Valve Performance of Self-Expanding vs. Balloon-Expandable TAVR in Patients with a Small Aortic Annulus

Five-Year Results From the OCEAN-TAVI Registry

Fumiaki Yashima, MD, on behalf of the OCEAN-TAVI investigators

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Disclosure of Relevant Financial Relationships

Within the prior 24 months, I have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

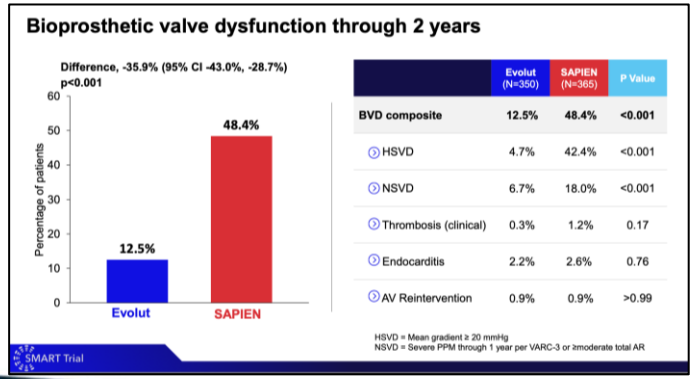
Nature of Financial Relationship	Ineligible Company
Grant/Research Support	None
Consultant Fees/Honoraria	Edwards, Medtronic
Individual Stock(s)/Stock Options	None
Royalties/Patent Beneficiary	None
Executive Role/Ownership Interest	None
Other Financial Benefit	None

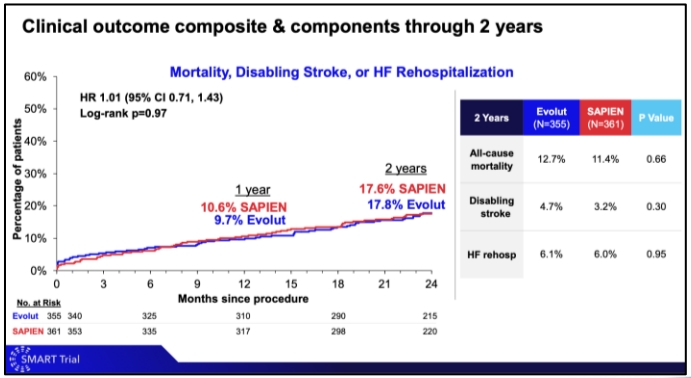
All relevant financial relationships have been mitigated.
Faculty disclosure information can be found on the app

Introduction

- Although the SMART* trial [1,2] demonstrated superior short-term valve performance of self-expanding valves (SEVs) compared to balloon-expandable valves (BEVs) in patients with a small aortic annulus (SAA) undergoing transcatheter aortic valve replacement (TAVR) for aortic stenosis (AS), data comparing the long-term performance and durability of SEVs and BEVs in this population remain limited.

* SMall Annuli Randomized To Evolut™ or SAPIEN™





1) Herrmann HC, et al. N Engl J Med. 2024;390:1959-1971.
2) The 2-year results of the SMART trial, presented at CRT 2025

Objectives

- We sought to assess 5-year valve performance and clinical outcomes in TAVR patients with a small aortic annulus, using contemporary transcatheter heart valves (Evolut PRO and Sapien 3).
  - Bioprosthetic valve dysfunction (BVD)
  - All-cause mortality, stroke, or heart failure (HF) rehospitalization
  - Bioprosthetic valve failure (BVF)

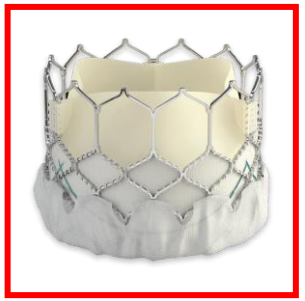
Study population

- Data for this study were retrospectively extracted from the OCEAN-TAVI registry, which consists of 16 high-volume TAVR centers in Japan.
  - August 2018 - September 2019
  - Only patients with Evolut PRO and Sapien 3 valves

OCEAN annual meeting in January 2025

Acknowledgements: The authors thank the investigators and institutions that have participated in the OCEAN-TAVI registry.

