

TAVI in Small Annulus: How to Overcome Prosthesis Patient Mismatch

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Disclosure

- ✓ Receipt of honoraria or consultation fees: Medtronic, Abbott, Edwards Lifesciences

Japanese TAVI Patients have small body size



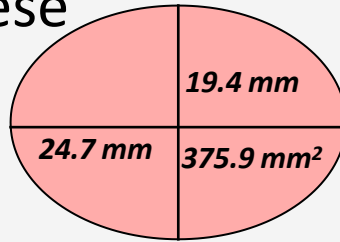
Initial 800 pts @Tokai Univ. Hosp.

- ✓ Age 84yo (median)
- ✓ Female 62.7%
- ✓ STS 6.4 (median)
- ✓ BSA **1.46** (median)
- ✓ BW **50.8**kg (median)
- ✓ NYHA 2.4
- ✓ Clinical Frailty Scale 3.5

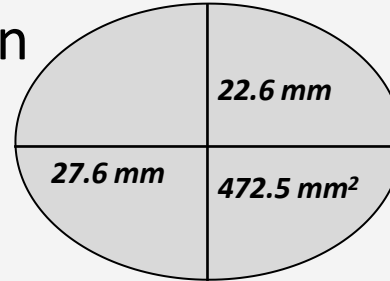


Current Japanese TAVI Patients have small body size

Japanese



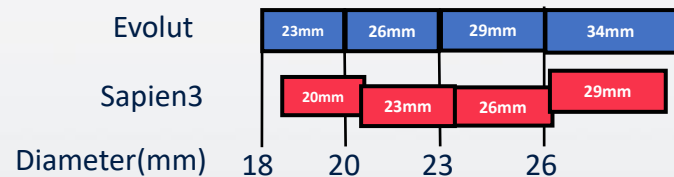
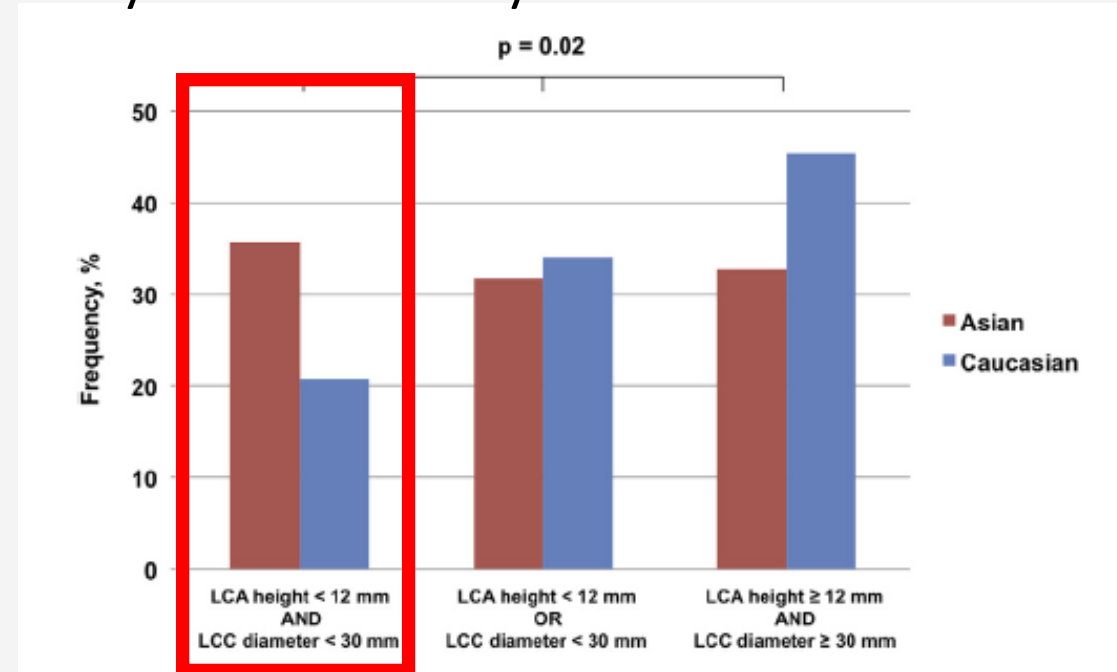
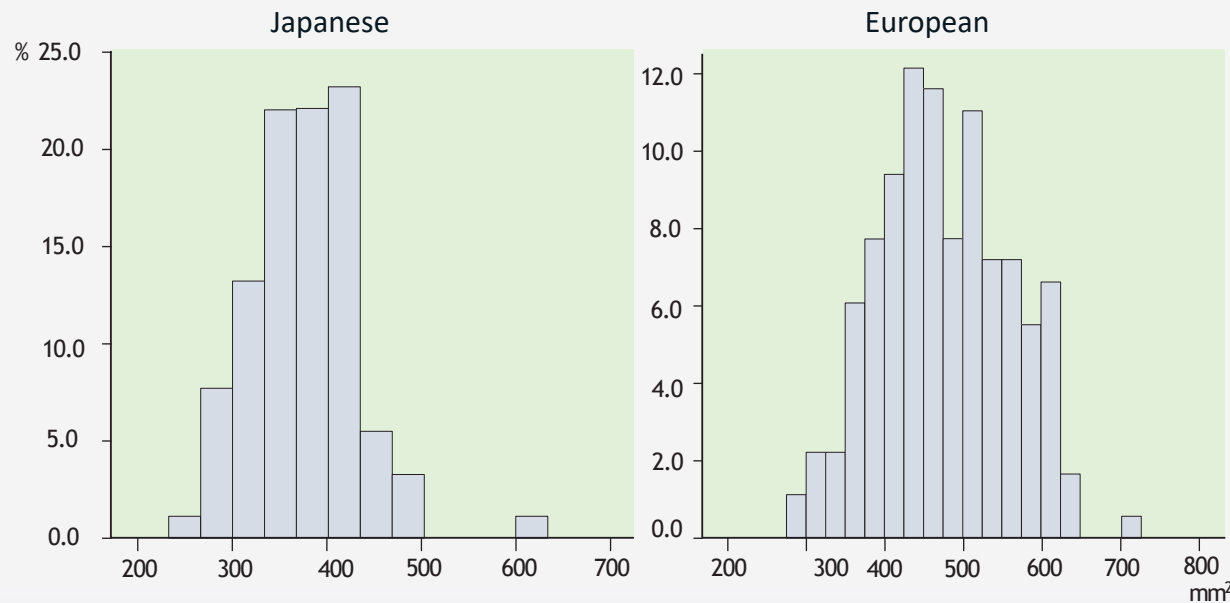
European



