

BRIEF COMMUNICATION

Mitral Valve Surgical Volume and Transcatheter Mitral Valve Repair Outcomes: Impact of a Proposed Volume Requirement on Geographic Access

Sreekanth Vemulapalli, MD; Julie Prillinger, PhD; Vinod Thourani, MD; Robert W. Yeh, MD, MSc

BACKGROUND: There is an open Centers for Medicare and Medicaid Services National Coverage Decision for Transcatheter Mitral Valve Repair (TMVr) and a recent multisociety consensus document suggesting that TMVr centers should achieve pre-specified mitral valve replacement or repair (MVRr). Yet, little is known about the MVRr volume–TMVr outcome relationship.

METHODS AND RESULTS: Using Centers for Medicare and Medicaid Services administrative claims from January 1, 2016 to December 31, 2018, we computed the Pearson correlation coefficient and performed multivariable hierarchical modeling to estimate the MVRr volume to TMVr outcome relationship for mortality and heart failure hospitalization. Additionally, we assessed the impact of the consensus recommendations on geographic access to care by hospital referral region. Total annualized MVRr volume was <11 to 1552 (median 96, interquartile range 53, 167). One-year survival, 1-year heart failure hospitalization after TMVr were not correlated with MVRr volume. After patient risk-adjustment for age, sex, and significant Elixhauser Comorbidities, there remained no significant correlation between institutional MVRr volume and 1-year mortality (estimate -0.010 , SE 0.047 , $P=0.834$) or heart failure hospitalization (estimate -0.011 , SE 0.045 , $P=0.808$) after TMVr. Raising the restriction on TMVr from 20 to 40 MVRr/y results in ≈ 30 million individuals having to travel outside of their hospital referral region to undergo TMVr, with a disproportionate impact in the Midwest and Southeast.

CONCLUSIONS: There is no relationship between MVRr volumes and TMVr outcomes. Additionally, adoption of an annual MVRr volume ≥ 40 for performance of TMVr disproportionately impacts geographic access in the Midwest and Southeast and their large black and Hispanic populations.

Key Words: mitral regurgitation ■ mitral valve repair ■ mitral valve replacement ■ valvular disease ■ volume-outcomes

Transcatheter mitral valve repair (TMVr) was approved in the United States in 2013 for the treatment of severe degenerative mitral regurgitation in high-risk surgical patients.^{1,2} Recently, the COAPT (Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation) trial³ has led to a US Food and Drug Administration label expansion of TMVr to patients with severe functional mitral regurgitation (FMR) and symptoms refractory to optimal medical management. As a result, the Centers for Medicare and Medicaid Services (CMS)

have reopened the national coverage decision for TMVr in degenerative mitral regurgitation and FMR. To ensure quality, a multisociety consensus document suggests centers providing TMVr should achieve pre-specified mitral valve replacement or repair (MVRr).⁴

The goal of this study was to (1) describe the relationship between institutional MVRr volume and TMVr outcomes among sites performing both procedures and (2) describe potential geographic changes in access to TMVr based on proposed institutional MVRr volume requirements among all MVRr sites.

Correspondence to: Sreekanth Vemulapalli, MD, 2301 Erwin Rd. Box 3026, Durham, NC 27710. E-mail: sreekanth.vemulapalli@duke.edu

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Nonstandard Abbreviations and Acronyms

CMS	Centers for Medicare and Medicaid Services
MVRr	Mitral valve replacement or repair
TMVr	transcatheter mitral valve repair

METHODS

The authors declare that all supporting data are available within the article. The study was a retrospective analysis of a deidentified database and thus exempt from institutional review board approval. Deidentified health information can be used without authorization or any other permission specified in the Health Insurance Portability and Accountability Act Privacy Rule, and this study was therefore exempt from informed consent procedures.

Population

The study population includes patients undergoing TMVr (*International Classification of Diseases, Tenth Revision [ICD-10]: O2UG3JZ*) from January 1, 2017 to December 31, 2017 with at least 1 year of continuous pre- and postprocedure fee-for-service Medicare as determined by the CMS Inpatient and Denominator Files. Because only 26.8% of all patients undergoing MVRr in the United States have Medicare insurance,⁵ we estimated total MVRr volume by dividing each institution's CMS average MVRr volume (mitral repair or mitral replacement defined as *ICD-10: O2UG0, O2QG0, and O2RG0*) over 3 years (2016–2018) by the national proportion of Medicare patients (0.268).

