New York Transcatheter Valves

2018

PATIENT FOCUSED EVIDENCE-BASED APPROACH

Alternate Vascular Access for TAVR

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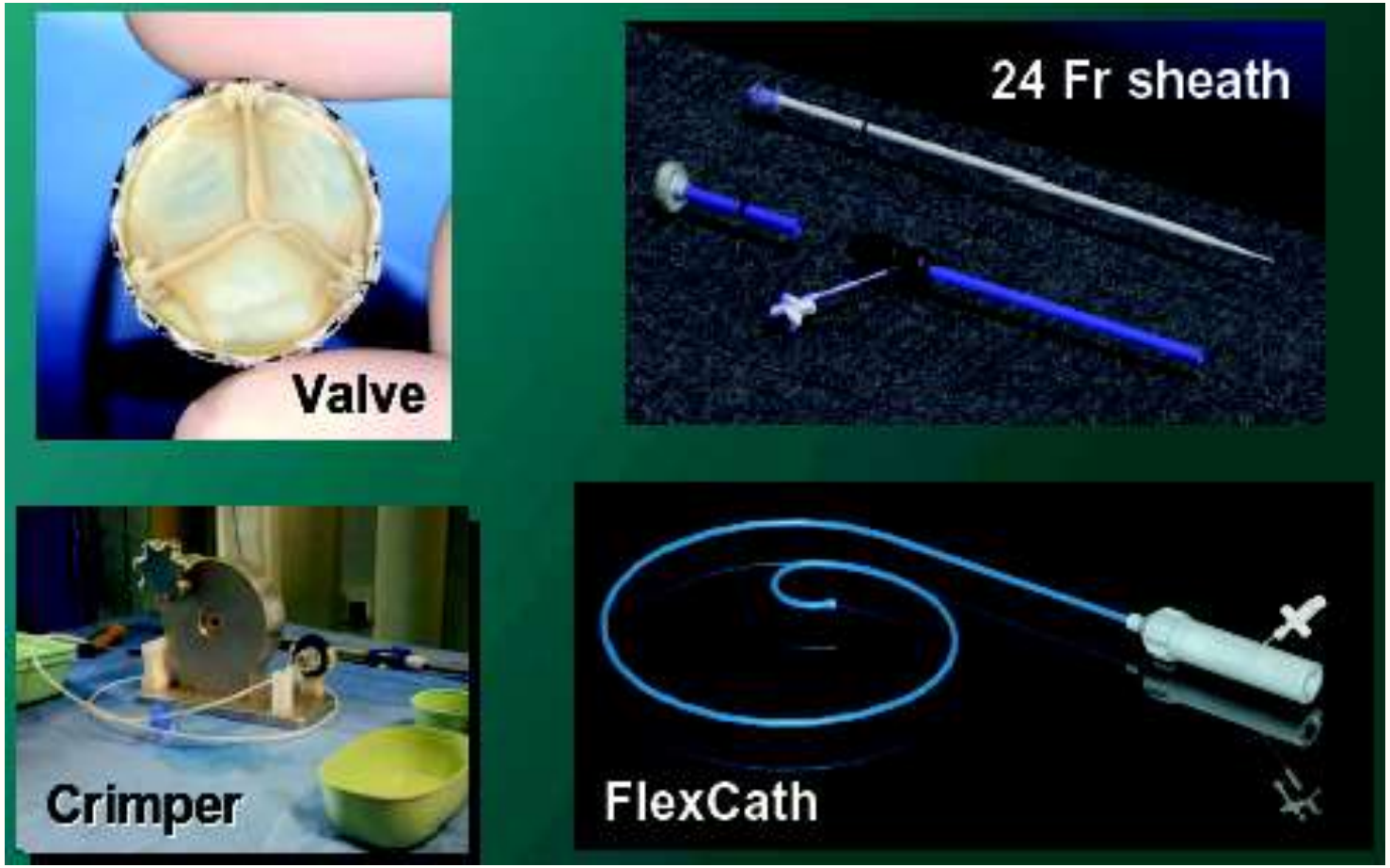
REQUIRED

