Inter-Racial Differences in Characteristics and Outcomes After TAVR: TP-TAVR Registry

Do-Yoon Kang, MD

Associate Professor, University of Ulsan College of Medicine,

Heart Institute, Asan Medical Center, Seoul, Korea

Disclosure

- I, Do-Yoon Kang, DO NOT have a conflict of interest related to this presentation.

Racial Disparity and TAVR Outcome Difference

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).

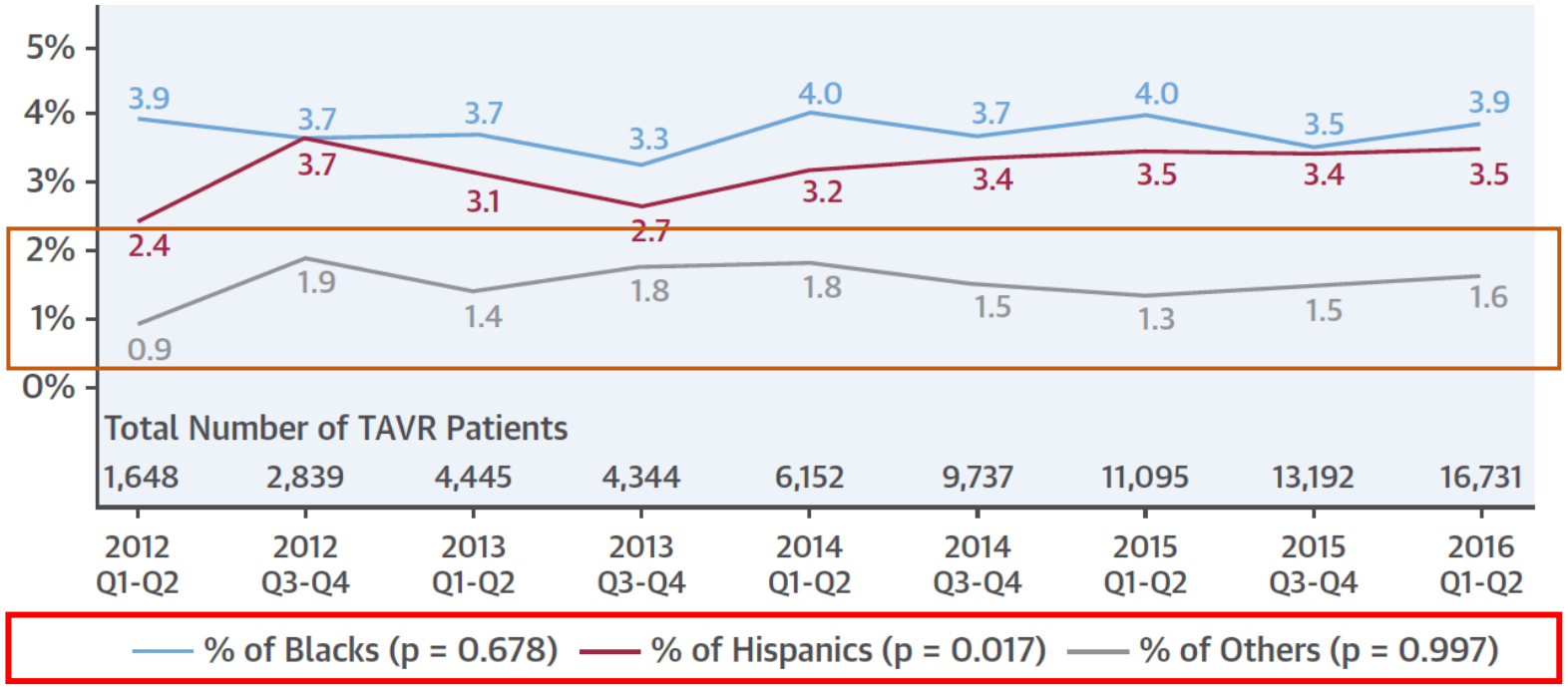
BACKGROUND Racial disparities in cardiovascular diseases are well described. Whether the racial disparities observed in surgical aortic valve replacement also exist with TAVR remains unknown.

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.

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

STATE-OF-THE-ART REVIEW

Transcatheter Aortic Valve Replacement in Asia

Present Status and Future Perspectives

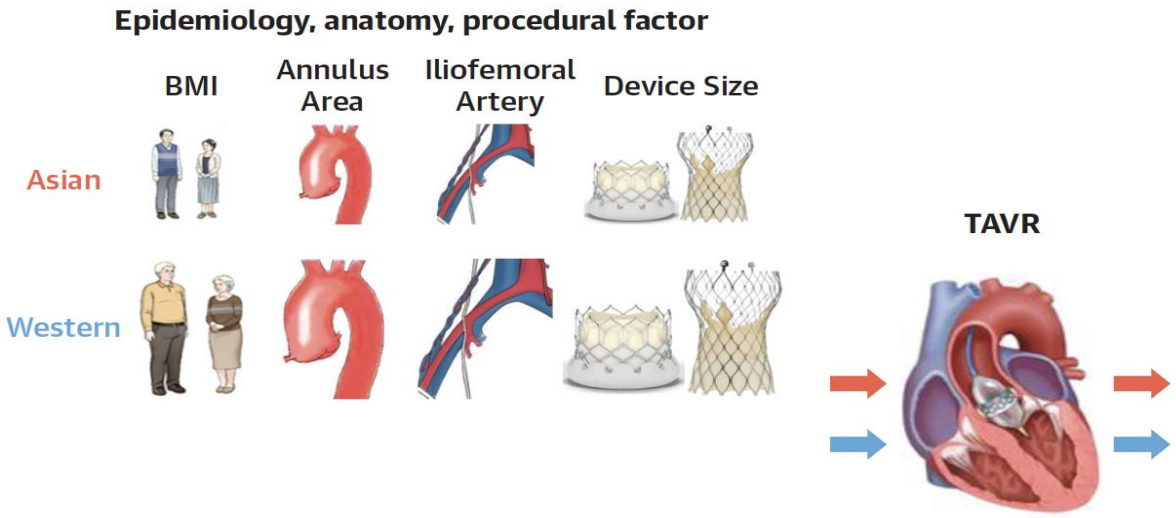
Cheol Hyun Lee, MD, PhD,[a,*] Taku Inohara, MD, PhD,[b,*] Kentaro Hayashida, MD, PhD,[b] Duk-Woo Park, MD, PhD[c]

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/).

