Rates of death and stroke equivalent for surgery and TAVR at 2 years

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Intermediate-risk patients with severe aortic stenosis who receive minimally invasive transcatheter aortic valve replacement, known as TAVR, have similar rates of death and disabling strokes after two years compared with those undergoing standard open heart surgical replacement, according to a study presented at the American College of Cardiology's 65th Annual Scientific Session. Patients receiving TAVR also experienced shorter hospital stays and lower incidence of some major complications compared with those undergoing surgery.

Data from this non-inferiority trial—the first to evaluate TAVR in patients who are considered intermediate-risk—suggests TAVR is at least as safe and effective as surgery in these patients. Overall, the primary endpoint of all-cause death and disabling strokes was comparable at two years, 19.3 percent for TAVR and 21.1 percent for surgery. Among TAVR patients with transfemoral placement of the valve—the least invasive of two approaches in which the device is implanted through a small incision in the groin—the combined rate of death and disabling stroke was lower, 16.8 for TAVR compared with 20.4 percent for surgery (p-value=0.05).

"For the past five years, TAVR has been growing in use and acceptance largely based upon clinical evidence from multiple randomized controlled trials, but these have been limited to patients at the highest risk for surgery," said Martin B. Leon, M.D., professor of medicine and director of the Center for Interventional Vascular Therapy at Columbia University Medical Center-New York Presbyterian Hospital and co-

principal investigator of the PARTNER trials. "Here, we demonstrate outcomes related to death and stroke, which are equivalent in these patients and may be superior in the transfemoral group."

To perform TAVR, a surgeon threads a replacement valve to the heart through a catheter placed in the groin or chest. 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 this randomized controlled PARTNER 2A trial, outcomes using the SAPIEN XT valve were compared with open-heart surgery valve replacement among 2,032 intermediate-risk patients treated between December 2011 and November 2013 at 57 sites, all but two in the U.S. Patients were randomly assigned; 1,011 to TAVR and 1,021 to surgery. Of those in the TAVR group, 76 percent underwent transfemoral placement, and the rest had transthoracic placement in which the new valve is thread through a cut in the chest wall. "When we compare transthoracic TAVR patients to those having surgery, they are about the same, so whatever benefit achieved related to lower rates of death and strokes was clearly in the transfemoral group," Leon said.

Researchers also found significant differences in secondary clinical endpoints looking at time in the hospital, valve function and major complications, some favoring TAVR, some surgery. For example, TAVR patients spent less time in the hospital overall—the average time in the ICU was two days with TAVR versus four days with surgery, and the average hospitalization for TAVR was six days compared to nine days with surgery. TAVR also appeared to improve the aortic valve areas more than surgery, meaning that the quality of the valve's performance was better as measured by echocardiography during follow-up points through two years.

Compared to surgery, TAVR also yielded significantly lower rates of acute kidney injury, severe bleeding events and new onset atrial fibrillation, a heart rhythm problem that is a common complication of open procedures. The surgery group, on the other hand, had fewer major vascular complications and leakage around the valve (para-valvular regurgitation).

The heart team discussed each individual case to determine if patients were indeed intermediate-risk. Baseline characteristics were comparable. All patients were followed for at least two years and will continue to be followed for five years.

"The two-year follow-up allows enough time to accurately assess the relative performance of these two valve replacement therapies," Leon said, adding that he suspects these findings will potentially affect clinical guidelines for TAVR in the future. "We know surgery is good, but it is still a major procedure and for many patients, a less-invasive approach may be the preferred alternative. As we continue to evolve the procedure and technology, it's important to know whether TAVR is an effective alternative in these lower risk patients."

Aortic stenosis happens when the aortic valve narrows or is blocked and therefore does not open fully. As a result, the amount of blood that can flow through the valve into the aorta and out to the body is restricted. If the condition is untreated, which usually involves valve replacement, the risk of death is 25 percent the first year after symptoms appear, and the risk rises to 50 percent the second year.

Roughly 1 in 5 patients undergoing surgical aortic valve replacement in the U.S. are estimated to be intermediate-risk; so together, intermediate- and high-risk patients comprise the top quartile of all patients needing an aortic valve replacement.

The study was funded by Edwards LifeSciences.

This study was simultaneously published online in *The New England Journal of Medicine* at the time of presentation.

The SAPIEN XT device used in this trial is an older model transcatheter. The same research team will present findings comparing the SAPIEN 3, the newest generation of the device, to surgery.

Vinod Thourani, M.D., professor of surgery and medicine and chief of cardiothoracic surgery at Emory Hospital Midtown and co-director of the Structural Heart and Valve Center at Emory University School of Medicine, will present that study, "Sapien 3 Transcatheter Aortic Valve Replacement versus Surgery in Intermediate-Risk Patients with Severe Aortic Stenosis: A Propensity-Matched Comparison of One-Year Outcomes," on Sunday, April 3, 2016, at 10:45 a.m. CT/11:45 a.m. ET/3:45 p.m. UTC in the Main Tent (North Hall B1).

Provided by American College of Cardiology