Valve durability: in favor of Self-expandable valves

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Initial thoughts

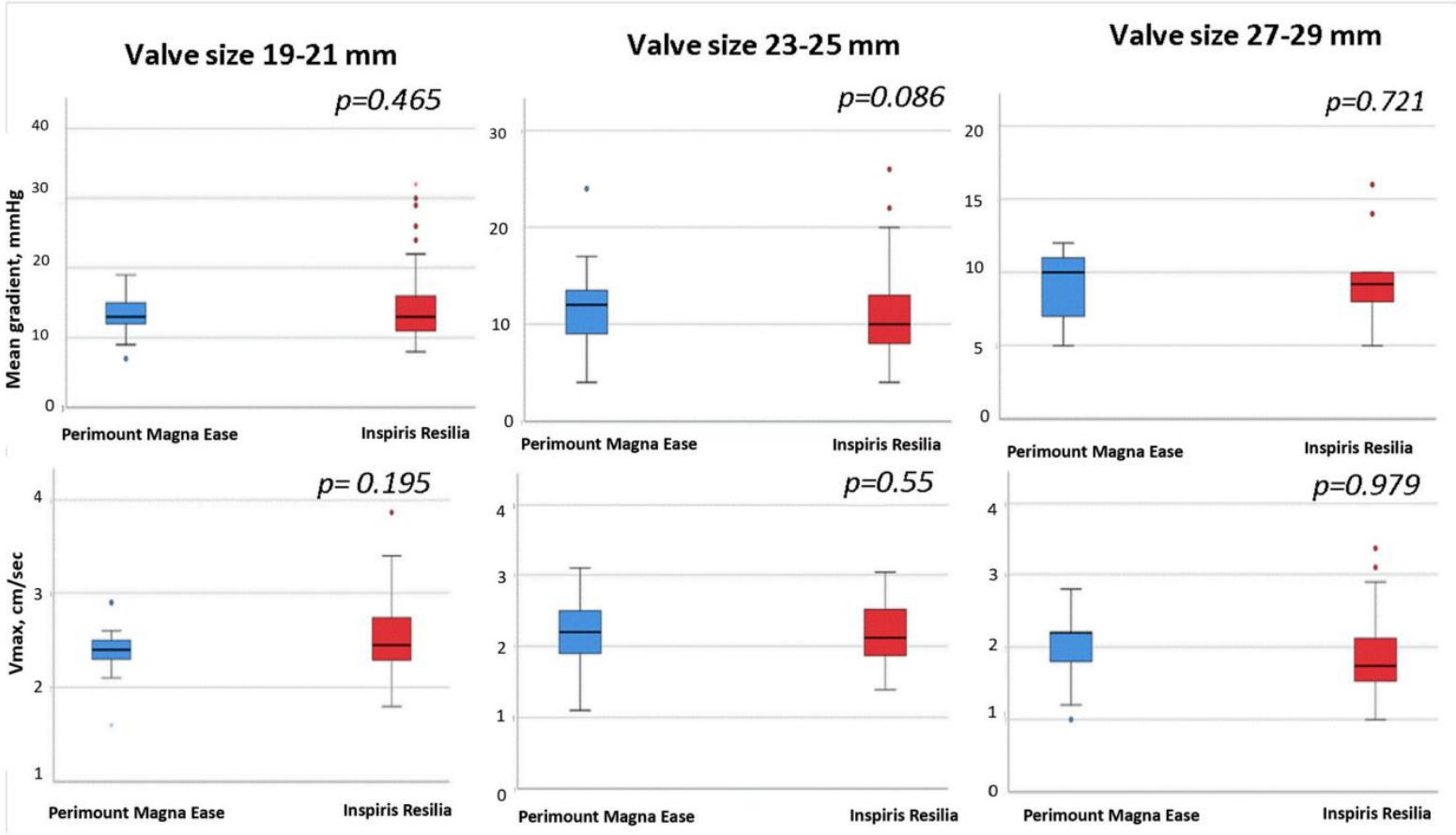
- Durability is crucial for clinical outcome after biological aortic valve implantation.
- Its importance is increasing as patients referred to TAVR are younger (goal: 20 instead of 10 years).
- For years, surgical series have used reoperation as a marker of valve failure → underestimation of valve failure.
- Durability of TAVI seems to be at least (or even longer) than SAVR

Differences among devices

Characteristic	Implications
Mechanism of expansion (balloon vs self)	Risk of PVL and annulus rupture
Position of leaflets (intra- vs supra-annular)	Valve haemodynamics and others
Repositionable vs no repositionable	Precision of implantation
Retrievable vs no retrievable	Precision of implantation
Short vs tall	Coronary obstruction, coronary access
Material of stent (Co-Cr, Co-Ni, nitinol, polymer)	PVL
Radial force	PVL
Presence of out-skirt	PVL
Material of leaflets (bovine vs porcine pericardium)	Iliofemoral requirements, durability?
Delivery system size	Iliofemoral requirements
Flexibility of delivery system	Vascular complications, ease of implantation
Range of sizes available	Range of aortic annulus
Others: need for pre- and post-dilatation, visibility, intermediate sizes	Sizing precision

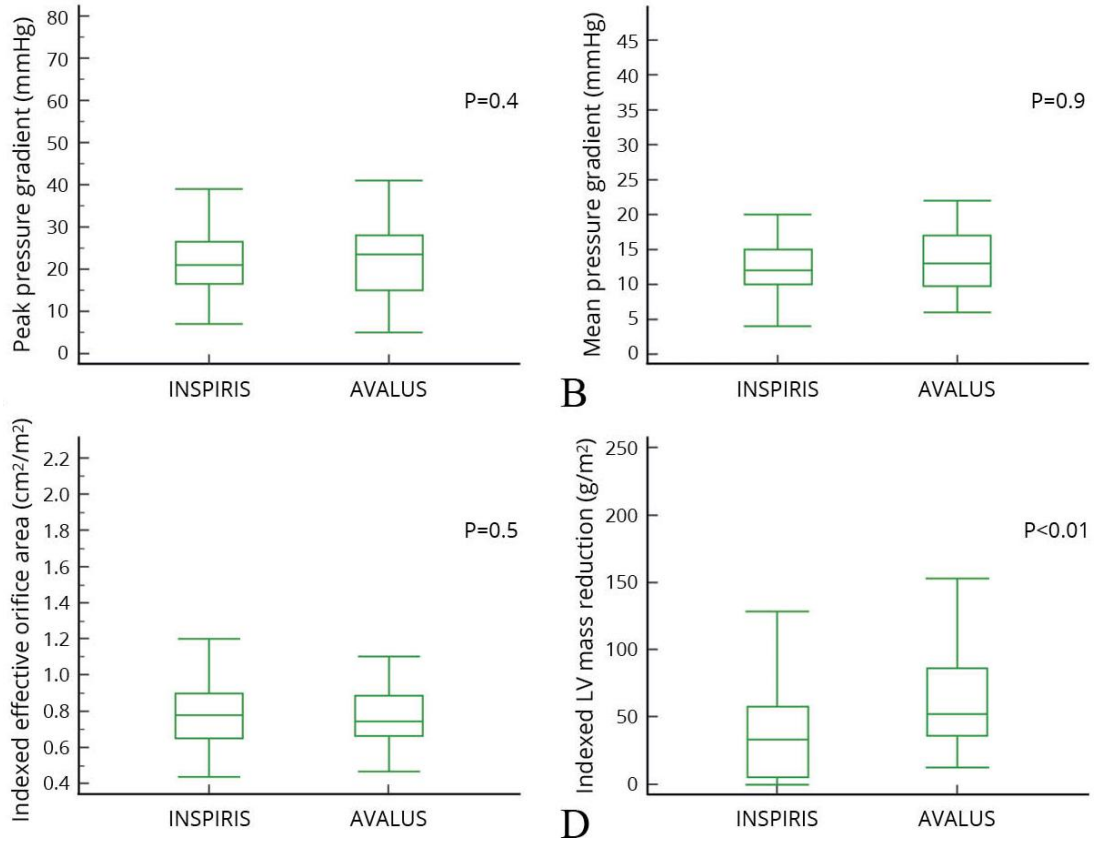
Article

Perimount MAGNA Ease vs. INSPIRIS Resilia Valve: A PS-Matched Analysis of the Hemodynamic Performances in Patients below 70 Years of Age



Francica A, et al. Perimount MAGNA Ease vs. INSPIRIS Resilia Valve: A PS-Matched Analysis of the Hemodynamic Performances in Patients below 70 Years of Age. J Clin Med. 2023;12:2077.

Two innovative aortic bioprostheses evaluated in the real-world setting. First results from a two-center study



Chiariello GA, et al; AVARIS Registry. Two innovative aortic bioprostheses evaluated in the real-world setting. First results from a two-center study. J Cardiovasc Surg. 2023;64:338-347.

Ann Thorac Cardiovasc Surg 2024: 30; 22-00083

Online August 23, 2022
doi: 10.5761/atcs.cr.22-00083

Case Report

A Case of TAV-in-SAV in a Patient with Structural Valve Deterioration after Surgical Aortic Valve Replacement with the INSPIRIS RESILIA Valve

...da, Koichi Maeda, Kazuo Shimamura, Kizuku Yamashita, Ai Kawamura,
...d Shigeru Miyagawa

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Congenital & Pediatric: Research

0003-4975/$36.00
https://doi.org/10.1016/j.athoracsur.2022.09.026

Early Concerning Outcomes for the Edwards Inspiris Resilia Bioprosthesis in the Pulmonary Position

Check for updates

Sameh M. Said, MBBCh, MD,[1,2] Gurumurthy Hiremath, MD,[3] Varun Aggarwal, MBBS,[3] John Bass, MD,[3] Sandeep Sainathan, MD,[4] Mahmoud I. Salem, MD,[5] and Shanti Narasimhan, MBBS[3]

> Cardiovasc Interv Ther. 2023 Jul;38(3):358-359. doi: 10.1007/s12928-023-00923-0. Epub 2023 Mar 15.

