



TAVI & durabilité des bioprothèses

Cédric Delhaye
CHU Lille

DÉCLARATION DE LIENS D'INTÉRÊT AVEC LA PRÉSENTATION

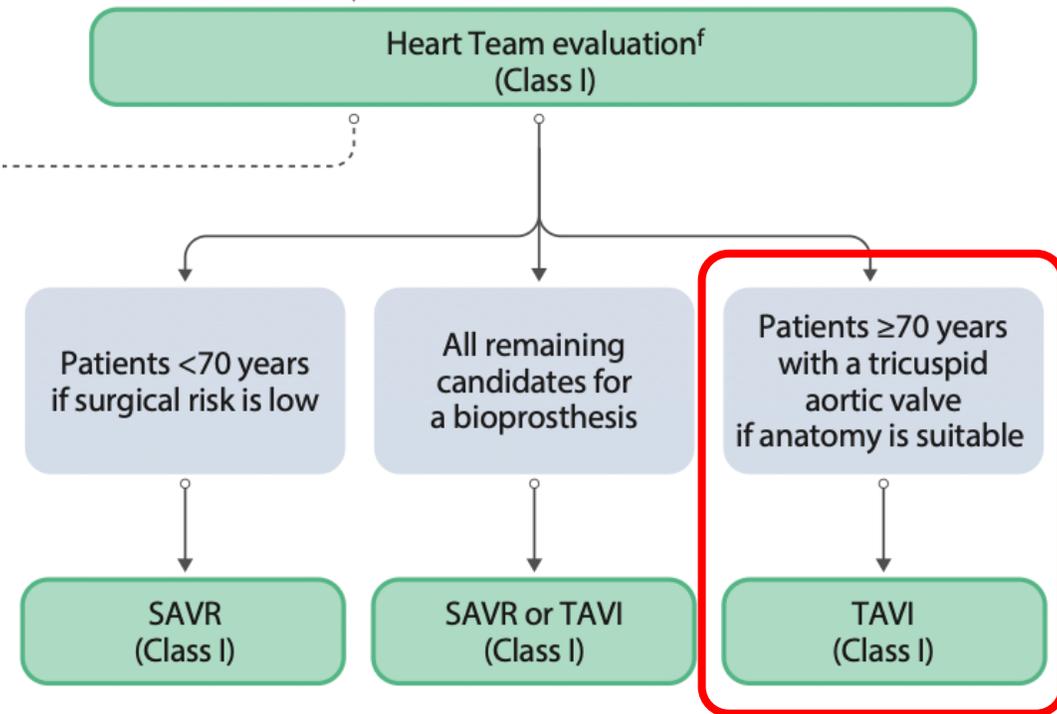
Speaker's name : Cédric DELHAYE, Lille

Je déclare les liens d'intérêt potentiel suivants :

Consultant : Abbott, Asahi, Medtronic

Les patients sont de plus en plus jeunes...

2025 ESC/EACTS Guidelines for the management of valvular heart disease

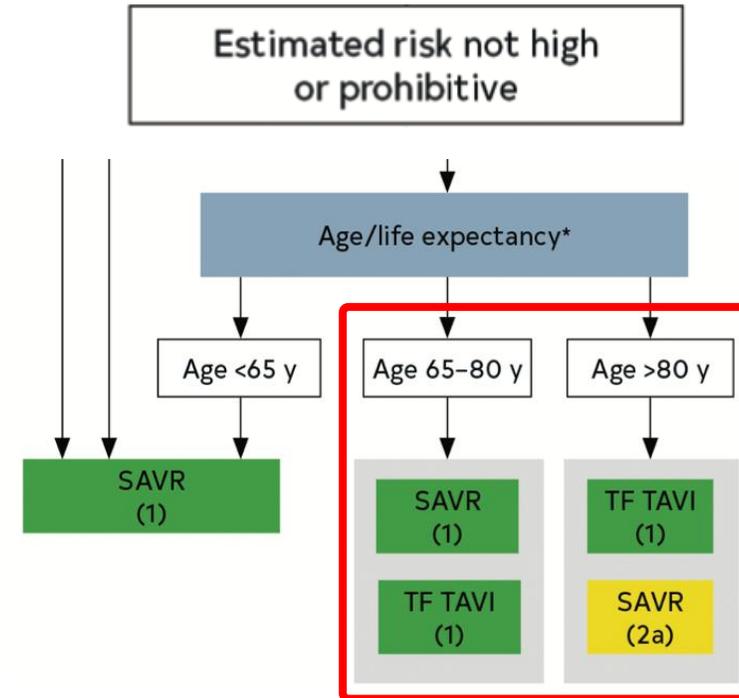


Praz F et al. European Heart Journal (2025) 00, 1–7.

ACC/AHA CLINICAL PRACTICE GUIDELINE

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease

A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines



Otto C, Circulation. 2021;143:e72–e227.

Médiane de Survie après RVAo

High risk

Median age: 79.3±6.2

Median survival:

5.8 years (5.4-6.5)

Intermediate risk

Median age: 80±5.8

Median survival:

7.3 years (7.0-7.9)

Low risk

Median age: 74.3±6.4

80-84 years

8.2 years (7.8-8.8)

75-79 years

10.5 years (10.1-11.2)

70-74 years

12.5 years (11.7-13.2)

< 80 ans

60

65

70

75

80

85

90

Patient age (years)

Médiane de Survie après RVAo

High risk

Median age: 79.3±6.2

Median survival:

5.8 years (5.4-6.5)

Espérance de vie > durabilité des prothèses ?

Low risk

Median age: 74.3±6.4

80-84 years

8.2 years (7.8-8.8)

75-79 years

10.5 years (10.1-11.2)

70-74 years

12.5 years (11.7-13.2)

< 80 ans

60

65

70

75

80

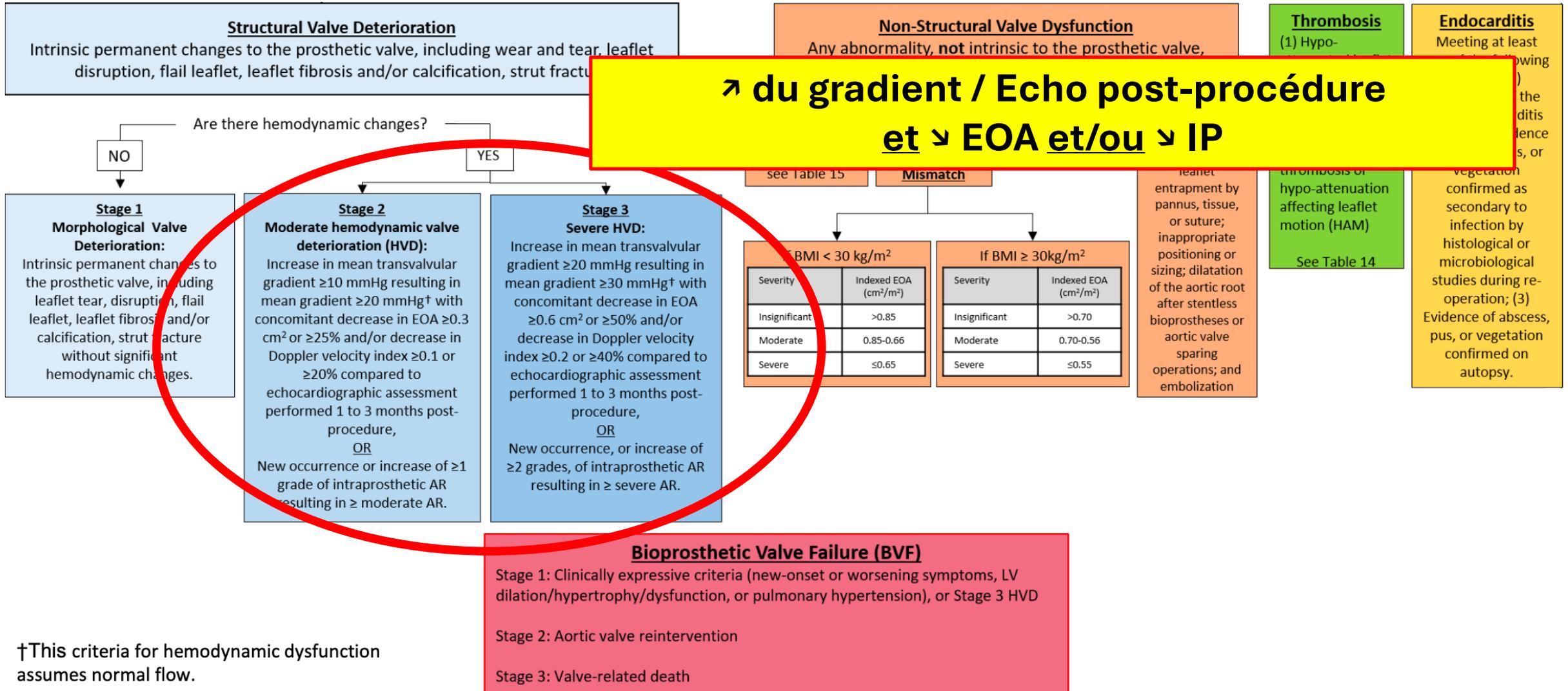
85

90

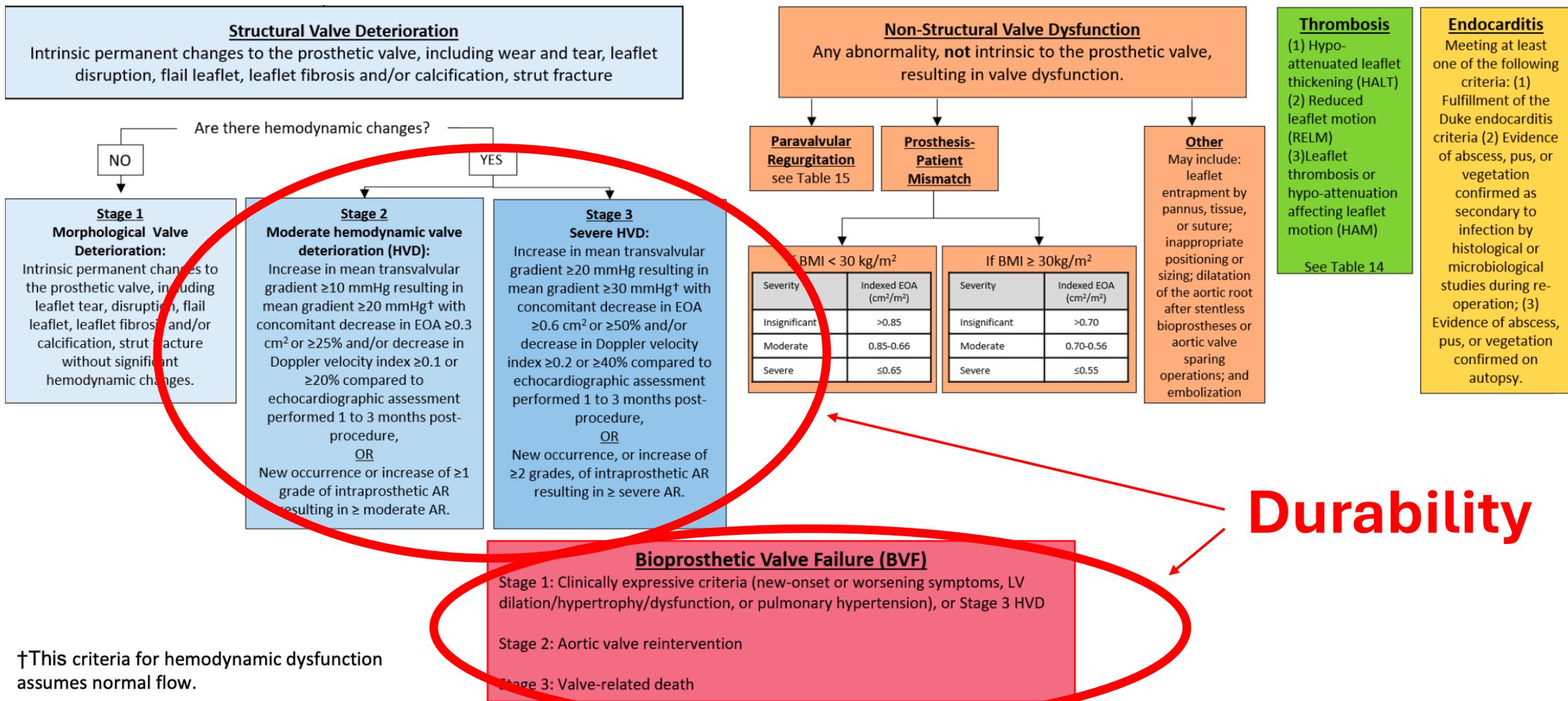
Patient age (years)

Définition de la durabilité ?

