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Contemporary Operator Procedural Volumes and Outcomes for TAVR and MTEER in the US

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Abstract

IMPORTANCE: Recent evidence suggests that hospital-level associations between procedural volume and outcomes for transcatheter aortic valve replacement (TAVR) and mitral transcatheter edge-to-edge repair (MTEER) may be plateauing. Less is known about the operator volumes-outcomes association in the contemporary era.

OBJECTIVE: To determine whether an operator-level volume-outcomes association exists for TAVR and MTEER in the contemporary era.

DESIGN, SETTING, AND PARTICIPANTS: This cohort study examined data from patients undergoing TAVR or MTEER between January 2020 and December 2023 included in the Society of Thoracic Surgeons (STS)/American College of Cardiology (ACC) Transcatheter Valve Therapies (TVT) Registry, a national all-comers real-world registry. Consecutive patients undergoing TAVR for aortic stenosis or MTEER for mitral regurgitation were included. Data analysis was performed from October 2024 to December 2025.

EXPOSURE: TAVR or MTEER.

MAIN OUTCOMES AND MEASURES: The primary outcome measures were (1) 30-day all-cause mortality, (2) a 30-day composite outcome, and (3) in-hospital procedural complications following TAVR or MTEER. Data from the STS/ACC TVT Registry were analyzed for patients undergoing TAVR or MTEER between 2020 and 2023. The primary analysis assessed the association between operator volume and 30-day outcomes using a 2-level random-effects logistic regression model. The interaction between operator and hospital volumes and the association between TAVR and MTEER outcomes were also evaluated.

RESULTS: A total of 358 943 patients underwent TAVR at 827 hospitals (7524 operators; median [IQR] annual volume, 24 [11–47]), and 51 407 patients underwent MTEER at 493 hospitals (2483 operators; median [IQR] annual volume, 12 [7–19]). For TAVR, median (IQR) patient age was 79.0 (73.0–85.0) years, and 152 186 patients (42.4%) were female; for MTEER, median (IQR) patient age was 79.0 (71.0–84.0) years, and 23 402 patients (45.5%) were female. Low-volume operators demonstrated inferior process of care measures compared with high-volume operators. In adjusted analyses, a higher risk of 30-day mortality (odds ratio [OR], 1.13; 95% CI, 1.02–1.26; $P = .02$) and in-hospital complications (OR, 1.09; 95% CI, 1.03–1.16; $P = .005$) was observed for low-volume TAVR operators (<15/y) compared with high-volume operators (>37/y). For MTEER, in-hospital complications (OR, 1.31; 95% CI, 1.11–1.56; $P = .002$) were higher for low-volume operators (<8/y) compared with high-volume operators (>16/y), while 30-day mortality was not different (OR, 1.16; 95% CI, 0.96–1.41; $P = .12$). Associations were consistent across hospital volume strata. Operator-level outcomes for TAVR and MTEER were not correlated.

CONCLUSIONS AND RELEVANCE: In this cohort study, results from a large, contemporary US registry demonstrate a persistent inverse association between operator volume and patient outcomes for both TAVR and MTEER. These findings may help inform future policies aimed at ensuring optimal outcomes.

Transcatheter therapies have revolutionized the care of patients with valvular heart disease, but as with the widespread implementation of any new technology, concerns remain about maintaining clinical quality and replicating the observed outcomes in pivotal clinical trials. Professional societies and Medicare have focused on procedural volume requirements for hospitals as a proxy for quality of care.[1–4] These recommendations are based on prior studies demonstrating an inverse association between hospital-level procedural volumes and outcomes for both transcatheter aortic valve replacement (TAVR) and mitral transcatheter edge-to-edge repair (MTEER).[5,6] In a more contemporary analysis of more than 400 000 patients undergoing TAVR or MTEER, we observed no difference in in-hospital mortality based on hospital volumes for either procedure. There were nominal differences in 30-day mortality for TAVR and no differences for MTEER.[7] This suggests that the association between hospital-level volumes and short-term outcomes may be approaching a plateau as these technologies have matured.

Less is known about contemporary operator-level associations of volume and outcomes for TAVR and MTEER. Two prior studies, one involving high- and intermediate-risk patients undergoing TAVR between 2015 and 2017[6] and the other involving patients undergoing MTEER mostly for primary mitral regurgitation (MR) between 2013 and 2018,[8] reported an inverse correlation between operator volumes and procedural and 30-day outcomes for both procedures. With more than 100 000 TAVR and 15 000 MTEER procedures performed annually in the US by an increasing number of operators,[9] there is an urgent need to reexamine operator-level considerations for transcatheter valve procedures in the contemporary era. Accordingly, in this study, we assessed the association between operator volumes and outcomes in a contemporary, large national registry of patients undergoing TAVR or MTEER.

Methods

Data Source

Details of the Society of Thoracic Surgeons (STS)/American College of Cardiology (ACC) Transcatheter Valve Therapies (TVT) Registry have been published previously.[10] Briefly, this registry, launched in 2011, collects data on all US patients undergoing TAVR or MTEER with commercially approved devices, as mandated by the US Centers for Medicare & Medicaid Services (CMS). Standardized data elements, quality checks by the National Cardiovascular Data Registry, and annual independent audits ensure data integrity. Use of TVT Registry data for research was approved by institutional review boards at Advarra and Beth Israel Deaconess Medical Center with a waiver of informed consent. This study was conducte and reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines.

Study Population

Patients undergoing TAVR and MTEER procedures from January 2020 to December 2023 were included.

Assessment of Hospital and Operator Procedural Volumes

Annualized volume for a hospital or site (or operator) was calculated via the following method: [Total number of TAVR or MTEER procedures at each hospital (or by each operator) × 12]/Total number of months between first and last procedure at that hospital (or by that operator).

Patient records from hospitals that had performed fewer than 20 TAVR or MTEER procedures over the study period or missing data for the 30-day composite end point were excluded (eFigure 1 in Supplement 1).

The total number of TAVR and MTEER procedures performed by each operator was determined using their unique National Provider Identifier, allowing accurate tracking across hospitals. Since CMS requires at least 2 operators (an interventional cardiologist and a cardiac surgeon) for TAVR, we conducted 2 analyses: one assigning the operator with the highest lifetime volume (calculated from inception of the TVT Registry to December 2023) as primary and another assigning the lowest lifetime volume as the primary. For MTEER, which does not mandate 2 operators, cases involving 2 operators were attributed to the operator with the higher lifetime MTEER volume.

