

DEBATE:

*DURABILIDAD DE LA VALVULA
BALÓN-EXPANDIBLE*

Pilar Jiménez Quevedo. Hospital Clínico San Carlos. Madrid

Proctoring: Abbott, Edwards and Products&features



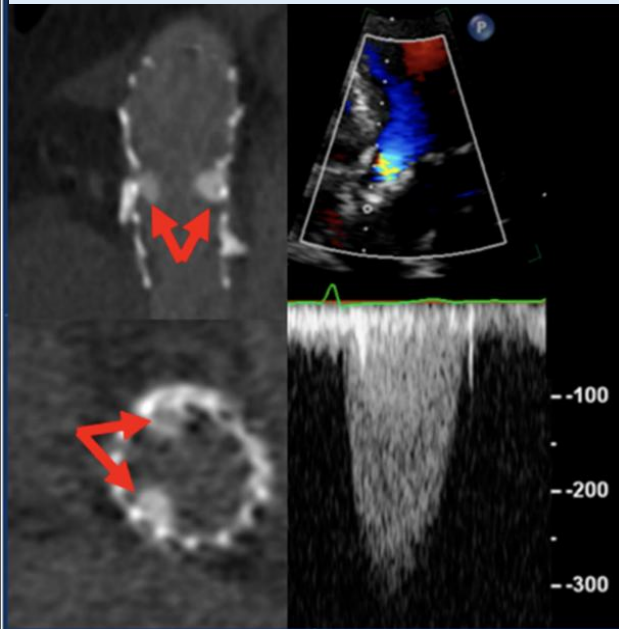
Summary

- 1.-Definitions
- 2.-The Overall magnitude of the problem
- 3.-BEV durability
- 4.- New technologies to improve durability



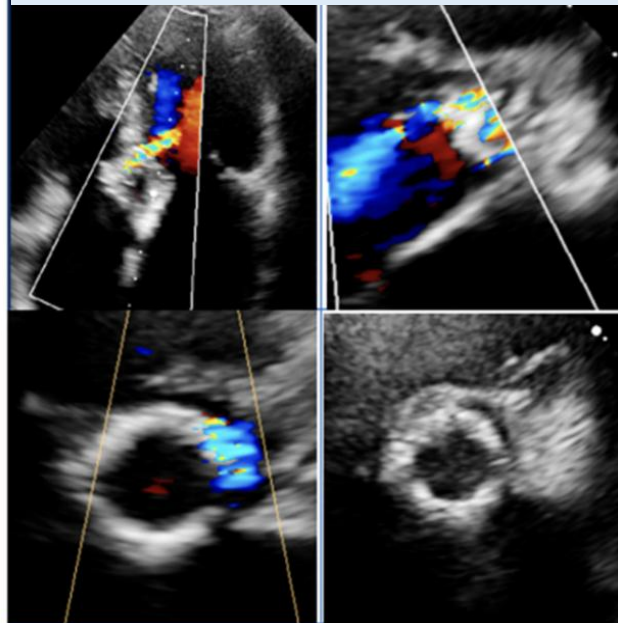
Bioprosthetic Valve Dysfunction after TAVI

