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Racial, ethnic and socioeconomic disparities in patients undergoing transcatheter mitral edge-to-edge repair

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ABSTRACT

Background: Transcatheter mitral edge-to-edge repair (TEER) is an increasingly common procedure performed on patients with severe mitral regurgitation. This study assessed the impact of race/ethnicity and socioeconomic status on in-hospital complications after TEER.

Methods: Cohort-based observational study using the National Inpatient Sample between October 2013 and December 2018. The population was stratified into 4 groups based on race/ethnicity and quartiles of neighborhood income levels. The primary outcome was in-hospital complications, defined as the composite of death, bleeding, cardiac and vascular complications, acute kidney injury, and ischemic stroke.

Results: 3795 hospitalizations for TEER were identified. Patients of Black and Hispanic race/ethnicity comprised 7.4% and 6.4%, respectively. We estimated that White patients received TEER with a frequency of 38.0/100,000, compared to 29.7/100,000 for Blacks and 30.5/100,000 for Hispanics. In-hospital complications occurred in 20.2% of patients and no differences were found between racial/ethnic groups ($P = 0.06$). After multilevel modelling, Black and Hispanic patients had similar rate of overall in-hospital complications (OR: 0.84, CI:0.67–1.05 and OR: 0.84, CI:0.66–1.07, respectively) as compared to White patients, however, higher rates of death were observed in Black patients. Individuals living in income quartile-1 had worse in-hospital outcomes as compared to quartile-4 (OR: 1.19, CI:0.99–1.42).

Conclusion: In this study assessing racial/ethnic disparities in TEER outcomes, aged-adjusted race/ethnicity minorities were less underrepresented as compared to other structural heart interventions. Black patients experienced a higher rate of in-hospital death, but similar overall rate of post-procedural adverse events as compared to White patients. Lower income levels appear to negatively impact on in-hospital outcomes.

Brief summary: This study appraises race/ethnic and socioeconomical disparities in access and outcomes following transcatheter mitral edge-to-edge repair. Racial minority groups were less underrepresented as compared to other structural heart interventions. While Black patients experienced a higher rate of in-hospital

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death, they experienced similar overall rate of post-procedural complications compared to White patients. Lower income levels also appeared to negatively impact on outcomes.

1. 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 up to 9.3% of individuals over the age of 75 [1]. MR is most often primary from degenerative pathology of the leaflets but can also occur secondary to left ventricular or atrial pathology.

Increased societal interest in healthcare equity has focused new attention on racial/ethnic disparities in many areas of medicine [2]. Racial disparities in several aspects of valvular heart disease management have been well-documented, including echocardiographic surveillance [3] as well as receipt of aortic valve surgery [4]. Racial/ethnic minorities often have more pre-procedural comorbidities and are less likely to receive state-of-the art mitral valve repair as compared to mitral valve replacement [5,6].

In recent years, transcatheter mitral edge-to-edge repair (TEER) with MitraClip (Abbott Structural, Menlo Park, CA) has emerged as an effective catheter-based therapy for patients presenting with both primary and secondary MR. [7] Whether racial/ethnic disparities extend to TEER has not been clearly established; therefore, given the increasing frequency of this procedure, the question regarding potential differences in patient populations is critical to assess. Hence, we aimed to explore the impact of race/ethnic and socioeconomic status on the rate of death and in-hospital complications among individuals undergoing TEER with MitraClip.

2. Methods

The National Inpatient Sample (NIS) was used 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 [8]. The NIS database was queried to identify hospitalizations for TEER between October 2013 and December 2018.

We used the ICD 9th Revision (ICD-9) procedure code 35.97 (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 TEER during hospitalization. Patient demographic variables were extracted, including sex, race, and median neighborhood household income according to the ZIP code imputed from Census data, 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 comorbidities were assessed using the Charlson comorbidity index (CCI) and Elixhauser comorbidity score (ECS) both of which are widely-used scores to quantify comorbidity burden in retrospective studies of different racial/ethnic groups [9,10]. Two authors (R.T.S. and S.S.S.) independently verified the ICD-9 and ICD-10 codes that corresponded to each comorbidity component of the scores as well as outcomes of interest (Supplemental Table 1 and 2), and any disagreements in exclusion or exclusion of ICD codes were discussed with a third individual (R.B.).

2.1. Study outcomes

The primary outcome of interest was total major adverse events, defined as the composite of in-hospital death; bleeding, cardiac and vascular complications; acute kidney injury (AKI); and 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 in-hospital complications were identified with the same process as was used to identify comorbidity codes.

2.2. Statistical analysis

The cohort of hospitalizations for TEER was stratified by self-reported race/ethnicity and by quartiles of median ZIP code household income. Three racial groups with limited numbers of patients were combined into a single (“Other”) group to facilitate the analysis. This group comprised 91 patients of Asian/Pacific Islander ethnicity, 16 Native Americans, and 90 “other race” patients. The other three groups (White, Black, and Hispanic) were left unchanged for the study. Median ZIP code incomes were 0-$45,999, $44,000–$58,999, $56,000–$78,999 and above $79,000 for quartiles 1 to 4 in 2018, respectively. Urban location was defined as counties in metropolitan areas of 50,000 people or more.

Initial analyses were conducted comparing the baseline characteristics of patients in each racial/ethnic group and neighborhood ZIP code income quartile. 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 summarized categorical variables as counts and proportions and compared groups used chi-square or Fisher exact test. Continuous variables were summarized as median [interquartile range (IQR)] and were analyzed with the Kruskal-Wallis test. Post-hoc pair-wise group comparisons of continuous variables were evaluated with the Siegel-Tukey test. The Cochran-Armitage trend test was used for detecting linear trends for changes in the number of LAAC procedures among individuals of White versus non-White race/ethnicity over the time. 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. These logistic regression models were used to assess the associations between race and income quartiles, and in-hospital major adverse events, and have all been adjusted for age, sex, type of admission (elective/non-elective) and relevant comorbidities (Supplemental Table 3). Adjustment variables 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. The reference groups for all models were white patients and those from income quartile-4 (highest median income level). The results from these models are displayed as odds ratios (OR) with 95% confidence intervals (CI). All *P*-values are 2-sided with a significance threshold of <0.05. All statistical analyses were conducted using R version 4.0.3 [12]. Institutional review board and ethics committee approval was obtained from The Western University Health Science Research Ethics Board.

