Racial Disparities in TAVR: Similarities and Differences

Duk-Woo Park, MD

Asan Medical Center, Ulsan University College of Medicine, Seoul, Korea

Disclosure

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Racial Disparity and TAVR Outcome Difference

Literatures Review

STATE-OF-THE-ART REVIEW

Racial and Ethnic Differences in Treatment and Outcomes of Severe Aortic Stenosis

A Review

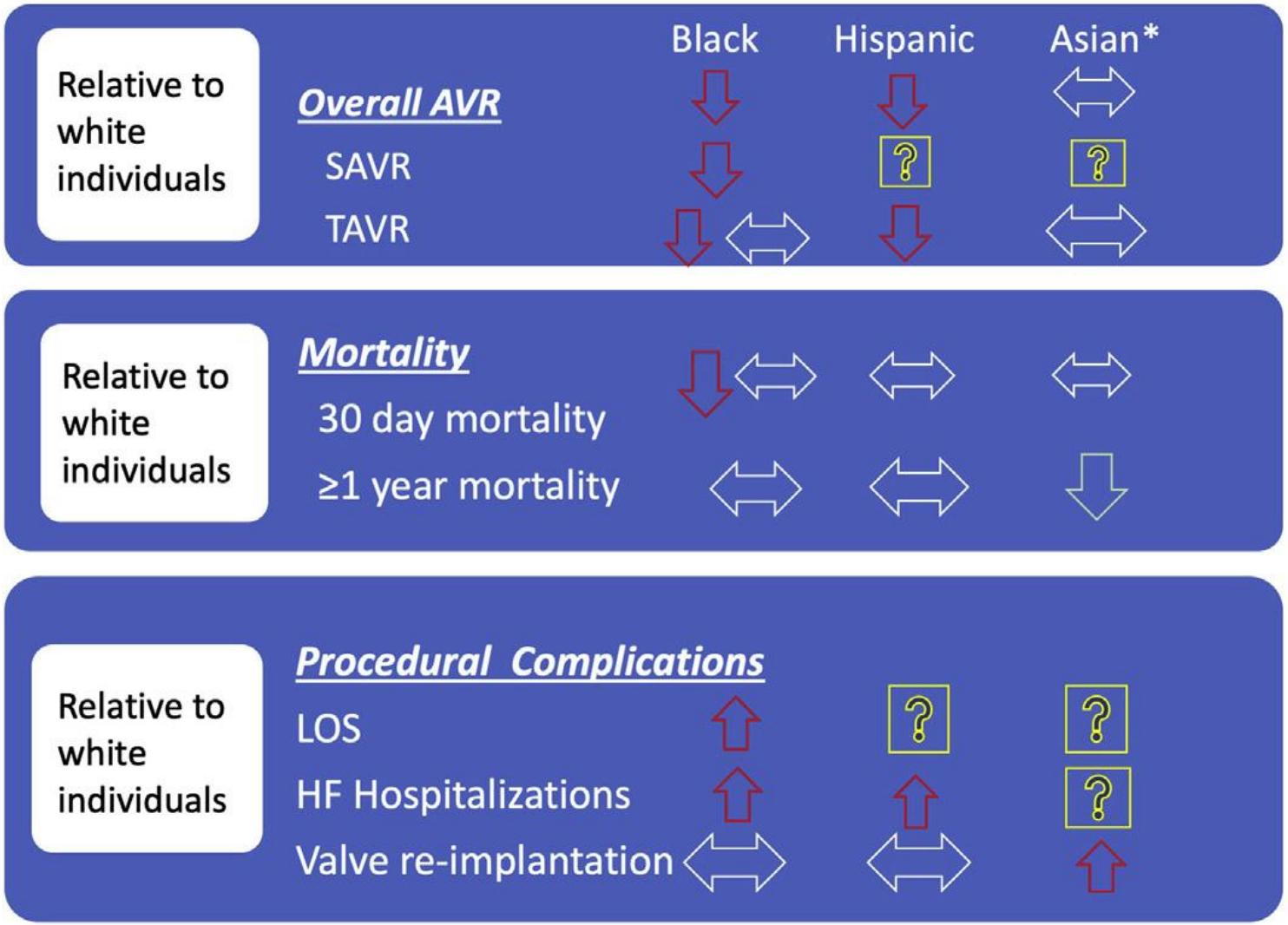
Jimica B. Wilson, BS,[a] Larry R. Jackson II, MD,[b] Francis E. Ugowe, MD,[c] Terrell Jones, BS,[d] George S.A. Yankey, Jr, MD,[c] Colin Marts, BA,[d] Kevin L. Thomas, MD[b]

ABSTRACT

Aortic stenosis (AS) is among the most common valvular heart diseases encountered in the United States. In this review the authors examine differences between racial and ethnic groups in the epidemiology and management of severe AS, explore potential explanations for these findings, and discuss the implications for improving the delivery of care to racially and ethnically diverse populations. Underrepresented racial and ethnic groups experience a paradoxically lower prevalence or incidence of AS relative to white subjects, despite having a higher prevalence of traditional risk factors. Historically, UREGs with severe AS have had lower rates of both surgical and transcatheter aortic valve replacement and experienced more post-surgical complications, including, bleeding, worsening heart failure, and rehospitalization. Last, UREGs with severe AS have an increased risk for morbidity and mortality relative to white patients. To date much of the research on AS has examined black-white differences, so there is a need to understand how other racial and ethnic groups with severe AS are diagnosed and treated, with examination of their resulting outcomes. Overall, racial and ethnic disparities in health care access and care delivery are a public health concern given the changing demographics of the U.S. population. These differences in AS management and outcomes highlight the need for additional research into contributing factors and appropriate interventions to address the lower rates of aortic valve replacement and higher morbidity and mortality among UREGs. (J Am Coll Cardiol Intv 2020;13:149-56)

Wilson JB et al. J Am Coll Cardiol Intv 2020;13:149–56

Outcomes of Patients With Severe Aortic Stenosis by Race and Ethnicity



Wilson JB et al. J Am Coll Cardiol Intv 2020;13:149–56

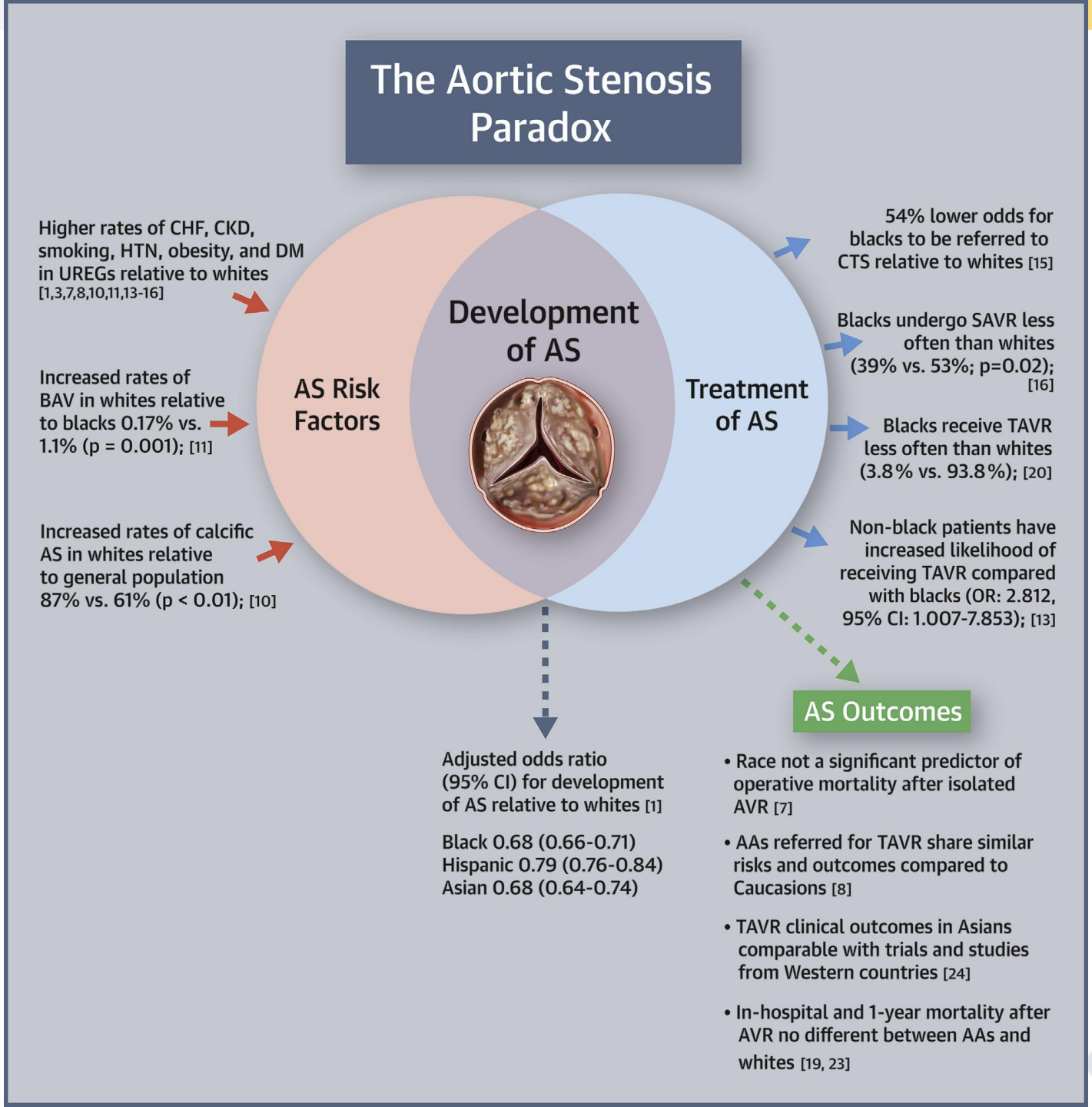
“AS Paradox”

