Atualização em Valvopatias Mitral e Aórtica

RESULTADOS TARDIOS DE BIOPRÓTESES CONVENCIONAIS E PERCUTÂNEAS

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Fundação Universitária de Cardiologia

Declaração de Potencial Conflito de Interesse

Nome do Palestrante:

Renato A. K. Kalil

Título da Apresentação:

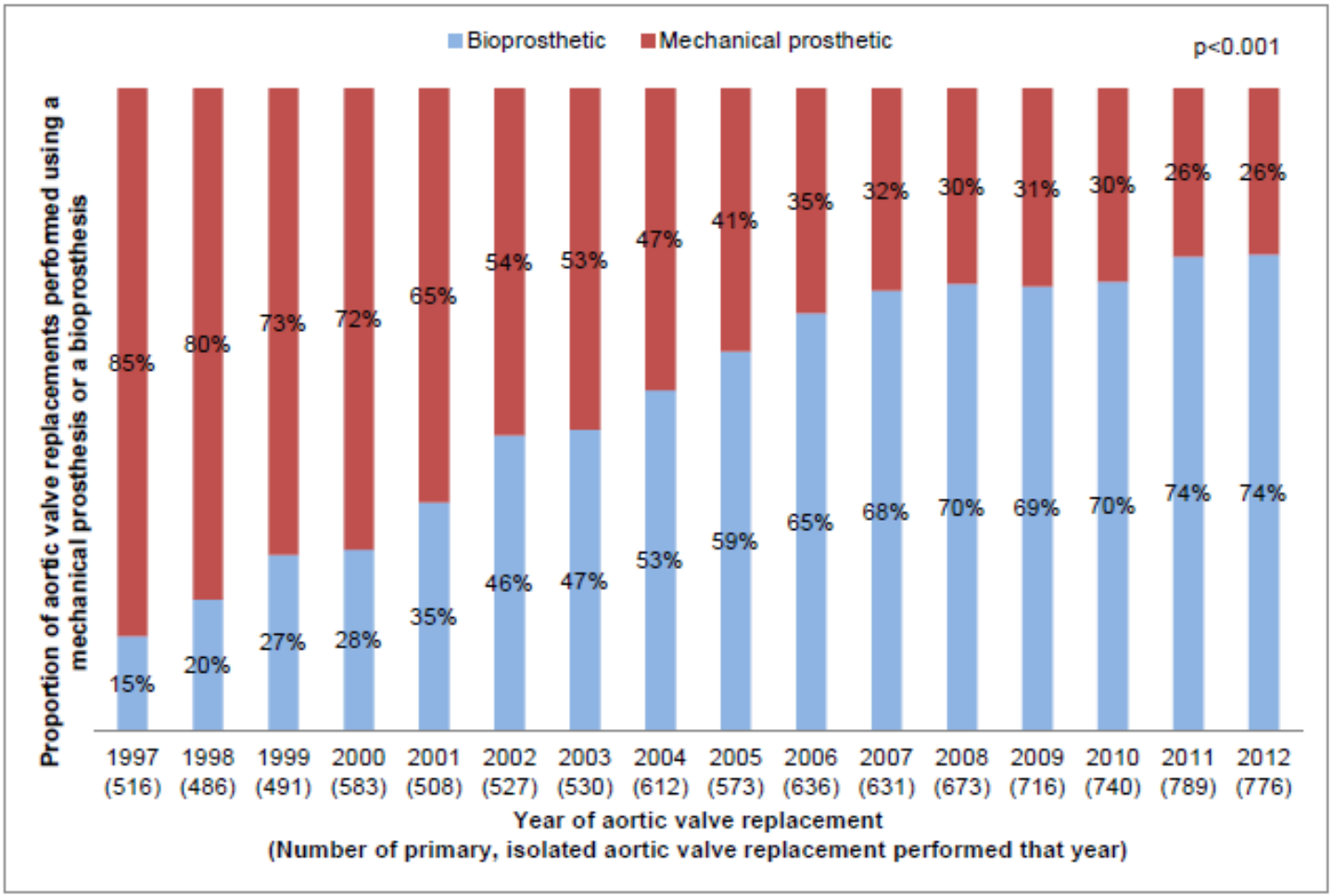
Atualização em Valvopatias Mitral e Aórtica

RESULTADOS TARDIOS DE BIOPRÓTESES CONVENCIONAIS E PERCUTÂNEAS

Não possuo nenhum conflito de interesse relacionado a esta apresentação

Survival and Long-term Outcomes Following Bioprosthetic vs Mechanical Aortic Valve Replacement in Patients Aged 50 to 69 Years

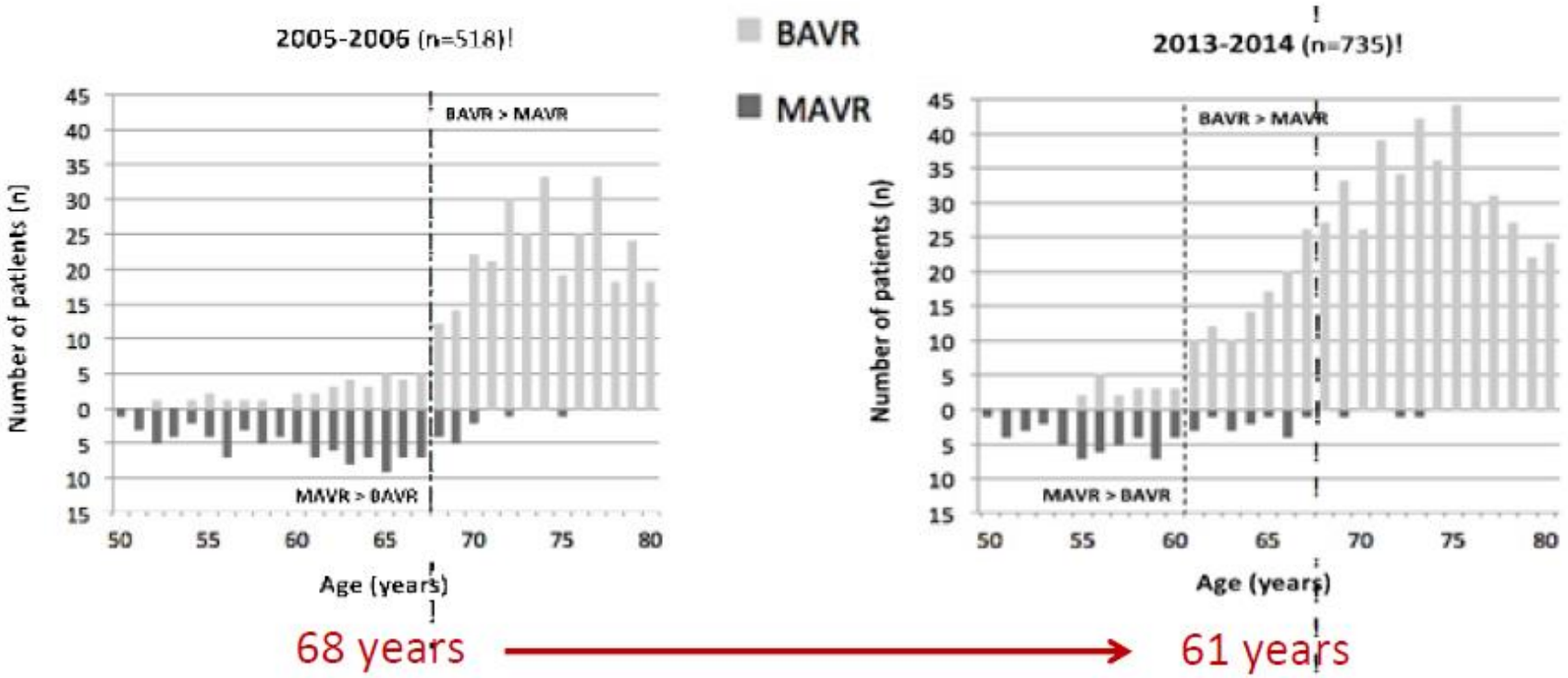
eFigure 2. Trend in Mechanical versus Bioprosthetic Valve Usage for Aortic Valve Replacement in Patients Aged 50 to 69 in New York State[a]



Based on NY Registry - Chiang et al

JAMA. 2014;312(13):1323-1329.

Surgical bioprosthetic aortic valves



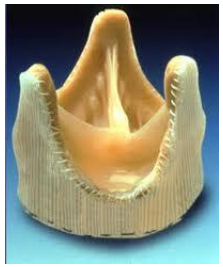
De Backer et al. JACC CV. 2016; 9:1152-8

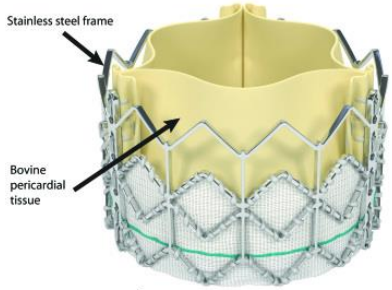
Processamento das Biopróteses

- Fresh-frozen
- Freeze-dried
- Formaldeido
- *Glutaraldeído*
- Glicerol
- No-React
- L-Hydro
- Liofilização
- Integrity technology
- Pré-incubação em etanol
- Triglycidyl amine
- .....

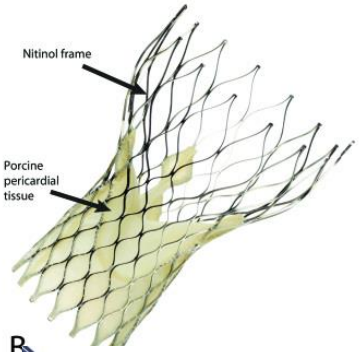
- Fascia lata
- Dura-máter
- Pericárdio
- Valva aórtica
- Veia jugular bovina

Biopróteses Consolidadas:
Valva aórtica porcina
Pericárdio bovino
Preservação em glutaraldeído




Stainless steel frame
Bovine pericardial tissue

A


Nitinol frame
Porcine pericardial tissue

B

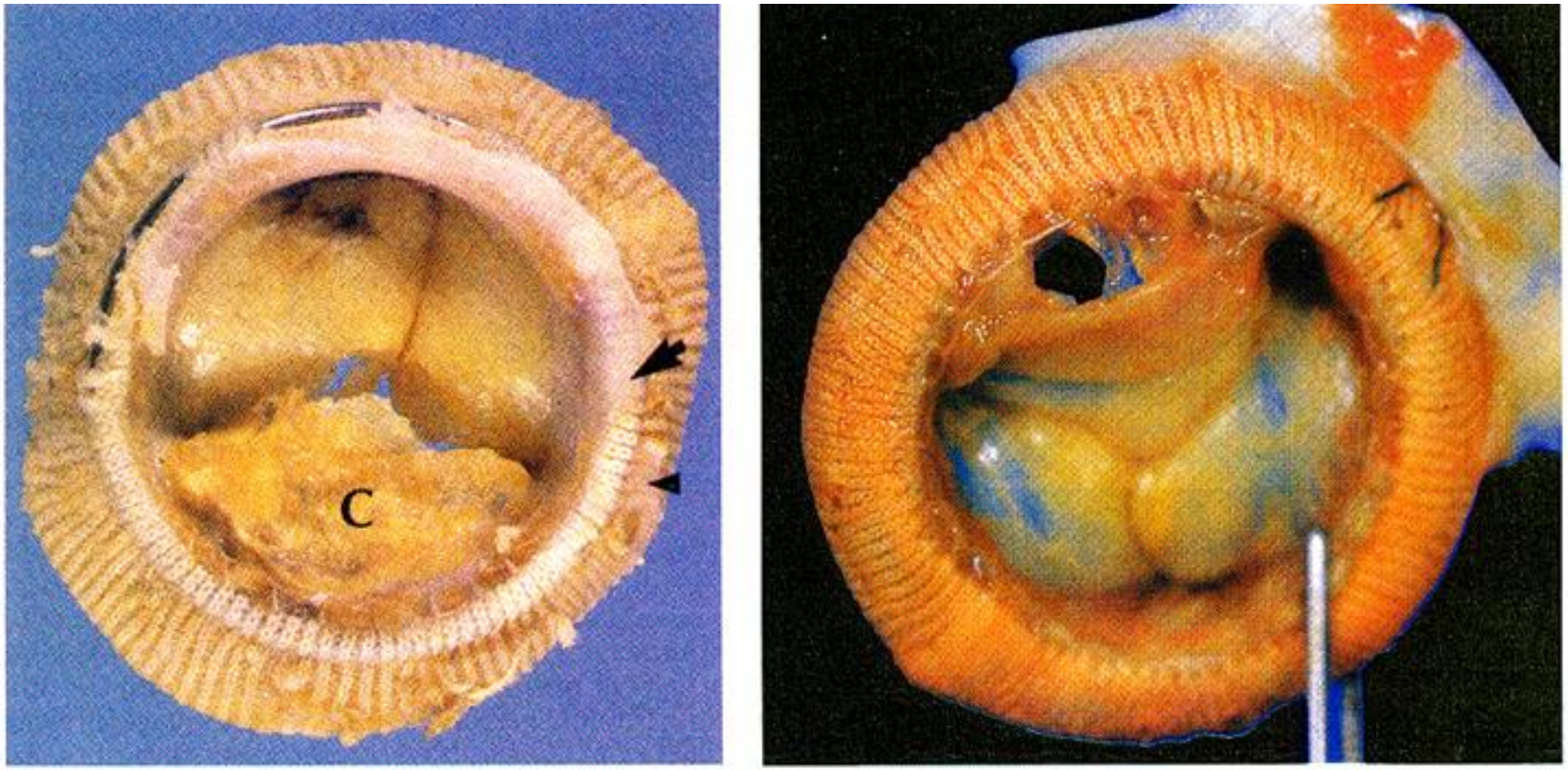
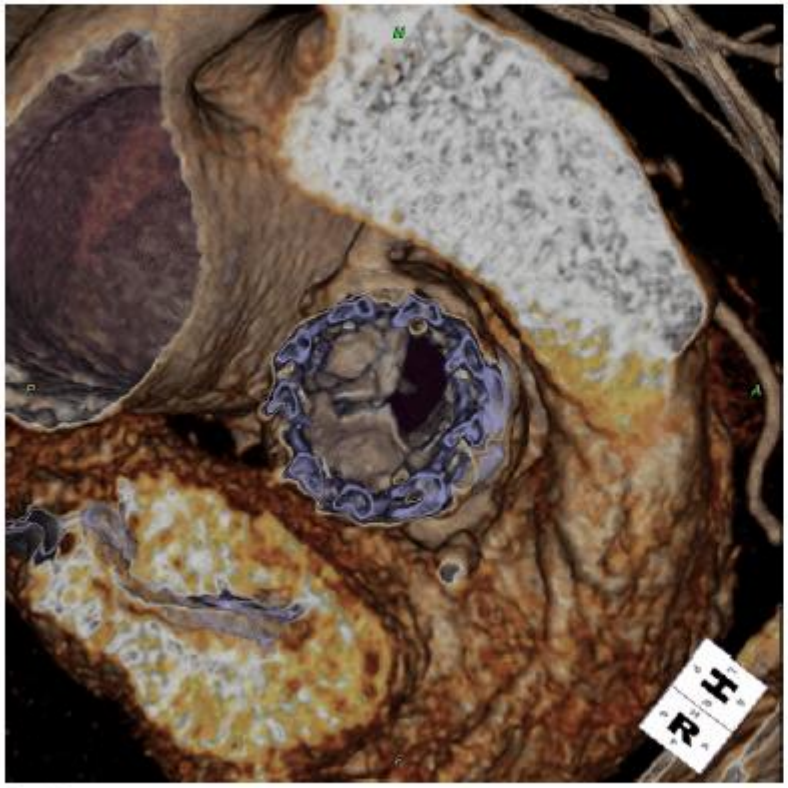


FIGURE 37–50 Structural deterioration of bioprosthetic valves. **A,** Valve failure related to mineralization and collagen degeneration. **B,** Cuspal tears and perforations. These processes may occur independently, or they may be synergistic. (**A,** From Virmani R, Burke AP, Farb A: Pathology of valvular heart disease. *In* Rahimtoola SH [ed]: Valvular Heart Disease. *In* Braunwald E [series ed]: Atlas of Heart Diseases. Vol 11. Philadelphia, Current Medicine, 1997, p 1.26; **B,** From Manabe H, Yutani C [eds]: Atlas of Valvular Heart Disease. Singapore, Churchill Livingstone, 1998, p 158.)