	Japanese	European	p value
Patient number	90	Valve size	
sDiam, mm	19.4 ± 2.0	Aortic annulus size	
lDiam, mm	24.7 ± 1.9	SEV (N=355)	BEV (N=361)
Relation lDiam/sDiam	1.28 ± 0.10	Mean area (mm ²)	380.9 ± 34.2 382.8 ± 33.9
Perimeter, mm	70.3 ± 5.0	Mean perimeter (mm)	70.3 ± 3.2 70.4 ± 3.2
CAAD (perimeter derived), mm	22.4 ± 1.6	SMART Trial	
Area, mm ²	375.9 (333.8 - 410.7)		
CAAD (area derived), mm	21.8 ± 1.6		

Current Japanese TAVI Patients have small body size

- 70% of TAVI patients in Japan have 18-23mm diameter (Area derived)
- Due to small SOV and low coronary height, Asian pts carry risk of coronary obstruction



Watanabe Y et al, Asia intervention 2016

Yoon SH, Ohno Y et al, AJC 2015

Potential risk of TAVI in small anatomy



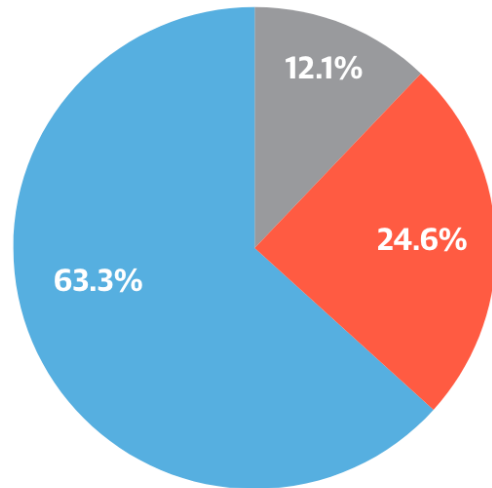
140cm 40kg

- ✓ PPM (Prosthesis Patient Mismatch)
- ✓ Coronary occlusion/ Sinus sequestration
- ✓ Vascular complication

PPM after TAVI

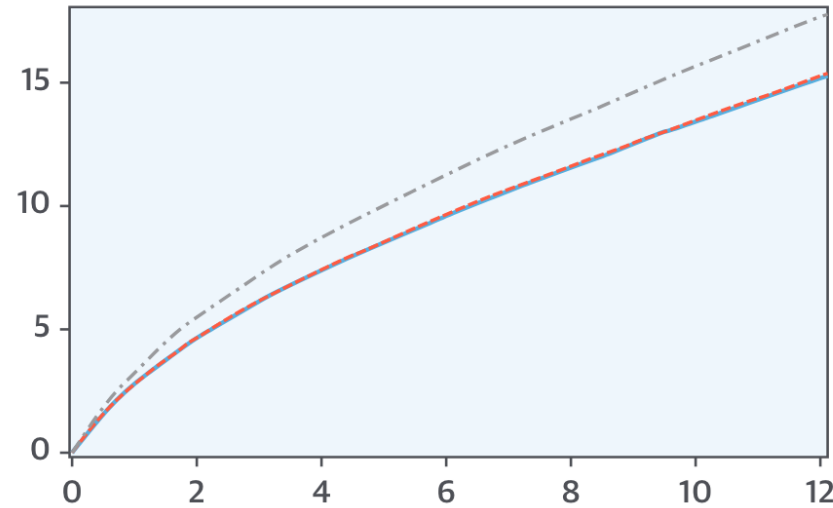
From the STS/ACC TVT Registry (n= 62,125)

