

# Device Closure Complication

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# Method

## Case collection

- Material : Proglide, Femoseal, Exoseal
- Period : 2013.04.01 ~ 2014.03.31
- Patient selection
  - Compression using the femoral artery device in patients (n = 1000)
  - FA angiography patient = 848
- Statistics : PASW Statistics 18 Program

# Method

## How to construct?

- Puncture : antegrade & retrograde puncture
  - antegrade puncture : n = 898
  - retrograde puncture : n = 102
- FA angiography : AP angiography
- Hematoma : Hematoma is generally defined as a collection of blood outside of blood vessels
- Oozing : after 30 minute, leaking out slowly

# Method Closure Device



## Proglide

- Non-absorbable 3-0 polypropylene suture
- Exchange device
- 100% outside the artery



## Femoseal

- Collagen Plug
- Anchor inside the artery

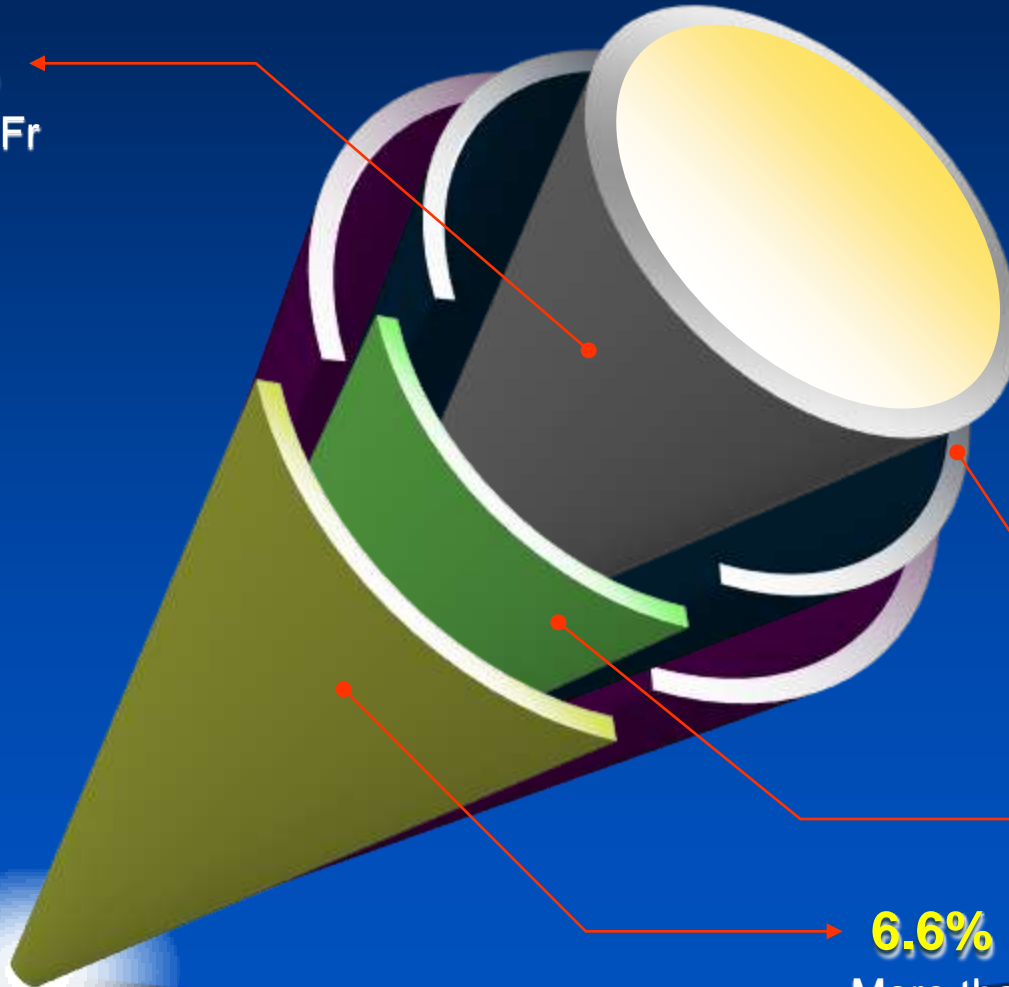


## Exoseal

- Polyglycolic acid Plug
- No sheath exchange
- 100% outside the artery

# Method Sheath Size

**16.9%**  
Below 6Fr



**46.4%**  
7F

**30.1%**  
8F

**6.6%**  
More than 9Fr

# Complication by sheath size

		Complication			Total
		None	Hematoma	Oozing	
Sheath size	Number (Below 6Fr %)	98 (58 %)	14 (8.3%)	56 (33.1%)	169 (100%)