Subclinical leaflet thrombosis



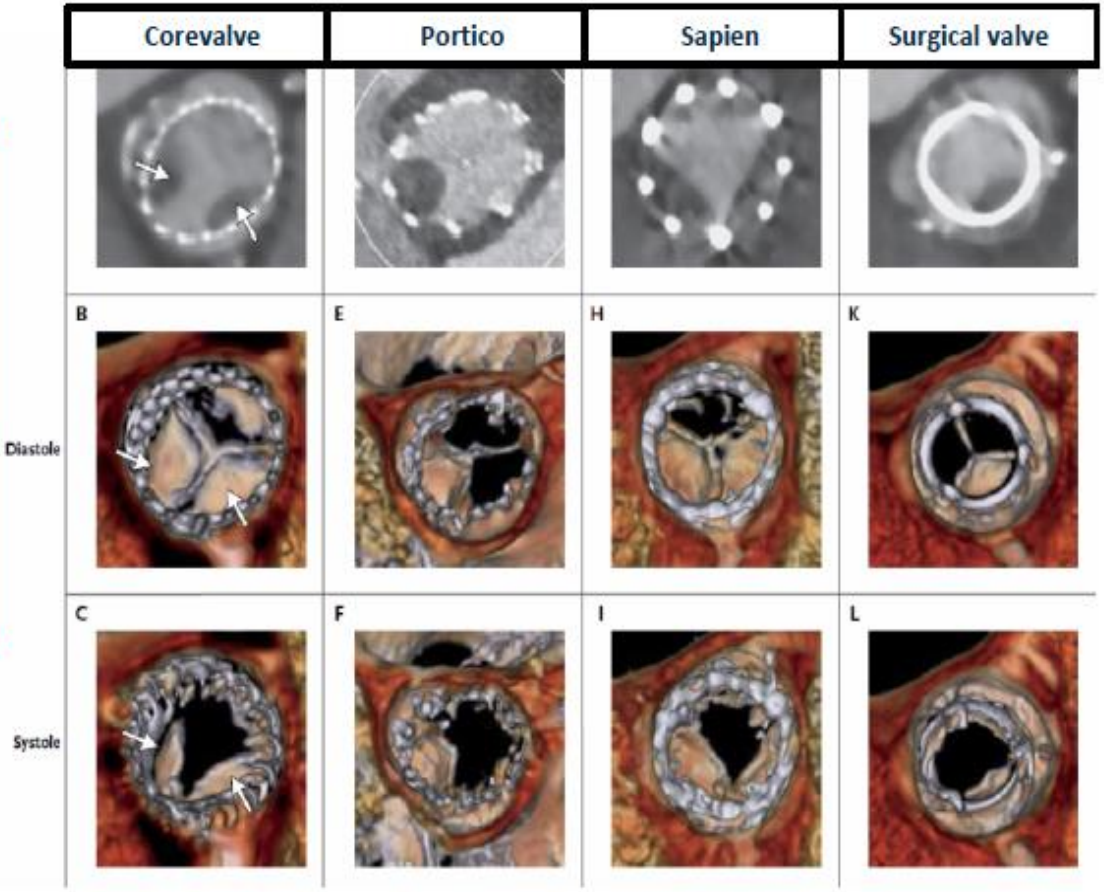
- Observed in all types of bio -prosthetic aortic valves
- Not associated with symptoms or high transvalvular gradient
- (N)OAC may prevent and resolve reduced leaflet thrombosis
- Uncertain association with increased risk of stroke/TIA and valve durability

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

Subclinical Leaflet Thrombosis in Bioprosthetic Valves

Makkar RR et al. *N Engl J Med. 2015;373:2015-24.*

- ✓ *Incidence: 17 of 132 patients (13%)*
- ✓ *Reduced incidence with oral anticoagulation (0% vs 29%, p=0.04) Restoration of leaflet motion in all 11 patients who received oral anticoagulation*
- ✓ *Higher incidence of stroke/TIA in patients with leaflet motion abnormality (18% vs 1%, p=0.007)*

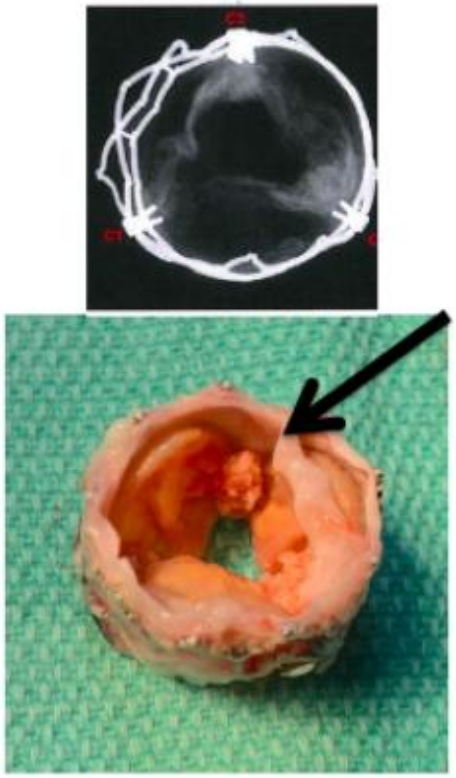


STRUCTURAL VALVE DEGENERATION

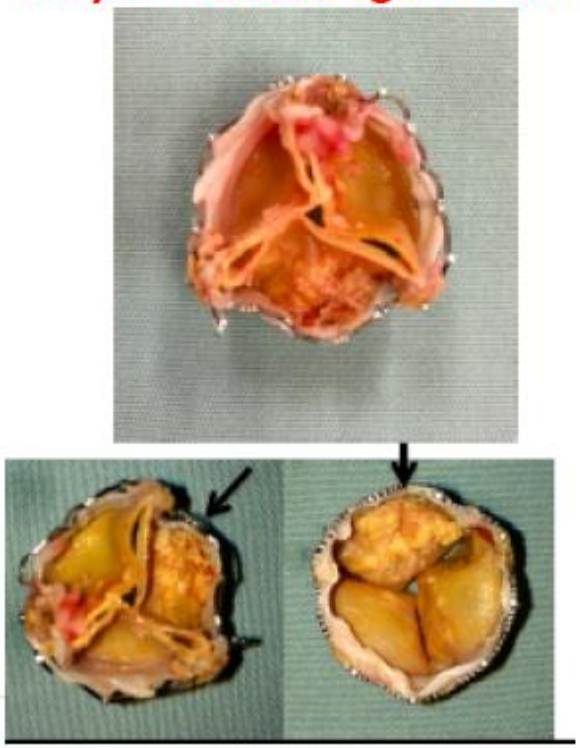
Presented by Dvir at EuroPCR 2016

Pathological Examinations

Severely calcified valve

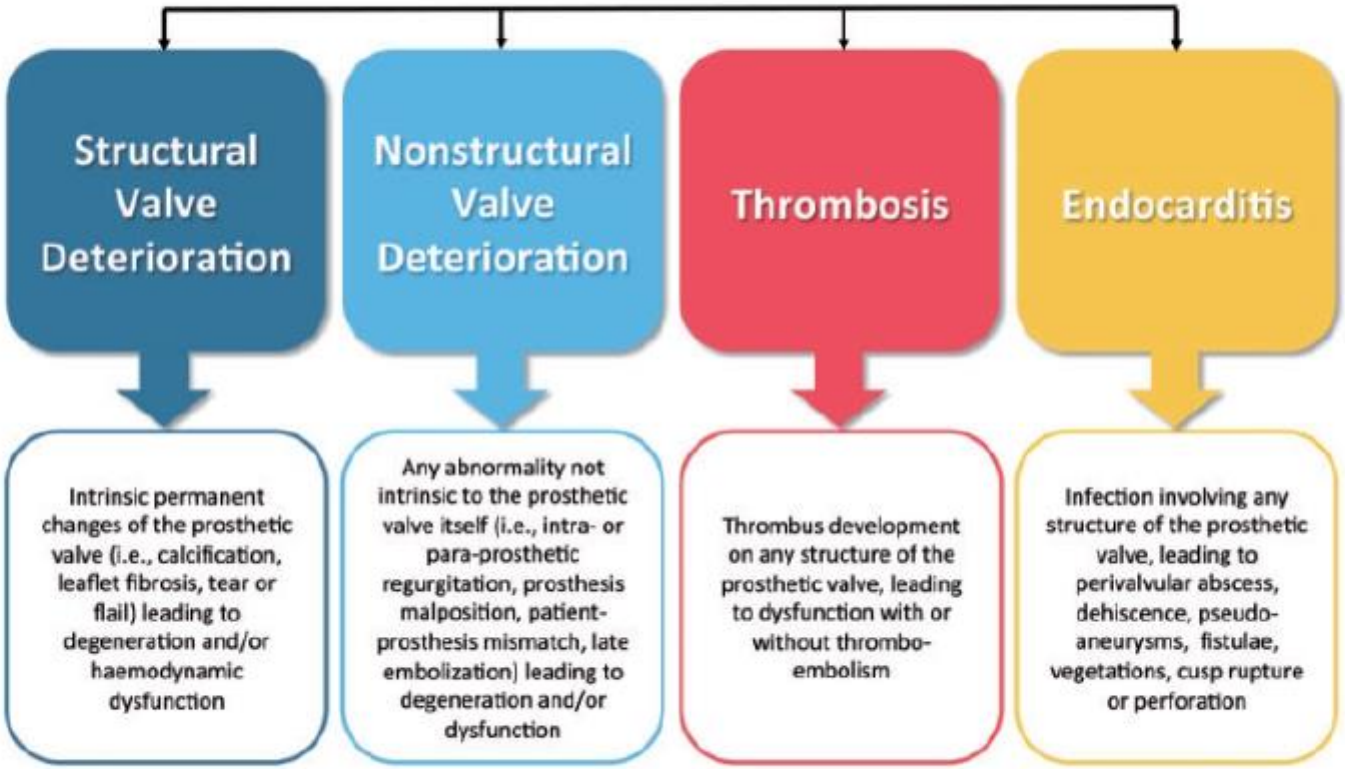


Asymmetric degeneration



Symmetric degeneration

Bioprosthetic valve dysfunction



Capodanno et al . Eur Heart J. 2017; 38:3382-90

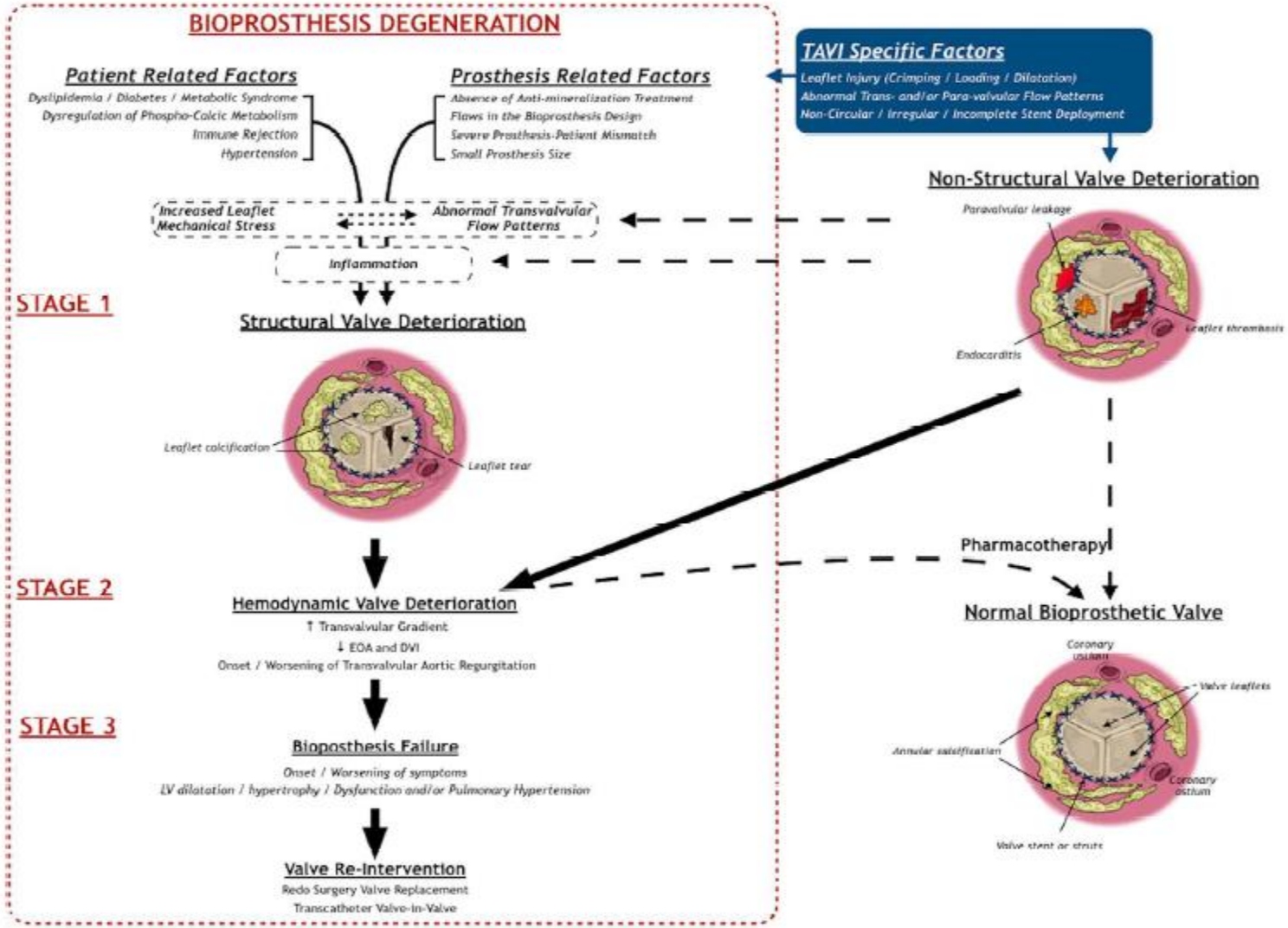


Figure 1 Risk factors, mechanisms and hemodynamic consequences of bioprosthetic valve deterioration. This figure shows the interaction between patient-related and prosthesis-related factors in the pathogenesis of structural and non-structural valve deterioration. The definitions of stages 1, 2 and 3 of structural valve deterioration are presented in table 1 and illustrated with cases in figure 2, 3 and 5. Some factors specific to TAVI devices and procedures may increase the mechanical stress on valve leaflets and disturb transvalvular flow patterns, which may, in turn, promote accelerated valve deterioration. Schematic representations of the transcatheter valves with structural or non-structural SVD are adapted with permission from.[56] DVI, Doppler velocity index; EOA, effective orifice area; LV, left ventricle; SVD, structural valve deterioration; TAVI, transcatheter aortic valve implantation.

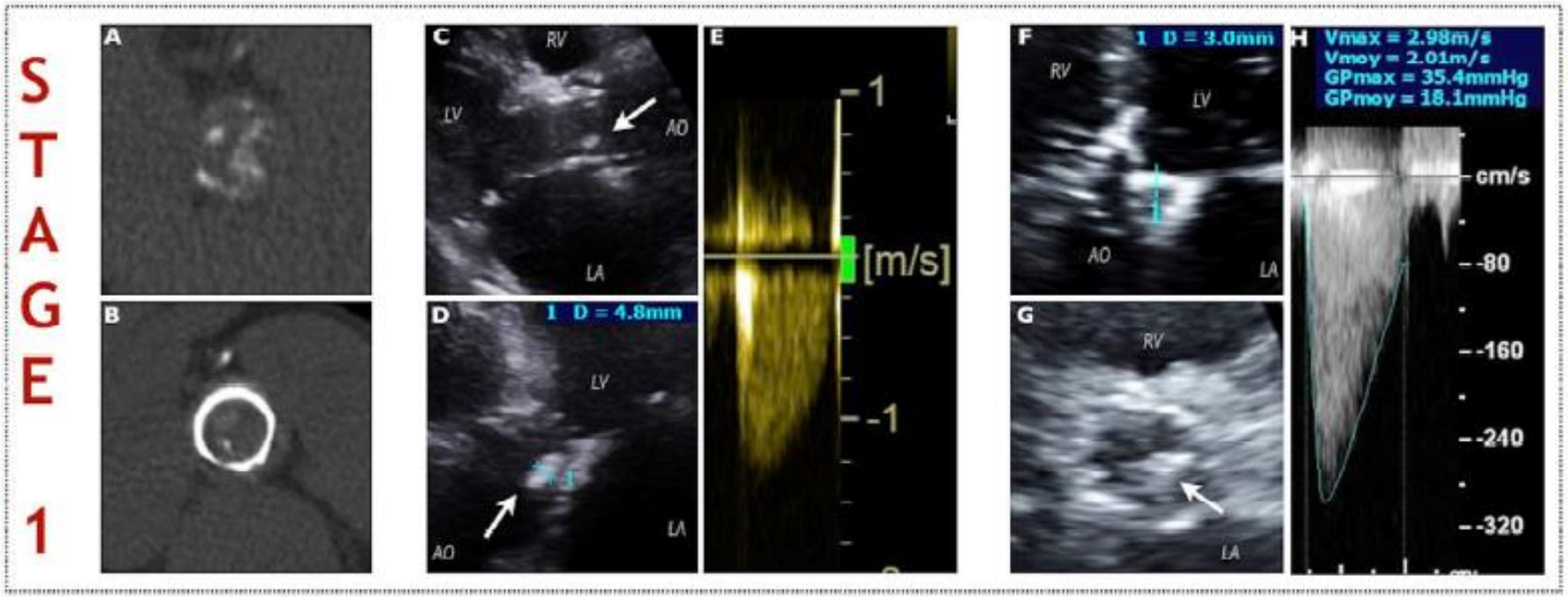


Figure 2 Illustrative cases of the stage 1 of structural valve deterioration. Multidetector CT images of calcification of valve leaflets but with no evidence of valve hemodynamic deterioration in a Medtronic Freestyle stentless bioprosthesis #23 (A) and Carpentier-Edwards Magna stented bioprosthesis #23 (B). TTE images of a SAPIEN 3 bioprosthesis with fibrocalcific remodelling of valve leaflets and thickening (leaflet thickness: 4.8 mm) (white arrows, C and D) but with a low mean gradient (5 mm Hg) (E). TTE images of a SAPIEN 3 with structural valve deterioration (leaflet thickening [3 mm], F and G, white arrow) and a moderately high mean gradient (18 mm Hg) (H). However, the mean gradient at discharge post-TAVI 3 years ago was already moderately elevated (16 mm Hg) due to prosthesis–patient mismatch. There is thus no valve hemodynamic deterioration in this case. TAVI, transcatheter aortic valve implantation; TTE, transthoracic echocardiography.

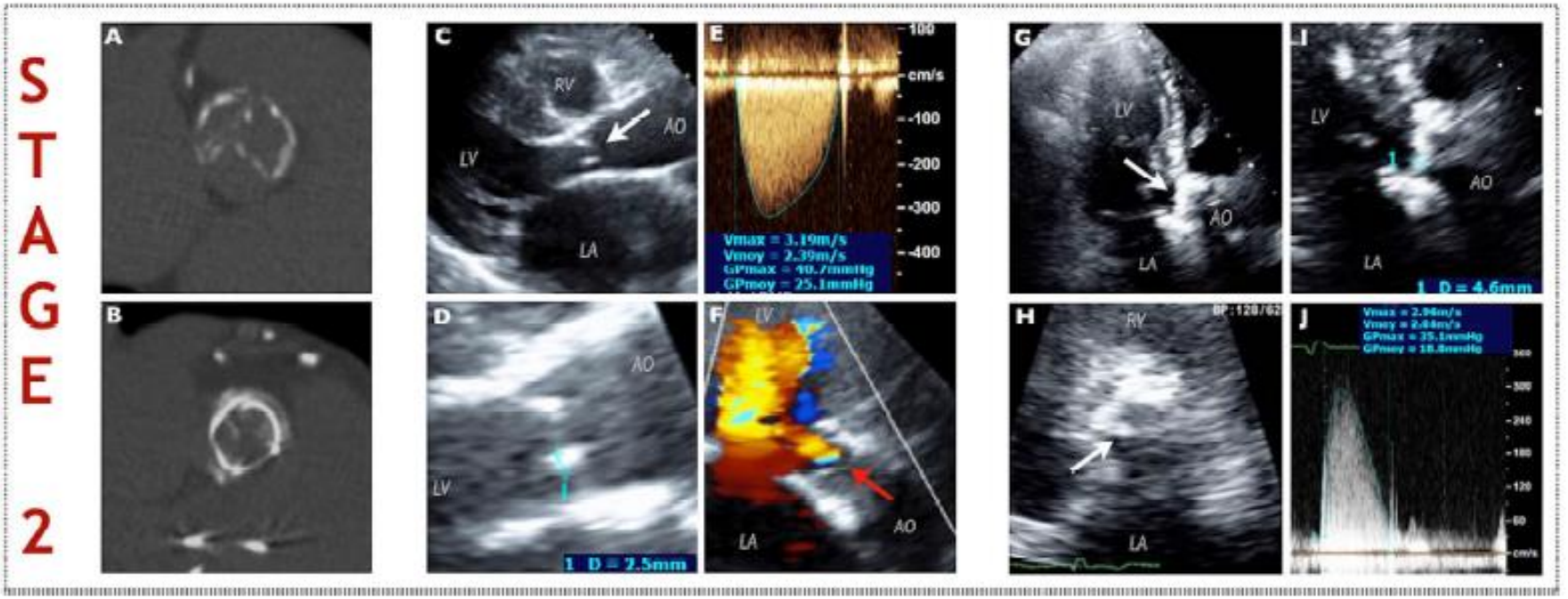


Figure 3 Illustrative cases of the stage 2 of structural valve deterioration. Multidetector CT images of leaflet calcification of Medtronic Freestyle stentless bioprosthesis #25 and Carpentier-Edwards Perimount stented bioprosthesis #23 in patients with valve hemodynamic deterioration during follow-up (A and B). TTE images of SAPIEN 3 bioprosthesis with valve leaflet fibrocalcific remodelling and thickening (C, white arrow, and D) and evidence of hemodynamic valve deterioration: the mean gradient (E) increased during follow-up (25 mm Hg vs 11 mm Hg at discharge), and the effective orifice area decreased (0.81 vs 1.78 cm^2). A new mild transvalvular central regurgitation was also present (F). TTE images show a SAPIEN 3 valve with structural valve deterioration (G–I) visible at TTE and increase in mean gradient (19 mm Hg vs 6 mm Hg at discharge; (J) with concomitant decrease in effective orifice area (1.58 vs 2.4 cm^2). TTE, transthoracic echocardiography.

