JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY VOL. 81, NO. 6, 2023
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PUBLISHED BY ELSEVIER

ORIGINAL INVESTIGATIONS

Impact of Transcatheter Mitral Valve Repair Availability on Volume and Outcomes of Surgical Repair

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ABSTRACT

BACKGROUND The impact of transcatheter edge-to-edge repair (TEER) on national surgical mitral valve repair (MVr) volume and outcomes is unknown.

OBJECTIVES This study aims to assess the impact of TEER availability on MVr volumes and outcomes for degenerative mitral regurgitation.

METHODS MVr volume, 30-day and 5-year outcomes, including mortality, heart failure rehospitalization and mitral valve reintervention, were obtained from the Society of Thoracic Surgeons database linked with Medicare administrative claims and were compared within TEER centers before and after the first institutional TEER procedure. A difference-in-difference approach comparing parallel trends in coronary artery bypass grafting outcomes was used to account for temporal improvements in perioperative care.

RESULTS From July 2011 through December 2018, 13,959 patients underwent MVr at 278 institutions, which became TEER-capable during the study period. There was no significant change in median annualized institutional MVr volume before (32 [IQR: 17-54]) vs after (29 [IQR: 16-54]) the first TEER ($P = 0.06$). However, higher-risk (Society of Thoracic Surgeons predicted risk of mortality ≥2%) MVr procedures declined over the study period ($P < 0.001$ for trend). The introduction of TEER was associated with reduced risk-adjusted odds of mortality after MVr at 30 days (adjusted OR: 0.73; 95% CI: 0.54-0.99) and over 5 years (adjusted HR: 0.75; 95% CI: 0.66-0.86). These improvements in 30-day and 5-year mortality were significantly greater than equivalent trends in coronary artery bypass grafting.

CONCLUSIONS The introduction of TEER has not significantly changed overall MVr case volumes for degenerative mitral regurgitation but is associated with a decrease in higher-risk surgical operations and improved 30-day and 5-year outcomes within institutions adopting the technology. (J Am Coll Cardiol 2023;81:521–532) © 2023 by the American College of Cardiology Foundation.

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Patrick O'Gara, MD, served as Guest Associate Editor for this paper. Christopher M. O'Connor, MD, served as Guest Editor-in-Chief for this paper.

ISSN 0735-1097/$36.00 https://doi.org/10.1016/j.jacc.2022.11.043

ABBREVIATIONS AND ACRONYMS

ACSD = Adult Cardiac Surgery Database

CMS = Centers for Medicare & Medicaid Services

DiD = difference-in-difference

DMR = degenerative mitral regurgitation

MR = mitral regurgitation

MVr = surgical mitral valve repair

STS = Society of Thoracic Surgeons

TAVR = transcatheter aortic valve replacement

TEER = transcatheter edge-to-edge repair

The U.S. Food and Drug Administration approval of transcatheter edge-to-edge repair (TEER) for degenerative mitral regurgitation (DMR) in 2013 led to rapid adoption of TEER for prohibitive risk patients with severe DMR.[1] This percutaneous option has transformed the management discussion for the multidisciplinary heart team evaluating patients with severe DMR, with promising safety and midterm durability in patients at elevated risk.[2,3] The introduction of transcatheter options may also have the potential to impact the surgical management of DMR, whether through optimized multidisciplinary patient evaluation, more strategic patient selection based on valve anatomy, or other changes in care. In a parallel scenario for severe aortic stenosis, the commercial introduction of transcatheter aortic valve replacement (TAVR) in prohibitive and high-risk individuals was initially associated with an unanticipated increase in both transcatheter (TAVR) and surgical aortic valve replacement (SAVR) volume, accompanied by a decline in SAVR mortality over time.[4] Whether the adoption of TEER is associated with similar trends in volume and patient outcomes for surgical mitral valve repair (MVr) remains unknown. Further, given the recently defined valve "centers of excellence" and requirement to offer all commercially available surgical and transcatheter therapies to achieve this classification, there is a need to further assess the effect of access to transcatheter options on surgical outcomes.[5] Using the Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database (ACSD) in the DMR population, we aimed to: 1) evaluate overall annualized MVr volumes and volumes by risk-strata; and 2) compare 30-day and 5-year outcomes within centers, before and after the introduction of TEER.

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METHODS

DATA SOURCES. Primary study data from July 2011 through December 2018 was obtained from the STS ACSD, which contains prospectively maintained, deidentified data on cardiac surgical patients from 95% of all cardiac surgery centers in the United States since its inception in 1989.[6] To assess outcomes beyond 30-days, including mortality, heart failure readmission and mitral valve reintervention, linkage to Centers for Medicare & Medicaid Services (CMS) administrative claims data was performed through an established linkage approach with indirect identifiers.[7] Finally, to identify sites performing TEER and the date of first TEER at each site, sites in the STS ACSD were matched to sites in the STS/American College of Cardiology Transcatheter Valve Therapies registry, which contains procedural and outcomes data for TEER, by hospital National Provider Identifier number.[8] This analysis was approved by the Duke University Institutional Review Board with patient consent waived before data analysis.

PATIENT AND INSTITUTIONAL POPULATION. The STS ACSD was queried for patients undergoing elective or urgent isolated surgical MVr or attempted repair with subsequent replacement for moderate or severe DMR. Importantly, in the STS ACSD, sites are required to indicate whether the initial surgical plan was for mitral repair or replacement, regardless of what procedure was subsequently performed. In alignment with prior ACSD analyses, a hierarchical algorithm was used to define the etiology of mitral regurgitation (MR); primary MR was defined as degenerative disease or pure annular dilation.[9] Isolated MVr included patients who underwent concomitant tricuspid repair, patent foramen ovale or atrial septal defect closure or surgical ablation for atrial fibrillation, as per prior ACSD analyses.[9] Exclusion criteria were reoperative mitral surgery, any degree of mitral stenosis, preoperative cardiogenic shock or need for mechanical support, endocarditis, and papillary muscle rupture.

