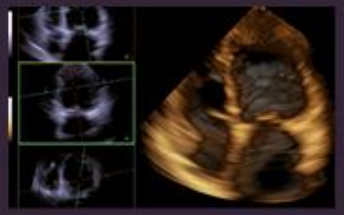

EuroValve
March 10-11, 2016

TAVI minimazing complications
Vascular access

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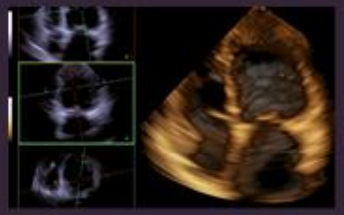
www.eurovalvecongress.com



EuroValve
March 10-11, 2016

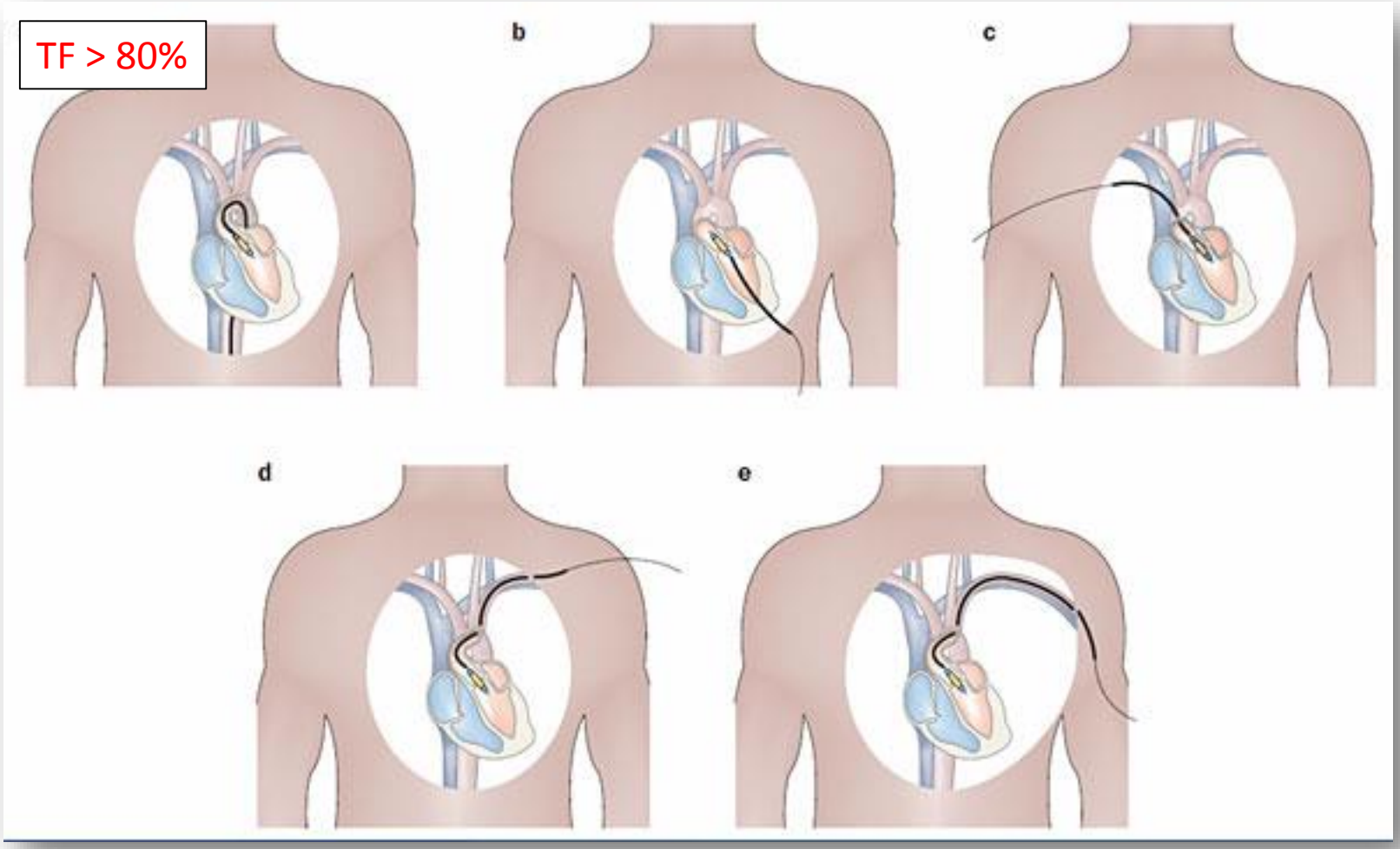
Faculty disclosure

Joelle Kefer

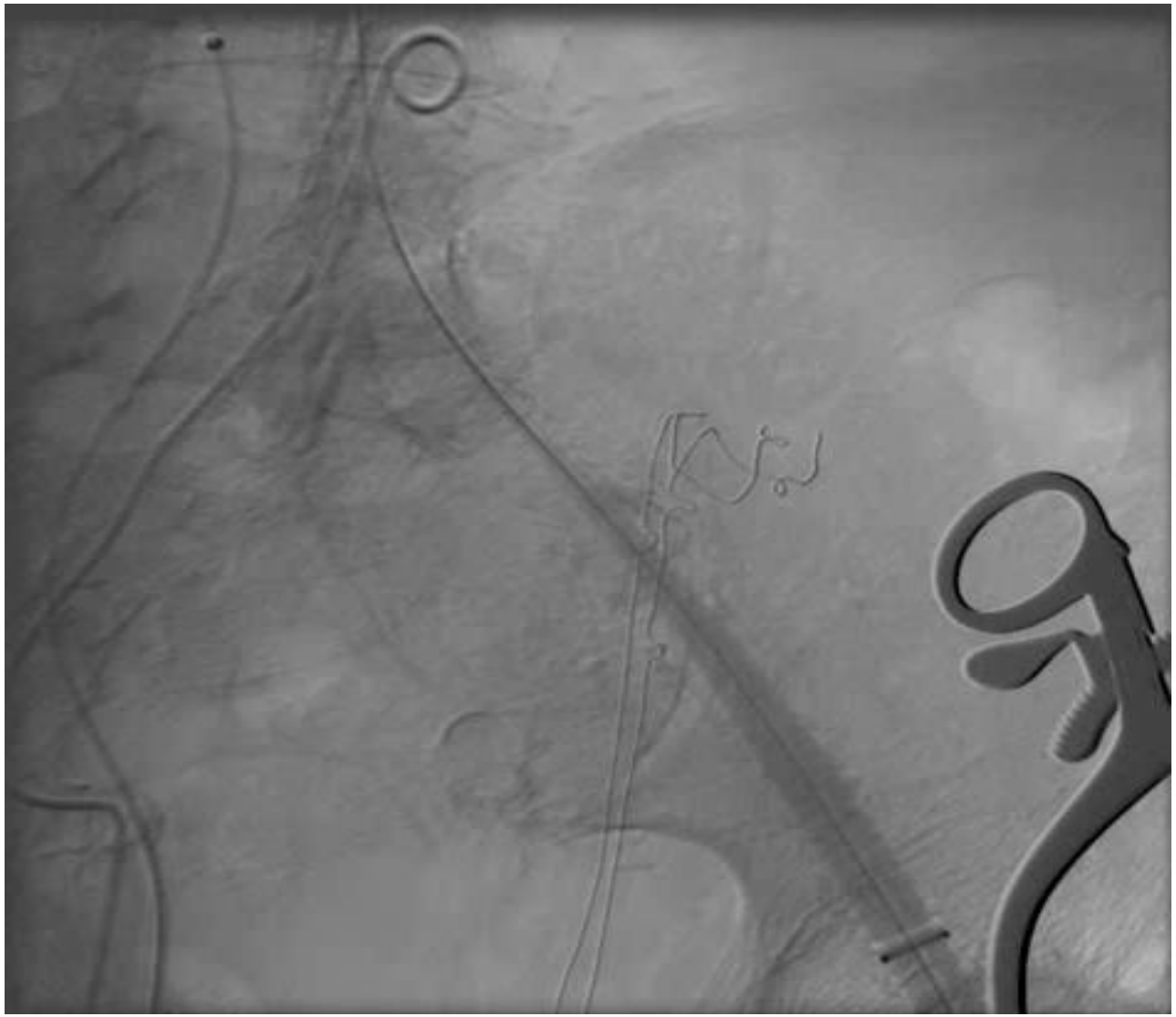
I disclose the following financial relationships:

Consultant for StJude Medical
Receive grant/research support from Abbott Vascular

