ELSEVIER

Long-Term Mechanical Support With the HeartMate II LVAS

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ABSTRACT

Background. The use of left ventricular assist devices (LVAD) is an accepted therapy for patients with refractory heart failure. The HeartMate II is a small (350 g), implantable, axial-flow pump (nonpulsatile flow), which is designed to support the left ventricle for extended periods of time. Here we have reported our initial single-center clinical experience with this device as a bridge to heart transplantation.

Materials and Methods. Between March 2002 and December 2008, 18 transplantable adult patients were supported on long-term HeartMate II LVAS at our institution. The cohort included 15 men with an overall mean age of 52 ± 8.4 years (range, 31–64 years). Primary indications for implantation were ischemic cardiomyopathy (CMP; n = 13) and idiopathic CMP (n = 5). All heart failure patients were New York Heart Association (NYHA) functional class IV. None of them had undergone prior open heart surgery. Implantation was performed via cannulation of the left ventricular apex and ascending aorta, and in each case was an elective procedure.

Results. Mean support time was 217 ± 212.3 days (range, 1–665 days). Early (30-day) mortality was 27.7% (n = 5) due to multiple organ failure and sepsis as main causes of death. Bleeding requiring reoperation occurred in 6 cases (33.3%). Cerebral hemorrhage occurred in 1 case. There were 2 driveline infections and no device failure. Twelve subjects (66.6%) were successfully discharged home. Overall, 9 patients (50%) underwent transplantation and 3 are awaiting a suitable organ (2 were discharged home and 1 is in hospital). At latest follow-up, the survival rate after heart transplantation was 66.6% (n = 6).

Conclusions. Long-term HeartMate II LVAS can successfully bridge patients to heart transplantation. Good mid- and long-term results may support the use of this device even for a permanent solution in nontransplantable subjects.

LEFT VENTRICULAR ASSIST DEVICE (LVAD) support is an accepted treatment for patients with end-stage heart failure.[1–3] The increased applicability and excellent results with LVADs have revolutionized the available treatment options. Success with LVADs as bridge-to-transplant (BTT) therapy has led to their successful use as an alternative to transplantation, ie, as a permanent support.[3] Until recently, most patients who have undergone LVAD implantation as BTT therapy have been supported by first-generation devices to provide pulsatile blood flow at physiologic rates, mimicking normal blood circulation. Tremendous success has been achieved with these devices, but their use is associated with significant comorbidity, which is related to several factors: the need for an extensive surgical dissection, a large pump, and a large-diameter percutaneous lead. Even more important, their long-term durability was limited.

Second-generation continuous-flow LVADs were first investigated to reduce the size of the devices and to eliminate the need for external venting, which was required with long-term pulsatile LVADs. The Hemopump, an implantable axial-flow LVAD was based on the principle of an Archimedes screw.[4] The HeartMate II pump (already

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approved by the US Food and Drug Administration for BTT use) incorporates axial flow and rotary pump technology.[5,6] The simple design provides greater long-term mechanical reliability, with only a single moving part: the internal rotor. Further, as a result of the small size of the pump, the risk of pump-pocket infections has been drastically reduced. Here in we have reported our experience with the device.

MATERIALS AND METHODS

Between March 2002 and December 2008, we enrolled 18 patients with severe heart failure. There were 15 men and 3 women of overall mean age of 52 ± 8.4 years (range, 31–64 years), and mean body surface area (BSA) of 1.76 ± 0.18 m^2 (range, 1.54–1.96 m^2). The indication for use was BTT in all subjects. The diagnosis was ischemic cardiomyopathy (CMP) in 13 and idiopathic CMP in 5 patients. At the time of preoperative evaluation, all 18 subjects were New York Heart Association (NYHA) functional class IV and receiving optimal medical management in the hospital. Nine patients were being supported by an intra-aortic balloon pump (Datascope) and 1 by a Jostra RotaFlow (Maquet Cardiopulmonary AG, Hirrlingen, Germany) extracorporeal membrane oxygenation (ECMO) system before receiving the LVAD.

The HeartMate II was placed in 1 subject after age HeartMate XVE device failed. Implantation via cannulation of the left ventricular apex and ascending aorta was performed traditionally. Patients received routine, postimplantation medical support. We adopted the anticoagulation protocol proposed by Thoratec Inc.[5] Once subjects were stabilized and became ambulatory, proper nutrition, rehabilitation, and education became the focus of care. After discharge from the hospital, patients returned to our heart failure clinic for monthly routine follow-up at a decreasing frequency, depending on their needs. Serial echocardiographic studies were performed at regular intervals for inpatients and outpatients to evaluate the adequacy of ventricular unloading.

Device

The HeartMate II consists of an internal axial-flow blood pump with a percutaneous lead that connects the pump to an external portable system driver and power source. The impeller spins on blood-lubricated bearings powered by an electromagnetic motor. The approximate weight of the pump is 350 g and its approximate size is 7.0 cm in length and 4.0 cm in maximal diameter. The pump operates in a range of 6000 to 15,000 rpm and is capable of generating up to 10 L/min of flow at an approximate pressure of 100 mm Hg.