Institutions were considered TEER-capable if the first TEER was performed at any point before the final 3 months of the study period (date identified through the Transcatheter Valve Therapies registry). Sites with an annualized TEER volume in the 5th percentile (6 cases per year) or lower or not performing at least 1 TEER each year in the study period were excluded to avoid labeling sites that had only performed a handful of TEER or initiated and discontinued their TEER program during the study period as TEER-capable.

The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

Manuscript received July 20, 2022; revised manuscript received October 31, 2022, accepted November 7, 2022.

OUTCOMES AND COVARIATES. The first outcome of interest was STS ACSD institutional annualized procedural volume for intended MVr (MVr or attempted repair with subsequent replacement). Annualized volume was calculated by total repairs at each institution divided by total months in the study period times 12. The primary 30-day outcome was operative mortality, with secondary 30-day outcomes including in-hospital mortality, major morbidity, composite major morbidity/mortality, and "mitral adverse outcome." Operative mortality was defined as any death during index hospitalization before discharge or after discharge but within 30 days of surgery. Major morbidity was defined as the composite of: 1) permanent stroke; or 2) acute renal failure, including new dialysis, or increase in creatinine to twice baseline or >2.0 mg/dL; or 3) prolonged ventilation longer than 24 hours; or 4) deep sternal wound infection; or 5) reoperation, as per the validated, National Quality Forum–endorsed STS mortality and major morbidity quality metric.[9-11] "Mitral adverse outcome" was defined as postoperative MR severity moderate/severe, operative death, heart failure readmission, or mitral valve (MV) reintervention within 30 days after index operation. The primary long-term outcome using Medicare linkage was mortality, whereas secondary outcomes included heart failure hospitalization and MV reintervention. The diagnosis codes defining each event in the Medicare database are listed in Supplemental Table 1 and have been shown to correlate well with physician adjudication.[12] All multivariable models included predetermined, clinically significant, preoperative covariates based on the established STS 2008 valve models.[11] Specific covariates are listed in Supplemental Table 2.

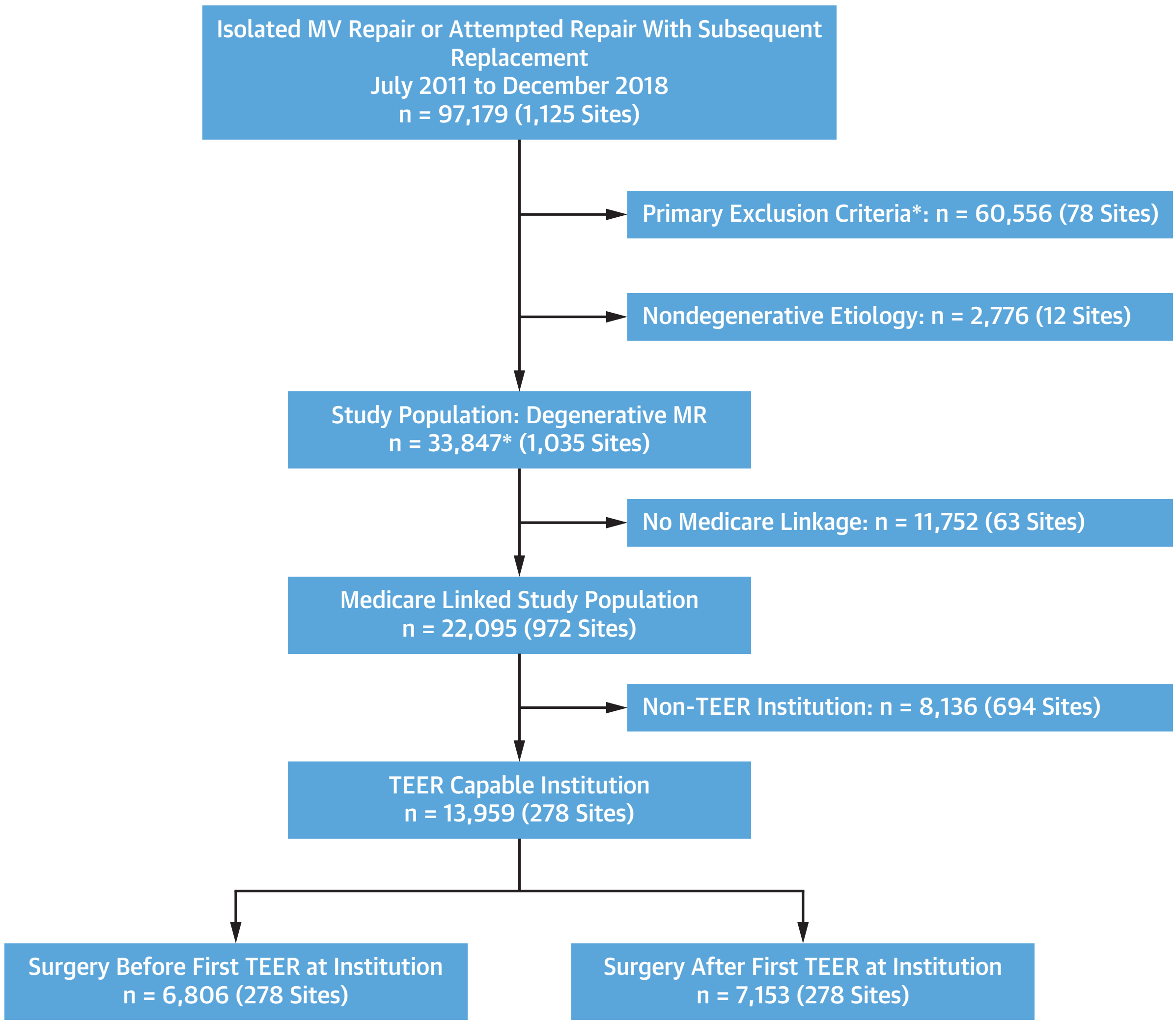
STATISTICAL ANALYSIS. Descriptive analysis. Continuous variables are presented as median and interquartile ranges (first and third quartiles) and categorical variables are presented as counts and frequencies. Study groups were compared with the chi square test for categorical variables and the Wilcoxon rank-sum test for continuous variables. For each analysis, a $P < 0.05$ was considered statistically significant. Statistical analyses were performed using SAS version 9.4 (SAS Institute).

