TAVI for Patients with Peripheral Artery Disease

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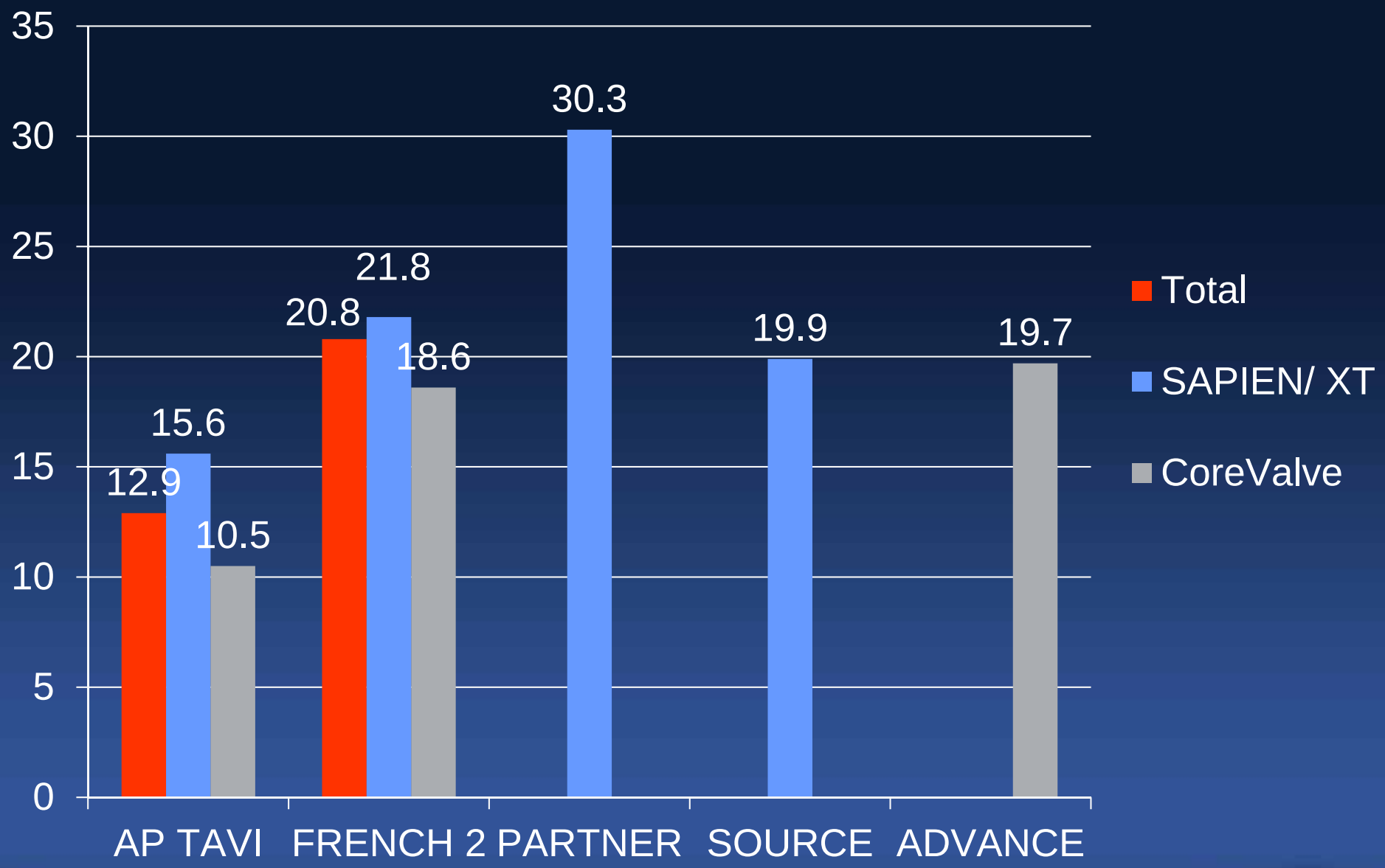
RCT and Registry Baseline Data

	AP TAVI			FRENCH 2			PARTNER		SOURCE		ADVANCE
Design	Registry			Registry			RCT		Registry		Registry
Treament	Total	Edw	Core	Total	Edw	Core	Edw(B)	Edw(A)	Edw (I)	Edw (II)	Core
No.	202	96	106	3195	2107	1043	179	348	1038	1269	162
Age, yr	78.4	78.1	78.7	82.7	82.3	82.5	83.1	83.6	81.2	81.1	81
Male, %	54.1	52.1	56.0	51	46.6	48.5	45.8	57.8	44.5	41.3	49.4
STS score	4.4	4.7	4.3	6.4	5.8	-	11.2	11.8	-	-	-
EuroSCORE,%	19.2	19.4	19.0	21.9	22.2	24.7	26.4	29.3	27.6	25	19.2
NYHA, III,IV,%	72.2	79.7	67.6	75.9	75.5	76.1	92.2	94.3	-	-	79.6
PAD, %	12.9	15.6	10.5	20.8	21.8	18.6	30.3	43.4	19.9		19.7
CAD, %	50.9	63.5	48.6	47.9	48.7	46.9	67.6	74.9	-	-	57.6
Prior MI, %	-	-	-	16.4	17	15.0	18.6	26.8	-	-	16
Prior CABG, %	7.3	9.3	1.5	18.2	18.2	18.1	37.4	42.6	-	-	21.4
Prior Stroke, %		10.4	4.8	10	10	10	27.4	29.3	5.5	6.1	-
Prior PCI, %	34.5	41.7	24.6	-	-	-	30.5	34	-	-	31.1

1. N Engl J Med. 2010;363:538 2. N Engl J Med. 2011;364:1781 3. N Engl J Med. 2012;366:1705
4. TCT 2010 5. J Am Coll Cardiol . 2010;55:1080

AP TAVI registry

Incidence of Peripheral Artery Disease



AP TAVI registry

30-day Outcomes

	Total (n=194)	Edward (n=96)	CoreValve (n=98)	P value
Mortality	8 (4.1%)	5 (5.2%)	3 (3.1%)	NS
Major Stoke	2 (1.0%)	1 (1.0%)	1 (1.0%)	NS
Vascular Complication	6 (3.1%)	3 (3.1%)	3 (3.1%)	NS
AKI ≥ Stage 2	2 (1.0%)	1 (1.1%)	1 (1.0%)	NS
Post AR ≥ Moderate	22 (11.8%)	7/92 (7.6%)	15/95 (15.8%)	0.083
Implant of ≥ 2 valves	12 (6.2%)	0	12 (12.2%)	< 0.001
Device success	158 (91.4%)	86 (89.6%)	72 (73.5%)	0.004
Permanent Pacemaker	23 (11.9%)	1 (1.2%)	22 (22.2%)	< 0.001
Coronary obstruction	4 (2.1%)	1 (1.2%)	3 (3.1%)	NS

AP TAVI registry

Baseline MDCT Characteristics

	Asian Registry (n = 202)	CHOICE trial (n = 241)
Aortic Annulus Measurement		
Area, mm^2	444.7 ± 83.5	444.5 ± 73.5
Perimeter, mm	76.7 ± 7.1	76.7 ± 6.4
Eccentricity index	0.84 ± 0.07	0.86 ± 0.07
Femoral artery diameter, mm		
Right	7.0 ± 1.2	7.8 ± 1.4
Left	7.0 ± 1.1	7.8 ± 1.5
Coronary artery height, mm		
Right	15.2 ± 3.1	13.3 ± 2.8
Left	13.6 ± 2.6	13.5 ± 2.1

Asian Patients with Aortic Stenosis have smaller femoral arteries

Required Arterial Access Diameter

SAPIEN XT

Valve Size	Sheath size	Diameter
23mm	18F	> 6.0mm
26mm	19F	> 6.5mm
29mm	20F	> 7.0mm

CoreValve

Valve Size	Sheath size	Diameter
26mm	18F	> 6.0mm
29mm		
31mm		

Baseline MDCT Characteristics

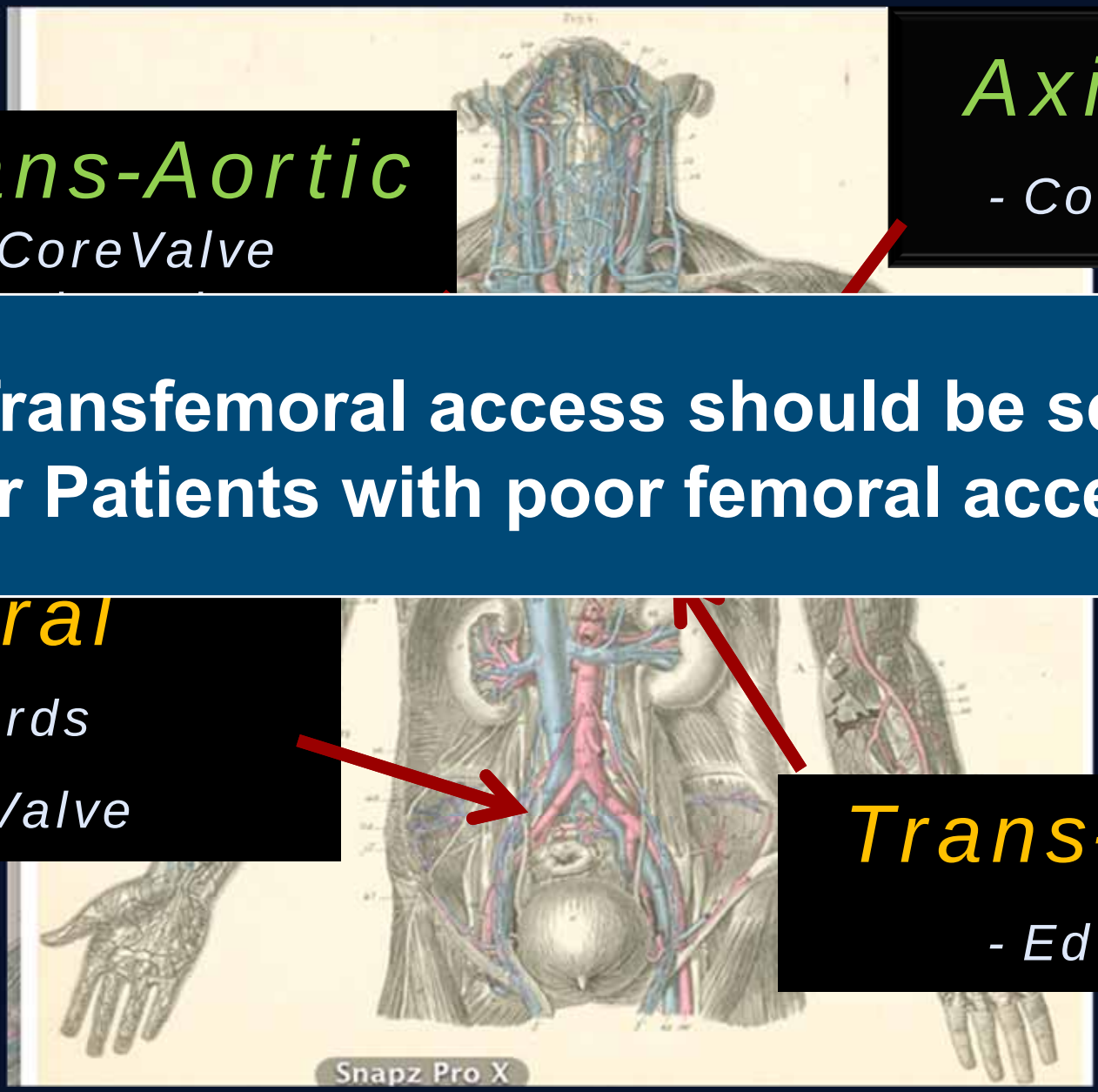
	Right Femoral Artery (n= 153)	Left Femoral Artery (n=148)
Femoral artery diameter, mm		
> 7.0 mm	81 (40.1%)	78 (38.6%)
6.0 – 7.0 mm	48 (23.8%)	47 (23.3%)
< 6.0 mm	24 (11.9%)	23 (11.4%)

Bilateral FA diameter < 6.0 mm was observed in 13 (6.4%) patients. Among them, 9 (5.1%) pts were not diagnosed as PAD.

Both FA diameter < 6.0 mm was independent predictor of major vascular complication

(HR, 29.41: 95% CI, 0.003 – 0.41: p = 0.008).

