

Alternative Access for Transcatheter aortic valve replacement

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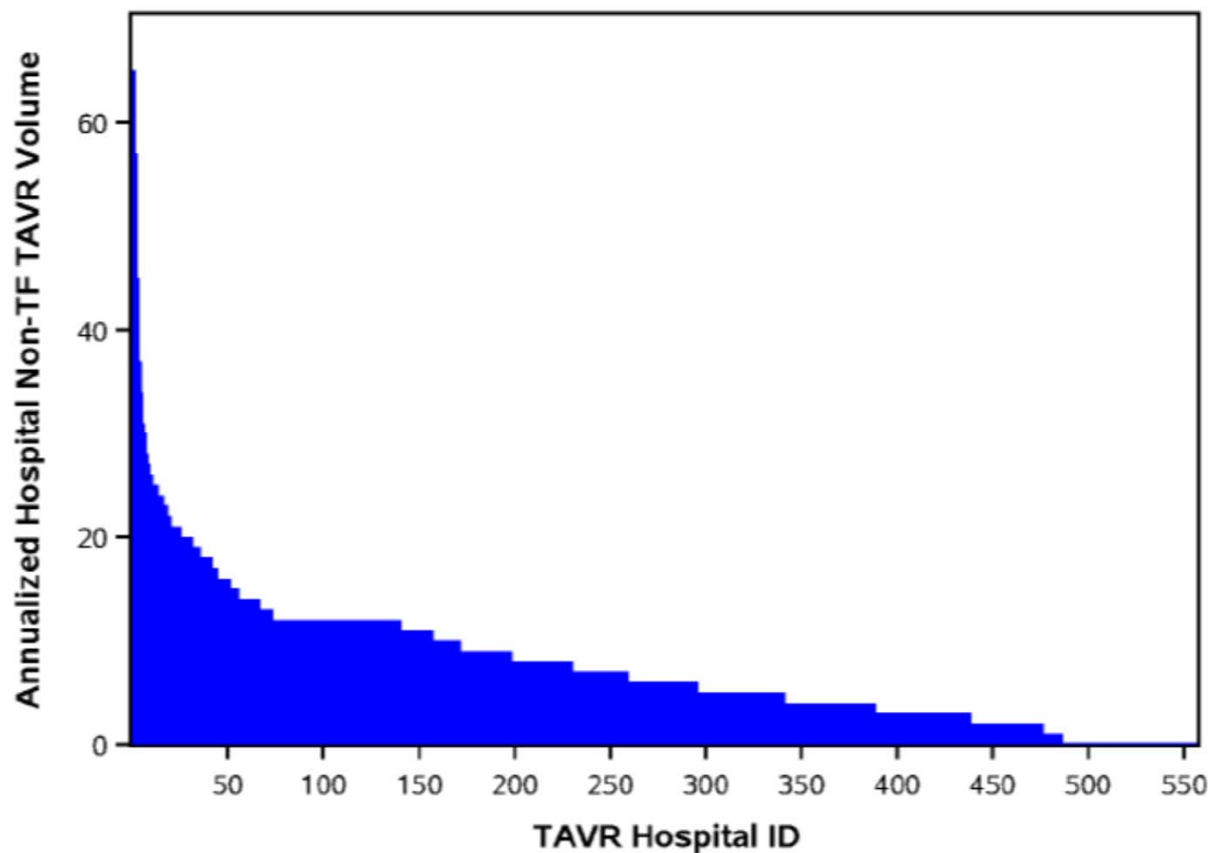
Detroit, MI

DISCLOSURES

- Proctor for Edwards Lifesciences

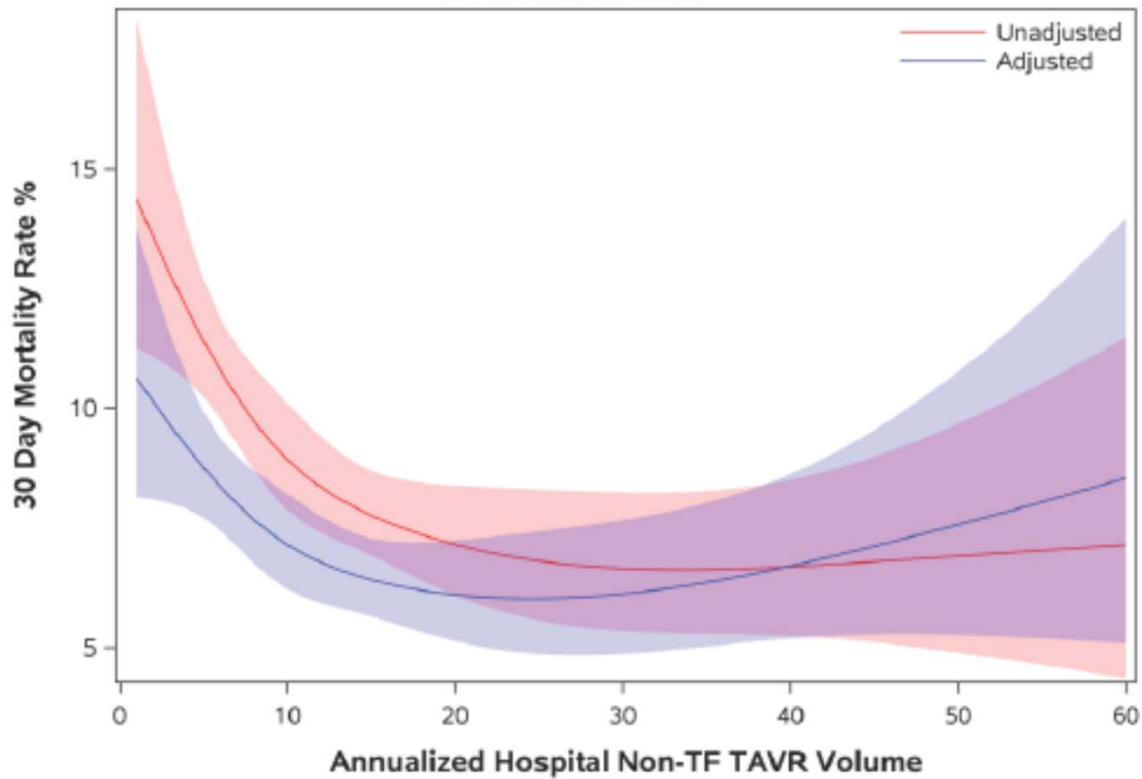
Alternative Access

Wide variation in Annual Volume

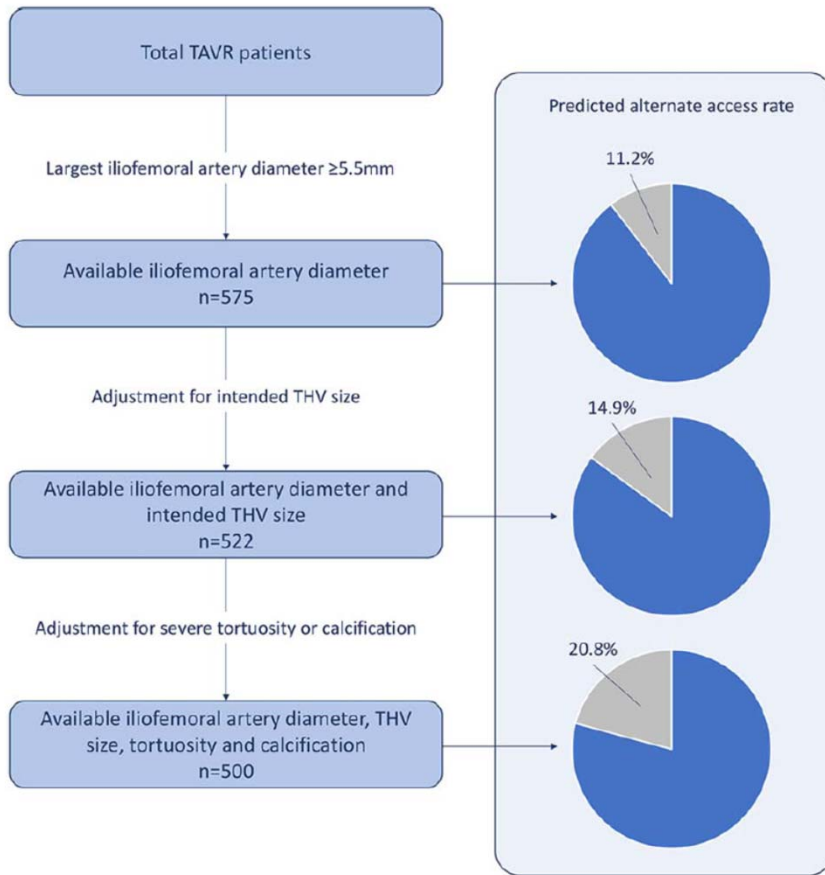


Mortality for non-TF TAVR Related to Volume

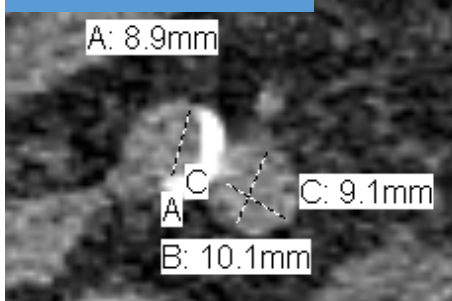
Non-TF TAVR
(n=8,644 at 486 sites)



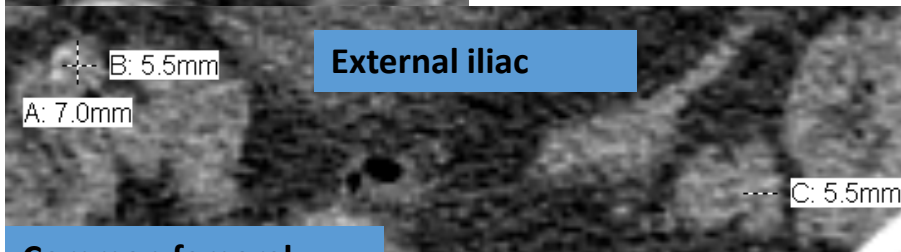
As many as 20% may need alternative access



Common iliac



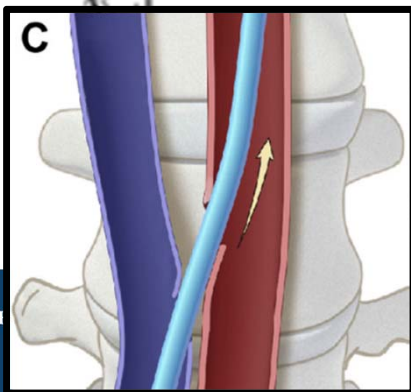
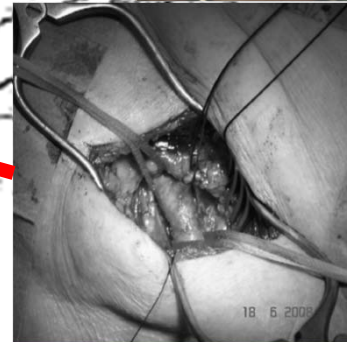
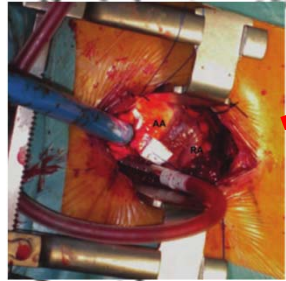
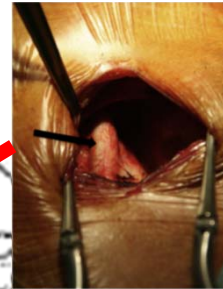
External iliac



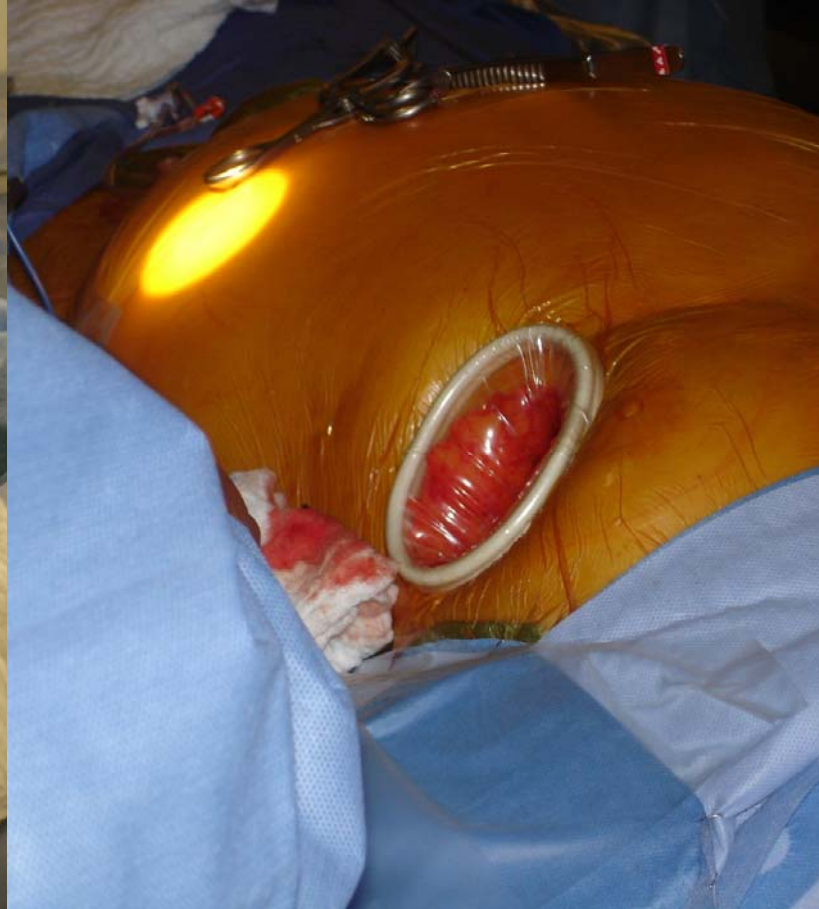
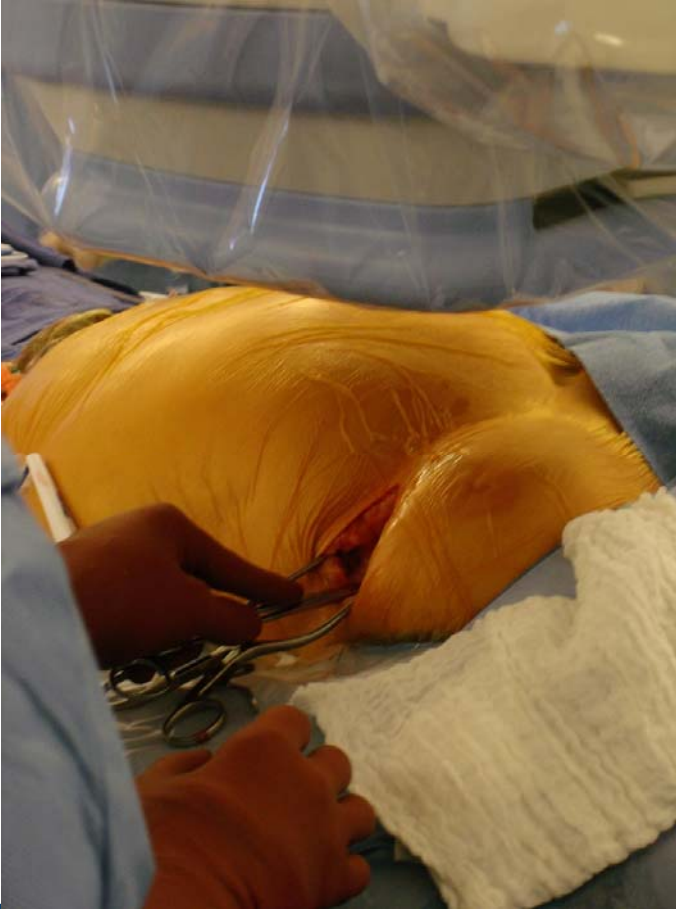
Common femoral



