



CardioVascular  
Learning Network

CME

**FROM INNOVATION  
TO IMPACT**

Improving the Speed,  
Safety, and Efficacy  
of Arterial Thrombus  
Removal

# Faculty

## **Daniel K. Han, MD**

Professor of Surgery

Chief of Vascular Surgery at Mount Sinai  
Morningside

Associate Program Director of Vascular  
Surgery Residency and Fellowship  
New York City, New York

## **Nicolas J. Mouawad, MD, MPH, MBA, DFSVS, FRCS, FACS, RPVI**

Chief, Vascular and Endovascular Surgery  
Chair, Department of Surgery  
McLaren Health  
Bay City, Michigan

## **Leigh Ann O'Banion, MD**

Associate Professor of Surgery  
University of California, San Francisco-Fresno  
Fresno, California

## **Alex Powell, MD**

Medical Director-Interventional Radiology  
Miami Cardiac and Vascular Institute  
Miami, Florida

## **Bhaskar Purushottam, MD, FACC, FSCAI, FSVMB**

President, Midwest Heart and Vascular  
Associates  
Interventional Cardiologist and Endovascular  
Medicine  
Monument Health Rapid City Hospital, Rapid  
City, South Dakota  
Medical Director, Monument Health Research

# Faculty Disclosures

- **Daniel K. Han, MD:** Consultant—Penumbra Inc.
- **Nicolas J Mouawad, MD, MPH, MBA, DFSVS, FRCS, FACS, RPVI:** Consultant—Boston Scientific, Inari Medical, Medtronic, Shockwave Medical; Speakers Bureau—WL Gore; proctor—Terumo Aortic
- **Leigh Ann O'Banion, MD:** Consultant—Abbott, Medtronic, Penumbra Inc., Shockwave; research funding—Abbott, Gore, Medtronic, Shockwave; data and safety monitoring board—Reflow Medical
- **Alex Powell, MD:** Speakers Bureau—Penumbra Inc.
- **Bhaskar Purushottam, M.D., FACC, FSCAI, FSVMB,** has disclosed no relevant financial relationship with any ineligible company (commercial interest)

# Program Information

- Provided by HMP Education, LLC, an HMP Global Company
- Supported by an educational grant from Penumbra Inc.

# Learning Objectives

- Understand endovascular tools today are safer and easier to use than previously
- Explain the evolution of these tools and what is now available, including the challenges of older-generation technology
- Analyze data suggesting endovascular thrombus removal may provide clinical benefit versus open surgical techniques
- Evaluate a variety of applications with computer-assisted vacuum thrombectomy (CAVT) technology



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# Arterial Thrombus Removal

**Daniel K. Han, MD**

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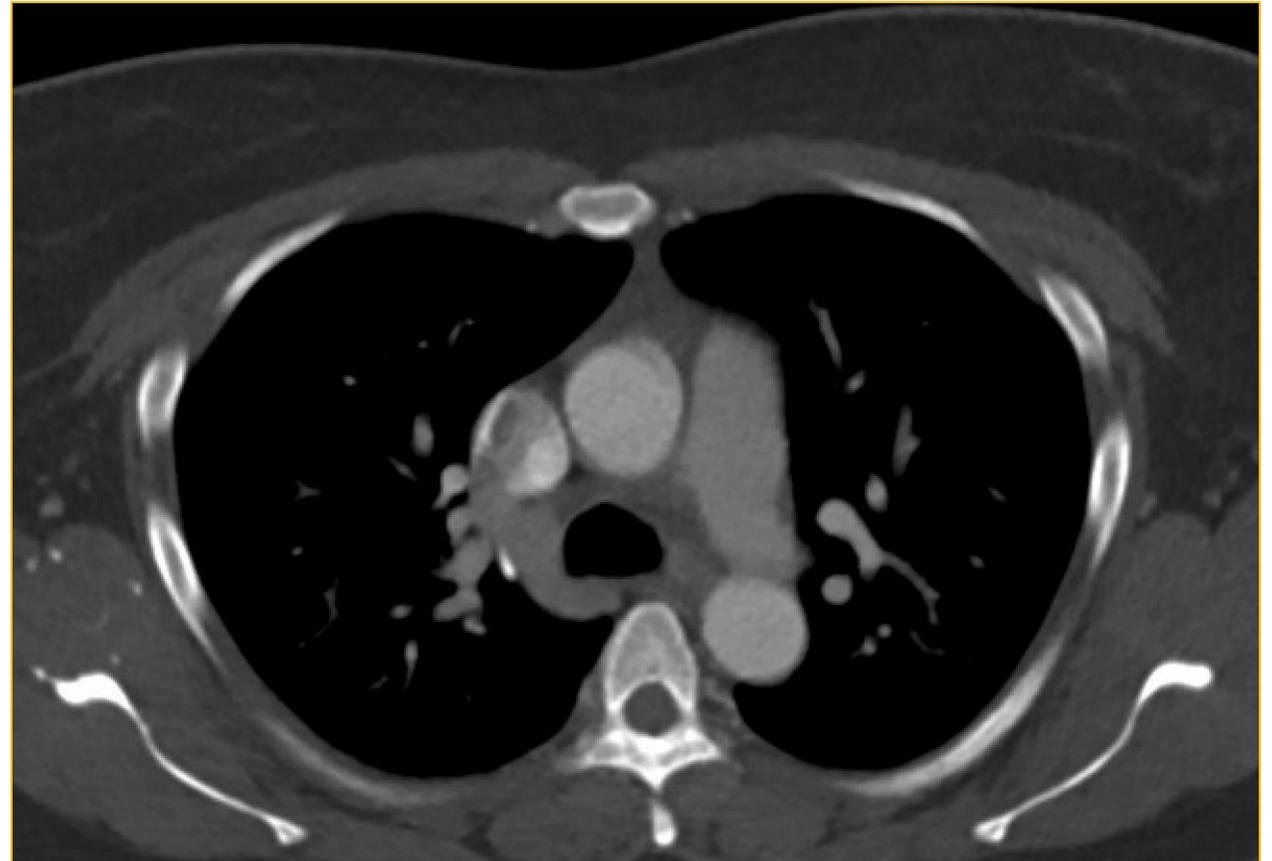
Associate Program Director of Vascular  
Surgery Residency and Fellowship

New York City, New York

# Patient Presentation

45 year old female originally seen in 2022, for L CFA embolic occlusion s/p emergent femoral cutdown and Fogarty embolectomy.

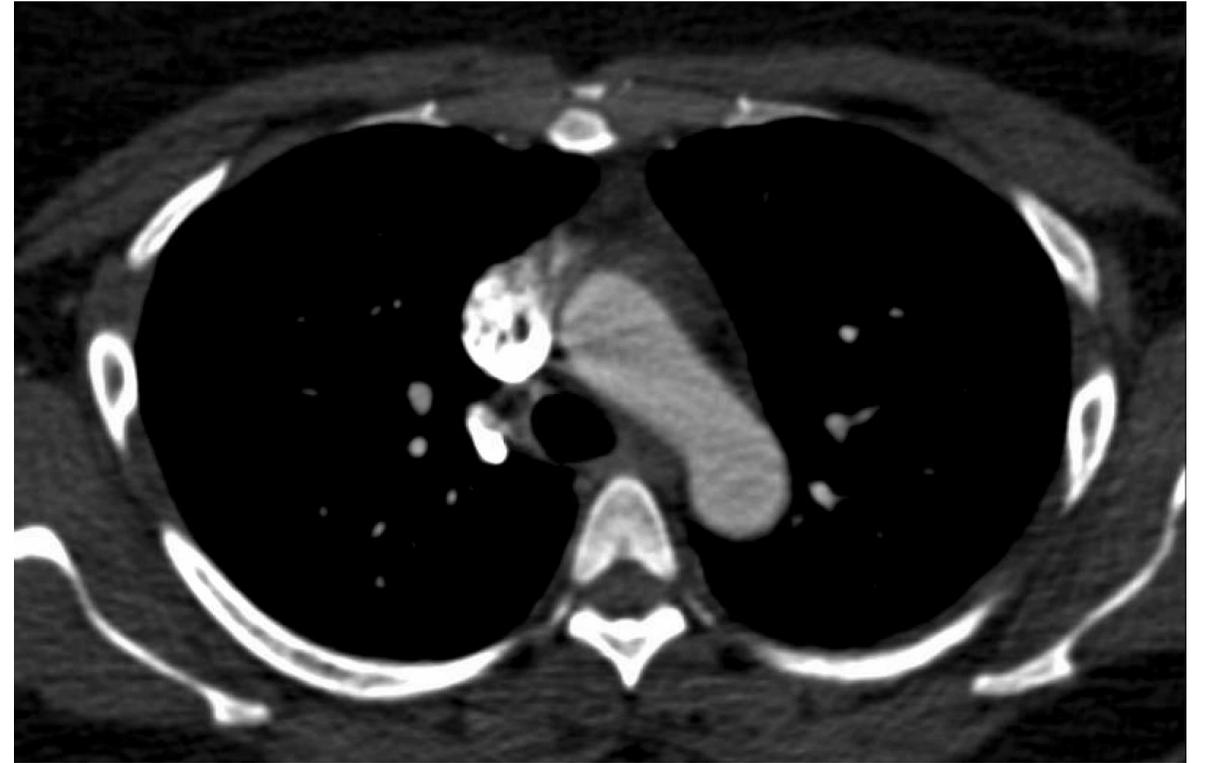
- Embolic source: intraluminal aortic thrombus
- Discharged on Eliquis



# Imaging—CTA



Initial



Follow Up at 6 Months

# Patient Presentation

About 1.5 years after CFA cutdown and embolectomy

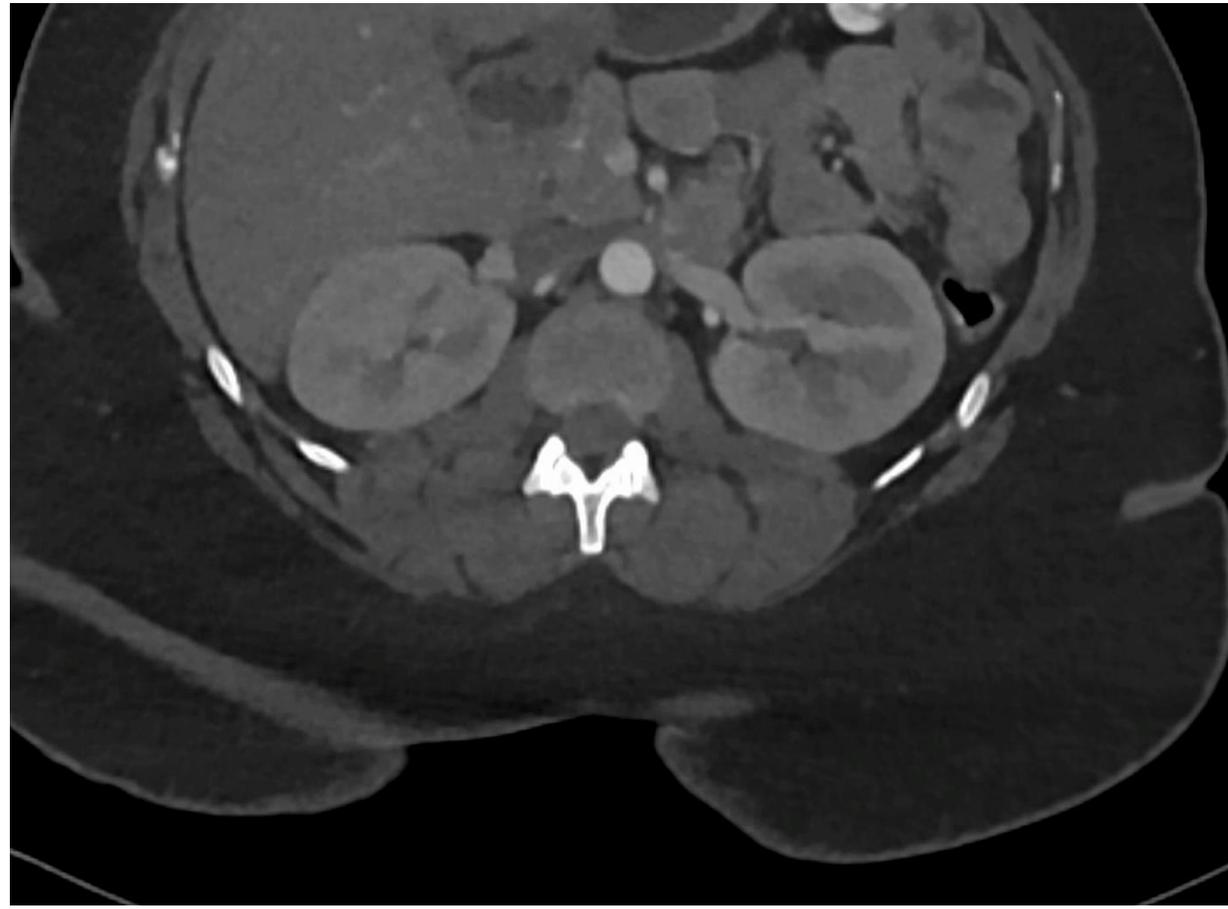
Re-presenting with **1-day** L foot pain, coolness, and numbness.

Has been off Eliquis for 1 month due to insurance issues.

## Vascular:

- No mottling or wounds
- Slower capillary refill of left foot
- Bilateral palpable femoral pulses & dopplerable biphasic popliteal signals
- Right Dorsalis pedis / Posterior tibial artery signals
- **No L pedal signals + Numbness of L foot.** No motor deficits

# Imaging—CTA



# Summary

45F with ALI (Rutherford 2A) likely embolic from known aortic thrombus

## Challenges

- Multi-level occlusions: distal SFA, popliteal artery, and tibial segments
- Growing aortic thrombus

## Treatment options

- **Open repair**
  - Fem cutdown and Fogarty thrombectomy +/- popliteal cutdown
  - Fem to tibial bypass
- **Endovascular repair**
  - CDT (Rutherford 2A)
  - Single-stage endovascular thrombectomy
    - Pharmacomechanical thrombectomy, CAVT

# STILE Trial

(Surgical vs CDT)

- Study design: RCT | N=393 | ALI  $\leq$  14 days
  - Compared CDT vs surgery
- Key findings
  - 33% crossover from CDT to surgery
  - Higher bleeding complications with CDT
  - No difference in efficacy or safety between rt-PA and UK
  - Surgical arm showed better
    - Amputation-free survival at 1 year
    - Freedom from recurrent ischemia

Treatment Arm	Major Hemorrhage	Intracranial Hemorrhage
Catheter-Directed Thrombolysis (CDT)	<b>12.5%</b> (32/256)*	<b>1.6%</b> (4/256)*
Surgical Revascularization	5.5% (14/256)*	0%

# TOPAS Trial

*(Surgical vs CDT)*

- Study design: RCT | N=544
- UK trial: CD urokinase vs open surgery

Treatment	6-Month Amputation-Free Survival <i>P=NS</i>	1-Year Amputation-Free Survival <i>P=NS</i>	Major Hemorrhagic Complications <i>P=.005</i>
CDT	71.8%	65%	12.5%
Surgery	74.8%	69.9%	5.5%

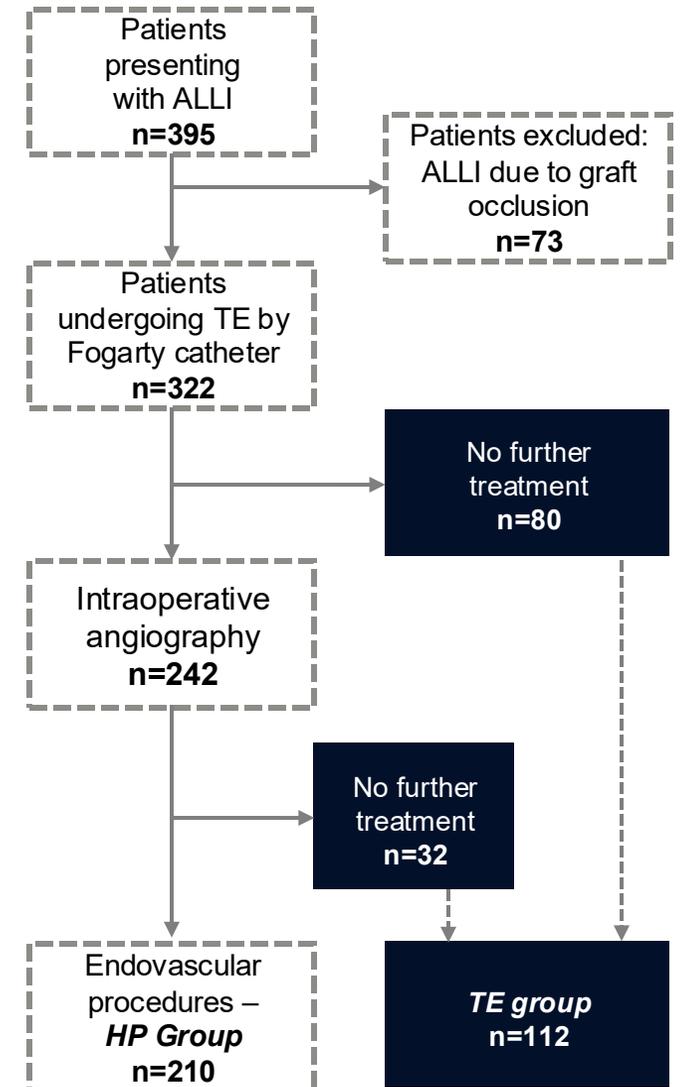
# Fogarty Embolectomy vs Hybrid

(Surgical + endovascular)

From the Society for Vascular Surgery

The combination of surgical embolectomy and endovascular techniques may improve outcomes of patients with acute lower limb ischemia

Gianmarco de Donato, MD, Francesco Setacci, MD, Pasqualino Sirignano, MD, Giuseppe Galzerano, MD, Rosaria Massaroni, MD, and Carlo Setacci, MD, *Siena, Italy*



# Results: Fogarty Embolectomy vs Hybrid

*(Surgical + endovascular)*

- **Estimated primary patency better for Hybrid Group**
  - 2 years: **70.4%** vs **90.4%** ( $P < 0.01$ )
  - 5 years: **66.3%** vs **87.1%** ( $P < 0.01$ )
- **Estimated freedom from reintervention**
  - 1 year: **82.1%** vs **94.4%** ( $P = 0.04$ )
  - 5 years: **73.7%** vs **89%** ( $P = 0.04$ )

# Summary

45F with ALI (Rutherford 2A) likely embolic from known aortic thrombus

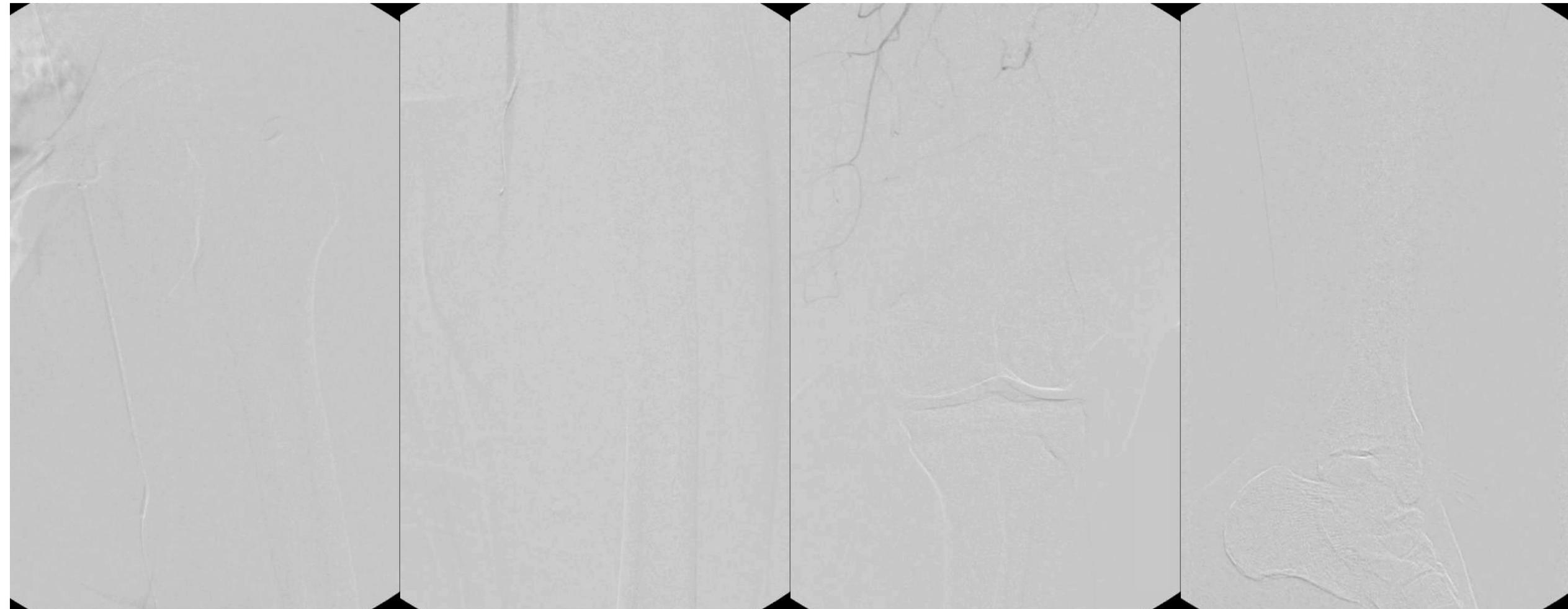
## Challenges

- Multi-level occlusions: distal SFA, popliteal artery, and tibial segments
- Growing aortic thrombus

## Treatment options

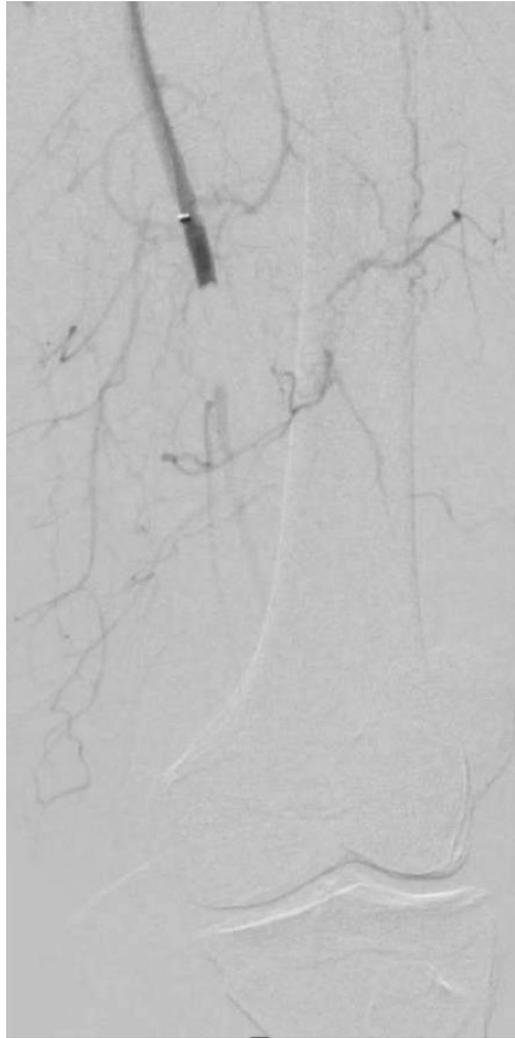
- **Open repair**
  - Popliteal cutdown and Fogarty thrombectomy
  - Fem to tibial bypass
- **Endovascular repair**
  - CDT (Rutherford 2A)
  - **Single-stage endovascular thrombectomy—CAVT**

# Diagnostic LLE Angiogram

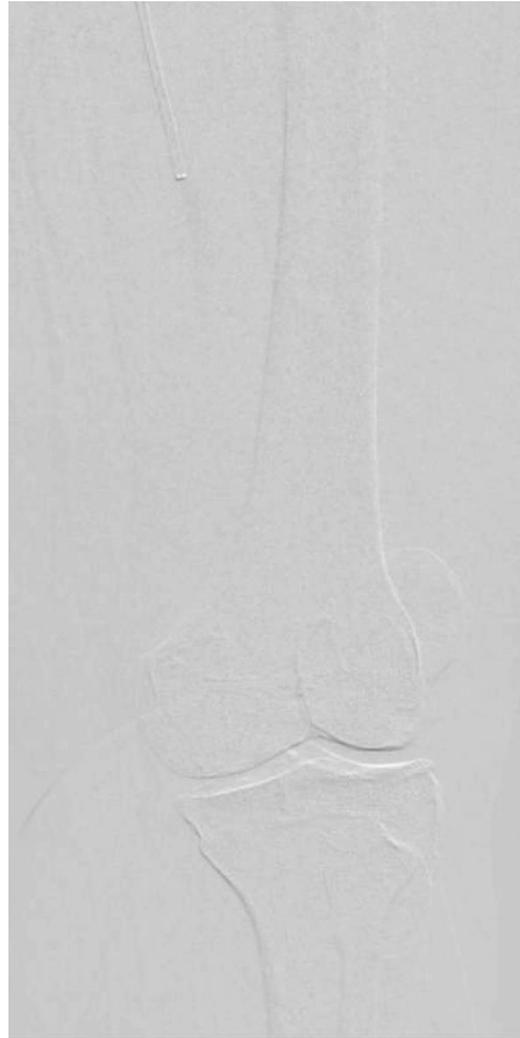


LLE = left lower extremity.

