LITHOTRIPSY IN PAD

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Disclosures

- None

Peripheral Artery Disease

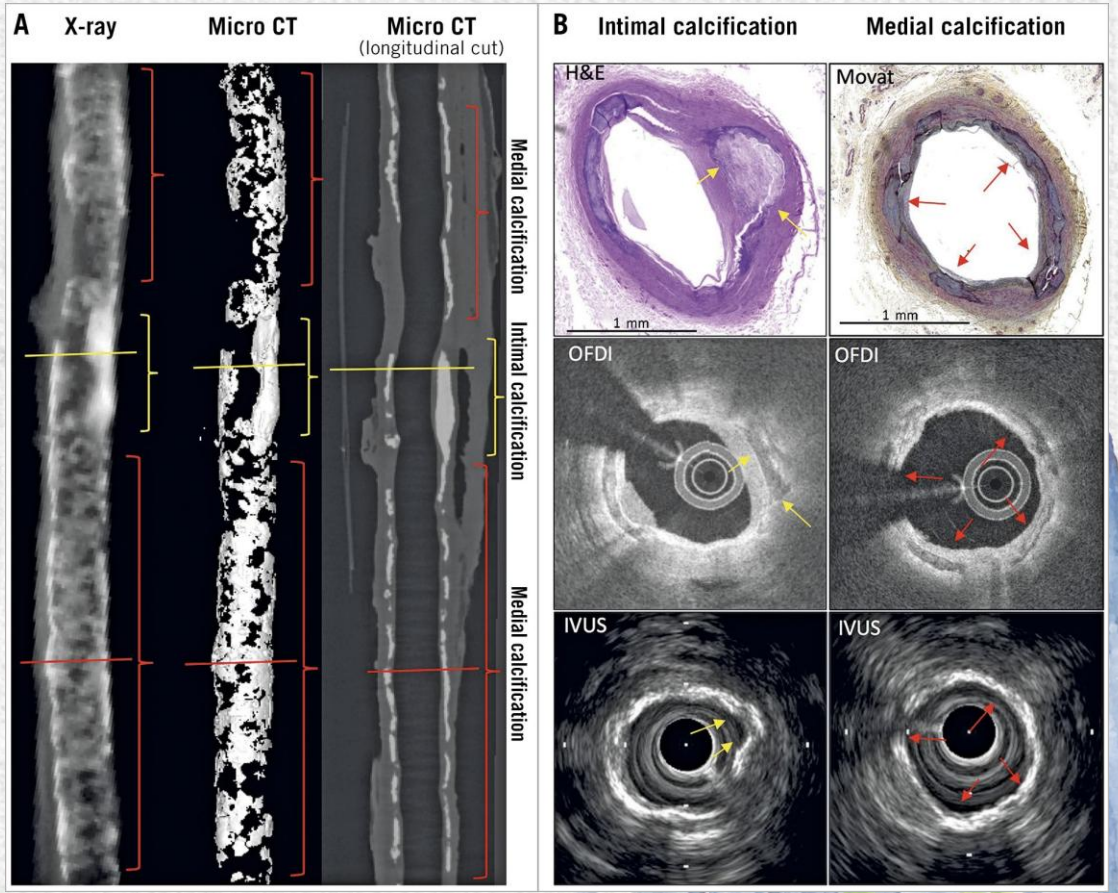
- 200 million people worldwide
  - Contributor to functional limitation, quality of life, and increased risk of CV morbidity and mortality.

- 20% have some degree of intravascular calcification.
  - Prevalent with PAD, especially diabetes mellitus or chronic kidney disease.

Zemaitis MR et al. Peripheral Arterial Disease. Treasure Island: StatPearls Publishing; 2025 Jan-.