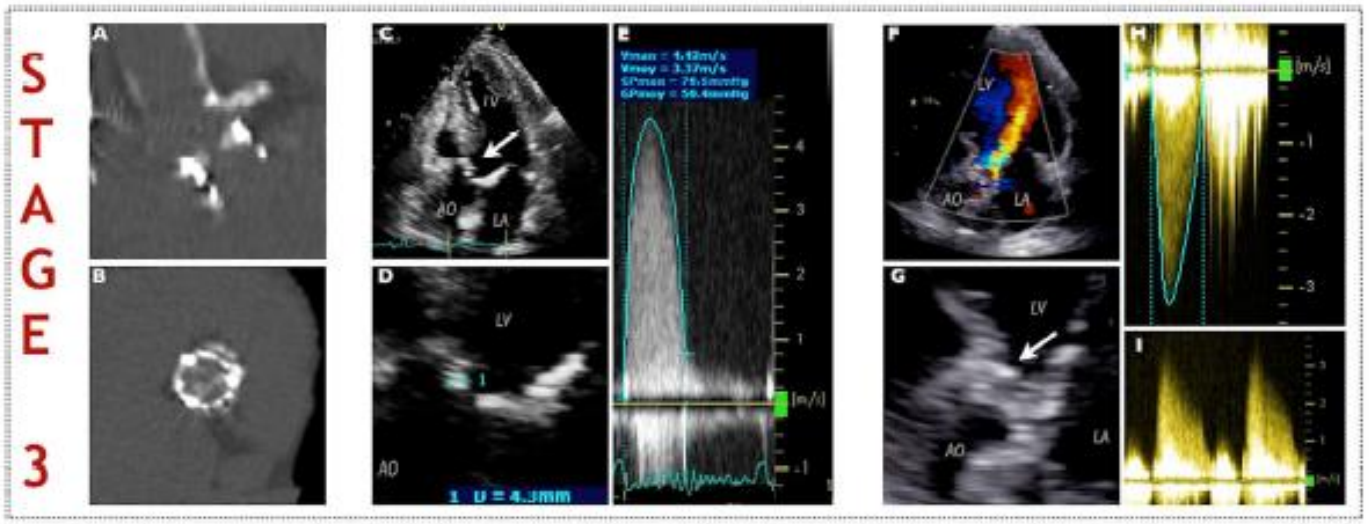


Figure 5 Illustrative cases of the stage 3 of structural valve deterioration. Multidetector CT images with important leaflet mineralisation and thickening of SAPIEN 3 valves that required reintervention (valve-in-valve) (A and B). TTE images of a failed surgical bioprosthesis implanted 13 years ago (C–E). Structural valve deterioration with leaflet hyperechogenicity (C, white arrow) and thickening (D) with restriction in leaflet motion and hemodynamic valve deterioration leading to severe prosthetic valve stenosis (mean gradient: 50 mm Hg; E). Patient implanted with a surgical bioprosthesis 11 years ago and presenting with a thickened and teared leaflet (G, white arrow) and severe transvalvular regurgitation (F and I). The mean gradient is also increased (22 mm Hg), (H), as a results of mild-to-moderate valve stenosis and increase in transprosthetic flow related to the severe aortic regurgitation. AO, aorta; LA, left atrium; LV, left ventricle; RV, right ventricle; TTE, transthoracic echocardiography.

Salaun E, *et al*. *Heart* 2018;**0**:1–10. doi:10.1136/heartjnl-2017-311582

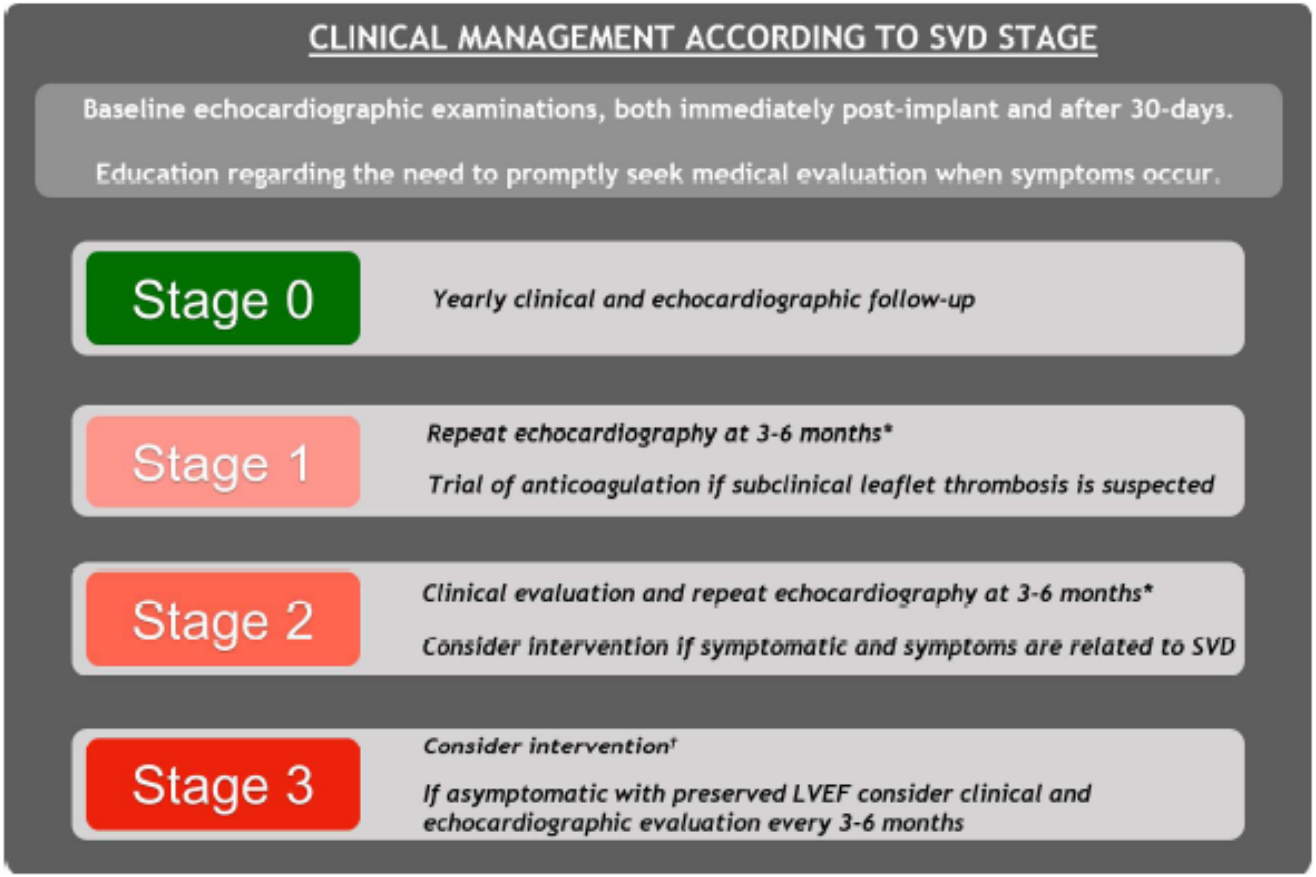
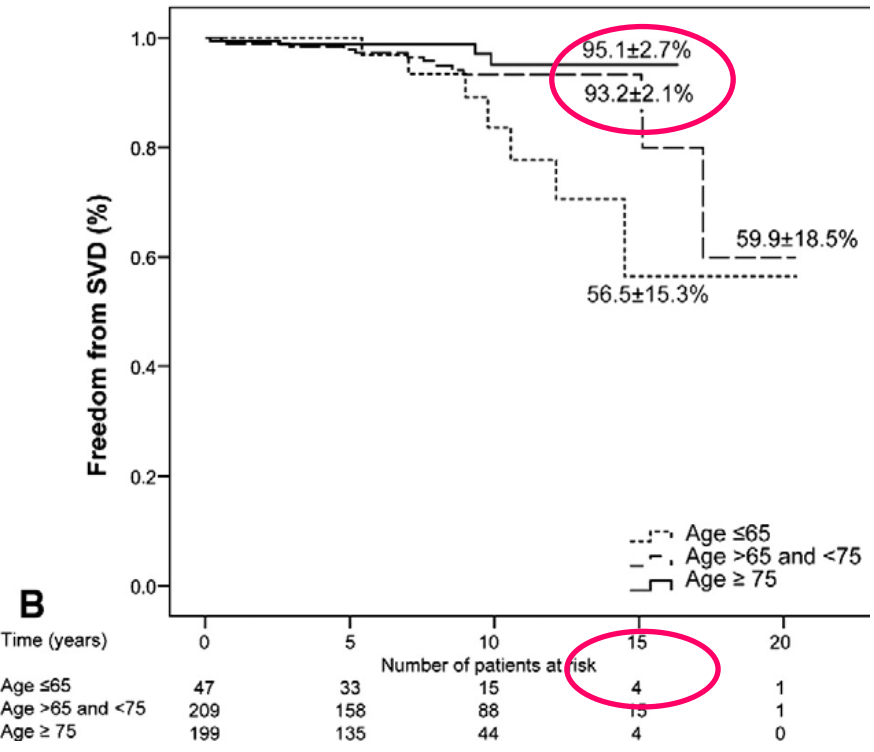


Figure 4 Clinical management of patients with a bioprosthesis according to SVD stage. In stages 1 and 2, closer clinical and Doppler echocardiographic follow-up should be considered. Valve reintervention should be considered in patients with stage 3 and symptoms and/or depressed left ventricular ejection fraction. The choice between redo surgery versus transcatheter valve-in-valve procedure should be individualised according to: (1) assessment of surgical risk; (2) feasibility of the transcatheter procedure; and (3) presence of factors that may increase the risk of futility of valve-in-valve procedure: that is, small surgical bioprosthesis or severe pre-existing PPM. This figure is adapted with permission from Dvir *et al*.[13] *After initial diagnosis, then if stable every 12 months in patients with stage 1, and every 6–12 months in patients with stage 2. †In patients with symptoms or impairment in left ventricle systolic function. HVD, hemodynamic valve deterioration; LVEF, left ventricular ejection fraction; SVD, structural valve deterioration.

Sobrevida livre de degeneração estrutural da bioprótese Ao

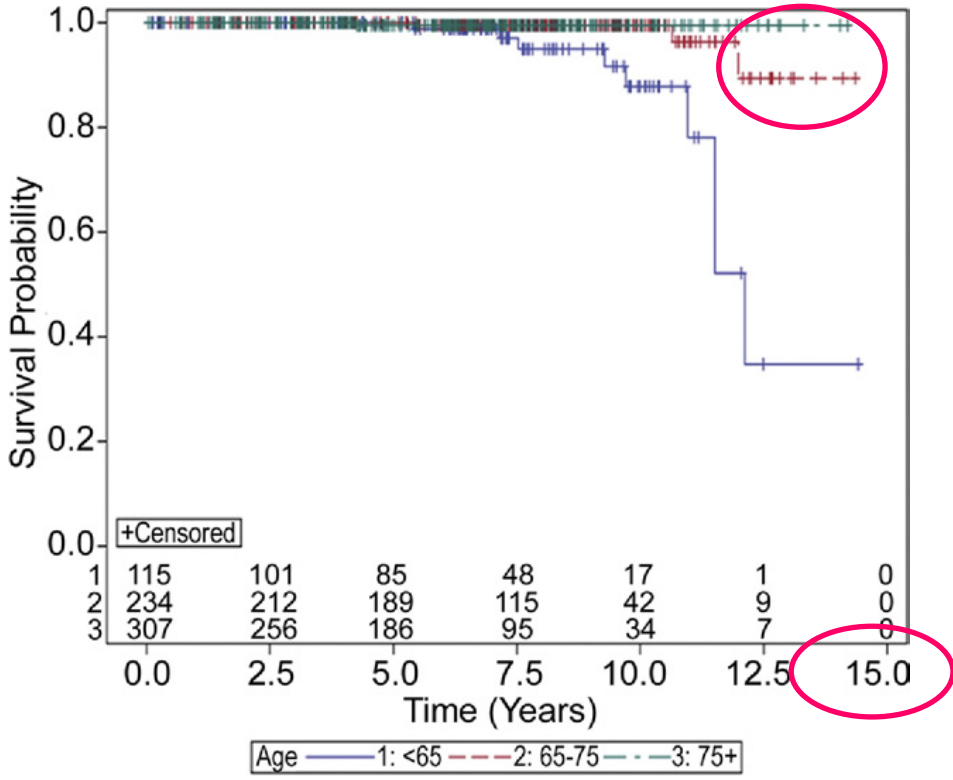
Biocor StJude porcina

Eichinger WB e cols
German Heart Center Munich
Ann Thorac Surg 2008;86:1204 –11



Carpentier-Edwards Pericardial Bioprosthesis

McClureRS e cols, Brigham and Women's Hospital ,Harvard Medical School
Ann Thorac Surg 2010;89:1410-1416



Pericárdica e Porcina, 3 modelos

n=2979
>65anos
período
1993-2007,
Mayo,
Mass Gen e
Brigham

Biopróteses
Medtronic
Sorin
Carpentier

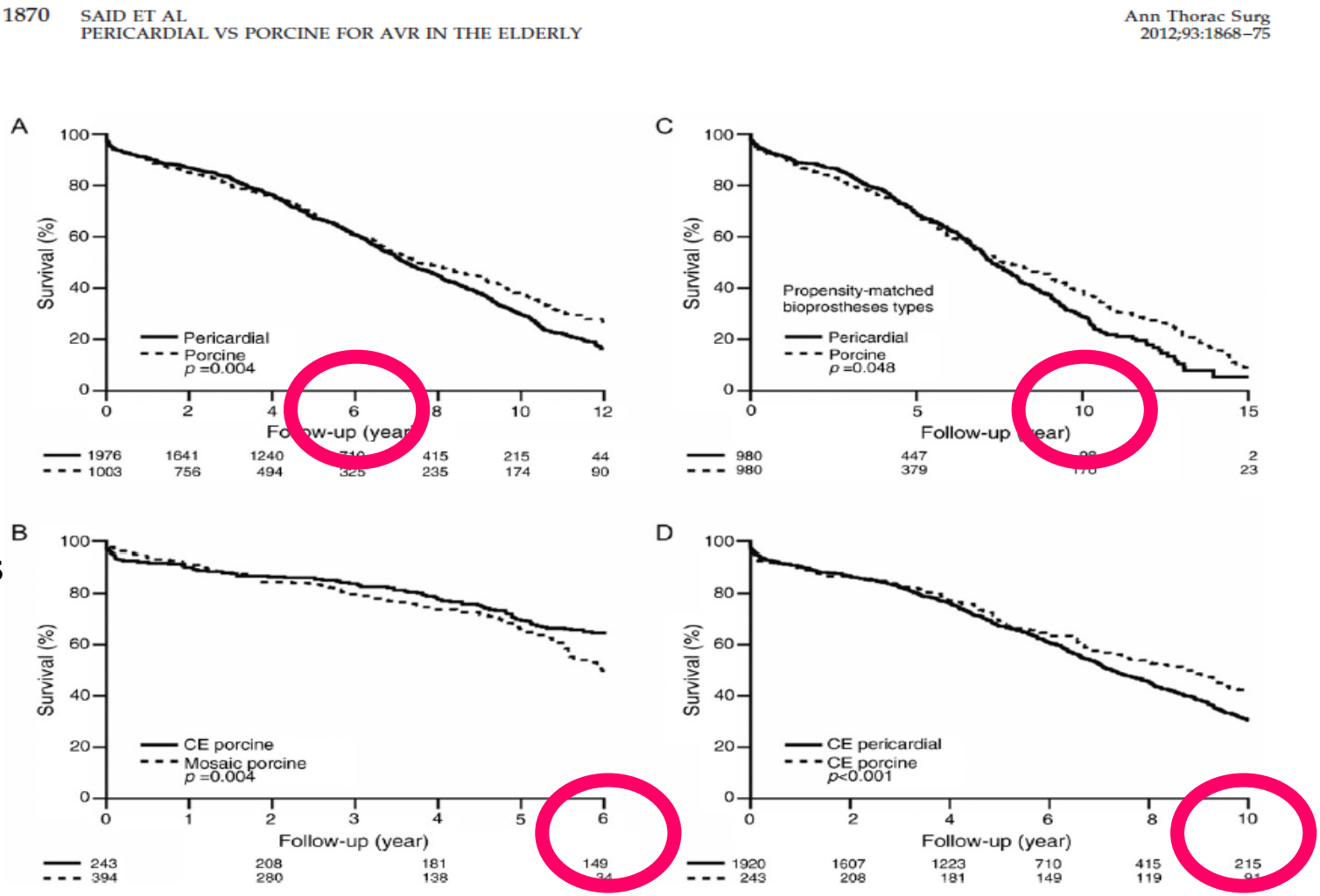


Fig 1. Kaplan-Meier graphs show survival of elderly patients after aortic valve replacement. (A) There was no survival advantage for patients with pericardial (solid line) over porcine (dashed line) bioprostheses (p = 0.05). (B), Survival is shown between the two most commonly used porcine brands, the Medtronic Mosaic (dashed line) and the Carpentier-Edwards Perimount (CE, solid line). (C) Survival is compared between propensity-matched pericardial (solid line) and porcine (dashed line) bioprostheses types. (D) There was no survival advantage for the Carpentier-Edwards (CE) Perimount (solid line) over the porcine type (dashed line); in fact, thex porcine brand appeared to have a survival advantage (p < 0.001).

Do Pericardial Bioprostheses Improve Outcome of Elderly Patients Undergoing Aortic Valve Replacement? Said SM et al (Mayo, Mass Gen & Brigham) **Ann Thorac Surg 2012;93:1868 –75**

Do Pericardial Bioprostheses Improve Outcome of Elderly Patients Undergoing Aortic Valve Replacement?

Sameh M. Said, MD,* Elena Ashikhmina, MD, PhD, Kevin L. Greason, MD, Rakesh M. Suri, MD, PhD, Soon J. Park, MD, Richard C. Daly, MD, Harold M. Burkhart, MD, Joseph A. Dearani, MD, Thoralf M. Sundt III, MD, and Hartzell V. Schaff, MD

Division of Cardiovascular Surgery, Mayo Clinic, Rochester, Minnesota; Division of Cardiac Surgery, Massachusetts General Hospital, Boston, Massachusetts; and Division of Anesthesia, Brigham and Women's Hospital, Boston, Massachusetts

Background. Pericardial bioprostheses have favorable echocardiographic hemodynamics in the aortic position compared with porcine valves; however, there are few data comparing clinical outcomes. Our objective was to assess the late results of the two valve types.

