New York Transcatheter Valves 2019

PATIENT FOCUSED EVIDENCE-BASED APPROACH

Alternate Vascular Access of TAVR

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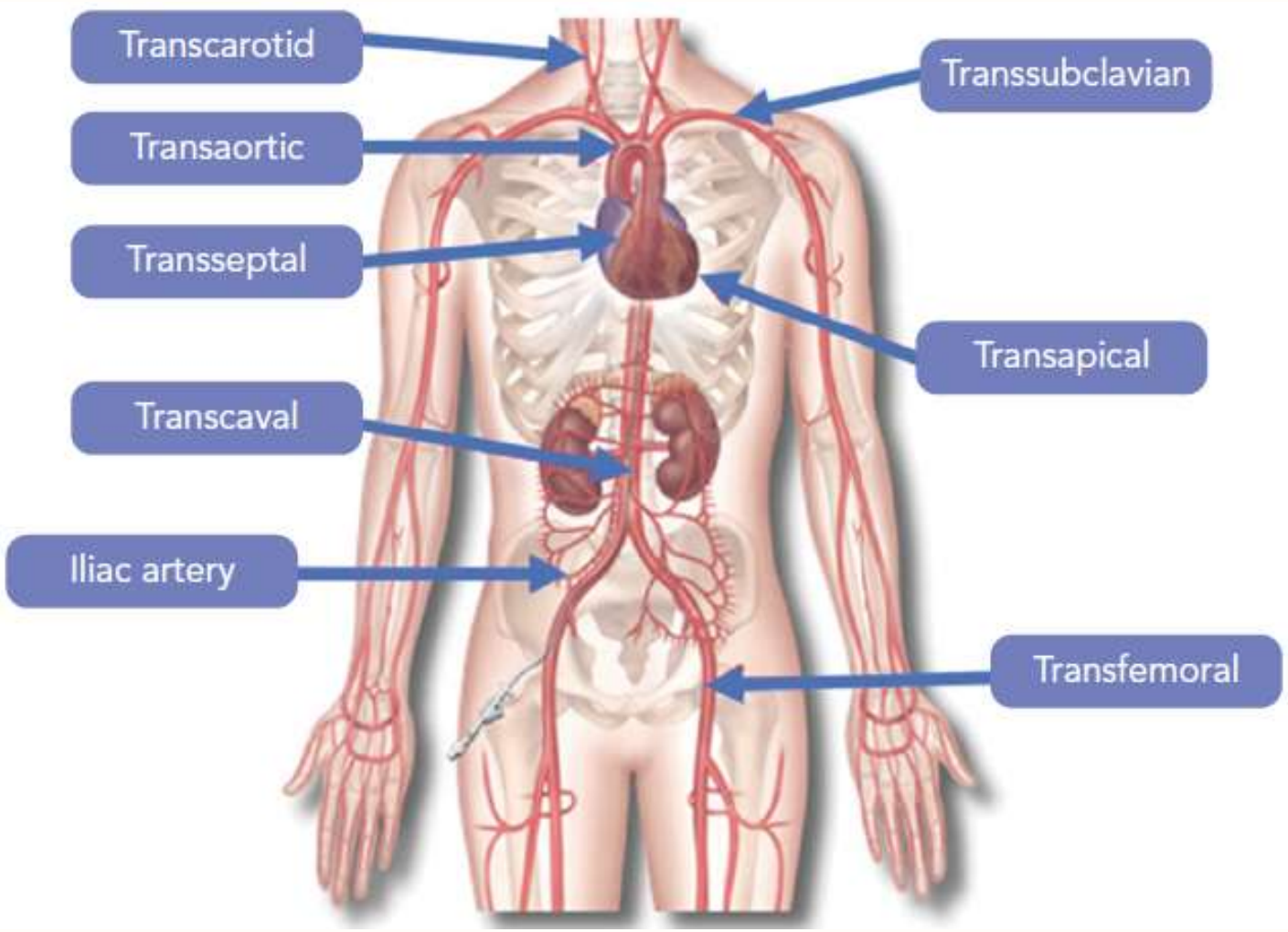
REQUIRED

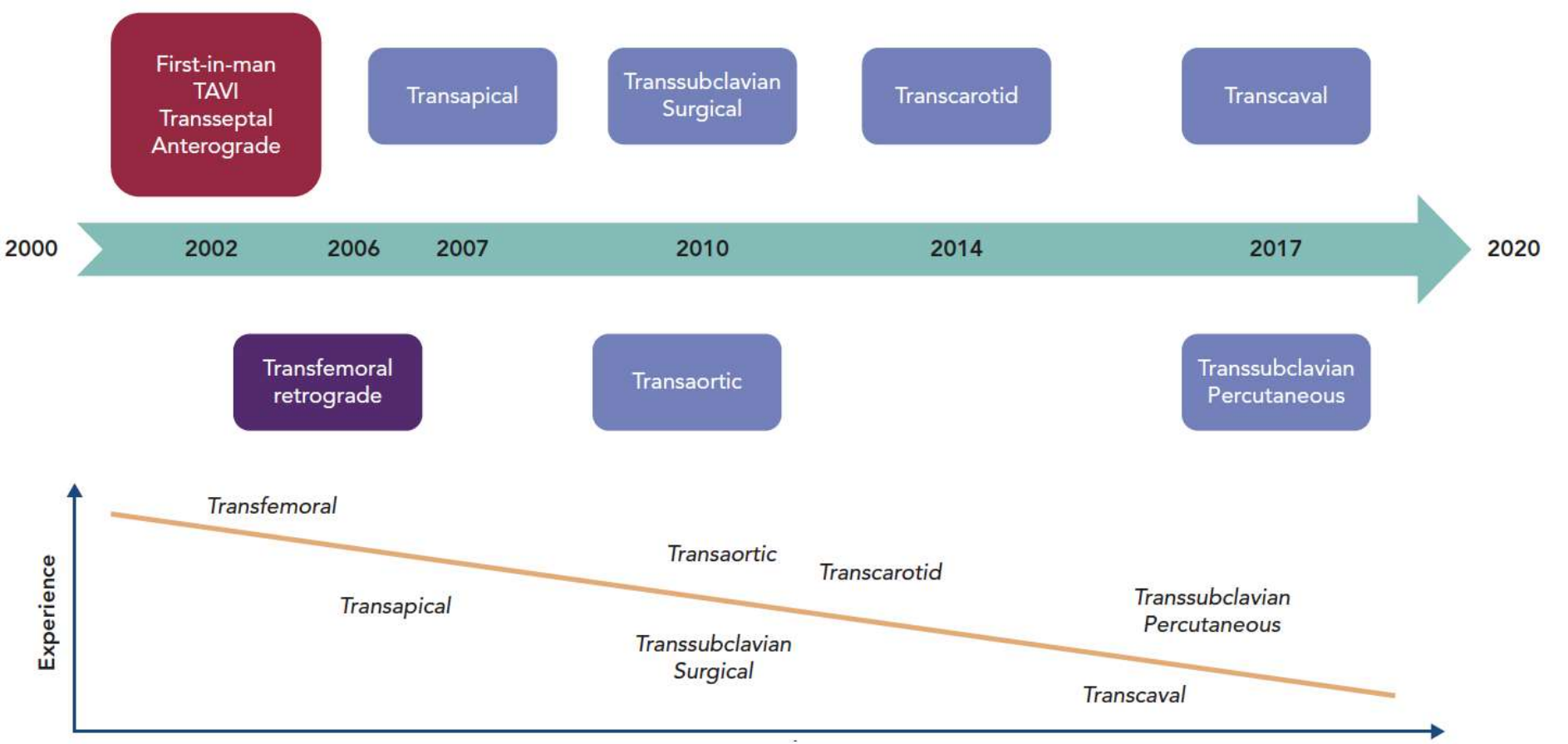
Gian Paolo Ussia , MD

I have no relevant financial relationships

Alternate Access for TAVI



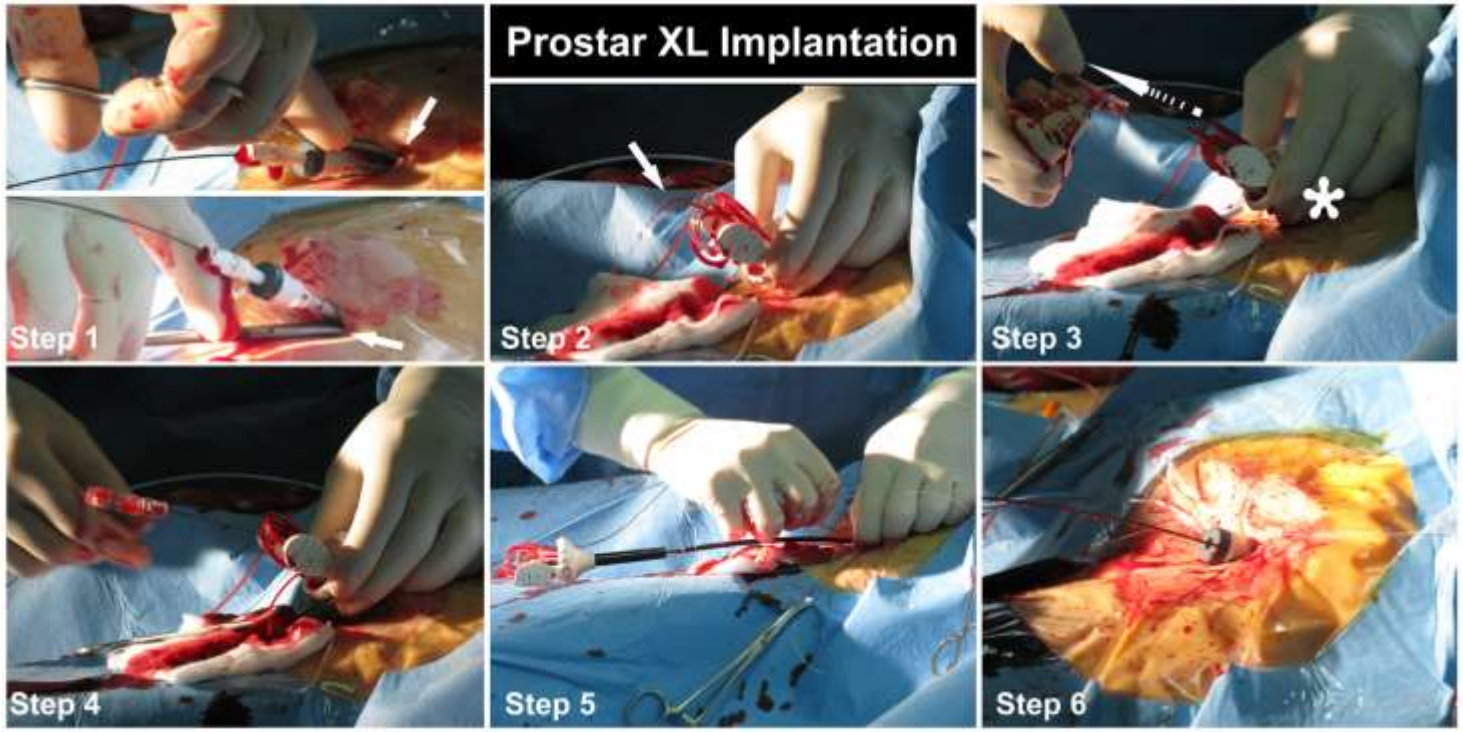
Evolution in TAVI Access



TAVI = transcatheter aortic valve implantation.