# SFA/Popliteal Thrombectomy

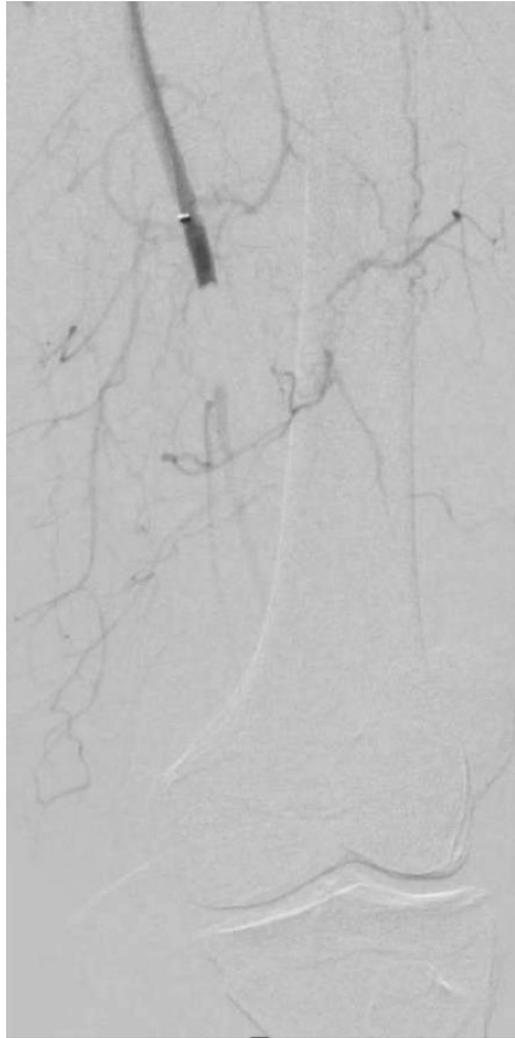


Initial



Post-computer-aided  
mechanical thrombectomy

# SFA/Popliteal Thrombectomy



Initial



Post-computer-aided  
mechanical thrombectomy



# SFA/Popliteal Thrombectomy



Initial

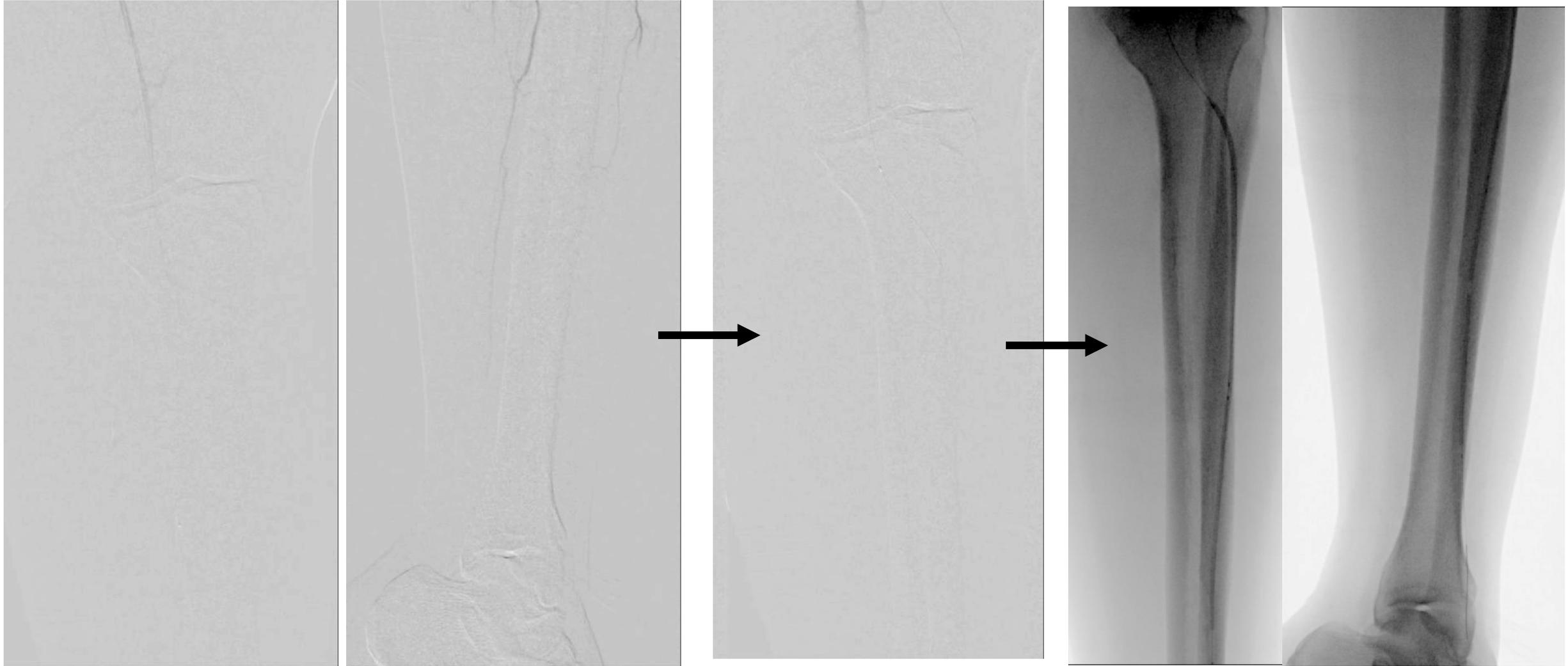


Post-computer-aided  
mechanical thrombectomy



Nitroglycerin

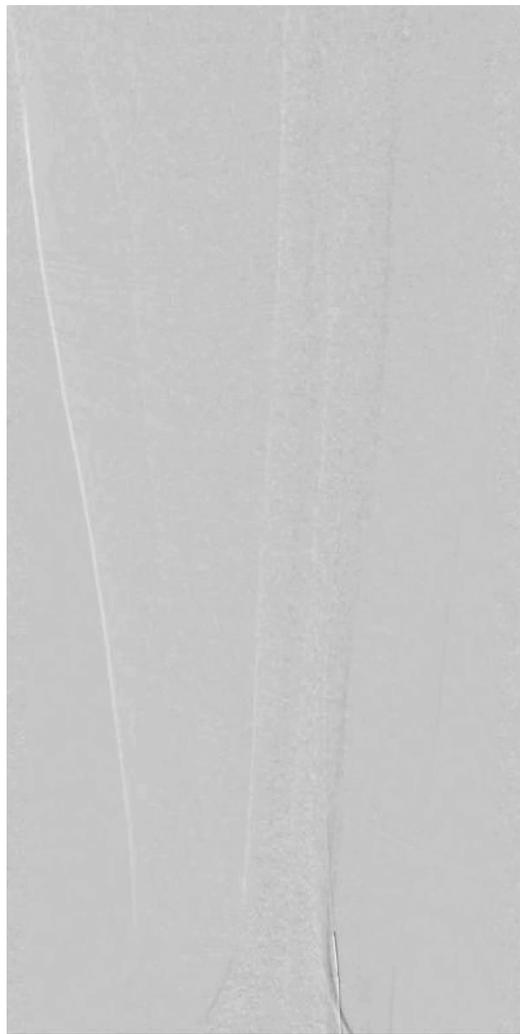
# Tibial Thrombectomy



Post-coronary mechanical  
thrombectomy system

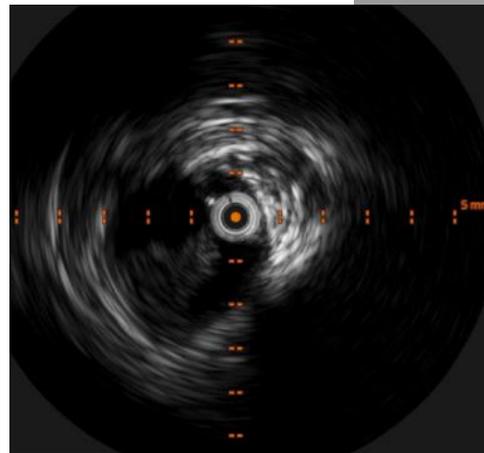
2.5-2.0 x 200mm tapered balloon

# Completion



# Post-Operative Course

- Palpable DP
- L foot pain resolved, and numbness resolved
- Maintained on heparin gtt
- Hematology with continued hypercoagulable workup
- Staged TEVAR during hospital stay
- Discharge home on POD3 on apixaban
- 2-week post-operative duplex with in-line flow from CFA to AT w/o stenoses + no L foot symptoms



TEVAR = thoracic endovascular aortic repair; POD = post-operative day; CFA = common femoral artery; AT = anterior tibial.

# Conclusion

## Expanded options for endovascular arterial thrombectomy

- **Lightning Bolt 7:** CAVT + TORQ steerable tip + Bolt mode (modulated aspiration) facilitates SFA/popliteal thrombus removal
- **Lightning Bolt 6X with TraX:** Integrated dilator allows atraumatic transition into tibial vessels and allows for larger bore aspiration thrombectomy in smaller vessels
- **CAT RX:** For distal tibial access with focal thrombus, able to maintain wire access



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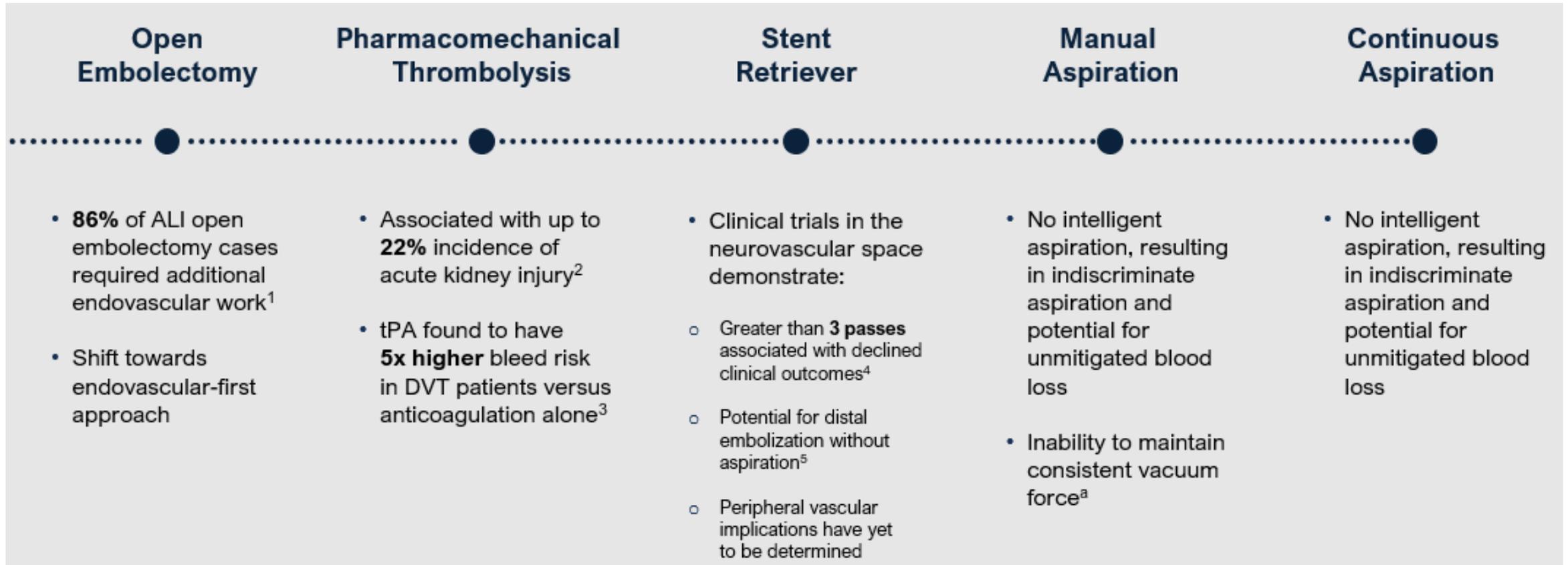
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# Evolution of Endovascular Thrombectomy

**Alex Powell, MD**

Medical Director-Interventional Radiology  
Miami Cardiac and Vascular Institute  
Miami, Florida

# Evolution of Endovascular Thrombectomy



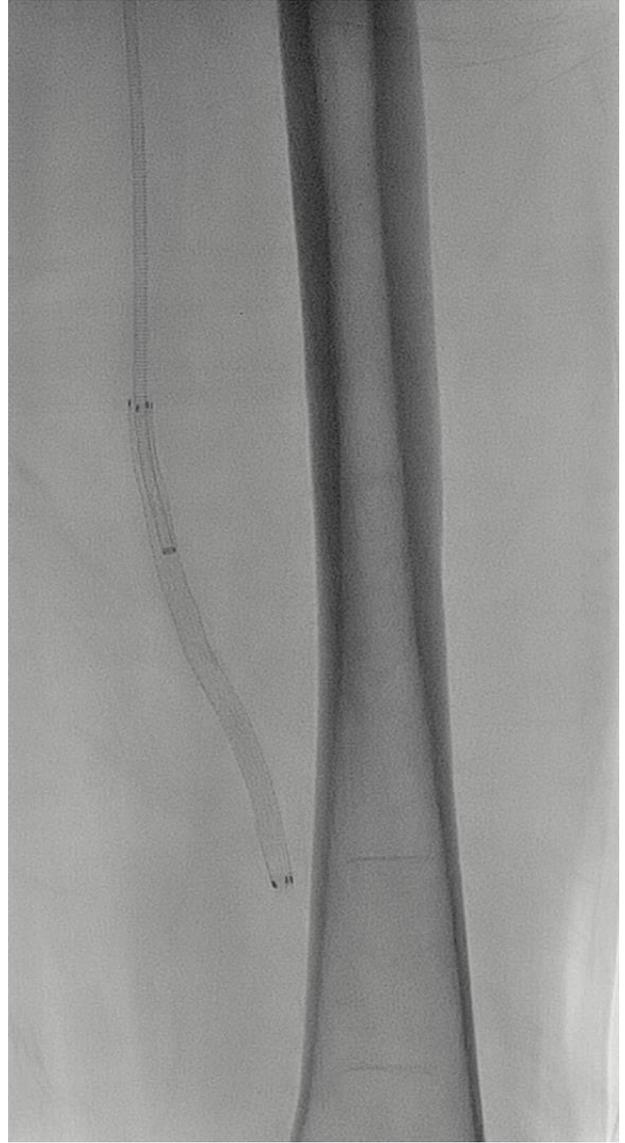
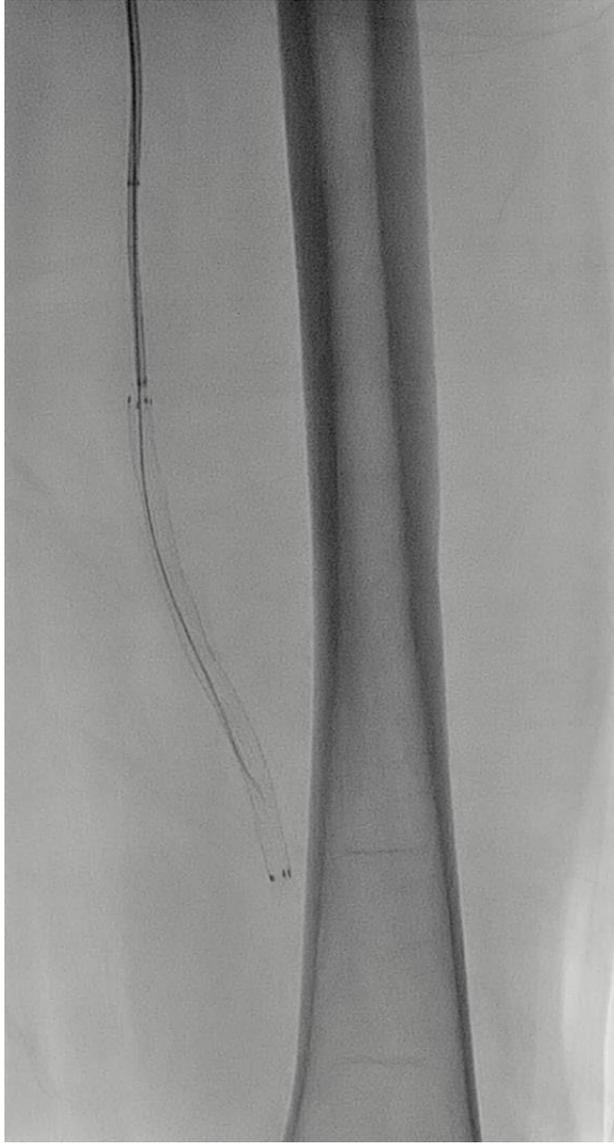
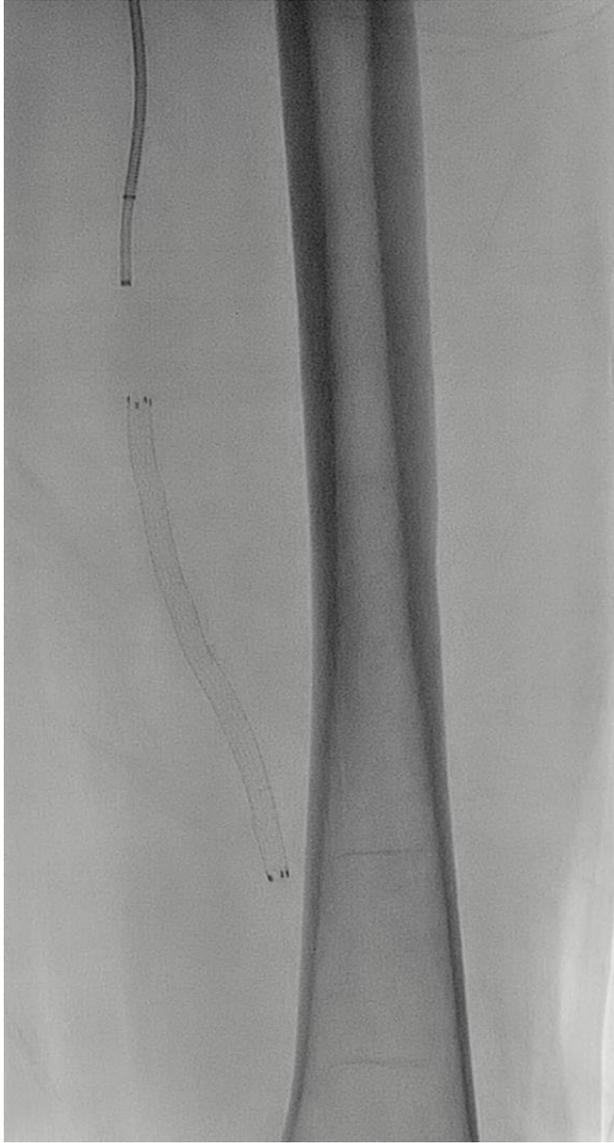
tPA = tissue plasminogen activator.

# 2018 Case



CAT 6







# Computer-Aided Vacuum Thrombectomy (CAVT)

- Advantages
  - Decreased blood loss
  - Faster/more efficient clot removal

# Innovation of CAVT

## Lightning® 7 & 12

### 1<sup>st</sup> Generation CAVT

Single pressure differential-based algorithm designed to mitigate blood loss



## Lightning Flash® 1.0

**Dual clot detection algorithms:** for quicker clot detection and patent flow detection<sup>a</sup>

**Flash mode,** extraction mode, and sampling mode.

## Lightning Flash 2.0 with Select +™

**Enhanced algorithmic sensitivity and optimized valve cadence with “Gallop mode” (expedited venous thromboembolism clot removal)**



## Lightning Bolt®

Modulated aspiration designed to rapidly ingest clot at the tip of the catheter

**Lightning Bolt 7 and Lightning Bolt 6X with TraX™:** Modulated aspiration with dilator for below-the-knee (BTK) navigation

**Lightning Bolt 12:** Bolt 2.0 software engineered for improved clot removal efficiency



<sup>a</sup>Compared to Indigo System Lightning 12 and Lightning 7.

# Next Generation

Lightning 7 Procedural Example



Lightning Bolt 7 Procedural Example



## CAT™ 6 with Separator™ 6



Video recordings taken by and on file at Penumbra, Inc. Tests performed at Penumbra, Inc.  
Bench test results may not be indicative of clinical performance.

## Lightning Bolt® 6X



Video recordings taken by and on file at Penumbra, Inc. Tests performed at Penumbra, Inc.  
Bench test results may not be indicative of clinical performance.