Prosthesis-Patient Mismatch (PPM)



- Severe (Sev)
- Moderate (Mod)
- None

Mortality (%)



PPM

--- Sev PPM (EOAi <0.65 cm²/m²) - - - Mod PPM (EOAi 0.65-0.85 cm²/m²)
 — No PPM (EOAi >0.85 cm²/m²)

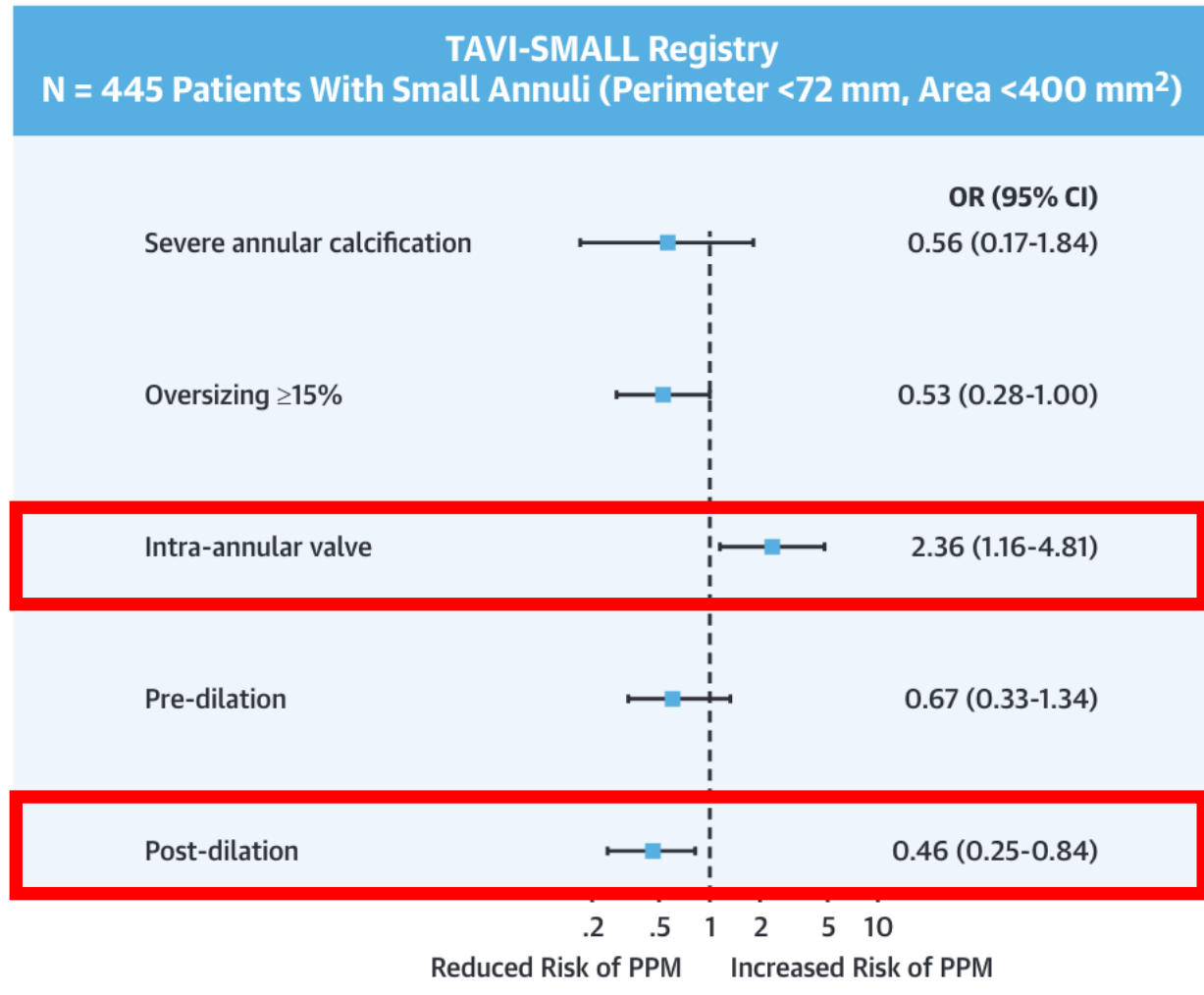
Number at Risk Adjusting for Baseline Covariates:

	Day 0	Month 4	Month 8	Month 12
No PPM	23,635	21,080	16,734	13,136
Mod PPM	8,983	7,995	6,277	4,831
Sev PPM	4,152	3,626	2,976	2,130