	Number (7Fr %)	343 (73.9%)	19 (4.1%)	102 (22%)	464 (100%)
	Number (8Fr %)	227 (75.4%)	16 (5.3%)	58 (19.3%)	301 (100%)
	Number (More than 9Fr %)	42 (63.6%)	5 (7.6%)	19 (28.8%)	66 (100%)
	Number (Total %)	710 (71%)	44 (4%)	235 (23.5%)	1000 (100%)

If the sheath size is small,  
the complications will be reduced!

# Complication by sheath size

## Below 6Fr & More than 9Fr

- Retrograde puncture patient (Below 6Fr) : 67
  - I. Hematoma : 5.97% (n = 4 )
  - II. Oozing : 20.89% (n= 14 )
- Retrograde puncture patient(More than 9Fr) : 66
  - I. Hematoma : 7.60% (n = 5)
  - II. Oozing : 28.8% (n = 19)
- Antegrade puncture patient (Below 6Fr) : 102
  - I. Hematoma : 10.78% (n = 11)
  - II. Oozing : 40.2% (n = 41)

# Complication by device type

		Complication			Total
		None	Hematoma	Oozing	
Device type	Number (Proglide %)	528 (73.7%)	31 (4.3%)	157 (21.9%)	716 (100%)
	Number (Femoseal %)	86 (73.5%)	9 (7.7%)	22 (18.8%)	117 (100%)
	Number (Exoseal %)	46 (70.8%)	5 (7.7%)	14 (21.5%)	65 (100%)
Number (Total %)		660 (73.5%)	45 (5%)	193 (21.5%)	898 (100%)

Small size hematoma(below 36 cm<sup>2</sup>) – Femoseal (9 case)

Large size hematoma(greater than 36cm<sup>2</sup>) – Proglide (17 case)

Post oozing complication – Most of Ecchymosis (Mild Oozing)