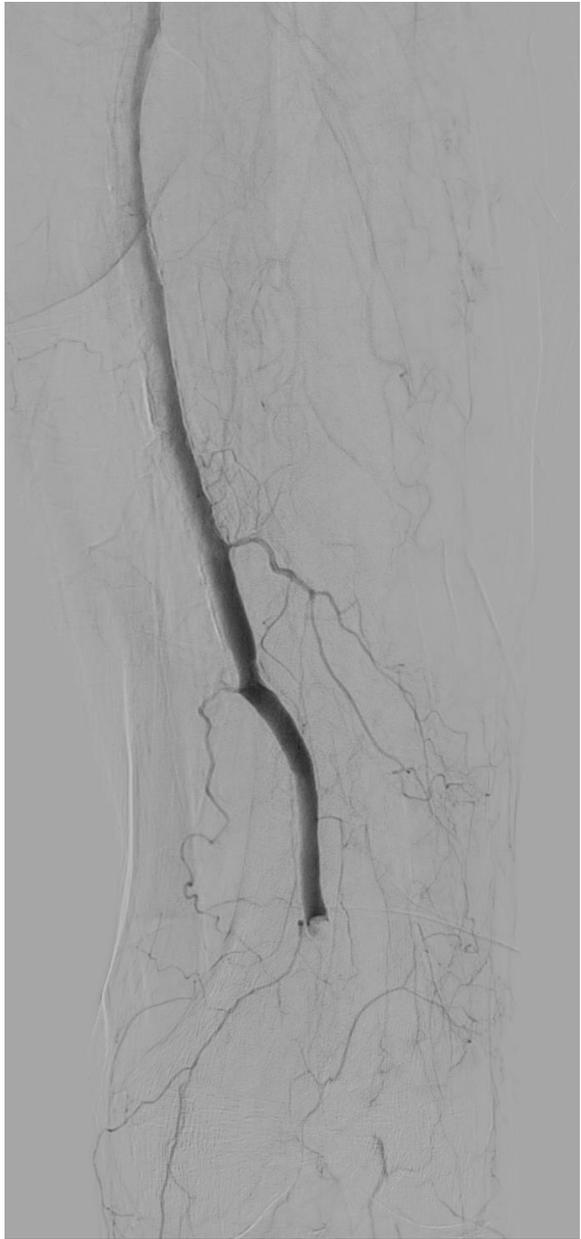
# Catheter Evolution



# Current Practice



# Baskets



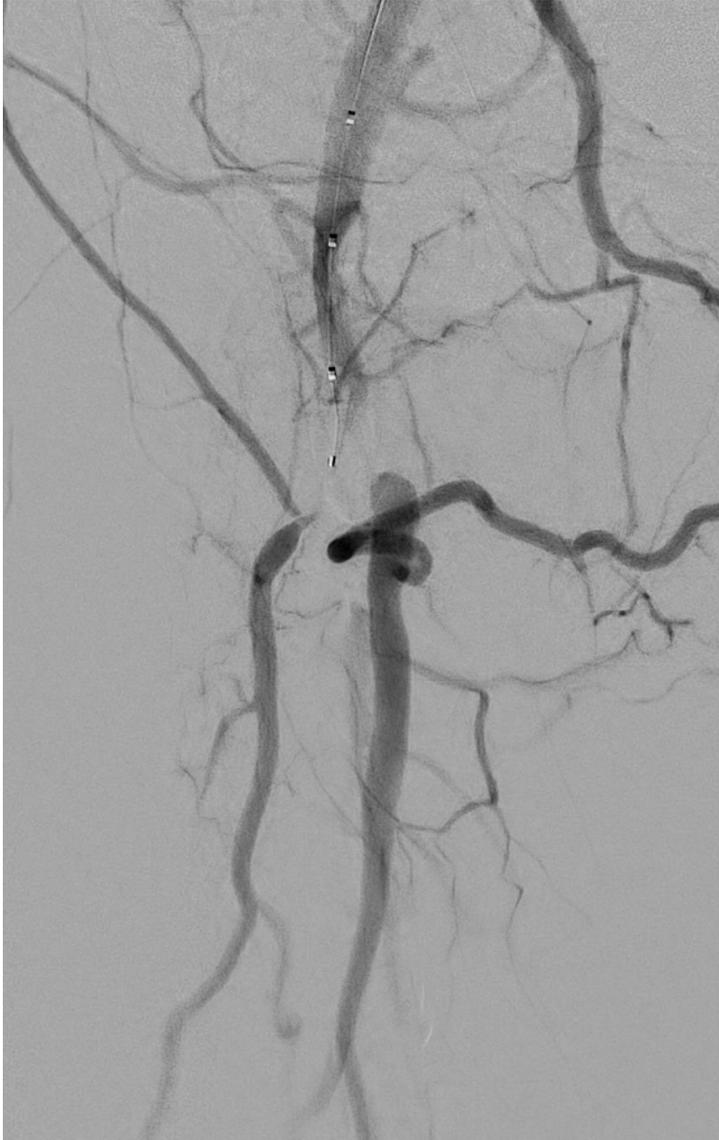
# Diffuse arterial narrowing as a result of intimal proliferation: A delayed complication of embolectomy with the Fogarty balloon catheter

Charles R. Bowles, M.D., Cornelius Olcott IV, M.D., Robert L. Pakter, M.D., Charles Lombard, M.D., John Thomas Mehigan, M.D., and Joseph F. Walter, M.D., Palo Alto, Calif.

Most complications of embolectomy with the Fogarty balloon catheter are recognized early and have received ample attention in the surgical and radiologic literature. However, the delayed complication of diffuse arterial narrowing causing severe ischemia has received little emphasis, perhaps because follow-up arteriography is not always performed. This report describes five patients—women 43 to 62 years of age—with progressive leg ischemia discovered 2 to 4 months after embolectomy with the balloon catheter. Angiography showed a characteristic pattern of severe, smooth narrowing of that portion of the artery in which balloon embolectomy was performed. Pathologic examination of arterial specimens, available in two of the five patients, revealed marked intimal cellular proliferation, which narrowed the arteries severely without evidence of thrombosis, significant atheromatosis, or active arteritis. The cause appears to be intimal damage by the balloon. Embolectomy with the balloon catheter should be done especially carefully in relatively young women. (*J VASC SURG* 1988;7:487-94.)



# History: Recent OSH LLE Intervention via Right Access (Closure Device Used)—Pt Now Presents with RLE ALI I



OSH = outside hospital; LLE = left lower extremity; RLE = right lower extremity.

# Conclusions

- Continuous improvements in technology and our experience has made suction/endovascular thrombectomy our first-line treatment for essentially all cases of acute arterial ischemia
- Technology is not yet perfect—one day there should (will?) be a “set it and forget it” technology



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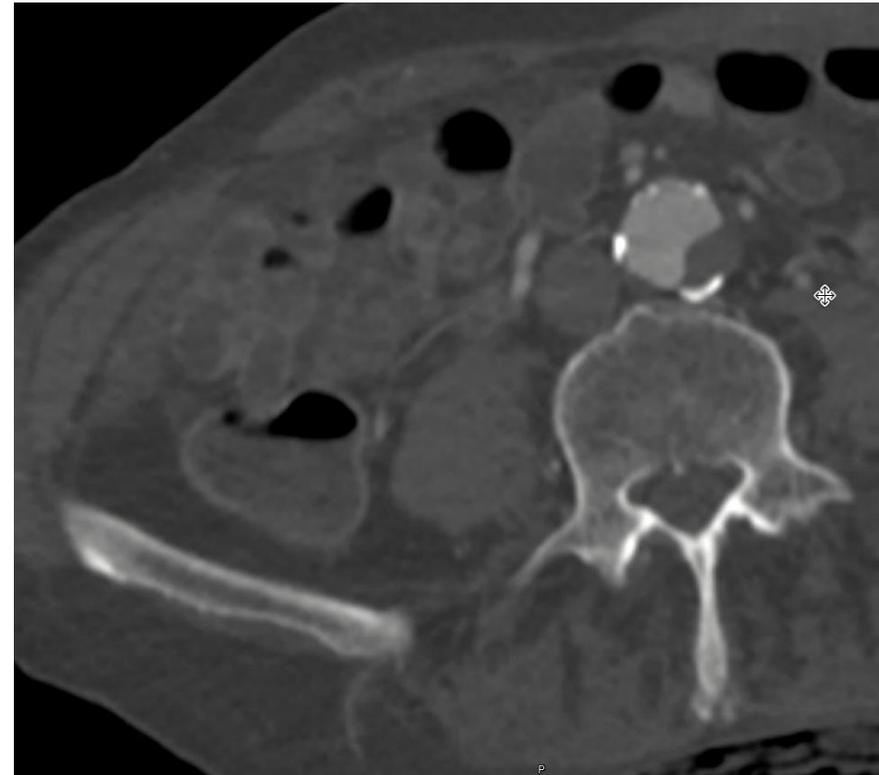
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# The Case I Wish I Never Started

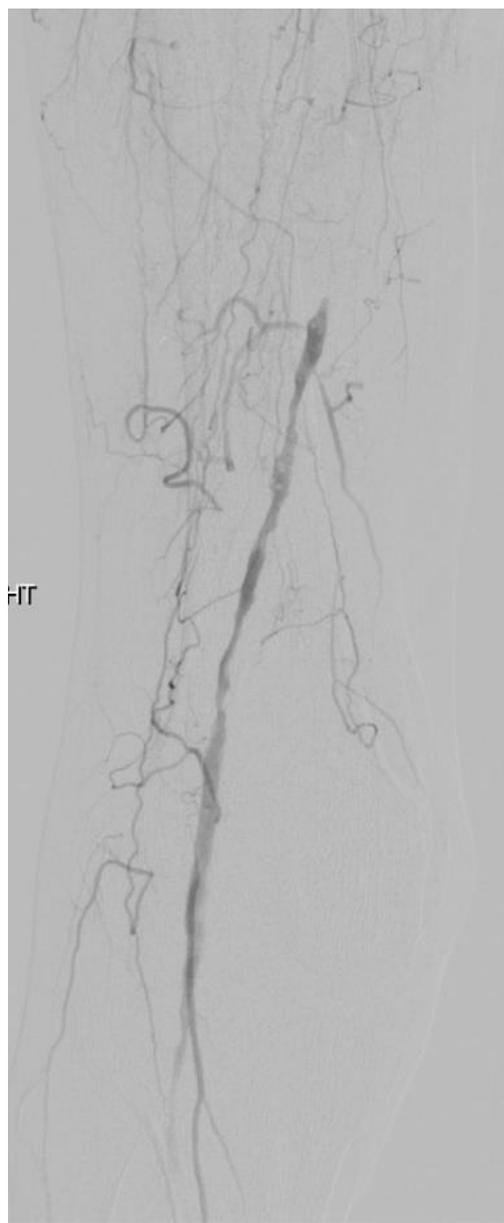
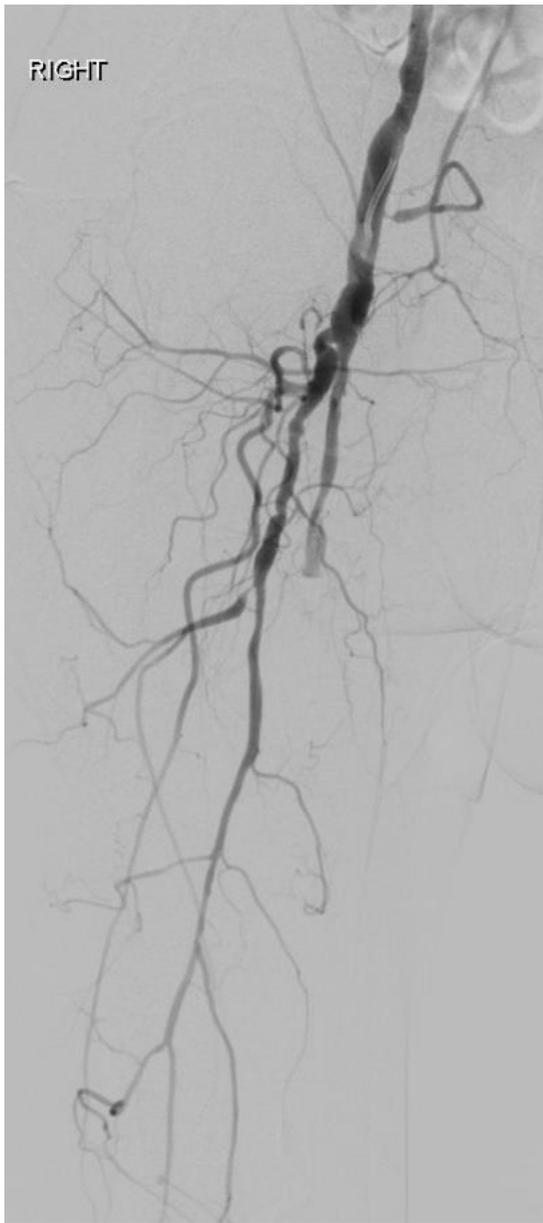
**Nicolas J. Mouawad, MD, MPH, MBA,  
DFSVS, FRCS, FACS, RPVI**  
Chief, Vascular and Endovascular Surgery  
Chair, Department of Surgery  
McLaren Health  
Bay City, Michigan

# The Case I Wish I Never Started... But Was Glad I Had CAVT!

78M COPD, DM, smoker with CLTI RLE with US demonstrating monophasic flow in the RLE with TBI=0

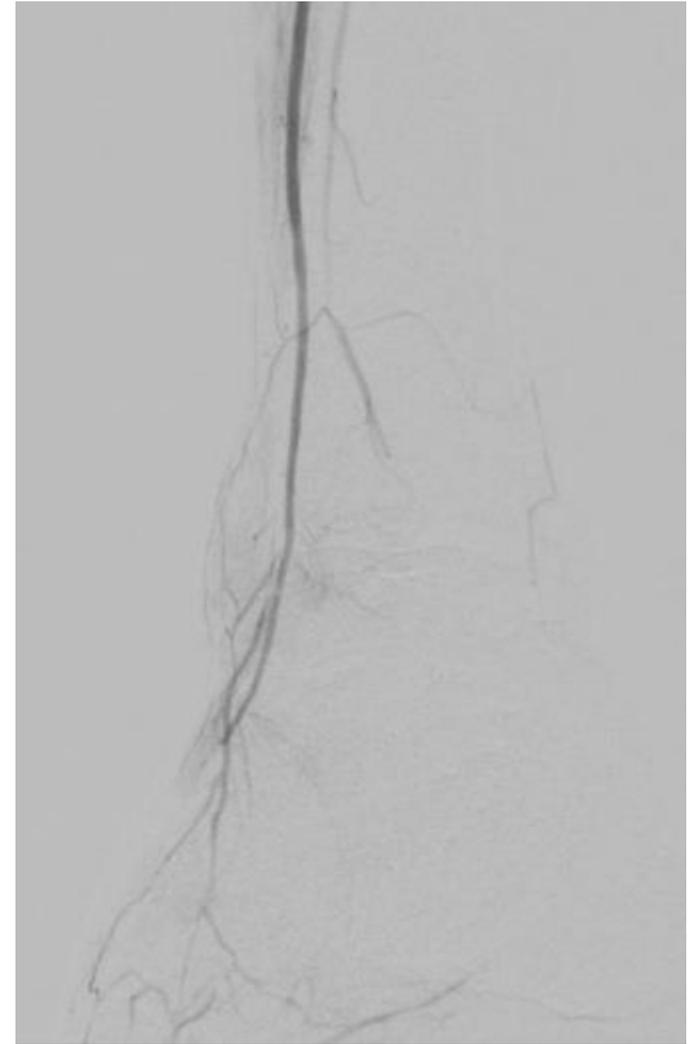
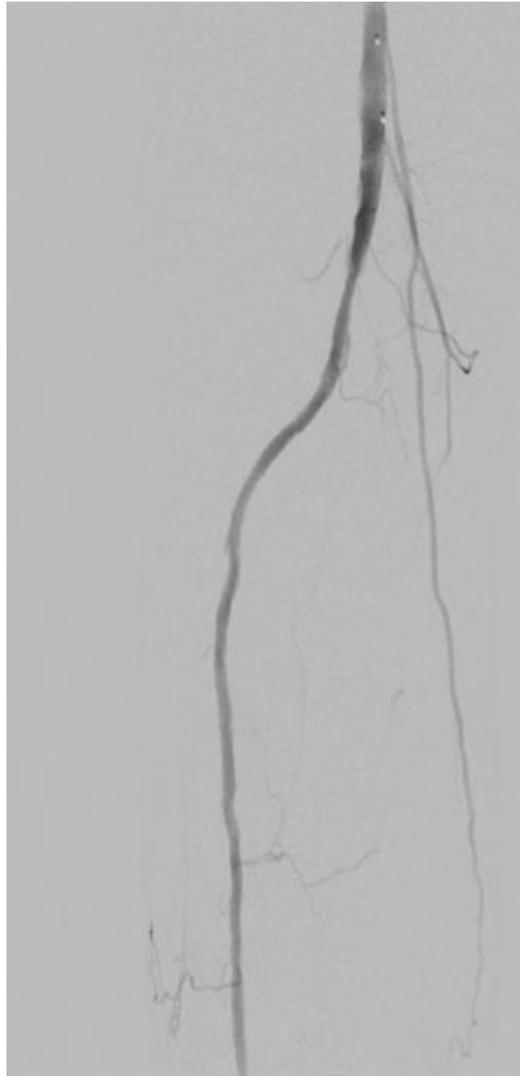
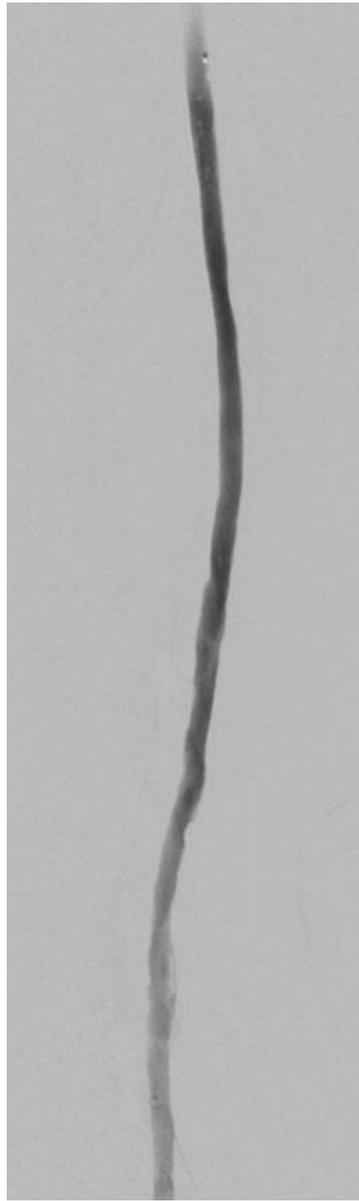
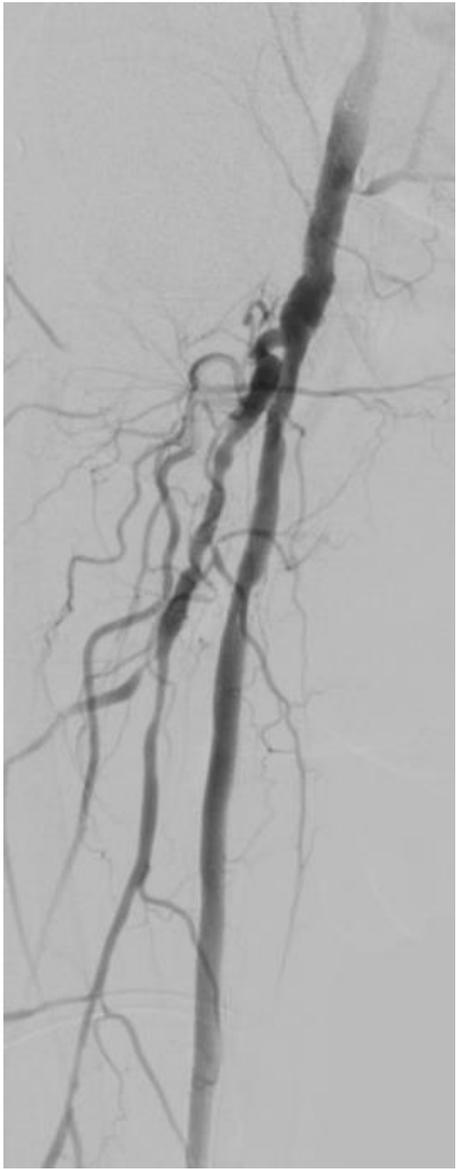


COPD = chronic obstructive pulmonary disease; DM = diabetes mellitus; CLTI = chronic limb-threatening ischemia; US = ultrasound; TBI = toe brachial index.



Just your standard SFA CTO with calcified tibial disease...