Overall annualized volume and trends by risk strata. To compare trends in annualized volume after vs before the introduction of TEER, a nonparametric, paired Ranked-Sign test was used. We then examined trends in intermediate-risk (age ≥75 years or STS PROM ≥2% and <6%) and high-risk (STS predicted risk of mortality [PROM] ≥6% independent of age) patients as the proportion of overall MVr cases per year due to relatively low numbers in these populations.[13] The process was repeated with an alternative definition for risk strata including intermediate (age ≥75 years or STS PROM ≥2% and <4%) and high (STS PROM ≥4% independent of age). The significance of each trend was assessed using the Cochran-Armitage test.

MVr outcomes before and after TEER availability. We first compared differences in patient outcomes before and after TEER availability at TEER-capable sites. To do this, differences in operative and long-term outcomes were assessed with univariate and multivariable regression models for patients undergoing surgical MVr after vs before (reference) TEER capability at the associated institution. For 30-day outcomes, we used generalized estimating equations logistic regression to compute unadjusted and adjusted odds ratios and 95% CI taking hospital clustering into account. For long-term outcomes, we used a time-to-event approach. For mortality, we plotted Kaplan-Meier curves and used the log-rank test followed by a multivariable Cox proportional hazards model with robust sandwich estimation to account for hospital clustering. For nonfatal outcomes, death was considered a competing risk. As such, we plotted cumulative incidence curves and used Gray's test followed by multivariable Fine & Gray regression models to compute subdistribution HRs and 95% CI.

Next, we used the difference-in-difference (DiD) technique to account for possible temporal improvements in surgical perioperative care. This approach compares the change in outcomes for a treatment group subject to a change (in this case, MVr patients influenced by the introduction of TEER) to a control group that is unlikely to be affected by this change.[14] Therefore, the "quasi-experimental" DiD strategy accounts for potential unmeasured time-varying confounders (generalized improvements in surgical and perioperative care) to enhance causal inference.[15] Our control group consisted of patients who underwent isolated elective or urgent coronary artery bypass grafting (CABG) using the internal mammary artery. To make the 2 populations as similar as possible, the same exclusion criteria were applied for the control as for the study population. All DiD models included binary indicators for study/control populations and timing before or after the first TEER and an interaction term between these 2 variables that yields DiD estimates. Covariates for adjusted models were the same as listed in Supplemental Table 2. The parallel trends assumption was evaluated visually, comparing event rates by year in control and study groups in the before period and statistically, with an interaction term between study/

FIGURE 1 **Study Population Consort Diagram**



The initial population included 22,095 patients ≥65 years of age from 972 institutions meeting inclusion and exclusion criteria based on characteristics and etiology of mitral regurgitation and with successful Medicare claims linkage. Analysis further focused on 13,959 patients from 278 sites initiating a transcatheter mitral edge-to-edge repair (TEER) program during the study period. An **asterisk** (*) indicates that primary exclusion criteria were reoperative mitral surgery, any degree of mitral stenosis, severity of mitral regurgitation less than moderate, urgent/emergent operative status, preoperative cardiogenic shock or need for mechanical support, endocarditis, papillary muscle rupture, and age <65 years (ie, ineligible for Medicare claims linkage). MR = mitral regurgitation; MV = mitral valve.

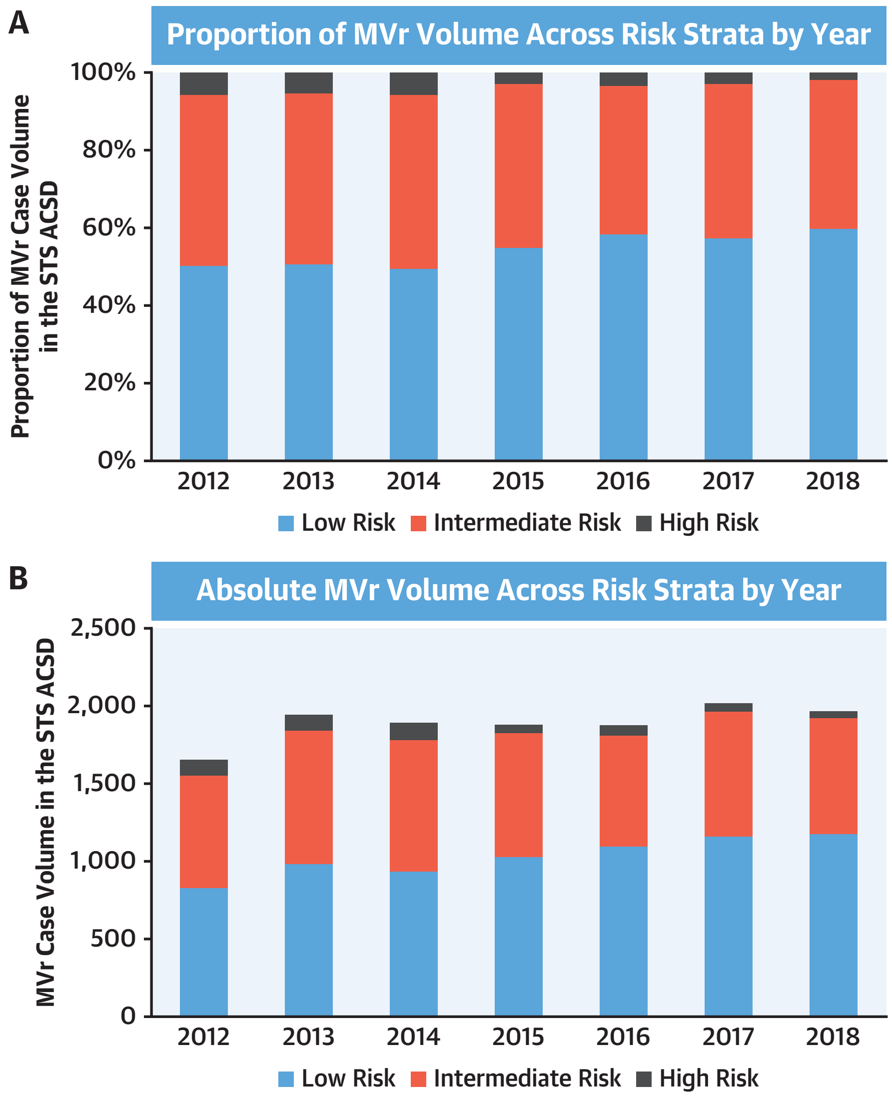
control variable and year in a model limited to the before period.

