運動療法は心不全患者のQOLを向上する（LBCT, abstract # 5219）

HF-ACTION QOLサブ解析：体系化した運動療法によりQOLが早期に改善し維持される

HF-ACTION QOL Substudy: Early and sustained quality of life improvements seen with structured exercise program

運動療法に参加した心不全患者はQOLが速やかに向上し、この効果が少なくとも1年間持続すると2008年American Heart Association学会で発表された。運動または通常の治療に無作為に割り付けられた患者2,331人においていくつかの臨床エンドポイントにおける運動の効果が認められた、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）を掘り下げて観察するために、研究者らはサブスタディを行った。運動に割り付けられた患者が監視下運動療法を36セッション終了した3ヵ月後に、カンザスシティ心筋症アンケート（KCCQ－心不全により日常生活がどのように制限を受けるかに関する23の質問による調査）の全体のスコアは、統計学的および臨床的に有意な100点中平均5点の改善が認められた。運動療法群で5ポイントおよび通常治療群で3ポイントの早期の健康状態の改善がみられ（p=0.0005）、これは長期にわたり持続した。さらに運動療法群において通常治療群と比較し臨床的に意味のある改善が3ヵ月後（54%対28%、p≤0.001）および1年後（53%対33%、p≤0.0001）にも認められた。

Full Text

Heart failure patients who participated in exercise training quickly improved their quality of life, and this continued for at least a year, researchers reported at the American Heart Association's Scientific Sessions 2008. The Effect of Exercise Training on Health-related Quality of Life in Patients with Chronic Heart Failure: An HF-ACTION Substudy was presented as a late-breaking clinical trial.

"These findings are particularly important because this is the best medicated population in a heart failure trial that I have ever seen presented or published," said Ileana Pina, M.D., chair of the HF-ACTION steering committee and a professor of medicine at Case Western Reserve University in Cleveland, Ohio. "This is really evidence-based care. No one can say, 'Well, they weren't well-medicated so maybe the exercise was taking the place of medication.' The benefits from exercise are on top of medication and devices."

Researchers conducted the substudy to take a deeper look at one of the secondary endpoints of The Heart Failure and A Controlled Trial Investigating Outcomes of Exercise Training (HF-ACTION) trial, which showed positive effects from exercise on some clinical endpoints, on 2,331 patients randomized to exercise or usual care, said Kathryn E. Flynn, Ph.D., first author on the quality-of-life substudy and an assistant professor in psychiatry and behavioral sciences at the Center for Clinical and Genetic Economics, part of the Duke Clinical Research Institute, Durham, N.C.

"The two sides of this study - HF-ACTION and the quality of life substudy - make this a very holistic look at heart failure patients and exercise training," Flynn said.

During the first three months of the study, when those patients randomized to exercise were completing their 36 supervised training sessions, the exercise group's overall score on the Kansas City Cardiomyopathy Questionnaire (KCCQ) improved a statistically and clinically significant average of five points on the 100-point scale.

Patients in the usual care group, who were encouraged to exercise at least three times a week, improved three points on the scale. The modest two-point difference between the groups had a highly statistically significant p-value of 0.005, with improvements in the exercise group persisting over time, she said.

After three months, 54 percent of the heart failure patients in the exercise group had gained at least five points on the KCCQ, compared to 28 percent in the usual care group, and after one year, 53 percent of the exercise group and 33 percent in usual care had at least a five-point gain. Again the differences between groups was highly statistically significant (p-value = 0.0001), she said.

With 2,331 patients from 82 sites in the United States, Canada and France, HF-ACTION is the largest randomized, controlled trial ever done on heart failure and exercise training. The patients, average age 59, were followed for an average of 2.5 years. In the entire HF-ACTION patient population, 94 percent of participants were on either ACE inhibitors or angiotensin receptor blockers (ARBs) and 95 percent were on beta-blockers, indicating good compliance with evidence-based treatment guidelines, the researchers said.

Flynn said this is the first large study to use the KCCQ, a 23-question survey that asks patients how heart failure limits them in daily activities such as housework or climbing a flight of stairs without stopping, as well as how heart failure limits their enjoyment of life or restricts them socially. The KCCQ was designed to be a more sensitive measure than previously used surveys. It was fairly new when the study began and is now widely used in clinical practice, Flynn said.

Pina said she has used the KCCQ clinically with every new patient in her office for at least eight years and none have refused to answer the survey, which takes about eight minutes to complete.

"On the contrary, patients are happy that we care not just about how they feel symptomatically but also how they feel about their symptoms and ability to function," she said.

The HF-ACTION patients were randomized to exercise or to usual care in which they were given the American College of Cardiology/American Heart Association recommendation to perform at least 30 minutes of moderate intensity exercise most days of the week. The exercise group received a much more intense and extensive multi-stage, guided exercise program that began with 36 supervised training sessions with a goal of three times a week working up to 40-minute sessions of exercise bracketed by 10-minute warm-up and cool-down cycles. They also received treadmills or exercise bikes for home use and were encouraged to work toward a goal of five exercise sessions per week, she said.

They were given the KCCQ at baseline and every three months for the first year of follow-up. They then answered the questionnaire annually for up to four years.

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