CardioVascular Learning Network

Calcified SFA/Popliteal Artery Disease

What’s in the Endovascular Toolbox?

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Faculty Disclosures

- **Paul J. Foley, MD**: Consultant—Shockwave Medical, Endologix
- **Thuy Pham Ryan, DO**: Consultant—Philips; Advisory Board—Philips; Speaker's Bureau—Philips, Shockwave Medical
- **Frank R. Arko III, MD**: Consultant—Penumbra
- **Carlos J. Guevara, MD, FSIR** has disclosed no relevant financial relationship with any ineligible company (commercial interest)

Program Information

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- HMP Education acknowledges Shockwave Medical for their (financial/in-kind) support of this accredited medical education activity

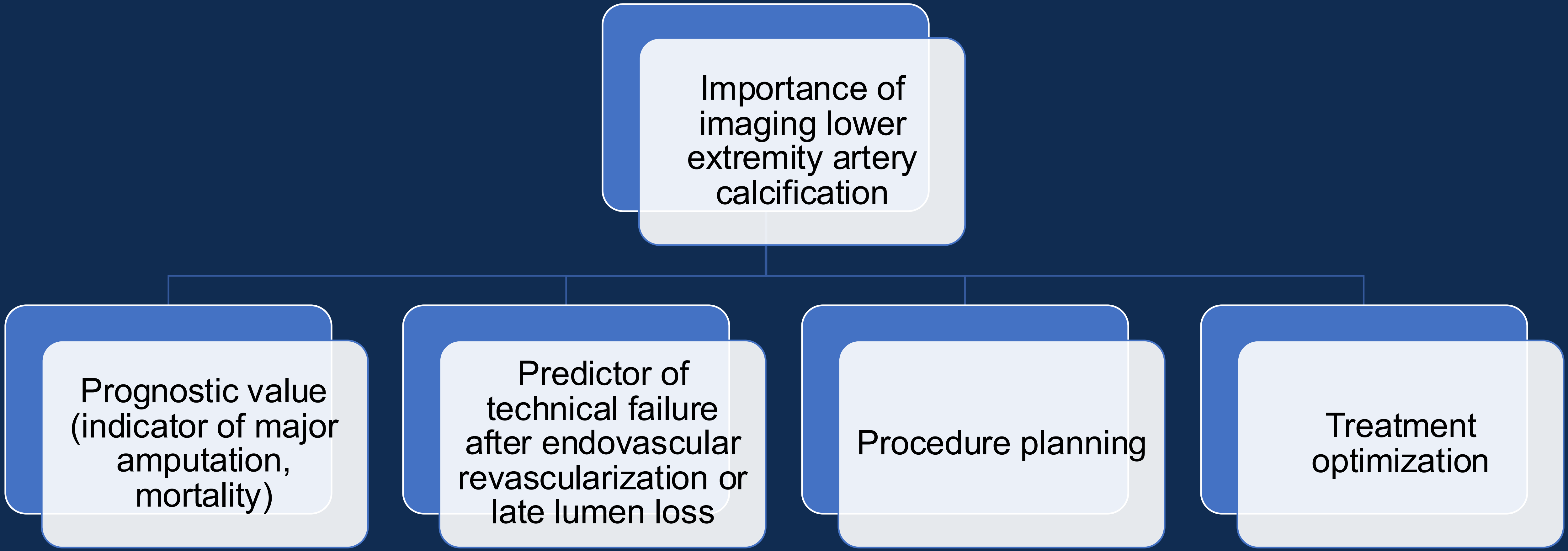
Learning Objectives

- Identify calcium in the superficial femoral artery and popliteal artery with various imaging modalities
- Examine methods to cross calcified lesions in the SFA/popliteal artery
- Analyze endovascular tools to treat calcium in the superficial femoral and popliteal artery
- Develop a treatment algorithm for calcified lesions in the SFA/popliteal artery

SFA = superficial femoral artery.

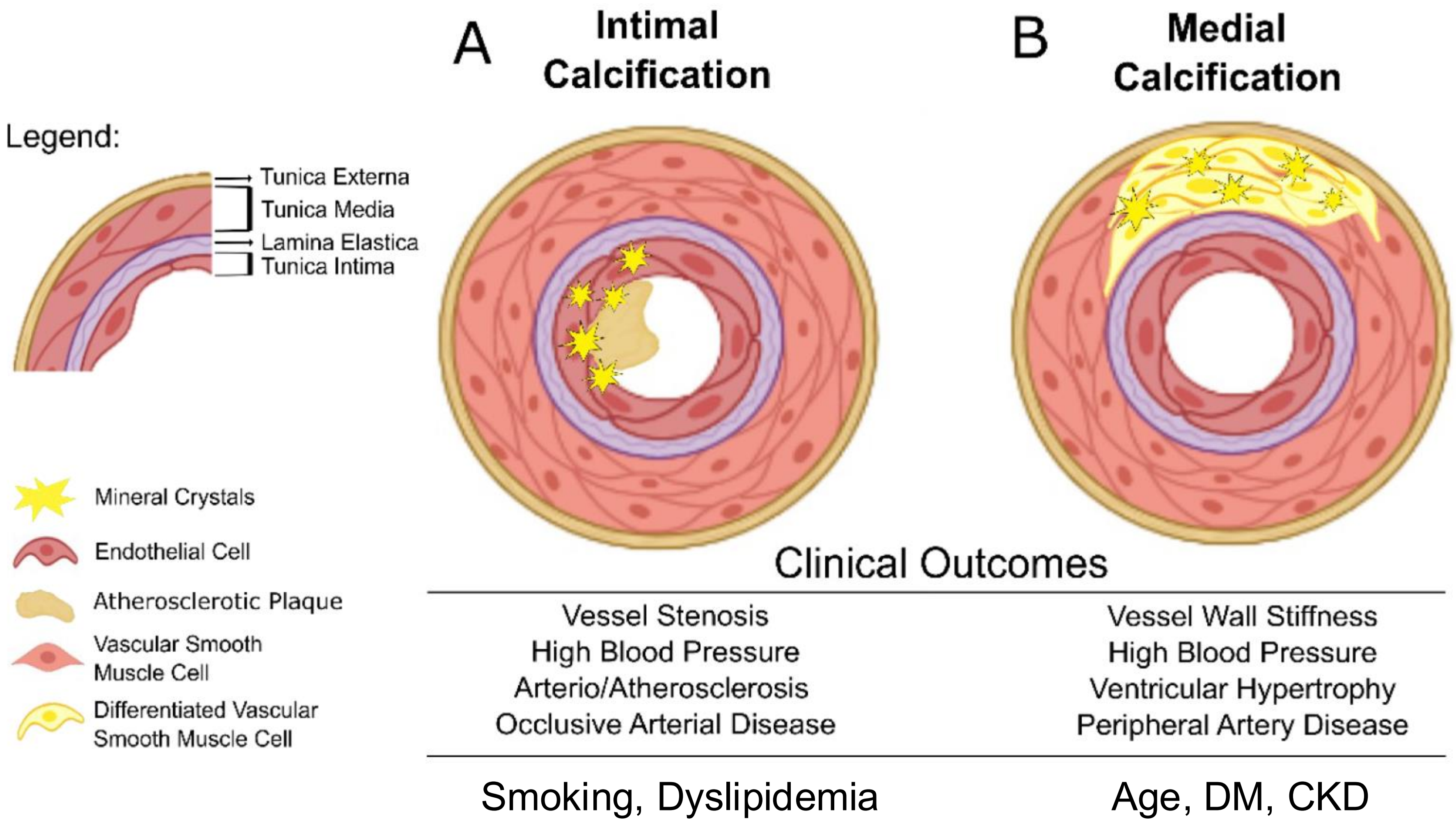
Calcium in the Superficial Femoral and Popliteal Artery:
My Approach to Imaging

Thuy Pham Ryan, DO



Dong Y, et al. *Front Cardiovasc Med.* 2023;10:1271100. Marreiros C, et al. *Int J Mol Sci.* 2022;23(24):16114.

Not All Calcium Is the Same in the Lower Extremity!

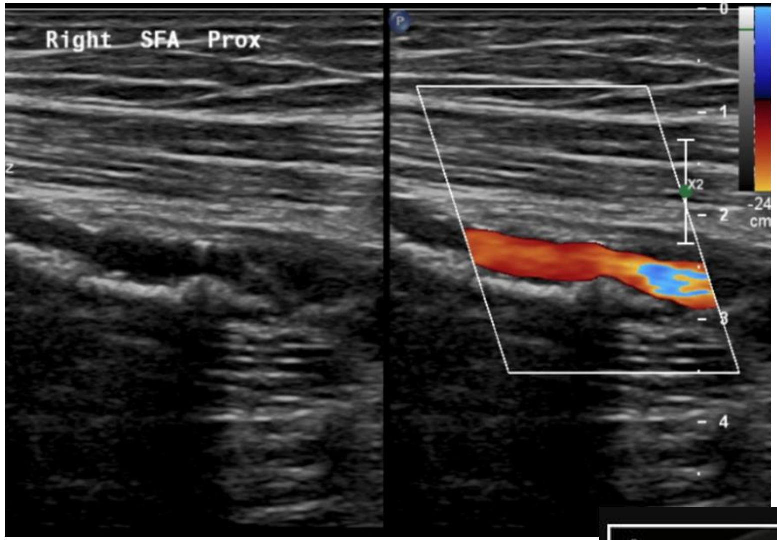


DM = diabetes mellitus; CKD = chronic kidney disease.

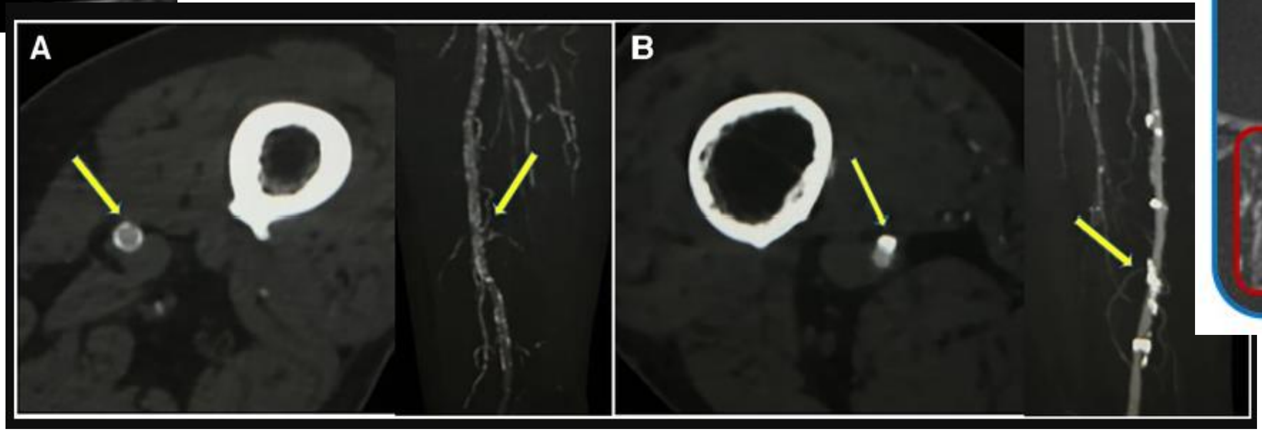
Dong Y, et al. *Front Cardiovasc Med.* 2023;10:1271100. Marreiros C, et al. *Int J Mol Sci.* 2022;23(24):16114.

Imaging Calcium in the SFA/Popliteal Artery – Non-Invasive

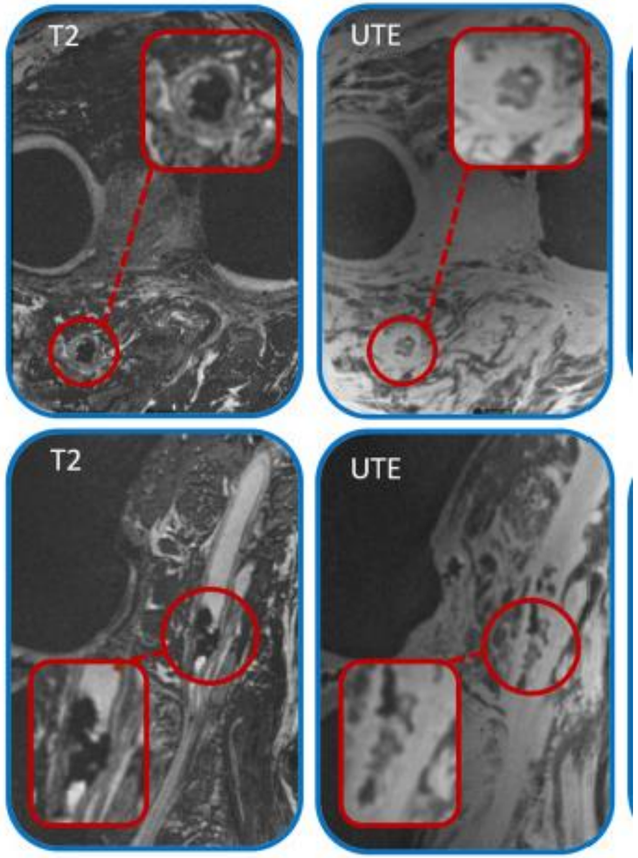
Duplex US (DUS)



CTA



MRI/MRA

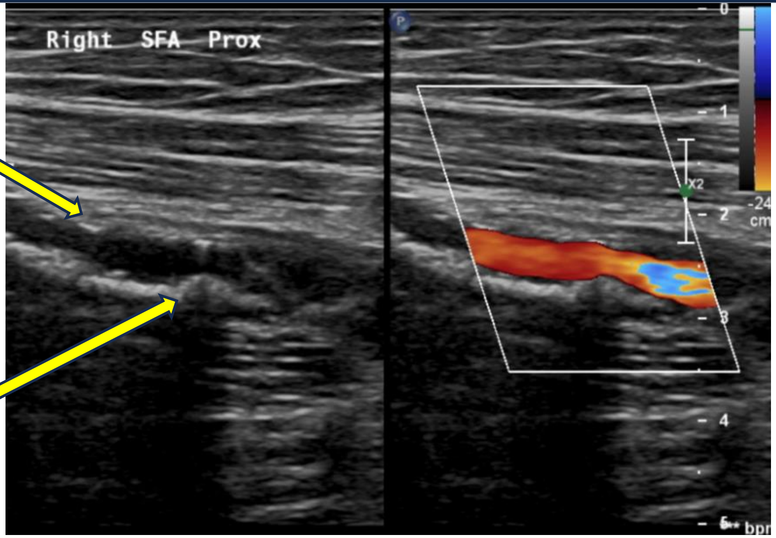


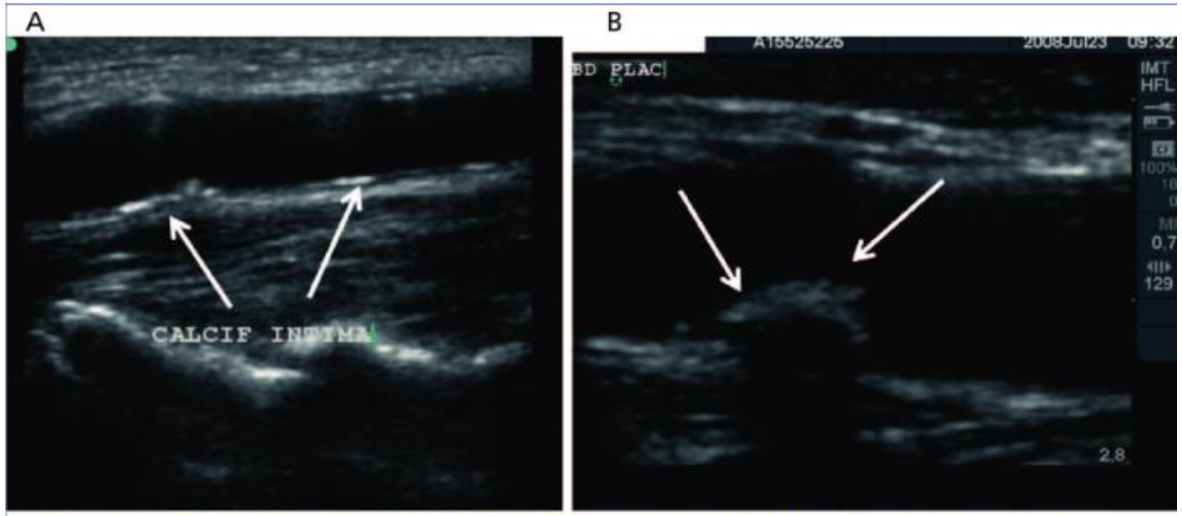
US = ultrasound; MRI = magnetic resonance imaging; MRA = magnetic resonance angiography; CTA = computed tomography angiography.
Dong Y, et al. *Front Cardiovasc Med.* 2023;10:1271100. Csore J, et al. *J Vasc Surg Cases Innov Tech.* 2023;9(4):101263.

