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Right Ventricular Function and Left Ventricular Assist Device Placement: Clinical Considerations and Outcomes

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ABSTRACT

The HeartMate II is an axial-flow left ventricular assist device that is approved for the treatment of advanced heart failure as a bridge to transplant or destination therapy. Despite the success of this device, right ventricular failure remains a persistent problem in most studies. Right ventricular dysfunction is usually defined as the need for right heart mechanical support or the persistent requirement for inotropes to support right heart function beyond 14 days. Over 21 months, 45 patients with end-stage heart disease underwent placement of the HeartMate II at our institution. This continuous cohort of patients underwent a retrospective review to evaluate the incidence of right heart failure. The perioperative survival was 91% with no incidents of mechanical support for the right ventricle and no requirements for inotropes beyond 14 days. This survival was consistent to beyond 1 year at the time of the study, and 18% of patients underwent heart transplant with 100% survival.

INTRODUCTION

Treatment of end-stage heart disease now includes the use of left ventricular assist devices (LVADs) as standard therapy. The REMATCH trial[1] established the safety and efficacy of mechanical support for end-stage heart failure. The Ochsner mechanical assist program began in 1993 and has been involved in early trials, such as REMATCH, to establish the efficacy and safety of mechanical support for heart failure. It was also involved in trials of the first-generation nonpulsatile, axial flow devices. The HeartMate II (Thoratec Corporation, Pleasanton, CA) is an axial flow device that has been tested extensively and is currently approved for use as a bridge to heart transplant or as destination therapy for advanced heart failure.

The assessment of right ventricular (RV) function is of paramount importance when evaluating patients for LVAD. Failure of the right ventricle in the perioperative period is the leading cause of morbidity and mortality following placement of an LVAD. Inability of the right ventricle to provide adequate flow to the left side of the heart contributes to serious problems of malperfusion such as renal failure, hepatic failure, and coagulopathy. This may necessitate institution of temporary or permanent mechanical support of the right heart. Patients with RV failure have a longer hospital stay and reduced survival following the placement of an LVAD.[2,3]

The pivotal studies of LVADs as bridge to transplant or destination therapy established the incidence and clinical significance of RV failure after LVAD placement. The HeartMate XVE bridge to transplant study of 280 patients reported the use of a right ventricular assist device (RVAD) in 11% of patients.[4] The HeartMate II was one of the next generation axial flow devices developed after the volume displacement pumps. In the HeartMate II bridge to transplant trial, 6% of 484 patients required an RVAD. The total incidence of RV failure was 20% with 14% of patients requiring inotropic support for more than 14 days after LVAD implant.[5]

Beginning in October 2008 we began implanting the HeartMate II device as a bridge to transplant. Over the next 21 months, 45 patients underwent implantation with this device. There were no incidences of mechanical right heart support, and no patients were discharged on inotropes for RV dysfunction. In this article we review our experience with this device and the evaluation and management of right heart failure in the perioperative period.

METHODS

This study was approved by the Institutional Review Board. All patients implanted with the HeartMate II device during the study period were included

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Table 1. Number of Implants by Year

Year	No. Implants
2008	8
2009	15
2010	22
Total	45

in this retrospective review. Charts and records were reviewed and analyzed for patient factors and outcomes. The end points considered were need for inotropes for more than 14 days, need for mechanical right heart support, perioperative mortality, and mortality at 1 year.

The surgical technique included median sternotomy and cardiopulmonary bypass. The device was placed at normothermia with the heart beating and perfused. Adjunctive techniques included tricuspid valve repair for severe regurgitation and aortic valve repair for mild or greater aortic insufficiency. Sternal closure was delayed in most cases to allow for correction of coagulopathy and to optimize right heart function in the early postoperative period.

RESULTS

From October 2008 to July 2010, 45 patients underwent surgery to implant the HeartMate II LVAD for mechanical circulatory support (Table 1). All patients implanted with the device were in New York Heart Association class III or IV heart failure. They all were on inotrope therapy or unable to tolerate inotrope therapy due to arrhythmias. Early in the program, patients were all implanted as a bridge to transplant until the HeartMate II was approved for destination therapy. The patient population included elective surgery as well as urgent procedures for patients in acute heart failure undergoing peripheral circulatory support with intra-aortic balloon counterpulsation or peripheral mechanical support with the Abiomed (Danvers, MA) Impella system.

Patient demographics and hemodynamic parameters are listed in Table 2. There were 14 female and 31 male patients. The principal diagnosis was dilated cardiomyopathy in 62% of patients with 38% of patients having ischemic cardiomyopathy. The incidence of moderate to severe RV failure on preoperative echocardiography was 60%.

No patients required inotropes for more than 14 days, and no patients were discharged on home inotrope infusion. There was also no incident of mechanical right heart support.

The perioperative survival was 91% in this group of patients. All patients in the study survived beyond 1 year, except individuals who were less than 1 year from implant at the time of the study. There were 4 deaths in the perioperative period due to multiorgan failure. There were no perioperative strokes or major morbidity, and all patients were discharged home in good condition. Eight patients have been successfully bridged to transplant with 100% survival (Table 3).