Access Routes For TAVI



Trans-Aortic
- CoreValve

Axillary
- CoreValve

Non-Transfemoral access should be selected for Patients with poor femoral access

Femoral
- Edwards
- CoreValve

Trans-apical
- Edwards

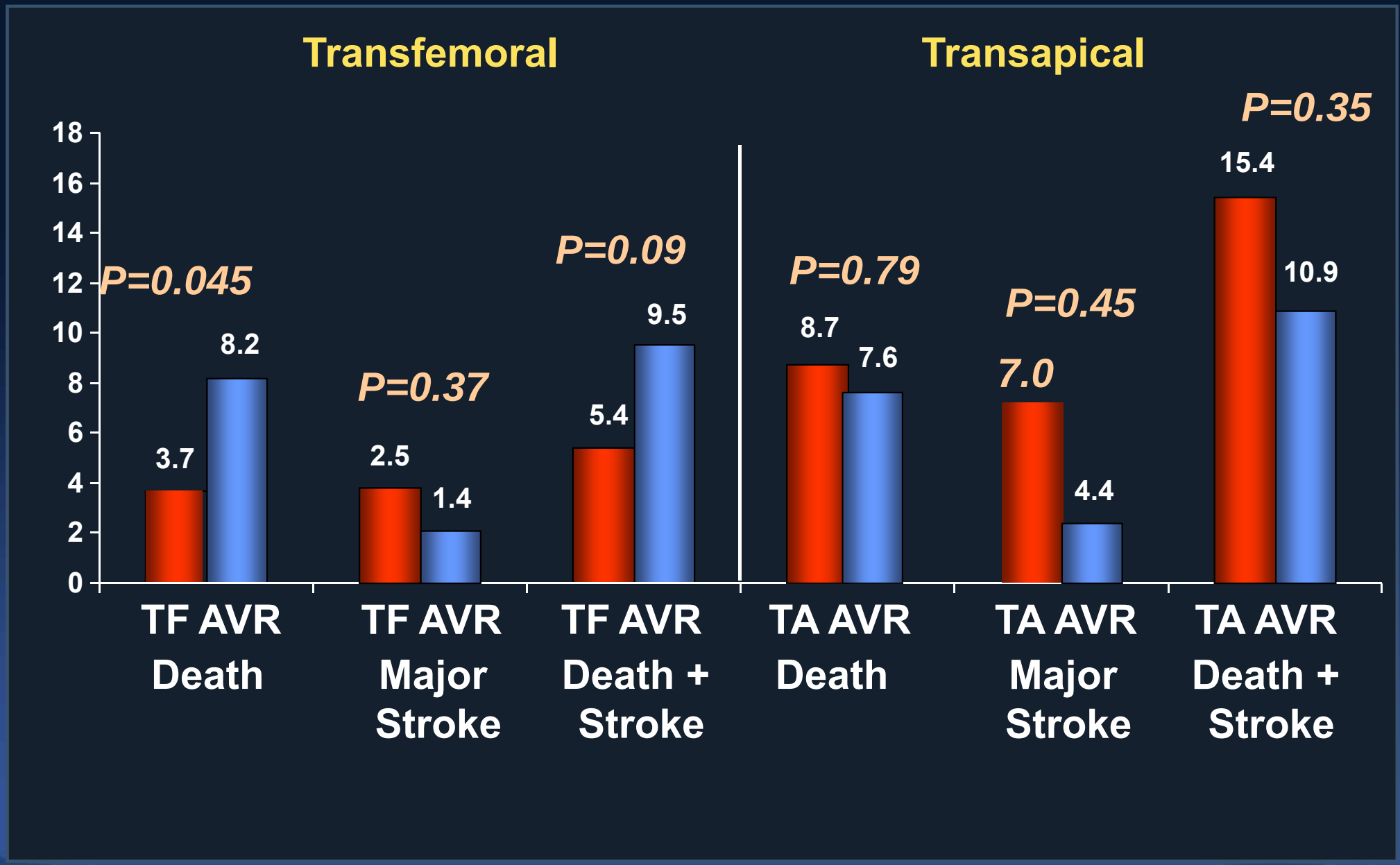
Still Transfemoral is preferred
Because...

- ***Better outcome***
- ***Better QOL***
- ***Quicker discharge***
- ***Smaller upcoming New device***

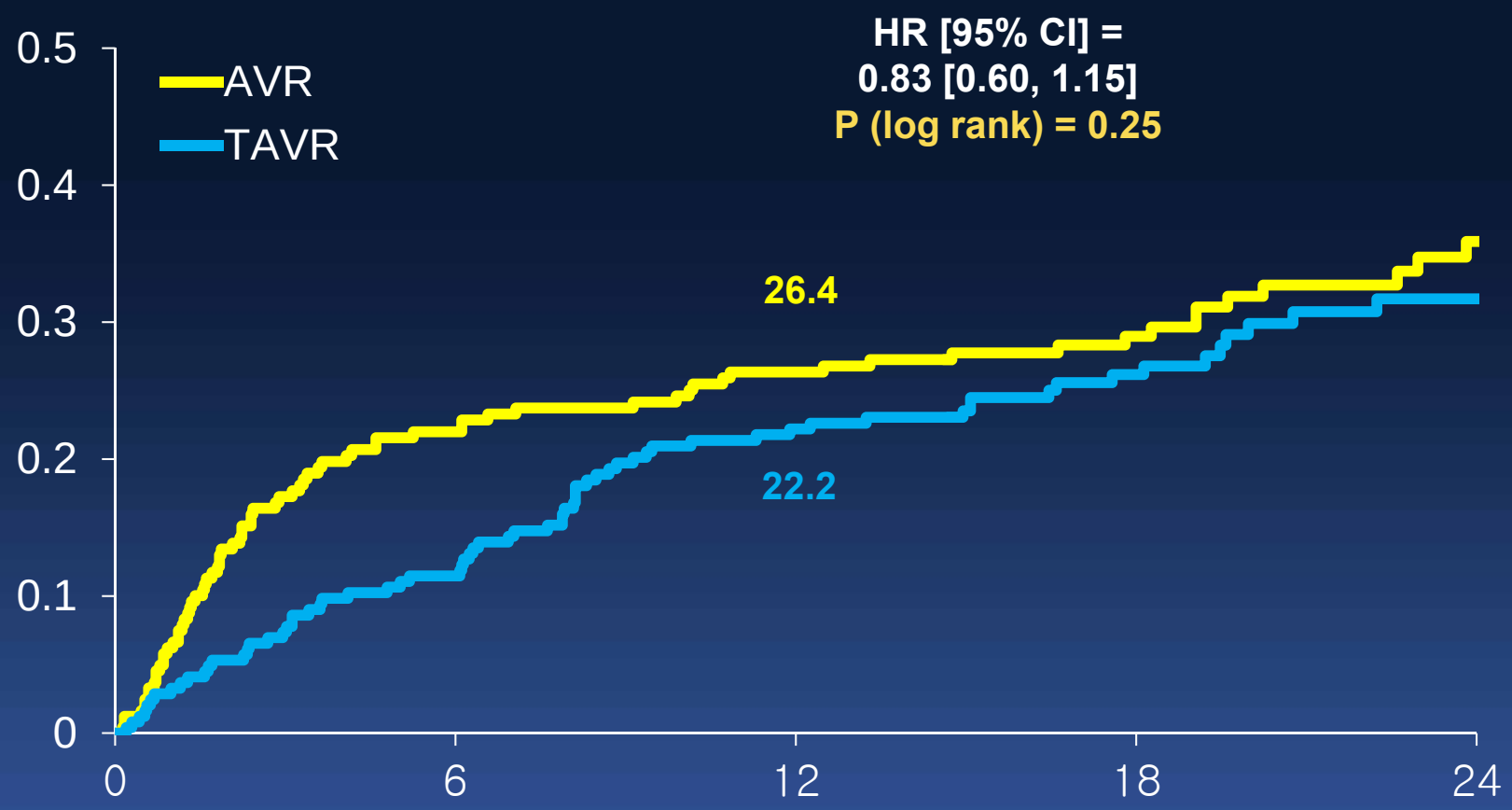
PARTNER trial TF vs TA (ITT)
Baseline Characteristics

Characteristic	*TF cohort (N = 492)*	*TA cohort (N = 207)*	*p-value*
Age (yr)	84.4 + 6.7	83.2 + 6.5	0.03
Male sex - %	57.8	55.8	0.67
STS Score	11.7 + 3.3	11.8 + 3.5	0.70
Logistic EuroSCORE	29.1 + 16.1	29.8 + 15.9	0.61
NYHA			0.94
II - %	6.1	5.3	
III or IV - %	93.9	94.7	
CAD - %	74.6	78.9	0.24
Previous MI - %	26.4	33.2	0.08
Prior CV Intervention - %			
Prior CABG - %	39.4	52.9	<0.001
Prior PCI - %	31.5	37.8	0.13
Prior BAV - %	11.8	11.8	1.00
Cerebrovascular disease - %	25.4	35.7	0.01

PARTNER: 30 Day Outcomes (AT)

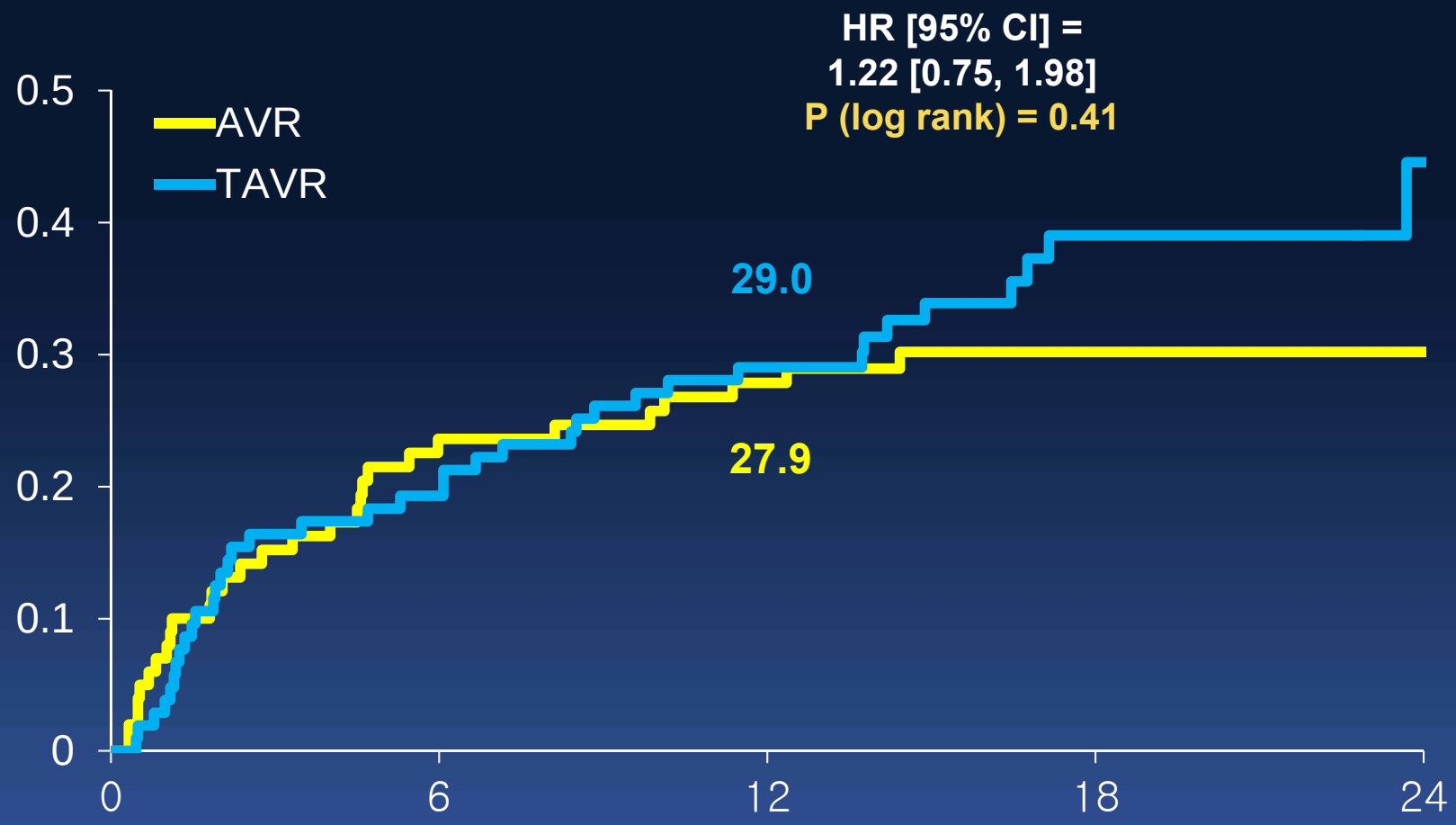


PARTNER Trial: All-Cause Mortality
Transfemoral (N=492)



