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Short communication



# Pre-procedural barriers to accessing novel treatments for aortic stenosis among racial/ethnic minorities in the veterans affairs healthcare system



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| ARTICLE INFO  | A B S T R A C T  |
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| Keywords:<br>Aortic stenosis<br>TAVR<br>SAVR<br>Disparities<br>Race | Background: Novel structural heart procedures offer life-saving treatment advantages, yet little is known about pre-procedural barriers to care by race/ethnicity.<br>Methods: All echocardiograms performed at a Veterans Affairs hospital from 2015 to 2019 were reviewed to identify patients with severe aortic stenosis and their access to transcatheter aortic valve replacement (TAVR) by race/ethnicity.<br>Results: From 19,403 echocardiograms, 355 individuals were identified to have severe aortic stenosis (72.6% White, 9.8% Hispanic, 3.9% Black). There was a non-significant trend towards increased TAVR treatment among White compared to non-White patients (OR 2.02, CI 0.96–4.24, $p = 0.063$ ), which attenuated after adjustment for age and comorbidities. Reasons for not undergoing replacement included poor procedural candidacy (25.3%), loss of follow-up (17.8%), and patient refusal (16.4%).<br>Conclusions: Racial/ethnic inequities were not detected in novel structural heart treatment within the VA. However, a high proportion of eligible patients did not receive procedural treatment due to patient refusal or loss of follow-up, highlighting barriers that require further study. |

## 1. Background

The development of transcatheter aortic valve replacement (TAVR) as a minimally invasive alternative to surgical aortic valve replacement (SAVR) has expanded life-saving treatment options for patients with severe aortic stenosis (SAS). The Veteran's Health Administration (VHA) provides a unique opportunity to study this novel procedure, since it removes insurance status from the usual barriers to care.

Studies on racial/ethnic disparities within the VHA are mixed, with some studies suggesting less disparity within the VHA compared to non-VHA facilities with respect to all-cause and cardiovascular mortality [1]. However, others demonstrate continued racial/ethnic inequities in cardiovascular care, such as hyperlipidemia, diabetes, and hypertension management [1,2]. While prior studies have examined racial/ethnic differences in post-procedural TAVR outcomes, they do not capture the important population of patients who may be eligible, but never receive treatment [3]. This has left gaps in knowledge about whether preprocedural barriers may differentially impact vulnerable patient populations.

# 2. Methods

We examined racial and ethnic differences in access to TAVR and SAVR among patients with SAS from the VA Palo Alto Healthcare System (VAPAHS) in California, a leading structural heart center offering TAVR procedures to Veterans since 2011. We reviewed reports of all transthoracic echocardiograms performed at the VAPAHS from November 2015 to October 2019 to identify those with SAS by echocardiographic criteria (aortic valve area < 1 cm<sup>2</sup> and/or aortic valve gradient >40 mmHg) [4]. Medical records were reviewed for age, race/ethnicity, treatment approach, and outcomes. For patients who did not receive valve replacement, detailed review of clinic notes, advance care planning documentation, and documentation of death was completed to identify reasons for lack of procedural treatment. Treatment alignment with patient preferences or goals of care was determined from clinical notes. For qualitative analyses, all patients with a diagnosis of SAS were included (n = 355).

For quantitative analyses by race/ethnicity (n = 307), patients with race/ethnicity missing (n = 35) and racial groups with low numbers

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(Asian/Pacific Islander n = 6, Native American n = 7) were excluded. Categorical variables were represented using frequencies and percentages. Fisher exact test and test of proportions were used to evaluate for differences in age and comorbidity burden by race/ethnicity. Multivariate logistic regression was used to determine likelihood of receiving a TAVR by race/ethnicity (White vs. non-White, which included Black Hispanic, White Hispanic, and non-Hispanic Black populations), with adjustment for age and baseline comorbidities (diabetes, hypertension, chronic kidney disease, coronary artery disease, congestive heart failure, stroke, pacemaker, atrial fibrillation/flutter, chronic obstructive pulmonary disease, prior AVR, and prior coronary artery bypass graft surgery). Analyses were performed using the data analytic software R (4.0) [5]. A *p* value <0.1 was considered to represent a non-significant trend and p < 0.05 to be significant.

## 3. Results

Over four years, 19,403 echocardiograms were performed. SAS was identified by echocardiogram in 355 individuals (98% male, mean age 77 $\pm$ 10). The highest represented races/ethnicities were non-Hispanic White (NHW or White) (258 patients, 73%), Hispanic (35 patients, 10%), and non-Hispanic Black (NHB or Black) (14 patients, 4%). Almost all patients (95% White, 94% Hispanic, 93% Black) were seen in cardiology clinic within one year of diagnosis, without significant differences by race/ethnicity.

Among patients with SAS (n = 355), 61% received procedural treatment. Among those treated, SAVR was performed in 45% (NHW 74%, Black 5%, Hispanic 10%), and TAVR was performed in 55% (NHW 77%, Black 2%, Hispanic 7%). There was no significant difference in age between NHW, Black, and Hispanic populations undergoing TAVR (p = 0.48). There was significantly more diabetes in Black compared to NHW patients (71.4% vs 39.9%, p = 0.04). There was a trend towards NHW patients having an increased likelihood of receiving TAVR compared to non-White patients, although this was not statistically significant (NHW 34% vs. non-White 20%, NHW vs. non-White OR 2.02, CI 0.96–4.24, p = 0.063). This attenuated after adjustment for age and comorbidities (NHW vs non-White adjusted OR 1.84, CI 0.83–4.06, p = 0.13). There were no significant racial/ethnic differences in 30-day mortality (overall

1.9%) or 1-year mortality (overall 6.8%) after TAVR.

