Racial Disparities in the Utilization and Outcomes of Structural Heart Disease Interventions in the United States

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Background—Data on race- and ethnicity-based disparities in the utilization and outcomes of structural heart disease interventions in the United States are scarce.

Methods and Results—We used the National Inpatient Sample (2011-2016) to examine racial and ethnic differences in the utilization, in-hospital outcomes, and cost of structural heart disease interventions among patients ≥65 years of age. A total of 106 119 weighted hospitalizations for transcatheter aortic valve replacement, transcatheter mitral valve repair, and left atrial appendage occlusion were included. The utilization rates (defined as the number of procedures performed per 100 000 US people >65 years of age) were higher in whites compared with blacks and Hispanics for transcatheter aortic valve replacement (43.1 versus 18.0 versus 21.1), transcatheter mitral valve repair (5.0 versus 3.2 versus 3.2), and left atrial appendage occlusion (6.6 versus 2.1 versus 3.5), respectively ($P<0.001$). Black and Hispanic patients had distinctive socioeconomic and clinical risk profiles compared with white patients. There were no significant differences in the adjusted in-hospital mortality or key complications between patients of white race, black race, and Hispanic ethnicity following transcatheter aortic valve replacement, transcatheter mitral valve repair, or left atrial appendage occlusion. No difference in cost was observed between white and black patients following any of the 3 procedures. However, Hispanic patients incurred modestly higher cost with transcatheter mitral valve repair and left atrial appendage occlusion compared with white patients.

Conclusions—Racial and ethnic disparities exist in the utilization of structural heart disease interventions in the United States. Nonetheless, adjusted in-hospital outcomes were comparable among white, black, and Hispanic patients. Further studies are needed to understand the reasons for these utilization disparities. (*J Am Heart Assoc*. 2019;8:e012125. DOI: 10.1161/JAHA.119.012125.)

Key Words: aortic stenosis • atrial fibrillation • left atrial appendage • mitral valve regurgitation • transcatheter aortic valve implantation

Racial and ethnic disparities in the access, provision of care, and outcomes of cardiovascular interventions are well documented.[1-4] However, whether such disparities exist in the rapidly growing field of structural heart disease (SHD) interventions is unknown. The current literature is limited to a few studies suggesting less utilization but acceptable short-term outcomes of transcatheter aortic valve replacement (TAVR) in patients of black race.[5,6] However, large-scale data on the impact of race/ethnicity on the utilization and outcomes of TAVR and other SHD interventions are lacking. We sought to investigate race- and ethnicity-based disparities in the utilization and outcomes of the 3 most common SHD interventions: TAVR, transcatheter mitral valve repair (TMVr), and percutaneous left atrial appendage occlusion (LAAO) using a national representative database.

Methods

Study Data

The Nationwide Inpatient Sample (NIS) was queried to derive patient-relevant information between November 2, 2011 and December 31, 2016. The NIS is the largest publicly available all-payer claims-based database. We selected November 2, 2011 as the starting time for our study because it was the date when TAVR was approved by the Food and Drug Administration. The NIS contains data on patient discharges from 1000 hospitals in 45 states, with safeguards to protect the privacy of individual patients, physicians, and hospitals.

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Clinical Perspective

What Is New?

- Racial and ethnic disparities exist in the utilization of contemporary structural heart disease interventions in the United States.
- The magnitude of this disparity varies among different procedures.

What Are the Clinical Implications?

- There is an unmet need to understand the etiology of racial and ethnic disparity in structural heart disease interventions and to identify effective strategies for its mitigation.

These data are stratified to represent ≈20% of US inpatient hospitalizations across different hospital and geographic regions (random sample). National estimates of the entire US hospitalized population are calculated using the Agency for Healthcare Research and Quality sampling and weighting method. The Institutional Review Board exempted the study from board approval and waived the requirement for informed consent because the NIS is a publically available deidentified database.