1. UREGs relative to white patients possess higher rates of traditional AS risk factors, such as CHF, CKD, smoking, hypertension, obesity, and DM.

2. **The paradox whereby UREGs cluster more AS risk factors relative to whites but display a lower burden of disease.**

3. A lower incidence of bicuspid AV, lower likelihood of developing calcific AS, and potential variations in AS genetic risk predilection may, in part, explain variances in AS prevalence.

UREG = underrepresented racial and ethnic group



TVT Registry, 2011-2016, N=70,221

JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 12, NO. 10, 2019

Racial Disparities in the Utilization and Outcomes of TAVR

TVT Registry Report

Mohamad Alkhouli, MD,[a,b,*] David R. Holmes, Jr, MD,[a,*] John D. Carroll, MD,[c] Zhuokai Li,[d] Taku Inohara, MD, PhD,[d] Andrzej S. Kosinski,[d] Molly Szerlip, MD,[e] Vinod H. Thourani, MD,[f] Michael J. Mack, MD,[g] Sreekanth Vemulapalli, MD[d,h]

ABSTRACT

OBJECTIVES This study sought to evaluate racial disparities in the performance and outcomes of transcatheter aortic valve replacement (TAVR).

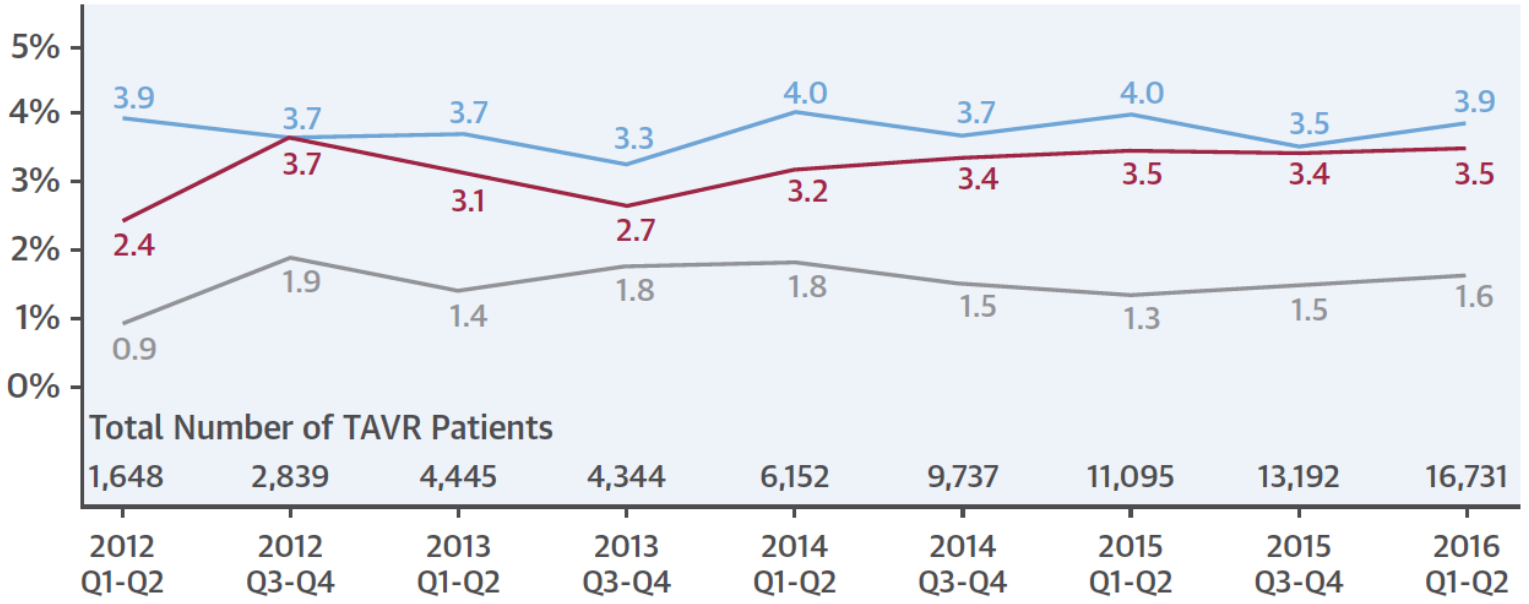
BACKGROUND Racial disparities in cardiovascular diseases are well described. Whether the racial disparities observed in surgical aortic valve replacement also exist with TAVR remains unknown.

METHODS Patients undergoing TAVR between November 2011 and June 2016 were identified in the American College of Cardiology/Society of Thoracic Surgeons/Transcatheter Valve Therapy Registry. We described the racial distribution, and the risk-adjusted in-hospital morbidity, and mortality stratified by race. We evaluated 1-year outcomes in a subset of patients via linkage to Medicare (Centers for Medicare and Medicaid Services) claims.

Alkhouli M et al. J Am Coll Cardiol Intv 2019;12:936–48

CENTRAL ILLUSTRATION **Race-Stratified Differences in the Use and Outcomes of TAVR in the United States**

Utilization of TAVR Among Racial Minorities



Baseline Characteristics Non-White vs. White	In-Hospital Outcomes Non-White vs. White		One Year Outcomes Non-White vs. White	
Younger Age	Death	↔	Death	↔
More Females	Myocardial Infarction	↔	Myocardial Infarction	↔
More Medicare Insurance	Stroke	↔	Stroke	↔
Longer 5-Meter Walk Distance	Major Bleed	↔	Major Bleed	↑ Black
Higher STS Score	Pacemaker	↔	Valve Interventions	↔
More Aortic Insufficiency	Vascular Complications	↔	HF Hospitalizations	↑ Black, Hispanic
More Non-Elective TAVR				

Alkhouli, M. et al. J Am Coll Cardiol Intv. 2019;12(10):936-48.

TAVR in ASIA

JACC: ASIA VOL. 1, NO. 3, 2021

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/).

