



ROMA 2026

CONGRESSO
25 – 27 Giugno



**Come rendere la TAVI meno invasiva e
completamente endovascolare in tutti i pazienti**

Dr. Enrico Romagnoli

**Fondazione Policlinico Universitario
Agostino Gemelli, IRCCS, Roma**

TAVI “lite” program - background



The “Big Five” complications after TAVI

TABLE 4 Association of Short-Term Complications With Outcomes

Complications in 30 Days After TAVR	1-Year Mortality	
	Adjusted HR (95% CI)	p Value
Major stroke	5.38 (3.05 to 9.50)	<0.001
Minor stroke	0.57 (0.14 to 2.29)	0.425
Life-threatening bleed	1.60 (1.03 to 2.49)	0.038
Major bleed	1.46 (1.08 to 1.97)	0.013
Major vascular event	0.77 (0.46 to 1.27)	0.302
New pacemaker	0.99 (0.65 to 1.49)	0.948
Acute kidney injury stage 3	4.92 (2.74 to 8.84)	<0.001
Moderate/severe paravalvular leak	1.88 (1.29 to 2.73)	0.001
Mild paravalvular leak	1.26 (0.96 to 1.65)	0.091

All models included all complications and also adjusted for age, sex, prior coronary artery bypass graft, percutaneous coronary intervention, mortality risk score, nontransfemoral access, and baseline KCCQ-OS score. Negative KCCQ-OS estimates indicate a decrease in quality of life. A 5-point change in KCCQ-OS is considered clinically significant.

CI = confidence interval; HR = hazard ratio; TAVR = transcatheter aortic valve replacement.

SPECIAL ARTICLE

VALVULAR HEART DISEASE

Valve Academic Research Consortium 3: Updated Endpoint Definitions for Aortic Valve Clinical Research



Major



Minor

TABLE 5 Bleeding and transfusions*

Overt bleeding† that fulfils one of the following criteria:

Type 1

- Overt bleeding that does not require surgical or percutaneous intervention, but does require medical intervention by a health care professional, leading to hospitalization, an increased level of care, or medical evaluation (BARC 2)
- Overt bleeding that requires a transfusion of 1 unit of whole blood/red blood cells‡ (BARC 3a)

Type 2

- Overt bleeding that requires a transfusion of 2-4 units of whole blood/red blood cells‡ (BARC 3a)
- Overt bleeding associated with a haemoglobin drop of >3 g/dL (>1.86 mmol/L) but <5 g/dL (<3.1 mmol/L) (BARC 3a)

Type 3

- Overt bleeding in a critical organ, such as intracranial, intraspinal, intraocular, pericardial (associated with haemodynamic compromise/ tamponade and necessitating intervention), or intramuscular with compartment syndrome (BARC 3b, BARC 3c)
- Overt bleeding causing hypovolemic shock or severe hypotension (systolic blood pressure <90 mmHg lasting >30 min and not responding to volume resuscitation) or requiring vasopressors or surgery (BARC 3b)
- Overt bleeding requiring reoperation, surgical exploration, or re-intervention for the purpose of controlling bleeding (BARC 3b, BARC 4)
- Post-thoracotomy chest tube output ≥2 L within a 24-h period (BARC 4)
- Overt bleeding requiring a transfusion of ≥5 units of whole blood/red blood cells (BARC 3a) ‡
- Overt bleeding associated with a haemoglobin drop ≥5 g/dL (>3.1 mmol/L) (BARC 3b).

Type 4

- Overt bleeding leading to death. Should be classified as:
 - **Probable:** Clinical suspicion (BARC 5a)
 - **Definite:** Confirmed by autopsy or imaging (BARC 5b)

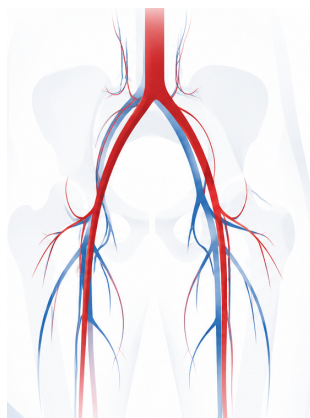


TABLE 6 Vascular and access-related complications*

Vascular complications‡

Major

One of the following:

- Aortic dissection or aortic rupture
- Vascular (arterial or venous) injury (perforation, rupture, dissection, stenosis, ischaemia, arterial or venous thrombosis including pulmonary embolism, arteriovenous fistula, pseudoaneurysm, haematoma, retroperitoneal haematoma, infection) or compartment syndrome resulting in death, VARC type ≥2 bleeding, limb or visceral ischaemia, or irreversible neurologic impairment
- Distal embolization (non-cerebral) from a vascular source resulting in death, amputation, limb or visceral ischaemia, or irreversible end-organ damage
- Unplanned endovascular or surgical intervention resulting in death, VARC type ≥2 bleeding, limb or visceral ischaemia, or irreversible neurologic impairment
- Closure device failure‡ resulting in death, VARC type ≥2 bleeding, limb or visceral ischaemia, or irreversible neurologic impairment

Minor

One of the following:

- Vascular (arterial or venous) injury (perforation, rupture, dissection, stenosis, ischaemia, arterial or venous thrombosis including pulmonary embolism, arteriovenous fistula, pseudoaneurysm, haematoma, retroperitoneal haematoma, infection) *not* resulting in death, VARC type ≥2 bleeding, limb or visceral ischaemia, or irreversible neurologic impairment
- Distal embolization treated with embolectomy and/or thrombectomy, *not* resulting in death, amputation, limb or visceral ischaemia, or irreversible end-organ damage
- Any unplanned endovascular or surgical intervention, ultra-sound guided compression, or thrombin injection, *not* resulting in death, VARC type ≥2 bleeding, limb or visceral ischaemia, or irreversible neurologic impairment
- Closure device failure‡ *not* resulting in death, VARC type ≥2 bleeding, limb or visceral ischaemia, or irreversible neurologic impairment

Access-related non-vascular complications

Major

One of the following:

- Non-vascular structure, non-cardiac structure§ perforation, injury, or infection resulting in death, VARC type ≥2 bleeding, irreversible nerve injury or requiring unplanned surgery or percutaneous intervention
- Non-vascular access site (e.g. trans-apical left ventricular) perforation, injury, or infection resulting in death, VARC type ≥2 bleeding, irreversible nerve injury or requiring unplanned surgery or percutaneous intervention

Minor

One of the following:

- Non-vascular structure, non-cardiac structure§ perforation, injury, or infection *not* resulting in death, VARC type ≥2, irreversible nerve injury, or requiring unplanned surgery or percutaneous intervention
- Non-vascular access site (e.g. trans-apical left ventricular) perforation, injury, or infection *not* resulting in death, VARC type ≥2 bleeding, irreversible nerve injury or requiring unplanned surgery or percutaneous intervention



ORIGINAL RESEARCH

FOCUS ON TRANSCATHETER AORTIC VALVE REPLACEMENT

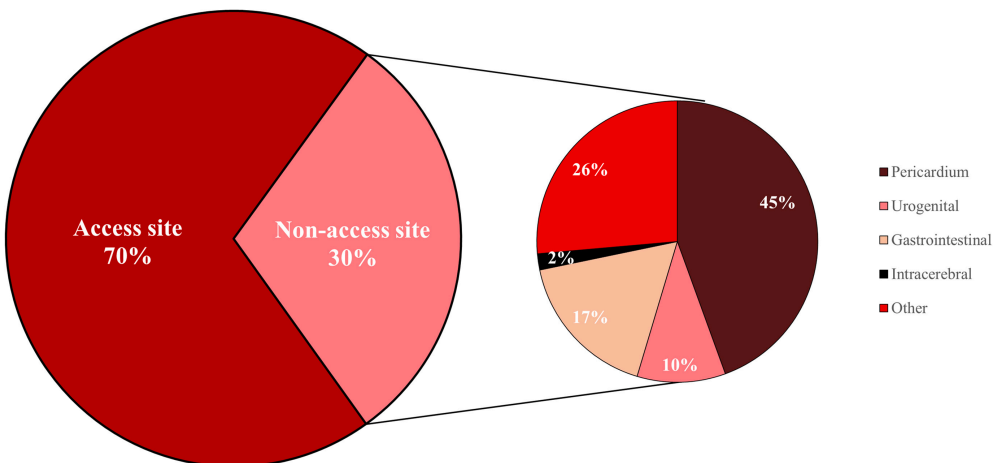
Bleeding in Patients Undergoing Transfemoral Transcatheter Aortic Valve Replacement

