心不全患者において運動は安全であり予後を改善する（LBCT, abstract＃3318）

HF-ACTIONの結果は心不全患者に対する運動療法を支持する

Results from HF-ACTION support intensive exercise for patients with heart failure

心不全患者における運動療法は安全であり、入院または死亡を有意には減少させないが、既に至適薬物治療を受けている患者においてもいくつかの臨床指標を改善する、との心不全と運動療法の効果を検討したコントロールトライアル（Heart Failure and A Controlled Trial Investigating Outcomes of Exercise Training ：HF-ACTION）の結果が2008年American Heart Association学会で発表された。このphase IIIトライアルでは心不全患者2,331人（平均年齢59歳、平均LVEF25%）を、運動強度および運動時間を増加させるプログラムの運動療法群または運動を推奨するが特にプログラムは組まない通常治療群に無作為に割り付けた。運動療法により通常治療と比較し、全ての原因による入院および死亡の複合である一次エンドポイントは有意には減少しなかったが、あらかじめ規定されていた主要な予後因子で補正した二次解析では一次エンドポイントが11%減少し（p=0.03）、二次エンドポイントである心血管死亡率および心不全による入院が15%減少した（p=0.03）。研究者らは、これらの結果から心不全患者に対する運動療法は支持されると述べている。

Full Text

Exercise training is safe in heart failure patients, does not significantly reduce hospitalization or death, but is associated with several improved clinical outcomes, even in those already receiving optimal medical care, researchers reported at the American Heart Association's Scientific Sessions 2008. The Heart Failure and A Controlled Trial Investigating Outcomes of Exercise Training (HF-ACTION) was presented as a late-breaking clinical trial.

The trial is the world's largest study of exercise training versus usual care in heart failure (HF) patients, said Christopher M. O'Connor, M.D., principal investigator and director of the Heart Center and professor of medicine at Duke University Medical Center in Durham, N.C.

The U.S.-government-funded, randomized, Phase III trial followed 2,331 heart failure patients (average age 59) at 82 sites in the United States, Canada and Europe for an average of 2.5 years. The patients were randomized to an exercise training program aimed at increasing workout intensity and duration or to usual care, in which they were encouraged to exercise, but without any specific program.

Researchers found no excess risk for heart attack, arrhythmia, angina or fractures in the exercise training group.

Although exercise training of heart failure patients was not associated with a statistically significant reduction of the primary endpoint of composite of all-cause hospitalization and death, the prespecified secondary analyses with adjustment for prespecified major prognostic factors revealed an 11 percent reduction (p-value = 0.03) in the study's primary endpoint and a 15 percent (p-value = 0.03) reduction in the secondary endpoint of cardiovascular mortality and heart failure hospitalization compared to the usual care group.

"Exercise training confers clinical benefits without excess risk for heart failure patients," O'Connor said. "There was a real question in the literature as to whether these high-risk patients could safely attempt exercise training and whether doctors should prescribe exercise training for these patients outside of a highly supervised environment." Most insurance and government health programs refuse to cover exercise training for heart failure patients because of a lack of clear clinical data showing benefits, he added.

The exercise group received a multi-stage, guided exercise program that began with 36 supervised training sessions with a goal of 30 minutes of exercise three times a week. At the 18th session, patients received a treadmill or exercise bicycle for home use, learned how to monitor their heart rate during exercise and were encouraged to try to complete five weekly exercise sessions of similar intensity and 40 minute duration.

The 36 supervised exercise sessions were modeled on the cardiac rehabilitation sessions provided to heart attack survivors, which are usually covered by insurance, O'Connor said. Patients in the usual care group received instructions based on the American College of Cardiology/American Heart Association recommendation to perform 30 minutes of moderate intensity exercise most days of the week.

An unusually high proportion of the patients received optimal medical care with more than 90 percent of them getting evidenced-based medical therapy for their heart disease. A significant number also had implantable cardioverter defibrillators, said David Whellan, M.D., M.H.S., co-principal investigator and associate professor of medicine (cardiology) at Thomas Jefferson Medical College in Philadelphia, Penn.

"Thus, the findings from the study need to be interpreted with the understanding that the improvement in outcomes were obtained while the patients were receiving exceptionally high quality of care," Whellan said.

After three months in the study, 52 percent of the exercise group were exercising at least three times a week for 40 minutes, a percentage that held fairly steady through the first year and then dropped off slightly, Whellan said. The median exercise time was maintained from 76 minutes per week at three months to 74 minutes per week at one year. At the one-year follow-up, 25 percent of the patients in the exercise group reported completing five sessions per week, he said.

"If you think about their degree of illness, the level of training by these patients was impressive," Whellan said.

Forty percent of the trial participants were members of minority groups and 28 percent were women. O'Connor credited the diversity to the medical centers involved and the U.S. government's encouragement for including populations that have traditionally been under represented in medical trials.

The average left-ventricular ejection fraction (LVEF) in the study was 25 percent, indicating moderate heart failure. More than half of the participants had a history of blood vessel blockage and about 40 percent had a history of heart attack, meaning the study has implications for a wide variety of heart failure patients.

"This is the most definitive study to guide policymakers, physicians, healthcare providers and health systems in regard to recommendations for exercise training in patients with heart failure," O'Connor said.

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