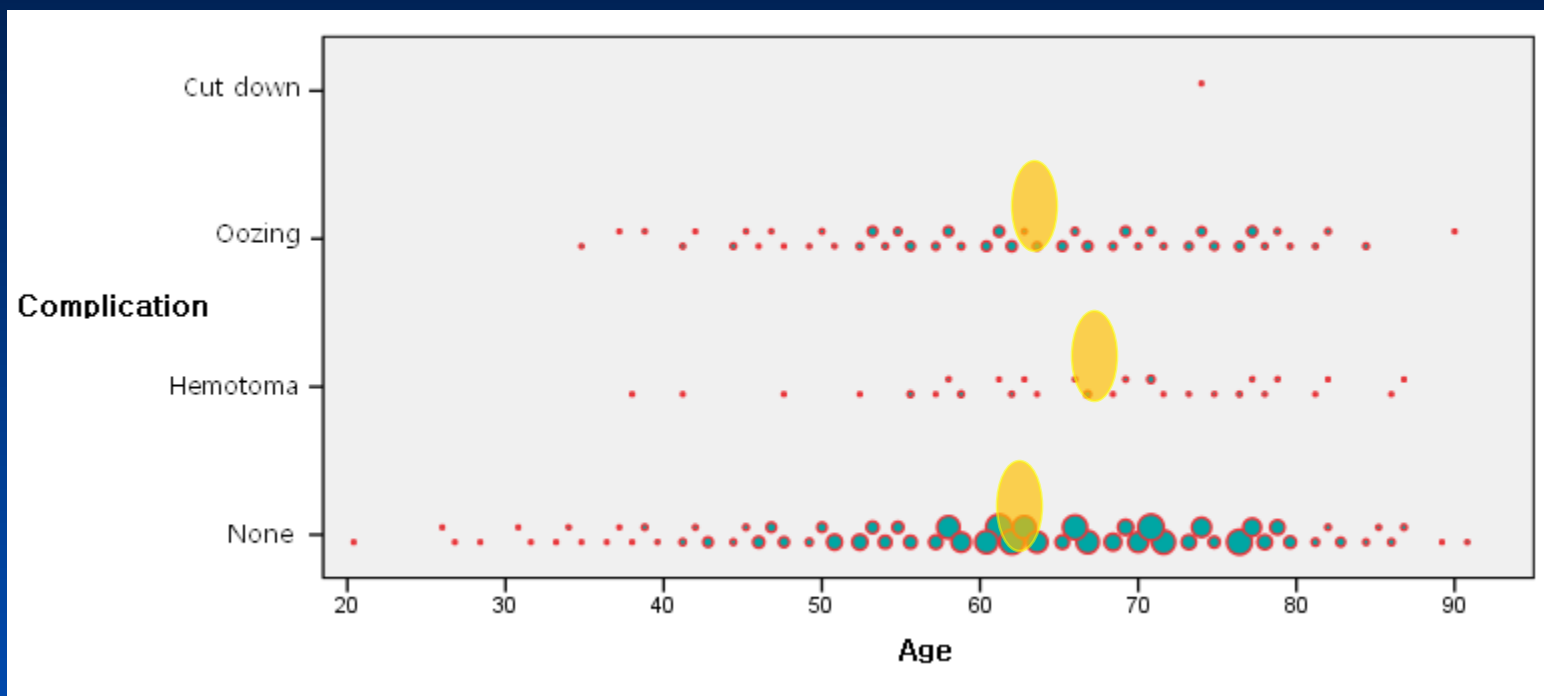
# Complication by patient sex

		Complication			Total	
		None	Hematoma	Oozing		
sex	Male	Number Male %	514 (74.5%)	32 (4.6%)	144 (20.9%)	690 (100%)
	Female	Number Female %	146 (70.2%)	13 (6.3%)	49 (23.6%)	208 (100%)
Total		Number Total %	660 (71%)	45 (5.4%)	193 (23.5%)	898 (100%)

