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## Original Research

## Racial Disparities Among Patients Undergoing Balloon-Expandable Transcatheter Aortic Valve Replacement



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## ABSTRACT

**Background:** Aortic stenosis is the most frequently acquired native valve disease. Transcatheter aortic valve replacement (TAVR) has emerged as a transformative intervention for patients with severe aortic stenosis. Despite its success, studies have shed light on racial and ethnic disparities in utilization and outcomes of TAVR.

**Methods:** Using the Transcatheter Valve Therapy Registry between November 2011 through June 2023, we evaluated volume trends of SAPIEN balloon-expandable TAVR performed by race/ethnicity, and its association with in-hospital and 1-year outcomes after the procedure.

**Results:** In the 12-year period, 395,618 patients were identified; 357,729 (90.42%) were White, 18,810 (4.75%) Hispanic, 15,100 (3.82%) Black, and 3979 (1.01%) Asian. There was an overall rising trend in proportional usage of TAVR among Hispanics (from 3.3% in 2011/2012 to 5.2% in 2023,  $P < .01$ ) and Asian patients (from 1.1% in 2011/2012 to 1.3% in 2023,  $P < .01$ ). Adjusted 1-year major adverse cardiac events (all-cause mortality, stroke, or rehospitalization) were comparable among Black patients (hazard ratio [HR], 1.00; 95% CI, 0.97-1.03;  $P = .82$ ) and lower among Asian (HR, 0.91; 95% CI, 0.86-0.97;  $P < .01$ ) and Hispanic patients (HR, 0.89; 95% CI, 0.86-0.91;  $P < .01$ ) compared with White patients.

**Conclusions:** Evidence supports favorable outcomes across different ethnic groups, despite the presence of higher levels of comorbidities and lower TAVR utilization. Modest improvements in TAVR utilization disparities among Asian and Hispanic patients have occurred since its introduction; however, utilization in Black patients remains low despite favorable outcomes. Further efforts are needed to understand the reasons and mitigate disparities in minority patients.

## Introduction

Aortic valve stenosis (AS) is the most frequently acquired native valve disease and its prevalence is increasing with an aging population, representing a major public health challenge.<sup>1</sup> For symptomatic patients with severe AS, surgical aortic valve replacement was the definitive treatment of AS until the introduction of transcatheter aortic valve replacement (TAVR).<sup>2</sup> TAVR has emerged as a transformative intervention for patients with AS, offering a less invasive alternative to traditional surgical aortic valve replacement and since its inception, the indications for TAVR have expanded to include patients in all risk categories.<sup>3</sup>

Despite its success, studies have shed light on racial disparities in the utilization and outcomes of TAVR procedures. Research suggests that minority patients, particularly Black and Hispanic patients, face lower

rates of TAVR utilization compared with their White counterparts, even after adjusting for clinical factors.<sup>4-7</sup> Moreover, evidence suggests that minority patients undergoing TAVR may experience different post-procedural complications, overall procedural success rates, and long-term survival rates as compared with White patients.<sup>8,9</sup> Racial minorities are usually underrepresented among patients undergoing TAVR in the United States (US) and hence the data are currently limited.<sup>10,11</sup> These findings underscore the need for a thorough investigation into the potential mechanisms driving these differences and the development of targeted interventions to mitigate disparities. Understanding the reasons behind these disparities requires a multifaceted approach, considering factors ranging from socioeconomic status and access to health care resources to cultural and patient preferences. Using the large, all-comers, real-world Society of Thoracic Surgeons (STS)/American College of

Abbreviations: MI, myocardial infarction; PPM, permanent pacemaker; TAVR, transcatheter aortic valve replacement.

Keywords: outcomes; race/ethnicity; transcatheter aortic valve replacement; trends.

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Cardiology Transcatheter Valve Therapy (TVT) Registry, we sought to evaluate trends in the volume of TAVR performed by race/ethnicity, and the association between race/ethnicity and in-hospital and 1-year outcomes after TAVR (Central Illustration).

Methods

TVT Registry and study population

The TVT Registry includes procedural and in-hospital outcomes of all patients undergoing TAVR with a commercially approved device. For the present analysis, all patients treated with the balloon-expandable SAPIEN 3 (Edwards Lifesciences Corporation) transcatheter aortic valve platform from November 2011 through June 2023 were included. Self-reported race/ethnic groups were categorized as follows: (1) non-Hispanic White (White); (2) non-Hispanic Black (Black); (3) Hispanic; and (4) Asian patients (Asian). Because the numbers of American/Pacific Islanders were small, such patients were not included in the present analysis. Procedural performance and in-hospital outcomes based on self-reported race/ethnic groups were reported. TVT Registry data were linked to Centers for Medicare & Medicaid Services (CMS) administrative claims data using direct patient identifiers to capture any additional mortality and stroke events not reported through the TVT Registry. The TVT Registry has been approved by a central institutional review board (Advarra) with a waiver of informed consent granted by the Duke University School of Medicine institutional review board under the Common Rule 45 CFR 46.3.

Study outcomes: In-hospital

The primary outcome was in-hospital all-cause mortality. Secondary outcomes included stroke, myocardial infarction (MI), new permanent pacemaker (PPM) or implantable cardioverter-defibrillator (ICD) placement, major or life-threatening bleeding, and vascular complications.

