Commentary: In the management of aortic stenosis volume is not enough

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The inverse relationship between procedure volume and outcomes has been demonstrated in a number of general and cardiac surgical procedures, including valvular and coronary artery bypass surgery.¹⁻³ Even before Vemulapalli and colleagues⁴ demonstrated a similar relationship in transcatheter aortic valve replacement (TAVR), volume (for surgical aortic valve replacement and percutaneous coronary intervention) had been used as a proxy for quality by the Centers for Medicare and Medicaid Services (CMS) for the establishment of TAVR programs.

Kurlansky and Bagiella⁵ elegantly discuss the volume–outcome relationship in TAVR that was recently reported in the *New England Journal of Medicine*.⁴ The inverse relationship between volume and outcome is clear from the smoothed curves presented in this study and supports the use of volume as a proxy for quality. However, as Kurlansky and Bagiella point out, where this proxy fails is in identifying the many excellent-quality, low-volume centers or the poorly performing high-volume centers. Using prior outcomes as a quality metric for a low-volume center can be similarly problematic because a single mortality can inflate an otherwise well-performing institution's outcomes to alarming levels due to the low denominator.

A recently published American Association for Thoracic Surgery, American College of Cardiology, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons (AATS/ACC/SCAI/STS) Expert Consensus Systems of Care Document acknowledged these difficulties and placed an emphasis on “direct measures of quality of care,” including risk-adjusted mortality and alternative outcomes (such as quality of life) measured in the hospital, at 30 days, and (ultimately) at 1 year.⁶ The AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document proposes that minimum volume requirements be used to ensure that a program has adequate statistical power to apply quality metrics and maintain effective processes of care.⁶ An effective multidisciplinary heart

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Central Message

Use of volume alone may oversimplify the assessment of a program's quality. Better metrics are required.

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team and the incorporation of shared decision making with patients are also recommended as quality requirements.⁶ CMS has recently updated requirements to establish and maintain TAVR programs. Volume requirements for established programs have decreased, requiring ≥ 50 aortic valve replacements (TAVR or surgical) per year, including ≥ 20 TAVR procedures. The CMS coverage is broadly in line with the recommendations of the AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document.

With the imminent, anticipated expansion of TAVR to low-risk patients, the use of low-frequency events such as mortality and stroke to measure the quality of low-volume programs will be even more difficult. Especially because the number of low-volume TAVR programs is expected to increase. Given that the expectations of excellent results are high in this low-risk patient population, never before has the measurement of quality been more important for the management of aortic stenosis. We agree with Kurlansky and Bagiella⁵ that the use of volume alone, whilst convenient, may oversimplify the assessment of quality. The metrics being developed by the STS/ACC Transcatheter Valve Registry should be a better measure. However, volume cannot be ignored because it increases confidence that outcomes are a true representation of a program's performance; it is easier to detect a poorly performing high-volume center than to detect a poorly performing low-volume center. Next, careful thought should be put toward how to rehabilitate an underperforming program.

Ultimately, information about the quality of a program should be available to assist patients in their decision about where their aortic valve disease is treated.

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