Relation of Institutional Mitral Valve Surgical Volume to Surgical and Transcatheter Outcomes in Medicare Patients

Colin M. Barker, MD[a], Matthew R. Reynolds, MD, MSc[b], Michael J. Reardon, MD[c], Joanna L. Van Houten, PhD, MPH[d,*], Shannon M.E. Murphy, MA[d], Sarah A. Mollenkopf, MPH[d,*], and Ted E. Feldman, MD[d]

There are limited data to support proposed increases to the minimum institutional mitral valve (MV) surgery volume required to begin a transcatheter mitral valve repair (TMVr) program. The current study examined the association between institutional MV procedure volumes and outcomes. All 2017 Medicare fee-for-service patients who received a TMVr or MV surgery procedure were included and analyzed separately. The exposure was institutional MV surgery volume: low (1 to 24), medium (25 to 39) or high (40+). Outcomes were in-hospital mortality and 1-year postdischarge mortality and cardiovascular rehospitalization. For MV surgery patients, in-hospital mortality rates were 6.4% at low-volume, 8.7% at medium-volume and 9.8% at high-volume facilities. Rates were significantly higher for low-volume [OR = 1.50, 95% CI (1.23 to 1.84)] and medium-volume [OR = 1.33, 95% CI (1.06 to 1.67)] compared with high-volume facilities. There was no statistically significant relationship between institutional MV surgery volume and in-hospital mortality for TMVr patients, either at low-volume [OR = 1.52, 95% CI (0.56, 4.13)] or medium-volume [OR = 1.58, 95% CI (0.82, 3.02)] facilities, compared with high-volume facilities. Across all volume categories, in-hospital mortality rates for TMVr patients were relatively low (2.3% on average). For both cohorts, the rates of 1-year mortality and cardiovascular rehospitalizations were not significantly higher at low- or medium-volume MV surgery facilities, as compared with high-volume. In conclusion, among Medicare patients, there was a relation between institutional MV surgery volume and in-hospital mortality for MV surgery patients, but not for TMVr patients. **(Am J Cardiol 2021;147:94−100)**

The Federal Drug Administration's recent approval expansion of transcatheter mitral valve repair (TMVr) to patients with secondary mitral regurgitation (MR) prompted a reconsideration of the national coverage determination (NCD) for reimbursement by the US Medicare program. A subsequent multisociety consensus statement[1] recommended an increased threshold from ≥25 to ≥40 annual mitral valve (MV) surgeries before hospitals can establish a new TMVr program. However, there are limited data to justify the increase. Although a volume-outcome relationship has been shown for invasive MV surgical procedures,[2−3] it is unknown whether the same relationship exists for MV surgical volume and outcomes of TMVr, a minimally invasive procedure with a favorable safety profile compared with open surgery and generally performed by a different cardiac specialty.[4−6] The objective of this study was to update the analysis done by Barker et al[5] that examined the association between institutional MV procedure volumes and outcomes in Medicare patients. First, we confirmed the level of association between institutional MV surgery volume and in-hospital mortality for both MV surgery and TMVr patients. Second, we examined the volume-outcome relationship for longer-term outcomes of mortality and cardiovascular rehospitalization up to 1 year postdischarge.

Methods

Patients enrolled in fee-for-service Medicare who received either a TMVr or MV surgery procedure in 2017 were included in the study. Data from January 1, 2017 through December 31, 2018 were derived from the 100% Medicare Limited Dataset Standard Analytic Files. The Medicare files contain detailed claims and beneficiary enrollment information including but not limited to diagnosis and procedure codes, facility ID, patient demographics, and death information. This study was exempt from institutional review board review under 45 CFR 46.101(b) as all data were de-identified and accessed in compliance with the Health Insurance Portability and Accountability Act.

The primary outcome was in-hospital mortality. Postdischarge outcomes of mortality and cardiovascular rehospitalization up to 1 year were also examined. Cardiovascular

[a]Vanderbilt University Medical Center, Nashville, TN, USA; [b]Baim Institute for Clinical Research, Lahey Hospital and Medical Center, Boston, MA, USA; [c]Houston Methodist Hospital, Houston, TX, USA; and [d]Edwards Lifesciences, Irvine, CA, USA. Manuscript received October 29, 2020; revised manuscript received and accepted January 19, 2021.

See page 99 for disclosure information.

*Corresponding authors: Tel: (949) 250-8729.

E-mail addresses: Joanna_VanHouten@edwards.com (J.L. Van Houten), Sarah_Mollenkopf@edwards.com (S.A. Mollenkopf).