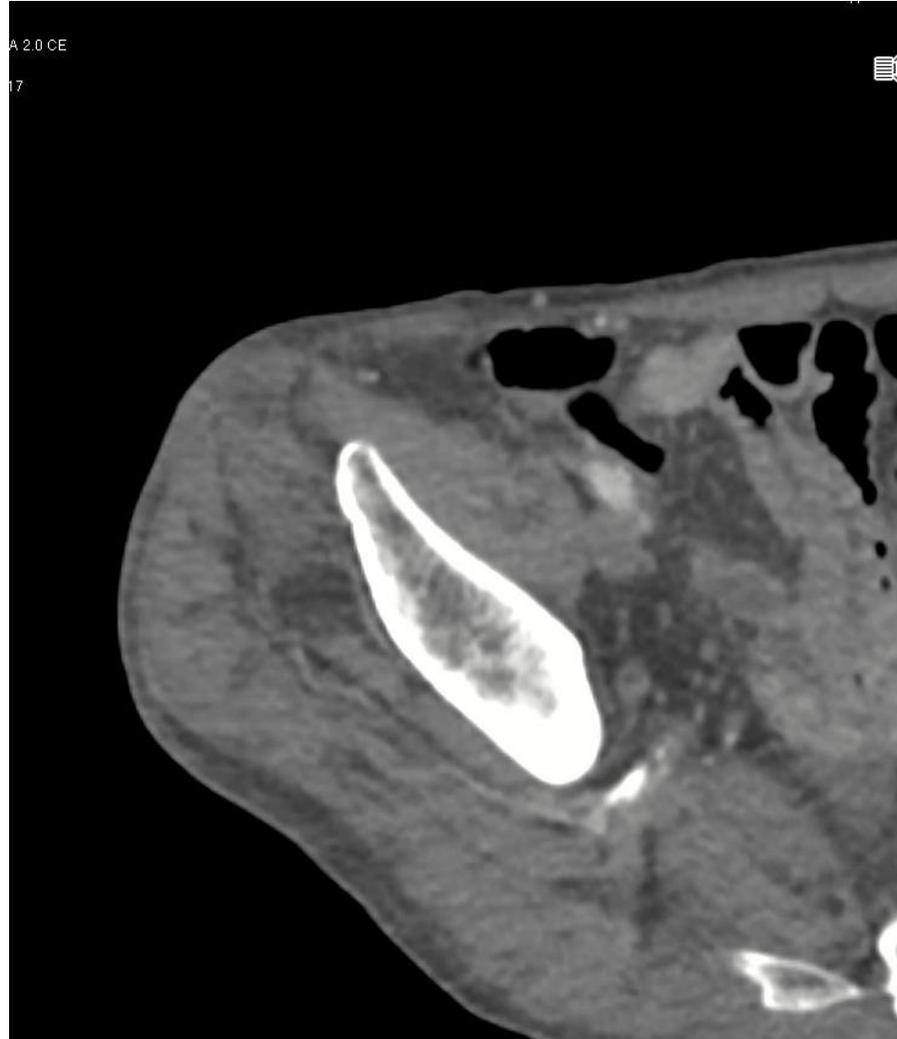
**CTO = chronic total occlusion.**



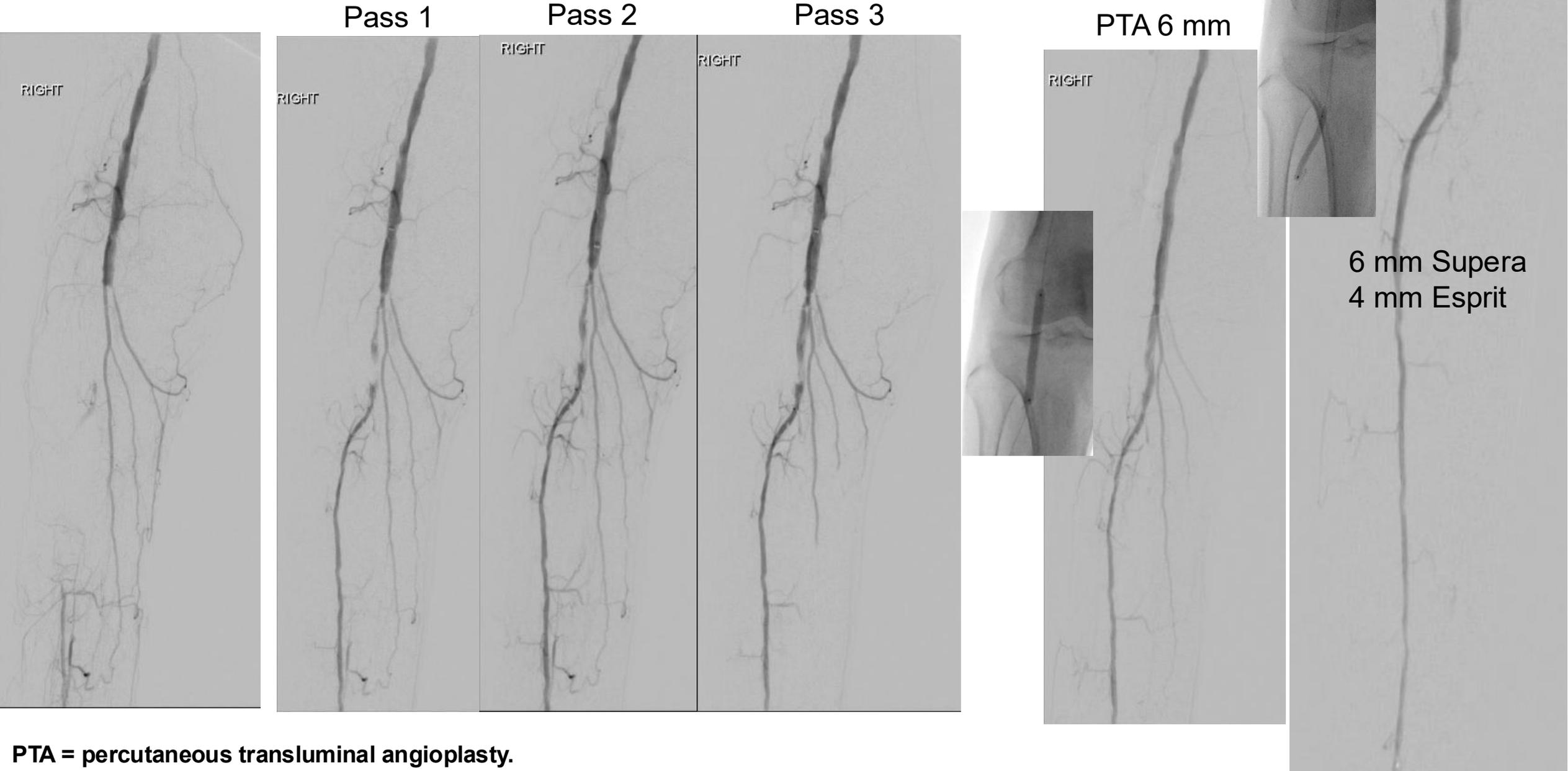
IVL + stenting SFA, IVL AT...Looks GREAT! Palpable popliteal, multiphasic DP signal

IVL = intravascular lithotripsy.

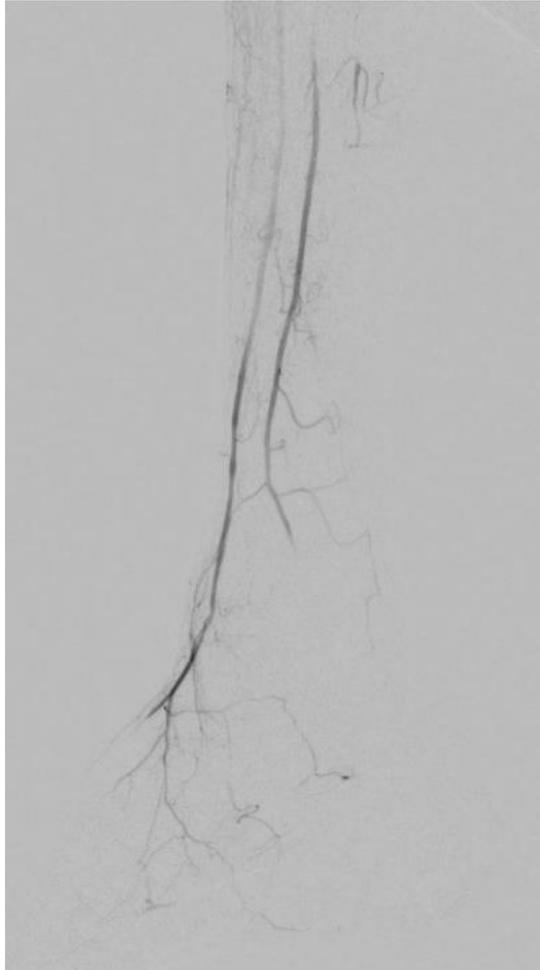
# Overnight...Popliteal Occludes ☹️



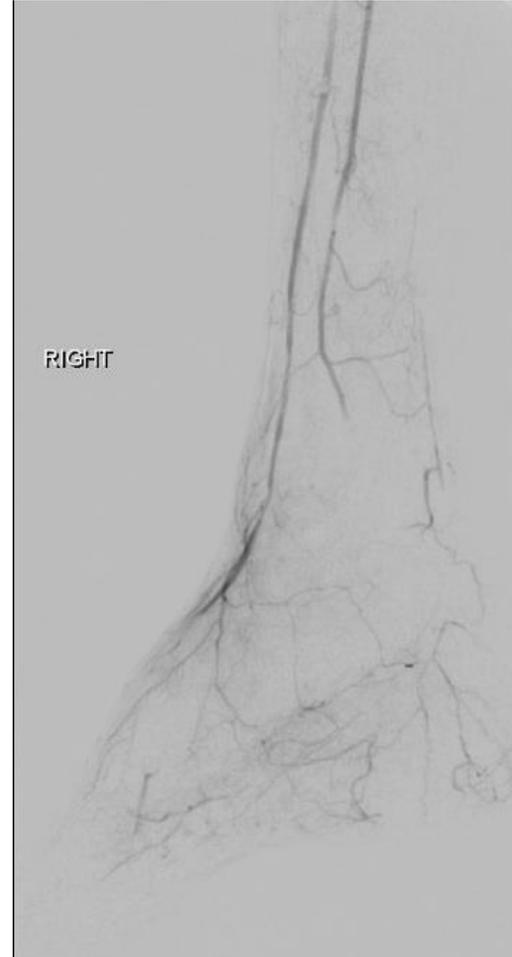
# Lightning Bolt 7



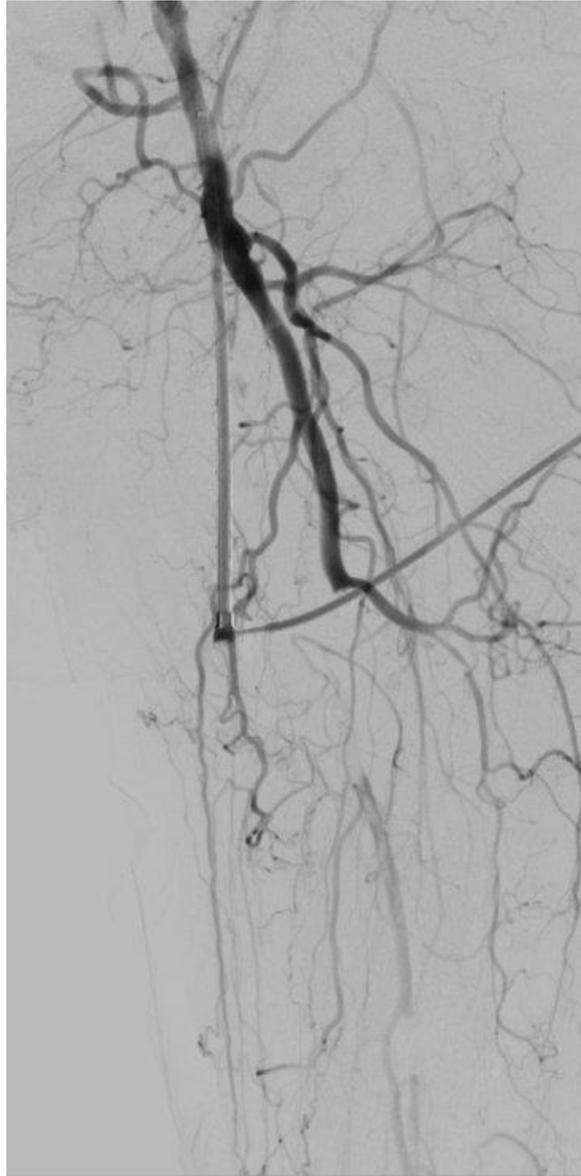
**UGH**



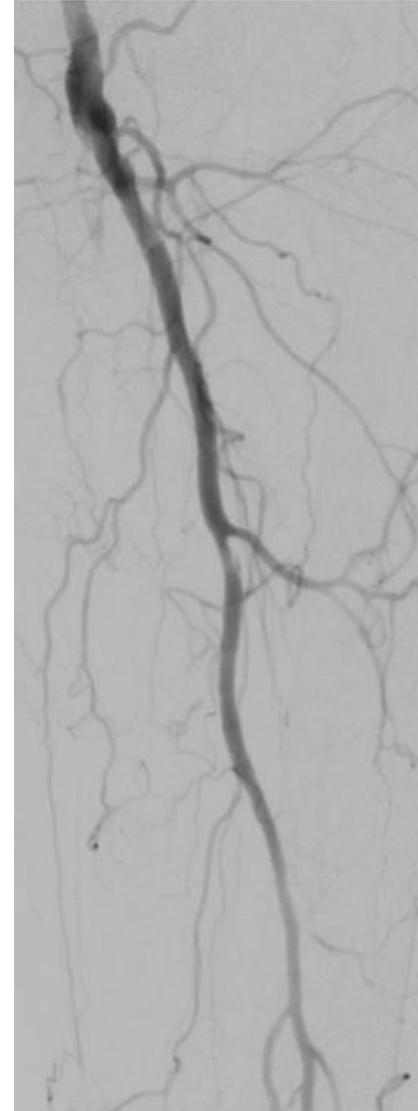
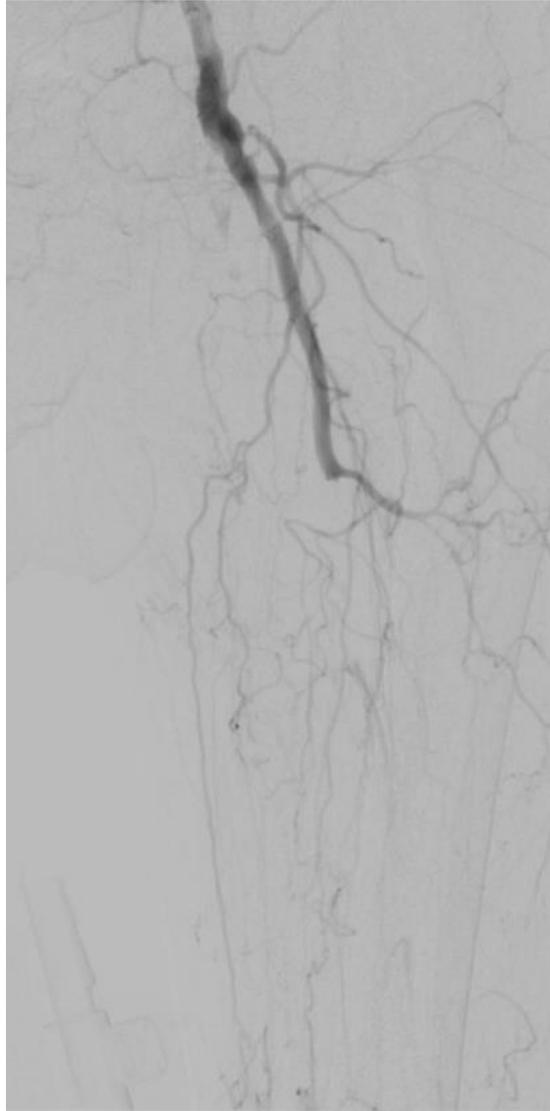
**CAT RX and NITRO,  
NITRO, NITRO**



**Oh No...**



# Bolt 6x to the Rescue! (Patient Back to Baseline)



**1 Month Later...Healed!**





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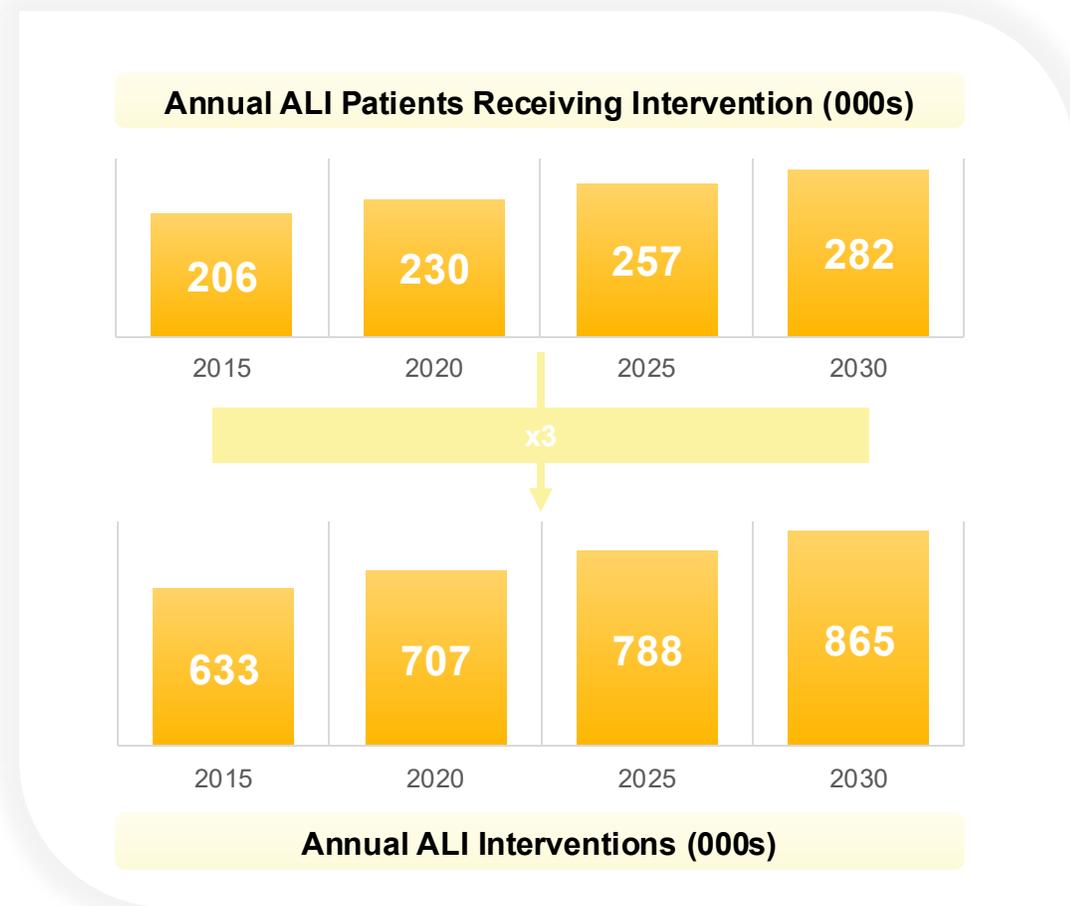
CME

# STRIDE: A Study of Patients with Lower Extremity Acute Limb Ischemia to Remove Thrombus—30-Day and 365-Day Outcomes

**Leigh Ann O'Banion, MD**

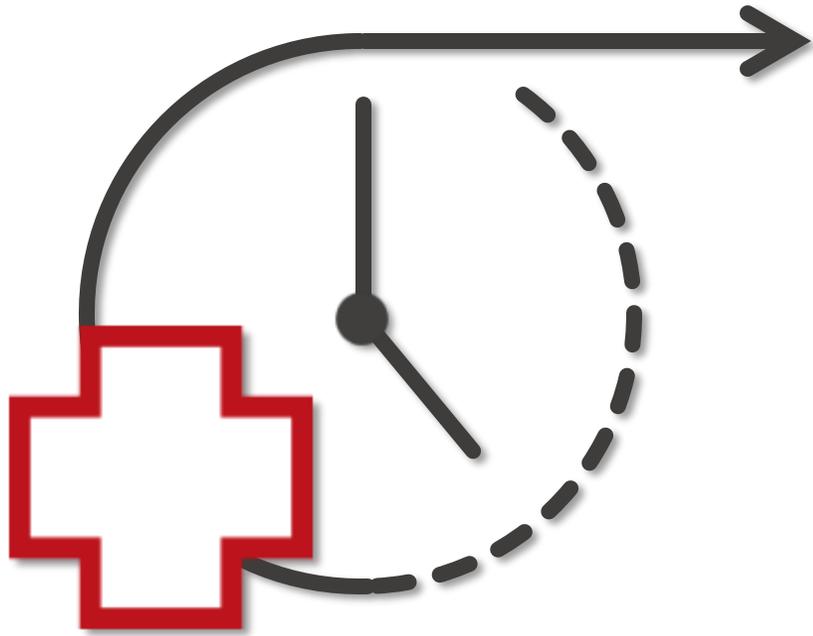
Associate Professor of Surgery  
University of California, San  
Francisco-Fresno  
Fresno, California

# Epidemiology and Treatment Challenges of ALI



- ALI incidence rates are as high as 259K
- Multiple therapies are common
- If the underlying lesion is not treated, ALI caused by thrombosis may have a recurrence rate of 43%
- When treated with lytics, 70% to 80% of patients will require additional interventions

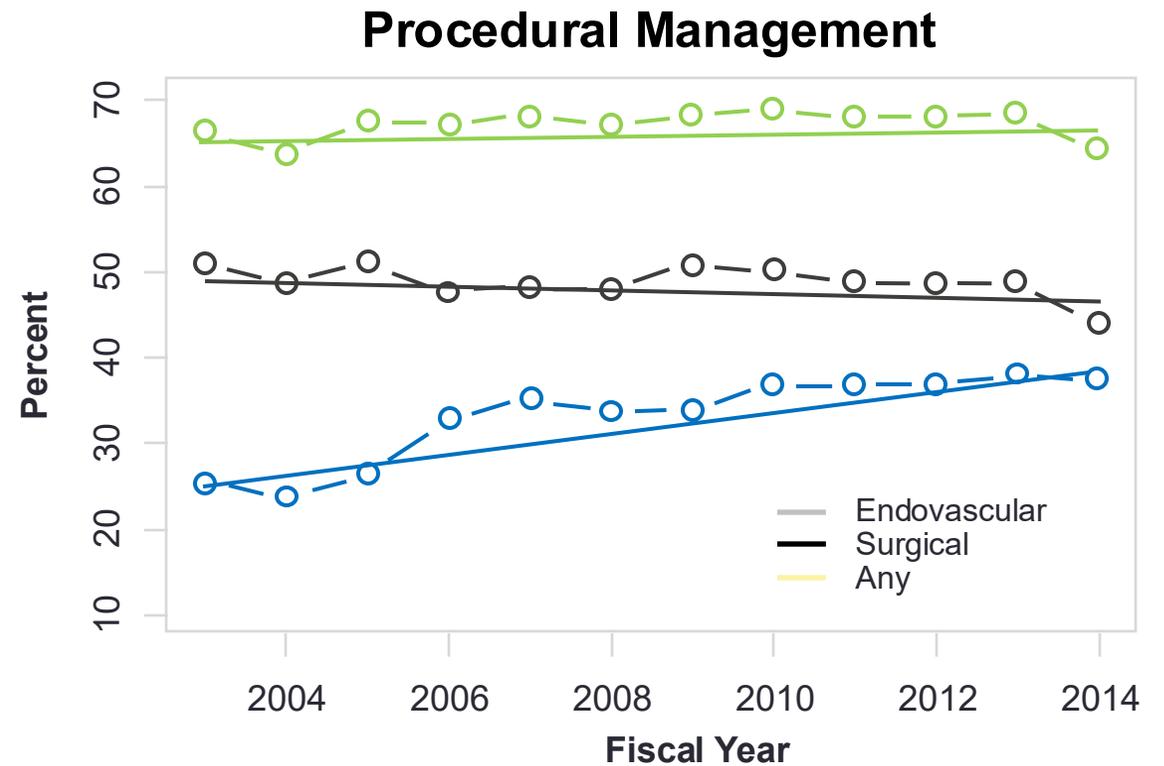
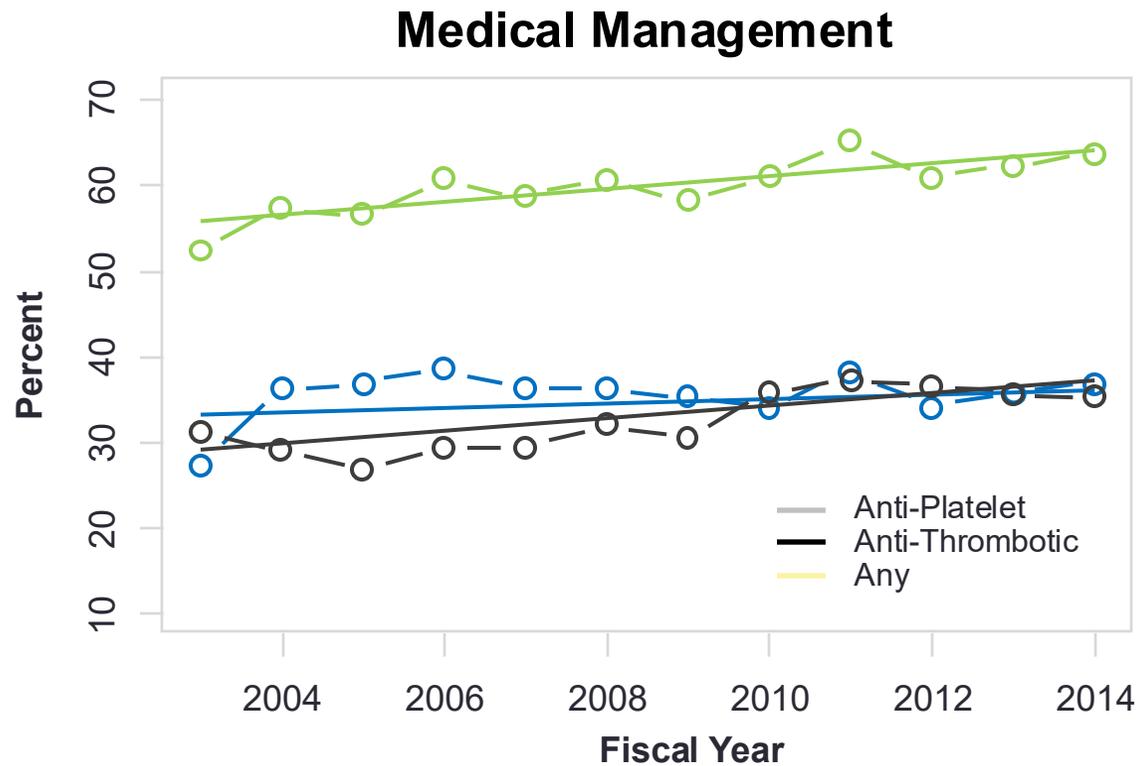
# Long-Term Issues: Mortality and Amputation



- ALI is associated with significant mortality and morbidity
  - In-hospital mortality between 9-12%
  - In-hospital amputation rates as high as 6-9%
- High limb loss, despite urgent revascularization
  - 5-yr amputation-free survival has been shown to be 36.7% in one study

# ALI-Trends in Management

Reported experience in Veterans Affairs Healthcare System (VAHS), N=10,636 (2003-2014)



# STRIDE Study Objective and Design

- **Objective:** Collect safety and performance data on the Indigo™ Aspiration System in a patient population with lower extremity acute limb ischemia (LE-ALI)
- 16 sites (13 USA, 3 EU)
- 119 patients (55 female, 64 male)
- **Primary safety endpoint**
  - Target limb salvage (TLS) at 30 days post-procedure
- **Key secondary safety and performance endpoints**
  - Technical success, patency at 30 days, TLS at 365 days, periprocedural major bleeding, mortality at 365 days
- Follow-up: 30, 180, and 365 days



30-day results  
published in JVS



365-day results  
published in JVS

# Indigo Aspiration System

## ENGINE™ Pump with Lightning® Aspiration Tubing

- Computer-assisted vacuum thrombectomy
- Continuous aspiration when engaged in thrombus
- Intermittent aspiration in patent vessel designed to minimize blood loss

**In the STRIDE Study, Lightning was used in 43.7% (52/119) of patients<sup>a</sup>**



<sup>a</sup>CAT™6 usage was 31.9% (38/119) and CAT8 usage was 35.3% (42/119). Multiple devices may have been used in a therapy session. Maldonado TS, et al. *J Vasc Surg.* 2024;79(3):584-592.

