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Ambulatory Extra-Aortic Counterpulsation in Patients With Moderate to Severe Chronic Heart Failure

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ABSTRACT

OBJECTIVES The study sought to assess feasibility, safety, and potential efficacy of a novel implantable extra-aortic counterpulsation system (C-Pulse) in functional class III and ambulatory functional class IV heart failure (HF) patients.

BACKGROUND 30% to 40% of HF patients suffer from poor functional status and quality of life (QoL) but are not in need of end-stage treatments. We undertook a multicenter single-arm study to assess the C-Pulse System in such patients.

METHODS New York Heart Association (NYHA) functional class III or ambulatory functional class IV HF patients were eligible. Safety was assessed continuously through 12 months. Efficacy measurements included changes from baseline to 6 and 12 months in NYHA functional class, Minnesota Living with Heart Failure (MLWHF) and Kansas City Cardiomyopathy Questionnaire (KCCQ) scores, 6-min walk distance (6MWD), and exercise peak oxygen consumption (pVO_2; 6 months only).

RESULTS Twelve men and 8 women (56.7 ± 7 years, 34 to 71 years of age) with ischemic (n = 7) or nonischemic (n = 13) cardiomyopathy were implanted. There was no 30-day mortality and no neurological events or myocardial infarctions through 12 months. At 6 months, there were 3 deaths (1 device-related). One-year survival was 85%. At 6 months, C-Pulse produced improvements in NYHA functional class (3.1 ± 0.3 to 1.9 ± 0.7, p = 0.0005), MLWHF (63.6 ± 19.9 to 40.2 ± 23.2, p = 0.0005), and KCCQ scores (43.6 ± 21.1 to 65.6 ± 21.5, p = 0.0002), but not 6MWD (275.5 ± 64.0 to 296.4 ± 104.9, p = NS) or pVO_2 (14.5 ± 3.6 to 13.1 ± 4.4, p = NS). Improvements continued at 12 months, with 6MWD change becoming statistically significant (336.5 ± 91.8, p = 0.0425).

CONCLUSIONS Use of C-Pulse in this population is feasible, appears safe, and improves functional status and QoL. A prospective, multicenter, randomized controlled trial is underway. (C-Pulse IDE Feasability Study-A Heart Assist System; NCT00815880) (J Am Coll Cardiol HF 2014;2:526–33) © 2014 by the American College of Cardiology Foundation.

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Functional status and quality of life (QoL) remain poor for at least 30% to 40% of chronic heart failure patients, who remain categorized in New York Heart Association (NYHA) functional class III or IV despite optimal evidence-based drug and electrophysiological device therapies (1). These patients with advanced heart failure are also at the greatest risk for heart failure-related hospitalization and mortality, with a 1-year mortality rate of at least 10% to 15% (2–4). While therapies such as cardiac transplantation or left ventricular assist devices (LVADs) may benefit the subset of this population with end-stage disease defined by the American College of Cardiology/American Heart Association as Stage D heart failure, these measures are generally not indicated for the vast majority of patients with Stage C heart failure (5). Moreover, the small number of available donor organs limits the application of cardiac transplantation, and LVADs are limited by the blood-contacting nature of their design and need for chronic anticoagulation, resulting in significant device-related adverse events of stroke, major bleeding, infection, and device failure (6). Thus, there is an unmet need for additional therapies for American College of Cardiology/American Heart Association Stage C and NYHA functional class III and ambulatory functional class IV heart failure patients.

SEE PAGE 534

One emerging approach to these patients is through the use of chronic ambulatory aortic counterpulsation (7–9). Aortic counterpulsation is a well-established mode of circulatory support that works by reducing left ventricular after-load during systole and augmenting blood pressure and systemic and coronary perfusion during diastole (10–12). While the application of aortic counterpulsation in acutely ill patients involves the use of an intra-aortic system (the intra-aortic balloon pump), implantable intra- and extra-aortic counterpulsation systems have been developed for chronic ambulatory use (13–16). One such system, the C-Pulse System (Sunshine Heart, Inc., Eden Prairie, Minnesota), includes a novel implantable, nonobligatory, non-blood contacting counterpulsation heart assist pump developed for minimally invasive implantation without the need for cardiopulmonary bypass (15,16).

The C-Pulse System was designed to provide an effective low-risk and low-cost mechanical heart assist device for use in patients with chronic American College of Cardiology/American Heart Association Stage C and NYHA functional class III and ambulatory functional class IV heart failure. The device is designed to be turned off safely or weaned if there is sustained cardiac recovery and similarly, in failure modes, is considered to have a low risk of death or disability, other than the recurrence of heart failure symptoms. No anticoagulants are required, reducing the risk of bleeding complications, and the extravascular nature of the implant mitigates the risk of intravascular thrombus formation, thromboembolism, and blood-borne infection. Preliminary studies suggest that this method of counterpulsation is feasible and safe (15,16). The present study was designed to further assess the feasibility, safety, and potential efficacy of the C-Pulse System in the intended population.

ABBREVIATIONS AND ACRONYMS

6MWD = 6-min walk distance

CT = computed tomography

LVAD = left ventricular assist device

NYHA = New York Heart Association

pVO_2 = peak oxygen consumption

PIL = percutaneous interface lead

QoL = quality of life

METHODS

PATIENTS. Patients 18 to 75 years of age were eligible for this study if they had American College of Cardiology/American Heart Association Stage C heart failure with a left ventricular ejection fraction ≤35% and remained in NYHA functional class III or ambulatory functional class IV despite optimal medical therapy. Patients were required to have been receiving optimal drug treatment (e.g., angiotensin-converting enzyme inhibitors, beta-blockers) for at least 3 months and to have had a biventricular pacemaker for at least 3 months, if indicated. Patients were also required to have an implantable cardioverter-defibrillator, if indicated. Other major inclusion criteria included a 6-min walk distance (6MWD) between 100 to 350 m and exercise peak oxygen consumption (pVO_2) between 10 and 18 ml/kg/min for men and 9 and 16 ml/kg/min for women. Major exclusion criteria included severe renal failure (estimated glomerular filtration rate <40 ml/min/1.73 m^2), severe chronic respiratory disease (forced expiratory volume ≤0.9 l/min), severe right heart failure (central venous pressure ≥20 mm Hg, elevated liver function tests beyond 3 times the upper limit of normal, or the

Thoratec; and has served on the Data Safety and Monitoring Board for BioStable. Dr. Peters holds intellectual property, stock, or stock options in Sunshine Heart, Inc.; and has received consulting fees. Dr. Verta is an employee of Sunshine Heart, Inc. and holds stock options. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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