Access Site Vascular and Bleeding Complications Following Transfemoral TAVI

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Definition of
Access Related Vascular Complications

- Major Complications
  - Clinical sequele

- Minor Complications
  - No clinical sequele

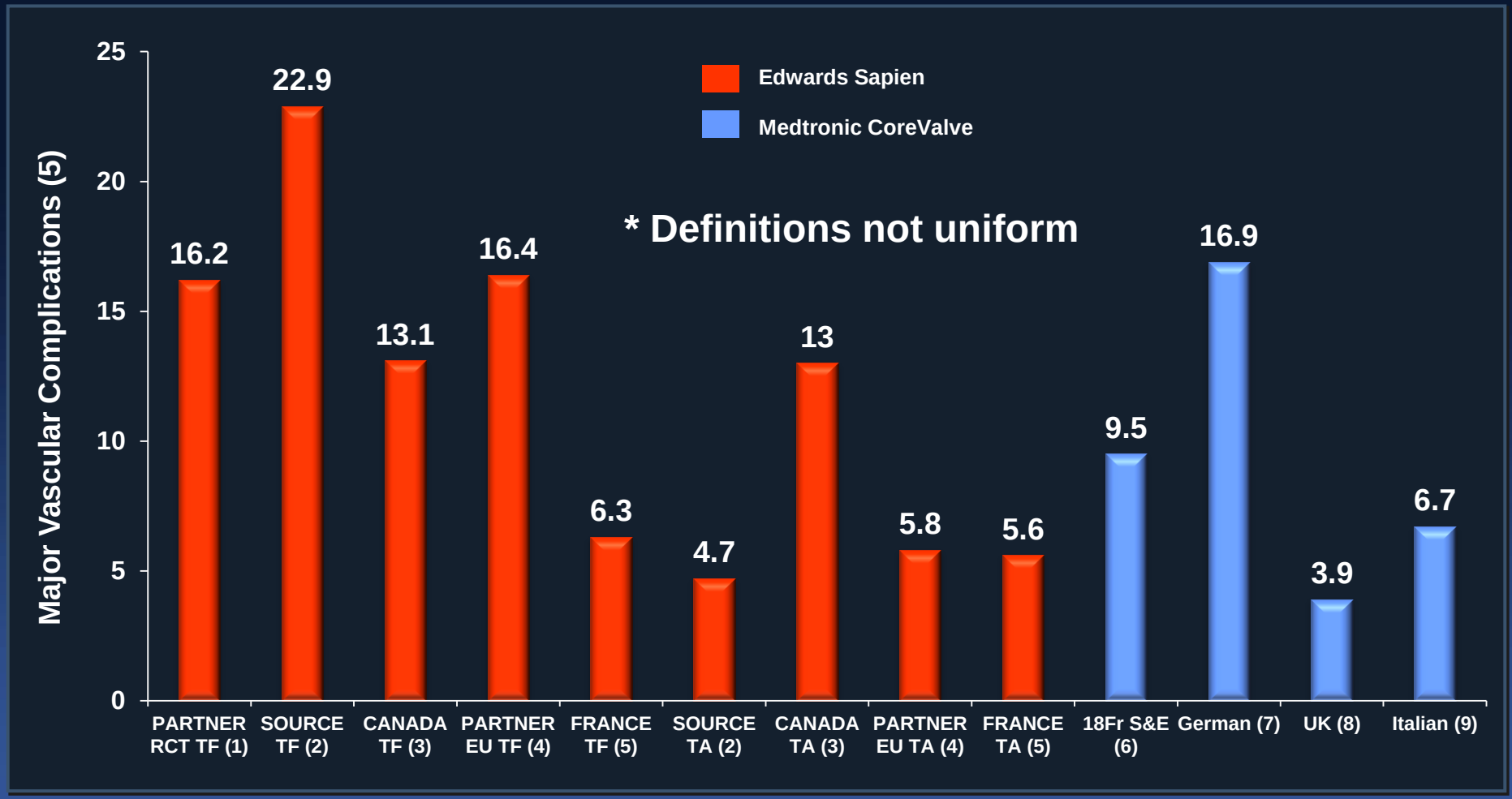
VARC-2- Major Vascular Complications

1. Any aortic dissection, aortic rupture, annulus rupture, left ventricle perforation, or new apical aneurysm/pseudo-aneurysm *OR*
2. *Access* site or access-related vascular injury (dissection, stenosis, perforation, rupture, arterio-venous fistula, pseudoaneurysm, hematoma, irreversible nerve injury, compartment syndrome, percutaneous closure device failure) *leading to death, life-threatening or major bleeding*, visceral ischemia,* OR
3. *Neurological* impairment *OR*

VARC-2- Major Vascular Complications

4. *Distal embolization* (non-cerebral) from a vascular source requiring surgery or resulting in amputation or irreversible end-organ damage OR
5. The use of *unplanned endovascular or surgical intervention* associated with death, major bleeding, visceral ischemia or neurological impairment *OR*
6. Any new ipsilateral *lower extremity ischemia* documented by patient symptoms, physical exam, and/or decreased or absent blood flow on lower extremity angiogram OR
7. Surgery for access site-related *nerve injury* OR
8. Permanent access site-related nerve injury

Incidence of Major Vascular Complications After TAVI*



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3. Rodes-Cabau J et al. J Am Coll Cardiol. 2010 Mar 16;55(11):1080-90.
4. Lefevre T et al. Eur Heart J. Nov 12
5. Eltchaninoff H et al. Eur Heart J. Sep 15.
6. Medtronic. Data on file. COR 2006-02: 18 Fr Safety & Efficacy Study Re-Analysis, August 14, 2009.
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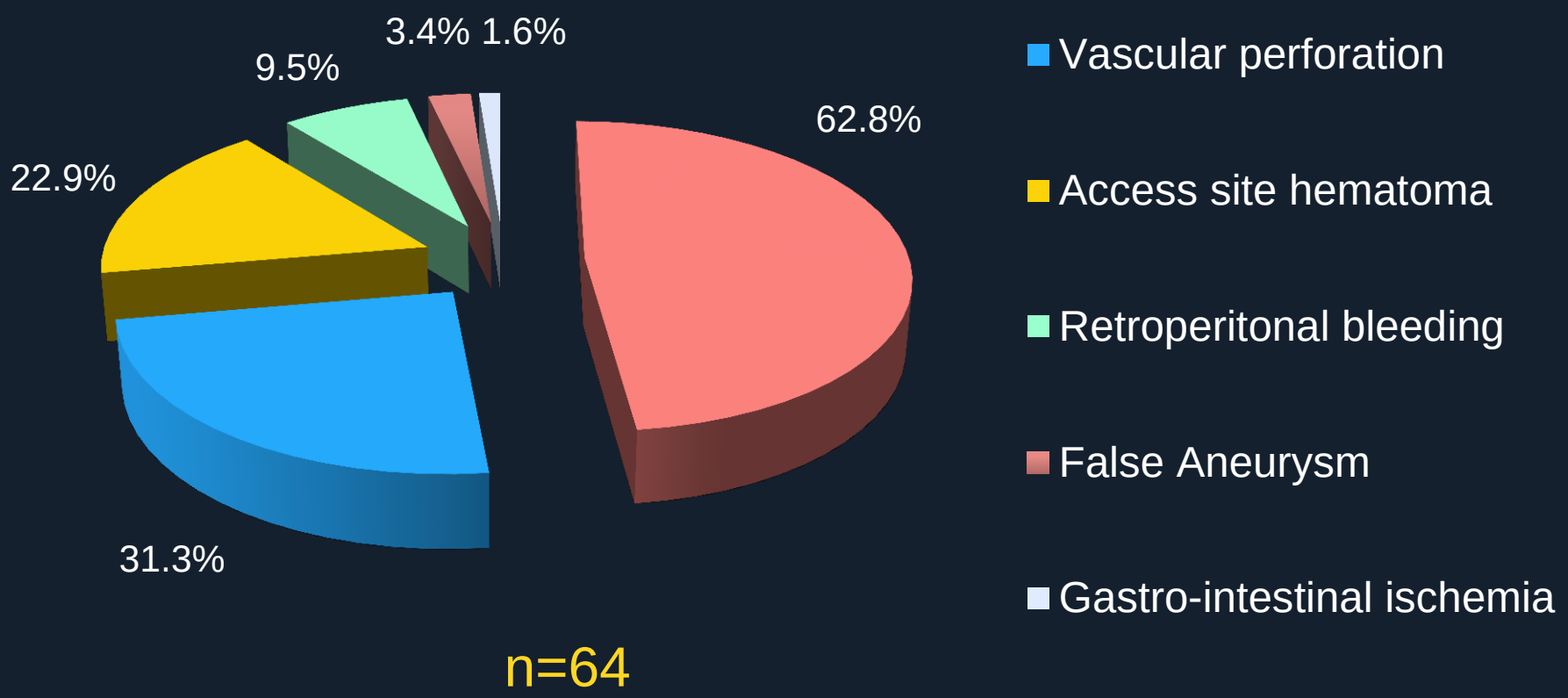
Vascular complications after TAVI
Meta-analysis

Outcomes	*Reported Rate min,max (%)*	*Cumulative rate*	*I^2 (%)*	*Rate Estimated (%)*	*[95% CI]*
Major	5.0-23.3	282/2417	81.3	11.9	[8.6,16.4]
Minor	5.6-28.3	203/2142	88.8	9.7	[6.7,14.0]
All	9.5-51.6	511/2740	92.6	18.8	[14.5,24.3]

