

Exercise is safe, improves outcomes for patients with heart failure

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Working out on a stationary bicycle or walking on a treadmill just 25 to 30 minutes most days of the week is enough to modestly lower risk of hospitalization or death for patients with heart failure, say researchers from Duke Clinical Research Institute (DCRI).

The findings stem from the HF-ACTION trial (A Controlled Trial Investigating Outcomes Exercise TraiNing), the most comprehensive study to date examining the effects of exercise upon patients with heart failure. The study was reported today as a late-breaking clinical trial at the American Heart Association's Scientific Sessions 2008 by Christopher O'Connor M.D., director of the Duke Heart Center and principal investigator of the trial, and David Whellan, M.D., of Thomas Jefferson University, co-principal investigator.

HF-ACTION enrolled 2331 patients at 82 study sites throughout the U.S., Canada and France. Patients were randomized into a group that received usual care or to a group that received usual care plus an exercise training program that began under supervision but then transitioned to home-based, self-monitored workouts.

Researchers hypothesized that participation in an exercise program would significantly lower the incidence of death and hospitalization among patients with heart failure.

A planned, secondary analysis, however, that took into account the strongest clinical factors predicting hospitalization or death, found

exercise to be significantly beneficial.

Researchers hope the findings will finally put to rest long-held fears that exercise may be too risky for some patients. "The most important thing we found from this study is that exercise is safe for patients with heart failure, and when adjustments were made for specific baseline characteristics, it significantly improved clinical outcomes," said O'Connor.

Whellan, who is also director of clinical research at the Jefferson Heart Center, says previous studies sent mixed signals, due, in part, to their small size. Some found exercise beneficial, but others did not, and there was limited safety data. "It took a study of this size and duration to determine that exercise is not only safe, but also effective in lowering risk of hospitalization or death for patients with heart failure."

Clinical guidelines say exercise should be considered for stable patients with heart failure, but the lack of definitive data about its long-term benefits has limited Medicare and other insurers from considering an intervention that should be covered.

Participants in HF-ACTION had a significant degree of heart failure, determined by left ventricular ejection rate (LVEF), a measure of how vigorously the heart pumps blood throughout the body. The patients' mean LVEF was 25; a value less than 35 is considered problematic. And they were already receiving optimal care. Ninety-five percent were taking medications for heart failure, such as ACE-inhibitors or beta-blockers, and 45 percent were using mechanical devices to boost their hearts' ability to pump or to treat arrhythmias. The average age of the patients was 59 and almost one-third of them were women.

"These patients were quite sick and were receiving exceptionally good care. That makes the gains they made in the exercise program all the

more remarkable," said Whellan.

Patients in the exercise arm started out slowly, with a goal of three, 30-minute workout sessions three times per week. After 18 sessions, they transitioned to workouts at home, with a goal of 40 minutes five days per week on a stationary bicycle or treadmill. Patients kept logs of their exercise times and heart rates.

In contrast, patients in the usual care arm continued their usual medical therapy and were simply encouraged to be active. Members of both groups received education about the value of exercise and supportive phone calls.

Investigators followed the patients for an average of two and half years, tracking various clinical measures of heart failure, quality of life, hospitalization, cardiac events and death rates.

During the study, 796 (68 percent) of patients in the usual care arm died or were hospitalized, compared to 759 (65 percent) in the exercise arm. There were 198 deaths (17 percent) among patients in the usual care arm, compared to 189 (16 percent) in the exercise arm.

In adjusting for clinical characteristics strongly predictive of outcomes, including history of atrial fibrillation, depression, LVEF status, and the patients' initial capacity for exercise, investigators found that exercise led to a significant 11 percent reduction in risk of hospitalization or death for those in the exercise group ($p = .03$).

They also found that those in the exercise group had a significant, 15 percent lower risk of death from cardiovascular disease and hospitalization due to complications of heart failure ($p = .03$), a secondary end point of the study.

"We feel these are important findings for patients and physicians alike," said Whellan. "It takes a lot of time and commitment to definitively answer a question that many of us had asked for years: Can exercise provide clinically significant benefit for patients with heart failure? Now we know that the answer is 'yes.' We also know that it is safe: There was no significant difference between the two study groups in the risk of heart attacks, arrhythmias, falls or fractures during the study period."

Investigators say there are some limitations to the study. The benefit of exercise may have been diminished somewhat by the fact that there was a sizable number of patients randomized to the usual care arm who actually decided to exercise on their own.

Researchers say there is important work that still needs to be done. "HF-ACTION was comprehensive and carefully conducted study that answered an important clinical question for all of us," says O'Connor. "But at the same time, it raises new ones: How will physicians incorporate these findings into their practice, and how will these programs be paid for? We are working on a cost/benefit analysis we hope will help answer some of these questions."

"This study has important implications for the 5 million Americans who have heart failure," noted Elizabeth G. Nabel, MD, director of the National Heart, Lung, and Blood Institute of the National Institutes of Health, which funded the \$37 million study. "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 patients can benefit from a low-risk method to improve their health."

Source: Duke University Medical Center

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