Incidence, Trends, Clinical Outcomes, and Predictors

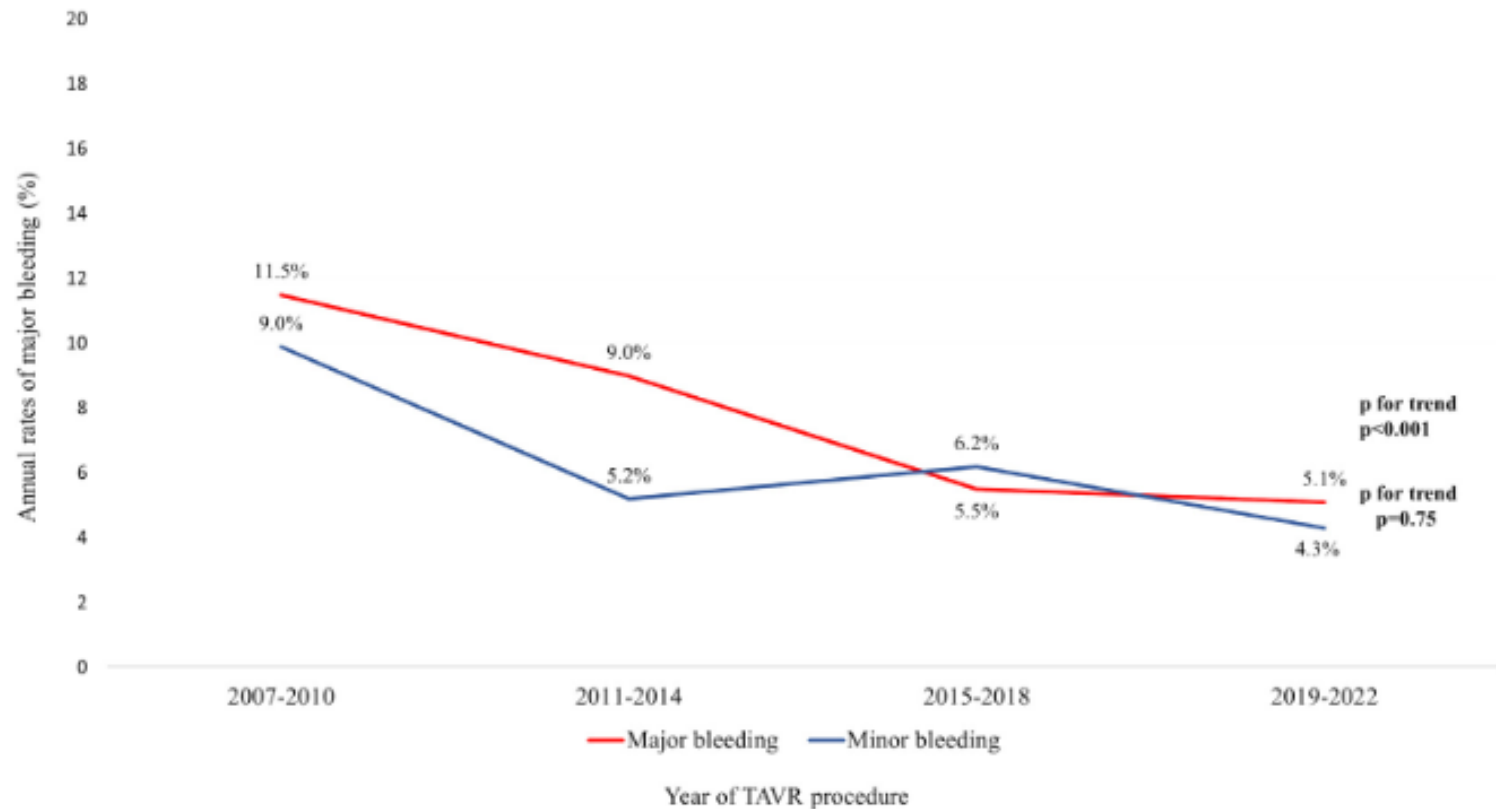
Astrid C. van Nieuwkerk, MD,^{a,*} Hugo M. Aarts, MD,^{a,b,*} Kimberley I. Hemelrijk, MD,^a Tomás Cantón, MD,

23,562 TF-TAVR between 2007 and 2022

Major bleeding 6.6%



Bleedings and Vascular Complications (related with primary or secondary access) still represent a major clinical issue in patients undergoing transfemoral TAVI.





ORIGINAL RESEARCH

FOCUS ON TRANSCATHETER AORTIC VALVE REPLACEMENT

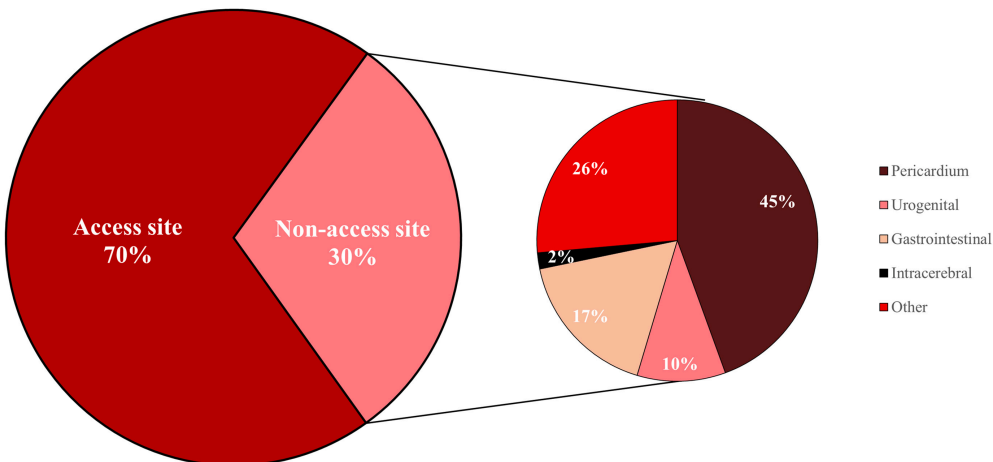
Bleeding in Patients Undergoing Transfemoral Transcatheter Aortic Valve Replacement

Incidence, Trends, Clinical Outcomes, and Predictors

Astrid C. van Nieuwkerk, MD,^{a,*} Hugo M. Aarts, MD,^{a,b,*} Kimberley I. Hemelrijk, MD,^a Tomás Cantón, MD,^c

23,562 TF-TAVR between 2007 and 2022

Major bleeding 6.6%



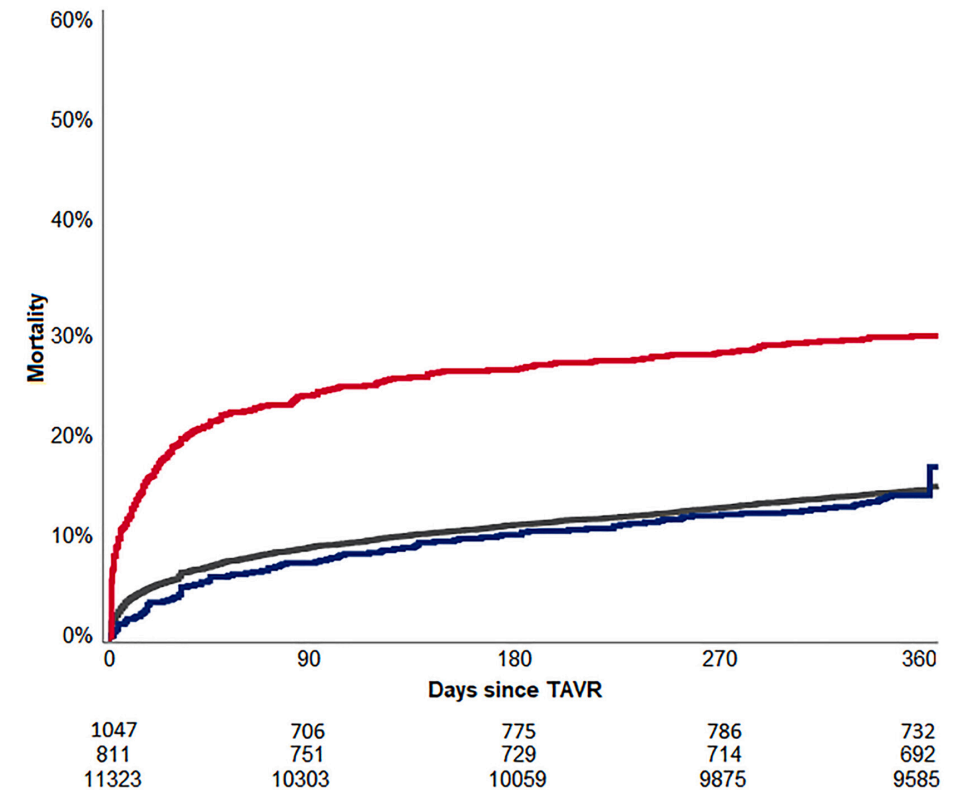
Bleedings and Vascular Complications (related with primary or secondary access)



still represent a major clinical issue in patients undergoing transfemoral TAVI.