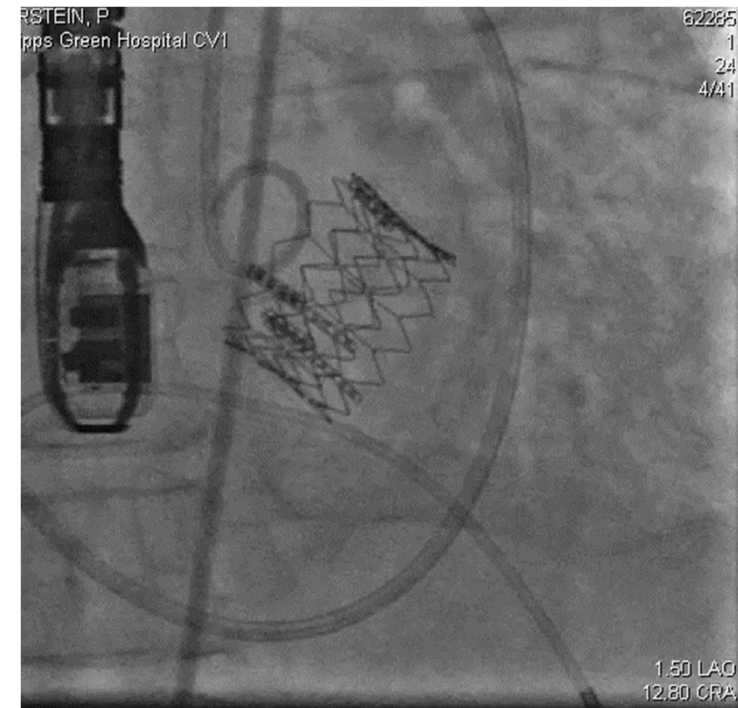
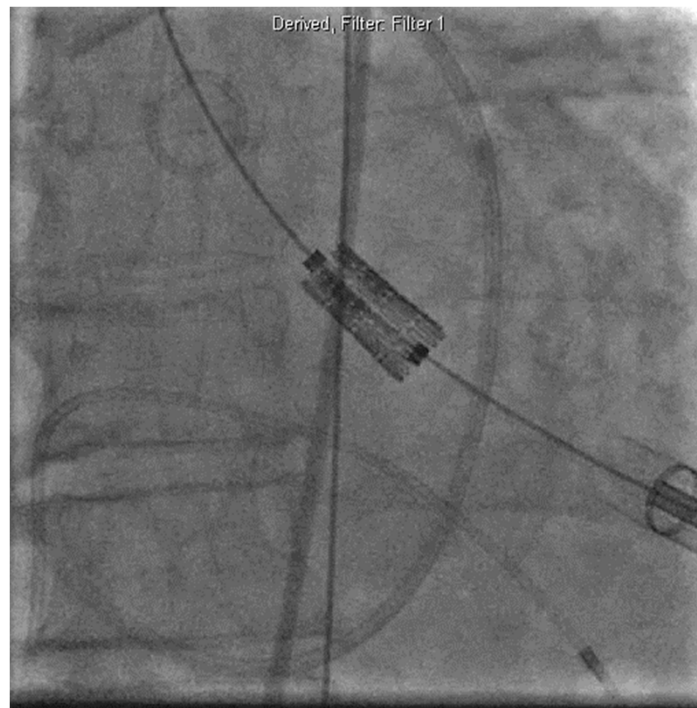
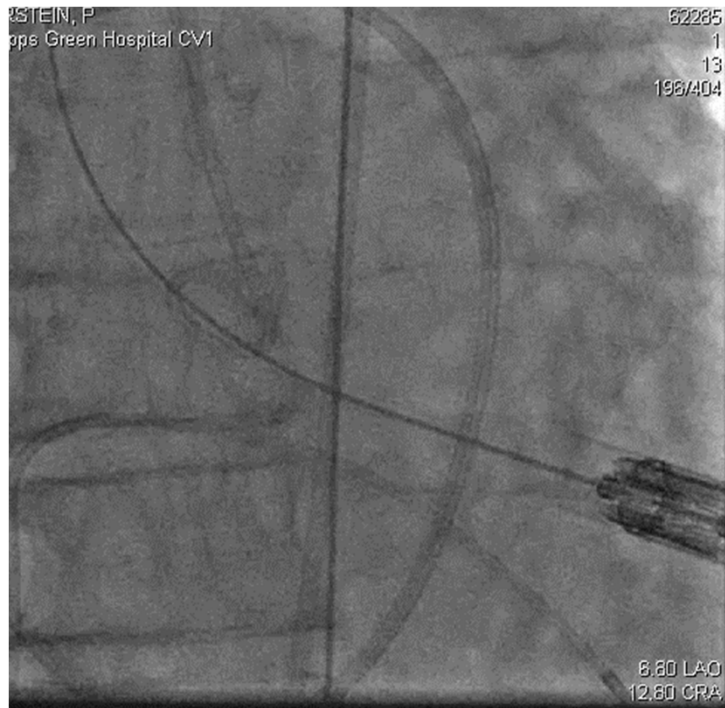
ALTERNATIVE ACCESS



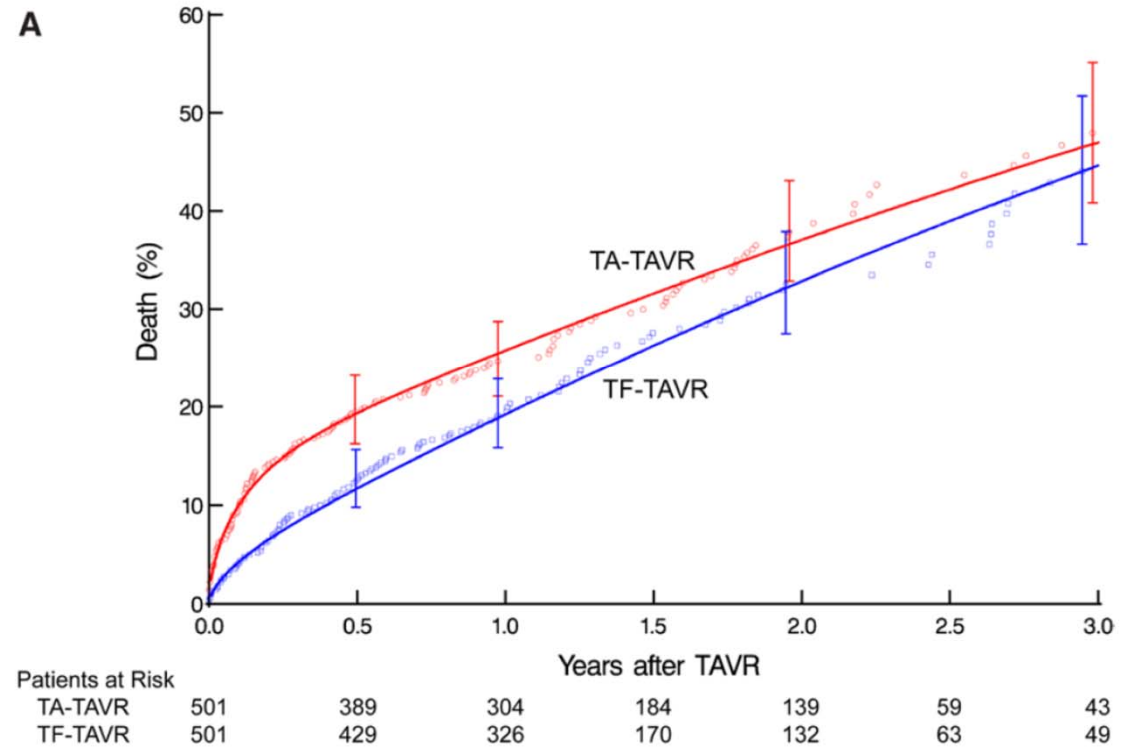
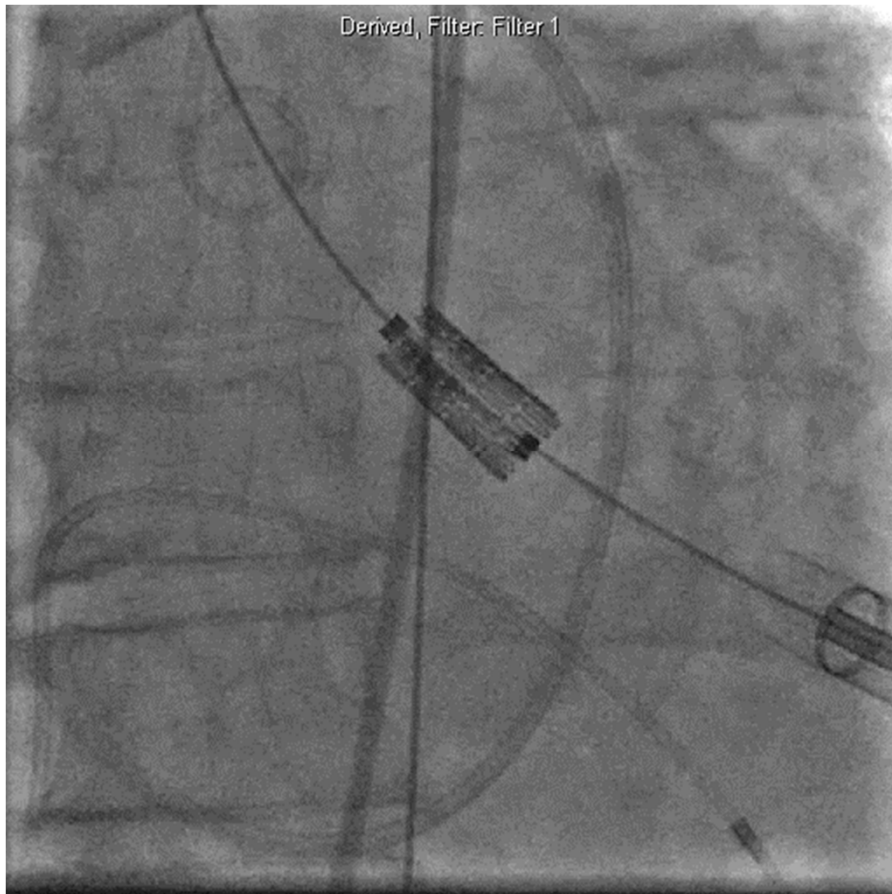
Transapical



Transapical



Probability of Death TA vs TF



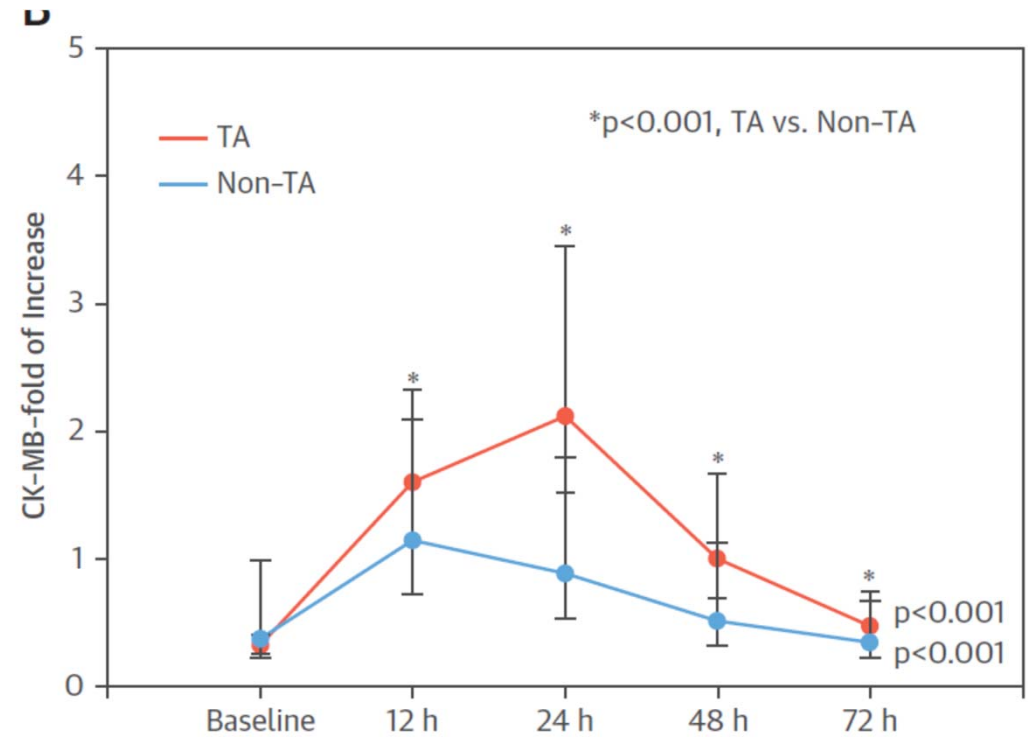
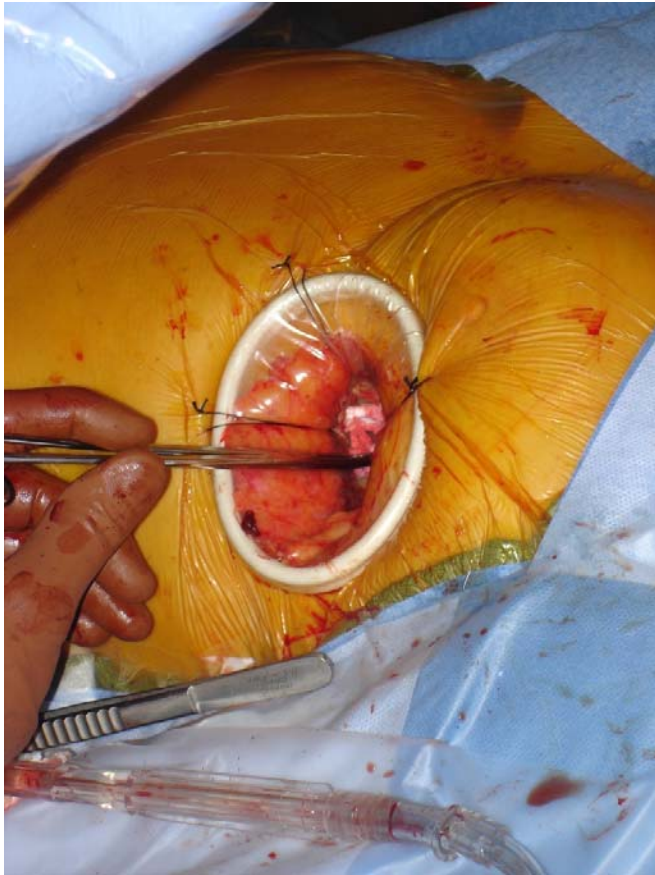
PARTNER II

1-year

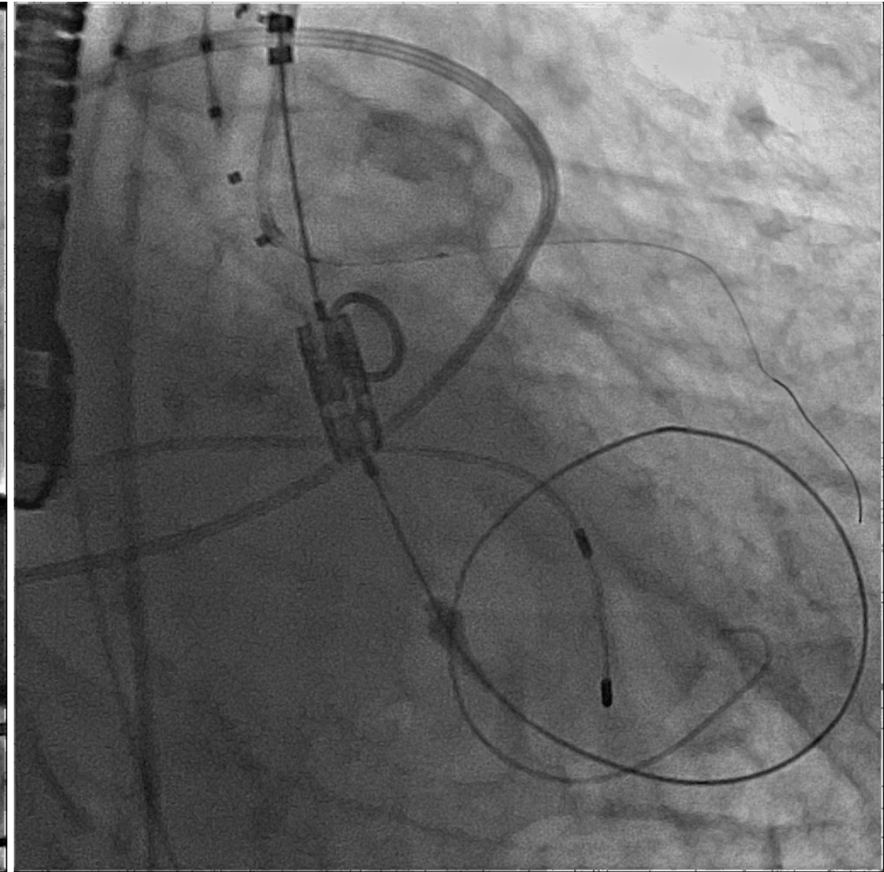
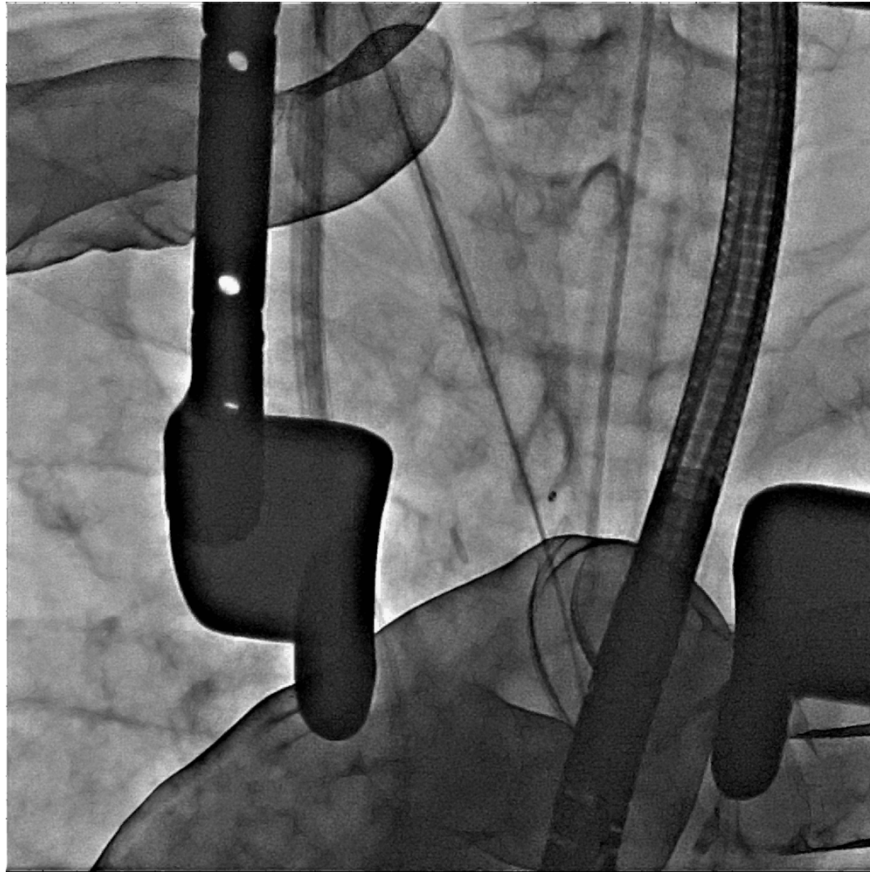
	PII XT N=775	PII S3 N=1077	PII Alternative N=236
All cause death	10%	7.4%	19.9%
Cardiac death	6%	4.5%	8.5%
Any stroke	6.9%	4.6%	11.3%
Myocardial Infarction	1.9%	0.3%	4.5%
Major Vascular Complication	8.8%	6.1%	6.9%
Major Bleeding	11.1%	4.6%	29.1%
New a-fib	5.9%	5.0%	23.8%

