

Clinical Impact of Prosthesis-Patient Mismatch (PPM) After TAVR

What is the Definition and Prognostic Impact of PPM after TAVR

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Disclosure

- Institutional grant/research funding to CardioVascular Research Foundation (CVRF, Korea) and/or Asan Medical Center from Daiichi-Sankyo, HK InnoN, Abbott, Boston Scientific, Edwards Lifescience, Medtronic, Daewoong Pharm, and ChongKunDang Pharm.

This Issue Was Initially Concerned in SAVR

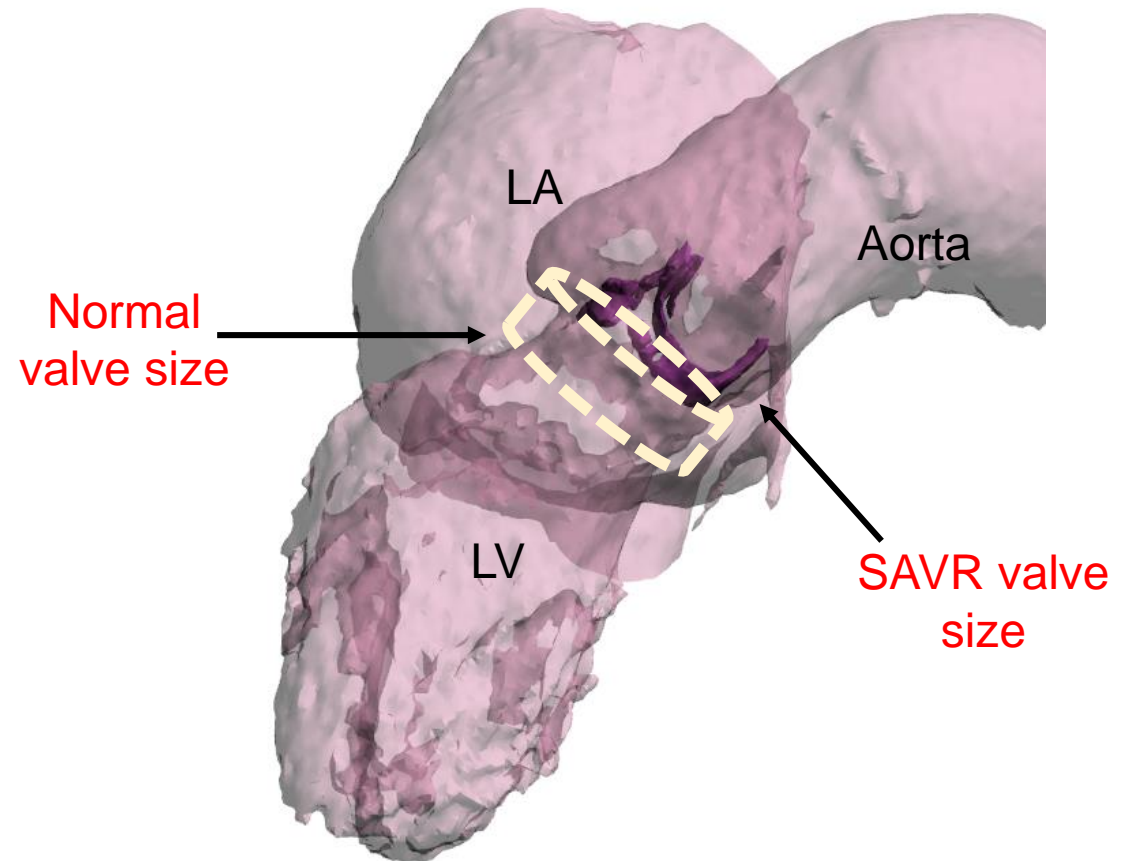
Undersized SAVR in Large Aortic Root : effective prosthetic valve area << normal human valve

Current Topics

The Problem of Valve Prosthesis-Patient Mismatch

SHAHBUDIN H. RAHIMTOOLA, M.D.

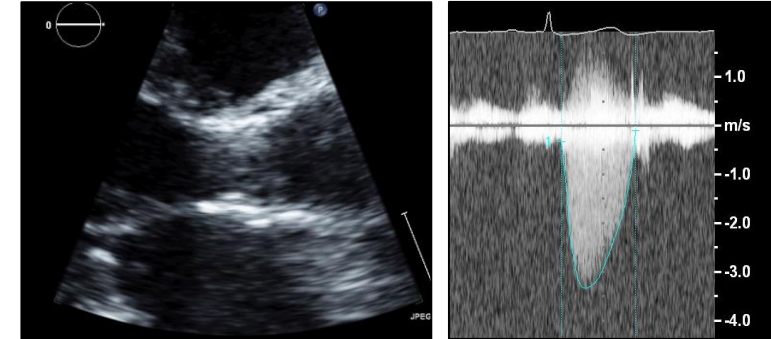
1978 definition of “Mismatch”



Definition of Prosthesis-Patient Mismatch

Prosthesis with normal function but too small for patient's **BSA**:

- ➔ Normal EOA but small indexed EOA
- ➔ High residual gradient following AVR



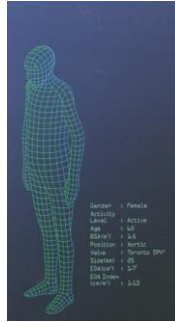
	None/Mild	Moderate	Severe	
Valve structure and motion	Usually normal	Usually normal	Usually normal	
Indexed EOA (cm^2/m^2)	>0.85	$0.85-0.65$	<0.65	
Indexed EOA (cm^2/m^2) in obese patients ($\text{BMI} \geq 30 \text{ kg}/\text{m}^2$)	>0.70	$0.70-0.60$ $0.70-0.55$	<0.60 <0.55	VARC-2 VARC-3

High residual gradient: mean gradient $> 20 \text{ mmHg}$

Methods to Define PPM: Measured vs. Predicted Indexed EOA (EOAi)

PATIENT

BSA= 1.95 m²
BMI= 29 kg/m²



PROSTHESIS



**SAPIEN 3
23 mm**

**MEASURED
EOAi**

**PREDICTED
EOAi**

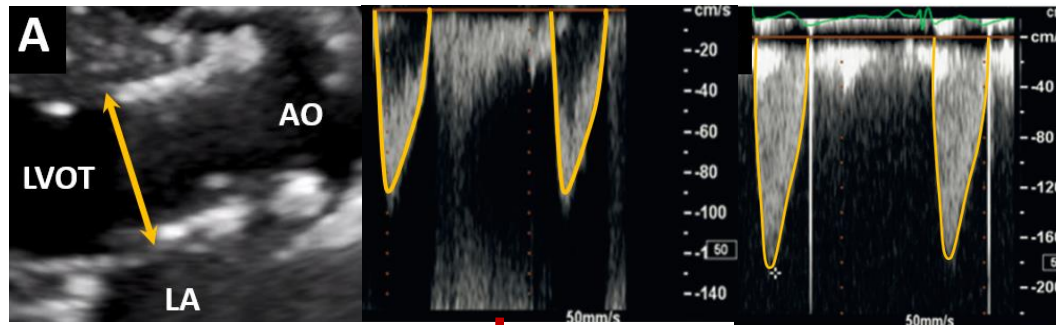


TABLE 2 Mean Gradient and EOA for Balloon-Expandable SAPIEN Valves

Valve Iteration	Prosthetic Valve Size, mm			
	20	23	26	29
SAPIEN				
EOA, cm ²	NA	1.56 ± 0.43 (1,212)	1.84 ± 0.52 (1,130)	NA
Mean gradient, mm Hg	NA	9.92 ± 4.27 (1,212)	8.76 ± 3.89 (1,130)	NA
DVI	NA	0.53 ± 0.13 (1,212)	0.53 ± 0.13 (1,130)	NA
SAPIEN XT				
EOA, cm ²	NA	1.41 ± 0.30 (545)	1.74 ± 0.42 (675)	2.06 ± 0.52 (251)
Mean gradient, mm Hg	NA	10.41 ± 3.74 (545)	9.24 ± 3.57 (675)	8.36 ± 3.14 (251)
DVI	NA	0.52 ± 0.10 (545)	0.54 ± 0.11 (675)	0.53 ± 0.11 (251)
SAPIEN 3				
EOA, cm ²	1.22 ± 0.22 (47)	1.45 ± 0.26 (471)	1.74 ± 0.35 (626)	1.89 ± 0.37 (326)
Mean gradient, mm Hg	16.23 ± 5.01 (47)	12.79 ± 4.65 (471)	10.59 ± 3.88 (626)	9.28 ± 3.16 (326)
DVI	0.42 ± 0.07 (47)	0.43 ± 0.08 (471)	0.43 ± 0.09 (626)	0.40 ± 0.09 (326)

Measured EOA= 1.23 cm²

Predicted EOA= 1.45 cm²

Measured EOAI = 0.63 cm²/m²

Predicted EOAI = 0.72 cm²/m²

Severe (Measured) PPM

vs. Moderate (Predicted) PPM

“Theoretical Concern on PPM clinical Impact?”