Study outcomes: 1-year

The primary outcome was 1-year all-cause mortality. Secondary outcomes included MI, stroke, readmission for heart failure, aortic valve

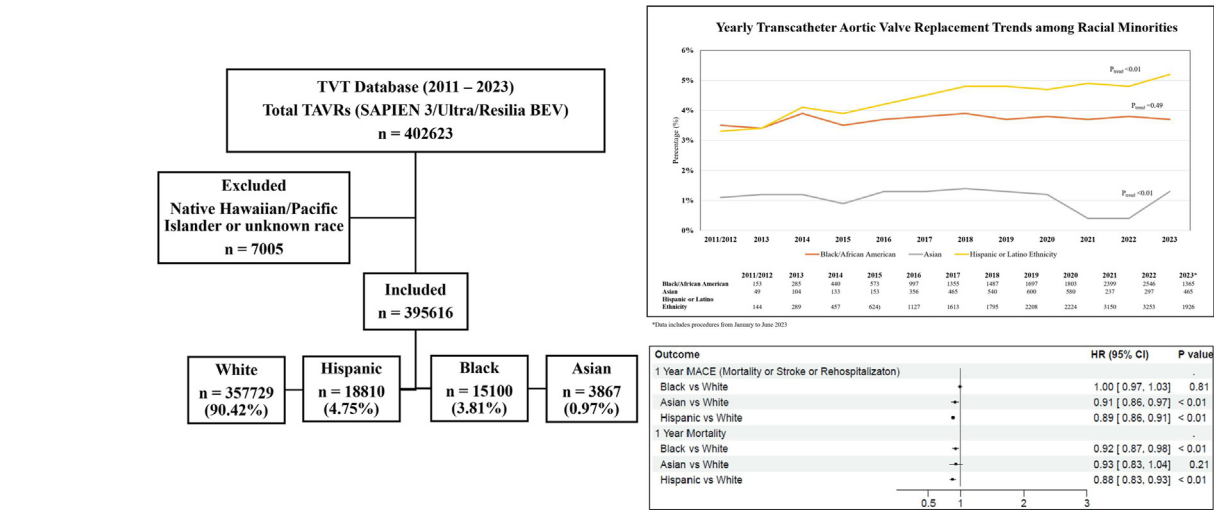
reintervention, and hospitalization for any bleeding, placement of new PPM or ICD.

Statistical analysis

Continuous variables were presented as mean (SD) or median (IQR) and were compared between groups using the 2-sample t test or Wilcoxon rank sum test. Categorical variables were given as frequencies and percentages and were compared using the  $\chi^2$  or Fisher exact test. The 30-day and 1-year adverse event rates were based on Kaplan-Meier estimates and all comparisons were made using the log-rank test. In-hospital and 1-year outcomes forest plots were generated by multivariable models adjusted with age, sex (male), body mass index, access site, prior percutaneous coronary intervention, prior coronary artery bypass graft surgery, prior stroke, carotid stenosis, peripheral arterial disease, hypertension, diabetes, chronic lung disease, immunocompromise, porcelain aorta, atrial fibrillation, creatinine, hemoglobin level, estimated glomerular filtration ratio, aortic valve mean gradient, left ventricular ejection fraction, mitral regurgitation, tricuspid regurgitation, New York Heart Association functional class III/IV, 5-meter walk test, Kansas City Cardiomyopathy Questionnaire-OS score, STS score, home oxygen, currently on dialysis, pacemaker, previous ICD, cardiogenic shock within 24 hours, aortic regurgitation, prior transient ischemic attack, endocarditis, heart failure within 2 weeks, prior MI, and procedure status: elective, urgent, emergent, and salvage. A probabilistic matching method was used to match data between TVT Registry and CMS claims data for eligible patients (age  $\geq 65$  years) based on their procedure date, birth date, and gender. The outcomes of mortality and stroke were evaluated for up to 1-year with CMS follow-up data (CMS-matched patients) and TVT Registry follow-up data.

Results

In the overall population of 395,618 patients who underwent TAVR with balloon-expandable SAPIEN 3 platform valves in the US, 357,729 (90.42%) were White, 18,810 (4.75%) were Hispanic, 15,100 (3.82%) were Black, and 3979 (1.01%) were Asian (Supplemental Table S1, Supplemental Figure S1). The overall population across all races was noted to be elderly with a median age between 77 and 80 years ( $P < .01$ ). Over 98% of patients were insured, with Medicare



Central Illustration.

Study flow and inclusion, yearly transcatheter aortic valve replacement (TAVR) usage trends, and 1-year outcomes. BEV, balloon-expandable valve; HR, hazard ratio; MACE, major adverse cardiac events; TVT, Transcatheter Valve Therapy.