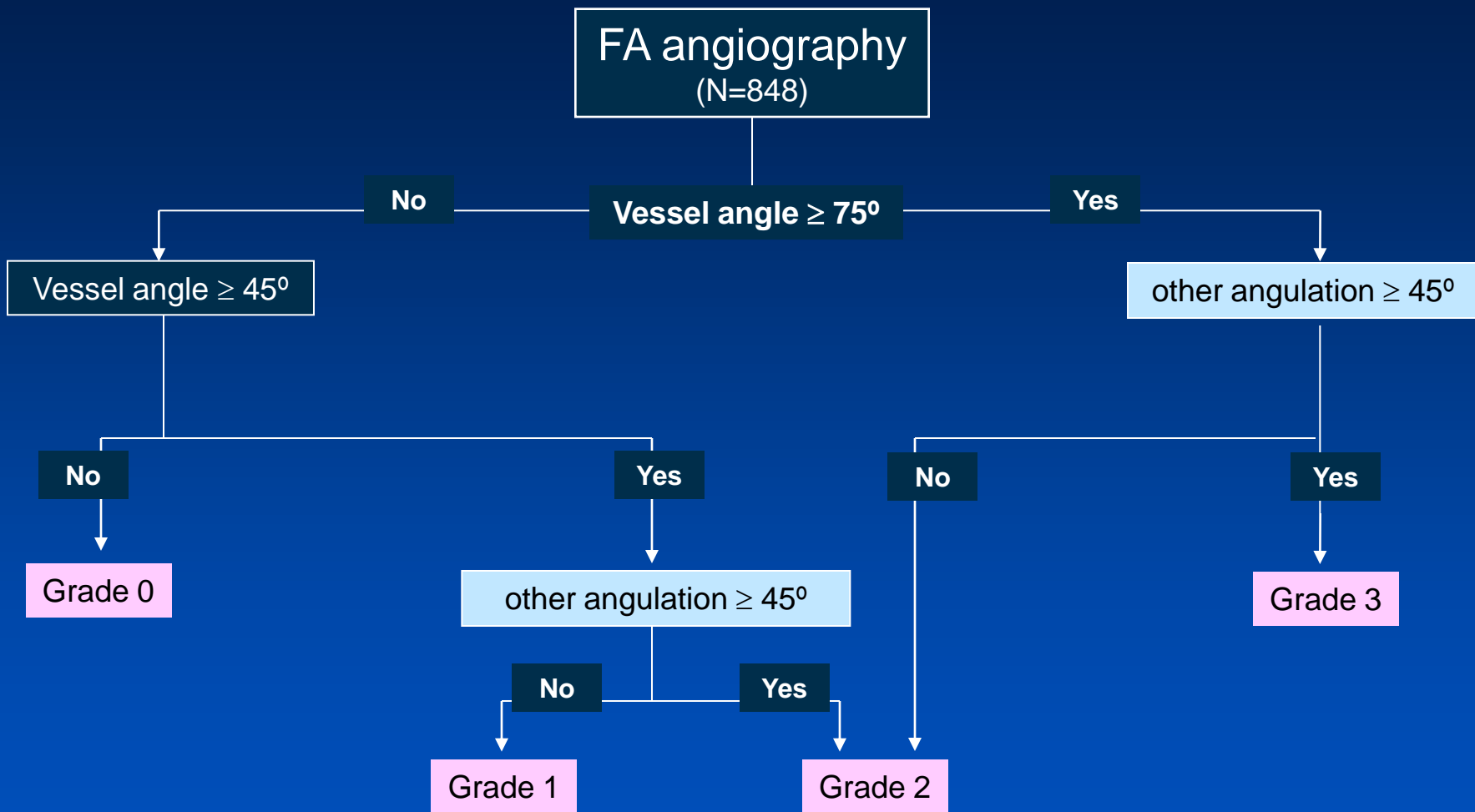
# Complication by procedure type

	Complication			
	None	Hematoma	Oozing	Total
Number (CAG %)	8 (66.7%)	1 (8.3%)	3 (25%)	12 (100%)
Number (PCI %)	560 (74.2%)	35 (4.6%)	160 (21.2%)	755 (100%)
Number (PTA %)	53 (79.1%)	3 (4.5%)	11 (16.4%)	67 (100%)
Number (TAVI %)	35 (71.4%)	3 (6.1%)	11 (22.4%)	49 (100%)
Number (TEVAR, EVAR %)	5 (33.3%)	2 (13.3%)	8 (53.3%)	15 (100%)
Number Total %	661 (73.6%)	44 (4.9%)	193 (21.5%)	898 (100%)