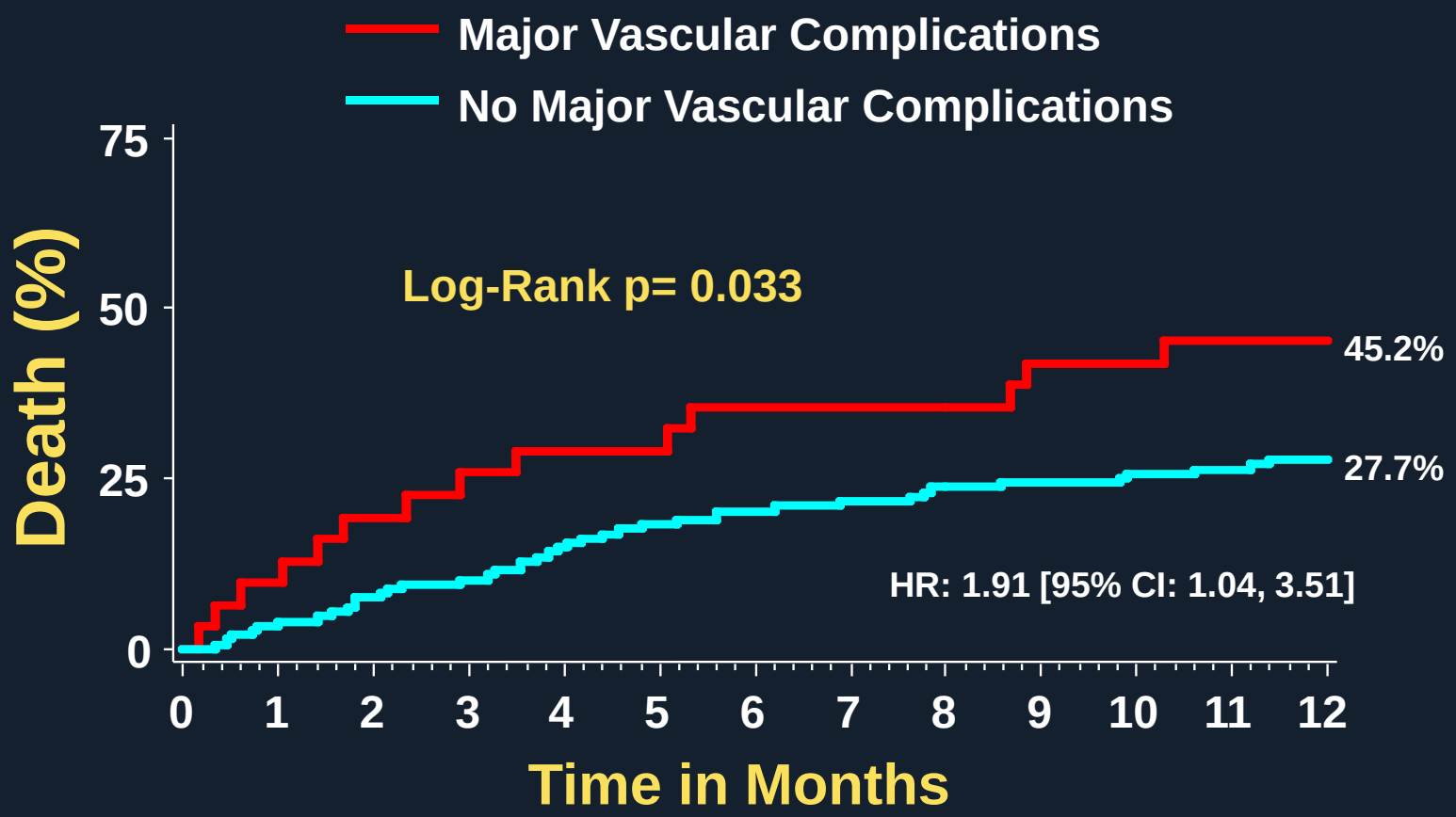
Généreux P et al. JACC 2012;59:2317

Major Vascular Complications
PARTNER 1 TF-Cohort A and B



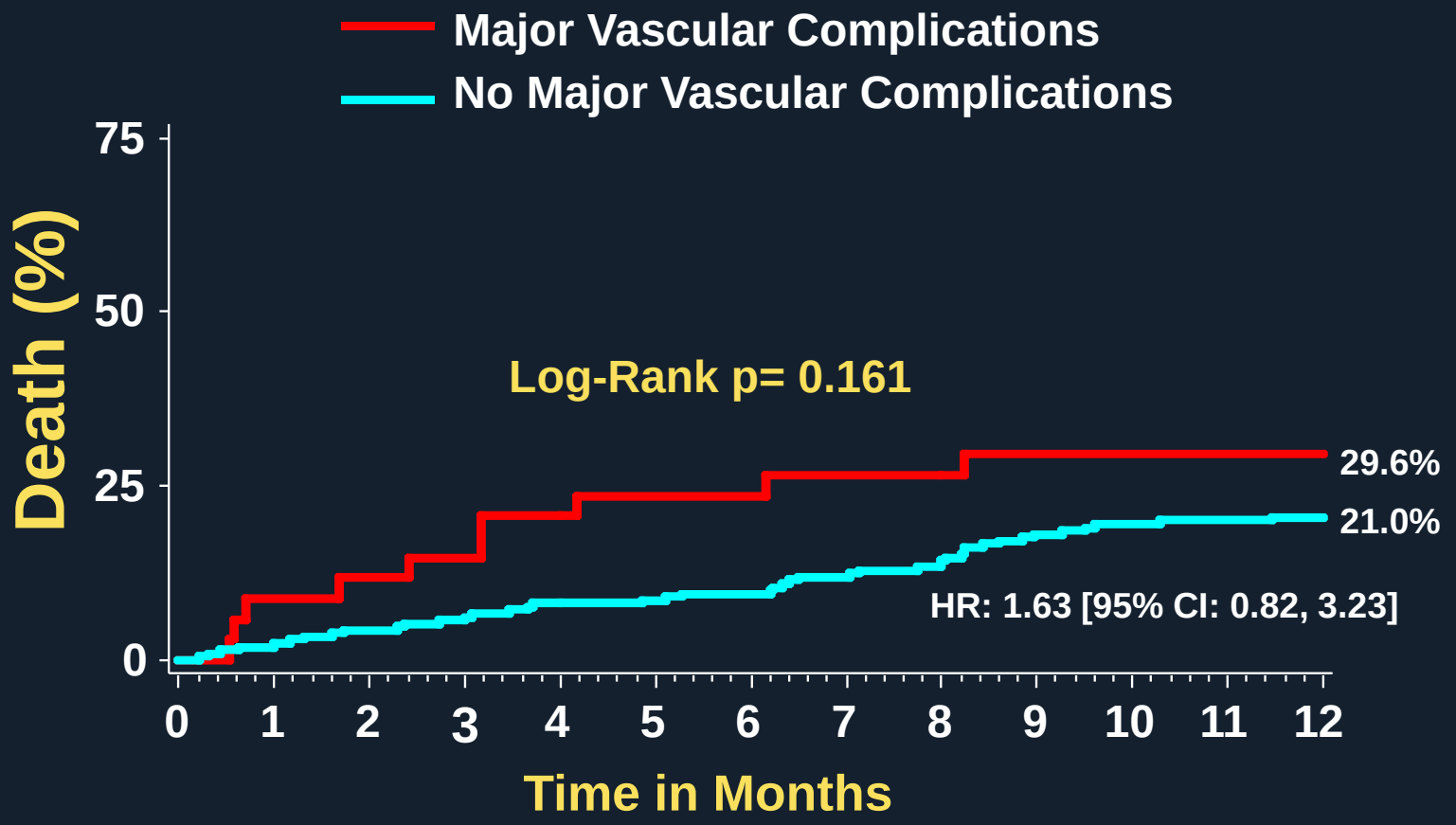
Genereux P et al. J Am Coll Cardiol 2012;60:1043

Vascular Complication and Mortality
PARTNER Cohort B (Inoperable)TF, Sapien



Number at risk				
Major VC	31	22	20	17
No Major VC	148	126	113	107

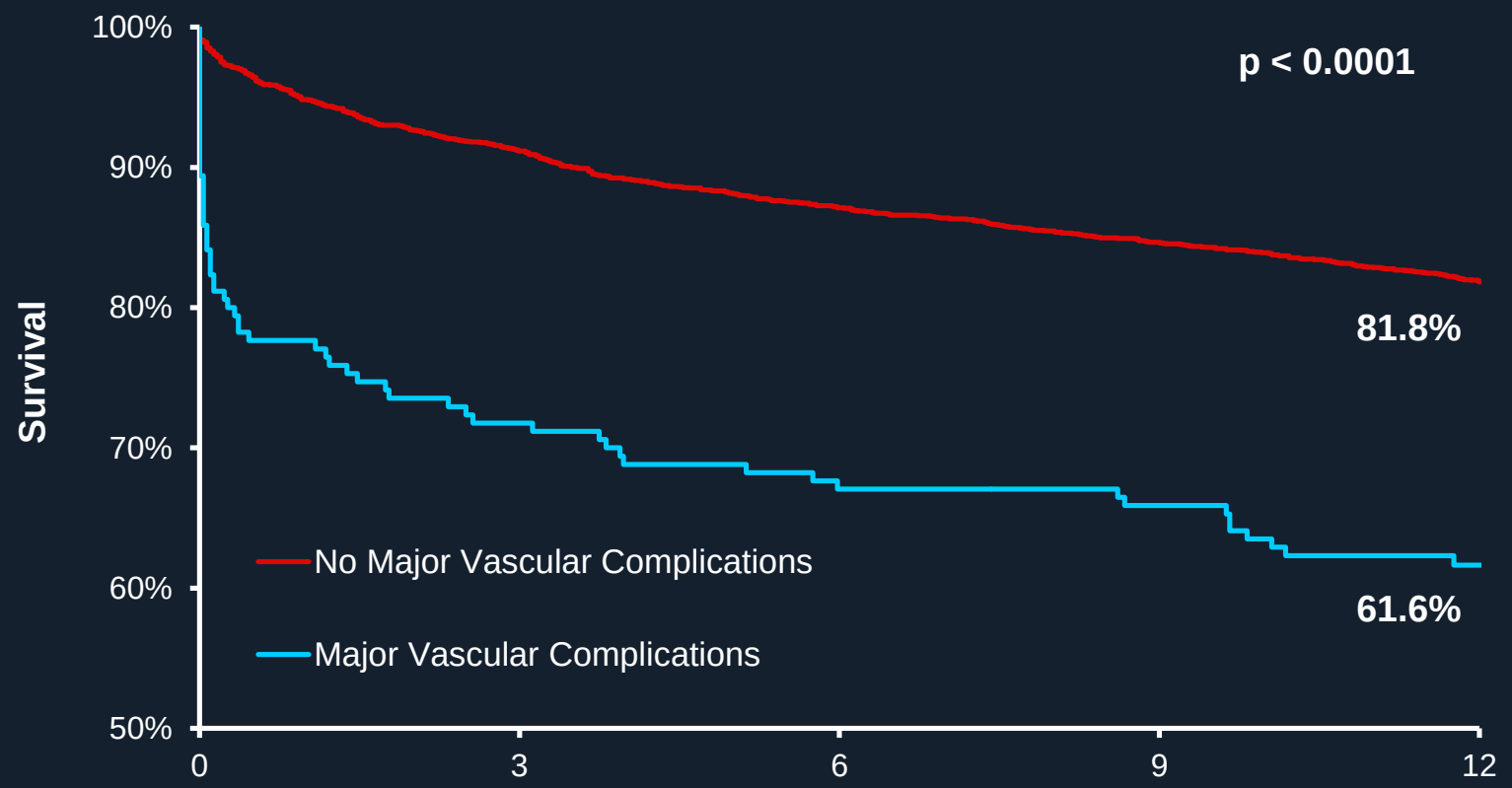
Vascular Complication and Mortality
PARTNER Cohort A (High-risk) TF, Sapien