Statistical Analysis

All results are expressed as mean values ± standard deviations. All analyses were performed using SPSS for Windows Release 11.5 (SPSS Inc, Chicago, Ill, United States).

RESULTS

The average duration of support was 217 ± 212.3 days (range, 1–665 days). All subjects survived the operation. Of the 18 implanted patients, 13 (72.2%) survived without significant complications in the early postoperative period with 12 (66.6%) discharged from the hospital in NYHA functional class I. Overall the surviving HeartMate II recipients were discharged at a mean of 38 days (range, 25–110 days) after implantation.

Nine subjects (50%) underwent heart transplantation. At latest follow-up their survival rate after heart transplantation was 66.6% (n = 6): 2 died of early primary graft failure unsuccessfully treated with peripheral ECMO support and 1 of sudden unknown causes at 8 months posttransplantation. During the first year posttransplantation there were 3 episodes of acute rejection greater than International Society for Heart and Lung Transplantation (ISHLT) grade 3A. All episodes were treated successfully with medications. LVAD support is ongoing in 3 patients who were discharged home and are awaiting a suitable organ. One subject was recently readmitted to the hospital due to fever and suspicion of infection.

None of the patients died while receiving the support device; 5 died during the early postoperative period (30-day mortality) due to a combination of right-sided heart failure and multiple system heart failure, leading to sepsis. Rethoracotomy for bleeding occurred in 6 subjects (33.3%), 1 of whom required factor VII administration without diffuse intravascular clotting. Thrombus generation in the noncoronary sinus occurred in 1 individual with extremely poor myocardial contractility associated with lack of aortic valve opening in the early postoperative period; it was treated successfully with high intravenous doses of heparin for a few days. Heparin-induced thrombocytopenia occurred in 1 subject who consequently received intravenously bivalirudin infusion in the early postoperative time as anticoagulation management. None of the devices removed at the time of transplantation showed a thrombus.

In the early postoperative period, 1 patient developed ventricular arrhythmias and ventricular fibrillation, possibly generated by contact of the intraventricular cannula with the endocardium due to a left ventricle chamber of insufficient volume. This subject needed electric cardioversion for resuscitation. Cerebral hemorrhage occurred in 1 patient. Two subjects underwent RVAD Levitronix CentriMag (Levitronix LLC, Waltham, Mass, United States) placement intraoperatively due to preoperative laboratory, hemodynamic, and echocardiographic signs of moderate right ventricular dysfunction considered not to be ideal for LVAD placement. Both subjects were successfully weaned from RVAD, which was removed through a right lateral mini-thoracotomy without reopening the sternum. Superficial driveline infection occurred in 2 individuals (11.1%), both of whom were successfully treated with aggressive daily local wound care. The HeartMate XVE to HeartMate II pump-exchange patient was discharged and underwent transplantation and is doing well.

Hemodynamic function improved from preoperative levels in all subjects during HeartMate II support. By 48 hours after device implantation, the average cardiac index had increased significantly from 1.8 ± 0.26 to 3.5 ± 0.9 L/min/m^2, and the pulmonary wedge pressure had decreased significantly from 23.7 ± 10 to 17.4 ± 5.2 mm Hg. Inotropic support was reduced after implantation: all subjects were

weaned within the first week. Serial echocardiographic studies showed improvement in left ventricular dimensions. In the 12 patients who were discharged, hemoglobin, hematocrit, and end-organ function had reached normal levels by the time of discharge and remain normal in all current outpatients. The technical performance of the HeartMate II has been excellent, and patients have been satisfied with this small and quiet pump. Before discharge, all subjects were trained in the care and use of their equipment and batteries. They participated in a physical rehabilitation program that comprised graduated ambulation within the hospital and treadmill exercise under observation. There were no life-threatening arrhythmias during rehabilitation. No device malfunction or system problem was seen in the outpatient setting.

DISCUSSION

Recently, several single- and multicenter studies have shown improved outcomes with the newer continuous-flow devices.[5,6] Frazier and coworkers[5] reported an 80% 1-year survival rate in a series of 43 patients on the HeartMate II, both as BTT and as permanent support, with markedly improved functional status and quality of life. The HeartMate II BTT multicenter study noted an actuarial survival rate of 89% at 1 month and 75% at 6 months after implantation. The incidence of adverse events may be different according to individual management practices among centers, eg, anticoagulation strategy. Our data were consistent with literature results. We had a positive experience with the HeartMate II, leading to the possibility to discharge several patients home, thus recovering a good social life, which we had not achieved with the paracorporeal devices. Discharging subjects home is an important therapeutic option both for the individuals and to optimize health-care resources, considering the long time on heart transplant waiting lists.

In conclusion, the low rates of postoperative mortality and of adverse events have proved the HeartMate II to be a successful device for BTT therapy. In addition, the favorably low thrombogenicity and low thromboembolic risk associated with the HeartMate II eventually make it ideal as a permanent support, particularly in nontransplantable patients.

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