Did ethno-racial disparities in access to transcatheter aortic valve replacement change over time?

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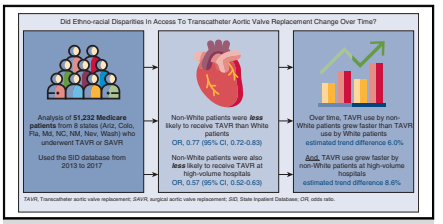
ABSTRACT

Objective: In this study we sought to evaluate whether disparate use of transcatheter aortic valve replacement (TAVR) among non-White patients has decreased over time, and if unequal access to TAVR is driven by unequal access to high-volume hospitals.

Methods: From 2013 to 2017, we used the State Inpatient Database across 8 states (Ariz, Colo, Fla, Md, NC, NM, Nev, Wash) to identify 51,232 Medicare beneficiaries who underwent TAVR versus surgical aortic valve replacement. Hospitals were categorized as low- (<50 per year), medium- (50-100 per year), or high-volume (>100 per year) according to total valve procedures (TAVR + surgical aortic valve replacement). Multivariable logistic regression models with interactions were performed to determine the effect of race, time, and hospital volume on the utilization of TAVR.

Results: Non-White patients were less likely to receive TAVR than White patients (odds ratio [OR], 0.77; 95% CI, 0.71-0.83). However, utilization of TAVR increased over time (OR, 1.73; 95% CI, 1.73-1.80) for the total population, with non-White patients' TAVR use growing faster than for White patients (OR, 1.06; 95% CI, 1.00-1.12), time × race interaction, $P = .034$. Further, an adjusted volume-stratified time trend analysis showed that utilization of TAVR at high volume hospitals increased faster for non-White patients versus White patients by 8.6% per year (OR, 1.09; 95% CI, 1.01-1.16) whereas use at low- and medium-volume hospitals did not contribute to any decreasing utilization gap.

Conclusions: This analysis shows initial low rates of TAVR utilization among non-White patients followed by accelerated use over time, relative to White patients. This narrowing gap was driven by increased TAVR utilization by non-White patients at high-volume hospitals. (JTCVS Open 2022;12:71-83)



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CENTRAL MESSAGE

Non-White patients were less likely to undergo TAVR than their White counterparts, however, this gap is narrowing because of increased TAVR use by non-White patients at high-volume hospitals.

PERSPECTIVE

Inequitable use of TAVR among non-White patients has been previously documented. However, dissemination of this new technology has rapidly expanded to new patient populations at a greater number of hospitals. Although non-White patients historically have had limited access to high-volume hospitals, it is unclear how increased TAVR dissemination would affect trends in its disparate use.

▶ Video clip is available online.

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This study was supported by a grant from the Georgetown-Howard Universities Center for Clinical and Translational Science and The Lee Folger Foundation.

Read at the 101st Annual Meeting of The American Association for Thoracic Surgery: A Virtual Learning Experience, April 30-May 2, 2021.

Received for publication May 1, 2021; revisions received May 25, 2022; accepted for publication July 1, 2022; available ahead of print Sept 1, 2022.

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2666-2736

https://doi.org/10.1016/j.xjon.2022.07.009

Abbreviations and Acronyms
DES = drug-eluting stent
ICD = International Classification of Diseases
OR = odds ratio
SAVR = surgical aortic valve replacement
SID = State Inpatient Database
TAVR = transcatheter aortic valve replacement

Transcatheter aortic valve replacement (TAVR) was first approved by the US Food and Drug Administration in 2011[1] and has since revolutionized the treatment of aortic valve disease. Broadening indications for TAVR have rapidly enabled more patients to avoid the early morbidity of a surgical aortic valve replacement (SAVR), and expanded the population of patients amenable to valve replacement.[2-7] Despite this rapidly expanding cohort, disparate access to this new technology for racial-ethnic minorities has been shown to persist,[8,9] a phenomenon that has been well described across numerous cardiovascular interventions.[10] Analysis of the Transcatheter Valve Therapy Registry has shown that among the 70,221 patients older than the age of 65 who underwent TAVR from 2011 to 2016, only 3.8% were Black and 3.4% were Hispanic—a significant under-representation compared with their proportion of the population.[8] Although it is also established that non-White patients are less likely than White patients to use high-volume hospitals,[11-14] it is unclear if this inequity has driven disparate access to TAVR.

In this study we used the State Inpatient Database (SID) from 2013 to 2017 to evaluate whether disparate access to TAVR among non-White patients has decreased over time as the availability of this new technology has expanded. We also sought to quantify the effect of hospital volume on racial disparities to determine if inequitable access to high-volume hospitals is a driver of inequitable TAVR utilization and whether expanded availability resulted in a change over time. A description of this background and objective can also be viewed in video form (Video 1). We hypothesized that ethno-racial inequity has decreased over time as TAVR use has expanded, and that this decreasing disparity is driven by increased utilization at low-volume hospitals.

METHODS

Patient Population and Data Sources

Data were collected using SID from 2013 to 2017 from 8 ethno-racially and geographically diverse states (Ariz, Colo, Fla, Md, NC, NM, Nev, Wash). State inpatient data was chosen for its ability to allow linkage with the American Hospital Association Yearly Survey and the Area Resource Health File. Together these 3 merged databases allow for the analysis of patient-level, hospital-level, and county-level data among a set of large and diverse states that represent nearly 20% of the US population. The institutional review board of Lifespan-Rhode Island Hospital approved this study with waived consent (00000396; approved October 31, 2018).

