Editorial

Portico at 1 Year
"There is Nothing Like First-Hand Evidence"

Gurpreet S. Sandhu, MD, PhD; Charanjit S. Rihal, MD

—Sir Arthur Conan Doyle. *A Study in Scarlet*, 1887

Long awaited, the St Jude Medical (St Paul, MN) Portico valve is a self-expanding percutaneous aortic valve prosthesis consisting of a Nitinol cage and leaflets made of bovine pericardium. Potential advantages of its design include large stent cell sizes and a relatively shorter height with minimal flaring, designed to prevent deep placement in the left ventricular outflow tract and lower pacemaker rates. In this issue of *Circulation: Cardiovascular Interventions*, Linke et al[1] present 1-year outcomes from the Portico prospective, multicenter registry (ClinicalTrials.gov, NCT01493284). A total of 222 patients with severe aortic stenosis and a mean age of 83 years (74% women) were enrolled in Europe and Australia, with the primary end point of all-cause 30-day mortality. Inclusion and exclusion criteria, as well as study design, are similar to previous intermediate and high-risk transcatheter aortic valve replacement (TAVR) trials, with an Society of Thoracic Surgery (STS) risk[2] requirement of ≥4. Patients with a lower STS risk score but deemed inoperable or high risk by the heart team were also included. A high proportion, one third, of valves required recapture and repositioning during the procedure. The implanted valves included an equal distribution of all 4 available sizes.

See Article by Linke et al

All-cause mortality was 3.6% (95% confidence interval, 1.8%–7.1%) at 30 days and 13.8% (95% confidence interval, 9.8%–19.3%) at 1 year, including 3 procedural deaths attributed to guidewire-related ventricular perforation, a clear opportunity for improvement. Overall, these results are not dissimilar those observed in other TAVR studies. The SURTAVI trial (Surgical Replacement and Transcatheter Aortic Valve Implantation)[3] of the self-expanding CoreValve prosthesis documented a 2-year all-cause mortality of 11.4% for TAVR and 11.6% for surgical aortic valve replacement. Contextually noteworthy is the meta-analysis of 12 182 patients from the US-based STS/American College of Cardiology transcatheter valve therapy registry by Holmes et al[4] that reported an all-cause mortality rate of 23.7% at 1 year. In the Linke study, the Kaplan–Meier estimated 1-year rate of major stroke was 5.8%, most of which occurred within 30 days of the procedure. In comparison, major stroke in SURTAVI was 2.6% and 4.5% for TAVR and surgical aortic valve replacement, respectively. The absence of a control surgical aortic valve replacement or other TAVR valve remains a shortcoming of the current study.

The elephant in the room that led to a pause in the original PORTICO study (Portico Re-sheathable Transcatheter Aortic Valve System US IDE Trial) remains unaddressed.[5] Valve leaflet thrombosis with reduced mobility was documented by computed tomography, but the current study only used echocardiography to assess the valve status at implantation and follow-up. Surprisingly, antiplatelet and anticoagulant therapies were left to the discretion of operators, and no further information is provided in the manuscript. Despite the absence of direct computed tomographic assessment, the mean aortic valve gradient of 8.4 mm Hg at 1 year, along with low aortic regurgitation rates, provides indirect reassurance. Overall, the underlying self-expanding structure of the Portico valve is similar to the clinically available CoreValve and Evolut valves by Medtronic. The Portico valve, besides being resheathable and repositionable like Evolut, incorporates a porcine pericardial cuff to mitigate paravalvular leakage while larger open cells in the stent struts conceivably improve access for future coronary interventions. With moderate aortic regurgitation noted in 5.5% of patients and moderate paravalvular leak in 5% (with no higher grades of aortic regurgitation or paravalvular leak documented), it largely fulfills the stated mechanical design objectives. Pacemaker rates of 13.6% at 30 days and 14.7% at 1 year are well within the 25.1% 30-day rates of permanent pacemaker implantation reported after self-expanding TAVR valves in a meta-analysis of 9785 patients in the STS/ACC TVT registry.[6] Thus, although Portico is a welcome addition to the TAVR armamentarium, the technology is evolutionary not disruptive, and its ultimate utilization and competitive advantages remain to be determined.

An increasing number of TAVR valves are being developed worldwide, and there have been significant procedural and technological advances (those involved in the early days can appreciate how smooth the procedures now are) that have provided a therapeutic boon for patients. More design and development need to done because all of the currently available and mostly similar valves have significant limitations. For balloon-expandable valves, their relatively bulky nature has necessitated cumbersome accommodations, like expanding sheaths, added steps of pulling balloons into valve stents, and manipulation of pusher tubes, all of which increase the potential for procedural mishaps or errors. The requirement for hypotension with high-speed pacing and the nonretrievable nature of balloon-expandable devices is a limitation.

The opinions expressed in this article are not necessarily those of the editors or of the American Heart Association.

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(*Circ Cardiovasc Interv*. 2018;11:e006335.
DOI: 10.1161/CIRCINTERVENTIONS.118.006335.)

***Circ Cardiovasc Interv* is available at**
http://circinterventions.ahajournals.org
DOI: 10.1161/CIRCINTERVENTIONS.118.006335

However, self-expanding valves experience unacceptably high pacemaker rates because of high annular radial forces, but a reduction in radial forces comes with the associated cost of higher paravalvular leak, as well as greater difficulty in precisely anchoring the stent struts to avoid deep-seating or pop-outs. Stent struts of self-expanding valves always cover the ostia of coronary arteries and can hinder subsequent percutaneous coronary. A significant percentage of valves in the current study required repositioning. The additive procedural complexity and potential for atheroma or thrombus embolization because of repeated capture and redeployment of suboptimally positioned devices can be problematic. Stroke associated with TAVR has led to the development of embolic protection devices, which although a welcome addition to the interventional armamentarium, also increase procedural complexity, length, and cost.

What then, would an ideal TAVR valve look like? The holy grail of easy deliverability under conscious sedation with optimal first-time deployment, low pacemaker rates, virtual absence of paravalvular leak, and affordability for patients and providers remains elusive—but is within sight. Dealing with bicuspid valves, bulky nodular calcification, and younger patients presents challenges. We have no doubt that these challenges will eventually yield to the onslaught of investment and innovation and that new entrants will drive improvements in quality, safety, and healthcare costs. In the far future living, growing, tissue-engineered valves may provide solutions for younger patients with congenital valve abnormalities. The authors are to be congratulated on a carefully performed prospective registry that will inform our practice.

Disclosures

Dr Rihal has received research support from Edwards Lifesciences, Medtronic, and Boston Scientific. The other author reports no conflicts.

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KEY WORDS: Editorials ■ aortic valve stenosis ■ heart valve prosthesis ■ stroke ■ transcatheter aortic valve replacement

Circulation
Cardiovascular Interventions

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Circ Cardiovasc Interv. 2018;11:
doi: 10.1161/CIRCINTERVENTIONS.118.006335
Circulation: Cardiovascular Interventions is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

Print ISSN: 1941-7640. Online ISSN: 1941-7632