Bioprosthetic Valve Dysfunction (VARC-3)



Bioprosthetic Valve Dysfunction (VARC-3)



Durabilité des prothèses TAVI / Chirurgie

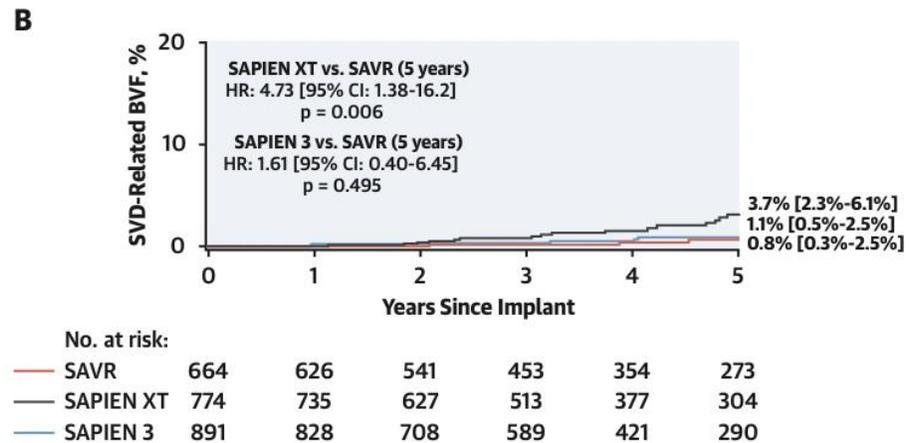
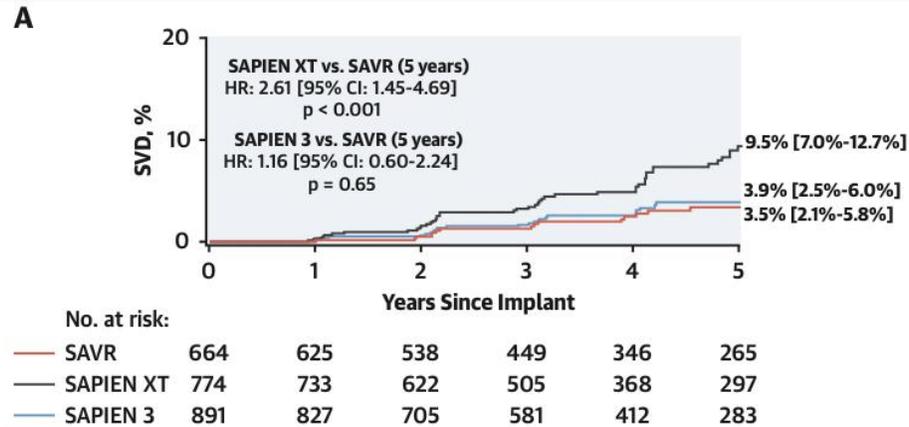
Que disent les études randomisées ?

Intermediate risk patients at 5 years

Plus de SVD et BVF avec la XT vs. SAVR

SVD et BVF similaires avec la S3 vs. SAVR

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

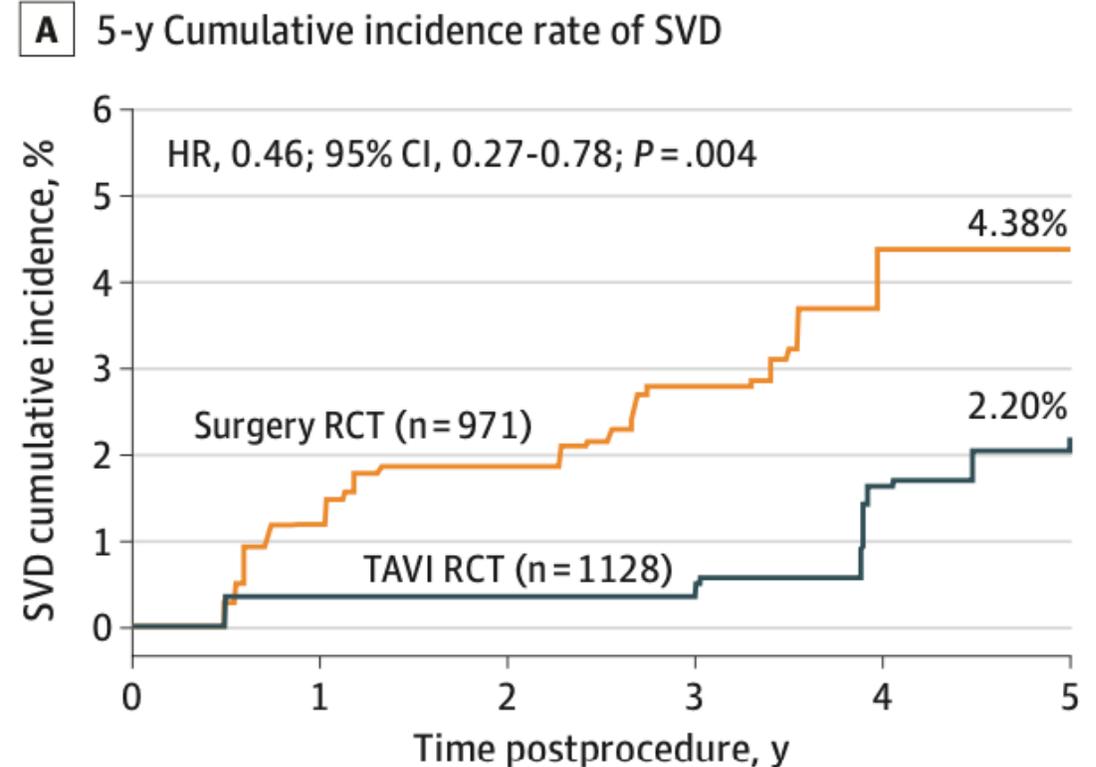


Pibarot P, J Am Coll Cardiol 2020;76:1830-43

Moins de SVD avec la Coreval/Evolut R vs. SAVR

JAMA Cardiology | Original Investigation

Structural Valve Deterioration After Self-Expanding Transcatheter or Surgical Aortic Valve Implantation in Patients at Intermediate or High Risk



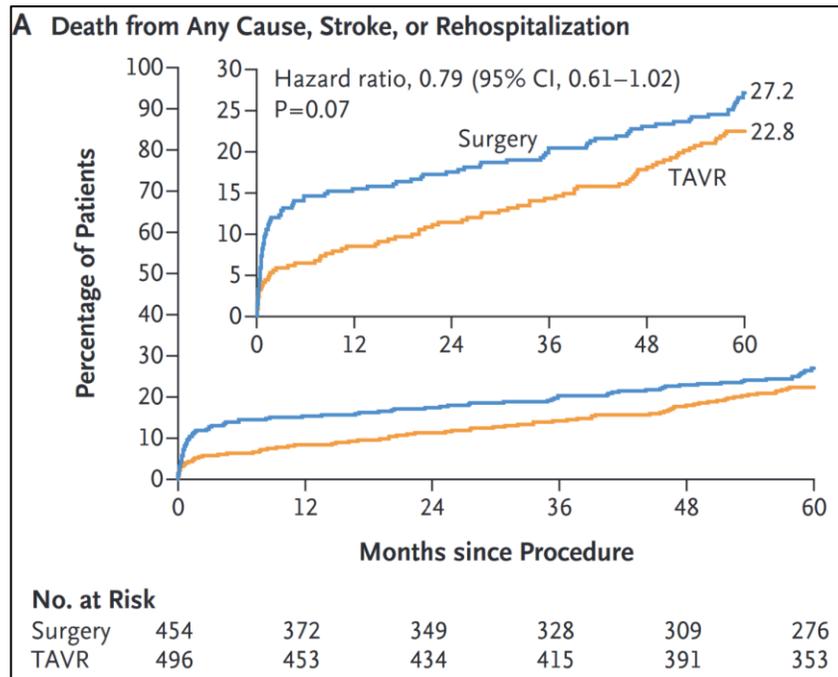
O'Hair D, JAMA Cardiol. 2022

Low risk patients at 5 years

ORIGINAL ARTICLE

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

PARTNER 3

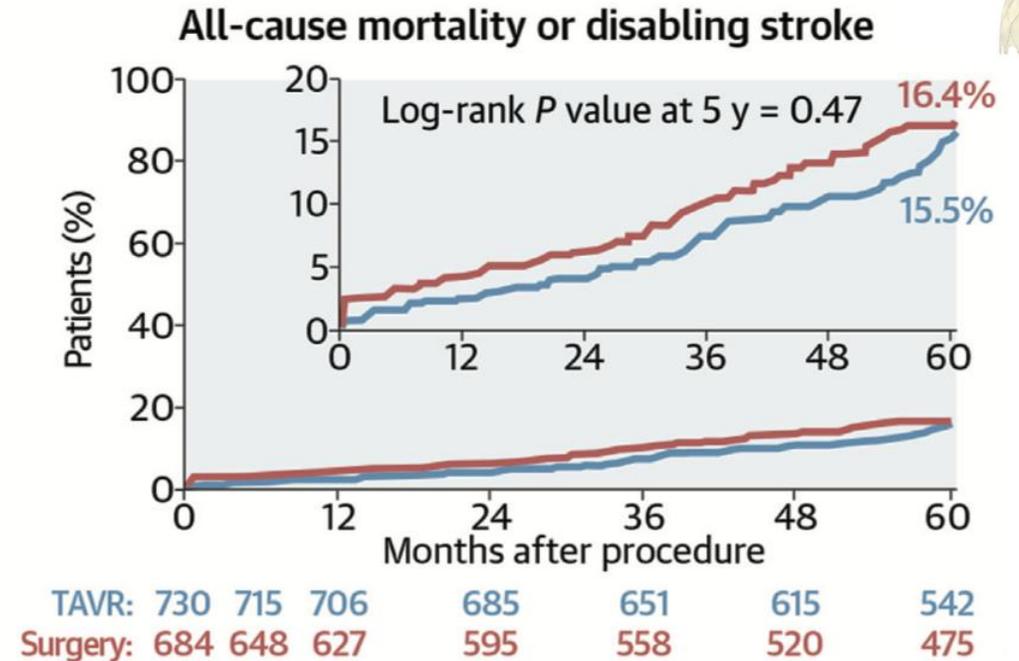


**Aortic valve reintervention:
2.6% TAVR vs 3.0% SAVR**

Mack MJ et al. NEJM 2023;389:1949-1960

5-Year Outcomes After Transcatheter or Surgical Aortic Valve Replacement in Low-Risk Patients With Aortic Stenosis

Evolut Low Risk



**Aortic valve reintervention:
3.3% TAVR vs 2.5% SAVR**

Forrest JK et al. JACC 2025;85:1523-1532

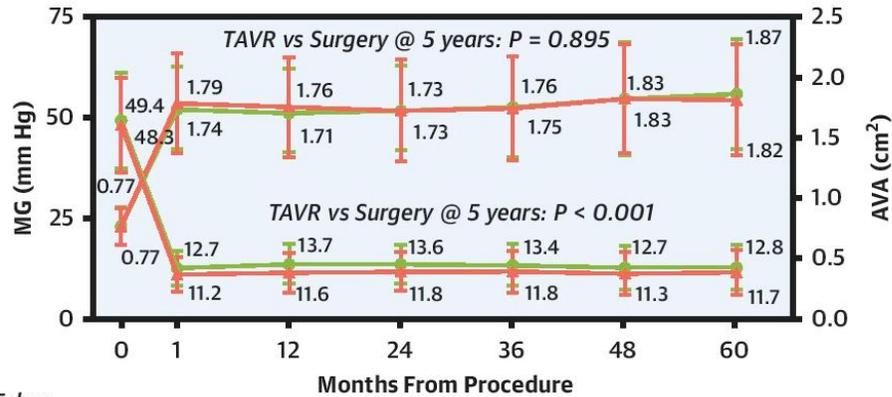
Low risk patients at 5 years

PARTNER 3



Similar hemodynamics with SAPIEN 3 TAVR vs SAVR

MG and AVA Through 5 Years by Treatment



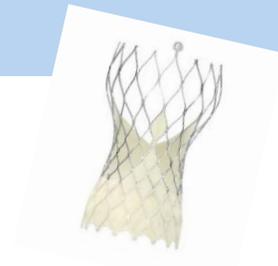
Number of Echos

TAVR (MG)	483	492	474	437	372	348	329
TAVR (AVA)	458	482	450	416	347	334	320
Surgery (MG)	442	432	391	360	304	305	282
Surgery (AVA)	424	415	371	342	289	295	275

—▲— Surgery —●— TAVR

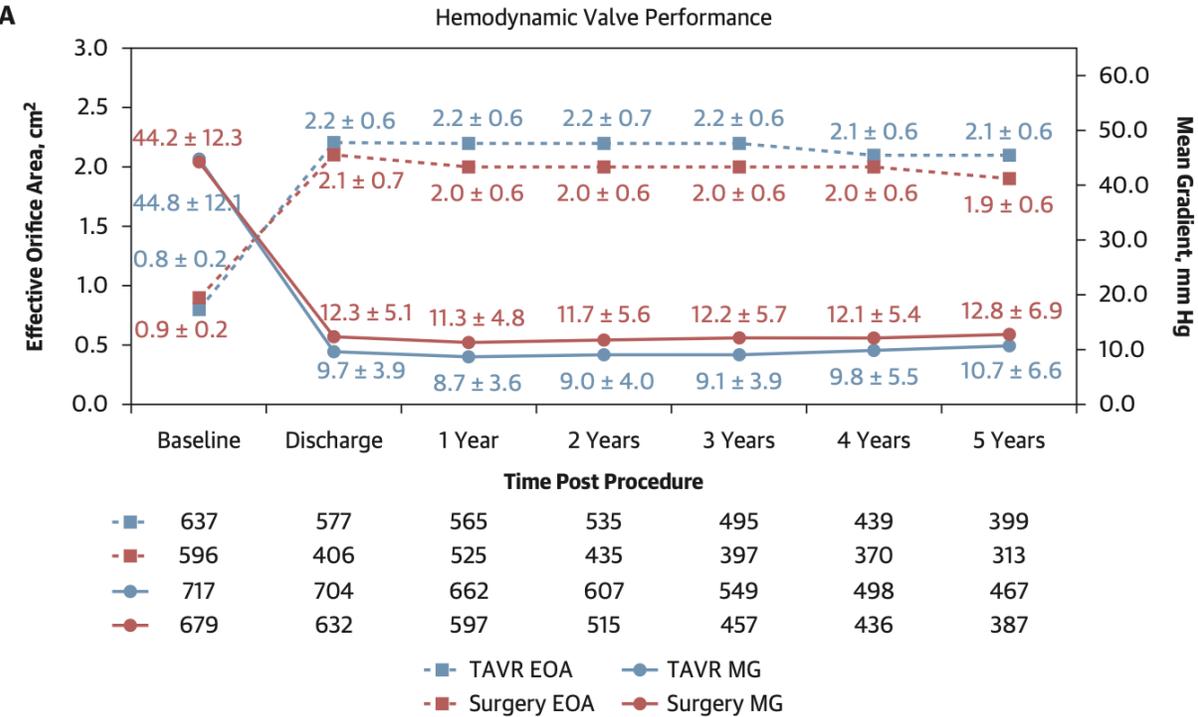
Similar and stable valve hemodynamics were observed for both treatment groups; severe PPM and ≥mild PVR at 30 days were not associated with an increased risk of clinical outcomes