**Table 1.** Baseline characteristics of TAVR subjects by race/ethnic groups.

Variables	White (n = 357,729)	Hispanic (n = 18,810)	Black (n = 15,100)	Asian (n = 3979)	P value
Age, y	80.0 (74.0, 86.0)	79.0 (72.0, 84.0)	77.0 (70.0, 83.0)	80.0 (74.0, 86.0)	<.01
Female sex	146,809 (41.0%)	8424 (44.8%)	8042 (53.3%)	1813 (45.6%)	<.01
Body mass index, kg/m <sup>2</sup>	28.2 (24.6, 32.7)	28.0 (24.6, 32.3)	28.8 (24.7, 33.9)	24.7 (22.0, 27.8)	<.01
Baseline STS score	3.9 (2.3, 6.4)	4.0 (2.3, 6.7)	4.2 (2.6, 7.1)	4.8 (2.9, 8.2)	<.01
STS score <4	175,399 (51.1%)	3209 (49.5%)	6718 (46.3%)	1514 (40.3%)	<.01
STS score 4-8	112,714 (32.8%)	5969 (32.9%)	4858 (33.5%)	1279 (34.0%)	.16
STS score >8	55,329 (16.1%)	3209 (17.7%)	2934 (20.2%)	964 (25.7%)	<.01
Hypertension	321,374 (89.9%)	17,197 (91.5%)	14,391 (95.3%)	3563 (89.6%)	<.01
Diabetes mellitus	131,747 (36.9%)	9512 (50.7%)	7854 (52.1%)	1923 (48.4%)	<.01
Insulin use	42,744 (33.0%)	3202 (34.2%)	2878 (37.2%)	533 (28.1%)	<.01
Chronic lung disease	115,481 (32.4%)	5238 (28.0%)	4972 (33.1%)	1125 (28.5%)	<.01
Home oxygen	27,908 (7.8%)	1088 (5.8%)	961 (6.4%)	141 (3.6%)	<.01
Atrial fibrillation/flutter	134,248 (37.6%)	4901 (26.2%)	3543 (23.5%)	1087 (27.4%)	<.01
Liver disease	4578 (3.1%)	405 (4.9%)	248 (4.0%)	30 (3.0%)	<.01
HF	102,502 (69.1%)	5807 (69.7%)	4514 (71.5%)	708 (70.9%)	<.01
HF hospitalization within the past year	29,872 (25.1%)	2310 (34.7%)	1858 (35.8%)	246 (29.3%)	<.01
HF within 2 weeks	241,175 (71.1%)	13,046 (73.0%)	10,653 (73.8%)	2790 (72.2%)	<.01
Baseline LVEF, %	55.76 ± 12.53	55.19 ± 13.41	54.34 ± 14.03	56.70 ± 13.73	<.01
Currently on dialysis	10,531 (2.6%)	1465 (7.8%)	2447 (16.2%)	339 (8.5%)	<.01
Prior PCI	114,837 (32.2%)	5246 (28.0%)	3682 (24.5%)	1237 (31.2%)	<.01
Prior CABG	64,034 (18.0%)	2648 (14.1%)	1497 (10.0%)	652 (16.5%)	<.01
Prior stroke	37,811 (10.6%)	2108 (11.3%)	2164 (14.4%)	437 (11.0%)	<.01
Peripheral arterial disease	83,081 (23.3%)	4040 (21.6%)	3572 (23.7%)	791 (20.0%)	<.01
Current/recent smoker	13,171 (6.3%)	566 (5.4%)	719 (8.2%)	101 (3.4%)	<.01
GFR, mL/min/1.73 m <sup>2</sup>	62.2 ± 24.8	62.5 ± 28.9	57.9 ± 32.9	59.0 ± 28.5	<.01

Values are median (IQR), n (%), or mean ± SD.

CABG, coronary artery bypass graft; GFR, glomerular filtration rate; HF, heart failure; LVEF, left ventricular ejection fraction; PCI, percutaneous coronary intervention; STS, Society of Thoracic Surgeons; TAVR, transcatheter aortic valve replacement.

being the most common form of insurance followed by private health insurance (Supplemental Table S2).

Although the overall number of TAVR increased over the years, there has been an overall falling trend in proportional usage of TAVR in White patients over the years (from 91.4% in 2011/2012 to 87.2% in 2023,  $P < .01$ ) (Supplemental Figure S2). Concurrently, there has been an overall rising trend in proportional usage of TAVR among Hispanic (from 3.3% in 2011/2012 to 5.2% in 2023,  $P < .01$ ) and Asian patients (from 1.1% in 2011/2012 to 1.3% in 2023,  $P < .01$ ), whereas the proportional TAVR usage among Black patients remained flat over the years (from 3.5% in 2011/2012 to 3.7% in 2023,  $P = .49$ ) (Central Illustration).

A male predominance was observed among White (59%), Hispanic (55%), and Asian (54%) patients. There was a female predominance among Black (53%) patients. Baseline median STS scores were higher among Asian (4.8%), and Black (4.2%) cohorts compared with White (3.9%) and Hispanic (4.0%) ( $P < .01$ ) patients. The incidence of hypertension (95.3%), diabetes (52.1%), chronic lung disease (33.1%), heart failure (71.5%), renal failure on dialysis (16.2%), and prior stroke (14.4%) was higher among Black patients compared with other cohorts ( $P < .01$ ) (Table 1). There was a higher frequency of bicuspid AS (7.3%) and annular calcification (83.2%) among Asian patients. Although aortic valve mean gradient was above 40 mm Hg across all cohorts, Black patients had a higher incidence of moderate/severe tricuspid regurgitation (21.5%) and elevated median right ventricular systolic pressure (45 mm Hg,  $P < .01$ ) (Supplemental Table S3).