Methods. We reviewed 2,979 patients aged 65 years or older undergoing aortic valve replacement with pericardial (n = 1,976) or porcine (n = 1,003) prostheses between January 1993 and December 2007. The most common pericardial prostheses were Carpentier-Edwards Perimount and Mitroflow, and the most common porcine valves were Medtronic Mosaic, Carpentier-Edwards, Hancock modified orifice, and St. Jude Biocor. Follow-up extended to a maximum of 16 years (mean, 5.2 ± 3.5 years).

Results. Survival at 5, 10 and 12 years was, respectively, 68%, 33%, and 21% overall, was 68%, 30%, and 16% for patients with pericardial bioprosthesis, and was 69%, 38% and 27% for the porcine group. In a multivariate model, long-term survival was reduced in patients with diabetes, renal failure, prior myocardial infarction, congestive heart failure, and older age, but late survival was not higher in the pericardial valve group. Overall freedom from reoperation was 96%, 92%, and 90% at 5, 10, and 12 years, and freedom from explant was 98%, 96%, and 94% during the same period. The reason for explant was structural valve deterioration in 50 patients (2%).

Conclusions. Despite the better hemodynamic performance documented in prior investigations, pericardial valves do not confer any survival advantage over porcine valves in patients aged 65 years or older undergoing aortic valve replacement.

(Ann Thorac Surg 2012;93:1868–75)

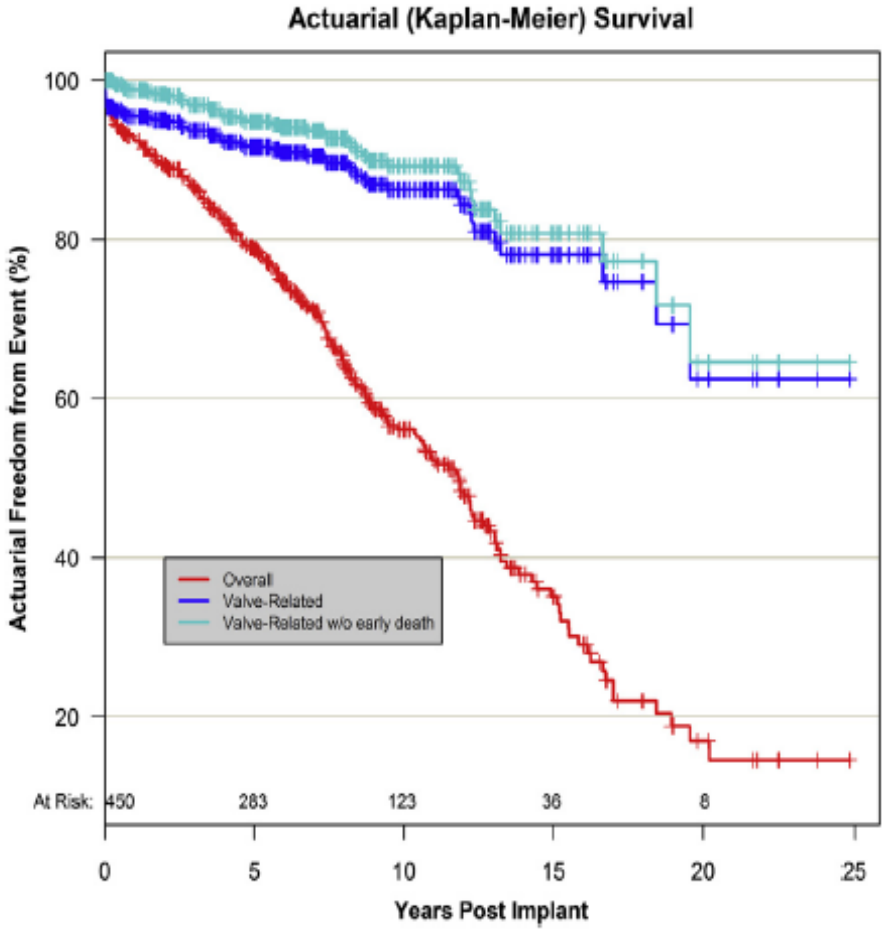


FIGURE 1. Kaplan-Meier estimates of overall and valve-related mortality.

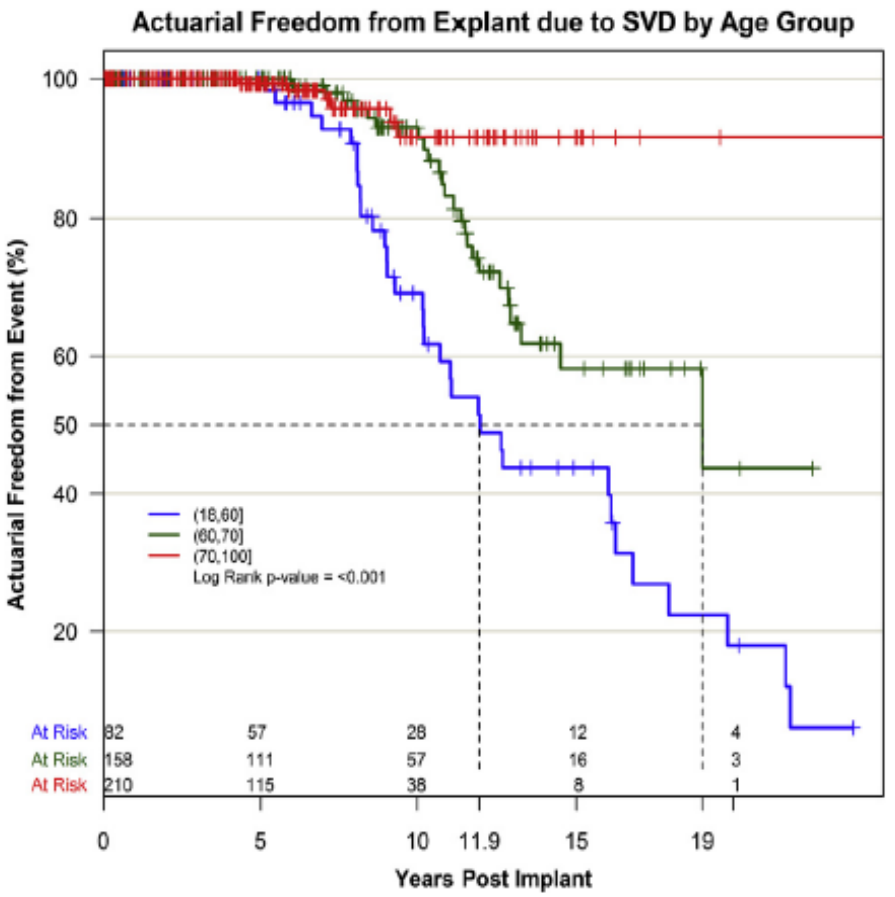


FIGURE 2. Kaplan-Meier estimates of explantation because of structural valve deterioration (*SVD*) stratified by age group.

Very late outcomes for mitral valve replacement with the Carpentier-Edwards pericardial bioprosthesis: 25-year follow-up of 450 implantations

J Thorac Cardiovasc Surg 2014

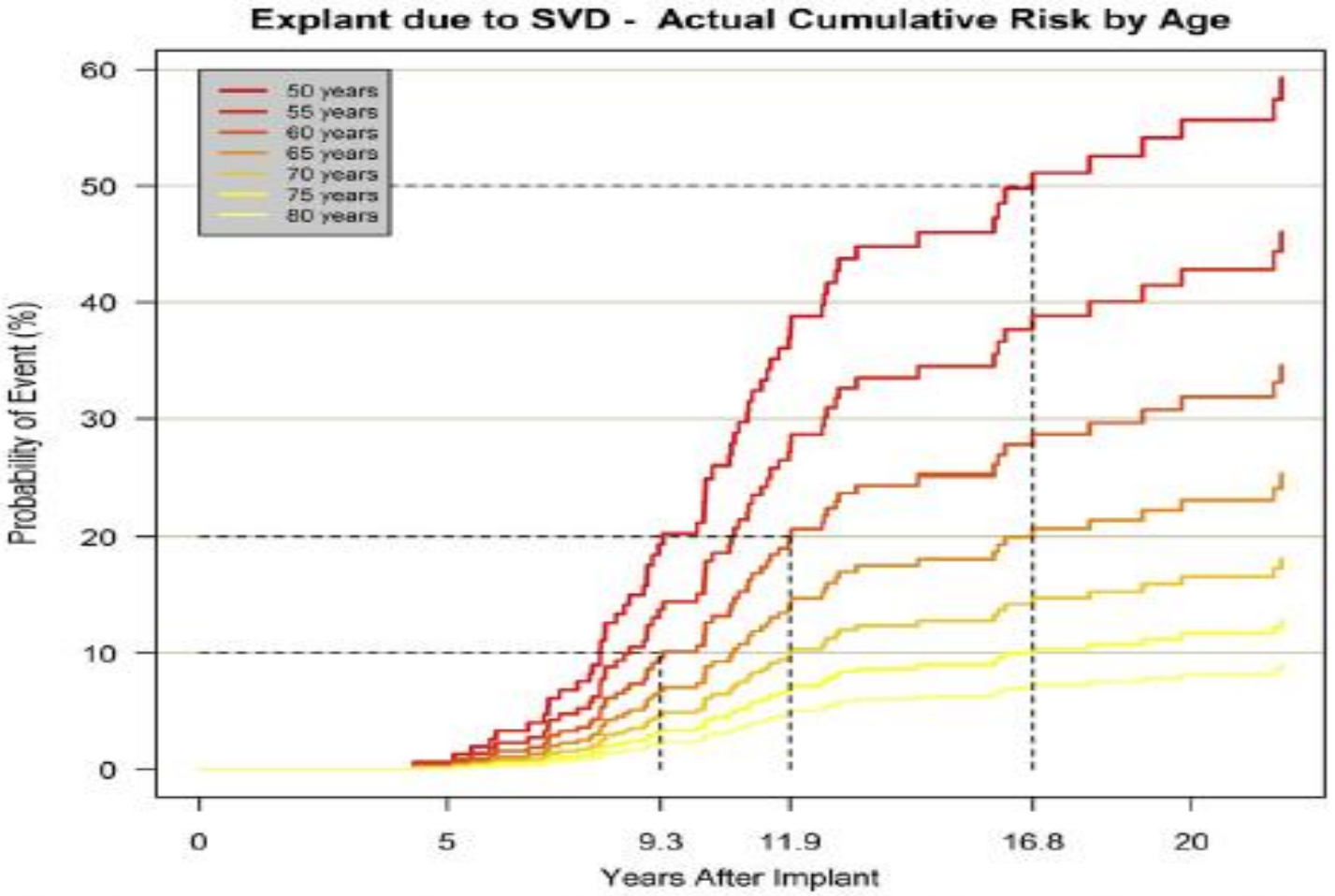


FIGURE 3. Competing risk estimates of explantation because of structural valve deterioration (*SVD*) stratified by age group.

Very late outcomes for mitral valve replacement with the Carpentier-Edwards pericardial bioprosthesis: 25-year follow-up of 450 implantations

Long-Term Survival After Bovine Pericardial Versus Porcine Stented Bioprosthetic Aortic Valve Replacement: Does Valve Choice Matter?

Table 1

Stented Bioprosthetic Aortic Valves Included in Study

Valves	Total (No.)	Isolated AVR (No.)	AVR+CABG (No.)
Bovine pericardial	1,411		
Carpentier-Edwards Perimount[a]	1,273	734	539
Sorin Mitroflow[b]	26	16	10
St. Jude Trifecta[c]	112	51	61
Porcine	599		
St. Jude Biocor[c]	128	46	82
Carpentier-Edwards Porcine[a]	210	111	99
Medtronic Hancock[d]	105	44	61
Medtronic Mosaic[d]	156	140	16

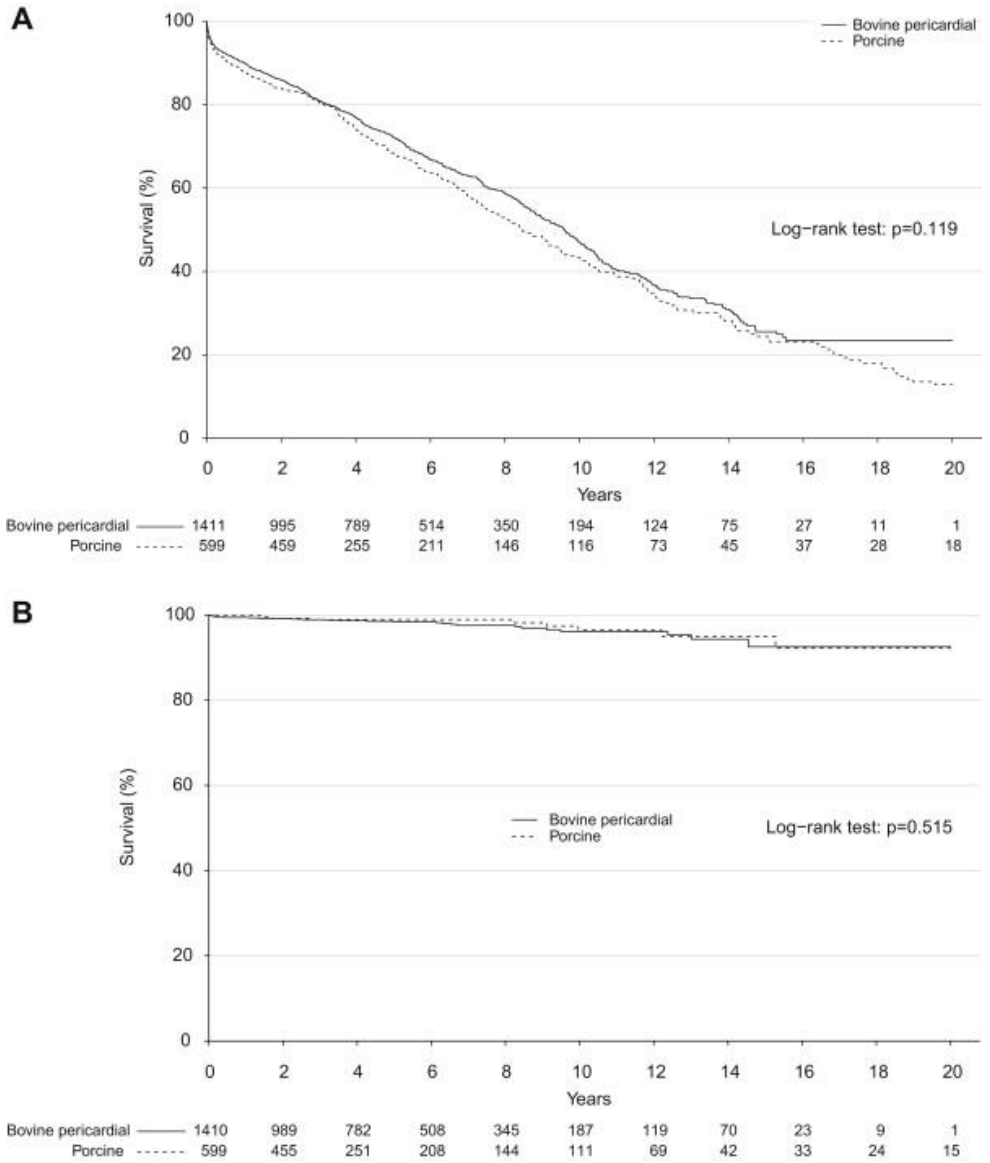
Ganapathi et al
Duke Univ, NC

Ann Thorac Surg
2015;100:550–9

Fig 2
Kaplan-Meier curves for patients with bovine pericardial (solid line) and porcine (dashed line) valves show

(A) _____ survival

(B)need for aortic valve reoperation.

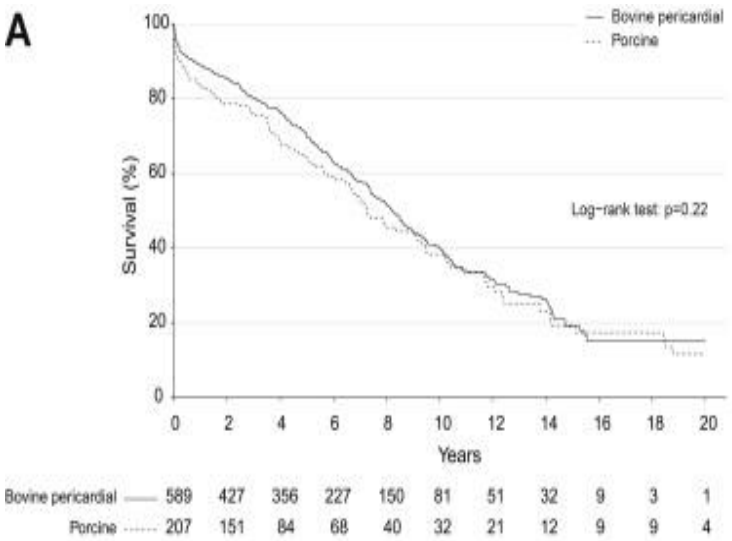


Ganapathi et al. Duke Univ, NC

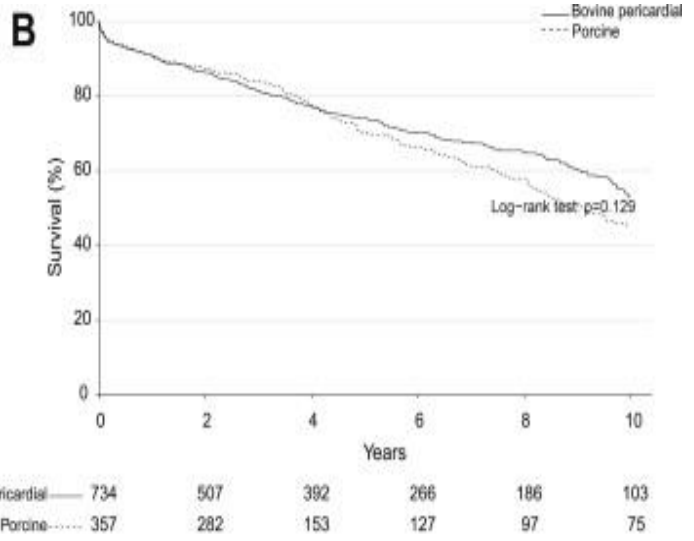
Ann Thorac Surg
2015;100:550–9

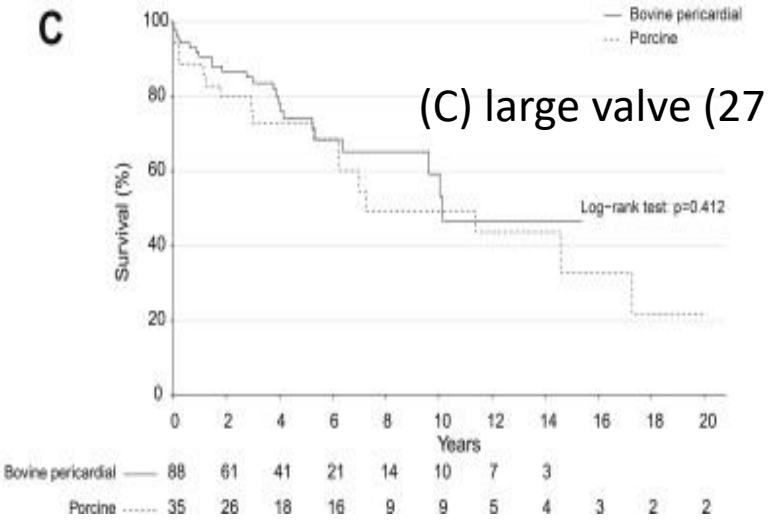
Fig 3
Overall survival analysis in patients with bovine pericardial (solid line) and porcine (dashed line) valves by subgroups with a…

(A) small valve (19 and 21 mm)



(B) medium valve (23 and 25 mm)





(C) large valve (27 and 29 mm).