Duplex US
Calcium: Hyperechoic (Bright White)

Calcium lining the intima

Calcium protruding into lumen





Arrows indicate the calcified areas: (A) linear calcification in the intima; (B) calcified or type 5 plaque (with posterior acoustic shadow). Clin J Am Soc Nephrol 2010;6(2):303-10.

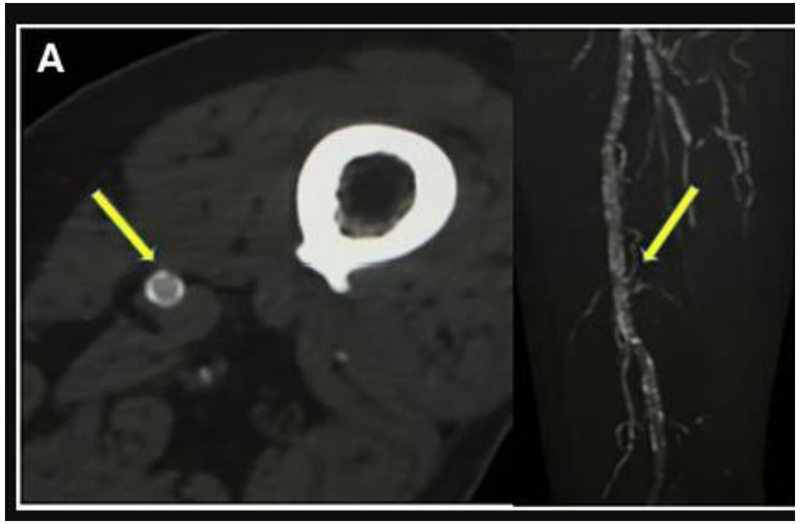
Pros
- Cost effective $, widely available
- No radiation
- No contrast
- Calcium burden
- Hemodynamics
- Follow-up imaging

Cons
- Operator/protocol dependent
- Longer exam time
- Smaller field of view (FOV)
- Extensive calcium (shadowing)

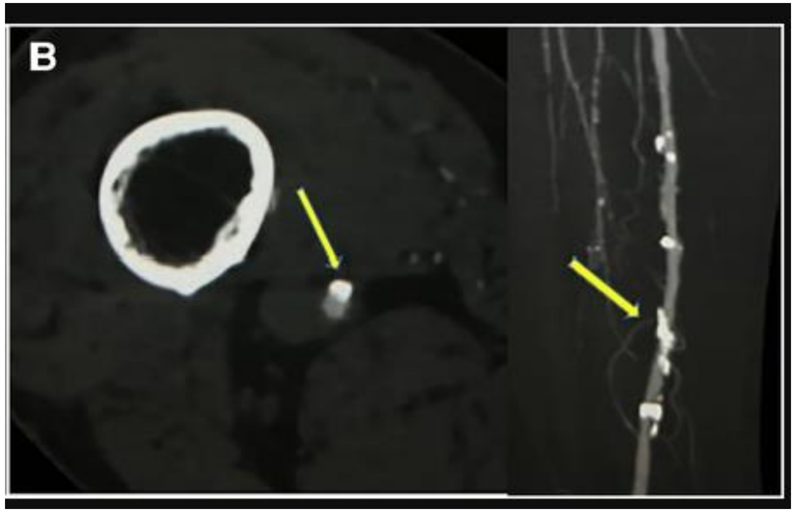
Dong Y, et al. *Front Cardiovasc Med.* 2023;10:1271100.

CT Angiography
Calcium = Bright White

Medial: Thinner, continuous



Intimal: Thicker, irregular, luminal narrowing



Pros

- High resolution, big FOV
- Quicker exam time
- Calcium burden/type
- 3D reconstruction
- Widely available
- Newer techniques (dual energy, photon counting)

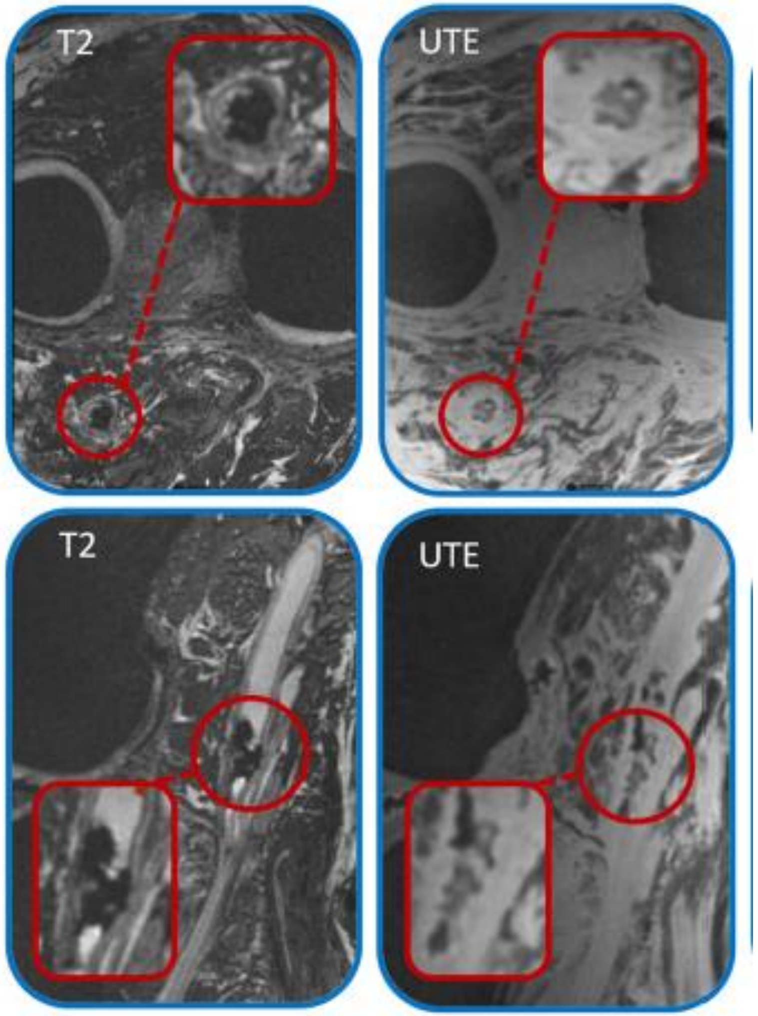
Cons

- Cost $$
- Radiation
- Iodine contrast
- Infrapopliteal vessels
- Extensive calcium (blooming artifact)
- No hemodynamic data

Dong Y, et al. *Front Cardiovasc Med.* 2023;10:1271100.

Contrast Enhanced or Non-Contrast Enhanced MRI/MRA

Calcium = Depends on the Sequencing



Pros

- High resolution, big FOV
- 3D reconstruction
- With or without contrast
- No ionizing radiation
- Soft-tissue contrast
- Infrapopliteal vessels
- Hemodynamics
- Newer techniques (more Ca info)

Cons

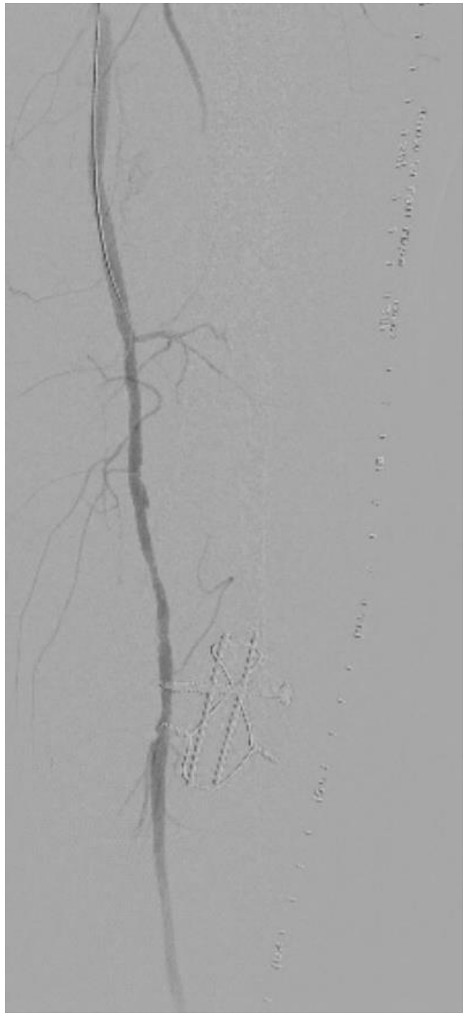
- Cost $$$
- Less sensitive for Ca (conventional techniques)
- Longer exam time
- Gadolinium contrast (NSF risk)
- Claustrophobia
- Non-MRI compatible implants
- Not as widely available

NSF = nephrogenic systemic fibrosis.

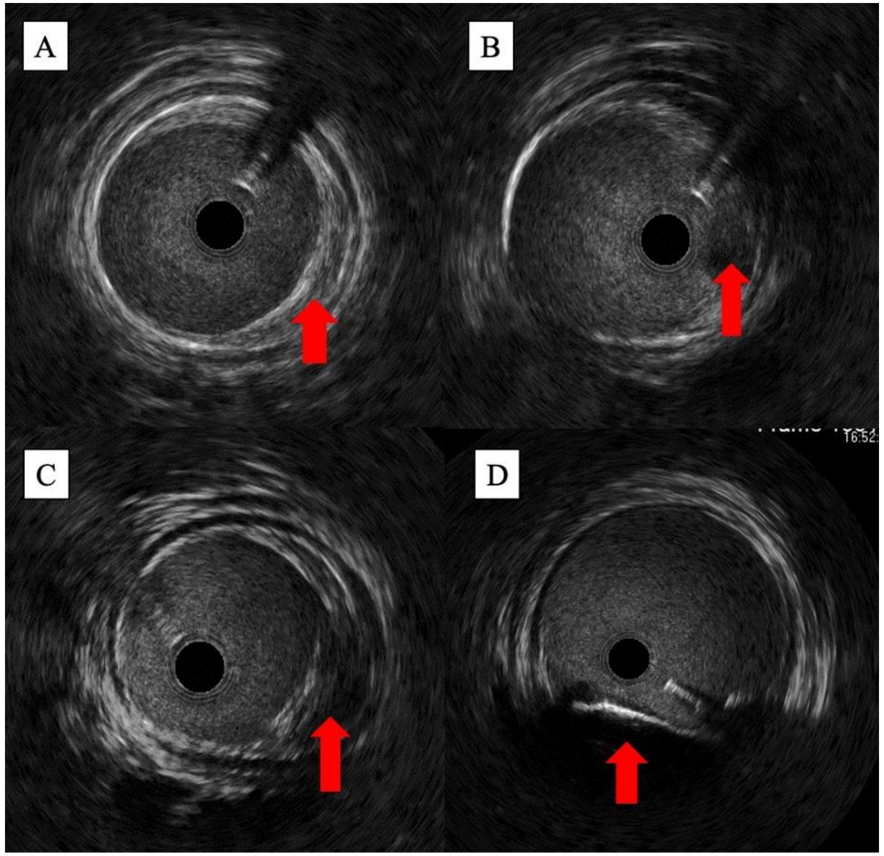
Dong Y, et al. *Front Cardiovasc Med.* 2023;10:1271100. Csore J, et al. *J Vasc Surg Cases Innov Tech.* 2023;9(4):101263.

Imaging Calcium in the SFA/Popliteal Artery – Invasive

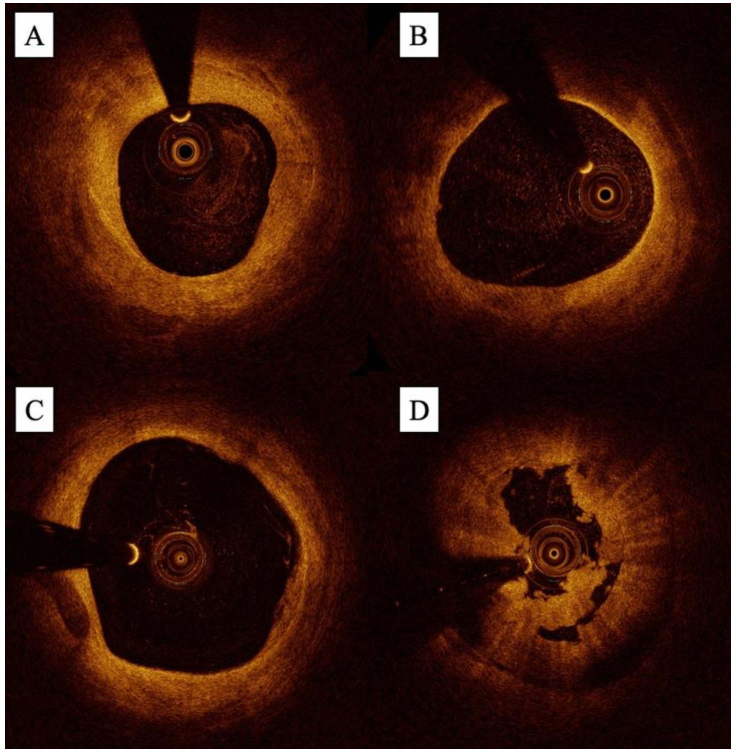
DSA



IVUS



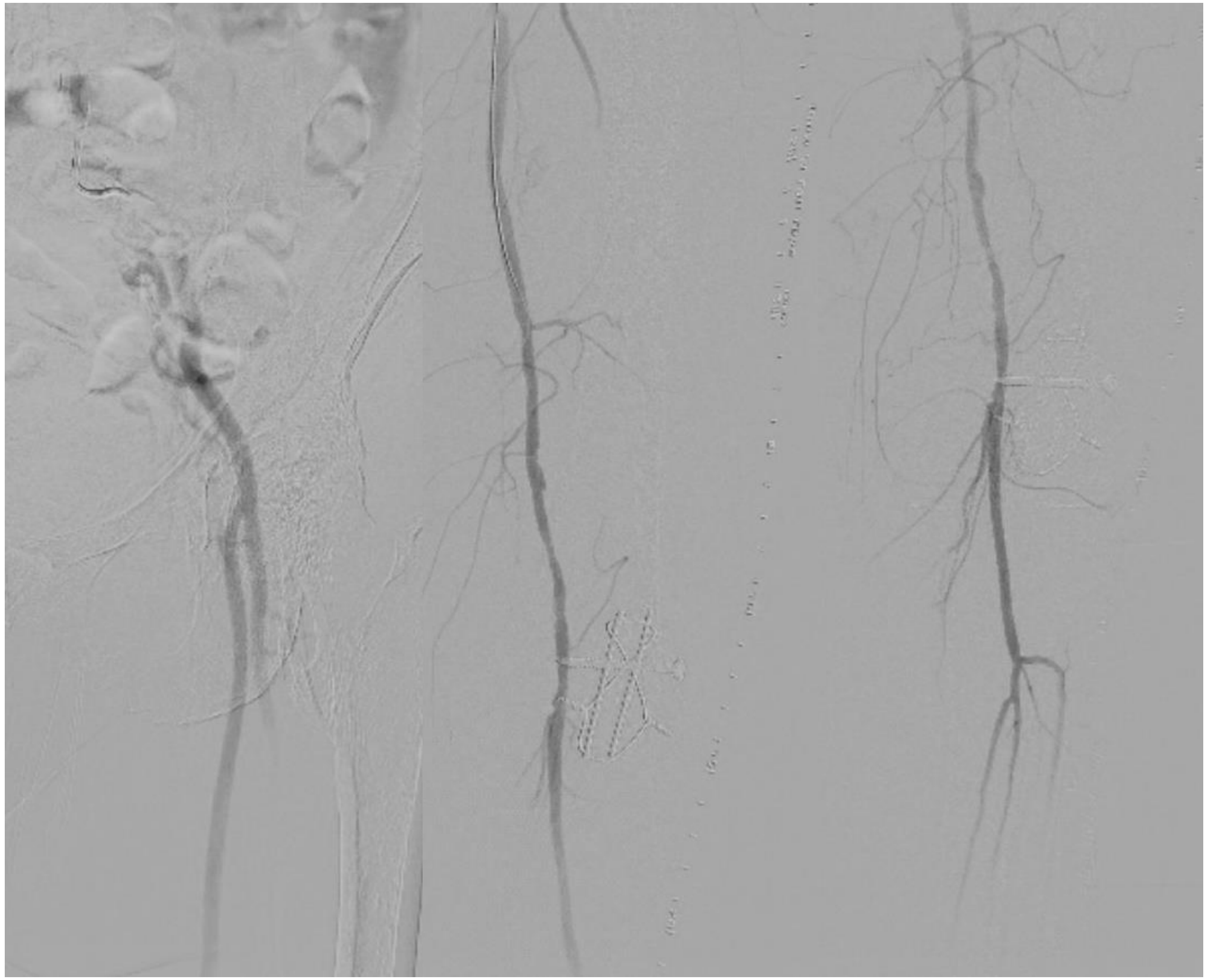
OCT



DSA = digital subtraction angiography; IVUS = intravascular ultrasound; OCT = optical coherence tomography.