Study Population

Patients who underwent TAVR, TMVr, and LAAO during the specific study period were identified using *International Classification of Diseases, Ninth Revision, Clinical Modification* (*ICD-9-CM*) and *Tenth Revision* (*ICD-10-CM*) codes (TAVR, 35.05, 35.06, 02RF3JZ, 02RF3KZ, 02RF38Z, 02RF37Z, 02RF3JZ, 02RF37H, 02RF38H, 02RF3JH, 02RF3KH; TMVr, 35.97, 02UG3JZ; and LAAO, 37.90, 02L73DK). We excluded patients with missing race information, those with procedures performed before Food and Drug Administration approval (October 25, 2013 for TMVr and March 13, 2015 for LAAO; Figure 1). We also confined our analysis to patients of white, black, and Hispanic origin. The numbers of patients of Asian, Native American, Pacific Islander, or "other" races were too small to allow meaningful analyses.

Study End Points

The primary end point was procedure utilization rate per race/ethnicity defined as the number of procedures performed per 100 000 US people >65 years of age. We selected this cutoff to minimize the potential confounding issue of lack of insurance coverage, given that most patients >65 years of age are eligible for the Centers of Medicare & Medicaid Services. The estimated numbers of white, black, and Hispanic population >65 years of age were obtained from the US Census website (www.census.gov). Secondary end points were risk-adjusted rates of in-hospital mortality and major morbidities for each procedure stratified by race/ethnicity.

Statistical Analyses

Weighted data were used for all statistical analyses. Descriptive statistics are presented as frequencies with percentages for categorical variables. Mean, standard deviation, median, 25th percentile, and 75th percentile are reported for continuous measures. To examine the association of race/ethnicity with intervention of choice and outcomes, multivariate logistic regression models were constructed using generalized estimating equations to account for the clustering of outcomes within hospitals. The following variables were included in the logistic regression risk adjustment model: age, sex, comorbidities (hypertension, diabetes mellitus, hyperlipidemia, coronary disease, congestive heart failure, carotid artery disease, vascular disease, prior sternotomy, chronic lung disease, renal insufficiency, liver cirrhosis, anemia, conduction disorder, atrial fibrillation, prior pacemaker or defibrillator, history of stroke, smoking), hospital characteristics (hospital size, urban versus rural location, teaching status), and socioeconomic factors (payer status, median household income). Odds ratios and 95% CIs were used to report the results of logistic regression. Further adjustments were made using the Bonferroni correction method to account for multiple comparisons of racial/ethnic groups. All *P* values were 2-sided with a significance threshold of <0.05. All statistical analyses were performed with SPSS version 24 (IBM Corporation, Armonk, NY).

Cost Analysis

The NIS contains data on total charges (the amount that hospitals billed for services) for each hospital discharge in
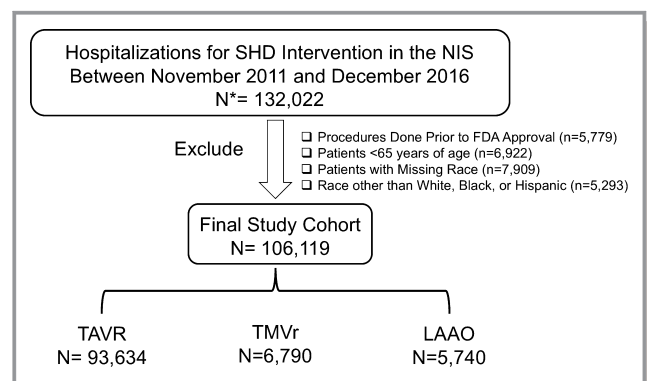
Figure 1. Study flowchart. FDA indicates Food and Drug Administration; LAAO, left atrial appendage occlusion; N, number; NIS, National Inpatient Sample; SHD, structural heart disease; TAVR, transcatheter aortic valve replacement; TMVr, transcatheter mitral valve repair. *Weighted.

the databases. However, the Agency for Healthcare Research and Quality provides supplementary cost-to-charge ratio files that allow accurate conversion of the hospital total charge data to cost estimates by multiplying total charges with the appropriate cost-to-charge ratio. The cost information used to calculate the cost-to-charge ratio for each hospital was obtained from the hospital accounting reports collected by the Centers for Medicare & Medicaid Services.