Number at risk				
Major VC	34	27	24	22
No Major VC	210	193	182	167

Vascular Complications and Mortality

SOURCE XT Registry: SAPIEN-XT



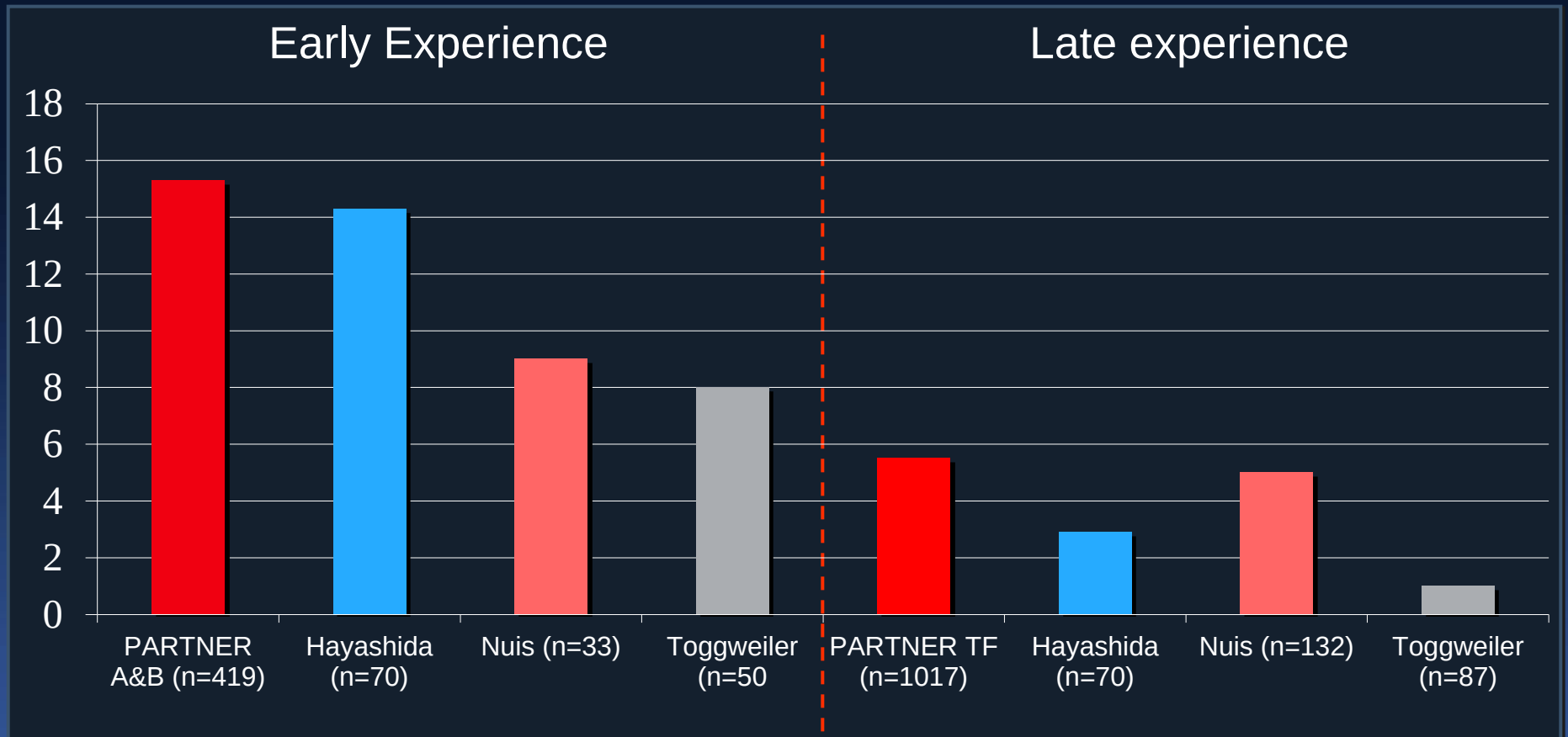
No. at Risk					
No Major VC	2518	2278	2171	2081	1561
Major VC	170	122	114	112	79

Can we prevent ?

Predictors of Major Vascular Complications

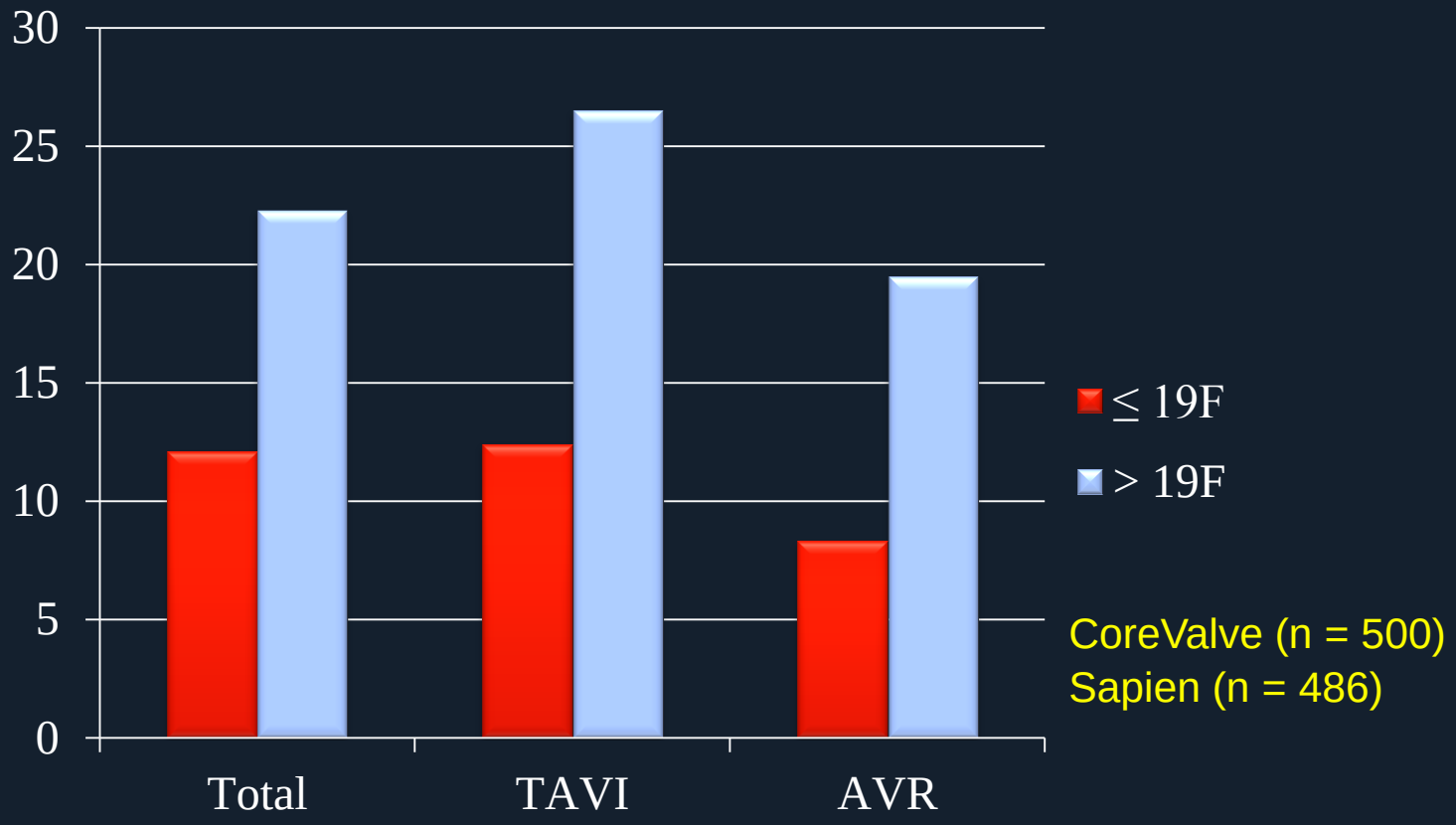
- Hayashida et al. JACC Intv 2012
  - *SFAR HR 186.2 [4.41, 7,855.11]*
  - *Early experience HR 3.66 [1.17, 11.49]*
  - *Femoral calcification HR 3.44 [1.16, 10.17]*
- Van Mieghem N et al. Am J Cardiol 2012
  - *Female gender HR 1.63 [1.12, 2.36]*
  - *>19Fr system 2.87 [1.68, 4.91]*
- Généreux et al. JACC 2012
  - *Female gender HR 2.31 [1.08, 4.98]*

Learning Curve and Vascular Complications



1. Fearon, ACC 2013
2. Hayashida, JACC Card Int 2011; 4(8): 851-8
3. Nuis, Am J Cardiol 2011; 107: 1824-1829
4. Toggweiler, JACC 2012; 59(2): 113-8

Sheath Size and Vascular Complications



Patients treated with the >19Fr sheath (ID) had

- Significantly more vascular complications (22% vs 12%, $p < 0.001$)
- more bailout interventions for access-related issues (20% vs 10%, $p < 0.001$)

Van Mieghem NM et al. Am J Cardiol 2012;110:1361

Required Arterial Access Diameter

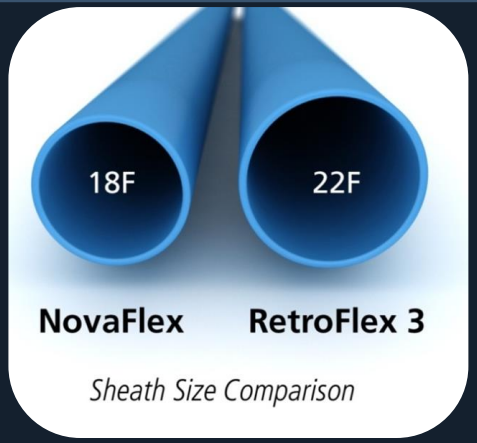
SAPIEN XT (before e-sheath)

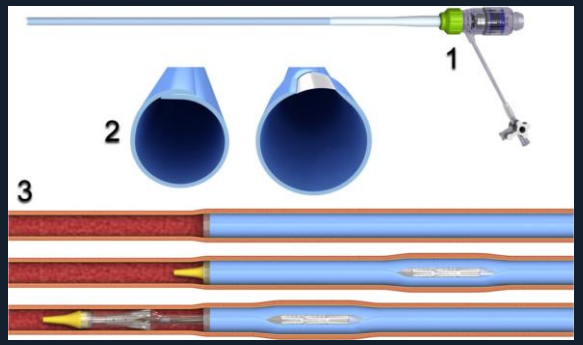
Valve Size	Sheath size	Diameter
23mm	18F	> 6.0mm
26mm	19F	> 6.5mm
29mm	20F	> 7.0mm

Improved Current Delivery System

Reduced Sheath Size: Expandable Sheath

Valve	Valve Size	Sheath ID	e-Sheath
SAPIEN THV	23mm	22F	
SAPIEN XT THV	23mm	18F	16F
SAPIEN THV	26mm	24F	
SAPIEN XT THV	26mm	19F	18F
SAPIEN XT THV	29mm	20F	19F





Edwards eSheath Expandable Introducer Sheath

The Edwards expandable sheath (1) features a fold that expands as the NovaFlex catheter moves through (2,3).