Finally, we performed a sensitivity analysis among higher-volume TEER centers (defined as performing an average of ≥20 TEER per year) to assess for a potential relationship between transcatheter procedural volume and surgical outcomes. Volume trends and 30-day and 5-year outcomes were again assessed in this subpopulation.

RESULTS

POPULATION AND TRENDS IN OPERATIVE VOLUME. Overall, 33,847 patients were identified who underwent MVr at 1,035 institutions during the study period (Figure 1). Of these, 22,095 (65.3%) patients at 972 institutions were successfully linked to Medicare claims (Supplemental Table 3). There were 278 sites meeting criteria as TEER-capable at some point

FIGURE 2 **Trend in MVr Volume at TEER-Capable Centers by Risk Strata**



The proportion **(A)** and absolute number **(B)** of mitral valve repair (MVr) cases in intermediate-risk and high-risk strata. Trends analysis revealed a parallel and significant downtrend in combined intermediate-risk and high-risk patients undergoing surgical MVr at TEER-capable centers. Intermediate risk: age ≥75 years and/or Society of Thoracic Surgeon (STS) Predicted Risk of Mortality ≥2% and <6%. High risk: STS Predicted Risk of Mortality ≥6% (regardless of age). ACSD = Adult Cardiac Surgery Database; MVr = surgical mitral valve repair; other abbreviation as in Figure 1.

during the study period (Supplemental Table 4), with median annualized TEER volume of 17 procedures (IQR: 11-25 procedures). Among the final study population of 13,959 patients undergoing MVr or attempted repair at these institutions, 6,806 (48.8%) surgeries were before and 7,153 (51.2%) after the first TEER at the institution. At an institution level, there was no significant change in median annualized MVr volume of 32 (IQR: 17-54) before the first TEER vs 29 (IQR: 16-54) after the first TEER (P = 0.06). Stratifying patients into intermediate-risk and high-risk groups (with 2 alternative definitions) and examining the proportion of overall MVr volume, there was a significant decrease in the proportion of both intermediate-risk and high-risk operations at TEER-capable centers ($P < 0.001$ for all trends) (**Figure 2,** Supplemental Figure 1).

30-DAY OUTCOMES BEFORE AND AFTER INTRODUCTION OF TEER AT TEER-CAPABLE SITES. Patients undergoing MVr after the introduction of TEER at TEER-capable

TABLE 1 Baseline Patient Characteristics Before and After Introduction of TEER

	Overall (N = 13,959)	Before First TEER (n = 6,806)	After First TEER (n = 7,153)	*P* Value
Characteristics and risk factors				
Age, y	72 (68-77)	73 (68-78)	72 (68-77)	<0.001
Female	6,835 (49.0)	3,507 (51.5)	3,328 (46.5)	<0.001
BMI, kg/m^2	25.8 (23.0-29.0)	25.9 (23.1-29.4)	25.6 (23.0-28.8)	<0.001
Chronic lung disease (moderate-severe)	848 (6.1)	515 (7.6)	333 (4.7)	<0.001
Dialysis	77 (0.6)	46 (0.7)	31 (0.4)	0.053
Cerebrovascular disease	1,338 (9.6)	675 (9.9)	663 (9.3)	0.177
Peripheral arterial disease	602 (4.3)	336 (4.9)	266 (3.7)	<0.001
Ever-smoker	4,203 (30.1)	1,235 (18.1)	2,968 (41.5)	<0.001
Heart failure (NYHA functional class III-IV)	3,210 (23.0)	1,889 (27.8)	1,321 (18.5)	<0.001
STS predicted mortality, %	1.3 (0.9-2.4)	1.5 (1.0-2.7)	1.2 (0.8-2.1)	<0.001
Postoperative length of stay, d	6 (5-8)	6 (5-8)	6 (5-8)	<0.001
Hemodynamic status				
Ejection fraction, %	60 (55-65)	60 (53-64)	60 (55-65)	<0.001
LVEDD, mm	52 (47-57)	52 (47-57)	51 (47-56)	0.288
PA systolic pressure, mm Hg	39 (31-50)	39 (31-50)	39 (30-49)	0.003
Mitral regurgitation severity				0.126
Moderate	1,161 (8.3)	591 (8.7)	570 (8.0)	
Severe	12,798 (91.7)	6,215 (91.3)	6,583 (92.0)	
Tricuspid regurgitation (moderate-severe)	4,557 (32.6)	2,280 (33.5)	2,267 (31.7)	<0.001
Aortic stenosis (any)	237 (1.7)	131 (1.9)	106 (1.5)	0.045
Aortic insufficiency (moderate-severe)	587 (4.2)	280 (4.1)	307 (4.3)	<0.001

Values are median (IQR) or n (%).

BMI = body mass index; LVEDD = left ventricular end diastolic diameter; NYHA = New York Heart Association, PA = pulmonary artery; STS = Society of Thoracic Surgeons; TEER = transcatheter edge-to-edge repair.

sites tended to be slightly younger (median age 72 years [IQR: 68-77 years] vs 73 years [IQR: 68-78 years]; $P < 0.001$) and less commonly presented with comorbidities, such as chronic lung disease (4.7% vs 7.6%; $P < 0.001$) and New York Heart Association functional class III or IV heart failure (18.5% vs 27.8%; $P < 0.001$) (**Table 1**). This shift was reflected by a slight but statistically significant downtrend in median STS PROM to 1.2% (IQR: 0.8%-2.1%) after the first TEER as compared to 1.5% (IQR: 1.0%-2.7%) before the introduction of TEER. MVr procedural details are presented in Supplemental Table 5.