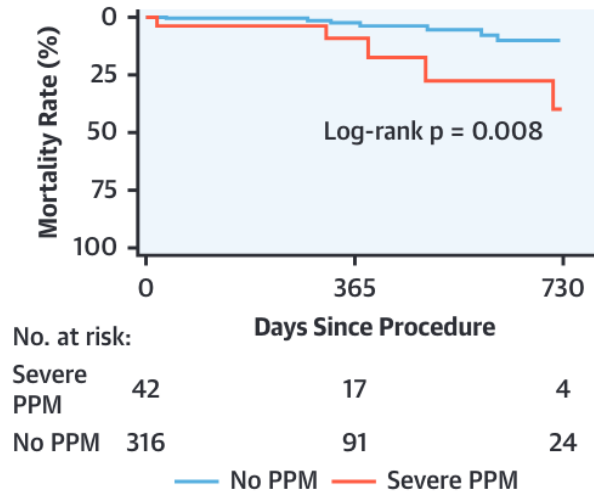
Herrmann, et al., J Am Coll Cardiol. 2018.

PPM after TAVI

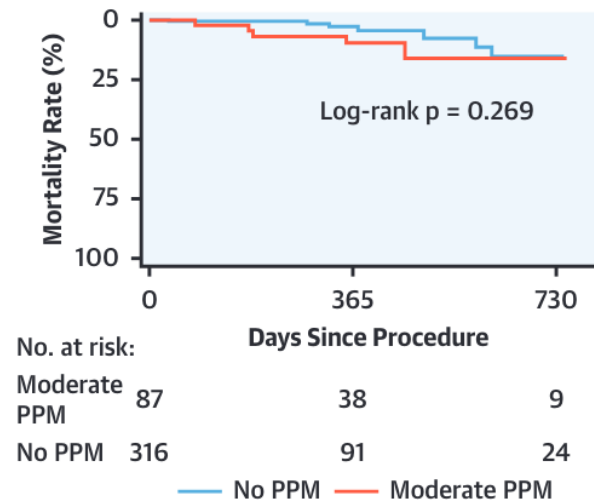
A



B

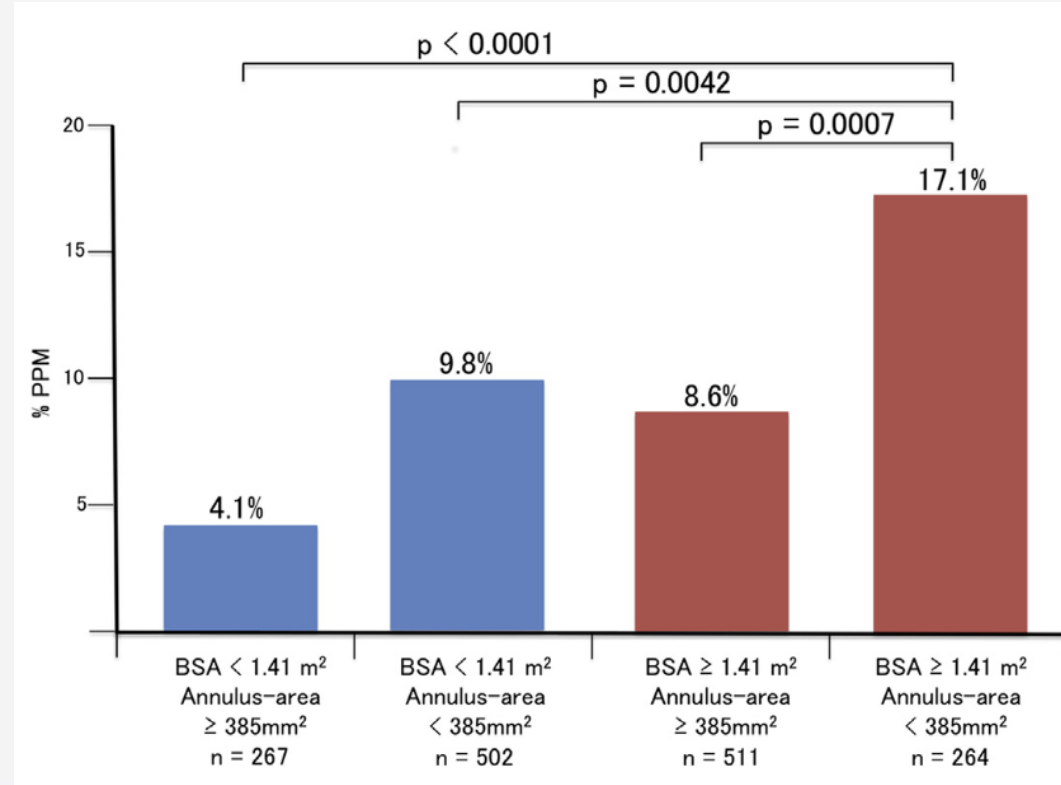


C





PPM after TAVI



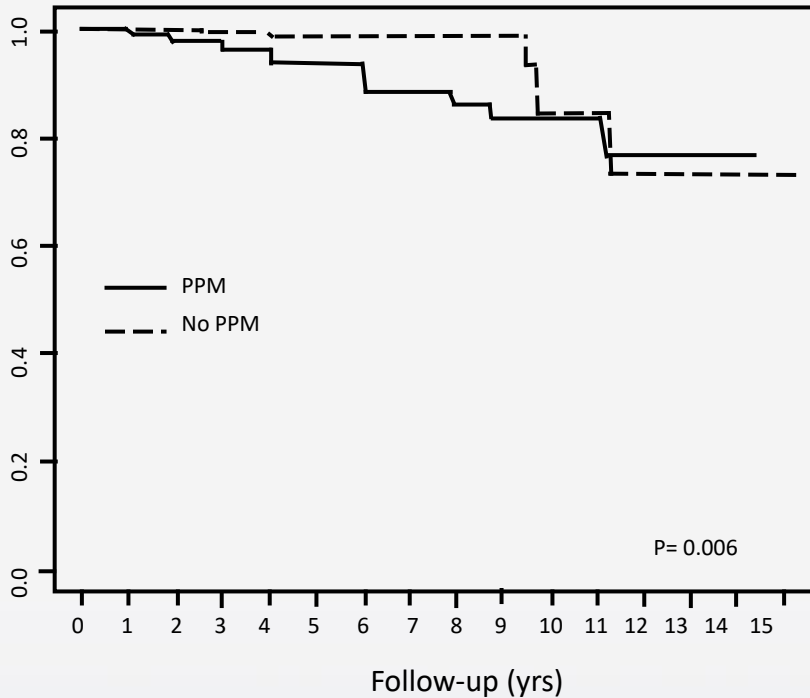
Incidence of PPM: 9.8%
Moderate PPM 8.9%
Severe PPM 0.7%

In both small and large BSA, small annulus was significantly associated with higher PPM.

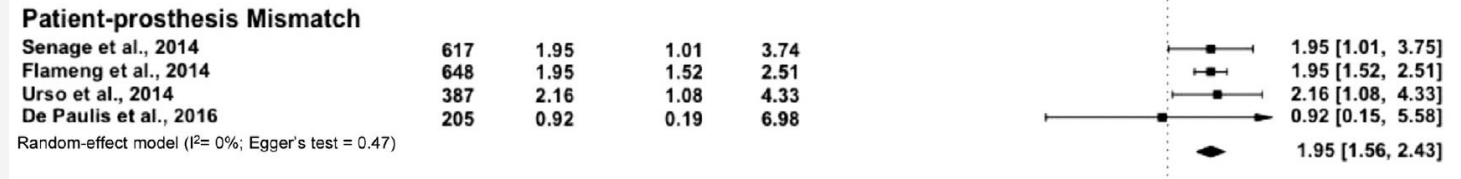
Miyasaka et al. JACC cardiovasc Interv 2018

Is PPM a potential risk for SVD?

PPM (Prosthesis-Patient Mismatch) related to SVD after SAVR



Flameng, et al., Circulation. 2010