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2015;100:550–9

Long-Term Survival After Bovine Pericardial Versus Porcine Stented Bioprosthetic Aortic Valve Replacement: Does Valve Choice Matter?

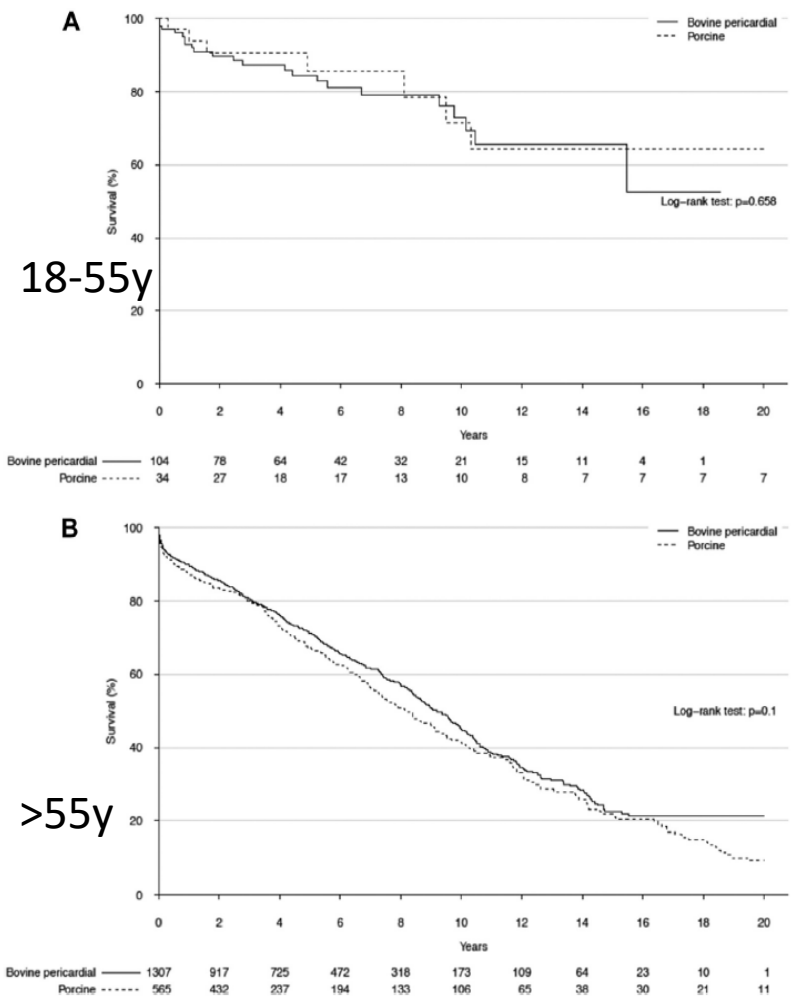

Fig 4. Overall survival analysis in patients with bovine pericardial (solid line) and porcine (dashed line) valves according patient age (A) 18 to 55 years and (B) age older than 55 years at aortic valve replacement.

Fungível = 1. Passível de ser substituído por outra coisa de mesma espécie, qualidade, quantidade e valor. 2.Substituível, não possuindo uma exclusividade que o impeça de ser reposto por coisa da mesma espécie.

In conclusion, for patients undergoing AVR with a stented bioprosthetic valve, with or without CABG, the choice of a porcine vs bovine pericardial bioprosthesis does not appear to affect long-term survival or the need for reoperation, regardless of valve size or patient age. As such, stented bioprosthetic valves would appear to be fungible, and therefore, valve choice should be driven by local market factors similar to other commodities.

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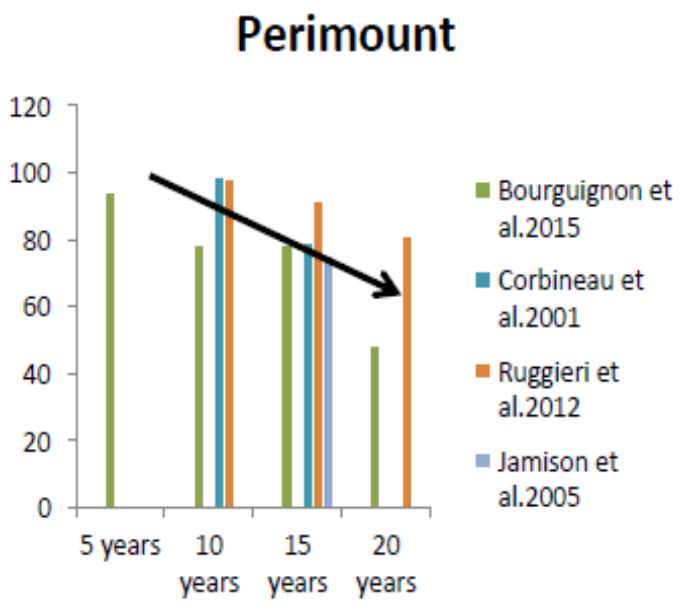
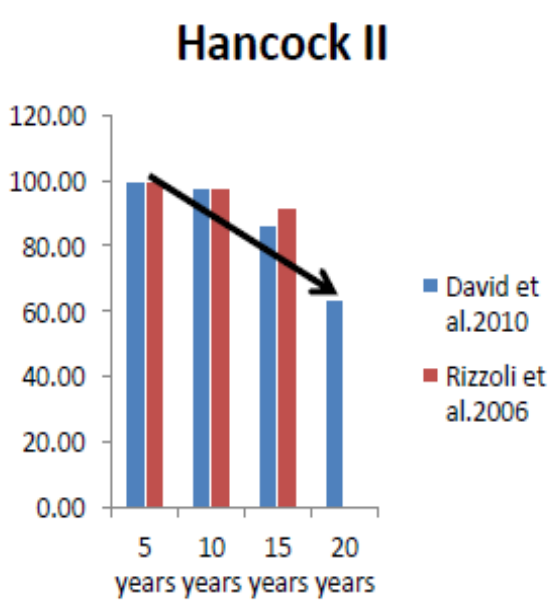
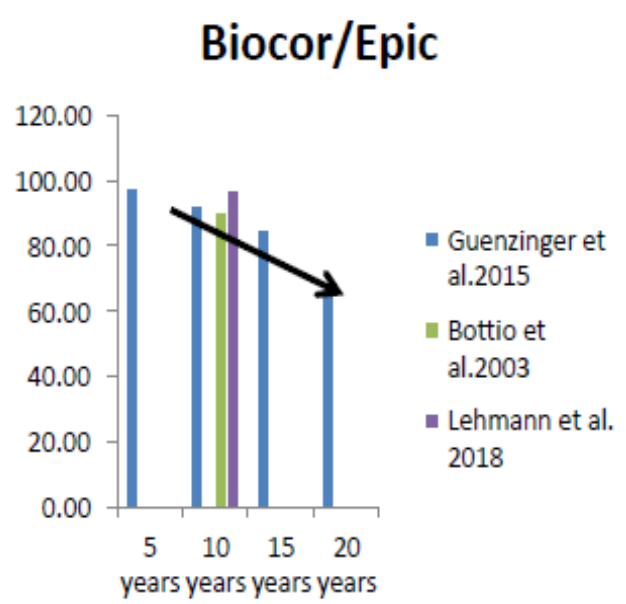
Duke Univ, NC

Ann Thorac Surg
2015;100:550–9

Freedom from Structural Valve Deterioration







Pathophysiology of structural valve deterioration: similarities and differences between TAVI and SAVR

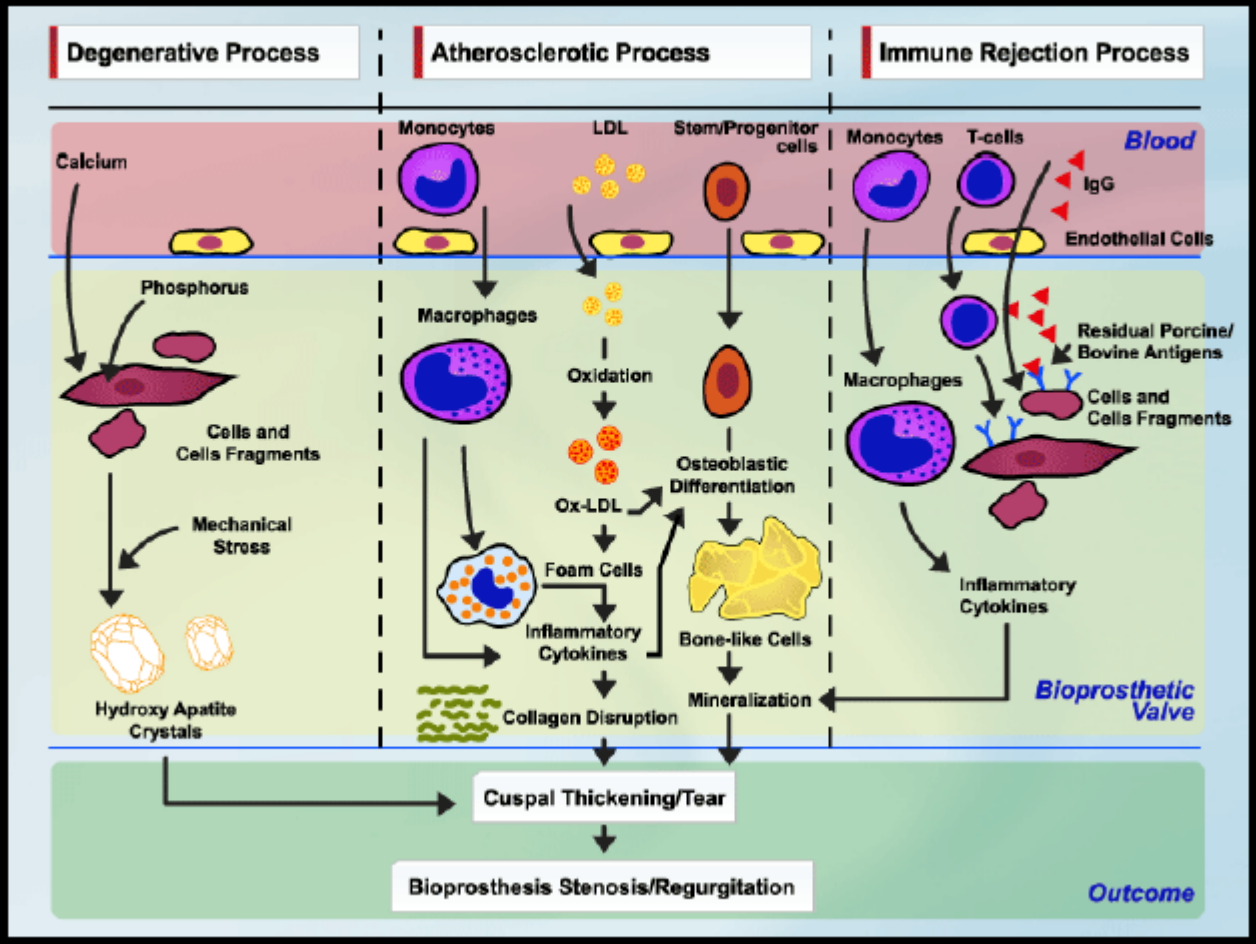
Philippe Pibarot, DVM, PhD, FACC, FESC, FASE
Canada Research Chair in Valvular Heart Disease

INSTITUT
UNIVERSITAIRE
DE CARDIOLOGIE
ET DE PNEUMOLOGIE
DE QUÉBEC

ESC
Council
Valvular Heart Disease

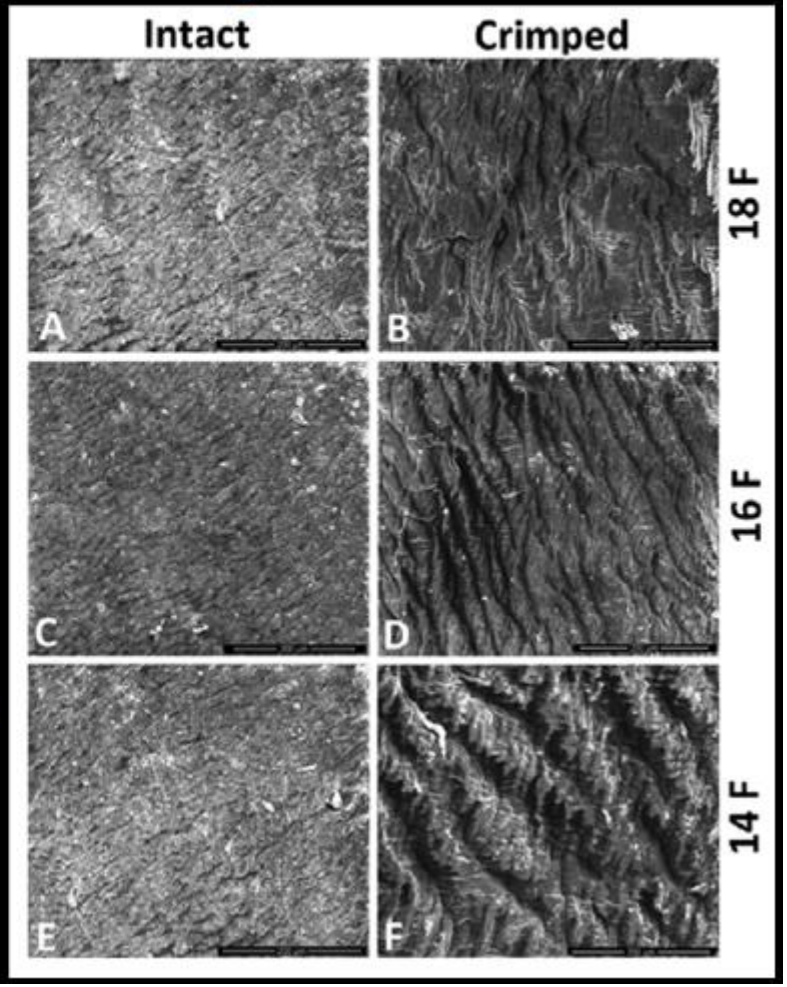
Université
LAVAL

Pathogenesis of Bioprosthesis SVD



Pibarot & Dumesnil, Circulation 119:1034-48, 2009

The Effect of Crimping / Loading on Pericardial Leaflets



Leaflet injury during valve loading and delivery was more important with balloon-expandable versus self-expanding THVs

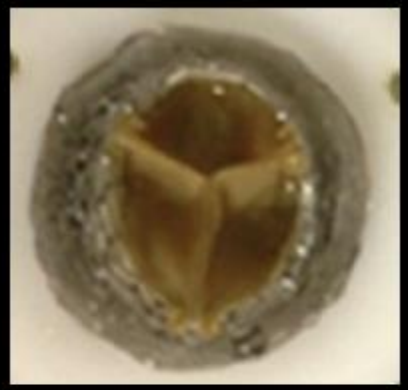
Alavi et al. Ann Thorac Surg; 2014;97:1260–6
Amahzoune et al. Eur J Cardiothorac Surg 2013;43:488–93.

Effect of THV Stent Expansion on Leaflets Kinetics

Underexpansion

Increased pinwheeling and leaflet bending stress

Optimal Expansion



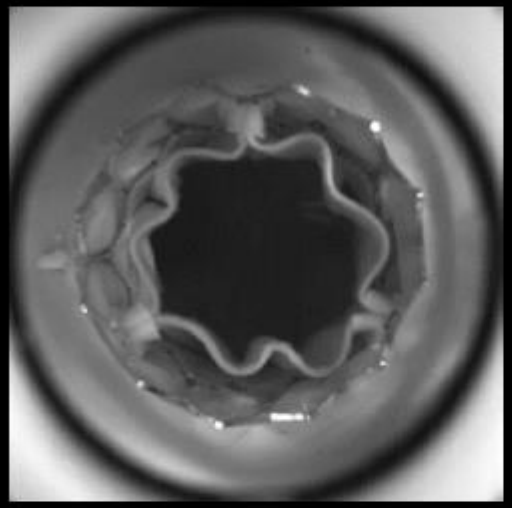
Overexpansion

Increased leaflet tethering stress

Salaun et al. International Journal of Cardiology 208 (2016) 28–35

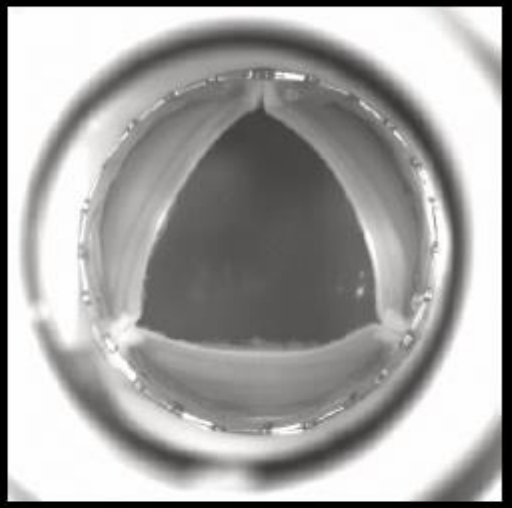
Effect of THV Stent Expansion on Leaflets Kinetics

Underexpansion



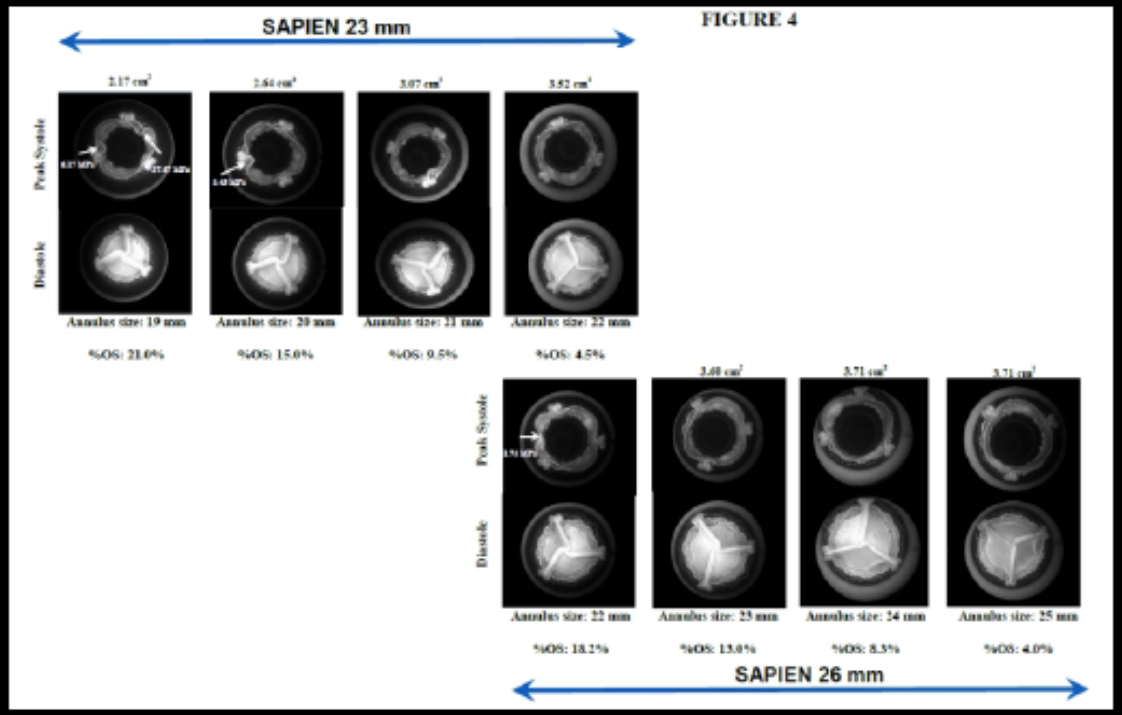
Increased pinwheeling and leaflet bending stress