Snyder DJ, et al. *Vasc Dis Manag*. 2023;20(7):E130-E139.

Digital Subtraction Angiography (DSA)
Calcium = Dark



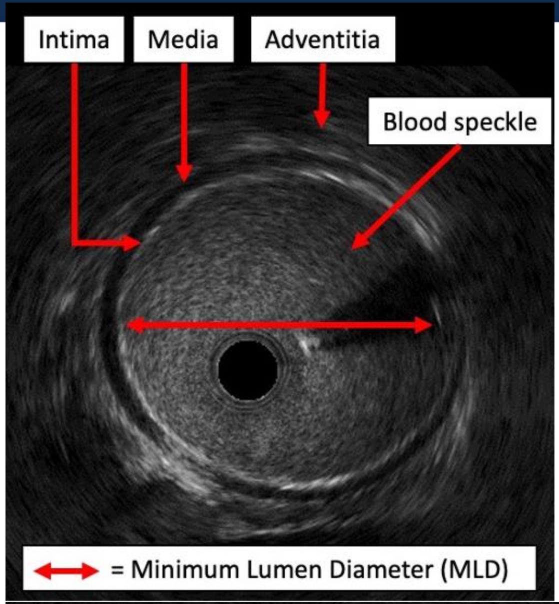
Pros
- High resolution
- Fast
- Treatment

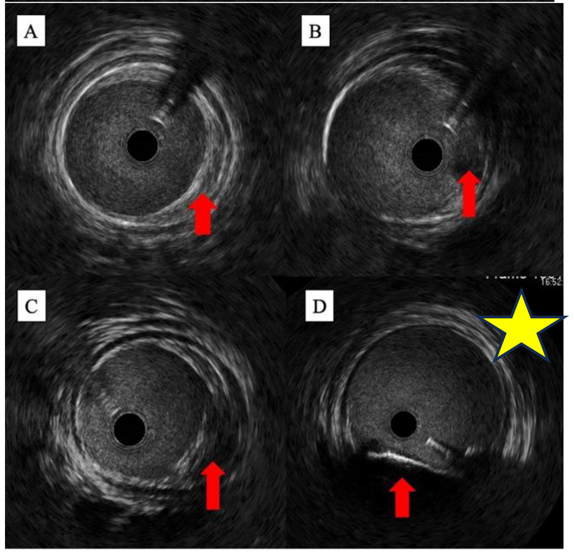
Cons
- Radiation
- Iodinated contrast
- 2D imaging
- Vessel wall info limited

Dong Y, et al. *Front Cardiovasc Med.* 2023;10:1271100.

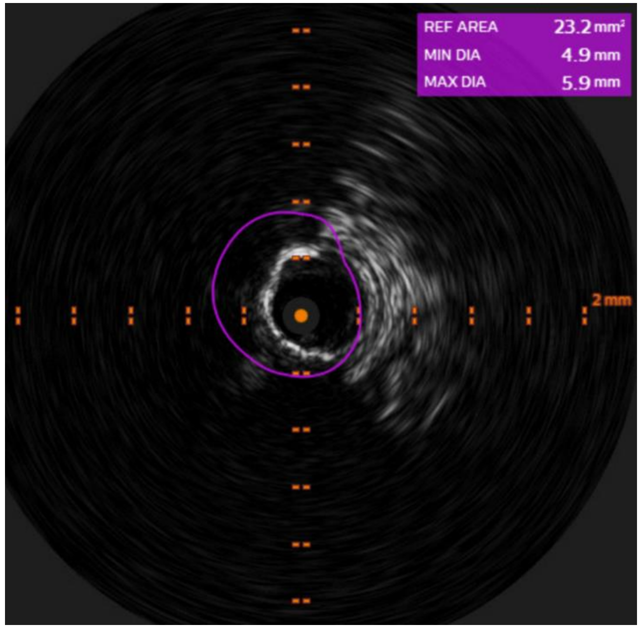
Intravascular Ultrasound (IVUS)

Calcium= Hyperechoic (Bright), Acoustic Shadowing





Intimal vs Medial
Eccentric vs Concentric
Circumferential
Obstructive
Reference Vessel Diameter



Pros

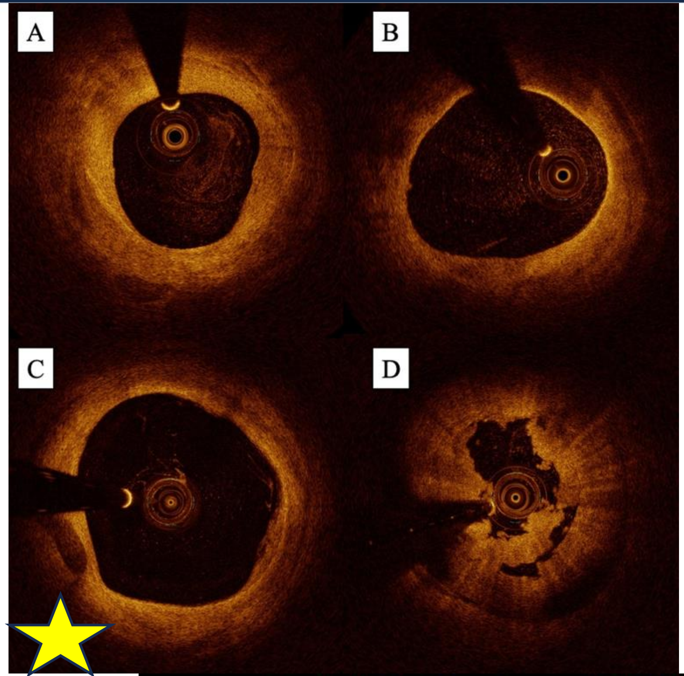
- Widely available
- No contrast
- Calcium info
- Vessel wall info
- Treatment optimization

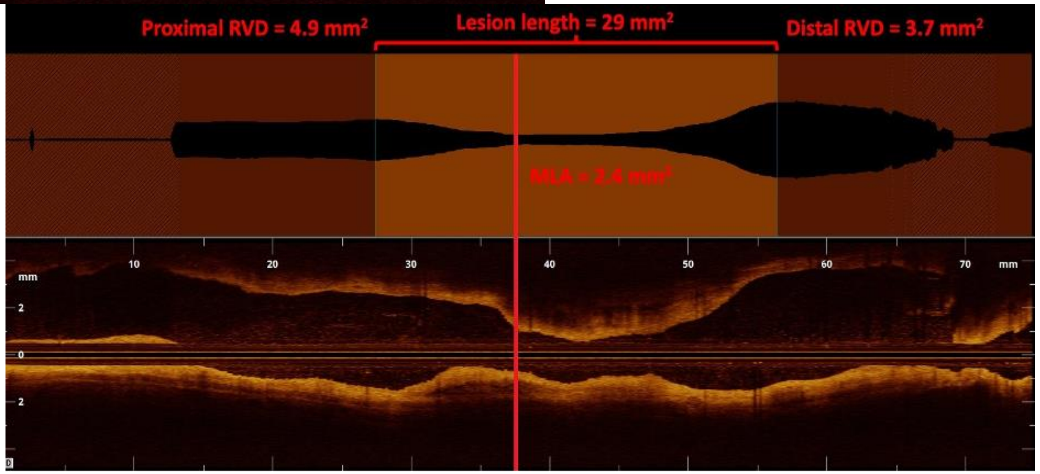
Cons

- Operator dependent
- Lower frame rate/resolution
- Cost

Snyder DJ, et al. *Vasc Dis Manag*. 2023;20(7):E130-E139.

Optical Coherence Tomography (OCT)
Calcium= Dark, Low Attenuation





Intimal vs Medial
Eccentric vs Concentric
Circumferential
Obstructive
Reference Vessel Diameter
<u>Disease Length</u>

Pros
- Higher frame rate/resolution
- Calcium info
- Vessel info
- Treatment optimization

Cons
- Less penetration depth
- Operator dependent
- Contrast/saline injection
- Cost, not as widely available

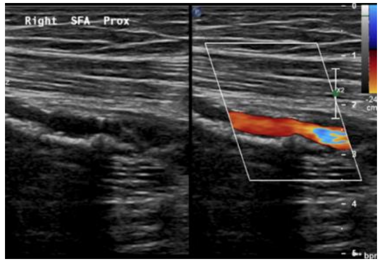
Snyder DJ, et al. *Vasc Dis Manag*. 2023;20(7):E130-E139.

My Approach To Imaging Calcium in SFA/Popliteal Artery

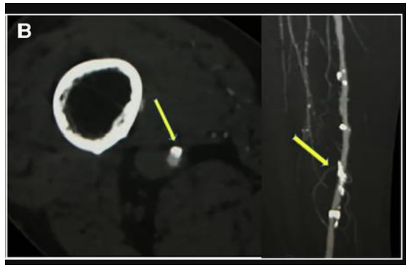
Why: CV and mortality outcomes, technical success, procedure planning, treatment optimization

Non-Invasive Imaging: **Diagnosis/Planning**

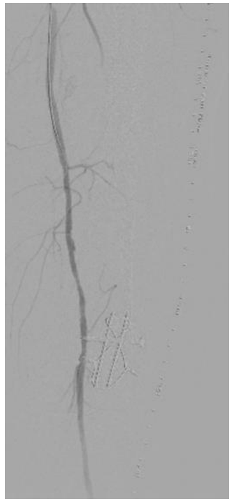
1. DUS: Ca detection
   - Calcium location, burden
   - Hemodynamics
   - Follow-up



2. CTA/MRI: Ca detection, characterization
   - Ca location, burden, length
   - Treatment planning

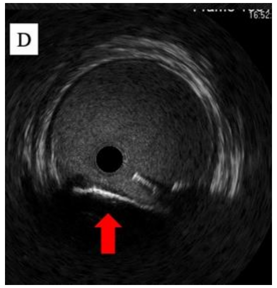


Invasive Imaging: **Treatment/Optimization**



1. DSA: Disease confirmation
   - Location, length: 2D
   - Treatment

2. IVUS/OCT: Ca characteristics
   - Ca burden, type: 360 deg
   - Vessel wall info
   - Treatment optimization
     - Lesion modification device selection
     - Appropriately sized balloons
     - Lower restenosis rates



Thank you!

Challenging SFA/Popliteal Calcium: Advanced Techniques to Cross and Treat

Carlos J. Guevara, MD, FSIR

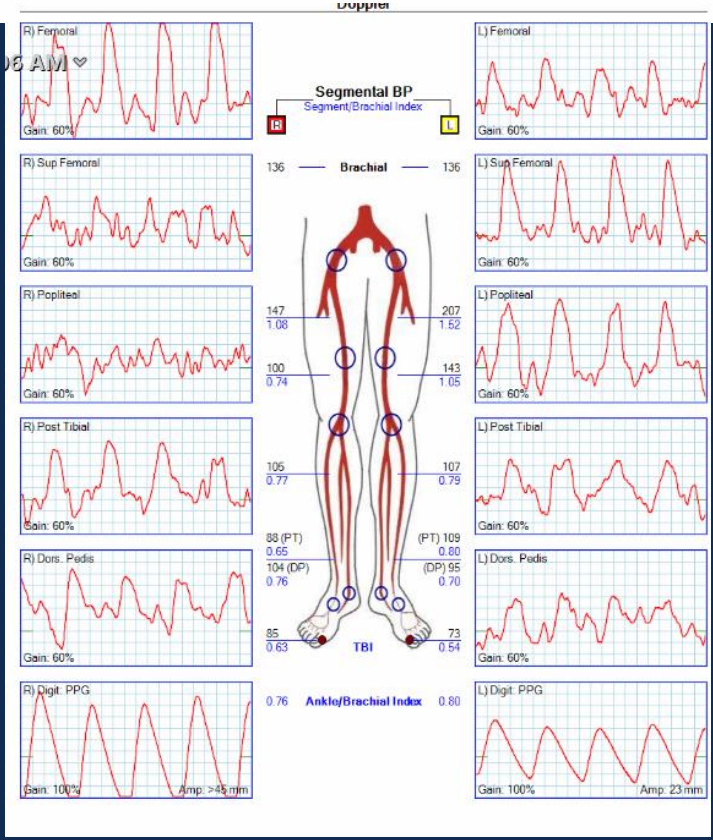
History

Previous Test: Yes	Smoke: Never	Hypertension: Yes
Diabetic: No	Hyperlipidemia: No	TIA/CVA: No
PVD: Yes	CAD: Yes	MI: ???
Prev Angioplasty: Yes	Prev Vasc Surg: No	Rest Pain: None
Claudication: Both	Skin Color Chg: None	Vascular Ulcers: None

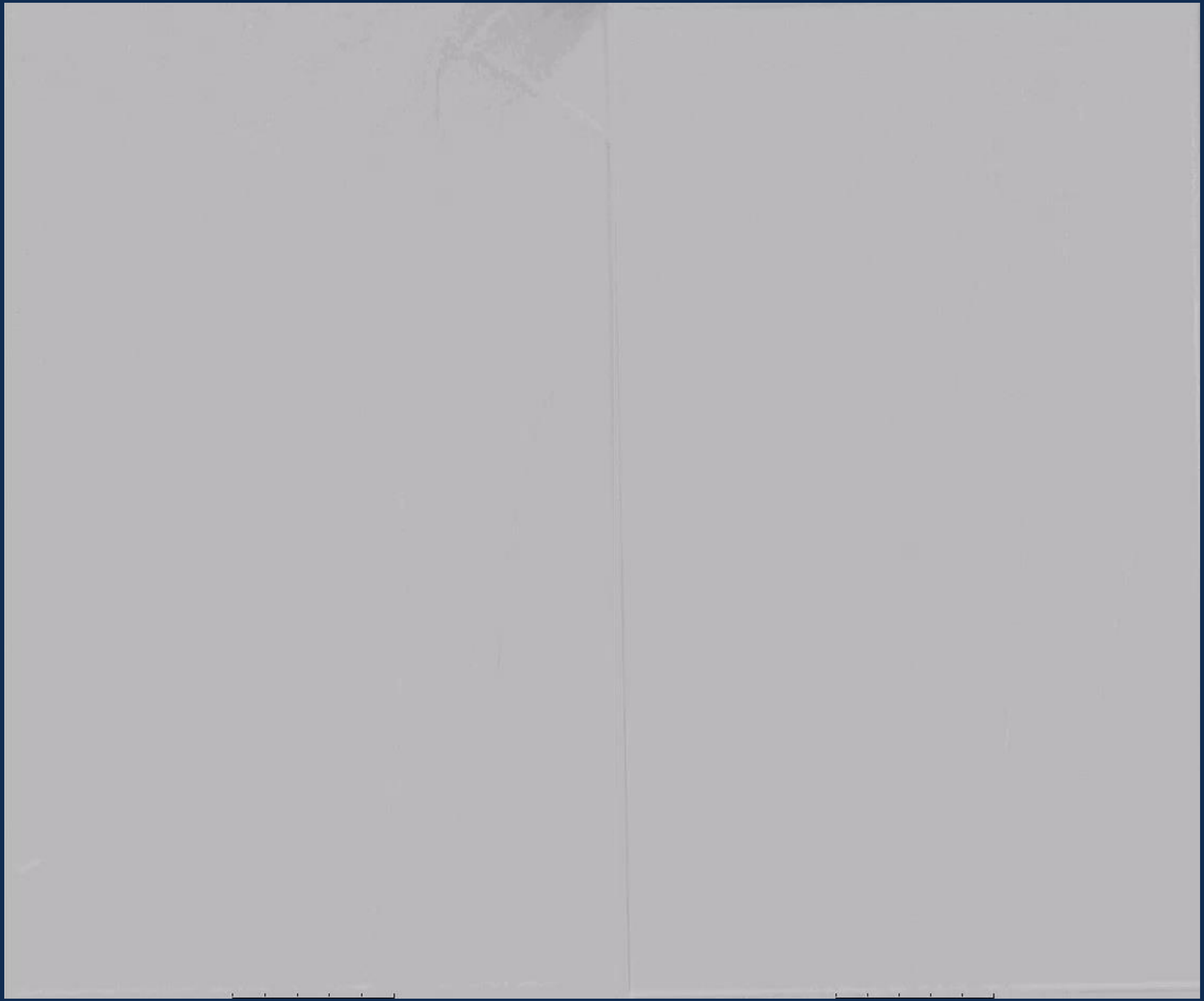
claudication lt leg

Segmental BP

Right			Left		
Brachial:	136	Index	Brachial:	136	Index
High Thigh:	147	1.08	High Thigh:	207	1.52
Low Thigh:	100	0.74	Low Thigh:	143	1.05
Calf:	105	0.77	Calf:	107	0.79
Ankle (PT):	88	0.65	Ankle (PT):	109	0.80
Ankle (DP):	104	0.76	Ankle (DP):	95	0.70
Digit:	85	0.63	Digit:	73	0.54



PVD = peripheral vascular disease; CAD = coronary artery disease; TIA/CVA = transient ischemic attack/cerebrovascular accident; MI = myocardial infarction; BP = blood pressure; TP = posterior tibialis; DP = dorsalis pedis; TBI = toe-brachial index.



