

# **Low Profile Endografts:**

***Expanding Treatment Options in Poor Iliac Access Patients***

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# Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

## Affiliation/Financial Relationship

- Grant/Research Support
- Consulting Fees/Honoraria
  
- Major Stock Shareholder/Equity
- Royalty Income
- Ownership/Founder
- Intellectual Property Rights
- Other

## Company

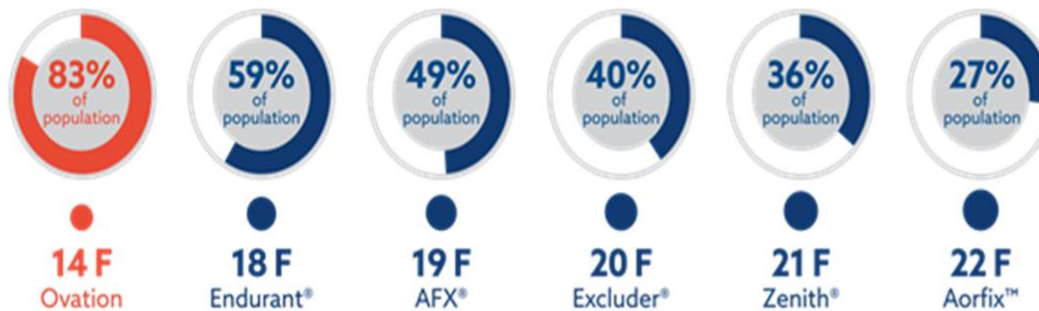
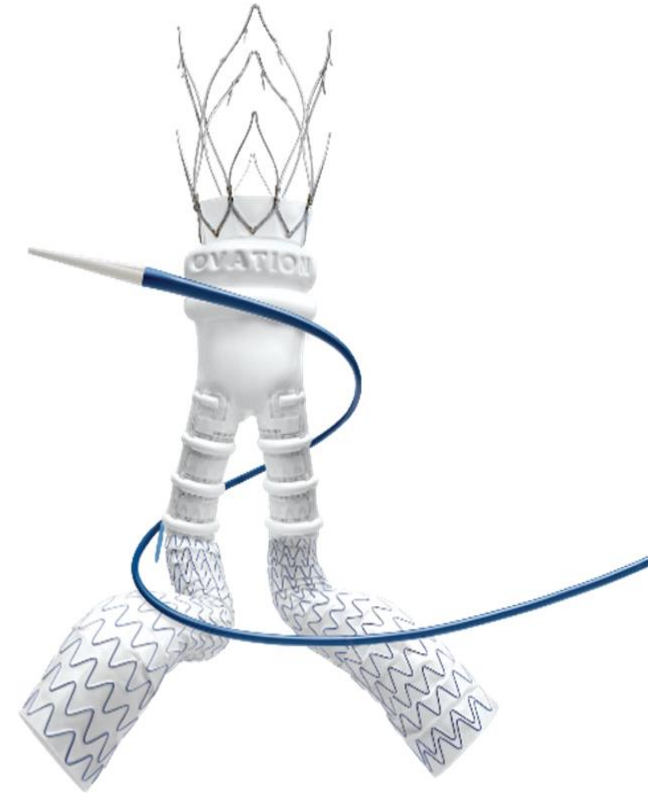
- None
- Abbott, Endologix, Boston Scientific, CSI, Medtronic, Bard
  
- None
- None
- None
- None
- None

# EVAR Background Considerations

- **Access: major determinant of amenability to an EVAR procedure**
- **↑ % of EVAR's are done percutaneously**
- **↑ % of EVAR's are done w/o anesthesia**
- **Low Profile systems → ↑ # EVAR cases**
- **A well-performing low profile system should ↑ % of P-EVAR cases, with shorter hospital stays and lower costs**

# Access size : Amenable to EVAR (IFU)

- Lowest profile of any FDA approved EVAR device
- Highly flexible limbs & delivery system
- CustomSeal™ polymer sealing ring conforms to each patient anatomy and protects the neck



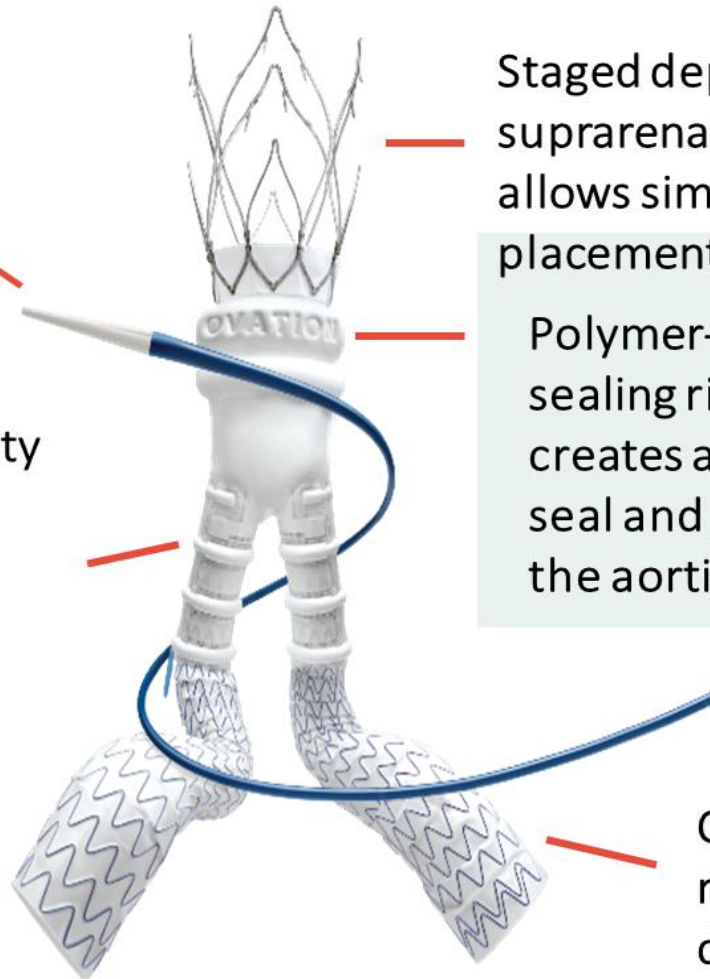
Dimensions listed are system outer diameters (OD)

**12F**

# Ovation Platform

14F OD ultra-low profile system enables smooth aneurysm access

Low permeability PTFE enables effective aneurysm exclusion and device patency



Staged deployment of suprarenal stent allows simple, precise placement

Polymer-filled sealing ring creates a custom seal and protects the aortic neck



Conformable, kink resistant PTFE iliac limbs designed to reduce risk of occlusion

# Premise of Fast-Track EVAR

## Traditional EVAR

- Femoral artery exposure<sup>1,2</sup>
- General anesthesia<sup>1</sup>
- ICU stay<sup>3</sup>
- 2 to 3 day LOS<sup>4,5</sup>

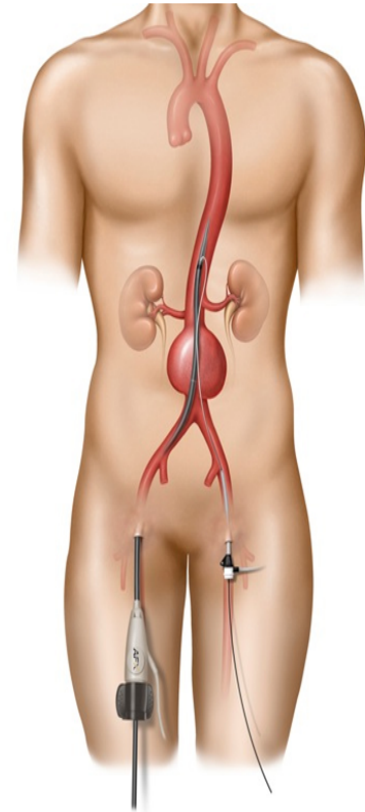
*increases perioperative morbidity  
and contributes to overall cost of  
EVAR*



## FAST-TRACK EVAR

- Percutaneous access
- No general anesthesia
- No ICU time
- Next-day discharge

*improves patient outcomes,  
patient satisfaction, and  
healthcare resource utilization*



1. Lederle et al. JAMA 2009;32(14):1535-1542
2. Manunga et al. J Vasc Surg 2013;58(5):1208-12. Mayo Clinic Study of PEVAR; 30% applicability based on anatomic criteria, with 23% bilateral / 7% unilateral PEVAR
3. The Endologix PEVAR Trial, Mean ICU Stay 1.3 (ProGlide) and 1.8 (Cutdown) days: Nelson et al. J Vasc Surg 2014;59:1181-94
4. The Advisory Board research and analysis, EVAR ICD-9 procedure code 39.71: 50<sup>th</sup> percentile tier, 2015 MEDPAR data
5. Vascular Quality Initiative (VQI): SVS PSO COPI Report 2014, EVAR across VQI centers from 2011 – 2014

# Least Invasive Fast-Track (LIFE) EVAR Registry

Objective: Demonstrate the clinical and cost benefits associated with the ultra-low profile (14F) *Ovation Abdominal Stent Graft* platform under the least invasive conditions defined in the Fast-Track EVAR protocol:



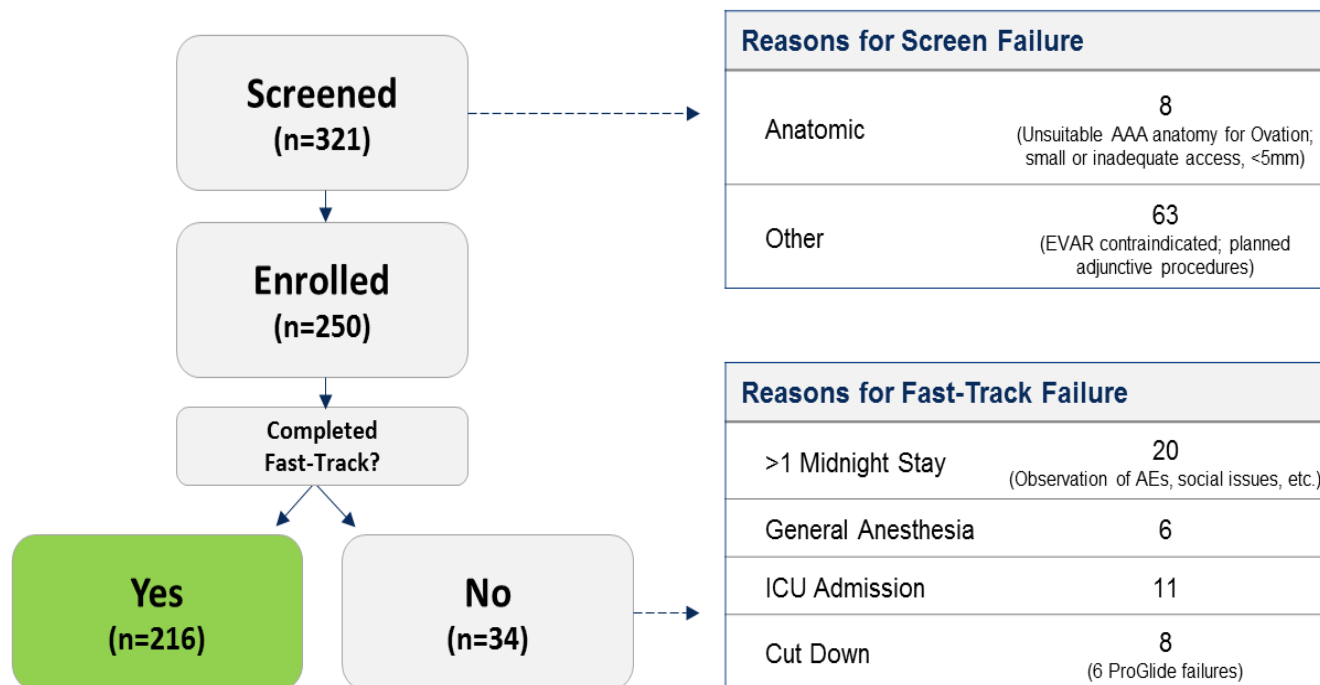
- *Percutaneous Access*
- *No General Anesthesia*



- *No ICU Admission*
- *Next-day Discharge*

# Fast-Track Completion

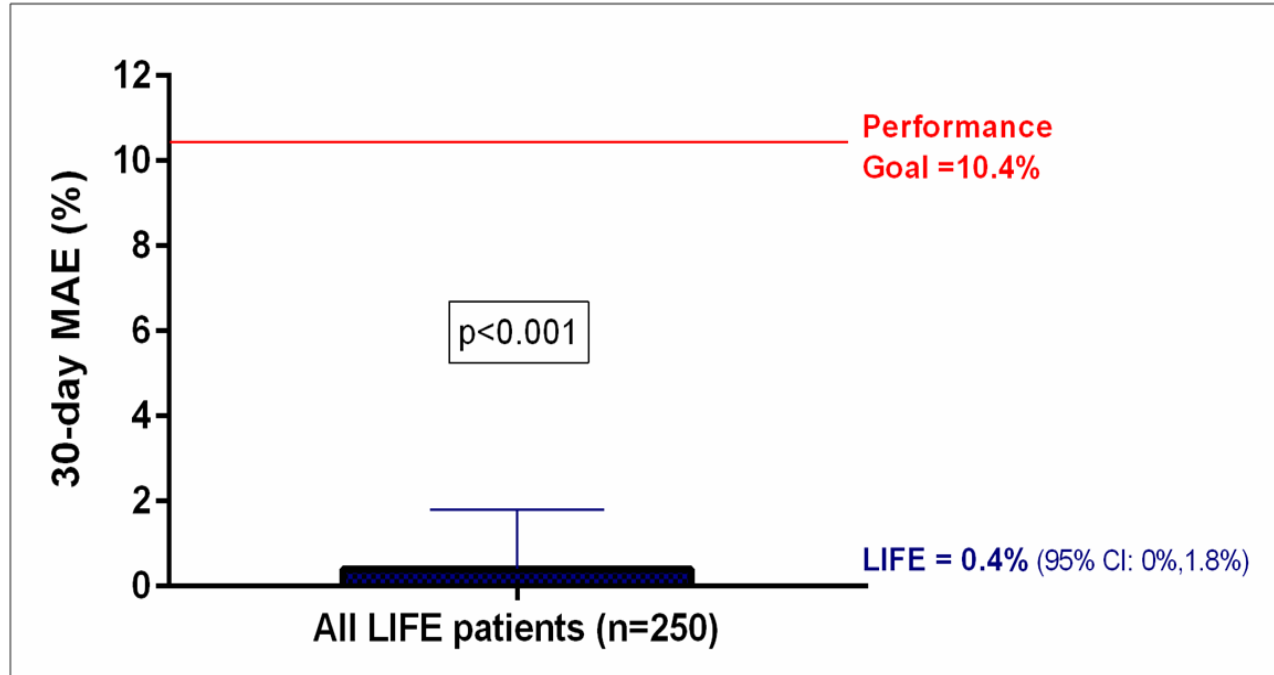
Fast-Track attempted in 100% and completed in 86% of patients;  
Bilateral PEVAR successful in 97% of patients



Note: Subject may have more than one reason for screen failure, or for moving from Fast-Track protocol



# No Device- or Procedure-Related Major Adverse Events



LIFE	Fast-Track	PEVAR	EVAR
0.4% (1/250)	0.5% (1/216) <sup>1</sup>	0% (0/26)	0% (0/8)

<sup>1</sup> MAE non-device nor procedure-related: death due to acute respiratory failure 28 days post procedure  
As of August 2, 2016

# LIFE Fast Track is More Cost Effective

Likely under-estimates savings

	PREMIER EVAR	LIFE FAST-TRACK	SAVINGS
Anesthesia	General, 84% \$500	Local, 100% \$300	\$200
Access	Cutdown* \$300	Bilateral PEVAR \$1,200	(\$900)
ICU	1.4 Days, 51% \$15,300	0 Days, 0% \$0	\$15,300
Non-ICU	2.3 Days \$12,900	1.2 Days \$6,700	\$6,200
30 day Reintervention	\$29.4k, 1.1% \$300	0% \$0	\$300
<b>TOTAL</b>	<b>\$29,300</b>	<b>\$8,200</b>	<b>\$21,100</b>

Average Costs per Patients

Index anesthesia costs based on all charge master line items related to anesthesia

\*30% applicability based on anatomic criteria, with 23% bilateral / 7% unilateral PEVAR (Manunga et al, J Vasc Surg, 2013)

# Fast Track P-EVAR with Ovation



	30-day results	Ovation LIFE EVAR	Traditional EVAR <sup>1</sup>
MAE Device/procedure related		0.5%	3-4%
Procedure Time min		84	110 <sup>2</sup>
ICU days		0	1.4 <sup>2</sup>
LOS days		1.2	2.9 <sup>3,4</sup>
30-day Readmission		1.6%	8%

1. 30d MAE rates for commercially available EVAR devices per US FDA SSED reports and post market global registries. Data on file. 2. Premier EVAR. 3. Chen SL et al. Perioperative Risk Factors for Readmission Following EVAR. Presented at SCVS, 2016. 4. Gupta PK, et al. Unplanned readmissions after vascular surgery. J Vasc Surg 2014;59:473-82.