Study flow chart



OCEAN-TAVI registry (Aug 2018 ~ Sep 2019)
Native AS patients who underwent TAVR with Evolut PRO or Sapien 3
CT annulus area ≤430 mm² (N=1443)

Non-transfemoral approach (N=84)
Emergent cases (N=21)

Evolut PRO	Sapien 3
N=234	N=640
Converted to BEV (N=1) Unsuccessful valve delivery (N=1)	Converted to SAVR (N=2) Bailout valve-in-valve (N=1) Unsuccessful valve delivery (N=1)
N=232	N=636
1:1 propensity score matching	
N=204	N=204

BEV, balloon-expandable valve
SAVR, surgical aortic valve replacement

Study endpoints (primary outcomes)

- Following endpoints similar to those in the SMART trial,

1) a composite of all-cause mortality, stroke, or HF rehospitalization within 5 years

2) a composite of BVD (bioprosthetic valve dysfunction) through 5 years
   - Hemodynamic structural valve deterioration (mean gradient ≥20 mmHg)
   - Nonstructural valve dysfunction (severe PPM* or at least moderate total AR**)
   - Clinical valve thrombosis
   - Endocarditis
   - Aortic valve reintervention

* PPM, prosthesis–patient mismatch

** AR, aortic regurgitation

Study endpoints (secondary outcomes)

- The secondary outcomes included 5-year all-cause mortality and bioprosthetic valve failure (BVF), defined according to the VARC-3 criteria [1].
- Bioprosthetic valve failure (BVF) definition:
  - **Stage 1:** Any bioprosthetic valve dysfunction with clinically expressive criteria* or irreversible Stage 3 HVD (hemodynamic valve deterioration)
  - **Stage 2:** Aortic valve reintervention
  - **Stage 3:** Valve-related death

* new-onset or worsening symptoms, LV dilation/hypertrophy/dysfunction, or pulmonary hypertension

1) Généreux P, et al. J Am Coll Cardiol. 2021;77:2717-2746.

Baseline Characteristics (1)

	Prematched cohort			Matched cohort			
	Evolut PRO	Sapien 3	P-value	Evolut PRO	Sapien 3	P-value	SD
	N=232	N=636		N=204	N=204		
Age, years old *	85 [81, 88]	85 [82, 88]	0.73	85 [82, 88]	85 [82, 88]	0.94	0.01
Female, n (%) *	208 (89.7%)	540 (84.9%)	0.08	180 (88.2%)	183 (89.7%)	0.75	0.05
Clinical frailty scale =<4, n (%) *	182 (78.4%)	481 (75.6%)	0.42	162 (79.4%)	165 (80.9%)	0.80	0.04
Body surface area, m² *	1.4 [1.3, 1.5]	1.4 [1.3, 1.5]	0.38	1.4 [1.3, 1.5]	1.4 [1.3, 1.5]	0.98	0.01
STS score, % *	6.2 [4.4, 9.6]	6.0 [4.1, 9.1]	0.28	6.2 [4.3, 10]	6.3 [4.0, 10.2]	0.49	0.01
NYHA 3 or 4, n (%) *	67 (28.9%)	176 (27.7%)	0.73	58 (28.4%)	59 (28.9%)	1.00	0.01
Dyslipidemia, n (%) *	123 (53.0%)	381 (59.9%)	0.07	114 (55.9%)	114 (55.9%)	1.00	<0.01
Diabetes mellitus, n (%) *	57 (24.6%)	182 (28.6%)	0.27	54 (25.6%)	51 (26.0%)	0.82	0.03
Hypertension, n (%) *	191 (82.3%)	538 (84.6%)	0.46	172 (84.3%)	169 (82.8%)	0.79	0.04
Atrial fibrillation, n (%) *	51 (22.0%)	118 (18.6%)	0.29	44 (21.6%)	44 (21.6%)	1.00	<0.01
Previous PMI, n (%) *	12 (5.2%)	25 (3.9%)	0.45	12 (5.9%)	14 (6.9%)	0.84	0.04
Previous MI, n (%) *	6 (2.6%)	25 (3.9%)	0.41	5 (2.5%)	2 (1.0%)	0.45	0.11
Previous PCI, n (%) *	35 (15.1%)	141 (22.2%)	0.02	32 (15.7%)	34 (16.7%)	0.89	0.03
Previous CABG, n (%) *	5 (2.2%)	10 (1.6%)	0.56	5 (2.5%)	5 (2.5%)	1.00	<0.01
Coronary artery disease, n (%) *	49 (21.1%)	202 (31.8%)	<0.01	45 (22.1%)	48 (23.5%)	0.81	0.04
Peripheral artery disease, n (%) *	23 (9.9%)	53 (8.3%)	0.50	18 (8.8%)	20 (9.8%)	0.87	0.03
Previous stroke, n (%) *	18 (7.8%)	65 (10.2%)	0.30	14 (6.9%)	15 (7.4%)	1.00	0.02
Chronic kidney disease, n (%)	157 (67.7%)	451 (70.9%)	0.36	145 (71.1%)	147 (72.1%)	0.91	0.02
Hemoglobin, g/dl *	11.4 [10.7, 12.5]	11.4 [10.3, 12.4]	0.32	11.3 [10.7, 12.3]	11.3 [10.4, 12.5]	0.94	0.02
Creatinine, mg/dl *	0.8 [0.7, 1.0]	0.9 [0.7, 1.1]	0.06	0.8 [0.7, 1.0]	0.8 [0.7, 1.0]	0.57	0.03
eGFR, ml/min/1.73 m² *	51.7 [41.5, 63.8]	49.8 [39, 62.7]	0.13	50.8 [41.2, 61.7]	52.5 [41.1, 62.8]	0.71	0.01
Albumin, g/dl *	3.8 [3.5, 4.1]	3.8 [3.5, 4.1]	0.79	3.8 [3.5, 4.1]	3.8 [3.5, 4.1]	0.95	0.03
CRBBB, n (%)	22 (9.5%)	70 (11.0%)	0.62	17 (8.3%)	24 (11.8%)	0.32	0.11
CLBBB, n (%)	4 (1.7%)	23 (3.6%)	0.19	4 (2.0%)	8 (3.9%)	0.38	0.12
Bicuspid aortic valve, n (%) *	10 (4.3%)	5 (0.8%)	<0.01	4 (2.0%)	5 (2.5%)	1.00	0.03