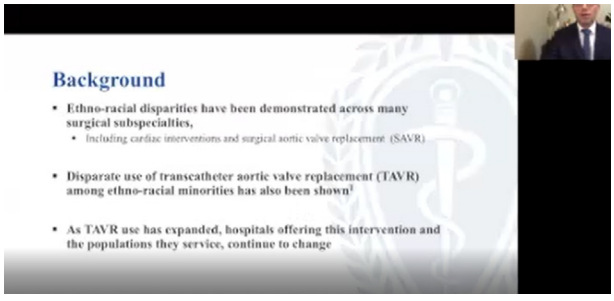
Medicare beneficiaries were included for analysis to isolate those with insurance coverage while minimizing any unmeasured confounding effects of payer status on access to surgery. Patients with aortic valve insufficiency (International Classification of Diseases [ICD] Ninth Revision [-9]: 396.3 and ICD 10th revision [-10]: I35.1, I06.1) were also excluded to ensure a more uniform cohort of those eligible for intervention, though we did not exclude patients on the basis of secondary diagnoses. ICD codes were used to identify patients who underwent TAVR (ICD-9: 35.05, 35.06; and ICD-10: 02RF38Z, 02RF38H) or SAVR (ICD-9: 35.21, 35.22; and ICD-10: 02RF07Z, 02RF08Z, 02RF0JZ, 02RF0KZ). We did not query ICD codes to include or exclude patients on the basis of concomitant procedures. Inclusion and exclusion criteria are shown in a consort diagram (Figure 1), with our final analytic cohort including 51,232 patients; 87.04% were White (n = 43,796) and 12.96% were non-White (n = 6522).

Outcomes and Independent Variables

Our main outcome of interest was the rate of TAVR utilization over time. To measure this, we identified the total number TAVRs performed and also calculated the proportion of TAVR compared with total aortic valve procedures (TAVR/TAVR + SAVR). The major independent predictors we included were time, race/ethnicity, and hospital volume. To analyze patients according to race/ethnicity we defined 2 groups, White and non-White, with the non-White category consisting of Black, Hispanic, Asian/Pacific Islander, American Indian, and patients listed as other, on the basis of SID data. Hospital volume was computed as a yearly average according to hospital and was categorized as low- (<50 per year), medium- (50-100 per year), or high-volume (>100 per year) according to total valve procedures (TAVR + SAVR) with cutoffs on the basis of existing literature.[15,16] Additional relevant covariates were selected to adjust for patient characteristics (age, sex, admission type, median income, Charlson Comorbidity Index score), hospital characteristics (hospital volume, teaching status), and location characteristics (hospital state, local percent of White population, and provider density). Provider density was defined by the Area Health Resources Files as health professional (physician, physician assistant, nurse practitioner, etc) and computed as the number of providers in the county of the patient's residence per 1000 population. Charlson Comorbidity Index score was included as the standardized comorbidity score available with the SID and has also been previously used for cardiac surgery populations.[17]

Statistical Analysis

Continuous variables are summarized as mean and SD and compared between groups using *t* test/Wilcoxon rank sum test depending on the distribution of the data, with median and interquartile range reported where applicable. Categorical variables were aggregated as frequencies and



VIDEO 1. The first author describing the background and objective of the study. Video available at: https://www.jtcvs.org/article/S2666-2736(22)00304-7/fulltext.

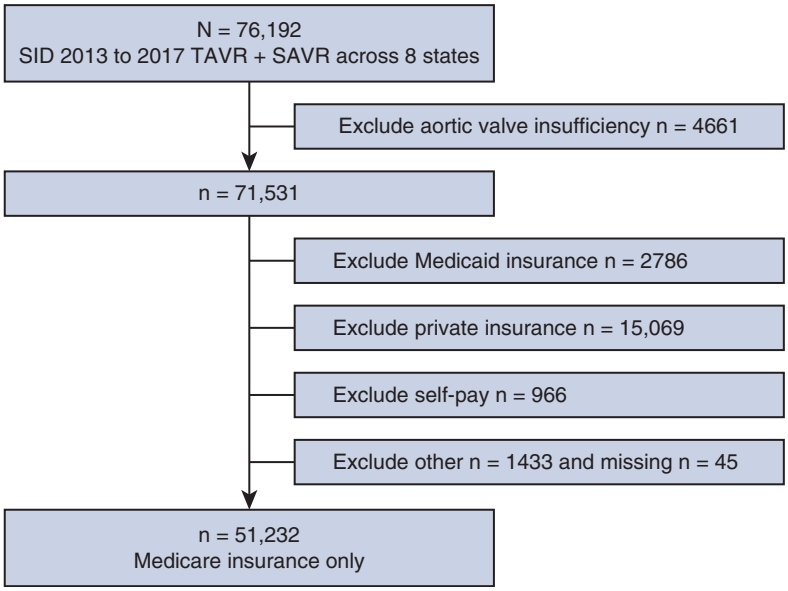


FIGURE 1. Consolidated Standards of Reporting Trials (*CONSORT*) diagram showing patients included for analysis after applying inclusion and exclusion criteria. *SID*, State Inpatient Database; *TAVR*, transcatheter aortic valve replacement; *SAVR*, surgical aortic valve replacement.

percentages and compared using the χ^2/Fisher exact test. For modeling, logistic regression was used to assess the overall time trend and disparity between race/ethnicity and hospital volume. A 2-way interaction term was included to assess whether any disparate use of TAVR according to race/ethnicity changed over time and a separate interaction term was included for race/ethnicity and hospital volume to determine if disparity was dependent on volume category. A 3-way interaction was then performed for time, race/ethnicity, and hospital volume to evaluate whether the time trend difference between race/ethnicities relied on hospital volume. The absolute trend and trend differences with 95% CI were computed. Analysis was performed using SAS 9.4 (SAS Institute Inc).