Bleeding severity

- Major
- Minor
- No bleeding



No at risk
Major bleeding
Minor bleeding
No bleeding

TAVI “lite” program - background



TAVI vascular risk

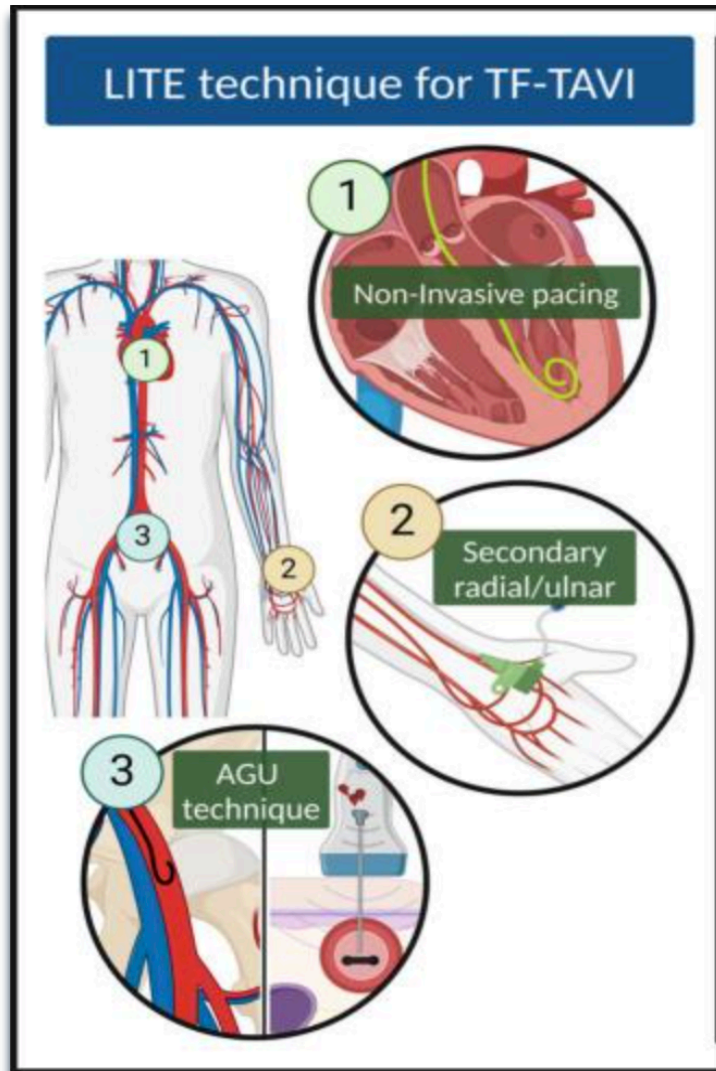
Multiple arterial access

Large-bore arterial access for device delivery

Advanced age and comorbidities of most patients



TAVI “lite” program - **rational**e



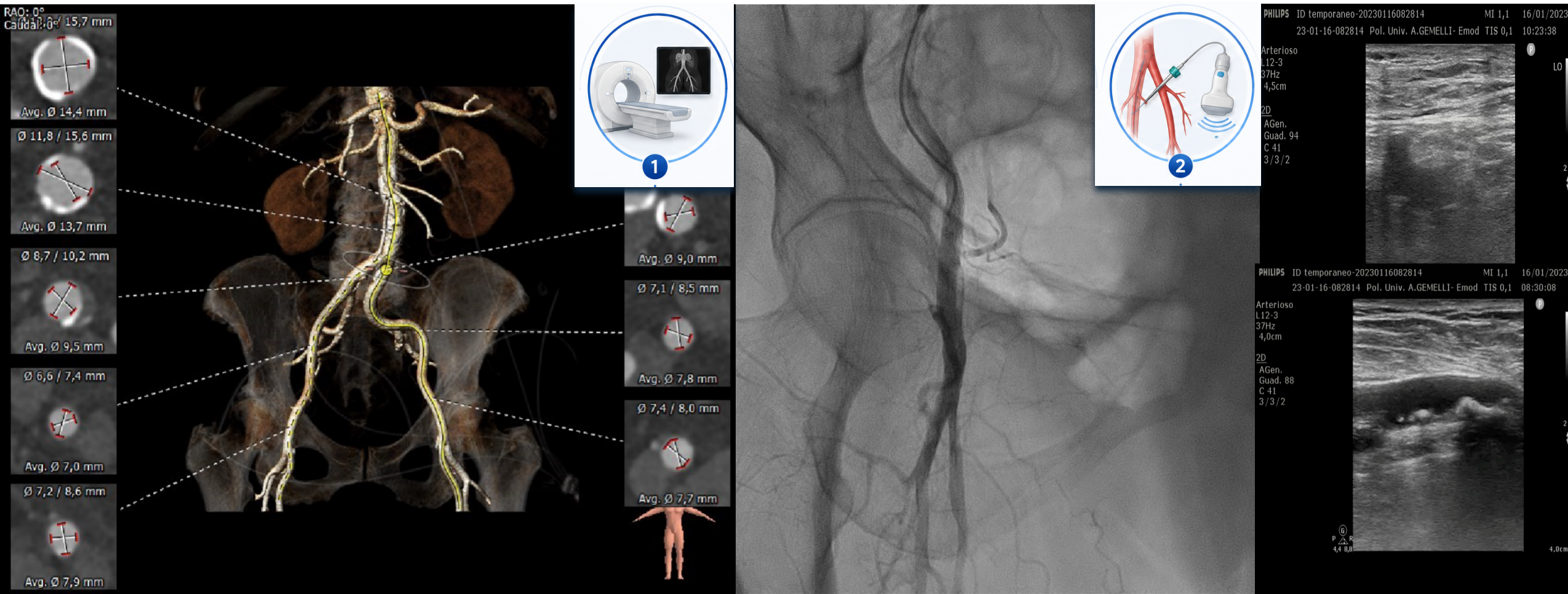
APPROCCIO LITE

LOW-IMPACT TRANSFEMORAL APPROACH





Precise TAVR access puncture using angiographic-guidewire-ultrasound guidance

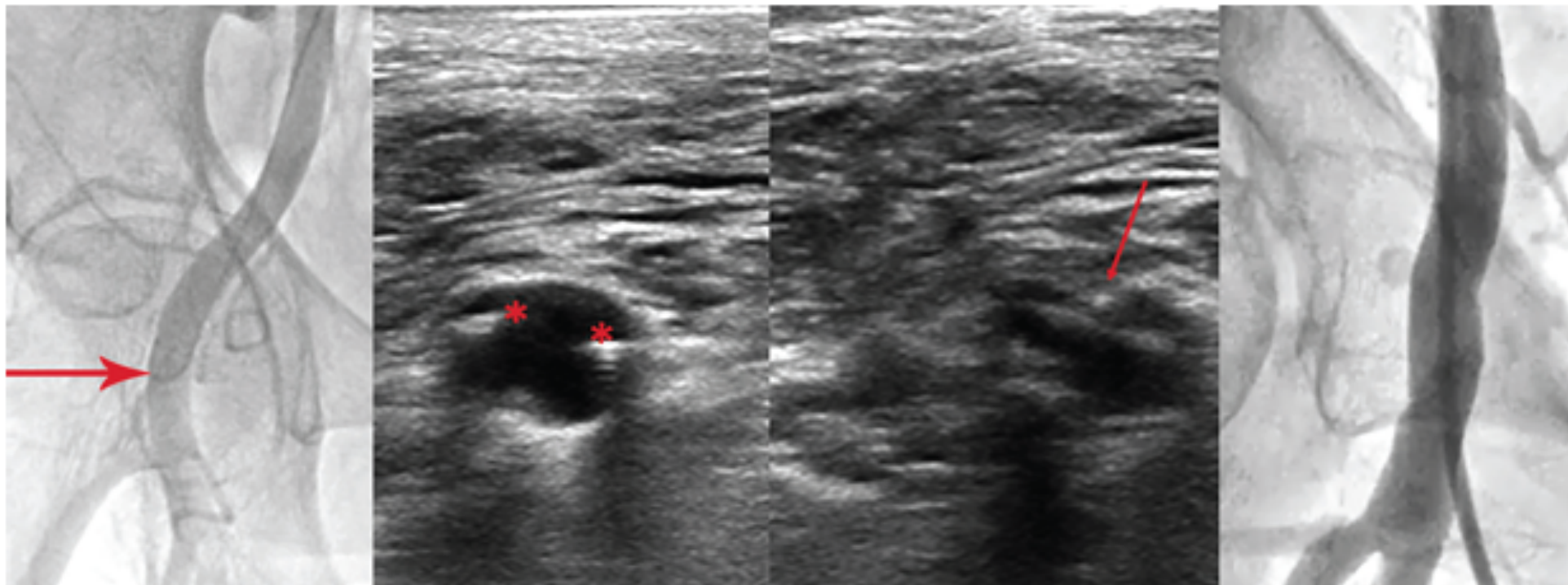




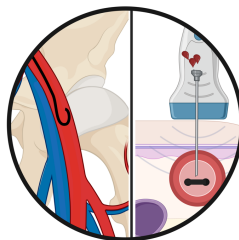
Precise TAVR access puncture using angiographic-guidewire-ultrasound guidance

BRIEF COMMUNICATION

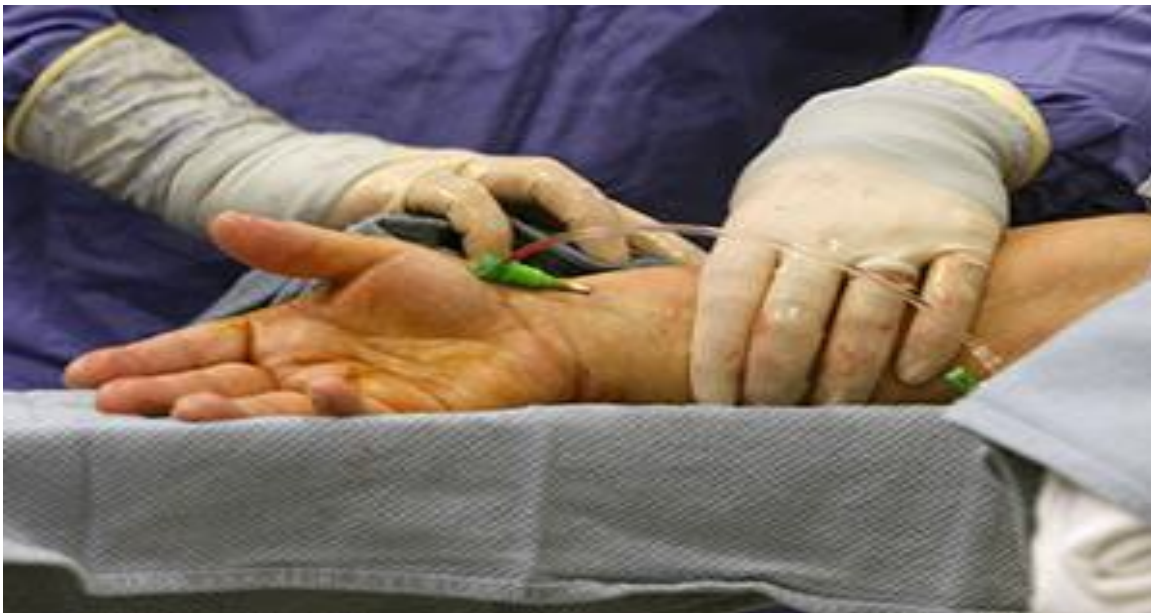
Angio-Guidewire-Ultrasound (AGU) Guidance for Femoral Access in Procedures Requiring Large Sheaths



Burzotta F. J Invasive Cardiol. 2019 Feb;31(2):E37-E39.



