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ORIGINAL STUDIES

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Safety-net hospitals versus non-safety centers and clinical outcomes after trans-catheter aortic valve replacement

Muhammad Adil Sheikh MD[1] | Salil V. Deo MD[2] | Haris Riaz MD[3] | Sajjad Raza MD[4] | Salah E. Altarabsheh MD[5] | Brigid Wilson PhD[2] | Yakov Elgudin MD[3] | Brian Cmolik MD[2] | Marc Pelletier MD[6] | Alan H. Markowitz MD[6]

[1]Division of Hospital Medicine, Department of Internal Medicine, University of Michigan, Ann Arbor, Michigan

[2]Louis Stokes Cleveland VA Medical Center, Cleveland, Ohio

[3]Division of Cardiovascular Diseases, Cleveland Clinic Foundation, Cleveland, Ohio

[4]Precision Analytics, Boston, Massachusetts

[5]Department of Cardiac Surgery, Queen Alia Heart Institute, Amman, Jordan

[6]Division of Cardiac Surgery, University Hospitals, Cleveland, Ohio

Correspondence
Muhammad Adil Sheikh, MD, Division of Hospital Medicine, Department of Internal Medicine, University of Michigan, Ann Arbor, MI.
Email: masheikh@med.umich.edu

Abstract

Objective: To compare post-procedural outcomes of trans-catheter valve replacement (TAVR) among safety-net (SNH) and non-safety net hospitals (non-SNH).

Background: SNH treat a large population of un-insured and low income patients; prior studies report worse outcome at these centers. Results of TAVR at these centers is limited.

Methods: Adults undergoing TAVR at hospitals in the US participating in the National In-patient sample (NIS) database from January 2014 to December 2015 were included. A 1:1 propensity-matched cohort of patients operated at SNH and non-SNH institutions was analyzed, on the basis of 16 demographic and clinical co-variates. Main outcome was all-cause post-procedural mortality. Secondary outcomes included stroke, acute kidney injury and length of post-operative stay.

Results: Between 2014 and 2015, 41,410 patients (mean age 80 ± 0.11 years, 46% female) underwent TAVR at 731 centers; 6,996 (16.80%) procedures were performed at SNH comprising 135/731 (18.4%) of all centers performing TAVR. SNH patients were more likely to be female (49% vs. 46%, $p < .001$); admitted emergently (31% vs. 21%; $p < .001$; at the lowest quartile for household income (25% % vs. 20%; $p < .001$) and from minorities (Blacks 5.9% vs. 3.9%; Hispanic 7.2% vs. 3.2%).Adjusted logistic regression was performed on 6,995 propensity-matched patient pairs. Post-procedural mortality [OR 0.99(0.98–1.007); $p = .43$], stroke [OR 1.009(0.99–1.02); $p = .08$], acute kidney injury [OR 0.99(0.96–1.01); $p = .5$] and overall length of stay (6.9 ± 0.1 vs. 7.1 ± 0.2 days; $p = .57$) were comparable in both cohorts.

Conclusion: Post-procedural outcomes after TAVR at SNH are comparable to national outcomes and wider adoption of TAVR at SNH may not adversely influence outcomes.

KEYWORDS

aortic valve disease, health care outcomes, transcatheter valve implantation

1 | INTRODUCTION

Trans-catheter aortic valve replacement (TAVR) has revolutionized the management of patients with severe aortic stenosis. Although it was initially approved for patients with a prohibitive surgical risk, TAVR has now been shown to be at least as efficacious as surgical AVR across all pre-operative risks.[1] With expansion to the lower risk cohort, the number of TAVR procedures performed is expected to increase further and it has already surpassed SAVR in terms of procedural volume. Therefore, it is relevant to examine factors that can influence outcomes after TAVR. Safety net hospitals (SNH) are centers that serve an unusually high percentage of Medicaid and uninsured population thereby serving a potentially vulnerable patient population.[2] Some studies have reported poorer clinical outcome for multi-valve procedures and complex cardiac surgery in safety net centers when compared to non-safety net hospitals[3]; however, similar data on TAVR is lacking. Given the broad acceptance of TAVR for severe aortic stenosis, we queried a national database to compare post-procedural outcome for TAVR at safety net hospitals.

2 | METHODS

2.1 | Cohort selection

The National Inpatient Sample (NIS) database is the largest administrative all-payer database in the United States consisting of more than seven million annual admissions. It contains data from 46 States and the District of Columbia.[4] The data, developed as a complex stratified sample, contains 20% admissions from all participating hospitals nationwide.