# Key Eligibility Criteria

## Key inclusion criteria

- Acute ( $\leq 14$  days) occlusion of lower limb artery(ies) (below inguinal ligament)
- Rutherford category I, IIa, or IIb score
- Firstline treatment with Indigo aspiration system
- $\geq 18$  years old

## Key exclusion criteria

- Target vessel size  $< 2$  mm
- Amputation in the ipsilateral limb
- Target thrombus in a saphenous vein bypass graft
- Absolute contraindication to contrast administration
- Life expectancy of  $< 1$  year

# Primary and Secondary Endpoints

## Primary performance endpoint

- Target limb salvage at 30 days post-procedure

## Secondary performance endpoints

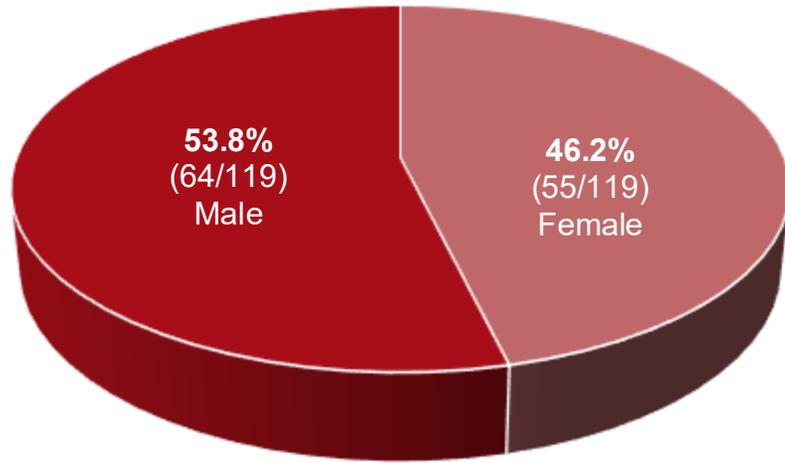
- Technical success (TIMI 2/3 flow rate immediately post-procedure)
- Improvement in modified SVS runoff score immediately post-procedure
- Improvement of Rutherford classification
- Patency at 30 days
- Target limb salvage at 365 days

## Secondary safety endpoints

- Device-related serious adverse events
- Peri-procedural major bleeding
- Mortality at 365 days

# Demographics and Medical History

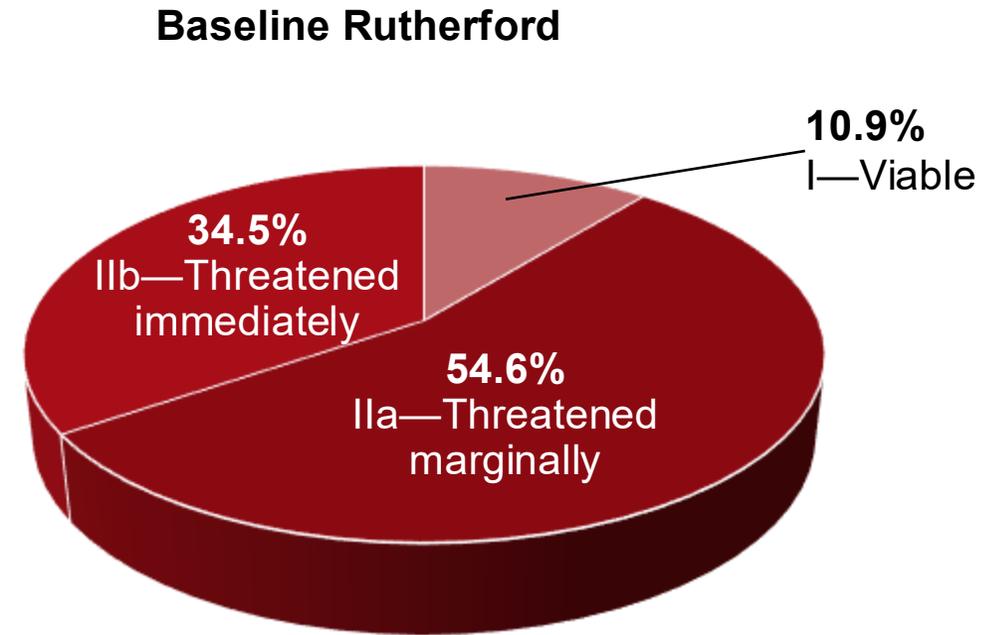
Near equal sex distribution



Demographics	(N=119)
Age (yrs, mean $\pm$ SD)	66.3 $\pm$ 13.27
Sex, female	46.2% (55/119)
Medical History	(N=119)
BMI (kg/m <sup>2</sup> , mean $\pm$ SD)	27.9 $\pm$ 6.21
Hypertension	86.6% (103/119)
Coronary artery disease	32.8% (39/119)
Atrial fibrillation	21.0% (25/119)
Hyperlipidemia	84.0% (100/119)
Previous intervention on the affected limb	53.8% (64/119)
Tobacco use within last 10 years	53.8% (64/119)
Diabetes mellitus	37.8% (45/119)
Renal failure/insufficiency	10.1% (12/119)
Previous bypass graft >6 months	17.6% (21/119)

# Thrombus, Lesion, and Clinical Severity

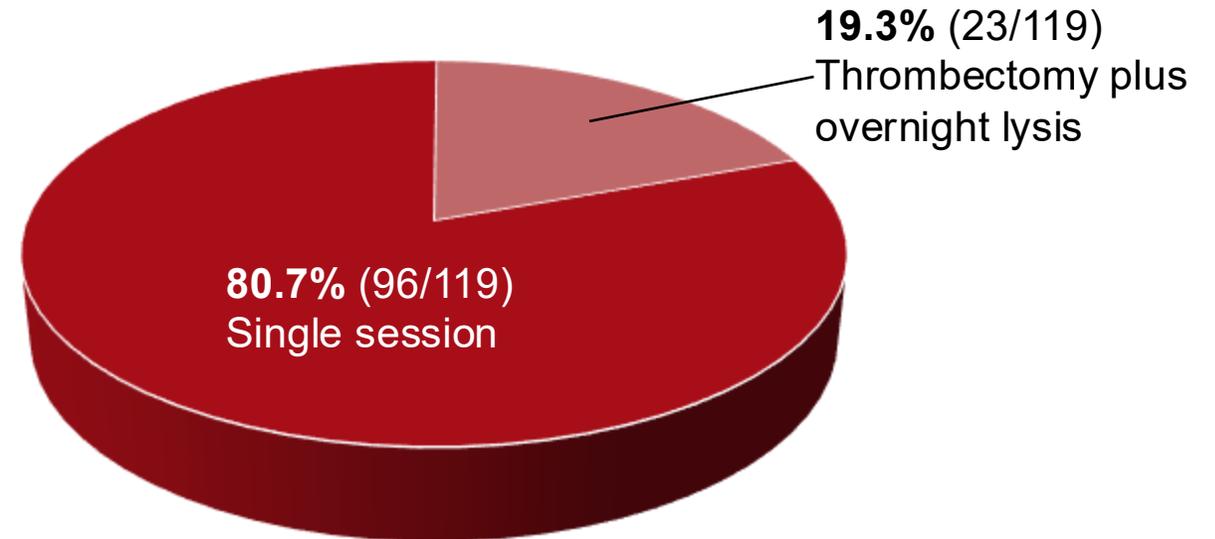
Thrombus and lesion evaluation	Mean ± SD or % or range (min, max)
Target thrombus length (n=113)	125.7 mm ± 124.7 (3.0, 627.0)
Target lesion diameter (n=97)	5.4 mm ± 1.8 (1.0, 10.0)
Tandem lesion (n=119)	18.5%
Modified SVS runoff score	Mean ± SD or range (min, max)
Pre-procedure (n=113)	10.0 (6.5, 16.0)



# Peri-Procedural Characteristics

Procedural characteristic	
<400 cc estimated blood loss volume <sup>a</sup> , % (n/N)	<b>82.8%</b> (96/116)
Median indigo aspiration time <sup>b</sup> [IQR] (minutes) (n=83)	<b>22.0</b> [12.0, 47.0]
Hospital stay	
Patient had an ICU stay, %(n/N)	<b>30.3%</b> (36/119)

Adjunctive thrombolytics permitted at the discretion of the treating physician



**60.5% (72/119) of STRIDE patients received no lytics at all.**

<sup>a</sup>Estimated blood loss was calculated by subtracting the amount of saline flush used from the total amount of aspirated material in the canister. <sup>b</sup>Time from first aspiration catheter insertion to last aspiration catheter removal.

ICU = intensive care unit.

Maldonado TS, et al. *J Vasc Interv Radiol.* 2024;35(3):S47.

# Results

Primary Endpoint	% (n/N)
Target limb salvage at 30 days	98.2% (109/111)
Secondary Endpoints and Other Outcomes	% (n/N) or Mean $\pm$ SD or range (min, max)
Technical success	96.3% (105/109)
Patency at 30 days	89.4% (101/113)
Improvement in modified SVS runoff score (pre- vs post-procedure)	6.3 $\pm$ 5.49 Range (-1.0, 18.0)
Major bleeding, peri-procedural <sup>a</sup>	4.2% (5/119)
Device-related SAEs <sup>b</sup>	0.8% (1/119)
Mortality at 30 days	3.4% (4/119)

<sup>a</sup>Major bleeding, peri-procedural: defined as bleeding w/n 2d of procedure, which is fatal or leads to drop in hemoglobin of  $\geq 5$  g/dl, or significant hypotension requiring inotropes, or requires surgery (other than vascular site repair), or symptomatic intracranial hemorrhage, or requires transfusion of 2 or 3 units of RBC or equivalent whole blood. Events (5) include: (i) retroperitoneal bleed on heparin, (ii) access site hemorrhage, (iii, iv) anemia requiring transfusion 2x, (v) pseudoaneurysm. <sup>b</sup>Related is definite or probable relatedness. All events until study exit noted.

SAE = serious adverse event; RBC = red blood cells.

Maldonado TS, et al. *J Vasc Surg.* 2024;79(3):584-592.

# Results

<b>Efficacy Endpoint</b>	<b>% (n/N)</b>
Target limb salvage at 365 days	88.5% (77/87)
<b>Safety Endpoint</b>	<b>% (n/N)</b>
Mortality at 365 days	12.0% (12/100)
<b>Patient-Reported Quality of Life</b>	<b>Median [IQR]</b>
VascuQoL-6 overall score improvement	7.0 [3.0, 11.0]

- 76.6% (49/64) patients achieved improvement in their quality of life (VascuQoL-6 improvement of at least 3.0 points)

# Historical Control Surgical Outcomes vs STRIDE

Outcome	Open Surgery	STRIDE <sup>a</sup>
Target limb salvage at 30 days	83.1% <sup>[2,b]</sup>	<b>98.2%</b> <sup>[1]</sup> (109/111)
Target limb salvage at 365 days	77.3% <sup>[2,b]</sup>	<b>88.5%</b> <sup>[1]</sup> (77/87)
Patency at 30 days	78.6% <sup>[3]</sup>	<b>89.4%</b> <sup>[1]</sup> (101/113)
Mortality at 30 days	13.2% <sup>[4]</sup>	<b>3.4%</b> <sup>[5]</sup> (4/119)
Mortality at 365 days	33.8% <sup>[4]</sup>	<b>12.0%</b> <sup>[1]</sup> (12/100)
Major bleeding, peri-procedural	21.0% <sup>[6,c]</sup>	<b>4.2%</b> <sup>[5]</sup> (5/119)

<sup>a</sup>STRIDE study was not a randomized or head-to-head study. Please refer to specific publications to review source for detailed patient and data collection methods for open surgical revascularization. <sup>b</sup>Composite limb salvage rate calculated, and data on file at Penumbra, Inc.

<sup>c</sup>Major bleeding definitions may vary across studies. Please refer to specific publications for details.

<sup>1</sup>Maldonado TS, et al. *J Vasc Surg.* 2024;80(4):1159-1168. <sup>2</sup>Veenstra EB, et al. *J Vasc Surg.* 2020;71(2):654-668. <sup>3</sup>Grip O, et al. *Br J Surg.* 2018;105(12):1598-1606. <sup>4</sup>Taha AG, et al. *J Vasc Surg.* 2015;61(1):147-154. <sup>5</sup>Maldonado TS, et al. *J Vasc Surg.* 2024;79(3):584-592. <sup>6</sup>Kolte D, et al. *Circ Cardiovasc Interv.* 2020;13(1):e008150.

# Treatment Outcomes and Healthcare Resource Utilization in Computer Assisted Vacuum Thrombectomy vs Open Embolectomy: The THRIVE Study

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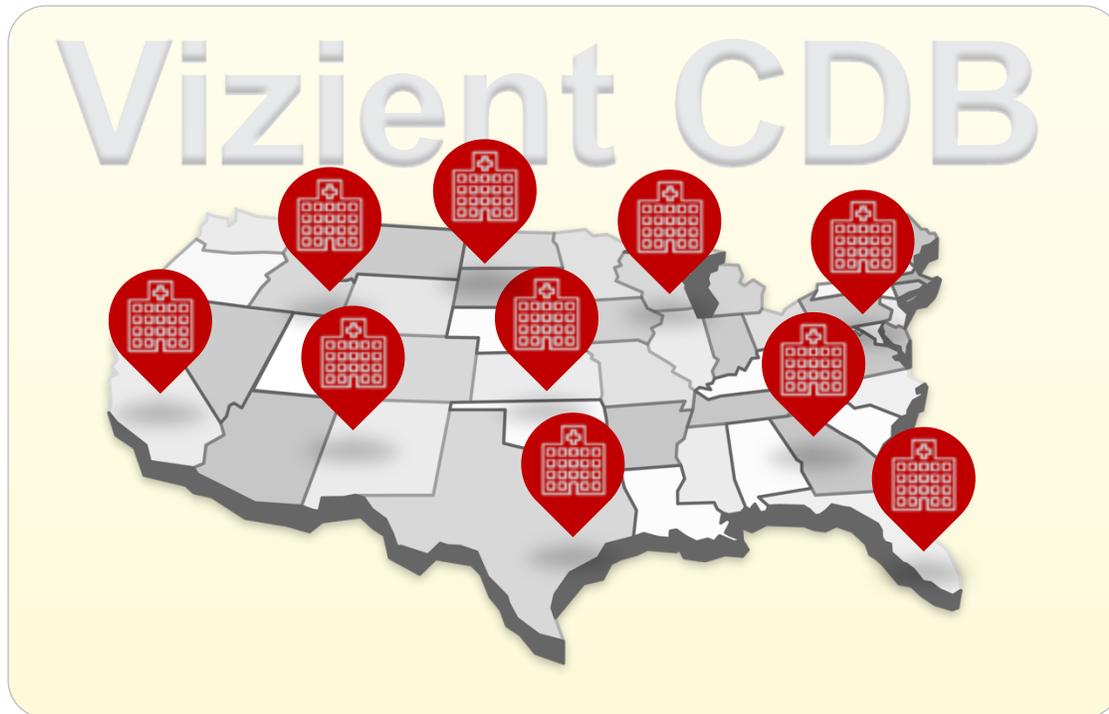
Charles Bailey, MD, RPVI, FSVS<sup>1</sup>, Bulent Arslan, MD<sup>2</sup>, Fakhir Elmasri, MD, FSIR, FPAIRS<sup>3</sup>, Sameh Sayfo, MD, MBA, FSCAI, FACC<sup>4</sup>, Martyn Knowles, MD, MBA, FACS<sup>5</sup>, Leigh Ann O'Banion, MD, RPVI, FACS, FSVS<sup>6</sup>

1. Emory University School of Medicine 2. Rush University Medical Center, 3. Lakeland Regional Health Medical Center, 4. Baylor Scott & White & The Heart Hospital Plano, 5. UNC Rex Hospital, 6. University of California, San Francisco-Fresno

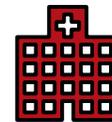
**Presented by Bulent Arslan, MD,  
at SIR 2025, March 31, 2025, and  
Charles Bailey, MD, at VAM 2025,  
June 6, 2025**

# ALI Study Objective and Data Source

Retrospective analysis of resource use and health outcomes among patients with lower extremity acute limb ischemia (ALI) managed with computer assisted vacuum thrombectomy (CAVT) with Lightning 7 and Lightning 12 compared to embolectomy alone (EA) or embolectomy with bypass (EAB) in the United States.



**Largest GPO in the United States, servicing ~42% of US claims**



**1,300+ hospitals**

- 98% of all AMCs
- 50+ health systems
- 750+ community hospitals



**Comprehensive data**



**10M inpatients and 180M hospital-based outpatients a year**

GPO = group purchasing organization; AMC = academic medical center.

US map image used under license from stock.adobe.com. Vizient Clinical Database [www.vizientinc.com]. Last updated 2023. Accessed May 2024. <https://www.vizientinc.com>. Bailey C, et al. *J Vasc Interv Radiol*. 2025;36(3 Suppl):S78.

# Study Methodology



## Time Period

2020Q3-2023Q3



## Age Cohort

Patients ≥ 18 years



## MS-DRGs

Limited to 270-272 (CAVT), 252-254 (embolectomy alone and embolectomy with bypass)



## Encounter Type

Inpatient and emergent ALI patients



## Principal Px Codes

**Embolectomy alone:** Extirpation of matter, open approach, iliac to peroneal arteries

**Embolectomy with bypass:** All the above and include secondary procedure of bypass/endarterectomy patch.

**CAVT:** Extirpation of matter, endovascular approach, of the iliac to peroneal artery



## Inclusion

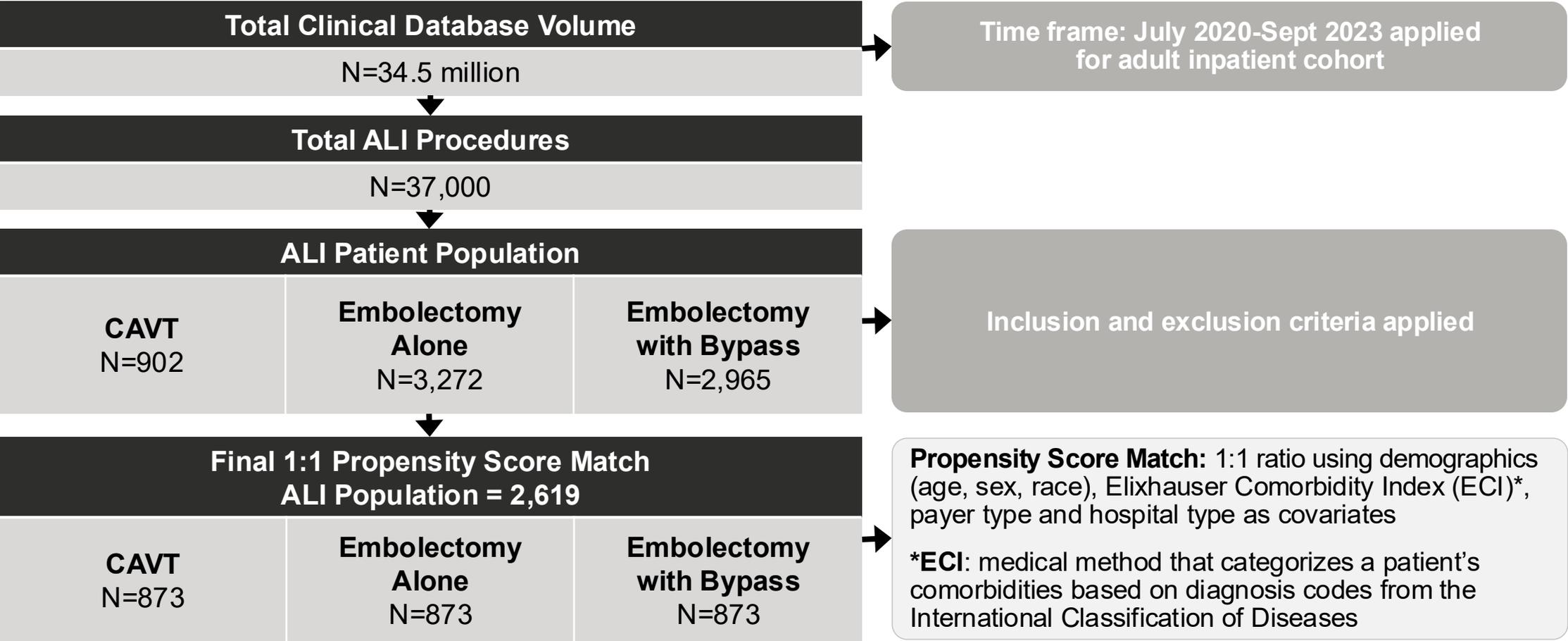
- CAVT (Lightning 7 and Lightning 12)



