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Commentary: When less is not more—volume-outcome relationships in aortic valve replacement

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Although surgical aortic valve replacement (SAVR) was previously the gold standard for the management of symptomatic aortic stenosis in patients who were acceptable surgical candidates, transcatheter aortic valve replacement (TAVR) has evolved from the main therapy for inoperable and high-risk patients to a reasonable option in intermediate-risk patients.¹ In low-risk patients, TAVR was shown to be noninferior compared with surgery, receiving Food and Drug Administration approval in low-risk patients. Clinical trials showed excellent early outcomes for both TAVR (<1% mortality) and SAVR (~1% mortality); as such, moving forward, we expect outcomes for SAVR to be scrutinized and compared with TAVR, particularly in patients at low surgical risk.^{2,3} As the number of patients undergoing TAVR continues to increase, the volume of SAVR will decrease, and whether SAVR should be performed at high-volume centers or centers of excellence becomes an increasingly relevant question.

In this issue of the *Journal*, Dewey and colleagues⁴ use the Texas Quality Initiative, a collaborative of 29 hospitals that perform cardiac surgical procedures in North Texas, to better understand the volume-outcome relationship for isolated SAVR in low-risk patients. Over a period of 5 years, from 2012 to 2017, hospitals were dichotomized into low

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Efforts should be made to mitigate the low volume–worse outcomes relationship in patients undergoing aortic valve replacement while preserving patients' access to care.

volume (<200 cases over 5 years) or high volume (≥ 200 cases). Inverse probability of treatment weighting was used to balance 26 baseline characteristics. Outcomes after inverse probability of treatment weighting were different between the low-volume and high-volume hospitals with an almost doubling in the odds of mortality in low-volume hospitals (odds ratio [OR], 1.95; 95% confidence interval [CI], 1.20-3.20) along with a higher risk of renal failure (OR, 2.25; 95% CI, 1.33-3.81) and 30-day readmission (OR, 1.61; 95% CI, 1.27-2.04). Taken together, these findings suggest that early outcomes after SAVR are better at high-volume hospitals compared with low-volume hospitals.

However, these findings must be interpreted in the context of some important study limitations, some of which have already been highlighted by the authors. The key limitation is that unmeasured or unknown confounders may bias the findings. At the patient level, determinants of outcomes such as socioeconomic status and frailty were not measured. The relationship between an individual surgeon's volume and outcomes was also not assessed. A surgeon's volume depends on the institution's volume and the number of surgeons in the hospital. As such, a surgeon at a low-volume hospital may still perform more SAVRs than one in a high-volume center staffed by more surgeons. It is

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also possible that surgeons could work at more than 1 center, such that patients at a low-volume center may be treated by a high-volume surgeon. Previous work by the same authors found that higher surgeon volume was associated with improved SAVR outcomes.⁵ Another limitation of the study is the exclusion of concomitant procedures such as coronary artery bypass grafting. This can not only affect the definition of “volume” but also limit generalizability because patients requiring concomitant surgery may represent an increasing proportion of patients undergoing SAVR as those with isolated aortic stenosis may be preferentially treated with TAVR. Furthermore, given the significance for policy-making, a more precise quantification of the volume-outcome relationship is necessary. The cutoff of 200 cases to denote low- versus high-volume institutions seems arbitrary; volume measured as a continuous variable would be more informative to statistically explore the underlying relationship with outcomes. Finally, the applicability of these results may be limited to the United States, where the annual median of cases in low-volume hospitals is very low.⁶

Although the volume-outcome relationship is pervasive throughout surgery and typically affects procedures that are complex and infrequent, interestingly, this relationship has also been demonstrated in cardiac surgery for some of the most commonly performed procedures, such as coronary surgery, SAVR, and mitral valve repair.⁷⁻¹⁰ This study adds to the literature and shows that in low-risk patients, procedural volume remains important to improving early outcomes. A volume-outcome relationship was also explored for TAVR using the Transcatheter Valve Therapy Registry of 555 hospitals. TAVR procedures showed higher mortality and more variation in low-volume hospitals compared with higher-volume hospitals.¹¹ Similar findings were seen in New York State with less postprocedural stroke in patients undergoing TAVR treated by experienced operators.¹²

