TCTAP 2023

TAVR with Severe PAD: Access Solution? Complication Management?

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Disclosure

• Disclose potential conflicts of interest: nil.



Outline

- Options of TAVI access sites
- Transfemoral access
- Non-transfemoral alternative access
- Transcaval access
- Transcaval access experience in VGHTC

Options of TAVI access sites

Transfemoral access

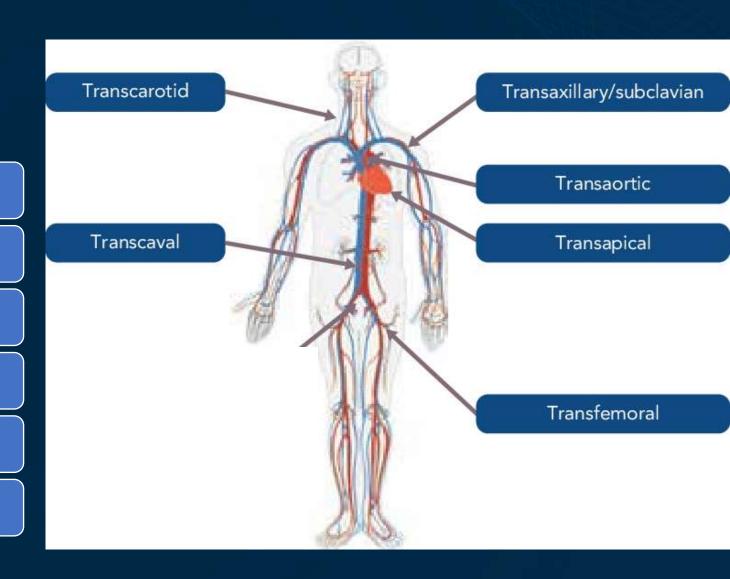
Transaxillary access

Transcarotid access

Direct aortic access

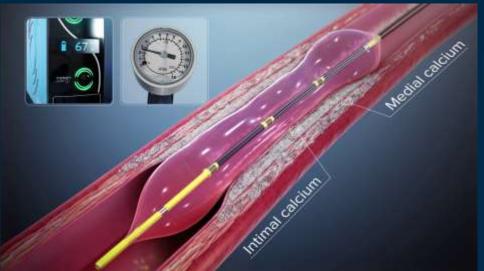
Transapical access

Transcaval access



Transfemoral access

- 18 French delivery sheath
 - A minimal vessel lumen diameter from the common femoral artery to the aortic valve of ≥ 5.5 mm
- InLine Evolut R sheath
 - Require a minimal diameter ≥ 5 mm
- Intravascular Lithotripsy(IVL) to facilitate TAVI access





COR	LOE	Recommendations
1	Α	 For symptomatic and asymptomatic patients with severe AS and any indication for AVR who are <65 years of age or have a life expectancy >20 years, SAVR is recommended.¹⁻³
1	A	 For symptomatic patients with severe AS who are 65 to 80 years of age and have no anatomic contraindication to transfemoral TAVI, either SAVR or transfemoral TAVI is recommended after shared decision-making about the balance between expected patient longevity and valve durability.^{1,4–8}
1	Α	 For symptomatic patients with severe AS who are >80 years of age or for younger patients with a life expectancy <10 years and no anatomic contraindication to transfemoral TAVI, transfemoral TAVI is recommended in preference to SAVR.^{1,4–10}

2020 ACC/AHA guideline for the management of patients with valvular heart disease. Circulation. (2021) 143:e72–e227



6. For patients with an indication for AVR for whom a bioprosthetic valve is preferred but valve or vascular anatomy or other factors are not suitable for transfemoral TAVI, SAVR is recommended. 1-3,11

• When transfemoral TAVI is not feasible, SAVR or palliative care options should be included in the shared decision-making discussion

2020 ACC/AHA guideline for the management of patients with valvular heart disease. Circulation. (2021) 143:e72–e227

Temporal Trends in Transcatheter Aortic Valve Replacement in France FRANCE 2 to FRANCE TAVI

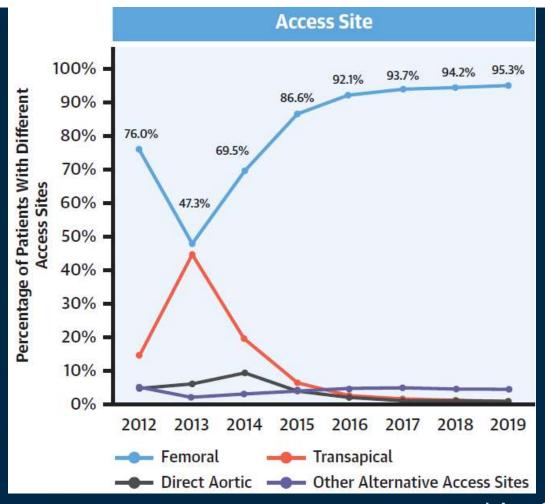
TABLE 3 Procedural Characteristics			
	FRANCE 2 (n = 4,165)	FRANCE TAVI (n = 12,804)	p Value
Location			
Catheterization laboratory	3,006/4,164 (72.2)	7,573/12,746 (59.4)	ref
Operating room	460/4,164 (11.0)	625/12,746 (4.9)	< 0.001
Hybrid room	698/4,164 (15.8)	4,548/12,746 (35.7)	< 0.001
General anesthesia	2,862/4,164 (68.7)	6,531/12,645 (51.7)	< 0.001
TEE guidance	2,527/4,164 (60.7)	3,672/11,373 (32.3)	< 0.001
Approach			
Transfemoral	3,058 (73.4)	10,602 (82.8)	ref
Transapical	732 (17.6)	541 (4.2)	< 0.001
Subclavian	241 (5.8)	385 (3.0)	< 0.001
Others	134 (3.2)	1,276 (10.0)	< 0.001
Valve type			
Edwards SAPIEN*	2,759 (66.2)	8,232 (64.3)	ref
Medtronic CoreValve	1,406 (33.8)	4,465 (34.9)	< 0.001
Others	0 (0.0)	107 (0.8)	s -
Need for a second valve	94 (2.3)	236 (1.8)	0.155
Conversion to surgery	49 (1.2)	65/12,557 (0.5)	< 0.001
Device success	3,970 (95.3)	12,139/12,544 (96.8)	<0.001

J Am Coll Cardiol. (2017)70:42-55.

2016 Annual Report of The Society of Thoracic Surgeons/ American College of Cardiology Transcatheter Valve Therapy Registry

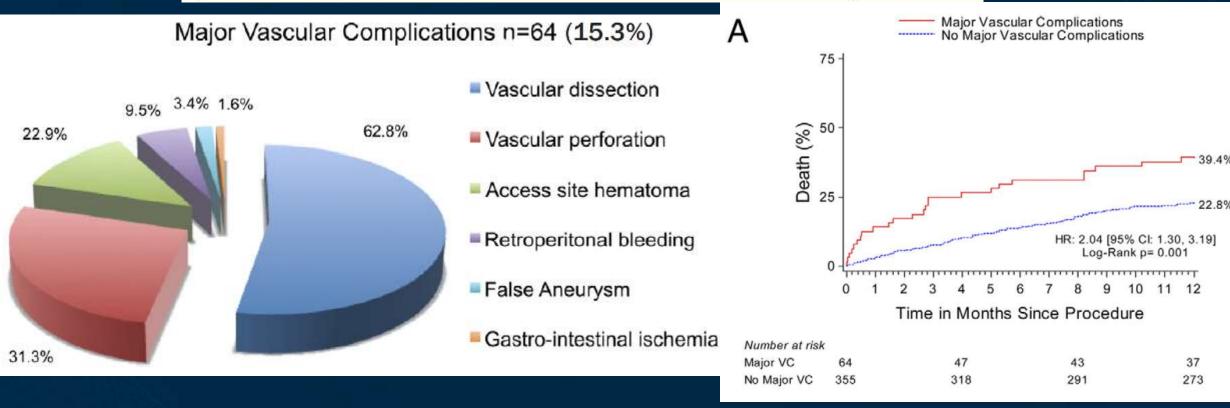
TABLE 1 Demographics,	Risk Scores, High-Ris	k Characteristics, a	nd Procedure Chara	cteristics of Patient	ts Undergoing TAVR	
	Overall $(N = 54,782)$	2012 (n = 4,627)	2013 (n = 9,052)	2014 (n = 16,295)	2015 (n = 24,808)	p Value
Access site						
Missing	311 (0.6)	32 (0.7)	76 (0.8)	91 (0.6)	112 (0.5)	< 0.0001
Femoral	40,596 (74.1)	3,512 (75.9)	4,277 (47.2)	11,313 (69.4)	21,494 (86.6)	
Transapical	9,318 (17)	671 (14.5)	4,024 (44.5)	3,111 (19.1)	1,512 (6.1)	
Other	4,557 (8.3)	412 (8.9)	675 (7.5)	1,780 (10.9)	1,690 (6.8)	

