**Racial, Ethnic and Socioeconomic Disparities in Patients Undergoing Transcatheter Mitral Valve Repair**

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**ABSTRACT**

**Aims:** In the past decade, transcatheter mitral valve repair (TMVR) has become an increasingly prevalent procedure performed on patients with mitral regurgitation and elevated surgical risk. This study aimed to assess the impact of race/ethnicity and socioeconomic status on in-hospital complication rates after TMVR.

**Methods and Results:** The United States National Inpatient Sample was used to identify 2504 hospitalizations for TMVR between October 2013 and December 2017. These patients were then stratified by race/ethnicity and quartiles of neighbourhood income levels. The primary outcome was total in-hospital major adverse events, defined as a composite of post-procedural bleeding, cardiac and vascular complications, acute kidney injury, and ischemic stroke, among patients of each race and socioeconomic quartile. Patients of black, Hispanic and “other” race/ethnicity were under-represented compared to their percentage of the U.S. population and comprised 19% of the total cohort. Black patients were significantly younger than white patients, generally had the highest burden of comorbidities and more frequently lived in low-income neighbourhoods. The primary outcome occurred in 20.5% of patients and there was a trend towards higher complication rates among racial/ethnic groups (P=0.05) while no significant differences were found across neighbourhood income quartiles (P=0.61). After multilevel modeling, the overall rate of in-hospital complications was significantly higher in Hispanic patients as compared to whites (OR: 1.47, CI 1.11-1.95, P=0.01).

**Conclusion:** Race/ethnicity minorities are markedly underrepresented among patients undergoing TMVR and accounted for slightly less than 20%. While black individuals presented with the highest burden of comorbidities, Hispanics had significantly higher rates of in-hospital complications. Socioeconomic status did not appear to negatively impact complication rates.

**KEY WORDS**: racial disparities, socioeconomic inequality, transcatheter mitral valve repair, mitral valve regurgitation

**ABBREVIATIONS AND ACRONYMS**

AHRQ: Agency for Healthcare Research and Quality

AKI: acute kidney injury

ANOVA: one-way analysis of variance

CCI: Charlson comorbidity index

ECS: Elixhauser comorbidity score

ICD-9: International Classification of Diseases, Ninth Revision

ICD-10: International Classification of Diseases, Tenth Revision

IQR: interquartile range

LOS: length of stay

MR: mitral regurgitation

NIS: National Inpatient Sample

TIA: transient ischemic attack

TMVR: transcatheter mitral valve repair

US: United States

**INTRODUCTION**

Mitral regurgitation (MR) is a common cardiac valvular disorder, with moderate or severe MR affecting an estimated 1.7% of the United States (U.S.) population and 9.3% of individuals over the age of 75.1 MR is most often caused by degenerative mitral valve disease, but can also occur secondary to myocardial infarction or dilated cardiomyopathy. In recent years, transcatheter mitral valve repair (TMVR) with MitraClip (Abbott Structural, Menlo Park, CA) has emerged as an effective transcatheter-based therapy for severe MR in patients deemed at high-risk for surgical interventions.2 Previous studies have demonstrated that this less invasive procedure has acceptably low rates of postprocedural mitral valve dysfunction and durable improvements in the severity of MR.3

Recently, the racial/ethnic and socioeconomic inequalities in the North American and European healthcare systems have been the subject of added focus, and cardiac procedures are not immune to these disparities. For surgical mitral valve procedures, racial and socioeconomic disparities have been well documented, with black and Hispanic patients having more pre-procedural comorbidities and being less likely to receive mitral valve repair as compared to valve replacement.4, 5 In-hospital mortality after mitral valve surgery has also been found to be higher in patients of lower income quartiles.6 Whether these disparities extend to TMVR, given the emerging nature of the procedure and difference in patient populations, has not been clearly established. Therefore, we aimed to explore the impact of race and socioeconomic status on in-hospital complication rates in individuals undergoing TMVR.

**METHODS**

The National Inpatient Sample (NIS) was used as the data source for this study. The NIS is the largest all-payer inpatient healthcare database in the US, and includes over 7 million unweighted hospitalizations each year.7 The NIS database was queried to identify all hospitalizations with TMVR as a primary procedure between October 2013 and December 2017.

We used the ICD 9th Revision (ICD-9) procedure code 3597 (Percutaneous Mitral Valve Repair with Implant) and the ICD-10 procedure code 02UG3JZ (Supplement Mitral Valve with Synthetic Substitute, Percutaneous Approach) to identify eligible participants who underwent TMVR as a primary procedure. Patient demographic variables were extracted, including sex, race, and median neighborhood household income according to ZIP code, along with data on hospital length-of-stay (LOS), patient comorbidities, and hospitalization costs. Patient records that did not include race/ethnic data or neighborhood income quartiles were excluded. The pre-procedural comorbidity burden among included patients was assessed using the Charlson comorbidity index (CCI)8 and Elixhauser comorbidity score (ECS).9,10 Two authors (R.T.S. and S.S.S.) independently verified the ICD-9 and ICD-10 codes that corresponded to each component of the scores.