Outcomes Assessment

All outcomes were site-reported as per the TVT data dictionary[11] and American Society of Echocardiography reporting standards.[12] Procedure-specific definitions were used for the combined end points.[7,13,14] The primary outcome measures were: (1) 30-day all- cause mortality; (2) 30-day composite outcome (TAVR: 30-day death, stroke, Valve Academic Research Consortium [VARC 2] major/life-threatening or disabling bleed, VARC stage 3 acute kidney injury or paravalvular leak rated moderate to severe; MTEER: 30-day death, stroke, heart failure hospitalization, or residual MR of 2 or higher); and (3) in-hospital procedural complications (see the eMethods in Supplement 1).

Statistical Analysis

The hospital or operator was the unit of analysis for assignment to a volume group. However, the patient was the unit of analysis for clinical variables and outcomes. Volumes were assessed as a continuous variable and in tertiles (low, medium, high). Spearman correlation was used to compare annualized operator TAVR and MTEER volumes. Baseline variables were compared across tertiles of annualized operator MTEER and TAVR volume. Categorical variables were assessed with Pearson χ^2 tests, and continuous variables (reported as median [IQR]) with Kruskal-Wallis tests. Unadjusted outcome rates were raw proportions by operator, while adjusted rates used average model-predicted probabilities. Restricted cubic splines examined nonlinear associations between case volume and outcomes. For adjusted outcome rates, a 2-level random-effects logistic regression model was fitted adjusting for variables listed in the eMethods in Supplement 1. To allow for model convergence, operators performing fewer than 5 procedures over the study duration (689 TAVR operators and 546 MTEER operators) were excluded. A 3-level (patients, operators, and hospitals) hierarchical structure was adopted with the use of random intercepts with a covariance matrix that accounted for clustering of patients and operators within hospitals. To minimize chance findings from multiple comparisons, testing was predefined only for the following volume categories: high operator/high hospital, low operator/high hospital, and low operator/low hospital. See the eMethods in Supplement 1 for assessment of operator-level interdependence between TAVR and MTEER procedures.

For missing adjustment variables, simple-imputation techniques were used; continuous variables were median imputed and categorical variables were imputed to mode values. The eMethods in Supplement 1 lists variables with more than 2% missing information.

All statistical analyses were performed at the Smith Center for Outcomes Research using SAS version 9.4 (SAS Institute). All *P* values were 2-tailed, with statistical significance set at .05. All confidence intervals were calculated at the 95% level.

Results

Between January 2020 and December 2023, a total of 358 943 patients undergoing TAVR at 827 hospitals by 7524 operators and 51 407 patients undergoing MTEER at 493 hospitals by 2483 operators across the US were included (Figure 1). For TAVR, median (IQR) patient age was 79.0 (73.0–85.0) years, and 152 186 patients (42.4%) were female; for MTEER, median (IQR) patient age was 79.0 (71.0–84.0) years, and 23 402 patients (45.5%) were female. For TAVR, when the operator with the highest lifetime volume was assigned as the primary operator, a total of 3040 distinct operators were identified (median [IQR] number of operators/hospital, 4 [3–6]). For MTEER, 1135 distinct operators were identified (median [IQR] number of operators/hospital, 2 [2–3]). The median (IQR) annual operator TAVR and MTEER volumes were 24 (11–47) and 12 (7–19) patients, respectively (eTable 1 in Supplement 1). This included 7.8% of operators performing 5 or fewer and 21.8% performing 10 or fewer TAVR procedures annually; for MTEER, 16.6% performed 5 or fewer and 42.1% performed 10 or fewer procedures annually. When assigning TAVR primary responsibility to the operator with the lowest case volume, 4384 distinct operators were identified, with similar median (IQR) annual volumes (24 [13–41]). Baseline characteristics across tertiles of annual TAVR and MTEER operator volumes are listed in Table 1.

Association Between Annual Operator TAVR Volumes and Outcomes

TAVR operators were categorized by annual volume into low (<15), medium (15–37), and high (>37) tertiles. Patient characteristics were generally similar across groups, with minor absolute differences. Patients undergoing TAVR by low-volume operators were more likely to be treated at low-volume (median annual volume, 113) and rural hospitals. Procedurally, low-volume operators were less likely to pursue valve-in-valve TAVR, alternative access TAVR, or minimal or moderate sedation during TAVR. Low-volume operators had longer procedure times, greater contrast use, higher postprocedure mean gradients, and more paravalvular regurgitation. Unadjusted and adjusted analyses (Table 2) demonstrated a significant inverse association between annual operator volumes and 30-day mortality (Figure 2A), procedural complications (Figure 2B), and the 30-day composite endpoint (Figure 2C). For TAVRs performed by low-volume operators, 30-day mortality (2.4% vs 2.0%; odds ratio [OR], 1.13; 95% CI, 1.02–1.26; $P = .02$), 30-day composite outcome (3.7% vs 3.2%; OR, 1.10; 95% CI, 1.01–1.19; $P = .03$), and in-hospital complications (7.1% vs 6.4%; OR, 1.09; 95% CI, 1.03–1.16; $P = .005$) were higher compared with high-volume operators. Results were similar when the lowest-volume operator was designated as the primary operator for TAVR (eFigure 2 in Supplement 1).

Association Between Annual Operator MTEER Volumes and Outcomes

MTEER operators were categorized by annual volume into low (<8), medium (8–16), and high (>16) tertiles. Patient characteristics were generally similar across groups, with minor absolute differences. Patients undergoing MTEER by low-volume operators were more likely to be treated at low-volume MTEER (median annual volume, 21) and rural hospitals. Procedure times, postprocedure mean gradient, and residual 2 or greater MR and length of stay were all higher for low-volume operators. Unadjusted and adjusted analyses (Table 2) demonstrated a significant inverse association between annual operator volumes and procedural complications (Figure 2E) and the 30-day composite end point (Figure 2F) but not for 30-day mortality (Figure 2D). For MTEER procedures performed by low-volume operators, the 30-day composite outcome (39.7% vs 35.3%; OR, 1.12; 95% CI, 1.03–1.21; $P = .007$) (see eTable 2 in Supplement 1 for a detailed breakdown of the composite end point) and in-hospital complications (4.0% vs 3.2%; OR, 1.31; 95% CI, 1.11–1.56; $P = .002$) were higher compared with high-volume operators; 30-day mortality was not statistically different (3.6% vs 3.2%; OR, 1.16; 95% CI, 0.96–1.41; $P = .12$). The corresponding numbers needed to harm (NNH) ranged from 143 to 250 for TAVR and 23 to 250 for MTEER.