Clinical Impact of PPM and Small Annulus on Structural Degeneration of Bioprosthetic Valves

- Small aortic annulus is associated with higher leaflet mechanical stress
 - ⇒ Leaflet mechanical stress is the main determinant of SVD
- Small aortic annulus is associated with higher risk of severe PPM
 - ⇒ Severe PPM is associated with increased risk of SVD in SAVR

Clinical Impact of PPM: Still Controversial Data

- Some studies showed that PPM after TAVR was associated with increased mortality and adverse cardiac events.
- In contrast, other studies have shown that PPM following TAVR was not associated with an increased risk for mortality and clinical outcomes.
- Long-term data on prognostic impact of PPM after TAVR on SVD is still lacking

Prosthesis–Patient Mismatch in Patients Undergoing Transcatheter Aortic Valve Replacement

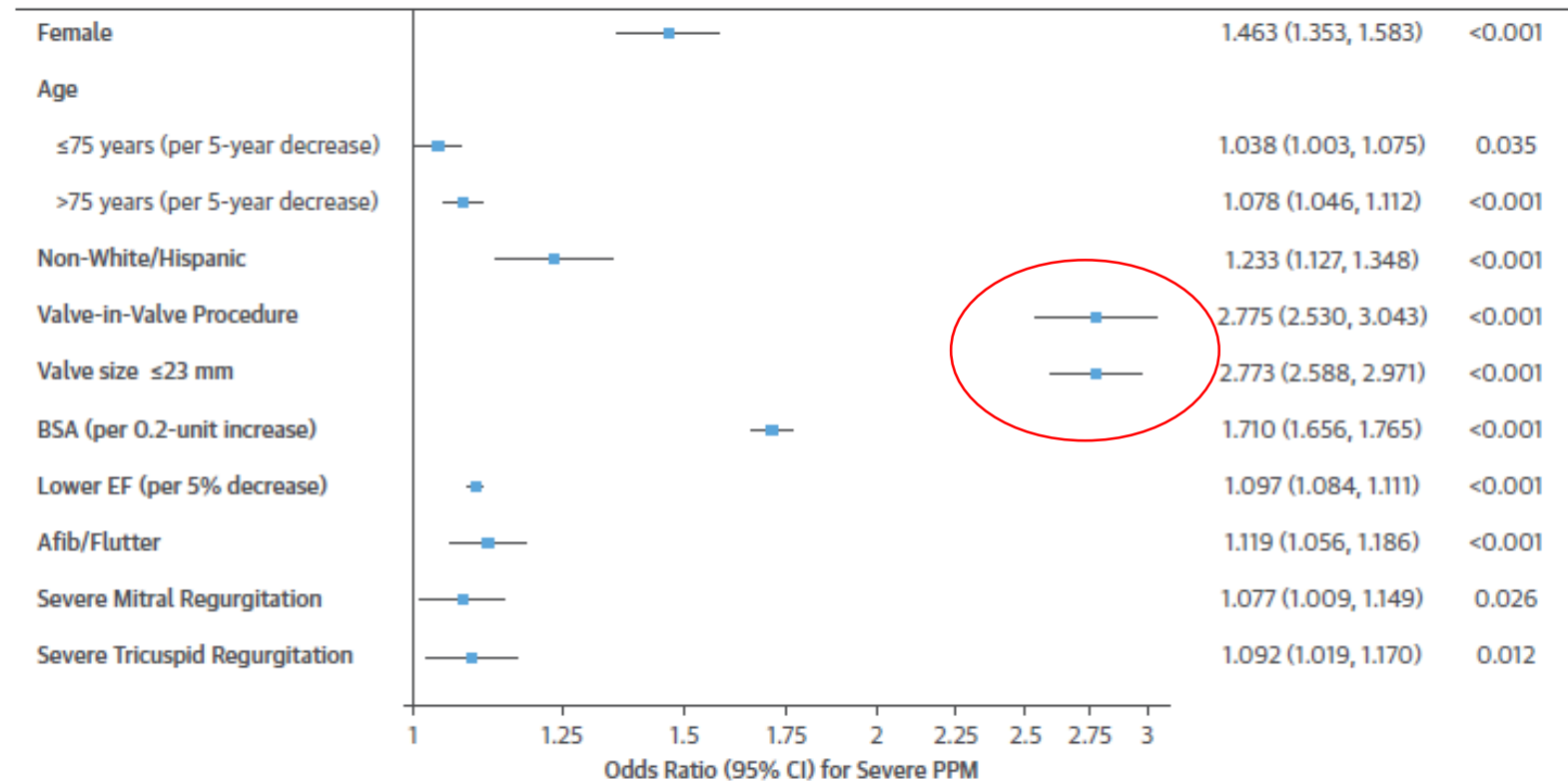


From the STS/ACC TVT Registry

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Predictors of severe PPM in TAVR

FIGURE 2 Forest Plot of Predictors of Severe PPM

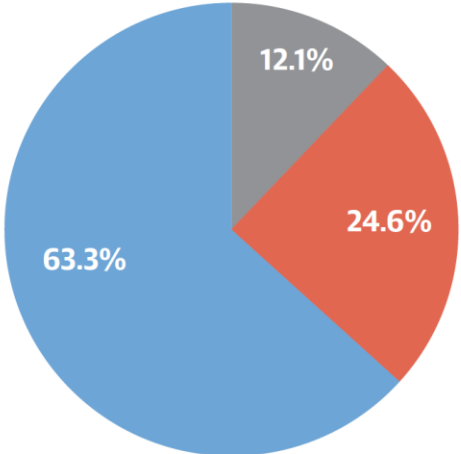


Significant predictors of severe PPM in a multivariate logistic regression model are shown in a Forest plot (values are odds ratios with 95% CI and p values). A fib = atrial fibrillation; BSA = body surface area; CI = confidence interval; EF = ejection fraction; PPM = prosthesis-patient mismatch.

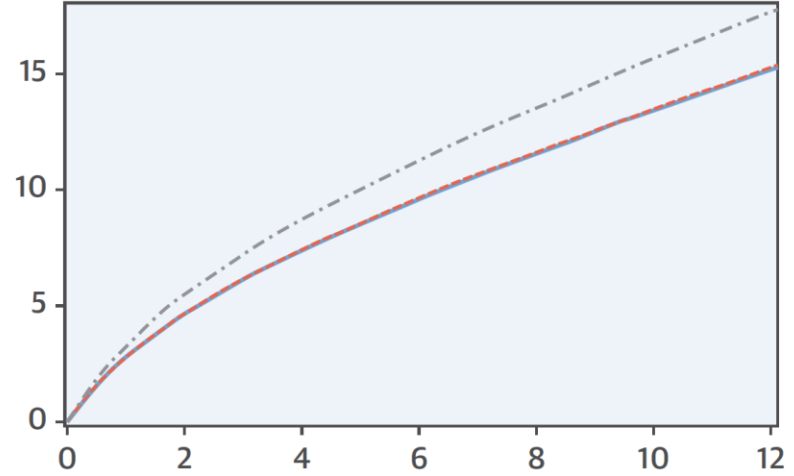
Clinical Impact of PPM (TVT registry, N=62,125)

CENTRAL ILLUSTRATION Incidence and Effect on Survival of Severe Prosthesis-Patient Mismatch After Transcatheter Aortic Valve Replacement

Prosthesis-Patient Mismatch (PPM) **Mortality (%)**



■ Severe (Sev)
 ■ Moderate (Mod)
 ■ None



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:

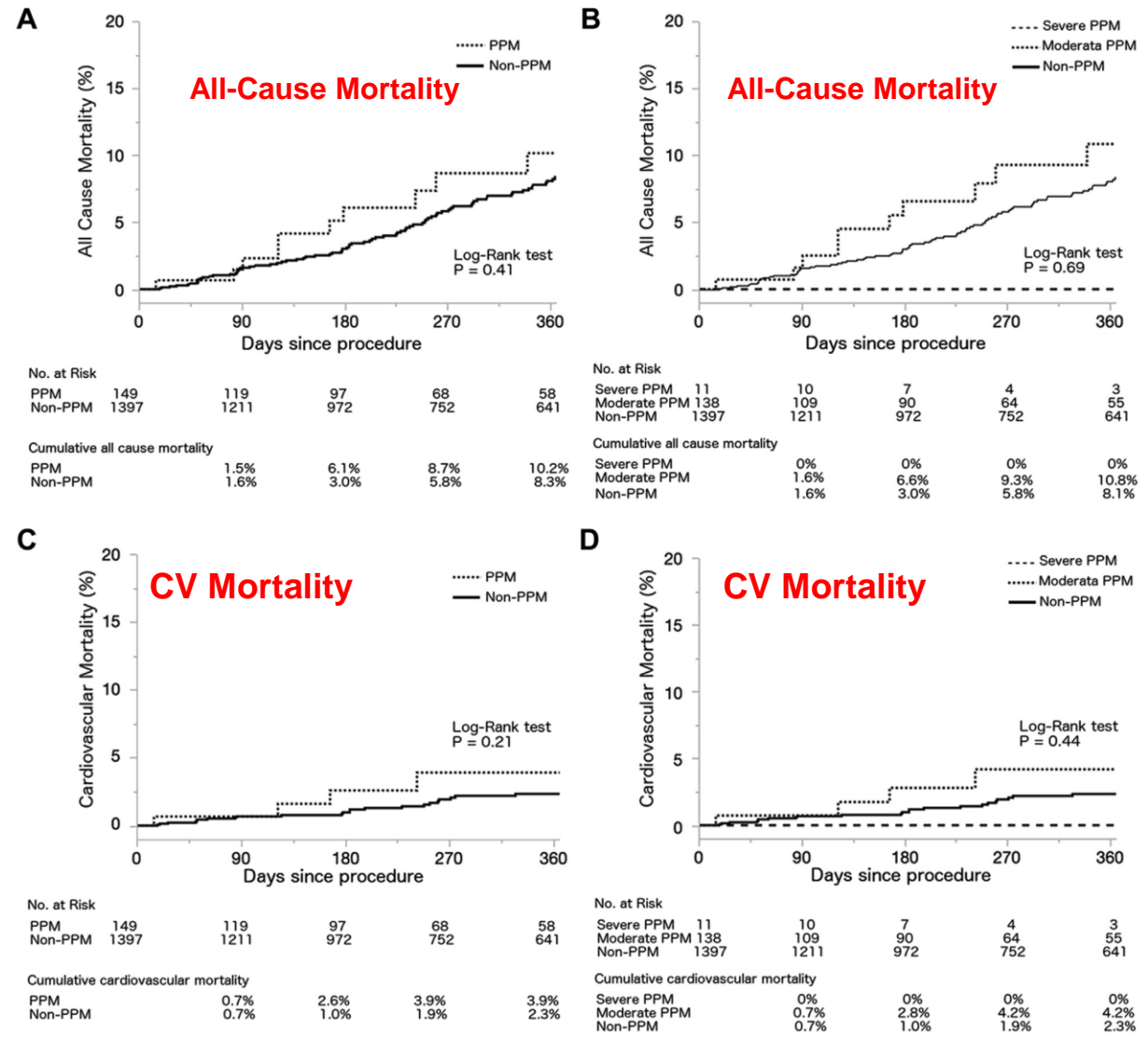
	Day 0	Month 4	Month 8	Month 12
No PPM	23,635	21,080	16,734	13,136
Mod PPM	8,983	7,995	6,277	4,831
Sev PPM	4,152	3,626	2,976	2,130

Herrmann, H.C. et al. J Am Coll Cardiol. 2018;72(22):2701-11.

Clinical Impact of PPM (OCEAN-TAVI registry, N=1,558)

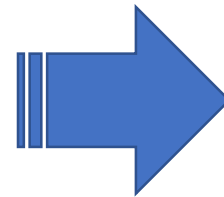
In Japanese Cohort, there was no association of the presence or severity of PPM with increased all-cause mortality and CV mortality.

FIGURE 3 Time-to-Event Curves for Cumulative All-Cause and Cardiovascular Mortality



Known Predictors of PPM

- Older age
- Female sex
- Diabetes
- Renal failure
- Large BSA
- **Small aortic annulus**
- **Small prosthetic valve size**
- SAVR vs. TAVR
- Bioprosthesis vs. mechanical valves in SAVR
- VinV vs. native TAVR
- Balloon expandable vs. self-expanding valves in TAVR



This is more common in Asians rather than in Western patients

STATE-OF-THE-ART REVIEW

Transcatheter Aortic Valve Replacement in Asia

Present Status and Future Perspectives



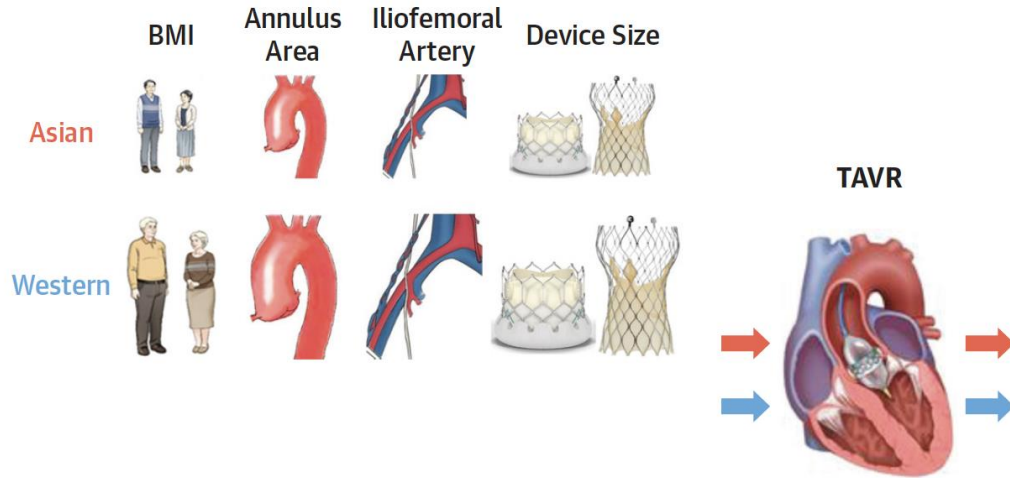
Cheol Hyun Lee, MD, PhD,^{a,*} Taku Inohara, MD, PhD,^{b,*} Kentaro Hayashida, MD, PhD,^b Duk-Woo Park, MD, PhD^c

ABSTRACT

Over the last decade, based on evidence from multiple randomized clinical trials, transcatheter aortic valve replacement (TAVR) has become the established treatment for patients with symptomatic severe aortic stenosis. Despite the overwhelming expansion of TAVR in Western countries, the initial uptake and widespread adoption of this procedure have been relatively delayed in Asian countries, owing to the high cost of devices; limited local health and reimbursement policies; and lack of specific training/proctoring program, specialized heart team, or dedicated infrastructure. Furthermore, it has not yet been determined whether there are substantial interracial and ethnic differences in the clinical characteristics, comorbidities, and anatomic features, as well as procedural and long-term outcomes, in patients receiving TAVR. In this review, we provide not only a comprehensive look at the current status and outcomes of TAVR in Asian populations compared with those of Western populations but also a perspective on the future of TAVR in Asia. (JACC: Asia 2021;1:279–293) © 2021 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

CENTRAL ILLUSTRATION Specific Clinical and Anatomic Features Replacement in Asian Populations

Epidemiology, anatomy, procedural factor



	Age	Male	BMI	LVEF	STS score
Asian	◀▶	◀▶	◀▶	◀▶	◀▶
Western	◀▶	◀▶	▲	◀▶	◀▶

	Valve area	Annulus area	Bicuspid	Device size	Transfemoral
Asian	◀▶	◀▶	▲	◀▶	◀▶
Western	◀▶	▲	◀▶	▲	◀▶

“PPM may be particularly relevant in Asian populations with unique anatomical features such as smaller annular dimensions or smaller valve implant size compared with Western populations”

Racial Differences in the Incidence and Impact of Prosthesis-Patient Mismatch After Transcatheter Aortic Valve Replacement