STS-ACC TVT Registry of Transcatheter Aortic Valve Replacement



Vascular Complications After Transcatheter Aortic Valve Replacement

Insights From the PARTNER (Placement of AoRTic TraNscathetER Valve) Trial



Management of vascular complications following transcatheter aortic valve implantation

	Overall	Patients with VCs	Patients without VCs	Р
	(n = 102)	(n = 22)	(n = 80)	
Bleeding				
Life-threatening	5 (4.9)	3 (13.6)	2 (2.5)	0.07
Major	4 (3.9)	2 (9.1)	2 (2.5)	0.22
Life-threatening or	9 (8.8)	5 (22.7)	4 (5.0)	0.02
major		10 10 10 10 10 10 10 10 10 10 10 10 10 1		
Blood transfusion (number of transfusions of ≥ 2 units of PRBCs)	9 (8.8)	3 (13.6)	6 (7.5)	0.37
30-day device success 30-day mortality	86 (84.3)	16 (72.7)	70 (87.5)	0.09
All cause	6 (5.9)	4 (18.2)	2 (2.5)	0.02
Cardiovascular	5 (4.9)	4 (18.2)	1 (1.3)	0.01
New permanent pacemaker implantation	20 (19.6)	5 (22.7)	15 (18.8)	0.7
Length of hospital stay (days)	9 [2—16]	9 [2—16]	9 [3-15]	0.57

Non-transfemoral alternative access

- Direct aortic access
- Transapical access
- Transaxillary access
- Transcarotid access
- Transcaval access



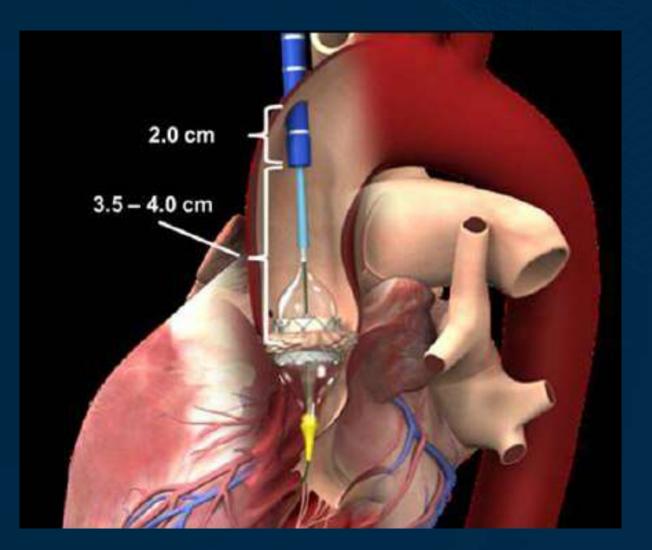
Non-transfemoral TAVI may be considered in patients who are inoperable and unsuitable for transfemoral TAVI.

2021 ESC/EACTS Guidelines for the management of valvular heart disease



Direct aortic access

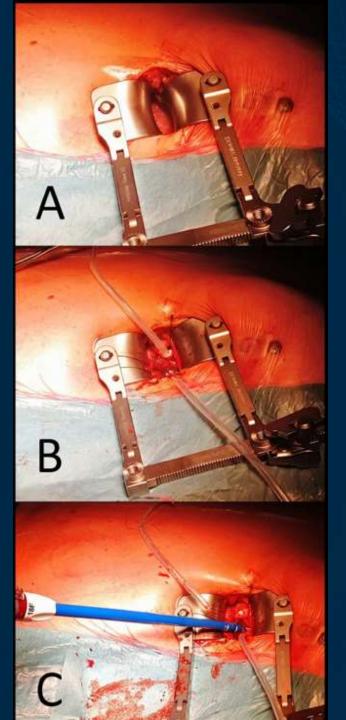
- Right antero-lateral minithoracotomy at second intercostal space
- Direct trans-aortic TAVI through an upper mini-sternotomy
- Contraindication
 - Thorax deformities, very short ascending aorta, porcelain aorta and the presence of a patent venous coronary artery bypass graft with proximal anastomosis on the ascending aorta



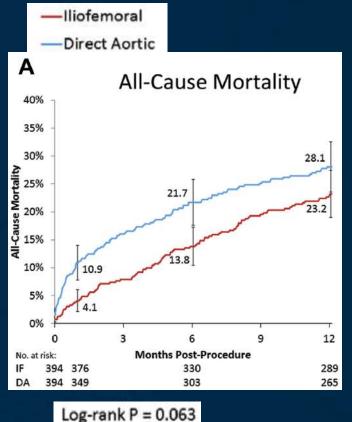


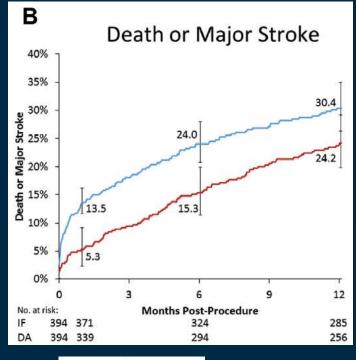
Transapical access

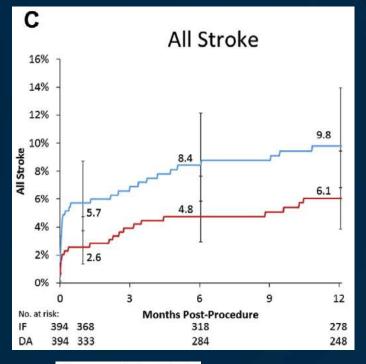
- Left antero-lateral mini-thoracotomy at the fifth intercostal space
- Only the Edwards Sapien balloonexpandable valve and the selfexpandable Symetis valve compatible
- Contraindication
 - Severely reduced left ventricular function, apical thrombus



Direct Aortic Access for Transcatheter Aortic Valve Replacement Using a Self-Expanding Device



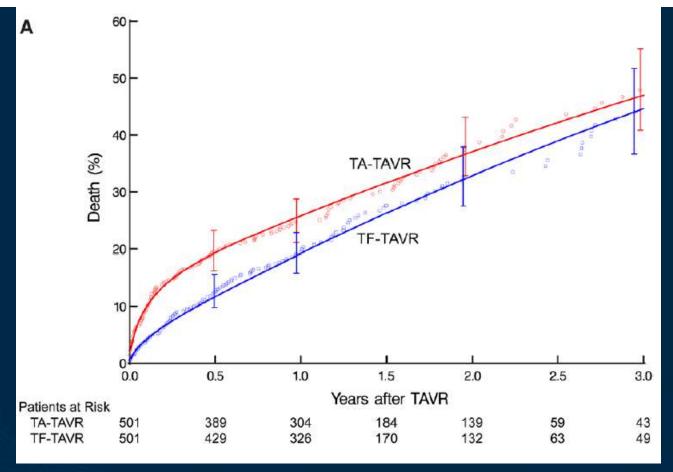




Log-rank P = 0.048

Propensity-Matched Comparisons of Clinical Outcomes After Transapical or Transfemoral Transcatheter Aortic Valve Replacement

A Placement of Aortic Transcatheter Valves (PARTNER)-I Trial Substudy



Comparative Survival After Transapical, Direct Aortic, and Subclavian Transcatheter Aortic Valve Implantation (Data from the UK TAVI Registry)

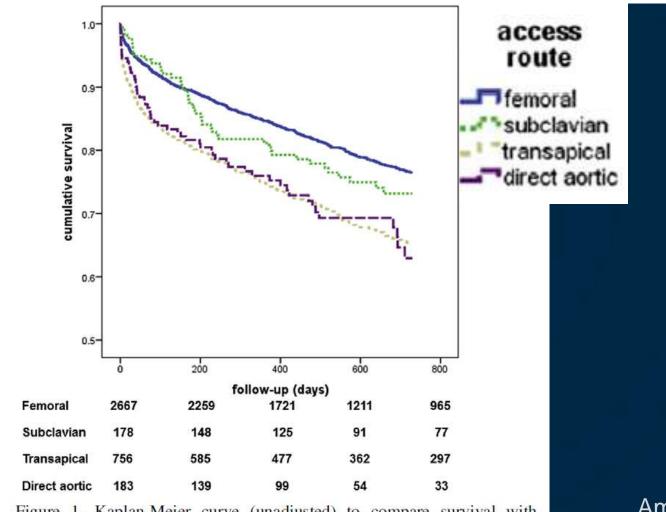
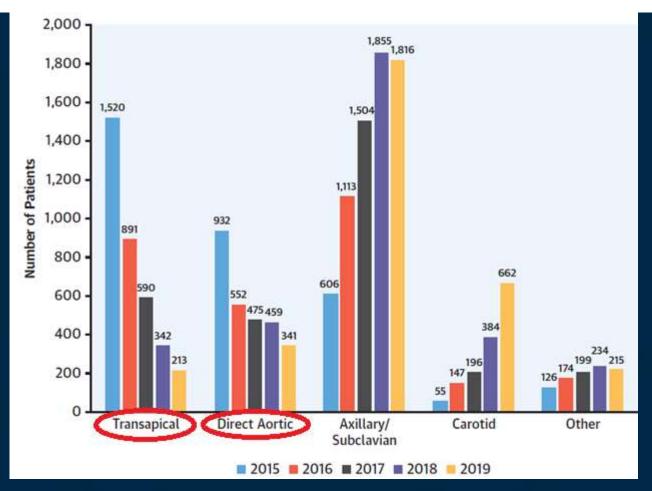


Figure 1. Kaplan-Meier curve (unadjusted) to compare survival with femoral versus nonfemoral access routes (p < 0.001).

