Outcomes after implantation of partial-support left ventricular assist devices in inotropic-dependent patients: Do we still need full-support assist devices?

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Objectives: Partial-support left ventricular assist devices (LVADs) represent a novel strategy for heart failure treatment. The Synergy Pocket Micro-pump (HeartWare Inc, Framingham, Mass), the smallest surgically implanted long-term LVAD, provides partial flow up to 4.25 L/min and was primarily designed for ''less sick'' patients with severe heart failure. This device is implanted minimally invasively without sternotomy or cardiopulmonary bypass. Early implantation in patients with Interagency Registry for Mechanically Assisted Circulatory Support class 4 and higher was shown to be feasible and associated with significantly improved hemodynamics and quality of life. The aim of this study was to present our experience with implementation of long-term partial circulatory support as a bridge to transplantation in patients with more advanced heart failure who were dependent preoperatively on inotropic support or intra-aortic balloon pump.

Methods: In this observational study, only inotropic or intra-aortic balloon pump–dependent patients with end-stage heart failure were included (n = 12). These patients underwent Synergy device implantation between February 2012 and August 2013.

Results: The mean preoperative Interagency Registry for Mechanically Assisted Circulatory Support class was 2.17 ± 0.84 (class 1, 25%; class 2, 33%; class 3, 42%). The mean age was 46 ± 15 years, and 33% were female. Preoperatively, 4 patients (33%) had at least 1 previous sternotomy, 3 patients (25%) were supported with a balloon pump, 1 patient (8%) had a previous full-support LVAD, and 4 patients (33%) had cerebrovascular events in the past. After device implantation, there were no right ventricular failures, device-related infections, hemorrhagic strokes, arterial or venous thromboembolisms, or worsenings of aortic and mitral regurgitation observed over the follow-up. The mean follow up was 174 ± 171 days (range, 5-764 days; cumulative, 3199 days). One patient (8%) died, 3 patients (25%) successfully underwent transplantation, 1 device (8%) was explanted after myocardial recovery, and 5 patients (42%) are still on ongoing support. Two patients (17%) were upgraded to a full-support LVAD after 65 days of mean support. A total of 11 of 12 patients (92%) were discharged from the hospital and are presently alive. Left ventricular end-diastolic diameter was significantly reduced 3 months after device implantation.

Conclusions: Partial LVAD support may be clinically efficacious in inotropic and intra-aortic balloon pump–dependent patients. On the basis of our experience and evidence of previous research, such patients may benefit from minimally invasive access, no need for sternotomy and cardiopulmonary bypass, a short implantation time, an easy exchange if necessary, and a lower risk of subsequent heart transplantation. Because the implantation is performed without sternotomy, device upgrade is feasible with a comparatively low operative risk and good clinical outcome. Our preliminary results show that partial-support devices may have the potential to replace full-support LVADs in the near future. (J Thorac Cardiovasc Surg 2014;148:1115-22)

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Abbreviations and Acronyms

IABP = intra-aortic balloon pump
INR = international normalized ratio
INTERMACS = Interagency Registry for Mechanically Assisted Circulatory Support
LVAD = left ventricular assist device
RVF = right ventricular failure

Cardiac transplantation remains the gold standard therapy for patients with end-stage heart failure. However, because of significantly restricted donor organ availability in a number of countries resulting in increased waiting times and mortality,[1] left ventricular assist devices (LVADs) are increasingly being applied as a life-sustaining bridge to transplantation.[2,3] Over the last 2 decades, major technologic improvements in mechanical circulatory support have been achieved, leading to the development of significantly smaller and more reliable continuous-flow systems.[4] In addition to these full-support devices that can provide up to 10 L/min of flow, partial-support devices recently became available.

The Synergy Pocket Micro-pump (HeartWare Inc, Framingham, Mass) is the smallest surgically implanted long-term LVAD, provides partial flow up to 4.25 L/min, and was designed for patients with severe heart failure without inotropic dependence (Interagency Registry for Mechanically Assisted Circulatory Support [INTERMACS] class 4-7).[5] Early implantation of this partial-support device in such patients was shown to be feasible and associated with significantly improved hemodynamics, end-organ perfusion, and quality of life. In the majority of patients, the device prevented progression to end-stage heart failure.[5-7] One of the most important benefits of this device is that it can be implanted with minimally invasive access with no need for sternotomy, resulting in fewer postoperative adverse events.