Overtchouck P, Modine T. Interv Cardiol Rev 2018;13:145-150

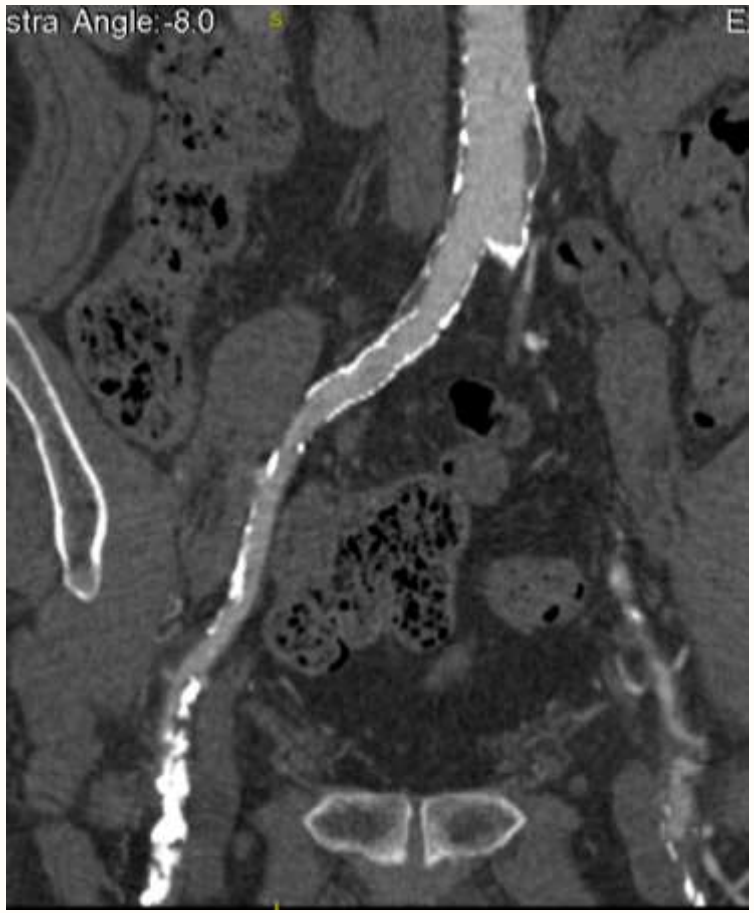
Transfemoral access

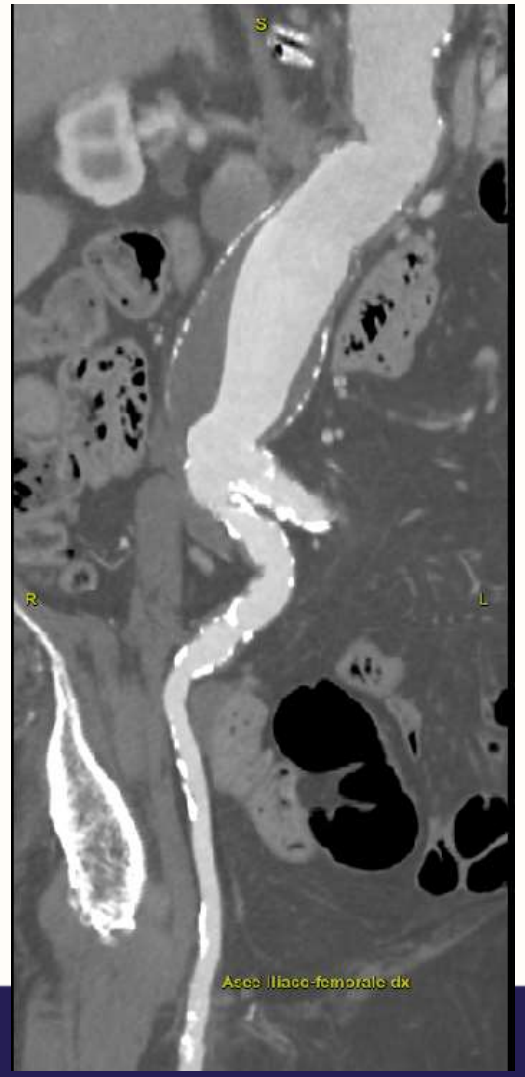


- Percutaneous approach
  - Prostar XL 10F
  - Perclose/Proglide
  - Perfect femoral artery puncture:
  - Common femoral artery
  - Central vessel (fluoro guided, echo guided)
  - Wire placement from the contra-lateral for managing complication
    - balloon artery occlusion
    - covered stent placement

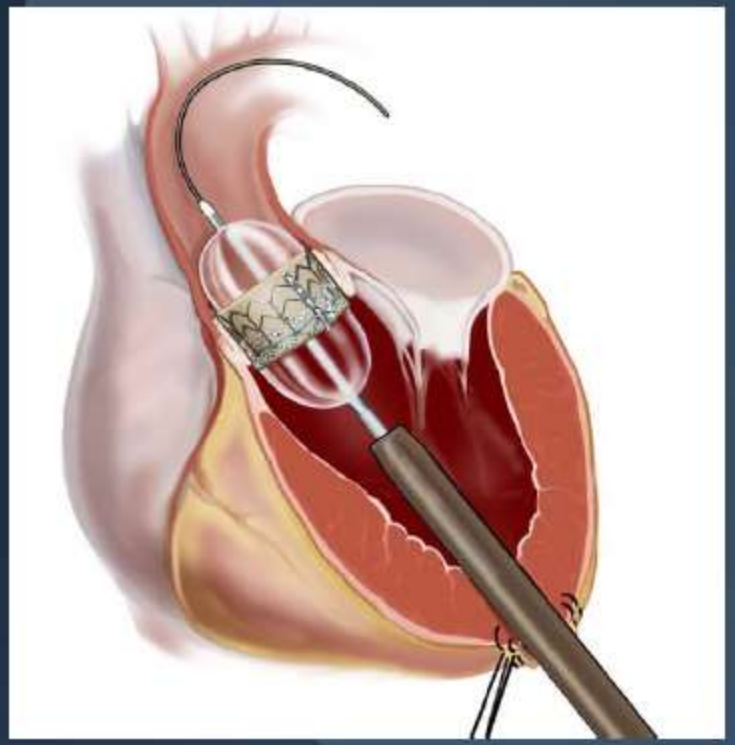
Difficult transfemoral tavr

The 15% of patients were unsuitable for Transfemoral access



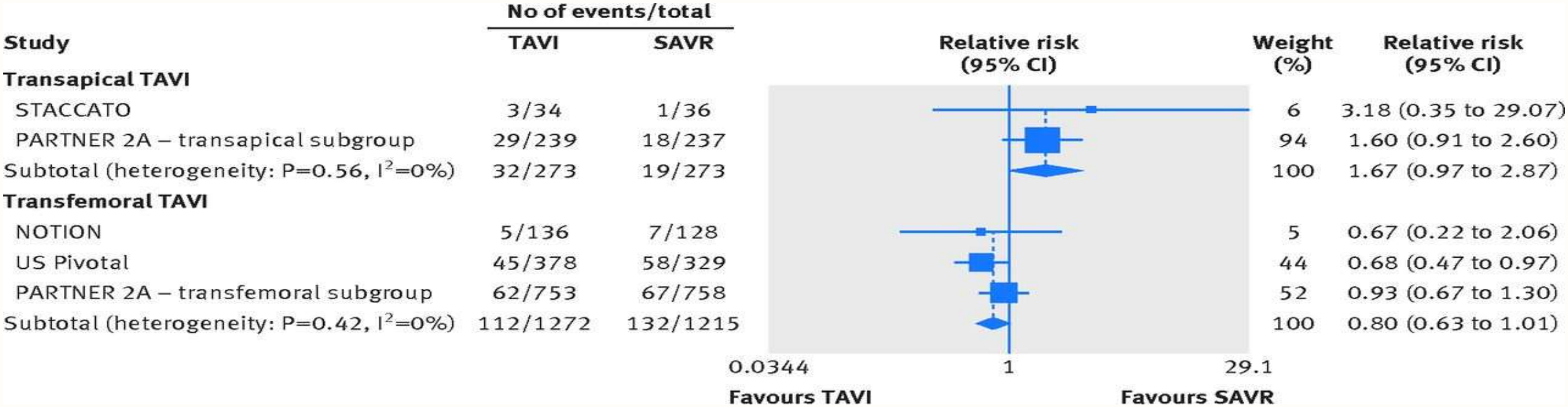


Apical access



Transapical access

Fig 4 Forest plot for relative risk of stroke at longest follow-up for transcatheter aortic valve implantation (TAVI) compared with surgical aortic valve replacement (SAVR) for severe aortic stenosis, by valve approach.



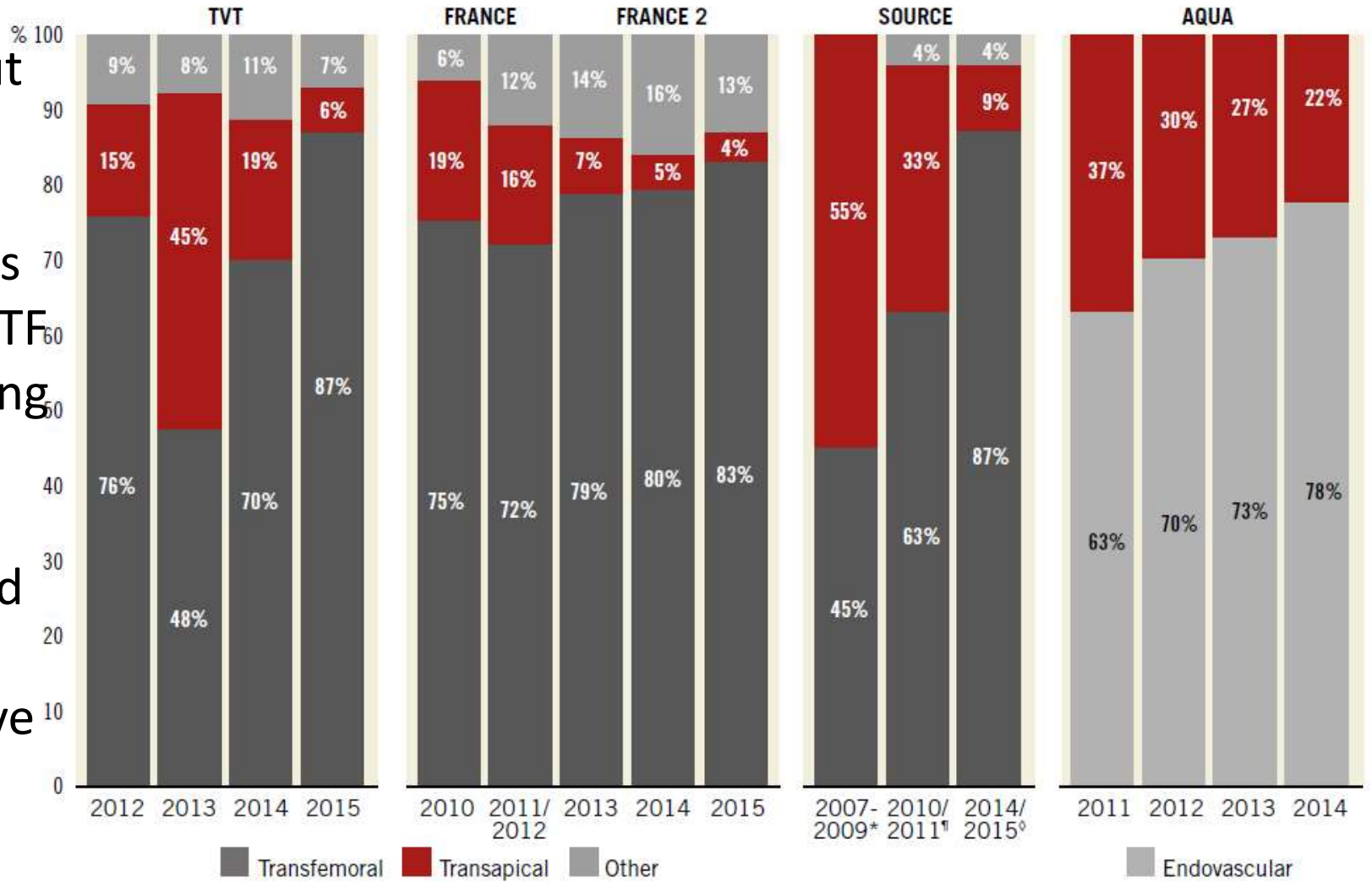
Reed A Siemieniuk et al. BMJ 2016;354:bmj.i5130

