

Innovation in the OBL: **The Expanding Role of IVL**

Supported by an educational grant from Shockwave IVL

Faculty

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Faculty Disclosures

- **Mary Costantino, MD, FSIR**

Consultant: Merit; Siemens

Research: Aveera; ORCA

Patent Owner, Investor: Moonrise

- **Sonya Noor, MD, FACS**

Advisory Board: Abbott; BSC; Cordis

Consultant, Speakers Bureau: Abbott; ASAHI; BSC; Cordis; ELGX

Research: BSC; ELGX; Shockwave

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Advisory Board: Cagent Vascular; Philips

Consultant: Evident Vascular

Speakers Bureau: Abbott Labs; BD Biosciences

Disclosures

- The faculty have been informed of their responsibility to disclose to the audience if they will be discussing off-label or investigational use(s) of drugs, products, and/or devices (any use not approved by the US Food and Drug Administration).
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 - This activity has been independently reviewed for balance.

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Learning Objectives

After participating in this activity, learners should be better able to

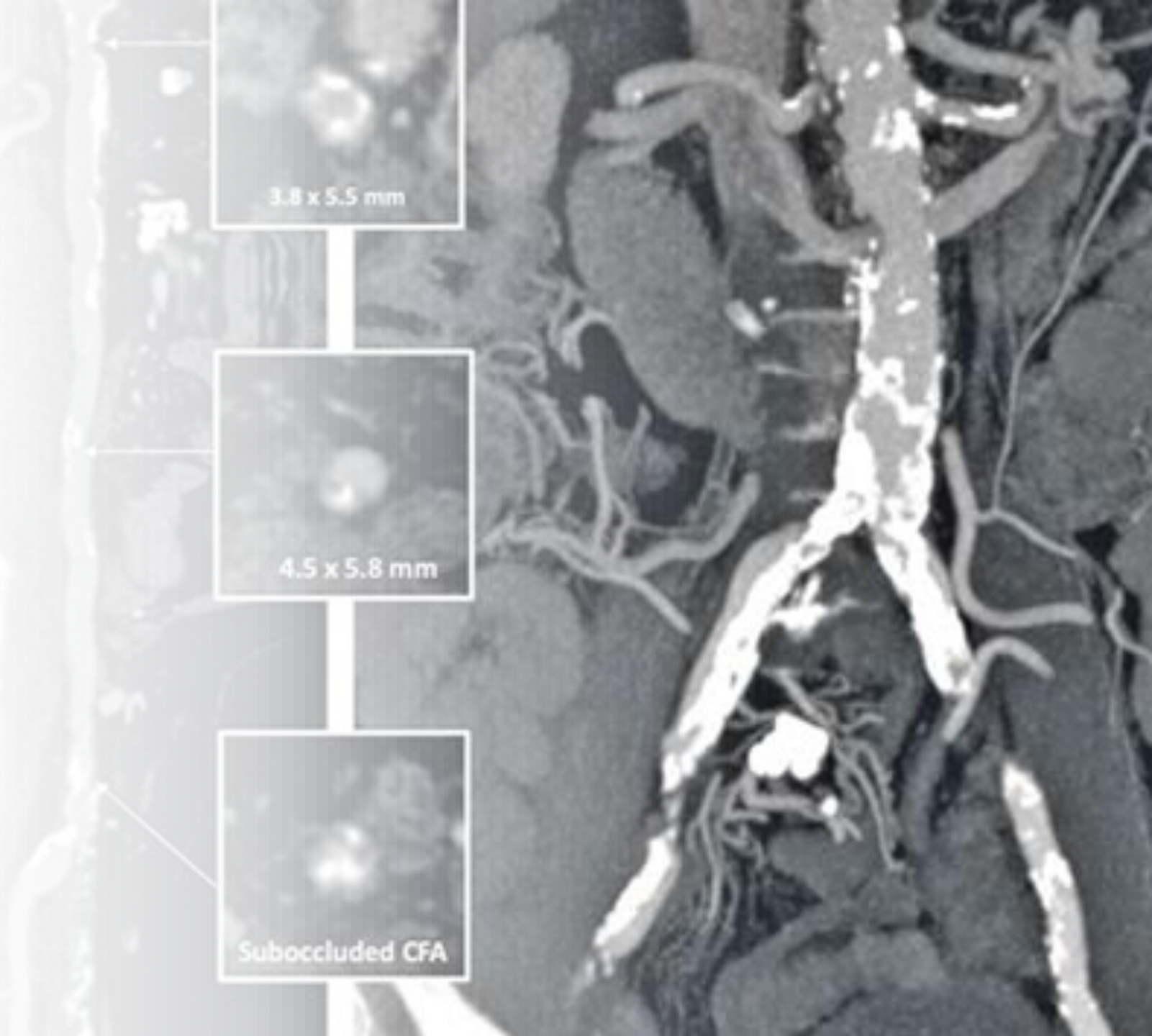
- Apply evidence-based strategies for incorporating intravascular lithotripsy (IVL) into the treatment of calcified peripheral arterial disease (PAD) in the office-based laboratory (OBL), using patient selection principles and case-based decision-making.
- Identify coding, reimbursement, and operational considerations that support the appropriate adoption and sustainable use of IVL in the OBL setting
- Evaluate best practices for transitioning IVL from the hospital to the OBL, including workflow optimization, multidisciplinary collaboration, and practice implementation strategies

Clinical Decision-Making: **Selecting the Right Patient for IVL**

Sonya Noor, MD, FACS

Clinical Associate Professor Dept. of Surgery, University of Buffalo
Director, Endovascular Services, Buffalo General Medical Center
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Buffalo, NY

Hostile Aorto-Iliac DX: any intervention : EVAR/TAVR



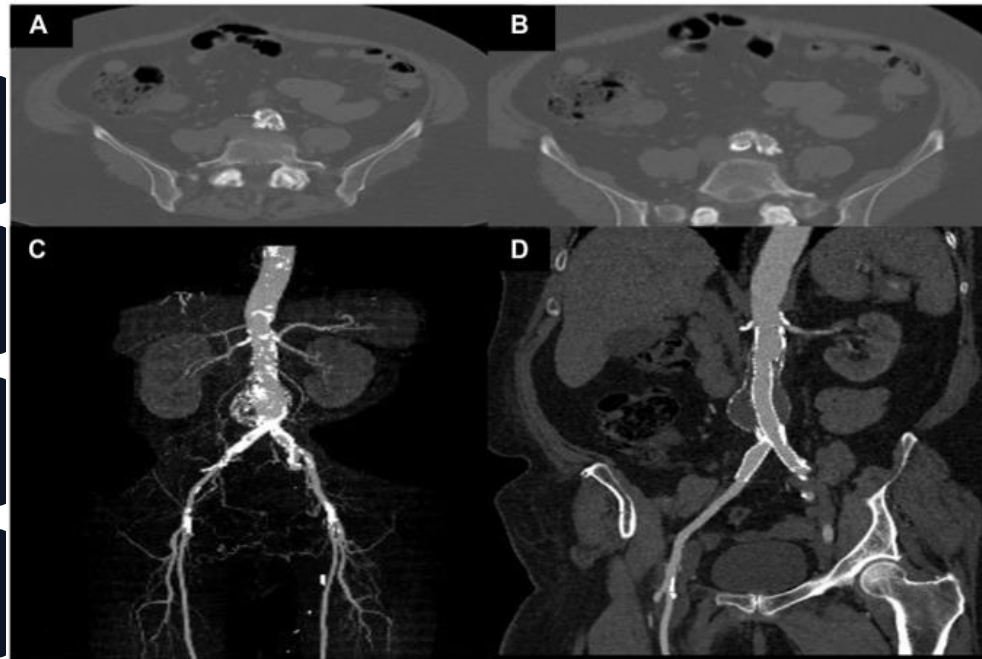
IVL Therapy in PAD

Historic use in Aorto- Iliac

TAVR/ TAVI

EVAR/ TEVAR /TAMBE

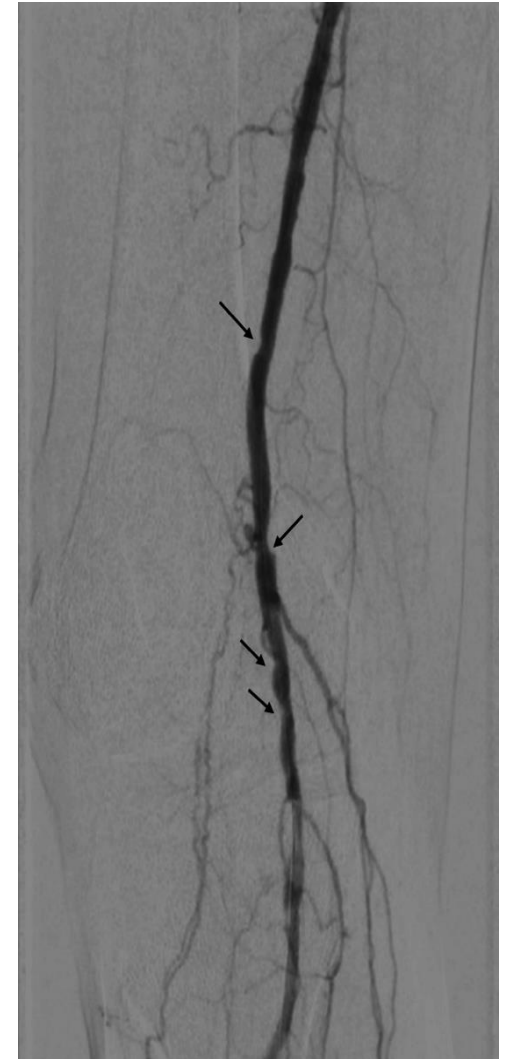
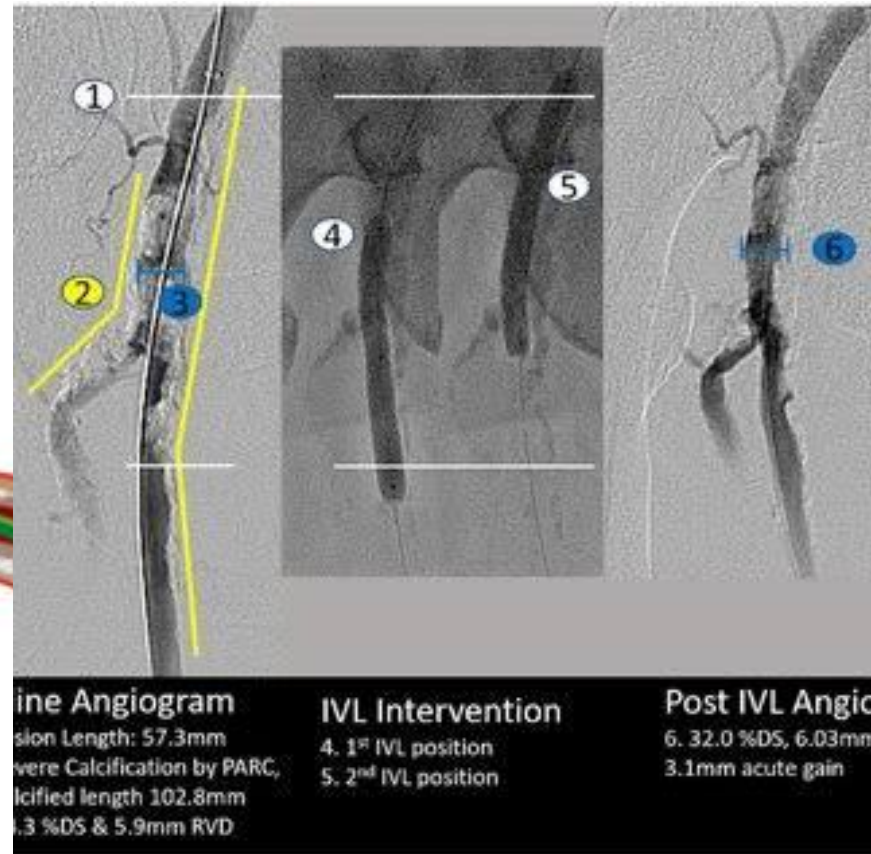
AORTO- ILIAC DX