To account for a potential operator learning curve effect, we conducted the following 2 sensitivity analyses using each operator's first recorded procedure in the TVT Registry as the index case: excluding procedures within the first 12 months and excluding operators' first 10 procedures. Results were qualitatively similar (eTables 3 and 4 in Supplement 1). We further also assessed the volume-outcomes association in the following specific subgroups of patients: low-risk TAVR (eTable 5 in Supplement 1) and degenerative vs functional MR for MTEER (eTable 6 in Supplement 1). Results were qualitatively similar for MTEER. For site-reported low-risk patients undergoing TAVR, low-volume operators were noted to have better outcomes compared with their higher-volume counterparts.

Interaction Between Annual Hospital and Operator Outcomes

For both TAVR and MTEER, the association observed between operator volume and outcomes for TAVR was consistent across strata of hospital volume (Table 3; eFigure 3 in Supplement 1). In addition, ORs for adverse events were consistently greater than 1 for low-volume operators across hospital volume strata, with larger absolute differences for MTEER than for TAVR, although not all comparisons reached statistical significance.

Correlation of Operator-Level Outcomes for TAVR and MTEER

A total of 873 operators performed both TAVR and MTEER procedures at 510 institutions (158 685 TAVR, 42 740 MTEER). Among these, the median (IQR) annual operator TAVR and MTEER volumes were 89 (51–144) and 23 (14–35) patients, respectively. There was a strong direct correlation between operator volumes for TAVR and MTEER (Pearson correlation coefficient = 0.49; $P < .001$). However, the correlations between deciles of risk-adjusted TAVR and MTEER outcomes were poor (eFigure 4 in Supplement 1).

Discussion

The current analysis includes more than 400 000 patients who underwent TAVR or MTEER in the US between 2020 and 2023, making it one of the largest and most contemporary studies on this topic to our knowledge. We made several key observations. First, although many operators perform these procedures nationwide (7524 operators for TAVR and 2483 for MTEER), more than one-fifth of TAVR operators and nearly half of MTEER operators perform 10 or fewer procedures annually–on average, fewer than 1 per month. Second, an inverse association was observed between annual operator volumes and the risk of the composite end point and complications after adjusting for differences in patient characteristics. Further, important process differences related to procedural efficiency and efficacy were noted between low- and high-volume operators for both procedures. The observed associations between operator volumes and outcomes was not modified by hospital volume. In other words, low-volume operators at both low- and high-volume hospitals had comparably worse outcomes than high-volume operators, regardless of hospital setting. Finally, we observed a strong correlation between operator-level TAVR and MTEER volumes; however, their associated outcomes were not correlated.

Amid the rapid expansion of procedural volumes, we demonstrate a persistent inverse association between operator volumes and outcomes for both TAVR and MTEER, even as hospital-level volume-outcomes associations appear to be plateauing. Notably, the association between operator volume and outcomes was independent of hospital volume. Prior analyses on this topic were conducted before approval of low-risk TAVR and MTEER for functional MR,[6,8] as well as the updated CMS National Coverage Determination (NCD) documents.[1,2] In addition, 4 generations of Abbott's MitraClip have been developed, with the fourth-generation device (MitraClip G4 [Abbott Cardiovascular]) becoming commercially available in November 2019, while Edwards Lifesciences' Pascal device (Edwards Lifesciences) has been available since September 2022. Accordingly, the study period reflects use of the most contemporary MTEER devices available at the time of analysis, which have been reported to demonstrate improved outcomes compared with earlier iterations.[15–17] It also includes patients undergoing MTEER for both primary and secondary MR. Our analysis thus offers a contemporary view of US practice, showing that between 2017 to 2023, hospitals performing TAVR rose by 49% and operators by 1.5-fold (150%); for MTEER, between 2018 to 2023, hospitals increased by 70% and operators by 3.4-fold (340%). This growth likely reflects the expanded procedural indications in the revised NCDs.

Importantly, both the NCDs specify volume minimums for hospitals but not for individual operators. In our earlier analysis,[7] we found no difference in in-hospital mortality for TAVR or MTEER based on hospital volume, with nominal differences in 30-day mortality for TAVR and no differences for MTEER. In contrast, in the current analysis, we observed a persistent inverse association in outcomes for TAVR and MTEER based on individual operator volumes at 30 days. These findings corresponded to an approximately 10% to 15% higher risk of adverse outcomes for low-volume operators compared with their higher-volume peers. These findings could be interpreted in 2 ways. On one hand, the modest NNHs, mostly non-significant hospital-operator interactions, and similar site-level outcomes suggest that hospitals and site directors are largely ensuring operators maintain satisfactory outcomes. Additionally, more low-volume operators were in rural hospitals, potentially improving access. On the other hand, there has been rapid growth in operators and hospitals performing these procedures, especially MTEER, more than 90% of which were in nonrural settings. Resulting volume splitting and redistribution have led many operators to average fewer than 1 to 2 cases per month. For rural patients, evidence indicates that traveling slightly farther to high-quality programs is preferable to using nearby low-volume sites, supporting the original idea of a “rational dispersion” of these technologies.[18]

Our analysis may help inform future policy documents for these procedures. It also highlights the potential challenges associated with further expansion of TAVR and MTEER to sites that do not currently meet volume requirements to initiate these programs, as this would lead to a further increase in low-volume operators and hospitals performing these procedures. To further inform these policies, long-term studies on transcatheter volumes and outcomes will be important to pursue. The use of real-world data to inform the development of process metrics of quality, such as volume, and direct measurement of quality outcomes will become increasingly important under the recently adopted Transitional Coverage for Emerging Technologies (TCET). Under TCET, in contrast to a permanent NCD, a temporary Medicare coverage approval is given, pending receipt of sufficient real-world evidence via a predetermined evidence development plan. This allows for the development of process and outcomes-based quality metrics in advance of an NCD to inform its creation.[19]