Bioprosthetic valve failure of the Inspiris Resilia valve during transcatheter valve implantation

Yoshikuni Kobayashi [1], Kazuaki Okuyama [2], Shingo Kuwata [2], Masashi Koga [2], Masaki Izumo [2], Yoshihiro Johnny Akashi [2]

European Journal of Cardio-Thoracic Surgery 2022, 62(2), ezac394
https://doi.org/10.1093/ejcts/ezac394 Advance Access publication 25 July 2022

...e this article as: Mehdiani A, Chekhoeva A, Klein K, Lichtenberg A. The first report of transcatheter aortic valve-in-valve im...
...nspiris Resilia® bioprosthetic valve. Eur J Cardiothorac Surg 2022; doi:10.1093/ejcts/ezac394.

The first report of transcatheter aortic valve-in-valve implantatio within the expandable Inspiris Resilia® bioprosthetic valve

Arash Mehdiani [a], Agunda Chekhoeva [a,*], Kathrin Klein[b] and Artur Lichtenberg [a]

Balloon vs Self-expandable

BALLOON-EXPANDABLE

Lotus

DirectFlow

Myval

Sapien

SELF-EXPANDABLE

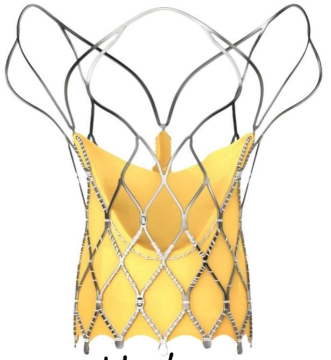
Jenavalve

Navitor

Evolut

Acurate

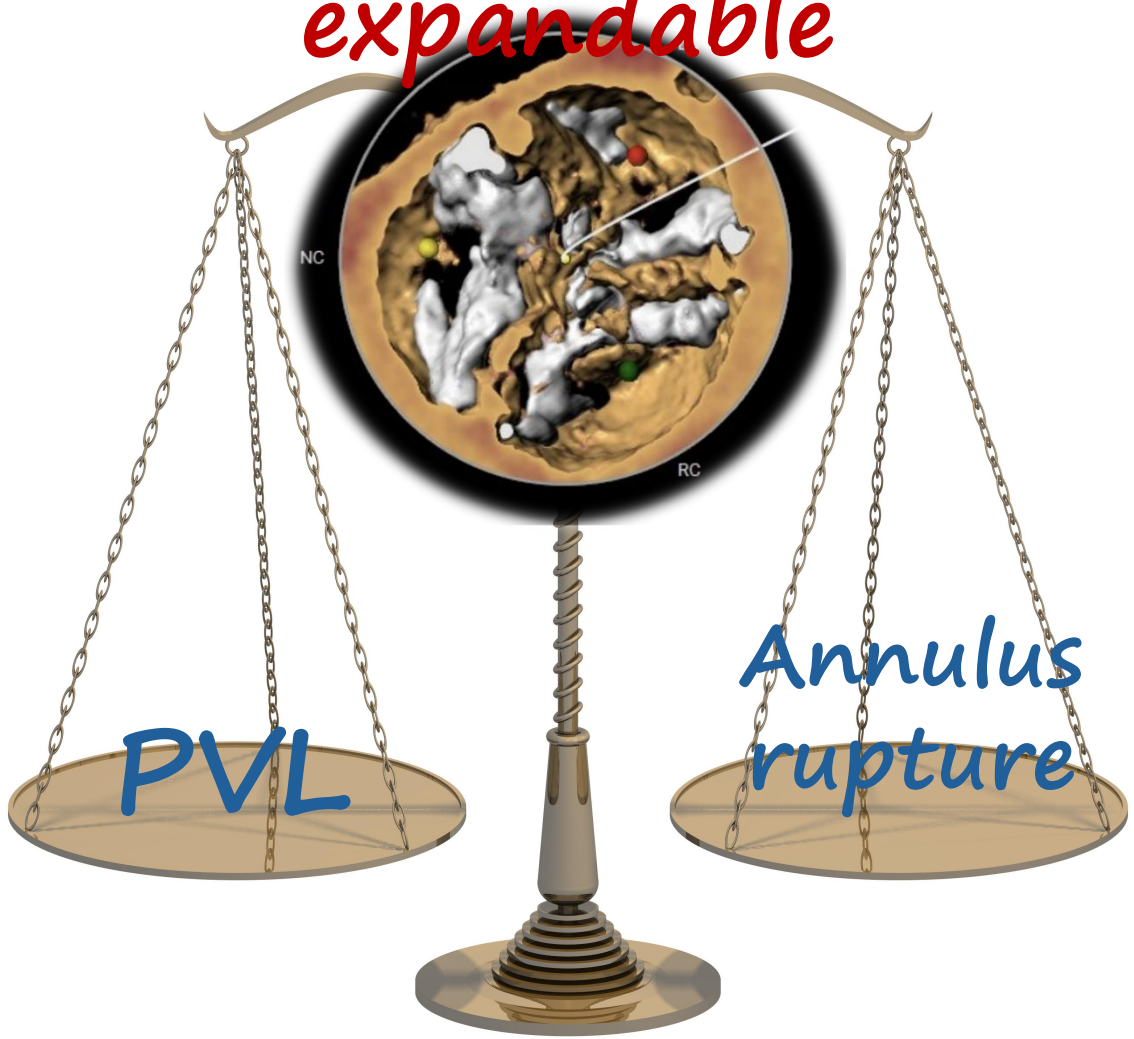
Allegra



Hydra

Vitaflow

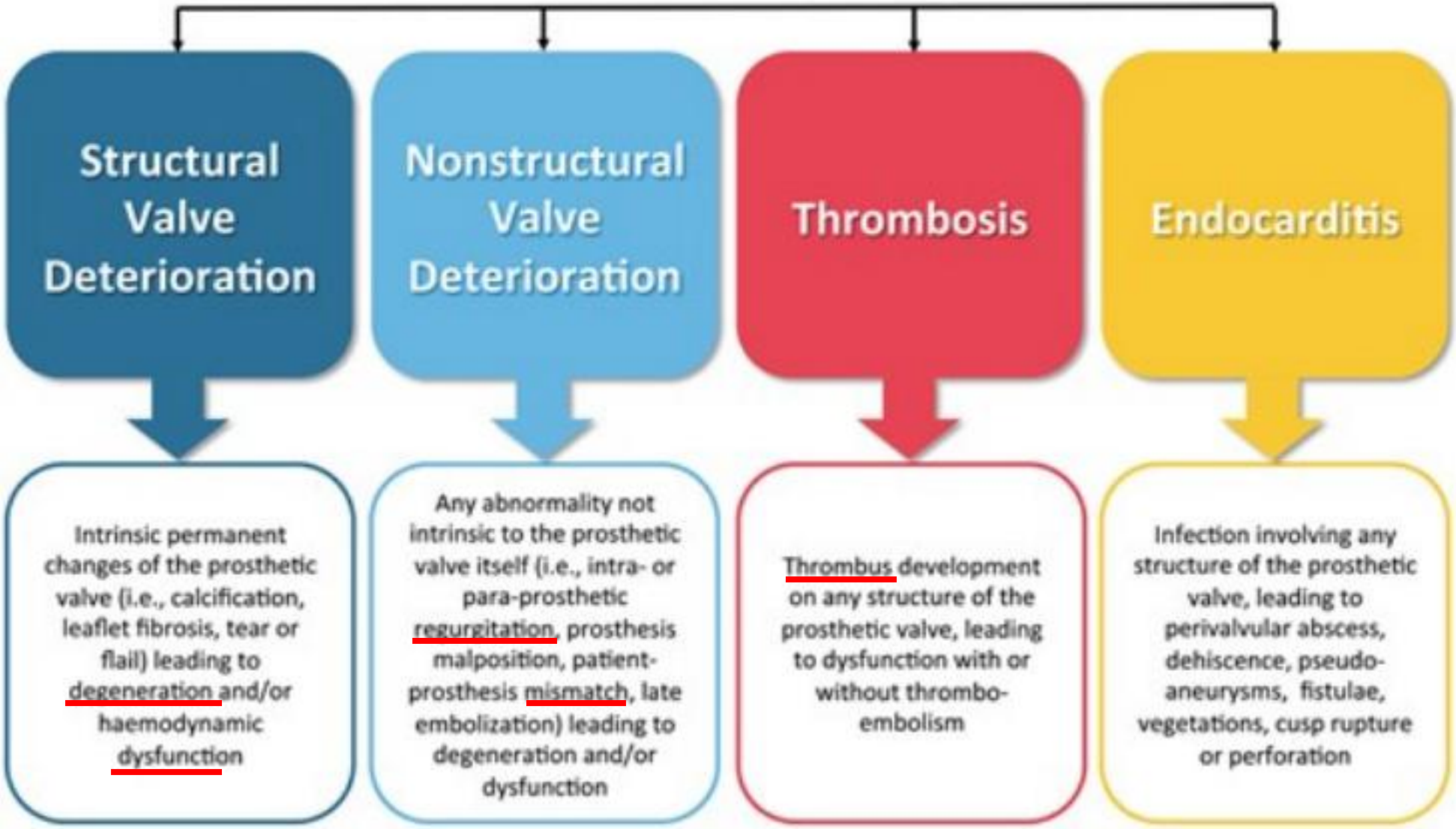
Balloon vs Self-expandable



Intra- vs supra-annular

Haemodynamics (trans-valvular gradients & effective orifice área)

