

A review of racial disparities in transcatheter aortic valve replacement (TAVR): accessibility, referrals and implantation

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Abstract: Racial disparities in transcatheter aortic valve replacement (TAVR) implantation results from several factors, including socioeconomic disparities, inherent biases in healthcare provision, fewer referrals to specialists and language barriers in some minority populations. In this review article, we discuss the current data on the racial disparities in TAVR, explore the prevalence of aortic stenosis in different demographics in the United States and we proffer practical solutions to these problems.

Keywords: Transcatheter aortic valve replacement (TAVR); racial disparities; advocacy; aortic stenosis (AS)

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Introduction

Although there have been a few studies (1-3) examining the influence of race on transcatheter aortic valve replacement (TAVR) procedure rates, this is the first review article to comprehensively summarize this topic whilst proffering solutions on how to reduce such disparities in TAVR implantation.

Aortic stenosis (AS) and its management

AS is a common cause of valvular heart disease present in almost 7% of patients older than 65 (4,5). It has a very high mortality with an average life expectancy of 1 year once the patient becomes symptomatic; which has numerous manifestations, including angina, syncope, or most commonly, heart failure (6,7).

In the United States (US), the chief cause of AS is degeneration and valvular calcification, so called senile

calcific AS (>50%). Other important causes include bicuspid valve disease causing 30–40% of cases (8-10), and rheumatic heart disease, which is more common in developing countries (11).

For several years, the standard therapy for AS was surgical replacement of the aortic valve, which improved survival and reduced morbidity but was only possible in patients with acceptable surgical risk due to the invasive nature of open heart surgery (12,13).

In recent years, TAVR has been shown in landmark trials (14,15) to be as effective and comparable as a treatment for severe symptomatic AS, especially in patients with high and intermediate surgical risk (i.e., patients with prior open-heart surgeries and multiple comorbidities).

Evolution of TAVR as an important treatment for AS

As the 15-year landmark approaches since the advent of

TAVR for AS (16), there has been a growing expertise among operators, advancement of TAVR technologies with better valves (17), lower complication and stroke rates, and lower rates of short-term mortality (15).

The US has a very expensive health care industry (18), and TAVR has been a welcome innovation for reducing this burden. Studies have shown reduced post-operative hospital stay (19) and reduced complication rate, despite slightly increased cost of procedure mainly due to the cost of the valve, which will likely reduce as it becomes a mainstay in therapy (20). TAVR has been employed for several off-label pathologies (21) including aortic regurgitation (22) and valve-in-valve therapies (23) with encouraging results, making the future of TAVR very promising.

Racial disparities in TAVR implantation

TAVR continues to be an expanding and improving alternative to open heart surgery with over 58,000 patients in the US getting this procedure for the treatment of severe symptomatic AS as of 2016 (23).

The number of TAVR procedures performed has doubled annually every year from 2012–2014, and increased by 8,000 from 2014 to nearly 25,000 in 2015 (24). However, despite this impressive increase, the percentage of African-American (AA) patients who received this therapy from 2012 to 2015 remained at 3.8% compared to 93% in Caucasians (24); the US population census bureau estimates AA to make up about 16% of the US adult population (25).

This has been corroborated by numerous single center studies (3,26,27). Cardiac comorbidities such as congestive heart failure, severe coronary artery disease (CAD), and non-cardiac comorbidities like cancer, end stage renal disease (ESRD), morbid obesity and prior cardiac surgery were common reasons for non-operative management of AS.

This is not solely due to an increased geographical density of Caucasians in centers that offer this therapy: a single center study done in a large urban area in the US with a relatively large AA population of 37% still showed that only 10% of those who received TAVRs were AA's compared to 90% who were Caucasians (3).

This disparity in implantation of TAVRs in non-Caucasian, especially AA population has been attributed to several factors including lack of physician trust among minorities, lower likelihood to be referred for specialized procedures, lower insurance rates and poorer socioeconomic status. Another reason given for this disparity was

significantly lower risk for developing severe AS among AA compared to Caucasians.

Explaining the racial disparities in TAVR implantation and accessibility

Studies have shown that AAs are less likely to receive other surgical procedures compared to Caucasians (28,29). The complete reason is not known but we summarize below the most important factors playing a role in this trend in relation to TAVR implantation.

Socioeconomic and health insurance disparities

It is a well-known fact that there are a higher number of uninsured AA patients compared to their Caucasian counterparts (30). Whilst 11% of Caucasians are uninsured, that number is around 31% for Native Americans and 32% for Hispanic Americans (31).