IVL in Infrainguinal Disease Disrupts intraluminal and medial Ca

- INFRAINGUINAL
- CFA/Profunda
- SFA
- POP
- ? Tibials

Small vessels
Females

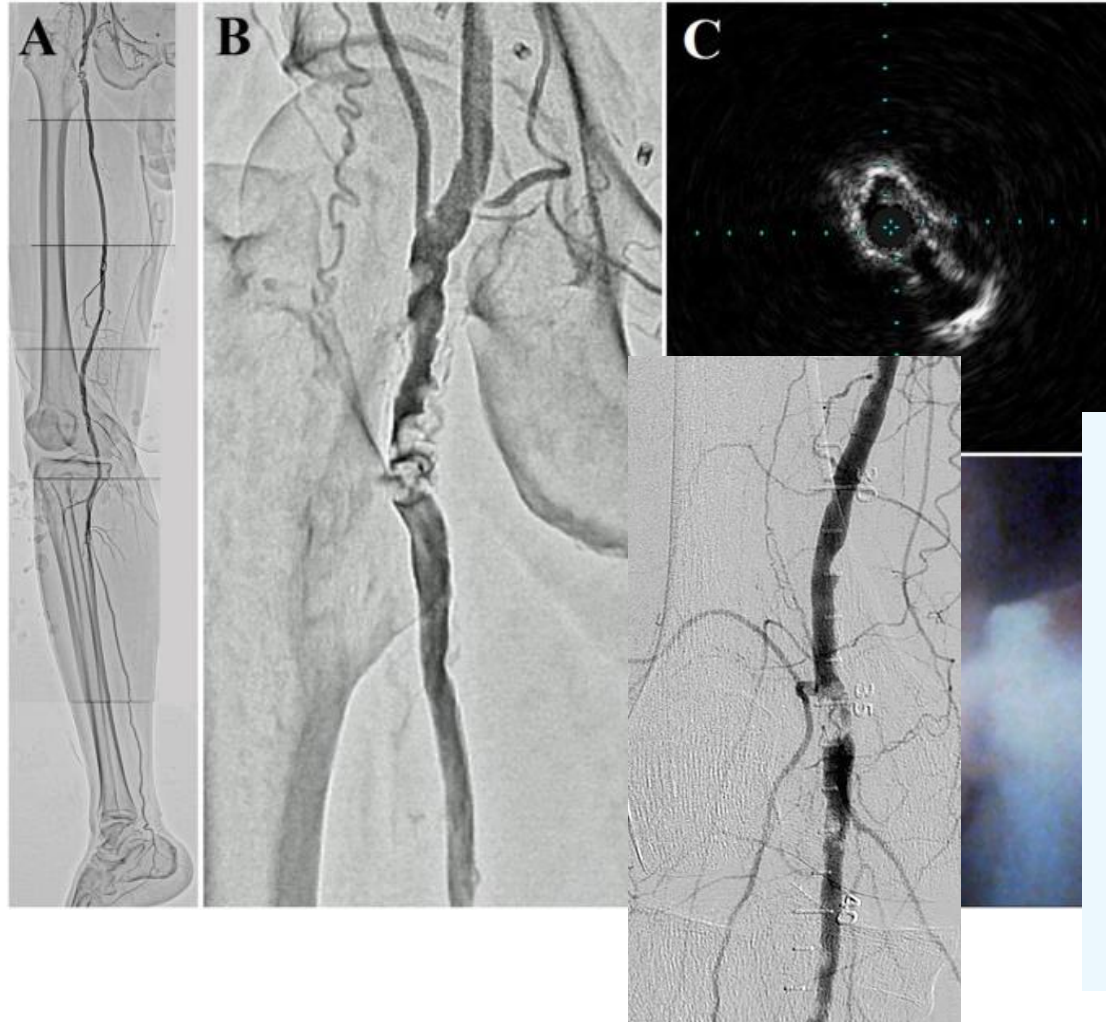
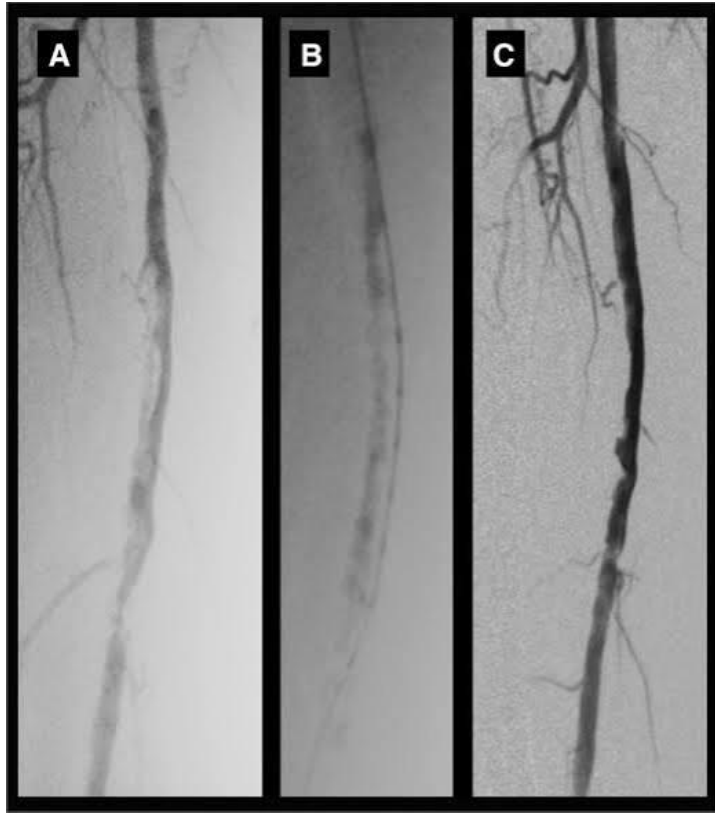


Patient Selection

- Anatomical location
- Aortic
- Iliac
- CFA
- PFA
- SFA
- POP
- Tibial
- NON-STENT ZONES
- SMALL VESSELS

- Pathology
 - Calcific-stained DX
 - Nodular/cauliflower/boulder
 - CTO
 - Stenosis
- DM
- ESRD
- Smokers