Bioprosthetic Valve Dysfunction

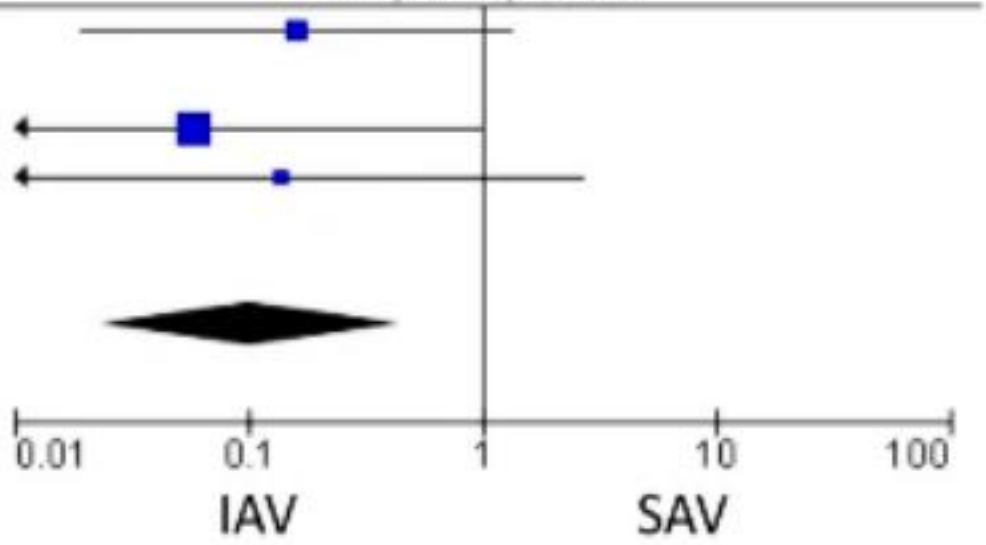


Valve thrombosis in intra-annular vs supra-annular TAV

A

Study or Subgroup	Experimental Events	Total	Control Events	Total	Weight	Odds Ratio M-H, Fixed, 95% CI
CHOICE	1	120	6	121	29.0%	0.16 [0.02, 1.36]
ELECT	0	27	0	29		Not estimable
REPRISE-III	0	305	16	607	53.9%	0.06 [0.00, 0.98]
SCOPE-I	0	358	3	355	17.2%	0.14 [0.01, 2.73]
SOLVE-TAVI	0	219	0	219		Not estimable
Total (95% CI)		**1029**		**1331**	**100.0%**	**0.10 [0.02, 0.45]**
Total events	1		25			

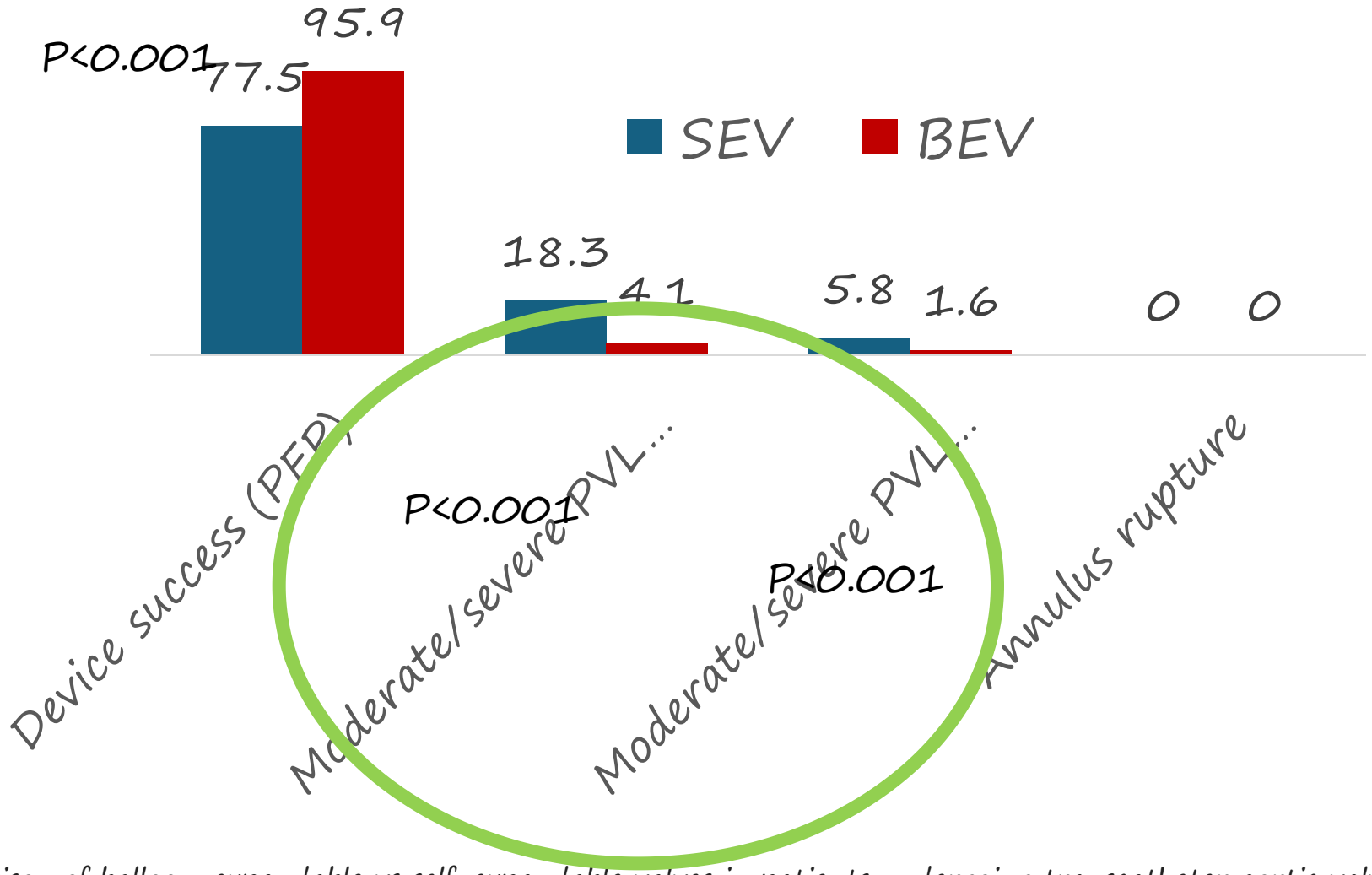
Heterogeneity: Chi² = 0.37, df = 2 (P = 0.83); I² = 0%
Test for overall effect: Z = 3.01 (P = 0.003)



Moreno R, et al. The risk of valve thrombosis is higher with intra-annular versus supra-annular transcatheter aortic valve prosthesis. A meta-analysis from randomized controlled trials. Clin Res Cardiol. 2021 Dec;110(12):2007-2009.

CHOICE trial

(241 patients randomized to BEV vs SEV)



Abdel-Wahab M, et al. Comparison of balloon-expandable vs self-expandable valves in patients undergoing transcatheter aortic valve replacement: the CHOICE randomized clinical trial. JAMA. 2014;311:1503-14.

SOLVE-TAVI: 5 yr FU

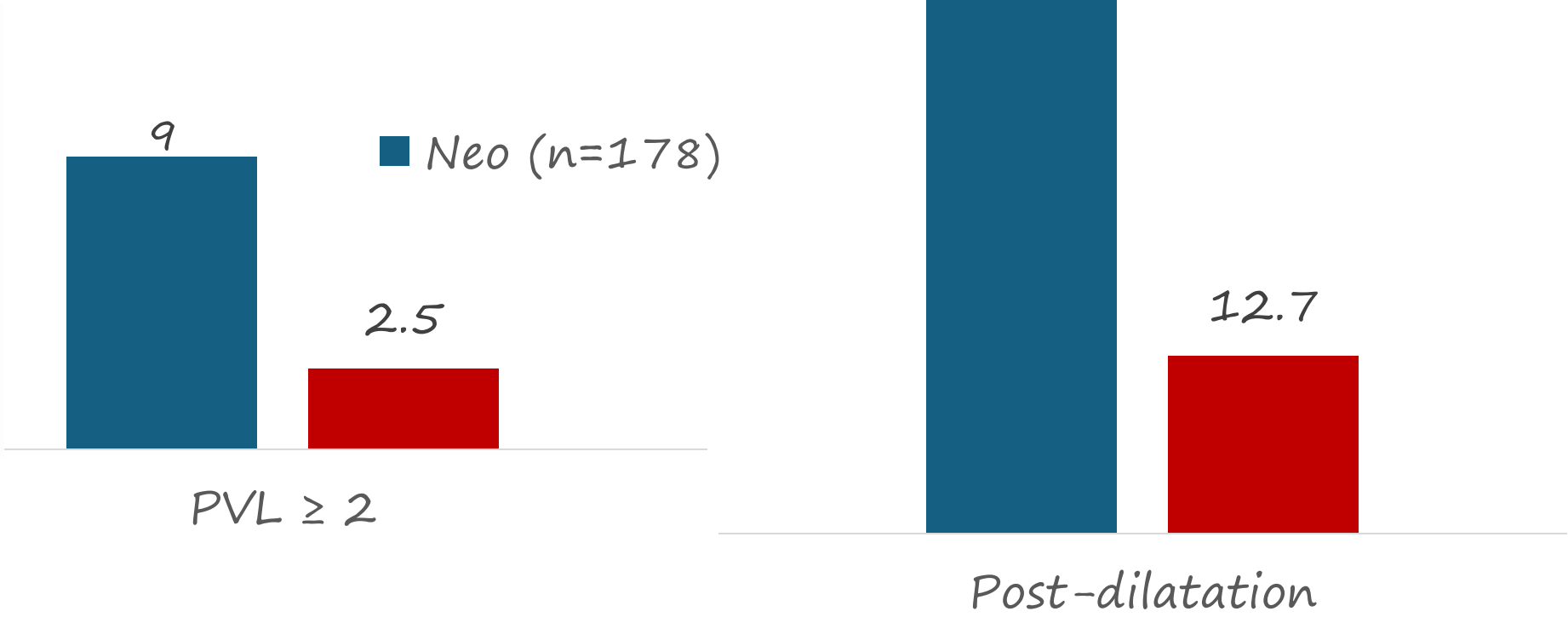
	SEV	BEV		Cause specific HR (95% CI)
	n (%)	n (%)		
Composite endpoint*	140 (67.7)	131 (63.4)	0.34	0.89 (0.70-1.13)
All-cause mortality	97 (48.5)	94 (47.6)	0.87	0.98 (0.74-1.30)
Stroke	4 (4.8)	19 (15.5)	0.001	5.04 (1.73-14.71)
Moderate/severe PVL	17 (9.0)	11 (5.8)	0.25	0.65 (0.30-1.37)
Permanent pacemaker implantation	63 (29.6)	49 (22.8)	0.12	0.75 (0.52-1.08)

*Composite of all-cause mortality, stroke, moderate/severe PVL, and permanent pacemaker implantation

Feistritzer HS. Impact of valve-type and anaesthesia strategy. 5-year follow-up of the SOLVE-TAVI trial. EuroPCR 2024.