Between January 2014 and December 2015, we identified admissions where TAVR was performed as the primary procedure. Important clinical co-morbidities viz. smoking status, dyslipidemia, prior myocardial infarction, atrial fibrillation, prior percutaneous intervention, prior CABG, chronic renal dysfunction, and dialysis dependence were identified. Hospital characteristics studied included hospital location (rural/urban) and geographical region (Midwest, South, East, West). Co-variates and clinical end-points were abstracted from provided International Classification of Diseases, Ninth Edition (ICD-9) and Tenth Edition (ICD-10) codes. We included both transapical and percutaneous TAVR, the relevant ICD-9 and ICD-10 codes used are listed in Table S1.

We studied differences in patient cohorts undergoing TAVR at SNH and non-SNH centers. Regional and hospital variation was also analyzed. We compared post-procedural outcome based on[1] in-hospital mortality[2] Major adverse clinical events viz. acute stroke, acute kidney injury[3] length of post-procedural stay.

2.2 | Statistical analysis

We initially determined the annual percentage of Medicaid and uninsured admissions for each participating hospital. From this, we then designated hospitals in the highest quartile as safety-net hospitals (SNH). The remaining were deemed non-safety net hospitals (non-SNH); this definition has been adopted in prior peer-reviewed publications.[3,5]

Statistical analysis was performed with R 3.5.2 (The R foundation for Statistical Computing).

National level results are presented by using weights provided in the data. Univariate comparison of baseline data between SNH and non-SNH centers was performed with the Chi^2 test (Scott Rao adjustment) or the two-tailed "t" test. Missing data in NIS is very rare.[6] Race (6.8%) was the only variable we encountered with missing data >0.3% (female gender—0.02%; elective admission—0.2%). For categorical data, the most common value was inserted in the missing fields. All continuous variables were complete and hence did not need to be imputed. We compared SNH status to obtain un-adjusted Odds Ratio (OR) for each end-point. Propensity matching was introduced as a robust technique to account for clinical confounders which impact outcome in observational data.[7] Hence, we created a 1:1 propensity matched subset from our study cohort for further analysis.

2.3 | Propensity score adjustment

Using multivariable weighted logistic regression, we obtained a propensity score (i.e., probability) for each patient to undergo the procedure at a SNH vs. non-SNH hospital. The co-variates included in the model were: age, sex, race, diabetes mellitus, congestive heart failure, carotid stenosis, prior CABG, prior stroke, prior percutaneous intervention, peripheral vascular disease, elective/non-elective admission status, chronic kidney disease, chronic obstructive pulmonary disease, hospital region, year of procedure, and weights provided for survey estimation of the data. Propensity scores derived from the logistic regression model were used to create a 1:1 matched dataset of SNH and non-SNH patients (Figure 1). We assessed model fit with bootstrapped pre- and post-match standardized differences (Figure 2).

Survey weighted logistic regression was performed to provide adjusted Odd's ratio (aOR) for each end-point studied. Analysis and reporting was conducted as per guidelines provided by the Agency for HealthCare Quality and Research (AHRQ).[4] Further details regarding

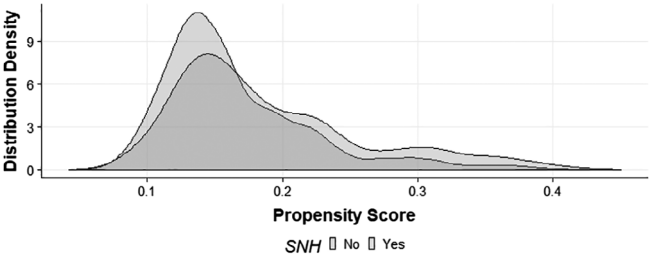

FIGURE 1 We calculated the propensity score (probability) of a patient in our study group to undergo TAVR at a safety-net center (SNH) versus a Non-SNH center. Adequate overlap in propensity scores permits appropriate 1:1 matching