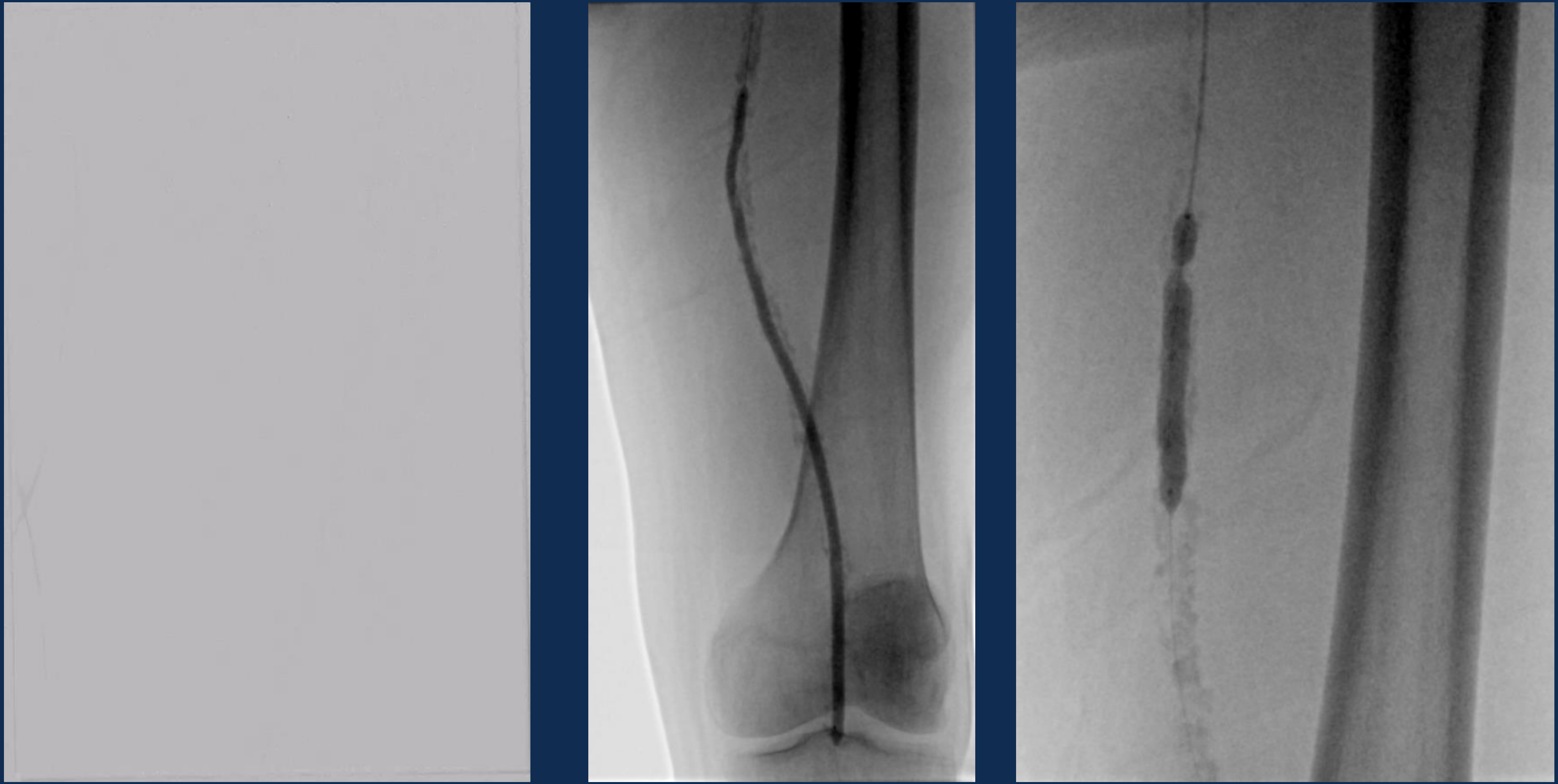
- 70s male, CAD, strong family history, HLD
    - Claudication
    - Failed conservative mgmt

- Flexibility
    - 035, 018, 014 platforms

- Most times dense calcium 035
    - This case 014
    - True lumen

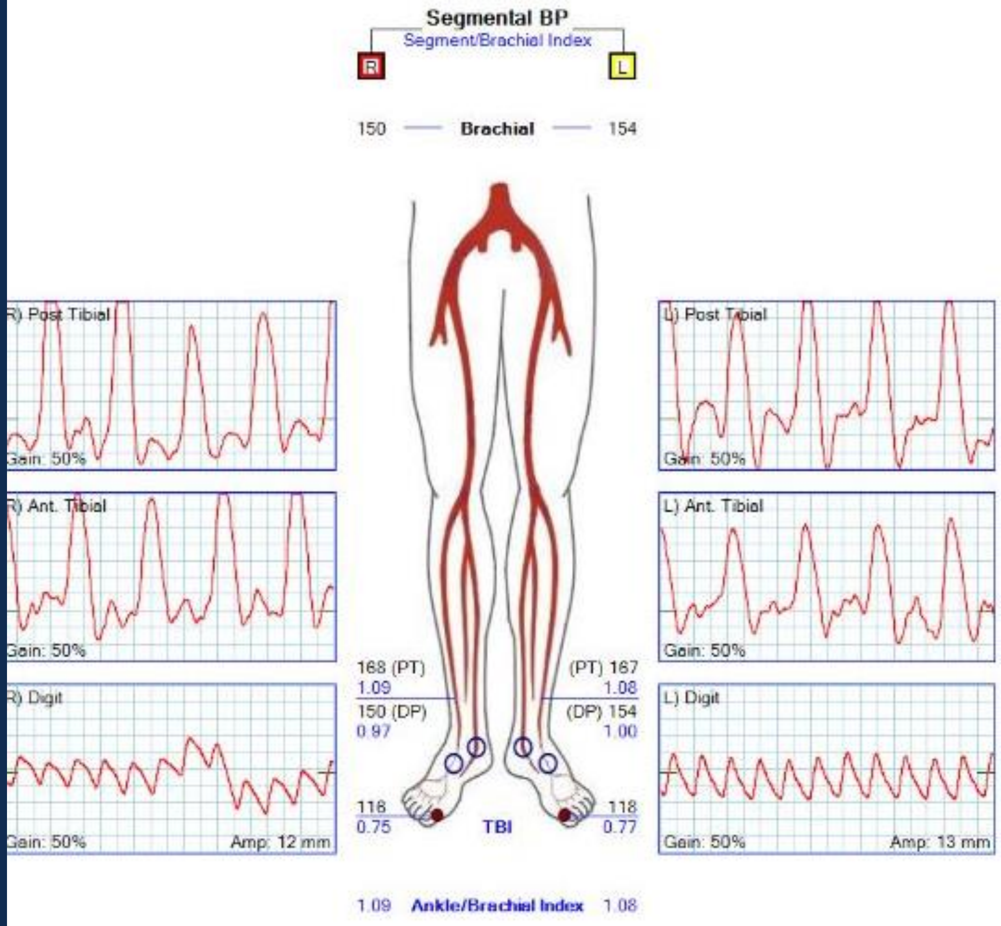
- Rx
    - IVL, BA, DCB

HLD = hyperlipidemia; Rx = prescription; IVL = intravascular lithotripsy; BA = balloon angioplasty.



Segmental BP

Right			Left		
Brachial:	150	Index	Brachial:	154	Index
Ankle (PT):	168	1.09	Ankle (PT):	167	1.08
Ankle (AT):	150	0.97	Ankle (AT):	154	1.00
Digit:	116	0.75	Digit:	118	0.77



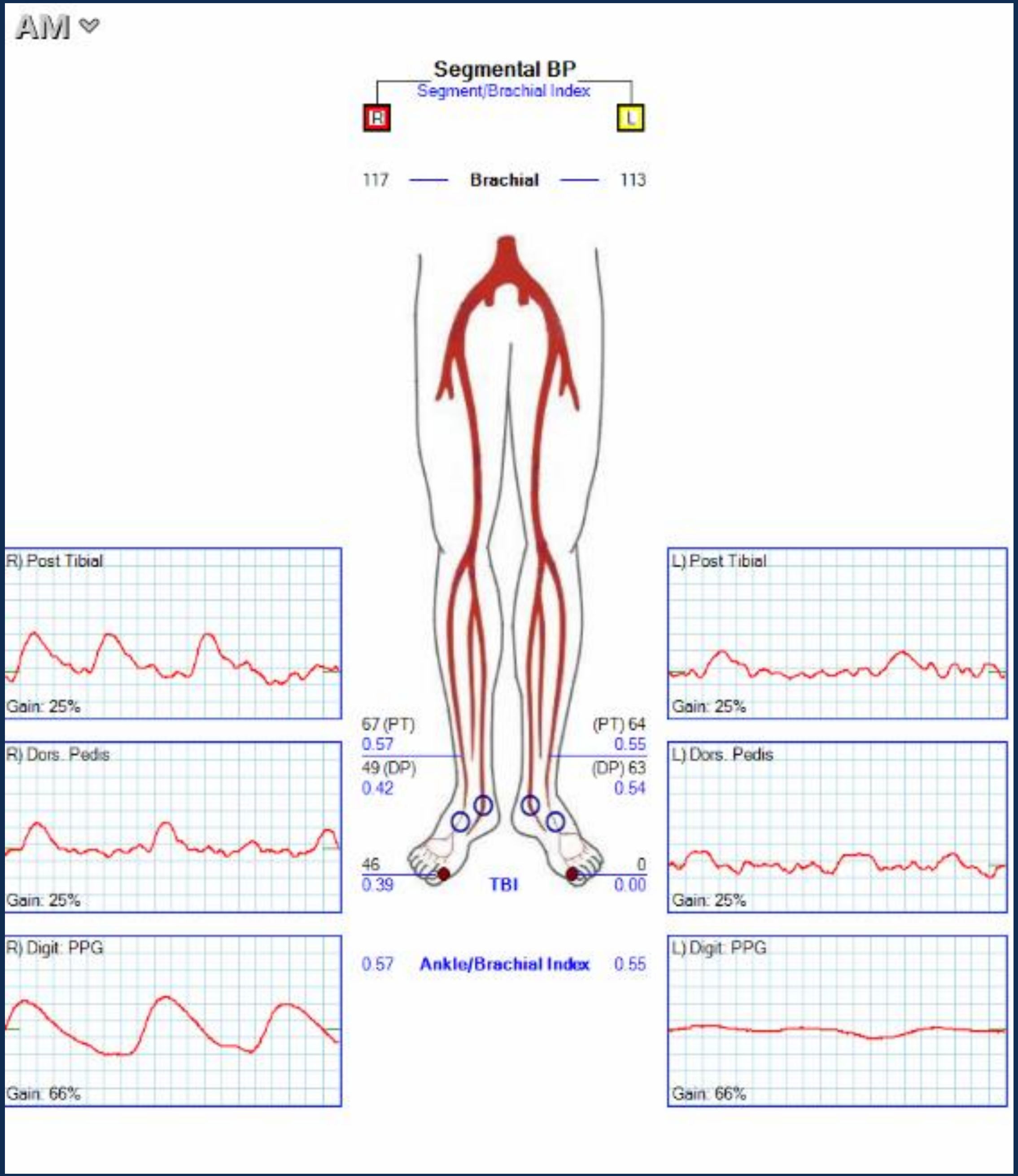
History

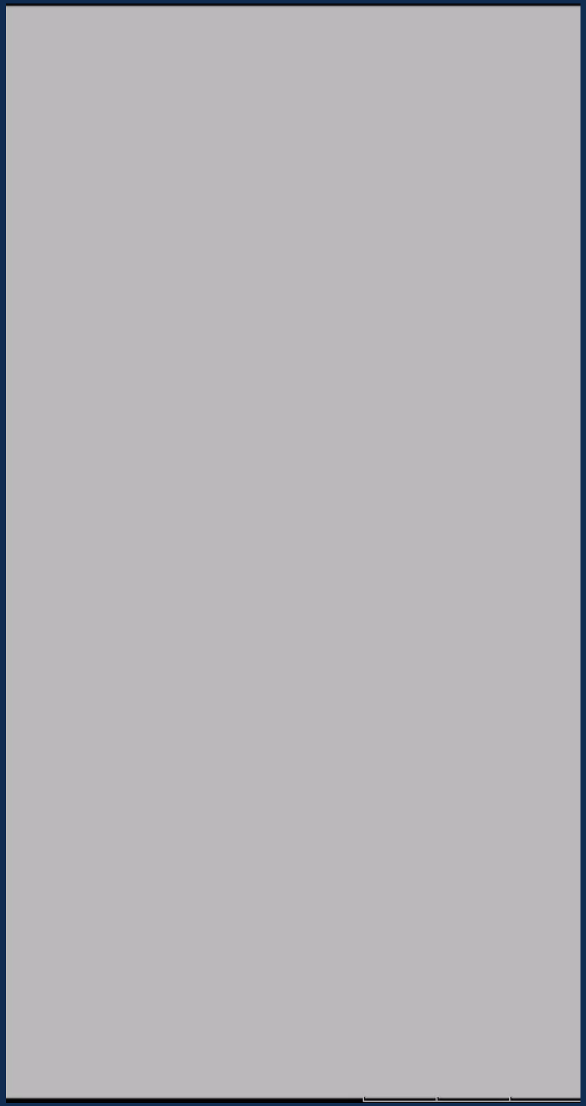
Previous Test: No	**Smoke:** Previous	**Hypertension:** Yes
Diabetic: Yes	**Hyperlipidemia:** Yes	**TIA/CVA:** Yes
PVD: No	**CAD:** Yes	**MI:** No
Prev Angioplasty: No	**Prev Vasc Surg:** No	**Surg. Follow Up:** No
Rest Pain: None	**Claudication:** Both	**Weak Pulse:** Both
Skin Color Chg: None	**Vascular Ulcers:** None	**Gangrene:** None

Segmental BP

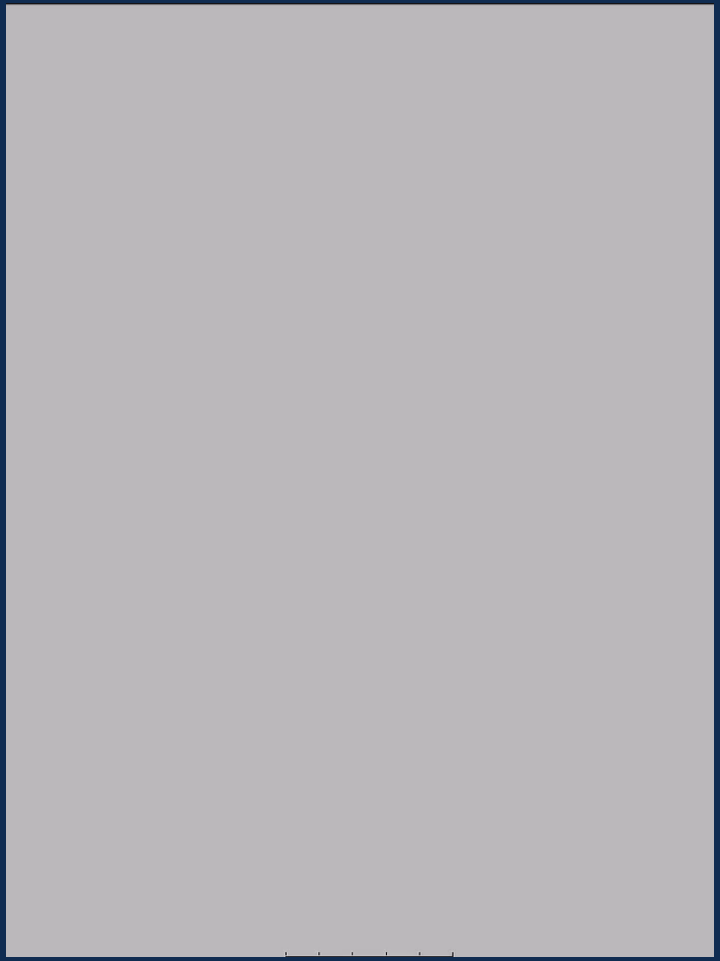
Right			Left		
Brachial:	117	Index	**Brachial:**	113	Index
Ankle (PT):	67	0.57	**Ankle (PT):**	64	0.55
Ankle (DP):	49	0.42	**Ankle (DP):**	63	0.54
Digit:	46	0.39	**Digit:**	0	0.00