**Study Outcomes**

The primary outcome of this study is total in-hospital complications, defined as the composite of bleeding, cardiac and vascular complications, acute kidney injury (AKI) and post-procedural stroke or transient ischemic attack (TIA). Bleeding outcomes comprised only post-procedural hemorrhage or hematoma, while cardiac complications included acute myocardial infarction, pericardial complications, complete heart block, cardiogenic shock, and need for emergency sternotomy. The ICD-9 and ICD-10 codes that corresponded to each of the above in-hospital complication were identified with the same process as was used to identify comorbidity codes and are detailed in **Supplemental Table 1 and 2**.

**Statistical Analysis**

The cohort of hospitalizations for TMVR was stratified by self-reported race/ethnicity and by quartiles of median ZIP code household income. Three racial groups with limited numbers of patients, Asian/Pacific islander, Native American, and “other”, were combined into a single (other) group to facilitate the analysis. The other three groups were white, black and Hispanic, and were left unchanged for the study. Median ZIP code incomes were 0-$43,999, $44,000-$55,999, $56,000-$73,999 and above $74,000 for quartiles 1 to 4 in 2017, respectively.

Initial analyses were conducted to compare the baseline characteristics of patients in each racial/ethnic group and neighborhood ZIP code income quartile, respectively. In accordance with the Healthcare Cost and Utilization Project data use agreement, when a variable contained less than 10 discharge records, “<10” was stated in Table cells. We expressed categorical variables as counts and proportions and compared groups used chi-square or Fisher exact test. Continuous variables were expressed as median [interquartile range (IQR)] and were analyzed with the Kruskal-Wallis test. Post-hoc pair-wise comparisons of continuous variables were evaluated with the Siegel-Tukey test. Adjusted P-values for each variable were adjusted for a survey sampling design by discharge-level weights, cluster and strata provided by NIS and recommended by AHRQ during survey-specific analysis.11

 Given the two-level hierarchical structure of the NIS database (i.e., patients are nested within hospitals), multilevel modelling was applied to account for intra-cluster correlation within hospitals and allow the intercepts to vary across hospitals. Multilevel multivariable logistic regression models were used to assess the associations between race and income quartiles, and in-hospital complications, and these models were adjusted for age, sex and relevant comorbidities. Relevant comorbidities were selected *a-priori* based on their clinical significance that may directly influence in-hospital outcomes and also those with a P-value <0.10 as determined by univariate analysis. One set of models was stratified by racial/ethnic groups and adjusted by neighborhood income quartiles, and the other model stratified by income quartiles and adjusted by race. Two similar models were used to assess the impact of individual comorbidities on in-hospital complications and were adjusted by racial/ethnic groups and neighbourhood income quartiles, respectively. The reference groups for all models were white patients and those from income quartile 4, the top quartile. The results from these models are displayed as odds ratios (OR) with 95% confidence interval (CI). All P-values are 2-sided with a significance threshold of <0.05. All statistical analyses were conducted using R version 3.6.3.12

Institutional review board and ethics committee approval was obtained from The Western University Health Science Research Ethics Board.

**RESULTS**

**Baseline demographics**

A total of 2736 hospitalizations for TMVR were identified from the NIS database, of these, 191 (6.9%) patients were excluded for missing race/ethnicity data and 46 (1.7%) for missing income quartile data, resulting in a final population of 2504 patients. Among this cohort, women comprised 1189 (48%) of the patients, 2027 (81%) were of white ethnicity, whereas black and Hispanic patients each comprised 7.4% and 6.0% of patients, respectively. A total of 1352 (54%) patients lived in ZIP code regions in the top half of income quartiles.

To assess the frequency with which patients from each racial/ethnic group underwent TMVR, we divided the number of patients in each group by the total population of elderly (over the age 65) Americans of each race/ethnicity.13 After adjustment for sampling design and discharge weights, white patients received TMVR with a frequency of 26.6/100,000, compared to 21.2/100,000 for blacks and 19.0/100,000 for Hispanics.

**Baseline patient characteristics**

 The baseline characteristics of patients stratified by race/ethnic groups and neighbourhood median income quartiles are outlined in **Table 1** and **Table 2**. White patients undergoing TMVR were significantly older (median age 82 [74-86] years for whites vs. 72 [62-80] for blacks vs. 79 [65-83.5] for Hispanics, P<0.001). Post-hoc analysis demonstrated a significant difference in the mean age of black vs. white patients (Siegel-Tukey test, P<0.001).