* Variables included in the propensity score matching model

Baseline Characteristics (2)

	Prematched cohort			Matched cohort			
	Evolut PRO	Sapien 3	P-value	Evolut PRO	Sapien 3	P-value	SD
	N=232	N=636		N=204	N=204		
<Pre-procedural echocardiographic data>							
Aortic valve area, cm² *	0.6 [0.5, 0.7]	0.6 [0.5, 0.7]	0.36	0.6 [0.5, 0.7]	0.6 [0.5, 0.8]	0.78	0.01
Aortic valve peak velocity, m/s	4.6 [4.1, 5.3]	4.4 [4.0, 5.0]	<0.01	4.6 [4.1, 5.2]	4.5 [4.1, 5.2]	0.62	0.04
Aortic valve mean pressure gradient, mmHg *	48.9 [38.5, 65.9]	45.4 [35.5, 58.9]	<0.01	47.4 [37.7, 63]	47.6 [37.0, 62.5]	0.98	0.02
Left ventricular ejection fraction, % *	64.9 [58.7, 69.0]	64.9 [59.0, 69.8]	0.73	64.9 [59, 69.1]	64.8 [58.0, 69.9]	0.92	0.03
Pre-procedural moderate or severe AR, n (%) *	19 (8.2%)	51 (8.0%)	1.00	16 (7.8%)	15 (7.4%)	1.00	0.02
Pre-procedural moderate or severe MR, n (%) *	29 (12.5%)	88 (13.8%)	0.66	22 (10.8%)	25 (12.3%)	0.76	0.05
Pulmonary hypertension, n (%) *	71 (34.1%)	159 (28.4%)	0.13	59 (32.2%)	58 (31.7%)	1.00	0.01
<MDCT data>							
Aortic annular area by MDCT, cm² *	362 [322, 391]	370 [344, 398]	<0.01	366 [323, 391]	363 [338, 390]	0.74	0.06
Left ventricular outflow tract calcification, n (%) *			<0.01			0.88	0.08
None	159 (68.5%)	541 (85.1%)		153 (75.0%)	148 (72.5%)		
Mild	36 (15.5%)	69 (10.8%)		30 (14.7%)	36 (17.6%)		
Moderate	22 (9.5%)	21 (3.3%)		15 (7.4%)	15 (7.4%)		
Severe	15 (6.5%)	5 (0.8%)		6 (2.9%)	5 (2.5%)		

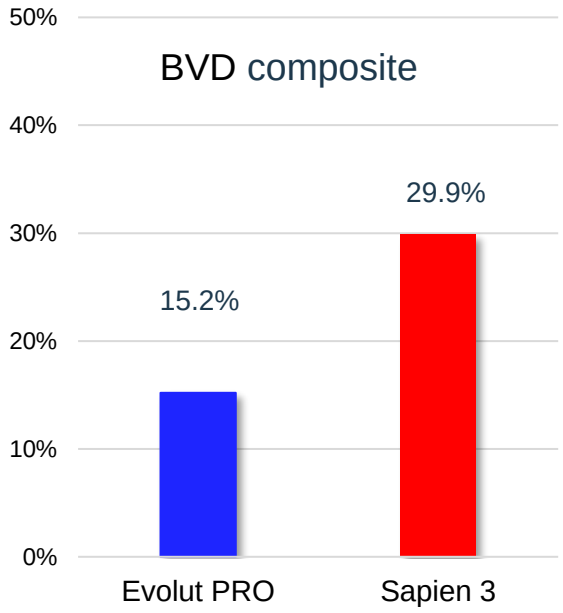
* Variables included in the propensity score matching model