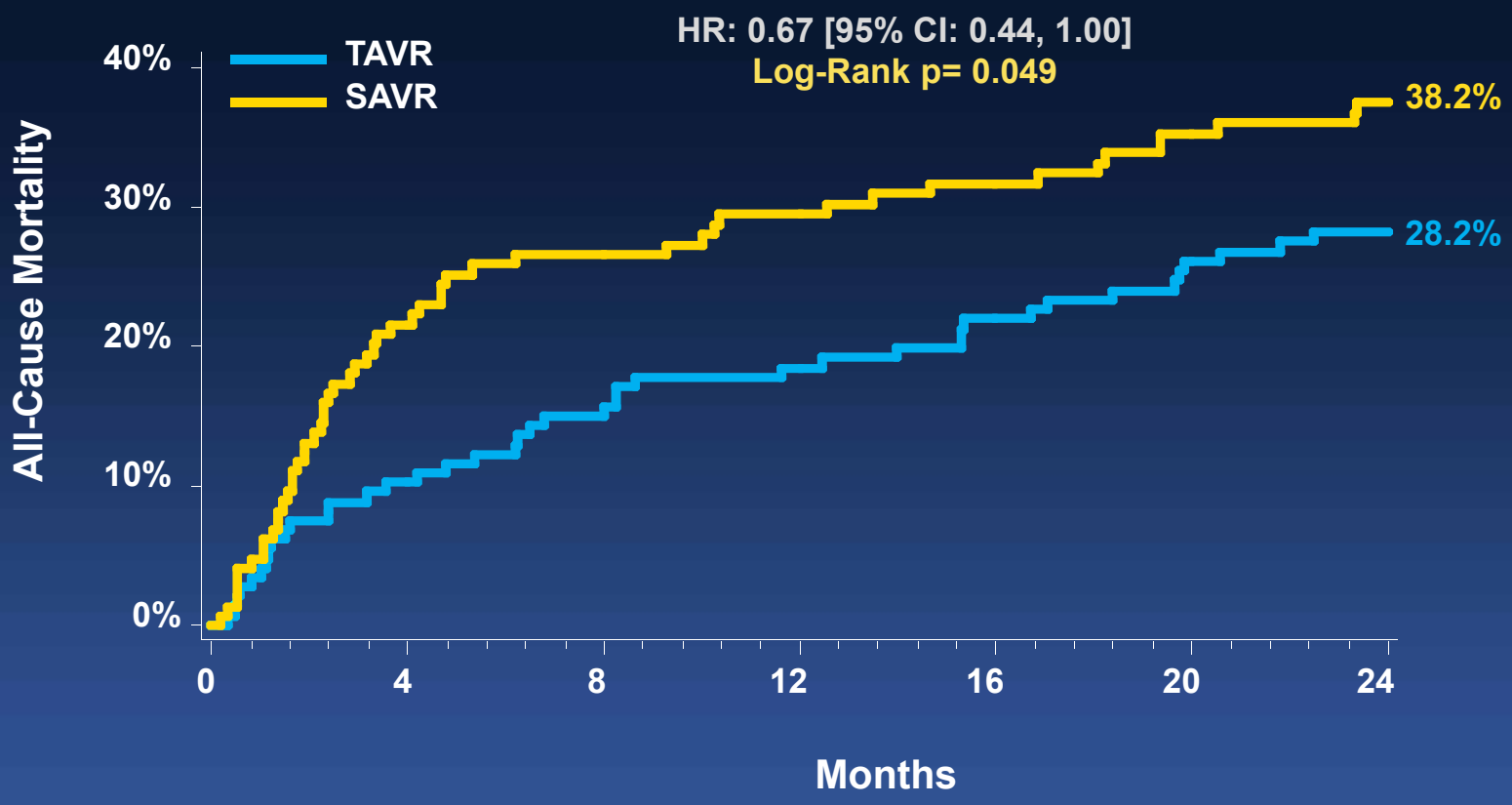
No. at Risk	Months				
TAVR	244	215	188	119	59
AVR	248	180	168	109	56

PARTNER Trial : All-Cause Mortality
Transapical (N=207)



No. at Risk			Months		
TAVR	104	83	72	28	8
AVR	103	72	68	30	9

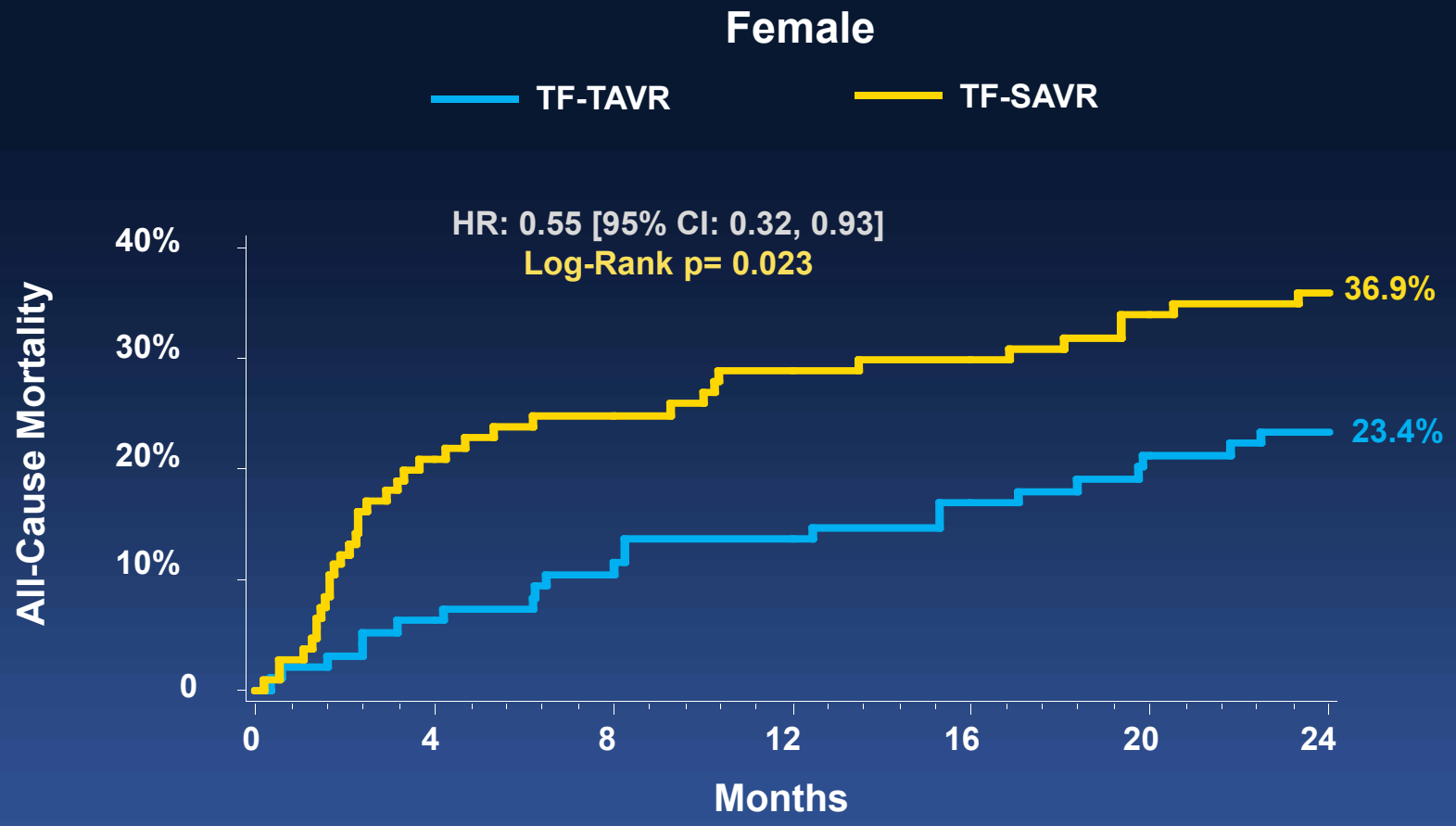
PARTNER Trial: All-Cause Mortality
Female Mortality TAVI vs. AVR



Numbers at Risk

TAVR	147	132	123	118	112	106	103
AVR	153	110	101	97	94	89	83

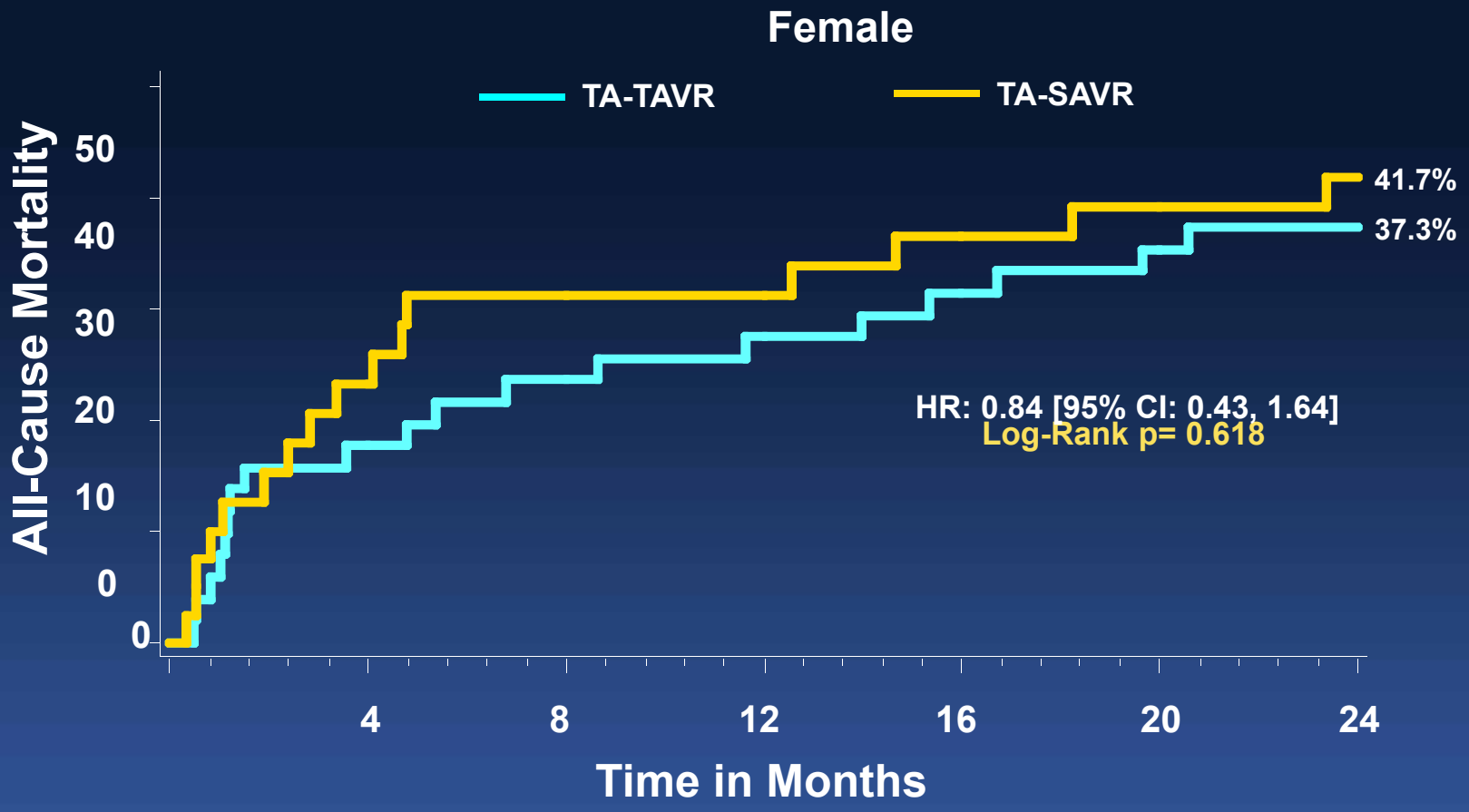
PARTNER Trial: All-Cause Mortality
Female Mortality TF-TAVI vs. AVR