The association between procedural volumes and outcomes is complex and requires deeper evaluation.[14,20–25] For instance, the interplay between procedural volumes and process measures can significantly influence outcomes. In our analysis, we observe suboptimal practice patterns among low-volume operators compared with their high-volume counterparts. Low-volume TAVR operators were less likely to use minimal or moderate sedation during TAVR, had longer procedure times, used more contrast, and had higher postprocedure mean aortic gradients and paravalvular regurgitation compared with their high-volume counterparts. These factors may have influenced 30-day outcomes and, perhaps more importantly, are likely to affect long-term outcomes.[26,27] An additional consideration is that low-volume operators performed more low-risk TAVR cases, where one could argue that optimal procedural planning and execution are even more critical.[28] Interestingly, low-volume operators had lower 30-day mortality for low-risk patients undergoing TAVR compared with higher-volume operators. These findings are hypothesis-generating and may reflect chance or the effects of multiple testing; they will require careful validation in future studies. This analysis does not explore the procedural optimization of the index TAVR for future TAV-in-TAV procedures, but its association with operator experience and volume warrants careful evaluation as well.

American and European professional societies have advocated for comprehensive valve centers of excellence based on the premise that such centers consistently achieve better outcomes across multiple transcatheter and surgical interventions.[29–31] Notably, our study found that while TAVR and MTEER volumes are closely correlated at the operator level, their outcomes are not, challenging the concept of a unified valve center of excellence. This mirrors discordance previously reported at the hospital level, now extended to operators.[7]

Limitations

We acknowledge the limitations of our analysis. As a retrospective observational study, it is potentially subject to residual and unmeasured confounding. All outcomes were site-reported and may be influenced by institutional bias. Although overall data missingness is low, certain variables, such as mitral leaflet calcification, have a high proportion of missing values. Because the TVT Registry includes only commercially performed cases, we may have underestimated the procedural volumes of operators and hospitals involved in clinical trials. Our interaction analyses between hospitals and operators may be underpowered and are unable to account for operators who perform procedures at multiple institutions. While annualized volumes are necessary for volume-outcomes assessment, they may miss temporal variation in operator case load; however, given the short study period, this is unlikely to have materially affected our findings. A learning curve analysis yielded qualitatively similar results. We also could not adjust for social factors or patient frailty. In the US, CMS requires TAVR procedures to be jointly performed by an interventional cardiologist and a cardiac surgeon, enhancing safety but complicating primary operator designation. Additionally, TAVR's multidisciplinary nature makes attributing outcomes to a single operator difficult. Procedural outcomes maybe influenced not only by operator and hospital volumes, but also by operator training and experience, including with specific devices.[32] To mitigate these limitations, we designated the operator with the highest cumulative experience as the primary operator in alignment with previous methodologies. A subgroup analysis that instead assigned the operator with the lowest lifetime experience as the primary operator yielded broadly similar results. Similarly, for MTEER procedures, the structural imager is critical to procedural success and efficacy, and expert consensus documents outline separate volume requirements for imaging operators.[33,34] However, this information is not captured in the TVT Registry, representing a limitation in assessing operator-level outcomes for MTEER. This deserves careful assessment in future studies. We also lacked information on operator training status (completion of a dedicated structural fellowship), and years of experience could only be indirectly accounted for. The observations reported are limited to a 30-day postprocedure window; longer-term follow-up will be important in future studies.

Conclusions

In conclusion, this cohort study's analysis of a large national registry of patients undergoing TAVR or MTEER indicates that low operator procedural volumes are common in the contemporary era. Operator volumes are inversely related to the adoption of best practices for these procedures and to risk-adjusted 30-day outcomes. Ensuring procedural safety, quality, and standardization as the number of sites and operators continues to expand will be crucial while also preserving adequate patient access.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Conflict of Interest Disclosures:

Dr de Lemos reported personal fees from serving as chair of a data and safety monitoring board for Varian Medical Systems outside the submitted work. Dr Chhatriwalla reported personal fees from Abbott Vascular, Edwards Lifesciences, and Medtronic and grants from Boston Scientific during the conduct of the study and personal fees from Abiomed and Rogers Towers outside the submitted work. Dr Brindis reported serving as Senior Medical Officer, External Affairs of the American College of Cardiology National Cardiovascular Data Registry. Dr Kaneko reported nonfinancial support from Edwards Lifesciences and personal fees from Abbott and Medtronic during the conduct of the study. Dr Batchelor reported serving as a consultant or on an advisory board for Abbott, Boston Scientific, Edwards Lifesciences, Johnson & Johnson, and Medtronic outside the submitted work. Dr Yeh reported contracts from the American College of Cardiology during the conduct of the study and grants and personal fees from Abbott Vascular, Edwards Lifesciences, and Medtronic outside the submitted work. Dr Vemulapalli reported grants from Cytokinetics, Edwards Lifesciences, the US Food and Drug Administration, and the US National Institutes of Health (R01 and UG3/UH3); advisory board, travel, and speakers bureau fees from Edwards Lifesciences; consulting or advisory board fees from Abbott Vascular, Astra Zeneca, Boehringer Ingelheim, and Cytokinetics; and serving on the Medtronic ALERT Steering Committee outside the submitted work. No other disclosures were reported.

Data Sharing Statement:

See Supplement 2.

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Key Points

Objective

Is there an operator level association of volume and outcomes for transcatheter aortic valve replacement (TAVR) and mitral transcatheter edge-to-edge repair (MTEER) in the contemporary era?

Findings

In this cohort study within a large, national US registry including 358 943 patients undergoing TAVR at 827 hospitals and 51 407 patients undergoing MTEER at 493 hospitals between 2020 and 2023, an inverse operator volume-outcomes association was observed for risk-adjusted 30-day outcomes with both procedures; associations were consistent across hospital volume strata. Low-volume operators demonstrated inferior process of care measures compared with their high-volume counterparts.

Meaning

Operator volumes for TAVR and MTEER impact the procedures' short-term outcomes and may have a bearing on future policies for these procedures.

