JACC: HEART FAILURE
VOL. 2, NO. 6, 2014

ISSN 2213-1779/$36.00
PUBLISHED BY ELSEVIER INC.
http://dx.doi.org/10.1016/j.jchf.2014.06.011

Cardiac Rehabilitation Improves Functional Capacity and Patient-Reported Health Status in Patients With Continuous-Flow Left Ventricular Assist Devices

The Rehab-VAD Randomized Controlled Trial

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ABSTRACT

OBJECTIVES This study examined the effects of a cardiac rehabilitation (CR) program on functional capacity and health status (HS) in patients with newly implanted left ventricular assist devices (LVADs).

BACKGROUND Reduced functional capacity and HS are independent predictors of mortality in patients with heart failure. CR improves both, and is related to improved outcomes in patients with heart failure; however, there is a paucity of data that describe the effects of CR in patients with LVADs.

METHODS Enrolled subjects (n = 26; 7 women; age 55 ± 13 years; ejection fraction 21 ± 8%) completed a symptom-limited cardiopulmonary exercise test, the Kansas City Cardiomyopathy Questionnaire (KCCQ), a 6-min walk test (6MW), and single-leg isokinetic strength test before 2:1 randomization to CR versus usual care. Subjects in the CR group underwent 18 visits of aerobic exercise at 60% to 80% of heart rate reserve. Within-group changes from baseline to follow-up were analyzed with a paired *t*-test, whereas an independent *t*-test was used to determine differences in the change between groups.

RESULTS Within-group improvements were observed in the CR group for peak oxygen uptake (10%), treadmill time (3.1 min), KCCQ score (14.4 points), 6MW distance (52.3 m), and leg strength (17%). Significant differences among groups were observed for KCCQ, leg strength, and total treadmill time.

CONCLUSIONS Indicators of functional capacity and HS are improved in patients with continuous-flow LVADs who attend CR. Future trials should examine the mechanisms responsible for these improvements, and if such improvements translate into improved clinical outcomes. (Cardiac Rehabilitation in Patients With Continuous Flow Left Ventricular Assist Devices:Rehab VAD Trial [RehabVAD]; NCT01584895) (J Am Coll Cardiol HF 2014;2:653–9) © 2014 by the American College of Cardiology Foundation.

Although heart transplantation is the treatment of choice for patients with end-stage heart disease, because of limited donor availability (1), the left ventricular assist device (LVAD) has become an established therapeutic option in appropriately selected patients. Continuous-flow LVADs are used as a bridge to recovery, a bridge to cardiac transplantation, and increasingly, as

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Manuscript received January 28, 2014; revised manuscript received June 13, 2014, accepted June 13, 2014.

ABBREVIATIONS AND ACRONYMS

6MW = 6-min walking distance

CPX = cardiopulmonary treadmill test

CR = cardiac rehabilitation

HF = heart failure

HS = health status

KCCQ = Kansas City Cardiomyopathy Questionnaire

LVAD = left ventricular assist device

UC = usual care

VO_2 = peak oxygen uptake

destination therapy in which the device remains in use for the life of the patient (2).

In addition to improved survival, some studies have shown improvements in functional capacity and health status (HS) following LVAD implantation (3,4). However, despite these improvements, many patients with LVADs continue to experience exercise intolerance and other heart failure (HF)-related symptoms (5,6). Leibner et al. (7) observed that cardiorespiratory fitness, as measured by peak oxygen uptake (VO_2), and ventilatory efficiency remained unchanged 1 year after LVAD implantation. Persisting functional limitations in this population can affect HF-related symptoms, HS, and, potentially, clinical outcomes (e.g., hospitalization) (8). As the durability of LVADs improve and duration of support is extended, the assessment and optimization of functional capacity and HS become key components in the long-term management of these patients.

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In patients with cardiovascular disease, cardiac rehabilitation (CR) improves survival, functional capacity, and quality of life (9–11). Among patients with stable HF, exercise training improves peak VO_2, reduces HF-related symptoms, and is associated with a lower risk for all-cause death or all-cause hospitalization (8,11–14).

In contrast, there is little evidence that describes the effects of exercise training in patients with LVADs. Hayes et al. compared 8 weeks of home- versus facility-based exercise and found that cardiorespiratory fitness and quality of life improved in both groups (15). Although the facility-based group showed a trend toward greater improvement, it did not reach statistical significance. The lack of statistical significance may have been due to the sample size ($n = 14$).

The aim of the present study was to determine the impact of a 6-week CR exercise program on cardiorespiratory fitness, muscle strength, and HS in patients with a continuous-flow LVAD. We hypothesized that these parameters would be improved among LVAD patients who underwent supervised exercise training compared with a non-exercising control group.

METHODS AND STUDY DESIGN

Patients who underwent LVAD implantation between June 2011 and September 2012 for any indication at Henry Ford Hospital were screened for participation. Eligibility criteria included a recently implanted continuous-flow LVAD (i.e., 1 to 6 months from surgery date), age older than 18 years, and patients had to be free of any major comorbidities or limitations that might interfere with exercise training. Exclusion criteria included patients who declined to attend CR or who attended a CR program outside of the Henry Ford Health System. The protocol was reviewed and approved by the Henry Ford Health System Institutional Review Board, and all subjects provided written informed consent.

Following baseline testing, patients were randomized in a 2:1 fashion to either 6 weeks of CR or usual care (UC). Randomization was conducted using a computer random number generator, with group assignments transferred to allocation cards sealed in opaque sequential envelopes. Staff members who conducted the follow-up testing at 6 weeks after baseline were blinded to group assignment.

PATIENT TESTING

Before group assignment, all patients underwent initial testing that consisted of a self-reported patient HS questionnaire, a symptom-limited cardiopulmonary treadmill test (CPX), a 6-min walk (6MW) test, and a maximal single-leg isokinetic test to measure strength. The order of administrating these tests remained the same for all patients at both time points (i.e., at baseline and follow-up). Patient-reported HS was obtained using the Kansas City Cardiomyopathy Questionnaire (KCCQ), a 23-item questionnaire to evaluate patient responses across 5 domains (i.e., physical function, symptoms, social function, self-efficacy, and quality of life) (16). The symptom-limited CPX test was then completed using the modified Naughton protocol (i.e., 1 metabolic equivalent increase per each 2-min stage). Expired air was sampled breath-by-breath and analyzed using a Medgraphics Ultima (Minneapolis, Minnesota) metabolic cart. Heart rate and blood pressure were measured in the supine and standing positions before exercise, at the end of each 2-min exercise stage, at peak exercise, and during recovery.

Gas exchange data were analyzed by a CPX core laboratory that was blinded to subject assignment. Gas exchange data were reported using 20-s interval averages. Peak values were identified from the highest interval value during the final minute of exercise. Ventilatory-derived anaerobic threshold was determined using the modified V-slope method by 3 independent reviewers. Minute ventilation to carbon dioxide slope was calculated using data from the