TAVR equivalent to surgery at 2 years among low-risk patients

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Patients undergoing transcatheter aortic valve replacement (TAVR) fared equally well compared with those undergoing open heart valve replacement surgery in terms of the combined risk of death, stroke or rehospitalization at two years, the primary endpoint of the PARTNER 3 trial being presented at the American College of Cardiology's Annual Scientific Session Together with World Congress of Cardiology (ACC.20/WCC).

TAVR is a procedure in which operators thread an artificial heart valve through an artery in the leg to replace a patient's malfunctioning valve. The procedure is approved by the U.S. Food and Drug Administration (FDA) for the treatment of severe aortic valve stenosis, a condition in which the heart's main valve doesn't open fully, in all patient risk groups for complications associated with surgery.

The PARTNER 3 trial focuses on patients for whom surgery poses a low risk, who are typically younger and who have fewer health problems than higher-risk patients. Last year, researchers reported that TAVR showed superior outcomes compared with surgery at one year among PARTNER 3 participants. The new findings indicate both approaches are equivalent to each other in this low-risk population in terms of outcomes occurring up to two years later.

"The one-year outcomes were only the first look at how these patients do, and this is the second look," said Michael J. Mack, MD, a cardiothoracic surgeon at Baylor Scott and White Health and the study's lead presenter. "On the basis of one-year data, many physicians were counseling patients that TAVR outcomes were better than surgery. Now, we see that the outcomes are roughly the same at two years."

PARTNER 3 enrolled 1,000 patients with severe aortic stenosis and a Society of Thoracic Surgeons risk score of less than 4%. All patients had a tricuspid (three leaflets) aortic valve. Half of the participants were randomly assigned to undergo TAVR with the SAPIEN 3 valve and half underwent surgery.

At two years, 11.5% of patients receiving TAVR and 17.4% of those receiving surgery died, suffered a stroke or were rehospitalized for cardiovascular problems, a difference in the composite primary endpoint that researchers reported as showing non-inferiority, meaning neither treatment was superior to the other.

In a secondary analysis, rates of death and stroke were found to be not significantly different between the two groups. Death occurred in 2.4% of those receiving TAVR and 3.2% of those receiving surgery, while stroke occurred in 2.4% of those receiving TAVR and 3.6% of those receiving surgery. Rehospitalization rates showed a significant difference in favor of TAVR; 8.5% of those receiving TAVR and 12.5% of those receiving surgery were rehospitalized for cardiovascular reasons during the study period.

The two-year outcomes also indicate patients undergoing TAVR had a significantly higher rate of valve thrombosis, the formation of blood clots on the valve, which occurred in 2.7% of patients in the TAVR group and 0.7% of those who received surgery at two years. However, there was no significant deterioration in the functioning of the valve itself between years one and two in either study group.

Researchers will continue to track patient outcomes for up to 10 years. "Longer-term outcomes are particularly important for this patient population because younger, low-risk patients have longer to live with this valve than patients that have been previously studied," Mack said. "Therefore, the durability of the valve is of utmost importance."

About 80% of patients in the U.S. who need valve

replacement for severe aortic stenosis fall into the low-risk category studied in PARTNER 3. While TAVR is appealing to many patients because it is a less invasive procedure than open heart surgery and has a shorter recovery time, the PARTNER 3 trial and other ongoing studies provide valuable data to help inform shared decision-making among doctors and patients, researchers said.

Mack said that the trial's findings are limited to patients with severe, symptomatic aortic stenosis with a tricuspid valve and the same inclusion criteria as patients who were enrolled in the study. The trial is also limited by a reduced follow-up rate among patients who received surgery compared with those who underwent TAVR.

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