Outcomes

The primary outcome was 1-year death as determined by the CMS denominator file. Secondary outcomes included 1-year heart failure hospitalization (*ICD-10: I09.81, I13.0, I13.2, I50* in the primary diagnosis position) and 1-year mitral reintervention, defined as repeat TMVr (*ICD-10: O2UG3JZ*) or MVRr (*ICD-10: O2UG0, O2QG0, and O2RG0*).

Geographic Access to TMVr by MVRr Volume

We described geographic access to TMVr by mapping all US hospitals performing MVRr as a function of those centers' total MVRr volume, using the cut points proposed in the multisociety consensus document (40 and 20 institutional mitral valve surgeries per year for new and established TMVr sites, respectively).⁴ Because care fragmentation and

1-year mortality increase after 30 minutes of travel in transcatheter aortic valve replacement,⁶ we marked a 30-mile radius around each hospital and overlaid population data from the US Census.⁷ Additionally, we assessed geographic access to care by calculating the proportion of the population living within a hospital referral region⁸ containing at least 1 center performing a number of MVRrs per year equal to or greater than a given minimum.

Statistical Analysis

Two methods were used to evaluate the association between surgical volume and MitraClip outcomes. First, we assessed the institutional correlation between MVRr volume and TMVr outcomes without risk adjustment using the Pearson correlation coefficient. To adjust for patient characteristics and hospital clustering of patients, we fit a model using mixed effects logistic regression with a random effect per hospital. Patient comorbidities were assessed in the year before TMVr based on Elixhauser Comorbidity.^{9,10} Covariates included in the final model were age at implant, sex, and comorbidities with a significant impact on outcomes. All analyses were performed on R version 3.5.1; the logistic regression was fit using the glmer in the lme4 package.

RESULTS

In the CMS fee-for-service population, TMVr institutional volume ranged from <11 to 191 procedures (median <11, interquartile range <11, 18) while total annualized MVRr volume was <11 to 1552 (median 96, interquartile range 53, 167).

One-year survival (FigureA), 1-year heart failure hospitalization (FigureB), and 1-year mitral valve reintervention ($R=-0.017$, $P=0.788$) after TMVr were not correlated with MVRr volume. After patient risk-adjustment for age, sex, and significant Elixhauser Comorbidities, there remained no significant correlation between institutional MVRr volume and 1-year mortality (estimate -0.010 , SE 0.047, $P=0.834$) or heart failure hospitalization (estimate -0.011 , SE 0.045, $P=0.808$) after TMVr.

Geographic access to TMVr under proposed volume requirements for existing (20/y) and new (40/y) sites is plotted by MVRr volume for the US population (FigureC) and black and Hispanic populations (FigureD). Gaps in geographic access exist within the Midwest and Appalachia and restriction of TMVr to sites performing ≥ 40 yearly MVRrs disproportionately impacts the upper Midwest and Southeast. Of the US population, 95.8% live in a hospital referral region where ≥ 1 hospital does >20 MVRr/y. Additionally, 86.5% of the US population lives in a hospital referral region where ≥ 1 hospital does >40 MVRr/y. Raising the restriction on TMVr from 20 to 40 MVRr/y