STRUCTURAL VALVE DETERIORATION



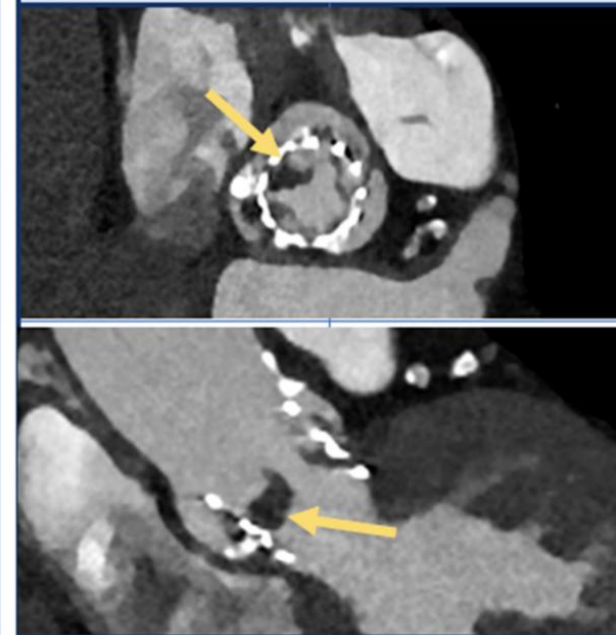
Calcification/Tears

NON-STRUCTURAL VALVE DETERIORATION

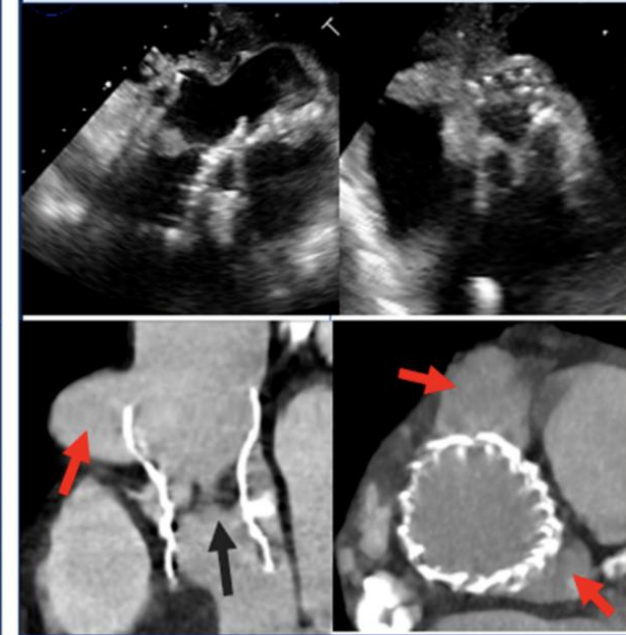


Patient Prosthesis Mismatch
Paravalvular Leak

THROMBOSIS



ENDOCARDITIS



REVERSIBLE



TYPE OF BIOPROTHETIC VALVE DYSFUNCTION

STRUCTURAL VALVE DETERIORATION

NON-STRUCTURAL VALVE DETERIORATION

THROMBOSIS

ENDOCARDITIS

HEMODYNAMIC CHANGES

STAGE 1: morfological
valve deterioration

STAGE 2: moderate
hemodinamical valve
deterioration

STAGE 3: severe
hemodinamical valve
deterioration

CLINICAL CONSEQUENCES

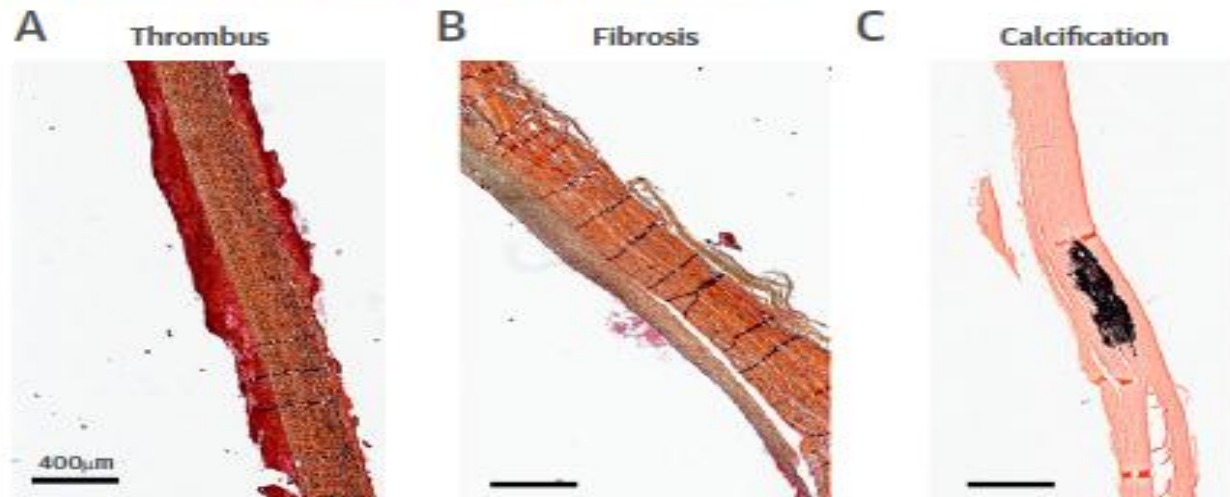
BIOPROTHESIS VALVE FAILURE



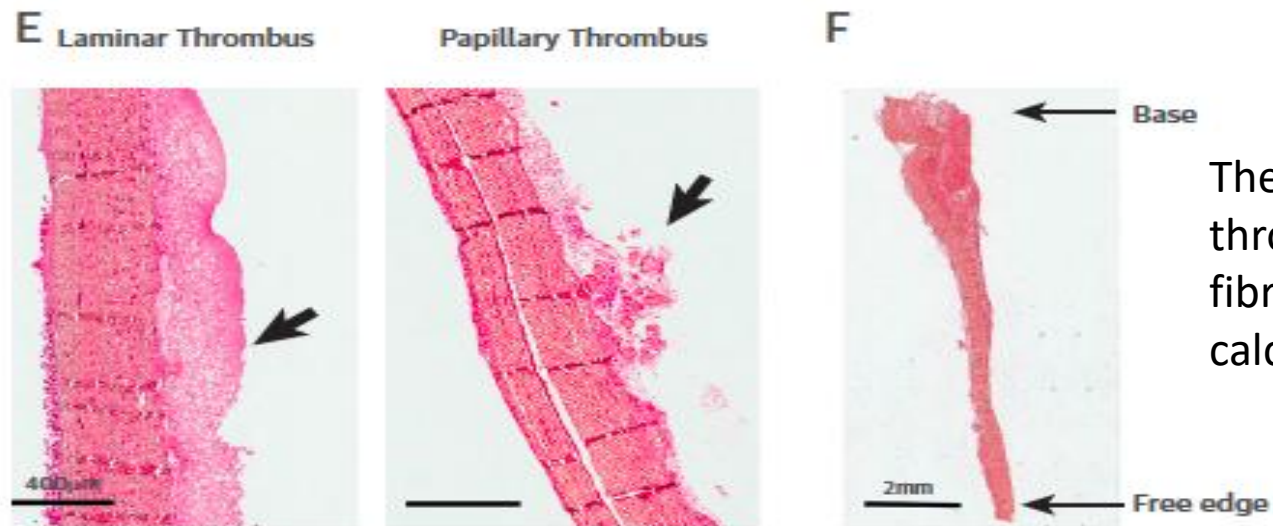
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Transcatheter Aortic Heart Valves