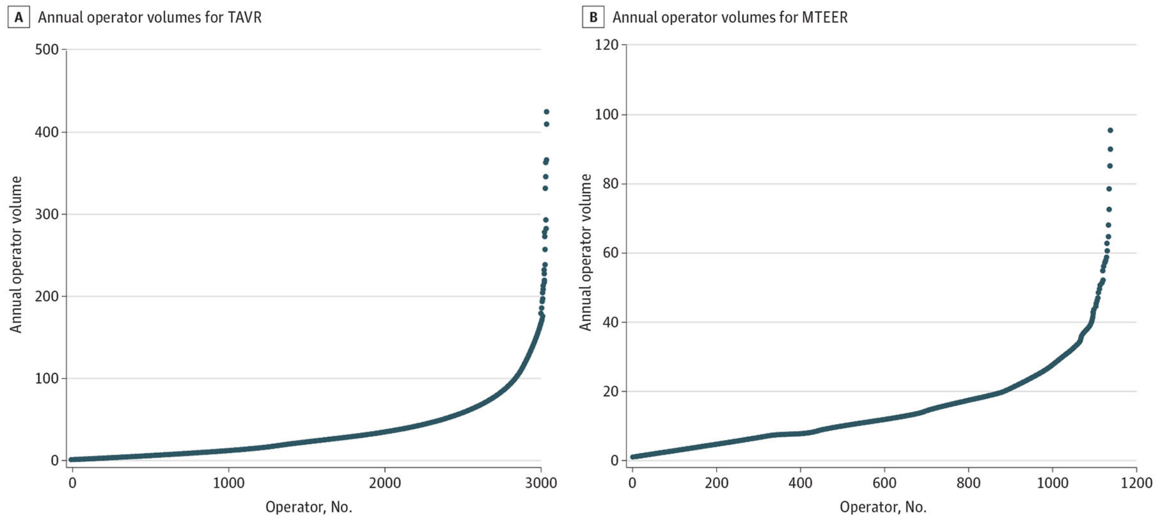

Figure 1.

Distribution of Annual Operator Volumes for Transcatheter Aortic Valve Replacement (TAVR) (A) and Mitral Transcatheter Edge-to-Edge Repair (MTEER) (B)

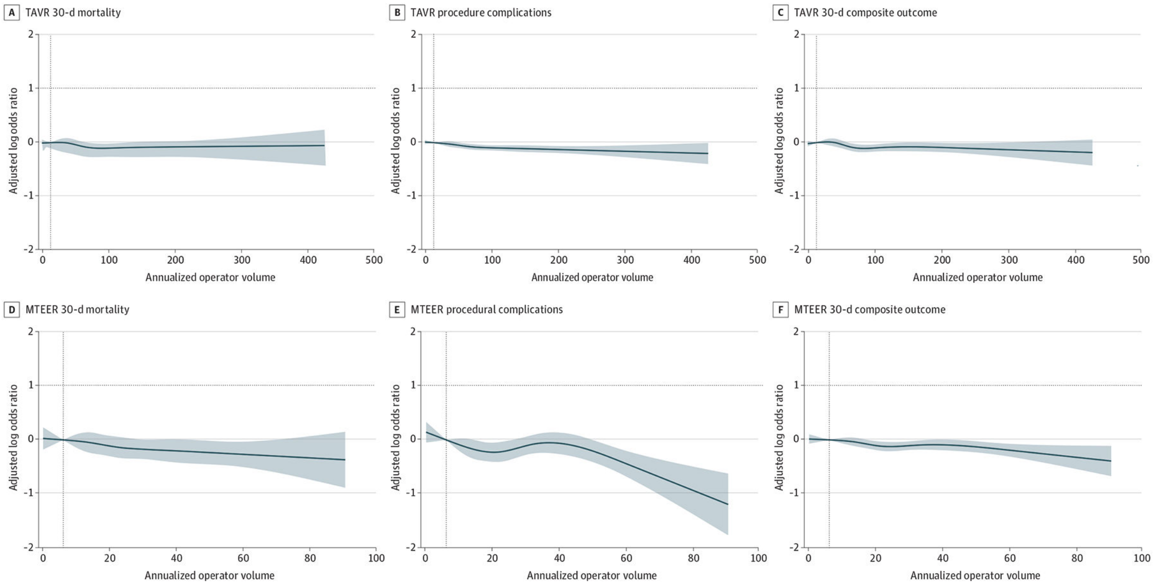

Figure 2. Scatterplot of Operator Volumes and 30-Day Mortality, Procedural Complications, and 30-Day Composite for Transcatheter Aortic Valve Replacement (TAVR) (A-C) and Mitral Transcatheter Edge-to-Edge Repair (MTEER) (D-F)

Calculated using log-transformed odds ratios obtained by restricted cubic splines (with shaded areas indicating 95%confidence intervals). Fifth percentile is used as reference.

Table 1.

Patient and Clinical Characteristics by Annualized Operator Transcatheter Aortic Valve Replacement (TAVR) and Mitral Transcatheter Edge-to-Edge Repair (MTEER) Volume Tertiles

