

Catheter-placed heart valve shows strong performance at two years

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Two-year data show comparable death and durability for catheter-placed heart valves and open-heart surgery in very old and ill patients, according to research presented today at the American College of Cardiology's 61st Annual Scientific Session. The Scientific Session, the premier cardiovascular medical meeting, brings cardiovascular professionals together to further advances in the field.

An estimated 5 percent of people age 75 and older have aortic stenosis, a progressive narrowing of the valve that controls blood flow to the heart. That number represents about 300,000 Americans. Every year some 50,000 of them undergo [open-heart surgery](#) to replace failing gateways, but at least one-third of patients do not have treatment despite symptoms because of other medical conditions, age or preference.

Last year the PARTNER trial reported preliminary results comparing standard open-heart surgery (AVR) with transcatheter [aortic valve replacement](#) (TAVR). In the study's Cohort A, 699 high-risk patients were randomly assigned to AVR (351) or TAVR (348). The TAVR group received a new valve via a [catheter](#) threaded to the heart through a leg artery or through a small incision between the ribs.

"We demonstrated that AVR and TAVR were equivalent at one year for [death rates](#) and treatment benefit," said Susheel Kodali, MD, co-director of the Heart Valve Center at Columbia University Medical Center/New York Presbyterian Hospital, New York. "Two-year [mortality data](#) are statistically indistinguishable – no suggestions of mortality benefit of one

procedure or another. We're now encouraged to think we have a less-invasive alternative that can treat many more of these patients who aren't getting treatment now."

The latest data present two-year findings for clinical endpoints including death and stroke, as well as careful evaluation of valve function over time. For the primary endpoint of death from any cause, results were 35 percent for AVR compared to 33.9 percent for TAVR. Outcomes were similar for death from cardiovascular causes: 20.5 percent for AVR vs. 21.4 percent for TAVR. Although the TAVR group had a nearly twice as many strokes in the first 30 days, that early benefit for surgery diminished. Over the course of follow-up, there was no significant difference in the risk of stroke between the TAVR and AVR groups (hazard ratio [95 percent CI] = 1.22 [0.67, 2.23], P=0.52).

"We're most concerned about valve durability, which you have to look at over five to 10 years, but any longer-term information is useful because trends tend to hold true over time," Dr. Kodali said. "We have no evidence that the initial good results in improved valve performance have deteriorated during the follow-up to this time point. TAVR appears to be as durable as AVR."

One finding about TAVR is relatively new. Unlike an open-heart procedure, where the surgeon has a direct view of the chest, a catheter-placed valve is guided entirely by imagery. As it is being implanted, there can be some leakage around the valve, called paravalvular regurgitation. This type of leakage is fairly common with TAVR and is usually mild.

"During this follow-up, we observed that significant leakiness around the valve was associated with higher subsequent mortality in TAVR patients, but it's important to note that overall mortality between the two groups is the same," Dr. Kodali said. "Now we have a target – we know what to fix

in the future. TAVR is already comparable to results for AVR in the most experienced surgeons' hands. If we can reduce these leaks, there's a good chance we can reduce mortality with TAVR even more."

Another aspect of this study is an improved collegiality between heart specialists, Dr. Kodali said. "For the first time, interventional cardiologists and surgeons are working very closely together in a [heart](#) team approach that requires their complementary skills."

Provided by American College of Cardiology

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