GRCI 5 Décembre 2018

Traitement Le TAVI en 2025: restera-t-il encore une place pour la chirurgie?

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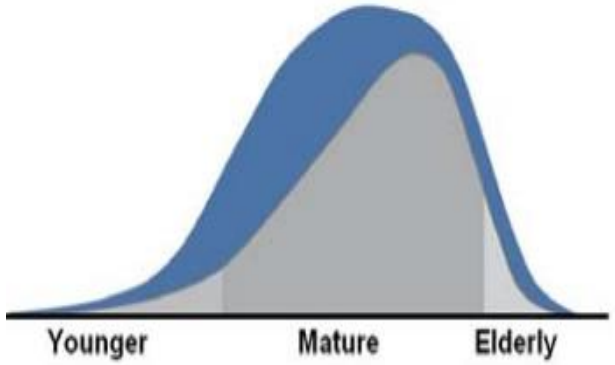
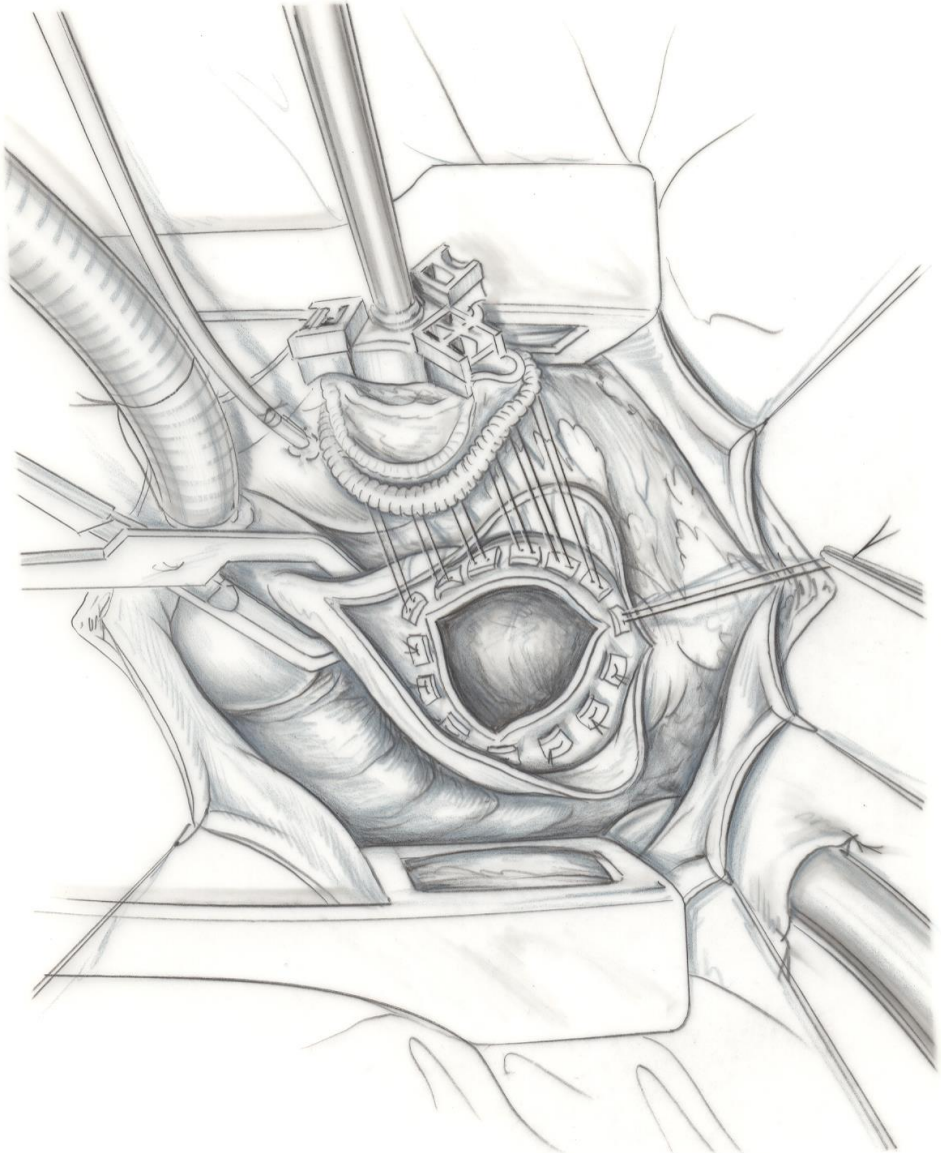
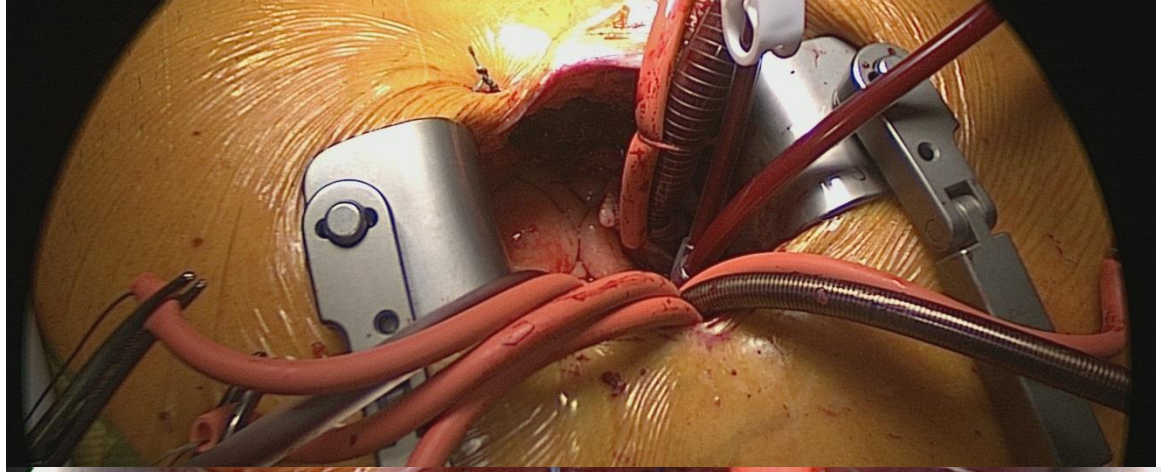
Expanding heart valve opportunity

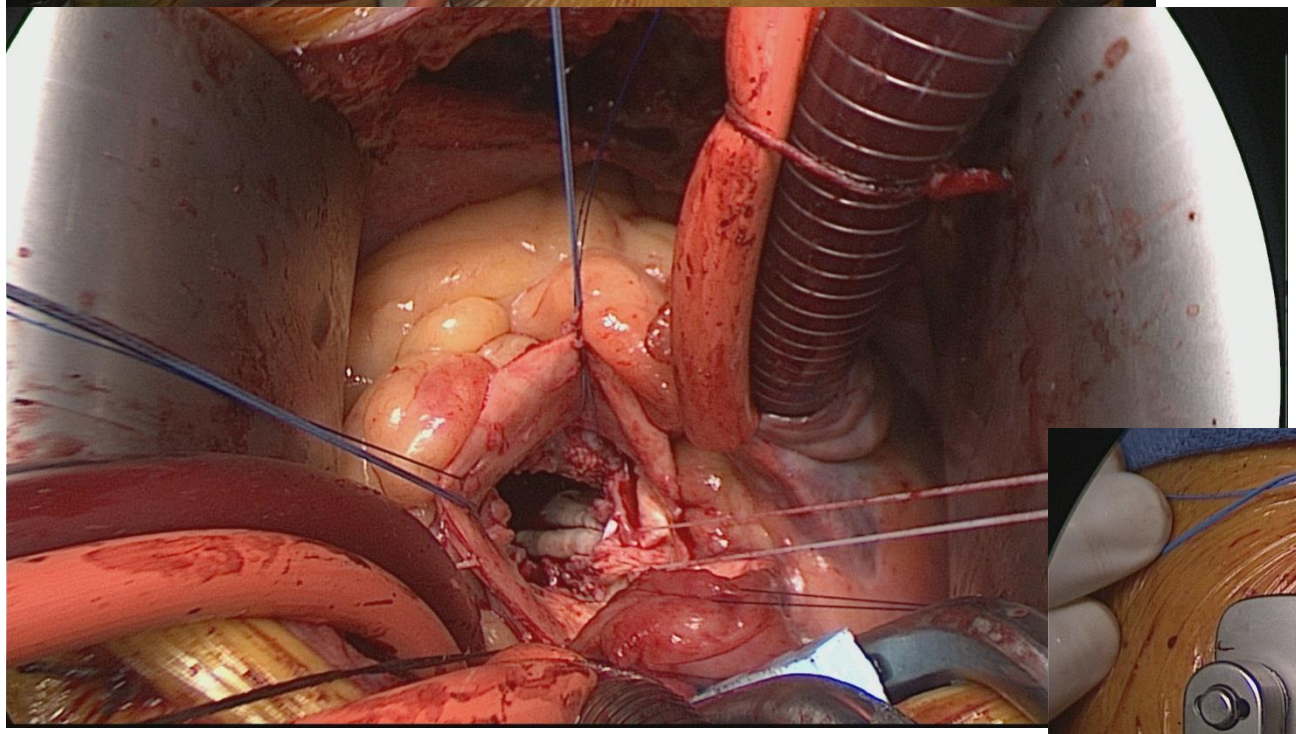
Aging global populations in developed markets
Expanding tissue valve segment:

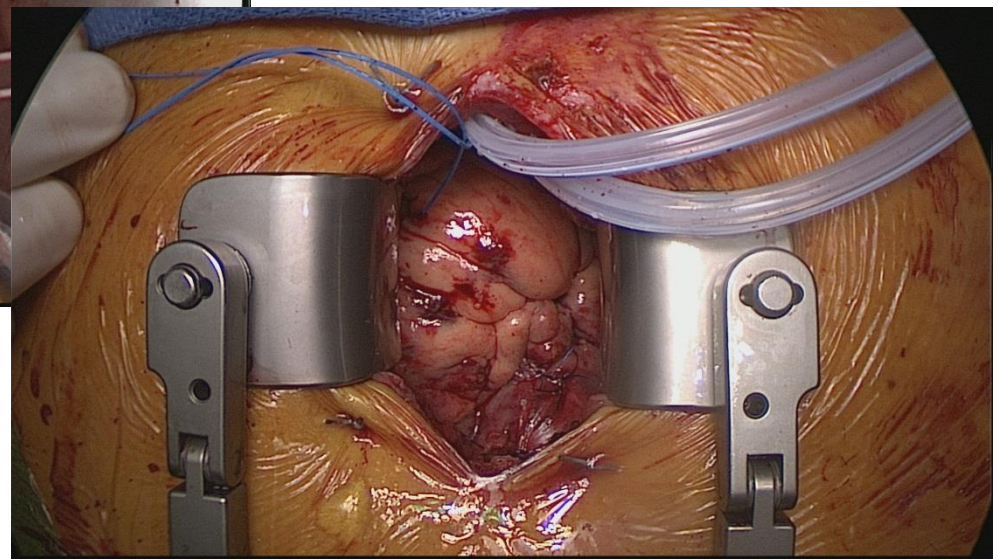
- **Addressing younger patients with innovative tissue valve solutions**
- **Growing incomes drive adoption of tissue valves in emerging markets**







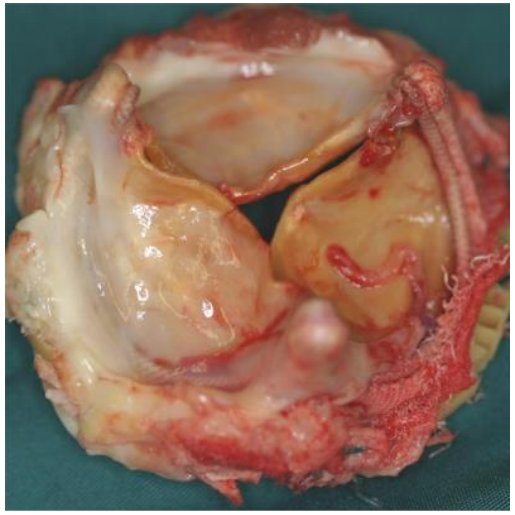




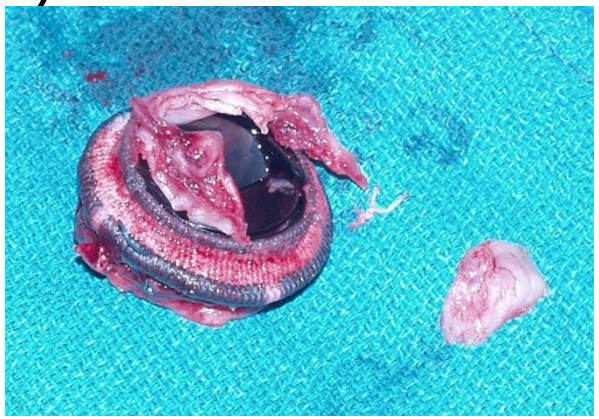
Results AVR

Risk of Re intervention Bioprothesis > 70 years = 10% 15/20 years

Early
Mortality 2,6% (95%CI:1.4-4.4%)
Stroke 1% (0-7%)
Reexploration for bleeding 3% (0-10%)
Reop for AR = 2% (0-16%)

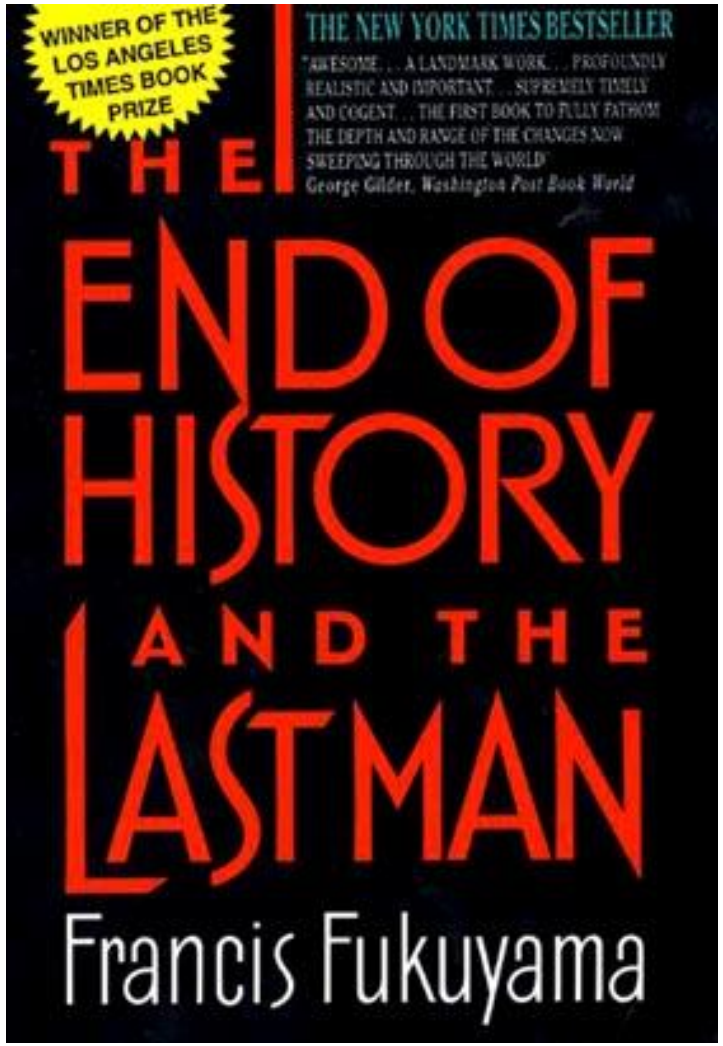


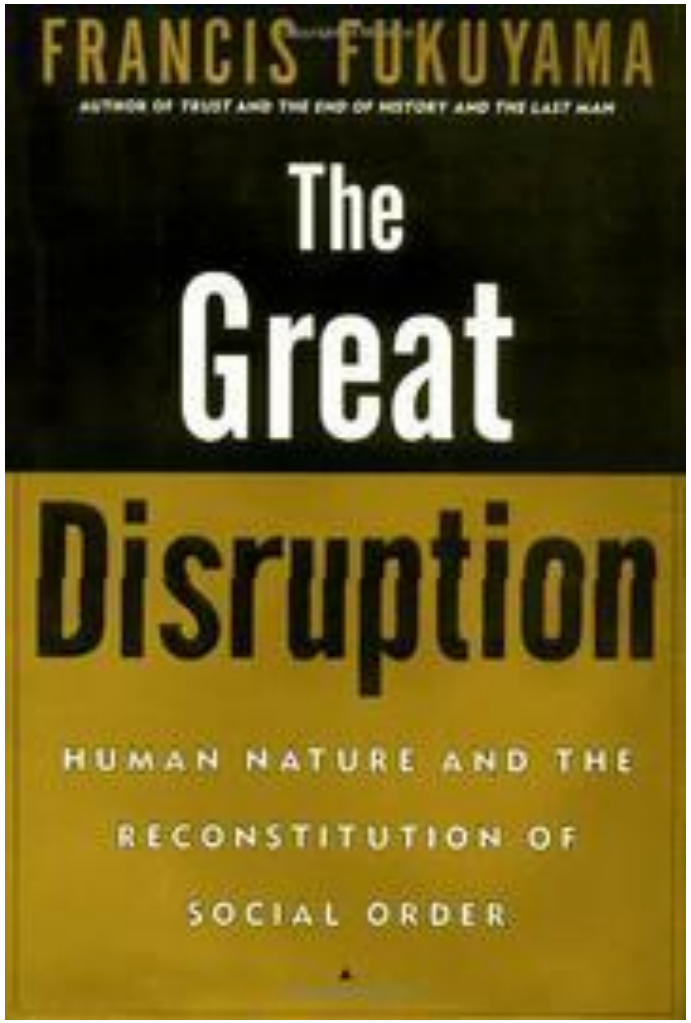
Late
Endocarditis 0.23%/pt-years (0-0.78%/pt-years)
Neuro complications 0.52%/pt-years
(0.95%/pt-years)



Re opération for AVR
2.4%/pt-years (0-4.2%/pt-years)

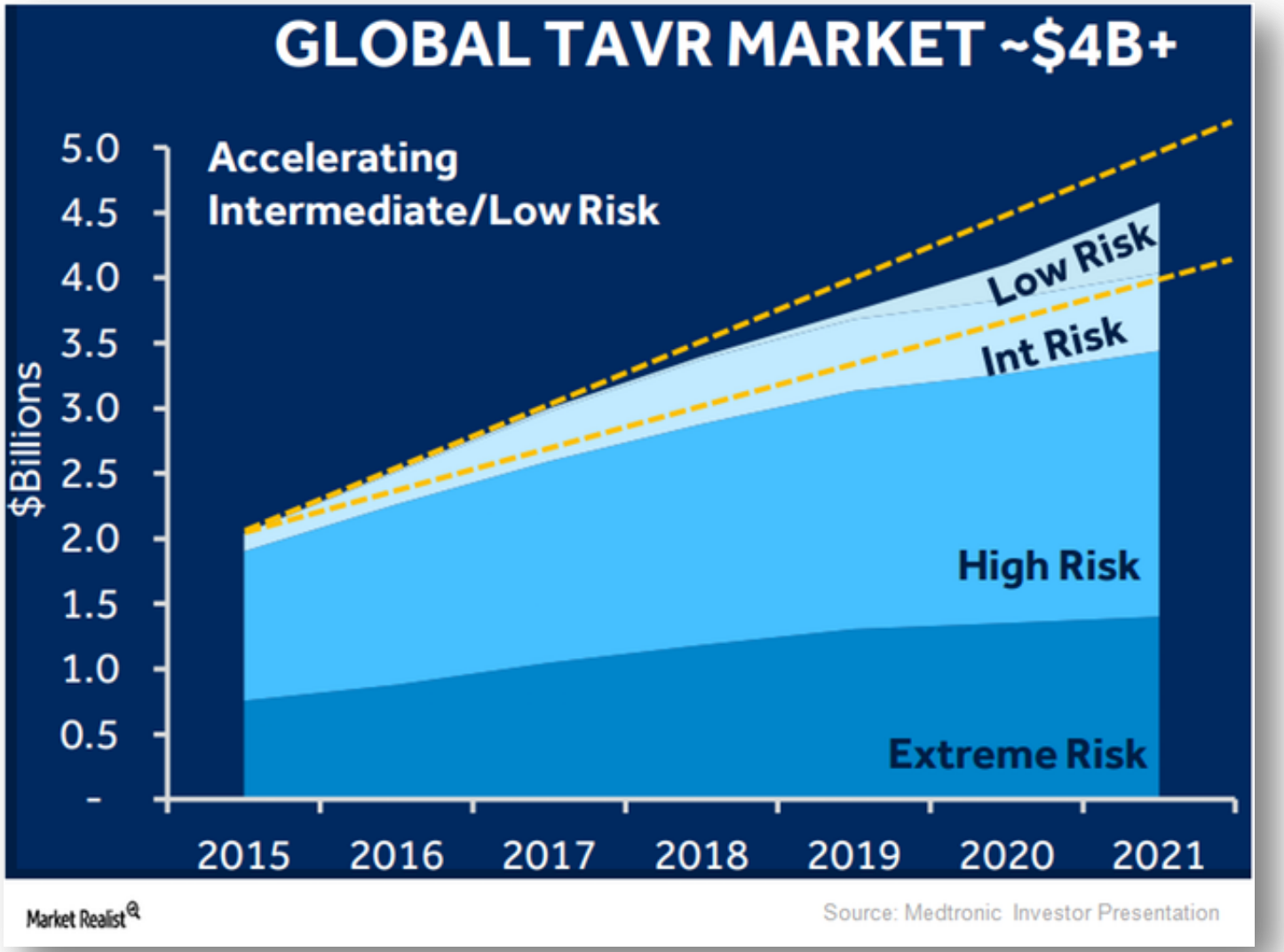
End of the debate?






TAVI
for all
AS patients ?

'Medtronic expects the overall TAVR segment to reach a market value of around $4.6 billion in 2021.'



PCR online
18 MAY 2016

Heart team should decide if TAVI is suitable for low-risk patients

TCT 2017: TAVI "should be the preferred strategy" for patients at intermediate-risk

31st October 2017 607

NEWS • INTERVENTIONAL | CRT 2018

Early Low-Risk TAVR Data Reassure, but Durability Questions Remain

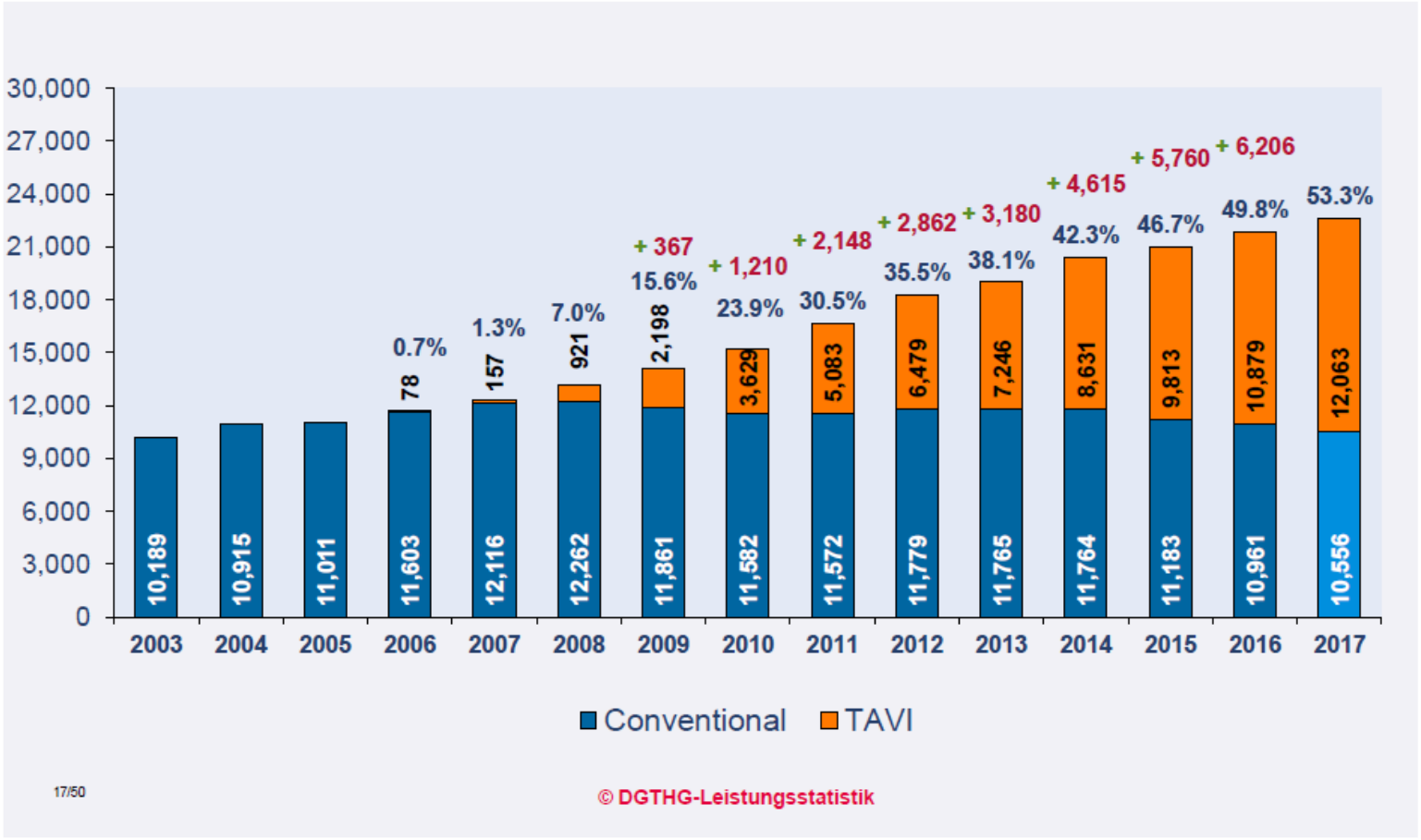
Will TAVI Be the Standard of Care in the Treatment of Aortic Stenosis?

