心室再建術の効果は根拠がない

STITCH：心不全患者に対しCABGに加え外科的心室再建を施行してもCABG単独と効果は同等である

STITCH: Surgical ventricular reconstruction plus CABG no better than CABG alone in heart failure patients

虚血性心不全に対する外科治療（STICH）トライアルの結果、冠動脈バイパス術（CABG）に加えて外科的心室再建術（SVR）を施行された患者はCABGのみを施行された患者と比較し状態が良好なわけではない、と2009年第58回American College of Cardiology学会で発表されNew England Journal of Medicineに掲載された。研究者らは左室駆出率≤35%で外科医がCABGを行うことにより管理できると判断した冠動脈疾患を有し、瘢痕化した機能不全組織が前壁ー心尖部にある患者（年齢中央値62歳、男性85%）をCABGのみ（499人）またはCABGに加えSVR（501人）を施行する群に無作為に割り付けた。どちらの手術も症状および運動耐容能を改善した。SVRは左室収縮末期容積指数を20%減少させたのに対し、CABGでは3%の減少であった。しかし、経過観察期間（中央値4年間）の死亡率または心原性の入院率は二群間で差がなかった（CABG群で56%、CABG/SVR群で57%）。またACCで発表されAmerican Heart Journalオンライン版に掲載されたSTICHトライアルサブ解析においては、SVRはQOLの改善もしくは他の臨床上の有益性を生み出すことなく医療費を増やす、と結論付けられた。

Full Text

A surgical procedure that reduces the size of a scarred, enlarged heart did not improve long-term survival or reduce the number of hospitalizations in patients with heart failure, according to research presented at the American College of Cardiology's 58th annual scientific session and simultaneously published in the New England Journal of Medicine.

The first phase of the Surgical Treatment for Ischemic Heart Failure (STICH) trial showed that patients who had surgical ventricular reconstruction (SVR) in addition to coronary artery bypass grafting (CABG) fared no better over an average of four years of follow-up than patients treated with CABG alone.

"Over the last decade, as we have been doing better at managing the myocardial infarctions that cause injury to the heart, these scars have gotten smaller and smaller," said Robert H. Jones, M.D., Mary and Deryl Hart Distinguished Professor of Surgery at Duke University Medical Center, Durham, NC. "Now we know that with good, intensive medical therapy and very good revascularization, there is no intrinsic value to SVR over bypass surgery alone."

Surgical ventricular reconstruction returns the ventricle to a more normal, compact size. At a smaller size, the heart experiences less stress and strain and, like a healthy heart, might regain the ability to temporarily expand to meet the body's demands for increased cardiac output. Previous studies have shown that one of the strongest predictors of survival in patients with heart failure is the size of the heart at the end-systolic volume.

For the study, investigators recruited 1,000 patients from 96 medical centers in 23 countries. Patients were required to have an ejection fraction of≤ 35 percent, coronary artery disease the surgeon felt could be well managed by CABG, and an area of scarred, dysfuctional tissue in the anterior-apical region. About half of patients had moderate-to-severe angina. Heart failure was deemed moderate-to-severe in a similar proportion, and more than 60 percent had triple-vessel disease. The median age was 62, and 85 percent of patients were men.

Patients were randomly assigned to undergo CABG alone (499 patients), or CABG plus SVR (501 patients). All patients received intensive medical therapy. Both surgeries improved symptoms and exercise capacity, and SVR was successful in reducing end-systolic volume index by 20 percent, compared to 3 percent with CABG. However, after a median follow-up of 4 years, there were no differences between the two groups in combined rates of death or hospitalization for cardiac causes (56 percent among patients in the CABG group and 57 percent among patients treated with both CABG and SVR).

"This is the first time that a proposed new heart operation has been tested in this way," Jones said. "Our findings emphasize the importance of taking what appear to be medical breakthroughs and subjecting them to very rigorous comparisons with the best available therapy."

A second report from the STICH trial presented at ACC and published online in the March 30 in the American Heart Journal, concluded that that SVR increases costs without improving quality of life or providing other clinical benefits.

For the quality of life substudy, investigators conducted interviews with patients before and after their surgeries to collect information on physical and social limitations, satisfaction, and other measures of quality of life. Both treatment groups improved their quality of life after surgery but there was no difference between the two groups throughout 3 years of follow-up.

This substudy also looked at the economic consequences in the United States of having surgical ventricular reconstruction including whether the procedure would be cost effective. Information was collected on the length of surgeries, post-operative time in the intensive care unit, total length of hospital stay, rates of rehospitalization, hospital billing data, and physician costs. Costs were assigned using the 2008 Medicare Fee Schedule. Total hospitalization costs were $14,595 higher for bypass combined with the ventricular reconstruction.

"The results of the STICH trial demonstrate that routine use of surgery to reconstruct the left ventricle does not improve survival, hospitalization, quality of life or cost benefit over bypass surgery alone," said George Sopko, M.D., a medical officer at NHLBI and co-author of the mortality paper in NEJM. "There is still much to learn from the rich source of information provided by this trial, and we look forward to additional analysis of the results as patients continue to be followed."

Surgical reconstruction initially showed encouraging results and improvement in heart failure symptoms in some non-randomized studies, according to Sopko. "As with many initially promising procedures, further rigorous scientific testing is needed before full acceptance into medical practice," he added.

Investigators have already enrolled more than 1,200 patients in the next phase of the STICH trial. It will answer an even more crucial question: whether bypass surgery itself is effective in improving long-term survival in patients with heart failure who are already receiving the best possible medical therapy.

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