Current state of alternative access for transcatheter aortic valve implantation

Jonas Lanz[1], MD, MSc; Adam Greenbaum[2], MD; Thomas Pilgrim[1], MD; Giuseppe Tarantini[3], MD, PhD; Stephan Windecker[1]*, MD

EuroIntervention 2018;14:AB40-AB52

- The first case of TA TAVI without cardiopulmonary bypass was performed in 2005
- TA approach rapidly emerged as the alternative access route to TF
- Its use has clearly declined owing to the high proportion of patients amenable to a TF approach, complications related to the TA access site, and the advent of a variety of alternative access strategies



Trans-subclavian/axillary Access

Safety and efficacy of the subclavian approach for transcatheter aortic valve implantation with the CoreValve Revalving System

Anna S Petronio, Marco De Carlo, Francesco Bedogni, Antonio Marzocchi, Silvio Klugmann, Francesco Maisano, Angelo Ramondo, Gian Paolo Ussia, Federica Ettori, Arnaldo Poli, Nedy Brambilla, Francesco Saia, Federico De Marco, and Antonio Colombo

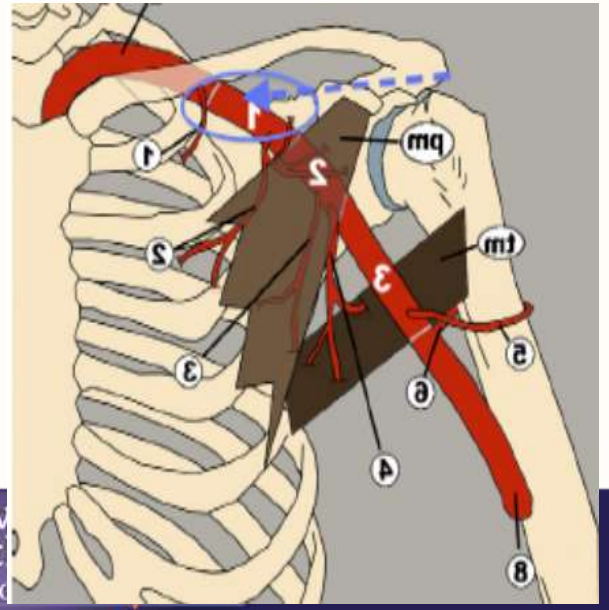
CIRCULATIONAHA/2009/930453

Table 5. Actuarial freedom from events at 6 months.

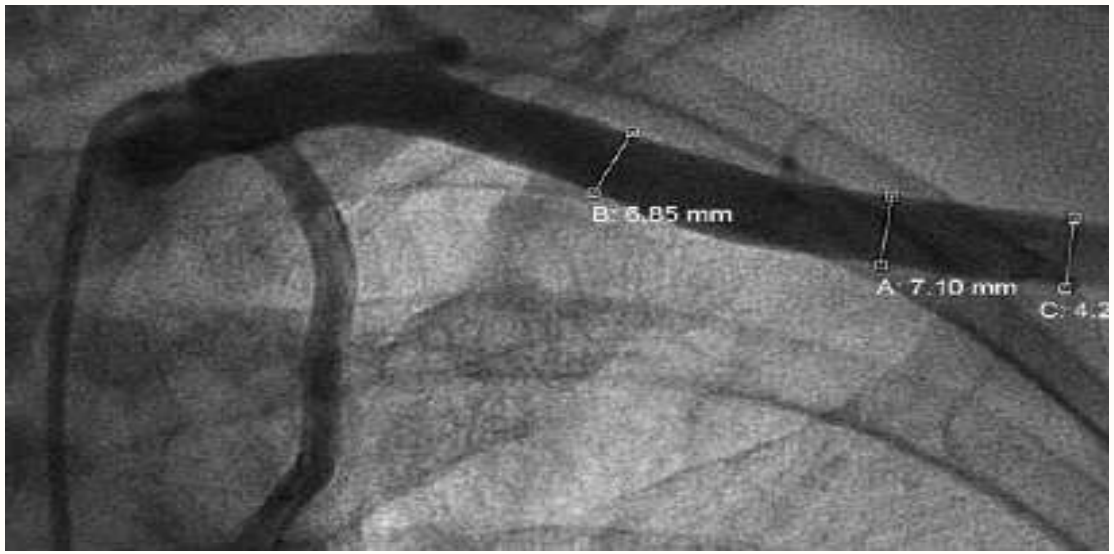
	Total (n=514)	Femoral (n=460)	Subclavian (n=54)	P
Death, %	89.1±1.5	88.6±1.6	93.3±3.8	>0.2
Cardiac death, %	95.8±0.9	95.5±1.0	97.9±2.1	>0.2
MACCEs, %	86.3±1.6	85.5±1.7	93.9±3.4	>0.2
MAVREs, %	87.9±1.5	87.9±1.6	88.5±4.5	>0.2

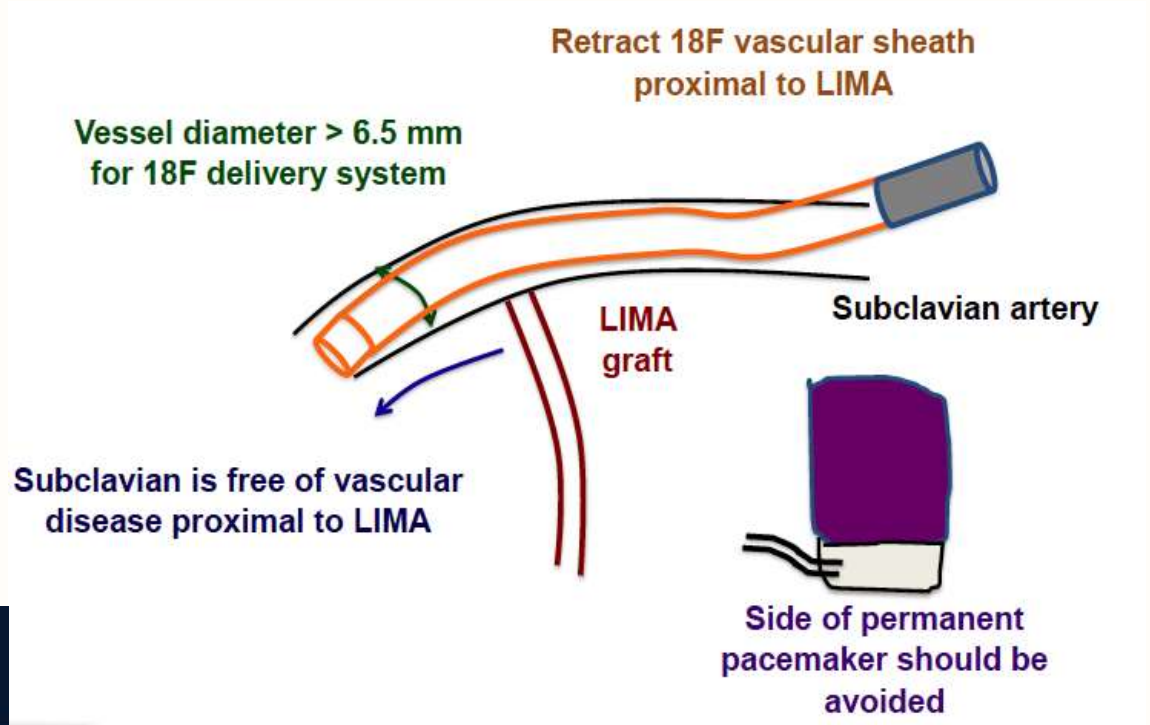
Trans subclavian / axillary access

- The surgical cutdown is performed through an infra clavicular incision
- percutaneous approach have been described with the insertion of a wire in the ipsilateral brachial artery externalised through the femoral artery or contralateral brachial artery for balloon occlusion or covered stent implantation in case of failure of the percutaneous closure system
- 3 to 5.8 % of patients in the FRANCE 2 registry (2010-2012)



Subclavian/axillary Access



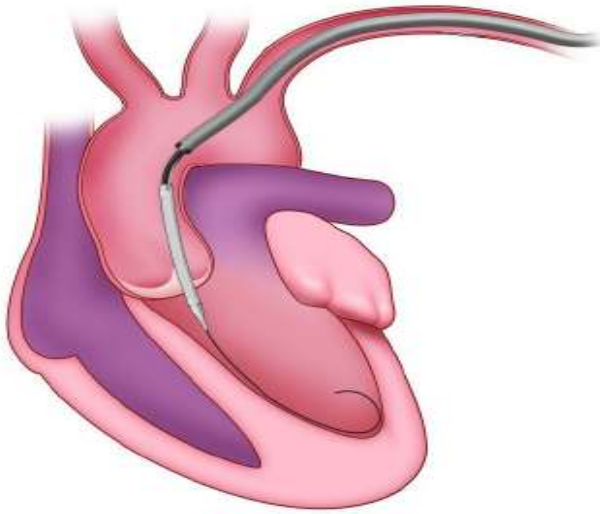


• *Advantages*

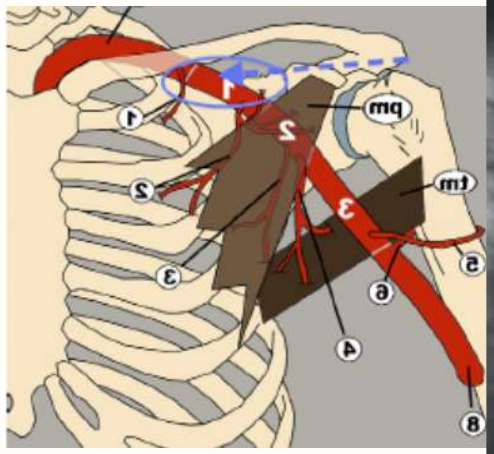
- No groin access, early mobilization
- Shorter route to the valve - more control
- Less manipulation in the arch
- Feasible under local anesthesia in most patients
- Option for concomitant PM implant