Table 2. Patient Demographics

Patient demographics	
Age (year)	23–72 (mean 51)
Sex	
• Male	31 (69.9%)
• Female	14 (31.1%)
Diagnosis	
• Ischemic cardiomyopathy	17 (37.8%)
• Nonischemic cardiomyopathy	28 (62.2%)
Right ventricular function	
• Normal	13 (28.9%)
• Low/mildly depressed	5 (11.1%)
• Moderately depressed	10 (22.2%)
• Severely depressed	17 (37.7%)

DISCUSSION

The success of the HeartMate II as a bridge to transplant and destination therapy has been established, and it is now approved for both purposes. Despite this success, RV dysfunction remains a significant problem following implementation of LV support. The preoperative assessment of right heart function and the perioperative management of RV failure remain active areas of investigation. Early in the mechanical support program at Ochsner these issues were recognized and discussed by the late Dr Clifford Van Meter, Jr.[6]

The incidence of right heart dysfunction and need for an RVAD was approximately 10% with the HeartMate XVE. This incidence has decreased with the use

Table 3. Outcomes

Outcomes	Number
RV failure	None
Survival	41/45 (91%)
LVAD patients transplanted	8

Abbreviation: RV, right ventricular; LVAD, left ventricular assist device.

of the HeartMate II device, although the prevalence of right heart dysfunction remains a common problem. A comparison of both devices revealed a similar incidence of right heart dysfunction between the 2 devices: 35% of the HeartMate XVE group and 41% of HeartMate II patients required more than 14 days of inotropic support. However, operative mortality was lower in the HeartMate II group with a lower requirement for RVAD support. Despite the improvements, the authors[7] noted that right heart dysfunction remains a persistent clinical problem after LVAD placement.

The preoperative evaluation of right heart function is an important component of patient selection for LVAD placement. Patients requiring biventricular support have a lower survival compared with univentricular support. A high index of suspicion for right heart failure and planned biventricular support may improve outcomes. By identifying preoperative predictors of the need for RVAD and planning biventricular support, 1 program reported increased survival. They used cardiac index, right ventricular stroke work index (RVSWI), severe RV dysfunction, creatinine, previous surgery, and systolic blood pressure to plan for biventricular support and increased survival from 29% to 51% in the patients requiring biventricular assist devices.[8,9]

Several other studies have also developed risk models for RV failure based on preoperative factors. In 1 study,[3] preoperative vasopressors, bilirubin 2 mg/dL, aspartate aminotransferase 80 IU, and creatinine 2.3 mg/dL predicted RV failure and the need for RVAD support. Another recent study by Drakos and colleagues[10] analyzed 175 patients undergoing LVAD implantation from 1993 to 2008 and identified 3 factors significantly associated with RV failure. These factors were preoperative need for intra-aortic balloon counterpulsation, increased pulmonary vascular resistance, and implantation for destination therapy.

Impaired RV contractility reflecting impaired hemodynamics as measured by low pulmonary artery pressure, elevated central venous pressure, and low RV stroke work index are important parameters to consider when evaluating patients for possible RV failure. Low RVSWI has been significantly associated with the need for an RVAD.[11] The same group demonstrated that the RVSWI can be used as a measure of RV contractility, and this value is directly commensurate with the incidence of RV failure and need for inotropes for more than 14 days.[12]

The perioperative survival in this continuous cohort of patients was 91%. All patients were discharged home with no major morbidity including no hemodialysis, no strokes, and no need for inotrope infusions. The 4 deaths were due to multiorgan failure stemming from hepatic failure. This occurred in 2 critically ill patients in multiorgan failure preoperatively due to cardiogenic shock. The other 2 patients were chronic heart failure patients with ischemic cardiomyopathy on home inotrope therapy for more than 1 year. In all cases, the RV function was adequate as measured by central venous pressure less than 15 mmHg and cardiac index greater than 2.0 L/m^2 measured by pulmonary artery catheter. The LVAD flow in these patients was also maintained at acceptable levels indicating adequate right heart function to allow for left heart filling. Right heart function was also examined by transesophageal echocardiography and found to be sufficient.

The use of continuous-flow pumps has reduced the incidence of mechanical support for the right ventricle compared to the earlier generation of pulsatile devices such as the HeartMate XVE. The HeartMate II trial for destination therapy reported a 4% incidence of right heart support with an RVAD.[13] Our current series of implanting the HeartMate II device had no requirement for mechanical support of the right ventricle. There was also no requirement for inotropic support beyond 14 days. The lower than expected incidence of right heart dysfunction could be due to several reasons. Elective placement of the device is preceded by admitting the patients preoperatively and evaluating right heart function. Patients are then optimized with inotropic support, judicious diuresis to lower right heart filling pressure, and intra-aortic balloon pump if necessary. Sternal closure is delayed for 24 to 48 hours if there is coagulopathy or right heart dysfunction. Limiting the amount of blood products transfused, allowing the right ventricle time to recover with the sternum open, and using nitric oxide contribute to optimizing the performance of an impaired right ventricle. Returning to the operating room to close the sternal incision allows irrigation of any retained thrombus and is an excellent opportunity to adjust the LVAD speed under guidance of transesophageal echocardiography performed by our team of cardiac anesthesiologists.

CONCLUSION

Our results using the HeartMate II LVAD are encouraging. The survival of patients in this series with end-stage heart disease and serious metabolic derangements is above 90%, and this endures beyond 1 year after implant. Overall, the HeartMate II has demonstrated a reduced requirement for mechanical support of the right ventricle; however, RV failure defined as the need for inotrope infusion beyond 14 days remains a consistent problem in most studies. Although the number of patients in this series is too small to draw definite conclusions, there was no

requirement for an RVAD or continuous inotrope support for RV dysfunction. Eighteen percent of our patients have been successfully bridged to transplant with complete success.

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