PARTNER shows similar 1-year survival for catheter-based AVR and open AVR in high-risk patients

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Less invasive catheter-based aortic valve replacement and open valve-replacement surgery have a similar one-year survival for patients at high risk for surgery.

Results from The PARTNER (Placement of AoRTic traNscathetER valves) Trial — the world's first randomized clinical trial of a transcatheter aortic heart valve — were published in the *New England Journal of Medicine*.

"These results show that a balloon-expandable transcatheter valve replacement in patients at high risk for surgery is as safe and effective as open surgery, which is the 'gold standard' for most patients," says the study's first author, Dr. Craig Smith, chairman of the Department of Surgery at NewYork-Presbyterian Hospital/Columbia University Medical Center and the Johnson & Johnson Distinguished Professor and the Valentine Mott Professor of Surgery at Columbia University College of Physicians and Surgeons. The study was conducted at 26 centers in the United States, Germany and Canada.

Aortic valve replacement treats severe aortic stenosis, a narrowing of the valve that restricts blood flow from the heart and is associated with a high risk for death if left untreated. Annually, some 200,000 people in the U.S. need a new heart valve.

"Many patients with aortic stenosis are at high risk for complications and death following open surgery due to advanced age, poor left ventricular function, and other co-morbidities. For these patients, a less invasive treatment may be desirable," says
Dr. Martin Leon, the study's co-principal investigator, associate director of the Cardiovascular Interventional Therapy (CIVT) Program at NewYork-Presbyterian Hospital/Columbia University Medical Center, and professor of medicine at Columbia University College of Physicians and Surgeons.

The transcatheter valve procedures take about 90 minutes, compared with four to six hours for open heart surgery. In open heart surgery, the surgeon cuts through the breastbone, stops the heart, removes the valve and replaces it. Recovery is also better for the transcatheter procedures: median ICU stay was 3 days vs. 5 days (tranacatheter vs. open surgery); total hospital stay showed a similar magnitude of difference.

A total of 699 patients with severe aortic stenosis who were high risk for surgery were randomly assigned to receive the less invasive transcatheter aortic valve replacement (TAVR) or traditional aortic valve replacement (AVR).

Patients in the TAVR group were implanted with the Edwards SAPIEN heart valve, made of bovine pericardial tissue leaflets hand-sewn onto a metal frame, via one of two catheter-based methods — either navigated to the heart from the femoral artery in the patient's leg, or through a small incision between the ribs and into the left ventricle. (The approach was chosen based on whether the patient's femoral artery could accommodate the size of the device.) The replacement valve was then positioned inside the patient's existing valve, using a balloon to deploy the frame, which holds the replacement valve in place. These procedures are performed on a beating heart, without the need for cardiopulmonary bypass and its associated risks. Patients in the AVR group received a

valve replacement device through open heart surgery.

The study showed that in the first 30 days after the procedure, death from any cause occured in 3.4 percent of patients in the TAVR group, compared with 6.5 percent in the AVR group. But after a year, the risk for death was roughly the same at 24.2 percent vs. 26.8 percent, respectively.

Additionally, there were several differences in cardiovascular outcomes following the procedures. Major strokes were more common in the TAVR group than the AVR group at 30 days (3.8 percent vs. 2.1 percent) and after a year (5.1 percent vs. 2.4 percent). Major vascular complications were more frequent after TAVR (11.0 percent vs. 3.2 percent), whereas major bleeding (9.3 percent vs. 19.5 percent) and new-onset atrial fibrillation (8.6 percent vs. 16.0 percent) were more frequent after AVR. Symptom improvement favored TAVR at 30 days, but was similar after one year. Para-valvular regurgitation was more frequent after TAVR than AVR.

Dr. Smith notes that stroke and vascular complications remain a concern for TAVR, although their incidence has decreased since the previous cohort was reported in September 2010. "Clinical experience and device development is helping us mitigate these risks," he says.

Patients meeting the criteria for the trial — aortic stenosis and high risk for surgery — make up less than 5 percent of those receiving AVR. Going forward, these data support future trials that would expand the patient population to include intermediate-risk patients.

In September 2010, The PARTNER Trial reported that in patients who were not candidates for AVR, TAVR was associated with a dramatic (20 percent) improvement in one-year survival and reduced symptoms, compared with standard medical intervention, including a combination

of watchful waiting, medications and balloon aortic valvuloplasty.

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