## Exclusion

- **If an encounter had more than one procedure or used more than one product on the same day or preceding day, the encounter was excluded**
- Encounters with Dx of gangrene and ulceration
- CAVT encounters are excluded if systemic thrombolysis is utilized

# Methodology



# Patient Demographics

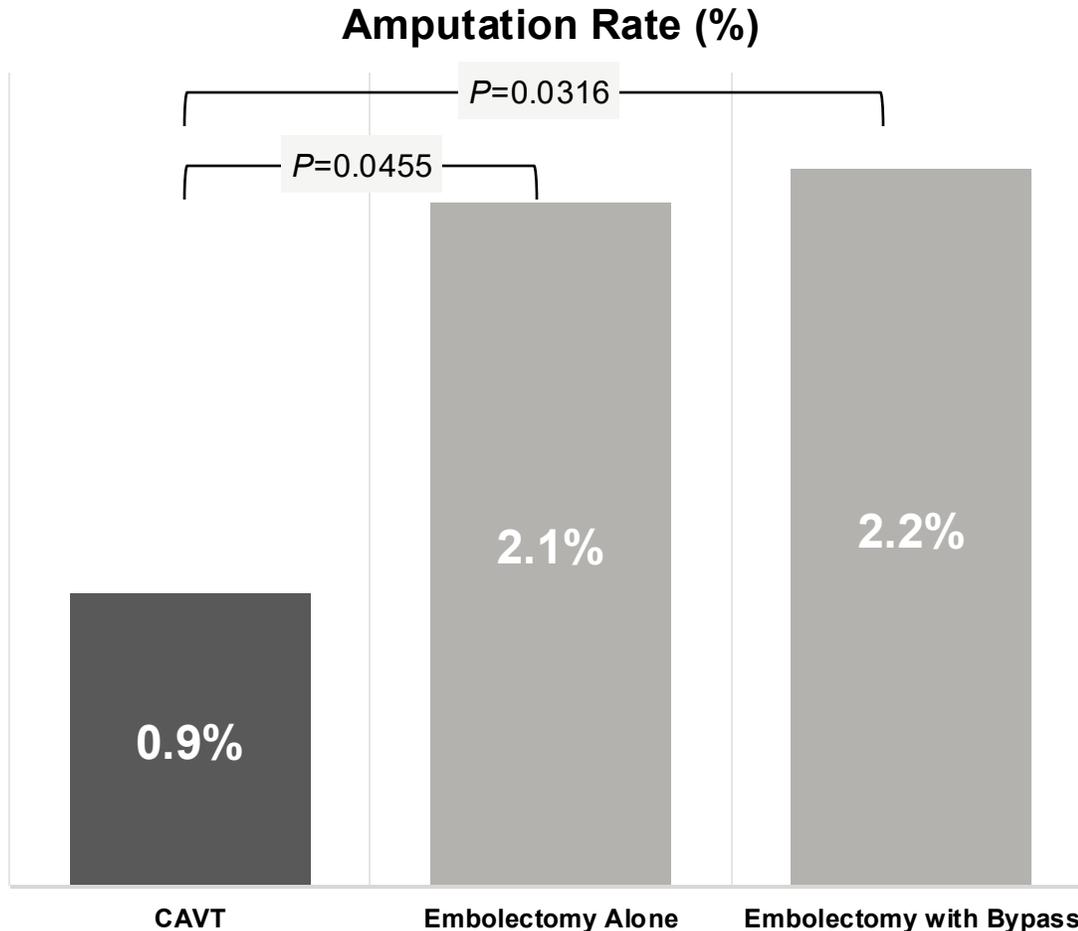
Characteristics	CAVT % (Volume)	Embolectomy Alone % (Volume)	Embolectomy with Bypass % (Volume)
<b>Sex</b>			
Female	43.3 (378)	43.2 (377)	43.5 (380)
Male	56.7 (495)	56.8 (496)	56.5 (493)
<b>Race</b>		<i>P-value=0.0001</i>	<i>P-value=0.0001</i>
White	72.2 (630)	64.8 (566)	63.6 (555)
Black	17.5 (153)	20.7 (181)	22.6 (197)
Hispanic	7.4 (65)	7.0 (61)	7.4 (65)
Asian	None Reported	None reported	None Reported
Other	2.9 (25)	7.4 (65)	6.4 (56)
<b>Age</b>			
Mean (SD)	64.8 (14.26)	65.9 (15.01)	66.0 (12.31)
Median (Range)	65.5 (18.0, 100.4)	65.5 (18.9, 102.2)	65.9 (18.6, 99.1)

**Sex:** Differences were **not** found to be statistically significant when comparing CAVT to all other modalities

**Race:** Differences in race were found to be **statistically significant** across the distribution when comparing CAVT to embolectomy alone and embolectomy with bypass

**Age:** Differences were **not** found to be statistically significant when comparing CAVT to other modalities

# ALI Amputation Rates



The STRIDE study reported a 98.2% limb salvage rate.<sup>a</sup>

CAVT showed a statistically significant lower amputation rate when compared to embolectomy alone and embolectomy with bypass. Rate is similar to the one seen in the STRIDE study.

Resource utilization cost associated with a lower extremity amputation:

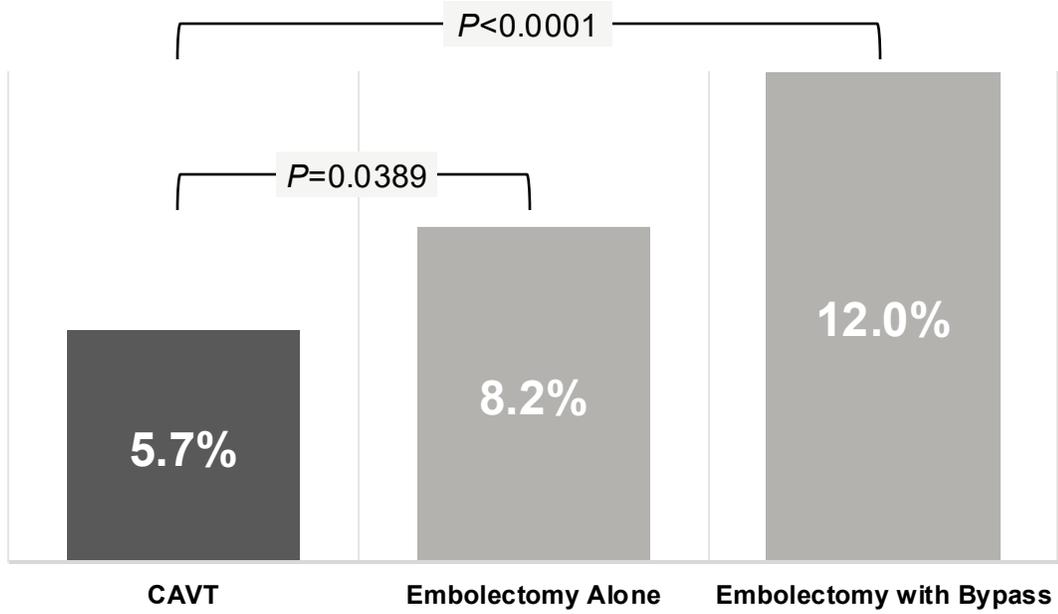
**Additional \$110,000<sup>b</sup> per patient**

<sup>a</sup>43.7% of cases within STRIDE used Lightning. <sup>b</sup>The resource utilization cost of a lower extremity amputation includes the amputation procedure, therapy, and prosthetics.

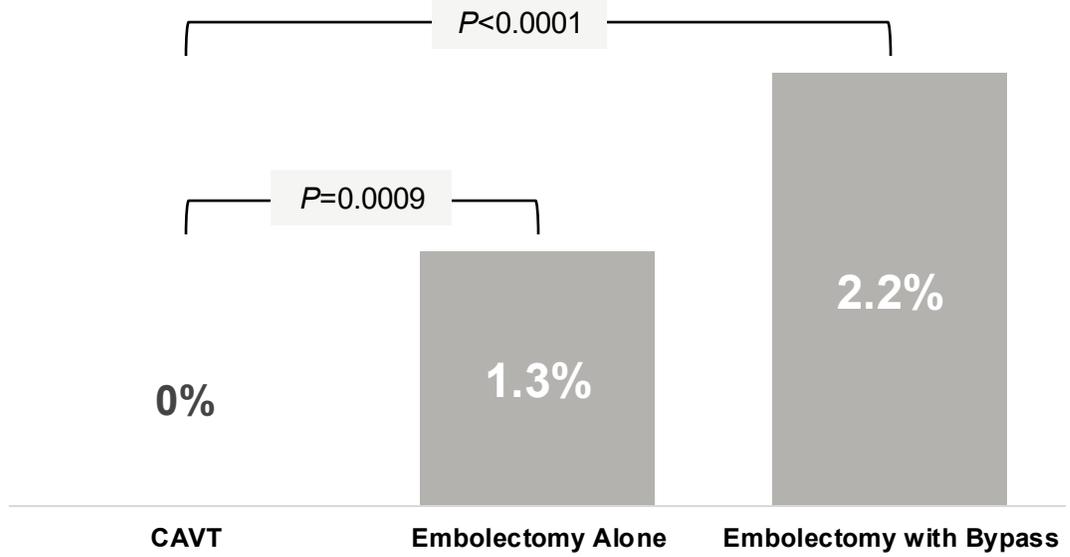
Vizient Clinical Database [www.vizientinc.com]. Last updated 2023. Accessed May 2024. <https://www.vizientinc.com>. Bailey C, et al. *J Vasc Interv Radiol*. 2025;36(3 Suppl):S78. Maldonado T, et al. *J Vasc Surg*. 2024;79(3):584-592. Smith R [www.thewca.com]. Last updated April 4, 2023. Accessed March 2025. <https://www.thewca.com/blog/the-hidden-costs-of-amputations>.

# Complication Rates

### Composite Complication



### Post-Operative Infection



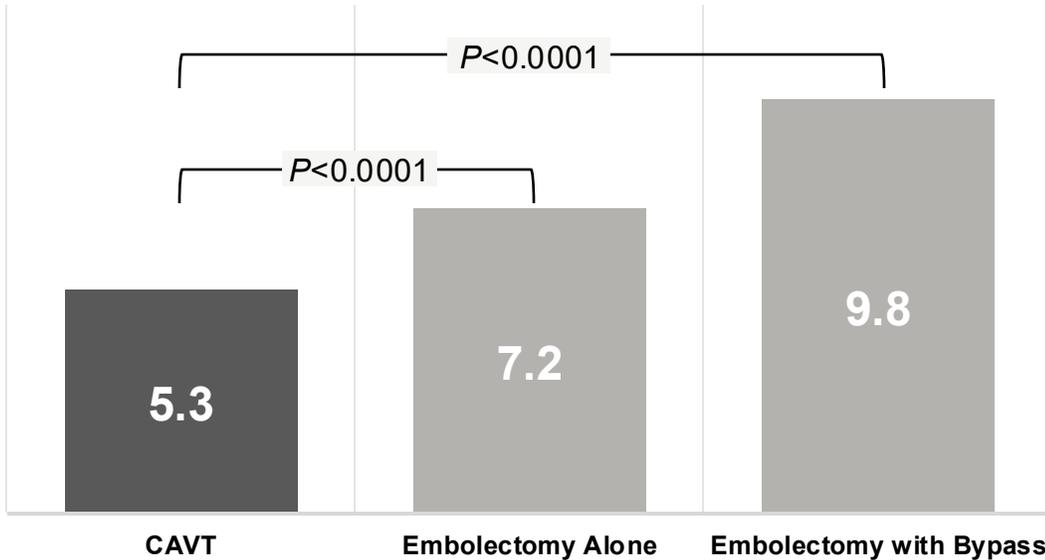
Composite Complication Rate is a Vizient-determined measure with its components: in-hospital stroke, GI hemorrhage prevention, post-operative infection, hospital-acquired AMI, readmit for infection due to previous care, readmit for other complications of internal device/implant/graft, readmit for other surgical wound complications, infection/inflammation due to internal device/implant/graft, post-operative shock, aspiration pneumonia, *C. diff*.

GI = gastrointestinal; AMI = atypical mycobacterial infection.

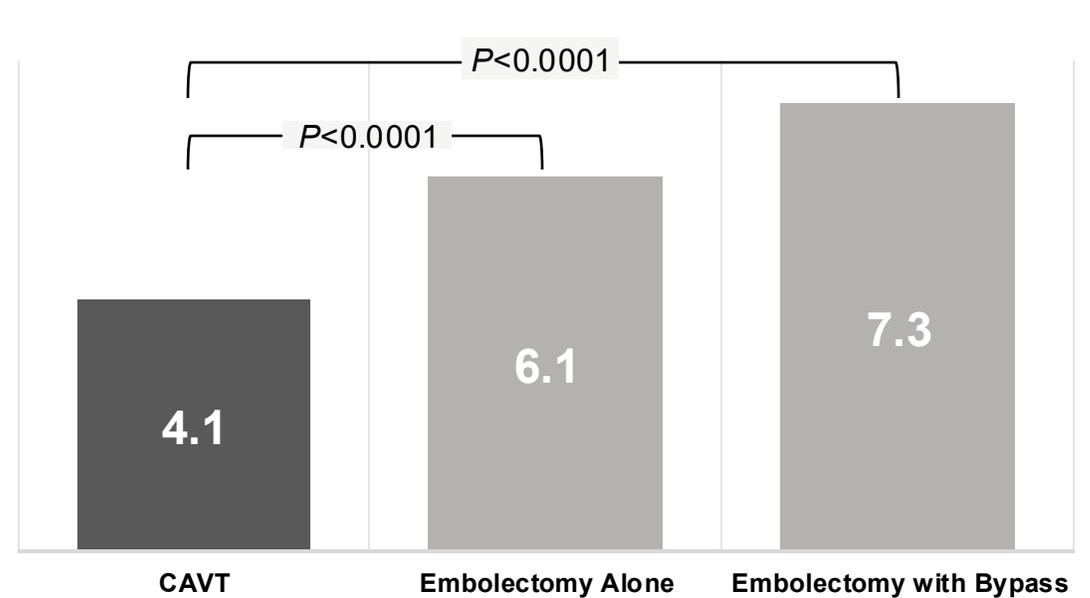
Vizient Clinical Database [www.vizientinc.com]. Last updated 2023. Accessed May 2024. <https://www.vizientinc.com>. Bailey C, et al. *J Vasc Interv Radiol*. 2025;36(3 Suppl):S78.

# Length of Stay (Days)

Mean Observed Length of Stay (Days)



Mean Post-Procedure Length of Stay (Days)

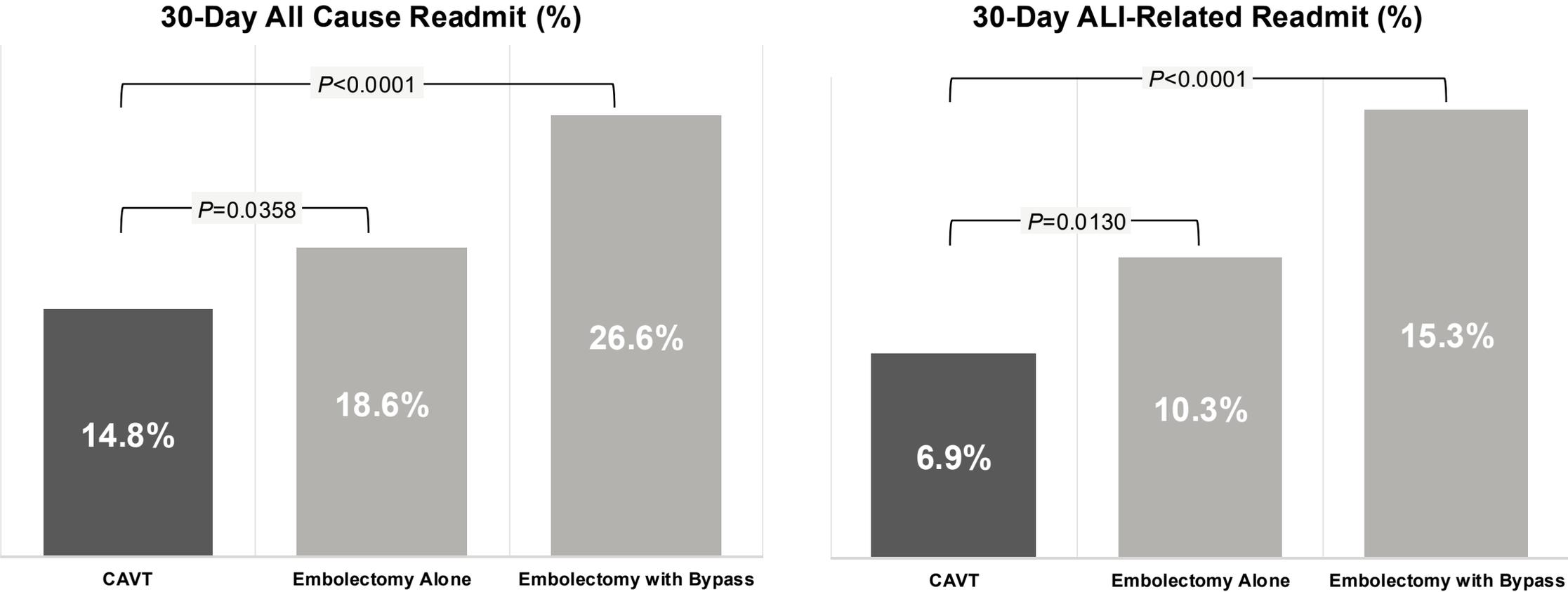


Patients treated with CAVT had lower post-procedure length of stay when compared to embolectomy without adding ICU stay

ICU = intensive care unit.

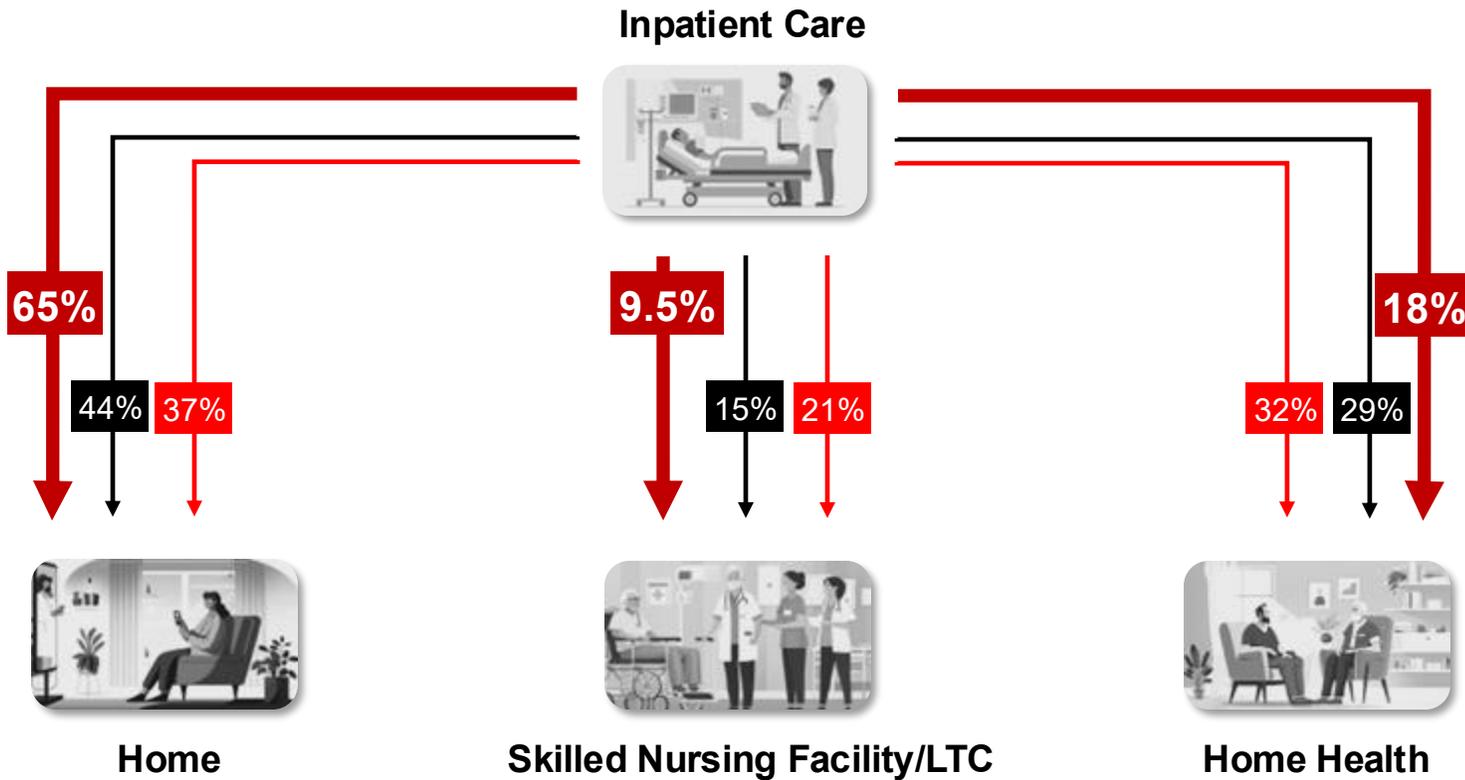
Vizient Clinical Database [www.vizientinc.com]. Last updated 2023. Accessed May 2024. <https://www.vizientinc.com>. Bailey C, et al. *J Vasc Interv Radiol*. 2025;36(3 Suppl):S78.

# Readmissions



Vizient Clinical Database [www.vizientinc.com]. Last updated 2023. Accessed May 2024. <https://www.vizientinc.com>. Bailey C, et al. *J Vasc Interv Radiol*. 2025;36(3 Suppl):S78.

# Discharge Disposition



Patients managed with CAVT had the highest rate of discharge to home compared to other modalities ( $P < 0.0001$ )

Embolectomy alone and embolectomy with bypass patients were statistically more likely to need skilled nursing facility/LTC ( $P = 0.0005$  and  $P < 0.0001$ , respectively) or home health support at discharge ( $P < 0.0001$ ) when compared to those managed with CAVT

**Management Modality**

- CAVT
- Embolectomy Alone
- Embolectomy with Bypass

LTC = long-term care.

Images used under license from stock.adobe.com. Vizient Clinical Database [www.vizientinc.com]. Last updated 2023. Accessed May 2024. <https://www.vizientinc.com>. Bailey C, et al. *J Vasc Interv Radiol*. 2025;36(3 Suppl):S78.