3. Results

3.1. Baseline patient characteristics

A total of 4071 hospitalizations for TEER were identified, of which 221 (5.4%) were excluded for missing race/ethnicity data and 61 (1.5%) for missing income quartile data, resulting in a final population of 3795 patients. Among this cohort, women comprised 1781 (47%) of the patients, and 3067 (81%) were of White race/ethnicity, with Black and Hispanic patients comprising 7.4% and 6.4% of patients, respectively. Most (92%) of the TEER procedures were performed in urban-teaching hospitals.

To assess the frequency with which patients from each racial/ethnic group underwent TEER, we divided the number of patients in each group by the total population of elderly (over the age 65) Americans of each race/ethnicity based on 2018 U.S. Department of Health and Human Services data [13]. After adjustment for sampling design and discharge weights, White patients received TEER with an estimated frequency of 38.0/100,000 over the study period, compared to 29.7/100,000 for Blacks and 30.5/100,000 for Hispanics.

The baseline characteristics of patients stratified by race/ethnic groups and neighborhood median income quartiles are outlined in Table 1 and Table 2, respectively. Whites undergoing TEER were significantly older (81 [74.5–86] years, versus 72 [62–80] for Blacks and 79 [68–85] for Hispanics, $P < 0.001$). Significant differences were observed in the age of Black versus White patients ($P < 0.001$) and Hispanic versus White patients ($P = 0.02$).

Despite their younger age, Black patients had higher burden of pre-procedural comorbidities, with the CCI and ECS scores being significantly different between races (P < 0.001 for CCI, P = 0.02 for ECS). These differences 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 Blacks.

Differences were also found in the socioeconomic makeup of patients in each racial/ethnic group, with 50% of Blacks living in the lowest median household income neighborhoods quartile, as compared to 30% of Hispanics and 19% of Whites ($P < 0.001$). Median age rose steadily from the quartile-1 to quartile-4 (78 [71–84] versus 82 [75–86], P < 0.001), and patients in the lower income quartiles had g higher rates of key-comorbidities rendering higher median CCI scores ($P = 0.001$). The proportion of patients living in rural regions also declined precipitously as income quartile rose (31% in quartile-1 versus 1.1% in quartile-4, $P < 0.001$). Interestingly, even though patients living in lower income neighborhoods had greater medical complexity, hospitalization costs were over $3300 higher in patients living in quartile-4 neighborhoods as compared to quartile-1 (P < 0.001) despite no differences in median length-of-stay ($P = 0.82$).

The yearly trends in number of TEER procedures performed on patients of White and non-White race/ethnicity was analyzed using the Cochrane-Armitage test in Supplemental Fig. 1, and no significant differences were found ($P_{trend} = 0.71$). Moreover, the distribution of TEER procedures performed on patients living in urban versus rural regions also did not change over time ($P = 0.25$), Supplemental Fig. 1.

3.2. Racial/ethnic differences and clinical outcomes

The rates of in-hospital complications stratified by race/ethnicity and neighborhood income quartiles are shown in Table 1 and Table 2, respectively. In-hospital major adverse events occurred in 766 (20.2%) patients, driven primarily by 535 (14.1%) acute kidney injury events. While in-hospital complication rates did not differ between neighborhood income quartiles ($P = 0.27$), there was a trend towards differences between racial/ethnic groups ($P = 0.06$), with Blacks having the highest adverse event rate as compared to Whites (25% versus 19%, $P = 0.03$), followed by Hispanics (24% versus 19%, $P = 0.12$). Bonferroni correction for multiple comparisons revealed an absence of statistical significance for Black patients. A total of 67 (1.8%) patients died in-hospital, and while death rates differed between racial/ethnic groups ($P = 0.043$), no differences were found between income quartiles ($P = 0.89$). The rate of death was highest in patients of "other" and Hispanic race/ethnicity (3.9% in "other" versus 2.9% in Hispanics versus 1.5% in Whites).

3.3. Factors associated with in-hospital adverse events

After multilevel modelling, there were no differences in the overall rate of in-hospital major adverse events among patients of White versus Black (OR: 0.84, CI: 0.67–1.05) and White versus Hispanic (OR: 0.84, CI: 0.66–1.07) race/ethnicity; however, individuals in the "other" race/ethnicity did experience higher complication rates (OR: 1.36, CI: 1.06–1.74, $P = 0.01$), Fig. 1-A. Among the individual in-hospital major adverse events, significant differences included higher rates of bleeding among individuals of "other" race/ethnicity (OR: 1.84, CI: 1.10–3.07); cardiac complications among Hispanics (OR: 1.50, CI: 1.02–2.20, $P = 0.04$); and stroke/TIA among Blacks (OR: 11.84, CI: 3.33–42.12, $P < 0.001$). Notably, higher adjusted rates of death were observed among patients of Black (OR: 2.92, CI: 1.11–7.72, $P = 0.03$) and "other" race/ethnicity patients (OR: 8.11, CI: 3.74–17.55, P < 0.001), Fig. 1-A. Among median household income quartiles, individuals living in quartile-2 experienced less overall in-hospital major adverse events compared to quartile-4 (OR: 0.78, CI: 0.65–0.92, $P = 0.004$), Fig. 1-B.

The effect that adjusting for racial/ethnic groups and neighborhood income quartiles had on their corresponding models was analyzed in an ad hoc sensitivity analysis. For these models, in-hospital adverse events were adjusted only by age, sex, type of admission and relevant comorbidities. Three differences were found in the models stratified by racial/ethnic groups (Fig. 1-C): bleeding complication rates among Black patients gained statistical significance ($P = 0.03$); and bleeding complications in "other" race/ethnicity patients and AKI among Black patients lost statistical significance ($P = 0.07$ and $P = 0.16$, respectively). Similarly, two differences were found in the income-stratified models, and most prominently, the bleeding rate between quartile-1 and quartile-4 gained statistical significance (P = 0.03), Fig. 1-D.