0002-9149/

https://doi.org/10.1016/j.amjcard.2021.01.044

Table 1
Patient and hospital characteristics for MV surgery and TMVr patients by MV surgery institutional volume

Patient and hospital characteristics	MV surgery patients			TMVr patients		
	MV surgery institutional volume					
	Low (n = 2,369)	Medium (n = 1,758)	High (n = 12,483)	Low (n = 237)	Medium (n = 379)	High (n = 2,819)
Age (years)[a,c,d]	69.7 ± 8.9	70.2 ± 9.0	70.1 ± 8.9	77.6 ± 9.4	78.7 ± 8.1	80.0 ± 8.7
Women	1123 (47.4%)	829 (47.2%)	5893 (47.2%)	128 (54.0%)	177 (46.7%)	1352 (48.0%)
Race[*,†,‡,§]						
White	2004 (84.6%)	1540 (87.6%)	10730 (86.0%)	205 (86.5%)	329 (86.8%)	2515 (89.2%)
Black	202 (8.5%)	119 (6.8%)	956 (7.7%)	12 (5.1%)	22 (5.8%)	165 (5.9%)
Hispanic	40 (1.7%)	20 (1.1%)	134 (1.1%)	–	11 (2.9%)	23 (0.8%)
Asian	41 (1.7%)	15 (0.9%)	184 (1.5%)	–	–	43 (1.5%)
Unknown	82 (3.5%)	64 (3.6%)	479 (3.8%)	–	–	73 (2.6%)
Patient Region[*,†,‡,§]						
Midwest	766 (32.3%)	379 (21.6%)	3040 (24.4%)	66 (27.8%)	78 (20.6%)	557 (19.8%)
Northeast	279 (11.8%)	338 (19.2%)	2771 (22.2%)	33 (13.9%)	56 (14.8%)	570 (20.2%)
South	831 (35.1%)	678 (38.6%)	4610 (36.9%)	95 (40.1%)	135 (35.6%)	1038 (36.8%)
West	493 (20.8%)	363 (20.6%)	2062 (16.5%)	43 (18.1%)	110 (29.0%)	654 (23.2%)
Elixhauser score[c]	5.3 ± 3.7	5.4 ± 3.6	5.4 ± 3.7	7.8 ± 4.1	7.4 ± 3.8	7.2 ± 3.9
Hospital Region[*,†,‡,§]						
Northeast	268 (11.3%)	337 (19.2%)	2797 (22.4%)	33 (13.9%)	57 (15.0%)	573 (20.3%)
South Atlantic	368 (15.5%)	336 (19.1%)	2479 (19.9%)	49 (20.7%)	82 (21.6%)	626 (22.2%)
East North Central	555 (23.4%)	245 (13.9%)	2044 (16.4%)	65 (27.4%)	37 (9.8%)	298 (10.6%)
East South Central	154 (6.5%)	137 (7.8%)	896 (7.2%)	–	19 (5.0%)	183 (6.5%)
West North Central	207 (8.7%)	128 (7.3%)	1224 (9.8%)	–	36 (9.5%)	268 (9.5%)
West South Central	330 (13.9%)	207 (11.8%)	1022 (8.2%)	41 (17.3%)	33 (8.7%)	205 (7.3%)
Mountain	205 (8.7%)	150 (8.5%)	613 (4.9%)	26 (11.0%)	50 (13.2%)	201 (7.1%)
Pacific	282 (11.9%)	218 (12.4%)	1408 (11.3%)	16 (6.8%)	65 (17.2%)	465 (16.5%)
Bed size[*,†]	300 ± 149	370 ± 179	593 ± 312	323 ± 183	470 ± 179	583 ± 289
Teaching hospital[*,†,‡]	1303 (55.0%)	1248 (71.0%)	10511 (84.2%)	172 (72.6%)	320 (84.4%)	2451 (86.9%)

Note: Categorical baseline variables reported as frequencies (%) and continuous variables as means ± standard deviation; Numbers based on patient counts <11 not reported per Medicare data use agreement. MV = mitral valve; TMVr = transcatheter mitral valve repair.

* Significant difference between low-volume and high-volume for MV surgery patients

† Significant difference between medium-volume and high-volume for MV surgery patients

‡ Significant difference between low-volume and high-volume for TMVr patients

§ Significant difference between medium-volume and high-volume for TMVr patients

rehospitalization was defined as ICD-10 codes I00-I99 in the primary position.[7] The main predictor was 2017 MV surgery volume for the procedure hospital. Hospitals were categorized into 3 groups based on the current requirements and those recommended by the societies[1] to begin a TMVr program: low-volume (1 to 24 surgeries), medium-volume (25 to 39), and high-volume (40+). Hospital characteristics, including volumes, were obtained using the 2017 Definitive Healthcare Hospital & IDN Database. Definitive Healthcare uses a proprietary algorithm derived from the Centers for Medicare & Medicaid Services (CMS) Standard Analytical Files to estimate all-payor procedure volumes for US hospitals.[8] Although only Medicare patients were examined for outcomes, hospital volume classifications were based on all-payer data since MV surgery is also performed on commercially-insured patients.[9–10]