Several studies have shown a significant difference in advanced cardiac procedures with reduced access to patients who are racial minorities (32) or of a lower socioeconomic status (33).

Due to the private and often for-profit nature of the American health insurance industry, it is not surprising that the insurance companies are not willing to cover such an expensive procedure regardless of the benefits already enumerated above. The cheaper option of the open surgical aortic valve replacement remains the default option for the low-income class in the US. Since older patients are most affected by this pathology, lower socioeconomic class patients, often older minorities have only Medicare insurance (34); which has very stringent reimbursement requirements and multiple exclusions for approval of TAVR (35). On the other hand, patients with a combination of private and Medicare insurance were shown to get the procedure more often (3) in a single center study. As such, disparities exist even among Medicare-aged patients (36).

Many uninsured minorities less than 65 years old, with severe AS, may be unaware of their eligibility for government support programs such as Medicaid, due to ignorance or language barriers. For example, almost 70–80% of uninsured Hispanic and AA children are eligible for Medicaid and other programs (37).

Hence, we advocate widespread outreach in multilingual pamphlets and programs encouraging health insurance and health seeking behaviors among minorities and informing

them about their eligibility for insurance.

Disparities in specialist referrals

A post hoc analysis in a study by Sleder *et al.* (2) revealed that AA patients with severe AS were less likely to be referred to cardiology, more likely to decline an intervention, or be lost to follow-up. Another study showed that fewer cardiac referrals and follow-up appointments were made to Hispanic and AA patients and patients with lower socioeconomic status (34). This can be extrapolated to TAVR as well.

AAs are at increased risk for earlier onset AS (38), making it even more important to seek care as symptomatic AS has a grave prognosis (39).

We advocate early specialty referrals for minorities, encouraging minority patients to get health insurance or be covered by support programs and lobby for the acceptance of these patients into specialists' practices.

Cultural differences and lack of understanding of the procedure

In looking for possible reasons for disparities in TAVR implantation, cultural differences and beliefs are often underestimated. Similar trends of racial disparities are seen in AA patients with CAD (40). Examples of manifestation of these cultural differences include seeking care late, late symptom recognition and late intervention (41,42). These reasons are also relevant to the minority of patients with severe AS who may be candidates for TAVR.

In a study by Minha *et al.* (1), AA patients were significantly more likely to refuse AVR compared to Caucasians ($P=0.04$). Other trends among minorities included the perception of being "too old" for the TAVR procedure despite the mean age of the procedure over the last 5 years being 83 years (43) pointing towards a poor understanding of the risks and benefits by the patients, mistrust between these patients and their providers who are often Caucasians (44).

Another cultural difference is in decision-making: in minority patients, medical decisions are more likely to be reached from a group decision by many family members who may dissuade the patient without a full understanding of the procedure (45). As an example, they may believe that TAVR has risks commensurate to an open-heart bypass or AVR despite decreased stroke and mortality rates in patients at high pre-operative risk.

It may be important to ask patients and family members reasons for refusing potentially lifesaving therapy in the form of a survey or discussion and analyzing and relaying this information in the form of a frequently asked questions (FAQ) brochures written in simple and easy to understand language.

We suggest an increase in the education of minority patients and their extended family members about the procedure and potential benefits and risks. We recommend the use of simple English communication, brochures and proper language translators if necessary rather than using family members who may not be able to understand what physicians are specifically asking or for whom it may be culturally inappropriate to discuss such issues with the patient, a likely more senior family member.

These steps to address language barriers and increase understanding of the procedure have been shown to improve outcomes (46).

To that effect, we advocate that education and understanding of minority beliefs and practices including but not limited to, family be assimilated into medical education starting in medical school and reinforced through practice including the faculty. This will hopefully have an effect at increasing awareness of these matters in the medical community as a whole.

Encouraging training programs for cultural competency have been launched by the ACGME and AAMC (47). We believe that better understanding of minority populations will increase access to TAVR and other medical procedures.

The US is projected to have a majority non-white population by 2050; hence as the demographics change, we must foster increased diversity in physicians and other healthcare workers as this helps to increase understanding, reduce language barriers, promote trust and can influence their non-minority colleagues on cultural competent practices.

