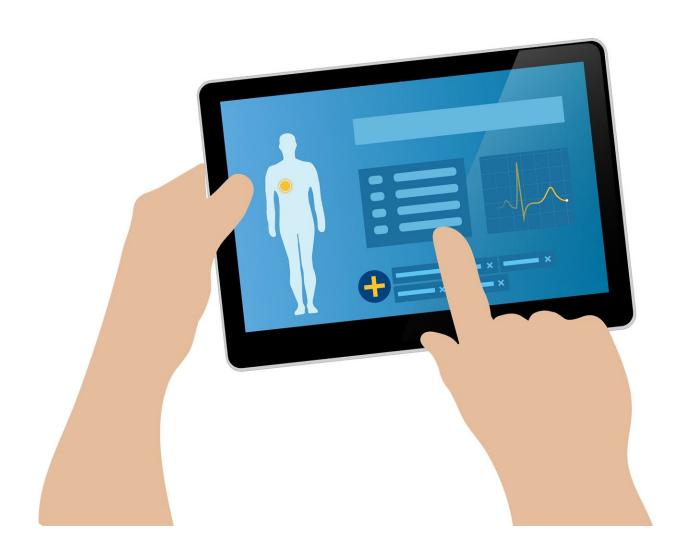


Study finds TAVR is safe treatment for patients with bicuspid valve disease

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For many patients with a bicuspid aortic valve that needs replacing, transcatheter aortic valve replacement (TAVR) appears to be a safe treatment option with low complication rates, according to a study published in *JACC: Cardiovascular Interventions*. The study found patients with bicuspid valves who were at increased risk for surgery had a 30-day and one-year mortality rate and stroke rate that was similar to patients with the more common tricuspid valves.

An estimated 2% of the U.S. population has an <u>aortic valve</u> with two leaflets (bicuspid) instead of three (tricuspid). The aortic valve is a oneway valve between the heart and the aorta, the main artery from the heart that distributes oxygen-rich blood to the body. The leaflets, or flaps, normally open widely and close securely to regulate blood flow. This allows blood to flow from the heart to the aorta and prevents blood from flowing backwards into the heart. Having a bicuspid valve requires regular monitoring by a physician since it can lead to an increased risk of heart valve complications. Prior research has shown that up to 20% of people with a bicuspid valve will need replacement at some point.

"No one's valve works as well at age 70 as it does at age 20, but in patients with a bicuspid aortic valve, it's more likely to wear out and require replacement," said study lead author John K. Forrest, MD, director of the Structural Heart Disease Program at Yale University School of Medicine and Yale New Haven Hospital.

Since studies of TAVR have traditionally excluded bicuspid patients, until now it has not been known how these patients fare when they are treated with the procedure. To answer this question, the researchers used data from the STS/ACC TVT Registry, which collects data of all commercial TAVR cases in the U.S. They analyzed 932 patients with bicuspid valve disease who underwent TAVR with one of two valves, the Evolut R or Evolut PRO, between July 2015 and September 2018.



The patients in the study were at increased surgical risk, based on a number of factors including their age and whether they had <u>medical</u> <u>conditions</u> such as diabetes, prior surgery, stroke or peripheral vascular disease. The majority of bicuspid patients in this study were at intermediate or high surgical risk.

These patients were compared to similar patients with tricuspid valve disease who underwent TAVR during that same time period. The study found similar rates of death from any cause at 30 days (2.6% vs. 1.7%) and one year (10.4% vs. 12.1%), as well as the rate of stroke at 30 days (3.4% vs. 2.7%) and one year (3.9% vs. 4.4%).

In the last decade, TAVR has become an increasingly popular way to replace aortic valves. TAVR is a minimally invasive procedure in which a catheter is used to deliver a replacement valve to the site of the old valve, thus avoiding <u>open-heart surgery</u>. While initially reserved for patients whose poor health makes an open-heart valve replacement too risky, recent studies have shown that in patients with tri-leaflet aortic stenosis, TAVR is a viable option even for low-risk patients.

"This study suggests TAVR is a viable option for patients with bicuspid valve disease who are at increased surgical risk," Forrest said. "It will be very important to continue to monitor these <u>patients</u> to see how the valves perform in 10 or 15 years."

More information: *JACC: Cardiovascular Interventions*, <u>DOI:</u> <u>10.1016/j.jcin.2020.03.022</u>

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