TAVI : Vascular access

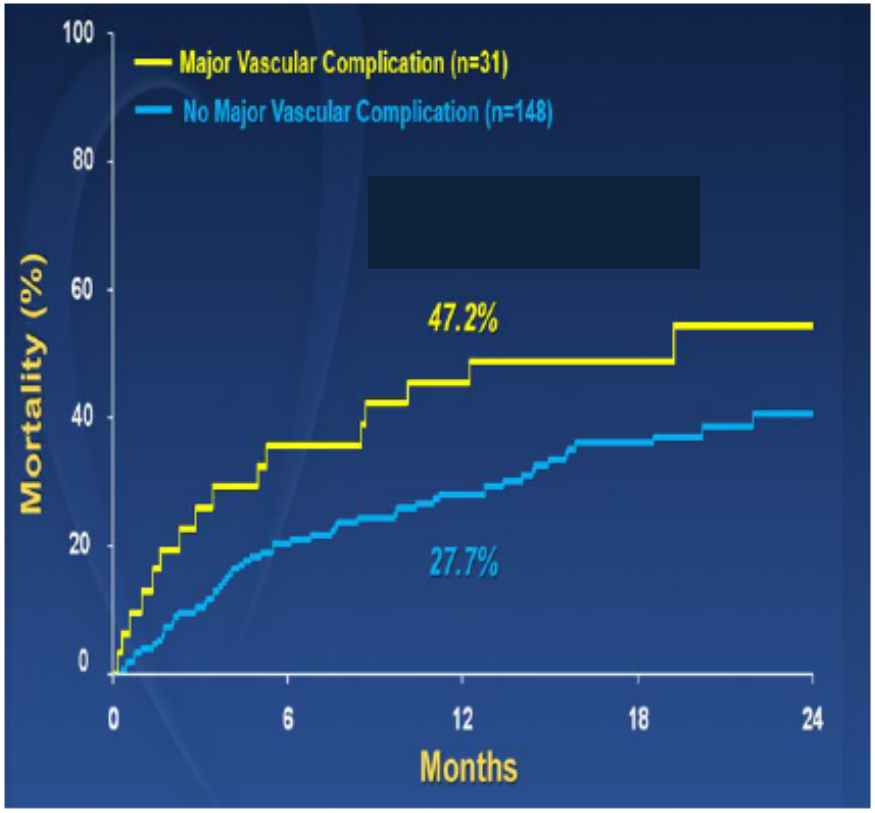


Major vascular complication

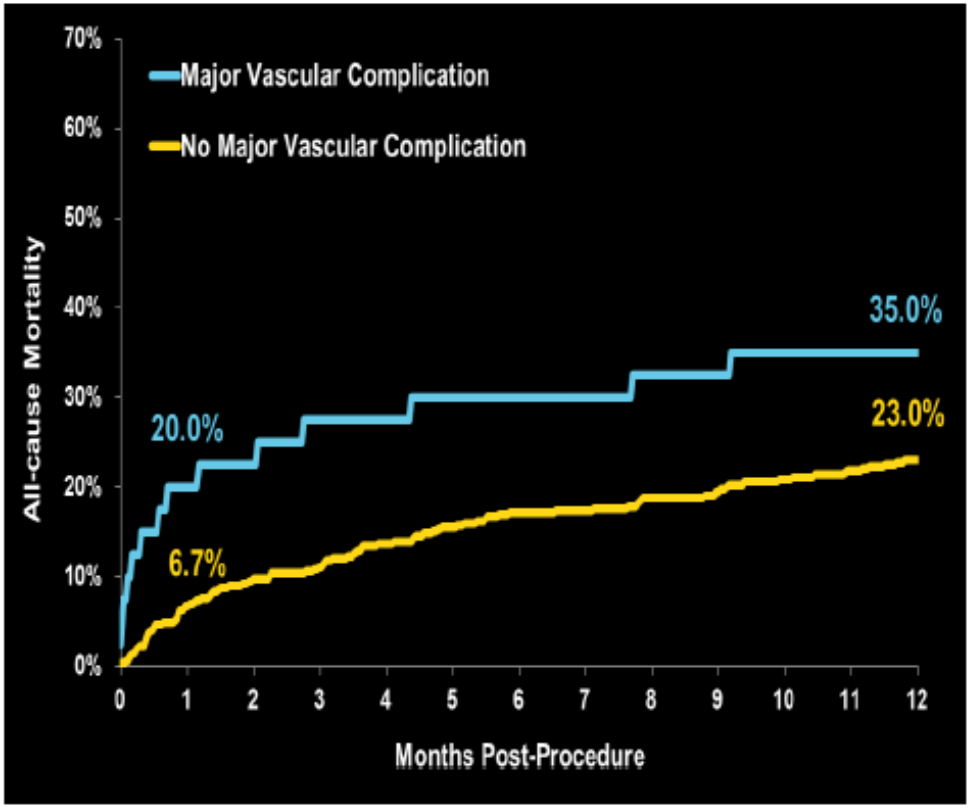


Major vascular complications increase mortality after TAVI

Partner 1 Trial



CoreValve Extreme Risk Trial



Updated standardized endpoint definitions for transcatheter aortic valve implantation: The Valve Academic Research Consortium-2 consensus document*

A. Pieter Kappetein, Stuart J. Head, Philippe Généreux, Nicolo Piazza, Nicolas M. van Mieghem, Eugene H. Blackstone, Thomas G. Brott, David J. Cohen, Donald E. Cutlip, Gerrit-Anne van Es, Rebecca T. Hahn, Ajay J. Kirtane, Mitchell W. Krucoff, Susheel Kodali, Michael J. Mack, Roxana Mehran, Josep Rodés-Cabau, Pascal Vranckx, John G. Webb, Stephan Windecker, Patrick W. Serruys, and Martin B. Leon

Major vascular complications

- Any aortic dissection, aortic rupture, annulus rupture, left ventricle perforation, or new apical aneurysm/pseudoaneurysm OR
- Access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arterio-venous fistula, pseudoaneurysm, hematoma, irreversible nerve injury, compartment syndrome, percutaneous closure device failure) *leading to* death, life-threatening or major bleeding,* visceral ischemia, or neurological impairment OR
- Distal embolization (noncerebral) from a vascular source requiring surgery or resulting in amputation or irreversible end-organ damage OR
- The use of unplanned endovascular or surgical intervention *associated* with death, major bleeding, visceral ischemia or neurological impairment OR
- Any new ipsilateral lower extremity ischemia documented by patient symptoms, physical exam, and/or decreased or absent blood flow on lower extremity angiogram OR
- Surgery for access site-related nerve injury OR
- Permanent access site-related nerve injury

Minor vascular complications

- Access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arterio-venous fistula, pseudoaneuysms, hematomas, percutaneous closure device failure) *not leading to* death, life-threatening or major bleeding,* visceral ischemia, or neurological impairment OR
- Distal embolization treated with embolectomy and/or thrombectomy and not resulting in amputation or irreversible end-organ damage OR
- Any unplanned endovascular stenting or unplanned surgical intervention not meeting the criteria for a major vascular complication OR
- Vascular repair or the need for vascular repair (via surgery, ultrasound-guided compression, transcatheter embolization, or stent-graft)

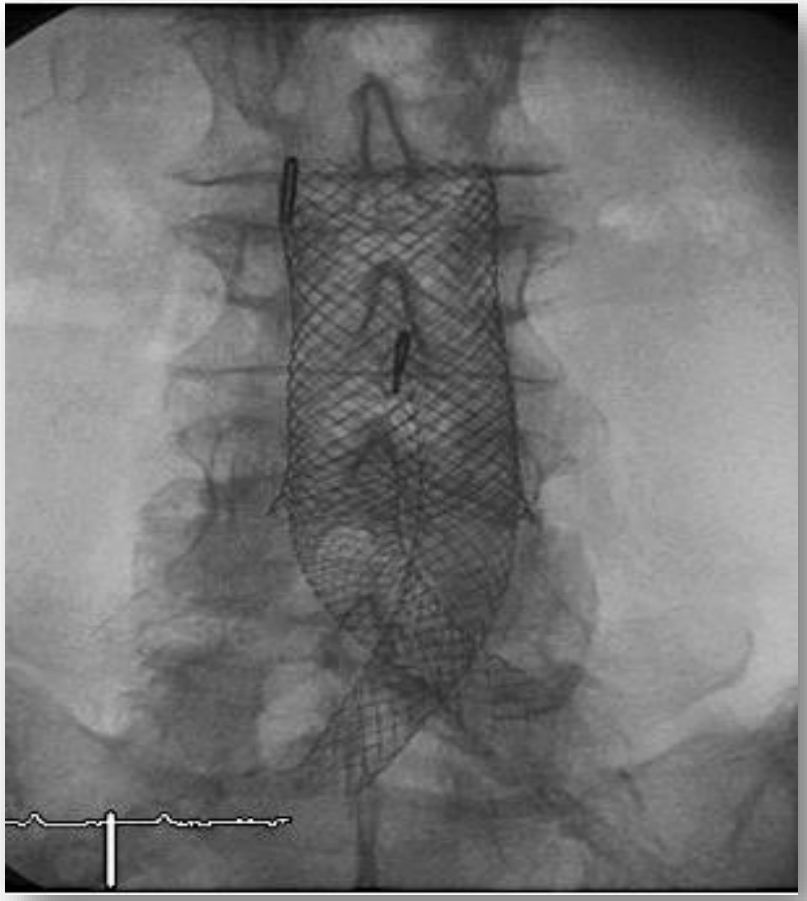
Percutaneous closure device failure

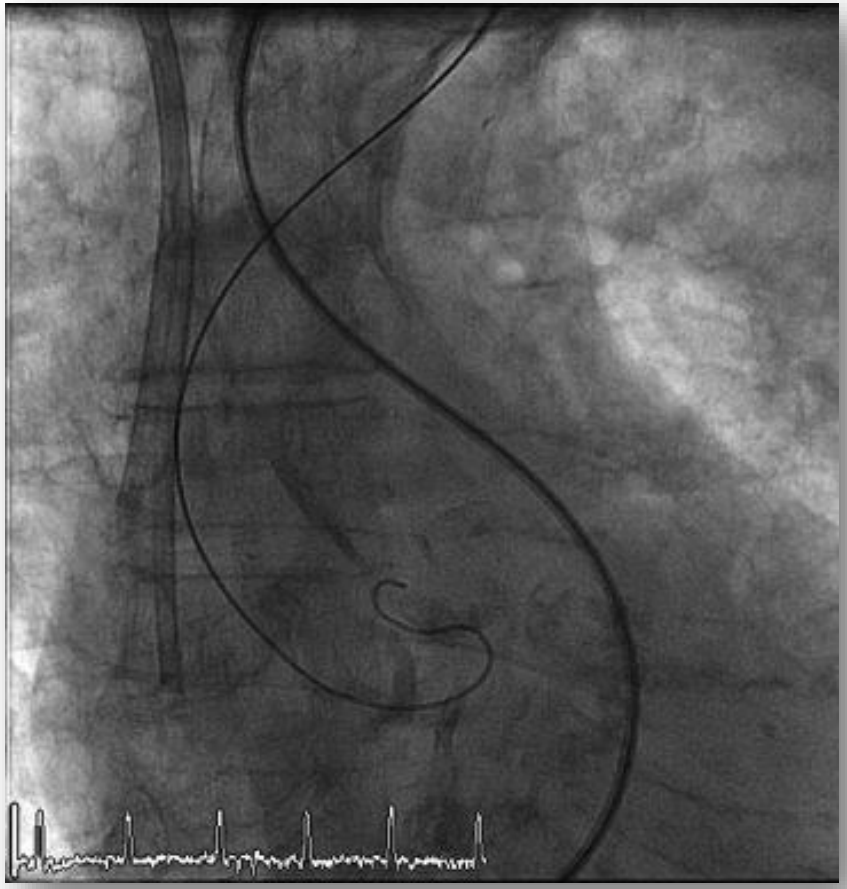
- Failure of a closure device to achieve hemostasis at the arteriotomy site leading to alternative treatment (other than manual compression or adjunctive endovascular ballooning)

How to prevent vascular complications ?