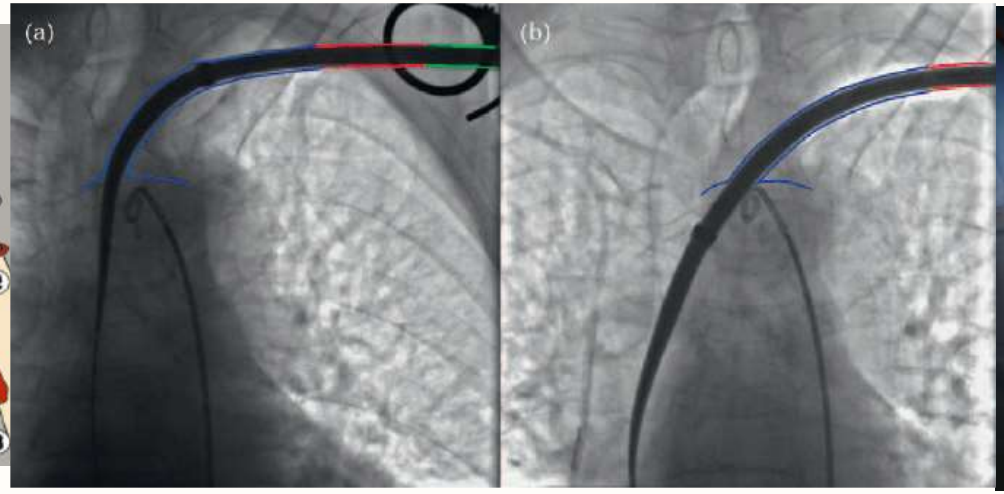
• *Disadvantages*

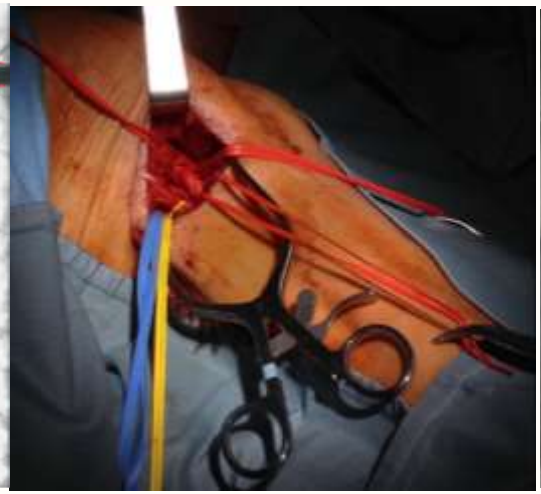
- Requires surgical exposure
- Subclavian artery lesions
- Open LIMA
- Neurologic embolic events
- Potential dramatic vessel complication (intra-thoracique)
- Nerve lesions
- Postoperative hematoma



Distal axillary artery Access





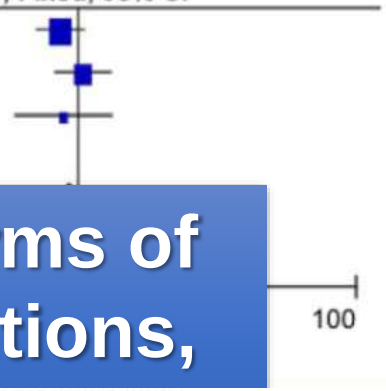


Transubclavian versus transfemoral

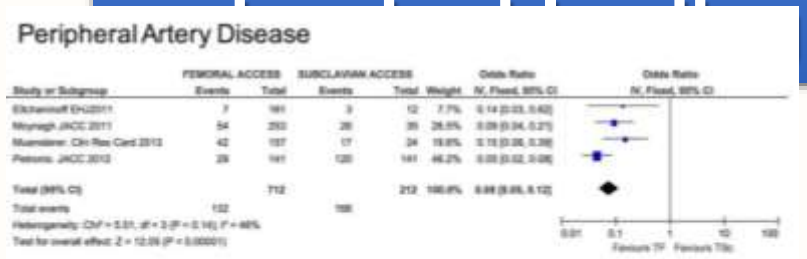
Meta-analysis of six studies including 4,504 patients (3,886 TF and 618 TSc)

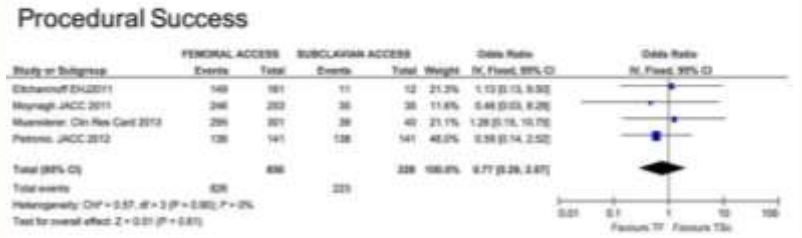
1-YEAR mortality

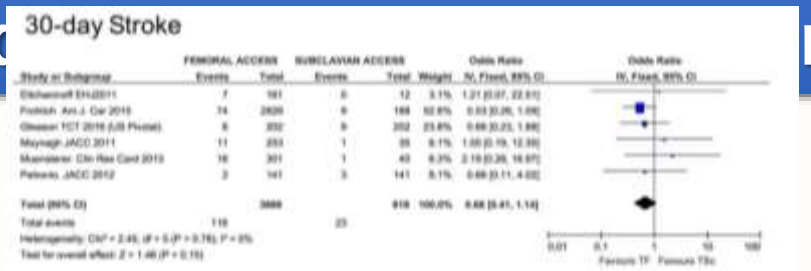
Study or Subgroup	FEMORAL ACCESS Events	Total	SUBCLAVIAN ACCESS Events	Total	Weight	Odds Ratio IV, Fixed, 95% CI
Frohlich Am J. Car 2015	388	2828	33	188	50.7%	0.75 [0.51, 1.10]
Gleason TCT 2016 (US Pivotal)	50	202	47	202	37.1%	1.08 [0.69, 1.71]
Muensterer. Clin Res Card 2013	56	301	9	40	12.2%	0.79 [0.35, 1.75]

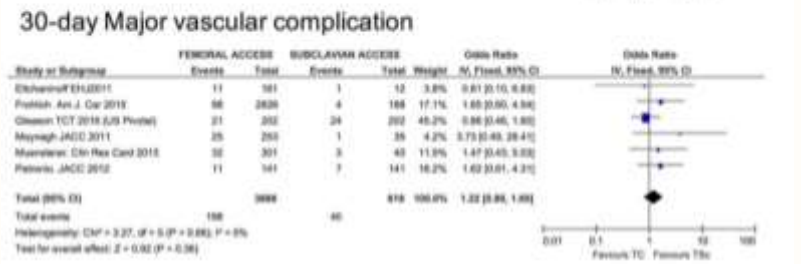


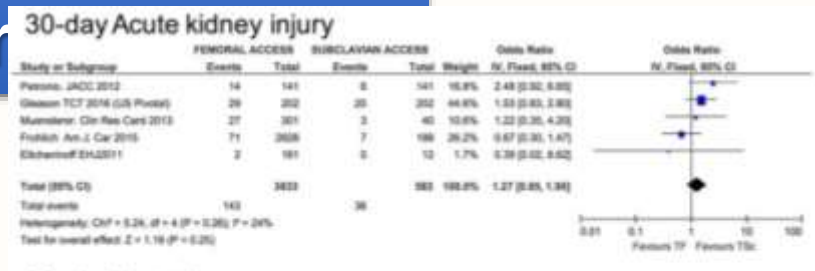
TSc resulted comparable to TF approach in terms of 30-day and 1-year mortality, vascular complications,