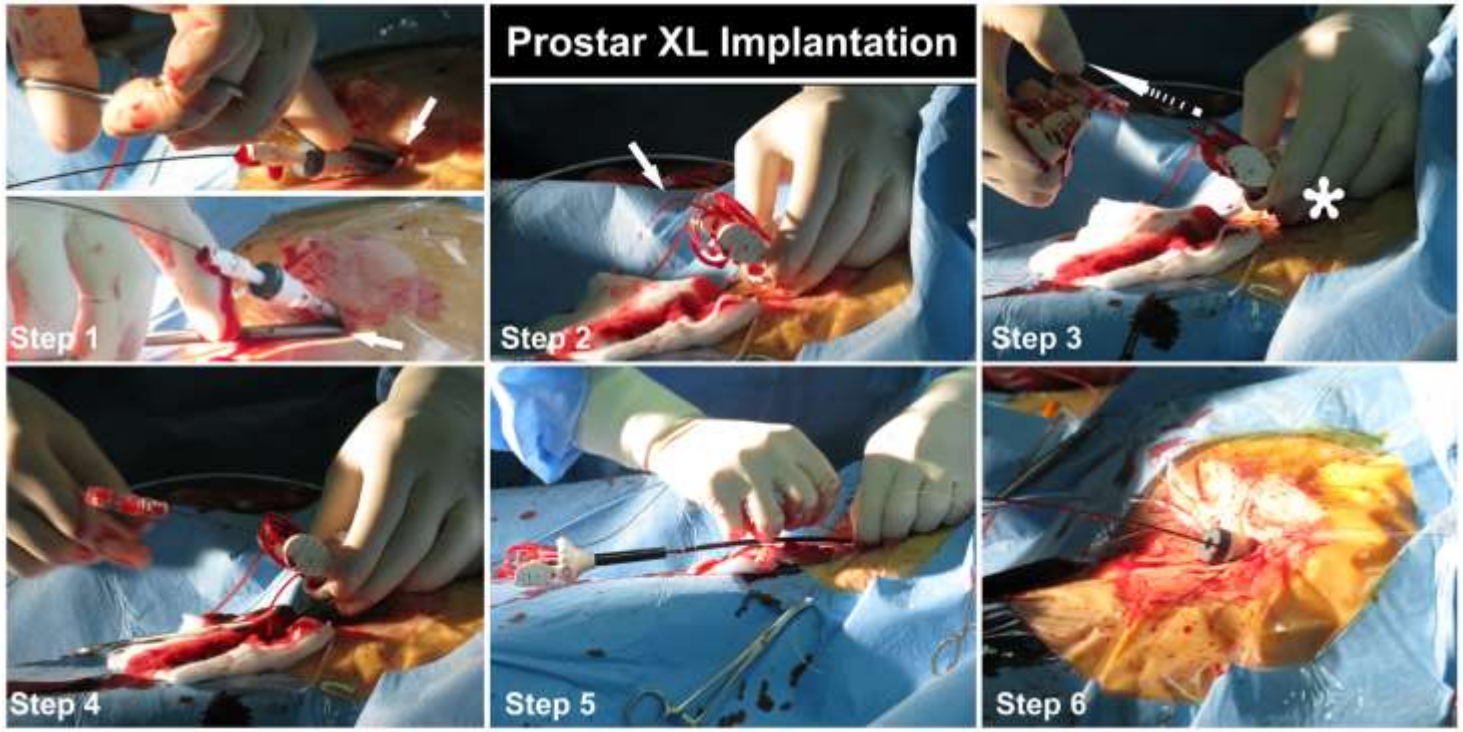
Gian Paolo Ussia

I have no relevant financial relationships

Transcatheter Valves 2007



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

Edwards SAPIEN 3 Transfemoral System

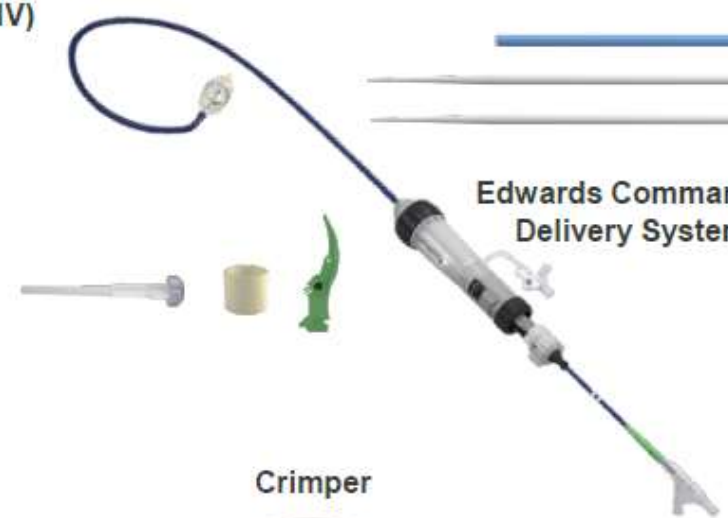
Color Coded System

Green	Purple	Orange
23 mm THV	26 mm THV	29 mm THV

Edwards SAPIEN 3 Transcatheter Heart Valve (THV)

Edwards eSheath Introducer Set

Edwards Commander Delivery System



NOTE:
A separate dilator kit is not included with the system

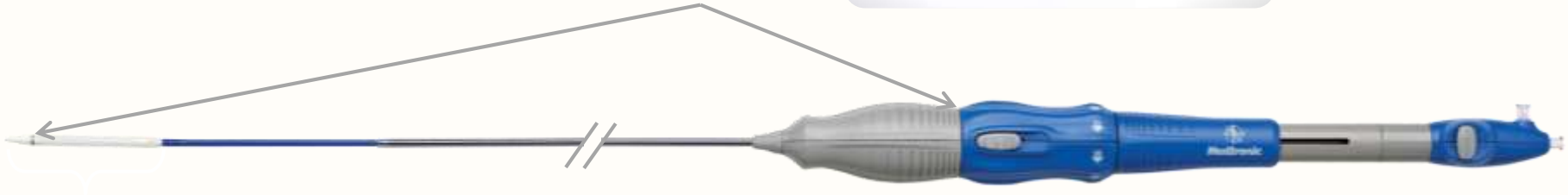
Edwards Transfemoral Balloon Catheter

Crimper

Atrion Devices (Inflation Devices)

Progress in Innovation
Enveo™ Delivery System

1. Enables predictable deployment through an intuitive handle with 1:1 response and improved valve release



2. Enhances insertion and tracking via a low profile, 18Fr catheter with hydrophilic coating

3. Facilitates delivery with an optional shorter-length catheter for subclavian and direct aortic access

4. Resheath & Reposition

Management of Vascul… in Transcatheter Aortic V…

Part 1: Basic Anatomy, Imaging, Sh…

Stefan Toggweiler, MD,*† Jonathon Leips…
Melanie Freeman, MBBS,* Marco Barban…
David A. Wood, MD,* John G. Webb, M…

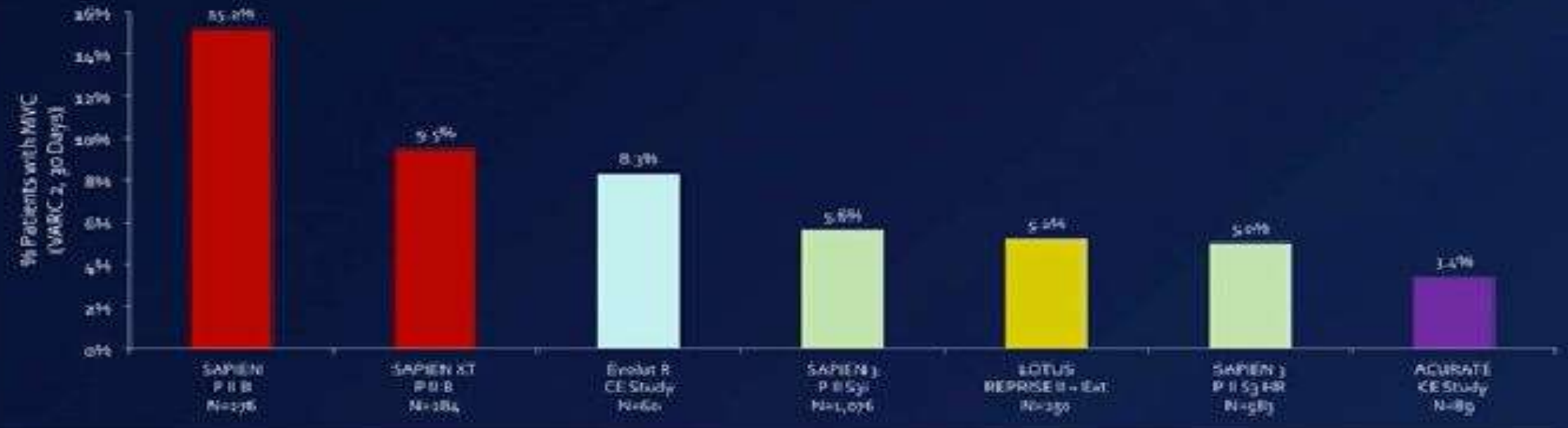
Table 1. Internal and External Diameter of Large Sheaths

Manufacturer	Sheath	Sheath Internal Diameter, F	Sheath External Diameter, mm
Edwards Lifesciences	RetroFlex 3 introducer sheath	22	8.4
		24	9.2
	NovaFlex introducer sheath	18	7.2*
		19	7.5
	Expandable Sheath	14	5.9*
		16	6.6*
		18	7.2*
		20	7.8*
Cook Medical	Check-Flo Introducer	18	7.2
St. Jude Medical	Ultimum	18	6.8
		20	7.6
		22	8.2
Onset Medical	SoloPath Balloon Expandable Transfemoral Introducer	19	7.3†
		20	7.7†
		21	8†
Gore Medical	DrySheath	16	6.2
		18	6.8
		20	7.5