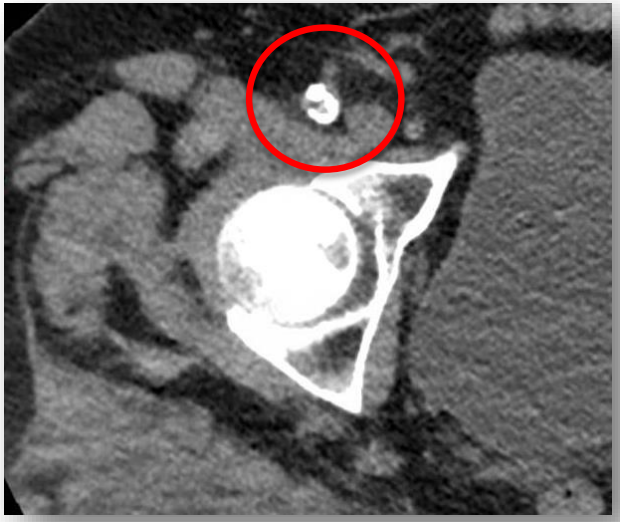
- ✓ Good screening (imaging)
- ✓ Use the SFAR
- ✓ Better profile of the sheath
- ✓ Technique of puncture
- ✓ Learning curve for closure devices

Vascular screening : Dont push the limits

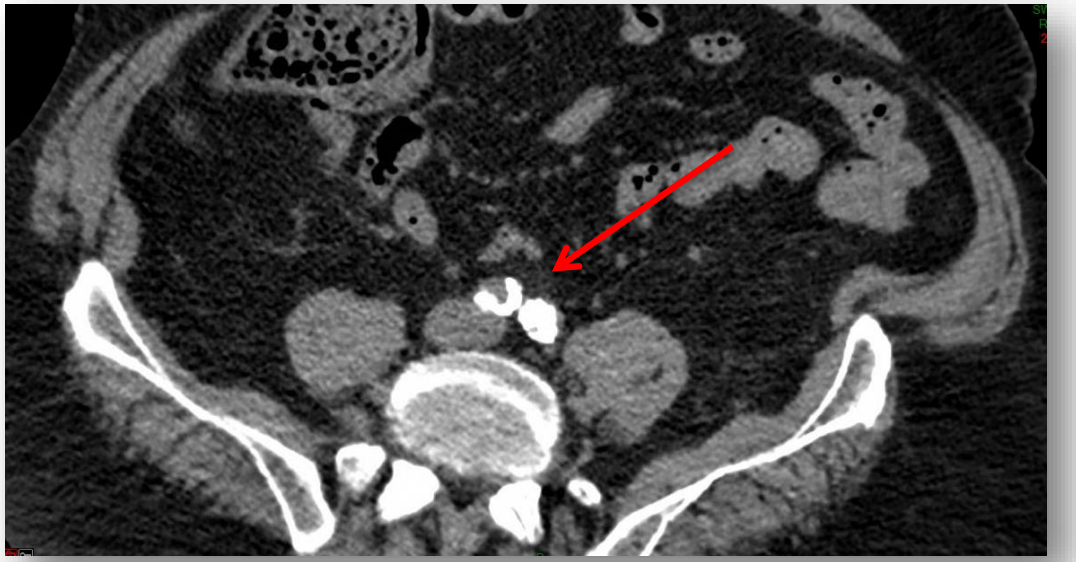




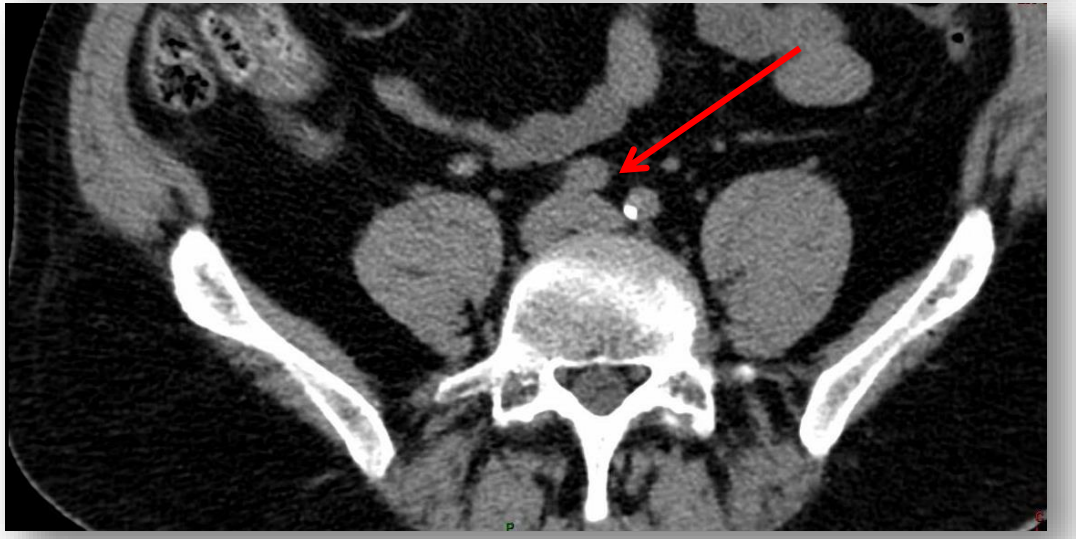
CT-scan no contrast



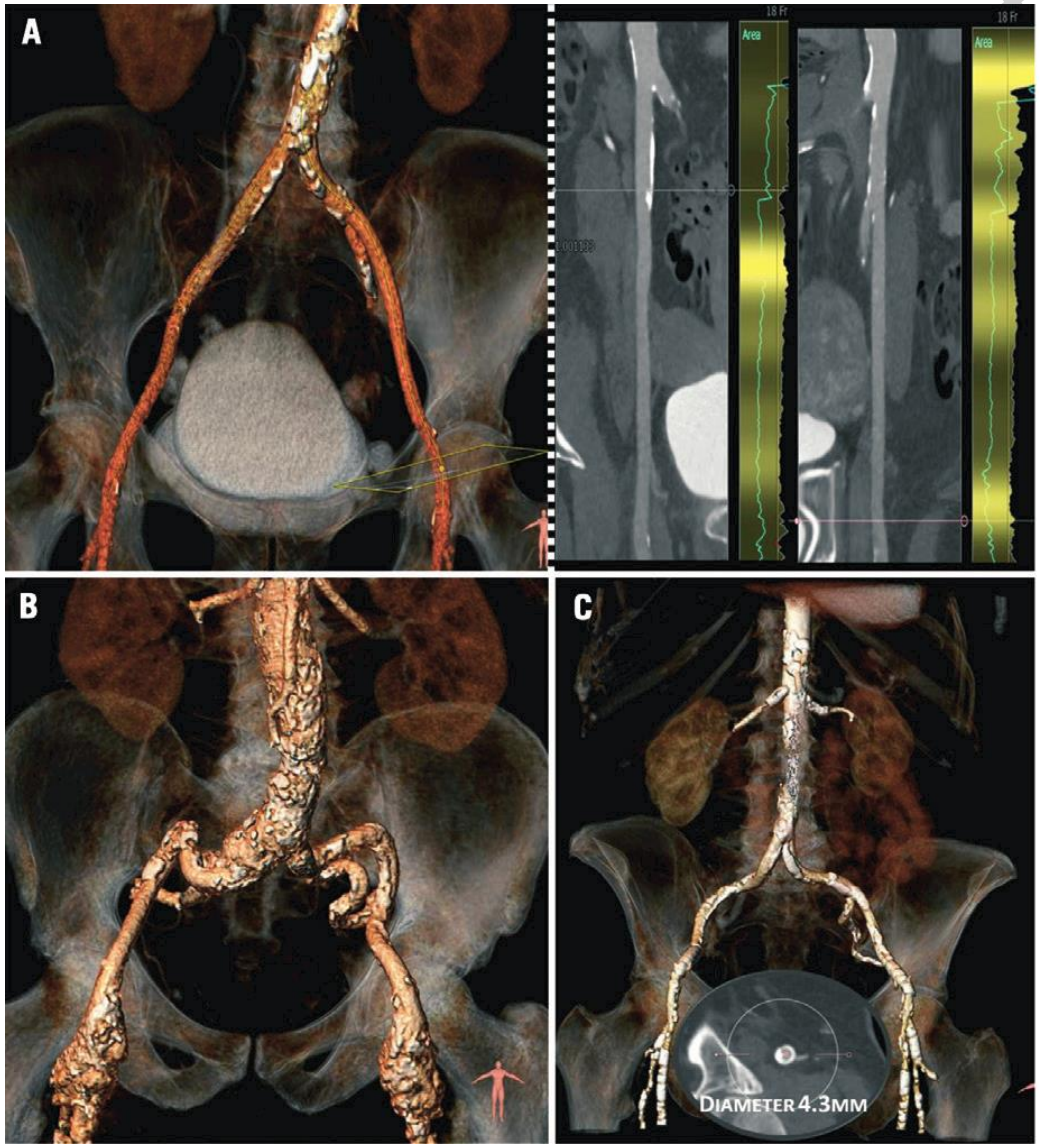
NO



YES



CT-scan with contrast



Preferred transfemoral access
– Low calcification
– Low tortuosity
– Sufficient diameter

