スタディの結果、心不全患者において薬物療法よりも CABGの方が成績は良好であった

STITCH: 心不全患者の一次解析では薬物療法を凌ぐ手術の有益性は認められな かったが、さらに綿密に調査するとより多くの事実が示唆された

STITCH: No advantage to surgery compared to medical therapy in primary analysis for heart failure patients, but a closer look suggests more

総死亡率に関していえば、動脈硬化性心不全患者においては薬物療法単独とそれにバイ パス手術を加えた場合の結果は同等であることが第60回American College of Cardiology 学会で発表された。しかし、このSurgical Treatment of Ischemic Heart Failure(STICH) トライアルの結果、冠動脈バイパス術により死亡または入院を合計したリスクに加え、 死亡、特に心疾患による死亡が有意に減少することが示された。研究者らは冠動脈疾患 による心不全または陳旧性心筋梗塞を有する患者を組み入れ、602人は理想的な薬物療 法のみの群へ、610人は CABGと理想的な薬物療法を組み合わせた群に無作為に割り付 けた。平均5年近くの経過観察の後に、薬物療法単独と比較しバイパス術により総死亡 率が 14%低下した。しかし、この結果は統計学的に有意ではなかった。バイパス術に より心血管疾患死 (19%) 、およびが死亡と全ての入院 (26%) も減少し、両方とも統 計学的に有意であった(それぞれp=0.05およびp<0.001)。

Full Text

When it comes to overall survival, patients with heart failure caused by atherosclerosis may do just as well with medication alone as when bypass surgery is added to the treatment plan, according to research presented at the American College of Cardiology's 60th Annual Scientific Session. Coronary artery bypass grafting (CABG) does, however, significantly reduce the risk of death specifically from heart disease, as well as the combined risk of death or hospitalization, the Surgical Treatment of Ischemic Heart Failure (STICH) trial found.

"We were unable to show a significant benefit for CABG in our primary analysis, but if you dive deeper, the data are much more supportive of bypass surgery," said Eric J. Velazquez, M.D., an associate professor of medicine and director of both the cardiac diagnostic unit and echocardiography laboratories at Duke University Medical Center in Durham, NC. "This information fills an important gap in how we should evaluate the opportunity for CABG in these patients."

STICH is the largest randomized, controlled study ever to compare CABG plus the best possible medical therapy to aggressive medical therapy alone in patients with coronary artery disease and heart failure.

In about two-thirds of patients with heart failure, the underlying cause is clogged coronary arteries, which deprive the heart muscle of enough blood and oxygen and impair its ability to pump fluids to the rest of the body. In bypass surgery, healthy arteries and veins are used to re-route blood around the blockages, in hopes of restoring heart function. Until now it has been unclear whether the risks of bypass surgery were worth taking, given recent life-saving advances in medical therapy.

For the study, researchers at 99 medical centers in 22 countries recruited patients with heart failure caused by coronary artery disease or a previous heart attack, randomly assigning 602 to ideal medical therapy alone and 610 to CABG plus ideal medical therapy. After an average of nearly five years of follow-up, they found that bypass surgery reduced the risk of death from any cause by 14 percent when compared to medical therapy. However, the finding was not statistically significant.

Bypass surgery also reduced the risk of cardiovascular death by 19 percent and the combined risk of death from any cause plus hospitalization for heart disease by 26 percent. Both findings were statistically significant (p=0.05 and p<0.001, respectively)

Fifty-five patients who were assigned to the surgery group never actually had the procedure, whereas 100 who were assigned to medical therapy eventually had CABG. When researchers analyzed the data only on patients who had their assigned treatment, they found that bypass surgery reduced the risk of death from any cause by 25 percent (p=0.005). Similarly, when they analyzed the data according to the treatment patients actually had, including the "crossovers" into the opposite group, they found that bypass surgery reduced the risk of death from any cause by 30 to 50 percent.

Researchers did note that bypass surgery had a higher upfront risk than medical treatment alone. In fact, it was only after two years that survival was better with bypass surgery.

"Although the totality of information supports CABG, there is an early hazard," Velazquez said. "The fairest approach is to evaluate each patient's prognosis. If they have a low likelihood of living two years or don't want to take the risk of having surgery, medical therapy may be the better option.

A separate STICH substudy evaluated whether imaging could be used to identify which patients are likely to benefit from bypass surgery. Researchers recruited a total of 601 patients to have one of two types of imaging tests: a nuclear perfusion scan or dobutamine echocardiography. These tests use different methods to evaluate poorly functioning heart tissue and determine if it is still alive. Viable tissue, as it is called, can often recover function once it has an adequate blood supply, while irreversibly damaged tissue cannot.

After nearly five years of follow-up, researchers found no relationship between the results of viability imaging and the effectiveness of bypass surgery. Imaging did provide valuable information on the likelihood of long-term survival, however. Overall, patients with living heart tissue were 40 percent less likely to die during follow-up when compared to patients with irreversible heart damage

"Assessing myocardial viability is useful in identifying the risk of patients and getting information about prognosis," said Robert O. Bonow, M.D., a professor of medicine and director of the Center for Cardiovascular Innovation at Northwestern University Feinberg School of Medicine in Chicago. "But when weighing results of viability testing versus other characteristics, it's not helpful in identifying which patients will benefit from surgery."

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