TA Access

Increased myocardial injury

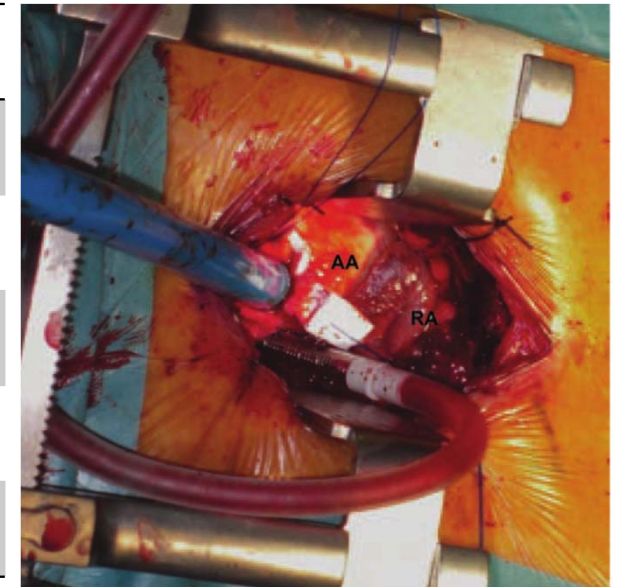


Transaortic Access



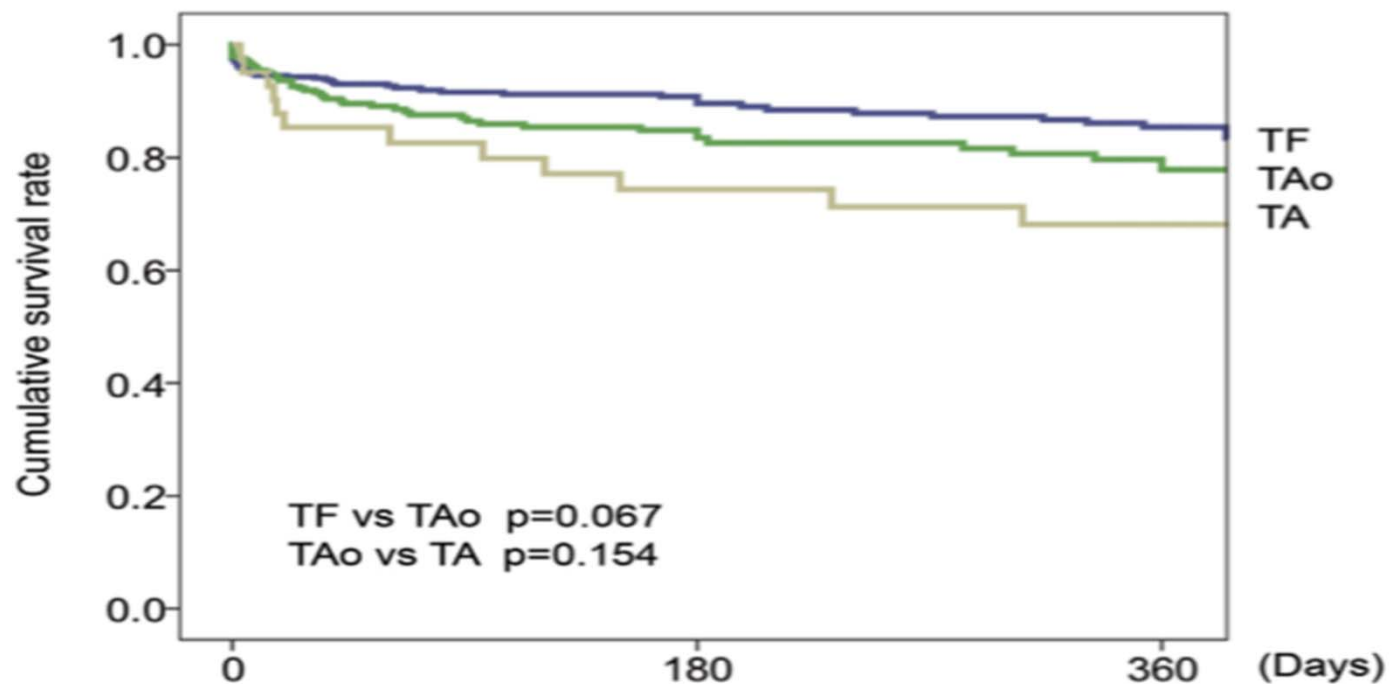
Transaortic US Data

	N=868
In-Hospital Mortality	8.1%
Stroke	2.5%
AKI	39.6%
Post-op LOS	8.9 ± 6.4 days
Discharge to Home	43.7%



TAVR

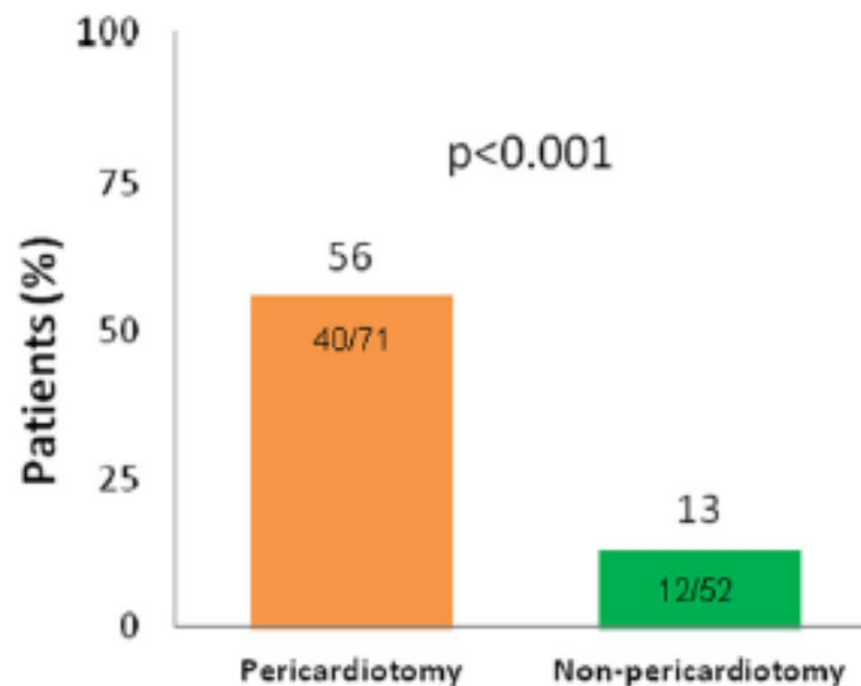
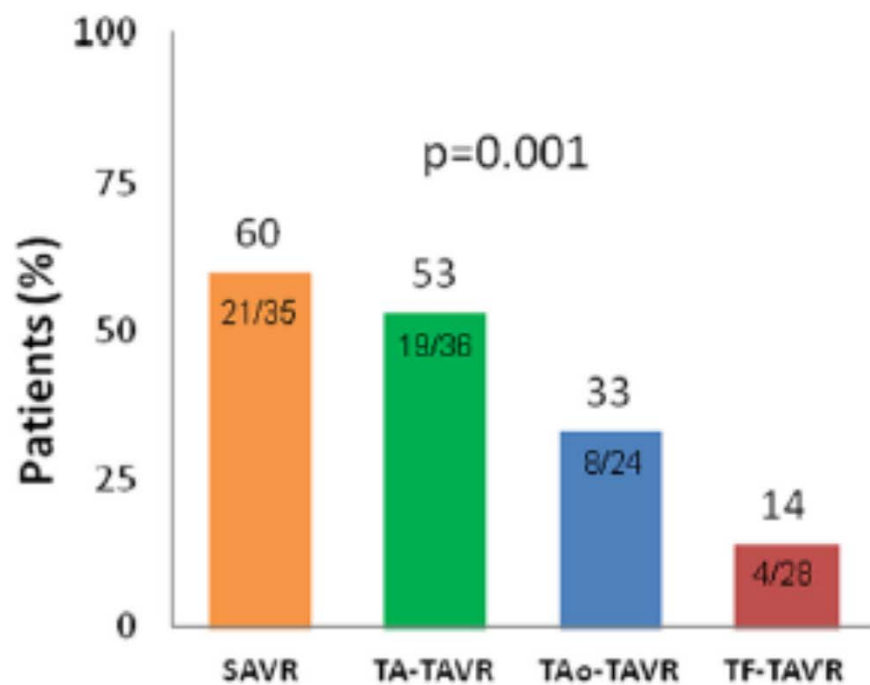
Survival According to Access



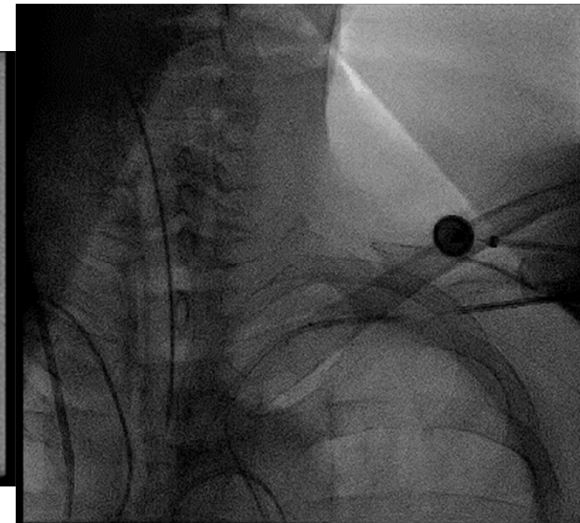
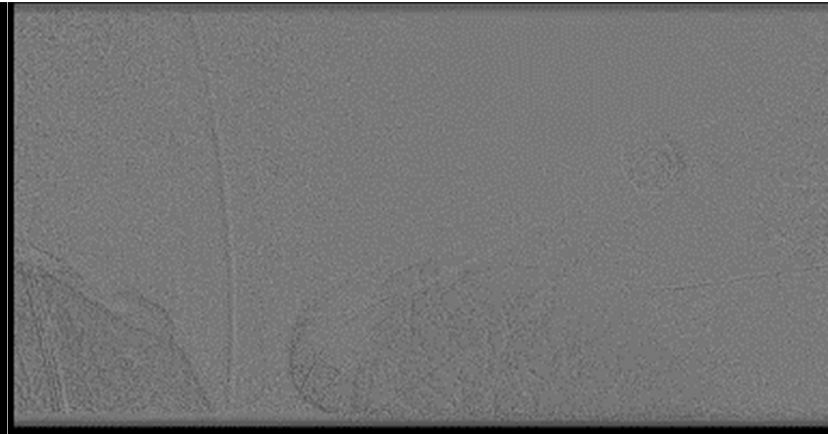
Number at risk

TF	467	287	69
TAo	289	126	28
TA	42	25	17

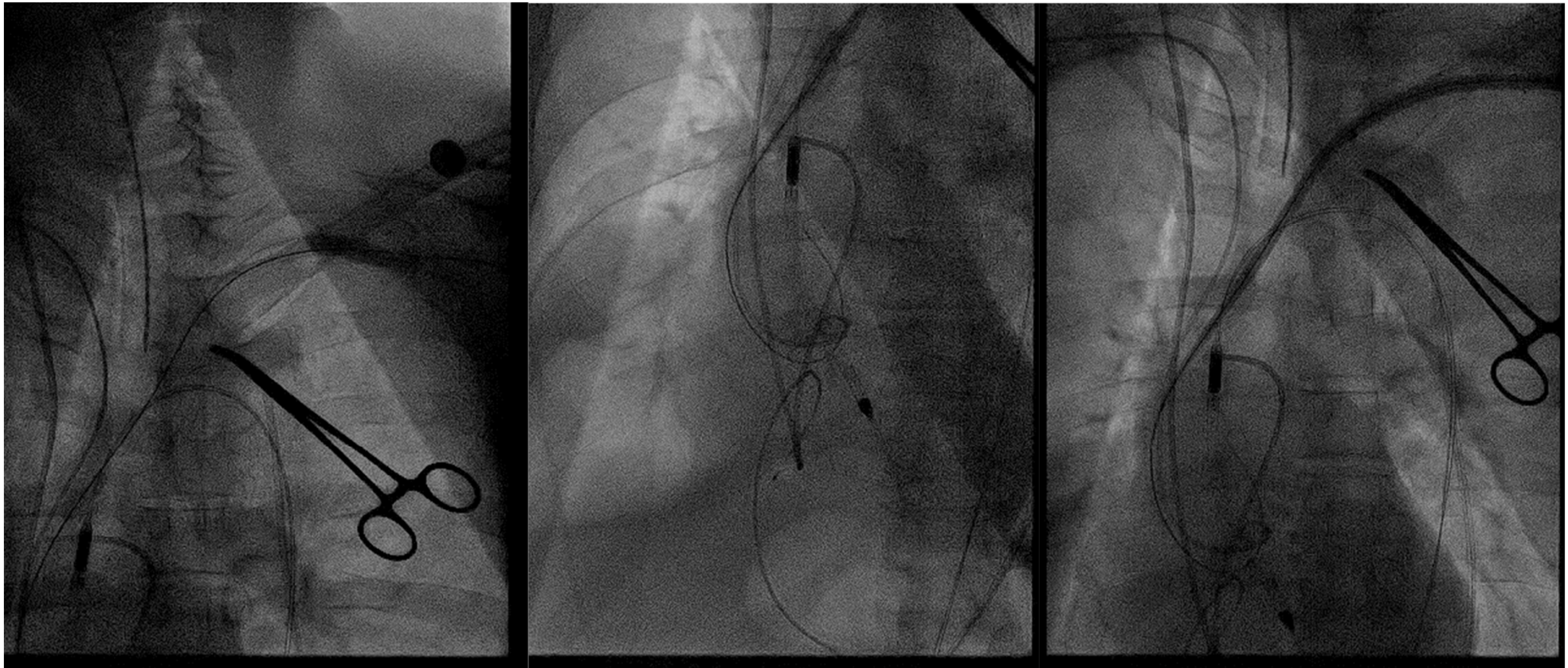
Incidence of Atrial Fibrillation Related to chest invasion