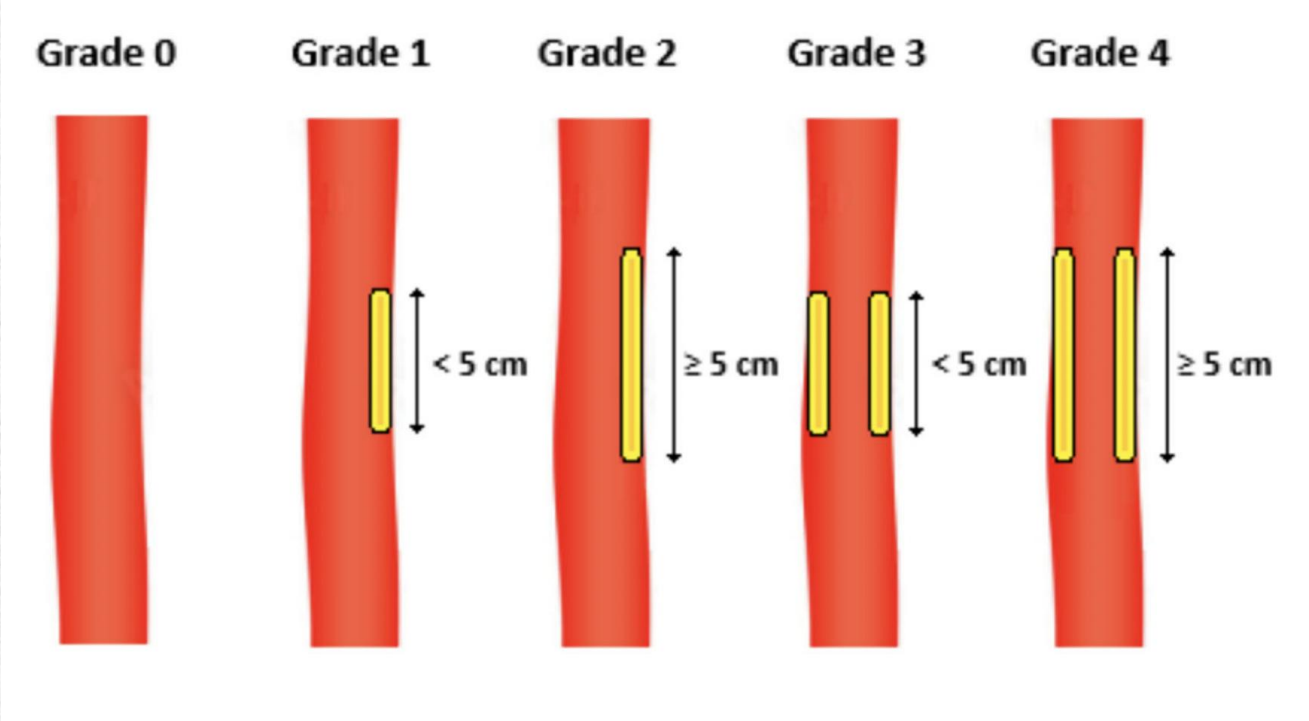
Calcium, the big problem

- Delivery of endovascular therapies.
- Suboptimal vessel expansion
- Risk of vascular complications
  - (restenosis, dissection, perforation, and distal embolization)
- Deep calcium is resistant to modification by NC or RA



Jinnouchi, Hiroyuki, et al. Intravascular imaging and histological correlates of medial and intimal calcification in peripheral artery disease. EuroIntervention. 2021. e688-e698.

Patterns of calcification



Peripheral Arterial Calcium Scoring System (PACSS)