In-hospital outcomes & post-procedural data

	Prematched cohort			Matched cohort		
	Evolut PRO	Sapien 3	P-value	Evolut PRO	Sapien 3	P-value
	N=232	N=636		N=204	N=204	
In-hospital all-cause mortality, n (%)	1 (0.4%)	4 (0.6%)	1.00	1 (0.5%)	1 (0.5%)	1.00
In-hospital disabling stroke, n (%)	3 (1.3%)	3 (0.5%)	0.20	2 (1.0%)	1 (0.5%)	1.00
Major bleeding, n (%)	15 (6.5%)	39 (6.1%)	0.87	11 (5.4%)	8 (3.9%)	0.64
In-hospital minor bleeding, n (%)	11 (4.7%)	24 (3.8%)	0.56	9 (4.4%)	10 (4.9%)	1.00
Major vascular complication, n (%)	12 (5.2%)	25 (3.9%)	0.45	9 (4.4%)	10 (4.9%)	1.00
Minor vascular complication, n (%)	15 (6.5%)	32 (5.0%)	0.40	10 (4.9%)	14 (6.9%)	0.53
Second valve required, n (%)	1 (0.4%)	0 (0.0%)	0.27	0 (0.0%)	0 (0.0%)	1.00
New pacemaker implantation, n (%)	30 (12.9%)	34 (5.3%)	<0.01	26 (12.7%)	10 (4.9%)	0.01
Conversion to open surgery, n (%)	0 (0.0%)	4 (0.6%)	0.58	0 (0.0%)	1 (0.5%)	1.00
<Post-procedural echocardiographic data>						
Effective orifice area, cm^2	1.6 [1.4, 1.9]	1.5 [1.3, 1.8]	<0.01	1.6 [1.4, 2.0]	1.5 [1.3, 1.8]	<0.01
Indexed effective orifice area, cm^2/m^2	1.2 [1.0, 1.4]	1.1 [0.9, 1.3]	<0.01	1.2 [1.0, 1.4]	1.1 [0.9, 1.3]	<0.01
Peak velocity, m/s	2.1 [1.8, 2.4]	2.5 [2.2, 2.7]	<0.01	2.0 [1.8, 2.3]	2.5 [2.2, 2.8]	<0.01
Mean gradient, mmHg	8.4 [6.0, 11.0]	13.0 [9.8, 16.0]	<0.01	8.0 [5.9, 11.0]	13.1 [10.3, 16.6]	<0.01
Mean gradient >=20mmHg, n (%)	8 (3.5%)	53 (8.4%)	0.01	6 (3.0%)	25 (12.3%)	<0.01
Severe PPM, n (%)	4 (1.7%)	11 (1.7%)	1.00	4 (2.0%)	4 (2.0%)	1.00
Moderate or severe AR, n (%)	5 (2.2%)	6 (0.9%)	0.18	4 (2.0%)	3 (1.5%)	1.00

PPM, prosthesis–patient mismatch. AR, aortic regurgitation

Bioprosthetic valve dysfunction (BVD) through 5 years

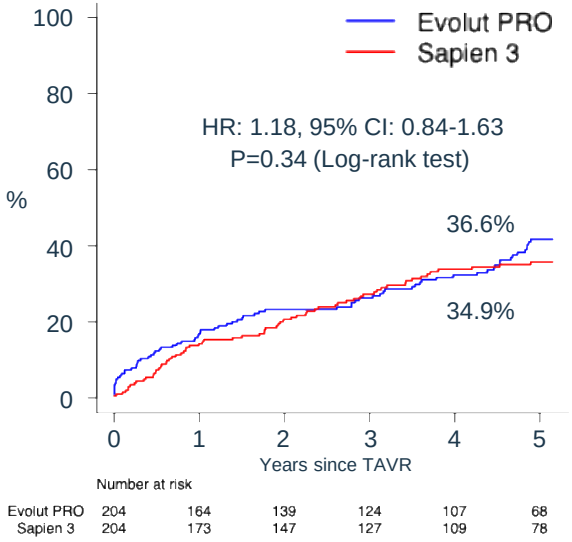


	Evolut PRO (N=204)	Sapien 3 (N=204)	P value
BVD composite	31 (15.2%)	61 (29.9%)	<0.01
HSVD *	9 (4.4%)	45 (22.1%)	<0.01
NSVD **	21 (10.3%)	35 (17.2%)	0.06
Severe PPM	8 (3.9%)	30 (14.7%)	<0.01
Moderate or severe AR	15 (7.4%)	7 (3.4%)	0.12
Thrombosis	4 (2.0%)	2 (1.0%)	0.69
Endocarditis	1 (0.5%)	1 (0.5%)	1.00
AV Reintervention	0 (0.0%)	1 (0.5%)	1.00