Severe Calcium Staining/ Nodular/ Boulder-Like



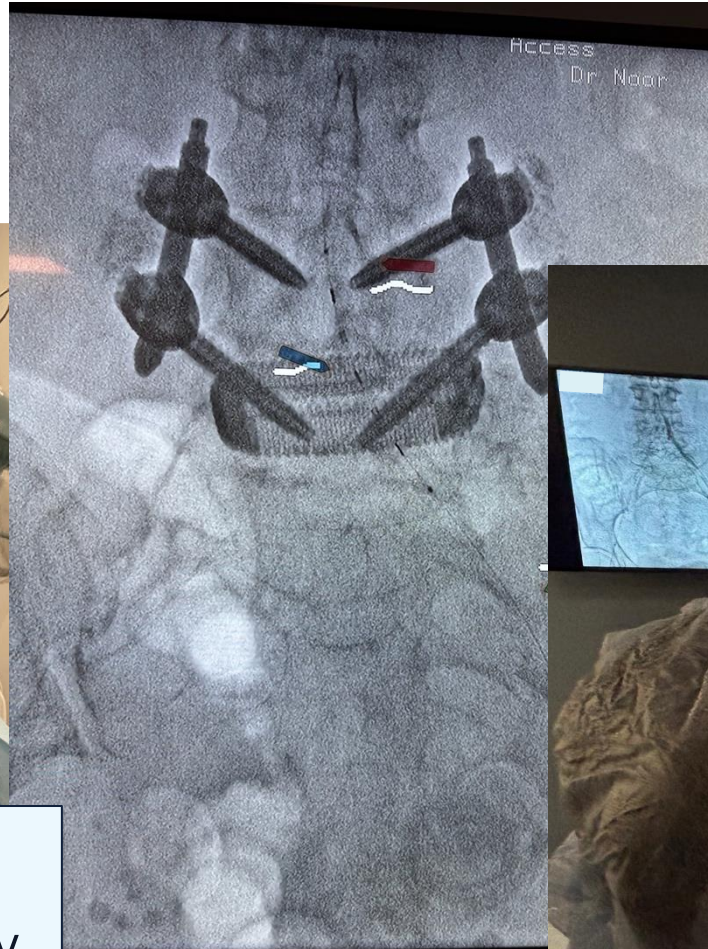
Pathology

- Calcific-stained DX nodular/cauliflower/ boulder
- CTO
- Stenosis

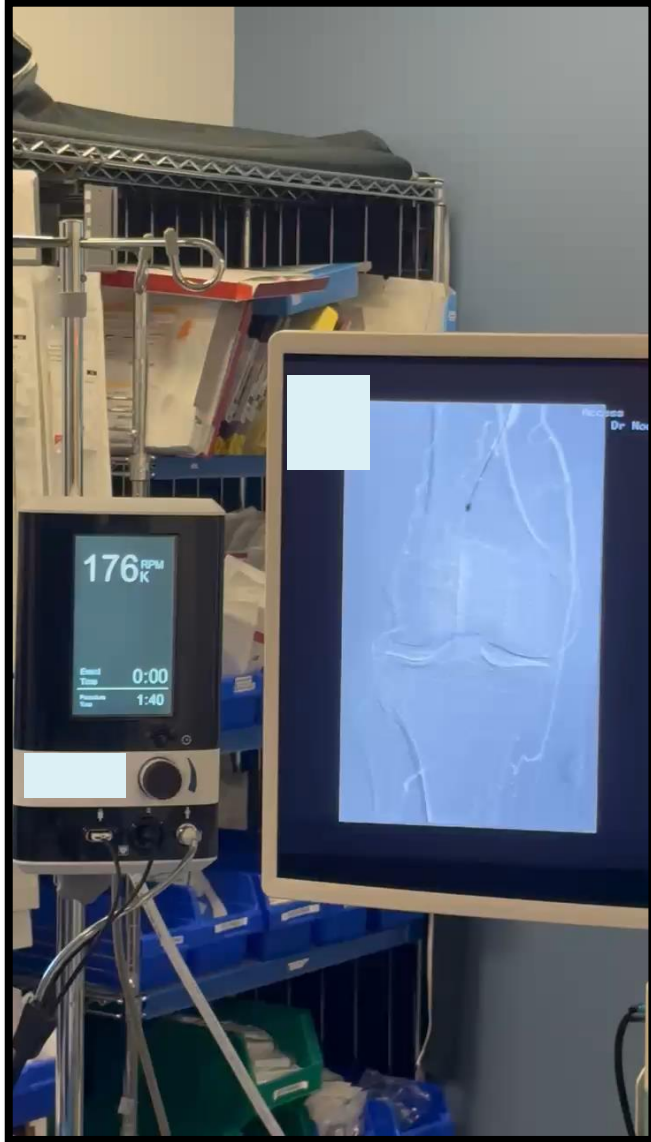
IVL in AIOD: Challenging Pts: OBESE



Obese patients
with AIOD/ back surgery



Challenging Patients: SFA/POP Severe Disease



Role of atherectomy
with IVL

STENTING

DRUG ELUTION

Standalone with PTA

Optimizing Procedural Success: **Case-Based Applications of IVL in the OBL**

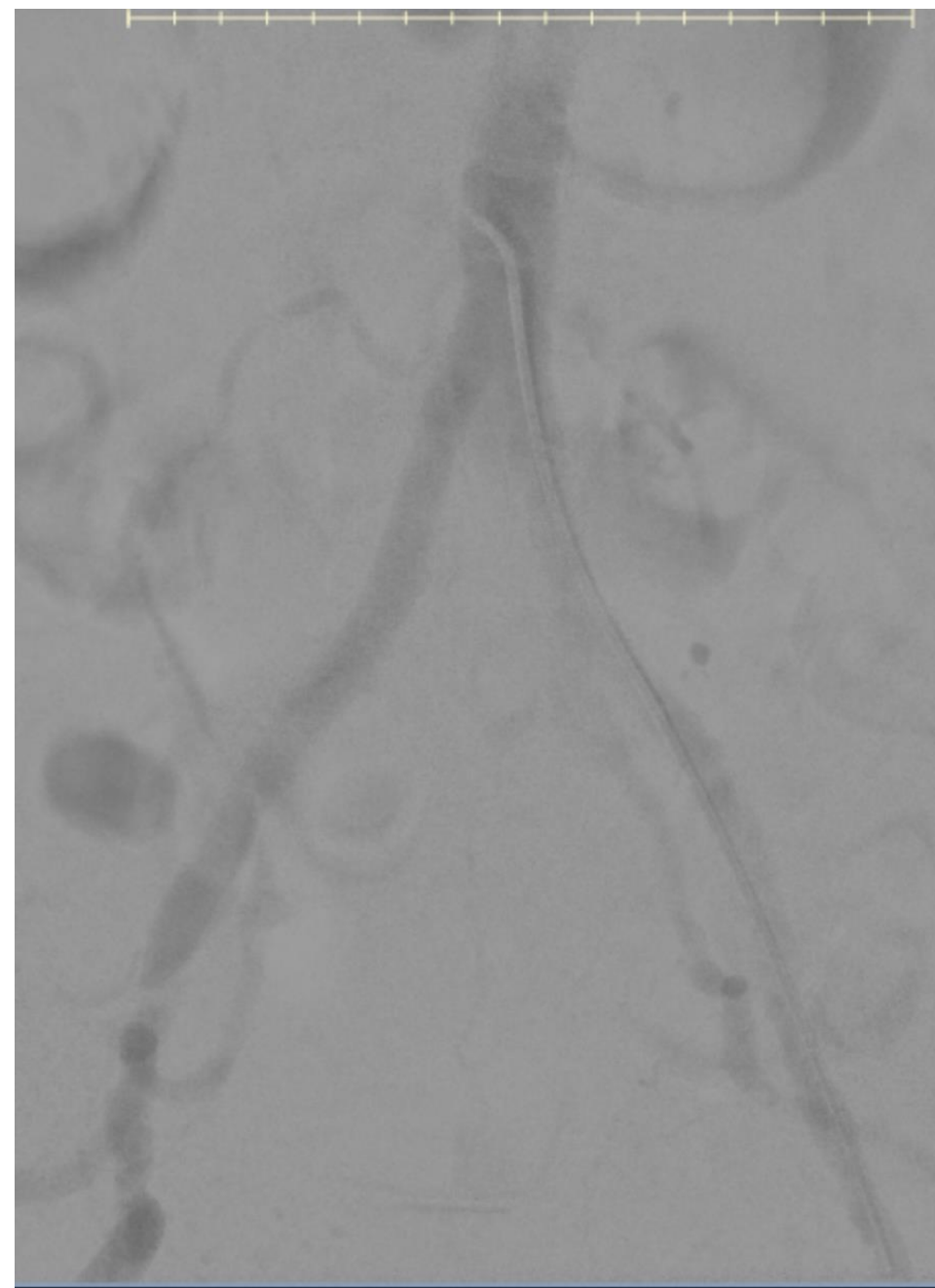
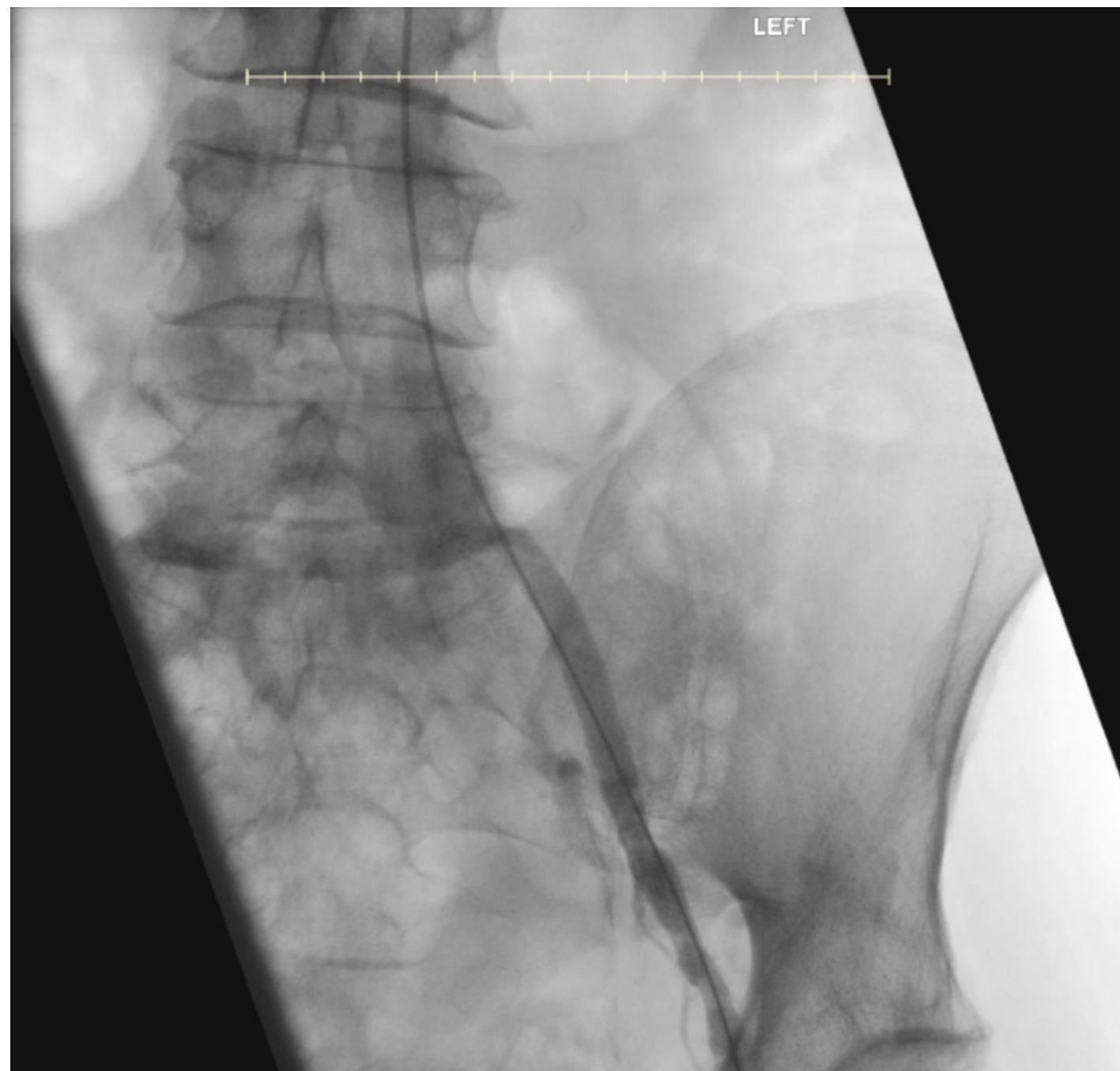
Mary Costantino, MD, FSIR

Owner, Advanced Vascular Centers

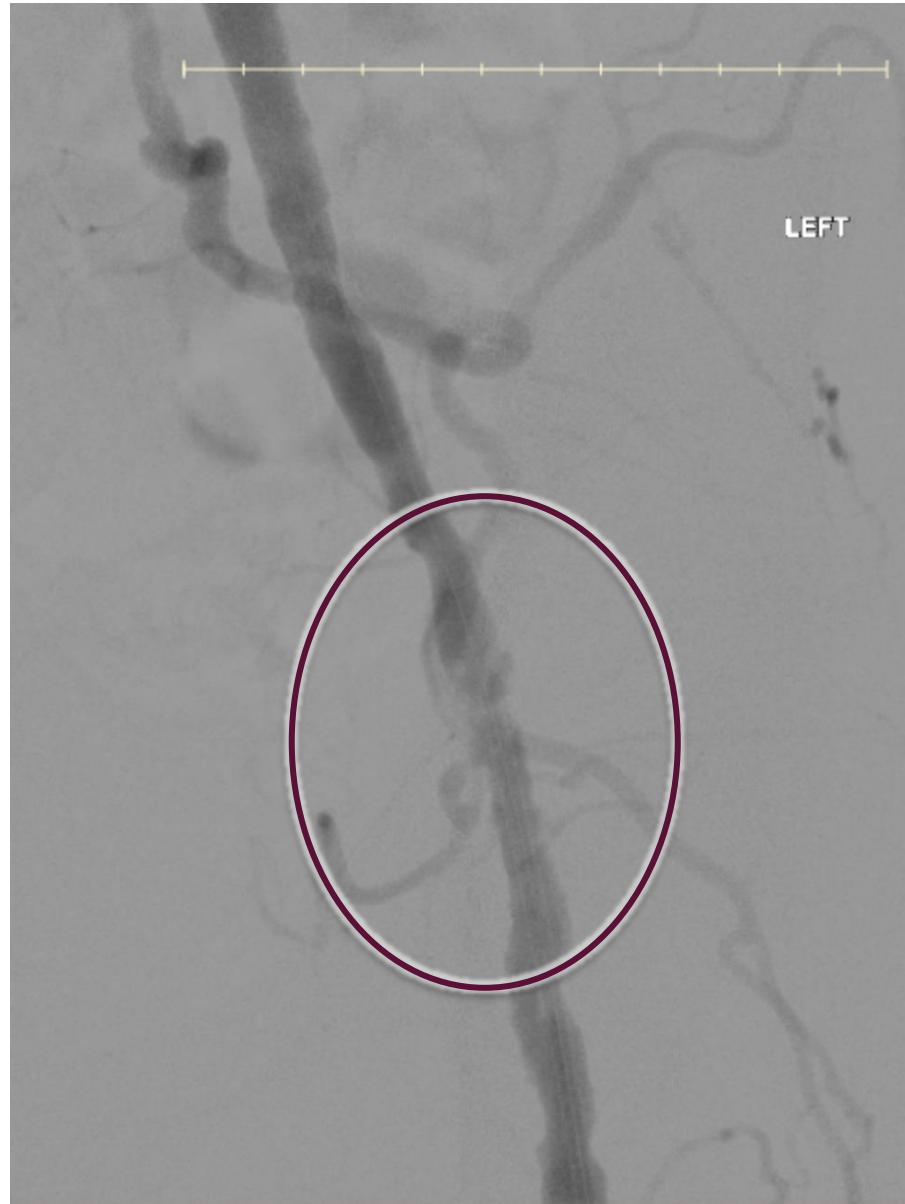
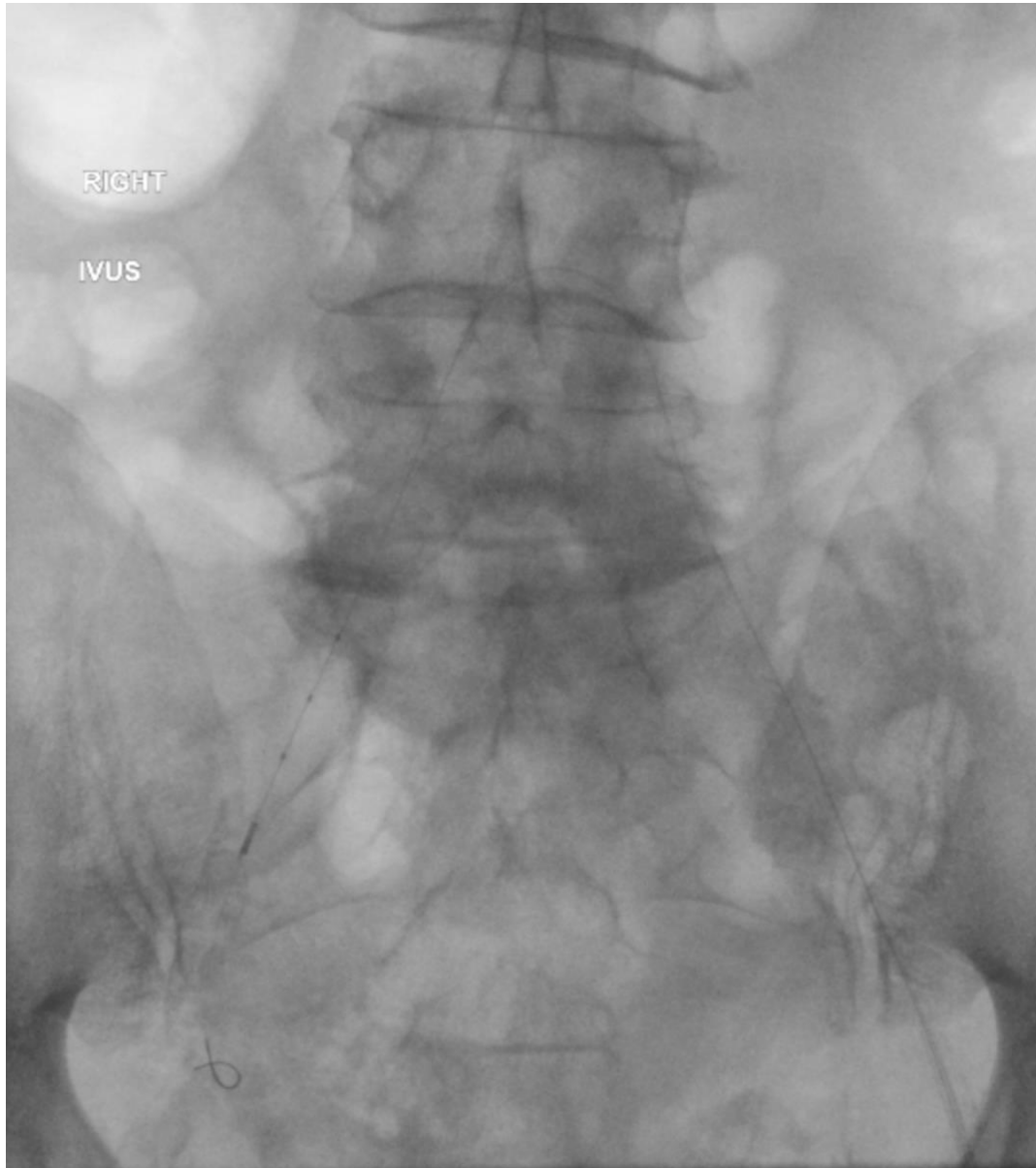
Portland, OR