Preventing vascular complication related to the secondary access:



Contributing Factor:



CT analysis on primary access only

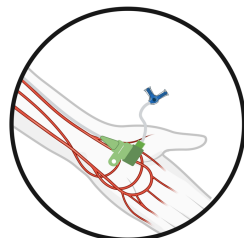


No ultrasound-guided puncture



Inadequate closure techniques

**Secondary access is not at “low-risk”
It deserves equal planning and precision as the primary TAVR access site.**



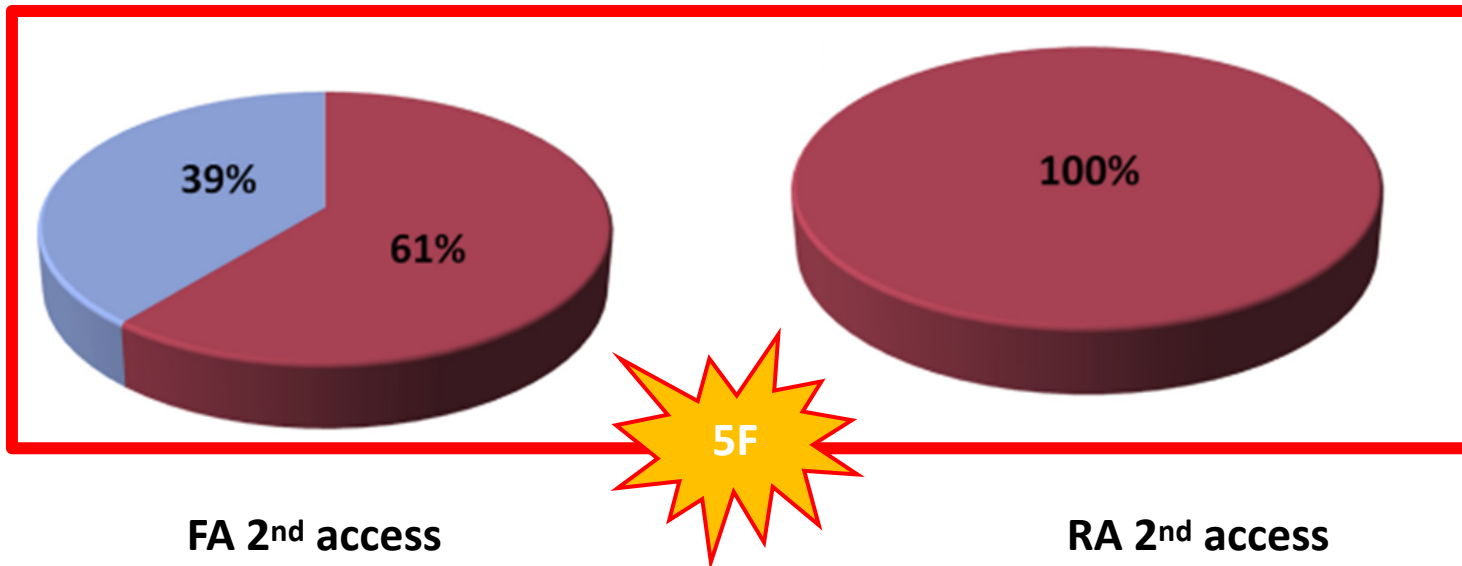


Impact of the Use of Transradial Versus Transfemoral Approach as Secondary Access in Transcatheter Aortic Valve Implantation Procedures

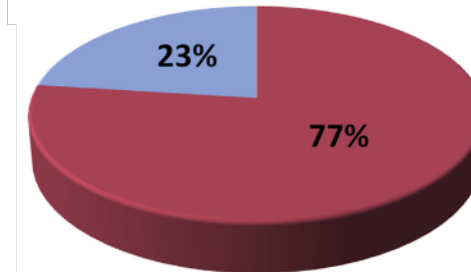


Ricardo Allende, MD, Marina Urena, MD, Juan G. Cordoba, MD, Henrique Barbosa Ribeiro, MD, Ignacio Amat-Santos, MD, Robert DeLarochellière, MD, Jean-Michel Paradis, MD, Daniel Doyle, MD, Siamak Mohammadi, MD, Mélanie Côté, MSc, Omar Abdul-Jawad, MD, Maria del Trigo, MD, María Rosario Ortas, MD, Louis Laflamme, MS, Jérôme Laflamme, MS, Hugo DeLarochellière, MD, Eric Dumont, MD, and Josep Rodés-Cabau, MD*

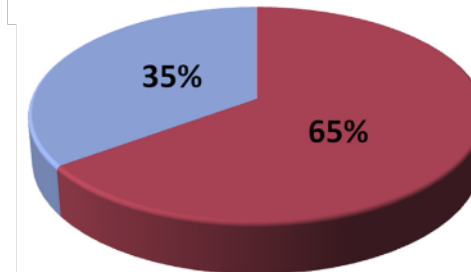
Major Vascular complications (462 consecutive patients)



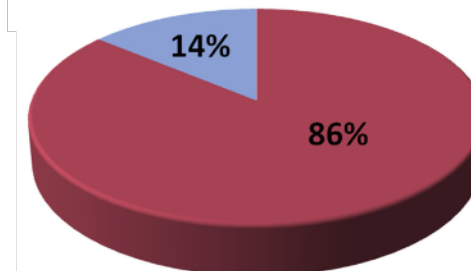
Overall VC



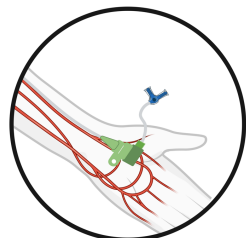
Major VC



Minor VC



■ Related to the primary access
■ Related to the secondary access



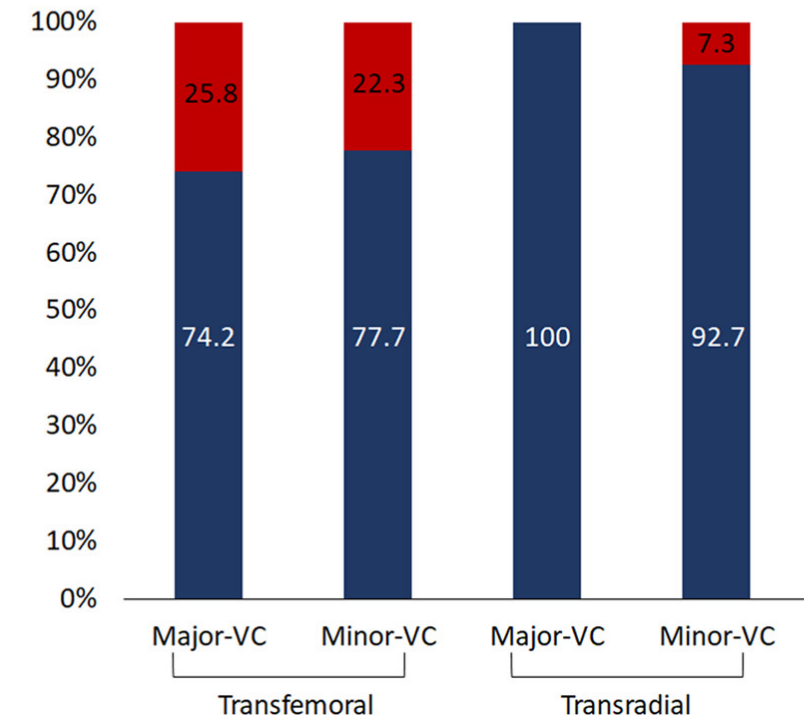


Multicenter study including 4949 patients who underwent TAVR

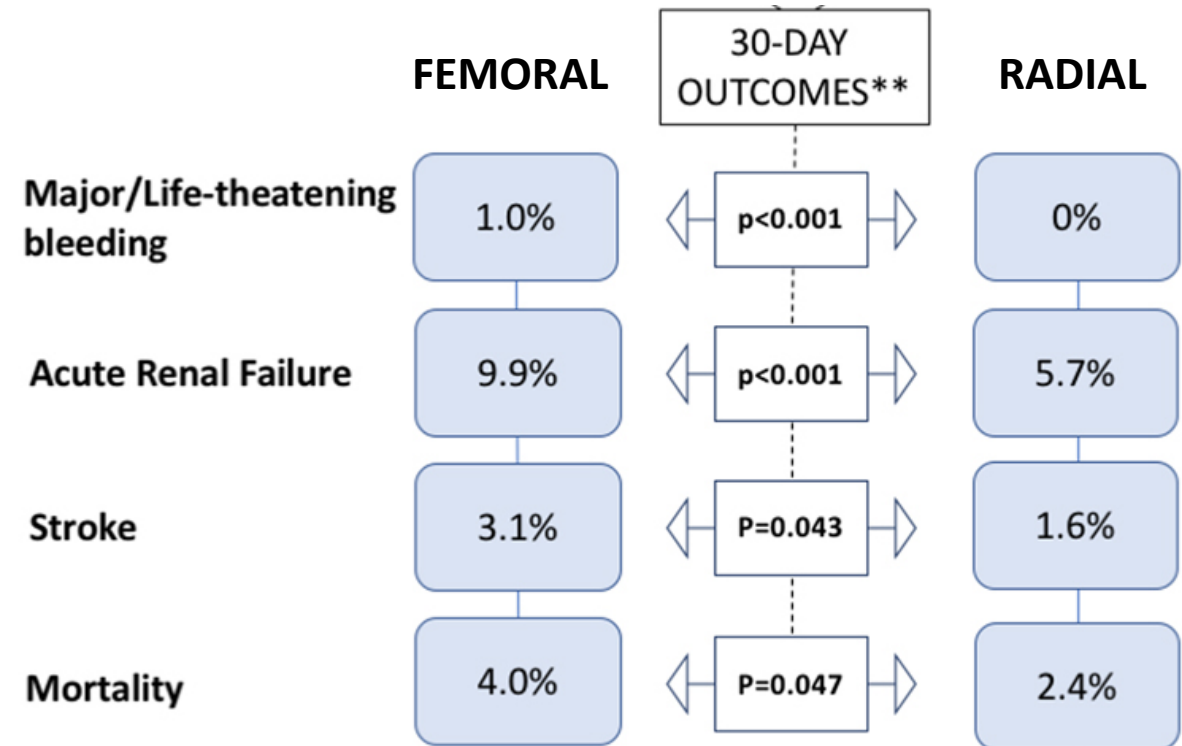
STRUCTURAL HEART DISEASE

Comparison of Transfemoral Versus Transradial Secondary Access in Transcatheter Aortic Valve Replacement

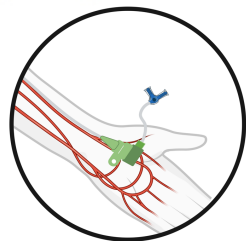
Lucía Junquera, MD, Marina Urena, MD, Azeem Latib, MD, Antonio Muñoz-Garcia, MD,