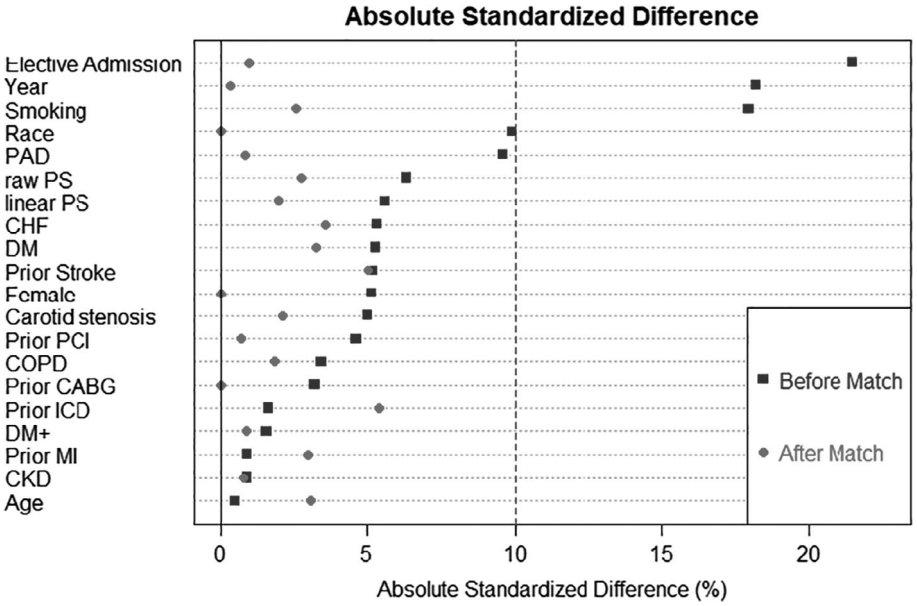

FIGURE 2 This figure presents the standardized difference in means between cohorts for each co-variate included in the multi-variable logistic regression model before and after matching. As demonstrated by the red circles, we observed significant overall improvement in standardized differences post-match

the multivariable regression model, standardized difference in study variables between cohorts and Rubin's rules for propensity analysis are provided in the online supplement.

The study was exempted from Institutional Board Review at Case Western Reserve University as it contained publicly available, patient de-identified data.

3 | RESULTS

Our study cohort consisted of 41,410 patients (mean age 80 ± 0.11 years, 46% female) who underwent TAVR between January 2014 and December 2015 at 731 centers nationwide. Transapical TAVR was performed in 4110/41410 (9.9%) TAVR patients. Of the total TAVR procedures, 6,994 (16.80%) procedures were performed at safety net centers. Safety net hospitals comprised 135/731 (18.4%) total hospitals performing TAVR during the study period. Average procedural volume during the 2-year period did not differ between SNH (115 procedures) and non-SNH (107 procedures).

Table 1 provides an overview of demographic information for TAVR procedures stratified by safety net status. Patients undergoing TAVR at SNH were more likely to be female (49% vs. 46%, $p < .001$), admitted emergently (31% vs. 21%; $p < .001$) and at the lowest quartile for household income (25% % vs. 20%; $p < .001$). Minority races (Blacks 5.9% vs. 3.9%; Hispanic 7.2% vs. 3.2%) formed a larger proportion of TAVR patients at SNH.

Prior to propensity matching, all-cause mortality was comparable at 2.4% and 2.8% in SNH and non-SNH hospitals, respectively [OR 0.99(0.98–1.004)]. Acute kidney injury ($p = .70$) and stroke rates ($p = .56$) were also similar between cohorts.

After propensity matching, we identified 6,995 patient-pairs distributed 1:1 in SNH and non-SNH hospitals. As demonstrated in Table 2, demographics in both cohorts were comparable with a significant improvement in standardized differences for each co-variate. The standardized difference in liner propensity scores improved significantly after matching (5.282 → 0.552).

In the propensity matched data, 2.4 ± 0.4% and 2.9 ± 0.4% died in the SNH and non-SNH centers, respectively. Stroke was observed in 2.2 ± 0.4% (SNH) vs. 1.2 ± 0.4% (non-SNH), while 10% patients from either cohort suffered acute kidney injury. In the matched dataset, studied end-points of post-procedural mortality [aOR 0.99 (0.98–1.007); $p = .43$], stroke [aOR 1.009 (0.99–1.02); $p = .08$], and acute kidney injury [aOR 0.99 (0.96–1.01); $p = .5$] were comparable (Figure 3). Overall length of stay was also similar between the groups (6.9 ± 0.1 vs. 7.1 ± 0.2 days; $p = .57$). We also observed that SNH status was not associated with increased mortality after transapical-TAVR [OR 0.52, 0.16–1.61; $p = .25$].

4 | DISCUSSION

Our propensity-matched analysis of approximately 7,000 patient pairs discovered important findings regarding performance of SNH in regards to TAVR. First, a substantial proportion (∼20%) of the TAVR procedures performed in the US are performed in SN hospitals. Second, the performance of SNH is comparable to non-safety net centers in regards to key clinical outcomes. This was true for not only for post-procedural mortality but also for other clinically relevant end points such as acute kidney injury and hospital length of stay. Third, the procedural volumes did not differ between the SNH and non SNH.