Required Arterial Access Diameter

CoreValve (currently used)

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

Vascular Cx and New Delivery System

SAPIEN vs. SAPIEN XT in PARTNER IIB

	SAPIEN (n=271)		SAPIEN XT (n=282)		
Events	**n**	**%**	**n**	**%**	**p-value**
Vascular:					
Major	42	15.5	27	9.6	0.04
Minor	20	7.4	14	5.0	0.23
Bleeding:					
Disabling	34	12.6	22	7.8	0.06
Major	44	16.4	44	15.7	0.84
Patients with transfusions	80	29.5	73	25.9	0.40

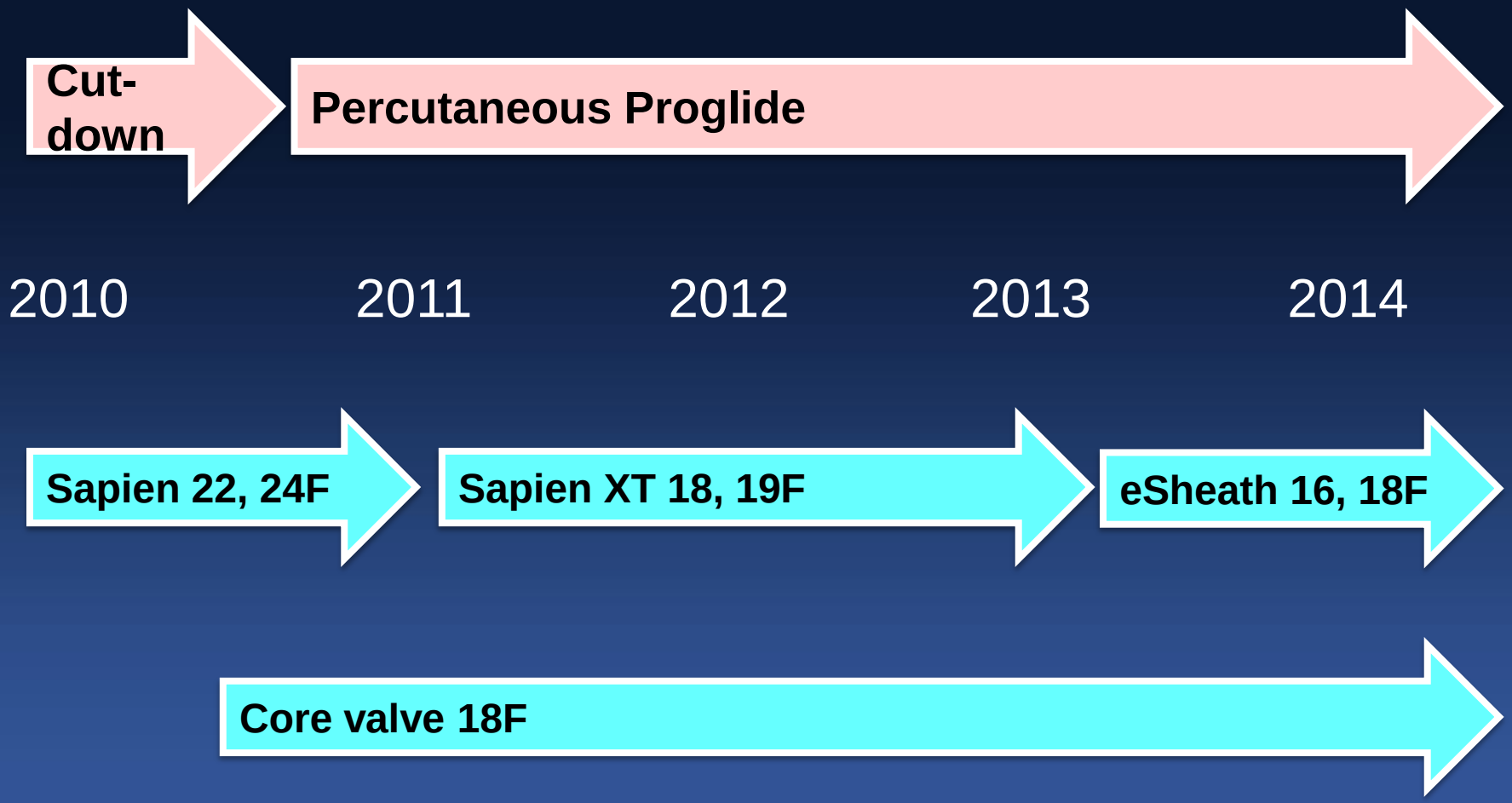
Vascular Complications and New Delivery System

CoreValve with Accutrack system

	MCV N=90	MCV + AT N=68	P Value
Life-Threatening Bleed	28 (31.1)	8 (11.9)	0.005
AKI Stage 3	13 (14.4)	1 (1.5)	0.005
Major Vascular Complications	13 (14.4)	2 (2.9)	0.015
Combined Safety Endpoint	37 (41.1)	10 (14.9)	<0.001

AMC Experience

Access Site Management in AMC



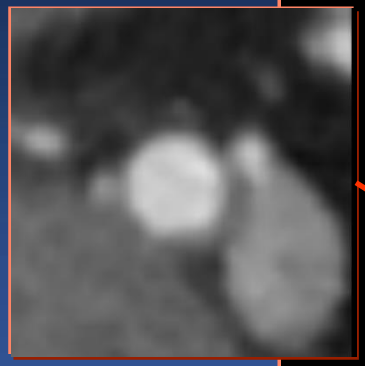
30-day Outcomes

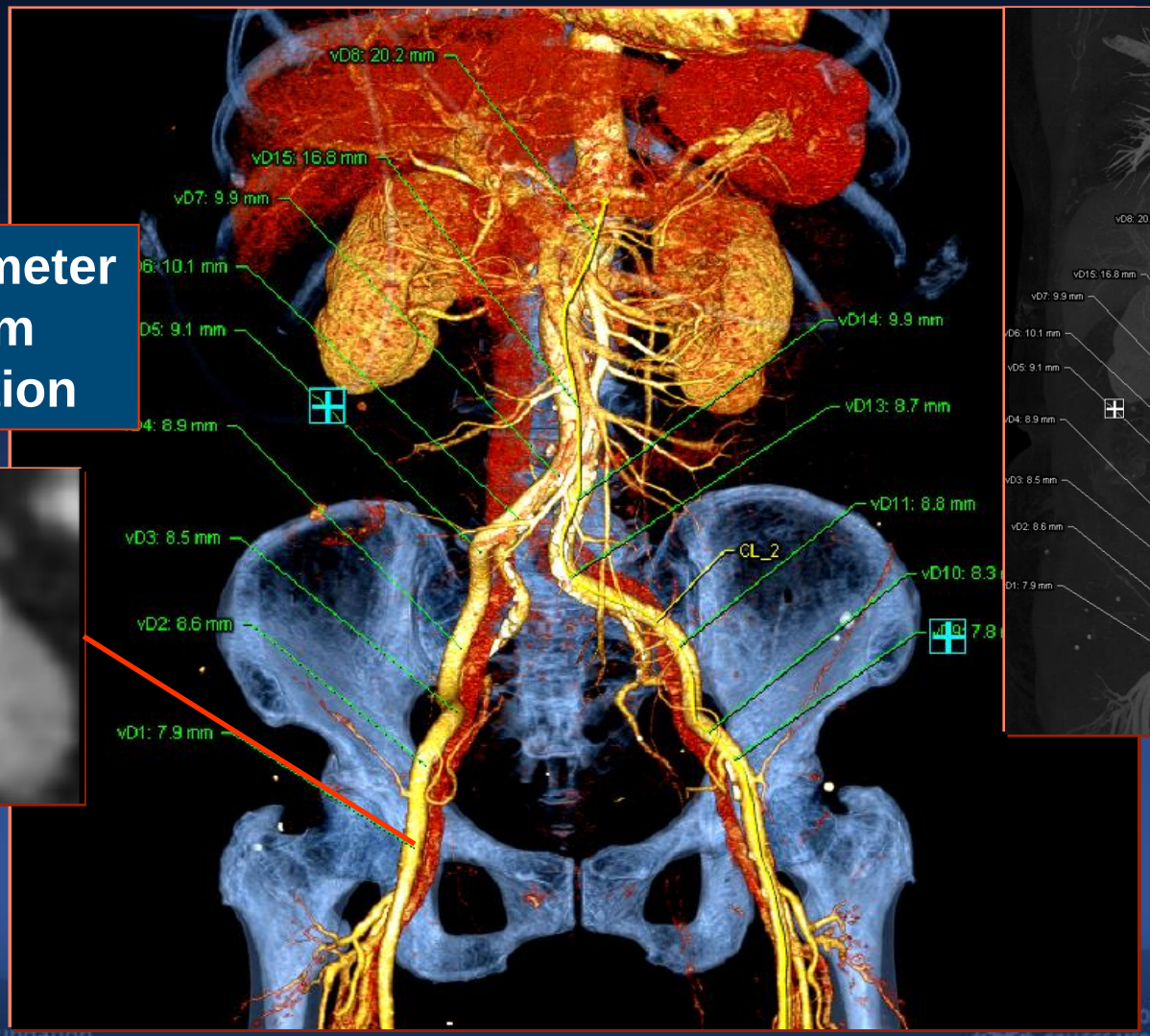
	Total (n=194)	Edward (n=96)	CoreValve (n=98)	P value
Mortality	8 (4.1%)	5 (5.2%)	3 (3.1%)	NS
Major Stoke	2 (1.0%)	1 (1.0%)	1 (1.0%)	NS
Vascular Complication	6 (3.1%)	3 (3.1%)	3 (3.1%)	NS
AKI ≥ Stage 2	2 (1.0%)	1 (1.1%)	1 (1.0%)	NS
Post AR ≥ Moderate	22 (11.8%)	7/92 (7.6%)	15/95 (15.8%)	0.083
Implant 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

Patient selection

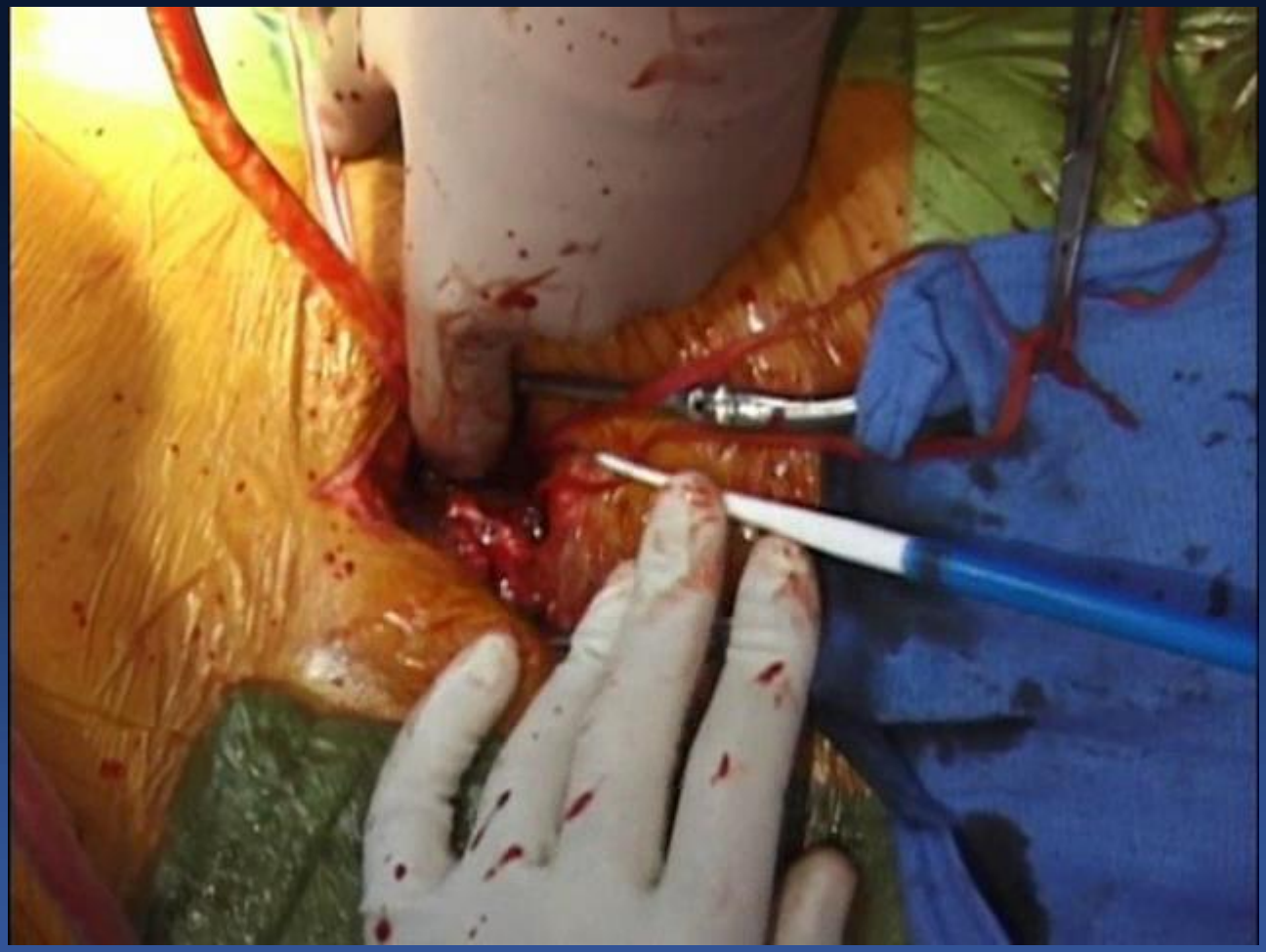
Vascular Access Screening
CTA: 3D reconstruction