Results

Utilization Rate of SHD Interventions Per Race/Ethnicity

A total of 106 119 weighted hospitalizations for SHD interventions were included in our analysis. In the overall cohort, white patients constituted 91.7%, 88.5%, and 92.3% of all patients who underwent TAVR, TMVr, and LAAO, respectively. The utilization rate (number of procedures/100 000 people >65 years of age) was significantly higher in white patients compared with black and Hispanic patients for all 3 procedures: TAVR (43.1 versus 18.0 versus 21.1), TMVr (5.0 versus 3.2 versus 3.2), and LAAO (6.6 versus 2.1 versus 3.5), respectively ($P<0.001$; Figure 2). Regional variations were, however, observed in the percentage of black and Hispanic patients among all patients undergoing SHD interventions (Table 1).

Baseline Risk Profile Among Racial Groups

There were notable differences in demographic, socioeconomic, and clinical characteristics across the racial/ethnic groups. Across all 3 SHD interventions, black and Hispanic patients were younger, included more women, and were more

Table 1. Regional Variations in Distribution of White, Black, and Hispanic Patients Among all Patients Undergoing Common Structural Heart Disease Interventions in the United States

Race/Ethnicity	Region			
	Northeast	Midwest	South	West
TAVR				
White	94.3%	95.1%	90.4%	89.0%
Black	3.3%	3.8%	5.2%	2.3%
Hispanic	2.4%	1.0%	4.4%	8.6%
TMVr				
White	91.6%	91.9%	87.1%	87.7%
Black	5.9%	4.8%	5.9%	3.1%
Hispanic	2.5%	3.2%	7.0%	9.2%
LAAO				
White	87.0%	89.4%	87.9%	87.5%
Black	4.3%	4.3%	4.4%	2.1%
Hispanic	2.2%	2.1%	3.3%	10.4%

LAAO indicates left atrial appendage occlusion; TAVR, transcatheter aortic valve replacement; TMVr, transcatheter mitral valve repair.

likely to be treated at urban, teaching, and large hospitals than patients of white race (Table 2). They also had significantly higher proportions of patients in the lowest quartile of household income. Clinical risk profile also differed among the 3 groups. Hypertension and diabetes mellitus were more prevalent among black and Hispanic patients. Black patients also had significantly higher prevalence of renal insufficiency and anemia but less prior sternotomy compared with white patients. Differences in the prevalence in clinical risk factors among the 3 racial/ethnic groups are shown in Table 2.
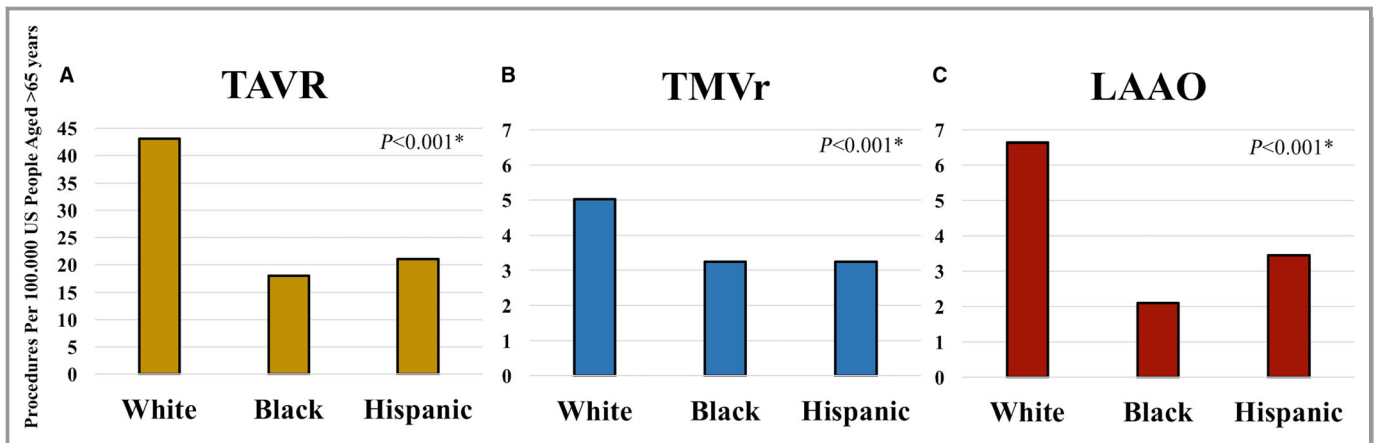
Figure 2. Racial and ethnic differences in the utilization of common structural heart interventions in the United States. **A**, Racial/ethnic differences in the utilization of TAVR. **B**, Racial/ethnic differences in the utilization of TMVr. **C**, Racial/ethnic differences in the utilization of LAAO. LAAO indicates left atrial appendage occlusion; TAVR, transcatheter aortic valve replacement; TMVr, transcatheter mitral valve repair.

