

Midterm stroke, death rates comparable for TAVR, standard surgery

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All-cause and cardiovascular mortality were similar for transaortic valve replacement compared to open-heart surgery in high-risk older patients at three years with no increased risk of stroke after 30 days, according to results from the PARTNER study presented today at the American College of Cardiology's 62nd Annual Scientific Session.

The transcatheter aortic valve replacement (TAVR) system was investigated as an alternative to open-heart surgery for high-risk patients with severe <u>aortic stenosis</u>—narrowing of a main circulatory gateway in the heart that reduces blood flow. This condition affects roughly 300,000 Americans age 75 or older, who often have multiple health issues that make surgery especially risky. Recovery from catheter-based valve replacement typically takes a few days compared with four to eight weeks for open-heart surgery, which may be a benefit in a high-risk patient population.

The multi-center PARTNER study assigned 699 high-risk patients with faulty <u>aortic valves</u> to standard surgery (351 patients) or TAVR (348 patients). At three years, all-cause mortality was nearly identical in both groups: 44.8 percent for standard surgery compared to 44.2 percent for TAVR. <u>Cardiovascular mortality</u> rates also were statistically indistinguishable at 30.2 percent for standard surgery and 30.1 percent for TAVR. Both groups displayed similar improvements in symptoms that have been maintained for three years.

"One of the concerns has been the durability of the valve, but there



seems to be no structural deterioration thus far," said Vinod H. Thourani, MD, associate professor of <u>cardiac surgery</u> and co-director of the Structural Heart and Valve Center at Emory University School of Medicine in Atlanta. "It works as it's supposed to work, and hemodynamic performance is excellent past the three-year mark and comparable to surgical valve replacement."

With the much higher stroke rate reported for TAVR at 30 days, the other concern in this study has been whether a higher <u>stroke risk</u> would persist beyond that 30-day periprocedural window. None appeared at two or three years. TAVR stroke rates were 6 percent at one year, 7.7 percent at two years and 8.2 percent at three years, compared with 3.2 percent, 4.9 percent and 9.3 percent for standard surgery.

"After 30 days, TAVR patients don't have that many strokes," Dr. Thourani said. "At three years the surgery group's stroke rate has caught up with and slightly surpassed the TAVR rate but not to statistical significance."

Leaks around the valve were common soon after the procedure and were overwhelmingly higher in the TAVR group, and even mild aortic leakage is associated with a higher mortality rate after any valve replacement procedure, Dr. Thourani noted.

"In these first-generation transcatheter procedures, we have equivalent midterm outcomes between TAVR and the gold-standard surgical valve replacement in high-<u>risk patients</u> with severe aortic stenosis," Dr. Thourani said. "However, paravalvular leak continues to increase mortality at three years. Physicians should adopt innovative imaging technologies for more accurate sizing to help decrease these leak rates during TAVR."

The phase III study will follow patients for five years to assess durability



of the TAVR device and longer-term outcomes.

More information: Dr. Thourani will present the study "Three-Year Outcomes after Transcatheter or Surgical Aortic Valve Replacement in High-Risk Patients with Severe Aortic Stenosis" on Monday, March 11, at 8:00 a.m., in Moscone Center, South, Esplanade Ballroom.

Provided by American College of Cardiology

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