Minimal diameter
Rt. FA 7.8 mm
No calcification

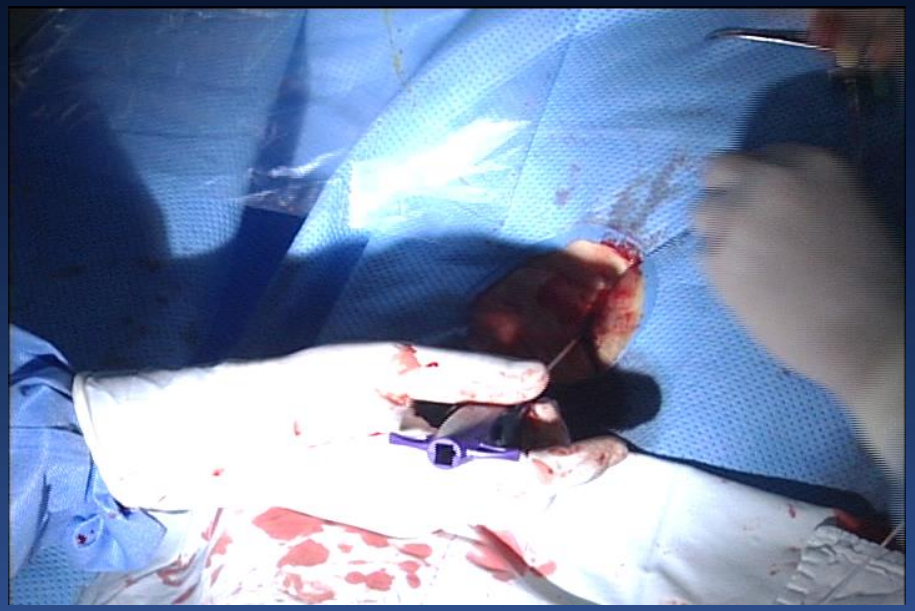




Surgical Cut-down and 22 Fr Sheath Insertion

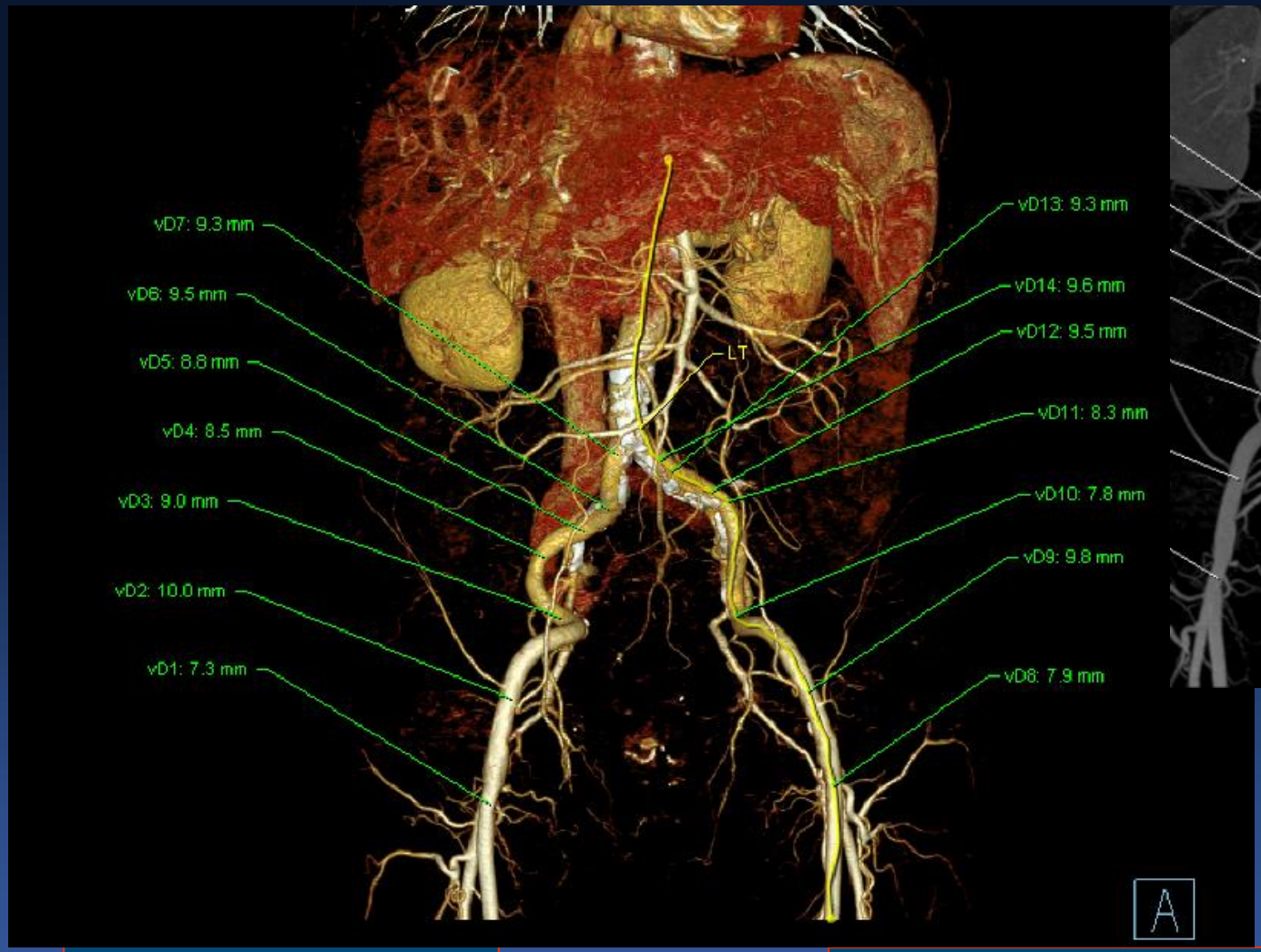


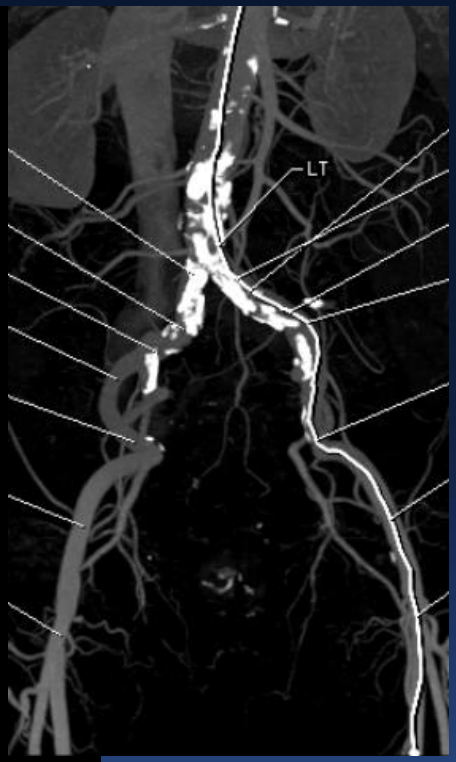
Two or Three ProGlides



ProStar XL: Not available in Korea

Case 1 – Iliofemoral CT Angio





Minimal diameter
Rt. FA 7.3 mm

Minimal diameter
Lt. FA 7.8 mm

Pre-procedural Angiography

26mm Sapien XT, 18F Sheath

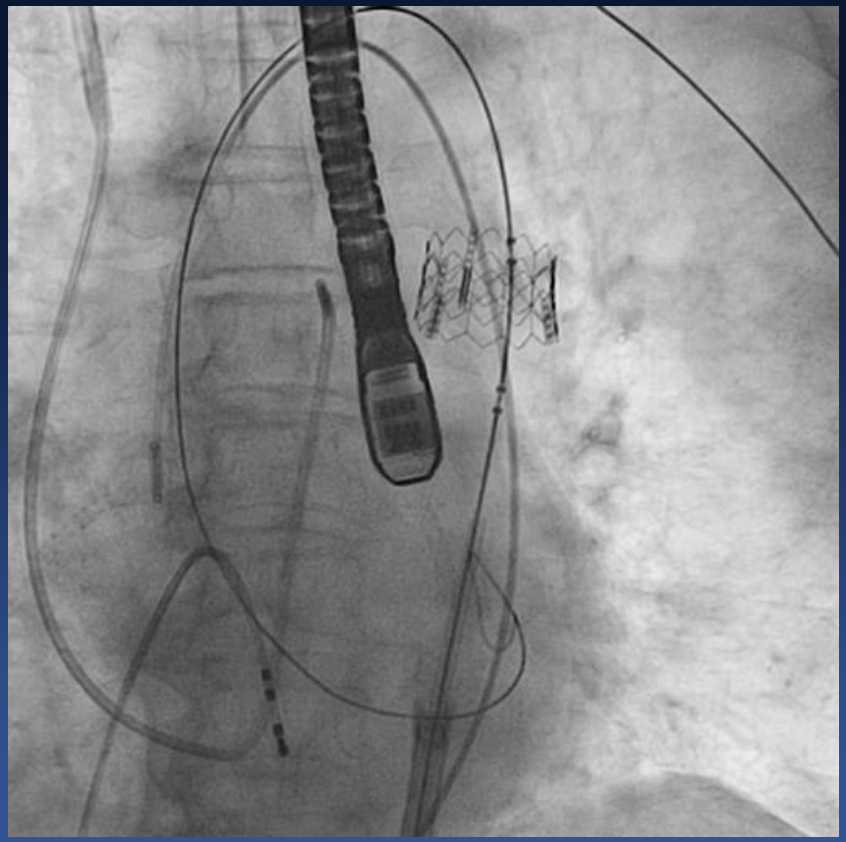
Final Angiography

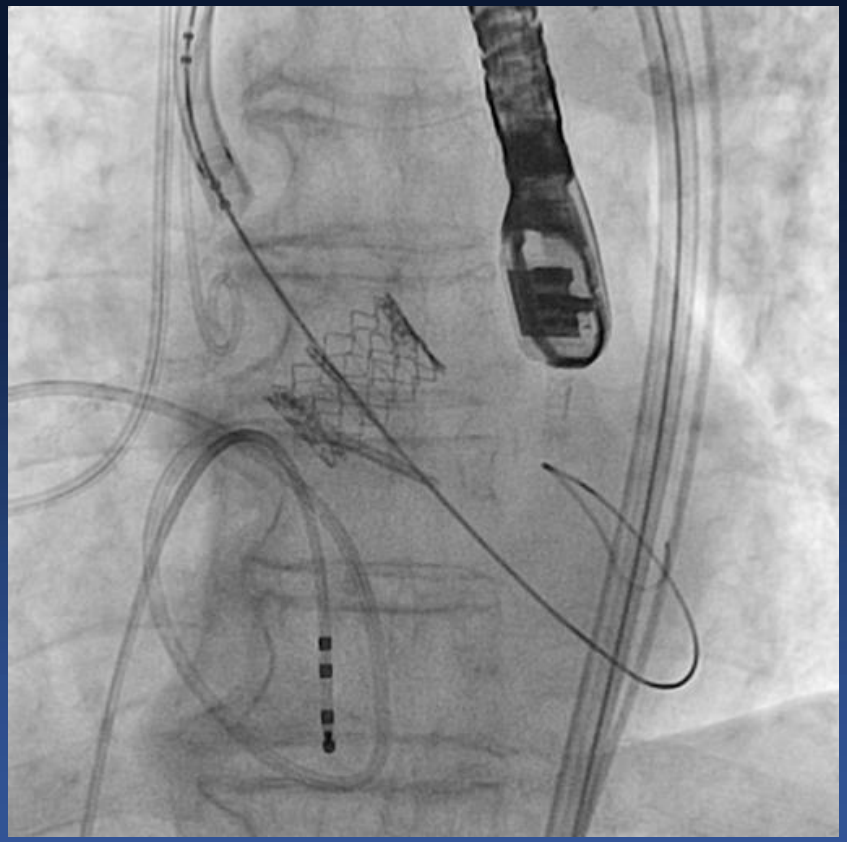
Management of Access Complication

- ***Ilio-femoral rupture***
  - Surgery, occlusion balloon, covered stent
- ***Dissection***
  - Balloon or stent
- ***Infection***
  - Medication or surgery
- ***Stenosis/thrombosis***
  - Balloon or surgery, rarely stenting
- ***Avulsion***
  - Occlusion balloon and prompt surgery
- ***Pseudoaneurysm***
  - Compression, thrombin injection, surgery
- ***Bleeding***
  - Compression, hemostasis