Safety-net hospitals (SNH) are defined by Institute of Medicine as those centers that "organize and deliver a significant level of health care and other related services to uninsured, Medicaid and other vulnerable patients". Almost 25% of all hospital admissions within the United States are in SNH; many of them are teaching academic

TABLE 1 Overview of TAVR procedures performed between January 2014 and December 2015 according to safety-net status

Variables studied	SNH *N* = 6,996	Non-SNH *N* = 34,414	*p* value	% Missing
Age (years)	80.85 (8.87)	80.89 (8.53)	.90	–
Females[a]	3,430 (49.0)	15,995 (46.5)	.07	.01%
Weekend admission	545 (7.2)	1,800 (5.2)	.06	–
Elective admission[a]	4,875 (69.7)	27,130 (79.1)	<.001	.24%
Carotid stenosis	310 (4.4)	1,900 (5.5)	.10	–
Congestive heart failure	2,675 (38.2)	14,055 (40.8)	.38	–
COPD	2,345 (33.5)	10,990 (31.9)	.26	–
Diabetes mellitus	2,225 (31.8)	10,110 (29.4)	.07	–
Complicated diabetes mellitus	480 (6.9)	2,230 (6.5)	.61	–
Dyslipidemia	3,330 (47.6)	16,965 (49.3)	.31	–
Peripheral arterial disease	1765 (25.2)	10,155 (29.5)	.009	–
Chronic kidney disease	2,465 (35.2)	12,270 (35.7)	.77	–
Prior stroke	505 (7.2)	2,010 (5.8)	.04	–
Prior CABG	855 (12.2)	4,570 (13.3)	.37	–
Prior ICD insertion	125 (1.8)	545 (1.6)	.58	–
Prior MI	550 (7.9)	2,625 (7.6)	.78	–
Prior PCI	885 (12.7)	3,840 (11.2)	.148	-
Race[a]			<.001	6.8%
White	5,365 (79.9)	28,620 (89.8)		
Black	395 (5.9)	1,230 (3.9)		
Hispanic	485 (7.2)	1,045 (3.2)		
Others	470 (7)	980 (3.1)		
Median household income quartile (adjusted for zip code)[a]			.06	1.4%
First quartile	1725 (25)	6,875 (20.3)		
Second quartile	1,685 (24.5)	8,905 (26.3)		
Third quartile	1,495 (21.7)	9,070 (26.7)		
Fourth quartile	1985 (28.8)	9,060 (26.7)		

Note: Categorical data presented as count (percentage); Continuous data presented as mean (standard errors).
Abbreviations: CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; ICD, implantable cardioverter defibrillator; MI, myocardial infarction; non-SNH, non-safety net hospitals; PCI, percutaneous intervention; SNH, Safety net hospital.
[a]Percentages calculated after excluding missing data.

centers in large metropolitan areas SNH have higher proportion of patients from racial and ethnic minorities and non-English-speaking residents. Patients residing in markets of SNH were found to be less educated, have lower incomes levels and more likely to live at or below the federal poverty line.[8] More than 10 million patients are cared for at SNH annually and these centers are vital providers of specialty services to the vulnerable population they serve. In addition, they also provide comprehensive primary care and training programs for future safety net providers.[9] Thus, safety net hospitals play an essential role in healthcare delivery to the most vulnerable population of society.[2]

Surgical aortic valve replacement (SAVR) is among the most common adult cardiovascular procedures performed in US; approximately 40,000 SAVR were performed in 2015 alone.[10] TAVR was initially introduced for the relief of aortic stenosis in patients deemed "prohibitive" surgical risk. However, indications of this procedure have gradually expanded to include the lower risk cohort. The Food and Drug Administration (FDA), USA recently approved TAVR as a possible first-line procedure for all-comers needing isolated aortic valve replacement.[1] Hence, TAVR will eventually spread to all centers performing surgical aortic valve replacement; even smaller community hospitals in rural areas. Thus with proliferation of TAVR and expansion to the lower risk strata, the focus should now be on patient safety and refinement of outcomes.