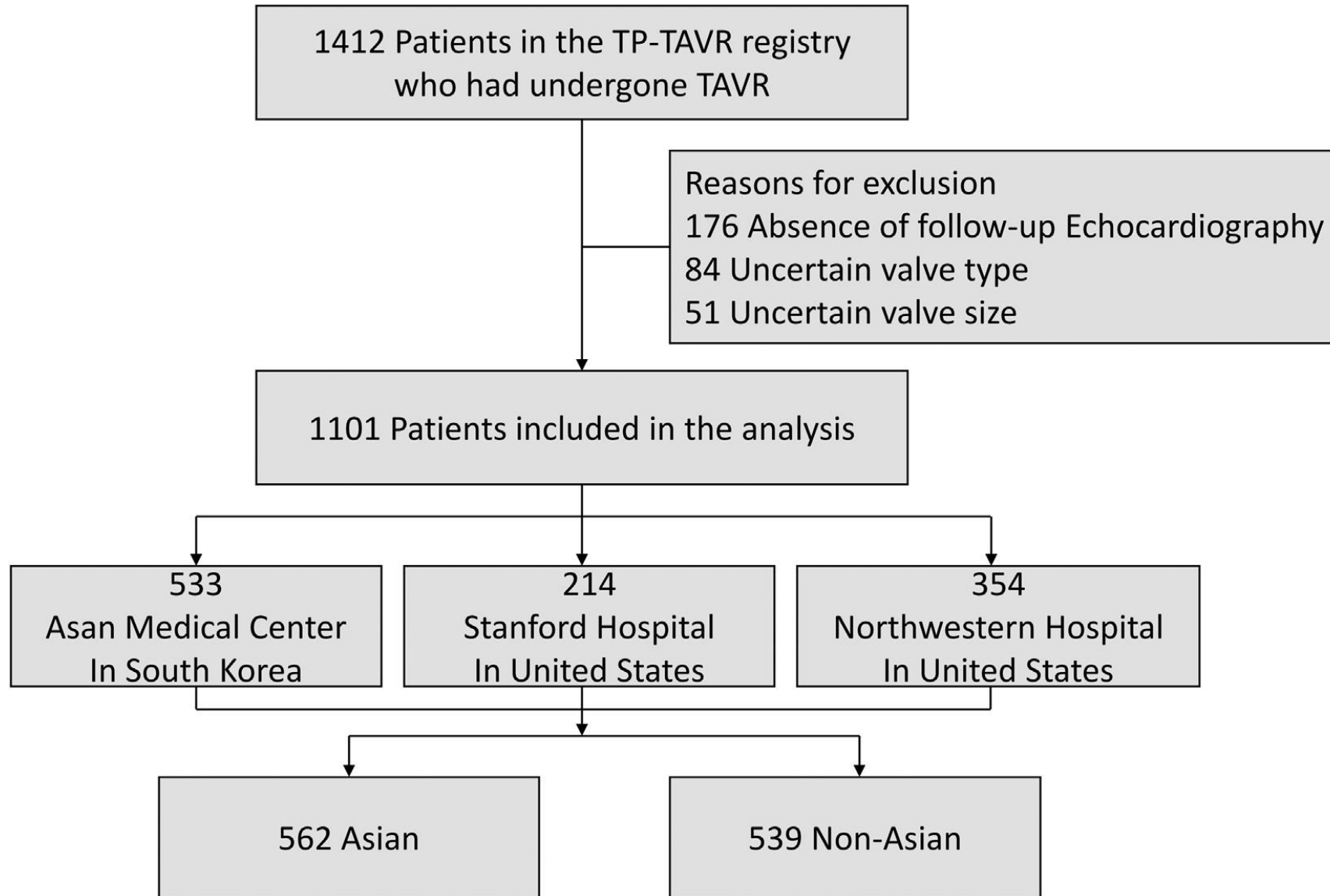
Hanbit Park, MD,^{a,*} Jung-Min Ahn, MD,^{a,*} Do-Yoon Kang, MD,^a Juyong Brian Kim, MD,^b Alan C. Yeung, MD,^b Takeshi Nishi, MD,^b William F. Fearon, MD,^b Eric Page Cantey, MD,^c James D. Flaherty, MD,^c Charles J. Davidson, MD,^c S. Christopher Malaisrie, MD,^c Sehee Kim, PhD,^d Sung-Cheol Yun, PhD,^d Euihong Ko, MD,^a Seung-Ah Lee, MD,^a Dae-Hee Kim, MD,^a Ho Jin Kim, MD,^e Joon Bum Kim, MD,^e Suk Jung Choo, MD,^e Duk-Woo Park, MD,^a Seung-Jung Park, MD^a

ABSTRACT

OBJECTIVES The aim of this study was to compare the incidence and prognostic significance of prosthesis-patient mismatch (PPM) after transcatheter aortic valve replacement (TAVR) according to racial groups.

BACKGROUND PPM after TAVR may be of more concern in Asian populations considering their relatively small annular and valve sizes compared with Western populations.

Study Flow Diagram of TP-TAVR Registry



Baseline Characteristics

TABLE 1 Baseline Characteristics of Patients According to the Presence of PPM and Racial Group

	Asian Group				Non-Asian Group				
	Overall (N = 562)	PPM (n = 189)	No PPM (n = 373)	P Value	Overall (N = 539)	PPM (n = 294)	No PPM (n = 245)	P Value	P Value ^a
Demographics and clinical risk factors									
Age, y	80.1 ± 5.6	79.8 ± 5.5	80.2 ± 5.7	0.45	79.5 ± 9.5	78.8 ± 9.9	80.3 ± 8.8	0.07	0.22
Male	286 (50.9)	97 (51.3)	189 (50.7)	0.88	310 (57.5)	178 (60.5)	132 (53.9)	0.12	0.03
BMI, kg/m ²	24.0 ± 3.6	24.6 ± 3.4	23.7 ± 3.7	0.007	28.5 ± 6.6	28.5 ± 6.6	28.4 ± 6.6	0.87	<0.001
BMI ≥30 kg/m ²	28 (5.0)	4 (2.1)	24 (6.4)	0.03	174 (32.3)	81 (27.6)	93 (38.0)	0.01	<0.001
BSA, m ²	1.60 ± 0.17	1.58 ± 0.17	1.63 ± 0.16	<0.001	1.91 ± 0.29	1.93 ± 0.28	1.88 ± 0.30	0.03	<0.001
SIS score, %	3.3 (2.9-4.9)	3.0 (2.1-4.6)	3.4 (2.4-5.0)	0.12	4.1 (3.0-6.8)	4.2 (3.0-6.5)	4.1 (3.0-7.0)	0.70	<0.001
NYHA functional class III or IV	199 (35.4)	65 (34.4)	134 (35.9)	0.72	294 (54.5)	156 (53.1)	138 (56.3)	0.45	<0.001
Diabetes	297 (52.8)	98 (51.9)	199 (53.4)	0.74	186 (34.5)	108 (36.7)	78 (31.8)	0.23	<0.001
Hypertension	490 (87.2)	164 (86.8)	326 (87.4)	0.83	445 (82.6)	245 (83.3)	200 (81.6)	0.60	0.03
Prior MI	46 (8.2)	18 (9.5)	28 (7.5)	0.41	14 (2.6)	7 (2.4)	7 (2.9)	0.73	<0.001
Hyperlipidemia	421 (74.9)	146 (77.2)	275 (73.7)	0.36	382 (70.9)	214 (72.8)	168 (68.6)	0.28	<0.001
Current smoker	26 (4.6)	8 (4.2)	18 (4.8)	0.75	64 (11.9)	34 (11.6)	30 (12.2)	0.81	0.132
Prior PCI	154 (27.4)	51 (27.0)	103 (27.6)	0.87	163 (30.2)	96 (32.7)	67 (27.3)	0.182	0.30
Prior CABG	28 (5.0)	13 (6.9)	15 (4.0)	0.14	94 (17.4)	59 (20.1)	35 (14.3)	0.08	<0.001
Prior stroke	76 (13.5)	26 (13.8)	50 (13.4)	0.91	56 (10.4)	29 (9.9)	27 (11.0)	0.66	0.11
Atrial fibrillation	65 (11.6)	23 (12.2)	42 (11.3)	0.75	213 (39.5)	127 (43.2)	86 (35.1)	0.06	<0.001
Peripheral artery disease	18 (3.2)	6 (3.2)	12 (3.2)	0.98	113 (21.0)	64 (21.8)	49 (20.0)	0.62	<0.001
Chronic lung disease	61 (10.9)	17 (9.0)	44 (11.8)	0.31	82 (15.2)	44 (15.0)	38 (15.5)	0.86	0.03
Chronic kidney disease ^b	421 (74.9)	133 (70.4)	288 (77.2)	0.08	158 (29.3)	92 (31.3)	66 (26.9)	0.27	<0.001
End-stage renal disease	21 (3.7)	10 (5.3)	11 (2.9)	0.17	20 (3.7)	14 (4.8)	6 (2.4)	0.16	0.98
Echocardiographic findings									
Bicuspid aortic valve	57 (10.1)	13 (6.9)	44 (11.8)	0.07	25 (4.6)	11 (3.7)	14 (5.7)	0.278	0.001
Aortic valve area, mm ²	0.60 (0.50-0.71)	0.60 (0.49-0.70)	0.60 (0.51-0.72)	0.13	0.70 (0.59-0.84)	0.70 (0.56-0.80)	0.74 (0.60-0.90)	<0.001	<0.001
Mean PG, mm Hg	57 ± 21	57 ± 21	57 ± 21	0.82	45 ± 14	46 ± 15	44 ± 14	0.053	<0.001
LV ejection fraction, %	58 ± 11	57 ± 12	58 ± 11	0.35	58 ± 13	57 ± 13	59 ± 13	0.08	0.48
Moderate to severe AR	107 (19.0)	33 (17.5)	74 (19.8)	0.50	58 (10.8)	30 (10.2)	28 (11.4)	0.65	<0.001
Moderate to severe MR	66 (11.7)	27 (14.3)	39 (10.5)	0.18	113 (21.0)	62 (21.1)	51 (20.8)	0.94	<0.001
Moderate to severe TR	34 (6.0)	19 (10.1)	15 (4.0)	0.005	84 (15.6)	49 (16.7)	35 (14.3)	0.45	<0.001
CT findings									
Annular perimeter, mm	75.7 ± 7.5	73.9 ± 7.7	76.6 ± 7.2	<0.001	78.4 ± 8.4	77.6 ± 8.4	79.3 ± 8.2	0.03	<0.001
Annular area, mm ²	441 ± 87	420 ± 86	451 ± 86	<0.001	461 ± 95	454 ± 95	469 ± 95	0.06	<0.001

Procedural Characteristics

TABLE 2 Procedural Characteristics and In-Hospital Outcomes According to the Presence of PPM and Racial Group