Numbers at Risk

TF-TAVR	96	90	84	81	77	73	71
TF-SAVR	112	81	75	71	70	66	61

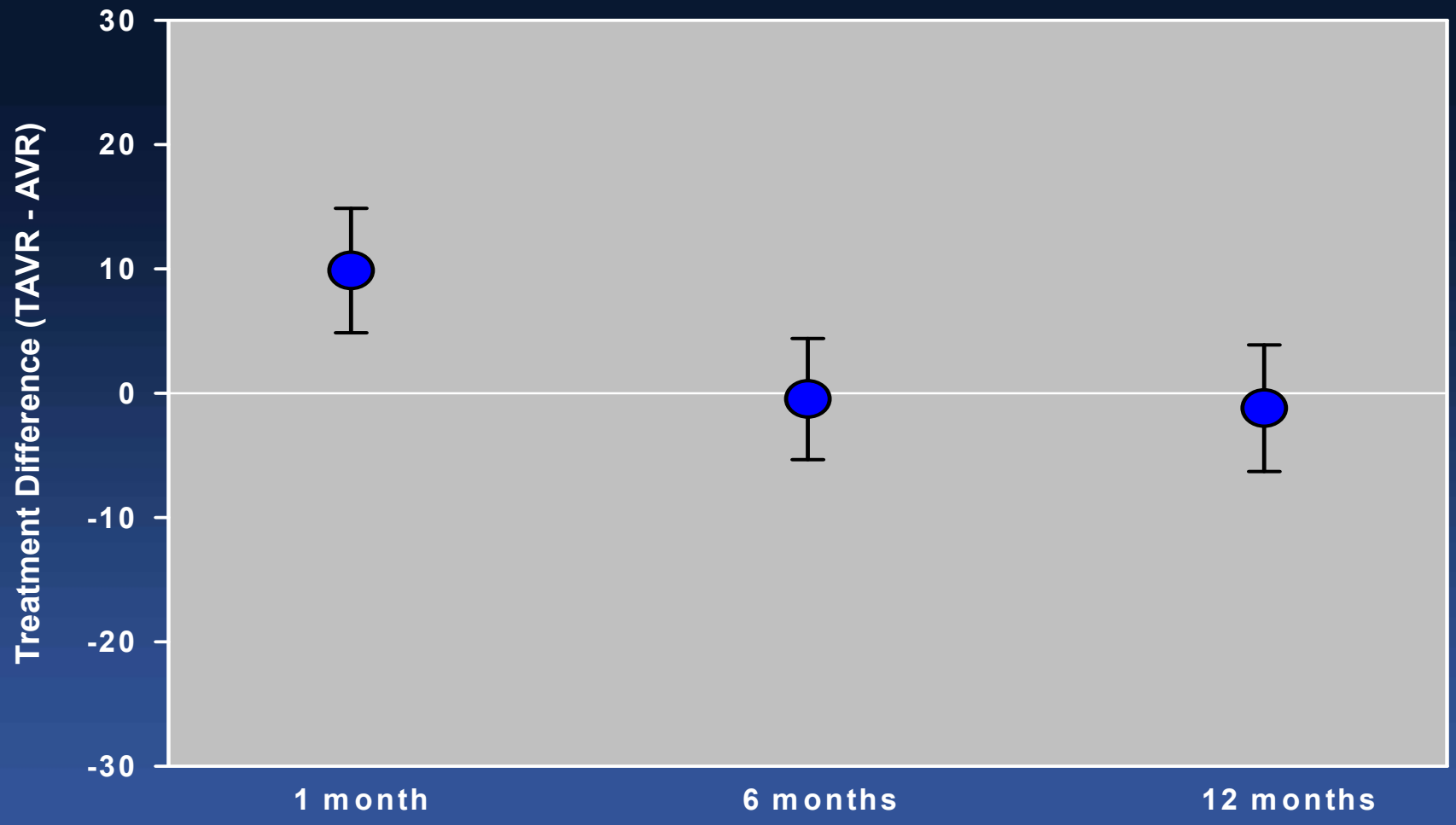
PARTNER Trial: All-Cause Mortality
Female Mortality TA-TAVI vs. AVR



Number at risk							
TA-TAVR	51	42	39	37	35	33	32
TA-SAVR	41	29	26	26	24	23	22

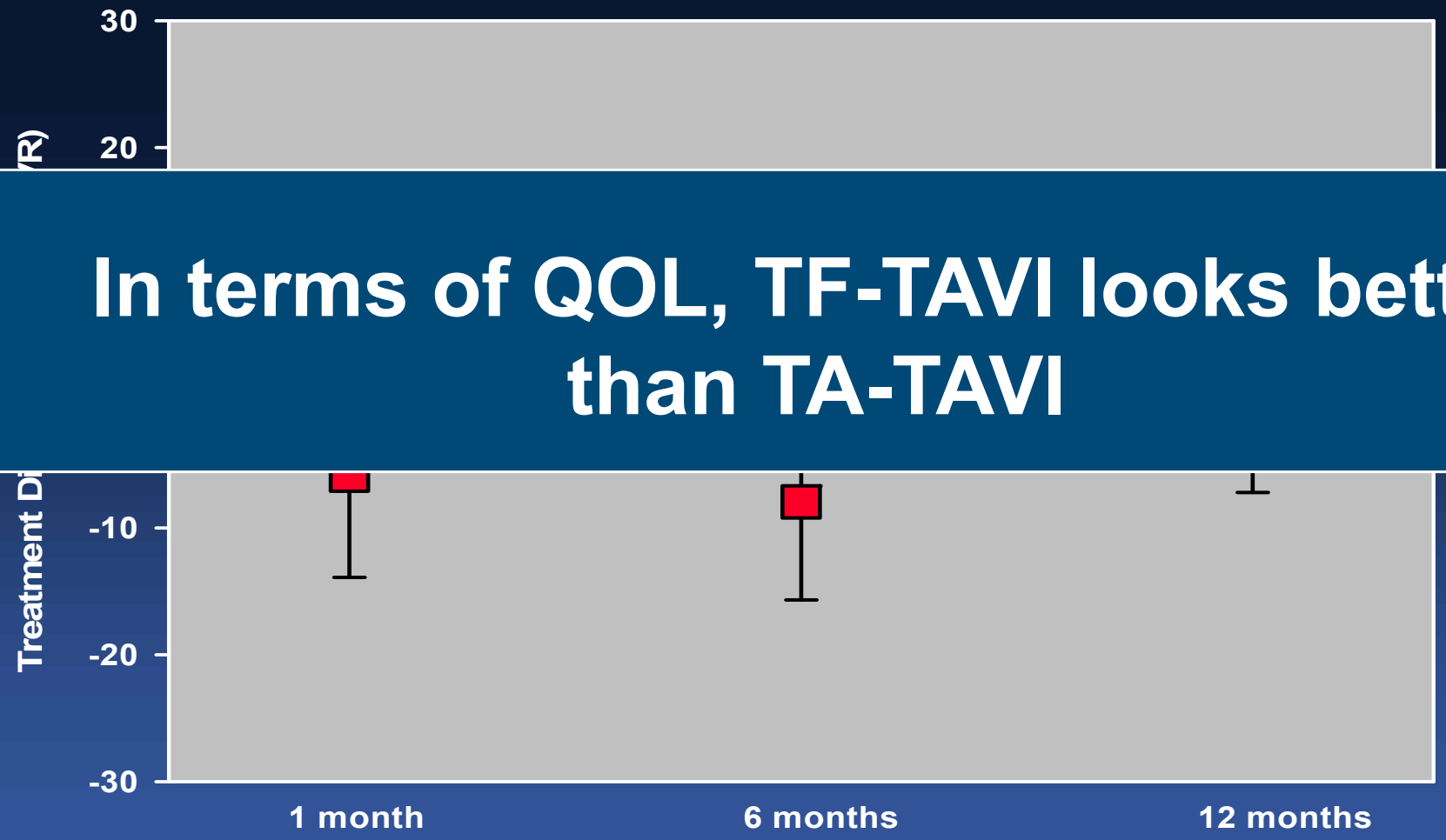
PARTNER Trial

KCCQ Overall Summary : TF group



PARTNER Trial

KCCQ Overall Summary : TA group



In terms of QOL, TF-TAVI looks better than TA-TAVI

PARTNER Trial
Procedural outcomes

Resource Category	TF-TAVI (N=234)	AVR (N= 221)	P value	TA-TAVI (N=101)	AVR (N= 91)	P value
Procedure Duration (min)	244±78	330±102	<0.001	224±76	354±104	<0.001
Total Hospital LOS, days	10.2 (7)	16.4 (12)	<0.001	14.7 (10)	16.1 (12)	0.39
ICU	3.3 (2)	5.6 (3)	<0.001	6.6 (3)	8.0 (4)	0.33
Non-ICU	6.9 (4)	10.8 (8)	<0.001	8.1 (6)	8.1 (7)	1.0
Post Procedure	7.4 (5)	13.5 (10)	<0.001	12.4 (9)	14.4 (9)	0.22
Major vasc. complication	13.2%	3.2%	<0.001	4.0%	4.4%	1.0
Major bleeding	9.4%	22.6%	<0.001	5.9%	20.9%	0.002

Issues about TF approach

- Alternative access is an important aspect of TAVI due to poor Transfemoral access

AND

- Reported better outcomes of TF-TAVI might be due to selection bias

HOWEVER

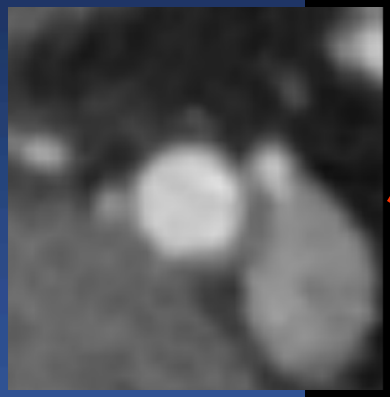
- TF is still preferred approach for better outcomes

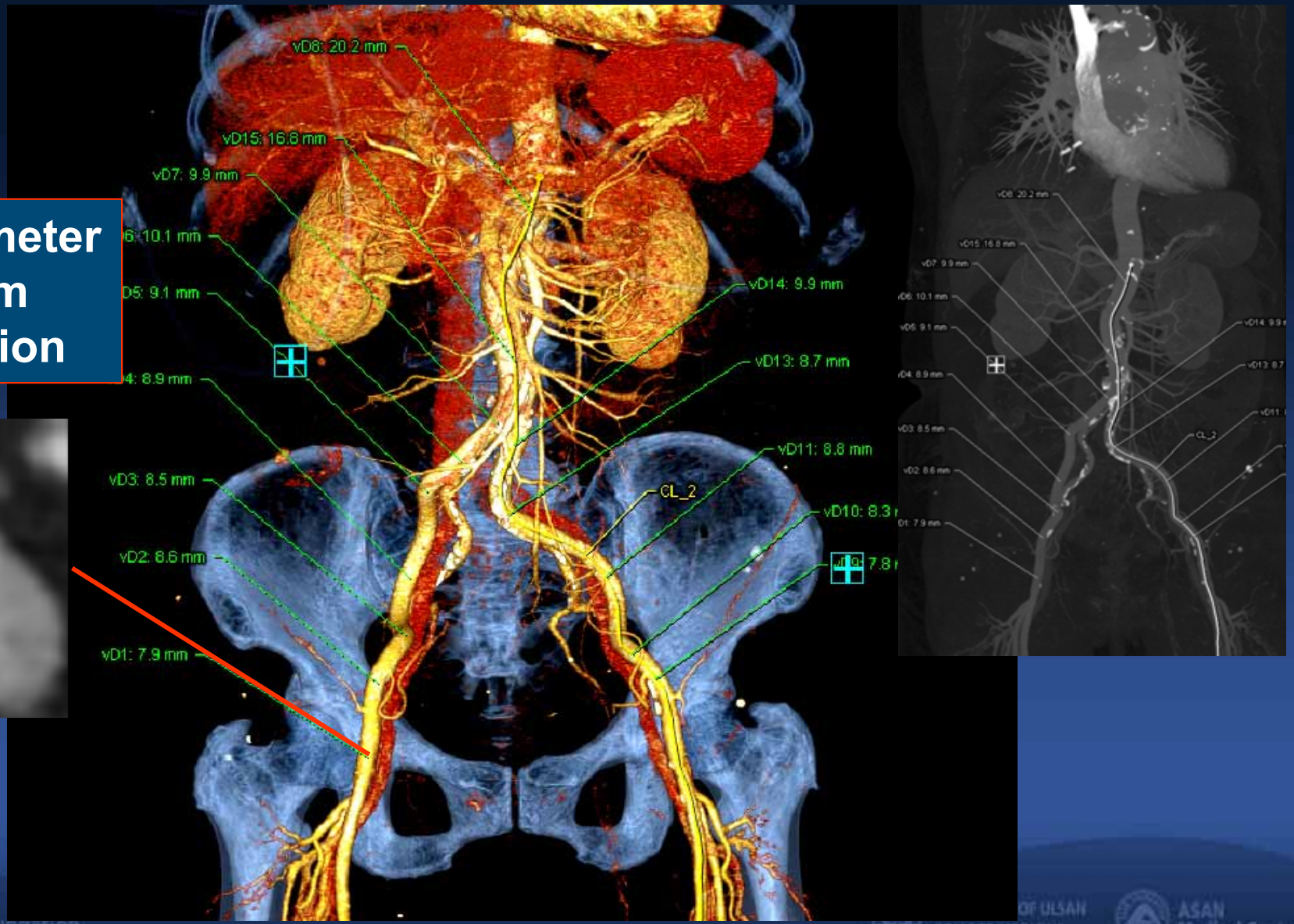
AMC Experience

Patient selection

Vascular Access Screening
CTA: 3D reconstruction

Minimal diameter
Rt. FA 7.8 mm
No calcification





Case Briefing

Brief Case Summary

86 y/o man with severe symptomatic AS admitted with CHF (NYHA class IV) TTE: severe AS (LVEF 58%) , moderate AR, apical akinesis