Characteristic	TAVR (n = 358 943)				MTEER (n = 51407)			
	%			*P* value	%			*P* value
	Tertile 1 (<15/y) (n = 20 918 patients; operators = 1013)	Tertile 2 (15–37/y) (n = 69 841 patients; operators = 1014)	Tertile 3 (>37/y) (n = 266 164 patients; operators = 1013)		Tertile 1 (<8/y) (n = 5182 patients; operators = 378)	Tertile 2 (8–16/y) (n = 12 295 patients; operators = 379)	Tertile 3 (>16/y) (n = 32 657 patients; operators = 378)	
Sociodemographic								
Age, median (IQR), y	79.0 (73.0–85.0)	79.0 (73.0–85.0)	79.0 (73.0–85.0)	.04	79.0 (72.0–84.0)	79.0 (72.0–84.0)	79.0 (71.0–84.0)	.002
Sex								
Female	42.5	42.6	42.3	.43	45.4	44.7	46.0	.048
Male	57.5	57.4	57.7		54.6	55.3	54.0	
Race, No./total No. (%)[a]								
Asian	309/20 918 (1.5)	797/69 841 (1.1)	4035/266 164 (1.5)	<.001	131/5182 (2.5)	271/12 295 (2.2)	876/32 657 (2.7)	<.001
American Indian	79/20 918 (0.4)	232/69 841 (0.3)	704/266 164 (0.3)		12/5182 (0.2)	49/12 295 (0.4)	123/32 657 (0.4)	
Black	962/20 918 (4.6)	2684/69 841 (3.8)	11 136/266164 (4.2)		582/5182 (11.2)	1201/12 295 (9.8)	3565/32 657 (10.9)	
Native Hawaiian or Pacific Islander	33/20 918 (0.2)	65/69 841 (0.1)	347/266 164 (0.1)		4/5182 (0.1)	14/12 295 (0.1)	67/32 657 (0.2)	
White	18884/20918 (90.3)	64573/69841 (92.5)	243 481/266164 (91.5)		4286/5182 (82.7)	10 518/12 295 (85.5)	27 142/32 657 (83.1)	
Missing	651/20918 (3.1)	1490/69 841 (2.1)	6461/266 164 (2.4)		167/5182 (3.2)	242/122 95 (2.0)	884/32 657 (2.7)	
Ethnicity, No./total No. (%)[a]								
Hispanic or Latino	1504/20 918 (7.2)	4383/69 841 (6.3)	13 144/266164 (4.9)	<.001	385/5182 (7.4)	892/12 295 (7.3)	1995/32 657 (6.1)	<.001
Not Hispanic or Latino	19414/20 918 (92.8)	65 458/69 841 (93.7)	253 020/266164 (95.1)		4797/5182 (92.6)	11403/12 295 (92.7)	30 662/32 657 (93.9)	
Body surface area, median (IQR), m^2	1.9 (1.8–21)	1.9 (1.8–21)	1.9 (1.8–21)	<.001	1.9 (1.7–2.0)	1.9 (1.7–2.0)	1.9 (1.7–2.0)	.03
Medical history								
Diabetes	38.6	39	37.6	<.001	28.6	29.7	29.3	.34
Peripheral artery disease	17.4	17.4	19.2	<.001	12.9	13.6	13.5	.39
Current smoker	7.1	6.9	6.4	<.001	6.9	7.3	7.4	.35

Characteristic	TAVR (n = 358 943)				MTEER (n = 51407)			
	%			P value	%			P value
	Tertile 1 (<15/y) (n = 20 918 patients; operators = 1013)	Tertile 2 (15–37/y) (n = 69 841 patients; operators = 1014)	Tertile 3 (>37/y) (n = 266 164 patients; operators = 1013)		Tertile 1 (<8/y) (n = 5182 patients; operators = 378)	Tertile 2 (8–16/y) (n = 12 295 patients; operators = 379)	Tertile 3 (>16/y) (n = 32 657 patients; operators = 378)	
Dialysis	3.6	3.5	3.4	.17	4.3	4.2	4.2	>.99
Prior MI	16.2	16.7	16.8	.10	23.2	24.9	24.0	.02
Prior PCI	30.0	30.0	28.8	<.001	29.5	29.7	30.0	.61
Prior CABG	13.4	14.0	14.0	.07	19.2	19.7	19.8	.59
Prior cardiac surgery	17.3	17.8	18.8	<.001	22.6	23.2	23.4	.46
Prior stroke or TIA	6.3	6.6	6.9	.001	6.1	6.6	6.4	.40
Severe lung disease receiving home oxygen	6.6	6.3	6.1	.003	9.6	9.8	8.7	<.001
Hostile chest	3.1	2.8	3.2	<.001	4.7	4.1	4.3	.17
Porcelain aorta	0.8	0.8	0.8	.76	0.4	0.5	0.3	.10
Atrial fibrillation or flutter	32.9	33.4	34.0	<.001	62	61.7	61.3	.53
Permanent pacemaker	10.6	10.6	10.6	.98	16.7	17.1	17.3	.58
Previous ICD	2.3	2.4	2.5	.03	17.4	17.9	17.7	.70
Conduction defect	29.8	29.9	33.3	<.001	43.6	19.3	28.5	.006
NYHA class IV within 2 wk	8.7	8.4	9.0	<.001	16.3	17.0	16.2	.12
Prior aortic valve procedure	7.3	7.0	8.6	<.001	8.7	8.0	8.8	.04
Testing								
LVEF, median (IQR), %	60.0 (53.0–63.0)	60.0 (53.0–63.0)	60.0 (53.0–64.0)	<.001	53.0 (36.0–60.0)	53.0 (35.0–60.0)	53.0 (34.0–60.0)	<.001
Hemoglobin, median (IQR), g/dL	12.5 (11.1–13.8)	12.6 (11.2–13.8)	12.6 (11.2–13.8)	.10	12.3 (10.8–13.6)	12.3 (10.9–13.6)	12.3 (10.9–13.6)	.98
eGFR, median (IQR), mL/min/1.73 m2[b]	86.9 (83.7–90.2)	86.9 (83.7–90.2)	86.9 (83.7–90.2)	.10	86.9 (84.2–90.7)	86.9 (84.2–90.7)	86.9 (84.2–91.3)	.002
Left main stenosis ≥50%	5.5	5.4	5.3	.21	5.3	5.7	6.1	.07
Proximal LAD ≥70%	12.1	12.0	11.3	<.001	11.7	12.4	13.2	.03
KCCQ overall score, median (IQR)	49.0 (30.2–69.8)	50.0 (31.3–70.8)	51.0 (31.8–72.2)	<.001	43.8 (26.0–63.0)	41.7 (25.0–62.5)	42.7 (25.0–63.5)	.09
Bicuspid aortic valve	6.5	6.6	6.7	.02	NA	NA	NA	NA
Moderate or severe MR	21.5	21.1	21.4	.23	NA	NA	NA	NA