	Asian Group				Non-Asian Group				P Value ^a
	Overall (N = 562)	PPM (n = 189)	No PPM (n = 373)	P Value	Overall (N = 539)	PPM (n = 294)	No PPM (n = 245)	P Value	
Procedural characteristics									
Procedure type				<0.001				0.07	0.07
Native	545 (97.0)	175 (92.6)	370 (99.2)		511 (94.8)	274 (93.2)	237 (96.7)		
Valve-in-valve	17 (3.0)	14 (7.4)	3 (0.8)		28 (5.2)	20 (6.8)	8 (3.3)		
Access site				0.91				0.009	0.99
Transfemoral	539 (95.9)	181 (95.8)	358 (96.0)		517 (95.9)	288 (98.0)	229 (93.5)		
Nontransfemoral	23 (4.1)	8 (4.2)	15 (4.0)		22 (4.1)	6 (2.0)	16 (6.5)		
Valve type				0.55				0.27	0.12
Balloon expandable	466 (82.9)	151 (79.9)	315 (84.5)		465 (86.3)	258 (87.8)	207 (84.5)		
SAPIEN XT	43 (7.7)	11 (5.8)	32 (8.6)		0 (0.0)	0 (0.0)	0 (0.0)		
APIEN 3	423 (75.3)	140 (74.1)	283 (75.9)		465 (86.3)	258 (87.8)	207 (84.5)		
Self-expandable	96 (17.1)	38 (20.1)	58 (15.5)		74 (13.7)	36 (12.2)	38 (15.5)		
CoreValve	9 (1.6)	3 (1.6)	6 (1.6)		13 (2.4)	4 (1.4)	9 (3.7)		
Evolut R	75 (13.3)	29 (15.3)	46 (12.3)		56 (10.4)	29 (9.9)	27 (11.0)		
Evolut PRO	7 (1.2)	4 (2.1)	3 (0.8)		5 (0.9)	3 (1.0)	2 (0.8)		
Lotus	5 (0.9)	2 (1.1)	9 (0.8)		0 (0.0)	0 (0.0)	0 (0.0)		
Size of the SAPIEN series				<0.001				0.08	0.80
20 mm	8 (1.4)	5 (2.6)	3 (0.8)		17 (3.2)	13 (4.4)	4 (1.6)		
23 mm	142 (25.3)	61 (32.3)	81 (21.7)		149 (27.6)	87 (29.6)	62 (25.3)		
26 mm	233 (41.5)	67 (35.4)	166 (44.5)		194 (36.0)	104 (35.4)	90 (36.7)		
29 mm	81 (14.4)	17 (9.0)	64 (17.2)		105 (19.5)	54 (18.4)	51 (20.8)		
Size of the CoreValve series				0.18				0.06	0.02
23 mm	13 (2.3)	8 (4.2)	5 (1.3)		11 (2.0)	8 (2.7)	3 (1.2)		
26 mm	45 (8.0)	15 (7.9)	30 (8.0)		24 (4.5)	9 (3.1)	15 (6.1)		
29 mm	27 (4.8)	12 (6.3)	15 (4.0)		27 (5.0)	17 (5.8)	10 (4.1)		
≥31 mm	7 (1.2)	2 (1.0)	5 (1.3)		12 (2.2)	2 (0.7)	10 (4.1)		

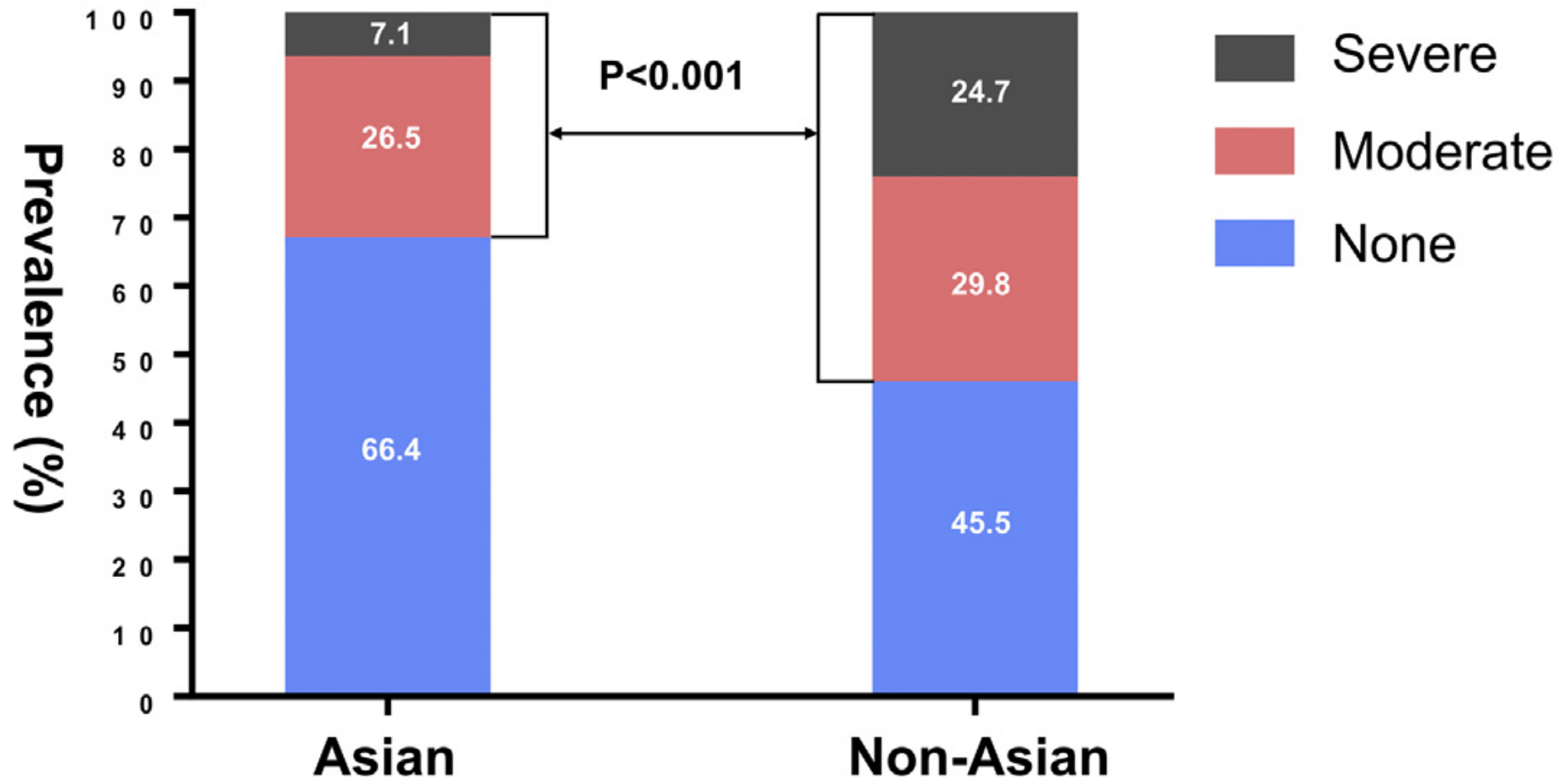
Echo Hemodynamics: Ratio Fallacy?

TABLE 3 Postprocedural Echocardiographic Data and Pattern of PPM According to Racial Groups

	Asian Group				Non-Asian Group				P Value ^a
	Overall (N = 562)	PPM (n = 189)	No PPM (n = 373)	P Value	Overall (N = 539)	PPM (n = 294)	No PPM (n = 245)	P Value	
LV ejection fraction, %	59 ± 9	59 ± 9	60 ± 9	0.16	58 ± 12	57 ± 12	59 ± 12	0.04	0.02
EOA, cm ²	1.50 ± 0.37	1.18 ± 0.18	1.67 ± 0.33	<0.001	1.52 ± 0.49	1.22 ± 0.25	1.88 ± 0.45	<0.001	0.56
Indexed EOA, cm ² /m ²	0.94 ± 0.22	0.73 ± 0.10	1.05 ± 0.18	<0.001	0.80 ± 0.25	0.63 ± 0.12	1.01 ± 0.20	<0.001	<0.001
Moderate PPM ^a	149 (26.5)	149 (78.8)	0 (0.0)	NA	161 (29.8)	161 (54.8)	0 (0.0)	NA	NA
Severe PPM ^a	40 (7.1)	40 (21.2)	0 (0.0)	NA	144 (24.7)	133 (45.2)	0 (0.0)	NA	NA
Peak velocity, m/s	2.5 ± 0.5	2.7 ± 0.5	2.4 ± 0.4	<0.001	2.4 ± 0.5	2.5 ± 0.5	2.2 ± 0.5	<0.001	<0.001
Pressure gradient, mm Hg	13 ± 5	16 ± 6	12 ± 4	<0.001	12 ± 6	14 ± 6	10 ± 4	<0.001	<0.001
≥20	68 (12.1)	43 (22.8)	25 (6.7)	<0.001	47 (8.7)	41 (13.9)	6 (2.4)	<0.001	0.70
≥40	1 (0.2)	1 (0.5)	0 (0.0)	0.34	0 (0.0)	0 (0.0)	0 (0.0)	>0.99	0.51
Paravalvular leakage, moderate to severe	20 (3.6)	4 (2.1)	16 (4.3)	0.19	1 (0.2)	0 (0.0)	1 (0.4)	0.46	0.45
Moderate to severe MR	28 (5.0)	10 (5.3)	18 (4.8)	0.81	26 (4.8)	13 (4.4)	13 (5.3)	0.63	0.28
Moderate to severe TR	26 (4.6)	9 (4.8)	17 (4.6)	0.91	34 (6.3)	19 (6.5)	15 (6.1)	0.87	0.51