Vascular Injury

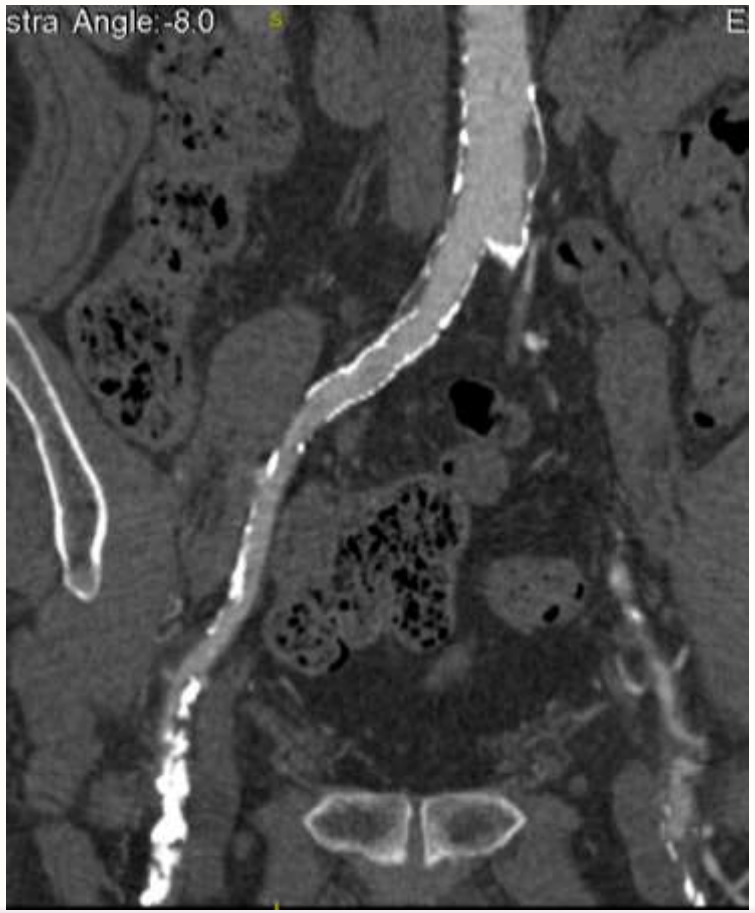
Rates Declining with Experience and New Technology

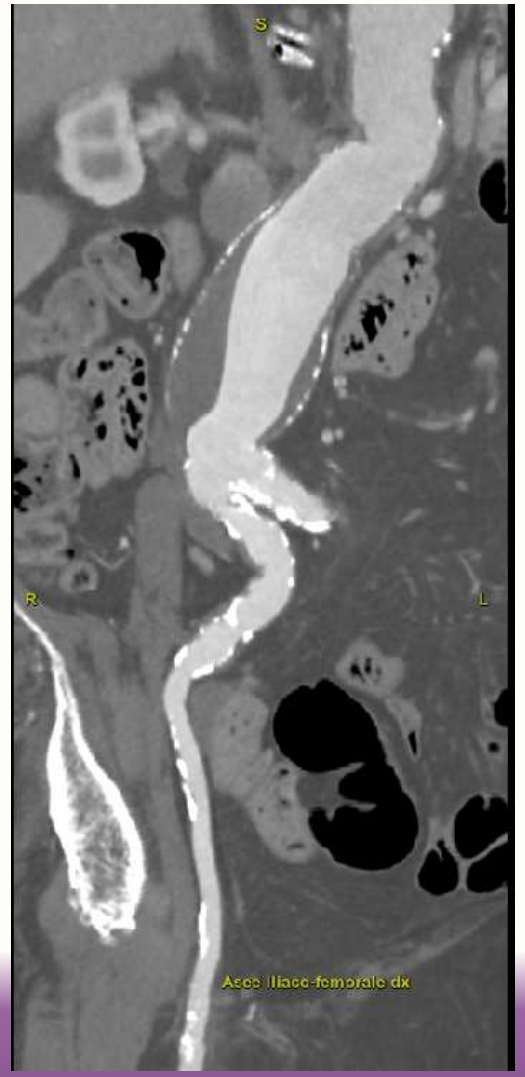
CoreValve SURTAVI Trial



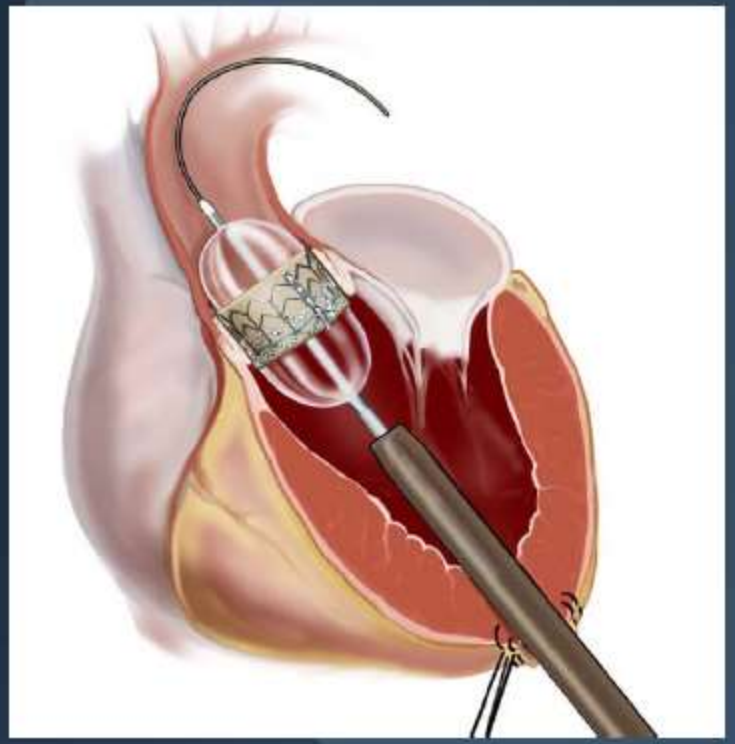
[1]Webb, et. al. *J Am Coll Cardiol Intv* 2015; 8: 1797-806; [2]Manoharan, et al., *J Am Coll Cardiol Intv* 2015; 8: 1359-67; [3]Kodali, et al., presented at ACC 2015; [4]Meredith, et al., presented at PCR London Valves 2014; [5]Kodali, et al., presented at ACC 2015; [6]Abizaid, et al., presented at CRT 2015

The 15% of patients wee usuitabloe for Transemoral access





Apical access



Current state of alternative access for transcatheter aortic valve impla

Jonas Lanz[1], MD, M
Giuseppe Tarantini[3], M
EuroIntervention 20

Anatomical constraints & limiting conditions	Mode of access & anaesthesia	Advantages	Disadvantages/specific complications
Transapical (TA)			
– Apical aneurysm, thrombus or severe hypertrophy – Intra-thoracic adhesions (previous cardiothoracic surgery) – Severe thoracic deformations – Poor LV function – Poor respiratory function	– Surgical: left-anterior mini-thoracotomy – General anaesthesia	– Anterograde procedure – Direct and short distance to aortic annulus (well-controllable delivery) – Favourable implantation angle, also in horizontal aorta – Accommodates large sheaths – Little interference with aorta – Technically feasible in almost everyone, independent of peripheral vessel site	– Higher invasiveness (access to chest & pleural cavity) – Direct myocardial injury – Respiratory compromise – Recovery time/chest discomfort – Device choice restricted to dedicated anterograde delivery systems – Risk of apical tear/rupture – Risk of pseudoaneurysm formation

