up the same on
all slides

Moderator:

Dierk Scheinert, MD
Leipzig, Germany

Operator:

Andrej Schmidt, MD
Leipzig, Germany

Panel:

Ralf Langhoff, MD
Berlin, Germany

Ravish Sachar MD
Raleigh, NC

Giovanni Torsello, MD
Münster, Germany

Thomas Zeller MD
Bad Krozingen, Germany

Disclaimers

This program is provided for general educational purposes only and should not be considered the exclusive source for this type of information. This training does not replace or supersede approved labeling. The content will be shared with healthcare professionals who seek a deeper understanding of the operation and use of Medtronic products and therapies with the intent of enhancing their knowledge of features and operations described in the clinician manuals. The patient data represented has been changed or removed to protect the privacy of the patient and is designed for educational purposes. At all times, it is the professional responsibility of the practitioner to exercise independent clinical judgment in a particular situation. Changes in a patient's disease and/or medications may alter the efficacy of a device or related features and results may vary.

COMPENSATION

This faculty is being paid as a consultant for the services being provided and will be reported in accordance with the Physicians Payment Sunshine Act (PPSA).

Off-Label:

- This program, sponsored by Medtronic, is intended to educate and train customers on the approved therapies and FDA indicated uses of Medtronic products.
- Medtronic product Instructions for Use can be found at <http://manuals.medtronic.com/>
- For questions related to an unapproved use of a Medtronic product, please contact Medtronic's Peripheral Office of Medical Affairs. Email: rs.oma@medtronic.com

Indications, Safety, Warnings

CAUTION STATEMENT

The content, case study, images, logos, charts, information, and opinions are those of the physician faculty presenting the material and do not necessarily reflect the opinions or position of Medtronic. The materials presented here are provided by and used with permission from the physician faculty. This information is intended only for users in markets where Medtronic products and therapies are approved or available for use as indicated within respective product manuals. Content on specific Medtronic products and therapies is not intended for users in markets that do not have authorization for use.

If you are located in the United States, please refer to the brief statement(s) at the end of this presentation to review applicable indications, safety and warning information. See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1.763.514.4000 and/or consult the Medtronic website at www.medtronic.com.

If you are located outside the United States, see the device manual for detailed information regarding instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.eu.

For applicable products, consult instructions for use on manuals.medtronic.com. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

Agenda

The Reality of PAD: Treatment Strategies for Improved Outcomes

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



Case Operator - Andrej Schmidt, MD

Moderator - Dierk Scheinert, MD

Introduction	Dierk Scheinert, MD <i>Universitätsklinikum Leipzig, Leipzig, Germany</i>
Live Case: Use of Directional Atherectomy and IN.PACT™ Admiral™ DCB for Long, Calcified Lesion	Andrej Schmidt, MD <i>Universitätsklinikum Leipzig, Leipzig, Germany</i>
Redefining the Management of PAD: A Critical Look at Calcium	Ralf Langhoff, MD <i>Sankt Gertrauden Krankenhaus, Berlin, Germany</i>
Clinical Evidence for Vessel Preparation Followed by DCB in the Most Challenging Lesions	Ravish Sachar, MD <i>North Carolina Heart & Vascular, UNC-Rex Healthcare, Raleigh, NC</i>
What is the Clinical Evidence for Long-term Effectiveness of DCB to Reduce Reinterventions?	Giovanni Torsello, MD <i>St. Franziskus-Hospital, Münster, Germany</i>
Additional Strategies, Tools & Techniques for Peripheral Vascular Therapies: A Pre-Recorded Case	Thomas Zeller, MD <i>Universitäts Herzzentrum Freiburg-Bad Krozingen, Bad Krozingen, Germany</i>
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