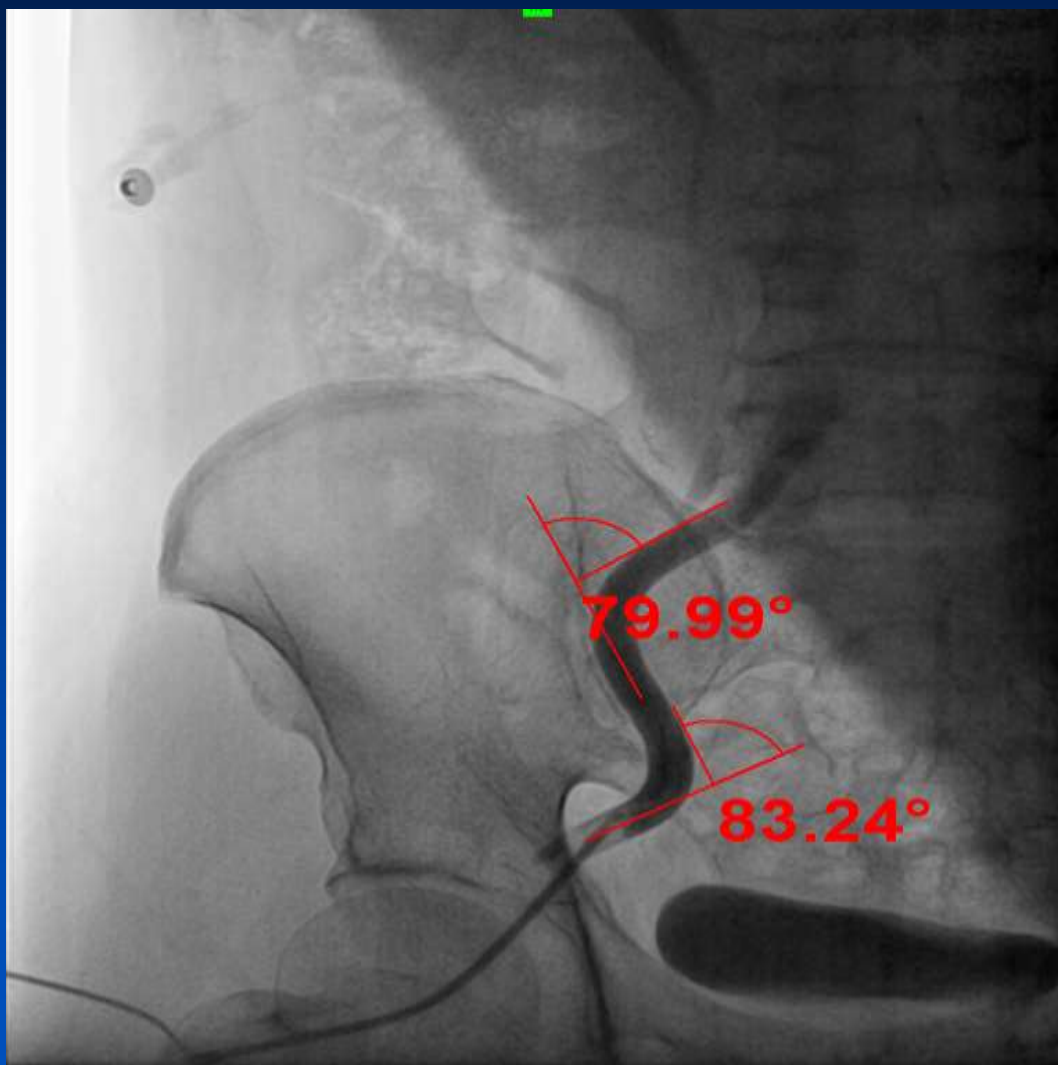
# Complication by patient age



Complication	Average	Number	STDEV
None	63.96	710	11.564
Hematoma	66.67	54	10.204
Oozing	64.15	235	10.95
Cut down	74	1	0
합계	64.16	1000	11.357



# FA tortuosity grade



Grade 1

$45^\circ \leq 1 \text{ angulation} < 75^\circ$

Grade 2

$75^\circ \leq \text{Vessel angulation}$ ,  
Other angulation  $< 45^\circ$   
or

$45^\circ \leq 2 \text{ angulation} < 75^\circ$

Grade 3

$75^\circ \leq \text{Vessel angulation}$   
 $45^\circ \leq \text{Other angulation}$

# Complication by tortuosity

		Complication			
		None	Hematoma	Oozing	Total
Tortuous	Number	434	25	141	601
	None %	(72.2%)	(4.2%)	(23.5%)	(100%)
	Number grade 1 %	83	10	27	120
		(69.2%)	(8.3%)	(22.5%)	(100%)
	Number grade 2 %	56	4	23	83
	(67.5%)	(4.8%)	(27.7%)	(100%)	
	Number grade 3 %	33	3	8	44
		(75%)	(6.8%)	(18.2%)	(100%)
	Number Total %	606	42	199	848
		(71.5%)	(5%)	(23.5%)	(100%)