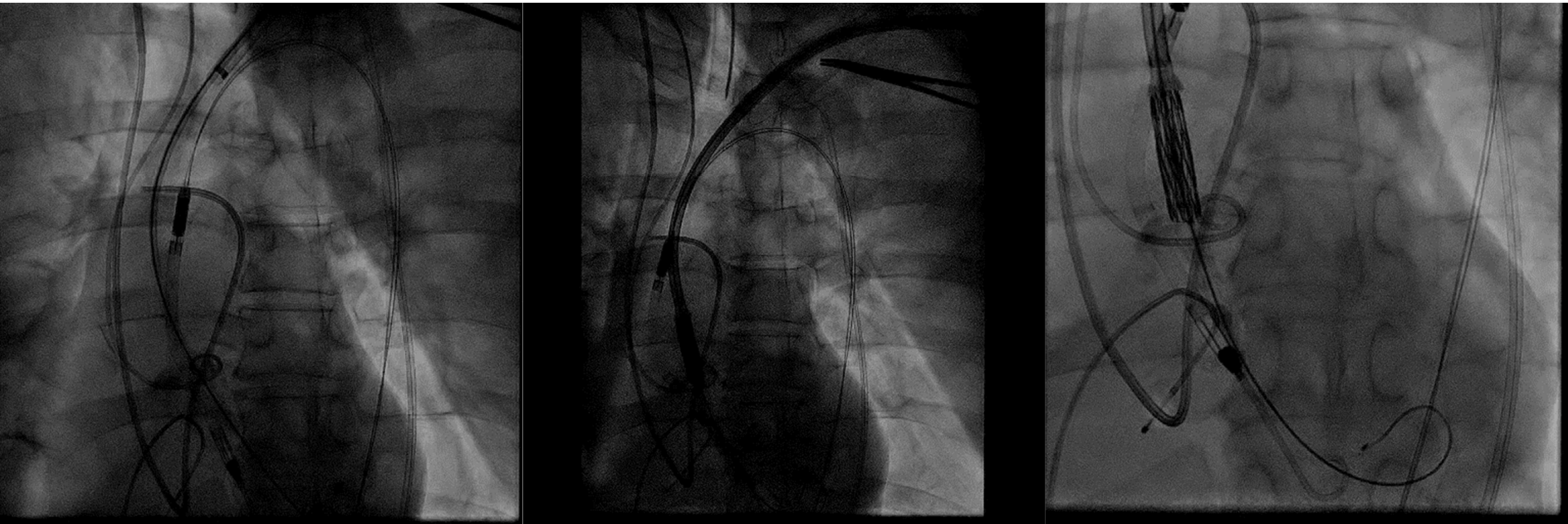
Transaxillary



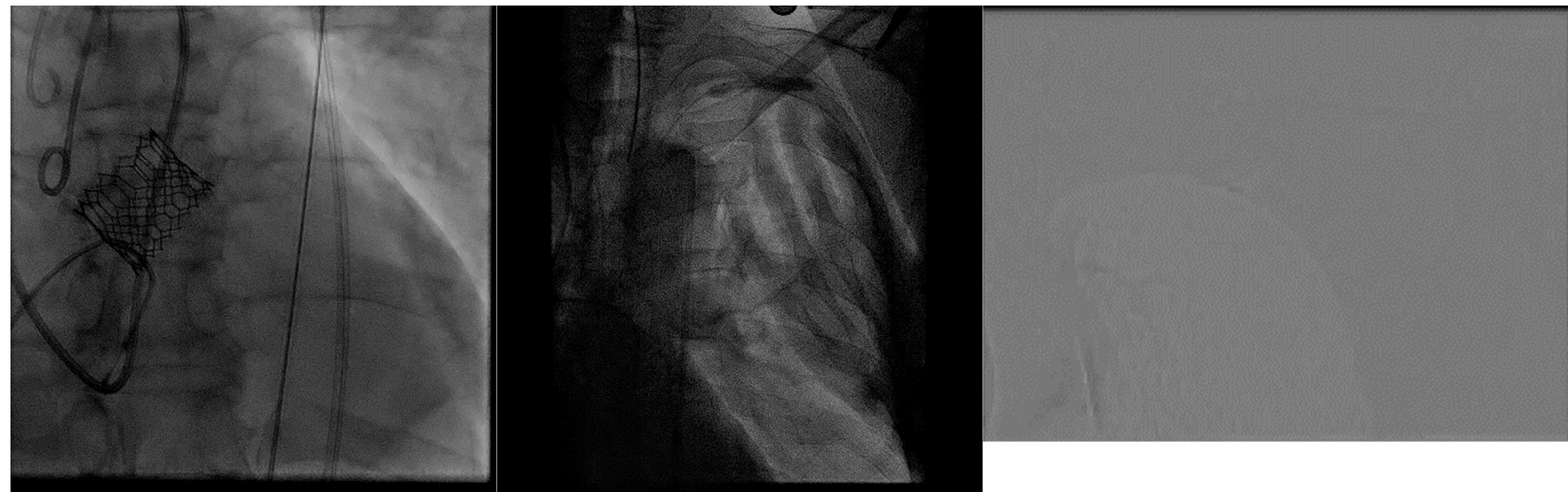
Transaxillary



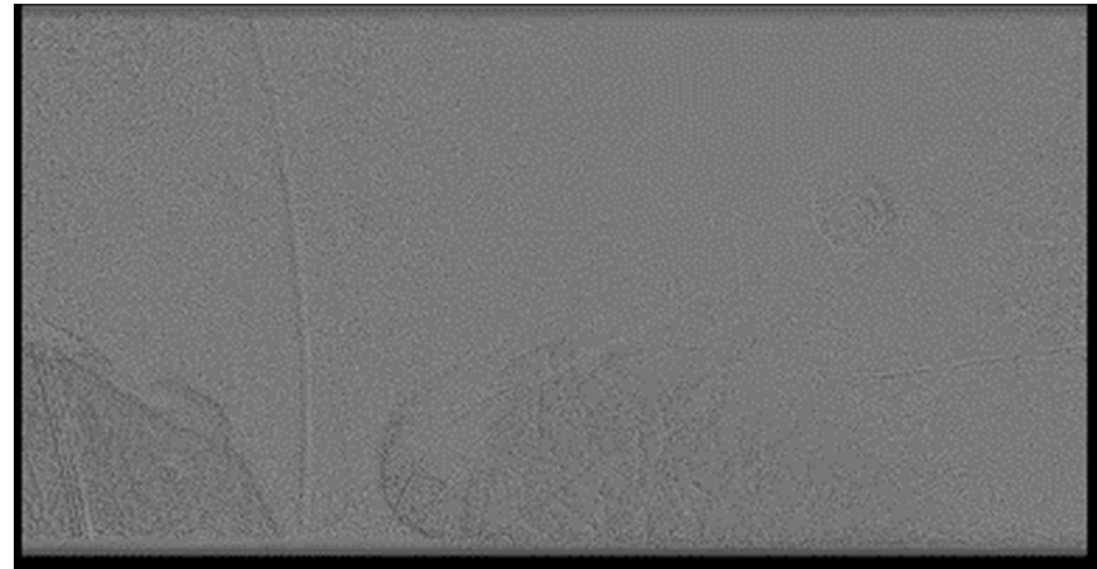
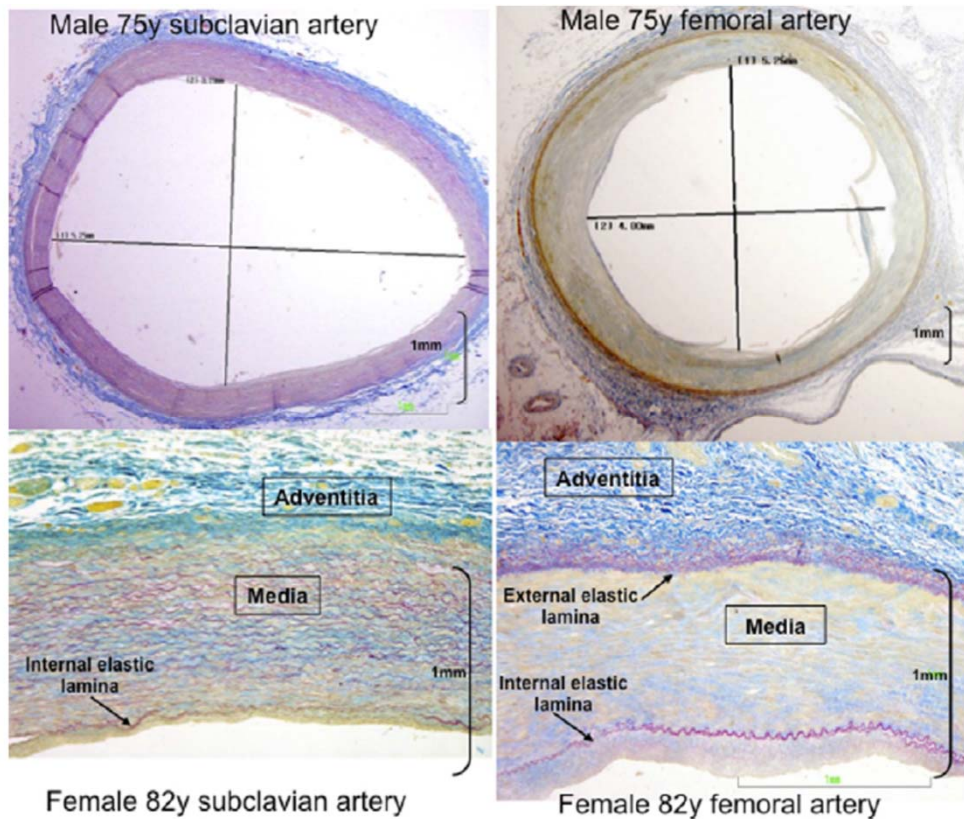
Transaxillary



Transaxillary



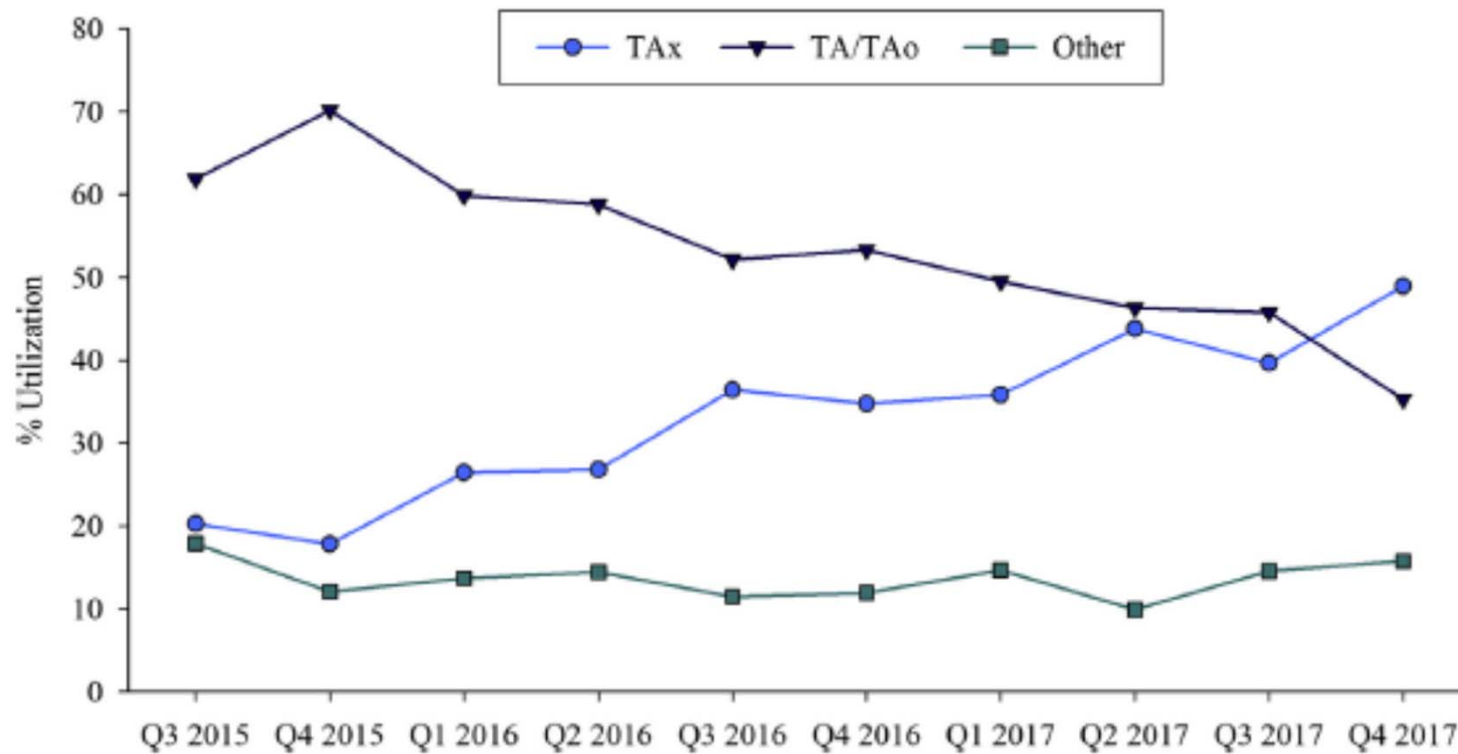
Subclavian Tissue differs Higher risk for dissection