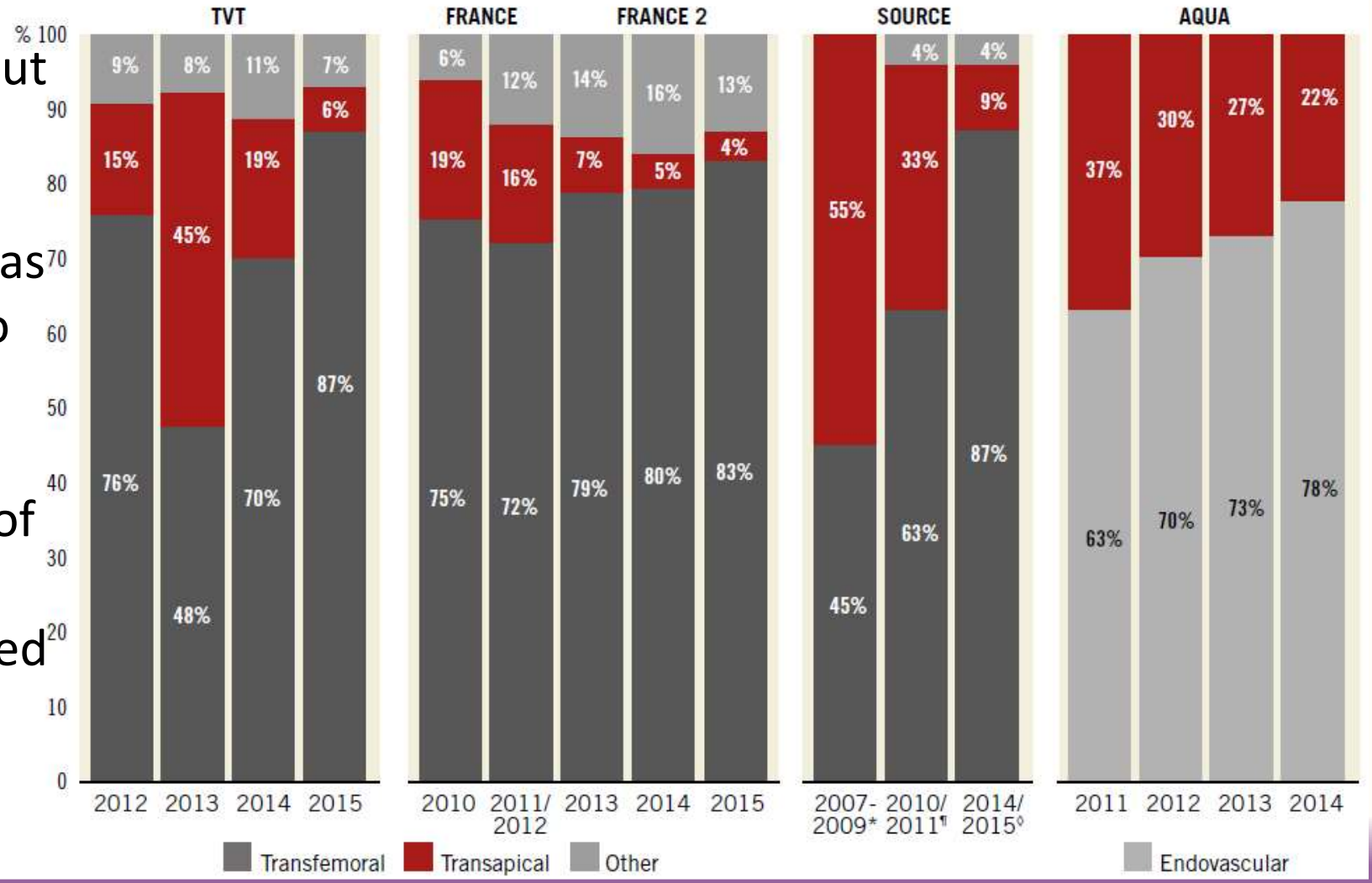
Study	Year*	Device	Delivery sheath (ID)	N	Age	STS-PROM (LES)	Endpoints					
							Def.	Major vascular complication (30-day)	Life-threatening bleeding (30-day)	Major bleeding (30-day)	Stroke (30-day)	Mortality (30-day) (1-year)
Transapical												
TRAVERCE trial[62]	2006-2008	Cribier-Edwards or SAPIEN	26 or 33 Fr	168	82	– 27%	–	–	–	–	2%	15% 37%
Partner IA trial[63]	2007-2009	SAPIEN	26 or 33 Fr	104	83¶	11.8%¶ (29.8%¶)	–	3.9%	–	8.8%	8%	8.7% 29.1%
PARTNER IA trial and continued access registry[64]	2007-2012	SAPIEN	24 or 26 Fr	1,100	85	12% (27.6%[65])	–	3.5%	–	8.8%	2.6%	8.7% (22.1%[65])
SOURCE XT registry[13]	2010-2011	SAPIEN XT	24 or 26 Fr	894	80	7.9% (21.9%)	VARC	3.5%	8.3%	13.9%	4.2%	10% 27.1%
PREVAIL TRANSAPICAL[66]	2009-2010	SAPIEN XT	24 or 26 Fr	150	82	7.5% (24.3%)	–	–	–	–	2.7%	8.7% 22.1%[67]
ACURATE neo TA[68]	2015-2016	ACURATE *neo*	≈ 19 Fr	60	80	4.3% (20.9%)	VARC-2	3.4%	1.7%	–	1.7%	8.3% –