Am J Cardiol. (2015) 116:1555–9

STS-ACC TVT Registry of Transcatheter Aortic Valve Replacement

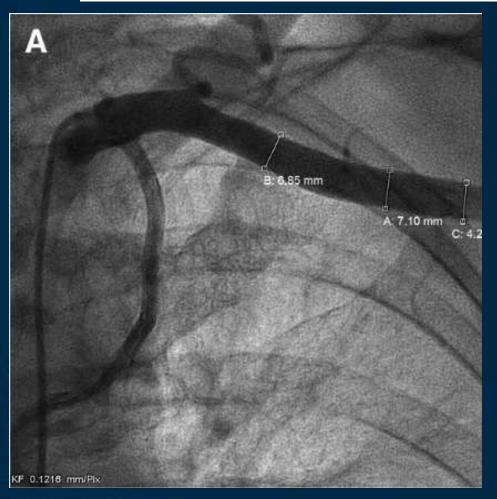


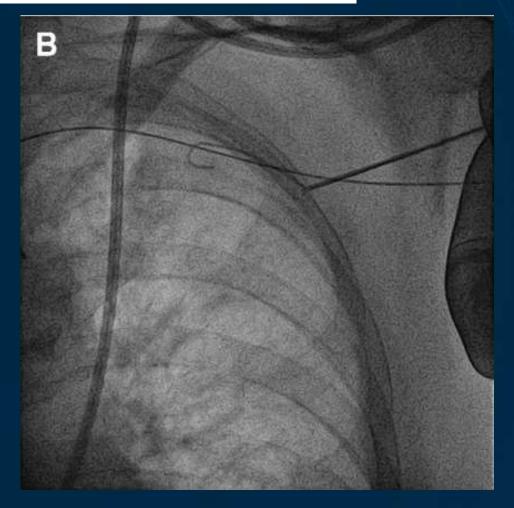
Transaxillary access

- The proximal third of the axillary artery represents the ideal target for approaches
 - Surgical cutdown approach
 - Percutaneous approach using percutaneous closure devices
- The left axillary/subclavian artery is usually used due to the anatomy of the vessel
- A minimal diameter ≥ 5.5mm is usually required

Direct Percutaneous Access Technique for Transaxillary Transcatheter Aortic Valve Implantation

"The Hamburg Sankt Georg Approach"

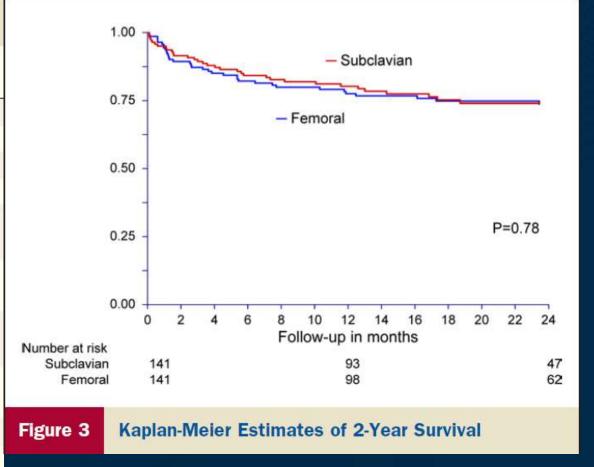




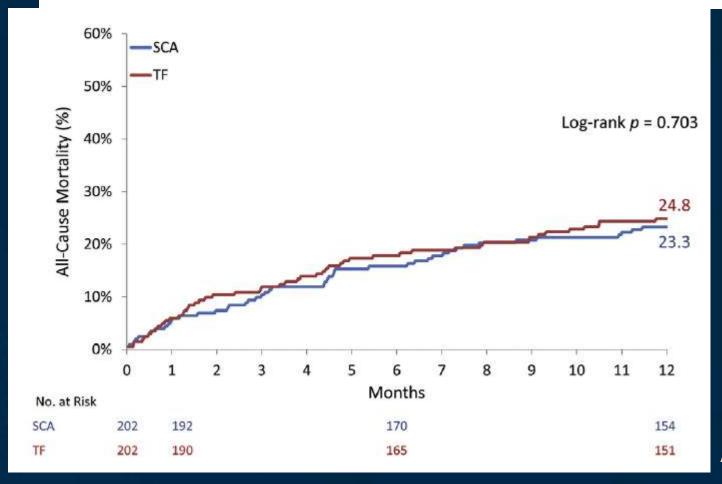
2-Year Results of CoreValve Implantation Through the Subclavian Access

A Propensity-Matched Comparison With the Femoral Access

Table 3	In-Hospital Outcome			
	Outcome	Subclavian Access	Femoral Access	p Value
All-cause m	ortality	7 (5.0)	6 (4.3)	0.78
Stroke		3 (2.1)	3 (2.1)	0.99
Myocardial i	infarction	0 (0)	0 (0)	0.99
Major vascu	lar complications	7 (5.0)	11 (7.8)	0.33
Minor vascu	lar complications	10 (7.1)	17 (12.1)	0.16
18-F access-related		3 (2.1)	16 (11.3)	0.003
Life-threatening bleeding events		11 (7.8)	8 (5.7)	0.48
18-F vascular complication-related		1(0.7)	6 (4.3)	0.05
Major bleeding events		51 (36.2)	43 (30.5)	0.31
18-F vasc	ular complication-related	4 (2.8)	12 (8.5)	0.04
Minor bleeding events		13 (9.2)	12 (8.5)	0.83
18-F vasc	ular complication-related	1(0.7)	8 (5.7)	0.02
Acute kidne	y injury/stage 3	6 (4.3)	14 (9.9)	0.02
New left but	ndle branch block	35 (24.8)	30 (21.3)	0.49
New perma	nent pacemaker	34 (24.1)	33 (23.4)	0.88



Subclavian/Axillary Access for Self-Expanding Transcatheter Aortic Valve Replacement Renders Equivalent Outcomes as Transfemoral



Axillary/Subclavian Transcatheter Aortic Valve Replacement

The Default Alternative Access?*

TABLE 1 Factors to Consider When Choosing Axillary/Subclavian Access in TAVR

Clinical	Anatomic
Cerebrovascular disease Prior CABG with patent internal thoracic artery graft Morbid obesity	Vessel size, especially at origins of vertebral and internal thoracic artery Vessel tortuosity Vessel calcification Aortic arch calcification Subclavian to arch angulation Aortic root angulation

Transcarotid access

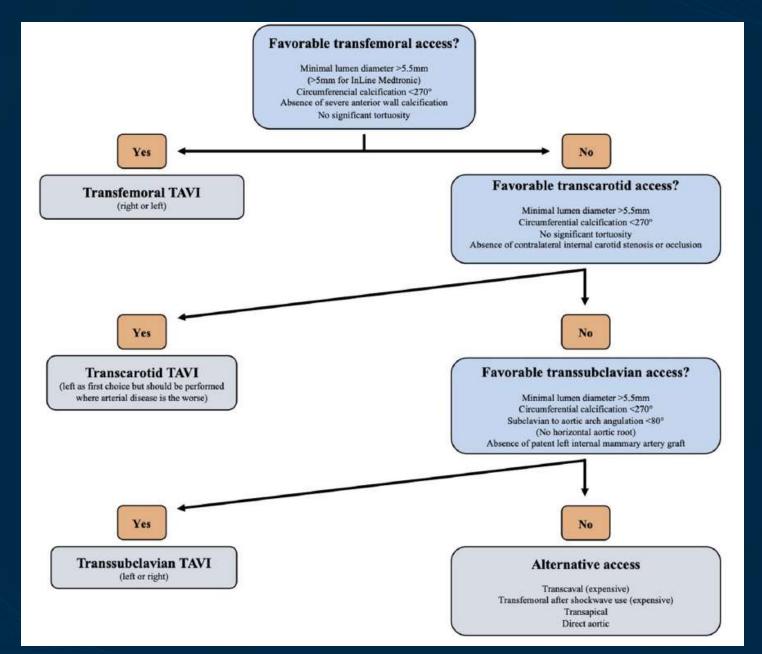
- Performed by surgical exposure of the common carotid artery
 - Not fully percutaneous
- Left common carotid artery is usually preferred
 - vascular access should be performed where arterial disease is the worse
- Contralateral significant common carotid artery stenosis or occlusion=> usually contraindication for transcarotid approach
- A minimal lumen diameter of the common carotid artery ≥5.5mm without >50% stenosis is required