Histological Analysis Providing Insight to Leaflet Thickening and Structural Valve Degeneration



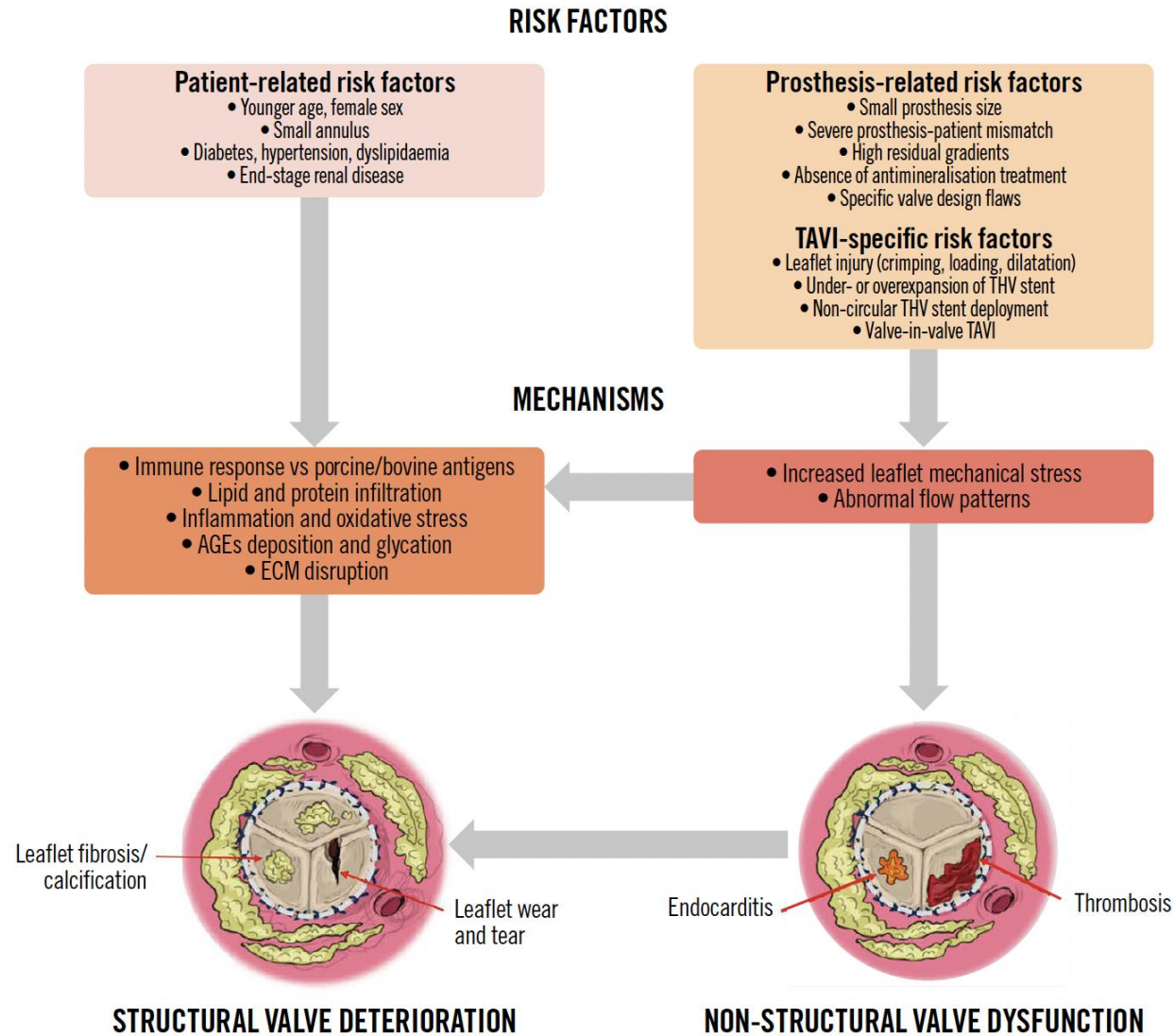
All Explanted transcatheter heart valves had adherent thrombus



There is a time-dependent degeneration of THVs consisting of thrombus formation, endothelial hyperplasia, fibrosis, tissue remodeling, proteinase expression, and calcification

The problem of the patient

Risk factors and mechanisms of structural valve deterioration and failure



The problem of the definition

EAPCI/EACTS structural BVD definition

There is either

(1) a high gradient at any echocardiography after aortic valve replacement (AVR)

OR

(2) an increase in gradient during follow-up

VARC-3 standardised structural BVD definition

There is either

(1) a high gradient at any echocardiography after aortic valve replacement (AVR)