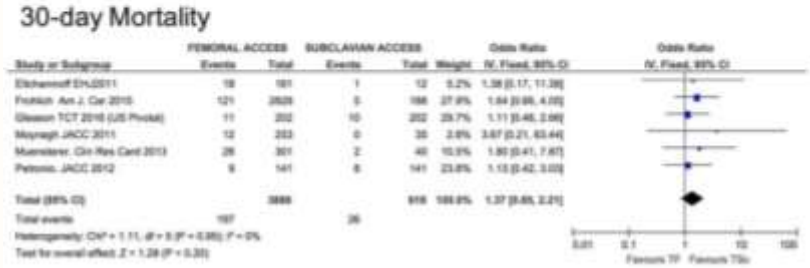










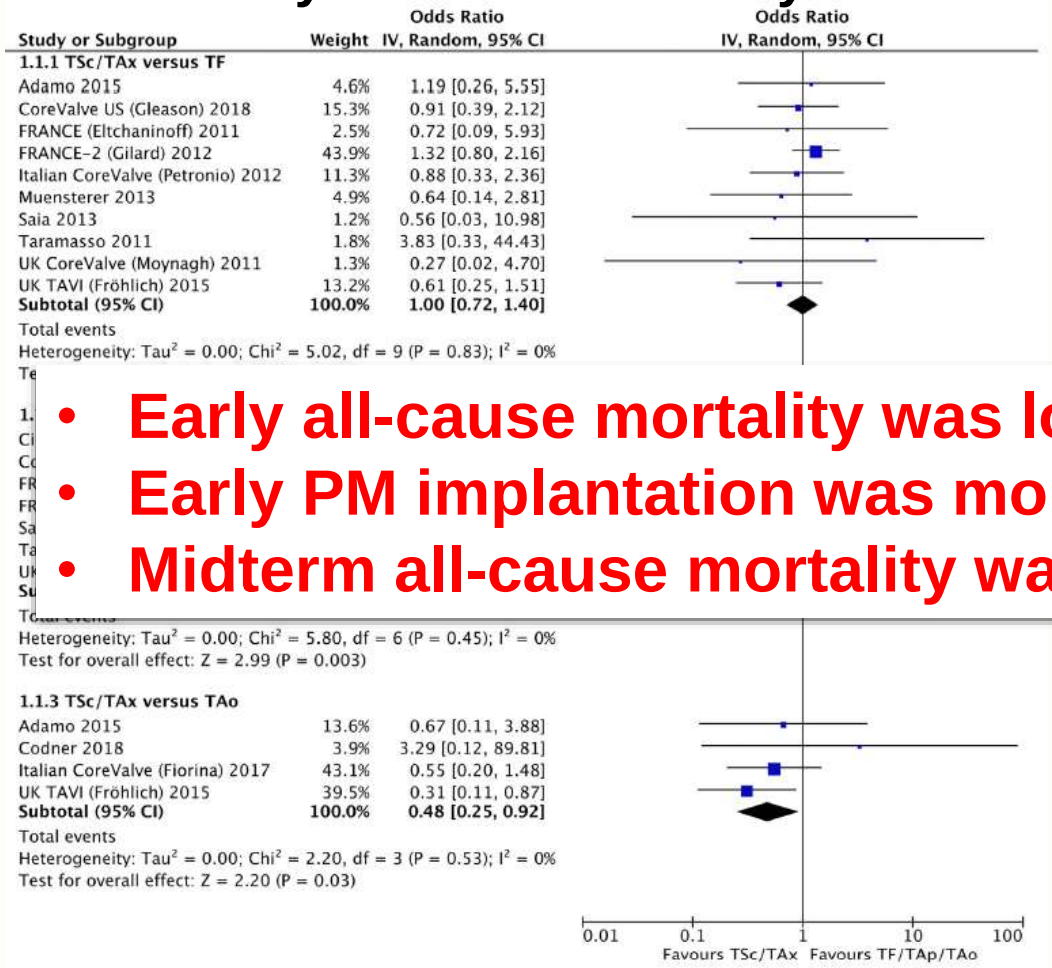


Amat-Santos IJ et al. Catheter Cardiovasc Interv 2018; 92:935–944

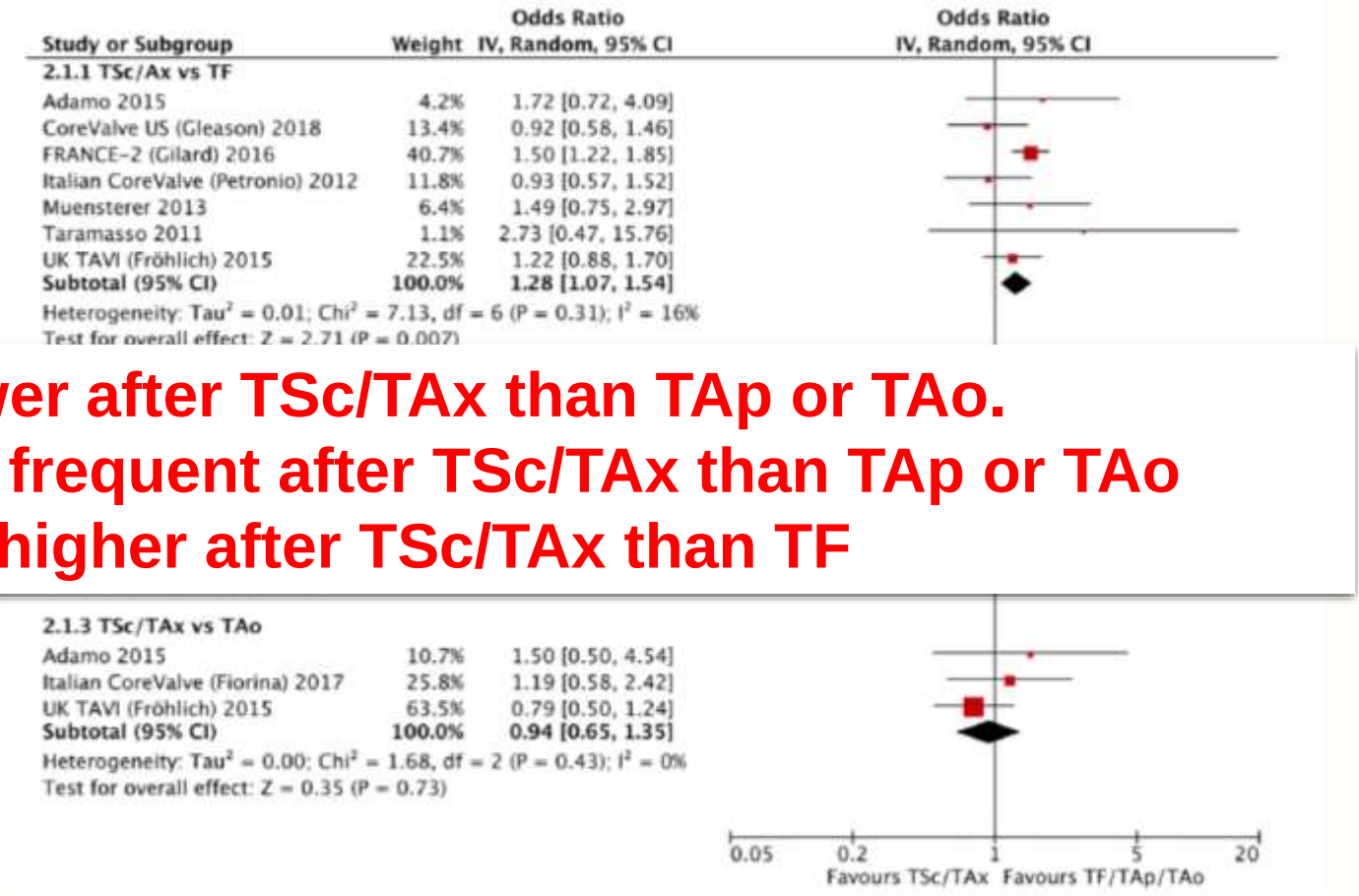
Transubclavian/axillary versus transfemoral, transapical, or transaortic

Meta-analysis of 12 studies including 10528 patients

Early all-cause mortality



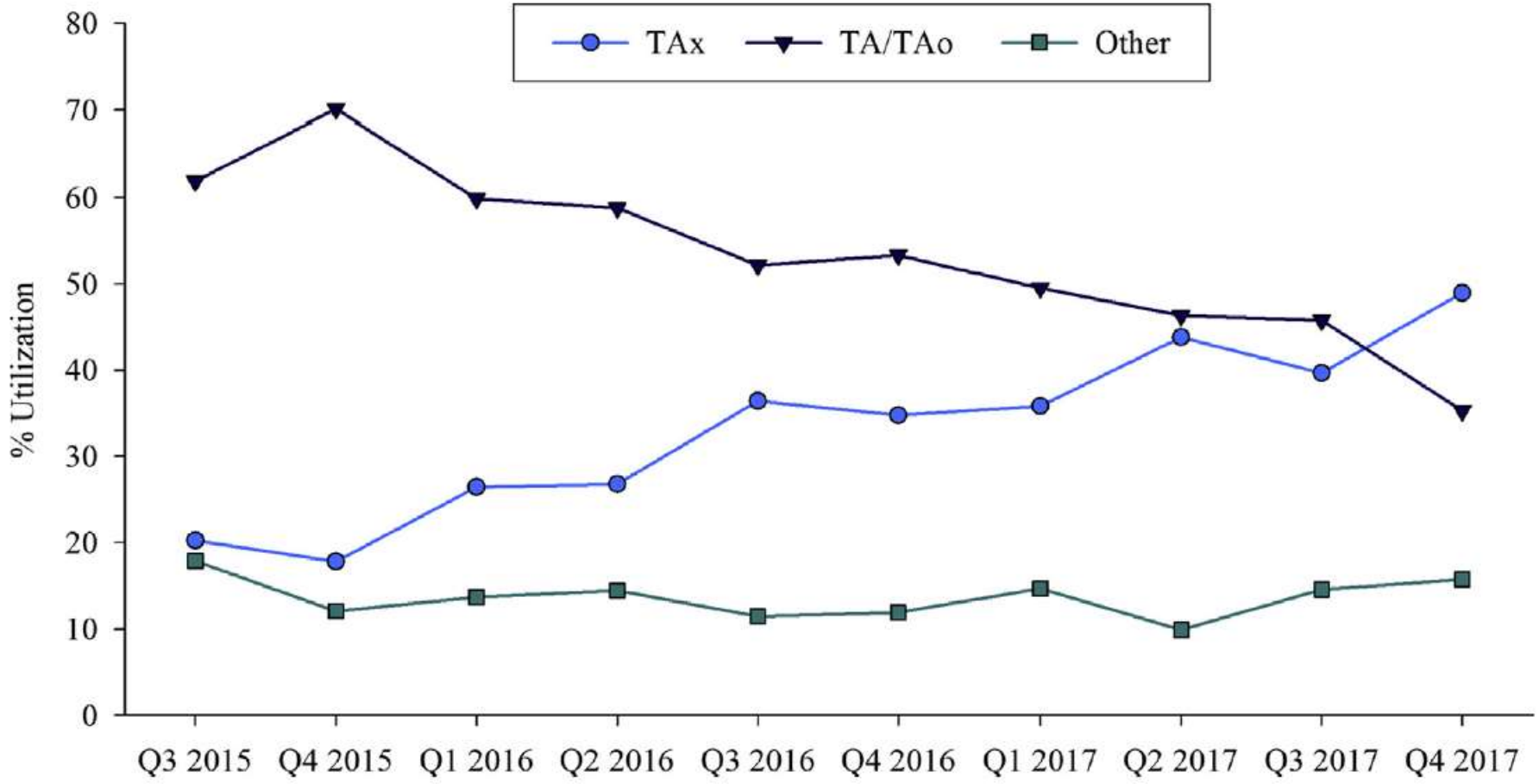
Midterm all-cause mortality



- **Early all-cause mortality was lower after TSc/TAx than TAp or TAo.**
- **Early PM implantation was more frequent after TSc/TAx than TAp or TAo**
- **Midterm all-cause mortality was higher after TSc/TAx than TF**

Takagi H et al. Heart&Lung 2019;1-11

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



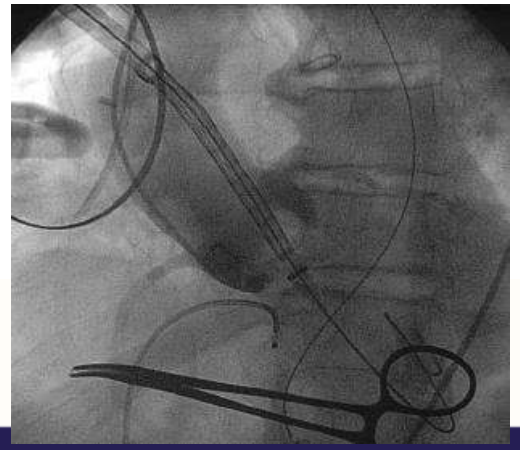
Percentage of transcatheter aortic valve replacement procedures using nontransfemoral access sites according to quarterly TVT (Transcatheter Valve Therapy) Registry data. Q = quarter; TA = transapical; TAo = transaortic; TAx = transaxillary.

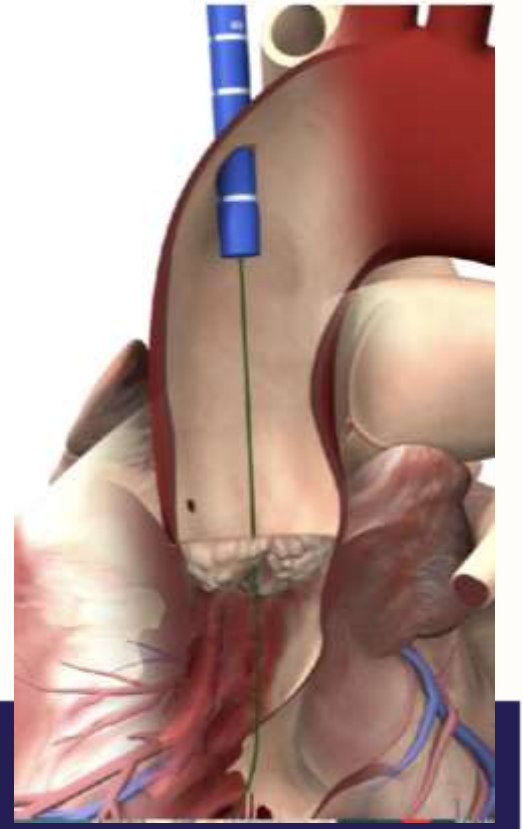
Direct aortic access

Direct aortic access

- Familiar & easy to learn for surgeons
- No LV puncture
  - Reduced risk of bleeding
  - No risk of apical aneurysm/decline in LV function
- No pleural separation
  - Less painful
- Allows large bore access
- Controlled valve deployment

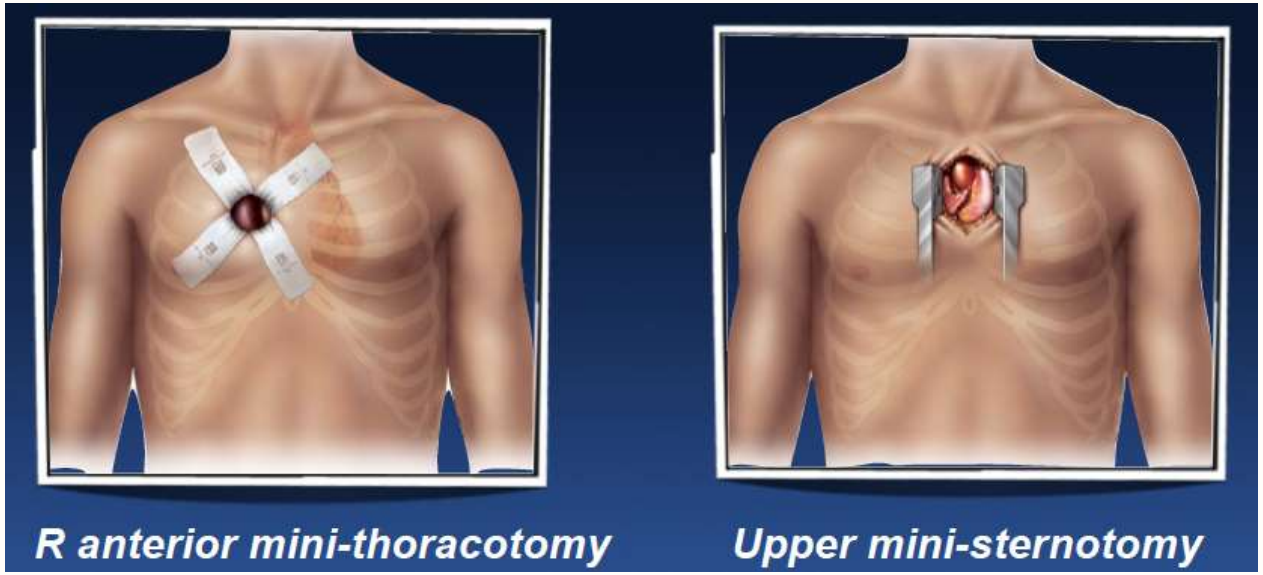
- Requires sternotomy or lateral thoracotomy
- Requires general anaesthesia
- Still pretty invasive
- Still pretty painful