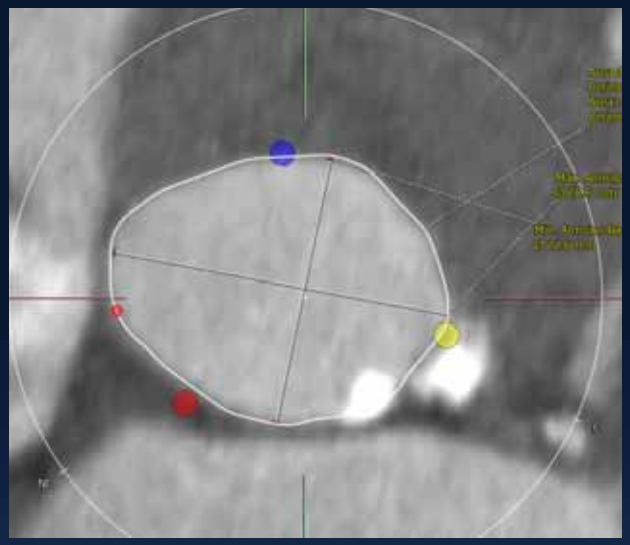
Past Medical History

Due to Co-morbidity, TF approach with local anesthesia was determined

Demographic Characteristics

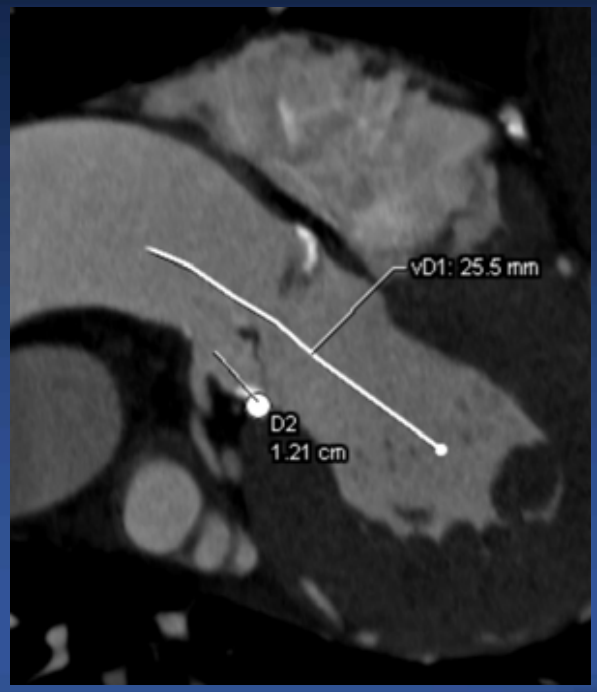
- Diabetes : N
- Hypertension : Y
- Hyperlipidemia : Y
- Smoking : N
- Family History : N
- BMI : 19.1
- Age : 86
- Sex : Male
- STS Mortality: 9.02%
- STS Morbidity: 33.56%
- Euro Score: 27.82%

Case Briefing



Max. diameter: 28.6 mm
Min. diameter: 22.6 mm
Mean diameter: 25.6 mm

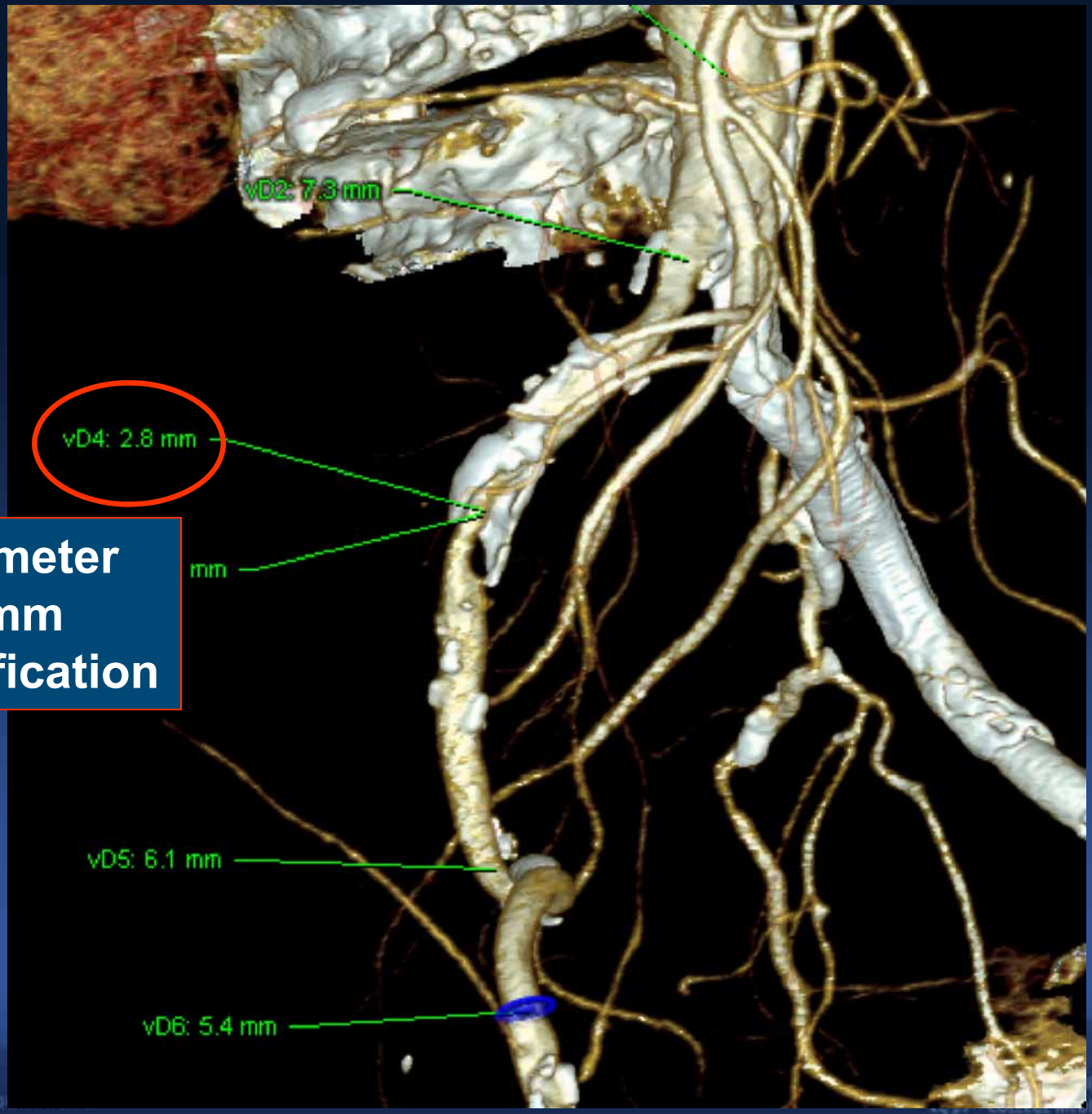
Annulus Area = 486 mm^2
Area derived diam. = 24.9 mm
Annulus Perimeter = 79.8 mm
Perimeter derived diam. = 25.4 mm