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

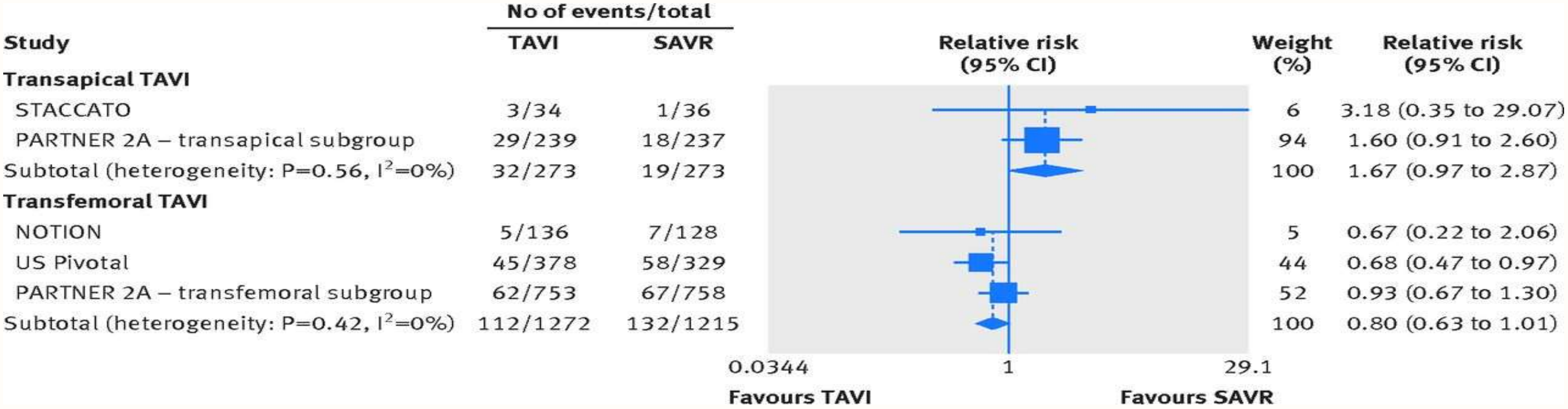
EuroIntervention 2018;14:AB40-AB52

- 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



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

GP Ussia

Subclavian Artery Access

When the femoral access is contraindicated

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

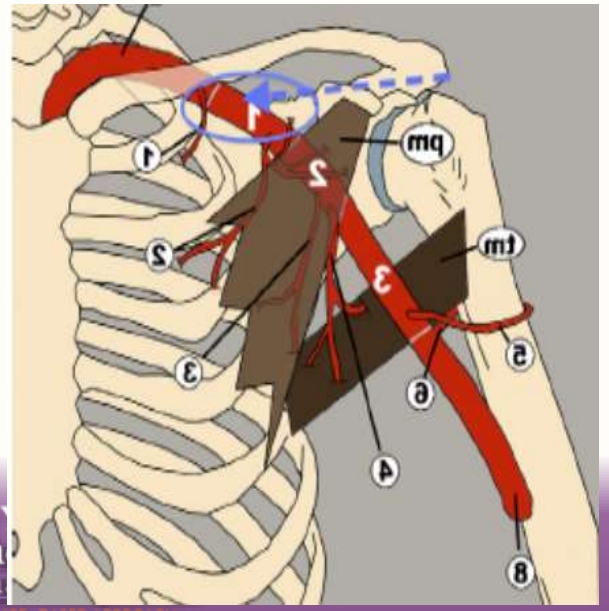
CIRCULATIONAHA/2009/930453

Table 5. Actuarial freedom from events at 6 months.

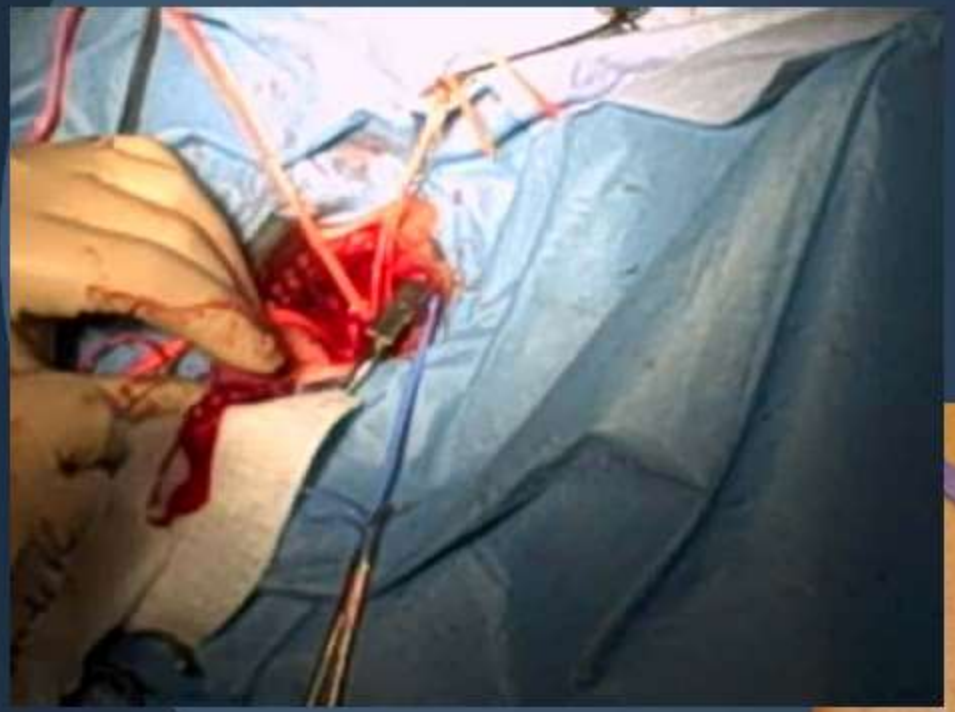
	Total (n=514)	Femoral (n=460)	Subclavian (n=54)	P
Death, %	89.1±1.5	88.6±1.6	93.3±3.8	>0.2
Cardiac death, %	95.8±0.9	95.5±1.0	97.9±2.1	>0.2
MACCEs, %	86.3±1.6	85.5±1.7	93.9±3.4	>0.2
MAVREs, %	87.9±1.5	87.9±1.6	88.5±4.5	>0.2

Trans subclavian / axillary access

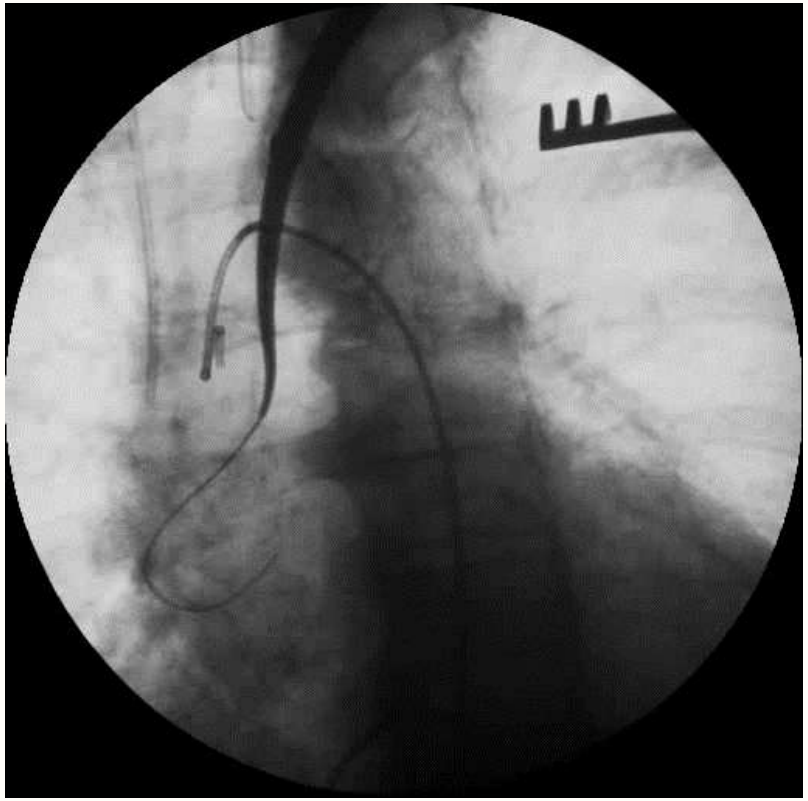
- The surgical cutdown is performed through an infra clavicular incision
- percutaneous approach have been described with the insertion of a wire in the ipsilateral brachial artery externalised through the femoral artery or contralateral brachial artery for balloon occlusion or covered stent implantation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