Direct aortic access

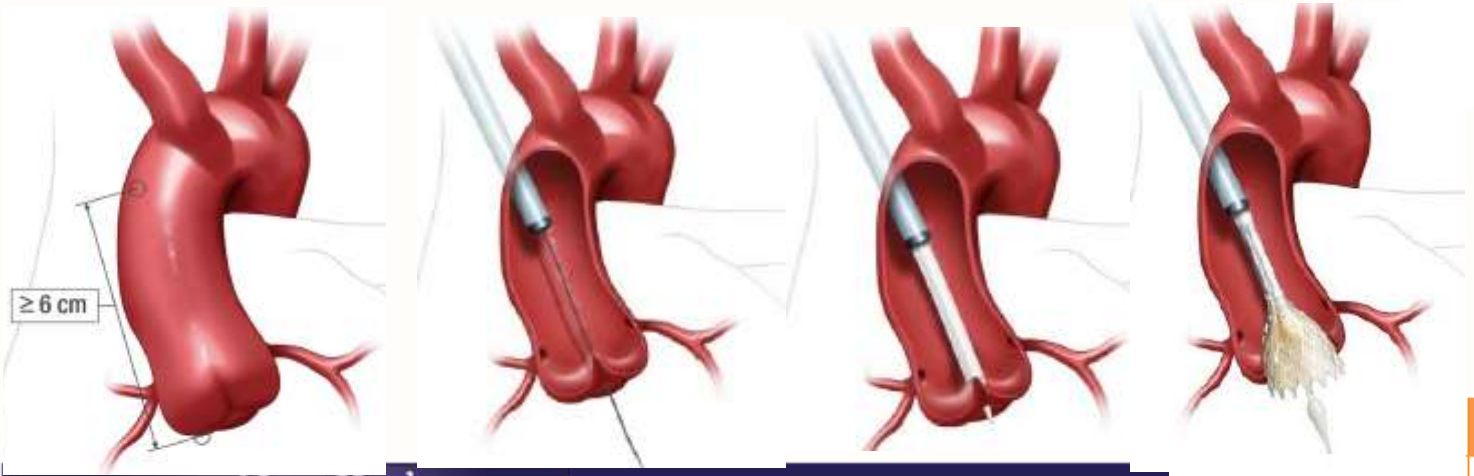
Mini-Thoracotmy or Mini-Sternotomy



Selection criteria confirmed with mandatory pre-operative CT scan:

- Aortic root angulation criteria (see table below)
- Basal plane to aortic access site distance ≥6 cm (see figure to right)
- Soft tissue depth allows for digital palpation of aortic access site
- Aortic access site free of calcification

Access site and delivery trajectory free of RIMA or patent RIMA graft



	Approach			
	Direct Aortic	Left Subclavian / Axillary	Right Subclavian / Axillary	Iliofemoral
Acceptable Aortic Root Angle*	Any angle	<70°	<30°	<70°

TAVR: Direct aortic access vs Femoral

- 394 matched pairs of IF and DA patients
- The all-cause mortality rate was significantly higher in the DA group than in the IF group at 30 days (10.9% vs 4.1%, P<0.0
23.2%

When femoral access is not feasible, DA access allows effective delivery of the valve but incurs an increased risk of death and adverse events, potentially the result of procedural differences.

ADULT CARDIAC

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

Daniel P. O'Hair, MD, Tanvir K. Bajwa, MD, Jeffrey J. Popma, MD, Daniel R. Watson, MD, Steven J. Yakubov, MD, David H. Adams, MD, Samin Sharma, MD, Newell Robinson, MD, George Petrossian, MD, Michael Caskey, MD, Timothy Byrne, MD, Neal S. Kleiman, MD, Angie Zhang, MS, and Michael J. Reardon, MD

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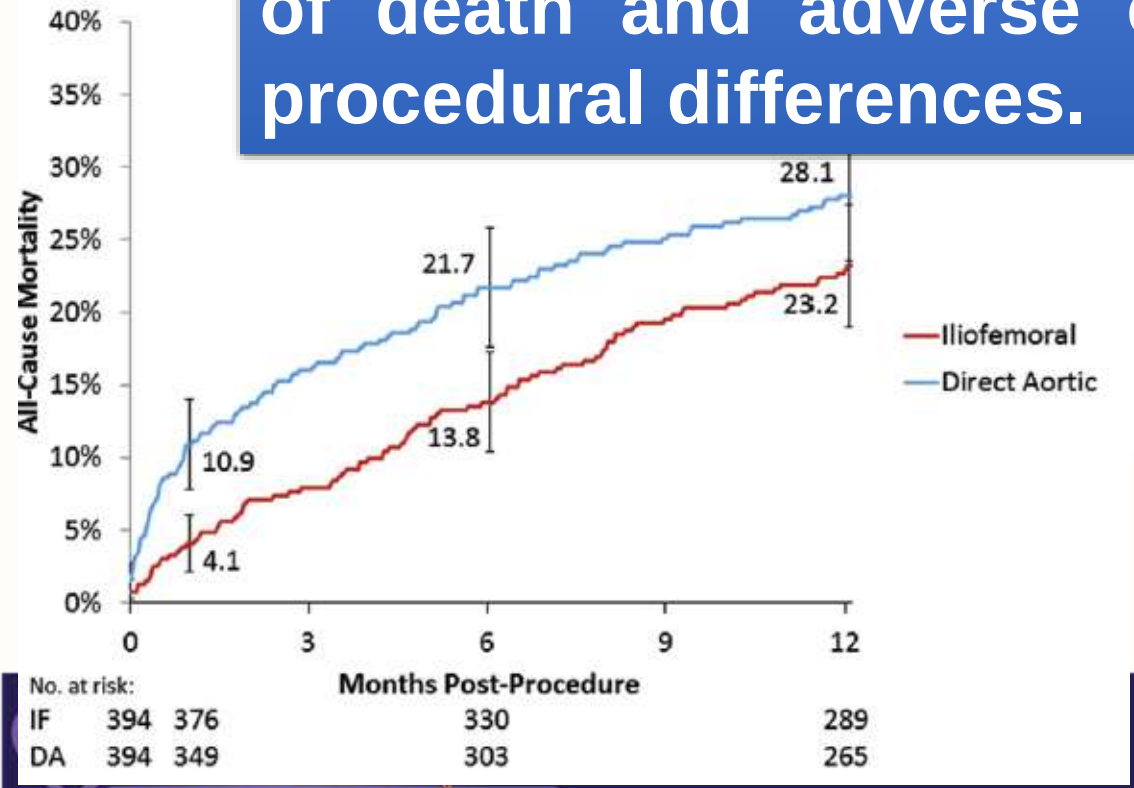


Days) for

		DA (n = 394) (%)	p Value
		13.5	<0.001
		10.9	<0.001
		10.7	<0.001
		4.2	0.028
Valve-related	5.0	6.6	0.269
Reintervention	1.5	0.8	0.327
All stroke	6.1	9.8	0.048
Major stroke	3.9	6.1	0.135
Bleeding event (major/life threatening)	40.1	69.6	<0.001
Major vascular complication	9.7	4.7	0.006
Myocardial infarction	1.8	2.6	0.372

Reintervention	1.5	0.8	0.327
All stroke	2.6	5.7	0.028
Major stroke	1.8	4.1	0.053
Bleeding (major/life threatening)	35.4	66.7	<0.001
Major vascular complication	9.4	4.1	0.003
Acute kidney injury[a]	10.0	19.7	<0.001
Myocardial infarction	0.3	1.0	0.179
Transfusion[b]	6.6	20.6	<0.001

O'Hair DP et al. Ann Thorac Surg 2018; 105:484–90

Trans-Carotid Access

Trans Carotid access

- First reported 2009
- Experience with carotid access
- presence of the vagus nerve and the respiratory tract.
- Left carotid access more coaxial with the ascending aorta
- FRANCE TAVI registry showed that up to 5.5 % of patients are now treated with the TC

Anatomical constraints & limiting conditions	Mode of access & anaesthesia	Advantages	Disadvantages/specific complications
Transcarotid (TC)			
– Min. vessel diameter <6 mm – Calcification and tortuosity – Short neck – Prior ipsilateral carotid artery intervention – Stenosis or occlusion of contralateral carotid artery or vertebral arteries – Anticipated difficult airway	– Surgical – General anaesthesia OR – Local anaesthesia with conscious sedation	– No interaction with descending & abdominal aorta – No myocardial injury – No chest wall injury, no entry in pleural cavity – No restrictions in presence of prior cardiac surgery – Rapid recovery	– Complications of access preparation (nerve injury) – Monitoring of cerebral perfusion required – Right-side: unfavourable alignment if steep angle between annular plane and horizontal axis

Transcarotid Transcatheter Aortic Valve Replacement

Feasibility and Safety

Darren Mylotte, MD,[a] Arnaud Sudre, MD,[b] Emmanuel Teiger, MD, PhD,[c] Jean François Obadia, MD, PhD,[d] Marcus Lee, MD,[a] Mark Spence, MD,[e] Hazem Khamis, MD,[f] Arif Al Nooryani, MD,[g] Cedric Delhaye, MD,[b] Gilles Amr, MD,[b] Mohamad Koussa, MD,[b] Nicolas Debry, MD,[b] Nicolo Piazza, MD, PhD,[h] Thomas Modine, MD, PhD[b]

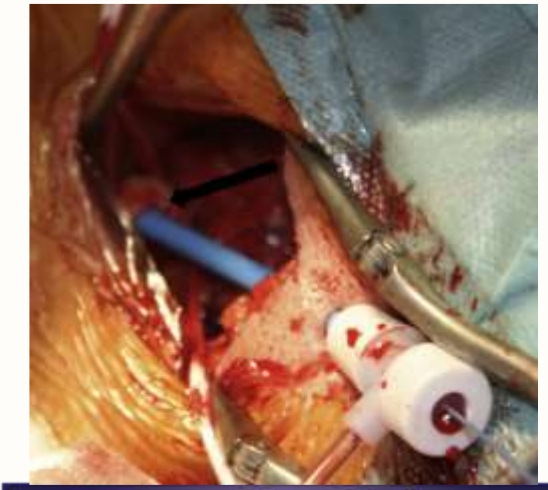


TABLE 3 Clinical Outcomes of Transcarotid TAVR Patients (N = 96)

Mortality	
Procedural	3 (3.1)
30-day	6 (6.3)
1-year	16 (16.7)
Bleeding	
Minor	34 (37.4)
Major	4 (4.2)
Life-threatening	4 (4.2)
Vascular complications	
Minor	4 (4.2)
Major	4 (4.2)
Myocardial infarction	1 (1.0)
Acute kidney injury (grade 3)	7 (7.3)
New pacemaker*	22 (26.5)
Hospital stay, days	11 (9-15)
Composite endpoints	
Device success	86 (89.9)
Early safety	89 (92.7)
Clinical efficacy	89 (92.7)

TABLE 4 Stroke and TIA in Transcarotid TAVR Patients (N = 96)