RESULTS

Patient Characteristics

Between 2013 and 2017, 51,232 Medicare beneficiaries underwent either TAVR (39.2%) or SAVR (60.8%). Their mean age was 76.8 ± 8.5 years, 59.7% were male, and 43,796 patients were White (87.0%) compared with 6522 non-White patients (13.0%). Collectively, of all procedures (TAVR and SAVR), 16.1%, 28.7%, and 55.3% were performed at low-, medium-, and high-volume hospitals, respectively; 25.7% were performed at teaching hospitals, and 77.2% of admissions were elective (Table 1). For TAVR procedures only, 5.4%, 28.1%, and 66.5% were performed at low-, medium-, and high-volume hospitals, respectively.

White patients were older than non-White patients (77.1 vs 74.7 years), more likely to be male (60.6% vs 54.3%), less multimorbid (Charlson Comorbidity Index score ≥5: 5.6% vs 6.8%), more likely to be admitted electively (78.8% vs 68.2%), and underwent more TAVR (40.0% vs 35.0%); all P values < .001 (Table 2). Examining differences in TAVR and SAVR use according to race for each state individually, we noted substantial differences between each state's White population based on US census data,[18] and the percentage of White patients who underwent TAVR and SAVR. Results are outlined in Table E1. These data demonstrate considerably greater TAVR use among White patients compared with their percent of each state's population (range, 27.2-37.7 percentage point difference) as well as greater SAVR use (range, 20.7-36.8 percentage point difference).

Demonstrating Overall Disparity and Time Trends

Logistic regressions were applied to estimate the odds of receiving TAVR versus SAVR and demonstrate the trend of TAVR utilization over time. The odds of receiving TAVR was 5.12 and 6.80 times higher at medium- and high-volume hospitals, respectively, relative to low-volume hospitals. Across all hospital volumes, the utilization of TAVR increased over time (odds ratio [OR], 1.73; 95% CI, 1.73-1.80). Non-White patients were less likely to receive TAVR compared with White patients (OR, 0.77; 95% CI, 0.71-0.83). Other factors predictive of greater TAVR use included older age, female sex, greater comorbidity, elective status, having surgery at a teaching hospital, and county/state level factors (Table 3).

Interacting Race, Time, and Hospital Volume

A 2-way interaction was performed to assess whether any disparate use of TAVR according to race/ethnicity changed over time, followed by a 2-way interaction to assess whether the disparity was dependent of hospital volume. Although the overall use of TAVR increased between 2013 and 2017, interacting race/ethnicity and time showed the trend increased for White (OR, 1.75; 95% CI, 1.72-1.79) and non-White (OR, 1.86; 95% CI, 1.77-1.79) patients, with non-White patient use of TAVR increasing at

TABLE 1. Descriptive statistics of overall Medicare patients (N = 51,232) who underwent TAVR or SAVR from 2013 to 2017

	Value
Median age (IQR), y	77.0 (71.0-83.0)
Sex	
Male	30,593 (59.7)
Female	20,632 (40.3)
Race	
White	43,796 (87.0)
Black	1974 (3.92)
Hispanic	3396 (6.8)
Asian/Pacific islander	392 (0.78)
American Indian	187 (0.37)
Other	573 (1.14)
Charlson Comorbidity Index scores	
0	6957 (13.6)
1-2	25,723 (50.2)
3-4	15,557 (30.4)
≥5	2995 (5.85)
Admission type	
Elective	39,513 (77.2)
Other	11,670 (22.8)
Annual hospital volume of TAVR + SAVR	
Median (IQR)	123.2 (72.4-218.4)
Hospital volume of TAVR + SAVR according to category	
Low (<50 procedures per y)	8231 (16.1)
Medium (50-100)	14,695 (28.7)
High (>100)	28,306 (55.3)
Teaching hospital	
Yes	12,971 (25.8)
No	37,383 (74.2)
County-level percent White population 2010	
Median (IQR)	75.2 (69.6-83.0)
County-level primary provider density per 1000	
Median (IQR)	0.80 (0.60-0.90)
State	
Arizona	6079 (11.9)
Colorado	3294 (6.4)
Florida	22,439 (43.8)
Maryland	3573 (7.00)
North Carolina	6635 (13.0)
New Mexico	849 (1.66)
Nevada	1867 (3.64)
Washington	6478 (12.6)
Procedure type	
SAVR	31,131 (60.8)
TAVR	20,101 (39.2)

Data are presented as n (%) except where otherwise noted. *TAVR*, Transcatheter aortic valve replacement; *SAVR*, surgical aortic valve replacement; *IQR*, interquartile range.

a 6.00% higher rate than for White patients (OR, 1.06; 95% CI, 1.00-1.12; Table 4).

A separate 2-way interaction was performed to evaluate if racial-ethnic disparity was mediated by hospital volume. In low-volume hospitals, the odds of receiving TAVR was higher for non-White patients compared with White patients by 19% (95% CI, 0.92-1.55). Medium-volume hospitals showed 18% (95% CI, 1.04-1.34) higher odds for non-White compared with White patients. At high-volume hospitals, however, the odds of receiving TAVR was 43% (95% CI, 0.52-0.63) lower for non-White versus White patients (Table 5).

To further investigate differences according to hospital volume, we performed a marginal analysis for all racial/ethnic categories instead of categorizing White versus non-White. At low-volume hospitals, Black, Hispanic, and "other" race/ethnicities all had higher odds of receiving TAVR compared with White patients, however all 95% confidence intervals crossed 1.00. The difference that we found in medium-volume hospitals in our 2-way interaction described previously was likely driven by Hispanic patients. The statistically significant difference that we found in medium-volume hospitals in our 2-way interaction described previously was likely driven by Hispanic patients. This population was 25% more likely than White patients to receive TAVR at medium-volume hospitals, whereas all other race categories were less likely than White patients. At high-volume hospitals, all race/ethnicity categories were less likely than White patients to receive TAVR. Full results are listed in Table E2.