‚TAVI should be the standard of care in AS patients'

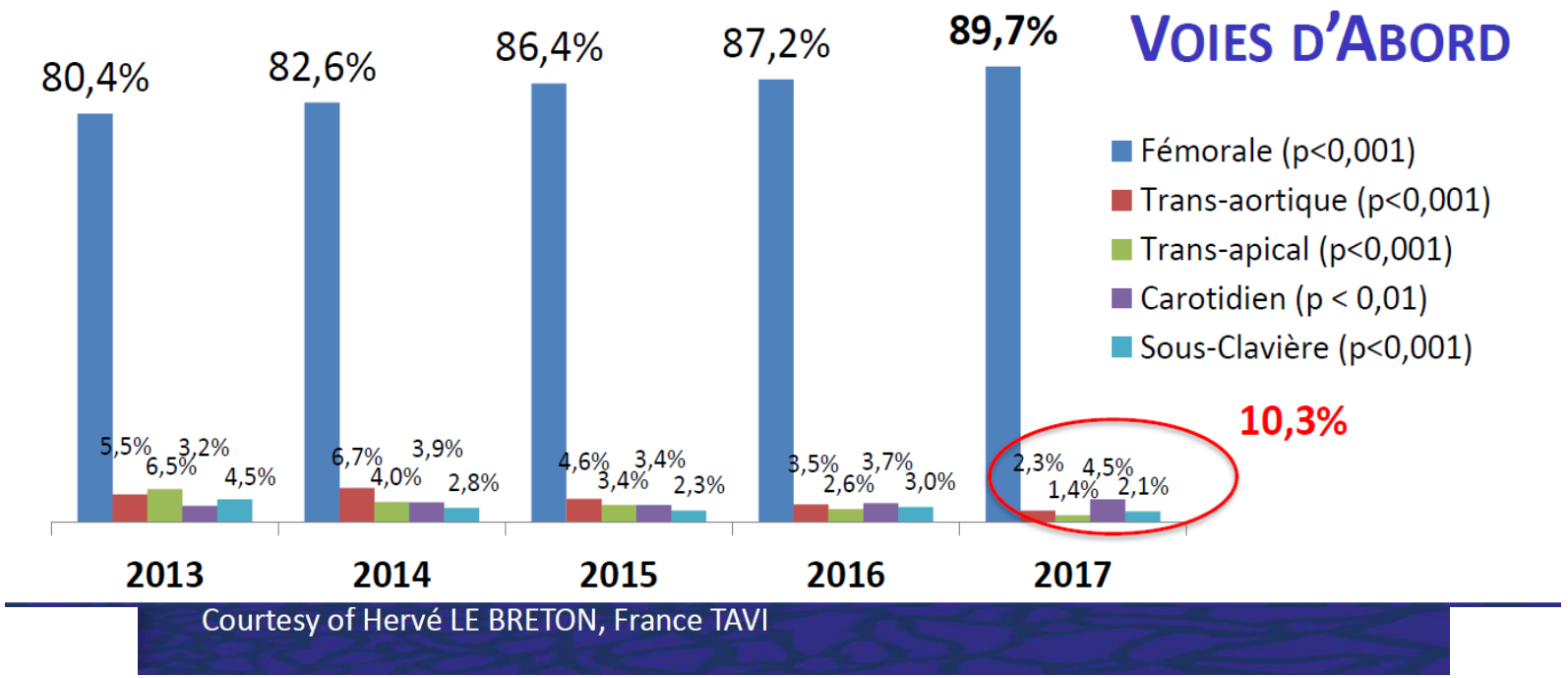
TAVR in all AS patients: **‚I predict that TAVR will be a HOMERUN!'**

Martin B. Leon - TVT 2017

TAVI vs. AVR in Germany

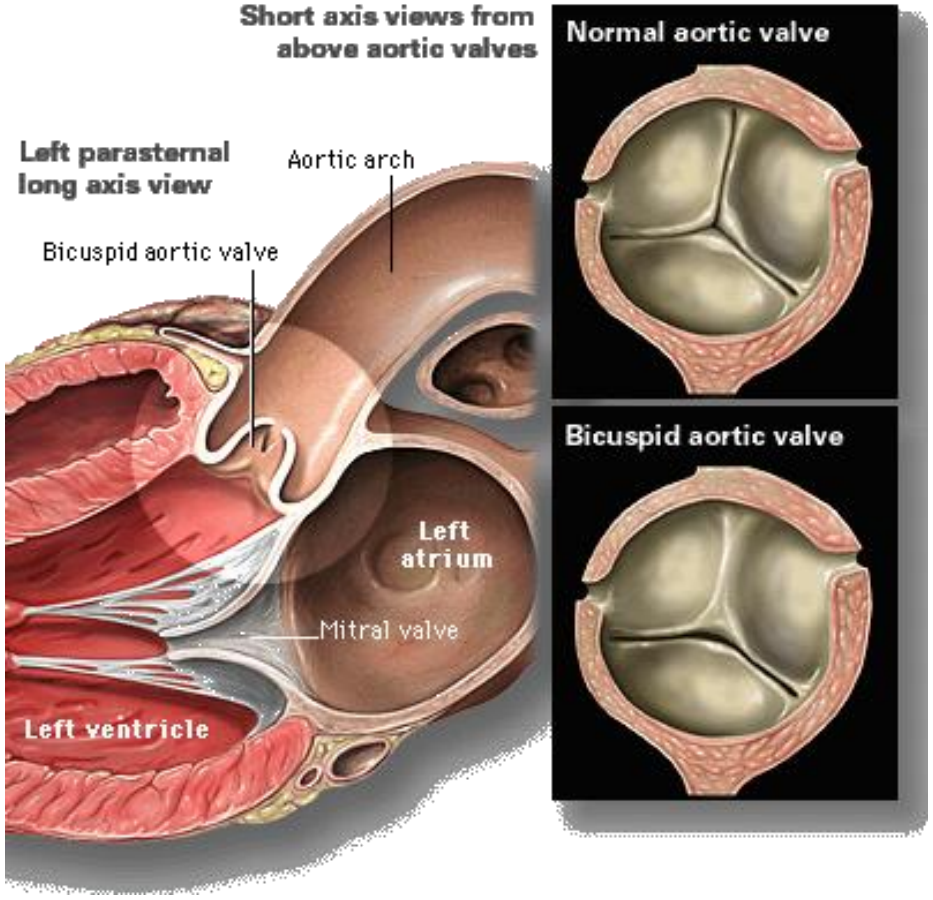


FRANCE TAVI

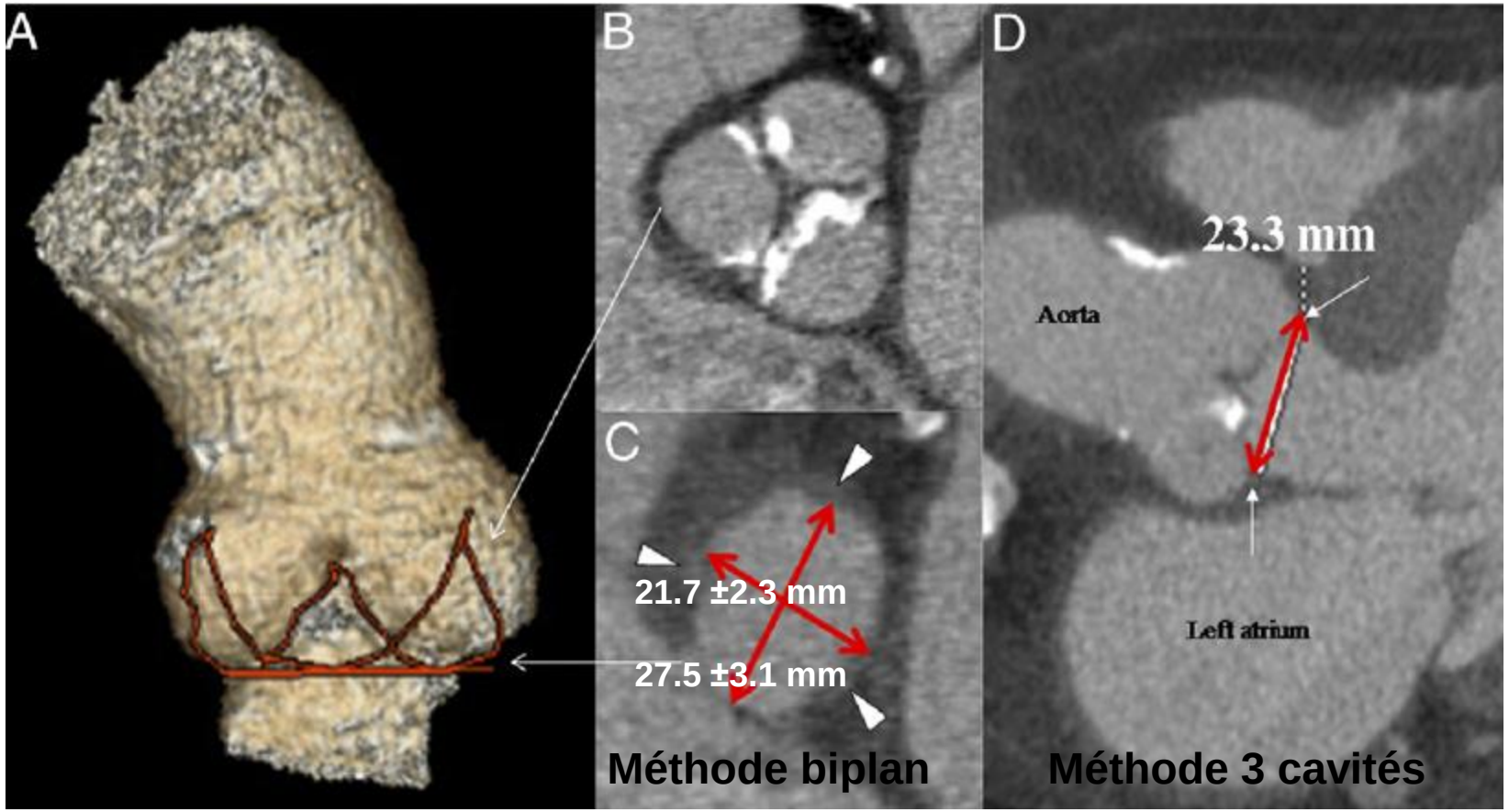


Courtesy of Hervé LE BRETON, France TAVI

Assessment Aortic Valve



Géométrie de l’anneau aortique



Forme ovalaire

Ø moyen anneau aortique TDM > ETT et ETO

Rational

In High risk patients, TAVR is non inferior to SAVR

Recent trial in intermediate risk patients showed non inferiority of TAVR

Center and registry data report good results of TAVR in selected low risk patient

How those data strongly support generalisation of TAVR indication in less sick patients?

Choix TAVI vs SAVR

STS/EuroSCORE II <4% (logistic EuroSCORE I <10%)[a]		+
STS/EuroSCORE II ≥4% (logistic EuroSCORE I ≥10%)[a]	+	
Presence of severe co-morbidity (not adequately reflected by scores)	+	
Age <75 years		+
Age ≥75 years	+	
Previous cardiac surgery	+	
Frailty[b]	+	
Restricted mobility and conditions that may affect the rehabilitation process after the procedure	+	
Suspicion of endocarditis		+
Anatomical and technical aspects		
Favourable access for transfemoral TAVI	+	
Unfavourable access (any) for TAVI		+
Sequelae of chest radiation	+	
Porcelain aorta	+	
Presence of intact coronary bypass grafts at risk when sternotomy is performed	+	
Expected patient–prosthesis mismatch	+	
Severe chest deformation or scoliosis	+	
Short distance between coronary ostia and aortic valve annulus		+
Size of aortic valve annulus out of range for TAVI		+
Aortic root morphology unfavourable for TAVI		+
Valve morphology (bicuspid, degree of calcification, calcification pattern) unfavourable for TAVI		+
Presence of thrombi in aorta or LV		+
Cardiac conditions in addition to aortic stenosis that require consideration for concomitant intervention		
Severe CAD requiring revascularization by CABG		+
Severe primary mitral valve disease, which could be treated surgically		+
Severe tricuspid valve disease		+
Aneurysm of the ascending aorta		+
Septal hypertrophy requiring myectomy		+

Ongoing issues with TAVI and Bioprosthesis in intermediate risks pts

PVL and Performance

Permanent Pacemaker (PM)

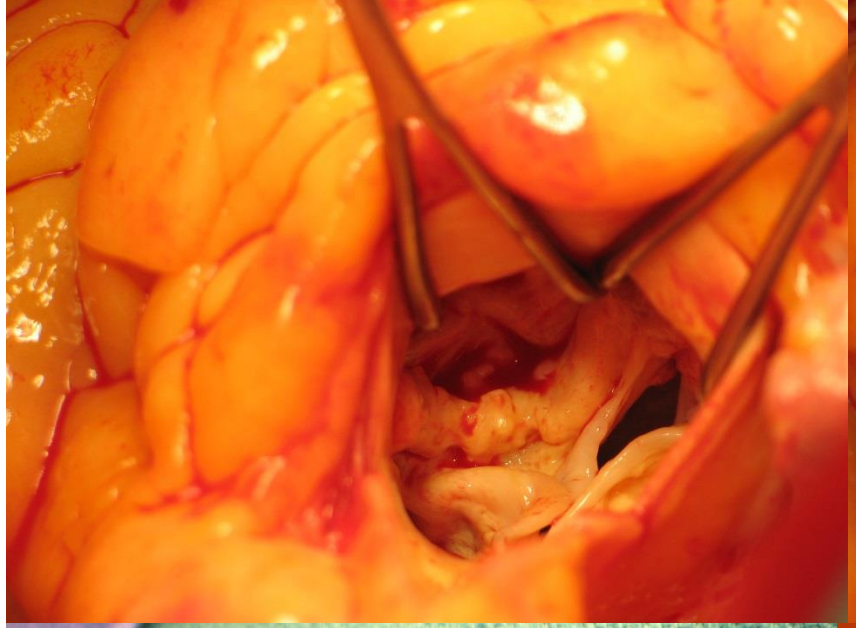
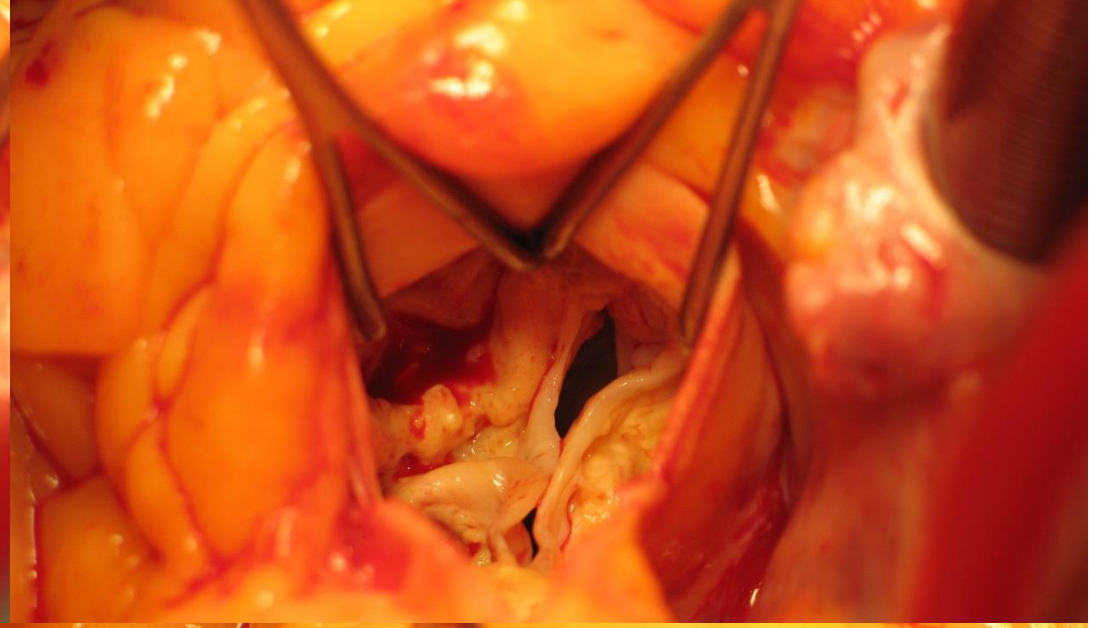
Stroke

Durability

Thrombosis

Economics

Which valve for which patient?

2017 ESC/EACTS Guidelines on the management of valvular heart disease

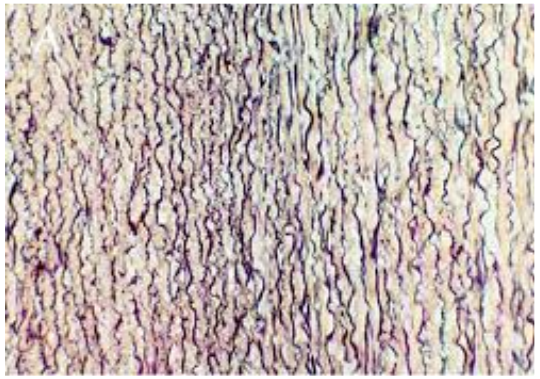
Data on TAVI are still very limited for patients younger than 75 years and for surgical low-risk patients, in whom SAVR remains the reference method. It has to be emphasized that younger patients differ with regard to anatomy (more bicuspid valves), which affects the results of TAVI (bicuspid valves were also in general excluded in clincial trials), and that long-term durability data for TAVI prosthetic valves are still lacking.

Available data from randomized controlled trials and large registries in elderly patients at increased surgical risk show that TAVI is superior in terms of mortality to medical therapy in extreme-risk patients,[80] non-inferior or superior to surgery in high-risk patients,[83-86] and non-inferior to surgery and even superior when transfemoral access is possible in intermediate-risk patients.[87-90] In these studies on intermediate risk, the mean patient age was 82 years, mean STS score was 5.8%, and a high percentage were considered frail. Thus, the results are valid only for comparable patient groups.

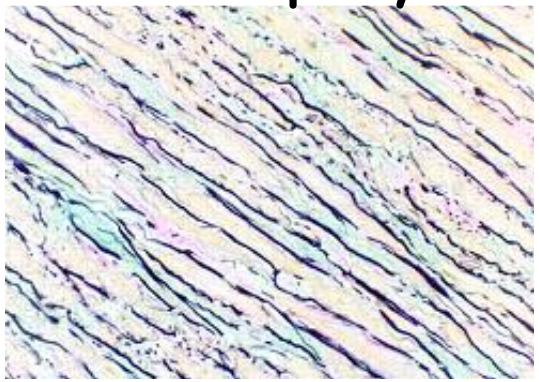
Etiology

$$\text{Wall tension} = \frac{\text{pressure x radius}}{2\ (\text{thickness aortic wall})}$$

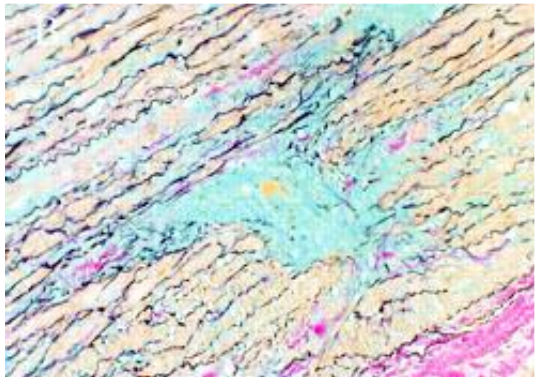
Normal



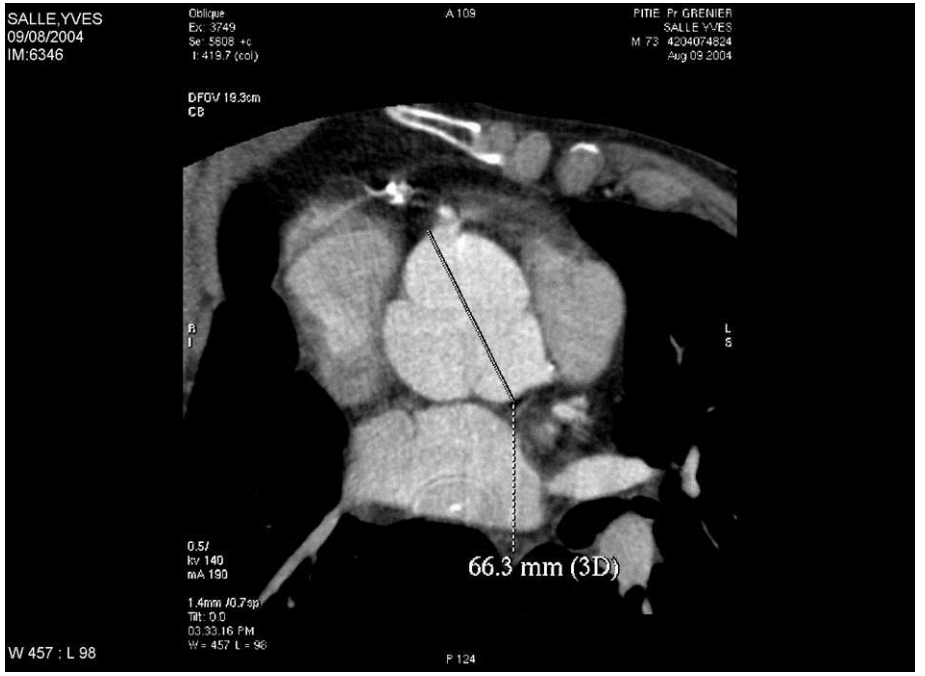
Bicuspidy



Marfan



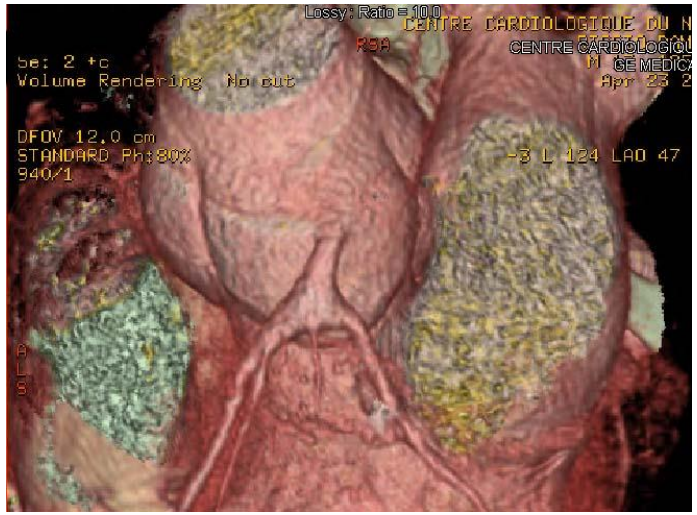
TDM with cardiac synchronisation



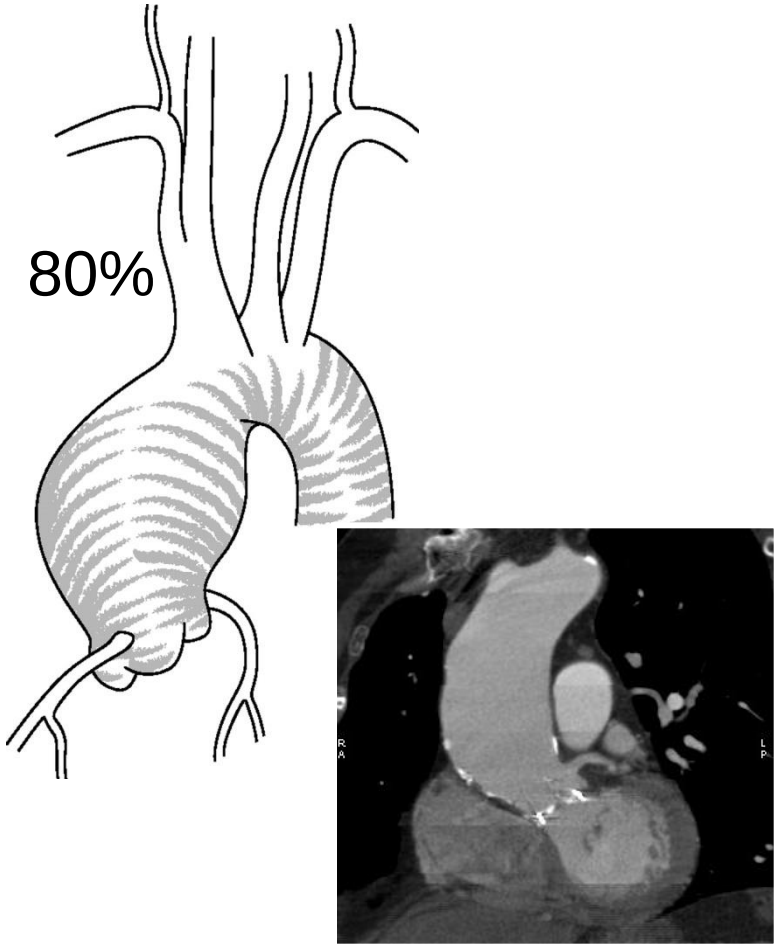
Confirmation of diameters

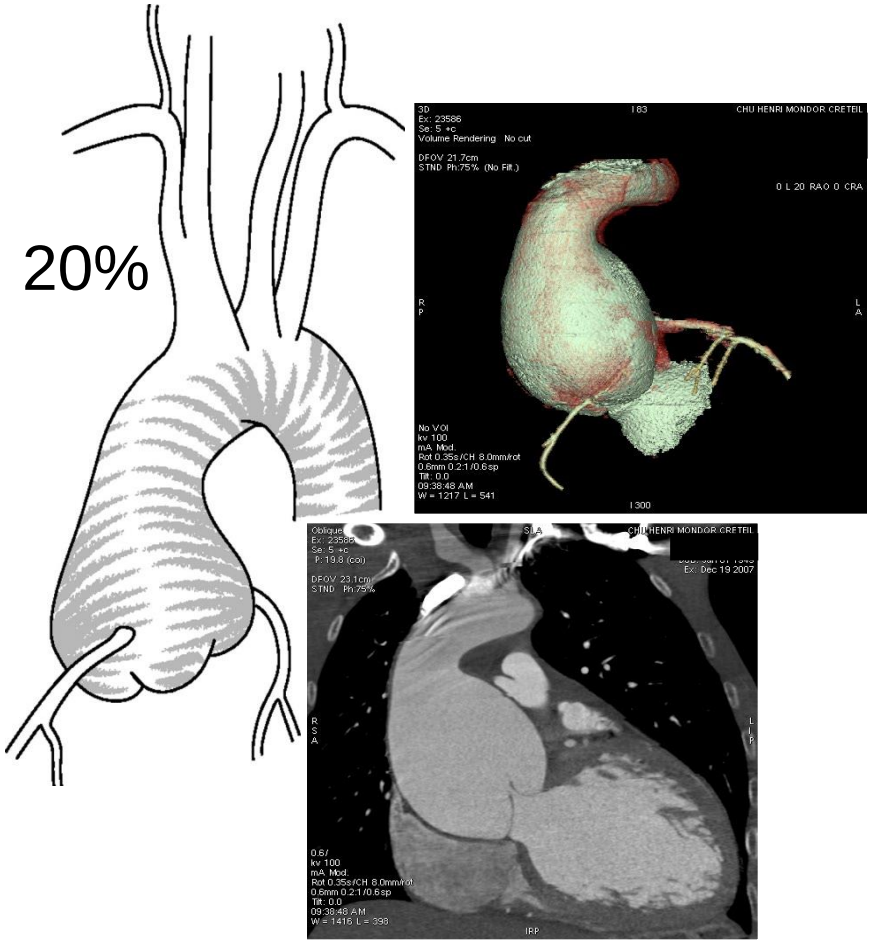
Aortic arch

3D Reconstruction



Two morphotypes

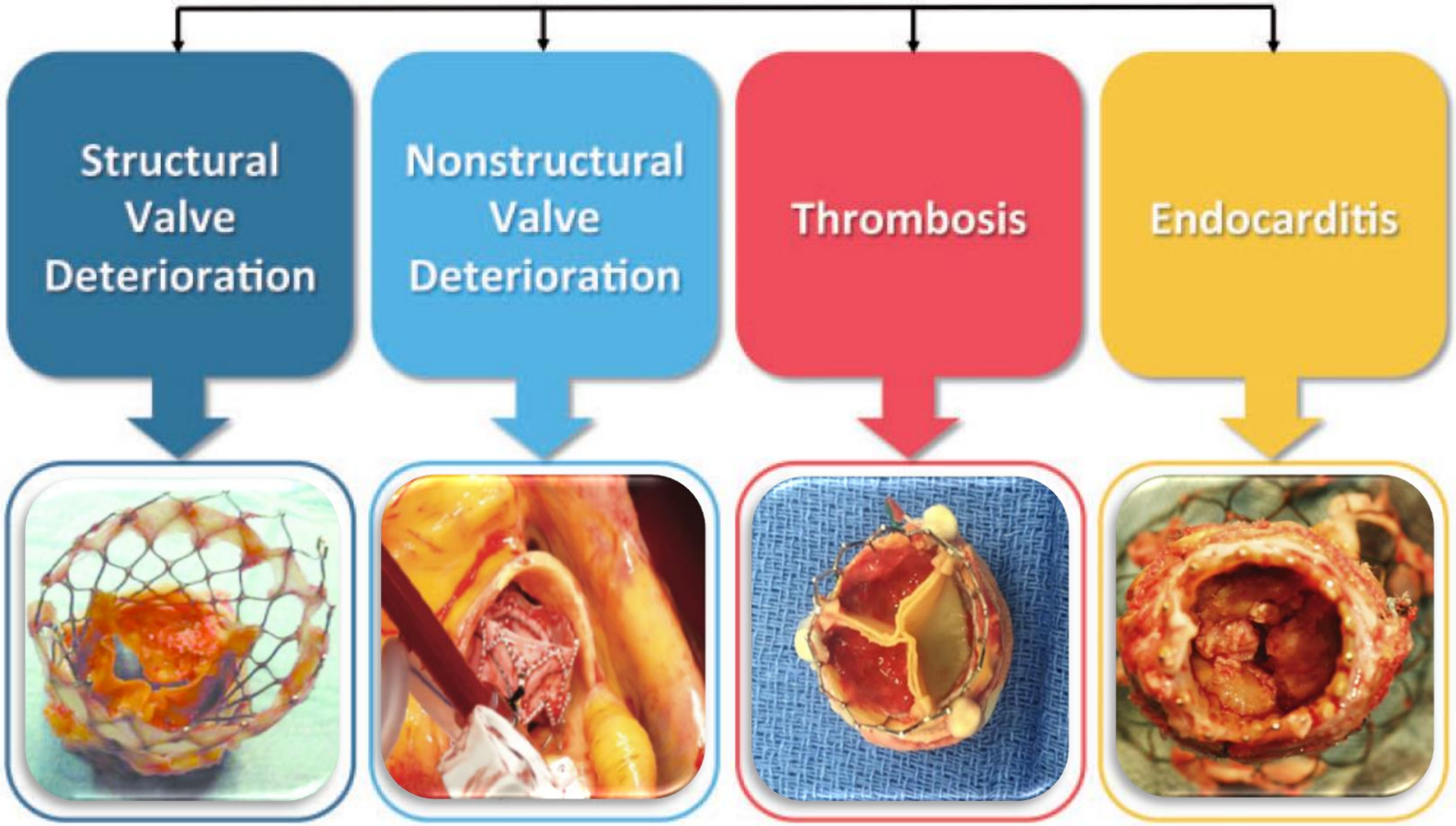




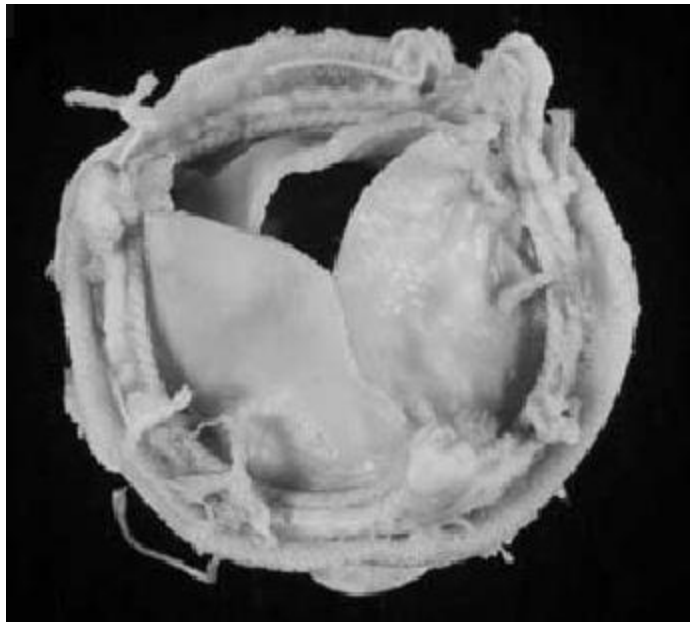
B. Aortic root or tubular ascending aorta aneurysm[e] (irrespective of the severity of aortic regurgitation)		
Aortic valve repair, using the reimplantation or remodelling with aortic annuloplasty technique, is recommended in young patients with aortic root dilation and tricuspid aortic valves, when performed by experienced surgeons.	I	C
Surgery is indicated in patients with Marfan syndrome, who have aortic root disease with a maximal ascending aortic diameter ≥50 mm.	I	C
Surgery should be considered in patients who have aortic root disease with maximal ascending aortic diameter:	IIa	C
• ≥45 mm in the presence of Marfan syndrome and additional risk factors[f], or patients with TGFBR1 or TGFBR2 mutation (including Loeys-Dietz syndrome)[g]		
• ≥50 mm in the presence of a bicuspid valve with additional risk factors[f] or coarctation.		
• ≥55 mm for all other patients.		
When surgery is primarily indicated for the aortic valve, replacement of the aortic root or tubular ascending aorta should be considered when ≥45 mm, particularly in the presence of a bicuspid valve.[h]	IIa	C

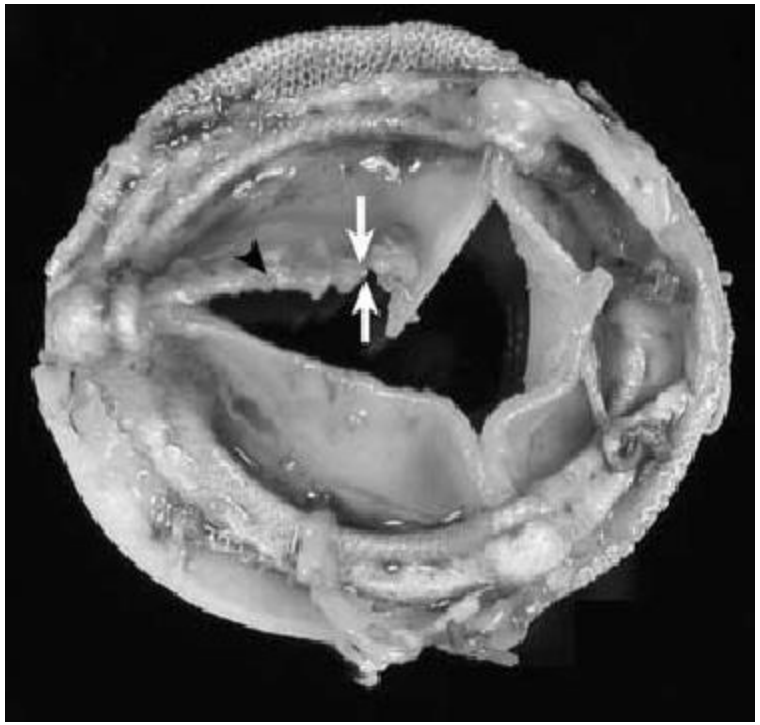
ESC/EACTS GUIDELINES – 2017

Causes of Bioprosthetic Valve Dysfunction



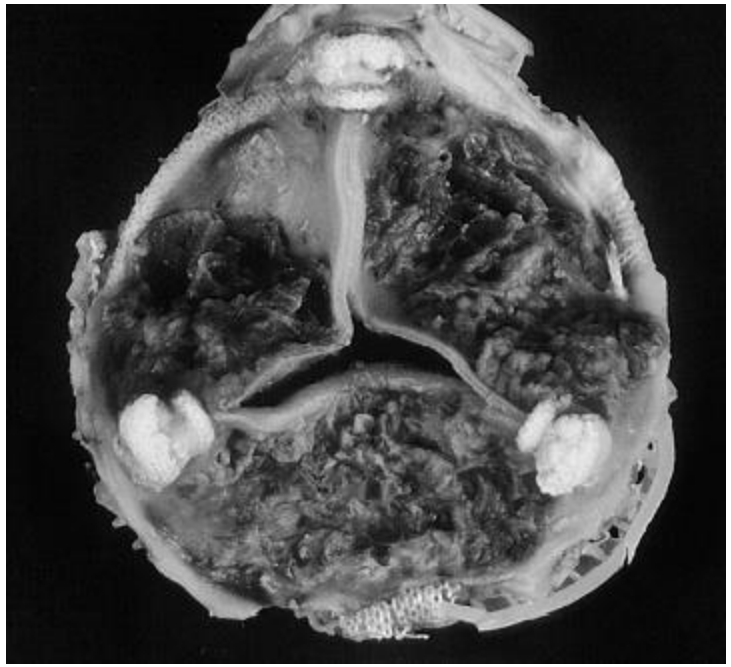
Modified from Capodanno et al. EJCTS 2017; 52:408–417



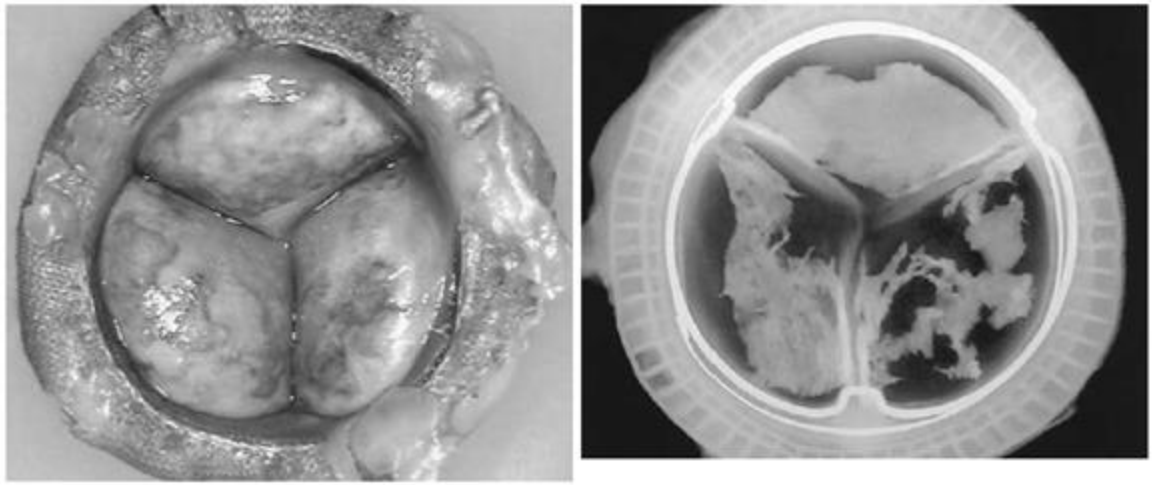


A CE valve that had been in place for 15 years. This prosthesis shows extensive calcification of the cusps (asterisks) and a tear (arrows) at one stent post. The tissue close to this tear shows nodular thickening (arrowhead).