#### Postprocedure follow-up and outcomes

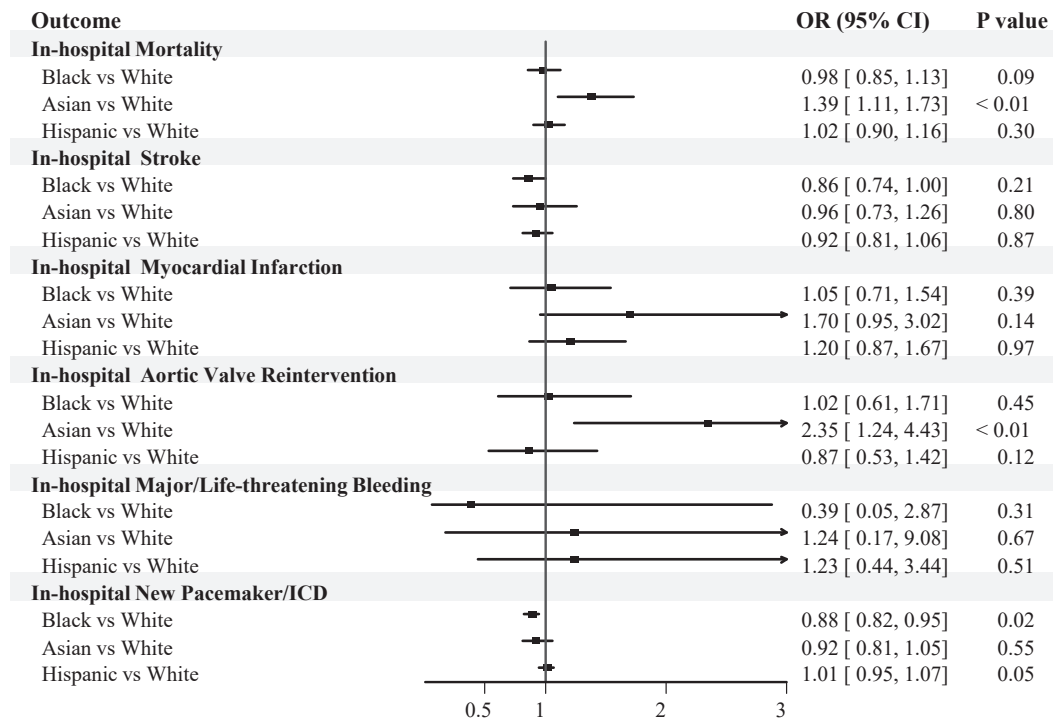
Median ICU length of stay was 21 to 24.5 hours across all cohorts. However, the average hospital length of stay was longer among Black (3.4 days), and Asian (3.1 days) patients, compared with White (2.8 days) and Hispanic (3.0 days) patients ( $P < .01$ ). In-hospital all-cause mortality and cardiac death was higher among Black (1.6% and 0.9%) and Asian patients (2.1% and 1.2%), respectively. However, Black

patients had similar adjusted in-hospital mortality (OR, 0.98; 95% CI, 0.85-1.13) compared with White patients; whereas Asian patients had a higher adjusted in-hospital mortality (OR, 1.39; 95% CI, 1.11-1.73) compared with White patients. Adjusted in-hospital aortic valve reintervention was also higher among Asian patients (OR, 2.35; 95% CI, 1.24-4.43) compared with Whites. The common indication for valvular reintervention was due to aortic insufficiency across all races (28.6% White, 20.0% Hispanic, 20.0% Black, and 26.3% Asian;  $P = .44$ ), with endocarditis as the second common reason in White and Hispanic patients (13.7% White vs 17.1% Hispanic vs 8.9% Black vs 5.3% Asian,  $P = .50$ ), whereas aortic stenosis was the second common reason among Black and Asian patients (20.0% vs 21.1%,  $P = .10$ ) (Supplemental Table S4). Adjusted in-hospital incidence of new PPM/ICD was lower among Black patients (OR, 0.88; 95% CI, 0.82-0.95) compared with White patients (Figure 1).

Unadjusted 1-year all-cause mortality and cardiac death were higher among Black (12.8% and 3.4%) and Asian patients (11.7% and 3.1%) respectively (Table 2, Supplemental Figure S3). However, adjusted 1-year major adverse cardiac events (mortality or stroke or rehospitalization) were comparable among Blacks (hazard ratio [HR], 1.00; 95% CI, 0.97-1.03;  $P = .82$ ) and lower among Asian (HR, 0.91; 95% CI, 0.86-0.97;  $P < .01$ ), and Hispanic patients (HR, 0.89; 95% CI, 0.86-0.91;  $P < .01$ ) compared with White patients (Figure 2). Adjusted 1-year aortic valve reintervention rate was higher among Asian patients (HR, 2.20; 95% CI, 1.47-3.27) compared with White patients. Overall stroke rates at 1 year were low and Hispanics had the lowest stroke rate of 2.4% (Supplemental Figure S4). One-year, all-cause readmission rates were higher among Black patients at 33.3% (Table 2, Supplemental Figure S5).

#### Discussion

To the best of our knowledge, the present analysis is the largest, most contemporary analysis of race/ethnic differences in balloon-expandable TAVR uptake and outcomes from the all-comers TAV Registry. The most relevant findings of the present study are as follows:



OR = Odds Ratio, CI = Confidence Interval, ICD = Implantable Cardioverter-Defibrillator