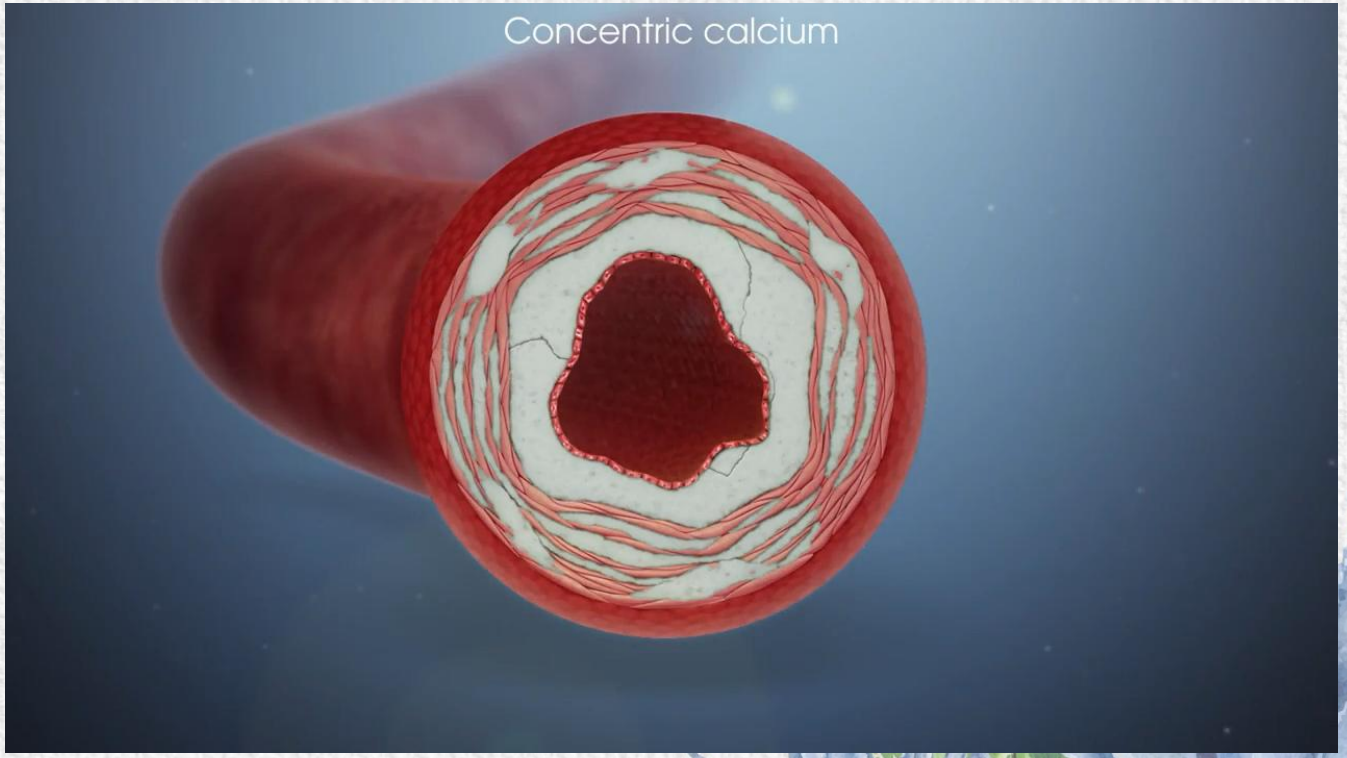
Fig. 2. The fluoroscopic (panel A) and digital subtraction angiographic (panel B) appearance of severe calcification involving the SFA.

Kaneta G, et al. Eligibility of common- femoral artery atherosclerotic disease for endovascular treatment—the CONFESS study. *Eur J Vasc Endovasc Surg*. 2022;64:684–691.

Intravascular Lithotripsy

- Angioplasty catheter
  - Multiple emitters that provide pulsatile sonic pressure energy.

- Advantages:
  - Does not affect local or soft tissues
  - No emboli.
  - Disrupt superficial and deep calcium
  - Leave nothing behind



Tepe et al. IVL for Peripheral Artery Calcification. JACC: CARDIOVASCULAR INTERVENTIONS VOL. 14, NO. 12, 2021