US TAVI data

Most commonly used alternative

FIGURE 1 Temporal Trends in the Volume of Each Nonfemoral Access Route



Higher rates of stroke

Retrospective data

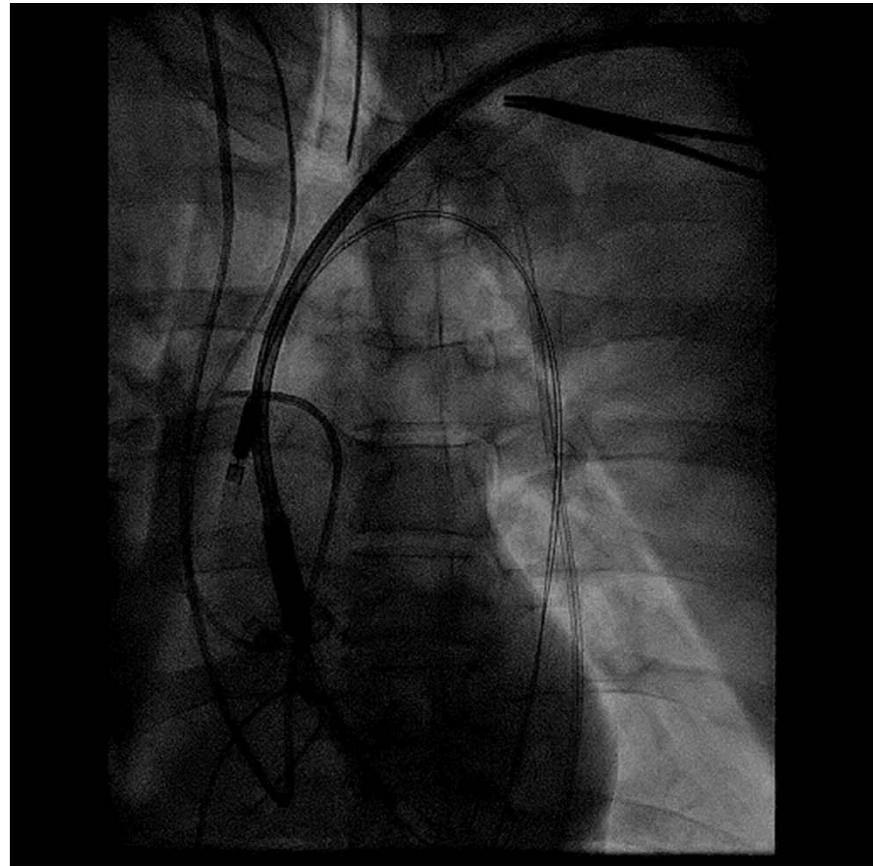
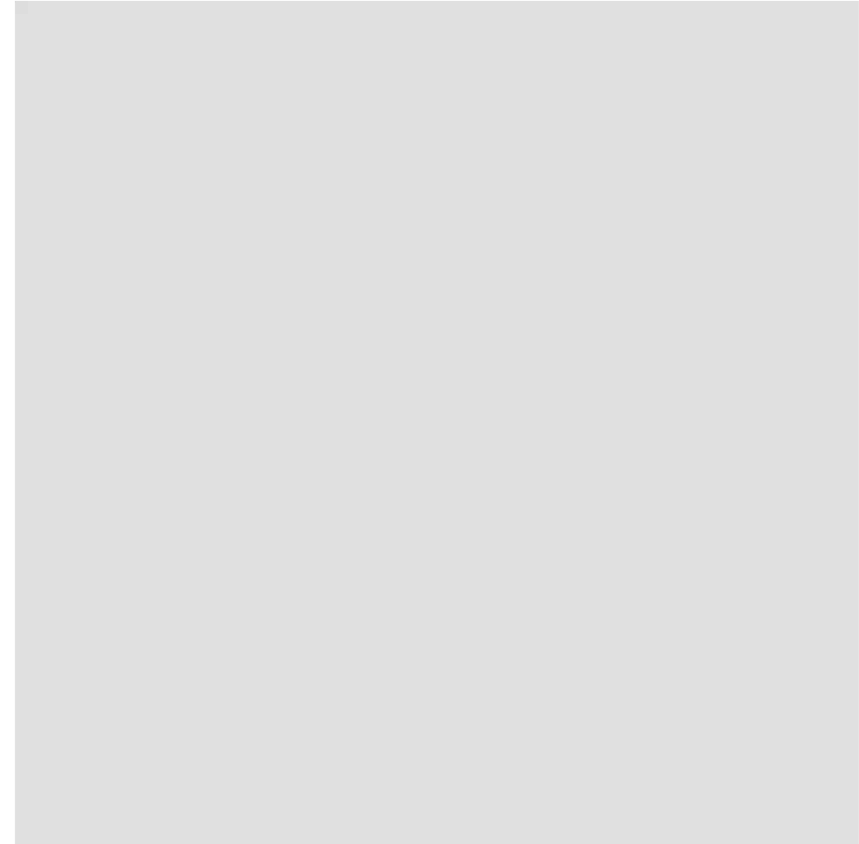
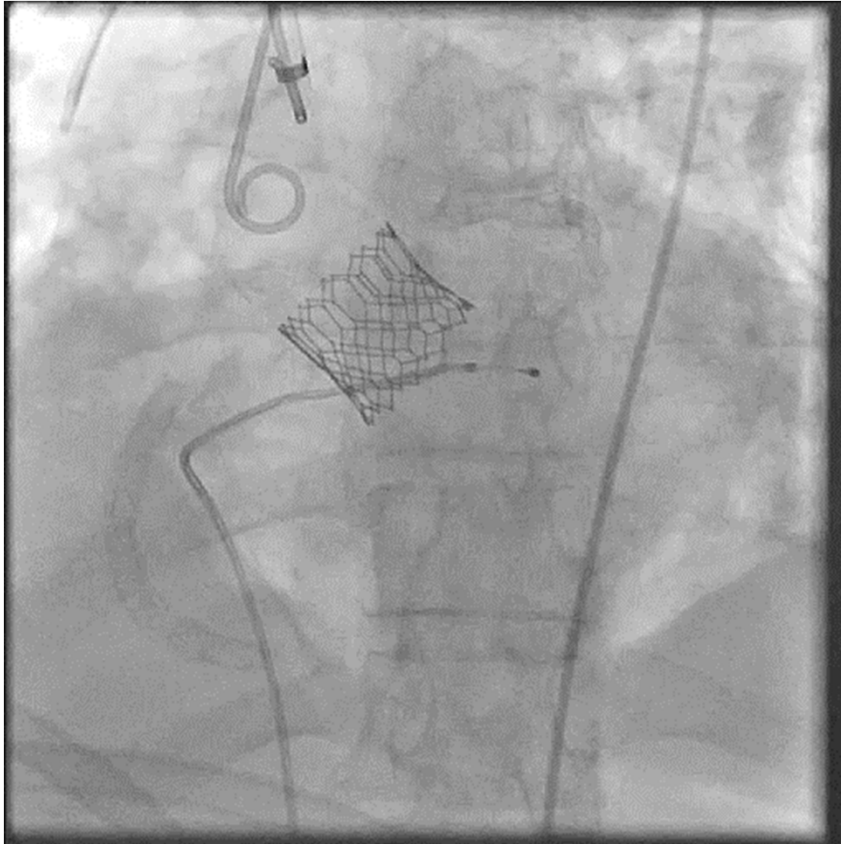


TABLE 3 Unadjusted 30-Day Outcomes by Access Route

	Transfemoral	TAx	TA/TAo
All-cause mortality	1,288 (2.4)	62 (5.4)	147 (8.5)
All stroke	1,049 (1.9)	74 (6.1)	51 (2.9)
New-onset atrial fibrillation	930 (1.6)	24 (2.0)	219 (12.4)
All readmissions	4,511 (8.7)	131 (12.0)	248 (15.6)
New requirement for dialysis	301 (0.6)	9 (0.8)	43 (2.5)
New pacemaker	5,221 (9.3)	144 (12.0)	183 (10.4)
Life-threatening bleeding	56 (0.1)	5 (0.5)	8 (0.5)
Major vascular complication	643 (1.1)	31 (2.5)	34 (1.9)

Transcarotid

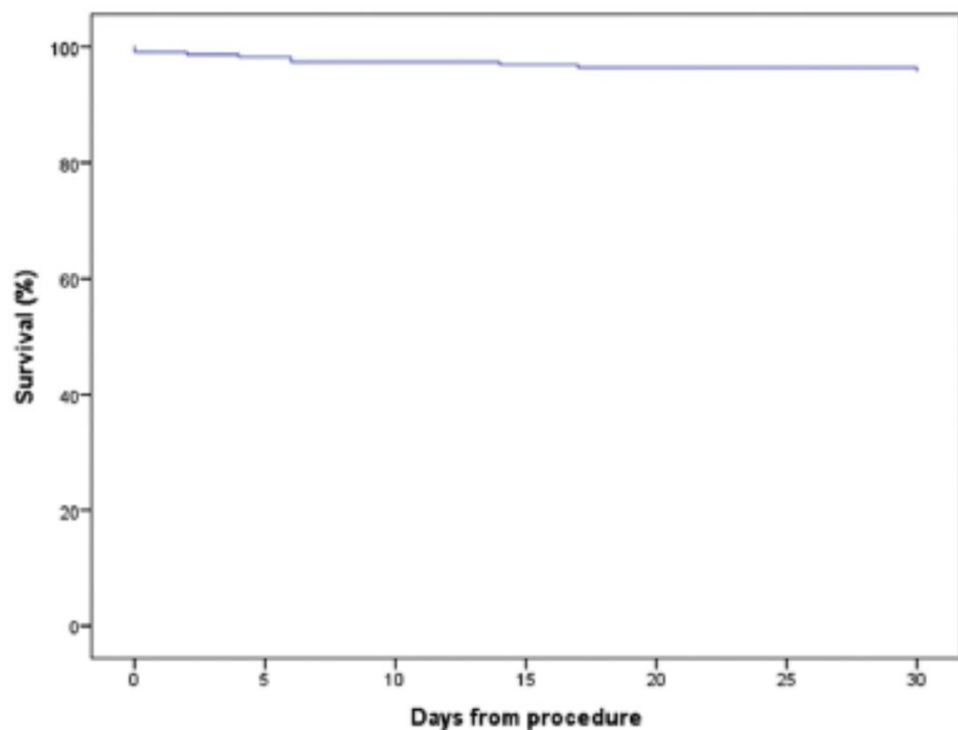


Transcarotid Comparison to TA/TAo

Outcomes	Propensity Score-Matched Data*		
	TA/TAo (n=163)	TC (n=94)	P Value
Mortality	4.6	2.1	0.37
Stroke/TIA	3.5	2.1	0.67
New pacemaker implantation	13.2	8.8	0.34
New-onset atrial fibrillation	19.0	3.2	0.002
Myocardial infarction	4.4	1.1	0.19
Major or life-threatening bleeding	19.9	4.3	0.002
Major vascular complication	10.7	3.2	0.05
Acute kidney injury (stage 2–3)	12.1	0	0.002
Median LOS, d	8 (6–12)	6 (3–8)	<0.001
Composite end points			
Device success	89.8	89.1	0.75
Early safety	71.7	92.6	0.002

Transcarotid access

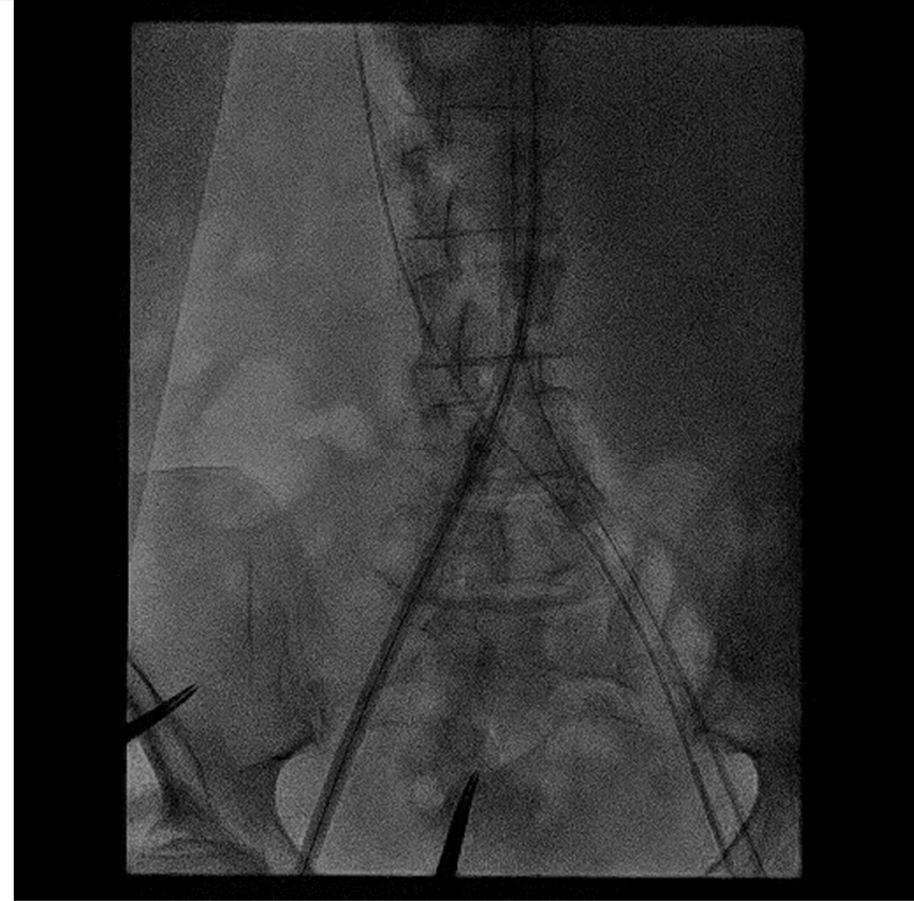
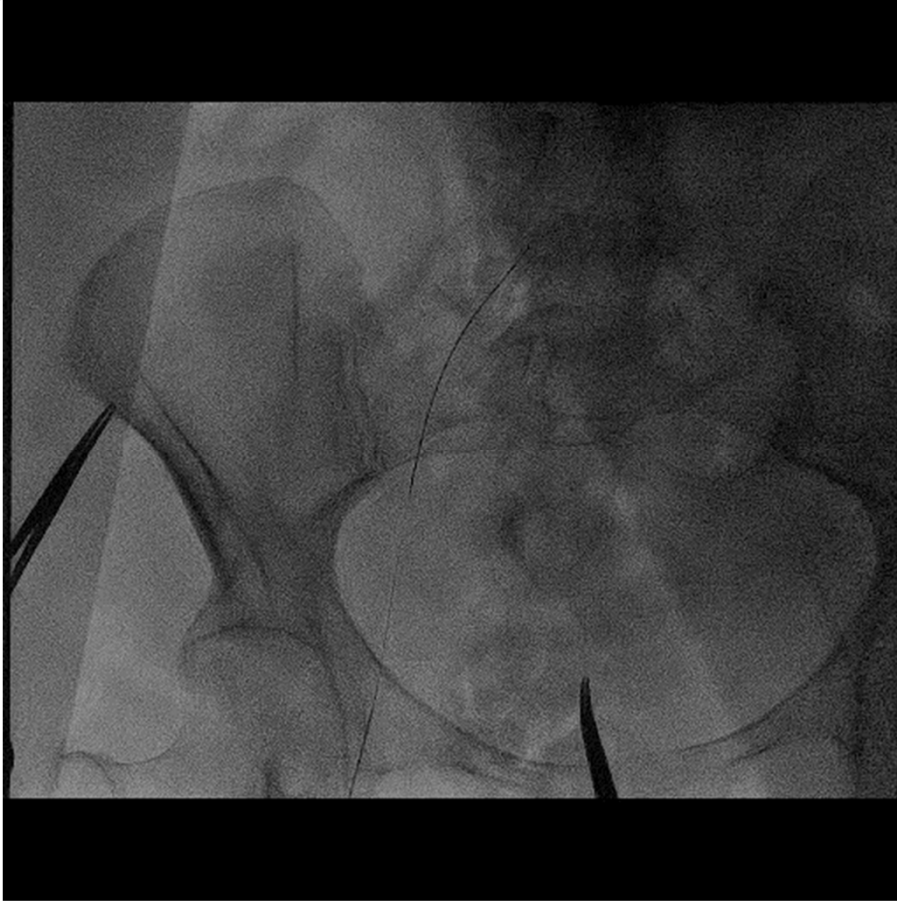
Low vascular complication and bleeding rates

