JACC: CARDIOVASCULAR INTERVENTIONS VOL. 11, NO. 21, 2018

PUBLISHED BY ELSEVIER

EDITORIAL COMMENT

Surgical Aortic Valve Replacement in the Transcatheter Aortic Valve Replacement Era

Implications for the Heart Team*

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The prevalence of aortic valve stenosis (AS) has only recently become clearer with previous hospital-based and retrospective studies underestimating this disease burden. In a primary care population of 2,500 patients older than 65 years, mild and moderate to severe AS was present in 34.6% and 0.7%, respectively (1). A meta-analysis of patients ≥75 years of age reported a pooled estimate of 12.8% patients with AS (2). The prevalence of AS increases exponentially with age (3); 8.3% of North America's population in 2025 are predicted to be ≥75 years of age, and there will be an estimated 0.8 million patients with severe symptomatic AS (2). Transcatheter aortic valve replacement (TAVR) was approved for use in 2011 in the United States for patients with severe AS who are not candidates for surgical aortic valve replacement (SAVR) and shortly thereafter for those considered at high or intermediate risk. As a result, the number of patients undergoing aortic valve procedures increased from 47.6 per 100,000 in 2009 to 88.9 per 100,000 in 2015; 45% of patients undergoing aortic valve procedures in 2015 were ≥80 years of age (4).

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In this issue of *JACC: Cardiovascular Interventions*, Kundi et al. (5) report trends of SAVR in hospitals with TAVR programs. Hospitals performing more than 1 TAVR and SAVR annually (85 hospitals of an initial 1,165 SAVR hospitals screened) were divided into quartiles on the basis of TAVR volume. SAVR volume decreased in the 2 highest volume TAVR quartiles only. In these quartiles, 30-day and 1-year SAVR mortality decreased; although mortality was not corrected for pre-operative risk, comorbidities and the Charlson comorbidity index suggested that patients undergoing SAVR in 2014 were at lower risk than those undergoing the procedure in 2011. There was no mortality improvement in non-TAVR hospitals or those in the lower 2 quartiles of TAVR volume. The outcomes of TAVRs with expanding used were unreported. The study raises a number of interesting points.

The decline in SAVR volume at the larger volume TAVR centers, together with a lower risk profile of the SAVR population, implies that higher risk patients are most likely appropriately undergoing TAVR rather than SAVR. The maintenance of surgical volume in the lower quartile TAVR- and non-TAVR centers may imply that some of the patient cohort undergoing SAVR does not have access to TAVR. Although not compared statistically, the seemingly lower 30-day and 1-year SAVR mortality at the higher volume TAVR centers compared with the lowest quartile and non-TAVR centers are likely a result of a difference in patient risk profile; however, these higher volume TAVR quartiles also had the highest volumes of SAVR, and this may have influenced mortality. TAVR is no longer an experimental procedure, and there remains no debate about its efficacy in the high surgical risk populations. In these patients, it should be available. The role of TAVR in lower risk, younger populations, those with bicuspid aortic valve, and when concomitant revascularization is required has yet to be

*Editorials published in *JACC: Cardiovascular Interventions* reflect the views of the authors and do not necessarily represent the views of *JACC: Cardiovascular Interventions* or the American College of Cardiology.

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ISSN 1936-8798/$36.00 https://doi.org/10.1016/j.jcin.2018.07.057

elucidated. Questions of durability, paravalvular leak, and pacemaker requirement, all of which are likely to have greatest significant impact on low-risk populations with greater life expectancy, are currently being investigated in randomized trials.

The criteria for accreditation of TAVR centers remains a subject of controversy, largely revolving around the issues of minimum TAVR and SAVR volumes. At the end of 2017 in the United States, there were more than 540 sites performing 48,000 TAVR procedures annually (unpublished data, V.H. Thourani, March 1, 2018.). The exclusion of 441 of 526 hospitals from Kundi et al.'s (5) analysis because of a failure to perform at least 1 SAVR and TAVR each year highlights the large number of centers performing low volumes of TAVR and SAVR.

An inverse relationship between TAVR morbidity and mortality and volume was demonstrated in the earlier adoption period and persisted up to 400 cases (6). This may have been a result of the learning curve given the rapid uptake of the technique at an increasing number of centers. The relationship between annual hospital procedure volume and outcomes has been demonstrated in SAVR but has yet to be explored in TAVR (7). In the Michigan State data, annual hospital rather than individual surgeon volume was related to outcomes. The relationship was present for high- but not low-risk patients (7). This suggests the importance of perioperative care (anesthesia, intensive care, other medical and surgical specialties, and allied health support) beyond that purely related to the procedure in the operating room. Although this raises the argument in favor of high-risk patients undergoing TAVR only at high-volume expert centers, evidence is urgently required to support this.

There is further debate as to the requirement of TAVR centers to have on-site cardiac surgery. Although the need for emergent cardiac surgery after attempted TAVR is low (1.07% in 2013, 0.7% each year from 2014 to 2016 at 79 European centers, not including need for emergent extracorporeal membrane oxygenation support), survival depends on rapid access to cardiopulmonary bypass and a skilled cardiac surgical team (8). Any comparison for the need of urgent surgical support after percutaneous coronary intervention is inappropriate, as in most cases (unlike after a TAVR complication), a percutaneous coronary intervention patient can be supported for transfer to a cardiac surgical center. Surgeons with dedicated training in transcatheter skills have much to offer after TAVR complications, with intimate understanding of anatomy of the cardiac valves and the skills to rapidly establish cardiopulmonary bypass, salvage catastrophes, and repair vascular access complications. Perhaps more important than the need for emergent surgical support is the need to have TAVR-trained surgeons represented on the heart team, especially given that the role of TAVR in younger and low-risk populations is under investigation.

Resource utilization is a major issue given the rapid increase in aortic valve procedures and an aging population. Economic analysis in the high-risk population has suggested that TAVR is cost-effective on the basis of conventional willingness-to-pay thresholds (9). Although costs at 30 days and 1 year remain higher than for SAVR, this may change with the projected decrease in TAVR device cost and procedural efficiency. The cost-effectiveness in the intermediate- and low-risk populations, expected to be less expensive in terms of post-operative care (shorter length of stay and reduced need for rehabilitation) should be presented in 2019. More than in the elderly, high-risk population, the cost-effectiveness in younger patients will reflect device durability and the need for additional procedures. Treatment of all currently eligible high- and extreme-risk TAVR candidates in the United States is estimated to be approximately $7 billion on the basis of current cost estimates (2). Many of these patients would not have undergone SAVR and thus would not have incurred the expense. Such expenditure on patients toward the end of life will be a matter of ethical and political debate.

There is a paradigm shift occurring in the treatment of aortic valve disease. The ideal aortic valve disease program requires cardiology and cardiac surgical expertise, together with a support network that includes anesthesia, intensive care, specialist surgical and medical services (neurology and aged-care medicine), nursing, and allied health. This is most likely to be found at a high-volume center and will lead to the best results, especially in high-risk patients. Correspondingly, the same argument can be made for performing SAVR at higher volume centers. Striking a balance between patient conveniences with a large number of low-volume centers versus improved clinical outcomes with regionalization of services should be guided with evidence. This is most likely to come from large population sets, and the importance of the Society of Thoracic Surgeons/American College of Cardiology TVT (Transcatheter Valve Therapy) registry in monitoring TAVR outcomes in community cannot be underestimated.

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KEY WORDS aortic valve stenosis, SAVR, TAVR