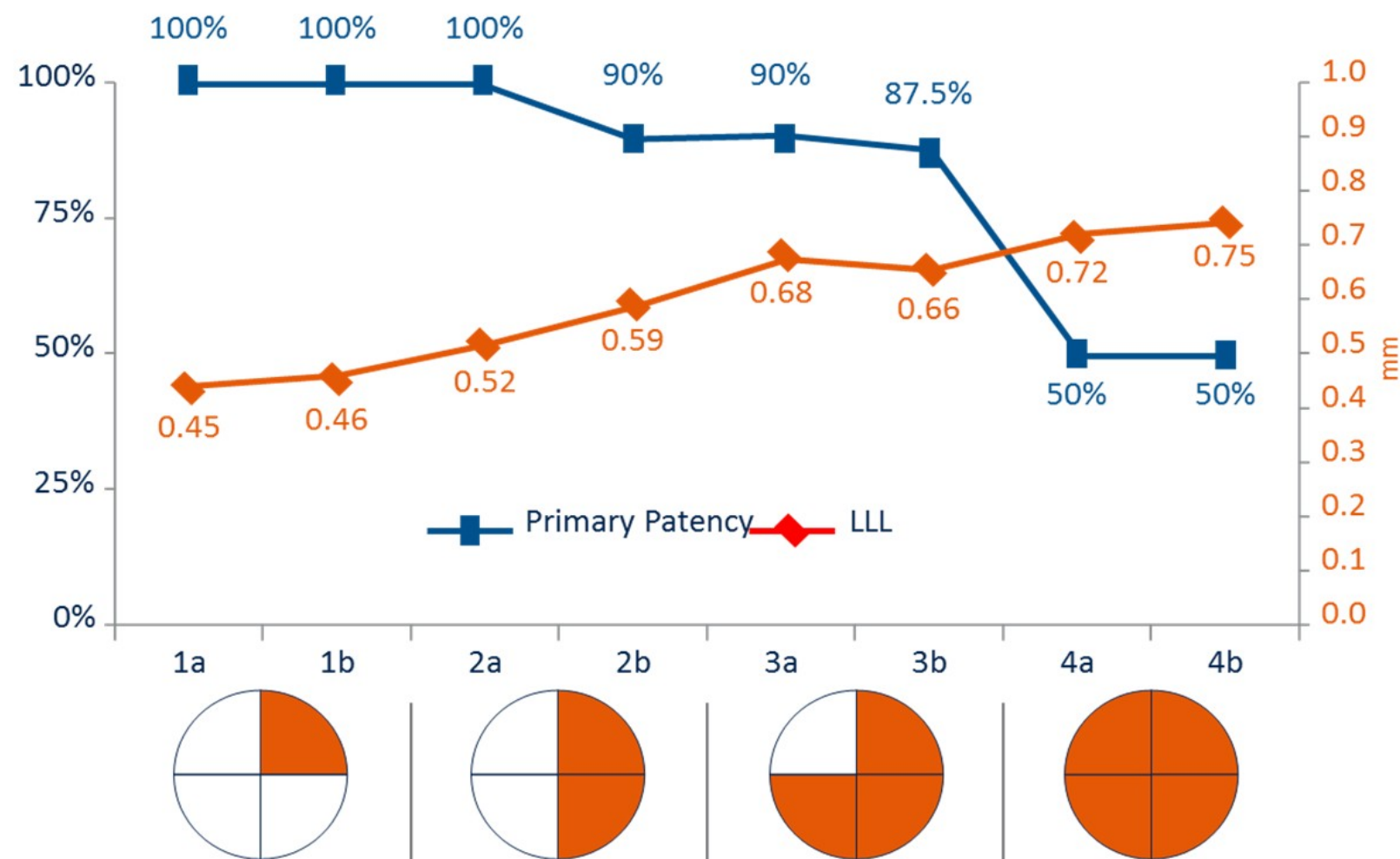
Outcome Limitations

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

1. Thieme M. JACC-CI 2017;10:1693-1690.
2. Scheinert D et al. CIRC CI 2018;11:1-10
3. Tepe G, IN.PACT Global CTO Charing Cross London, UK 2016.
4. Brodmann M, et.al. JACC CI. 2017;10:2114-2123.
5. Micari A, et al. JACC-CI. 2018;11:945-953.

6. Schroe H, et.al. CCI 2018;91:497-504.
7. Laird J, et al. J Endovasc Ther 2018;25:68-78
8. Laird J, et al. CCI 2010;3:267-76..
9. Lammer J et al. J Am Coll Cardiol 2013;62:1320-7.
10. Bosiers M et al. J Vasc Surg 2011;54:1042-50.
11. Fanelli F, et al. Cardiovasc Interv Radiol 37:898-907 (2014).