Several comorbidities were associated with overall in-hospital complications. Specifically, the presence of coagulopathy (OR: 7.03, CI: 5.88–8.40, $P < 0.001$), renal disease (OR: 3.63, CI: 3.22–4.10, P < 0.001) and peripheral vascular disease (OR: 1.67, CI: 1.43–1.95, P < 0.001) conferred the highest risk after adjustment for race/ethnicity and income quartiles (Fig. 2-A). Sensitivity analyses adjusting only by race/ethnicity (without income, Fig. 2-B) and by income quartile (without race/ethnicity, Fig. 2-C) yielded nearly identical results.

Given the low numbers of adverse events among patients of racial/ethnic minorities, the 3-non-white racial/ethnic groups were pooled to determine the overall differences in total complication rates (Fig. 2-D). In this analysis, the rate of cardiac and vascular complications, stroke/TIA and death were all higher among non-white patients ($P < 0.01$ for all); however, the rate of AKI was lower ($P = 0.04$). Further sensitivity analysis was performed by removing income quartiles, then, stroke ($P = 0.15$) and AKI ($P = 0.14$) lost their lost statistical significance (Fig. 2-E).

4. Discussion

In this study assessing racial/ethnic disparities in 3795 hospitalizations for TEER, 19% were of non-White race/ethnicity minorities. Over 50% of Blacks receiving TEER lived in neighborhoods in the lowest household income quartile, and Blacks and Hispanics had a median age that was 9 and 2 years younger than Whites, respectively. Despite these age differences, Blacks still had a higher burden of pre-procedural comorbidities. In-hospital major adverse events occurred in 20.2% of patients, driven primarily by the occurrence of AKI. After adjustments for pre-procedural differences, Blacks had a similar rate of overall in-hospital complications but higher rate of death, while among Hispanics, both death and in-hospital complication rates were similar to that of Whites. Low socioeconomic status also appears to negatively impact in-hospital outcomes. Graphical Abstract displays a summary of these findings.

Table 1
Baseline characteristics of the study population stratified by race.

