

EDITORIAL COMMENT

Different Health Care Systems With a Common Message



Experience Has a Major Impact on Transcatheter Aortic Valve Replacement Outcomes*

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The distribution of transcatheter and surgical cardiovascular therapy in countries around the world differs according to the history and culture of their health care system, the reimbursement system, ownership of health care facilities, economic health of the country, and the involvement of government in planning and control of the distribution of facilities and services. There has been nearly a decade-long surge in the number of patients with aortic stenosis undergoing transcatheter aortic valve replacement (TAVR) in multiple countries that is expected to accelerate (1). Studies like the one reported in this issue of *JACC: Cardiovascular Interventions*, by Wassef et al. (2) are important in expanding and updating an existing evidence base for making health care policy decisions as well as informing professional society recommendations as to the organization of care to maximize the benefit and minimize complications for novel procedures like TAVR.

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A question that is being asked around the world is whether the procedure has evolved to a state of maturity with advanced technologies and technique with low complication rates that there is no or a trivial learning curve and that subsequently there is no clinically meaningful relationship of outcomes to the

on-going volume of TAVR procedures performed at individual centers. If the answer is yes, then policymakers around the world might consider making TAVR a routine procedure that can be done at vast array of medical facilities. If the answer is no then policymakers would likely continue the center of excellence model with rational dispersion that would require some patients to travel distances, but the trip will be worth it, both for the patient and health care system, to receive the highest quality of care, avoiding higher complication rates at centers with less experience (3). The health care policymakers may then also consider a tiered system, as designed and established in British Columbia, that provides a balance of distributed regional centers for less complex and lower-risk procedures along with a central mega-center with experience and resources to treat the most complex and highest-risk patients (4).

It is in this context that these authors present the results of an international registry involving centers on 3 continents and examine the 2 questions of one, whether a learning curve with TAVR, and two whether a volume-outcome association can be demonstrated (2).

A total of 3,403 patients were treated at 16 centers that were all large, urban international academic teaching sites in North and South America, and Europe. The first patient included had their procedure performed January 6, 2005, and the last patient included had their procedure January 29, 2016.

LEARNING CURVE ANALYSIS

Cases were chronologically ordered into initial (1 to 75), early (76 to 150), intermediate (151 to 225), high (226 to 300), and very-high (>300) experience groups. The results of multivariate logistic regression analysis showed that TAVR procedural volume when

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used as a continuous variable was independently associated with 30-day mortality, major bleeding, and major adverse cardiac events. There was a decrease in all-cause mortality with increasing TAVR experience, with a 9.6% mortality rate with initial experience, 7.9% with early experience, and 3.3% with very high experienced operators. A composite safety endpoint also decreased with increasing experience from 27.5% to 14.9%.

ANNUAL VOLUME AND CLINICAL OUTCOMES ANALYSIS

For the analysis of a hospital volume-outcome association, institutions were stratified into 3 groups by annual TAVR case volume: low volume <50, moderate volume 50 to 100, and high volume >100 cases per year. For this analysis, 2,205 patients were included. All-cause mortality was significantly higher in the low-volume compared with the high-volume (8.8% vs. 3.9%; $p = 0.003$) centers. The early safety endpoint was worse for low-volume sites (34.3% vs. 26.4%; $p = 0.01$), as well as major bleeding (11.1%, vs. 4.9%; $p = 0.037$).

The authors conclude from their analyses that an important learning curve exists with TAVR. An experience of at least 225 procedures was associated with reduced TAVR mortality, whereas the early safety endpoint continues to improve beyond the 225 case volume. Furthermore, they conclude that annual procedural volume affects TAVR clinical outcomes and low-volume centers defined as an annual case volume <50 TAVR procedures are independently associated with higher mortality.

There are limitations to the study, including the relatively small number of patients for these advanced analyses, the somewhat arbitrary nature of defining volume categories, the changing technology used over the years, and the potential muted learning curve that may now exist at a later date. In addition, the volume-outcome analysis cannot be free from ongoing learning, because TAVR remains dynamic with expanding indications and new technologies and technique. Yet, the results stand firmly on this carefully performed study. This study supports the health care system structure with centers of excellence versus a widely distributed approach with many low-volume programs.

