Discharge Outcomes in Patients With Paracorporeal Biventricular Assist Devices

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Background. As waiting time for heart transplantation has increased, ventricular assist devices have become critical for "bridging" patients with end-stage heart failure. Because most reported post-discharge experience is with left ventricular assist devices (LVAD), we sought to evaluate the safety and feasibility of home discharge on paracorporeal biventricular assist devices (BIVAD).

Methods. We retrospectively reviewed the hospital course and post-discharge outcomes of 46 consecutive patients who received paracorporeal VADs as bridge to transplant. The success of home discharge was assessed by frequency and reasons for hospital readmission and survival to transplant.

Results. Thirty patients (65%) were successfully transferred from the intensive care unit and considered candidates for discharge. Of the 26 patients discharged home, 11 were supported with an LVAD and 15 with BIVADs. Median duration of support until transplant, explant, or death did not differ significantly between LVAD or BIVAD patients (91 days vs 158 days; $p = 0.09$). There were 26 readmissions for medical or device-related complications; 10 in 7 LVAD patients and 16 in 10 BIVAD patients, with no difference in median length of stay (17 days vs 25 days; $p = 0.67$). Out of hospital duration of support was similar between LVAD and BIVAD patients (61 days vs 66 days; $p = 0.87$) as were 6-month and 1-year event-free survival rates ($p = 0.49$).

Conclusions. Outcomes were similar in patients bridged to transplant on home paracorporeal BIVAD versus LVAD support. We recommend discharge for stable patients demonstrating device competency and adequate home care regardless of the need for univentricular or biventricular paracorporeal support.

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Ventricular assist devices (VADs) have proven to be an effective mechanical circulatory support strategy to promote survival in patients with end-stage heart failure [1, 2]. From their initial historical use for post cardiotomy shock, VAD indications have evolved to include cardiogenic shock, bridge to recovery, and long-term support for destination therapy or bridge to heart transplant [3].

Ventricular assist devices may be implanted to provide univentricular or biventricular support depending on the severity of hemodynamic compromise and end-organ failure, likelihood of recovery, and potential for cardiac transplant. The vast majority of durable VADs in current use provide isolated left ventricular support (LVAD) [4]. More recently, the total artificial heart (TAH; SynCardia Systems Inc, Tucson, AZ) has provided a mechanical option for patients with biventricular failure as a bridge to transplant [5, 6]. Some patients, however, receive paracorporeal VADs due to small body size, medical or surgical contraindications to implantable VADs, or surgeon preference. For these patients, the availability of a portable pneumatic driver has allowed greater mobility, improved quality of life, and discharge home [7].

Recent data from the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) reflect the increasing number and types of VADs being implanted in the United States, as well as the increasing number of implanting centers [8]. The challenge, however, for those patients in whom VADs are used as a bridge to transplant, is the continued shortage of organ donors [9]. For the growing number of patients awaiting cardiac transplant, the need for increased patient independence post VAD is amplified. Home discharge options become paramount for the patient and family, as well as for health care institutions that must bear the costs associated with VAD-related hospitalization.

In this study, we reviewed our experience with home discharge outcomes in patients implanted with paracorporeal biventricular assist devices (BIVADs) and compared them to those with paracorporeal LVADs. Our aim was to evaluate the safety and efficacy of home paracorporeal BIVAD support.

Patients and Methods

Patient Selection

We performed a retrospective medical record review of all patients who underwent surgical placement of a

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paracorporeal LVAD or BIVAD (Thoratec Corporation, Pleasanton, CA) as a bridge to cardiac transplant at our center between February 2004 and September 2009. This study was conducted with the approval of the Brigham and Women's Hospital Human Research Committee for review of medical records. Individual patient consent was not required as the analysis was performed using de-identified data.