Principal applications

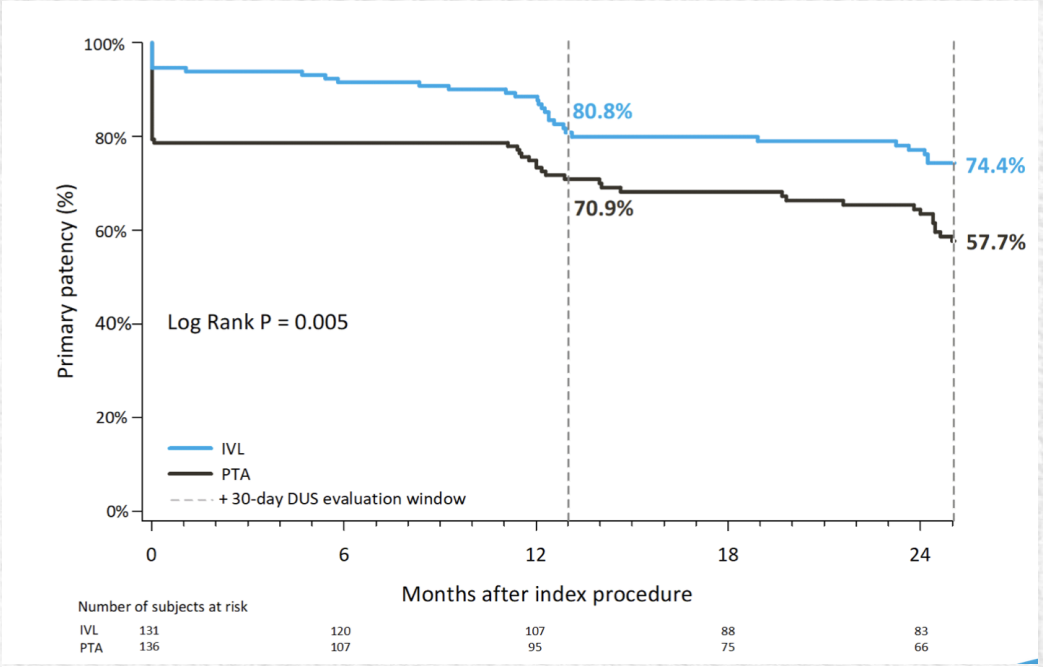
- Coronary calcium
- PAD
- Preparation for large bore access (TAVR, TEVAR)
- *MV calcification, AV calcification.

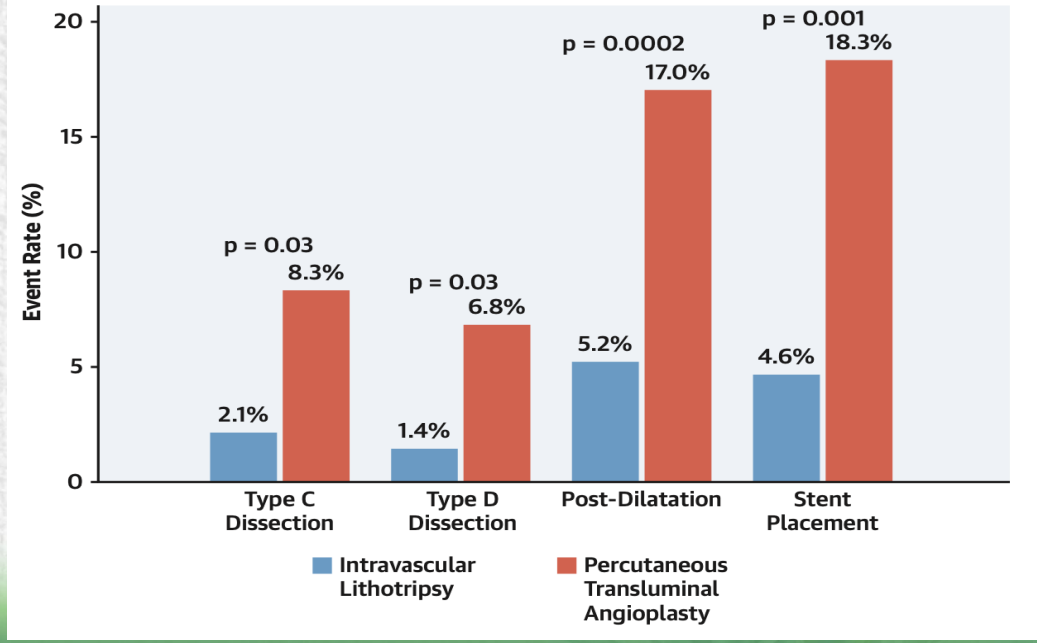
Gruslova et al. Review of intravascular lithotripsy for treating coronary peripheral artery. Catheter Cardiovasc Interv. 2024;103:295–307.