Pannus overgrowth after mitral valve replacement with a CE valve. Increased pannus can extend onto the cusp surfaces and can lead to thickening of the cusps, increasing its stiffness and thereby affecting its ability to open fully, ultimately resulting in stenosis and possibly incompetence when the collagen matures and the cusps retract like the pleats of an accordion.



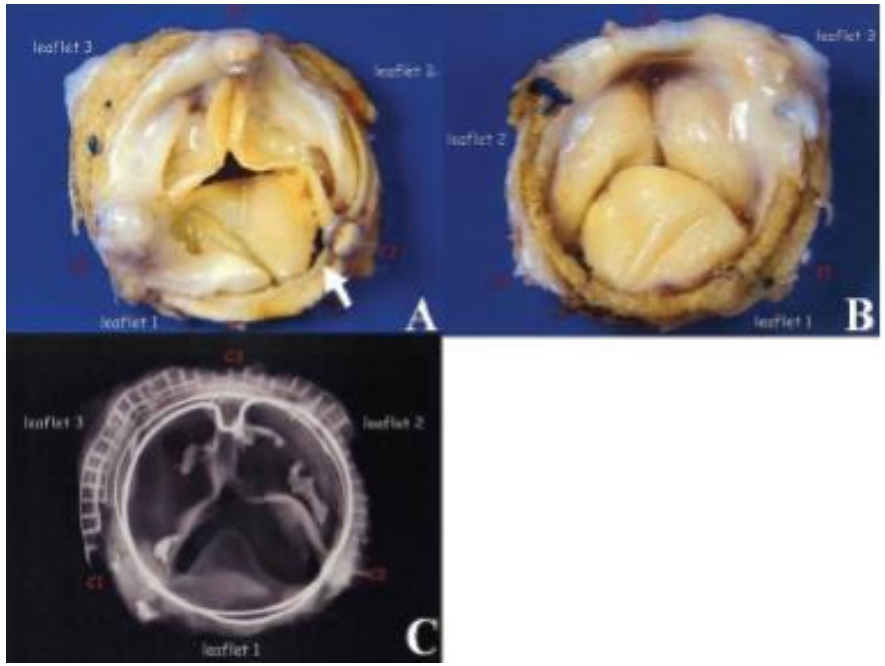
Extensive thrombosis of the prosthetic sinuses of Valsalva of a stenotic CE valve.



A CE valve explanted from a 75-year-old woman with history of chronic atrial fibrillation. It was rigid, heavily calcified, with minimal open movement of the 3 cusps. Specimen radiograph demonstrating extensive calcium deposits in the cusps*.

_____

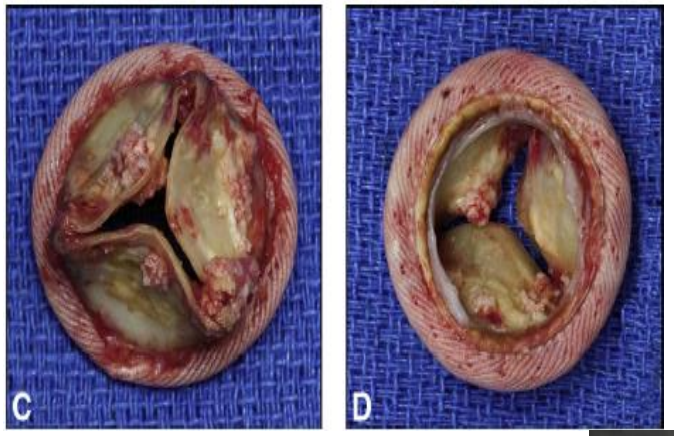
*There is evidence in the literature that extensive calcification of bioprosthetic valves depends on thrombosis of the leaflets



A CE valve showing pannus overgrowth and a tear in leaflet 1 (white arrow). X-ray of the valve showed calcification on leaflets 2 and 3.

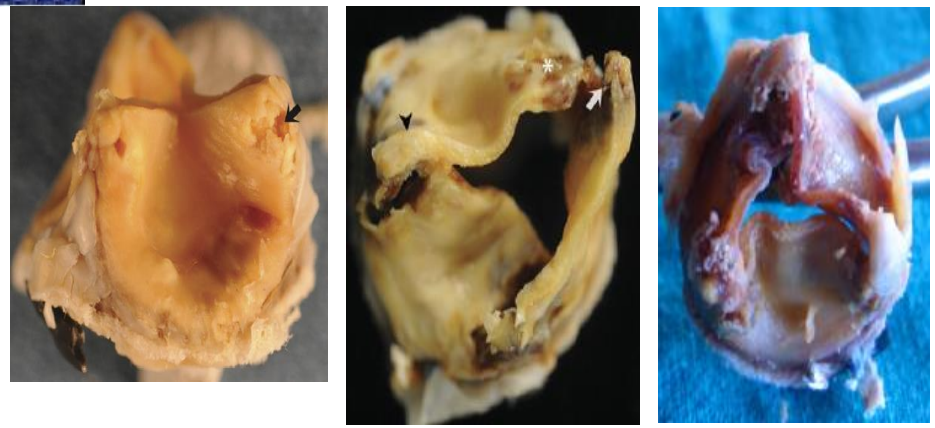
Pannus formation, on the cusps can shrink the cusps and cause regurgitation. Pannus itself can become calcified and lead to further valve dysfunction.

SJM Trifecta valve

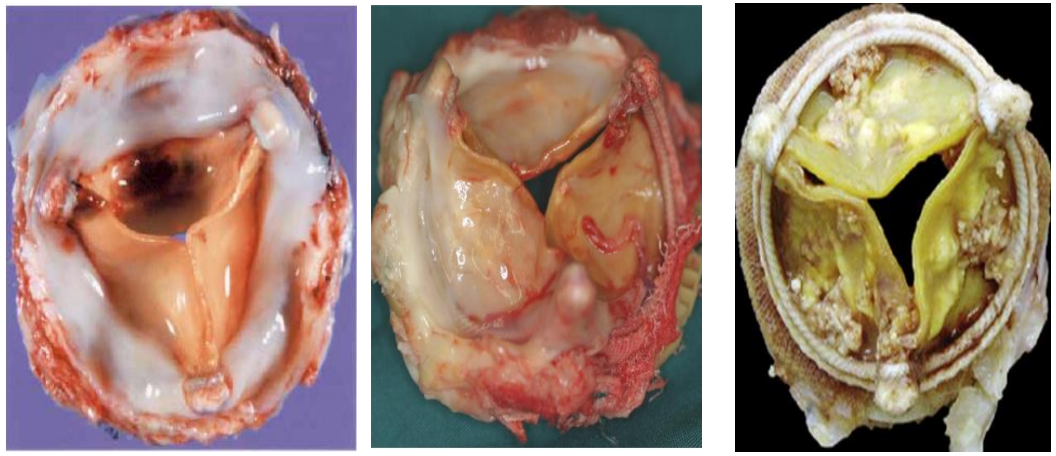


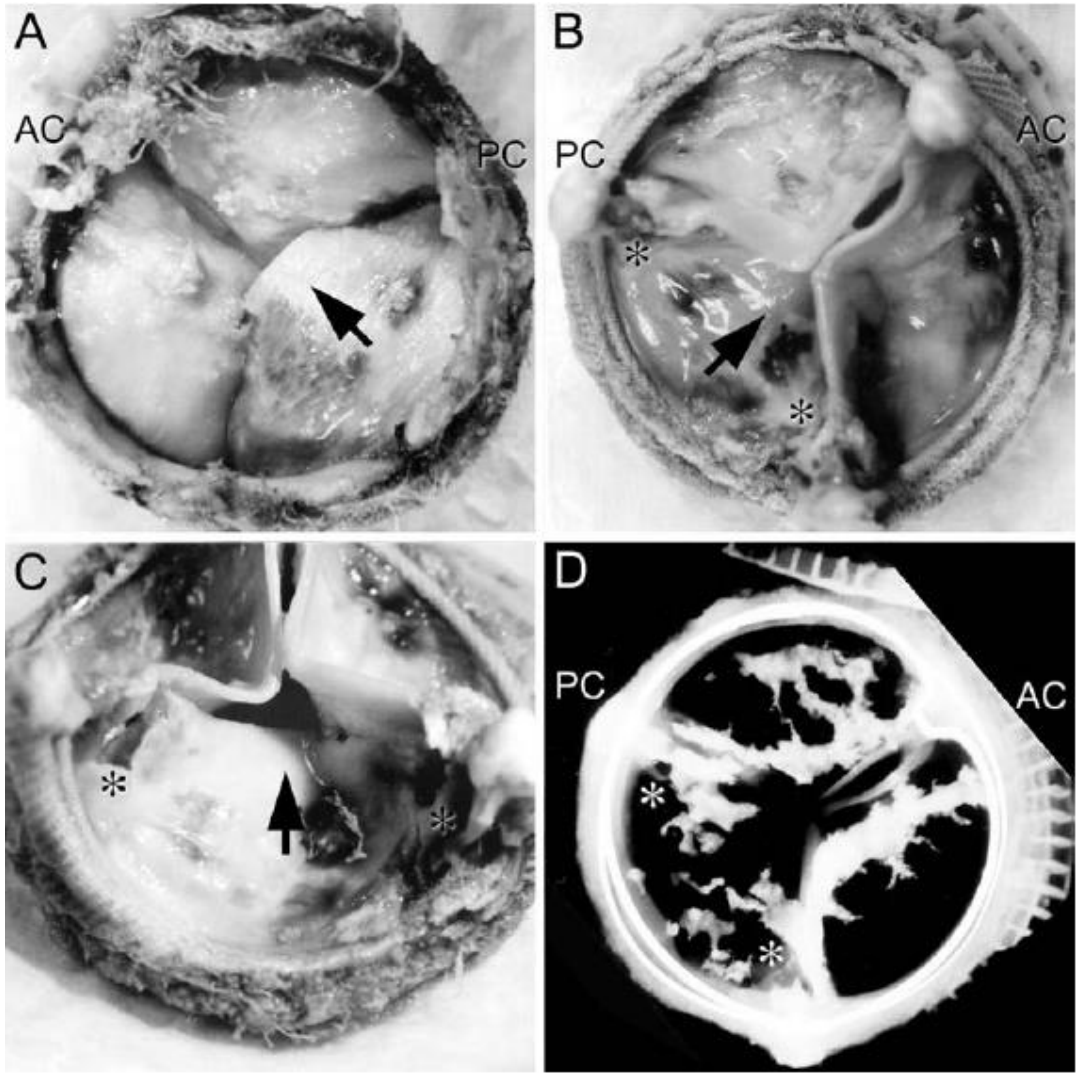
Current bioprosthetic valves are not recommended for patients younger than 60 years of age who require aortic valve replacement.

Sorin Mitroflow valves

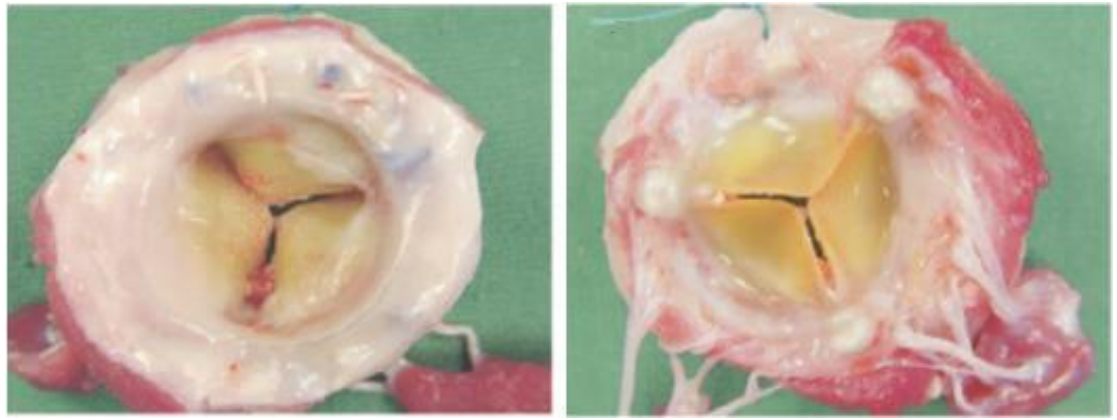


Carpentier-Edwards valves



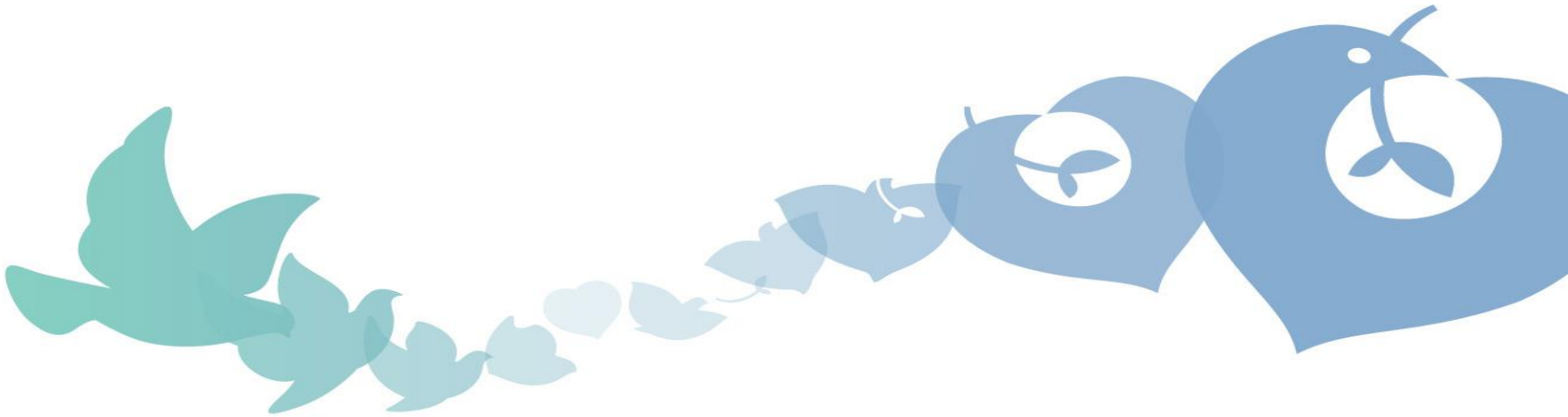


A CE valve from a 43-year-old female, at 16 years after implantation. The valve is rigid with multiple calcific deposits, pannus overgrowth, leaflet hematoma, various disruptions and multiple leaflet tears . X-ray analysis shows extensive calcium deposits in the cusps.



A CE valve from an adolescent sheep, at 5 months after implantation (pannus growth onto the leaflets).

Stented THV – Long term data comparison



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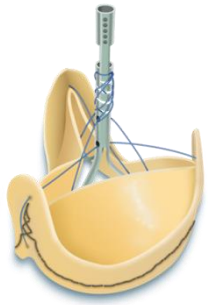
The Gold Standard in AVR



Surgical AVR with standard THV?

Bioprosthesis and Mechanical Valves

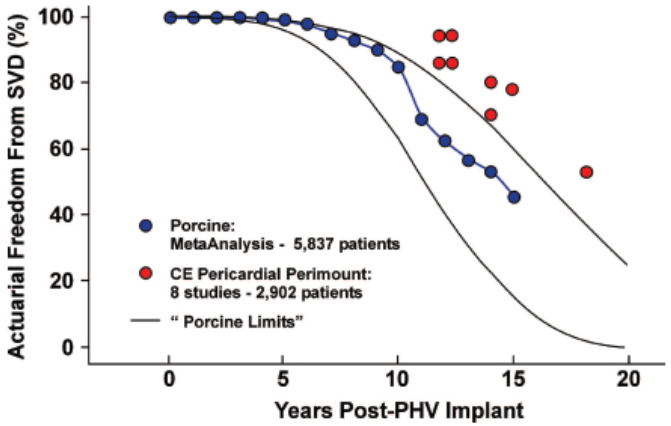


Figure 3. Porcine limits (black line) are the limits of SVD of earlier-model stented porcine bioprosthesis. Porcine (blue circles) is from a meta-analysis of later-model stented porcine bioprosthesis. Carpentier-Edwards is from studies of C-E pericardial Perimount valves (red circles). SVD indicates structural valve deterioration; CE, Carpentier-Edwards; and PHV, prosthetic heart valve. Reproduced from Rahimtoola et al[1] with permission of the publisher. Copyright © 2008, Elsevier.

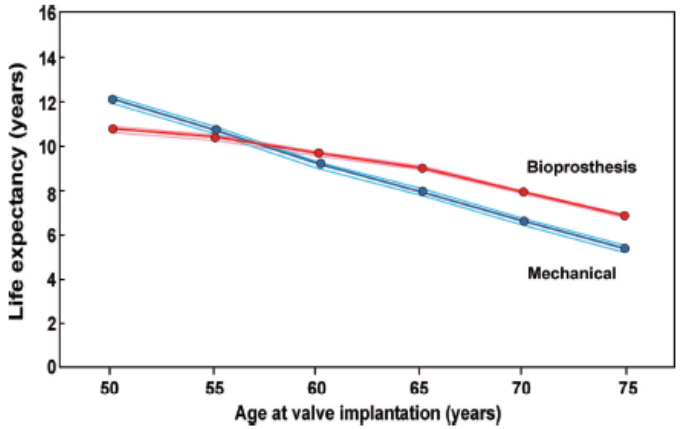
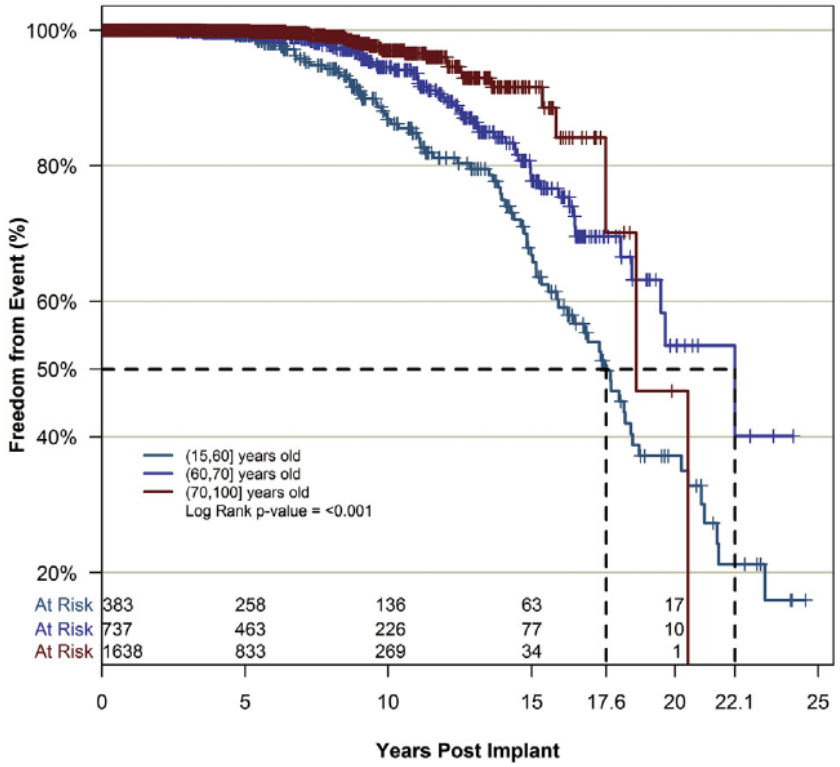


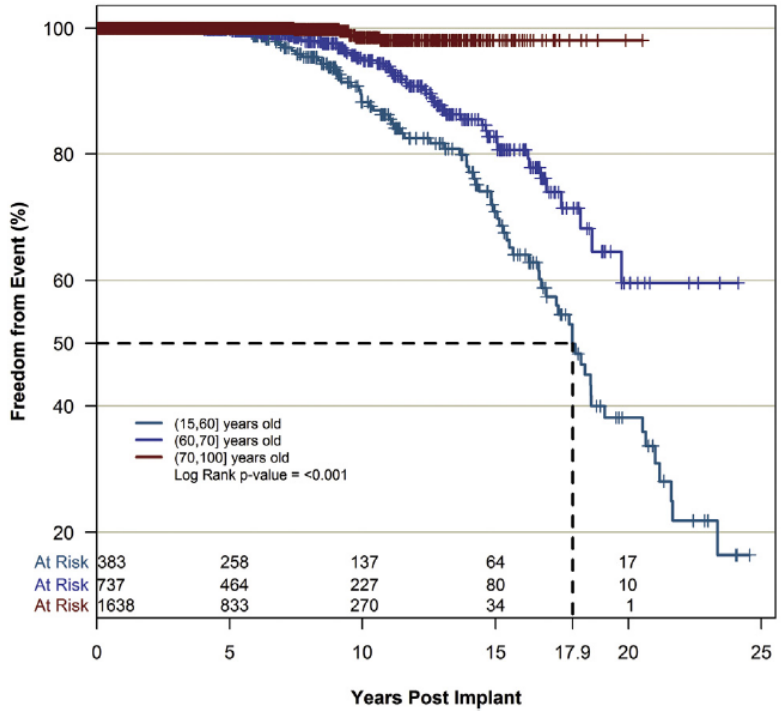
Figure 2. Event-free life expectancy after aortic valve replacement in the United States. Mean and 68% upper and lower confidence limits are shown. Adapted from van Geldorp et al[8] with permission of the publisher. Copyright © 2009, Elsevier.

Very Long-Term Outcomes of the Carpentier-Edwards Perimount Valve in Aortic Position

Thierry Bourguignon, MD, Anne-Lorraine Bouquiaux-Stablo, MD, Pascal Candolfi, PhD,

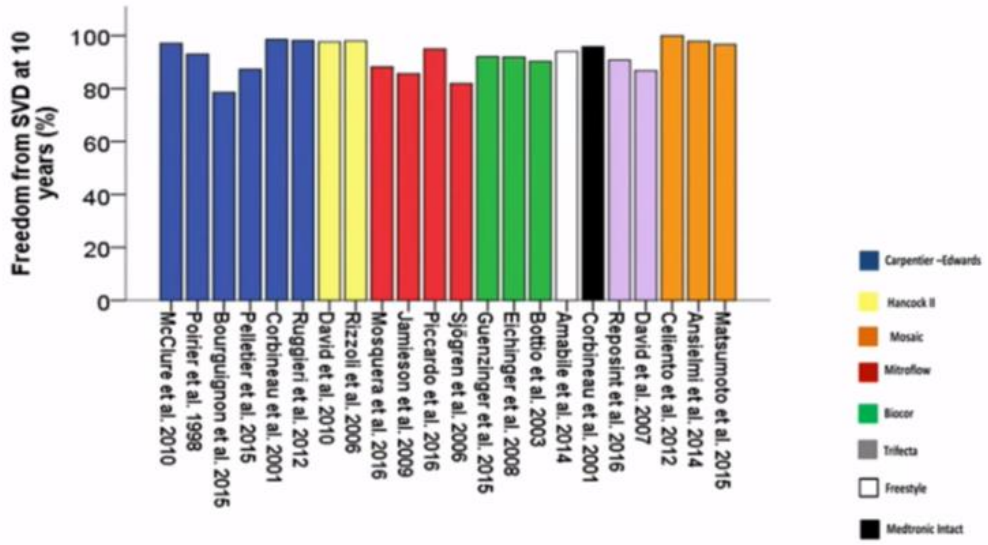


Freedom from structural deterioration

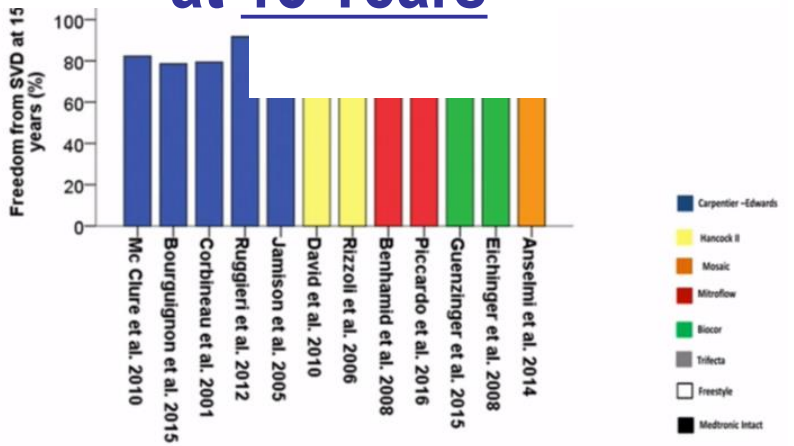


Freedom from reopration due to structural deterioration

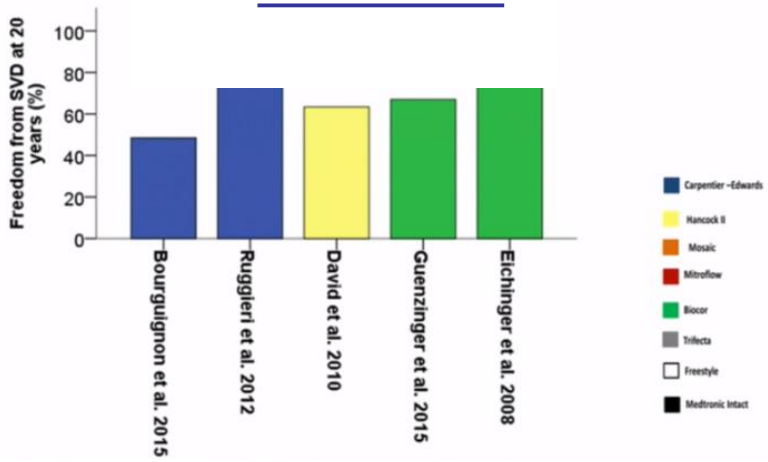
Freedom from SVD at 10 Years



Freedom from SVD at 15 Years



Freedom from SVD at 20 Years



Courtesy of T. Doenst:
Durability of Tissue Valves in the Aortic Position. September 2018. doi:10.25373/ctsnet.7029461.

Ongoing issues with TAVI and Bioprosthesis in intermediate risks pts

PVL and Performance

Permanent Pacemaker (PM)

Stroke

Durability

Thrombosis

Economics

Which valve for which patient?