■ VC related to primary access
■ VC related to secondary access



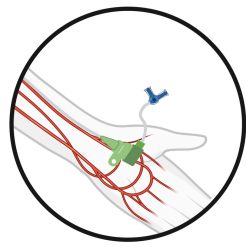
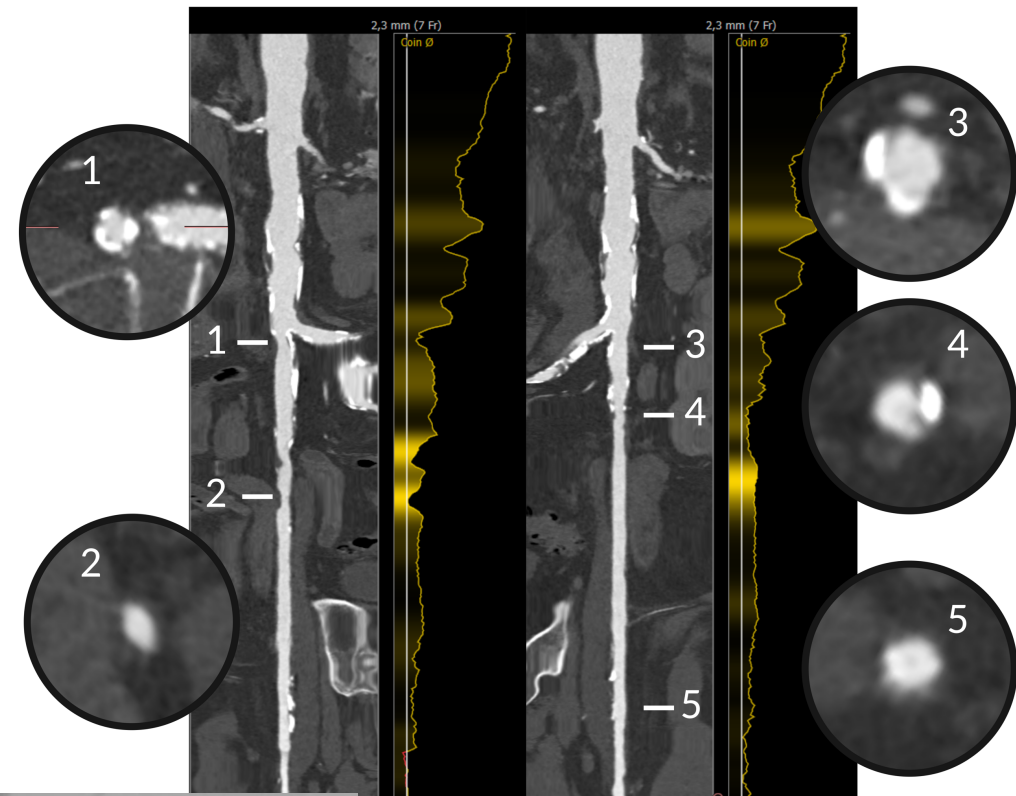
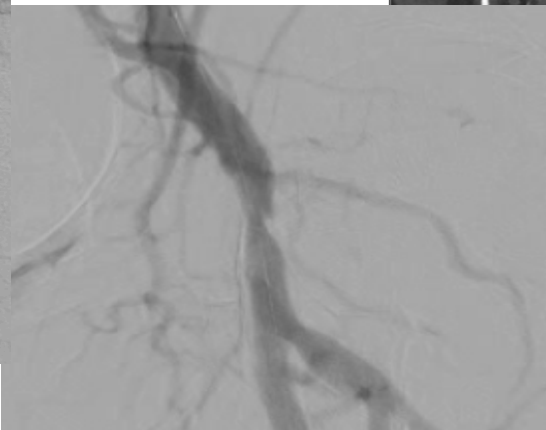
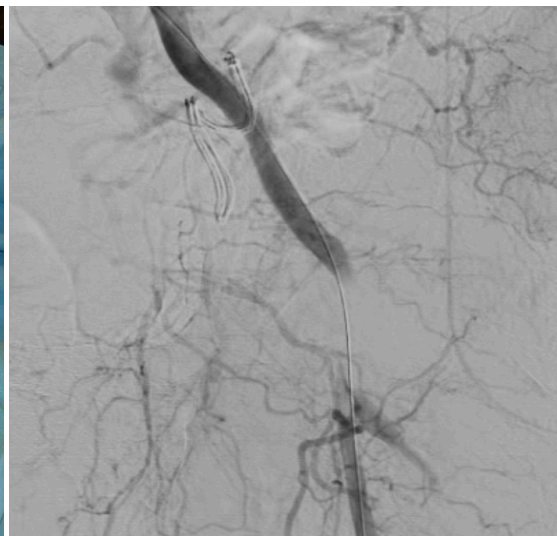
Junquera et al. Circ int 2020





Radial approach as the “secondary access”

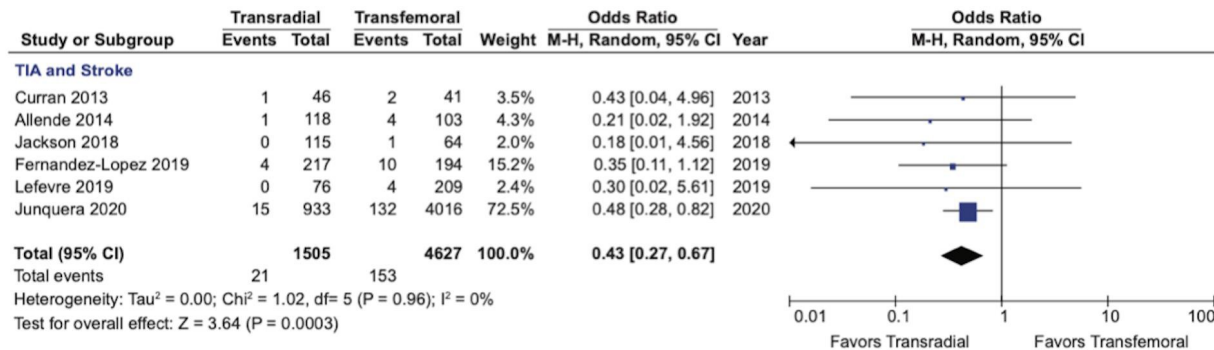
- to guide valve positioning,
- to check femoral-access hemostasis
- to manage eventual access-site complications



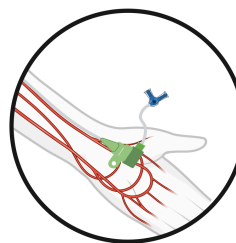
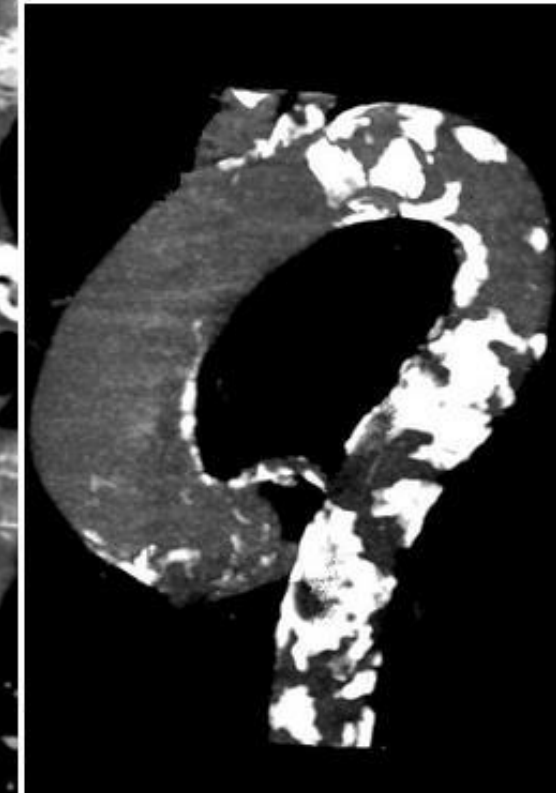
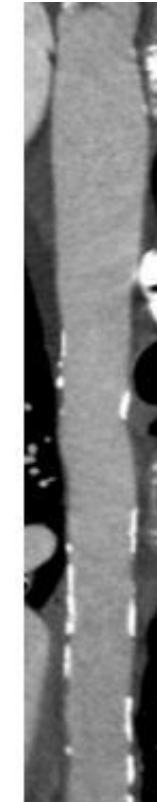
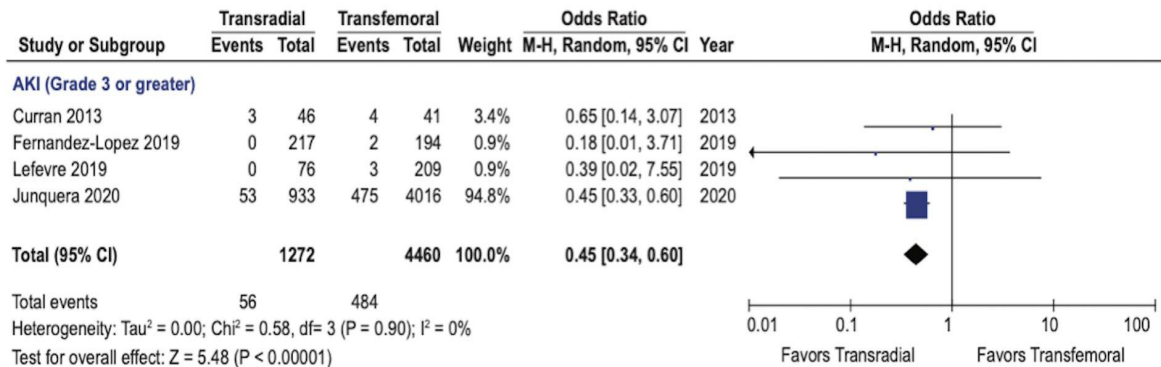


Radial approach as the “secondary access”