Evidence supporting IVL

- DISRUPT Trials

- DISRUPT PAD III
  - IVL vs PTA
  - Complex lesions
  - 129mm
  - CTO 30%





How is it use?

- Cover the connector cable
- Connect IVL catheter

- Ballon preparation 50/50
- No bubbles

IVL catheters

Catheter type	Application	Balloon diameter (mm)	Length (mm)	Max pulse count	Guidewire compatibility (in)	Sheath compatibility	Working length (cm)
S4	Peripheral (small vessel)	2.5–4.0	40	160	0.014	5F	135
M5	Peripheral (medium vessel)	3.5–6.0	60	300	0.014	6F	110
		6.5–7.0	60	300	0.014	7F	110
M5+	Peripheral (medium vessel)	3.5–6.0	60	180	0.014	6F	135
		6.5–7.0	60	180	0.014	7F	135
L6	Peripheral (large vessel)	8.0–9.0	30	300	0.018	7F	110
		10.0–12.0	30	300	0.018	8F	110
C2	Coronary	2.5–4.0	12	80	0.014	6F	138

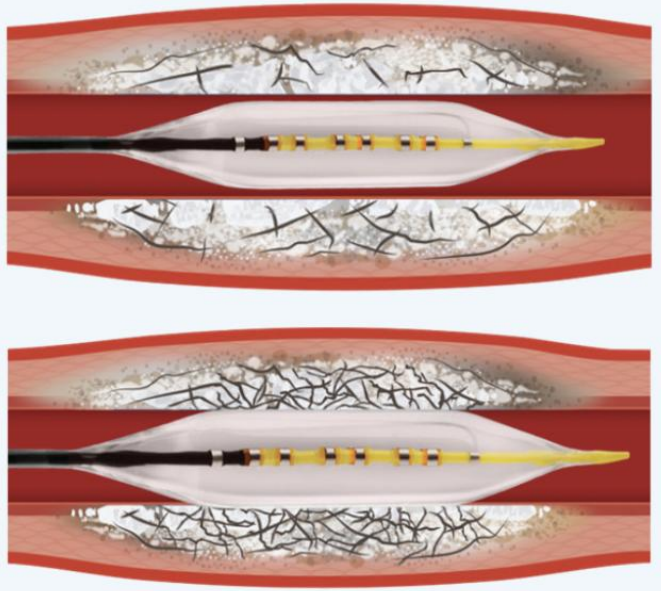
Sizing

- How to size?
  - CTA
  - Angiography
  - IVUS

What Is Optimal Sizing for Shockwave Peripheral IVL?

Sizing Recommendation for Peripheral IVL

Size 1.1:1 (Oversize by 10%) vs Reference Vessel Diameter to Facilitate Energy Transfer



Undersized

Energy loss, associated with less fracturing[1]

Optimal

Efficient energy transfer, associated with more fracturing, improved stenosis reduction, and improved patency[1-3]

Wall apposition facilitates efficient energy transfer, which is associated with more fracturing.[1]

Optimized balloon sizing (oversizing by 10%) leads to improved stenosis reduction and improved patency.[2,3]

Technical aspects of IVL therapy

- Before the procedure:
  - Preoperative assesment of target lesion.
  - 2 plane views with DSA, IVUS for pattern of calcification.
  - Diagnostic angiogram optional
  - PACSS not mandatory
  - EVUS according to operator

Saratzis A, et al. Shockwave Intravascular Lithotripsy Use in the Femoro-Popliteal Segment: Considerations From an Expert Pan-European Panel Regarding Best-Care Practice. J Endovasc Ther. 2024 Aug 12:15266028241266417.