Ochi A et al. Hear, Lung and Circulation 2020

Trial design

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 ($\leq 430 \text{ mm}^2$ by MDCT)

Randomization

1:1 stratified by site & sex

716 patients treated

SEV (N=355)

Medtronic Evolut PRO/PRO+/FX

BEV (N=361)

Edwards SAPIEN 3/SAPIEN 3 Ultra

Co-Primary Endpoints at 1 year with planned 5-year follow-up

Co-Primary Endpoint 1: Composite of mortality, disabling stroke, or heart failure rehospitalization through 12 months

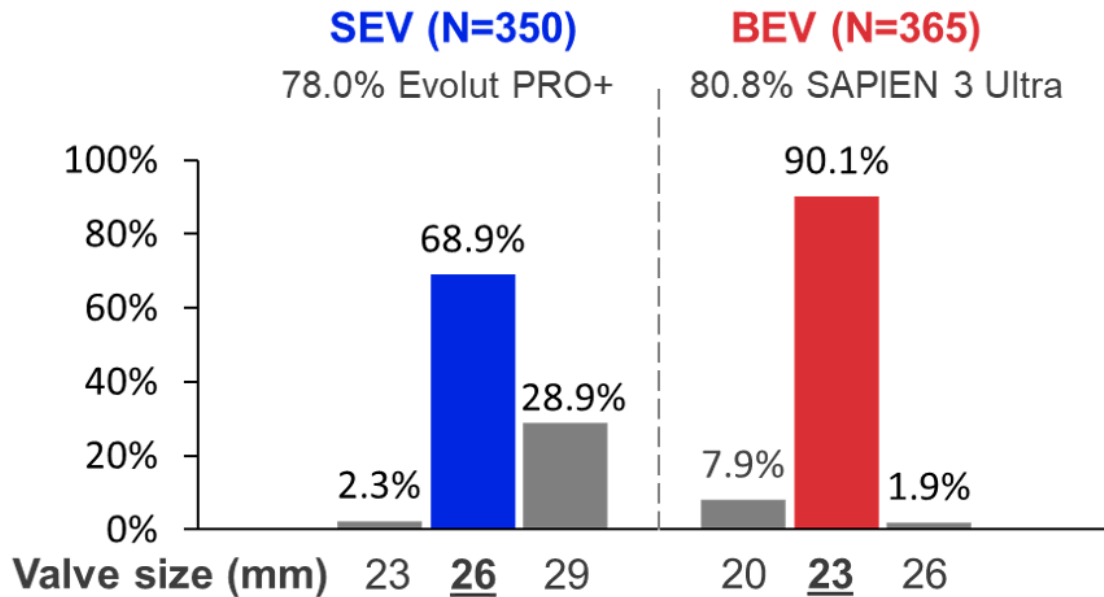
Co-Primary Endpoint 2: Bioprosthetic valve dysfunction through 12 months