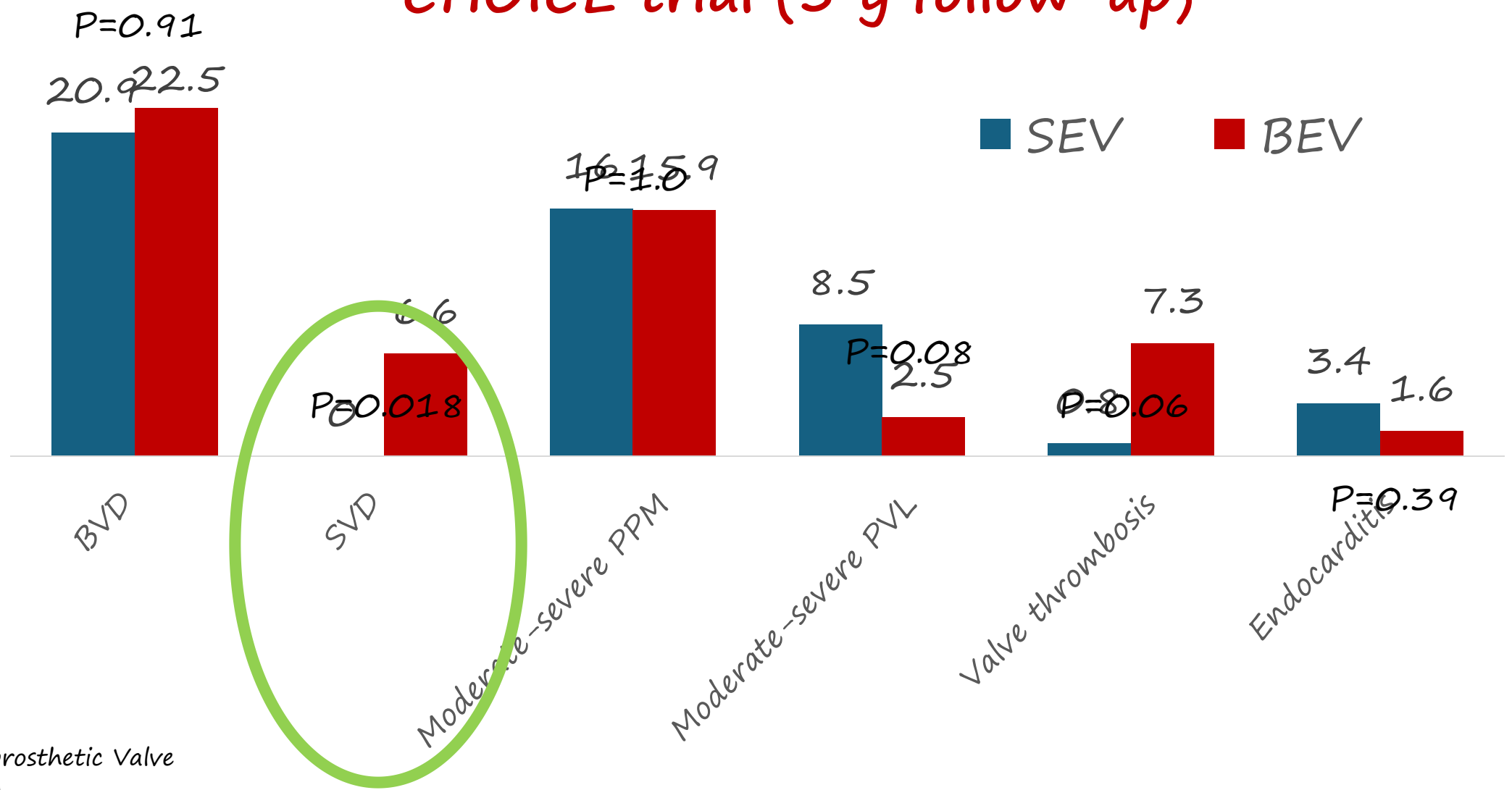
PRECISA study

(Prospective Evaluation Complementing the Investigation with Acurate Neo Device) Clinicaltrials no. NCT03846557



Tébar D, et al. Experience with the ACURATE neo and neo2 transcatheter aortic valves in Spain. The PRECISA (PRospective Evaluation Complementing Investigation with ACURATE devices) registry. Catheter Cardiovasc Interv. 2024;103:1015-1022.

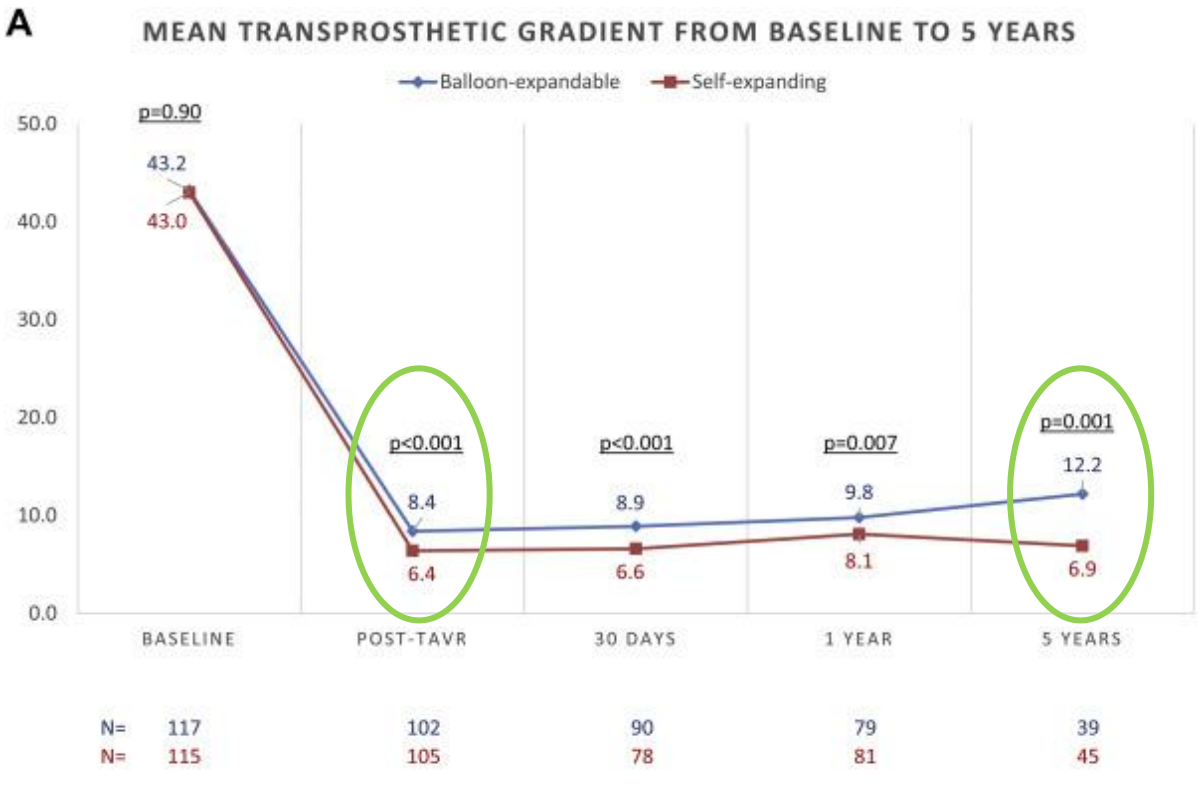
CHOICE trial (5 y follow-up)

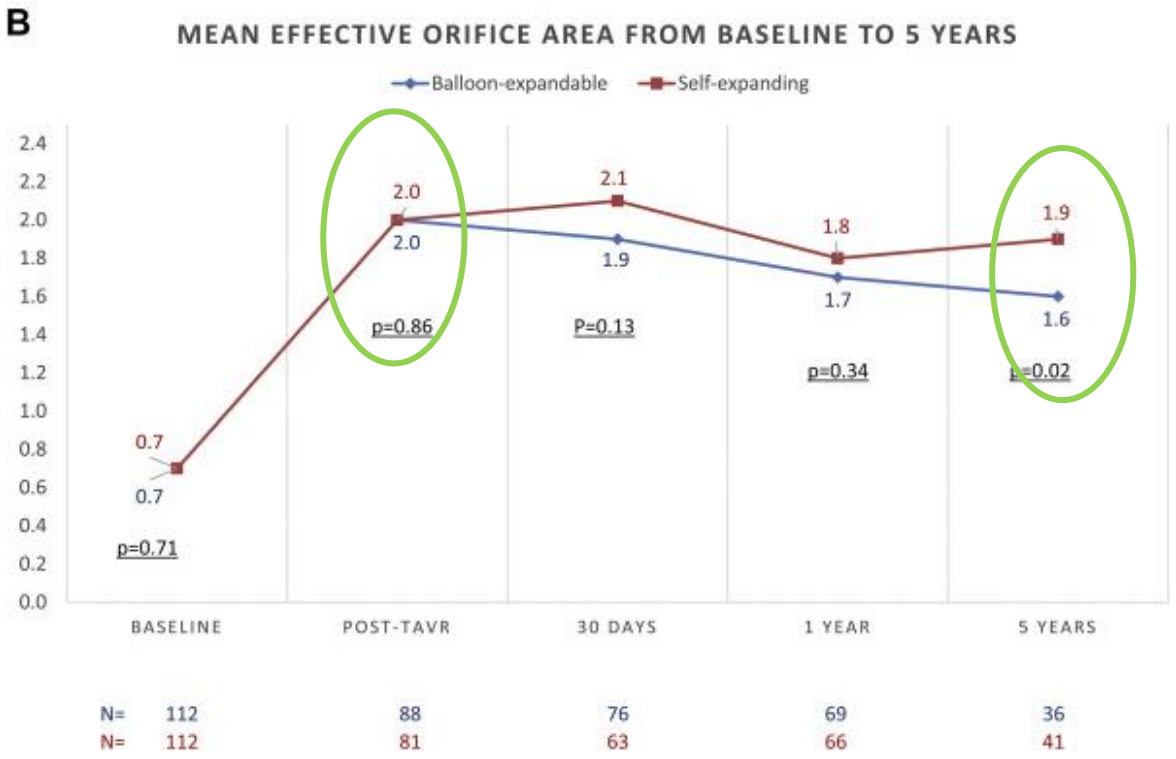


BVD = Bioprosthetic Valve Dysfunction
SVD: Structural valve deterioration.

Abdel-Wahab M, et al. 5-Year Outcomes After TAVR With Balloon-Expandable Versus Self-Expanding Valves: Results From the CHOICE Randomized Clinical Trial. JACC Cardiovasc Interv. 2020 May 11;13(9):1071-1082.