During procedure

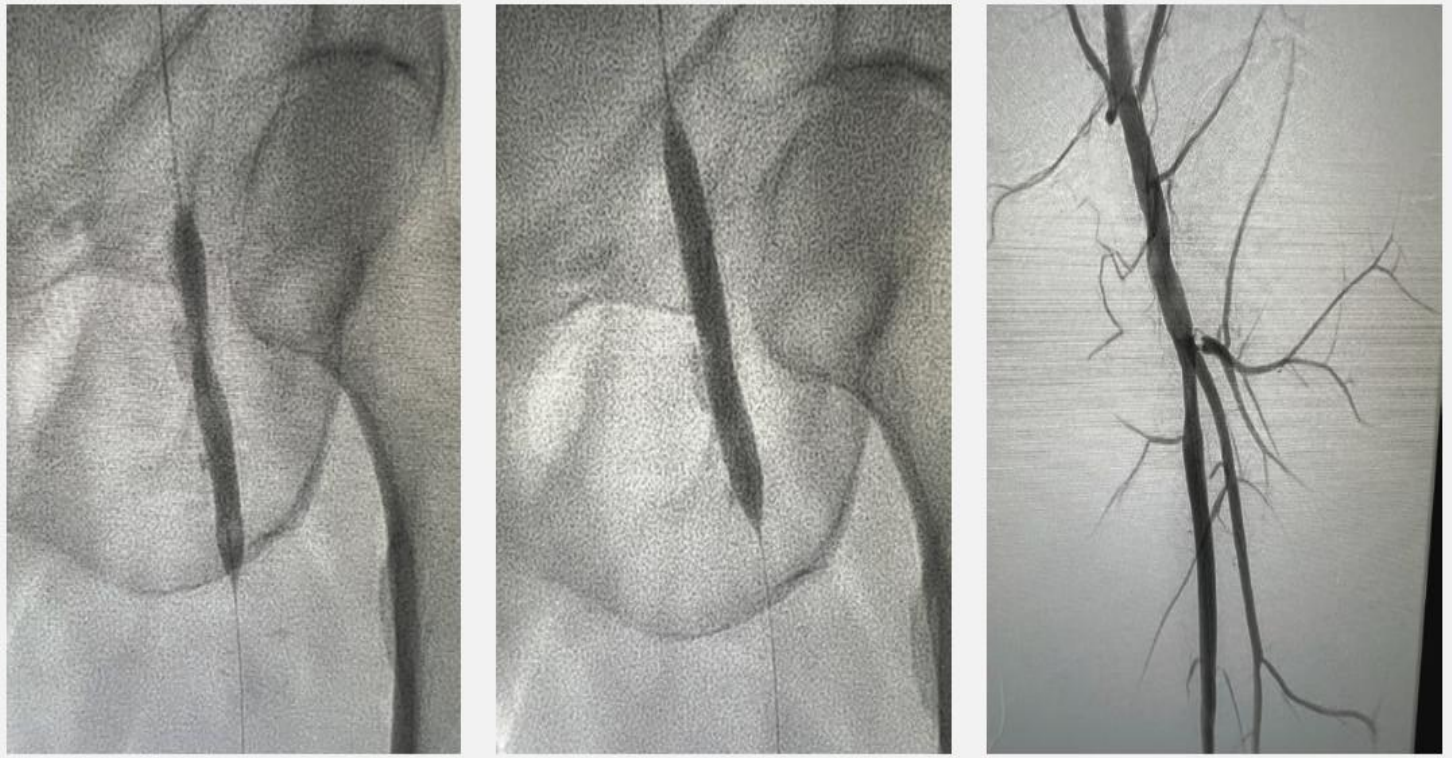
- Ipsilateal femoral approach.
  - Intraluminal crossing with 0.014’’ or 0.018’’ guidewire.
  - Subintimal crossing = not prohibitive. (more sessions)
- At least 2 sessions per lesion.
  - Overlap of 10mm.

- If non crossable, PTA 3.0 ballon.
- Coralline or eccentric lesions.
- Not recommended alone for embolic or thrombotic lesions.