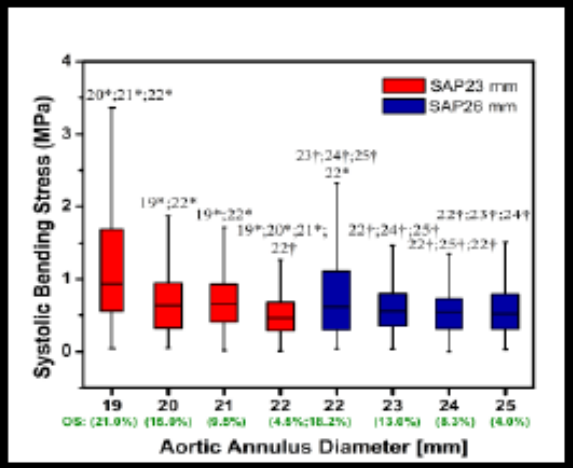
Overexpansion



Increased leaflet tethering stress

Effect of Annulus Size and Oversizing on TVH Leaflet Mechanical Stress

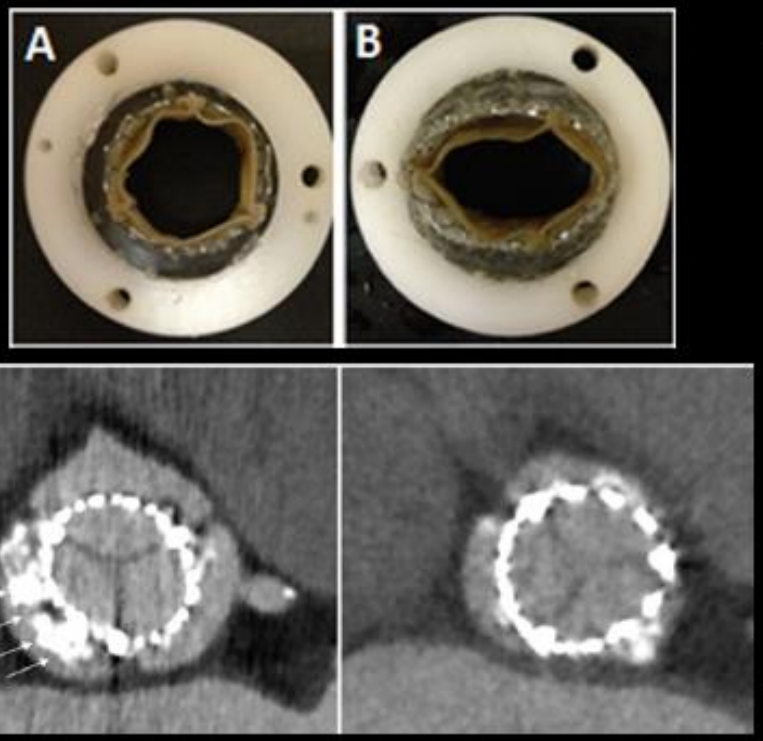




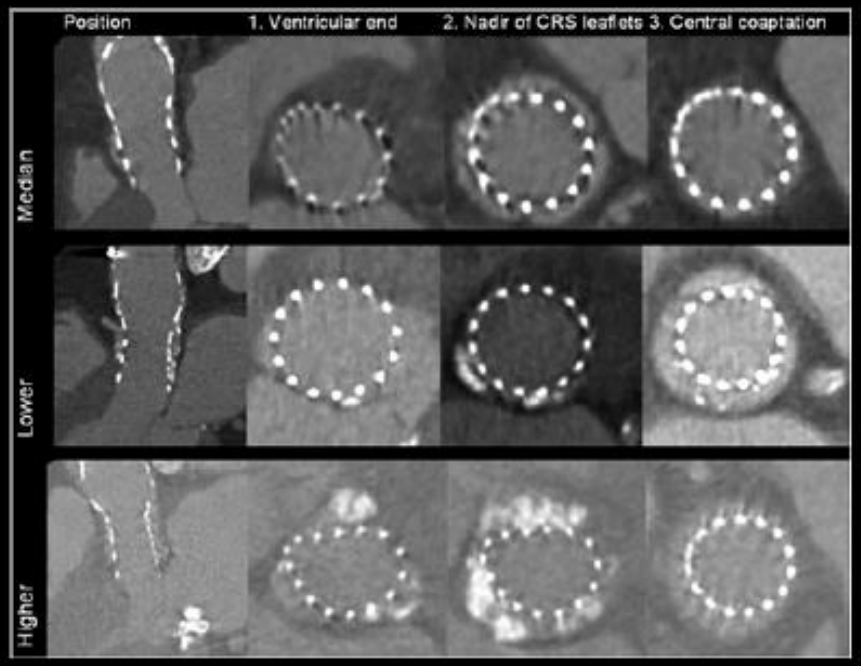
Maleki et al. Can J Cardiol 2015

Effect of Non-circular / Irregular Stent Deployment on Leaflet Mechanical Stress

Balloon-expandable THV



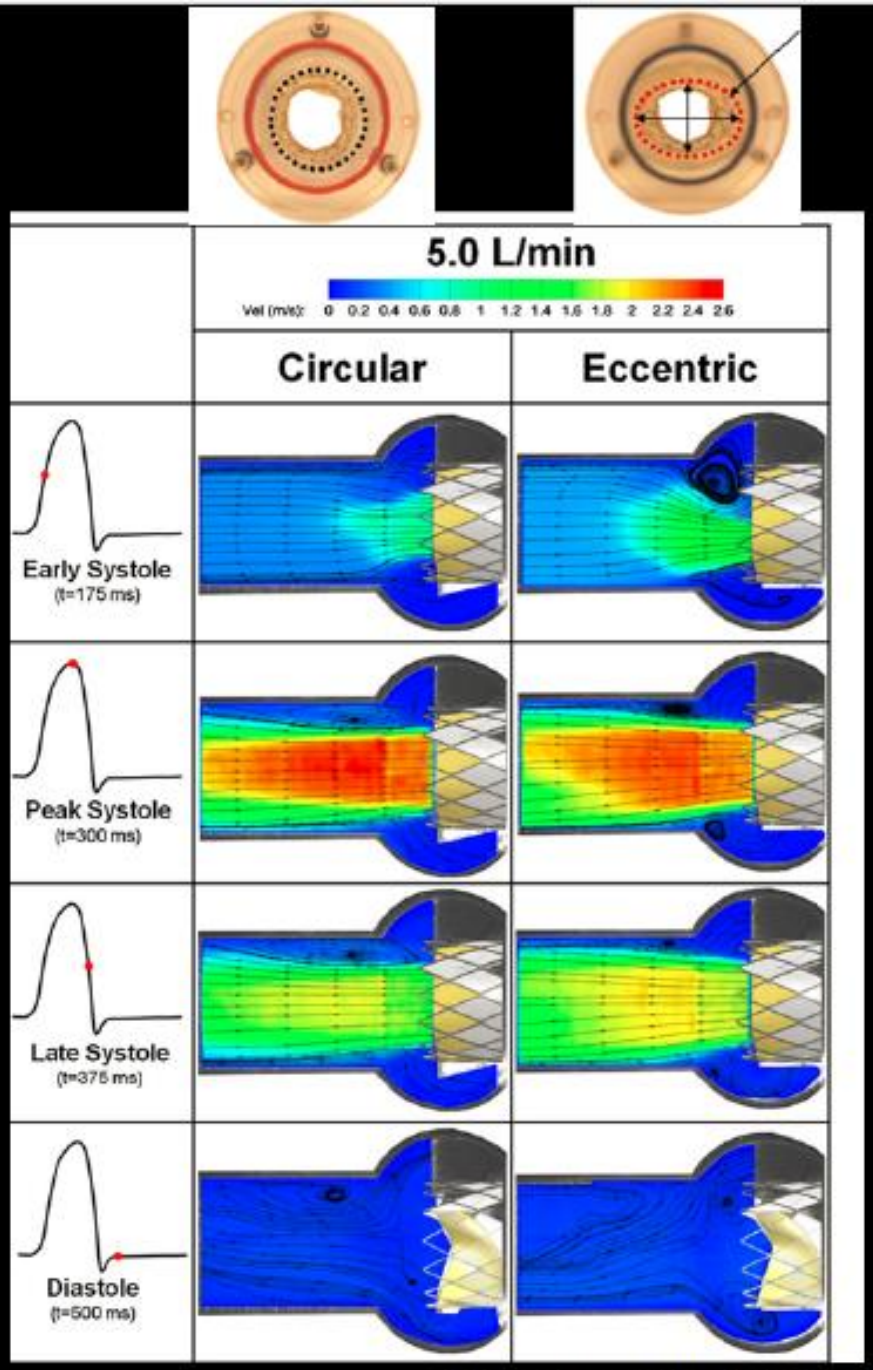
Self-expanding THV

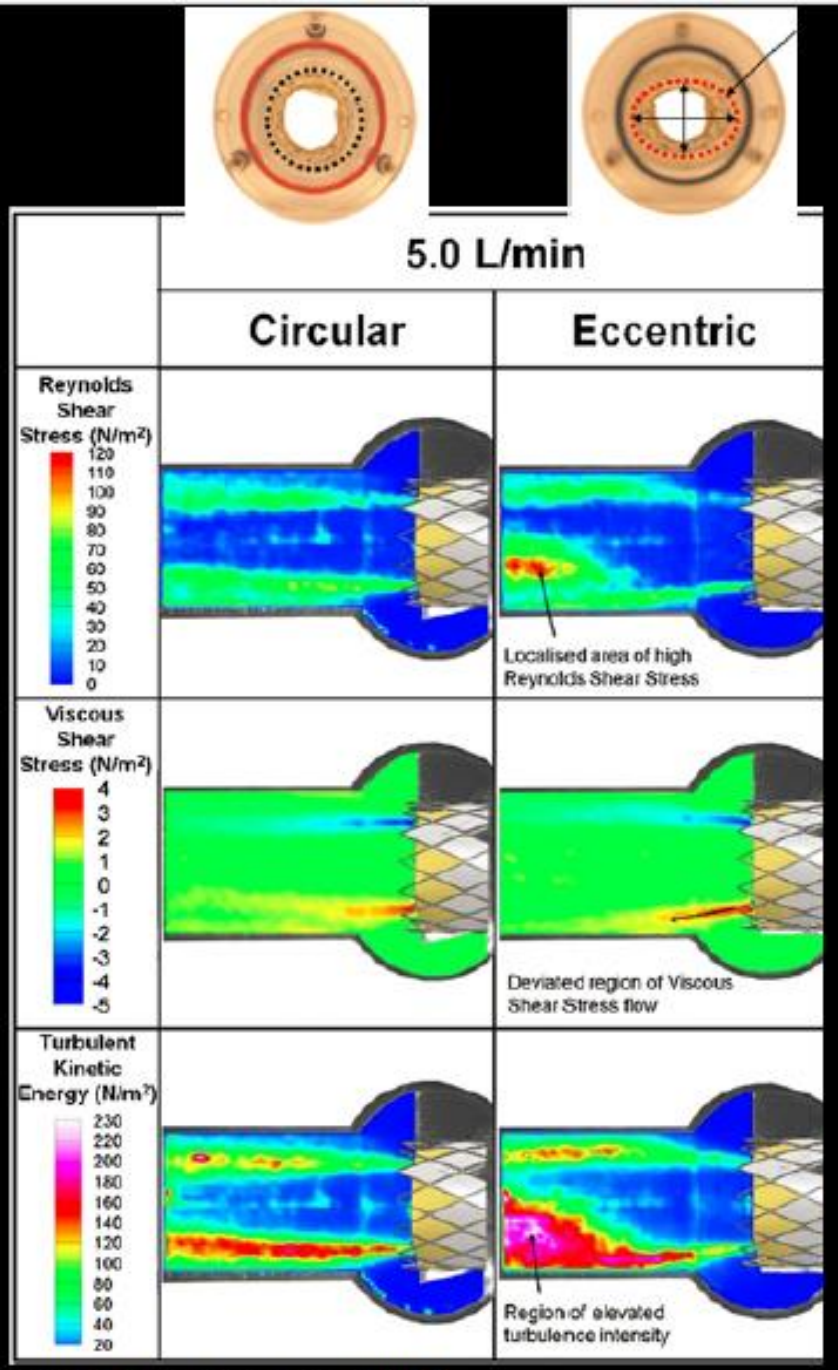


Non-circular / irregular deployment is more frequent with SE vs. BE THVs

Salaun et al. Int J Cardiol 2016
Delgado et al. JACCi 2009

Schultz et al. JACC 2009





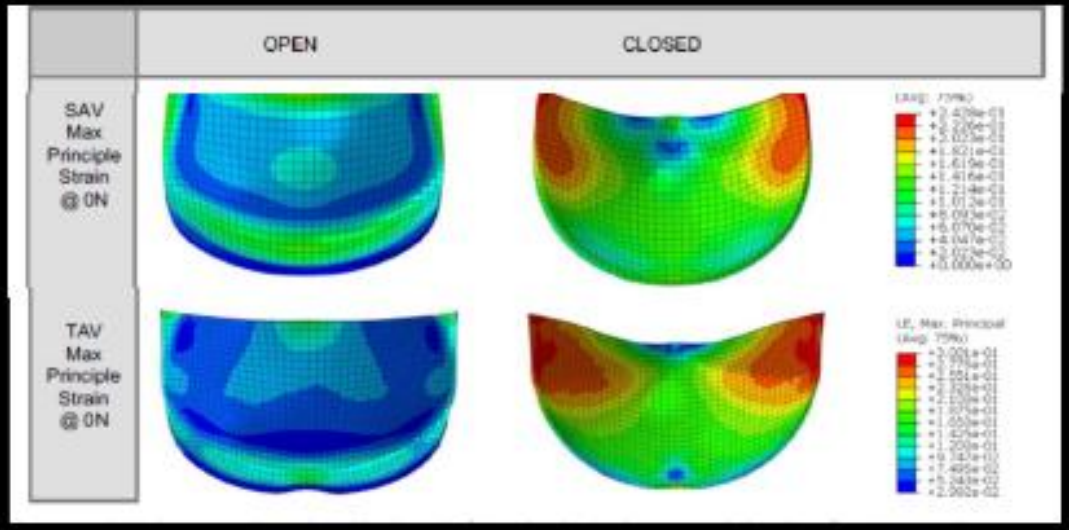
Gunning et al. Annals of Biomedical Engineering, 2014

Leaflet Mechanical Stress in TAVR vs. SAVR

In silico and in vitro studies suggest higher mechanical stress on leaflets of transcatheter vs. surgical valves

SAVR

TAVR



Expected Durability

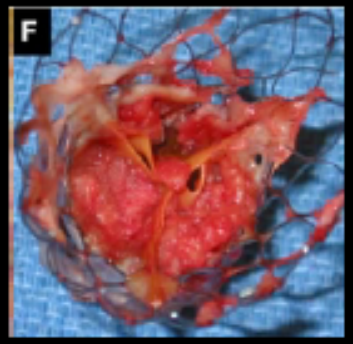
16 years

7.8 years

Martin J Bioo2015

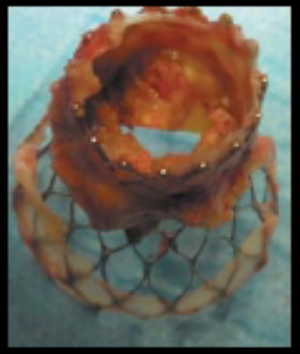
Valve Leaflet Thrombosis and Risk of Future SVD

Thrombosis



?

SVD



- **In the SAVORY registry, incidence of subclinical thrombosis was 13% in TAVI versus 4% in SAVR (p=0.001)**

Chakravarty et al. JAMA 2017

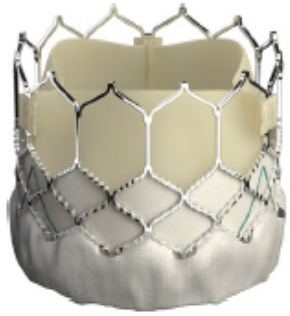
Conclusions

- **Although the results of midterm durability of the THVs are encouraging, their long-term durability remains largely unknown**

- **Several specifics inherent to the TAVI procedure (oversizing, manipulation, delivery, positioning, deployment) may cause injuries to the valve leaflets, increase leaflet mechanical stress and may thus limit the long-term durability of the THVs**

- **Valve thrombosis may predispose to SVD**

Should We Expect Long-Term Durability of TAVI and SAVR Prostheses to Be Different?



- TAVI leaflets are thinner (~0.25 mm vs ~0.4 mm in SAVR) to allow transcatheter-device delivery.
- TAVI leaflets experience higher stresses and strains, particularly in the presence of calcification and non-circular annuli resulting in asymmetric stent-frame deployment.
- The durability of TAVI might be even shorter if the prosthesis is under-expanded (due to TAVI oversizing).
- TAVI requires crimping and has more paravalvular leakage.
- First generation TAVI valves did not have anticalcification treatment.
- Data from computational, tissue-fatigue models suggest that, even when a TAVI is properly deployed, durability is predicted to be about 7.8 years less than SAVR.