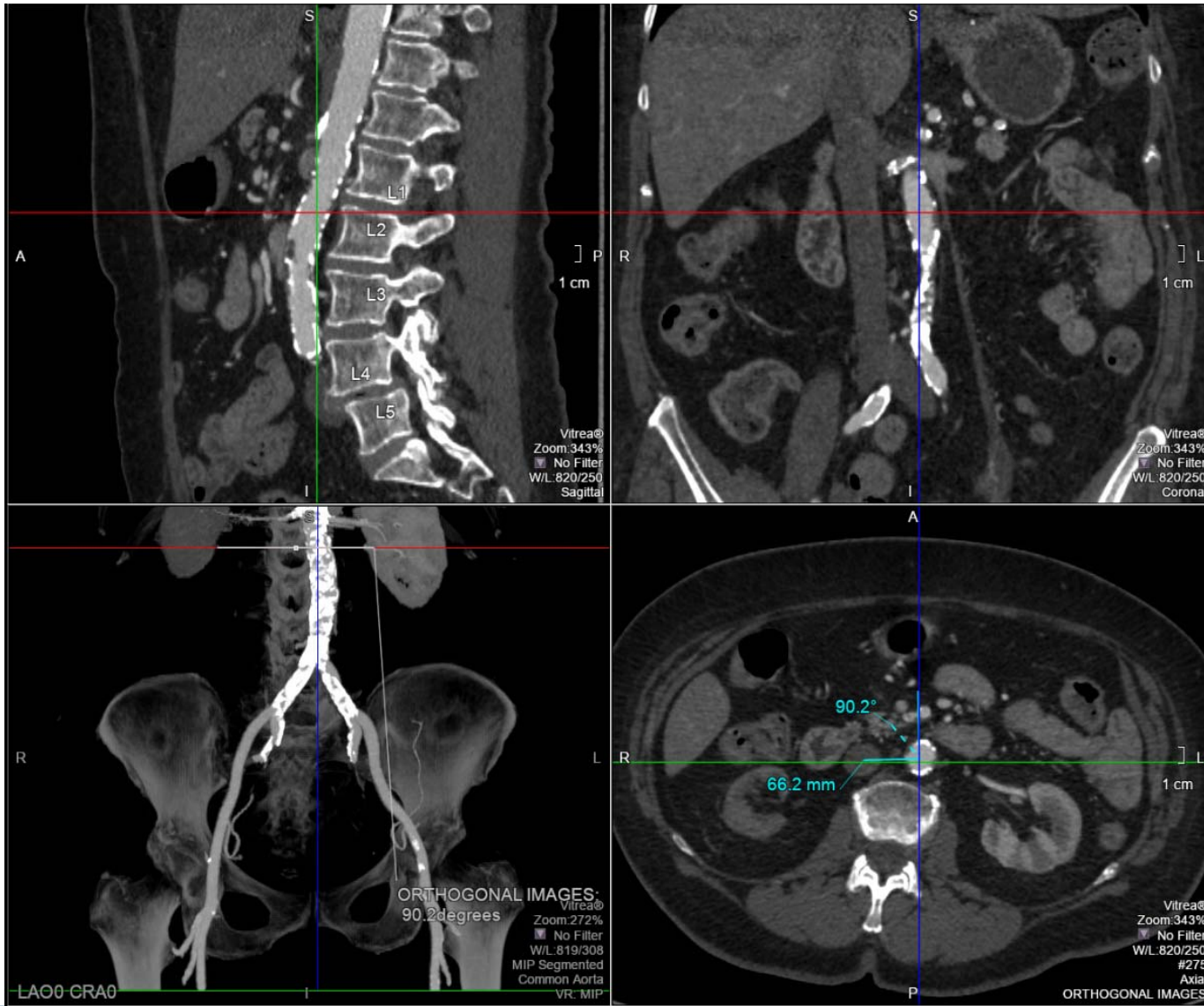


N° at risk	314	235	199	190	186	180	178

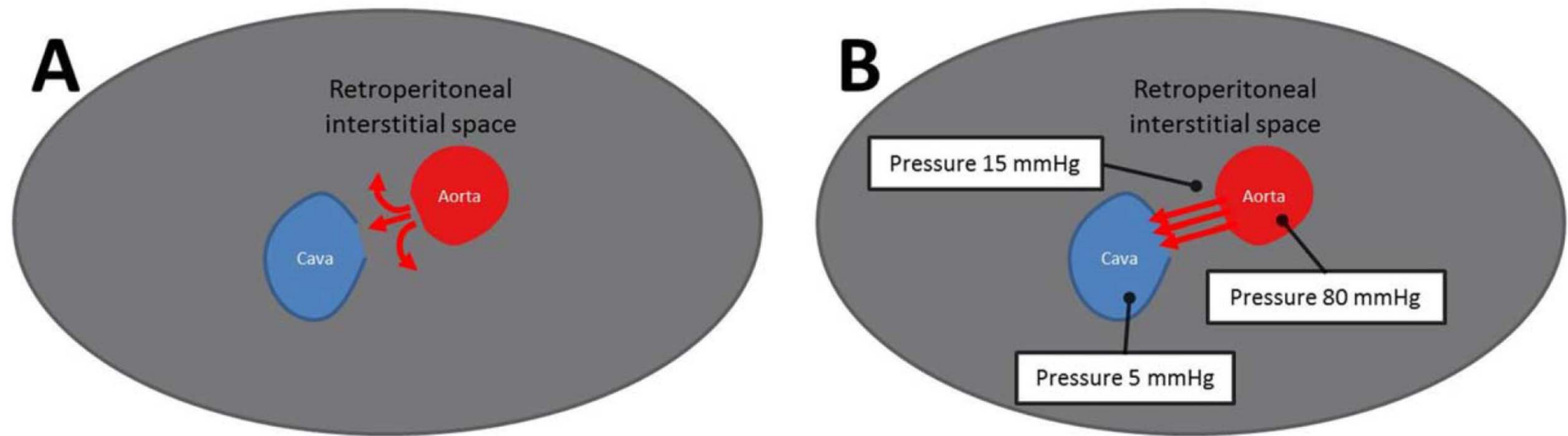
Procedural mortality	3 (1.0)
STEMI	2 (0.6)
Tamponade	3 (1.0)
Valve malpositioning	0.0
Major vascular complication	5 (1.6)
Major bleeding	13 (4.1)
Moderate to severe PVL on TTE	16 (5.1)
Post-implant echocardiographic mean gradient (mm Hg)	11 (8-13)
New permanent pacemaker	51 (16.2)
Stroke/TIA (30 days)	5 (1.6)
Hospital stay (days)	7 (5-10)
Mortality (30 days)	10 (3.2)

Attempted transfemoral

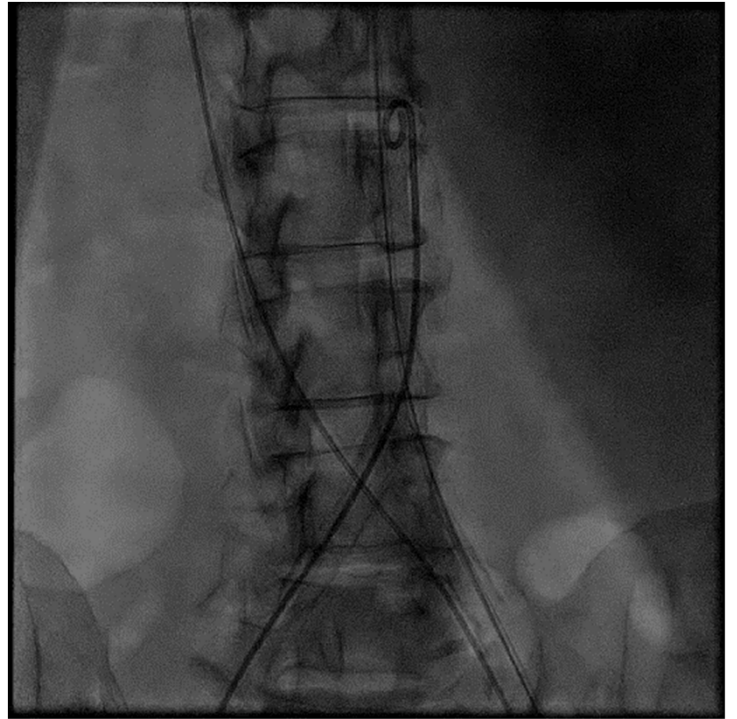
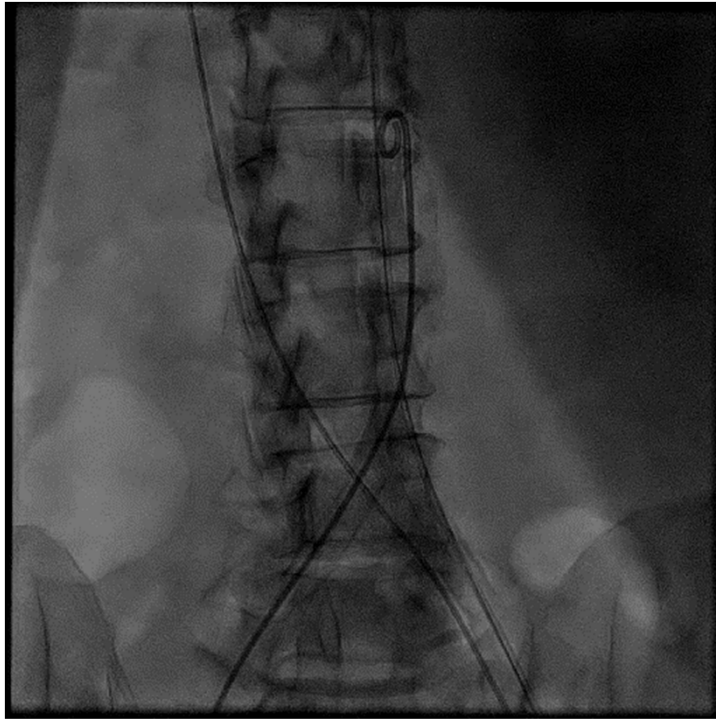
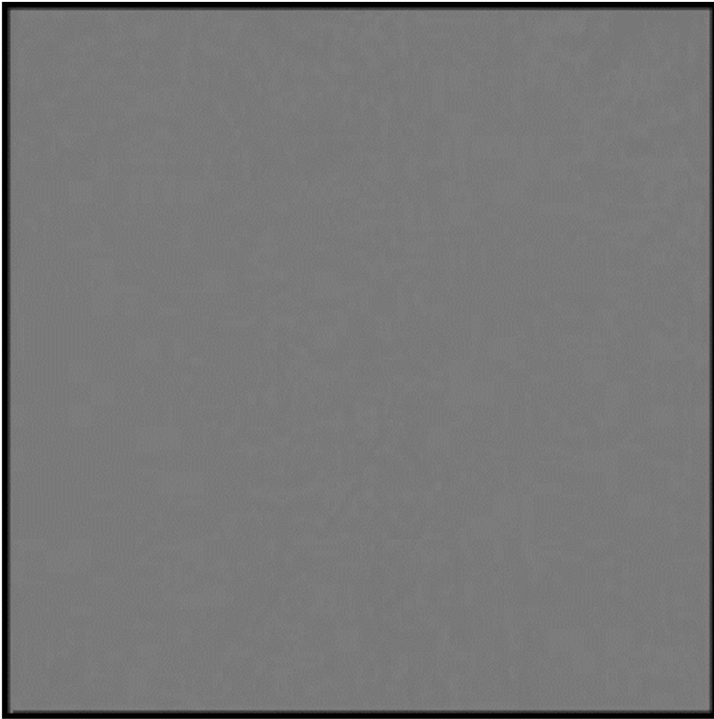




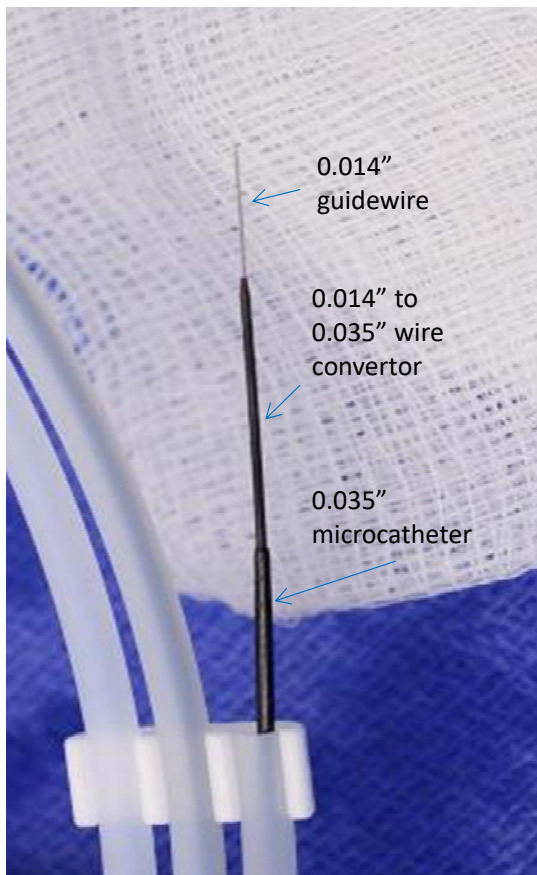
Why does transcaval work?



Transcaval



Assemble Crossing system



COAXIAL

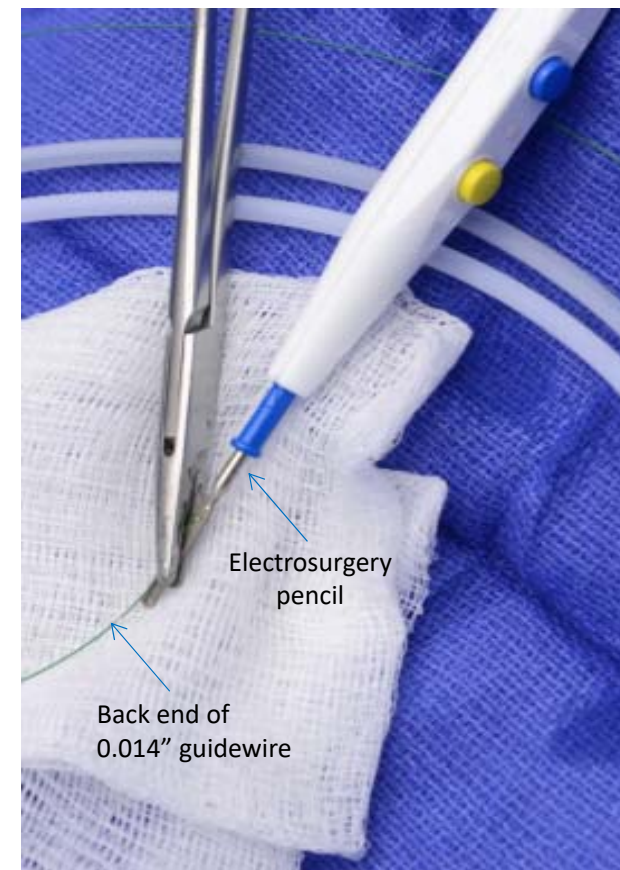
- *Astato XS 20*, inside a
- *Piggyback* wire convertor, inside a
- *Navicross* braided 0.035 microcatheter, to deliver later *Lunderquist*

ELECTROSURGERY

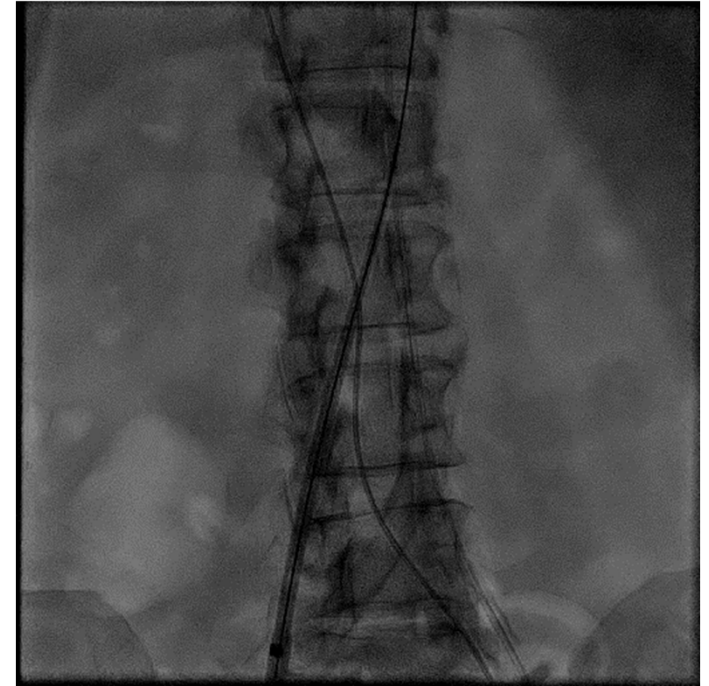
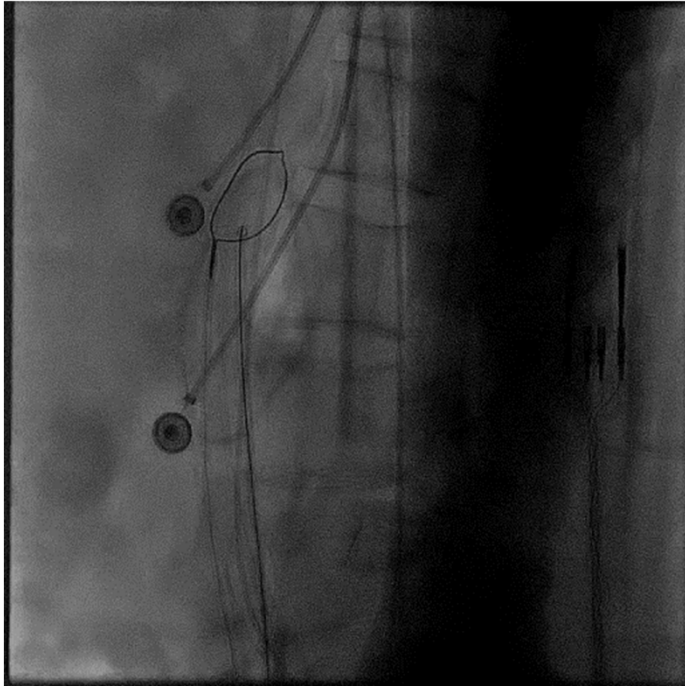
- No short circuits
- Ground pad without interposed metallic hips & pacemakers
- 50W "cutting" mode