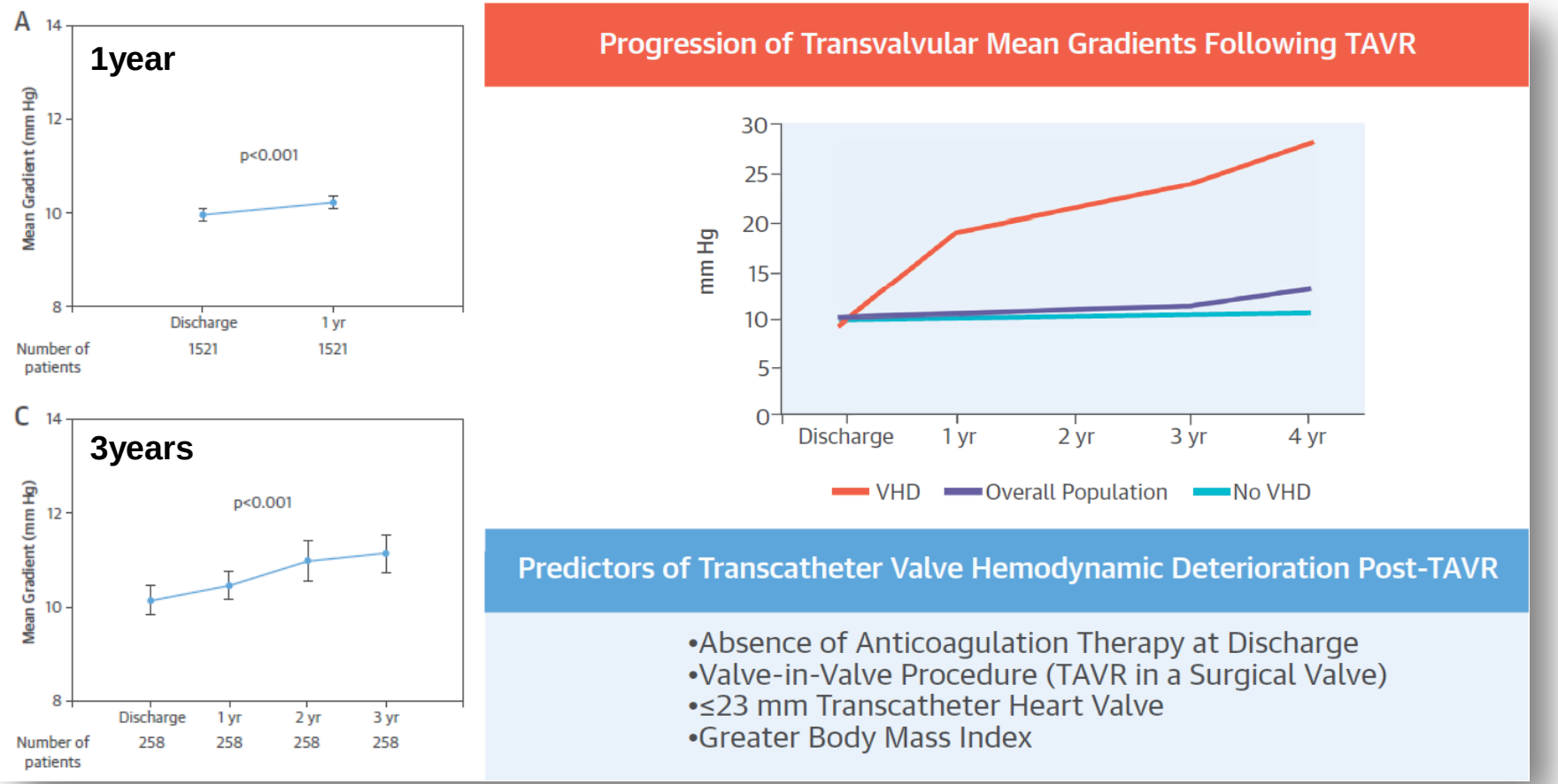
Structural valve deterioration after transcatheter aortic valve implantation

Farid Foroutan,[1,2] Gordon H Guyatt,[1] Catherine M Otto,[3] Reed A Siemieniuk,[1,4]

Study	Recruitment period	N	Age (years) (mean±SD)	Mean/median follow-up	SVD (%)	Type of SVD
Rodés-Cabau 2012	2005–2009	339	81.0±8.0	4 years	0	
Toggweiler 2013	2005–2007	88	83.0±7.0	5 years	3.4	One regurgitation, one stenosis, one mixed
Gotzmann 2014	2008–2010	150	79.0±6.0	2.2 years	2	Five regurgitation
Kovac 2016	2006–2008	126	82.4±6.4	2.8 years	0	
Bouleti 2015	2006–2009	122	81.5±8.4	3.6 years	4.1	Two regurgitation, three stenosis
Barbanti 2015	2007–2009	353	81.5±6.3	3.9 years	4.2	Two regurgitation, 11 stenosis
Gulino 2016	2007–2010	125	81.1±4.7	4.4 years	5.6	Three regurgitation, four stenosis
Sawaya 2016	2004–2008	410	82.3±5.6	5 years	0	
Papadopoulos 2016	2005–2015	312	79.8±5.8	4.1 years	0	
D'Onofrio 2016	2007–2013	338	80.3±6.7	1.8 years	0	
Ruparelia 2016	2007–2015	829	82.6±8.2	5 years	0	
Del Trigo 2016	2007–2014	1521	81.0±7.0	4 years	4.5	Not reported
Gilard 2016	2010–2012	4201	82.5±7.1	3.8 years	0	

Durability ?

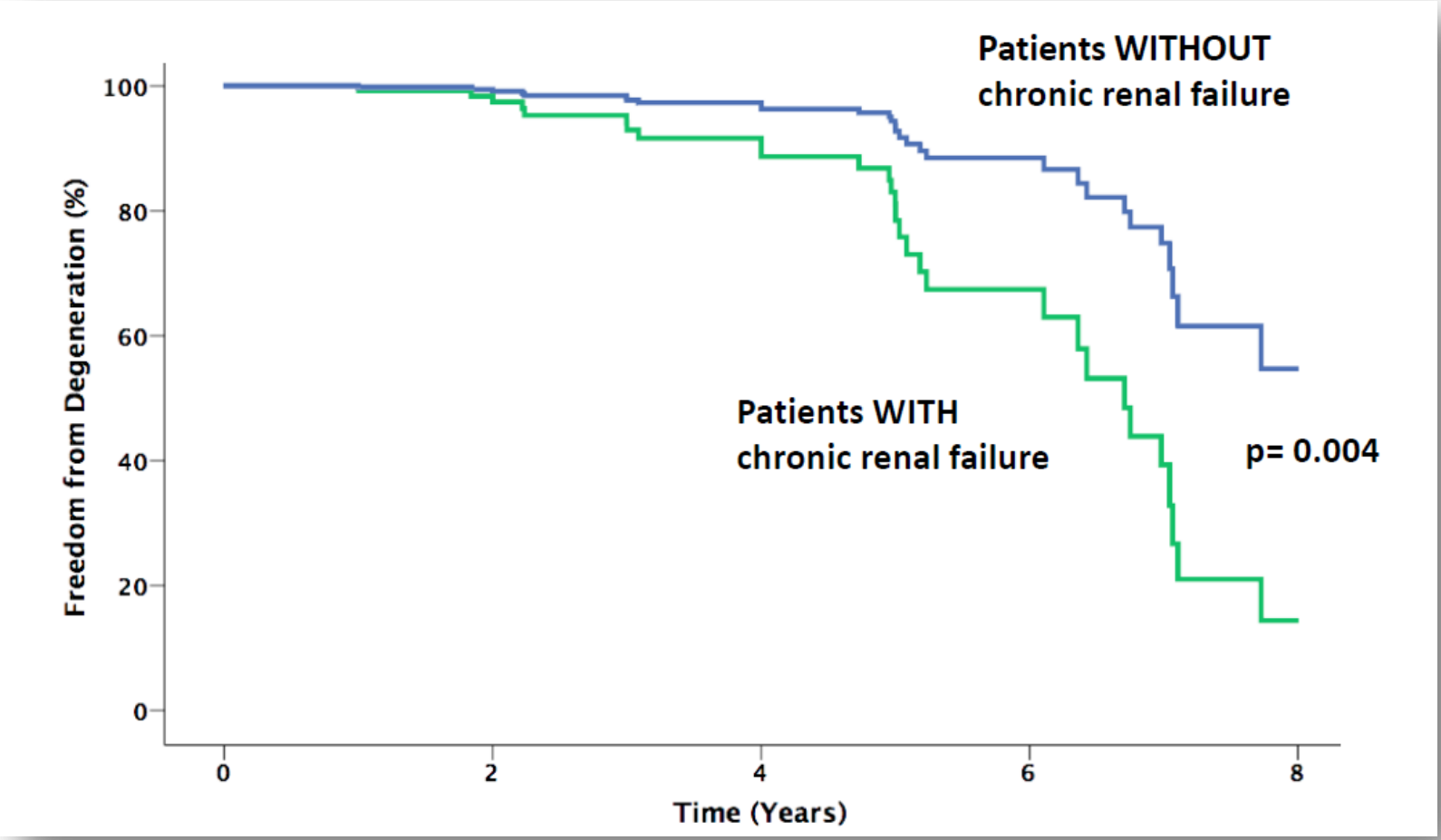
Progression of Mean Gradients 4Ys after TAVI; n=1521



Del Trigo et al. JACC 2016;67:644-55

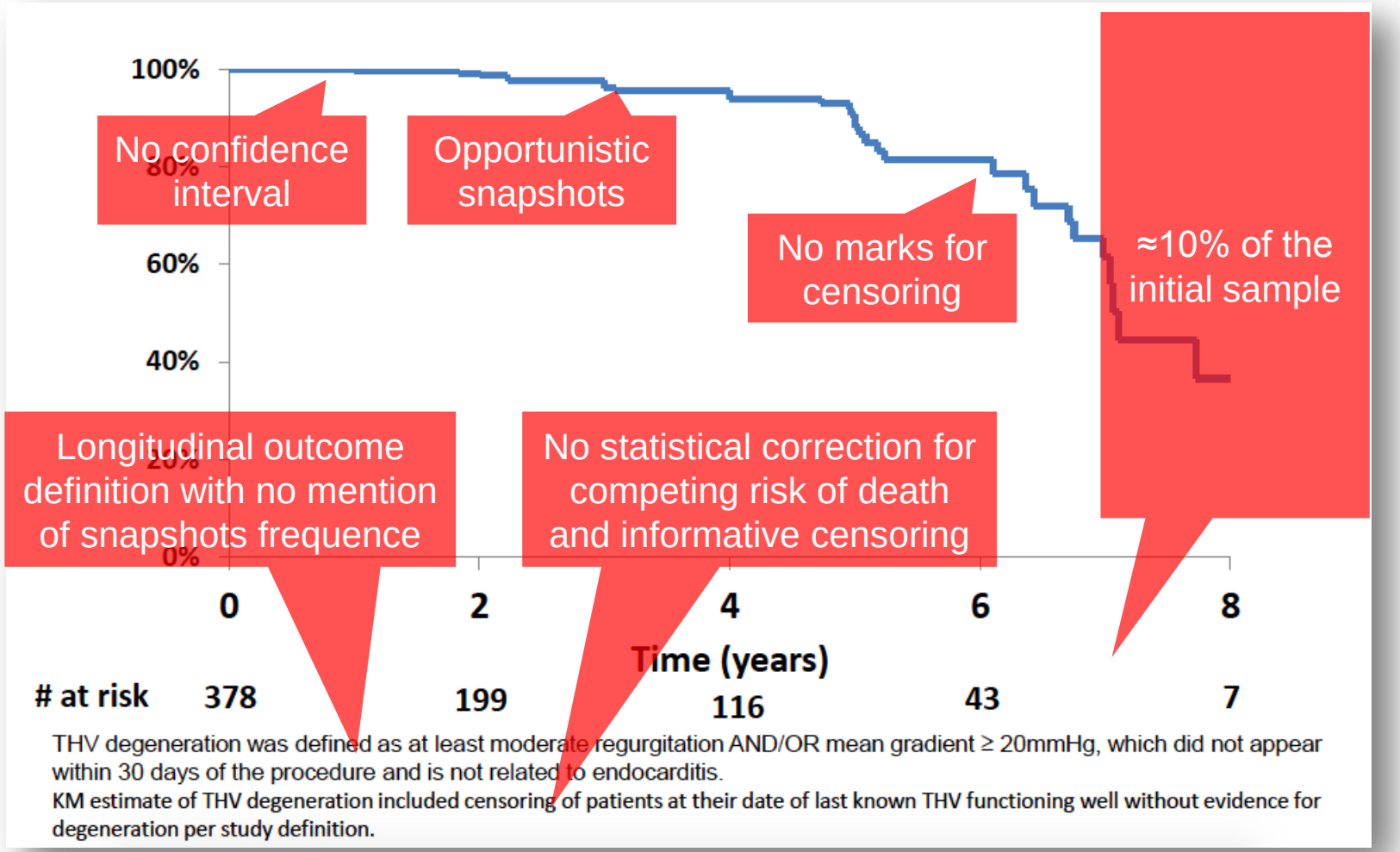
Freedom from THV Degeneration (n=378)

Combined Vancouver-Rouen Experience



Dvir D, et al. EuroPCR 2016, Paris

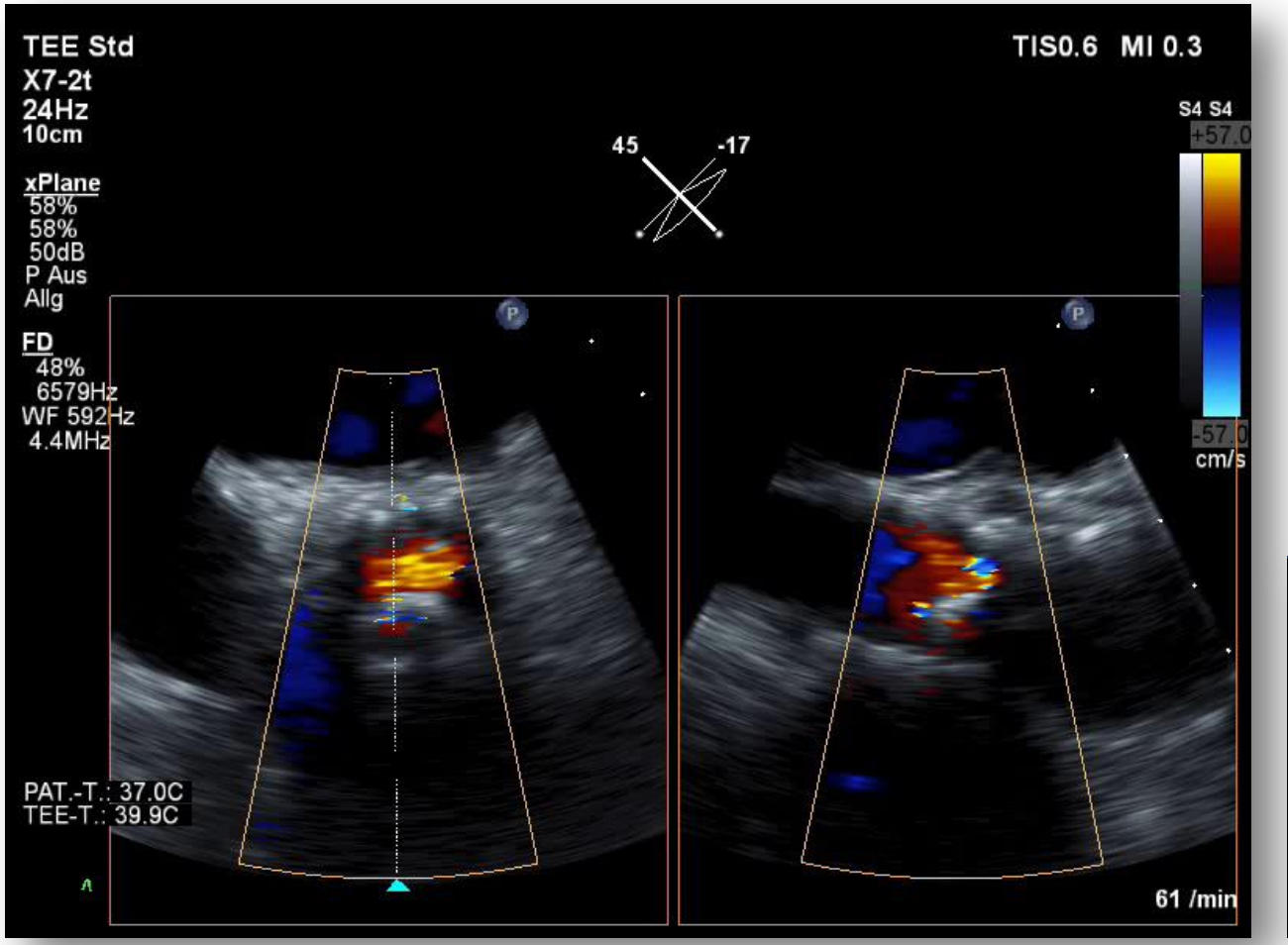
Freedom from THV Degeneration (n=378)



Dvir D, et al. EuroPCR 2016, Paris

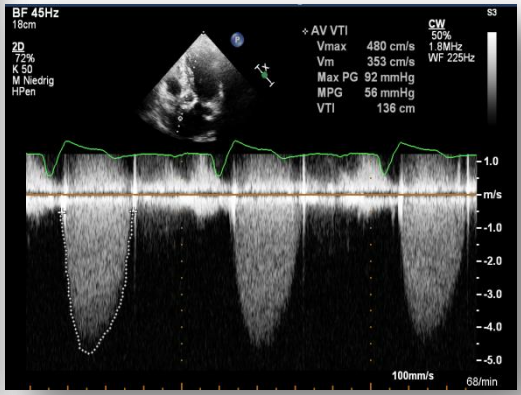
Structural Valve Deterioration 7 years after TAVI

Case report, 80 y/o female

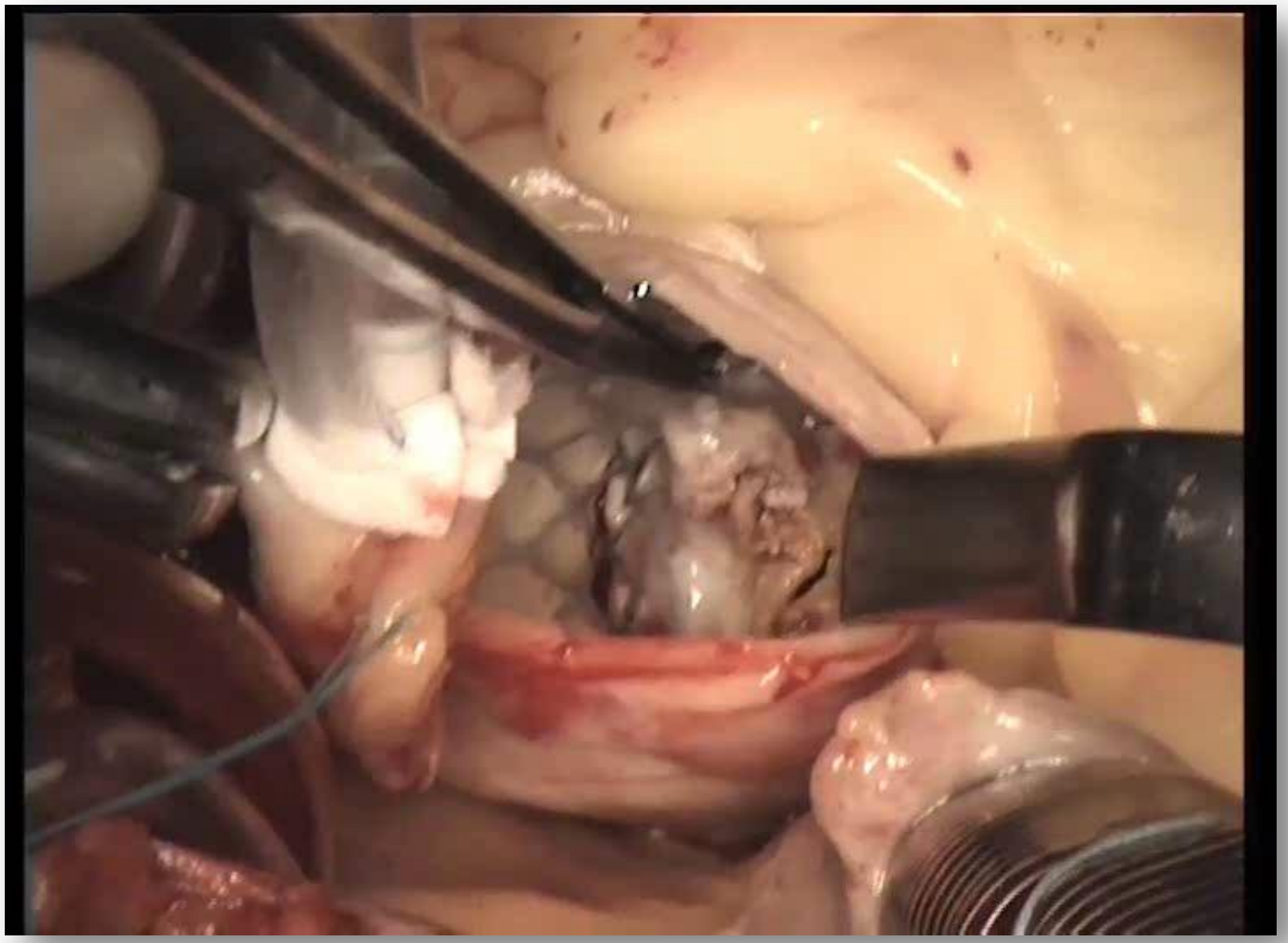


SVD after CoreValve 2009

- TEE at 7y follow-up
- AS severe, pMean 56mmHg
- AR moderate-severe

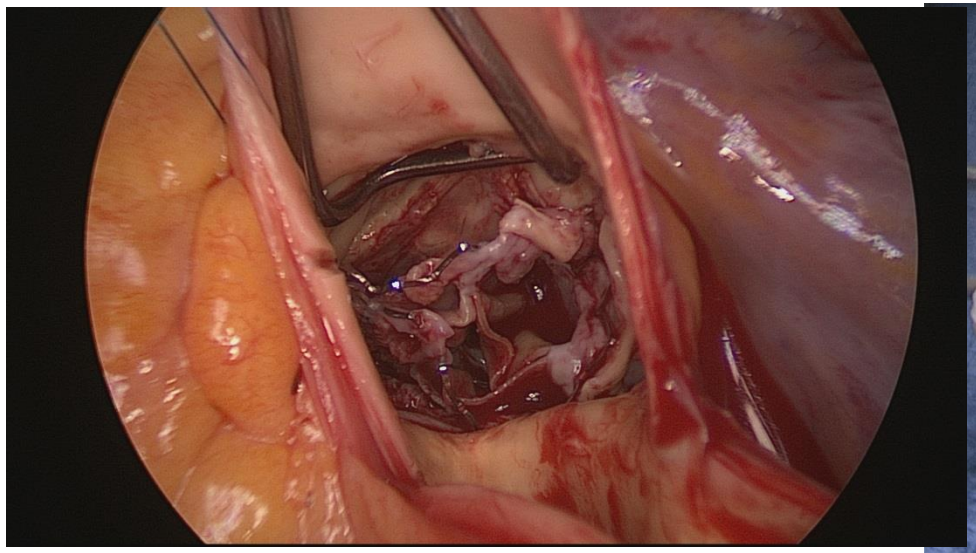


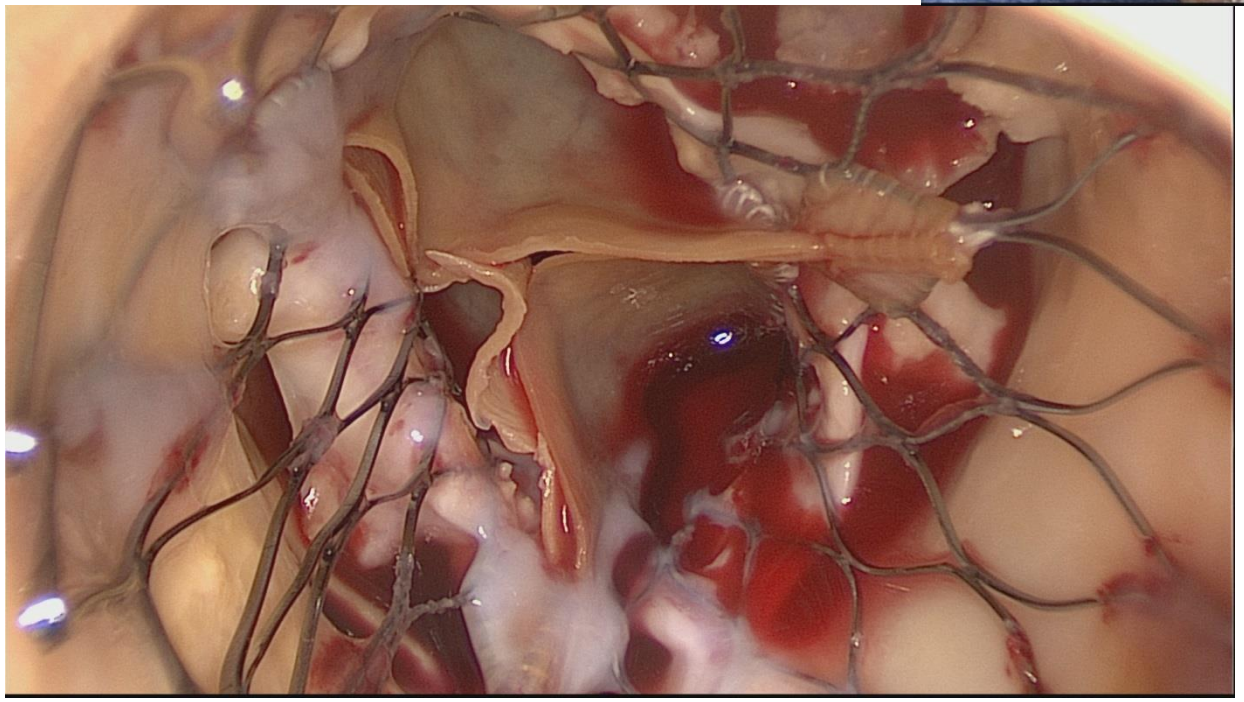
Structural Valve Deterioration in TAVI



- CoreValve Explant
- sAVR (CE-Perimount Magna Ease 23mm)
- Root enlargement
- Subvalv. myectomy
- Ao. asc replacement

Early failure 1 year after self expandable TAVR

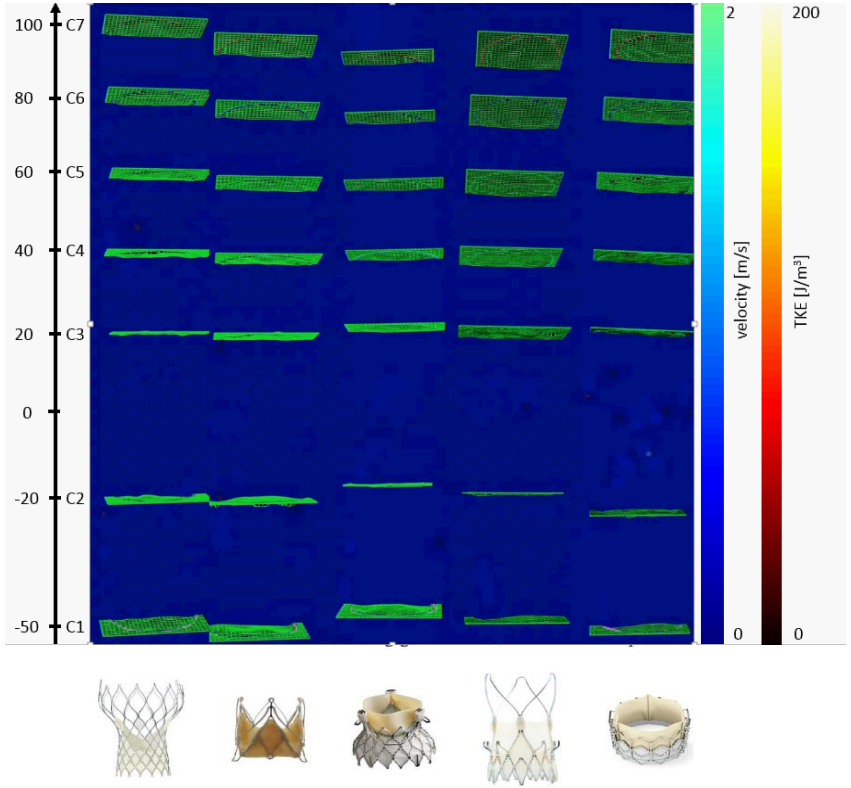




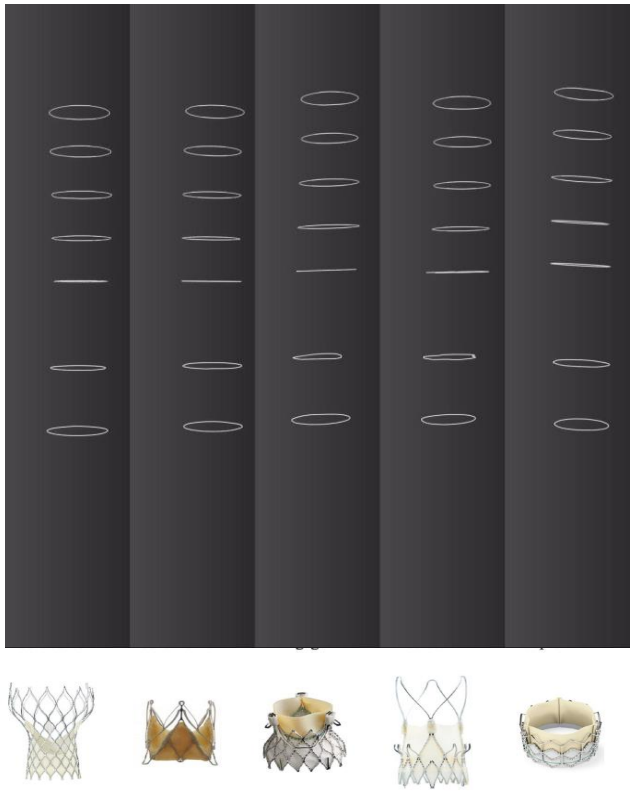
THV Device-anatomy Interaction – In vitro

Flow patterns and turbulences in TAVI

Time-resolved overlay of velocities in a 2-D coronal plane along with a 3-D rendering of TKE values of all TAVI valves



