SAPIEN 3 improves outcomes for major endpoints at one year

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Intermediate-risk patients who received transcatheter aortic valve replacement, known as TAVR, with the latest-generation valve fared better than patients receiving traditional surgical aortic valve replacement after one year, in a study presented at the American College of Cardiology's 65th Annual Scientific Session.

Patients who received the new valve showed improved outcomes for the study's primary endpoint, a combination of death, stroke and moderate or severe aortic insufficiency, a complication in which blood leaks across the replaced valve. The trial is the first to assess long-term outcomes of TAVR with SAPIEN 3 in intermediate-risk patients and is in line with findings from an earlier stage of the same study, which showed improved outcomes for SAPIEN 3 over surgery at 30 days after the procedure.

"This study shows the lowest mortality rate ever of any transcatheter valve platform after one year, which is very exciting for the management of aortic stenosis," said lead study author Vinod Thourani, M.D., professor of surgery and medicine at Emory University School of Medicine, chief of cardiothoracic surgery at Emory University Hospital Midtown and the co-director of the Emory Structural Heart and Valve Center. "A previous analysis by our team showed that almost 20 percent of all patients undergoing surgical aortic valve replacement in the United States are in the intermediate-risk category, so I believe that this could have a major impact on the treatment options we have available for many of these patients."

TAVR is currently approved for patients with severe aortic stenosis—narrowing of the valve in the heart's main artery—whose health profile makes them ineligible or high-risk candidates for open-heart valve replacement surgery. In the procedure, a cardiologist or cardiac surgeon threads a replacement valve to the heart through a catheter placed in the groin or ribs. This trial, called PARTNER 2, evaluated outcomes with the SAPIEN 3 valve, the latest modification of the balloon-expandable system used in these procedures, among intermediate-risk patients.

The trial involved more than 1,000 patients who received TAVR with SAPIEN 3 at 51 U.S. hospitals. Participants, who averaged nearly 82 years of age, had an STS risk score of 4 to 8, a range considered intermediate, on a scale developed by the Society of Thoracic Surgeons that quantifies the risks posed by open-heart surgery for a given patient.

To account for baseline differences, TAVR patients were compared by a propensity score analysis with patients randomized to receive surgical intervention in a precursor study, PARTNER 2A. Propensity scoring analysis is a statistical technique used to reduce bias from potential confounding variables, which in this case was used to identify surgical patients from a previous study who would be comparable to TAVR patients in this study.

In the study's primary endpoint, a composite of death, stroke and moderate or severe aortic insufficiency, TAVR was found to be superior to surgery at one year, occurring 9.2 percent less in the TAVR patients compared with surgery patients. TAVR was also superior to surgery for 2 out of 3 secondary outcomes, mortality and stroke. In unadjusted one-year outcomes, all-cause mortality was lower with TAVR, occurring in only 7.4 percent of TAVR patients as compared to 13 percent of patients receiving surgery. The rate of disabling strokes was also lower in TAVR patients, at 4.6 percent as compared to 8.2 percent in surgery patients.

Surgery was found to be superior to TAVR in moderate to severe aortic insufficiency, occurring in 1.5 percent of TAVR patients and in 0.4 percent of surgery patients. More than moderate aortic insufficiency has been associated with poorer outcomes after TAVR in past studies. In addition, TAVR patients needed pacemakers at a slightly higher rate at one year than did patients receiving surgery.

"Taken together, these results demonstrate substantial improvements in outcomes among intermediate-risk patients receiving the SAPIEN 3 valve as compared in a propensity score analysis in intermediate-risk patients receiving surgery," Thourani said. In addition, the intermediate-risk TAVR patients in the new trial showed marked improvements in outcomes as compared to high-risk TAVR patients in previous trials.

Several factors could account for the overall improved success of the SAPIEN 3 TAVR procedure, Thourani said. One is that the third-generation model has been modified with an outer skirt designed to reduce leaking by sealing gaps around the valve. Other alterations allow the valve to be delivered with a smaller catheter, increasing the percentage of procedures that can be performed via the femoral artery accessed through the groin, a route that is considered safer. Nearly 90 percent of TAVR procedures in the new trial were performed through the femoral artery. In addition, heart teams now have more experience performing TAVR, and improved imaging techniques have allowed physicians to utilize more precise information about the valve implantation site and the appropriate valve size.

"Because our techniques have significantly improved, the majority of these patients go home within a day or two after the procedure," Thourani said. "The improvements with the SAPIEN 3 valve have made this an easier procedure to perform and now this study shows that we can do it with extremely low complications and mortality. I believe we are on the cusp of a new indication for TAVR."

Patients in the trial will continue be followed for five years.

Provided by American College of Cardiology