CH Lee, T. Inohara, K. Hayashida, DW Park, JACC Asia: 2021 Dec, 1 (3) 279–293

Currently Available TAVR Devices in Asian Countries

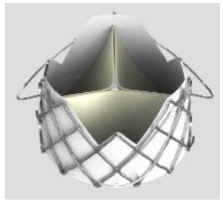
Edwards SAPIEN
Transcatheter Heart Valve System

Medtronic CoreValve
Evolut System

Boston Scientific
Accurate Aortic Valve System

Abbott Portico Transcatheter Aortic
Valve Implantation system

Venus Medtech
VenusA-Valve



JC Medical J·Valve™ Transcatheter Aortic
Valve Replacement system

MicroPort Vitaflow®
Aortic Valve System

Meril Life Sciences
Myval Transcatheter Aortic
Valve Implantation System

Vascular Innovations
Hydra Transcatheter Aortic Valve

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Currently Available TAVR Devices in Asian Countries

TABLE 1 Currently Available TAVR Devices in Asian Countries

Device	FDA Approval	CE Mark	Japan	Korea	China[a]	Taiwan	Hong Kong	India[a]	Singapore	Thailand	Malaysia	Vietnam	Philippines
Edwards													
Sapien 3	√	√	√	√	√	√	√	√	√	√	√	√	√
Medtronic													
Evolut R	√	√	√	√		√	√	√	√	√	√	√	√
Evolut PRO	√	√	√	√		√	√	√	√	√			
Evolut PRO+	√	√ October 2019	√										
Melody	√								√	√			
Abbott													
Portico	√	√				√	√		√	√			
Portico FlexNav	√ March 2020	√				√				√			
Boston Scientific													
Acurate neo	√ 2019					√ No cases done yet	√			√			√
Acurate neo2													

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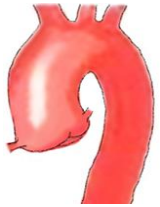
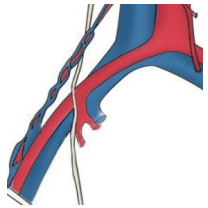
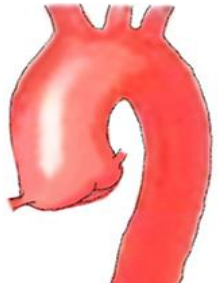
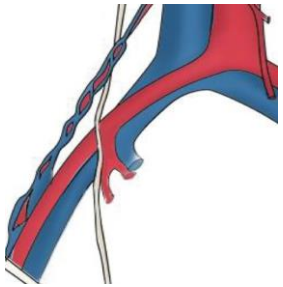
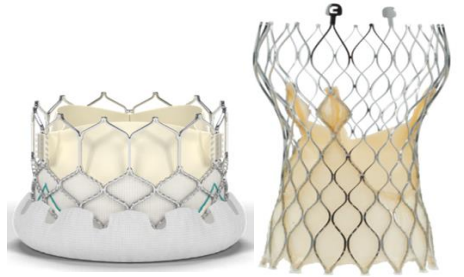
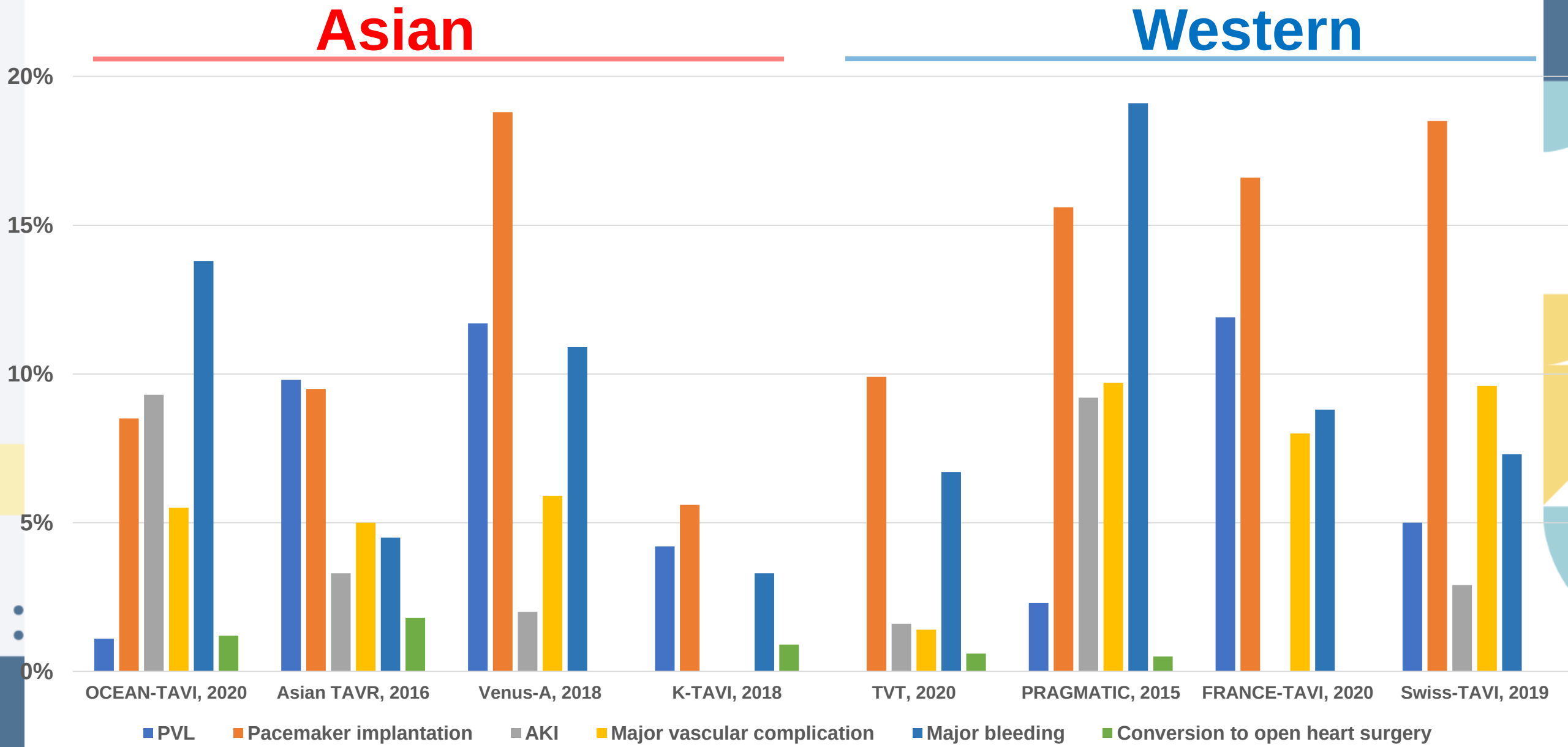
Baseline Clinical and Anatomical Difference

	BMI	Annulus Area	Iliofemoral artery	Device Size
Asian				
Western				

	Age	Male	BMI	LVEF	STS score
Asian	◄ ►	◄ ►		◄ ►	◄ ►
Western	◄ ►	◄ ►	▲	◄ ►	◄ ►

	Valve area	Annulus area	Bicuspid	Device size	Trans-femoral
Asian	◄ ►		▲		◄ ►
Western	◄ ►	▲		▲	◄ ►

Key Procedural Complications



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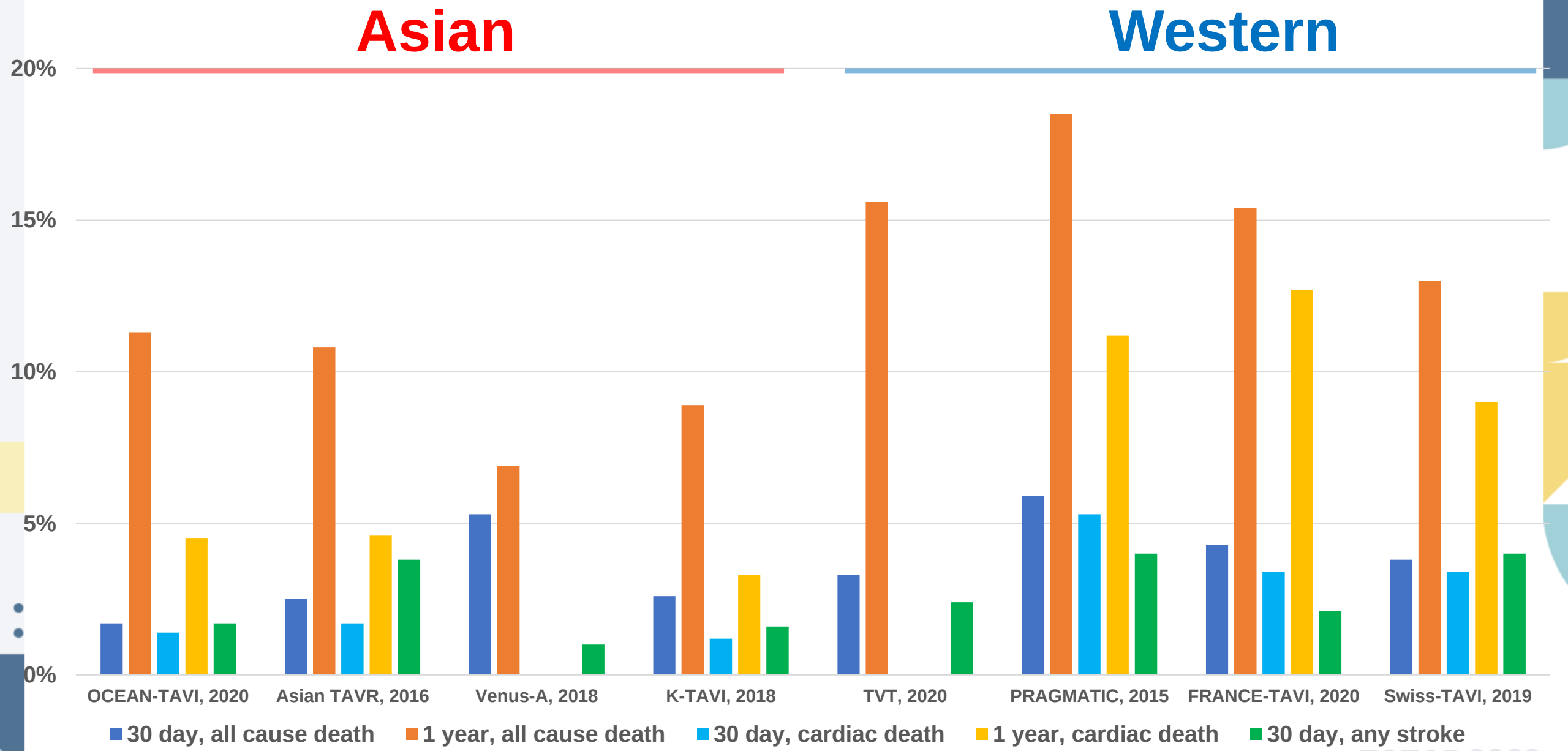
30-Day and 1-Year Clinical Outcomes