Evolut Low Risk

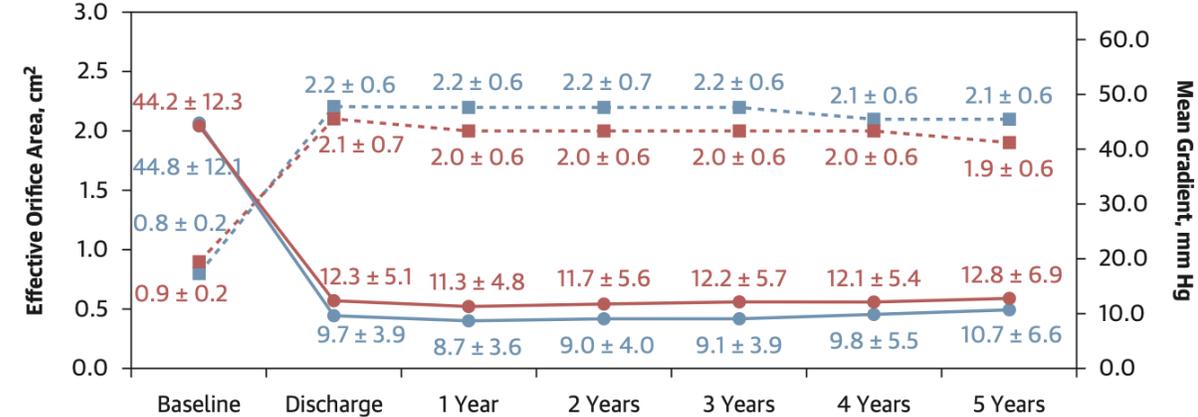


Better hemodynamics with Evolut TAVR vs SAVR

A



Hemodynamic Valve Performance

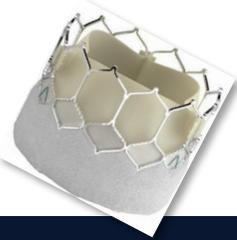


	Baseline	Discharge	1 Year	2 Years	3 Years	4 Years	5 Years
EOA (n)	637	577	565	535	495	439	399
Surgery EOA (n)	596	406	525	435	397	370	313
TAVR MG (n)	717	704	662	607	549	498	467
Surgery MG (n)	679	632	597	515	457	436	387

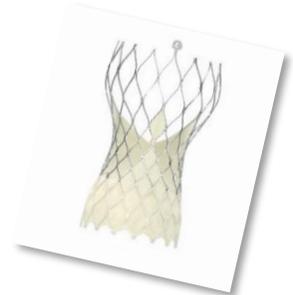
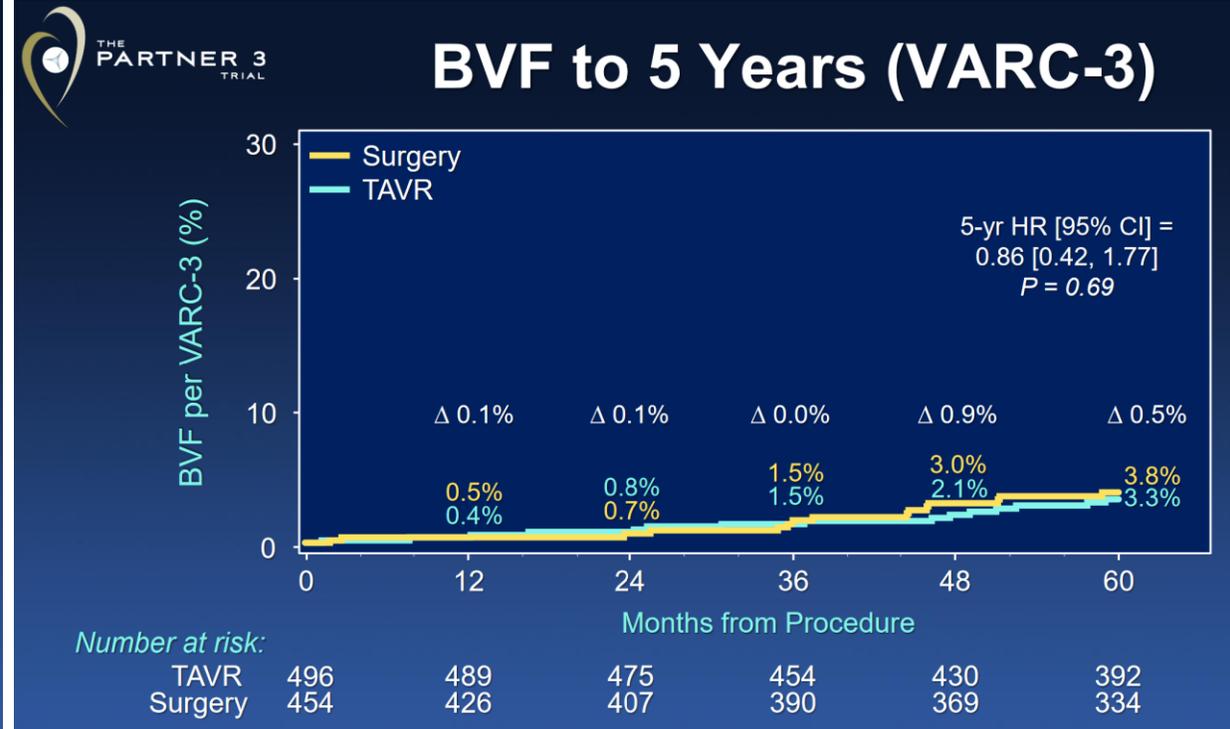
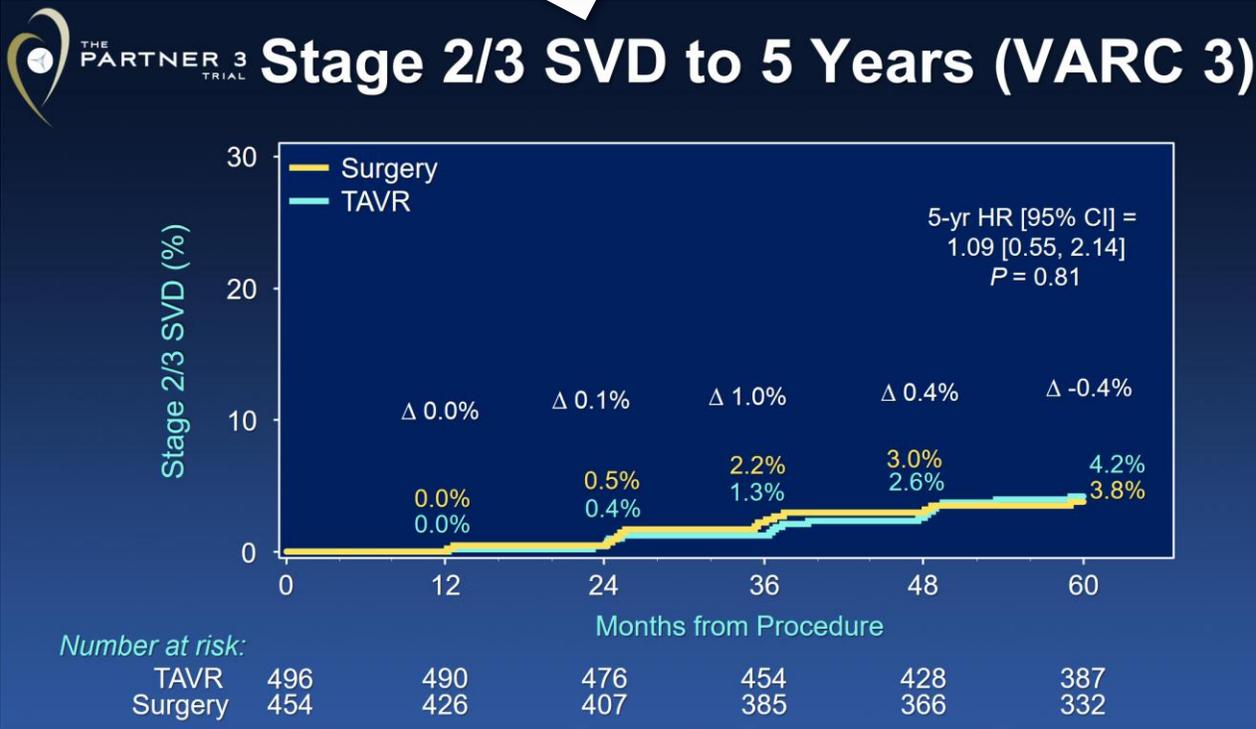
—■— TAVR EOA —●— TAVR MG
—■— Surgery EOA —●— Surgery MG

Low risk patients at 5 years

PARTNER 3
low risk



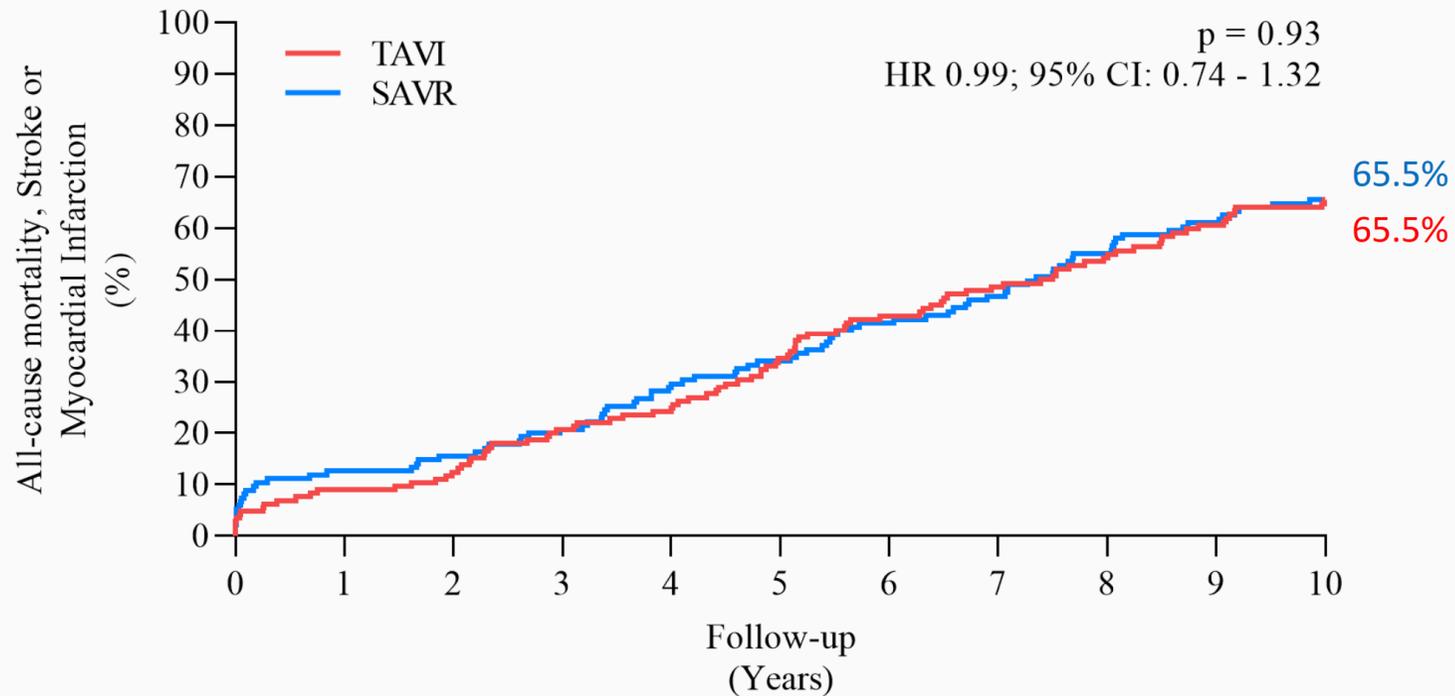
Similar durability at 5 years with Sapien 3 TAVR vs Surgery



NOTION Trial - 10 years

RCT TAVR (corevalve) vs. SAVR in lower risk patients ≥ 70 ans

All-cause mortality, Stroke, Myocardial infarction



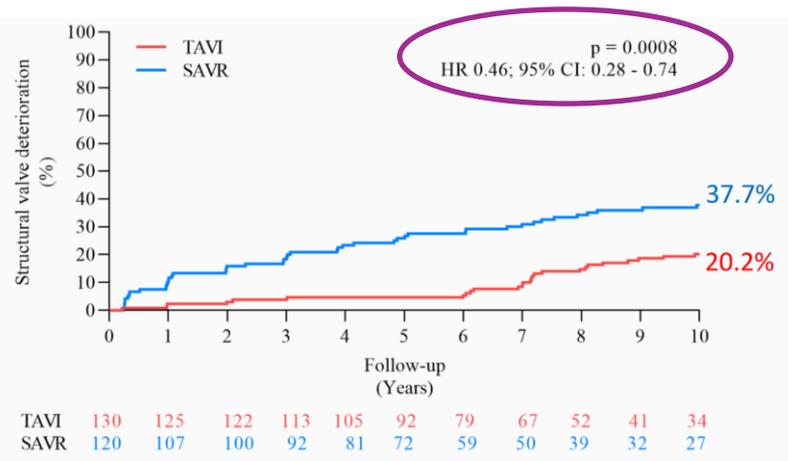
TAVI	145	133	128	116	110	93	81	73	65	56	49
SAVR	135	122	118	110	99	92	80	71	60	52	46