AND

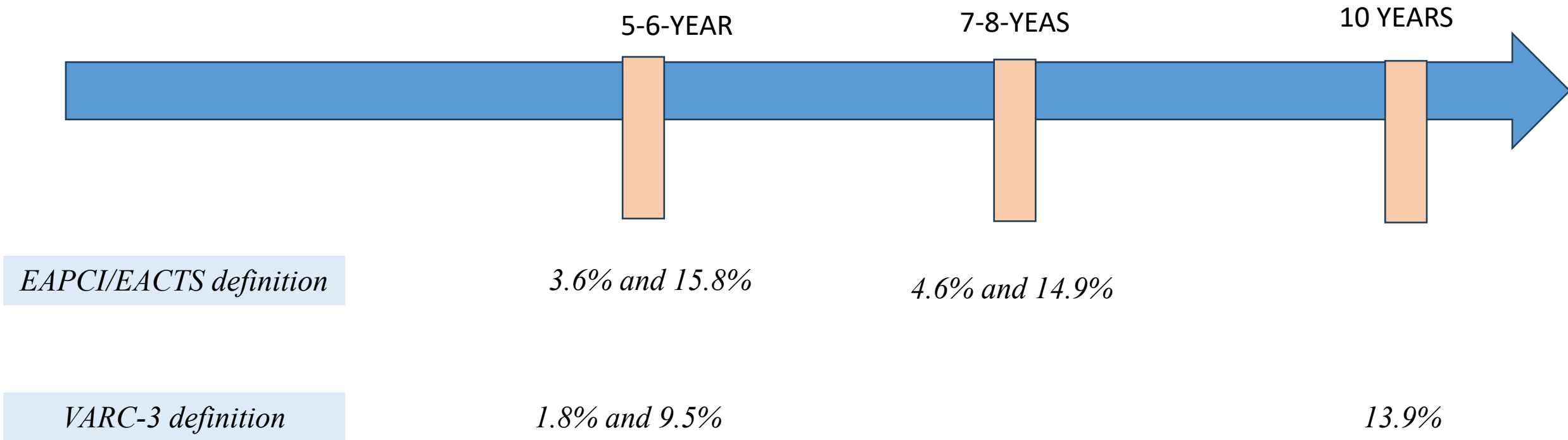
(2) an increase in gradient during follow-up

*The major disadvantage of the EAPCI/EACTS definition is that it **overestimates** the actual incidence of structural BVD as it include several cases of PPM, which is a non-structural BVD.*