LCA height: 12.1mm
RCA height: 12.8mm

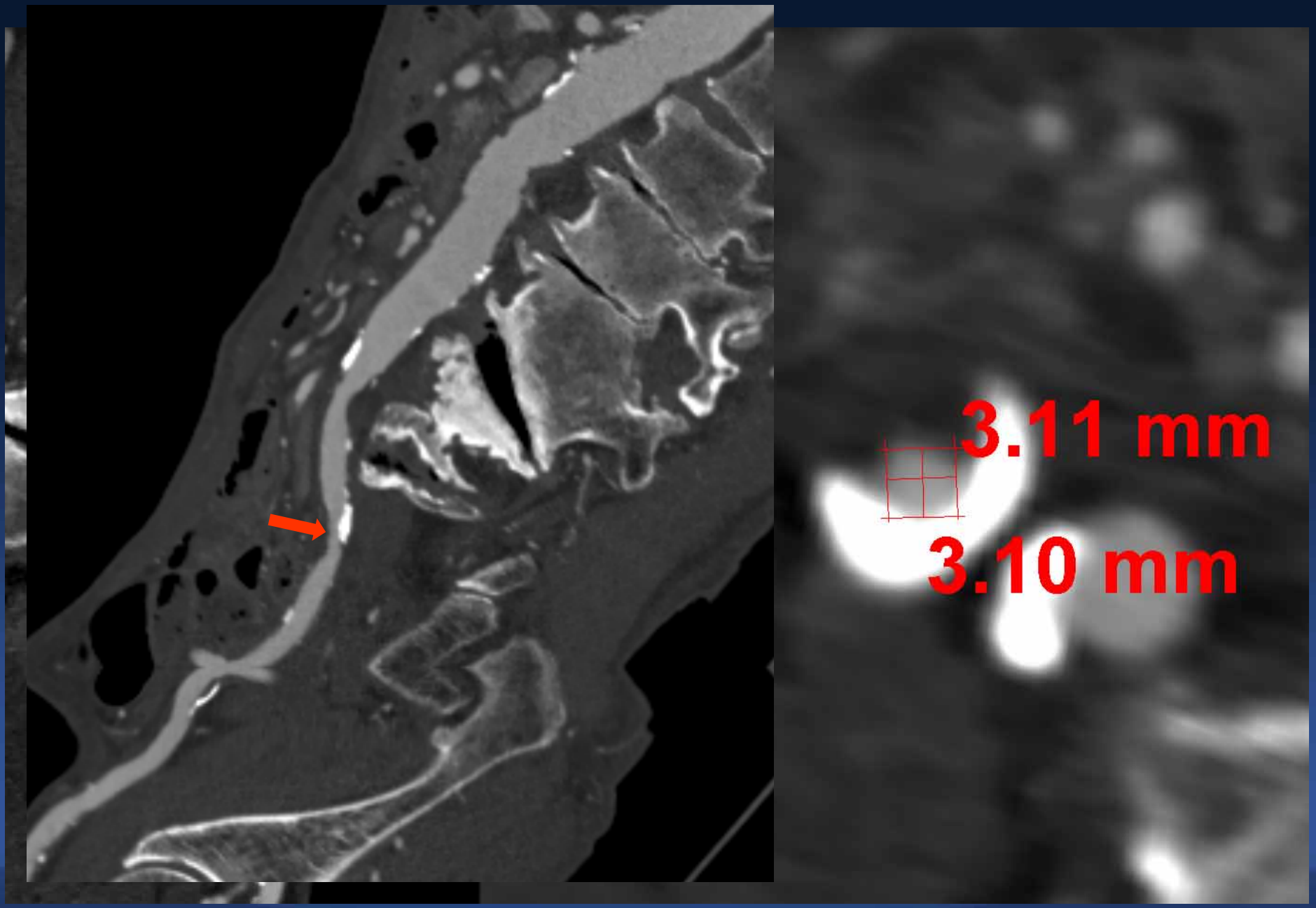
CT findings – Ileofemoral Angio

CT findings – Ileofemoral Angio



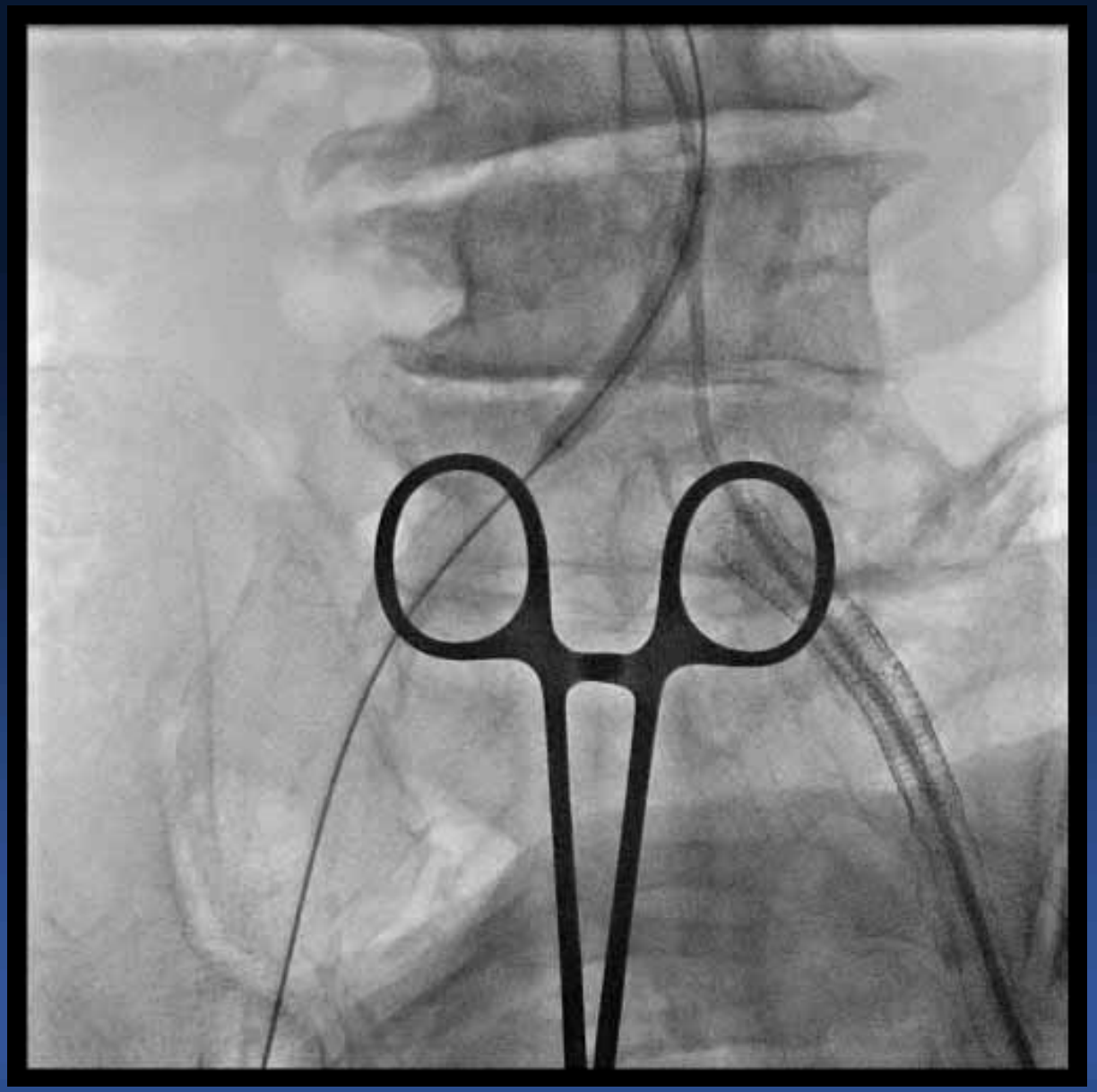
Minimal diameter
Rt. CIA 2.8 mm
Heavy calcification

CT findings – Rt. CIA



Pre-procedural angiography

PTA for Rt CIA



PTA for Rt EIA

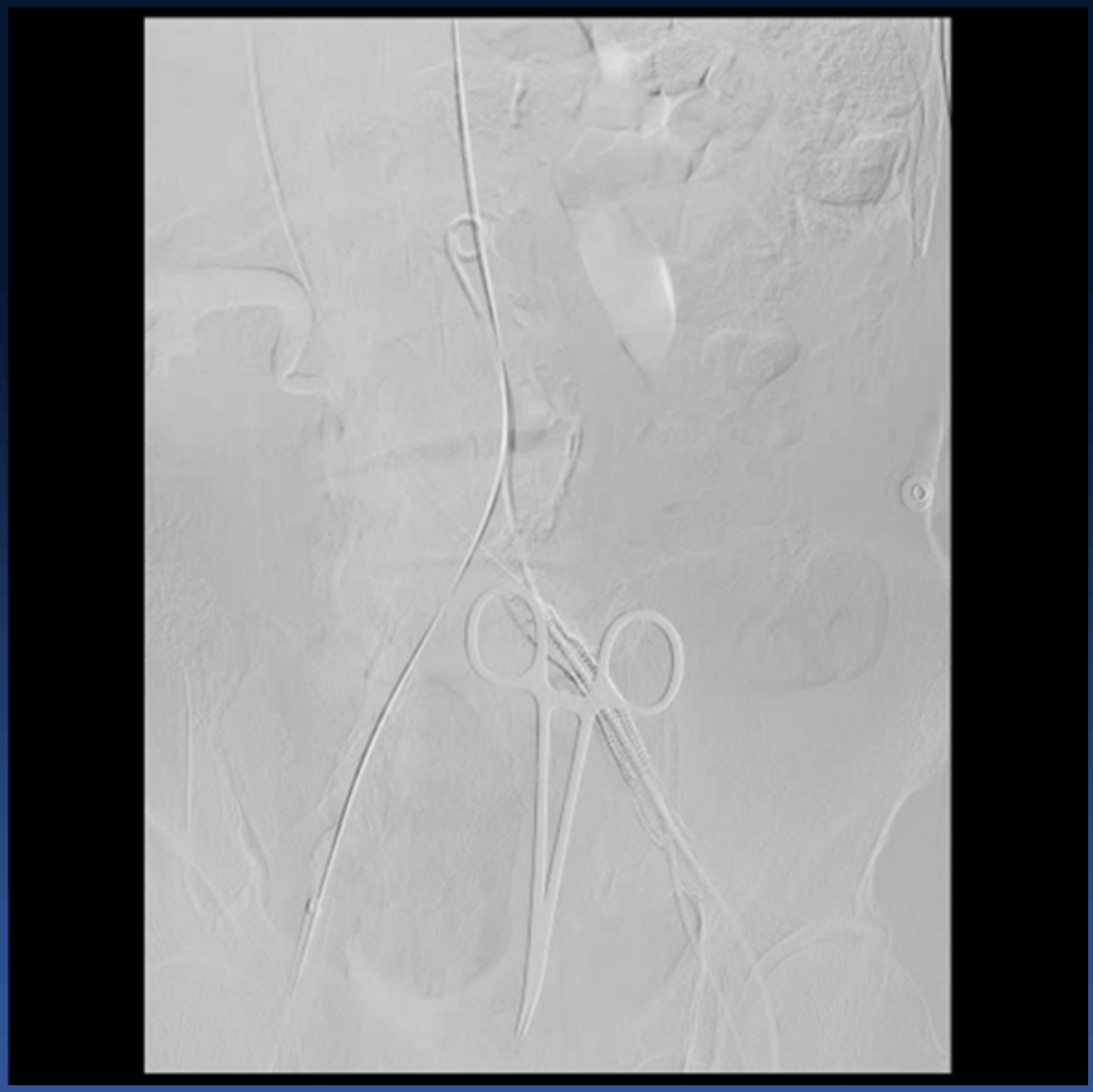
BAV

23mm Balloon

Implantation

SAPIEN XT 26mm

Final Iliac-femoral Angiography



Case Briefing

Brief Case Summary

72 y/o woman with severe symptomatic AS admitted with CHF (NYHA class III) TTE: severe AS with nomal LVEF

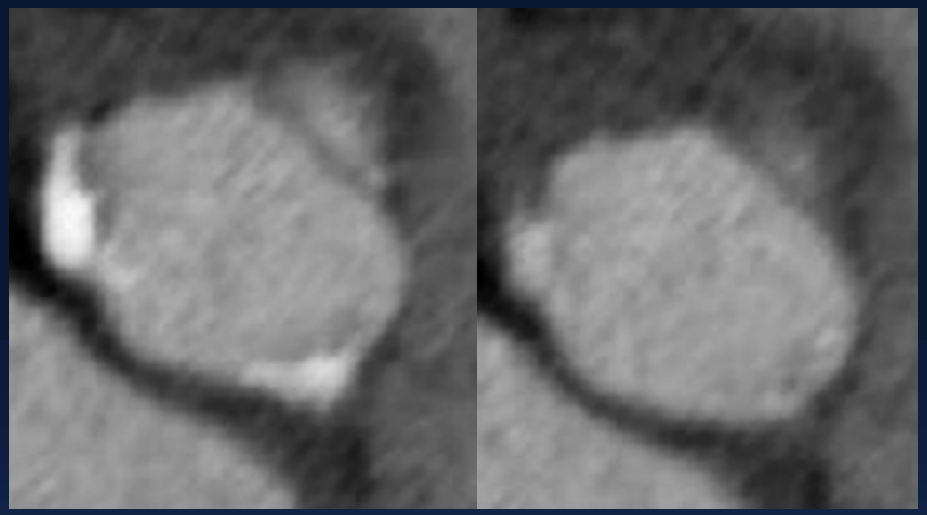
Due to the cerebral vascular disease, TF approach with local anesthesia was determined

- Other: h/o CVA event, bI CIA stenosis

Demographic Characteristics

- Diabetes : Y
- Hypertension : Y
- Hyperlipidemia : Y
- Smoking : N
- Family History : N
- BMI : 24.7
- Age : 72
- Sex : Female
- STS Mortality: 4.64%
- STS Morbidity: 25.45%
- Euro Score: 18.44%