CHOICE trial (5 y follow-up)





Abdel-Wahab M, et al. 5-Year Outcomes After TAVR With Balloon-Expandable Versus Self-Expanding Valves: Results From the CHOICE Randomized Clinical Trial. JACC Cardiovasc Interv. 2020 May 11;13(9):1071-1082.

Meta-Analysis of 3rd Generation BEV vs. SEV (16 Studies; 10,174 Patients)

SAPIEN 3

SAPIEN 3 Ultra

Vs.

Evolut PRO

Evolut PRO+

No Differences in All-Cause Mortality and Heart Failure Hospitalizations

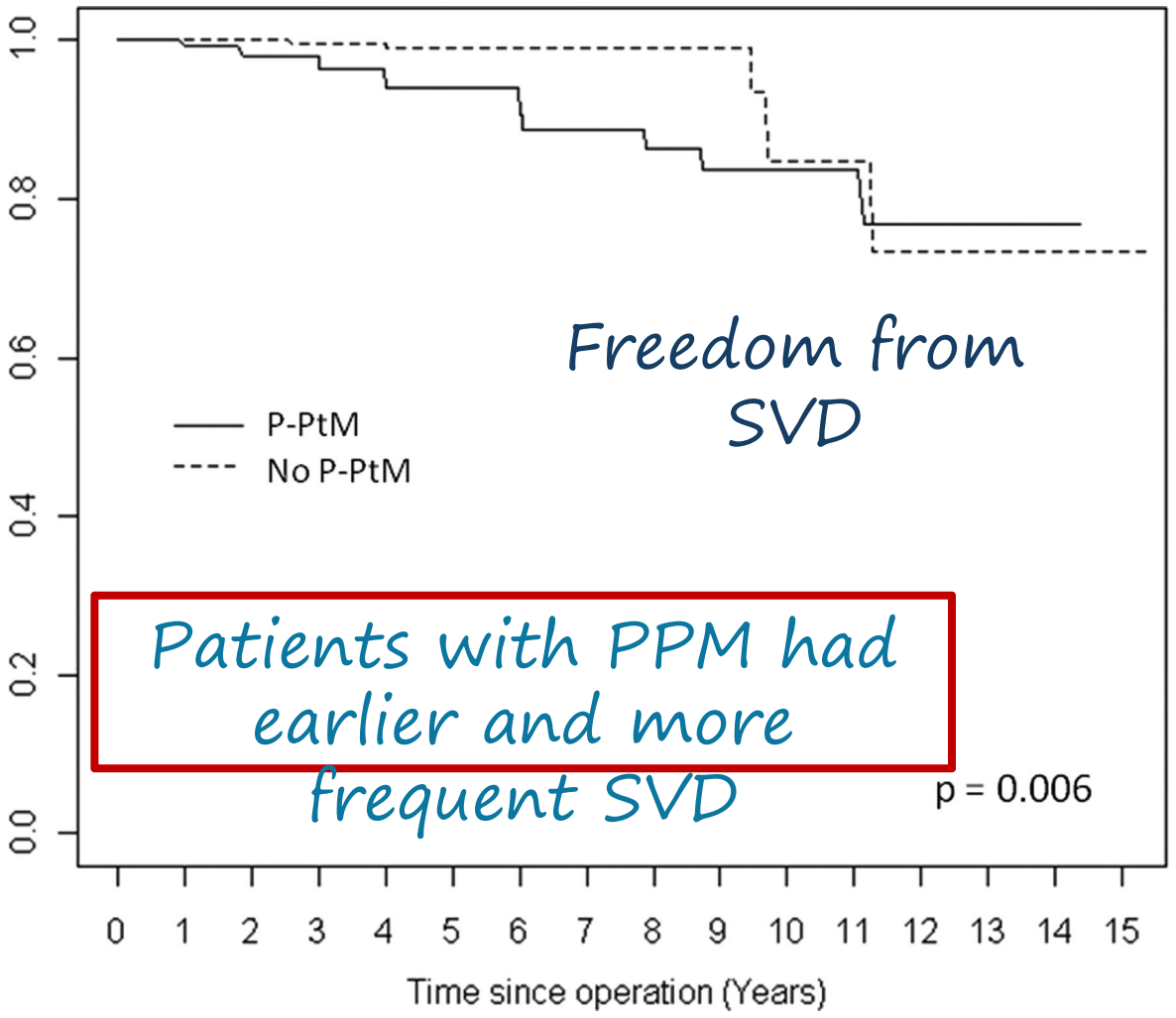
- ↓ TIA/Stroke
- ↓ Permanent Pacemaker Implantation
- ↓ Moderate or Severe PVL

- ↓ Moderate or Severe PPM
- ↓ Mean AV Gradient
- ↑ Effective Orifice Area

Siddiqui SA, et al. Outcomes of Transcatheter Aortic Valve Replacement Using Third-Generation Balloon-Expandable Versus Self-Expanding Valves: A Meta-analysis. J Soc Cardiovasc Angiogr Interv. 2024;3:102146.

Prosthesis / patient mismatch predicts SVD

- 564 patients receiving an aortic valve bioprosthesis (PPM: n=285).
- SVD: 40 (7%) at 6.1 yr mean FU.
- Patients without PPM: SVD exist only > 9 yr, and mainly as incompetence.
- Patients with PPM, SVD starts to occur after 2-3 years after SAVR and mainly as stenosis.

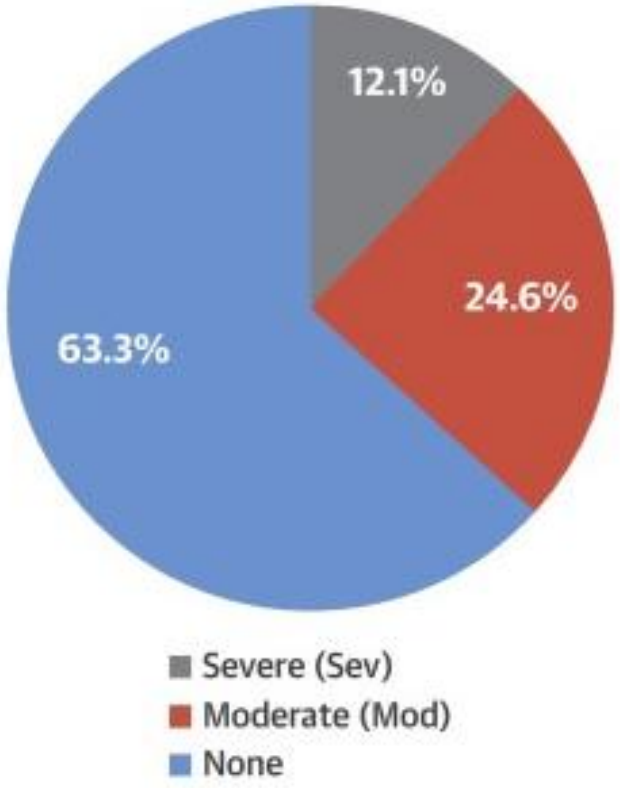


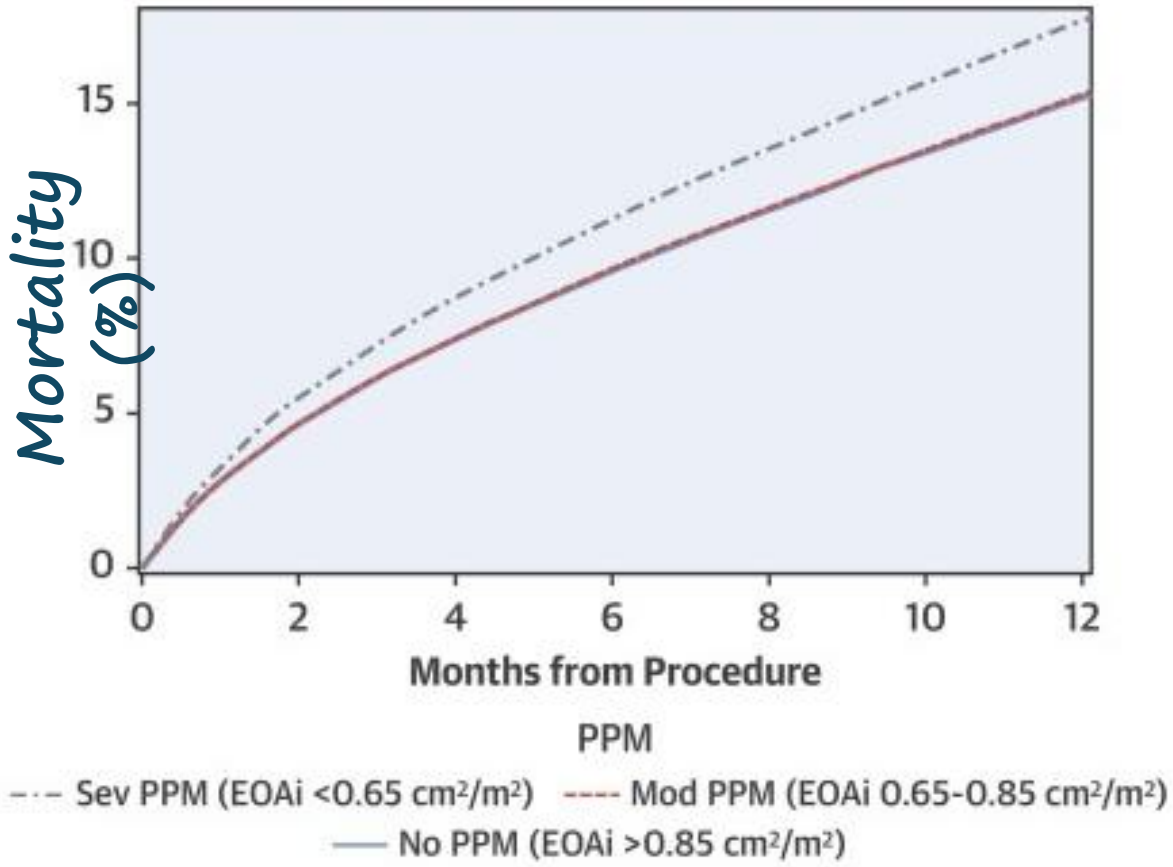
Flameng W, et al. Prosthesis-patient mismatch predicts structural valve degeneration in bioprosthetic heart valves. Circulation. 2010;121:2123-9.