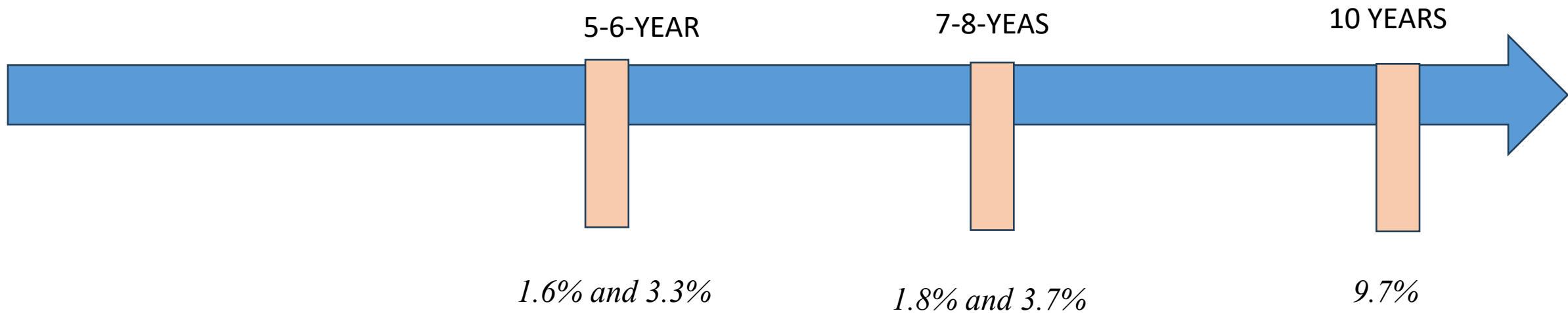
The problem of the definition

The incidence of Stage 2 or 3 SVD



Overall magnitude

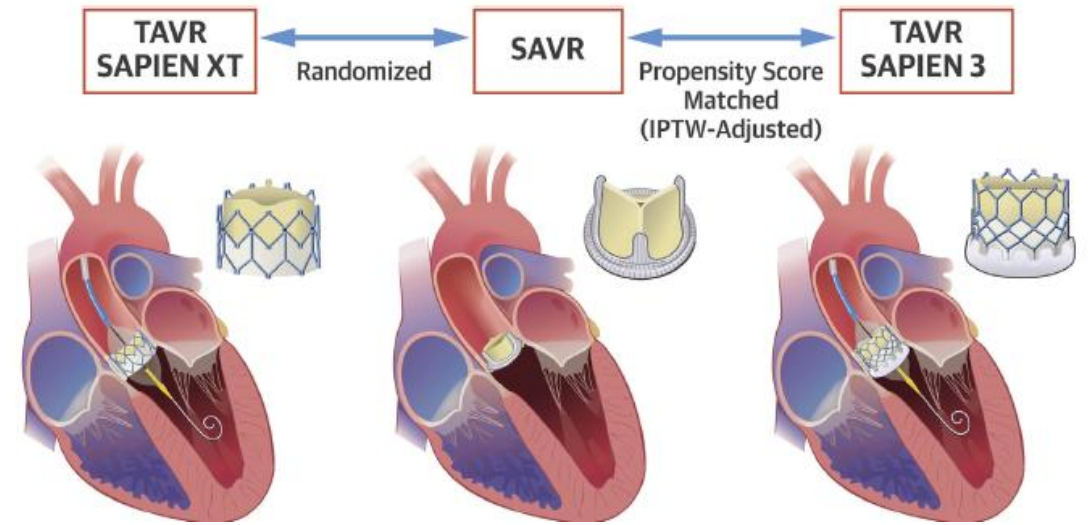
The incidence of BVF related to SVD



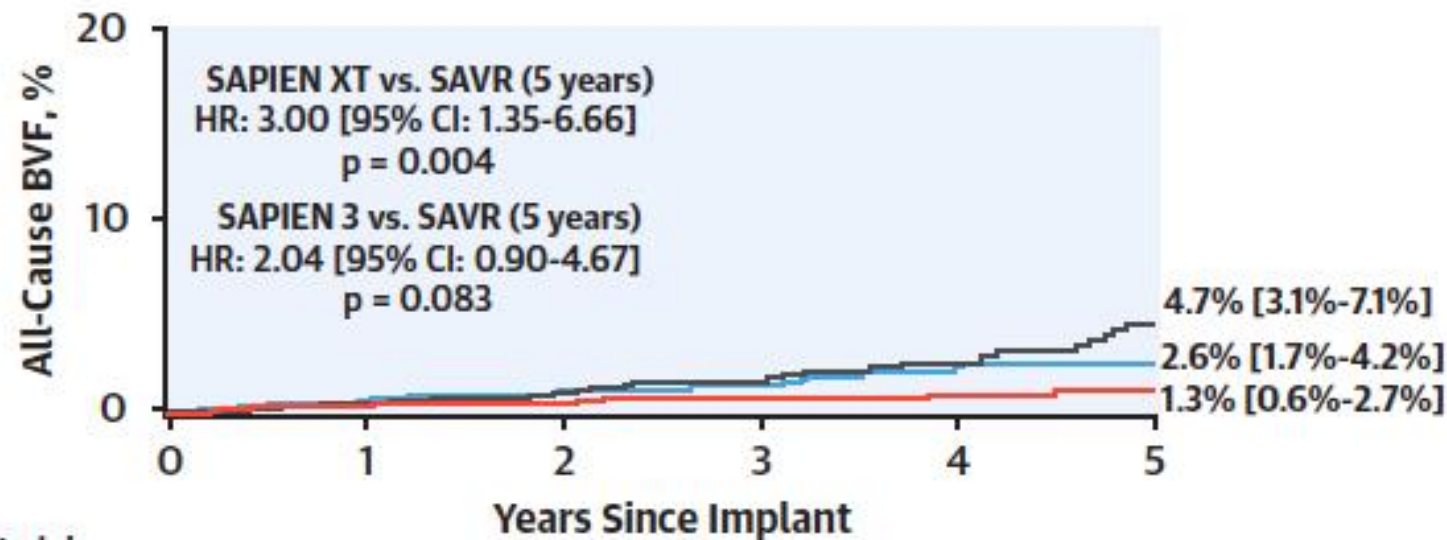
The problem of the device

VOL. 76, NO

Structural Deterioration of Transcatheter Versus Surgical Aortic Valve Bioprostheses in the PARTNER-2 Trial



C



No. at risk:		Years Since Implant					
		0	1	2	3	4	5
—	SAVR	936	762	643	536	423	321
—	SAPIEN XT	974	813	689	556	406	326
—	SAPIEN 3	1,069	909	764	628	451	312



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Current data from randomised trials TAVI vs. Surgery

5-yrs

8-yrs

10-yrs

PARTNER 2



Intermediate risk

Structural Deterioration of Transcatheter Versus Surgical Aortic Valve Bioprostheses in the PARTNER-2 Trial

JACC 2020

Expected 2025-6

SURTAVI



JAMA Cardiology | Original Investigation
Self-expanding Transcatheter vs Surgical Aortic Valve Replacement in Intermediate-Risk Patients
 5-Year Outcomes of the SURTAVI Randomized Clinical Trial

