Utilization and Mortality Trends in Transcatheter and Surgical Aortic Valve Replacement
The New York State Experience—2011 to 2012*

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Transcatheter aortic valve replacement (TAVR), arguably the most transformative and disruptive cardiovascular therapy introduced in the past decade, has become the default treatment for clinically appropriate inoperable patients at extreme risk for surgical aortic valve replacement (SAVR) and increasingly recommended for patients at high risk for SAVR. The rapid acceptance of this technology has been extraordinary. It was only 14 years ago that the first TAVR was performed by Cribier in Rouen France (1). In 2016, >100,000 patients are expected to undergo TAVR worldwide. The U.S. Food and Drug Administration approved the first-generation balloon-expandable Edwards SAPIEN valve (Edwards Lifesciences, Irvine, California) in November 2011 for inoperable patients and in October 2012 for patients at high surgical risk for SAVR. The self-expanding CoreValve device (Medtronic, Minneapolis, Minnesota) was approved in January 2014. The scientific foundation upon which TAVR rests is deep and wide. In the PARTNER (Placement of Aortic Transcatheter Valves) trial, TAVR compared with medical therapy in inoperable patients achieved an absolute reduction in overall mortality of 20%, the benefit persisting at 5 years (2,3). Similarly favorable outcomes were noted in the nonrandomized CoreValve U.S. pivotal extreme-risk study (4). For those at high surgical risk, randomized studies have demonstrated equal or superior outcomes in TAVR-treated patients (5–7). More recently, TAVR is being used in more moderate-risk patients, for which studies have been limited. In general, the largest studies of TAVR have focused on very high-risk patients or in lower risk groups for which the follow-up has been abbreviated (8). Furthermore, sparse population-based data from an entire region are available.

In this context, Hannan et al. (9) in this issue of JACC: Cardiovascular Interventions examined the New York’s Cardiac Surgery Reporting System database from 2011 and 2012. Their purpose was to compare propensity-matched 1-year mortality and utilization rates of TAVR and SAVR. Furthermore, they explored the relative outcomes of TAVR and SAVR across different pre-procedural risk ranges using the New York State (NYS) short-term risk model for valve patients. Looking back at this early TAVR experience, the authors found a 27% overall increase in aortic valve replacement between 2011 and 2012 in the state, predominantly driven by a 157% increase in TAVR, whereas SAVR procedures remained stable, increasing incrementally. During the same period, the percentage of SAVR patients at high risk decreased from 27% to 23%, and the number of TAVR patients who were at highest risk decreased from 83% to 76%, in part a result of high-risk patients being approved in 2012. There was no difference in 1-year mortality between TAVR and SAVR; furthermore, there was no difference in mortality for those with a lower (<3%) or higher NYS risk score (>3%). A 3% NYS risk score is...
roughly equivalent to a Society of Thoracic Surgeons risk score of ~8%.

What do these observational data from the NYS Surgical Database contribute to our understanding of TAVR and its role compared with SAVR? Although randomized studies remain the gold standard against which therapies are evaluated and approved, a well-conducted observational study such as this may be more generalizable, being carried out on a real-world population within a given geographic region where all procedures are captured (10,11). Additionally, a database such as this can help assess the safety and effectiveness of a novel technology as it moves beyond protocol-driven care and highly experienced centers to the broader community. Furthermore, it provides a unique opportunity to follow the evolution of both SAVR and TAVR.

In looking back at the early TAVR experience in NYS, the results are reassuring. The outcomes of TAVR and the trends in its use noted in the current study are consistent with what has been noted in both randomized and observational databases. The trends noted are similar to those observed in the Transcatheter Valve Therapy registry with marked growth in TAVR procedures with a modest decline in risk profile (12-14). Like the PARTNER trial, the current study found no difference in 1-year mortality between propensity-matched patients undergoing TAVR and SAVR (4). The pivotal randomized high-risk CoreValve trial found a significantly lower 1-year mortality rate that persisted to 2 years in the TAVR group (6,7). In contrast, in the NYS analysis, the authors noted that although the hazard ratios were not significantly different when comparing TAVR with SAVR, they ranged from 1.27 for patients with an NYS score >3% to 1.42 for patients with an NYS score <3%. If these ratios had persisted with a larger sample size, SAVR may have been superior to TAVR. However, essential variables for risk adjustment were not available, particularly frailty, in the propensity-matching process. Measures of frailty and disability are potent predictors of 30-day and 1-year mortality (15). Like the pivotal randomized studies of balloon-expandable and self-expanding transcatheter valves versus SAVR, the current study noted no significant interaction between risk profile and relative outcome of TAVR versus SAVR (4,7). A similar lack of interaction has been noted in other observational studies (16).

Where do we go from here? The inexorable use of TAVR in lower risk patients will continue. As lower risk patients are treated, the impact of residual aortic insufficiency, the need for a permanent pacemaker, and valve durability will be of increasing importance. Counterbalancing these potential limitations of TAVR are progressive enhancements in valve technology and procedural simplicity (17). Recent studies of the latest generation of the balloon-expandable SAPIEN 3 device have revealed very low rates of paravalvular aortic insufficiency and a 1.1% 30-day mortality rate in intermediate-risk patients (18,19). Trials to date suggest transcatheter valve durability is equal to SAVR at 5-year follow-up. We know much less about the longer term. Furthermore, defining which patients in the intermediate- or low-risk group who preferentially benefit from TAVR over SAVR will be imperative. As this therapy becomes more widespread, defining individual institutional outcomes is essential and will facilitate quality improvement efforts. Ensuring that TAVR in the real world is being appropriately used will require robust observational databases. Although we await the results of randomized trials of TAVR versus SAVR in intermediate-risk patients (PARTNER II [The PARTNER II Trial: Placement of AoRTic TraNscatheterER Valves and SURTAVI [Safety and Efficacy Study of the Medtronic CoreValve™ System in the Treatment of Severe, Symptomatic Aortic Stenosis in Intermediate Risk Subjects Who Need Aortic Valve Replacement]) and anticipate the start of 2 randomized trials of low-risk patients with balloon-expandable and self-expanding devices, this NYS experience will continue to enhance our understanding of how to best manage patients with severe aortic stenosis and help us to see forward as we look back.

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