TIA and stroke associated with secondary access sites



AKI associated with secondary access sites

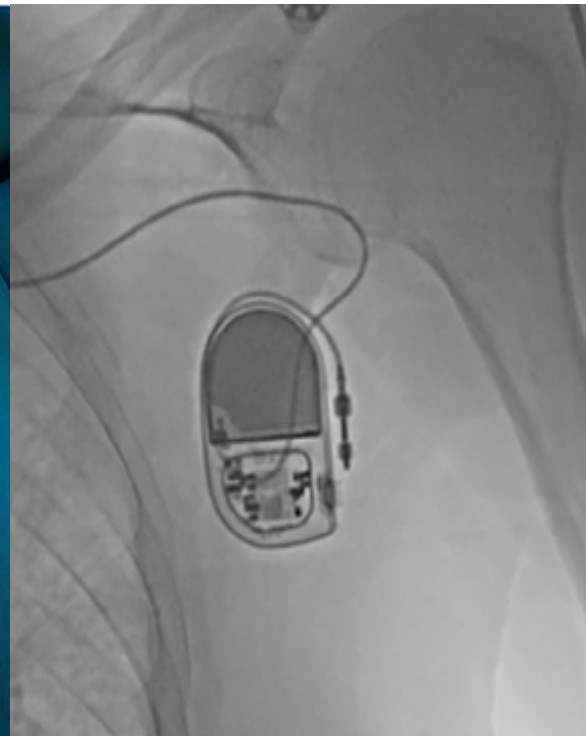
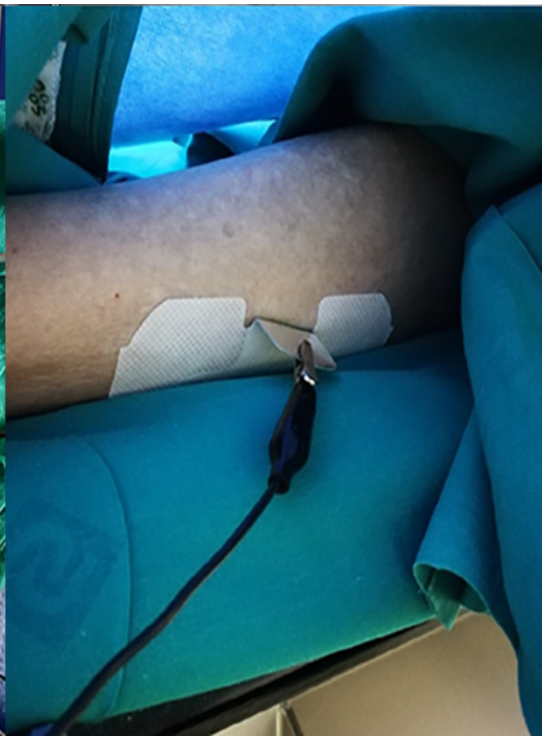
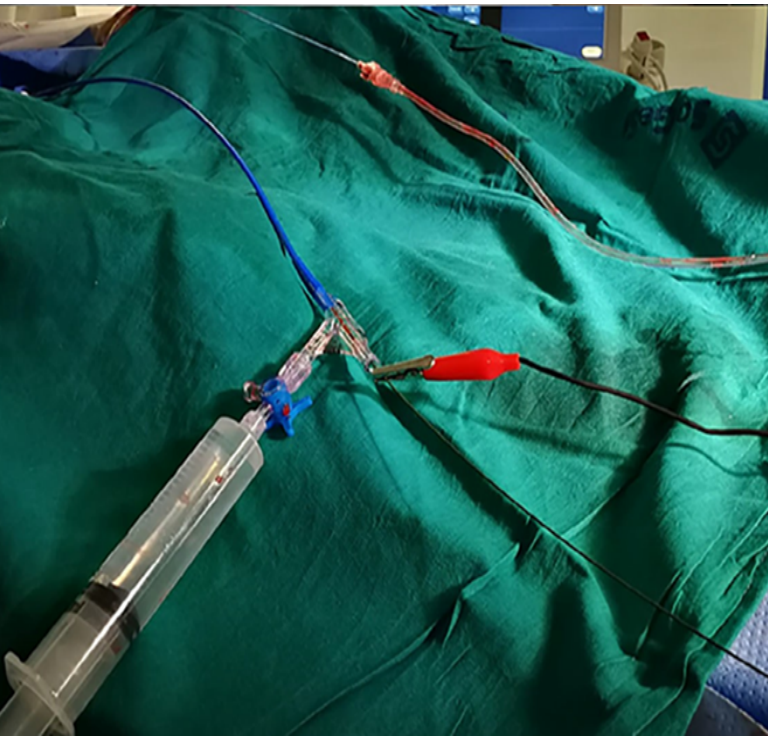
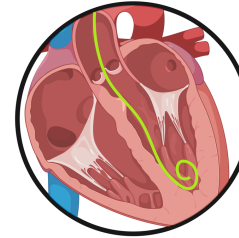




Non-invasive pacing

by retrograde left ventricle stimulation

by definitive pacemaker external programmer





ORIGINAL STUDIES

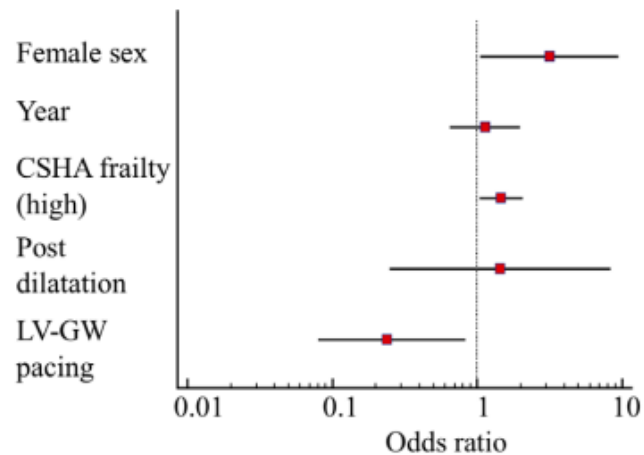
WILEY

STRUCTURAL

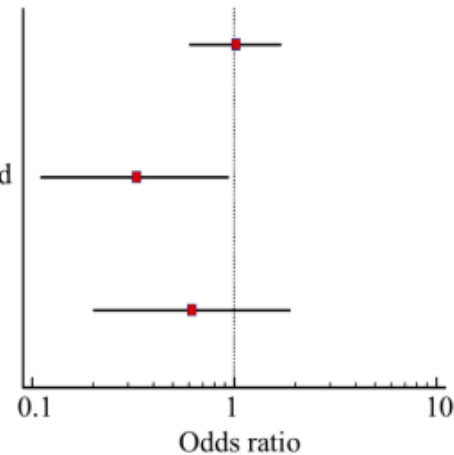
Ultrasound guided vascular access site management and left ventricular pacing are associated with improved outcomes in contemporary transcatheter aortic valve replacement: Insights from the OxTAVI registry

Rafail A. Kotronias MBChB MSc^{1,2} | Roberto Scarsini MD^{1,3} |
Giovanni L. De Maria MD PhD¹ | Skanda Rajasundaram BA¹ | Rana Sayeed MD¹ |
George Krasopoulos MD¹ | Catherine Grebenik MD¹ | Amar Keiralla MD¹ |
James D. Newton MD FRCP¹ | Adrian P. Banning MBBS MD¹ |
Rajesh K. Kharbanda MD PhD¹

Pericardial effusion



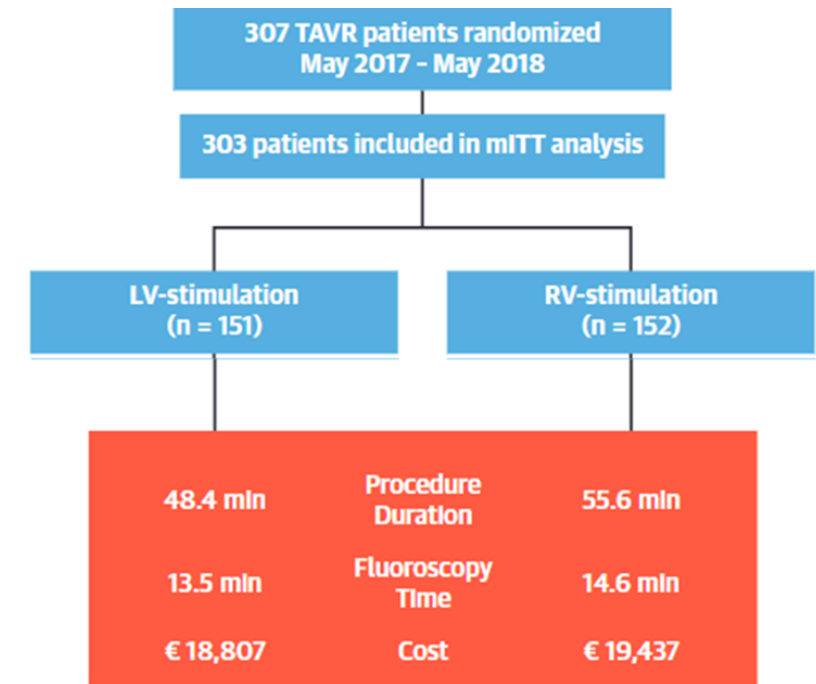
Access site complication



Left Ventricular Rapid Pacing Via the Valve Delivery Guidewire in Transcatheter Aortic Valve Replacement



Benjamin Faurie, MD,^{a,b} Géraud Souteyrand, MD,^c Patrick Staat, MD,^b Matthieu Godin, MD,^d Christophe Caussin, MD,^e Eric Van Belle, MD, PhD,^f Lionel Mangin, MD,^g Pierre Meyer, MD,^h Nicolas Dumonteil, MD,ⁱ Mohamed Abdellaoui, MD,^{a,b} Jacques Monségu, MD,^{a,b} Isabelle Durand-Zaleski, MD, PhD,^j Thierry Lefèvre, MD,^k for the EASY TAVI Investigators