PIGGYBACK

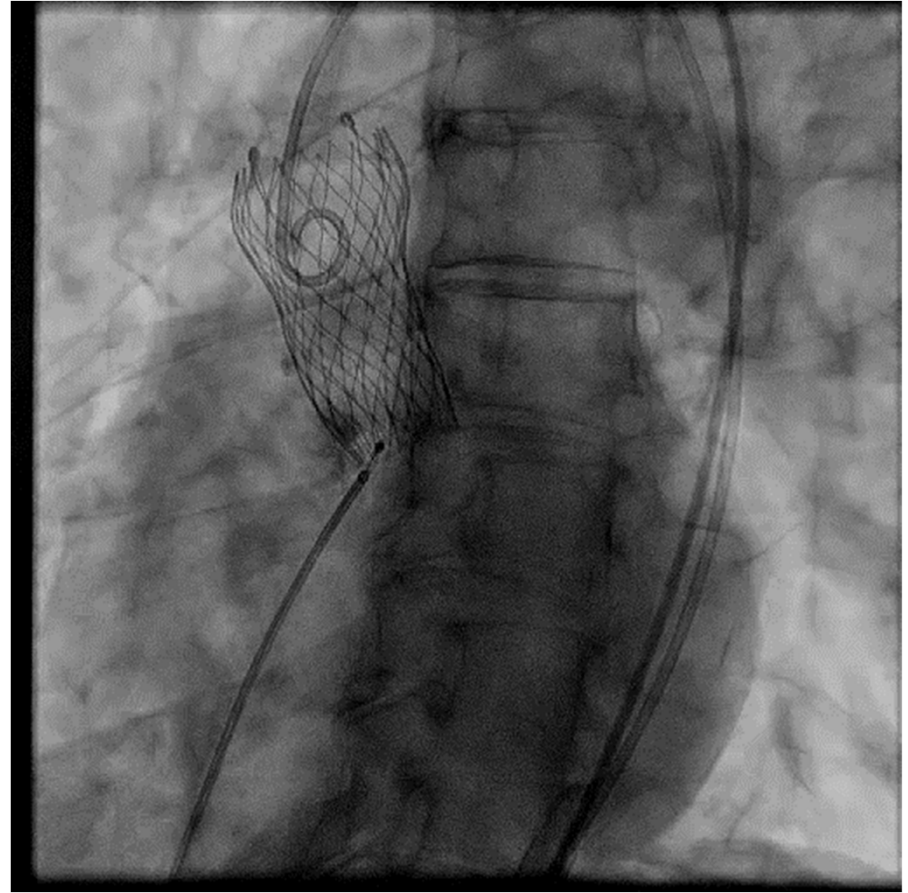
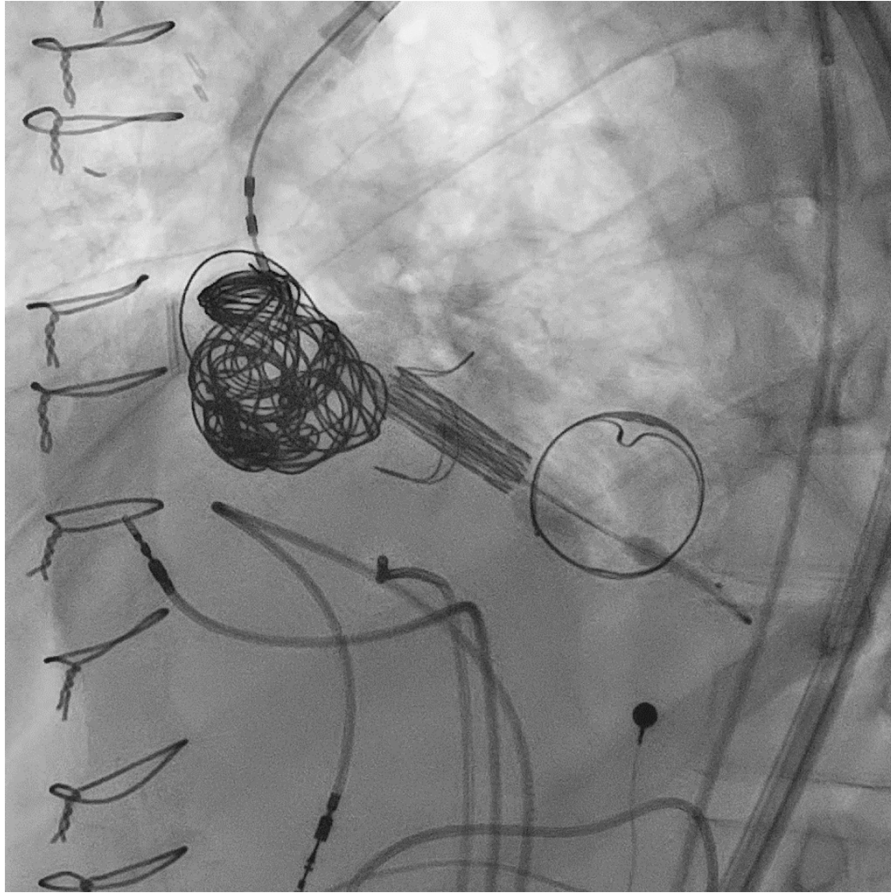
- Push to lock; Pull to unlock
- Keep free of blood/contrast



Transcaval



Complete Mission



Transcaval IDE main findings

NHLBI
Transcaval
TAVR
Prospective
Trial



Transcaval Success

- “Successful transcaval crossing, TAVR, and closing”



- 1 failure to cross
- No adverse event from the failure to cross

Device Success (Primary Endpoint)

- “Successful transcaval access and closure without immediate death or emergency surgery bailout”
- **98/100**
- 1 failure to cross
- 1 primary closure with covered stent after inadvertent withdrawal of closure device

MAJOR ENDPOINTS

Independently Adjudicated

n=100

NHLBI
Transcaval
TAVR
Prospective
Trial



BLEEDING		
	Transcaval-related	Count
Life-Threatening	Yes	6
	Indeterminate	1
	No	5
Major	Yes	5
	No	1
Minor	Yes	11
	No	8
None	-	62

Kappetein, *JACC*, 2012; 60:1438

VASCULAR COMPLICATIONS*		
	Transcaval-related	Count
Major	Yes	12
	Indeterminate	1
	No	6
Minor	Yes	13
	No	4
None	-	63

*Modified VARC-2 FISTULA OCCLUSION	
Pre-discharge (n=87)	49/100
30 days (n=76)	64/100

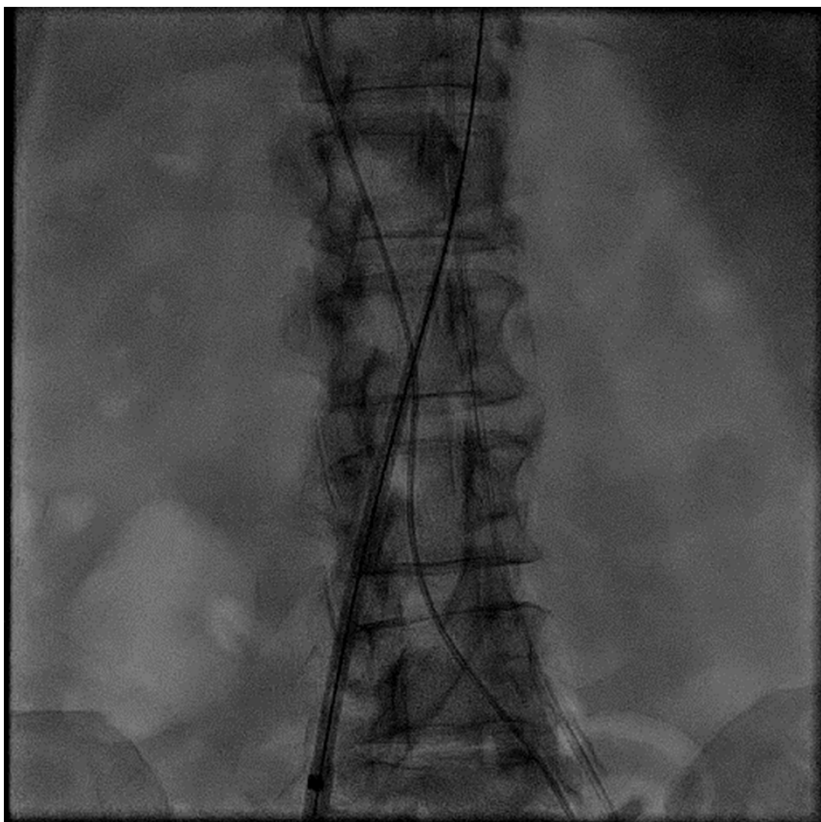
Transcaval bleeding and contemporary adjudicated TAVR trials

NHLBI
Transcaval
TAVR
Prospective
Trial

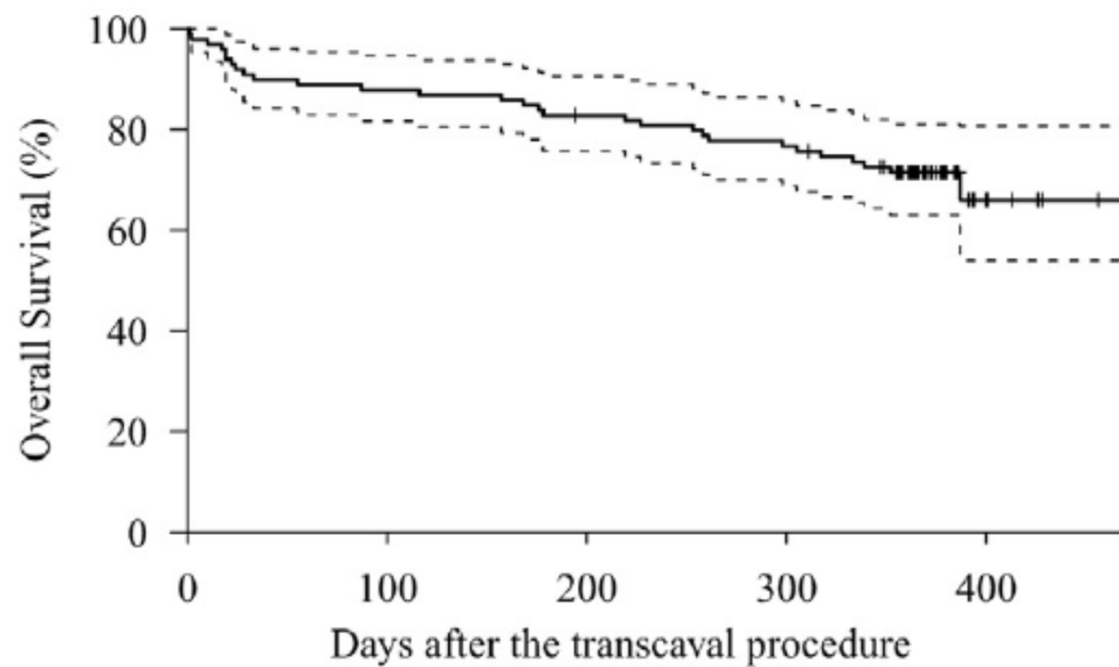


	Partner-II* Trans-femoral	Transcaval	Partner-II* Trans-apical or Trans-aortic
	n=775	n=100	n=236
STS predicted mortality	5.8%	9.6%	5.8%
Life-threatening or disabling bleeding	6.7%	12% (7% transcaval-related)	22.6%

Transcaval 1-year survival

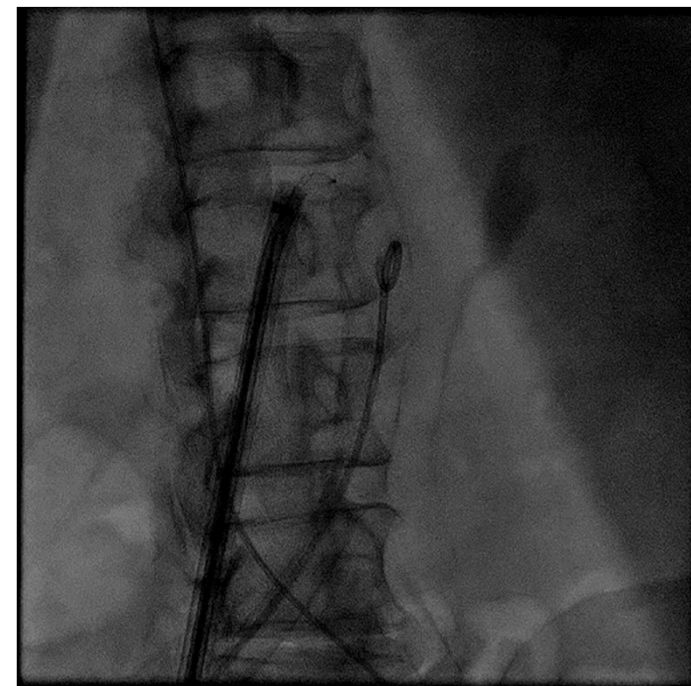
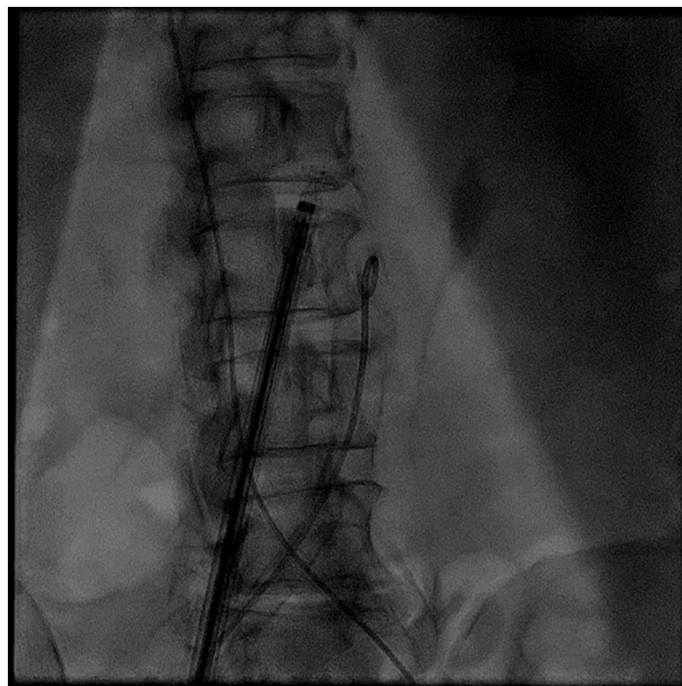


A

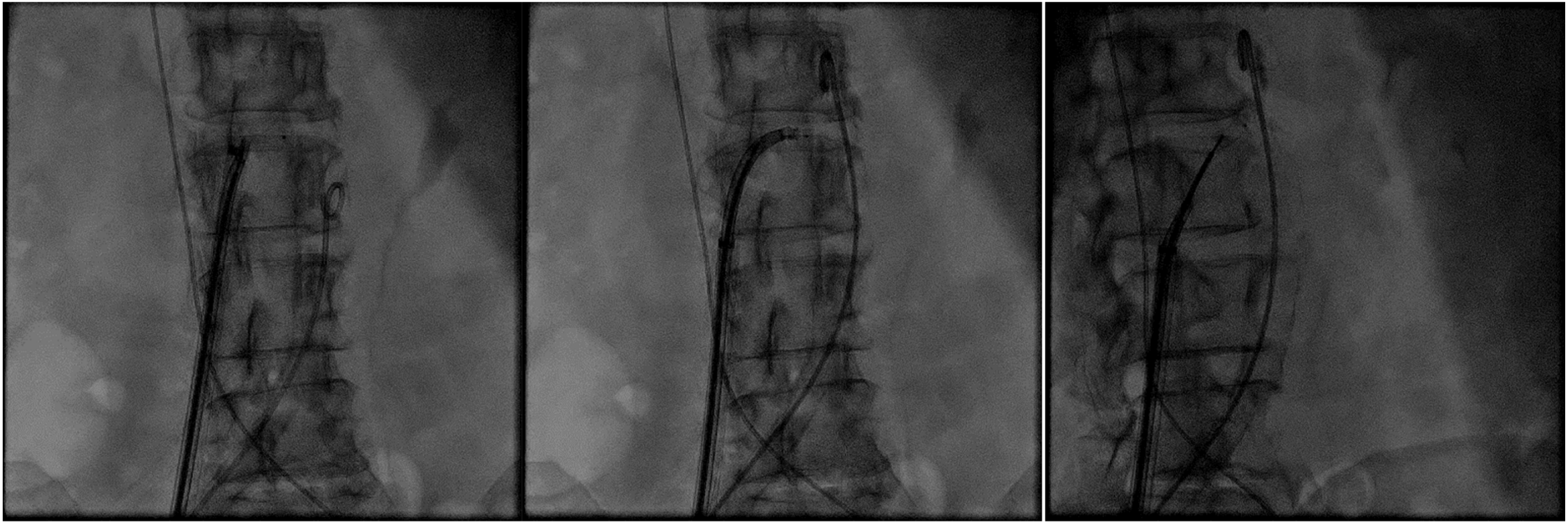


No. at risk 99 87 81 75 8

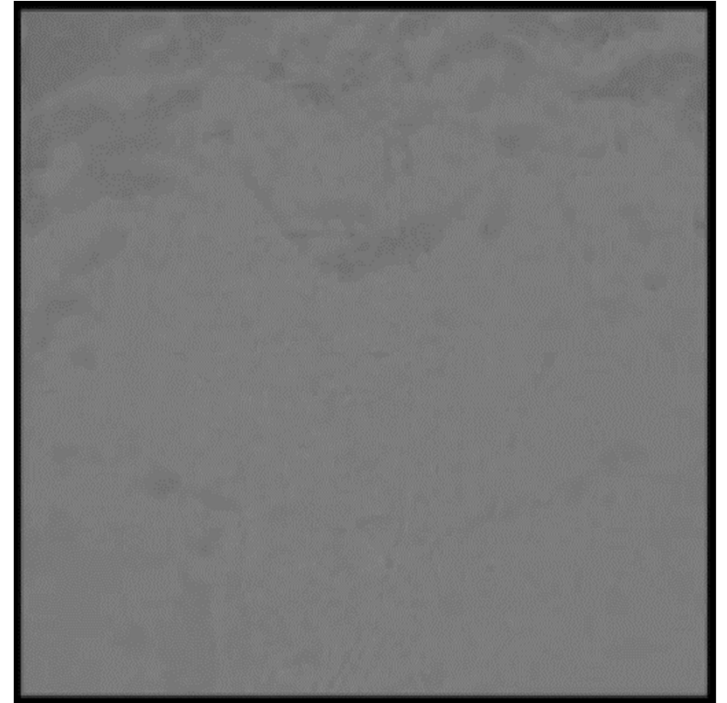
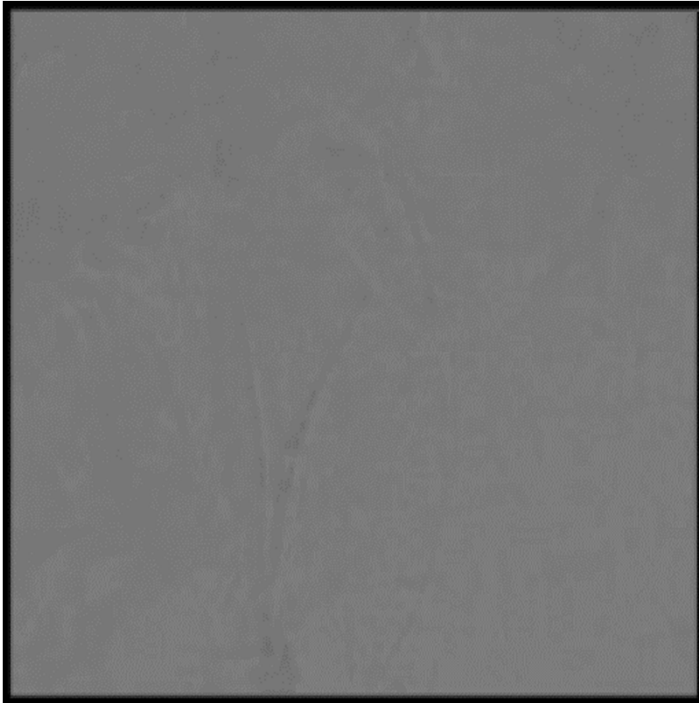
Transcaval Amplatz Duct Occluder