Case 1

- 67y Female, CLASS 2 PAT increases to diffuse monophasic with toe raises
- No prior CTA, no prior angiogram
- No femoral or tibial disease



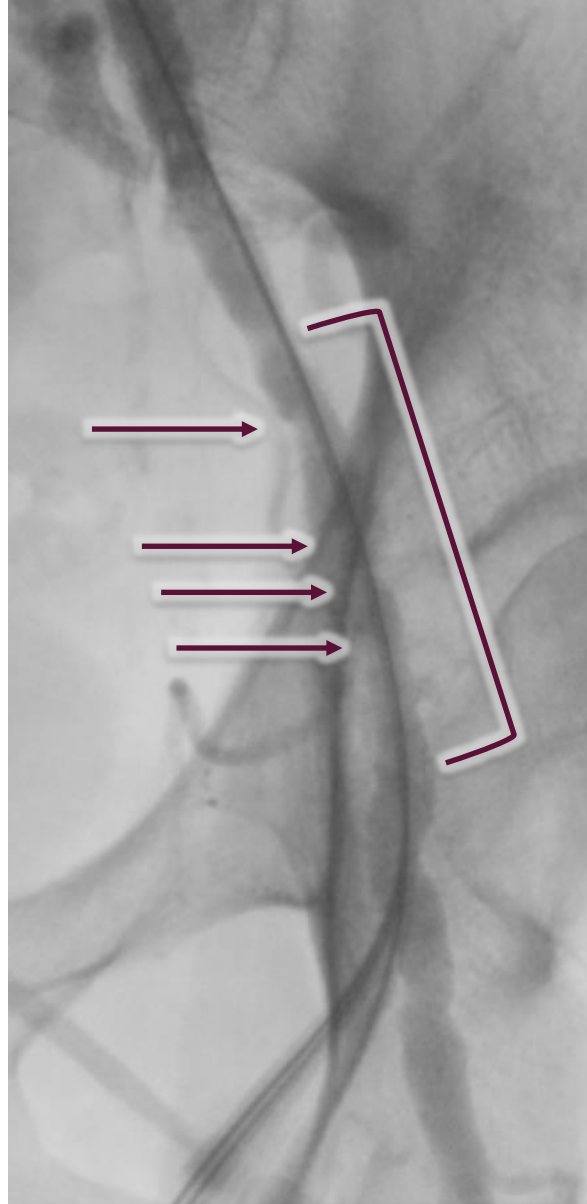
Jump Right into IVUS



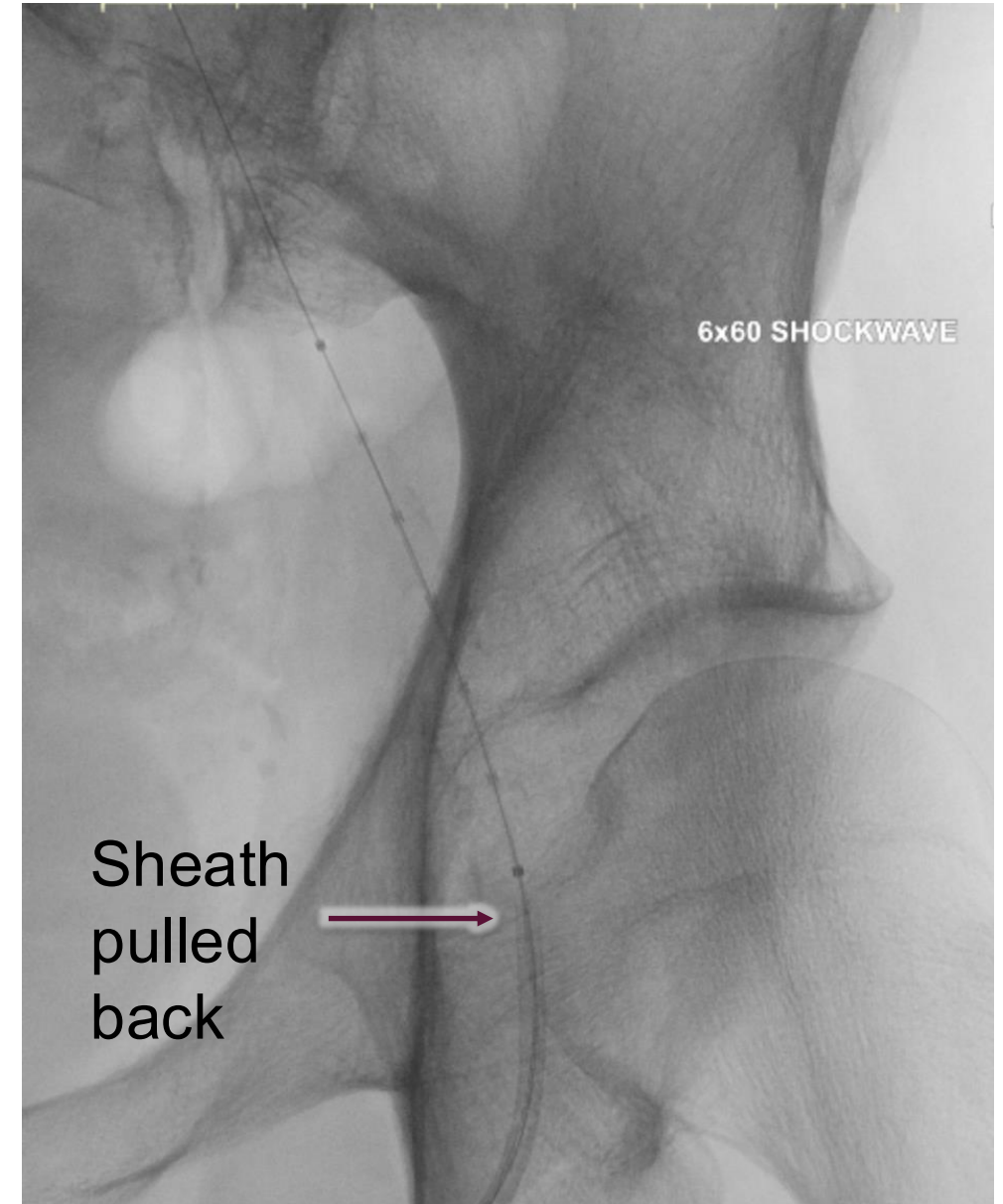
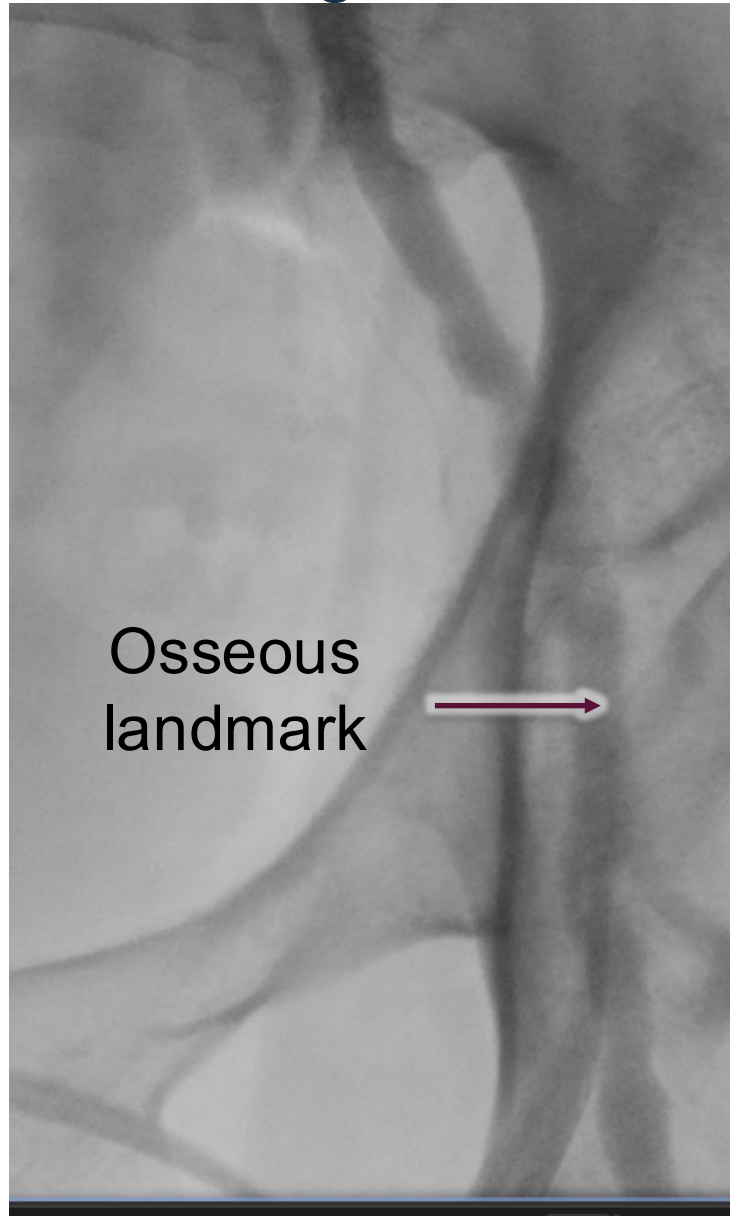
Whether I want it to be true or not...