Case 2: Very early painful memory

Two Sapien Retroplex, 22 Fr sheath

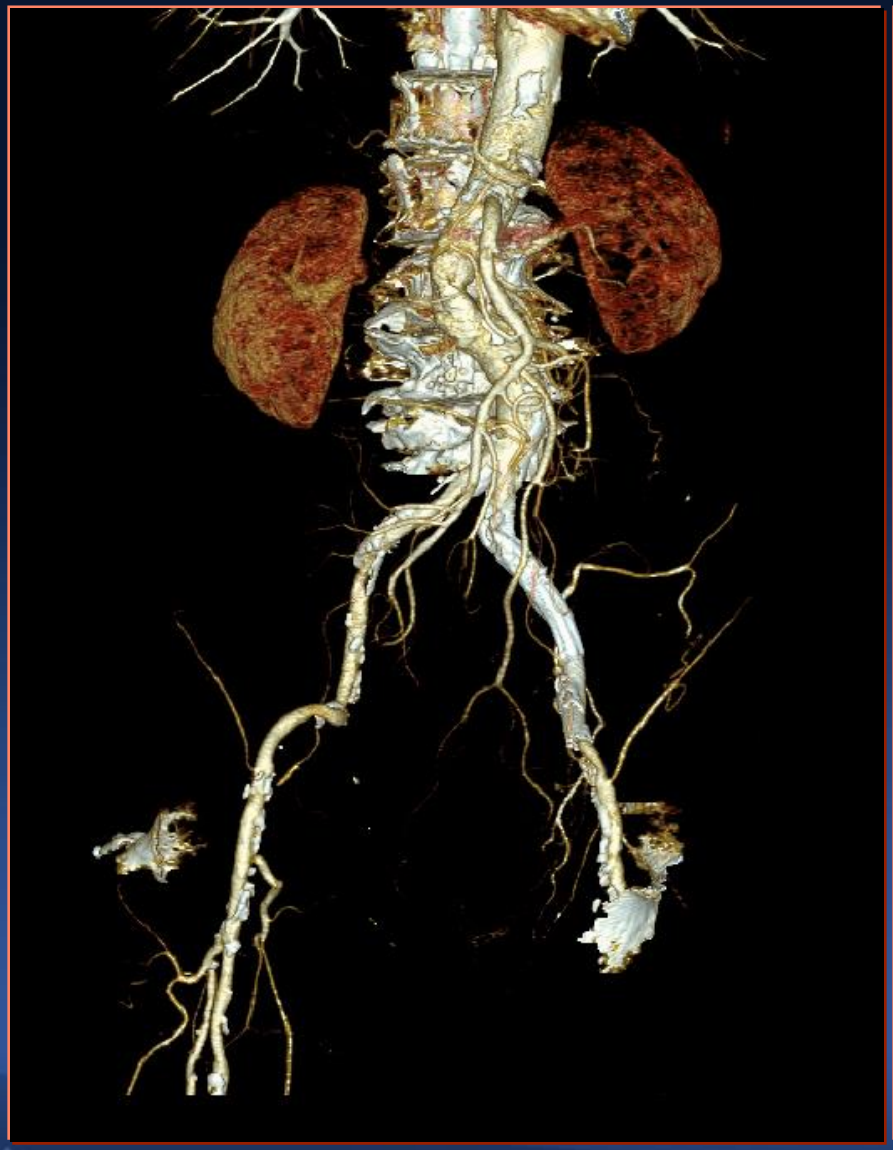




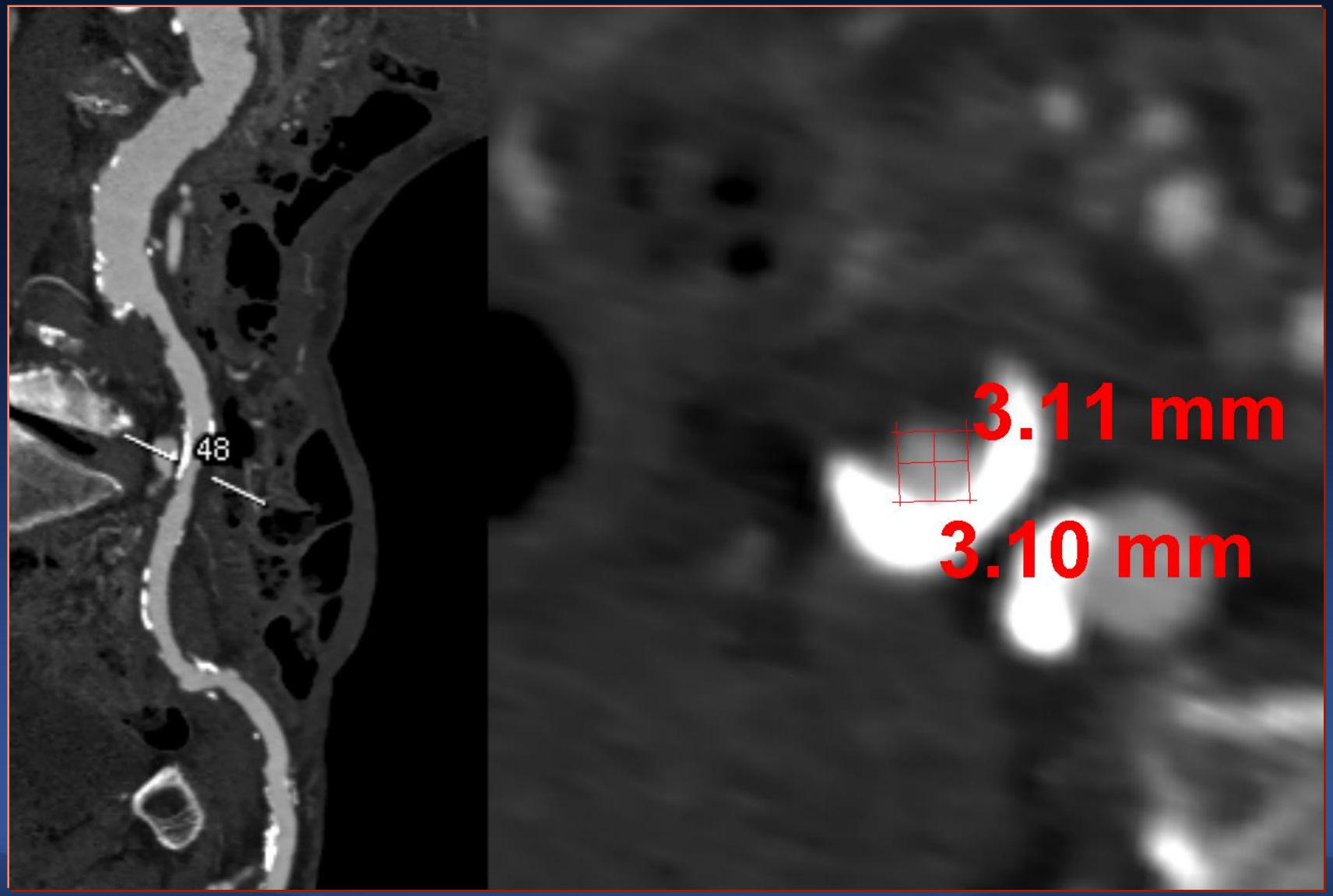
Arerial Avulsion and Perforation

➡ ***Balloon occlusion, emergent surgical repair***

Case 3: Iliofemoral CT Angio

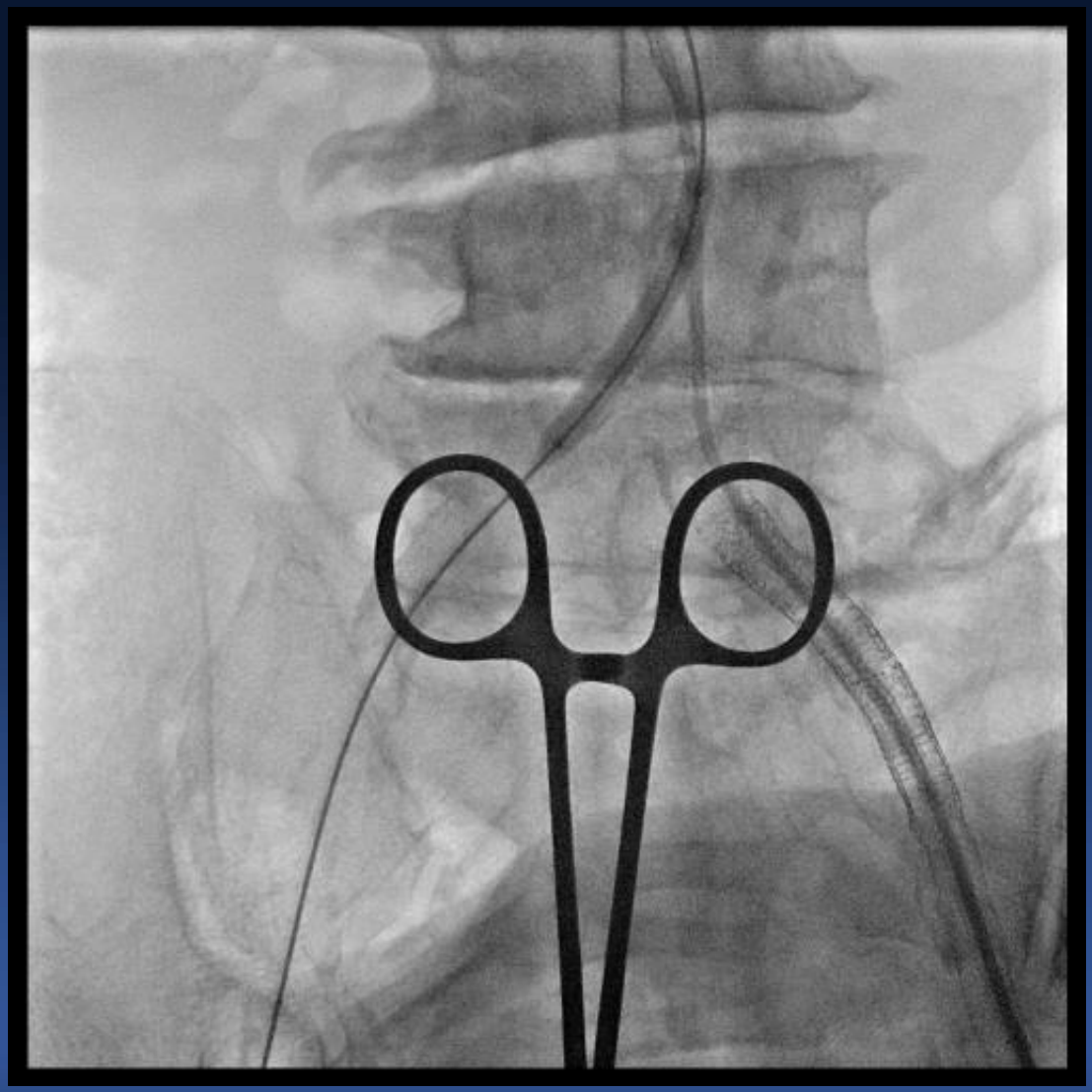


Iliofemoral CT Angio

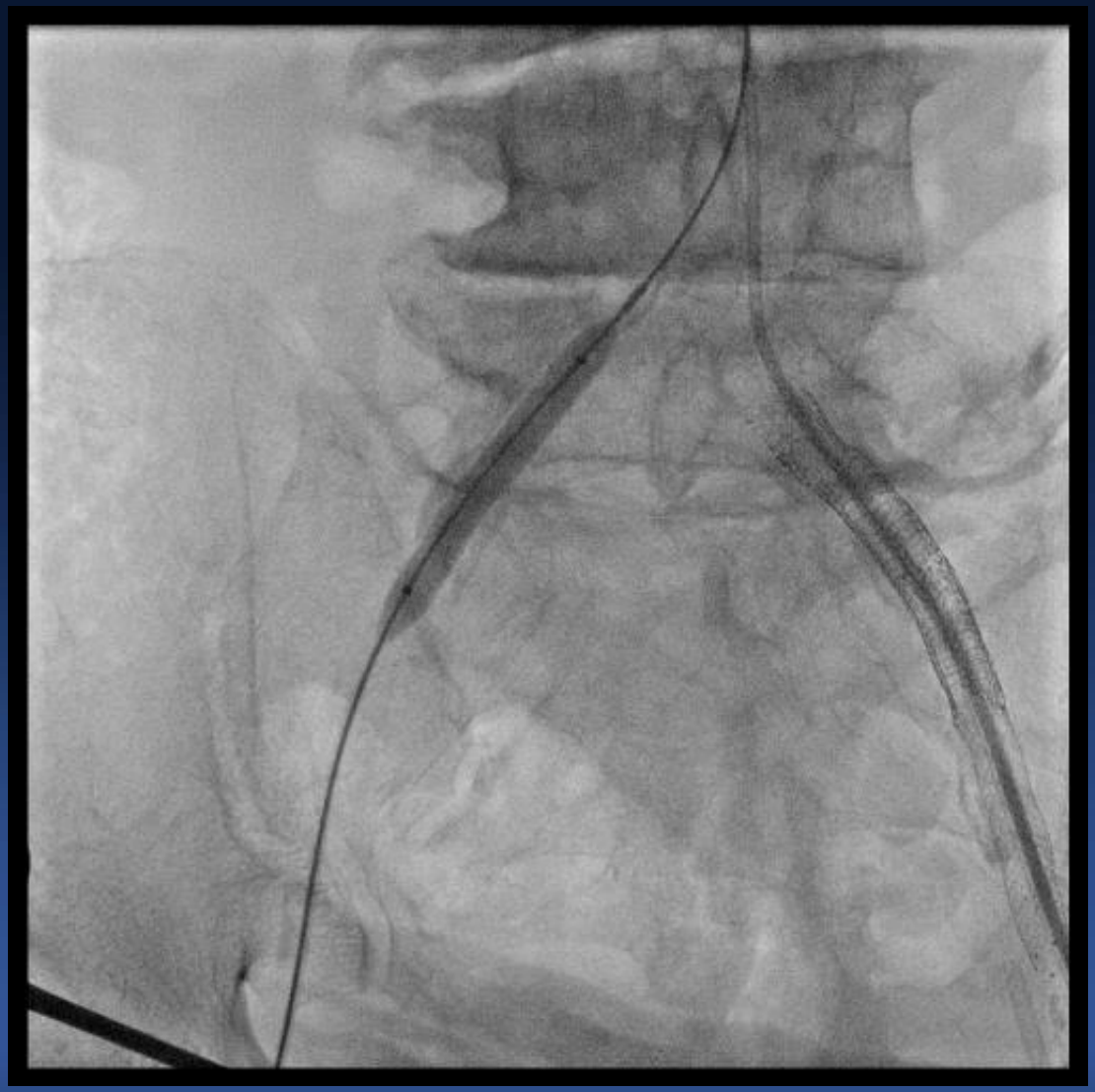


Pre-procedural Angiography

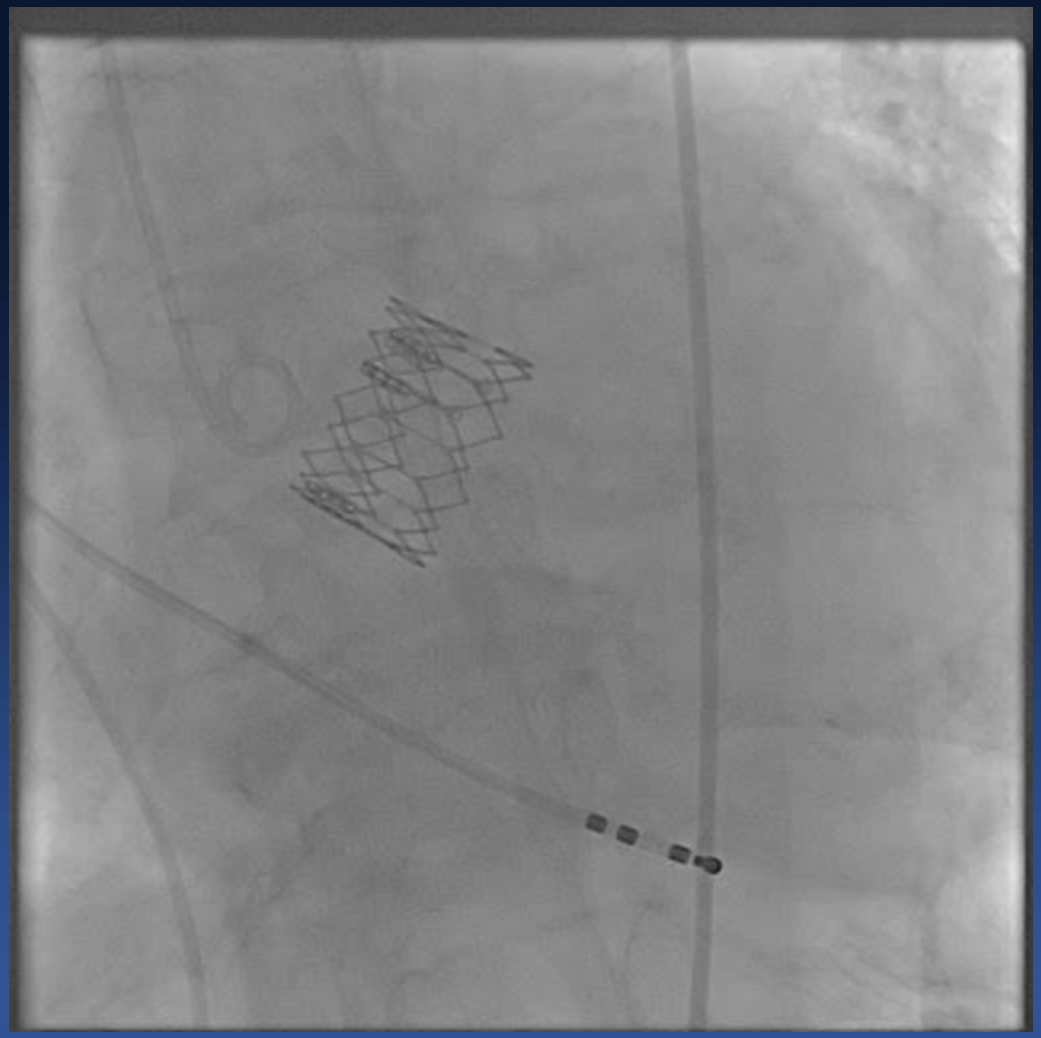
PTA for Rt CIA



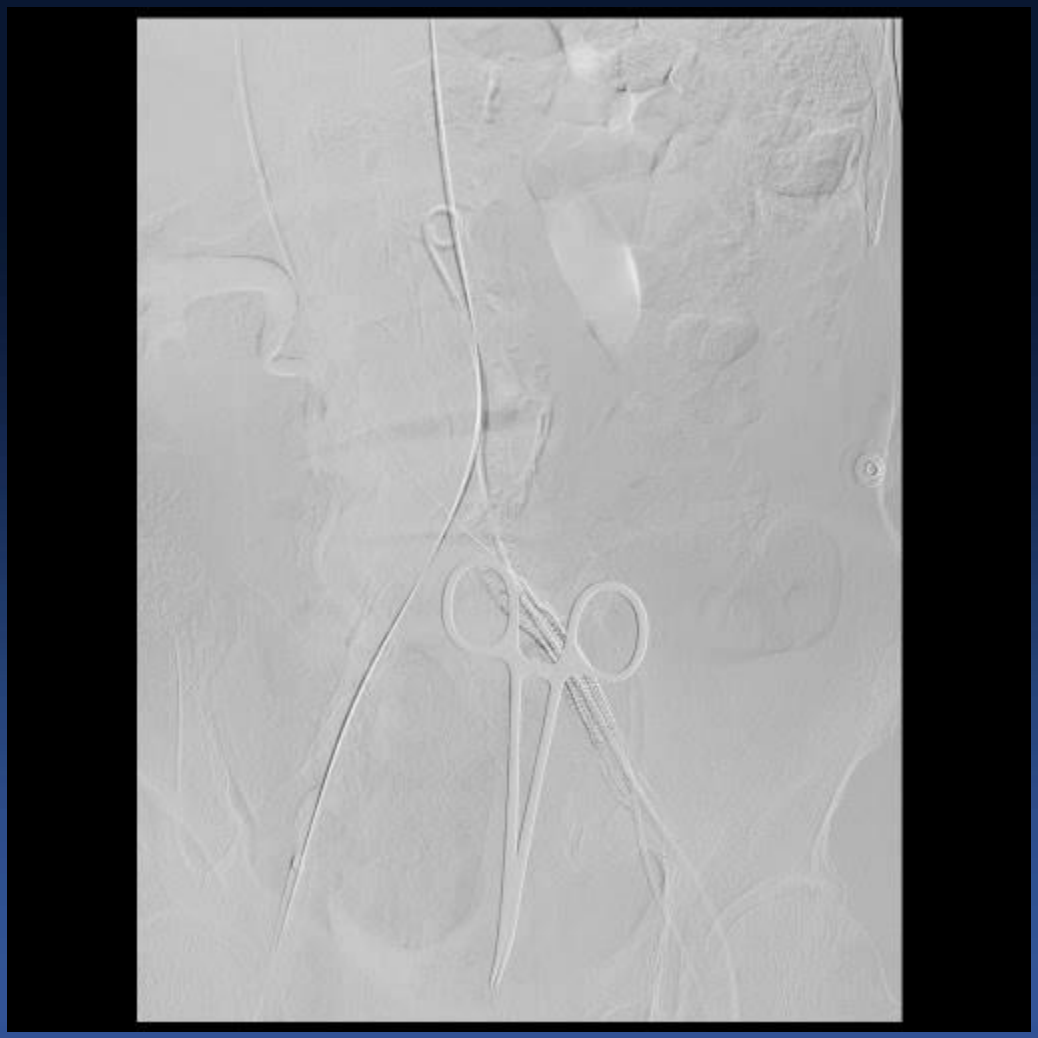
PTA for Rt EIA



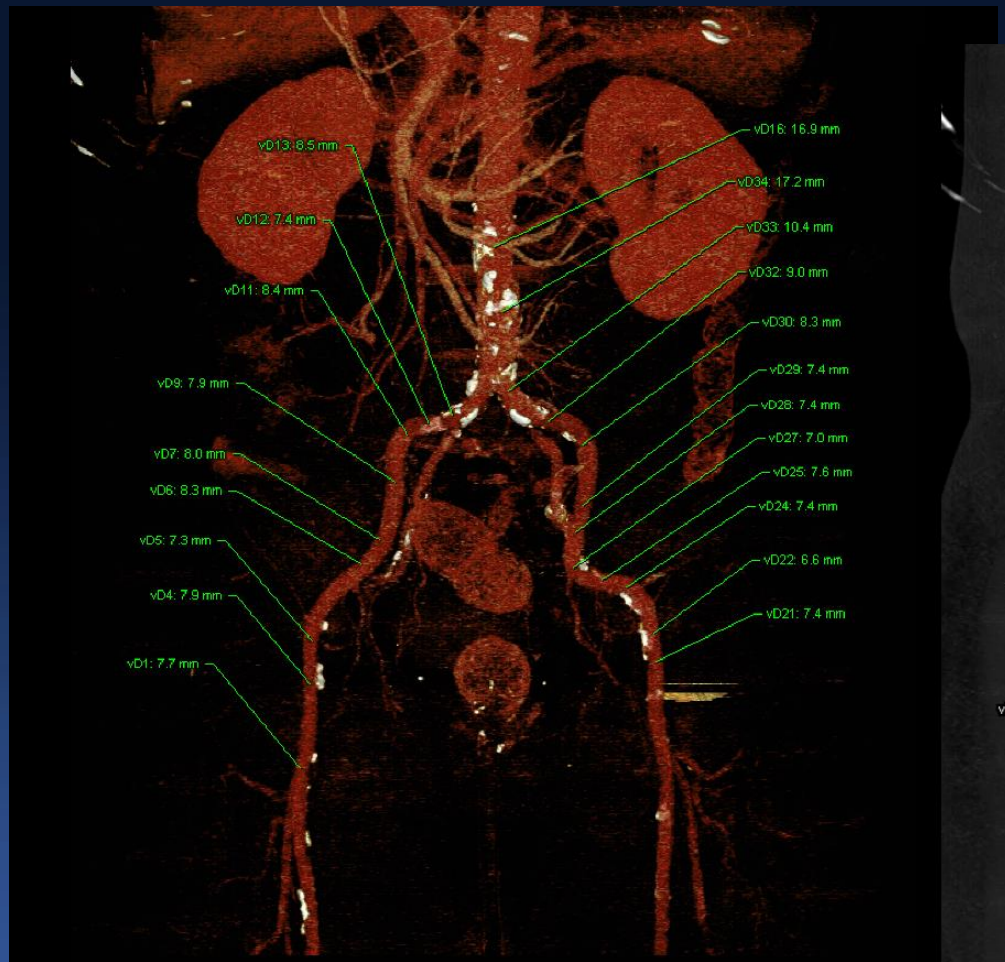