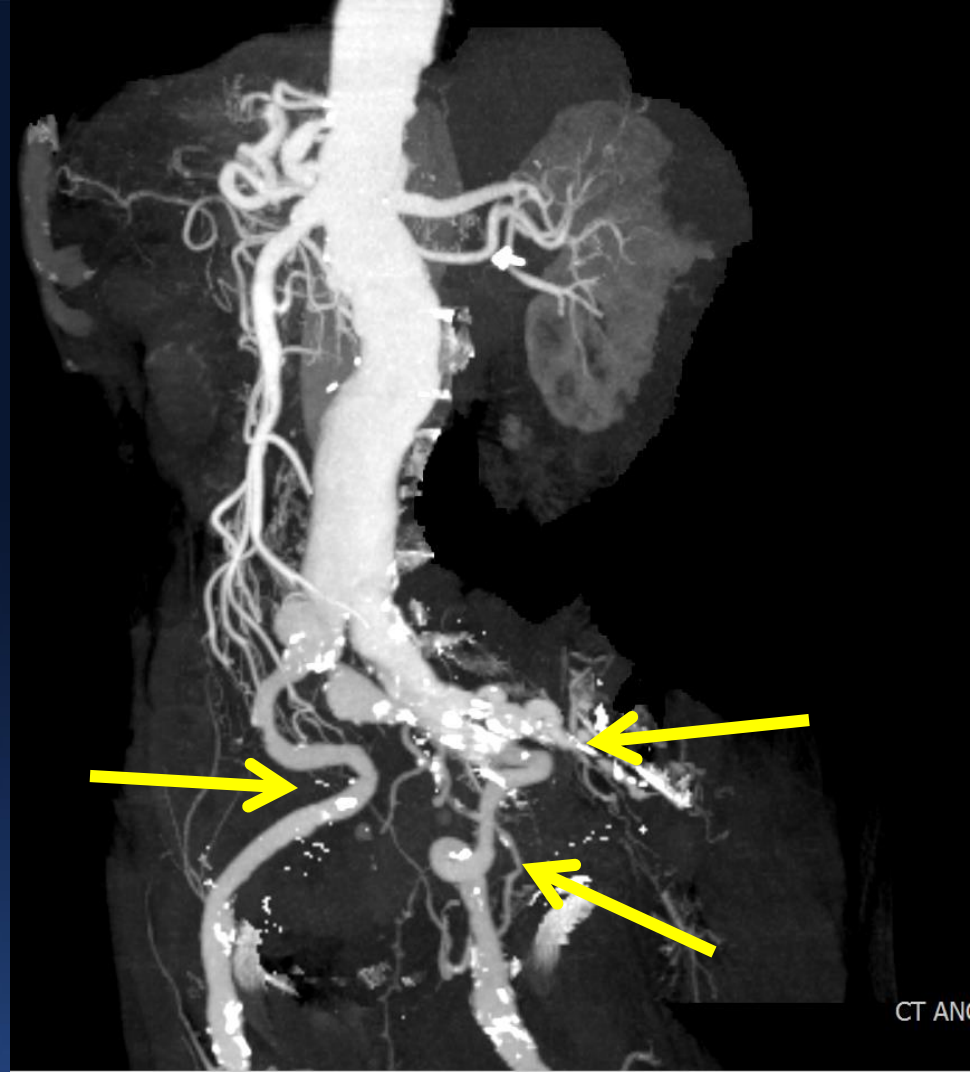
**Avg. Cost saving \$21,000/ procedure**

# Case Presentation #1

- **83 yo male with multiple comorbidities**
- **Severe CAD with CABG 1998; ischemic cardiomyopathy EF 25% with AICD**
- **COPD, former tobacco**
- **Rapidly advancing AAA size 4.3 → 5.7 cm within 6 months; new abdominal pain**
- **CTA: challenging anatomy**



**Juxtarenal angulation**

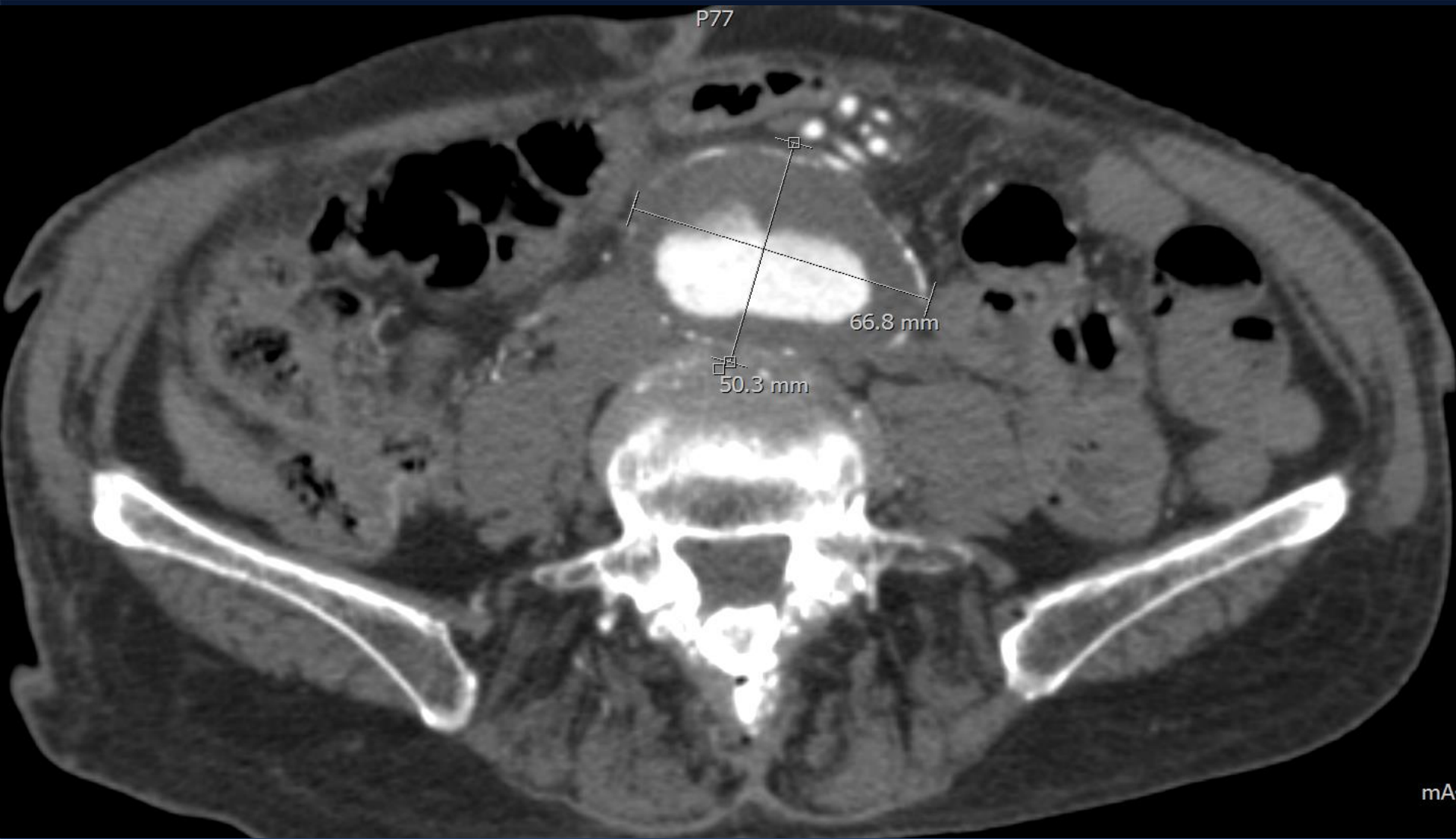


**Iliac tortuosity!**

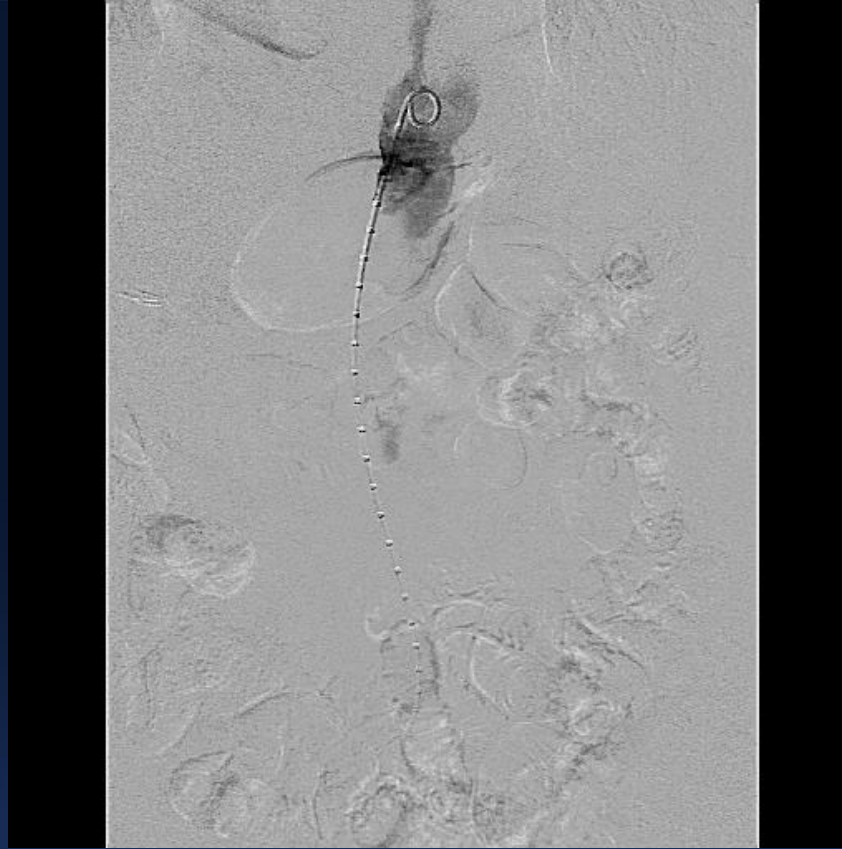


mA49

**Large neck just below renals**

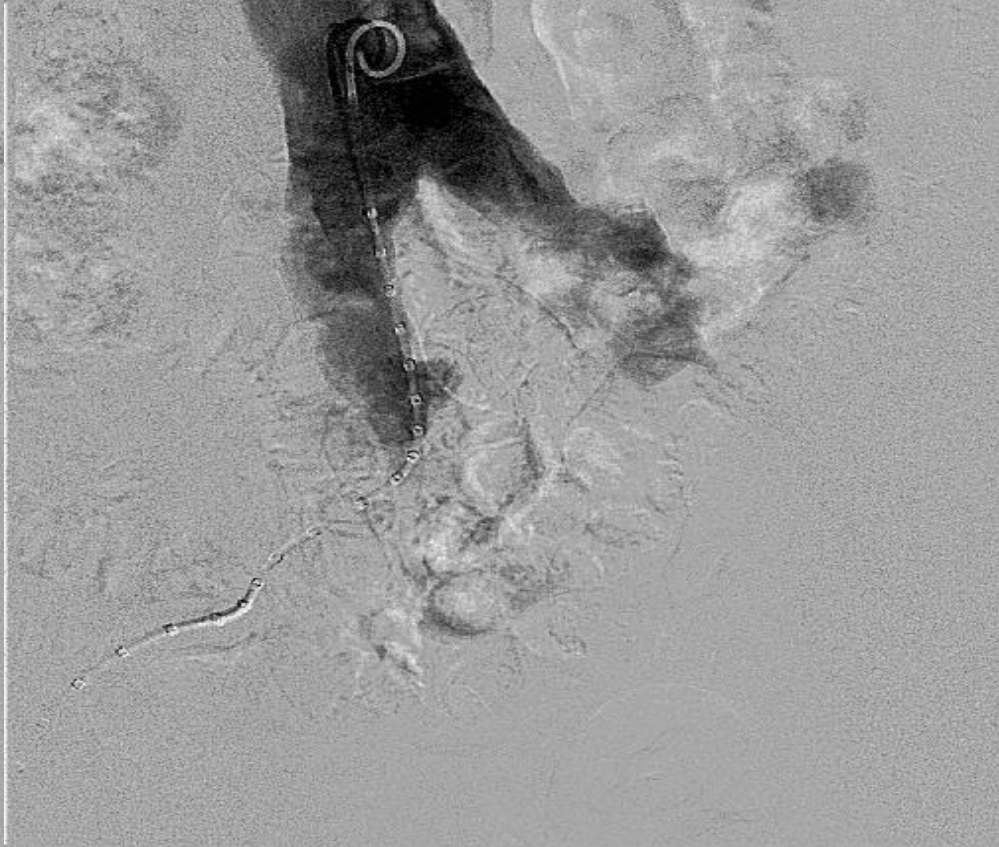
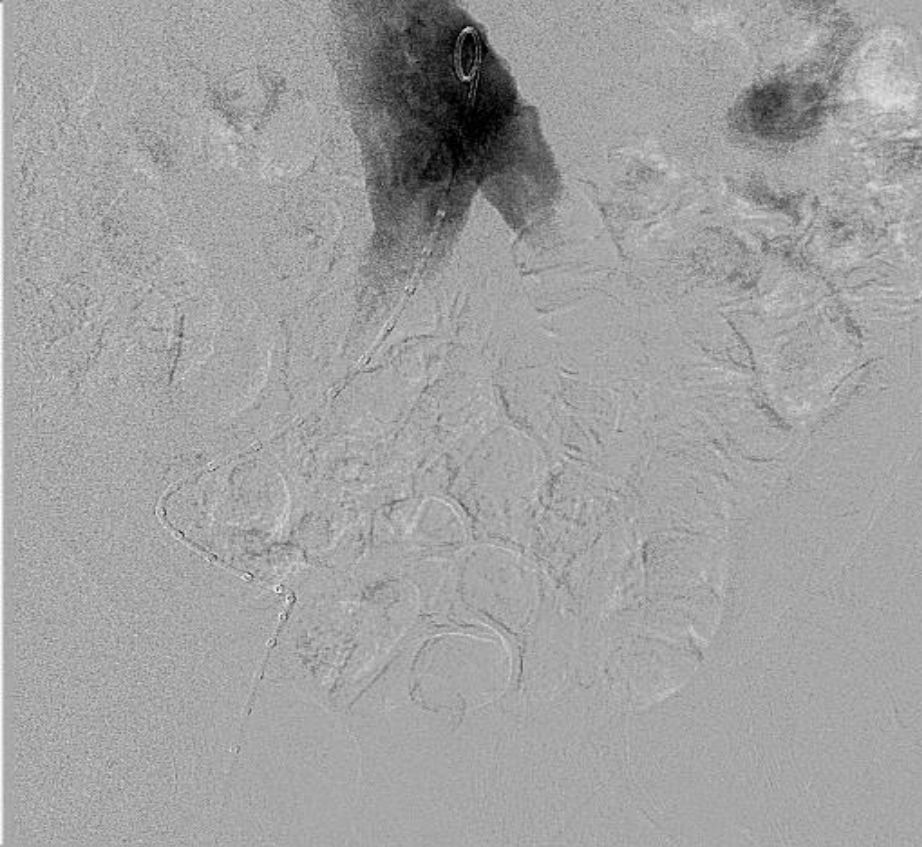