NOTION Trial - 10 years

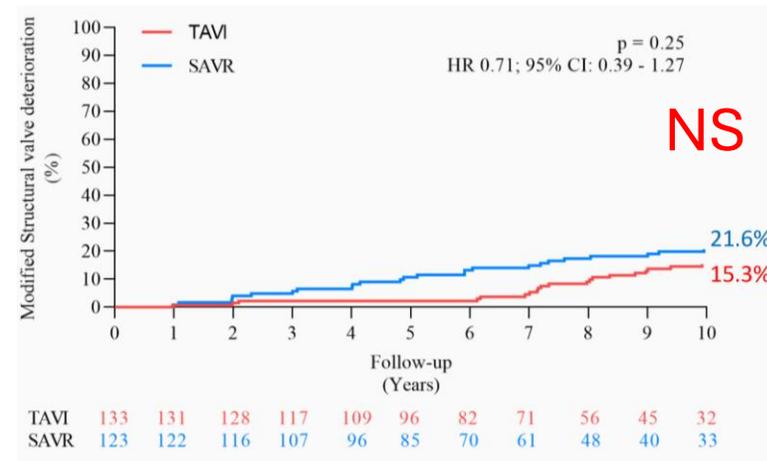
RCT TAVR (corevalve) vs. SAVR in lower risk patients ≥ 70 ans

Moins de SVD avec la Corevalve / SAVR

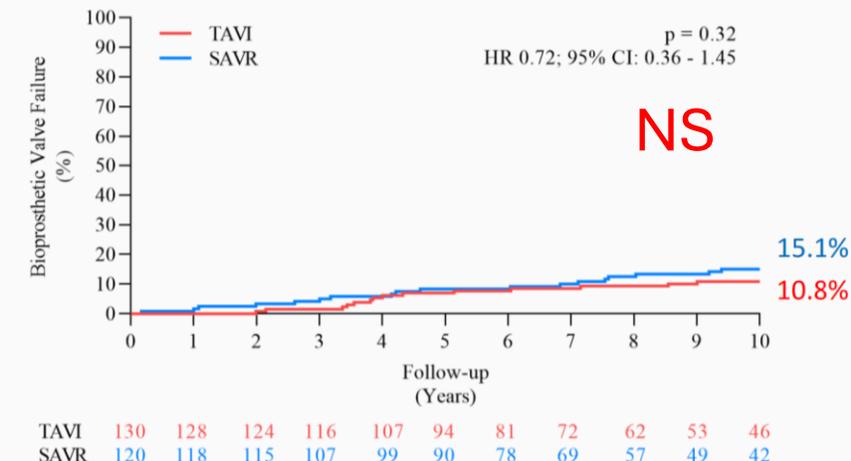
Structural Valve Deterioration



Modified SVD



Bioprosthesis Valve Failure



Moderate or severe haemodynamic SVD

- Mean gradient ≥ 20 mmHg OR
- Mean gradient ≥ 10 mmHg change from baseline OR
- Moderate/severe intra-prosthetic aortic regurgitation (new or worsening from baseline)

Mean gradient ≥ 20 mmHg AND
mean gradient ≥ 10 mmHg change from baseline

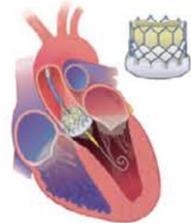
TAVI DURABILITY:

MIDTERM DURABILITY: SIMILAR IN TAVI vs SAVR
LONG-TERM DURABILITY: NEED MORE DATA TO CONFIRM

BIOPROSTHETIC VALVE FAILURE
Irreversible Stage 3 BVD
Any Stage of BVD with symptoms or events
Valve reintervention
Valve-related death



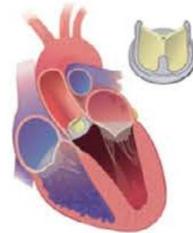
BENCHMARK



TAVI



SAVR

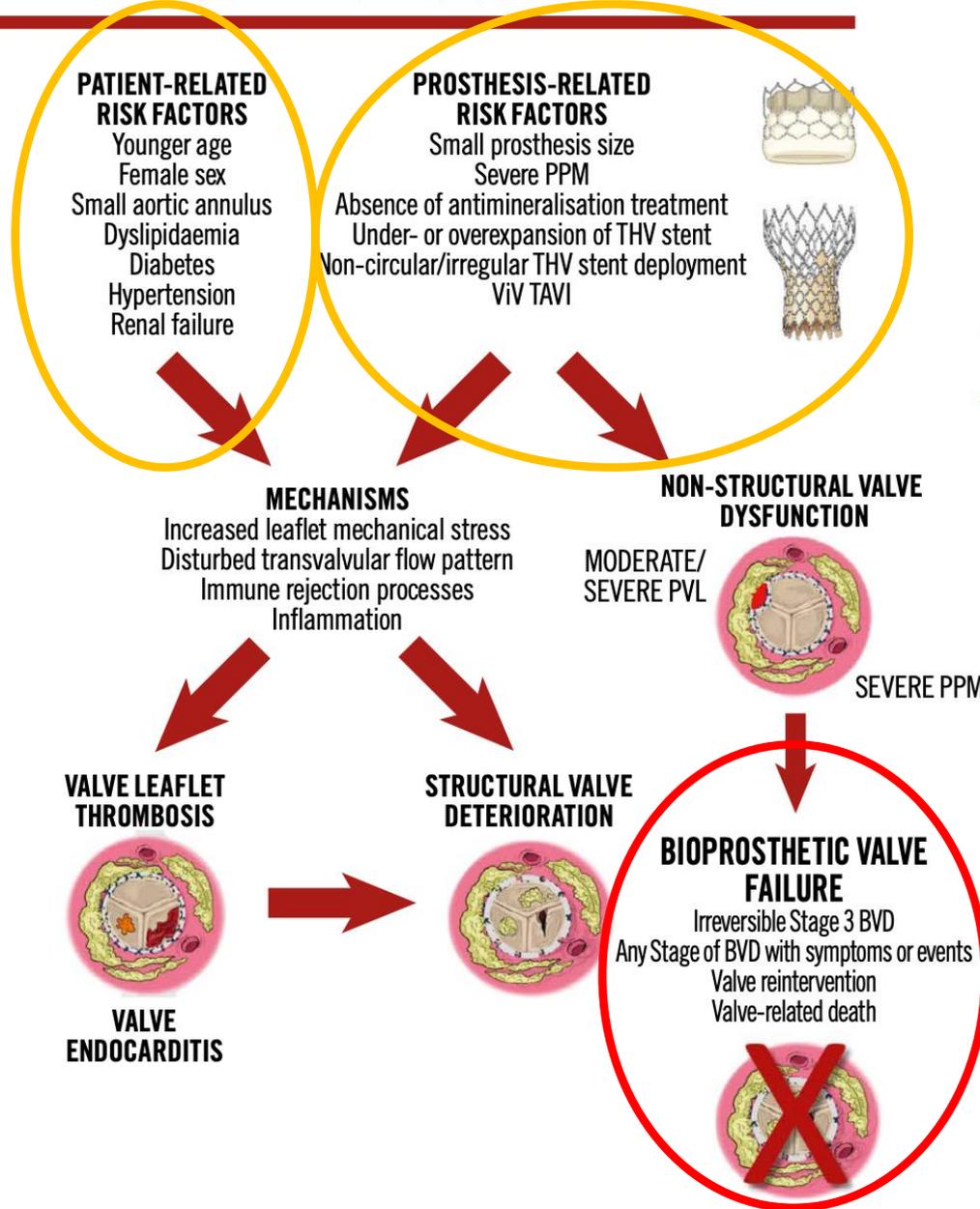


BVF at
5 years
<5%

BVF at
10 years
<15%

1-4%
vs
1-4%

10%
vs
14%

A**RISK FACTORS AND MECHANISMS OF VALVE FAILURE****E**

Différence de durabilité des prothèses TAVI entre-elles ?

Très peu de données +++



Sapien 3U



Evolut Fx

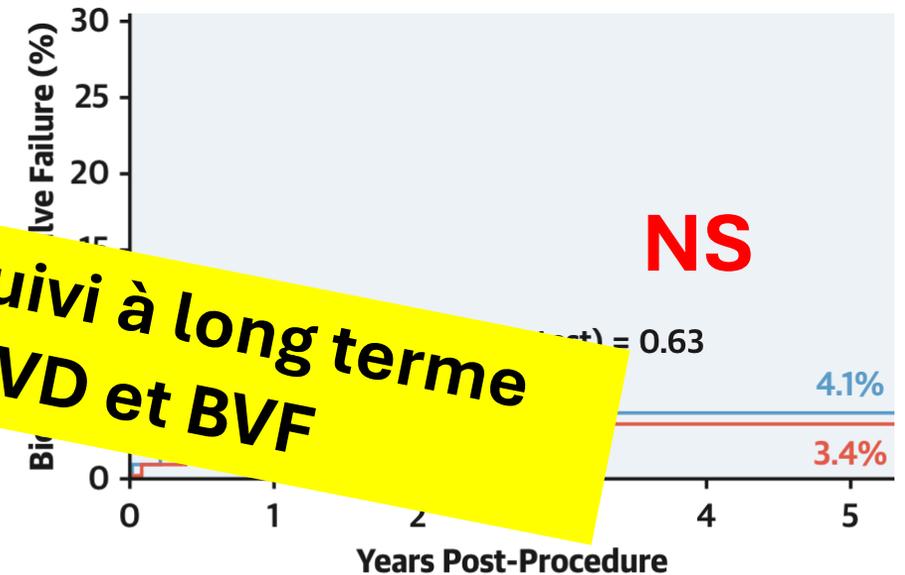
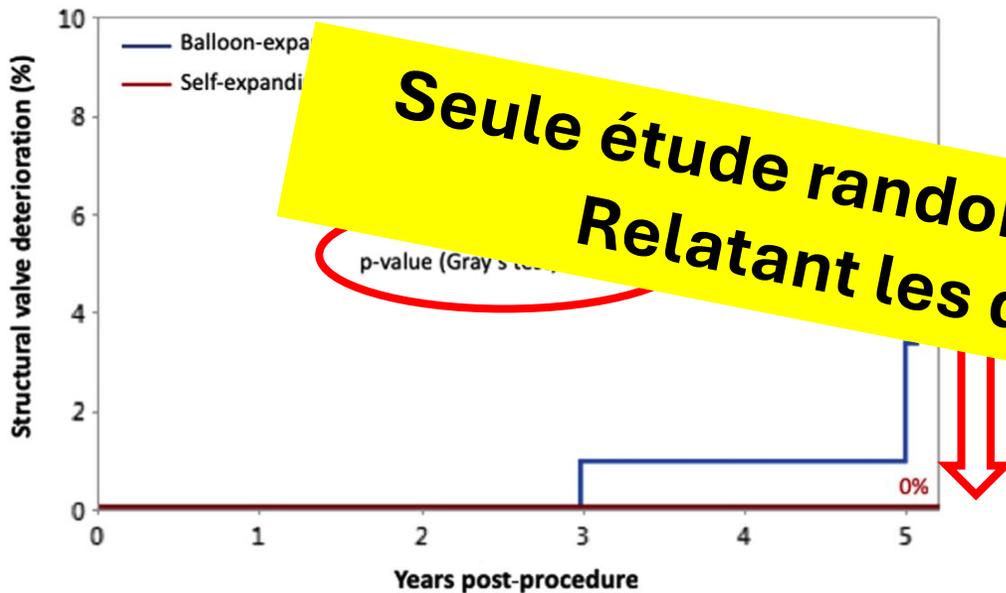
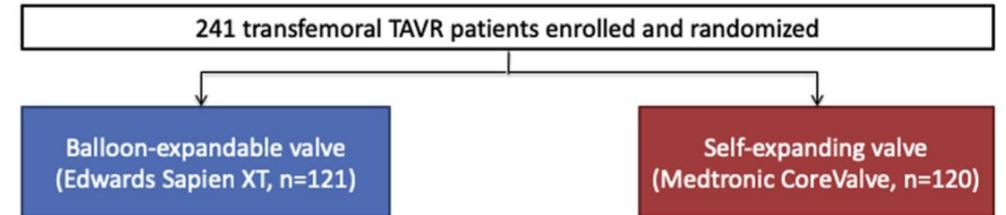


Navitor

Moins de SVD mais pas de BVF entre Corevalve et Sapien XT

5-Year Outcomes After TAVR With Balloon-Expandable Versus Self-Expanding Valves

Results From the CHOICE Randomized Clinical Trial



**Seule étude randomisée avec suivi à long terme
Relatant les données de SVD et BVF**

Number at risk

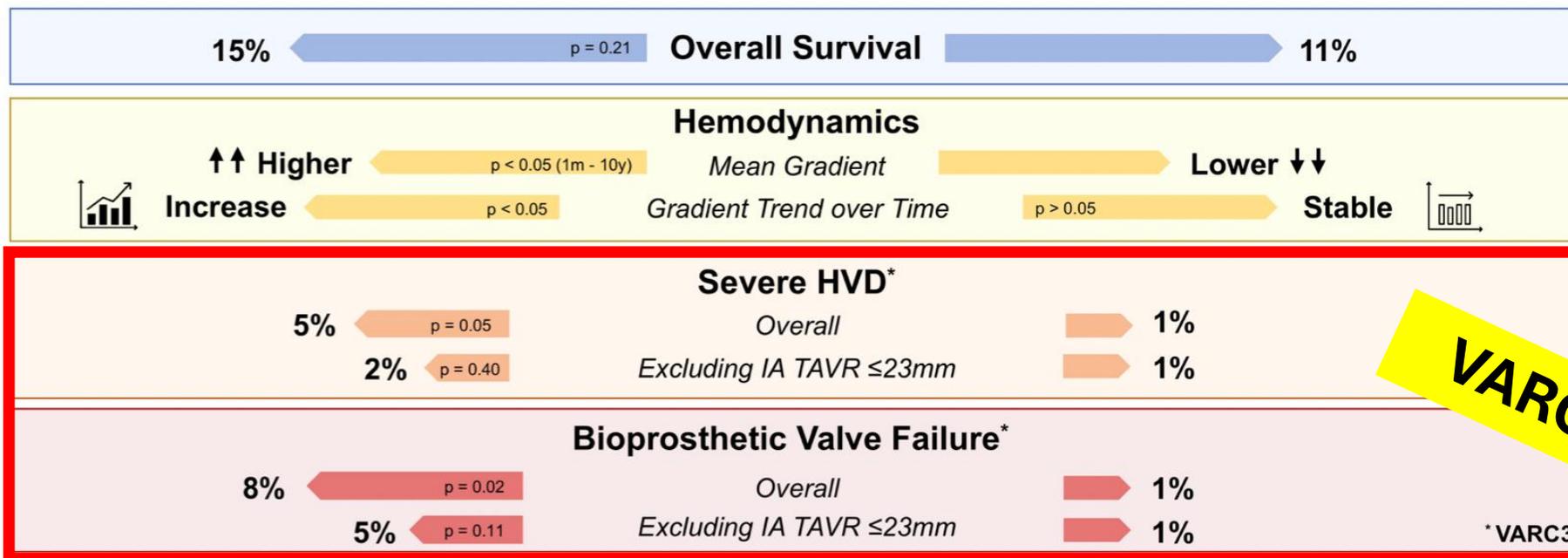
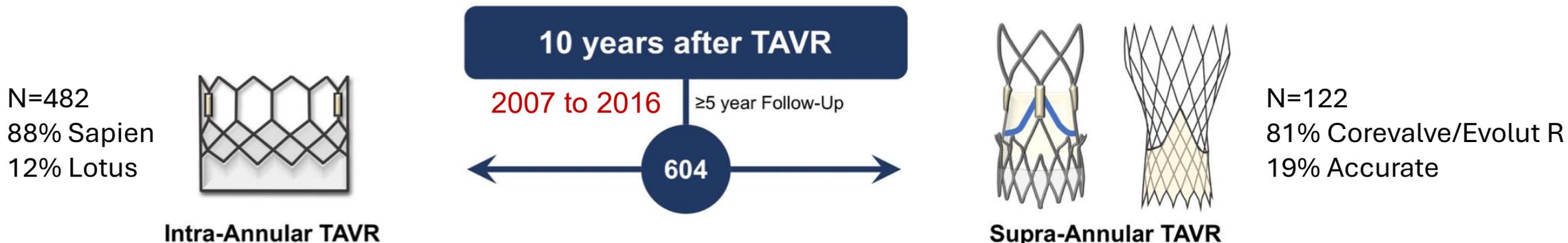
121	99	87	74	66	42
120	101	87	80	70	42

