Heart Failure Readmission Rates: Clinical Experience with the C-Pulse® Extra-Aortic Counterpulsation System

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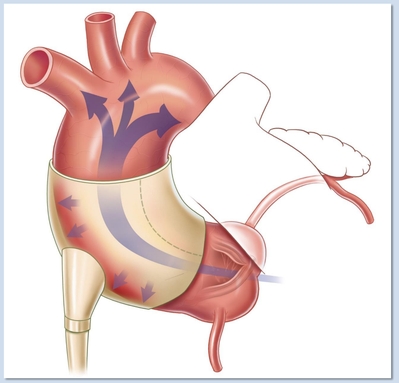
BACKGROUND

Heart failure-related readmission rates remain high. Readmission (RA) for heart failure reflects increased morbidity, impaired quality of life, and is a growing strain and economic burden on health care resources. In the EFFECT phase I study, 61.3% of patients had repeat hospitalization within one year of initial discharge, with the majority occurring shortly post-discharge or near end of life. An analysis of Medicare beneficiaries from 2007–2009 of 1,330,157 heart failure (HF) hospitalizations found 35% of patients readmitted for the same condition within 30 days. The C-Pulse® Heart Assist System (Sunshine Heart, Inc.) is an implantable, non-blood contacting device designed to provide long-term counterpulsation therapy for patients suffering from advanced heart failure. Implantable system components include a cuff placed around the ascending aorta, bipolar epicardial ventricular sensing leads, and a percutaneous driveline for system operation and pneumatic actuation (FIGURE 1,2). Results from a recently completed 20 patient FDA-approved feasibility study demonstrated improvements in NYHA class and quality of life. The US feasibility investigational study also gathered data to evaluate readmission in class III/ambulatory IV HF patients receiving the C-Pulse System.

FIGURE 1

METHODS

Between April 2009 and June 2011, twenty HF patients were enrolled in an FDA approved IDE prospective US feasibility study undergoing C-Pulse System implantation procedures at 7 centers. Safety endpoints included death, aortic disruption, neurologic events, myocardial infarction, and major infection at 6 months. Quality of life was assessed using the MLWHF and the KCCQ. RA data was collected throughout the study.



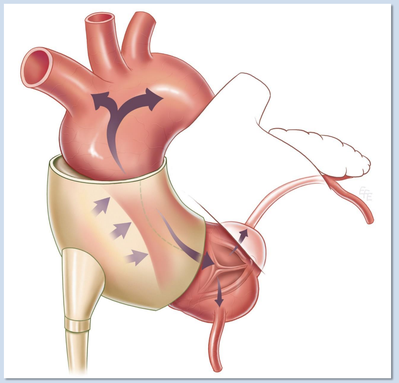


FIGURE 2

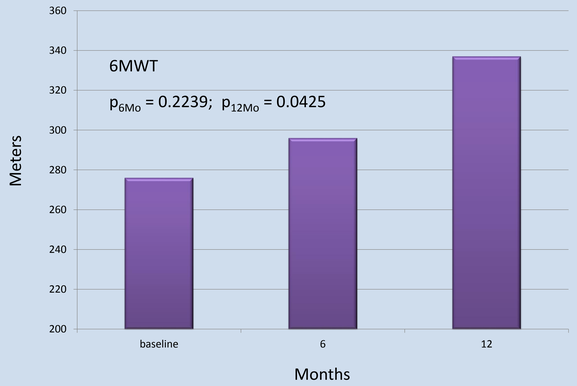
RESULTS

The study included 12 males, 18 NYHA class III and 2 ambulatory NYHA class IV patients, 7 ischemic and 13 non-ischemic. Mean age was 56±7 years. Baseline ejection fraction (EF) was 28% ± 6.1. There was no 30 day mortality and no neurologic events or myocardial infarctions through 12 months. At 6 months, there was 1 device related death. One year survival was 85%.

At 6 months, C-Pulse produced improvements in NYHA functional class, MLWHF and KCCQ scores. These improvements continued at 12 months, with improvement in 6MWD becoming statistically significant at 12 months (FIGURES 3-5).

Over 12 months, 3 of the 20 implanted C-Pulse feasibility study patients (15%) had 5 HF hospitalizations after device implantation (Clinical Events Committee adjudicated, occurring at 208 days, 205 and 345 days, 33 and 52 days). Two of the three patients had low device usage compliance prior to HF events (<30% usage).

FIGURE 3



RESULTS

FIGURE 4

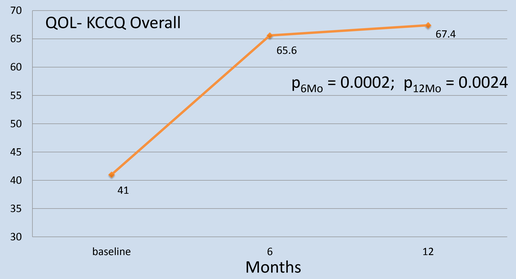
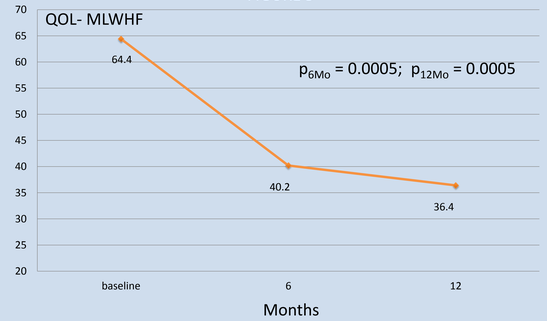


FIGURE 5



CONCLUSIONS

Recently published data has demonstrated preliminary indications of safety and efficacy of counterpulsation therapy with the C-pulse System for the management of chronic heart failure. Lifetime analysis work from the EFFECT study has shown an overall RA rate of 61.3% at 12 months in patients suffering from heart failure. In comparison, RA rates for patients undergoing C-pulse implantation during the Feasibility study appear to be greatly reduced at 30 days and at one year. Based on this study, RA rates for patients undergoing C-pulse implantation are significantly lower than RA rates reported for other forms of durable mechanical circulatory support at 30 days and 1 year.