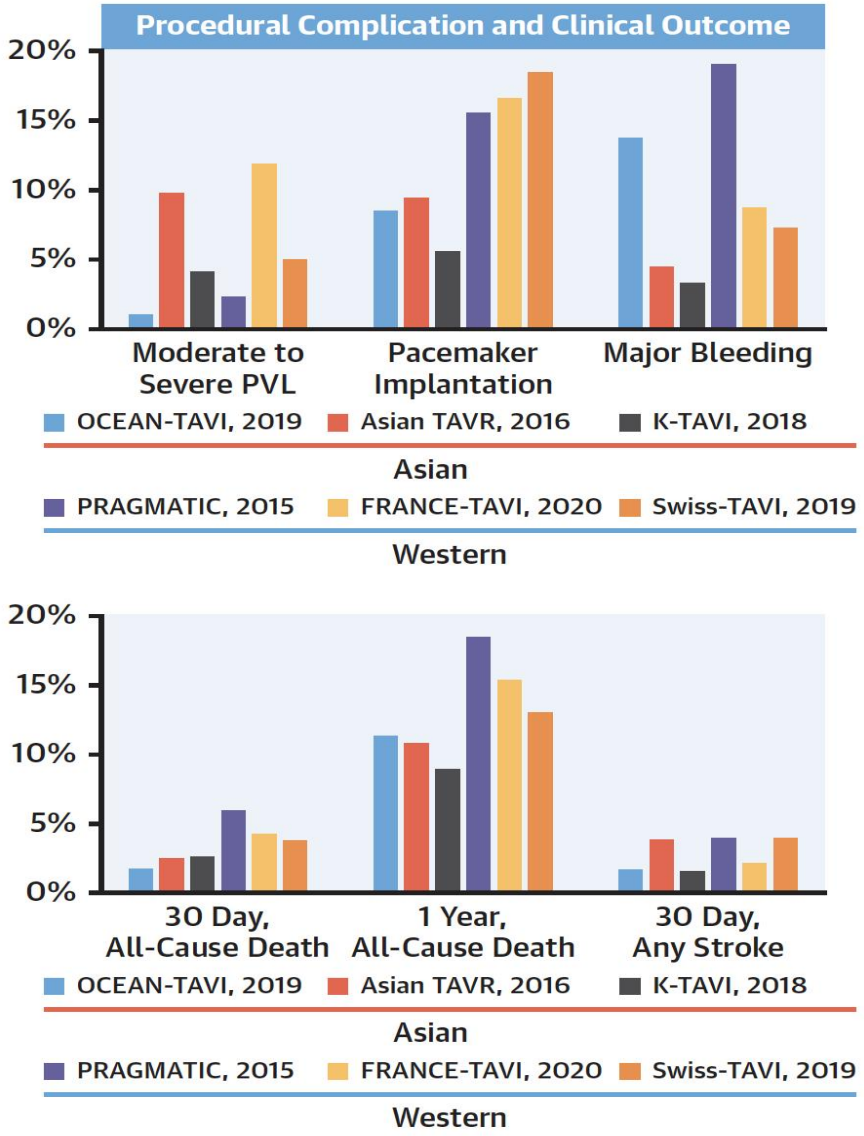
Lee CH, Park DW et al. JACC: Asia. 2021;1(3):279–293.

TAVR in Asian Population



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

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

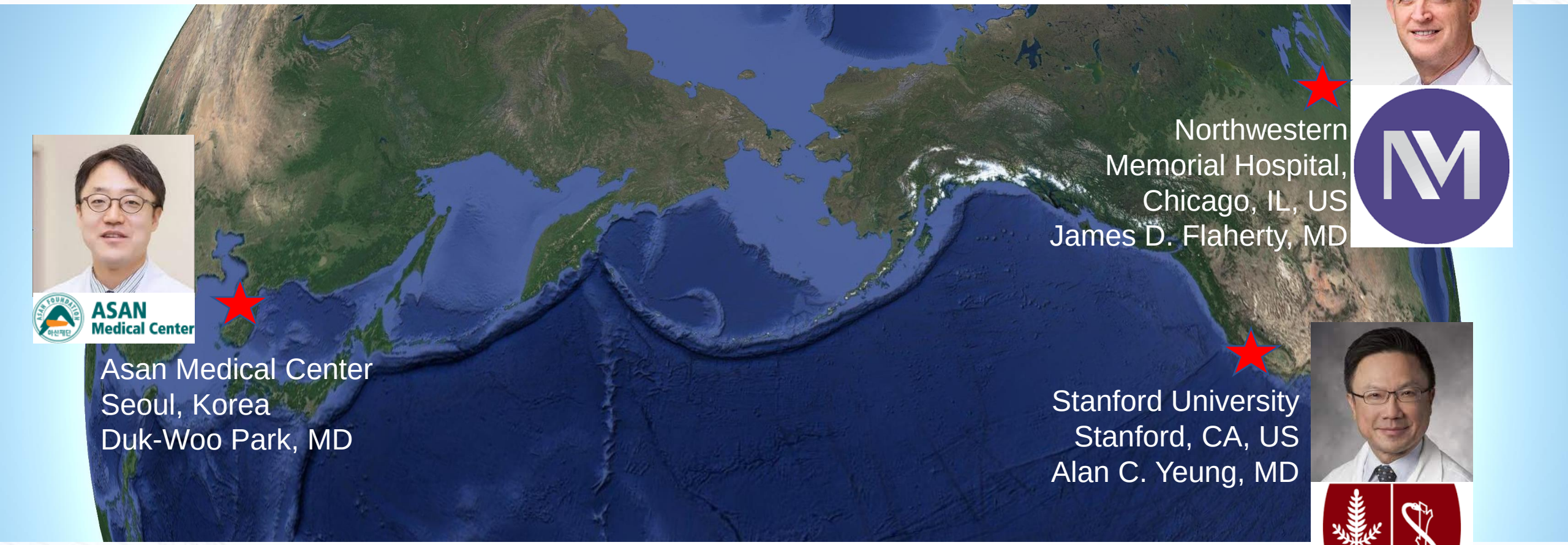


Lee, C.H. et al. JACC: Asia. 2021;1(3):279-293.