A 3-way interaction was then performed to evaluate any time trend differences between race/ethnicity and hospital volume. Results showed that TAVR use increased faster for White patients at low- (OR, 0.95; 95% CI, 0.71-1.28) and medium-volume hospitals (OR, 0.91; 95% CI, 0.83-1.00). At high-volume hospitals, however, TAVR rates increased faster for non-White patients (OR, 1.09; 95% CI, 1.01-1.16; Figure 2; Table 6).

DISCUSSION

These findings redemonstrate that non-White patients continue to suffer disparate access to TAVR compared with their share of the US population. However, with rapidly expanding use of this new technology, non-White patients' TAVR use increased faster than White patients, signaling a narrowing of the racial/ethnic gap. We have also shown that non-White patients are less likely to receive TAVR at high-volume hospitals compared with their White counterparts, however, this gap is also narrowing. These trends show that any improvement in racial inequity is likely being driven by decreasingly disparate TAVR utilization at high-volume hospitals, as opposed to broadening use at low- and medium-volume hospitals.

TABLE 2. Bivariate analysis of Medicare patients (N = 50,318) who underwent TAVR or SAVR from 2013 to 2017 according to race

	White (n = 43,796)	Non-White (n = 6522)	*P* value
Median age (IQR)	77.0 (71.0-83.0)	76.0 (69.0-82.0)	<.001
Sex			
Male	26,544 (60.6)	3538 (54.3)	<.001
Female	17,246 (39.4)	2983 (45.7)	
Median income in quartiles			
Quartile 1 (lowest)	9651 (22.5)	2223 (35.0)	<.001
Quartile 2	11,530 (26.9)	1553 (24.4)	
Quartile 3	11,580 (27.0)	1489 (23.4)	
Quartile 4 (highest)	10,142 (23.6)	1091 (17.2)	
Charlson Comorbidity Index scores			
0	6128 (14.0)	701 (10.8)	<.001
1-2	22,101 (50.5)	3209 (49.2)	
3-4	13,093 (29.9)	2170 (33.3)	
≥5	2474 (5.65)	442 (6.78)	
Admission type			
Elective	34,468 (78.8)	4448 (68.2)	<.001
Other	9284 (21.2)	2071 (31.8)	
Annual hospital volume of TAVR + SAVR in terciles			
Low	7122 (16.3)	1044 (16.0)	.001
Medium	12,527 (28.6)	2009 (30.8)	
High	24,147 (55.1)	3469 (53.2)	
Teaching hospital			
Yes	10,471 (24.3)	2289 (36.1)	<.001
No	32,646 (75.7)	4046 (63.9)	
County level percent White population 2010			
Median (IQR)	77.4 (71.3-84.3)	73.5 (63.6-74.3)	<.001
County level primary provider density per 1000			
Median (IQR)	0.8 (0.6-0.9)	0.8 (0.6-0.9)	<.001
State			
Arizona	5380 (12.3)	682 (10.5)	<.001
Colorado	3004 (6.86)	240 (3.68)	
Florida	18,500 (42.2)	3668 (56.2)	
Maryland	2800 (6.39)	501 (7.68)	
North Carolina	5862 (13.4)	702 (10.8)	
New Mexico	662 (1.51)	175 (2.68)	
Nevada	1560 (3.56)	289 (4.43)	
Washington	6028 (13.8)	265 (4.06)	
Procedure type			
SAVR	26,300 (60.1)	4250 (65.2)	<.001
TAVR	17,496 (40.0)	2272 (34.8)	

Data are presented as n (%) except where otherwise noted. *TAVR*, Transcatheter aortic valve replacement; *SAVR*, surgical aortic valve replacement; *IQR*, interquartile range.

The findings that non-White patients have greater comorbidity, undergo more nonelective operations, and are treated more commonly in teaching hospitals, is all consistent with previous research.[19-21] Although it is unsurprising that patients undergoing TAVR experience the same structural differences as patients undergoing treatment for other cardiovascular disease processes, it does pose the question, how does the availability of new technology affect the existing disparity? Previous studies have also explored this link between the dissemination of new surgical technologies and access disparity among vulnerable populations, an issue that remains relevant across various surgical subspecialties.[22-24] The rapidly expanding use of thoracic endovascular aortic repair over open repair provides a recent example of a revolutionary cardiovascular technology. Johnston and colleagues[25]

TABLE 3. Logistic regression of factors predicting TAVR over SAVR among Medicare patients from 2013 to 2017

Parameter	OR	95% CI	*P* value
Intercept	0.00	0.00-0.00	<.0001
Year	1.77	1.73-1.80	<.0001
Age	1.17	1.17-1.18	<.0001
Sex			
Male	Reference	–	–
Female	1.46	1.39-1.53	<.0001
Race			
White	–	–	–
Non-White	0.77	0.72-0.83	<.0001
Median income in quartiles			
Quartile 1 (low)	Reference	–	–
Quartile 2	0.98	0.92-1.05	.636
Quartile 3	0.97	0.91-1.04	.451
Quartile 4 (high)	1.00	0.92-1.06	.736
Charlson Comorbidity Index score			
0	Reference	–	–
1-2	3.09	2.84-3.36	<.0001
3-4	8.47	7.74-9.26	<.0001
≥5	17.2	15.1-19.5	<.0001
Elective admission			
No	Reference	–	–
Yes	1.53	1.44-1.62	<.0001
Annual hospital volume according to category			
Low	Reference	–	–
Medium	5.12	4.65-5.64	<.0001
High	6.80	6.19-7.47	<.0001
Teaching hospital			
No	Reference	–	–
Yes	2.04	1.92-2.16	<.0001
County-level percent of White population in 2010	0.99	0.99-0.99	<.0001
County-level primary provider density	0.86	0.78-0.94	.002
State			
Florida	Reference	–	–
Arizona	1.13	1.05-1.22	.002
Colorado	1.35	1.22-1.50	<.0001
Maryland	0.54	0.48-0.59	<.0001
North Carolina	0.89	0.82-0.96	.002
Nevada	0.92	0.81-1.06	.25
Washington	0.84	0.78-0.91	<.0001

OR, Odds ratio; *TAVR*, transcatheter aortic valve replacement; *SAVR*, surgical aortic valve replacement.