**>5.8 cm with documented ↑↑expansion**

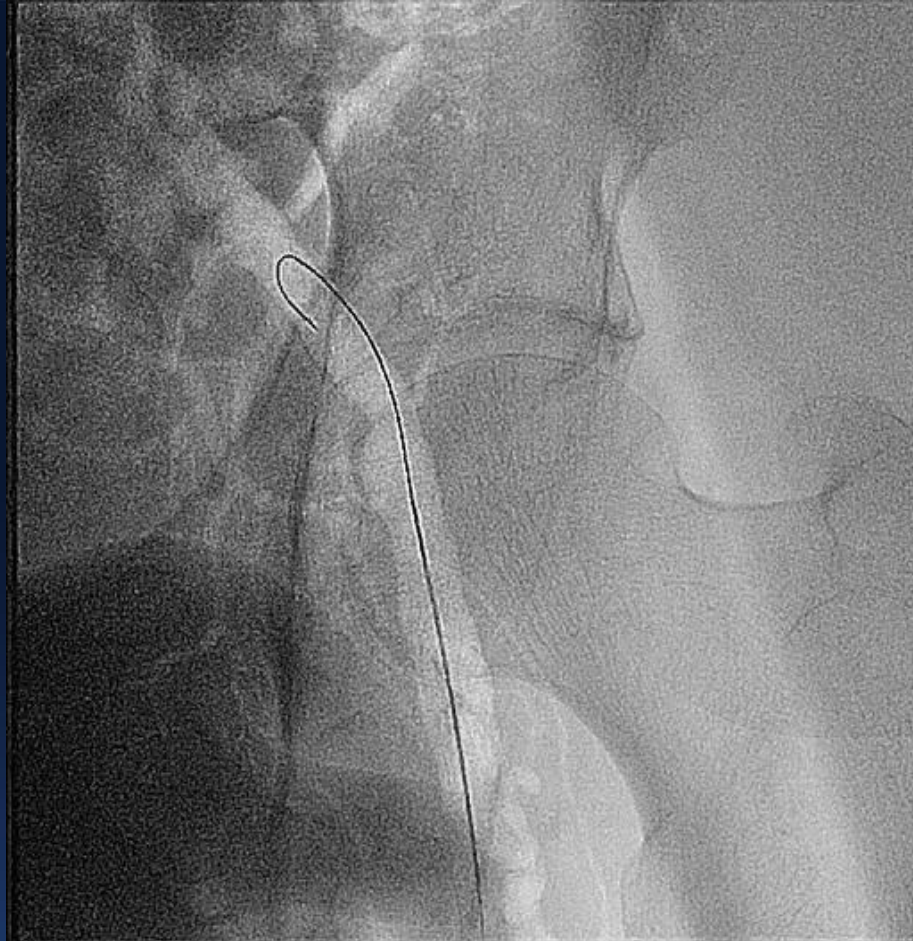
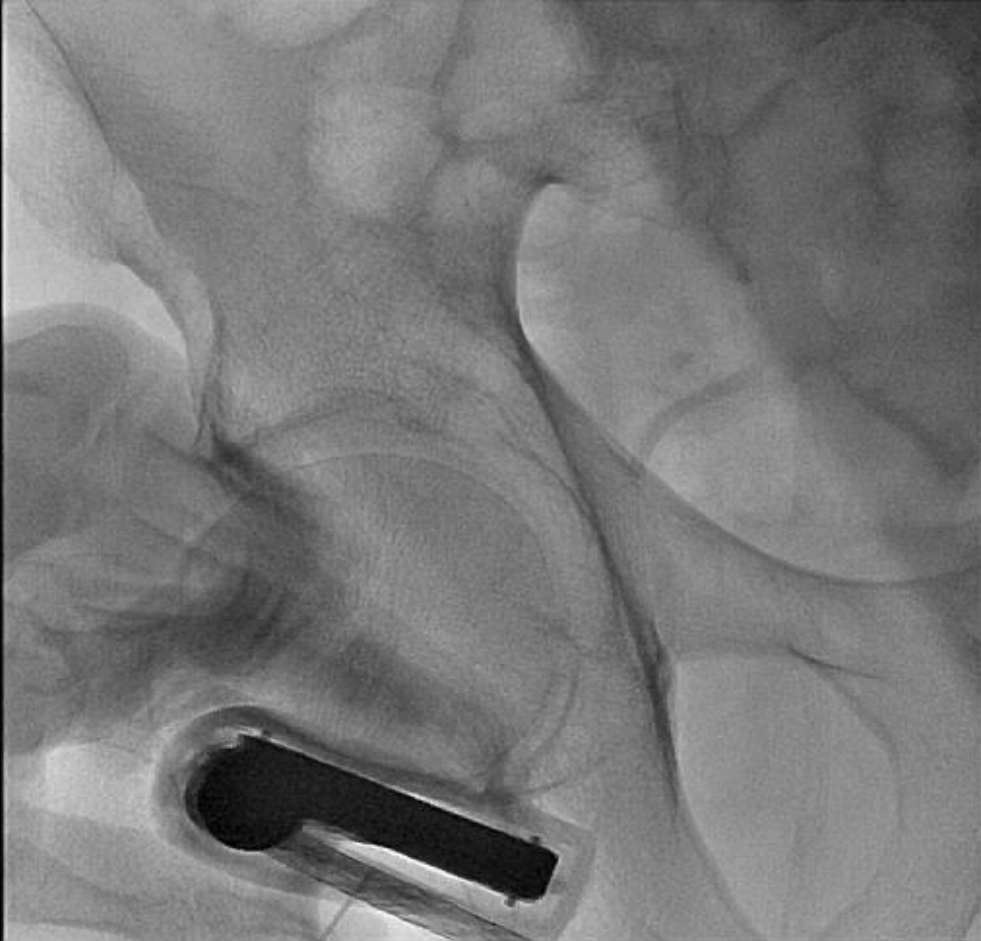


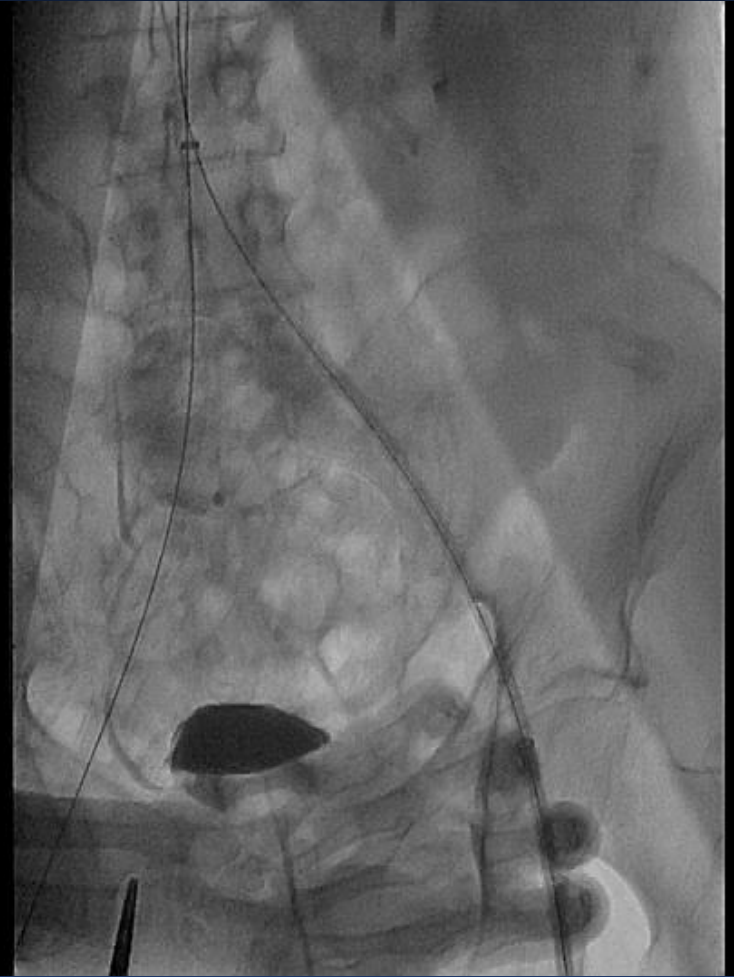
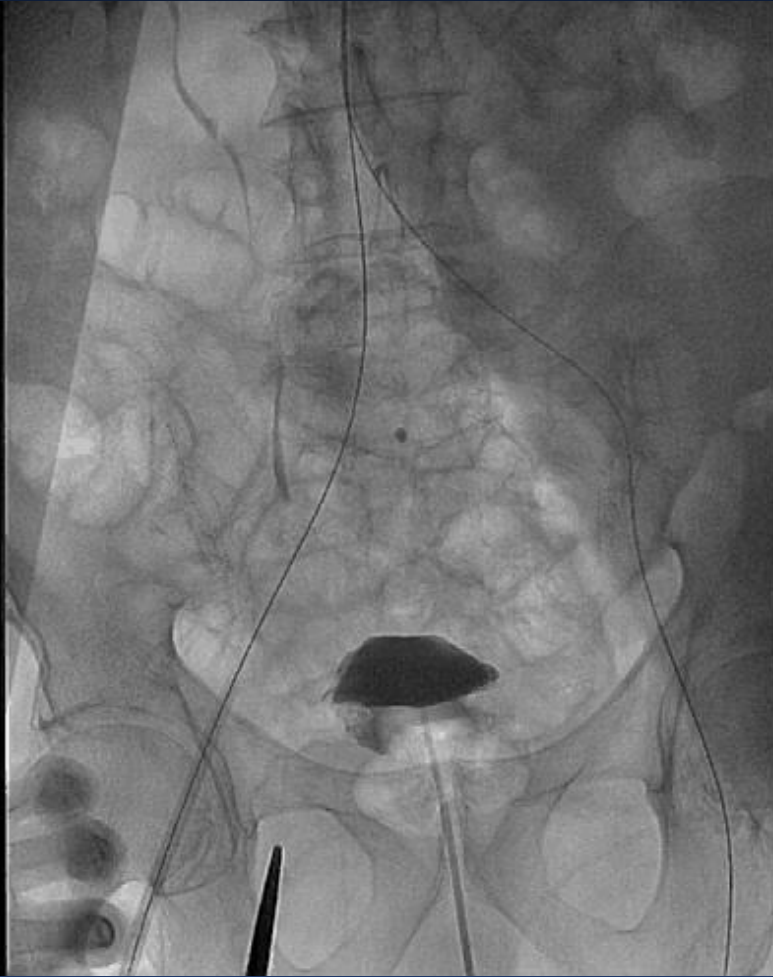
# Angulated Neck and Tortuous Iliacs