**Figure 1.**

**Adjusted in-hospital outcomes.** ICD, implantable cardioverter-defibrillator; OR, odds ratio.

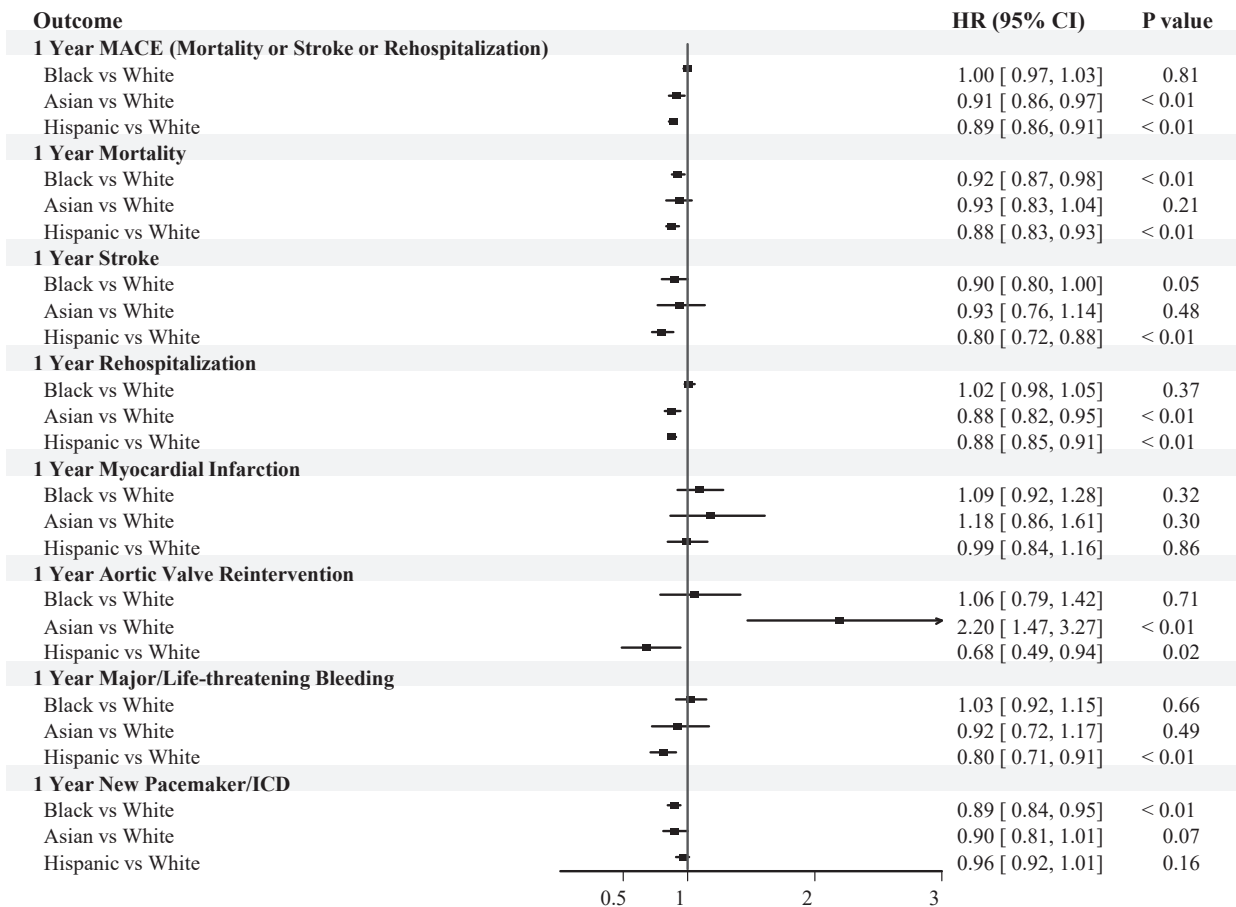
- Over the study period, the minority groups either saw a steady or a gradually increasing trend in usage of TAVR compared with White patients.
- Black patients appear to be sicker at presentation with a higher rate of comorbidities, more frequent moderate/severe tricuspid regurgitation, right ventricular dysfunction, longer index hospitalization, higher unadjusted all-cause in-hospital and 1-year mortality, and all-cause 1-year readmission rate. However, when compared with White patients, adjusted major adverse cardiac events, adjusted in-hospital and 1-year mortality were similar.
- Asian patients also appear to be sicker than White patients and have similar outcomes as Black patients, with higher unadjusted in-hospital and 1-year all-cause mortality. When compared with White patients, adjusted in-hospital mortality was higher, whereas adjusted 1-year mortality was similar.
- In-hospital and 1-year aortic valve reintervention was also higher among Asian patients.

**Table 2.** Postprocedure follow-up and outcomes of TAVR subjects by race/ethnic groups.

Variables	White (n = 357,729)	Hispanic (n = 18,810)	Black (n = 15,100)	Asian (n = 3979)	P value
Index hospitalization length of stay, d	2.6 ± 4.2	3.1 ± 4.5	3.4 ± 5.9	3.1 ± 4.9	<.01
ICU length of stay, h	23.0 (0.0, 31.0)	24.5 (3.3, 43.0)	24.0 (2.7, 42.4)	21.1 (0.0, 31.0)	<.01
In-hospital outcomes					
All-cause mortality	5052 (1.4%)	279 (1.5%)	239 (1.6%)	84 (2.1%)	<.01
Cardiac death	2749 (0.8%)	160 (0.9%)	138 (0.9%)	48 (1.2%)	<.01
Mean gradient at discharge, mm Hg	11.4 ± 5.7	12.2 ± 6.2	13.1 ± 6.3	11.1 ± 5.4	<.01
Mean gradient at 30 days, mm Hg	11.9 ± 5.6	12.8 ± 6.1	13.8 ± 6.3	12.1 ± 6.0	<.01
30-day LVEF, %	57.48 ± 10.68	57.42 ± 11.32	56.55 ± 12.20	58.47 ± 11.37	<.01
Mean gradient at 1 year, mm Hg	12.4 ± 6.1	13.8 ± 7.0	14.9 ± 6.7	12.6 ± 6.3	<.01
1-year LVEF, %	58.05 ± 10.07	58.46 ± 10.42	57.68 ± 11.61	59.22 ± 11.03	<.01
1-year outcomes					
All-cause mortality	30,052 (11.6%)	1331 (10.6%)	1364 (12.8%)	325 (11.7%)	<.01
Cardiac death	7252 (2.6%)	377 (2.8%)	377 (3.4%)	92 (3.1%)	<.01
All-cause mortality or stroke	37,293 (13.7%)	1602 (12.2%)	1638 (14.9%)	393 (13.6%)	<.01
New requirement for dialysis	2341 (0.8%)	160 (1.0%)	146 (1.2%)	31 (0.9%)	<.01
Valve related readmissions	4188 (1.6%)	197 (1.6%)	198 (1.8%)	39 (1.4%)	.16
Nonvalve related readmissions	73,331 (27.8%)	3260 (25.9%)	3489 (32.3%)	706 (25.9%)	<.01
Any readmissions	75,953 (28.7%)	3379 (26.7%)	3610 (33.3%)	733 (26.7%)	<.01
NYHA class improvement from baseline to 1 year	115,252 (81.2%)	5063 (82.2%)	4302 (79.4%)	1077 (78.5%)	<.01
KCCQ QOL score: Change from baseline to 1 year	50.0 (25.0, 62.5)	50.0 (25.0, 75.0)	37.5 (12.5, 62.5)	37.5 (12.5, 62.5)	<.01