TABLE 4. Two-way interaction between race/ethnicity versus time on the basis of logistic regression estimates

Race/ethnicity	Time trend	95% CI
White	1.75	1.72-1.79
Non-White	1.86	1.77-1.95
	Estimate	
Trend difference	1.06	1.00-1.12

reported that counter to their hypothesis, racial/ethnic minorities and patients with lower socioeconomic status were more likely to receive thoracic endovascular aortic repair over traditional open repair despite a previously described baseline disparity. Even after controlling for baseline comorbidity and treatment indication, they reasoned that greater disease severity and aneurysm morphology might not have been fully captured in their

TABLE 5. Two-way interaction demonstrating odds ratio (95% CI) between race/ethnicity versus hospital volume on the basis of logistic regression estimates

Race	Low volume (<50)	Medium volume (50-100)	High volume (>100)
White	0.0055 (0.0047-0.0063)	0.028 (0.024-0.031)	0.040 (0.036-0.045)
Non-White	0.0065 (0.0050-0.0085)	0.033 (0.0278-0.038)	0.023 (0.020-0.026)
Odds ratio	1.19 (0.92-1.55)	1.18 (1.04-1.34)	0.571 (0.518-0.629)

statistical controls, leading vulnerable populations to preferentially undergo the less invasive therapy. A similar phenomenon might be at play in our TAVR population, with racial/ethnic minorities historically presenting with more advanced disease processes[26-29] and delayed intervention.[30,31] Despite our results showing decreasing disparity over time at high-volume hospitals, it is also true that these institutions began with the greatest disparities, and any progress might represent some reversion to the mean. Historical disparity in those undergoing SAVR,[32,33] and persistent patient/hospital characteristics such as greater comorbidity, nonelective status, and disproportionate care at teaching hospitals[19-21] provides reason to be cautious that any progress toward decreasing the racial/ethnic gap might be reversed as TAVR use continues to expand to low-risk populations and structural causes of disparity remain unaddressed.

Our results also mirrored those of a similar investigation into drug-eluting stent (DES) versus bare-metal stent use and differences according to race/ethnicity. Hannan and colleagues[34] described an existing disparity with racial-ethnic minorities receiving a DES less frequently, despite it being considered the optimal treatment at the time. As overall use of the DES expanded, the ethno-racial disparity diminished in medium- and high-volume hospitals, though persisted in the lowest volume hospitals, leading the authors to suggest directing patients to high-volume hospitals could decrease disparity.

Hospital volume represents a potential driving factor of racial inequity for TAVR use as well. The initial approval of TAVR by the US Food and Drug Administration established procedural volume criteria,[1] with early evaluations showing decreased mortality and complication rates at high-volume centers.[35] Between 2013 and 2017, the number of sites performing TAVR in the United States increased from 277 to 554, with low-volume sites (<50 TAVRs annually) representing 39% of sites and performing 14% of cases by 2017.[36,37] Although it has previously been shown that market competition is one driver of TAVR adoption, it is not clear whether or not this would exacerbate or alleviate racial disparities,[38] as TAVR use increases across low-, medium-, and high-volume hospitals. The volume-outcome relationship was redemonstrated in 2019, when Vemulapalli and colleagues[39] also revealed Black and

