COUNTER HF™ CLINICAL STUDY

Arterial and Cardiac Hemodynamics in Advanced HF Patients Implanted with the C-Pulse® Counterpulsation Device: Implications for Myocardial Recovery

SUNSHINE HEART

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Introduction

The C-Pulse heart assist system is a counterpulsation technology used to treat patients with moderate to severe heart failure (NYHA class III or ambulatory class IV) and refractory to optimal medical and device therapy. The implantable device is placed outside the bloodstream and gives patients the ability to disconnect from the system.

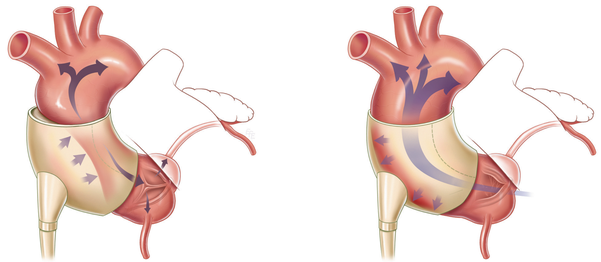

Figure 1. The cuff around the ascending aorta inflates during diastole and starts deflating shortly before ejection, thereby potentially increasing coronary blood flow and decreasing afterload.

Despite intensive medical and device therapy, many patients remain symptomatic with refractory NYHA class III and IV heart failure (HF). Therapeutic options are limited in this population, with the goal being stabilization of HF progression.

One approach is the use of an extra-aortic counterpulsation C-Pulse System, consisting of an extra-vascular cuff wrapped around the ascending aorta.

The C-Pulse operates on the principle of counterpulsation however, placement on the proximal ascending aorta may afford unique hemodynamic advantages over traditional counterpulsation devices.

We report for the first time, hemodynamic effects from advanced HF patients implanted with C-Pulse.

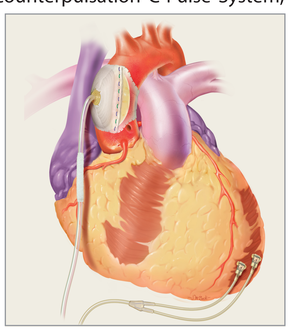

Figure 2: C-Pulse cuff on ascending aorta and epicardial leads used for timing of inflation and deflation of cuff.

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Methods and Results

Radial tonometry and office BP were measured in successive patients (N=6) NYHA Class III/IV, 5M, EF 17.2 ± 6.6%, age 67.8 ± 9.7 years (mean ± SD), during device optimization. Median time from implant was 180 days (range 1 - 1,356 days). Waveforms and blood pressure were obtained after 5 minute steady state OFF period followed by device optimization (ON).

Systolic and diastolic BP were maintained with optimization (refer to table). Myocardial perfusion indexed by subendocardial viability ratio (SEVR) significantly increased primarily resulting from increase in diastolic area, Ad. Cardiac ejection was enhanced; increased forward wave amplitude, P1, and reduced time to peak pressure, P2. Late systolic load from wave reflections was also reduced assessed by augmentation index (Aix).

(N = 6)	C-Pulse OFF	C-Pulse ON
Max Aortic BP (mmHg)	114.4 ± 4.4	114.3 ± 4.9
Diastolic BP (mmHg)	68 ± 13.4	65.7 ± 14.7
P1 (mmHg)	106.5 ± 6.0	109.3 ± 4.9†
Time to P2 (ms)	182 ± 20.8	161 ± 29.5*
SEVR	1.70 ± 0.45	1.99 ± 0.53†
Ad (mmHg*s)	44.3 ± 13.9	48.9 ± 14.7‡
Aix (P2/P1)	1.23 ± 0.13	1.04 ± 0.06†

Mean ± SD, Paired t-test, † p<0.01; *p=0.01; ‡ p<0.05

Table 1: Summary pulse wave analysis data during C-Pulse OFF and ON.

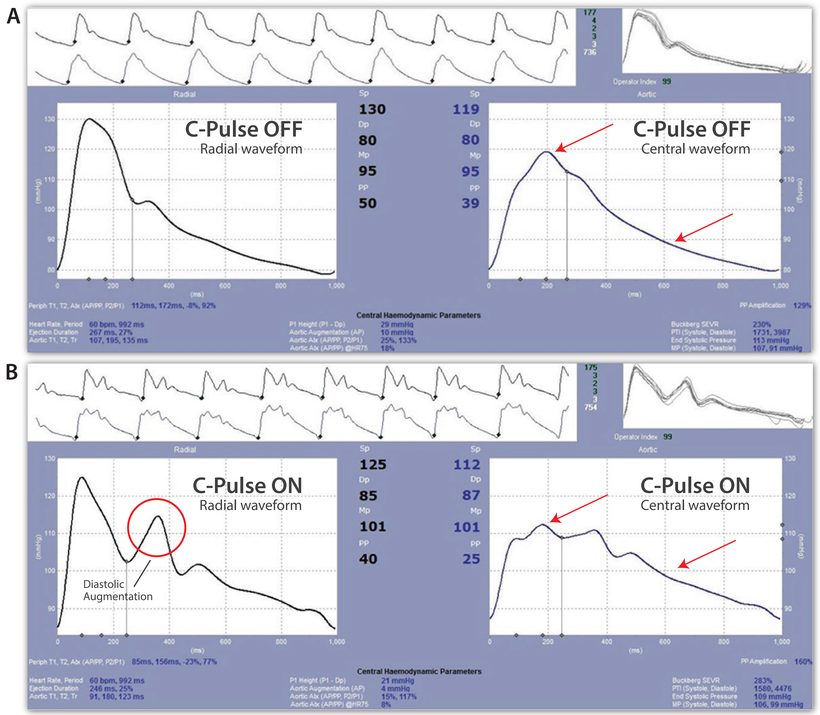

Figure 3. Pulse wave analysis reports showing radial waveforms and synthesized central waveform with C-Pulse OFF (A), and C-Pulse ON (B). Arrows indicate reduction in Aix and increased diastolic pressure with C-Pulse ON. Also, note increase in pulse pressure amplification with C-Pulse ON.

Conclusion

In this small cohort, C-Pulse increased myocardial perfusion and reduced early and late components of cardiac load. There was a novel scientific finding of reduced Aix. This may arise from aortic arch baroreceptor stimulation due to enhanced pulsatility or mechanical deformation from the cuff. These changes may translate into improved heart failure symptoms, cardiac reverse remodeling and possibly recovery. Further studies are needed to assess the mechanisms and their association with regression of heart failure.

Caution: C-Pulse is an Investigational device. The device is limited by Federal (United States) Law to investigational use only.

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