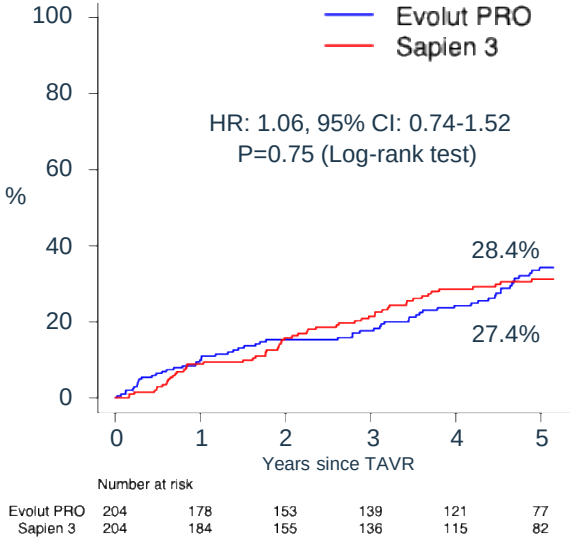
* HSVD (Hemodynamic structural valve deterioration) = Mean gradient ≥ 20 mmHg
** NSVD (Nonstructural valve dysfunction) = Severe PPM through 5 year per VARC-3 or ≥moderate total AR

Clinical outcomes through 5 years

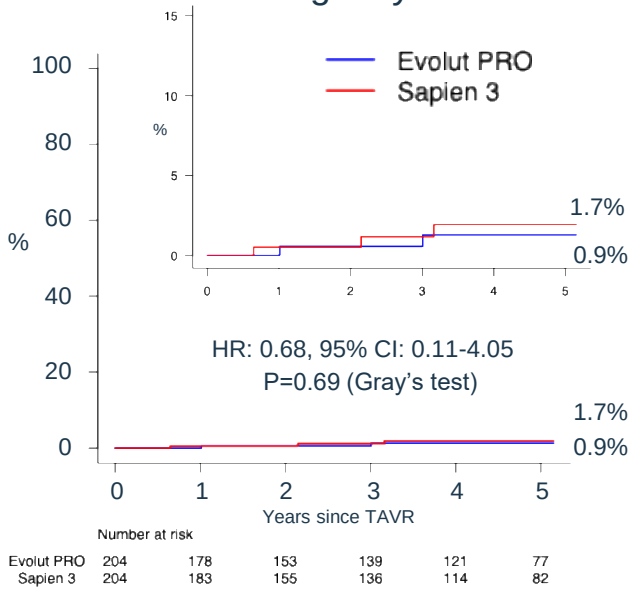
All-cause mortality, stroke or HF rehospitalization through 5 years



All-cause mortality through 5 years



Bioprosthetic valve failure (BVF) through 5 years

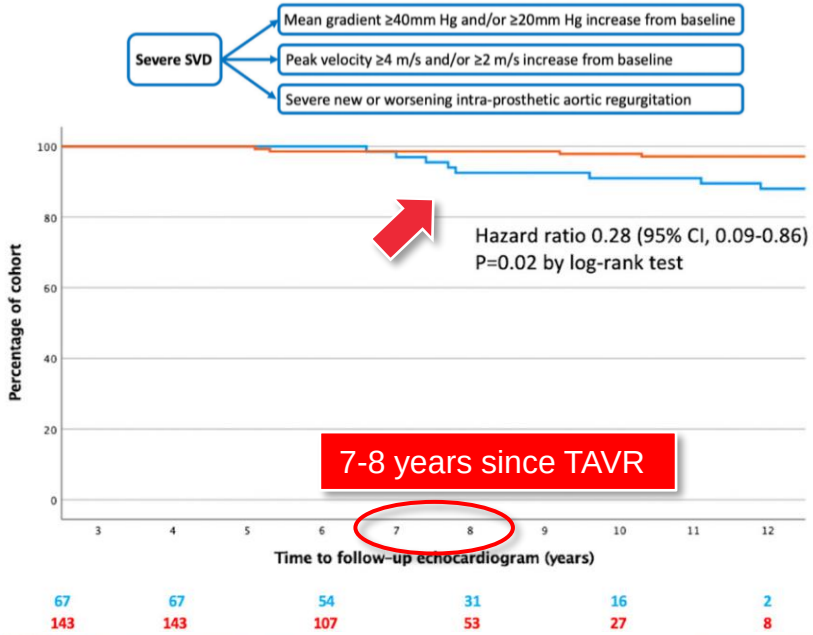


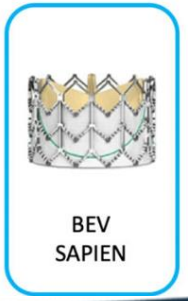
Discussion

- The present study is the first to report 5-year outcomes in TAVR patients with SAA, particularly focusing on echocardiographic follow-up data and BVD.
- Our findings were consistent with those of the SMART trial:
  - 5-year BVD in 15.2% with Evolut PRO vs. 29.9% with Sapien 3 ($p < 0.01$).
- Similar to the SMART trial, there were no significant differences in all-cause mortality, HF rehospitalization, or BVF.
- We suppose that a much larger sample size and longer follow-up periods are required to demonstrate the potential negative impact of severe PPM and higher gradients on long-term prognosis.