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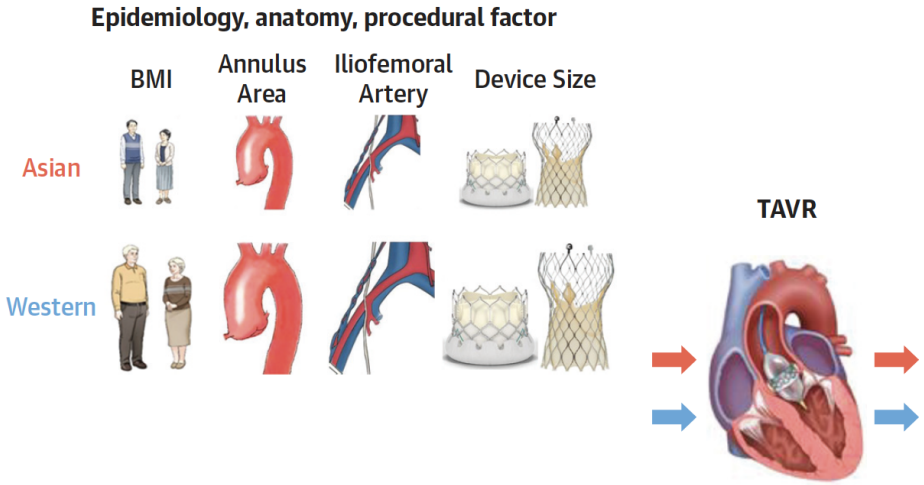
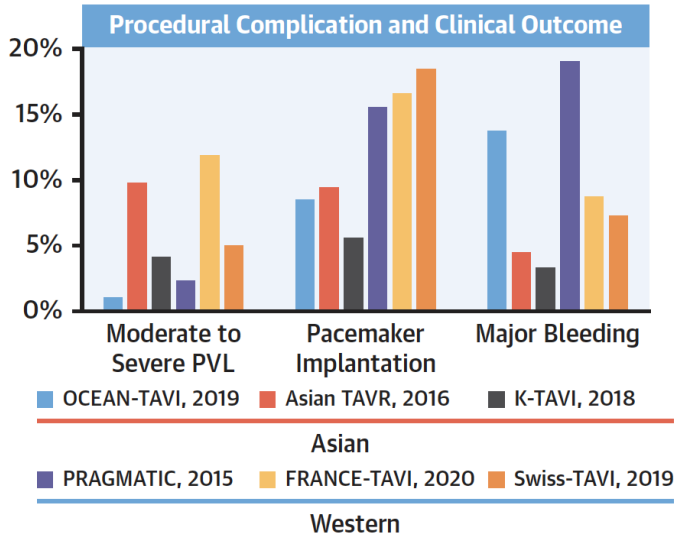
Key Summary

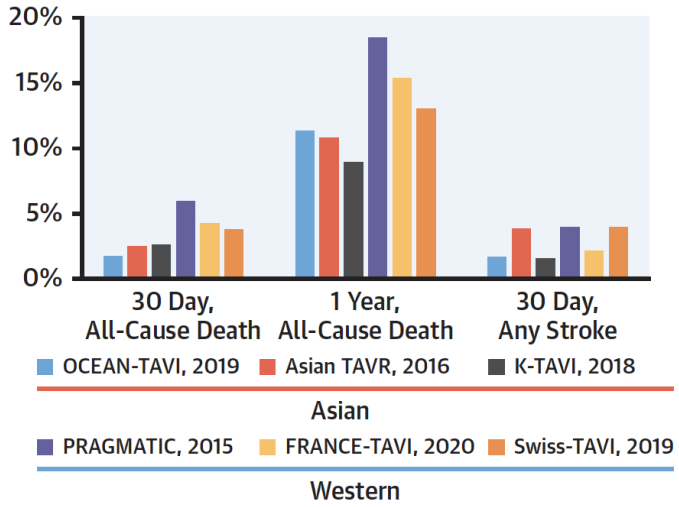
CENTRAL ILLUSTRATION **Specific Clinical and Anatomic Features and Outcomes of Transcatheter Aortic Valve Replacement in Asian Populations**



	Age	Male	BMI	LVEF	STS score
Asian	◄►	◄►		◄►	◄►
Western	◄►	◄►	▲	◄►	◄►

	Valve area	Annulus area	Bicuspid	Device size	Transfemoral
Asian	◄►		▲		◄►
Western	◄►	▲		▲	◄►





Lee, C.H. et al. JACC: Asia. 2021;1(3):279-293.

TP-TAVR Registry

Multi-National, Multi-Center, Multi-Ethnic Registry

Kang D-Y, et al. Heart 2022;0:1–9. doi:10.1136/heartjnl-2021-320364

Original research

Inter-racial differences in patients undergoing transcatheter aortic valve implantation

Do-Yoon Kang,[1] Jung-Min Ahn,[1] Juyong Brian Kim,[2] Alan Yeung,[2] Takeshi Nishi,[2] William Fearon,[2] Eric Page Cantey ,[3] James D Flaherty,[3] Charles J Davidson,[3] S Christopher Malaisrie,[3] Seo Young Park,[4] Sung-Cheol Yun,[4] Euihong Ko,[1] Hanbit Park,[1] Seung-Ah Lee,[1] Dae-Hee Kim ,[1] Ho Jin Kim ,[5] Joon Bum Kim,[5] Suk Jung Choo,[5] Duk-Woo Park ,[1] Seung-Jung Park[1]

► Additional supplemental material is published online only. To view, please visit the journal online (http://dx.doi.org/10.1136/heartjnl-2021-320364).

[1]Division of Cardiology, Asan Medical Center, University of Ulsan College of Medicine, Seoul, South Korea
[2]Department of Medicine, Division of Cardiovascular Medicine, Stanford University School of Medicine, Stanford, California, USA
[3]Northwestern University Feinberg School of Medicine, Chicago, Illinois, USA
[4]Department of Clinical Epidemiology and Biostatistics, Asan Medical Center, University of Ulsan College of Medicine, Seoul, South Korea
[5]Division of Thoracic and Cardiovascular Surgery, Asan Medical Center, University of Ulsan College of Medicine, Seoul, South Korea

Correspondence to
Dr Duk-Woo Park, Cardiology, Asan Medical Center, Seoul 05505, Korea (the Republic of); dwpark@amc.seoul.kr

ABSTRACT

Objective Little information exists about inter-racial differences in patients with aortic stenosis (AS) undergoing transcatheter aortic valve implantation (TAVI). We investigated whether differences in baseline characteristics between Asian and non-Asian population may contribute to disparities in clinical outcomes after TAVI.