In univariate analysis, there was a lower rate of the mitral adverse outcome (4.0% vs 6.6%; $P < 0.001$), operative mortality (1.1% vs 1.7%; $P = 0.032$), major morbidity (8.7% vs 11.3%; $P < 0.001$), and composite morbidity/mortality (8.9 vs 11.8%; $P < 0.001$) after the first TEER as compared to before (**Table 2**). After adjustment, there were lower odds of the mitral adverse outcome (adjusted OR [aOR]: 0.71; 95% CI: 0.58-0.86; $P < 0.001$), operative mortality (aOR: 0.73; 95% CI: 0.54-0.99; $P = 0.041$), major morbidity (aOR: 0.85; 95% CI: 0.73-0.98; $P = 0.026$), and composite morbidity/mortality (aOR: 0.71; 95% CI: 0.59-0.84; $P < 0.001$) after the first TEER compared with prior.

To account for general improvements in operative and perioperative care over the study period, a DiD analysis was then performed using a control population of 322,107 Medicare-linked CABG patients meeting inclusion/exclusion criteria. Parallel trends for the MVr and control groups were confirmed for all outcomes of interest (Supplemental Figure 2, Supplemental Table 6). With this approach, the adjusted *P* value for interaction was significant for operative mortality (aOR: 0.74; 95% CI: 0.56-0.97; interaction $P = 0.03$), suggesting that the introduction of TEER rather than other perioperative/operative care factors alone may have influenced surgical MVr outcomes. However, DiD interaction was not significant for in-hospital mortality, major morbidity, or the composite morbidity/mortality outcome, suggesting that the changes in these outcomes are not unique to MVr and may be due to temporal improvements in general operative/perioperative care (**Table 3**).

5-YEAR OUTCOMES BEFORE AND AFTER INTRODUCTION OF TEER AT TEER-CAPABLE SITES. Death. Linking the STS ACSD dataset with Medicare administrative claims data, median follow-up time was 5.1 years (IQR: 3.7-6.2 years) in the before TEER and 1.8 years (IQR: 0.9-3.0 years) in the after TEER group. The

TABLE 2 30-Day Outcomes for MVr After vs Before the First TEER at Associated Institution

	Surgical MV Repair or Attempted Repair					
	Event Frequencies		Unadjusted		Adjusted	
30-Day Outcome	Before	After	OR (95% CI)	*P* Value	OR (95% CI)	*P* Value
In-hospital mortality	83 (1.22)	61 (0.85)	0.77 (0.56-1.06)	0.107	0.97 (0.70-1.34)	0.839
Operative mortality	112 (1.65)	75 (1.05)	0.59 (0.44-0.79)	0.001	0.73 (0.54-0.99)	0.041
Major morbidity	769 (11.30)	623 (8.71)	0.78 (0.68-0.90)	<0.001	0.85 (0.73-0.98)	0.026
Composite mortality and major morbidity	800 (11.75)	638 (8.92)	0.64 (0.54-0.76)	<0.001	0.71 (0.59-0.84)	<0.001
Mitral adverse outcome[a]	426 (6.63)	278 (4.04)	0.63 (0.52-0.77)	<0.001	0.71 (0.58-0.86)	<0.001

Values are n (%) unless otherwise indicated. [a]Postoperative mitral regurgitation severity moderate/severe, operative death, heart failure readmission or MV reintervention within 30 days after index operation.
MV = mitral valve; MVr = mitral valve repair; other abbreviation as in Table 1.

mortality among MVr patients decreased significantly after TEER availability (3% vs 5% at 1 year, 7% vs 10% at 3 years, and 11% vs 17% at 5 years; log rank $P < 0.001$). In adjusted analysis, mortality was also significantly lower among patients undergoing MVr after TEER became available (3% vs 5% at 1 year, 7% vs 9% at 3 years, and 12% vs 15% at 5 years), with significantly lower hazard of death after TEER introduction (aHR: 0.75; 95% CI: 0.66-0.86) (**Figure 3**).

In a DiD analysis, there was a significant reduction in the hazard of death post-MVr as compared to post-CABG after the introduction of TEER (MVr aHR: 0.77; 95% CI: 0.68-0.87; interaction $P < 0.001$). Thus, the improved 5-year mortality in MVr patients may be attributable to the introduction of TEER rather than generalized improvements in operative and perioperative care.

Heart failure hospitalization and freedom from reintervention. There was a significantly lower risk of heart failure hospitalization at 1 year after the introduction of TEER (aHR: 0.87; 95% CI: 0.77-0.98). A similar DiD analysis compared to CABG was significant in an unadjusted analysis ($P < 0.001$) but was not significant after risk adjustment (MVr aHR: 0.87; 95% CI: 0.78-0.98; interaction $P = 0.181$). Similarly, the hazard of mitral valve reintervention at 5 years after MVr was lower after compared to before the first TEER (aHR: 0.72; 95% CI: 0.55-0.96) (Supplemental Figure 3); however, the DiD was not significant compared to mitral valve intervention after CABG (MVr aHR: 0.77; 95% CI: 0.58-1.02; interaction P = 0.275). These findings suggest that the improvements in heart failure hospitalization and MV reintervention after MVr may be attributable to temporal improvements in care rather than the introduction of TEER.