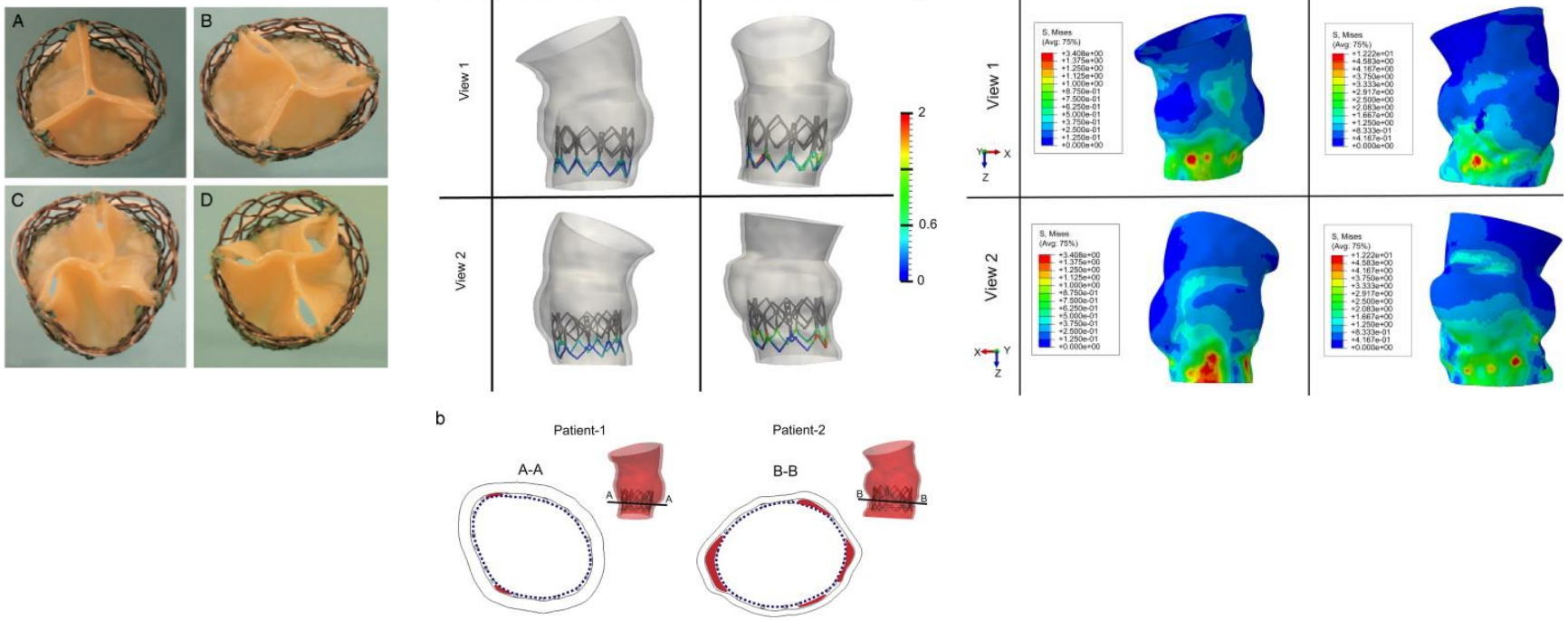
Time-resolved traces of particle ejected at level C3 of all TAVI valves



Giese et al. MAGMA 2018; 31:165-172

THV Device-anatomy Interaction – in vivo

Asymetric expansion and in-vivo fixation:



Morganti et al. J Biomech 2014;47:2547-55

Possible reasons for reduced THV durability

THV characteristics

- Lack of advanced anticalcification treatment
- Limited years of practice
- Leaflet morphology and design

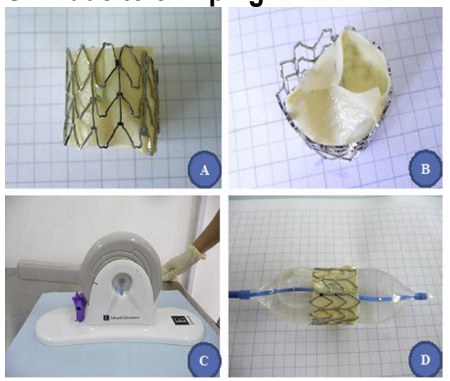
THV deployment

- Valve crimping
- Small sheath delivery / balloon inflation

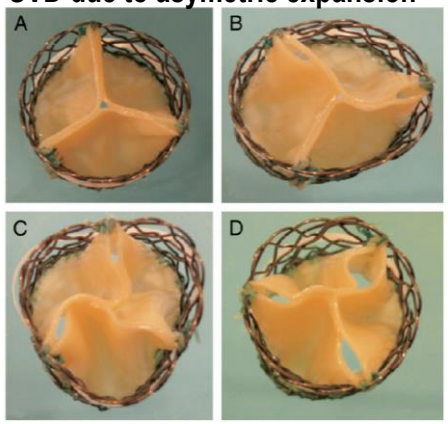
THV device-anatomy interaction

- No native valve decalcification
- Device underexpansion / asymetric expansion
- Paravalvular regurgitation

SVD due to crimping

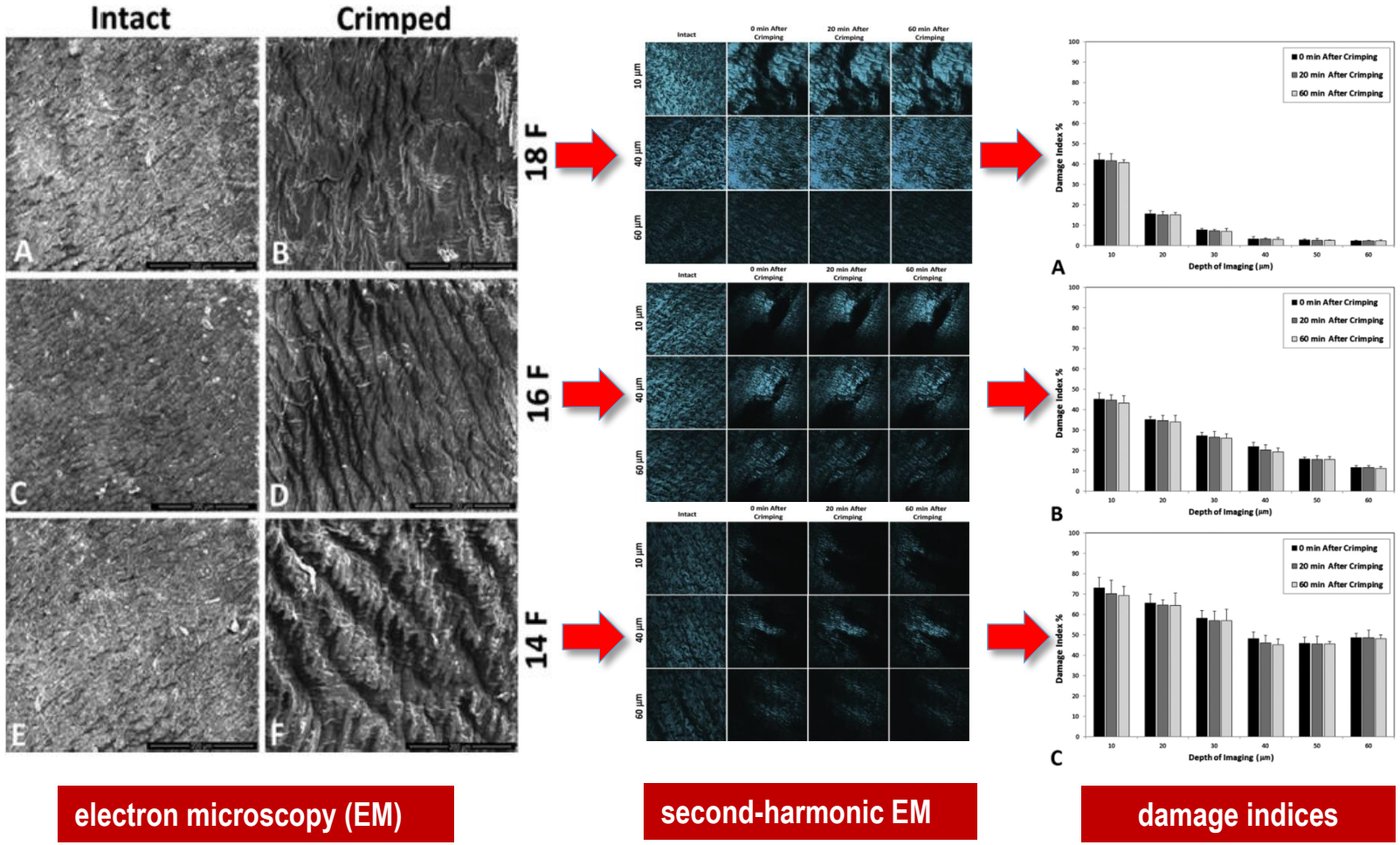


SVD due to asymetric expansion



Li et al. Ann Biomed Eng 2010
Sun et al. J Biomech 2010
Martin et al. J Biomech 2015
Kiefer et al. ATS 2011

Tissue Damage due to Crimping on Pericardial Leaflets

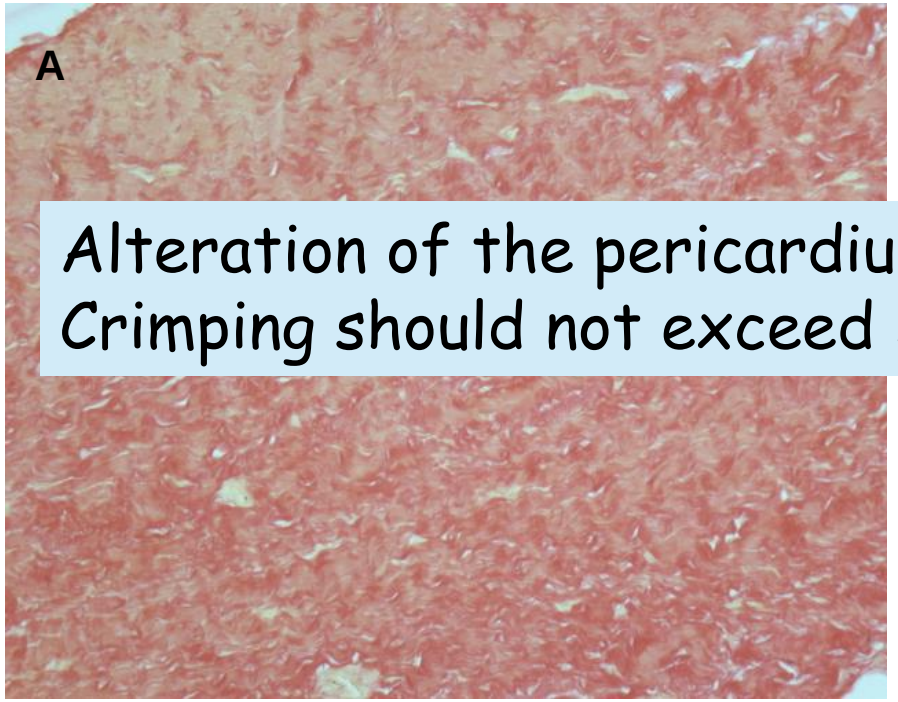


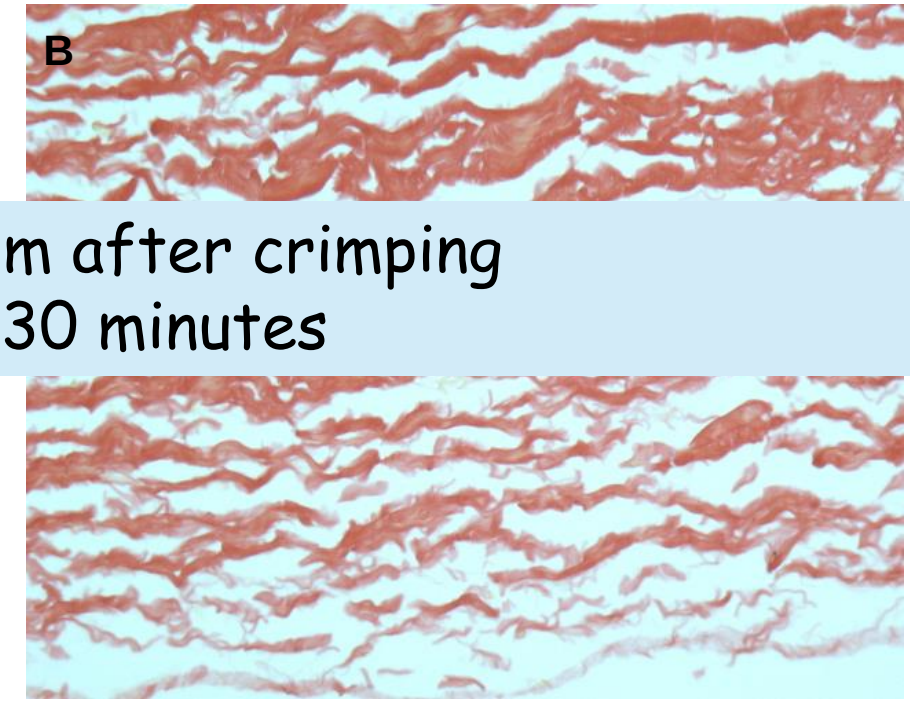
electron microscopy (EM)

second-harmonic EM

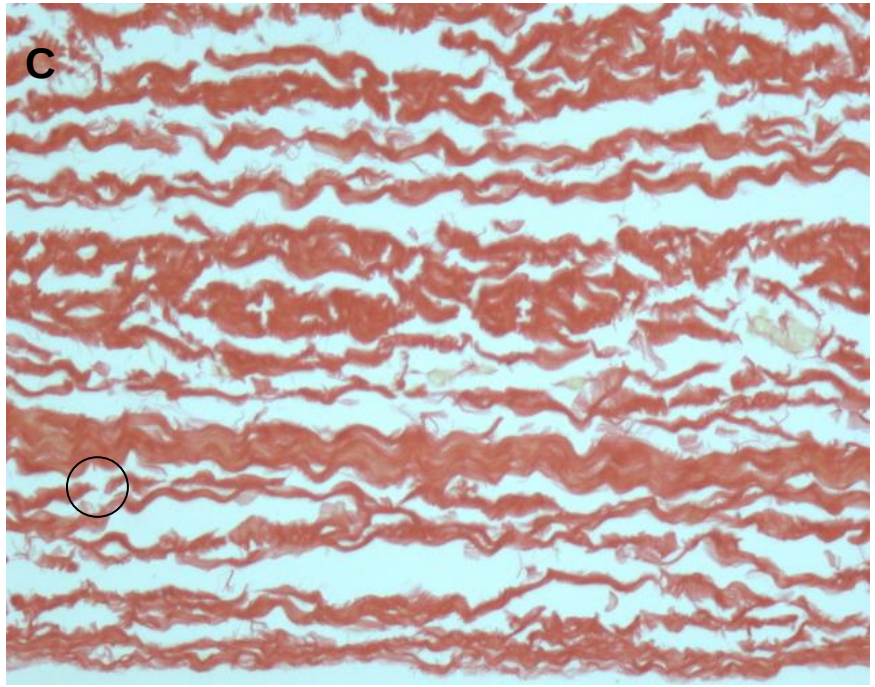
damage indices

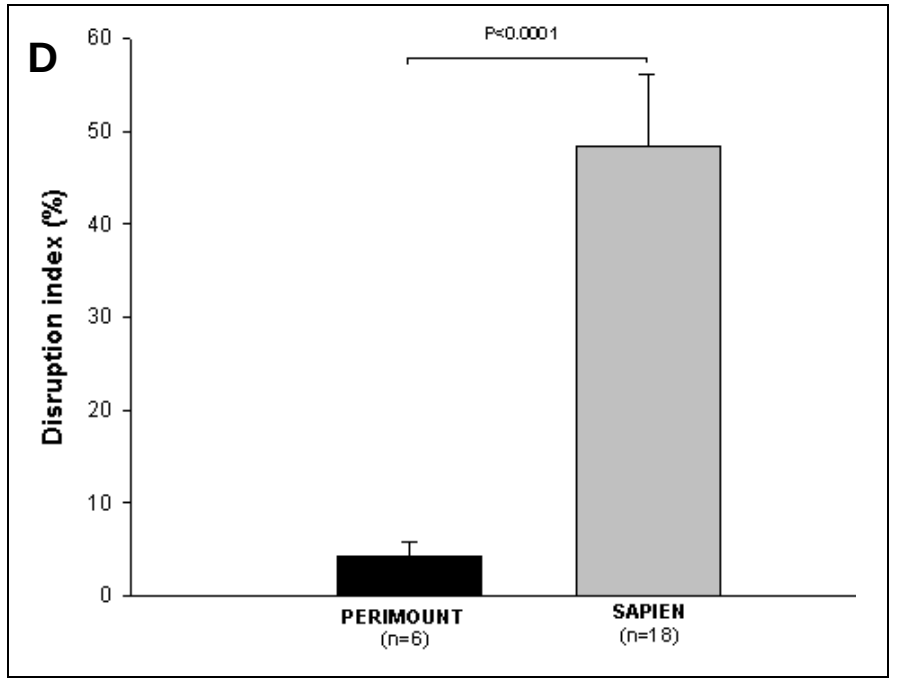
Alavi et al. ATS 2014;97:1260-66





Alteration of the pericardium after crimping
Crimping should not exceed 30 minutes





Ongoing issues with TAVI and Bioprosthesis in intermediate risks pts

PVL and Performance

Limited number of TAVR ViV procedures

Depends of the native aortic annulus

Importance of native annular anatomy (bicuspid, calcifications, septal hypertrophy)

Ongoing issues with TAVI and Bioprosthesis in intermediate risks pts

PVL and Performance

Permanent Pacemaker (PM)

Stroke

Durability

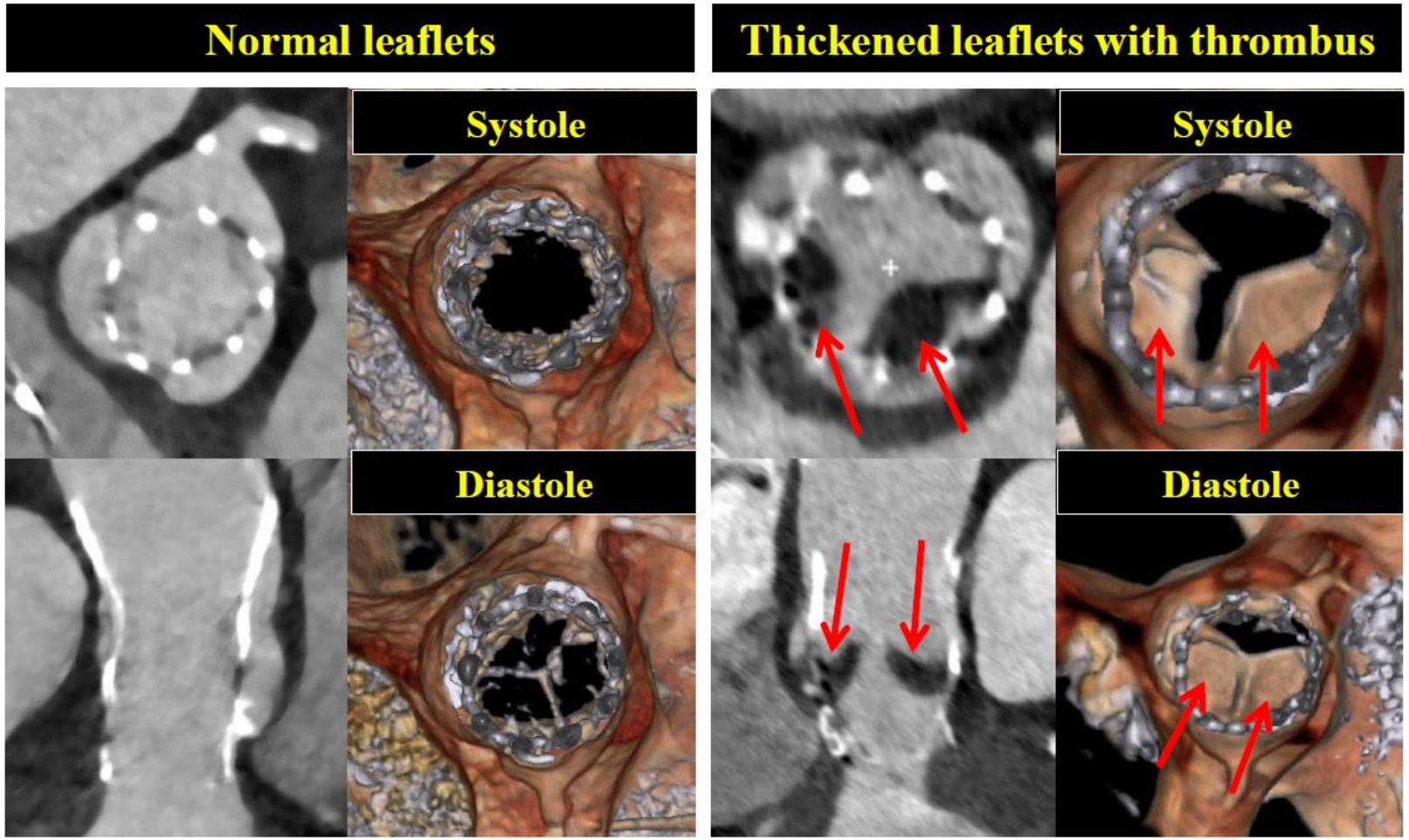
Thrombosis

Economics

Which valve for which patient?

Subclinical Valve Thrombosis in TAVI

by Volume-rendered 4D-CT



Manifest Valve Thrombosis after TAVI

JACC: CARDIOVASCULAR INTERVENTIONS
© 2017 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION
PUBLISHED BY ELSEVIER

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http://dx.doi.org/10.1016/j.jcin.2017.01.045

STRUCTURAL

Clinical Bioprosthetic Heart Valve Thrombosis After Transcatheter Aortic Valve Replacement

Incidence, Characteristics, and Treatment Outcomes

John Jose, MD, DM,[a,b] Dmitriy S. Sulimov, MD,[a] Mohamed El-Mawardy, MD,[a] Takao Sato, MD,[a,c] Abdelhakim Allali, MD,[a] Erik W. Holy, MD,[a] Björn Becker, MD,[a] Martin Landt, MD,[a] Julia Kebernik, MD,[a] Bettina Schwarz, MD,[a] Gert Richardt, MD,[a] Mohamed Abdel-Wahab, MD[a]

ABSTRACT

OBJECTIVES The aim of this study was to determine the incidence, characteristics, and treatment outcomes of patients diagnosed with clinical transcatheter heart valve thrombosis.

BACKGROUND Limited data exists on clinical or manifest transcatheter heart valve thrombosis. Prior studies have focused on subclinical thrombosis.

METHODS A retrospective analysis was conducted of prospectively collected data from a single-center registry that included 642 consecutive patients who underwent transcatheter aortic valve replacement between 2007 and 2015 (305 patients had self-expanding valves; balloon-expandable, n = 281; mechanically expanding, n = 56). Long-term oral anticoagulation (OAC) was indicated in 261 patients, while 377 patients received dual-antiplatelet therapy post-procedure. All patients underwent scheduled clinical and echocardiographic follow-up.

RESULTS The overall incidence of clinical valve thrombosis was 2.8% (n = 18). No patient on OAC developed thrombosis. Of the detected thrombosis cases, 13 patients had balloon-expandable, 3 had self-expanding, and 2 had mechanically expanding valves. Thrombosis occurred significantly more often with balloon-expandable valves (odds ratio: 3.45; 95% confidence interval: 1.22 to 9.81; p = 0.01) and following valve-in-valve procedures (odds ratio: 5.93; 95% confidence interval: 2.01 to 17.51; p = 0.005). Median time to diagnosis of valve thrombosis was 181 days. The median N-terminal pro-brain natriuretic peptide level was 1,318 pg/ml (interquartile range: 606 to 1,676 pg/ml). The mean transvalvular gradient and valve area were 34 ± 14 mm Hg and 1.0 ± 0.46 cm^2, respectively. Computed tomography showed hypoattenuating areas with reduced leaflet motion. Initiation of OAC resulted in significant reduction of transvalvular gradient and clinical improvement. No deaths were related to valve thrombosis.

CONCLUSIONS Clinical transcatheter heart valve thrombosis is more common than previously considered, characterized by imaging abnormalities and increased gradients and N-terminal pro-brain natriuretic peptide levels. It occurred more commonly after balloon-expandable transcatheter aortic valve replacement and valve-in-valve procedures. OAC appeared to be effective in the prevention and treatment of valve thrombosis. Randomized control trials are needed to define optimal antithrombotic therapy after transcatheter aortic valve replacement. (J Am Coll Cardiol Intv 2017;10:686-97) © 2017 by the American College of Cardiology Foundation.

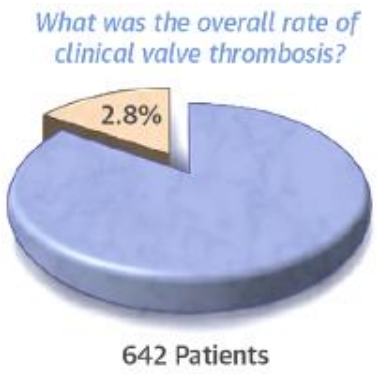
From the [a]Heart Center, Segeberger Kliniken (Academic Teaching Hospital of the Universities of Kiel, Lübeck, and Hamburg), Bad Segeberg, Germany; [b]Christian Medical College Hospital, Vellore, Tamil Nadu, India; and the [c]Tachikawa General Hospital, Nagaoka, Japan. Drs. Abdel-Wahab and Richardt have received institutional research grants from St. Jude Medical and Biotronik. Dr. Abdel-Wahab is a proctor for Boston Scientific. Dr. Richardt has received lecture fees from Edwards Lifesciences and Boston Scientific.

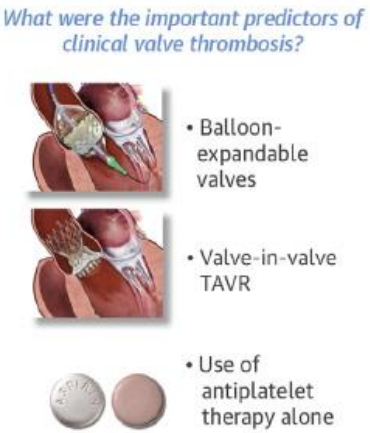
Importance

Limited data exists on clinical or manifest TAVI valve thrombosis. Prior studies focused on subclinical thrombosis.

Study Design

A retrospective analysis from a single-center registry,
642 TAVI patients, 2007-2015





Conclusion

TAVI valve thrombosis is more common than previously considered, characterized by imaging abnormalities and increased gradients and NTproBNP levels.

Jose et al. JACC. 2017;10:686-97

Subclinical Valve Thrombosis after TAVI

Clin Res Cardiol (2017) 106:85–95
DOI 10.1007/s00392-016-1052-3

ORIGINAL PAPER

Course of early subclinical leaflet thrombosis after transcatheter aortic valve implantation with or without oral anticoagulation

Philipp Ruile[1] · Nikolaus Jander[1] · Philipp Blanke[2] · Simon Schoechlin[1] · Jochen Reinöhl[1] · Michael Gick[1] · Juergen Rothe[1] · Mathias Langer[4] · Jonathon Leipsic[2] · Heinz-Joachim Buettner[1] · Franz-Josef Neumann[1] · Gregor Pache[4]

Received: 27 October 2016 / Accepted: 10 November 2016 / Published online: 16 November 2016

Abstract
Background After transcatheter aortic valve implantation, early leaflet thickening, presumably reflecting thrombus, has recently been described on computed tomography angiography (CTA) in ~10% of the patients. We sought to investigate the impact of the antithrombotic regimen on the course of leaflet thickening.
Methods The study comprised 51 patients with leaflet thickening. Based on the time period, patients without an established indication for anticoagulation were put on phenprocoumon plus clopidogrel for at least 3 months or on dual antiplatelet therapy with aspirin and clopidogrel. Follow-up CTAs were evaluated for leaflet restriction, assessed by four-point-grading score, and maximal thickness.
Findings The anticoagulation and the dual antiplatelet therapy group comprised 29 and 22 patients, respectively. After a median of 86 days, we obtained follow-up CTAs in 22 patients on anticoagulation and in 16 patients on dual antiplatelet therapy. Leaflet thickening progressed in 11 on dual antiplatelet therapy, but always regressed onanticoagulation. The course of leaflet restriction and maximal thickness was significantly different between the two groups ($P < 0.001$): in the dual antiplatelet therapy group, maximal thickness increased by a mean of 1.37 ± 1.67 mm ($P = 0.005$) and leaflet restriction score by a median 1[quartiles 0;2] ($P = 0.013$), whereas in the anticoagulation group, maximal thickness regressed by 2.57 ± 1.52 mm ($P < 0.001$) and leaflet restriction score decreased by 1[−4;0] ($P = 0.001$). After a median of 91 days after discontinuation of anticoagulation, CTA performed in ten patients revealed a significant recurrent increase in leaflet restriction score and maximal thickness ($P = 0.023$, $P = 0.007$). In the entire cohort, changes in leaflet restriction correlated significantly with changes in transvalvular pressure gradients ($r = 0.511$, $P < 0.001$).
Interpretation The course of leaflet restriction was fundamentally different depending on the presence or absence of anticoagulation, with consistent regression under phenprocoumon, but mostly progression under antiplatelet therapy alone. Changes in leaflet restriction were associated with changes in transvalvular pressure gradients.