Increase in clinical trials inclusion

Participation in clinical trials is also an important part of diversifying the patient demographic. It gives insightful data on outcomes of every racial group, increases initial experience and efficacy of a new technique in every racial group. The disparity in clinical trials is staggering; this is apparent in the TAVR PARTNER trial (15) where only 2.7% in the high-risk pool (19 out of 699) were AAs. This is not particular only to this trial, the recent WATCHMAN trials for left atrial appendage closure devices—another new

cardiac device (48,49) included very small percentages of AA patients. This is also true for recent cardiac medications after landmark trials for example the PARADIGM-HF trial (50) with only 5% of AAs.

It is not clear the exact reason for this trend of reluctance among AAs to participate in clinical and drug trials. It is likely multifaceted: Historical distrust exists among the AA community towards the medical community with cited historical reasons, with the Tuskegee syphilis experiments being an example among others (51,52). From the angle of the providers who are mainly Caucasians, there may be a disconnect and lack of understanding of the challenges and beliefs of AAs in the population that may lead them to refusing these procedures. Hence, a suggested approach for increasing clinical trial participation includes active advertising, explanation of procedures, and giving incentives to these communities to participate more. Also perhaps, having an enforced trial inclusion quota which has to be filled by minorities regardless of public or private trial funding status may help, as it will likely be used to treat these same patients once approved by the US Food and Drug Administration (FDA).

Advertising is not geared towards minorities, and university teaching hospitals that participated in the clinical trials performed most of the earlier cases of TAVR and are known to have the lowest complication rates (53) compared to non-teaching hospitals. AAs tend to go to community hospitals who do not have these facilities for TAVR and are less likely to be referred to tertiary hospitals with these facilities.

Differences in comorbidities and outcomes among different racial groups receiving TAVR

All studies in the literature have failed to find any significant differences in clinical outcomes post-TAVR between different races. Propensity-matched cohorts of Caucasians and AAs who underwent TAVR between 2011 and 2014 found no difference in operative and in-hospital mortality or complications rates between the two groups (54) a single center study by Minha *et al.* showed similar rates of 30-day and 1-year mortality between Caucasians and AAs who underwent TAVR (1)

Similarly, in most studies, there was no significant difference in co-morbidities (1,2,54) except for in a single center study by Yeung *et al.* (3) in which hypertension, heart failure and chronic renal failure were higher in AAs compared to European Americans, however, this study did

not find any racial disparities in regards to access to TAVR; as every patient in this single center study was similarly evaluated for AVR.

Society of Thoracic Surgeons (STS) Score has not been looked at in any of the larger TAVR racial comparisons and is an interesting factor that may help explain racial disparities in TAVR implantation and accessibility. Future studies that perform a comparative analysis which includes STS and EuroScore are encouraged.

The other side of the coin: racial differences in the prevalence of AS

An important argument is that the higher prevalence of AS among Caucasian Americans compared to their AA counterparts is completely responsible for perceived racial disparities in access and implantation of TAVRs.

Patel *et al.* found that AA patients have been found to be at significantly lower risk of developing severe AS compared to Caucasians (55). They found that despite controlling for other risk factors like age and etiology of aortic valve disease, race was still a statistically significant factor in prevalence of the disease. Other studies have corroborated the finding that the prevalence of AAs presenting with AS was much lower than the percentage of AAs in that area compared to their Caucasian counterparts (3)

There seem to be variances in the etiology of symptomatic AS between among races and this could be playing a role in the prevalence of the disease. Studies have shown AA with calcified aortic valves to be less likely to progress to AS (56). Patel *et al.* found that the incidence of severe AS was 0.3% in AAs compared to 0.9% in Caucasians. They also showed that AAs are less likely to have bicuspid aortic valves as the etiology of their severe AS compared to Caucasians.

The exact reason for this is unknown, and there are no specific genetic markers found to date that could put AAs at higher risk for developing symptomatic severe AS. Further research is needed in this area to elucidate the possible reasons for these reported differences in prevalence, but we do not believe that this is the sole reason for the disparities in TAVR implantation in AAs given the numerous aforementioned factors, which also play an active role.

Conclusions

Racial disparities in TAVR implantation result from multiple complex factors, including socioeconomic disparities, higher

rates of uninsured or underinsured patients, inherent biases in healthcare provision, and fewer referrals to specialists, poor cultural competency, language barriers, and physician distrust in some minority populations.

It is a daunting task to close this healthcare disparity gap, but we must attempt to reduce its effects in medicine and specifically in TAVR use due to its proven mortality benefits.

We advocate increasing specialist referrals, reducing socioeconomic gaps, increasing health insurance coverage, improving cultural competency among physicians, educating minorities in simple understandable language, diversifying the health care workforce, and intentionally increasing minority numbers in clinical trials.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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