*AVA $\leq 1.0 \text{ cm}^2$ (AVA_i $\leq 0.6 \text{ cm}^2/\text{m}^2$) or mean gradient $\geq 40 \text{ mmHg}$ or max velocity $\geq 4.0 \text{ m/s}$; 30-day predicted risk of surgical mortality $< 15\%$ by heart team assessment.

Valve and procedural data

Valve size

Aortic annulus size	SEV (N=355)	BEV (N=361)
Mean area (mm ²)	380.9 ± 34.2	382.8 ± 33.9
Mean perimeter (mm)	70.3 ± 3.2	70.4 ± 3.2



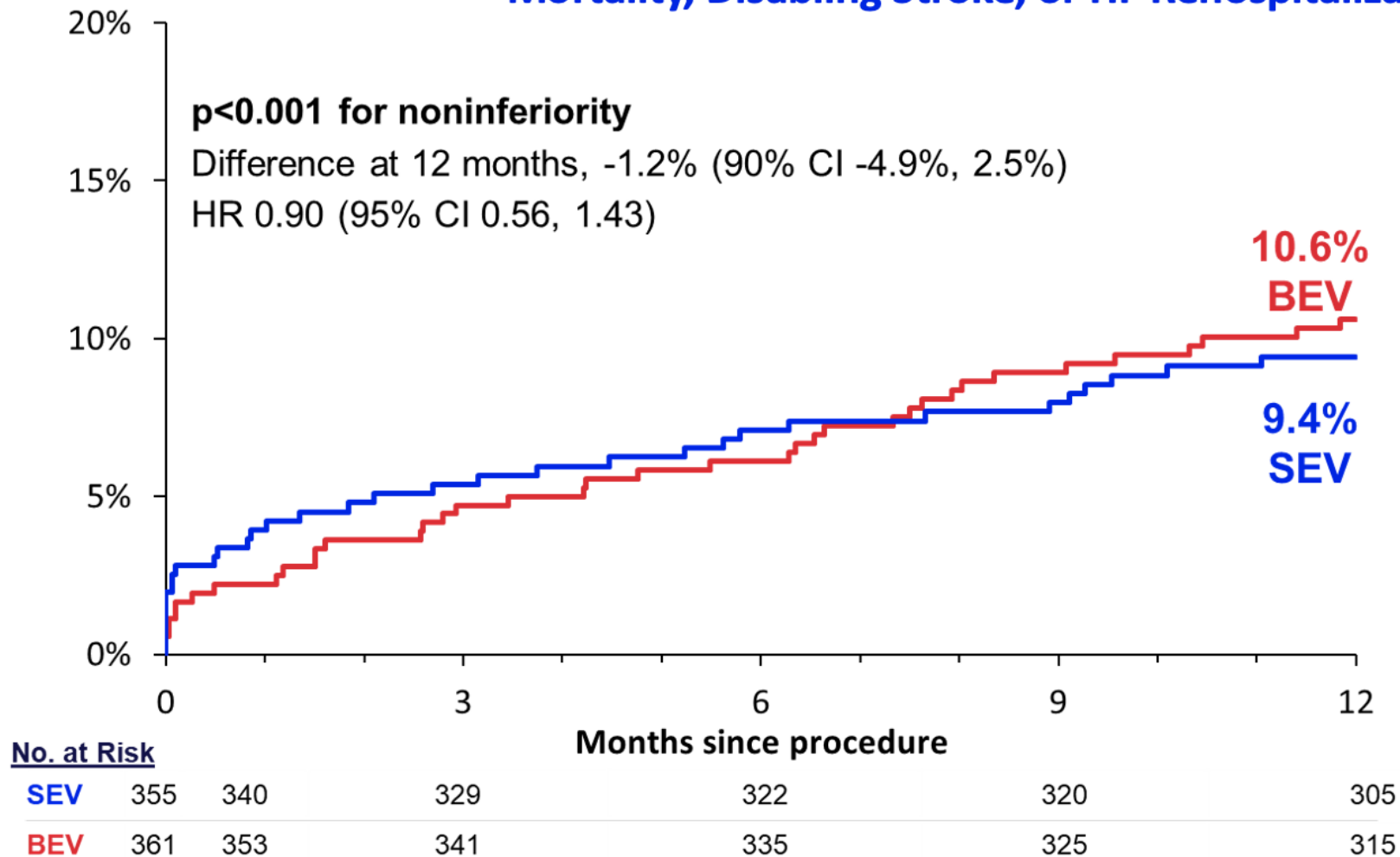
Procedural characteristics and outcomes

Characteristic	SEV (N=355)	BEV (N=361)	P Value ^a
Total time in the procedure room ^b (min)	116 ± 44	106 ± 43	0.002
Catheter (device) time in the body (min)	18 ± 15	14 ± 12	<0.001
Contrast volume ^c (ml)	121 ± 59	95 ± 43	<0.001
Valve embolization	1.1%	0.0%	0.06
Device success at 30 days (VARC-2) ^d	85.2%	59.2%	<0.001
Device success at 30 days (VARC-3) ^e	94.5%	86.6%	<0.001