Keywords Aortic stenosis · CTA · TAVR · TAVI · Thrombosis · Leaflet thickening

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[2] Center for Heart Valve Innovation, St. Paul's Hospital and University of British Columbia, Vancouver, Canada
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[4] Department of Radiology, Section of Cardiovascular Radiology, University of Freiburg, Freiburg im Breisgau, Germany

Introduction

In 2013, we reported the novel finding of hypo-attenuated leaflet thickening with leaflet restriction on computed tomography angiography (CTA) in a recently implanted transcatheter heart valve [1]. Subsequently, we and others reported the incidence of early leaflet thickening ranging between 5 and 10% for various aortic transcatheter heart valves based on larger cohorts with systematic early CTA

Ruile et al. Clin Res Cardiol 2017;106:85-95

528 Patients, Follow-up CT (60%) 5 days after TAVI

Leaflet thickening in 51 patients (9.7%)

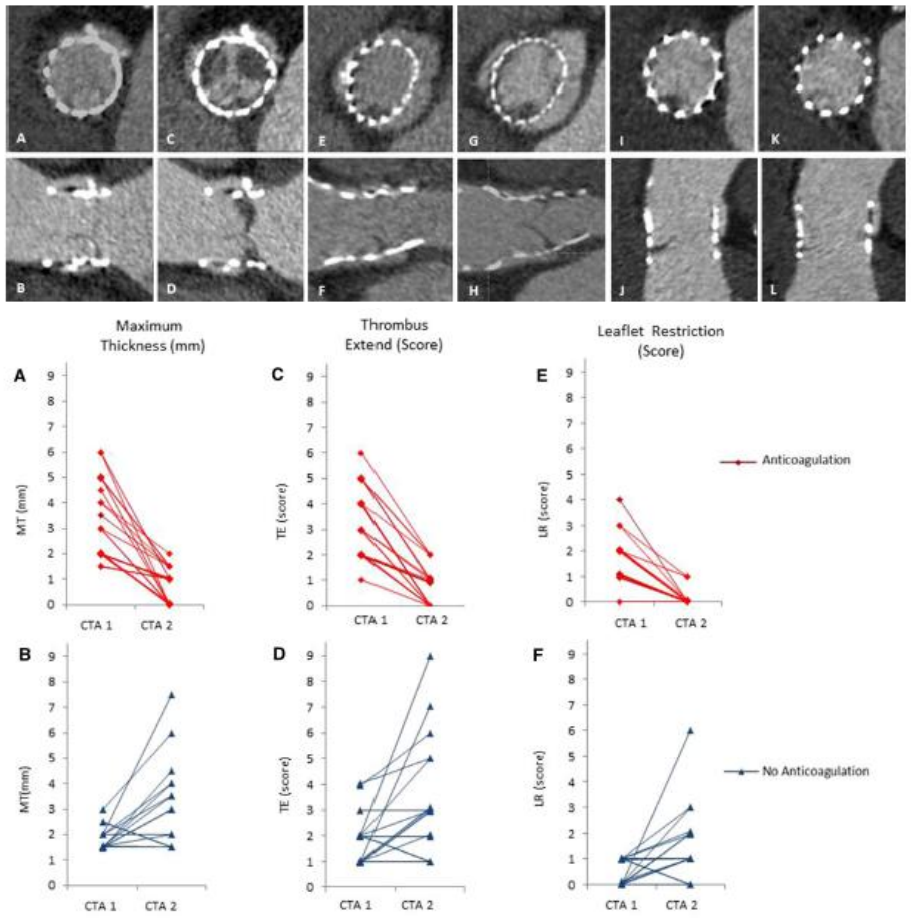
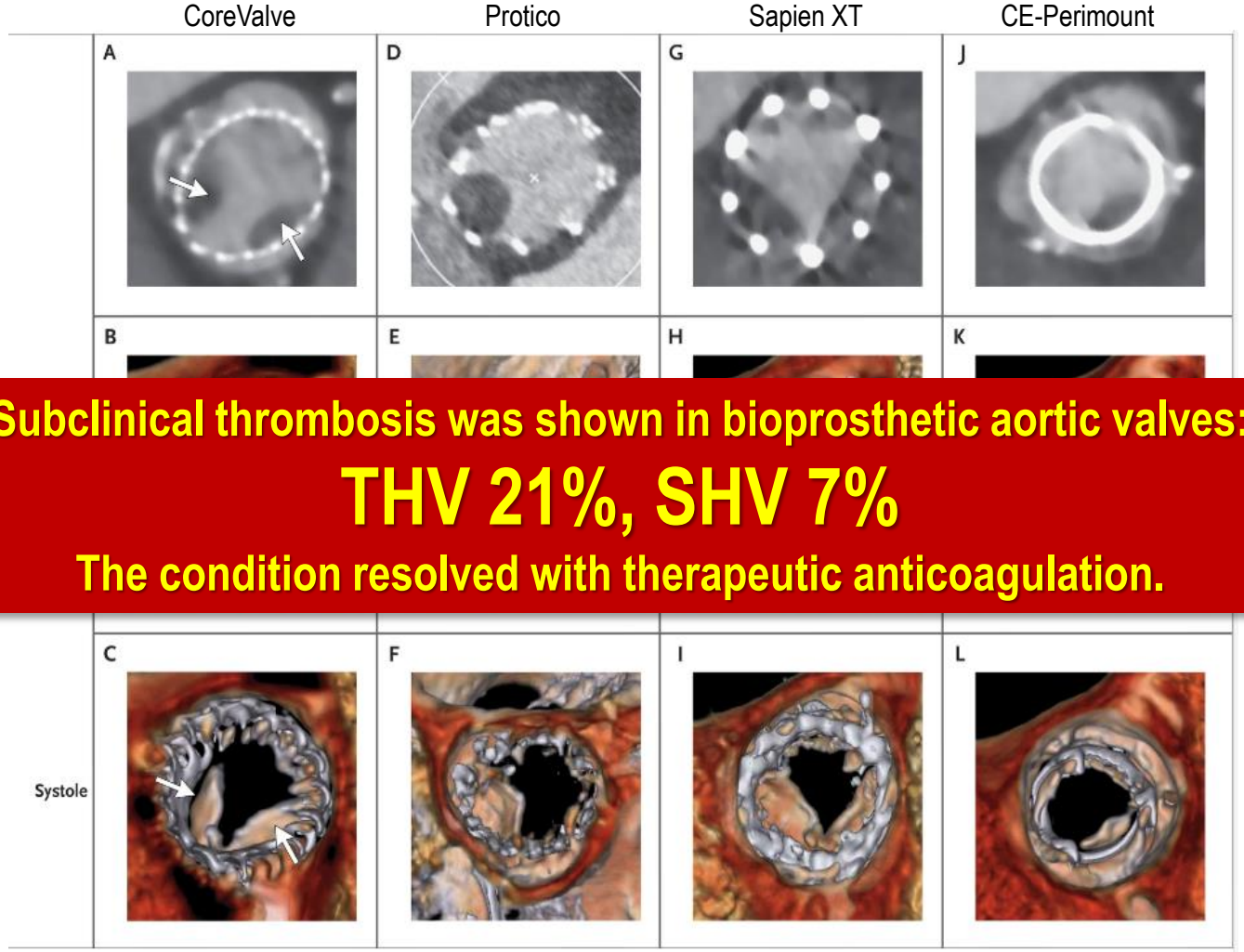


Fig. 2 Course of maximum thickness (MT, in mm) (**a**, **b**), thrombus extend (TE, score) (**c**, **d**), and leaflet restriction (LR, score) (**e**, **f**) between the first and second CTAs in patients on AC (**a**, **c**, **e**) or on DAPT (**b**, **d**, **f**)

Subclinical Thrombosis in Bioprosthetic Aortic Valves



Subclinical thrombosis was shown in bioprosthetic aortic valves:

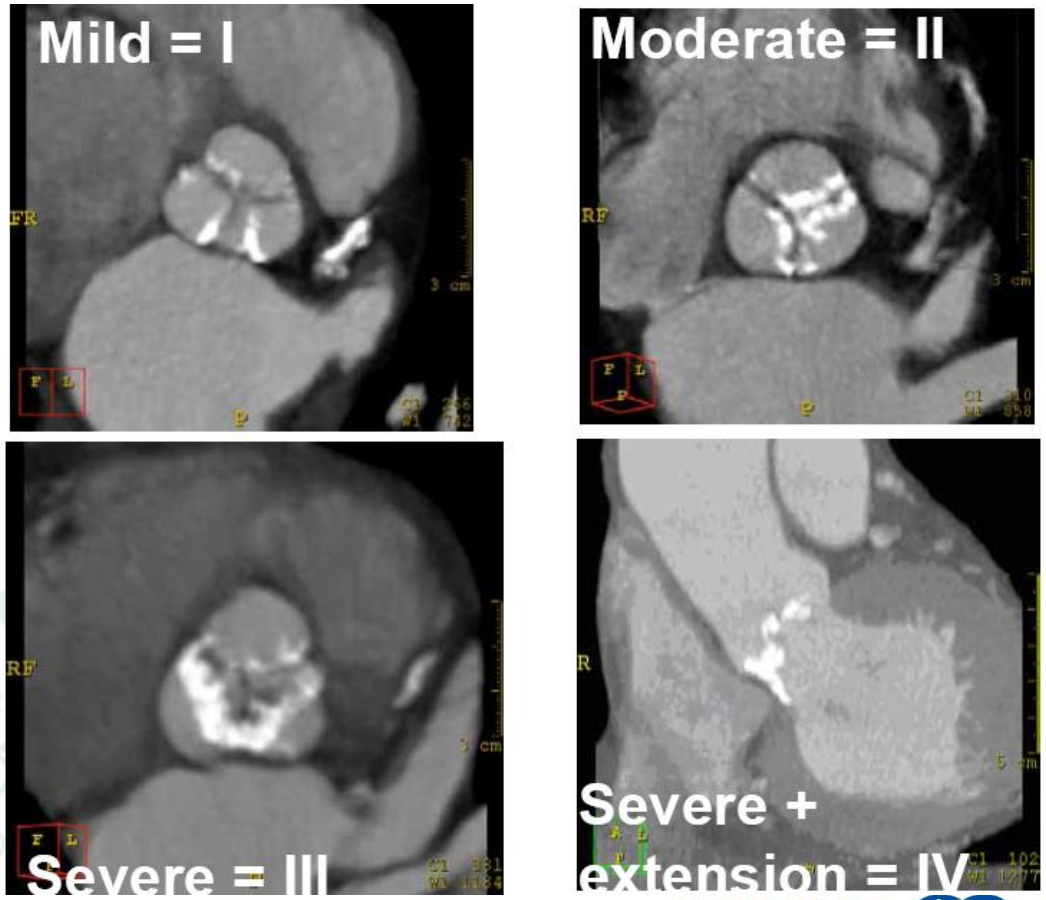
THV 21%, SHV 7%

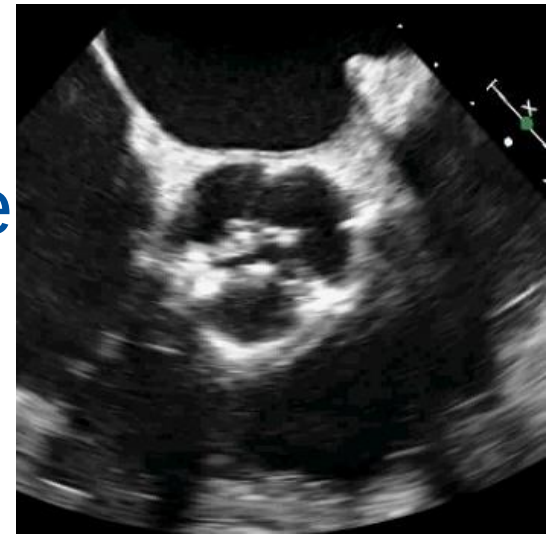
The condition resolved with therapeutic anticoagulation.

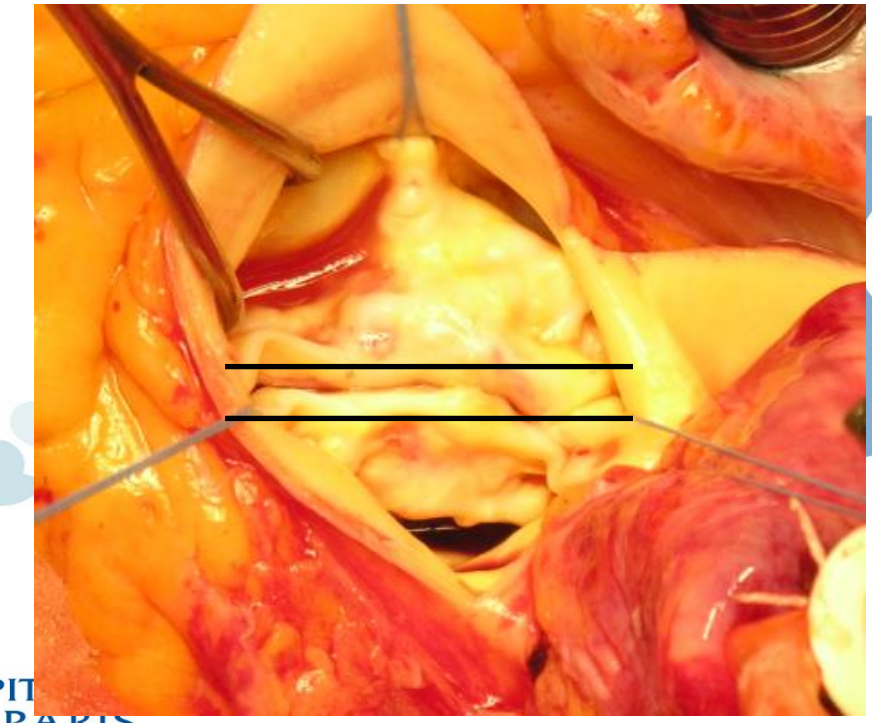
Makkar et al., NEJM 2015;373:2015-24

sub aortic septal hypertrophy
Consider balloon expandable

Anatomy,Calcifications, Bicuspid, Ecce





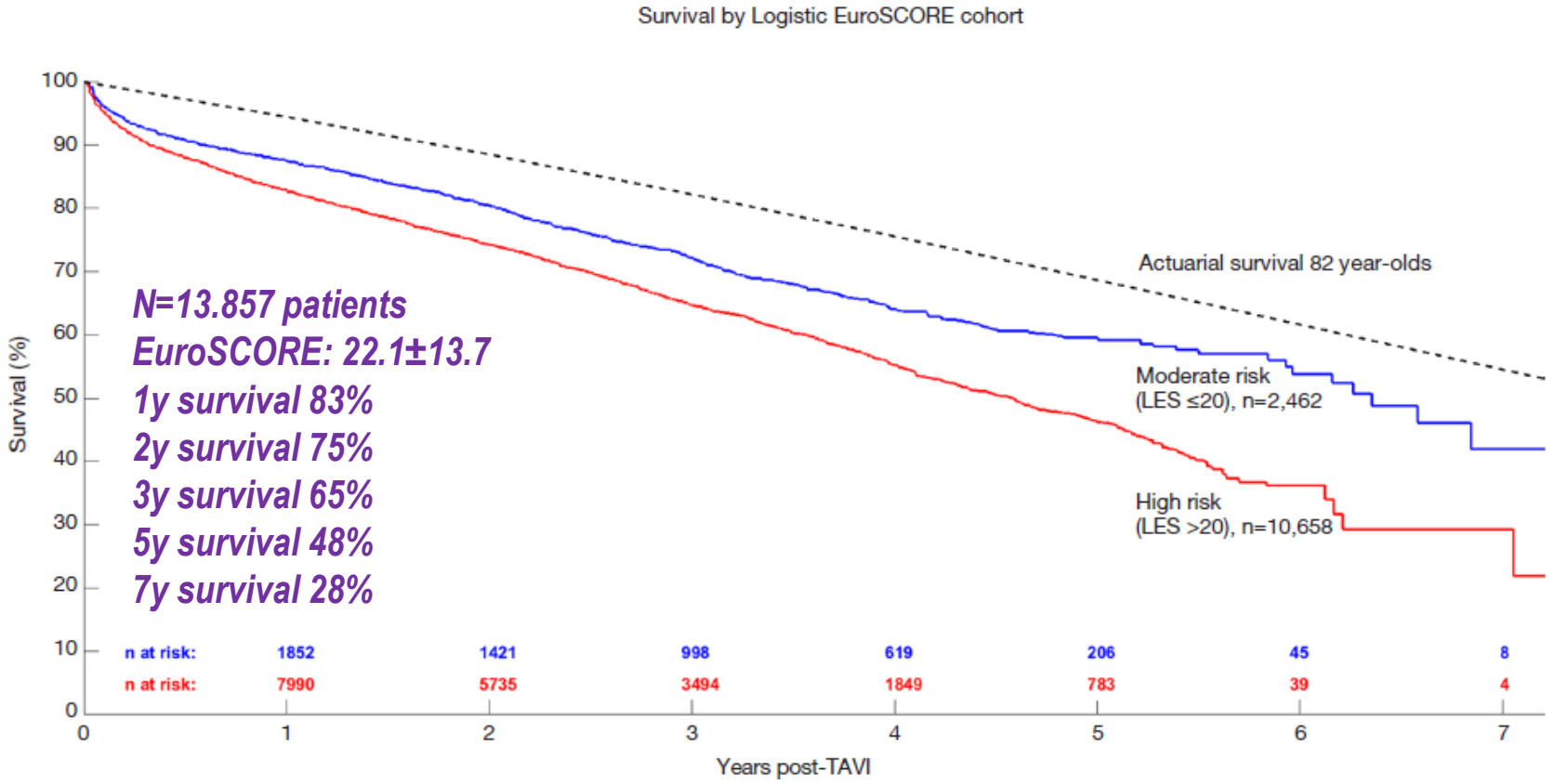


ASSISTANCE PUBLIQUE HÔPIT DE PARIS

Systematic Review

Long term outcomes of transcatheter aortic valve implantation (TAVI): a systematic review of 5-year survival and beyond

Adam Chakos[1], Ashley Wilson-Smith[1], Sameer Arora[2], Tom C. Nguyen[3], Abhijeet Dhoble[4], Giuseppe Tarantini[5], Matthias Thielmann[6], John P. Vavalle[2], Daniel Wendt[6], Tristan D. Yan[1,7], David H. Tian[1,8]



Ongoing issues with TAVI and Bioprosthesis in intermediate risks pts

PVL and Performance

Permanent Pacemaker (PM)

Stroke

Durability

Thrombosis

Economics

Which valve for which patient?

J Am Coll Cardiol. 2016 January 5; 67(1): 29–38. doi:10.1016/j.jacc.2015.10.046.

Cost-Effectiveness of Transcatheter Aortic Valve Replacement With a Self-Expanding Prosthesis Versus Surgical Aortic Valve Replacement

Matthew R. Reynolds, MD, MSC[*], Yang Lei, MSC[†,‡], Kaijun Wang, PHD[†], Khaja Chinnakondepalli, MS[†], Katherine A. Vilain, MPH[†], Elizabeth A. Magnuson, ScD[†,§], Benjamin Z. Galper, MD, MPH[‖], Christopher U. Meduri, MD, MPH[¶], Suzanne V. Arnold, MD, MHA[†,§], Suzanne J. Baron, MD, MSc[†,§], Michael J. Reardon, MD[#], David H. Adams, MD[**], Jeffrey J. Popma, MD[††], David J. Cohen, MD, MSc[†,§], and **on behalf of the U.S. CoreValve High Risk Investigators**

As expected, we found that procedural costs were substantially higher with TAVR than with SAVR, and that those costs were offset by savings from shortened hospital length of stay and a reduced need for post-discharge residential care. In this trial, those offsets were not sufficient for TAVR to achieve overall cost neutrality relative to SAVR, either in the short- or long-term. The conclusion that TAVR is nonetheless a reasonable value consequently hinges on the observed clinical benefits. These findings have important implications, as TAVR is evaluated in lower-risk AS patients. At current valve prices, length of stay would likely need to be at least 5 to 6 days shorter with TAVR than with SAVR in order to approach cost neutrality.

TAVI COST EFFECTIVENESS

TAVI MORE EXPENSIVE THAN SAVR

study

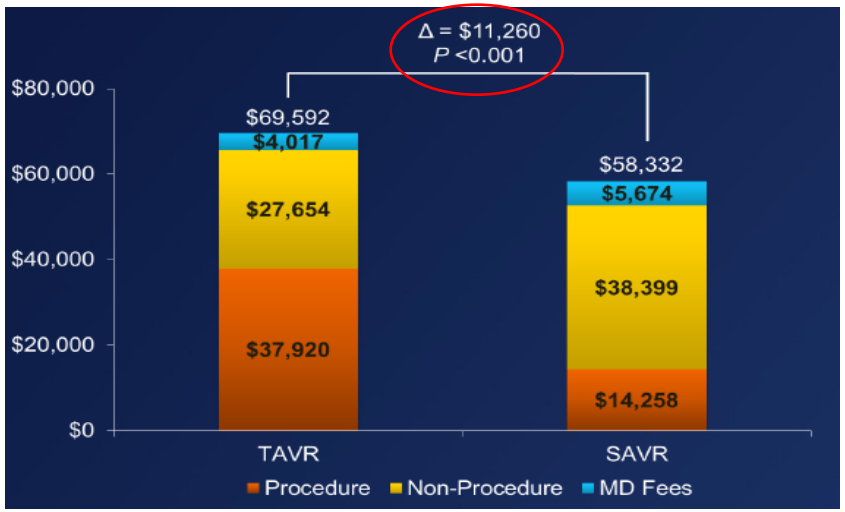
R. Orlando; Cost-effectiveness of transcatheter aortic valve implantation (TAVI) for aortic stenosis in patients who are high risk or contraindicated for surgery: a model-based economic evaluation

"…The results for TAVI compared with medical management in patients unsuitable for surgery are reasonably robust and suggest that TAVI is likely to be cost-effective. ***For patients suitable for SAVR, TAVI could be both more costly and less effective than SAVR…"***

Cost (£)	SAVR	TAVI
Procedure including hospital stay[a]	18,111.25	24,000.00
Adverse events[b]	1075.30	1078.98
Total	19,193.55	25,078.98

Corevalve high risk trial

R. M. Reynolds, Cost-Effectiveness of Transcatheter Aortic Valve Replacement with a Self-Expanding Prosthesis Compared with Surgical Aortic Valve Replacement in High Risk PatientsResults from the CoreValveUS High Risk Study



Cost-effectiveness of transcatheter aortic valve implantation (TAVI) for aortic stenosis in patients who are high risk or contraindicated for surgery: a model-based economic evaluation *R Orlando, M Pennant, S Rooney, S Khogali, S Bayliss, A Hassan, D Moore and P Barton*
HEALTH TECHNOLOGY ASSESSMENT VOLUME 17 ISSUE 33 AUGUST 2013ISSN 1366-5278

Systematic review of the cost-effectiveness of transcatheter aortic valve implantation

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TABLE 3. Projected raw costs of incremental cost-effectiveness ratio of transcatheter aortic valve implantation versus surgical aortic valve replacement

Investigator	QALYs gained by TAVI	Projected mean raw cost		Discounting rate (%)	ICER (local currency/QOL)	ICER ($US/QOL)*	WTPT ($US/QOL)*	Probability of cost-effectiveness
		TAVI	AVR					
Reynolds et al[10]	0.068 (TF-TAVI)	USD 96,743	USD 97,992	NA	AVR dominated by TF-TAVI	NA	50,000	0.709
Reynolds et al[10]	−0.070 (TA-TAVI)	USD 109,405	USD 99,499	NA	TA-TAVI dominated by AVR	NA	50,000	0.071
Gada et al[11]	−0.04 (TA-TAVI)	USD 56,730	USD 56,630	5.0	Dominated by AVR	NA	100,000	0.47

QALY, Quality-adjusted life-year; *TAVI*, transcatheter aortic valve implantation; *AVR*, aortic valve replacement; *ICER*, incremental cost-effectiveness ratio; *EUR*, euros; *NR*, not reported; *CAD*, Canadian dollars; *NA*, not applicable; *USD*, US dollars; *PARTNER*, Placement of Aortic Transcatheter Valve trial; *TF*, transfemoral; *TA*, transapical. *Converted to USD using exchange rates from www.xe.com, September 19, 2012. †The study did not evaluate quality of life, and a value of 0.06 was used to calculate the ICER.

Increase cost for TAVR vs SAVR

Could have a negative impact for cost containment if extended to intermediate risks

Ongoing issues with TAVI and Bioprosthesis in intermediate risks pts

PVL and Performance

Permanent Pacemaker (PM)

Stroke

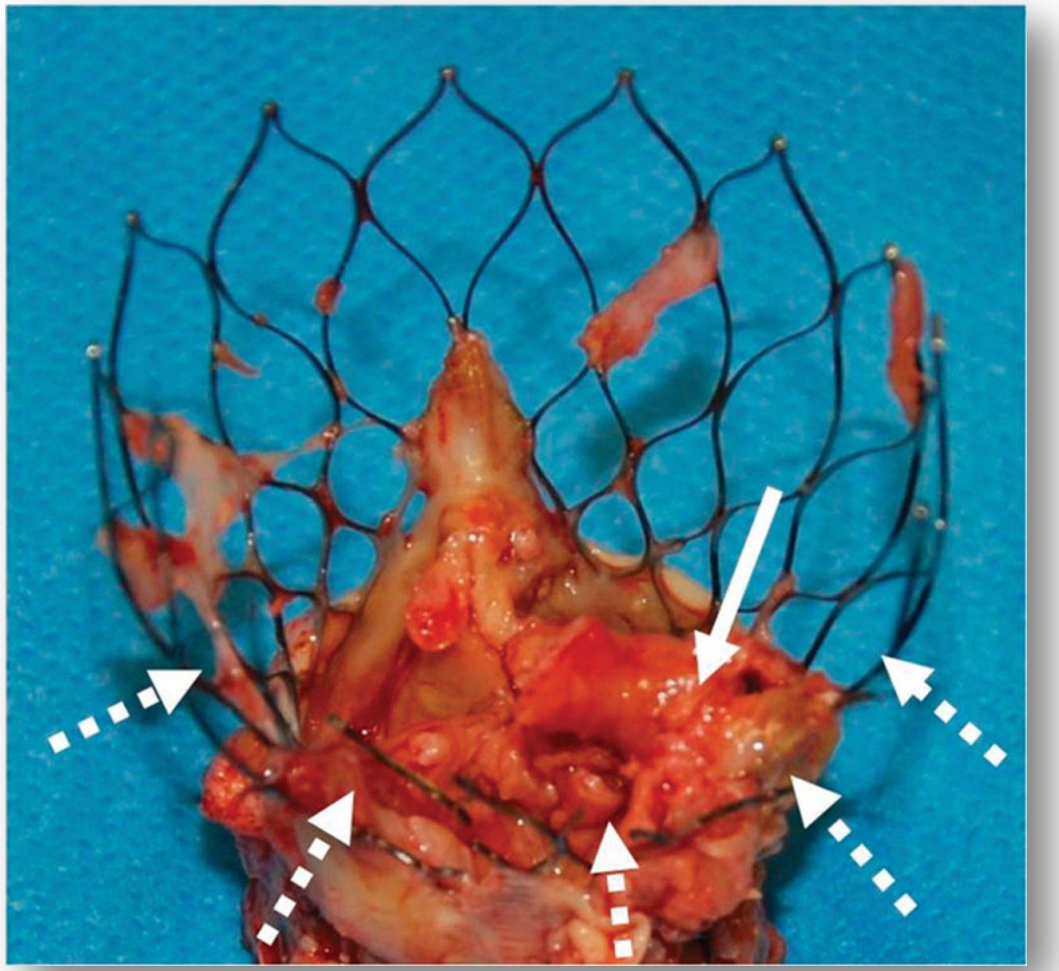
Durability

Thrombosis

Economics

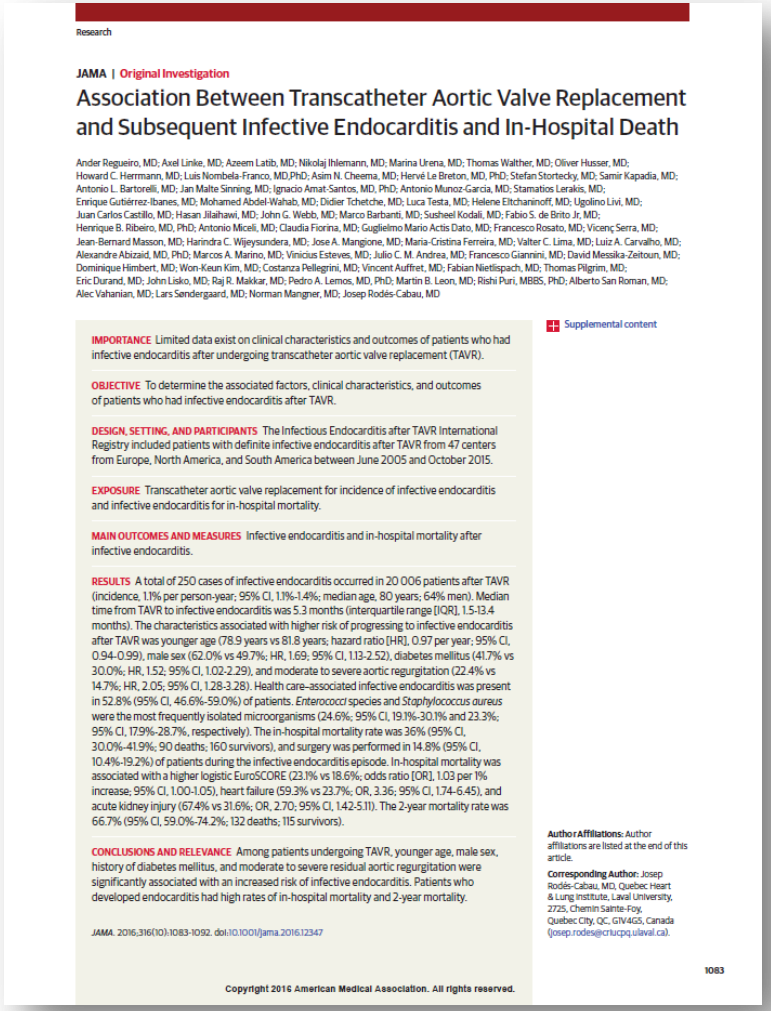
Which valve for which patient?