- Iliacs normal
- Heavy disease bilateral common femoral arteries
- Shockwave vs endarterectomy
- Prior to this year, I would have sent for endarterectomy

Disease



Evaluating Level of Sheath



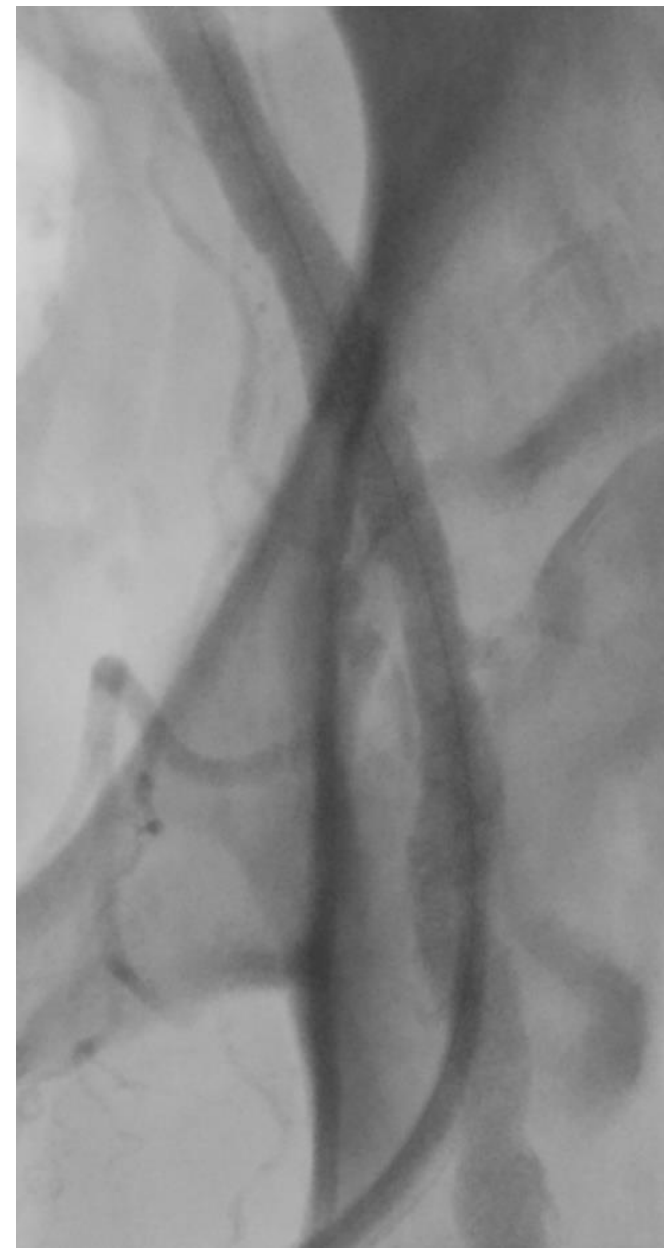
Shockwave – 360 sec



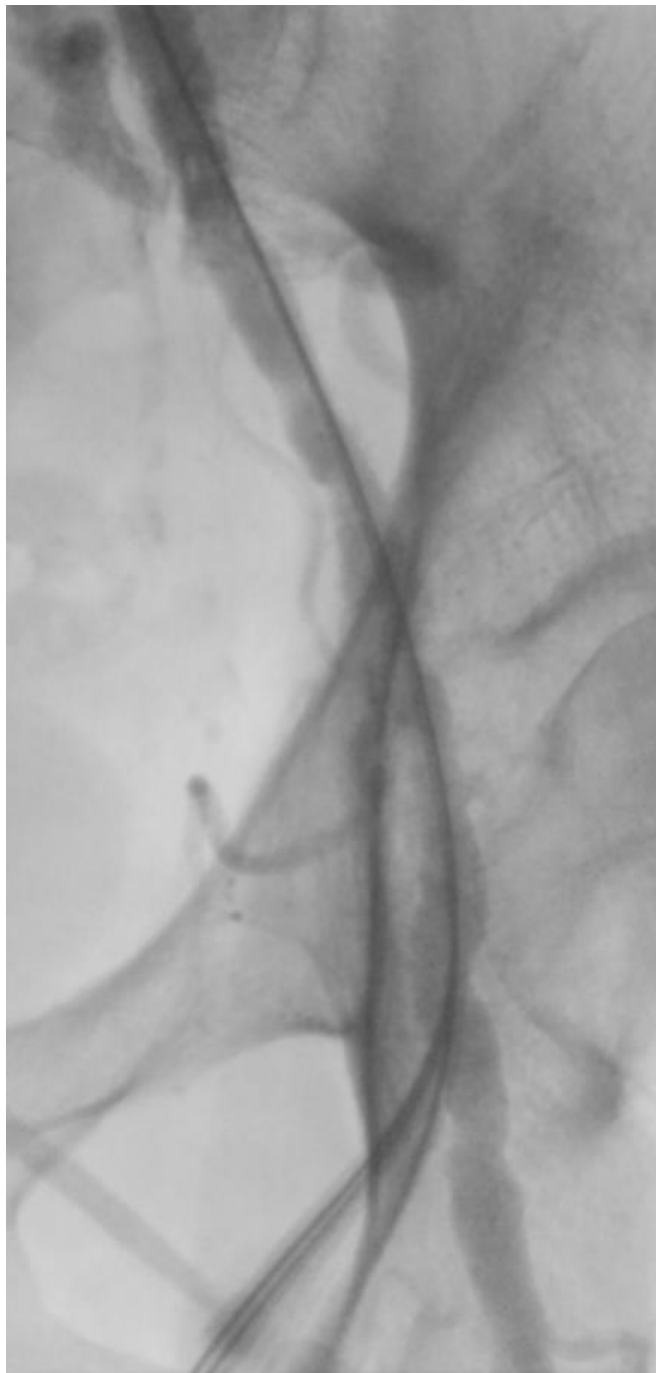
Advanced Sheath over Balloon



Final Result



Pre:



Post:



Case 2

- 75y Male, right lower leg numbness and rest pain, mild left distal toe numbness; able to walk 100 yards on level ground before having to rest but cannot go as far if there is an incline
- 65+ pack-year smoking history, quit for several years, then started smoking again due to life stressors (spouse's cancer diagnosis, relocation)
- He is moving 1 hr away in 7 days
- NEW CRF, severe COPD, 40-lb weight loss in 2 yrs, appears frail
- Left fem-pt bypass 6 yrs ago
- Rapid consult (by partner)
- Angio (by me) 4 days later

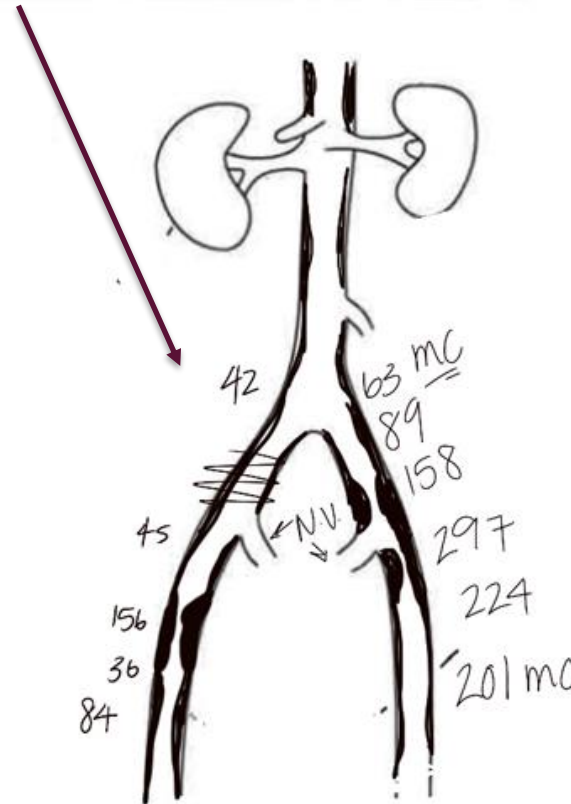
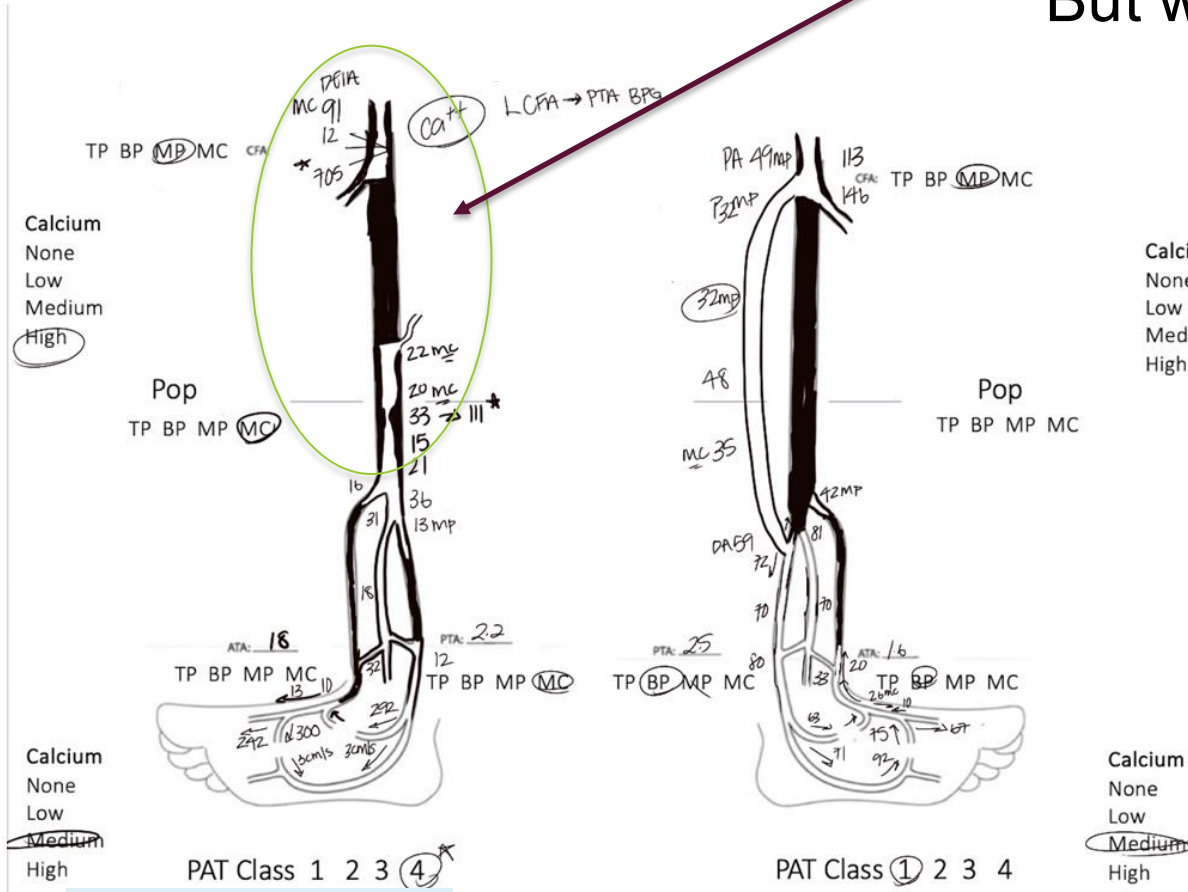
Case 2

Ultrasound – day of consult (Jill-o-gram)

This is my target...
But what about this...

GOALS

- Maintain left graft
- Figure out iliacs
- Try to get through right FA
- Avoid ESRD, rupture, death