Patient safety is the most important tenet for good healthcare delivery.[11] Studies report higher rates of failure to rescue at SNH.[3,5,12-14] However, unlike complex surgical procedures, post-procedural intensive care unit stay and overall length of stay is much less with TAVR. Recent studies report excellent outcome with a "minimalist" approach[15]; even next-day discharge in lower-risk patients is a

TABLE 2 Our propensity-matched subset consists of 6,995 patients in each cohort

	SNH (*N* = 6,995)	Non-SNH (*N* = 6,995)	*p* value	Pre-balance (*SD*)	Post-balance (*SD*)
Age (years)	80.8 (8.8)	80.6 (8.4%)	.67	−0.453	2.714
Carotid artery stenosis	310 (4.4%)	320 (4.6%)	.85	−5.009	−2.083
Congestive heart failure	2,675 (38.2%)	2,665 (38.1%)	.96	−5.314	−2.940
COPD	2,345 (33.5%)	2,325 (33.2%)	.88	3.388	1.210
Diabetes mellitus	2,225 (31.8%)	2,310 (33%)	.51	5.277	−7.057
Complicated DM	480 (6.9%)	495 (7.1%)	.82	1.531	1.413
Peripheral arterial disease	1,765 (25.2%)	1860 (26.6%)	.46	−9.597	0
Chronic kidney disease	2,465 (35.2%)	2,575 (36.8%)	.40	−0.864	1.047
Elective admission	4,880 (69.8%)	4,940 (70.6%)	.78		
Female	3,430 (49.0%)	3,500 (50.0%)	.59	−5.122	−2.280
Prior stroke	505 (7.2%)	510 (7.3%)	.94	5.174	3.862
Prior CABG	855 (12.2%)	950 (13.6%)	.33	−3.165	−0.218
Prior ICD	125 (1.8%)	120 (1.7%)	.88	1.579	−2.157
Prior MI	550 (7.9%)	590 (8.4%)	.61	0.879	−2.213
Prior PCI	885 (12.7%)	935 (13.4%)	.61	4.613	0.214
Race			.82	9.894	3.405
White	5,645 (80.7%)	5,585 (79.8%)			
Black	395 (5.6%)	400 (5.7%)			
Hispanic	485 (6.9%)	570 (8.1%)			
Others	470 (6.7%)	440 (6.3%)			
Smoking	1,145 (16.4%)	1,035 (14.8%)	.27	17.973	−5.625
Year of procedure			.95	18.210	2.568
2014	3,545 (50.7%)	3,575 (51.1%)			
2015	3,450 (49.3%)	3,420 (48.9%)			

Note: Both groups are well balanced. Propensity matching has significantly improved standardized differences (SD) for each covariate studied.
Abbreviations: CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; DM, diabetes mellitus; ICD, implantable cardioverter defibrillator; MI, myocardial infarction; non-SNH, non-safety net hospitals; PCI, percutaneous intervention; SNH, Safety net hospital.

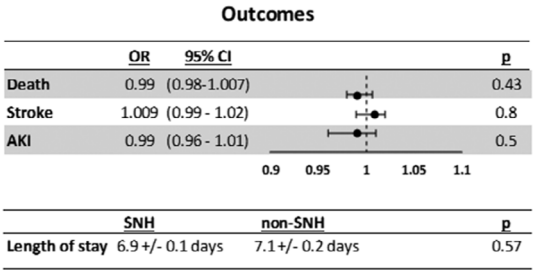

FIGURE 3 Primary outcomes in terms of post-procedural mortality, stoke and acute kidney injury (AKI) for TAVR performed at safety-net and non-safety-net centers were comparable

safe possibility.[16] Studies have reported an important volume-outcome relationship with TAVR[17,18] which further supports our findings as average volume between centers were comparable.

Recent evidence suggests safety net centers can provide comparable outcome for percutaneous interventions that percutaneous coronary interventions.[19] However, we believe that our study is the first to address this important issue in the TAVR arena.

4.1 | Strength and limitations

Our study has specific limitations inherent to the use of an administrative database. Diagnoses and procedures are liable to coding errors. Laboratory or hemodynamic data is not available for inclusion in the statistical models. However, the AHRQ adopts rigorous cross-checks to ensure correctness; as reported we found very few missing variables in the data-tables. Furthermore, we analyzed a 1:1 propensity matched national sample; the best statistical alternative to assess causality for observational data. Our study is the first that presents outcome of TAVR in safety-net hospitals and demonstrates that these centers are able to provide appropriate care for these patients.

5 | CONCLUSION

Among patients undergoing TAVR in the United States, a significant proportion is treated in safety-net hospitals. In the United States, results for TAVR at safety-net hospitals are comparable to national

outcomes. Hence, our study provides a strong basis for wider dissemination of TAVR among rural community hospitals.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

ORCID

Muhammad Adil Sheikh https://orcid.org/0000-0003-3701-090X

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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