What Constitutes Severe Calcification in Femopop Arteries and How does it Influence DCB Effectiveness: What can be done about it

Calcified Lesions Are Challenging to Treat

Calcium and DCB implications

Calcium and DCB

Disclosures

Calcified lesions are associated with high incidence of angiographic complications. Calcified lesions limit effectiveness of drug-coated balloons.

Contemporary clinical trials have excluded severely calcified lesions from studies.
DCB and Calcium

Ex-vivo and pre-clinical experiments confirm Calcium, not plaque burden, remains the real barrier for DCB drug uptake

A look at the data: 5 DCB Trials

1300 DCB patients, similar trial design, similar rigor

3. M.Brodmann - ILLUMENATE European Randomized Clinical Trial: 12-month Final Results from the Stellarex DCB – oral presentation, AMP 2016
4. S.Lyden - ILLUMENATE Pivotal Stellarex DCB IDE Study 12-month Results - oral presentation, TCT 2016
5. T.Zeller – Illumenate Global – oral presentation, LINC 2017

DCB and Calcium

1-year Primary Patency and Ca++

Context view from DCB Trials powered on a 1 year Primary Patency primary endpoint

Vessel Prep: How to do it

- From standard PTA to Atherectomy: "lesion preparation" may serve notoriously complex settings (such as de-novo or ISR, CTO and severe calcium) to:
  - Achieve desired lumen gain while limiting the need of implants
  - Enhance drug uptake
  - Evidence warranted to assess specific devices in specific settings

5 peer-reviewed calcium definitions

Bilateral / circumferential distribution = common marker of Calcium severity

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Vessel Prep: How to do it
- PTA
- Cutting-balloon
- Scoring balloon
- Non-conventional balloon
- Atherectomy device
- Lythoplasty

Plaque Scoring + DCB in Ca++
Angiosculpt designed to increase and stabilize lumen-gain through a controlled-dissection mechanism:
- ↓ Dissection severity and rate
- ↑ Luminal gain and ↓ recoil
- ↑ Balloon stability
- Potential ↑ drug uptake

Debulking + DCB in Ca++
DEFINITIVE AR suggests potential role of Atherectomy in long Ca++ lesions
more to learn from REALITY single-arm study:
DiRectional AthErectomy + Drug CoAted Balloon for the Treatment Long, Calcified Femoropopliteal Artery Lesions
N=150 (enrolling)
Sponsor: VIVA Physicians

DISRUPT PAD II
Intravascular Lithotripsy in Complex, Calcified Femoropopliteal Arteries
Effectiveness: Patency and CD-TLR at 12 months*

Conclusions
- Calcium limits optimal dilatation
- Circumferential distribution of calcium represents the main barrier for drug uptake
- Angiography underestimates calcium and makes angio-based study exclusions criteria mild and vague
- Bilateral calcium is the common marker of calcium severity in different grading systems
- Proper lesion preparation can increase the patency rate of DCBs in heavy calcified lesions
- Remains a need for consensus definitions of calcium across peripheral clinical trials

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