 Despite their younger age, black patients had higher burden of pre-procedural comorbidities, with the median CCI and ECS scores being significantly different between races (P<0.001 for CCI, P=0.02 for ECS). These disparities were driven by significant differences in chronic kidney disease (P<0.001), diabetes mellitus (P<0.001), congestive heart failure (P=0.003) and chronic pulmonary disease (P=0.001), all of which were highest among black patients.

Significant differences were found in the socioeconomic makeup of patients in each racial/ethnic group, with 51% of black patients living in the lowest ZIP code income quartile, as compared to 20% of whites and 31% of Hispanics (P<0.001). Given that black patients were over-represented in the lower ZIP code income quartiles, it is not surprising that significant differences were also found in the baseline characteristics of the income quartile stratification. Median age rose steadily from the quartile-1 to quartile-4 (79 [70-85] vs. 82 [75-86], P<0.001), and patients in the lower quartiles had greater median CCI scores (P=0.001) and rates of a few key comorbidities.

**In-hospital complications**

The primary outcome of total in-hospital major adverse events occurred in 513 (20.5%) of patients, driven primarily by 344 (13.7%) acute kidney injury events. In-hospital complication rates stratified by race/ethnicity and neighborhood income quartiles are shown in **Table 3**. While total complication rates did not differ between income quartiles (P=0.61), there was a trend towards between racial/ethnic groups (P=0.05), with black patients having the highest rates of total adverse events as compared to white patients (26.9% vs. 19.5%). Among the individual complications, only post-procedural bleeding rates differed between income quartiles (P=0.02) and there were no significant differences between racial groups. **Table 4** shows the interaction effects between racial/ethnic groups and ZIP code income quartiles, four of which were significant.

 A comparison of the number of procedures and complication rates over time for patients of white and non-white race/ethnicity is displayed in **Figure 1**. After dividing the data into 6-month intervals, the Cochrane-Armitage test demonstrated no statistically significant differences in the proportion of TMVR procedures performed on white and non-white patients over time (P=0.68).

After multilevel modelling with adjustment for income quartiles and relevant comorbidities (**Figure 2-A**), the rate of in-hospital major adverse events was significantly higher in Hispanic patients as compared to whites (OR: 1.42, CI 1.07-1.89, P=0.02). No significant difference in the overall complication rates was found when comparing white patients to blacks (P=0.52) or patients of “other” race/ethnicity (P=0.42). Among the individual component of in-hospital adverse events, significant differences included lower rates of bleeding complications (OR: 0.40, CI 0.20-0.80, P=0.01) and AKI (OR: 0.71, CI 0.52-0.97, P=0.03) in black patients.

 Among ZIP code household income quartiles, a significant difference in total in-hospital major adverse events was found between quartile-1 and quartile-3 (OR: 1.38, CI 1.11-1.72, P=0.004), driven by a higher rate of AKI among patients in low-income neighborhoods (OR: 2.04, CI 1.56-2.66, P<0.001), **Figure 2-B**.

The effect that adjusting for racial/ethnic groups and neighbourhood income quartiles had on their corresponding models was analysed in an ad hoc sensitivity analysis. For these models, in-hospital outcomes were adjusted by age, sex and relevant comorbidities only. No differences were found in the significance of the models stratified by racial/ethnic groups (**Figure 3-A**), and in the income-stratified models, bleeding complication in quartile-1 became significantly higher as compared to quartile-4 (P=0.02), **Figure 3-B**.

Additionally, several comorbidities were found to be associated with total-in hospital complications (**Figure 4**). Specifically, the presence of renal disease (OR: 3.88, CI 3.38-4.44, P<0.001) and congestive heart failure (OR 2.63, CI 2.12-3.25, P<0.001) conferred the highest risk after adjustment for race/ethnicity (**Figure 4-A**). This is noteworthy given that black patients had 15% higher rates of renal disease compared to any of the other racial/ethnic groups. Adjustment by ZIP code income quartiles yielded similar results (**Figure 4-B**).

Despite the fact that poorer patients had greater medical complexity, total hospitalization costs were over $4000 higher in patients in income quartile-4 as compared to quartile-1 (P<0.001) despite no differences in median LOS (P=0.96).

**DISCUSSION**

In this cohort study of 2504 patients who underwent TMVR, 81% were of white ethnicity and 54% lived in neighbourhoods in the top two income quartiles. The primary outcome of total in-hospital major adverse events occurred in 20.5% of patients, driven primarily by the occurrence of AKI. There are several important findings from the analysis of baseline characteristics and in-hospital complication rates. First, black and Hispanic patients had a median age that was 10 and 3 years younger than white patients, respectively. Despite these age discrepancies, black patients still had a significantly higher burden of pre-procedural comorbidities. Second, over 50% of black patients receiving TMVR lived in neighbourhoods in the lowest household income quartile. Third, despite these stark disparities, there were no significant differences in adjusted total in-hospital complication rates between white and black patients, but the complication rate among Hispanics was 47% higher, a significant result.