Nicolas M. Van Mieghem, MD, PhD; G. Michael Deeb, MD; Lars Søndergaard, MD, PhD; Eberhard Grube, MD, PhD; Stephan Windecker, MD; Hemal Gada, MD, MBA; Mubashir Mumtaz, MD; Peter S. Olsen, MD; John C. Heiser, MD; William Merhi, DO; Neal S. Kleiman, MD; Stanley J. Chetcuti, MD; Thomas G. Gleason, MD; Joon Sup Lee, MD; Wen Cheng, MD; Raj R. Makkar, MD; Juan Crestanello, MD; Barry George, MD; Isaac George, MD; Susheel Kodali, MD; Steven J. Yakubov, MD; Patrick W. Serruys, MD, PhD; Rüdiger Lange, MD; Nicolo Piazza, MD, PhD; Mathew R. Williams, MD; Jae K. Oh, MD; David H. Adams, MD; Shuzhen Li, PhD; Michael J. Reardon, MD; for the SURTAVI Trial Investigators

JAMA 2022

Expected 2026-7

PARTNER 3



Low risk

Transcatheter Aortic-Valve Replacement in Low-Risk Patients at Five Years

Mack MJ et al. DOI: 10.1053

N Engl J Med 2023

EVOLUT Low Risk



JACC Journals | JACC | Archives | Vol. 82 No. 22
4-Year Outcomes of Patients With Aortic Stenosis in the Evolut Low Risk Trial

Research Letter

John K. Forrest, G. Michael Deeb, Steven J. Yakubov, Hemal Gada, Mubashir A. Mumtaz, Basel Ramlawi, Tanvir Bajwa, Paul S. Teirstein, Didier Tchétché, Jian Huang, Michael J. Reardon, and on behalf of the Evolut Low Risk Trial Investigators

J Am Coll Cardiol 2023

NOTION 3

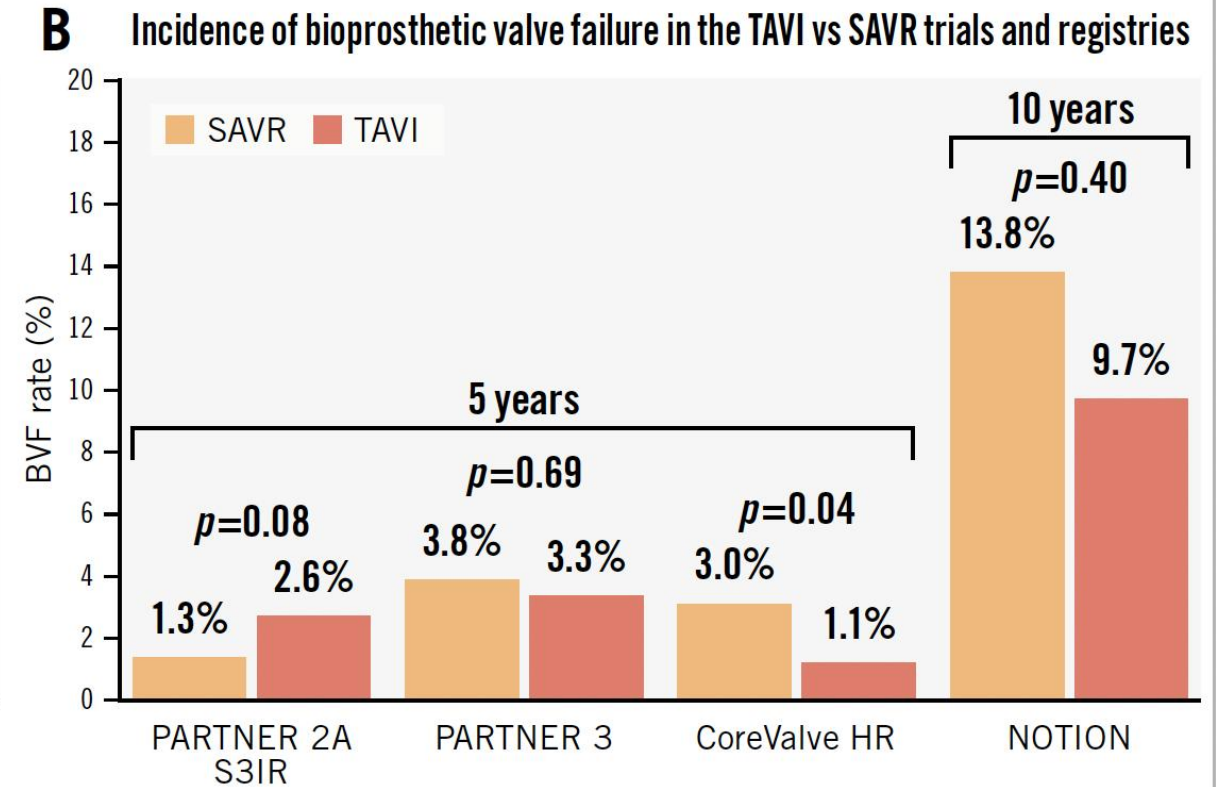
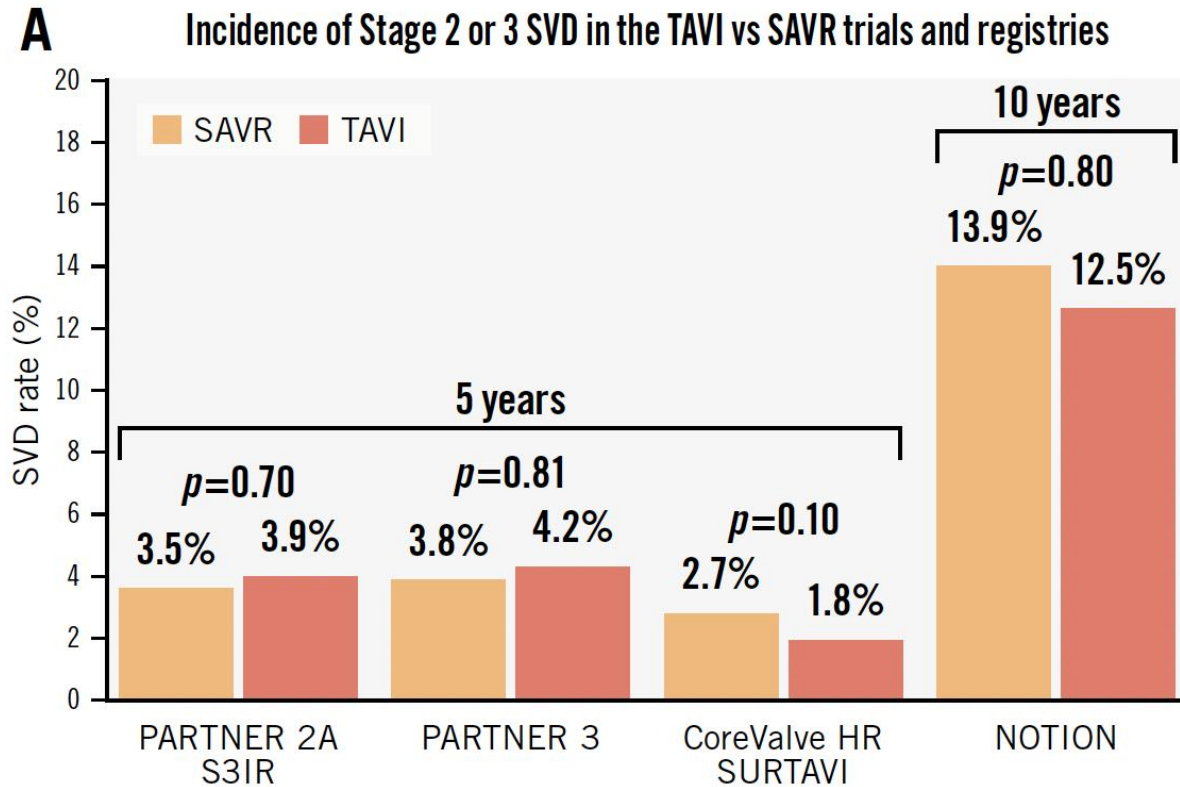