However, the policy implications of this study are complex. Although regionalization of surgical procedures to high-volume centers may improve outcomes, this raises competing concerns over equity and access to care, particularly as rural and underserved populations are disproportionately affected. As such, it may be more practical to understand and intervene in the pathways that improve outcomes at lower-volume centers. Preoperatively, optimal patient selection may improve outcomes. Previous work has shown that hospitals with a TAVR program had better surgical outcomes, likely as a result of improved patient selection by the heart team.¹³ Gonzalez and colleagues¹⁴ have shown that major complication rates postoperatively were similar between high- and low-volume centers, whereas failure-to-rescue rates were higher in low-volume centers, leading to greater mortality. Thus, care pathways to improve the early recognition and

treatment of major complications after surgery may reduce perioperative mortality at low-volume centers. The Michigan Society of Thoracic and Cardiovascular Surgeons Quality Collaborative includes 33 hospitals of various sizes that participate in quarterly in-person meetings to discuss state-wide quality improvement initiatives by examining individual hospital data in an unblinded manner and has led to protocol changes resulting in less postoperative complications.¹⁵ Another possible solution to improve outcomes at lower-volume centers would be to facilitate heart-team discussions and collaboration with more experienced high-volume centers to share expertise and help in decision-making regarding patient selection, treatment, and development of standardized postoperative pathways to optimize management of potential complications. The impact of these interventions should be evaluated and the volume-outcome relationship reassessed. While oftentimes “less is more,” when it comes to aortic valve replacement, volume and experience matter in optimizing outcomes for patients with aortic valve disease. Efforts should be made to mitigate the low volume–worse outcomes relationship in patients undergoing aortic valve replacement while preserving access to care.

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Commentary: The importance of surgical case volume in the transcatheter era

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What cardiac surgeon does not enjoy performing a low-risk aortic valve replacement (AVR)? The patients really benefit and are appreciative. The surgery is quick and within every surgeon's technical comfort zone. It is often the first procedure over which a teacher and pupil bond. Exposure is generally excellent, allowing both teacher and trainee to be facile. However, indications for transcatheter aortic valve replacement (TAVR), which already include high- and intermediate-risk populations, are expanding to include low-risk patients. Most surgeons can claim zero mortality in low-risk patients. Unfortunately, this does not mean they have cracked the surgical holy grail; rather, they have not done enough cases yet, as the paper by Dewey and colleagues in this issue of the *Journal* shows.¹

To evaluate the impact of case volume, the authors used a regional Society of Thoracic Surgeons database to identify

CENTRAL MESSAGE

Heart-team performance and appropriateness of care may have a greater impact on patient outcomes than case volume in the transcatheter era.

2066 low-risk patients who underwent isolated AVR. Centers performing more than 200 cases annually were classified as high-volume, whereas those performing fewer were classified as low volume. Just 3 of 29 hospitals in North Texas were high-volume, treating more than one half the patient population (53%). The study revealed greater mortality in the low-volume cohort compared with the high-volume cohort (hazard ratio, 1.95; 95% confidence interval, 1.2-3.2). Other quality surrogates also favored high-volume centers: postoperative renal failure, permanent pacemaker requirement, transfusion, and readmission rates.

Why is this? The authors highlight several factors, emphasizing institutional processes and resources, and "failure to rescue." The most resilient hospitals have robust processes and depth of staff, resulting in the ability to rescue patients who develop complications that might otherwise amplify into significant adverse outcomes, including mortality.² There are just 3 centers in the high-volume group, which could be centers of excellence independently of

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