Preliminary Results from the C-Pulse® System European Multicenter Study

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Background

The C-Pulse heart assist system (Sunshine Heart, Inc.) is an extra-aortic balloon counterpulsation device for the treatment of patients with moderate to severe heart failure of NYHA class III or ambulatory class IV, who are refractory to optimal medical and cardiac resynchronization therapy. As the device is placed outside the bloodstream the patient can temporary disconnect from the system and no anticoagulation is needed.

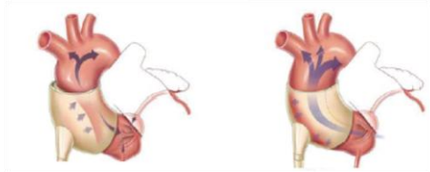

Figure 1. The balloon around the ascending aorta inflates during diastole and starts deflating shortly before ejection, thereby potentially increasing coronary blood flow and decreasing afterload.

Methods

The C-Pulse System OPTIONS-HF, is a prospective multi-center European post-market study. Patients can be included who are 18 years or older, have moderate to severe heart failure (ACC/AHA stage C, NYHA class III/IV ambulatory), are refractory to optimal medical therapy and non-responders to CRT. Patients with evidence of significant ascending aortic calcification, moderate or severe atherosclerotic disease, ascending aorto-coronary artery bypass grafts, any history of aortic dissection, severe mitral valve incompetence, moderate to severe aortic valve incompetence or systolic blood pressure less than 90 or greater than 140 mmHg are excluded.

Disclosure: H. Hotz provides consulting services for Sunshine Heart and received travel expenses. M. Seidel, J. Schmitto and T. Krabatsch declare no conflict of interest.

Results

	All Patients (N=6)
Mean SD (range) Age in years	60.8 10.05 (51, 79)
Gender	
Male	100.0% (6/6)
Co-morbidities	
Arrhythmia	50% (3/6)
Hyperlipidemia	67% (4/6)
Diabetes Mellitus	67% (4/6)
Smoking history	83% (5/6)
Cardiomyopathy	100% (6/6)
- Ischemic	67% (4/6)
- Non-Ischemic	33% (2/6)
Intermacs Profile	
4: Resting symptoms	34% (2/6)
5: Exertion Intolerant	50% (3/6)
6: Exertion Limited	17% (1/6)
NYHA	
III	83% (5/6)
IV	17% (1/6)
CRT	67% (4/6)
ICD Therapy	83% (5/6)

Table 1. Demographics

Between May and November 2013, we implanted the C-Pulse device in 6 male patients with a mean age ± SD of 60.8 ± 10.05 years. All were classified as heart failure ACC/AHA stage C and were on optimal medical therapy. Five patients had a functional status NYHA class III and one patient ambulatory NYHA class IV. Baseline mean left ventricular ejection fraction (LVEF) ± SD was 24% ±4%. Mean 6-Minute Walk Distance (6MWD) ± SD was 204 ±24.5m.

Surgical implantation was successful in all patients and did not require cardiopulmonary bypass. No stroke, myocardial infarction, major bleeding or major infection has occurred in relation to the device. One patient developed tachycardia with worsening heart failure 12 hours after surgery without stabilization under medication and underwent left ventricular assist device implantation 5 days post-procedure.

The five patients remaining for evaluation at 6 weeks improved clinically. Functional status improved by one NYHA class (Fig 2). LVEF increased by an average of 11.5% absolute (45% relative) and 6MWD improved by 44% at 6 weeks post implant (Fig 3 and 4). Data presented in this interim report are un-adjudicated and site-reported.

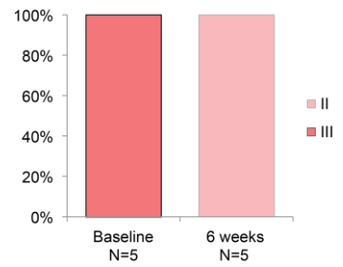

Figure 2. Improvements in NYHA

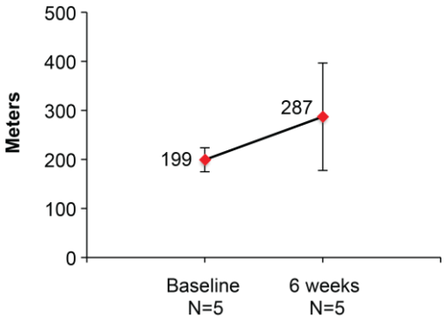

Figure 3. Improvements in 6MWD

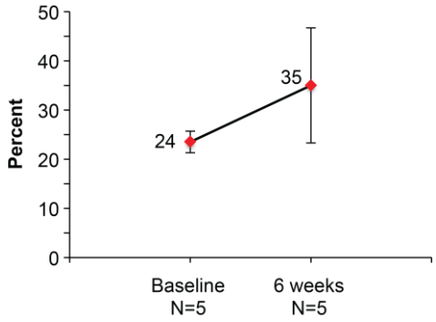

Figure 4. Improvements in LVEF

Conclusion

The C-Pulse system is a promising therapeutic option for patients with moderate to severe heart failure and may improve cardiac function over time.

The C-Pulse System is CE marked.

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