

Message from “real-world” data of transcatheter versus surgical aortic valve replacement

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Comparative outcomes between transcatheter aortic valve replacement (TAVR) and surgical aortic valve replacement (SAVR), which is one of the most important themes in structural heart disease intervention today, have largely been dependent on data from randomized controlled trials (1-4). However, randomized controlled studies do not actually reflect the outcomes of “real-world” TAVR versus SAVR because of relatively stringent inclusion and exclusion criteria. Furthermore, these trials and procedures are often performed in experienced, high-volume centers. In fact, we previously reported worse mortality in TAVR compared to SAVR when the meta-analysis was performed with propensity-matched studies from “real-world” data but similar mortality when only randomized controlled studies were pooled (5). This observation raised a concern that TAVR may not confer similar benefit compared to SAVR outside the randomized clinical trial setting. Accordingly, a large, non-randomized study to examine the real-world comparative outcomes between TAVR versus SAVR was clearly warranted.

The study by Brennan *et al.* has attempted to fill this gap in the literature in their article published in the *Journal of American College of Cardiology* (6) utilizing data from the Society of Thoracic Surgeons (STS)/American College of Cardiology Transcatheter Valve Therapy (TVT) for TAVR and STS National Database for SAVR. These two large United States registries are suitable sources to evaluate real-world data between TAVR

and SAVR. The inclusion interval was January 1, 2014 to September 30, 2015 for TAVR and July 1, 2011 to December 31, 2013 for SAVR.

Outcomes for SAVR and TAVR patients were compared in the intermediate-to-high risk patients stratified according to the STS-PROM scores. There were expected and unexpected results. Expectedly, perioperative outcomes (vascular complications, pacemaker implantation, red cell transfusions etc.) generally mirrored that of results from randomized controlled trials. Also, 1-year mortality was similar between TAVR and SAVR. The similar 1-year mortality was consistent among extensive sub-group analysis. These results suggest that TAVR confers similar mortality benefit compared to SAVR.

Unexpectedly, early mortality was significantly lower for TAVR, which was different from previous randomized controlled trials. Although, the Brennan analysis did not provide a breakup of the type of valve used in the TAVR cohort, the aforementioned results are in disagreement with the encouraging results of the SURTAVI (4) and PARTNER 2A (7) trials in intermediate risk patients suggesting a similar 30-day mortality with newer-generation valves. Whether similar enhancements in minimally invasive surgery over the last few years might likewise contribute to a comparable improvement in short-term survival remains unclear.

Although in aggregate, their findings are reassuring and appear to generally suggest clinical equipoise between

the two alternative approaches of valve replacement in the intermediate-to-high risk subsets of patients, a few limitations need to be acknowledged.

First, trans-femoral access was used in 76.3% in this study. This proportion could further rise with newer generation delivery systems with dramatic reductions in sheath sizes for both delivery platforms since their initial introduction, making trans-femoral delivery the preferred approach in most patients, a trend that could plausibly lower in-hospital mortality by lowering vascular and bleeding complications, compared to the trans-aortic or trans-subclavian routes of implantation. Nonetheless, this perspective has to be tempered by the fact that concomitant coronary artery bypass graft, which raises the surgical risk, was performed in 33.1% in the SAVR group. Whether isolated SAVR would have similar early mortality compared to TAVR requires further investigation.

Another unexpected finding was that risk of stroke continued to trend up during the follow-up period in TAVR group, although the overall rate of stroke was low and did not reach statistical significance. It is of great clinical interest and tempting to speculate whether this trend may be related to valve thrombosis and whether the routine addition of oral anti-coagulant post-TAVR would decrease stroke rate in TAVR. Finally, despite the meticulous efforts to match risk profiles between SAVR and TAVR groups, confounding from selection or assignment bias that occurred pre-procedurally for a variety of reasons including patient frailty, as acknowledged by the authors, could have skewed the results in favor of SAVR.

Should TAVR as an intervention be currently considered equivalent to SAVR for symptomatic, severe aortic stenosis at high and intermediate risk surgical risk in routine 'real-world' practice? Although there remain a few areas of uncertainty, such as outcomes in the bicuspid aortic valve, valve-in-valve, valve thrombosis, and especially long-term clinical outcomes in TAVR in comparison to SAVR, results from this research paper are reassuring and indicate that TAVR has evolved and matured into a robust alternative to SAVR. Ongoing technologic refinements with both FDA-approved platforms are likely to lead to

further reductions in short-term mortality and stroke risk in the near future.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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