TMVr and MV surgery patients were analyzed as separate cohorts. Baseline patient and hospital characteristics were reported and tested for statistically significant differences at $p < 0.05$ using chi-squared, Fisher's exact test, or t-test, as appropriate. For outcomes modeling, in-hospital mortality was analyzed using generalized estimating equations models and accounted for clustering by institution. Odds ratios (OR), 95% confidence intervals (CI) and p values were presented as measures of association. Postdischarge outcomes were depicted using Kaplan-Meier curves and analyzed using a Cox proportional hazard model with a robust sandwich estimator to adjust for institutional clustering. Cumulative martingale residuals plots and Kolmogorov-type supremum tests were used to confirm the proportional hazards assumption. Hazard ratios (HR), 95% CIs and p values were presented as measures of association. All outcome models were risk-adjusted using a propensity score based on patient [age, sex, race, region, 31 comorbidity indicators from the Elixhauser comorbidity index (ECI)[11]] and hospital (bed size, teaching status, region) characteristics, as well as two-way interactions among the hospital characteristics. Propensity score adjustment was used to allow for the inclusion of many potential confounders without impeding model convergence. To address the potential for underpowered analysis due to low TMVr procedure volumes and outcome events, a sensitivity analysis was performed using TMVr procedures in both 2017

Table 2
(a) Comorbidities for MV surgery and TMVr patients by MV surgery institutional volume

Patient and hospital characteristics	MV surgery patients			TMVr patients		
	MV surgery institutional volume					
	Low (n = 2,369)	Medium (n = 1,758)	High (n = 12,483)	Low (n = 237)	Medium (n = 379)	High (n = 2,819)
AIDS[a]	–	–	44 (0.4%)	0	–	–
Alcohol abuse[b]	64 (2.7%)	64 (3.6%)	266 (2.1%)	–	–	41 (1.5%)
Anemia	294 (12.4%)	205 (11.7%)	1527 (12.2%)	40 (16.9%)	67 (17.7%)	445 (15.8%)
Arrhythmia[a]	1114 (47.0%)	873 (49.7%)	6502 (52.1%)	167 (70.5%)	269 (71.0%)	1962 (69.6%)
CHF	1098 (46.3%)	803 (45.7)	5739 (46.0%)	177 (74.7%)	282 (74.4%)	2088 (74.1%)
Chronic pulm dis[a]	675 (28.5%)	462 (26.3)	3086 (24.7%)	93 (39.2%)	132 (34.8%)	949 (33.7%)
Coagulopathy	191 (8.1%)	154 (8.8)	1047 (8.4%)	35 (14.8%)	48 (12.7%)	365 (12.9%)
Depression	302 (12.7%)	227 (12.9)	1534 (12.3%)	40 (16.9%)	60 (15.8%)	367 (13.0%)
Diabetes (Comp)[c]	385 (16.3%)	275 (15.6)	1865 (14.9%)	58 (24.5%)	82 (21.6%)	538 (19.1%)
Diabetes (Uncomp) [c]	574 (24.2%)	387 (22.0)	2655 (21.3%)	77 (32.5%)	107 (28.2%)	675 (23.9%)
Drug abuse[b]	58 (2.4%)	51 (2.9)	257 (2.1%)	–	–	35 (1.2%)
Fluid & electrolyte	559 (23.6%)	366 (20.8)	2827 (22.6%)	80 (33.8%)	139 (36.7%)	970 (34.4%)
HTN (Comp)	848 (35.8%)	610 (34.7)	4429 (35.5%)	144 (60.8%)	221 (58.3%)	1666 (59.1%)
HTN (Uncomp) [b]	1470 (62.1%)	1136 (64.6)	7689 (61.6%)	174 (73.4%)	269 (71.0%)	1920 (68.1%)
Hypothyroidism [c]	385 (16.3%)	268 (15.2)	2113 (16.9%)	42 (17.7%)	102 (26.9%)	677 (24.0%)
Iron anemias[a]	37 (1.6%)	54 (3.1)	306 (2.5%)	–	17 (4.5)	103 (3.7%)
Liver disease	119 (5.0%)	106 (6.0)	671 (5.4%)	–	23 (6.1)	132 (4.7%)
Lymphoma	24 (1.0%)	25 (1.4)	146 (1.2%)	–	–	50 (1.8%)
Metastatic cancer	15 (0.6%)	-	98 (0.8%)	–	–	32 (1.1%)

(b) Comorbidities for MV surgery and TMVr patients by MV surgery institutional volume