Long-term follow-up data from UK TAVI registry

- Longer-term follow-up beyond 7-8 years is required to determine definitive differences in valve failure.





1) Ali N, et al. Catheter Cardiovasc Interv. 2023;101:932-942.

Study limitations

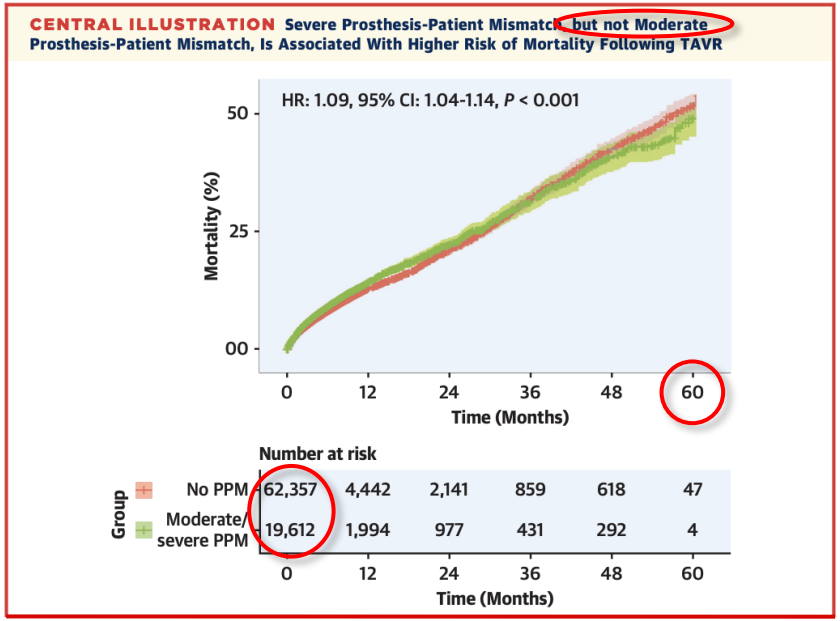
- This study was based on an observational, unblinded, and non-randomized registry. Even after propensity-score matching, residual confounding by unmeasured factors may persist.
- All patients were Japanese, which may limit generalizability.
- Echocardiographic data were not adjudicated by an independent core laboratory.
- Under-reporting of events or missing echocardiographic follow-up may have occurred.
- Longer follow-up is needed to clarify differences in valve durability and failure.