Mechanical circulatory support was offered to patients with severe refractory heart failure due to a nonischemic cardiomyopathy attributed to viral, valvular, familial or idiopathic etiologies, or an ischemic cardiomyopathy resulting from prior myocardial infarction or related to percutaneous or surgical coronary revascularization. The acuity of each patient's clinical presentation and urgency for mechanical circulatory support was classified according to INTERMACS profiles [10]. Left ventricular versus biventricular support was a surgical decision based on severity of right ventricular dysfunction determined by hemodynamics, echocardiography, and end-organ function. Patients implanted with temporary or isolated long-term right ventricular paracorporeal devices were excluded from the analysis.

Discharge Eligibility

Patients were deemed discharge eligible upon successful transfer from the cardiac surgical intensive care unit (ICU) to the step-down unit after VAD implantation. Only those patients who were on a stable outpatient medical regimen, having successfully completed a comprehensive education program on VAD function and troubleshooting, and with appropriate social support, were discharged home [11].

Outcomes

The primary outcome of this study was the proportion of patients who were discharged home with a VAD. Additional outcomes included duration of VAD support, out-of-hospital time with the VAD, number of VAD complications, and hospital readmissions, with the exclusion of admissions for heart transplant, back-up call for a donor heart, device weaning, and desensitization. Event-free survival was defined as survival free of death, heart transplant, or device explant due to myocardial recovery.

Medical Management

All patients were treated with aspirin, dipyridamole, and warfarin dosed to a target international normalized ratio of 2.5 to 3.5. Diuretics and anti-hypertensive agents were used as needed to treat edema and hypertension, respectively. During this period we did not routinely institute comprehensive neurohormonal blockade with angiotensin-converting enzyme inhibitors, beta-blockers, and aldosterone antagonists unless there was potential for myocardial recovery. Once transferred out of the ICU, patients worked daily with physical and occupational therapy to build the necessary strength and endurance for home ambulation and independence with activities of daily living. Nutrition consultation was also a key component of postoperative care as the majority of patients were malnourished prior to VAD implantation.

Adequate caregiver support was considered crucial for successful discharge. Patients needed to identify at least 1 and ideally 2 caregivers to be available for assistance and to learn about device management. The training program was gradual, with daily sessions geared to the patient's learning ability. In addition, caregivers met with a VAD nurse practitioner for at least 3 1-hour sessions. Before patients were eligible for discharge, they and their caregivers were required to demonstrate competency maintaining a logbook of VAD parameters, daily weights and vital signs, and with sterile wound care technique. They were also required to demonstrate a full knowledge in troubleshooting VAD alarms, and the ability to hand-pump the VAD and switch to a back-up portable driver.

Additional Support

A dedicated social worker played an active role in assisting patients and families in identifying support systems and adjusting to their illness. In addition, a VAD support group for patients living on mechanical circulatory support was initiated to foster emotional and social support and discuss strategies needed to manage living on a VAD. Community support and education were provided by the VAD nurse practitioners, who traveled to the patient's communities and educated first responders, local physicians, emergency room staff, visiting nurses, and other family members and friends on device function and care. In particular, emergency troubleshooting for device problems was reviewed in detail, and a specific plan for local emergency response utilizing both air and ground transportation was arranged.

After discharge, visiting nurses were responsible for wound care until the patient's primary caregiver took over the responsibility. For 2 weeks after discharge, the caregiver was required to provide constant supervision. After this time, the amount of supervision was left to the discretion of the patient and family. Routine visits were scheduled and all patients were seen by a surgeon, cardiologist, and nurse practitioner 2 weeks after discharge, and then monthly in the outpatient VAD clinic. Nurse practitioners also maintained regular phone contact.

Statistical Analysis

Statistical analyses were carried out using SAS version 9.2 (SAS Institute, Cary, NC). Descriptive statistics are reported as percentages, means $\pm$ standard error of the mean, and medians with interquartile range [25% to 75%]. The p values were calculated using the Wilcoxon rank-sum test for continuous variables and the χ^2 test for categorical values. In the instance where expected values in the contingency tables were below 5, p values were calculated using the Fisher exact test. Hazard ratios and Kaplan-Meier survival analyses were generated using MedCalc software version 12.2.1.0 (Mariakerke, Belgium). Censoring events included cardiac transplant or device explant for myocardial recovery.