In-hospital stroke or TIA	3 (3.1)
TIA	3 (3.1)
Stroke	0 (0)
Ipsilateral localization	1 (33)
Hemorrhagic stroke	0 (0)
In-hospital atrial fibrillation	1 (33)
CHA_2DS_2-VASc score*	3.8 ± 0.8
Aortic valve pre-dilation	3 (100)
THV post-dilation	1 (33)
30-day stroke or TIA	6 (6.3)
TIA	6 (100)
Stroke	0 (0)
Ipsilateral localization	2 (33)
Hemorrhagic stroke	0 (0)
In-hospital atrial fibrillation	4 (67)
Discharge anticoagulation	4 (67)
Discharge dual antiplatelet therapy	2 (33)

Circulation: Cardiovascular Interventions

ORIGINAL ARTICLE

Transcarotid Compared With Other Alternative Access Routes for Transcatheter Aortic Valve Replacement

Transcarotid versus transapical/transaortic

101 patients transcarotid TAVR vs 228 patients transapical or transaortic TAVR

Table 3. Clinical Outcomes at 30 Days of Patients Undergoing TA or TAo Versus TC Transcatheter Aortic Valve Replacement

Outcomes	Unmatched Data			Propensity Score-Matched Data*		
	TA/TAo (n=228)	TC (n=101)	*P* Value	TA/TAo (n=163)	TC (n=94)	*P* Value
Major vascular complication	16 (7.0)	3 (3.0)	0.20	10.7	3.2	0.05
Acute kidney injury (stage 2–3)	34 (14.9)	0	<0.0001	12.1	0	0.002
Median LOS, d	8 (6–11)	6 (3–8)	<0.001	8 (6–12)	6 (3–8)	<0.001
Composite end points						
Device success	197 (86.8)	86 (86.9)	1.0	89.8	89.1	0.75
Early safety	161 (70.6)	93 (92.1)	<0.0001	71.7	92.6	0.002

Transcarotid vascular access for TAVR is safe, feasible, and associated with encouraging short-term clinical outcomes in terms of mortality, stroke, and major vascular complications in pts who are not candidates to transfemoral TAVR

Chamadi C et al. Circ Cardiovasc Interv. 2018;11:e006388

Trans-caval Access

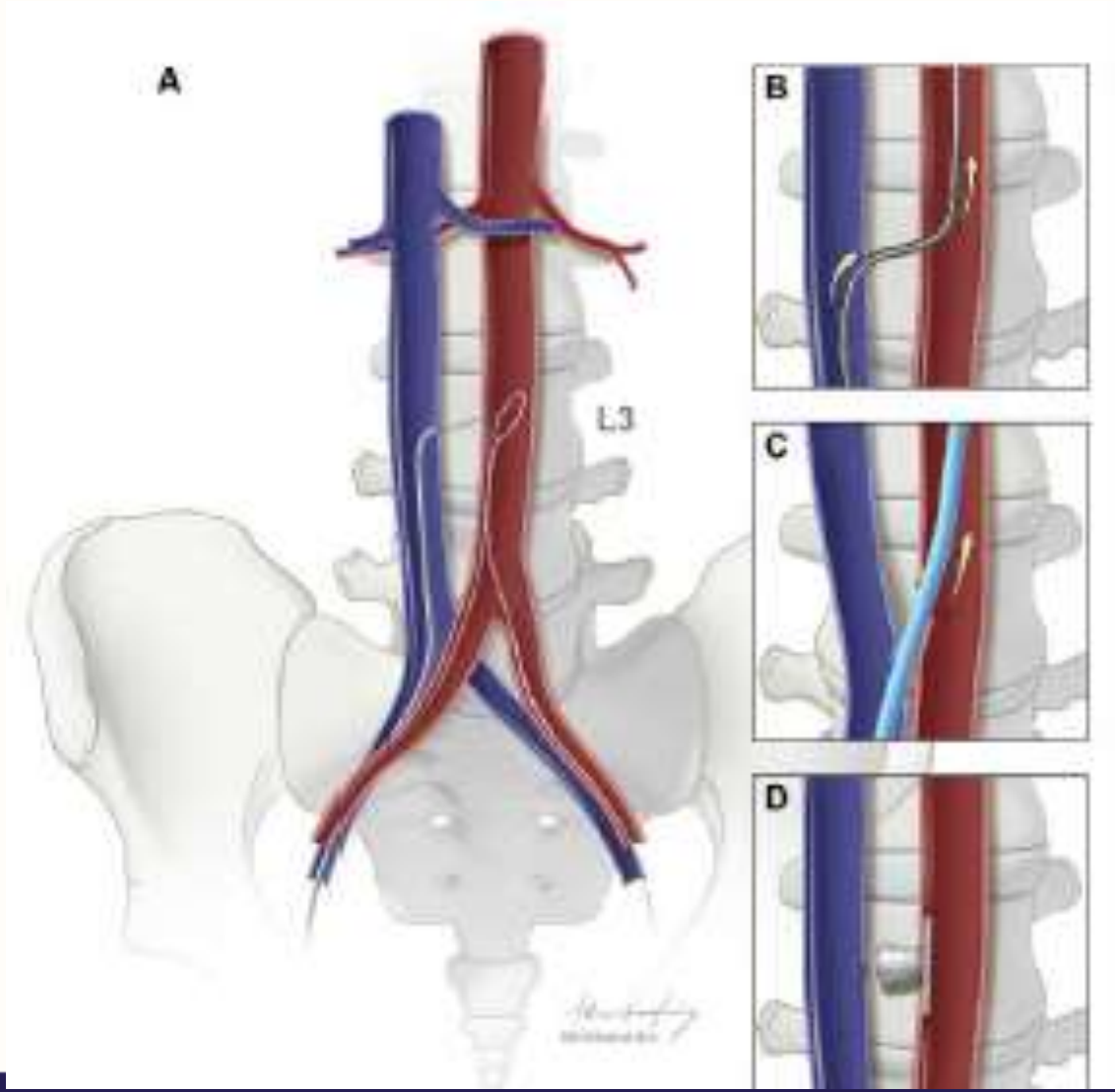
Schematic description of Caval-Aortic Access

A. A catheter directs a transfemoral vein guidewire from the inferior vena cava towards a snare target positioned in the adjoining abdominal aorta.

B. A catheter is advanced over the guidewire into the aorta and used to introduce a more rigid guidewire.

C. The valve introducer sheath is advanced from the vena cava into the aorta.

D. After completion of transcatheter aortic valve replacement, the aortocaval access tract is closed with a nitinol occluder.



Greenbaum AB et al. JACC 2014;63:2795-2804.

Outcome of trans-caval TAVI

The Fate of Transcaval Access Tracts

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

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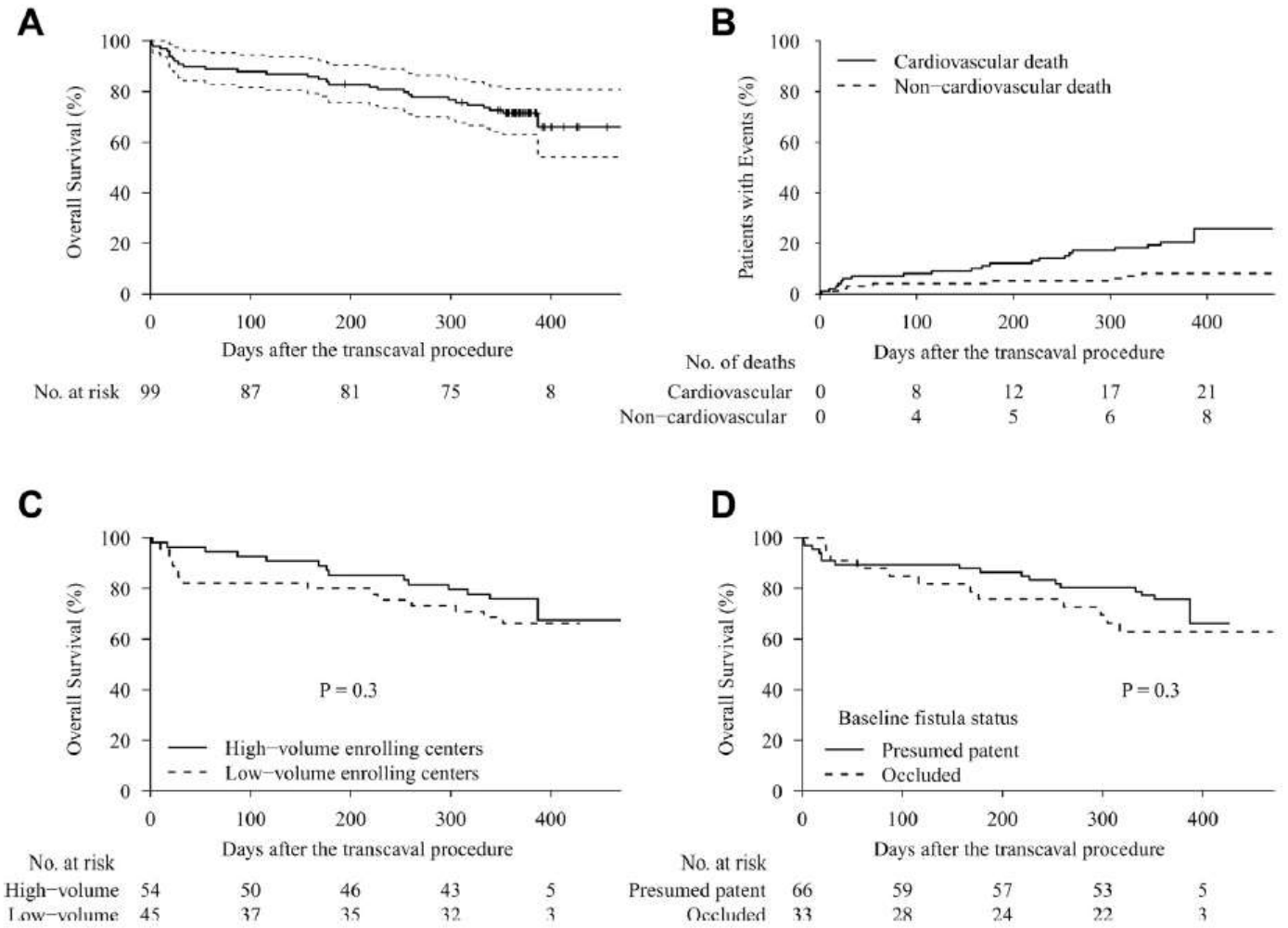
- 100 patients
- 29% of 12-month mortality.
- No vascular complications after discharge.
- 93% of fistulas were proven occluded
- Fistula patency was not associated with overall survival nor with heart failure admissions.
- No cases of occluder fracture or migration or visceral injury.



(A) Overall survival after transcaval TAVR. **(B)** Cardiovascular versus noncardiovascular mortality. **(C)** Survival by high- versus low-volume enrolling centers. Survival was lower at 30 days at low-volume centers but was not different after 1 year. **(D)** Survival by fistula patency status at the conclusion of the transcaval TAVR procedure. Survival was not different whether the fistula was occluded or patent. TAVR = transcatheter aortic valve replacement.

Lederman RL et al. JACC: Cardiovasc Interv 2019;12:448-456.