Consider alternative access routes
– Severe circumferential calcification
– Severe tortuosity
– Femoral aneurysm
– Insufficient diameter

Stortecky, Eurointervention 2013

SFAR : Sheath Femoral Artery Ratio

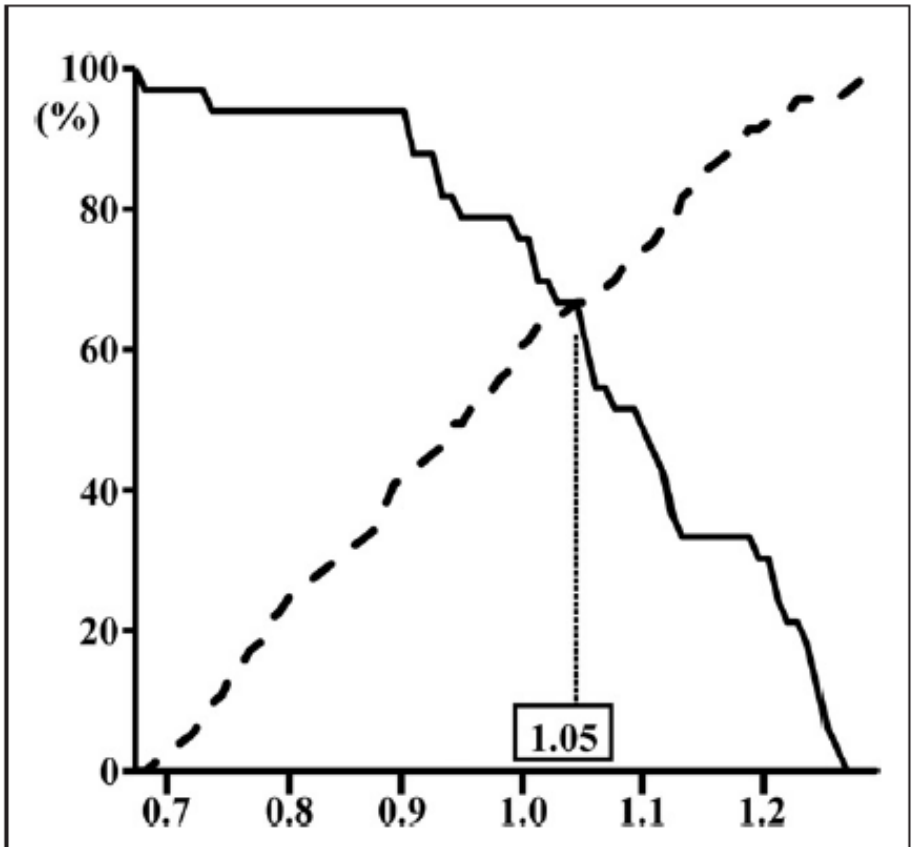


Figure 2. SFAR Threshold Predicts VARC Major Vascular Complications

The sensitivity and specificity curve identified the threshold sheath femoral artery ratio (SFAR) of 1.05 as predictive of VARC major vascular complications. **Solid line** = sensitivity; **broken line** = specificity. VARC = Valve Academic Research Consortium.

Hayashida et al, JACC Intv 2011;4:851-8

A SFAR > 1.05 predicts :

- Higher VARC major complications
- 30-day mortality

SFAR : ratio OD sheath and MLD FA

≥ 1.05

≥1.10 in absence of calcium

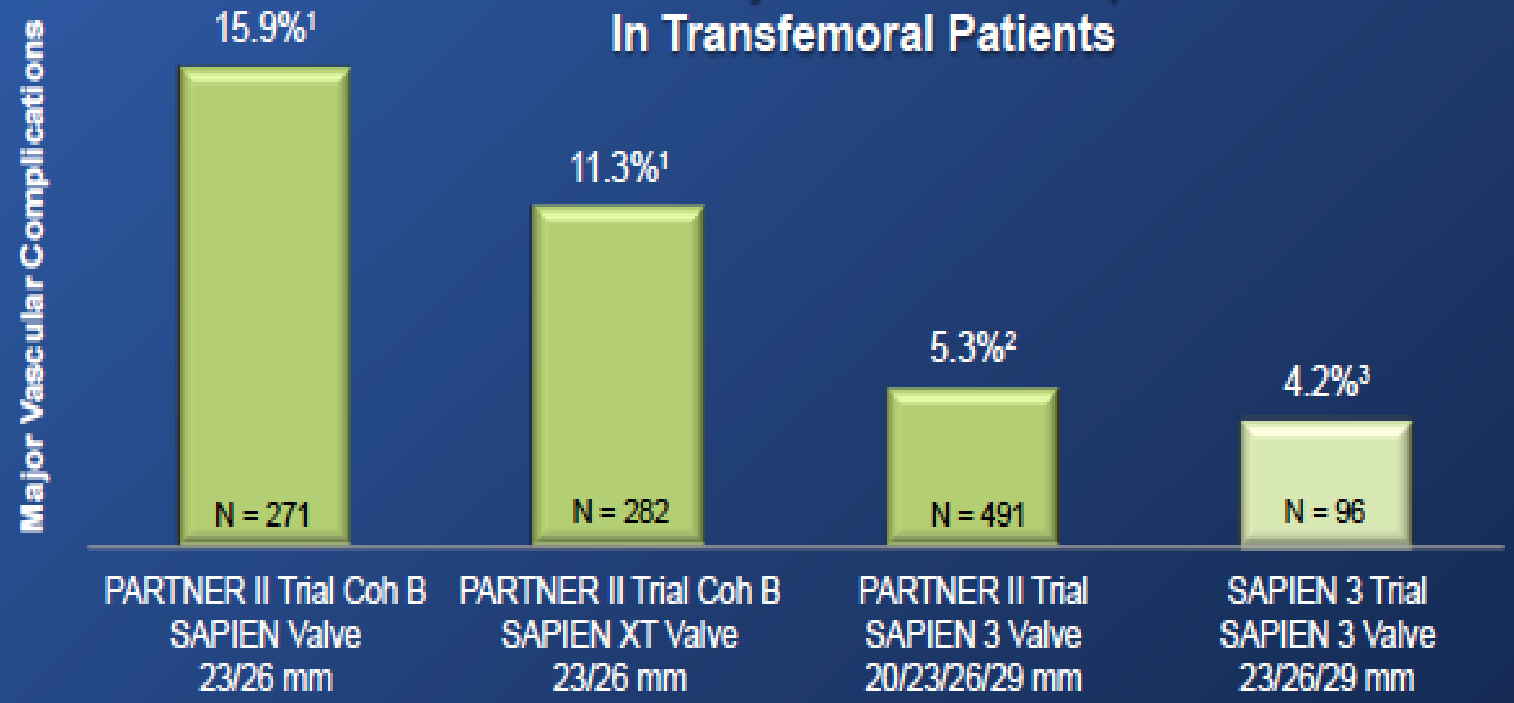
≥1.00 if circumferential calcification

Hayashida, JACC intv 2011

Access delivery sheath	Internal diameter	External diameter
Cook Medical Check-Flo®	18 Fr	7.2 mm
St. Jude Medical Ultimum™ UV	18 Fr	6.8 mm
Edwards RetroFlex 3 vascular sheath	22 Fr	8.4 mm
	24 Fr	9.2 mm
Edwards NovaFlex vascular sheath	18 Fr	7.2 mm
	19 Fr	7.5 mm
Edwards Lifesciences eSheath	16 Fr	6.6 mm
	18 Fr	7.2 mm
	20 Fr	7.8 mm
Terumo SoloPath® expandable introducer	18 Fr	4.3 mm/7.0 mm
	21 Fr	4.7 mm/8.0 mm

Stortecky, Eurointervention 2013

Reduction in Major Vascular Complications In Transfemoral Patients



			
Sheath	Edwards RetroFlex 3 Introducer Sheath Set	Edwards Expandable Introducer Sheath Set	Edwards eSheath Introducer Set
Sheath Size	22 / 24F	16 / 18F	14 / 16F
Minimum Vessel Access Diameter	7.0 / 8.0 mm	6.0 / 6.5 mm	5.5 / 6.0 mm

1. Data on file, Edwards Lifesciences
2. Kodali S., Clinical and Echocardiographic Outcomes at 30 Days with the SAPIEN 3 TAVR System in Inoperable, High-Risk and Intermediate-Risk AS Patients. Presented at ACC 2015, March 15, 2015; San Diego, California.
3. Webb J., Multicenter Evaluation of a Next-Generation Balloon-Expandable Transcatheter Aortic Valve. JACC, VOL .64,NO.21, pg.2238, 2014

Evolut Performance

Design Focus: Reduce Delivery Catheter Profile

~22 FR (OD)

18FR

CoreValve w/ 18FR Cook Sheath

~4 FR Reduction

14FR equiv. system (18FR OD)

18FR

CoreValve Evolut R w/ InLine Sheath

- 14 FR In-Line Sheath (true 14Fr)
- Or compatible with commercial 18 FR introducer