Saratzis A, et al. Shockwave Intravascular Lithotripsy Use in the Femoro-Popliteal Segment: Considerations From an Expert Pan-European Panel Regarding Best-Care Practice. J Endovasc Ther. 2024 Aug 12:15266028241266417.

Post IVL Therapy

- IVUS evaluation optional
- EVUS
  - Lesions >5mm in diameter
  - >20cm
  - Size uncertainty or dissection
- Plain BA for sizing
- Operators decision: DCB or DCB.
- Angiogram 5 minutes after therapy (IVL, DES, DCB)



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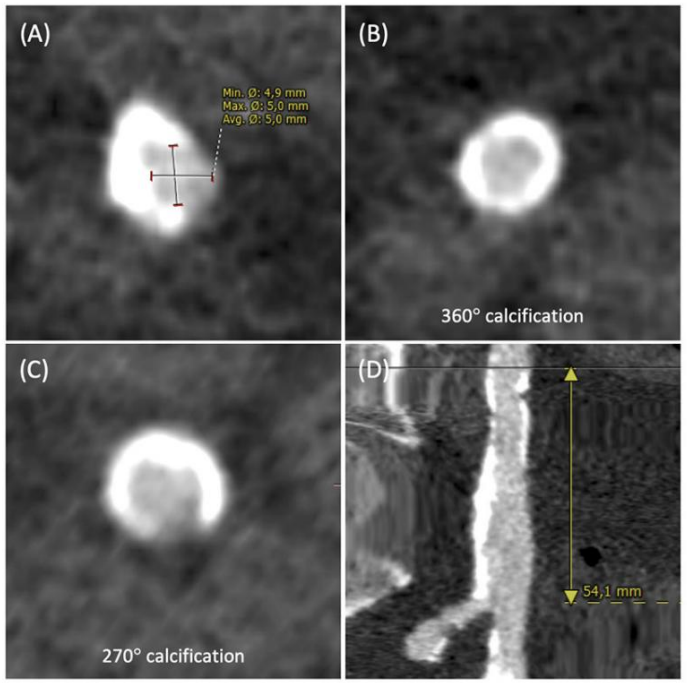
TAVR / TEVAR

- More circunferencial calcium it's better.
- MLD measures.
- Long lesions = Iliac to femoral



CT-based recommendations on feasibility of IVL-assisted TF-TAVI

--- Institutional Copenhagen recommendations ---

In case of local calcified stenosis < 20 mm length

- 360° calcified circumference with minimum lumen diameter ≥ 4.0 mm
- 270° calcified circumference with minimum lumen diameter ≥ 3.0 mm

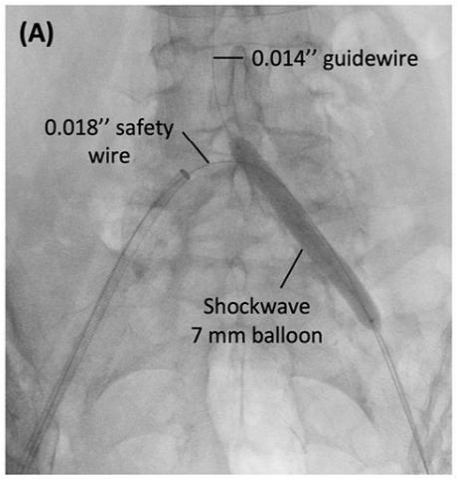
In case of more diffuse calcified vessel > 20 mm length

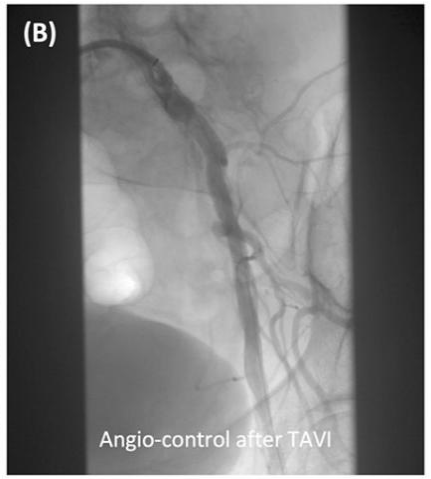
- 360° calcified circumference with minimum lumen diameter ≥ 4.5 mm
- 270° calcified circumference with minimum lumen diameter ≥ 3.5 mm

CT, computed tomography; IVL, intravascular lithotripsy; TF-TAVI, transfemoral transcatheter aortic valve implantation.

