TAVR-right for everyone?

Scott Shurmur MD

Transcatheter aortic valve replacement (TAVR) has been approved for clinical use in the United States since 2011. Initially approved only for patients with severe calcific aortic stenosis at high risk for surgical aortic valve replacement (defined as predicted mortality of greater than 8% in the 30-day perioperative period), the recently reported Partner 2A Trial cohort results suggest an expanding of the indication for TAVR.

The Partner 2A trial, reported in the April 28, 2016, issue of the *New England Journal of Medicine*, enrolled subjects with severe calcific aortic stenosis and an "intermediate" risk of mortality with surgical aortic valve replacement (SAVR), defined as a Society of Thoracic Surgeons predicted risk of 4-8%. These subjects were randomized to SAVR or TAVR with the Edwards Sapien XT valve used as the TAVR valve. In more than 75% of TAVR patients the valve could be placed transfemorally (as opposed to transthoracically). The results at two years were remarkable, as the primary endpoint (death from any cause or disabling stroke) was not different between the TAVR and SAVR groups. Similarly, no difference was detected at 30 days or one year. Individual endpoint components also did not differ, and stroke, once thought to be a particular problem with TAVR, was not increased in the TAVR group trial compared to SAVR.[1]

Like many trials involving evolving technologies, the Partner 2A trial used a TAVR valve which has largely already been replaced in clinical use. The current generation valve, the Sapien S3, has an increased fabric "sealing skirt" (Figures)[2] which has largely eliminated perivalvular aortic regurgitation, the presence of which had been associated with increased late mortality with previous generation TAVR valves. We lack large randomized trials with the S3 valve. However, in an interesting "observational study" presented at the annual American College of Cardiology Scientific sessions in April, 2016, about 1000 intermediate surgical risk patients who had received TAVR with the S3 valve were compared with the Partner 2A surgical cohort by propensity matching. While such analyses certainly have their limitations, the results were striking. The primary endpoint in this analysis was the composite of death, stroke, and moderate or severe aortic regurgitation. At one year TAVR with the S3 proved superior to SAVR in this analysis for the primary endpoint with a robust p value of <0.0001. And for the individual endpoints of death and stroke, TAVR with the S3 valve was superior to the matched Partner 2A SAVR patients. Moderate or greater aortic regurgitation (AR) was more frequent with TAVR than SAVR, but the one year rate of significant AR in the TAVR arm was low at 1.5%.[3,4]

The other commercially available TAVR valve, the Medtronic Core Valve, has shown superior survival when compared to SAVR at 1 and 2 years with a lower total stroke rate as well. Outcome data in intermediate risk patients is pending.

So where does this all leave us? It is becoming clear that individuals with severe aortic stenosis at intermediate or high risk for SAVR, without a compelling indication for surgical revascularization, can and perhaps should be treated with TAVR instead of SAVR. But the technique has its limitations, chief among them the uncertainty of the longevity of TAVR implants. They are, after all, bioprosthetic and have an expected longevity of 10-15 years in the aortic position. For younger patients at acceptable surgical risk, SAVR with mechanical implants remains the preferred approach. Eventually, even patients at low predicted surgical risk may be TAVR candidates. Mitral valve replacements with implants very similar to the current TAVR valves may soon be coming to the clinical arena as well, in the fascinating and rapidly evolving world of structural heart disease.