Popma J, TVT 2015

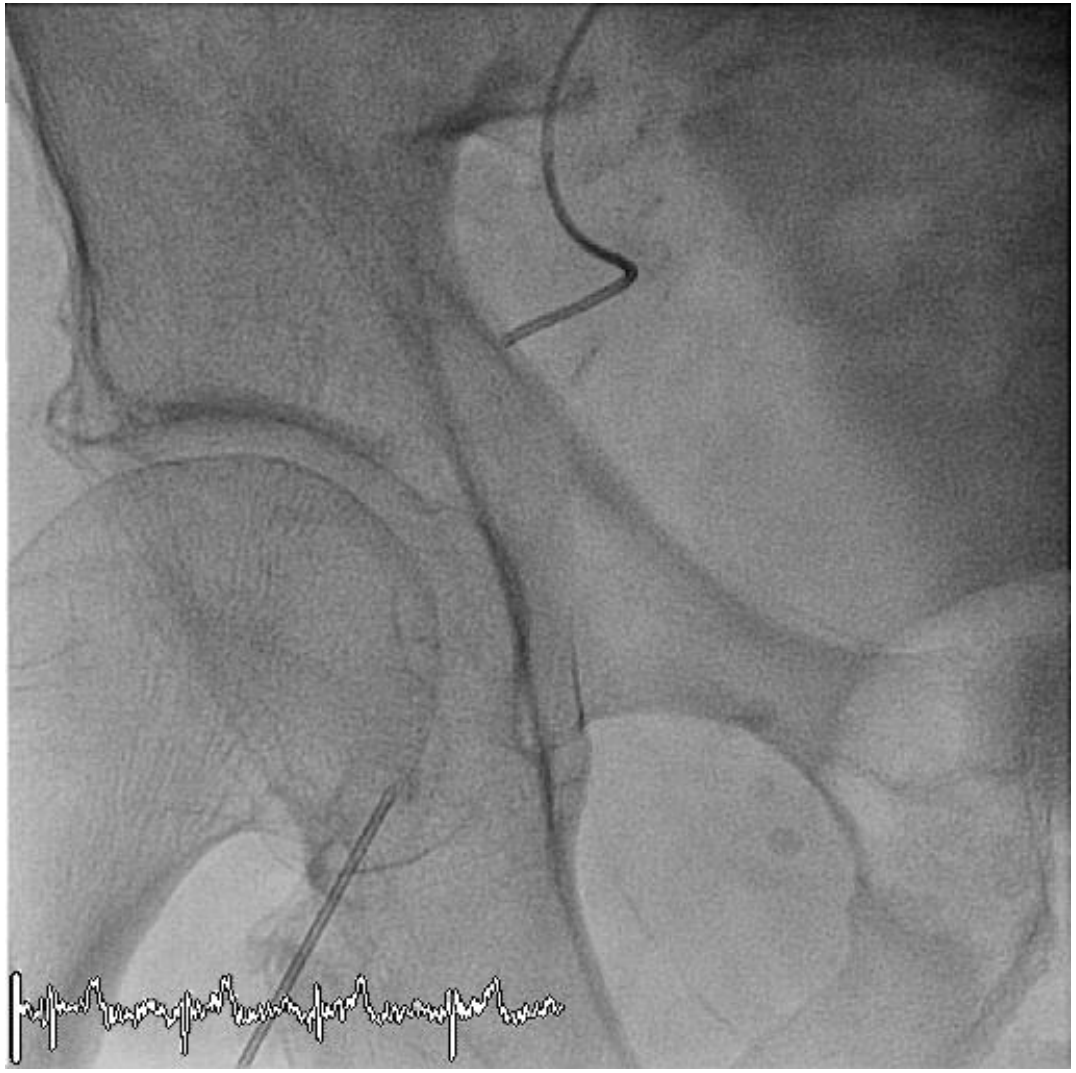
Technique of puncture

- ✓ Site of puncture
- ✓ Cross-over angio
- ✓ Insertion sheath on a stiff wire and under fluoroscopy

- ✓ Heparin after sheath insertion
- ✓ ACT monitoring > 250 sec

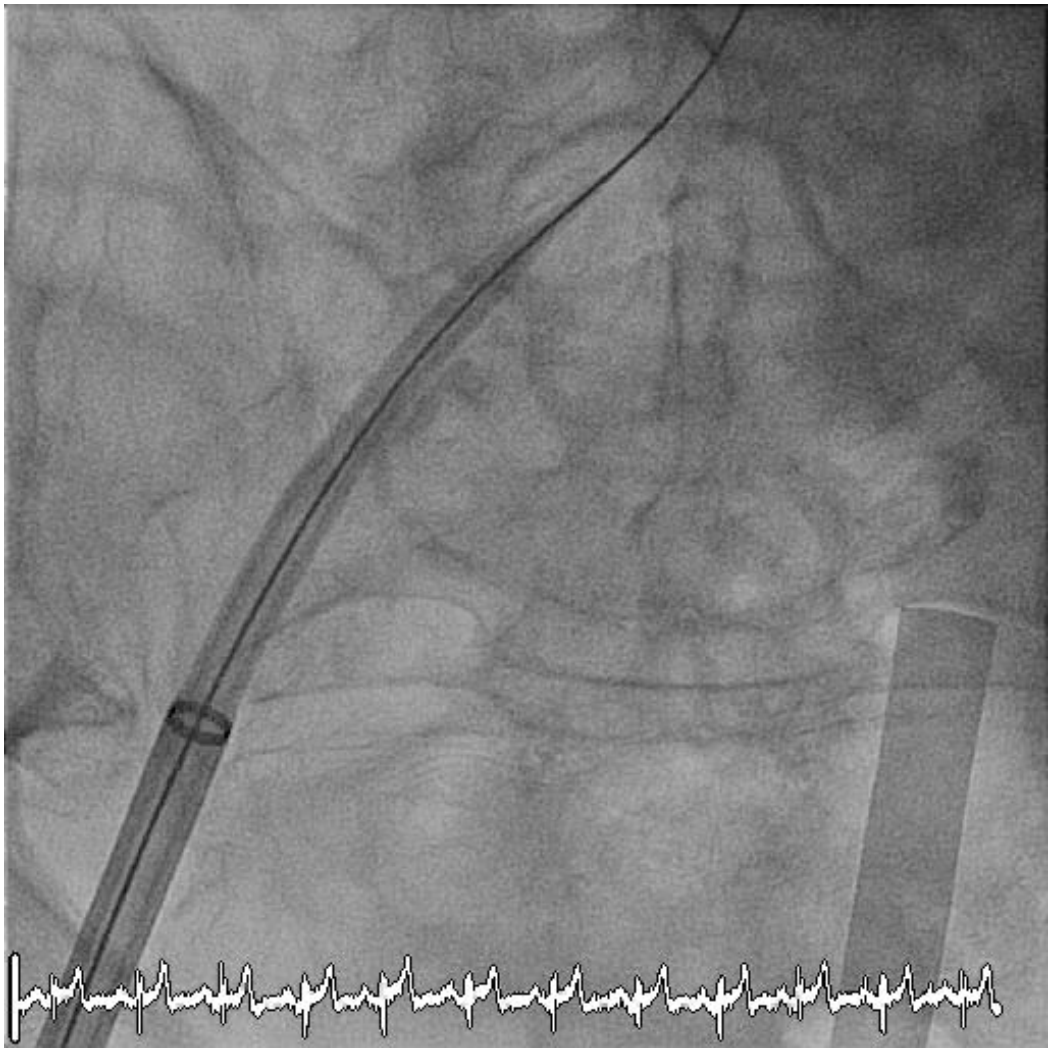
- ✓ Final angio
- ✓ covered stent available

Puncture site selection by cross-over angio



Common Femoral Artery

Sheath insertion on a stiff wire and under fluoroscopic guidance

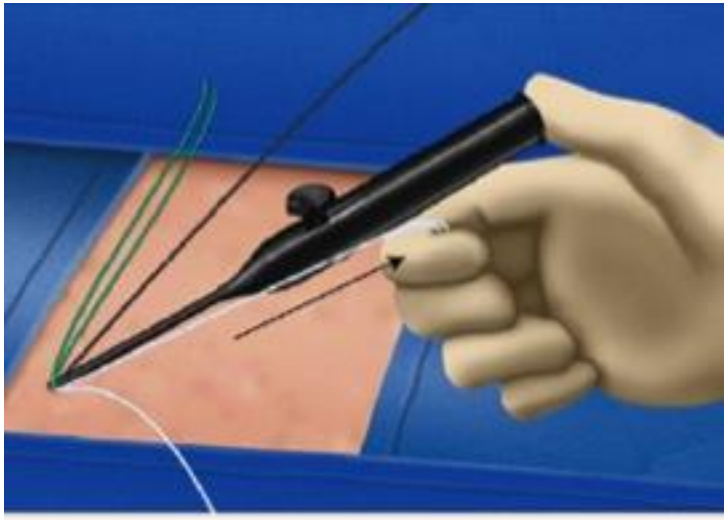


Systematic final angio

Rupture of the iliac artery treated by covered stent (from main access site LFA)

