

Researchers find benefits and drawbacks to two-step surgical approach for 'leaky heart valves'

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Patients with mitral and tricuspid valve regurgitation, a condition sometimes called "leaky heart valves," appeared to do better after two

years if they had a tricuspid valve repair at the time of mitral valve surgery, according to a study supported by the National Heart, Lung, and Blood Institute (NHLBI), a part of the National Institutes of Health. The primary findings were released at the American Heart Association's Scientific Sessions and published in the *New England Journal of Medicine*.

Researchers found [patients](#) who had the mitral [valve surgery](#) with the tricuspid annuloplasty were less likely to die, need a tricuspid valve reoperation, or have tricuspid regurgitation advance to a severe stage during a two-year period after treatment, compared to those who had the mitral valve surgery alone. However, patients who had both procedures were more likely to need a permanent pacemaker.

The surgical protocol aims to prevent regurgitation, which occurs when flaps on the heart valves don't close properly and blood flows backward into the heart. This can make it harder for blood to move efficiently throughout the body. In severe cases, regurgitation can increase the risk for an irregular heart rhythm, stroke, or heart failure.

More than 8 million Americans are diagnosed with some form of heart valve disease each year. A standard procedure for regurgitation that affects the mitral and tricuspid valves typically involves mitral valve surgery—which usually starts with minor tissue repair but could advance to valve repair or replacement. Decisions for adding a tricuspid annuloplasty vary widely. In this procedure, surgeons use a ring to reshape or resize a widening valve. While many patients, about 78%, with severe tricuspid regurgitation pair a tricuspid annuloplasty with mitral valve surgery, only about 4% with mild tricuspid regurgitation and 35% with moderate tricuspid regurgitation do so.

To help health professionals and patients make informed decisions about what to do in these cases, researchers from the Cardiothoracic Surgical

Trials Network (CTSN), which is supported by NHLBI, launched a multi-year randomized clinical trial in 2016 with patients being treated for worsening mitral valve regurgitation with mild to moderate tricuspid regurgitation. The surgical procedures took place at 39 medical centers in the United States, Canada and Germany.

For the study, researchers enrolled 401 patients who planned to have mitral valve surgery. They were then randomly assigned to one of two treatment groups. The first had the mitral valve surgery, and the other had mitral valve surgery, along with a tricuspid valve annuloplasty.

Researchers found that among patients who had the combined mitral valve and tricuspid valve repair, just 3.9% developed severe regurgitation, died, or needed a reoperation, compared to 10.2% who had the mitral valve surgery alone. Researchers observed no significant differences between patient groups in the number of major cardiovascular events, changes in functional status, or quality of life. However, 14.1% of patients who had the surgery and tricuspid annuloplasty needed a permanent pacemaker, compared to 2.5% who had the surgery alone.

In discussing these results, Annetine C. Gelijns, Ph.D., and Alan J. Moskowitz, M.D., the principal investigators of the study's data and clinical coordinating center at the Icahn School of Medicine at Mount Sinai, New York City, indicated that this trial delineates the important trade-off that patients face in deciding between the benefits of reducing the risk of tricuspid regurgitation progressing and increasing the risk of requiring a permanent pacemaker. These types of decisions vary for each patient.

Over the next few years, researchers will evaluate other clinical measures among trial participants to assess if there is a long-term benefit in pairing the tricuspid valve annuloplasty with mitral valve surgery.

"In addition to following the health outcomes of patients who received a pacemaker, we look forward to following those with milder forms of tricuspid [regurgitation](#) to assess their outcomes also," said Wendy C. Taddei-Peters, Ph.D., a [clinical trials](#) specialist in NHLBI's Division of Cardiovascular Sciences and a study coauthor.

"This trial and others will support a larger body of research that surgeons, professional societies, and medical organizations can use as they update surgical treatment guidelines in the future," said Marissa A. Miller, D.V.M., M.P.H., a study coauthor and senior advisor for cardiac surgical trials at NHLBI. "Our goal is to make these types of treatment decisions easier for patients and to support their long-term health outcomes."

More information: James S. Gammie et al, Concomitant Tricuspid Repair in Patients with Degenerative Mitral Regurgitation, *New England Journal of Medicine* (2021). [DOI: 10.1056/NEJMoa2115961](https://doi.org/10.1056/NEJMoa2115961)

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