Incidence of PPM According to the VARC-2 Criteria

Prosthesis-Patient Mismatch



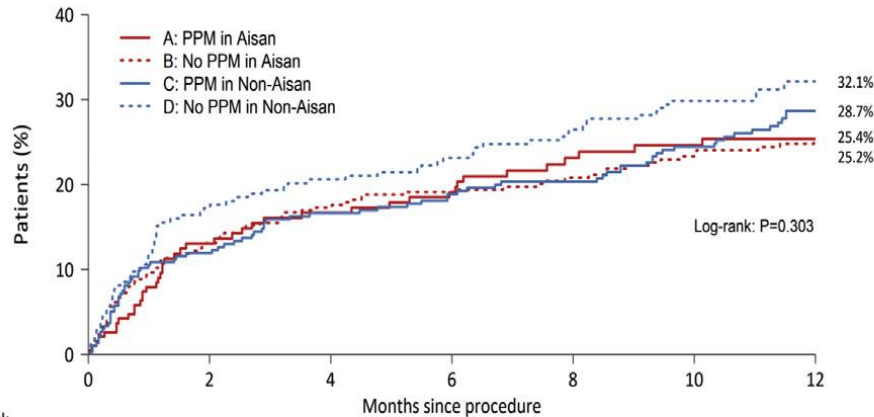
Independent Predictors of PPM

TABLE 4 Multivariate Analyses for Independent Predictors of Moderate or Severe Prosthesis-Patient Mismatch

	Overall Group (N = 1,101)		Asian Group (n = 562)		Non-Asian Group (n = 539)	
	OR (95% CI)	P Value	OR (95% CI)	P Value	OR (95% CI)	P Value
Race: Asian vs non-Asian (referent)	0.43 (0.31-0.60)	<0.001	–	–	–	–
Age ≥80 y	0.81 (0.61-1.06)	0.12	0.98 (0.66-1.46)	0.92	0.66 (0.45-0.98)	0.04
BMI, kg/m ²	1.03 (1.01-1.05)	0.046	1.06 (1.01-1.12)	0.03	1.00 (0.97-1.03)	0.87
BSA, per 0.1 m ²	1.43 (1.30-1.56)	<0.001	1.56 (1.36-1.79)	<0.001	1.37 (1.22-1.53)	<0.001
Prior CABG	1.52 (1.01-2.30)	0.047	1.71 (0.75-3.91)	0.21	1.44 (0.88-2.45)	0.14
Atrial fibrillation or flutter	1.26 (0.92-1.72)	0.15	0.90 (0.49-1.64)	0.73	1.47 (1.00-2.15)	0.05
Chronic kidney disease	0.97 (0.73-1.30)	0.85	0.74 (0.47-1.16)	0.18	1.27 (0.85-1.89)	0.24
Aortic valve area	0.27 (0.12-0.60)	0.001	0.22 (0.05-1.02)	0.053	0.29 (0.11-0.75)	0.01
Mean pressure gradient, per 10 mm Hg	0.99 (0.91-1.07)	0.79	0.94 (0.84-1.05)	0.29	1.09 (0.95-1.26)	0.23
Bicuspid aortic valve	0.67 (0.40-1.13)	0.13	0.79 (0.40-1.57)	0.50	0.63 (0.27-1.45)	0.28
LV ejection fraction ≤40%	0.76 (0.49-1.18)	0.22	0.76 (0.39-1.48)	0.43	0.80 (0.44-1.46)	0.47
Moderate to severe TR at baseline	1.29 (0.84-1.99)	0.24	2.52 (1.16-5.46)	0.02	0.97 (0.58-1.63)	0.91
Valve perimeter	0.94 (0.88-1.01)	0.10	0.97 (0.87-1.09)	0.64	0.94 (0.86-1.02)	0.11
Valve area, per 100 mm ²	1.22 (0.67-2.23)	0.52	0.81 (0.30-2.21)	0.68	1.45 (0.70-2.97)	0.31
Balloon-expandable THV	1.37 (0.94-2.02)	0.11	1.31 (0.76-2.26)	0.32	1.60 (0.92-2.78)	0.10
Postdilation performed	0.74 (0.55-0.99)	0.049	0.87 (0.58-1.33)	0.53	0.72 (0.46-1.12)	0.14

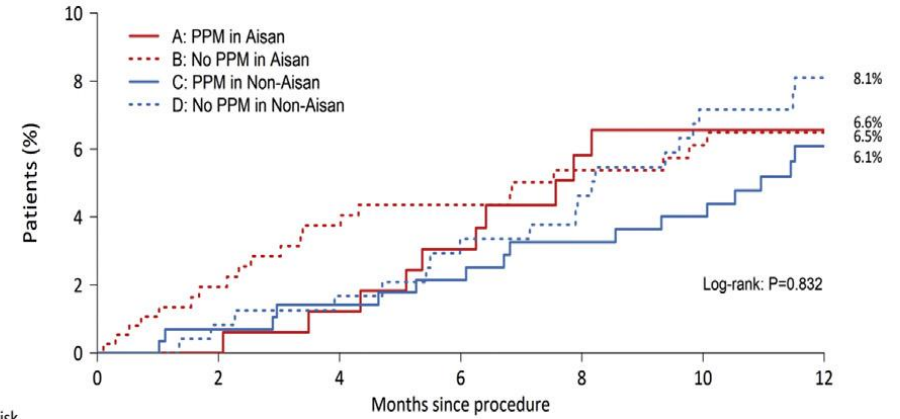
Primary Composite Outcome

A Primary outcome
: A composite of death, stroke or rehospitalization



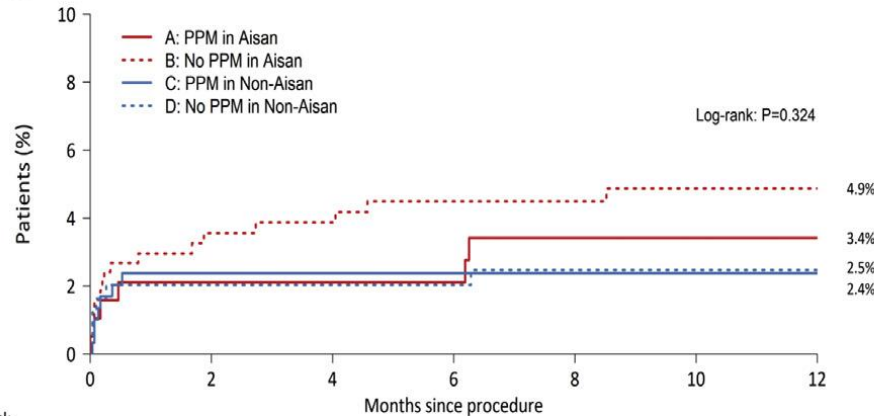
Number at risk	0	2	4	6	8	10	12
A	189	146	139	134	104	102	100
B	373	291	276	269	224	211	189
C	294	246	230	220	215	201	159
D	245	198	190	184	175	167	147

B Death



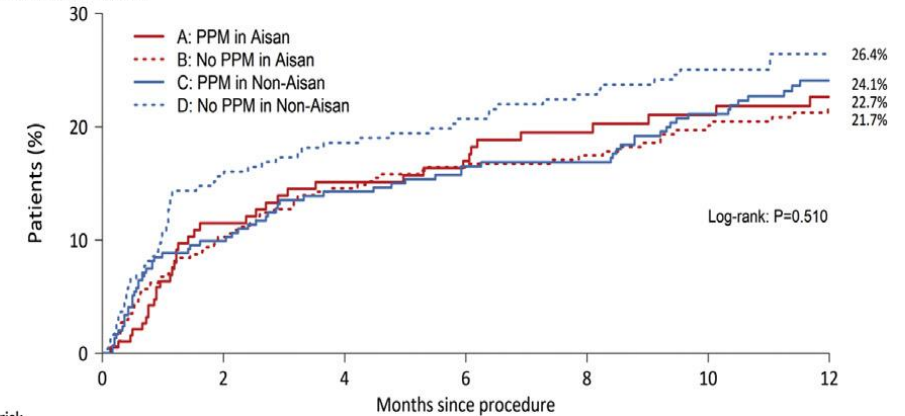
Number at risk	0	2	4	6	8	10	12
A	189	189	163	159	128	127	127
B	373	330	319	316	269	256	255
C	294	285	273	268	262	255	210
D	245	238	235	231	226	219	199

