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SAPIEN valve, surgery equivalent at five-years

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Five-year data suggest that the SAPIEN transcatheter heart valve is a feasible option for patients with severe aortic stenosis deemed to be at high risk for open-heart surgery, though valve leakage was more common with the first-generation valve evaluated in this study than with surgery, according to research from PARTNER I presented at the American College of Cardiology's 64th Annual Scientific Session.

When the blockage of an aortic valve becomes severe, replacement is the only real treatment choice, but many elderly and frail people are poor candidates for open-heart surgery to place a new valve. The PARTNER I trial randomly assigned 699 high-risk patients to valve replacement with standard surgery or transcatheter aortic valve replacement, known as TAVR, a less invasive procedure featuring a tiny metal frame containing a cow tissue valve, which is expanded by a balloon after placement in the target valve.

"The surprise is that there were no surprises," said Michael Mack, M.D., chief of cardiovascular disease at Baylor Scott and White Health in Dallas. "The findings at five years confirm the earlier findings that outcomes are equivalent in high-risk surgical patients with surgery and with TAVR." There were no signs of structural valve deterioration or loss of valve function with TAVR, he said.

The FDA has approved the SAPIEN valve for inoperable and high-risk operable patients.

At five years, death and stroke rates were statistically the same in both groups: 67.8 percent of TAVR patients and 62.4 percent of surgery patients had died, with median survival of 44.5 months with TAVR and 40.6 months with surgery. Stroke rates were 15.9 percent for TAVR patients and 14.7 percent for surgery patients. Rehospitalization rates and functional outcomes also were the same in both groups.

Transcatheter valves have not approached the low leakage rate around the valve that can be achieved by an open-heart operation. As in previous findings, the rate of moderate or severe leaking around the valve remained significantly higher for the TAVR group—14 percent with TAVR and 2.1 percent with surgery—and at five years, that higher leakage rate still led to an increase in deaths with the death rate in patients with leakage 9 percent greater than in patients who didn't have a significant leak. The first-generation valve used in this trial has already been replaced by a second-generation device that is approved in the United States, and a third-generation valve has been designed specifically to reduce leakage. Thirty-day results for the third-generation valve will be reported separately at the ACC meeting.

Data analysis identified several indications and cautions for both procedures. Kidney disease was a significant issue with TAVR but not surgery; a high Society of Thoracic Surgeons risk score, which indicates the patient is sicker at the time of treatment, was a predictor of death in the surgery group; and liver disease was a significant factor in both groups. TAVR patients will be followed annually for life in the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapies registry; surgery patients will not be followed beyond five years.

"You can look at this trial and say, 'there's no difference in the two arms, what's the big deal?,' but that's the major message," Mack said. "With a brand-new therapy using a first-generation device that represents most of

the experience of the clinical trial sites, outcomes were virtually identical to the standard of care for the last 50 years."

Provided by American College of Cardiology