Patient characteristics	All n = 3795	White n = 3067	Black n = 280	Hispanic n = 243	Other n = 205	P-value	Adjusted P-value*
Age (years)	81 (73–86)	81 (74.5–86)	72 (62–80)	79 (68–85)	79 (71–84)	**<0.001**	**<0.001**
Sex, Male	2014 (53)	1664 (54)	117 (42)	122 (50)	111 (54)	**<0.001**	**<0.001**
Elective admission†	2919 (77)	2385 (78)	203 (72)	171 (72)	160 (78)	**0.03**	**0.02**
Median household income							
0-25th percentile	842 (22)	597 (19)	141 (50)	72 (30)	32 (16)		
26-50th percentile	885 (23)	723 (24)	66 (24)	61 (25)	35 (17)	**<0.001**	**<0.001**
51-75th percentile	1040 (27)	871 (28)	51 (18)	65 (27)	53 (26)		
76-100th percentile	1028 (27)	876 (29)	22 (8)	45 (19)	85 (41)		
Patient location							
Urban‡	3243 (85)	2574 (84)	259 (92)	223 (92)	187 (91)	**<0.001**	**<0.001**
Rural	552 (15)	493 (16)	21 (7.5)	20 (8.2)	18 (8.8)		
Hospital teaching status and location							
Rural	<10 (0.2)	<10 (0.3)	<10 (0)	<10 (0)	<10 (0)		
Urban non-teaching	290 (7.6)	242 (7.9)	18 (6.4)	20 (8.2)	10 (4.9)		
Urban teaching	3496 (92)	2816 (92)	262 (94)	223 (92)	195 (95)	0.50	0.34
Hospital bed-size							
Small	211 (5.6)	173 (5.6)	15 (5.4)	15 (6.2)	<10 (3.9)		
Medium	702 (18)	607 (20)	50 (18)	23 (9.5)	22 (11)		
Large	2882 (76)	2287 (75)	215 (77)	205 (84)	175 (85)	**<0.001**	**<0.001**
Primary payer§							
Medicare	3314 (87)	2731 (89)	219 (78)	193 (79)	171 (83)		
Medicaid	90 (2.4)	40 (1.3)	23 (8.2)	19 (7.8)	<10 (3.9)	**<0.001**	**<0.001**
Private insurance	333 (8.8)	253 (8.3)	30 (11)	26 (11)	24 (12)		
Other	55 (1.5)	41 (1.3)	<10 (2.5)	<10 (2.1)	<10 (1.0)		
Comorbidities							
Dyslipidemia	2299 (61)	1867 (61)	165 (59)	143 (59)	124 (60)	0.86	0.86
Renal disease	1399 (37)	1073 (35)	149 (53)	99 (41)	78 (38)	**<0.001**	**<0.001**
Previous CABG	860 (23)	723 (24)	31 (11)	60 (25)	46 (22)	**<0.001**	**<0.001**
Previous PCI	763 (20)	629 (21)	53 (19)	43 (18)	38 (19)	0.63	0.62
Hypertension	3127 (82)	2489 (81)	250 (89)	210 (86)	178 (87)	**<0.001**	**<0.001**
Diabetes mellitus	993 (26)	711 (23)	104 (37)	108 (44)	70 (34)	**<0.001**	**<0.001**
Obesity	373 (9.8)	276 (9)	48 (17)	37 (15)	12 (5.9)	**<0.001**	**<0.001**
Smoking	1315 (35)	1075 (35)	109 (39)	74 (30)	57 (28)	**0.03**	**0.03**
Congestive heart failure	3169 (84)	2532 (83)	255 (91)	209 (86)	173 (84)	**0.002**	**0.002**
Myocardial infarction	586 (15)	462 (15)	49 (18)	45 (19)	30 (15)	0.38	0.37
Peripheral vascular disease	480 (13)	399 (13)	33 (12)	27 (11)	21 (10)	0.54	0.54
Cerebrovascular disease	517 (14)	422 (14)	43 (15)	25 (10)	27 (13)	0.38	0.38
Valvular disease	3395 (89)	2746 (90)	251 (90)	222 (91)	176 (86)	0.29	0.28
COPD	1067 (28)	866 (28)	110 (39)	45 (19)	46 (22)	**<0.001**	**<0.001**
Rheumatic disease	157 (4.1)	120 (3.9)	13 (4.6)	17 (7)	<10 (3.4)	0.13	0.12
Liver disease	101 (2.7)	68 (2.2)	11 (3.9)	12 (4.9)	10 (4.9)	**0.005**	**0.005**
Hypothyroidism	684 (18)	590 (19)	31 (11)	37 (15)	26 (13)	**<0.001**	**<0.001**
Coagulopathy	344 (9.1)	272 (8.9)	23 (8.2)	23 (9.5)	26 (13)	0.30	0.30
Cancer	137 (3.6)	120 (3.9)	<10 (1.8)	<10 (2.9)	<10 (2.4)	0.23	0.20
Anemia	417 (11)	295 (9.6)	63 (22)	39 (16)	20 (9.8)	**<0.001**	**<0.001**
Depression	266 (7)	217 (7.1)	25 (8.9)	14 (5.8)	10 (4.9)	0.31	0.31
Charlson comorbidity index	3 (1–4)	3 (1–4)	3 (2–5)	2 (1–4)	3 (2–4)	**<0.001**	**<0.001**
Elixhauser comorbidity score	13 (9–17)	13 (9–17)	14 (10–17)	12 (9–16)	14.5 (11–18)	**0.03**	**0.02**
Year of procedure							
2013 (October–December)	22 (0.6)	18 (0.6)	<10 (0.7)	<10 (0.4)	<10 (0.5)		
2014 (January–December)	207 (5.5)	166 (5.4)	15 (5.4)	11 (4.5)	15 (7.3)		
2015 (January–December)	504 (13)	404 (13)	29 (10)	35 (14)	36 (18)	0.45	0.44
2016 (January–December)	751 (20)	603 (20)	67 (24)	38 (16)	43 (21)		
2017 (January–December)	1020 (27)	836 (27)	73 (26)	66 (27)	45 (22)		
2018 (January–December)	1291 (34)	1040 (34)	94 (34)	92 (38)	65 (32)		
In-hospital adverse events							
Total major adverse events‖	766 (20)	593 (19)	69 (25)	57 (24)	47 (23)	0.06	0.06
Bleeding complications	98 (2.6)	79 (2.6)	<10 (2.5)	<10 (1.6)	<10 (3.9)	0.52	0.52
Cardiac complications	188 (5.0)	140 (4.6)	14 (5.0)	18 (7.4)	16 (7.8)	0.05	0.05
Vascular complications	41 (1.1)	31 (1.0)	<10 (0.4)	<10 (1.6)	<10 (2.4)	0.11	0.12
Stroke/TIA	28 (0.7)	23 (0.7)	<10 (1.4)	0 (0)	<10 (0.5)	0.29	0.28
Acute kidney injury	535 (14)	414 (14)	48 (17)	42 (17)	31 (15)	0.15	0.15
Death	67 (1.8)	47 (1.5)	<10 (1.8)	<10 (2.9)	<10 (3.9)	**0.045**	**0.043**
Length of stay (days, median)	2 (1–4)	2 (1–4)	3 (1–7)	3 (1–6)	2 (1–5)	**<0.001**	**<0.001**
<2 day	1445 (38)	1203 (39)	86 (31)	68 (28)	88 (43)	**<0.001**	**<0.001**
≥2 day	2350 (62)	1864 (61)	194 (69)	175 (72)	117 (57)		
Total index cost (USD)	41,665 (31,445-55,723)	41,473 (31,267-55,366)	42,071 (30,384-56,755)	42,045 (32,742-54,730)	44,597 (35,552-60,705)	**0.03**	**0.02**

Values are expressed as median (interquartile range) or counts (%) unless otherwise noted. Exact counts for variables with <10 patients are not detailed as per the Healthcare Cost and Utilization Project data use agreement. CABG: coronary artery bypass surgery. PCI: percutaneous coronary intervention. COPD: Chronic obstructive pulmonary disease. *Adjusted P-values for each variable were computed from adjusting sampling design by discharge-level weights, cluster and strata. †Type of admission was missing in 0.4%. ‡Urban location was defined as counties in metropolitan areas of >50,000. §Primary payer was missing in 0.1%. ‖Percentages may not add up to 100% since several patients experienced more than one complication. ¶Total cost was missing 0.6%.

Table 2
Baseline characteristics of the study population stratified by income quartile.