There is no doubt that TAVR outcomes continue to improve, and this is related to multiple factors, including expansion to lower-risk patients, more experienced teams, improved technologies and techniques, and optimizing patient selection. With lower rates of mortality and major complications, the

statistical analysis will become more difficult to show learning curves and volume-outcomes associations if a study focuses on single outcomes, or the number of cases is not very large. Therefore, future studies will need to have composite endpoints and a very large study population.

The Society of Thoracic Surgeons (STS) uses a clinically meaningful composite of mortality and morbidity to assess site performance with surgical aortic valve replacement (SAVR) and then assigning a 1- to 3-star rating system to help simplify site performance characterization, which is especially important for patients and families (5). Such a system is under development for TAVR by the STS-ACC TVT registry.

The experience with SAVR is relevant in another dimension. In a study using a statewide cardiothoracic surgical database a hospital volume-outcome relationship was shown for SAVR primarily in high-risk patients (6). This Michigan-based multicenter database is an extension of the STS database that includes a large number of preoperative and procedural variables key to performing such an analysis. The authors discuss 2 important practical considerations of these results relevant to TAVR. First, best practices of high-volume centers should be shared with all centers. Second, low-volume centers should consider referral of the highest-risk patients to a high-volume center that has excellent outcomes.

RELEVANCE TO THE U.S. HEALTH CARE SYSTEM

The U.S. health care system has unique characteristics, including its competitive nature with private and public health care systems competing for market share (7). This imposes a unique barrier to referring patients for advanced cardiovascular care and is getting more germane with the major shift of cardiologist from private and independent practices to being employed by a health system. Insurance barriers also exist even for patients with Medicare when they have a supplemental policy that defines in-network and out-of-network hospitals and physicians. Therefore, the lack of an organized system of care for valvular heart disease in the United States has many unique challenges not experienced in many other countries.

The Centers for Medicare & Medicaid Services (CMS) developed a National Coverage Decision (NCD) for TAVR in 2012 in partnership with professional cardiovascular societies. This led to a rollout of 582 TAVR centers as of July 1, 2018, and growth in TAVR volume exceeding 50,000 cases in 2017. The standards set forth in the NCD, including volume thresholds, represent the rational dispersion of a

major new therapy that has been associated with broad success of TAVR in the United States in terms of both access and high-quality care.

CMS is now reconsidering the NCD for TAVR (8). As part of this process, CMS has organized a Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) for July 25, 2018, at which time, the committee members will hear testimonies, review data, and then answer specific questions posed by CMS on the evidence supporting the need for volume thresholds for new and existing TAVR sites. The results of the MEDCAC meeting and the material that will be submitted to CMS by all interested parties will be part of the input that will be used by CMS to decide whether to continue the NCD with updates or terminate the NCD, removing any specific requirements on where, how, and by whom TAVR may be performed. This is a major crossroads for U.S. health care policy because TAVR is but one of the many transcatheter valve treatments that are being developed and are transforming the management of valvular heart disease.

Results from the study report here by Wassef et al. (2) suggest that there is a danger of lowering TAVR quality of care by doing away or relaxing volume requirements. This would create many new centers starting a new learning curve, result in more low-volume centers, and potentially diluting the case

volume and advanced skills of established and high-volume centers.

Therefore, despite the efforts of many parties to use training and proctoring to eliminate the TAVR learning curve, it continues to exist and needs to be acknowledged as new centers start TAVR programs. The study does not address the issue of access to TAVR and specifically does not study the impact of policies and facility distribution in different health care systems on access to TAVR. The study of quality has its challenges, but the study of access is much more complex and multifactorial, including socioeconomic factors, the ability of primary care clinicians to identify aortic stenosis, and other broad factors producing disparities of care. Until a definitive study shows access is a major problem in the United States, as well as other countries, we must emphasize quality of care with reasonable access rather than taking the McDonald's strategy of saturation of markets for business reasons. Our patients deserve better.

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