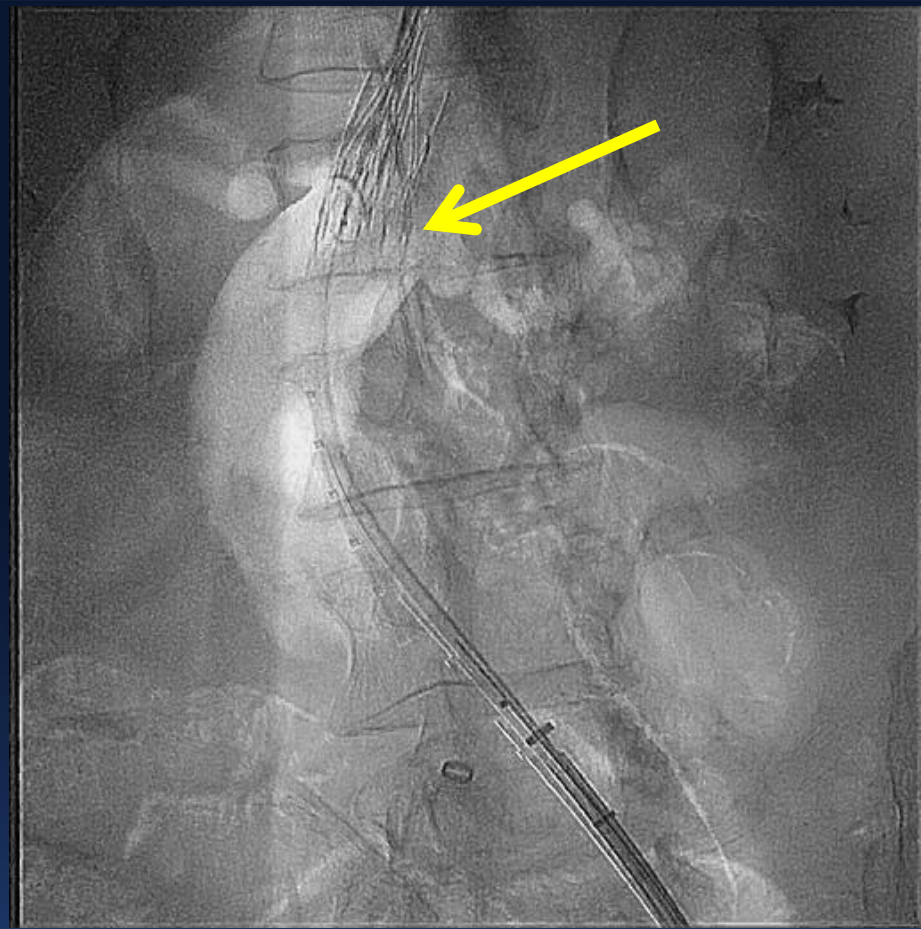


# TORTUOUS Iliacs

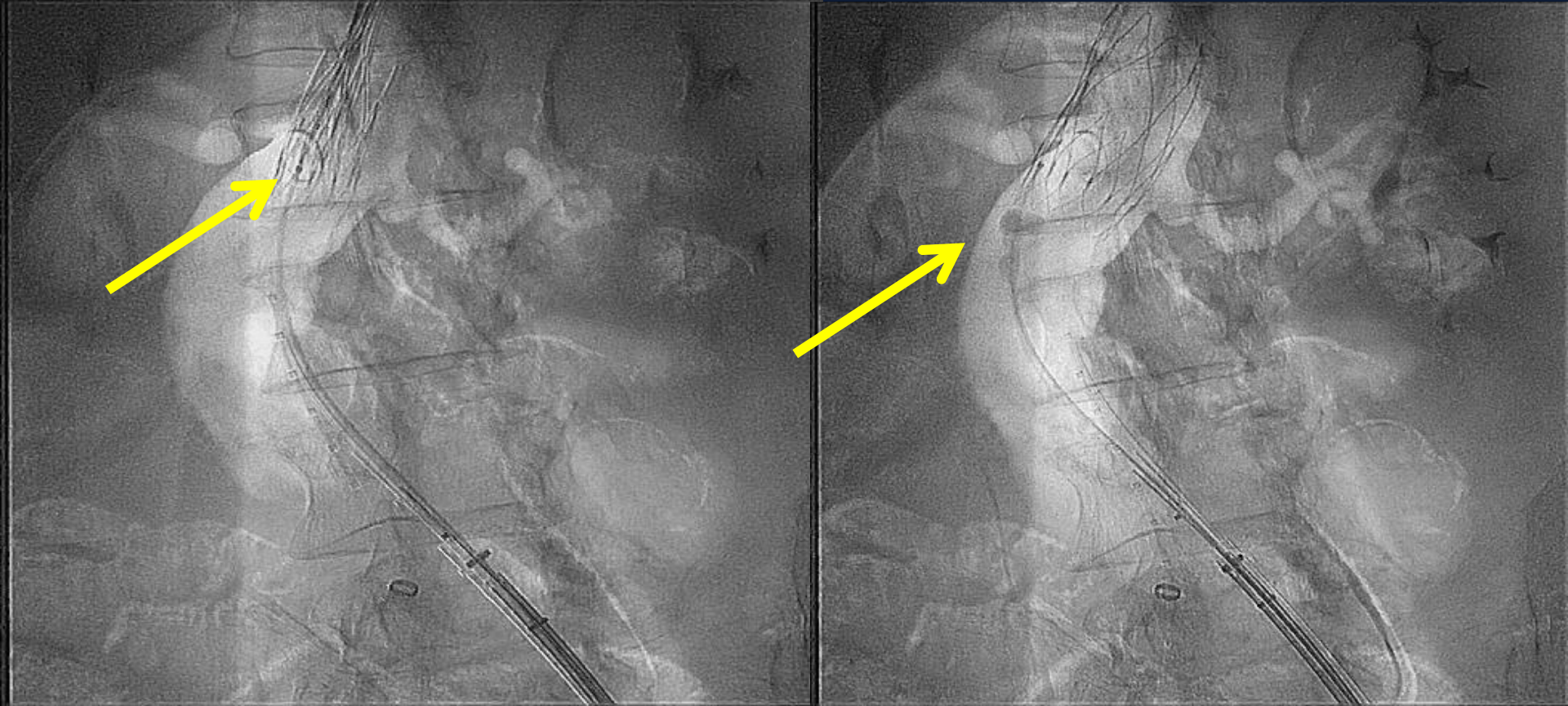




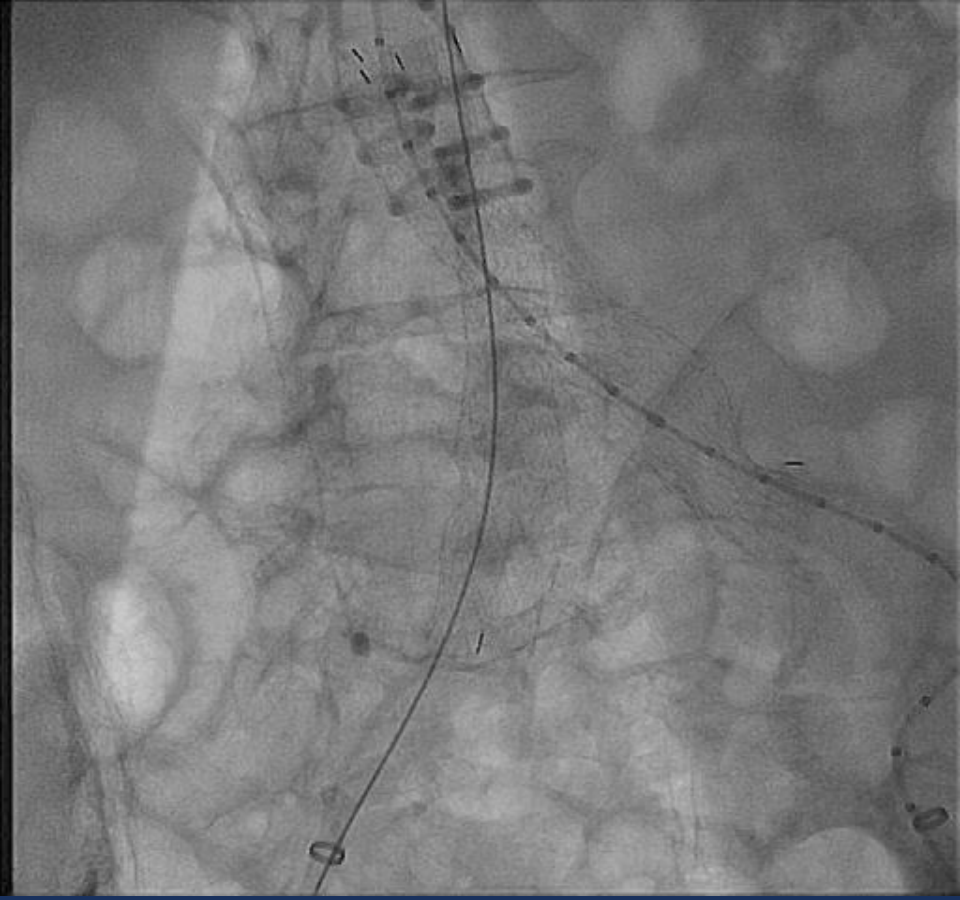
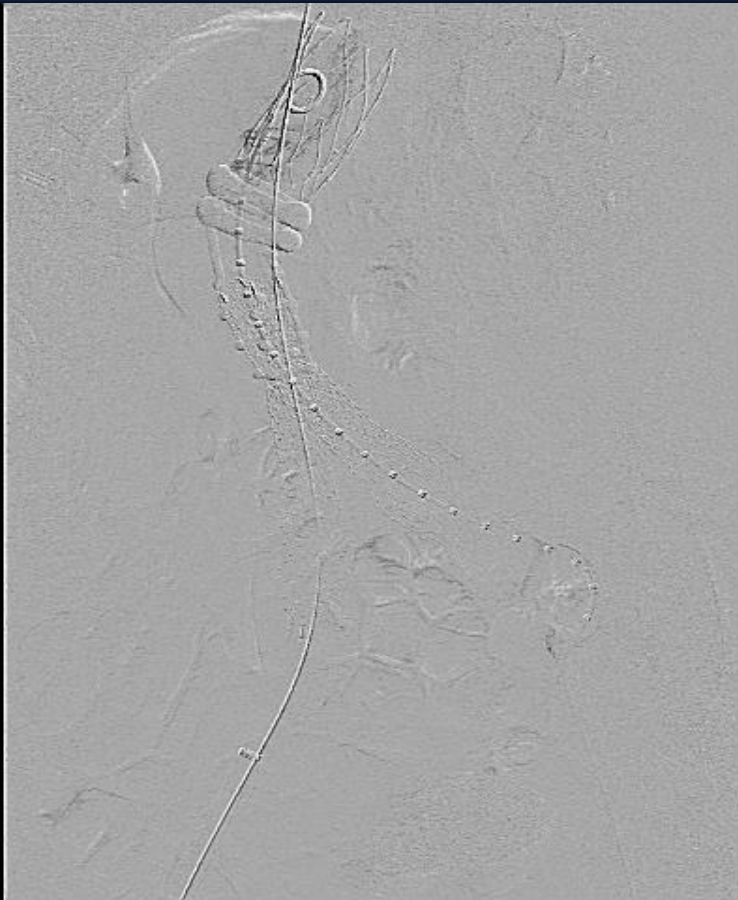
**16F sheaths up right and left-  
Initially over Lundequist, XC to Amplatz SuperStiff  
wires**

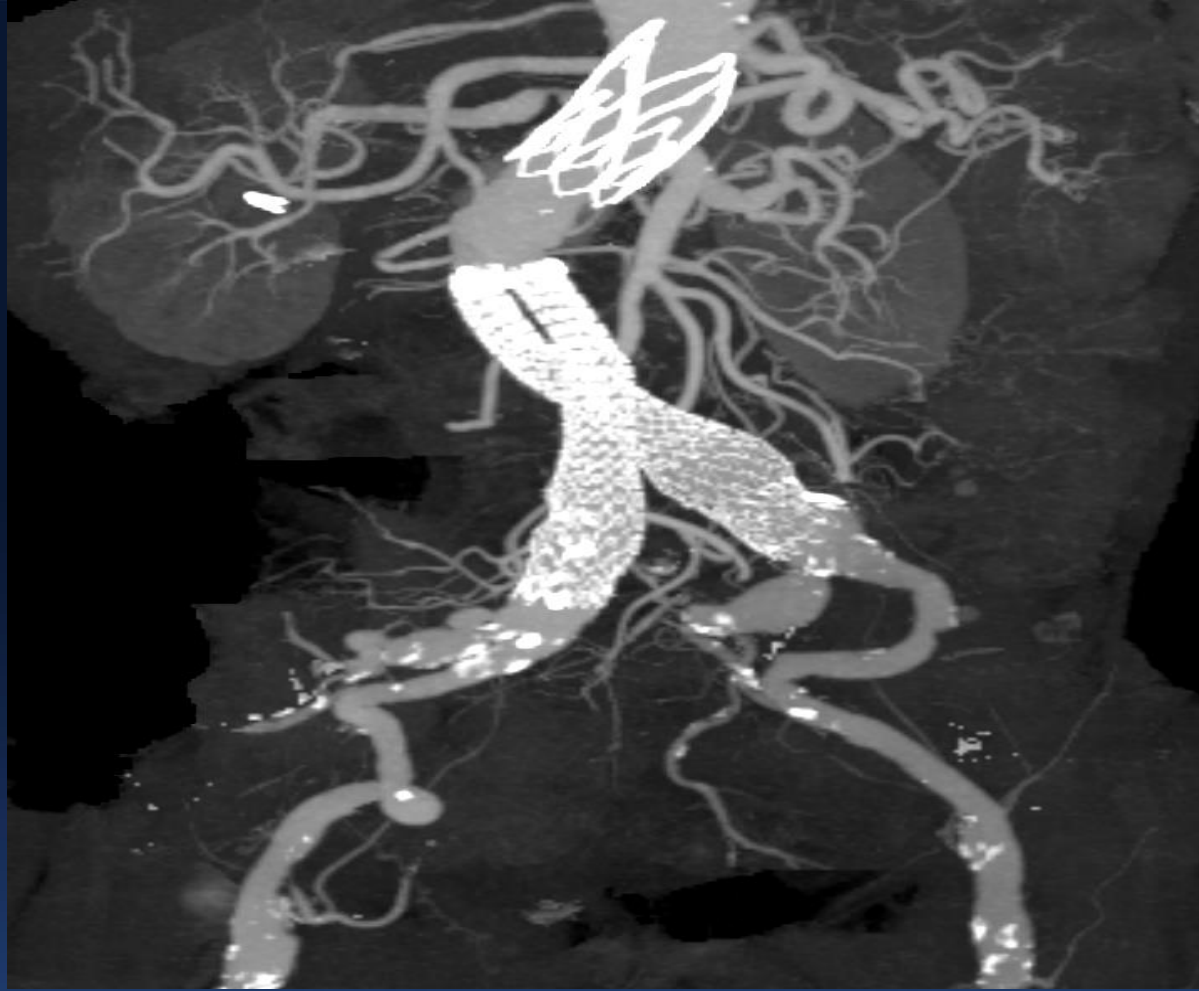


**Aggressive positioning;  
Wire back**



**Wire back, aggressive graft position,  
then forward pressure as ring fills**





**30 day CTA – Iliacs OK, no endoleaks**

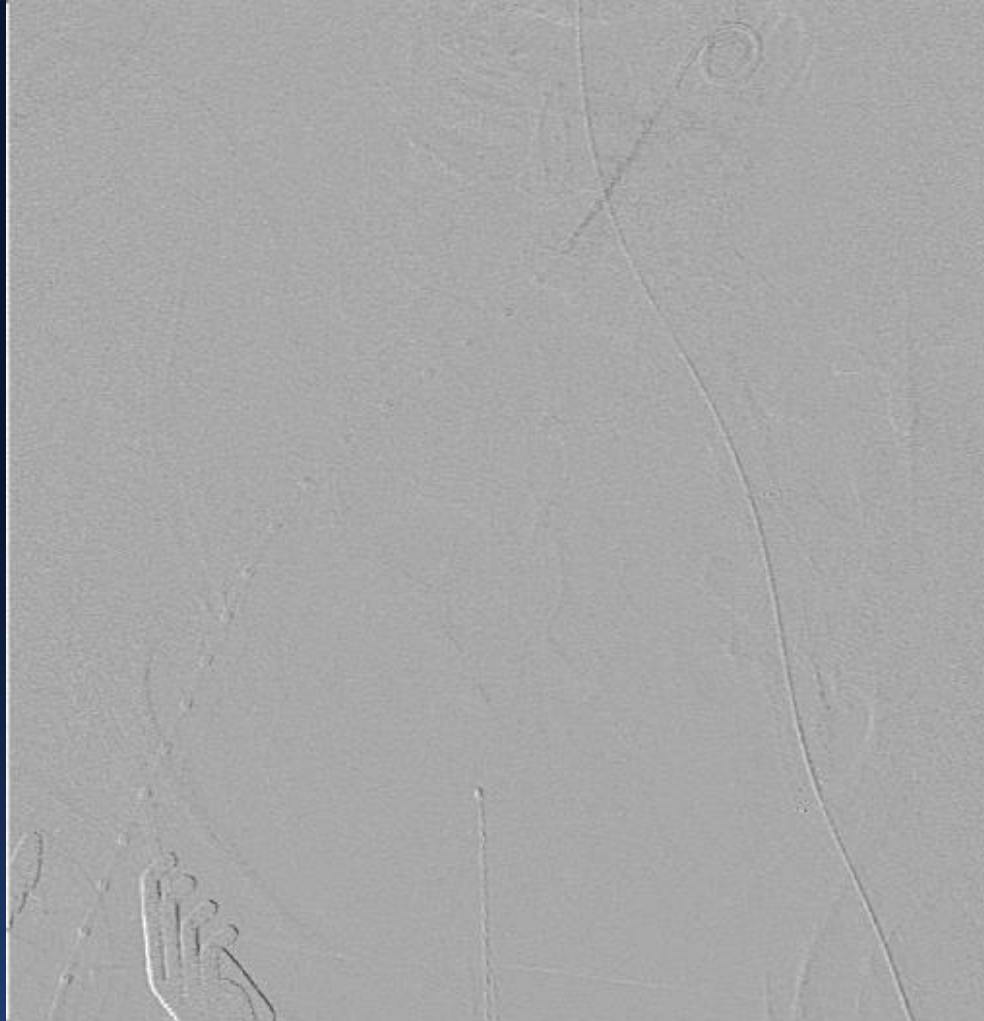
## Case 2



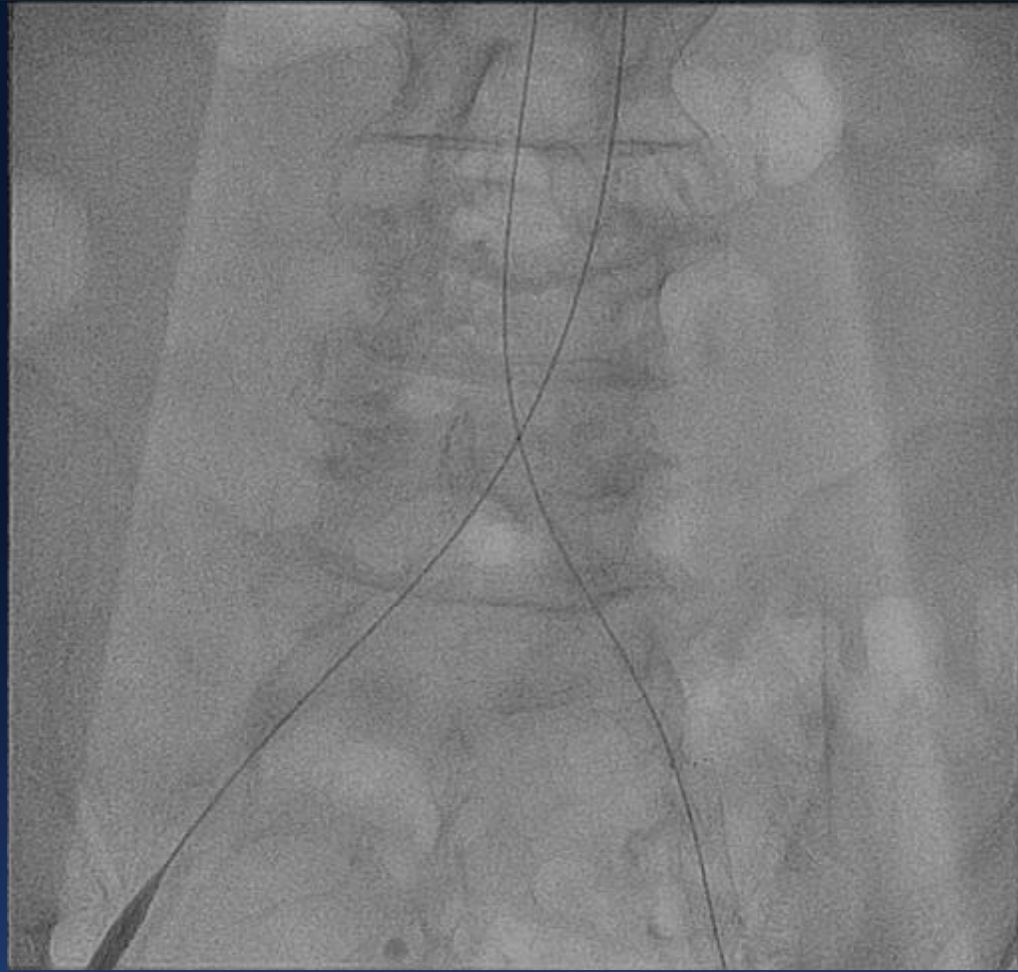
**Enter after R cutdown, trouble w L wiring..**