Rationale for International, Inter-racial Registry

- Less than <1% of TAVR in US in Asians
- TAVR late-comer in many Asian countries.
- Smaller annulus, valve size, and small access vessels in Asians
- Frequent bicuspid aortic valve in Asians.
- High prevalence of female gender in the older age groups in the Asian population.
- Culture of global learning will allow bi-directional education and optimal patient-care.

TransPacific (TP) - TAVR Registry



Asan Medical Center
Seoul, Korea
Duk-Woo Park, MD

Northwestern
Memorial Hospital,
Chicago, IL, US
James D. Flaherty, MD

Stanford University
Stanford, CA, US
Alan C. Yeung, MD

TP-TAVR Registry

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

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]

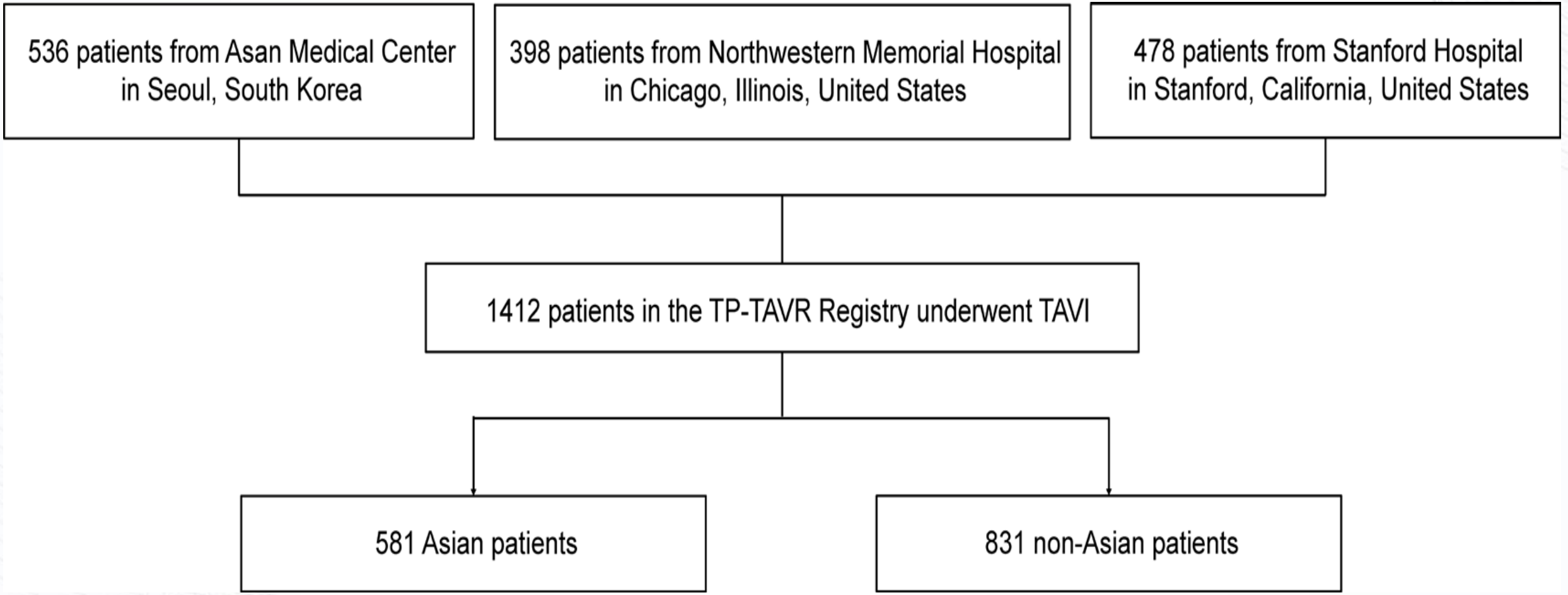
Recent data suggest significant inter-racial and interethnic differences in the prevalence, management and outcomes among patients with severe AS.[12–14] In particular, given that the majority of TAVI trials have been conducted in Western population from the USA and Europe and the adoption of TAVI has 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

Kang DY et al. Heart. 2022;108(19):1562-1570.

TransPacific (TP) - TAVR Registry



Kang DY et al. Heart. 2022;108(19):1562-1570.

Baseline Characteristics

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
Hyperlipidemia	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

Baseline Characteristics

Characteristic	Overall (N=1412)	Asians (N=581)	Non-Asians (N=831)	*P* Value
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, mmHg	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 (3+/4+)	223 (15.8)	70 (12.0)	153 (18.4)	0.002
Tricuspid insufficiency (3+/4+)	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

Kang DY et al. Heart. 2022;108(19):1562-1570.

Procedural Characteristics

Characteristic	Overall (N=1412)	Asian (N=581)	Non-Asian (N=831)	*P* Value
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)	
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 to 25	422 (29.9)	167 (28.7)	255 (30.7)	
26 to 28	631 (44.7)	287 (49.4)	344 (41.4)	
29 or larger	332 (23.5)	119 (20.5)	213 (25.6)	
Type of anesthesia				<0.001
Conscious sedation	814 (57.6)	432 (74.4)	382 (46.0)	
General anesthesia	598 (42.4)	249 (25.6)	449 (54.0)	
Concomitant PCI	57 (5.6)	29 (5.1)	28 (6.4)	0.45

Procedural & In-hospital Events

Characteristic	Overall (N=1412)	Asian (N=581)	Non-Asian (N=831)	*P* Value
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

Kang DY et al. Heart. 2022;108(19):1562-1570.

30-day Observed Clinical Outcomes

OUTCOME	Event Rate, n (%)*			Hazard Ratio† (95% Confidence interval)	*P* Value
	Overall (N=1412)	Asian (N=581)	Non-Asian (N=831)		
30 Days Outcomes					
Composite outcome of death, stroke, or rehospitalization	161 (11.5)	55 (9.5)	106 (13.0)	0.72 (0.52–1.00)	0.047
Death from any cause	26 (1.9)	8 (1.4)	18 (2.2)	0.63 (0.27–1.44)	0.27
Cardiac death	12 (0.9)	4 (0.7)	8 (1.0)	0.71 (0.21–2.34)	0.57
Non-cardiac death	14 (1.0)	4 (0.7)	10 (1.2)	0.56 (0.18–1.79)	0.56
Stroke	34 (2.4)	16 (2.8)	18 (2.2)	1.26 (0.64–2.47)	0.50
Death or stroke	56 (4.0)	21 (3.6)	35 (4.2)	0.79 (0.45–1.39)	0.41
Rehospitalization	115 (8.4)	39 (6.8)	76 (9.5)	0.71 (0.48–1.04)	0.08

Kang DY et al. Heart. 2022;108(19):1562-1570.