# Conclusion

Patients managed with CAVT demonstrated

- **Lower rates of amputation**, approximately half of embolectomy alone and embolectomy with bypass
- **Lower post-procedure lengths of stay** when compared to embolectomy without adding ICU day
- **Lower all-cause and related admission**
- **Lower composite complication rates and lower rates of post-operative infection** when compared to EA and EAB
- **More likely to be discharged to home** and less likely to need skilled nursing facility or long-term care or home health support at discharge

**Retrospective analysis of acute limb ischemia patients suggested improved clinical outcomes and reduced healthcare resource utilization with CAVT**



CardioVascular  
Learning Network

CME

# Lower Extremity Arterial Case Presentation: ISR CTO

**Bhaskar Purushottam, MD, FACC, FSCAI, FSVMB**

President, Midwest Heart and Vascular Associates  
Interventional Cardiologist and Endovascular  
Medicine

Monument Health Rapid City Hospital, Rapid City,  
South Dakota

Medical Director, Monument Health Research

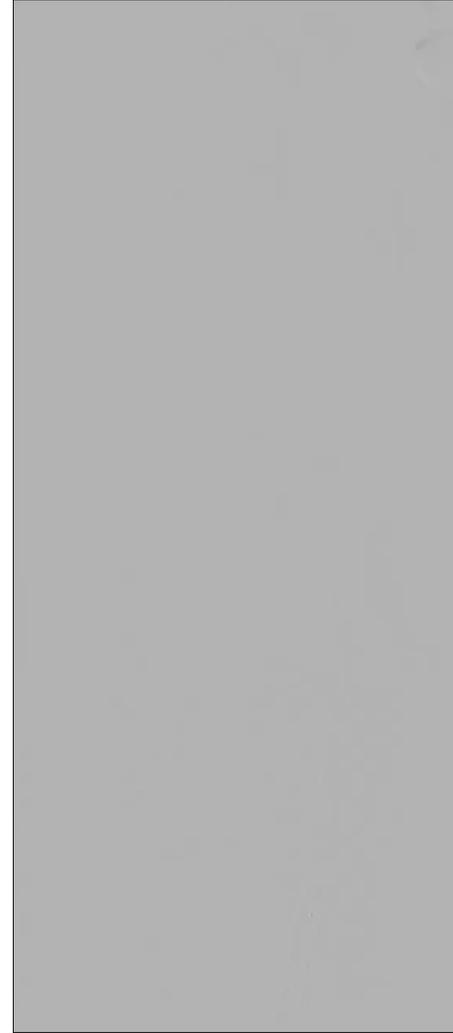
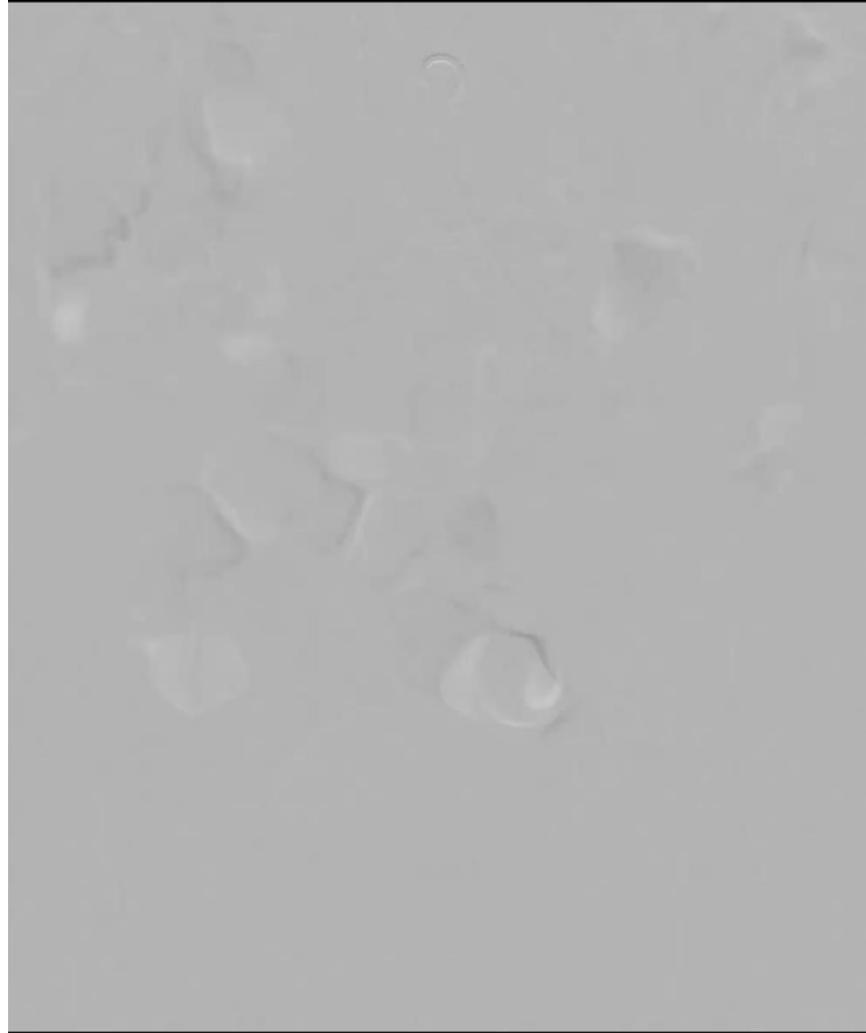
# Case 1: CLTI

- 72 yo M ex-smoker with known PAD, previous interventions [right SFA and popliteal artery stents], CAD, PCI, CABG, ICM with systolic CHF [LVEF of 25%], DM2, HTN, and dyslipidemia was seen in my clinic for non-healing right lower extremity wounds
- Arterial duplex reveals an occluded R SFA/pop stent with reconstitution occurring in the proximal right peroneal artery

# Right Lower Leg and Great Toe Wounds



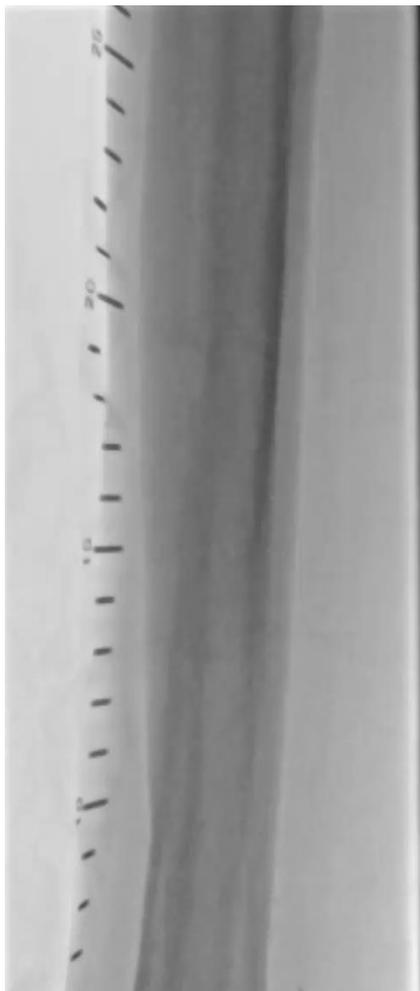
# Diagnostic Right Lower Extremity Angiograms



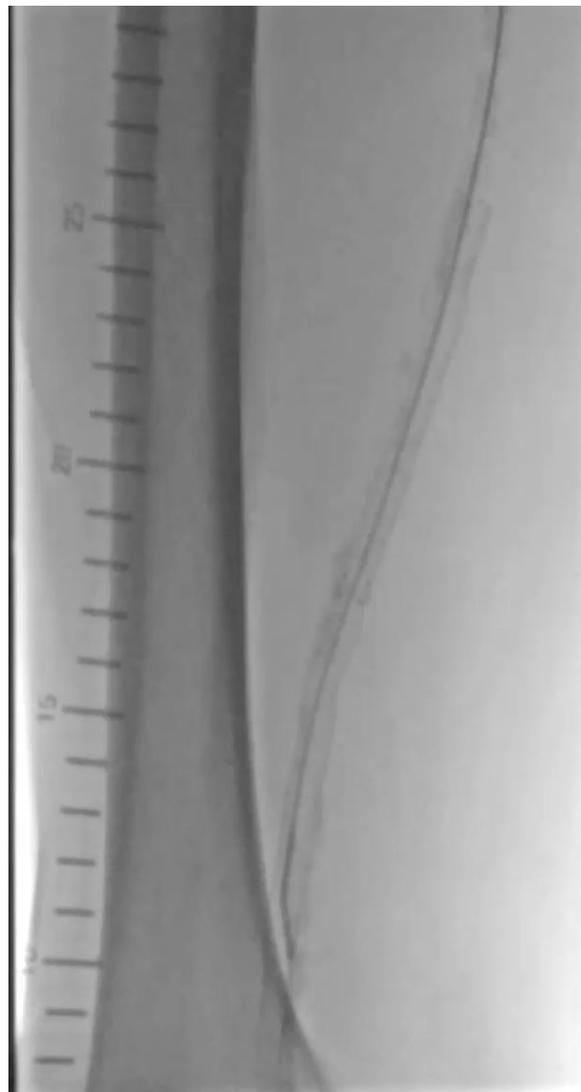
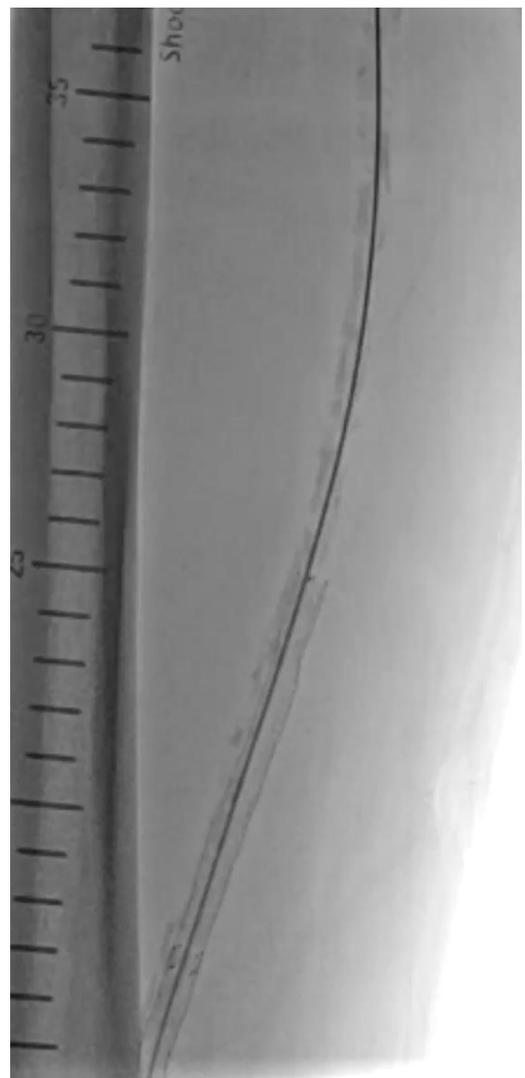
# Right Infrapopliteal Angiograms



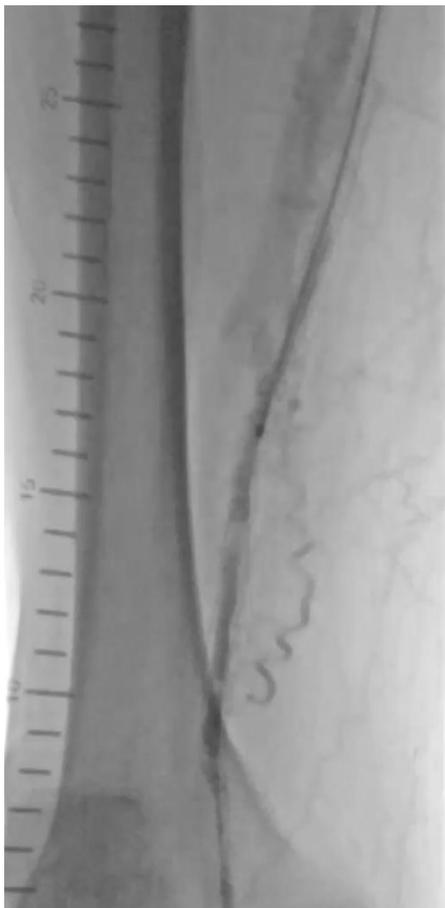
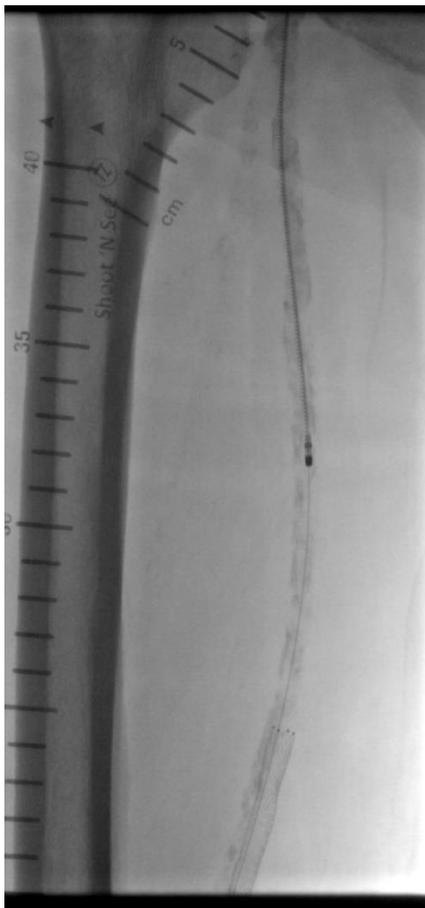
# Retrograde Approach



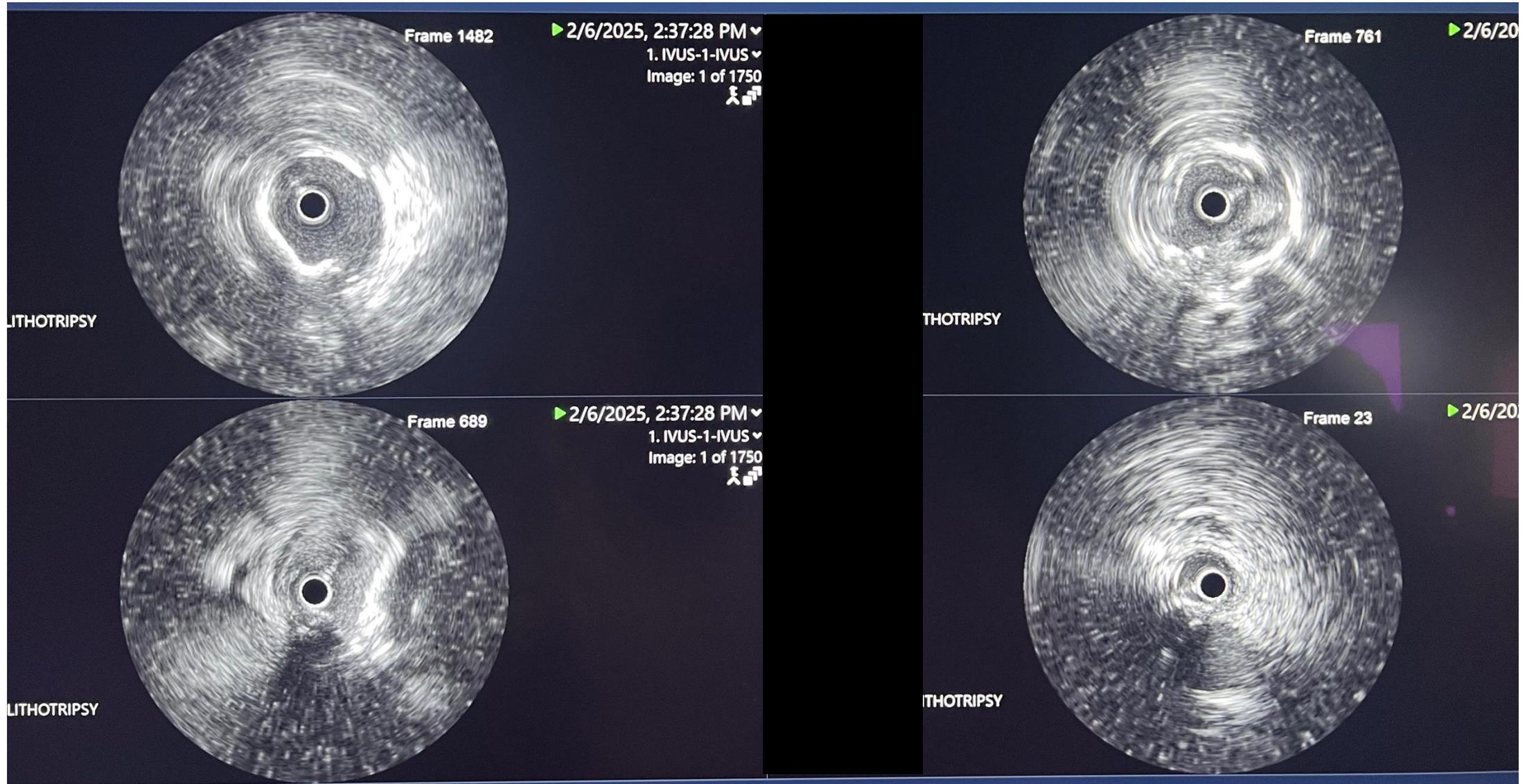
# Successful Cross via Antegrade Approach



# Rotarex Thrombectomy/Atherectomy



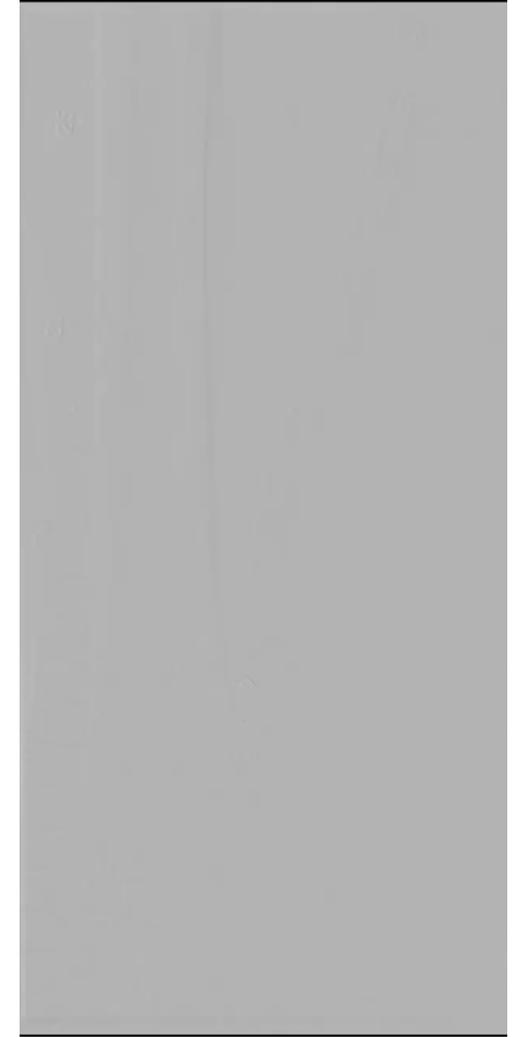
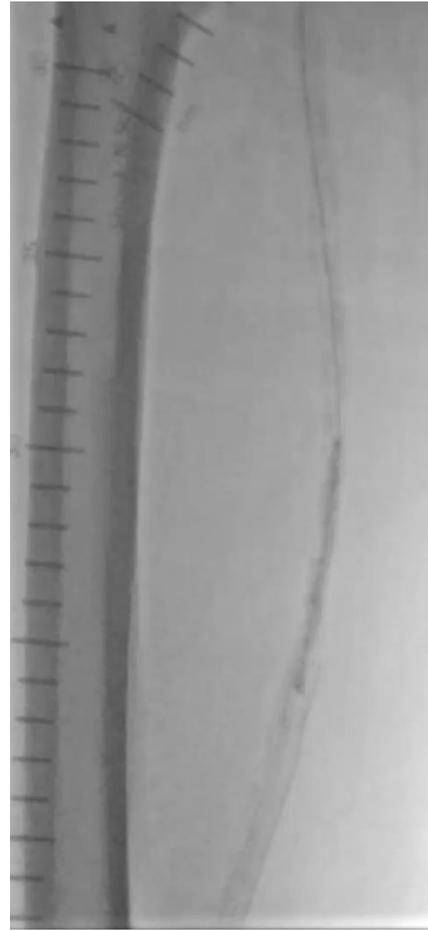
# IVUS



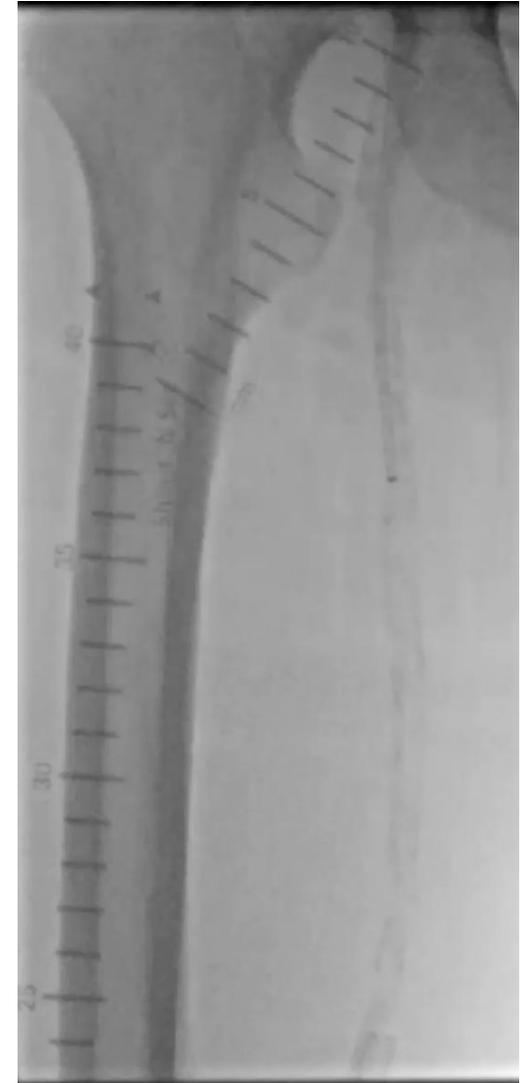
IVUS = intravascular ultrasound.