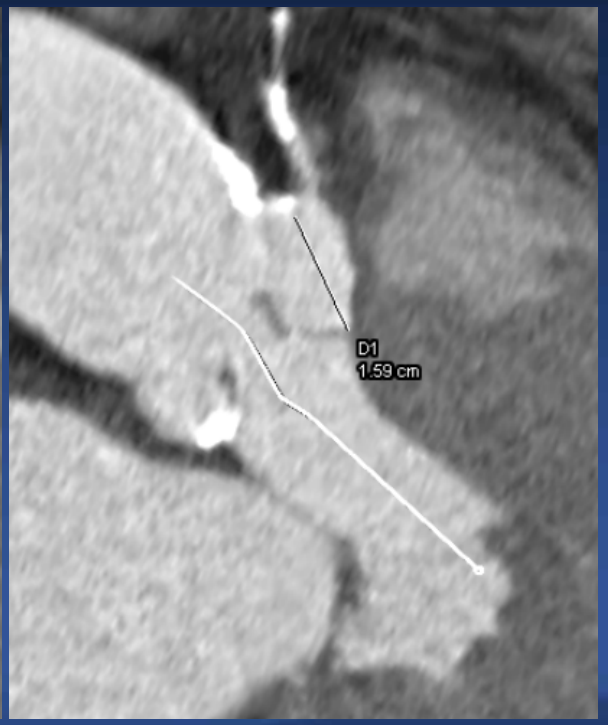
Case Briefing



Max. diameter: 24.9 mm
Min. diameter: 19.0 mm
Mean diameter: 22.0 mm

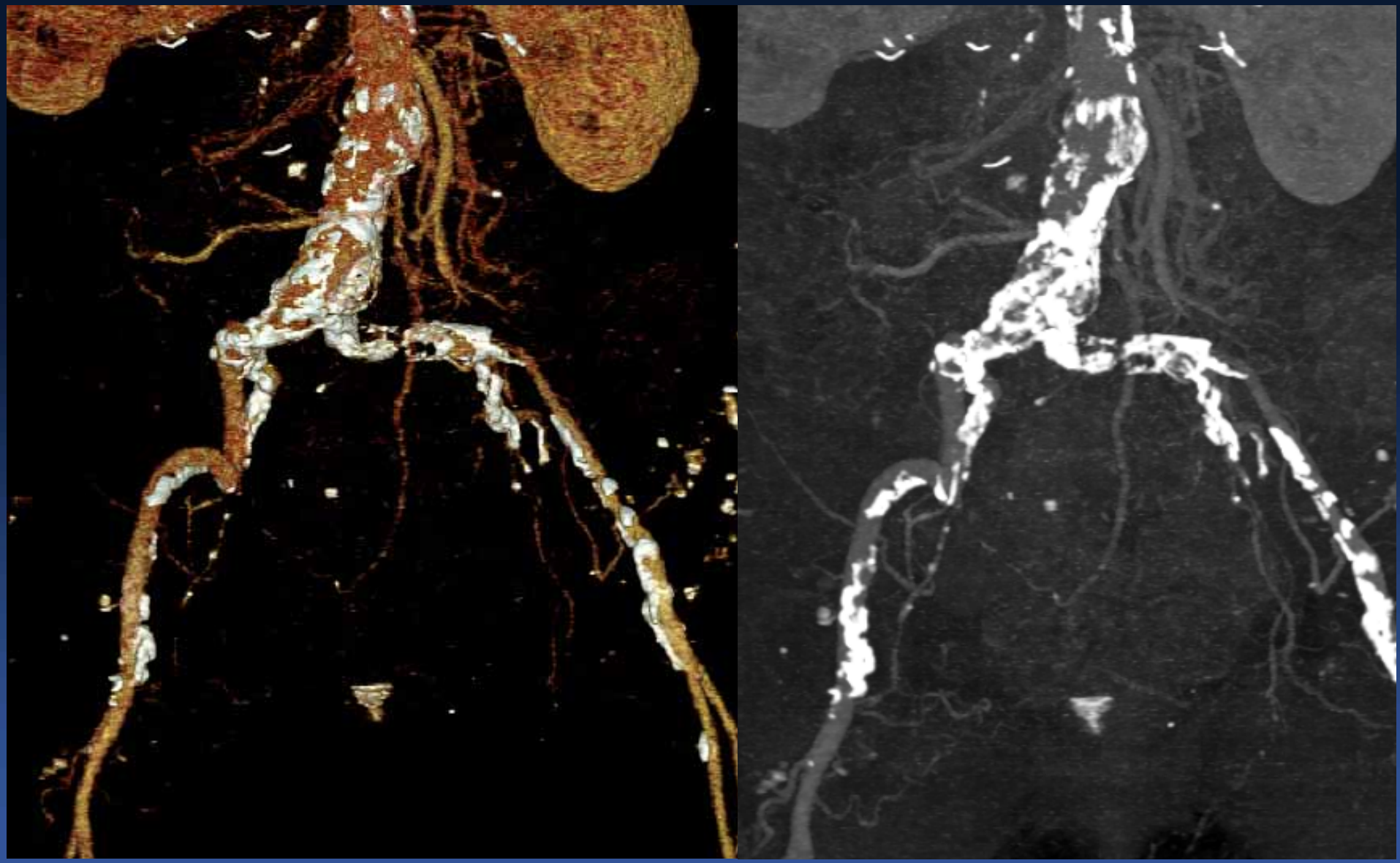
Annulus Area = 379 mm^2
Area derived diam. = 22.0 mm
Annulus Perimeter = 71.3 mm
Perimeter derived diam. = 22.7 mm

LCA height: 12.7mm
RCA height: 15.9mm

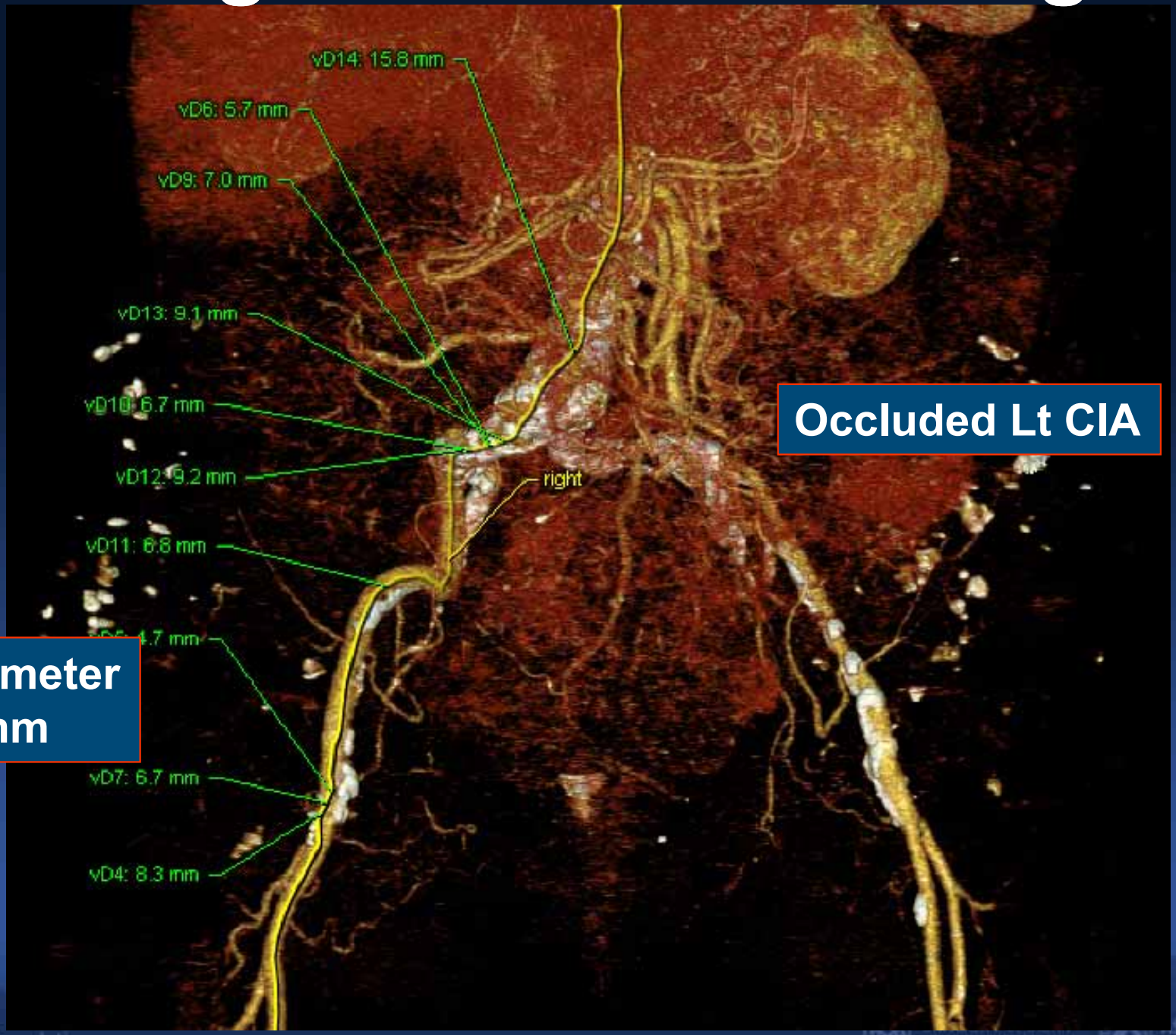


Gated cardiac CT: annulus assessment

CT findings – Ileofemoral Angio



CT findings – Ileofemoral Angio



CT findings – Rt Ileofemoral Angio

Severe Calcification

Pre-procedural Iliac-femoral Angiography

BAV

20mm

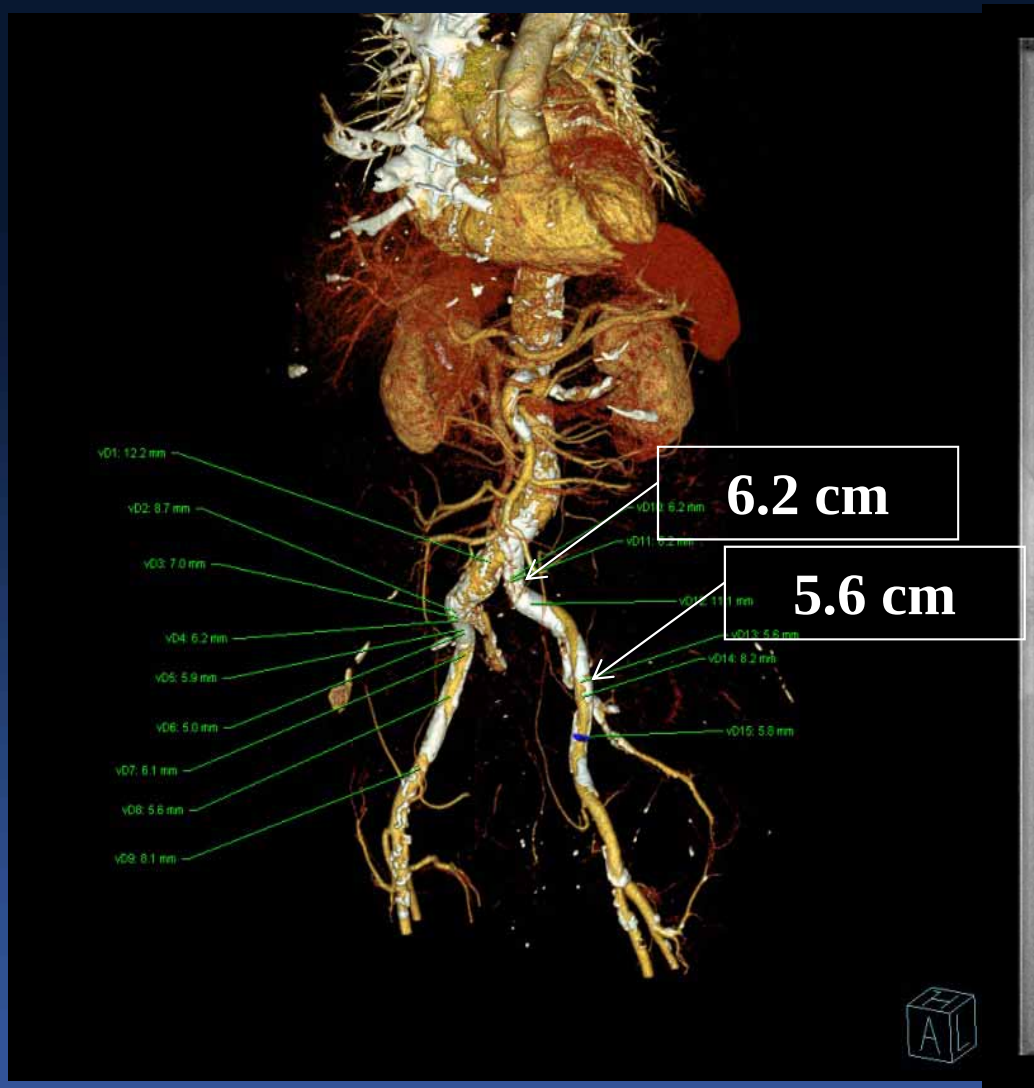
Implantation

Edward SAPIEN XT valve 23mm size

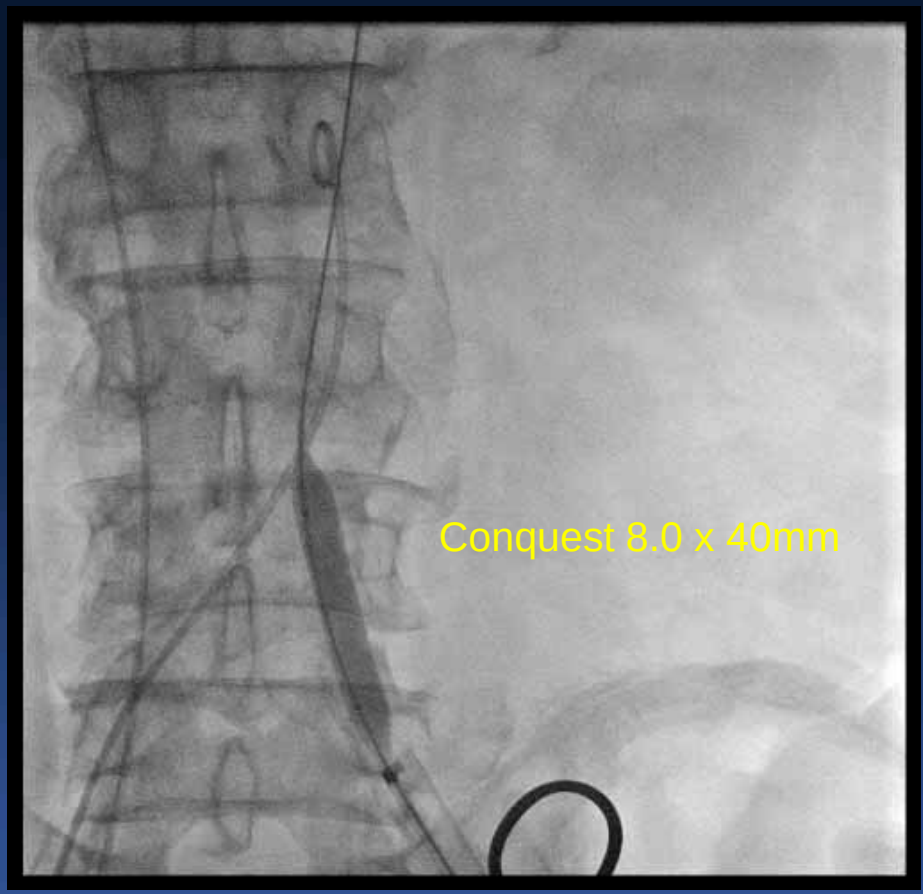
Post-procedural Ilio-femoral Angiography