C Stroke



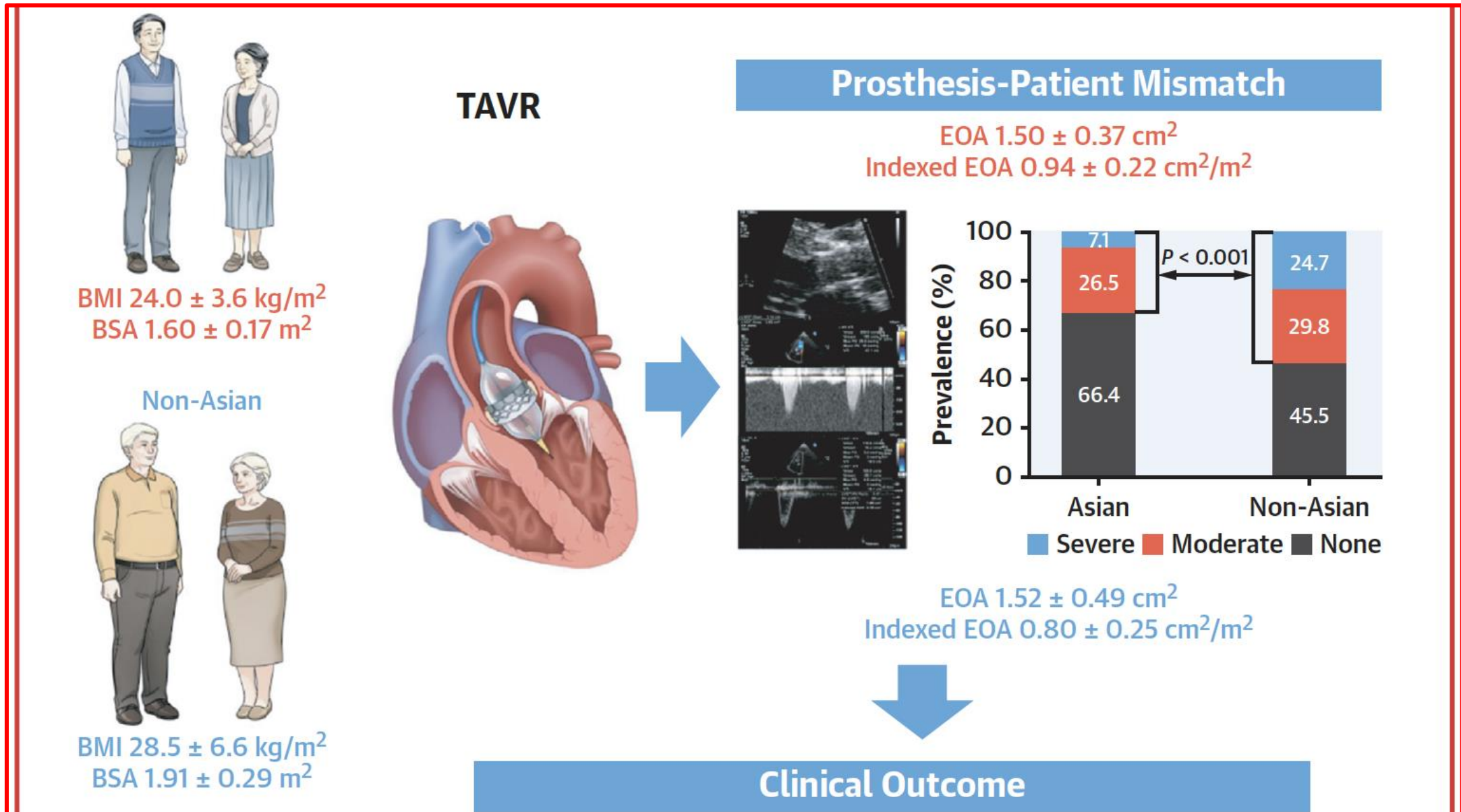
Number at risk	0	2	4	6	8	10	12
A	189	185	185	185	149	149	149
B	373	318	312	305	305	252	252
C	294	288	288	288	288	288	288
D	245	241	241	241	225	225	225

D Rehospitalization

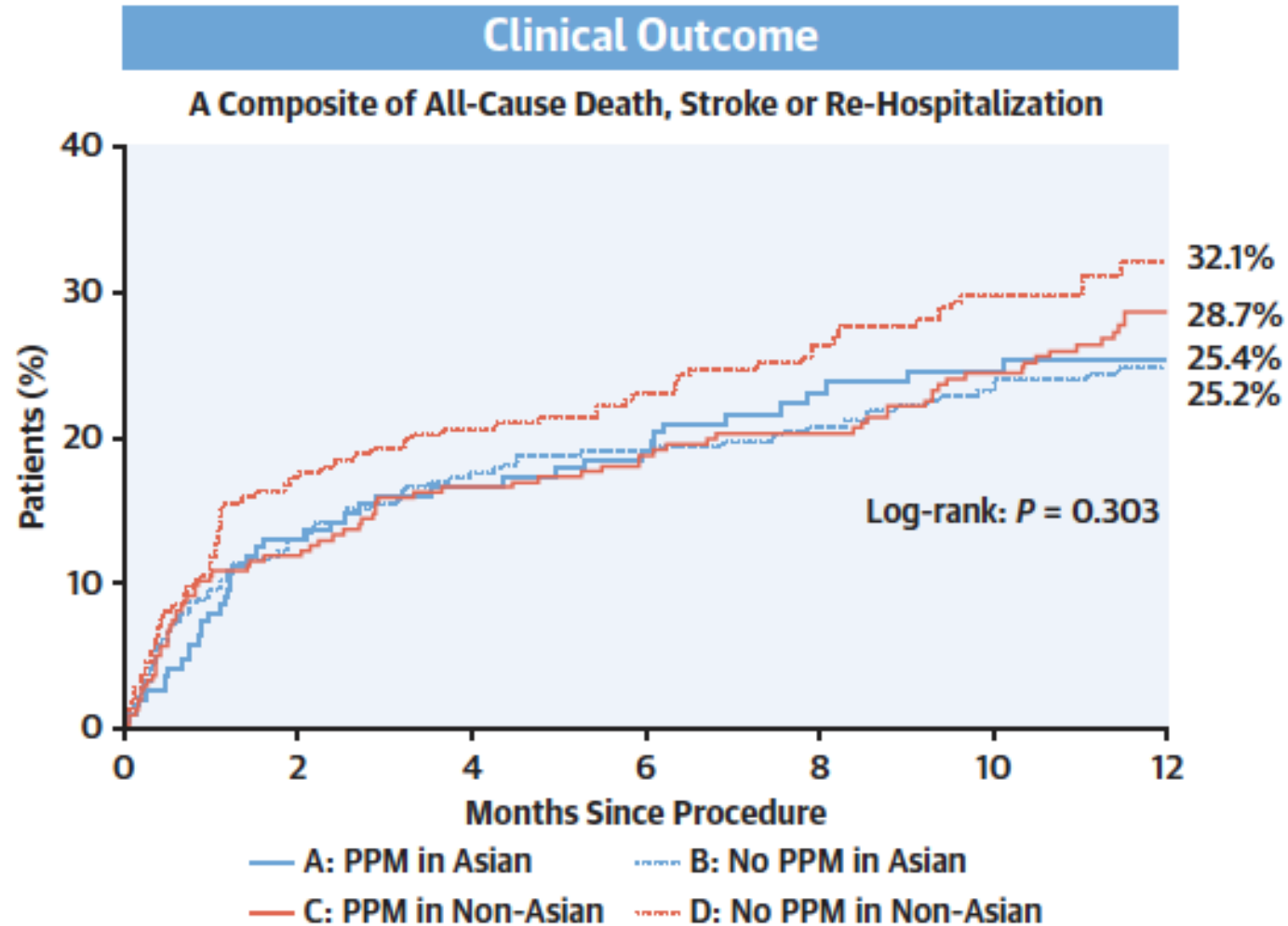


Number at risk	0	2	4	6	8	10	12
A	189	149	141	136	118	103	96
B	373	296	279	271	225	212	189
C	294	251	235	224	221	204	162
D	245	201	193	187	180	171	162