Values are mean ± SD, median (IQR), or n/N (%), n = events (Kaplan-Meier estimate %).

ICU, intensive care unit; KCCQ, Kansas City Cardiomyopathy Questionnaire; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; QOL, quality of life; TAVR, transcatheter aortic valve replacement.



HR = Hazard Ratio, CI = Confidence Interval, MACE = Major Adverse Cardiac Events, ICD = Implantable Cardioverter-Defibrillator

**Figure 2.**

**Adjusted 1-year outcomes.** HR, hazard ratio; ICD, implantable cardioverter-defibrillator; MACE, major adverse cardiac events.

### Access disparities

The US Census Bureau reported the demographic breakdown in the US as follows: 75% White, 19.1% Hispanic, 13.6% Black, and 6.3% Asian.<sup>12</sup> Consistent with prior literature, our analysis found differential access to TAVR among racial/ethnic groups.<sup>10,13</sup> A unique finding of our study not seen in prior studies is the rising trend of TAVR usage among the minority groups.<sup>14</sup> This trend, however, trails TAVR adoption compared with White US patients disproportionately. Access disparities are likely multifactorial and attributable to various factors, including socioeconomic status, geographic location, and health care infrastructure.<sup>15</sup> Socioeconomic factors, including income, education level, and health insurance status, significantly influence access to specialized cardiovascular care. This is consistent with earlier findings that suggest when comorbidities and other factors are accounted for, racial disparities in outcomes may be less pronounced.

An important finding of our study is the elevated all-cause 1-year readmission rates among Black patients and the low rate of Kansas City Cardiomyopathy Questionnaire score improvement in Black and Asian patients (Table 2). This is likely attributed to the higher rate of comorbidities and baseline higher rate of concomitant valvular heart disease and heart failure observed in these cohorts prior to the index procedure. Appropriate access to timely health care and management could theoretically curb the severity of comorbidities at the time of presentation.<sup>16</sup> It is well described that racial and ethnic minorities are disproportionately affected by lower socioeconomic status, limiting their ability to seek timely medical interventions.<sup>17</sup> Disparities in health

care delivery, including variations in referral patterns, access to advanced cardiac care centers, and quality of care, likely contribute to differential utilization rates among racial groups.<sup>16</sup> Lack of awareness, education, and culturally competent outreach programs may also contribute to lower rates of TAVR utilization among minority patients.<sup>16</sup>

### Outcomes disparities

Research suggests that racial and ethnic minorities undergoing TAVR may encounter differing outcomes compared with their White counterparts. Various factors, including preexisting comorbidities, genetic variances, and socioeconomic influences, contribute to these differences.<sup>18</sup> Moreover, implicit biases and cultural elements may impact the decision-making process, thus affecting patient outcomes.

The present study highlights that the Asian population has higher adjusted rates of in-hospital mortality and aortic valve reinterventions, which is a unique finding that may not have been clearly documented in previous studies. Among Black patients, the study corroborates earlier research indicating similar adjusted mortality outcomes compared to White patients but also points out higher readmission rates, which could be indicative of broader systemic health care issues. A plausible explanation could be that the Black and Asian cohorts exhibited a higher rate of comorbidities, potentially resulting in prolonged lengths of stay for index procedures and increased unadjusted morbidity and mortality. However, upon adjusting for relevant factors, we found that minority groups, apart from the Asian cohort, demonstrated



comparable in-hospital and 1-year outcomes compared with White patients. The Black population had in-hospital outcomes which were similar despite having higher comorbidities and being sicker in comparison. The level of sickness did not, therefore, seem to preclude a good outcome with TAVR.