Prosthesis / patient mismatch after TAVR increases mortality

62,125 TAVI patients between 2014 and 2017

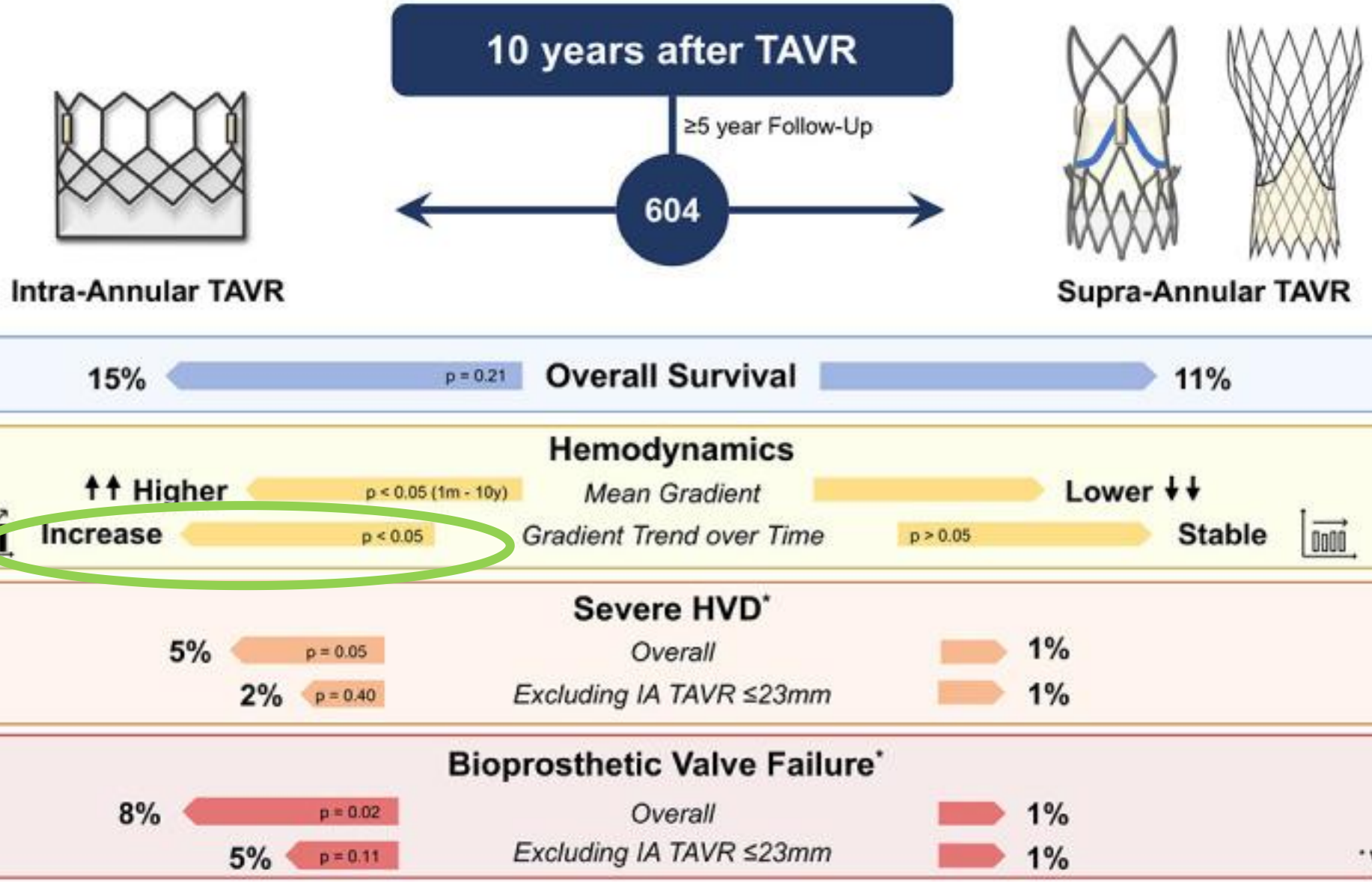
PPM





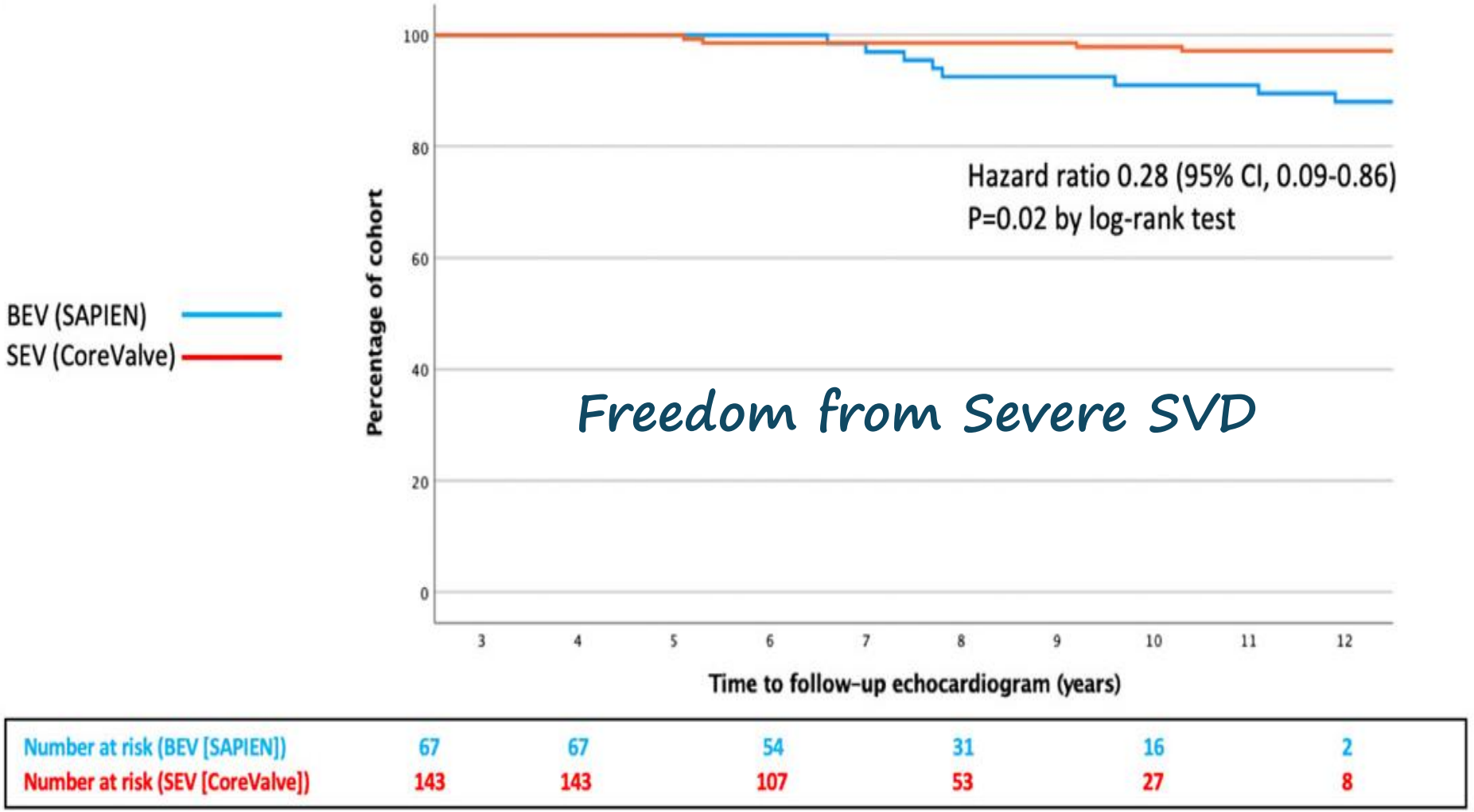
Herrmann HC, et al. Prosthesis-Patient Mismatch in Patients Undergoing Transcatheter Aortic Valve Replacement: From the STS/ACC TVT Registry. J Am Coll Cardiol. 2018;72:2701-2711.

Valve durability: self-expandable valves



Scotti A, et al. 10-Year Impact of Transcatheter Aortic Valve Replacement Leaflet Design (Intra- Versus Supra-Annular) in Mortality and Hemodynamic Performance. Front Cardiovasc Med. 2022;9:924958.