Bagur R, et al. Heart. 2017;103:1756-1759
Martin C, et al. J Biomech 2015;48:3026–34

TAVI a longo prazo

Centre for
Heart Valve Innovation
St. Paul's Hospital, Vancouver

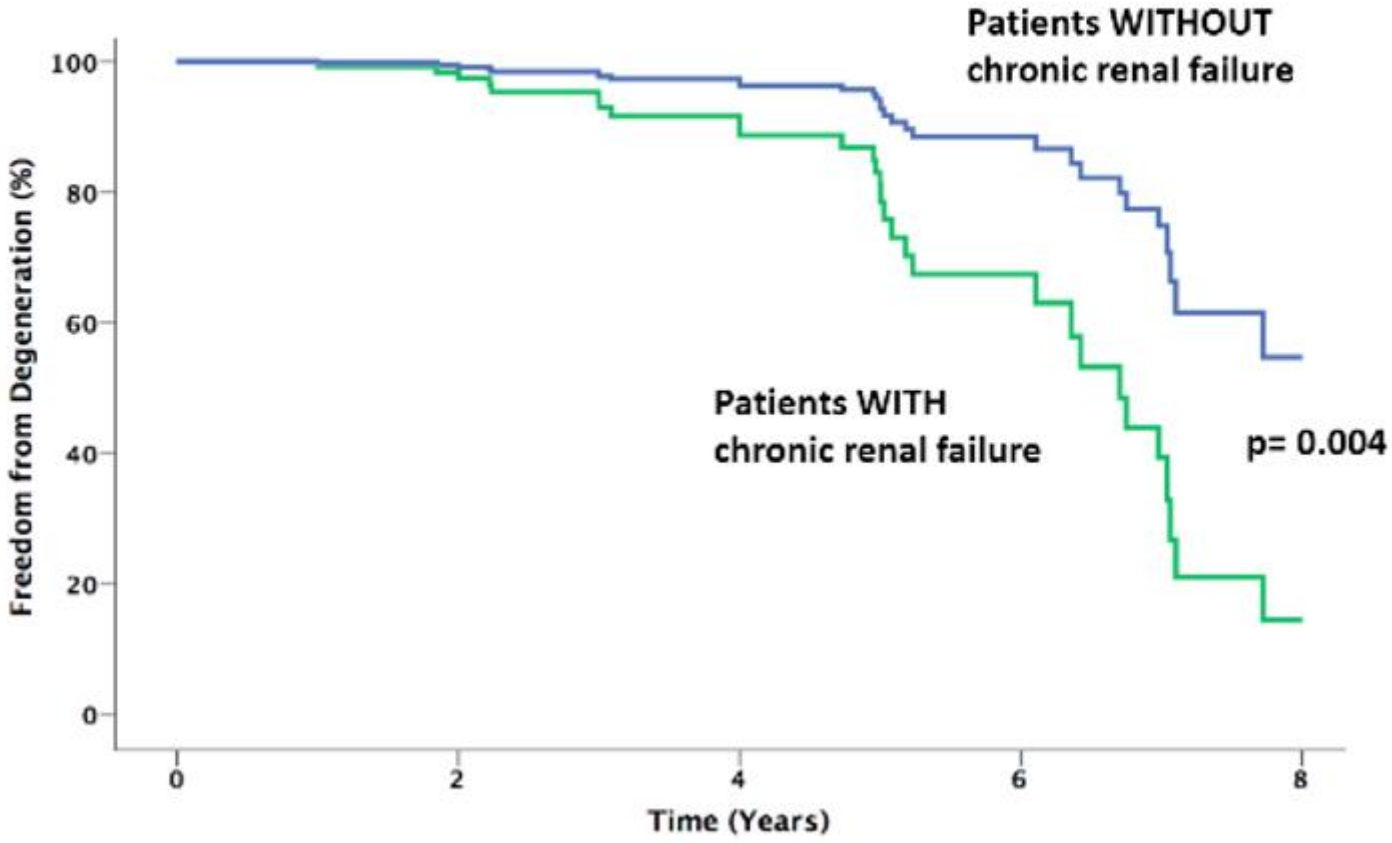
2016 euro PCR

First look at long-term durability of transcatheter heart valves:
Assessment of valve function up to 10-years after implantation

Danny Dvir, St. Paul's Hospital, Vancouver, Canada.

On behalf of coauthors: Helene Eltchaninoff, Jian Ye, Arohumam Kan, Eric Durand, Anna Bizios, Anson Cheung, Mina Aziz, Matheus Simonato, Christophe Tron, Yaron Arbel, Robert Moss, Jonathon Leipsic, Hadas Ofek, Gidon Perlman, Marco Barbanti, Michael A. Seidman, Philippe Blanke, Robert Yao, Robert Boone, Sandra Lauck, Sam Lichtenstein, David Wood, Alain Cribier, John Webb

Freedom from THV degeneration



Summary

- The current analysis includes a first look at long-term durability after TAVI, evaluating cases performed 5-14 years ago with early-generation balloon-expandable THV devices.
- In this preliminary report, a significant increase in degeneration rate was observed between 5-7 years after TAVI.
- Estimate of THV degeneration (resulting in at least moderate stenosis AND/OR regurgitation) was ~50% within 8 years.
- Renal failure was the strongest correlate of THV degeneration.

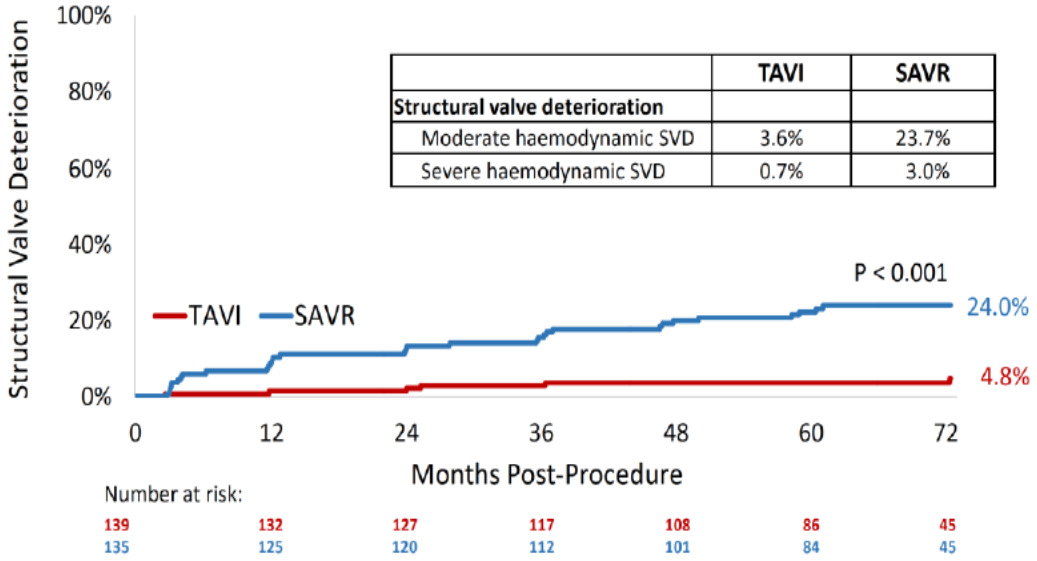
STRUCTURAL VALVE DETERIORATION IN TAVI VS. SAVR

expandingTHV

NOTION I TRIAL: 6-Year Follow-up

Presented by L. Sondergaard at EuroPCR 2018

	TAVI	SAVR
Structural valve deterioration		
Moderate haemodynamic SVD	3.6%	23.7%
Severe haemodynamic SVD	0.7%	3.0%



Thyregod *et al.*
Transcatheter Versus Surgical Aortic Valve Replacement

Creatinine level >2 mg/dl	2/145 (1.4)	1/135 (0.7)
History of hypertension	103/145 (71.0)	103/135 (76.3)
Peripheral vascular disease	6/145 (4.1)	9/135(6.7)
Prior cerebrovascular accident	24/145 (16.6)	22/135 (16.3)
Chronic lung disease	17/145 (11.7)	16/135 (11.9)
Cardiac risk factors		
Prior PCI	11/145 (7.6)	12/135 (8.9)
Pre-existing pacemaker	5/145 (3.4)	6/135 (4.4)
Prior MI	8/145 (5.5)	6/135 (4.4)
Prior AF/atrial flutter	40/144 (27.8)	34/133 (25.6)

Values are mean ± SD or n/N (%). *No statistical significant differences between groups were found for any variable.

AF = atrial fibrillation; EuroSCORE = European System for Cardiac Operative Risk Evaluation; MI = myocardial infarction; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; SAVR = surgical aortic valve replacement; STS-PROM = Society of Thoracic Surgeons Predicted Risk Of Mortality; TAVR = transcatheter aortic valve replacement.

ABLE 2 Procedural Characteristics

TAVR	
Procedural success*	139/142 (97.9)
Total procedure time, min	90.3 ± 38.6
Local anesthesia	26/142 (18.3)
Use of inotropes	86/142 (60.6)
Implantation of >1 valve prosthesis	4/142 (2.8)
Conversion to surgery	3/142 (2.1)
Transfemoral access	137/142 (96.5)
Transsubclavian access	5/142 (3.5)
Valve size implanted	
23 mm	2/142 (1.4)
26 mm	57/142 (40.1)
29 mm	69/142 (48.6)
31 mm	14/142 (9.9)
SAVR	
Total procedure time, min	177.2 ± 39.8
Conversion to other procedure†	2/134 (1.5)
Use of inotropes	48/133 (36.1)
Valve size implanted	
19 mm	11/132 (8.3)
21 mm	42/132 (31.8)
23 mm	45/132 (34.1)
25 mm	32/132 (24.2)
27 mm	2/132 (1.5)

Values are n/N (%) or mean ± SD. *Defined as leaving the catheterization room with a functional transcatheter self-expanding prosthesis. †1 apico-aortic conduit and 1 apical TAVR with a balloon-expandable bioprosthesis.

Abbreviations as in Table 1.

Desfecho:
<>P =>20mmHg

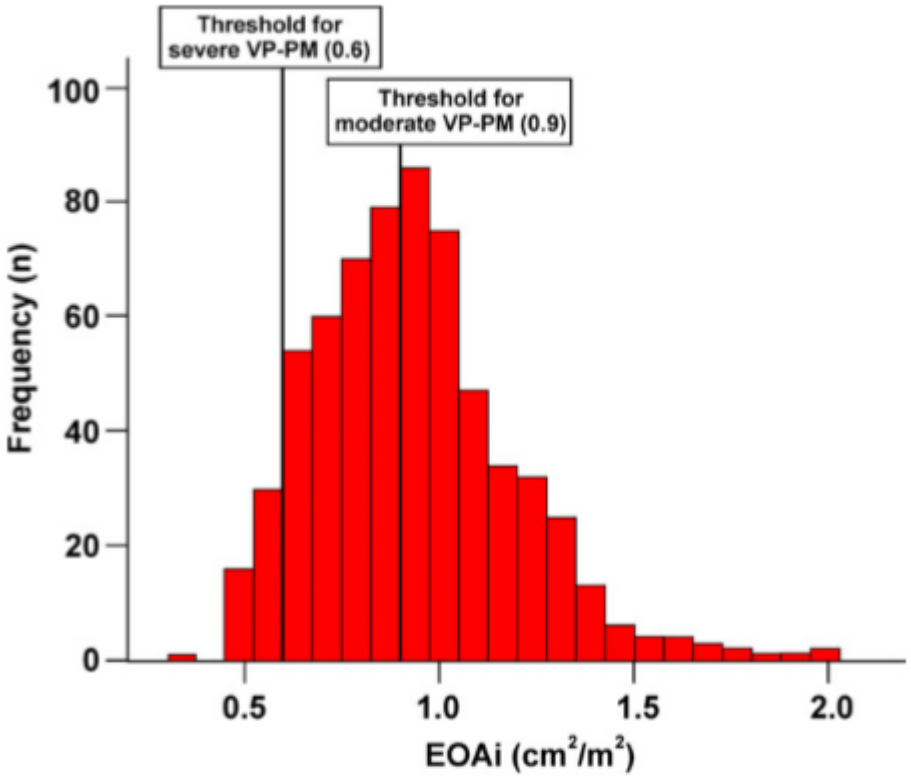


Figure 8 **EOAI of 1 Prosthesis Type**

Histogram distribution of EOAi at 6 months after aortic valve replacement in 113 patients of the same type and size (Edwards Perimount size 23). The mean value of 1.82 cm^2/m^2 may be the only parameter inserted into a reference table. Most patients would have moderate VP-PM, many would have mild VP-PM, and few would have severe VP-PM. Abbreviations as in Figure 7. Adapted and modified, with permission, from Bleiziffer et al. (45).

Table 2 Studies on surgical and transcatheter bioprostheses valve durability

Study (reference)	Model of bioprosthesis	Nb Pts.	Bioprostheses valve durability 2-Year FU HVD stage (%) Reintervention (%)	5-Year FU HVD stage (%) Reintervention (%)	10-Year FU HVD stage (%) Reintervention (%)	>10 years FU HVD stage (%) Reintervention (%)
Surgical bioprostheses						
Jamieson *et al*[57]	Carpentier-Edwards SAV	1823	– –	– –	– –	Stage ≥2: 25.1% at 15 years, 36.0% at 18 years Reintervention: 6%
Briand *et al*[17]	Various	217	– –	Stage ≥2: 30% –	– –	– –
David *et al*[58]	St Jude Medical Toronto SPV	357	– –	– –	– Stage 3 and/or reintervention: 14%	– Stage 3 and/or reintervention: 31% at 12 years
David *et al*[59]	Hancock II	1134	– –	– Stage 3 and/or reintervention: 0.3%	– Stage 3 and/or reintervention: 2.4%	– Stage 3 and/or reintervention: 36.6% at 20 years
Senage *et al*[23]	Sorin Mitroflow (12A and LX models)	617	Stage 3: 0.8% –	Stage 3: 8.4% –	– –	– –
Forcillo *et al*[60]	Carpentier-Edwards	2405	– –	– Reintervention: 2.0%	– Reintervention: 4.0%	– Reintervention: 33.0% at 20 years
Mahjoub *et al*[14]	Various	203	– –	– –	Stage 1: 24%; stage ≥2: 20% –	– –
Bach *et al*[61]	Medtronic Freestyle	725	– –	– Reintervention: 0.3%	– Reintervention: 3.5%	– Reintervention: 16.7%
Guenzinger *et al*[62]	St Jude Medical Biocor	455	– –	Stage 3: 2.1% –	Stage 3: 7.9% –	Stage 3: 15.2% at 15 years, 33% at 20 years –
Johnston *et al*[8]	Carpentier-Edwards Perimount	12 569	– –	– –	– –	Stage ≥2: 2.1% Reintervention: 1.2%
Bourguignon *et al*[13]	Carpentier-Edwards Perimount	2659	– –	– –	Stage ≥2: 5.8% Reintervention: 4.6%	Stage ≥2: 21.4% at 15 years, 51.5% at 20 years Reintervention: 16% at 15 years, 34.3% at 20 years
Repossini *et al*[63]	Freedom Solo	565	– –	Stage 3: 2.8% Reintervention: 1.4%	Stage 3: 9.2% Reintervention: 8.1%	– –
Transcatheter bioprostheses						

Table 2 Studies on surgical and transcatheter bioprostheses valve durability

Study (reference)	Model of bioprosthesis	Nb Pts.	Bioprostheses valve durability 2-Year FU HVD stage (%) Reintervention (%)	5-Year FU HVD stage (%) Reintervention (%)	10-Year FU HVD stage (%) Reintervention (%)	>10 years FU HVD stage (%) Reintervention (%)
Transcatheter bioprostheses						
Toggweiler *et al*[36]	Cribier-Edwards (n=49) SAPIEN (n=39)	88	– –	Stage ≥2: 3.4% Reintervention: 0%	– –	– –
Barbanti *et al*[37]	Third-generation CoreValve Device	179	– –	Stage 1: 2.8%; stage 3: 1.4% Reintervention: 0.6%	– –	– –
Kapadia *et al*[38]	SAPIEN	358	– –	– Reintervention: 0%	– –	– –
Mack *et al*[39]	SAPIEN	348	– –	Stage ≥2: 5.8% Reintervention: 0%	– –	– –
Bouleti *et al*[64]	SAPIEN (n=112) CoreValve (n=12)	123	– –	Stage ≥2: 3.3% –	– –	– –
Del Trigo *et al*[31]	SAPIEN, SAPIEN XT (n=738) CoreValve (n=756), Others (n=27)	1521	Stage ≥2: 2.8% –	Stage 2: 1.4%; stage 3: 3.1% –	– –	– –
Thourani *et al*[65]	SAPIEN 3	1077	– –	– –	– –	– –
Tarantini *et al*[66]	SAPIEN, SAPIEN XT, SAPIEN 3 (n=84) CoreValve (n=87)	171	– –	Stage 3: 0.6% Reintervention: 0.6%	Stage 3 (5–8 years): 1.8%	– –
Daubert *et al*[40]	SAPIEN	86	Stage ≥2: 2.3% –	Stage ≥2: 4.7% Reintervention: 1.2%	– –	– –
Douglas *et al*[41]	SAPIEN	2482	– –	Stage 2: 0.45%; stage 3: 0.44% Reintervention: 0.2%	– –	– –
Reardon *et al*[44]	CoreValve	864	Stage ≥2: 0% Reintervention: 0%	– –	– –	– –

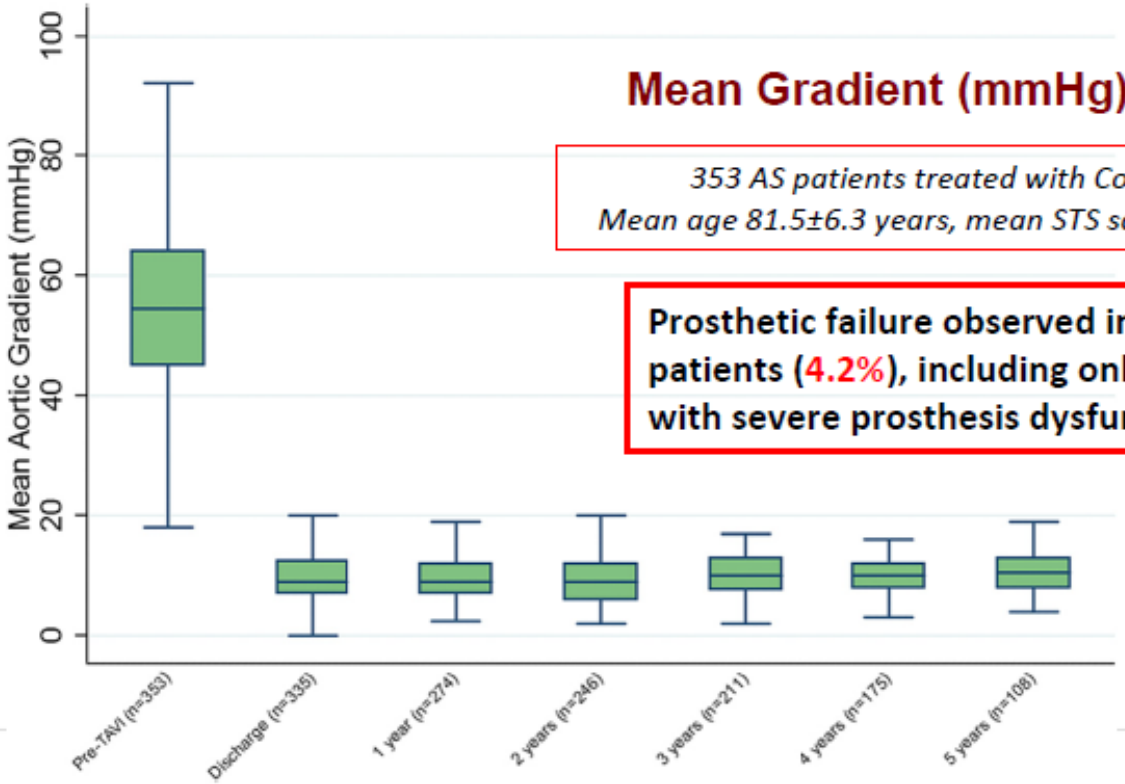
For definitions of stage 1, 2, 3 SVD: see table 1.
FU, follow-up; HVD, hemodynamic valve deterioration; Nb Pts., or n, number of patients.

THV Hemodynamic Performance - Registries

Self-expanding THV

8 Italian Centers (353 pts): 5-Year Follow-up

Barbanti et al, J Am Coll Cardiol Intv 2015;8:1084–91



353 AS patients treated with CoreValve;
Mean age 81.5±6.3 years, mean STS score 9.5±10.0%

Prosthetic failure observed in only 15 patients (4.2%), including only 5 cases with severe prosthesis dysfunction.