Table 2. Baseline Characteristics of Patients Undergoing Common SHD Interventions in the United States Stratified by Race/Ethnicity

Baseline Characteristics	TAVR				TMVr				LAAO			
	White n=85 845	Black n=3833	Hispanic n=3956	*P* Value	White n=6010	Black n=415	Hispanic n=365	*P* Value	White n=5300	Black n=180	Hispanic n=260	*P* Value
Age, mean±SD, y	82±7	80±7	81±7	<0.001	81±7	76±7	80±6	<0.001	77±6	74±5	77±6	<0.001
Female sex	46.5%	60.6%	51.5%	<0.001	45.5%	60.2%	52.1%	<0.001	39.7%	50.0%	42.3%	0.017
Socioeconomics												
Medicare primary payer	94.0%	90.9%	91.4%	<0.001	93.9%	91.6%	89.0%	<0.001	95.3%	100%	96.2%	0.001
Urban location	85.0%	88.3%	87.2%	<0.001	91.4	90.9%	94.5%	<0.001	93.6%	972%	100%	<0.001
Teaching hospital	88.9%	93.7%	92.7%	<0.001	91.4%	100%	97.6%	<0.001	85.4%	100%	86.7%	0.032
Large hospital	76.0%	80.6%	78.3%	<0.001	75.1%	73.5%	85.4%	<0.001	64.6%	87.5%	80.0%	<0.001
0 to 25th percentile income*	20.1%	50.6%	33.4%	<0.001	21.8%	54.4%	28.2%	<0.001	17.0%	38.9%	36.0%	<0.001
Medical comorbidities, %												
Diabetes mellitus	35.6%	45.8%	48.3%	<0.001	23.2%	32.5%	45.2%	<0.001	28.3%	41.7%	48.1%	<0.001
Hypertension	83.9%	87.6%	86.8%	<0.001	79.0%	86.7%	82.2%	<0.001	81.5%	94.4%	90.4%	<0.001
Hyperlipidemia	42.2%	38.7%	40.5%	<0.001	28.8%	25.3%	34.2%	0.021	15.4%	19.4%	21.2%	0.017
Congestive heart failure	36.2%	39.9%	36.9%	<0.001	46.8%	61.4%	43.8%	<0.001	24.5%	36.1%	36.5%	<0.001
Carotid artery disease	7.6%	5.3%	5.8%	<0.001	2.7%	3.6%	1.4%	0.148	1.8%	1.0%	3.8%	0.01
Coronary artery disease	58.6%	58.7%	59.6%	0.423	53.2%	51.8%	47.9%	0.130	46.4%	30.6%	40.4%	<0.001
Vascular disease	25.9%	25.8%	25.8%	0.974	14.5%	14.5%	12.3%	0.524	9.3%	16.7%	9.6%	0.005
Renal insufficiency	35.4%	48.5%	39.3%	<0.001	37.5%	57.8%	37.0%	<0.001	19.0%	50.0%	17.3%	<0.001
Obstructive lung disease	30.7%	30.5%	29.1%	0.084	28.4%	34.9%	12.3%	<0.001	15.7%	25.0%	11.5%	0.001
Liver cirrhosis	1.1%	0.9%	1.5%	<0.001	0.7%	0.6%	2.7%	<0.001	0.8%	2.8%	1.9%	0.003
Anemia	24.3%	36.0%	35.4%	<0.001	23.8%	33.7%	26.0%	<0.001	13.8%	27.8%	23.1%	<0.001
AFib/flutter	45.6%	30.0%	32.7%	<0.001	64.1%	50.6%	60.3%	<0.001	99.6%	97.2%	100.0%	<0.001
Conduction disorders	17.2%	14.5%	18.5%	<0.001	4.7%	2.4%	4.1%	0.095	3.4%	1.2%	1.9%	0.019
Prior ICD/pacemaker	14.5%	9.8%	14.3%	<0.001	23.7%	28.9%	23.3%	0.053	26.5%	27.8%	21.2%	0.144
Prior sternotomy	23.4%	12.5%	22.7%	<0.001	29.8%	16.9%	39.7%	<0.001	20.7%	2.8%	13.5%	<0.001
Prior stroke	12.2%	11.9%	9.7%	<0.001	13.8%	10.8%	15.1%	0.173	23.9%	30.6%	25.0%	0.113
Smoking	18.8%	15.5	12.8%	<0.001	15.1%	19.3%	13.7%	0.052	7.2%	5.6%	1.9%	0.004
Elixhauser comorbidity index score, mean±SD	4.1±%2.8	6.2±4.1	4.6±3	<0.001	4.2±2.7	7.5±4	4.2±2.7	<0.001	5.1±2	9.4±3	5.2±2.4	<0.001