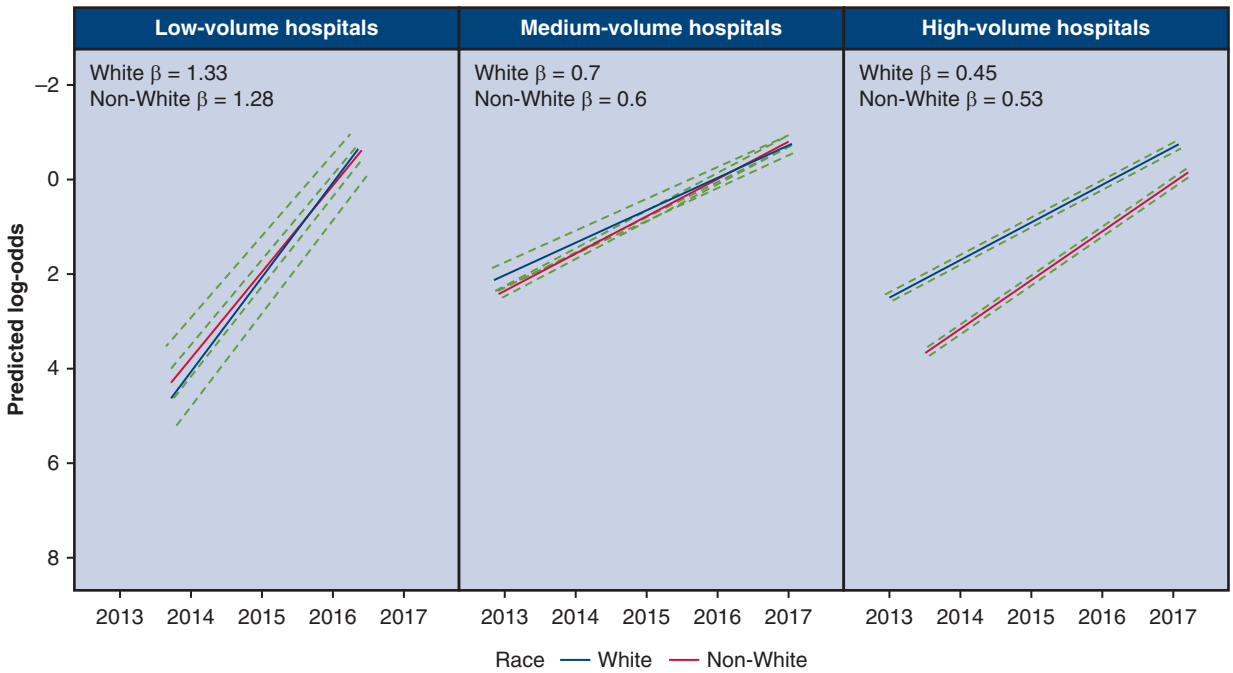


FIGURE 2. Transcatheter aortic valve replacement use increased faster (higher β) for *White* patients (*solid line*) versus non-White patients (*dotted line*) at low- and medium-volume hospitals. However, non-*White* patients saw a greater increase at high-volume hospitals.

TABLE 6. Three-way interaction between race/ethnicity, time, and hospital volume on the basis of logistic regression estimates

Race	Hospital volume		
	Low (<50)	Medium (50-100)	High (>100)
White	3.79 (3.39-4.24)	2.01 (1.94-2.08)	1.56 (1.53-1.60)
Non-White	3.61 (2.74-4.76)	1.83 (1.68-1.99)	1.70 (1.59-1.81)
Trend difference	0.95 (0.71-1.28)	0.91 (0.83-1.00)	1.09 (1.01-1.16)

Hispanic patients were more likely to undergo TAVR in the lowest quartile hospitals according to volume. The idea that vulnerable populations disproportionately receive care at low-volume hospitals has been the focus of study across various cardiovascular interventions,[12,14] and is confirmed with our finding that at high-volume hospitals, racial/ethnic minorities were 43% less likely to undergo TAVR than White patients. Although the effect on outcomes remains beyond the scope of this present study, access to hospitals performing TAVR does appear to be influenced by race/ethnicity. Similar to the investigation into DES use,[34] our findings suggest that any decreased racial/ethnic inequity is being driven by progress at high-volume hospitals, providing a high-yield target for future policy and further investigation. Although it is unclear how the continued rapid growth of TAVR will be distributed among low- versus high-volume hospitals, it is important to continue monitoring these trends.

This study has several limitations. First, the analysis was limited to only 8 states. Although these states are large, geographically and ethno-racially diverse, and represent nearly 20% of the US population, they might not be representative of the country as a whole. Second, although using SID did allow for linkage of patient-level, hospital-level, and county-level data through linkage to American Hospital Association and Area Health Resources Files databases, it does not capture granular information on indications for intervention or outcomes measures. Although this prevented us from stratifying patients on the basis of concomitant procedures, we were able to instead focus on top-line numbers of TAVR versus SAVR to describe the broad dissemination patterns of the new technology in its early years. The SID also only captures those that have made it to the point of intervention, without the ability to assess referral pathways, access to specialists, or social/cultural factors that might influence patients' health decisions or act as barriers to receiving care. Finally, use of TAVR has continued to expand, with increased use among intermediate- and low-risk populations, as well as increased penetration into medium- and low-volume hospitals. Future work will be necessary to continue examining long-term trends, as the population undergoing TAVR continues to evolve.

CONCLUSIONS

This multistate evaluation is representative of a large, ethno-racially heterogeneous patient population of >50,000 patients who underwent TAVR or SAVR, and allows for an early examination of how TAVR is being

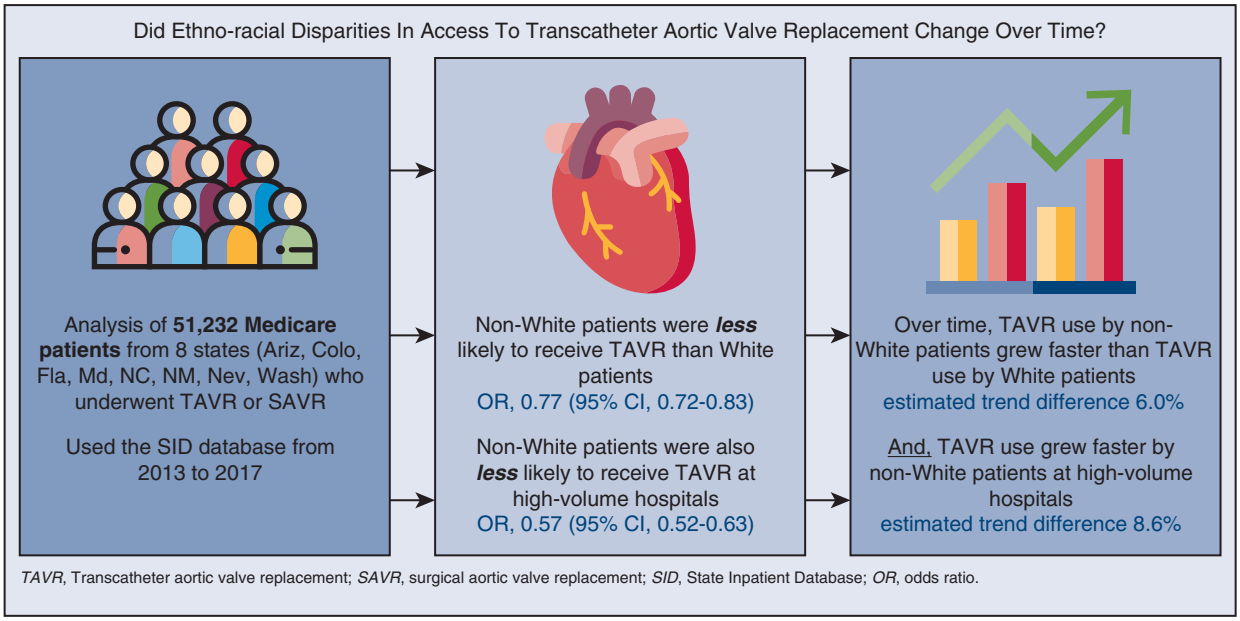


FIGURE 3. Did ethno-racial disparities in access to transcatheter aortic valve replacement change over time?