No. at risk:

— Balloon-Expandable	121	99	87	77	69	46
— Self-Expanding	120	100	86	79	70	42

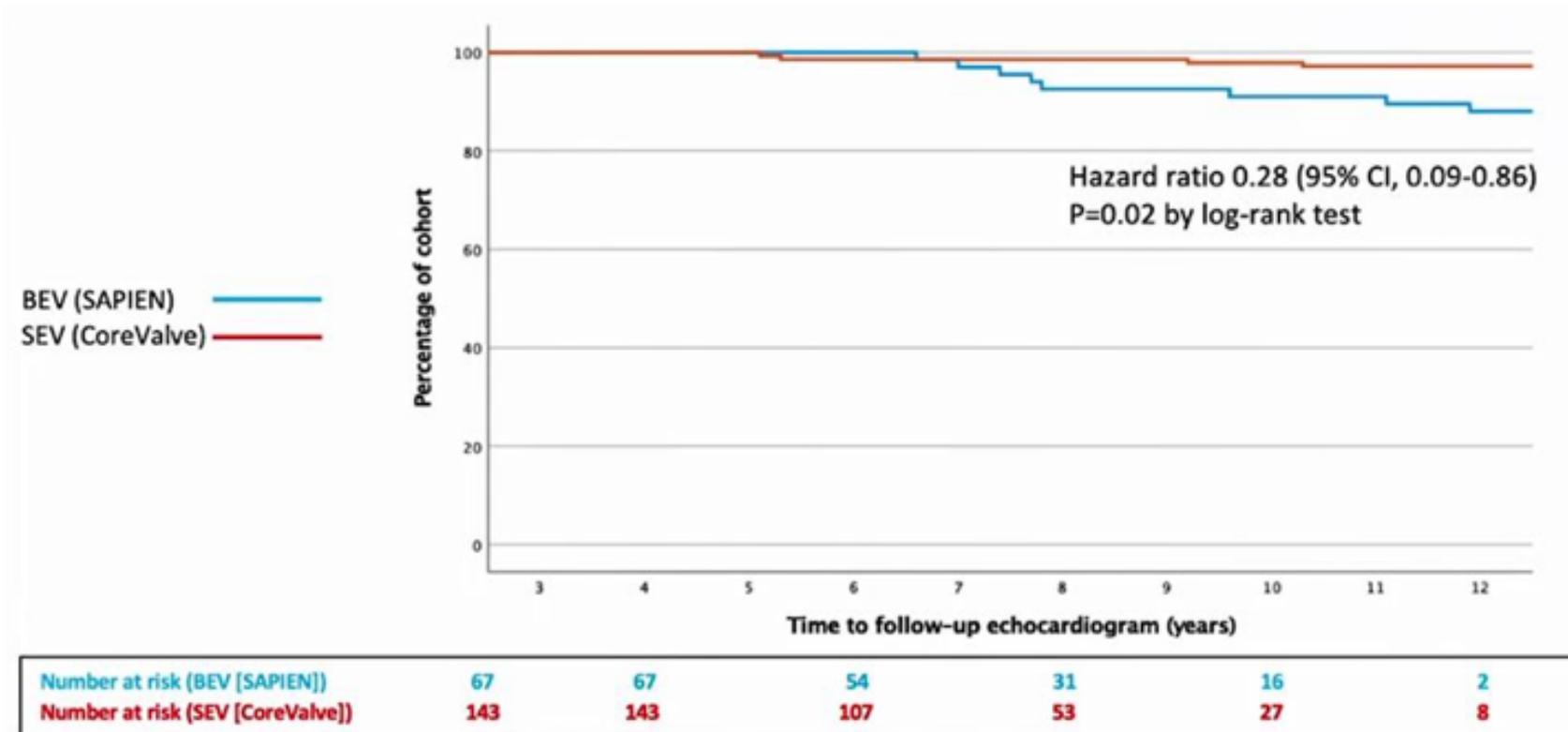
Moins de SVD et de BVF avec prothèses supra-annulaires

PUREVALVE registry



Moins de Severe SVD à 10 ans avec SEV vs. BEV

UK TAVI registry at 10 years



Comparison of valve types

Higher proportion of SAPIEN BEV developed severe SVD compared to CoreValve SEV (8/67 [11.9%] vs. 5/143 [3.5%]; p=0.02)

Les pistes ?

Le design de la prothèse

Stress mécanique plus élevé pour les prothèses balloon-expandable

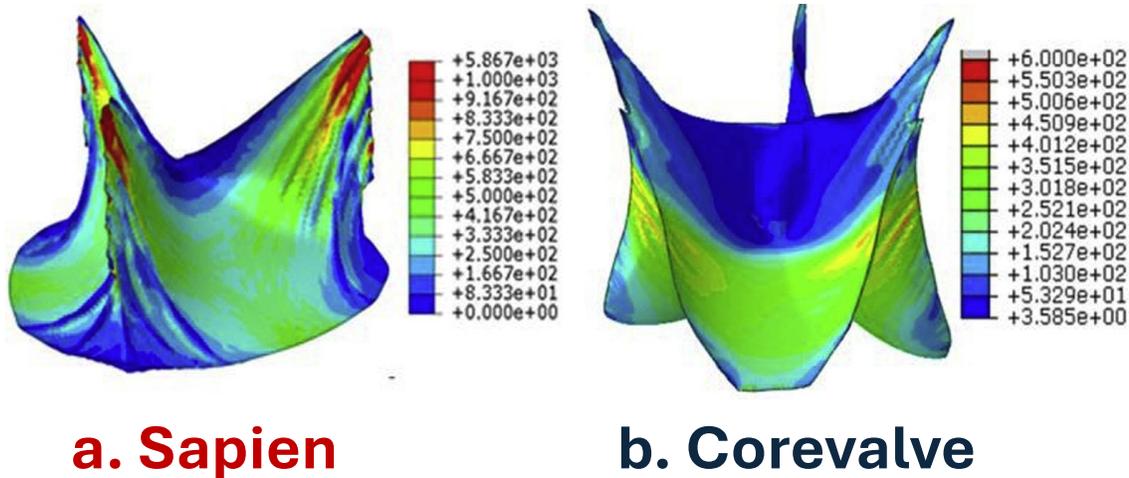
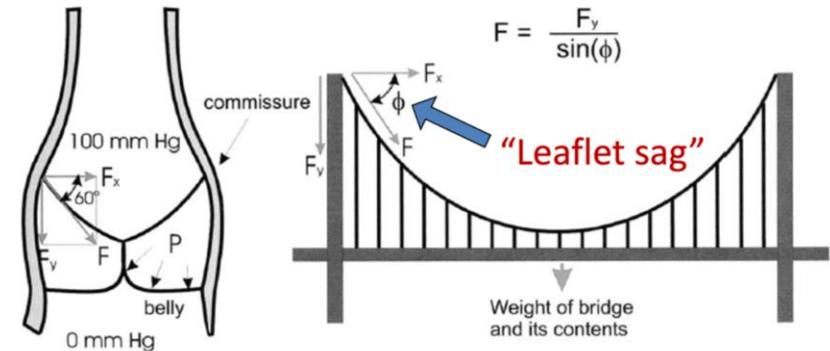


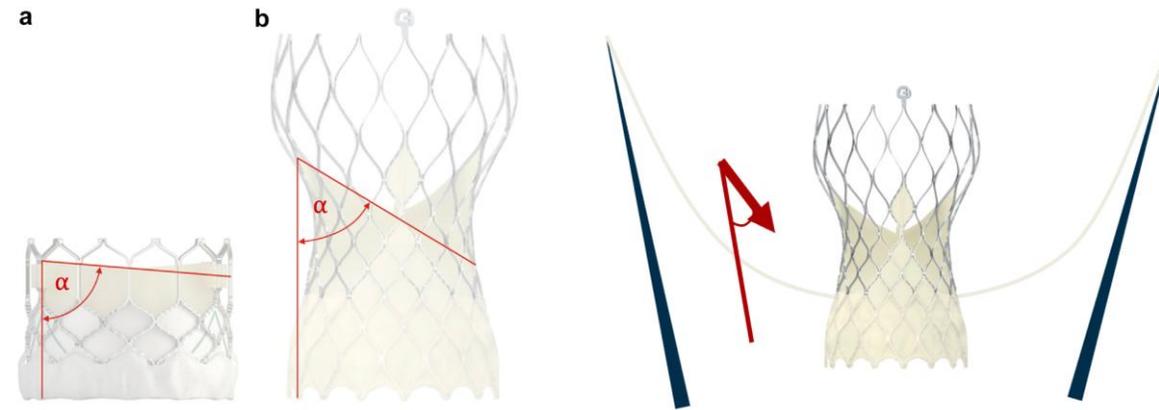
Figure 1. Maximum principal stress on the leaflets of a) Sapien and b) CoreValve.

Self-expanding valve had 40% lower peak mechanical stress

The greater the "sag" (ϕ), the lower the loaded stress on the leaflets



High and angled take-off optimizes leaflet sag & reduce leaflet stress



Thromboses de valve infracliniques

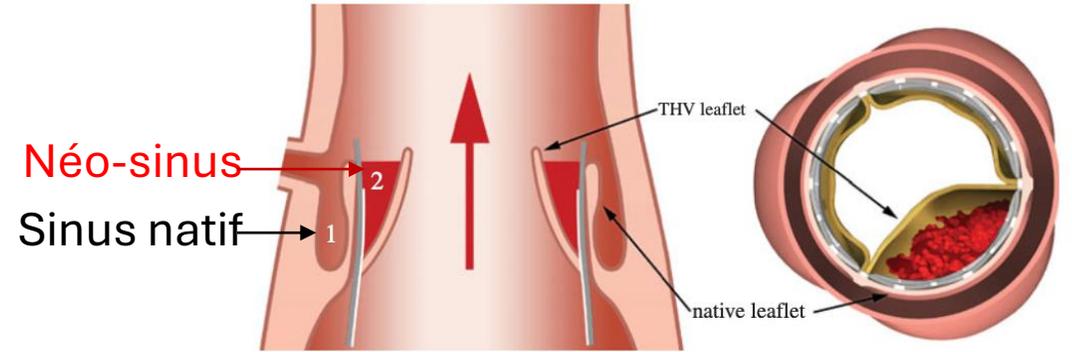
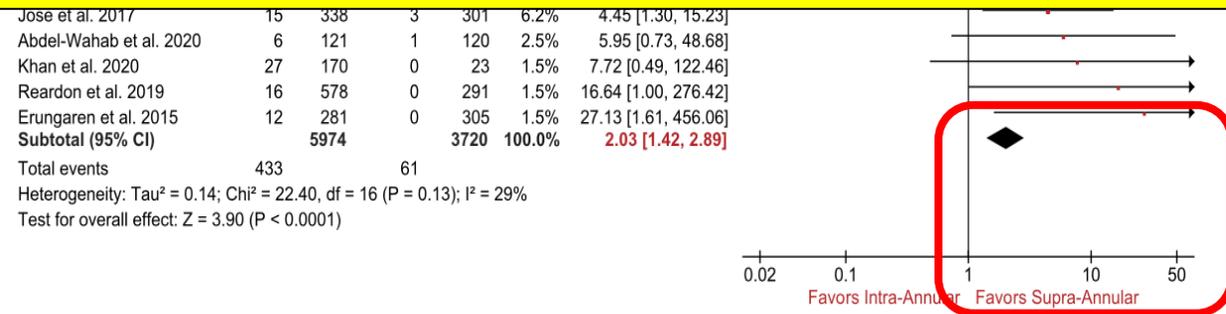
Prothèses intra vs. supra-annulaires

Meta-analysis (19 studies)