Patient and hospital characteristics	MV surgery patients			TMVr patients		
	MV surgery institutional volume					
	Low (n = 2,369)	Medium (n = 1,758)	High (n = 12,483)	Low (n = 237)	Medium (n = 379)	High (n = 2,819)
Obesity	392 (16.5%)	272 (15.5%)	1963 (15.7%)	48 (20.3%)	49 (12.9%)	359 (12.7%)
Other neuro dis[b]	167 (7.0%)	130 (7.4%)	769 (6.2%)	19 (8.0%)	32 (8.4%)	252 (8.9%)
Peripheral vasc dis[a,b]	501 (21.1%)	372 (21.2%)	2938 (23.5%)	111 (46.8%)	139 (36.7%)	1049 (37.2%)
Paralysis	24 (1.0%)	15 (0.9%)	125 (1.0%)	–	–	39 (1.4%)
Peptic ulcer	31 (1.3%)	29 (1.6%)	210 (1.7%)	–	–	57 (2.0%)
Psychoses	21 (0.9%)	10 (0.6%)	88 (0.7%)	–	–	12 (0.4%)
Pulm circ disorder [a]	588 (24.8%)	479 (27.2%)	3471 (27.8%)	105 (44.3%)	141 (37.2%)	1143 (40.5%)
RA or CVD [c]	114 (4.8%)	87 (4.9%)	685 (5.5%)	21 (8.9%)	25 (6.6%)	158 (5.6%)
Renal failure [c]	503 (21.2%)	370 (21.0%)	2742 (22.0%)	107 (45.1%)	149 (39.3%)	1090 (38.7%)
Tumor	139 (5.9%)	107 (6.1%)	841 (6.7%)	23 (9.7%)	32 (8.4%)	260 (9.2%)
Heart valve disease[y,z]	1685 (71.1%)	1342 (76.3%)	9803 (78.5%)	213 (89.9%)	326 (86.0%)	2477 (87.9%)
Weight Loss [d]	130 (5.5%)	91 (5.2%)	589 (4.7%)	16 (6.8%)	23 (6.1%)	261 (9.3%)

Note: Baseline comorbidities reported as frequencies (%); Numbers based on patient counts <11 not reported per Medicare data use agreement; CHF = congestive heart failure; Circ = circulation; Comp = complicated; CVD = cardiovascular disease; Dis = disease; HTN = hypertension; MV = mitral valve; Neuro = neurological; Pulm = pulmonary; RA = rheumatoid arthritis; TMVr = transcatheter mitral valve repair; Uncomp = uncomplicated; Vasc = vascular.

[a] Significant difference between low-volume and high-volume for MV surgery patients.
[b] Significant difference between medium-volume and high-volume for MV surgery patients.
[c] Significant difference between low-volume and high-volume for TMVr patients.
[d] Significant difference between medium-volume and high-volume for TMVr patients.

and 2018 to further evaluate the relationship between MV surgical volume and TMVr in-hospital mortality. Analytic data sets were created using the Instant Health Data platform from Panalgo and all statistical analyses were conducted using SAS software version 9.4 (SAS Institute, Cary, North Carolina).

Results

In 2017, a total of 16,610 Medicare patients underwent MV surgery, with 14.3% of surgeries performed at low-volume facilities, 10.6% at medium-volume facilities, and 75.2% at high-volume facilities (Table 1). The majority of MV surgery patients were male (52.8%), white (85.9%), and 70.1 years on average. A total of 3,435 Medicare patients underwent TMVr (i.e., 6.9% at low-volume, 11.0% at medium-volume, 82.1% at high-volume facilities). The majority were white (88.8%) and the average age was 79.7 years. TMVr patients had a greater number of baseline comorbidities than MV surgery patients (mean ECI score = 7.2 vs 5.4, respectively). In both cohorts, there were statistically significant baseline differences in patient age,

Table 3
MV and TMVr patient outcomes by MV surgery institutional volume

Outcome	n (%) with event	Comparison	Measure of association[a] (95% CI)	p value
MV surgery outcomes by MV surgery institutional volume (n = 16,610)				
In-hospital mortality	Low: 233 (9.8%)	Low vs High	1.50 (1.23, 1.84)	<0.01[b]
	Med: 152 (8.6%)	Medium vs High	1.33 (1.06, 1.67)	0.01[b]
	High: 802 (6.4%)			
Postdischarge mortality	Low: 209 (9.8%)	Low vs High	1.16 (0.95, 1.41)	0.15
	Med: 160 (10.0%)	Medium vs High	1.20 (0.98, 1.48)	0.08
	High: 935 (8.0%)			
Cardiovascular rehospitalization	Low: 600 (28.1%)	Low vs High	1.09 (0.98, 1.21)	0.13
	Med: 436 (27.1%)	Medium vs High	1.05 (0.93, 1.19)	0.40
	High: 3042 (26.0%)			
TMVr outcomes by MV surgery institutional volumes (n = 3,435)				
In-hospital mortality	Low: <11	Low vs High	1.52 (0.56, 4.13)	0.41
	Med: 12 (3.2%)	Medium vs High	1.58 (0.82, 3.02)	0.17
	High: 62 (2.2%)			
Postdischarge mortality	Low: 45 (19.5%)	Low vs High	0.91 (0.57, 1.44)	0.69
	Med: 78 (21.3%)	Medium vs High	1.01 (0.77, 1.33)	0.93
	High: 583 (21.2%)			
Cardiovascular rehospitalization	Low: 79 (34.2%)	Low vs High	0.71 (0.55, 0.92)	0.01[b]
	Med: 137 (37.3%)	Medium vs High	0.94 (0.78, 1.14)	0.52
	High: 1066 (38.7%)			

Note: Numbers based on patient counts <11 not reported per Medicare data use agreement; Med = medium; MV = mitral valve; TMVr = transcatheter mitral valve repair.