Procedure

- Bifemoral.
  - For security.
- 7Fr sheath.
  - Fits for all ballons
- Post-dilatation with NC if neccesary.





IVL-assisted TF-TAVI – Step-by-step instructions

(1) Arterial puncture + skin incision
(2) Insert a **7F sheath**
(3) Deploy 2x ProGlide vascular closure device(s)
(4) Re-insert a 7F sheath
(5) Introduction of **0.014" guidewire** (e.g., Extra Support coronary wire)
(6) Prepare Shockwave balloon with 50%/50% saline/contrast solution and ensure balloon is free of air bubbles!
(7) OTW insertion of **Shockwave M5 catheter**
(8) Use marker bands to align with lesion

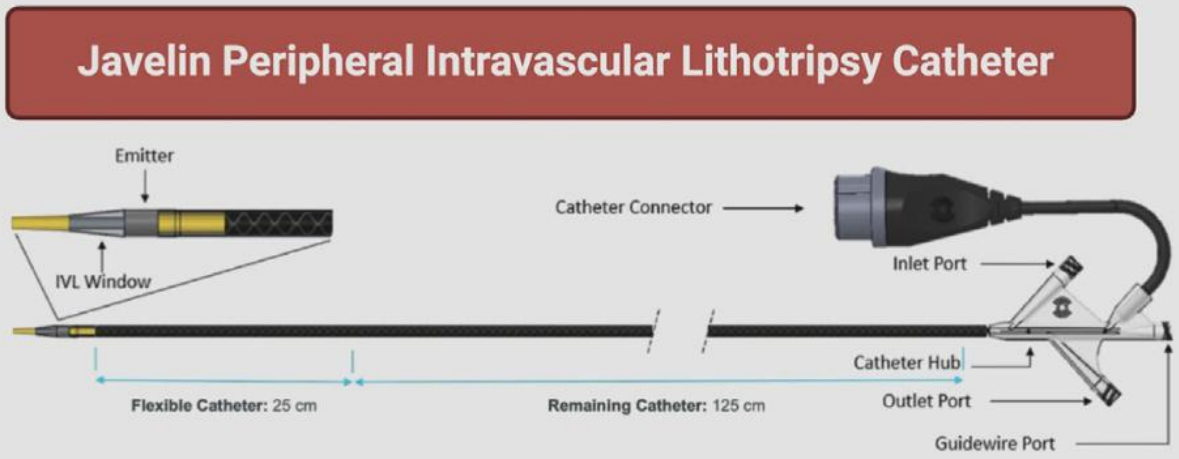
(9) **Inflation** of Shockwave balloon to **4 atm**
(10) Apply one **cycle of 30 IVL pulses**
(11) **Increase inflation** of Shockwave balloon to **6 atm**
(12) **Deflation** of the Shockwave balloon

Repeat
Max. 10 cycles

(13) Remove the Shockwave M5 catheter
(14) Exchange the 0.014'' guidewire for a **stiff guidewire**
(15) Additional PTA with a **non-compliant balloon**, if needed
(16) Insert the **large bore TAVI introducer sheath**

IVL, intravascular lithotripsy; OTW, over-the-wire; PTA, percutaneous transluminal angioplasty; TAVI, transcatheter aortic valve implantation; TF, transfemoral.

What's next?



- Forward-positioned sonic emitter
- Low-pressure pulses
- Target deep and superficial calcium
- Over-the-wire compatibility (0.014")

Conclusions

- IVL therapy
  - Safe
  - Simple
  - Effective

- Alternative when dealing with calcification.

- Allows DCB therapy (leave nothing behind)