EDITORIAL COMMENT

Transcatheter Aortic Valve Replacement Is Growing Up, But Kids Do the Darndest Things*

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In this issue of JACC: Cardiovascular Interventions, Webb et al. (1) report the 2-year follow-up of the B arm of the PARTNER II (Placement of Aortic Transcatheter Valves II) trial in which patients with severe inoperable symptomatic aortic stenosis were randomized to receive transcatheter aortic valve replacement (TAVR) with the SAPIEN versus the SAPIEN XT valve (Edwards Lifesciences, Irvine, California). Both valves are balloon-expandable bovine pericardial bioprostheses. The SAPIEN valve is delivered using a 22- or 24-F introducer sheath, whereas the lower-profile SAPIEN XT valve is delivered using a smaller 18- or 19-F sheath. Both groups of patients were required to have vascular access capable of receiving either valve.

F E W E R V A S C U L A R C O M P L I C A T I O N S

Not surprisingly, the current trial found that the lower-profile SAPIEN XT produced substantially fewer vascular complications and fewer major vascular complications resulting in fewer blood transfusions. Placing smaller devices inside arteries is safer than implanting larger ones. That’s where the expected results end. Remarkably, the lower-profile XT valve did not cause fewer early deaths or fewer early strokes than the first-generation SAPIEN. In the past, vascular complications and the need for blood transfusion have almost always translated into increased morbidity and mortality (2-5). This result is logical. This inoperable group of fragile, unstable patients likely would destabilize with the pain and blood loss associated with vascular injury. Although indeed the fewer complications caused by the XT implantation is a laudable and obviously a preferable outcome, why didn’t fewer complications and more facile implantation translate into fewer deaths and fewer strokes? This later finding is even more surprising because the current trial employed stricter neurological surveillance than did the PARTNER I trial. The answer probably lies in experience. The operators in the PARTNER II trial were usually the same as those from the PARTNER I trial, and though complications occurred more frequently with the early-generation valve, seasoned operators probably dealt with them in a more expedient, effective manner, leading to fewer deaths and strokes in the second trial.

PARAVALVULAR LEAK

In the current study, the incidence of moderate or severe paravalvular leak (PVL) was about 20%, almost double that seen in the PARTNER I trial and not different between the 2 arms of the trial even though the SAPIEN valve used in 1 arm was identical between the PARTNER I and II trials. The authors postulate that the difference is one of different core lab grade interpretation rather than an actual increase in the rate of this complication. This seems logical because reported mortality was similar between the 2 PARTNER trials. Because post-TAVR aortic regurgitation is accepted as a cause of increased mortality (6-8), yet mortality was not different, the magnitude of PVL was also probably not significantly different between the PARTNER I and II trials. Although the whole issue of PVL may be rendered moot by ever-improving

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TAVR designs that reduce or prevent PVL, the assessment of PVL is still relevant. Often missed in this assessment of PVL is its impact on the left ventricle (LV). This impact is based, not only on the severity of the leak itself, but also on its interaction with LV compliance. Thus, a relatively smaller leak could have more impact on a very stiff LV than a greater leak on a more compliant LV (9), so that PVL severity by itself is probably not an adequate determinant of outcome.

**MATURING OF TAVR: PARTNER I VERSUS PARTNER II**

Thus, the lower-profile SAPIEN XT TAVR led to fewer vascular complications, fewer major vascular complications, and less bleeding than did the bulkier first-generation SAPIEN valve (1). This outcome was predictable (did we need a trial to prove it?); indeed, it would have been very surprising if the next-generation valve had had no benefit. However, we have learned more than that from this trial. Two-year mortality was similar and substantial (about 35%) between both arms of this trial, also similar to the PARTNER I trial. This high rate almost surely stems from the very ill nature of these inoperable patients. In order to reach an STS score of 10 to 12 (found in the 2 trials), patients must have significant extracardiac comorbidities, conditions not treated by TAVR. Thus, improvement in the valve did not improve mortality. However, an apparent reduction in stroke rate between the PARTNER I and II trials and likely more effective treatment of vascular complications when they occur indicate improved operator judgment and skill as the procedure has matured—and this is only the beginning. Further refinement in valve design, patient selection, and operator skill will make TAVR progressively safer to employ, and as procedures become safer, they become more applicable. What will the TAVR of a decade from now be like? New designs are already reducing PVL (10). Valve profile will progressively decrease toward some theoretical minimum. Although surely structural deterioration will be a concern as it is with all biological valves, especially as they are applied to younger patients, it is interesting that TAVR in older patients has shown very little sign of this complication. Could it be that the inherent differences in TAVR design compared with other bioprostheses somehow conveys better durability? Finally, carotid protection devices in concert with easier delivery will likely further decrease stroke risk.

These advances will challenge us in our management decisions. Will each new advance require a clinical trial for vetting? How will new designs affect our decisions about treatment with surgical valve replacement? How will patient preference affect our decisions even when their preference goes counter to existing data? It will be a great, but gratifying, challenge to help TAVR grow up to be an adult member of our therapeutic armamentarium. Hang on to your hats, it will be quite a ride!

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