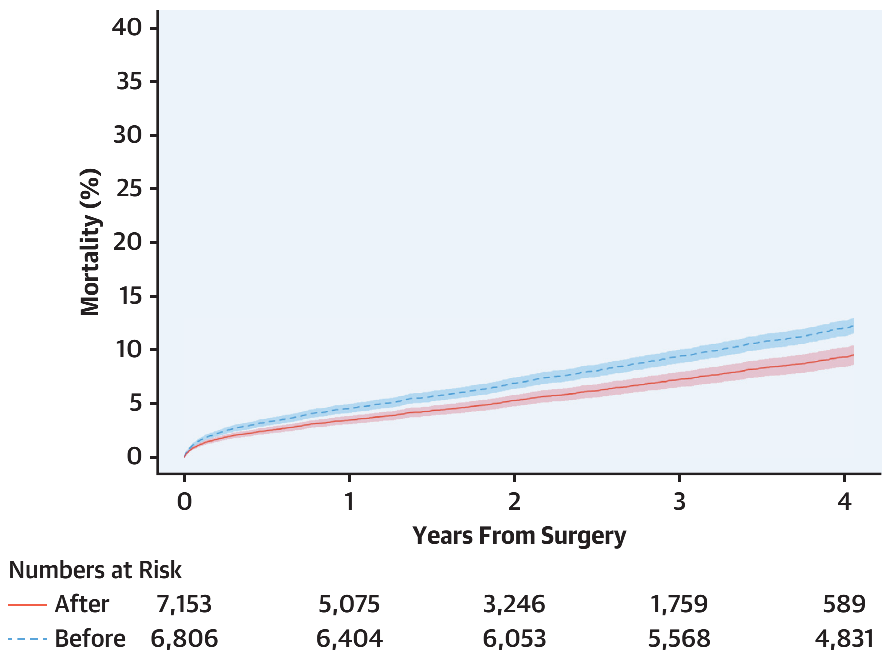
SENSITIVITY ANALYSIS: HIGHER-VOLUME TEER CENTERS. Limiting the analysis to the 101 institutions performing ≥20 TEER per year after initiating a TEER program, 6,287 patients underwent MVr, including 2,571 (40.9%) before and 3,716 (59.1%) after TEER (Supplemental Table 7). Median annualized

TABLE 3 Difference-in-Difference Analysis for Operative Outcomes After MVr vs CABG (Control)

		Unadjusted			Adjusted		
30-Day Outcome	Interaction Group	OR (95% CI)	*P* Value	Interaction *P* Value	OR (95% CI)	*P* Value	Interaction *P* Value
In-hospital mortality	After vs before TEER: CABG	1.02 (0.92-1.12)	0.762	0.058	1.07 (0.97-1.18)	0.178	0.363
	After vs before TEER: MVr	0.74 (0.55-1.01)	0.062		0.92 (0.68-1.25)	0.613	
	DiD: OR	0.73 (0.53-1.01)	0.058		0.86 (0.63-1.19)	0.363	
Operative mortality	After vs before TEER: CABG	0.93 (0.84-1.01)	0.098	0.001	0.98 (0.89-1.07)	0.623	0.029
	After vs before TEER: MVr	0.59 (0.44-0.78)	<0.001		0.72 (0.55-0.95)	0.020	
	DiD: OR	0.63 (0.48-0.84)	0.001		0.74 (0.56-0.97)	0.029	
Major morbidity	After vs before TEER: CABG	0.86 (0.82-0.90)	<0.001	0.077	0.88 (0.84-0.92)	<0.001	0.781
	After vs before TEER: MVr	0.76 (0.67-0.87)	<0.001		0.86 (0.75-0.98)	0.027	
	DiD: OR	0.89 (0.78-1.01)	0.077		0.98 (0.86-1.12)	0.781	
Composite mortality and major morbidity	After vs before TEER: CABG	0.75 (0.71-0.81)	<0.001	0.016	0.77 (0.72-0.82)	<0.001	0.244
	After vs before TEER: MVr	0.62 (0.53-0.74)	<0.001		0.71 (0.60-0.83)	<0.001	
	DiD: OR	0.82 (0.70-0.96)	0.016		0.91 (0.78-1.06)	0.244	

CABG = coronary artery bypass grafting; DiD = difference in difference; other abbreviations as in Tables 1 and 2.

FIGURE 3 Adjusted Post-MVr Mortality After vs Before the First TEER



Adjusted proportional hazards analysis revealed reduced mortality for MVr patients undergoing surgery after compared to before the first TEER at the specific site (3% vs 5% at 1 year, 7% vs 9% at 3 years, and 12% vs 15% at 5 years). **Shaded area** represents the 95% CI. Abbreviations as in **Figures 1 and 2**.

MVr volume was similar after (38 [IQR: 19-66]) compared to before (36 [IQR: 19-65]) the introduction of TEER. After adjustment, there was no significant difference in odds of in-hospital mortality, operative mortality, or major morbidity before vs after TEER among this cohort, but there were significantly lower odds of composite major morbidity/mortality (aOR: 0.72; 95% CI: 0.50-0.87; $P = 0.003$) and the mitral adverse outcome (aOR: 0.65; 95% CI: 0.48-0.88; $P = 0.005$) (Supplemental Table 8). A DiD analysis revealed no significant differences among the 30-day outcomes after comparing to trends in CABG outcomes (Supplemental Table 9). However, similar to the primary analysis, after-TEER patients had significantly reduced 5-year mortality (unadjusted HR 10.2% vs 15.8%, aHR: 0.75; 95% CI: 0.61-0.92) (Supplemental Figure 4), which remained significant in a DiD analysis (interaction $P = 0.012$).