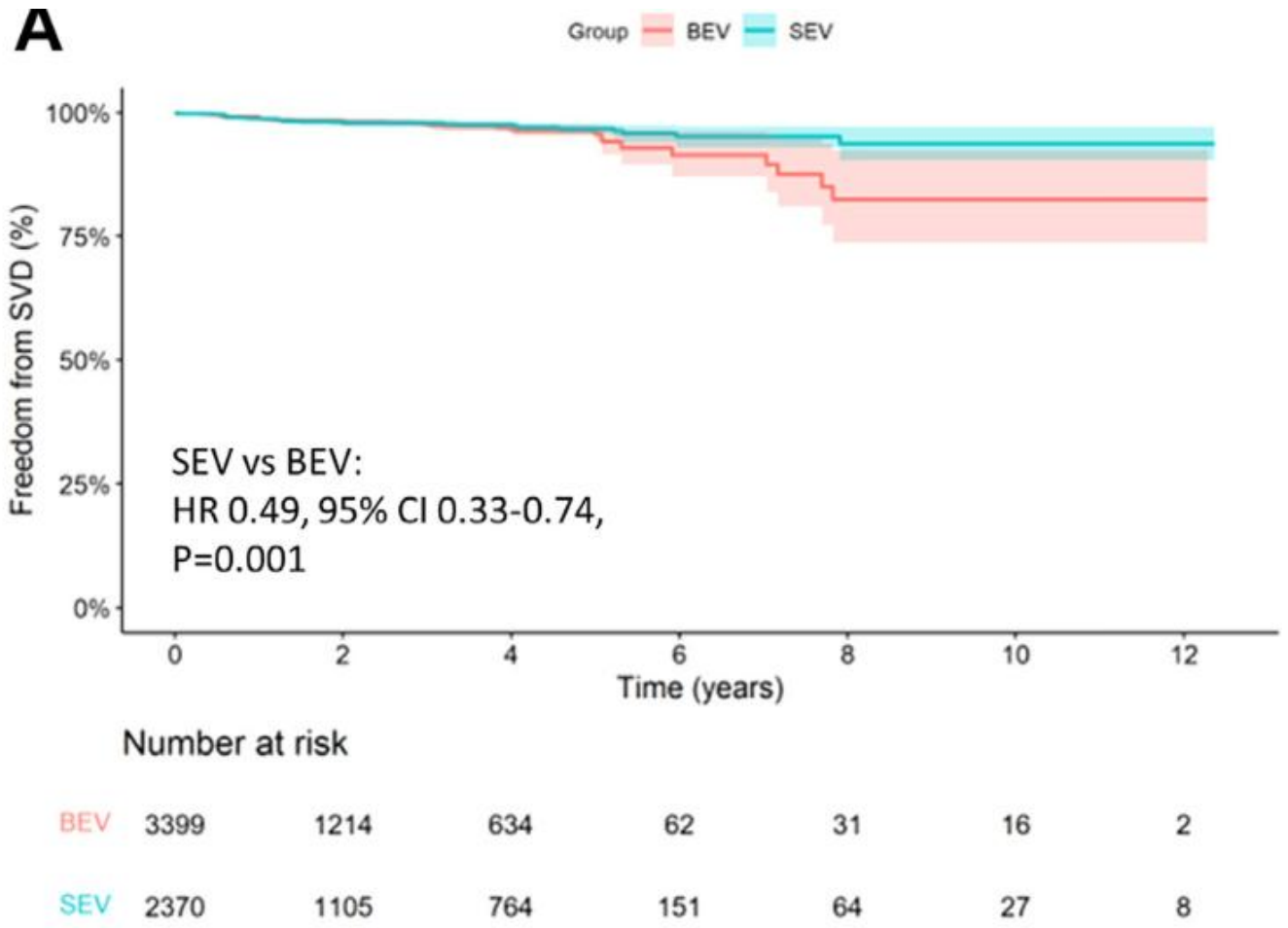
UK TAVI registry



Number at risk (BEV [SAPIEN])	67	67	54	31	16	2
Number at risk (SEV [CoreValve])	143	143	107	53	27	8

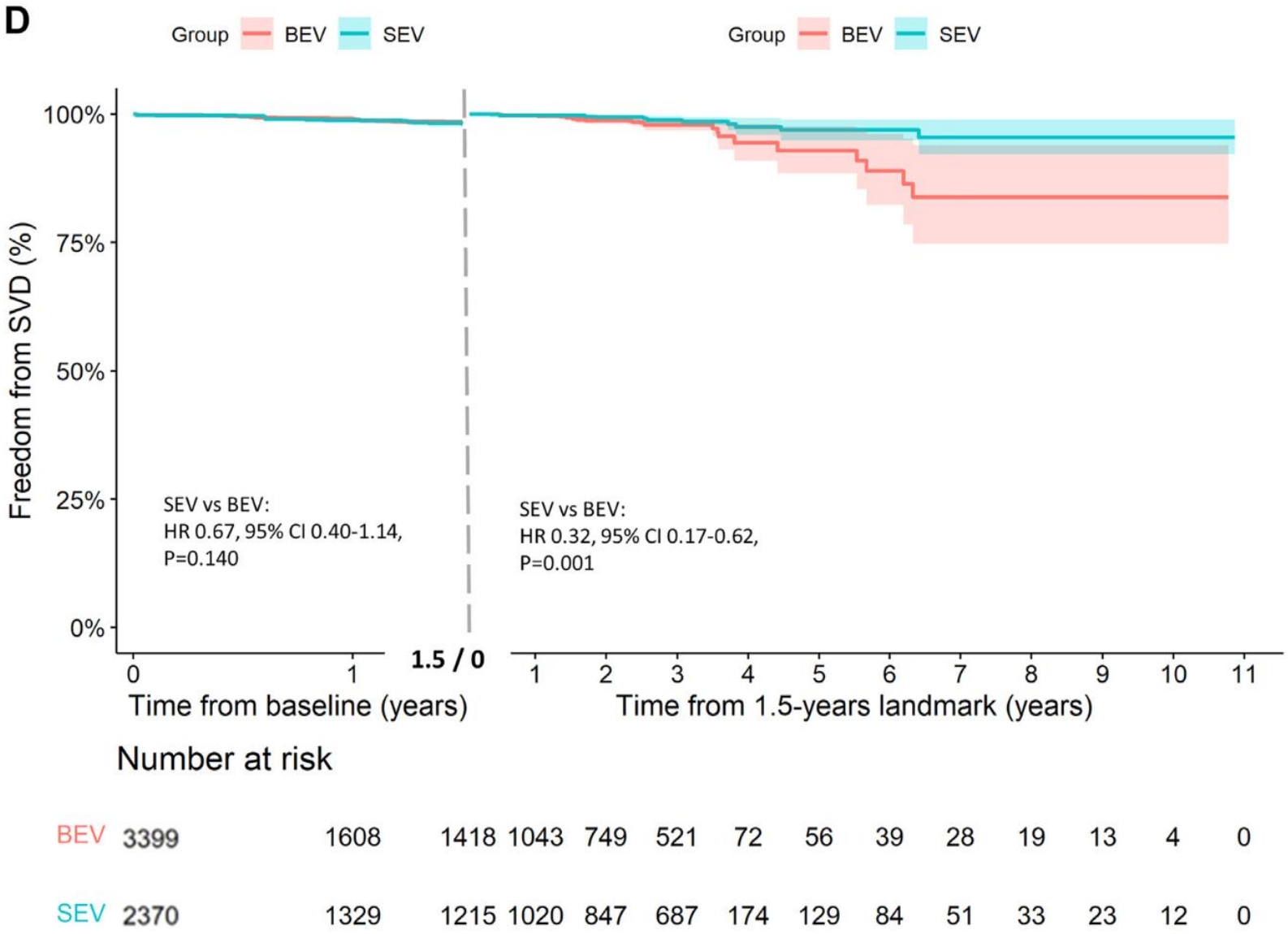
Ali N, et al. Long-term durability of self-expanding and balloon-expandable transcatheter aortic valve prostheses: UK TAVI registry. Catheter Cardiovasc Interv. 2023;101:932-942.

5769 patients (BEV: 3399 patients; SEV: 2370 patients) from 6 studies.



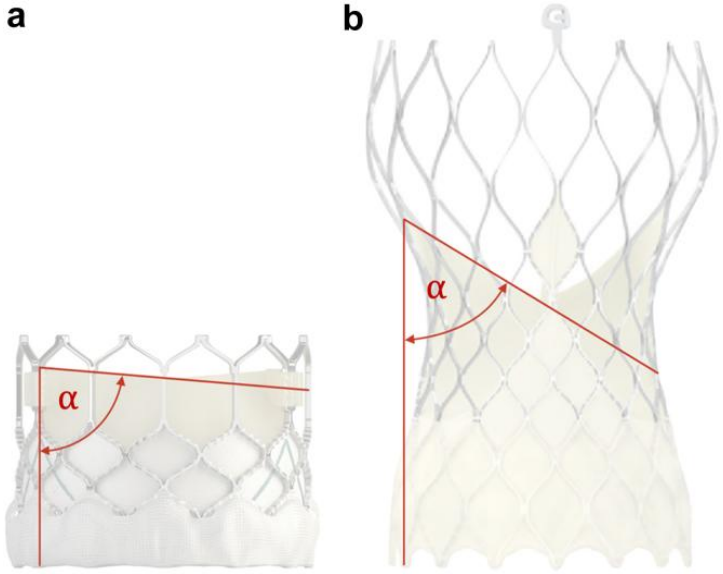
Jacquemyn X, et al. Late Outcomes After Transcatheter Aortic Valve Implantation with Balloon- Versus Self-Expandable Valves Meta-Analysis of Reconstructed Time-To- Event Data
Cardiol Clin 2024;42:373-387.

Valve durability: self-expandable valves



Jacquemyn X, et al. Late Outcomes After Transcatheter Aortic Valve Implantation with Balloon- Versus Self-Expandable Valves Meta-Analysis of Reconstructed Time-To- Event Data
Cardiol Clin 2024;42:373-387.

In vitro studies suggest that leaflet mechanical stress is higher in BEV vs supra-annular SEV



	Data			
	Self-expanding THV		Balloon expandable THV	
	Early generation CoreValve-26 mm	New generation EVOLUT PRO 26 mm	Early generation Edwards SAPIEN 23 mm	New generation SAPIEN-3 23 mm
MTPG (mmHg)	9.60 ± 0.50*†	8.70 ± 0.30*†	11.96 ± 0.10*†	10.50 ± 0.29*†
EOA (cm^2)	1.48 ± 0.02*†	1.70 ± 0.02*†	1.31 ± 0.01*†	1.57 ± 0.05*†
GOA (cm^2)	2.19 ± 0.08†	2.18 ± 0.08	2.06 ± 0.001*†	2.14 ± 0.001

Abbreviations: BE, balloon expandable; EOA, effective orifice area; GOA, geometric orifice area; MTPG, mean transprosthetic gradient; SE, self-expanding; THV, transcatheter heai valve.

*$p < 0.05$ between early vs new generation within the same type of THV.

†$p < 0.05$ between BE vs SE THV within the same generation.

Stanová V, et al. Leaflet Mechanical Stress in Different Designs and Generations of Transcatheter Aortic Valves: An in Vitro Study. Struct Heart. 2023;8:100262.