Femoral vs non femoral peripheral access

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY VOL. 74, NO. 22, 2019

Femoral Versus Nonfemoral Peripheral Access for Transcatheter Aortic Valve Replacement

21,611 patients from FRANCE TAVI registry compared using pre-specified propensity score based matching between groups

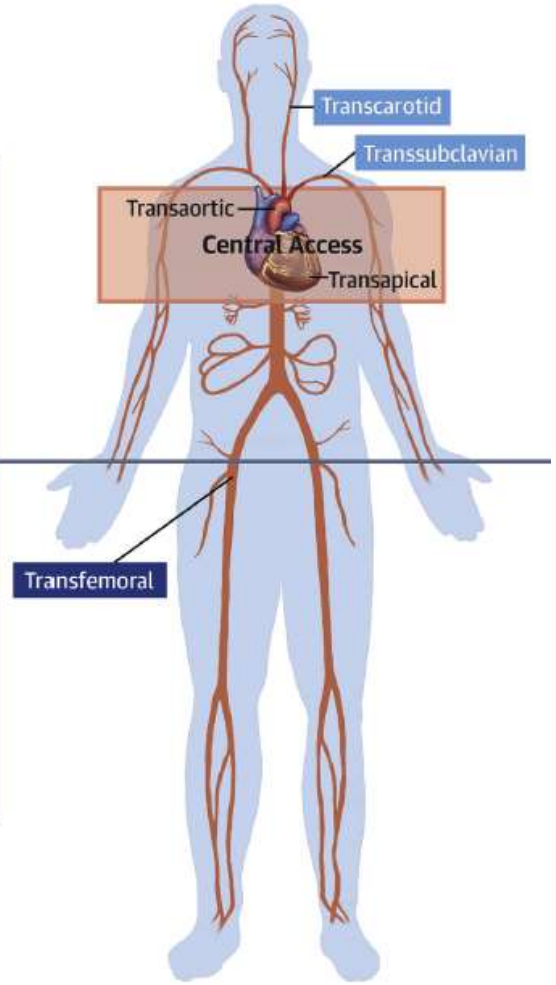
n-FP and FP TAVR provided similar results and a similar safety profile, except for a 2-fold lower rate of major vascular complications or unplanned vascular repairs in the n-FP TAVR group.

Non-Femoral Peripheral Vascular Access N = 1,616
Mean Logistic EuroSCORE I = 19.95%

Complications	n (%)
Operative mortality	64 (3.96)
Stroke	54 (3.34)
Unplanned vascular repair	51 (3.16)

Impact of Access Type on Outcome of the Matched Population

	OR* (95% CI)	P Value
Operative mortality	1.29 (0.87-1.94)	0.21
STEMI	0.81 (0.19-3.87)	0.77
Stroke	1.38 (0.88-2.19)	0.16
Annulus rupture	0.14 (0.00-1.62)	0.13
Aortic dissection	1.63 (0.32-10.45)	1.63
Tamponade	1.38 (0.73-2.65)	0.32
PM insertion	0.95 (0.78-1.16)	0.61
Renal failure	1.39 (0.92-2.11)	0.12
Major bleeding	1.06 (0.81-1.39)	0.68
Unplanned vascular repair	**0.41 (0.29-0.59)**	**<0.001**
Major vascular complications	**0.45 (0.21-0.93)**	**0.03**
Surgery under bypass	0.41 (0.09-1.52)	0.18

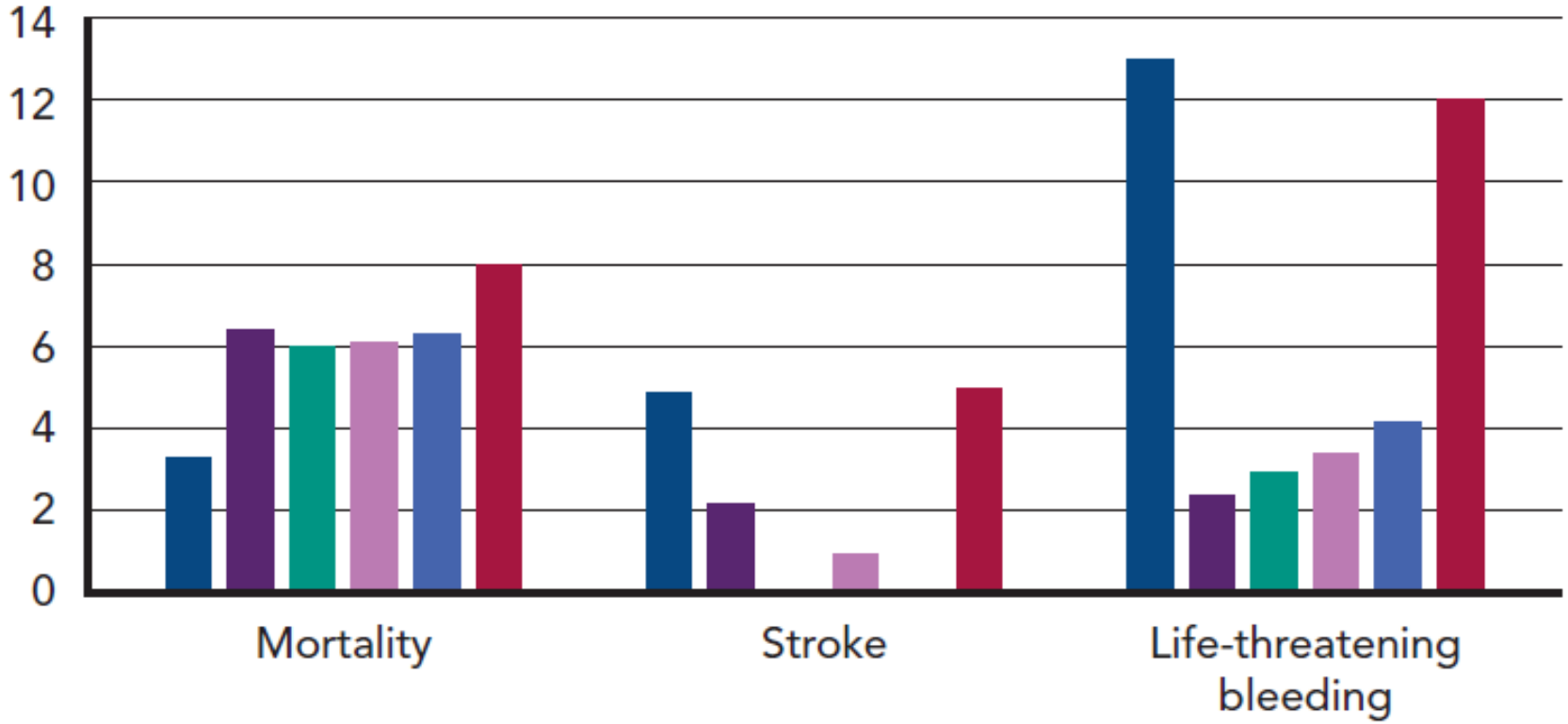


Complications	n (%)
Operative mortality	583 (2.92)
Stroke	362 (1.81)
Unplanned vascular repair	1,288 (6.44)

Femoral Peripheral Vascular Access N = 19,995
Mean Logistic EuroSCORE I = 16.99%

Beurtheret S et al. J Am Coll Cardiol 2019;74: 2728-39

Comparative 30-day all-cause mortality, stroke and life-threatening bleeding rates in high-risk patients treated with the different transcatheter aortic valve implantation approaches

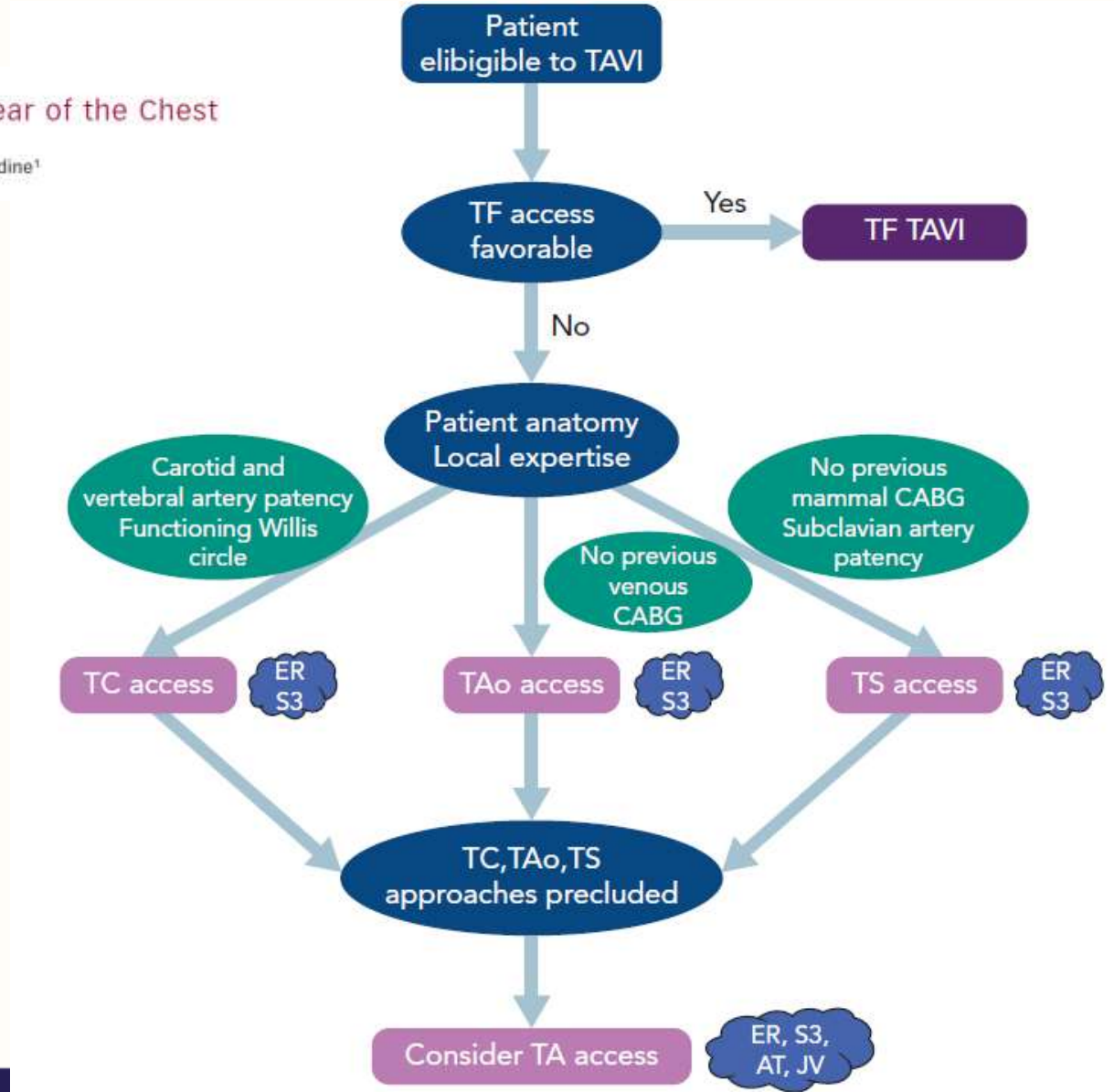


Overtchouck P, Modine T. Interv Cardiol Rev 2018;13:145-150.

Algorithm for alternative approach selection

Alternate Access for TAVI: Stay Clear of the Chest

Pavel Overtchouk[1] and Thomas Modine[1]



AT = ACURATE TA; JV = JenaValve; ER = Evolut R; S3 = SAPIEN 3; TA = transapical; TAo = transaortic; TC = transcarotid; TF = transfemoral; TS = trans-subclavian.

Overtchouck P, Modine T. Interv Cardiol Rev 2018;13:145-150.

Take home message

- Select the best valve for the patient
- Select the best access
- Select the best access taking in consideration the surgical expertise available
- Perfom the procedure in the best and safest way for the patient
- Probably in the future less need of aternate vascular access to femoral artery
- Peripheral hostile access are more prevalent in high risk patient population
- The intermediate or low risk usually has more favourable anatomies

Thank You