Methods We performed a registry-based, multinational cohort study of patients with severe AS who underwent TAVI at two centres in the USA and one centre in South Korea. The primary outcome was a composite of death, stroke or rehospitalisation at 1 year.

Results Of 1412 patients, 581 patients were Asian and 831 were non-Asian (87.5% white, 1.7% black, 6.1% Hispanic or 4.7% others). There were substantial differences in baseline characteristics between two racial groups. The primary composite outcome was significantly lower in the Asian group than in the non-Asian group (26.0% vs 35.0%; HR 0.73; 95% CI 0.59 to 0.89; p=0.003). However, after adjustment of baseline covariates, the risk of primary composite outcome was not significantly different (HR 0.79; 95% CI 0.60 to 1.03; p=0.08). The all-cause mortality at 1 year was significantly lower in the Asian group than the non-Asian group (7.4% vs 12.5%; HR 0.60; 95% CI 0.41 to 0.88; p=0.009). After multivariable adjustment, the risk of all-cause mortality was also similar (HR 1.17; 95% CI 0.73 to 1.88; p=0.52).

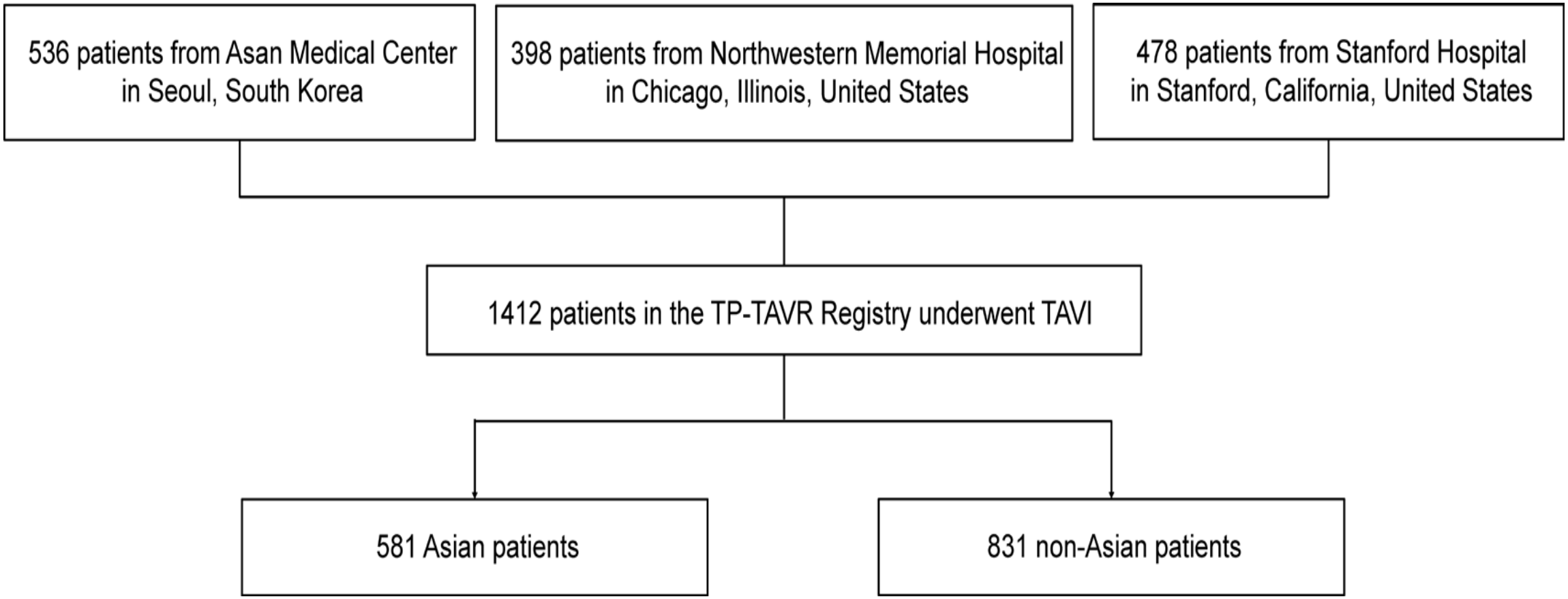
procedures is rapidly increasing worldwide and has currently surpassed the number of isolated surgical aortic valve replacements (SAVRs).[10 11]

Recent data suggest significant inter-racial and interethnic differences in the prevalence, management and outcomes among patients with severe AS.[12–14] In particular, given that the majority of TAVI trials have been conducted in Western population from the USA and Europe and the adoption of TAVI has been more delayed in Asia, further clinical investigations of TAVI are required in Asian population who have unique anatomical features (ie, lower body surface area, smaller aortic valve annulus sizes and smaller vascular access sites).[15–17] However, clinical studies specifically reporting potential inter-racial and international differences of TAVI patients are still lacking.[18] We therefore assessed differences in baseline demographic, clinical, anatomical and procedural characteristics according to different racial groups (Asian vs non-Asian), and evaluated how these differences were related to differences in clinical outcomes following TAVI using a multinational, multiracial transpacific transcatheter aortic valve replacement (TP-TAVR) registry. We also evaluated these baseline and outcome differences nationally (USA vs South Korea).

METHODS

Study population, database and procedures

TP-TAVR Registry



DY Kang and DW Park et al. Heart 2022;0:1–9.

Baseline Characteristics

Table 1 Baseline demographic, clinical and anatomical characteristics of patients

Characteristic	Overall (N=1412)	Asians (N=581)	Non-Asians (N=831)	P value
Demographics				
Age, years	80.2±8.0	80.1±5.7	80.3±9.3	0.58
Men	755 (53.5)	294 (50.6)	461 (55.5)	0.08
Body mass index, kg/m^2*	26.6±6.1	24.00±3.59	28.4±6.8	<0.001
STS score†	5.05±3.48	4.16±3.07	5.66±3.62	<0.001
NYHA class III/IV heart failure‡	610 (43.2)	206 (35.5)	404 (48.6)	<0.001
Comorbidities				
Diabetes mellitus	590 (41.8)	306 (52.7)	284 (34.2)	<0.001
Hypertension	1216 (86.1)	508 (87.4)	708 (85.2)	0.26
Current smoking	69 (4.9)	47 (8.1)	22 (2.6)	<0.001
Hyperlipidaemia	1046 (74.1)	437 (75.2)	609 (73.3)	0.45
Prior MI	160 (11.3)	32 (5.5)	128 (15.4)	<0.001
Prior PCI	405 (28.7)	161 (27.7)	244 (29.4)	0.54
Prior CABG	178 (12.6)	31 (5.3)	147 (17.7)	<0.001
Prior stroke	160 (11.3)	77 (13.3)	83 (10.0)	0.07
Atrial fibrillation or flutter	403 (28.5)	72 (12.4)	331 (39.8)	<0.001
Peripheral vascular disease	227 (16.1)	22 (3.8)	205 (24.7)	<0.001
Chronic lung disease	177 (12.5)	61 (10.5)	116 (14.0)	0.06
Current dialysis	53 (3.8)	23 (4.0)	30 (3.6)	0.84
Echocardiographic or CT findings				
Aortic valve area, cm^2	0.67±0.20	0.62±0.17	0.72±0.21	<0.001
Aortic valve mean gradient, mm Hg	50.0±18.8	56.7±21.3	45.2±15.2	<0.001
Bicuspid aortic valve	90 (6.4)	58 (10.0)	32 (3.9)	<0.001
Left ventricular ejection fraction, %	57.1±12.8	57.8±11.6	56.5±13.67	0.06
Mitral insufficiency (moderate/severe)	223 (15.8)	70 (12.0)	153 (18.4)	0.002
Tricuspid insufficiency (moderate/severe)	165 (11.7)	39 (6.7)	126 (15.2)	<0.001
Systolic annular perimeter on CT, mm	77.0±8.3	75.6±7.7	78.0±8.6	<0.001
Systolic annular area on CT, mm^2	450.3±94.5	440.0±89.1	457.7±97.6	0.001

DY Kang and DW Park et al. Heart 2022;0:1–9.