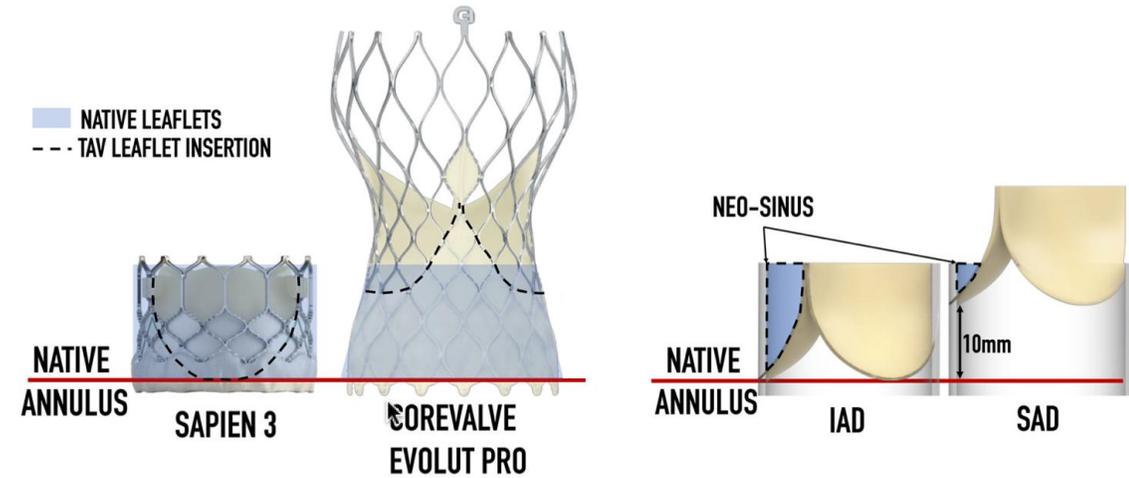
Incidence of SLT in *intra-annular* valves compared with *supra-annular*

Study or Subgroup	Intra-Annular		Supra-Annular		Weight	valves Risk Ratio		SLT Risk Ratio	
	Events	Total	Events	Total		IV, Random, 95% CI	IV, Random, 95% CI		
Intra-Annular vs Supra-Annular									
Vollema et al. 2017	16	128	0	0		Not estimable			
Hansson et al. 2016	28	405	0	0		Not estimable			
Nührenberg et al. 2019	21	138	11	48	13.2%	0.66	[0.35, 1.27]		
Yanagisawa et al. 2019	41	436	4	49	8.4%	1.15	[0.43, 3.08]		
Marwan et al. 2017	17	73	1	5	3.3%	1.16	[0.19, 7.06]		
Basra et al. 2018	16	50	1	5	3.3%	1.60	[0.26, 9.67]		
Waksman et al. 2020	5	45	1	16	2.6%	1.78	[0.22, 14.09]		
Subtotal (95% CI)	5974	3720	100.0%	2.03	[1.42, 2.89]				

Moins de Thromboses infracliniques avec les prothèses supra-annulaires



Midha et al. Circulation 2017

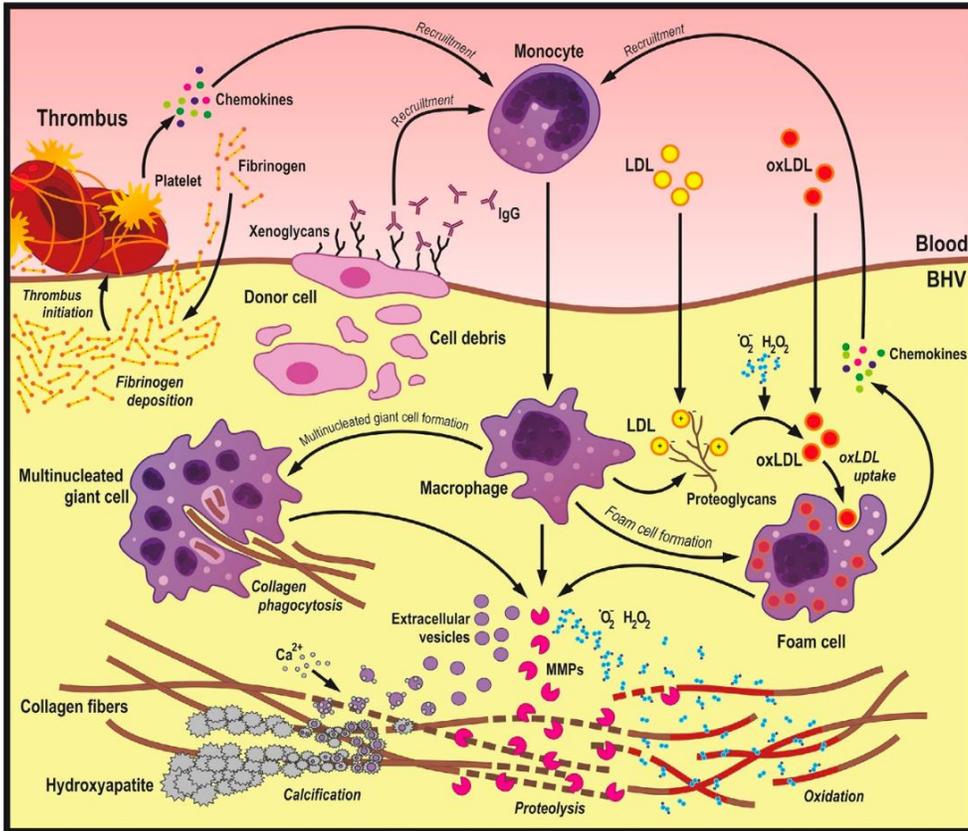


Madukauwa-David et al. Ann. Biomed. Eng. 2020

Thrombose de valve ↔ dégénérescence ?

Chronic inflammation in relation to SVD

Two types of Calcium distribution

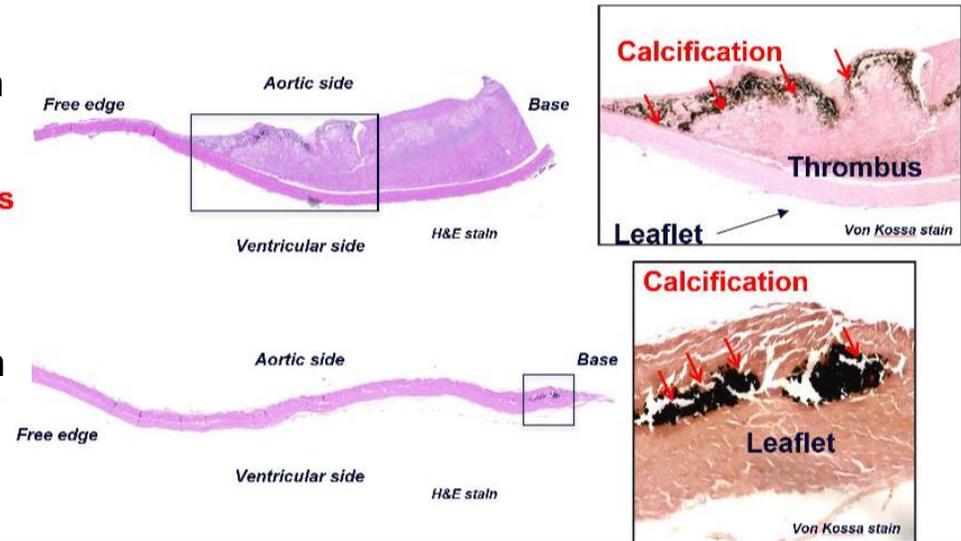


Extrinsic calcification

Within thrombus

Intrinsic calcification

Within leaflet



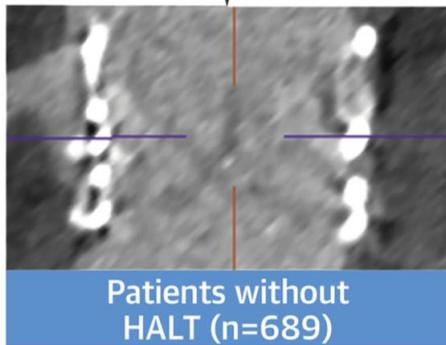
Plus de SVD en cas de thromboses infra-cliniques précoces

Long-Term Follow-Up of Hypoattenuated Leaflet Thickening After Transcatheter Aortic Valve Replacement

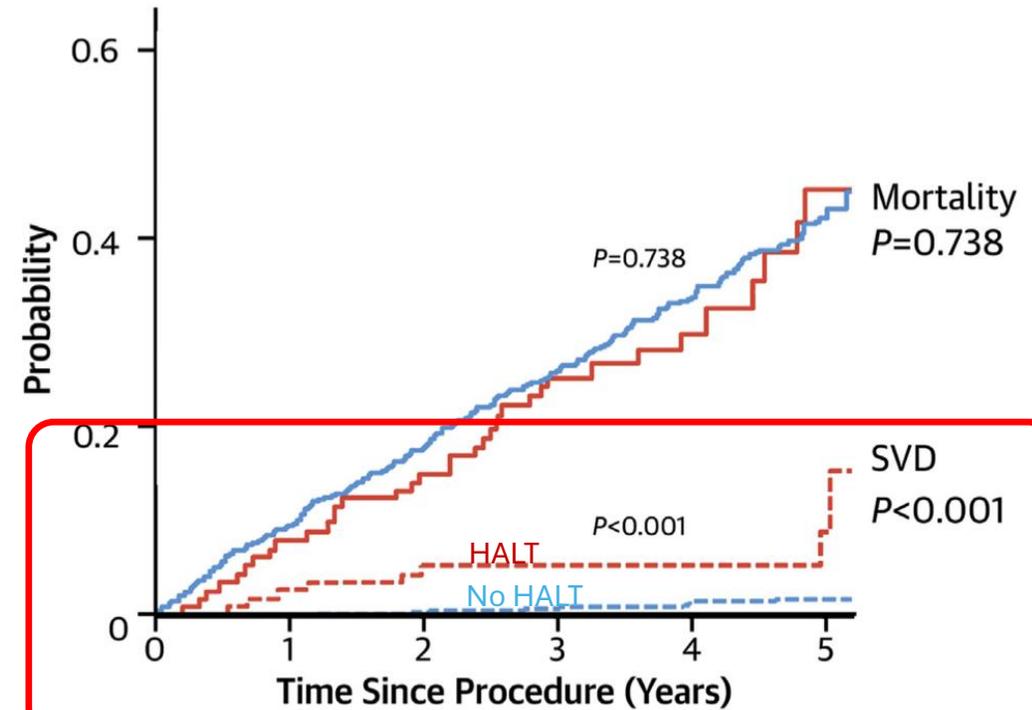


Leaflet Thickening After TAVR:
Long-Term Follow-up Among 821 Patients

Post-TAVR CTA → Intermittent (D)OAC (n=17)



g post-TAVR-CTA n = 785



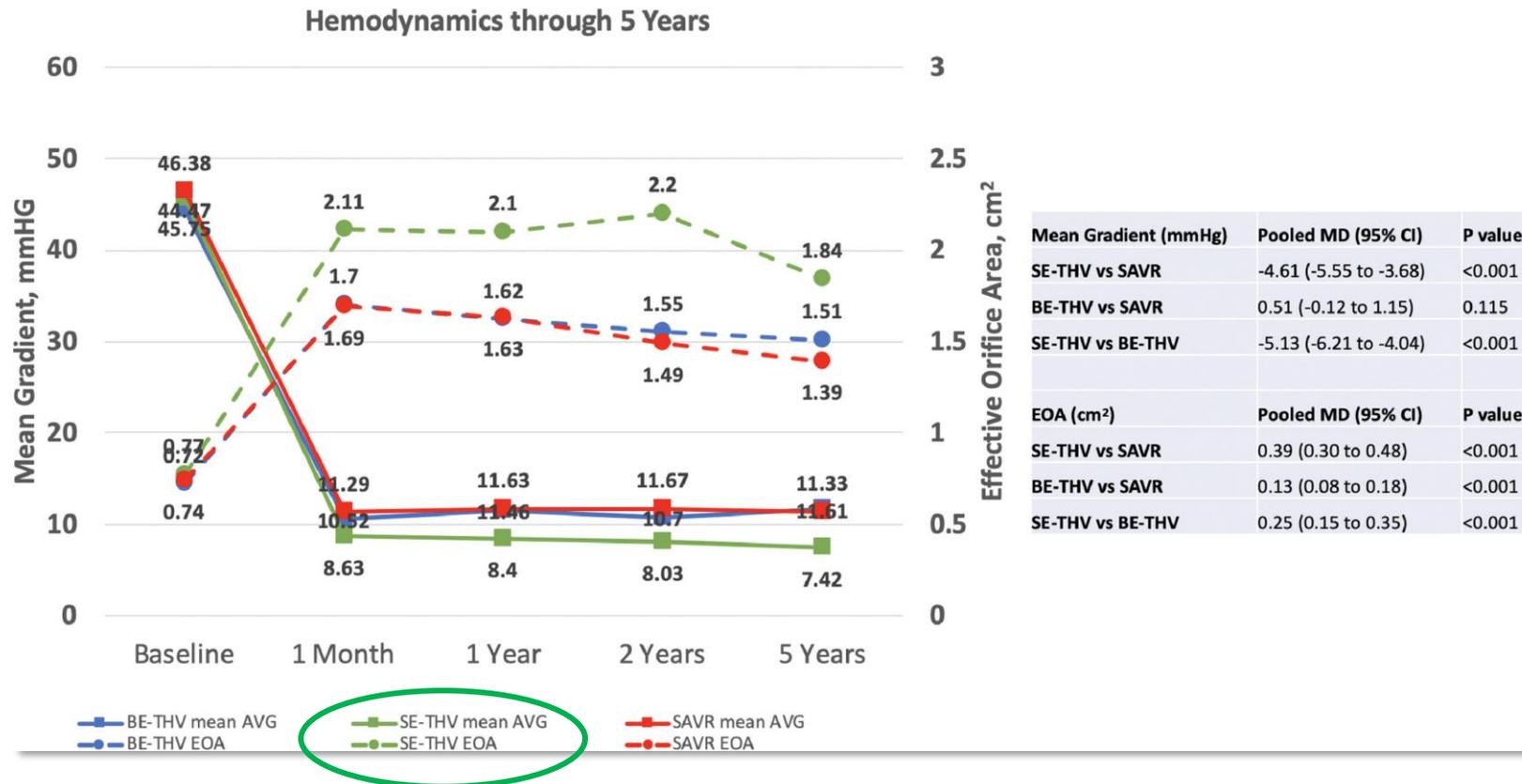
No. at risk:

— (blue)	No HALT	689	617	552	461	310	189
— (red)	HALT	115	101	91	74	42	15
- - - (blue)	No HALT	689	449	435	378	242	154
- - - (red)	HALT	115	76	70	60	29	13

SVD = symptomatic hemodynamic valve deterioration

L'Hémodynamique

Gradients moins élevés et surfaces plus grandes avec les valves self-expanding



Gradients moins élevés et surfaces plus grandes avec les valves self-expanding

Encore plus marqué pour les petits anneaux

Bioprosthetic Valve Performance After Transcatheter Aortic Valve Replacement With Self-Expanding Versus Balloon-Expandable Valves in Large Versus Small Aortic Valve Annuli

Insights From the CHOICE Trial and the
CHOICE-Extend Registry

Mohammad Abdelghani, MD,^{a,b} Nader Mankerious, MD,^a Abdelhakim
Jatinderjit Kaur, MD,^a Dmitriy S. Sulimov, MD,^a Constanze Merten, MD,^a
Franz-Josef Neumann, MD,^a Christian Frerker, MD,^a Thomas Kurz, MD,^a
Gert Richardt, MD,^a Mohamed Abdel-Wahab, MD^{a,h}

Prosthesis-patient mismatch after transcatheter implantation of contemporary balloon-expandable and self-expandable valves in small aortic annuli

Pier Pasquale Leone MD, MSc^{1,2,3} | Damiano Regazzoli³
Giuliano Costa MD⁵ | Rui Teles MD⁶
Maurizio Taramasso MD, PhD⁷ | Federico De Marco MD¹⁰
Faraj Kargoli MD¹ | Yohei Ohno MD¹⁰
Alfonso Ielasi MD¹² | Flavio Ribichini MD¹⁶
Won-Keun Kim MD¹⁵ | Francesco Maisano MD¹⁸
Nicolas M. Van Mieghem MD, PhD¹⁷ | Antonio Colombo MD^{2,3}
Bernhard Reimers MD³ | Azeem Latib MD^{1*}

Implantation of contemporary transcatheter aortic valves in small aortic annuli: the international multicentre TAVI- SMALL 2 registry

Pier Pasquale Leone^{1,2,3}, MD, MSc; Damiano Regazzoli³, MD; Mat
Francesco Cannata^{2,3}, MD; Antonio Mangieri³, MD; Thijmen W. Hol
Marco Barbanti⁶, MD; Rui Teles⁷, MD; Marianna Adamo⁴, MD; Ma
Jörg Reifart⁹, MD; Federico De Marco¹⁰, MD; Francesco Giannini¹¹,
Yohei Ohno¹², MD; Francesco Saia¹³, MD; Andrea Buono¹⁴, MD; Al
Mauro Chiarito^{2,3}, MD; Dario Bongiovanni³, MD, PhD; Ottavia Coz
Flavio Ribichini¹⁶, MD; Diego Maffeo¹⁴, MD; Giuliano Chizzola⁴, M
Won-Keun Kim¹⁷, MD; Francesco Maisano¹⁸, MD; Corrado Tambur
Nicolas M. Van Mieghem⁵, MD, PhD; Antonio Colombo^{2,3}, MD; Be
Azeem Latib^{1*}, MB, BCh; on behalf of the TAVI-SMALL Investigat

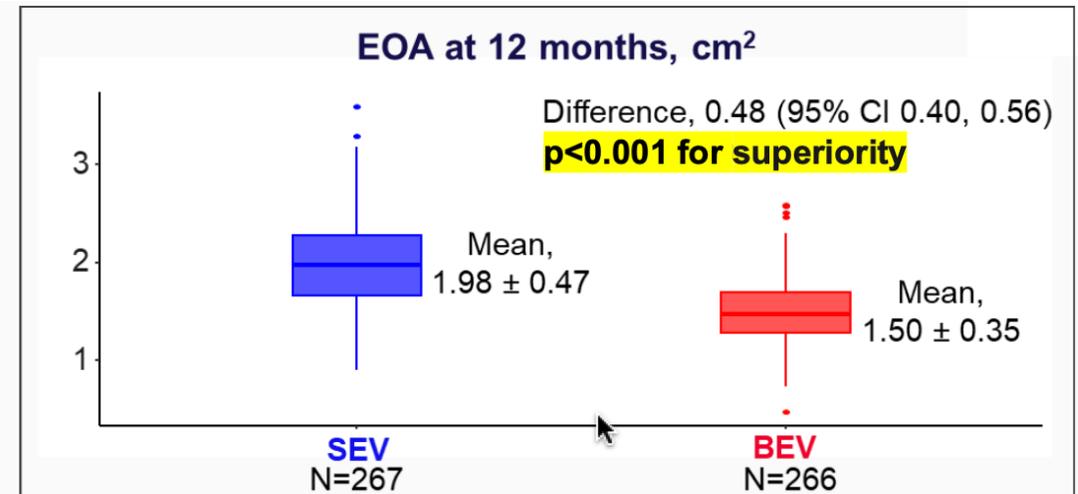
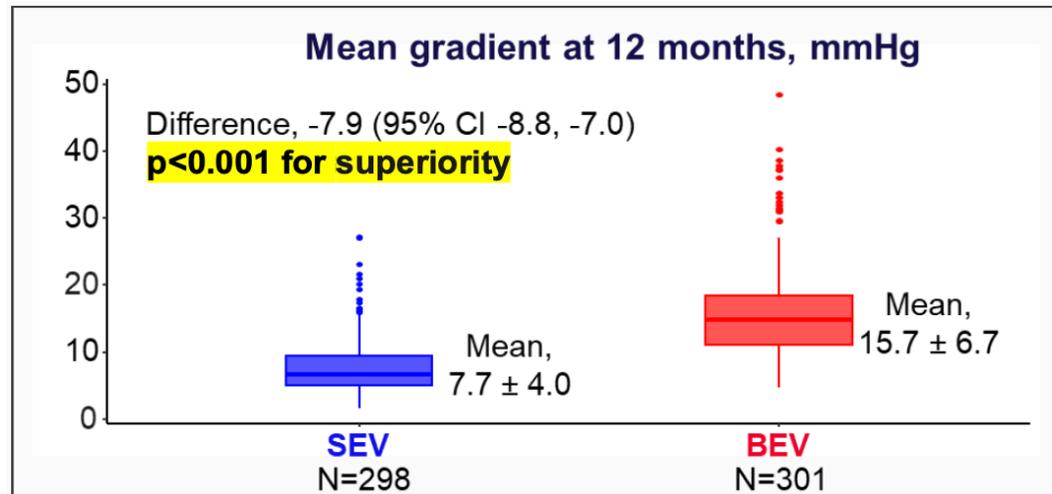
Evolut PRO and SAPIEN ULTRA Performance in Small Aortic Annuli

The OPERA-TAVI Registry

Andrea Scotti, MD,^{a,*} Matteo Sturla, MD,^{a,*} Giuliano Costa, MD,^b Francesco Saia, MD,^c Thomas Pilgrim, MD,^d
Mohamed Abdel-Wahab, MD,^e Philippe Garot, MD,^f Caterina Gandolfo, MD,^g Luca Branca, MD,^h
Ignacio Amat Santos, MD,ⁱ Darren Mylotte, MD,^j Francesco Bedogni, MD,^k Ole De Backer, MD,^l
Luis Nombela Franco, MD,^m John Webb, MD,ⁿ Flavio Luciano Ribichini, MD,^o Andrea Mainardi, MD,^o
Stefano Andreaggi, MD,^o Alessandro Mazzapicchi, MD,^c Daijiro Tomii, MD,^d Pietro Laforgia, MD,^f
Stefano Cannata, MD,^g Claudia Fiorina, MD,^h Simone Fezzi, MD,^j Enrico Criscione, MD,^k Mattia Lunardi, MD,^o
Enrico Poletti, MD,^h Mattia Mazzucca, MD,^k Angelo Quagliana, MD,^l Nicholas Montarello, MD,^l
Breda Hennessey, MD,^m Matias Mon-Noboa, MD,^m Myriam Akodad, MD,ⁿ David Meier, MD,^{n,p}
Federico De Marco, MD,^q Marianna Adamo, MD,^h Carmelo Sgroi, MD,^h Claudia Maria Reddavid, MD,^h
Roberto Valvo, MD,^k Orazio Strazzieri, MD,^h Silvia Crescenza Motta, MD,^h Valentina Frittitta, MD,^h
Elena Dipietro, MD,^h Alessandro Comis, MD,^h Chiara Melfa, MD,^h Mariachiara Cali, MD,^h Sofia Sammartino, MD,^h
Giulia Laterra, MD,^{h,r} Holger Thiele, MD,^e Lars Sondergaard, MD,^l Corrado Tamburino, MD,^h Marco Barbanti, MD,^{h,i}
Azeem Latib, MD^{h,i}

SMART Trial results - a landmark head-to-head randomized controlled TAVI trial

SMall Annuli Randomized To Evolut or SAPIEN = SMART Trial

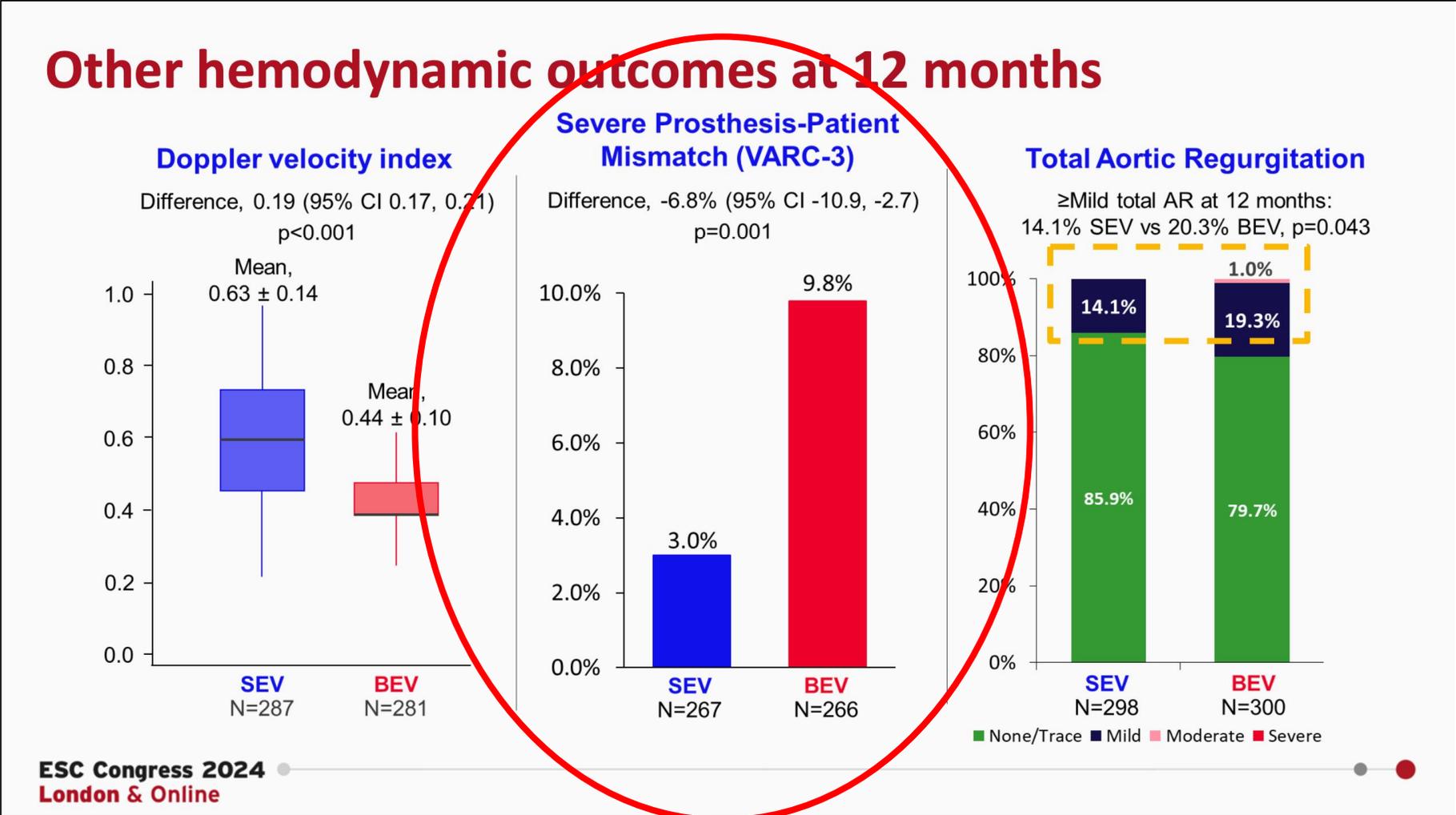


Tchetche D, ESC 2024

Herrmann HC et al. N Engl J Med 2024;390:1959-1971

Moins de mismatch sévère avec les prothèses self-expanding

SMART



Tchetche D, ESC 2024

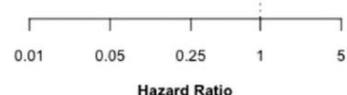
Herrmann HC et al. N Engl J Med 2024;390:1959-1971

Patient-prosthesis mismatch in SAVR patients

Mismatch in SAVR pts promotes SVD

Author(s) and Year	Sample Size	HR	Low	High	Hazard Ratio [95% CI]
Patient-prosthesis Mismatch					
Senage et al., 2014	617	1.95	1.01	3.74	1.95 [1.01, 3.75]
Flameng et al., 2014	648	1.95	1.52	2.51	1.95 [1.52, 2.51]
Urso et al., 2014	387	2.16	1.08	4.33	2.16 [1.08, 4.33]
De Paulis et al., 2016	205	0.92	0.19	6.98	0.92 [0.15, 5.58]
Random-effect model ($I^2=0\%$; Egger's test = 0.47)					1.95 [1.56, 2.43]

Risk factors:
Patient-prosthesis mismatch (HR 1.95)



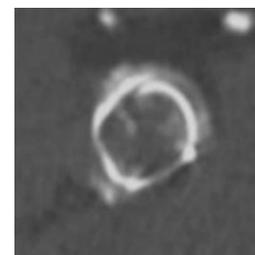
PPM



SVD

Determinants of aortic bioprosthetic valve calcification assessed by multidetector CT

Haïfa Mahjoub, Patrick Mathieu, Eric Larose, Abdelaziz Dahou, Mario Sénéchal, Jean-Gaston Dumesnil, Jean-Pierre Després, Philippe Pibarot



194 pts with bioprosthetic SAVR, FU= 7.9±3 yrs
24% developed calcification on CT.