Comparison of Transcarotid vs. Transfemoral Transcatheter Aortic Valve Implantation

Table 3. Postoperative Outcomes			
Variable	TC-TAVI (n=83)	TF-TAVI (n=643)	P value
Mean gradient (mmHg)	10.3±4.6	10.7±6.6	0.558
Aortic valve surface (cm²)	1.8±0.6	1.7±0.7	0.110
Aortic regurgitation ≥ Grade 2	12 (14.4)	94 (14.6)	0.969
Hospital stay (days)	12.4±7.7	12.0±8.7	0.729
Early safety ^A	72 (86.7)	558 (86.1)	0.993
30-day clinical efficacy ^B	66 (79.5)	538 (83.6)	0.341
Procedural mortality	2 (2.4)	8 (1.2)	0.391
30-day mortality	7 (8.4)	32 (5.0)	0.189
TIA	1 (1.2)	1 (0.2)	0.086
Stroke	1 (1.2)	17 (2.6)	0.428
Tamponade	1 (1.2)	9 (1.4)	0.886
Bleeding with shock	0 (0)	8 (1.2)	0.307
New dialysis	0 (0)	7 (1.1)	0.339
Myocardial infarction	1 (1.2)	2 (0.3)	0.232
Major vascular complication	1 (1.2)	32 (4.9)	0.121
Infectious complication	5 (6.0)	45 (7.0)	0.741
Permanent pacemaker implantation	17 (20.5)	135 (21.0)	0.914

Transaxillary compared with transcarotid access for TAVR: a propensity-matched comparison from a French multicentre registry

Outcomes	Transcarotid TAVR (n=201)	Transaxillary TAVR (n=113)	Effect size (95% CI)	<i>p</i> -value
Procedural and in-hospital outcomes				
Device success	192 (95.4)	108 (95.5)	0.95 (0.28-3.16)*	0.93
Acute kidney injury 2-3	27 (13.5)	25 (22.5)	1.72 (0.90-3.27)*	0.10
New pacemaker implantation	38 (19.0)	22 (19.5)	0.99 (0.53-1.81)*	0.97
LT or major bleeding	11 (5.7)	4 (3.6)	0.62 (0.18-2.13)*	0.44
Minor bleeding	19 (9.3)	3 (2.7)	0.26 (0.07-0.92)*	0.035
Major vascular access complications	17 (8.5)	10 (9.0)	1.20 (0.48-2.96)*	0.70
Minor vascular access complications	14 (7.0)	3 (2.7)	0.31 (0.08-1.15)*	0.078
Main access haematoma	21 (10.3)	4 (3.6)	0.29 (0.09-0.92)*	0.034
Hospital stay, days, median (IQR)	8 (6-11)	9 (6-13)	0.84 (0.67-1.05)**	0.12
AR grade ≥II	19 (9.3)	6 (5.4)	0.54 (0.20-1.45)*	0.22
Transprosthetic maximal velocity, m/s, mean (SD)	2.1 (0.8)	2.2 (0.9)	0.10 (-0.08-0.29)#	0.25
1-month and 1-year outcomes				
1-month mortality	9 (4.5)	6 (5.5)	1.23 (0.40-3.70)*	0.71
1-month clinical efficacy	173 (85.9)	100 (88.6)	1.22 (0.57-2.58)*	0.61
1-month safety	172 (85.8)	100 (88.6)	1.38 (0.64-2.94)*	0.40
1-month stroke/TIA	14 (6.8)	4 (3.2)	0.52 (0.14-1.84)*	0.31
1-year all-cause mortality, n (KM, %)	23 (19.1)	16 (16.1)	0.83 (0.41-1.70)§	0.62



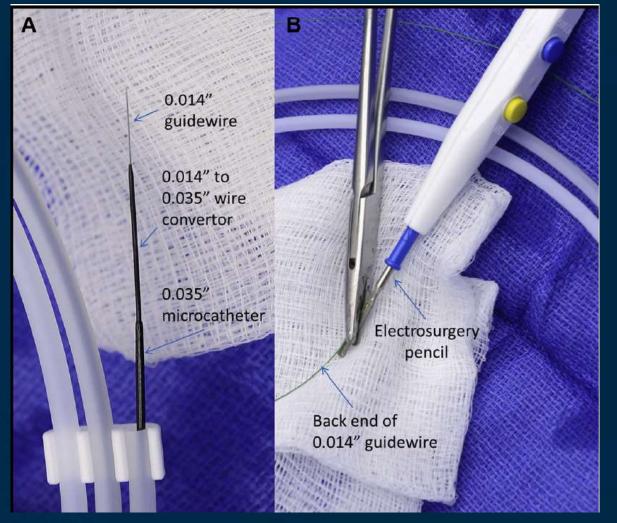
Transcaval access

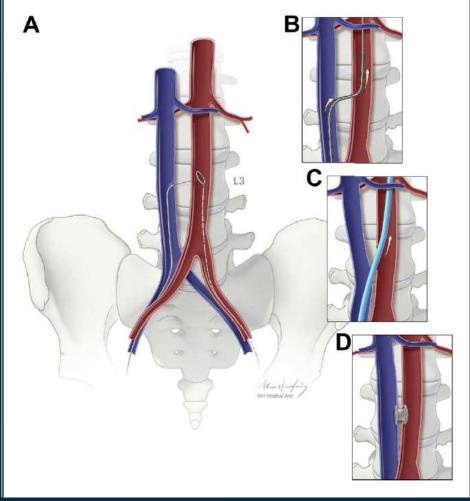


Transcaval access

- Greenbaum at al. described the first successful human experience in 2014.
- Pre-procedure contrast CT to identify an ideal target site for crossing from the inferior vena cava to the abdominal aorta
 - Infra-renal aorta
 - Avoid any significant aortic wall calcification or interfering abdominal structures
- Caval-aortic crossing
 - Right femoral vein access for caval-aortic crossing and transcaval heart valve delivery.
- Aorto-caval tract closing
 - Occluder devices approved for PDA or intracardiac defect closure

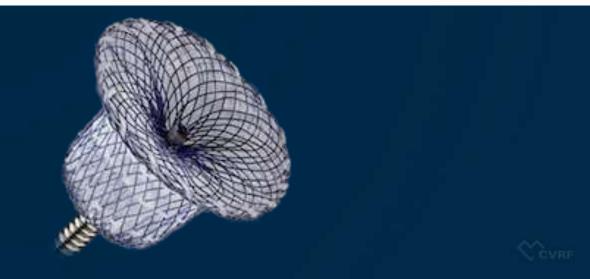








Sheath	> 18Fr ID fully expanded	<= 18Fr ID fully expanded
Aorto-caval tract length ≤7 mm	8 mm Amplatzer Muscular VSD Occluder	6 mm Amplatzer Muscular VSD Occluder
Aorto-caval tract length >7 mm	10/8 Amplatzer Duct Occluder generation 1	8/6 Amplatzer Duct Occluder generation 1



Transcaval Access and Closure for Transcatheter Aortic Valve Replacement

A Prospective Investigation

TABLE 3 Outcomes Through 30 Days (N = 100)	
Death within 30 days	7 Cardiovascular 1 Noncardiovascular
Stroke	5 Ischemic
Myocardial infarction	2 Peri-procedural
Contrast nephropathy requiring dialysis	2
Acute kidney injury classification	Grade 0 (n = 87) Grade 1 (n = 9) Grade 2 (n = 0) Grade 3 (n = 3)
Thrombocytopenia $<$ 50 \times 10 3 / μl	5 (4 with patent fistula)
Non-access-related bleeding (e.g., gastrointestinal)	15
Transfusion during TAVR/after TAVR/during or after TAVR	14/30/35
Transfusion units among those transfused (median) ($n = 35/100$)	2.0 (2.0, 4.0)
Follow-up CT scan before discharge	87
Post-TAVR length of stay (days), median (quartiles)	4 (2-6)
Post-TAVR intensive care unit length of stay (days), median (quartiles)	1 (1-3)
VARC-2 composite early safety*	75