Characteristic	TAVR (n = 358 943)				MTEER (n = 51407)			
	%			*P* value	%			*P* value
	Tertile 1 (<15/y) (n = 20 918 patients; operators = 1013)	Tertile 2 (15–37/y) (n = 69 841 patients; operators = 1014)	Tertile 3 (>37/y) (n = 266 164 patients; operators = 1013)		Tertile 1 (<8/y) (n = 5182 patients; operators = 378)	Tertile 2 (8–16/y) (n = 12 295 patients; operators = 379)	Tertile 3 (>16/y) (n = 32 657 patients; operators = 378)	
Degenerative etiology of MR	11.9	12.7	13.1	<.001	65.0	66.8	64.7	<.001
Functional etiology of MR	4.1	4.3	4.3	<.001	30.7	30.3	31.9	<.001
Moderate or severe TR	18.5	18.4	18.5	.88	49.3	48.6	51.2	<.001
STS PROM, median (IQR)[c]	3.2 (2.0–5.3)	3.1 (2.0–5.1)	3.1 (1.9–5.2)	.002	5.9 (3.6–9.4)	6.0 (3.7–9.6)	5.8 (3.6–9.4)	<.001
High risk (site-reported)	30.3	28.7	32.5	<.001	NA	NA	NA	NA
Low risk (site-reported)	29.8	32.0	27.7	<.001	NA	NA	NA	NA
Process of care measures								
Transfemoral access	96.9	96.9	96.0	<.001	NA	NA	NA	NA
Valve-in-valve procedure	5.4	5.4	6.7	<.001	NA	NA	NA	NA
Embolic protection use	10.4	9.8	14.6	<.001	NA	NA	NA	NA
Minimal or moderate/conscious sedation	55.1	54.2	58.9	<.001	NA	NA	NA	NA
Procedure duration, median (IQR), min	70.0 (53.0–93.0)	65.0 (50.0–87.0)	60.0 (45.0–82.0)	<.001	109.0 (79.0–150.0)	101.0 (74.0–138.0)	85.0 (61.0–118.0)	<.001
Contrast volume, median (IQR), mL	84.0 (56.0–120.0)	80.0 (50.0–115.0)	70.0 (50.0–100.0)	<.001	NA	NA	NA	NA
Mean gradient at end of procedure or hospital discharge, mean (median [IQR]), mm Hg	11.1 (10.0 [7.0–14.0])	11.2 (10.0 [7.0–14.0])	10.9 (10.0 [7.0–14.0])	<.001	4.5 (4.0 [3.0–5.0])	4.4 (4.0 [3.0–5.0])	4.4 (4.0 [3.0–5.0])	.02
No postprocedure aortic paravalvular regurgitation	56.9	57.5	60.1	<.0001	NA	NA	NA	NA
Postprocedure residual MR ≥2+	NA	NA	NA	NA	6.5	5.4	5.8	.02
Length of stay, median (IQR), d[d]	1.0 (1.0–2.0)	1.0 (1.0–2.0)	1.0 (1.0–2.0)	<.001	1.0 (1.0–2.0)	1.0 (1.0–2.0)	1.0 (1.0–2.0)	<.001
Hospital characteristics								
Annual hospital volume, median (IQR)	112.8 (68.8–164.8)	111.2 (66.4–168.0)	167.0 (112.3–267.9)	<.001	20.9 (13.1–34.6)	21.7 (15.7–34.3)	44.6 (30.4–66.9)	<.001
Bed size, median (IQR)	436.0 (326.0–645.0)	431.0 (320.0–600.0)	513.0 (349.0–714.0)[d]	<.001	513.0 (355.0–710.0)	515.0 (365.0–691.0)	540.0 (364.0–781.0)	<.001
Region								

Characteristic	TAVR (n = 358 943)				MTEER (n = 51407)			
	%			P value	%			P value
	Tertile 1 (<15/y) (n = 20 918 patients; operators = 1013)	Tertile 2 (15–37/y) (n = 69 841 patients; operators = 1014)	Tertile 3 (>37/y) (n = 266 164 patients; operators = 1013)		Tertile 1 (<8/y) (n = 5182 patients; operators = 378)	Tertile 2 (8–16/y) (n = 12 295 patients; operators = 379)	Tertile 3 (>16/y) (n = 32 657 patients; operators = 378)	
South	36.8	39.5	32.9	<.001	34.2	37.6	37.9	<.001
Midwest	23.2	24.8	23.2		20.9	23.1	19.6	
West	23.1	19.0	20.5		22.9	22.0	28.5	
Northeast	16.8	16.7	23.4		18.8	17.3	14.0	
Type of hospital								
Rural	11.5	11.0	7.7	<.001	8.0	7.6	5.7	<.001
Suburban	27.8	29.1	27.8		24.3	30.9	23.2	
Urban	60.7	59.9	64.5		67.7	61.5	71.2	
Teaching hospital	61.7	59.8	67.0	<.001	66.9	65.7	65.9	.28

Abbreviations: CABG, coronary artery bypass graft; eGFR, estimated glomerular filtration rate; ICD, implanted cardioverter/defibrillator; KCCQ, Kansas City Cardiomyopathy Questionnaire; LAD, left anterior descending coronary artery; LVEF, left ventricular ejection fraction; MI, myocardial infarction; MR, mitral regurgitation; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; STS PROM, Society of Thoracic Surgeons Predicted Risk of Mortality; TIA, transient ischemic attack; TR, tricuspid regurgitation.

SI conversion factor: To convert hemoglobin from g/dL to g/L, multiply by 10.

[a] Data on race and ethnicity were self-reported.

[b] eGFR based on Modification of Diet in Renal Disease equation.

[c] STS PROM for isolated surgical aortic valve replacement (for patients undergoing TAVR) and for isolated mitral valve repair or replacement (for patients undergoing MTEER).

[d] For patients discharged alive.

Table 2.