Patient characteristics	All n = 3795	Quartile 1 *n* = 842	Quartile 2 *n* = 885	Quartile 3 *n* = 1040	Quartile 4 *n* = 1028	P-value	Adjusted P-value*
Age (years)	81 (73–86)	78 (71–84)	80 (73–86)	81 (74–86)	82 (75–86)	**<0.001**	**<0.001**
Sex, Male	2014 (53)	428 (51)	449 (51)	571 (55)	566 (55)	0.08	0.08
Elective admission†	2919 (77)	633 (76)	679 (77)	800 (77)	807 (79)	0.49	0.49
Race/ethnic group							
White	3067 (81)	597 (71)	723 (82)	871 (84)	876 (85)		
Black	280 (7.4)	141 (17)	66 (7.5)	51 (4.9)	22 (2.1)	**<0.001**	**<0.001**
Hispanic	243 (6.4)	72 (8.6)	61 (6.9)	65 (6.2)	45 (4.4)		
Other	205 (5.4)	32 (3.8)	35 (4)	53 (5.1)	85 (8.3)		
Patient location							
Urban‡	3243 (85)	579 (69)	682 (77)	965 (93)	1017 (99)	**<0.001**	**<0.001**
Rural	552 (15)	263 (31)	203 (23)	75 (7.2)	11 (1.1)		
Hospital teaching status and location							
Rural	<10 (0.2)	<10 (0.4)	<10 (0.5)	<10 (0.2)	<10 (0)		
Urban non-teaching	290 (7.6)	65 (7.7)	80 (9)	65 (6.2)	80 (7.8)		
Urban teaching	3496 (92)	774 (92)	801 (91)	973 (94)	948 (92)	0.12	**0.01**
Hospital bed-size							
Small	211 (5.6)	64 (7.6)	52 (5.9)	58 (5.6)	37 (3.6)		
Medium	702 (18)	148 (18)	173 (20)	174 (17)	207 (20)		
Large	2882 (76)	630 (75)	660 (75)	808 (78)	784 (76)	**0.005**	**0.003**
Primary payer§							
Medicare	3314 (87)	725 (86)	772 (87)	912 (88)	905 (88)		
Medicaid	90 (2.4)	35 (4.2)	27 (3.1)	18 (1.7)	10 (1)	**<0.001**	**0.002**
Private insurance	333 (8.8)	66 (7.8)	72 (8.1)	92 (8.9)	103 (10)		
Other	55 (1.5)	16 (1.9)	13 (1.5)	17 (1.6)	<10 (0.9)		
Comorbidities							
Dyslipidemia	2299 (61)	518 (62)	536 (61)	631 (61)	614 (60)	0.89	0.89
Renal disease	1399 (37)	343 (41)	341 (39)	358 (34)	357 (35)	**0.01**	**0.01**
Previous CABG	860 (23)	209 (25)	213 (24)	229 (22)	209 (20)	0.08	0.08
Previous PCI	763 (20)	176 (21)	178 (20)	211 (20)	198 (19)	0.85	0.85
Hypertension	3127 (82)	723 (86)	715 (81)	858 (82)	831 (81)	**0.02**	**0.02**
Diabetes mellitus	993 (26)	262 (31)	229 (26)	288 (28)	214 (21)	**<0.001**	**<0.001**
Obesity	373 (9.8)	93 (11)	106 (12)	92 (8.8)	82 (8)	**0.01**	**0.01**
Smoking	1315 (35)	291 (35)	312 (35)	349 (34)	363 (35)	0.83	0.83
Congestive heart failure	3169 (84)	722 (86)	753 (85)	857 (82)	837 (81)	**0.03**	**0.03**
Myocardial infarction	586 (15)	157 (19)	140 (16)	138 (13)	151 (15)	**0.01**	**0.01**
Peripheral vascular disease	480 (13)	110 (13)	122 (14)	115 (11)	133 (13)	0.30	0.30
Cerebrovascular disease	517 (14)	124 (15)	118 (13)	134 (13)	141 (14)	0.70	0.70
Valvular disease	3395 (89)	737 (88)	806 (91)	921 (89)	931 (91)	**0.046**	**0.04**
COPD	1067 (28)	276 (33)	267 (30)	275 (26)	249 (24)	**<0.001**	**<0.001**
Rheumatic disease	157 (4.1)	21 (2.5)	44 (5)	49 (4.7)	43 (4.2)	**0.03**	**0.04**
Liver disease	101 (2.7)	30 (3.6)	26 (2.9)	19 (1.8)	26 (2.5)	0.12	0.12
Hypothyroidism	684 (18)	153 (18)	166 (19)	183 (18)	182 (18)	0.91	0.91
Coagulopathy	344 (9.1)	60 (7.1)	94 (11)	89 (8.6)	101 (9.8)	0.06	0.06
Cancer	137 (3.6)	26 (3.1)	34 (3.8)	34 (3.3)	43 (4.2)	0.56	0.55
Anemia	417 (11)	99 (12)	107 (12)	107 (10)	104 (10)	0.40	0.40
Depression	266 (7)	62 (7.4)	54 (6.1)	79 (7.6)	71 (6.9)	0.60	0.61
Charlson comorbidity index	3 (1–4)	3 (2–5)	3 (2–4)	2 (1–4)	2 (1–4)	**<0.001**	**<0.001**
Elixhauser comorbidity score	13 (9–17)	13 (9–18)	13 (9–17)	13 (9–17)	12.5 (9–17)	0.40	0.40
Year of procedure							
2013 (October–December)	22 (0.6)	<10 (0.2)	<10 (0.8)	<10 (0.7)	<10 (0.6)		
2014 (January–December)	207 (5.5)	51 (6.1)	52 (5.9)	59 (5.7)	45 (4.4)		
2015 (January–December)	504 (13)	114 (14)	103 (12)	141 (14)	146 (14)	0.32	0.31
2016 (January–December)	751 (20)	191 (23)	180 (20)	195 (19)	185 (18)		
2017 (January–December)	1020 (27)	218 (26)	234 (26)	284 (27)	284 (28)		
2018 (January–December)	1291 (34)	266 (32)	309 (35)	354 (34)	362 (35)		
In-hospital adverse events							
Total major adverse events‖	766 (20)	183 (22)	160 (18)	209 (20)	214 (21)	0.27	0.27
Bleeding complications	98 (2.6)	19 (2.3)	11 (1.2)	36 (3.5)	32 (3.1)	**0.01**	**0.01**
Cardiac complications	188 (5.0)	38 (4.5)	37 (4.2)	56 (5.4)	57 (5.5)	0.45	0.45
Vascular complications	41 (1.1)	<10 (0.7)	<10 (0.7)	14 (1.3)	15 (1.5)	0.21	0.22
Stroke/TIA	28 (0.7)	<10 (0.6)	<10 (0.6)	<10 (0.8)	10 (1.0)	0.71	0.71
Acute kidney injury	535 (14)	137 (16)	121 (14)	137 (13)	140 (14)	0.23	0.23
Death	67 (1.8)	17 (2.0)	14 (1.6)	17 (1.6)	19 (1.8)	0.89	0.89
Length of stay (days)	2 (1–4)	2 (1–5)	2 (1–4)	2 (1–4.25)	2 (1–4)	0.82	0.82
<2 day	1445 (38)	306 (36)	336 (38)	398 (38)	405 (39)	0.60	0.60
≥2 day	2350 (62)	536 (64)	549 (62)	642 (62)	623 (61)		
Total index cost (USD)	41,665 (31,445-55,723)	40,622 (30,587-53,686)	39,514 (29,964-51,032)	42,419 (32,084-55,864)	43,958 (33,605-59,603)	**<0.001**	**<0.001**