disseminated. We showed that despite existing racial/ethnic disparity, TAVR use grew faster among vulnerable populations than among their White counterparts, a trend driven by increasing use in high-volume hospitals, and visualized in our Graphical Abstract (Figure 3). Future research is needed to confirm long-term trends and verify continued progress as the new technology expands to intermediate- and low-risk populations and is available at more medium- and low-volume hospitals.

Webcast

You can watch a Webcast of this AATS meeting presentation by going to: https://aats.blob.core.windows.net/media/Publications/AM21_A13%20-%20Transcatheter%20Aortic%20Valve%20Replcmnt_SAVR%201.mp4-B.mp4.

Conflict of Interest Statement

The authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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Key Words: TAVR, SAVR, race/ethnicity, disparity, hospital volume

Discussion

Presenter: Dr Brian D. Cohen

Dr Hersh Maniar. Dr Cohen, that was a really—it's a thought-provoking study with regard to access to TAVR and racial disparities. Our invited discussant to open the conversation is Dr Danny Chu from UPMC. Danny, do you want to lead us off with some questions for Dr Cohen?

Dr Danny Chu (*Pittsburgh, Pa*). Yes. Thank you. I congratulate the team for this well-done and timely study on racial disparity of TAVR utilization and thank the authors for providing me the manuscript well ahead of time for review. I appreciate the association giving me the privilege to discuss this paper. Dr Cohen and colleagues performed, in retrospective observations, a cohort population-based study of 51,000 patients or so who underwent aortic valve replacement via either a SAVR approach or a TAVR approach from 2013 to 2017 using the administrative State Inpatient Database from 8 states aiming to test their hypothesis that racial disparity in aortic valve replacement procedures has decreased over time as TAVR use has expanded and that this decreasing disparity is driven by the increased utilization at low-volume centers. The team here used the Charlson Comorbidity Index for risk adjustment and adjusted regression methods to adjust for potential confounding covariants. The authors conclude that the increased TAVR utilization in non-White patients was driven by increased utilization in high-volume centers. I have a few questions for you, and I will be asking them one at a time. Number one, it was not clear from the manuscript whether your cohort included only isolated primary nonredo aortic valve replacements. What are your exclusion criteria for this particular study?

Dr Brian D. Cohen (*Washington, DC*). Great. Thank you very much, Dr Chou, and thank you for the clarifying question. Our inclusion criteria included any Medicare beneficiary who underwent TAVR or SAVR over our time period of interest. We then excluded anybody with aortic valve insufficiency on the basis of ICD code. We chose this cohort, specifically those of Medicare, to focus on a patient population that was largely approved to undergo TAVR during our time period of interest and tried to mitigate any confounding effects of insurance status as much as possible. We did not include or exclude patients on the basis of concomitant procedures or have the data to determine native valve versus redo operations. This was one of the limitations of using the State Inpatient Databases, given the constraints of data collection and inconsistencies in how some might code primary versus secondary procedures. More fundamentally, we were interested in describing dissemination trends of this transformational technology. And so, while there's certainly important differences in indications among these different categories, we were looking at the top-line numbers of TAVR versus SAVR over time and how they may change.

Dr Chu. Right. Number two, your manuscript described exclusion of patients with aortic valve insufficiency. What did the patient have next, aortic stenosis, aortic insufficiency? Were these patients excluded? How would this change your results and/or conclusions?

Dr Cohen. Yes. So, we did exclude patients with aortic valve insufficiency on the basis of their ICD codes. However, when excluding patients, we didn't dive deeper into primary versus secondary diagnoses, similar to before, as a limitation of how someone might code primary versus secondary diagnoses in State Inpatient Databases. So, if a patient carried both diagnoses, they would've been excluded with that method, and again, on the basis of limitations of data collection. To answer your question more specifically, how it would change our results and provide some numbers, we did exclude 4600 patients with aortic valve insufficiency. And then going back to look over some of the secondary diagnoses, 625 carried the diagnosis of aortic stenosis and that being compared with >51,000 that were

included for the analysis. So, I don't think it would've had a substantial effect one way or the other given the numbers but do recognize that it's a limitation of the data set.

Dr Chu. Great. One of the contraindications for TAVR is aortic valve endocarditis. Did you exclude endocarditis patients? If not, might this partly explain your findings?

Dr Cohen. Right. So, we did not exclude patients with endocarditis. To the extent that racial minorities are at increased risk of endocarditis, it would favor SAVR over TAVR as you pointed out. However, the literature shows ethnoracial minorities less likely to undergo SAVR compared with their White counterparts, and specifically, that remains true after presenting with endocarditis. So, I think, while your question is obviously important and provides another example of disparate access to surgical care, I don't believe it could be used to explain our findings as I can't say that non-White patients aren't getting TAVR because they're all getting SAVR when that isn't the case on the basis of existing literature.

