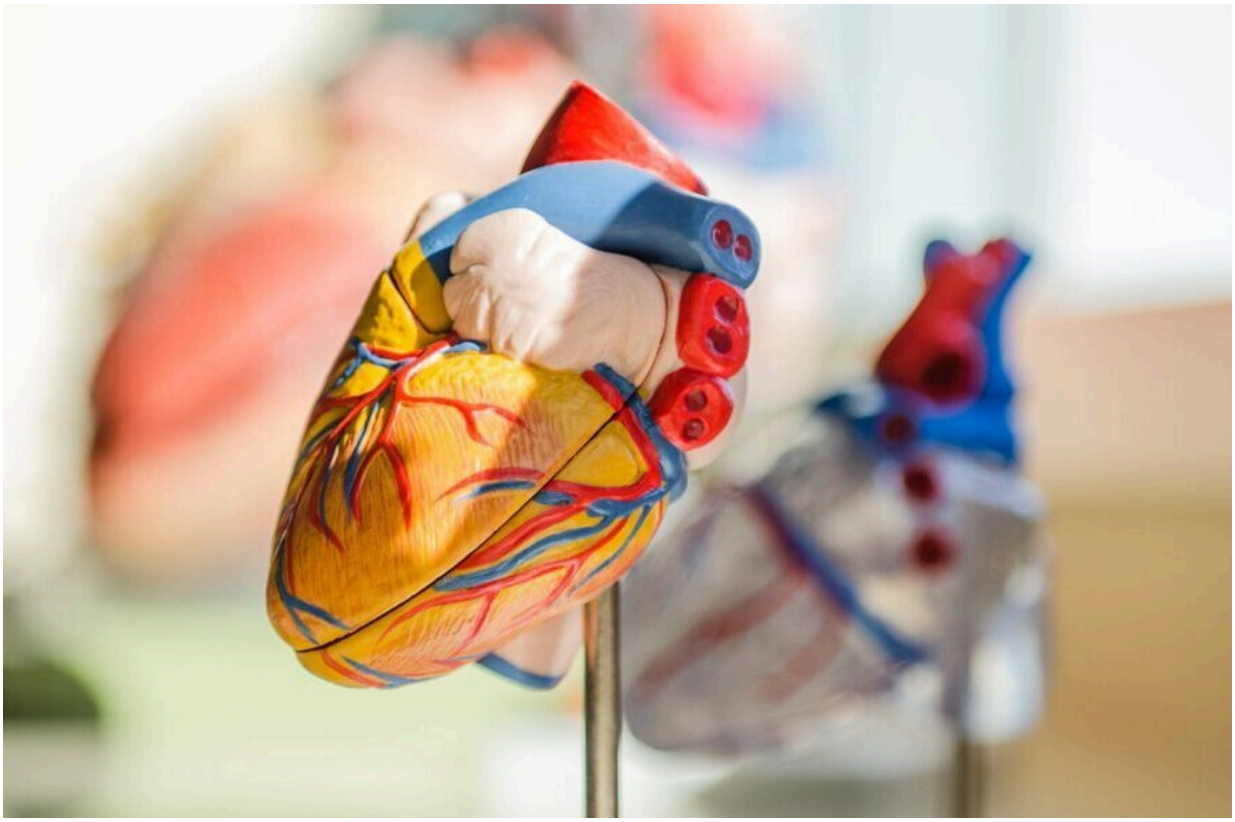
Transcatheter mitral valve repair shown to be safe and effective in real world setting

March 6 2023



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The largest study to examine outcomes for patients treated outside a clinical trial setting with a minimally invasive procedure to repair a poorly functioning mitral valve in the heart found that the procedure was

safe and resulted in a successful repair for nearly 9 out of 10 patients, researchers reported at the American College of Cardiology's Annual Scientific Session Together With the World Congress of Cardiology. Patients whose procedure was successful were half as likely to die within one year compared with those in whom the procedure was unsuccessful.

"Our analysis showed that in an older patient population with limited therapeutic options, transcatheter-based mitral valve repair was safe and was effective in reducing valve leakage from severe to moderate or less in almost 90% of patients," said Raj R. Makkar, MD, associate director of the Smidt Heart Institute at Cedars-Sinai Medical Center in Los Angeles and lead author of the study.

