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The Thoratec Implantable Ventricular Assist Device (IVAD): Initial Clinical Experience

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ABSTRACT

Background. The Thoratec Implantable Ventricular Assist Device (IVAD) is the only FDA-approved intracorporeal biventricular cardiac assist device. It is a titanium-coated version of its predecessor, the Paracorporeal Ventricular Assist Device (PVAD). The blood pump is compatible with the portable TLC-II driver, making home discharge feasible.

Methods. Nine consecutive patients were implanted with the IVAD from June 2005 through March 2006. The indications for support were acute heart failure in 6 cases and chronic heart failure in 3 cases. All patients were managed with maximal medical therapies including intravenous inotropic drugs prior to implant.

Results. All patients survived the surgical implant. Six patients were considered successful: 3 patients discharged to home and subsequently received transplantation, 2 are awaiting transplantation (1 at home and 1 in-house), and 1 patient was successfully explanted. Three patients expired postoperatively because of multiple organ system failure (2 patients) and pulmonary hemorrhage (1 patient). There were no device malfunctions. There was 1 localized driveline site infection and 1 thromboembolic event with partial visual loss.

Conclusions. The IVAD is a unique device capable of providing uni- or bi-ventricular support for either acute or chronic heart failure conditions. Its versatility permits bridge to transplant or recovery options. Home discharge is feasible.

INTRODUCTION

The Implantable Ventricular Assist Device (IVAD) (Thoratec Corporation, Pleasanton, CA, USA) is the only FDA-approved intracorporeal biventricular cardiac assist device (Figure 1). The technology is nearly identical to its predecessor, the external Paracorporeal Ventricular Assist Device (PVAD), with the exception that it is titanium coated with a fill-empty sensor [Farrar 2000; Reichenbach 2001]. Modification of the driveline with a fabric coating allows for tissue ingrowth at the exit site. Compatibility with the TLC-II portable driver permits mobility and home discharge. The purpose of this report is to describe our initial clinical experience with the device.

MATERIALS AND METHODS

Nine consecutive patients were implanted with the IVAD between June 2005 and March 2006. There were 7 men and 2 women. The mean age was 50 years (range, 27-70 years). The average body surface area was 2.02 m^2 (range 1.59-2.41 m^2). The indications for support were acute myocardial infarction (AMI) with shock (6 patients), idiopathic dilated cardiomyopathy (1 patient), adriamycin-induced cardiomyopathy (1 patient), and amyloid cardiomyopathy (1 patient). All patients were managed with maximal medical therapies including intravenous inotropic drugs prior to implant.

The implant technique of the IVAD was similar to that of the PVAD. Important considerations, however, included preparation of the ventricular assist device (VAD) pocket for the blood pump. In 8 of the 9 cases, a pre-peritoneal pocket was easily established between the rectus muscle and rectus sheath. In 1 case, an intra-peritoneal position was chosen to avoid kinking of the inflow conduit. Another important consideration was fixation of the units to the tissue to prevent kinking of the inflow conduit. Although limitations of pocket size help prevent kinking, the soft inflow conduit can kink if oriented improperly or allowed to move with motion. For example, in 1 bilateral ventricular assist device (BIVAD) case (Figure 2), the left ventricular assist device (LVAD) shifted in orientation with patient turning and slid overtop the right ventricular assist device (RVAD) resulting in acute inflow obstruction with cardiogenic shock and pulmonary edema. Operative exploration with re-orientation and fixation of the blood pumps resolved the problem. All subsequent implants are fixed to the fascia and/or costal margin.

Postoperative management of the IVAD was similar to the PVAD except for the sensor that indicates complete filling and emptying; there is no longer a need for the flash test. Compatibility with the portable TLC-II permits ambulation and home discharge, identical to that observed with the

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Figure 1. Thoratec IVAD.