Notably, a standout metric revealed in the present study was that adjusted rates of in-hospital and 1-year aortic valve reintervention were higher among Asian patients. This trend may be partly attributed to the smaller aortic root and valve dimensions often observed in Asian patients compared with Western patients, necessitating the use of smaller TAVR valves.<sup>19,20</sup> However, as recently reported by Eng et al,<sup>21</sup> midterm clinical outcomes associated with the use of small balloon-expandable valves were similar to those associated with the use of larger balloon-expandable valves despite the elevated echo gradient. Additionally, we also found a higher prevalence of bicuspid aortic valves (7.3%) and annular calcification (83.2%) among Asian patients as compared with White patients and this may impact TAVR outcomes as seen in our study (Supplemental Table S1). Another relevant finding of our study revealed that adjusted in-hospital incidence of new PPM/ICD was lower among Black patients compared with White patients. This finding was observed in prior studies and likely requires further investigation.<sup>22</sup>

In summary, this study aligns with previous research in many aspects but also provides novel insights, particularly regarding Asian patients and the lower-risk TAVR cohort. It emphasizes the need for multifaceted strategies to address racial disparities in TAVR utilization and outcomes, a call to action that is consistent with the broader body of literature on this topic. These prior studies encompassed a substantial cohort comprising both high- and intermediate-risk populations, revealing the underutilization of TAVR among minority groups despite exhibiting comparable adjusted in-hospital and 1-year outcomes.<sup>10,18</sup> Building upon this foundation, our study harnesses the extensive sample size of the TVT Registry and extends its scope to a much larger and more contemporary cohort encompassing a lower-risk TAVR population—an aspect not previously explored. This expansion enables corroborating prior studies that support the safety and comparable adjusted outcomes of minority groups in comparison to White patients. The study notes a significant increase in TAVR utilization among minority groups, although they still lag behind White patients. This reflects a gradual change that has been observed in other studies, indicating an ongoing shift in health care practices and possibly increased awareness or access to TAVR for these minority patients.

#### Potential solutions

To address racial disparities in TAVR, a comprehensive approach is essential. This involves implementing targeted educational initiatives tailored for health care providers and patients alike, enhancing access to health care resources in underserved communities, establishing the prevalence of disease with comprehensive screening of minorities, and crafting culturally sensitive care models.<sup>23</sup> Furthermore, integrating diversity and inclusion efforts within medical education and promoting awareness of implicit biases are vital steps toward fostering a more equitable health care system.

#### Study limitations

Although the study uses rigorous statistical methods and a probabilistic matching method to enhance the accuracy of its findings, it shares common limitations with other registry-based studies, such as potential reporting biases and the self-reported nature of sex, gender, and race/ethnicity. Although we strive to address sex and gender dimensions in our research, there are limitations in our data set that restrict a comprehensive analysis. As such, the generalizability of our

findings may be limited in terms of how they relate to diverse gender identities and experiences. Plus, race and ethnicity are a social construct without a genetic basis and are often based on physical characteristics, cultural expression, and identification of people of different geographic regions. The present analysis utilized data from a large US national database with site-reported clinical and outcome end points and may suffer from inherent limitations related to erroneous underreporting or overreporting although standardized forms and definitions were utilized for data collection. The study end points were site adjudicated and not by an independent clinical adjudication committee. Although we performed rigorous adjustments on the outcome measures, residual unmeasured confounding of the study results cannot be excluded. Furthermore, our study only included balloon-expandable TAVR valves. Although these valves represent the majority of TAVR nationally, there is potential site variation with some sites that predominantly use self-expanding valves. ZIP code data were not available which would have enabled the determination of whether ZIP code and its social determinants, distance from the hospital where the implant took place, type of hospital, and implant volume could have potentially impacted outcomes. If there were site-level differences in the racial and ethnic composition of patients, the current analysis may not identify the true proportions of racial and ethnic minorities that were undergoing TAVR, introducing potential bias. We performed a probabilistic (success rate 86%) rather than a deterministic match with the CMS data.

#### Conclusion

Our study echoes previous literature while also providing novel insights detailed above, acknowledging that socioeconomic status and access to health care are critical factors contributing to disparities in TAVR utilization and outcomes. This study reinforces the notion that these disparities are multifactorial and require a comprehensive approach to address. There is strong evidence supporting favorable adjusted outcomes across different ethnic groups, despite the presence of higher levels of comorbidities among minority patients. Although demonstrating similar outcomes and performing well compared with White patients, racial disparities persist in TAVR utilization, posing a substantial obstacle to achieving health equity in cardiovascular care. Addressing these disparities demands a multifaceted approach, including policy reforms, community engagement, provider training, and research efforts.

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#### Declaration of competing interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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## Ethics statement and patient consent

This study utilized data from the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (TVT) Registry. The Transcatheter Valve Therapy Registry has been approved by a central institutional review board (Advarra) with a waiver of informed consent granted by the Duke University School of Medicine institutional review board under the Common Rule 45 CFR 46.3.

## Supplementary material

To access the supplementary material accompanying this article, visit the online version of the *Journal of the Society for Cardiovascular Angiography & Interventions* at [10.1016/j.jscai.2024.102495](https://doi.org/10.1016/j.jscai.2024.102495).