Values are expressed as median (interquartile range) or counts (%) unless otherwise noted. Exact counts for variables with <10 patients are not detailed as per the Healthcare Cost and Utilization Project data use agreement. CABG: coronary artery bypass surgery. PCI: percutaneous coronary intervention. COPD: Chronic obstructive pulmonary disease. *Adjusted P-values for each variable were computed from adjusting sampling design by discharge-level weights, cluster and strata. †Type of admission was missing in 0.4%. ‡Urban location was defined as counties in metropolitan areas of >50,000. §Primary payer was missing in 0.1%. ‖Percentages may not add up to 100% since several patients experienced more than one complication. ¶Total cost was missing 0.6%.

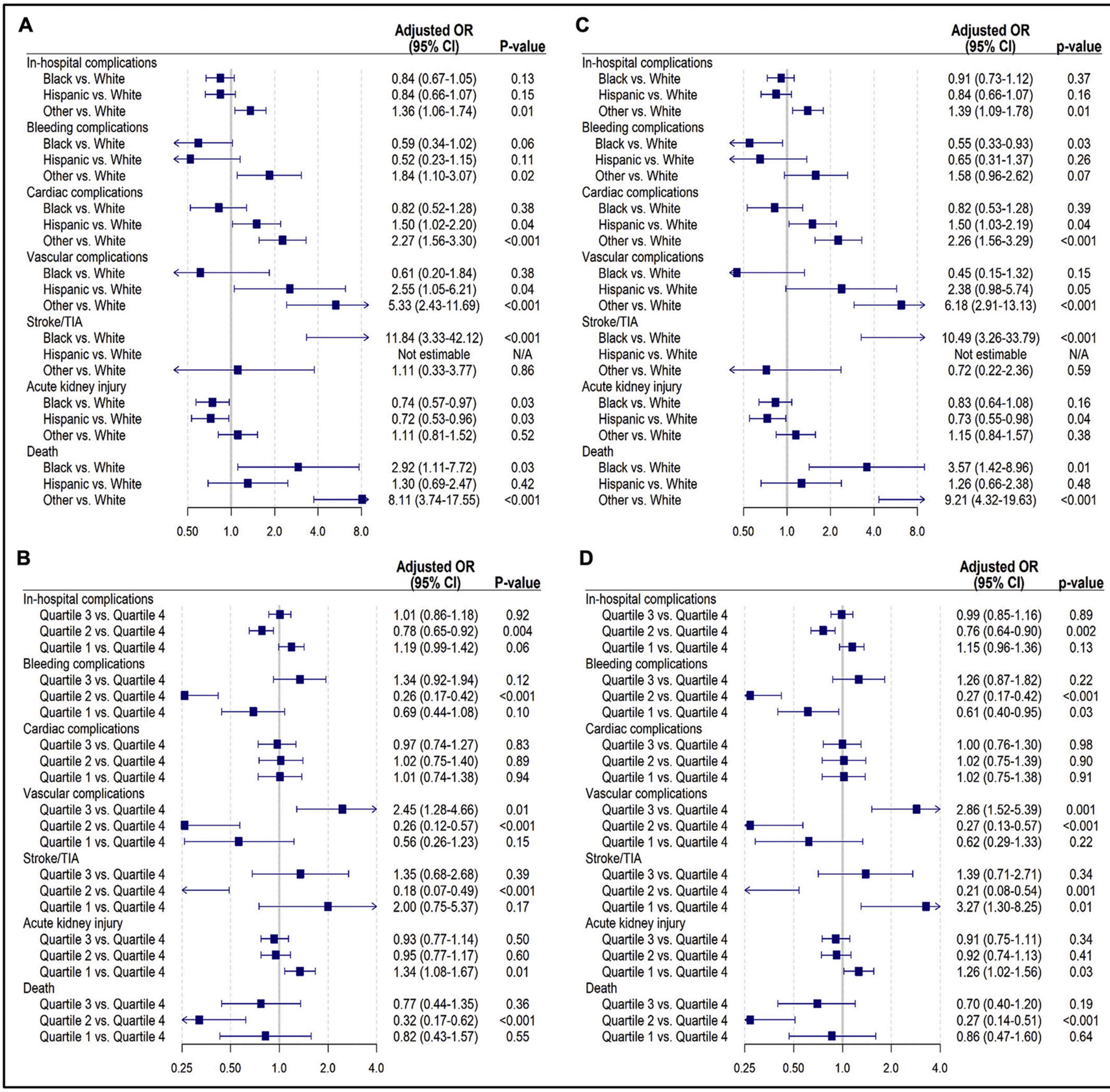

Fig. 1. Forest Plot showing multilevel multivariable regression analysis for in-hospital major adverse events adjusted by age, sex, admission type, and relevant comorbidities. **(A)** Stratified by racial/ethnic groups and adjusted by ZIP code median household income quartiles. **(B)** Stratified by ZIP code median household income quartiles and adjusted by racial/ethnic groups.
Sensitivity analysis to determine the effect that adjustment by racial/ethnic and neighborhood income quartiles had on their corresponding model for in-hospital major adverse events. Multilevel multivariable regression analysis adjusted by age, sex, admission type, and relevant comorbidities. **(C)** Stratified by racial/ethnic groups. **(D)** Stratified by ZIP code median household income quartiles. OR: odds ratio; CI: confidence interval; TIA: transient ischemic attack.

4.1. Racial disparities in TEER

Individuals of racial/ethnic minorities have historically been underrepresented in clinical trials [14], and the clinical trials that led to approval of TEER in the U.S. failed to report outcomes stratified by race/ethnicity [15,16]. It is also well-known that certain group of patients do not have equal access to care for valvular heart disease [17]. For instance, compared with their White counterparts, Blacks are less likely to be referred to cardiac surgery for treatment of aortic valve disease, although there appears to be no difference among Hispanics [18–20].