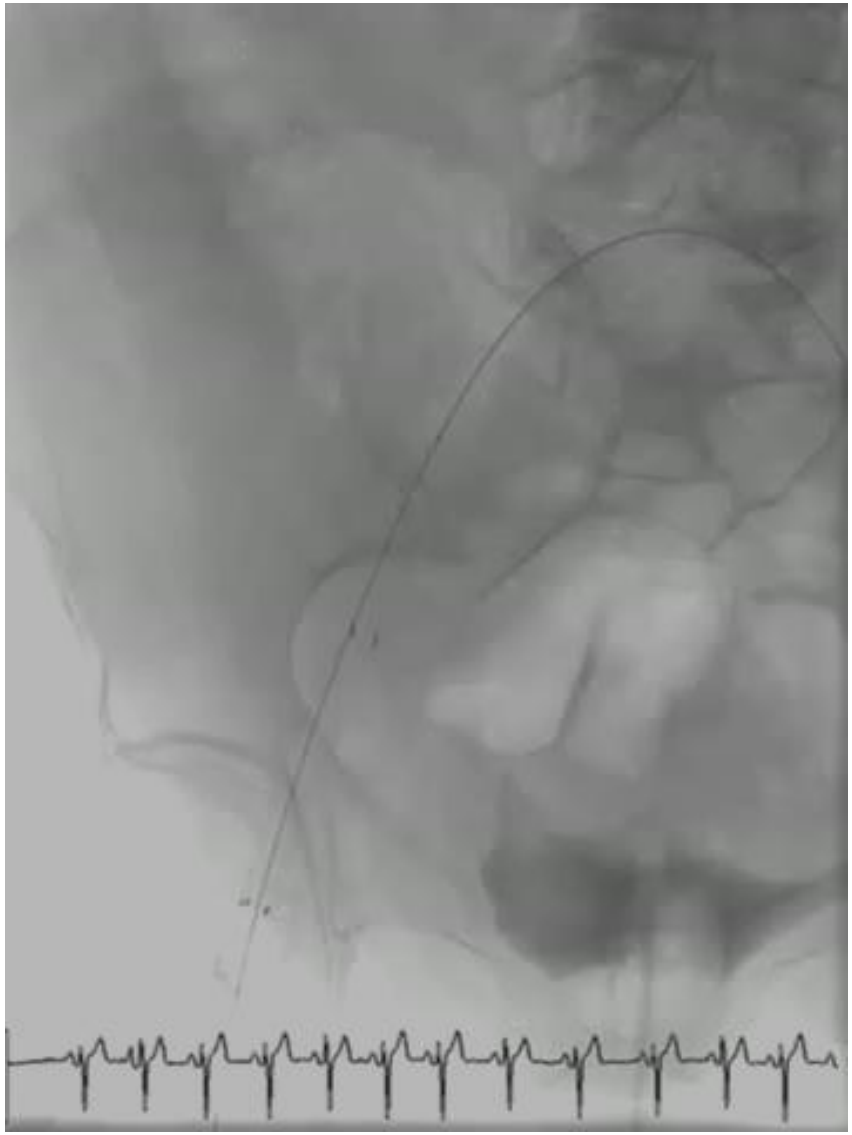
Closure devices : learning curve

Puncture site common femoral artery



Prostar failure :
Puncture site too high
CFA – EIA
Retroperitoneal bleeding

Prostar failure : minor vascular complication

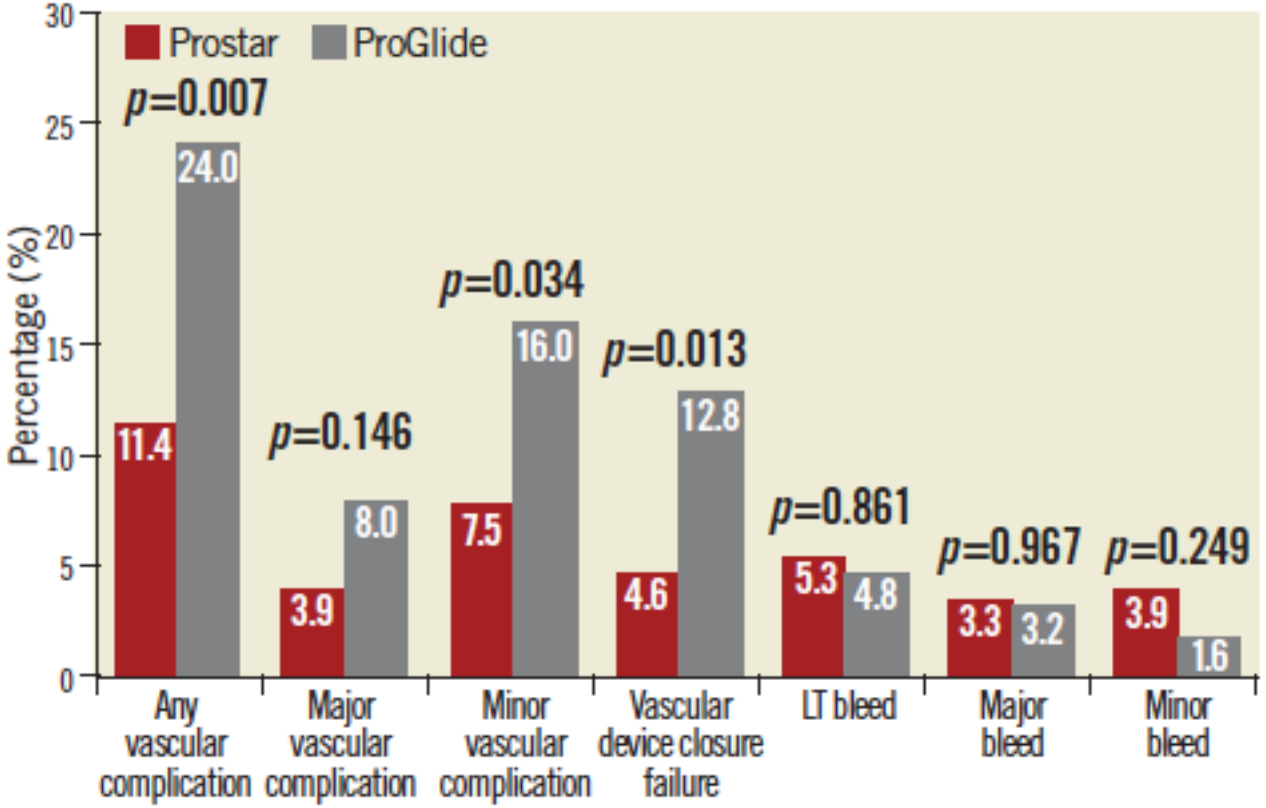


Covered stent by a cross-over technique

Comparison of suture-based vascular closure devices in transfemoral transcatheter aortic valve implantation

Marco Barbanti[1]*, MD; Piera Capranzano[1], MD; Yohei Ohno[1], MD; Simona Gulino[1], MD; Carmelo Sgroi[1], MD; Sebastiano Immè[1], MD; Claudia Tamburino[1], MD; Stefano Cannata[1], MD; Martina Patanè[1], MD; Daniele Di Stefano[1], MD; Denise Todaro[1], MD; Emanuela Di Simone[1], MD; Wanda Deste[1], MD; Giuseppe Gargiulo[1], MD; Davide Capodanno[1], MD, PhD; Carmelo Grasso[1], MD; Corrado Tamburino[1,2], MD, PhD