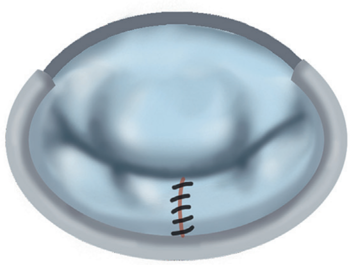
DISCUSSION

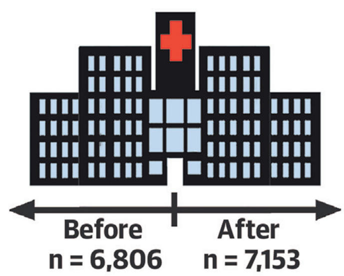
TEER is increasingly used for patients with severe DMR who are at prohibitive risk for surgical MVr. However, the impact of TEER availability on the volume and outcomes of MVr remains poorly described. In this analysis, the introduction of TEER has led to several major findings: 1) there was no significant change in overall annualized MVr volume at institutions offering TEER; however, there was a significant downtrend in both intermediate-risk and high-risk MVr volume; 2) the risk of mitral adverse outcome and 30-day operative mortality decreased; and 3) 5-year mortality after MVr decreased (**Central Illustration**). Using the DiD approach to address potential confounding of advances in surgical technique or perioperative care over time, the improvement in 30-day and 5-year mortality remained significant, suggesting that the findings may be attributable to the introduction of TEER.

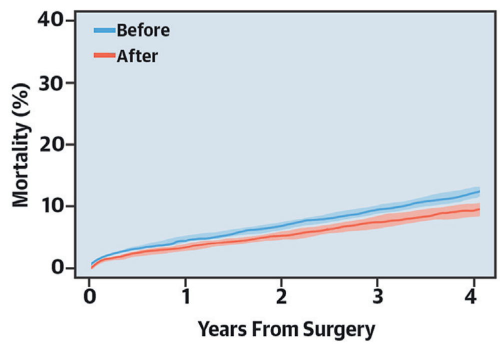
Multiple factors may contribute to the observed effect of TEER availability on MVr outcomes. First, the capability to choose percutaneous options may impact referral patterns and surgical patient selection. After the introduction of TEER at each site, the median STS PROM for MVr patients decreased from 1.5% to 1.2%, a shift which may represent the fact that "borderline" surgical candidates were being referred for TEER once this option became available. To explore this hypothesis, we examined the proportion of intermediate-risk and high-risk patients

CENTRAL ILLUSTRATION Assessing the Impact of Transcatheter Edge-to-Edge Mitral Valve Repair on Surgical Mitral Valve Repair Volume and Outcomes

Surgical Mitral Valve Repair (MVr):	Comparator:	Results: Surgery After First Transcatheter Edge to Edge Repair (TEER)
n = 13,959 for Degenerative Mitral Regurgitation (DMR) from the Society of Thoracic Surgeons (STS) registry with Centers for Medicare and Medicaid Services (CMS) linkage for long-term outcomes	Surgery performed before vs after date of institution's first transcatheter mitral valve repair	• No significant change in annual MVr volume • Downtrend in higher-risk MVr • Improved risk adjusted 30-day mortality • Improved risk adjusted 5-year mortality







Lowenstern AM, et al. J Am Coll Cardiol. 2023;81(6):521–532.

Using the Society of Thoracic Surgeons Adult Cardiac Surgery Database, volume and outcomes of surgical mitral valve repair (MVr) were compared before versus after the first transcatheter edge-to-edge (TEER) mitral valve repair was performed at each institution. Although the introduction of TEER did not significantly affect MVr volume, there was an associated downtrend in higher-risk MVr cases, accompanied by improved 30-day and 5-year mortality.

undergoing MVr across the study period and found a steady downtrend in these higher-risk cases. Second, comprehensive evaluation by a multidisciplinary "heart team" may drive improved MVr outcomes. As with TAVR, evaluation for TEER includes input from surgeons, invasive and noninvasive cardiologists, and other members of the heart team before performing the procedure.[16] The potential impact of this evaluation process on patient selection and outcomes has been shown for the management of both coronary artery disease and aortic stenosis.[17] Although the exact implementation and evolution of the heart team model at each site is not known, it remains an integral component in the CMS national coverage model and it is reasonable to extrapolate that the introduction of TEER leads to more formalized evaluation of all MR patients in this model. In the context of DMR, this analysis reveals that most patients are low risk by STS PROM (median 1.5% before and 1.2% after TEER), and this measure alone may not adequately estimate patient and anatomic factors considered by the heart team. Furthermore, the slight downtrend in intermediate-risk patients (by PROM and age) may suggest that "indication creep" has occurred with lower-risk patients already being referred to TEER.

The term "halo effect" has been used by many in the cardiovascular communities to describe the effect of new technologies on the volume and outcomes associated with existing standard of care treatments.[18-20] Whether it is a more comprehensive workup before participation in a clinical device trial, more robust medical optimization or patient interest in pursuing sites with the newest treatment options, the availability of percutaneous repair techniques may support improvements in the volume and quality of surgical techniques with which they are theoretically competing.[21] In the analysis of the STS ACSD examining the impact of TAVR availability at a given center on SAVR volume and outcomes, Brennan et al[4] extended the application of the halo effect, finding that TAVR availability increased surgical volumes and improved outcomes, including lower mortality, for aortic valve replacement patients treated at centers with TAVR. In the context of MV practice, multiple single-institution series have shown similar concurrent growth of TEER and surgical MVr volumes since the introduction of TEER.[22] One analysis using the Nationwide Readmissions Database found improved in-hospital outcomes among patients who underwent MV surgery at a TEER-capable center.[23] However, these prior analyses suffered from limited characterization of the surgical cohort due to reliance on administrative codes, inability to capture when a center adopted TEER, and limited ascertainment of echo-based and long-term outcomes. Furthermore, although these studies excluded patients with mitral stenosis and endocarditis, the investigators could not discern the etiology of the MR, which is an important consideration in treatment selection. As such, the present analysis is the first to examine the relationship between TEER availability and MVr operative and long-term outcomes specifically focused on DMR. Surgical MVr volumes remained steady after the introduction of TEER, with a slight downtrend among all institutions and slight uptrend at the high-volume TEER sites (neither trend was statistically significant). Although these patterns appear contrary to those observed in the aortic stenosis population and in the aforementioned single institutional series, the relative stability in MVr volume as high-/intermediate-risk cases decreased suggests that the halo effect may be present with an influx of low-risk cases. Further extending findings in similar prior short-term studies, 5-year outcomes improved with decreased mortality among patients who underwent MVr after TEER availability at the institution.