[a] Odds ratio for in-hospital mortality, hazard ratio for postdischarge mortality and cardiovascular hospitalization. CI = confidence interval.

[b] Statistically significant at p <0.05.

race, region and select ECI categories (Table 2) across hospital volume categories. There were also significant differences in hospital characteristics where patients at high-volume facilities were more likely to be treated at teaching hospitals with larger bed sizes in the Northeast or South Atlantic regions.

Propensity score adjusted results (Table 3) found a significant relationship between MV surgery volume and in-hospital mortality for MV surgery patients, but did not find a similar relationship for TMVr patients. For MV surgery patients, adjusted analyses showed in-hospital mortality rates to be significantly higher for both low-volume and medium-volume facilities, as compared with high-volume facilities. There was no statistically significant relationship between institutional MV surgery volume and in-hospital mortality for TMVr patients. Across all volume categories, the observed in-hospital mortality rate for TMVr patients was relatively low: 2.3% for all TMVr patients as compared with 7.2% for MV surgery patients. Figure 1 displays the differences in in-hospital mortality rates across hospital volume categories by patient cohort.

The sensitivity analysis for TMVr in-hospital mortality inclusive of both 2017 and 2018 data confirmed the results of the main analysis. After more than doubling the sample size (n = 8,572), there was still no statistically significant relationship between institutional MV surgery volume and in-hospital mortality for TMVr patients, either at low-volume [OR = 0.95, 95% CI (0.44, 2.04)] or medium-volume [OR = 1.04, 95% CI (0.63, 1.71)] facilities, as compared with high-volume facilities.

For postdischarge outcomes, with respect to both MV surgery and TMVr patients, the rates of mortality and cardiovascular rehospitalization were not significantly higher at low- or medium-volume institutions, as compared with high-volume institutions (Table 3, Figure 1). Of note, cardiovascular rehospitalization rates were significantly lower for TMVr patients treated at low-volume compared with high-volume institutions. There were no significant differences in cardiovascular rehospitalization rates for TMVr patients at medium-volume versus high-volume institutions.

Discussion

In accordance with our previously published findings,[5] this updated analysis found a significant inverse relationship between hospital MV procedure volume and in-hospital mortality for MV surgery patients, but no relationship for TMVr patients. Furthermore, no significant relationships were observed between hospital MV surgical volumes and postdischarge outcomes (mortality, cardiovascular rehospitalizations) for both MV surgery and TMVr patients.

This study adds to the growing body of literature[2–3,5–6,12–19] on volume-outcome relationships for MV procedures and further addresses the policy implications of imposing increased MV surgery volume requirements for TMVr. Similar to other MV surgery volume-outcome studies,[2–3,5] short-term mortality was significantly lower at high-volume facilities. More recent volume-outcome studies[2–14,20] have addressed the TMVr volume-outcome relationship. These studies were conducted using a variety of data sources, study designs and methodologies, but all demonstrated improved TMVr patient outcomes with higher

