

Study finds similar outcomes for repair or replacement of damaged heart valves

November 18 2013

New research presented today at the 2013 Scientific Sessions of the American Heart Association by researchers at the Perelman School of Medicine at the University of Pennsylvania found no difference in outcomes at one-year between two recommended surgical options for treating ischemic mitral regurgitation (IMR) – repair of the leaky valve or its replacement with an artificial valve.

Mitral regurgitation – where blood flows backwards toward the lungs during the contraction of the heart instead of forwards – affects millions of people in the U.S. and can pose serious health consequences, most prominently ongoing and worsening [heart failure](#). Guidelines currently recommend either repair or replacement of severe mitral leak caused by ischemic mitral insufficiency when medical alternatives have failed.

"While the medical community has traditionally gravitated towards valve repair as a preferred treatment option, the evidence in this study does not suggest that [mitral valve repair](#) is superior," said lead study author Michael Acker, MD, chief, Division of Cardiovascular Surgery and director, Penn Medicine Heart and Vascular Center. "Further patient follow-up is needed to confirm the findings of this trial, but we believe these results should be very helpful for cardiologists and surgeons in choosing an appropriate approach for this growing patient population."

This multi-center study, the Severe MR randomized trial (of which cardiac surgeons at Penn were the leading enrollers), is the first [randomized clinical trial](#) comparing these two options to treat IMR. Both

approaches offer benefits and risks, but as of yet no study has rigorously evaluated these approaches to see if the trade-offs result in significant differences in patient outcomes.

Conducted by the Cardiothoracic Surgical Trials Network (CTSN), a consortium supported by the National Heart, Lung, and Blood Institute (NHLBI), National Institute of Neurological Disorders and Stroke (NINDS) of the National Institute of Health, along with the Canadian Institutes of Health Research (CIHR), the research was published simultaneously in the *New England Journal of Medicine*.

The study enrolled 251 patients who were diagnosed with IMR, which is due to a valve deformation that occurs after a heart attack. The participants were evenly randomized to receive either surgical repair (a valve tightening procedure called an annuloplasty) or a prosthetic replacement mitral valve.

The participants were then monitored at one, six, and 12 months after their procedure. The primary endpoint of the study was the degree of left ventricular shrinkage (reverse remodeling) which correlates to improvement in heart function and the lessening of heart failure symptoms. The study also measured various health outcomes, including rates of death, recurrent mitral valve leak, severe [heart](#) problems or stroke, re-hospitalizations, and quality of life.

After a year a follow-up, there were almost no differences in ventricle shrinkage or health between the two treatments. The only significant change was a higher rate of recurrent regurgitation in the repair group (32.6 percent of repair patients versus 2.3 percent of replacement patients).

"The increased level of recurrent regurgitation falls in line with valve replacement offering more durable long-term protection," noted

Annetine Gelijns, Ph.D., CTSN investigator at the Icahn School of Medicine at Mount Sinai and corresponding author of the study.

"However, these regurgitations did not lead to any noticeable increases of health problems among patients in the repair group."

The study investigators will continue to monitor the participants for 12 more month, as well as an analysis of predictors of recurrent mitral valve leak, which may help identify patient groups better suited for repair or replacement.

In addition to Penn, the study was carried out at 21 participating CTSN centers across the United States and Canada.

Provided by University of Pennsylvania School of Medicine

Citation: Study finds similar outcomes for repair or replacement of damaged heart valves (2013, November 18) retrieved 24 April 2024 from <https://medicalxpress.com/news/2013-11-similar-outcomes-heart-valves.html>

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