AO
P 2.8 x 2.8 cm 48 cm/s
M 2.1 x 2.2 cm 36 cm/s
D 1.2 x 1.6 cm 39 cm/s

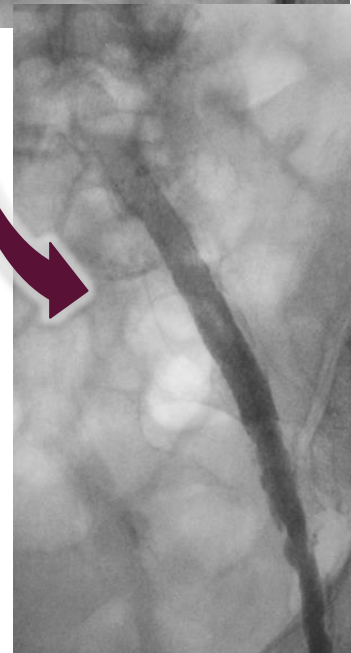
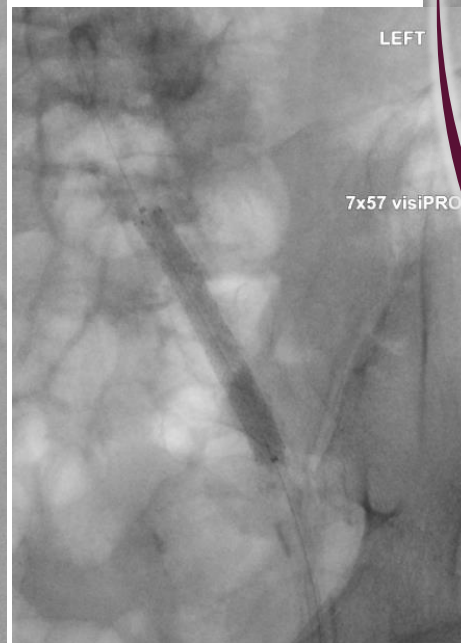
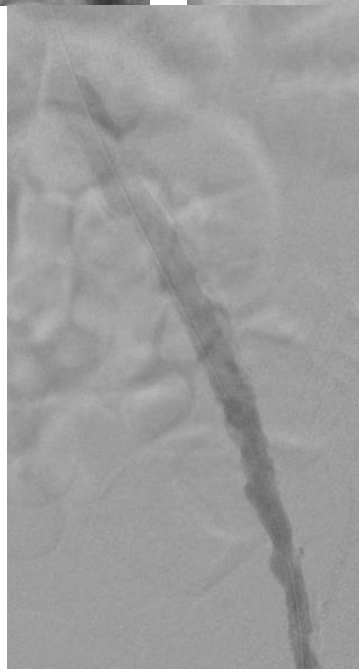
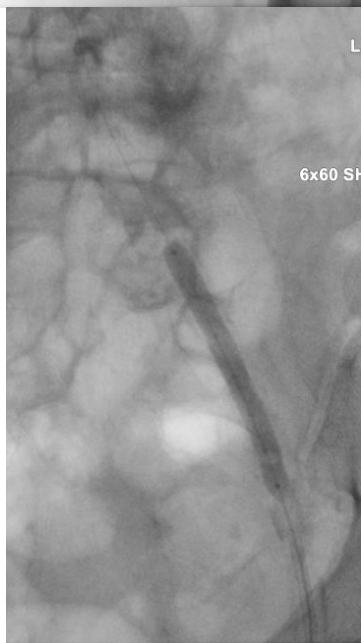
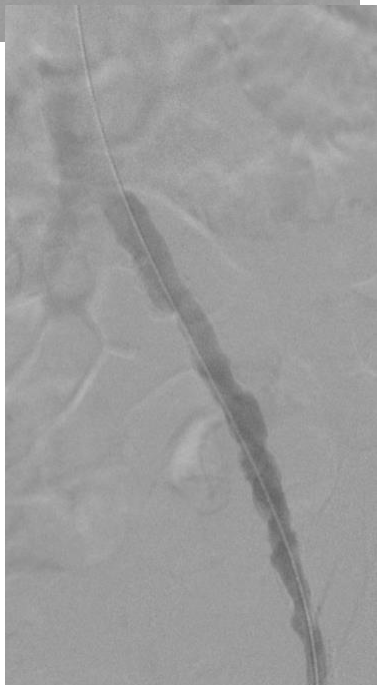
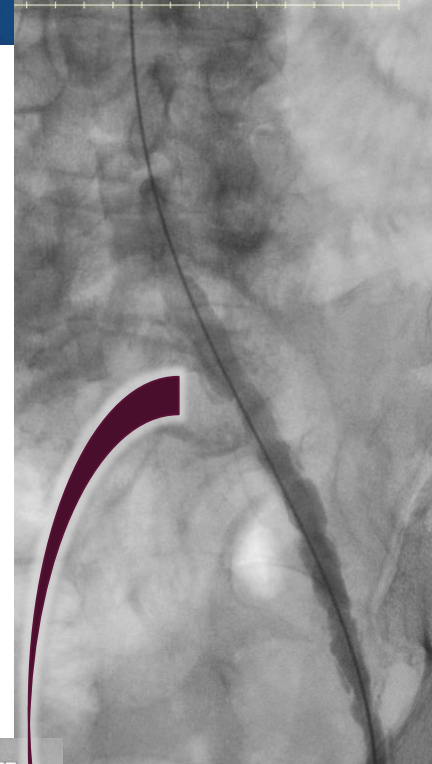
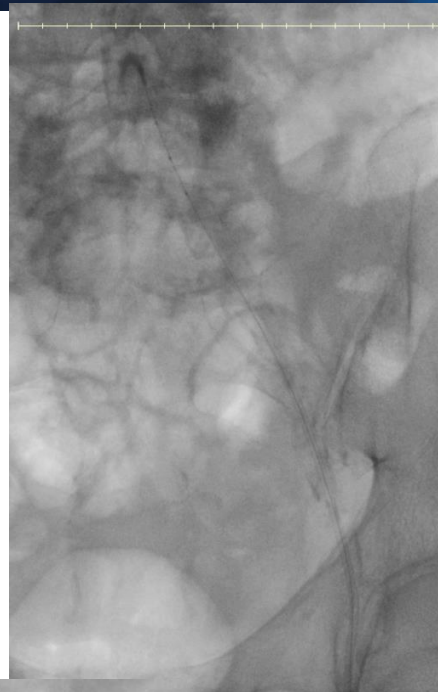
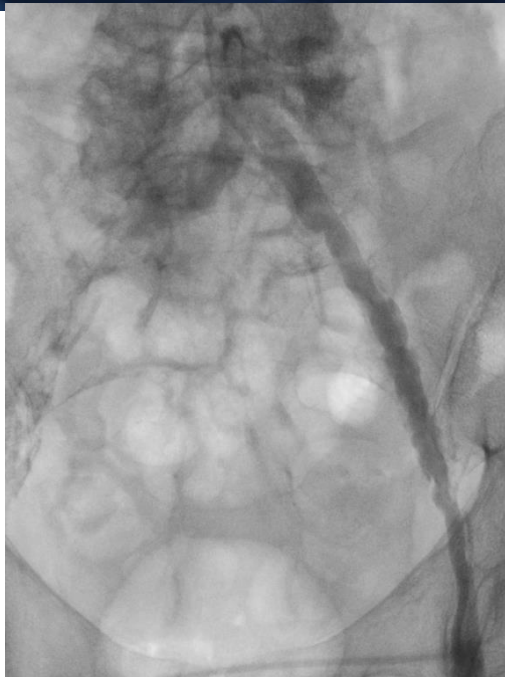
overlying
power gas
limited vis
in segments

Access issues: right CFA, right PT, right AT, left graft, radial

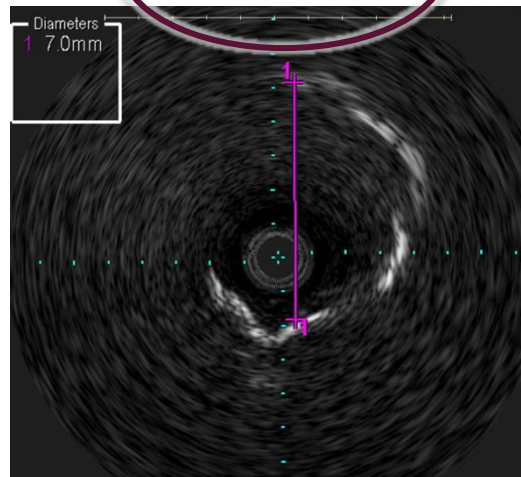
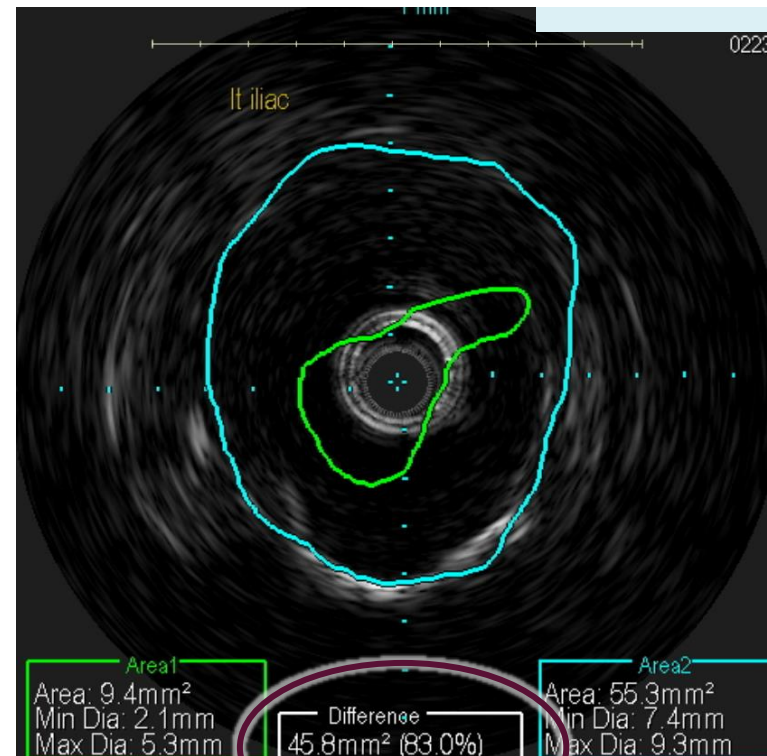
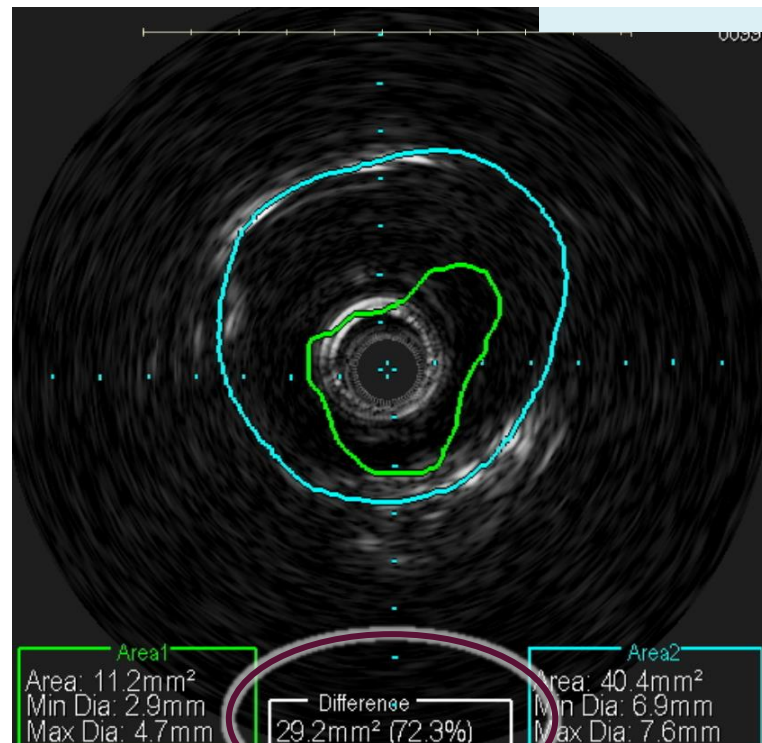
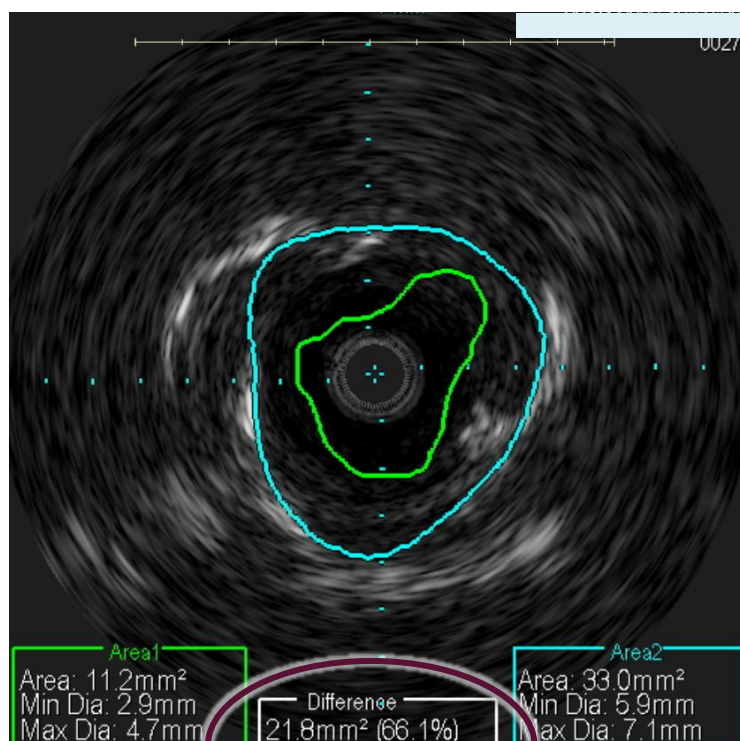
Case 2

- GFR 44
- What I did
 - Diagnostic angio, treat the iliacs, poke on the femoral
- Challenges
 - Left CFA high stick (lots of scarring)
 - Required stiff dilator
 - Placing a 7 French
 - Crossing the bifurcation
 - Accessing the right CFA
 - Stenting right iliac without sheath up and over
 - Placing a radial 7 French
- Answer to all of these issues: Shockwave