Dr Chu. Number four, you demonstrated that disparate access to TAVR technology is still persistent albeit less so in the current era for non-White patients. What do you suggest is the rationale behind this disparity? Is it an access issue or inherent patient-level differences?

Dr Cohen. So that is the fundamental question that drives this work, drives a lot of similar work that doesn't have a simple answer. What we've provided was a highly descriptive analysis trying to quantify patterns of dissemination of this new technology. To do that, we designed it as our 3-way interactions to see if inequity was changing over time. We saw it was decreasing, and we introduced hospital volume as one area to try to key in on where those changes were happening finding that it decreased on the basis of increased use at high-volume hospitals. That said, more to your question and more fundamentally, racial disparity in medicine is multifactorial and broader than just who has access to these high-volume hospitals. This study doesn't address patient-related factors, cultural or social differences in who seeks care, who agrees to surgery, it doesn't delve deeper into provider- or system-level factors such as referral pathways or reimbursement incentives, and we actively sought to minimize the effects of payer status looking only at Medicare beneficiaries. So that was what we tried to do and what we weren't able to do, but what we showed was it provided a window into these patterns of dissemination and how those patterns are changing, how the dissemination is changing.

Because ethnoracial minorities historically have less access to high-volume hospitals, there is some reasonable thought that increasing TAVR use at low-volume hospitals would have alleviated some disparity, but data that we have doesn't support that hypothesis. By showing the decreasing racial disparities was driven by high-volume hospitals, hopefully, this helps provide a better target for future investigation, future interventions. If the goal is to reverse ethnoracial disparity, looking at those patient-related factors, looking at the referral pathways, looking at all the other factors to drive more equitable use within high-volume hospitals is a reasonable target on the basis of these data.

Dr Chu. My final question is, number five, please comment on the validity of risk adjustment for cardiac surgical procedures using the Charlson Comorbidity Index with ICD-9 or 10 diagnosis codes. Again, I thank the AATS for the privilege to discuss this fine paper. Thank you.

Dr Cohen. Thank you. And we did use the Charlson Comorbidity Index as a standard when using these large data sets, the State Inpatient Database as well as using the nationwide inpatient sample. There is evidence looking specifically at its use in minimally invasive mitral valve surgery showing it has a predictive value not significantly different from STS or EuroSCORE II, but there is more substantial evidence of its value for nonsurgical cardiac disease or general thoracic surgery as well. In our case, we used it as a standard tool that was associated with our data set though. And thank you, Dr Chu. I appreciate you serving as our discussant and asking these great questions.

Dr Chu. Thank you.

TABLE E1. Percentage of population who underwent TAVR and SAVR broken down by race and state, with the percentage of White population listed for each state

	2013		2014		2015		2016		2017		
	SAVR	TAVR	SAVR	TAVR	SAVR	TAVR	SAVR	TAVR	SAVR	TAVR	White population
Arizona											
White	84.2	92.0	84.4	89.7	81.8	89.2	86.2	89.0	81.2	88.8	54.1
Non-White	15.8	8.0	15.6	10.3	18.1	10.8	13.8	11.0	18.7	11.2	
Colorado											
White	88.3	92.9	89.0	94.7	90.0	90.2	87.4	93.4	87.5	93.3	67.7
Non-White	11.6	7.2	11.0	5.3	10.1	9.9	12.6	6.6	12.5	6.7	
Florida											
White	79.1	85.3	81.2	85.8	79.1	86.5	80.1	85.1	79.7	83.7	53.2
Non-White	20.8	14.7	18.9	14.3	20.9	13.5	20.0	15.0	20.2	16.3	
Maryland											
White	86.1	92.3	81.9	86.8	80.2	88.9	77.3	80.3	81.5	85.1	50.0
Non-White	13.9	7.7	18.2	13.2	19.9	11.0	22.8	19.8	18.5	14.9	
North Carolina											
White	87.0	90.1	87.0	90.3	87.8	90.5	88.6	89.5	86.6	88.6	62.6
Non-White	13.1	10.0	13.1	9.7	12.3	9.4	11.4	10.5	13.5	11.3	
New Mexico											
White	77.8	50.0	72.5	73.7	69.3	70.0	78.9	80.3	69.7	77.4	36.8
Non-White	22.3	50.0	27.6	26.3	30.8	30.1	21.1	19.7	30.3	22.6	
Nevada											
White	81.2	89.4	79.4	86.9	81.9	82.5	78.8	83.2	79.8	87.4	48.2
Non-White	18.9	10.7	20.6	13.1	18.1	17.6	21.1	16.7	20.3	12.7	
Washington											
White	94.0	94.8	94.1	95.8	94.1	95.4	93.9	95.3	92.3	95.3	67.5
Non-White	6.1	5.2	6.0	4.2	5.8	4.6	6.2	4.8	7.7	4.8	

SAVR, Surgical aortic valve replacement; *TAVR*, transcatheter aortic valve replacement.

TABLE E2. Marginal analysis of all race/ethnicity categories by hospital volume

Hospital volume	Race/ethnicity category	Odds ratio estimate	95% Confidence limit	
			Lower	Upper
Low	Black	1.17	0.79	1.73
	Hispanic	1.02	0.75	1.38
	Asian/Pacific Islander	0.80	0.32	2.02
	Other	1.39	0.83	2.30
Medium	Black	0.91	0.76	1.09
	Hispanic	1.26	1.11	1.42
	Asian/Pacific Islander	0.74	0.48	1.14
	Other	0.95	0.70	1.30
High	Black	0.69	0.61	0.78
	Hispanic	0.52	0.46	0.57
	Asian/Pacific Islander	0.84	0.65	1.08
	Other	0.83	0.67	1.01

Odds ratios are calculated by comparing all race/ethnicity categories with the White patient population.