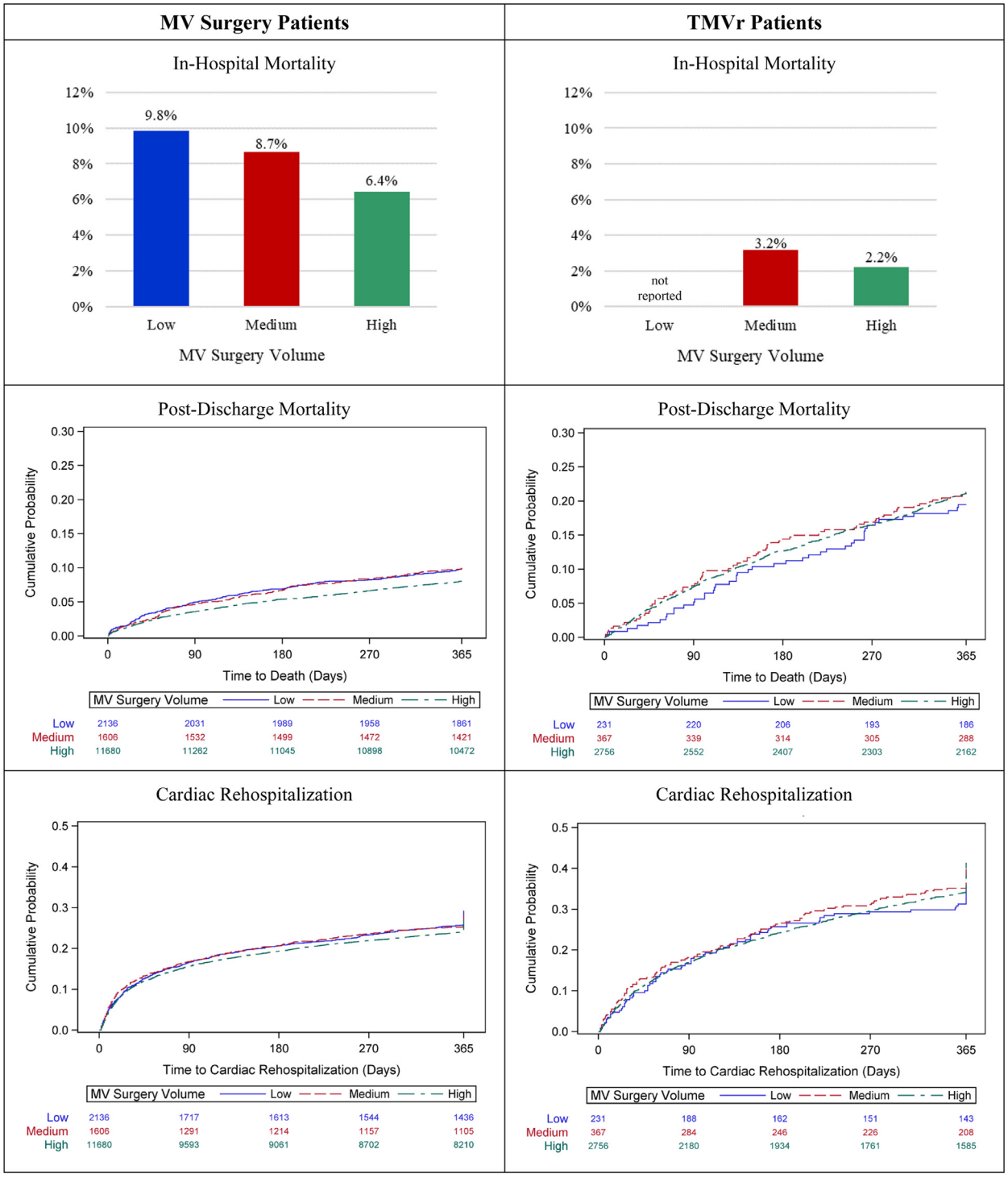

Figure 1. In-hospital mortality, postdischarge mortality and cardiac rehospitalization by MV surgery volume for MV surgery and TMVr patients. Note: Numbers based on patient counts <11 not reported per Medicare data use agreement; MV = mitral valve; TMVr = transcatheter mitral valve repair.

TMVr procedure volumes. The goal of this update was to fill a gap in the literature by examining the relationship between MV surgical volume and TMVr outcomes.

Similar to the current study, a recent analysis by Vemulapalli et al[6] addressed this gap by examining 1-year mortality and heart failure hospitalization in 2017 Medicare patients. Both studies confirmed a lack of association between institutional MV surgery volume and TMVr outcomes, although with notable differences in method. Vemulapalli et al's method of approximating all-payer volumes did not account for differing payer case mix by individual hospitals. Both studies accounted for hospital clustering,

although the current study additionally adjusted for hospital characteristics (i.e., bed size, teaching status and region). The current study also operationalized MV surgical volume categories according to the proposed volume requirements in the multisociety consensus statement to explicitly measure the policy implications of the change.

Currently, many patients are not offered advanced or innovative therapies due to restrictions limiting availability. Unlike many other current therapies, there are already rigorous protocols in place for the management of TMVr patients to ensure the appropriateness, quality, and safety of the therapy. This includes review by a multi-disciplinary heart team, preprocedural technical review by the device maker, intra-procedural evaluation by the interventional imager and interventional cardiologist, and subsequent mandatory follow-up. These components are important for TMVr evaluation and therapy and should remain. However, reconsideration of the association between MV surgical volume and TMVr site eligibility is warranted as the multisociety consensus statement proposed increase to the minimum surgical volume requirement would unnecessarily limit patient access.

Many clinical and technical requirements are already involved in starting a successful TMVr program. Careful patient selection, advanced procedural imaging, attention to appropriate medical therapy (particularly for patients with functional MR), and the ability to manage procedural complications, among other factors in addition to operator skill, are needed to achieve optimal TMVr outcomes. While high MV surgical volume might be assumed to indicate the presence of these important programmatic supports, our data do not suggest that surgical volume influences TMVr clinical outcomes. Clinically, it appears that TMVr is safe regarding in-hospital mortality rates even in centers that do not have a high-volume MV surgery program.