AFib indicates atrial fibrillation; ICD, internal cardioverter defibrillator; LAAO, left atrial appendage occlusion; n, number; SHD, structural heart disease; TAVR, transcatheter aortic valve replacement; TMVr, transcatheter mitral valve repair.
*Based on the average household income for the residence zip code.

Outcomes and Cost of SHD Interventions Stratified by Race/Ethnicity

Despite the underutilization of SHD interventions in racial and ethnic minorities, no significant differences in hospital outcomes were observed with a few exceptions. With TAVR there were no statistically significant differences in in-hospital death, key post-TAVR complications, or rate of nonhome discharge among the 3 groups (Table 3). Similarly, in-hospital outcomes following TMVr and LAAO were similar

Table 3. In-Hospital Outcomes Following Transcatheter Aortic Valve Replacement Stratified by Race/Ethnicity

In-Hospital Outcomes	Race/Ethnicity	Unadjusted Rate	Adjusted Rate	OR	95% CI	P Value	Bonferroni Adjusted P Value
Death	White	2.8%	Reference				
	Black	2.1%	2.20%	0.79	0.63 to 0.99	0.04	0.11
	Hispanic	3.3%	2.38%	1.12	0.91 to 1.38	0.28	0.84
Stroke	White	2.3%	Reference				
	Black	2.6%	2.31%	1.01	0.79 to 1.28	0.21	0.99
	Hispanic	2.3%	2.19%	0.95	0.67 to 1.09	0.96	0.62
Pacemaker	White	12.6%	Reference				
	Black	13.0%	13.40%	1.06	0.96 to 1.17	0.25	0.74
	Hispanic	15.4%	16.21%	1.29	1.17 to 1.41	<0.001	<0.001
New dialysis	White	1.1%	Reference				
	Black	1.6%	1.20%	1.11	0.87 to 1.42	0.40	0.90
	Hispanic	1.8%	1.24%	1.13	0.89 to 1.44	0.32	0.95
Vascular complications	White	7.0%	Reference				
	Black	6.6%	6.40%	0.92	0.81 to 1.05	0.22	0.67
	Hispanic	9.5%	10.21%	1.46	1.30 to 1.63	<0.001	<0.001
Nonhome discharge	White	25.3%	Reference				
	Black	25.4%	24.50%	1.00	0.93 to 1.09	0.95	0.99
	Hispanic	21.8%	21.50%	0.85	0.78 to 0.92	<0.001	<0.001

OR indicates odds ratio.

across all racial/ethnic groups (Table 4). Although there were statistically significant differences in the cost of SHD procedures among the 3 groups, the magnitudes of these differences were small (Table 5).