In view of the reports of the successful treatment of low-risk patients with the Synergy Pocket Micro-pump, the question arises as to whether patients eligible for a full-support LVAD also would benefit from the Synergy device as a bridge to transplantation. The aim of this study was to present the outcomes of inotropic-dependent patients undergoing long-term partial support as a bridge to transplantation.

PATIENTS AND METHODS

Study Population

The study design was a retrospective review of the prospectively collected data and did not require ethical approval. Data were collected from the UK national ventricular assist device database. Twelve consecutive patients dependent on an inotropic or intra-aortic balloon pump (IABP) were included who underwent long-term support with the Synergy LVAD between July 2007 and August 2013 in Harefield Hospital and University Hospital Goettingen. Implantation strategy was as a bridge to transplantation for therapy-refractory end-stage heart failure. Prospectively collected data included detailed information on patients' demographics and baseline clinical characteristics, laboratory, echocardiographic and hemodynamic parameters, and intraoperative variables and postoperative outcomes.

Definitions

Liver failure was defined as a 2-fold elevation of the upper limit of the normal range of at least 2 liver function parameters. Any postoperative renal dysfunction that required dialysis/hemofiltration was defined as renal failure. Respiratory failure was defined as any impairment of respiratory function requiring reintubation or mechanical ventilation after LVAD implantation. Right ventricular failure (RVF) was defined as impairment of right-sided function resulting in the need for a short-term or long-term right ventricular assist device.

Surgical Techniques

All Synergy Pocket Micro-pump implantations were performed off-pump as described previously.[2,3,6,7] Preparation for left atrial cannulation was performed by exposure of the confluence of the right pulmonary veins through a 7- to 10-cm right-sided thoracotomy in the fourth intercostal space. In all cases, the pericardium was opened directly over the pulmonary veins to provide direct access to the cannulation area. An additional 4-cm subclavicular incision was made for the formation of a small subcutaneous pocket. The pump was then placed in the subcutaneous tissue inferior to the subclavian artery and frontal to the right pectoralis major muscle. After heparin administration, a silicone inflow cannula with a titanium tip and Dacron cuff was inserted into the left atrium using the Seldinger technique between the insertions of the right upper and lower pulmonary veins and secured with two 4-0 polypropylene purse string sutures. The proximal end of the cannula was tunneled through the second intercostal space to the subcutaneous pocket. A polytetrafluoroethylene outflow graft was used to perform an end-to-side anastomosis to the right subclavian artery. After retrograde de-airing of the pump, the proximal end of the inflow graft was connected to the device and the pump was started. Under echocardiographic monitoring, the pump speed was then gradually increased from 20,000 rpm to a maximum of 28,000 rpm. While increasing the speed of the device, pump current, cardiac output, pulmonary artery wedge pressure, and arterial pressure were monitored with echocardiographic visualization of the flow from the left atrium into the device. After setting up the final speed and flow at approximately 3 L/min, the surgical wounds were closed using the standard method.

Driveline Placement

In all cases, the percutaneous driveline was externalized after a short subfascial course directly under the right subcostal margin.

Anticoagulation Protocol

Intravenous heparin was administered postoperatively after a minimum of 12 hours as a continuous infusion to progressively increase activated partial thromboplastin time to 50 to 70 seconds when the cumulative chest tube drainage decreased to less than 50 mL/h and the coagulation profile returned to near normal levels. Platelet aggregation inhibitors were used as a part of the anticoagulation protocol; 75 mg of aspirin and 75 mg of clopidogrel daily were immediately started after extubation. After chest drain removal and tolerating oral medication, warfarin was administered to maintain the international normalized ratio (INR) between 2.5 and 3.5. The heparin infusion was continued until the INR range was attained. In cases when INR decreased to less than 2.5 and patients were not on heparin infusion, low-molecular heparin was used in a usual dose of 1.5 mg/kg body weight to ensure an appropriate anticoagulation status during this time period.