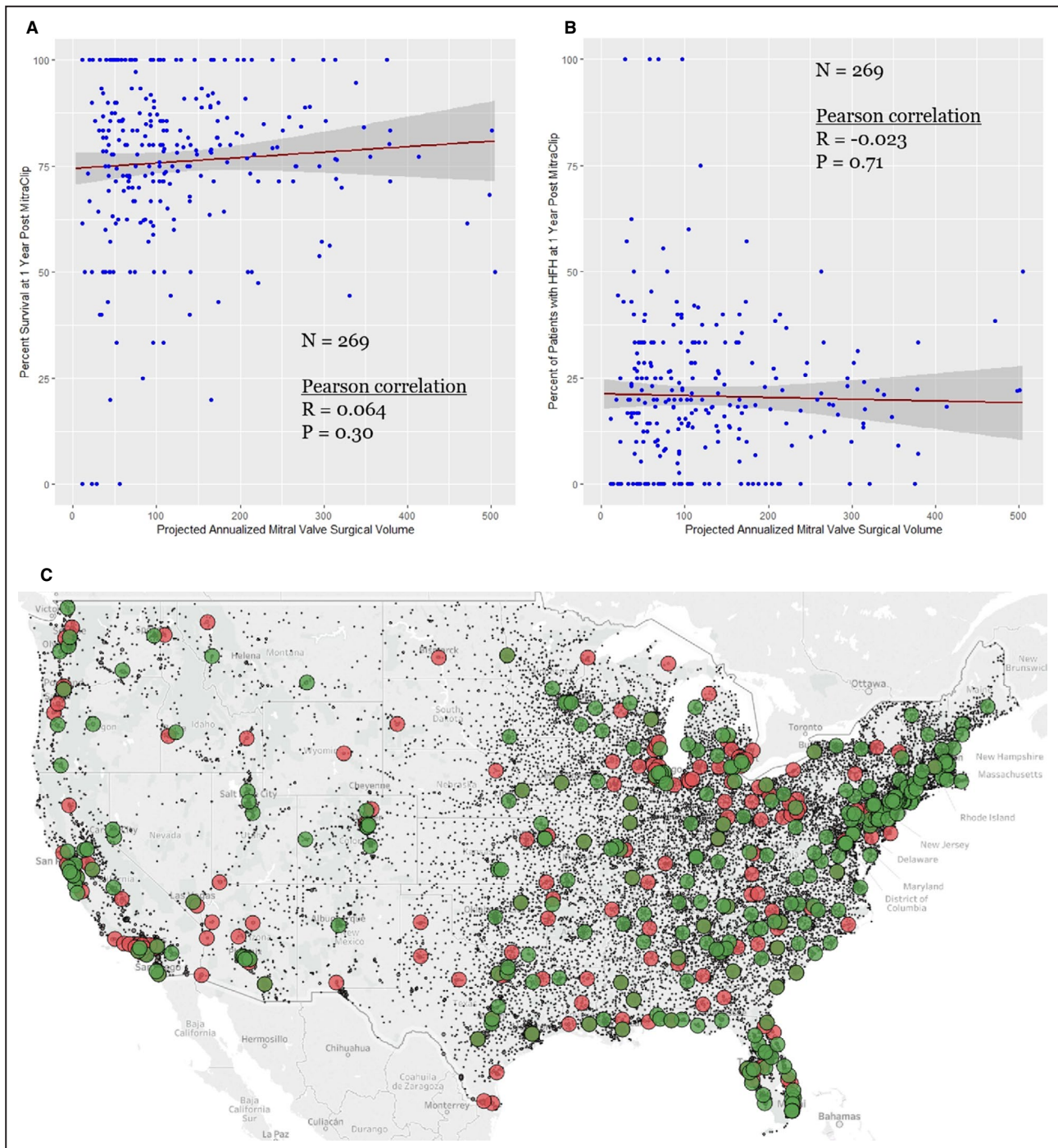


Figure. TMVr Outcomes by Mitral Valve Surgical Volume and the Geographic Distribution of Mitral Valve Surgical Centers by Volume.