A report from the U.S. Department of Health and Human Services showed that in 2018, 23% of individuals aged 65 years and older were part of racial/ethnic minority populations, with Blacks and Hispanics accounting for 12% and 7%, respectively [13]. Our study identified that 19% of patients who underwent TEER were of non-White race/ethnicity, among these, Blacks and Hispanics accounted for 7.4% and 6.4%, respectively. Based on adjusted number of TEER performed per 100,000 individuals, Black and Hispanic patients less frequently received TEER than Whites; however, there appear to be less disparities in access to TEER compared to what has been reported for transcatheter aortic valve

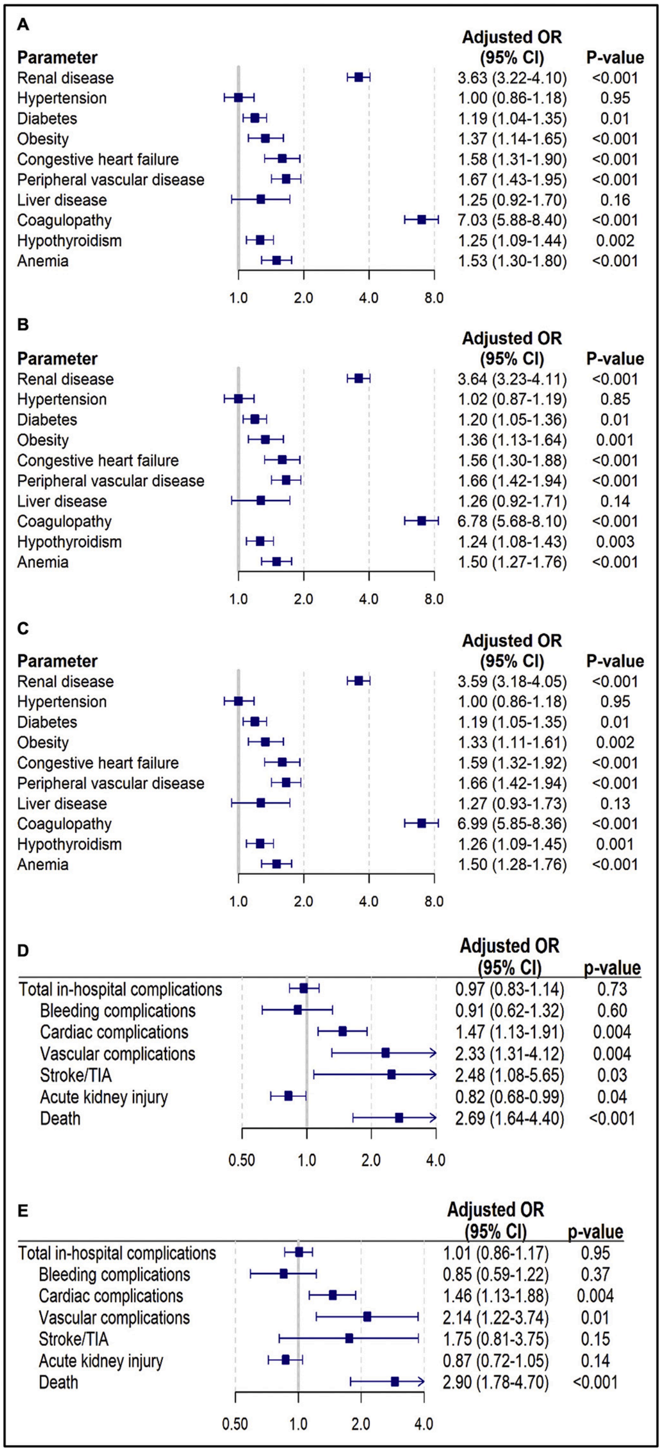

Fig. 2. Forest Plot showing multilevel multivariable regression analyses for comorbidities associated with in-hospital major adverse events. **(A)** Adjusted by age, sex, admission type, racial/ethnic groups, and ZIP code median household income quartiles. Sensitivity analysis adjusted by age, sex, admission type, and by racial/ethnic groups **(B)** and by ZIP code median household income quartiles **(C)**.
Stratified by white versus non-white populations. **(D)** Adjusted by age, sex, admission type, relevant comorbidities, and ZIP code median household income quartiles. **(E)** Adjusted by age, sex, admission type, and relevant comorbidities (without income quartile). OR: odds ratio; CI: confidence interval; TIA: transient ischemic attack.

implantation and left atrial appendage closure [10,21]. Furthermore, these estimates were aged-adjusted for the available U.S. Census data on individuals aged 65 years and older, hence, these disparities may decrease in a population of over 75 years old, which is the median age of patients undergoing TEER.

This finding of disparities in access to TEER may be related to racial differences in prevalence of significant MR. However, previous studies have demonstrated that mitral valve disorders occur with roughly equal prevalence regardless of race/ethnicity [18]. Unfortunately, only one single-centre study from England has assessed the racial differences in the prevalence of MR, with estimates of 6.7% of Whites and 5.3% of Blacks having moderate or severe MR. [22] Therefore, systemic inequalities may instead be resulting in individuals of racial minorities not receiving the indicated procedures with the same frequency.

Similar to our analysis, Elbadawi et al. [23] showed that the average age for Black patients undergoing TEER was over 10 years younger (67.2 versus 77.7 years), yet Blacks experienced higher rates of chronic kidney disease, pulmonary disease, and diabetes. Black patients often exhibit higher prevalence of comorbid conditions such as hypertension, diabetes, congestive heart failure, and chronic kidney disease. Blacks and Hispanics have also been shown to be younger in two studies on surgical MV repair and replacement, both of which found no significant differences in post-procedural outcomes between Black and White patients [6,24]. However, Hispanics have been previously identified to experience worse periprocedural outcomes when seeking care for various cardiac and non-cardiac diseases, including heart failure and a broad spectrum of surgical procedures [25,26].