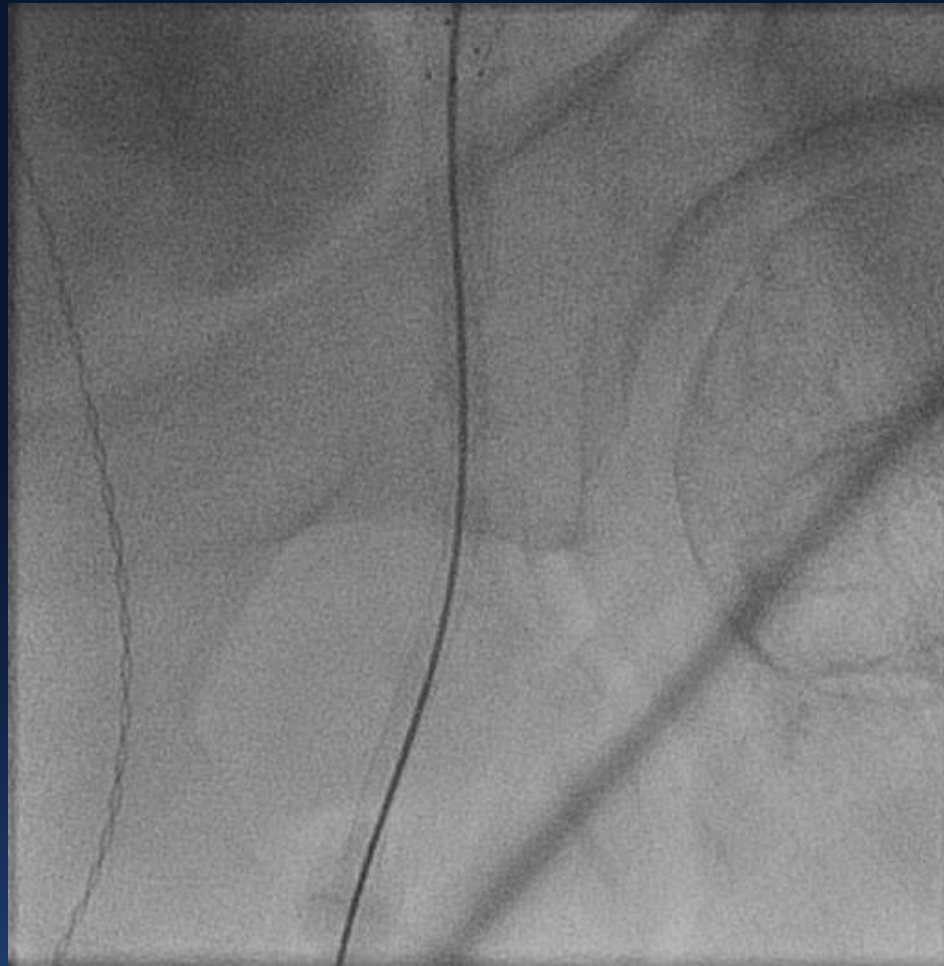


**LEIA stent OK, but iliacs ~ small**

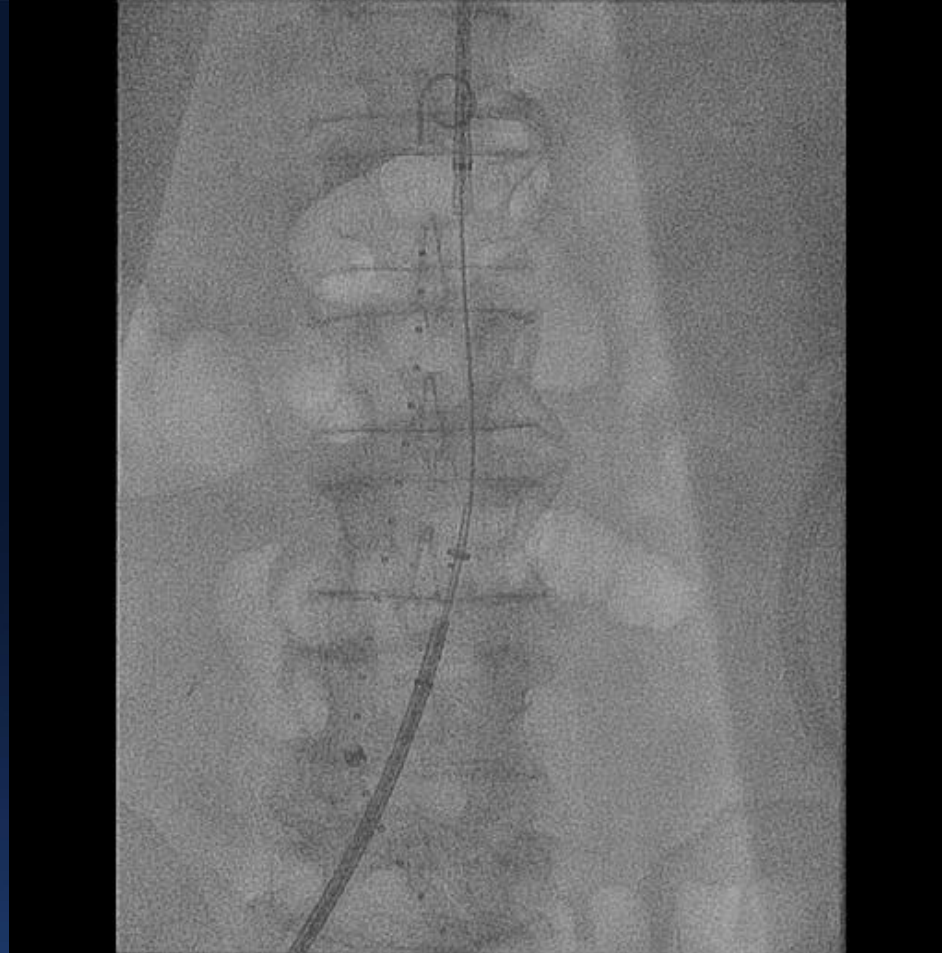


# Trouble getting 12 and 14 F Dilators up

## *Change in EVAR Plan*



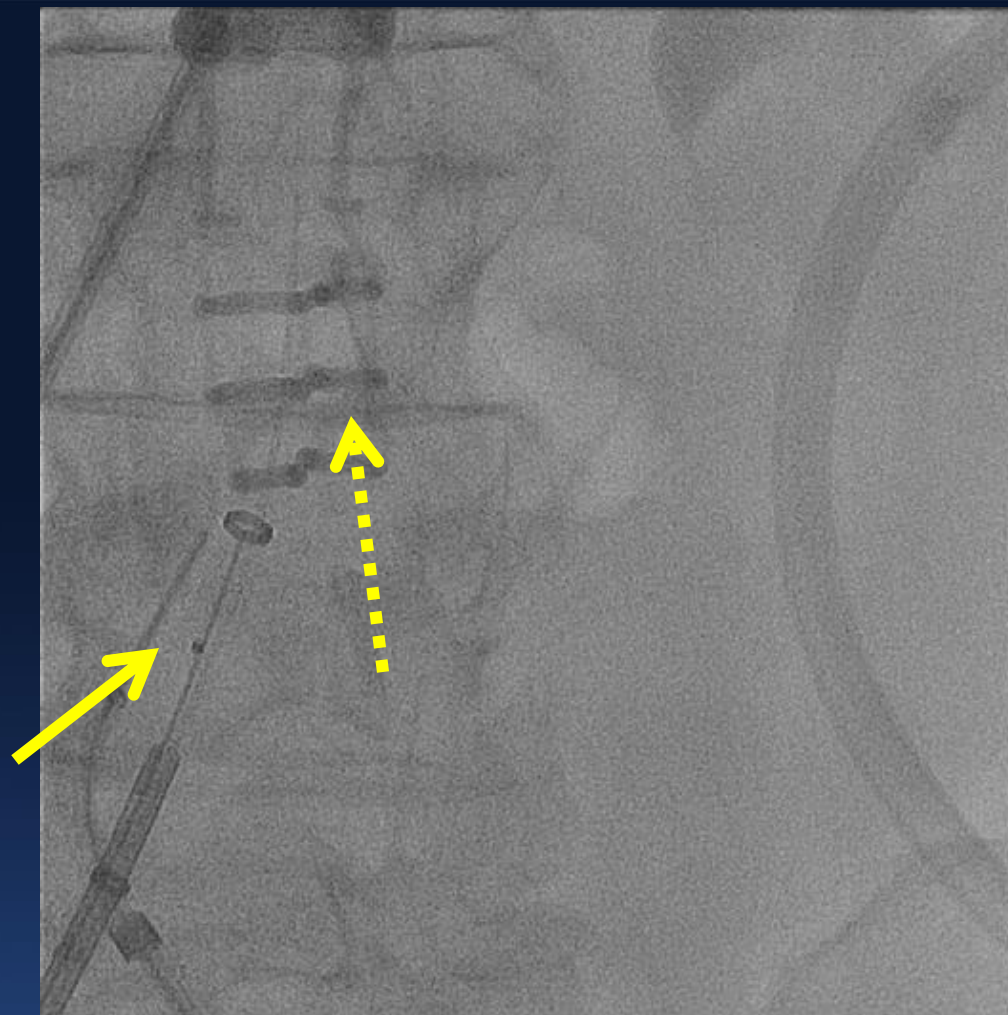
# Pre-close Left Hurry Up Tri-Vascular Jacob



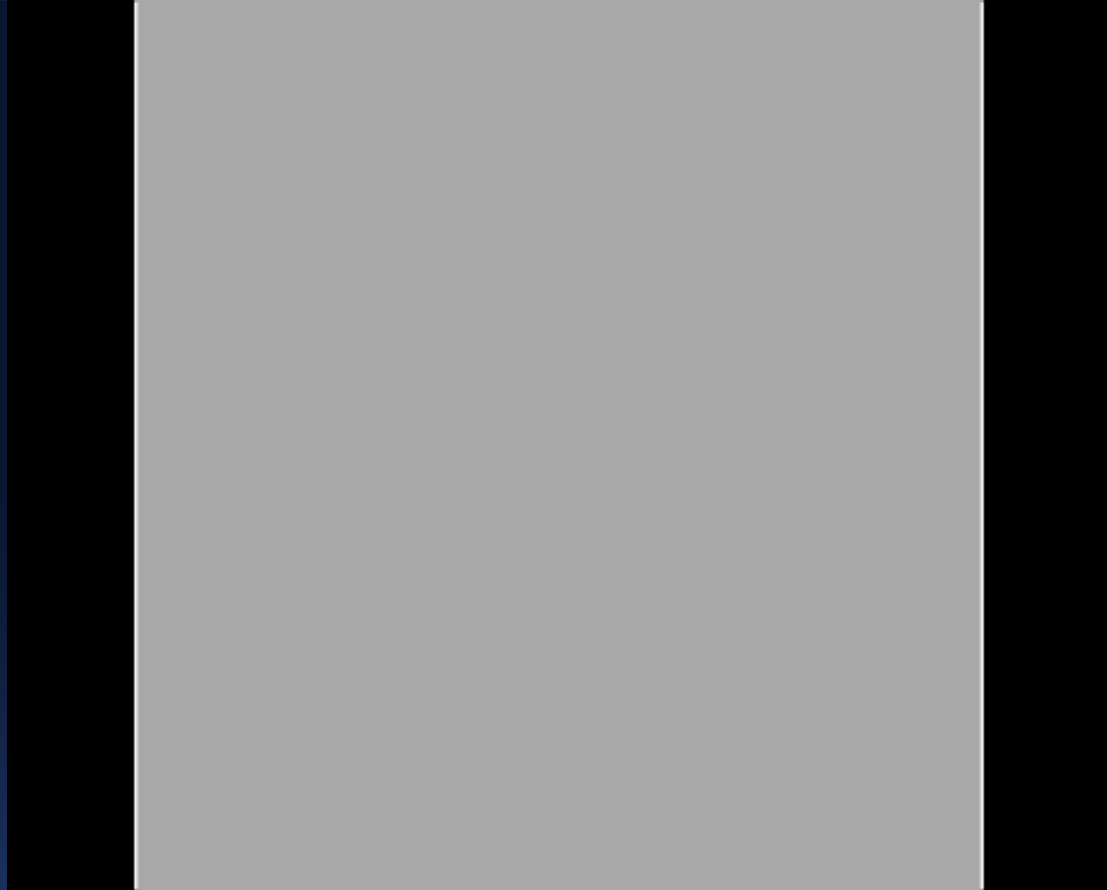
# Deploying “Middle Crown”