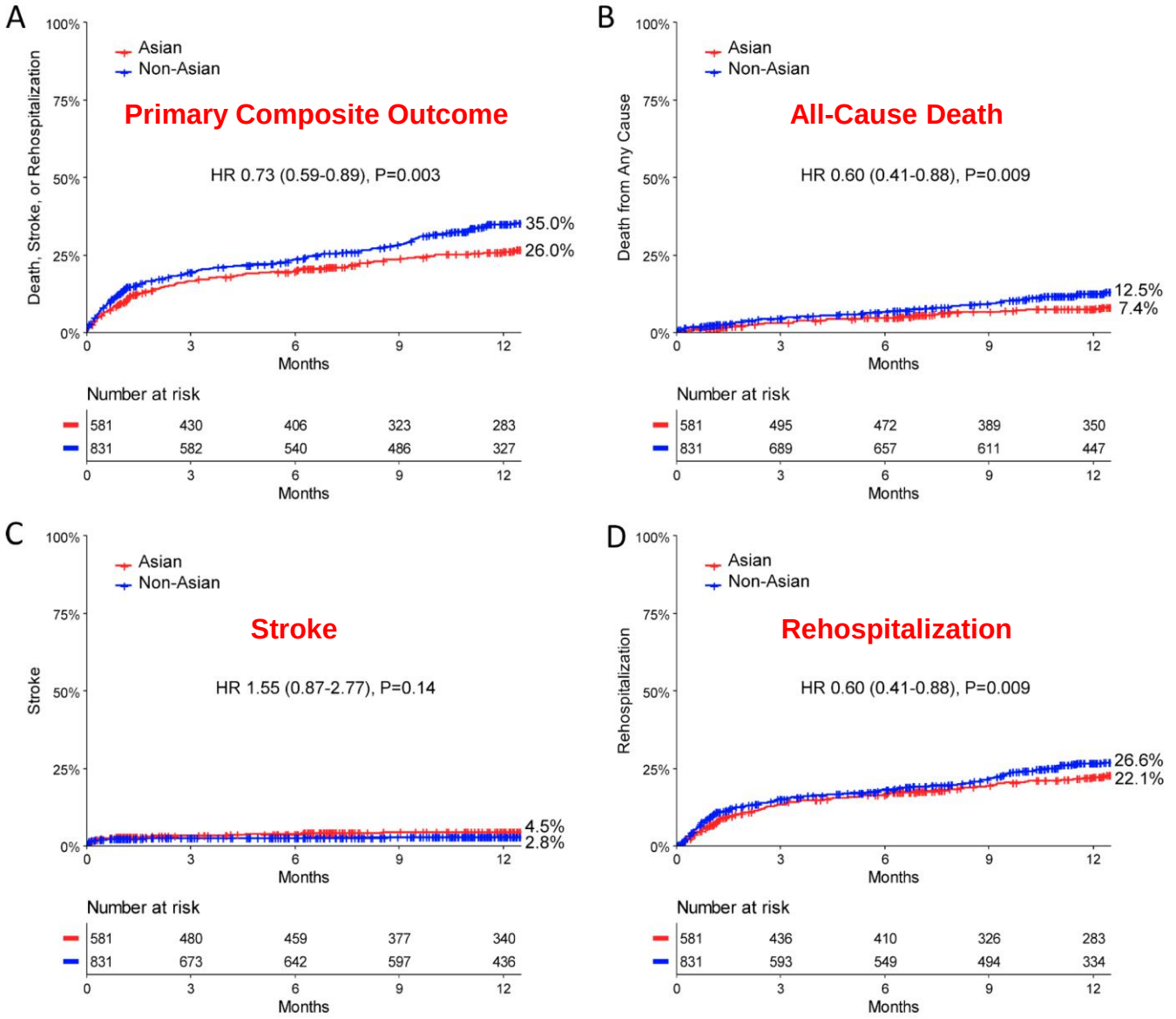
Procedural Characteristic and Complications

Table 2 Procedural characteristics and in-hospital outcomes

Characteristic	Overall (N=1412)	Asian (N=581)	Non-Asian (N=831)	P value
Procedural characteristics				
Procedure type				
Native	1339 (94.8)	561 (96.6)	778 (93.6)	0.02
Valve-in-valve	73 (5.2)	20 (3.4)	53 (6.4)	
Access site				<0.001
Transfemoral	1361 (96.4)	558 (96.0)	803 (96.6)	
Transapical	23 (1.6)	19 (3.3)	4 (0.5)	
Transaortic	10 (0.7)	3 (0.5)	7 (0.8)	
Subclavian	1 (0.1)	0 (0.0)	1 (0.1)	
Others	17 (1.2)	1 (0.2)	16 (1.9)	
Valve type				0.34
Balloon expandable	1174 (83.1)	476 (81.9)	698 (84.0)	
Self-expandable	238 (16.9)	105 (18.1)	133 (16.0)	
Prosthesis size, mm				0.01
20	27 (1.9)	8 (1.4)	19 (2.3)	
23–25	422 (29.9)	167 (28.7)	255 (30.7)	
26–28	631 (44.7)	287 (49.4)	344 (41.4)	
29 or larger	332 (23.5)	119 (20.5)	213 (25.6)	
Type of anaesthesia				<0.001
Conscious sedation	814 (57.6)	432 (74.4)	382 (46.0)	
General anaesthesia	598 (42.4)	249 (25.6)	449 (54.0)	
Concomitant PCI	57 (5.6)	29 (5.1)	28 (6.4)	0.45
Moderate to severe paravalvular leakage	24 (1.7)	14 (2.4)	10 (1.2)	0.13
Conversion to open cardiac surgery	12 (0.8)	4 (0.7)	8 (1.0)	0.58
In-hospital event				
Death	22 (1.6)	7 (1.2)	15 (1.8)	0.50
Stroke	33 (2.3)	16 (2.8)	17 (2.0)	0.49
Death or stroke	52 (3.7)	22 (3.8)	30 (3.6)	0.98
Myocardial infarction	13 (0.9)	8 (1.4)	5 (0.6)	0.22
Life-threatening or disabling bleeding	36 (2.5)	26 (4.5)	10 (1.2)	<0.001
Major vascular complication	38 (2.7)	24 (4.1)	14 (1.7)	0.009
New permanent pacemaker	122 (8.6)	33 (5.7)	89 (10.7)	0.001
New-onset atrial fibrillation	40 (2.8)	11 (1.9)	29 (3.5)	0.11

DY Kang and DW Park et al. Heart 2022;0:1–9.