TAVI “lite” program – the evolution



Developed & standardized

2015-2016

Technique and first series reported

2019

Systematically adopted

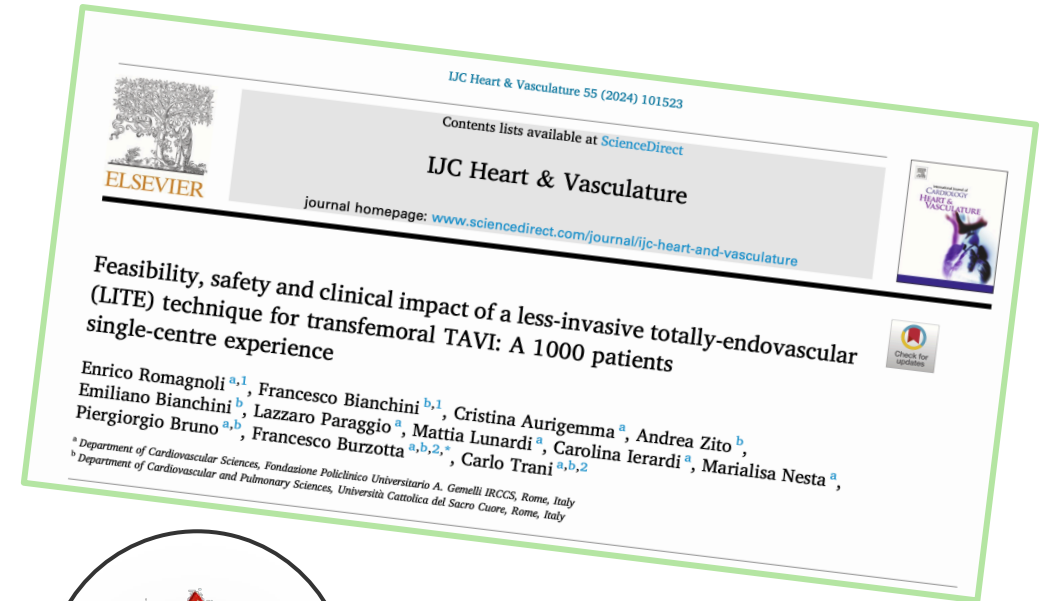
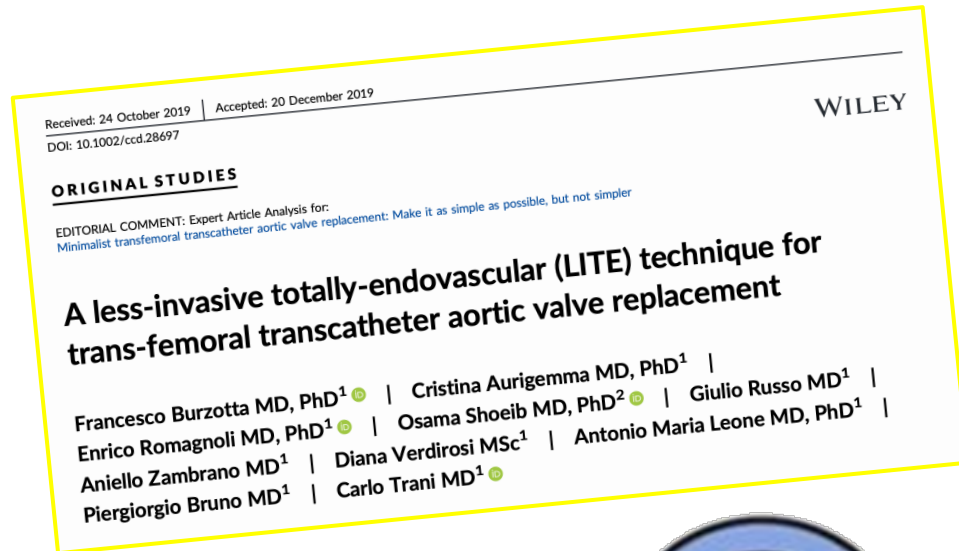
2017

>1500 pts treated

2026

2023

1000 pts treated



peri-procedural
mortality



access-related
major-VCs

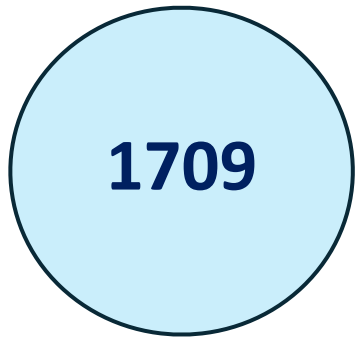


≥ type 2
bleedings

TAVI “lite” program – feasibility

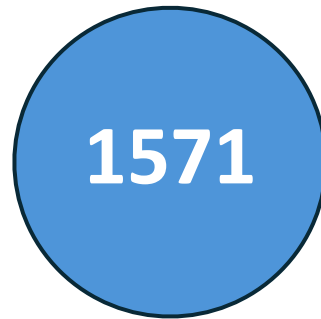


Consecutive patients
referred for TAVI by the
Heart-Team



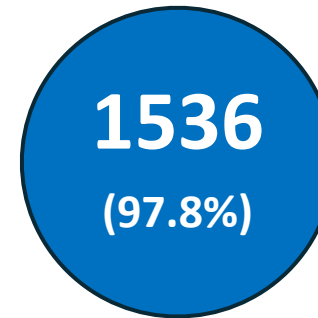
Transfemoral
access not
feasible,
alternative access
adopted

TransFemoral-TAVI attempted
according to LITE technique
(study population by
intention to treat)



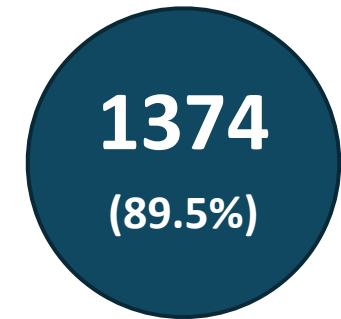
21: Transvenous PM
8: Ancillary TFA
6: Transvenous PM + TFA

LITE-TAVI
(per protocol)



127: Transvenous PM
23: Contralateral TFA
7: Transvenous PM + Contralateral TFA
5: Surgical bail-out

Procedure completed
with only a single TF a
secondary radial/ulnar



TAVI “lite” program – population



Demographics

Age (years)	80.5 ± 7.0
Female gender	564 (55.2)
BMI (kg/m ²)	26.5 ± 4.5
Diabetes mellitus	294 (28.8)
COPD (≥ moderate)	226 (22.1)
CKD (GFR <60ml/min/1.73m ²)	344 (33.7)
Atrial fibrillation	343 (33.6)
Peripheral artery disease	225 (22.0)
Prior stroke	82 (8.0)
Prior ACS	120 (12.0)
LVEF(%)	55.5 ± 11.7

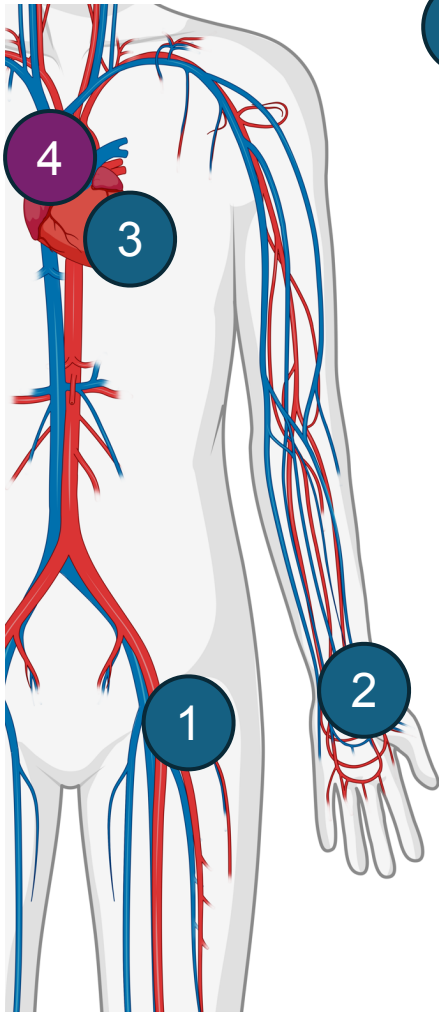
Clinical presentation

Urgent	174 (17.0)
Elective	848 (83.0)
NYHA class III-IV	597 (58.4)

Risk scores

EuroScore II (%)	6.3 ± 7.1
TAVR mortality score	3.4 ± 2.5
STS Mortality	4.4 ± 2.7
Low risk	585 (57.2)
Intermediate risk	327 (32.0)
High risk	110 (10.8)

TAVI “lite” program – procedures



1

Main arterial access site

Left femoral	30%
Right femoral	70%

14 Fr	84.3%
>14 Fr	15.7%

3

Cardiac pacing modality

LV pacing through guidewire	86%
Permanent PM programmer	13%
Temporary PM at procedure' start	1%
Need for bail-out temporary PM	6%

2

Secondary access site

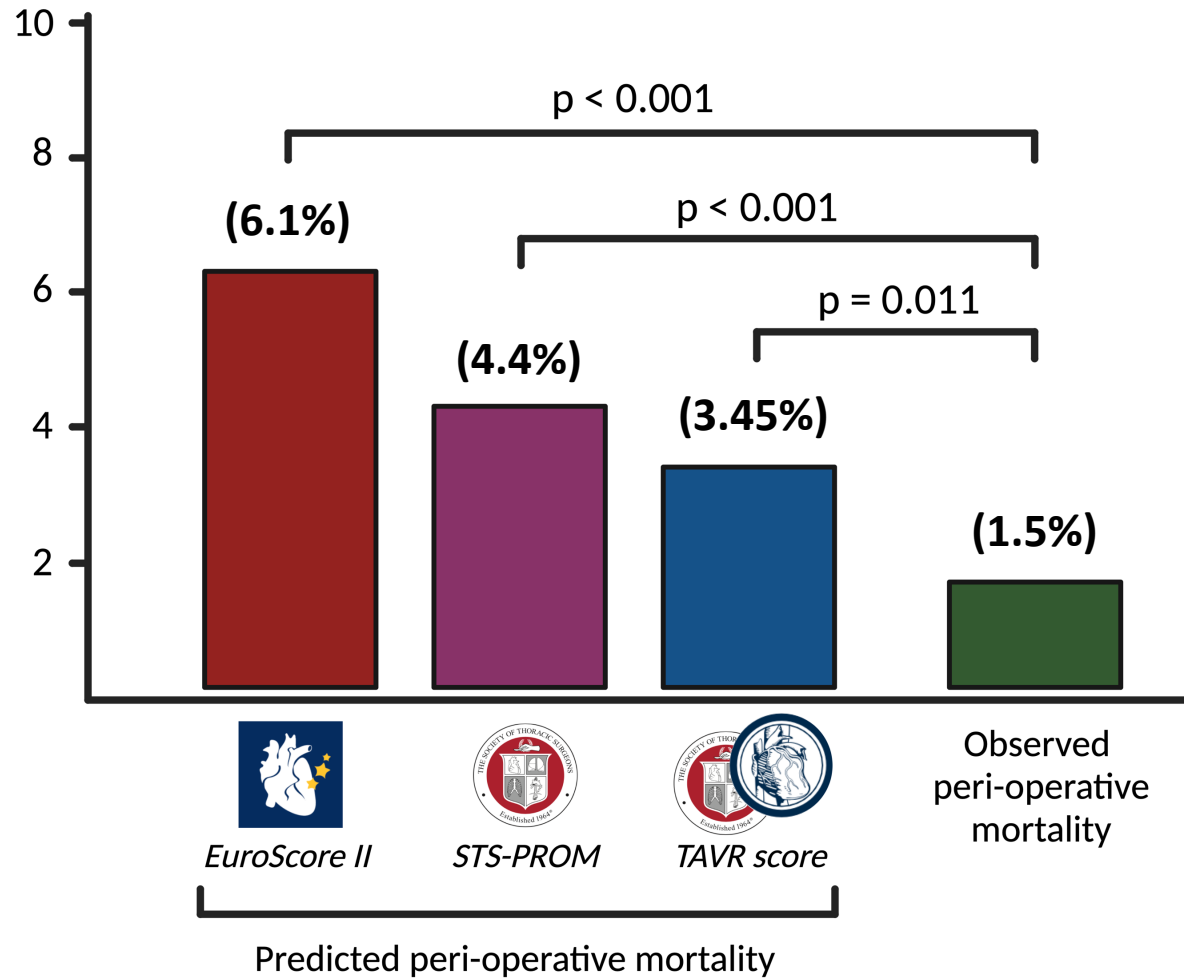
Radial artery	95%
Ulnar artery	4%
Contralateral femoral	1%