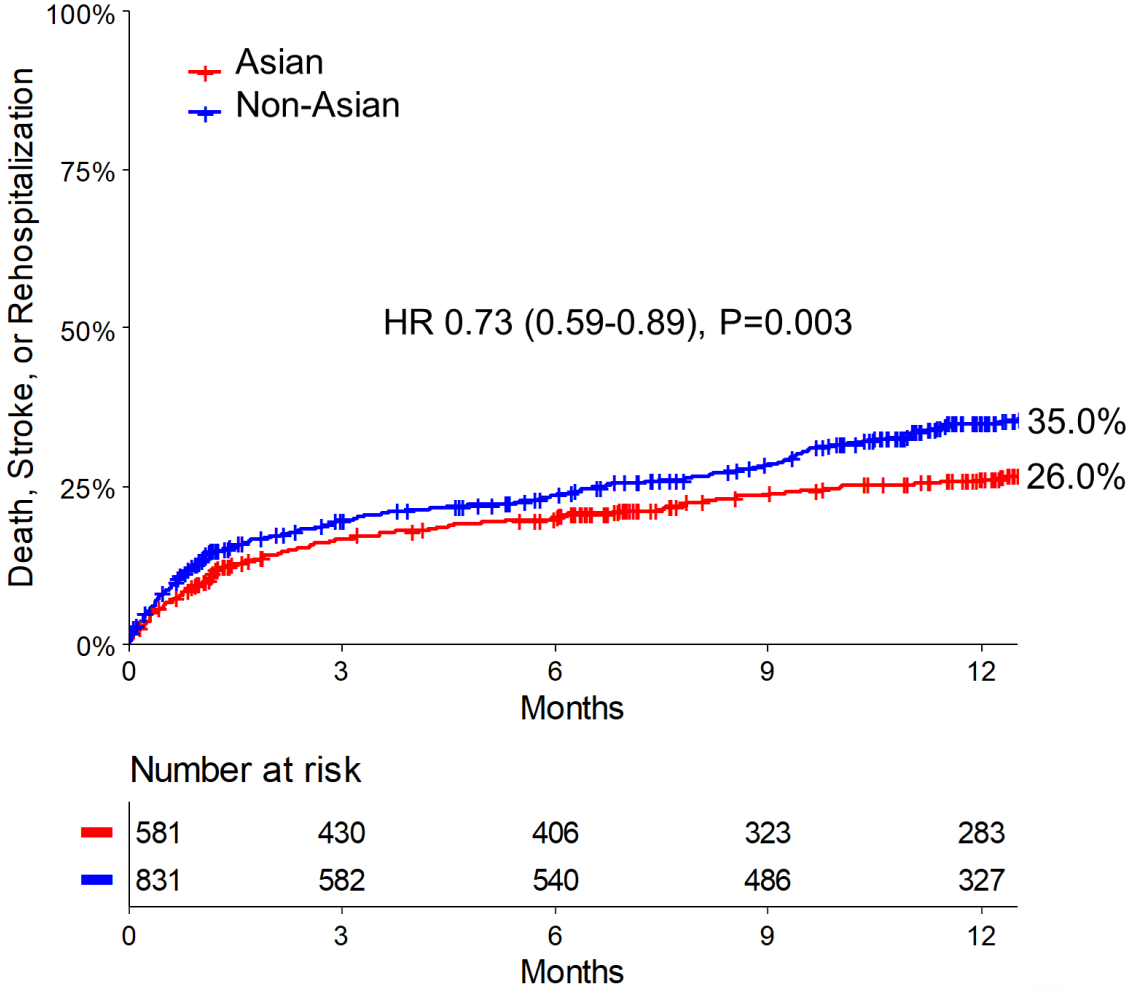
12-month Observed Clinical Outcomes

OUTCOME	Event Rate, n (%)*			Hazard Ratio† (95% Confidence interval)	*P* Value
	Overall (N=1412)	Asian (N=581)	Non-Asian (N=831)		
12 Months Outcomes					
Primary composite outcome of death, stroke, or rehospitalization	395 (31.4)	136 (26.0)	259 (35.0)	0.73 (0.59–0.89)	0.003
Death from any cause	126 (10.5)	37 (7.4)	89 (12.5)	0.60 (0.41–0.88)	0.009
Cardiac death	31 (2.6)	12 (2.5)	19 (2.7)	0.91 (0.44–1.88)	0.80
Non-cardiac death	95 (8.1)	25 (5.1)	70 (10.0)	0.52 (0.33–0.81)	0.004
Stroke	46 (3.5)	24 (4.5)	22 (2.8)	1.55 (0.87–2.77)	0.14
Death or stroke	161 (13.0)	54 (10.4)	107 (14.6)	0.66 (0.47–0.93)	0.02
Rehospitalization	301 (24.8)	112 (22.1)	189 (26.6)	0.82 (0.65–1.04)	0.10