Kaplan-Meier Curves of 1-Year Outcomes



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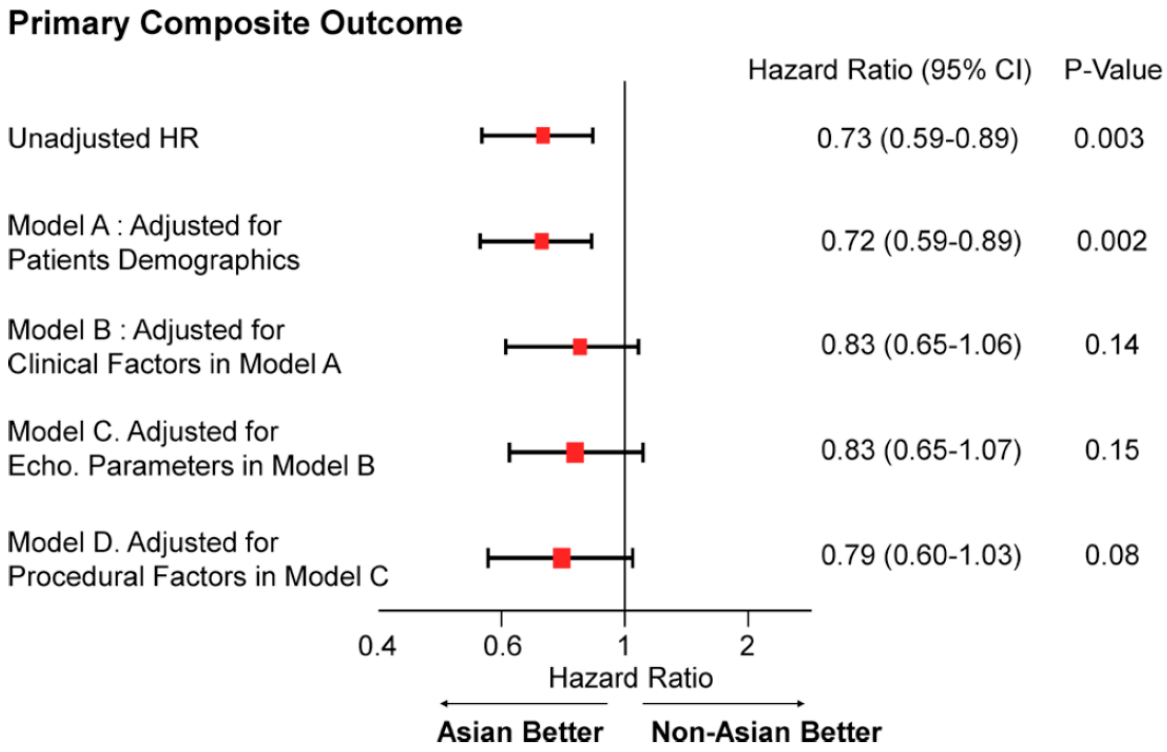
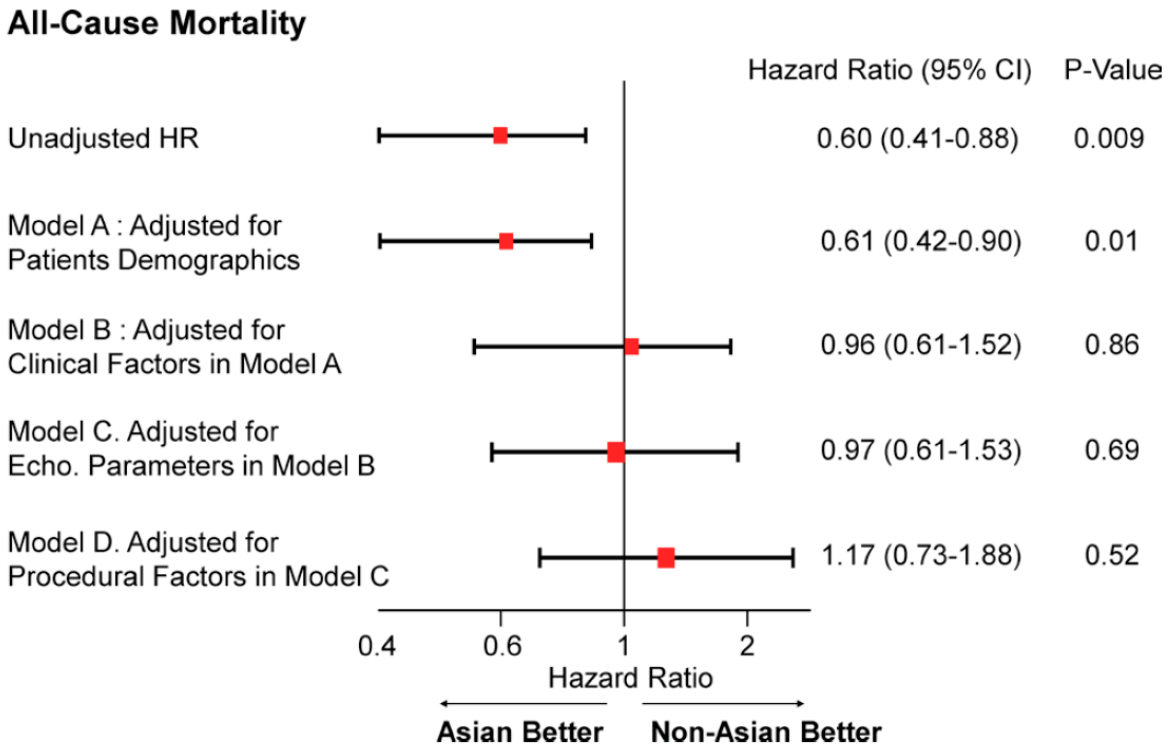
Unadjusted and Adjusted Outcomes



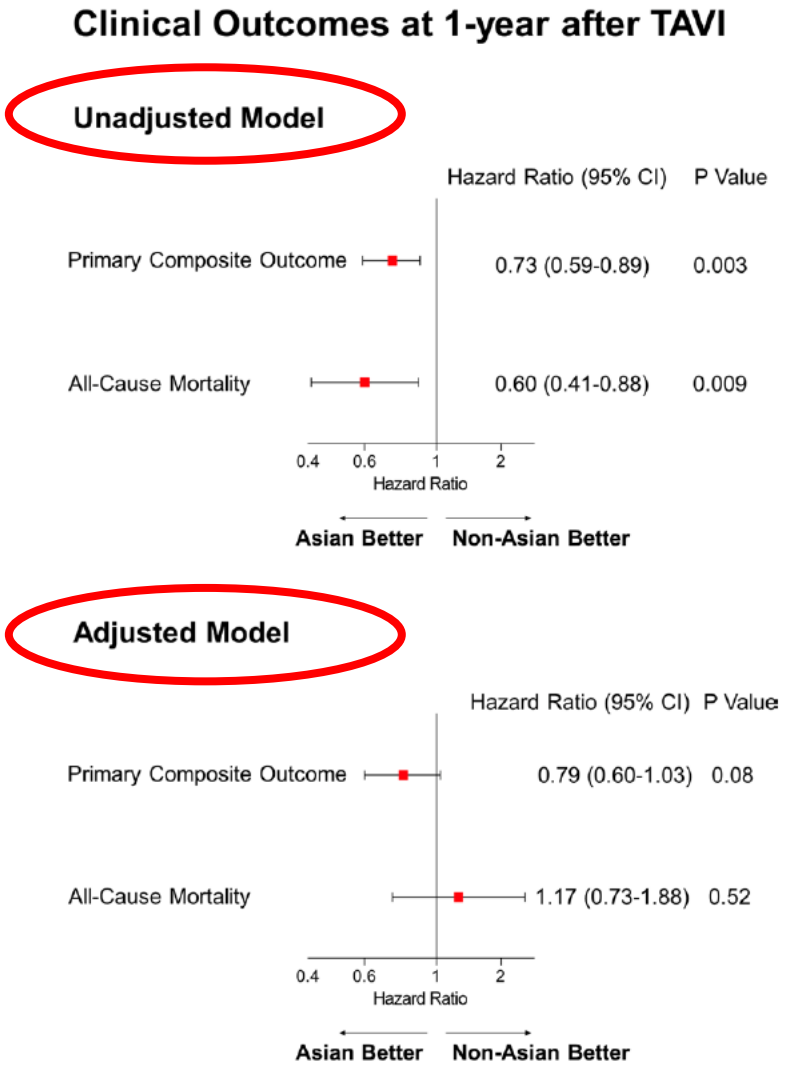


"Observed inter-racial differences in clinical outcomes were largely explained by baseline differences in clinical, anatomical and procedural factors"

DY Kang and DW Park et al. Heart 2022;0:1–9.

Key Messages

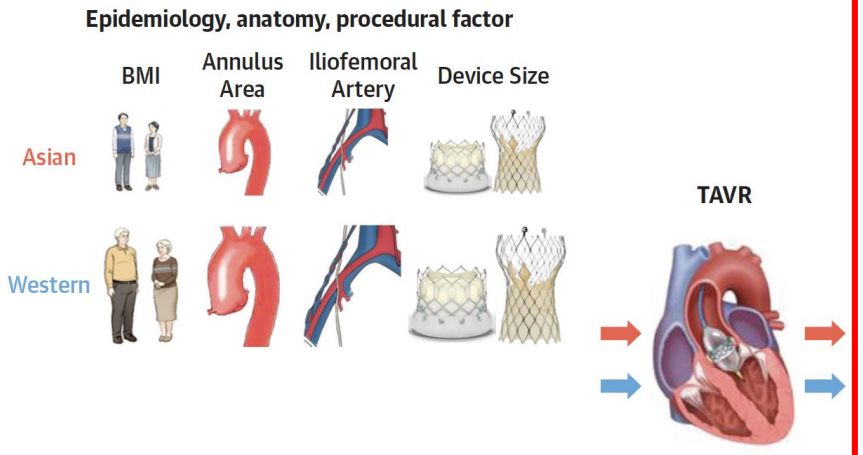
Characteristics	Asian	Non-Asian
Age	≈	
Gender	≈	
BMI		▲
STS score		▲
Diabetes		▲
Hypertension	≈	
Prior PCI	≈	
Prior CABG		▲
Atrial fibrillation		▲
ESRD on Dialysis	≈	
Aortic Valve Area		▲
Transaortic pressure gradient	▲	
Bicuspid AV	▲	
Aortic Annular area on CT		▲
LV Ejection fraction	≈	
Valve-in-valve TAVI		▲
Transfemoral approach	≈	
Valve type	≈	
Valve size		▲
In-hospital event		
Death or stroke	≈	
Bleeding complication	▲	
Vascular complications	▲	
New permanent pacemaker		▲
New-onset AF	≈	



DY Kang and DW Park et al. Heart 2022;0:1–9.

