Editorial

The future direction of post-transcatheter aortic valve replacement re-interventions: insights from the Society of Thoracic Surgeons National Database

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Transcatheter therapy has revolutionized aortic valve replacement and benefited thousands of patients over the last decade. Based on the results of highly selected randomized trials, transcatheter aortic valve replacement (TAVR) has been deemed acceptable at all risk levels, such that predicted operative risk has been removed from the latest American College of Cardiology (ACC) and American Heart Association (AHA) guidelines. Therapy is now guided solely by anatomic considerations, age and life expectancy (1).

This paradigm shift has resulted in an explosion of TAVR and a decline in surgical aortic valve replacement (SAVR), as demonstrated by the Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database (ACSD) and the STS/ACC Transcatheter Valve Therapy Registry (2). For instance, in 2022, 98,504 TAVRs were performed in the United States, an increase from 4,666 in 2012. The rate of TAVR use increased even further after the United States Food and Drug Administration (FDA) approval for use in low-risk patients. Concurrent to these increases have been significant decreases in isolated SAVR, with only 17,568 procedures performed in 2022, a decline of 36% from 2012.

One would hope that these practice changes are evidence-based. However, data demonstrates that the decline in SAVR is not necessarily guideline-driven (3-6). Substantial indication creep has been identified, such that TAVR is being preferentially used in two populations that were not included in comparative trials of TAVR and SAVR (bicuspid aortic valves) (4,6). or included in only small numbers (less than 65 years of age) (5).

Despite ACC/AHA guidelines, which currently recommend SAVR in patients less than 65 years of age, over 50% of these patients in the United States are presently being treated with TAVR as opposed to SAVR (5). Administrative healthcare claims data from New York, New Jersey and California were used to identify 9,557 patients under 65 years old undergoing SAVR (5). The incidence of TAVR increased from 7.1% in 2013 to 54.7% in 2021. More importantly, in a propensity-matched cohort of 1,994 pairs of patients, those undergoing TAVR had higher eight-year mortality (27.5% *vs.* 15.3%, P<0.001) than those undergoing SAVR. In addition, Medicare claims data has likewise been used to demonstrate that bicuspid aortic valves undergoing aortic valve replacement with TAVR have higher mortality than seen in matched SAVR cohorts (4,6).

The findings of increased mortality with TAVR as opposed to SAVR in these two cohorts, those with bicuspid valves and those less than 65 years old, combined with the increased penetrance of TAVR in these populations, should give us a moment of pause as we consider the appropriate therapeutic application of transcatheter aortic valve technology. This pause should be even more significant in the face of recently reported longitudinal outcomes of SAVR from the STS ACSD. In this report, the long-term mortality of 42,586 low-risk patients undergoing isolated SAVR was 12.4% at eight years (7). These are excellent results and serve as a new "gold standard" for which all

aortic valve replacement therapies should be judged against.

Finally, these trends in TAVR use should also be viewed in the context of the potential need to perform cardiac surgery later in these patients—both aortic valve surgery and non-aortic valve surgery after TAVR. While there was an inherent assumption initially that a patient receiving a TAVR would not be an operative candidate, this paradigm has shifted. Cardiac surgery after TAVR is now the fastest-growing operation in the STS ACSD. Between 2012 and March 2023, 5,547 patients who previously underwent TAVR subsequently underwent cardiac surgery—2,485 underwent non-SAVR cardiac surgery, and 2,972 underwent SAVR (8). The frequency of cardiac surgery after TAVR increased by over 4,000% overall and 145% yearly. Most importantly, the 30-day mortality risk in these patients was quite significant, 15.5% in the entire cohort, far greater than that predicted by existing STS Risk models. In addition, of those requiring aortic valve replacement, over a third required a concomitant aortic or aortic root procedure.

The assumption that cardiac surgery after TAVR is safe or comparable to cardiac surgery without previous TAVR is misguided. Given this new evidence, patients who may be of reasonable/low operative risk when TAVR is being considered should be carefully evaluated for SAVR by the heart team. For instance, in a young patient who receives an initial TAVR and subsequently requires a redo SAVR for either structural or non-structural valve failure, or requires a coronary artery bypass grafting (CABG) or mitral valve repair or replacement, their risk profile will have changed due to the presence of a TAVR. The operative risk in these scenarios may be up to five to six times higher than if the patient had undergone open heart surgery at the time of the TAVR. A new STS Risk Calculator designed to address these patients is now available. These are essential considerations to consider when counseling patients, particularly young patients, those with bicuspid aortic valves, and those with other potential ischemic or structural heart diseases, about treatment options for calcific aortic stenosis.

TAVR is unquestionably one of the most successful recent innovations in cardiovascular care and an excellent example of so-called "Human Centered Design"—whereby a product is developed that is easy and effective to deliver and is in tune with the needs and emotions of key stakeholders (patients, physician, and payors). In addition, the adoption of TAVR has entered a phase where even the "late majority" and "laggards" are now comfortable with the technology. These accolades aside, it is imperative that we, as a community of cardiovascular specialists, ask hard questions and ensure appropriate and thoughtful application of the technology for our patients. Currently, it seems that the application of transcatheter technology has crept forward of existing evidence-based medicine, especially in the context of the excellent results of SAVR and the high risk of mortality of cardiac surgery after TAVR. We look forward to working collectively with all stakeholders as we design and implement future studies in this space, which will continue to inform our patients of the shared decision-making process around therapeutic interventions for aortic valve replacement.

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Footnote

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