Infective Endocarditis after TAVI



Orban et al. Circulation. 2013;127:e265-e266

Association Between TAVI and Infective Endocarditis



Research

JAMA | Original Investigation

Association Between Transcatheter Aortic Valve Replacement and Subsequent Infective Endocarditis and In-Hospital Death

Ander Regueiro, MD; Axel Linke, MD; Azeem Latib, MD; Nikolaj Ihlemann, MD; Marina Urena, MD; Thomas Walther, MD; Oliver Husser, MD; Howard C. Herrmann, MD; Luis Nombela-Franco, MD,PhD; Asim N. Cheema, MD; Hervé Le Breton, MD, PhD; Stefan Stortecky, MD; Samir Kapadia, MD; Antonio L. Bartorelli, MD; Jan Malte Sinning, MD; Ignacio Amat-Santos, MD, PhD; Antonio Munoz-Garcia, MD; Stamatios Lerakis, MD; Enrique Gutiérrez-Ibanes, MD; Mohamed Abdel-Wahab, MD; Didier Tchetche, MD; Luca Testa, MD; Helene Eltchaninoff, MD; Ugolino Livi, MD; Juan Carlos Castillo, MD; Hasan Jilaihawi, MD; John G. Webb, MD; Marco Barbanti, MD; Susheel Kodali, MD; Fabio S. de Brito Jr, MD; Henrique B. Ribeiro, MD, PhD; Antonio Miceli, MD; Claudia Fiorina, MD; Guglielmo Mario Actis Dato, MD; Francesco Rosato, MD; Vicenç Serra, MD; Jean-Bernard Masson, MD; Harindra C. Wijeysundera, MD; Jose A. Mangione, MD; Maria-Cristina Ferreira, MD; Valter C. Lima, MD; Luiz A. Carvalho, MD; Alexandre Abizaid, MD, PhD; Marcos A. Marino, MD; Vinicius Esteves, MD; Julio C. M. Andrea, MD; Francesco Giannini, MD; David Messika-Zeitoun, MD; Dominique Himbert, MD; Won-Keun Kim, MD; Costanza Pellegrini, MD; Vincent Auffret, MD; Fabian Nietlispach, MD; Thomas Pilgrim, MD; Eric Durand, MD; John Lisko, MD; Raj R. Makkar, MD; Pedro A. Lemos, MD, PhD; Martin B. Leon, MD; Rishi Puri, MBBS, PhD; Alberto San Roman, MD; Alec Vahanian, MD; Lars Søndergaard, MD; Norman Mangner, MD; Josep Rodés-Cabau, MD

IMPORTANCE Limited data exist on clinical characteristics and outcomes of patients who had infective endocarditis after undergoing transcatheter aortic valve replacement (TAVR).

OBJECTIVE To determine the associated factors, clinical characteristics, and outcomes of patients who had infective endocarditis after TAVR.

DESIGN, SETTING, AND PARTICIPANTS The Infectious Endocarditis after TAVR International Registry included patients with definite infective endocarditis after TAVR from 47 centers from Europe, North America, and South America between June 2005 and October 2015.

EXPOSURE Transcatheter aortic valve replacement for incidence of infective endocarditis and infective endocarditis for in-hospital mortality.

MAIN OUTCOMES AND MEASURES Infective endocarditis and in-hospital mortality after infective endocarditis.

RESULTS A total of 250 cases of infective endocarditis occurred in 20 006 patients after TAVR (incidence, 1.1% per person-year; 95% CI, 1.1%-1.4%; median age, 80 years; 64% men). Median time from TAVR to infective endocarditis was 5.3 months (interquartile range [IQR], 1.5-13.4 months). The characteristics associated with higher risk of progressing to infective endocarditis after TAVR was younger age (78.9 years vs 81.8 years; hazard ratio [HR], 0.97 per year; 95% CI, 0.94-0.99), male sex (62.0% vs 49.7%; HR, 1.69; 95% CI, 1.13-2.52), diabetes mellitus (41.7% vs 30.0%; HR, 1.52; 95% CI, 1.02-2.29), and moderate to severe aortic regurgitation (22.4% vs 14.7%; HR, 2.05; 95% CI, 1.28-3.28). Health care–associated infective endocarditis was present in 52.8% (95% CI, 46.6%-59.0%) of patients. *Enterococci* species and *Staphylococcus aureus* were the most frequently isolated microorganisms (24.6%; 95% CI, 19.1%-30.1% and 23.3%; 95% CI, 17.9%-28.7%, respectively). The in-hospital mortality rate was 36% (95% CI, 30.0%-41.9%; 90 deaths; 160 survivors), and surgery was performed in 14.8% (95% CI, 10.4%-19.2%) of patients during the infective endocarditis episode. In-hospital mortality was associated with a higher logistic EuroSCORE (23.1% vs 18.6%; odds ratio [OR], 1.03 per 1% increase; 95% CI, 1.00-1.05), heart failure (59.3% vs 23.7%; OR, 3.36; 95% CI, 1.74-6.45), and acute kidney injury (67.4% vs 31.6%; OR, 2.70; 95% CI, 1.42-5.11). The 2-year mortality rate was 66.7% (95% CI, 59.0%-74.2%; 132 deaths; 115 survivors).

CONCLUSIONS AND RELEVANCE Among patients undergoing TAVR, younger age, male sex, history of diabetes mellitus, and moderate to severe residual aortic regurgitation were significantly associated with an increased risk of infective endocarditis. Patients who developed endocarditis had high rates of in-hospital mortality and 2-year mortality.

Supplemental content

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JAMA. 2016;316(10):1083-1092. doi:10.1001/jama.2016.12347

Importance

Limited data exist on clinical characteristics and outcomes of pts with infective endocarditis (IE) after TAVI

Study Design

International Registry, IE after TAVI, 47 sites in Europe, North and South America, 2005-2015.

Results

- A total of 250 cases with IE occurred in 20006 pts after TAVR = **Endocarditis incidence 1.1%**
- Characteristics associated with higher risk of IE after TAVI was: **younger age**, **male**, **diabetes**, and **mod-severe AR**
- Most frequently **Enterococci spec.** and **Staph. aureus**
- In-hospital mortality was **36%**, and **14.8%** underwent surgery
- The 2-year mortality rate was **66.7%**

Regueiro et al. JAMA. 2016;316:1083-1092.

Ongoing issues with TAVI and Bioprosthesis in intermediate risks pts

PVL and Performance

Limited number of TAVR ViV procedures

Depends of the native aortic annulus

Importance of native annular anatomy (bicuspid, calcifications, septal hypertrophy)

Background

- TF = gold standard
- But: 10 to 15% of patients are ineligible to TF approach

STS/ACC TVT registry

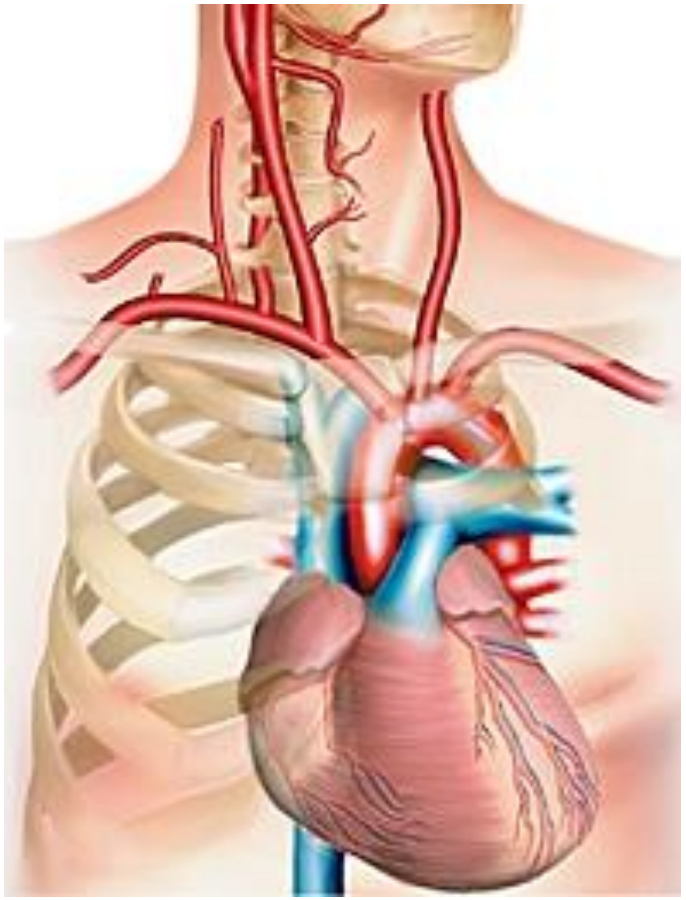
Variable	Level	Overall (N=54782)		2012 (N=4627)		2013 (N=9052)		2014 (N=16295)		2015 (N=24808)		P-value+
Access Site	Missing	311	0.6	32	0.7	76	0.8	91	0.6	112	0.5	<.0001
	Femoral	40596	74.1	3512	75.9	4277	47.2	11313	69.4	21494	86.6	
	Transapical	9318	17	671	14.5	4024	44.5	3111	19.1	1512	6.1	
	Other	4557	8.3	412	8.9	675	7.5	1780	10.9	1690	6.8	

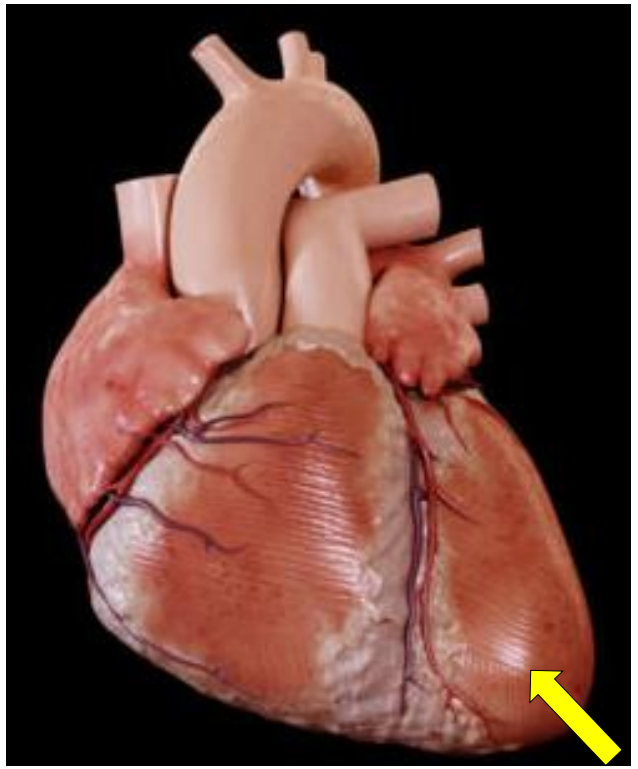
Grover et al, JACC 2016

	FRANCE 2		FRANCE TAVI			
	2010 (n = 1,378)	2011/2012 (n = 2,385)	2013 (n = 2,512)	2014 (n = 3,177)	2015 (n = 4,293)	p Value for Trend
Approach						
Transfemoral	1,036 (75.2)	1,712 (71.8)	1,976 (78.7)	2,534 (79.8)	3,563 (83.0)	ref
Transapical	265 (19.2)	390 (16.3)	178 (7.1)	144 (4.5)	166 (3.9)	<0.001
Subclavian	70 (5.1)	164 (6.9)	120 (4.8)	101 (3.2)	114 (2.7)	<0.001
Others	7 (0.5)	119 (5.0)	238 (9.5)	398 (12.5)	450 (10.5)	<0.001

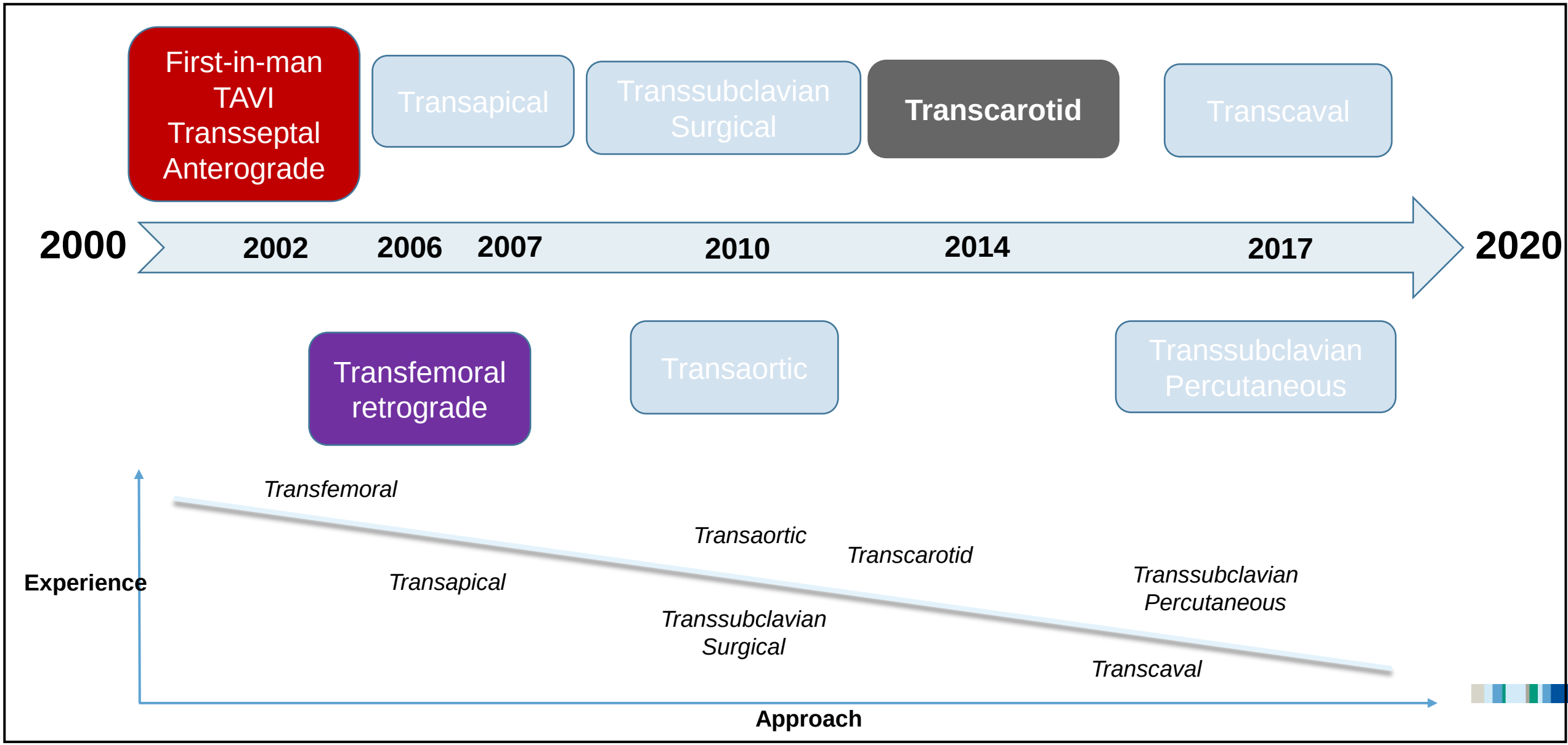
3.4% of patients in FRANCE TAVI (150 procedures in France in 2015, with increasing use)Auffrey et al, JACC 2017

TAVI
Autres voies d’accès





Relative experience with alternative approaches



Good candidate

Annulus > 18mm et <27mm

no bicuspidy …

eccentricity index low

Calcifications “spreaded”

Enough High with coronaries

5 Steps for MSCT Analysis of Aorto-Iliac Arteries

SIZING

CALCIFICATIONS

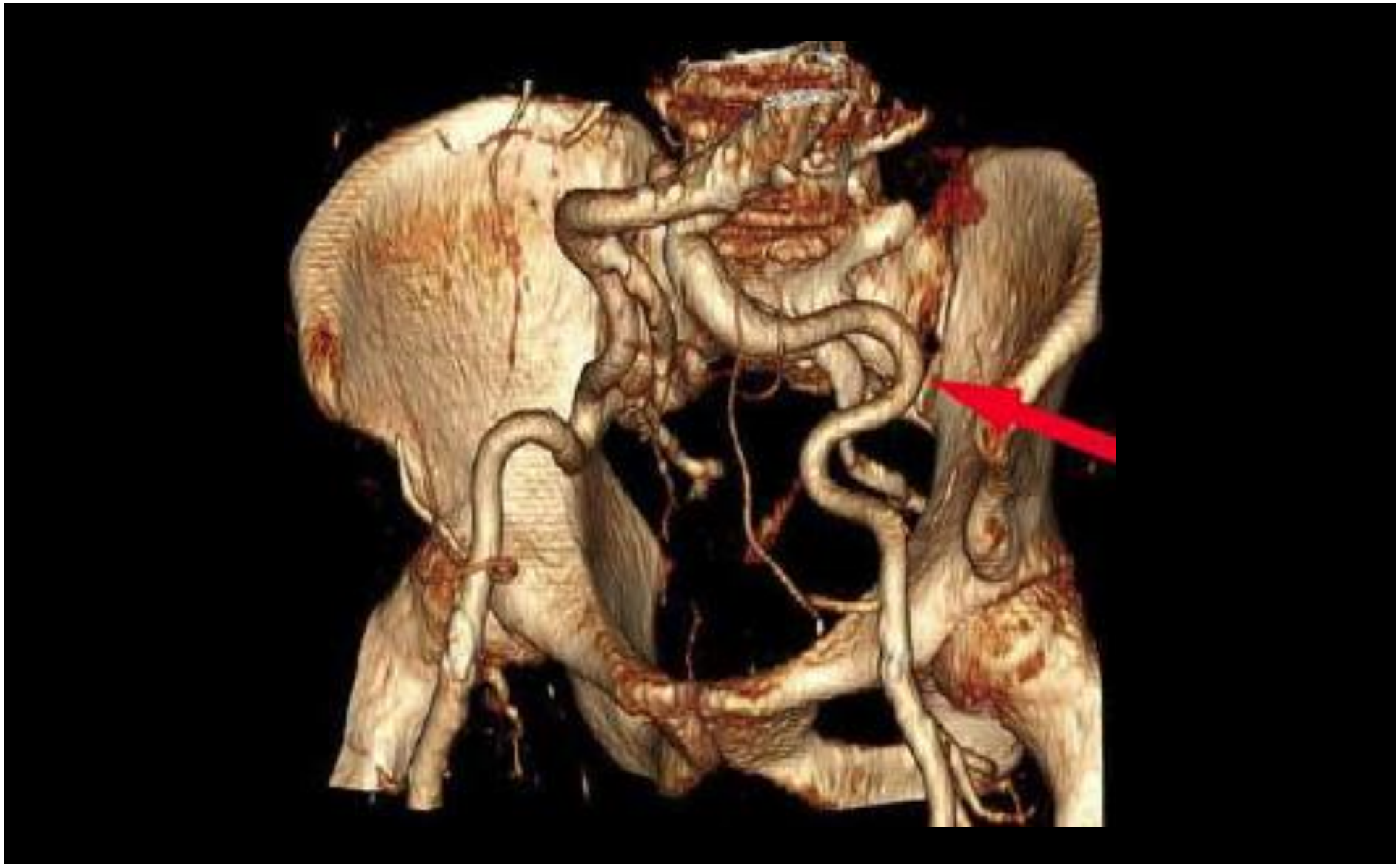
TORTUOSITY

ANGULATION

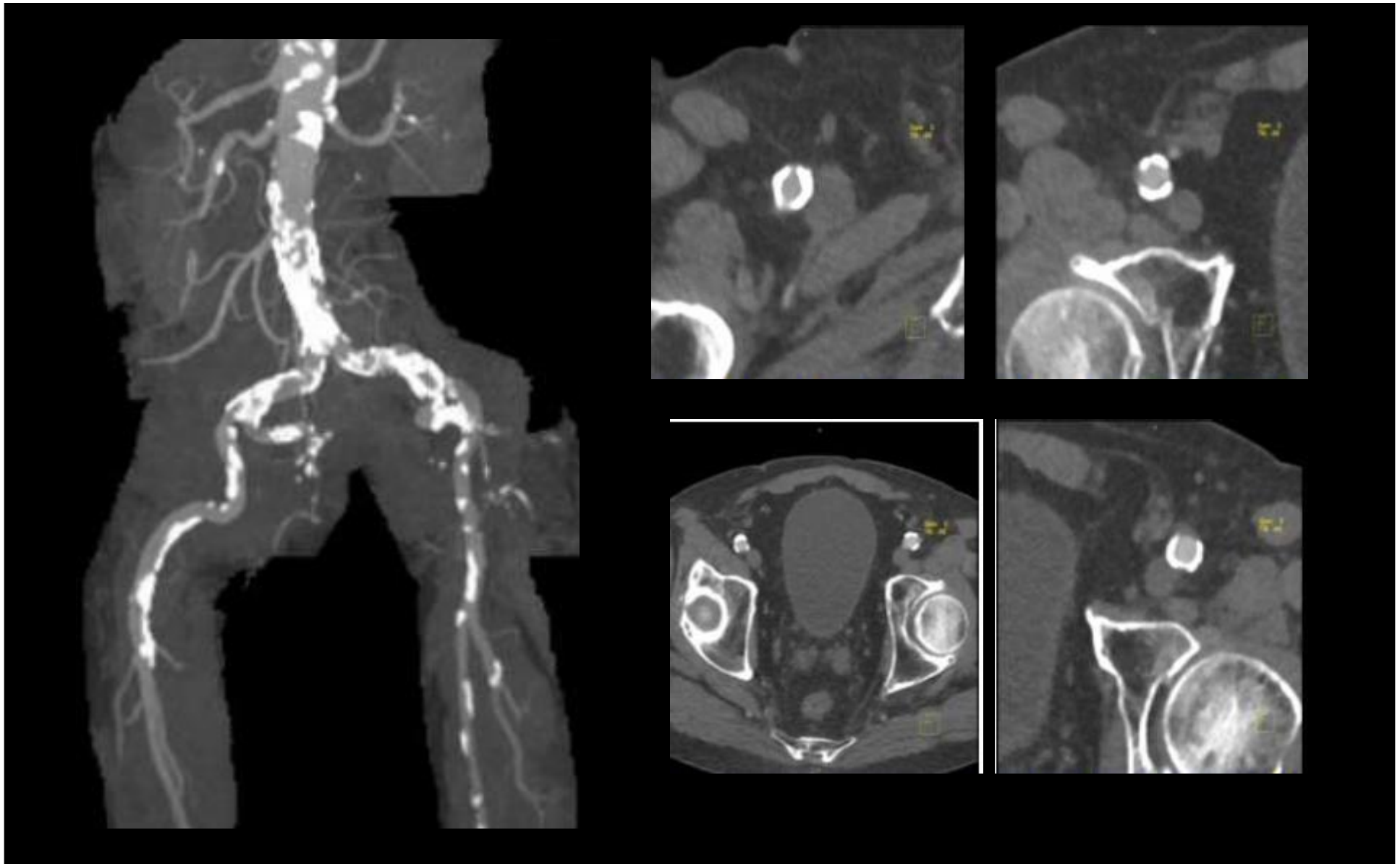
CONTRAINDICATIONS

Tortuosity

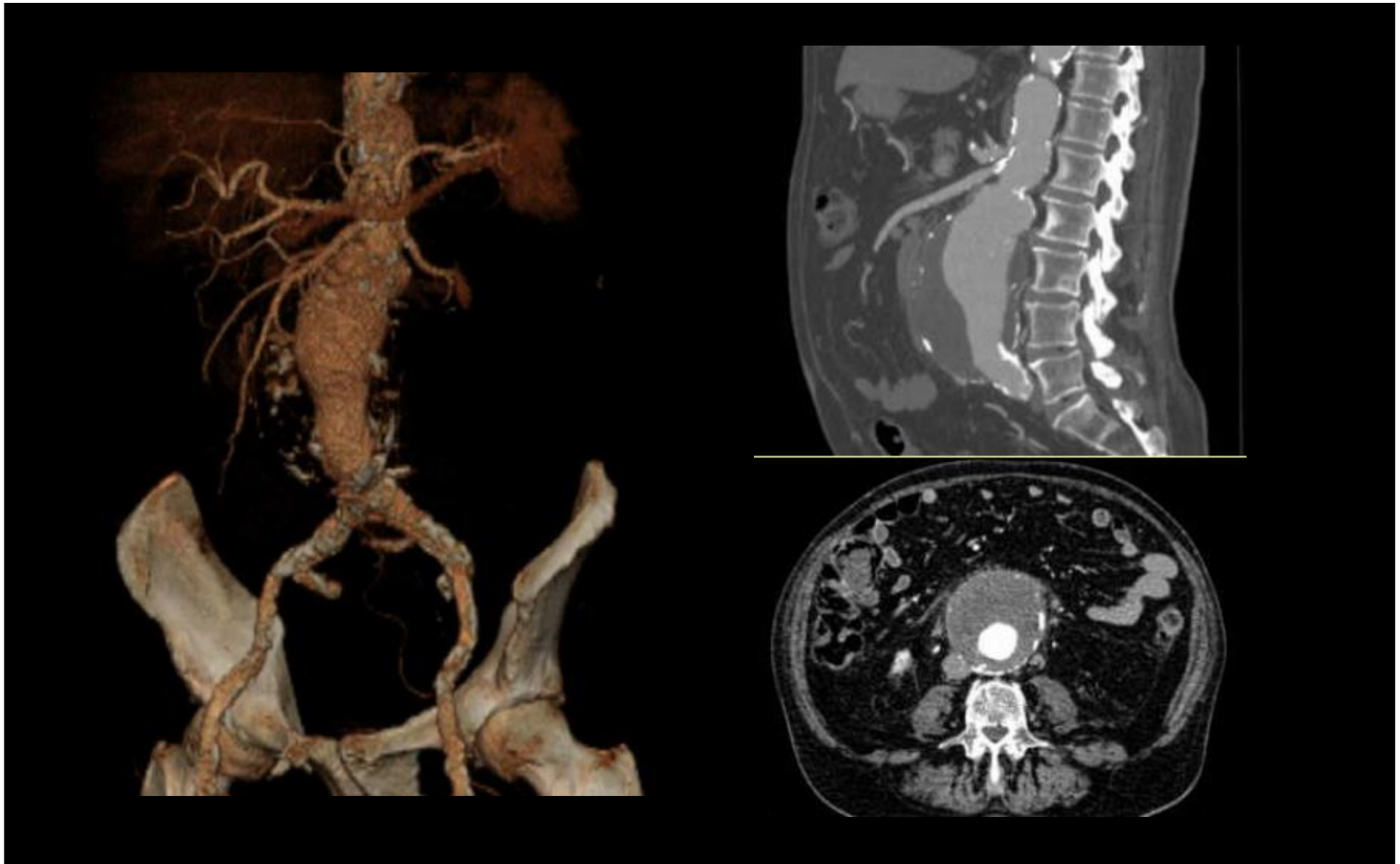
Angulation > 90°



Calcifications « Calcified Ring > 60% »

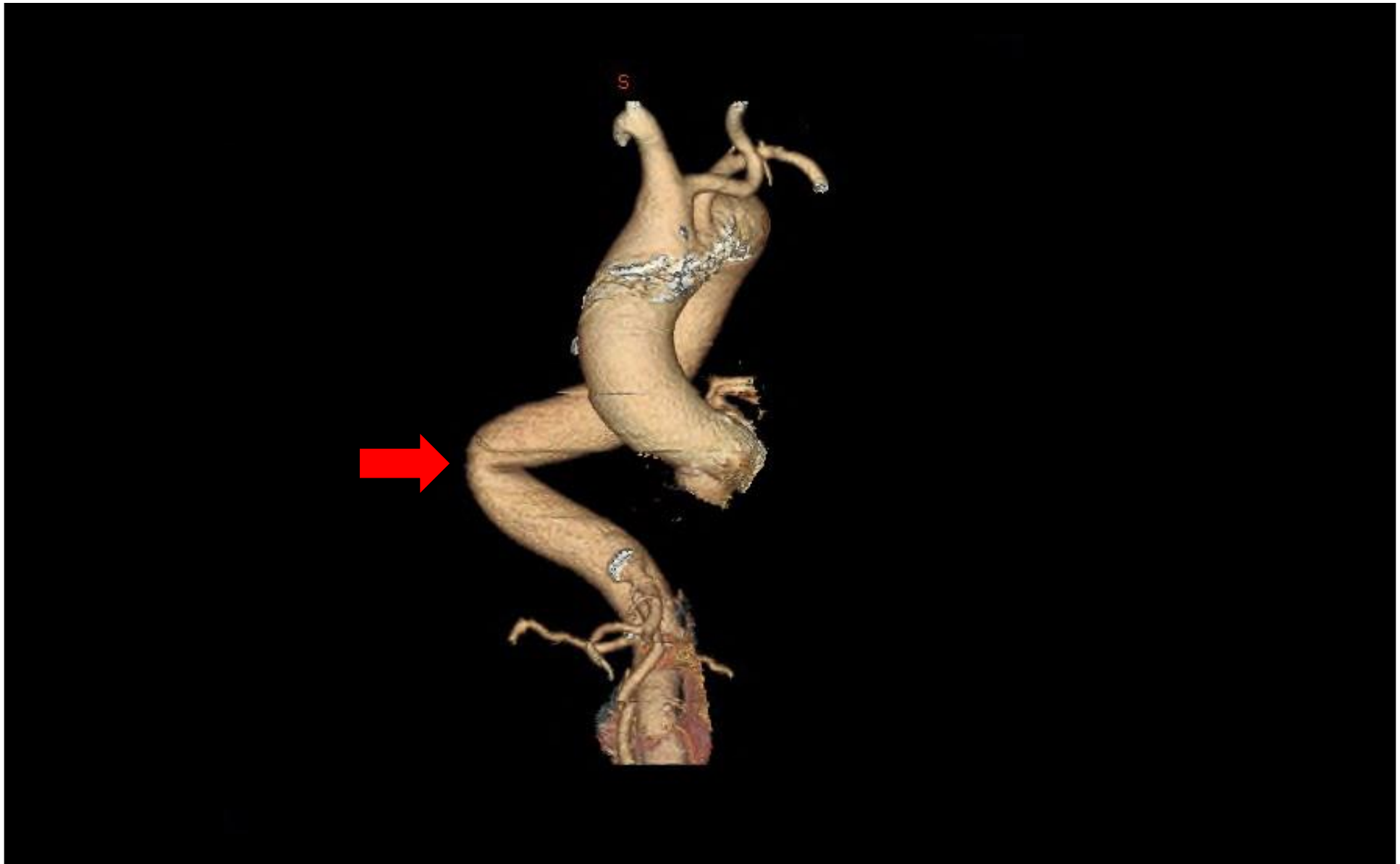


ABDOMINAL ANEURYSM



Previously Treated Abdominal Aneurism

Severe Angulation Of The Aorta



Double Severe Angulation Of The Aorta

Embolic Plaques

A Propensity-Matched Comparison With the Femoral Access

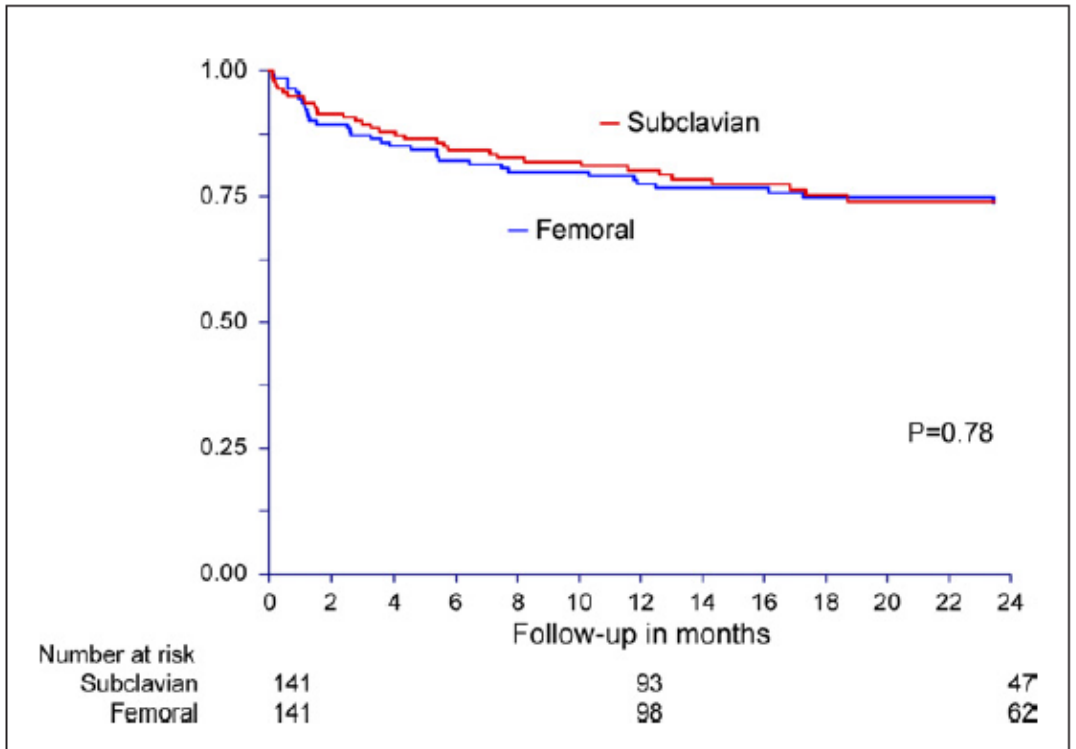
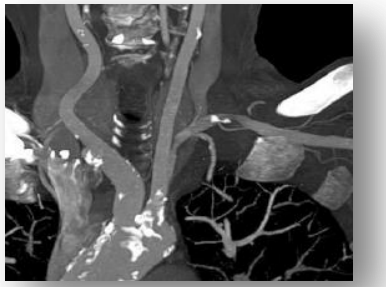


Figure 3 **Kaplan-Meier Estimates of 2-Year Survival**

Red line = subclavian group; **blue line** = femoral group.