Transcatheter or surgical aortic valve implantation: 10-year outcomes of the NOTION trial

Hans Gustav Horsted Thyregod^{1*}, Troels Højsgaard Jørgensen^{2†}, Nikolaj Ihlemann³, Daniel Andreas Steinbrüchel^{1‡}, Henrik Nissen⁴, Bo Juel Kjeldsen⁵, Petur Petursson⁶, Ole De Backer², Peter Skov Olsen¹, and Lars Søndergaard²

EJH 2024

INCIDENCE OF SVD AND BVF IN TRIALS AND REGISTRIES



Clinical Studies Comparing THV Durability In BEV versus SEV



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Study	Study design (number of patients)	Surgical risk (mean age)	Definition of BVD/BVF	Type of AVR	Stage 2-3 SVD-related BVD (Stage 3 SVD)	SVD-related BVF (all-cause BVF)	Duration of follow-up
FRANCE 2 Registry Didier et al ⁵² 2018	Multicentre registry (n=4,210)	High risk (83 y)	EAPCI/ EACTS	TAVI TAVI-BEV TAVI-SEV	13.3% (2.5%) (2.2%) (1.8%) =	Not reported	5 years
CHOICE Abdel-Wahab et al ⁵¹ 2020	RCT (n=241)	High risk (82 y)	EAPCI/ EACTS	TAVI-SAPIEN XT TAVI-CoreValve	6.6% 0.0%	4.1% 3.4% =	5 years
UK TAVI Ali et al ⁵³ 2023	Multicentre registry (n=221)	High/int risk (79 y)	EAPCI/ EACTS	TAVI-BEV XT TAVI-SEV	22.4% 9.8% ≠	4.5% 1.4% =	7 years

Stage 3 SVD was more frequent in BEVs versus SEVs (11.9% vs 3.5%; p=0.02)