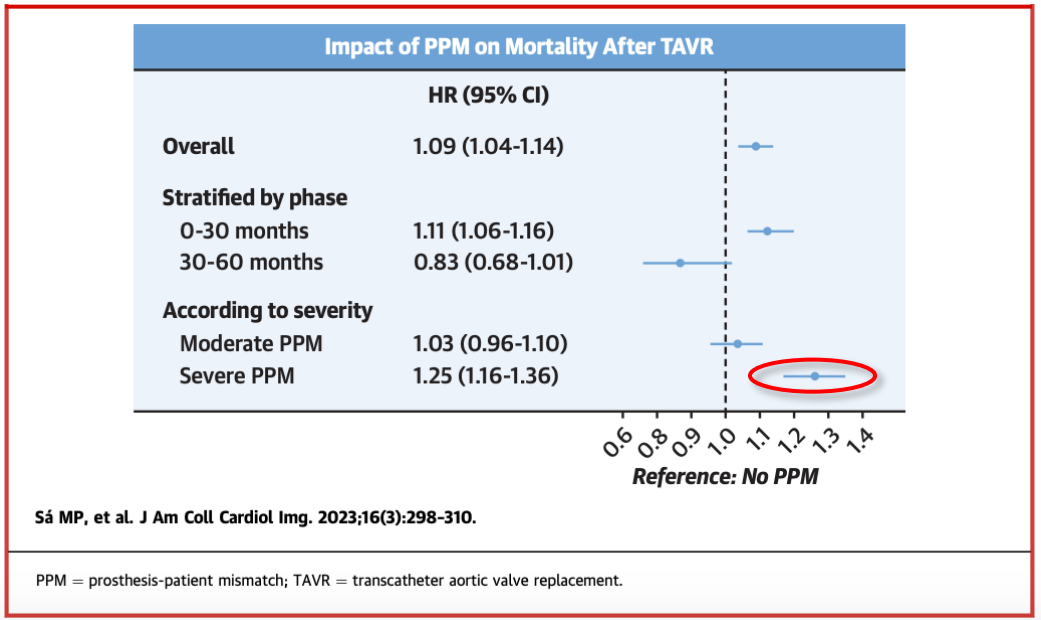
Conclusions

- In TAVR patients with a small aortic annulus, Evolut PRO and Sapien 3 valves showed comparable 5-year rates of all-cause mortality, stroke, and HF rehospitalization.
- Evolut PRO valves were associated with larger effective orifice areas (EOAs) and lower transvalvular pressure gradients over 5 years compared with Sapien 3 valves; however, there was no significant difference in bioprosthetic valve failure.

Backup slides

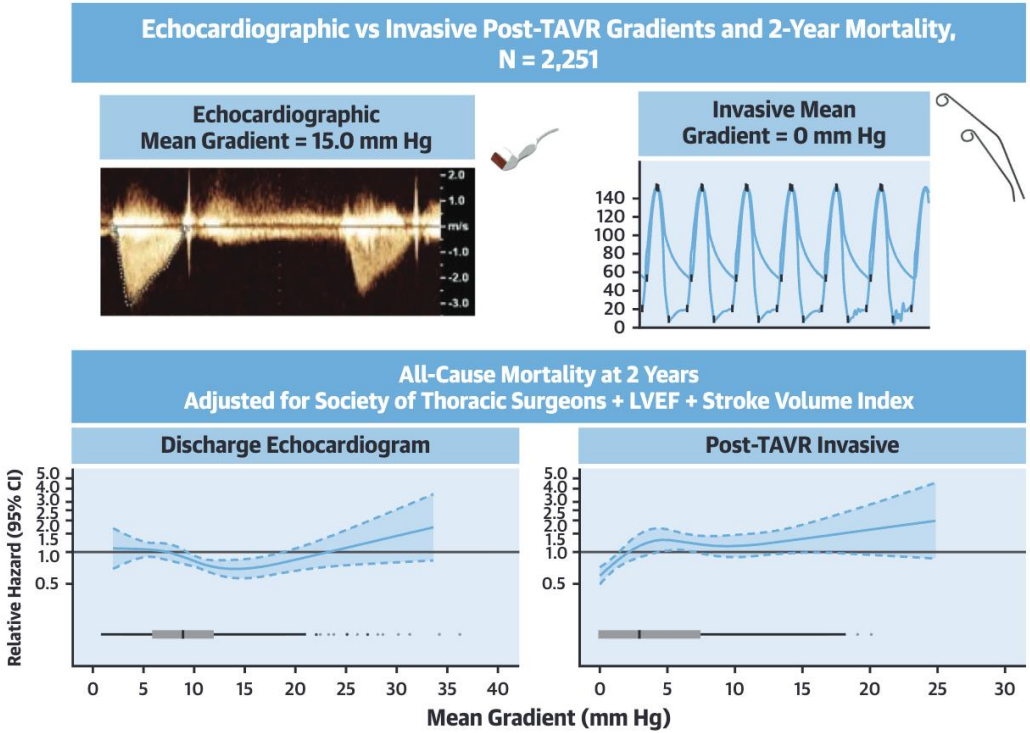
TAVR PPM meta-analysis





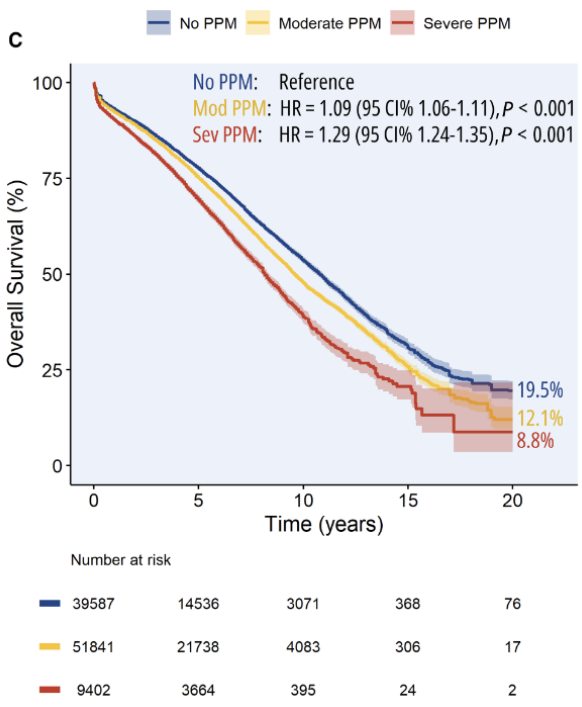
1) Sá MP,et al. JACC Cardiovasc Imaging. 2023;16:298-310.