Discussion

There were 3 salient findings of our study. (1) Common SHD interventions are performed less frequently in black and Hispanic patients compared with white patients. (2) Significant differences exist in demographic, socioeconomic, and clinical characteristics among white, black, and Hispanic patients who undergo SHD interventions in contemporary US practice. (3) In-hospital morbidity, mortality, and the cost of common SHD interventions were comparable across the 3 racial/ethnic groups.

A main highlight of our findings is that black and Hispanic patients each constituted only ≈4% of the total population of patients who underwent a SHD intervention between 2011 and 2016 in the United States. This is in contrast with their much higher representation in the overall elderly US population aged >65 years (11%, and 7%, respectively). Although striking, this finding is in agreement with several previous similar observations. For example, among all patients who underwent surgical aortic valve replacement in the United States between 1999 and 2011, only 3.2% were black.[7]

Similar observations were made with regard to TAVR. In the Society of Thoracic Surgery/American College of Cardiology Transcatheter Valve Therapy (ACC/STS TVT) registry, black and Hispanic patients each constituted 3.4% of the overall TAVR population between 2012 and 2015.[8,9] Also, black and Hispanic patients constitute only 5.8% and 4.7% of patients who underwent TMVr in the ACC/STS TVT registry between November 2013 and September 2015, respectively.[10] Although the racial differences in the utilization rate appear to be less striking with TMVr than with TAVR, caution should be used in interpreting these data due to the small number of patients of racial and ethnic minorities overall who underwent TMVr in the early commercial experience in the United States.

The etiology of these large differences in the utilization of common SHD interventions is likely multifactorial, including race- and ethnic-specific differences in the prevalence of specific cardiac pathologies (eg, aortic stenosis), lack of access to advanced SHD interventions, differences in cultural values and acceptance of invasive treatment, or system-related biases in the provision of care to racial and ethnic minorities. For example, Patel et al found that the prevalence of severe aortic stenosis in black patients is much lower than its prevalence in white patients (0.29% versus 0.91%, adjusted odds ratio 0.41, 95% CI 0.33–0.50, P<0.001), although no difference existed in the prevalence of severe mitral regurgitation between the 2

Table 4. In-Hospital Outcomes Following Transcatheter Mitral Valve Repair and Left Atrial Appendage Occlusion Stratified by Race/Ethnicity

In-Hospital Outcomes	Race/Ethnicity	Unadjusted Rate	Adjusted Rate	OR	95% CI	P Value	Bonferroni Adjusted P Value
Transcatheter mitral valve repair							
Death	White	2.2%	Reference				
	Black	1.6%	1.52%	0.69	0.41 to 1.17	0.17	0.38
	Hispanic	1.9%	1.80%	0.82	0.46 to 1.45	0.49	0.99
Stroke	White	0.8%	Reference				
	Black	1.6%	1.16%	1.45	0.84 to 2.48	0.18	0.77
	Hispanic	0.9%	0.97%	1.22	0.72 to 2.05	0.47	0.99
New dialysis	White	1.0%	Reference				
	Black	2.3%	1.47%	1.47	0.89 to 2.40	0.13	0.54
	Hispanic	1.9%	1.30%	1.29	0.78 to 2.14	0.32	0.99
Vascular complications	White	4.7%	Reference				
	Black	2.4%	3.14%	0.67	0.39 to 1.16	0.15	0.45
	Hispanic	2.7%	2.90%	0.62	0.34 to 1.10	0.10	0.30
Nonhome discharge	White	14.7%	Reference				
	Black	11.9%	13.30%	0.90	0.70 to 1.16	0.43	0.99
	Hispanic	13.5%	16.98%	1.15	0.90 to 1.47	0.25	0.80
Left atrial appendage occlusion							
Pericardial tamponade	White	0.8%	Reference				
	Black	2.8%	1.40%	1.83	0.67 to 4.96	0.24	0.71
	Hispanic	0.5%	0.53%	0.66	0.42 to 1.05	0.08	0.23
Nonhome discharge	White	4.4%	Reference				
	Black	8.3%	5.14%	1.17	0.72 to 1.90	0.53	0.99
	Hispanic	7.7%	6.36%	1.45	0.86 to 2.43	0.16	0.49