**Angio, adjust, deploy proximal crown**

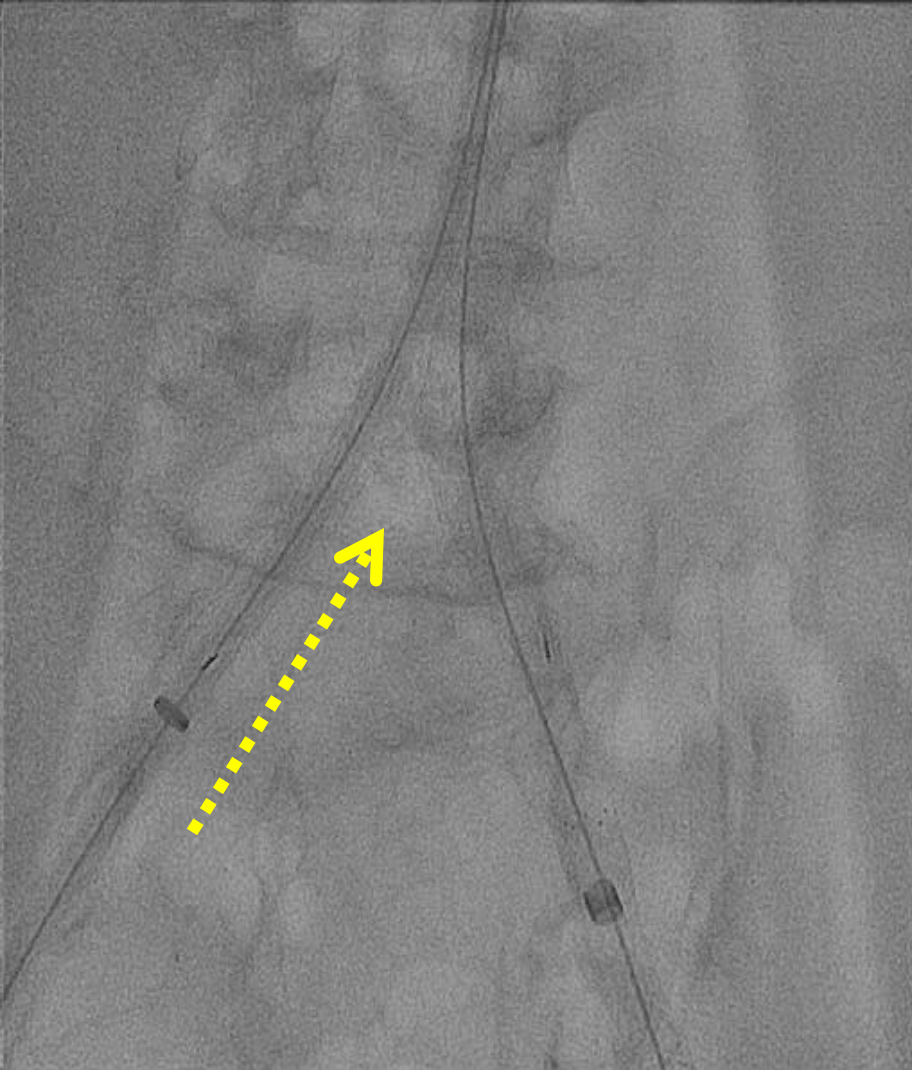


# Tough gate cannulation Deflectable morph catheter



# Type 1 leak

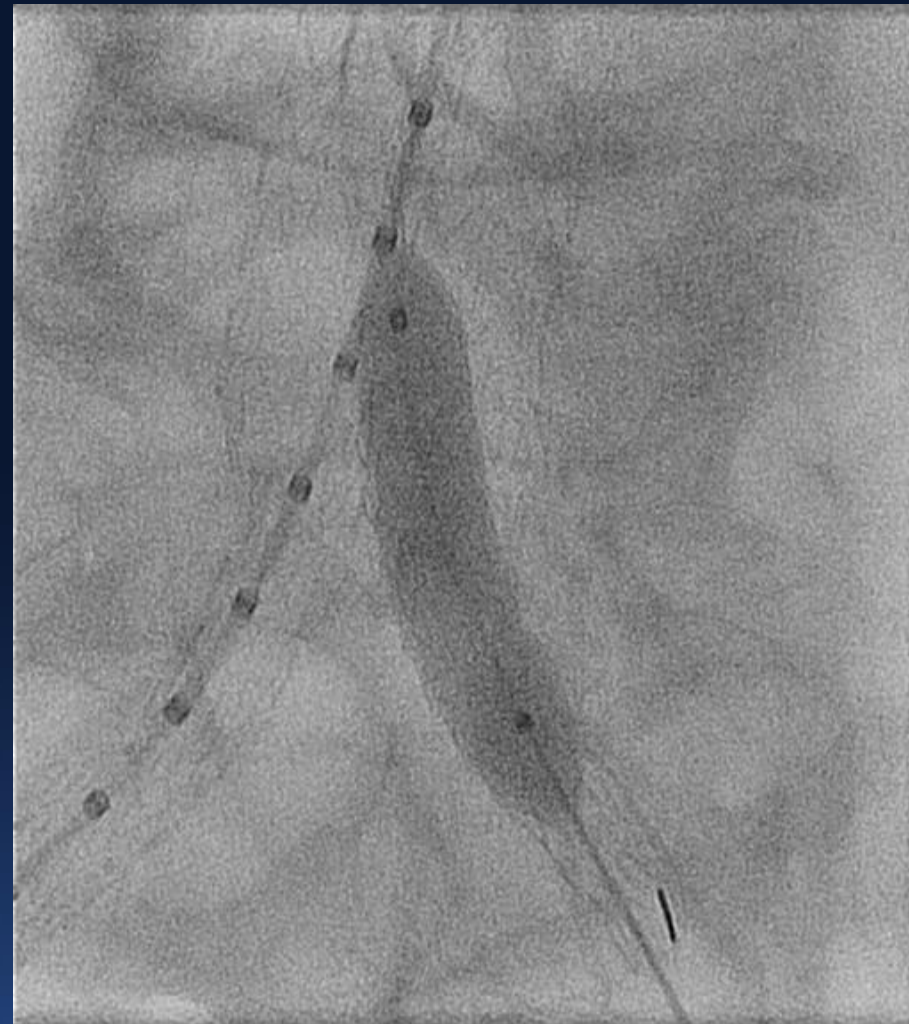




**Difficult to advance  
R sheath**

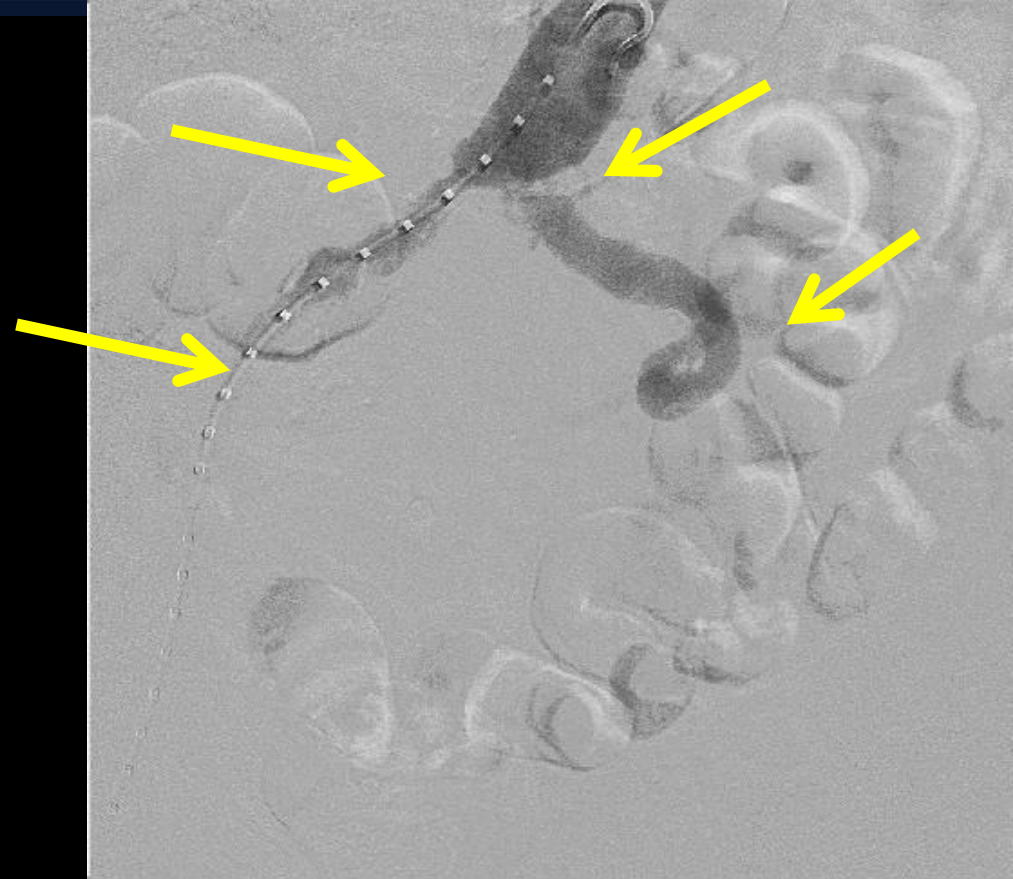


**Palmaz Stent**



**No Endoleak  
LCIA kink....**

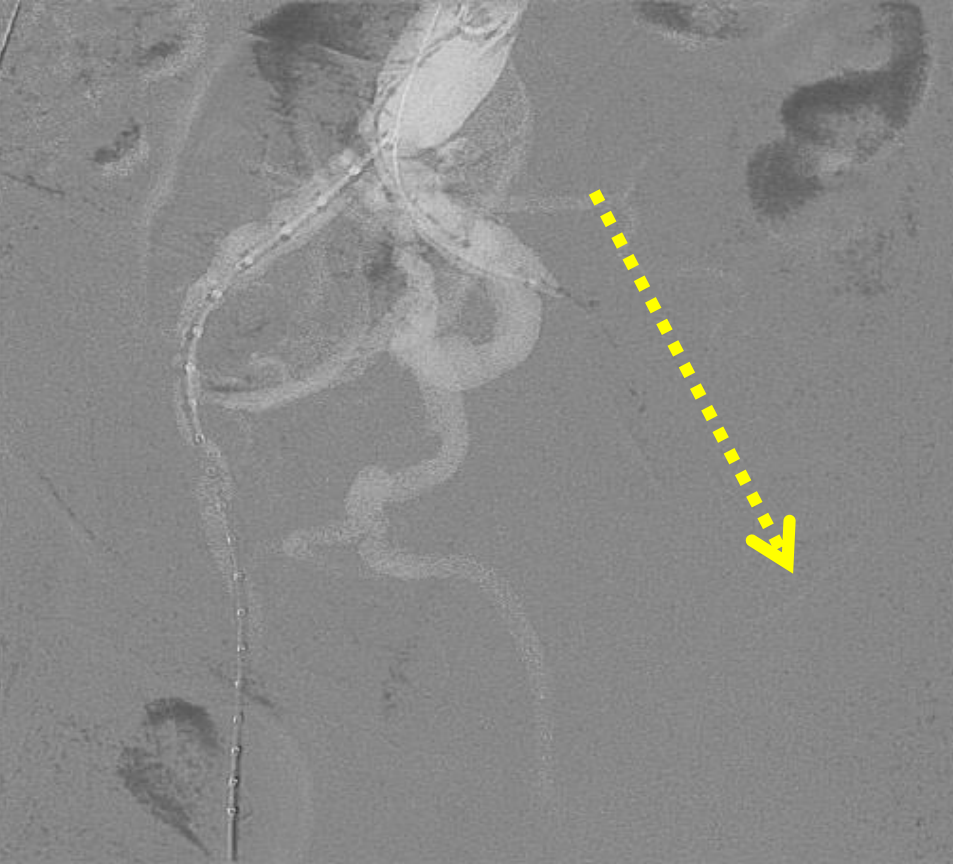
## Case 3



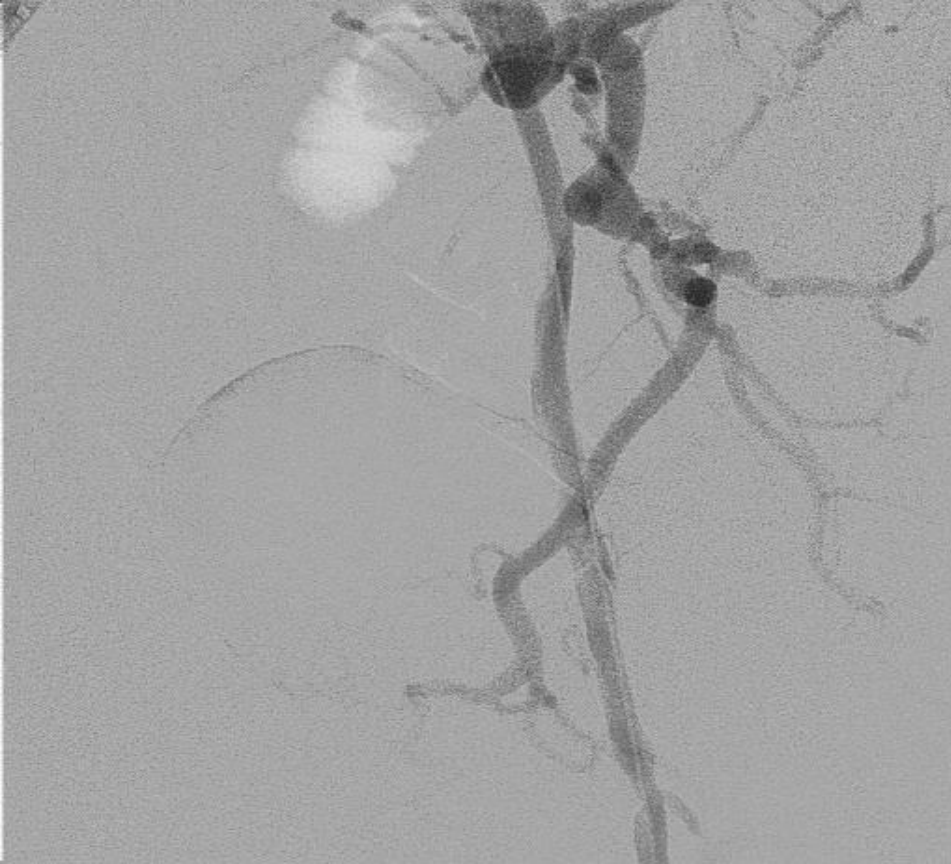
**Large gentleman, severe COPD and CAD,  
5.3 enlarging AAA ,AND LEIA CTO,  
bilateral CIA disease**



## Even challenges in “good leg”



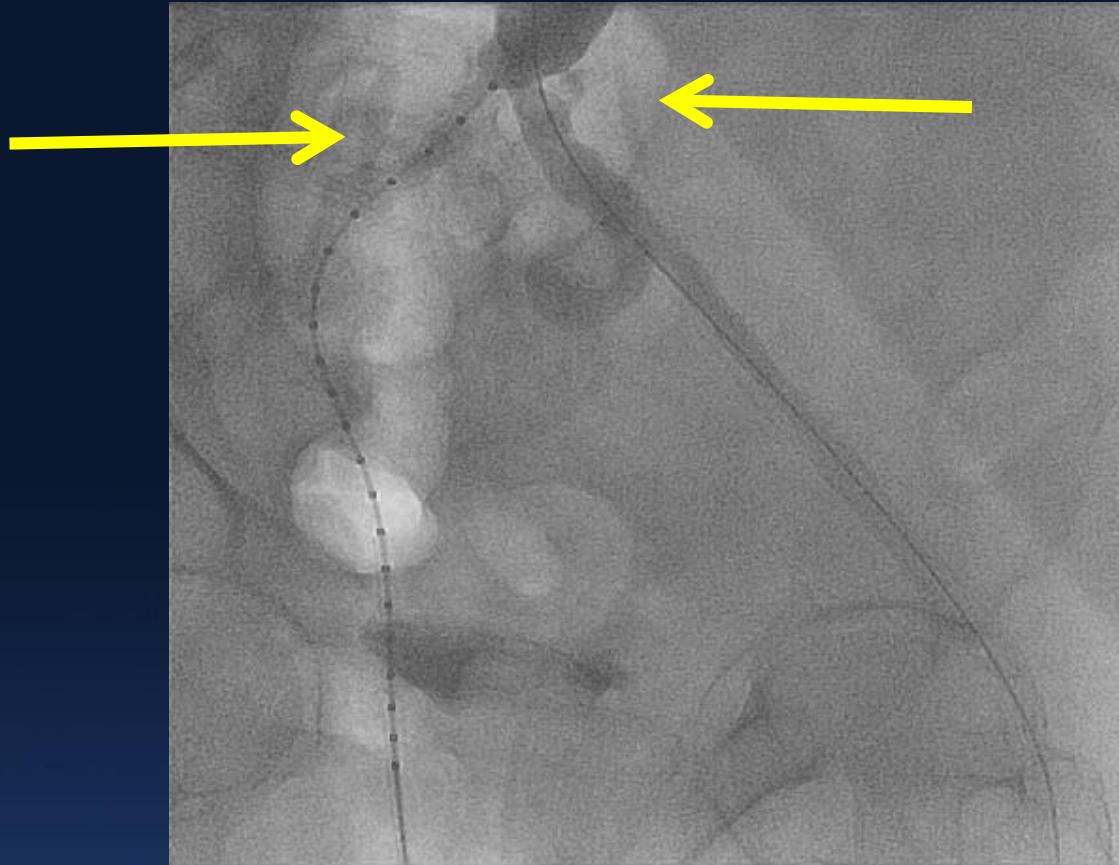
## Crossing from L Brachial (Rare) need for Re-entry