Alkhouli et al. [21] published an analysis of race-stratified TEER outcomes using the NIS database from 2011 to 2016 which used weighted hospitalizations, the differences in mean ages between racial/ethnic groups was lower than our study and no significant differences in in-hospital outcomes were reported. The present study also shows that among both Black and Hispanic patients, the adjusted overall complication rate was 16% lower than in Whites, however, the interpretation of this result should be in the context of the relatively low event rates and, therefore, its inherent inability to detect statistically significant differences. The reasons for higher rates of death and other complications among non-white patients remain unclear. One hypothesis is that patients of racial minorities more frequently receive TEER at lower quality hospitals, as has been demonstrated in coronary artery bypass graft surgery [27]. However, while higher proportions of Black and Hispanic patients lived in urban neighborhoods, there were no significant differences in the proportion of patients treated at urban versus rural and teaching versus non-teaching hospitals, decreasing the likelihood that hospital factors are the cause. An additional factor could be racial disparities in health insurance, as the percentage of uninsured Blacks and Hispanics was 9.6% and 16.7% in 2019, respectively, as compared to 5.2% of Whites [28]. While most of the patients were elderly, and thus not using private health insurance, significant racial/ethnic differences were found in the primary hospitalization payer, and lower rates of health insurance in adulthood could have resulted in delayed cardiac care and more advanced disease.

Even though TEER is considered a zero-contrast procedure, we found an incidence of AKI of 14.1%, and this is in line with a recently published study of 721 patients [29]. There are multiple potential causes of post-procedural AKI, including transient hypotensive episodes during the procedure [30], along with pre- and post-procedural anemia, which has been found to be associated with AKI after transcatheter aortic valve implantation [31]. However, their exact contribution to complication rates have not been elucidated. Previous landmark trials [16,32] of TEER only reported need for hemodialysis, and so were not able to be used for comparison. Notably, no previous study has assessed the racial/ethnic differences in terms of AKI after TEER.

An additional finding is that patients of "other" race/ethnicity had a significantly higher rate of bleeding complications after adjustment. Given that Asian/Pacific Islander patients comprised almost half of this group, one hypothesis for this difference may be related to racial differences in anticoagulation during the TEER procedure or effect of post-procedural antithrombotic therapy. Previous research into this mechanism has been limited, and the optimal weight-based heparin dosing and activated clotting time target has previously been shown to be similar between white, Chinese, Malay and Indian patients [33]. However, an analysis of patients of various racial/ethnic groups undergoing coronary angiogram and intervention showed higher bleeding rates and prolonged radial hemostasis times among Japanese patients as compared to non-Japanese counterparts [34]. Nonetheless, given the limited nature of this data, it is difficult to draw firm conclusions as to causes.

In contrast to the body of evidence on racial/ethnic disparities, even less is known about the socioeconomic disparities surrounding mitral valve interventions. Vassileva et al. [35] previously reported that in-hospital mortality for surgical mitral valve repair was higher among patients of lower income quartiles. In this study, patients in quartile-2 had significantly lower complication rates and those in quartile-1 trended towards being significantly higher. Despite no differences in average length-of-stay, hospitalization costs increased as income quartile rose, and patients in quartile-4 had median hospitalization costs of over $3000 higher than those in quartile-1. Like the racial/ethnic group analysis, hospital quality and geographic location could explain the differences in hospitalization costs. However, while significant differences were found in hospital size and location/teaching status, the absolute differences were small, making the cause difficult to identify from in this study. Overall, individuals living in wealthier neighborhoods appear to have lower medical complexity but receive greater intensity of medical services, which is consistent with other analyses about the relationship of medical comorbidities versus utilization among disadvantaged groups [36].

4.2. Limitations

This study has several limitations. First, given that it is a retrospective analysis of the NIS database, it relies on the accuracy of ICD-9 and -10 coding for extrapolation of data, and coding errors could have occurred during data entry, representing a risk for ascertainment bias. Moreover, because there are still relatively few Blacks and Hispanics who underwent TEER, the relatively low rate of post-procedural events among the racial/ethnical minorities limits the statistical power of the models. Second, there are no ICD-9/10 codes for degenerative MR and functional MR, which are significantly different pathologies of mitral valve incompetence that could affect outcomes. However, TEER was only approved for degenerative MR during the study period. Third, data regarding the time between MR diagnosis and procedure date, and the use of guideline-directed medical and resynchronization treatments is missing; these data are important especially given the relatively low disparities in access to TEER itself. Fourth, complications post-TEER may also be impacted by other confounders that were not captured in the NIS database, including procedural time and type of anesthesia. Fifth this study is also limited to in-hospital complications, given the structure of NIS data, and longer-term outcomes and readmission rates are beyond the scope of this analysis. Finally, it is well established that insurance systems and health care access influence quality of care and equality of access opportunity; therefore, the implications of our findings, although reassuring to some extent, may not be generalized outside the U.S.

5. Conclusion

In this study assessing racial/ethnic disparities in TEER outcomes, aged-adjusted race/ethnicity minorities were less underrepresented as compared to other structural heart interventions. Black patients were younger, had the highest comorbidity burden, and experienced a higher rate of in-hospital death while similar rate of post-procedural adverse events as compared to White patients. Socioeconomic status was also found to have a negative impact, as patients in the lowest neighborhood income levels experienced higher number of complications as compared to those in the highest income level.

Author contributions

Each author has contributed to the present work as follows:

Robert Sparrow and Rodrigo Bagur: Conception and design of the study.

Robert Sparrow, Yun-Hee Choi and Rodrigo Bagur: 1) Acquisition, analysis and interpretation of data; 2) drafting of the manuscript; and 3) final approval of the manuscript submitted.

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Declaration of Competing Interest

Dr. Lindman has served on the scientific advisory board for Roche Diagnostics, has received research grants from Edwards Lifesciences and Roche Diagnostics, and has consulted for Medtronic. Dr. Tang is a consultant for Abbott, Medtronic and W. L. Gore & Associates. Dr. Kaneko is a consultant for Edwards Lifesciences, Medtronic, Abbott, 4C Medical, CardioMech and Cook Medical. The remaining authors have nothing to disclose inherent to the content of this manuscript.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcard.2021.09.037.

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