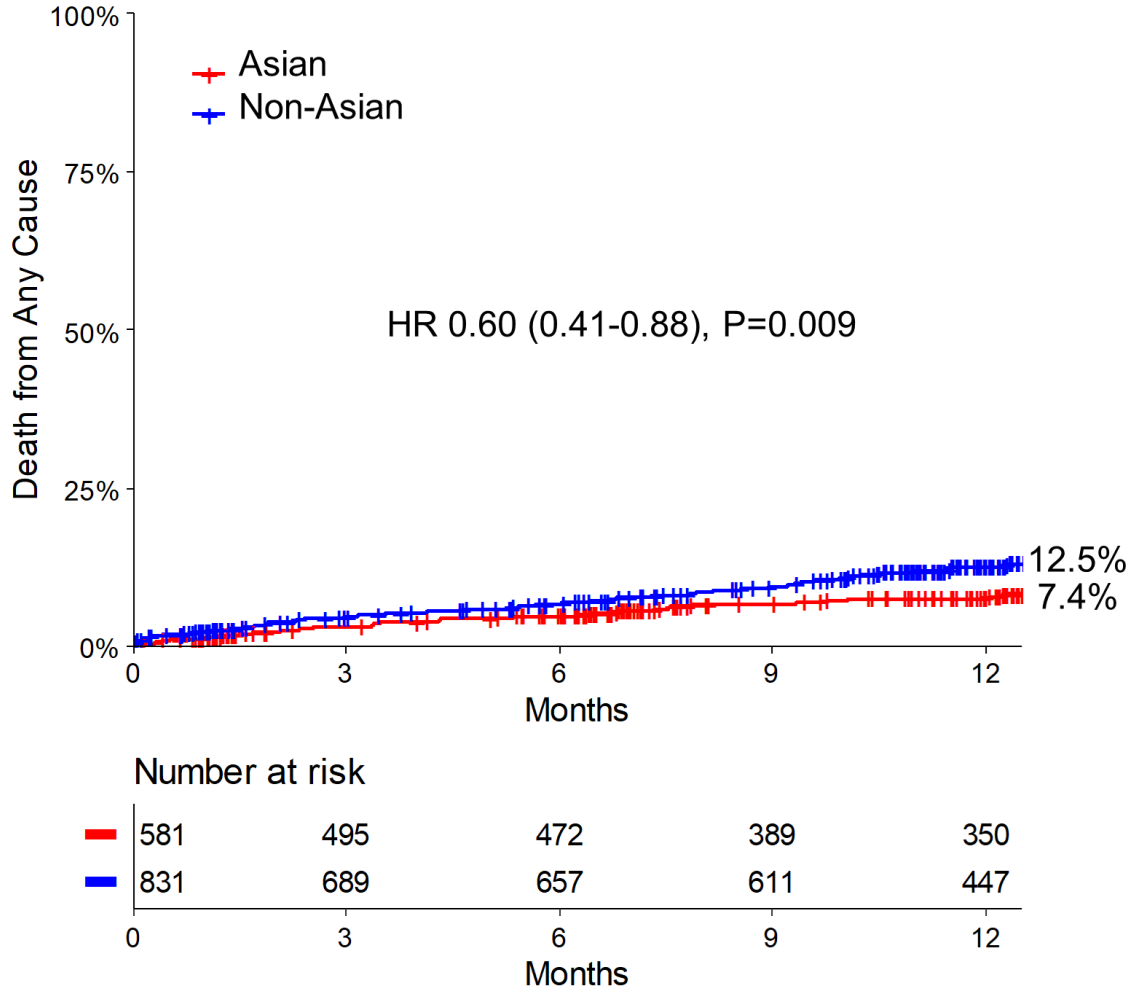
Kang DY et al. Heart. 2022;108(19):1562-1570.

