Cardio Centrum Berlin

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.

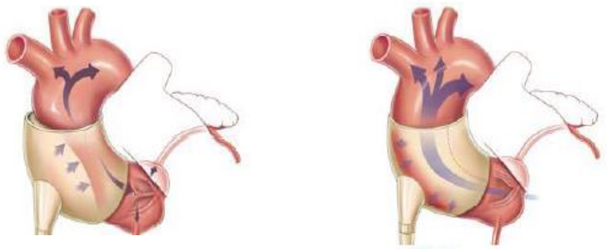

Figure 1: The balloon around the ascending aorta inflates during diastole and starts to deflate shortly before systole. Thereby it increases coronary blood flow and decreases afterload.

It has CE marking and is an investigational device in the US and Canada where a feasibility study already showed promising results. We wish to report our experience with the first implantations in Europe.

Methods

Patients were selected according to the inclusion and exclusion criteria of the C-Pulse System European Multicenter Study, OPTIONS-HF.

Results

Between May 2013 and November 2013 we implanted the C-Pulse heart assist system in six male patients with a mean age ± SD of 60.5 ± 9.2 years.

All were classified as heart failure ACC/AHA stage C, were on optimal medical and five patients also on cardiac resynchronization therapy. Five patients were NYHA class III and one patient was ambulatory NYHA class IV. Two patient were classified as INTERMACS level 4, three as level 5 and one as level 6. Mean left ventricular ejection fraction (LVEF) ± SD was 22% ± 4%.

Surgical implantation was successful in all patients and does not require cardiopulmonary bypass. So far no stroke, myocardial infarction, major bleeding or major infection due to the device occurred.

Patient no.	1	2	3	4	5	6
Type of cardiomyopathy	ethyltoxic	idiopathic	ischemic	ischemic	ethyltoxic/ischemic	ischemic
Gender	male	male	male	male	male	male
Age	63	54	55	51	61	79
INTERMACS	5	4	5	5	6	4
NYHA class baseline	III	IV	III	III	III	III
NYHA class follow-up	II	-	II	II	II	II
LVEF baseline	25%	15%	20%	25%	25%	22.5%
LVEF follow-up	55%	-	30%	25%	35%	30%
MACE	-	LVAD	-	-	-	-
Patient weaned	after 6.5 months	-	-	-	-	-
Follow-up in d	335	5	284	193	152	249

Table 1: Clinical characteristics of the patients at baseline and follow-up.

One patient developed tachycardia with worsening heart failure 12 hours after surgery without stabilization under medication. The tachycardia prevented the C-Pulse® heart assist system from supporting the heart properly and the patient underwent left ventricular assist device implantation after 5 days.

The other five patients benefited from the C-Pulse treatment. Their functional status improved by one NYHA class. So far LVEF has increased in most patients by an average ± SD of 11.5% ± 9.9%. One patient could be weaned from the system after 6.5 months.

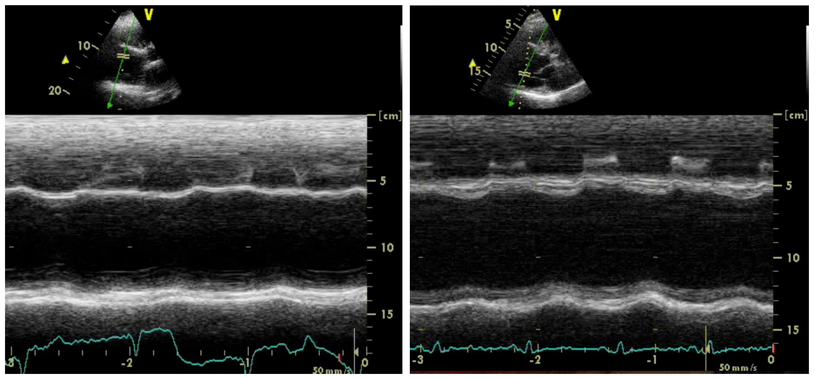

Figure 2: Transthoracic echocardiogram (TTE) of the left ventricle in m-mode at baseline (a) and at follow-up after 7 weeks (b) of patient 3.

Conclusion

The C-Pulse heart assist system can improve cardiac function and seems to be a promising therapeutic option for patients with moderate to severe heart failure.

Disclosure: H. Hotz provides consulting services for Sunshine Heart and received travel expenses. A. Schulz, M. Reinartz, E. Potapov, M. Seidel, L. Theres, L. Bruch, J. Schmitto, R. Hetzer and T. Krabatsch declare no conflict of interest.