POINT: Access to transcatheter aortic valve replacement should be limited to high-volume surgical centers

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See related articles by Robert Sade on pages 1439-40 and Philip Green et al on pages 1444-5.

A document describing characteristics of the heart team to perform transcatheter aortic valve replacement (TAVR) was recently developed for the Centers for Medicare and Medicaid Services and the Food and Drug Administration.¹ Among those characteristics were three that are relevant to this discussion: cardiac surgeon criteria, interventional cardiologist criteria, and institutional requirements for programmatic volumes. These three characteristics are germane to the question of whether there is a relationship between the volume of procedures performed by a program/surgeon and patient outcomes.

The association of volume with outcomes was first noted in 1979 when hospital surgical volume was associated with better outcomes.² The same relationship was found in major cancer surgery³ and in urological oncology.⁴ The most complex cystectomy operations had two to three times lower mortality rates in high- than in low-volume centers.⁵ This outcome was not found in simple urological procedures, leading to the idea that big procedures should be performed at big hospitals and small procedures should be performed at small hospitals.⁶

One study of the volume-outcomes metric showed that approximately 39% of the effect is related to the surgeon and 61% is the institutional effect.⁷ Other factors drive the association between volume and outcomes as well: hospital size, urban location, teaching mission, staffing ratios, and patient demographic factors, such as age, length of stay, and accompanying procedures.⁸

An early article that used Medicare data to evaluate 12 major cancer and major cardiovascular surgical procedures

showed a significant inverse relationship between hospital volume and mortality rates.⁵ When the same group looked at surgeon volume in an analysis of more than 500,000 patients, the results were dramatic and even more conclusive, showing that surgeon volume is inversely related to operative mortality for all procedures examined.⁷ The authors concluded: "In the absence of other information about the quality of surgery at the hospitals near them, Medicare patients undergoing selected cardiovascular or cancer procedures can significantly reduce their risk of operative death by selecting a high-volume hospital." The excess of deaths associated with lower-volume hospitals, according to one analysis, is 10,000 lives that could be saved by selective referral to high-volume hospitals.⁹

The issue of procedural volume-outcome relationships is international. In the United Kingdom, the Bristol scandal of poor outcomes in pediatric cardiac surgery in the late 1980s was sensationalized in medical journals and the public media. European medical journals rendered opinions that fewer pediatric cardiac centers were needed in the United Kingdom, which would lead to increased volume of referral pediatric cardiac centers, among many other effects. As a result of the Bristol debacle, the British government established policy that, in effect, recognized and validated the volume-outcome relationship.¹⁰

Specific cardiovascular procedure volume-outcome relationships have been investigated. A study of carotid endarterectomy showed dramatic decreases in the incidence of death, stroke, and length of stay as a function of surgeon volume.¹¹ Procedural volume as a marker for coronary artery bypass graft (CABG) surgery has similar results: approximately a 3% reduction in mortality rate for CABG surgery in high-volume hospitals and approximately a 15% reduction in morbidity and mortality from highest to lowest quartile volume.¹² High surgeon volume was also associated with approximately a 30% reduction in 30-day mortality rate. This article similarly studied the outcomes in many patients in the Society of Thoracic Surgeons database and found significantly better outcomes for patients older than 65 years undergoing CABG, but no difference in lower risk and younger patients. The article concluded that hospital volume had limited value as a quality metric for CABG.¹²

Data from the New York State database show that hospitals with a higher CABG surgery volume also have lower risk-adjusted mortality rates; high-volume hospitals and surgeons both had a 30% to 40% reduction in risk-adjusted

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mortality rates.¹³ The combination of a high-volume surgeon and a high-volume hospital had far better results than the combination of a low-volume surgeon and a low-volume hospital. As a result, New York developed a policy intended to enhance outcomes, setting specific CABG requirements of 200 a year for hospitals and 50 a year for surgeons. Pennsylvania also mandated reporting of outcomes, and analysis showed nearly identical volume-outcome relationships.¹⁴ The surgeon volume-mortality relationship showed lower mortality rates with greater surgical volume, and this relationship was stronger than hospital volumes.

Another indication that the surgeon's experience in CABG procedures is a critical factor in determining outcomes is provided by the observation that when the same surgical team uses the same systems in high- and low-volume hospitals, the survival outcomes are not statistically different.¹⁵

In aortic valve replacement (AVR) surgery, higher surgeon volumes are associated with better outcomes, and the effect is substantially augmented in the case of complex operations, such as reoperative AVR.¹⁶ Similar results were found when hospital volume was related to outcomes of CABG, AVR, and mitral valve replacement: the surgeon-volume relationship was robust.^{17,18}

Elective thoracic aortic aneurysm surgery shows the same volume-outcome relationship—mortality for all aortic operations is much better in high-volume centers. It is interesting that thoracoabdominal operations were not performed by the low-volume centers at all; they referred all those procedures to high-volume centers.¹⁹ Heart transplantation shows the same thing: heart transplant outcomes are worse at low-volume centers.²⁰ Type A aortic dissection outcomes show further proof of this concept; as volume increases, outcomes improve for this operation.²¹

Clearly, the volume-outcome relationship advantage in high-volume centers disproportionately benefits high-risk patients, but one study reached the counterintuitive conclusion that operations in high-volume programs benefited low-risk patients more than high-risk patients. In this study, even very-low-risk patients had substantially better outcomes in high-volume centers.²²

It seems logical that poor results in one type of operation could correlate with poor results in others as well. This logic has been confirmed: hospitals that performed badly with CABG surgery also performed badly with AVR and mitral valve replacement, both by institution and by surgeon.²³ This suggests that suboptimal results in percutaneous coronary interventions (PCIs) and AVR might predict suboptimal results in TAVR.

Regarding the interventional volume-outcome relationship, the international PCI community does well in fairly simple interventions, but in the more complicated interventions, the volume-outcome relationship is robust.²⁴ High-volume PCI centers had dramatically better outcomes and

mortality rates versus low-volume centers. The same is true of patients going to emergency CABG surgery.²⁵ The authors concluded that there is no doubt in the PCI literature that the volume-outcome relationship remains strong.

Another interesting question is whether the surgeon's specialty makes a difference. A study of biliary surgery in children found that it makes no difference whether a pediatric or a general surgeon performs the procedure. The outcomes are the same regardless of the surgeon's specialty; what matters is the volume of pediatric cholecystectomies the surgeon performs.²⁶ This suggests that it is irrelevant whether an interventional cardiologist or a cardiac surgeon performs TAVR—the one with the most experience is likely to perform better.

Data from the early experience with TAVR clearly show that as experience increases, results also improve.²⁷ This holds true for patients undergoing TAVR by the transapical approach, which shows far better outcomes in the second 150 cases in a series than in the initial 150 cases.²⁸ There is no question that as one gains experience, one gets better at TAVR.

This information has substantial implications for health policy. The National Agenda to Improve Patient Safety of the Agency for Healthcare Research and Quality says this: "Localizing specific surgeries and procedures to high-volume centers" is a high priority area for patient safety research.²⁹ The data overwhelmingly support the volume-outcome relationship. Therefore, the complex cardiovascular procedure of TAVR should be limited to high-volume centers.

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