Transcaval Access and Closure for Transcatheter Aortic Valve Replacement

A Prospective Investigation

New	Transcaval-Related	Count (n = 99)	Details
Bleeding			
Life- threatening	Yes	6	5 RPH (large [n = 2]; moderate [n = 2]; small [n = 1]) 1 Covered aortic and iliac stents, no RPH
	Indeterminate	1	1 Thoracic aortic dissection from Corevalve Evolut R
Vascular compl	ications		
Major	Yes	12	 9 RPH (any size) + major or life-threatening bleeding 1 Covered stent for extravasation 1 Primary closure with covered aortic and femoral artery stents 1 Noncovered aortic stent for local dissection
	Indeterminate	1	1 Thoracic aortic dissection from Corevalve Evolut R

Transcaval Versus Transaxillary TAVR in Contemporary Practice: A Propensity-Weighted Analysis

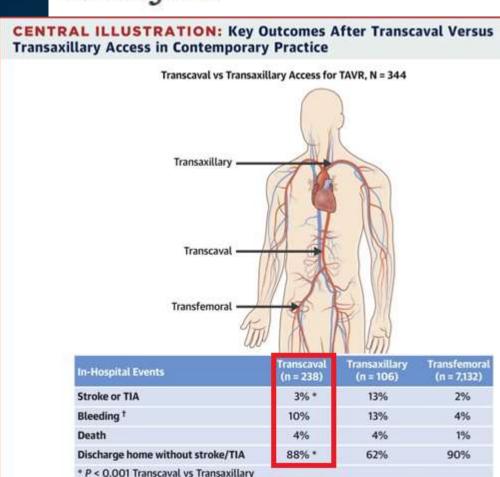


TABLE 1	Numbers of Patients Selected to Undergo Nonfemoral
TAVR at 8	8 Individual Sites, by Access Route

Site	Nonfemoral	Transcaval	Transaxillary	Carotid	Thoracic
1	34	34 (100.0)		-	-
2	57	5 (8.8)	48 (84.2)	1 (1.8)	3 (5.3)
3	109	80 (73.4)	7 (6.4)	20 (18.3)	2 (1.8)
4	63	63 (100.0)	21—2	-	(: — ()
5	38	15 (39.5)	_	-	23 (60.5)
6	46	28 (60.9)	14 (30.4)	4 (8.7)	120
7	32	4 (12.5)	18 (56.3)	4 (12.5)	6 (18.8)
8	28	9 (32.1)	19 (67.9)	-	-
All	407	238 (58.5)	106 (26.0)	29 (7.1)	34 (8.4)

Values are n or n (%).

TAVR = transcatheter aortic valve replacement.

J Am Coll Cardiol Intv. 2022;15(9):965–975.

† Major or life-threatening bleeding (VARC-3 ≥ Type 2)

Transcaval access experience in VGHTC



Case 1

- Age: 58
- Gender: male
- Past medical history:
 - Type 2 diabetes mellitus
 - CAD s/p PCI, s/p CABG(LIMA to LAD, SVG to OM, SVG to RCA)
- TTE:
 - Trans-AV peak/mean pressure gradient: 42/21mmHg
 - An aortic valve area (AVA) of 0.7 cm2
 - The LVEF is 28%
- EuroScore II: 22.2%



Options of access sites

Transfemoral access

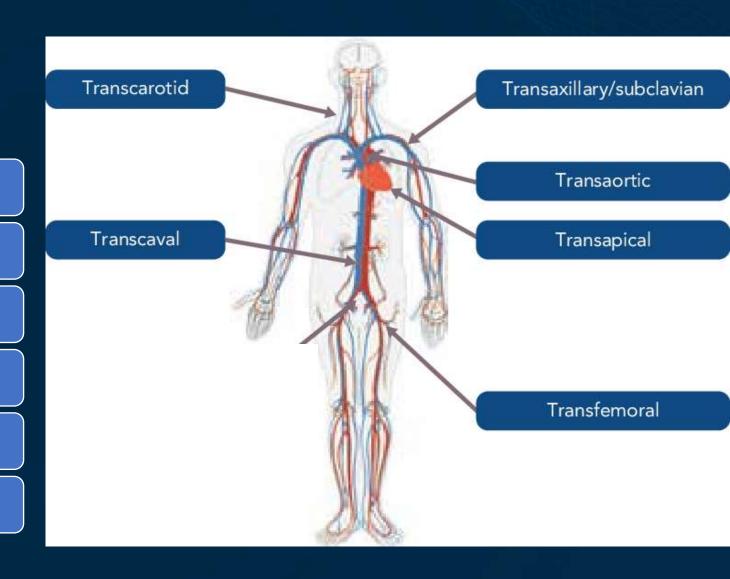
Transaxillary access

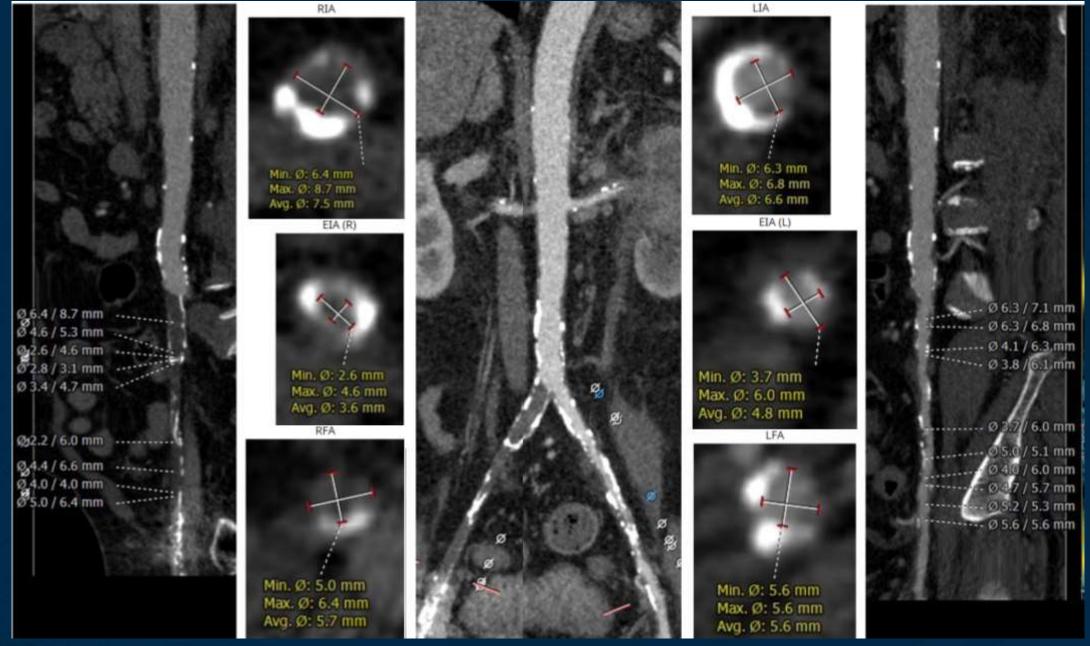
Transcarotid access

Direct aortic access

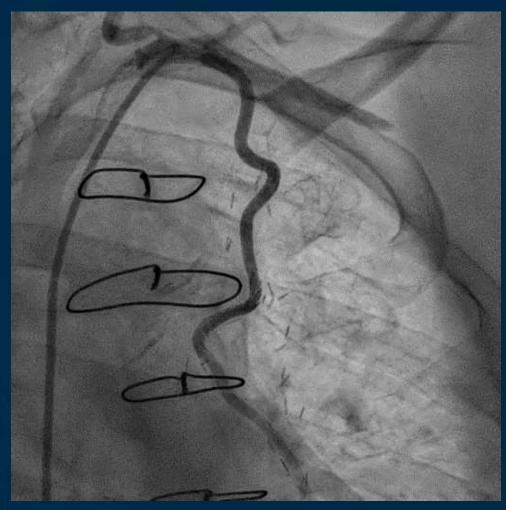
Transapical access

Transcaval access

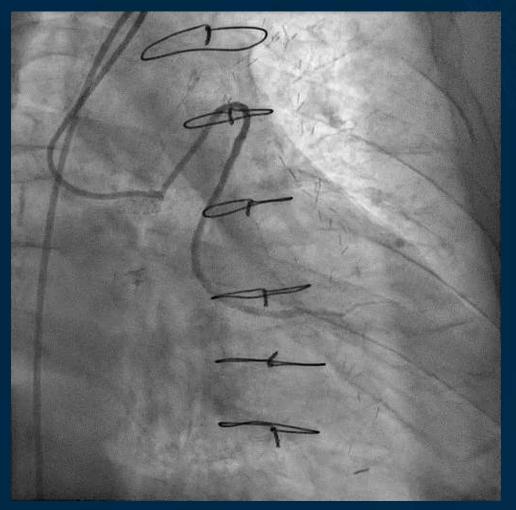




Coronary angiography



Patent LIMA to LAD



Patent AO-SVG-OM1 graft

Carotid ultrasonography

- Heterogenous, irregular surface, plaques caused eccentric 50% diameter stenosis over the left CCA bifurcation.
- Heterogenous, smooth surface, plaques caused eccentric 45% diameter stenosis over the right CCA bifurcation.