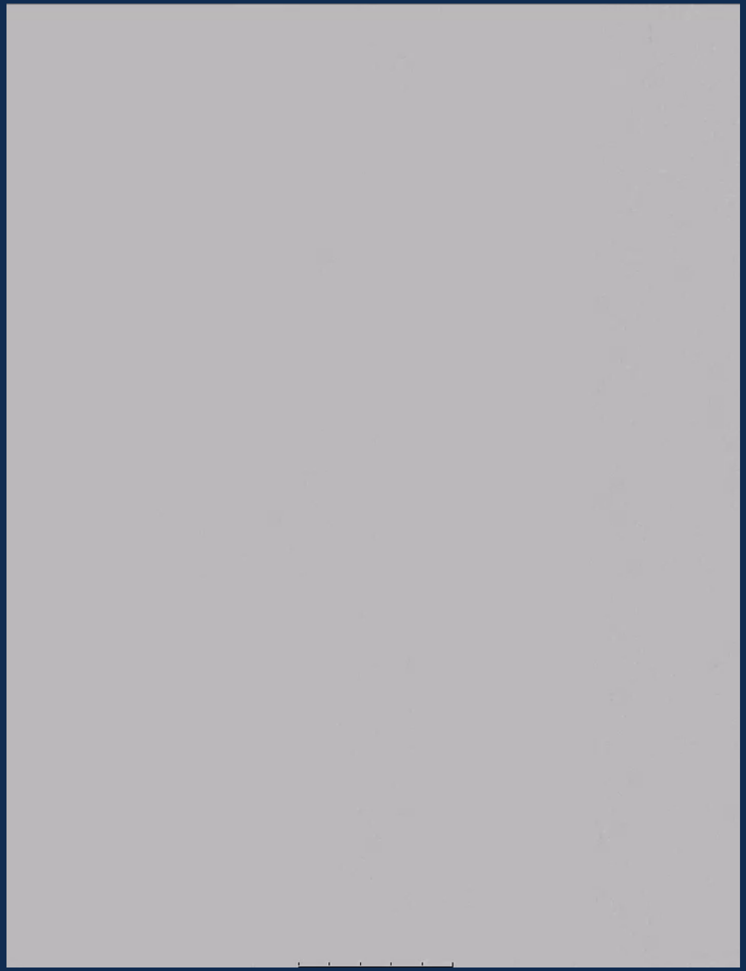
70s male, HLD, CAD, prior smoker, unable to ambulate without walker





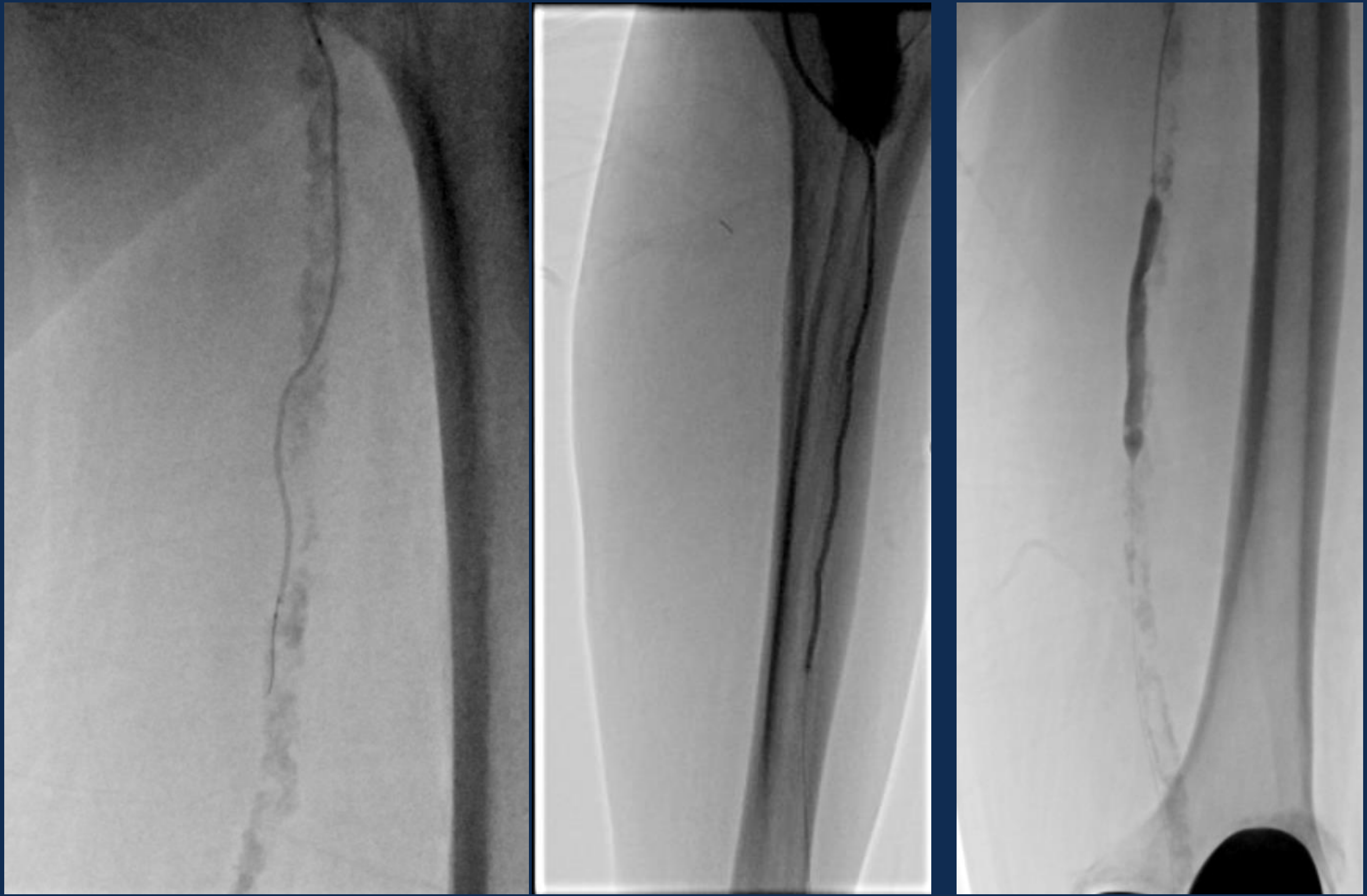
- Dense exophytic calcium
- Difficult access and closure





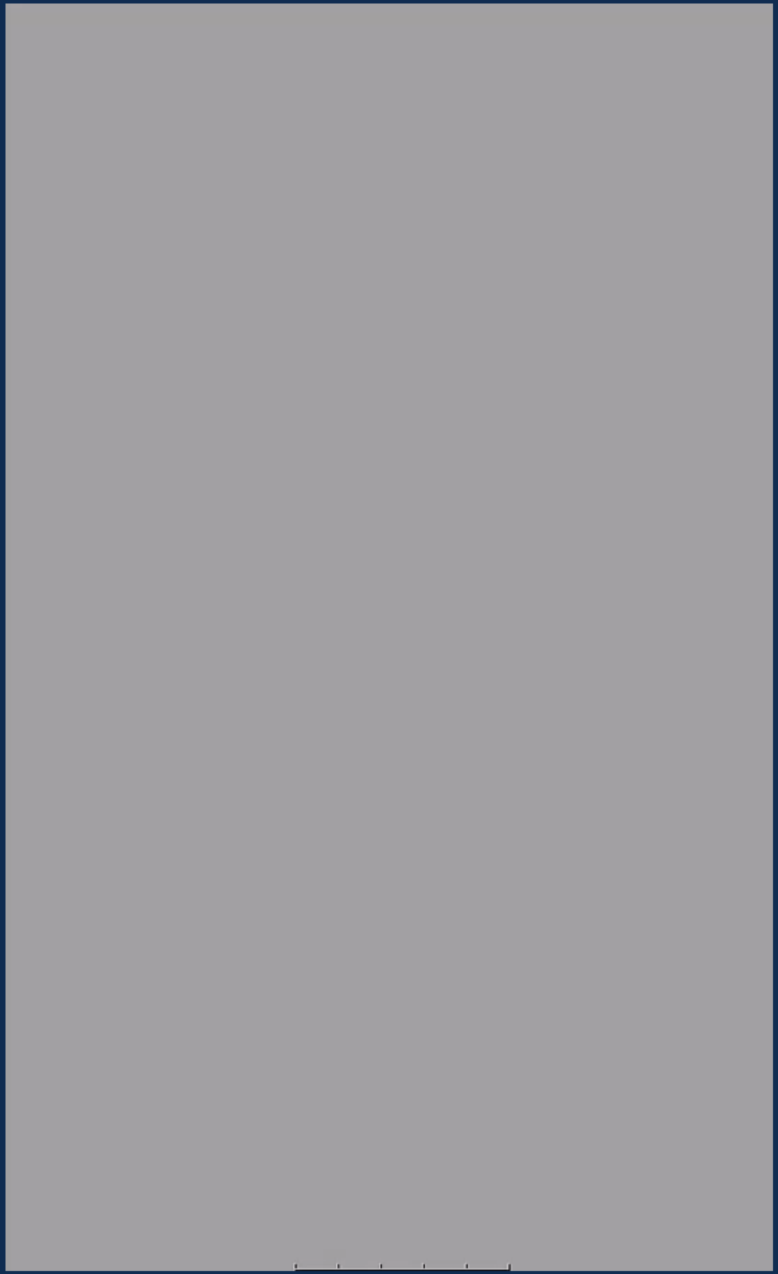
- Long segment SFA occlusion, P1 occlusion
- Occluded AT

AT = atrial tachycardia.

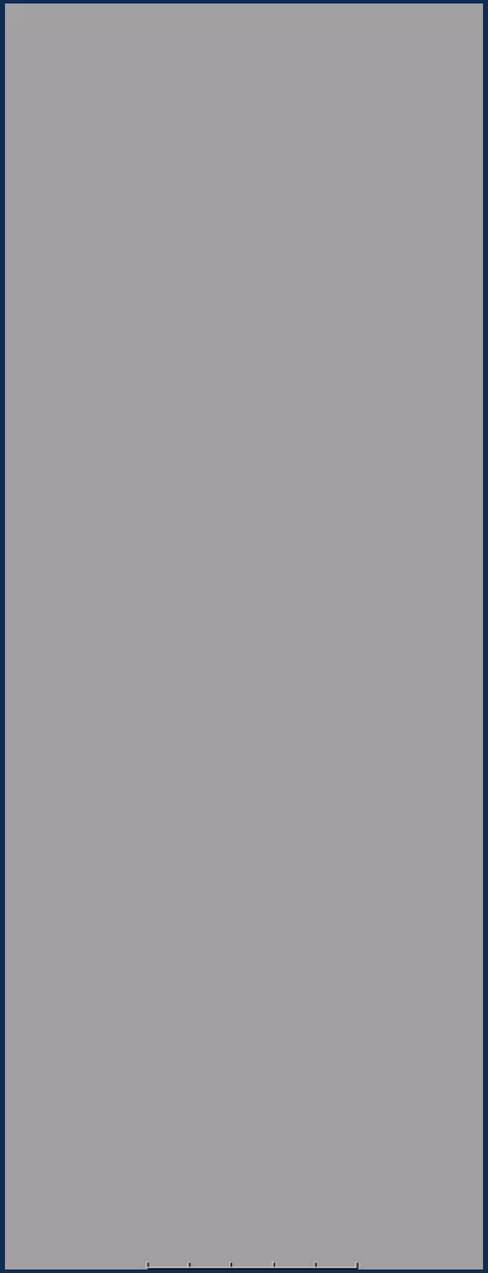


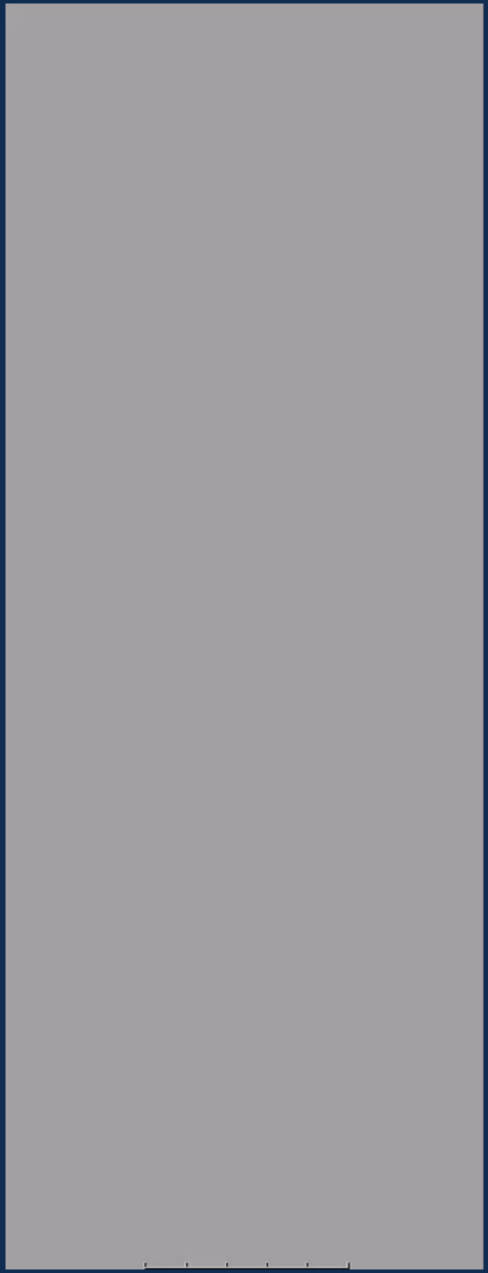
- True lumen
  - Pros
  - Cons
- Through and through
- Use diseased vs first
- +/- predilate
- IVL, POBA, stent

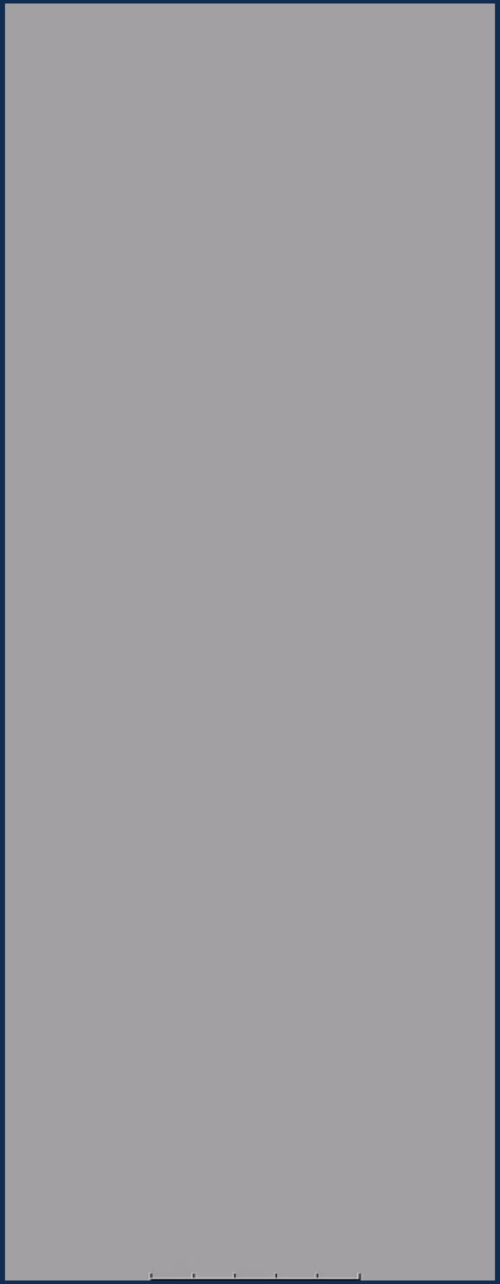
POBA = plain old balloon angioplasty.