## References

- Nkomo VT, Gardin JM, Skelton TN, Gottdiener JS, Scott CG, Enriquez-Sarano M. Burden of valvular heart diseases: a population-based study. *Lancet*. 2006;368(9540):1005–1011. [https://doi.org/10.1016/S0140-6736\(06\)69208-8](https://doi.org/10.1016/S0140-6736(06)69208-8)
- Bourantas CV, Serruys PW. Evolution of transcatheter aortic valve replacement. *Circ Res*. 2014;114(6):1037–1051. <https://doi.org/10.1161/CIRCRESAHA.114.302292>
- Tang GHL, Verma S, Bhatt DL. Transcatheter aortic valve replacement in low-risk patients: a new era in the treatment of aortic stenosis. *Circulation*. 2019;140(10):801–803. <https://doi.org/10.1161/CIRCULATIONAHA.119.041111>
- Rodriguez-Gabella T, Voisine P, Puri R, Pibarot P, Rodés-Cabau J. Aortic bioprosthetic valve durability: incidence, mechanisms, predictors, and management of surgical and transcatheter valve degeneration. *J Am Coll Cardiol*. 2017;70(8):1013–1028. <https://doi.org/10.1016/j.jacc.2017.07.715>
- McNeely C, Zajarias A, Fohrtung R, et al. Racial comparisons of the outcomes of transcatheter and surgical aortic valve implantation using the Medicare database. *Am J Cardiol*. 2018;122(3):440–445. <https://doi.org/10.1016/j.amjcard.2018.04.019>
- Cruz Rodriguez B, Acharya P, Salazar-Fields C, Horne A. Comparison of frequency of referral to cardiothoracic surgery for aortic valve disease in Blacks, Hispanics, and Whites. *Am J Cardiol*. 2017;120(3):450–455. <https://doi.org/10.1016/j.amjcard.2017.04.048>
- Yeung M, Kerrigan J, Sodhi S, et al. Racial differences in rates of aortic valve replacement in patients with severe aortic stenosis. *Am J Cardiol*. 2013;112(7):991–995. <https://doi.org/10.1016/j.amjcard.2013.05.030>
- Holmes DR, Mack MJ, Alkhouli M, Vemulapalli S. Racial disparities and democratization of health care: a focus on TAVR in the United States. *Am Heart J*. 2020;224:166–170. <https://doi.org/10.1016/j.ahj.2020.03.008>
- Alqahtani F, Aljohani S, Amin AH, et al. Effect of race on the incidence of aortic stenosis and outcomes of aortic valve replacement in the United States. *Mayo Clin Proc*. 2018;93(5):607–617. <https://doi.org/10.1016/j.mayocp.2017.11.026>
- Alkhouli M, Holmes DR, Carroll JD, et al. Racial disparities in the utilization and outcomes of TAVR: TVT registry report. *JACC Cardiovasc Interv*. 2019;12(10):936–948. <https://doi.org/10.1016/j.jcin.2019.03.007>
- Nathan AS, Yang L, Yang N, et al. Racial, ethnic, and socioeconomic disparities in access to transcatheter aortic valve replacement within major metropolitan areas. *JAMA Cardiol*. 2022;7(2):150–157. <https://doi.org/10.1001/jamacardio.2021.4641>
- United States Census Bureau. QuickFacts Data. Accessed April 17, 2024. <https://www.census.gov/quickfacts/fact/table/US/RHI125222#RHI125222>
- Gupta A, Mori M, Wang Y, et al. Racial/ethnic disparities in aortic valve replacement among Medicare beneficiaries in the United States, 2012–2019. *Am J Med*. 2024;137(4):321–330.e7. <https://doi.org/10.1016/j.amjmed.2023.12.026>
- Reddy KP, Faggioni M, Eberly LA, et al. Enrollment of older patients, women, and racial and ethnic minority individuals in valvular heart disease clinical trials: a systematic review. *JAMA Cardiol*. 2023;8(9):871–878. <https://doi.org/10.1001/jamacardio.2023.2098>
- Riley WJ. Health disparities: gaps in access, quality and affordability of medical care. *Trans Am Clin Climatol Assoc*. 2012;123:167–174.
- Caraballo C, Ndumele CD, Roy B, et al. Trends in racial and ethnic disparities in barriers to timely medical care among adults in the US, 1999 to 2018. *JAMA Health Forum*. 2022;3(10):e223856. <https://doi.org/10.1001/jamahealthforum.2022.3856>
- Institute of Medicine. *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care (with CD)*. The National Academies Press; 2003:12875. <https://doi.org/10.17226/12875>
- Ali A, Mather JF, McMahon S, et al. Racial and ethnic disparities in the use of transcatheter aortic valve replacement in the State of Connecticut. *Cardiovasc Revasc Med*. 2022;37:7–12. <https://doi.org/10.1016/j.carrev.2021.06.120>
- Lee CH, Inohara T, Hayashida K, Park DW. Transcatheter aortic valve replacement in Asia: Present Status and Future Perspectives. *JACC Asia*. 2021;1(3):279–293. <https://doi.org/10.1016/j.jacasi.2021.10.006>
- Tay ELW, Ngiam JN, Kong WK, Poh KK. Management of severe aortic stenosis: the Singapore and Asian perspective. *Singapore Med J*. 2018;59(9):452–454. <https://doi.org/10.11622/smedj.2018103>
- Eng MH, Khalili H, Vavalle J, et al. 3-year outcomes of balloon-expandable valves: 20-mm vs Larger Valves ( $\geq 23$  mm). *JACC Cardiovasc Interv*. 2024;17(17):2041–2051. <https://doi.org/10.1016/j.jcin.2024.06.001>
- Jaiswal V, Peng Ang S, Hanif M, et al. The racial disparity among post transcatheter aortic valve replacement outcomes: a meta-analysis. *Int J Cardiol Heart Vasc*. 2023;44:101170. <https://doi.org/10.1016/j.ijcha.2023.101170>
- Jackson CS, Gracia JN. Addressing health and health-care disparities: the role of a diverse workforce and the social determinants of health. *Public Health Rep*. 2014;129(1\_suppl 2):57–61. <https://doi.org/10.1177/00333549141291S211>