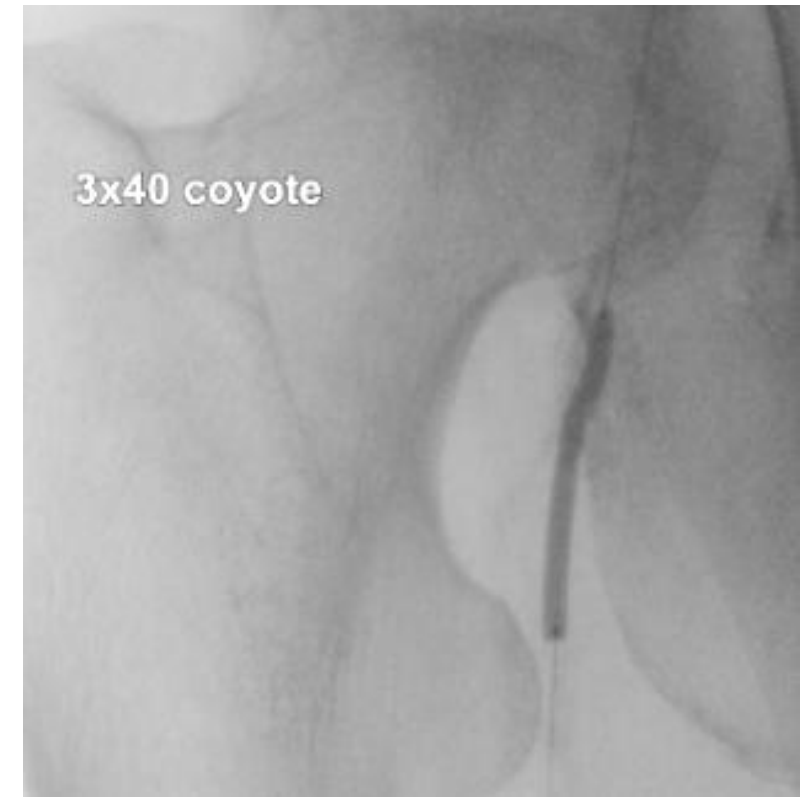
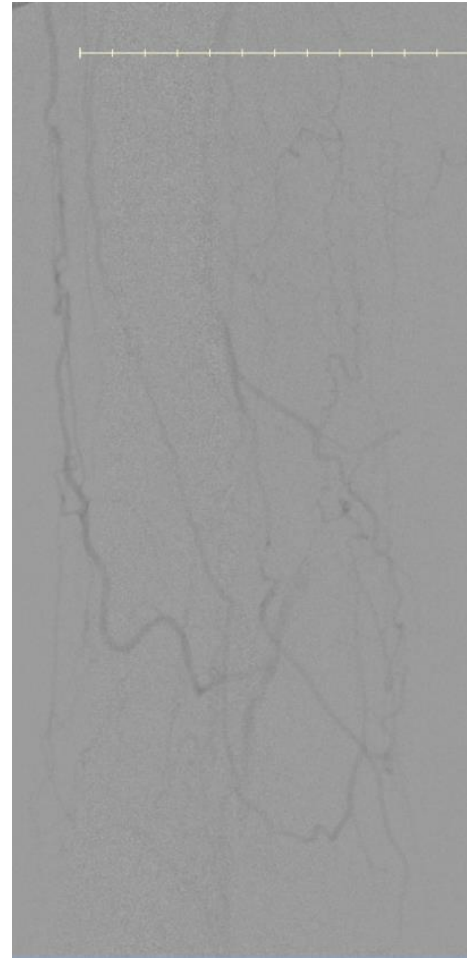
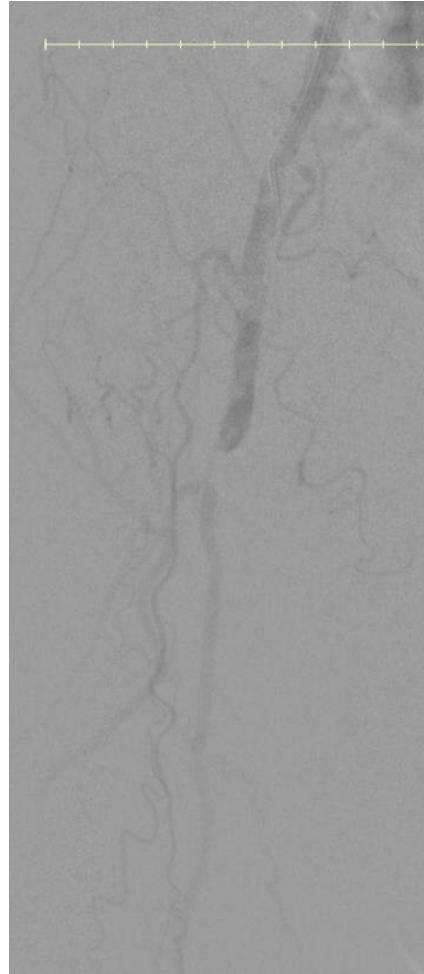
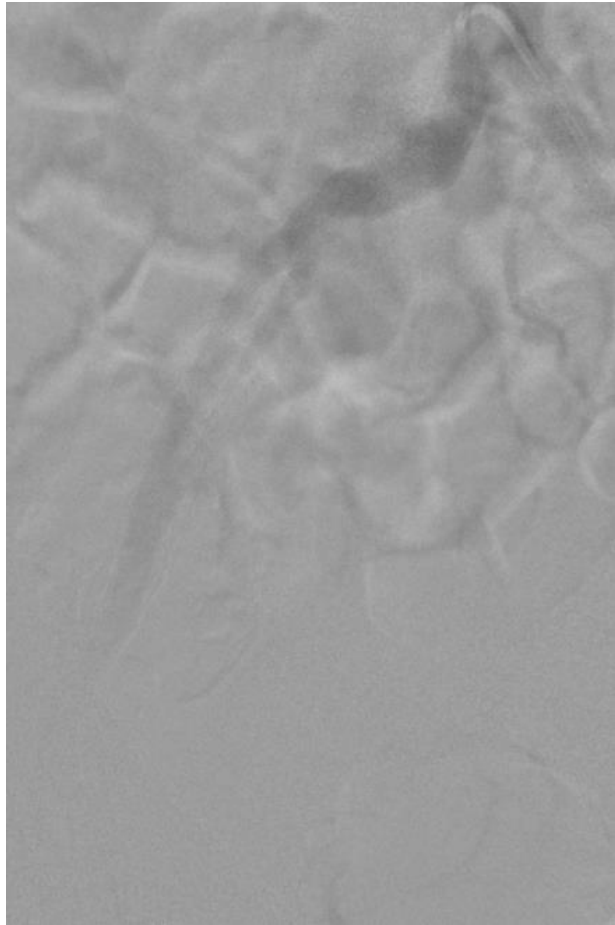


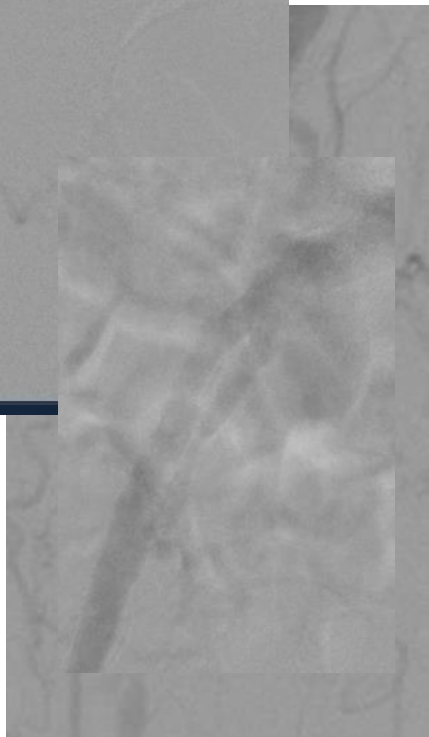
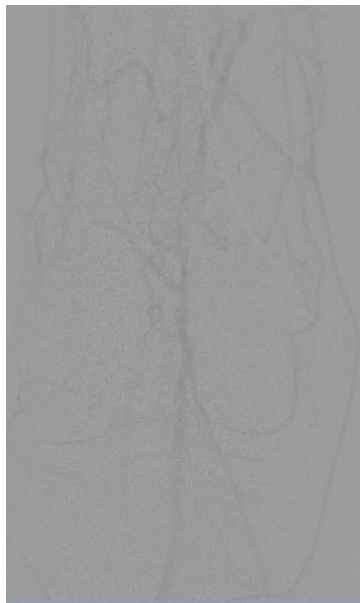
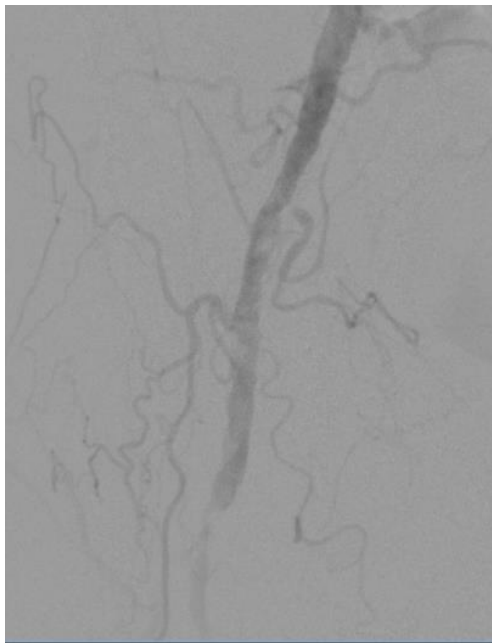
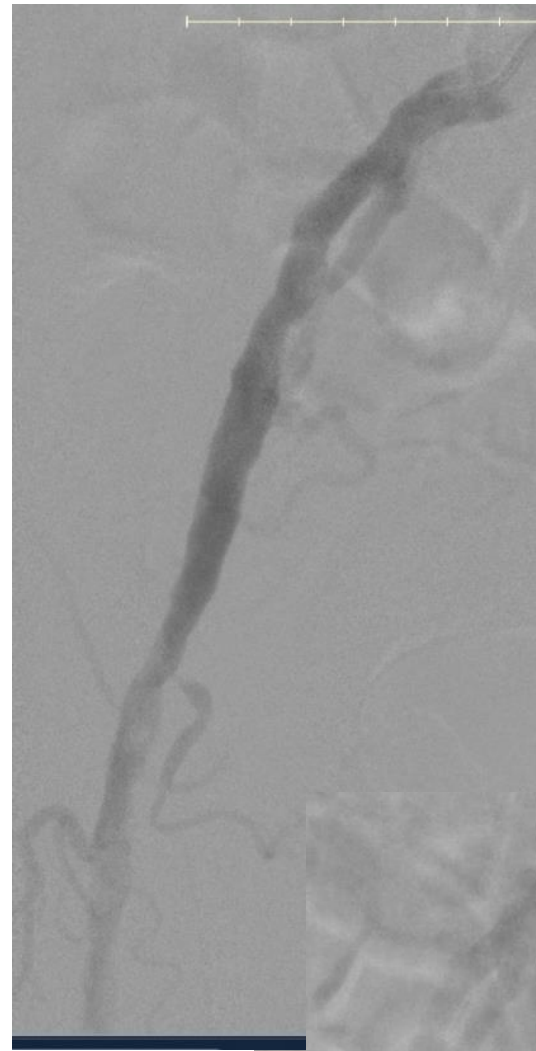


IVUS Unveiled the Real Stenosis



Diagnostic Right Iliac and Lower Extremity, Angioplasty Profunda





Case 2

- Since I was there, nice that I could do something more than angioplasty
- Shockwave coursed with ease over the bifurcation
 - Don't recommend treating any iliac without prep for bailout

Shockwave

- Opened my door for treating additional segments (common femoral artery)
- Significant advancement in calcification, no atherectomy matches this
- Hoping tibial IVL is next
- Site neutrality – we should be able to use the best product, regardless of the site of service
 - OBL SOS 11
 - ASC SOS 24
 - Hospital SOS 21 (inpatient), 22 (on-campus outpatient), 19 (off-campus hospital outpatient)



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Place of service codes

Place of Service Code Set

Place of service codes

Process for Requesting New Codes or Modification of Existing Codes

Place of Service Code Set

Place of Service Code Set

Place of Service Codes for Professional Claims

Database (updated May 2, 2024)

Listed below are place of service codes and descriptions. These codes should be used on professional claims to specify the entity where service(s) were rendered. Check with individual payers (e.g., Medicare, Medicaid, other private insurance) for reimbursement policies regarding these codes.