OR indicates odds ratio.

groups (1.35% in whites versus 1.45% in blacks, respectively).[11] Other studies have also reported significantly lower prevalence of aortic stenosis and atrial fibrillation among black and Hispanic patients compared with white patients.[1,11–13] However, differences in access to care and acceptance of invasive interventions among various racial and ethnic groups are well documented.[13,14] In addition, over half of the patients of black race were classified in the lowest household income quartile compared with ≈20% of white patients. Whether this striking difference in the socioeconomic status among patients of various racial groups is associated with less access to advanced care among these groups remains to be studied. Assessing the role of these and other factors on the observed disparity requires a dedicated prospective registry that collects data on epidemiological, clinical, and demographic characteristics among different racial groups.

Table 5. Cost of Hospitalization for Common Structural Heart Disease Interventions Stratified by Race/Ethnicity

Procedure	White			Black				Hispanic			
	Median	25th Percentile	75th Percentile	Median	25th Percentile	75th Percentile	P Value vs White	Median	25th Percentile	75th Percentile	P Value vs White
TAVR	$49 424	$38 452	$63 407	$49 328	$38 492	$65 900	0.88	$51 295	$40 152	$67 846	0.06
TMVr	$42 764	$32 295	$57 710	$41 410	$31 447	$52 995	0.36	$40 875	$33 198	$54 556	<0.001
LAAO	$24 304	$18 206	$31 050	$25 596	$16 502	$30 400	0.06	$26 467	$21 002	$34 310	<0.001

$ indicates US dollar; LAAO, left atrial appendage occlusion; TAVR, transcatheter aortic valve replacement; TMVr, transcatheter mitral valve repair.

Our study also suggests no differential impact of race/ethnicity on the morbidity, mortality, and cost of common SHD interventions with the exception of a modestly higher cost of TMVr and LAAO in Hispanic patients. These data are reassuring and are in line with prior studies suggesting comparable adjusted outcomes of surgical and transcatheter valvular interventions among patients of various races.[1,5,6,15,16] Nonetheless, these findings need to be confirmed in further studies given the youth of the SHD interventional field and the small number of patients of racial and ethnic minorities who have received those interventions to date.

Limitations

First, the NIS is an administrative database that collects data for billing purposes. Hence, it is subject to under-, over-, or erroneous coding. However, accurate coding for high-cost procedures and hard clinical end points (eg, death) are highly incentivized, and hence, this limitation is unlikely to impact the main end points of our study. Second, excluding patients with missing race data or patients with races or ethnicities other than white, black, and Hispanic might affect the outcomes of this study. Nonetheless, race was recorded in 93.7% of patients. Third, race is self-reported and not verified, which can lead to ascertainment bias in certain racial minorities. Fourth, although rigorous risk adjustment was performed for secondary end points, data on laboratory values, imaging findings, and procedural characteristics are not available in the NIS. Hence, differences in these parameters among the 3 groups in our study could not be adjusted for. Fifth, this study spans the early US experience with SHD interventions (2011-2016). Whether some of our results could be explained by the limited access to such interventions in their early commercial dissemination remains uncertain. However, this is unlikely to be a major factor, as patients of racial or ethnic minorities are more likely to receive care at large, urban, and teaching hospitals, which are more likely to offer those procedures. Finally, the procedural rate stratified by race is calculated by dividing the number of procedures in each racial group by the number of US adults >65 years of age in the same group. Although uncommon, in some procedures (eg, TAVR, TMVr), a small number of patients could have had a repeat procedure during the study period, and this might have affected the calculation. However, the percentage of those patients in contemporary registries is <0.5%, and this is unlikely to impact our results.[10,17]

Conclusions

Significant racial and ethnic disparities exist in the utilization of common SHD interventions and in the characteristics of patients undergoing these procedures in the United States. However, after risk adjustments, no differences were noted in short-term outcomes among white, black, and Hispanic patients. Further studies are needed to understand the reasons for these disparities and to identify effective strategies for their mitigation.

Disclosures

None.

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