The most common reasons for not undergoing valve replacement (Fig. 1) were poor procedural candidacy (25%, 37 patients – 25 White, 3 NHB, 5 Hispanic), death (20%, 29 patients - 17 White, 1 NHB, 7 Hispanic), loss of follow-up (18%, 26 patients – 19 White, 2 NHB, 2 Hispanic), and patient refusal (16%, 24 patients – 19 White, 1 NHB, 2 Hispanic). Additionally, 11 patients (7%) were referred but still undergoing evaluation at the time of publication, and 19 patients (13%) were asymptomatic, therefore not meeting indications for treatment. There were no significant differences in reasons for non-treatment by race/ ethnicity.

Among the 29 who died in the time between echocardiographic diagnosis and valve replacement, 31% died before, and 69% died after their first visit to cardiology clinic for evaluation. Among those deemed poor TAVR candidates, the primary reason was that treatment would not alter life expectancy, often due to metastatic cancer, advanced dementia, and end-stage renal disease. A small number of patients had contraindications such as active infection and bleeding, or severe vascular disease limiting transcatheter access.

#### 4. Discussion

In this study, we report that the majority of Veterans with SAS were referred to, and seen by, cardiology within one year of diagnosis – without differences by race/ethnicity. 60% of patients diagnosed with SAS subsequently underwent valve replacement, with a non-significant trend towards more treatment with TAVR among White patients, that attenuated after adjustment for age and comorbidities.

To our knowledge, this is the first study to report referral patterns, procedural use, and outcomes for TAVR by race/ethnicity within the VA system. Prior studies of non-VA populations have demonstrated lower TAVR use among Black patients during the earliest periods of TAVR adoption [3], which have narrowed over time [6], however, inequities in access among Hispanic individuals persist [7]. In our study, differences in treatment by race did not reach statistical significance and resolved after adjustment for age and comorbidities. This raises the question of whether VHA patients in particular are less impacted by traditional barriers to receiving specialty cardiovascular care. Possible

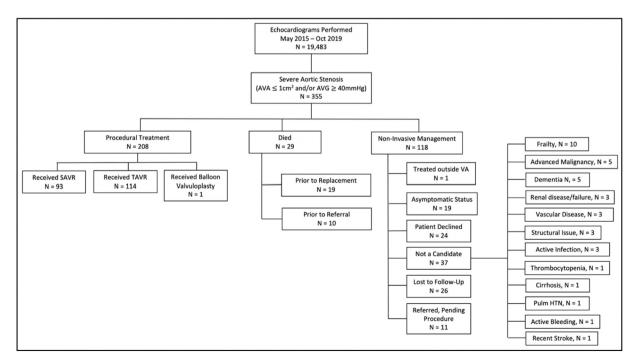


Fig. 1. Reasons for Not Undergoing Aortic Valve Replacement in Patients with Severe Aortic Stenosis.

reasons for this could range from systemic differences, such as universal insurance coverage, to increased social support, such as covered transportation costs, on-campus housing, and centralized health records [1], which improve specialty healthcare access for vulnerable Veterans.

Despite these advantages, the VHA may bear its own unique barriers to care that warrant further investigation. The proportions of Black and Hispanic patients in our study were lower than national VHA demographics [8], which could reflect variation in baseline AS prevalence [9], or more worrisome, disparities in access to initial referral for recommended diagnostic imaging.

Among those not receiving procedural treatment, over 30% were due to loss to follow-up or patient refusal rather than clinical reasons. Detailed chart review showed that most patients who declined replacement did so because the procedure did not align with their personal preferences or goals of care, with no difference in refusal by race/ ethnicity. However, weighing the concordance of a procedure with one's personal goals or preferences is inextricably linked to a patient's understanding of the true risks and benefits of a procedure. Historical distrust in the healthcare system has been shown to play a role in research participation among certain populations [10]. In some cases, chart review revealed that patients expressed a lack of familiarity with the procedure, although there was no measurable difference by race. Further research is required to determine optimal methods of patient education to address the complex decision-making needs of patient populations from diverse racial, cultural, linguistic and educational backgrounds.

Of the patients who died before valve replacement, some were critically ill transfers from external facilities who were too sick to tolerate intervention. In other cases, it is unclear whether pre-procedural death was premature, and if so, the degree to which this may have been influenced by limited resources, lack of social support, higher baseline morbidity, or healthcare access.

Limitations of our study include a small sample size, and predominantly Caucasian and male cohort. Some Veterans could have sought care outside the VHA, especially after the inception of the Mission Act of 2018, though our detailed chart review makes this unlikely. While we recognize that "loss to follow-up" is not a clinical reason for not receiving TAVR, we include it as a category for non-treatment given its systemic implications and potential for intervention. Importantly, patients who are never identified to have SAS in the first place are not included in this study and may represent an unmeasured source of disparities in structural heart care within the VHA.

#### 5. Conclusion

In the VHA system at an established structural heart program, we found no significant difference in novel procedural treatment for SAS by race/ethnicity, which may reflect recent aggressive measures on the part of the VHA to improve access and care for all Veterans. However, the findings that a high proportion of patients did not receive procedural treatment due to loss to follow-up or patient refusal suggest areas for further investigation. Particularly in the setting of widespread cardiac procedural deferrals due to the COVID-19 pandemic, this study highlights areas in which we must remain vigilant to address mounting barriers to delivering equitable life-saving care.

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#### CRediT authorship contribution statement

**AK** Writing – Original Draft **SG** Formal Analysis, **PH** Supervision **CY** Conceptualization, Writing - Reviewing & Editing, Supervision.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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