Limitations of Calcium for Endovascular Therapy



Calcium distribution evaluation by CTA (circumf.) and DSA (longitud.); "a" <3cm and "b" >3cm

- 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
- Fanelli, F. et al. Cardiovasc Interv Radiol 2014;37:898-907.

How is Calcification Addressed in DCB Clinical Trials?

Clinical Trial Angiography Core Labs

Beth Israel	SynvaCor	Genae Associates, Belgium	No Core Lab
ILLUMENATE US ILLUMENATE Global	LEVANT 2 IN.PACT SFA IN.PACT Global Imaging Cohorts ILLUMENATE EU ILLUMENATE FIH	LEVANT 1 (FIH)	LEVANT Global Ranger Global

Core Lab Definitions of Severe Calcium Vary

Bilateral Calcification

Beth Israel ¹⁻³	SynvaCor ⁴⁻¹¹
<p>Severe calcification:</p> <ul style="list-style-type: none"> Radiopacities noted on both sides of the arterial wall and extending more than 1 cm of length prior to contrast injection or digital subtraction. 	<p>Severe calcification:</p> <ul style="list-style-type: none"> 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°) in nature <ul style="list-style-type: none"> on both sides of the vessel lumen extending 2cm or greater on a single AP view <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> Classified as exophytic calcification, significantly impedes blood flow in the vessel.

1. Brodmann, M. AMP 2017.

2. Krishnan, P. et al. Circulation 2017;136.

3. Schroe, H. et al. Catheter Cardiovasc Interv 2017;91.

4. Schroeder, H. et al. Catheter Cardiovasc Interv 2015;86.

5. Schroeder, H. et al. Circulation 2017;135.

6. Rocha-Singh, K. LINC 2017.

7. Rosenfield, K. et al. N Engl J Med 2015;373.

8. Tepe, G. et al. (2015). Circulation 131;5.

9. Brodmann, M. et al. JACC-Cardiovasc Interv 2017;10.

10. Scheinert, D. et al. CIRC-Cardiovasc Interv 2018;11

11. Tepe, G. et al. JACC-Cardiovasc Interv 2019;12..

Calcium Grading System

Bilateral Calcification

Beth Israel ¹⁻³	SynvaCor ⁴⁻¹¹	PACSS ¹²
<p>Severe calcification:</p> <ul style="list-style-type: none"> Radiopacities noted on both sides of the arterial wall and extending more than 1 cm of length prior to contrast injection or digital subtraction. 	<p>Severe calcification:</p> <ul style="list-style-type: none"> 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°) in nature <ul style="list-style-type: none"> on both sides of the vessel lumen extending 2cm or greater on a single AP view <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> Classified as exophytic calcification, significantly impedes blood flow in the vessel. 	<p>Grading System: Severe Calcification</p> <p>Grade 3: bilateral calcification < 5cm; a) intimal calcification; b) medical calcification; c) mixed type</p> <p>Grade 4: bilateral calcification ≥ 5cm; a) intimal calcification; b) medical calcification; c) mixed type</p>

1. Brodmann, M. AMP 2017.
 2. Krishnan, P. et al. Circulation 2017;136.
 3. Schroe, H. et al. Catheter Cardiovasc Interv 2017;91.
 4. Schroeder, H. et al. Catheter Cardiovasc Interv 2015;86.

5. Schroeder, H. et al. Circulation 2017;135.
 6. Rocha-Singh, K. LINC 2017.
 7. Rosenfield, K. et al. N Engl J Med 2015;373.
 8. Tepe, G. et al. (2015). Circulation 131;5.

9. Brodmann, M. et al. JACC-Cardiovasc Interv 2017;10.
 10. Scheinert, D. et al. CIRC-Cardiovasc Interv 2018;11
 11. Tepe, G. et al. JACC-Cardiovasc Interv 2019;12.
 12. Rocha-Singh, K. et al., Catheter Cardiovasc Interv. 2014;1.

Summary

- Presence of calcium 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 trails 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