The C-Pulse® system is a non-blood contacting, non-obligatory assist device implanted externally on the ascending aorta and is based on the principle of counterpulsation. Algorithms based on R-wave detection increase coronary blood flow during diastole and reduce arterial impedance during systole with potential benefits on diastolic function and improved coupling of the ventricle and arterial system. Optimization of C-Pulse timing can be performed during acute ON/OFF interventions.

Purpose

Primary: To determine if exit site management changes used in the OUS reduced the infection rate as compared to the US study.
Secondary: To compare the US and OUS exit site infection rates (ESI) to known LVAD published historical data where inadequate exit site management may have contributed to higher infection rates.

Methods

C-Pulse was implanted in the US feasibility IDE study (n=20, 12 male, age 56.7 ± 7 years) and OUS post market study (n=12, 9 male, age 59.7 ± 8.8 years). Infection events were collected from implant through 12 months and adjudicated by an independent clinical events committee.

Results

ESI for the US and OUS studies were 40% (8/20) and 8.3% (1/12) respectively with MRSA/staph aureus as the most common organism. Reduced ESI in the OUS C-Pulse study are attributed to an improved exit site wound care regimen, stabilization of the DL to promote exit site healing, and strict patient compliance to maintain DL connections.

Conclusion

Early results from the C-Pulse OUS study demonstrate that proper exit site DL stabilization and monitoring can effectively reduce the rate of C-Pulse ESI to acceptable levels as compared to the US study experience and known LVAD published historical data. Best practices for C-Pulse DL management have been incorporated into the ongoing US pivotal trial.

For Europe: The C-Pulse System is CE marked.
For US: Caution: C-Pulse is an Investigational device. The device is limited by Federal (United States) Law to investigational use only.