

Transcatheter valve replacement safe in those with unusual valve anatomy

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Compared with patients who had a typical tricuspid aortic valve, patients with a more unusual bicuspid aortic valve had a similar rate of death but a higher likelihood of stroke after undergoing a procedure to replace the valve by threading surgical equipment through an artery, according to research presented at the American College of Cardiology's 68th Annual Scientific Session.

While most people are born with an [aortic valve](#) that has three flaps (tricuspid), some are born with two of the flaps fused together, creating a bicuspid valve. This is the most common congenital anomaly of the [heart](#), present in up to 1 percent of the general population. A bicuspid valve is more likely to leak or narrow, a condition called stenosis.

The study, which focused on [patients](#) for whom [open heart surgery](#) would pose an intermediate or high risk, bolsters the case for performing transcatheter aortic valve replacement (TAVR) in those with a bicuspid valve who suffer from stenosis, researchers said.

"Based on this study, patients with bicuspid [aortic valve stenosis](#) who are at intermediate or high risk for open heart surgery can be safely treated by balloon-expandable TAVR with an acceptable risk," said Raj Makkar, MD, associate director of Cedars-Sinai Heart Institute and the study's lead author. "Our study supports the notion that carefully selected patients with bicuspid [aortic stenosis](#) can avoid surgery and be treated with this less invasive option."

Severe aortic stenosis causes the heart's aortic valve to narrow, preventing proper flow of blood. Untreated, it leads to fatigue and other symptoms and increases the risk of other heart problems. Doctors can use either TAVR or open heart surgery to restore proper functioning of the faulty valve.

Previous studies have shown TAVR to be better

than or as good as conventional surgery for patients at high and intermediate cardiovascular risk, which typically includes older patients and those with multiple health problems. Research is underway to determine whether TAVR's benefits extend to younger and often healthier people, in whom open heart surgery is less risky.

Determining TAVR's risks and benefits in people with a bicuspid aortic valve is key to answering this question because a bicuspid valve is the most common cause of aortic stenosis in younger patients. While some previous studies have examined TAVR in those with a bicuspid valve, they were smaller and used older types of replacement valves. Most TAVR trials have excluded patients with bicuspid aortic stenosis, leading to a paucity of data in this patient population.

For the new study, researchers analyzed data from the STS/ACC TVT registry of more than 80,000 patients who underwent TAVR between 2015 and 2018. They matched 2,691 patients who had a bicuspid valve with an equal number of patients with a tricuspid valve based on 25 variables (so the two groups were as similar as possible) and compared outcomes between the two groups.

Rates of death from any cause were similar between the two groups at 30 days and one year after the procedure, with 2.6 and 2.4 percent of those in the bicuspid and tricuspid groups, respectively, dying within 30 days and 10.8 and 12.1 percent of those in the bicuspid and tricuspid groups, respectively, dying within a year. There were also no significant differences between the two groups in terms of how well the replacement valve functioned.

Patients with a bicuspid valve showed a 50 percent higher risk of any type of stroke at 30 days, which occurred in 2.4 percent of these patients compared with 1.6 percent in the tricuspid group. While this is

a [significant difference](#), the stroke rate of 2.4 percent is still considered relatively low, according to the researchers.

"The results indicate that survival, stroke and valve function were very acceptable and similar to tricuspid aortic stenosis, which is the more common type of aortic stenosis," Makkar said.

While procedural complication rates were low overall, patients with a bicuspid valve were significantly more likely to have their procedure converted from TAVR to open heart surgery due to problems encountered during the procedure, which occurred in 0.9 percent of those in the bicuspid group and 0.4 percent of those in the tricuspid group. Makkar said that further research is needed to understand why these complications were more common in those with a bicuspid valve.

"Using a CT scan prior to the procedure to predict which bicuspid valves should be triaged to surgery rather than TAVR is a crucial area of research," Makkar said.

The study included only patients who were considered at intermediate or [high risk](#) for open heart [surgery](#). Determining the risks and benefits of TAVR in younger, lower-risk patients with bicuspid aortic stenosis would require a randomized trial, Makkar said.

More information: Makkar will present the study, "Outcomes of Transcatheter Aortic Valve Replacement with Balloon-Expandable Sapien3 Valve in Bicuspid Aortic Stenosis: An analysis of the STS/TVT Registry," on Sunday, March 17, at 8:00 a.m. CDT in Main Tent, Great Hall at the ACC's Annual Scientific Session, March 16–18, 2019 in New Orleans

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