PPM = strongest predictor of valve calcification
(OR =3.67; 95% CI: 1.25–10.6; P=0.01).

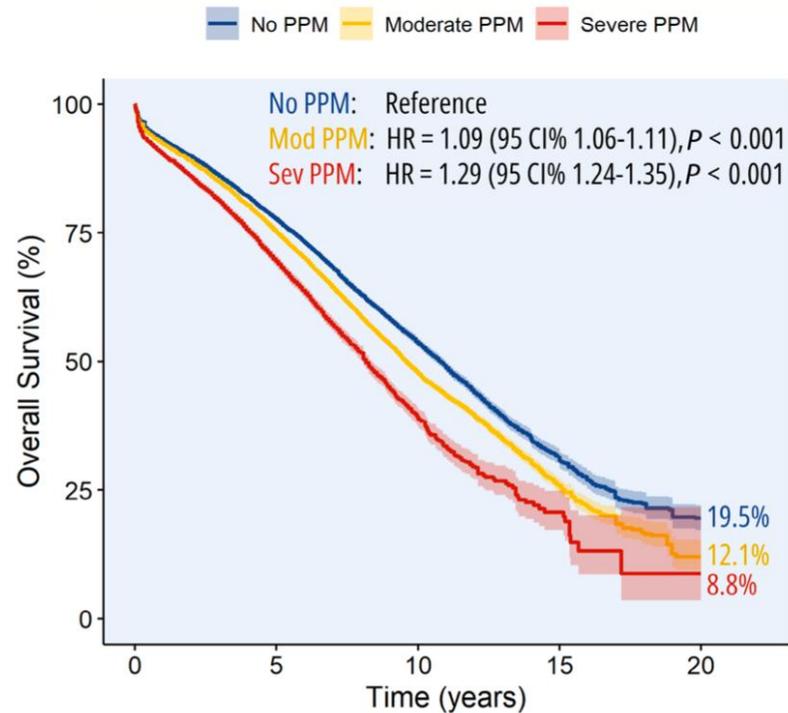
Table 3 Multivariable predictors of bioprosthetic valve calcification

	OR	95% CI	p Value
Age (per 1 year increment)	0.96	0.92 to 1.01	0.1
Time interval since BPV implantation (per 1 year increment)	1.16	1.05 to 1.29	0.003
Calcium–phosphorus product (per 0.1 increment)	1.11	1.01 to 1.23	0.02
Prosthesis–patient mismatch	3.67	1.25 to 10.6	0.01

BPV, bioprosthetic valve.

Impact du mismatch sévère sur la mortalité

Meta-analysis - SAVR

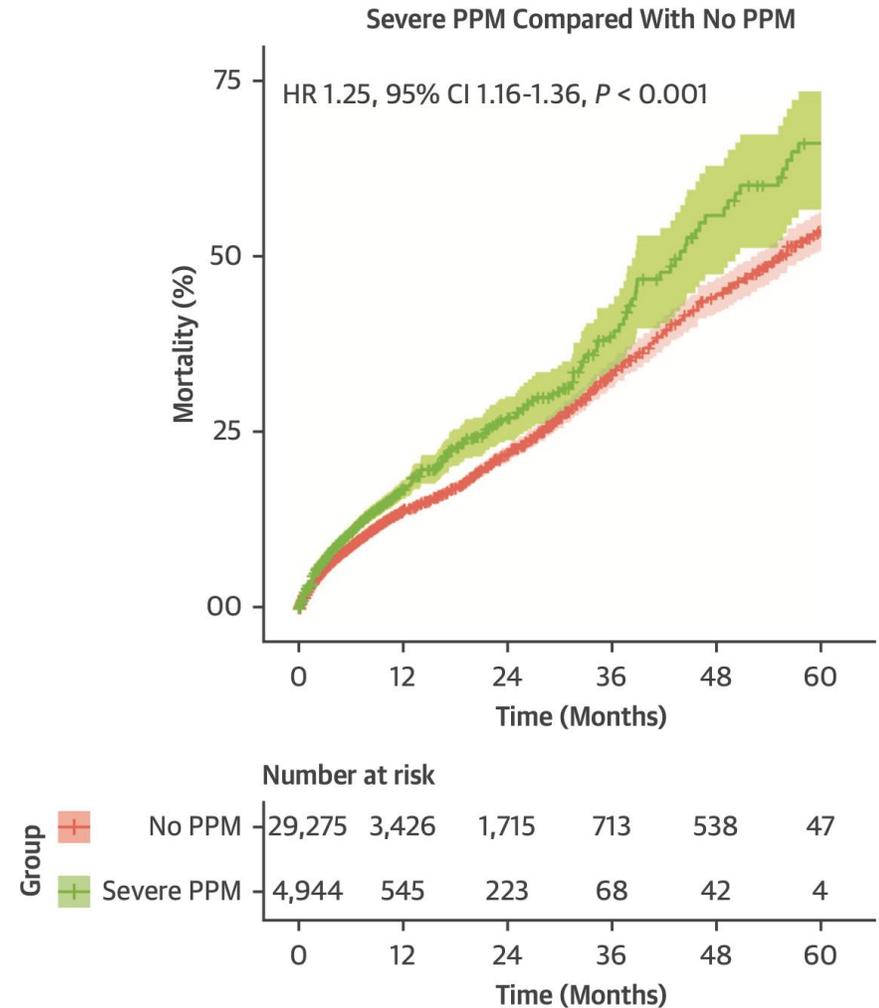


Number at risk

Time (years)	0	5	10	15	20
No PPM	39587	14536	3071	368	76
Moderate PPM	51841	21738	4083	306	17
Severe PPM	9402	3664	395	24	2

Sá M et al. J Am Heart Assoc. 2024;13:e033176.

Meta-analysis - TAVR



Number at risk

Time (Months)	0	12	24	36	48	60
No PPM	29,275	3,426	1,715	713	538	47
Severe PPM	4,944	545	223	68	42	4

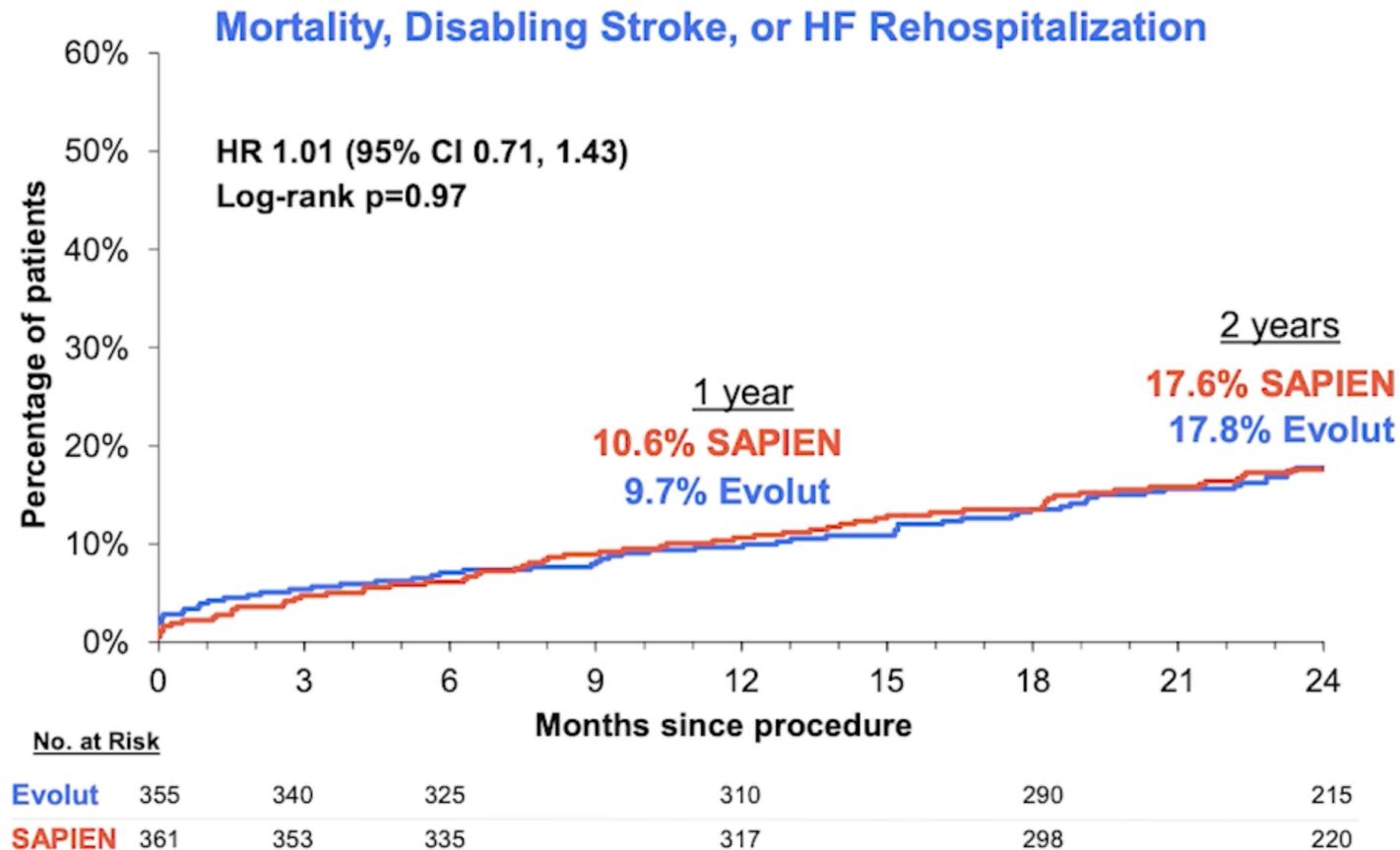
Sá M et al. J Am Coll Cardiol Img 2023;16:298–310.

Auto-expansible vs. Ballon-expansible dans les petits anneaux

Pas d'impact clinique à 2 ans

SMART trial

Clinical outcome composite & components through 2 years



5-Year Results of the Randomized SOLVE-TAVI Trial

447 intermediate- to high-risk pts with symptomatic aortic stenosis



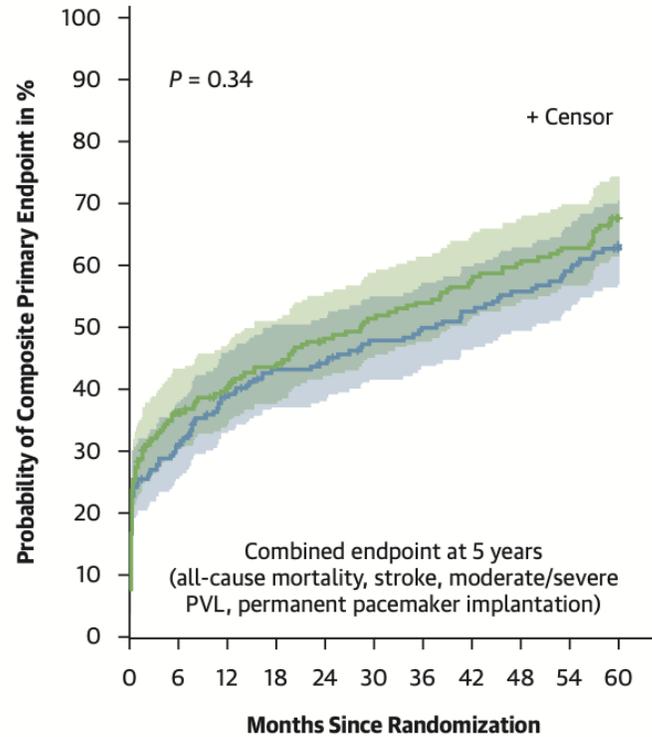
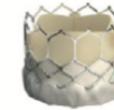
Symptomatic Aortic Stenosis With TAVR Indication



SEV

Valve Strategy

BEV



Endpoint	HR (95% CI)
Composite Primary Endpoint	0.89 (0.70-1.13)
All-Cause Mortality	0.98 (0.74-1.29)
Stroke	4.84 (1.65-14.18)
Moderate/Severe PVL	0.64 (0.30-1.37)
Permanent Pacemaker	0.75 (0.52-1.08)

Favors BEV 0.5 0.7 1 1.4 2 Favors SEV

— BEV 218 149 125 114 110 98 94 89 83 77 37
 — SEV 218 133 120 111 99 93 88 80 75 71 29

BEST Study

Patients eligible to percutaneous transfemoral TAVI either with BE-valve or SE-valve

1862 Patients 1:1

n=1989; completed enrollment Oct 2024

BE-Valve
N=931

Versus

SE-Valve
N=931

Stratification sur anatomie (BAV vs TAV)



Primary endpoint : all-cause death at 90 days

Secondary endpoints including all-cause death at 12 months

Suivi à 10 ans



PHRC-N 2020



Take Home Message

- La durabilité des prothèses TAVI est une question essentielle au moment où l'espérance de vie des patients implantés augmente.
- Plus de 20 ans après l'implantation du premier TAVI, la durabilité de ces prothèses est éprouvée et semble au moins similaire aux prothèses chirurgicales.
- Des études comparant les prothèses TAVI de nouvelles générations et utilisant les définitions standardisées VARC-3 (SVD & BVF) sont en cours avec des suivis prévus à très long-terme (SMART, BEST).

Merci !

cedric.delhaye@chru-lille.fr