^aContinuous variables compared using t-tests; categorical variables compared using chi-squared tests. Valve embolization compared using Fisher's Exact test. ^bData available for 354 SEV and 361 BEV patients. ^cData available for 347 SEV and 357 BEV patients. ^dEvaluated according to VARC-2 criteria in 291 SEV and 319 BEV patients. ^eEvaluated according to VARC-3 criteria in 327 SEV and 328 BEV patients.

Co-primary endpoint 1: Clinical outcome composite through 12 months powered for noninferiority

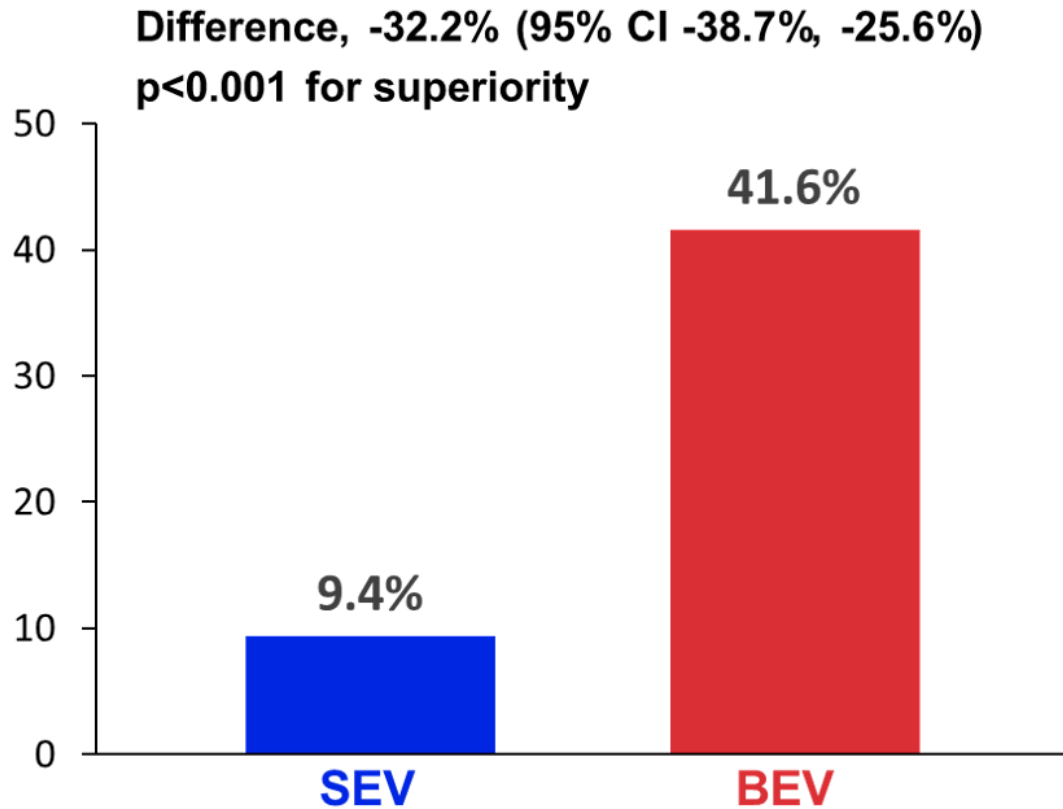
Mortality, Disabling Stroke, or HF Rehospitalization



12 Months	SEV (N=355)	BEV (N=361)	HR (95% CI)
All-cause mortality	5.1%	5.9%	0.88 (0.47, 1.65)
Disabling stroke	3.1%	2.6%	1.26 (0.52, 3.03)
HF rehossp	3.8%	3.5%	1.11 (0.51, 2.44)

Co-primary endpoint 2: BVD through 12 months powered for superiority

Bioprosthetic Valve Dysfunction through 12 months



	SEV (N=350)	BEV (N=365)	P Value
BVD composite	9.4%	41.6%	<0.001
⊙ HSVD	3.2%	32.2%	
⊙ NSVD	5.9%	18.2%	
⊙ Thrombosis (clinical)	0.3%	0.3%	
⊙ Endocarditis	0.6%	2.3%	
⊙ AV Reintervention	0.9%	0.6%	