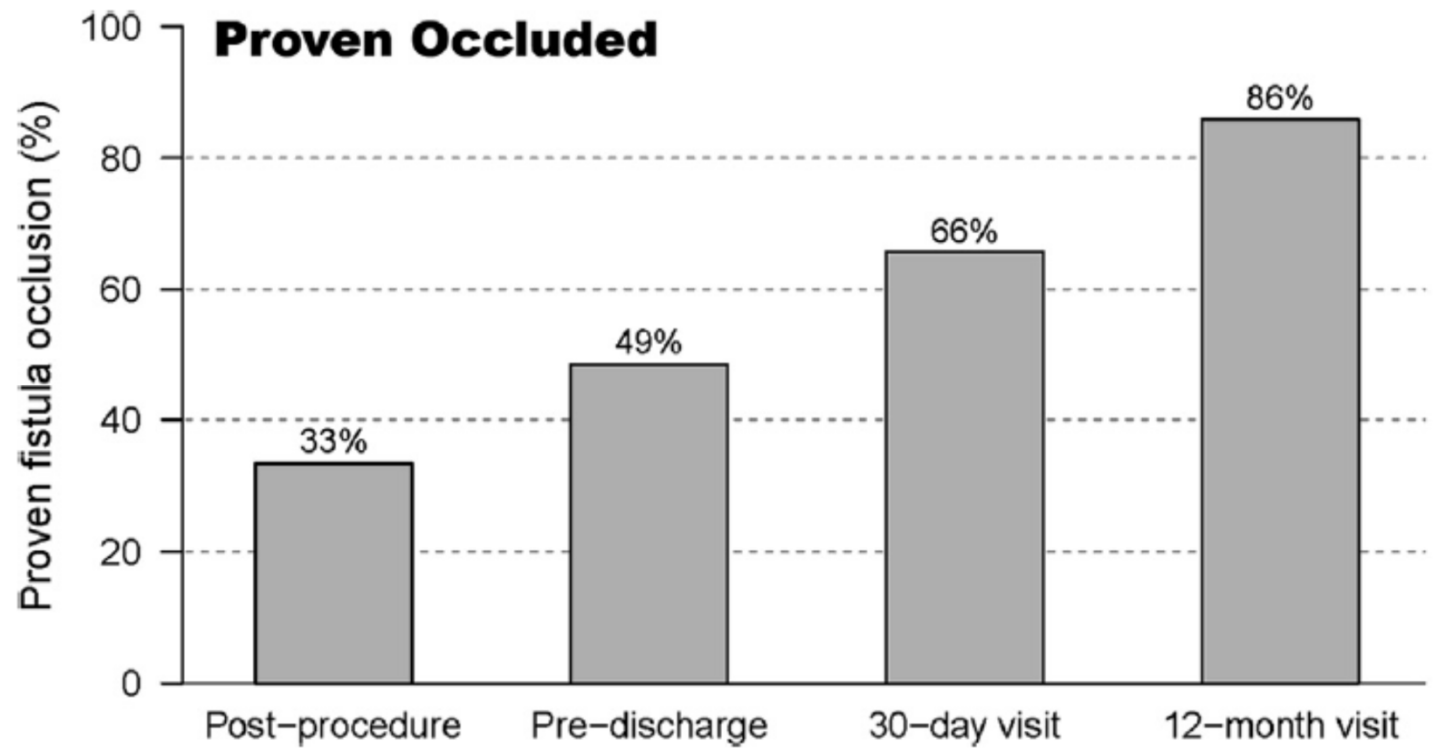
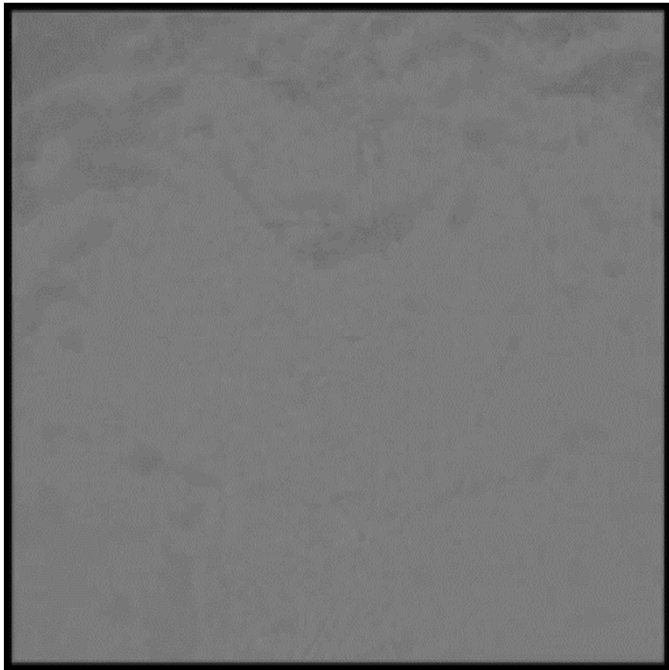
Transcaval



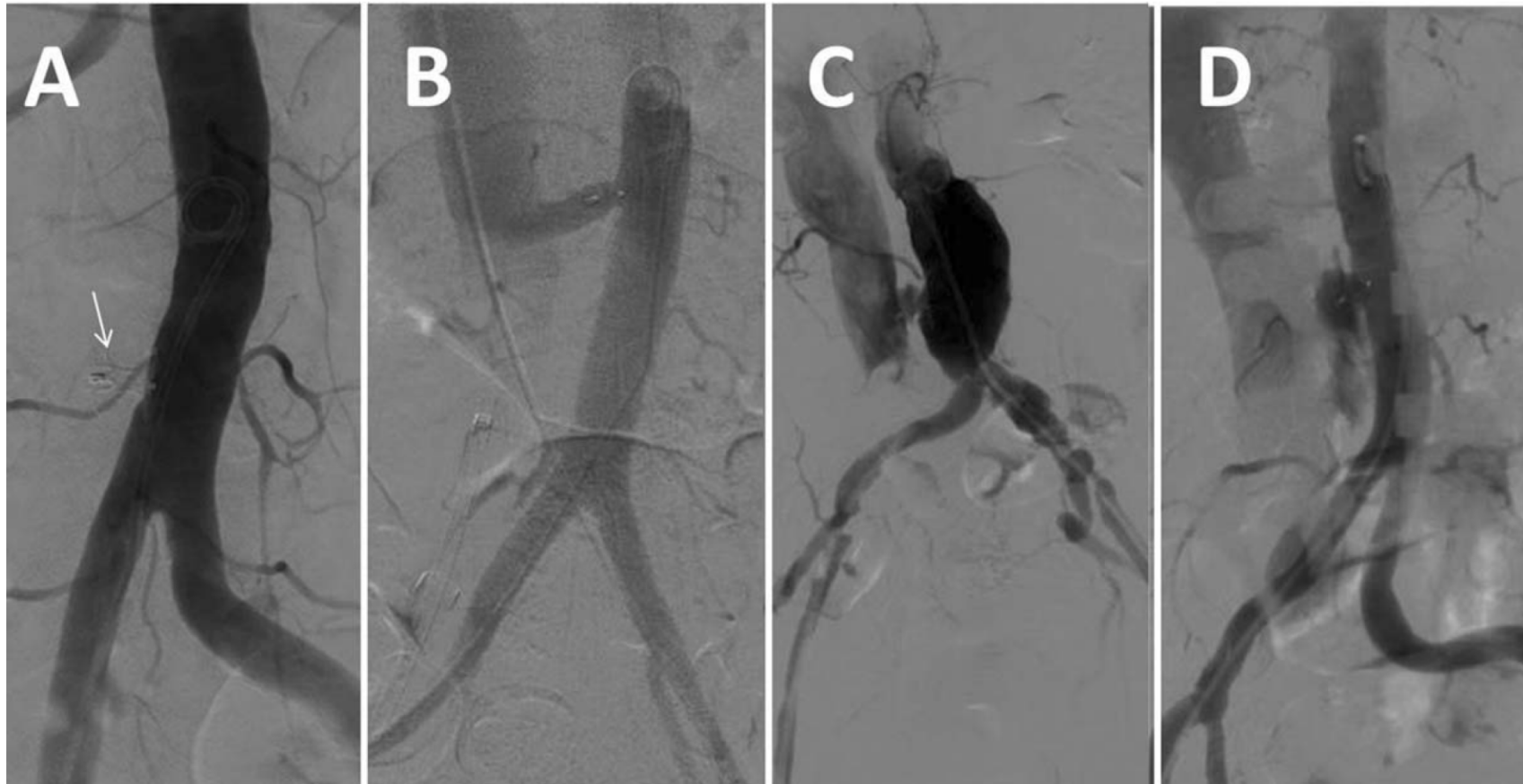
Transcaval



Transcaval closure rate

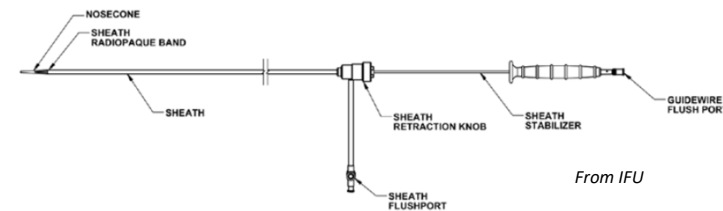


Patterns of Completion Angiography



■ Trivascular Ovation iX Iliac Limb Extension Stent Graft

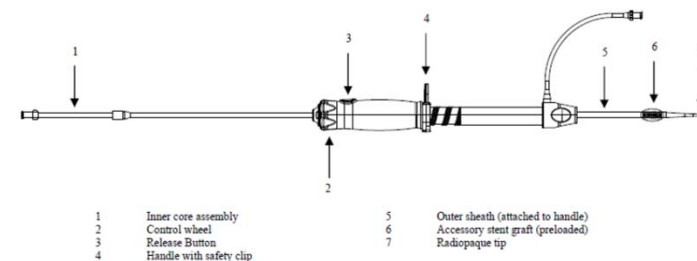
Aorta diameter for transcaval bailout	Diameter x length (device)	OD
<15mm	16 x 45mm	13Fr = 4.3mm
≤16mm	18 x 45mm	13Fr = 4.3mm
≤18mm	22 x 45mm	14Fr = 4.7mm
≤25mm	28 x 45mm	15Fr = 5mm



• Endologix AFX Iliac Limb Extension

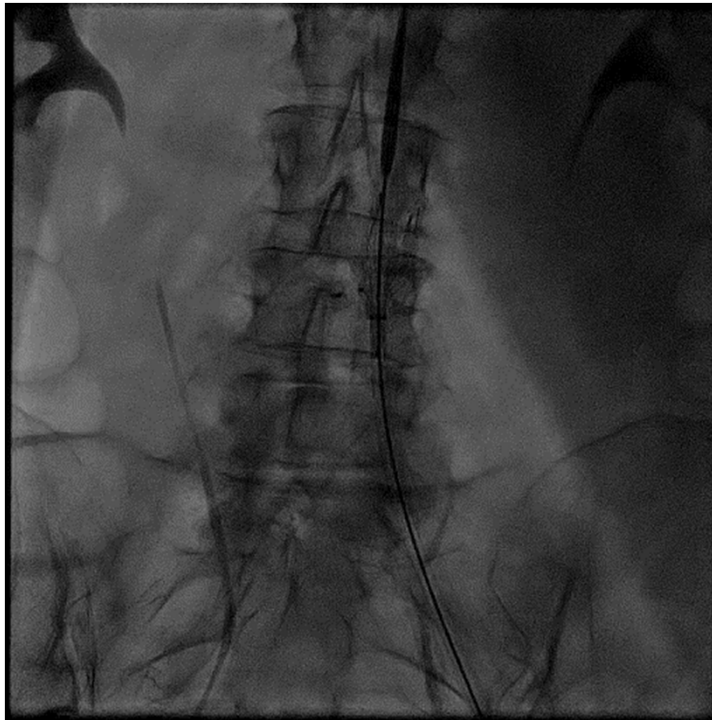
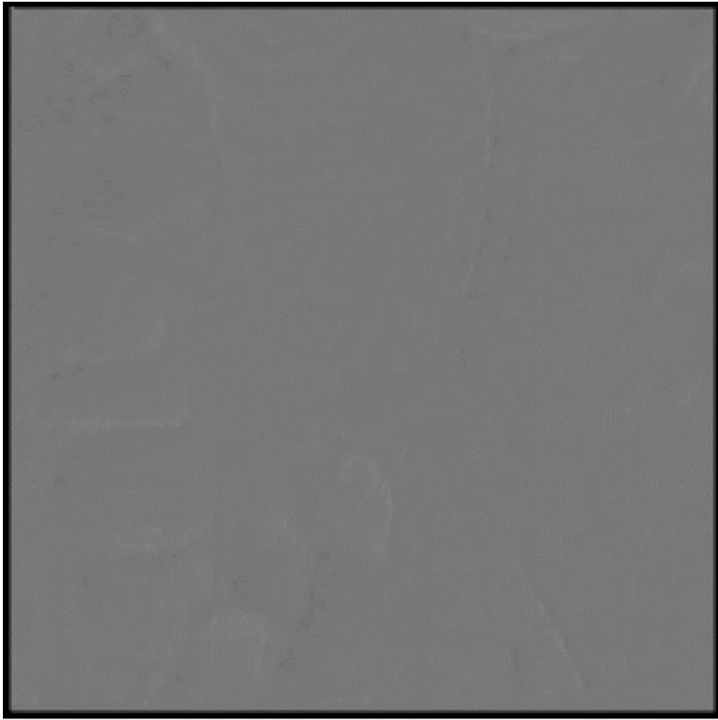
Aorta diameter	Model	Diameter x length (device)	OD bare	AFX Introducer May pass 5.5mm iliac
≤ 14mm	I16-16/C55	16x55mm (iliac limb)	4.7mm	Optional
≤ 18mm	I20-20/C55	20x55mm (iliac limb)	4.7mm	Optional
18-23mm	A25-25/C55	25x55mm (aortic extension)	N.A.	17Fr (mandatory) = 6.3mm OD
20-26mm	A28-28/C55	28x55mm (aortic extension)	N.A.	17Fr (mandatory) = 6.3mm OD

Figure 5. AFX Endovascular AAA Delivery System for Extension Stent Grafts



- Size to vessel lumen at least ~10% oversizing
- Use area-derived aka or “average” diameter
- Both are self-expanding, conforming, do not crenellate, and achieve hemostasis in failure of transcaval closure device

Transcaval bleeding management



Summary

- Vascular complications
 - Significant morbidity and mortality in TAVR
- CT screening imperative
 - Sheath/vessel ratio key
- Contemporary TAVR sheaths
 - Smaller sheaths but still up to 20% rates of alternative access



Alternative Access Summary

- Alternative Access
 - Transseptal
 - Apical
 - Transaortic
 - Carotid
 - Supersternal
 - Transaxillary
 - Transcaval
- Thoracic access
 - More bleeding
 - More atrial fibrillation
- HF prefer extra-thoracic access
 - Transcaval
 - Transaxillary
 - Transcarotid