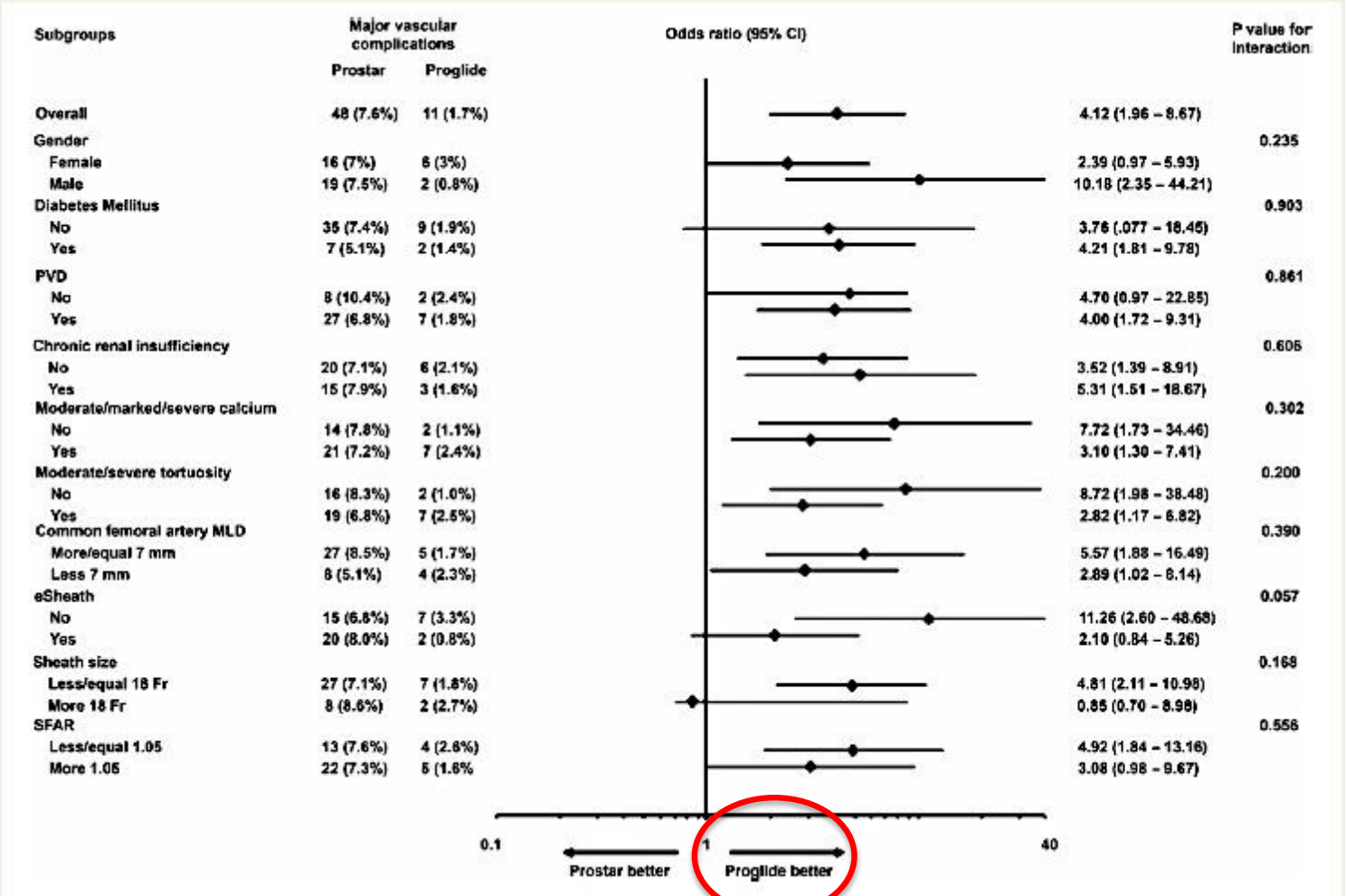
EuroIntervention 2015;11:690-697

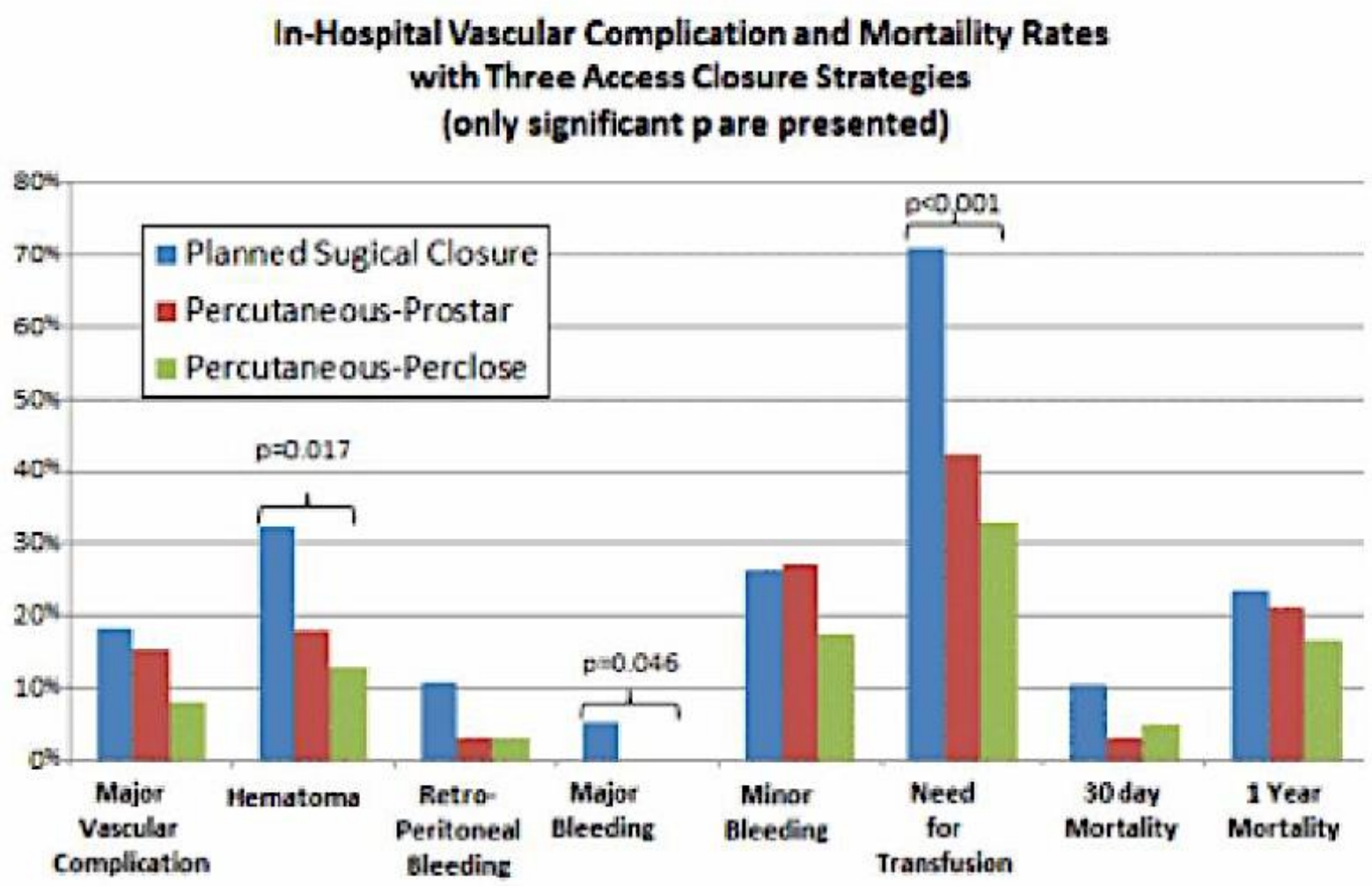


Barbash et al, Eur H J 2915

Comparison of vascular closure devices for access site closure after transfemoral aortic valve implantation

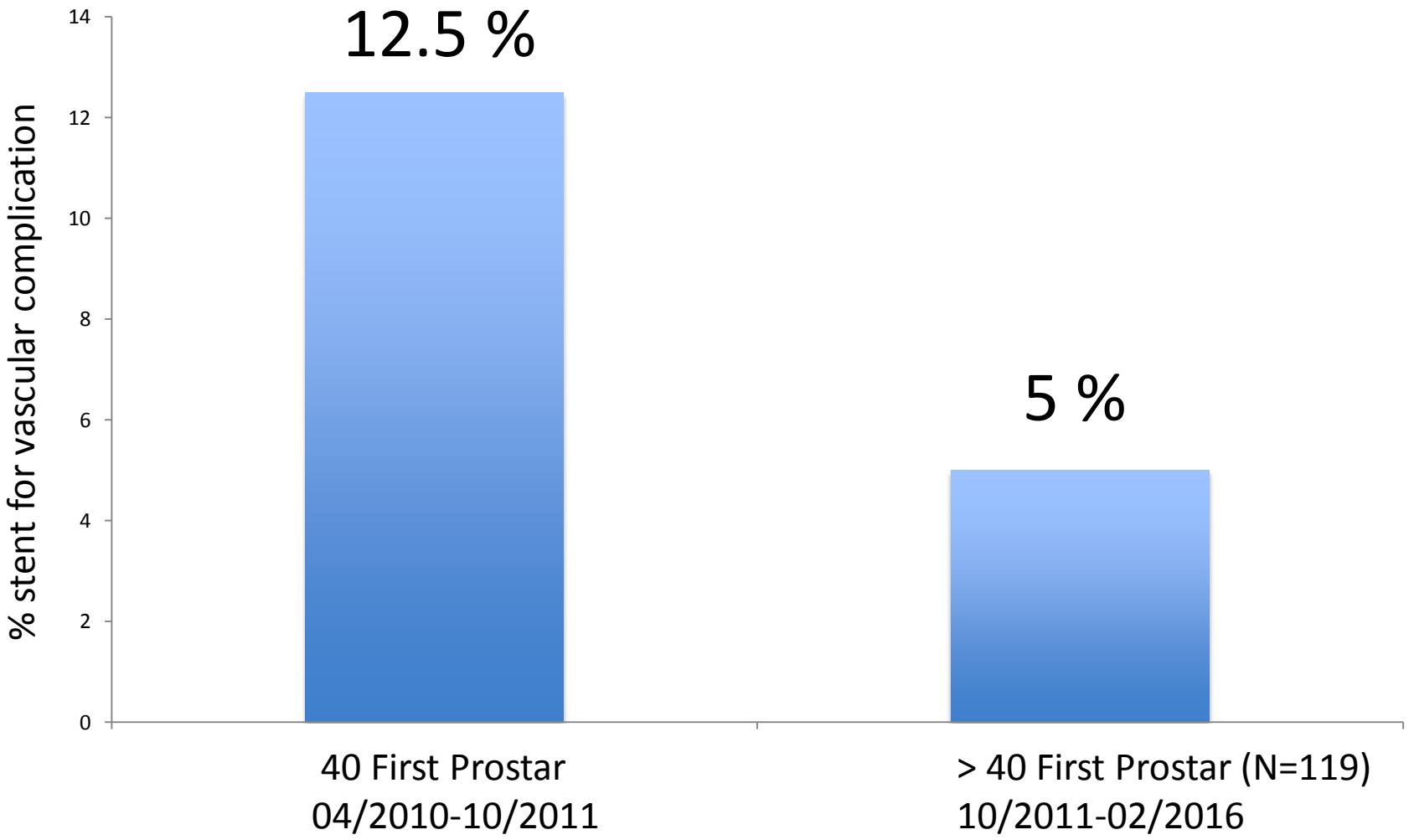
Israel M. Barbash[1†*], Marco Barbanti[2†], John Webb[3], Javier Molina-Martin De Nicolas[4], Yigal Abramowitz[5], Azeem Latib[6], Caroline Nguyen[7], Florian Deuschl[8], Amit Segev[1], Konstantinos Sideris[9], Sergio Buccheri[2], Matheus Simonato[3], Francesco Della Rosa[4], Corrado Tamburino[2], Hasan Jilaihawi[5], Tadashi Miyazaki[6], Dominique Himbert[7], Niklas Schofer[8], Victor Guetta[1], Sabine Bleiziffer[9], Didier Tchetche[4], Sebastiano Immè[2], Raj R. Makkar[5], Alec Vahanian[7], Hendrik Treede[8], Rüdiger Lange[9], Antonio Colombo[6], and Danny Dvir[3]