The mitral valve is one of four valves in the heart. It controls blood flow from the left atrium to the left ventricle, preventing blood from flowing the other way. Mitral valve leakage, or regurgitation, occurs when the valve doesn't close completely, permitting blood to flow back into the left atrium. It's a common heart problem, affecting more than 1 in 10 people aged over 75 years.

Some patients have secondary mitral valve regurgitation that is caused by a poorly functioning left ventricle, the heart's main pumping chamber. Regurgitation caused by failure of the mitral valve itself (i.e., not due to left ventricular failure) is known as isolated degenerative mitral valve regurgitation and is the most frequent reason for isolated mitral valve surgery in the Western world, Makkar said.

Transcatheter edge-to-edge repair (TEER) is a minimally invasive procedure in which a catheter (a long flexible tube) is used to place a tiny clip in the mitral valve to help it close properly and prevent blood from leaking back into the left atrium. TEER is approved by the U.S. Food and Drug Administration for mitral valve repair in patients with severe isolated mitral valve regurgitation who, due to age or other health

problems, are considered at high risk for complications from conventional mitral valve surgery.

Since 2011, the Society for Thoracic Surgery (STS) and the American College of Cardiology have jointly maintained the Transcatheter Valve Therapy (TVT) Registry, which collects data on safety and outcomes for all patients in the U.S. who undergo a transcatheter procedure to repair or replace a heart valve outside of a clinical trial. Data in the registry include patient demographics and health status, adverse event rates and patient outcomes at 30 days and one year after the transcatheter procedure.

Makkar and his colleagues analyzed data for all 19,088 patients in the registry who underwent TEER for moderate to severe isolated degenerative mitral valve regurgitation between January 2014 and June 2022. Patients who had undergone either surgery or a prior transcatheter procedure to repair a mitral valve were excluded, as were patients with secondary mitral valve regurgitation. The average age of included patients was 82 years and 49% were women. According to a risk-calculation tool developed by the STS, the patients' median risk of dying within 30 days of surgery was 4.6%.

The study's primary endpoint was mitral regurgitation (MR) success, defined as moderate or better residual MR without severe stenosis, or narrowing, of the mitral valve. Other endpoints included death in the hospital or within 30 days or one year after the procedure.

Results of the analysis showed that MR success was achieved in 88.9% of patients and MR of mild or less severity without severe stenosis in 64.2%. Among patients whose procedure was successful, 14% died, compared with 26.7% of those whose procedure was unsuccessful, a 51% reduction in the risk of death. Among those whose procedure was successful, the death rate was lower for those with residual MR of mild

or less severity (12.3%) than for those with residual MR of moderate severity (18%).

"We found that over the eight-year period that we studied, the procedural success rate increased from 81.5% in 2014 to 92.2% in 2022," Makkar said. "Optimal success—a reduction in residual mitral leakage to mild or less—was attained in 64% of patients overall, but that increased from 44.6% in 2014 to 71.7% in 2022."

He said that some of the reasons for the increasing procedural success rate were greater physician experience with the procedure and technological advances in successive generations of the clip device, known as the MitraClip.

The study has limitations due to its observational, retrospective design, Makkar said. It lacks a control group of patients treated with surgery or medical therapy to which the outcomes of patients receiving TEER could be compared. Patients in the registry would likely have been too ill to be eligible for randomized trials that compared TEER with mitral valve surgery or medical therapy, he said.

"Outcomes in the registry patient population cannot be compared with those seen in the highly selected patients treated in clinical trials," he said.

Additionally, patients in the registry were treated at many different sites. Sites could have over-reported the severity of patients' MR at study entry and underreported the degree of residual MR following the transcatheter procedure. Finally, the registry includes follow-up data for only one year, which may not be long enough to predict the long-term durability of the transcatheter procedure, Makkar said.

More information: Conference:

www.expo.acc.org/ACC23/Public/Enter.aspx

Transcatheter Valve Therapy (TVT) Registry:
www.ncdr.com/WebNCDR/tvt/publicpage

Provided by American College of Cardiology