There are limitations of these retrospective, claims-based analyses. Procedural success (i.e., level and duration of MR reduction) is a primary measure of effectiveness but is not available in claims data. Instead, mortality and cardiovascular rehospitalizations were evaluated, which are also key outcomes, but impacted by a variety of additional factors and only a proxy for procedural success. Procedural success may also be associated with both operator/institutional volumes and observed patient outcomes. The Definitive Healthcare database, used to categorize hospitals by procedure volume, approximates volumes by a proprietary algorithm and is not an exact count. However, all-payer institutional volume seems to be a better proxy of hospital experience than alternatives used in other studies such as bed size, Medicare-only volumes, or registry data.[12–14,20] This analysis does not distinguish functional from degenerative MR. While the majority of TMVr procedures in 2017 were for degenerative MR, the MV surgery cohort, and to a lesser extent the TMVr cohort, is heterogenous with respect to etiology. However, we do not expect an association between MR etiology and hospital procedure volume that would bias the results. While risk-adjustment accounted for measured baseline comorbidity differences, it is possible that residual confounding remained for patient characteristics not captured in claims data (i.e., MR severity, frailty, hemodynamics, etc.). Patients with private insurance were not included, although the bias of excluding younger and healthier patients with commercial coverage would be similar across patient cohorts and volume categories. Since the current NCD requirements are based on surgical volumes at the institutional level, the current analysis did not account for individual operator experience, although operator volume is a likely predictor of patient outcomes and may mediate the hospital volume-outcome relationship.[14–15] The lower counts of TMVr patients at low- and medium-volume facilities and overall low outcomes rates may impact the power and generalizability of the results, although this limitation was partially addressed by conducting a sensitivity analysis that achieved similar results after adding 2018 TMVr procedures.

These findings confirm the posited volume-outcome relationship of MV surgery, while the lack of relationship for TMVr patients reflects the relative safety and fundamentally different risk profile of TMVr compared with surgery. These results also indicate procedure volumes of one cardiac specialty are not inherently associated with patient outcomes from transcatheter procedures performed by a different cardiac specialty. While the importance of a multidisciplinary heart team cannot be overemphasized, from a policy perspective, our findings do not support increasing the current annual MV surgery volume requirement to begin a new TMVr program.

Disclosures

This study was supported by Edwards Lifesciences in Irvine, CA; however, the publication of study results was not contingent on Edwards Lifesciences' approval or censorship of the manuscript. The external authors and study sponsors participated in the study design, data analysis, data interpretation, and development of the report, and gave approval to submit for publication.

CMB, MJR, MRR have consulting relationships with Edwards Lifesciences. CMB is an advisory board member for Medtronic and Boston Scientific. MJR and MRR have consulting relationships with Medtronic. JVH, SM, SAM, TEF are employees of Edwards Lifesciences, the study sponsor.

Authors' Contributions

All authors contributed to the concept, study design and interpretation of the data; JVH and SM contributed to the data analysis. Initial manuscript draft was developed by JVH and SM, which was substantially improved by all authors. We confirm that the manuscript has been read and approved by all authors.

Colin M. Barker: conceptualization, methodology, validation, writing (original & review/editing), visualization.

Matthew R. Reynolds: conceptualization, methodology, validation, writing (original & review/editing).

Michael J. Reardon: validation, writing (original & review/editing).

Joanna L. Van Houten: conceptualization, methodology, software, investigation, validation, data curation, writing (original & review/editing), visualization, project administration.

Shannon M. E. Murphy: conceptualization, methodology, software, formal analysis, investigation, validation, data curation, visualization, writing (original & review/editing).

Sarah A. Mollenkopf: conceptualization, methodology, validation, writing (original & review/editing), visualization, resources, supervision, project administration, funding acquisition.

Ted E. Feldman: conceptualization, validation, writing (original & review/editing).

Previous Presentation

This updated data were not previously presented.

Data Sharing Statement

The data that support the findings of this study are available from the Center for Medicare and Medicaid Services, but restrictions apply to the availability of these data and were used under license for the current study; therefore, they are not publicly available.