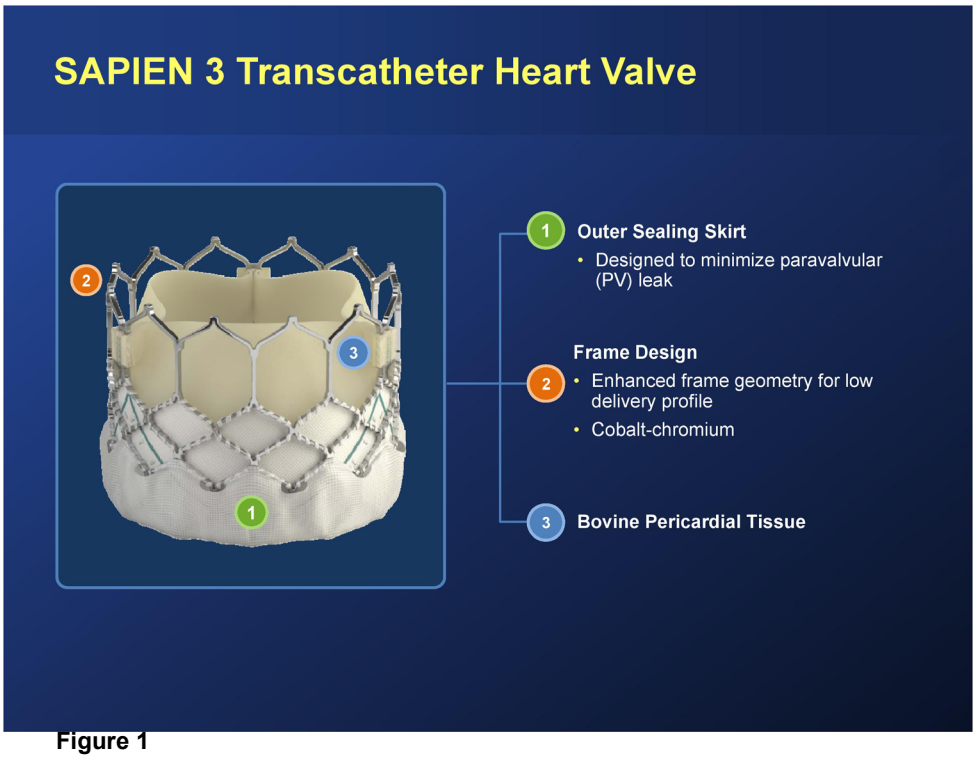

Figure 1

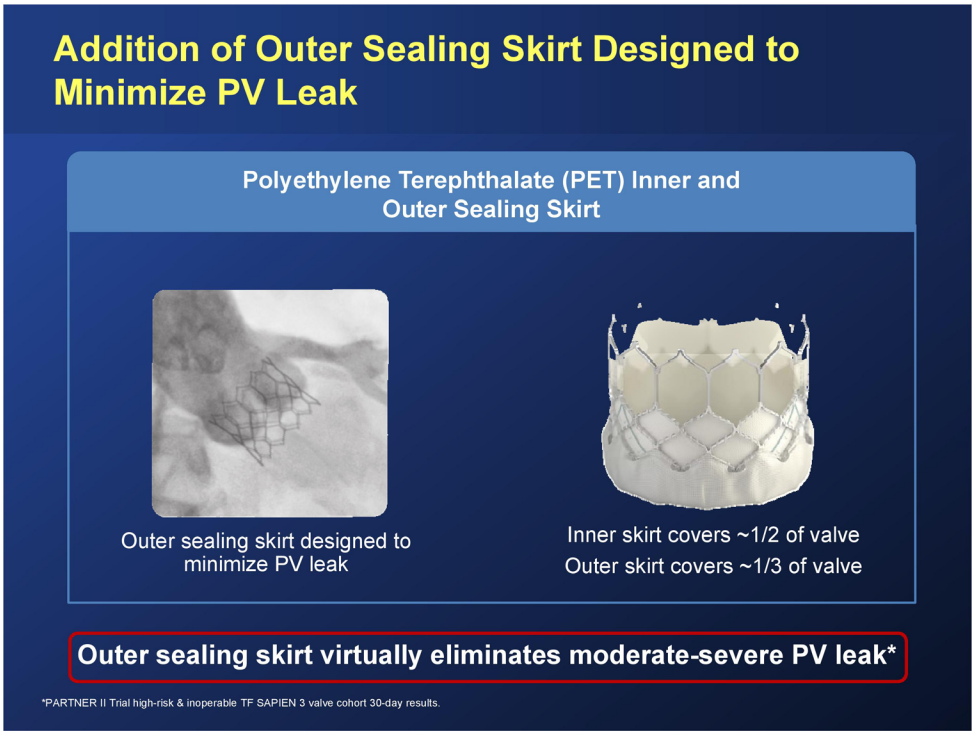

Figure 2

Author Affiliation: Scott Shurmur is a chief of Cardiology at Texas Tech University Health Sciences Center in Lubbock, TX.
Received: 05/05/2016
Accepted: 06/08/2016
Published electronically: 07/15/2016
Conflict of Interest Disclosures: none
Corresponding Author : Scott Shurmur MD
Contact Information: scott.shurmur@ttuhsc.edu
DOI: 10.12746/swrccc2016.0415.193

References

1. Leon MB, Smith CR, Mack MJ, *et al*. Transcatheter or surgical aortic – valve replacement in intermediate – risk patients. *New Engl J Med* 2016; 374 (17): 1609-1620.
2. Reproduced with permission, Edwards Lifesciences, Irvine, CA
3. Thourani V, Kodali S, Makkar RR, *et al*. Transcatheter aortic valve replacement versus surgical replacement in intermediate risk patients: a propensity score analysis. *Lancet* 2016 April 1. doi:10.1016/S0140-6736 (16)30073-3. [Epub Ahead of print].
4. Adams DH, Popna JJ, Reardon MJ, *et al*. Transcatheter aortic-valve replacement with a self-expanding prosthesis. *New Engl J Med* 2014; 370 (19): 1790-1798.