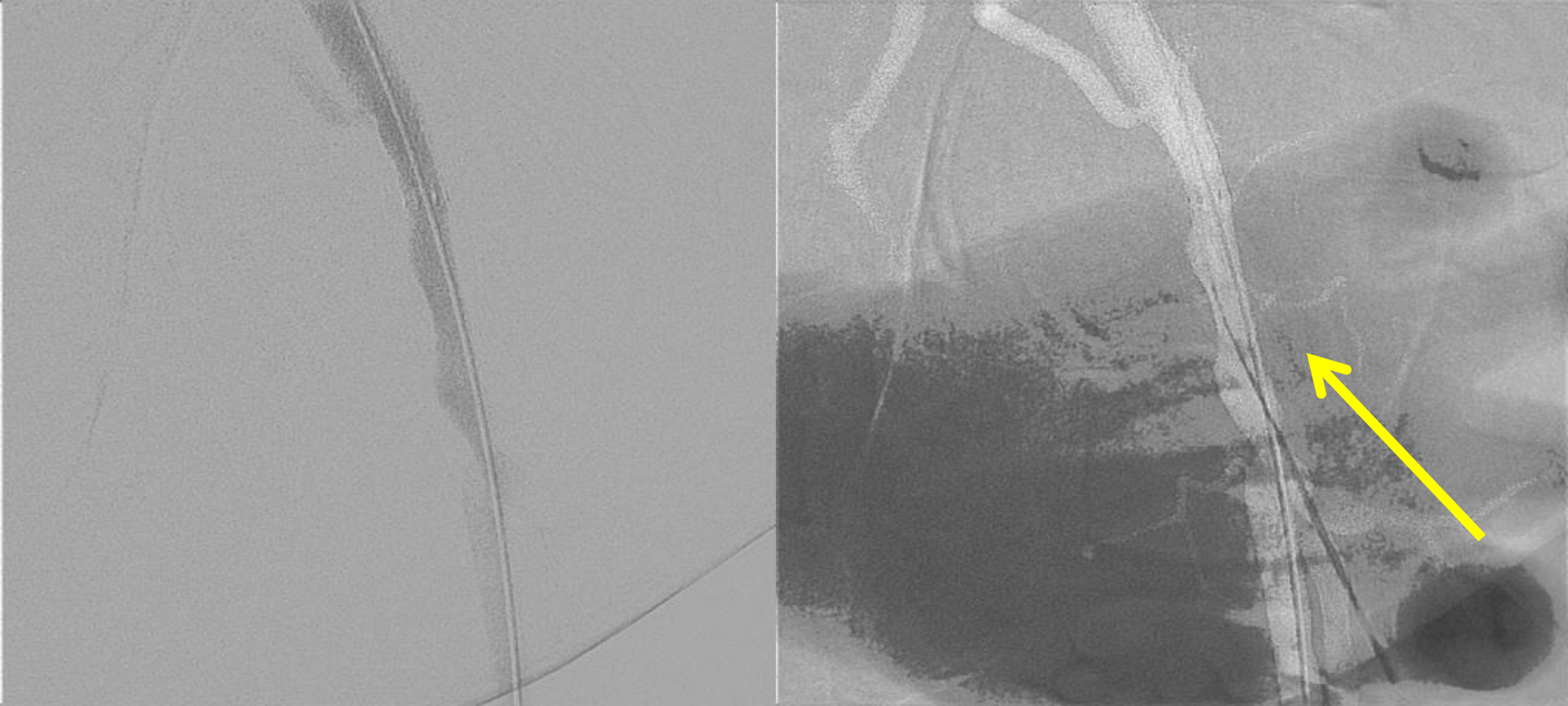
**Nitinol stent LEIA/pLCFA**



**PTA**

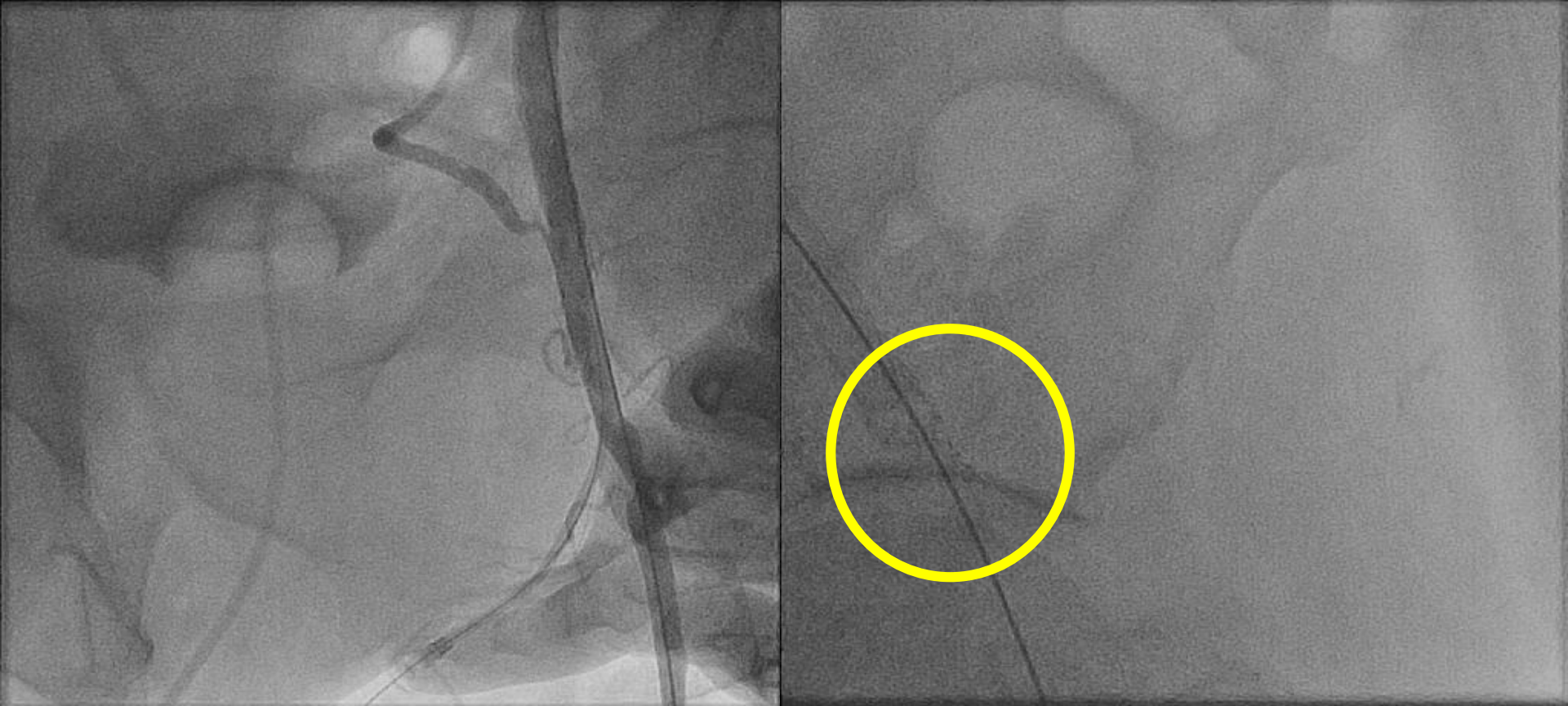


**Improved, plan for EVAR for AAA and CIA disease**

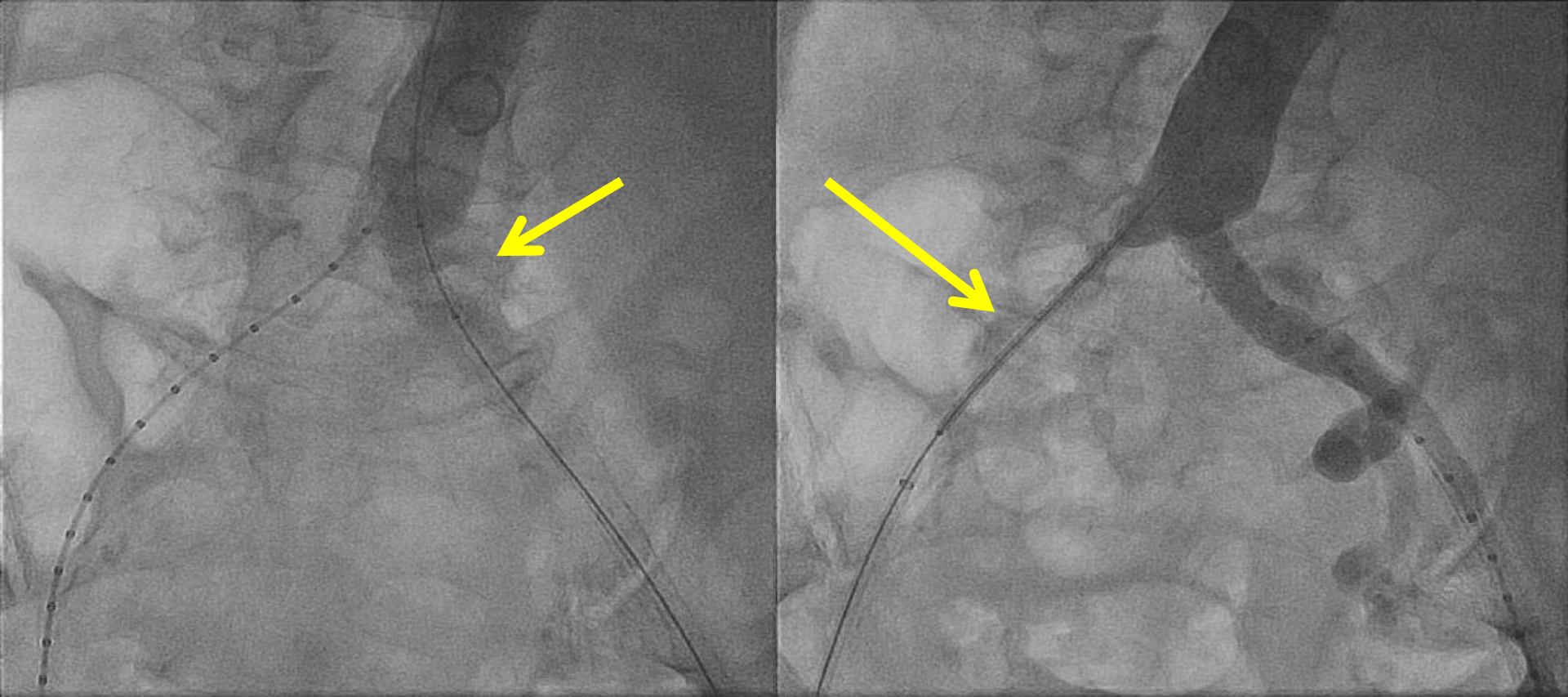


## Roadmap, vascular ultrasound-assisted access LCFA access





## Distorted LEIA stent after 8F sheath following Pre-close



## Change in Plans: Stent L and R CIA's, EVAR another day





**Dissection LCFA**



**DCB**

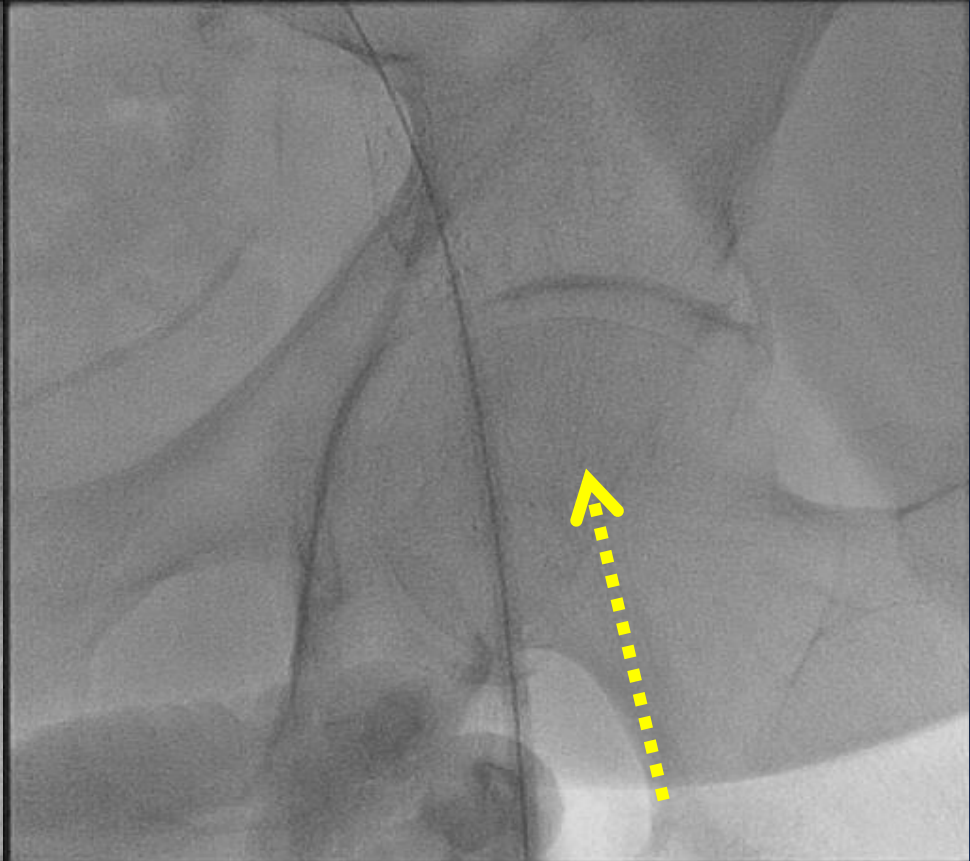
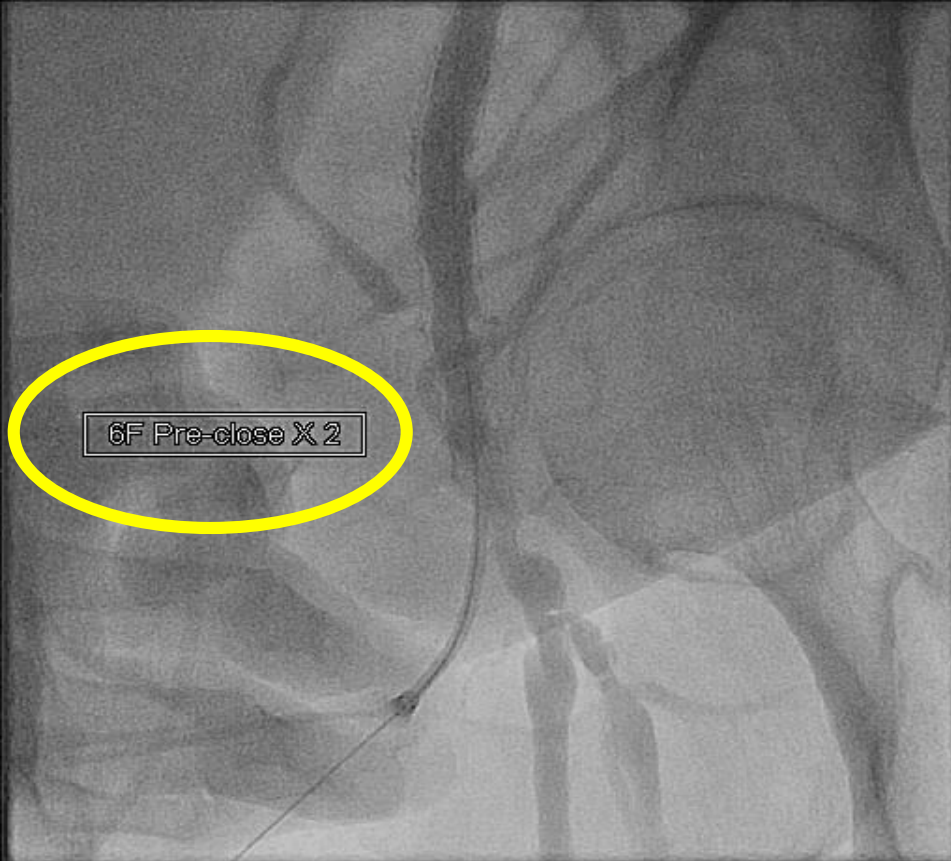




**Return for EVAR ~ 2-3 months**

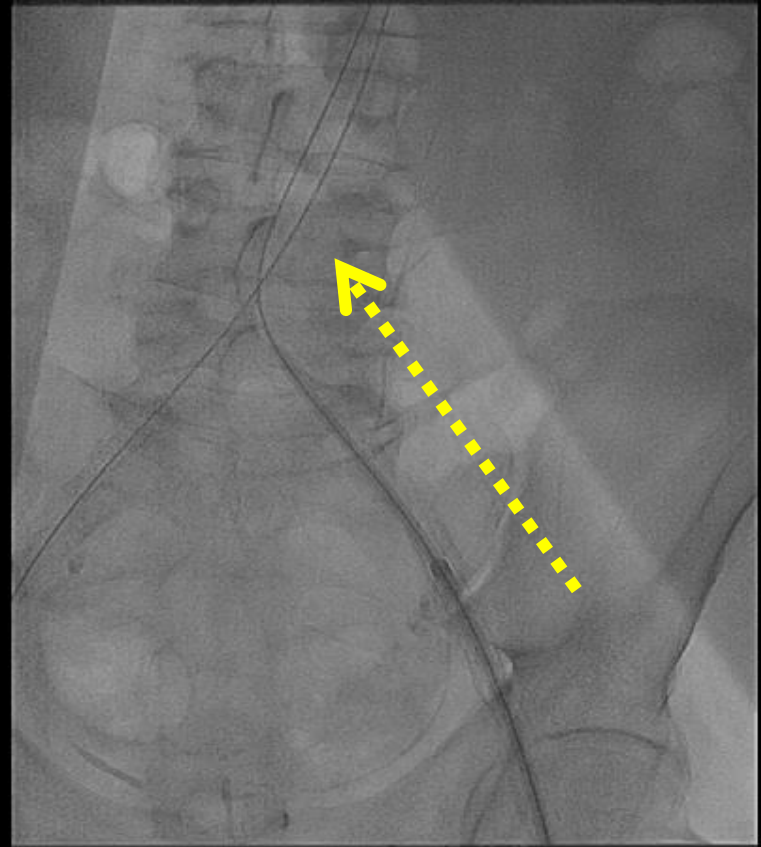
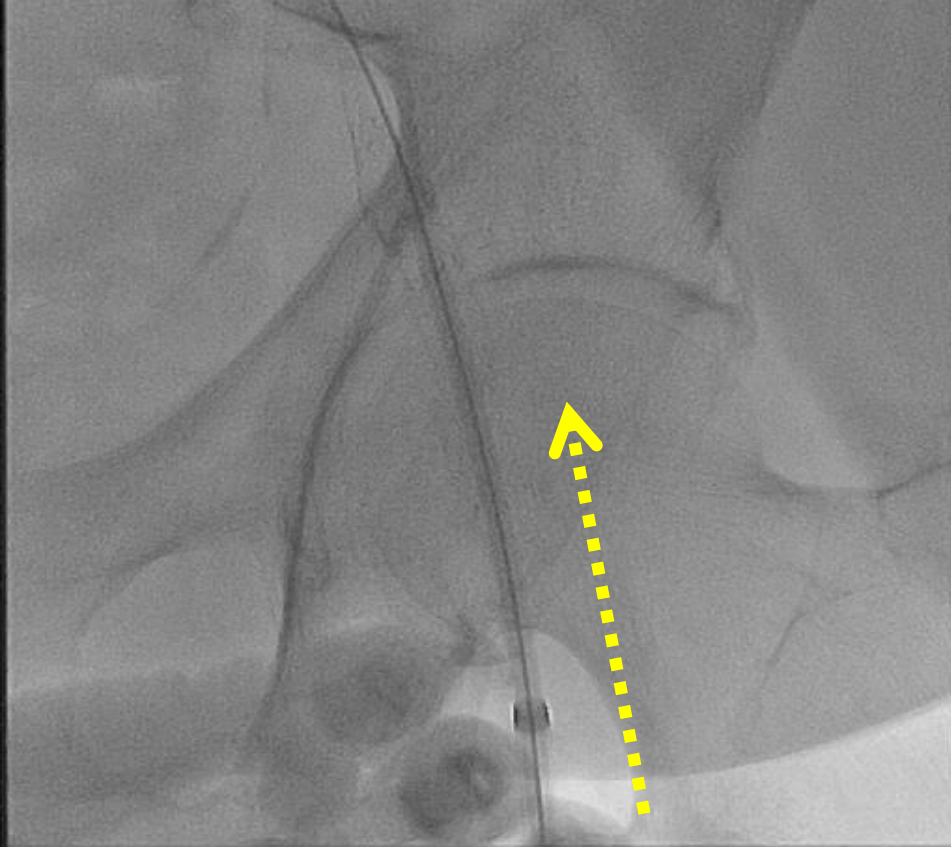


