

Extra STICH not necessary in surgical treatment of heart failure

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Results from the first comparative effectiveness study of two surgical treatments for heart failure will likely change practice for surgeons and cardiologists evaluating treatment options for some of their sickest patients, according to investigators in the Duke Clinical Research Institute (DCRI).

Researchers presented data from the study, known as the STICH Trial (Surgical Treatment for Ischemic [Heart Failure](#)) at the American College of Cardiology's 58th Annual Scientific Session. Findings are also online in the [New England Journal of Medicine](#).

STICH researchers examined outcomes between two groups of patients who received optimal medical therapy and coronary [bypass](#) surgery. One group received bypass alone; patients randomized to the second group received bypass plus an additional procedure, surgical ventricular reconstruction (SVR). Surgical ventricular reconstruction reduces the size of damaged tissue in the ventricular wall, making the pumping chamber smaller and stronger. Physicians saw the patients twice a year for four years.

The study showed that SVR made no difference between the two groups in terms of the key clinical outcomes, death and cardiac hospitalization.

"Heart surgeons have been using SVR for over twenty years, believing that taking this extra step in surgically reshaping the left ventricles of those with the weakest hearts might give them an extra boost," says

Robert Jones, M.D., a cardiothoracic surgeon in the Duke Heart Center and the lead author of the study. "Now we know it does not."

Investigators say the result was somewhat surprising because it flies in the face of conventional wisdom that among patients with heart failure, anything that makes the heart smaller and more normally shaped makes it stronger, and stronger is better. In addition, it is well known that other interventions, such as beta-blockers, ACE-inhibitors and cardiac resynchronization - therapies that also resize and reshape the heart - are associated with better outcomes.

From 2002 to 2007, STICH enrolled 2136 patients with coronary artery disease at 127 sites world-wide. All of the participants were eligible for a bypass procedure and had severe heart failure, reflected by a left ventricular ejection fraction of less than 35 percent. One thousand of the participants were subsequently randomized into the current study; 499 patients were randomized to receive only coronary bypass, 501 received bypass plus SVR.

Researchers gathered biological information, conducted imaging studies and collected data on quality of life and cost. (Details about quality of life and cost data will be presented separately by Duke's Daniel Mark, M.D., the P.I. of that study).

Investigators found that both surgical options were extremely effective in easing chest pain and increasing patients' ability to exercise, as measured by a 6-minute walk. But the gains were equal between the two groups.

Likewise, there was no meaningful difference between the two groups when it came to the primary endpoints. The combined outcome of death or cardiac hospitalization occurred in 57 percent of the patients who received bypass alone, compared with 56 percent of those who got

bypass plus SVR. Death occurred in 28 percent of the bypass patients and in 27 percent of the SVR group. Hospitalization occurred in 41 percent of the bypass patients compared with 40 percent of the group who also received SVR.

"These are definitive findings, and we have to conclude from them that there is no justification to offer SVR to these patients," says Jones.

"The study does raise questions about the 'smaller is better theory,'" says study co-author, Eric Velazquez, M.D., an expert in heart failure at Duke.

Jones says a plausible reason for seeing no benefit from SVR is that bypass and medication alone may be sufficient to enable the heart to recover from injury - at least to become strong enough for moderate, day-to-day activities. "And one day, we might find that medicines alone might be sufficient," he said.

Jones was alluding to another part of the STICH trial that is still under way. Investigators are still following 1212 heart failure patients randomized to receive only medicine versus those in another group who are receiving medicine and bypass. "Which is better? We expect to be able to answer that question in 2011," said Jones.

Source: Duke University Medical Center

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