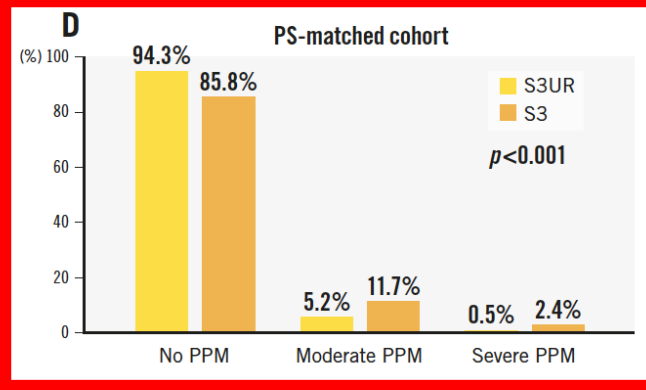
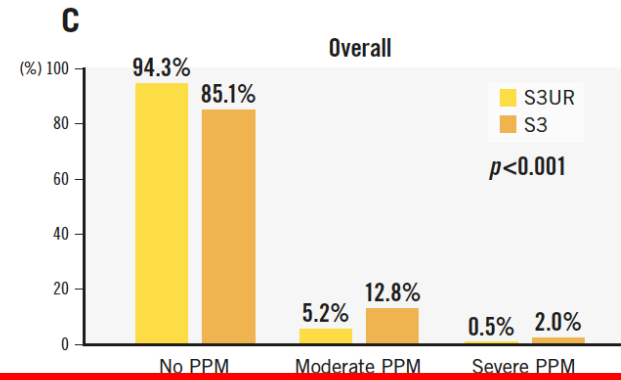
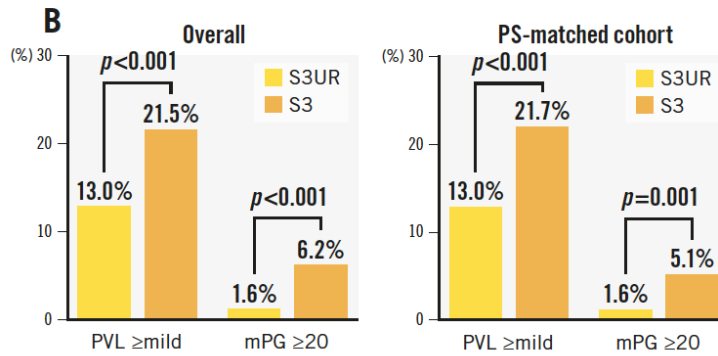
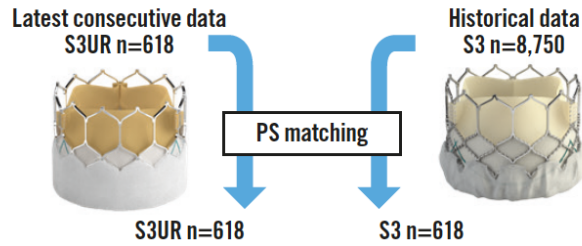
HSVD = Mean gradient \geq 20 mmHg

NSVD = Severe PPM per VARC-3 or \geq moderate total AR



Comparison of valve performance between S3UR and S3 THVs as evaluated according to the incidence of PPM, PVL \geq mild, and mPG \geq 20 mmHg in the entire cohort and in the PS-matched cohort.

A  OCEAN-TAVI registry database

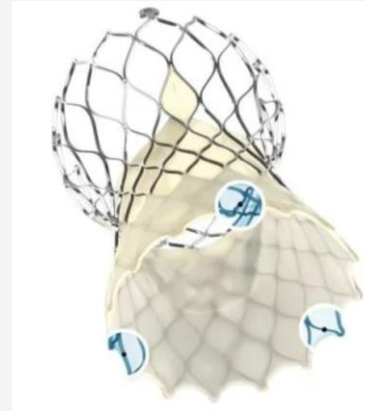


NAVITOR	All	23mm	25mm	27mm	29mm	p
N	456	118	190	105	43	0.4267
no-PPM	418 (91.7)	103 (87.3)	179 (94.2)	96 (91.4)	40 (93.0)	
moderate-PPM	26 (5.7)	10 (8.5)	7 (3.7)	6 (5.7)	3 (7.0)	
Severe-PPM	12 (2.6)	5 (4.2)	4 (2.1)	3 (2.9)	0	

Yamamoto M, et al.,
EuroIntervention. 2023

Shirai S, et al.,
JACC Asia. 2024

Right Valve for the Right Patient/Anatomy



Ease of Use/
Shorter proc. time

++

+

+

Valve Performance/
Durability

++

+++

++

Coronary Access

++

+

+

Repeatability

++

+

+

Vessel access

+

++

+++