Unadjusted and Adjusted Outcomes by Annualized Operator Volume Tertiles[a]

Outcome	Overall	Tertile 1	Tertile 2	Tertile 3	*P* value[a]	No. needed to harm for low vs high volume
TAVR						
No.	n = 358 943; Operators = 3040	n = 20 918; Operators = 1013	n = 69 841; Operators = 1014	n = 266164; Operators = 1103	NA	NA
30-d Mortality, %	2.0	2.4	2.1	2.0	.004 (Adjusted P value: .07)	250
OR (95% Cl)	NA	1.13 (1.02–1.26)	1.02 (0.95–1.09)	NA		NA
P value	NA	.02	.63	NA		NA
Procedural complication, %	6.5	7.1	6.7	6.4	<.001 (Adjusted P value: .001)	143
OR (95% CI)	NA	1.09 (1.03–1.16)	1.06 (1.02–1.10)	NA		NA
P value	NA	.005	.006	NA		NA
30-d Composite, %	3.3	3.7	3.4	3.2	.001 (Adjusted P value: .06)	200
OR (95% CI)	NA	1.10 (1.01–1.19)	1.04 (0.98–1.10)	NA		NA
P value	NA	.03	.18	NA		NA
MTEER						
No.	n = 51407; Operators = 1135	n = 5182; Operators = 378	n = 12 295; Operators = 379	n = 32 657; Operators = 378	NA	NA
30-d Mortality, %	3.3	3.6	3.6	3.2	.10 (Adjusted P value: .09)	250
OR (95% CI)	NA	1.16 (0.96–1.41)	1.15 (1.00–1.32)	NA		NA
P value	NA	.12	.05	NA		NA
Procedural complication, %	3.3	4.0	3.2	3.2	.01 (Adjusted P value: .005)	125
OR (95% CI)	NA	1.31 (1.11–1.56)	0.99 (0.86–1.14)	NA		NA
P value	NA	.002	.88	NA		NA
30-d Composite, %	36.6	39.7	38.7	35.3	<.001 (Adjusted P value: .02)	23
OR (95% CI)	NA	1.12 (1.03–1.21)	1.05 (0.99–1.12)	NA		NA
P value	NA	.007	.11	NA		NA

Abbreviations: NA, not applicable; OR, odds ratio.

[a]Type III *P* value for crude/observed outcomes.

Table 3.

Outcomes by Annualized Operator and Hospital Volume Tertiles for Transcatheter Aortic Valve Replacement (TAVR) and Mitral Transcatheter Edge-to-Edge Repair (MTEER)

Hospital volume	Operator volume[a]			*P* value for interaction
	Low	Intermediate	High	
TAVR				
30-d Mortality				
Low, %	2.2	2.1	2.0	.53
OR (95% CI)	1.22 (0.97–1.53)	1.14 (0.99–1.31)	1.08 (0.94–1.24)	
P value	.09	.06	.27	
Intermediate, %	2.3	1.8	1.9	
OR (95% CI)	1.25 (1.05–1.49)	0.98 (0.87–1.11)	1.04 (0.95–1.14)	
P value	.01	.80	.37	
High, %	2.0	2.0	1.9	
OR (95% CI)	1.05 (0.90–1.23)	1.03 (0.93–1.13)	1 [Ref]	
P value	.54	.58	NA	
30-d Composite				
Low, %	3.3	3.5	3.2	.19
OR (95% CI)	1.10 (0.91–1.32)	1.19 (1.07–1.33)	1.07 (0.96–1.20)	
P value	.33	.002	.22	
Intermediate, %	3.6	2.9	3.0	
OR (95% CI)	1.18 (1.02–1.36)	0.97 (0.87–1.07)	0.99 (0.92–1.07)	
P value	.02	.50	.86	
High, %	3.2	3.1	3.0	
OR (95% CI)	1.04 (0.92–1.19)	1.03 (0.95–1.11)	1 [Ref]	
P value	.50	.44	NA	
In-hospital procedural complications				
Low, %	7.6	7.0	6.6	.34
OR (95% CI)	1.16 (1.01–1.34)	1.13 (1.03–1.25)	1.06 (0.96–1.17)	
P value	.03	.01	.27	

Hospital volume	Operator volume[a]			*P* value for interaction
	Low	Intermediate	High	
Intermediate, %	6.9	6.0	6.4	
OR (95% CI)	1.04 (0.93–1.17)	0.97 (0.89–1.06)	0.98 (0.92–1.06)	
P value	.51	.49	.67	
High, %	7.0	7.0	6.4	
OR (95% CI)	1.10 (1.01–1.20)	1.08 (1.03–1.14)	1 [Ref]	
P value	.04	.003	NA	
MTEER				
30-d Mortality				
Low, %	3.0	2.8	3.9	.15
OR (95% CI)	1.15 (0.85–1.56)	1.07 (0.84–1.37)	1.78 (1.05–3.00)	
P value	.37	.56	.03	
Intermediate, %	2.8	3.2	2.7	
OR (95% CI)	1.03 (0.71–1.49)	1.21 (0.98–1.51)	0.98 (0.80–1.19)	
P value	.88	.08	.80	
High, %	3.5	3.4	2.8	
OR (95% CI)	1.30 (0.97–1.75)	1.15 (0.93–1.43)	1 [Ref]	
P value	.08	.19	NA	
30-d Composite				
Low, %	37.0	34.9	26.4	.31
OR (95% CI)	1.31 (1.12–1.53)	1.14 (0.99–1.30)	1.02 (0.76–1.37)	
P value	.001	.06	.89	
Intermediate, %	40.4	39.0	34.8	
OR (95% CI)	1.35 (1.14–1.61)	1.30 (1.14–1.49)	1.16 (1.03–1.31)	
P value	.001	<.001	.02	
High, %	32.4	33.9	31.5	
OR (95% CI)	1.03 (0.92–1.16)	1.00 (0.92–1.10)	1 [Ref]	
P value	.59	.98	NA	
In-hospital procedural complications[b]				

Hospital volume	Operator volume[a]			P value for interaction
	Low	Intermediate	High	
Low, %	3.6	3.1	4.3	.37
OR (95% CI)	1.14 (0.89–1.47)	0.99 (0.81–1.22)	1.44 (0.93–2.23)	
P value	.29	.94	.10	
Intermediate, %	4.0	3.0	3.0	
OR (95% CI)	1.30 (0.98–1.74)	0.94 (0.77–1.14)	0.96 (0.82–1.13)	
P value	.07	.52	.64	
High, %	4.3	3.4	3.2	
OR (95% CI)	1.40 (1.09–1.79)	1.01 (0.83–1.22)	1 [Ref]	
P value	.008	.93	NA	

Abbreviations: OR, odds ratio; Ref, reference.

[a]Crude incidence rates followed by adjusted ORs and 95% confidence intervals are provided. For all comparisons, high/high is reference. To avoid chance findings due to multiple comparisons, we a priori decided to statistically test for an interaction only the following volume categories: high operator/high hospital vs low operator/high hospital vs low operator/low hospital.

[b]Hierarchical modeling was not pursued since the model did not converge.