1-year Clinical Outcomes by Asian vs. Non-Asian

Death, Stroke, or Rehospitalization



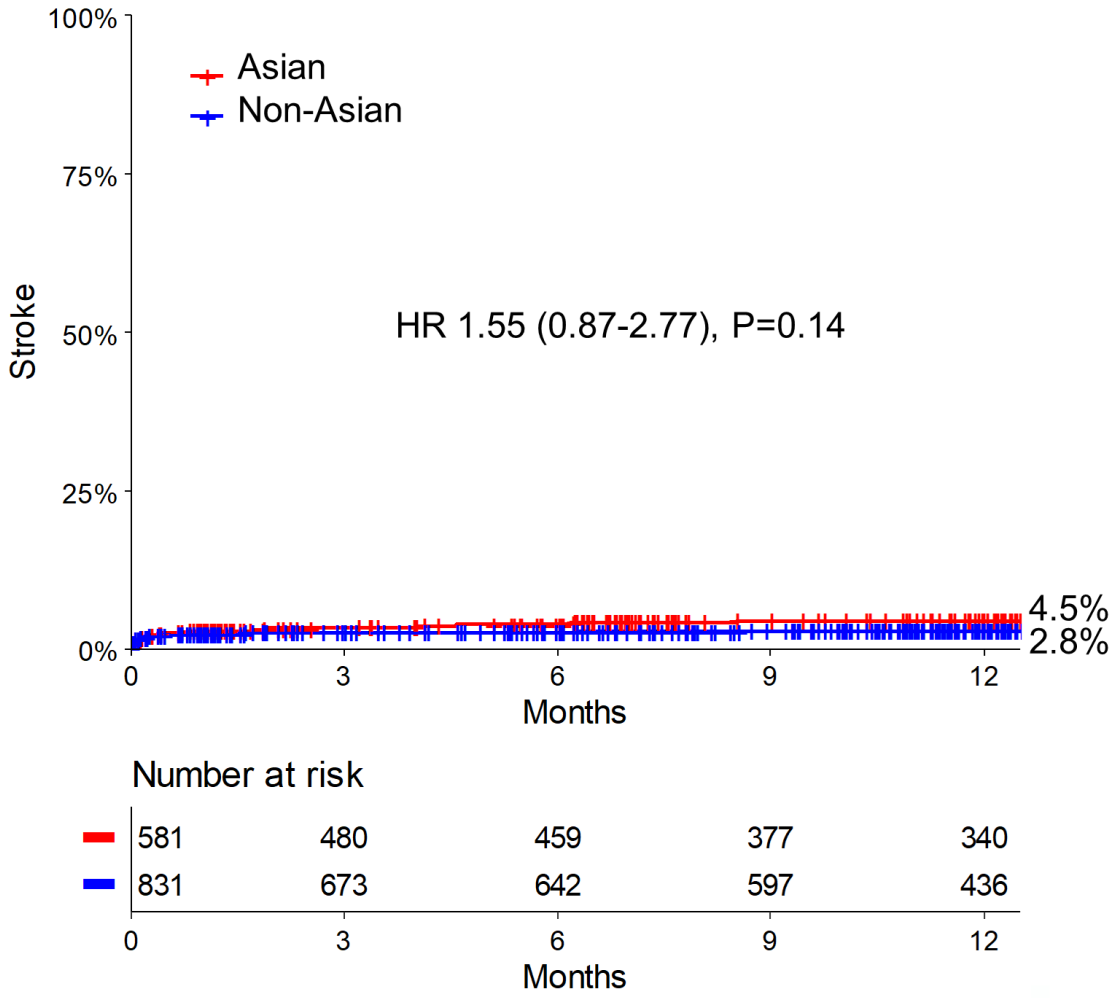
All-cause Death



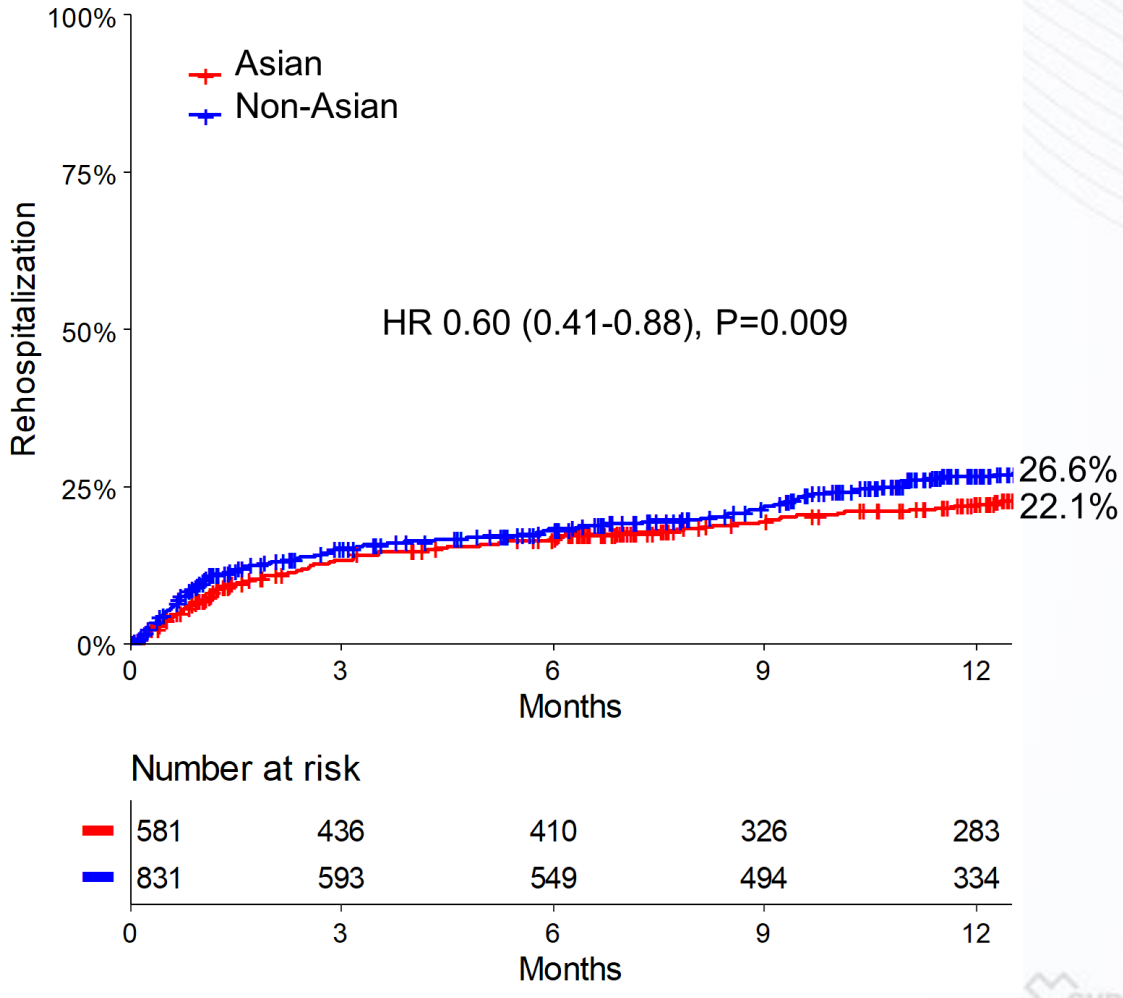
Kang DY et al. Heart. 2022;108(19):1562-1570.