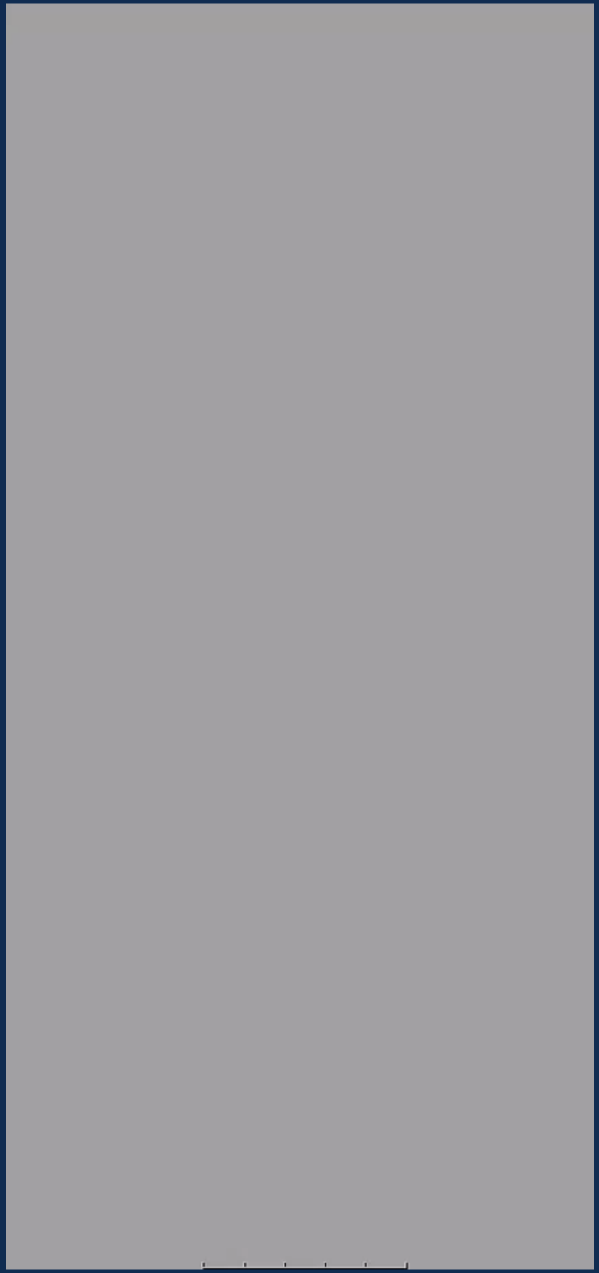


- 90-year-old male
  - Heel wound
  - Occluded distal CFA to tibials
- Through and through access
  - Preserve-recanalize PFA origin
  - Do not re-enter distal to tibial reconstitution
- Combination of 035 and 014
- IVL, POBA, stents









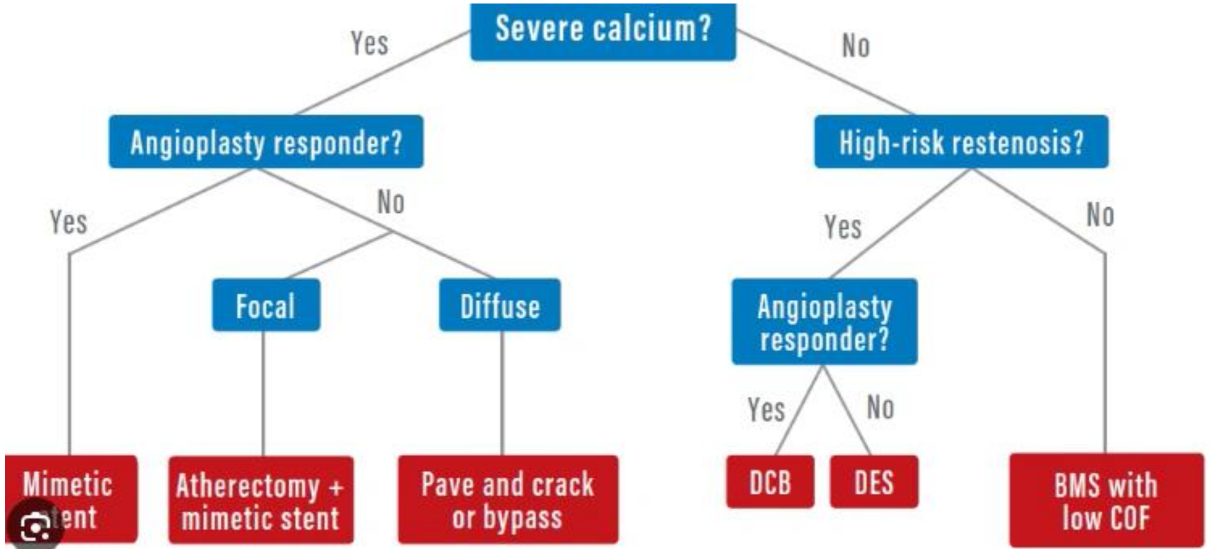
Endovascular Management of Calcified SFA Disease in Limiting Claudication: Comparative Analysis of Vessel Compliance, IVL, Atherectomy, and DCB

Frank R. Arko III, MD

DCB = drug-coated balloon.

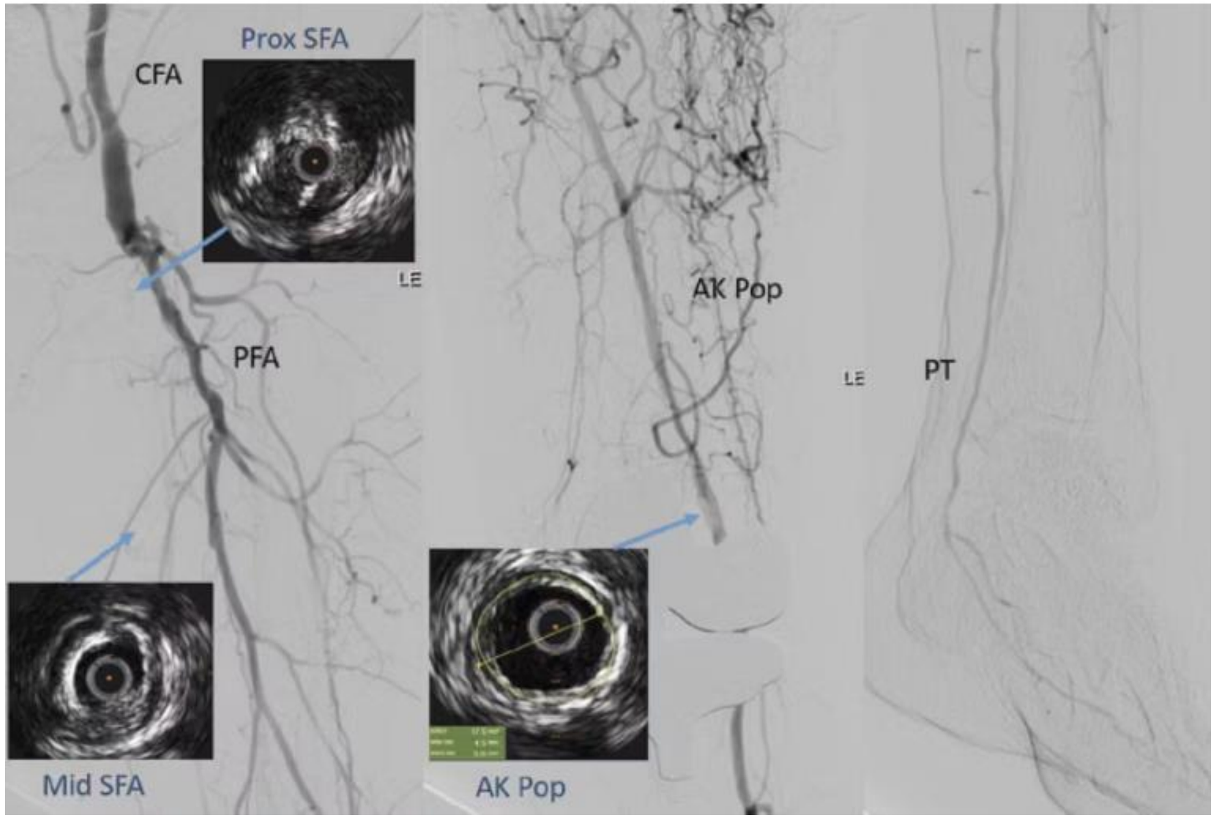
Introduction

- **Overview**: Calcified SFA lesions pose significant challenges in treating patients with claudication
- **Importance**: Understanding vessel compliance and the role of various endovascular therapies is crucial for optimal patient outcomes



Pathophysiology of Calcified SFA Disease

- **Mechanism**: Calcification leads to vessel stiffening, reducing compliance
- **Consequences**: Impaired drug delivery, increased risk of restenosis, and procedural complications

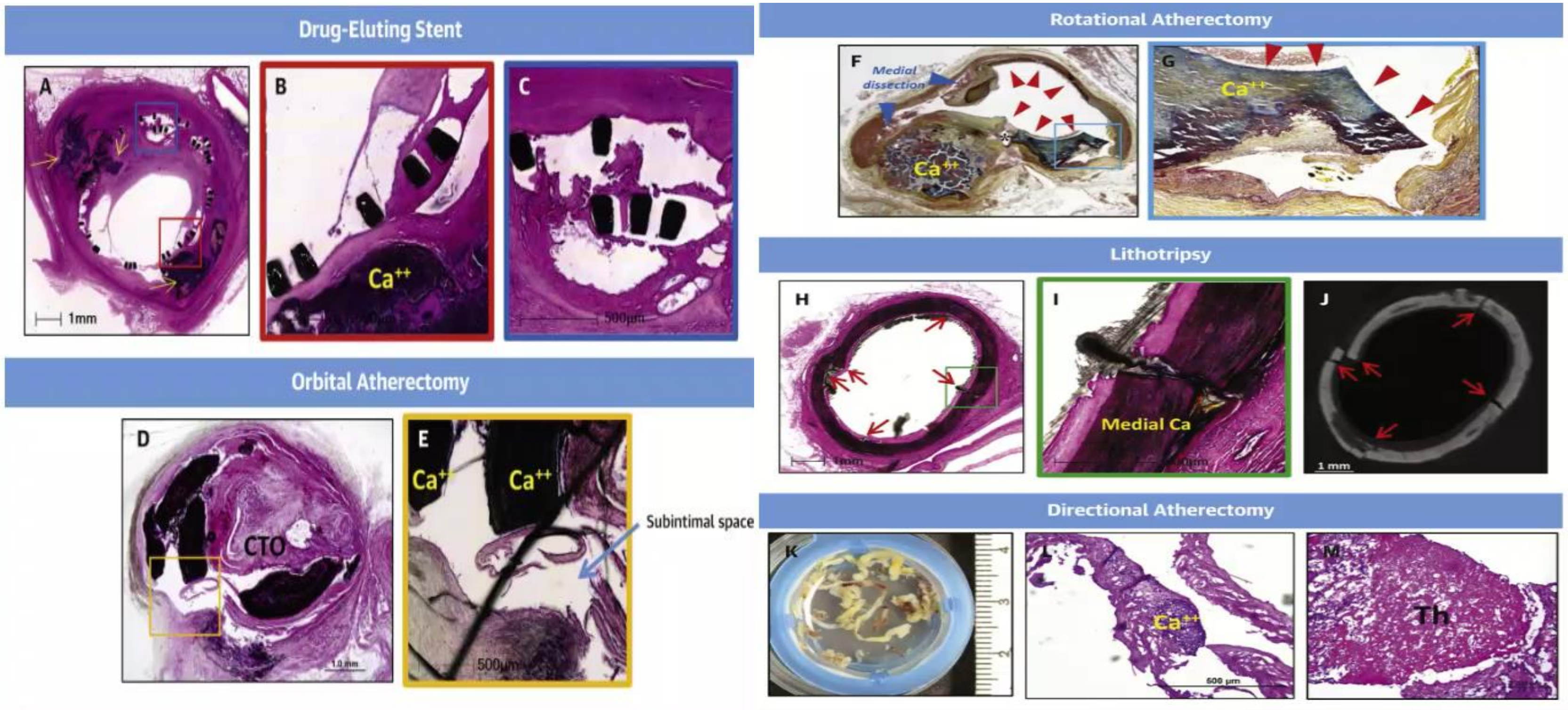


PFA = profunda femoral artery; CFA = common femoral artery; AK = above-knee; PT = posterior tibial.

Guevara CJ, et al. Endovascular Today. March 2023. Accessed June 16, 2025. https://evtoday.com/articles/2023-mar/achieving-success-in-calcified-sfa-and-popliteal-lesions.

Vessel Compliance and Its Impact

- **Definition**: Vessel compliance refers to the ability of the artery to expand and contract with pressure changes
- **Impact**: Low compliance in calcified vessels increases the risk of dissection and restenosis



Lanzer P, et al. *J Am Coll Cardiol*. 2021;78(11):1145-1165.

Intravascular Lithotripsy (IVL)

Inspired by urological applications but designed for cardiovascular systems.

Lithotripsy

- 30 years of safety data in kidney stone treatment
- **Sonic pressure waves** preferentially impact hard tissue, disrupt calcium, and leave soft tissue undisturbed

Cardiovascular Lithotripsy

- Miniaturized and arrayed lithotripsy emitters for localized lithotripsy at the site of the vascular calcium
- **Optimized for the treatment of cardiovascular calcium**

Peripheral IVL Catheters

FDA. Accessed June 16, 2025. https://www.accessdata.fda.gov/cdrh_docs/pdf22/K221041.pdf.

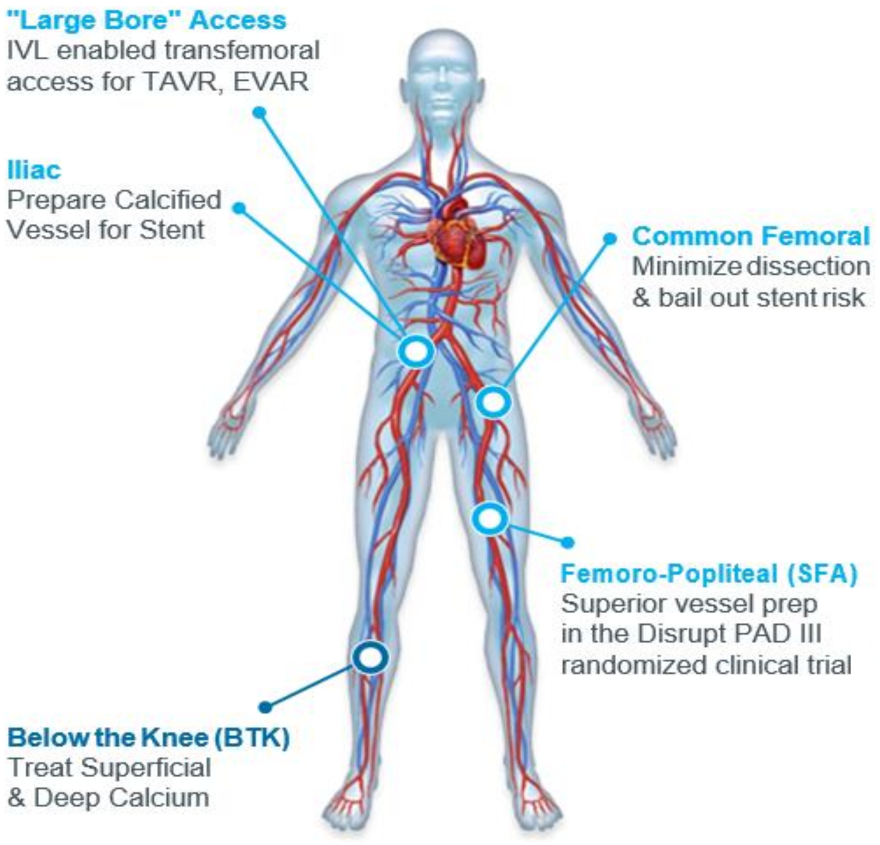
Large Body of Published Evidence across Broad Range of Applications

Patients in DISRUPT PAD Clinical Program

>40	Peer-reviewed publications
>1600	Patients in DISRUPT PAD clinical program

DISRUPT PAD Program Highlights

- Randomized clinical trial demonstrating superiority in vessel prep and avoidance of provisional stenting
- Real-word registry supporting most common applications and adjunctive therapies
- Long-term follow-up
- Patient-level meta-analysis showing consistent safety and efficacy across vessel beds



Common Peripheral IVL Applications

NIH. Accessed June 16, 2025. https://clinicaltrials.gov/study/NCT02369848.