Small Registries Evaluating Durability In Balloon Expandable Valves

Study	Study design (number of patients)	Surgical risk (mean age)	Definition of BVD/BVF	Type of AVR	Stage 2-3 SVD-related BVD (Stage 3 SVD)	SVD-related BVF (all-cause BVF)	Duration of follow-up
Durand et al ⁹⁶ 2019	Multicentre registry (n=1,403)	High risk (83 y)	EAPCI	TAVI-BEV	10.9%	1.9% (1.9%)	7 years
Ferreira-Neto et al ¹⁰³ 2020	Single-centre registry (n=212)	High risk (80 y)	VARC-3	TAVI-BEV	30.2%	9.3%	8 years
Sathananthan et al ¹⁰⁵ 2021	Single-centre registry (n=235)	High risk (82 y)	EAPCI/ EACTS	TAVI-BEV	6.5%	2.6%	10 years
Orvin et al ⁹¹ 2019	Multicentre registry (n=450)	High risk (82 y)	EAPCI/ EACTS	TAVI-BEV	12.3%	3.3%	5.6 years
Deutsch et al ⁹² 2018	Single-centre registry (n=300)	High risk (81 y)	EAPCI/ EACTS	TAVI-BEV	14.9%	3.7%	7 years
Barbanti et al ¹⁰² 2018	Single-centre registry (n=288)	High risk (81 y)	EAPCI/ EACTS	TAVI-BEV	8.26%	4.51%	8 years

13,8%

4,2%



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Ongoing trials comparing new generations of BEVs versus SEVs

The SMART Trial (ClinicalTrials.gov: NCT04722250)

The BEST trial (ClinicalTrials.gov: NCT05454150)

Both trials are expected to extend follow-up until 10 years to compare THV durability in BEVs versus SEVs.



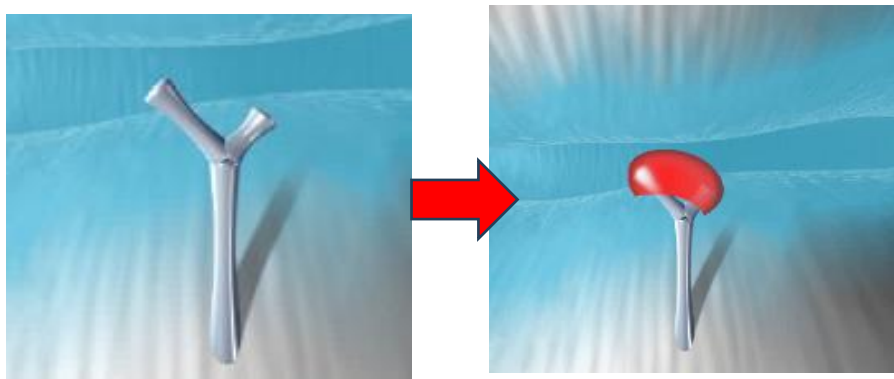
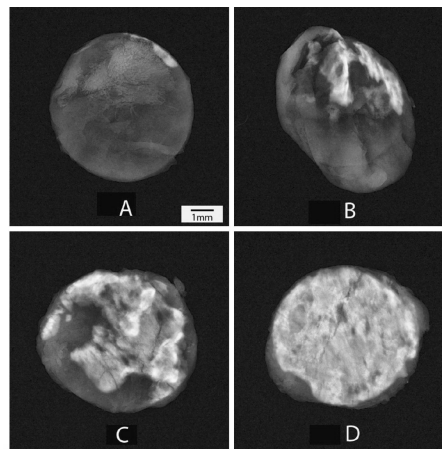
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The problem is presence of **residual phospholipids** and **residual free aldehyde** functional groups due to glutaraldehyde fixation in tissue preparations and storage

Aldehyde reduction in a novel pericardial tissue reduces calcification using rabbit intramuscular model

Hao Shang¹ · Steven M. Claessens¹ · Bin Tian¹ · Gregory A. Wright¹

The glutaraldehyde fixation prevents immune response against porcine or bovine tissues

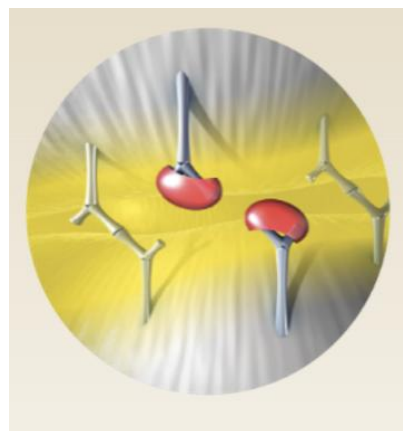


Stable capping

the glutaraldehyde- treated bovine pericardium tissue was treated with an amine

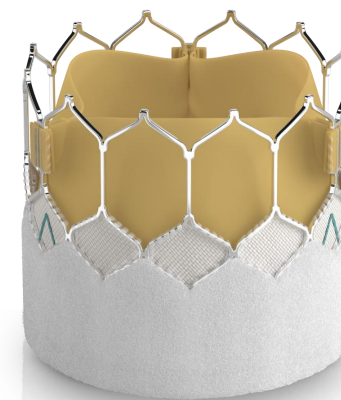


@Car



Dry tissue storage

Glycerolization replaces calcium-attracting glutaraldehydes



SAPIEN 3 Ultra
RESILIA valve

Conclusions

We have recent longer-term reinsuring data on the absence of alarm on TAVI durability vs surgical bioprostheses in randomized trials.

Further data are required to facilitate a comparison between BEV and SEV in terms of durability. This is currently being investigated through ongoing trials.

New tissue technology is being developed with the objective of increasing durability. However, this must be proven in clinical trials..