1-year Clinical Outcomes by Asian vs. Non-Asian

Stroke



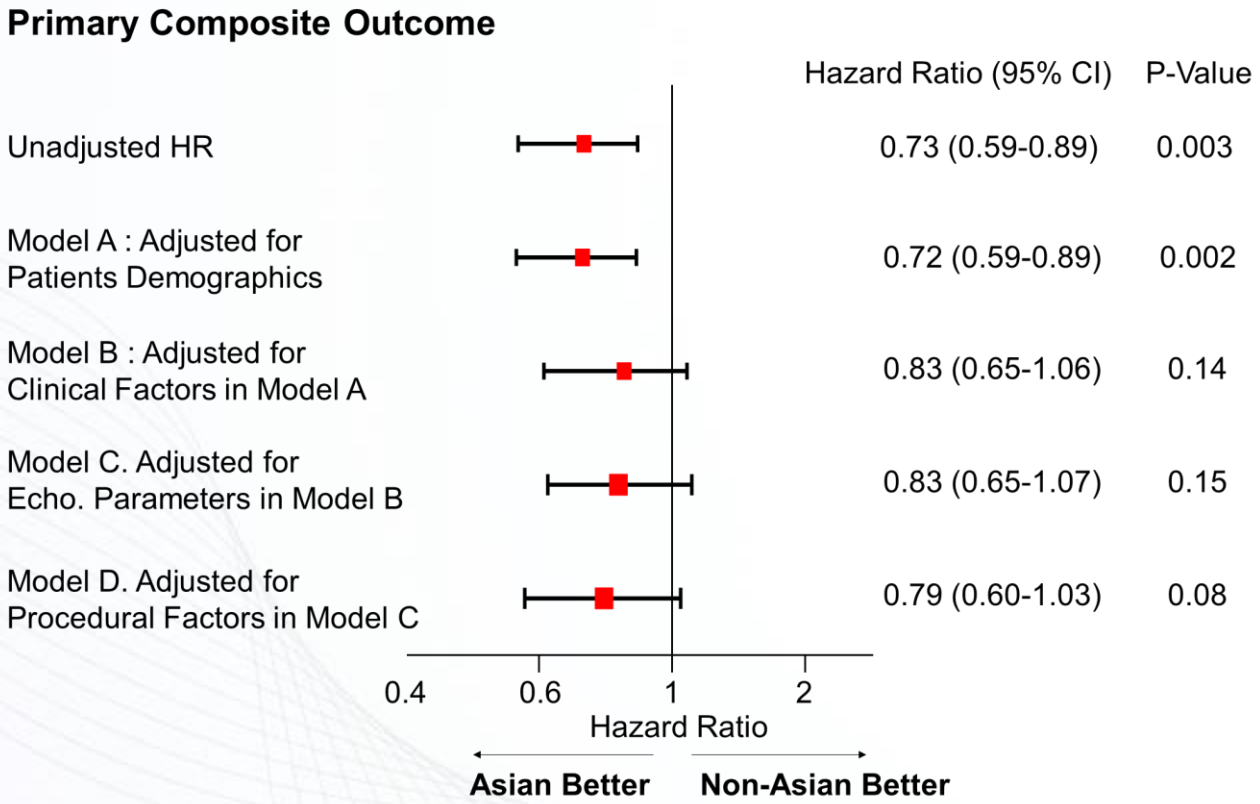
Rehospitalization

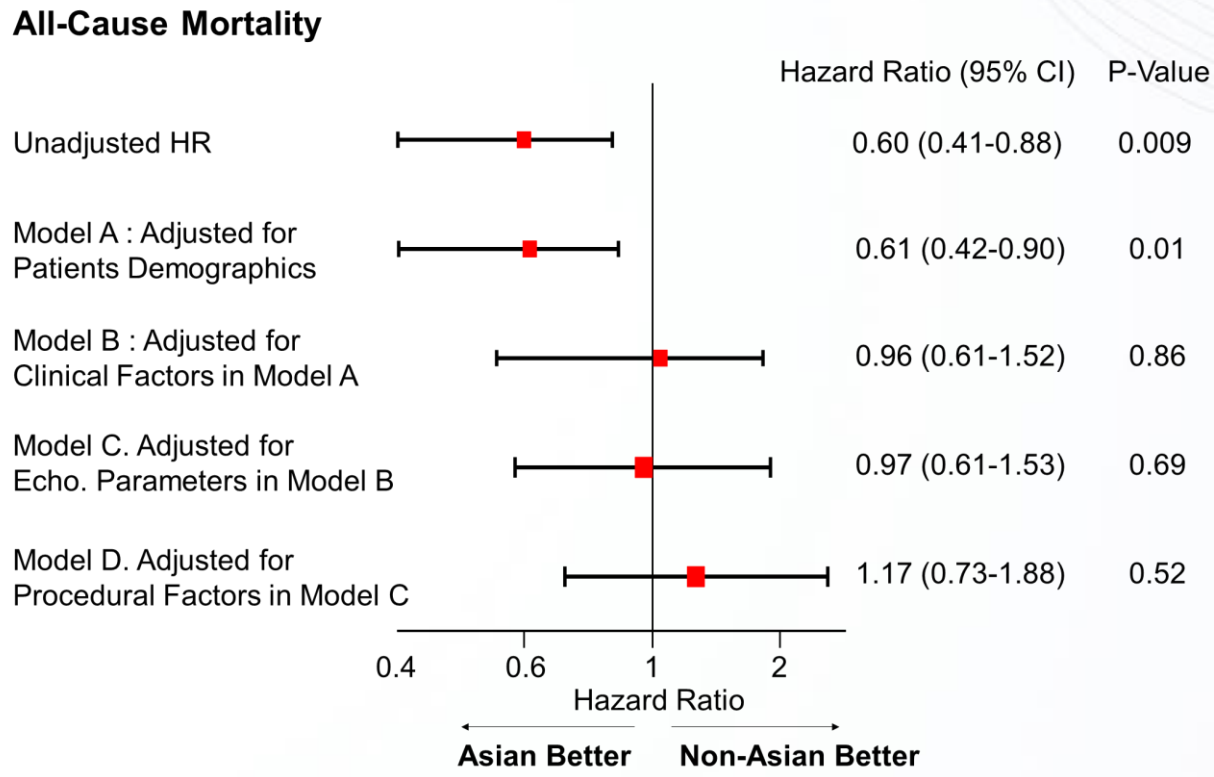


Kang DY et al. Heart. 2022;108(19):1562-1570.

Stepwise Adjustment of Clinical Outcomes

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





Kang DY et al. Heart. 2022;108(19):1562-1570.

Stepwise Adjustment of Clinical Outcomes

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

OUTCOMES	Univariable Analysis		Final Multivariable Analysis	
	HR (95% CI)	*P* value	HR (95% CI)	*P* value
Death, stroke, or rehospitalization	0.73 (0.59–0.89)	<0.01	0.79 (0.60–1.03)	0.08
Death	0.60 (0.41–0.88)	<0.01	1.17 (0.73–1.88)	0.52
Cardiac death	1.00 (0.51–1.99)	0.99	1.71 (0.68–4.31)	0.26
Non-cardiac death	0.52 (0.33–0.81)	<0.01	1.03 (0.59–1.81)	0.91
Stroke	1.55 (0.87–2.77)	0.14	0.71 (0.31–1.63)	0.71
Death or stroke	0.73 (0.52–1.01)	0.06	0.92 (0.60–1.42)	0.71
Rehospitalization	0.82 (0.65–1.04)	0.09	0.79 (0.58–1.08)	0.14

Kang DY et al. Heart. 2022;108(19):1562-1570.