Subclavian



Approach: Surgical

Closure: Surgical

Critical point : No dedicated devices, kinking at the origin

Pros: Shorter distance

Risks: Dissection

Clinical experience : Medium

Good candidate

- No calcification,
- No tortuosity
- Easy access to artery

TransAortic

Approach: Surgical

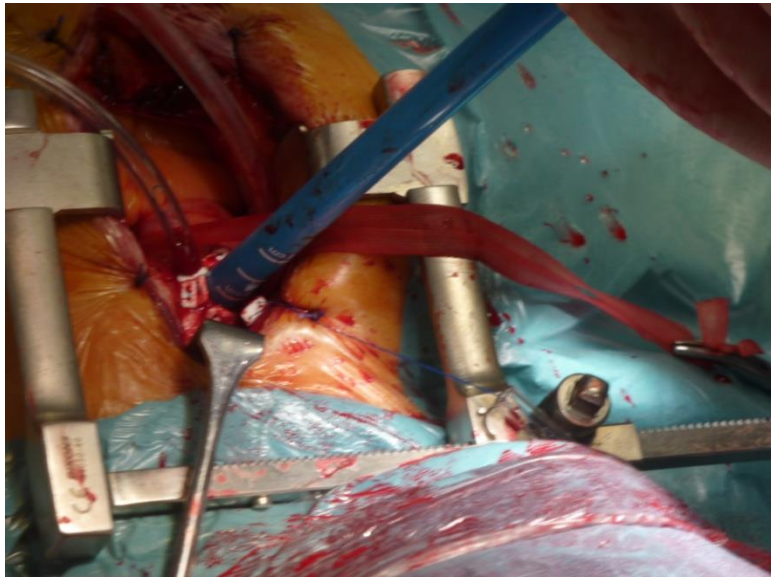
Closure: Surgical

Critical point : Distance to aortic valve > 6cm

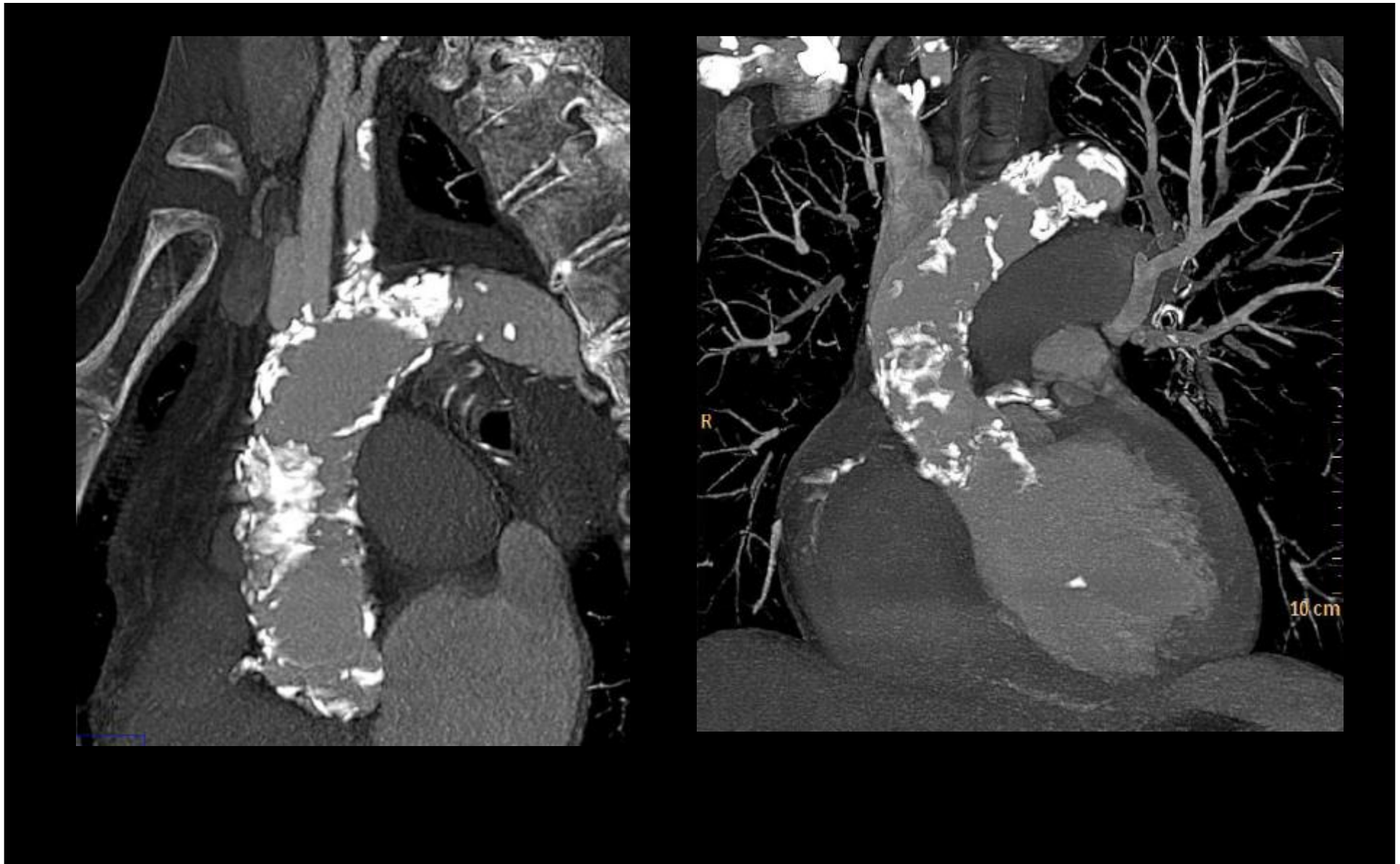
Pros: Easy access, familiar for cardiac surgeons

Risks: Dissection

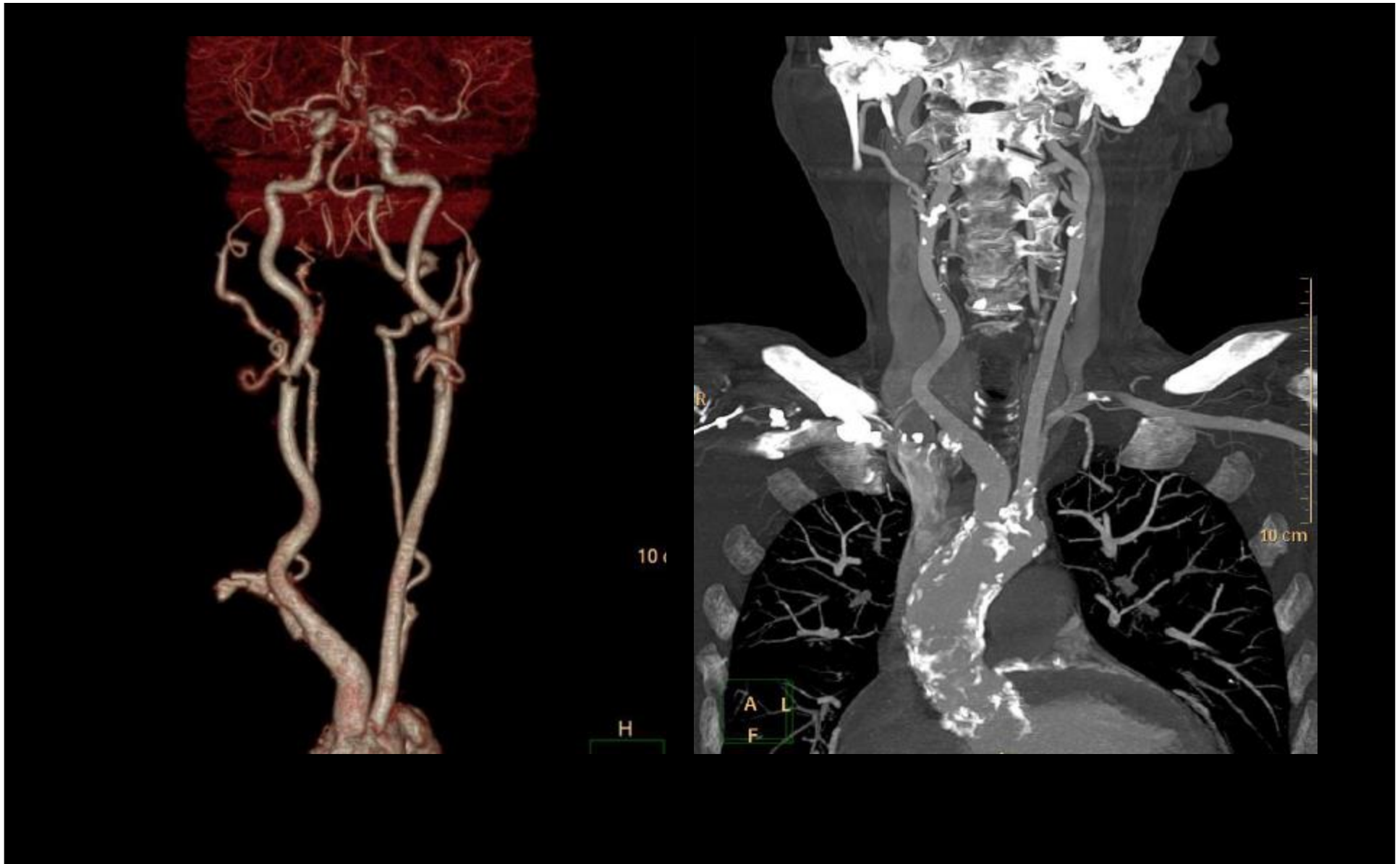
Clinical experience : Small



Limitations: Aortic Calcifications

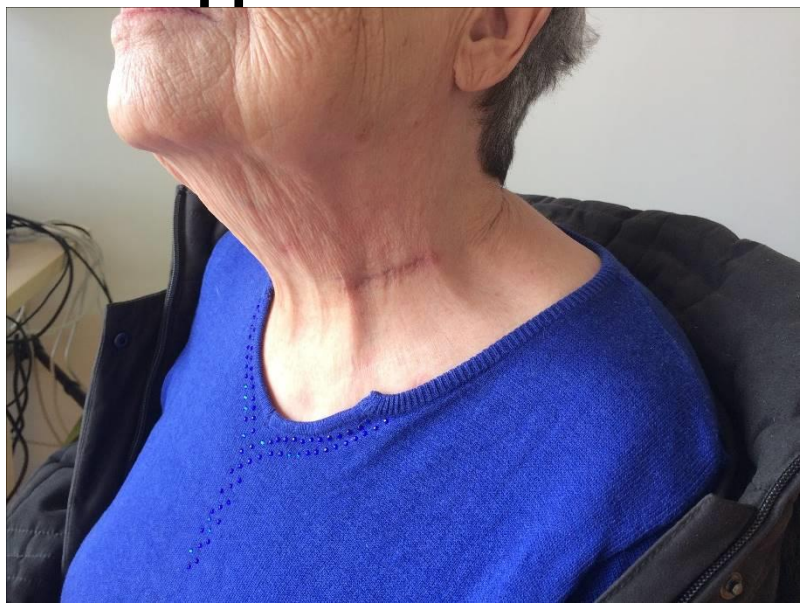


Carotid



Why Carotid artery?

- The femoral approach is possible only in 80% of cases.
- Apical:problematic in respiratory insufficiency, higher †
- Trans aortic: chest opening, indirect access
- Subclavian: fragility and tuortuosity of the vessel
- The carotid approach offers a direct vascular access to the aortic valve, easily accessible, well known approach



Transcarotid procedure/ Anesthesia

Anesthesia:

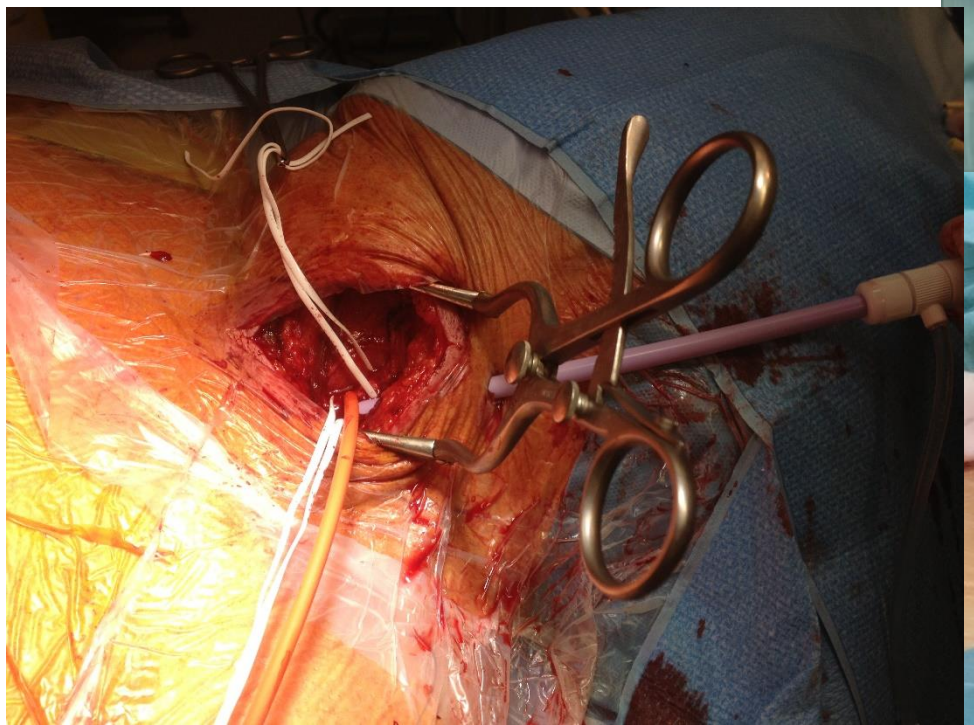
- General (can be done regional block)
- Radial catheter, and venous peripheral line
- NIRS
- Warming blanket
- 5 cm curvilinear incision 2 finger breaths from the manubrium

Transcarotid procedure/ TAVI

Small 30 silicone drain on the introducer sheath

Sheath introduction and prosthesis deployment

Self expendable or ballloon expendable (Certitude)

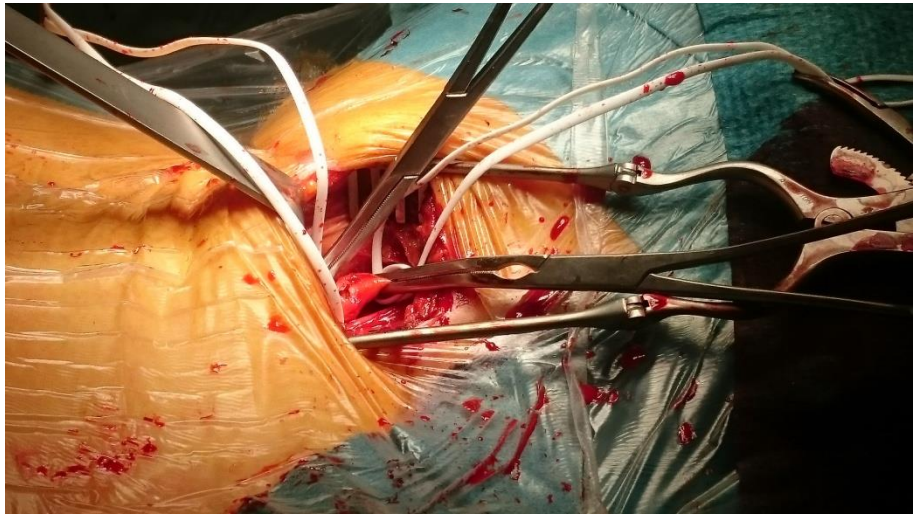


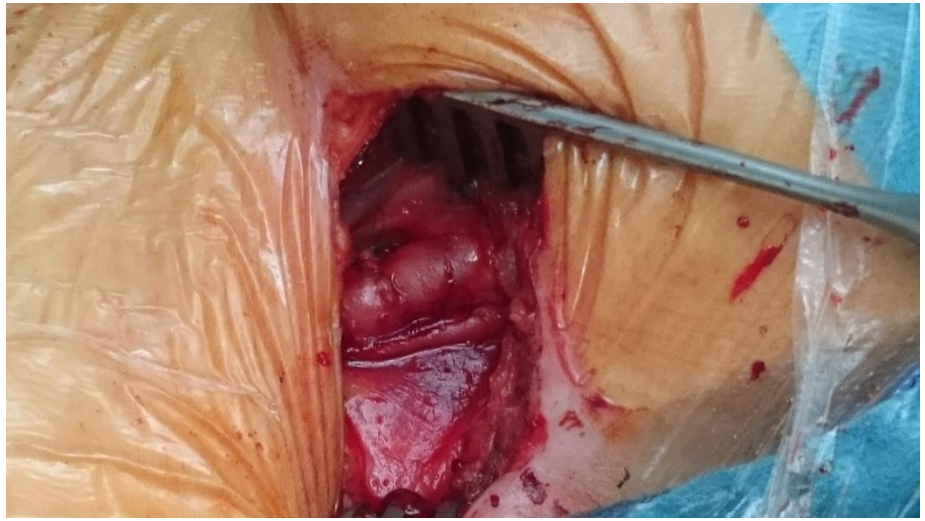
Transcarotid procedure/ Closure

Removal of sheath, clamping of the carotid

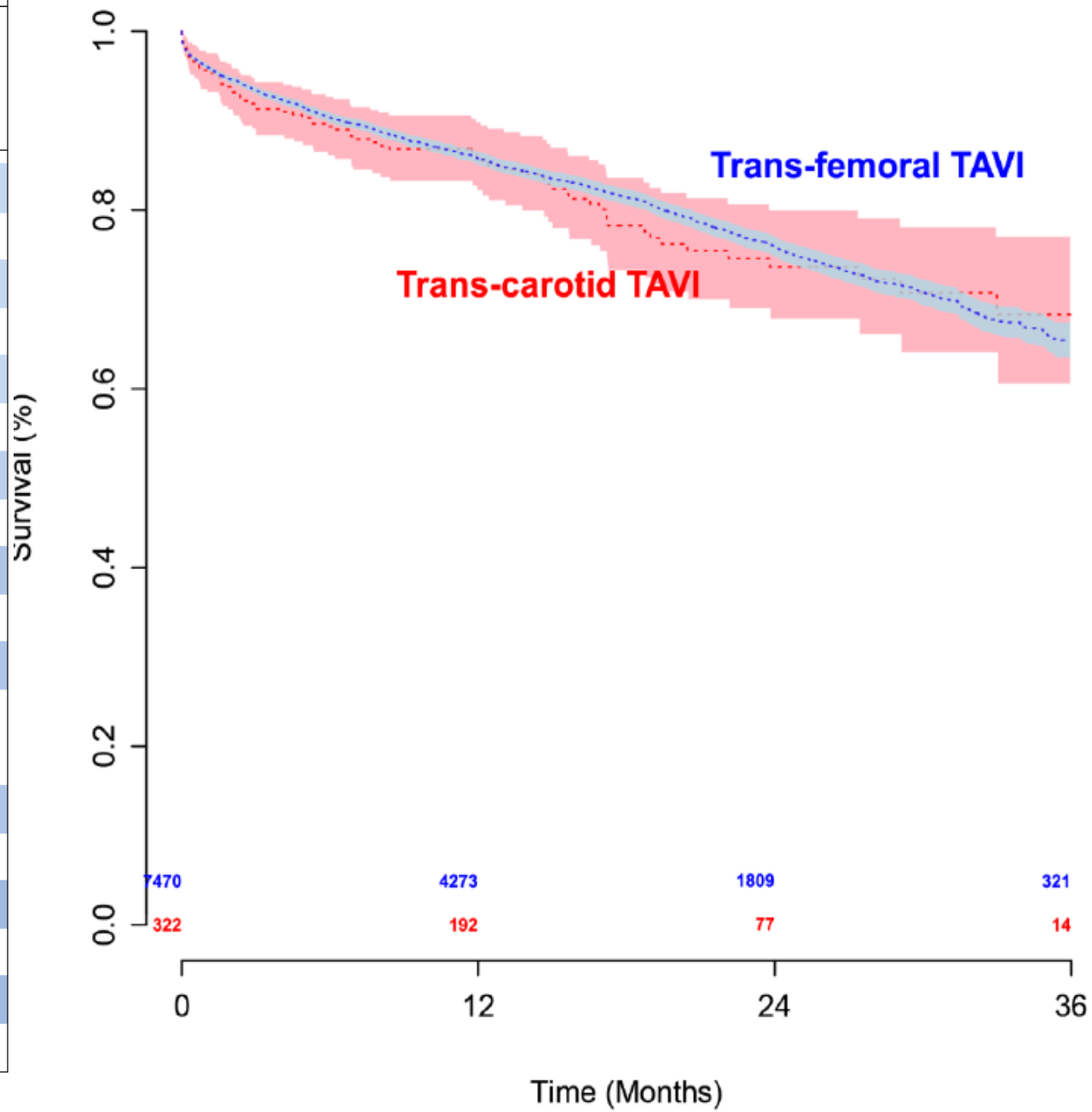
Vascular closure, carotid purging

Closure on a small drain

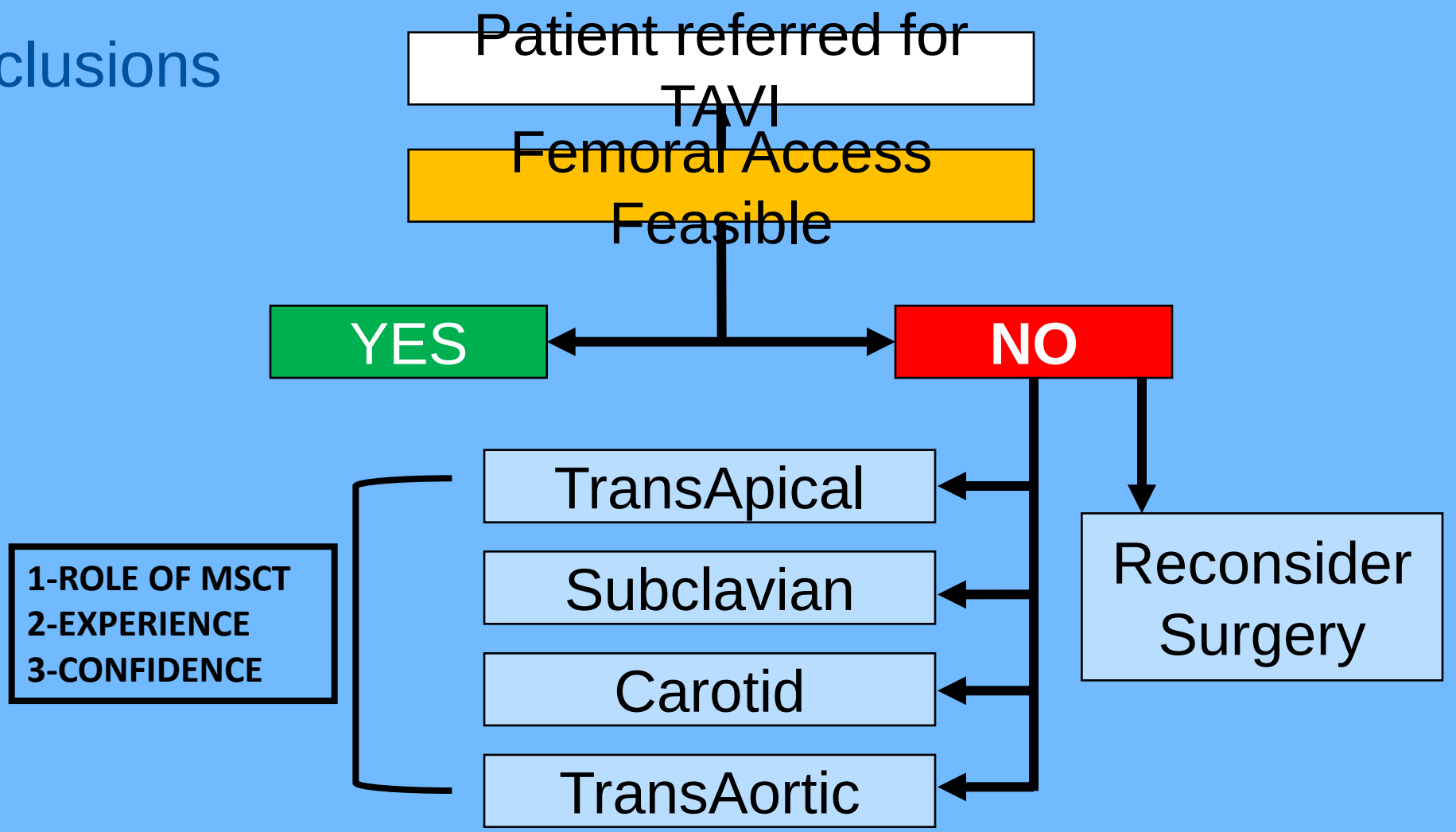




Variable	All patients (11033)	Trans-carotid access (435)	Trans-femoral access (10598)	p-value
Procedural&30-day mortality	419 (3.8%)	18 (4.1%)	401 (3.8%)	0.73
Procedural mortality	103 (0.9%)	3 (0.7%)	102 (1%)	0.80
30-day mortality	315 (2.9%)	15 (3.4%)	300 (2.8%)	0.46
Annulus rupture	50 (0.4%)	0 (0%)	50 (0.5%)	0.27
Aortic dissection	37 (0.3%)	0 (0%)	37 (0.3%)	0.40
Valve migration	121 (1.1%)	6 (1.4%)	115 (1.1%)	0.48
Cardiac tamponade	234 (2.1%)	7 (1.6%)	227 (2.1%)	0.61
Coronary obstruction	33 (0.3%)	0 (0%)	33 (0.3%)	0.64
Urgent surgery	50 (0.4%)	2 (0.5%)	48 (0.5%)	0.99
Stroke	219 (2.0%)	19 (4.4%)	200 (1.9%)	0.001
STEMI	22 (0.2%)	3 (0.7%)	19 (0.2%)	0.05
Permanent pacemaker Implantation	1689 (15.3%)	82 (18.9%)	1607 (15.2%)	0.04
Vascular complications	827 (7.5%)	14 (3.2%)	813 (7.7%)	< 0.001
Infections	449 (4.1%)	29 (6.7%)	420 (4.0%)	0.01
Bleeding	535 (4.8%)	40 (9.2%)	495 (4.7%)	< 0.001
Pulmonary Embolism	15 (0.1%)	1 (0.2%)	14 (0.1%)	0.45
Renal failure	376 (3.4%)	22 (5.1%)	354 (3.3%)	0.06
Renal dialysis	349 (3.2%)	22 (5.1%)	327 (3.1%)	0.03



Conclusions



8 DECEMBRE 2018

SAVE THE DATE

PRÉSIDENTS DU SEMINAIRE

Pr Thierry FOLLIGUET – Pr Emmanuel TEIGER

COMITÉ D'ORGANISATION

Pr Thierry Folliguet, Pr Emmanuel Teiger, Dr Christian Breton, Dr Bernard Carette, Dr Jacques Chevrier, Dr Daniel Gusmini, Dr Philippe Jauffrion, Dr Khalifé Khalife, Dr Alain Shqueir

EN COLLABORATION AVEC

Hôpital Henri Mondor *et les associations de cardiologie :*
Val de Marne, Champagne Ard'Aisne, Cardiologues de l'Est

Chers Amis, chers Confrères,

Nous avons le plaisir de vous inviter au 1er rendez-vous **« CardioConnexion : de la ville à l'hôpital »** qui aura lieu le **8 décembre 2018** de 10h - 18h.

La cardiologie évolue rapidement et nécessite une approche globale afin de traiter au mieux nos patients. Le parcours de santé du patient entre la médecine de ville et l'hôpital
(et vice versa) est le socle de la prise en charge des patients.

Ce séminaire a pour but de favoriser une approche centrée sur le patient et le partage d'expérience à destination des professionnels de santé impliqués dans la prise en charge des patients avec des pathologies cardiovasculaires complexes (valvulaires, coronaires et rythmologiques).

Rejoignez-nous au **Manoir de Gressy** pour une journée d'étude conviviale entre cardiologues hospitaliers et libéraux, urgentistes, réanimateurs, anesthésistes, gériatres et diabétologues.

En espérant vous retrouver nombreux

Pr Thierry FOLLIGUET et Pr Emmanuel TEIGER

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