

EMBARGOED Until 11:30 a.m. Eastern Time, Wednesday, November 12th, to coincide with presentation at the annual meeting of the American Heart Association Scientific Sessions 2008

Exercise Improves Quality of Life for Heart Failure Patients

DURHAM, N.C. – Heart failure patients who regularly exercise fare better and feel better about their lives than do similar patients who do not work out on a regular basis, say researchers at Duke University Medical Center.

The findings, reported today at the annual meeting of the American Heart Association's Scientific Sessions 2008, go a long way toward addressing concerns about the value of exercise for the nation's five million patients with heart failure. They also raise important policy questions for the country's Medicare program and other insurers.

“Past studies have sent mixed signals about the merit of exercise for patients with heart failure. The HF-ACTION study (A Controlled Trial Investigating Outcomes Exercise TraiNing) shows that exercise is not only safe for patients, but also helps to improve the quality of their lives, overall,” says Kathryn Flynn, PhD, a health services researcher at Duke Clinical Research Institute (DCRI) and lead author of the study.

HF-ACTION is the largest clinical trial to date examining the value of exercise in the treatment of heart failure. Investigators enrolled 2331 patients with moderate to severe heart failure at 82 sites throughout the U.S., Canada and France from 2003 to 2008.

Funded by a \$37 million grant from the National Heart, Blood, and Lung Institute, researchers randomized participants to receive either standard care or standard care plus an exercise program. The exercise regimen consisted of three months of supervised aerobic training on a bicycle or treadmill, followed by instruction for continued home-based training. Researchers set the exercise goal at five, 40-minute workouts, or 200 minutes of exercise per week. Participants reached about 60 percent of that goal at one year.

Participants had significant heart failure upon entering the study, measured by diminished left ventricular ejection fraction (mean, 25 percent). Ninety-five per cent of the patients were taking medications for heart failure, such as ACE-inhibitors or beta-blockers, and 40 percent were using mechanical devices to boost their hearts' ability to pump or to treat arrhythmias. The average age of the patients was 59; 28 percent were women.

Upon enrollment, patients filled out the Kansas City Cardiomyopathy Questionnaire (KCCQ), a 23-item measure shown to be responsive to underlying clinical changes in patients with heart failure. The KCCQ generated an overall measure of quality of life and subscale measures reflecting the patients' physical limitations, symptoms, quality of life and social restrictions. Participants completed the questionnaire at three-month intervals for the first 12 months, and annually thereafter. The average time of follow-up was two and one-half years.

There were no significant differences between the two patient groups at baseline. The average overall KCCQ score among patients in both groups was 66.

At three months, patients in both groups showed improvement, with patients in the usual care group registering a three-point gain on the KCCQ score and those in the exercise group showing a five-point gain ($p = .0005$). Previous reports had defined a five-point gain as clinically significant.

Researchers also found that a higher percentage of those in the exercise group experienced more robust gains. At three months, 54 percent of those in the exercise group saw a five-point gain in overall KCCQ score, while only 28 percent of those in the usual care group met that goal. ($p = .0001$).

Exercise group members consistently outscored those in the usual care group on all subscale measures on the KCCQ, as well. “And the best news is that while the gains were modest, they were sustained over time,” says Flynn.

Researchers say the findings are important because they demonstrate that a relatively low-cost and readily available intervention can significantly improve the quality of life for heart failure patients, a finding that may be important for the country’s Medicare program, which currently does not pay for exercise therapy for patients with heart failure.

“We found that a majority of those who exercised reported a five-point improvement in the KCCQ scale. That means that they experienced significant improvement in many aspects of their day-to-day activities, such as working, walking, being able to dress, bathe, and getting out to visit family and friends,” says Ileana Piña, MD, a professor of medicine at Case Western Reserve University and chair of the HF-ACTION Steering Committee. Piña, who is a Quality Scholar at the Cleveland VA, says clinicians should consider using the KCCQ inventory on a regular basis. “It is a quick and easy method to find out valuable information about patients’ health status. It only takes about eight minutes to fill out, which is a small burden for patients.”

“This study has important implications for the 5 million Americans who have heart failure,” noted Elizabeth G. Nabel, MD, NHLBI director. “As the number of people affected by heart failure is expected to rise with the aging U.S. population, it is promising to know that regular aerobic activity can not only help patients extend their lives, but exercise can also positively impact their everyday activities and outlook.”

Additional authors on the study include senior author, Kevin Weinfurt, DCRI, Steven Keteyian, co-chair of the HF-ACTION Steering Committee, Henry Ford Hospital; Kerry Lee, Christopher O’Connor, Kevin Schulman, Li Lin, James Blumenthal, Stephen Ellis, and William Kraus, from DCRI; David Whellan, Jefferson Medical College; Nancy Houston Miller, Stanford University; Jonathan Howlett, Dalhousie University; Dalane Kitzman, Wake Forest University, John Spertus, Mid America Heart Institute; and Lawrence Fine and Lawton Cooper; National Heart, Lung, and Blood Institute.

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