Options of access sites

Transfemoral access

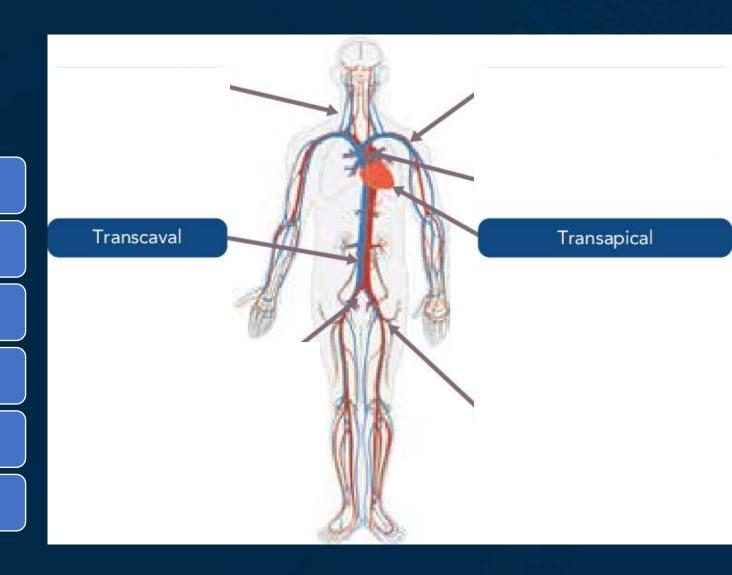
Transaxillary access

Transcarotid access

Direct aortic access

Transapical access

Transcaval access



Options of access sites

Transfemoral access

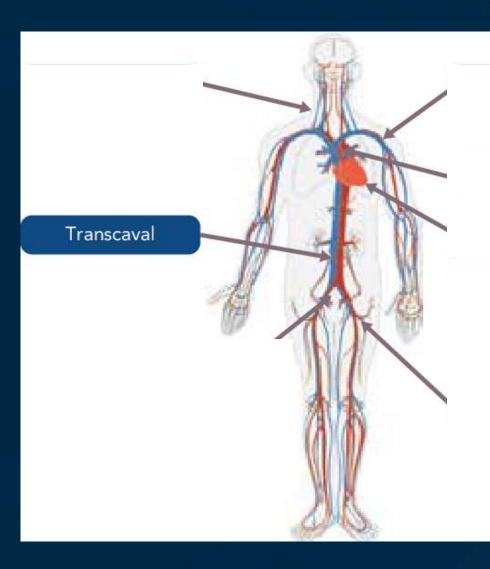
Transaxillary access

Transcarotid access

Direct aortic access

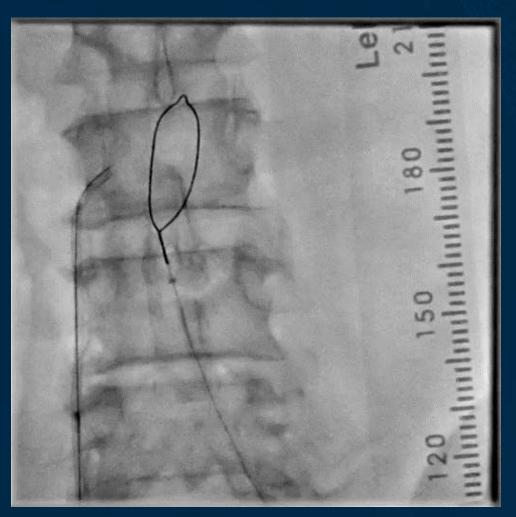
Transapical access

Transcaval access



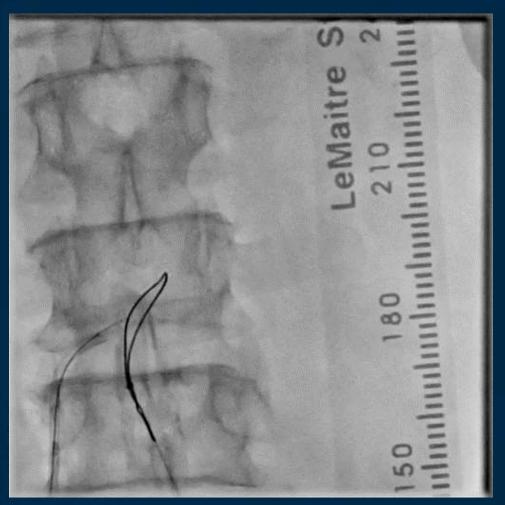


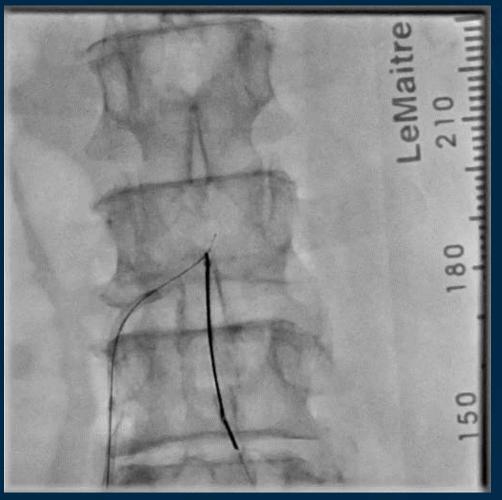
Amplatz goose neck snare



Astato 20 wire supported with a 0.035 CXI







Cutting mode of the electrosurgery pencil with energy set to 40 W

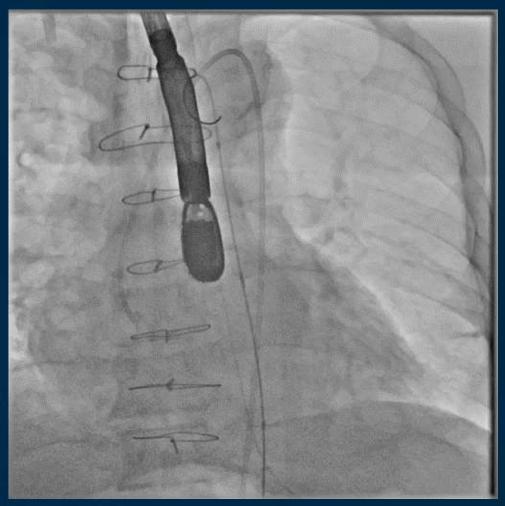




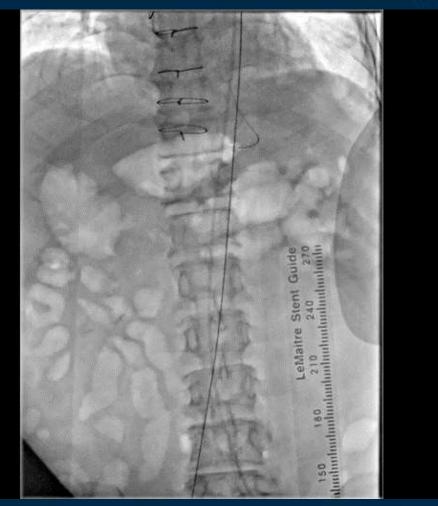


0.035 CXI across the aorta





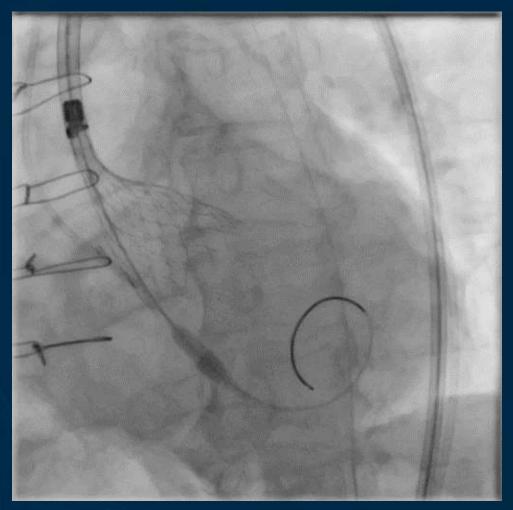
Lunderquist extra-stiff guidewire



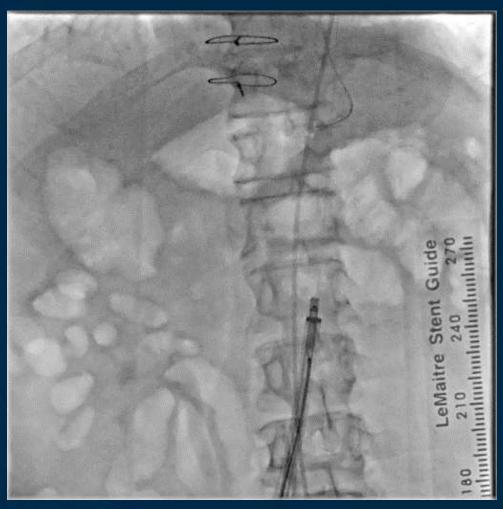