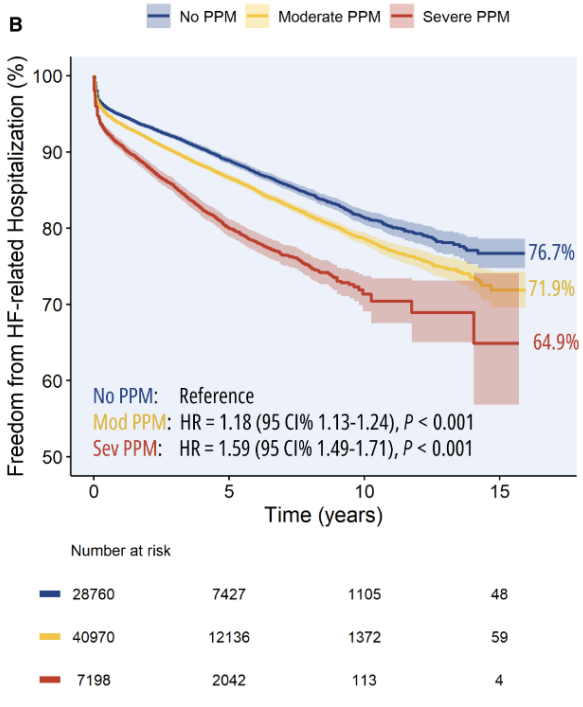
Impact of transaortic gradients on mortality: echocardiographic and invasive measurements

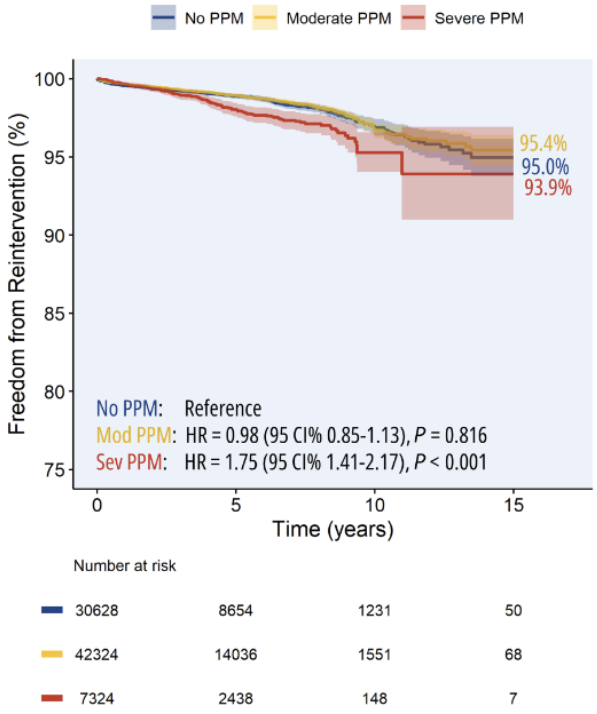


1) Khalili H, et al. JACC Cardiovasc Interv. 2022;15:1837-1848.

SAVR PPM meta-analysis







1) Sá MP, et al. J Am Heart Assoc. 2024;13:e033176.

Procedural data

	Prematched cohort			Matched cohort		
	Evolut PRO	Sapien 3	P-value	Evolut PRO	Sapien 3	P-value
	N=232	N=636		N=204	N=204	
Valve size, n (%)			<0.01			<0.01
20mm, n (%)	0 (0.0%)	66 (10.4%)		0 (0.0%)	27 (13.2%)	
23mm, n (%)	46 (19.8%)	512 (80.5%)		36 (17.6%)	164 (80.4%)	
26mm, n (%)	163 (70.3%)	58 (9.1%)		146 (71.6%)	13 (6.4%)	
29mm, n (%)	23 (9.9%)	0 (0.0%)		22 (10.8%)	0 (0.0%)	
Local anesthesia, n (%)	163 (70.3%)	423 (66.5%)	0.33	141 (69.1%)	140 (68.6%)	1.00
Puncture, n (%)	225 (97.0%)	609 (95.8%)	0.55	197 (96.6%)	193 (94.6%)	0.47
Pre-dilation, n (%)	181 (78.0%)	191 (30.0%)	<0.01	155 (76.0%)	62 (30.4%)	<0.01
Post-dilation, n (%)	33 (14.2%)	161 (25.3%)	<0.01	27 (13.2%)	52 (25.5%)	<0.01