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Commentary: The complexity of complications

Marvin D. Atkins, MD, and Michael J. Reardon, MD

In this edition of the *Journal*, the structural heart team from the Brigham and Women's Hospital in Boston present their midterm outcomes of transfemoral transcatheter aortic valve replacement in 866 patients.¹ The mean patient age was 80 years, and >60% were deemed intermediate or high risk. The majority of patients received a balloon-expandable device (86.5%) and were treated with the latest generation of balloon-expandable or self-expanding prostheses (71%). The study focused on periprocedural complications and their longitudinal outcomes on mid-term survival. The group reported low mortality at 30 days (2.8%) and a 1-year mortality of 11.8%, even in these intermediate- and high-risk groups. A new permanent pacemaker (PPM) was required in 7.9% of patients, and this did not appear to have an effect on survival at 5 years. Greater than mild paravalvular leak (PVL) occurred in 4.4%, and survival at 2 years was significantly worse in these patients compared with those with mild PVL. This mortality risk appeared to be attenuated at 5 years for unclear reasons. Any new postoperative stroke occurred in 3.9% and was categorized as mild, moderate, and severe. Severe stroke occurred in 7 patients (0.8%) and was associated with significantly worse 5-year survival. Nonsevere stroke was not associated with an increased mortality risk. The groups of patients were divided into an early era (2011-2014) and a late era (2015-2018), and the previous outcomes were examined. Over the time intervals, PVL greater than mild decreased significantly as operator experience, patient selection, and

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CENTRAL MESSAGE

The complications of stroke, paravalvular leak and pacemaker can affect the long term outcome from transfemoral TAVR. Low risk TAVR should focus on reducing these.

changes in transcatheter aortic valve replacement (TAVR) device design improved.

The authors should be commended for their excellent results. They highlight the (fortunately) infrequent complications associated with TAVR, namely new stroke, greater than mild PVL, and the need for a new PPM. Efforts to further improve the results of TAVR should be focused on mitigating the risks of these 3 specific complications. The outcomes of this study cannot be extrapolated to low-risk patients, given that the majority of patients were in the intermediate- and high-risk cohorts. Presumably, low-risk patients should have a lower atherosclerotic aortic arch burden and thus a lower risk of periprocedural stroke, as was seen in the low-risk trials, leading to a low-risk indication.^{2,3} Low-risk patients are also less likely to have preexisting conduction disturbances, increasing their likelihood of needing a new PPM. Rates greater than mild PVL continue to be low, especially with improvements in device design, but might be adversely affected in those low-risk patients who are more likely to present with bicuspid disease and eccentric calcium deposits.

TAVR has been shown in randomized clinical trials to have equivalent^{4,6} or superior⁷ outcomes in patients with intermediate or high surgical risk, and the TAVR results in the present study are in line with those findings. Continuing advances in device design, deployment techniques, and stroke prevention are aimed at mitigating 3 of the most common, albeit low-risk, complications of TAVR: new PPM, greater than mild PVL, and periprocedural stroke. As TAVR is increasingly performed in

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patients at low surgical risk, of younger age, and with longer life expectancy, the longitudinal outcomes of these adverse events will play a significant role. The low-risk trials for TAVR plan to follow patients out to 10 years, and the midterm results should be available in the next 2 to 3 years to shed further light of the results of TAVR and surgical AVR (SAVR) in this low-risk patient population. As long as TAVR has at least equivalent intermediate-term results to SAVR, patients will continue to demand this less invasive option.

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Commentary: Mid-term outcomes in a real-world transcatheter aortic valve replacement population

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In this edition of the *Journal*, Percy and colleagues¹ present a series of 866 patients who underwent transfemoral transcatheter aortic valve replacement (TAVR) at Brigham and Women's Hospital between 2011 and 2018. The authors compared 5-year survival in patients with and without peri-procedural complications. The complications of interest were periprocedural stroke, paravalvular leak (PVL), new

CENTRAL MESSAGE

Midterm survival after TAVR is lower in high- and intermediate-risk patients who have a severe perioperative stroke. The impact of complications on outcomes in low-risk patients requires more study.

left bundle
branch block,
and permanent
pacemaker

(PPM) implantation. These complications appear to occur more frequently after TAVR than surgical aortic valve replacement (SAVR) in some randomized trials.²⁻⁴ Their impact on long-term prognosis is of particular concern in younger, low-risk patients who would also be excellent candidates for SAVR, which has proven excellent long-term outcomes.⁵

Patients in this study had a mean age of 80 years, a mean Society of Thoracic Surgery surgical risk score of 4.8%, and were followed for a median of 36 months. Stroke

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