These results enhance our understanding of how MR is managed at a variety of institutions throughout the United States, but simultaneously raise questions about the best approach to optimize outcomes in the future. With 2 trials actively enrolling to assess the outcomes of TEER in intermediate surgical risk patients with DMR, there will be increasing pressure on institutions to add TEER capability if indications for this procedure expand into lower risk populations.[13,24] As expected, there was a pronounced downtrend in MVr for the highest-risk patients across the study period, but there was also a significant downtrend in the intermediate population as well. Thus, the impact of TEER on patient selection for MVr may extend beyond the current TEER indications, which apply to only prohibitive-risk patients. MVr is a technically complex operation requiring an experienced team for patient evaluation and a durable operative repair.[25] The recently developed requirements to be considered a valve “center of excellence” emphasize immediate accessibility to all therapeutic approaches. The findings of the present study confirm the conclusion that a systematic evaluation by a heart team able to direct patients towards either surgical or transcatheter approaches enhances both short-term and long-term surgical outcomes. Possibly more important than assessment of patient level risk factors, a tailored treatment decision based on valve pathology has been and will continue to be essential, reflected by the reduction in mitral adverse outcomes, which includes residual moderate/severe MR at 30-days, in the present study. Longer-term imaging studies are necessary to assess how the availability of TEER impacts the durability of repair among patients undergoing MVr.

STUDY LIMITATIONS. First, this analysis is subject to the usual barriers of a retrospective, large registry study, including selection bias and unmeasured confounding. Second, the availability of TEER at an institution does not necessarily confer that a patient was evaluated for transcatheter repair or evaluated by a multidisciplinary heart team, although this assumption was deemed reasonable for the purposes of this study as it is required by the CMS mitral national coverage decision.[26] Furthermore, the introduction of newer generations of TEER devices late in the study period may have influenced the decision between MVr and TEER, particularly in those with borderline anatomy. However, there is no clear evidence on the impact of modern TEER devices on patient selection and consensus documents on anatomic suitability for TEER were not developed until after the study period.[27] Third, the hierarchical algorithm used to establish the DMR is imperfect and some patients with non-DMR or mixed MR may have been included in the study population, although this algorithm has been previously published and used in the STS database.[9] Fourth, there are no validated cutoffs for risk strata in the MVr population. The intermediate-risk criteria for an ongoing clinical trial were used for this study, but the most appropriate cutoff for intermediate risk may be an even lower predicted risk of mortality. Fifth, MVr is a heterogeneous operation. Intraoperative variables, such as sternotomy vs minimally invasive thoracotomy vs robotic assisted repair and specific repair techniques, including annuloplasty, leaflet resection, neochords, and chordal transfer, were not included in multivariable models. This analytic decision was based on the principle that risk analysis should focus on preprocedure patient characteristics and pathology, as has been used for prior STS risk models, rather than surgical approaches, which frequently change during the course of an operation.[11] Sixth, as the study is limited to patients ≥65 years of age with successful linkage to Medicare fee-for-service claims, the observed trends and outcomes of MVr may not be seen in younger patients or those with alternative payors, such as Medicare Advantage plans. However, given the fact that the median age of TEER in the United States is 82 years old (IQR: 74-86 years), we expect that the majority of the effects of TEER on MVr would apply to this older population being evaluated for the transcatheter option.[28] Furthermore, the characteristics of patients linked and not successfully linked to Medicare were clinically similar, suggesting that no systematic biases existed in the linked population. Finally, these results reflect outcomes at relatively high-volume mitral centers both before and after TEER was introduced and may not be generalizable to lower-volume or new centers adopting TEER.

CONCLUSIONS

The introduction of TEER for DMR has not significantly impacted annualized MVr volume in TEER institutions from 2011 to 2018. However, adoption of this transcatheter technique was also associated with an improvement in 30-day MVr outcomes and 5-year mortality. Should randomized evidence support expanding TEER into lower-risk patient populations, to achieve the longitudinal durability and safety of MVr, it will be essential to understand the mechanisms of patient selection for surgery vs TEER and how evaluation for this minimally invasive option affects those eventually undergoing surgical repair.

FUNDING SUPPORT AND AUTHOR DISCLOSURES

This work was supported by an internal grant to Duke University (ADSTAR program) by Abbott. The authors are responsible for the study design, analysis, interpretation, and manuscript. This work was also supported in part by the National Institutes of Health (5T32HL069749-17 to Dr Vekstein). Dr Lowenstern has received consulting fees from Edwards Lifesciences. Dr Thourani has received consulting or research fees from Abbott Vascular, Boston Scientific, CryoLife/Artivion, Edwards Lifesciences, Jenavalve, Medtronic, and Shockwave. Dr Cohen has received research grant support from Edwards Lifesciences, Abbott, Boston Scientific, and Medtronic; and has received consulting fees from Edwards Lifesciences, Abbott, Boston Scientific, and Medtronic. Mr Lindman is a member of the Scientific Advisory Board for Roche Diagnostics; and has received grants and/or research support from Edwards Lifesciences and Roche Diagnostics. Dr Vemulapalli has received grants/contracts from the American College of Cardiology, Society of Thoracic Surgeons, Cytokinetics, Abbott Vascular, National Institutes of Health (R01 and SBIR), and Boston Scientific; and has received consulting fees/been on advisory board with Janssen, American College of Physicians, HeartFlow, and Edwards LifeSciences. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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PERSPECTIVES

COMPETENCY IN PATIENT CARE AND PROCEDURAL SKILLS: The availability of TEER has not affected the volume of surgical MVr but can improve the outcomes of surgical MVr, possibly because of more comprehensive evaluation and patient selection.

TRANSLATIONAL OUTLOOK: Further investigation is needed to understand the factors responsible these improvements and optimize care for patients with mitral regurgitation.

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KEY WORDS heart team, mitral regurgitation, mitral valve repair, transcatheter

APPENDIX For supplemental tables and figures, please see the online version of this paper.