Small annulus: SMART trial

Prospective, randomized controlled, post-market trial conducted at 83 international sites
All-comer trial with all surgical risk categories including bicuspid patients

Key eligibility
- Symptomatic severe AS*
- Small aortic annulus (≤ 430 mm² by MDCT)

Randomization
1:1 stratified by site & sex

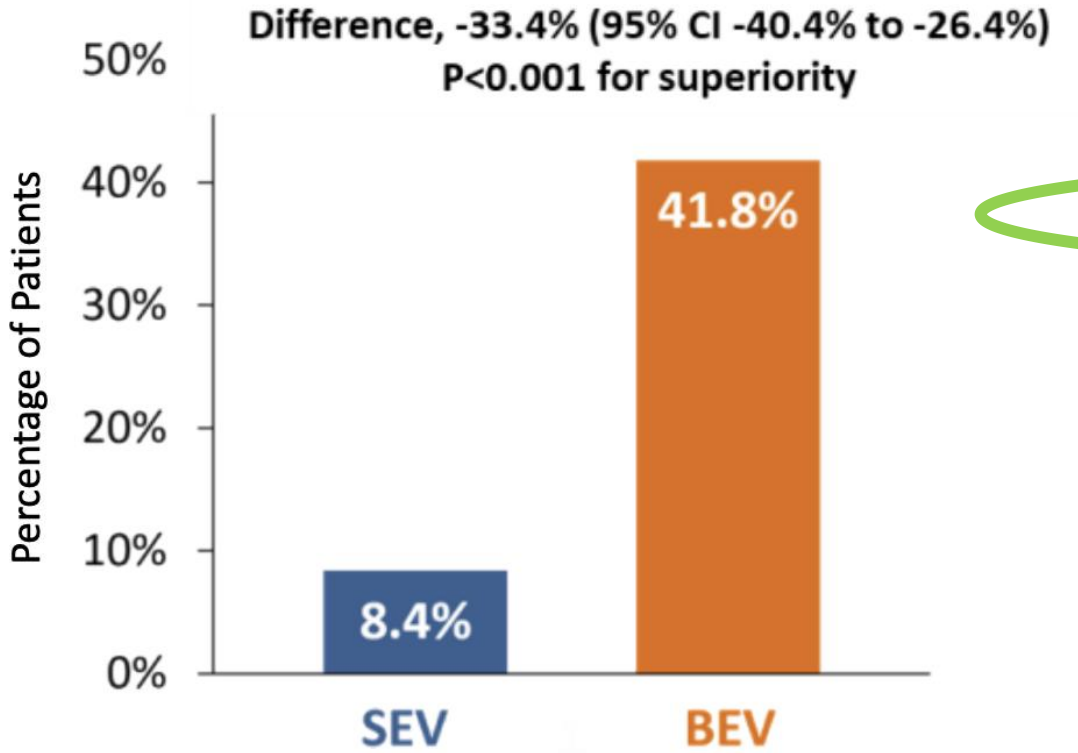
SEV (N=355)	BEV (N=361)
Medtronic Evolut PRO/PRO+/FX	Edwards SAPIEN 3/SAPIEN 3 Ultra
SEV Women (N=320)	BEV Women (N=317)

637 women randomized

*AVA ≤1.0 cm2 (AVAi ≤0.6 cm²/m²) or mean gradient ≥40 mmHg or max velocity ≥4.0 m/s; 30-day predicted risk of surgical mortality <15% by heart team assessment.

Herrmann HC, et al; SMART Trial Investigators. Self-Expanding or Balloon-Expandable TAVR in Patients with a Small Aortic Annulus. N Engl J Med. 2024;390:1858-1871

SMART trial



***BVD pre-specified powered endpoint in women for superiority**

	SEV (N=307)	BEV (N=313)	P-value
BVD composite	8.4%	41.8%	<0.001
HSVD	3.2%	32.9%	<0.001
NSVD	4.7%	17.4%	<0.001
Thrombosis	0.3%	0.3%	0.98
Endocarditis	0.3%	2.0%	0.06
AV Reinterv	0.7%	0.3%	0.54

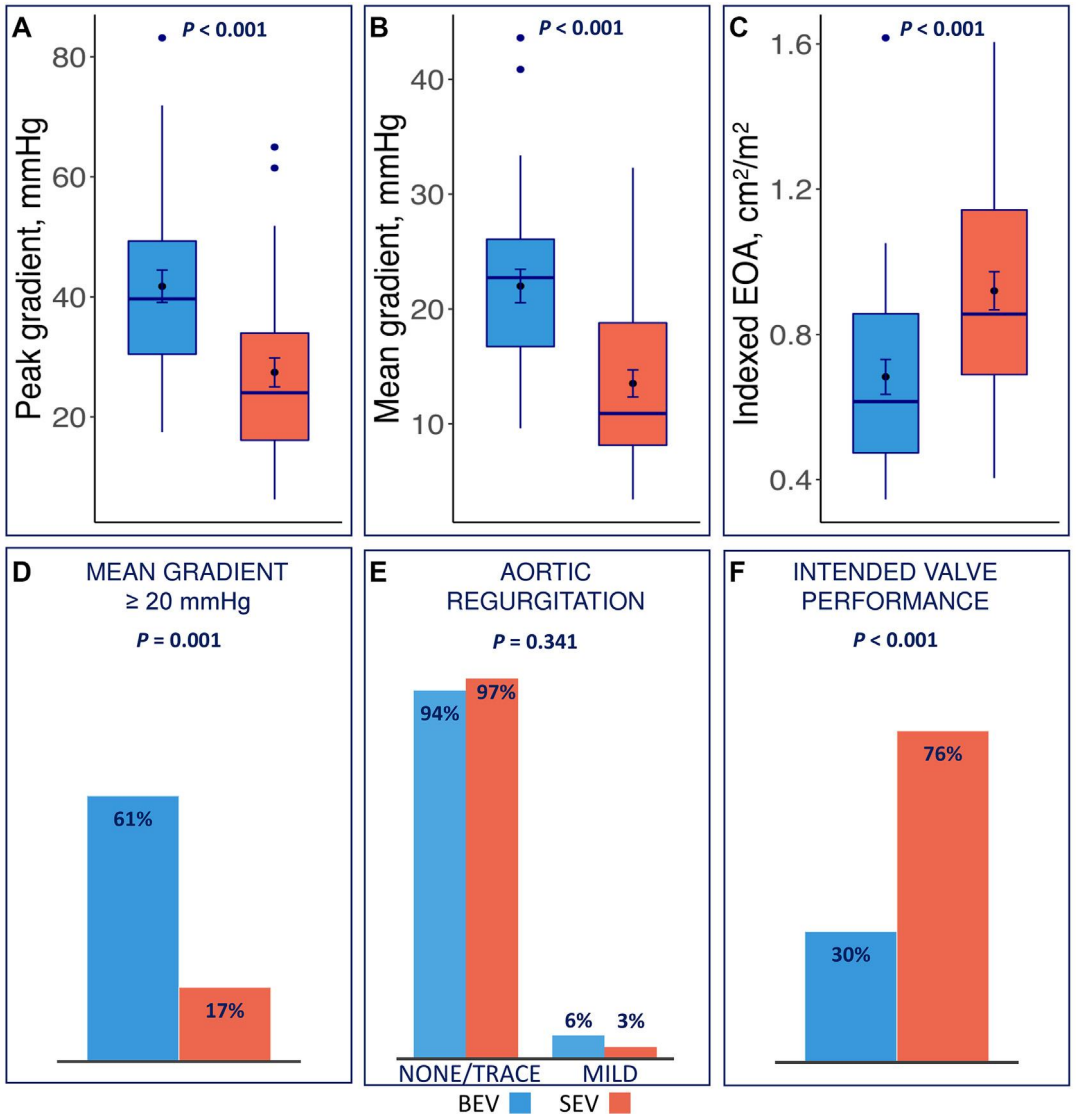
HSVD = Mean gradient ≥ 20 mmHg
NSVD = Severe PPM per VARC-3 or ≥moderate total AR

Herrmann HC, et al; SMART Trial Investigators. Self-Expanding or Balloon-Expandable TAVR in Patients with a Small Aortic Annulus. N Engl J Med. 2024;390:1858-1871.

Valve-in-valve procedures

LYTEN trial

- 98 patients with degenerated biological SAVR referred for TAVR.
- Randomized to BAV vs SEV.
- 1-year echocardiographic follow-up.

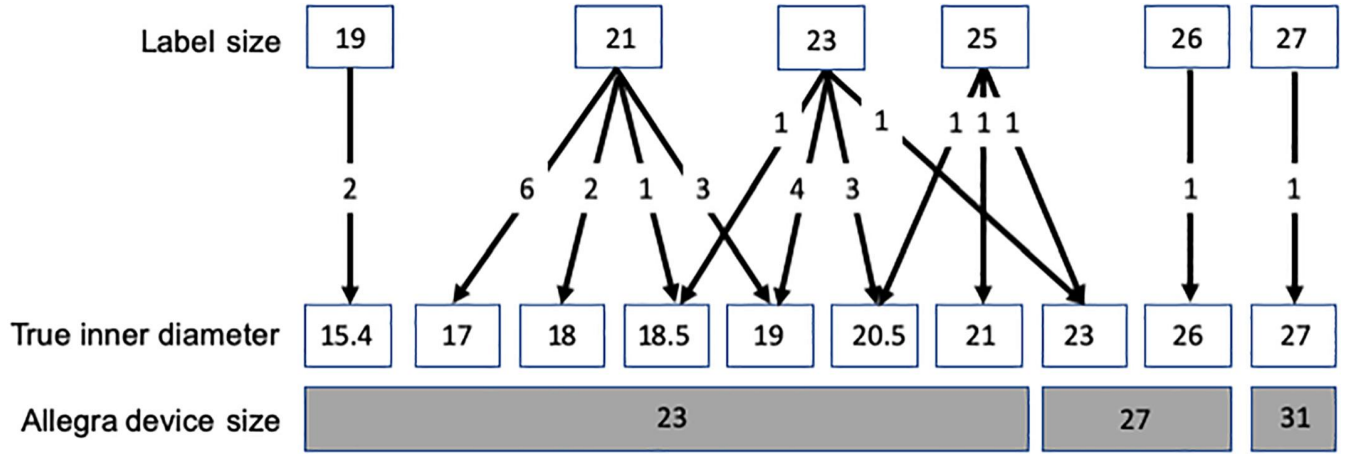


Nuche J, et al. Balloon- vs Self-Expanding Transcatheter Valves for Failed Small Surgical Aortic Bioprostheses: 1-Year Results of the LYTEN Trial. JACC Cardiovasc Interv. 2023;16:2999-3012.

Valve-in-valve procedures

SAVIV registry

29 patients undergoing VIV with Allegra device



- Post-TAVI trans-valvular gradients: 17.4 ± 12.3 and 8.4 ± 6.1 mmHg, respectively.
- Device success: 28 patients (96.6%).
- VIVAL-2 trial: ongoing (Edwards vs Allegra in VIV procedures).

Moreno R, et al. Transcatheter aortic valve implantation for degenerated aortic valves: Experience with a new supra-annular device. The Spanish Allegra valve-in-valve (SAVIV) registry. Catheter Cardiovasc Interv. 2021;98:365-370.

Self-expandable valves have better durability data:

- Less valve thrombosis.
- Less PP mismatch.
- Less SVD.

This has to be considered for valve selection in patients at younger age and/or higher risk of SVD