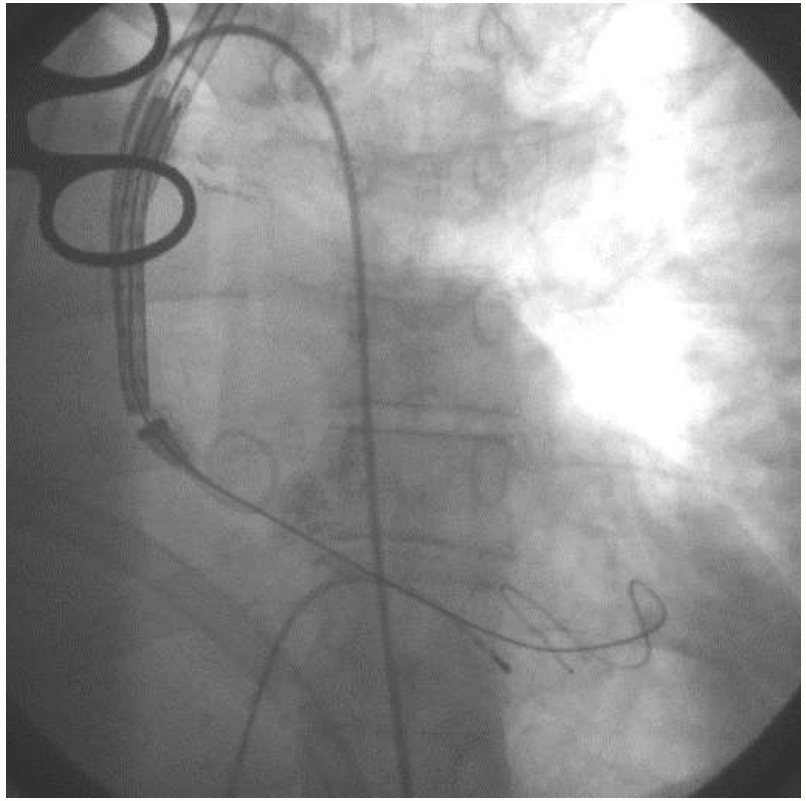


Subclavian access



Trans-Subclavian/proximal axillary





Trans Subclavian access

Anatomical constraints & limiting conditions	Mode of access & anaesthesia	Advantages	Disadvantages/specific complications
Transaxillary (TAx)			
– Min. vessel diameter <6 mm – Calcification and tortuosity – Patent internal mammary artery graft¶ – Pacemaker¶ – Anatomical variants of aortic arch and course of brachial plexus	– Surgical OR – Percutaneous – General anaesthesia OR – Local anaesthesia with conscious sedation	– Accessible in obese patients – 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	– More delicate than femoral artery (vascular dissection, rupture) – Not accessible for effective manual compression – Right-side: unfavourable alignment, particularly if angle between annular plane and horizontal axis >30°

Study	Year*	Device	Delivery sheath (ID)	N	Age	STS-PROM (LES)	Endpoints					
							Def.	Major vascular complica-	Life-threaten-ing	Major bleeding	Stroke (30-day)	Mortality (30-day)
Transaxillary												
Italian CoreValve Registry[44]	2007-2011	CoreValve	18 Fr	141	83	– (23.7%)	VARC	(5%§#)	(7.8%§#)	(36.2%§#)	(2.1%§)	5.7%§ –
CoreValve US Pivotal Trial and continued access registry[45]	2011-2014	CoreValve	18 Fr	202	81	9.7% (20.7%)	VARC	11.9%	11.4%	27.8%	6.5%	5.4% 23.3%
CoreValve ADVANCE study◊	2010-2011	CoreValve	18 Fr	96	81	– (22.8%)	VARC	8.5%	4.2%	9.5%	4.3%	7.3% –

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

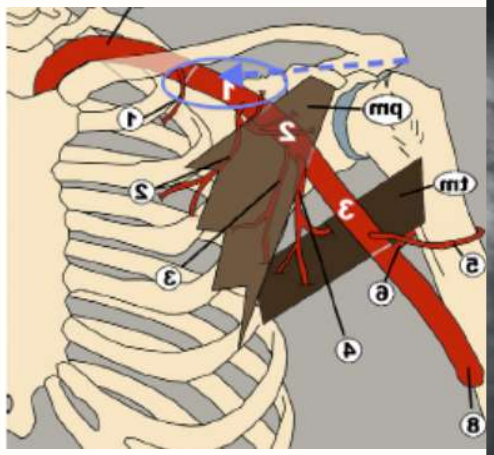
Original article

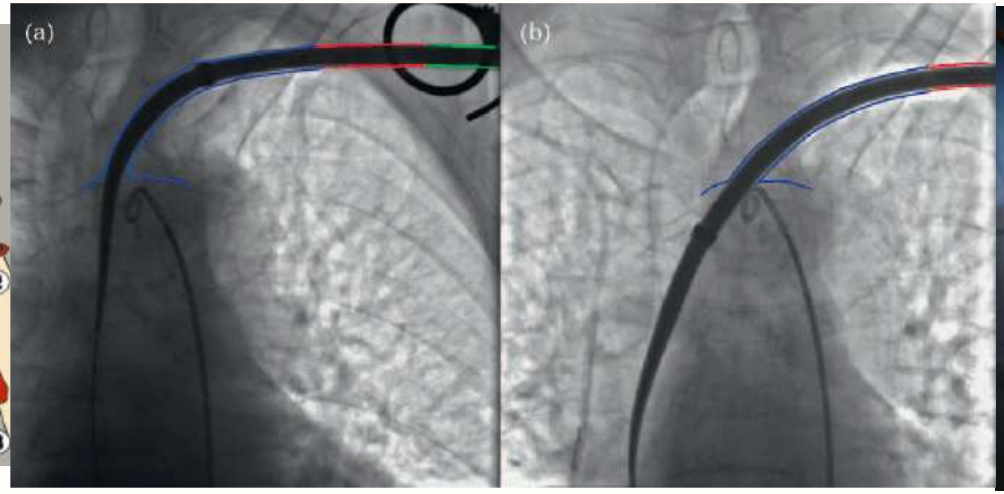
FIC Federazione Italiana di Cardiologia
Italian Federation of Cardiology

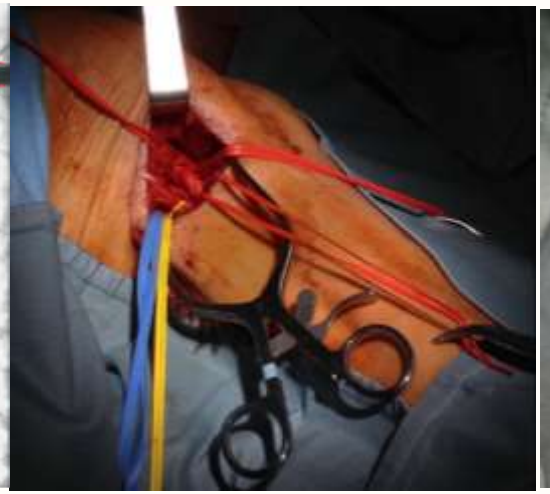
Transcatheter aortic valve implantation through distal axillary artery: novel option for vascular access

Gian Paolo Ussia[a], Valeria Cammalleri[a], Andrea Ascoli Marchetti[b], Kunal Sarkar[a], Pasquale De Vico[c], Saverio Muscoli[a], Domenico Sergi[a], Massimo Marchei[a], Arnaldo Ippoliti[b] and Francesco Romeo[a]