A, Institution-level correlation between mitral surgical volume and 1-year mortality after TMVr. Excludes 5 US hospitals with FFS Medicare mitral valve surgery volume >150 cases/y. Similar results were observed when including those hospitals ($R=0.034$, $P=0.572$). 5 US hospitals with surgical mitral valve volume <11 not represented in figure (per CMS suppression policy) but included in regression analysis. **B**, Institution-level correlation between mitral surgical volume and 1-year heart failure hospitalization after TMVr. Excludes 5 US hospitals with FFS Medicare mitral valve surgery volume >150 cases/y. Similar results were observed when including those hospitals ($R=-0.023$, $P=0.70$). 5 US hospitals with surgical mitral valve volume <11 are not represented in figure (per CMS suppression policy) but were included in regression analysis. **C**, US population and US hospitals stratified by institutional mitral surgical volume. Black dots represent central points of zip codes with >1000 residents. Green dots represent US hospitals with >40 mitral valve repairs or replacements/year. Red dots represent US hospitals with 20 to 40 mitral valve repairs or replacements/year. **D**, US black and Hispanic population and US hospitals stratified by institutional mitral surgical volume. Black dots represent central points of zip codes with >1000 residents. Green dots represent US hospitals with >40 mitral valve repairs or replacements/year. Red dots represent US hospitals with 20 to 40 mitral valve repairs or replacements/year. **E**, US Hospital Referral Regions categorized by annual volume of the highest volume mitral valve surgical institution in each referral region. CMS indicates Centers for Medicare and Medicaid Services; FFS, fee for service; MVRR, mitral valve replacement or repair; and TMVr, transcatheter mitral valve repair.