# Roadmap and vascular ultrasound – assisted micro-puncture access

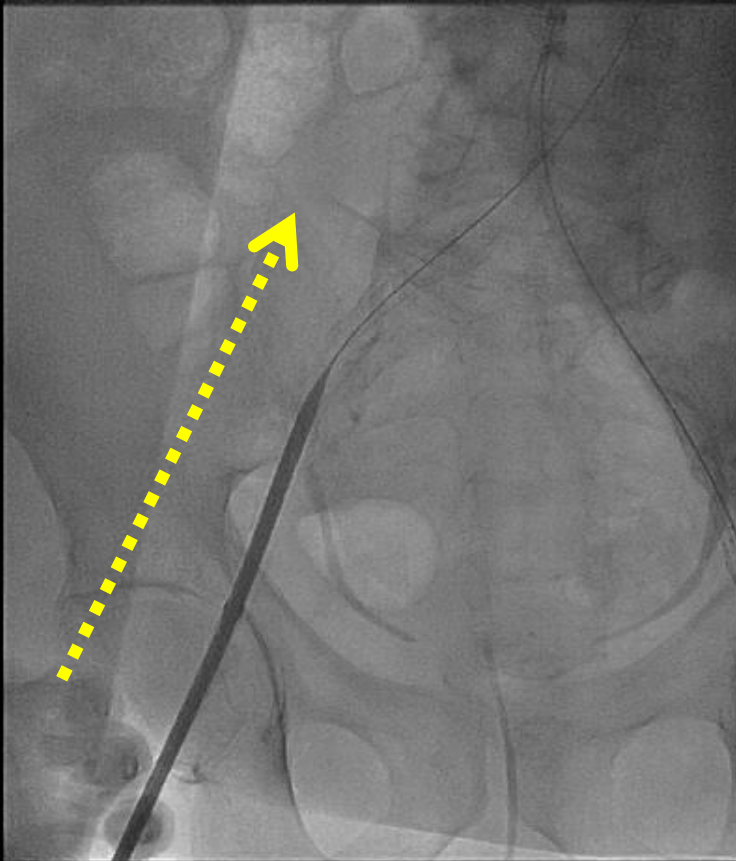


**Dilator carefully up on left**

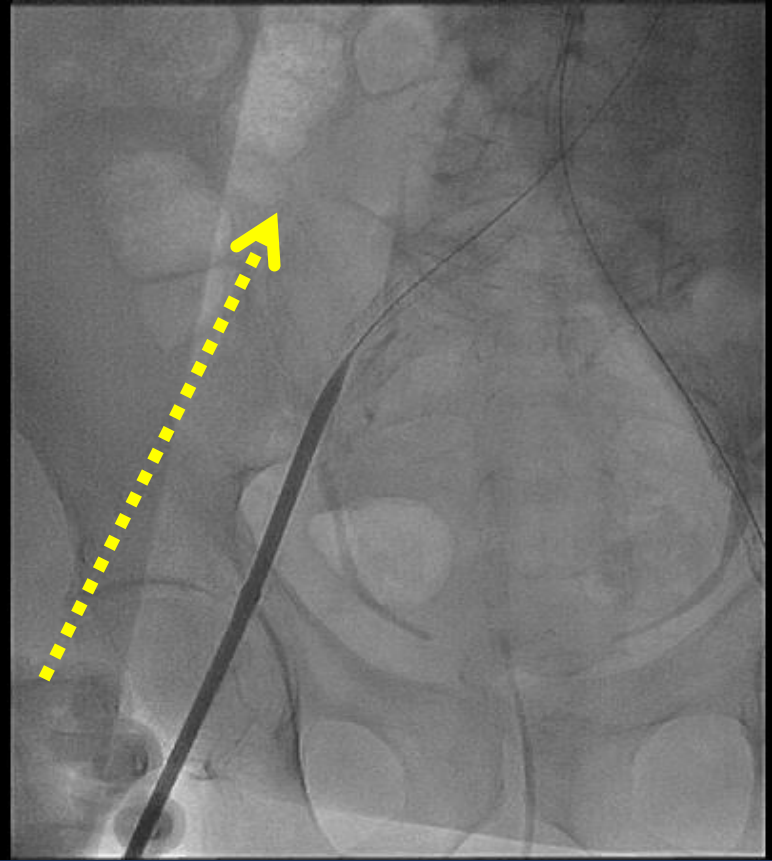




**12F sheath carefully up through stents**

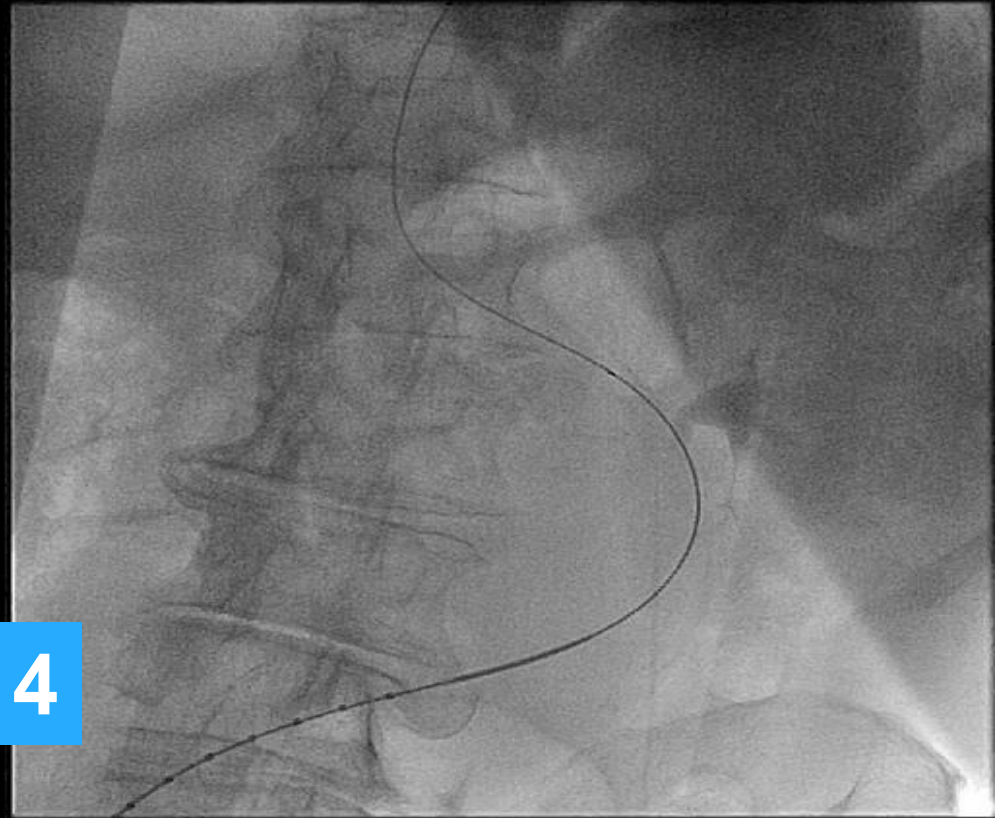


**Dilator up  
through R stents**



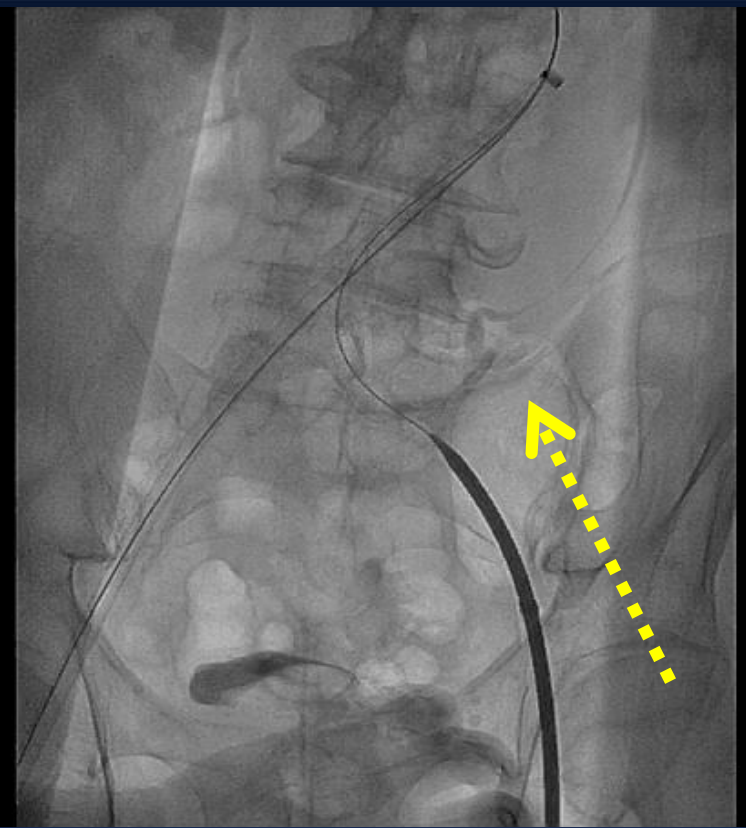
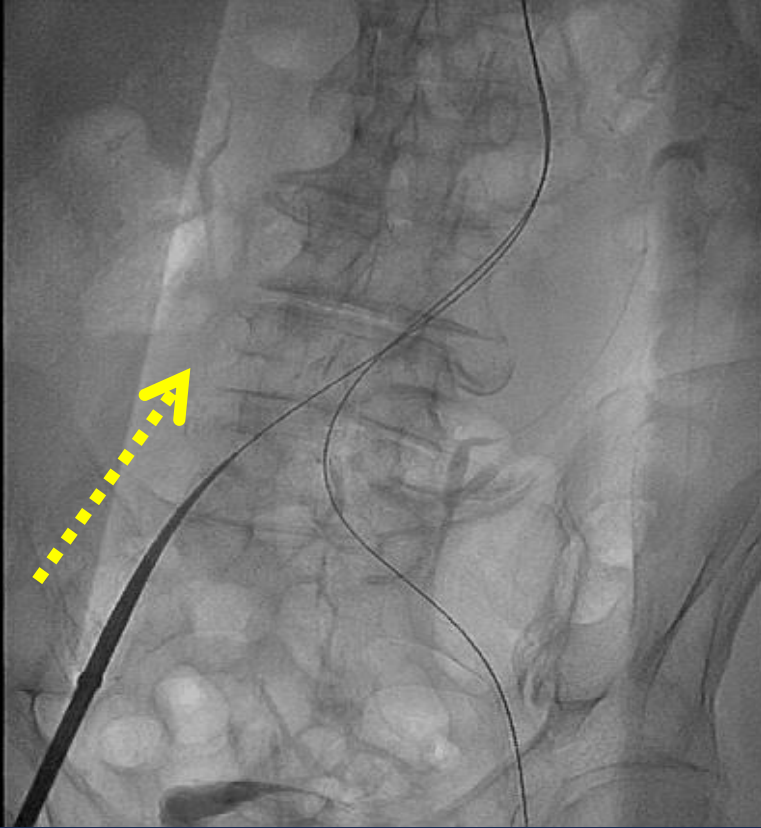
**14F sheath up on left**





## Case 4

# Severely tortuous Aorta, neck, and iliacs



**Low Profile sheaths (16F right, 12F left) up**



34mm Main Body (Ovation)

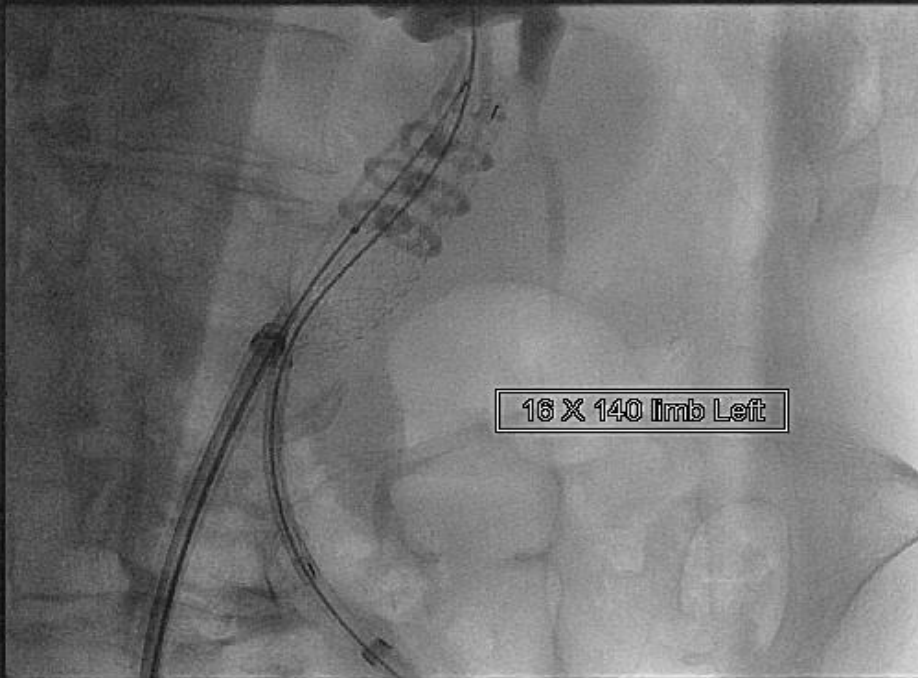




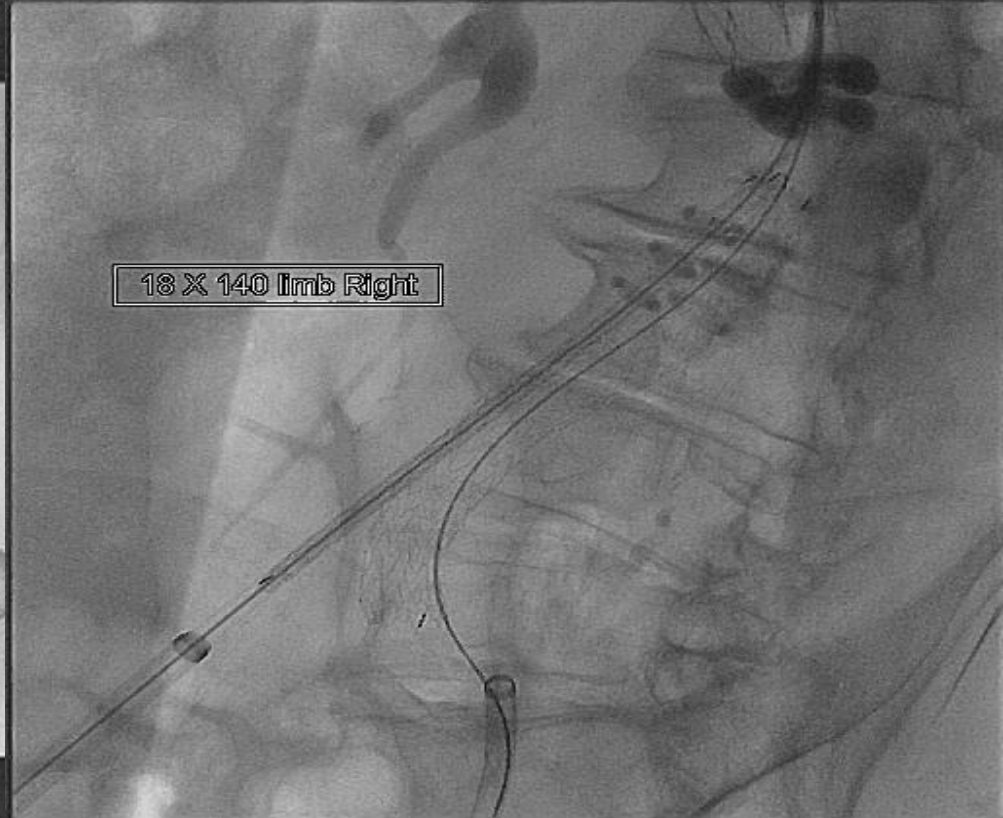
**Pressure held forward as polymer fills**







16 X 140 Iimb Left



18 X 140 Iimb Right

0 mm HG gradient (none)



# Conclusions

- **There is a trend toward development of lower profile EVAR systems**
- **Lower profile endograft devices may increase the number of patients eligible for EVAR, reduce the need for routine general anesthesia and ICU, and also decrease hospital length of stay, costs, and major adverse events in appropriately selected patients**

# Thank You for Your (Kaola- ty) Attention!

