

Heart valve procedure safe for patients with common heart defect

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A new analysis conducted by investigators at the Cedars-Sinai Smidt Heart Institute shows for the first time that patients with a common heart defect who undergo catheter-based valve replacement procedures have the same survival and complication rates as patients without the defect who undergo the same procedure.

Published June 11 in *JAMA: The Journal of the American Medical Association*, the analysis compares outcomes for 2,726 [patients](#) born with a bicuspid [aortic valve](#)-two leaflets that open and close with every heartbeat-with 79,096 patients born with the normal three leaflets on their aortic valves. Both groups of patients were diagnosed with [aortic stenosis](#), a stiffness of the valve's leaflets that reduces the ability to fully open and close and causes the heart's aortic valve to narrow and the [heart muscle](#) to become thicker and sometimes weaker.

Aortic stenosis usually affects people 60 and older, but patients born with bicuspid aortic valve often experience it at a younger age. About 1% of the population is born with bicuspid aortic valve.

TAVR (transcatheter aortic valve replacement) is a minimally invasive, catheter-based procedure during which an interventional cardiologist repairs the valve by placing a new valve into the aorta. For patients with normal aortic valves, the procedure is generally considered less risky and easier to recover from than open-heart surgery. But until now, there was not enough data to prove the TAVR procedure also is safe for patients with bicuspid valves.

"In our analysis, we looked at all the bicuspid anatomy patients and found that death rates were no different than patients who had the normal number of leaflets and TAVR," said Raj Makkar, MD, vice president of Cardiovascular Innovation and Intervention at Cedars-Sinai and the Stephen R. Corday Chair in Interventional Cardiology. "This is important because many of the pivotal studies on TAVR did not include bicuspid patients due to concern that these valves may not expand and work in fish-mouth like narrowing in bicuspid anatomy."

The analysis also showed that bicuspid patients were slightly more likely than tricuspid patients to have a stroke within 30 days of the procedure. Based on these findings, Makkar says "carefully selected patients with bicuspid aortic valve stenosis can be treated with TAVR, sparing them more invasive open-heart surgery and longer recovery times since most patients can be discharged home the day after the procedure."

Makkar's TAVR analysis of patients at 552 U.S. medical centers showed:

- 2.6% of bicuspid patients died within 30 days of the procedure, compared to 2.5% of tricuspid patients, a difference that is not statistically significant.
- 10.5% of bicuspid patients died within one year of the procedure, compared to 12% of tricuspid patients, a difference that is not

statistically significant.

- The 30-day stroke rate was higher for bicuspid patients (2.5%) than for tricuspid patients (1.6%).
- The risk of procedural complications requiring [open-heart surgery](#) was significantly higher in the bicuspid group (0.9%) than the tricuspid cohort (0.4%).
- Both groups experienced the same quality of life as measured by the Kansas City Cardiomyopathy Questionnaire.

"This study highlights a critical evaluation that may help some patients avoid unnecessary surgery and complications," said Eduardo Marbán, MD, Ph.D., director of the Smidt Heart Institute. "Here at Cedars-Sinai, we put the patient first. Many, but not all, patients with bicuspid aortic valve are candidates for TAVR. The care of each patient is individualized, and those who would benefit more from surgery will be appropriately managed by the appropriate faculty on our team."

Provided by Cedars-Sinai Medical Center

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