# Unable to Advance the Bolt 7

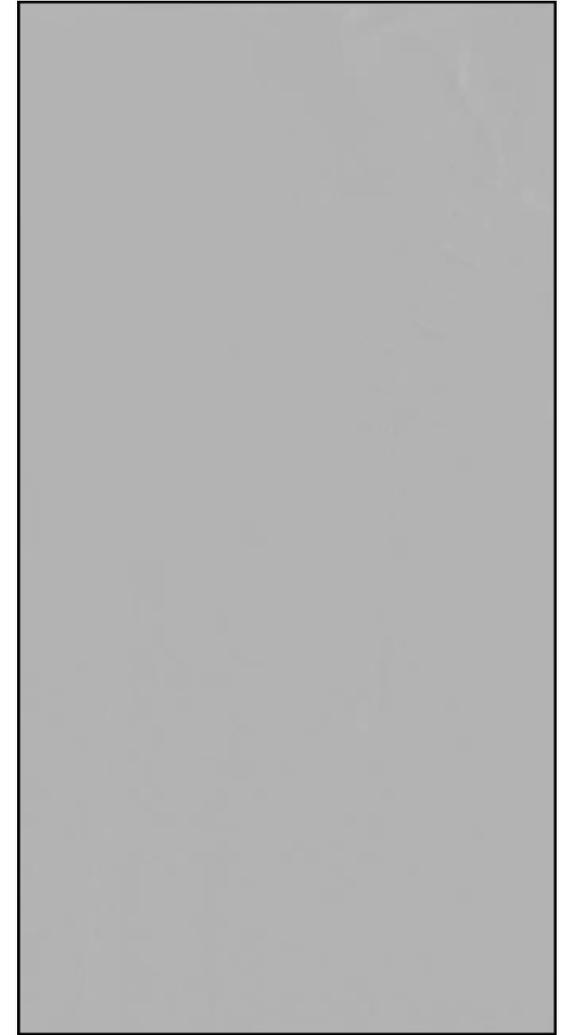
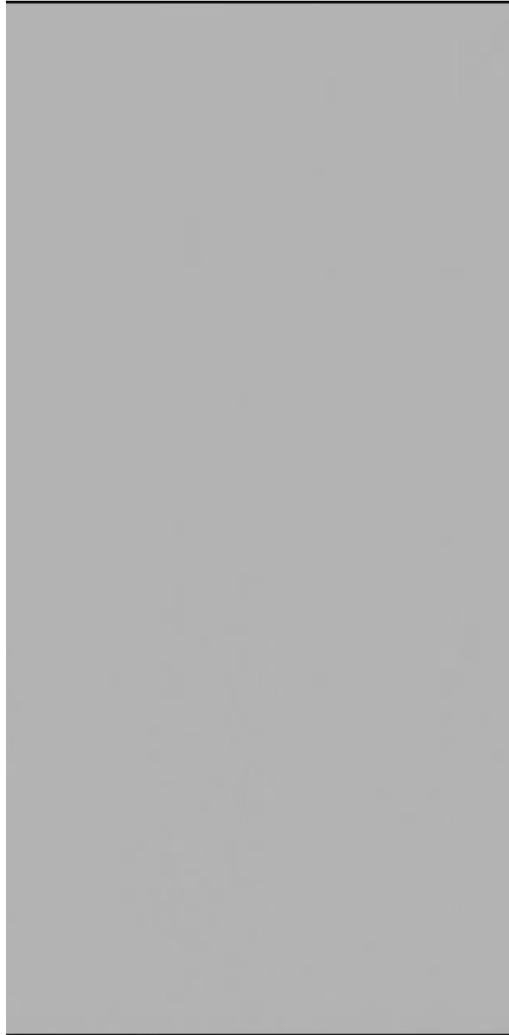
# Intravascular Lithotripsy



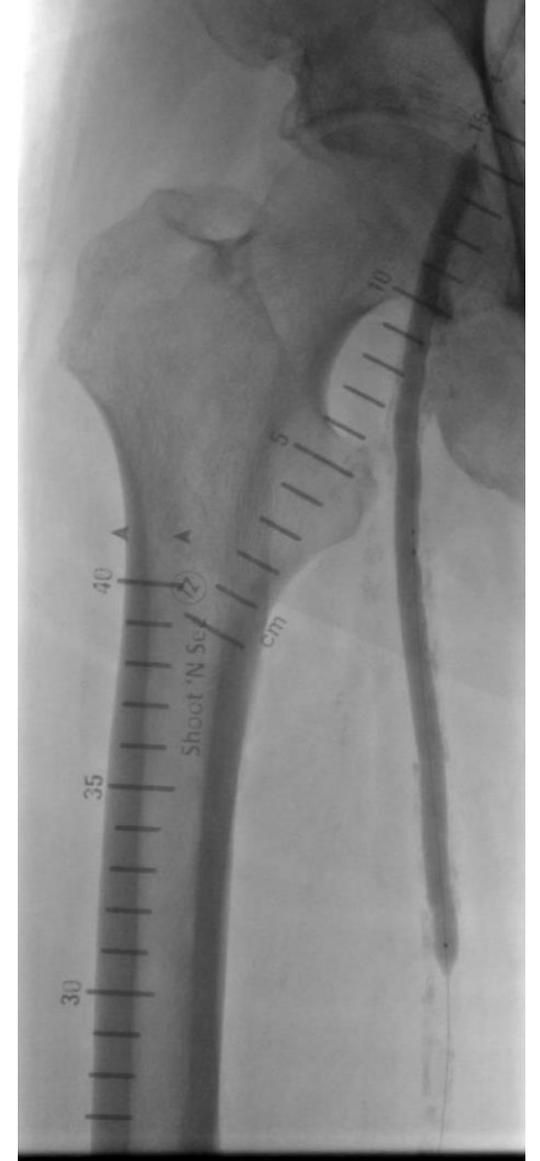
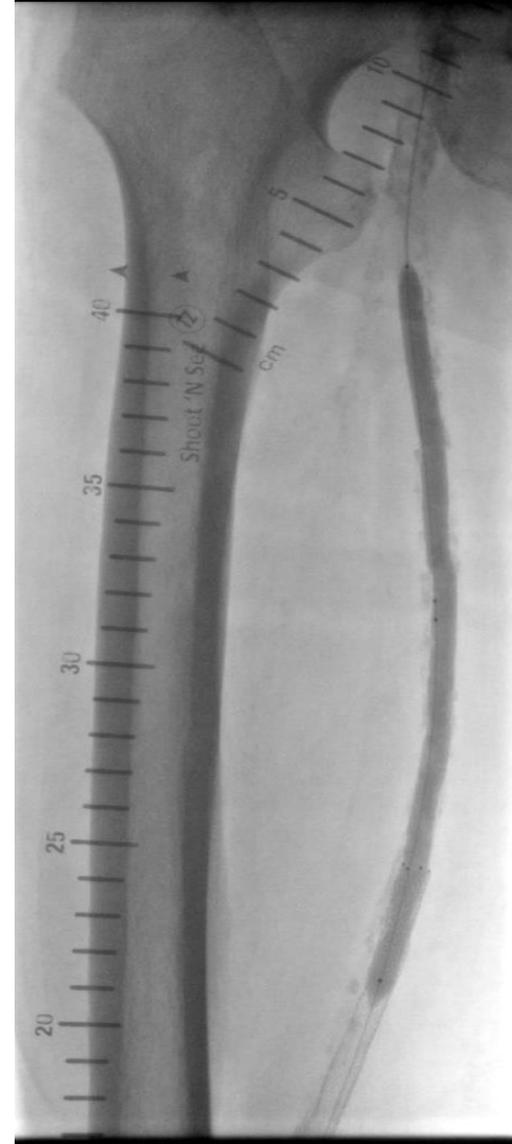
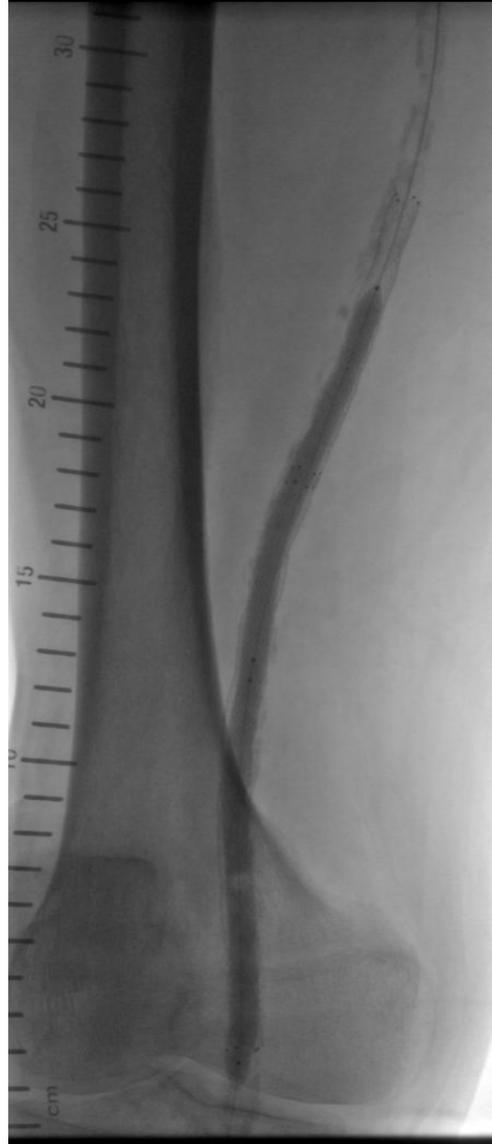
# Bolt 7



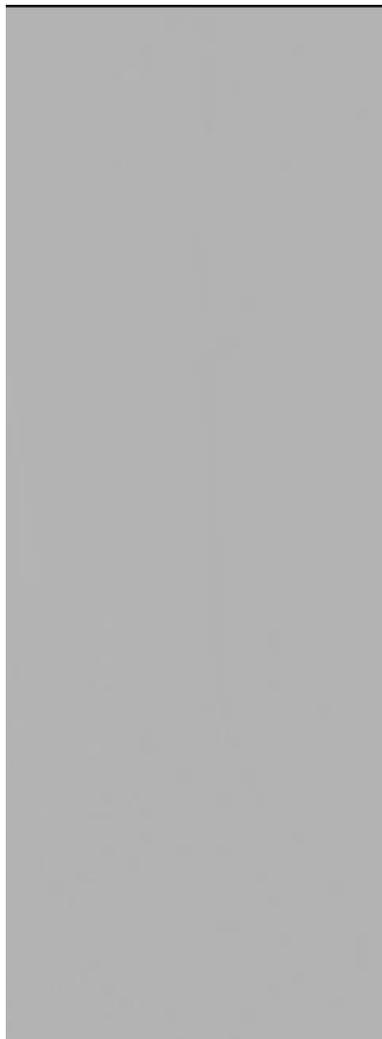
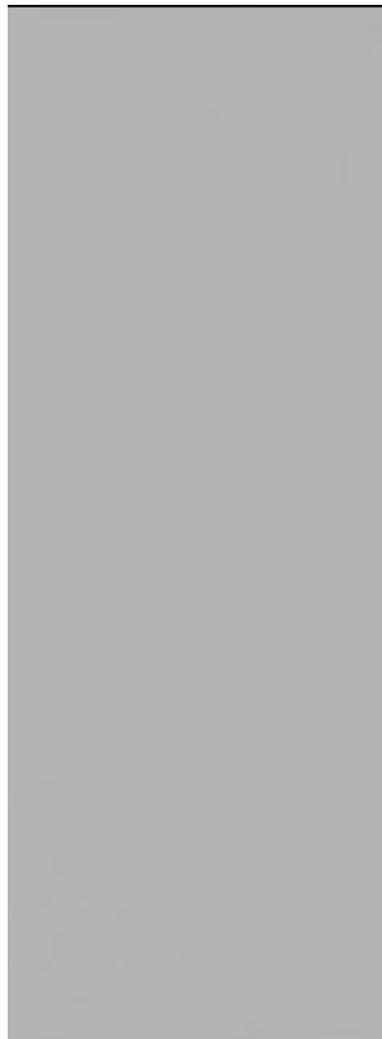
# Post-Bolt 7 Angiograms



# Drug-Coated Balloon Angioplasty



# Final Angiograms

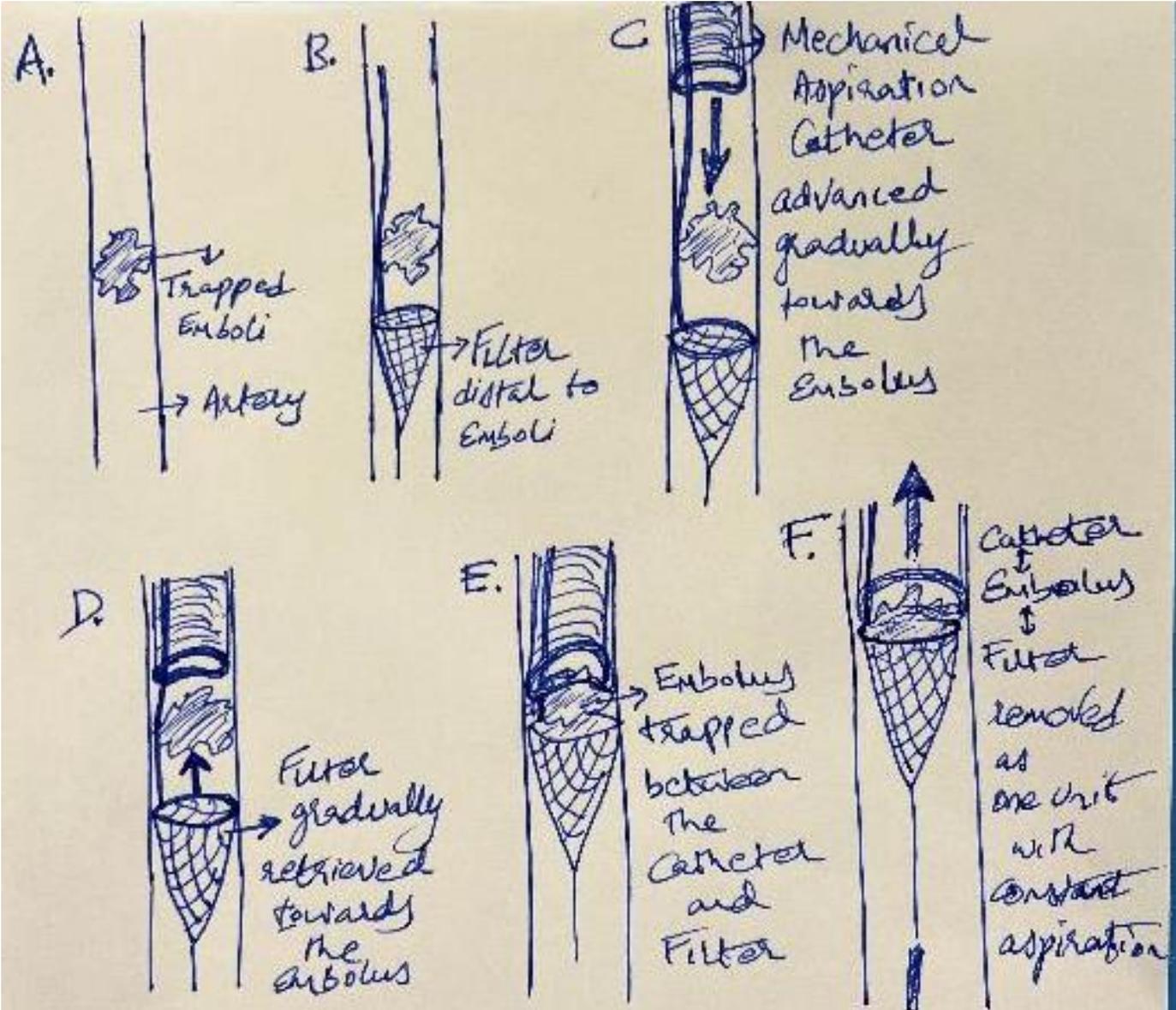


# Right Popliteal and SFA Angiograms



**Thanks**

# Removal of Debris Using the Filter



# Bolt 7 Technique

Define Clot

- 1) Length
- 2) Branches
- 3) ISR
- 4) Bypass Graft
- 4) Embolic

1) Connect (F to F)

- 2) Engage when close
- 3) Engage Head or Tail
- 4) First Engage

Do NOT cross to THEN ASPIRATE

Clot Aspirated with Lightning Mode then ALGORITHM

↓

BOLT MODE

WAIT 20 secs for Bolt to work, then ~~Reassess~~

Tongue @ Lightning / Stop @ Bolt

---

**CROSSED**

→ Blood Flowing  
Remove with Aspiration  
Clean Hemostat Valve  
Angio / IVUS

→ Blood NOT Flowing  
Pull back to patent lumen  
Check tubing

[REDACTED]

Remove with Aspiration to reassess

**NOT CROSSED**

Blood flowing  
Pull back to patent lumen  
Re Engage the Clot Area  
(Closed or Blood Lost)

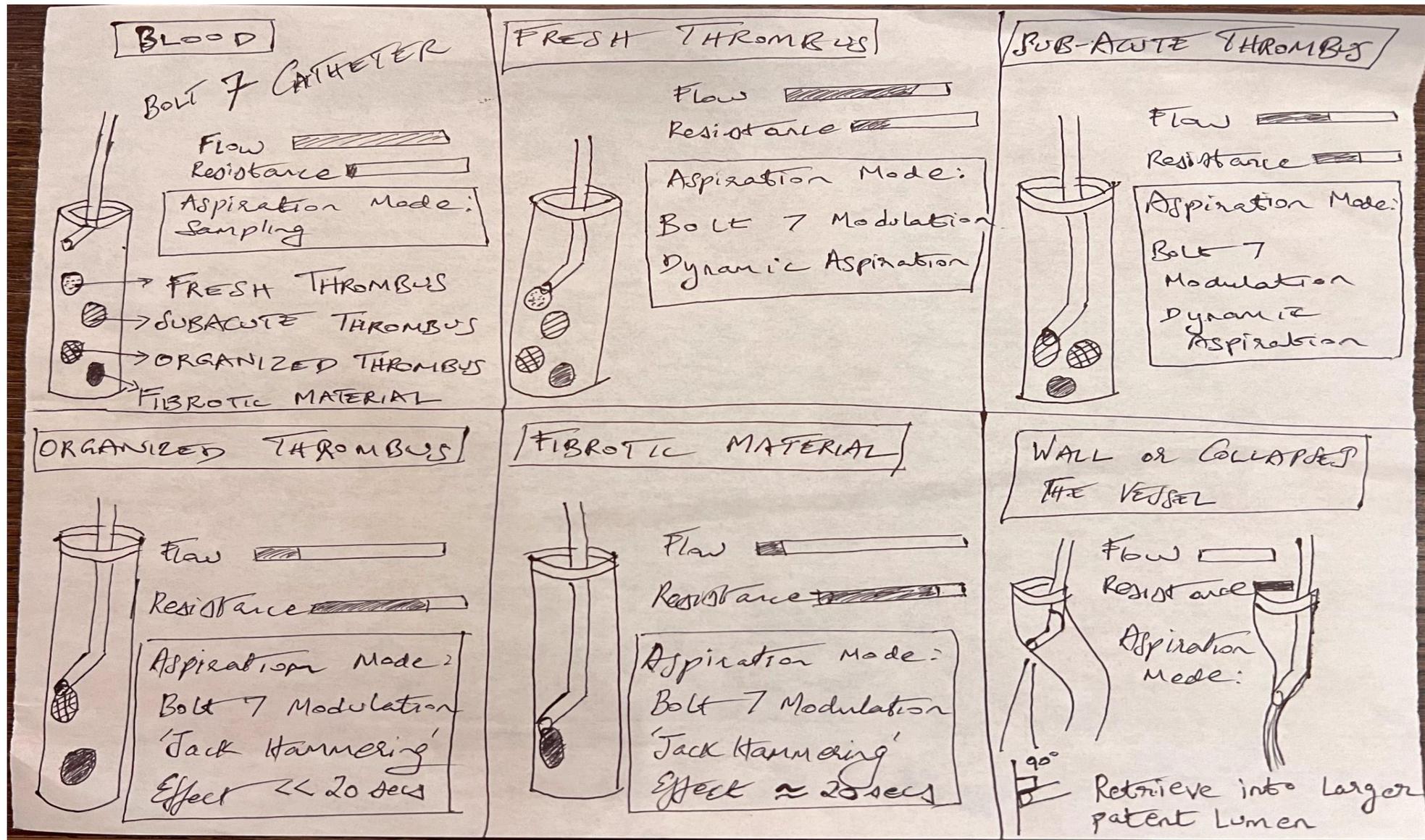
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Blood NOT flowing  
Pull back gently to Patent lumen  
Check tubing to H

[REDACTED]

Remove with Aspiration to reassess

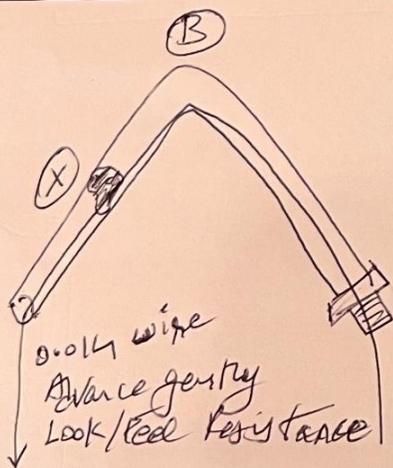
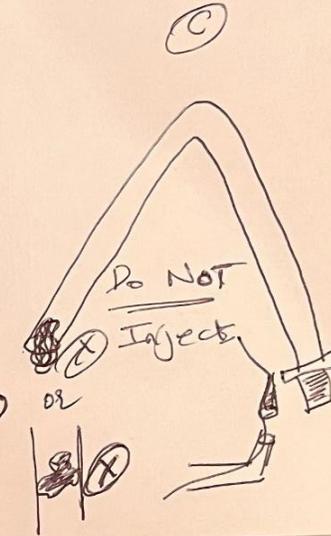
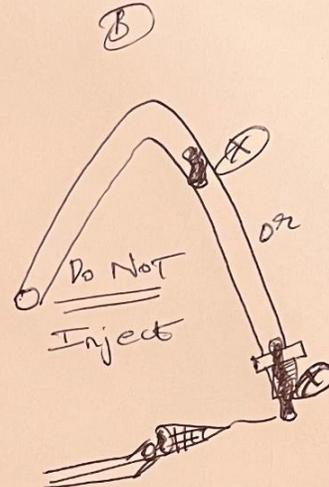
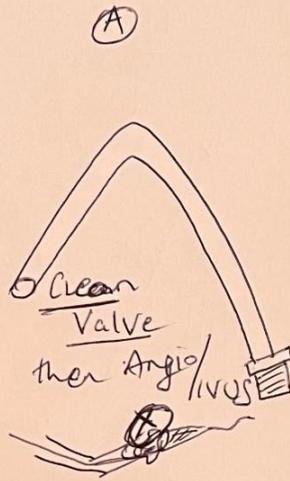
# Dynamic Bolt Modulation Behaviors



# Resistant Filling Defect

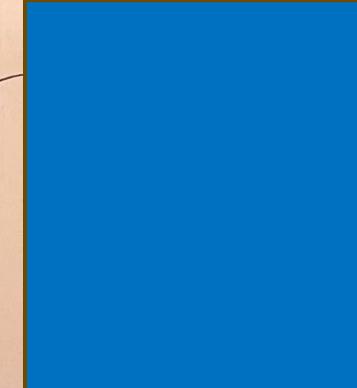
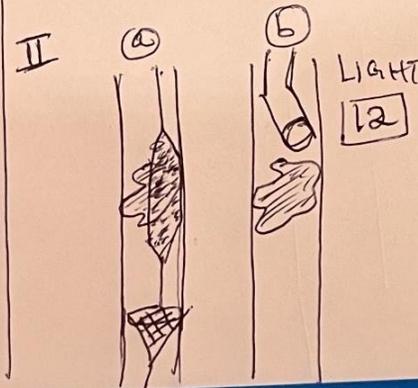


Trap  
 ↓  
 Sandwich  
 ↓  
 Aspirate  
 Remove as one unit



Remove Guiding  
 Sheath  
 ↓  
 Aspiration  
 leaving stiff  
 0.014 wire  
 for  
 ASST Access

I Think Surgery



# Objective Analysis of Bolt Modulation