Femoral artery tortuosity  $\neq$  increased complication

# Case

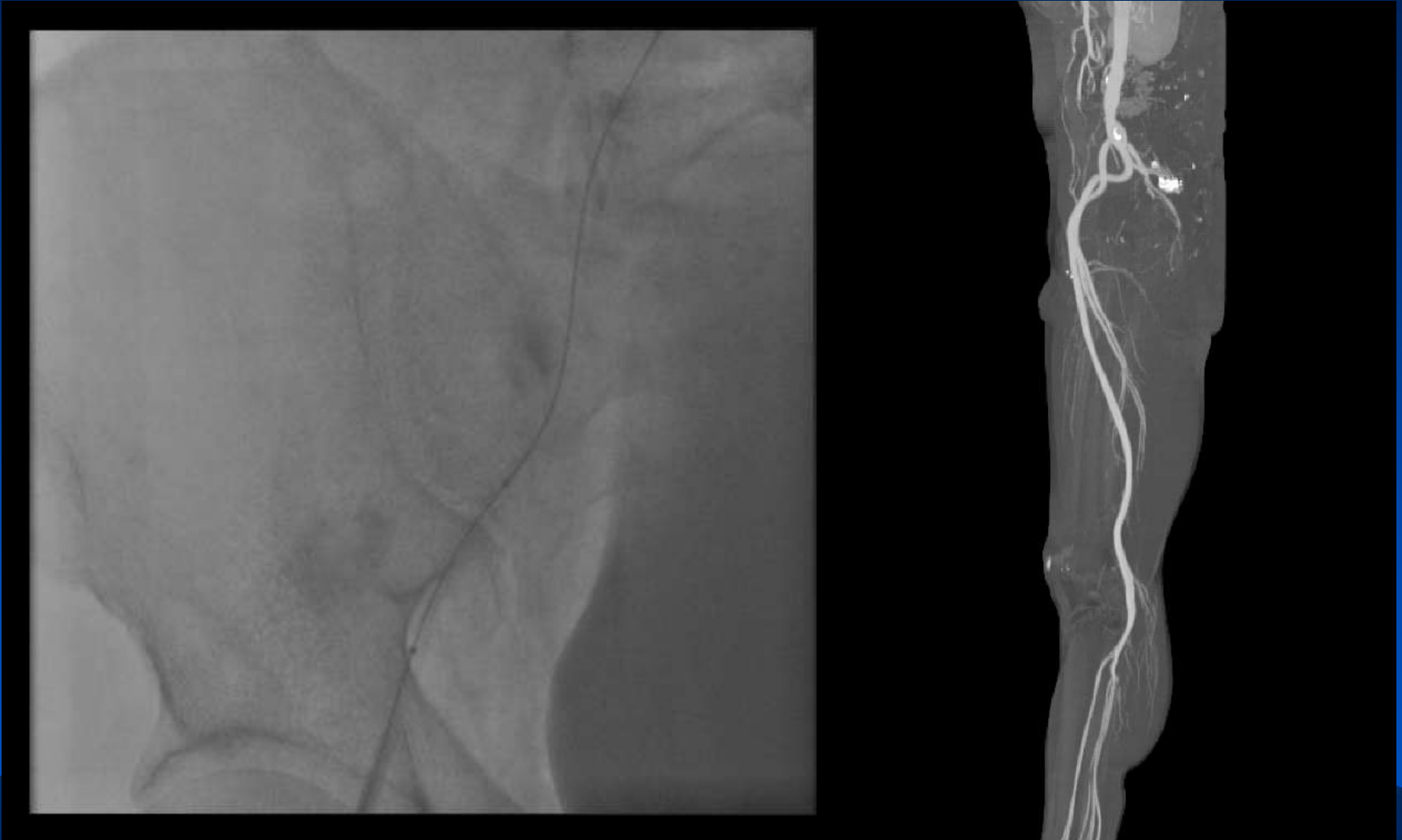
FA angiography



Lower Extre, CT



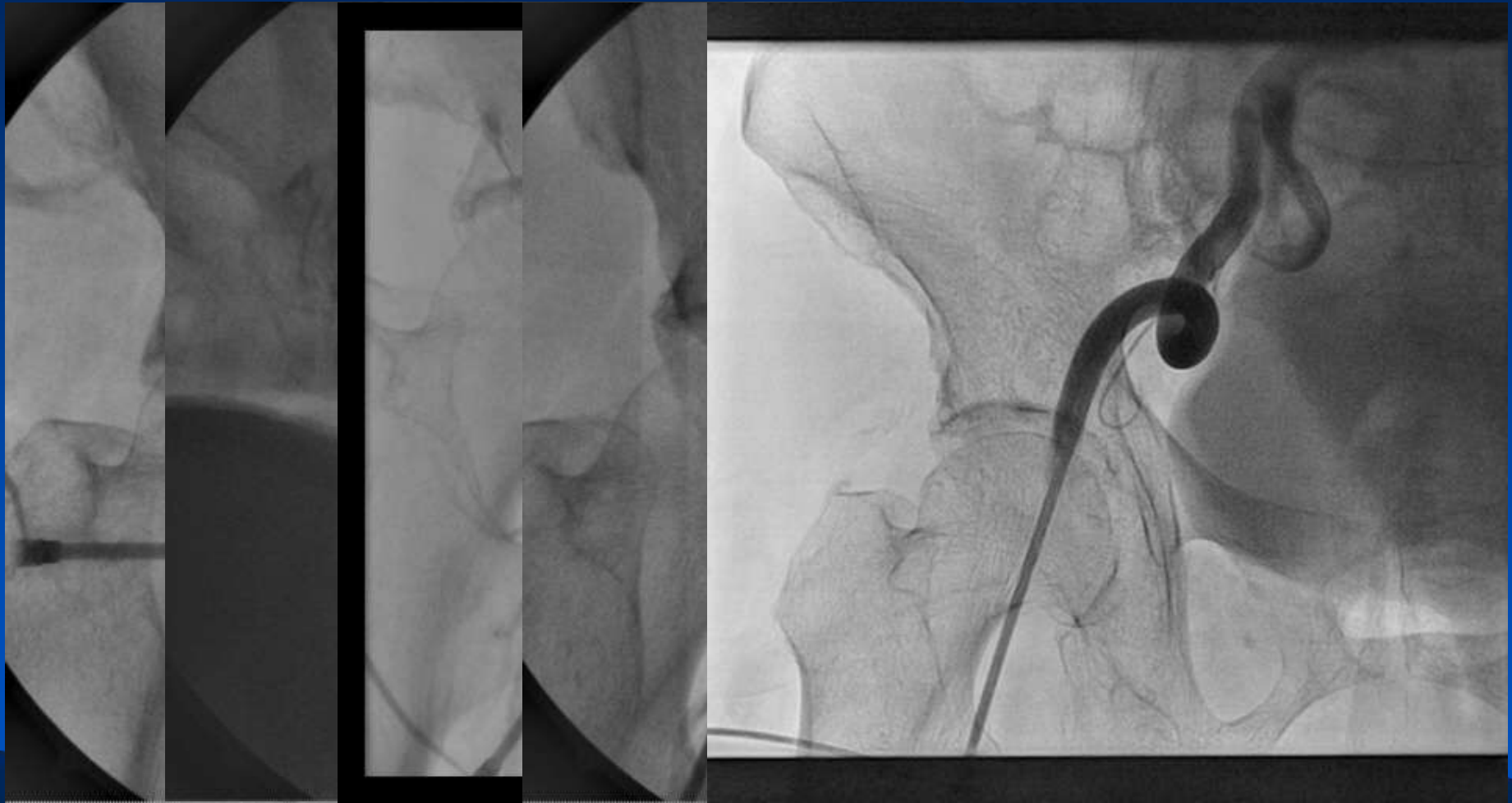
# Case Perforation



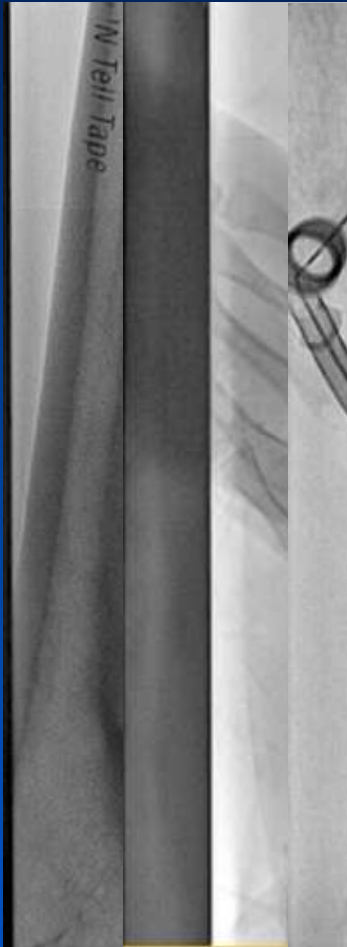


# Case

## FA angiography



# Case Cut down



# Conclusion

- **The larger sheath size will have many complication?**
  - 6Fr complications : hematoma(8.3%), oozing(33.1%)
  - 6Fr retrograde puncture : hematoma(5.97%), oozing(20.89%)
  - More than 9Fr : hematoma(7.6%), oozing(28.8%)
- **The PTA procedure patient will have many complication?**
  - TEVAR&EVAR : hematoma(13.3%), oozing(53.3%)
  - TAVI : hematoma(6.1%), oozing(22.4%)
  - PTA : hematoma(4.5%), oozing(16.4%)

# Conclusion

- FA tortuosity will be reduce complications?
  - Decisions through AP FA angiography is limited ; oblique 45° FA angiography
- Prior to use, review the Instructions