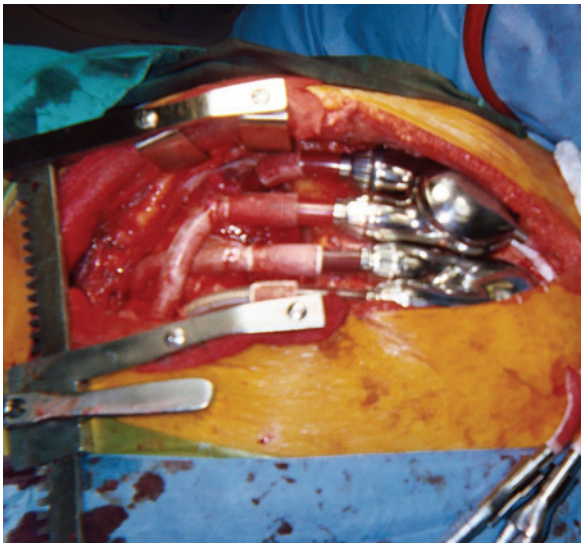

Figure 2. Implantable BIVAD.

PVAD. For the discharged patients, there were no outpatient problems with the blood pump or console. One patient developed an exit site infection that was localized to the driveline and not the blood pump. This complication was managed with an incision over the driveline tract, irrigation with antibiotic solution, and placement of a vacuum-assisted drainage system for 2 weeks. Once the tract was grossly clean, platelet gel was applied, and the wound closed with no recurrence of the infection.

Outpatient activities included frequent travel and social gatherings as well as monthly returns to the clinic. There were no bleeding complications; 1 thromboembolic event occurred (ie, partial visual defect) in 1 patient who could not initially tolerate anti-platelet therapy because of frequent nosebleeds. Anticoagulation management consisted of Coumadin therapy to maintain an international normalized ratio between 3.0 and 4.0 and anti-platelet therapy with Clopidigrel 75 mg daily and aspirin 81 mg daily.

RESULTS

There were 3 BIVADs and 6 LVADs. All patients survived the surgical implant. Six patients were considered successful: 3 patients discharged to home and subsequently received transplantation, 2 are awaiting transplantation (1 at home and 1 in-house), and 1 patient was successfully explanted. Three patients expired: 2 patients presented with AMI-shock and died of multiple organ system failure—both awoke from the surgery neurologically intact, but eventually succumbed to hepatorenal failure despite adequate VAD flows. One patient presented with heart failure as a result of adriamycin-induced cardiomyopathy—she acutely decompensated from a saddle pulmonary embolus resulting in cardiopulmonary collapse. Despite pulmonary thrombectomy and placement of the BIVAD, a separate extracorporeal membrane oxygenation unit was needed for refractory hypoxia; postoperative pulmonary hemorrhage and multiple organ system failure resulted in her demise. There were no device malfunctions. There was 1 localized driveline site infection and 1 thromboembolic event with partial visual loss.

Overall, patients were extremely satisfied with the simplicity of the device and were easily trained with the intention of discharge to home. The only readmissions were the 1 thromboembolic event with partial loss of vision and the localized driveline site infection.

DISCUSSION

The IVAD device is the only FDA-approved implantable biventricular assist device available. The versatility of the unit is similar to the PVAD in terms of its application and features. The advantage over the PVAD is its implantability. The titanium coating permits subcutaneous insertion (ie, preperitoneal or intra-abdominal) translating into an inherent decreased risk of infection. In addition, patient body image is enhanced by virtue of its relative invisibility.

The device is considerably smaller and lighter than other implantable VADs, such as the Heartmate I (Thoratec Laboratories) and Novacor (World Heart Corporation, Ottawa, ON, Canada). Thus, a larger patient population can be served with IVAD, including small adults and, potentially, large children and adolescents. The implantation technique is relatively simple, with options for atrial or ventricular inflow depending upon the circumstances. It is conceivable that off-pump implantation is possible.

The only other FDA-approved BIVADs are the Abiomed BVS5000 and the AB5000 (Abiomed, Inc., Danvers, MA, USA). Although the Abiomed devices are more commonly used for acute cardiogenic shock settings, the devices are not approved for outpatient use or bridge to transplant. Likewise, the Berlin Heart Excor (Berlin Heart AG, Berlin, Germany) and the Medos VAD (Medos Medizintechnik AG, Stolberg,

Germany) are biventricular units, but they are paracorporeal and not FDA-approved [Samuels 2004].

In conclusion, the ability of the IVAD to be used in a variety of conditions is an attractive feature, particularly in view of its compatibility with a portable driver allowing for home discharge. We have been impressed with the versatility of its use in both acute and chronic heart failure settings with both bridge to transplant and recovery outcomes. It is not inconceivable that it may serve as a destination therapy device in specific settings.

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