Inter-Racial Disparity of PPM Incidence



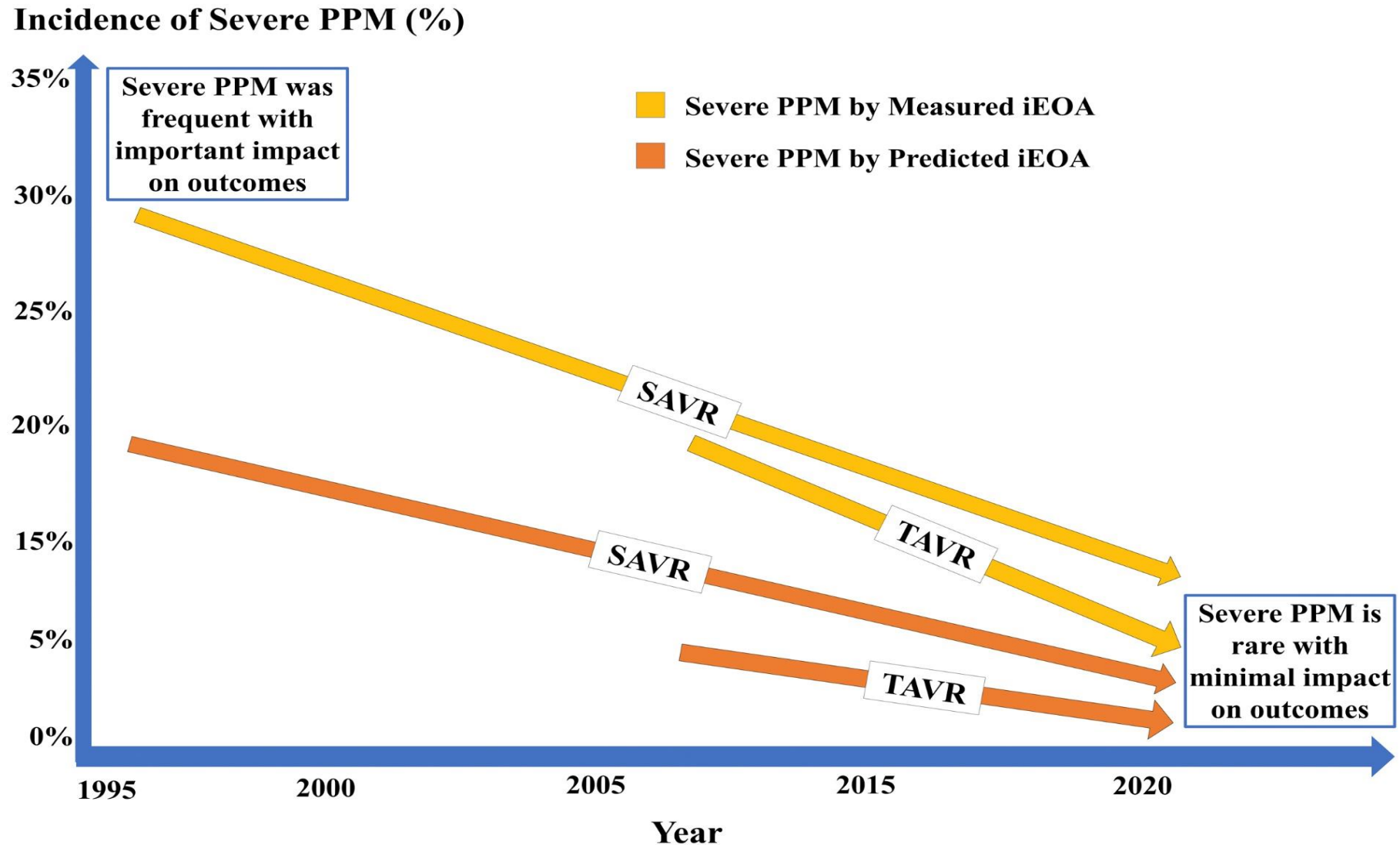
Inter-Racial Disparity of PPM Impact



Key Lessons from the TP-TAVR registry

- In this multi-racial, multi-national registry, Asian patients had a significantly lower incidence of PPM than did Western patients.
- Several race-specific predictors for PPM were identified.
- Regardless of racial group, the 1-yr risk for the primary composite of death, stroke, or rehospitalization and mortality was similar between the PPM and no-PPM groups.

PPM in the TAVI Era: Is it Becoming Obsolete?



Summary: PPM - Still Unknown Issue

- The definition of PPM is arbitrary/controversial; an accurate definition is required to correctly classify patients with hemodynamic obstruction and properly assess the implications of PPM.
- PPM – pathologic finding or just physiologic phenomenon
- PPM – is it the ratio fallacy (mainly driven BSA)?
- Modifiable or non-modifiable factors?
- PPM – key determinant for valve type choice? (self-expandable with larger EOA >> balloon-expandable)
- Most importantly, it is still uncertain whether PPM may impair TAVR durability and how this phenomenon is applied in decision-making of valve choice and risk stratification.

Supplementary

Incidence and Impact of PPM by Measured and Predicted EOAI Methods in PARTNER 2A Trial and S3i Registry

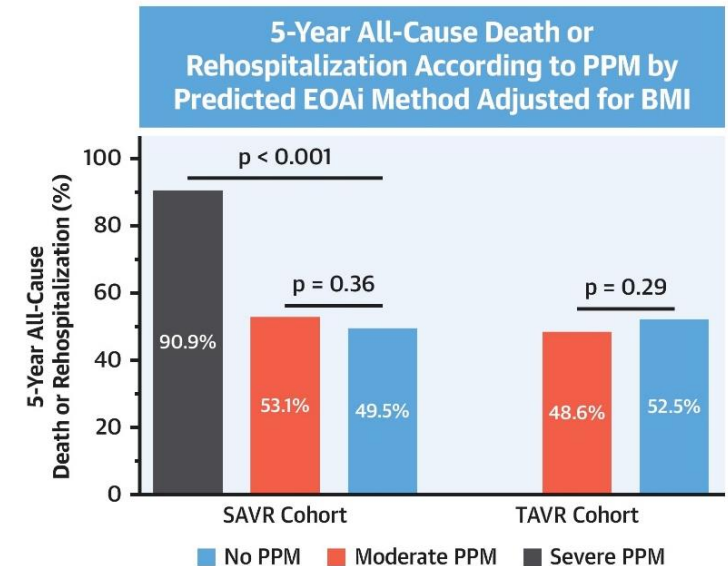
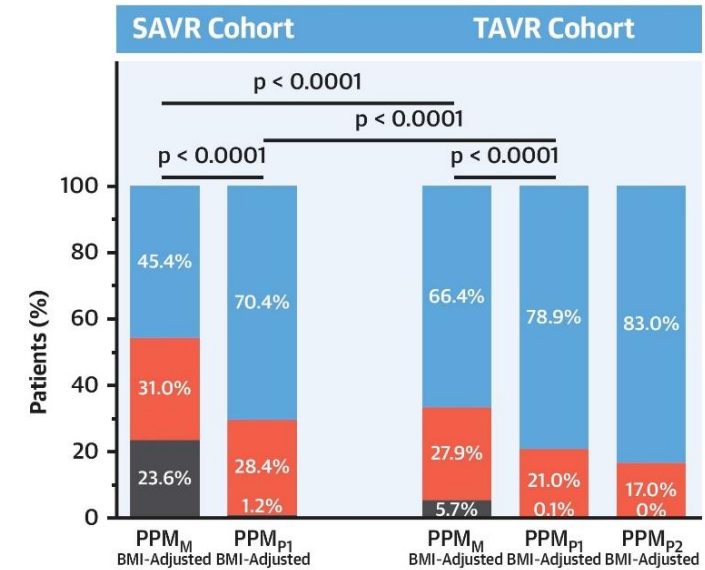
INCIDENCE OF PROSTHESIS-PATIENT MISMATCH

- 1- Incidence of severe PPM is markedly lower with predicted vs. measured EOAI
- 2- TAVR has lower incidence of severe PPM compared to SAVR, regardless of the EOAI method used to identify PPM.

IMPACT OF PROSTHESIS-PATIENT MISMATCH ON OUTCOMES

- 1- In SAVR, severe PPM by the predicted EOAI method is rare but independently associated with worse outcomes.
- 2- In TAVR, severe PPM by the predicted EOAI method is absent
- 3- In both SAVR and TAVR, moderate PPM is not associated with worse outcomes

Ternacle, J. et al. J Am Coll Cardiol Interv. 2021;14(13):1466-77.



Study / Trial	Definition of PPM	Incidence of Severe PPM	Impact on Mortality
Meta-Analysis – SAVR (Head 2012)	Predicted	10 %	HR: 1.84*
STS Registry – SAVR (Fallon 2018)	Predicted	11 %	HR: 1.19*
PARTNER 1 – SAVR vs. TAVR (Pibarot 2014)	Measured	28 vs. 20 %*	HR: 1.78* vs. 0.52
CORE VALVE HR – SAVR vs. TAVR (Zorn 2015)	Measured	21 vs. 7 %*	HR: 1.60* (SAVR+TAVR)
PARTNER 2A-S3i – SAVR vs. TAVR (Ternacle 2021)	Predicted/Measured	24 vs. 6 %*	HR: 1.34* vs. 1.27
PARTNER 3 – SAVR vs. TAVR (Pibarot 2020)	Measured	6 vs. 5 %	HR: 1.31 (SAVR+TAVR)
TVT Registry – TAVR (BE and SE) (Herrmann 2018)	Measured	12 %	HR: 1.19*
TVT Registry – TAVR (SE only) (Tang 2021)	Measured	5.3 %	HR: 1.00 (SAVR+TAVR)
TAVI – SMALL Registry (Leone 2021)	Measured	9.4 %	HR: 4.27*