J Cardiovasc Med 2014, 15:







Transaortic Transcatheter Aortic Valve Implantation: Step-by-Step Guide

Vinnie Bapat, FRCS, CTh, and Rizwan Attia, MRCS

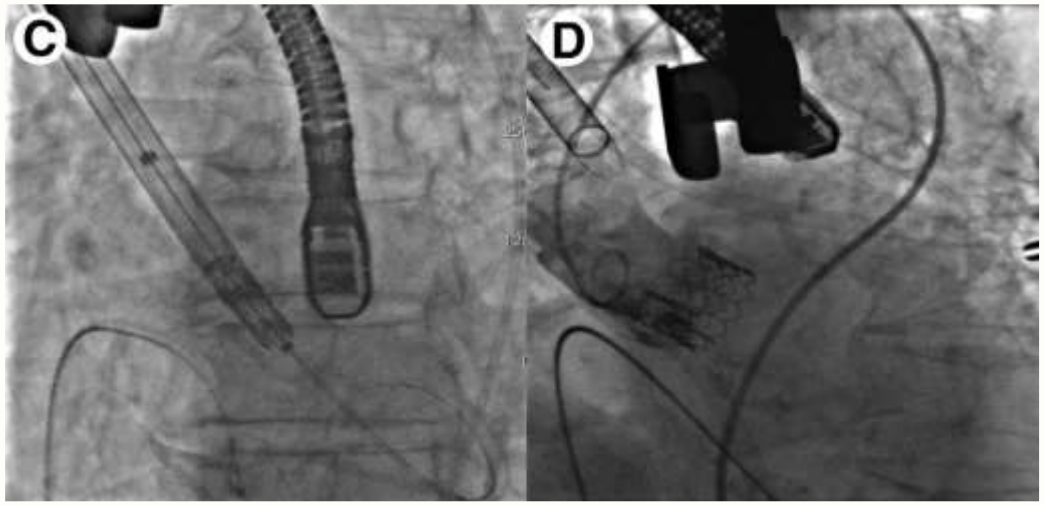


Figure 4. (A and B) Mini J sternotomy has been performed to visualize the ascending aorta that is marked with the aid of fluoroscopy and TEE (black arrow). (C) This is the site of aortic purse strings sutures. (D) Mini right thoracotomy in the 2nd intercostal space. TAo zone is marked out on fluoroscopy and TEE. (Color version of figure is available online at http://www.semthorcardiovascsurg.com.)

- First description 2009
- reverse T- or right J-shaped sternotomy down to the second intercostal space or mini-right thoracotomy
- Good controllability of THV positioning.
- life-threatening bleeding complications comparable to TA.

Current state of alternative access for transcatheter aortic valve implantation

Jonas Lanz[1], MD, MSc; Adam Greenbaum[2], MD; Thomas Pilgrim[1], MD;
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Eur

Anatomical constraints & limiting conditions	Mode of access & anaesthesia	Advantages	Disadvantages/specific complications
Transaortic (TAo)			
– Lack of calcium-free target entry window – Distance aortic entry site to annulus <5 cm – Severe chest deformations – Hx of CABG, prior sternotomy◊ – Close proximity of innominate vein and/or aorta to upper third of sternum◊ – Ascending aorta to the right of the midline, horizontally angulated aorta◊ – Poor respiratory function*	– Surgical: - upper mini-sternotomy OR - right thoracotomy (2. ICS) – General anaesthesia	– Access familiar to cardiac surgeons – Short and direct working distance (well-controllable delivery) – No interaction with aortic arch – Independent of peripheral artery size – Accommodates all sheath sizes – No direct myocardial injury – Rapid installation of CPB possible Mini-sternotomy: – Avoids opening of pleural cavity – Rapid conversion to full sternotomy possible	– Invasiveness – Recovery time/chest discomfort – Respiratory compromise (thoracotomy) – Intercostal bleeding, neuralgia (thoracotomy)

Study	Year*	Device	Delivery sheath (ID)	N	Age	STS-PROM (LES)	Endpoints					
							Def.	Major vascular complication (30-day)	Life-threatening bleeding (30-day)	Major bleeding (30-day)	Stroke (30-day)	Mortality (30-day) (1-year)
Transaortic												
CoreValve ADVANCE DA study[32]	2012-2014	CoreValve	18 Fr	92	82	5.9% (20.3%)	VARC-2	6.5%	10.9%	6.6%	1.1%	4.4% 17.9%
CoreValve US Pivotal Trial and continued access registry[31]	2011-2014	CoreValve	18 Fr	394	83	9.7% –	VARC	4.1%	Life–threatening and major combined: 66.7%		5.7%	10.9% 28.1%

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 3.4 % 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]

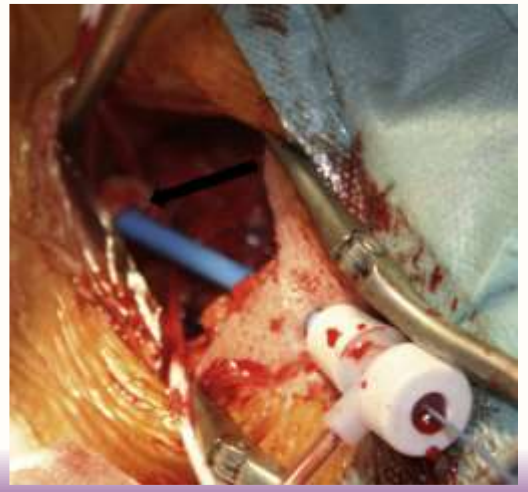

TABLE 3 Clinical Outcomes of Transcarotid TAVR Patients (N = 96)

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)

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

Transinnominate (TI)			
– Deformity of cervical spine restricting neck extension – Thyroid disease/previous surgery – Severe calcifications of innominate artery or its base at aortic arch	– Surgical: cut-down, if located at upper third of sternal manubrium, otherwise mini-sternotomy – General anaesthesia	– No injury to chest wall, pleural cavity or myocardium – Short and direct working distance (well-controllable delivery) – No interaction with aortic arch – Often free of adhesions despite previous cardiac surgery – Rarely atheromatous or calcified – Accommodates all sheath sizes – Faster recovery than transthoracic accesses	– Not accessible for direct compression in case of bleeding complications – Unfavourable trajectory in case of horizontally angulated aortic root – Tracheal, vascular or nerve injuries


Alternate Access for TAVI: Stay Clear of the Chest

Pavel Overtchouk[1] and Thomas Modine[1]

1. Centre Hospitalier Regional et Universitaire de Lille, Lille, France

Trans Caval access

- The TCv approach allows large introducer sheath size
- wire crossing from the inferior vena cava into the aorta through retroperitoneum
- precise preoperative planning with multi-slice CT.
- Aortic calcifications in the crossing area
- to avoid tearing of the aortic wall and effective closing of the artificially created closing by a cardiac-type occluder device