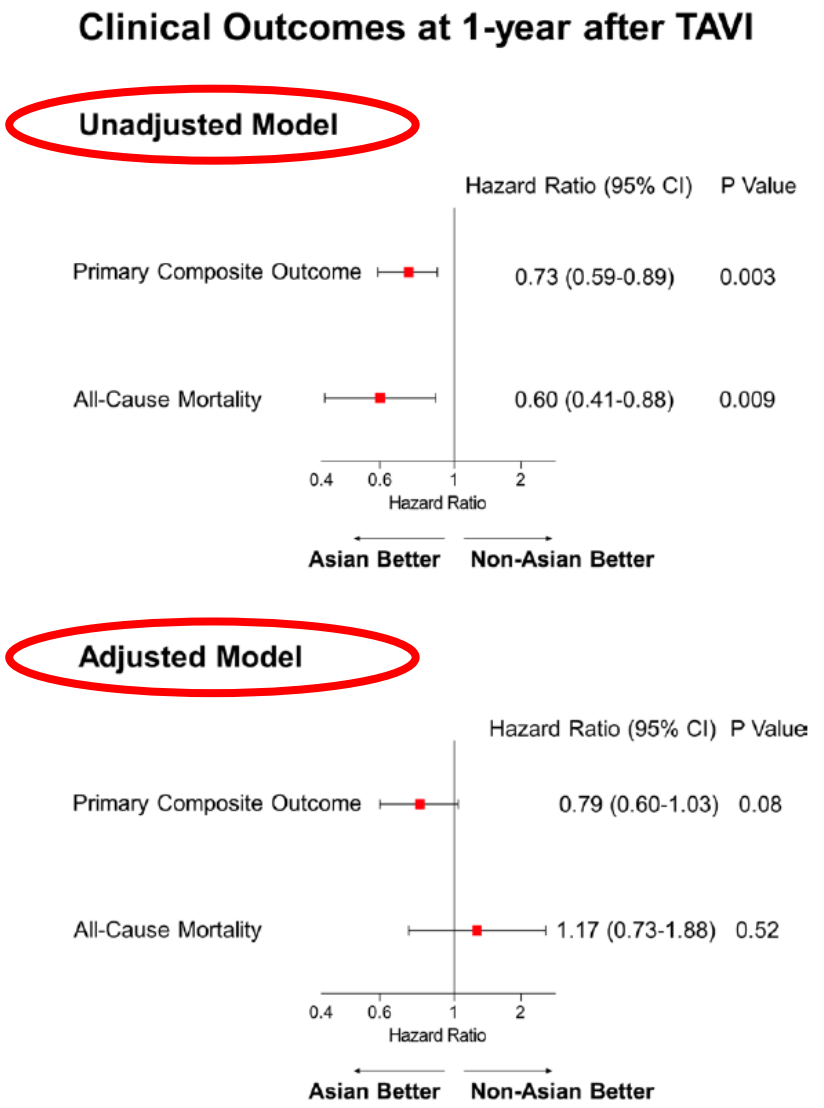
Limitations

- Selection and ascertainment bias
- Inter-site variability in care
- Data from high-volume centers
- Non-captured risk factors (frailty, socioeconomic factors, medications)
- Lack of core lab CT / Echo data
- Short clinical follow-up (1 year)

Kang DY et al. Heart. 2022;108(19):1562-1570.

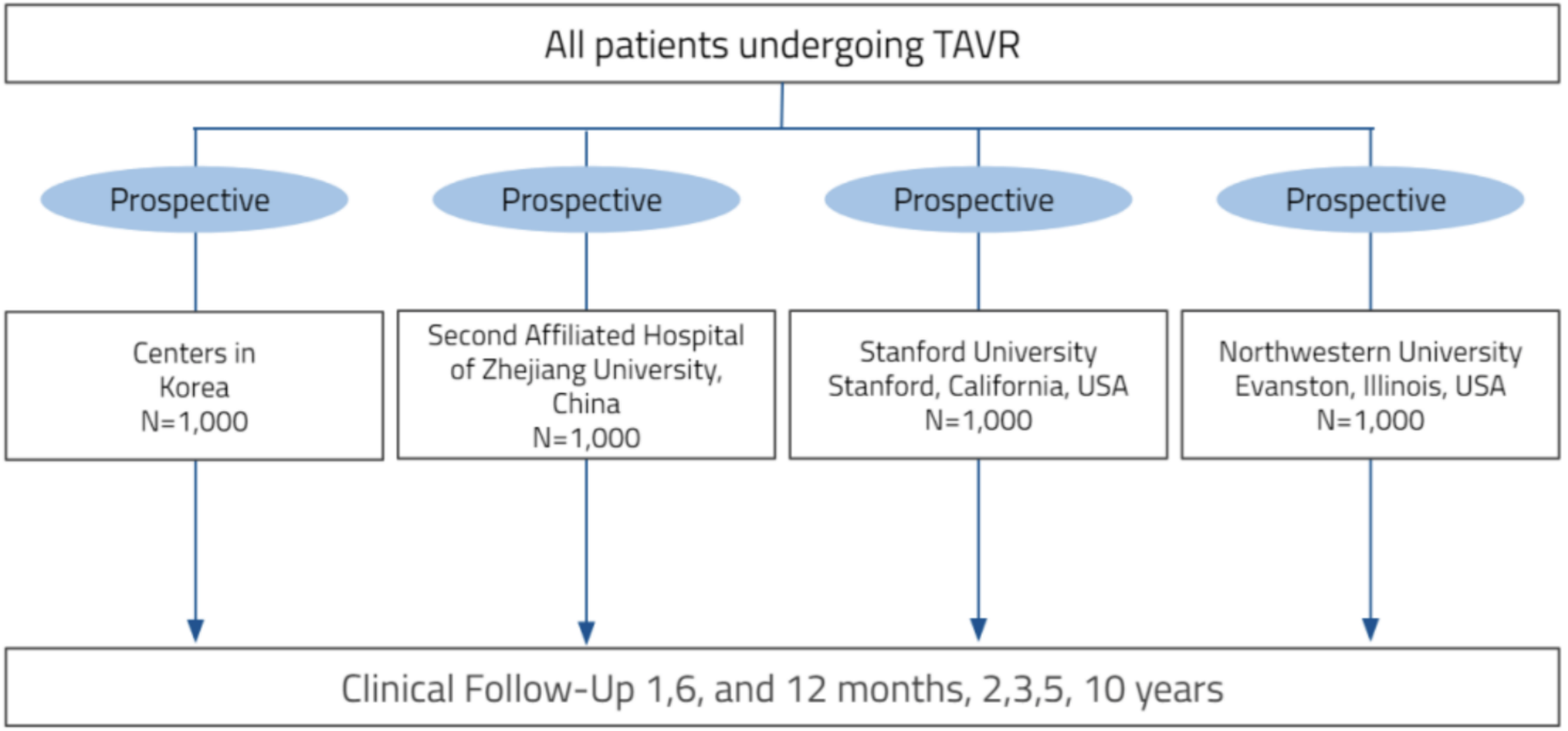
Key Messages

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	≈	



Kang DY et al. Heart. 2022;108(19):1562-1570.

2ND Wave of TP-TAVR Registry



Conclusion :
Unmet Issues Still Exist in 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.
- Future research into racial/ethnic disparities can help optimize TAVR procedures in Asia Pacific countries.