The findings of this study build upon those from previous research, both in surgical mitral valve repair and TMVR. Elbadawi et al.14 previously analysed racial disparities among patients undergoing TMVR using the 2012 - 2016 NIS database. Similar to our analysis, the average age for black patients was over 10 years lower (67.2 vs. 77.7 years), yet black patients had higher rates of chronic kidney and lung disease and diabetes. That study compared only black and white patients and using propensity matched scoring found lower complication rates in whites.

 Black and Hispanic patients have also been found to be significantly younger in several studies on surgical MV repair and replacement.5, 15 Previous studies have demonstrated that mitral valve disorders occur with roughly equal prevalence regardless of race,16 so systemic inequalities may be resulting in very elderly individuals of racial minority not receiving the indicated procedures with the same frequency.

This study also identified that the utilization of TMVR is lower among black and Hispanic patients, based on the calculations of number of procedures performed per 100,000 individuals. Similar findings have previously been reported in studies of transcatheter aortic valve replacement and other structural heart disease interventions.17, 18

In contrast to this body of research on racial/ethnic disparities, even less research has been conducted into the socioeconomic disparities surrounding mitral valve surgery and TMVR. Vassileva et al.6 previously reported that in-hospital mortality for surgical mitral valve repair was higher among patients of lower income quartiles, but this is the first study that analyzes in-hospital complications and focuses on TMVR. Fortunately, total-in hospital complication rates were very similar among patients of different ZIP code income quartiles, both before and after adjustment for racial/ethnic groups. However, despite no differences in complication rates or average length of hospital stay, hospitalization costs increased as income quartile rose, and patients in Quartile-4 had mean hospitalization costs over $4000 higher than those in Quartile-1. Agarwal et al. has found similar differences in hospitalization costs in a variety of conditions, including patients treated for ST-elevation myocardial infarction, pulmonary embolism and ischemic stroke.19-21 The mechanisms underpinning these differences are not known.

**Limitations**

Our study has several limitations. Given that this study is a retrospective analysis of the NIS database, it relies on the accuracy of ICD-9 and ICD-10 coding. Complications post-TMVR may also be impacted by cofounders that were not captured in the NIS database, including the etiology and severity of MR, and pre-procedural anticoagulation and other medications. There are also still relatively few black and Hispanic undergoing TMVR, and relatively low post-procedural events and patients of racial minority likely limited the statistical power of the models. This study is also limited to in-hospital complications, and longer-term 30-day outcomes and readmission rates were therefore not captured.

**CONCLUSION**

This is the large study assessing racial/ethnic disparities in TMVR outcomes, race/ethnicity minorities were markedly underrepresented, and accounted for slightly less than 20%. Black patients had a higher comorbidity burden, but patients of Hispanic ethnicity did experience a higher rate of post-procedural adverse events as compared to white patients. Socioeconomic status did not have an impact on in-hospital complication rates following TMVR.

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**Figure legends**

**Figure 1: Number of transcatheter mitral valve repair procedures performed (red/navy) and 6-month complication rates (orange/light blue) per 6-month period for patients of white and non-white race/ethnicity, respectively.** Cochran-Armitage trend test demonstrated no statistically significant difference in complication rates over the time between white and non-white race/ethnicity (P=0.68).

**Figure 2: Figure 2: Burden of comorbidities expressed as mean Charlson Comorbidity Index (CCI, red) and Elixhauser Comorbidity Score (ECS, navy) in relationship with total complication rates (light blue).**

**Figure 3: Forest Plot showing** **multilevel multivariable regression analysis for in-hospital major adverse events adjusted by age, sex, relevant comorbidities, and racial/ethnic and neighbourhood income quartiles. A)** Stratified by racial/ethnic groups and adjusted by ZIP code median household income quartiles. **B)** Stratified by ZIP code median household income quartiles and adjusted by racial/ethnic groups. OR: odds ratio; CI: confidence interval; TIA: transient ischemic attack.

**Figure 4: Forest Plots showing a sensitivity analysis to determine the effect that adjustment by racial/ethnic and neighbourhood income quartiles had on their corresponding model for in-hospital major adverse events.** Multilevel multivariable regression analysis adjusted by age, sex, and relevant comorbidities. **A)** Stratified by racial/ethnic groups. **B)** Stratified by ZIP code median household income quartiles. OR: odds ratio; CI: confidence interval; TIA: transient ischemic attack.

**Figure 5: Forest plot showing multilevel multivariable regression analysis for comorbidities associated with in-hospital major adverse events. A)** Adjusted by racial/ethnic groups. **B)** Adjusted by median household income quartiles. OR: odds ratio; CI: confidence interval.