4

TAVI systems

Self expandable family	67%
Balloon expandable family	33%

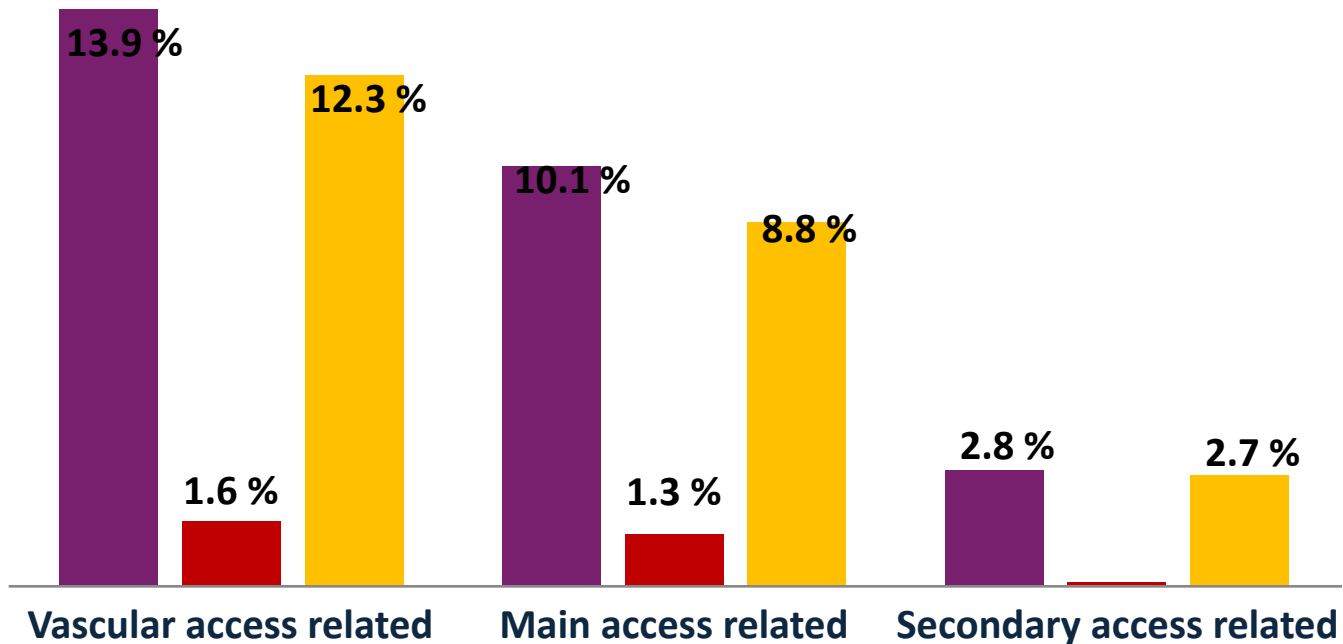
TAVI “lite” program – 30-day mortality





Bleeding classification

■ total ■ Major ■ Minor



Bleeding

Type 5	0
Type 4	8 (0.5)
Type 3	21 (1.3)
Type 2	48 (3.0)
Type 1	119 (7.5)

Access related bleeding complications

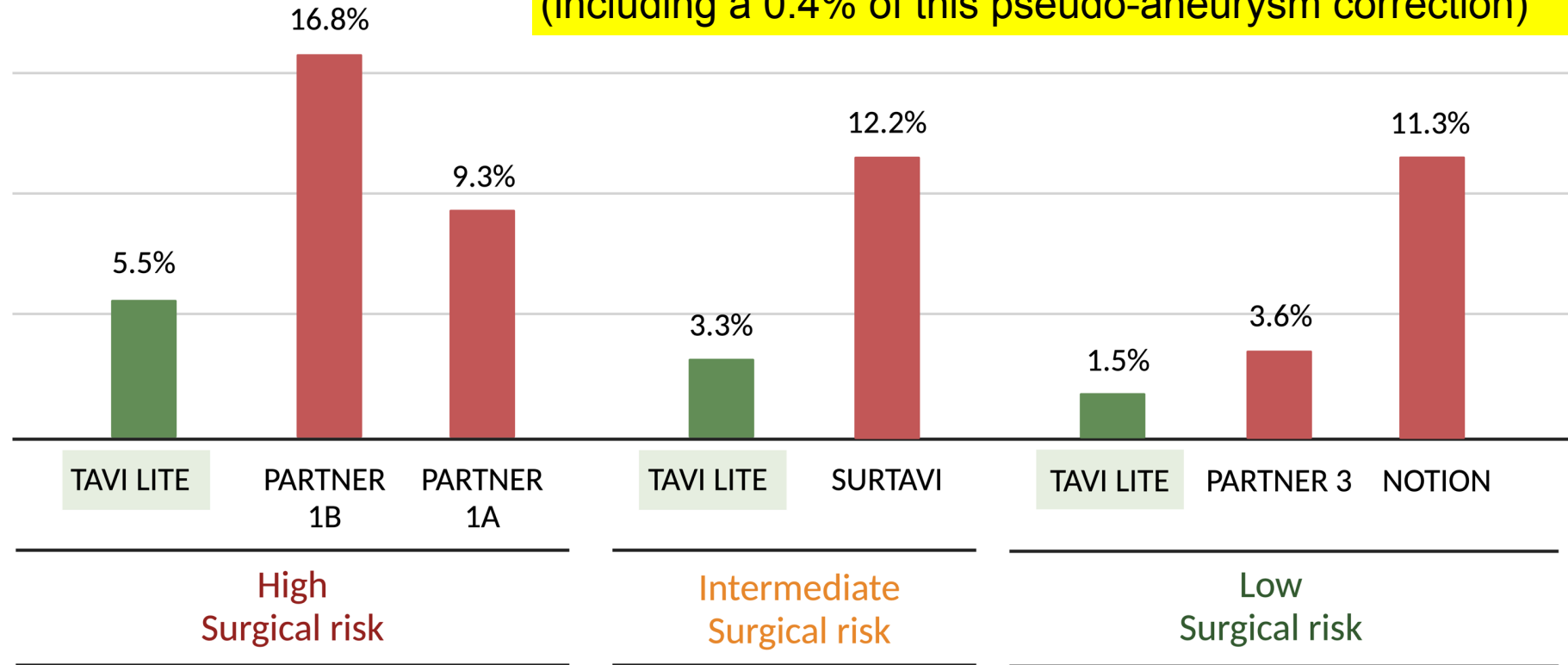
Type 4	1 (0.1)
Type 3	9 (0.6)
Type 2	9 (0.6)

TAVI “lite” program – Major bleedings



Overall need for vascular surgery= 0.8%
(including a 0.4% of this pseudo-aneurysm correction)

Life-threatening or
major bleeding
(VARC-2)

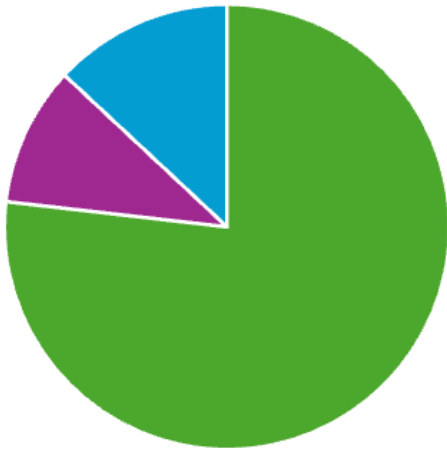
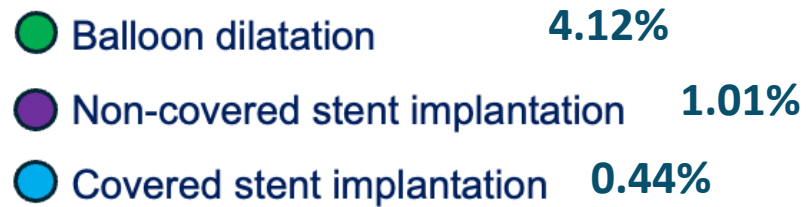


Age, Mean (%)	82.9	83.1	83.6	82.1	80.0	79.1	73	79
STS PROM, Mean (%)	10.2	11.2	11.8	5.2	4.4	2.6	1.9	2.9
TFA, (%)	100	100	70.1	100	93.6	100	100	96.6

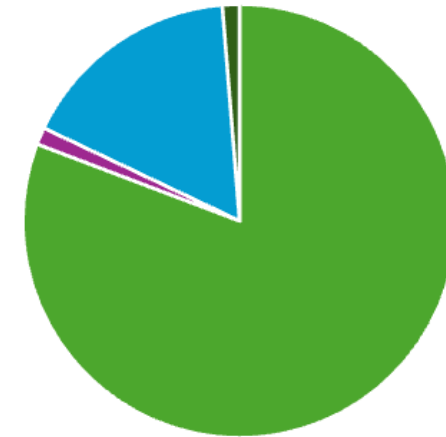
TAVI “lite” program – Vascular complications management



6.8% of the procedures required intervention



Vascular access to fix the complication





A Less-Invasive Totally-Endovascular (LITE) Technique for Transfemoral TAVI is...

feasible...

... and seems to warrant a very low rate of serious complications !!!