How IVL Cracks Calcium

- Expanding and collapsing vapor bubble creates a short burst of **sonic pressure waves**
- Sonic pressure waves travel through the vessel with an effective pressure of **~50 atm**
- A **localized field effect** within the vessel fractures both **intimal and medial** calcium

NIH. Accessed June 16, 2025. https://clinicaltrials.gov/study/NCT02369848.

Peripheral IVL System: Clinical Programs

DISRUPT PAD I	DISRUPT PAD II	DISRUPT BTK	DISRUPT PAD III	Observational Registry
Pre-market	Post-market	Post-market	Post-market	Post-market
Single Arm	Single Arm	Single Arm	Randomized	Single Arm
N=35	N=60	N=20	N=400	N=1000
2014	2015	2017	2017	2017

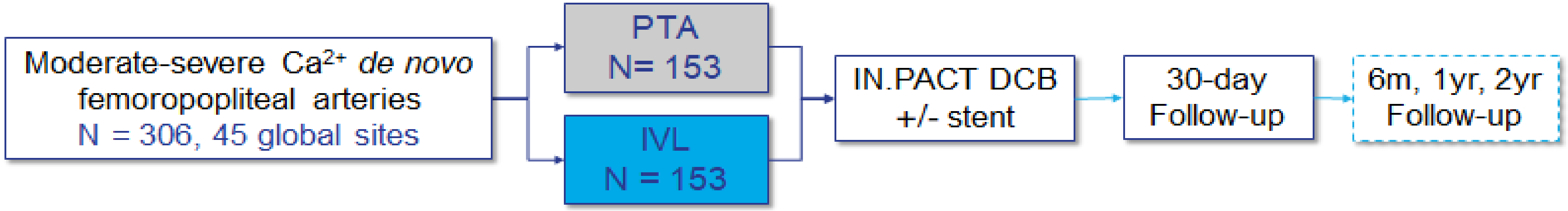
Study Completed (DISRUPT PAD I, DISRUPT PAD II, DISRUPT BTK, DISRUPT PAD III)

Enrolling (Observational Registry)

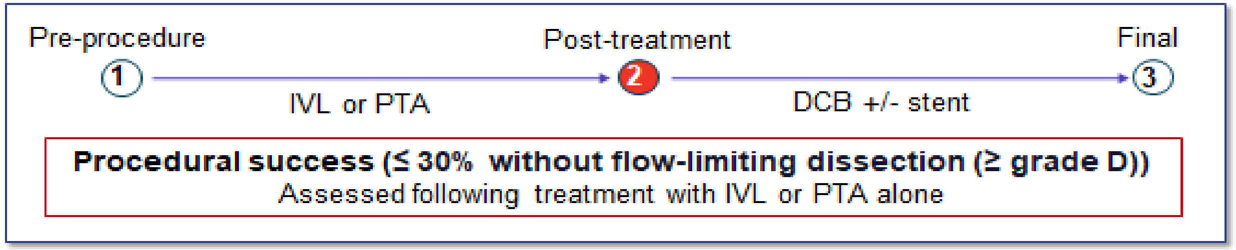
Objective: To study the safety and effectiveness of the IVL System in the treatment of **calcified**, stenotic femoropopliteal peripheral arteries.

NIH. Accessed June 16, 2025. https://clinicaltrials.gov/study/NCT04585763; NCT02369848; NCT05007925; NCT05881421.

PAD III Is the Largest-Ever RCT of Calcified Lesions



Primary Endpoint: Procedural success



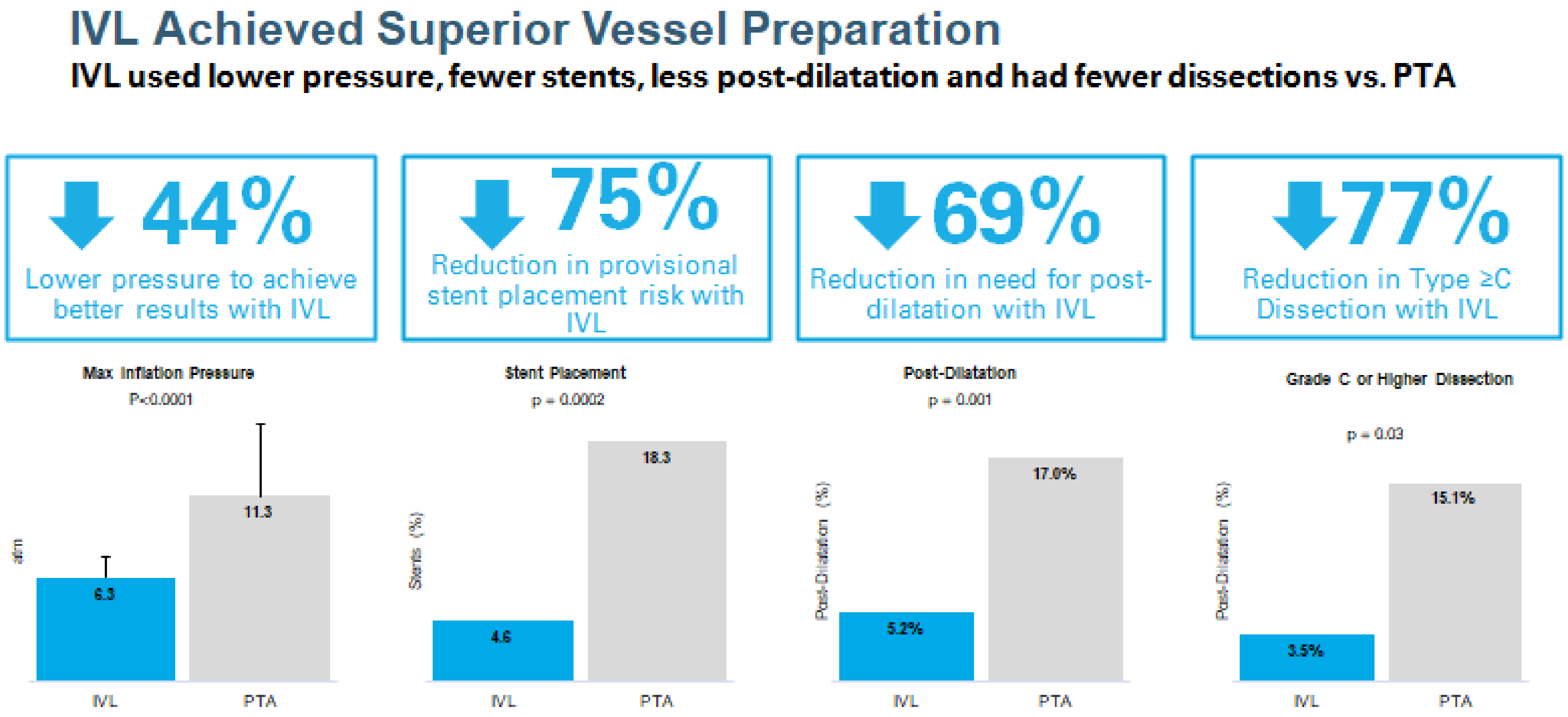
Secondary Endpoints at 30 days: Major Adverse Events, CD-TLR, ABI, RC, WIQ

Powered Secondary Endpoint at 12 months: Primary patency*

*Freedom from CD-TLR and freedom from restenosis determined by DUS or angiogram in >/50% stenoids; **Acute PTA failure requiring a stent at any time during index procedure will be counted as a loss of primary patency.

NIH. Accessed June 16, 2025. https://clinicaltrials.gov/study/NCT05881421.

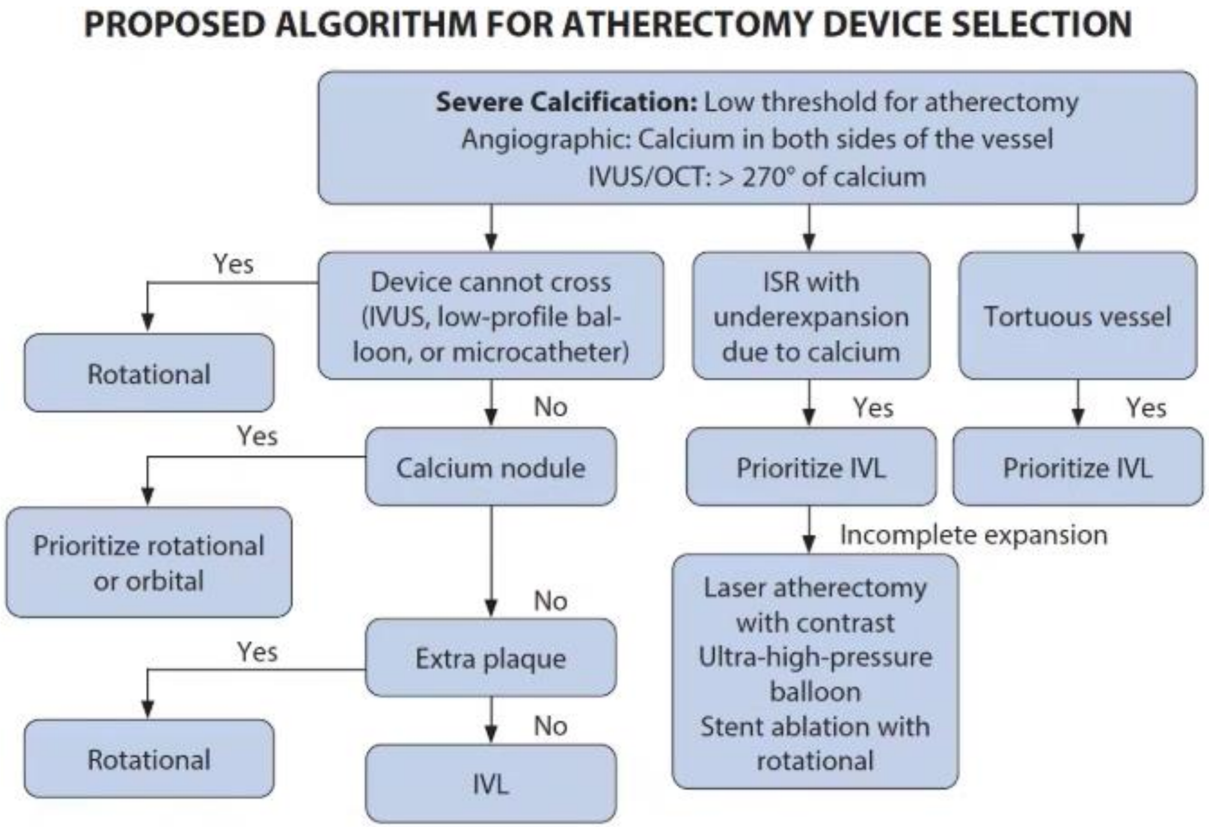
PAD III Is the Largest-Ever RCT of Calcified Lesions



NIH. Accessed June 16, 2025. https://clinicaltrials.gov/study/NCT05881421.

Atherectomy

- **Mechanism**: Mechanical plaque removal to debulk lesions
- **Types**: Directional, rotational, and orbital atherectomy
- **Considerations**: Requires embolic protection; risk of vessel injury

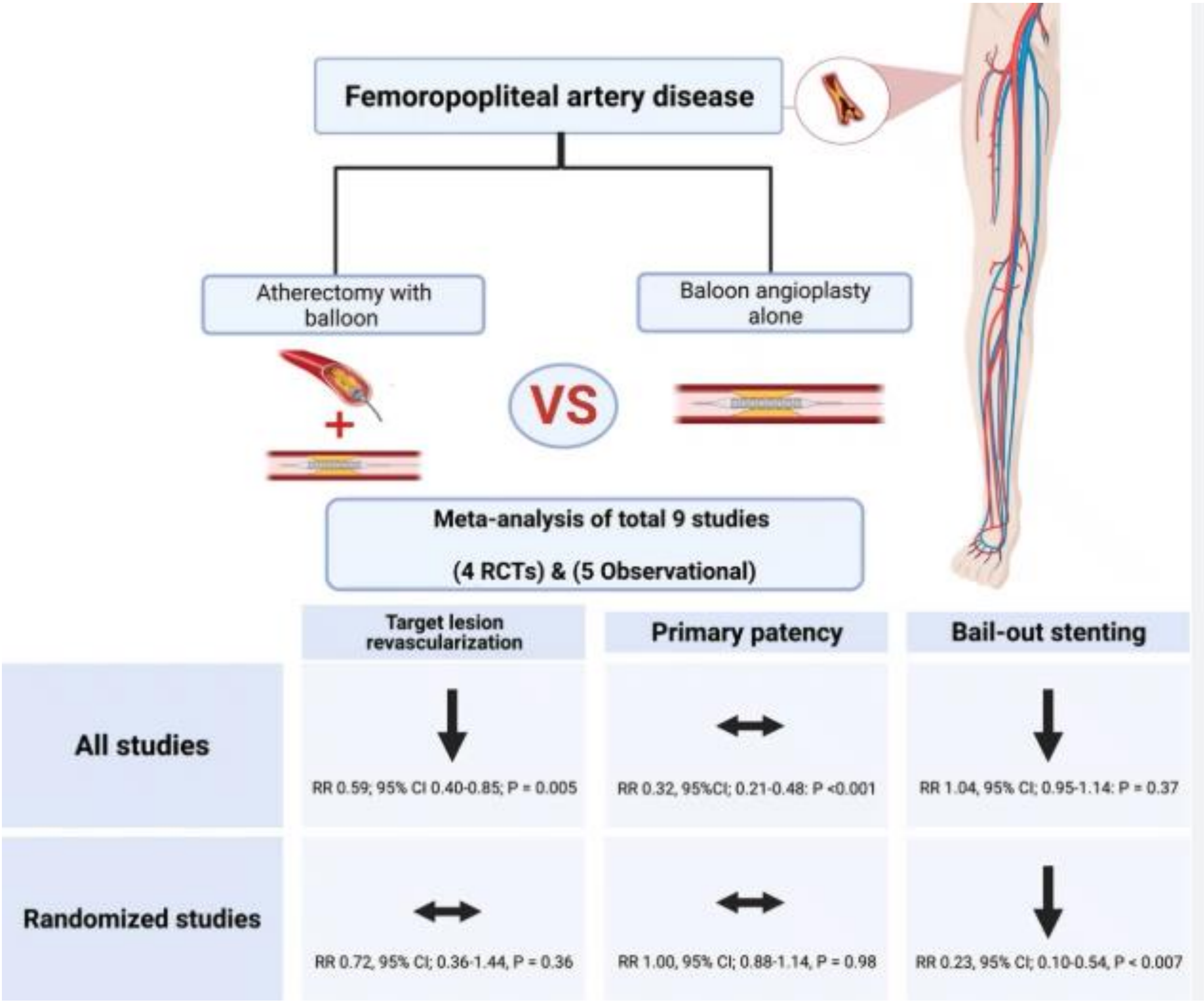


ISR = in-stent restenosis.

Kearney K, et al. Cardiac Interventions Today. January/February 2024. Accessed June 16, 2025. https://citoday.com/articles/2024-jan-feb/atherectomy-and-intravascular-lithotripsy-for-calcium-modification.