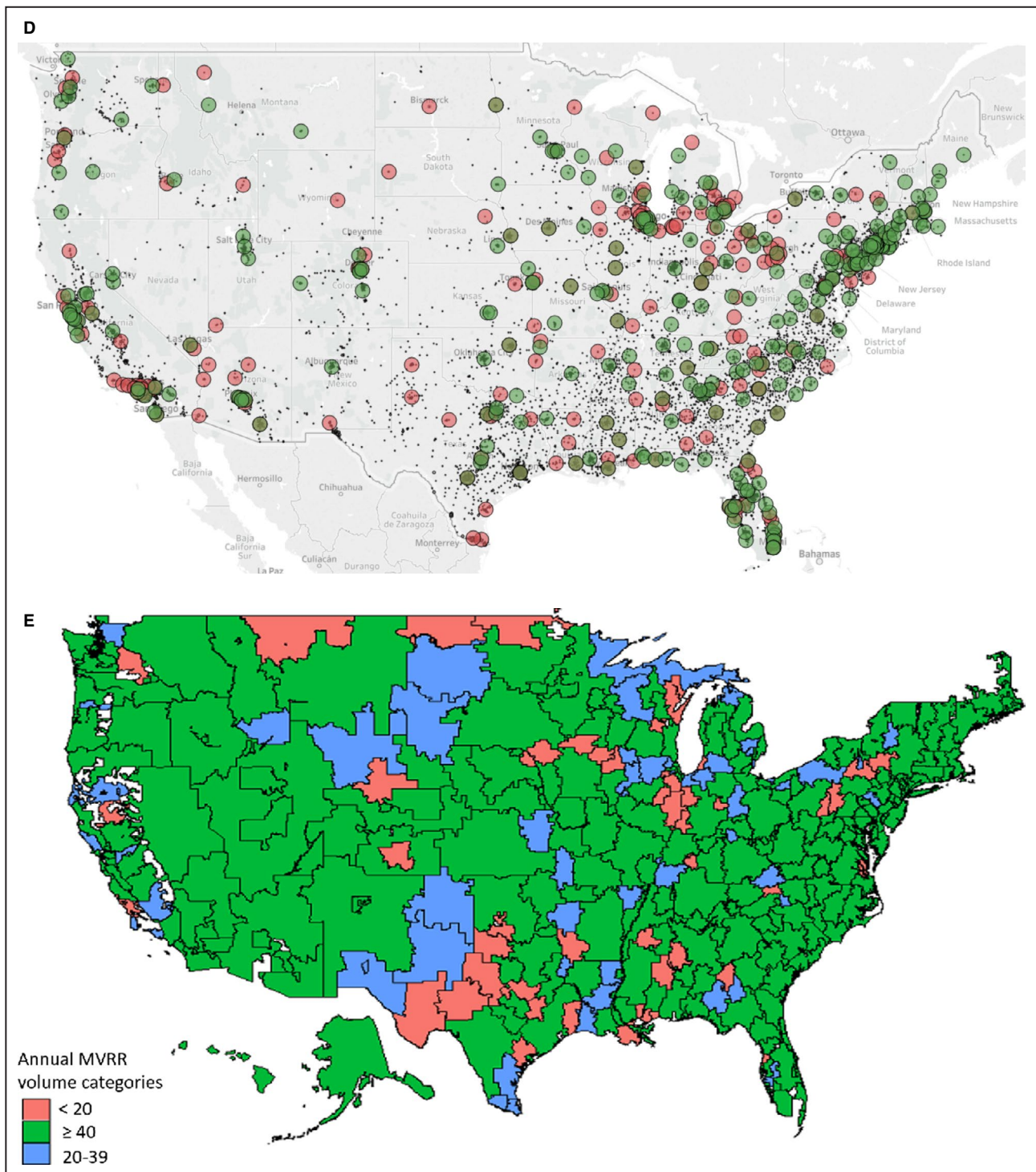


Figure. (Continued)

results in ≈ 30 million individuals having to travel outside of their hospital referral region to undergo TMVr.

DISCUSSION

The main findings of this analysis of the relationship between institutional MVRr volumes and TMVr outcomes are: First, in an institutional-level analysis, there

is no significant association between annualized MVRr volume and 1-year mortality, 1-year heart failure hospitalization, and 1-year mitral reintervention after TMVr. Second, adjustment for comorbidities did not change this finding for 1-year TMVr mortality or 1-year heart failure hospitalization. Third, restriction of TMVr to centers performing ≥ 40 MVRr/y might preferentially reduce geographic access to TMVr in the Midwest

and Southeast and their large black and Hispanic populations.

There is a known operator and institutional volume-outcome relationship in mitral^{11–13} and aortic¹⁴ valve interventions. Subsequently, volume thresholds have been adopted to ensure quality in transcatheter aortic valve replacement¹⁵ and are proposed in TMVr.⁴ These recommendations are based on correlation between volumes and same-procedure outcomes. No studies have examined the relationship between MVRr volumes and TMVr outcomes. In our first-of-a-kind analysis, we found no correlation between MVRr volume and TMVr outcomes, even after adjustment for patient comorbidities. As a result, it is unclear whether an MVRr volume threshold will ensure quality of TMVr outcomes.

One potential unintended consequence of volume requirements to ensure quality is restriction of geographic access to care. Of note, driving times of >30 minutes have been tied to increased care fragmentation and mortality in transcatheter aortic valve replacement,⁶ and patients who are able to travel for elective cardiovascular procedures are more likely white, male, and privately insured.¹⁶ Based on our analysis, tying TMVr availability to MVRr volumes of ≥ 40 per year appears to disproportionately impact geographic access in the Midwest and Southeast, where a substantial fraction of blacks and Hispanics are located.

Limitations of this analysis include using Medicare fee-for-service data and historical data on the percentage of mitral surgical patients covered by fee-for-service Medicare to calculate total institutional MVRr volumes. This method does not account for institutional variation in the case mix of Medicare patients. Second, although we performed risk adjustment using Medicare claims to define patient comorbidities, claims data lack some relevant anatomic and laboratory data. Third, we analyzed predominantly degenerative mitral regurgitation TMVr. Our results may not be reflective of FMR. However, MVRr has never been proven versus medical therapy in FMR and thus the rationale for MVRr volumes as a quality benchmark for TMVr in FMR is unclear.

In conclusion, in the context of an open CMS national coverage decision for TMVr and a multisociety consensus document suggesting minimal MVRr volumes for TMVr performance, we find no relationship between MVRr volumes and TMVr outcomes. Additionally, adoption of an annual MVRr volume ≥ 40 for performance of TMVr disproportionately impacts geographic access in the Midwest and Southeast and their large black and Hispanic populations.

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Affiliations

From the Duke Clinical Research Institute, Durham, NC (S.V.); Division of Cardiology, Department of Medicine, Duke University Medical Center, Durham,

NC (S.V.); Margolis Center for Healthcare Policy, Duke University, Durham, NC (S.V.); Abbott, Santa Clara, CA (J.P.); Department of Cardiovascular Surgery, Marcus Valve Center, Piedmont Heart Institute, Atlanta GA (V.T.); Smith Center for Outcomes Research Institute (R.W.Y.) and Division of Cardiology, Department of Medicine (R.W.Y.), Beth Israel Deaconess Medical Center, Boston, MA.

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