1. Bonow RO, O'Gara PT, Adams DH, Badhwar V, Bavaria JE, Elmariah S, Hung JW, Lindenfeld J, Morris A, Satpathy R, Whisenant B, Woo YJ. 2019 AATS/ACC/SCAI/STS expert consensus systems of care document: operator and institutional recommendations and requirements for transcatheter mitral valve intervention: a joint report of the American Association for Thoracic Surgery, the American College of Cardiology, the society for cardiovascular angiography and interventions, and the society of thoracic surgeons. *J Am Coll Cardiol* 2019;76:96–117.
2. Gammie JS, O'Brien SM, Griffith BP, Ferguson TB, Peterson ED. Influence of hospital procedural volume on care process and mortality for patients undergoing elective surgery for mitral regurgitation. *Circulation* 2007;115:881–887.
3. Badhwar V, Vemulapalli S, Mack MA, Gillinov AM, Chikwe J, Dearani JA, Grau-Sepulveda MV, Habib R, Rankin JS, Jacobs JP, McCarthy PM, Bloom JP, Kurlansky PA, Wyler von Ballmoos MC, Thourani VH, Edgerton JR, Vassileva CM, Gammie JS, Shahian DM. Volume-outcome association of mitral valve surgery in the United States. *JAMA Cardiol* 2020;5:1092–1101.
4. Feldman T, Foster E, Glower DD, Kar S, Rinaldi MJ, Fail PS, Smalling RW, Siegel R, Rose GA, Engeron E, Loghin C, Trento A, Skipper ER, Fudge T, Letsou GV, Massaro JM, Mauri L. Percutaneous repair or surgery for mitral regurgitation. *N Engl J Med* 2011;364:1395–1406.
5. Barker CM, Reardon MJ, Reynolds MR, Feldman TE. Association between institutional mitral valve procedure volume and mitral valve repair outcomes in Medicare patients. *JACC: Cardiovasc Interv* 2020;13:1137–1139.
6. Vemulapalli S, Prillinger J, Thourani V, Yeh RW. Mitral valve surgical volume and transcatheter mitral valve repair outcomes: impact of a proposed volume requirement on geographic access. *J Am Heart Assoc* 2020;9:e016140.
7. Rogers T, Khan JM, Edelman JJ, Waksman R. Summary of the 2018 medicare evidence development & coverage advisory committee (MEDCAC) for transcatheter aortic valve replacement. *Cardiovasc Revasc Med* 2018;19:964–970.
8. Fulton L, Kruse CS. Hospital-based back surgery: geospatial-temporal, explanatory, and predictive models. *J Med Internet Res* 2019;21:e14609.
9. Bonnet V, Boisselier C, Saplacan V, Belin A, Gérard J, Fellahi J, Hanouz J, Fischer M. The role of age and comorbidities in postoperative outcome of mitral valve repair: a propensity-matched study. *Medicine (Baltimore)* 2016;95:e3938.
10. Schnittman SR, Itagaki S, Toyoda N, Adams DH, Egorova NN, Chikwe J. Survival and long-term outcomes after mitral valve replacement in patients aged 18 to 50 years. *J Thorac Cardiovasc Surg* 2018;155. 96-102 e11.
11. Elixhauser A, Steiner C, Harris DR, Coffey RM. Comorbidity measures for use with administrative data. *Med Care* 1998;36:8–27.
12. Yeo I, Kim LK, Wong SC, Cheung JW, Itagaki S, Chikwe J, Egorova NN. Relation of hospital volume with in-hospital and 90-day outcomes after transcatheter mitral valve repair using MitraClip. *Am J Cardiol* 2019;124:63–69.
13. Gad MM, Ahuja KR, Bazarbashi N, Karrthik AK, Kaur M, Mick SL, Reed GW, Tuzcu EM, Krishnaswamy A, Kapadia SR. The impact of hospital characteristics on the outcomes of interventional cardiac procedures. *JACC Cardiovasc Interv* 2019;12:1872–1874.
14. Chhatriwalla AK, Vemulapalli S, Szerlip M, Kodali S, Hahn RT, Saxon JT, Mack MJ, Ailawadi G, Rymer J, Manandhar P, Kosinski AS, Sorajja P. Operator experience and outcomes of transcatheter mitral valve repair in the United States. *J Am Coll Cardiol* 2019;74:2955–2965.
15. Birkmeyer JD, Stukel TA, Siewers AE, Goodney PP, Wennberg DE, Lucas FL. Surgeon volume and operative mortality in the United States. *N Engl J Med* 2003;349:2117–2127.
16. Butala NM, Bucholz EM, Kolte D, Elmariah S. Association of hospital inpatient percutaneous coronary intervention volume with clinical outcomes after transcatheter aortic valve replacement and transcatheter mitral valve repair. *JAMA Cardiol* 2020;5:464–468.
17. Salemi A, Gaudino M, Bakaeen F, Mao J, Hameed I, Khan FM, Rong LQ, Wingo M, Girardi LN, Sedrakyan A. Operator volume to outcome relationship in mitral and aortic valve replacement. *J Am Coll Cardiol* 2019;74:2821–2822.
18. Vassileva CM, Boley T, Markwell S, Hazelrigg S. Impact of hospital annual mitral procedural volume on mitral valve repair rates and mortality. *J Heart Valve Dis* 2012;21:41–47.
19. Weiner MM, Hofer I, Lin HM, Castillo JG, Adams DH, Fischer GW. Relationship among surgical volume, repair quality, and perioperative outcomes for repair of mitral insufficiency in a mitral valve reference center. *J Thorac Cardiovasc Surg* 2014;148:2021–2026.
20. Chhatriwalla AK, Vemulapalli S, Holmes DR Jr., Dai D, Li Z, Ailawadi G, Glower D, Kar S, Mack MJ, Rymer J, Kosinski AS, Sorajja P. Institutional experience with transcatheter mitral valve repair and clinical outcomes: insights from the TVT registry. *JACC Cardiovasc Interv* 2019;12:1342–1352.