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EDITORIAL COMMENT

Understanding the Volume-Outcome Curve in Contemporary Transcatheter Aortic Valve Replacement

Complications or Failure to Rescue?

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In 1979, Luft et al asked whether complex surgical interventions should be concentrated at high-volume hospitals.[1] Across about 1,500 U.S. hospitals and 12 surgical procedures, they demonstrated that mortality declined as institutional volume increased for certain operations and concluded that higher-volume centers should perform complex procedures. This has shaped accreditation policy in many procedural fields ever since. Forty-five years later, transcatheter aortic valve replacement (TAVR), the leading treatment strategy for patients with severe aortic stenosis, has developed its own volume-outcome literature.[2,3] The current Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) requires a minimum of 20 TAVR cases per year, which is lower than the 50 cases per year recommended by the 2018 AATS/American College of Cardiology (ACC)/SCAI/Society of Thoracic Surgeons (STS) Expert Consensus.[2,4] The landmark 2019 STS/ACC transcatheter valve therapy (TVT) Registry study confirmed an inverse association between institutional transfemoral TAVR volume and 30-day mortality.[5] However, the mechanism underlying this volume-outcome relationship has remained unclear. Failure to rescue (FTR) was introduced in the surgical literature in the early 1990s and defined as the rate of in-hospital death among patients who developed a major complication. It offers one way to examine whether the volume-mortality relationship is reflected by fewer complications at higher-volume centers or better handling of complications (ie, rescue) once they occur.[6] This question takes on additional importance because ongoing discussions around the CMS NCD have proposed removing minimum procedural volume requirements, mandatory cardiac surgeon evaluations, on-site surgical backup, and registry participation as conditions of coverage.[7]

In this issue of *JACC Interventions*, Shah et al[8] address this question using the STS/ACC TVT Registry, studying nearly half a million patients across 808 U.S. sites between 2017 and 2023. Institutional TAVR volume was modeled both in quartiles and as a continuous variable using cubic splines, and the authors examined the following outcomes: 30-day mortality, major complications, and FTR (defined as 30-day risk-adjusted mortality following a major complication). The key finding in this study is that lower-volume centers (Q1, ≤51 cases/year) had significantly higher rates of 30-day mortality and major complications than the highest-volume centers (Q4, 127-598 cases/year), whereas the overall unadjusted FTR rate was 11.0% and remained relatively stable across the 7-year study period; however, risk-adjusted FTR was significantly higher in 2020-2023 than in 2017. The authors attribute this trend to pandemic-era health system strain. In addition, FTR did not differ significantly across volume quartiles, and modeling volume as a continuous variable showed no threshold effect. Interestingly, despite the absence of a volume-FTR association, there was substantial between-hospital variation in FTR,

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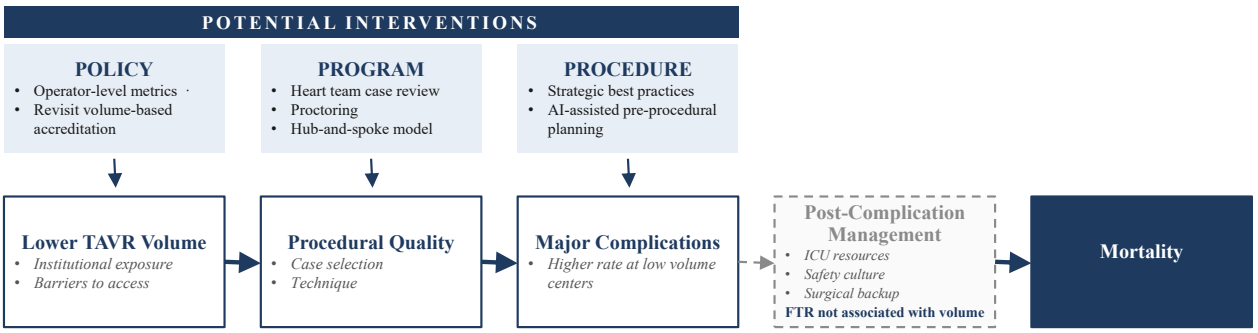
FIGURE 1 Volume-Outcome Relationship in Contemporary Transcatheter Aortic Valve Replacement and Opportunities for Quality Improvement



AI = artificial intelligence; FTR = failure to rescue; ICU = intensive care unit.

suggesting that hospital-level factors other than volume contribute to differences in rescue capability across institutions. Among the hospital characteristics examined, only larger hospital size (>500 beds) was associated with lower FTR, a finding the authors linked to intensive care unit staffing, emergency response infrastructure, and institutional safety culture rather than just the procedural volume itself.

These findings describe the current relationship between institutional TAVR volume and outcomes in a contemporary national cohort, and they are largely consistent with prior reports from the TVT Registry. Similar to earlier analyses, lower institutional volume continues to be associated with higher 30-day mortality and major complication rates. However, this analysis adds an important new observation: Rescue capability, as measured by FTR, appears to be similar across volume strata in contemporary U.S. practice. This is notable because earlier surgical literature has reported the opposite pattern, where higher FTR rather than increased complication rates accounted for most of the volume-mortality relationship in high-risk operations.[9] This may suggest that contemporary TAVR has matured to the point where rescue pathways are reasonably standardized across the field, even at lower-volume centers. From a clinical standpoint, this suggests that the institutional volume-mortality association in TAVR is more likely related to differences in complication rates (driven by case selection, valve sizing, vascular planning, and intraprocedural technique) rather than to differences in handling complications once they occur (**Figure 1**). Notably, FTR rose to approximately 37% following catastrophic complications and did not differ by volume quartile, suggesting that once the most severe events occur, rescue capability is limited across the volume spectrum and prevention is the primary opportunity for improvement. From a policy standpoint, this weakens the rescue-capacity rationale for institutional volume thresholds. Instead, it supports a shift toward operator-level metrics and outcomes-based quality measures, particularly because ongoing CMS NCD discussions reconsider current volume and infrastructure requirements to broaden TAVR program certification and improve access in rural areas.

There are several limitations worth keeping in mind when interpreting these findings. First, complications are not captured identically across centers in the TVT Registry. Higher-volume programs tend to have more robust data collection infrastructure and may report borderline events more completely, leading to misclassification bias. Second, the observational design and reliance on registry data with limited hospital-level details limit the ability to fully account for residual confounding from unmeasured hospital and ecosystem factors such as multidisciplinary heart team experience, intensive care infrastructure, or referral patterns. The substantial between-hospital variation in FTR observed in this study suggests that such factors may be relevant. Third, this analysis examines institutional volume rather than operator-level volume. Contemporary TVT Registry data show that operator-level volume continues to be inversely associated with adverse outcomes, with an approximately 10%-15% higher risk of adverse outcomes for low-volume operators.[10] Future studies examining operator-level FTR within the same TVT Registry cohort would help clarify whether the persistent volume-mortality signal reflects institutional, operator, or broader ecosystem factors. In addition, formal causal

mediation analyses could help quantify the extent to which the institutional volume-mortality association is mediated through major complications versus rescue capability and would provide a more rigorous test of the prevention-versus-rescue framework suggested by these findings.

Overall, this analysis is an important step forward in understanding the volume-outcome curve in contemporary TAVR, and it provides a useful reframing of the institutional volume-mortality question into its complication and rescue components. This analysis emphasizes the importance of identifying and supporting the lowest-volume programs, where institutional differences in complications and mortality concentrate, through structured proctoring and outcome-based quality monitoring rather than blanket volume thresholds applied uniformly across the field.

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