Current state of alternative access for transcatheter aortic valve implantation

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Anatomical constraints & limiting conditions	Mode of access & anaesthesia	Advantages	Disadvantages/specific complications
Transcaval (TCv)			
– Lack of calcium-free target window – Proximity of renal arteries or aorto-iliac bifurcation to target entry site (15 mm) – Pedunculated abdominal aortic atheroma – Bilateral iliofemoral artery occlusion (precluding bail-out procedures) – Celiac and superior mesenteric artery obstruction (risk of mesenteric ischaemia) – Aortic stent graft and aneurysm¶	– Percutaneous – General anaesthesia	– True percutaneous procedure – No myocardial injury – No chest wall injury, no entry in pleural cavity – Accommodates all sheath sizes – Standard working position for operator, most distant from radiation source	– Risk of retroperitoneal bleeding – Risk of residual aorto-caval fistula with haemodynamic compromise – Risk of bowel injury

Study	Year*	Device	Delivery sheath (ID)	N	Age	STS-PROM (LES)	Endpoints					
							Def.	Major vascular complication (30-day)	Life-threatening bleeding (30-day)	Major bleeding (30-day)	Stroke (30-day)	Mortality (30-day) (1-year)
Transcaval												
Transcaval access and closure[55]	2014-2016	SAPIEN XT, SAPIEN 3, CoreValve & Evolut R	Mean sheath OD: 8.0 mm	100	80	9.6% –	VARC-2	19.2%§#	12.1%§#	6.1%§#	5%§	8%§ –

Review Article

Vascular approaches for transcatheter aortic valve implantation

Isaac Pascual[1], Amelia Carro[2], Pablo Avanzas[1], Daniel Hernández-Vaquero[1], Rocío Díaz[1], Jose Rozado[1], Rebeca Lorca[1], María Martín[1], Jacobo Silva[1], César Morís[1]

TRANSFEMORAL		
ILIOFEMORAL COMPLICATIONS		**AORTIC COMPLICATIONS**
Dissection Rupture Access site infection Access site bleeding	Stenosis/Thrombosis/Occlusion Artery avulsion Pseudoaneurysms Failed percutaneous closure	Aortic aneurysm Aortic rupture Aortic dissection Retroperitoneal hemorrahage
TRANSAPICAL	**TRANSAXILLARY**	**TRANSAORTIC**
Apical puncture bleeding Myocardial tears Apical scarring Blood flow obstruction (LAD) Aneurysm formation Chronic pain	Subclavian artery thrombosis Subclavian artery dissection Subclavian artery stenosis	Tearing of the aorta Deep wound infection Mediastinitis RIMA graft injury Right ventricle laceration IC artery pseudoaneurysm

Figure 1 TAVI-related major vascular complications according to access routes. TAVI, transcatheter aortic valve implantation; LAD, left anterior descendent; RIMA, right internal mammary artery; IC, intercostals.

Alternate Access for TAVI: Stay Clear of the Chest

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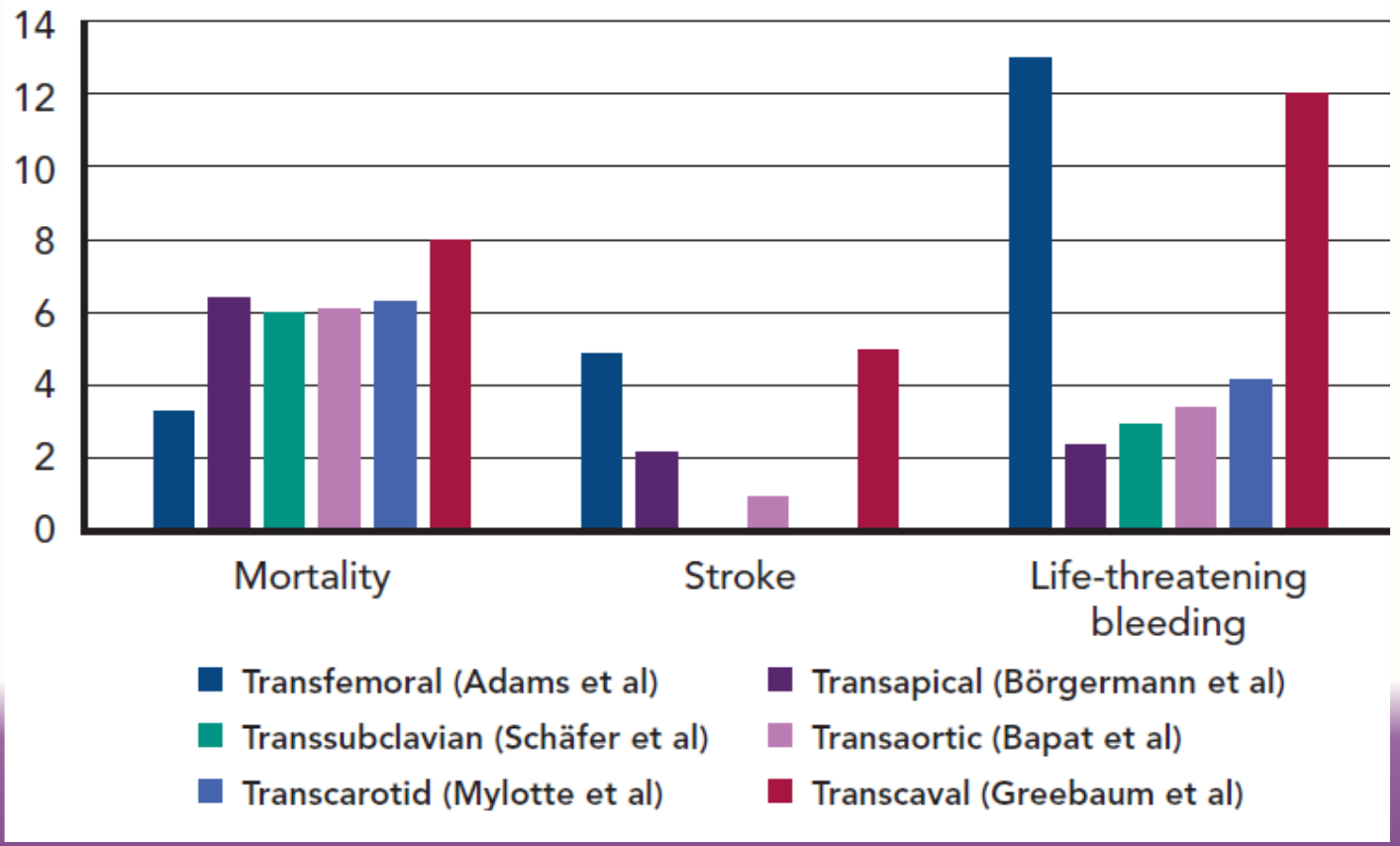
Figure 4: Comparative 30-day all-cause mortality, stroke and life-threatening bleeding rates in high-risk patients treated with the different transcatheter aortic valve implantation approaches



Conclusion

- The gold standard for TAVR should be full percutaneous approach, local anestehesia , sedation
- Transfemoral approach is the less invasive and the best tolerated
- When anatomy is not favourable alternatives should be cosidered alternative approaches for TAVI have reasonable safety and efficacy profile in selected patient population
- The decision of the best access for TAVR should be taken for every single patient in a multidisciplinary discussion

Thank you