Final Angiography

M / 73 Severe AS with PAD



First, PAD Balloon

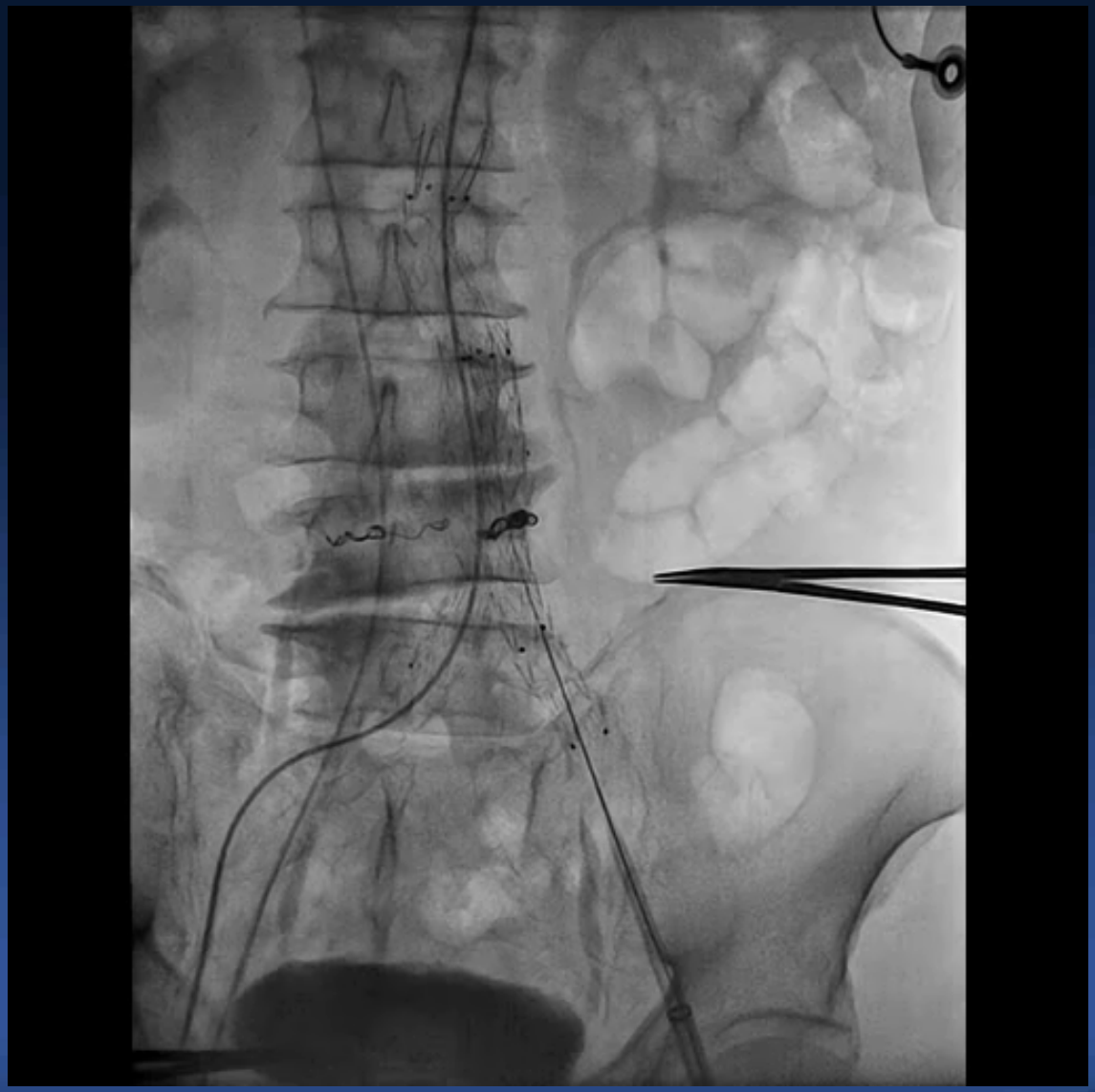


Final Peripheral Angiography

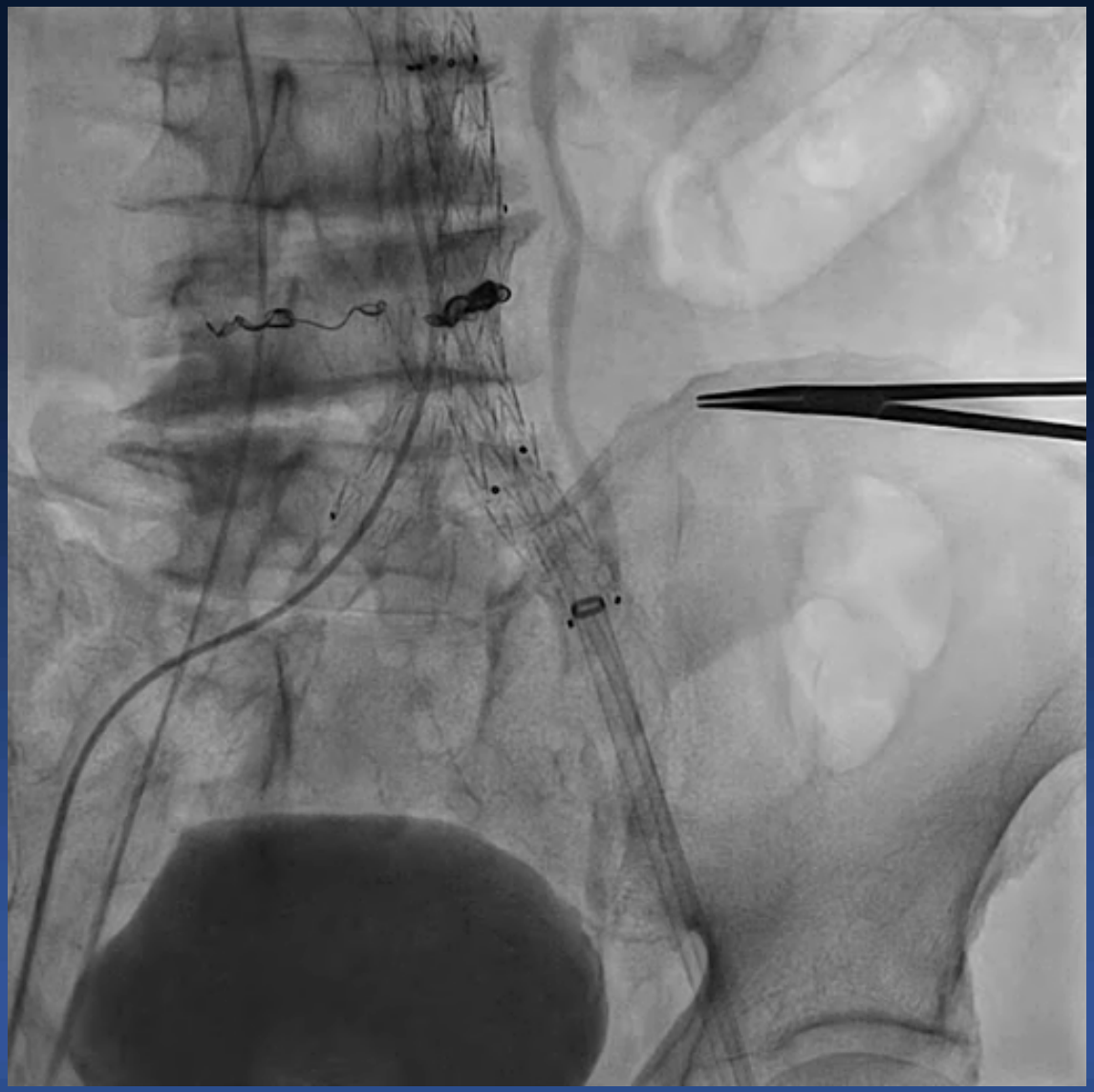
M / 75 severe AS
s/p EVAR (12’)

- Infrarenal AAA 5.0cm
- Main body
  Endurant 23mm x 145
-Contralimb
  Endurant 16mm x 95

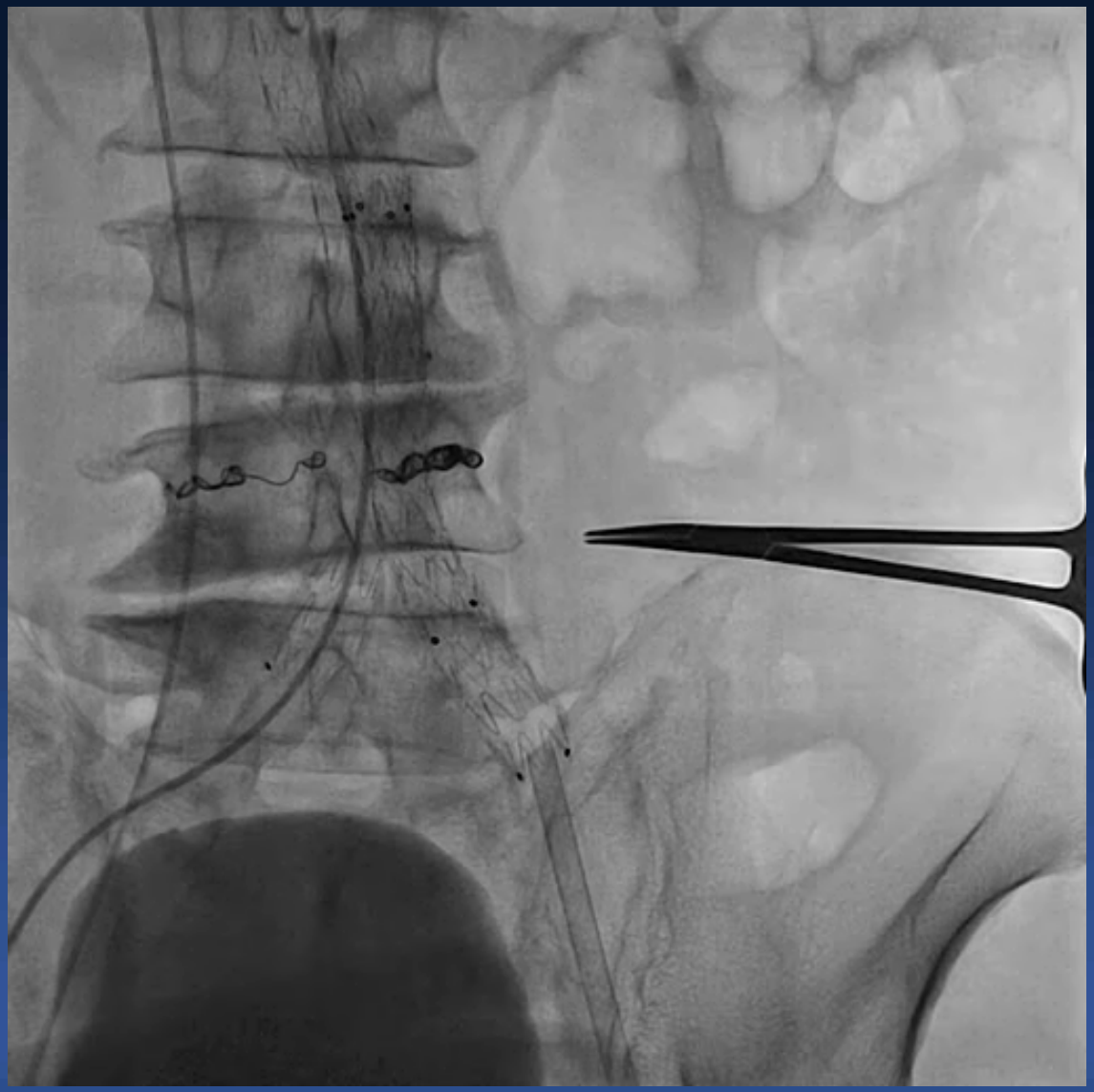
Iliac Thrombus After TAVI



Suction for Iliac Thrombus



Final Peripheral Anginography



Conclusions

- Asian patients have small femoral artery and MDCT can detect undiagnosed PAD
- Trans-femoral approach is preferred due to better outcomes. However, alternative access is an important option for patients with poor femoral access
- Integration of PTA technique and upcoming TAVI devices, Transfemoral-TAVI can be applicable and tolerated for patients with PAD