Commentary: Today’s solution… tomorrow’s problem

Thomas E. MacGillivray, MD

Over the last decade, transcatheter aortic valve replacement (TAVR) volumes have surged, with an associated decline in the number of surgical aortic valve replacements (SAVRs) being performed for patients with aortic stenosis.1 Several clinical trials have demonstrated the periprocedural safety and short-term efficacy of TAVR for all patient risk groups.2 Now commercially available, TAVR is the recommended treatment for most older patients and intermediate- or high-risk patients with severe aortic stenosis who have limited predicted long-term survival. Increasingly, younger, low-risk patients are requesting and receiving TAVR. While we await the long-term durability data, is this prudent?

Fukuhara and colleagues3 from the University of Michigan have highlighted an alarming observation concerning TAVR explants. Incidence of mortality after native TAVR explant was 14.2%. The majority of the native TAVR explant deaths were in patients considered low- (41%) or intermediate-risk (31%) at the time of TAVR implant. Many of the patients required combined or complex procedures, given the technical challenges of dissecting free the embedded transcatheter valve, but even isolated TAVR explant with SAVR had a mortality of 18.2%. Of “paradoxical” note, in the group of 24 patients undergoing reoperative surgery for valve-in-valve (VIV) TAVR explant, there were no operative (30-day) deaths, even though 62.5% of patients were high-/extreme-risk at the time of TAVR implant. Furthermore, the long-term survival in the native TAVR explant cohort was significantly worse compared with the VIV-TAVR explant cohort.

Over the 10-year study period at the University of Michigan, the 8-year cumulative incidence of TAVR explant was 1.9% and 14.1% in the native TAVR and VIV-TAVR cohorts, respectively. Although this incidence seems acceptably low, the true incidence of patients with indications for TAVR explant may be much greater. Of the 1834 patients who underwent TAVR or VIV-TAVR, nearly one half of the patients (n = 882) died without TAVR intervention. Given that the median time to TAVR explant in this study was 1.8 years, it could be that more patients had an indication for TAVR explant, but this was not offered due to perceived high risk. Food and Drug Administration approval for TAVR has occurred incrementally—in high-risk patients in 2012, intermediate-risk patients in 2016, and low-risk patients in 2019—and retrospective analyses and registries only record the procedures we perform and not procedures that we do not offer. The startling data from this study and other corroborating registries4 should give us all pause as we consider the lifetime management for patients with aortic stenosis.

Most bioprosthetic valves are expected to fail over time. For older and/or higher-risk patients whose life expectancy is limited by comorbid conditions, TAVR should be the procedure of choice because the need for valve reintervention will be unlikely. In younger and healthier patients whose life expectancy is greater than 10 to 15 years, SAVR should be highly recommended by the Heart Team. Should that prosthesis fail over time, redo SAVR or VIV-TAVR can then be more safely performed than TAVR explant. Today’s solution should not create tomorrow’s problem.
References