NOTE: Please direct questions related to billing place of service codes to your Medicare Administrative Contractor (MAC) for assistance.

Place of Service Code(s)	Place of Service Name	Place of Service Description
01	Pharmacy	A facility or location where drugs and other medically related items and services are sold, dispensed, or otherwise provided directly to patients. (Effective October 1, 2003) (Revised, effective October 1, 2005)
02	Telehealth Provided Other than in Patient's Home	The location where health services and health related services are provided or received, through telecommunication technology. Patient is not located in their home when receiving health services or health related services through telecommunication technology. (Effective January 1, 2017) (Description change effective January 1, 2022, and applicable for Medicare April 1, 2022)
03	School	A facility whose primary purpose is education. (Effective January 1, 2003)
04	Homeless Shelter	A facility or location whose primary purpose is to provide temporary housing to homeless individuals (e.g., emergency shelters, individual or family shelters). (Effective January 1, 2003)
05	Indian Health Service Free-standing Facility	A facility or location, owned and operated by the Indian Health Service, which provides diagnostic, therapeutic (surgical and non-surgical), and rehabilitation services to American Indians and Alaska Natives who do not require hospitalization. (Effective January 1, 2003)
06	Indian Health Service Provider-based Facility	A facility or location, owned and operated by the Indian Health Service, which provides diagnostic, therapeutic (surgical and non-surgical), and rehabilitation services rendered by, or under the supervision of, physicians to American Indians and Alaska Natives admitted as inpatients or outpatients. (Effective January 1, 2003)
07	Tribal 638 Free-standing Facility	A facility or location owned and operated by a federally recognized American Indian or Alaska Native tribe or tribal organization under a 638 agreement, which provides diagnostic, therapeutic (surgical and non-surgical), and rehabilitation services to tribal members who do not require hospitalization. (Effective January 1, 2003)
08	Tribal 638 Provider-based Facility	A facility or location owned and operated by a federally recognized American Indian or Alaska Native tribe or tribal organization under a 638 agreement, which provides diagnostic, therapeutic (surgical and non-surgical), and rehabilitation services to tribal members admitted as inpatients or outpatients. (Effective January 1, 2003)
09	Prison/ Correctional Facility	A prison, jail, reformatory, work farm, detention center, or any other similar facility maintained by either Federal, State or local authorities for the purpose of confinement or rehabilitation of adult or juvenile criminal offenders. (Effective July 1, 2006)

Listen here

↓

se: Shockwave

Eagerly Awaiting....

- SHOCKIFY Trial – Shockwave vs surgical endarterectomy for calcified severe common femoral artery stenosis: design and rationale of the SHOCKIFY Trial
- Endarterectomy vs IVL + DCB
- Single site
- Primary endpoint 6-month safety, freedom from death, major adverse limb events and major adverse cardiovascular events, 1-yr efficacy (primary patency)
- CFA 60%-100% stenosis with moderate to severe Ca⁺⁺2

Only downside...

SHOCK



Shoot



Building a Successful IVL Program in the OBL

Mike Watts, MD, FSIR

Interventional Radiologist

Vascular Institute of Atlantic Medical Imaging

Vineland, NJ

Why Bring IVL into the OBL?

- IVL treats the heavily calcified lesions that drive amputation risk in CLI and complex PAD
- Moving IVL into the OBL expands access for limb-threatened patients — same-day, familiar setting
- IVL is catheter-based and outpatient-appropriate — no hospital OR required
- Physician control over IVL case selection, scheduling, and catheter inventory
- Site-of-service economics can work for IVL when cases are selected and reimbursed correctly

IVL Workflow Integration

- Patient selection — calcified PAD/CLI lesions where IVL changes the outcome
- Pre-procedure — confirm calcification on duplex/CTA, size the vessel, plan IVL catheter selection
- Day of IVL — access, cross the lesion, deliver IVL, then DCB or stent as needed; IVUS to confirm result
- Fold IVL into your standard PAD pathway rather than treating it as a special case
- Recovery and follow-up — access checks, follow-up imaging, track patency

Staffing for IVL Cases

- Whole team trained on the IVL generator and catheter setup
- Roles — physician, RN/RT for sedation and monitoring, scrub tech for IVL prep, radiologic tech
- IVL-specific skills — connecting and priming the catheter, generator operation, pulse delivery
- Lean on vendor / clinical-specialist support early while the team builds proficiency
- IVL proficiency comes with repetition — protect case volume

IVL Inventory Management

- IVL catheters are high-cost and vessel-sized (diameter × length) — stock the sizes matching your case mix
- The IVL generator is a capital item — one per lab, kept charged and maintained
- Par levels with lot and expiration tracking on every catheter
- Don't over-stock — match IVL inventory to scheduled, pre-authorized cases

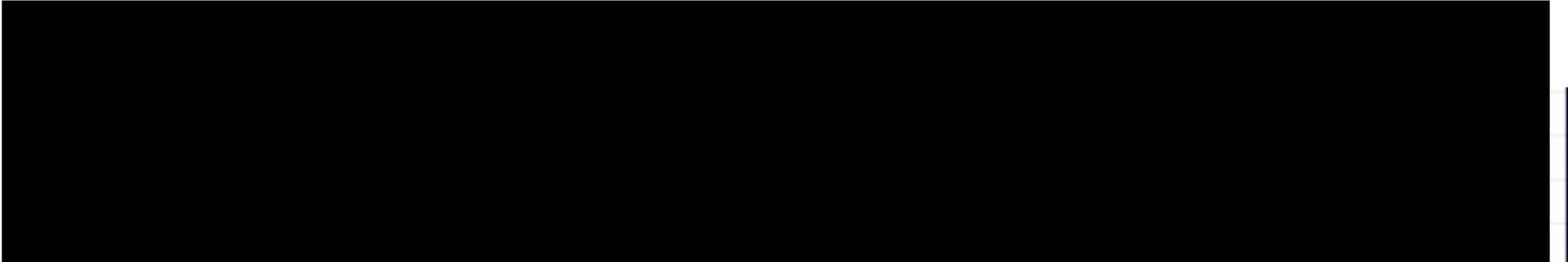
IVL Coding and Reimbursement

IVL Reimbursement Framework

- The IVL catheter is a significant cost — reimbursement must cover the device for the program to be viable
- Know the codes — the PAD intervention plus how the IVL catheter/supply is captured in the OBL setting
- Site-of-service — OBL non-facility rate; model your margin per IVL catheter before you schedule
- Pre-authorization is where IVL gets denied — often mislabeled “investigational” for peripheral use
- Track every IVL case — authorized, denied, appealed, paid
- Assume balloon cost exceeds \$3K

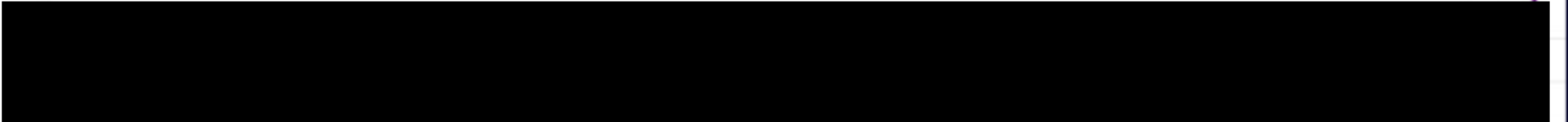
My Reimbursement Experience: Commercial

930633101



(37279) IV LITHOTRP FPVT W/IN SM ART	1	\$10,725
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900375013



(37279) IV LITHOTRP FPVT W/IN SM ART	1	\$10,725
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My Reimbursement Experience: Commercial

MRN	Procedure	Count of Charge	Count	Sum of Payments
930636914				
	(37279) IV LITHOTRP FPVT W/IN SM ART	1		\$0
930161136				
	(37279) IV LITHOTRP FPVT W/IN SM ART	1		\$4,858
22298073				
	(37262) IV LITHOTRP IVT W/IN SM ART	1		\$3,572
	(37279) IV LITHOTRP FPVT W/IN SM ART	1		\$9,716

My Reimbursement Experience: Medicare Advantage

930148022			
	(37262) IV LITHOTRIP IVT W/IN SM ART	1	\$0
930054520	(37279) IV LITHOTRIP FPVT W/IN SM ART	1	\$0
	(37262) IV LITHOTRIP IVT W/IN SM ART	1	\$0
930103273			
	(37279) IV LITHOTRIP FPVT W/IN SM ART	1	\$9,810
930103273	(37262) IV LITHOTRIP IVT W/IN SM ART	1	\$0

My Reimbursement Experience: Medicare

930593971

(37262) IV LITHOTRIP IVT W/IN SM ART 1 \$5,873

(37279) IV LITHOTRIP FPVT W/IN SM ART 1 \$3,993

920580658

(37262) IV LITHOTRIP IVT W/IN SM ART 1 \$2,929

(37279) IV LITHOTRIP FPVT W/IN SM ART 1 \$3,983

930635970

(37262) IV LITHOTRIP IVT W/IN SM ART 1 \$0

(37279) IV LITHOTRIP FPVT W/IN SM ART 1 \$0

920580658

(37279) IV LITHOTRIP FPVT W/IN SM ART 1 \$3,993

What the Data Taught Us

- Traditional Medicare — most predictable for IVL in appropriate CLI/PAD cases; Iliac might break even
- Medicare Advantage — frequent IVL pre-auth friction; peer-to-peer often required, still may not get paid
- Commercial payers — highest variability; some still call peripheral IVL “investigational” despite the evidence
- Persistence pays — an evidence-based appeal overturns a meaningful share of IVL denials
- Document calcification and medical necessity — your strongest defense at every payer

Overturning Denials: Our Appeal Letter

- When IVL is denied at pre-authorization, we respond with a standardized, evidence-based appeal letter
- It cites the clinical evidence, guideline support, and the patient-specific medical necessity for IVL
- Purpose — convert denials to approvals and build a paper trail for peer-to-peer review
- A fill-in-the-blank template — customized per patient and ready to send fast

What Our Appeal Letter Argues

- Medical Background — the PAD diagnosis, lesion location, failed conservative and prior therapy, and the limb-threat and quality-of-life impact; diagnostics confirming heavy calcification that limits plain balloon angioplasty
- Clinical Rationale for IVL — published evidence supports IVL for calcified PAD; it modifies calcium while preserving vessel architecture for DCB or stent, where plain angioplasty risks poor expansion, dissection, and stent under-expansion or fracture (Laird, RESILIENT trial, 2010)
- Consequences of Denial — without IVL: incomplete revascularization, persistent ischemia, reintervention, escalation to more invasive care, added hospitalization, and higher total cost of care
- Requested Action — reconsider and reverse the denial, approve IVL coverage, offer supporting documentation, and specify the exact CPT/HCPCS codes and modifiers being appealed

IVL Documentation Best Practices

- Document calcification — the single most important justification for IVL (imaging, IVUS, angiographic calcium)
- Medical necessity — symptoms, ABI/toe pressures, failed conservative therapy, Rutherford class
- Lesion detail — calcification severity, length, and vessel tied directly to why IVL was chosen
- Operative note — IVL catheter size(s), pulses delivered, and post-IVL result
- Link every billed IVL code to its supporting documentation; keep denial and appeal records

Keys to Long-Term Success

- Select the right IVL candidates — calcified lesions where IVL changes the outcome
- Build a repeatable IVL workflow and train the whole team
- Own IVL pre-authorization and appeal denials aggressively with evidence
- Track IVL volume, approval rate, and margin per catheter
- Partner with billing/coding on IVL codes and revisit them annually
- Let strong outcomes build your referral base

Key Takeaways

- IVL brings calcium modification for limb-threatened patients into the OBL
- Reimbursement is make-or-break — cover the catheter and master IVL pre-auth
- Use your payer data and a standardized appeal letter to win IVL denials
- Documentation — especially calcification — protects every IVL claim
- Build for repeatability and long-term IVL program sustainability

Thank You