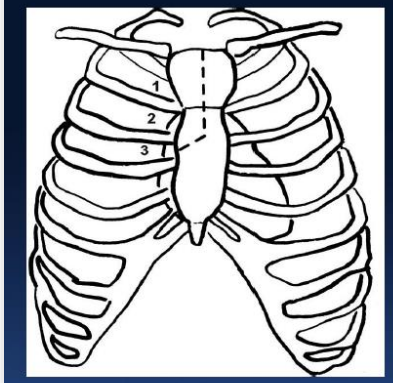
WHC Minha et al. TCT 2013

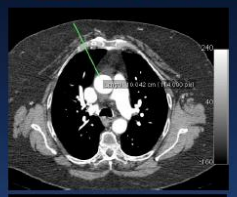
Learning curve : CUSL experience



Alternative access : importance of imaging and preparation of the case

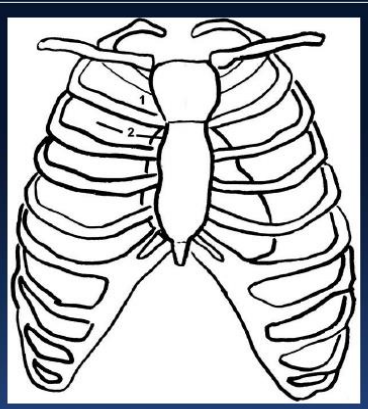
Mini-Sternotomy

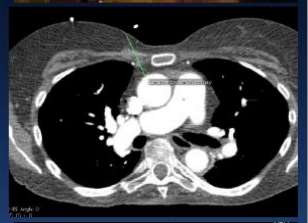




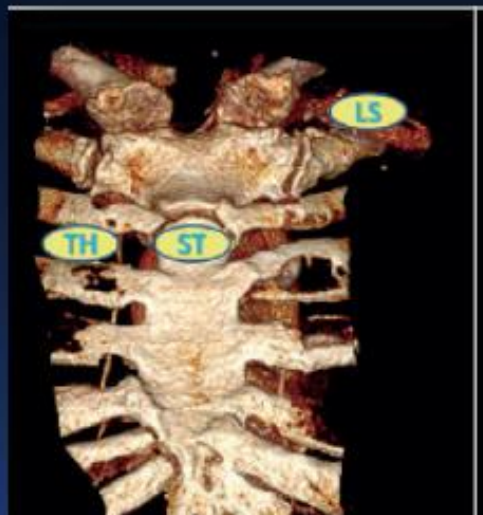
Aorta in Midline
Obese patients
Poor lung function

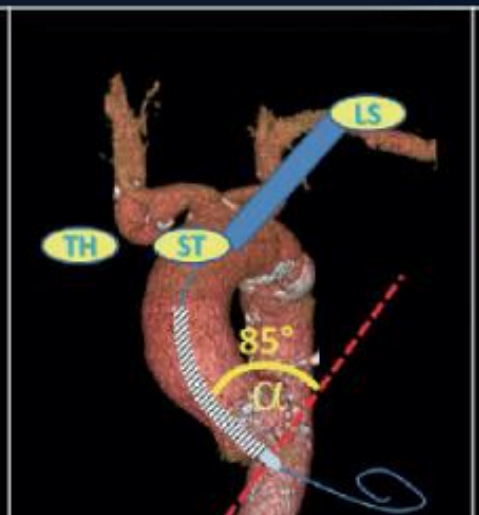
Mini-Thoracotomy

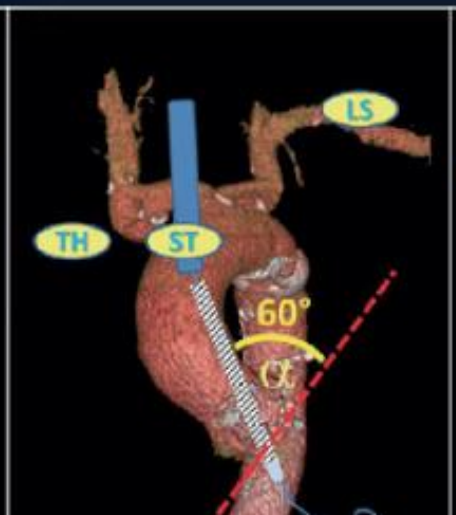


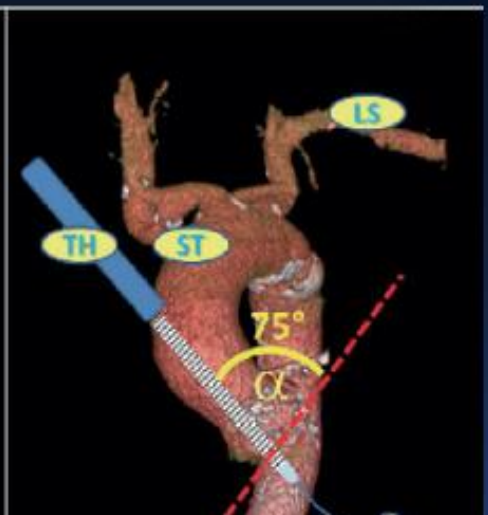


Aorta on right
Redo with patent graft







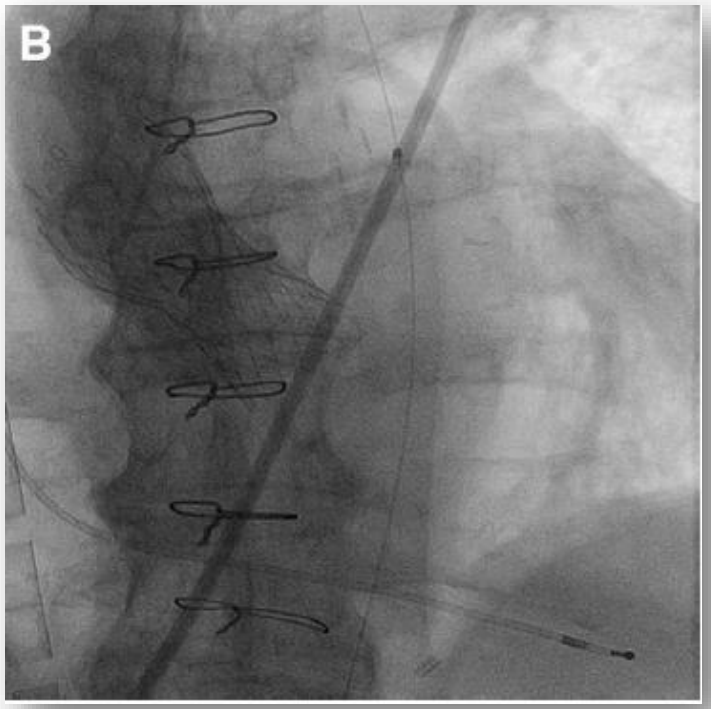


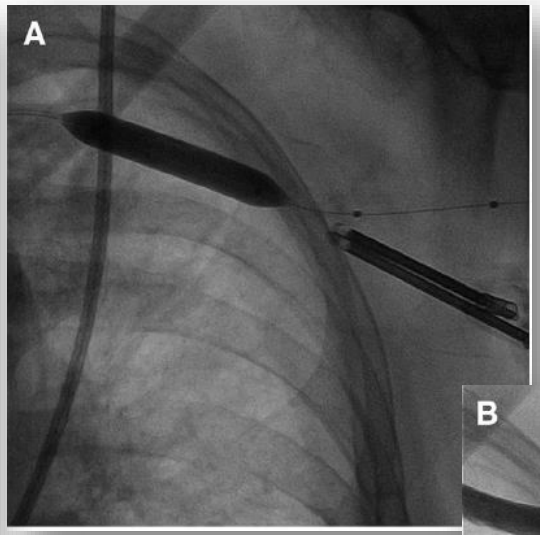
V Bapat, TVT 2015

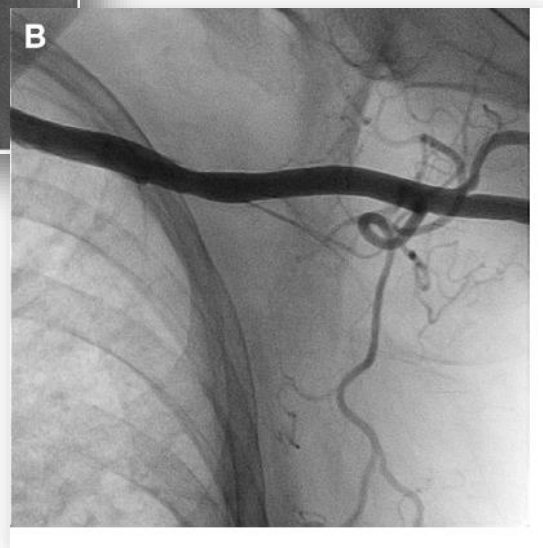
Direct Percutaneous Access Technique for Transaxillary Transcatheter Aortic Valve Implantation

"The Hamburg Sankt Georg Approach"

Ulrich Schäfer, MD,* Yen Ho, MD,† Christian Frerker, MD,* Dimitry Schewel, MD,* Damian Sanchez-Quintana, MD,‡ Joachim Schofer, MD,§ Klaudija Bijuklic, MD,§ Felix Meincke, MD,* Thomas Thielsen, MD,* Felix Kreidel, MD,* Karl-Heinz Kuck, MD*







Transcatheter aortic valve implantation through carotid artery access under local anaesthesia†

Alexandre Azmoun*, Nicolas Amabile, Ramzi Ramadan, Saïd Ghostine, Christophe Caussin, Sahbi Fradi, François Raoux, Philippe Brenot, Remi Nottin and Philippe Deleuze

European J card Thorac Surg 2014;46:693-698

Table 3: Early safety end points (at 30 days)

	n = 19
All	
Intraoperative death (aortic annulus rupture), *n* (%)	1 (5.3)
Cardiovascular death (MOF), *n* (%)	1 (5.3)
Stroke	0
Life-threatening, disabling or major bleeding	0
Acute kidney injury	0
Myocardial infarction	0
Vascular access-site complication	0
Valve-related complication	0
New permanent pacemaker implantation, *n* (%)	3 (15.8)
Sepsis	0
Mean aortic transvalvular pressure gradient, mmHg	8 ± 4
Moderate paravalvular leak, *n* (%)	1 (5.3)

Minimizing vascular complications

- ✓ Prevention is key of success
- ✓ Preparation of the case
- ✓ « Plan B » just in case
- ✓ Treatment of complications as low invasive as possible (balloon, covered stent)
- ✓ Learning curve
- ✓ Profile of the sheaths and delivery catheters