Drug Coated Balloons

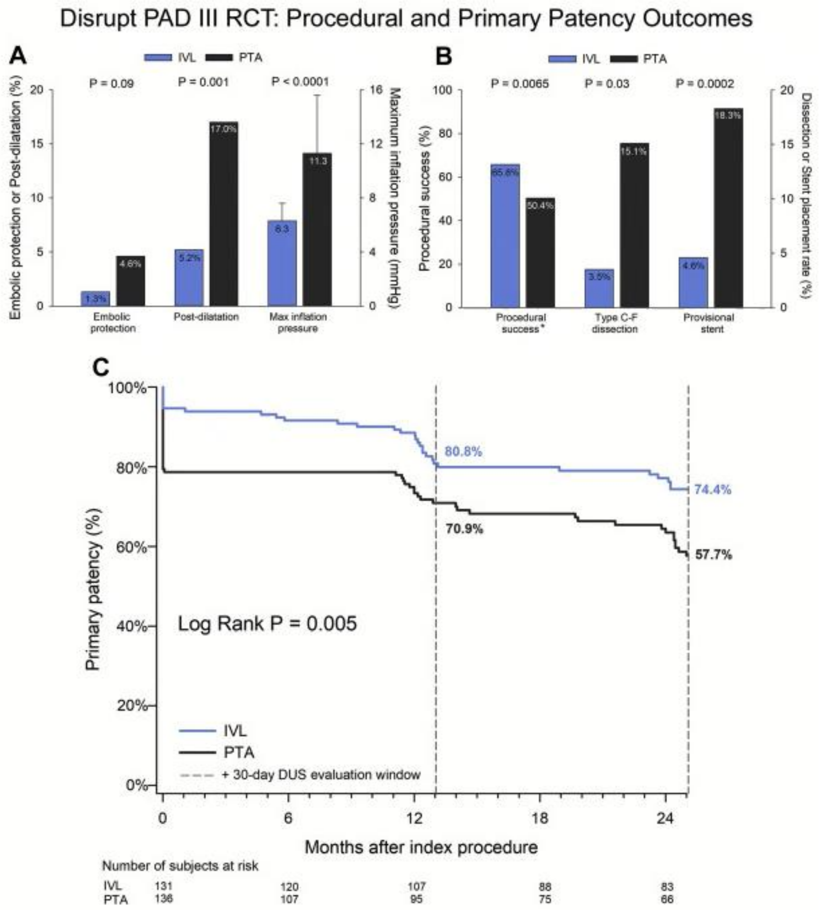
- **Mechanism**: Balloon angioplasty combined with antiproliferative drug delivery to prevent restenosis
- **Limitations**: Reduced efficacy in calcified lesions due to impaired drug uptake



Abusnina W, et al. ***J Soc Cardiovasc Angiogr Interv*****. 2022;1(6):100436.**

Comparative Efficacy: IVL vs Atherectomy

- **Study**: A retrospective cohort study comparing IVL-DCB and Atherectomy-DCB for calcified common femoral artery disease
- **Findings**: Both approaches showed similar rates of target lesion revascularization (TLR) and complications
- **Conclusion**: IVL and atherectomy are comparable in efficacy for calcified lesions



Tepe G, et al. *J Soc Cardiovasc Angiogr Interv*. 2022;1(4):100341.

Vessel Compliance Post-Treatment

- **IVL**: Significant increase in vessel compliance post-treatment
- **Atherectomy**: Moderate improvement in compliance; dependent on lesion characteristics
- **DCB**: Minimal impact on compliance; efficacy depends on prior vessel preparation

Table 1. Mid-term primary patency.

Outcome	IVL	PTA	*P* value
Primary patency at 1 y	80.5% (99/123)	68.0% (87/128)	.017
Freedom from provisional stenting at index procedure	95.4% (146/153)	81.7% (125/153)	<.0001
Freedom from CD-TLR at 1 y	95.7% (132/138)	98.3% (114/116)	.94
Freedom from restenosis at 1 y	90.0% (99/110)	88.8% (87/98)	.48
Primary patency at 2 y	70.3% (78/111)	51.3% (58/113)	.003
Freedom from provisional stenting at index procedure	95.4% (146/153)	81.7% (125/153)	<.0001
Freedom from CD-TLR at 2y	91.5% (108/118)	91.2% (93/102)	.56
Freedom from restenosis at 2y	83.0% (78/94)	76.3% (58/76)	.19

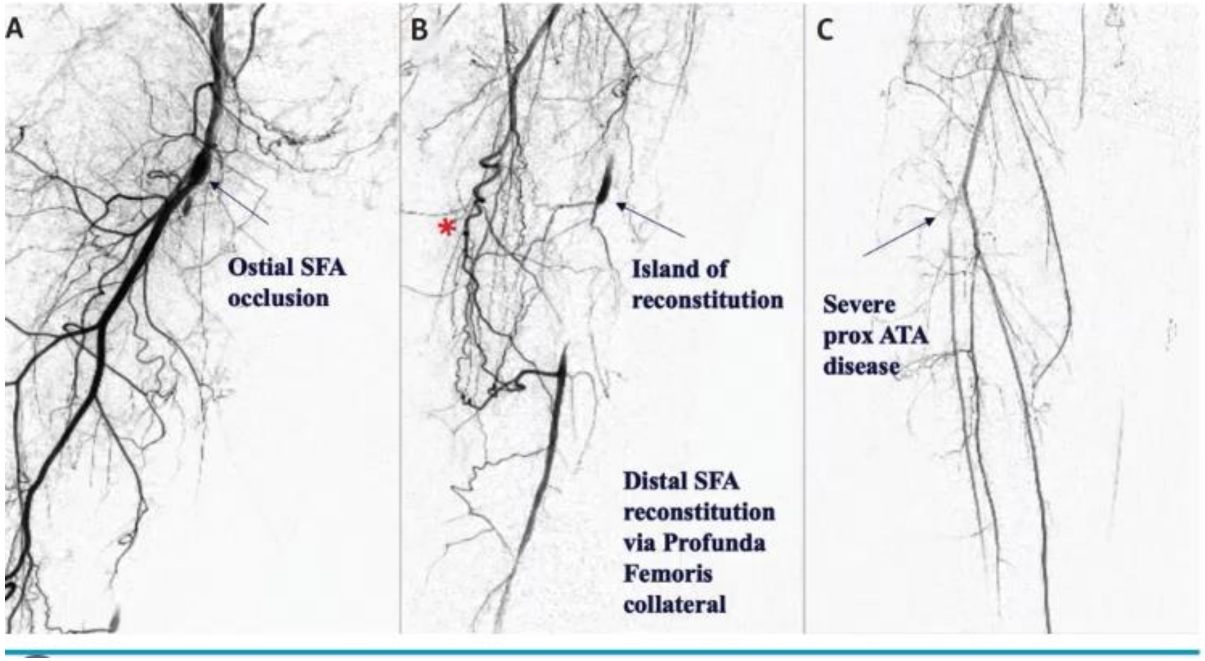
Tepe G, et al. *J Soc Cardiovasc Angiogr Interv*. 2022;1(4):100341.

Procedural Considerations

- **IVL**: Non-invasive; low risk of vessel injury
- **Atherectomy**: Requires embolic protection; higher procedural complexity
- **DCB**: Requires adequate vessel preparation; risk of restenosis if not properly prepped

TABLE 2. TYPICAL INDICATIONS FOR USE OF PERIPHERAL IVL IN TREATING CALCIFIED LESIONS

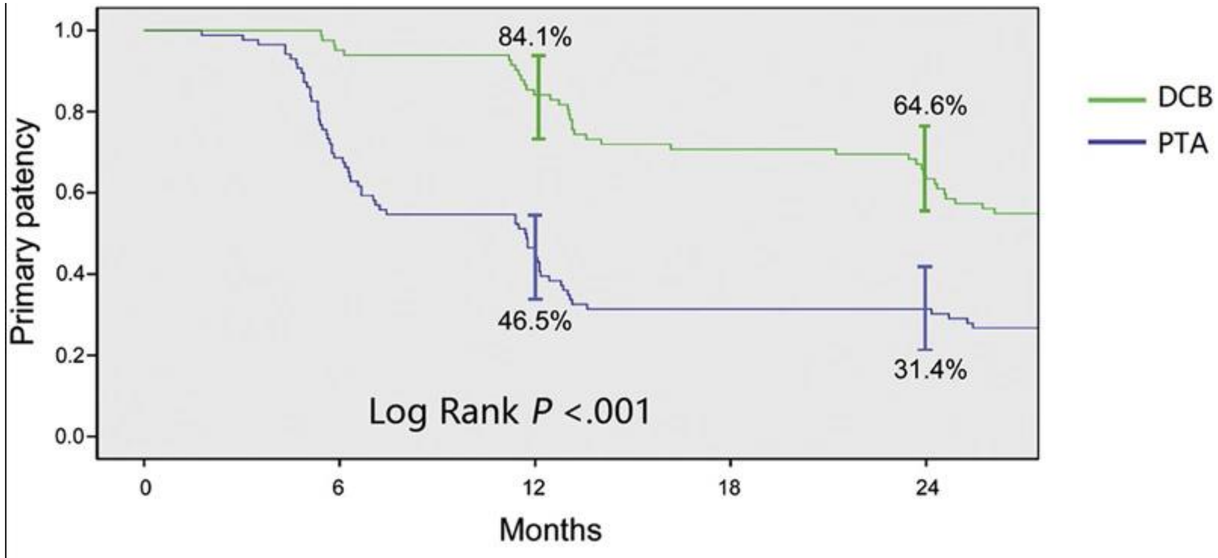
Preparation Phase
1. Peripheral calcification noted on fluoroscopy or noninvasive imaging (computed tomography, magnetic resonance imaging, positron emission tomography, or vascular ultrasound).
2. Evidence of an undilatable lesion despite high-pressure noncompliant balloon dilatation as lesion preparation.
3. Evidence of stent under expansion, either on intravascular imaging or angiographically.
4. Evidence of heavy calcification noted on intravascular imaging (intravascular ultrasonography or optical coherence tomography).



Mufarrih SH, et al. *J Crit Limb Ischem*. 2024:4(2):e34-e43. Memon S, et al. *J Crit Limb Ischem*. 2021;1(2):e73-e78.

Clinical Outcomes

- **IVL-DCB**: High primary patency rates; low restenosis
- **Atherectomy-DCB**: Comparable outcomes; may be preferred for complex lesions
- **DCB alone**: Effective in non-calcified lesions; less effective in calcified lesions



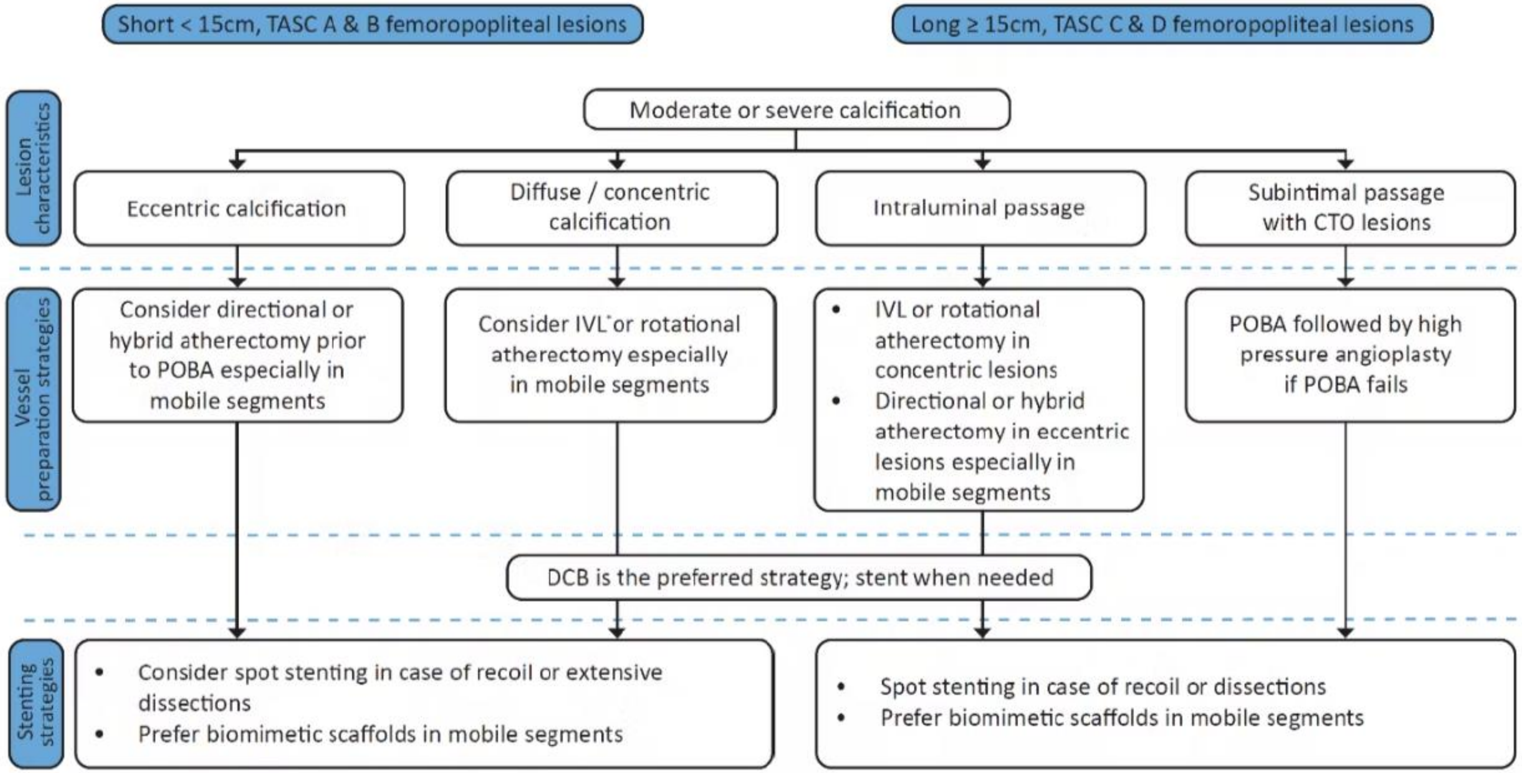
Number of subjects at risk

DCB	100	78	69	58	53
PTA	100	59	47	27	27

Xu Y, et al. ***JACC Cardiovasc Interv*****. 2018;11(23):2347-2353.**

Patient Selection Criteria

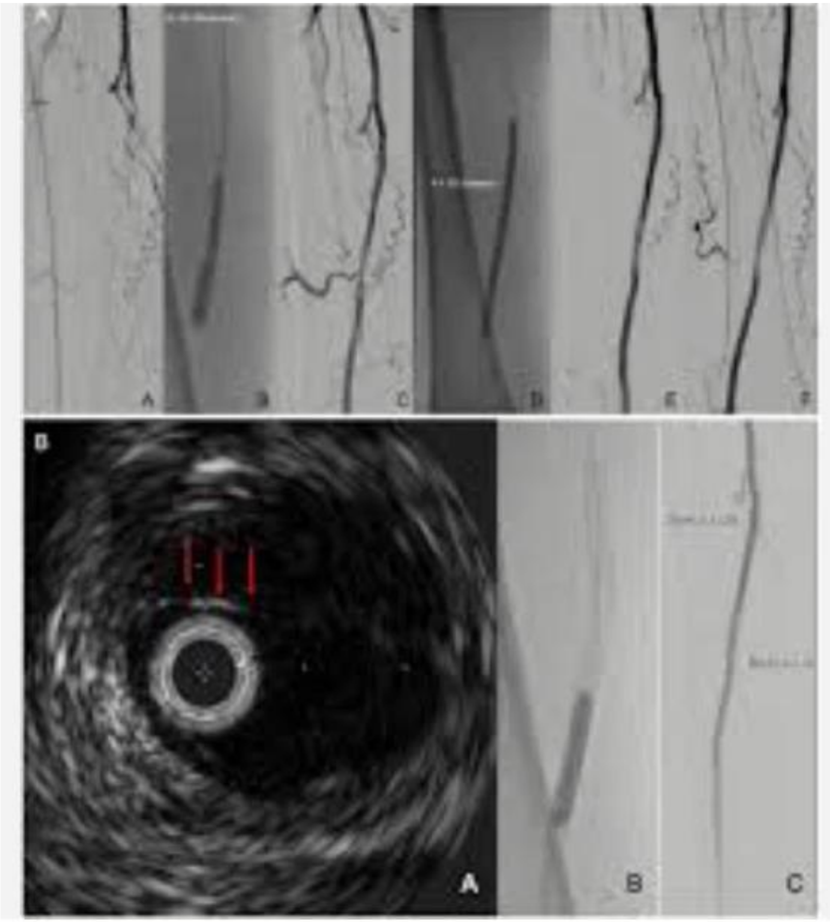
- **Ideal Candidates**: Patients with claudication and heavily calcified SFA lesions
- **Considerations**: Assess lesion morphology, vessel size, and patient comorbidities



Rammos C. Endovascular Today. September 2024. Accessed June 16, 2025. https://evtoday.com/articles/2024-sept/my-femoropopliteal-complex-lesion-treatment-algorithm.

Algorithm for Treatment Selection

- **Step 1**: Assess lesion calcification and vessel compliance
- **Step 2**: Select appropriate vessel preparation technique (IVL or atherectomy)
- **Step 3**: Apply DCB therapy if vessel is adequately prepared
- **Step 4**: Monitor for restenosis and reintervention as needed



Stavroulakis K, et al. ***J Endovasc Ther*****. 2023;30(1):106-113.**

Conclusion

- A variety of techniques are currently used to address access calcific lesions in the SFA
- Minimizing patient impact and maintaining good flow is imperative
- There are limitations to every technique used and understanding these is important for deciding what is best
- There are novel approaches to addressing access which may reduce the need for adjunctive stenting and other techniques
- **Recommendation**: Tailor treatment approach based on individual patient and lesion characteristics

Q&A