18 Fr dryseal sheath



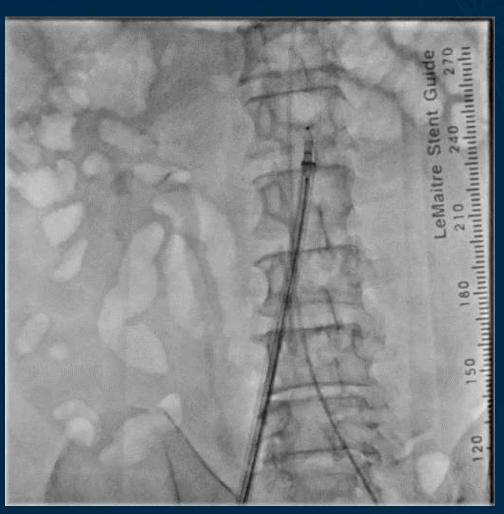
CoreValve Evolut R 29 mm



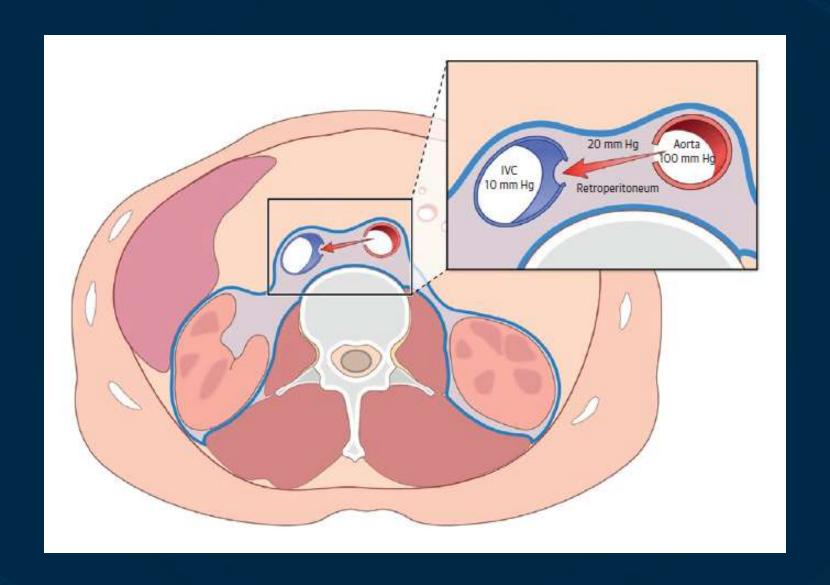
Valve delivered with a 14 Fr inline sheath

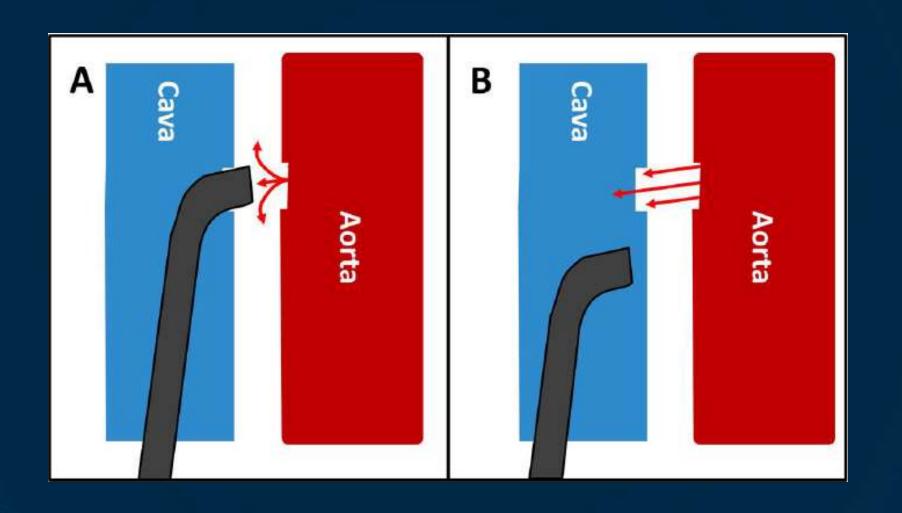


10/8 Amplatzer Duct Occluder I mounted on an Agilis SML curl deflectable sheath



Withdraw the TAVI introducer sheath









Horizontal deflection of the device









Case 2

- Age: 87
- Gender: male
- Past medical history:
 - ESRD under regular hemodialysis
 - Hypertension
- Chief complaint: chest tightness and dyspnea since last month
- TTE:
 - Mean aortic pressure gradient of 41 mmHg
 - An aortic valve area (AVA) of 0.86 cm2
- STS score: 20.3%









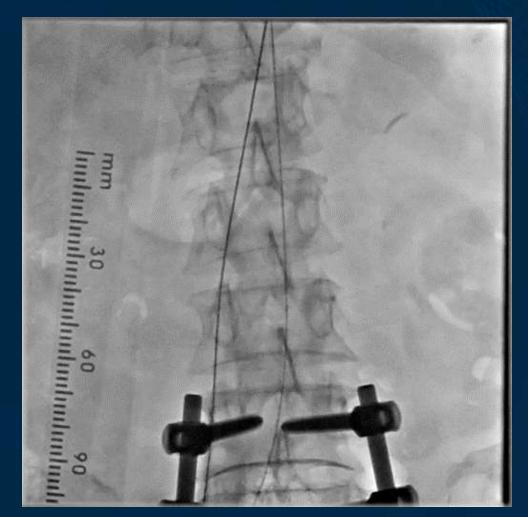




NC emerge 3.0 x 20 mm PTCA balloon

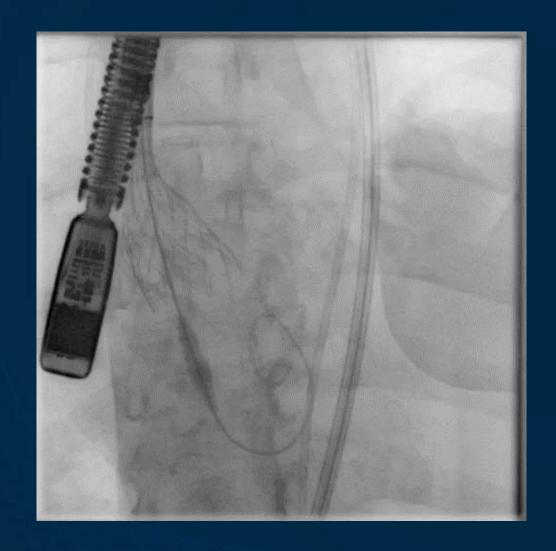


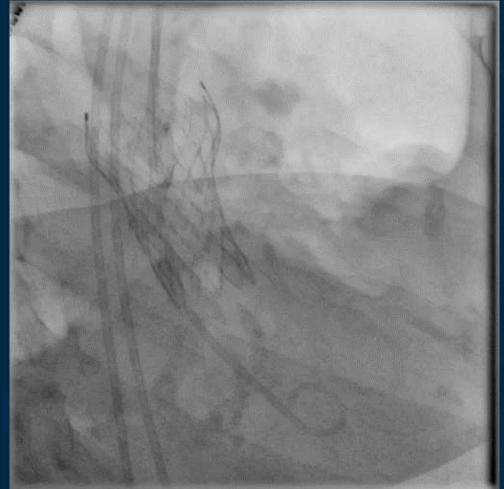
Lunderquist extra-stiff guidewire + DMS-1 14 Fr dilator