Sapien XT 26mm, e-Sheath 18F

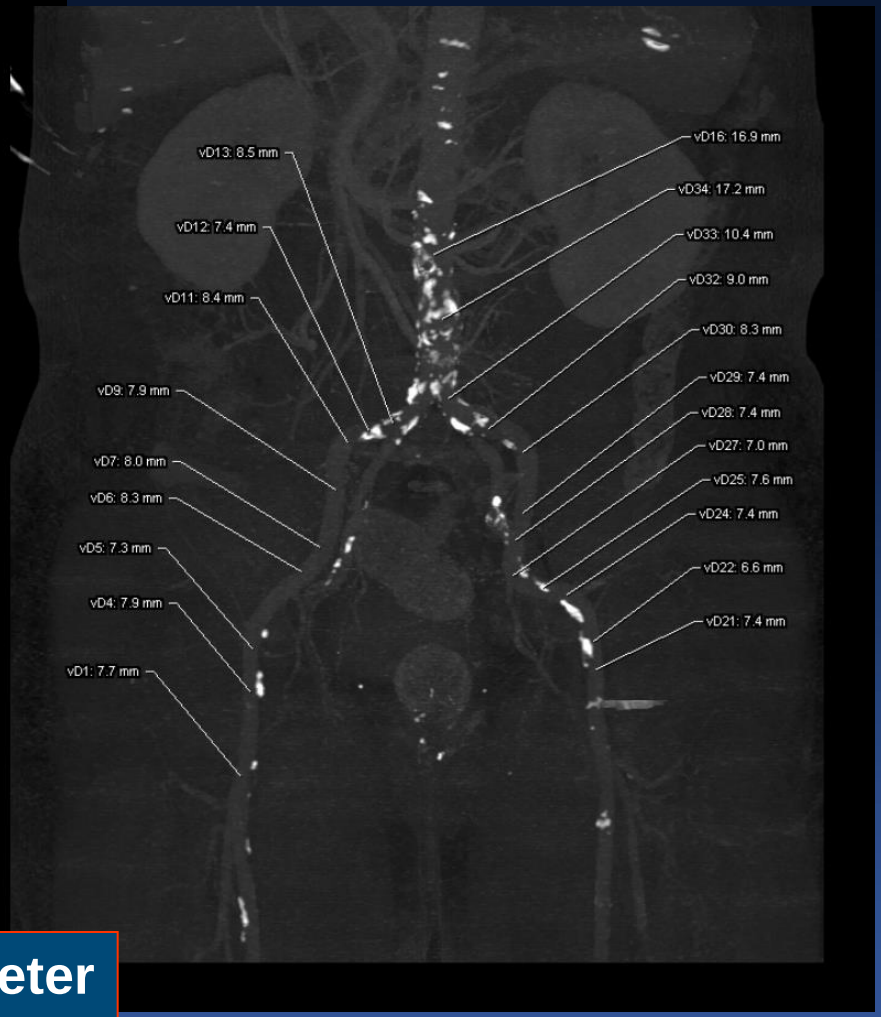


Final Iliac-femoral Angiography



Case 4: Iliofemoral Angio





Minimal diameter Rt. FA 7.3 mm

Minimal diameter Lt. FA 6.6 mm

Pre-procedural Iliac-femoral Angiography

CoreValve 29mm, Sheath 18F

Follow-up

In-hospital Course

- Permanent pacemaker was inserted due to complete AV Block after successful CoreValve Implantation.
- Inguinal mass was observed at right inguinal but the size was decreased.

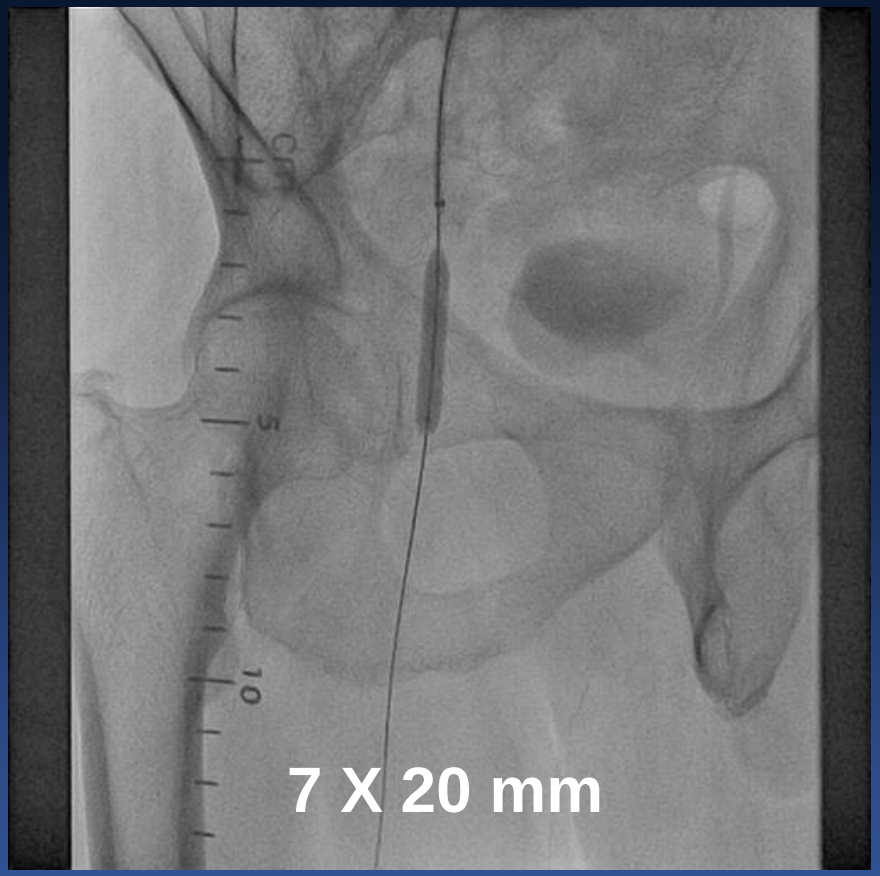
Outpatient History

- Rt side claudication occurred.
- Thrill was felt at right puncture site.
- Ankle-brachial index in the right side was 0.73.

Stenosis at Access Site

Angiography

Balloon Angioplasty



Vascular Access Complication: TF

- Vascular access complication can be associated with acute fatal outcome of TF-TAVI.
- With accumulation of experience and improvement of device, the incidence of vascular complications is decreasing.
- New-generation device will overcome the contemporary limitation of access site complication.
- Integration of PTA technique sometimes enables safe TF-AVI in selected cases.