Prosthesis-Patient Mismatch

CENTRAL ILLUSTRATION Specific Clinical and Anatomic Featur
Replacement in Asian Populations



	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"

Lee, C.H. et al. JACC: Asia. 2021;1(3):279–293.

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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.

HB Park, DW Park et al. J Am Coll Cardiol Intv 2021;14:2670–2681

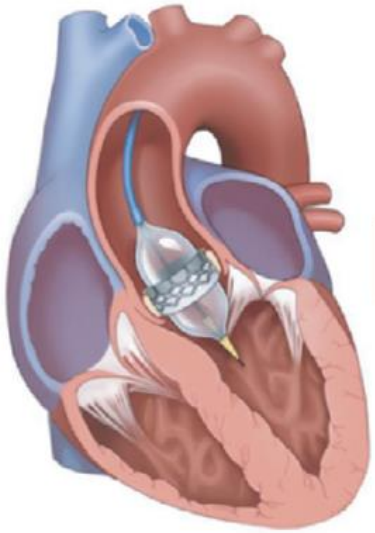
Inter-Racial Disparity of PPM Incidence

BMI 24.0 ± 3.6 kg/m^2
BSA 1.60 ± 0.17 m^2

Non-Asian

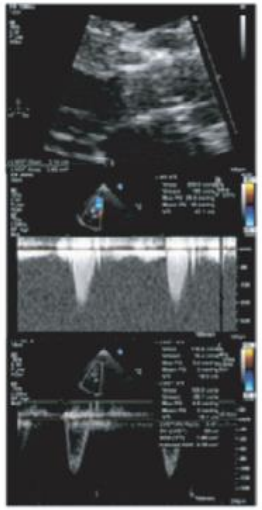
BMI 28.5 ± 6.6 kg/m^2
BSA 1.91 ± 0.29 m^2

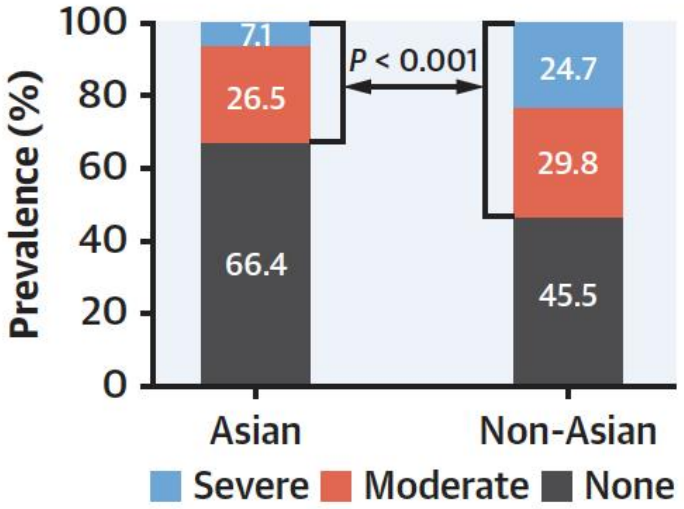
TAVR



Prosthesis-Patient Mismatch

EOA 1.50 ± 0.37 cm^2
Indexed EOA 0.94 ± 0.22 cm^2/m^2



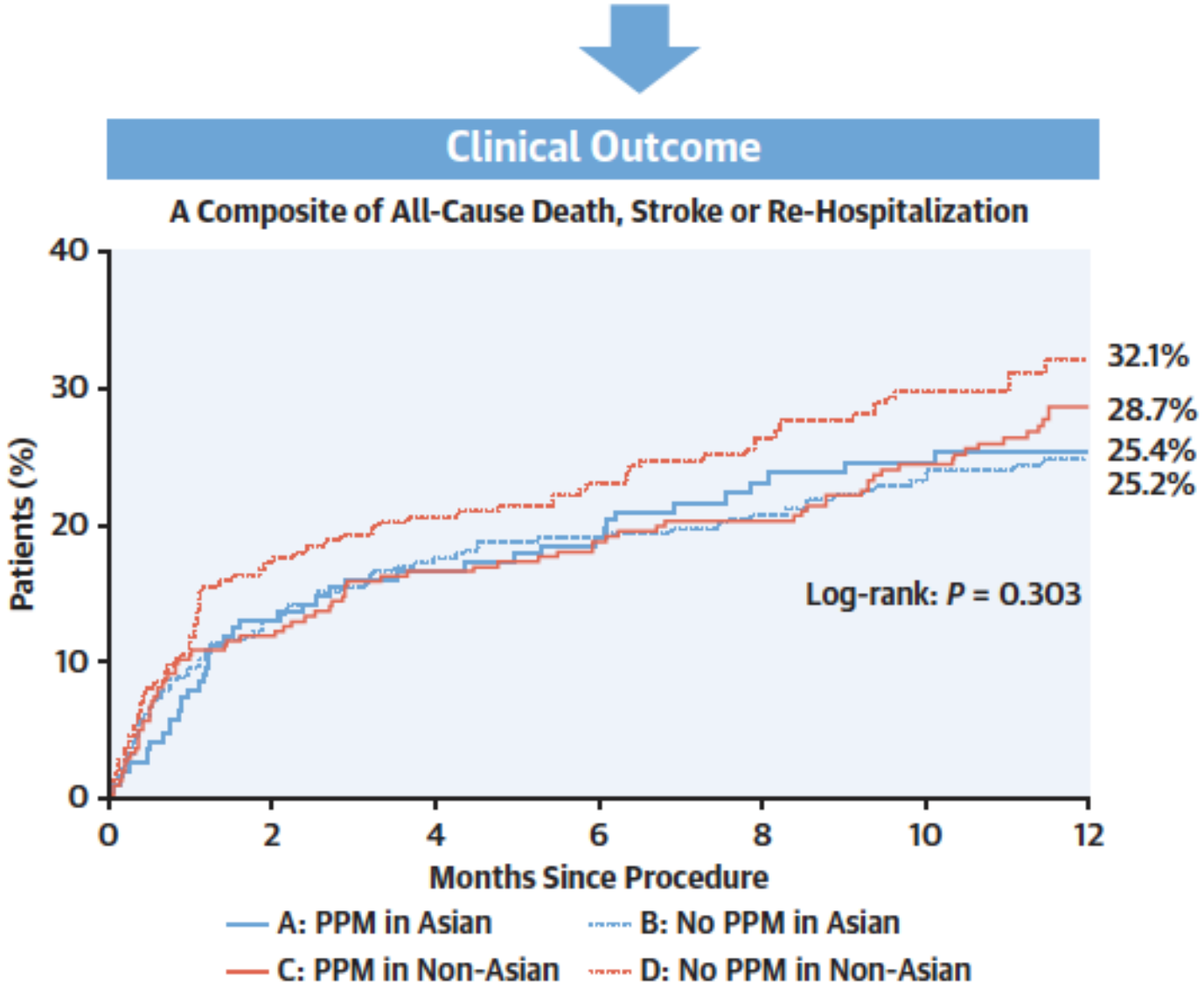


EOA 1.52 ± 0.49 cm^2
Indexed EOA 0.80 ± 0.25 cm^2/m^2

Clinical Outcome

HB Park, DW Park et al. J Am Coll Cardiol Intv 2021;14:2670–2681

Inter-Racial Disparity of PPM Impact



HB Park, DW Park et al. J Am Coll Cardiol Intv 2021;14:2670–2681

Summary:
Inter-Racial Disparity in TAVR

- Given increased life expectancy in the Asia Pacific, the field of TAVR is rapidly expanding.
- There were substantial interracial differences in clinical, anatomic, and procedural characteristics in TAVR patients.
- There were specific population- and health care system–related challenges to TAVR use in Asia.
- Future research into racial/ethnic disparities can help optimize TAVR procedures in Asia Pacific countries.