18 Fr dryseal sheath

CoreValve Evolut R 26 mm





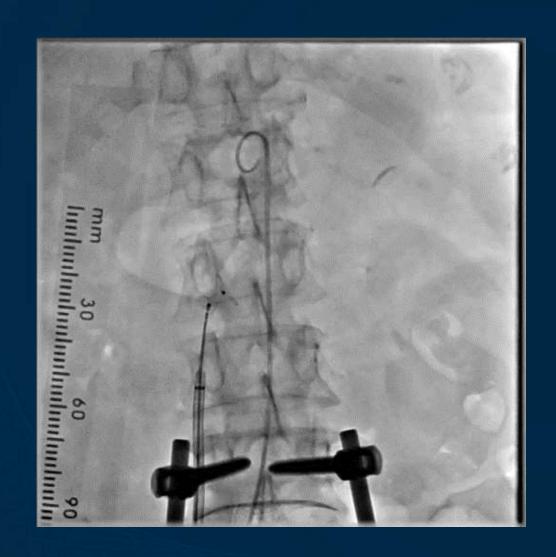




Agilis SML curl deflectable sheath



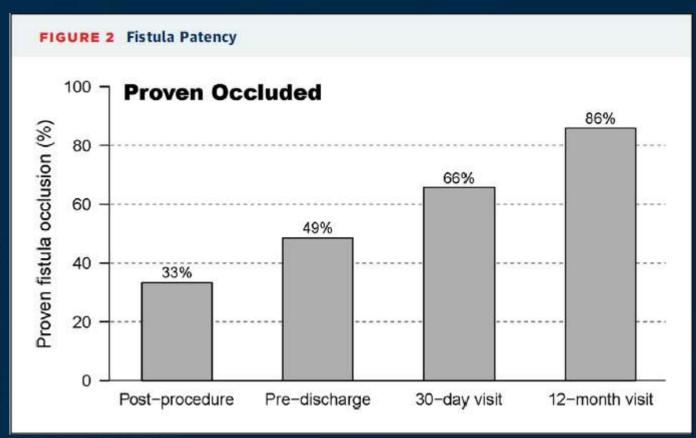
10/8 Amplatzer Duct Occluder I





The Fate of Transcaval Access Tracts

12-Month Results of the Prospective NHLBI Transcaval Transcatheter Aortic Valve Replacement Study



Fistula patency was not associated with overall survival (p = 0.37), nor with heart failure admissions (15% if patent vs. 23% if occluded; p = 0.30).

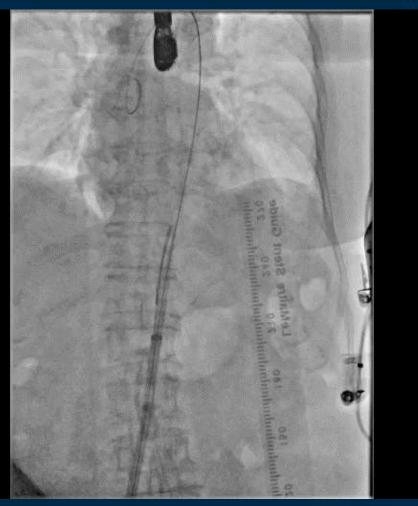
Case 3

- Age: 83
- Gender: female
- Past medical history:
 - Hypertension
 - Chronic kidney disease, stage 3
 - Asthma
- Chief complaint: chest tightness and dyspnea for months
- TTE:
 - Mean aortic pressure gradient of 83 mmHg
 - An aortic valve area (AVA) of 0.76 cm2
- STS score: 12.4%





Aortography



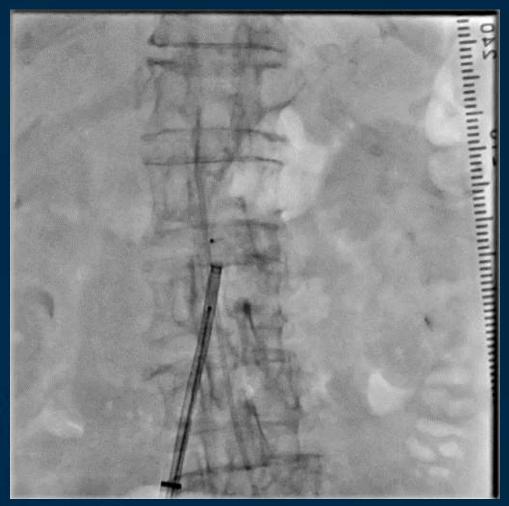
18 Fr dryseal sheath

CoreValve Evolut R 26 mm











10/8 Amplatzer Duct Occluder I



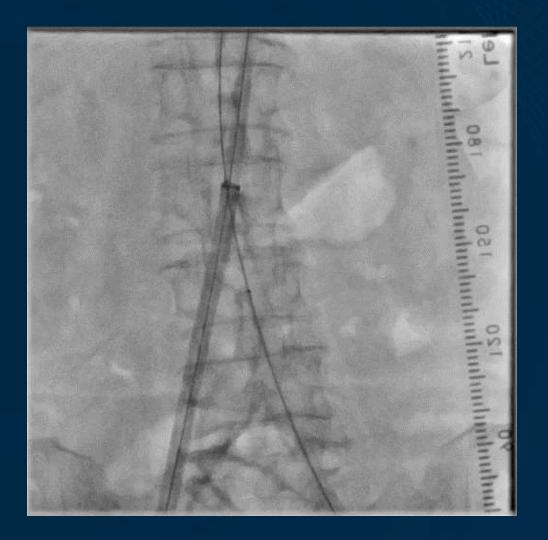






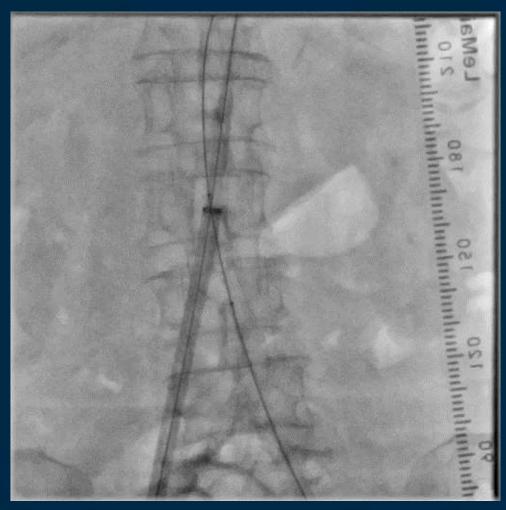
- Immediate hypotension, SBP dropped to 20 mmHg
- CVP rose to 40 mmHg
- c/w acute left to right shunting, LV tamponade by RV





NC emerge 6.0 x 12 mm





Tyshak II 20 x 40 mm balloon catheter

- SBP recovered to 100 mmHg
- CVP dropped back to 10 mmHg







ST. JUDE 12 Fr sheath from RFA





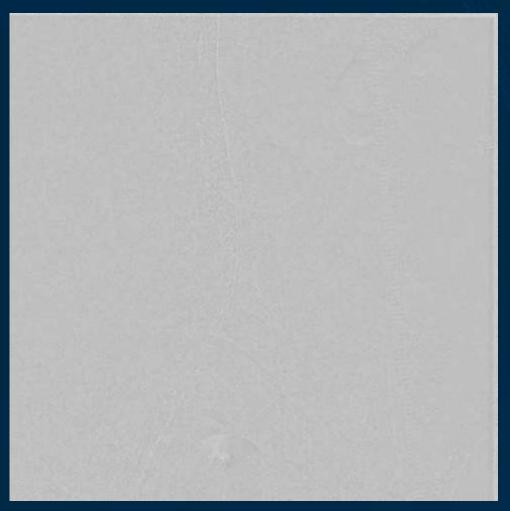
Begraft 12 x 59 mm stent graft



Begraft 14 x 49 mm stent graft



Post-occlusion AOG



Post-occlusion IVC Angio

DATE	NA	K	CL	CA	BUN	CREAT
1100721	142	3.8		8.2	20	0.94
1100723	141	3.8		8.1	17	0.98
1100726	143	3.4			27	0.83
1100804	142	3.6			33	0.94
1100926	142	4.3	TAVI	8.8	25	1.20
1100928					14	0.96
1100929	137	4.6			41	1.37
1101001	144	4.0			28	1.17
1101001						
1101012	142	3.5			68	1.53
1101013	142	3.4			49	1.17
1101014					41	1.23
1101015	139	2.6			25	1.06
1110420		4.1	108			1.34
1110713						1.76
1111019						1.39
1120412						1.27

Conclusion

- Transfemoral approaches are precluded in about 5% of TAVI patients
- Transaxillary and transcarotid accesses have been associated to similar outcomes to the transfemoral TAVI
- Trans-caval TAVI should be considered when all peripheral accesses are precluded
 - Completely percutaneous, early patient mobilization
 - Femoral-like ergonomics, femoral-like radiation
 - Important access for TEVAR, impella, BASILICA
- Hemodynamic compromise caused by extravasation or by intolerable aorto-caval fistula with right ventricular failure should be treated promptly
 - Aortic balloon tamponade
 - Covered stent implantation