VALVE HEMODYNAMIC DETERIORATION AFTER TAVI

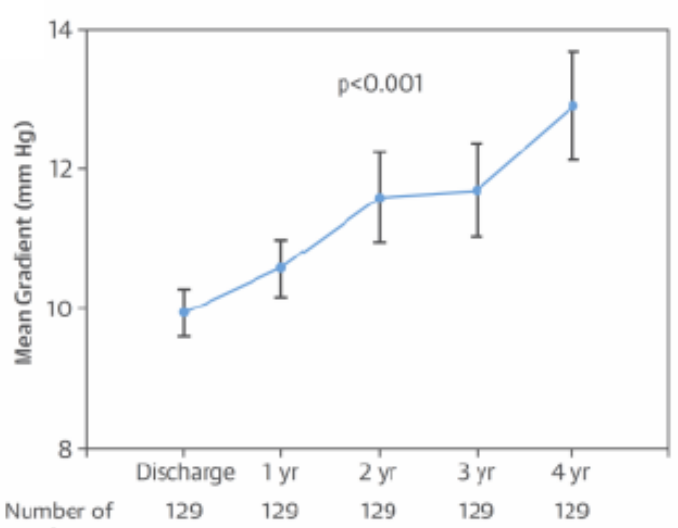
Del Trigo et al. *J Am Coll Cardiol* 2016;67:644-55

Multicenter registry (10 centers, N=1,521, enrollment period 2007-2014)

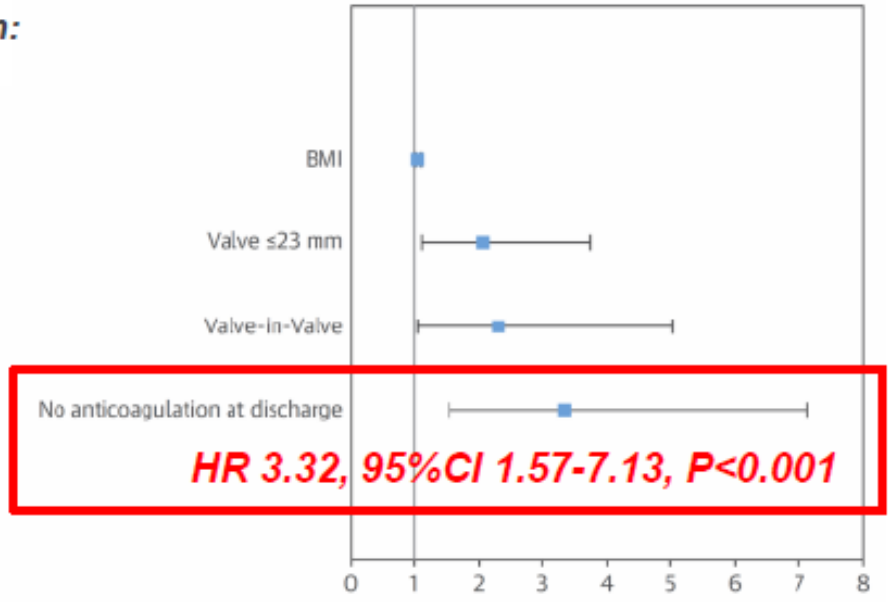
VHD observed in 4.5% patients (N=68) during FU (20±13 months)

Mean Gradient during FU

Transprosthetic gradient progression: 0.30±4.99 mmHg/year



Predictors of VHD



Valve hemodynamic deterioration (VHD) defined as an absolute change in mean gradient ≥10 mmHg

STRUCTURAL VALVE DETERIORATION: MULTICENTER EXPERIENCE

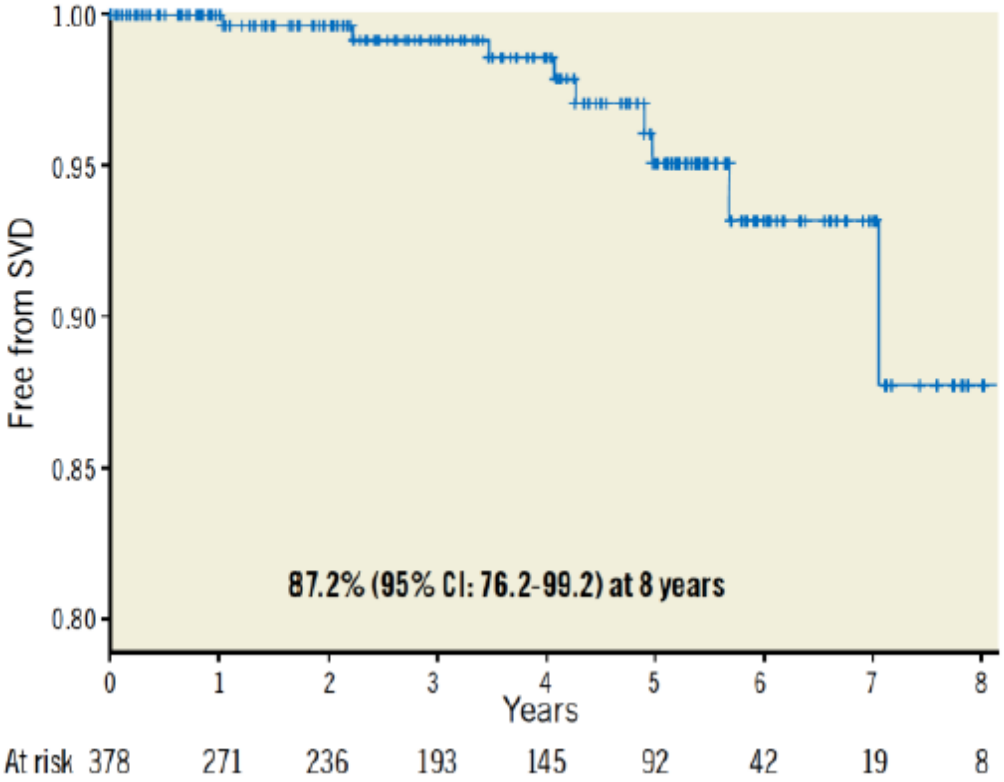
Eltchaninoff et al, EuroIntervention 2018;14:e264-e271

N= 1,521

Moderate SVD: ***mean transprosthetic gradient ≥20 mmHg and <40 mmHg and/or ≥10 and <20 mmHg change from baseline and/or moderate new or worsening intraprosthetic aortic regurgitation.***

Severe SVD: ***mean gradient ≥40 mmHg and/or ≥20 mmHg change from baseline and/ or severe new or worsening intraprosthetic aortic regurgitation***

Freedom from Moderate or Severe Structural Valve Deterioration



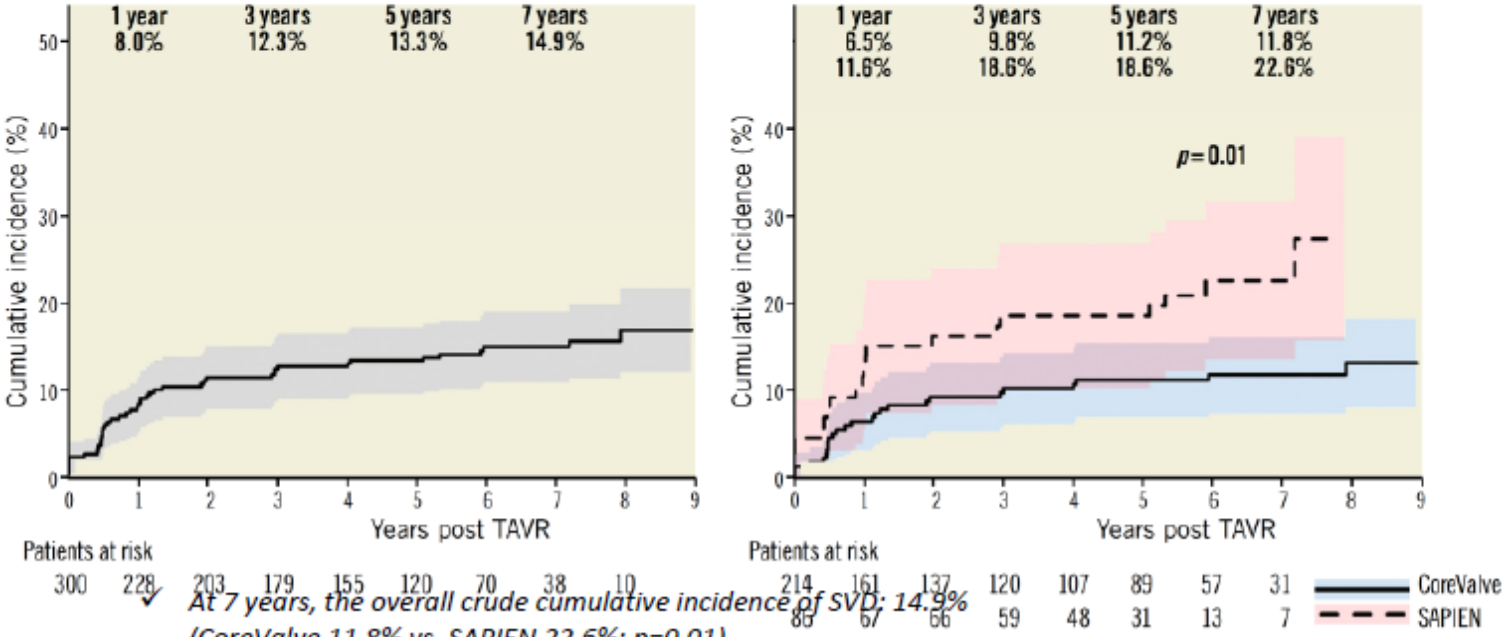
VALVE HEMODYNAMIC DETERIORATION: THE MUNICH EXPERIENCE

Deutsch et al, EuroIntervention 14:41-49;2018

N= 300

Mean transprosthetic gradient ≥20 mmHg and <40 mmHg and/or ≥10 and <20 mmHg change from baseline and/or moderate new or worsening intraprosthetic aortic regurgitation

Cumulative Incidence of Moderate Structural Valve Deterioration

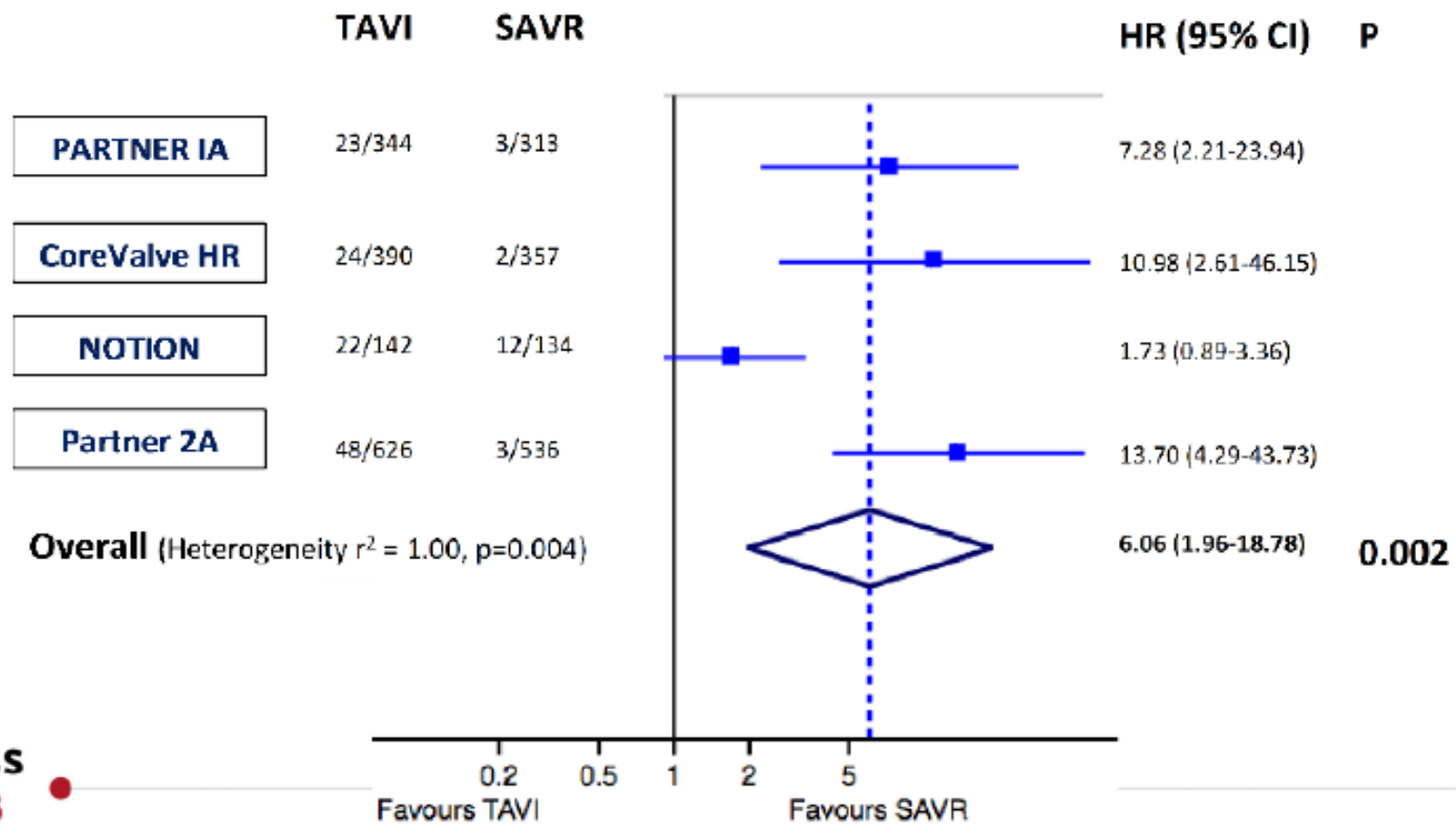


- ✓ *At 7 years, the overall crude cumulative incidence of SVD: 14.9% (CoreValve 11.8% vs. SAPIEN 22.6%; p=0.01).*
- ✓ *Late BVF (severe haemodynamic SVD or repeat intervention): 11 patients (n=8 SAPIEN/n=3 CoreValve)*

PARAVALVULAR REGURGITATION IN TAVI VS. SAVR

Meta-analysis of RCTs Comparing TAVI vs. SAVR

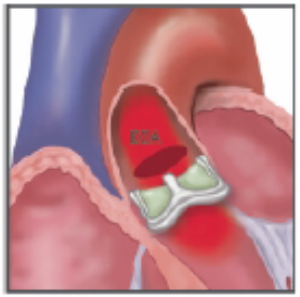
Siontis et al *Eur Heart J.* 2016 Dec 14;37(47):3503-3512

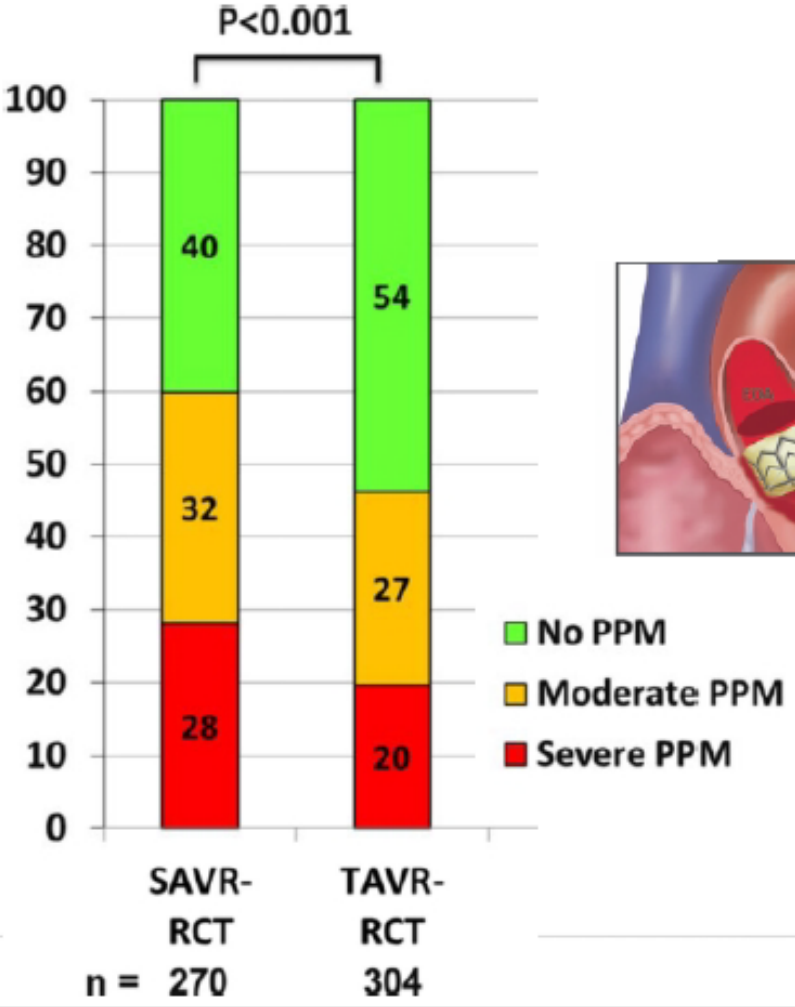


PROSTHESIS-PATIENT MISMATCH IN TAVI VS. SAVR

Pibarot et al, J Am Coll Cardiol. 2014 Sep 30;64(13):1323-34

PARTNER 1A





SURGICAL RISK	LIFE EXPECTANCY < 2 Years	2-5 years	5-10 years	10-15 years	15-20 years
Prohibitive	Conservative Management	TAVI	TAVI *Uncertain Durability†*	TAVI *Unknown Durability†*	TAVI *Unknown Durability†*
High	Conservative Management	TAVI	TAVI *Uncertain Durability†*	TAVI or SAVR *TAVI: Unknown Durability†* *SAVR: ↑ Risk of Re-intervention**	TAVI or SAVR *TAVI: Unknown Durability†* *SAVR: ↑↑ Risk of Re-intervention**
Intermediate	Conservative Management	TAVI	TAVI or SAVR *TAVI: Uncertain Durability†*	SAVR *↑ Risk of Re-intervention**	SAVR *↑↑ Risk of Re-intervention**
Low	Conservative Management	SAVR	SAVR	SAVR *↑ Risk of Re-intervention**	SAVR *↑↑ Risk of Re-intervention**

Figure 6 Selection of TAVI versus SAVR according to valve durability, life expectancy and surgical risk. Orange cells: conservative management should be considered; green cells: TAVI may be considered; light beige : TAVI or SAVR may be considered; blue: SAVR should be considered. *The valve durability to life expectancy ratio may be <1.0, and the patient is at risk for reintervention, which may be a surgical redo valve replacement or a transcatheter valve-in-valve procedure. †Uncertain durability: there is very limited data to support valve durability between 5 and 10 years post-TAVI; unknown durability: there is, until now, no data to establish the durability of TAVI valves beyond 10 years. In such situations, the valve durability to life expectancy ratio is unknown. ↑, increased risk; ↑↑, markedly increased risk. SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation.

Atualização em Valvopatias Mitral e Aórtica

RESULTADOS TARDIOS DE BIOPRÓTESES CONVENCIONAIS E PERCUTÂNEAS

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